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Original Paper

The Impact of the COVID-19 Pandemic on Hepatobiliary and Pancreatic Surgical Services in Singapore: Retrospective Quantitative Study

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Abstract

Background: At the height of the COVID-19 pandemic, the hepatopancreatobiliary (HPB) unit had to reorganize its surgical case volume due to the rationing of health care resources. We report on a local audit evaluating the impact of COVID-19 on the HPB unit and the HPB surgical oncology practice.

Objective: The aim of this study was to review the impact of the COVID-19 pandemic on the HPB unit's elective and emergency surgical cases. The secondary aims were to investigate the impact on the HPB surgical oncology operative case volume.

Methods: We performed a comparative audit of the HPB unit surgical case volume for January-June 2019 (baseline) and 2020 (COVID-19). Elective and emergency cases performed under general anesthesia were audited. Elective cases included hernia and gallbladder operations and liver and pancreatic resections. Emergency cases included cholecystectomies and laparotomies performed for general surgical indications. We excluded endoscopies and procedures done under local anesthesia. The retrospective data collected during the 2 time periods were compared. This study was registered in the Chinese Clinical Trial Registry (ChiCTR2000040265).

Results: The elective surgical case volume decreased by 41.8% (351 cases in 2019 compared to 204 cases in 2020) during the COVID-19 pandemic. The number of hernia operations decreased by 63.9% (155 in 2019 compared to 56 in 2020; $P<.001$) and cholecystectomies decreased by 40.1% (157 in 2019 compared to 94 in 2020; $P=.83$). The liver and pancreatic resection volume increased by 16.7% (30 cases in 2019 compared to 35 cases in 2020; $P=.004$) and 111.1% (9 cases in 2019 compared to 19 cases in 2020; $P=.001$), respectively. The emergency surgical workload decreased by 40.9% (193 cases in 2019 compared to 114 cases in 2020). The most significant reduction in the emergency workload was observed in March (41 to 23 cases, a 43.9% reduction; $P=.94$), April (35 to 8 cases, a 77.1% reduction; $P=.01$), and May (32 to 14 cases, a 56.3% reduction; $P=.39$); however, only April had a statistically significant reduction in workload ($P=.01$).

Conclusions: The reallocation of resources due to the COVID-19 pandemic did not adversely impact elective HPB oncology work. With prudent measures in place, essential surgical services can be maintained during a pandemic.

Trial Registration: Chinese Clinical Trial Registry (ChiCTR2000040265); https://tinyurl.com/ms9kpr6x

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KEYWORDS

audit; coronavirus; COVID-19; pandemic; surgery; impact; cancer; liver, pancreas; resource; elective surgery

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Introduction

COVID-19 was first detected in Wuhan, China, in November 2019. Singapore registered its first COVID-19 case on January 23, 2020 [1]. Tan Tock Seng Hospital (TTSH) was designated as the main hospital to provide support to the National Centre for Infectious Diseases (NCID). TTSH is one of the largest tertiary hospitals in Singapore, with more than 1500 hospital beds. The surgical division of TTSH was tasked with augmenting the NCID workforce to handle the crisis.

The hepatopancreatobiliary (HPB) unit of TTSH started triaging and scaling down its operative and clinical workload as resources were reallocated preferentially for COVID-19–related care. International guidelines and opinion statements advocated for postponing non–oncology-related services, and thus, services for patients with benign gallbladder disorders and hernias were postponed for several months [2]. Despite the drop in overall case volume, it was possible to maintain essential surgical services in a pandemic situation through rapid situational audits to generate localized strategies [3]. Medication shortages, the unavailability of blood products and hospital beds, and delays for essential surgical procedures negatively impacted clinical care. Thus, many patients with non–COVID-19–related illnesses were not prioritized, and this could impact the quality and timeliness of care.

Rescheduling elective surgical operations became a norm to reduce the transmission of COVID-19 from hospital staff to the community and preserve hospital resources for patients with COVID-19 [4]. The general principle of triaging for elective surgical operations advocates a progressive reduction proportionate to pandemic escalation [5,6]. Triaging is critical to ensure fair, equitable, and just redistribution of public health resources. Professional societies and associations started providing guidance as evidence continued to emerge. The United Kingdom National Health Service published a guide listing surgical procedures and the suggested timeframe for each procedure [7]. Not all guidance will be generalizable across all health care systems, and hence, local policies remain integral.

Locally, it was agreed that the unit shall not compromise on the quality of care for patients without COVID-19, and thus, we established good practices like the index admission cholecystectomy policy, early operation for patients with pancreatic cancer and jaundice, and timely hepatic resections for resectable liver cancers continued to prevail. There are no data from HPB units about the impact of the COVID-19 pandemic on the provision of day-to-day services. We will be reporting our audit evaluating the impact of COVID-19 at its peak on our unit and its impact on HPB malignancy operations.

Methods

Ethical Considerations

This study was an audit of the effects of the COVID-19 outbreak on the HPB surgical unit and thus was exempt from ethics board review [8]. This study did not result in a departure from routine clinical care and no patient contact was made nor were any patient identifiers retrieved, stored, or disseminated.

Background Information on the HPB Service

The HPB surgical service included 4 full-time faculty. Each faculty member was assigned to acute general surgery on-call duty 1 day per month and specialist HPB on-call duty 1 week per month. During pre–COVID-19 times, the service had 4.5 days allocated for procedures that required general anesthesia and shared a half-day list with other teams for local anesthesia procedures. According to the 2017-2018 audit, the unit had an annual case mix of 90 liver resections, 50 pancreatic resections, 350 biliary surgical procedures, 185 hernia procedures, and 90 unclassified major and minor procedures under general anesthesia. Biliary surgical procedures include elective and emergency cholecystectomy as well as complex biliary procedures. Hernia procedures include operations for inguinal, umbilical, and incisional hernias. Liver and pancreatic resections were routinely done as elective surgical operations. Cholecystectomy and hernia operations can be done either in an elective or emergency setting depending on the presenting symptoms of the patient. Elective surgical operations were defined as operations that can be scheduled in advance for medical conditions that were not immediately life-threatening. Emergency surgical operations were defined as operations that were done emergently, during the same admission, due to a potentially life-threatening medical condition.

We audited the surgical workload of the HPB team for the months of January-June and compared the workload in 2019 (baseline) with 2020 (COVID-19). The number of operations performed during these periods was collected from the surgeons' electronic case log. The different types of surgical procedures were sorted and classified based on the fixed charge code assigned to each operation. The retrospective data collected during the 2 time periods were compared. This study was registered in the Chinese Clinical Trial Registry (ChiCTR2000040265) and is reported in line with the Strengthening the Reporting of Cohort Studies in Surgery criteria [9]. We compared the workload between the years 2019 and 2020 using the chi-square test to examine differences, and P values <.05 were considered statistically significant. The primary aim of the study was to review the impact of the COVID-19 pandemic on the HPB unit's elective and emergency surgical case volume. The secondary aims were to investigate the effects of the COVID-19 pandemic on the HPB surgical oncology services.

General Precautions

The donning of surgical masks was mandatory within hospital premises. Twice daily temperature monitoring was compulsory and unwell staff were instructed to report to the occupational health clinic. All members of the HPB service were fitted for N95 masks and completed personal protective equipment (PPE) and powered air-purifying respirator training. To reduce the risk of COVID-19 transmission and minimize the impact on surgical services, the team was divided into 2 subteams to minimize interactions between members. Physical distancing among team members was reinforced continuously via audio broadcasts in the wards, email and WhatsApp chat group reminders, flyers in the elevator lobbies, and regular updates by senior hospital management. Nursing staff were appointed

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as safe distancing ambassadors and encouraged to flag any violations. Gatherings after ward rounds and during meals were stopped, and multidisciplinary meetings, journal clubs, and morbidity rounds were conducted remotely. The HPB service was segregated into 2 subteams with no cross-coverage at the registrar and consultant levels. Minimal cross-coverage among junior staff to sustain essential patient care activities was permitted to ensure compliance with junior physician duty hours. For example, if a junior physician covering team A is post call at noon, a junior physician from team B can provide basic coverage for patients under team A (eg, completing discharge documents and attending to nursing flags). Outpatient clinic lists were screened 2 weeks before the scheduled visit by the team consultants and registrars, and nonurgent cases were postponed. Cases were deemed nonurgent if patients were asymptomatic (eg, patients that were asymptomatic after biliary colic or hernia referrals). In addition, patients who were followed up after dyspepsia, surveillance endoscopies for intestinal metaplasia or colonic adenomatous polyps, liver cysts, cystic neoplasms of the pancreas, and so on, were seen via teleconsult and provided new appointments as per routine clinical care. Clinic patient lists were screened starting from April 7, 2020. The patient service associates followed up with new appointments and logistical inquiries. A script template was made available by senior management to ensure consistency in communication between health care workers and patients or next-of-kin.

Precautions for Elective Surgical Operations

HPB multidisciplinary tumor board meetings remained operational, and these were conducted over a web-based platform with the radiologist, medical oncologist, and gastroenterologist. As staff were recruited to manage the NCID, a shortage of operation room nurses and anesthetists mandated a reduction in elective operation rooms. Thus, the operating lists were centralized and shared across the department. The committee consisted of the director of the operating rooms, the chief triage surgeon, and an anesthetist. Patients were categorized into groups A (procedures to be done in <2 weeks, eg, oncology), B (procedures to be done in <2 months, eg, symptomatic gallstones), and C (procedures that can be postponed by 3-6 months, eg, bariatric surgical operations). All listings were triaged weekly. Individual surgeons were permitted to approach the director of the operating rooms and the head of the department for expedited listing for justifiable reasons on a case-by-case basis. Chest x-rays were routinely done at the preoperative anesthetic clinic. Patients were informed that their elective operations could be cancelled and rescheduled if they tested positive for COVID-19. For suspected COVID-19 cases, the patients were isolated and the elective operation would only proceed after 2 negative nasopharyngeal swabs. An intubation-extubation protocol permits only the anesthetist and an assistant in full PPE (N95 mask, face shield, water-resistant gown, hairnet, and gloves) to be in the operating room during the intubation and extubation process and 5 minutes after. This protocol ensured that at least 2 cycles of gas exchange are completed and reduced COVID-19 transmission risk. Viral particles have been detected in the smoke generated by surgical energy devices used to cut and seal tissue during surgical procedures [10]. As COVID-19 transmission could occur due to the use of surgical energy devices, staff were made aware of this and educated via emails and circulars. The number of surgical team members was limited to 3 per case. The concentration of surgical smoke is higher in laparoscopic procedures than in open procedures. To mitigate this risk, we minimized the venting of smoke from trocars [11]. Further, a locally designed, 3D-printed, custom-made device was used to evacuate surgical smoke in a closed circuit.

The Impact of the COVID-19 Pandemic

To free up critical care beds for patients with COVID-19, the division of surgery reduced the number of surgical intensive care unit (SICU) beds, high-dependency unit (HDU) beds, and general ward surgical beds. HDUs are intermediate care units between the SICU and general wards, where the ratio of nurses to patients (1:4) is higher than for general ward beds. HDU beds can support invasive monitoring (intraarterial catheters and central venous pressure monitoring) and noninvasive ventilatory support. SICU beds offer a 1:2 ratio of nurses to patients and invasive support, such as endotracheal intubation and continuous renal replacement therapy. HDU beds were reduced from 28 to 10 and SICU beds were reduced from 10 to 8. Thus, the number of major elective general surgery procedures had to be reduced. As our hospital hosted the NCID, staff and resources were diverted to upscale the clinical needs of the NCID to combat COVID-19. As a result, polyclinic and general practice referrals were diverted to other hospitals, selected ambulance cases were diverted to nearby hospitals, and all listed surgical patients were triaged by the central committee. Further, the segregation of designated “clean” and “dirty” surgical teams was done to reduce the risk of health care transmission and ensured a critical specialist pool was available all day and night to sustain essential services, including HPB oncology.

Results

Our unit performed 351 elective surgical procedures from January-June 2019. The procedures included 155 hernia repairs, 157 gallbladder operations, 30 liver resections, and 9 pancreatic resections. A total of 204 elective surgical procedures were performed from January-June 2020. This included 56 hernia repairs, 94 gallbladder operations, 35 liver operations, and 19 pancreatic resections (Table 1). In 2020, all patients with pancreatic resection had malignancies, and the majority of patients who underwent liver operations had malignancies (30/35, 86%). Of the 5 patients with benign liver disease, 3 had symptomatic giant liver cysts and underwent cyst deroofing operations, 1 patient was offered an operation for recurrent pyogenic cholangitis due to multiple episodes of sepsis, and the last patient had a pyogenic liver abscess masquerading as hepatocellular carcinoma (HCC). The gallbladder operations were mainly done laparoscopically. The pancreatic resections were done using an open approach, except for 2 laparoscopic distal pancreatectomies. Of the 35 liver resections, 17 (49%) were done laparoscopically. The number of hernia operations decreased by 63.9% (155 in 2019 compared to 56 in 2020; P<.001) and cholecystectomies decreased by 40.1% (157 in 2019 compared to 94 in 2020; P=.83). The liver and pancreatic

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resection volume increased by 16.7% (30 cases in 2019 compared to 35 cases in 2020; *P*=.004) and 111.1% (9 cases in 2019 compared to 19 cases in 2020; *P*=.001), respectively.

Figure 1 shows the elective surgical workload from January-June 2020. We did not operate on any patients with an active or past diagnosis of COVID-19. The reduction in case volume for gallbladder operations started in February 2020 and continued until April 2020, after which it returned to a "new normal," and it is still well below the expected baseline state. Similarly, the reduction in caseload for hernia operations started in April 2020 and has reached the baseline rates from June 2020. The liver and pancreatic procedure volume did not decrease.

Figure 2 shows the emergency surgical procedures from January-June in 2019 (n=193) and 2020 (n=114). Emergency cases included superficial abscesses, acute appendicitis, acute cholecystitis, obstructed hernias, obstructed small or large bowel tumors, and perforated intraabdominal viscera. The emergency surgical workload reduced from 193 to 114 cases (40.9% reduction). The most significant reduction in the emergency surgical workload was observed in March (41 to 23 cases, 43.9% reduction; *P*=.94), April (35 to 8 cases, 77.1% reduction; *P*=.01), and May (32 to 14 cases, 56.3% reduction; *P*=.39); however, only April had a statistically significant reduction in workload (*P*=.01).

Table 1. A comparison of the characteristics of elective surgical operations done in 2019 (n=351) and 2020 (n=204).

Type of elective operation	January-June 2019, n (%)[a]	January-June 2020, n (%)[a]
Liver operation[b]		
Benign liver pathology	1 (3.3)	5 (14.3)
Minor resection (<2 segments)	21 (70)	17 (48.6)
Major resection (>3 segments)	8 (26.7)	13 (37.1)
Pancreatic resection[c]		
Distal pancreatectomy	1 (11.1)	2 (10.5)
Whipple or total pancreatectomy	8 (88.9)	17 (89.5)
Gallbladder operation[d]		
Laparoscopic cholecystectomy	137 (87.2)	80 (85.1)
Open cholecystectomy	7 (4.5)	6 (6.4)
Cholecystectomy with common bile duct exploration	13 (8.3)	8 (8.5)
Hernia repair[e]		
Laparoscopic hernia repair	82 (52.9)	32 (57.1)
Open hernia repair	73 (47.1)	24 (42.9)

[a]Percentages are calculated based on the category totals for each year.

[b]This category comprised 8.5% (30/351) of elective operations in 2019 and 17.2% (35/204) of elective operations in 2020; *P*=.004.

[c]This category comprised 2.6% (9/351) of elective operations in 2019 and 9.3% (19/204) of elective operations in 2020; *P*=.001.

[d]This category comprised 44.7% (157/351) of elective operations in 2019 and 46.1% (94/204) of elective operations in 2020; *P*=.83.

[e]This category comprised 44.2% (155/351) of elective operations in 2019 and 27.5% (56/204) of elective operations in 2020; *P*<.001.

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Figure 1. Elective procedures performed by the hepatopancreatobiliary unit in January-June 2020.

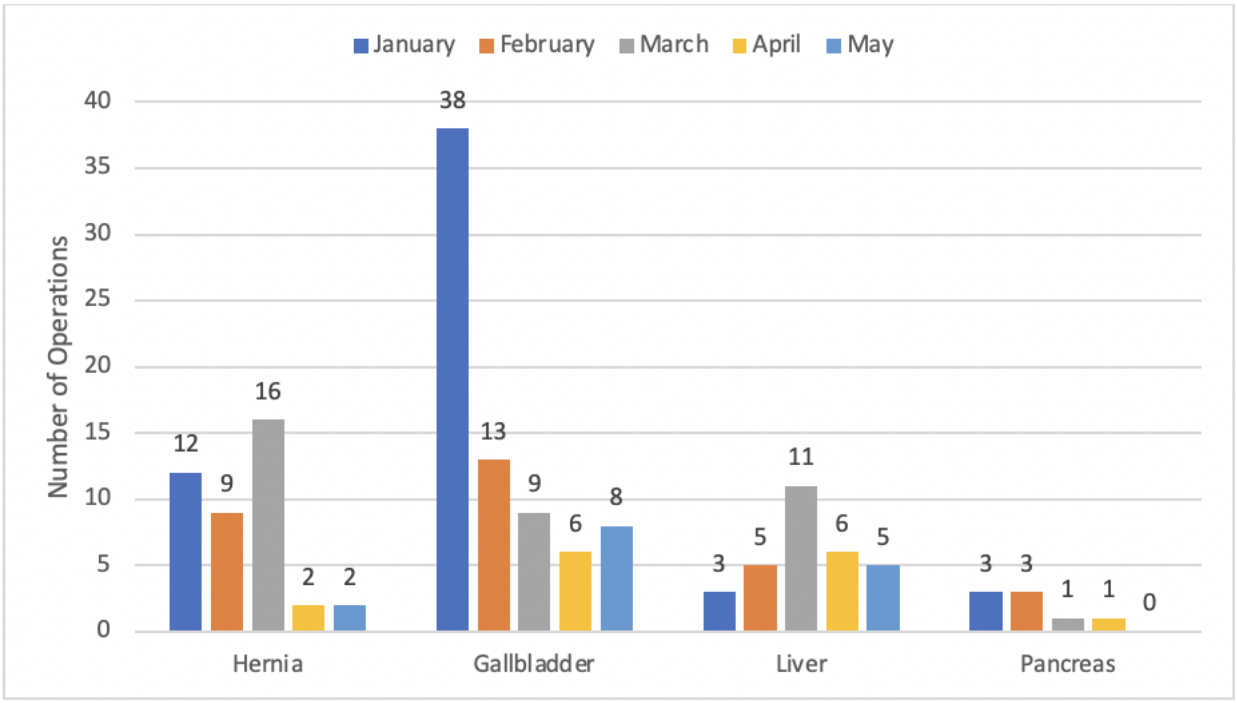
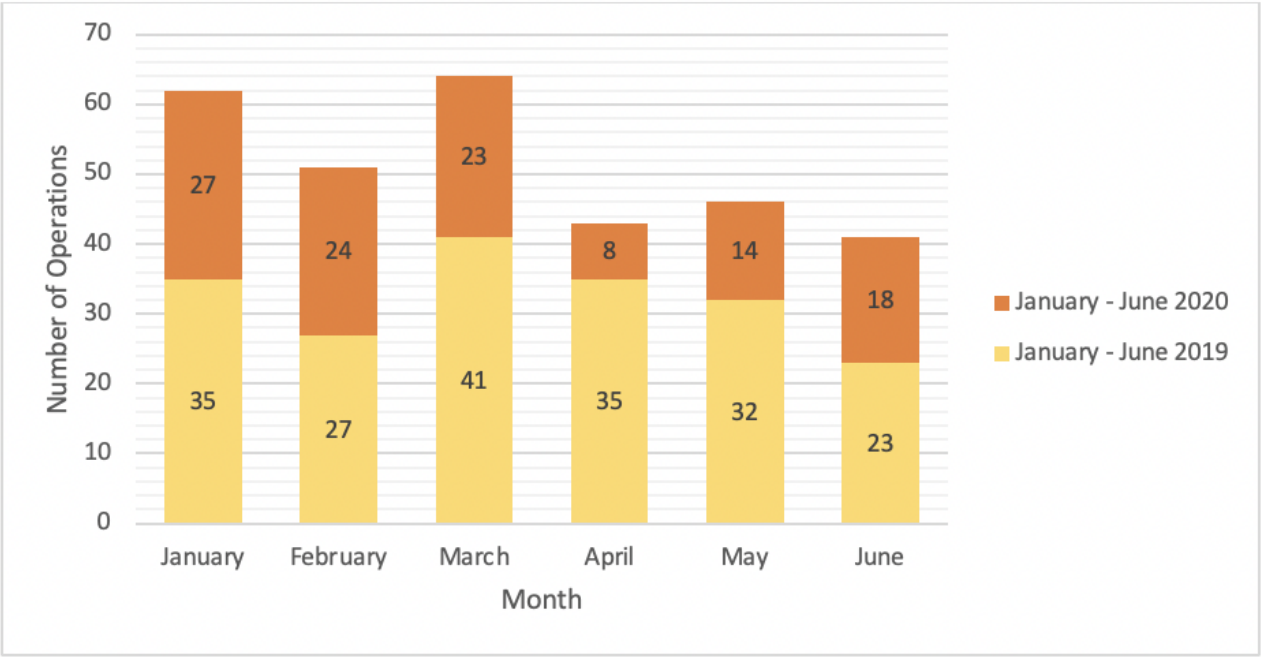


Figure 2. Emergency procedures performed by the hepatopancreatobiliary unit in January-June 2019 and 2020.



Discussion

Principal Findings

The reallocation of resources during the COVID-19 pandemic impacted our elective benign surgical work and emergency surgical services but did not adversely impact elective HPB oncology work. We observed an increase in the HPB oncology volume during the COVID-19 pandemic. These findings emphasize that measures taken for resource reallocation were appropriate and fulfill the principles of distributive justice in public health ethics.

Locally, many measures were implemented to ensure that patients who needed urgent, prompt, or early elective surgical procedures were not deprived of this opportunity by having their procedures canceled or postponed due to the COVID-19 pandemic. As the pandemic escalated, designated individual operating lists were reduced, and lists were made communal for the whole surgical division. Our results showed that with

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the previously mentioned framework in place, essential surgical operations can still be prioritized in a pandemic.

We witnessed a substantial drop in our elective cholecystectomy and hernia workload, and this was attributed to the success of our triaging system. There was a nonstatistically significant reduction in the cholecystectomy workload, partly as symptomatic gallstone disease was the primary contributor to our unit's workload. The most significant impact of triaging was observed in the inguinal hernia procedure workload (P<.001). By postponing nonurgent elective cases, the HPB unit continued to provide timely and adequate services for patients with HPB malignancies. We witnessed a paradoxical increase in the volume of both liver (P=.004) and pancreatic (P=.001) resections. This phenomenon has not been reported before and merits discussion.

Elective HPB Malignancy Cases

The increase in HPB oncology volume was an interesting result from this study. The underlying reasons for this were multifactorial. In pre–COVID-19 times, patients with symptomatic gallstones and hernias competed for slots on the operating room lists. During the COVID-19 pandemic, due to effective triaging mechanisms, even though overall resources were reduced, the relative number of resources increased for patients with HPB cancers. Another contributing factor could be the placement of patients with HPB cancers on the waiting list as priority was given to this group of patients. Potentially, this phenomenon may not be observed in low-volume HPB units with shorter waiting times or geographies with low disease prevalence for HCC and pancreatic cancer. Locally, the disease burden of HCC is substantial due to the high seroprevalence of the hepatitis B virus and the emergence of nonalcoholic fatty liver disease [12]. Unlike breast cancers, there are no effective neoadjuvant chemotherapy or hormone therapy treatments, and hence delaying operations can impact survivorship [13-15]. In patients with pancreatic cancer or cholangiocarcinoma presenting with obstructive jaundice, emergency operation is crucial in obtaining curative treatment and preventing the development of cholangitis. Sud et al [16] investigated the impact of surgical delays on survival for different cancers and estimated that a delay in operation for pancreatic cancers could lead to >30% reduction in survival at 6 months and >17% reduction in survival at 3 months. The American College of Surgeons, Society of Surgical Oncology, and European Society of Medical Oncology have provided inpatient management guidelines for patients with HPB cancers that are in line with our stance to offer surgical operations in oncologically resectable cases [6,13,17].

Elective Nonmalignancy Cases

We continued to prioritize patients with symptoms of groin pain or recurrent attacks of biliary colic to reduce the impact on quality of life and maintain good patient-reported outcomes [18,19]. The number of first outpatient visits to surgical clinics for new patients decreased by about one-half. This ensured that only symptomatic patients were referred to the clinics. As the local cases of COVID-19 came under control, restrictions were eased, and the number of cases of cholecystectomies and hernias increased in June 2020. The cholecystectomy workload has not recovered to that of pre–COVID-19 times. This could be due to a fear of visiting public hospitals and seeking treatment at private health care facilities among patients. As the outpatient referral pattern resumes slowly, we expect the workload for hernia and gallbladder surgical operations to be restored gradually.

Emergency Cases

In our experience, the emergency workload reduced gradually. From March 2020, the effect was significant due to hospital guidance for complete ambulance diversion for non–COVID-19–related illnesses. This trend continued during the ensuing months. Further, the "circuit breaker" period of April-May 2020 also resulted in a reduction in the number of walk-in patients in the emergency department. Surgical patients suspected to have COVID-19 were isolated and required to have nasopharyngeal COVID-19 swabs done. Patients with pending swabs that required lifesaving surgical procedures were operated on with full PPE in a specialized operating room designed for COVID-19 operations. Patients with superficial abscesses and patients who were hemodynamically stable were managed with antibiotics first until their swabs were negative. Patient investigations and management were not delayed under the pretext of COVID-19. We did not change the local policy of managing acute appendicitis, acute cholecystitis, hollow viscus perforation, or obstructed hernia due to the COVID-19 pandemic.

Strengths and Limitations

Strict adherence to triaging guidelines was essential to ensure the appropriate allocation of limited resources. Due to the nature of the triaging system, we had to be flexible with our schedule to perform the essential surgical operations. We had a team coordinator who was responsible for informing patients of the timing of their operations and ensured that the required preoperative workups were arranged. We created a separate list of patients who were willing to come in for their operations on short notice and thus managed to fill in the empty slots if there were cancellations. Memorial Sloan Kettering Cancer Center in the United States had a similar framework to ours for triaging patients for "essential" cancer operations, and they had managed to continue operating on patients with cancer even as COVID-19 cases escalated in the United States [20].

There were a few limitations to our audit. Firstly, we did not collect hospital-wide admissions data and reported only the HPB unit data as a department-wide audit would introduce heterogeneity. For example, the colorectal surgical service had minimal elective hernia and gallbladder volume, and vascular surgical services do not participate in emergency or elective general surgical pathologies. Secondly, we did not report on the clinical outcomes of patients as the primary intent was to audit the impact of COVID-19 on the service and not to report clinical outcomes This is also one reason why we did not submit this study for ethical approval. Lastly, we did not conduct audits on the availability of blood products, medications, and intensive care beds. In a multicenter study including 34 pediatric oncology centers from 19 countries, Saab et al [21] reported that essential treatments were delayed, and certain centers had shortages of

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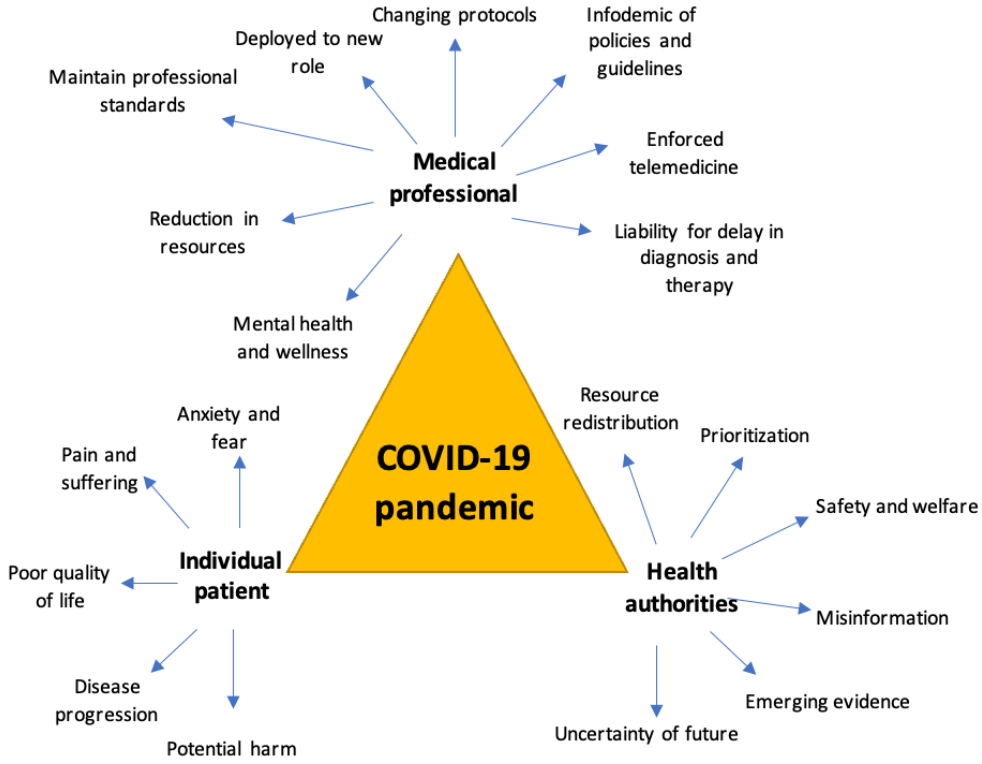
blood products, beds, and medications. However, we did not observe any cancellations due to logistics or resource issues.

Conclusions

The COVID-19 pandemic will continue for the months ahead [22], and our audit reassures various stakeholders (Figure 3) that the measures implemented locally remain valid and proportionally appropriate to maintain the functionality of the HPB surgical oncology service. Our results have shown that with a well-organized protocol in place, essential surgical procedures can still proceed in a pandemic despite resource reallocation and rationing.

Figure 3. Implications for stakeholders during the COVID-19 pandemic.



Conflicts of Interest

None declared.

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Abbreviations

HCC: hepatocellular carcinoma
HDU: high-dependency unit
HPB: hepatopancreatobiliary
NCID: National Centre for Infectious Diseases
PPE: personal protective equipment
SICU: surgical intensive care unit
TTSH: Tan Tock Seng Hospital

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Original Paper

The Association Between Preoperative Patient-Reported Health Status and Postoperative Survey Completion Following Arthroplasty: Registry-Based Cohort Study

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Abstract

Background: Patient-reported outcome measures (PROMs) are commonly used to report outcomes after hip and knee arthroplasty, but response rates are rarely complete. Given that preoperative health status (as measured by PROMs) is a strong predictor of outcomes (using the same measures) and that these outcomes may influence the response rate, it is possible that postoperative response rates (the proportion of patients providing preoperative PROMs who also provide postoperative PROMs) may be influenced by preoperative health status.

Objective: This study aims to test the association between preoperative PROMs and postoperative response status following hip and knee arthroplasty.

Methods: Data from the PROMs program of the Australian national joint registry were used. The preoperative PROMs were the Oxford Hip Score or Oxford Knee Score, The EQ-5D Utility Index, and the EQ visual analog scale (VAS) for overall health. Logistic regression, adjusting for age, sex, BMI, and the American Society of Anesthesiologists (ASA) Physical Status Classification System, was used to test the association between each preoperative PROM and response status for the 6-month postsurgery survey.

Results: Data from 9499 and 16,539 patients undergoing elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) for osteoarthritis, respectively, were included in the analysis. Adjusting for age, sex, BMI, and ASA, there was no significant difference in response status at the postoperative follow-up based on the preoperative Oxford Hip or Knee Scores (odds ratio [OR] 1.00, 95% CI 0.99-1.01 for both; *P*=.70 for THA and *P*=.85 for TKA). Healthier patients (based on the EQ VAS scores) preoperatively were more likely to respond postoperatively, but this difference was negligible (OR 1.00, 95% CI 1.00-1.01 for THA and TKA; *P*=.004 for THA and *P*<.001 for TKA). The preoperative EQ Utility Index was not associated with the postoperative response rate for THA (OR 1.14, 95% CI 0.96-1.36; *P*=.13) or TKA patients (OR 1.05, 95% CI 0.91-1.22; *P*=.49).

Conclusions: The likelihood of responding to a postoperative PROMs survey for patients undergoing hip or knee arthroplasty was not associated with clinically important differences in preoperative patient-reported joint pain, function, or health-related quality of life. This suggests that the assessment of postoperative outcomes in hip and knee arthroplasty is not biased by differences in preoperative health measures between responders and nonresponders.

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KEYWORDS

total knee arthroplasty; total hip arthroplasty; patient-reported outcomes; perioperative medicine; postoperative medicine; knee surgery; arthroplasty; quality of life; surgical outcomes; cohort study; survey; health survey; hip; knee;

Introduction

Patient-reported outcome measures (PROMs) are commonly used to provide the patient's perspective on outcomes such as pain, function, and quality of life after arthroplasty. However, response rates are rarely complete and vary between institutions and patients. If postoperative response rates are influenced by the preoperative severity of symptoms and quality of life, this would be a source of bias when estimating the average outcome from surgery because preoperative patient-rated pain, function, and quality of life are highly predictive of the corresponding postoperative outcomes, both short and long term [1-6]. Unfortunately, the outcome scores of nonresponders (by definition) cannot be measured, so it is not possible to know if there is bias in the response rate based on postoperative outcomes.

Measuring the association between preoperative PROMs scores and response status may provide insight into any potential postoperative responder bias. Evidence of responder bias would suggest that caution should be taken when interpreting average postarthroplasty PROMs from incomplete groups and that greater efforts to improve response rates may provide less biased results.

This study aims to determine if preoperative PROMs are associated with postoperative response status in patients undergoing elective hip or knee arthroplasty.

Methods

Overview

This retrospective cohort study uses a convenience sample of observational routinely collected data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) PROMs program. The AOANJRR collects data on joint replacement surgery performed in all (over 300) hospitals in Australia performing arthroplasty surgery. The AOANJRR PROMs program was initiated in 43 hospitals in 2018 and data available from July 30, 2018, to January 38, 2020, were used for this study. Participating hospitals were chosen for the PROMs program to provide a cross-section of hospital types (including high and low volume, public and private, and metropolitan and regional) across Australian states and territories.

The study population included all patients undergoing elective total hip arthroplasty (THA) or elective total knee arthroplasty (TKA) for osteoarthritis at one of the 43 participating institutions who provided preoperative PROMs data. There were no exclusions. Data were collected directly from patients who entered their responses electronically (via smartphone, tablet, or computer) through the AOANJRR online data collection system. A telephone follow-up was performed for those who did not respond electronically. A more detailed description of the processes involved in the PROMs data collection for this cohort is provided elsewhere [7].

The primary outcome was response to the postoperative PROMs survey at 6 (minimum 5, maximum 8) months post surgery (yes or no) in patients who provided preoperative PROMs data. Predictor variables were preoperative PROMs scores: EQ-5D-5L Utility Index, EQ visual analog scale (VAS; an overall measure of quality of life from zero to 100 with 100 being the best possible health), and Oxford Hip/Knee Scores (joint-specific scores of pain and function from 0 to 48, with 48 being the best possible score). These PROMs were chosen for inclusion in the PROMs program by an international working group based on their common use among registries and in the clinical community, their validity and responsiveness to change in this population (arthroplasty), and their associated responder burden [7]. Using both PROMs provides a joint-specific profile (from the Oxford Score, allowing the collection of patient outcomes that are highly relevant to joint replacement and greater sensitivity to change from joint surgery) and a general health profile (from the EQ-5D scores, providing a better picture of overall health and allowing comparison with other health conditions).

Ethics Approval

The following Australian ethics committees approved the pilot program from which these data were drawn: University of South Australia Human Research Ethics Committee (HREC; 200890), Sydney Local Health District Ethics Review Committee (RPAH Zone, HREC/18/RPAH/90), Calvary Health Care Adelaide HREC (18-CHREC-F004), Mater Misericordiae Ltd HREC (HREC/18/MHS/45), St Vincent's Health and Aged Care HREC (HREC 18/14), University of Tasmania HREC (H0017292), Calvary Health Care Tasmania HREC (010418), St John of God HREC (1408), and Calvary Health Care (ACT; 25-2018). Consent was obtained for the collection and use of data, but consent was not obtained for the analyses used in this report as data were analyzed anonymously.

Statistical Analysis

Data were analyzed descriptively, and logistic regression analyses adjusted for age, sex, American Society of Anesthesiologists (ASA) Physical Status Classification System score [8], and BMI were performed to test the association between each preoperative PROM score and response status. The association being tested is described visually in a directed acyclic graph (Multimedia Appendix 1). These covariates were chosen as they are key demographic and clinical variables routinely collected by the AOANJRR with a potential to impact the study outcome. A P value <.05 was considered statistically significant. Missing data were not imputed, as missingness was the dependent variable.

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Results

Data on 25,988 procedures were included in the analysis: 9449 THA and 16,539 TKA. The overall response rate post surgery for those who provided preoperative PROMs data was 82% (n=21,418), which varied from 41% (48/116) to 97% (208/215) between hospitals. For those who provided preoperative PROMs data, the distribution of patient characteristics based on response status for the postoperative survey is provided for THA and TKA in Tables 1 and 2, respectively. The proportion of female patients was between 3% and 4% higher for responders than nonresponders, for both THA and TKA. Differences between responders and nonresponders were less for other characteristics (sex, ASA, and BMI) except for healthier patients (ASA class 2 vs 3) being more likely to respond in the TKA group. The representativeness of responders versus nonresponders for this cohort has been previously reported [9].

The association between preoperative PROMs scores and postoperative response status, unadjusted and adjusted for age, sex, ASA score, and BMI, is provided for THA and TKA in Tables 3 and 4, respectively.

Patients undergoing THA or TKA who responded to the postoperative PROMs survey had significantly better preoperative scores for quality of life using the EQ VAS compared to nonresponders, but these differences were small (<2 points on a 100-point scale) and unlikely to be clinically important [10].

There was no significant association between the preoperative Oxford score or EQ-5D Utility Index and postoperative response status for patients undergoing THA or TKA (Tables 3 and 4). For the Oxford Scores, the differences were small (<1 point, smaller than a clinically important difference [11]) and the CIs were small.

Table 1. Summary of patient characteristics for those undergoing total hip arthroplasty who provided preoperative patient-reported outcome measures data by postoperative response status.

Variable	Did not respond (n=1752)	Responded (n=7697)	Total (N=9449)
Age (years), mean (SD)	65.8 (12.1)	66.2 (11.3)	66.1 (11.5)
Sex, n (%)			
Female	883 (50.4)	4159 (54.0)	5042 (53.4)
Male	869 (49.6)	3538 (46.0)	4407 (46.6)
ASA[a,b], n (%)			
1 (normal health)	160 (9.2)	558 (7.4)	718 (7.7)
2 (mild systemic disease)	949 (54.9)	4237 (56.0)	5186 (55.8)
3 (severe systemic disease)	600 (34.7)	2681 (35.4)	3281 (35.3)
4 (severe disease a threat to life)	21 (1.2)	89 (1.2)	110 (1.2)
BMI (kg/m^2)[c], n (%)			
Underweight (<18.50)	18 (1.1)	48 (0.7)	66 (0.8)
Normal (18.50-24.99)	341 (20.8)	1313 (19.7)	1654 (19.9)
Preobese (25.00-29.99)	597 (36.3)	2314 (34.6)	2911 (35.0)
Obese class 1 (30.00-34.99)	408 (24.8)	1773 (26.5)	2181 (26.2)
Obese class 2 (35.00-39.99)	178 (10.8)	823 (12.3)	1001 (12.0)
Obese class 3 (≥40.00)	101 (6.1)	410 (6.1)	511 (6.1)

[a]ASA: American Society of Anesthesiologists.

[b]Excludes 154 procedures with unknown ASA score.

[c]Excludes 1125 procedures with unknown BMI.

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Table 2. Summary of patient characteristics for those undergoing total knee arthroplasty who provided preoperative patient-reported outcome measures data by postoperative response status.

Variable	Did not respond (n=2818)	Responded (n=13,721)	Total (N=16,539)
Age (years), mean (SD)	67.9 (9.5)	67.7 (8.8)	67.7 (9.0)
Sex, n (%)			
Female	1556 (55.2)	7998 (58.3)	9554 (57.8)
Male	1262 (44.8)	5723 (41.7)	6985 (42.2)
ASA[a,b], n (%)			
1 (normal health)	122 (4.5)	623 (4.6)	745 (4.6)
2 (mild systemic disease)	1425 (52.0)	7430 (55.3)	8855 (54.8)
3 (severe systemic disease)	1167 (42.6)	5271 (39.2)	6438 (39.8)
4 (severe disease a threat to life)	26 (0.9)	108 (0.8)	134 (0.8)
BMI[c](kg/m^2), n (%)			
Underweight (<18.50)	3 (0.1)	12 (0.1)	15 (0.1)
Normal (18.50-24.99)	274 (10.7)	1080 (9.3)	1354 (9.6)
Preobese (25.00-29.99)	797 (31.2)	3301 (28.5)	4098 (29.0)
Obese class 1 (30.00-34.99)	778 (30.4)	3553 (30.7)	4331 (30.7)
Obese class 2 (35.00-39.99)	433 (16.9)	2088 (18.1)	2521 (17.9)
Obese class 3 (≥40.00)	272 (10.6)	1531 (13.2)	1803 (12.8)

[a]ASA: American Society Anesthesiologists.

[b]Excludes 367 procedures with unknown ASA score.

[c]Excludes 2417 procedures with unknown BMI.

Table 3. Preoperative PROMs scores in patients undergoing total hip arthroplasty by response status post surgery.

PROMs[a]	Did not respond, mean (SD)	Responded, mean (SD)	Total, mean (SD)	Adjusted[b] odds ratio (95% CI)	*P* value
EQ-5D-5L Utility	0.29 (0.37)	0.29 (0.37)	0.29 (0.37)	1.14 (0.96-1.36)	.13
EQ VAS[c]	63.7 (21.0)	65.2 (21.1)	65.0 (21.1)	1.00 (1.00-1.01)	.004
Oxford Hip Score	19.1 (8.7)	18.9 (9.0)	18.97 (8.99)	1.00 (0.99-1.01)	.70

[a]PROM: patient-reported outcome measure.

[b]Adjusted for age, sex, American Society Anesthesiologists score, and BMI; represents the likelihood of responding at 6 months.

[c]VAS: visual analog scale.

Table 4. Preoperative PROMs scores in patients undergoing total knee arthroplasty by response rate post surgery.

PROMs[a]	Did not respond, mean (SD)	Responded, mean (SD)	Total, mean (SD)	Adjusted[b] odds ratio (95% CI)	*P* value
EQ-5D-5L Utility	0.39 (0.35)	0.40 (0.35)	0.39 (0.35)	1.05 (0.91-1.22)	.49
EQ VAS[c]	66.7 (19.8)	68.3 (19.5)	68.0 (19.6)	1.00 (1.00-1.01)	<.001
Oxford Knee Score	21.0 (8.7)	20.8 (8.4)	20.8 (8.5)	1.00 (0.99-1.01)	.85

[a]PROM: patient-reported outcome measure.

[b]Adjusted for age, sex, American Society Anesthesiologists score, and BMI; represents the likelihood of responding at 6 months.

[c]VAS: visual analog scale.

Discussion

Principal Results

For patients undergoing THA and TKA, there were no significant or clinically important differences in the preoperative Oxford scores or EQ Utility Index between those who responded to the postoperative survey and those who did not respond. There was evidence that patients with worse overall preoperative health on the EQ VAS for THA and TKA were less likely to respond, but these differences were small (<2-point difference

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on a 100-point scale for THA and <1-point difference for TKA, based on unadjusted data).

The findings suggest that arthroplasty patients who respond to PROMs surveys postoperatively are largely representative of patients who responded preoperatively regarding their preoperative PROMs. Similarly, the findings suggest that the postoperative outcomes data that are captured represent the full spectrum of patients regarding their capacity for improvement.

Comparison With Prior Work

We have previously reported on the association between patient characteristics and response rates to PROMs surveys in this population, showing that postoperative responders are largely representative of the population undergoing surgery, with respect to age, sex, comorbidity, and BMI [11]. However, this study was not able to comment on the representativeness of preoperative PROMs data compared to all patients undergoing surgery, as data from nonresponders are not available. Similarly, we were unable to determine any association between postoperative PROMs and response rate.

Consistent with our findings, a study of Swedish Fracture Register participants found no significant differences in PROMs at baseline or at 1 year between responders and nonresponders [12]. However, *nonresponders* were patients who did not respond to the initial survey request but responded to a reminder. Therefore, patients who never responded were not included in the analysis.

In a registry study of total hip replacement recipients, nonresponders to follow-up surveys were found to have significantly worse EQ-5D and Oxford Hip Scores preoperatively [13]. The difference in baseline Oxford Hip Scores between responders and nonresponders at 6 months was 3 points, not a clinically important difference but larger than the difference found in this study. Similar findings were reported from the Swedish Knee Ligament Register, where responders to postoperative surveys were found to have better preoperative scores in two of the domains of the Knee Injury and Osteoarthritis Outcomes Score, but the differences were of questionable clinical importance [14].

A large UK study of postoperative survey response predictors at 6 months showed that better general health preoperatively (measured by the EQ Utility Index) was associated with increased probability of responding. This is consistent with our findings regarding general health using the EQ VAS [15].

Limitations

The study findings should be interpreted in light of any limitations. The findings may not be generalizable to other countries or regions. The study findings may not be applicable to other periods of follow-up. The analysis was limited to available covariates, and the findings may be influenced by unmeasured confounders such as socioeconomic status. Furthermore, interaction from other variables (eg, patient characteristics) was not tested. However, the study used a large sample from a variety of hospitals, maximizing the power to detect any potential preoperative differences and the ability to generalize within Australia.

Future Directions

Future studies assessing potential attrition bias in the reporting of patient-reported outcomes after surgery should include all likely confounders such as patient socioeconomic status, education, and specific comorbidities rather than the restrictive set of patient-level variables used in this study. Consideration should also be given to surgeon- and hospital-level variables when assessing factors that may influence response rates to postoperative surveys, although such data are rarely collected in a systematic manner.

Conclusions

Patients responding to postoperative PROMs surveys following THA and TKA do not have clinically important differences in preoperative PROMs compared to those not responding. Preoperative scores are strong predictors of postoperative patient-reported outcomes, but this study suggests that the assessment of postoperative outcomes in hip and knee arthroplasty is not biased by differences in preoperative health measures between responders and nonresponders.

Acknowledgments

The authors acknowledge the support of registry staff, including Sophie Rainbird, in the preparation of this manuscript.

Data Availability

The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) is declared by the Commonwealth of Australia as a federal quality assurance activity under section 124X of the Health Insurance Act, 1973. This declaration ensures freedom from subpoena and absolute confidentiality of information held by the registry. A declaration as a Quality Assurance Activity by the Commonwealth Minister of Health prohibits the disclosure of information that identifies individual patients or health care providers that is known solely as a result of the declared quality assurance activity.

External access to and use of deidentified AOANJRR data is permitted but must be in accordance with AOANJRR policies (Ref No POL.S3.3, S3.4, S3.5) available on the registry website [16]. Requests for data can be made by contacting the AOANJRR manager by email at admin@aoanjrr.org.au.

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Authors' Contributions

All authors contributed to the concept and conduct of the study, and edited and approved the final manuscript. The manuscript was drafted by IAH and the statistical analysis was performed by YP.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Directed acyclic graph for the association between preoperative patient-reported outcome measures and postoperative survey response.
[PNG File , 47 KB - periop_v5i1e33414_app1.png]

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Abbreviations

AOANJRR: Australian Orthopaedic Association National Joint Replacement Registry
ASA: American Society of Anesthesiologists
HREC: Human Research Ethics Committee
OR: odds ratio
PROM: patient-reported outcome measure
THA: total hip arthroplasty
TKA: total knee arthroplasty
VAS: visual analog scale

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Original Paper

The Reduction in Medical Errors on Implementing an Intensive Care Information System in a Setting Where a Hospital Electronic Medical Record System is Already in Use: Retrospective Analysis

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Abstract

Background: Although the various advantages of clinical information systems in intensive care units (ICUs), such as intensive care information systems (ICISs), have been reported, their role in preventing medical errors remains unclear.

Objective: This study aimed to investigate the changes in the incidence and type of errors in the ICU before and after ICIS implementation in a setting where a hospital electronic medical record system is already in use.

Methods: An ICIS was introduced to the general ICU of a university hospital. After a step-by-step implementation lasting 3 months, the ICIS was used for all patients starting from April 2019. We performed a retrospective analysis of the errors in the ICU during the 6-month period before and after ICIS implementation by using data from an incident reporting system, and the number, incidence rate, type, and patient outcome level of errors were determined.

Results: From April 2018 to September 2018, 755 patients were admitted to the ICU, and 719 patients were admitted from April 2019 to September 2019. The number of errors was 153 in the 2018 study period and 71 in the 2019 study period. The error incidence rates in 2018 and 2019 were 54.1 (95% CI 45.9-63.4) and 27.3 (95% CI 21.3-34.4) events per 1000 patient-days, respectively (P<.001). During both periods, there were no significant changes in the composition of the types of errors (P=.16), and the most common type of error was medication error.

Conclusions: ICIS implementation was temporally associated with a 50% reduction in the number and incidence rate of errors in the ICU. Although the most common type of error was medication error in both study periods, ICIS implementation significantly reduced the number and incidence rate of medication errors.

Trial Registration: University Hospital Medical Information Network Clinical Trials Registry UMIN000041471; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000047345

(JMIR Perioper Med 2022;5(1):e39782) doi:10.2196/39782

KEYWORDS

clinical information system; electronic medical record; intensive care unit; medical error

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Introduction

Background

Clinical information systems in intensive care units (ICUs), such as intensive care information systems (ICISs), have been developed to aggregate patient information, improve operational efficiency, and obtain accurate records. A commercial ICIS consists of a critical care flowsheet; computerized physician order entry (CPOE); and interfaces with bedside monitors, ventilators, and other external devices. It also has the capability to interface with other hospital systems [1].

Studies have reported that ICIS implementation is associated with both desirable and undesirable effects. The desirable effects of ICISs include improved efficiency and quality of care, improved data utilization and security, and reduced documentation time [2-5]. By contrast, the undesirable effects of ICISs include the occurrences of ICIS-related errors, reduced speed and efficiency due to poor system usability, interruption of established workflows, and the risk of system failure [5-8]. Meanwhile, the effect on the length of stay in the ICU is controversial [9,10].

In particular, when both an ICIS and a hospital electronic medical record (EMR) system are used simultaneously, the differences in performance and operability of both systems, as well as the low level of interactivity between them, can lead to new errors. ICISs are generally interfaced with EMRs because EMR systems are used for many hospital tasks; on the other hand, limitations in the level and direction of information coordination can prevent the sufficient integration of EMRs and ICISs. However, if ICISs are built into EMRs as modules, the integration of both systems would improve.

Motivation for ICIS Implementation in Our Hospital

The EMR has been used throughout Tokyo Women's Medical University Hospital since 2014. Given that the EMR was not well suited for use in the ICU, the vital sign and prescription dashboards remained separate; therefore, paper-based orders and flowsheets were used concurrently. Subsequently, a critical incident occurred in the ICU, and inadequate records became a serious issue during the investigation of the incident. As a result, the order and charting procedures in the ICU were revised for the EMR to be used more; however, as mentioned earlier, this led to an increase in staff workload. Thus, the introduction of a commercial ICIS was planned during the reorganization of ICUs at the hospital.

ICIS Implementation and Medical Errors in the ICU

No study has focused on the changes in error incidence in ICUs after the implementation of a commercial ICIS adding to an EMR. However, some studies have reported the effects of ICIS implementation on medication errors. A comparison of a paper-based ICU and a computerized ICU with an ICIS for medication errors showed that the incidence of medical prescription errors was 3.42% (44 errors in 1286 prescriptions) in the ICU with an ICIS compared with 27.04% (331 errors in 1224 prescriptions) in the paper-based ICU [11]. By contrast, a study in a pediatric ICU reported that ICIS implementation did not significantly reduce the prescription error rate, from 8.8% (14 errors in 159 prescriptions; 95% CI 4.4-13.2) before ICIS implementation to 4.6% (12 errors in 257 prescriptions; 95% CI 2.0-7.2) 6 months after ICIS implementation [12]. A study comparing handwritten orders with CPOE orders in a cardiac ICU reported that the error rate of prescription errors decreased from 44.8% (819 errors in 1829 prescriptions) with handwritten orders to 0.8% (16 errors in 2094 prescriptions) with CPOE [13]. Similarly, there have been reports that CPOE implementation contributed to a decrease in prescription errors in an ICU and a decrease in parenteral nutrition medication errors in a neonatal ICU [14,15].

Objectives

Although the various advantages of ICIS implementation in ICUs have been reported, the role of an ICIS in preventing errors in an ICU remains unclear. This study aimed to investigate the changes in the incidence and type of errors in the ICU before and after ICIS implementation in a setting where an EMR system is already being used and where an ICIS is not integrated with the EMR system.

Methods

Study Design and Setting

This study was a retrospective analysis of the errors in the general ICU (18 beds, 1:2 nurse to patient ratio) of a university hospital (1335 beds) before and after ICIS implementation by using data from an incident reporting system. An ICIS (PrimeGaia PRM-7400, Nihon Kohden Corp) was implemented in the ICU. After a step-by-step implementation lasting 3 months, the ICIS was used in all patients starting from April 1, 2019.

Ethics Approval

The study was approved by the Institutional Review Board of Tokyo Women’s Medical University (approval #5224; June 20, 2019), and the need for informed consent was waived due to the retrospective study design. All methods in the study were performed in accordance with the relevant guidelines and regulations.

Before ICIS Implementation (April 2018 to September 2018)

An EMR system (HOPE EGMAIN, Fujitsu Japan Limited) was already in use in the ICU and has many components, including CPOE with a clinical decision support system (CDSS), documentation, flowsheet, patient care instruction, and ordering and viewing functions for laboratory tests and imaging studies. However, given that the CPOE was not optimized for use in the ICU, paper-based orders were used for the dosage of continuous injection drugs. The orders for mechanical ventilation, mechanical circulatory support, and renal replacement therapy settings were also paper based. In addition, nurses had to manually enter the dosages of continuous injection drugs; the fluid balance; and the parameters derived from bedside monitors, ventilators, and other monitors into the EMR flowsheet (Figure 1). This input process was time-consuming and contributed to the heavy workload of ICU nurses. The EMR flowsheet was

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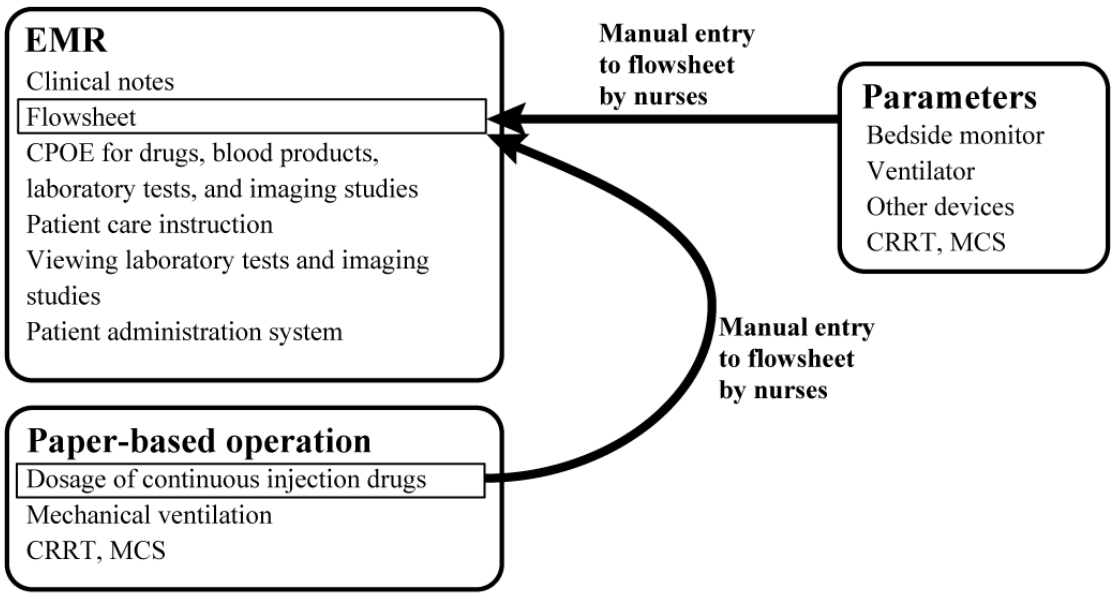
not optimized as an information tool for critically ill patients and was slow to operate.

Figure 1. Workflow in the study period before ICIS implementation (April 1, 2018, to September 30, 2018). CPOE: computerized physician order entry; CRRT: continuous renal replacement therapy; EMR: electronic medical record; ICIS: intensive care information system; MCS: mechanical circulatory support.



ICIS Implementation Process

A multidisciplinary implementation project team consisting of physicians, nurses, pharmacists, clinical engineers, and hospital system engineers was formed to determine the system specifications and prepare for implementation. The development of the ICIS began in October 2017. The ICIS was rolled out in October 2018, and training sessions for physicians and nurses also began in October 2018. The ICIS was launched on January 8, 2019. Considering the smooth adaptation and heterogeneity of patients, physicians, and nurses, incremental implementation was chosen. The project team modified the system and operational procedures during implementation.

After ICIS Implementation (April 2019 to September 2019)

The major components of the implemented ICIS included a critical care flowsheet; CPOE without CDSS; an interface with bedside physiologic monitors, ventilator, and other external devices; and an interface with an EMR system. The ICIS replaced the CPOE, flowsheet, and patient care instruction of the EMR system, and nurses no longer had to manually enter the dosages of drugs and parameters because the parameters were automatically registered into the system. However, the level of coordination between the EMR system and ICIS was low (Figure 2). Most of the drugs administered in the ICU were prescribed with the ICIS, and the ordering information was sent to the EMR system and the logistics system of the pharmacy department. In contrast, narcotics, drugs that require approval or registration (broad-spectrum antibiotics, drugs for chemotherapy, and rarely used drugs), and blood products had to be prescribed in both systems. Oral medications, laboratory tests, and imaging tests had to be ordered using the EMR system. The laboratory test results were displayed in the ICIS, while the imaging tests and their findings could be viewed only in the EMR system. The order of settings of mechanical ventilation, mechanical circulatory support, and renal replacement therapy was maintained using a paper-based system to avoid excessive workflow changes for ICU physicians and nurses. Given that the EMR system and ICIS were not integrated and that the ICU staff needed to operate both systems simultaneously, dual displays were equipped on the bedside computers to ensure operational efficiency.

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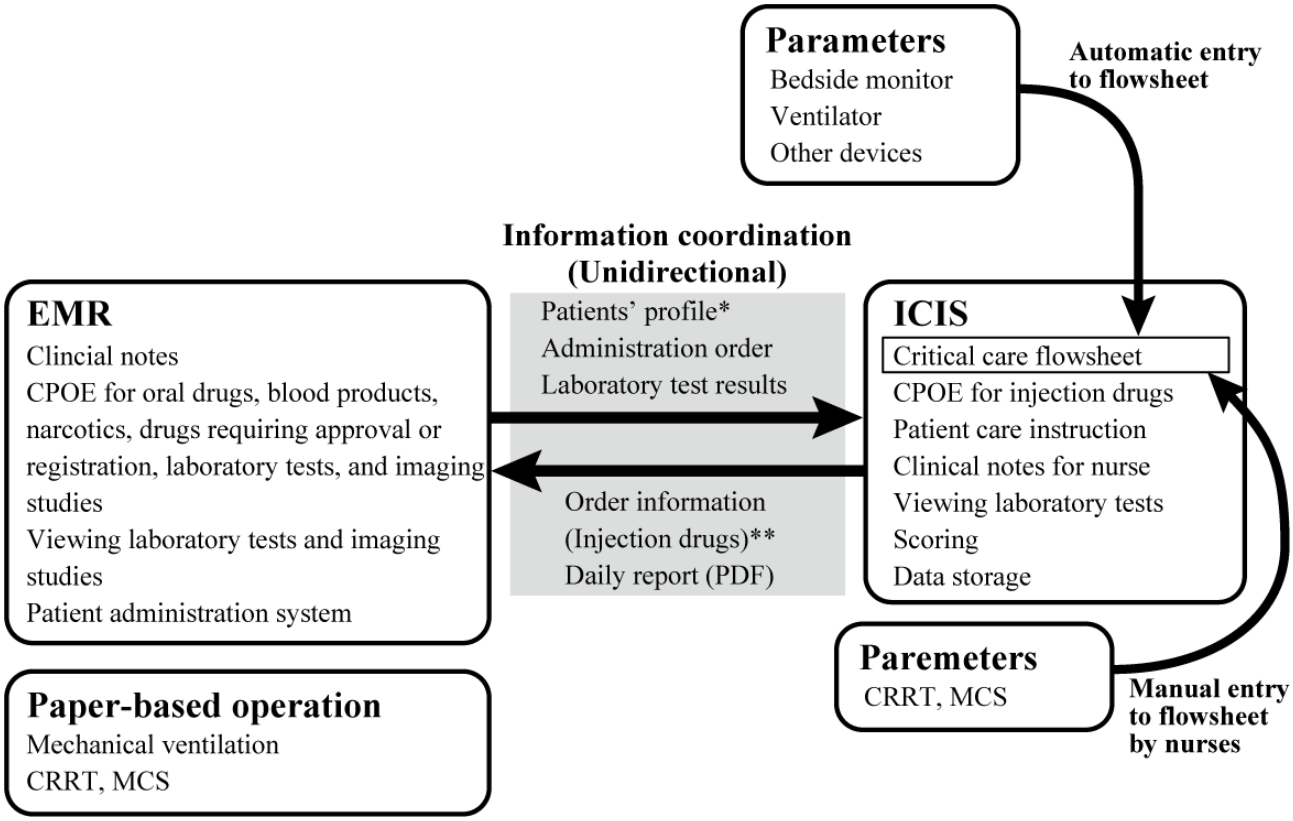
Figure 2. Workflow in the study period after the completion of a step-by-step implementation of ICIS (April 1, 2019, to September 30, 2019). CPOE: computerized physician order entry; CRRT: continuous renal replacement therapy; EMR: electronic medical record; ICIS: intensive care information system; MCS: mechanical circulatory support. *The patients' basic profiles are sent from the EMR to the ICIS, except for information on their allergies and contraindications. **Blood products, narcotics, and drugs that require approval or registration (broad-spectrum antibiotics, drugs for chemotherapy, and rarely used drugs) need to be ordered in both the EMR system and ICIS. Changes in the orders are not synchronized.



Data Collection and Outcomes

Data of ICU errors in a 6-month period 1 year before the ICIS implementation (April 1, 2018, to September 30, 2018) and 3 months after ICIS implementation (April 1, 2019, to September 30, 2019) were extracted from the incident reporting system to determine the number and incidence rate of errors. The incident reporting system in the hospital was based on voluntary self-reporting. All error reports were submitted using a computer-based form and were reviewed by safety managers in departments that handle errors and by the Patient Safety Management section. Information regarding the length of stay and patients' treatment departments in the ICU was collected from the ICIS and EMR system during the study period. We defined all events reported in the incident reporting system as errors in this study. The errors were classified into 7 types on the basis of the classification system of the Japan Council for Quality Health Care (Table 1) [16]. The errors were classified into 8 levels according to severity and influence based on the National University Hospital Council of Japan's classification system in the incident reporting system (Table 2) [17]. The type and level of errors were preliminarily determined by the staff filling the report and were reviewed and adjudicated by safety managers in the departments that handle errors.

The primary outcomes in this study were the number and incidence rate of errors during the 6-month study period. The secondary outcomes included the number and incidence rates of errors by category and type, the patient outcome level of errors, the number and incidence rate of ICIS-related errors, and the composition of treatment departments.

Table 1. Classification of the type of errors recommended by the Japan Council for Quality Health Care.

Type of errors	Description
Medication	Errors related to medication or blood transfusion
Line, tube, or drain	Errors related to lines (venous routes or catheters), tubes (endotracheal tube or nasogastric tube), and drain (drainage tube from body cavities or wounds)
Equipment/devices	Errors related to medical equipment and devices
Diagnostic testing	Errors related to laboratory and imaging tests
Therapeutic	Errors related to treatments or procedures
Nursing care	Errors related to nursing care
Miscellaneous	None of the above

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Table 2. Classification of the level of severity and influence of errors recommended by the National University Hospital Council of Japan.

Level	Continuity of injury	Severity of injury	Description (NCC MERP[a] Category)
0	None	N/A[b]	Errors or malfunctions in medicines and medical devices occurred but did not reach the patient (B).
1	None	N/A	There was no actual harm to the patient (but there was a possibility of some influence) (C).
2	Transient	Mild	Treatment was not required (enhanced patient observation, mild change in vital signs, examination for confirmation of safety, etc) (D).
3a	Transient	Moderate	A simple procedure or treatment was required (disinfection, poultice, skin suture, administration of analgesics) (E).
3b	Transient	Severe	A substantial procedure or treatment was required (significant change in vital signs, use of mechanical ventilation, surgery, prolongation of hospital stay, hospitalization, fracture, etc.) (F).
4a	Permanent	Mild-moderate	Permanent disability or sequelae remained without significant functional impairment or cosmetic problems (G or H).
4b	Permanent	Moderate-severe	Permanent disability or sequelae remained with significant functional impairment or cosmetic problems (G or H).
5	Death	N/A	Death (excluding that due to the natural course of the underlying disease) (I).
Others	N/A	N/A	Errors to which the classification was not able to be applied.

[a]NCC MERP: National Coordinating Council for Medication Error Reporting and Prevention.

[b]N/A: not applicable.

Statistical Analysis

Categorical variables are presented as frequencies and percentages, and Fisher exact test was used to analyze statistical significance. Continuous variables are presented as median and IQR, and we used a nonparametric test (Mann-Whitney test) for continuous variables. The incidence rate of errors was calculated as the number of events per 1000 patient-days. The incidence rates of errors in the study periods were compared by their 95% CIs calculated using the Poisson distribution and exact conditional test. Statistical significance was set at $P<.05$. All statistical analyses were conducted using R Statistical Package 4.1.1 (The R Foundation for Statistical Computing).

Results

Demographics

From April 1, 2018, to September 30, 2018, 755 patients were admitted to the ICU, and 719 patients were admitted from April 1, 2019, to September 30, 2019. The total lengths of stay during the 2018 and 2019 study periods were 2828 and 2600 patient-days, respectively (Table 3). The median lengths of stay in 2018 and 2019 were similar (1.6 days). The compositions of the treatment departments of patients were also similar between 2018 and 2019, and cardiovascular surgery, neurosurgery, thoracic surgery, and gastrointestinal surgery were the major departments. The patient characteristics were comparable between 2018 and 2019. The ICU was staffed with a 1:2 nurse to patient ratio with 9 intensivists (3 to 4 during weekdays and 1 at night and on weekends). Staffing did not change between the 2 periods.

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Table 3. Demographic data of the intensive care unit.

	Apr-Sep 2018	Apr-Sep 2019	*P* value
Patients admitted, n	755	719	N/A[a]
Total length of stay (patient-days), n	2828	2600	N/A
Length of stay (days), median (IQR)	1.6 (0.8-3.6)	1.6 (0.9-3.0)	.24
Patient characteristics			
Age (years), median (IQR)	63 (47-74)	64 (45-72)	.42
Male gender, n (%)	434 (57.5)	420 (58.4)	.76
Race			.93
Asian-Japanese, n (%)	747 (98.9)	711 (98.9)	
Asian-other, n (%)	4 (0.5)	5 (0.7)	
White, n (%)	2 (0.3)	2 (0.3)	
Other, n (%)	2 (0.3)	2 (0.3)	
Patients by treatment department			.49
Cardiovascular surgery, n (%)	264 (35.0)	268 (37.3)	
Neurosurgery, n (%)	242 (32.1)	196 (27.3)	
Gastrointestinal surgery, n (%)	68 (9.0)	65 (9.0)	
Thoracic surgery, n (%)	80 (10.6)	95 (13.0)	
Urology and renal transplantation, n (%)	31 (4.1)	30 (4.2)	
Endocrine surgery, n (%)	5 (0.7)	3 (0.4)	
Miscellaneous surgery, n (%)	24 (3.2)	19 (2.6)	
Medical, n (%)	41 (5.4)	43 (5.9)	

[a]N/A: not applicable.

Evaluation Outcomes

The number of errors was 156 in the 2018 study period and 71 in the 2019 study period. The error incidence rates in 2018 and 2019 were 55.2 (95% CI 46.8-64.5) and 27.3 (95% CI 21.3-34.4) events per 1000 patient-days, respectively (*P*<.001; Table 4). Approximately 40% of errors occurred in patients treated in the cardiovascular surgery department in both periods, and there was no significant difference in the composition of treatment departments in which the errors occurred.

The number and incidence rate of ICIS-related errors in the 2019 study period were 10 (10/71, 14%) and 3.8 (95% CI 1.8-7.1) events per 1000 patient-days, respectively (Table 4). All ICIS-related errors were associated with the CPOE component of the ICIS, and the major background factors of the errors were inadequate coordination between the ICIS and EMR system (4 events due to an inability to synchronize orders between both systems), unfamiliarity with ICIS operations (3 events), inadequate confirmation (2 events), and specifications of the ICIS (1 event).

During both the periods, there were no significant changes in the composition of the types of errors (*P*=.14), and the most common type of error was medication error (Table 5). The number of errors related to medication decreased from 78 in 2018 (78/156, 50.0%) to 31 in 2019 (31/71, 43.7%), and the incidence rate of medication errors significantly decreased from 27.5 events per 1000 patient-days in 2018 (95% CI 21.8-34.4) to 11.9 events per 1000 patient-days in 2019 (95% CI 8.1-16.9; Table 5). The second most common type of error was errors related to line, tube, or drain. The number of errors decreased from 53 in 2018 (53/156, 34.0%) to 24 in 2019 (24/71, 33.8%), but the percentage of total errors remained the same. The incidence rate of errors related to line, tube, or drain significantly decreased from 18.7 events per 1000 patient-days in 2018 (95% CI 14.0-24.5) to 9.2 events per 1000 patient-days in 2019 (95% CI 5.9-13.7; Table 5). There was no difference in the severity and influence level of errors in both periods (*P*=.59), and level 1 and 2 errors accounted for most of the errors. The incidence rate in level 1 errors was reduced by one-third, and the incidence rate in each of the level 2 and 3a errors was reduced by one-half (Table 6).

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Table 4. Errors in the periods of April 2018 to September 2018 and April 2019 to September 2019.

	Apr-Sep 2018	Apr-Sep 2019	*P* value
Total errors, n	156	71	N/A[a]
Incidence rate of total errors, events per 1000 patient-days (95% CI)	55.2 (46.8-64.5)	27.3 (21.3-34.4)	<.001
Errors by treatment department, n (%)			.18
Cardiovascular surgery	59 (37.8)	30 (42.3)	
Neurosurgery	25 (16.0)	11 (15.5)	
Gastrointestinal surgery	25 (16.0)	13 (18.3)	
Thoracic surgery	5 (3.2)	0 (0.0)	
Urology and renal transplantation	6 (3.8)	5 (7.0)	
Endocrine surgery	0 (0.0)	0 (0.0)	
Miscellaneous surgery	1 (0.6)	2 (2.8)	
Medical	34 (21.8)	8 (11.3)	
Nondepartment	1 (0.6)	2 (2.8)	
ICIS[b]-related errors, n (%)	N/A	10 (14.1)	N/A
ICIS-related errors incidence rate, events per 1000 patient-days (95% CI)	N/A	3.8 (1.8-7.1)	N/A

[a]N/A: not applicable.

[b]ICIS: intensive care information system.

Table 5. Type of errors in periods of April 2018 to September 2018 and April 2019 to September 2019.

Type of errors	Apr-Sep 2018		Apr-Sep 2019		*P* value
	n (%) (N=156)	Incidence rate[a]	n (%) (N=71)	Incidence rate[a]	
Medication	78 (50.0)	27.5 (21.8-34.4)	31 (43.7)	11.9 (8.1-16.9)	<.001
Line, tube, or drain	53 (34.0)	18.7 (14.0-24.5)	24 (33.8)	9.2 (5.9-13.7)	.004
Equipment/devices	11 (7.1)	3.9 (1.9-7.0)	4 (5.6)	1.5 (0.4-3.9)	.12
Diagnostic testing	6 (3.8)	2.1 (0.8-4.6)	1 (1.4)	0.4 (0.01-2.1)	.13
Therapeutic	1 (0.6)	0.4 (0.01-2.0)	3 (4.2)	1.2 (0.2-3.4)	.36
Nursing care	6 (3.8)	2.1 (0.8-4.6)	5 (7.0)	1.9 (0.6-4.5)	>.99
Miscellaneous	1 (0.6)	0.4 (0.01-2.0)	3 (4.2)	1.2 (0.2-3.4)	.36

[a]The incidence rate of the type of errors is presented as events per 1000 patient-days and 95% CI.

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Table 6. Severity and influence level of errors in periods of April 2018 to September 2018 and April 2019 to September 2019.

Level of errors	Apr-Sep 2018		Apr-Sep 2019		*P* value
	n (%) (N=156)	Incidence rate[a]	n (%) (N = 71)	Incidence rate[a]	
Level 0	23 (14.7)	8.1 (5.2-12.2)	7 (9.9)	2.7 (1.1-5.5)	.009
Level 1	44 (28.2)	15.2 (11.3-20.9)	26 (36.6)	10.0 (6.5-14.7)	.07
Level 2	47 (30.1)	16.6 (12.2-22.1)	19 (26.8)	7.3 (4.4-11.4)	.002
Level 3a	33 (21.2)	11.7 (8.0-16.4)	14 (19.7)	5.4 (2.9-9.0)	.01
Level 3b	7 (4.5)	2.5 (1.0-5.1)	5 (7.0)	1.9 (0.6-4.5)	.78
Level 4a	0 (0.0)	0	0 (0.0)	0	N/A[b]
Level 4b	0 (0.0)	0	0 (0.0)	0	N/A
Level 5	0 (0.0)	0	0 (0.0)	0	N/A
Others	2 (1.3)	0.7 (0.09-2.6)	0 (0.0)	0	N/A

[a]The incidence rate of the level of errors is presented as events per 1000 patient-days and 95% CI.

[b]N/A: not applicable.

Discussion

Principal Results

Three important clinical observations were made in this study. First, the number and incidence rate of errors after ICIS implementation in the ICU were halved compared with those before the implementation. Second, the most common type of error was medication error before and after implementation, and the number and incidence rate of errors related to medication significantly decreased. Third, 14% (10/71) of the errors after the implementation were relevant to the ICIS.

The incidence of errors in the ICU differs between a study and its settings. In a study on the nature and incidence of adverse events and medical errors, the incidence rate of adverse events in the medical ICU and coronary care unit was 80.5 events per 1000 patient-days [18]. The incidence rate of critical incidents in a multidisciplinary ICU was 34 events per 1000 patient-days [19]. In the study of a voluntary card-based event reporting system in 3 ICUs, the incidence rates of reported patient safety events were 55.5, 25.3, and 40.3 events per 1000 patient-days in the medical ICU, cardiothoracic ICU, and surgical ICU, respectively [20]. In addition, the incidence rate of patient safety events differed by ICU intensity: 44.1 and 24.9 events per 1000 patient-days in level 3 (higher intensity) and level 2 (lower intensity) ICUs, respectively [21]. Considering the severity and influence level of errors reported in this study, the error incidence rates for both periods were comparable to those reported in previous studies.

Although the various benefits of ICIS implementation have been reported, the role of an ICIS in preventing errors in an ICU has not been clarified. Several studies reported a decrease in documentation and charting time after ICIS implementation, thus leaving more time for patient assessment, patient care, and other nursing activities [2,4,22,23]. A study on the relationship between patient safety and nursing workloads showed that higher nursing workloads might be related to a greater number of patient safety incidents in general wards [24]; that is, the workload of ICU nurses can affect the incidence of errors. Considering that the number of patients, total length of stay, and length of ICU stay were similar for both study periods, the changes in nurses' workload and increased productivity from the workload reduction by ICIS might have contributed to error reduction.

Furthermore, the simplification and integration of drug prescription and the presentation of information by ICIS might have contributed to an improvement in the quality of patient care by the ICU staff. Considering that the CPOE and flowsheet of the EMR system used for ICU patients before ICIS implementation were not optimized for critical care settings, paper-based orders were used simultaneously. A study on the effect of EMR implementation on medical ICUs reported that the incidence rate of medication errors increased after the implementation despite the survival benefits [25]. The composition of the user interface within the ICU electronic environment has been reported to affect the task load, task completion time, number of cognition errors related to identification, and subsequent use of patient data [7]. In addition, the use of dashboards that visualize electronic health record information has been reported to decrease the time and difficulty of data gathering; reduce cognitive load, time to task completion, and errors; and improve situation awareness [26]. Improvements in the user interface with ICIS might have led to a reduction in both workload and errors.

As discussed, medication is a major cause of errors in the ICU, and incidence rates of errors related to medication have been reported to range from 1.2 to 947 errors per 1000 patient-days [18,27-30]. The incidence rate has been reported to be higher in medical ICUs than in surgical ICUs [31]. The administration of parenteral drugs, including catecholamines and vasopressors, analgesics and sedatives, antimicrobials, coagulation-related drugs, insulin, and electrolytes, have been found to be associated with errors in the ICU [29]. Frequent dosage changes of these drugs, such as after cardiac surgery, can also increase the risk of medication errors.

The number and incidence rate of medication errors significantly decreased after ICIS implementation in this study. The influence

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of the implementation of an integrated ICIS on the incidence of medication errors in ICUs is not well documented. A study comparing a paper-based ICU and a computerized ICU 10 months after ICIS implementation reported significantly lower incidence and severity of medication prescription errors in an ICU using an ICIS than in a paper-based ICU [11]. By contrast, several studies have addressed the effect of CPOE implementation on the incidence of medication errors. Some studies reported that CPOE implementation in the ICU significantly reduced the incidence of medication errors compared to paper-based orders, whereas another study reported that duplicate orders of medication increased after CPOE and CDSS implementation [12,13,32-35]. The guidelines for safe medication use in the ICU recommend CPOE implementation to decrease medication errors and prevent adverse drug events [36]. Given that CPOE is a major component of an ICIS, the reduction in the number and incidence rate of medication errors in this study could be attributed to the implementation of the ICIS.

In this study, the number and incidence rate of errors related to line, tube, or drain also significantly decreased after ICIS implementation. Mion et al [37] reported that the incidence rate of patient-initiated device removal was 22.1 events per 1000 patient days. In another study, the incidence rate of the accidental removal of devices was 2.3 events per 1000 device-days, and the most frequently removed device was a gastric tube (10.2 events per 1000 device-days) [38]. Unlike medication errors, the ICIS did not have a function that was directly related to the reduction of errors related to line, tube, or drain. However, the changes in nurses' workload by the ICIS might have contributed to the error reduction.

In this study, 14% (10/71) of the errors after ICIS implementation were relevant to the ICIS. Although the incidence of errors related to an integrated ICIS with several components is not well documented, the results of studies on CPOE may be applied since it contributed to ICIS-related errors in this study. In a study on duplicate medication order errors, 13% of incidents in medical ICUs and 6% in surgical ICUs were reported to be CPOE related, and the incidence rate of duplicate orders of medication increased from 11.6 errors per 1000 patient-days to 41.6 errors per 1000 patient-days after CPOE implementation [35,39]. These percentages and incidence rates of errors are comparable to the results of our study.

Limitations

This study has several limitations. First, this study was performed in a single institution with a single ICIS and with a single combination of an ICIS and EMR system. Given that the work environment and human resources in an ICU vary from hospital to hospital, the type, number, and incidence rate of errors can be affected by differences in facilities. Furthermore, there are many systems in ICISs and EMRs, and their combinations have many patterns. Therefore, the settings in which the system is used also differ between an ICU and a hospital. However, no research has examined the changes in medical errors before and after ICIS implementation in an ICU where an EMR system is already in use, and we are convinced that this is one of the strengths of this study. Second, owing to the before-and-after design nature of this study, bias in both the 2018 and 2019 study periods cannot be excluded. However, given that there was no significant difference in the number of patients, patient days, the length of ICU stay, or the composition of treatment departments of patients in the ICU during the 2 periods, we believe that the situation surrounding the ICU staff has not changed remarkably. In addition, most medical staff continued to perform the same ICU duties during both periods. Third, the voluntary self-reporting system has limitations in that the reporting of errors depends on the ICU staff and on the culture and atmosphere for reporting errors in departments or organizations; thus, all errors may not be completely reported. As a result, underreporting of small errors may occur, leading to some bias. However, given that the composition of the level of errors was similar in both periods and that the ICU staff were regularly educated about medical safety, their attitudes toward error reporting and the culture and atmosphere of the ICU toward errors did not change significantly.

Conclusions

We performed a retrospective analysis of the errors in the ICU before and after ICIS implementation in a setting where an EMR system is already in use. ICIS implementation was temporally associated with a 50% reduction in the number and incidence rate of errors in the ICU. Although the most common type of error was medication error in both study periods, the number and incidence rate of medication errors significantly decreased after ICIS implementation. The ICIS-related errors accounted for 14% (10/71) of the errors after the implementation. Our analysis suggests that ICIS could play a pivotal role in preventing errors even in a setting where an EMR system is already in use.

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Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

YS managed the ICIS implementation project, designed the study, collected and analyzed the data, and wrote the manuscript. NS and MI helped manage the ICIS implementation and prepared the manuscript. TN helped design the study and reviewed the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CDSS: clinical decision support system
CPOE: computerized physician order entry
EMR: electronic medical record
ICIS: intensive care information system
ICU: intensive care unit

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Original Paper

Long-Term Postoperative Pain Prediction Using Higher-Order Singular Value Decomposition of Intraoperative Physiological Responses: Prospective Cohort Study

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Abstract

Background: Long-term postoperative pain (POP) and patient responses to pain relief medications are not yet fully understood. Although recent studies have developed an index for the nociception level of patients under general anesthesia based on multiple physiological parameters, it remains unclear whether these parameters correlate with long-term POP outcomes.

Objective: This study aims to extract unbiased and interpretable descriptions of how the dynamics of physiological parameters change over time and across patients in response to surgical procedures and intraoperative medications using a multivariate-temporal analysis. We demonstrated that there is an association (correlation) between the main features of intraoperative physiological responses and long-term POP, which has a predictive value, even without claiming causality.

Methods: We proposed a complex higher-order singular value decomposition method to accurately decompose patients' physiological responses into multivariate structures evolving over time. We used intraoperative vital signs of 175 patients from a mixed surgical cohort to extract three interconnected, low-dimensional, complex-valued descriptions of patients' physiological responses: multivariate factors, reflecting subphysiological parameters; temporal factors, reflecting common intrasurgery temporal dynamics; and patients' factors, describing interpatient changes in physiological responses.

Results: Adoption of the complex higher-order singular value decomposition method allowed us to clarify the dynamic correlation structure included in the intraoperative physiological responses. Instantaneous phases of the complex-valued physiological responses of 242 patients within the subspace of principal descriptors enabled us to discriminate between mild and not-mild (moderate-severe) levels of pain at postoperative days 30 and 90. Following rotation of physiological responses before projection to align with the common multivariate-temporal dynamic, the method achieved an area under curve for postoperative day 30 and 90 outcomes of 0.81 and 0.89 for thoracic surgery, 0.87 and 0.83 for orthopedic surgery, 0.87 and 0.88 for urological surgery, 0.86 and 1 for colorectal surgery, 1 and 1 for transplant surgery, and 0.83 and 0.92 for pancreatic surgery, respectively.

Conclusions: By categorizing patients into different surgical groups, we identified significant surgery-related principal descriptors. Each of them potentially encodes different surgical stimulation. The dynamics of patients' physiological responses to these surgical events were linked to long-term POP development.

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KEYWORDS

tensor decomposition; multivariate-temporal decomposition; long-term postoperative pain; higher-order singular value decomposition; SVD

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Introduction

Background

Persistent pain after acute postoperative pain (POP) occurs in 10% to 50% of patients after common surgical procedures such as cardiac, thoracic, spinal, or orthopedic surgeries [1]. Although even mild levels of persistent POP are associated with decreased physical and social activities [2], 2% to 10% of patients experiencing this type of pain may develop severe levels of pain, delaying their recovery and return to normal daily functioning [3,4]. Furthermore, persistent POP leads to increased direct medical costs through the use of additional resources. Persistent POP appears to be a critical and unrecognized clinical problem [1]. Consequently, the prediction of patients at risk of developing this type of pain, which could inform primary and secondary prevention strategies, has remained inadequate [5].

POP is assumed to stem from various interacting factors including biological, psychological, and social determinants [6]. In different studies [7,8], psychological factors (ie, depression, psychological vulnerability, stress, and catastrophizing) have been suggested as risk factors for the development of persistent POP. Level of education and female sex were seen by some as unlikely to be coupled with persistent POP [7]. However, Holtzman et al [9] identified female sex as a risk factor for developing persistent POP. The relationship between anxiety and the development of persistent POP remains unclear. Although various studies have suggested a significant link between preoperative anxiety and higher levels of persistent POP [10,11], others studies have been unable to replicate this finding. In a systematic review evaluating the association between anxiety and persistent POP in patients undergoing different types of surgery, Hinrichs-Rocker et al [7] found no clear link between the two. In a meta-analysis evaluating 29 research studies, Theunissen et al [12] found that preoperative anxiety was associated with persistent POP in only 55% of the studies.

A frequently replicated finding suggests that the severity of acute POP [1,13,14], especially movement-evoked pain [15-17], is the most striking risk factor significantly associated with persistent POP. Basbaum [18] found that neuroplastic changes in the central nervous system resulting from high intensities of acute POP were a reason for developing persistent pain. In all these studies on the effect of acute POP on the development of persistent POP, a single measurement of acute pain (mean daily value or the worst pain) was examined, and the temporal dynamics of acute pain were discarded. In recent years, the acute POP dynamic (POP trajectory) as a quantification of all apparent and latent factors modulating POP duration and resolution has been examined using different methods to identify abnormal POP resolution [19,20]. Chapman et al [19] approximated daily pain trajectories using a linear mixed model to increase the amount of information extracted from POP recordings. Through this method, 3 pain trajectory patterns were unfolded, yielding new information about the dynamics of POP resolution in a limited time window after surgery. Later, Althaus et al [20] used a latent growth curve on the average pain intensities over the first 5 days after surgery to analyze the mediating effects of POP trajectories within the association between relevant preoperative psychosocial features and chronic POP. Notably, these extensions to pain trajectories generally focused on the daily abstractions of pain intensity ratings and discarded potentially meaningful data pertaining to intraday variations. Furthermore, they used constrained models to approximate the complex dynamic of POP resolution. Baharloo et al [21] extended this line of research by considering POP intensity observations including intraday variations as a time series and used wavelets to approximate the POP temporal dynamics associated with persistent POP.

Objectives

Although these studies are encouraging, their strategies are inherently limited by a lack of analysis of intraoperative nociception, that is, the sensory nervous system's response to harmful or potentially harmful stimuli. Pain is a subjective sensory and emotional experience, and every individual may respond differently to a painful stimulus. The characteristics of this response may indicate further development of persistent pain. Hence, we argue that to find a solution to this complex problem, we need to carefully analyze the inherent response to a painful stimulus to characterize the intricate nature of persistent pain. This involves analyzing many parameters, including physiological, emotional, and neuroendocrine parameters. In this study, we considered some of the physiological responses to surgical injury to study how individuals react to a noxious stimulus.

As the autonomic nervous system continuously responds to various surgical stimuli during surgery, vital signs such as heart rate, blood pressure, and respiration can be used as indicators of these responses. During general anesthesia, when a sufficient dose of an anesthetic agent is applied to prevent a response to the skin incision and subsequent surgical trauma, physiological responses induced by surgical stress are not completely attenuated [22]. The sympathetic nervous system inherently changes physiological parameters such as local blood flow, blood pressure, and heart rate in response to noxious stimulation. Anesthetic agents also interfere with this system at different levels. Among the physiological parameters, heart rate and blood pressure may also be modulated by parasympathetic tone [23]. If modeling methods are limited only to physiological parameters, it remains unclear whether any given signal among these multivariate time series results from changes to surgical insults (ie, fluid shifts and nociception from tissue injury) or from the modulation of anesthetic parameters (eg, changes in anesthetic depth). These challenges are compounded by inherent delays in the coupled system owing to the pharmacokinetic and pharmacodynamic principles. Hence, monitoring and analyzing the time series of patients' physiological responses in relation to a variety of surgical stimuli and nociception imbalance under general anesthesia helps us to indirectly characterize the behavior of the autonomic nervous system in response to nociceptive stimuli, if the temporal dynamics of anesthetic factors can be accounted for alongside similar assessments of the autonomic nervous system. Therefore, such integrated analyses of time series may provide a clue for the development of persistent POP.

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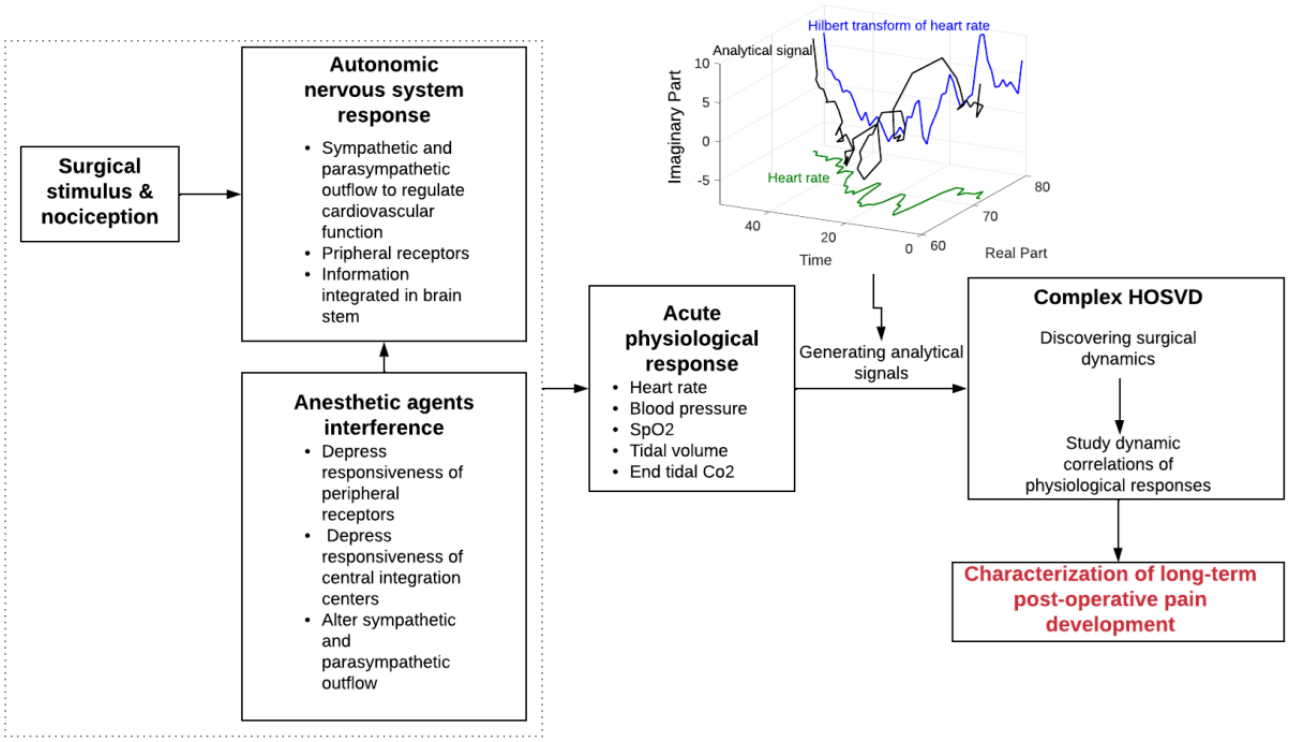
Hemodynamic regulation is the result of dynamic interactions between coupled biological systems of different scales and temporal frequencies. Cross-spectral analysis, which determines the relationship between 2 time series as a function of frequency, is a solution for revealing such dynamic interactions in general. However, when the dominant frequencies and scales are unknown or occur over a wide range, it is difficult to use cross-spectral analysis in an exploratory manner. Furthermore, when dealing with nonstationary time series characterized by short and irregularly occurring events, as is the case with intraoperative vital signs, cross-spectral analysis is less descriptive.

This study used the complex higher-order singular value decomposition (HOSVD) method to explore dynamic correlations with lead or lag relations in intraoperative vital signs. The complex-valued vital signs were generated using the original ones and their Hilbert transforms. The key idea was to organize complex-valued vital signs into a third-order tensor with three axes corresponding to individual vital signs (physiological parameters), time during surgery, and patients. We then fit the HOSVD to identify a set of low-dimensional complex-valued factors (features) that capture variability along each of these 3 axes.

Complex HOSVD identifies separate low-dimensional complex-valued factors, each of which corresponds to subphysiological parameters with common within-surgery dynamics and variable across-patient dynamics. We then investigated how surgical mechanisms in different procedures emerged as the patients' physiological responses occurred. The investigation elucidated how the particular dynamics of each surgical service were captured in individual factors, which had different characteristics. We discuss how complex HOSVD can extract descriptors of physiological responses in which individual factors potentially correspond with interpretable activities such as tidal volume determination and autonomic regulation during surgery.

Finally, we used the complex-valued factors as new bases to describe physiological responses. After projection onto the subspace, the complex correlations between each intraoperative time series and the complex-valued factors were manifested in the magnitudes and phases of the correlations. We used the phases of the correlations to predict *mild* versus *moderate-severe* levels of pain on postoperative days 30 and 90. We demonstrated that the dissimilarities between these 2 pain categories were relatively expressed in the phase information of the physiological responses with respect to surgical dynamics. Figure 1 illustrates the relationship between the proposed tasks and the underlying biological subsystems.

Figure 1. Flow diagram of the work proposed in this study. Multivariate intraoperative vital signs as indicators of the dynamic interplay among the surgical stimulus, autonomic nervous system, and anesthetic agents are analyzed through tensor decomposition to characterize long-term postoperative pain.



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Methods

Discovering Surgical Multivariate-Temporal Dynamics Through Complex HOSVD

Intraoperative Vital Sign Recording

During surgery, patients experience various disturbances with respect to the normal activities of different body systems. Therefore, it is essential to monitor a patient's physiological status. Physiological monitoring systems can continuously measure and monitor various vital signs using electrodes and sensors connected to the patient. Routinely measured vital signs may include electrical activity of the heart (through an ECG), heart rate, respiratory rate, blood pressure, cardiac output, body temperature, peripheral capillary oxygen saturation (SpO_2), end-tidal carbon dioxide ($EtCO_2$), and exhaled tidal volume.

Blood pressure is the pressure generated by circulating blood on the walls of blood vessels and usually points to the pressure in the large arteries. Blood pressure is commonly expressed as systolic and diastolic pressures. Systolic pressure refers to the amount of pressure in the arteries when the heart contracts to pump blood into circulation. Diastolic pressure refers to the pressure when the heart relaxes after contraction. During surgery, blood pressure can be measured using invasive and noninvasive methods. Invasive monitoring of blood pressure involves direct estimation of arterial pressure by inserting a cannula into an appropriate artery. This provides continuous beat-by-beat monitoring of the patient's blood pressure. Noninvasive monitoring uses an oscillometric technique with an automated cuff.

SpO_2 is measured noninvasively using a pulse oximeter to provide an approximation of the arterial hemoglobin oxygen saturation. A sensor is clipped over the finger, and the pulse oximeter continuously emits and absorbs a light wave passing through the capillaries. As the oxygen binding of hemoglobin causes changes in the color of blood, variations in the red and infrared light absorption spectra in the arterial phase provide an estimate of the oxygen content within the arterial system. The pulse oximeter also provides heart rate in beats per minute, with an average rate of over 5 to 20 seconds.

$EtCO_2$ represents the amount of carbon dioxide in exhaled gas. Tidal volume represents the volume of air displaced between inhalation and exhalation. These 2 parameters can be used to assess ventilation.

Isoflurane and sevoflurane (both included in the same class of medicines) were used as inhaled anesthetic agents in this study, both of which are known to have a depressive effect on the autonomic nervous system. The end-tidal concentration of inhalational anesthetic gases, such as isoflurane and desflurane, is related to the alveolar concentration of the anesthetic, which in turn is related to the concentration of anesthetic gas at the target effect site (eg, the central nervous system). End-tidal concentrations of anesthetic gas are measured in real time throughout anesthesia as an indicator of the depth of anesthesia. Increasing amounts of anesthesia lead to amnesia, hypnosis, muscle relaxation, and eventual suppression of sympathetic responses to noxious stimuli such as incision. Anesthetic management often requires a balance between the amount of anesthetic delivered and the degree of noxious stimuli, which is further modulated by interindividual differences in anesthetic sensitivity.

It is commonly accepted that the degree of noxious stimuli observed during surgery denotes the degree of tissue injury, which is also related to POP intensity. No direct measures of noxious stimuli are available in clinical practice. However, by considering the amount of anesthetic administered following incision and the physiological variabilities observed in this period in the presence of a given amount of anesthesia, we can deduce the overall relationship between nociceptive-triggered sympathetic stimulation and anesthesia-induced sympathetic suppression. Without considering indicators of both physiological and anesthetic states simultaneously, it remains difficult to ascribe any given change in one of these dimensions to a third entity such as surgical nociception.

In this study, we used eight vital parameters—heart rate, heart rate-SpO_2, SpO_2, systolic blood pressure, diastolic blood pressure, $EtCO_2$, tidal volume exhaled, and end-tidal concentration of isoflurane and sevoflurane—as superficial and imperfect indicators of autonomic nervous system activity or state. These parameters were subjected to tensor decomposition analysis to characterize long-term POP.

Long-term POP was defined as a self-reported mean value of pain on postoperative day 30 using a numeric rating scale (0=no pain and 10=worst pain). Although this method is not an ideal assessment of pain, and its potential subjective bias makes it less reliable, different studies have reported a significant correlation between this method and the pain measured by different candidate technologies such as physiological parameters or cerebral hemodynamic changes for pain assessments [24].

Application of Singular Value Decomposition to Large-Scale Intraoperative Data Analysis

Before describing complex-HOSVD in our analysis, we first discuss the potential application of singular value decomposition (SVD) to large-scale intraoperative data analysis. Consider a recording of I_1 intraoperative vital signs over I_3 different patients. We assume that vital signs are recorded at I_2 time points for each patient, but recordings of variable duration can be cut to a common window of time to fit in with this constraint. The collection of these series is naturally represented as an $I_1 \times I_2 \times I_3$ array of vital signs and a third-order tensor such as . Each member of this tensor, $a_i 1 i 2 i 3$, denotes the recorded value of each vital sign i_1 at time point i_2 for patient i_3.

Given that patients experience various surgical stimuli, such large multiway arrays (tensors) are challenging to analyze and interpret, particularly when recordings are performed over a wide range of surgical services. Physiological responses to identical surgical stimuli exhibit significant interpatient variability.

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Under the assumption of having the intraoperative vital signs recorded for just 1 patient, we obtained a matrix, $\mathbf{A}_{I1I2}$, which holds the values for each vital sign i_1 and time point i_2. Such a matrix is difficult to interpret when different vital signs with distinct temporal dynamics are involved in experiments.

SVD summarizes this matrix by carrying out a decomposition into R number of ranked-one matrices (components), such as in equation 1, to approximate the original data matrix.

where ° denotes the outer product of the vectors. This decomposition provides a low-dimensional subspace (a new coordinate system) with R dimensions to describe the original high-dimensional data with I_1 or I_2 dimensions. Whenever decomposition is applied, we use the terms dimensions, components, and ranked-one matrix or tensor interchangeably, but they convey the same meaning. Each ranked-one matrix, indexed by r, holds a coefficient across vital signs, u_{ri1}, and a coefficient across points in time v_{ri2}. These vectors represent the multivariate-temporal dynamics discovered in the original data matrix. In this paper, we call the vectors U_r temporal modes (factors; yellow and green vectors in Figure 2A). Each coefficient (element) of the multivariate (or temporal) mode vectors contains 2 important pieces of information. The absolute value of the coefficient provides a measure of the contribution of a particular vital sign (or time point) for that mode. If the coefficient is complex valued (as is the case with this study), the angle defined by the real and imaginary parts provides an explanation of the phase of that coefficient (element) in relation to the others vibrating at the frequency associated with that particular mode [25]. To account for the variability of vital signs among patients and to simplify data tensor A, one approach is to concatenate multiple data matrices such as $\mathbf{A}_{I1I2}$ (one for each patient), thereby converting the data tensor into an $I_1 \times I_2 I_3$ matrix and then applying SVD to this matrix (Figure 2B). In this way, the R temporal modes are of length $I_2 I_3$ and do not capture the common temporal dynamics across patients.

In this study, we performed decomposition directly on the original data tensor A (Figure 2C) rather than transforming it into a matrix. The HOSVD method then provides the following decomposition:

Analogous to SVD, we can think of $U^{(1)}$ as a prototypical pattern across intraoperative vital signs and $U^{(2)}$as a temporal dynamic across time. These multivariate and temporal modes represent dynamics that are common among patients. The third set of modes, $U^{(3)}$, *patient factors* (Figure 2C), represents patient-specific variations in the multivariate-temporal dynamics identified by the method.

Furthermore, to capture the propagating dynamics, the real-valued vital signs are augmented with their Hilbert transforms to form a complex-valued third-order tensor such as . The HOSVD decomposition in equation 2 also holds for the complex-valued tensor X [26]. The complex-HOSVD identifies dynamic factors that carry additional information related to phase. Figure 2D illustrates a single multivariate factor plotted with respect to magnitude and phase, where each element of the multivariate factor represents a particular vital sign recorded during surgery. The phase was plotted between 0 and 2π, representing the relative phases of the elements. The phase plotted on a circular grid exhibited an interesting feature. All elements of the multivariate factor showed the same phase, except for the element associated with the contribution of tidal volume. The tidal volume is selected by the anesthesiologist during surgery, but it still influences the heart rate and blood pressure in patients.

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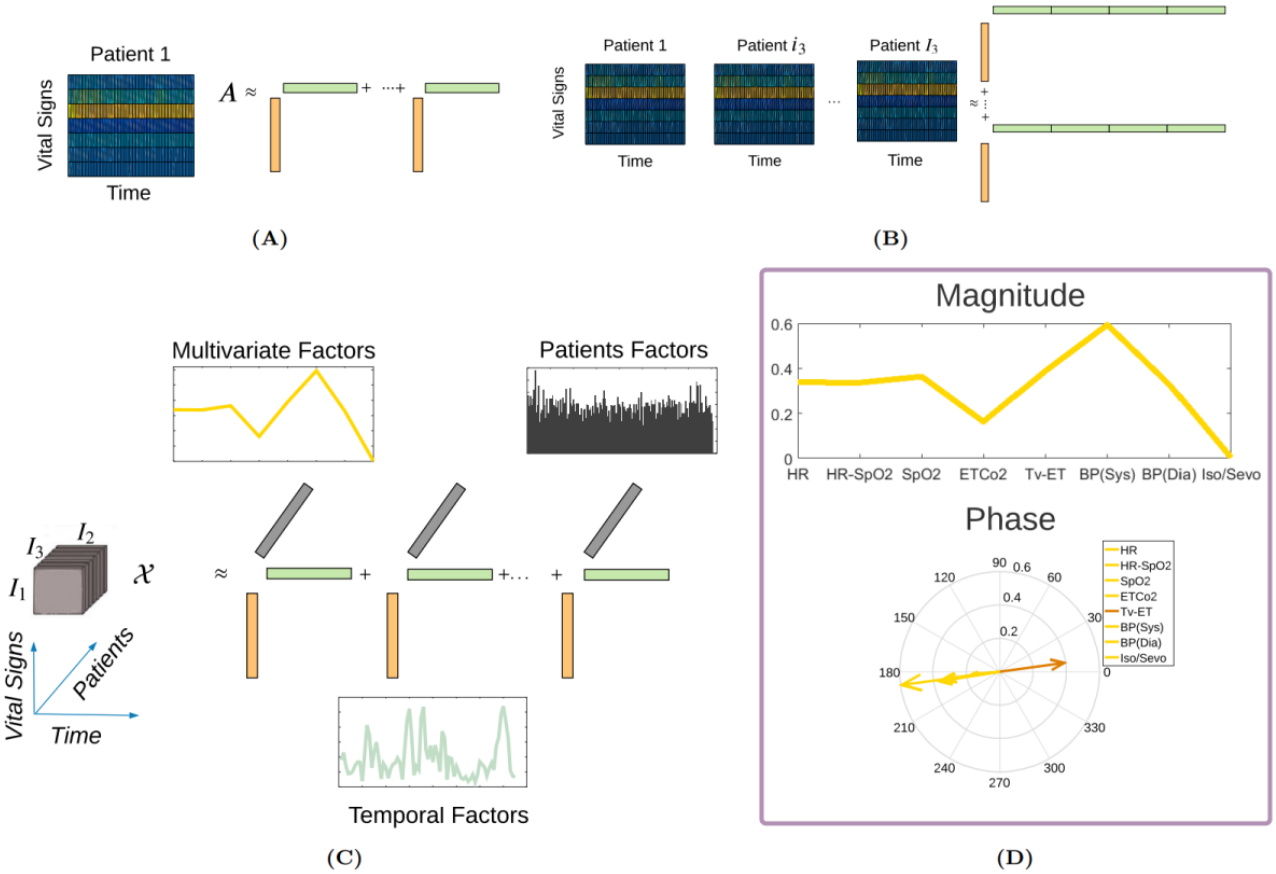
Figure 2. Shaping data matrices/tensors for decomposition. (A,B) Singular value decomposition summarizes matrix A by carrying out a decomposition into R number of ranked-one matrices. (C) Decomposition of third-order tensor X provides prototypical pattern across intraoperative vital signs (multivariate factors), temporal dynamic across time (temporal factors) and patients-specific variations (patients factors). (D) Illustration of a single multivariate factor plotted with respect to magnitude and phase.



Ethics Approval

This prospective cohort study was approved by the University of Florida Institutional Review Board-01 (IRB #201500153) as the National Institutes of Health–funded the Temporal Postoperative Pain Signatures (TEMPOS) protocol.

Results

Experimental Setup and Discovered Surgical Dynamics

Overview

In this study, we designed and tested a complex-HOSVD–based metric projection to characterize patients' physiological dynamics from intraoperative vital signs collected during surgery at a rate of 1 sample per minute for at least 75 minutes. The intraoperative vital signs were augmented by the Hilbert transform [27] to create complex vital signs. Here, a 2D tensor (matrix) represents the time-varying dynamics of the different intraoperative vital signs for each patient. The 175 second-order tensors constructed from the intraoperative vital signs of 175 patients undergoing a relatively wide range of surgical procedures, including orthopedic, urology, colorectal, transplant, pancreatic and biliary, and thoracic procedures, were stacked on top of each other to generate a 3D tensor to discover mixed surgical dynamics. The complex principal multivariate-temporal factors extracted through complex HOSVD were compared with the multivariate-temporal dynamics extracted after grouping the patients based on their surgical service. The complex-HOSVD decomposition resulted in an approximation of the multivariate factor and temporal factors with sizes of 8×4 and 75×32, respectively. Thus, a total of 128 (F=4×32) features were extracted from 600 features of the tensors.

The complex-HOSVD characterized surgical dynamics over a wide range of surgical services (refer to Table 1 for the list of surgical services). Remarkably, complex-HOSVD extracted only 4 multivariate factors to capture within-patient and across-patient intraoperative dynamics. The temporal evolution of these multivariate factors was captured by 32 temporal factors and showed substantially different characteristics potentially affected by surgical services. The multivariate-temporal factors of the complex-HOSVD are shown in Figure 3. The first multivariate factor (red in Figure 3A) indicated a strong contribution of tidal volume for this factor. As stated before , the anesthesiologist selects this variable during surgery, and it can impact the patient's hemodynamic response by changing the venous return to the heart, heart rate, and cardiac output. The corresponding elements of this mode oscillated in the same phase (Figure 3B). The second multivariate mode (blue in Figure 3A) emphasizes the contribution of heart rate and blood pressure for this factor. According to its phase plot (Figure 3C), all elements of this factor had the same phase, except for the element associated with the participation of tidal volume. The

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third multivariate mode (green in Figure 3) indicates a slightly different elemental participation from that indicated by the second factor. The phase information for this multivariate mode indicates a phase difference between blood pressure and the other elements of this mode (Figure 3D). Finally, the fourth multivariate mode (yellow in Figure 3A) highlights the contribution of SpO_2 and $EtCO_2$ while also revealing the phase difference between these two and the other contributing elements for this mode (Figure 3E).

Table 1. List of studied surgical services and number of patients in each pain group, in each case.

Surgery	Total number of patients, n	Number of patients in pain group, n (%)	
		Mild	Moderate-severe
Thoracic	37	24 (65)	13 (35)
Orthopedics	35	22 (63)	13 (37)
Urology	60	52 (87)	8 (13)
Colorectal	65	51 (78)	14 (22)
Transplant	11	8 (73)	3 (27)
Pancreas and biliary	34	25 (74)	9 (26)

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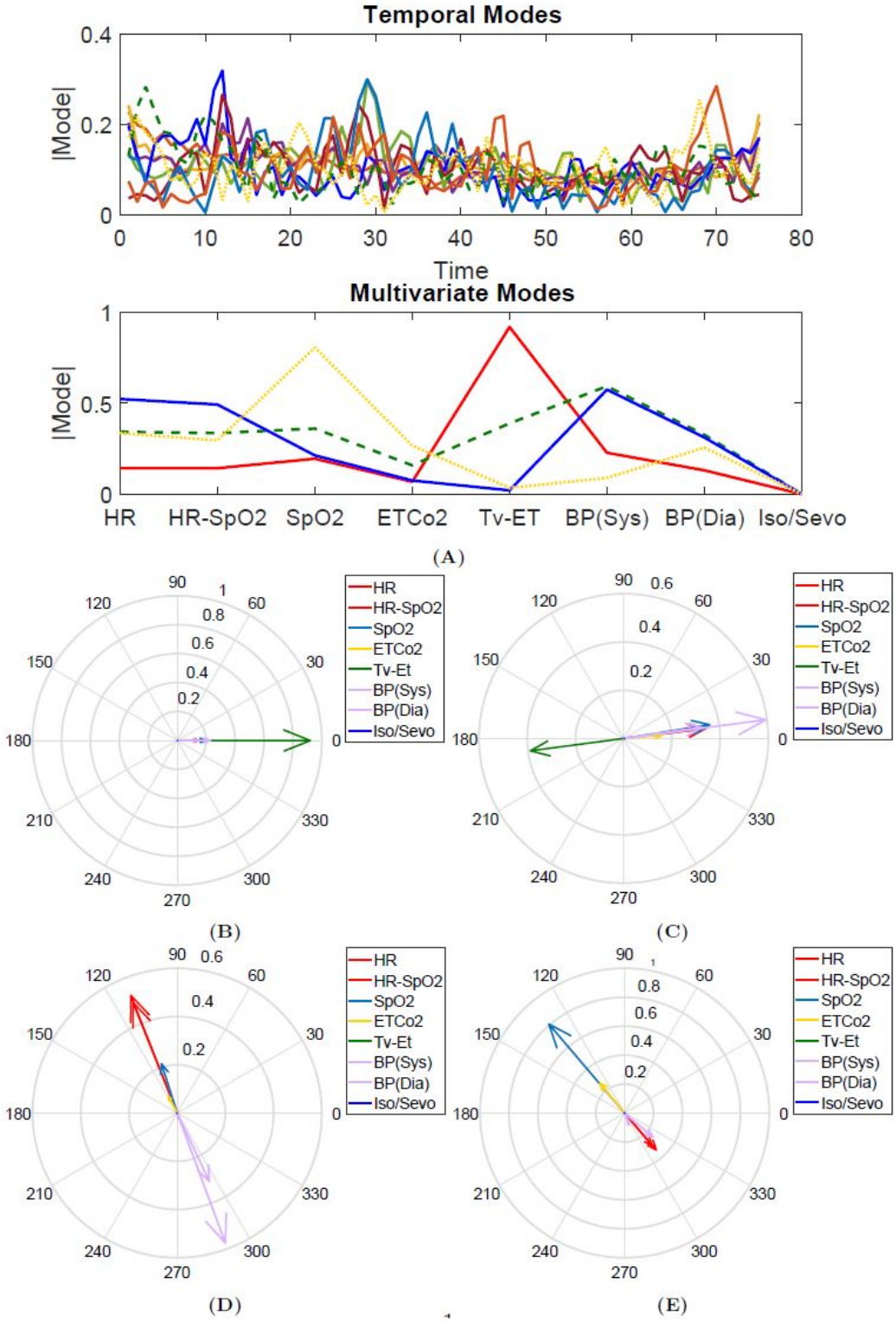
Figure 3. Illustration of the multivariate and temporal factors extracted through complex higher-order singular value decomposition (HOSVD). (A) The outer product of the temporal and multivariate factors generates the contributing components in the decomposition of X. For intraoperative vital signs, each of the elements of a multivariate mode represents a particular vital sign. The magnitude and phase of the element explain how the vital signs are related to each other within that factor. The phase of each element describes the relative phase of the vital sign's vibration relative to the other vital signs for that multivariate factor. This depiction allows for interpretation of the complex HOSVD output for intraoperative vital signs. Each multivariate factor identifies the vital signs involved in that pattern of physiological response in addition to the relative phase of that vital sign's activation time. (B, C, D, E) The phase portraits associated with the multivariate factors are shown in red, blue, green, and yellow.



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Grouping Patients Based on Surgical Service and Discovery of Surgery-Related Features

Different surgical procedures lead to different patterns of tissue injury. Hence, the type of procedure specifies the organ, organ system, or tissue involved as well as the degree of invasiveness. The influence of the type of surgery on the development of chronic POP is well established. Longer and more complicated operations, as well as those associated with neuropathic patterns of POP, are often linked with a higher risk of chronic pain development, although the pattern is irregular and also related to the type of tissue involved in the surgery. In our analysis, the evolutionary dynamics of intraoperative vital signs had a temporal factor that was significantly affected by the type of surgery. Therefore, in this section, we divided the patients into subgroups related to different surgical procedures and investigated surgery-related features associated with the development of long-term POP. Surgery-related features may correspond to a power increase or decrease distributed over multiple intraoperative vital signs as well as changes in the activation of oscillating frequencies of multivariate factors expressed by temporal modes. In this study, the input to the complex HOSVD algorithm was built from the time-varying contents of 7 intraoperative vital signs with a length of 50 minutes (starting 10 minutes before incision time during surgery). The peri-incisional period was selected in an effort to standardize the phase of surgery as well as to account for potential differences in POP in short- duration procedures versus long-duration procedures. Data were extracted from the Epic electronic health record system by Epic Systems Corporation, which contains an anesthetic information management module. We increased the number of patients in each subgroup by decreasing the length of intraoperative vital signs. We divided 242 patients into 6 groups based on the surgical services they received. The surgical groups included thoracic, orthopedic, urological, colorectal, transplant, and pancreatic and biliary surgeries. The surgical services and surgeries used in this study and the number of patients in each surgery group are summarized in Table 1.

We attempted to identify how surgery-specific mechanisms are associated with patients' physiological responses over the course of the procedure. Here, we showed that complex-HOSVD could characterize surgery-related dynamics using the physiological responses of a group of patients who underwent the same surgical procedure. Figure 4 illustrates the surgical dynamics characterized by complex-HOSVD for two types of surgery (orthopedic and thoracic). Once again, complex HOSVD summarized both the within-patient physiological responses and the across-patient dynamics in quite a few multivariate factors. These factors offer slightly different elemental contributions while exhibiting the same relative phase portrait. The time course of these factors was substantially different for the different types of surgeries. In essence, the multivariate factors indirectly encoded the sympathetic activities to compensate for variations in hemodynamic parameters (eg, autonomic regulation) under general anesthesia, and these signatures were modulated by the physiological state during surgery (captured by temporal factors).

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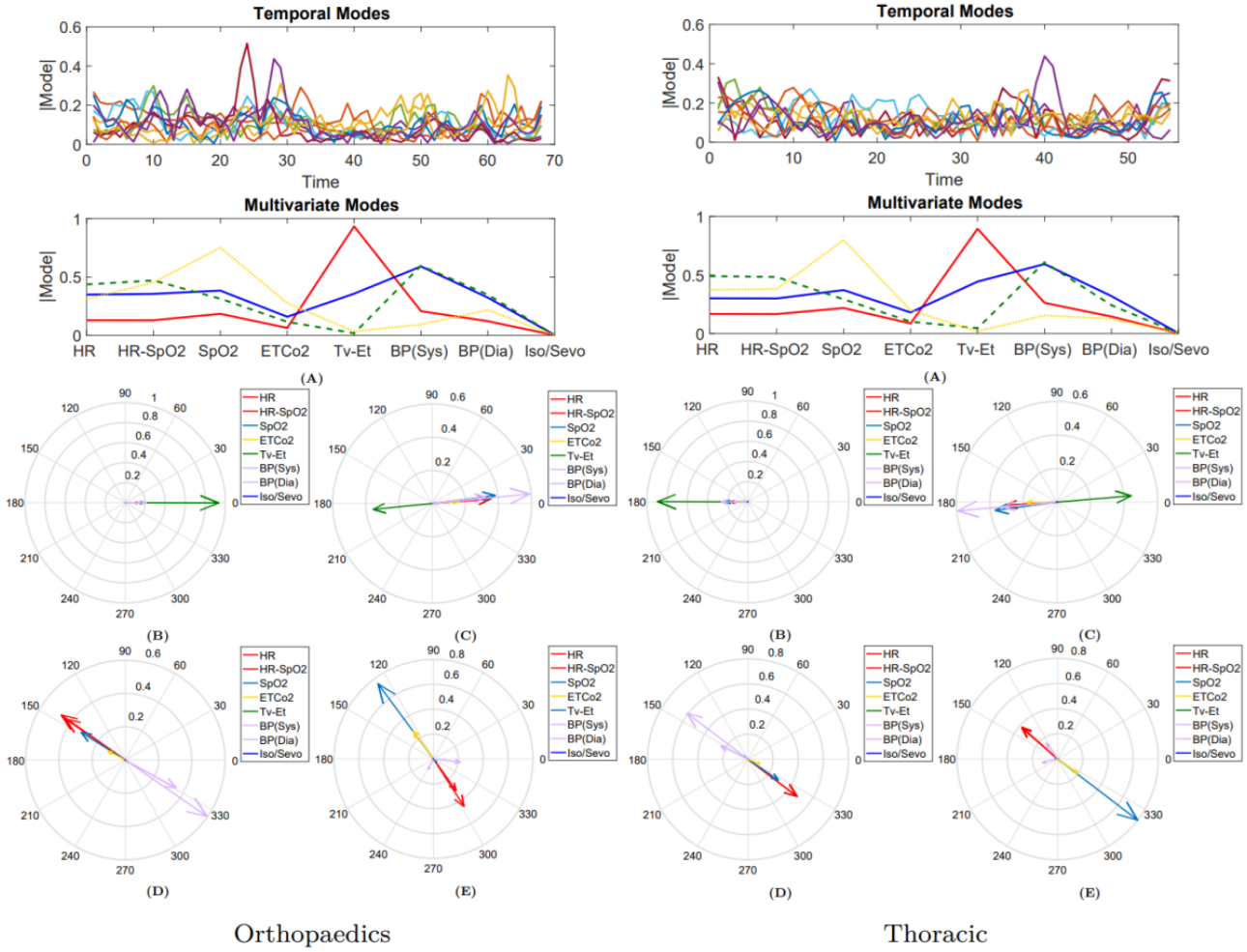
Figure 4. Comparison of the multivariate and temporal factors extracted through complex higher-order singular value decomposition (HOSVD) for 2 different surgical services. (A) The outer product of the temporal and multivariate factors generates the contributing components in the decomposition of X. For intraoperative vital signs, each of the elements of a multivariate mode represents a particular vital sign. The magnitude and phase of the element explain how the vital signs are related to each other within that factor. The phase of each element describes the relative phase of the vital sign's vibration relative to the other vital signs for that multivariate factor. This depiction allows for interpretation of the complex HOSVD output for intraoperative vital signs. Each multivariate factor identifies the vital signs involved in that pattern of physiological response in addition to the relative phase of that vital sign's activation time. (B, C, D, and E) In orthopedic and thoracic surgeries, the phase portrait associated with the multivariate factors is shown in red, blue, green, and yellow.



Physiological Responses During Surgery and POP

Overview

The complex principal multivariate-temporal factors extracted through complex HOSVD were used as new bases to describe the correlations of physiological dynamics and to gain insight into any lead or lag relations among individual responses expressed in instantaneous phases of the complex vital signs.

We divided 242 patients (mean age 62 years, SD 8 years), of which 128 (52.9%) participants were women, into 2 groups based on verbal evaluation of average pain on days 30 and 90 after surgeries including orthopedics, thoracic, urology, colorectal, transplant, and pancreatic biliary surgeries. Patients reporting an average pain intensity of ≤3 were categorized as *mild*. Patients reporting an average pain intensity >3 were considered *not-mild* or *moderate-severe*. This distinction is clinically relevant, as moderate to severe pain ratings generally require analgesic interventions [28]. The number of patients in each group is reported in Table 1.

The subspace provided by complex HOSVD can be used directly in a classification task. However, the corresponding bases do not contain any category information that is functional in modeling the dissimilarity among the categories of data. To obtain the most salient multivariate-temporal factors for this classification task, we used a rank feature method based on the Fisher ranking, and the top 3 components were selected. The projection was performed on a 3D data manifold, which in our study was the top 3 dimensions that provided the highest Fisher scores. The phase information of the projected data points was used to classify *mild* versus *moderate-severe* classes on postoperative days 30 and 90 through linear discriminant analysis (LDA).

Results for Postoperative Day 30

We investigated the performance of LDA using a 5-fold cross-validation procedure. The method achieved a true positive rate (TPR) and positive predictive value (PPV) of 0.69 and 0.60 for thoracic surgery, 0.77 and 0.67 for orthopedic surgery, 1 and 0.75 for transplant surgery, and 0.63 and 0.71 for urological

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surgery, respectively. In contrast, the PPV and TPR for the *moderate-severe* class was 0.44 and 0.57 in pancreatic surgery and 0.43 and 0.86 in colorectal surgery, respectively. The results are presented in Table 2. Figures 5 and 6 show the scatter plot of the phase information for patients projected onto the 3D subspace for different surgical groups. Patients with moderate-severe pain on postoperative day 30 were almost well clustered in the thoracic, orthopedic, transplant, and colorectal surgical groups. This finding indicates that the dynamics of patients' physiological responses to surgical stimulation are linked to long-term POP development. Many patients in the same pain category responded to surgical stimulation, with a small band of variation in their phases. This phenomenon was captured even better for moderate-severe levels of pain on postoperative day 90 (Figure 6).

Table 2. Performance of LDA[a] to discriminate moderate-severe versus mild pain categories for postoperative day 30 without rotation. The phase information of the projected data points on a 3D manifold was used in the experiments. The patients were categorized based on their surgical services

Surgery	Confusion matrix (patients)				Precision (PPV[b])	Sensitivity (TPR[c])	Specificity (TNR[d])	AUC[e]
	TP[f]	FP[g]	FN[h]	TN[i]				
Thoracic	9	6	4	18	0.60	0.69	0.75	0.78
Orthopedics	10	5	3	17	0.67	0.77	0.77	0.80
Urology	5	2	3	50	0.71	0.63	0.96	0.87
Colorectal	6	1	8	50	0.86	0.43	0.98	0.75
Transplant	3	1	0	7	0.75	1	0.88	0.92
Pancreas and biliary	4	3	5	22	0.57	0.44	0.88	0.80

[a]LDA: linear discriminant analysis.

[b]PPV: positive predictive value.

[c]TPR: true positive rate.

[d]TNR: true negative rate.

[e]AUC: area under curve.

[f]TP: true positive.

[g]FP: false positive.

[h]FN: false negative.

[i]TN: true negative.

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Figure 5. The phase information of the projected data points onto a 3D manifold extracted using complex higher-order singular value decomposition. Mild (blue dots) versus moderate-severe (red dots) levels of pain on day 30 after surgery are considered for this plot.

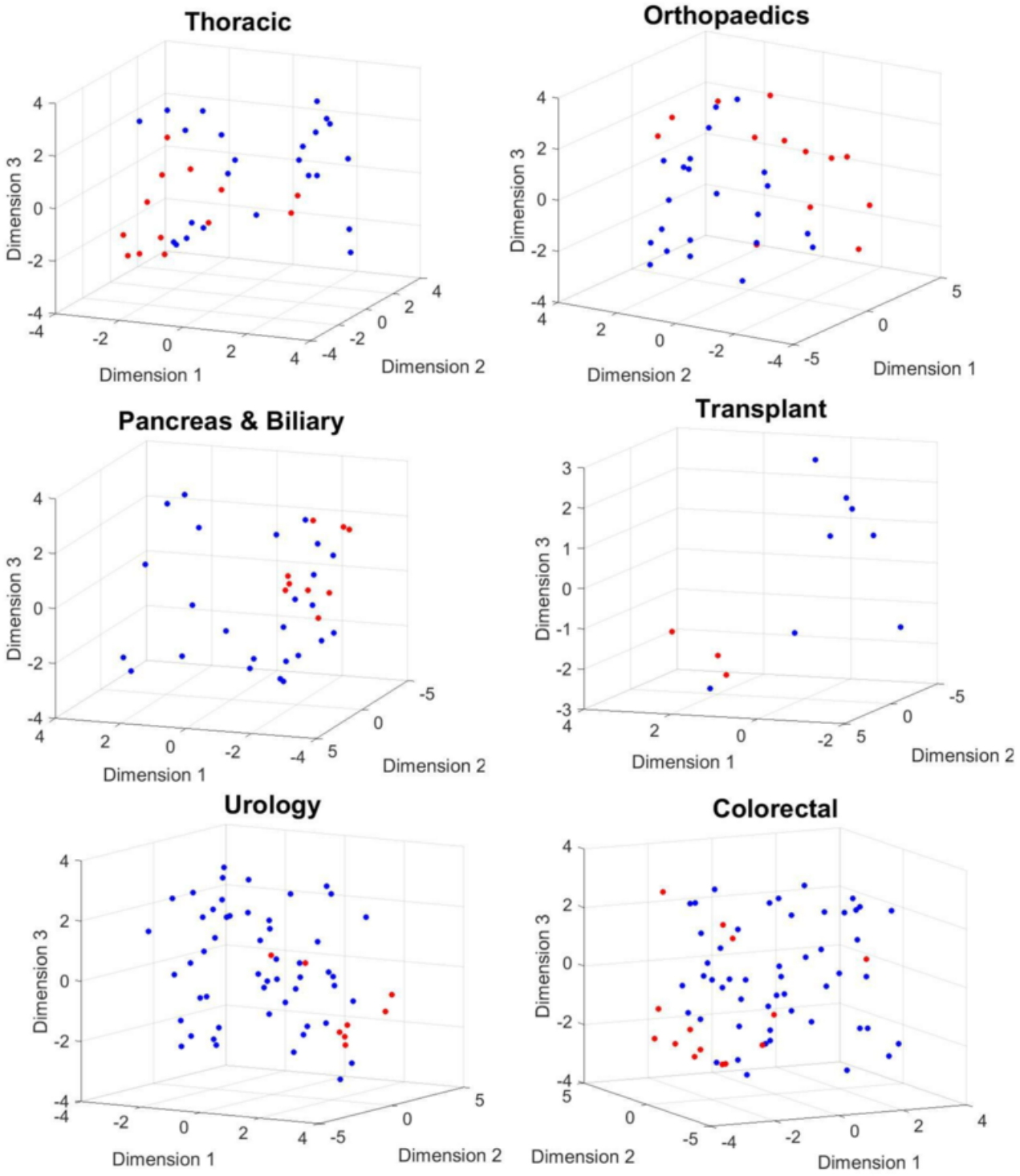

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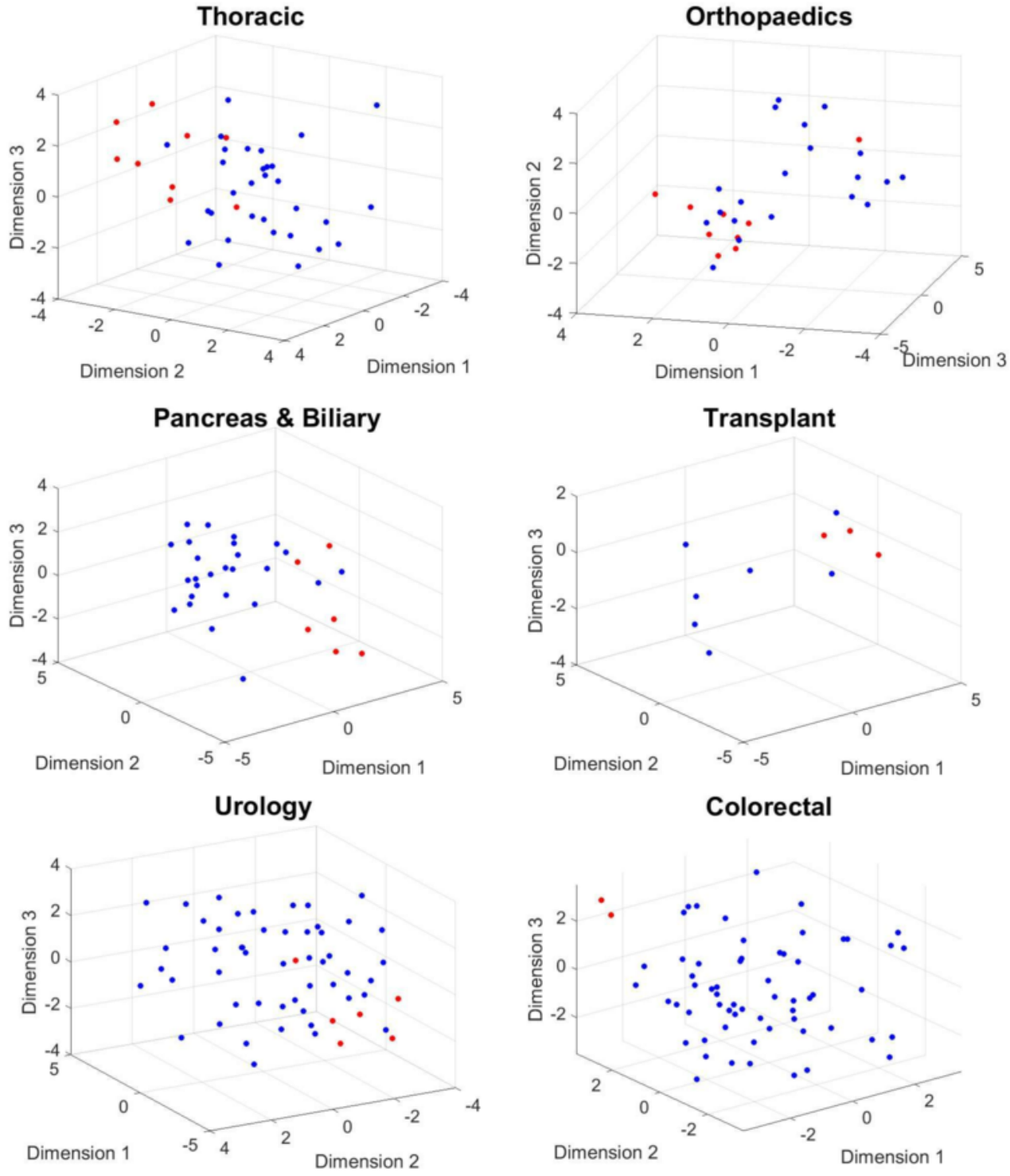
Figure 6. The phase information of the projected data points onto a 3D manifold extracted using complex higher-order singular value decomposition. Mild (blue dots) versus moderate-severe (red dots) levels of pain on day 90 after surgery are considered for this plot.



Results for Postoperative Day 90

Given that healing times vary between procedures, and the International Classification of Diseases defines persistent POP as lasting for at least 3 months after surgery, we repeated the exact set of experiments to classify patients who reported *mild* versus *moderate-severe* levels of pain on postoperative day 90. We observed that although the number of patients included in the *moderate-severe* class decreased for all surgical groups, we achieved almost the same or higher performances in detecting patients who developed *moderate-severe* versus *mild* levels of pain (except for urological and orthopedic surgeries). The results are summarized in Table 3.

Figure 7 compares the contributing multivariate-temporal factors for the first 3 leading components with the highest Fisher scores, differentiating between *mild* and *moderate-severe* levels of pain on postoperative days 30 and 90 for thoracic surgery. For postoperative day 30, the first and second multivariate factors

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emphasized the roles of heart rate and blood pressure. The activation of the second multivariate mode (green vector) was captured within two distinct temporal factors (green and yellow vectors). Figure 5 illustrates that almost all patients who developed moderate-severe levels of pain on postoperative day 30 had negative phases with respect to the first and second dimensions, mostly focusing on changes in heart rate and blood pressure. For postoperative day 90, the first and second multivariate factors emphasized the roles of heart rate and blood pressure. The activation of the first multivariate mode (blue vector) was captured within two distinct temporal factors (blue and green vectors). Figure 6 illustrates that almost all patients who developed moderate-severe levels of pain on postoperative day 90 had positive phases with respect to the first and third dimensions and negative phases with respect to the second dimension.

Table 3. Performance of LDA[a] to discriminate moderate-severe versus mild pain categories for postoperative day 90 without rotation. The phase information of the projected data points on a 3D manifold was used in the experiments. The patients were categorized based on their surgical services.

Surgery	Confusion matrix (patients)				Precision (PPV[b])	Sensitivity (TPR[c])	Specificity (TNR[d])	AUC[e]
	TP[f]	FP[g]	FN[h]	TN[i]				
Thoracic	6	2	3	29	0.75	0.67	0.94	0.87
Orthopedics	6	5	3	15	0.55	0.67	0.75	0.73
Urology	2	1	4	49	0.67	0.33	0.98	0.88
Colorectal	2	0	0	60	1	1	1	1
Transplant	2	1	1	6	0.67	0.67	0.86	0.90
Pancreas and biliary	4	2	2	24	0.67	0.67	0.92	0.92

[a]LDA: linear discriminant analysis.

[b]PPV: positive predictive value.

[c]TPR: true positive rate.

[d]TNR: true negative rate.

[e]AUC: area under curve.

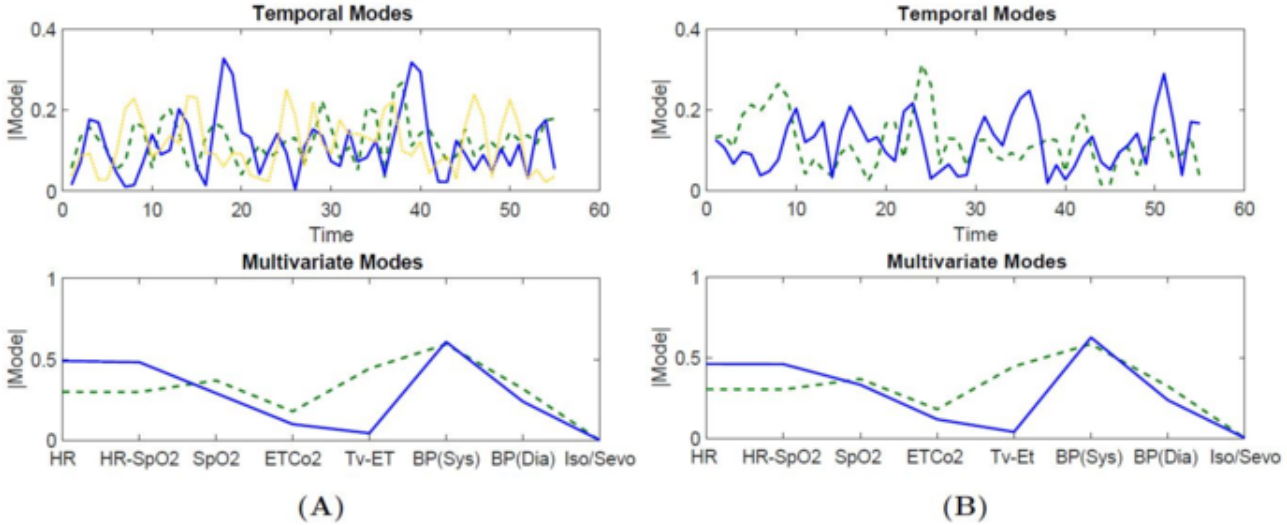
[f]TP: true positive.

[g]FP: false positive.

[h]FN: false negative.

[i]TN: true negative.

Figure 7. The contributing multivariate-temporal factors (blue, green, and yellow indicate rank from the highest to the lowest) for thoracic surgery. (A) Postoperative day 30: The multivariate modes show that the most dissimilarities between mild and moderate-severe levels of pain are encoded in variations of heart rate and blood pressure (blue and green vectors). Time evolution of the multivariate modes are encoded in temporal modes. (B) Postoperative day 90: The two multivariate factors (blue and green vectors) emphasize the strong contribution of heart rate and blood pressure while they have distinct phase portraits.



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Rotating the Physiological Responses With Respect to Patients' Dynamic Variation

Overview

As discussed earlier, each complex HOSVD component identifies subphysiological parameters (multivariate factor) with common intrasurgery temporal dynamics (temporal factor), which were differentially activated across patients. Overall, the complex HOSVD model uncovered a reasonable portrait of surgical dynamics (population dynamics), in which distinct subsets of physiological parameters were active at different times during surgery and whose variation across patients was encoded in individual dynamic variables. Until now, we have used the common multivariate-temporal dynamics as new bases to describe physiological responses; hence, we discarded individual dynamic variations encoded in *patient factors*. However, for a better representation of the dynamics, it is essential to associate each principal component (as one base of the subspace) with each dynamic mode of the patients' physiological responses. The coordinate systems provided by the common multivariate-temporal factors and the patients' multivariate-temporal dynamics are not necessarily the same (ie, not aligned) [29]. Given that all factors extracted through complex HOSVD are complex-valued factors, the patient-specific variations for the multivariate-temporal dynamics identified by the method contain scaling and rotational adjustments that appear in the outer product of the multivariate-temporal dynamics with the patients' factors.

Figure 8 illustrates multivariate dynamic changes across 5 patients in transplant surgery. For simplicity, temporal factors are discarded in this figure, but the same adjustments apply for temporal factors as well.

To compare the complex correlations between each physiological response and the extracted multivariate-temporal dynamics, it was essential to have a common coordinate system for all patients. Simultaneously, to account for the dynamic variation across patients, instead of rotating the dynamics, the complex conjugate of elements given by the patients' factors may be used to scale and rotate the physiological responses before projection onto the subspace. The process can be performed separately for each complex HOSVD component. From a geometric point of view, the process can be considered an active transformation in which the position of a point changes in a coordinate system, whereas a passive transformation changes the coordinate system in which the point is described. Figure 9 illustrates how the process works.

Once the new projections were obtained, we repeated the same set of experiments to explore the dynamic correlations in intraoperative vital signs. Again, the phase information of the projected data points was used to classify *mild* versus *moderate-severe* classes on postoperative days 30 and 90 through LDA.

Figure 8. The multivariate dynamic variation for different patients in transplant surgery. For intraoperative vital signs, each of the elements of a multivariate mode represents a particular vital sign. The magnitude and phase of the element explain how the vital signs are related to each other within that factor. The phase of each element describes the relative phase of the vital sign's vibration relative to the other vital signs for that multivariate factor. Although the elements of the multivariate factors for different patients have the same relative phase, the dynamics are not exactly aligned.

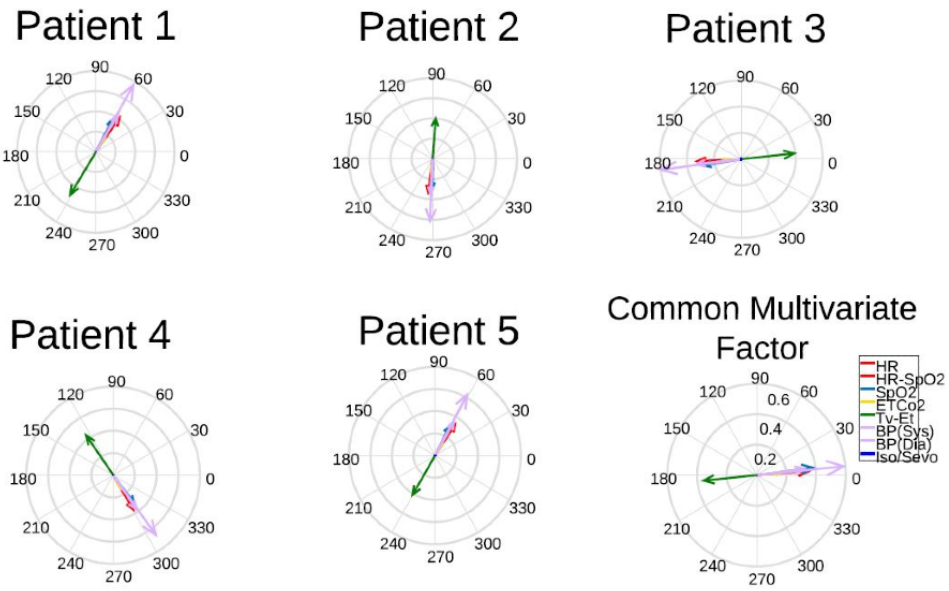

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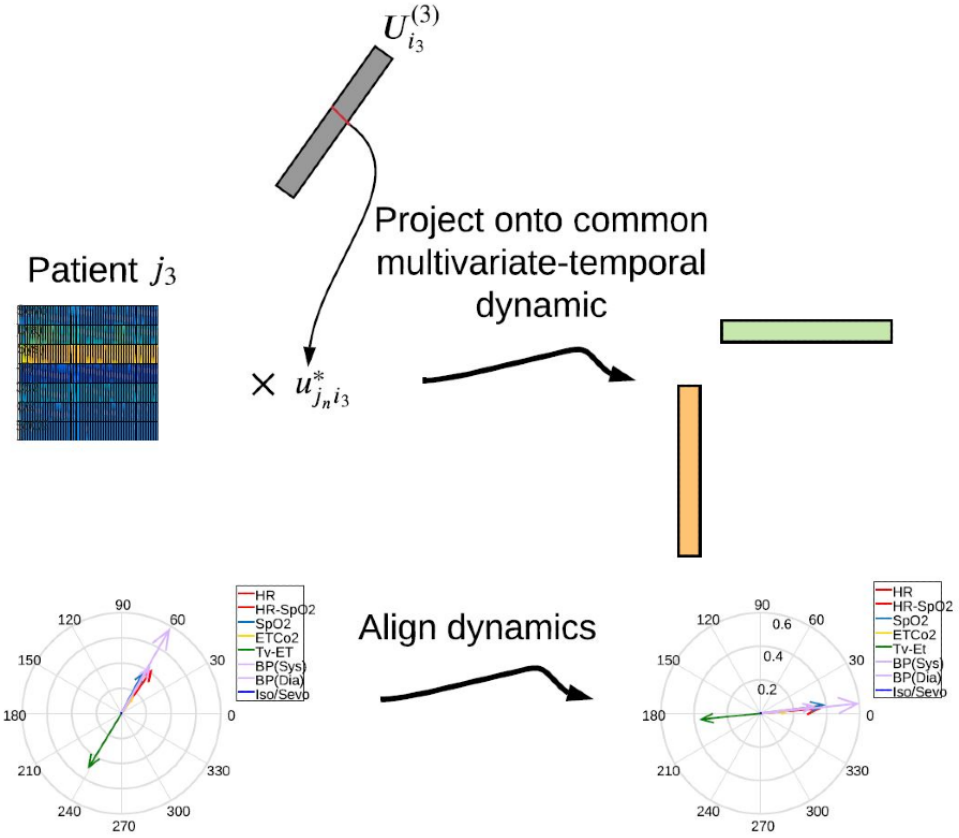
Figure 9. Rotation of physiological responses before projection to align with the common multivariate-temporal dynamic. For simplicity, one component is shown here.



Results for Postoperative Day 30

We noticed that the TPR, or the PPV for the class of moderate-severe pain in the five groups related to thoracic, orthopedic, colorectal, transplant, and pancreatic and biliary surgeries, improved compared with the results of the method without rotation of physiological responses. The TPR and PPVs were 0.69 and 0.75 for thoracic surgery, 0.77 and 0.83 for orthopedic surgery, 1 and 1 for transplant surgery, 0.57 and 0.73 for colorectal surgery, and 0.67 and 0.67 for pancreatic and biliary surgery, respectively. In contrast, the PPV and TPR for the *moderate-severe* class in urological surgery remained the same. The results are summarized in Table 4. Figures 10 and 11 show the scatter plot of the phase information for patients projected onto the 3D subspace for different surgical groups. The phase information of the physiological responses of the patients in the same group of pain was more similar to each other than to those in the other groups (thoracic, orthopedic, transplant, pancreas and biliary, and colorectal surgical groups). This again emphasizes that the dynamics of patients' physiological responses to surgical stimulation are associated with long-term POP development. We observed the same pattern in the results for postoperative day 90 (Figure 11).

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Table 4. Performance of LDA[a] to discriminate moderate-severe versus mild pain categories on postoperative day 30 when the physiological responses are rotated before projection. The phase information of the projected data points on a 3D manifold was used in the experiments. The patients were categorized based on their surgical services.

Surgery	Confusion matrix (patients)				Precision (PPV[b])	Sensitivity (TPR[c])	Specificity (TNR[d])	AUC[e]
	TP[f]	FP[g]	FN[h]	TN[i]				
Thoracic	9	3	4	21	0.75	0.69	0.88	0.81
Orthopedics	10	2	3	20	0.83	0.77	0.91	0.87
Urology	5	2	3	50	0.71	0.63	0.96	0.87
Colorectal	8	3	6	48	0.73	0.57	0.94	0.86
Transplant	3	0	0	8	1	1	1	1
Pancreas and biliary	6	3	3	22	0.67	0.67	0.88	0.83

[a]LDA: linear discriminant analysis.

[b]PPV: positive predictive value.

[c]TPR: true positive rate.

[d]TNR: true negative rate.

[e]AUC: area under curve.

[f]TP: true positive.

[g]FP: false positive.

[h]FN: false negative.

[i]TN: true negative.

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Figure 10. The phase information of the projected data points onto a 3D manifold extracted using the complex higher-order singular value decomposition. Mild (blue dots) versus moderate-severe (red dots) levels of pain on day 30 after surgery are considered for this plot.

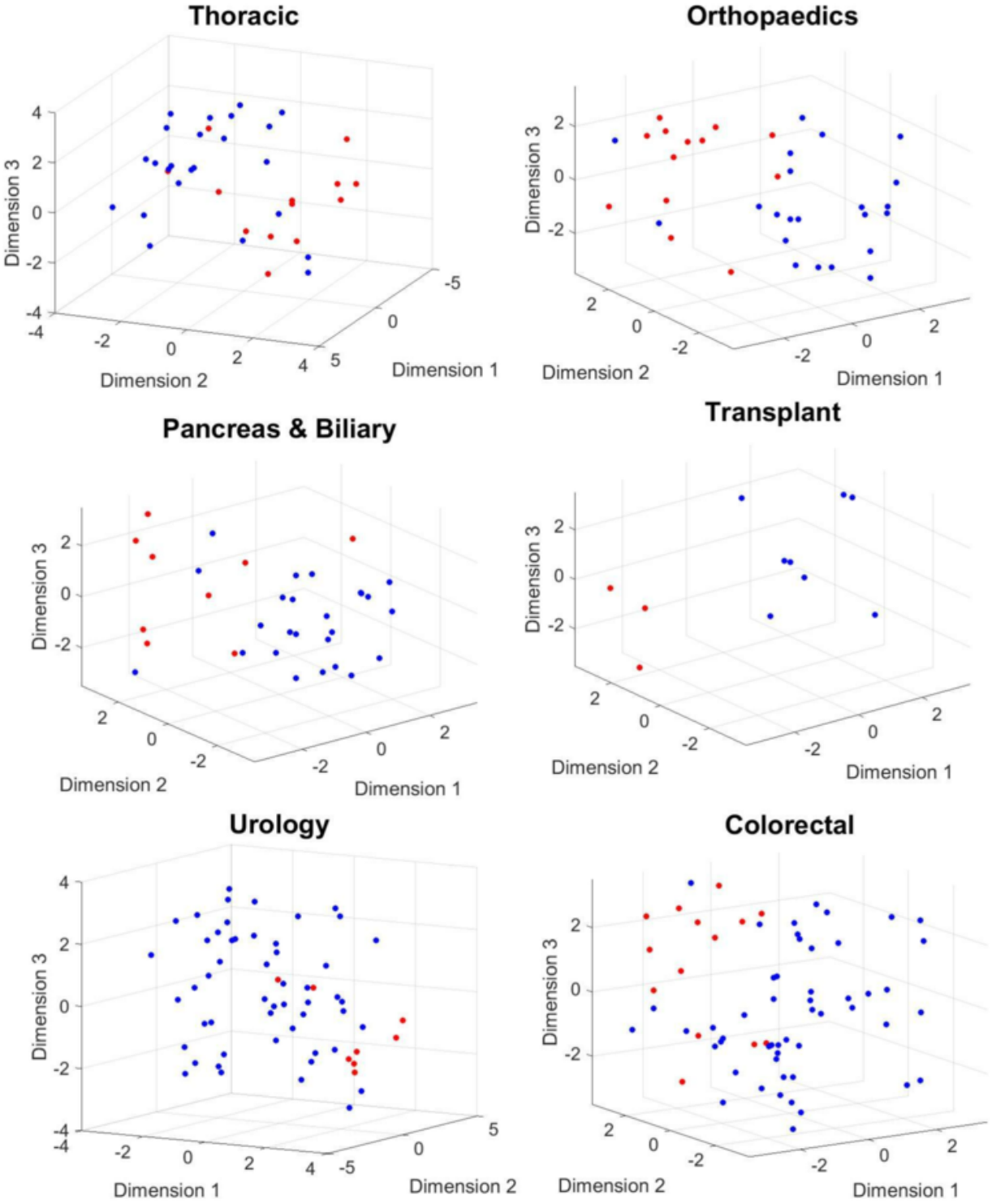

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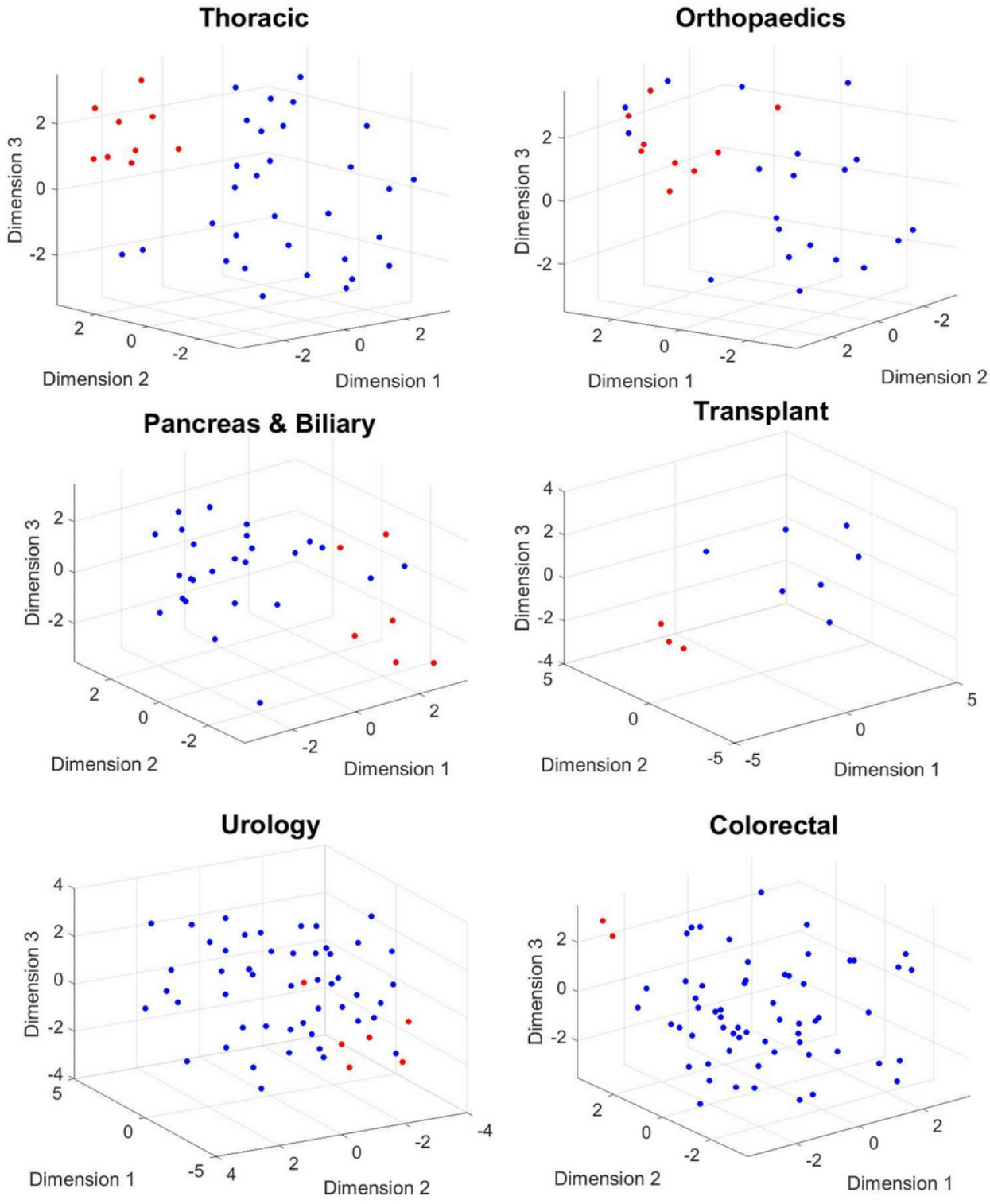
Figure 11. The phase information of the projected data points onto a 3D manifold extracted using the complex higher-order singular value decomposition. Mild (blue dots) versus moderate-severe (red dots) levels of pain on day 90 after surgery are considered for this plot.



Results for Postoperative Day 90

We repeated the set of experiments to classify patients who reported *mild* versus *moderate-severe* levels of pain on postoperative day 90. We observed that the TPR and the PPV for the class of moderate-severe pain in the three groups related to thoracic, orthopedic, and transplant surgery increased. The results are summarized in Table 5.

The phase information of the projected data points on a 3D manifold was used in the experiments. The patients were categorized based on their surgical services.

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Table 5. Performance of LDA[a] to discriminate moderate-severe versus mild pain categories on postoperative day 90 when the physiological responses are rotated before projection.

Surgery	Confusion matrix (patients)				Precision (PPV[b])	Sensitivity (TPR[c])	Specificity (TNR[d])	AUC[e]
	TP[f]	FP[g]	FN[h]	TN[i]				
Thoracic	8	2	1	29	0.80	0.89	0.94	0.89
Orthopedics	7	4	2	16	0.64	0.78	0.80	0.83
Urology	2	1	4	49	0.67	0.33	0.98	0.88
Colorectal	2	0	0	60	1	1	1	1
Transplant	3	0	0	7	1	1	1	1
Pancreas and biliary	4	2	2	24	0.67	0.67	0.92	0.92

[a]LDA: linear discriminant analysis.

[b]PPV: positive predictive value.

[c]TPR: true positive rate.

[d]TNR: true negative rate.

[e]AUC: area under curve.

[f]TP: true positive.

[g]FP: false positive.

[h]FN: false negative.

[i]TN: true negative.

Discussion

Principal Findings

This study introduced a new type of multivariate-temporal decomposition of intraoperative vital signs to explore signatures that can accurately discriminate patients who develop *mild* or *moderate-severe* pain on postoperative days 30 and 90. The method takes advantage of the fact that complex-HOSVD decomposes data into a sum of rank-1 tensors, which is a combination of modes or signatures. This method arranges the multivariate trajectory of intraoperative vital signs of various patients in a 3D data array with dimensions indexed by vital sign variable, time, and patient. This is the first time that multivariate-temporal decomposition of complex-valued intraoperative vital signs has been proposed to analyze long-term POP. Using a multivariate time structure helped us to accurately describe the dynamics of intraoperative vital signs and to find a lower-dimensional projection where differences between individual responses were encoded in the phases of complex vital signs. The primary advantage of complex HOSVD is that it discovers and examines multivariate-temporal behavior. However, complex multivariate-temporal factors are difficult to interpret as amplitude and phase relations because of Hilbert transform properties, which weigh more sudden transitions than episodes during which intraoperative vital signs change slowly. Further research is necessary to compensate for this behavior.

Although clinical verification has not yet been undertaken, this study presents a physiological interpretation of the model. This interpretation focused on the spectral dynamics of different vital signs during surgery. For the intraoperative vital signs time series used in this study, the spectral band was within the frequency band of the autonomic nervous system responding to a surgical stimulus under general anesthesia, which established the sampling rate. Variability in physiological parameters during surgery is a result of a dynamic interaction between surgery-induced perturbations in the circulatory system and the short-term compensatory response to regulate them. For instance, short-term circulation control by the baroreceptor reflex or vasomotor tone is best described by feedback models. Circulation control can be identified by a pair of input-output signals. Regarding the baroreceptor reflex, blood pressure and heart rate act as input and output signals, respectively. The transfer function parameters in the feedback system determine the input-output relation. Although the gain defines the amplitude relationship of the input-output signals, the phase determines the delay between the two. For baroreceptor reflex, the phase of the transfer function quantifies the phase shift between blood pressure and heart rate. Multivariate factors can be considered patterns of prototypical short-term circulation control in patients. Hence, the complex-valued elements of the multivariate factors may correspond to the attributes of the transfer function. In this setting, the absolute value of the elements might correlate with the gain of the transfer function, and the angle might indicate the delay between the input and output signals. For example, the strong contribution of heart rate and blood pressure and the phase shift between them in one of the extracted multivariate factors might correspond to circulation control by the baroreceptor reflex (Figure 3D). Temporal factors are highly dependent on the surgical type; therefore, they are more difficult to interpret. However, they may serve as indicators of circulation control activity during surgery.

Conclusions

POP affects the quality of life and is associated with increased morbidity, longer recovery time, prolonged duration of opioid use, and higher health care costs. It can also lead to depression and anxiety, which can in turn worsen pain. Unfortunately, this postoperative complication remains undertreated and poorly

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controlled in most patients [30]. In this study, we showed that common features collected during routine anesthesia are predictive of POP-related outcomes and the development of chronic pain. The outcome of this study has potential clinical utility in using preventive treatments or starting treatment plans including medications, lifestyle changes, and therapies even before the development of moderate to severe levels of pain.

Limitations

Our study was limited by the sampling rate of intraoperative vital signs, verbal evaluation of POP, and the small number of surgical patients involved. A higher sampling rate of vital signs would allow for a more comprehensive analysis of autonomic nervous system activity. A larger number of patients would provide valid testing of hypotheses regarding temporal and multivariate factors within surgeries. Finally, a more reliable method for assessing POP would remove noise from the data set.

This study was also limited because we considered only a small subset of relevant variables that could affect POP. In particular, we did not consider the response of patients to noxious stimuli and how it changes the effect of anesthetics and adjuvants on the dynamics of physiological parameters. This causes a failure to extract a partial correlation between the input parameters and POP.

Regarding the anesthetics delivered for the cases studied in this model, it is noteworthy that sympathomimetic agents are commonly used in anesthetics at our institution, as are both short- and long-acting beta-receptor blockers. Moreover, these agents are usually administered as bolus doses, and it remains unclear how to best model such episodic impulses into the system.

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Conflicts of Interest

None declared.

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Abbreviations

$EtCO_2$: end-tidal carbon dioxide
HOSVD: higher-order singular value decomposition
LDA: linear discriminant analysis
POP: postoperative pain
PPV: positive predictive value
SpO_2: peripheral capillary oxygen saturation
SVD: singular value decomposition
TPR: true positive rate

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Original Paper

Demonstration and Performance Evaluation of Two Novel Algorithms for Removing Artifacts From Automated Intraoperative Temperature Data Sets: Multicenter, Observational, Retrospective Study

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Abstract

Background: The automated acquisition of intraoperative patient temperature data via temperature probes leads to the possibility of producing a number of artifacts related to probe positioning that may impact these probes' utility for observational research.

Objective: We sought to compare the performance of two de novo algorithms for filtering such artifacts.

Methods: In this observational retrospective study, the intraoperative temperature data of adults who received general anesthesia for noncardiac surgery were extracted from the Multicenter Perioperative Outcomes Group registry. Two algorithms were developed and then compared to the reference standard—anesthesiologists' manual artifact detection process. Algorithm 1 (a slope-based algorithm) was based on the linear curve fit of 3 adjacent temperature data points. Algorithm 2 (an interval-based algorithm) assessed for time gaps between contiguous temperature recordings. Sensitivity and specificity values for artifact detection were calculated for each algorithm, as were mean temperatures and areas under the curve for hypothermia (temperatures below 36 °C) for each patient, after artifact removal via each methodology.

Results: A total of 27,683 temperature readings from 200 anesthetic records were analyzed. The overall agreement among the anesthesiologists was 92.1%. Both algorithms had high specificity but moderate sensitivity (specificity: 99.02% for algorithm 1 vs 99.54% for algorithm 2; sensitivity: 49.13% for algorithm 1 vs 37.72% for algorithm 2; F-score: 0.65 for algorithm 1 vs 0.55 for algorithm 2). The areas under the curve for time × hypothermic temperature and the mean temperatures recorded for each case after artifact removal were similar between the algorithms and the anesthesiologists.

Conclusions: The tested algorithms provide an automated way to filter intraoperative temperature artifacts that closely approximates manual sorting by anesthesiologists. Our study provides evidence demonstrating the efficacy of highly generalizable artifact reduction algorithms that can be readily used by observational studies that rely on automated intraoperative data acquisition.

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KEYWORDS

temperature; intraoperative; artifacts; algorithms; perioperative; surgery; temperature probe; artifact reduction; data acquisition; accuracy

Introduction

Body temperature is a critical vital sign, and its measurement during surgery is an integral part of standard American Society of Anesthesiologists monitoring [1,2]. Intraoperative hypothermia has been associated with perioperative complications, such as surgical wound infections, cardiac morbidity, coagulopathy, impaired drug metabolism, and prolonged recovery [3-7]. Given its profound impact on postoperative outcomes, accurately accounting for intraoperative temperature in large perioperative database studies is of paramount importance. Unfortunately, intraoperative temperature readings usually contain a number of artifacts. Mechanistically, these artifacts may be a result of temperature probes that are suboptimally placed, temperature probes that accidentally fall out of a patient's oral cavity or nasal orifice, low readings resulting from the probe warming up from room temperature to a patient's core temperature, or readings associated with the repositioning of temperature probes [8,9]. Although some studies have proposed temperature artifact–reducing algorithms, their validation remains lacking, and the most widely cited algorithm relies on equal time intervals across measurements—a condition that is frequently violated within many large data sets [10]. Our study aims to address these knowledge and performance gaps, as we compare the performance of two novel temperature artifact reduction algorithms to that of manual artifact removal by three board-certified anesthesiologists, using a large intraoperative temperature database.

Methods

Ethics Approval

This study was approved by the institutional review board (approval number: HIC 1206010438).

Study Design

This was a multicenter, observational, retrospective study of data that were collected by the Multicenter Perioperative Outcomes Group (MPOG) consortium after institutional review board approval. The MPOG registry contains the anesthetic data of over 14 million procedures from over 48 medical centers. This consortium has rigorously collected and standardized information regarding anesthetic and surgical encounters with patient-level data [11]. The number of individual surgical procedures, the diversity of participants, and its wide geographic coverage make this database a very rich data source for drawing precise and reliable estimates. Both large academic medical centers and community hospitals contribute to this database, thereby yielding a large, representative, national sample. This database is among the largest anesthetic registries in the United States, and algorithm evaluation via the use of this registry would make algorithms generalizable across a wide array of institutions.

The study plan, including the sample size assessment, was published prior to data extraction and analysis [12].

Inclusion and Exclusion Criteria

Anesthetic records of patients aged over 18 years who were undergoing general anesthesia with an endotracheal tube for noncardiac surgery were included in this study. The exclusion criteria comprised cases with an American Society of Anesthesiologists Physical Status of 5 or 6, temperature probes placed at sites other than the nasopharynx or the oropharynx, cases in which an endotracheal tube was not used for general anesthesia, or cases with less than 3 temperature readings in the anesthetic records. These temperature recordings were extracted from anesthesia charts. Only intraoperative readings were used for artifact detection.

After the cohort was selected by using the inclusion and exclusion criteria, a convenience sample of 200 noncardiac surgical cases from an anonymized institution within the MPOG consortium was chosen.

End Points

The primary study end point was to assess the sensitivity and specificity of the two algorithms for detecting artifacts in automated intraoperative temperature recordings by comparing them to a reference standard—manual artifact detection by three anesthesiologists. The other study end points included measures of agreement (by case) between each algorithm and between the algorithms and the experts' adjudications for mean temperatures and areas under the curve (AUCs). AUCs for temperature readings below 36 °C were used for this analysis. The AUC for the time multiplied by temperature readings below 36 °C was calculated for each patient after excluding artifacts, as adjudicated by the algorithms or the experts. The use of AUCs for temperature readings under 36 °C served as an index that combined the duration and severity of patient hypothermia [13].

Algorithm Definitions

Algorithms 1 and 2 are depicted in Figure 1. Briefly, temperatures below 32 °C and above 40 °C were excluded. The algorithms' logics were then used to identify potential artifacts in accordance with their flowcharts. Algorithm 1—the slope-based algorithm—calculated the linear curve fit of 3 adjacent temperature data points. Data points that had a slope of greater than 0.08 were excluded. The algorithm then calculated the absolute temperature difference between the previous data point and the next data point. Temperatures with an absolute change of greater than 0.25 °C from the previous temperature were excluded.

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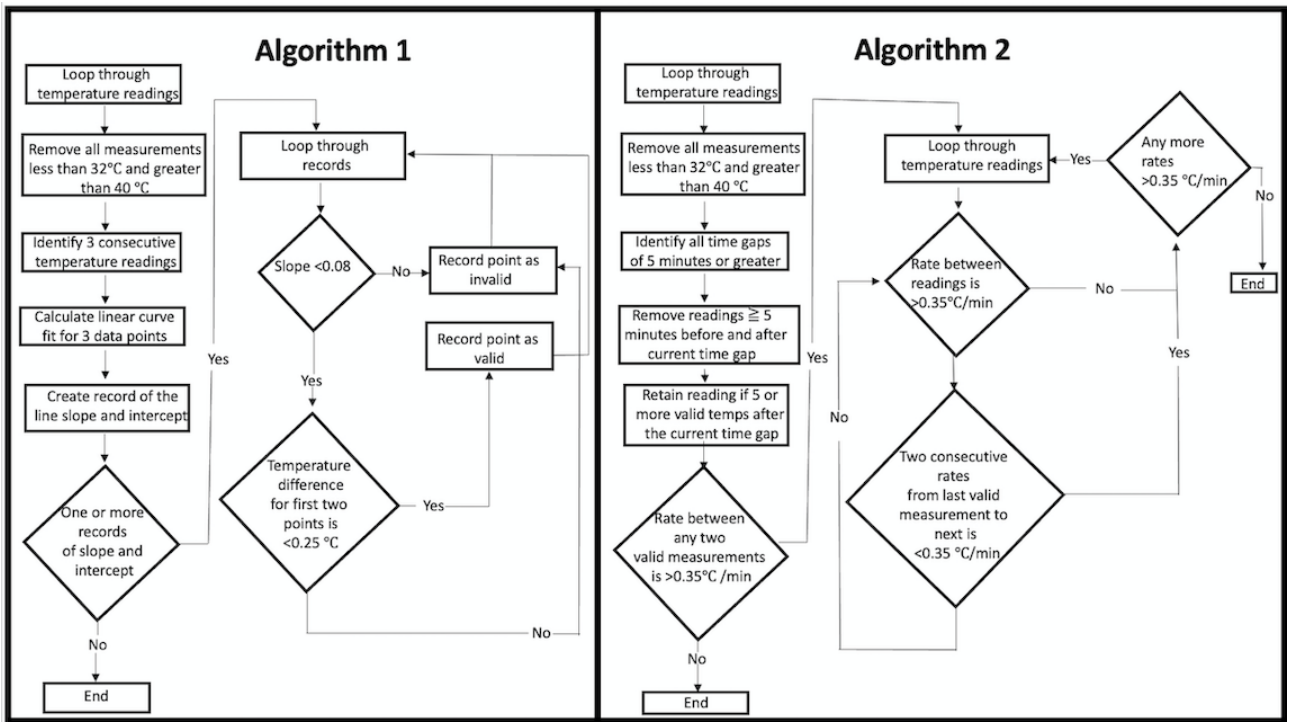
Figure 1. The algorithms used for the reduction of artifacts in intraoperative temperature recordings.



Algorithm 2—the interval-based algorithm—assessed for time gaps between contiguous temperature recordings that were more than 5 minutes apart. If there were less than 5 temperature recordings after the time gap, they were recorded as artifacts. If, however, there were more than 5 recordings after the measurement gap, then the slope between the last valid temperature recording and the next temperature recording was calculated, and if the slope was less than 0.35 °C per minute, then the temperature points were retained. Otherwise, they were marked as artifacts.

Adjudication by Experts

Three board-certified anesthesiologists independently identified artifacts in temperature readings of intraoperative cases; each anesthesiologist was blinded to the other anesthesiologists' results and the algorithms' calculations. In the event of discordance, the majority rule (ie, agreement among at least 2 of the 3 anesthesiologists) was followed. We used an innovative approach to present time-temperature readings to the experts, for which we developed software on the JavaFX (Oracle Corporation) and Java 11 JDK (Oracle Corporation) platforms. The program first extracted patient temperature data to a flat file. Each record incorporated a unique patient identifier, temperature, and time stamp. The data were then written to an HTML file, using a FreeMarker Java template. The file used the JavaScript Google Visualization application programming interface to display intraoperative temperatures for each case in a scatterplot, which displayed temperatures on the vertical axis and time on the horizontal axis (Multimedia Appendix 1). Experts marked readings that they considered to be artifacts. The results were recorded and abstracted to a datasheet.

Statistical Analysis

Statistical analyses were performed by using SAS version 9.4 (SAS Institute Inc). Descriptive statistics were performed on all extracted temperature readings, including readings deemed artifactual by each algorithm and the expert-adjudicated values.

The results of the manual artifact identification by the experts (majority rule) and the two algorithms were also compared by using Bland-Altman plots for both mean temperatures and AUCs for hypothermic temperature readings. For these AUCs, we computed the average height between successive time points and corresponding interval widths to estimate the segment areas. We aggregated the areas for temperatures under 36 °C to obtain the total area for each surgical case.

Sample Size Justification

Although we conducted an observational descriptive analysis without inferential aims, we performed a power analysis to establish the extent to which the data set would define bias and limits of agreement. After a literature review, we were not able to find similar studies that could be used to guide the sample size estimation. Based on our pilot data, the mean sample difference in AUCs for temperature readings below 36 °C between the experts and each algorithm was 0.2 (SD 1.02) minutes×°C. Using the methodology developed by Lu et al [14], we determined that we would require a sample size of 147 patient records to achieve 80% power to detect agreement when the confidence level of the level of agreement was set to 0.950 and the confidence level of the CIs for the levels of agreement was set to 0.95. The maximum allowable difference was 2.56 minutes×°C, which was much lower than our prespecified, clinically meaningful value of 4 minutes×°C. To account for the possibility of including cases without any temperature recordings and to be well beyond the 80% power threshold, an a priori decision was made to include 200 intraoperative cases, which were analyzed for this study.

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Results

Study Characteristics

A total of 27,683 temperature readings from 200 anesthetic records were analyzed by the algorithms and the anesthesiologists. The median temperature reading count per case was 103 (IQR 51-185.5). A histogram depicting the temperature curve is presented in Multimedia Appendix 2. There was unanimous agreement among the anesthesiologists for 92.1% (25,496/27,683) of the temperature readings; they identified 89 records as artifacts. An additional 200 readings were noted as artifacts by using the majority rule, resulting in a total of 289 temperature readings that were considered to be artifacts.

Sensitivity and Specificity for Artifact Detection

Among the 27,683 temperature readings, a total of 411 temperature points were identified as artifacts by the slope-based algorithm, and 236 points were identified as artifacts by the interval-based algorithm. Notably, these rejections were not limited to a few cases. Of the 200 cases, 81 (40.5%) had at least one rejection by the slope-based algorithm, and 89 cases (44.5%) had at least one rejection by the interval-based algorithm. In comparison, 88 cases (44%) were adjudicated to have artifacts by the anesthesiologists. The mean number of rejections for each of the 200 cases was 2.1 for the slope-based algorithm and 1.2 for the interval-based algorithm.

As expected, both algorithms had a high specificity for artifact detection (slope-based algorithm: 99.02%; interval-based algorithm: 99.54%), while the slope-based algorithm appeared to be better than the interval-based algorithm in terms of sensitivity (49.13% vs 37.72%). The F-score was 0.65 for the slope-based algorithm and 0.55 for the interval-based algorithm.

AUC Estimates for Hypothermic Temperature Readings

Comparisons between the AUCs for hypothermic temperature readings from raw data and those from anesthesiologists showed no appreciable differences in the patient-averaged summaries (Figure 2). However, some differences were seen in extremely low temperatures readings, such as the positive bias toward the raw data in the analyzed curves. This bias was seen because such low temperature readings were frequently adjudicated to be artifactual by experts and discarded in their AUC calculations, but they were used for AUC calculations with the raw data. Similar results were obtained after comparing each algorithm to the raw data (Figure 2 and Multimedia Appendix 3).

Previously, an AUC of 60 minutes×°C was used as a standard unit of reference; multiples of 60 minutes×°C were shown to be associated with adverse patient outcomes [10]. Our Bland-Altman plots indicated a bias value of greater than 60 minutes×°C between experts and raw values (−86.26 minutes×°C), between algorithm 1 and raw values (−106.04 minutes×°C), and between algorithm 2 and raw values (−70.73 minutes×°C). This indicates that the application of these algorithms may make hypothermia-based temperature analyses more meaningful than analyses based on raw data alone when assessing the impact of hypothermia on patient outcomes.

Interestingly, both the bias between experts and the slope-based algorithm (19.78 minutes×°C) and the bias between experts and the interval-based algorithm (−15.53 minutes×°C) were less than 60 minutes×°C, suggesting that after the raw data were evaluated by experts or by either of the algorithms, the resulting measures of hypothermia were similar and were within accepted measures of clinical relevance.

In order to better characterize the agreement, we assessed the performance of the algorithms in evaluating a clinically meaningful measure. Large AUCs for hypothermic temperature readings (time under 36 °C × temperature value of under 36 °C) have been shown to be associated with poor postoperative outcomes, including increased lengths of hospital stay and the need for a blood transfusion [10]. We used a similar approach to compare such AUCs for each case after artifact removal by experts and artifact removal by the slope-based algorithm (algorithm 1) and the interval-based algorithm (algorithm 2; Figure 3 and Figure 4). These methodologies have been used in similar studies comparing 2 modalities of measurement [15].

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Figure 2. Bland-Altman plots for the interrater agreement analysis of areas under the curve for hypothermia; 95% limits of agreement are shown with light blue lines, bias is shown as a dotted black line, and the agreement bias of 2 methods is shown as a solid red line. Each dot represents a surgical case.

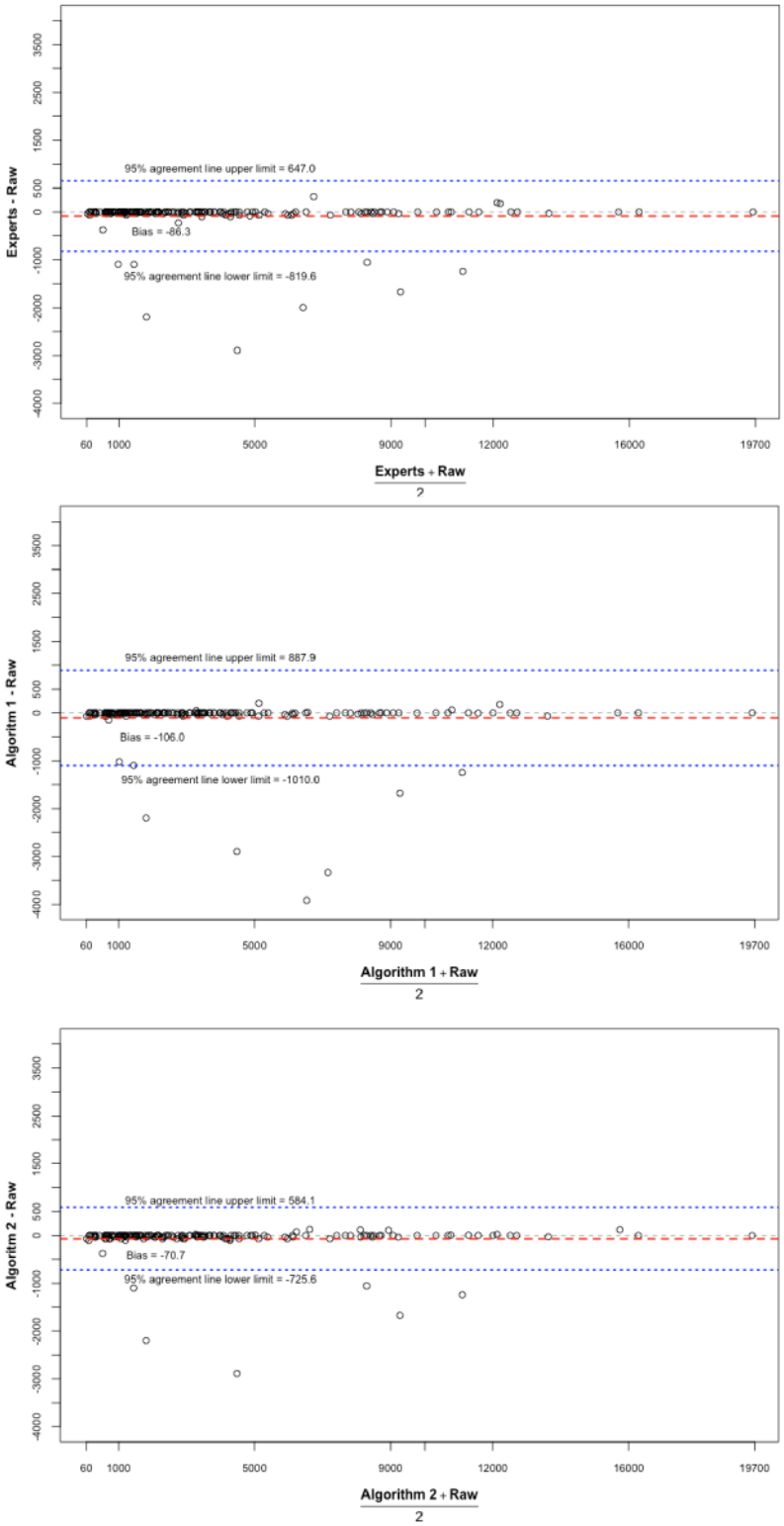

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Figure 3. Scatter plots showing the distribution of AUCs for hypothermia (time under 36 °C × hypothermic temperature value) for the cases after artifact removal by the algorithms versus the anesthesiologists (experts). Each dot indicates a case. Values on the red line indicate cases that have temperature readings with similar AUCs after artifact removal by experts and by algorithm 1 (left) and algorithm 2 (right). Values to the right of the red line indicate fewer hypothermic temperatures marked as artifacts by the algorithm (compared to those marked by experts), leading to larger AUCs calculated by the experts compared to those calculated by the algorithms. AUC: area under the curve.

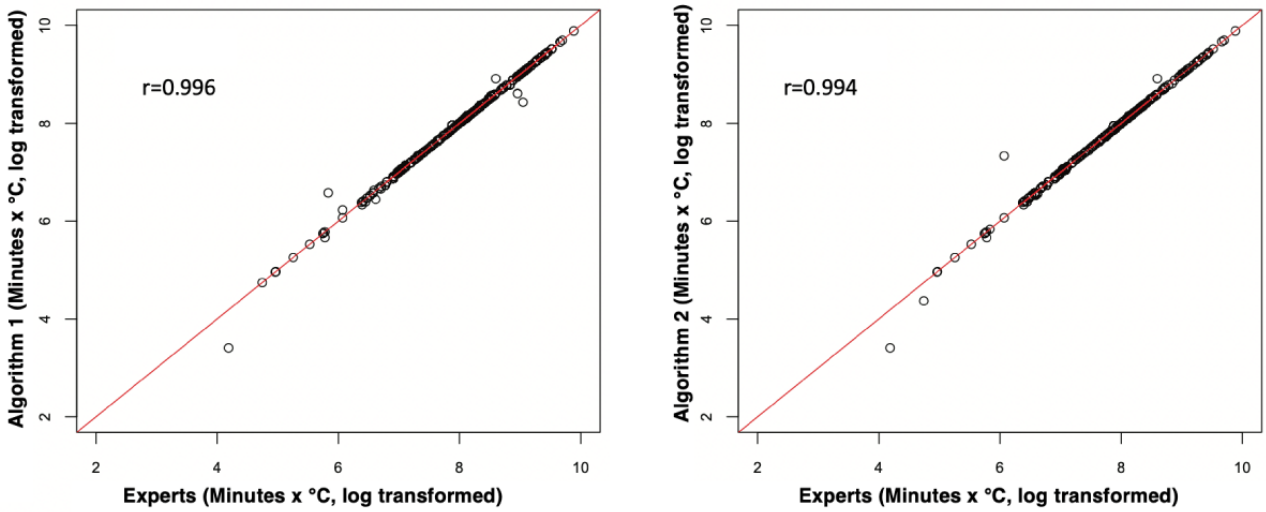
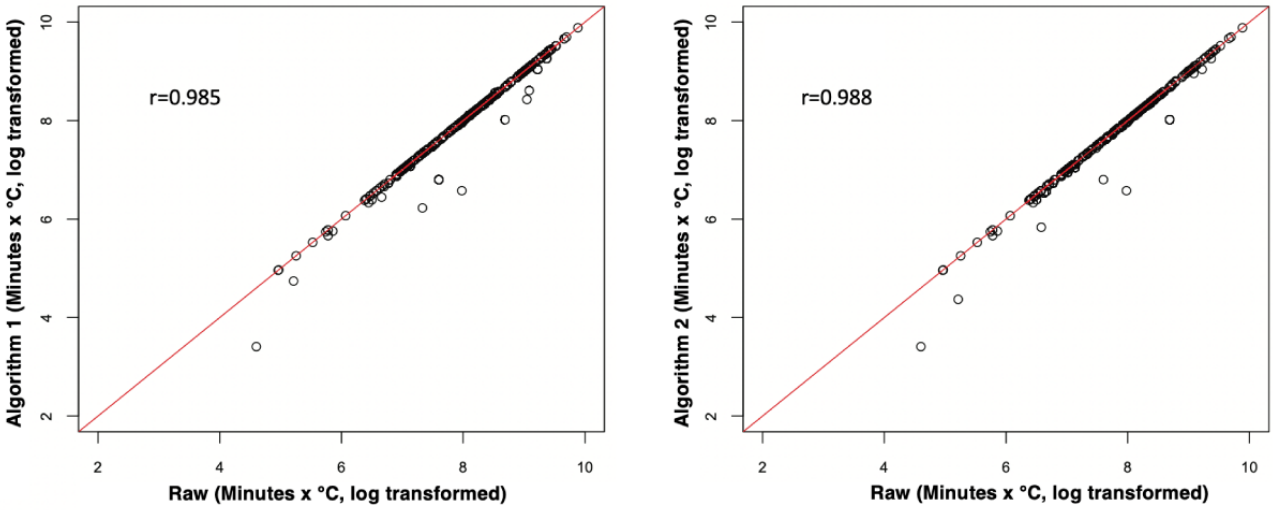


Figure 4. Scatter plots showing the distribution of AUCs for hypothermia (time under 36 °C × hypothermic temperature value) for the cases after artifact removal by the algorithms versus the raw values. Each dot indicates a case. Values on the red line indicate cases that have temperature readings with similar AUCs before (raw values) and after artifact removal by algorithm 1 (left) and algorithm 2 (right). Values to the right of the red line indicate the number of hypothermic temperatures marked as artifacts by the algorithm (as compared to the raw values), leading to larger AUCs calculated from the raw data compared to those calculated by the algorithms. AUC: area under the curve.



Mean Temperature Estimates

Mean temperature readings for each patient record were calculated after artifact removal via the methods we described. The mean temperature reading profiles, in which the raw data were compared to anesthesiologists' majority rule–based results, showed no appreciable differences (Figure 5). However, as with the AUCs, bias in mean temperature was seen at extremely low temperatures. The mean temperature readings for each of the two algorithms before and after artifact removal followed a similar trend (Figure 5 and Multimedia Appendix 4).

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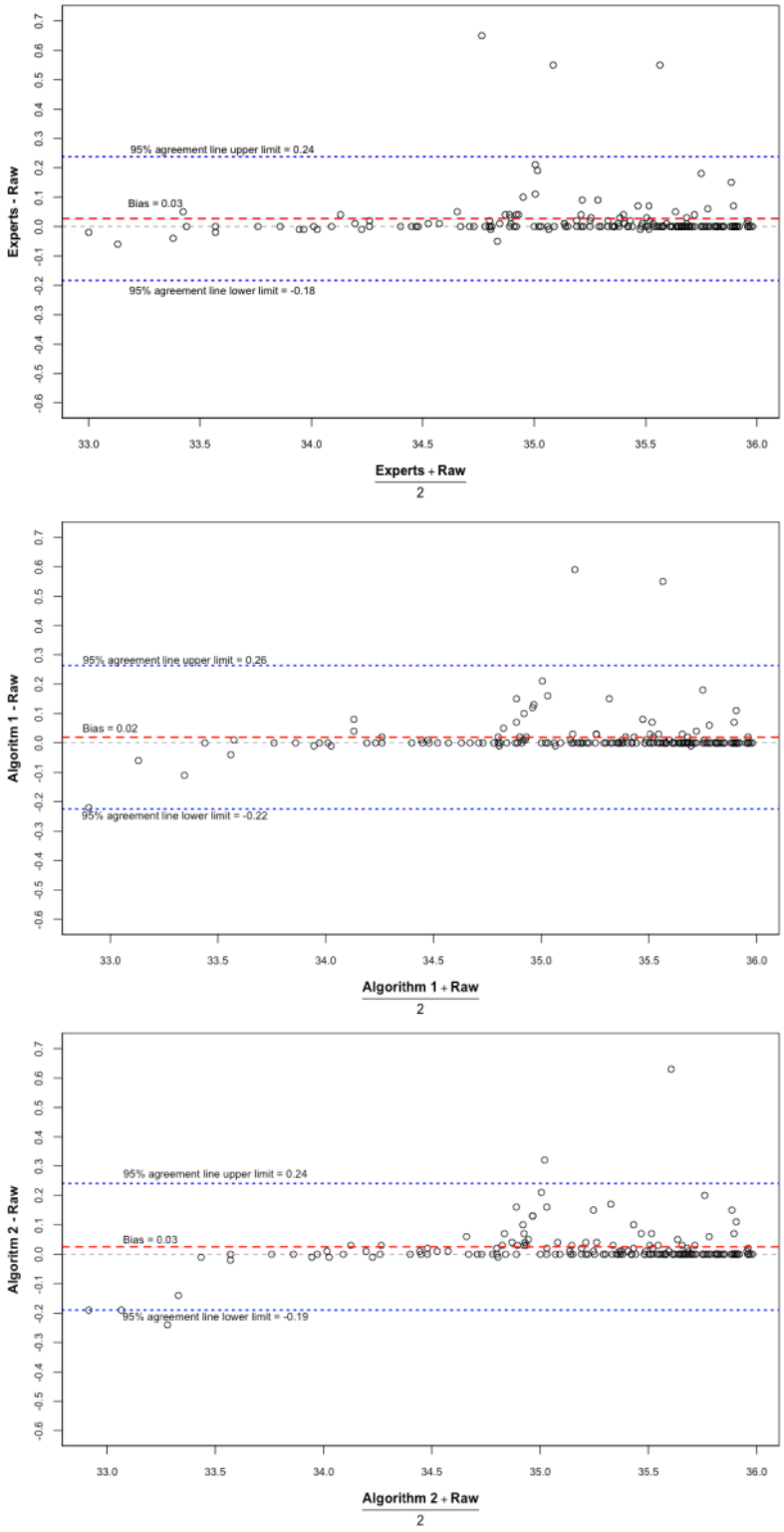
Figure 5. Bland-Altman plots for the interrater agreement analysis of mean temperatures; 95% limits of agreement are shown with light blue lines, bias is shown as a dotted black line, and the agreement bias of 2 methods is shown as a solid red line. Each dot represents a surgical case.



Clustering of the Artifacts

In order to describe clusters, we considered a cluster to be 3 or more consecutive temperature readings that were adjudicated as artifacts. We compared the distributions of the number of clusters per case among the three methods (manual artifact detection by anesthesiologists, the use of the slope-based algorithm [algorithm 1], and the use of the interval-based algorithm [algorithm 2]), as depicted in Multimedia Appendix 5. There was very good interrater reliability for the number of artifactual data points (Gwet AC1 statistic 0.876, 95% CI 0.833-0.92) [16]. The distributions of the cluster sizes in each case among the three methods is shown in Multimedia Appendix 6.

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Discussion

This study has important findings. First, the overall rate of intraoperative temperature artifacts in the sample, which was obtained via automated electronic health record data capture, was low (point estimate 0.01, 95% CI 0.009-0.011). To the best of our knowledge, our study is the first of its kind to address the validity of raw intraoperative temperature recordings. Thus, mean temperature values derived from raw data closely approximate those derived by experts and may be directly used for research purposes. Second, the slope-based algorithm can filter intraoperative temperature artifacts, closely approximating manual sorting by anesthesiologists. The artifact reduction algorithm can thus be used by studies that evaluate the effect of intraoperative hypothermia on patient outcomes. This algorithm can also serve as a powerful tool for gauging the quality of temperature data capture by a particular medical center via comparisons to other medical centers. In addition, our methodology can be used to validate similar algorithms aimed at discerning artifacts associated with other vitals, such as intraoperative blood pressure.

Our intraoperative temperature recordings are similar to those in other studies evaluating intraoperative temperatures [17,18]. The majority of patients under general anesthesia tend to experience a decrease in core body temperature [19,20]. This pattern of change varies widely based on the type and duration of surgery [21]. We saw similar patterns in our random sample of intraoperative temperature records, which indicated that our sample was not biased toward a particular subset of patients or surgeries. Studies that have attempted to filter out artifacts related to intraoperative temperature measurements lack generalizability [10]. One of the key strengths of our study is that, given the adaptability of the algorithms, they can be applied by a particular medical center to filter intraoperative artifacts both for research and for quality initiative purposes.

Our study has some limitations. First, due to the lack of a true gold standard, manual artifact sorting by anesthesiologists was considered a reasonable method for assessing the performance of artifact detection. An alternate methodology for measuring the artifacts could have been correlating esophageal temperatures with temperature measurements that were simultaneously captured from other sites, such as the bladder. However, very few patients receive more than 1 temperature measurement modality. Moreover, bladder temperatures lag behind esophageal temperatures, which would make identifying a true artifact difficult [1]. Additionally, each modality has its own limitations, undermining the very notion of any single gold standard source of core temperature readings. For example, bladder temperature measurement devices are strongly influenced by urine flow [22]. Second, the algorithms were only validated for cases in which nasopharyngeal or oropharyngeal temperature probes were used. However, these probes are used for intraoperative temperature measurement among the vast majority of patients. Third, this study had a retrospective design. We chose to use this study design, as conducting this study in real time would have been very resource intensive. Moreover, having an observer could have resulted in changes in clinician behavior. Due to the retrospective nature of this study, we included cases in which patient temperature data were automatically acquired via oropharyngeal probes or nasopharyngeal probes. These probes generally use thermistors or thermocouples, which are considered standard for clinical use, though this was not a standardized part of the study protocol, given its retrospective design [1]. Further, the algorithms' calculations are based on changes in temperature and gradients of temperature change during an anesthetic encounter, and the algorithms would fail to detect artifacts if temperature probes were inappropriately placed for the entirety of an anesthetic encounter. Fourth, it is possible that outliers could have heavily influenced our observations. In order to address this, we performed sensitivity analyses of our results by re-estimating our result summaries via the jackknife method—a "leave one observation out at a time" approach. The jackknife estimates revealed that there were no highly influential observations. The bias estimates remained largely unchanged (Multimedia Appendix 7). Fifth, we would also like to emphasize that while the slope-based algorithm achieved a modest F-score, significant room for improvement exists. However, this algorithm may be an important first step in addressing the validity of automated intraoperative temperature recordings and may serve as a scaffold for further improved algorithms. Finally, the algorithms may poorly extrapolate temperature-time curves that include time gaps or time periods in which data were not collected, and they may mask intraoperative temperature shifts that could have occurred during these periods. Such anomalies, however, happened infrequently and were detectable upon investigation.

In summary, it is widely recognized that intraoperative temperature monitoring is key to postoperative patient outcomes. Our study provides highly generalizable artifact reduction algorithms that can be used as standard open-access tools to filter out artifacts in large database studies. They can also be used as tools for assessing the quality of intraoperative temperature recordings at various centers. Further investigations should assess our slope-based algorithm's performance for other intraoperative databases and populations.

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Authors' Contributions

AB, DY, FD, and RBS conceived and designed the study, performed the data analysis, interpreted the data, and prepared manuscript. RD, NLP, KS, MRM, and SK conceived and designed the study, interpreted the data, and prepared the manuscript. GM performed the data analysis and interpreted the data.

Conflicts of Interest

RBS holds an equity position in Johnson & Johnson.

Multimedia Appendix 1
Intraoperative temperatures for a surgical case displayed as a function of time. Red dots indicate the temperature points that were adjudicated by an anesthesiologist as artifactual.
[PNG File , 61 KB - periop_v5i1e37174_app1.png]

Multimedia Appendix 2
Histogram showing the distribution of raw temperature data in the study cohort.
[PNG File , 296 KB - periop_v5i1e37174_app2.png]

Multimedia Appendix 3
Bland-Altman plots for the interrater agreement analysis of areas under the curve (AUCs) for hypothermia; 95% limits of agreement are shown with light blue lines, bias is shown as a dotted black line, and the agreement bias of 2 methods is shown as a solid red line. Each dot represents a surgical case.
[PNG File , 103 KB - periop_v5i1e37174_app3.png]

Multimedia Appendix 4
Bland-Altman plots for the interrater agreement analysis of mean temperature; 95% limits of agreement are shown with light blue lines, bias is shown as a dotted black line, and the agreement bias of 2 methods is shown as a solid red line. Each dot represents a surgical case.
[PNG File , 125 KB - periop_v5i1e37174_app4.png]

Multimedia Appendix 5
Distribution of the number of temperature clusters (3 consecutive artifactual temperature readings), as adjudicated by experts, algorithm 1, and algorithm 2.
[PNG File , 349 KB - periop_v5i1e37174_app5.png]

Multimedia Appendix 6
Distribution of the size of the clusters per case for the three methods (experts, algorithm 1, and algorithm 2).
[DOCX File , 25 KB - periop_v5i1e37174_app6.docx]

Multimedia Appendix 7
Table depicting jackknife analysis versus full data to understand potential outlier effects.
[DOCX File , 14 KB - periop_v5i1e37174_app7.docx]

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Abbreviations

AUC: area under the curve
MPOG: Multicenter Perioperative Outcomes Group

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Original Paper

Definition and Classification of Postoperative Complications After Cardiac Surgery: Pilot Delphi Study

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Abstract

Background: Postoperative complications following cardiac surgery are common and represent a serious burden to health services and society. However, there is a lack of consensus among experts on what events should be considered as a “complication” and how to assess their severity.

Objective: This study aimed to consult domain experts to pilot the development of a definition and classification system for complications following cardiac surgery with the goal to allow the progression of standardized clinical processes and systems in cardiac surgery.

Methods: We conducted a Delphi study, which is a well-established method to reach expert consensus on complex topics. We sent 2 rounds of surveys to domain experts, including cardiac surgeons and anesthetists, to define and classify postoperative complications following cardiac surgery. The responses to open-ended questions were analyzed using a thematic analysis framework.

Results: In total, 71 and 37 experts’ opinions were included in the analysis in Round 1 and Round 2 of the study, respectively. Cardiac anesthetists and cardiac critical care specialists took part in the study. Cardiac surgeons did not participate. Experts agreed that a classification for postoperative complications for cardiac surgery is useful, and consensus was reached for the generic definition of a postoperative complication in cardiac surgery. Consensus was also reached on classification of complications according to the following 4 levels: “Mild,” “Moderate,” “Severe,” and “Death.” Consensus was also reached on definitions for “Mild” and “Severe” categories of complications.

Conclusions: Domain experts agreed on the definition and classification of complications in cardiac surgery for “Mild” and “Severe” complications. The standardization of complication identification, recording, and reporting in cardiac surgery should help the development of quality benchmarks, clinical audit, care quality assessment, resource planning, risk management, communication, and research.

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KEYWORDS

Delphi study; cardiac surgery; postoperative complications; morbidity; postoperative; cardiology; postoperative; surgery; complications; cardiac; health services; society; pilot; development; system; surgeons; anesthetists; clinical; quality; resources; risk management; communication; research

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Introduction

The use of risk prediction tools in cardiac surgery is predominantly focused on the risk of mortality [1]. In the United Kingdom, the mortality rates after all cardiac surgery are some of the lowest in the world despite increasing age, risk profile, and frailty of patients [2]. Complications after surgery, however, are common [3,4] and, depending on severity, can have a debilitating impact on patients' quality of life [5], increase hospital length of stay [6], and hence increase health care costs [7,8]. It is therefore essential that efforts should be "directed to further reducing morbidity and length of stay" [2] and that adequate systems are developed to better predict, anticipate, plan, and mitigate the risks for severe surgical complications. Although efforts are made to preempt postoperative complications in cardiac surgery using various technologies [9-11], the lack of a consensual and standard definition and classification of postoperative complications in cardiac surgery, however, acts as an important barrier to developing adequate monitoring and reporting systems for cardiac surgery complications [12].

This pilot study aimed to address this issue by using the Delphi method [13] to answer the following research questions:

1. What are domain experts' opinions on the usefulness of a definition and classification of surgical complications following cardiac surgery?
2. How do domain experts define what events constitute surgical complications following cardiac surgery?
3. How do domain experts classify surgical complications following cardiac surgery?

Methods

Ethical Statement

This study (Health Research Authority REC18/YH/0366) was approved by the University of Strathclyde Department of Computer and Information Sciences Ethics Committee (ID 837).

The Delphi Method

The Delphi method is a well-established expert consultation method building on the premise that group opinion is more valid and reliable than individual opinion that can be heavily influenced by cognitive bias [13]. The Delphi method uses a multistaged survey system that can be used to reach expert consensus on complex topics and loosely defined concepts and to conduct forecasting or horizon scanning [14].

The original Delphi method, also known as the Classical Delphi, consists of 2 or more rounds of questionnaires administrated by mail to an expert panel. Round 1 focuses on the experts' opinions in an open-ended manner. After analyzing Round 1, Round 2 asks the experts to rank the statements or questions according to the opinions stated in the previous round. Rounds continue until consensus is reached on some or all questions. [13] This study used the e-Delphi method, which is a similar process to the Classical Delphi but administered as an online web survey [13]. The overall study process is outlined in Figure 1.

To guarantee experts' anonymity in the study, the experts remained anonymous in both rounds, meaning the participants' responses in Round 1 and Round 2 were not linked. This decision was done due to choosing the "all-rounds" approach, in which potential participants are invited to take part in subsequent rounds regardless of whether they participated in the previous rounds. It has been shown that this approach can improve representation of opinions and can reduce the chances of false consensus. [15]

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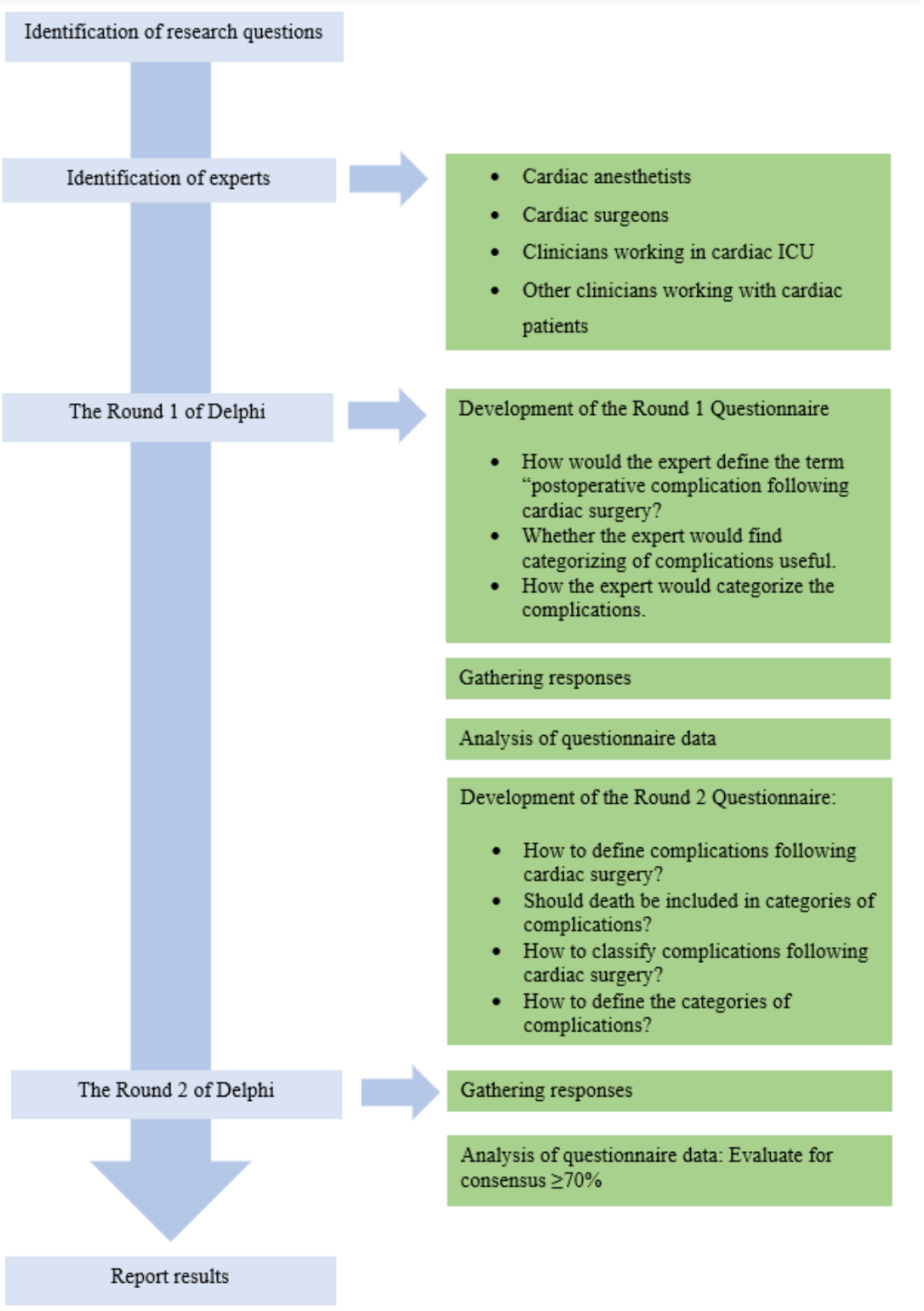
Figure 1. Delphi study process. ICU: intensive care unit.



Identification of Experts

Cardiac surgery experts were identified as follows: cardiac anesthetists, cardiac surgeons, and anesthetists specializing in working with cardiac patients perioperatively or in intensive care. Since this was a pilot study to develop a definition and classification for postoperative complications in cardiac surgery, mailing lists of the following professional associations were used to invite prospective participants to the Delphi study: *Association for Cardiothoracic Anaesthesia and Critical Care*, *European Association of Cardiothoracic Anaesthesiology and Intensive Care*, *The Society for Cardiothoracic Surgery*, and *The UK Society for Computing and Technology in Anaesthesia*. Through these avenues, the invitation was sent to thousands of potentially eligible participants depending on the number of members in each society. In addition to these methods, cardiac anesthetists and cardiac surgeons in 3 Scottish cardiac centers were contacted directly via email: Golden Jubilee National

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Hospital, Royal Infirmary of Edinburgh, and Aberdeen Royal Infirmary (64 potential participants, 27 of them cardiac surgeons and 37 of them cardiac anesthetists).

Methods of Analysis

The survey questionnaires were provided in English, and the data from the questionnaires were exported from Qualtrics [16] and stored in a Microsoft Excel spreadsheet. R version 4.1.1. [17] and NVivo version 12 [18] were used for quantitative and qualitative analyses, respectively.

Consensus

The consensus level was determined to be 70%, similar to other related studies in health research [19-21]. Descriptive statistics were used to analyze the experts' opinions, using frequencies of responses for questions that were not open-ended. If the frequency was 70% or higher, the experts were deemed to have reached consensus on this particular response.

All responses were considered in the analysis; however, consensus was calculated based on how many experts answered each question. Partially filled responses were also included, as other published studies have done in the past [22,23].

The strategy for an event of nonconsensus was to critically evaluate and discuss the respondents' answers and to revise the questions in the subsequent rounds.

Qualitative Analysis

Round 1 of the study largely included open-ended questions to determine a variety of ways the experts would choose to define and categorize complications following cardiac surgery. The thematic analysis framework [24] was used to analyze the responses to the open-ended questions, and the results were included as options for responses in the subsequent round of the study as in the Delphi method [25].

A sample of the data was coded separately by 3 researchers to ensure coding coherence and consistency. Once coding consistency was established through the initial sample coding, data coding was conducted by 1 researcher (LL). Coding consistency and thematic analysis were subsequently discussed, and conflicts were resolved at regular meetings of the study investigative team, which includes substantial expertise in mixed methods and qualitative research (MMB).

Following the guidance of Hasson et al [25], statements that were identified as identical or similar were grouped as common concepts. Once specific themes were created, the statements within a thematic group were synthesized into a single summary statement after discussion between the study investigators. The wording was kept as close as possible to the statements that had been provided by the experts. Any unique statement provided by the experts with no related statement was kept as worded originally and included directly in Round 2.

Results

Delphi Study Round 1

For Round 1, the questionnaire was designed to explore the experts' general opinions regarding the definition of "postoperative complication following cardiac surgery" and categorizing postoperative complications.

The questionnaire (see Multimedia Appendix 1) started with a filter question to make sure that only eligible experts would be included in the study: "Are you in any way involved with cardiac surgery patients? (Can be preoperatively, intra-operatively and/or postoperatively)." If the answer to the question was "no," the participant was directed to the end of the survey.

The questionnaire consisted of 3 parts: (1) the background of the expert; (2) how the expert would define the term "postoperative complication following cardiac surgery"; and (3) whether the expert would find categorizing of complications useful, and, if yes, how the expert would categorize the complications.

The data in this study were collected through online questionnaires via Qualtrics [16]. The Round 1 questionnaire was sent out twice to professional societies and to other potential experts between August 27, 2019, and September 24, 2019. In total, the Round 1 questionnaire was open for 6 weeks and closed on October 8, 2019.

Expert Demographics

Overall, 71 experts were eligible to take part in Round 1 of the study based on being involved with a cardiac surgery patient pathway. The majority (67/71, 94%) of the respondents were based in the United Kingdom, 2 (2/71, 3%) were from Saudi Arabia, 1 (1/71, 1%) was from Australia, and 1 (1/71, 1%) was from Bahrain.

Most of the respondents (45/71, 63%) specialized in both cardiac anesthesia and cardiac critical care, 23 (23/71, 32%) specialized in cardiac anesthesia only, and 3 (3/71, 4%) specialized in cardiac critical care only. It is important to note that none of the participants stated that they were cardiac surgeons. This is further discussed in the *Limitations* section. In terms of experience, the mean number of years worked in the specialty was 16.63 (SD 8.70) years, and the median number of years was 16 (IQR 12.5) years.

Most of the participating experts were involved with the surgery itself (67/71, 94%), decision making (eg, if patient is fit for surgery; 64/71, 90%), preoperative assessment (63/71, 89%), and cardiac intensive care unit (63/71, 89%). Some respondents also were involved with long-term follow-up of the patient (8/71, 11%) and in other ways (7/71, 10%), such as acute and chronic pain management and perioperative echocardiography.

Defining the Term "Postoperative Complication"

Comments were received from 50 experts on how they would define the term "Postoperative Complication" in cardiac surgery. The definitions emerging from Round 1 of the study were then used in the Round 2 questionnaire to reach consensus on a single definition.

All proposed definitions focused on different impacts of complications on the patient, institution, and surgery itself (eg, delayed recovery, impact on patient's quality of life, and hospital length of stay). Hence, for simpler analysis, these statements were analyzed thematically [24] and categorized under themes

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based on the definitions that the experts offered. For example, the concept of "An unplanned adverse event occurring after cardiac surgery that may be caused or compounded by the surgical process" included statements such as "The event can be unplanned," "The event must be harmful or unfavorable," "The complication must be present following cardiac surgery, specifically," and "The event must occur after surgery and is unlikely to occur if the patient did not have the surgery." These common themes were then grouped and synthesized under common characteristics of the complications such as "unplanned," "adverse event," "cardiac surgery," and "surgery." All characteristics and themes can be found in Table 1.

Table 1. How experts voted for each characteristic that defines the term "complication after cardiac surgery" (N=38).

Theme	Complication characteristic	Results, n (%)
The event can have an impact on patient's survival or quality of life and longevity.	Affects quality of life	35 (92)
The complication must be present following cardiac surgery, specifically.	Following cardiac surgery, specifically	33 (87)
The event must occur after surgery and is unlikely to occur if the patient did not have the surgery.	Due to surgical process	33 (87)
The event must be harmful or unfavorable.	Adverse event	28 (74)
The event can have an impact on hospital length of stay.	Delay in hospital discharge	28 (74)
Due to the event, the patient might have to stay in the hospital for longer and can adversely affect rapid recovery to good health.	Delay in recovery	28 (74)
The event can be expected but unplanned.	Unplanned	27 (71)
The event can be unexpected.	Unexpected	23 (61)

The responses for each definition were then mapped onto each characteristic to find what the experts deemed important to define what constitutes a postoperative complication following cardiac surgery, which could then be used for conducting Round 2 of the Delphi study.

Usefulness of Classifying Postoperative Complications

Responses to the question as to whether they thought it is useful to define and classify postoperative complications for cardiac surgery were provided by 51 experts. Of these 51 experts (Table 2), 23 (45%) thought it was "Extremely useful," and 20 (39%) thought it is "Very useful." Combining these percentages, based on the predetermined consensus level of 70%, it can be concluded that the experts have reached the consensus that it is very useful to classify postoperative complications for cardiac surgery, with a consensus level of 84%.

Table 2. Experts' opinions on the usefulness of classifying postoperative complications following cardiac surgery (N=51).

Usefulness	Results, n (%)
Extremely useful	23 (45)
Very useful	20 (39)
Moderately useful	5 (10)
Slightly useful	2 (4)
Not at all useful	1 (2)

The experts provided various reasons why they thought it is useful to classify postoperative complications for cardiac surgery, which included improving audit and quality measurement, helping with planning and management, risk management and communications, and helping to improve research in the field. Some of the participants responded in the following ways when asked to explain why defining and classifying complications is useful:

> *Classification may help to understand causative factors and allocation of resources in prevention.* [Expert R1.P56]

> *This [classification of complications] could then be used to good effect in discussions with patients and families as they would gain consistent information from various members of the multi-disciplinary team.* [Expert R1.P13]

> *Categorising complications would be useful] to facilitate [...] research and to target therapies appropriately to prevent or decrease incidence.* [Expert R1.P61]

Categories of Postoperative Complications

Overall, 48 experts stated how many categories postoperative complications should have. Most of the respondents wanted 3 to 5 grades to categorize complications: Of the 48 respondents, 16 (33%) voted for 3 grades, 12 (25%) voted for 4 grades, and 14 (29%) voted for 5 grades. Some (26/48, 54%) also named the categories they offered, and it became clear that respondents offered the following variations as a common answer:

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Mild/Moderate/ Severe

None/Mild/Moderate/Severe

Mild/Moderate/Severe/Death

None/Mild/Moderate/Severe/Death

All 26 experts who provided categories included mild/moderate/severe as the category combination. This means that consensus was reached that the categories for postoperative complications for cardiac surgery will be classified as "Mild," "Moderate," and "Severe." Since many respondents offered "Death" as a separate class, the experts were asked to decide whether to add that to the categories in Round 2 of the study. Since no complication would be categorized as "None," this was not added to the categories.

Defining the Categories of Postoperative Complications

Experts also provided possible definitions for each category that they proposed. To analyze the suggested definitions, the thematic analysis, explained in detail in the *Qualitative Analysis* section, focused on characteristics that each complication category could have. Like in the *Defining the Term "Postoperative Complication"* section, the characteristics provided by experts for each category of complications were collated so that similar characteristics were merged into one, and unique characteristics were left in their initial form [14]. The final list of characteristics proposed by the experts was as follows: effect on overall length of stay in hospital, effect on final outcome, length of the complication, clinical relevance, impact on the patient, occurrence of the complication, therapeutic intervention required, and impact on the institution

These factors were then related to a level of complication. For example, the question "What is the effect on overall length of stay in hospital?" was converted into "No consequential effect on overall length of stay" for the Mild level of complication, "Some effect on overall length of stay" for the Moderate level of complication, and "Extended length of stay" for the Severe level of complication. These statements were then used in Round 2 of the Delphi study so experts could vote on which characteristics were most important to define each complication category.

Delphi Study Round 2

Development of the Questionnaire

The Round 2 survey (see Multimedia Appendix 2) of the Delphi study was sent to the same societies and contact list from the Scottish cardiac centers as described in the *Identification of Experts* section. To take part in Round 2, the experts were not required to have taken part in Round 1 of the study, as per the "all rounds" approach [15]. Just like in Round 1, the experts had to answer the filter question to make sure they were eligible to participate.

The aims of Round 2 of the study were to reach consensus regarding the following:

1. How do the experts define what constitutes a "postoperative complication following cardiac surgery" based on the responses from Round 1 of the study?
2. Should death be included in the categories of complications?
3. How do experts define each category of complications based on the characteristics collated from Round 1 of the study?

The choices for answers for the questions were collated based on the results of Round 1 of the study. Just like in Round 1, descriptive statistics were used to analyze the opinions of experts, using frequencies of responses for questions that were not open-ended. If the frequency of a response was 70% or higher, the experts were deemed to have reached consensus on this particular response.

Round 2 of the questionnaires were sent on June 2, 2020, and a reminder was sent on June 16, 2020. The survey was open for 4 weeks (closed on June 30, 2020).

Overall, 46 experts took part in the survey, and 37 of them finished the survey. As done in the previous round, we also included responses from participants who partially completed the survey in this round.

Experts' Definition of What Constitutes "Postoperative Complications Following Cardiac Surgery"

Experts voted for each characteristic (see the *Defining the Term "Postoperative Complication"* section) to define what constitutes a complication after cardiac surgery. Consensus was reached that all characteristics (Table 1), apart from "Unexpected," should be included in the final definition.

Combining these characteristics into a sentence resulted in the following definition:

> *A complication following cardiac surgery is an unplanned adverse event that occurs following cardiac surgery that can cause delay in recovery, cause delay in hospital discharge, and affect patient's quality of life and is likely to happen due to the surgical process.*

Including "Death" in the Classification of Postoperative Complications

Of 37 experts, 31 (84%) thought that "Death" should be included in the classification of postoperative complications. As a result, consensus was reached that the complications should be categorized in 4 levels: "Mild," "Moderate," "Severe," and "Death."

Defining the "Mild," "Moderate," and "Severe" Complication Categories

Based on the proposed characteristics that were collated from experts' responses (described in the *Defining the Categories of Postoperative Complications* section), consensus was reached on definitions for "Mild" complications (Table 3). Hence, a complication following cardiac surgery is classified as "Mild" if the complication has the following characteristics: The complication has no consequential effect on the final patient outcome (28/37, 76%), and the complication has a minimal impact on the patient (27/37, 73%).

Similarly, as shown in Table 4, a complication following cardiac surgery is classified as "Severe" if the complication is potentially life-threatening (34/37, 92%), there is a consequential or long-standing impact on the patient (31/37, 84%), or a notable

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amount of intervention is required due to this complication (26/37, 70%).

The experts did not reach consensus on the definition for "Moderate" complications due to none of the characteristics receiving 70% or more of the votes (Table 5). However, one could argue that the definition of moderate is known, as it is neither mild nor severe. This is further discussed in the *Limitations* section.

Table 3. Characteristics of "Mild" complications (N=37).

Characteristic	Results, n (%)
Minimal impact on patient	28 (76)
No consequential effect on final outcome	27 (73)
No or only short-term clinical relevance	19 (51)
No or small amount of intervention required	19 (51)
No notable effect on overall length of stay	17 (46)
Mildly debilitating	7 (19)
Common	7 (19)
Minimal impact on institution	6 (16)
Lasting 1 week to 1 month	4 (11)

Table 4. The characteristics of "Severe" complications (N=37).

Characteristic	Results, n (%)
Potentially life-threatening	34 (92)
Consequential or long-standing impact on the patient	31 (84)
Notable amount of intervention required	26 (70)
Extended length of stay	25 (68)
With sustained relevance and life-limiting	25 (68)
Severely debilitating	21 (57)
Lasting 3 months to 1 year	7 (19)
Notable or long-standing impact on institution	5 (14)
Uncommon	2 (5)

Table 5. The characteristics of "Moderate" complications (N=37).

Characteristic	Results, n (%)
Some effect on overall length of stay	23 (62)
Acutely important but less clinical consequence long-term	22 (59)
Some intervention required	22 (59)
Some effect on final outcome	20 (54)
Moderately debilitating	19 (51)
Limited impact on patient	18 (49)
Lasting 1 month to 3 months	4 (11)
Less common	4 (11)
Limited impact on institution	4 (11)

Finally, to understand the experts' understanding of which specific complications could fall into the established complication categories, experts were also asked to provide examples for each proposed complication level, examples of which were hemodynamic instability as a "Mild" complication, atrial fibrillation as a "Moderate" complication, and acute renal failure as a "Severe" complication. A list of examples of complications and how they were categorized by experts can be found in Multimedia Appendix 3. However, since there is currently no single nomenclature for surgical complications, unlike for clinical diagnosis (ie, the International Statistical Classification of Diseases-10), the classifications can vary,

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especially in the "Moderate" group. Hence, the list of complications and their categories presented in Multimedia Appendix 3 should be interpreted with caution.

Discussion

Principal Findings

We present the results of a pilot Delphi study that aimed to define and categorize complications following cardiac surgery. The study reached a consensus on the following: It is useful to define and categorize complications following cardiac surgery, how the complications following cardiac surgery are defined, and how the complications following cardiac surgery are classified.

The experts justified the usefulness of defining and categorizing surgical complications following cardiac surgery by stating it could help with audit and quality control, planning and management, risk management and communication, and research.

Consensus was reached on the characteristics of postoperative complications, and hence the following definition was formed:

A complication following cardiac surgery is an unplanned adverse event that occurs following cardiac surgery that can cause delay in recovery, cause delay in hospital discharge, and affect patient's quality of life and is likely to happen due to the surgical process.

In the Clavien-Dindo classification system, complications were defined as "any deviation from the normal postoperative course," and conditions that are inherent to the procedure and are expected were termed to be "sequelae" [26]. However, the definition from this Delphi study provides a more precise explanation of a complication. Also, as the Clavien-Dindo definition was created for general surgery, the definition presented in this study makes an important point that the Clavien-Dindo definition does not: A complication following cardiac surgery is an event that is unlikely to happen without surgery, specifically in our case, cardiac surgery. When it comes to the definition of "sequelae," it can be argued that some adverse events following surgery can be expected, especially with existing and emerging preoperative prediction models. With improved data collection in electronic health records, more models predicting complications following surgery can be developed, meaning that many complications can be predicted and monitored on a real-time basis. Various studies have been published to predict fluid requirement [27], septic complications [28], hypotensive episodes [29], and clinical deterioration in general [30].

This study achieved consensus on how to categorize complications following cardiac surgery and how the categories are defined. It was agreed that the categories should be "Mild," "Moderate," "Severe," and "Death." According to the experts, a "Mild" complication is a complication that has no consequential effect on the final patient outcome and has minimal impact on the patient. The experts agreed that a "Severe" complication is a complication that is potentially life-threatening, requires a notable amount of intervention, and has a consequential or long-standing impact on the patient.

Limitations

Study Sample

In Round 1 and Round 2 of the study, 51 and 37 experts completed the study, respectively. According to publications discussing the Delphi method, both rounds of the study had a sufficiently large sample size, as it does not depend on statistical power but rather on group dynamics for coming to consensus among experts. Hence, an expert panel usually consists of 10 to 30 experts [31]. Furthermore, since this was an e-Delphi study, it can be expected that the experts were not influenced by one another, as the respondents did not know what other respondents had said; therefore, the group dynamic came through each individual from analysis of experts' responses.

As seen from the results of the study, most experts were cardiac anesthetists and intensivists; however, no cardiac surgeons took part in the study. Historically, the decision as to whether a patient will be operated upon is primarily made by the surgeon. Understanding surgeons' views on defining and classifying complications in cardiac surgery would be useful. Hence, we have involved surgeons in an ongoing study regarding system requirements for a clinical decision support predicting complications. However, 90% of the participants in this study were involved with decision making, which is common with the creation of preassessment clinics, where decisions about patient care are made by multidisciplinary teams [32].

Although this is a pilot study that aimed to develop a classification system for complications in cardiac surgery, in future work, a more international panel of experts is needed to increase the impact of the classification system. Although experts within the European Association of Cardiothoracic Anaesthesiology and Intensive Care were invited, the majority of the professional societies were UK-based societies, which explains the lack of responses from international experts. Since the standards in cardiac surgery are common internationally [32], it is likely that results would be similar; however, the consensus would be more representative and more reliable to be put into practice. In addition, the societies were mostly related to cardiac anesthesia; only one (The Society for Cardiothoracic Surgery) was specific to cardiac surgeons. This explains why no cardiac surgeons took part in the study. However, it can be expected that, if surgeons took part in this study, the results would be similar due to growing interest in investigating postoperative outcomes other than mortality and an interest by both surgeons and anesthetists in improving patient outcomes beyond survival [33]. Hence, in our future study, cardiac centers will be contacted directly to allow for a more international panel, and more efforts will be directed toward recruiting more cardiac surgeons to participate.

Defining "Moderate" Complications

No consensus on the definition of "Moderate" complication was reached. Delphi studies do not always reach consensus on all aspects of the study [34]. Categorization decisions are often made based on the extreme categories rather than on the middle category [35]. This has been addressed with, for example, the

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American Society of Anesthesiologists (ASA) Classification [36], in which there is no “moderate” category. Historically, there have been concerns about the subjectivity of the ASA status [37], and the same problem can occur with our complication classification. To categorize complications appropriately, actions and consequences of each category need to be considered. With a “Mild” complication, some medicines might have to be administered, for example for urinary retention, but in general, no notable action that requires time and resources is needed. With a “Severe” complication, whether it is kidney failure or a stroke, dialysis or thrombectomy, respectively, might be needed. Both interventions are time-consuming and resource-intensive. When it comes to the moderate category, however, it is uncertain whether it is more on the “Mild” or “Severe” side. On one hand, it is generally unclear regarding what action needs to be taken; on the other hand, it provides the users with a spectrum of categories and therefore the possibility to offer more nuance to the problem. As shown by Mayhew et al [37], for the ASA physical status classification, providing example cases for each classification improved objectivity and reduced variability in classification. Hence, we also asked experts to provide examples for each category. However, further work is needed to provide examples; hence, it important to keep in mind that for personalized use, each complication, regardless of which category it falls into, needs an individual treatment approach, depending on the patient’s current state and medical history.

Conclusion

Using the Delphi method, this pilot study shows cardiac anesthetists’ and cardiac intensivists’ requirements for a standardized definition and classification of postoperative complications in cardiac surgery. Standardization of complication identification, recording, and reporting in cardiac surgery could help the development of future quality benchmarks, clinical audits, care quality assessment, resource planning, risk management, performance comparisons or communication, and research.

Acknowledgments

We would like to thank the professional societies mentioned in the *Identification of Experts* section for distributing our surveys to potential participants and the experts who participated in this study. We would also like to thank Diane Morrow and Ramsay Meiklem for assisting with coding for thematic analysis.

Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Delphi study Round 1 questionnaire.
[DOCX File , 17 KB - periop_v5i1e39907_app1.docx]

Multimedia Appendix 2
Delphi study Round 2 questionnaire.
[DOCX File , 16 KB - periop_v5i1e39907_app2.docx]

Multimedia Appendix 3
Examples of postoperative complications and their proposed classifications as "Mild," "Moderate," or "Severe.".
[DOCX File , 18 KB - periop_v5i1e39907_app3.docx]

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Abbreviations

ASA: American Society of Anesthesiologists

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Original Paper

The Use of Machine Learning to Reduce Overtreatment of the Axilla in Breast Cancer: Retrospective Cohort Study

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Abstract

Background: Patients with early breast cancer undergoing primary surgery, who have low axillary nodal burden, can safely forego axillary node clearance (ANC). However, routine use of axillary ultrasound (AUS) leads to 43% of patients in this group having ANC unnecessarily, following a positive AUS. The intersection of machine learning with medicine can provide innovative ways to understand specific risks within large patient data sets, but this has not yet been trialed in the arena of axillary node management in breast cancer.

Objective: The objective of this study was to assess if machine learning techniques could be used to improve preoperative identification of patients with low and high axillary metastatic burden.

Methods: A single-center retrospective analysis was performed on patients with breast cancer who had a preoperative AUS, and the specificity and sensitivity of AUS were calculated. Standard statistical methods and machine learning methods, including artificial neural network, naive Bayes, support vector machine, and random forest, were applied to the data to see if they could improve the accuracy of preoperative AUS to better discern high and low axillary burden.

Results: The study included 459 patients; 142 (31%) had a positive AUS; among this group, 88 (62%) had 2 or fewer macrometastatic nodes at ANC. Logistic regression outperformed AUS (specificity 0.950 vs 0.809). Of all the methods, the artificial neural network had the highest accuracy (0.919). Interestingly, AUS had the highest sensitivity of all methods (0.777), underlining its utility in this setting.

Conclusions: We demonstrated that machine learning improves identification of the important subgroup of patients with no palpable axillary disease, positive ultrasound, and more than 2 metastatically involved nodes. A negative ultrasound in patients with no palpable lymphadenopathy is highly indicative of low axillary burden, and it is unclear whether sentinel node biopsy adds value in this situation. Further studies with larger patient numbers focusing on specific breast cancer subgroups are required to refine these techniques in this setting.

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KEYWORDS

breast cancer; preoperative screening; machine learning; artificial intelligence; artificial neural network; breast; cancer; axillary node; metastasis; metastatic; preoperative; axillary clearance; metastases; oncology

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Introduction

The contemporary management of the axilla in breast cancer aims to reduce unnecessary intervention while providing optimal oncological safety. Historically, given the well-recognized importance of axillary node status on breast cancer prognosis [1], any patient with axillary disease underwent a complete axillary node clearance (ANC). Several key trials have since reduced the indications for ANC, including evidence that isolated tumor cells [2] and micrometastases [3] were clinically insignificant as well as results of the ACOSOG Z11 trial [4], which demonstrated that in patients with T1-2 breast cancer who had no clinically palpable axillary nodes, with 2 or fewer positive macrometastatically involved axillary nodes at sentinel node biopsy (SNB), no further axillary treatment was necessary. More patients are consequently able to forego ANC, a large surgical procedure with significant morbidity [5], without inferior oncological survival outcomes. The accurate identification of this group of patients is therefore crucially important to ensure they do not receive unnecessary surgical treatment of the axilla.

Axillary ultrasound (AUS) is used nearly ubiquitously in UK breast oncology centers to assess the axilla preoperatively in breast cancer. Typically, a suspicious node viewed on AUS may be biopsied and can be clipped to aid intraoperative identification [6]. When patients are 'fast-tracked' to ANC on the basis of a positive AUS, up to 43% of these may have 2 or fewer involved nodes [7] and are thus overtreated. Since AUS was not used in the ACOSOG Z11 trial, this discrepancy remains, and the bypassing of SNB prevents identification of patients who could have safely avoided ANC.

Artificial neural networks are a form of supervised machine learning based on the simplest computational model of a neuron—the 'perceptron.' Connections between nodes in consequent layers of a network are weighted probabilistically; following input at the first layer with information about variables describing an item in a data set, which is prelabelled (eg, as 'dog' or 'cat'), the network attempts to correctly categorize the label of the item. This process is repeated on the training set of data while the model updates weights of connections between each iteration to minimize the error of its categorization. Once optimized, it can be deployed on the test set to verify its accuracy.

The aim of this study was to undertake a retrospective pilot study to deploy machine learning methods (ie, artificial neural networks) and traditional statistical models (ie, linear regression) to aid identification of patients with no clinically palpable nodes and a positive preoperative AUS who have low axillary nodal burden. The rational for this is that better identification of this subgroup of patients can reduce the number of patients who undergo unnecessary ANC on the basis of a preoperative positive AUS, which turns out to be clinically insignificant.

Methods

Ethics Approval

The study was registered as a clinical audit with the ethics committee of Guy's Hospital, London, United Kingdom and was approved in February 2019 (institutional reference number 7608).

Data Collection

The first part of this study was to analyze retrospectively the use of preoperative AUS in patients with breast cancer at our tertiary care center. Women with confirmed breast cancer treated at Guy's Hospital, London, United Kingdom, who had an AUS preoperatively between 2012 and 2014 were retrospectively identified from a departmental database. The results of the AUS and the patients' sex; age; date of birth; primary tumor size, grade, and type; as well as receptor phenotype were recorded alongside the results of any axillary surgical intervention and breast surgery. Lymph nodes were evaluated with ultrasound using the following criteria for reporting an abnormal node: diffuse or focal cortical enlargement, loss of lymph node fatty hilum, and enlarged nodal size [8]. All data were fully anonymized.

The second part of this study was to use machine learning and statistical methods to try and improve identification of patients with high or low axillary burden. High burden in patients was defined as more than 2 macrometastatic axillary nodes. Low burden was defined as 0, 1, or 2 macrometastatic nodes or isolated tumor cells or micrometastases in patients.

Both types of models were given the following patient characteristics to predict nodal burden: patient age, estrogen receptor and HER2 status, tumor grade, presence of associated ductal carcinoma in-situ, tumor type (eg, invasive ductal carcinoma and invasive lobular carcinoma), tumor size, presence of lymphovascular invasion, and the result of a preoperative AUS.

Machine Learning Methods

After collection and deidentification of data, the data set was preprocessed using pandas [9], matplotlib [10], and scikit [11], which are open-source data analysis and manipulation tools built in the Python programming language. A total of 70% of the data was randomly selected to form the training set, on which predictive models were developed, with the other 30% designated as the test set. The resultant nodal burden of each patient was labelled as 1 or 0 to indicate low and high nodal burden respectively, and this feature was designated as the label to be predicted by the model. Categorical variables were one-hot encoded, and numerical variables were scaled to between 0 and 1 using the MinMaxScaler function. TensorFlow [12] and Keras were used to design the artificial neural network (ANN). A dense, feed-forward ANN with 3 layers of 11, 6, and 1 neuron, respectively, was constructed with backpropagation optimized using Adam [13]. Support vector machine, random forest, and naive Bayes classifier methods were also used for comparison with the ANN.

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Statistical Methods

Logistic regression is a well-known and widely used technique for predicting binary variables and carrying out discriminant analysis when the predictor variables are not all normally distributed [14]. It was used for classification here by choosing the predicted group as the group with the larger predicted probability of membership.

Logistic regression is a standard methodology, and the only nontrivial problem was estimation of the sensitivity and specificity. These would have been overestimated if computed in-sample from fitted data. We therefore used a computationally feasible method for out-of-sample estimation—k-fold cross-validation; this is a better use of data compared to estimating sensitivity on a hold-out sample.

The model was fitted k times, leaving out each 'fold' in turn, and predictions were then made for that fold using the fit to the other folds only. Folds were produced by shuffling high and low burden cases separately and then dividing the sample so that the percentage of high-burden cases was as equal between the folds as possible. We used 5 folds, which is usually taken as sufficient, and moving to 10 folds made very little difference.

The method is not Bayesian but can be made so using a 'vague prior.' Laplace's method of integration was used to obtain a Bayesian solution, and when this was done, the probability that a patient had low or high burden shifted slightly toward 1/2, by about 0.02, so the Bayesian methodology gave a slightly less certain prediction. However, the classification was unchanged, so the Bayesian refinement was not used.

Results

A total of 459 patients with breast cancer who had undergone a preoperative AUS before SNB or primary surgery with ANC were included. Patient characteristics are detailed in Table 1. All patients were women, with a mean age of 57.1 (SD 13.9) years. Mean tumor size was 28.3 (SD 24.05) mm, of which 319 (69.5%) were invasive ductal carcinoma, and 69 (15%) were invasive lobular carcinoma.

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Table 1. Patient characteristics. All patients were female.

Characteristics	All patients (N=459)	Low burden (≤2 nodes; n=392)	High burden (>2 nodes; n=67)
Age (years), mean (range, SD)	57.11 (28-88, 13.85)	57.48 (29-88, 13.80)	54.97 (28-86, 14.05)
Tumor size (mm), mean (range, SD)	28.29 (1.1-180, 24.05)	25.48 (1.1-180, 20.4)	44.99 (3-180, 35.1)
Tumor histology, n (%)			
Invasive ductal carcinoma	319 (69.5)	260 (66.3)	55 (82.1)
Invasive lobular carcinoma	69 (15)	56 (14.3)	8 (11.9)
Other invasive types	41 (8.9)	39 (10)	2 (3)
Isolated in situ disease	30 (6.5)	30 (7.7)	0 (0)
Tumor grade, n (%)			
1	48 (10.5)	45 (11.5)	3 (4.5)
2	204 (44.4)	177 (45.2)	27 (40.3)
3	176 (38.3)	139 (35.5)	37 (55.2)
Not specified	2 (0.4)	2 (0.5)	0 (0)
Invasive tumor with associated DCIS[a], n/N (%)[b]			
High grade	194/269 (72.1)	7/222 (3.2)	0/47 (0)
Intermediate grade	68/269 (25.3)	58/222 (26.1)	10/47 (21.3)
Low grade	7/269 (2.6)	157/222 (70.7)	37/47 (78.7)
Receptor phenotype, n (%)			
Luminal A	332 (72.3)	283 (72.2)	67 (71.6)
Luminal B	30 (6.5)	23 (5.9)	48 (10.5)
Triple negative	65 (14.2)	58 (14.8)	6 (9)
HER2	13 (2.8)	8 (2.2)	5 (7.5)
Not specified	19 (14.1)	20 (5.1)	1 (1.5)
Primary surgery, n (%)			
WLE[c]	257 (56)	210 (53.6)	25 (37.3)
Mastectomy	193 (42)	151 (38.5)	41 (61.2)
Lymphovascular invasion present	114 (24.8)	73 (18.6)	41 (61.2)

[a]DCIS: ductal carcinoma in situ.

[b]The total number of patients in this category was 269/459 (58.6%); the total number of patients with low burden (≤2 nodes) was 222 (56.6%); and the total number of patients with high burden (>2 nodes) was 47 (70.2%). All the other percentages under this category are calculated based on these denominators.

[c]WLE: wide local excision.

Accuracy of Preoperative AUS

The preoperative AUS was positive in 142 (31%), negative in 285 (62.09%), and inconclusive in 32 (6.97%) patients. Among patients with a positive ultrasound, 54 (38.03%) had more than 2 positive axillary nodes at ANC, and 88 (62%) had 2 or fewer nodes. Among patients with a negative ultrasound, 304 (95.9%) had 2 or fewer than 2 positive nodes at SNB (Table 2). In the subgroup of patients with a negative AUS and a tumor size of 20 mm or less, the number of patients with 2 or fewer positive nodes at SNB was 5 (2.78%). The sensitivity and specificity of ultrasound overall from these data was 0.809 (95% CI 0.715-0.902) and 0.777 (95% CI 0.736-0.818), respectively. The accuracy was 0.820 (95% CI 0.778-0.862).

Table 2. Axillary nodal burden of patients with positive and negative ultrasound.

Nodal burden	Ultrasound negative (N=317), n (%)	Ultrasound positive (N=142), n (%)
Two or fewer nodes	304 (95.9)	88 (62)
More than 2 nodes	13 (4.1)	54 (38)

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Application of Machine Learning and Statistical Models

All machine learning and statistical models applied to these data delivered improved specificity when compared to preoperative AUS (Table 3).

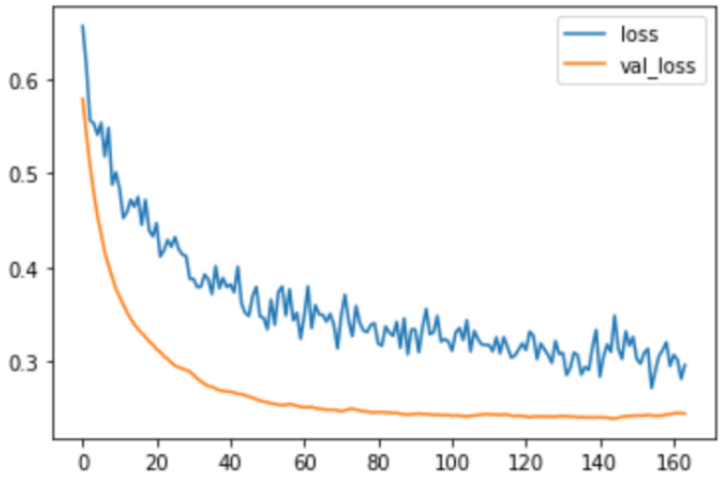
The best performing model was logistic regression, with a specificity of 0.950. This was achieved by sacrificing sensitivity, which was 0.462. If logistic regression had been used on this patient cohort, 66/459 (14.3%) patients who had a positive AUS and low axillary burden would have been identified as such and avoided unnecessary ANC; 20/459 (4.3%) patients would have been wrongly classified as having low burden, but these would then have undergone SNB as per current practice and likely been identified as having high burden at that point. The most important covariates identified by logistic regression were abnormal AUS, lymphovascular invasion, tumor size, as well as invasive ductal and invasive lobular carcinoma tumor types.

The ANN, support vector machine, naive Bayes, and random forest classifiers all outperformed preoperative ultrasound's specificity, but none were able to improve on its sensitivity (Table 3). The ANN was stopped early after 163 epochs of training (Figure 1), reaching a specificity of 0.9355 and a sensitivity of 0.7273. As such, the ANN had the highest accuracy (0.919) of all models, including logistic regression. When performing on the test set, the ANN correctly identified 21 of the 24 patients with a positive ultrasound and low burden.

Table 3. Comparison of preoperative ultrasound with logistic regression and machine learning models.

Method	Specificity	Sensitivity	Accuracy
Preoperative axillary ultrasound	0.809	0.777	0.820
Logistic regression	0.950	0.462	0.880
Naive Bayes	0.947	0.476	0.874
Artificial neural network	0.936	0.727	0.919
Support vector machine	0.934	0.615	0.904
Random forest	0.911	0.455	0.874

Figure 1. Training of the artificial neural network over 163 epochs.



Discussion

Principal Findings

Our results demonstrate that logistic regression and machine learning methods can be used effectively to reduce the number of patients undergoing ANC unnecessarily. As current practice leads to 43% of patients with early breast cancer, nonpalpable axillary nodes, and a positive ultrasound receiving such overtreatment, this is a valuable addition to the preoperative workup of breast cancer patients, and there are significant implications on clinical practice.

In this data set, logistic regression performed best. The particular success of logistic regression's high specificity came at a cost of poor sensitivity. However, this trade-off is favorable in the case of axillary staging because patients deemed as low risk will undergo SNB. Thus, the potential group of patients wrongly classified as having low burden by logistic regression will be identified and not left without treatment. For this reason, despite the ANN's accuracy outperforming the other models, logistic regression is the best model for the problem presented by the data. Indeed**,** a recent meta-analysis of clinical prediction models found that logistic regression tends to perform better than machine learning methods in this setting [15] as a predictor of disease in a data set of relatively low dimensions and size.

This study confirms that machine learning can be successfully deployed in the preoperative assessment of patients with breast cancer, despite not being able to outperform logistic regression's optimization of specificity for this task. The ANN developed the greatest overall accuracy, meaning it would have been the

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most useful tool if SNB following negative imaging was not standard of care. Larger and higher dimensional data sets will likely provide an arena in which machine learning can excel, particularly when considering its potential to combine image analysis techniques using convolutional neural networks and standard data in the form used in this study [16].

The fact that none of the models could improve on the sensitivity of AUS underlines the value of this imaging modality for helping rule out axillary disease in the clinically node negative breast cancer population. Evidence from a meta-analysis of 5139 patients showed that ultrasound's negative predictive value was 0.951 (95% CI 0.941-0.960) in this setting [17]. Despite this, patients with a negative ultrasound still undergo a SNB, and this may be considered surgical overtreatment in the same sense that ANC is used unnecessarily in the ultrasound positive group. This issue is currently being addressed in the SOUND randomized control trial [18]. Adaption of machine learning and statistical methods could be used on large data sets to help identify the approximately 4% of patients with no clinically palpable disease and a negative ultrasound but with more than 2 macrometastatically involved axillary nodes. This could lead to future selective use of SNB in this patient subgroup, analogous to the selective use of ANC, which is now common practice among patients with nodal burden identified on SNB.

There are several limitations to this study. They stem principally from the fact that this study is a proof-of-concept idea demonstrating the application of machine learning techniques in a breast surgery cohort, applied to a specific clinical and radiological problem within the general breast cancer patient population but not able to further delineate important risk differences between subgroups in this population. For example, it has not included several important patient factors and data points, which may prove important to refining models before implementation in a real-world scenario; examples of parameters that the authors would like to include in further models include menopausal status and lymph node biopsy pathology results. A further limitation of this study's applicability to clinical practice was that it did not consider patients undergoing primary systemic therapy, the indications for which have increased [19]. In this patient group, the use of ultrasound is less important as staging magnetic resonance imaging is often used alongside SNB to assess response to treatment. Another key limitation of this study was that our data set was relatively small; deployment of the same models on much larger sets of patient data would be necessary to further validate our results. Furthermore, with larger training sets, model performance may improve. This could allow for suture large studies on specific breast cancer patient subgroups, for example invasive lobular carcinoma. A further interesting future consideration will be to include particular aspects of ultrasound data, for example cortex to hilum ratios when computing predictive models, or to combine data predictive methods with computer vision techniques looking directly at the ultrasound images obtained from each patient.

Conclusions

AUS's poor specificity renders it ineffective to reliably identify patients with a clinically negative axilla and significant nodal burden (ie, more than 2 macrometastatic nodes), despite it being attractive as a noninvasive and widely available tool. The addition of logistic regression and machine learning methods can provide valuable predictions based on patient characteristics and the AUS result, which can greatly reduce the surgical overtreatment of the axilla and significantly improve the accuracy of identification of high nodal burden among patients with no clinically palpable disease. This two-part improvement in preoperative axillary staging is highly desirable and has the potential to spare many patients unnecessary axillary surgery; however, given the heterogenous nature of the patient population in this study, further refinement of the models with international multicenter trials are warranted to confirm the results.

Conflicts of Interest

None declared.

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Abbreviations

ANC: axillary node clearance
ANN: artificial neural network
AUS: axillary ultrasound
SNB: sentinel node biopsy

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Original Paper

Experiences of Health Care Professionals Working Extra Weekends to Reduce COVID-19–Related Surgical Backlog: Cross-sectional Study

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Abstract

Background: During the quiescent periods of the COVID-19 pandemic in 2020, we implemented a weekend-scheduled pediatric surgery program to reduce COVID-19–related backlogs. Over 100 staff members from anesthesiologists to nurses, surgeons, and administrative and supporting personnel signed up to work extra weekends as part of a novel weekend elective pediatric surgery program to reduce COVID-19–related backlog: *Operating Room Ramp-Up After COVID-19 Lockdown Ends-Extra Lists* (ORRACLE-Xtra).

Objective: In this study, we sought to evaluate staff perceptions and their level of satisfaction and experiences with working extra scheduled weekend elective surgical cases at the end of the 3-month pilot phase of ORRACLE-Xtra and identify key factors for participation.

Methods: Following the pilot of ORRACLE-Xtra, all perioperative staff who worked at least 1 weekend list were invited to complete an online survey that was developed and tested prior to distribution. The survey collected information on the impact of working weekends on well-being, overall satisfaction, and likelihood of and preferences for working future weekend lists. Logistic regression was used to estimate the association of well-being with satisfaction and willingness to work future weekend lists.

Results: A total of 82 out of 118 eligible staff responded to the survey for a response rate of 69%. Staff worked a median of 2 weekend lists (IQR 1-9). Of 82 staff members, 65 (79%) were satisfied or very satisfied with working the extra weekend elective lists, with surgeons and surgical trainees reporting the highest levels of satisfaction. Most respondents (72/82, 88%) would continue working weekend lists. A sense of accomplishment was associated with satisfaction with working on the weekend (odds ratio [OR] 19.97, 95% CI 1.79-222.63; *P*=.02) and willingness to participate in future weekend lists (OR 17.74, 95% CI 1.50-200.70; *P*=.02). Many (56/82, 68%) were willing to work weekend lists that included longer, more complex cases, which was associated with a sense of community (OR 0.12, 95% CI 0.02-0.63; *P*=.01).

Conclusions: Staff participating in the first 3 months of the ORRACLE-Xtra program reported satisfaction with working weekends and a willingness to continue with the program, including doing longer, more complex cases. Institutions planning on implementing COVID-19 surgical backlog work may benefit from gathering key information from their staff.

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KEYWORDS

staff; wait-list; surgery; health care delivery; patient safety; quality improvement; patient satisfaction; COVID-19; practice redesign; burnout; preoperative; pediatric; perioperative; surgery; surgical staff; surgeon; healthcare; health care; staff perception;

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workforce; stress; work; occupational health; occupational safety; perception; workload; nurse; nursing; anesthesiologist; health care provider; health care professional; cross-sectional; online survey

Introduction

The COVID-19 pandemic has had a significant impact on health care delivery. Several jurisdictions canceled nonurgent surgeries repeatedly as each wave imposed pressure on the health care infrastructure [1-6]. Surgical wait-lists increased due to the cancelations, causing further delays to accessing surgical care [4,6-11]. In children, the timing of surgery can affect growth, development, and long-term outcomes [12,13]. Various models of increasing operating room throughput have been proposed to manage the COVID-19–related backlogs [8,14-18]. These include the triage of surgical patients for acuity and disease progression, longer operating hours during weekdays, addition of weekend surgical lists, or a combination of these [3,7,8,15,16,19,20].

During the quiescent periods of the pandemic between January and April 2021, our institution implemented a novel program to mitigate the rapid increase in the surgical wait-list: *Operating Room Ramp-Up After COVID-19 Lockdown Ends-Extra Lists* (ORRACLE-Xtra). The ORRACLE-Xtra program scheduled weekend elective surgery lists of high-volume, low-acuity daycare procedures to reduce COVID-19–related backlog at our tertiary pediatric hospital [7]. Having not historically scheduled elective surgery on weekends, these weekend lists were in addition to the planned weekday activity. The program hinged on staff volunteering for extra shifts, and they were encouraged to request lists of interest or those that worked with their personal schedules. As this program launched during the peak of the second wave, it was possible that participation in ORRACLE-Xtra would have a negative impact on staff due to the increased workload. To our knowledge, the impact of COVID-19 surgical backlog recovery work on staff has not been previously reported, particularly work performed during the pandemic. This information would be useful in the planning of COVID-19 surgical recovery activities, which depend greatly on human resources.

Our aims for this cross-sectional survey study were to (1) determine staff perceptions of, experiences with, and level of satisfaction with working extra scheduled weekend elective surgical lists in the 3-month pilot phase of ORRACLE-Xtra; (2) assess the likelihood of staff continuing to support our weekend program; and (3) identify factors that will maximize engagement in the weekend elective surgery program in the longer term.

Methods

Study Design and Participants

The study setting was the perioperative department at The Hospital for Sick Children in Toronto, ON, an academic pediatric hospital that serves children aged 0 to 18 years. We surveyed all perioperative staff who participated in the pilot phase of ORRACLE-Xtra. Based on a total of 118 eligible staff, we needed a minimum of 95 respondents to achieve a margin of error of 5% with a 95% CI. We followed the Consensus-Based Checklist for Reporting of Survey Studies (CROSS) guidelines for reporting surveys [21].

Staff received an email invitation to complete the online survey at the end of the 3-month pilot phase, with a reminder sent one week later. The survey remained open during April 2021. All responses were anonymous, and consent was implied by participation in the survey.

Questionnaire

The ORRACLE-Xtra steering committee, which comprised representatives from staff groups and included nursing (preoperative, intraoperative, and postoperative), administrative support, technical support, and physicians (anesthesiologists and surgeons), developed the questionnaire. The survey collected information on overall satisfaction with working weekend elective lists, impact of working weekends on aspects of well-being (job satisfaction; sense of achievement, accomplishment, and community; burnout; career development possibilities; and increased workload), and likelihood of and preferences for working future weekend lists (Multimedia Appendix 1).

The survey included 12 questions. Questions 1 to 3 included information regarding each respondent's role, department, surgical specialty lists they had worked on, and number of lists worked. Questions 5 to 12 ascertained the level of satisfaction with weekend lists, perceptions on well-being, and the respondents' preferences for future weekend lists.

We tested the questionnaire according to previously published guidelines and methodology [21-25]. The process included internal piloting for clarity, flow, and timing using a convenience sample of 3 members of the ORRACLE-Xtra steering committee. No significant changes were needed following their feedback.

Statistical Analysis

Survey responses were collected and managed using REDCap (Vanderbilt University), a secure online electronic data capture tool [26,27]. Data were summarized as frequencies or percentages for categorical variables. Univariate analyses were conducted to explore the association between covariates and outcome variables to identify the covariates to include in the final multivariable models. Logistic regression was used to evaluate the association of well-being with satisfaction with working weekend elective lists and willingness to work future weekend lists or future weekend lists with longer or more complex operative cases, adjusting for confounders and interactions. We dichotomized satisfaction with working on weekend elective lists as "yes" if respondents were "very satisfied" or "satisfied" (vs "neither satisfied nor dissatisfied," "dissatisfied," or "very dissatisfied"). We considered respondents willing to participate in future weekend lists and willing to sign up for weekend lists with longer or more complex cases if they reported "definitely," "probably," or "possibly" versus "probably not" or "definitely not." We included covariates in the models for staff role (categorical); number of

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weekend shifts worked (continuous); each of the 5 surgical services (binary); sense of accomplishment, community, and well-being; burnout; career development possibilities; increased workload; and job satisfaction (binary: "a great deal," "quite a bit," or "somewhat" vs "very little" or "not at all") (Multimedia Appendix 2). If staff worked more than 1 type of service list during the pilot, we classified them under the first surgical service. We reported results as odds ratios (ORs) and CIs, and a 2-tailed *P* value ≤.05 was considered statistically significant. Statistical analyses were performed using SAS (version 9.4; SAS Institute).

Ethics Approval

This study was approved by the Quality Improvement Committee at The Hospital for Sick Children (QIP-2021-01-08).

Results

Demographics

Of 118 eligible staff, 82 (69%) responded to the survey. Table 1 outlines the demographics of respondents, including anesthesiologists, nurses, service attendants, surgeons, and surgical trainees. Staff worked a median of 2 weekend lists (IQR 1-9) with a cumulative total of 230 weekend lists.

Table 1. Characteristics of respondents (N=82).

Characteristic	Anesthesiologist	Nurse	POCU[a] attendant	Surgeon	Surgical trainee
Respondents, n (%)	26 (32)	34 (41)	1 (1)	17 (21)	4 (5)
Weekend lists worked, median (IQR)	2 (1-2)	3.5 (2-6)	3 (3-3)	2 (1-4)	3.5 (3-4)
Clinical area[b], n					
Dentistry (n=15)	7	4	1	3	—
Ophthalmology (n=20)	8	5	1	6	—
Orthopedics (n=3)	3	—[c]	—	—	—
Otolaryngology (n=9)	4	2	—	3	—
Preanesthesia clinic (n=1)	1	0	—	—	—
Perianesthesia nursing (n=17)	0	17	—	—	—
Intraoperative nursing (n=2)	0	2	—	—	—
Plastic surgery (n=17)	5	8	—	2	2
Urology (n=14)	4	5	—	3	2

[a]POCU: perioperative care unit.

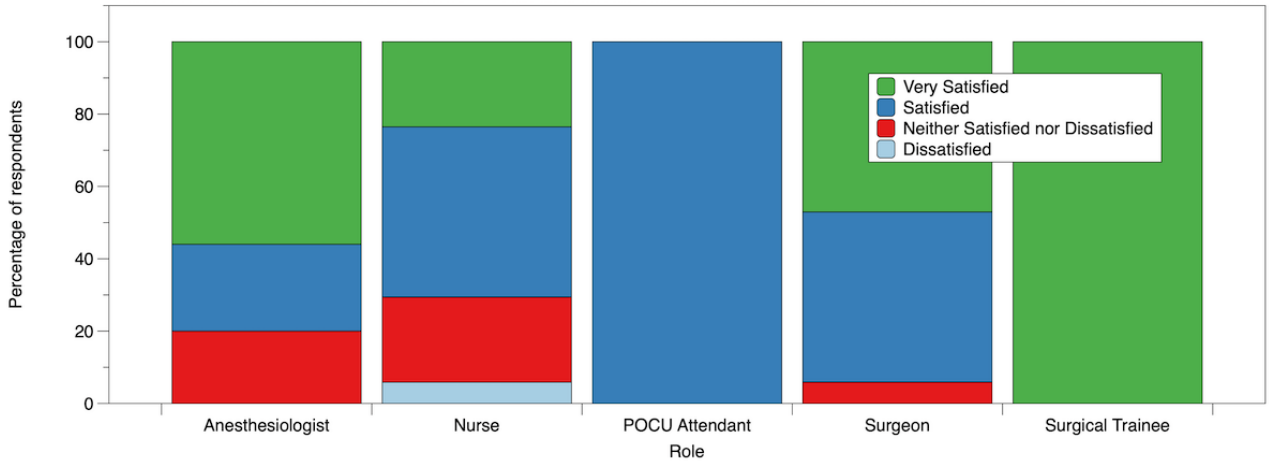
[b]Some staff worked in more than 1 clinical area.

[c]Not applicable.

Satisfaction With Working Weekends

Of 82 staff members, 65 (79%) were satisfied or very satisfied with working the extra weekend elective lists (Figure 1 and Multimedia Appendix 3). Surgeons and surgical trainees reported the highest levels of satisfaction. Only 2 (2%) out of 82 respondents expressed dissatisfaction with working the ORRACLE-Xtra weekends, and none reported being very dissatisfied.

Figure 1. Staff satisfaction with working weekend elective lists. POCU: perioperative care unit.



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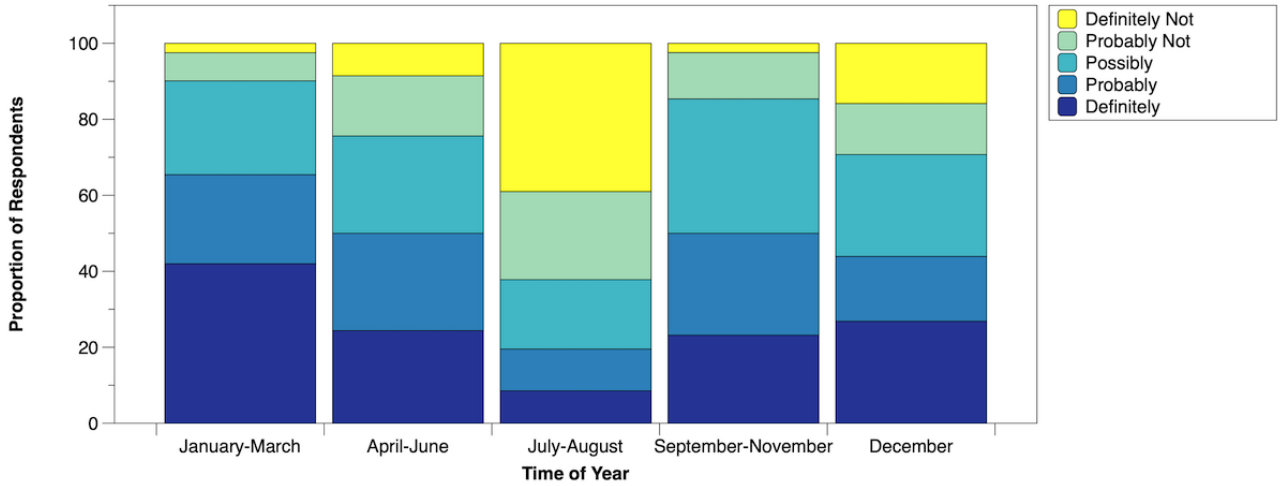
Perceptions of Working Weekend Elective Lists

Most respondents perceived working the weekend elective surgery lists to have a positive impact on their sense of accomplishment and community, as well as overall job satisfaction. There were no statistically significant differences in self-reported career development, well-being, and burnout for staff who were satisfied with their weekend surgery experience. Surgeons and nurses were more likely to experience a sense of accomplishment from working the weekend lists while also being more likely to report that the work contributed to their sense of burnout.

Respondents were more willing to work extra weekends during nonsummer months, with a preference for the winter months (Figure 2).

Figure 2. Likelihood of staff willing to work a weekend schedule at different times of the year.



Continued Participation in the Weekend Surgery Program

Of 82 staff members, 72 (88%) would be willing to continue working weekend lists and 56 (68%) would be willing to work weekends if cases were longer or more complex.

Multivariable Analyses

Participants' sense of accomplishment was significantly associated with satisfaction with working on the weekend (OR 19.97, 95% CI 1.79-222.63; *P*=.02) (Figure 3A).

Figure 3B shows the factors associated with the willingness to work lists with more complex cases. A sense of community was associated with a willingness to participate in future weekend lists with more complex cases (OR 0.12, 95% CI 0.02-0.63; *P*=.01). A sense of accomplishment was associated with a willingness to participate in future weekend elective lists (OR 17.74, 95% CI 1.50-200.70; *P*=.02) (Figure 3C).

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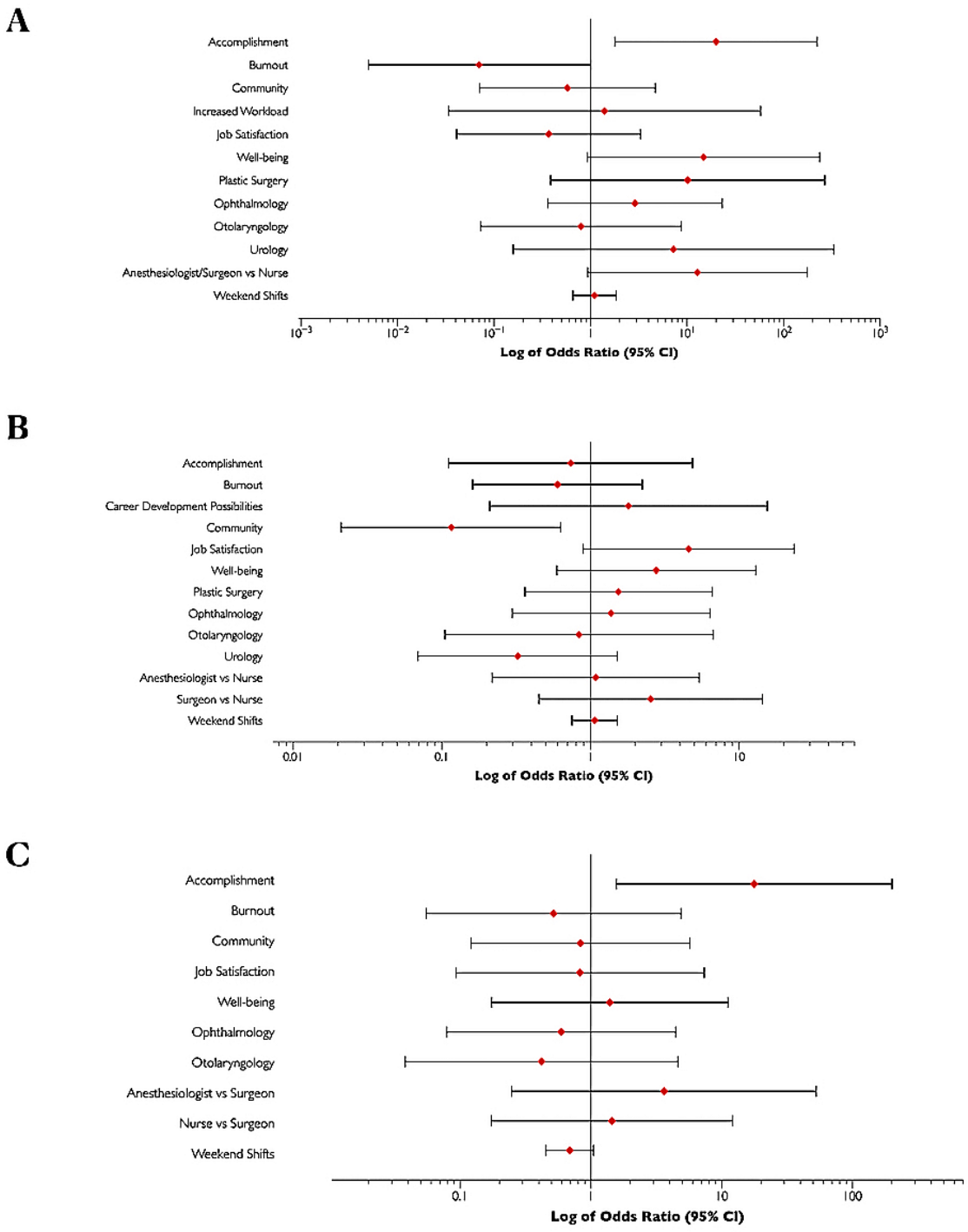
Figure 3. Multivariable logistic regression of factors associated with (A) satisfaction working weekend surgery; (B) willingness to work weekend lists with longer, more complex cases; and (C) willingness to work future weekend lists.



Discussion

Principal Findings

Our survey results demonstrate high overall satisfaction and positive feedback from staff working weekend elective surgical lists in the ORRACLE-Xtra program. A sense of accomplishment and community was associated with the intent to work weekend elective lists in the future, with a preference for nonsummer periods. Most staff would also be willing to work weekends that included longer and more complex cases.

Comparison With Prior Work

The burden of COVID-19 on health care workers has been unprecedented, with several studies reporting health workers experiencing inadequate preparedness, emotional challenges, insufficient equipment and information, and work burnout [7,28-37]. Health care workers dealing directly with patients infected with COVID-19 in critical care areas experienced significant burden from increased workloads and the likelihood of dissatisfaction and burnout [33]. In contrast, as the pandemic led to a slowdown in surgical cases, surgical staff had relatively

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lower workloads. We piloted the ORRACLE-Xtra program during a period when the number of COVID-19 cases affecting the pediatric population was relatively low, during the winter months, and when several public lockdowns were in place. This situation may have contributed to our success in attracting volunteer staff to work the weekend lists.

Further, with ongoing cycles of pandemic lockdowns, working the weekends was associated with satisfaction and a sense of accomplishment among respondents. This finding is unexpected, especially during a pandemic, but may be explained by the opportunity offered to engage in meaningful work and contribute to reducing the growing surgical wait-list. Surgeons were grateful to secure extra operating time when regular weekday opportunities were reduced. The cancelation of surgeries and reduced weekday workload around the study period may also have mitigated the sense of work burnout from working on weekends. An in-depth assessment of burnout was beyond the scope of this study and may yield different results. However, as staff could choose their availability for weekend lists, this sense of autonomy may have mitigated feelings of loss of control, creating a positive experience and environment [38-40]. A few participants in the nursing group did report dissatisfaction, and work is underway to investigate causes using qualitative methodology.

Participants reported interest in working lists with longer and more complicated cases. This finding was surprising as the goal of the weekend list was low-acuity, high-volume cases to help minimize the number of required staff and stress levels among staff while managing cohorts of children who had their procedures deferred for more urgent cases during the waves of surgical slowdown. However, the sense of community associated with a willingness to work longer cases is consistent with reported efforts to improve workplace morale and reduce burnout by building cohesive teams [38-40].

Impact on Future Planning

A key strength of our study is the high response rate and the availability of information for the planning of future weekend surgeries. Staff indicated their willingness to continue working weekend surgery, with preference for the nonsummer months of the year. This allowed institutional leaders to extend the ORRACLE-Xtra program for an additional 9 months, developing a weekend schedule cognizant of staff preferences and availability that addressed the surgical backlog while mitigating work-related burnout.

Limitations

Our study has several limitations. First, as a survey, the data are limited to the questions posed to the respondents. However, we also included open-ended questions to allow respondents to provide additional feedback. The qualitative data helped further explain some of the unexpected findings from our study. Second, we used a single question to gather information on the sense of burnout, which may underestimate the scope of burnout among staff. While the sense of accomplishment and community associated with working weekend surgery are encouraging, it would be important to check in with staff regularly if the program continues. Finally, our results are based on a 3-month pilot and the status, needs, and demands will change as the pandemic unravels. We would need to conduct a follow-up survey to assess whether working weekend lists would lead to fatigue in the longer term.

Conclusion

Staff working the first 3 months of the ORRACLE-Xtra program reported satisfaction with working weekends. A sense of accomplishment and community was associated with satisfaction and willingness to continue working weekend surgery, including longer, more complex cases. Integrating considerations of staff well-being and preferences is important for the implementation and planning of future surgical backlog recovery work. Institutions planning on implementing COVID-19 surgical backlog work would benefit from gathering key information from their staff.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Staff satisfaction survey.
[PDF File (Adobe PDF File), 43 KB - periop_v5i1e40209_app1.pdf]

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Multimedia Appendix 2
Variables used in univariate and multivariate analyses.
[DOCX File , 18 KB - periop_v5i1e40209_app2.docx]

Multimedia Appendix 3
Satisfaction with working weekend elective shifts.
[DOCX File , 18 KB - periop_v5i1e40209_app3.docx]

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Abbreviations

CROSS: Consensus-Based Checklist for Reporting of Survey Studies
OR: odds ratio
ORRACLE-Xtra: Operating Room Ramp-Up After COVID-19 Lockdown Ends-Extra Lists

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Original Paper

An Accessible Clinical Decision Support System to Curtail Anesthetic Greenhouse Gases in a Large Health Network: Implementation Study

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Abstract

Background: Inhaled anesthetics in the operating room are potent greenhouse gases and are a key contributor to carbon emissions from health care facilities. Real-time clinical decision support (CDS) systems lower anesthetic gas waste by prompting anesthesia professionals to reduce fresh gas flow (FGF) when a set threshold is exceeded. However, previous CDS systems have relied on proprietary or highly customized anesthesia information management systems, significantly reducing other institutions' accessibility to the technology and thus limiting overall environmental benefit.

Objective: In 2018, a CDS system that lowers anesthetic gas waste using methods that can be easily adopted by other institutions was developed at the University of California San Francisco (UCSF). This study aims to facilitate wider uptake of our CDS system and further reduce gas waste by describing the implementation of the FGF CDS toolkit at UCSF and the subsequent implementation at other medical campuses within the University of California Health network.

Methods: We developed a noninterruptive active CDS system to alert anesthesia professionals when FGF rates exceeded 0.7 L per minute for common volatile anesthetics. The implementation process at UCSF was documented and assembled into an informational toolkit to aid in the integration of the CDS system at other health care institutions. Before implementation, presentation-based education initiatives were used to disseminate information regarding the safety of low FGF use and its relationship to environmental sustainability. Our FGF CDS toolkit consisted of 4 main components for implementation: sustainability-focused education of anesthesia professionals, hardware integration of the CDS technology, software build of the CDS system, and data reporting of measured outcomes.

Results: The FGF CDS system was successfully deployed at 5 University of California Health network campuses. Four of the institutions are independent from the institution that created the CDS system. The CDS system was deployed at each facility using the FGF CDS toolkit, which describes the main components of the technology and implementation. Each campus made

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modifications to the CDS tool to best suit their institution, emphasizing the versatility and adoptability of the technology and implementation framework.

Conclusions: It has previously been shown that the FGF CDS system reduces anesthetic gas waste, leading to environmental and fiscal benefits. Here, we demonstrate that the CDS system can be transferred to other medical facilities using our toolkit for implementation, making the technology and associated benefits globally accessible to advance mitigation of health care–related emissions.

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KEYWORDS

clinical decision support; sustainability; intraoperative; perioperative; anesthetic gas; waste reduction; fresh gas flow

Introduction

Background

In recent years, the medical community has come to widely recognize the health impacts of climate change and its own critical contribution and role in turning back the tide toward a safe and healthy planet [1]. Notably, the health care sector accounts for 8.5% of all greenhouse gas (GHG) emissions in the United States [2]. Volatile anesthetic agents are potent GHGs and contribute up to 5% of the total carbon dioxide (CO_2) emissions of the National Health Service in the United Kingdom and >50% of the surgical emissions in North America [3,4]. The most commonly used volatile anesthetic agents—sevoflurane, isoflurane, and desflurane—have global warming potentials that are 130 to 2540 times greater than the global warming potential of CO_2 on a 100-year time horizon [5]. By safely reducing fresh gas flow (FGF), the carrier for anesthetic gases, we can decrease the waste and environmental impact of volatile anesthetic agents while simultaneously reducing cost per case [6-8].

Anesthesia professionals in the United States have historically avoided using low FGF rates because of theoretical safety concerns regarding the accumulation of compound A, a byproduct of sevoflurane processing by CO_2 absorbents, which has shown nephrotoxic effects in animal models [9]. However, substantial research was never able to replicate these results in human studies, thus invalidating the concern, and the European Common Market never adopted these low-flow guidelines [10]. Furthermore, the new generation of CO_2 absorbents lacks strong hydroxide bases and thus does not produce compound A. Research has shown that the use of low FGF is safe and effective [11,12]. Considering that the US Food and Drug Administration still recommends maintaining FGF at >2 L per minute with sevoflurane to minimize the production of compound A, low FGF with sevoflurane is currently considered an *off-label* practice [13]. Attitudes on the safety of low FGF rates have evolved, but institution-level behavioral modifications have been difficult to achieve without the proper tools [14]. Educational initiatives alone infrequently result in sustained behavioral change [15], whereas point-of-care visual reminders can promote changes in anesthesia professional behavior that reduce anesthetic gas waste [16]. However, maintenance of these initiatives requires significant time and effort, which are scarce resources in a high-capacity hospital.

Implementation of an FGF Clinical Decision Support System

Electronic clinical decision support (CDS) systems, which enhance clinical decision-making with real-time prompts and reminders [17], can also help enact behavioral change. The ideal CDS system is accurate, concise, flexible, easy to use, and imparts a minimal cognitive load [18]. Previous studies have demonstrated the utility of CDS systems to optimize anesthetic care and patient safety [19]. Directed CDS alerts have been shown to improve clinician compliance with reducing FGF [20]. Of note, previous CDS tools have lacked generalizability and portability because of reliance on heavily customized proprietary anesthesia information management systems (AIMSs). Deploying CDS systems can be challenging and must be grounded in the mission of an organization, not just the IT systems [21]. To date, no formalized and widely deployable FGF CDS alert has been expanded across different health systems, lessening the global impact of the technology. Recently, a CDS system within a commercial electronic health record (EHR) was developed and validated by the University of California San Francisco (UCSF) Medical Center [22]. A validation study by Olmos et al [22] at UCSF demonstrated that the CDS system effectively reduced FGF rates, volatile anesthetic consumption, and financial costs in the operating room (OR) and that the effects were sustained beyond a year after implementation. In this study, we describe the implementation of the FGF CDS system at UCSF, with subsequent implementation across the University of California (UC) Health network, a system that has pledged to reach carbon neutrality by 2025 [23]. We accomplished this objective by sharing a portable framework, or toolkit, whose core elements are compatible with most commercially available and proprietary AIMSs. Specifically, our implementation study describes the following aspects:

- The detailed technical framework to build, deploy, and track a CDS alert that prompts anesthesia professionals to lower FGF rates (notable FGF CDS system terms and definitions are described in Textbox 1)
- The management guidance to facilitate the integration of the CDS tool into clinical practice through education initiatives
- The launch timeline and characteristics of each FGF CDS system implemented by individual UC Health systems

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Textbox 1. Notable terms and definitions for understanding the fresh gas flow clinical decision support toolkit implementation.

- Global warming potential
  - The amount of energy the emissions of 1 ton of a gas will absorb over a given period in years compared with the emissions of 1 ton of carbon dioxide
- Minimum alveolar concentration (MAC)
  - The minimum concentration of an inhaled anesthetic present in alveoli at 1 standard atmosphere of atmospheric pressure that prevents skeletal muscle movement in response to a surgical incision in 50% of patients; MAC values are used to compare potency among inhaled anesthetic agents
  - The concentration of inhaled anesthetic required to achieve this end point decreases with age [24]
- Fresh gas flow rate
  - The total volume of gas that flows from the anesthetic machine into the breathing system per minute; fresh gas flow serves as the carrier for volatile anesthetic gases
- MAC-hour
  - The average MAC during a treatment period multiplied by the duration of treatment in hours
  - Does not fully encapsulate inhalational anesthetic use, which also depends on fresh gas flow rate
- Best Practice Advisory
  - The brand name for rule-based clinical decision support alerts within the Epic electronic health record (Epic Systems Corporation)
- Middleware
  - A device integration solution for capturing and transmitting anesthesia ventilator data (and other physiological data) to the electronic health record (eg, Capsule Medical Device Integration Platform [Capsule Technologies, Inc, a subsidiary of Philips Healthcare])

Methods

Project Approval and Launch

In early 2018 at UCSF, a committee of clinical informaticians, anesthesia professionals, and a physician sustainability champion convened to develop a simple and transferable IT solution to reduce FGF and, in turn, reduce the carbon footprint of ORs. The result was a CDS alert that worked within the Best Practice Advisory (BPA) framework of the Epic EHR (Epic Systems Corporation) to track real-time FGF and prompt anesthesia professionals to reduce FGF when the rate exceeded a defined threshold. The project was presented to departmental informatics and institution medical executive committees and adapted based on their feedback. In August 2018, the CDS alert launched within UCSF's ORs, and subsequent volatile anesthetic waste reduction was validated [22]. In January 2021, the UC Office of the President sponsored a committee to develop and formalize the FGF CDS toolkit and launch it UC Health wide. Figure 1 outlines the implementation design of the FGF CDS toolkit.

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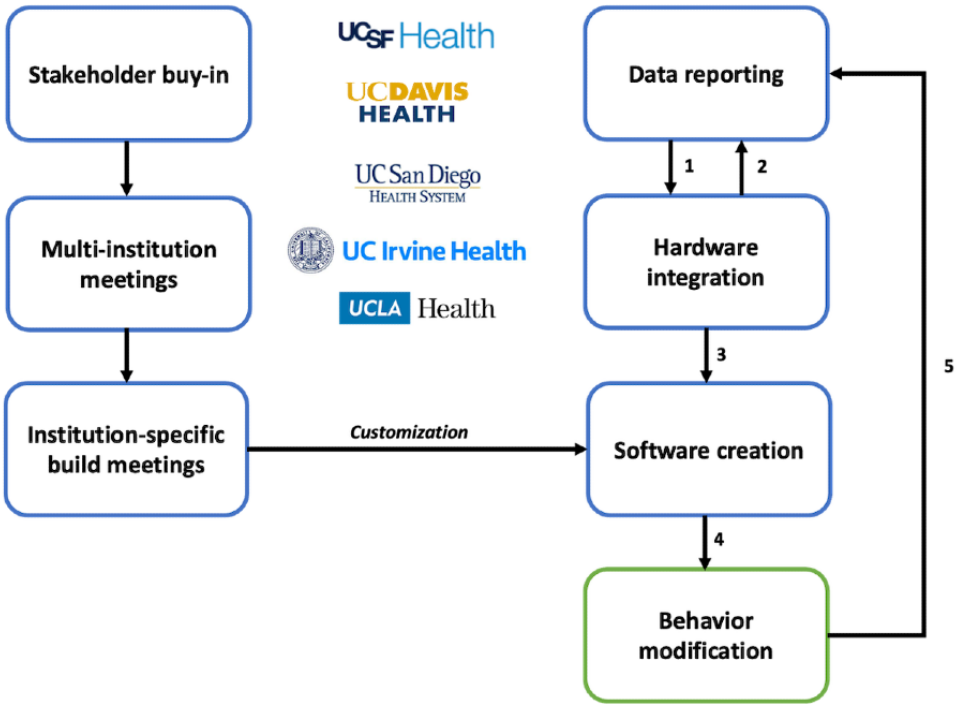
Figure 1. Fresh gas flow clinical decision support (CDS) toolkit implementation design. Major steps in launching a fresh gas flow CDS system at multiple institutions; step 1: based on data reporting, determine whether all necessary information is being captured in the electronic health record (EHR); step 2: if anesthesia hardware (eg, ventilators) does not transmit necessary reporting data, work with institution engineers to capture this in the EHR for data reporting and future CDS creation; step 3: CDS software design based on device data goals and institution-specific goals as framework; step 4: implementation of CDS system (with institution-specific modifications) within the EHR promotes behavior modification and subsequent reduction of anesthetic gas use; and step 5: modified clinician behavior generates additional data that can guide adjustments to the CDS system.



Ethical Considerations

As part of a prior research study analyzing the effectiveness of the FGF CDS system, the Human Research Protection Program's Institutional Review Board approval was obtained for tracking FGF and CDS alert data at UCSF (19-28183). Subsequent implementations across the other UC Health institutions were performed under the auspices of quality improvement to reduce the environmental impact of anesthetic gases.

Toolkit Design

The implementation process was documented and assembled into an informational toolkit to facilitate uptake of the CDS system at other health care facilities. There are 4 major components of the FGF CDS toolkit: education, hardware integration, software build, and data reporting.

Initial Assessment and Education

The initial assessment of clinician perceptions and knowledge gap regarding low FGF and subsequent targeted education to address evidence-based practice are critical before any intervention. When UCSF first launched the FGF CDS system, the sustainability and informatics leads presented at faculty meetings, trainee lectures, and grand round lectures to describe the sustainability benefits of low FGF use, the physics behind gas consumption, and details of the CDS system. This education continued in subsequent academic years after the initial FGF CDS system launch. During the first UC-wide work group meeting, the CDS system was demonstrated to informaticians, anesthesiologists, and clinical sustainability champions, along with data to support its efficacy. These site leaders, in turn, presented education materials to their trainees, faculty, and leadership at trainee lectures, faculty meetings, and departmental grand rounds. Shortly before the FGF CDS system launch at each institution, the respective clinical sustainability champions reinforced this content with additional presentations and email reminders. Essential roles and responsibilities for successful FGF CDS toolkit implementation are summarized in Figure 2.

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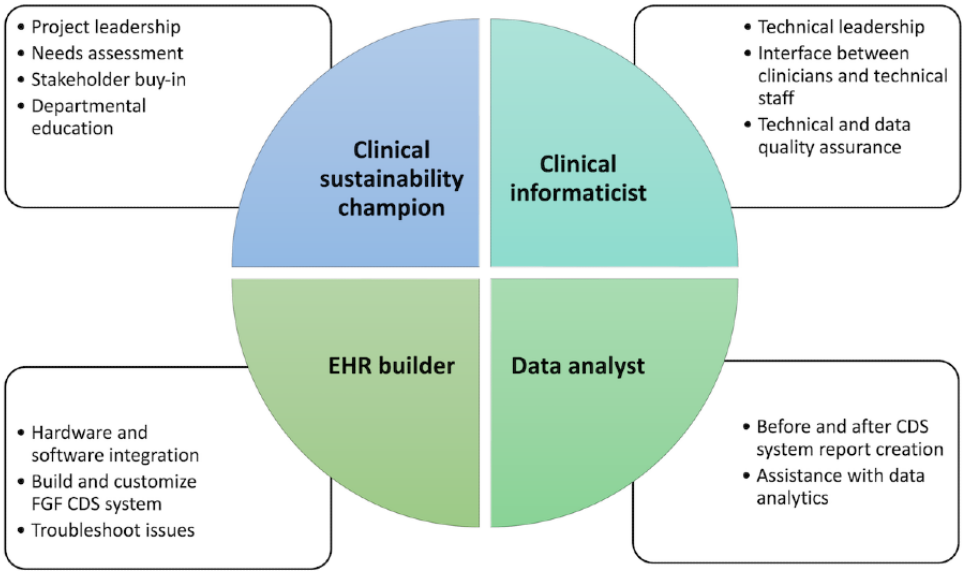
Figure 2. Essential roles and responsibilities for a successful fresh gas flow (FGF) clinical decision support (CDS) toolkit. EHR: electronic health record.



Hardware Integration

Before building the FGF CDS software tool, we performed an inventory of all the anesthesia ventilator machines used in ORs and their corresponding middleware outputs (eg, Capsule Medical Device Integration Platform [Capsule Technologies, Inc, a subsidiary of Philips Healthcare] used at UCSF). Multimedia Appendix 1 presents examples of the machines we use in UCSF's ORs. Through Capsule, our AIMS was able to capture the following essential data elements for implementing the FGF CDS toolkit:

1. Set anesthetic concentration of sevoflurane, desflurane, and isoflurane (%): this value is the inspired concentration of volatile anesthetic that the practitioner sets on the anesthesia machine. This value is distinct from the actual inspired concentration delivered to a patient, which is measured by the gas analyzer.
2. FGF rate (L per minute): this value is the sum of all agents, including air, oxygen, and nitrous oxide (N_2O).
3. End-tidal anesthetic concentration of sevoflurane, desflurane, and isoflurane (%) measured by the gas analyzer.
4. Cumulative anesthetic agent liquid consumption (mL): this volume is reported by some commercial ventilators (Multimedia Appendix 1) but may also be calculated [25].

The first 2 data elements in the aforementioned list are the *required minimum* to build a functioning FGF CDS system. The last 2 elements are useful for tracking and reporting FGF reduction impact metrics.

Software Build

CDS Alert Design

At UCSF, we designed our CDS system with the goal of changing behavior without clinical disruption. First, we implemented an intraoperative CDS system with a real-time *active* (readily visible) alert to practitioners to prompt change. By contrast, a passive alert may not be readily visible (eg, one would have to scroll within the EHR to find it). Second, to prioritize patient safety and avoid disruptions to clinician workflow in a high-intensity OR setting, we chose a *noninterruptive* CDS system. The noninterruptive colored alert appears on the side of the screen, which imparts the necessary information without interrupting clinician workflow. This design is in contrast to an interruptive CDS system, which requires the clinician to respond to the alert before continuing EHR use. Our institution at UCSF felt that an interruptive CDS system would have an adverse effect on the anesthesia team, especially if an interruptive alert fired during a serious patient event. Furthermore, interruptive CDS systems may be more likely to cause alert fatigue and thus would have diminished efficacy [26,27].

FGF CDS Alert Rules

We developed a set of rules for the firing of the FGF CDS system (Textbox 2; Figure 3). These rules are evaluated every minute.

Notably, our CDS system does not activate during delivery of N_2O without a volatile anesthetic agent but will fire if N_2O is used in conjunction with a volatile anesthetic agent. We excluded cases with isolated use of N_2O because it is very rare to use this agent exclusively during the maintenance phase of a procedure at our institution. However, the FGF CDS alert could easily be adapted to consider sole delivery of N_2O.

Over multiple meetings, UCSF informaticians shared the technical specifications and report builds with the UC Office of the President's sustainability committee leaders and EHR builders from each institution. The UC Health center-specific champions worked with their respective department leadership and IT build teams to select an FGF CDS alert type and FGF threshold to fit the needs and goals of their individual departments.

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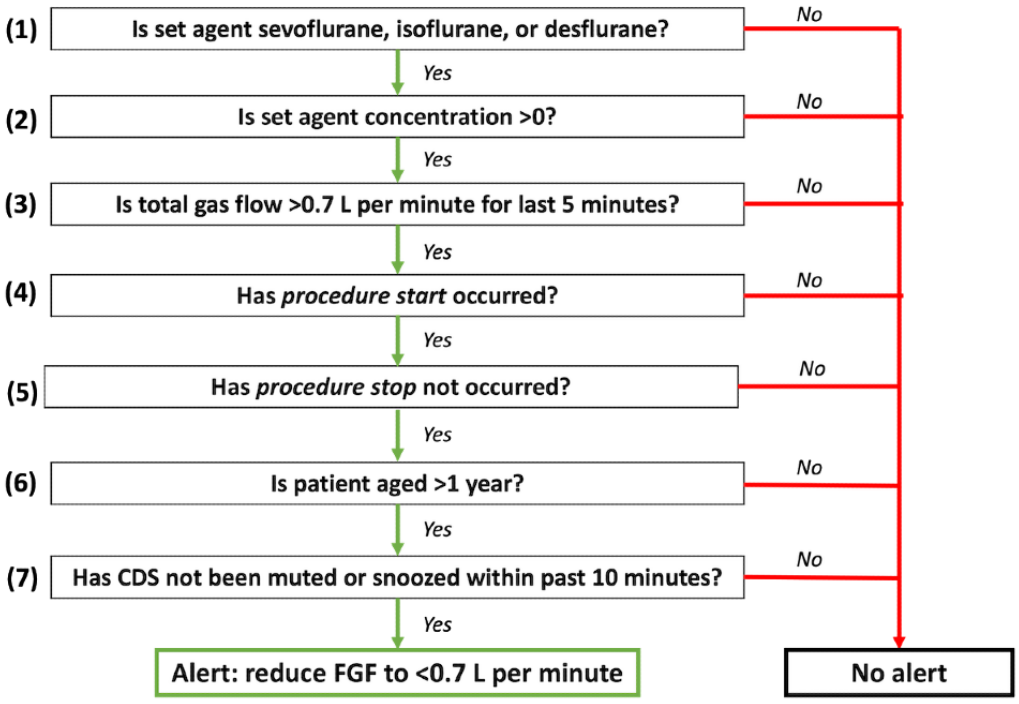
Textbox 2. Rules for the firing of the fresh gas flow clinical decision support system.

- Rule 1 requires that at least one of the 3 anesthetic agents (sevoflurane, isoflurane, or desflurane) is the set agent.
- Rule 2 requires that the agent is currently in use (dial concentration is >0).
- Rule 3 requires that the set agent has a flow rate higher than the selected threshold (eg, 0.7 L per minute) for at least the last 5 consecutive minutes.
  - We chose a lookback time window of 5 minutes because we did not want abrupt, reactive changes to patient status to result in firing of the clinical decision support alert.
- Rule 4 requires that the procedure start timing event has been activated in the electronic health record.
  - This rule excludes the induction period, when the anesthesia team is typically occupied with positioning the patient, performing additional procedures, and optimizing hemodynamics. We felt that delivering an alert during this time would be disruptive to care. Furthermore, anesthesia induction frequently necessitates higher flows of anesthetic gases to quickly reach steady state plasma concentrations.
- Rule 5 requires that the procedure stop timing event has not been activated.
  - This rule helps to exclude the emergence period.
- Rule 6 requires that the patient is aged >1 year.
  - The physiology of very young patients entails unique anesthetic delivery.
- Rule 7 allows the anesthesia professional to snooze the Best Practice Advisory for a period of 10 minutes.
  - We incorporated this snooze feature and an option to turn off the clinical decision support system entirely if needed because of clinical circumstances such as circuit leak or code scenario.

Figure 3. Fresh gas flow (FGF) clinical decision support (CDS) alert firing rules: these are the alert firing rules at the University of California San Francisco, based on real-time data captured in the operating room. These rules run every minute within the anesthesia information management system.



Postimplementation Reporting

The primary outcome measure for efficiency of anesthetic administration was mL of liquid volatile anesthetic agent consumed per MAC-hour (the average MAC [minimum alveolar concentration] during a treatment period multiplied by the duration of treatment in hours) during the maintenance phase of anesthesia. This metric, mL per MAC-hour, is analogous to the inverse of miles per gallon, or *gas mileage*. To improve efficiency, one should minimize the *gas used* (volume) while maximizing the *amount of anesthesia provided* (MAC-hour). Furthermore, we can calculate total cost savings based on reduced anesthetic consumption. In addition, the age-adjusted MAC-hours of general anesthesia (as defined in Textbox 1) were calculated to (1) normalize the outcome metric related to anesthetic durations among different cases, and (2) assess the impact of our intervention on anesthetic administration practices at our institutions. Figure 4 shows the change in anesthetic gas

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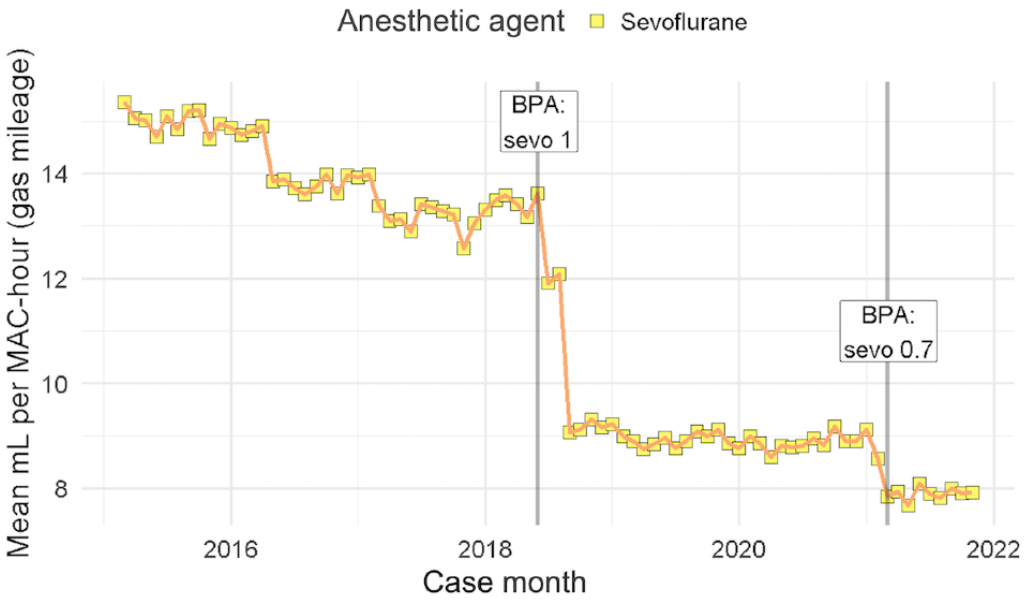
efficiency after CDS system implementation and changes in the firing threshold at UCSF [22].

We used the following exclusion criteria for reporting:

- Locations: pediatric induction rooms, non-OR anesthesia locations (eg, interventional radiology, magnetic resonance imaging, and endoscopy) because of machine incompatibility, and labor and delivery
- Cases that used >1 volatile anesthetic agent (sevoflurane, isoflurane, or desflurane) during maintenance, defined as the presence of a single flow sheet entry for a set volatile agent concentration (%) >0 for >1 agent
- Cases with a short delivery of volatile anesthetic agent, defined as <15 minutes of recorded volatile anesthetic agent delivery per flow sheet

With Microsoft SQL server, we extracted data directly from the Epic Clarity database. Textbox 3 shows pseudocode for how we calculated the MAC-hour per mL of volatile anesthetic agent used on a per-case or per-clinician level. The primary difference between the per-case and per-professional-per-case basis is the time windows over which the metrics are calculated. On a per-professional-per-case basis, only the portion of the maintenance phase during which the anesthesia professional was *logged in* would be taken into consideration. Thus, the maintenance phase may be split among professionals. It is also important to note that with a supervision model, multiple anesthesia professionals may have overlapping time periods because attending anesthesiologists and supervisees (certified registered nurse anesthetists and resident anesthesiologists) may hand off the case at different times. SQL code was shared with data report writers at each institution for translation into local database query language. Data on number of times the alert was fired were also extracted using Epic's BPA Cube reporting system, providing additional insight into behavioral modification at the clinician level (Figure 5). Each institution was asked to track at least 1 month of pre–CDS system data to evaluate the impact of FGF CDS system implementation.

Figure 4. Mean mL per case of anesthetic agent per MAC-hour (the average minimum alveolar concentration [MAC] during a treatment period multiplied by the duration of treatment in hours) over time. The first mL per MAC-hour, or gas mileage, reduction occurred after the University of California San Francisco launched the fresh gas flow clinical decision support system with a rate threshold of 1 L per minute. In February 2021, the rate threshold was dropped to 0.7 L per minute and resulted in another drop in mL per MAC-hour of sevoflurane. BPA: Best Practice Advisory; sevo 0.7: sevoflurane 0.7 L per minute; sevo 1: sevoflurane 1 L per minute.



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Textbox 3. Pseudocode for calculating the mL of volatile anesthetic agent per MAC-hour (the average minimum alveolar concentration [MAC] during a treatment period multiplied by the duration of treatment in hours) used on a per-case or per-clinician level.

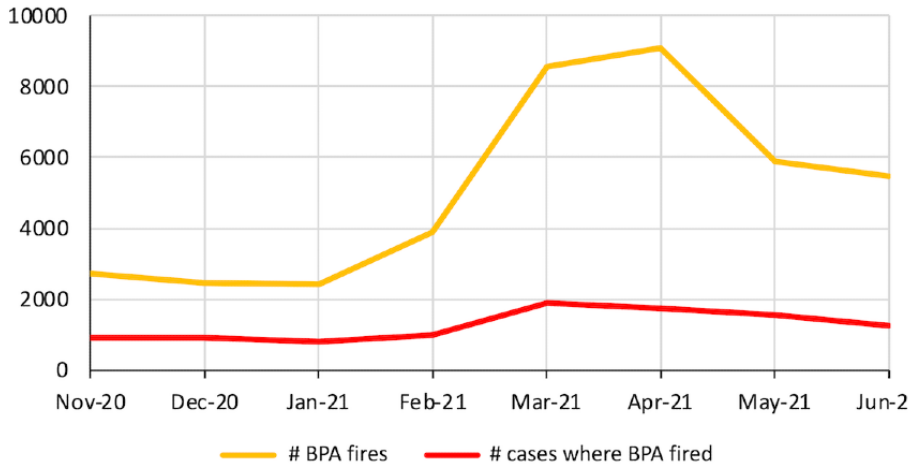
Pseudocode for a given case or anesthesia professional

- %Times based on procedure or anesthesia professional time logs
  - procedure_start=procedure or professional start time
  - procedure_stop=procedure or professional stop time
  - anesthetic_gas_stop=time of last nonzero set anesthetic delivery percentage
- %Anesthesia professional in case
  - case_duration = procedure_stop – procedure_start
- %Mark induction time period
  - induction_tp=time of first set anesthetic delivery percentage >0 to procedure_start
- %Mark maintenance time period
  - maintenance_tp=procedure_start to the earlier time of (procedure_stop or anesthetic_gas_stop)

Pseudocode for a given inhalational anesthetic agent (isoflurane, sevoflurane, or desflurane) over case_duration

- %Calculate volume of inhalational anesthetic liquid used during maintenance
  - set_agent_volume = cumulative anesthetic volume consumed at end of maintenance_tp – cumulative anesthetic volume consumed at end of induction_tp
- %Calculate average age-adjusted MAC during maintenance
  - age_ adjusted_MAC = average of all end-tidal anesthetic concentrations recorded during maintenace_tp / age-adjusted MAC of inhaled anesthetic agent [24]
- %Calculate MAC-hours of treatment exposure
  - MAC_hrs = age_adjusted_MAC × hours of maintenance_tp
- %Calculate mL per MAC-hour
  - ml_per_MAC_hr = set_agent_volume / MAC_hrs

Figure 5. Fresh gas flow clinical decision support system firing rate after fresh gas flow threshold reduction.



Results

On the basis of the build of the FGF CDS system at UCSF, modified versions were subsequently implemented across the UC Health network. Table 1 summarizes the individualized approaches of each UC Health system, identified as UC-A through UC-D to anonymize campuses, to implement the FGF CDS alert. The rationale for these adjustments to our noninterruptive active CDS system were based on each health

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system's department-level and anesthesia professional–level feedback.

Two health systems—UC-C and UC-D—took on the same CDS system build as UCSF: a noninterruptive active CDS with FGF alert thresholds of 0.7 L per minute and 1 L per minute, respectively. UC-A launched an interruptive active CDS system. Finally, UC-B introduced a passive CDS system with an FGF threshold of 1 L per minute. Figure 6 depicts the differences in passive versus active alert appearance: flow sheets, noninterruptive alert, and interruptive alert. With the interruptive workflow, the pop-up window (Figure 6) must be dismissed before using other EHR workflows within the AIMS.

Table 1. Clinical decision support (CDS) system characteristics and launch timeline.

	Health system				
	UCSF[a]	UC-A[b]	UC-B[b]	UC-C[b]	UC-D[b]
CDS system type	Active	Active	Passive	Active	Active
CDS system display	Noninterruptive	Interruptive	Flow sheet	Noninterruptive	Noninterruptive
FGF[c] alert threshold (L per minute)	0.7	0.7	1	0.7	1
Education dates	July 2018	October 2021[d]	May 2019[e]; December 2021[d]	February 2021[e]; October 2021[d]	April 2021[e]; March 2022[d]
Launch date	September 2018	October 2021	December 2021	December 2021	May 2022

[a]UCSF: University of California San Francisco.

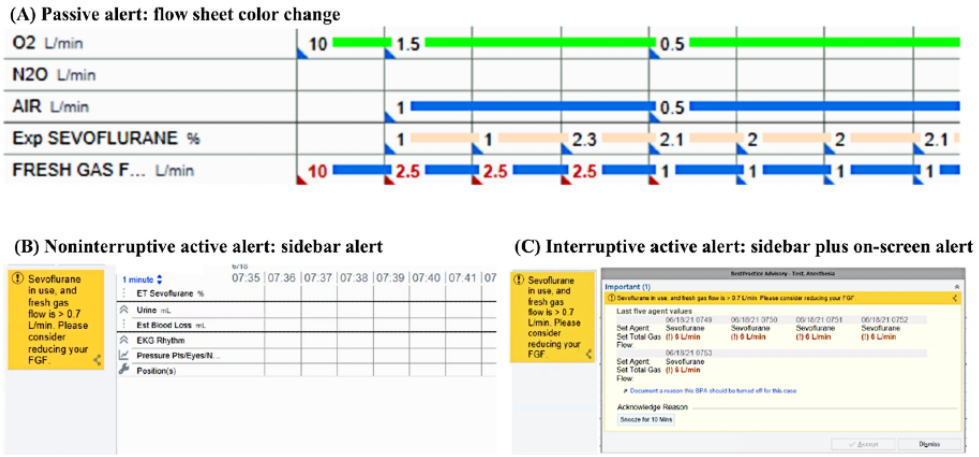
[b]UC-A, UC-B, UC-C, and UC-D: University of California Health system, identified as such to anonymize campuses.

[c]FGF: fresh gas flow.

[d]Best Practice Advisory tool training.

[e]Initial introduction of low-flow anesthesia.

Figure 6. Comparison of different fresh gas flow clinical decision support alerts. (A) Depiction of a passive alert in the form of a color change in the anesthesia information management system (AIMS) flow sheet. (B) Depiction of a noninterruptive active alert in the form of a yellow sidebar alert in the AIMS interface with further details and action items on cursor hover-over. (C) Depiction of an interruptive active alert in the form of both yellow sidebar alert and on-screen pop-up window. The pop-up window must be addressed to interact with other AIMS functions.



Discussion

Overview

Our development and deployment of a CDS toolkit across multiple institutions demonstrates the feasibility and utility of a portable and reproducible CDS system for reducing anesthetic gas use. We describe the institutional process for implementation and how an integrated CDS system can be used to reduce the waste, cost, and carbon footprint of ORs. Our CDS toolkit can be deployed at other institutions using the popular and commercial Epic Systems EHR. Moreover, our methods can be translated into other AIMSs with identification of the proper data elements and ability to host a real-time CDS system. Widespread use of this toolkit could curb the impact of the health care system on climate change.

Principal Findings

Our study describes the implementation of the FGF CDS system at UCSF, which was documented and assembled as an informational toolkit, and subsequent implementation at 4 other UC Health centers using the FGF CDS toolkit. Modifications to the CDS system were made after discussion from the key stakeholders at each facility. Deployment of the CDS system at all UC Health centers in this study was considered successful because the CDS system is currently in active clinical use at each center. A validation study showing that the CDS system effectively reduces anesthetic gas waste has been conducted at

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UCSF [22], and data collection to quantify and compare the amount of gas waste reduction among the different UC Health centers is in progress. Our study presents the FGF CDS toolkit for implementation and further shows that institutions outside of the UCSF are able to successfully modify and deploy the CDS system, making the technology accessible to the wider health care network. A primary limitation of comparable efforts to reduce anesthetic gas waste is the difficulty in transferring the technology outside of the creator institution.

Balancing benefit with burden to clinicians is always challenging when introducing any disruptive solution in health care. We were careful to create a CDS that fired with the right criteria, right information, right person, right time, and with the right intervention [28]. We also incorporated a snooze feature and a disabling feature to increase flexibility, as well as a simple and adaptable reporting structure to capture relevant data and facilitate future modifications. As demonstrated, each institution took a slightly different timeline and different approach to intervention (eg, passive vs active and noninterruptive vs interruptive).

Barriers to Implementation

During the FGF CDS system implementation, we encountered educational, technology, and operational barriers. First, the concern for compound A formation was a reflexive response when we approached our colleagues. As this concern was anticipated from project initiation, we created educational directives to target these misconceptions before our CDS system implementation. Periodic education was required when new anesthesia staff or trainees joined the department. In addition, training and re-education was needed to establish comfort when adjunctive changes coincided with our initiative to reduce anesthetic gas waste with low FGF rates (ie, introduction of new anesthesia machines); for example, under low FGF rates, some machines may require the gas dial to be set higher than intended to overpressurize the circuit to achieve the desired MAC for general anesthesia.

From a technological perspective, some institutions had different middleware being used at different locations (eg, Capsule vs DeviceConX). The difference in middleware necessitated separate evaluations to map and discriminate the data values coming into the AIMS flow sheets and data reports. Much work and effort went into troubleshooting and fixing any errors to ensure the robustness of data.

We encountered some logistical barriers during the CDS system implementation. Our objective was to oversee a simultaneous rollout of the CDS system implementation across 4 UC Health hospitals after the implementation at UCSF. However, this goal was quite difficult given the need to accommodate the project within different work queues and IT-related priorities of each academic medical center, and the rollout was staggered among the sites. Second, some of the UC Health hospital systems only recently arrived at the final data report writing because of resource delays (eg, analyst availability) and the need for generating iterative data reports to allow for data scrutinization and to ensure data validity. Finally, shorter cases with a small maintenance phase constitute the majority of cases at some UC Health hospitals, but our CDS solution is most robust during longer cases with longer maintenance phases. A different approach or research study will be required to address the conservation of fresh gas and inhaled anesthetic at the time of induction and emergence.

Comparison With Prior Work

To our knowledge, this is the first such FGF CDS system that has been launched across a large health network and that can be widely adopted by other institutions. Nair et al [20] demonstrated a reduction in anesthetic gas waste after implementation of a CDS system built into their proprietary EHR; however, their solution lacked ease of portability. Luria et al [29] demonstrated results similar to those of Nair et al [20] in a simulation both with and without the Low Flow Wizard (Apollo anesthesia machine; Drägerwerk AG & Co). Other studies have found evidence for the benefit of physical point-of-care reminders and educational initiatives [16,30]. Our CDS toolkit, which comprises technology combined with education and an established framework for implementation, provides an accessible route and step-by-step guide for other institutions to reduce their anesthetic gas waste.

Limitations

There are several limitations to our FGF CDS toolkit. First, although the 5 sites where the CDS system was deployed were distinct and nonoverlapping health care systems, they were all academic centers within a single large health care network, which may limit the generalizability of our contributions; for example, institutional and anesthesia professional behavior at a small, private health care facility may be different and lead to variations in ease of implementation, available resources, and outcomes. Second, our CDS system may not be applicable in all perioperative settings. There are certain cases where high-flow inhalational agents need to be used; for example, during emergency situations, during pediatric inhalational inductions, and in select cardiothoracic surgery cases. Although our CDS system was designed to allow for such exclusion criteria and not fire the BPA under certain circumstances, it will not be effective in reducing FGF during these situations. Third, our CDS system uses the Epic EHR platform, which, although widely available, is not the platform used at all hospitals. Knowing that many institutions do have other EHR systems, we lay out the technical details and the necessary steps to import this CDS system into ORs that use other AIMSs.

Future Directions

Studies comparing the extent of anesthetic gas waste reduction among the 5 UC Health campuses with the FGF CDS system deployed will provide additional insight into the effectiveness of various CDS system features. The CDS system and gas waste reduction will be optimized based on knowledge gained from these studies. Furthermore, we plan to support and encourage implementation of the CDS system at other health care facilities to collectively make a larger impact in anesthetic gas waste mitigation.

Conclusions

Without compromising patient safety, health care systems should align their perioperative conservation and sustainability practices with the goals of the United Nations Intergovernmental Panel

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on Climate Change, whose Sixth Assessment Report unequivocally linked human influence to the rapid rates of global warming. The report further warned of dire consequences for the planet if strong, rapid, and sustained reductions in GHG emissions are not accomplished [31]. Reducing FGF has significant ecological and economic benefits in reduction of emissions from inhaled anesthetics and cost savings from less gas consumption [32].

As clinical informaticians and anesthesiologists, we can do our part to champion solutions to reduce the release of anesthetic GHG into the atmosphere. We showcased a system that achieved this aim as well as financial savings [22]. With adoption of this FGF CDS toolkit, health systems can track behavior modification, anesthetic gas use, GHG emissions, and cost per case while providing extensive opportunities for research and quality improvement. We show that EHR technologies can be used to benefit humankind by prompting hospital systems and clinicians to participate in sustainability efforts while providing high-quality care. This implementation initiative represents a crucial step in curtailing GHG emissions for the welfare of our patients and our planet alike.

As more health care professionals are becoming aware of the environmental impacts of the health care industry, we hope that the dissemination of this toolkit will facilitate the implementation of this CDS tool at other institutions for widespread adoption of low FGF nationally to advance health care decarbonization. With practices gradually evolving, anesthesia professionals should join forces through anesthesiology organizations, from regional to national societies, to advocate for *off-label* use of low FGF with sevoflurane as an evidence-based practice to counter the outdated Food and Drug Administration guidelines for anesthesia professionals [13].

Acknowledgments

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Data Availability

The data underlying this paper cannot be shared publicly to protect the privacy of institutions and patients. The derived data may be shared on reasonable request to the corresponding author.

Authors' Contributions

PR contributed to the implementation, data acquisition, analysis, and interpretation and drafted and critically revised the article. A Shah contributed to the design and implementation and critically revised the article. RK contributed to the data acquisition, analysis, and interpretation and critically revised the article. NS contributed to the design and implementation and critically revised the article. EM contributed to the design and implementation and critically revised the article. AA contributed to the design and implementation and critically revised the article. A Shapiro contributed to the design and implementation and critically revised the article. RD contributed to the implementation and critically revised the article. CY contributed to the data analysis and interpretation and drafted and critically revised the article. JS contributed to the data acquisition and analysis and critically revised the article. CD contributed to the design and implementation and critically revised the article. KW contributed to the implementation, data analysis, and interpretation and critically revised the article. DR contributed to the design and implementation and critically revised the article. SG contributed to the design, implementation, data analysis, and interpretation and critically revised the article.

Conflicts of Interest

AS is a paid consultant for Doximity and Wolters-Kluwer. EM receives speaker fees from Edwards Lifesciences, royalties from UpToDate, and honoraria from the Anesthesia Patient Safety Foundation for social media work.

Multimedia Appendix 1
University of California San Francisco anesthesia ventilator devices and data available via Capsule Medical Device Integration Platform (Capsule Technologies, Inc, a subsidiary of Philips Healthcare).
[DOC File , 37 KB - periop_v5i1e40831_app1.doc]

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Abbreviations

AIMS: anesthesia information management system
BPA: Best Practice Advisory
CDS: clinical decision support
CO2: carbon dioxide
EHR: electronic health record
FGF: fresh gas flow
GHG: greenhouse gas
MAC: minimum alveolar concentration
N2O: nitrous oxide
OR: operating room
UC: University of California
UCSF: University of California San Francisco

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Viewpoint

The Case for the Anesthesiologist-Informaticist

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Abstract

Health care has been transformed by computerization, and the use of electronic health record systems has become widespread. Anesthesia information management systems are commonly used in the operating room to maintain records of anesthetic care delivery. The perioperative environment and the practice of anesthesia generate a large volume of data that may be reused to support clinical decision-making, research, and process improvement. Anesthesiologists trained in clinical informatics, referred to as informaticists or informaticians, may help implement and optimize anesthesia information management systems. They may also participate in clinical research, management of information systems, and quality improvement in the operating room or throughout a health care system. Here, we describe the specialty of clinical informatics, how anesthesiologists may obtain training in clinical informatics, and the considerations particular to the subspecialty of anesthesia informatics. Management of perioperative information systems, implementation of computerized clinical decision support systems in the perioperative environment, the role of virtual visits and remote monitoring, perioperative informatics research, perioperative process improvement, leadership, and change management are described from the perspective of the anesthesiologist-informaticist.

(JMIR Perioper Med 2022;5(1):e32738) doi:10.2196/32738

KEYWORDS

anesthesia; anesthesiology; AIMS; anesthesia information management systems; clinical informatics; anesthesia informatics; perioperative informatics; health information; perioperative medicine; health technology

Introduction

The digital evolution of health care is occurring at an accelerating rate, and clinical practice is increasingly informed by software such as electronic health records (EHRs). EHRs in the United States spread widely after the establishment of government incentive programs, and their adoption has spurred the development of information technology systems within health care including software for billing and laboratory systems. The rapid generation of large quantities of electronic forms of patient data has benefits to health care including electronic storage, easy dissemination, and expanded use in research-, clinical-, or business-related processes. The perioperative environment is data-rich, and anesthesia care generates large quantities of patient data that may potentially be captured for later secondary clinical or operational use [1,2]. Data in health care has been described as “big data,” and its increase in quantity, variety, and rapidity of data generation has defied legacy attempts at storage and use [3]. This change has necessitated the development of the discipline of biomedical informatics and the subdiscipline of clinical informatics. New techniques and tools have been created to capture, store, manipulate, and visualize data, transforming it into usable information. Eventually, artificial intelligence trained on this captured data may drive predictive analytics that inform clinical decision-making in real time in the operating room.

Anesthesiologists are at the forefront of the digital transformation of health care as it applies to the perioperative environment. Anesthesiologist-informaticists must grapple with the effective use and optimization of anesthesia information management systems (AIMS) and EHRs. Although AIMS have been shown to have several benefits around improvement in clinical documentation and reimbursement, there have been concerns around the high costs and resistance to changes in

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clinical work patterns [4]. Clinical informatics researchers are beginning to use the data captured in these systems to improve patient safety, quality, and care outcomes [5]. Two examples of efforts to reuse electronic data for research are the Anesthesia Quality Institute's National Anesthesia Clinical Outcomes Registry [6] and the Multicenter Perioperative Outcomes Group, which receives data from over 30 anesthesia departments AIMS [7].

In this paper, we aim to introduce clinical informatics to anesthesiologists and describe how they have the potential to make unique contributions to the field. We start by reviewing the definitions of informatics and related disciplines, as this can be a source of confusion to those outside the field. We then provide further background on the broad scope of clinical informatics as a medical specialty, and discuss options for anesthesiologists who might have interest in further training. We follow this with an overview of anesthesiology informatics and related topics including electronic anesthesia records, perioperative computerized decision support, and virtual patient care. We conclude with a brief review of perioperative informatics research and the role of the anesthesiologist-informaticist in leading and managing change in organizations, with particular focus on health care information technology as applied to the perioperative setting.

Informatics Defined

The concept of informatics comes from the philosophy of information, where information is defined as “data plus meaning.” The term “informatics” derives from computer science and in part from information science, with some European academic departments of computer science retaining this name [8,9]. The definitions of the informatics disciplines related to health care are briefly summarized in Table 1.

Table 1. Definitions of informatics disciplines.

Informatics discipline	Definition
Bioinformatics	The study of information in biology, especially molecular biology, and often used to refer to data generated by genomics research [10]
Biomedical informatics	The study of information as applied to biomedical science and used to inform clinical care, medical research, and public health [11]
Clinical informatics	The medical specialty involved in the use and management of information generated by patient care, clinical research, and electronic health record systems [12]
Public health informatics	The discipline involved in managing information in public health such as vaccine registries, biosurveillance, outbreak information, and disease surveillance [13]
Medical informatics	The management of information in health care settings [14] now often used to describe nursing or dental informatics, as opposed to clinical informatics which refers to the physician-led medical specialty
Pathology informatics	An early subdiscipline of clinical informatics, focusing on laboratory information systems, analysis of pathology images, and the use of information generated in pathology practice and research [15]
Anesthesiology informatics	A subdiscipline of clinical informatics dealing with the use of information generated by anesthesia practice and the management of anesthesia information management systems.
Surgery informatics	A subdiscipline of clinical informatics dealing with the use of information generated by surgical research and practice

Clinical Informatics

Anesthesiologists are hospital-based physicians who are trained to care for patients throughout their life span, ranging from pediatric to geriatric patients. Anesthesiologists are mainly found in the operating room, obstetrics suite, pain clinic, and the intensive care unit (ICU); however, they have significant clinical interaction with many hospital departments. They are physicians positioned to have a good overview of hospital systems because of their wide-ranging interactions with other clinical disciplines and their understanding of both medical and surgical perspectives on patient care. Anesthesiologists are focused on patient safety and quality improvement as a routine part of their work in many institutions, often working to improve perioperative processes and outcomes. For these reasons, after obtaining additional training, anesthesiologists may find themselves well suited to working in clinical informatics, either as a department-level physician champion or engaged in a system-wide informatics leadership role.

The current era of clinical informatics began with the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, created under Title XIII of the American Recovery and Reinvestment Act (ARRA). This Obama-administration legislation established a series of incentives for the “meaningful use” of EHRs and created the Office of the National Coordinator for Health Information Technology (ONC) to lead national efforts at improving health care information technology. This need led to the widespread adoption of EHRs in the United States and renewed interest in these systems' administration and governance [16]. The HITECH legislation established meaningful use as part of a set of priorities for developing health care information technology. At first, it entailed a series of stages with incentives for using the capabilities of EHRs and later with financial penalties for not using them [17].

Interoperability and exchange of electronic patient health data between institutions remain a significant concern for the discipline of clinical informatics. Patient sovereignty over their health data has been an elusive goal. The idea of a personal

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health record controlled and managed by the patient [18] who would then grant access to health care providers has not been developed into an essential part of the health care system. A system of health information exchanges has provided some degree of regional portability of patient data without ownership by any participating health care institutions [19]. True interoperability has not been achieved although efforts to create standards for accessing health data from EHRs have been made. The Health Level 7 (HL7) standard Fast Healthcare Interoperability Resources (FHIR) is one such protocol for standardized messaging that can facilitate the exchange of health information through health care information exchanges or between institutions [20].

Clinical informatics is a medical specialty at the intersection of health systems science, clinical care delivery, and information technology. All informaticists, including anesthesiologist-informaticists, must understand the broad issues involved with EHR administration and regulatory reporting, data messaging, and health information exchange. Efforts at improving the use of EHRs and the data contained therein are part of the overall goals of this specialty. In addition, anesthesia informatics encompasses specialty-specific concerns and competencies related to using the informatics body of knowledge across the perioperative clinical and research environments. Anesthesia-informaticians work toward improving clinician workflows, patient safety, and care quality in the perioperative arena [21].

Informatics is not synonymous with health care information technology (HIT), and clinical informaticians are distinct from HIT professionals. Information technology is a practical discipline that refers to the operational management of enterprise computer systems, software, and resources [14]. In contrast to HIT, clinical informatics is a scientific discipline that includes theoretical and practical knowledge regarding the use of information to improve systems in health care and address the triple aim of enhancing the quality of care for populations and individual patients and improving the cost-effectiveness of care. Clinical informatics has increasingly been called on to address provider satisfaction, burnout, and the equity of care delivery [22]. Notable goals of the informatics specialty include implementation and optimization of EHRs, the reuse of EHR data, the creation of computerized decision support tools, and the maintenance of privacy and security of health care information systems.

The medical specialty of clinical informatics encompasses the clinical care of patients, a systems-based understanding of the health care environment, and an understanding of information technology. Accordingly, informaticists must have mastery of medical knowledge, informatics, the health care system, the evaluation and function of health care information systems, human factors including how clinicians interact with those systems, and how to lead and manage change in organizations. The latter includes managing teams, understanding the discipline of project management, and effective strategic and financial planning for health information systems [23].

There are several roles for physicians specializing in clinical informatics. An executive-level role, the chief medical informatics officer or chief clinical informatics officer, has been created at many hospitals and health care systems. Often reporting to the chief medical officer, chief information officer, or both, this physician bridges between the clinical concerns of the medical staff and the technical health care information technology needs in an organization. She may provide clinical oversight for the electronic health record and delegate requests for informatics resources for clinical, research, or business intelligence purposes [24]. A second typical physician role is the physician champion, who is often involved with EHR implementation, ongoing optimization, and provider education. Leadership and change management are core competencies for clinical informaticists. Both chief medical informatics officers and physician champions take part in the organizational change management of EHR use and related clinical workflows [25]. Clinical informatics competency has become essential for other physicians in leadership roles ranging from department chairpersons, medical directors, clinical quality officers, and those involved with the administration of value-based care. Clinical informaticists may intersect with various careers across clinical operations in health care systems, clinical or basic biomedical research, or the industry of creating health care information technology tools.

Informatics Training Options

As clinical informatics has now become part of the medical school curriculum and residency training clinical competencies, there are several options for practicing anesthesiologists who would like to obtain additional training. The American Medical Informatics Association (AMIA) offers an online continuing medical education course called the “AMIA 10 x 10”, which is equivalent to an introductory graduate course in clinical informatics. The original intent of this course was to train 10,000 individual clinicians in informatics by 2010 [26]. The 10 x 10 online course is a good first step for practicing anesthesiologists who would like to learn more about clinical informatics with minimal time commitment.

At many institutions, master's degree–level training is available in biomedical informatics for those wishing to specialize in clinical informatics. The AMIA has defined a curriculum for core competencies for graduate education in biomedical informatics. These include fundamental skills around formulating and solving scientific problems, familiarity with scientific issues in biomedicine and population health, theories and methodologies particular to biomedical informatics, and technology-based skills and approaches [27]. Interested anesthesiologists may elect to pursue a master’s degree online or on a part-time basis while they continue to practice. This may appeal to anesthesiologists who plan to integrate perioperative informatics research with ongoing clinical practice. Some physicians may elect to continue their education and pursue a doctorate in philosophy (PhD) in biomedical informatics. This pathway, while not as common for trained physicians, has been undertaken by some who are planning to devote a significant portion of their career to informatics research. The National Libraries of Medicine (NLM) has been the primary supporter of graduate and postgraduate training in biomedical informatics since the 1970s and has provided

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graduate and postdoctoral fellowships for training in informatics [28].

The formalization of clinical informatics as a medical specialty started in 2007 when the American Medical Informatics Association became a full member of the Council of Medical Specialty Societies, a group of organizations that offer board certification through the American Board of Medical Specialties (ABMS) [29]. A core content outline was developed [23], and fellowship training requirements were described [30]. Permission was granted in 2010 for ABMS board certification administered jointly by the American Board of Pathology and the American Board of Preventative Medicine [31]. The first clinical informatics board certification cohort was in 2013. From 2013 through 2018, there were 1983 certifications issued, with 71 anesthesiologists receiving board certification. In terms of surgical specialists, during the same timeframe, 44 certificates were issued to general surgeons, 39 to obstetricians and gynecologists, 14 to ophthalmologists, 12 to head and neck surgeons, 10 to urologists, 5 to orthopedic surgeons, 3 to thoracic surgeons, 2 to colorectal surgeons, 2 to neurosurgeons, and 2 to plastic surgeons [32].

There is currently a practice pathway to board certification open to anesthesiologists and other physicians, requiring 25% effort dedicated to clinical informatics in 3 of the 5 years prior to application to take the board examination. The practice pathway to board certification will end after 2022, and after that time, interested physicians must complete a 2-year Accreditation Council of Graduate Medical Education (ACGME)–accredited fellowship in clinical informatics to attain eligibility for ABMS board certification in clinical informatics [32]. Physicians from any specialty may enter fellowship training. The fellowship programs are administered through a clinical department that may be from any primary medical specialty.

Finally, the AMIA Health Informatics Certification (AHIC) is open to physicians and nonphysicians who have completed an informatics graduate degree (master's or doctorate) and who have qualifying work experience in health care informatics. Anesthesiologists or other physicians interested in certification via the AHIC pathway must have spent at least 20% of their work time in health informatics during 8 of the preceding 10 years, or 50% or more time in health informatics work during 6 of the past 8 years. Qualifying candidates must pass a multiple-choice examination to earn their certification [33]. We expect that after the close of the practice pathway to ACGME board certification at the end of 2022, certification via AHIC will appeal to anesthesiologists who are working in clinical informatics on a part-time or full-time basis.

Anesthesiology Informatics

Anesthesiology informatics involves the intersection of medical care for surgical and procedural patients, perioperative clinical decision support, the management of anesthesia information systems, and anesthesia informatics research (Figure 1). Anesthesiologist-informaticists often act as physician champions for their anesthesia information management systems that capture patient vital signs, ventilator parameters, and medication administrations to form a complete and accurate medical record of anesthetic care. [21] Pain Medicine subspecialist anesthesiologists routinely use enterprise EHRs for patient care and may be involved in developing or using clinical decision support systems (CDSS) focused on the safe treatment of patients with acute or chronic pain [34,35]. Colleagues focused on resident and medical student education may run advanced, computerized simulation centers [36]. Anesthesiologist-informaticists involved in quality assurance, patient safety, or research may be interested in the secondary use of clinical data to measure patient outcomes across or between clinical populations. As of 2016, most board-certified anesthesiologist-informaticists had additional informatics duties outside of their clinical department while working as anesthesiologists. The majority did not have formal training in informatics [37].

A significant part of the effort of anesthesiologist-informaticists goes toward the implementation, optimization, and management of anesthesia information management systems (AIMS) which are the EHR components that keep the record of the intraoperative course of patients undergoing anesthesia. The AIMS may solely deal with tracking intraoperative vital signs, medication administration, and intraoperative events or may be more complex and encompass preoperative evaluation and postoperative care documentation. In turn, these systems may supply data for advanced analytics and visualization for clinical or research purposes [4,38].

The Society for Technology in Anesthesia (STA) is an international organization for anesthesiologists who have a particular interest in the technologies used in the operating room and the perioperative environment. The STA was founded in 1988 to improve the quality of patient care by improving technology and may serve as a home organization for anesthesiologists with a special interest in clinical informatics [39]. The STA mission encompasses all technology used in anesthesia practice and including but not limited to the digital technologies of interest to clinical informaticists. Outside of the STA, in an effort to improve the dissemination of knowledge in the field, an open-access journal explicitly dedicated to perioperative informatics, *JMIR Perioperative Medicine*, was founded in 2018.

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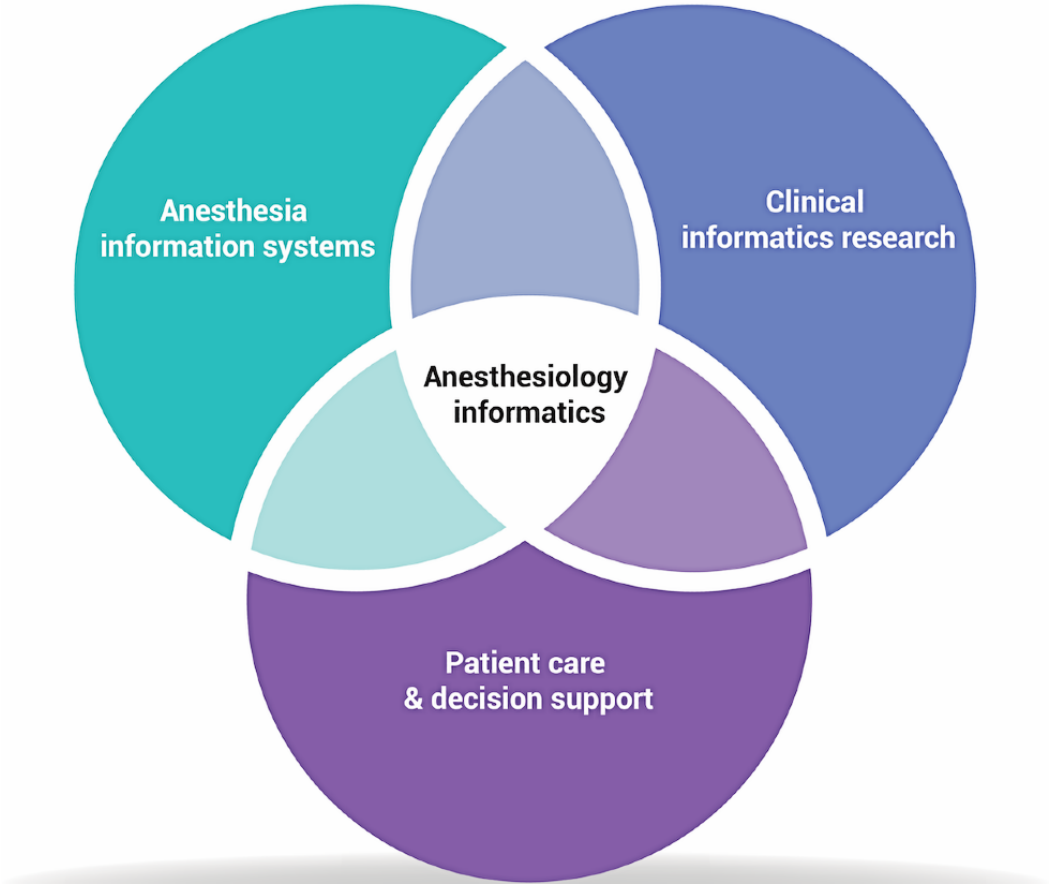
Figure 1. Anesthesiology informatics.



Management of Perioperative Information Systems

The Anesthesia Patient Safety Foundation (APSF) was founded in 1985 with the purpose of improving patient safety throughout the entire perioperative period. This process of renewed emphasis on safety in anesthesia led to many critical monitoring advances, such as widespread intraoperative use of pulse oximetry and continuous capnography. The APSF, as an industry leading organization in patient safety, determined that, to take the next step in improving the quality and safety of anesthesia care, the profession had to embrace the importance of clinical informatics and automated perianesthetic data management. This would enable anesthesiologists to pinpoint the problems responsible for preventable anesthetic morbidity and mortality [40].

Information systems used by anesthesiologists to obtain historical and laboratory information about patients include the hospital EHRs and laboratory information systems. Health information exchanges may be used to obtain history, imaging, or lab data from outside facilities. Anesthesia information management systems are used for the documentation of the pre- and intraoperative portions of patient care. Subspecialty colleagues may use specialized electronic record systems or decision support systems in the practice of critical care medicine [41] or pain medicine. Additional components to perioperative information systems are used to manage operating room staffing, patient flow, and case scheduling. [42]. Core competencies of clinical informaticians in the perioperative environment include understanding these systems and leading efforts at system implementation and ongoing optimization.

Anesthesiologist-informaticists who manage these information systems must understand the regulations and ethical considerations around patient privacy and data security. These concerns range from safeguarding patients by understanding the regulations enacted in 1996 by the HIPAA (Health Insurance Portability and Accountability Act) and the modifications from the 2013 Final Omnibus Rule, which added rules regarding breach notification. Anesthesiologist-informaticists may be champions for secure messaging in the hospital and operating room, using secure text or voice communications.

The oversight of remote monitoring systems for the operating room or ICU may fall under the purview of critical care anesthesiologists. These systems must be designed safely, with emphasis on an intuitive user experience and clear workflow to facilitate safe and effective patient care [43]. These ICU telehealth systems lend themselves to large-scale research by collecting data across clinical sites [44]. Dashboards for displaying information about the status of patients in the operating room or ICU have similar design and deployment considerations. These tools for data visualization can be used for practical purposes like improving turnover time in the operating room.

Tracking perioperative patient flow using radiofrequency identification for real-time location tracking is also becoming part of the informaticist's competencies. There has been an

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interest in using these technologies to track equipment locations in the hospital and the perioperative environment [45] For example, video laryngoscopes or ultrasound machines used for the practice of regional anesthesia could be tracked inside the operating room and supporting areas.

Clinical Decision Support in the Perioperative Environment

A major goal of informatics as a specialty has been to provide computerized clinical decision support to clinicians at the point of care. Quality clinical decision support has been characterized by the "five rights," which involves delivering accurate information, to the right person, in the proper format, through the right channels, and at the right time in the clinical workflow [46]. Examples of essential clinical decision support include order sets, such as postoperative order sets for use in the postanesthesia care unit that provide a previously determined selection of medications, using safe and reasonable dosage ranges. Computerized provider order entry is another basic form of decision support. Limitations on dosing can help prevent error, and automated checks against patient allergies and drug-drug interactions may occur. This may be especially helpful to improving medication safety in the operating room, as anesthesiologists order, compound, and administer medications directly in the operating room without a second clinician or nurse checking their work. Clinical decision support systems in the operating room as part of the AIMS may alert providers to allergies, medication interactions, or the need to treat alterations in patient hemodynamics. They can also give reminders as to the timely and appropriate administration of perioperative antibiotics and beta-blockers [47].

Alarm fatigue is well-known to anesthesiologists from the operating room [48] and is a topic relevant to the design and implementation of CDSS. When alarms are too frequent or meaningless, providers pay less attention to the signals, with the potential result that important, critical information may be missed. This is not only an issue in the operating room and the critical care environment, but has relevance to the design of clinical decision support pop-up messages in the AIMS or EHRs for alerting providers of an order with potential drug interactions or other patient safety issues [49]. Informaticians must design and manage CDSS to maintain potential safety benefits while minimizing clinician alarm fatigue and maintaining vigilance when presented with alerts.

Virtual Visits

There has been a surge in interest in the use of telehealth for patient visits during the COVID-19 pandemic to decrease patient throughput inside health care facilities. Indeed, widespread implementation of telehealth was undoubtedly a positive consequence of the pandemic and is here to stay. The idea of a medical virtualist as a distinct specialty for the provision of telehealth has been proposed [50]. Clinical informaticists consider telehealth systems as part of their expertise in health care information systems. Telemedicine systems may improve access to surgical specialists and decrease the time patients wait to be seen. Telehealth systems may facilitate postoperative follow-up by reducing patient travel time [51]. For anesthesiologist-informaticists, the use of virtual visits may include making preoperative and postoperative patient evaluation available without requiring patients to travel to the health care facility before or after their surgery [52].

Remote monitoring may be considered a form of virtual care. This has become commonplace in the ICU, with remote monitoring by intensivists providing additional patient safety [53]. Anesthesiologists using a team-based approach to care may monitor a patient's vital signs and anesthesia care information remotely from outside the operating room. Some facilities include video capability to observe the patient during anesthesia and surgery remotely [54].

Other forms of virtual interaction with the patient may include the asynchronous use of patient portals where patients may message providers, review their medical records, or request medication refills [55]. Pain medicine subspecialist anesthesiologists make extensive use of these patient portals to facilitate communication with patients. The Open Notes movement has made it so that many institutions provide full and immediate access to the patient of their medical records in an online format, which has led to improved communication between patients and clinicians [56].

Perioperative Informatics Research

Anesthesiologist-informaticists may be involved in clinical informatics research. The collection of patient information by EHRs and AIMS allows for data warehousing and secondary data reuse to inform extensive database studies. This can facilitate perioperative outcomes research through the use of data from large numbers of patients and quality improvement programs. It may become possible to solve challenging-to-answer clinical research questions that require large amounts of retrospective patient data for achieving adequate statistical power [57]. Two well-known examples of large anesthesia data aggregators are the Anesthesia Quality Institute's National Anesthesia Clinical Outcomes Registry [6] and the Multicenter Perioperative Outcomes Group, a data warehouse fed from multiple anesthesia information management systems [7]. The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) is an example of an extensive collection of surgical outcomes data.

There are persistent issues with the quality of data obtained from AIMS, especially missing or duplicated values [58]. Issues related to poor documentation quality and missing data are also found in EHR databases and present one of the major challenges that informaticists face when doing research. As techniques have been developed to work around data quality issues, the future design of EHRs and clinical databases may better address data quality concerns.

Further directions in informatics research include machine learning and natural language processing to obtain information from the accessible text portions of EHR data [59]. The improvement of how data is indexed from EHRs using ontologic

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approaches to make data computable and interchangeable between different electronic records is ongoing.

Perioperative Process Improvement, Leadership, and Change Management

Informaticists use health care systems knowledge and health information technology knowledge in an increasingly computerized clinical care setting to lead and affect change and improvements in clinical environments. It has been theorized that failures in the implementation of computerized clinical information systems have behavioral causes. For this reason, informaticists must develop leadership and change management competencies [60]. They may also be called upon to use their expertise to inform health care policy decisions.

Leadership efforts by anesthesiologist-informaticists include quality improvement in the perioperative environment. Quality improvement or quality assurance using EHR and AIMS data to compare patient outcomes against standard quality measures has become an important part of ensuring patient safety and reporting to insurance payors or regulatory authorities.

Burnout among anesthesiologists and surgical specialists has been reported to be at significant levels [61]. The computerization of clinical work—and specifically EHRs that are difficult to use—has been tied to decreased provider satisfaction and has been partly blamed for the trend toward clinician burnout [62]. Informaticists have a role in preventing and mitigating burnout by optimizing EHR systems to improve clinician workflows.

Informaticists may help perioperative clinicians with improving clinical documentation, including preoperative patient evaluations. They also teach providers how to document clinical care efficiently and effectively, with emphasis given to problematic issues like copying and pasting text from old records. Changing rules around clinical documentation may be monitored by anesthesiologist-informaticists who can then, in turn, disseminate information to colleagues and assist with changes in EHR templates and clinical workflows. Anesthesiologist-informaticists may be called on to map provider workflows in the operating room environment with an eye toward process improvement.

Ransomware attacks against health care systems and data breaches involving patient medical records are now frequently reported, and trained clinical informaticists can help lead efforts directed at risk mitigation and emergency response. Disaster planning for events such as the COVID-19 pandemic and other as-yet-unforeseen events requires attention to informatics infrastructure.

Informing clinicians regarding the use of social media in such a way as to ensure patient privacy falls under the responsibilities of the clinical informaticist. Anesthesiologists may use social media for sharing and disseminating information from the medical literature. Many anesthesia conferences including the American Society of Anesthesiologists' Annual Meeting and the New York State Society of Anesthesiologists' Post-Graduate Assembly now commonly use social media to inform attendees and have transmitted hashtags for use in attendee social media posts.

Conclusions

Anesthesiologist-informaticists have value in leading implementation and ongoing optimization efforts for anesthesia information management systems. They may improve clinical decision support systems for perioperative care or improve remote monitoring for patients in the operating room.

Anesthesiologist-informaticists will face a growing number of challenges in the future - acceleration in the use of perioperative health care information technology continues. There is increased volume and rapidity of data collection in the operating room environment. This will present challenges in how to best warehouse and transform this data for secondary use in research, clinical decision support, and informing business decisions in health care organizations. Integrating consumer health data into the preoperative EHR will present challenges around how to best use these data for preoperative evaluation and to improve patient outcomes, and require clinician oversight. As improving machine learning techniques make artificial intelligence a routine part of predictive analytics and advanced clinical decision support in the operating room, anesthesiologist-informaticists will be called on to ensure safe, effective, and ethical use of these new technologies.

In this paper, we have described the discipline of clinical informatics, presented options for anesthesiologists who would like to obtain further informatics training, and attempted to make the case that the anesthesiologist-informaticist can make significant contributions to meeting the challenges of the emerging field of perioperative informatics.

Conflicts of Interest

None declared.

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Abbreviations

ABMS: American Board of Medical Specialties
ACGME: Accreditation Council for Graduate Medical Education
ACS NSQIP: American College of Surgeons National Surgical Quality Improvement Program
AIMS: anesthesia information management system
AMIA: American Medical Informatics Association
APSF: Anesthesia Patient Safety Foundation
ARRA: American Recovery and Reinvestment Act
CDSS: Clinical Decision Support System
EHR: electronic health record
FHIR: Fast Healthcare Interoperability Resources
HIPAA: Health Insurance Portability and Accountability Act
HITECH: Health Information Technology for Economic and Clinical Health
HL7: Health Level 7
ICU: intensive care unit
NLM: National Libraries of Medicine
ONC: Office of the National Coordinator
STA: Society for Technology in Anesthesia

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Viewpoint

Worldwide Presence of National Anesthesia Societies on Four Major Social Networks in 2021: Observational Case Study

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Abstract

Background: Although the presence of medical societies on social networks (SNs) could be interesting for disseminating professional information, there is no study investigating their presence on SNs.

Objective: The aim of this viewpoint is to describe the worldwide presence and activity of national anesthesia societies on SNs.

Methods: This observational study assessed the active presence (≥1 post in the year preceding the collection date) of the World Federation of Societies of Anesthesiologists member societies on the SNs Twitter, Facebook, Instagram, and YouTube. We collected data concerning each anesthesia society on the World Federation of Societies of Anesthesiologists website.

Results: Among the 136 societies, 66 (48.5%) had an active presence on at least one SN. The most used SN was Facebook (n=60, 44.1%), followed by Twitter (n=37, 27.2%), YouTube (n=26, 19.1%), and Instagram (n=16, 11.8%). The SN with the largest number of followers was Facebook for 52 (78.8%) societies and Twitter for 12 (18.2%) societies. The number of followers was 361 (IQR 75-1806) on Twitter, 2494 (IQR 1049-5369) on Facebook, 1400 (IQR 303-3058) on Instagram, and 214 (IQR 33-955) on YouTube. There was a strong correlation between the number of posts and the number of followers on Twitter (r=0.95, 95% CI 0.91-0.97; P<.001), Instagram (r=0.83, 95% CI 0.58-0.94; P<.001), and YouTube (r=0.69, 95% CI 0.42-0.85; P<.001). According to the density of anesthetists in the country, there was no difference between societies with and without active SN accounts.

Conclusions: Less than half of national anesthesia societies have at least one active account on SNs. Twitter and Facebook are the most used SNs.

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KEYWORDS

social network, social media; anaesthesia; society; Facebook; Twitter; Instagram; YouTube

Introduction

In a globalized world, social networks (SNs) have taken a major place in the medical field and are essential tools for promoting research, medical innovations, and news from each specialty (eg, prompting novel techniques and disseminating new findings in congresses). For a medical society, the wide dissemination of each of its activities and news about its specialty is necessary to reach a large audience (eg, professionals of the sector, patients, residents, and medical students). In this context, the use of SNs by medical societies allows every information to be disseminated very quickly and at a low cost.

The most followed SNs are Facebook (2.79 billion users), YouTube (2.29 billion users), Instagram (1.29 billion users), and Twitter (396 million users) [1,2]. It has been recently described that among professionals working in anesthesia, intensive care medicine, and emergency medicine, 78% consulted Facebook, 41% Instagram, 40% YouTube, and 17%

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Twitter at least once a week [3]. This professional use of SNs is expected to increase with the arrival of young physicians, as it was reported that 35% of medical students used Twitter for teaching purposes [4]. Moreover, younger generations are increasingly using SNs as their primary means of finding information about a brand or society (this use even exceeds that of internet search engines among 16- to 24-year-olds), and the primary reason for using social media is to "stay up-to-date with news and current events" [1]. The time spent using SNs is constantly increasing from 1 hour and 51 minutes per day in 2015 to 2 hours and 25 minutes per day in 2020 [1]. Finally, several articles describe the value of using SNs (and in particular Twitter) for medical education [5,6]. Thus, more and more teachers and societies in several medical specialties are using SNs to highlight their educational content [7,8]. These elements illustrate the interest and importance for a society wishing to have visibility to position itself on SNs.

It is known that, for a given medical journal, articles that benefit from exposure on SNs are more cited than articles that are not [9,10]. Thus, more and more journals are using SNs to optimize their visibility into the scientific community. It is thus likely that a medical society present on SNs will be more visible to the medical community. The viral transmission of information that these networks allow is probably a key element to promote initiatives, valorize research results, and inform about trainings or congresses. However, although the presence of medical societies on SNs could be interesting for disseminating professional information, there is no study investigating their presence on SNs.

The objective of this study was to explore the worldwide presence and activity on SNs of national anesthesia societies.

Methods

Ethical Considerations

As a retrospective analysis of publicly available data that did not involve human subjects (and in accordance with French laws), this study was exempt from institutional ethics board review [11]. The results are reported in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement [12].

Objectives

The main objective of this work was to describe the presence of the World Federation of Societies of Anesthesiologists (WFSA) member societies on the most popular SNs (ie, Twitter, Facebook, Instagram, and YouTube). The secondary objective was to assess the factors within societies (and their country) associated with the presence or absence of these societies from SNs.

Data Collection

To limit the impact of profile variations on SNs, the entire data collection was carried out manually over 20 consecutive days in May 2021.

We determined the active presence or absence of WFSA anesthesia societies on SNs using the societies' list available on the WFSA website [13]. An active presence on a given network was defined as the publication of at least one item of content (eg, post, tweet, and video) by the account over the 12 months preceding the collection. For each anesthesia society on each SN, the screening for finding SN accounts had a step-by-step procedure, which is as follows: (1) the name of the society was entered into the SN search engine using the language used to name the society on the WFSA website; (2) if no account was found after this first step, a similar search was carried out using the language of the country if it differed from the language used on the WFSA website (eg, Chinese and Arabic); (3) if no account was found after the second step, a similar search was conducted using the acronym of the society's name (eg, "ASA" for the American Society of Anesthesiologists); and (4) if no account was found after the third step, we performed an internet search using the Google search engine and using the keywords [society name] and [SN name] (eg, "Taiwan Society of Anesthesiologists Twitter").

If no account was found on an SN after the abovementioned steps, the society was considered not to have an active account on that network and was categorized as "absent." An identified account of a society that had not published for more than a year was considered inactive and was therefore also categorized as "absent."

When an account was found, the following data were collected from the public information presented on the accounts concerned: (1) for Twitter—number of tweets, number of followers, and year of creation of the account; (2) for Facebook—number of followers and year of creation of the account (there were no data concerning the number of posts for a given account on Facebook); (3) for Instagram—number of posts and number of followers (there were no data concerning the year of creation of a given account on Instagram); and (4) for YouTube—number of videos, number of followers, and year of creation of the account.

The following data for each society were collected from the WFSA website: preferred language of the society, number of society members, and number of physician anesthesia providers as well as their density in the country. For societies that did not indicate a preferred language on the WFSA website, the language that was considered to be preferred was that of the home country or the company's website if it had one.

Statistical Analysis

The values are presented as number and percentage (n, %) for qualitative variables, and as median (IQR) for quantitative variables. After ensuring the nonnormal distribution of the data by a Shapiro-Wilk test, quantitative variables were compared using a Mann-Whitney test. The qualitative variables were analyzed using a chi-square test. The Pearson correlation test was used to assess the strength of the association between 2 quantitative variables. A multivariable analysis was realized to identify factors related to anesthesia societies that were associated with the existence of at least one active account on SNs. Variables presenting $P<0.3$ in the univariable analysis were included in the multivariable analysis, which was performed using a logistic regression model with a backward stepwise model. The results are presented as odds ratio (OR) with 95% confidence intervals.

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All statistical tests were 2-sided, and the .05 probability level was used to establish statistical significance. All statistics were produced using PRISM (v8.0.2, GraphPad Software) and MedCalc (v14, MedCalc Software Ltd) software.

Results

Population Description

A total of 136 anesthesia societies were analyzed. Of these 136 societies, 66 (48.5%) had an active presence on at least one SN. The most used SN was Facebook (60/136, 44.1%), followed by Twitter (37/136, 27.2%), YouTube (26/136, 19.1%), and Instagram (16/136, 11.8%). All SNs had a fraction of accessible but inactive accounts (Figure 1). The number, geographical location, and type of SNs actively used by national anesthesia societies are summarized in Figure 2 and supplemental Figure S1 (Multimedia Appendix 1). The SN with the largest number of followers was Facebook for 52/66 societies (78.8% of societies present on SNs) and Twitter for 12/66 societies (18.2%; Figure 3). Only 2 societies had Instagram (1/66 society; 1.5%) or YouTube (1/66 society; 1.5%) as their first source of followers (Figure 3).

Figure 1. Proportion of national anesthesia societies with an account on Twitter (A), Facebook (B), Instagram (C), and YouTube (D). An active presence on a given network was defined as the publication of at least one item of content (eg, post, tweet, and video) by the account over the 12 months preceding the data collection; 136 societies were analyzed.

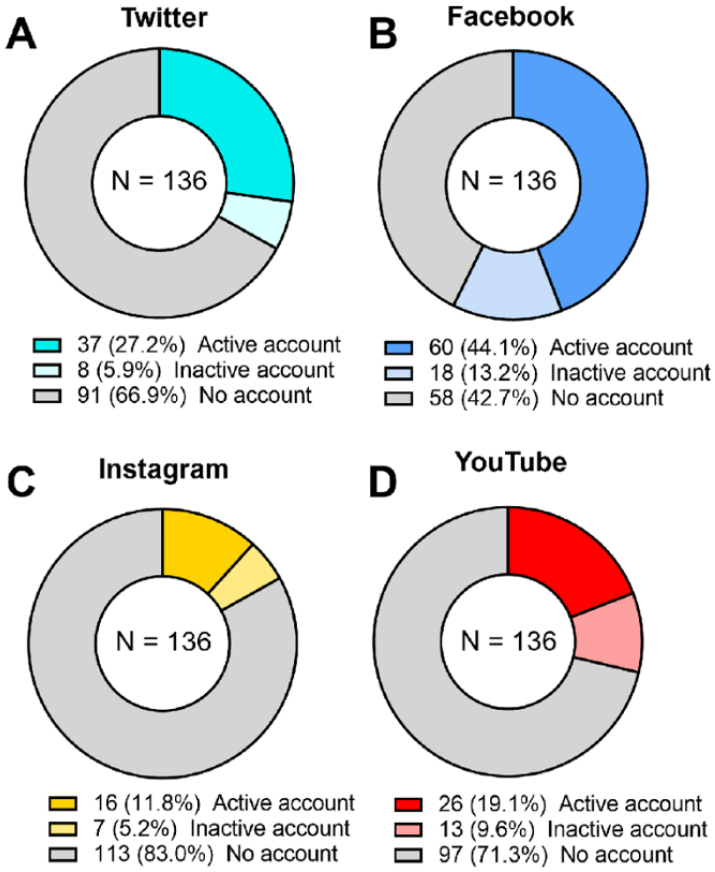

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Figure 2. Number and type of social networks actively used by national anesthesia societies across the world.

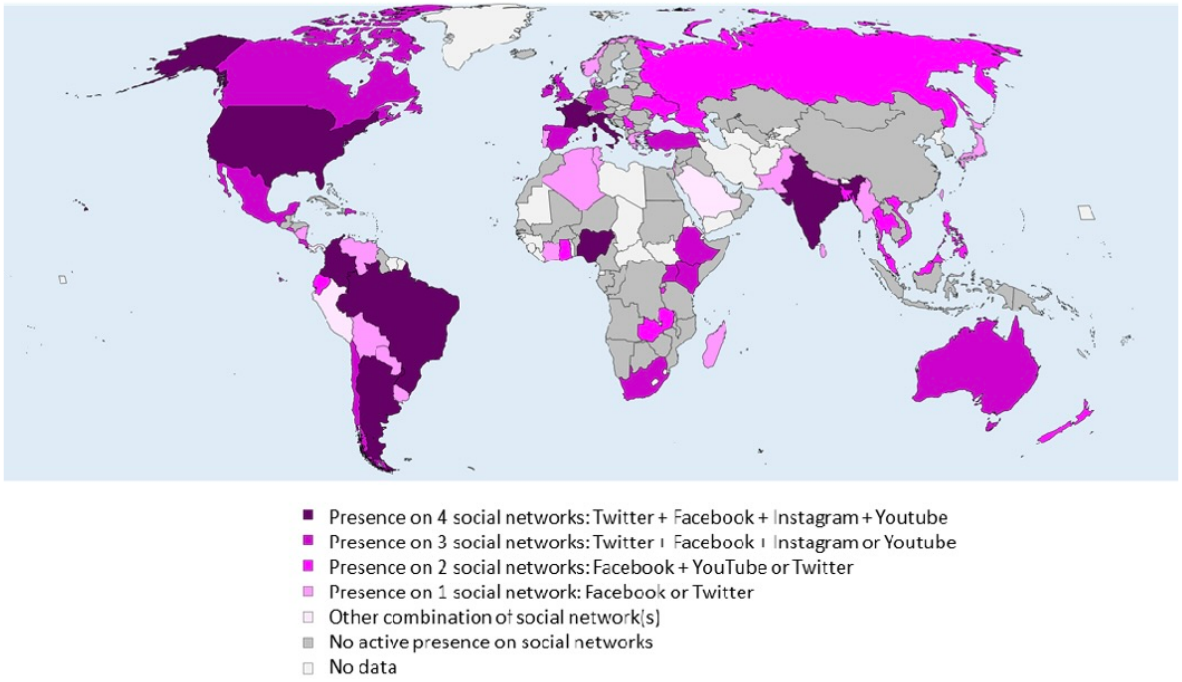
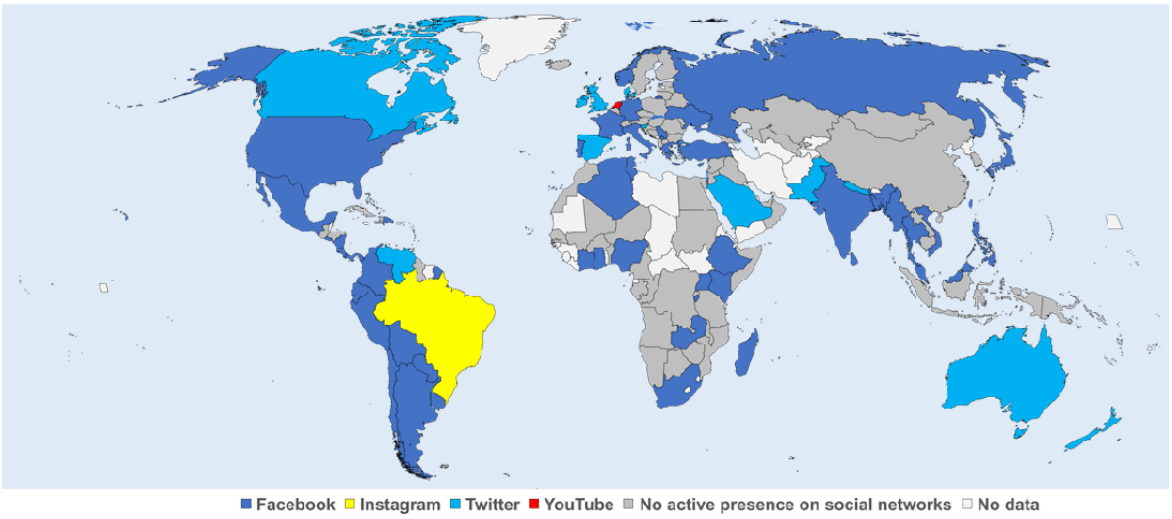


Figure 3. Active social network account with the largest number of followers among national anesthesia societies across the world.



Activity of Anesthesia Societies on SNs

The first anesthesia societies' accounts on SNs were created in 2009-2010 with faster growth for the number of Facebook accounts; 2011 and 2016 were the 2 years with the highest number of account creation for this SN (>11 accounts per year; Figure 4). Growth in the number of accounts on other SNs was slower, with 2017 and 2020 being the years with the highest number of accounts created on Twitter (>6 accounts per year) and 2020 the year with the highest number of accounts created on YouTube (>10 accounts; Figure 4). There were no publicly available data concerning the creation date of Instagram accounts.

Among the 66 societies with at least one active account on SNs, the number of followers was 361 (IQR 75-1806) on Twitter, 2494 (IQR 1049-5369) on Facebook, 1400 (IQR 303-3058) on Instagram, and 214 (IQR 33-955) on YouTube (Figure 5, part A). The number of posts (eg, tweet and video) on the accounts was 295 (IQR 66-1459) on Twitter, 152 (IQR 54-560) on Instagram, and 25 (IQR 6-132) on YouTube (there were no publicly available data on the number of Facebook posts; Figure 5, part B). The individual data for each company are available in Multimedia Appendix 2.

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Figure 4. Proportion of national anesthesia societies with an active account on Twitter, Facebook, and YouTube over time. The ordinate scale is logarithmic. There were no publicly available data concerning the creation date of Instagram accounts.

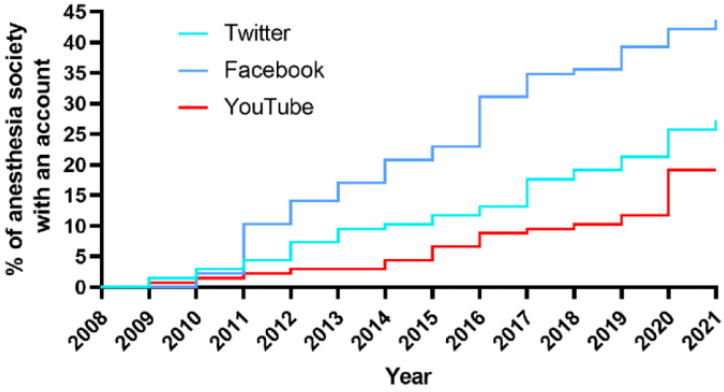
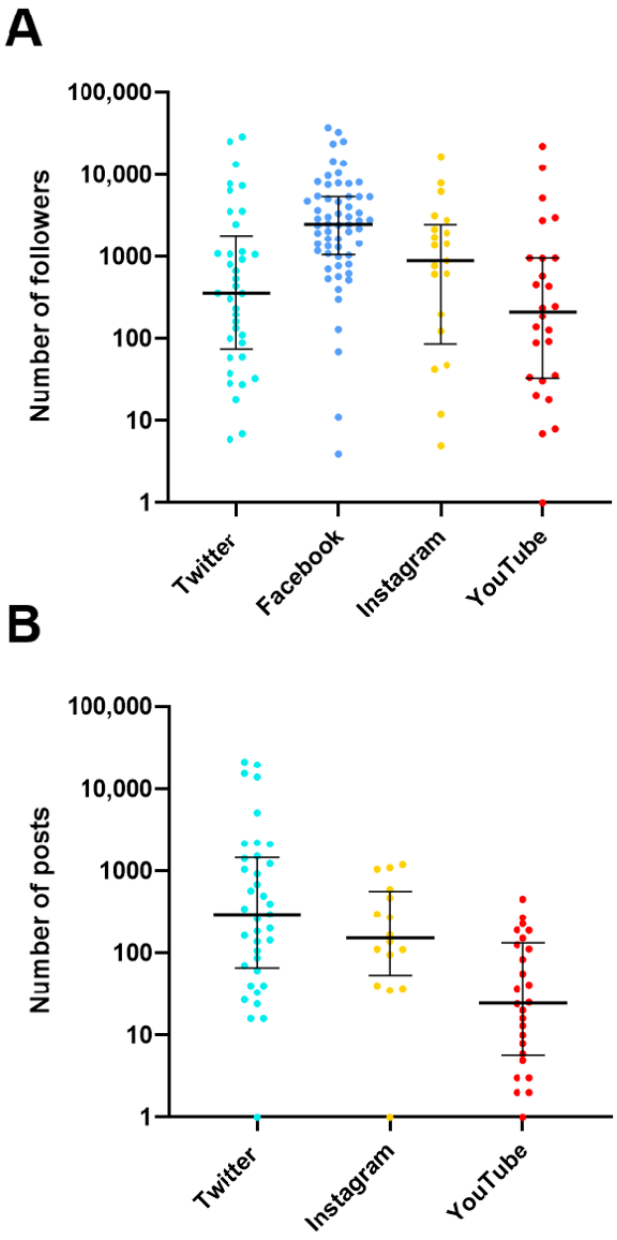


Figure 5. Numbers of followers (A) and posts (B) of national anesthesia societies' active social network accounts. The ordinate scale is logarithmic. The number of followers and posts are presented as dot plots with the median and interquartile range. There were no publicly available data on the number of Facebook posts over time.



There was a strong correlation between the number of posts and the number of followers on Twitter (r=0.95, 95% CI 0.91-0.97; P<.001), Instagram (r=0.95, 95% CI 0.58-0.94; P<.001), and YouTube (r=0.69, 95% CI 0.42-0.85; P<.001). There was a

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correlation between the number of members of a society and the number of followers on Instagram (r=0.86, 95% CI 0.63-0.95; P<.001); however, there was no correlation between the number of members of a society and the number of followers on Twitter (r=–0.04, 95% CI –0.37 to –0.30; P=.82), Facebook (r=0.09, 95% CI –0.18 to 0.34; P=.52), and YouTube (r=0.20, 95% CI –0.21 to 0.55; P=.32). There was a moderate correlation between the number of physician anesthesia providers in the country and the number of followers on Twitter (r=0.55, 95% CI 0.27-0.75; P<.001) and Facebook (r=0.44, 95% CI 0.21-0.63; P=.001); however, there was no correlation between the number of physician anesthesia providers in the country and the number of followers on Instagram (r=0.49, 95% CI –0.01 to 0.79; P=.05) and YouTube (r=0.15, 95% CI –0.26 to 0.52; P=.46).

Characteristics of National Anesthesia Societies With or Without Active Presence on SNs

Anesthesia societies with at least one active account on SNs had more members and were located in countries with a higher number of physician anesthesia providers (Table 1). There was no difference between societies with and without active social networking accounts according to the density of anesthetists in the country and the proportion of physician anesthesia provider members in the society (Table 1). The group of societies with at least one active account on SNs had more Spanish-speaking societies but fewer French-speaking societies compared with the group of societies without any account on SNs (Table 1).

We performed a multivariable analysis including the number of physician anesthesia providers, their density in the country, and the preferred language of the society. Spanish as society's preferred language was associated with the existence of at least one active account on SNs (OR 5.39, 95% CI 1.46-20.00; P=.01). The number of physician anesthesia providers and their density in the country were not associated with the existence of at least one active account on SNs (OR 1.00, 95% CI 1.00-1.00; P=.25 and OR 1.02, 95% CI 0.97-1.06; P=.47, respectively).

Table 1. Characteristics of national anesthesia societies with or without an active presence on social networks.

Characteristics	With an active presence on at least one social network (n=66)	Without an active presence on social networks (n=70)	*P* value
Anesthesia society members, n (IQR)	317 (100-1144)	70 (28-245)]	<.001
Physician anesthesia providers in the country, n (IQR)	1050 (376-4464)	290 (60-1000)	<.001
Physician anesthesia providers' density in the country (per 100,000 population), n (IQR)	6.57 (1.67-15.17)	6.01 (0.62-12.5)	.22
Percentage of physician anesthesia providers in the country, n (IQR)	44.8 (25.8-69.1)	42.8 (26.4-74.0)	.86
Preferred language of the society, n (%)			.007
English	42 (64)	52 (74)	
Spanish	16 (24)	3 (4)	
French	5 (8)	11 (16)	
Other or unknown	3 (4)	4 (6)	

Discussion

Principal Findings

To our knowledge, we describe for the first time the presence and activity of national anesthesia societies on SNs. We also explore for the first time the link between these societies' characteristics and their presence (or lack thereof) on SNs. Less than 50% of WFSA member societies have at least one active account on SNs. This number is low, especially since the first accounts were created more than 10 years ago. At a time when people spend almost 2.5 hours a day on SNs, it is interesting to note that many societies have not yet been willing or able to integrate SNs into their communication strategy [1]. However, it is interesting to note a recent (2020) increase in the number of anesthesia society accounts on Twitter and YouTube. This may reflect an awareness of the importance of having a wide visibility for a medical society, which is now partly achieved through these networks. The evolution of the number of societies present on SNs in the coming years will show whether this trend of increasing the number of accounts continues.

The worldwide distribution of societies with and without an active presence on SNs is heterogeneous. The majority of the active societies are from America, Western Europe, Southeast Asia, and Oceania. We could have made the hypothesis that low-income countries with less access to new information technologies would have less presence on SNs. Nevertheless, we observe that several anesthesia societies from high-income countries are also absent from SNs (eg, Sweden, Austria, Belgium, Switzerland, and South Korea) while several societies from transitional countries are active (eg, Burundi, Ghana, Madagascar, Venezuela, and Nigeria). Furthermore, the density of physician anesthesia providers was not associated with the presence or absence of a national society on SNs. These data suggest that, more than purely economic, demographic, or social factors, the presence or absence of a society on SNs may be the result of the individual initiatives of each society and its willingness to position itself or not on these networks. Thus, the fact that a Spanish-speaking society is more likely to have an active account on SNs compared with English- or French-speaking societies reflects the dynamics of South American societies on these networks. Finally, there are

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probably also geopolitical factors that may explain the absence of some societies (eg, Cuba and China) on SNs created by US companies. China also has its own ecosystem of SNs (eg, WeChat and Sina-Weibo), and it is therefore likely that the communication of the Chinese Society of Anesthesiology (which represents 72,000 physician anesthesia providers) is carried out through these national networks.

By far, the most used SN by anesthesia societies is Facebook, which has more and older accounts. Facebook is also the SN with the highest number of followers for the majority of societies. This is consistent with the fact that it is the SN with the most users in the world [1]. If Facebook is a network used by all age groups (in 2020, 76% of 18- to 24-year-olds used it vs 79% of 30- to 49-year-olds), Instagram and Twitter are networks used mainly by young people with respectively 75% and 44% of users among 18- to 24-year-olds (vs 47% and 26% among 30- to 49-year-olds, respectively) [14]. Moreover, while 61% of Facebook users have attended university, 69% of Instagram users and 75% of Twitter users did the same [15]. Finally, while men constitute the majority of Facebook and Twitter users (56% and 68% of users, respectively), women represent the majority on Instagram (57%) [16]. Therefore, Instagram and Twitter networks reach, on average, younger people with a higher level of education compared with Facebook; and more women use Instagram compared with any other SN platform. Taken together, these data suggest that it appears important to increase the presence of anesthesia societies on Twitter and Instagram to gain and maintain visibility among the younger educated generations, part of which comprises junior physicians and medical students. In this context, it is interesting to note that several large anesthesia societies with a strong presence on SNs have the most followers on Twitter (eg, Australia, New Zealand, Canada, Spain, United Kingdom, and Ireland).

Regardless of the SNs analyzed, the number of followers was strongly correlated to the volume of publication of the account. Maintaining and improving one's presence on SNs therefore requires regular publication of information about the society and the specialty, which is a constant task requiring a real investment of time and sometimes money from the society. This perhaps explains why, on all SNs, there was a variable proportion of accounts created, which were inactive due to a lack of organized logistics or lack of willingness to maintain the accounts. The number of followers on Facebook and Twitter correlated with the number of physician anesthesia providers in a given country but not with the number of society members in that country. These data may suggest that Facebook and Twitter accounts reach a broad audience (ie, all physician anesthesia providers) beyond the society members who originate the account. The fact that the number of followers on Instagram correlates strongly with the number of members of the society but not with the overall number of physician anesthesia providers suggests, on the other hand, that the followers of this SN mainly come from the society itself and that it reaches less broadly the whole anesthetic community in a country. However, these suggestions are only hypotheses, and more detailed surveys within each country would be needed to interpret these results with certainty.

Limitations

Despite the interesting results, our study has several limitations. First, this work was limited to anesthesia societies that are members of the WFSA. The selection of this population allowed us to have access to information on the societies available on the WFSA website (eg, preferred language and number of members) and enabled us to analyze only the existing and active societies. However, we did not include all national societies worldwide. The fact that the WFSA includes a majority of the existing societies probably limits the bias induced by this choice. Second, the data on the number of physician anesthesia providers in a country and their density are from the 2015-2016 period [17]. New measurements are currently underway, but it is possible that some of these data have changed between 2015 and 2021. However, it is unlikely that there has been a major change in density or medical ratios during this period. Third, even a standardized manual account search procedure has its flaws. Some societies may use a pseudonym other than their society name or an acronym or misspelled name when they register. It is therefore possible that our referencing, while rigorous, has missed some societies active on SNs. Fourth, we only focused on 4 SNs. However, since Facebook, Twitter, Instagram, and YouTube are part of the 5 most visited website in the world and given the low rate of the anesthesia societies' presence on these major networks, it would probably have been wasteful to seek their presence on other SNs [1]. Fifth, we did not assess the relative impact of social media presence for the societies studied (eg, likes or retweets per post, number of visualizations of videos, and number of followers). We can thus describe the presence of these societies on social media but cannot define the impact of such presence on their visibility.

In conclusion, the rate of national anesthesia societies having at least one account on SNs appears relatively low in view of societal developments in SN use. This low presence rate suggests that there is still significant room for improvement in highlighting anesthesia on SNs. Each medical society could consider its communication strategy and give itself the means to use this communication tool to promote its activity and initiatives. The active or inactive presence of a society on SNs does not seem to be influenced by the socioeconomic context or the density of anesthetists in the country. Thus, being present on SNs appears to be more the result of a strategic choice by the society than the human or material means available to achieve this.

What is Known

- SNs have taken a major place in the medical field, but the worldwide presence of national anesthesia societies on SNs is not known.

What is New

- Among 136 societies, 66 (48.5%) had presence on at least one SN.
- The most used SN was Facebook (60/136, 44.1%), followed by Twitter (37/136, 27.2%).
- Less than half of anesthesia societies have an active account on SNs.

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Acknowledgments

Support for this study was provided solely from departmental sources.

Data Availability

The raw data supporting the conclusions of this manuscript can be made available upon request by the authors to any qualified researcher.

Authors' Contributions

TC was involved in study conception and design, in acquisition of data, in analysis and interpretation of data, and in manuscript draft. EO, CG, NV, CH, and JS were involved in acquisition of data, in interpretation of data, and in manuscript draft. VC, BV, and EB were involved in the study conception and design, in interpretation of data, and in manuscript revision. All authors read and approved the final manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Presence on social networks of national anesthesia societies that are members of the World Federation of Societies of Anesthesiologists. Each line corresponds to a country, and each column to a social network. If the national society is present on a given network, the corresponding box is colored (light blue for Twitter, dark blue for Facebook, yellow for Instagram, and red for YouTube). If the society is not present on the social network, the box is gray.
[PDF File (Adobe PDF File), 57 KB - periop_v5i1e34549_app1.pdf]

Multimedia Appendix 2
Individual data of social network activity for each anesthesia society.
[XLSX File (Microsoft Excel File), 21 KB - periop_v5i1e34549_app2.xlsx]

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Abbreviations

OR: odds ratio
SN: social network
STROBE: Strengthening the Reporting of Observational studies in Epidemiology
WFSA: World Federation of Societies of Anesthesiologists

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Review

The Use of Electronic Consultations in Outpatient Surgery Clinics: Synthesized Narrative Review

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Abstract

Background: Electronic consultations (eConsults) are an increasingly used form of telemedicine that allows a nonspecialist clinician to seek specialist advice remotely without direct patient-specialist communication. Surgical clinics may see benefits from such forms of communication but face challenges with the need for intervention planning.

Objective: We aimed to use the Quadruple Aim Framework to integrate published knowledge of surgical outpatient eConsults with regard to efficacy, safety, limitations, and evolving use in the era of COVID-19.

Methods: We systematically searched for relevant studies across four databases (Ovid MEDLINE, Embase, Scopus, and Web of Science) on November 4, 2021, with the following inclusion criteria: English language, published in the past 10 years, and data on the outcomes of outpatient surgical eConsults.

Results: A total of 363 studies were screened for eligibility, of which 33 (9.1%) were included. Most of the included studies were from the United States (23/33, 70%) and Canada (7/33, 21%), with a predominant multidisciplinary focus (9/33, 27%). Most were retrospective audits (16/33, 48%), with 15% (5/33) of the studies having a prospective component.

Conclusions: The surgical eConsult studies indicated a possible benefit for population health, promising safety results, enhanced patient and clinician experience, and cost savings compared with the traditional face-to-face surgical referral pathway. Their use appeared to be more favorable in some surgical subspecialties, and the overall efficacy was similar to that of medical subspecialties. Limited data on their long-term safety and use during the COVID-19 pandemic were identified, and this should be the focus of future research.

(JMIR Perioper Med 2022;5(1):e34661) doi:10.2196/34661

KEYWORDS

telemedicine; telehealth; electronic consultation; electronic referral; surgery; outpatient; consultation; usage; review; referral; advice; communication; framework; efficacy; safety; limit

Introduction

Background

The SARS-CoV-2 pandemic has potentiated an increased uptake of telemedicine by health practitioners [1-4]. Telemedicine refers to a broad range of electronic services that obviate the need for face-to-face interactions but maintain the same patient-physician relationship [5-10].

An emerging component of telemedicine is electronic consultations (eConsults). eConsults are asynchronous clinician-to-clinician consultations via a secure web-based platform. They allow a primary care provider (PCP), such as a physician, nurse practitioner, or physician assistant, to seek

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nonurgent specialist advice remotely without direct contact between the patient and specialist [11]. eConsults may be used to replace an in-person consultation or ensure that an appropriate workup is completed before a face-to-face visit. They represent a well-documented, asynchronous replacement of the *curbside* consultation. eConsults differ from electronic triage systems that prioritize the urgency of patient-specialist consults rather than replacing them.

The entry point for the PCP into the eConsult system depends on the structure of the health service [12]. In *optional-pathway* services, the PCP is able to choose to refer their patient via a face-to-face pathway or via an eConsult. Conversely, in *single-pathway* services, the PCP must refer the patient via an eConsult, and the specialist can then decide if a subsequent face-to-face visit is necessary (Figures 1 and 2) [13-16]. Some eConsult services set clear criteria, such as mandatory investigations before lodging an eConsult. The information returned from the specialist via the eConsults provides the PCP with assistance with diagnosis, imaging interpretation, and advice on management [17]. The web-based communication platform may be a health service–specific program, or a shared electronic medical record (EMR), where the correspondence is recorded [18,19]. Outcomes include scheduling a face-to-face appointment if required or giving management advice virtually. In some cases, eConsults undergo an iterative process in which the specialist requests further information before making a decision.

Figure 1. Basic flowchart of the *optional-pathway* electronic consultation (eConsult) referral process. Primary care providers (PCP) are given a choice between referring via a traditional in-person visit or via an eConsult.

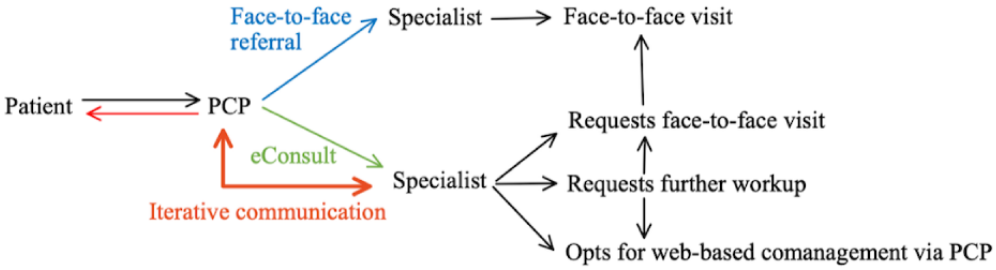
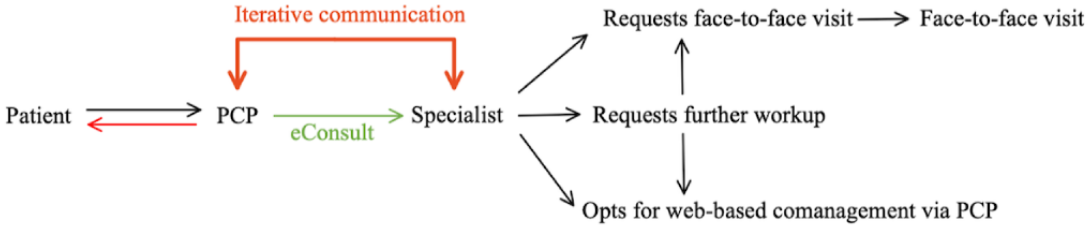


Figure 2. Basic flowchart of the *single-pathway* electronic consultation (eConsult) referral process. In this structure, all specialist referrals are submitted as eConsults. PCP: primary care provider.



eConsults address the limitations of the current medical system. From an equity perspective, disadvantaged demographics [20-23] can engage specialists, as eConsults are more economical for these groups, by bypassing social barriers and reducing travel and work expenses [24,25]. eConsults can address lengthy specialist wait times [26] to obviate specific bottlenecks in the referral pathway [27]. The lack of physical contact in eConsults means that they can still operate even within social distancing restrictions [28-31].

The feasibility of eConsults in medicine has been studied extensively [32-38]; however, their role in the surgical stream is less well-understood [39-41]. Surgical and medical eConsults differ in the variety of conditions, and those surgical conditions may require an intervention. At face value, this may imply that surgical subspecialties lend themselves less to eConsults as a face-to-face visit may be inevitable for assessment and consent [42]. Multispecialty studies have shown different patterns of eConsult use in medical and surgical conditions. For example, the eConsult requester seemed more likely to be a nurse practitioner familiar with surgical compared with medical eConsults [43]. Another study suggested that PCPs deem surgical eConsults to be of lower quality than medical eConsults [44].

Objectives

The aim of this review is to build on previous systematic reviews of eConsults by focusing specifically on utility and outcomes in surgical outpatients. We synthesize our assessment using the Quadruple Aim Framework [45], which helps guide the assessment of ideal health service performance outcomes. The four components of this framework are (1) improving the health of the population, (2) enhancing patient experience of care, (3) reducing per capita cost of health care, and (4) improving the work life of health care clinicians and staff. These 4 goals are interrelated and serve to maximize the primary goal of improving population health. The role of the Quadruple Aim Framework in eConsult evaluation has been established elsewhere [12,46] and was used in a recent eConsult systematic review [40]. For the purposes of this review, we use *clinicians* to refer to PCPs and specialists.

Methods

Protocol

This study used a narrative review with a systematic approach. We used the PRISMA (Preferred Reporting Items for Systematic

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Reviews and Meta-Analyses) guidelines to conduct the search strategy.

Search Strategy

On November 4, 2021, we conducted a search of four databases (Ovid MEDLINE, Ovid Embase, Web of Science, and Scopus). The reference lists of review articles were scanned for additional studies. Electronic referrals (*eReferrals*) differ slightly from *eConsults* in that their primary goal is to expedite a patient's workup before an in-person specialist visit; however, terminology in this field is variable [47], and, for the purpose of this review, these terms were combined. Thus, the search terms were one for eConsults (eg, *eConsult* and *eReferral*) and one for surgical subspecialties (eg, *surgery* and *orthopaedics*; Multimedia Appendix 1). The search was limited to articles in English and those published in the past 10 years (2011-2021), given that most modern eConsult platforms were studied after 2010.

Eligibility Criteria

The inclusion criteria were studies on outpatient surgical eConsults, eReferrals, and store-and-forward telemedicine consults that included dedicated surgical articles and articles that included surgical eConsults as a subanalysis of a multispecialty cohort. We only included eReferral services that allowed for iterative PCP-specialist communication. We only included original studies (including observational and experimental studies) of outpatients. We excluded studies on asynchronous clinician-to-clinician communication that did not use an appropriate platform for shared patient information (eg, surgical wound images). We excluded all conference abstracts, case reports, editorials, notes, and letters.

Study Selection

The titles and abstracts of the obtained articles were screened by an investigator (TP) as per the inclusion criteria. Moreover, 2 investigators (TP and HT) critically appraised all the included articles independently. Disagreements regarding article inclusion were resolved through discussion between the 2 investigators.

Data Extraction

Data were extracted into a Microsoft Excel spreadsheet independently by 2 investigators (TP and HT) into categories corresponding to the relevant study objectives. Extracted data included study variables (author, title, year, country, and surgical subspecialty), eConsult service design, study outcome data, and study conclusions.

Narrative Synthesis

A narrative synthesis was more appropriate than other synthesis methods (including meta-analysis), given the significant heterogeneity in eConsult service designs and outcome measures and the overlapping eConsult data between studies [48]. The data were synthesized by grouping together similar outcome metrics across all studies to provide a range and by grouping surgical subspecialties together to compare findings across and within different fields. The obtained narrative synthesis information was subdivided into sections using the Quadruple Aim Framework as a guide. In cases where systematic reviews were identified, we extracted key discussion points to include in our study. The findings of our narrative synthesis were depicted in tabular and schematic diagram form. Individual appraisals of study quality were not performed because of time and personnel constraints and were beyond the scope of this review.

Results

Overview

A total of 33 studies were included (Figure 3). The characteristics of the studies analyzed are outlined in Table 1, and detailed descriptions of the studies are provided in Multimedia Appendix 2 [11,18,19,27,39,40,43,44,49-73]. Most of the included studies were published in the past 5 years (26/33, 79%), and half were from surgical journals (17/33, 52%), mainly from North America (30/33, 91%). eConsults were most represented in urology, otolaryngology, and obstetrics and gynecology.

Most of the included studies used a retrospective audit of EMR data with or without a mandatory PCP exit survey. Most of these studies used data from a single health service network, and only 1 of the studies combined surgical eConsult data from multiple hospital platforms [49]. Of the retrospective studies, 12% (4/33) were pre- versus postimplementation studies [18,27,50,51]. Approximately 3% (1/33) of the studies used feedback from post-eConsult surveys to assess the ability of the specialist to incorporate this feedback into their practice [44]. Only 15% (5/33) of the studies used a prospective design in their analysis [27,44,50,52,53]. None of these studies randomized patients to an eConsult or a face-to-face visit. Most studies assessed clinician satisfaction, with only 6% (2/33) of the studies assessing patient satisfaction with surgical eConsults [11,53].

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Figure 3. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of the included studies. eConsult: electronic consultation.

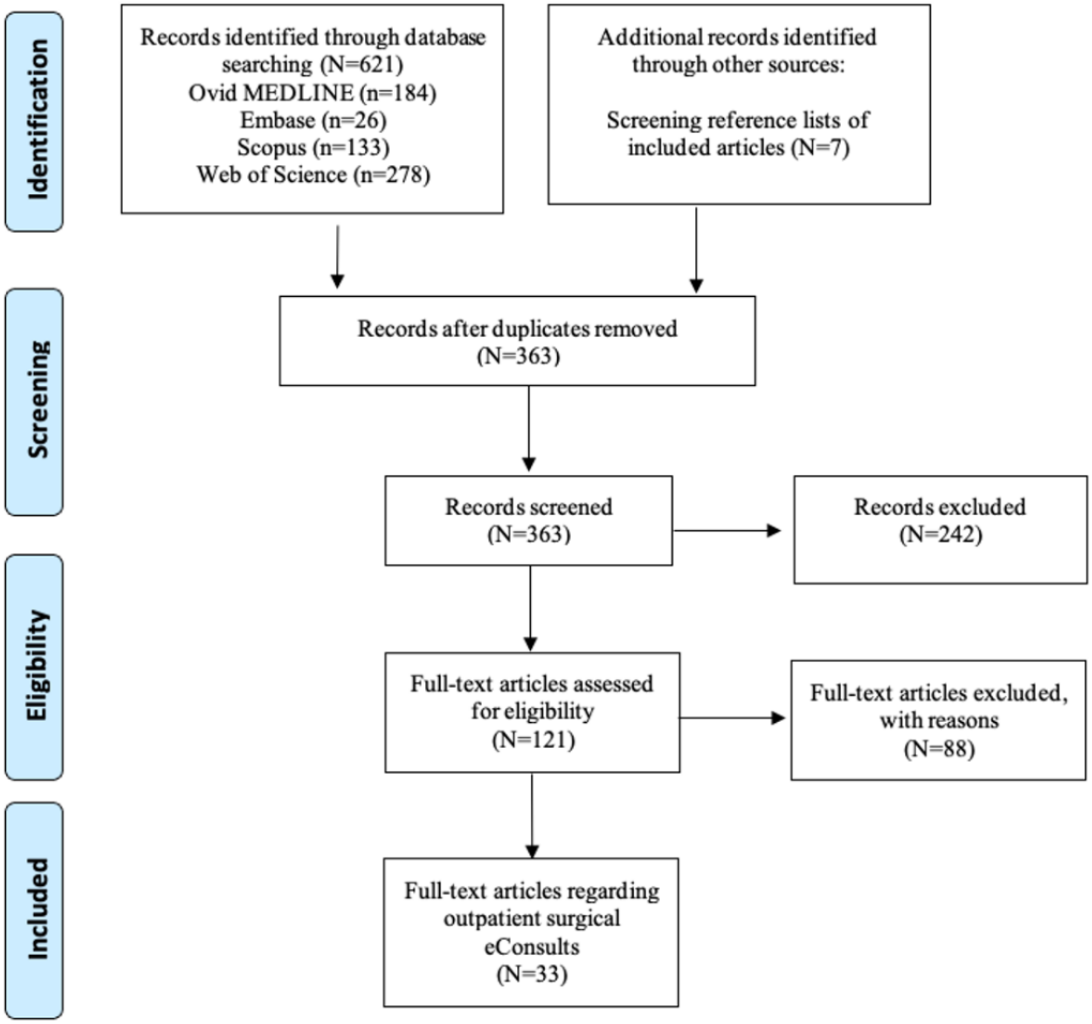

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Table 1. General characteristics of the included studies (N=33).

Characteristic	Studies, n (%)
Year of publication	
2010-2013	3 (9)
2014-2015	4 (12)
2016-2017	7 (21)
2018-2019	9 (27)
2020-2021	10 (30)
Country of origin	
United States	23 (70)
Canada	7 (21)
New Zealand	1 (3)
Nigeria	1 (3)
Spain	1 (3)
Surgical subspecialty	
Urology	7 (21)
Otolaryngology	3 (9)
Obstetrics and gynecology	3 (9)
Orthopedics	2 (6)
Pediatric surgery	2 (6)
General surgery	2 (6)
Vascular surgery	2 (6)
Anesthesiology	1 (3)
Maxillofacial	1 (3)
Neurosurgery	1 (3)
Multispecialty	9 (27)
Type of journal	
Surgical	17 (52)
Health services	7 (21)
Medical informatics	5 (15)
Medicine	3 (9)
General	1 (3)
Type of article	
Retrospective audit	16 (48)
Mixed methods—retrospective audit+survey	7 (21)
Prospective observational cohort study	4 (12)
Systematic review	3 (9)
Mixed methods—retrospective audit+prospective study	1 (3)
Cross-sectional+qualitative study	1 (3)
Survey	1 (3)

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Improving Population Health

Pattern of eConsult Use Among Clinicians

Surgical eConsult use is increasing [27,43,54-57]—one of the studies showed a 50-fold increase in annual eConsults over their 3-year study period (103 is 2012 vs 5023 in 2015) [55]. In *optional-pathway* services, surgical eConsults constituted a minority of the total surgical referrals, ranging from 1.8% to 5.8% [11,43,58]. Although this suggests that PCPs still prefer face-to-face referrals for surgical conditions, it is likely because of the relatively recent introduction of eConsults; some telehealth initiatives implemented during the SARS-CoV-2 pandemic have received widespread support from clinicians to remain in place [74]. Overall, eConsults were used less frequently for surgical compared with medical conditions [43,50,58-60]. However, Saxon et al [43] found that the percentage of surgical referrals that were eConsults was increasing at almost twice the rate compared with medical referrals, suggesting that PCPs have become more comfortable referring surgical patients, with 6% (2/33) of the studies suggesting that eConsults were replacing face-to-face visits altogether [51,61]. The most frequent subspecialties to use eConsults were orthopedics in 6% (2/33) of the studies [50,59], otolaryngology and obstetrics and gynecology in 3% (1/33) of the studies [60], and preoperative evaluation in another study [43]. Uptake was variable across surgical subspecialties partly because of PCPs' exposure to the subspecialty—Parikh et al [49] found that 62.7% (69/110) of patients of neurosurgery versus 12.3% (74/600) of patients with diabetes mellitus were referred to specialists as eConsults, suggesting PCPs seek virtual guidance for presentations with which they have less experience in management. Most studies suggested that management inquiries were the most common reason for the eConsult [52,62,63].

For outcomes, 9% (3/33) of the studies showed that PCPs adopted a new course of action in 20% to 62% of surgical eConsults [52,63,64]. In the remaining cases, the eConsult still served to reinforce current management. Liddy et al [60] found that new or additional actions were recommended less in the surgical stream compared with almost all the medical subspecialties. This finding may again be a reflection of PCP inexperience with surgical subspecialties; hence, they seek the reassurance of their management plan more frequently than for the more common medical presentations.

Patient Safety With eConsults Compared With the Traditional Referral Pathway

A unique safety concern in surgical eConsults was the use of virtual comanagement in cases where an operation was necessary. Only 12% (4/33) of the studies reported safety end points. Castaneda et al [65] found no difference in 5-year mortality between patients who had an eConsult versus the general population data. Another study on patients with vascular conditions found no cases of death or hospitalization in 54 eConsult patients over a 90-day period [11]. In a 2-year study on 1013 very low-risk patients of gynecology, 14.5% (147/1013) were rereferred for a face-to-face visit within 6 months because of ongoing issues for the same condition; however, none had a malignancy attributable to the presenting complaint, and there were no deaths over the 2 years [61]. A study on general surgery eConsults found that 11% (4/36) of virtually managed patients required emergency department care [66]. In total, 2 of these patients who were hospitalized had both been scheduled for additional diagnostic workup before a face-to-face visit, suggesting that no patients had a worse outcome from virtual comanagement. Promisingly, no study identified an increase in adverse outcomes with surgical eConsults, despite this being raised as a concern in patient and clinician surveys [75].

Approximately 12% (4/33) of the studies looked indirectly at patient safety. In 3% (1/33) of the studies, contingency for rereferral was made in 45.7% (160/350) of eConsults [65], and another study found that 43% (30/69) of neurosurgical eConsults showed no documentation of PCP follow-up [49]. Accordingly, surgical eConsult proformas, including rereferral plans and automated safeguards to ensure follow-up, need to be integrated into health systems. A third study found that specialists who dealt with a higher volume of eConsults spent less time responding per eConsult [44], suggesting that services that allow for manageable loads for each specialist may indirectly increase patient safety by freeing up the time of the specialist. The final study found that eConsults used in preoperative evaluation had no significant effect on preventable operation cancellation rates during their 5-year study period [55]. This implies that eConsults do not risk suboptimal care from surgery cancellations; however, the postoperative outcomes of preoperative eConsult patients were not studied. We could not identify any studies that used eConsults for routine surgical follow-up. A recent study demonstrated that early postoperative PCP follow-up was associated with a 47% decreased risk of hospital readmission at 30 days in high-risk patients with surgical complications, and eConsults can further augment this benefit by facilitating prehospital specialist input [76]. eConsults achieve this by improving PCP-hospital communication, given that rates of PCP-specialist communication are very low after discharge, and issues with communication have been shown to negatively affect the care of up to 25% of recently discharged patients [77].

eConsults can promote safety. The studies on *single-pathway* eConsult services (4/33, 12%) showed that 3.1% to 17% of eConsults deemed by the PCP to not require a face-to-face evaluation were changed to an in-person evaluation [50,52,62,64]. These patients would not have been seen by a specialist in the absence of an eConsult and possibly had better long-term outcomes because of the safety net of an eConsult service.

Despite these reassuring safety findings, as also observed by Vimalananda et al [39], we could not identify any studies that listed adverse events as the primary outcome. Furthermore, there were no long-term safety data, with the longest follow-up period being 5 years, and no studies that included complications treated by other health services. The lack of randomization in all studies and the triage of low-risk patients to eConsults and high-risk patients to in-person consultations mean that safety data are skewed away from patients who are more complex and sicker. Another safety concern not addressed in the data is the outcomes of patients treated solely by the PCP using specialist advice from eConsults of previous patients with a similar surgical condition.

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Surgical Yield of eConsults

Ulloa et al [66] examined the surgical yield of eConsults, defined as the proportion of face-to-face specialist visits that are subsequently scheduled for surgery. Surgical yield is a reflection of the ability to triage patients requiring nonoperative management before a face-to-face visit, which can be improved by eConsults. Surgical yield is an important efficiency measure for surgical services, which has significant funding implications. Note that high rates of surgical yield are condition specific and may imply that there were patients not seen face to face who required surgery. The authors found that there was a nonsignificant trend in favor of eConsults increasing surgical yield (46% (53/114) vs 35%; *P*=.07) and observed no increased adverse outcomes in the eConsult group. Together, these findings suggest that surgical eConsults maximize the efficiency of surgical care delivery without compromising safety; however, larger studies are required.

Health Outcomes of Patients Following an eConsult

Despite the aforementioned benefits of eConsults, patient outcomes were marginally improved, as evidenced in medical subspecialties [78,79]. There is hope that surgical eConsults will decrease the rate of emergency department presentations during the increasingly lengthy wait period for in-person evaluation; however, this is yet to be studied.

Role of Surgical eConsults in the COVID-19 Era

We could only identify 3% (1/33) of studies on surgical eConsults that addressed issues during the COVID-19 pandemic [54], whereas there were reported increases in the number of medical eConsults in the same period [30,80]. One of these studies found a trend of increased eConsult use by PCPs, and the rate of subsequent face-to-face referrals also increased. The latter paradoxical finding requires exploration in surgical subspecialties, as it may reflect eConsults being used for different patient presentations compared with before the pandemic. At our service, we have an increasingly large backlog of surgical outpatients because of the pandemic who would benefit from virtual specialist advice even in the absence of face-to-face appointments. Furthermore, elective surgery cancellations have increased operation wait times, and these patients could be more efficiently optimized virtually via eConsults rather than attending a face-to-face preadmission clinic.

Enhancing Patient Experience of Care

Patient Satisfaction With Surgical eConsults

Only 6% (2/33) of studies directly assessed patient satisfaction with surgical eConsults and found that a minority (6% (1/17) and 19% (65/342), respectively) of patients preferred the traditional referral pathway [11,53]. Reservations about eConsults were addressed in some services by allowing for a section in the eConsult where patient preference for a face-to-face consultation can be noted [44]. There also remain many questions regarding the patient's right to access the surgeon's response. When the eConsult information is added to the patient's EMR, their access rights may be governed by laws of freedom of information; however, when a private or outsourced eConsult platform is used, disclosure of information may not be straightforward. State-based legislation must keep pace with eConsult uptake to ensure that patients can gain equitable access to their eConsult. The paucity of firsthand data for patient experience is because of the convenience of using retrospective analysis of PCP exit surveys, which most studies used. In these studies, PCPs thought that 93% to 94.4% of surgical eConsults had good or excellent value for their patients [50,60,63].

Rate of Avoided Face-to-face Consultations Because of Surgical eConsults

In *optional-pathway* eConsult services, the rate of face-to-face visits following eConsults was 5.4% to 36% [11,18,43,56,57,65]. The rate was higher for *single-pathway* eConsult services, at 37% to 92.6%, as there is no triage process for low-acuity conditions [44,64,66,67]. The rates of face-to-face follow-up after eConsults were similar between surgical and medical specialties [43,44], suggesting that surgical conditions do not require in-person evaluation more frequently despite the interventional nature of the specialty. Surgical conditions with low rates of face-to-face follow-up or high requirements for prereferral investigations benefit more from eConsults than conditions that are immediately scheduled for an in-person visit with no additional workup (ie, the traditional referral pathway). For example, in a retrospective study of 472 urology eConsults, Chertack et al [68] found that only 23% of patients referred for renal cysts required a face-to-face consultation compared with 80% (24/30) of patients with an elevated prostate-specific antigen (PSA), confirmed in another study (89% (42/47) of elevated PSA cases and after further workup in 11% (5/47) of cases [67]). One could speculate that raised PSA frequently necessitates shared decision-making, requiring an in-person visit. Services with specific criteria for which an eConsult can take place or those with dedicated triage clinicians [61,65] can increase the rates of resolved eConsults, with 3% (1/33) of the studies showing no cases of face-to-face follow-up when eConsults were triaged appropriately [61]. Similarly, some subspecialties still require a reasonable percentage of face-to-face visits, ranging from 90.2% (1761/1952) in otolaryngology to 71.6% (277/387) in obstetrics in one of the studies [44]. This may be a reflection of the variability in reliance on physical examination between subspecialties, with those that lean more heavily on imaging requiring fewer face-to-face visits.

There is a glaring lack of data regarding the underlying characteristics of *resolved* eConsults (ie, not scheduled for a face-to-face visit)—why some surgical conditions, subspecialties, or eConsult questions are more or less likely to avoid a face-to-face visit. Furthermore, each surgical subspecialty sees a diverse range of conditions, and broad generalizations about the viability of each subspecialty for eConsults would belie the heterogeneity of the patient population. In addition, generalizations cannot be made about which subspecialties benefit more from low rates of subsequent face-to-face referral in *optional-pathway* eConsult services, as this will vary according to the eligibility criteria for eConsults.

Studies on *single-pathway* eConsults defined avoided unnecessary face-to-face visits as cases where the PCP had

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contemplated a face-to-face referral but decided not to as a result of the eConsult. eConsults that result in virtual management cannot be included, as PCPs often submit questions via eConsults that they would not have referred as face-to-face consultations. Most studies on surgical eConsults showed them to avoid a face-to-face visit in 33% to 68% of patients [50,52,60,62,64]. Avoidance rates for surgical subspecialties appear similar to those for medical subspecialties. Approximately 6% (2/33) of multispecialty studies found that orthopedics had the highest rate of unnecessary referral avoidance, at 38% (~62/162) and 55% (~6/11), respectively, while also showing that otolaryngology had the lowest rate, at 15% (~4/26) and 8% (~1/12), respectively [50,60]. A single-specialty orthopedic study found a similar rate of referral avoidance [62], and therefore, it represents a promising subspecialty in which eConsults should play an increasing role. Conversely, single-specialty studies on otolaryngology eConsults have not replicated this low rate of referral avoidance [52], and thus, further studies must be conducted. Reducing avoidable face-to-face visits not only saves patients time and money but is also beneficial to clinicians—Kinberg et al [18] suggested that avoided referrals free up specialists' time for patients who require a more urgent review. They found that the mean wait time for face-to-face specialist visits decreased from 60.8 to 42.8 days following eConsult implementation. Another study noted similar trends of reduction in elective surgery wait times [27].

Time Savings as a Result of Surgical eConsults

Estimates for the time taken for specialist responses ranged from 19.9 hours to 3.6 days [49,50,56,57,59,62,64,68]. The corresponding waiting time via a traditional face-to-face visit ranged from 54 to 482.5 days [50,52,62]. Approximately 6% (2/33) of the studies noted that the time to treatment onset was also shorter with eConsults, showing that time savings probably translate to patient benefit [49,53].

Approximately 6% (2/33) of urological studies noted that eConsults increased the efficiency of patient care by expediting their workup [69,70], in some cases dramatically (eg, Bergman et al [69] reported a decreased time from documented hematuria to completed a workup from 404 to 192 days). This is especially true in surgical subspecialties where a radiological or procedural diagnosis is common and is not usually ordered by the PCP alone.

Improving the Work Life of Clinicians

The proportion of PCPs who rated surgical eConsults as having good or excellent value for themselves ranged from 87% to 97% [11,50,60,62-64], with an educational benefit in 60% to 89% [44,62]. A critical factor in PCP satisfaction is the quality of the specialist response. Tuot et al [44] was the only study to examine eConsultant competencies and found that a lower referral volume (<900 per year), a physician rather than nurse reviewer, and more time spent per referral (>7 minutes) were associated with higher-quality surgical and medical eConsults, as judged by the PCP. There was hope that PCP education would gradually obviate the need for future eConsults regarding the same issue; however, specialist surveys noted that PCPs often repeat questions [59]. Approximately 3% (1/33) of the studies demonstrated that a feedback session for specialists to improve their eConsult response quality resulted in a significant increase in high-quality eConsult reviews at 3 months [44]—a similar feedback session could be used for PCPs to improve their referral quality, with more frequent sessions being used to sustain long-term benefits.

eConsults undoubtedly alter the relationship between PCPs and specialists; in many cases, eConsults are replacing the informal *curbside* conversation. Although this traditional form of specialist consultation is still widely used, Gupte et al [59], in a survey of PCPs, found that the formal documentation of surgical eConsults was seen as a key drawcard. Indeed, although medicolegal concerns are often cited as an issue with eConsults, the permanent electronic recording of PCP-specialist consultations confers a degree of medicolegal protection when compared with undocumented curbside conversations [52]. Other features associated with eConsult uptake have been studied elsewhere [81]; a pertinent finding is that PCPs with longer practicing time are less likely to submit eConsults, which suggests that familiarity with the curbside system fosters an unwillingness to adopt new methods. It is possible that mandatory eConsults or investigations before face-to-face visits deter veteran PCPs from using eConsults; however, the specific reasons for this trend require further investigation.

Surveys of specialists noted that eConsults freed up face-to-face appointment times, and most indicated that eConsults did not increase their workload [50,59]. However, specialist satisfaction with surgical eConsults has been much more variable and more poorly studied than PCP satisfaction. Most specialists were able to respond to the eConsult within 20 minutes [44,52,56,60,63,64]. Kinberg et al [18] noted a decrease in cancellations or failure to attend face-to-face otolaryngology clinics from 38.9% (1141/2932) to 19.3% (713/3686) after eConsult implementation. One could speculate that the eConsult system allowed for triaging of patients who were anxious to seek in-person evaluation.

Approximately 6% (2/33) of the studies noted an unanticipated use of eConsults by clinicians. Gupte et al [59] found that 73.3% (487/664) of orthopedic eConsults were initiated by an orthopedic clinician using the eConsult system for ease of generating a preoperative chart review. Frequent spot checks to ensure the *PCP* is not the same as the *specialist* should be performed in all eConsult services to ensure this practice is not taking place. Parikh et al [49] noted that neurosurgeons electronically contacted 12% (8/69) of patients directly; however, this may represent a more well-rounded eConsult and does not mean that the guidelines were being deliberately disregarded. Direct patient contact may reduce time delays arising from obtaining patient information secondhand through the PCP and should be encouraged when it is being used to supplement, and not replace, the eConsult. Furthermore, details of contact between the patient and specialist need to be accessible to the PCP to ensure that they remain informed of the patient's case and maintain their educational benefit.

Reducing Per Capita Cost of Health Care

All cost-saving analyses found that surgical eConsults were associated with reduced costs to patients and health services

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[43,50,51,58,60]. Some studies drew similar conclusions on indirect outcomes, such as differences in specialist payments [53,54]. Approximately 6% (2/33) of the studies found that savings were because of reduced outpatient rather than inpatient costs, possibly from a reduction in diagnostic tests and procedures and more rapid initiation of treatment [51,58]. Anderson et al [51] also found that health service cost savings were greater in orthopedics than in the 3 medical specialties, possibly because orthopedic visits involve more costly procedures, which yield greater savings when avoided.

The caveat to these results is that all studies were limited in their ability to estimate cost savings because of the large number of variables that cannot be accounted for, such as costs incurred outside a given health service. Furthermore, the longest comprehensive cost analysis was 3 years.

Discussion

Principal Findings

A summary of the findings of this review within the Quadruple Aim Framework (Table 2 and Figure 4) shows that surgical eConsults have benefits at every step of the referral pathway. We found that surgical eConsults showed significant benefits in time and cost savings, reducing surgical outpatient wait times and increasing access to surgical care in underserved patient populations. Although the uptake in surgical subspecialties has been less enthusiastic than in medical subspecialties, the broad outcomes are similar in the 2 fields. Although many concerns common to medical and surgical eConsults (such as workload increases, medicolegal protection, and reimbursement) were found to be unfounded or surmountable, specific surgical concerns (eg, the erosion of the patient-surgeon relationship before surgery) could still be addressed.

Table 2. Summary of the benefits, limitations, and future work for surgical electronic consultations (eConsults) within the Quadruple Aim Framework.

Category	Benefits	Limitations	Future work
Improving population health	• Safety comparable with traditional referral systems • Increased or equal surgical yield • Yields a new or confirmed course of PCP[a] management • Alterations in PCP referral behavior	• Frequent lack of contingency for rereferral • Frequent lack of documentation of PCP follow-up • Clinicians with higher volumes of eConsults spend less time per eConsult	• Randomized studies to assess long-term patient outcomes • Long-term studies on safety • Change in eConsult use since the COVID-19 pandemic
Enhancing the patient experience of care	• Decreased wait time for a surgical opinion • Increased efficiency of care • Avoidance of unnecessary face-to-face consultations • Drive time savings • Decreased wait time for face-to-face and elective surgery • Decreased unnecessary invasive investigations	• Impersonal nature of eConsults • Patient privacy issues • Common patient preference for face-to-face consultations	• Large-scale surveys of patient satisfaction • Identification of viable conditions for eConsults in each surgical subspecialty • Empirical evaluation of eConsults in expediting patient workup
Improving the work life of clinicians	• High PCP satisfaction • PCP education • Reduction in failed-to-attend consultations	• Medicolegal ramifications • Technological limitations • Difficulties with eConsults from external health services • Increased specialist workload • Inappropriate and incomplete referrals • Repetitive questions from PCPs • Variability in eConsult delivery platforms	• Large-scale surveys of specialist satisfaction • Studies on factors associated with high-quality eConsults • Studies assessing the prevalence of specialist-patient communication in eConsults
Reducing per capita cost of health care	• Cost savings to patient and health service	• Funding model implementation concerns • Insufficient specialist reimbursement	• Confirmation of reduced unnecessary diagnostic procedures with eConsults • Long-term studies on cost savings

[a]PCP: primary care provider.

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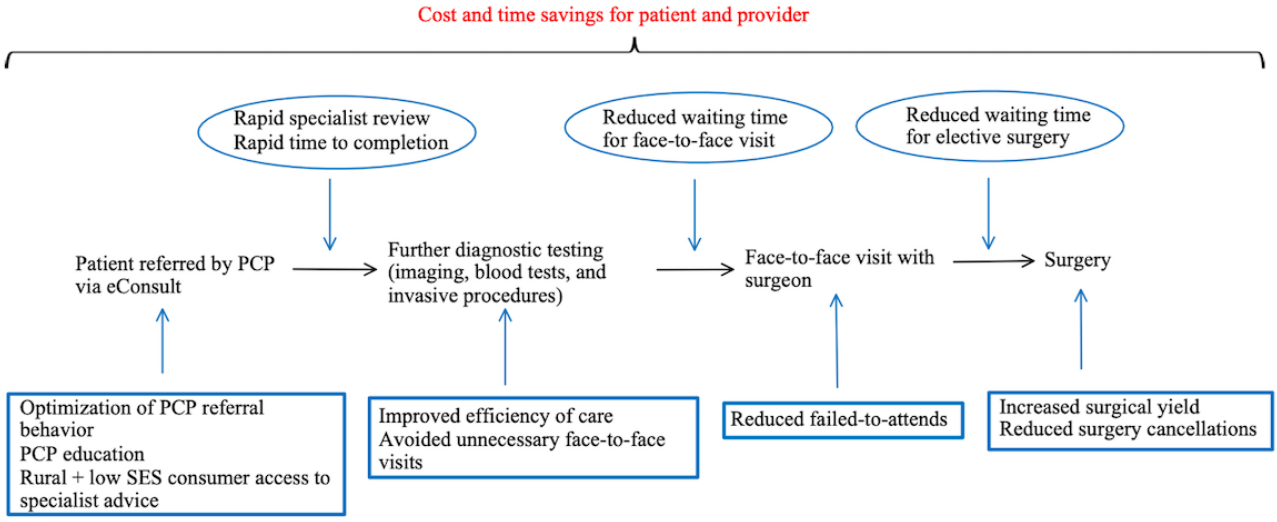
Figure 4. A schematic representation of some of the benefits of surgical electronic consultations (eConsults). PCP: primary care provider; SES: socioeconomic status.



Comparison With Prior Work

This paper builds on 2 recent systematic reviews of combined medical and surgical eConsults [39,40,82,83]. The 2019 review by Vimalananda et al [39] included 63 studies in their analysis, most of which were observational, which is similar to our findings. They were able to identify 2 studies on medical subspecialties (nephrology and endocrinology) that compared the clinical outcomes of eConsult patients with face-to-face referrals, whereas we could identify no such studies on patients of surgery. Liddy et al [40] included 43 studies in their analysis and were notably able to show cost savings because of eConsult use. Our finding on cost savings is also consistent with a scoping review that suggested target key areas where money can be saved using telehealth (eg, mitigating the need for expensive, unnecessary procedures) [84]. This and our overall findings should be reassuring to health services looking to implement surgical eConsults into their workflow. The most common barriers to eConsult implementation that we identified—namely, medicolegal, workload, and reimbursement concerns—are very similar to recent articles dedicated to this topic [81,85-88] and, therefore, were not discussed in this paper.

Limitations of This Review

Limitations include that the studies were from a limited cohort from 3 well-established eConsult services, and only 3% (1/33) of the studies were performed in a low socioeconomic status country [71]. There is a significant overrepresentation of some subspecialties, and all data were observational, which raises the possibility of unknown factors causing the outcomes described in this review. Randomization has been used in medical eConsult studies [89,90]; however, this may not be reflective of real-world conditions. At this stage, it would be advisable for further work to shift its focus from well-established markers of eConsult benefits to analyzing pitfalls and safety concerns. We did not conduct individual appraisals of study quality. Furthermore, it was impossible to include all the multispecialty studies where surgery was a subanalysis of the broader population, given that our search strategy missed studies that did not include a surgical term in the title or abstract. Our exclusion of non-English articles may also have missed other studies from low socioeconomic status countries. Concerns such as medicolegal issues and management responsibilities were raised in the discussion sections of some papers but could not be included in the data.

Future Directions

There are some important understudied components of surgical eConsults. An example is the effect of differing patient-surgeon relationships before a major operation on patient satisfaction with a virtual platform. Furthermore, we identified factors associated with a high-quality eConsult response, and this can be leveraged in future work that can explore these features, such as prior telemedicine training, to optimize the quality of responses. Other work can confirm the economical use of diagnostic investigations within the eConsult system. Finally, assessment of eConsult outcomes in specific surgical subspecialties (eg, cardiothoracic surgery) may show benefits associated with eConsults for a specific specialty.

Conclusions

In conclusion, eConsults represent a safe and advantageous alternative to face-to-face consultations in surgical clinics. Specific surgical subspecialties and conditions appear to benefit more from eConsults, although, even in cases where an in-person visit is needed, eConsults serve to expedite the patient's workup. For most outcomes, surgical eConsults performed similarly to medical eConsults. Most limitations of surgical eConsults are system-level issues that can be addressed by appropriate implementation protocols, including clinician training and automatic safeguards. Future work on surgical eConsults should further elucidate long-term safety considerations, patient perspectives, and the effects of evolving practices during the COVID-19 pandemic.

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Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 15 KB - periop_v5i1e34661_app1.docx]

Multimedia Appendix 2
Summary of the included studies.
[DOCX File , 30 KB - periop_v5i1e34661_app2.docx]

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Abbreviations

eConsult: electronic consultation
EMR: electronic medical record
eReferral: electronic referral
PCP: primary care provider
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA: prostate-specific antigen

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Review

Improving Postoperative Care Through Mindfulness-Based and Isometric Exercise Training Interventions: Systematic Review

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Abstract

Background: Mindfulness-based cognitive therapy and isometric exercise training (IET) interventions are relatively new approaches to maintain physical functioning, alleviate pain, prevent joint stiffness and muscular atrophy, and positively influence other postoperative care outcomes.

Objective: The aim of this review was to identify the impacts of mindfulness-based interventions (MBIs) and IET and, more specifically, their combination, which have not previously been assessed to our knowledge.

Methods: Studies were identified by searching the PubMed and Cochrane databases within the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) algorithm format and using relevant keyword combinations, which resulted in 39 studies meeting the inclusion criteria.

Results: In general, MBI was shown to positively impact both pain relief and physical functioning, while IET positively impacted physical functioning. Numerous other benefits, including improved quality of life and decreased postoperative opioid use, were also described from both interventions; however, further research is needed to confirm these findings as well as to determine other possible benefits. No studies were found that combined MBI and IET.

Conclusions: Despite many positive results from each individual intervention, there is a lack of information about how the combination of MBI and IET might impact postoperative care. The combination of these two interventions might prove to be more effective than each individual intervention alone, and the findings from this review show that they could even be complementary. Going forward, research should be expanded to study the possible benefits of the combination of MBI and IET in postoperative care routines as well as other possible combinations.

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KEYWORDS

postoperative care; mindfulness; isometric exercise; mindfulness-based interventions; meditation; cognitive therapy; improving care; postoperative; systematic review

Introduction

Postoperative care routines are particularly important in determining the long-term outcomes of many surgical procedures. Occupational therapy and physical therapy are examples of postoperative care with proven utmost importance not only in situations where the musculoskeletal system is the primary focus of the surgery but also in other surgeries on the breast, abdomen, genital, cardiovascular, and pulmonary systems, as well as other organs [1-3]. Numerous postoperative interventions have been tested in different clinical settings designed to maximize recovery or functioning, alleviate pain, prevent joint stiffness and muscular atrophy, and improve mental capabilities and coordination [4,5]. Recently, two intervention

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types have grown in popularity: mindfulness-based cognitive therapy (MBCT) [6] and isometric exercise training (IET) interventions [7].

Patients naturally feel stressed before surgery and during recovery. MBCT is employed as a group-based intervention, combining mindfulness meditation trainings with cognitive behavioral therapy elements [6]. Although originally used to prevent relapse in patients with depression, MBCT employed in postoperative settings is used to address preoperative anxieties, and may also influence physical functioning and overall pain relief. Patients who had higher mindfulness scores also had lower pain levels after hysterectomy procedures [8] and hand surgeries [9], demonstrating a direct relationship between mindfulness and postoperative pain relief. A different study suggested that only certain facets of mindfulness, such as the ability to describe internal experiences and to act with awareness, may be the factors contributing to optimizing psychological and physical functioning postoperatively [10]. Further research into MBCT and its impact postoperatively is needed to confirm these findings. Regardless, there is clearly a foundation in the literature surrounding mindfulness techniques and postoperative outcomes.

IET interventions are used similarly to mindfulness-based interventions (MBIs) regarding pain relief, but may be more influential in postoperative physical functioning. IET is performed by increasing muscle tension while preventing joint motion, most often by providing unmoving resistance during an exercise [11]. A meta-analysis/systematic review of 33 randomized controlled trials showed that exercise interventions can improve pain, stiffness, muscle strength, maximal oxygen uptake, and position sense (awareness) [7]. Previous research also shows that breast cancer patients who participated in a brief IET intervention showed alterations in tumor tissue gene expression [12], suggesting that exercise may have direct effects on biological mechanisms associated with cancer development and progression. IET might also influence other postoperative outcomes and their effects could be bolstered by their combination with MBI, although further research is needed.

Since MBI is more centered around the mental aspects of postoperative recovery and IET around the physical aspects of postoperative recovery, it is hypothesized that the combination of these interventions may result in even more positive postoperative results in comparison to the results observed when used individually. While other postoperative interventions are also used (which are briefly mentioned in the Discussion section), we decided to focus solely on MBI and IET for simplicity, and as an overarching example of the importance of combining mental and physical interventions in postoperative settings. Future research should expand upon this review and include other intervention types in varying combinations compared with the individual physical and mental interventions.

Thus, the aim of this systematic review was to examine the currently published medical literature on MBI and IET, and evaluate the impact of such interventions overall and specifically the overarching benefits of their inclusion in the postoperative care setting.

Methods

This systematic review implemented an algorithmic approach to review all of the currently available English medical literature on MBI or isometric exercises in the setting of postoperative care using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) principles (Figure 1). A comprehensive search of the medical literature in the PubMed and Cochrane databases was performed by one author (AR) on September 14, 2021, using the key words “mindfulness” AND “postoperative” OR “isometric exercise” AND “postoperative.” The search string was generated and the records that were not specific to MBI or IET were excluded. Articles published in a language other than English were not eligible for inclusion. No date restriction was applied. Titles and abstracts were screened by one author (AR), followed by assessment of full-text articles for eligibility and inclusion. The senior author (AHJ) supervised the process to prevent bias and checked the references. On initial and secondary searches, papers lacking a specific focus on postoperative care or those without an accessible full-text article were excluded. For completion of the search, the references of the selected publications were additionally screened with the same inclusion criteria mentioned above. The quality of the papers was assessed using the ROBINS-I (Risk Of Bias In Non-randomized Studies-of Interventions) risk of bias tool with the results reported in Multimedia Appendix 1. Only papers with low overall bias were included in this study.

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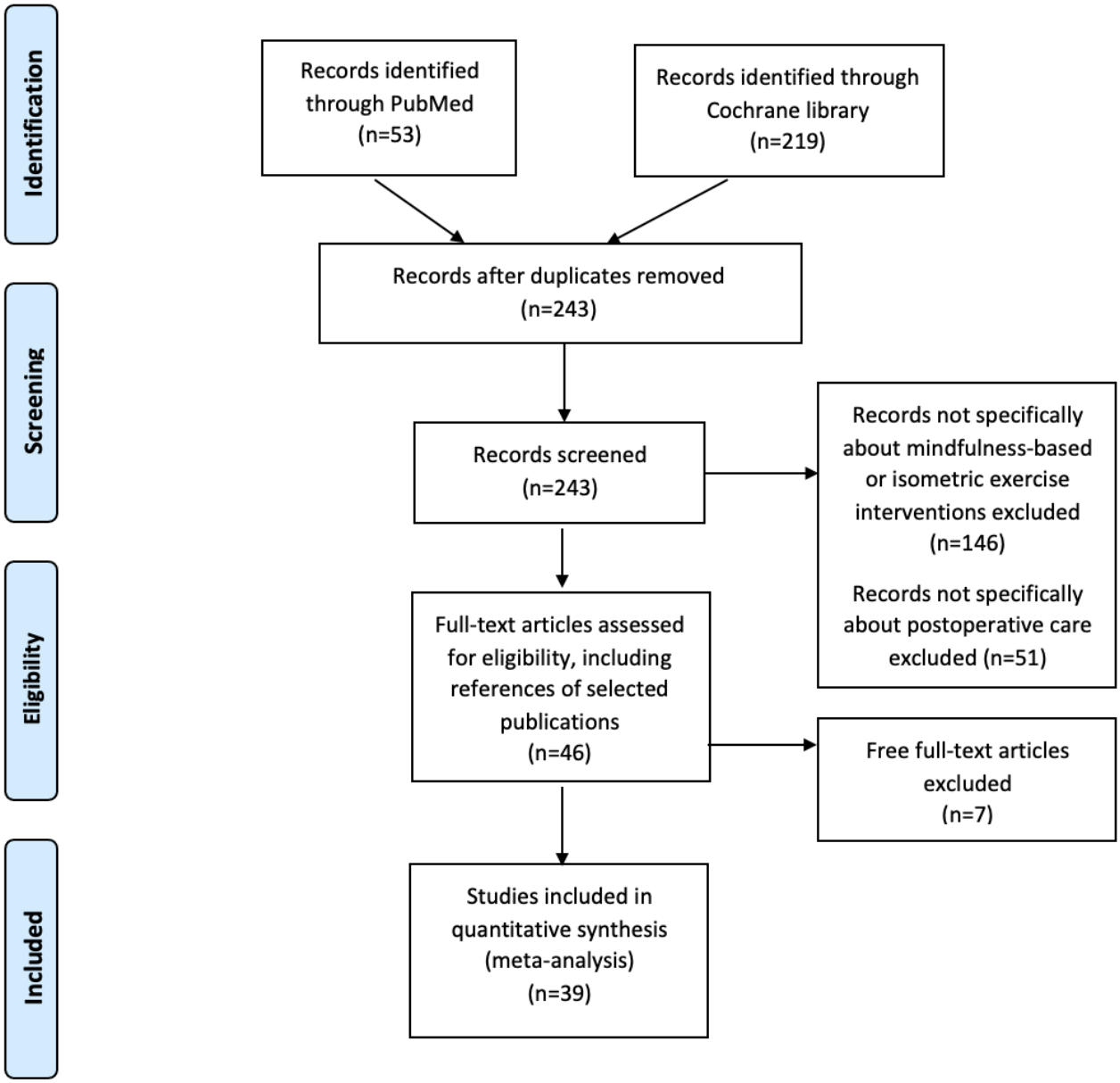
Figure 1. Search strategy for our systematic review to find the currently published medical literature describing usage of mindfulness-based interventions or isometric exercise interventions in postoperative care settings.



Results

Characteristics of Included Articles

We finally included 39 full manuscripts that met our inclusion criteria. Table 1 and Table 2 define the characteristics of the final selected papers for each intervention type separately. Currently ongoing trials were not included in the final analysis. As no papers were found that combined MBI and IET outcomes, results from each category are discussed separately.

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Table 1. Characteristics of the studies reported on the use of a mindfulness-based intervention (MBI) in postoperative (PO) care settings and the outcomes of such interventions.

Reference	Study design	Surgery	Patients, N	Intervention(s)	Duration of intervention(s)	PO outcomes
Hanley et al [13]	Randomized controlled trial	Total joint arthroplasty	118	MF[a] of breath (MoB), MF of pain (MoP), or CB[b] pain psychoeducation	One 20-min session 3 weeks before surgery	MoP decreased PO pain intensity and interference; MoB and MoP decreased PO opioid use
Weekes et al [14]	Randomized controlled trial	Arthroscopic rotator cuff repair	146	Relaxation exercise and control	One 5-min video and educational pamphlet	No difference in PO pain or physical function, but MBI decreased narcotic consumption at 2 weeks
Hanley et al [15]	Randomized controlled trial	Total joint arthroplasty	285	MF meditation, hypnotic suggestion, or CB pain psychoeducation	One 15-min session	MBI decreased preoperative opioid desire and increased PO physical function
Shao et al [16]	Randomized controlled trial	Breast cancer surgery	144	MBI or control	One 20-min session 5 days/ week for 6 weeks	MBI decreased PO depressive and sleep disorder symptoms
Linshaw et al [17]	One-group pretest-posttest	Mastectomy or lumpectomy for breast cancer	11	Stress Management and Resiliency Training–Relaxation Response and Resiliency Program (SMART-3RP)	8-week course	MBI improved sleep and anxiety/depression scores
Chavez et al [18]	Nonrandomized controlled trial	Lumbar spine surgery	48	Preoperative MF-based stress reduction training or control	At least one 2.5-hour class; up to 8 classes	MBI improved PO physical function and lowered system-pain interference
Haisley et al [19]	Randomized controlled trial	Minimally invasive foregut surgery	52	Virtual reality meditation/MF sessions or standard care	6 sessions	MBI patients reported higher satisfaction, and lower PO pain, anxiety, and nausea scores
Dowsey et al [20]	Randomized controlled trial	Total joint arthroplasty	127	MF-based stress reduction program or treatment as usual	8-week program	MBI improved PO pain and physical function
Yi et al [21]	Nonrandomized controlled trial	Lumbar spine surgery	48	MF-based stress reduction intervention or control	At least one 2.5-hour class; up to 8 classes	MBI group reported less PO pain but there was no difference in prescription opioid drug use
Stoerkel et al [22]	Randomized controlled trial	Breast cancer surgery	100	Treatment as usual or treatment with a "self-care toolkit"	Minimum of one listening per audio file (7 total)	MBI improved scores of pain interference, fatigue, and satisfaction with social roles. The MBI group also had less PO pain, lower erythrocyte sedimentation rate, and reduced anxiety scores
Pruthi et al [23]	Randomized controlled trial	Breast cancer surgery	29	Wearable EEG[c] MF sensing headset device and control	3 min every day for 3 months	No differences in quality of life, fatigue, and stress, but MBI group reached outcomes sooner and had higher satisfaction
Xu and Liao [24]	Randomized controlled trial	Hip fracture fixation	100	MF-CB intervention and control group	90-min sessions 1-2 times per week	MBI group had higher general self-efficacy and lower self-perceived burden scores
Kiran et al [25]	Randomized controlled trial	Coronary artery bypass surgery	150	Rajyoga and control	3 times/day for 10 min each for 5 days	Rajyoga group had lower PO anxiety and cortisol levels

[a]MF: mindfulness.

[b]CB: cognitive behavioral.

[c]EEG: electroencephalography.

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Table 2. Characteristics of the studies reporting the use of isometric exercise training (IET) interventions in postoperative care settings and the outcomes of such interventions.

Reference	Study design	Surgery	Patients, N	Intervention(s)	Duration of intervention(s)	Postoperative outcomes
Tapia et al [26]	Randomized controlled trial	Autologous arteriovenous fistula for hemodialysis in the upper limbs	60	IET or control	8 weeks	IET showed an increase in hand grip and better main Doppler ultrasound maturation measurements
Tapia et al [27]	Randomized controlled trial	Hemodialysis	27	IET or control	8 weeks	IET showed an increase in hand grip and clinical and Doppler ultrasound maturation measurements
Taufik et al [28]	Randomized controlled trial	Nonarticular tibia fracture	32	IET and ROME[a] or ROME only	IET and ROME: 3 times per day; ROME: 1 time per day	IET showed higher mean bone-specific alkaline phosphatase levels and lower Hummer scale callus scores
Hong and Lee [29]	Case study	Total knee replacement	1	VR[b] training with ROME, IET, and PT[c]	One 60-min session	Improved muscle strength, proprioception, balance, and gait ability
Auerbach et al [30]	One-group pretest-posttest	Heart transplantation	36	IET and control	One 3-min session	IET group had reduced/unchanged Doppler aortic flow parameters
Sisk et al [31]	Randomized controlled trial	Anterior cruciate ligament reconstruction	24	ES[d] and IET or IET alone	IET: 3 times a day for 6 weeks; ES: 8 hours a day, 7 days per week for 6 weeks	No difference in isometric quadriceps strength
Huikuri et al [32]	Randomized controlled trial	Aortic valve replacement	26	Chronic aortic regurgitation and control	IET handgrip test before and after surgery	Left ventricular mass regression was smaller in patients with the most depressed ventricular responses to preoperative exercise
Huikuri and Takkunen [33]	Nonrandomized controlled trial	Mitral valve surgery	28	Groups based on mean mitral valve pressure increase during IET (>4 mmHg or ≤4 mmHg)	IET handgrip test before and after surgery	Positive correlation between the change in mean mitral valve pressure gradient during IET and changes in left ventricular functioning during exercise
Huikuri et al [34]	Randomized controlled trial	Mitral valve replacement	24	Mitral regurgitation and control	IET handgrip test before and after surgery	Positive correlation between ejection fraction changes preoperatively and postoperative resting ejection fraction changes
Huikuri [35]	One-group pretest-posttest	Mitral valve replacement	11	Mitral regurgitation	IET handgrip test before and after surgery	Improved ventricular function after surgery and left ventricular response to stress caused by IET
Tapia et al [36]	Randomized controlled trial	Native vascular access maturation for chronic kidney disease	67	IET and control	8 weeks	IET showed an increase in hand grip and improved clinical and Doppler ultrasound maturation measurements
Tal-Akabi et al [37]	Randomized controlled trial	Lower limb surgery	62	High-intensity or regular-intensity strength IET	3 weeks	High-intensity IET group lifted a greater maximal lift
Martinez Carnovale et al [38]	Randomized controlled trial	Radiocephalic arteriovenous fistula maturation	36	ES and IET or IET alone	8 weeks	ES and IET group had increased clinical and Doppler ultrasonography maturation measurements
Vaegter et al [39]	Randomized controlled trial	Total knee replacement	14	Cold pressor stimulation with aerobic IET	2 sessions (before surgery and 6 months postoperative)	Association between preoperative exercise–induced hypoalgesia and postoperative pain relief

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Reference	Study design	Surgery	Patients, N	Intervention(s)	Duration of intervention(s)	Postoperative outcomes
Shaw et al [40]	Randomized controlled trial	Anterior cruciate ligament reconstruction	103	IET and control	Every day for 2 weeks	IET improved knee flexion and extension range, reduced symptom scores and sports-related postoperative problems, and lower incidence of abnormal knee laxity
Sashika et al [41]	Randomized controlled trial	Total hip arthroplasty	23	IET and ROME or control	6 weeks	IET improved maximum isometric torque on both hip sides, gait speed, and cadence
Rosenfeldt et al [42]	Randomized controlled trial	Cardiac surgery	117	IET and relaxation or control	30 min IET and 20 min relaxation 3 times per week for 2 weeks	No significant changes in quality of life, rates of postoperative atrial fibrillation, or length of hospital stay

[a]ROME: range of motion exercise.

[b]VR: virtual reality.

[c]PT: physical therapy.

[d]ES: electrical stimulation.

Impacts of MBI

Many of the papers included in this aspect of the review cited two main benefits of MBI use: pain relief (as measured through pain medication use) and improvements in physical functioning. In comparison to other interventions such as "hypnotic suggestion" and "cognitive behavioral pain education," MBI decreased pain medication desire and anxiety, and increased postoperative physical function in a randomized controlled trial on total joint arthroplasty with 258 patients [15]. The study investigators delivered MBI, "hypnotic suggestion," and "cognitive behavioral pain psychoeducation" in multiple 15-minute group sessions as part of a 2-hour preoperative education program [15]. Physical function was found to be significantly higher in patients that engaged in MBI trainings 3 months after lumbar spine surgery, and system-pain interference was significantly lower at both 3 and 12 months after the intervention [18]. System-pain interference is especially important for spine surgeries, and methodologies that improve this aspect of recovery are highly sought after. A different study on total joint arthroplasty procedures also showed long-term improvements in pain and function after 12 months in patients who participated in an MBI centered on stress reduction [20]. These two studies collectively demonstrate that mindfulness interventions can influence long-term postoperative outcomes and may have implications for this type of care. Interestingly, one study separated mindfulness into two categories, mindfulness of breath and mindfulness of pain, and found that both categories decreased post total joint arthroplasty opioid use, but only mindfulness of pain decreased postoperative pain intensity and interference scores [13]. These results suggest that general MBI might not be as sufficient as more specific interventions focused on pain relief.

Other studies showed less conclusive results regarding the influence of MBI on pain relief and physical functioning. One study reported no difference in opioid use but decreased postoperative pain 1 month after lumbar spine surgery in the MBI patient group [21], indicating that effects may vary according to the procedure. Another study did not find differences in quality of life, fatigue, or stress following MBI postsurgery for breast cancer, but did note that the mindfulness group perceived the interventions to work better, were more satisfied with their quality-of-life outcomes, and reported higher utilizations of the mindfulness techniques during the study period [23]. While these reported outcomes could be stipulated for other postoperative care conditions, more studies with longer-term outcome analysis research are needed to draw a meaningful conclusion. Lastly, a different study reported no significant improvement in the quality of life of participants who received a 2-week period of MBI compared with those who only received the usual postoperative care [14]. The investigators stated that the intervention for such a short period of time was not sufficient to create a long-lasting impact [14]. They proposed that an increase in the duration of the intervention could result in more conclusive changes, furthering the idea that MBIs may be influential in long-term outcomes.

Besides pain relief and physical function, numerous other benefits were discussed in introducing MBI in postoperative care routines. One study found that MBI effectively decreased depressive and sleep disorder symptoms both 1 month and 3 months post breast cancer surgery [16]. Similarly, another study showed that sleep and anxiety/depression scores can also be improved in postoperative patients using MBI [17]. These two studies demonstrated that the beneficial impacts of MBI are not limited to pain relief and improving physical function, but that such interventions act on multiple levels of recovery. A particularly interesting study investigated the effects of "Rajyoga" interventions (a type of mindfulness meditation focused on teaching self-esteem via self-realization and improvement, charging the self, and positive attitudes), and found that patients in this intervention had lower anxiety and serum cortisol levels on the 2nd and 5th postoperative days [25]. Relatedly, patients who received MBI centered on cognitive behavior multiple times a week post hip fracture fixation surgery reported higher general self-efficacy and lower self-perceived burden scores [24], which may be related to decreases in depressive symptoms and improvements in pain relief.

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Two studies employed newer technological innovations to introduce MBI to the postoperative care routine. The first study employed a "self-care toolkit" that consisted of "guided audio mind-body" techniques, an acupressure wristband, and a journal [22]. The researchers found significantly higher scores in pain interference, fatigue, and satisfaction with social roles; significantly smaller increases in the inflammatory marker erythrocyte sedimentation rate, C-reactive protein, and postoperative pain; and significantly reduced anxiety levels measured by validated outcome measures [22]. The numerous effects noted by these authors could be due to the combination of techniques or caused by each individual technique, but more research is needed to confirm the exact reason behind this observation. The second study took advantage of new technological innovations to combine MBI with virtual reality. Patients who participated in this postoperative care routine reported higher satisfaction as well as lower pain, anxiety, and nausea compared with those of the control patients [19]. Virtual reality has recently been increasing in use postoperatively, as discussed in the "Currently Ongoing Trials" section below, and will likely pave the way for postoperative care routines in the future.

Impacts of IET

IET interventions were found to be utilized most commonly following cardiac and orthopedic surgeries. In fact, IET and its impact in the postoperative setting of any other surgical procedure were not discussed by any published article. Extending this type of intervention to other surgical procedures will be an important step in understanding the overall impact of IET on postoperative care in general. In the meantime, the benefits of IET will only be known for cardiac and orthopedic surgeries, which are discussed below.

Numerous studies cited in this review demonstrated that IET aids in postoperative recovery from cardiac surgeries. Doppler ultrasound maturation, which is indicative of blood flow efficiency, is an especially important measurement taken after cardiac surgeries. An older study used Doppler measurements and showed that isometric exercise is well-tolerated by postoperative heart transplant patients [30]. Several newer studies showed meaningful improvement in the Doppler ultrasound maturation measurements up to 2 months postoperatively in the group of patients undergoing IET compared with the control groups [26,27,36,38], suggesting that postoperative recovery is aided by isometric exercise. Hand grip is another indicator of postoperative recovery in cardiac surgery patients and was shown to be similarly improved by IET [26,27,36]. The Heikki V Huikuri lab of the University of Oulu in Finland studied the effects of IET and mitral/aortic valve replacement surgeries, providing numerous influential and high-quality publications on the topic. They showed that there was a positive correlation between the change in mean mitral valve pressure gradient and left ventricular functioning during IET [33], and a positive correlation between preoperative ejection fraction (EF) changes and postoperative resting EF changes, indicative of reduced ventricular response to afterload stress following IET [34]. Thus, to access the success of postoperative IET, it may be important to take preoperative measurements of cardiac function, resting EF, and ventricular response to afterload stress (EF changes) for comparison. In another study by this group, patients with the most depressed ventricular responses to preoperative isometric exercises had smaller left ventricular mass regression post aortic valve replacement [32]. Further research is needed to confirm and expand upon this. Lastly, they also showed that ventricular function and response to stress improved with a postoperative IET [35].

Similar benefits were also found when applying IET in orthopedic postoperative care settings with different measures of their effects. Patients in the IET group that underwent surgery for nonarticular tibia fractures were found to have significantly higher amounts of mean bone-specific alkaline phosphatase (indicative of improved osteoblastic activity) and lower Hummer scale callus scores, which are both correlated with shortened healing time [28]. Similarly, patients who performed straight leg raises and isometric quadriceps contractions every day for 2 weeks post anterior cruciate ligament (ACL) reconstruction showed significant improvements in knee flexion and extension, lessened symptom scores and sports-related complications at 6 months postoperation, and lowered abnormal knee laxity incidences [40]. Low-resistance IET and eccentric hip abductor exercises post total hip arthroplasty significantly improved the maximum isometric torque on both hips, gait speed, and cadence [41], furthering the notion that IET is beneficial to improving physical function. Combining IET with virtual reality and conventional physical therapy improved the patient's muscle strength, proprioception, balance, and gait ability during their recovery from total knee replacement surgery in a recent case study [29]. Although this study only reported the results for one patient, it demonstrated that multiple postoperative care approaches can potentially be combined to maximize recovery. This study may guide the introduction of different combinations such as MBI and IET to optimize postoperative care in the future. Despite a different study that compared the combination of electrical stimulation and IET and found no significant difference in isometric quadriceps strength post-ACL reconstruction [31], combining postoperative care techniques with various combinations and regimens may be a future direction to optimize outcomes and mandate future evaluations in carefully controlled settings. A similar but more recent study combined IET with electrical stimulation post total knee replacement, and found that this technique was successful in relieving pain 6 months after surgery [39], corroborating the idea of combining techniques in creating a synergic impact in enhanced recovery.

The specific patient populations and their prerequisites may also influence the ideal targeted intervention, which could impact their postoperative outcomes. Defining such a modality may require extensive preoperative evaluations of the target group and in-depth knowledge of the expected postoperative changes and recovery demands. For example, elderly patients may have increased difficulty in recovering from surgery and with overall pain management than other patients, and thus may benefit from targeted postoperative care. For this population, IET resulted in greater maximal lift weights and therefore more improved physical functioning post lower limb surgery [37]. Similarly, a different study noted that there are significant

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differences in strength and recovery from surgery between competitive and recreational athletes [31], indicating the importance of patients' backgrounds in determining postoperative outcomes. Thus, postoperative care should be tailored to individual patients to maximize results and create unanimous enhanced recovery across different patient populations.

Although most reports of postoperative IET showed beneficial outcomes, one study did not report a strong positive effect. In this study, exercises specifically tailored for relaxation were not found to influence pain scores or shoulder function after arthroscopic rotator cuff repair [42]. The only effect noted by these researchers was a decrease in narcotic consumption 2 weeks postoperatively [42], suggesting that IET may exert more influence on more intrusive surgeries such as total knee or joint replacements.

Currently Ongoing Trials

In addition to the results discussed above, there are also numerous clinical trials employing variations of MBI or IET during postoperative care that are currently undergoing patient recruitment and/or are in the follow-up stage. Twelve examples of currently ongoing clinical trials are described in Table 3 [43-54].

Table 3. Characteristics of currently ongoing clinical trials on the use of a mindfulness-based intervention (MBI) or isometric exercise training (IET) in postoperative (PO) care settings.

Reference/identifier	Study design	Surgery	Intervention(s)	Outcomes to be reported
Olbrecht et al [43]	Randomized controlled trial	Nuss repair of pectus excavatum	Combining MBI and VR[a]	PO pain intensity
Coca-Martinez et al [44]	Randomized controlled trial	Valve replacement	IET, nutritional support, and emotional reinforcement	Incidence of PO complications
ClinicalTrials.gov, NCT04225169 [45]	Randomized controlled trial	Total knee replacement	Diaphragmatic MBI breathing exercise	PO pain, anxiety, and depression
ClinicalTrials.gov, NCT04167852 [46]	Randomized controlled trial	Bariatric surgery	MBI via a mobile platform	Accessibility to patients
ClinicalTrials.gov, NCT02104349 [47]	Randomized controlled trial	Spine surgery	MBI or music therapy group	PO pain
ClinicalTrials.gov, NCT04788329 [48]	Randomized controlled trial	Hand surgery	MBI training in "Prepare for Surgery, Heal Faster"; MBI in "Wim Hof Method"	PO pain intake and pain intensity
ClinicalTrials.gov, NCT04848428 [49]	Randomized controlled trial	Cardiac surgery	Web-based MBI	PO pain intake, pain intensity, pain interference, mindfulness, pain acceptance, pain-related catastrophic thoughts, and psychological well-being
ClinicalTrials.gov, NCT04855968 [50]	Randomized controlled trial	Shoulder arthroscopy	MBI via Headspace app	PO pain and opioid consumption
ClinicalTrials.gov, NCT04293249 [51]	Randomized controlled trial	Total joint arthroplasty	MBI or control (both prior to surgery)	Preoperative and perioperative PO pain intake, anxiety
ClinicalTrials.gov, NCT04518085 [52]	Randomized controlled trial	Breast cancer surgery	MBI or hypnosis	PO pain intake, fatigue, stress, biomarker levels
Packiasabapathy et al [53]	Randomized controlled trial	Cardiac surgery	Perioperative MBI	Program feasibility, PO pain, sleep, psychological well-being, cognitive function, and delirium
ClinicalTrials.gov, NCT03681405 [54]	Randomized controlled trial	Gynecological surgery	MBI or attention control	Adverse events, PO pain, sleep disturbances, and psychological distress

[a]VR: virtual reality.

Discussion

Main Findings

Although there are numerous benefits to MBIs and IET in postoperative care routines, namely surrounding pain relief and physical functioning, we found that none of the studies combined the two techniques. This was a particularly interesting finding, especially given the wide range of possible benefits each patient can obtain from each individual modality, and the potential synergistic impact that patients could gain from the combination of these two techniques. For example, patients exposed to both interventions might demonstrate increased pain relief (as seen from the MBI results) and physical functioning (as seen from the MBI and IET results) as well as other postoperative outcomes in comparison to exposure to only one of the interventions. Although MBI and IET use in postoperative settings has begun only recently, it is important to understand

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the benefits of their combination going forward to fully maximize postoperative patient care. We believe that the combination of interventions mainly focused on the mind settings (MBI) and physical-based interventions, especially those that can be used in the immediate postoperative period even with different immobilization settings (eg, IET), could make an ideal combination in the postoperative setting. Further research is needed to support this hypothesis and studies going forward should examine this combination in a well-controlled setting.

Future Directions

As touched upon briefly, any measure that can help lower pain scores, improve mobility, or help with other postoperative outcomes should be utilized. This is especially true for higher-risk surgeries in which patients may learn via an MBCT on how to prepare for surgery, be better able to tolerate the surgical procedure's impact, and use IET to facilitate their recovery from the surgery. In particular, these interventions may also be important for cancer patients who are recovering from surgery, since this patient group has been shown to demonstrate lower mindfulness scores than average, although with extensive variability [55]. Thus, cancer patients may be a potential target group for future interventions and to test the combination and potential synergic impact of an MBI and IET on their postoperative recovery.

Other intervention types outside the scope of this review were also found in the literature search. These include "Healing Touch" [56], hypnosis [57], art therapy [58], massage therapy [59], music therapy [60], and olfactory mental imagery [61,62]. Although these interventions utilized different methodologies from MBIs and IET, they may employ similar facets of mindfulness and/or exercise. These intervention types may be important to tailoring postoperative care to individual patients; however, further research into the impact of each modality alone or in combination in the setting of postoperative care is needed to improve our understanding of the optimal postsurgery care options in particular patient groups for any specific type of procedure.

As technology continues to advance, it is also important for postoperative care interventions to keep up with new innovations. This was demonstrated in this review through studies that used virtual reality settings and mobile platforms to reach their participants. As technology will continue to advance in the coming years, further innovative approaches would need to be tested to find their true benefits in advancing the postsurgical care outcome. More patient populations can be reached using technological innovations, and this has become even more important during the COVID-19 pandemic as many patients were forced into home-based programs. As an example, the Perioperative Pain Self-Management (PePS) program was created to conduct cognitive behavioral therapy sessions over the phone with rural veterans who may not have had access to this type of care otherwise [63]. Similar programs will continue to grow in importance as telemedicine increases in popularity, especially in the setting of disadvantaged communities (eg, low socioeconomic groups, underserved areas, transgender communities, ethnic minorities). It is important for the postoperative care routines to follow suit, especially in those vulnerable and disadvantaged communities.

Conclusions

It is clear from the studies discussed in this review that there are numerous benefits to including an MBI or IET in postoperative care settings. These effects notably include pain relief and physical functioning, and may be influential in determining various other long-term outcomes. However, there were no studies found to date that combined MBI and IET. This was surprising since the combination of these two interventions might prove to be more effective than each individual intervention alone, and the findings from this review show that they could even be complementary (ie, MBIs are more effective for pain relief and physical function in surgical preparation and IET in recovery for physical function). As previously noted, it is also important to tailor postoperative care to individual patients and some patients might benefit more from combining interventions. Going forward, research should be expanded to study the possible benefits of the combination of MBI and IET in postoperative care routines as well as other possible combinations.

Authors' Contributions

AR conceptualized the study and wrote the first draft of the manuscript. Both authors contributed to the manuscript with their expertise, and read and edited the submitted version. Both authors approved the submitted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
ROBINS-I risk of bias tool results for papers assessed in this review.
[DOCX File , 20 KB - periop_v5i1e34651_app1.docx]

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Abbreviations

ACL: anterior cruciate ligament
EF: ejection fraction
IET: isometric exercise training
MBCT: mindfulness-based cognitive therapy

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MBI: mindfulness-based intervention
PePS: Perioperative Pain Self-Management
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
ROBINS-I: Risk Of Bias In Non-randomized Studies-of Interventions

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Corrigenda and Addenda

Correction: Automated Intraoperative Short Messaging Service Updates: Quality Improvement Initiative to Relieve Caregivers' Worries

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In "Automated Intraoperative Short Messaging Service Updates: Quality Improvement Initiative to Relieve Caregivers' Worries" (JMIR Perioper Med 2022;5(1):e36208) the authors noted one error.

In the originally published article's *Acknowledgments* section, two names were inadvertently misspelled.

These names have now been corrected to "Carl Davidson-Desbiens" and "Mireille Dessureault" in the following statement:

> *Finally, we express our gratitude to Carl Davidson-Desbiens, Mireille Dessureault, and Sherley Durand from General Electric Healthcare as they adapted the operating room (OR) clinical information software and made this project possible.*

The correction will appear in the online version of the paper on the JMIR Publications website on July 15, 2022, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Original Paper

The Potential Impacts of a Digital Preoperative Assessment Service on Appointments, Travel-Related Carbon Dioxide Emissions, and User Experience: Case Study

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Abstract

Background: The National Health Service (NHS) cannot keep up with the demand for operations and procedures. Preoperative assessments can be conducted on the internet to improve efficiency and reduce wait times for operations. MyPreOp is a cloud-based platform where patients can complete preoperative questionnaires. These are reviewed by a nurse who determines whether they need a subsequent face-to-face appointment.

Objective: The primary objective of this study is to describe the potential impact of MyPreOp (Ultramed Ltd) on the number of face-to-face appointments. The secondary objectives are to examine the time spent on preoperative assessments completed using MyPreOp in NHS Trusts and user ratings of usability and acceptability.

Methods: The study design was a case study service evaluation. Data were collected using the MyPreOp system from 2 NHS Trusts (Guy's and St Thomas' and Royal United Hospitals Bath) and the private BMI Bath Clinic during the 4-month period from September to December 2020. Participants were adults of any age and health status at the participating hospitals who used MyPreOp to complete a preoperative assessment before a scheduled surgery. The primary outcome was the number of face-to-face appointments avoided by patients who used MyPreOp. The investigated secondary outcomes included the length of time spent by nurses completing preoperative assessments, associated travel-related carbon dioxide emissions compared with standard care, and quantitative user feedback. User feedback was assessed at all 3 sites; however, the other outcomes could only be examined in the Royal United Hospitals Bath sample because of data limitations.

Results: Data from 2500 participants were included. Half of the assessed patients did not need a further face-to-face appointment and required a median of only 5.3 minutes of nurses' time to review. The reduction in appointments was associated with a small saving of carbon dioxide equivalent emissions (9.05 tons). Patient feedback was generally positive: 79.8% (317/397) of respondents rated MyPreOp as easy or very easy to use, and 85.2% (340/399) thought the overall experience was good or very good.

Conclusions: This evaluation demonstrates the potential benefits of MyPreOp. However, further research using rigorous scientific methodology and a larger sample of NHS Trusts and users is needed to provide strong evidence of MyPreOp's efficacy, usability, and cost-effectiveness.

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KEYWORDS

preoperative care; preoperative period; telemedicine; telehealth; appointments; cost-effective; economic

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Introduction

Background and Rationale

The UK National Health Service (NHS) is unable to keep up with the demand for operations and procedures; it has failed to meet its 18-week waiting time goal since 2016 [1-3]. Preoperative assessments are essential to mitigate patient risk during surgery and support their recovery [4-7]. However, across the NHS, these assessments are predominantly administered using nonstandard, paper-based questionnaires [8-10]. With >10 million operations and procedures occurring each year [11,12], conducting these assessments to a high standard is time-intensive. The Royal College of Anaesthetists (RCoA) recommends 30- to 45-minute appointments; however, preoperative assessments can take up to 2 hours [6,8,13-15]. Health care staff often need to manually transfer the data collected into hospital information technology systems, which introduces another opportunity for error and hinders rapid screening of patients [16]. The Digital by Default report determined that preoperative assessments could be conducted remotely in 40% of cases, eliminating 1.2 million appointments and saving up to £48 (US $76) million [17]. Therefore, reducing the need for nurses and health care assistants to collect patient health records would be significantly valuable in terms of saving both time and cost.

Solution Overview

MyPreOp (Ultramed Ltd) is a cloud-based platform that empowers patients to complete preoperative assessments on the web, thereby improving data quality, streamlining admission procedures, and ultimately saving time and costs [18]. Patients can complete the questionnaire in their own time and choose to share their data with their health care provider (retaining ownership). MyPreOp uses decision-support algorithms to determine what questions to ask depending on patients' previous responses (reducing the number of questions they have to complete), to analyze the data to determine the American Society of Anesthesiologists (ASA) grade of patients [19], and to recommend the National Institute for Health and Care Excellence–guided preoperative tests [20]. The data and analysis are currently reviewed by a registered nurse in MyPreOp's clinician portal, and the patient is moved along the appropriate care pathway.

MyPreOp is hosted on Google Cloud [21] and is compliant with Fast Healthcare Interoperability Resources (FHIR) Health Level 7 standards of interoperability [22,23], so the preoperative assessment report can be easily incorporated into patients' electronic health records. MyPreOp automatically codes data using the Systematized Nomenclature of Medicine–Clinical Terms (SNOMED CT) [24,25] and generates International Classification of Diseases–10 (ICT-10) codes for comorbidities [26,27], providing a standardized clinical summary.

Potential Benefits of Solution

MyPreOp has the potential to provide several key benefits for patients, clinicians, and health systems. It can provide patients with control over their personal health records and could improve the patient experience by increasing convenience, minimizing hospital visits, and decreasing the need to discuss sensitive topics. MyPreOp also includes built-in links to provide patients with easy access to accurate information about their procedure. Clinical benefits could include reducing the time clinicians spend conducting assessments and analyzing data, allowing them to spend more time on high-value care activities.

The use of digital preoperative assessments could also have significant economic benefits for health systems. According to RCoA requirements, conducting 12,000 preoperative assessments currently requires 7.2 whole time equivalent (WTE) nurses and 3.6 WTE health care assistants [6]. In comparison, a preoperative assessment service using MyPreOp requires about 3.7 WTE nurses and 1.1 WTE health care assistants. After including the costs for MyPreOp [28], this represents a potential 38% reduction in service costs. By enabling home completion of preoperative assessments, MyPreOp is also likely to reduce travel costs for the patient (and carers) and environmental costs from that travel.

Aims and Objectives

This study aims to evaluate the potential of MyPreOp (Ultramed Ltd) to provide clinical and economic benefits when replacing the current standard of care. Specifically, the aim is to investigate the impact of the MyPreOp system on the time and environmental costs associated with preoperative assessments in 1 clinical site where it has been adopted and to examine ratings of its usability and acceptability in 3 clinical sites. The objectives of this case study are as follows:

1. Measure the time saved through the use of MyPreOp by assessing the number of face-to-face appointments avoided and the time spent by nurses completing the MyPreOp process at Royal United Hospitals Bath (RUHB) NHS Trust
2. Estimate the reduction in travel and associated carbon dioxide (CO_2) emissions because of the reduction in face-to-face appointments at RUHB NHS Trust
3. Examine quantitative feedback about MyPreOp from users in 3 clinical sites (RUHB NHS Trust, Guy's and St Thomas' [GSTT] NHS Trust, and BMI Bath Clinic)
4. Compare patient responses to questions about the usability of MyPreOp with a previous service evaluation

Methods

Study Design

This investigation used a case study design (Table 1) to perform a formative service evaluation of data collected during the use of MyPreOp at 2 NHS Trusts and a private hospital. A case study framework [29] was used to structure the process of the evaluation. A formative service evaluation [30] was conducted to assess how well MyPreOp achieves its main aim of streamlining the preoperative assessment process in its early implementation [31]. This will provide preliminary evidence to inform future clinical investigations and cost analyses of the MyPreOp system. As the data used were collected and anonymized by a second party with informed consent, formal ethical approval for this evaluation was unnecessary.

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Table 1. Case study framework [29,32,33].

Number	Stage	Outcome
1	Plan	Description of problem, case, and research questions
2	Design	Construction of case study design and linkage of research questions and available data
3	Prepare	Selection of NHS[a] Trusts with appropriate data and sufficient sample sizes
4	Collect	Collection of MyPreOp use and patient feedback data from the MyPreOp analytics dashboards and the MyPreOp system
5	Analyze	Descriptive analysis and validation of data
6	Create	Drafting of the case study (this paper)
7	Share	Submission of the case study for publication in a peer-reviewed journal (this paper)

[a]NHS: National Health Service.

Context and Participants

This study evaluated version 2 of MyPreOp. Versions 1 and 2 are similar from a patient perspective; however, version 2 is FHIR–based and cloud-based and includes a clinician portal. A total of 2 NHS Trusts using version 2 were included in this study: RUHB [34] and GSTT [35]. Data from the private BMI Bath Clinic were also included in the analysis of user feedback [36]. These hospitals were selected as they had used the MyPreOp system with the largest number of patients and had the most data available for analysis per site, and as they had the specific customizations and collaborations needed to collect the relevant data. These included the system being set up to ask relevant user feedback questions, statuses within the system that facilitated user feedback, statistics about face-to-face appointments, and an understanding of how the clinical sites' processes aligned with the statuses being entered into the system (so the face-to-face appointment data could be verified). The other hospitals that used MyPreOp version 2 were excluded because of low numbers of submissions (n<300) or a high degree of customization, meaning relevant data could not be collected. Most of the analysis was conducted on data from RUHB, as they have been using MyPreOp version 2 for a longer period than the other sites and, therefore, have the largest body of service data.

All available patient submissions on MyPreOp during the study period were included in the analysis, regardless of age, health status, or type of surgery so the analysis would reflect typical patient use. However, the number of submissions included for each specific analysis varied depending on certain factors, such as whether the nurse had marked the submission as complete or whether the patient had answered a specific question.

Data Collection

Anonymized operational data were collected from and processed by the MyPreOp system at each of the clinical sites for a 4-month period from September 1, 2020, to December 31, 2020. One of the authors (JL) created data sets from the raw JSON data using BigQuery SQL and manually examined a small subset of data to check that it was being processed correctly.

Raw data were automatically collected and compiled using the MyPreOp system. Clinicians use their MyPreOp portal to set patients' status as they move through the process (eg, requiring a face-to-face appointment with a nurse or anesthetist). The number of avoided face-to-face appointments was assumed to be the number of patients who progressed through the entire process without having their status set to requiring a face-to-face appointment. The system also tracks the length of time from the start of nurses' processing of a patient on MyPreOp to the assessment being uploaded into the patient's record.

The amount of carbon emissions saved by using MyPreOp was calculated from patient-reported data about their distance from the hospital (in miles) and the mode of transit they usually use to travel to the hospital (car, motorcycle, bus, train, bicycle, or walking), although these data were only available for RUHB, as the other sites chose to ask their patients different questions. Patients who did not need face-to-face appointments were assumed to have avoided one return trip to the hospital. A carbon footprint calculating website [37] was used to calculate the approximate CO_2 equivalent (CO_2e) of the travel avoided by using MyPreOp.

User feedback data were collected from patient feedback questions presented at the end of the MyPreOp questionnaire and stored in the MyPreOp system.

Data Analysis

A descriptive analysis was conducted by one of the authors (JL) to summarize the data collected. The same author created visualizations of the data in DataStudio (Google). No statistical analyses were conducted because of the limitations of the study design and the collected data. The service evaluation at RUHB identified the percentage of patients who were not listed as requiring face-to-face follow-up appointments, the mean and median of nurse time spent on assessments, and an estimate of CO_2 emissions avoided by reducing the number of patients seen for face-to-face appointments. Usability data collected from the 3 clinical sites examined in this study were summarized and compared with a previous service evaluation of MyPreOp in different NHS Trusts [38].

Results

Overview

During the 4-month period of data collection (September 1, 2020, to December 31, 2020), there were 2500 MyPreOp submissions from patients at the three clinical sites: 71.08% (n=1777) were from patients at RUHB, 16.24% (n=406) were from GSTT, and 12.68% (n=317) were from BMI Bath. The

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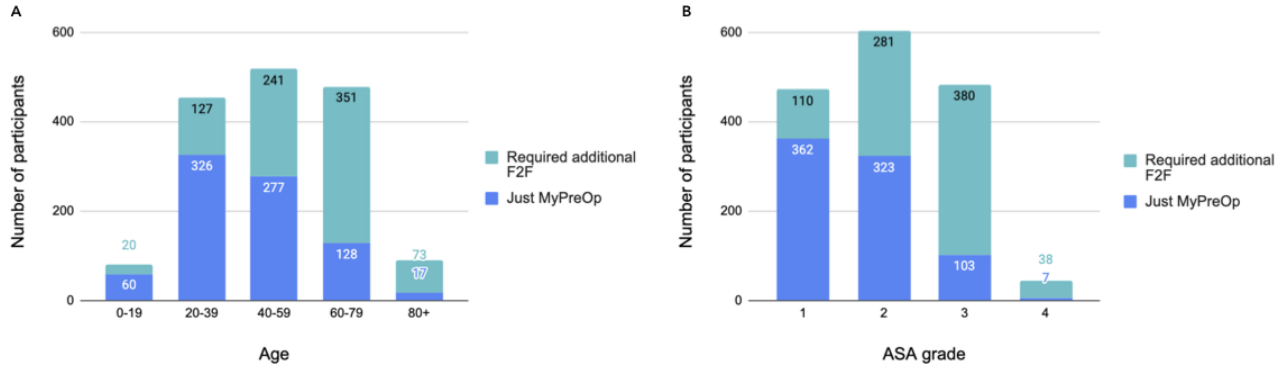
total number of patients assessed for each outcome measure is reported for the individual analyses, as it does not always equal the total number of submissions. This is because patients were not required to answer all questions, and not all submissions had progressed through the whole system to completion at the time of data collection.

Face-to-face Appointments Avoided

Of the patients who used the MyPreOp assessment at RUHB during the 4-month period, half (813/1630, 49.88%) did not require any further face-to-face follow-up. The total sample for this analysis included patients who completed the assessment and those who had been flagged on the system as requiring a face-to-face assessment but had not yet had the appointment. It excluded patients whose preoperative assessments had not yet been processed. The number of patients requiring face-to-face appointments varied by age and ASA grade (Figure 1). The totals differed slightly, as a small minority of patients who did not have their age or ASA grade correctly entered into the system were excluded from the analysis. There was a greater number of patients aged <60 years who did not require a face-to-face appointment (663/1051, 63.08%) than those who did (388/1051, 36.92%), although this was more pronounced at younger ages. A similar trend was observed for ASA grades, with more patients with lower ASA grades (1 and 2) avoiding face-to-face appointments than those with higher grades. Data on face-to-face appointments avoided for GSTT and BMI Bath could not be included in this analysis, as the process of nurses flagging the patients who required a face-to-face assessment on the system could not be fully validated throughout the entire trial period, unlike with RUHB.

Figure 1. Proportions of (A) patients needing face-to-face appointments by age and (B) American Society of Anesthesiologists grade (data from the Royal United Hospitals Bath). ASA: American Society of Anesthesiologists; F2F: face-to-face.



Nursing Time Spent Completing MyPreOp

The distribution of time that nurses at RUHB spent completing MyPreOp assessments for patients who did not require a face-to-face appointment was heavily skewed to the short side. The median amount of time nurses spent completing assessments was 5.3 (IQR 3.2-12.9) minutes and the mode was 2 minutes; significantly shorter than the mean time of 49.9 minutes (SD 454.7 minutes; n=860). The data were skewed heavily to the right by the inclusion of a small percentage of assessments that had a long time between start and completion (94/860, 10.9% of assessments took nurses longer than an hour to complete). If those assessments were excluded, the mean time to complete the assessment was 6.8 minutes (SD 7.4 minutes; n=766). However, as time spent on the assessment was measured by the difference between when it began and when it was marked as complete, the cause of these delays could not be accounted for in this analysis.

CO_2 Reduction

The vast majority of RUHB patients (1583/1757, 90.1%) used a car as their usual mode of transit to the hospital. Half of the respondents (771/1541, 50.03%) lived between 5 and 15 miles away from the hospital, about a third (517/1541, 33.55%) lived >15 miles away from the hospital, and the remaining 16.42% (253/1541) lived within 5 miles of the hospital. Information about patients' usual mode of transit was combined with their distance from the hospital (Table 2) and the data on the number of avoided appointments to calculate potential carbon savings. Over the 4-month period, the reduction in face-to-face appointments at RUHB is estimated to have resulted in a total carbon savings of 9.05 tons of CO_2e.

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Table 2. Distance that patients need to travel to get to Royal United Hospitals Bath hospitals stratified by mode of transit (N=1541).

Mode of transport	Distance from hospital (miles), n (%)		
	0-5	5-15	≥15
Car (n=1402)	177 (13)	732 (52)	493 (35)
Bus (n=56)	17 (30)	27 (48)	12 (21)
Train (n=16)	1 (6)	4 (25)	11 (69)
Motorcycle (n=2)	1 (50)	1 (50)	0 (0)
Bicycle (n=8)	5 (63)	3 (38)	0 (0)
Walk (n=57)	52 (91)	4 (7)	1 (2)
Total (n=1541)	253 (16)	771 (50)	517 (34)

User Feedback

User feedback was examined using data from both NHS Trusts (RUHB and GSTT) and the private BMI Bath Clinic. Across the 3 sites, 87.94% (2195/2496) of patients reported completing MyPreOp on their own. Of the patients who reported having assistance completing MyPreOp, only 3.8% (10/266) were helped by a member of staff; the remaining patients were assisted by relatives, friends or neighbors, or parents or guardians. To facilitate the evaluation and improvement of MyPreOp, patients were also asked if they consented to have their anonymized data used for research. Of those who responded (from GSTT, RUHB, and BMI Bath), 81.89% (1741/2126) said that they were happy for their anonymized data to be used.

As the clinical sites did not all use the same user feedback questions, the remaining analyses were conducted separately for each site data set. BMI Bath assessed the length of time the patients required to complete MyPreOp. Nearly half of the patients completed MyPreOp within ≤30 minutes (131/301, 43.5%), and less than a quarter of patients needed >45 minutes (65/301, 21.6%).

At GSTT, a total of 403 patients completed MyPreOp assessments over the 4-month period. Most of these patients responded to the patient feedback questions provided at the end of the MyPreOp questionnaire; however, they were not mandatory, so the number of respondents varied per question. MyPreOp was generally rated highly on user feedback: 79.8% (317/397) rated MyPreOp as easy or very easy to use, with only 6.3% (25/297) finding it difficult or very difficult to use, and 85.2% (340/399) thought the overall experience was good or very good with only 3.3% (13/399) rating it as poor or very poor. At RUHB, patients were asked if they had any concerns about MyPreOp; 88.1% (1548/1757) reported having none.

Users at GSTT were also asked to provide feedback on the additional supporting information provided by the system. Furthermore, 82.9% (320/386) of patients thought that the information provided by MyPreOp about what to expect next in their preoperative pathway was somewhat or very easy to understand, and 80.6% (312/387) of patients rated the additional health information provided as quite or very useful.

Discussion

Principal Findings

The data from the RUHB NHS Trust demonstrated that half of the patients who used the MyPreOp service for their preoperative assessment did not require a face-to-face appointment. This is higher than the Digital by Default's 2012 estimate that 40% of secondary care preoperative appointments could be avoided by using remote screening [17] but will need to be confirmed in larger, more diverse samples. The reduction in appointments was most prominent in users who were younger and healthier (as indicated by a low ASA score). Therefore, the impact of the service could be limited, as younger and healthier patients might be more likely to have more straightforward and rapid preoperative assessments.

A reduction in preoperative assessment appointments has the potential to save nurses' time. The RCoA recommends that preoperative assessments be scheduled to last 30 minutes (for day patients) to 45 minutes (for inpatients) [6]. According to the time logs from the MyPreOp data, nurses at RUHB spent a median of approximately 5 minutes on patients who did not need a face-to-face appointment. During the period of data collection, 49.88% (813/1630) of the patients at RUHB avoided an appointment. If the time spent on an average patient is 33 minutes (the RCoA assumes a ratio of 80% day patients and 20% inpatients [6]), and the median time spent on patients who avoided an appointment is 5 minutes, an estimate of the average time saved for each of those 813 patients was 28 minutes. In this sample, this would represent approximately 379 hours saved. Although this estimation is based on a relatively small sample, it illustrates MyPreOp's potential to reduce the time nurses spend on preoperative assessments. However, over half of the users reported needing at least 30 minutes to complete their assessment, so potential time savings for patients appear to be more limited. These findings should be examined in a clinical trial to establish further evidence of the impact of MyPreOp on time spent on preoperative assessments.

A reduction in face-to-face appointments also has the potential to reduce travel, which could save time for patients and contribute to reducing carbon emissions. The amount of carbon savings identified in this study (9.05 tons) is small compared with the United Kingdom's net CO_2 emission (351.5 million tons in 2019) [39]. However, transport is the biggest contributor

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to CO_2 emissions in the United Kingdom (34% in 2019) [39,40], with road transport (particularly passenger cars) accounting for the largest proportion of emissions in that sector [41,42]. Therefore, reducing car use is one of several key strategies for reducing transport-related carbon emissions [43,44]. Although any preoperative assessment–related travel reductions associated with remote preoperative assessments will not be a large proportion of road transport, it is aligned with the NHS's net zero carbon goal [45].

Overall, most patients at GSTT rated MyPreOp fairly positively on the user feedback questions. These results are similar to a previous service evaluation of MyPreOp version 1 (unpublished data), which found high ratings of overall experience (974/1193, 81.64% rated it as good or excellent) and ease of use (1119/1193, 93.8% thought it was very easy or easy enough to use) [38]. The data assessed from GSTT in this service evaluation found a slightly lower rating for ease of use (317/397, 79.9% rated MyPreOp as easy or very easy to use). The wording of the usability questions varied slightly between the 2 evaluations (*very easy* or *easy* in this assessment compared with *very easy* or *easy enough* in the previous one), which could have affected ratings. However, the variation seems to come from fewer people rating MyPreOp as *very easy* in this assessment (173/397, 43.6%) compared with the previous one (697/1193, 58.43%); ratings for *easy* (144/397, 36.3%) and *easy enough* (422/1193, 35.37%) were similar. It is possible that sample demographics influenced the ratings, and research in larger and more diverse samples will be necessary to explore potential demographic differences in acceptability and usability further to evaluate any potential impact of MyPreOp on health inequalities.

Limitations of the Study

A major limitation on the interpretability of the study is that it was a service evaluation without a rigorous, pre-established methodology or statistical analysis. To mitigate this, the Standards for Reporting Qualitative Research checklist was used in the preparation of this paper (Multimedia Appendix 1 [46]). However, it cannot provide strong evidence of any positive or negative impacts of MyPreOp on the outcomes examined and only demonstrates the feasibility of the solution and its potential impacts. A controlled clinical trial is necessary to provide evidence of the efficacy of MyPreOp in reducing the time, economic, and environmental costs of preoperative assessments.

The data were provided to the academic team in a processed form because of difficulties and concerns about accessing the Ultramed system. One author (JL) used SQL queries to extract JSON data into tables. This introduces a potential for bias and conflict of interest, as the quality of the data depends on the accuracy of those queries, which were not validated by a second author.

The measure of avoided face-to-face appointments is limited, as it uses the patient statuses set by nurses in MyPreOp as an indicator of whether the patient had a face-to-face appointment. There was no external validation of the accuracy of these statuses and whether the patient actually avoided a face-to-face appointment.

Another limitation is that the data were only available for individual NHS Trusts for most of the outcomes measured. A compilation of data from each of the Trusts would have provided larger samples from more diverse populations. For example, many of the patient feedback questions included at the end of the MyPreOp questionnaires varied depending on the Trust and could not be collated. This raises another limitation: the user feedback questions displayed at the end of MyPreOp were selected by the individual Trusts and based on what they perceived to be most useful to them, not a usability theory or framework. The lack of a theoretical framework and validated measure, as well as the difference in wording between Trusts, introduce potential bias in the evaluation of usability and acceptability.

Future Directions

Further research is needed to examine the cost and time benefits of MyPreOp on a larger scale. This should be conducted as a proper academic study and include a full health economic assessment (including environmental costs) instead of a service evaluation, as a pre-established methodology will increase the credibility of the results. A comparison of the time and costs of using MyPreOp compared with current standards of care would also provide a more compelling argument for the use of digital preoperative assessment services in general and MyPreOp in particular [47,48].

More research into patient usability would also be beneficial [49]. Future studies should include a theory-based qualitative examination of patient feedback regarding acceptability and usability. This will likely be particularly important for older users, as there is an increasing number of older adults undergoing surgery [50], and there tends to be a greater digital exclusion of older people [51,52]. Evaluating the usability of digital health solutions in older adults—and other groups who might struggle to access digital services—is important to ensure that MyPreOp and other digital solutions do not worsen existing health inequalities.

Conclusions

The aim of this evaluation was to describe the data being collected by MyPreOp and to provide an assessment of the potential benefits of its implementation. From the data included in this study, a reduction in the number of face-to-face appointments was observed; however, this appeared to vary depending on age and ASA grade. A potential reduction in the time spent on preoperative assessments that did not require a face-to-face appointment was observed for nurses but not for patients. The reduction in face-to-face appointments was demonstrated to have a potential impact on travel-related CO_2e emissions. The study also found generally positive ratings for MyPreOp. However, the quantity and quality of the evidence, as well as the methodology of this service evaluation, are not sufficient to provide strong support for the efficacy and usability of MyPreOp. Further studies should be conducted using rigorous scientific methods and including more clinical sites to evaluate a greater range of outcomes, including cost-effectiveness, compared with the current standard of care and qualitative user feedback.

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Acknowledgments

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Authors' Contributions

MMI drafted the case study in collaboration with JL, who provided the processed data and feedback on the analyses. JL and IM revised the paper, with final revisions from AC and EM.

Conflicts of Interest

JL is an employee of Ultramed Ltd. JL was responsible for retrieving the raw data from the Ultramed system and processing it using BigQuery (SQL) and DataStudio (Google) to produce the analyzed data and graphs. JL was also involved in the drafting and revision of the case study. EM is the editor-in-chief of JMIRx Med.

Multimedia Appendix 1
Standards for Reporting Qualitative Research checklist [46].
[DOCX File , 22 KB - periop_v5i1e28612_app1.docx]

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Abbreviations

ASA: American Society of Anesthesiologists
CO_2e: CO_2 equivalent
GSTT: Guy's and St Thomas'
NHS: National Health Service
RCoA: Royal College of Anaesthetists
RUHB: Royal United Hospitals Bath
WTE: whole time equivalent

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Original Paper

Innovative App (ExoDont) and Other Conventional Methods to Improve Patient Compliance After Minor Oral Surgical Procedures: Pilot, Nonrandomized, and Prospective Comparative Study

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Abstract

Background: Postoperative care is influenced by various factors such as compliance, comprehension, retention of instructions, and other unaccounted elements. It is imperative that patients adhere to the instructions and prescribed regimen for smooth and placid healing. ExoDont, an Android-based mobile health app, was designed to ensure a smooth postoperative period for patients after a dental extraction. Besides providing postoperative instructions at defined intervals, the app also sends drug reminders as an added advantage over other available, conventional methods.

Objective: The aim of this study was to compare the compliance rate of individuals with respect to the prescribed regimen and postoperative instructions. Additionally, we aimed to assess any changes in the postoperative complication rate of patients assigned to 3 categories: the verbal, verbal plus written, and ExoDont app-based delivery groups.

Methods: We conducted a pilot, nonrandomized, and prospective comparative study in which patients after tooth extraction were assigned to 3 groups—verbal (Group A), verbal plus written (Group B), and ExoDont app-based delivery (Group C)—based on the eligibility criteria, and a 1-week follow-up was planned to obtain the responses regarding compliance and postoperative complications from the participants.

Results: In total, 90 patients were recruited and equally divided into 3 groups. Compliance to prescribed drug was found to be the highest in Group C, where of the 30 participants, 25 (83%) and 28 (93%) followed the entire course of antibiotics and analgesics, respectively. For postoperative instructions, higher compliance was observed in Group C in relation to compliance to diet restrictions (P=.001), not rinsing for 24 hours (P<.001), and warm saline rinses after 24 hours (P=.001). However, the difference was not significant for smoking restrictions (P=.07) and avoiding alcohol (P=.16). Moreover, the difference in postoperative complication rate was not statistically significant among the 3 groups (P=.31).

Conclusions: As evident from the results, it is anticipated that the ExoDont app will be helpful in circumventing the unaccounted possibilities of missing the prescribed dosage and postoperative instructions and ensuring the smooth recovery of patients after dental extraction. However, future studies are required to establish this app-based method of delivery of postoperative instructions as a viable option in routine clinical practice.

(JMIR Perioper Med 2022;5(1):e35997) doi:10.2196/35997

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KEYWORDS

ExoDont; mHealth; mobile health; Android app; dental extraction; postoperative; oral surgery; dentistry; teledentistry; mobile app

Introduction

Patient compliance plays an important role in the early and efficient recovery process after dental extraction. It is defined as the degree to which a patient adheres to the prescribed medication, postoperative instructions, self-care, or any therapy sessions given by the doctor. Moreover, the postoperative care period depends on the ability of the patient to comprehend and implement the guidelines as advised by the treating doctor to minimize any surgery-related complications and associated morbidity and improve the quality of life [1].

The lack of adherence to posttreatment guidelines is classified as a major global problem by the World Health Organization [2]. Studies have estimated that around 20%-50% of patients do not take their medication appropriately [3,4]. The reason for this noncompliance could be multifold, including language barriers, low health literacy, inadequate surgeon-patient communication, patient's inability to concentrate on instructions due to postoperative stress, emotional and psychological state, and other involuntary reasons such as confusion or forgetfulness [5,6]. This clearly demonstrates the need for a system or method to foster adherence in patients and help reduce postoperative complications due to noncompliant issues.

Multiple studies have focused on the methods of dissemination of postoperative instructions after surgery and their influence on the overall quality of treatment. The method of dissemination plays a substantial role in determining the level of postoperative stress and anxiety, pain, postoperative complications, and, most importantly, compliance in patients [7,8]. These studies have compared conventional verbal methods with verbal plus written methods [9], phone-call follow-ups [10], and pictorial methods [8] as viable options for the dissemination of postoperative instructions. However, there is limited literature available for the application of current technology in imparting postoperative instructions after minor oral surgical procedures.

With the advent of the smartphone era and people turning toward mobile apps to accomplish their daily goals, there has been a tremendous growth in technology-based health care delivery systems. In the field of oral surgery, there are multiple apps available that improve access to health care, clinical management, drug guidelines, education, and telecommunication, etc. Smartphone apps such as iResus, BNF, and Snellen are available for these purposes [11]. Based on similar principles, the ExoDont app was developed to ensure compliance in patients for prescribed drug regimen and postoperative instructions dissemination. ExoDont is an Android-based hybrid app aimed at fostering treatment adherence in patients undergoing dental extractions. It is an attempt toward making the public more self-reliant regarding their prescribed medication dosage, frequency, and duration with a personalized, easy-to-use, and innovative app-based system that displays reminders at the appropriate times for taking medication and illustrates postoperative instructions.

As the first part to the project, the development of the ExoDont app, its feasibility, functionality, and preliminary field-testing results were presented in a previous report [12]. As a second part, this study described a detailed comparison of conventional (verbal and verbal plus written) and ExoDont app-based methods of postoperative instructions dissemination. The primary objective of this study was to evaluate and compare patients' compliance to the postoperative instructions and prescribed drug regimen with respect to the 3 groups of dissemination methods: verbal, verbal plus written, and app-based. As a secondary objective, the complication rate after tooth extraction was evaluated and compared for the 3 groups.

Methods

Study Design

This was a pilot, nonrandomized, and prospective comparative study carried out in the outpatient department of oral and maxillofacial surgery of a tertiary dental care institute. All study participants were well-informed about the study, and written informed consent was obtained. A sample size of 90 patients was recruited, and the patients were assigned to 3 different groups based on the methods of dissemination of postoperative instructions as per the eligibility criteria. The first group, labeled "Group A," received only verbal instructions; the second group, labeled "Group B," received both verbal and written instructions in the form of a pamphlet; and the third group, labeled "Group C," received ExoDont app-based postoperative instructions and medication reminders.

Ethics Approval

This study was conducted at a tertiary dental care institute at the Faculty of Dentistry, Jamia Millia Islamia, Delhi over a period of 3 months. Ethical approval was obtained from the Institutional Ethical Committee of the Faculty of Dentistry, Jamia Millia Islamia, Delhi, under proposal number 2(1/10/291/JMI/IEC/2020). Informed consent was obtained from the participants for being a part of the study.

Postoperative Instructions and Treatment Protocol

The postoperative treatment protocol was established, comprising antibiotics and analgesics along with postextraction instructions to be given to patients after tooth extraction. A list of common postoperative instructions was formulated by referring to previously existing data [1]. The same postextraction instructions were then disseminated through the 3 methods: in the form of verbal instructions to Group A patients; verbal as well as written instructions through a well-designed pamphlet in the 3 languages of English, Hindi, and Urdu (Figure 1) to Group B patients; and through the ExoDont app to Group C patients (Figure 2).

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Figure 1. Written postoperative instructions in the form of a pamphlet for Group B patients.

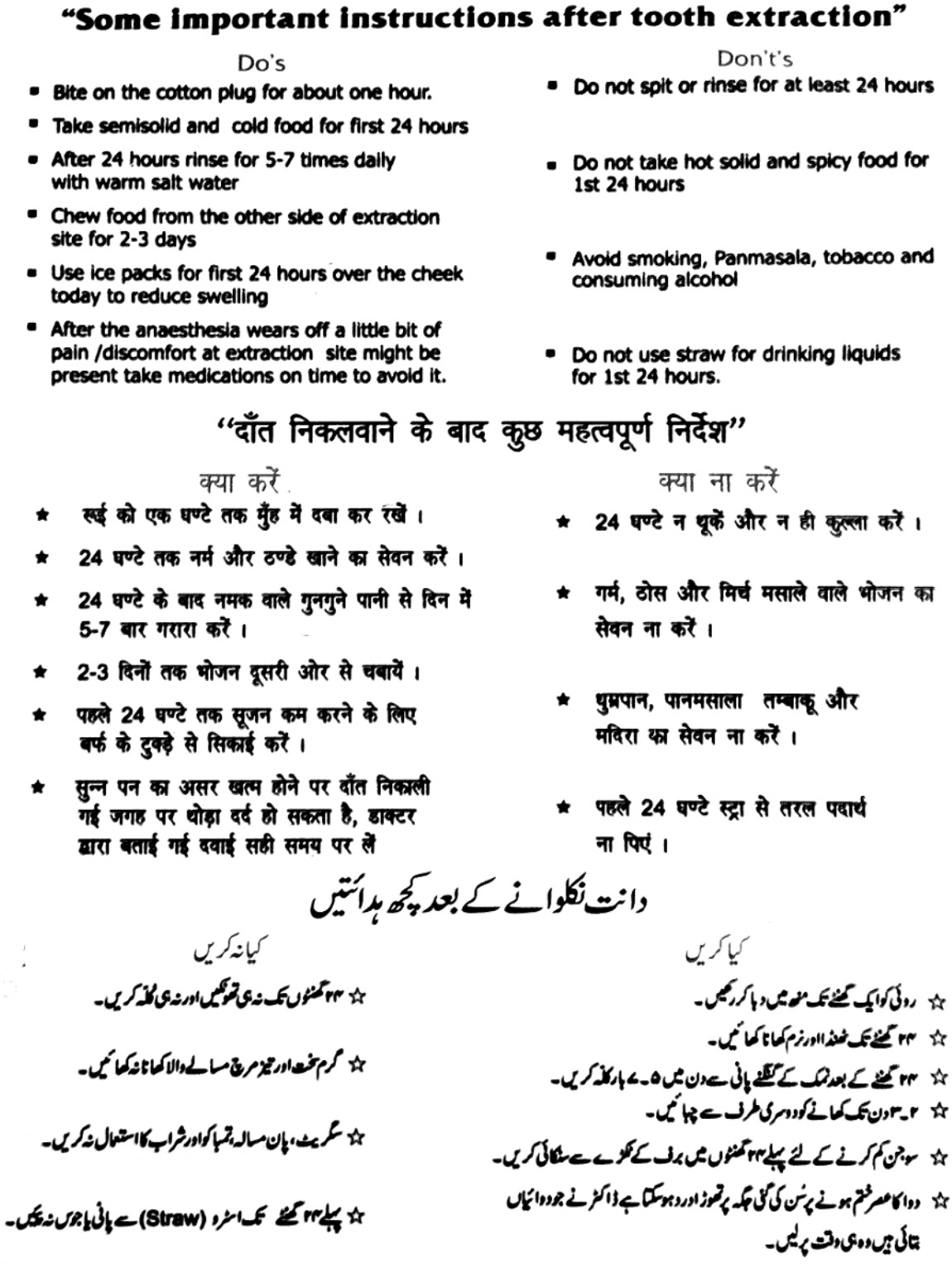

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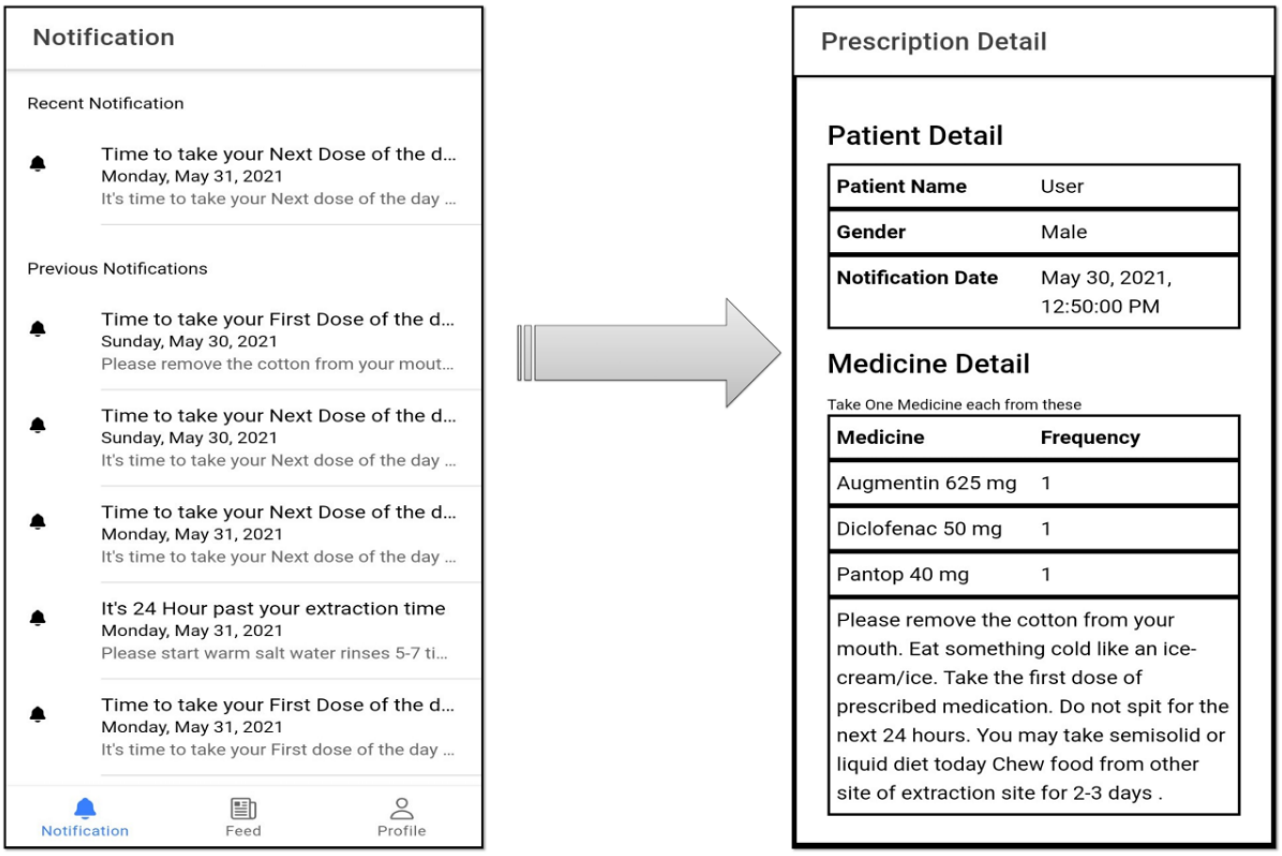
Figure 2. ExoDont app-based postoperative instructions in the form of notifications for Group C patients.



Workflow of the ExoDont App

ExoDont is a notification-based Android app, which sends out pop-ups reminding patients about their prescribed dosage of medicine and the postoperative instructions to follow. The ExoDont app has been described in detail in a previous study [12].

The ExoDont app supports 2 platforms—1 for the surgeon and administrative staff and 1 for the patient. The administrative staff enters the patients' details such as name, age, gender, time and date of the procedure, and phone number on the ExoDont webpage. Subsequently, the administrative staff has to choose from the list of options the names of the antibiotics and analgesics to be used, duration for each of these drugs, and frequency for which the patient has to take the prescribed drug. The options for the duration of the drug regimen are available as short course (3 days), standard course (5 days), and long course (7 days).

After the tooth extraction, patients have to download the app on their smartphone from the Google Play Store. Patients receive an introductory message as soon as they log on the app. This message displays the demographic details of the patient and the date and time of the procedure as entered by the administrative staff. Based on the time of the procedure, patients would receive scheduled reminders for postoperative instructions and prescribed drug at defined intervals as shown in Table 1.

Table 1. Content of ExoDont notifications for postoperative instructions and drug reminders.

Time from procedure	Message content
1 hour	• Remove the ice pack • Eat something soft and cold such as ice cream • Take the first dose of antibiotics and analgesics
8-12 hours (depending on the drug chosen by the administrative staff)	• Take the second dose of antibiotics and analgesics • Avoid hot and hard food • Chew only on the opposite side
16-24 hours (depending on the drug chosen by the administrative staff)	• Take the third dose of antibiotics and analgesics • Start warm saline rinses 4-5 times daily • Brush regularly

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Patient Inclusion and Exclusion Criteria

Adult patients (aged >18 years) undergoing routine tooth extraction at the department of oral and maxillofacial surgery were included in the study. Patients with psychological disorders or mental conditions that created difficulties in language comprehension and those with medical conditions that made them prone to postoperative complications were not included in the study. Additionally, patients who could not read the instruction pamphlet (for Group B) and those who did not have a smartphone (for Group C) were not included in either of the 2 groups; however, they were included in Group A. Recruitment continued as per the eligibility criteria until the target of 30 participants for each group was reached.

Procedure

Simple intra-alveolar extraction was performed by the treating surgeon in the outpatient department of oral and maxillofacial surgery. After the extraction, patients were given a written prescription for the drugs to be taken. Subsequently, postoperative instructions were given to each patient verbally by the surgeon. Patients in Group A received only verbal instructions in 1 of the 3 languages—Hindi, Urdu, or English—whichever they found convenient. The patients in Group B received a pamphlet containing written postoperative instructions, printed in all 3 languages—Hindi, Urdu, and English—along with verbal instructions. Lastly, patients in Group C were asked to download the free ExoDont app from the Google Play Store on their smartphones, through which they received reminders for postoperative instructions and drug intake.

Data Collection

Each patient was called to the outpatient department of oral and maxillofacial surgery for follow-up 1 week after the extraction, and their responses to a group-specific feedback form were obtained (Multimedia Appendix 1). The patients who could not report after 1 week were followed up through a phone call. In the group-specific feedback form that was administered by the investigators, yes-or-no questions for each drug taken and postoperative instruction followed were asked separately. The criteria for compliance measurement were set at 100% of the prescribed dosage and postoperative instructions followed by the patients, since the course duration of 3 to 7 days was very short. All the complications were reported directly by patients during their follow-up and assessed by the treating surgeon according to the standard criteria of evaluation.

Data Analysis

The analysis of data collected in response to the feedback form was done using SPSS statistical package (version 10.0; IBM Corp). Chi-square test was applied to compare the rates of compliance and complication in the 3 groups. The level of significance was set at $P<.05$.

Results

Participant Demographics

A total of 90 patients were recruited with 30 participants in each group. The mean age of the patients who participated in the study was 40.4 (range 25-56) years for Group A, 36.2 (range 21-52) years for Group B, and 34.3 (range 19-47) years for Group C. Of the 90 patients who participated in the study, 53 (59%) were men and 37 (41%) were women. Among each group of 30 patients, 18 (60%) men and 12 (40%) women were in Group A; 19 (63%) men and 11 (37%) women were in Group B; and 16 (53%) men and 14 (47%) women were in Group C. The most common teeth to be extracted were mandibular molars, followed by the maxillary molars.

Comparative Evaluation of Groups A (Verbal), B (Verbal Plus Written), and C (App-Based)

The chi-square test revealed higher compliance rate in Group C to antibiotics ($P<.001$), analgesics ($P<.001$), diet restrictions ($P=.001$), not rinsing for 24 hours ($P<.001$), and warm saline rinses after 24 hours ($P=.001$). However, no significant differences were found among the 3 groups for postoperative instructions relating to smoking restrictions ($P=.07$) and avoiding alcohol ($P=.16$). A detailed analysis of the comparison has been presented in Table 2. Some of the postoperative complications observed in all 3 groups were bleeding, dry socket, infection, and pain. A majority (82%, 74/90) of the participants did not experience any complications. The difference observed in the 3 groups for the rate of postoperative complications was not significant ($P=.31$; Table 3).

Table 2. Comparison of compliance in Group A (verbal), Group B (verbal plus written), and Group C (app-based).

Compliance	Group A (n=30), n (%)	Group B (n=30), n (%)	Group C (n=30), n (%)	*P* value
Antibiotics	10 (33)	13 (43)	25 (83)	<.001
Analgesics	13 (43)	10 (33)	28 (93)	<.001
Diet restrictions	22 (73)	15 (50)	28 (93)	.001
Not rinsing for 24 hours	10 (33)	20 (67)	26 (87)	<.001
Smoking restrictions	20 (67)	25 (83)	27 (90)	.07
Avoiding alcohol	24 (80)	20 (67)	26 (87)	.16
Warm saline rinses	8 (27)	14 (47)	23 (77)	.001

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Table 3. Comparison of postoperative complications in Group A (verbal), Group B (verbal plus written), and Group C (app-based).

	Group A (n=30), n (%)	Group B (n=30), n (%)	Group C (n=30), n (%)	*P* value
Complications				.31
Bleeding	2 (7)	0 (0)	1 (3)	
Dry socket	5 (17)	5 (17)	1 (3)	
Infection	1 (3)	0 (0)	0 (0)	
Pain	0 (0)	0 (0)	1 (3)	
None	22 (73)	25 (83)	27 (90)	

Intergroup Comparison

Comparison between Groups A and B revealed no significant differences between the 2 groups in relation to the compliance to antibiotics (*P*=.43) and analgesics (*P*=.43); adherence to postoperative instructions such as compliance to diet restrictions (*P*=.06), warm saline rinses (*P*=.11), smoking restrictions (*P*=.14), and alcohol restrictions (*P*=.24); or the rate of postoperative complications (*P*=.35). However, higher compliance to not rinsing for 24 hours (*P*=.01) was observed in Group B.

When compared to Group A, Group C had higher compliance to antibiotics (*P*<.001) and analgesics (*P*<.001). Most postoperative instructions such as diet restrictions (*P*=.04), not rinsing for 24 hours (*P*<.001), warm saline rinses (*P*<.001), and smoking restrictions (*P*=.03) also showed higher compliance in the app-based group. However, the difference was not significant for alcohol restrictions during the postoperative phase (*P*=.49) and the rate of postoperative complications (*P*=.10).

Similarly, the comparison between the verbal plus written (Group B) and app-based delivery (Group C) groups showed significant differences for compliance to drug regimen (antibiotics: *P*=.001; analgesics: *P*<.001) and postoperative instructions such as compliance to diet restrictions (*P*<.001) and warm saline rinses (*P*=.02). However, the differences were not significant for compliance to not rinsing for 24 hours (*P*=.07), smoking restrictions (*P*=.14), and alcohol restrictions (*P*=.07) and the rate of postoperative complications (*P*=.71).

Feedback for the Written Instructions

According to the responses from patients in Group B, 23 (77%) out of 30 participants found the pamphlet for written instructions useful. Second, most (15/30, 50%) of the patients referred to the pamphlet only once, followed by 0 times (9/30, 30%; Table 4).

Table 4. Feedback for the written instructions.

Question, response	Patient (n=30), n (%)
Was the pamphlet with written instructions helpful?	
Yes	23 (77)
No	7 (23)
How many times did you refer to the pamphlet during the week?	
0	9 (30)
1	15 (50)
2	4 (13)
3	1 (3)
>3	1 (3)

Feedback for the ExoDont App-Based Delivery of Instructions

Based on the responses of Group C patients from the feedback form, the ExoDont app was found useful by 83% (25/30) of the patients. However, 13% (4/30) of the users found it inconvenient due to the ExoDont app's requirement of an active internet connection throughout the duration of its use. Furthermore, a small number of patients did not receive timely notifications due to some technical issues that might have occurred during the entry of data or an unstable internet connection (Table 5). It was reported that the ExoDont app helped the most in adherence to the drug regimen (70%, 21/30), followed by postoperative instructions for diet restrictions (67%, 20/30) and warm saline rinses (63%, 19/30; Table 5).

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Table 5. Feedback for the ExoDont app-based delivery of instructions.

Question, response	Patient (n=30), n (%)
Did you find the ExoDont app useful?	
Yes	25 (83)
No	5 (17)
Did the ExoDont app cause any inconvenience?	
Yes	4 (13)
No	26 (87)
Which of the following instructions did the app help you with?	
Taking medication	21 (70)
Ice pack and semisolid diet in the first 24 hours	20 (67)
Warm saline rinses	19 (63)
Avoiding smoking and alcohol	16 (53)

Discussion

Principal Findings

In this study, Group A patients were found the least compliant for their prescribed dosage of antibiotics, whereas Group C showed a higher rate of compliance than the other groups (P<.001). Additionally, a higher compliance rate for the analgesics prescription (P<.001) was observed in Group C. A similar trend was observed in adherence to postoperative instructions. Intergroup comparison also produced results in favor of the app-based delivery system, followed by the verbal plus written method of dissemination of postoperative instructions. The ExoDont app-based system was able to accomplish its goal of improving patient compliance after a dental extraction. Although the compliance rates in Group C toward drugs and postoperative instructions were found to be higher, the app did not seem to have any prominent effect on the reduction of complication rates. This can be attributed to the fact that the complications following dental extraction depend on a number of variables—alteration of any or none of which may have an impact on the occurrence of complications. These factors include the technique used by the surgeon, patient characteristics, severity of trauma to the tissue, any underlying health conditions, and the number and type of teeth extracted [13].

Verbal postoperative instructions given to patients are a part of routine postoperative care. However, compliance to this conventional method varies. Blinder et al [9] studied patient compliance to postoperative instructions after oral surgical procedures in 3 groups—verbal, written, and verbal plus written instructions—where the highest compliance (60%) was observed in the verbal plus written group, followed by 36% in the written group and only 4% in the verbal group. This can be attributed to the patient's mental capacity to retain information, which is different for every patient. In this study, of the 30 participants in Group B, 9 (30%) did not refer to the written instructions through a pamphlet at all, and 15 (50%) only referred to them once, which signifies patient unacceptability toward written medical information. A previous study by Alvira-González et al [1] hypothesized that patients would remember information if the mechanism behind it were explained to them. Therefore, additional written information was given to the third group in addition to the verbal and written methods. However, no major difference in the adherence to postoperative instructions was found regarding the manner of the presentation of instructions in this study. This again raises concerns about the practicality of presenting written information as postoperative instructions to patients. Other elements such as phone call follow-ups [10] and visual graphics [8] have also been used for disseminating postoperative instructions, which achieved better results than conventional verbal and written practices.

Multiple studies have discussed the importance of the delivery method of postoperative instructions in the postoperative care of patients [1,8-10]. The importance of postoperative instructions cannot be overemphasized in the adequate healing of the socket and soft tissues after dental extraction. Failure to adhere to postoperative instructions and medication prescription may lead to delayed healing and increased risk of postoperative complications, adding to physical and emotional stress and increasing monetary expenditure to patients. Some of the commonly observed postextraction complications are dry socket or alveolar osteitis, which can cause considerable pain to an individual; postoperative infection at the site of surgery; postextraction hemorrhages; and paresthesia [1]. A positive correlation between the occurrence of alveolar osteitis and lack of compliance toward instructions such as using mouthwash or refraining from smoking has been established previously [14].

The field of perioperative management has seen huge technological advancements in recent times, advocating the use of smartphone apps to ensure a stress-free and easy recovery of the patient. In this regard, some of the apps available are "Teen Pocket PATH" [15] for medication adherence, "Panda" app [16] for postoperative pain management, and "Buddy Healthcare" [17]—a broad platform that provides preoperative assessment; reminders for patients as to when to stop eating and drinking and start taking medications; instructions for physiotherapy exercises; wound care instructions; a list of medications after surgery; and monitoring of recovery progress after surgery by care personnel. Other mobile apps being used for medication adherence are "RxmindMe" [18], which informs

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patients when the dose is due and additionally has a provision for recording when the dose was taken; and "SmartTrack" [19], which sends alerts if patients miss a dose for inhaler devices. The ExoDont app differs from these available systems in that it delivers specific postoperative instructions designed for patients undergoing dental extraction and drug reminders for medication adherence. The requirement of an uninterrupted internet connection is primarily needed when several mobile health (mHealth) apps and devices are being created and promoted each day. ExoDont, similar to other mHealth apps, requires an internet connection for sending timely notifications, which could also be listed as its drawback.

The role of preoperative anxiety and stress as an aggravating factor for postoperative pain has been well-established [20]. To foster compliance and reduce complications in patients, the dissemination methods of instructions could be modified to include newer and innovative techniques that reduce the burden on patients to remember numerous instructions and alleviate the anxiety factor in patients anticipating surgery, thus minimizing postoperative pain. Current evidence in postoperative management has been in favor of technology-based health care delivery systems. The use of mobile apps in postoperative care has been found to reduce a substantial amount of time, travel, and cost to patients along with a higher satisfaction level for both patients and providers [21,22]. Therefore, in an attempt to provide a well-optimized postoperative recovery period, the innovative mobile app ExoDont was introduced. The notification-based ExoDont app enables benefit for users of all ages because it does not require any manual inputs from the patients. The ExoDont app presents a user-friendly environment, even for those who are not adept with the use of smartphones. The results obtained from this study suggest that the ExoDont app had been well-received by a group of patients and, therefore, can be used in the future for the advancement of technology in the field of perioperative management.

There are, however, a few limitations to this study that need to be discussed. First, there was a lack of homogeneity among the 3 groups in the selection of patients for the type and number of the teeth to be extracted, which could have altered the rate of complications assessed. However, since a majority of the teeth to be extracted were mandibular molars, the differences have not been substantial. The selection of a specific type and number of teeth to be extracted could be considered in future studies to test the validity of the app. Second, the study does not take into account the educational level or health literacy of the patients, which can influence the perception of individuals using an mHealth app such as ExoDont. The comparison was drawn from a subset of the population. Future studies could include a larger sample size by using a multicentric approach to test the app across different centers with varying literacy levels. Third, since this was a pilot study, a nonrandomized design was used to enroll patients into the 3 groups, with different eligibility criteria for each group. This approach does not generate conclusive evidence for comparison among the 3 groups. Therefore, more randomized trials are required to accurately evaluate the benefits of the ExoDont app over conventional methods and determine the difference in the postextraction rate of complications among the groups.

Conclusion

This study promotes the use of technology to ensure the smooth and efficient postoperative recovery of patients after minor oral surgical procedures. As established through this study, the ExoDont app succeeded in fostering compliance in patients to the prescribed drug regimen and adherence to postoperative instructions in a subset of the population. This study encourages the use of the app-based delivery method of postoperative instructions over conventional verbal and written methods, which could play a beneficial role in bridging the gap between the surgeon and patient and improve compliance in patients. Although the app has been found to be effective in this study, more randomized studies are required to establish the advantage of this app-based dissemination method of instructions over other conventional techniques.

Data Availability

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Group-specific feedback forms for Groups A, B, and C.
[DOCX File , 15 KB - periop_v5i1e35997_app1.docx]

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Abbreviations

mHealth: mobile health

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Original Paper

In-hospital Enrollment Into an Electronic Patient Portal Results in Improved Follow-up After Orthopedic Surgery: Cluster Randomized Controlled Trial

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Abstract

Background: Electronic patient portal (EPP) use is associated with lower no-show rates and increased patient satisfaction. However, there are disparities in enrollment into these communication platforms.

Objective: We hypothesized that guided inpatient enrollment into an EPP would improve clinical follow-up and EPP use rates for patients who underwent orthopedic surgery compared to the usual practice of providing information in the discharge summary.

Methods: We performed a randomized controlled trial of 229 adult patients who were admitted to the hospital for an orthopedic condition that required a 3-month follow-up visit. Patients were cluster-randomized by week to either the control or intervention group. The control group received information on how to enroll into and use the EPP in their discharge paperwork, whereas the intervention group was actively enrolled and taught how to use the EPP. At 3 months postdischarge, the patients were followed to see if they attended their follow-up appointment or used the EPP.

Results: Of the 229 patients, 83% (n=190) presented for follow-up at 3 months (control: 93/116, 80.2%; intervention: 97/113, 85.8%; *P*=.25). The likelihood of EPP use was significantly higher in the intervention group (control: 19/116, 16.4%; intervention: 70/113, 62%; odds ratio [OR] 8.3, 95% CI 4.5-15.5; *P*<.001). Patients in the intervention group who used the EPP were more likely to present for postsurgical follow-up (OR 3.59, 95% CI 1.28-10.06; *P*=.02).

Conclusions: The inpatient enrollment of patients who underwent orthopedic surgery into an EPP increased EPP use but did not independently result in enhanced follow-up. Patients who were enrolled as inpatients and subsequently used the portal had the highest likelihood of 3-month follow-up.

Trial Registration: ClinicalTrials.gov NCT03431259; https://clinicaltrials.gov/ct2/show/NCT03431259

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KEYWORDS

outcomes; orthopedic; electronic health records; surgery; eHealth; patient portals

Introduction

The proper follow-up and collection of patient-reported outcomes is critical to ensuring successful patient care [1-3]. Traditional clinical outcomes and patient-reported outcomes provide clinicians, institutions, and insurers with valuable, reliable measures of the quality of patient outcomes after surgical intervention and can help improve patients' overall satisfaction and progress [4-6]. Despite increased policy-driven and financial incentives, orthopedic surgeons struggle to gather

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this information, because historically, follow-up with patients with orthopedic trauma has been poor [7,8]. Finding new ways to engage patients, ensuring that they follow the schedule, and providing outcome data are important goals for all surgeons [1,9-12].

Previous studies have demonstrated that electronic tools, such as electronic patient portals (EPPs), can be valuable methods of achieving these goals [13-15]. These apps give patients the opportunity to manage their own health, with options to view appointments, renew prescriptions, request authorizations for specialist appointments, and access quality health and wellness information. More recently, patients also have the option to use apps to complete web-based questionnaires [12,16,17].

EPP use is associated with lower no-show rates and increased patient satisfaction. However, it is known that there are disparities in patient enrollment into these communication platforms [18,19]. The decreased enrollment and use of EPPs have been previously associated with demographic (age, language, and race) and treatment factors, but strategies to mitigate these disparities have not yet been assessed. Therefore, in this study, we hypothesized that guided inpatient enrollment into an EPP would improve clinical follow-up and EPP use rates for patients who underwent orthopedic surgery compared to the usual practice of providing information on how to enroll in the discharge summary.

Methods

Study Design and Setting

In total, 240 patients presenting to the Massachusetts General Hospital for inpatient orthopedic surgery were prospectively enrolled in this randomized controlled study. The trial used a cluster randomization method. The patients were recruited between February 2018 and February 2019 and followed for 3 months.

Participants

Members of the research team screened and approached all eligible patients to ask for consent. All patients aged ≥18 years admitted to the hospital for an orthopedic condition with the need for outpatient follow-up were eligible for the study. Patients were excluded if they were unable to consent for themselves, could not communicate in English, or did not possess a smartphone.

Ethics Approval

Institutional review board approval (IRB 2017P001594) was obtained prior to the initiation of the study, and all patients were given a fact sheet if they consented.

Description of Experiment, Treatment, or Surgery

Eligible patients were cluster-randomized by week into 2 groups. The control group received information on how to enroll into and use the EPP in their discharge paperwork, whereas the intervention group was actively enrolled and taught how to use the EPP.

Description of Follow-up Routine

In the period between hospital discharge and follow-up, patients from both groups who were registered in the EPP were requested to fill out a survey on their personal device and received a notification of their upcoming clinic appointment.

Variables, Outcome Measures, Data Sources, and Bias

For all enrolled patients, their age, gender, race (coded as White vs non-White), zip code, and admission diagnosis or service were recorded. Division of race into White and non-White was done to improve the robustness of the statistical analysis. The median income for each patient was abstracted using the zip code of the patient's residence based on US census data, and the percentage of patients with an income less than the median state income was calculated [20].

Patients were followed for 3 months to ascertain if they completed their follow-up orthopedic clinic appointment and if they used the EPP to read or send a message with their providers, view a result, or answer a survey during the time period from their discharge to their follow-up.

Demographics and Description of the Study Population

A total of 229 patients were included (116 patients randomized to the control group and 113 patients randomized to the intervention group). The average patient age was 53.5 (SD 16.4) years. Of the 229 patients, 49.8% (n=114) were male and 16.2% (n=37) were non-White. In total, 31% (n=71) of the patients were admitted for the management of an acute traumatic injury, whereas 9.6% (n=22) were admitted for the treatment of an acute musculoskeletal infection. Demographic characteristics were balanced between the intervention and control groups, suggesting successful randomization (Table 1).

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Table 1. Descriptive statistics of patient demographics and the test of balance.

Variable	All patients (N=229)	Control (n=116)	Intervention (n=113)	*P* value
Age (years), mean (SD)	53.5 (16.4)	54.5 (16.7)	52.4 (16.0)	.34[a]
Gender, male, n (%)	114 (49.8)	61 (52.6)	53 (46.9)	.39[b]
Median income by zip code (2018; US $), mean (SD)	82,039 (27,091)	80,888 (27,853)	83,221 (26,358)	.52[a]
Less than the median Massachusetts income, n (%)	120 (52.4)	67 (57.8)	53 (46.9)	.10[b]
Race, non-White, n (%)	37 (16.2)	17 (14.7)	20 (17.7)	.58[b]
Injury, n (%)	71 (31)	34 (29.3)	37 (32.7)	.57[b]
Injury or acute infection, n (%)	93 (40.6)	45 (38.8)	48 (42.5)	.57[b]
Subspecialty, n (%)				.57[b]
Joints	75 (32.8)	38 (32.8)	37 (32.7)	.93[b]
Oncology	9 (3.9)	5 (4.3)	4 (3.5)	N/A[c]
Sports or shoulder	10 (4.4)	5 (4.3)	5 (4.4)	N/A
Spine	41 (17.9)	23 (19.8)	18 (15.9)	N/A
Trauma	94 (41)	45 (38.8)	49 (43.4)	N/A
Outcome variable, n (%)				
Follow-up at 3 months	190 (83)	93 (80.2)	97 (85.8)	.25[b]
Any use of the electronic patient portal	89 (38.9)	19 (16.4)	70 (62)	<.001[b]

[a]*P* value was obtained from a 2-tailed *t* test with unequal variance.

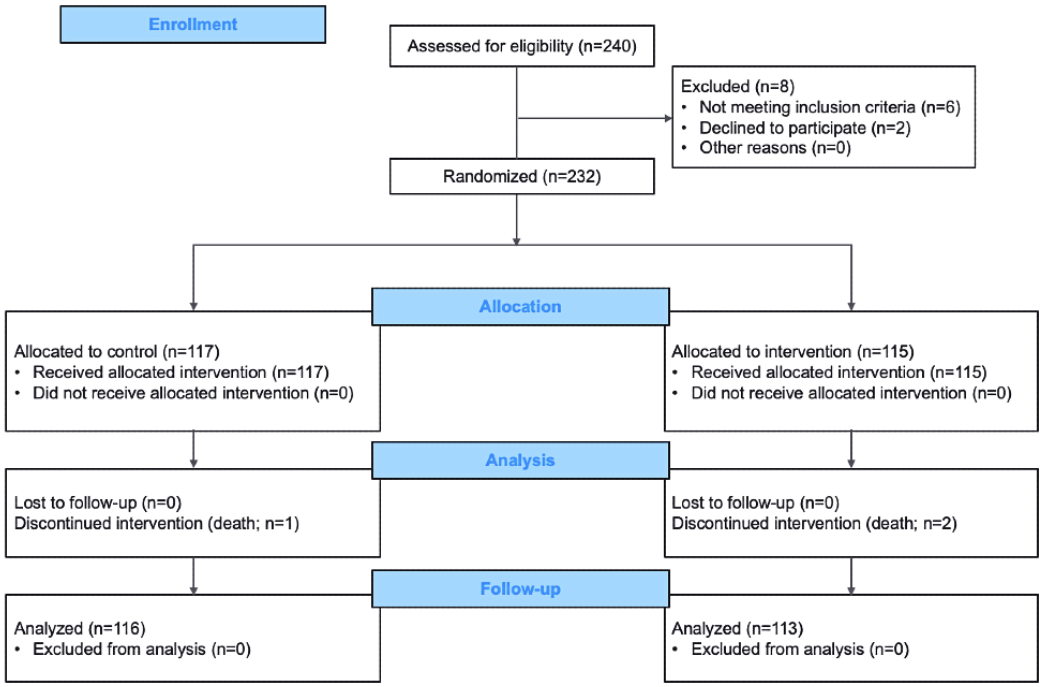
[b]*P* value was obtained from a chi-squared test or Fisher exact test.

[c]N/A: not applicable.

Accounting for All Patients

Patient enrollment is displayed with a flow diagram (Figure 1).

Figure 1. Patient enrollment based on CONSORT (Consolidated Standards of Reporting Trials) flow template.



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Statistical Analysis and Study Size

Descriptive statistics were used for the demographic data. Differences between groups were assessed using the chi-square or Fisher exact test for categorical variables and the 2-tailed *t* test or ANOVA for continuous variables. Demographic or treatment factors associated with improved follow-up or EPP use were assessed using forward stepwise logistic regression modeling to avoid overfitting. We also performed a subgroup analysis assessing the effects of the patient's race and average median income. A robustness analysis exploring the likelihood of enrolling in an EPP or completing follow-up in all patients was also performed. Significance was set at $P<.05$. Stata statistical software (version 14; StataCorp) was used for all analyses.

An a priori power analysis was completed to determine the sample size. We assumed an existing follow-up rate of 70%, and to detect an approximate 10% difference in follow-up with an α of .05, we calculated an approximate sample size of 200 patients distributed equally between both groups.

Results

Of the 229 patients, 83% (n=190) presented for follow-up at 3 months (control: 93/116, 80.2%; intervention: 97/113, 85.8%; $P=.25$ by chi-square analysis not accounting for interaction effects). In total, 38.9% (89/229) of all patients used the EPP, but use was significantly different between the control and intervention group (control: 19/116, 16.4%; intervention: 70/113, 62%; odds ratio [OR] 8.3, 95% CI 4.5-15.5; $P<.001$; Table 1). Inpatient enrollment into the EPP did not independently result in an increase in the 3-month follow-up rates (OR 1.50, 95% CI 0.75-3.02; $P=.26$; see model 1 in Table 2). Patients who used the EPP were significantly more likely to complete a follow-up visit (OR 3.47, 95% CI 1.46-8.26; $P=.005$; see model 2 in Table 2). In addition, patients in the intervention group who used the EPP were more likely to present for postsurgical follow-up (OR 3.59, 95% CI 1.28-10.06; $P=.02$; see model 3 in Table 2).

Table 2. The likelihood of 3-month clinic follow-up based on inpatient enrollment into the electronic patient portal (EPP) with and without interaction effects to account for use of the EPP.

Variable	Model 1, logistic regression without interaction effects, RR[a] (95% CI)	Model 2, logistic regression without interaction effects, OR[b] (95% CI)	Model 3, logistic regression with interaction effects, OR (95% CI)	*P* value
Treatment (inpatient enrollment)	1.50 (0.75-3.02)	N/A[c]	N/A	.26
Any use of the EPP	N/A	3.47 (1.46-8.26)	N/A	.005
Interaction effect (inpatient enrollment*any use of the EPP)				
Control*no use	N/A	N/A	Reference	N/A
Control*use	N/A	N/A	2.35 (0.50-10.99)	.28
Intervention*no use	N/A	N/A	0.80 (0.35-1.86)	.61
Intervention*use	N/A	N/A	3.59 (1.28-10.06)	.02

[a]RR: relative risk.

[b]OR: odds ratio.

[c]N/A: not applicable.

Subgroup Analysis by Race and Median Income

Among the 229 patients, 28.8% (n=66) of White patients enrolled in the EPP, whereas only 6.1% (n=14) of non-White patients enrolled ($P=.07$ by Fisher exact test). This difference was driven by enrollment disparity in the control group. For non-White patients, only 1 out of 17 in the control group enrolled in the EPP (but did not use it). In contrast, of the 20 non-White patients in the intervention group, 13 (65%) registered and used the EPP ($P<.001$ by Fisher exact test comparing intervention vs control for both groups). Once enrolled, use of the EPP was not statistically different between White and non-White patients ($P=.81$ by Fisher exact test). No statistical differences in EPP registration ($P>.05$), use ($P>.05$), or clinical follow-up ($P>.05$) were observed for median income.

Robustness Analysis

To compare our results to prior studies on the likelihood of enrolling in an EPP, we performed a backward stepwise logistic regression using measured demographic factors for all patients. We found that older age (OR 0.97, 95% CI 0.95-0.99; $P=.03$) and non-White race (OR 0.13, 95% CI 0.02-1.09; $P=.06$) were associated with decreased odds of EPP enrollment.

Discussion

Principal Findings

Tracking patient outcomes following orthopedic surgery is often difficult due to variable and poor follow-up. Electronic apps such as EPPs may be able to bridge this gap by engaging patients following hospital discharge [1,9-12]. In this randomized controlled study, we found that guided inpatient enrollment of patients who underwent orthopedic surgery into an EPP increased EPP use, but this did not independently result in enhanced follow-up. Patients who were enrolled as inpatients and subsequently used the portal had the highest likelihood of 3-month follow-up. In addition, we found that guided inpatient enrollment was associated with increased registration and use of the EPP in non-White patients.

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In 2 recent studies of patients who underwent orthopedic surgery, EPP use was associated with lower no-show rates and increased patient satisfaction [18,19]. Both studies also found significant disparities in EPP enrollment based on demographic and treatment factors, but neither assessed strategies to mitigate these disparities [18,19]. Our results suggest that a method to improve the registration and use of EPPs, especially by disadvantaged groups, is to enroll patients while they are still inpatients following surgery. Although this may not independently result in improved follow-up rates, it is a standardized method to improve EPP registration and use for all patients, especially since EPP use is known to improve patient care. For example, a recent systematic review by Schwebel and Larimer [21] demonstrated that SMS text messaging improved patient compliance to appointments, whereas Bigby et al [22] had comparable results through phone calls or manual letters in an outpatient primary care setting.

Multiple retrospective studies have demonstrated that EPP use improves the likelihood of attending follow-up visits [18,19,23]. Using a prospective framework, we also found that EPP enrollment and use was associated with improved follow-up, but simple enrollment in an EPP was not independently associated with improved follow-up. This result suggests that a possible explanation for results in prior retrospective studies between EPP registration and use and enhanced follow-up may be due to patient confounding. Patients who are motivated to register and enroll in an EPP are also more likely to present for clinical follow-up. As in other social interactions frameworks, our findings suggest that patient portal apps may improve follow-up rates and survey completion if some preconditions are met: (1) patients need to be widely exposed and aware of the patient portal and (2) patients need to incorporate the use of the app into their daily routines with relevant content and context (ie, “stickiness” and appropriate context). To reinforce the importance of using these portals to patients, clinicians may need to implement a few changes in their practice. First, someone from the clinical team should enroll patients in the app either while they are still an inpatient or in the outpatient clinics to ensure successful enrollment and an understanding of the app. Next, to make the notifications from the app more readily accessible to patients, there needs to be an update to the app that includes notifications in forms more immediate than email reminders such as SMS text messaging or app push notifications. Finally, surgeons should also encourage communication through the patient portal, so patients feel more motivated to check and use the app.

Finally, in our supplemental analysis, we observed that non-White race was associated with decreased odds of EPP enrollment. For non-White patients, only 1 out of 17 patients in the control group signed up for the EPP, and that patient never used it. In contrast, of the 20 non-White patients in the intervention group, 65% used the EPP. This analysis suggests that standardized enrollment only partially alleviates the barriers to benefits from EPP use. Future studies should further assess the effects of guided enrollment in disadvantaged groups [18].

There were several important limitations to this study that may have impacted the results. First, we specifically approached English-speaking patients with active email addresses and smartphones. If we learned that they did not have either upon interview, we would exclude them from the study. This exclusion criteria may have decreased enrollment from the older patient population as well as patients from lower socioeconomic backgrounds who were less likely to be technologically active, although we attempted to mitigate this in our analysis by including median income by zip code. Future studies are needed to assess the effects of guided inpatient enrollment specifically in disadvantaged groups based on existing literature and our study [18,19]. Based on the post hoc power analysis, our results lacked the statistical power (power=25.6%) to detect no differences in clinical follow-up rates. We may have similarly been limited by the sample size for our subgroup analysis of non-White race, although our sample estimates are proportional to state population statistics [20]. We also referred to the non-White subgroup as disadvantaged not due to race alone but other socioeconomic features measured in our data set. Therefore, although this can be generalized in aggregate, it may not be true for any single patient. With a larger sample size, it may be that guided enrollment, especially for some patient populations, would have statistically and clinically relevant differences in follow-up rates.

Conclusions

The inpatient enrollment of patients who underwent orthopedic surgery into an EPP increased EPP use, but this did not independently result in enhanced follow-up. Patients who were enrolled as inpatients and subsequently used the portal had the highest likelihood of 3-month follow-up. Future studies targeted toward disadvantaged groups are critically needed.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 102 KB - periop_v5i1e37148_app1.pdf]

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Abbreviations

EPP: electronic patient portal
OR: odds ratio

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Original Paper

Incidence of Postoperative Pain at 7 Days After Day Surgery Reported Using a Text Messaging Platform: Retrospective Observational Study

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Abstract

Background: The most frequent complication observed after ambulatory surgery is acute postoperative pain.

Objective: The purpose of this study was to evaluate the late incidence of postoperative pain at 7 days after day surgery.

Methods: We retrospectively included patients who underwent day surgery under general or regional anesthesia and those who underwent local anesthesia in Rouen University Hospital from January 2018 to February 2020. Data collected were moderate-to-severe pain reports defined as numeric rating scale (NRS)>3/10 at 1 day (secondary end point) and 7 days (primary end point) after surgery. These data were collected using a semi-intelligent SMS text messaging platform to follow up with the patient at home after ambulatory surgery. Univariate and multivariate analyses were performed to analyze the risk factors for pain.

Results: We analyzed 6099 patients. On the day after the surgery, 5.2% (318/6099) of the patients presented with moderate-to-severe pain: 5.9% (248/4187) in the general or regional anesthesia group and 3.7% (70/1912) in the local anesthesia group. At 7 days after the surgery, 18.6% (1135/6099) of the patients presented with moderate-to-severe pain, including 21.3% (892/4187) of the patients in the general or regional anesthesia group and 12.7% (243/1912) of the patients in the local anesthesia group. General surgery (odds ratio [OR] 1.54, 95% CI 1.23-1.92; *P*<.01) and orthopedic surgery (OR 1.66, 95% CI 1.42-1.94; *P*<.01) were associated with more late postoperative pain risk. Male gender (OR 0.66, 95% CI 0.57-0.76; *P*<.01), ophthalmology surgery (OR 0.51, 95% CI 0.42-0.62; *P*<.01), and gynecologic surgery (OR 0.67, 95% CI 0.50-0.88; *P*=.01) were associated with less late postoperative pain risk. The rate of emergency consultation or rehospitalization at 7 days after the surgery was 11.1% (679/6099). Late postoperative pain (OR 2.54, 95% CI 1.98-3.32; *P*<.001), general surgery (OR 2.15, 95% CI 1.65-2.81; *P*<.001), and urology surgery (OR 1.62, 95% CI 1.06-2.43; *P*=.02) increased the risk of emergency consultation or rehospitalization. Orthopedic surgery (OR 0.79, 95% CI 0.63-0.99; *P*=.04) and electroconvulsive therapy (OR 0.43, 95% CI 0.27-0.65; *P*<.001) were associated with less rates of emergency consultation or rehospitalization.

Conclusions: Our study shows that postoperative pain at 7 days after ambulatory surgery was reported in more than 18% of the cases, which was also associated with an increase in the emergency consultation or rehospitalization rates.

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KEYWORDS

day surgery; postoperative pain; emergency consultation; rehospitalization; ambulatory management; pain management; postsurgery; postoperative; ambulatory surgery; hospitalization; health care; mobile health; mobile platform

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Introduction

Outpatient surgery represents a major challenge in the organization of care. The increasing number of outpatient surgeries highlights the need to ensure the highest level of safety for each patient. Establishing contact with patients after surgery is part of care in outpatient surgery, and it is strongly recommended by several practice guidelines to improve the management of postoperative complications at home [1]. This is increasingly done via automated information through SMS text message reminders. Several studies [2,3] have shown the benefit of using SMS text message reminders among patients with high blood pressure for decreasing their systolic blood pressure compared with usual care at 12 months and improvements in patients' medication adherence. One study [4] developed a bank of text messages for the prevention of recurrent cardiovascular events. In another study [5], SMS text message reminders and a smartphone app were used successfully to monitor and reduce the alcohol consumption of military veterans—from a median of 5.6 units per drinking day in the first week to 4.7 units by the last week during the 4 weeks of study. For outpatient surgery, previous studies have shown that the use of SMS text message reminders before the surgery increased the rates of compliance with preoperative instructions [6], reduced the number of cancellations in gastrointestinal endoscopy [7], and decreased the rate of conversion to full-time hospitalization [8]. SMS text messaging might be an interesting alternative to follow patients at home during the postoperative period.

One of the adverse events observed after surgery is postoperative pain. A recent multicentric German cohort study of 50,523 inpatients found that pain scores on the first postoperative day were high, even though they were only minor surgical procedures frequently performed in outpatient surgery [9]. A few other studies [10-12] have shown that after day surgery, the incidence of moderate-to-severe postoperative pain ranged from 25% to 65%. These studies [10-12] sought to evaluate the pain at home after ambulatory surgery even though the analgesic strategies were better. There are French guidelines that highlight the importance of anticipating the management of postoperative pain [13]. These guidelines cover specific instructions from the beginning of anesthesia consultation with the prescription of a postoperative analgesic integrating a multimodal strategy, the precise times for taking the medication, and finally, the possible recourse in case of insufficient treatment [14]. In the intraoperative period, the emphasis is on strategies using infiltrations and peripheral blocks in addition to the multimodal analgesia strategy, including the use of nonsteroidal anti-inflammatory drugs [15,16]. In fact, a very recent study [17] on the latest technique of pain management in 2228 patients showed that only 7% of the patients rated their pain as more than 3/10 on the day after the surgery. However, studies have mainly focused on the early evaluation of pain (the first 3 or 4 days after the surgery) without always considering the occasional prolonged nature of this pain [18]. Time after surgery also influences the frequency and severity of pain following surgery. In a Dutch study conducted in 1490 surgical inpatients, 41% of the patients reported moderate or severe pain on the day of surgery, with a declining rate of 14% after 4 days [19]. Similarly, Peuchot et al [17] showed that the incidence of outpatients with pain at 7 days after the surgery was 2.60%. However, a recent study [8] showed that there are multiple distinct trajectories of acute postoperative pain intensity, with 63% of the hospitalized patients reporting high or moderate-to-highly stable and sustained pain in the first 7 days after the surgery. These postoperative pain trajectories were predominantly defined by patient factors and not surgical factors.

The purpose of this monocentric study was to evaluate the incidence of late postoperative pain at 7 days after day surgery via automated information with SMS text message reminders and to assess the risk factors for late pain occurrence.

Methods

Ethics Approval

Ethics approval for this study (ethics committee 2058568) was provided by the noninterventional research committee based at Rouen University Hospital in France (Chairperson Professor LM Joly, approval E2017-37), as per the French law. The requirement for written informed consent was waived by the committee.

Study Design

We performed a retrospective study in the day surgery unit of the Rouen University Hospital from January 2018 to February 2020. All outpatients were included in this study. We included all patients who underwent regional or general anesthesia (we could not distinguish general anesthesia from regional anesthesia in the database) by an anesthesiologist and those who underwent local anesthesia by the surgeon for day surgery. Patients who did not show up for their surgery or did not receive the various SMS text messages sent at the time of the procedure were not included in this study.

Enrolment Procedure

At the Rouen University Hospital, the patient's day surgery pathway begins with a consultation with the anesthesiologist at least 48 hours before the surgical procedure for those receiving general or regional anesthesia. These patients receive an analgesic prescription at the end of the anesthesia consultation (to obtain analgesics at the pharmacy prior to the ambulatory surgery) and information concerning the use of analgesics during the same consultation [14]. The anesthesiologist insists on the importance of systematically taking the prescribed treatment postoperatively, even in the absence of pain. Two types of prescriptions are available depending on the expected postoperative pain. The anesthesiologist fills either Prescription A for moderate pain (expected numeric rating scale (NRS)>3, range 0-10) and Prescription B for severe pain (expected NRS> 6, range 0-10). Prescription A combines paracetamol-codeine (500 mg/30 mg) every 6 hours systematically during the first 2 days, which is extensible to 5 days (the quantity dispensed by the pharmacy was sufficient for 5 days) and ketoprofen (100 mg) every 12 hours systematically during the first 2 days maximum. Prescription B combines paracetamol-codeine (500 mg/30 mg) every 6 hours systematically during the first 2 days, which is extensible to 5 days (the quantity dispensed by the

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pharmacy was sufficient for 5 days), ketoprofen (100 mg) every 12 hours systematically during the first 2 days maximum, and morphine sulfate (10 mg) every 6 hours systematically for 2 days if NRS>6 (range 0-10). The local anesthesia group received the prescription of paracetamol-codeine (500 mg/30 mg) every 6 hours systematically during the first 2 days, which was extensible to 5 days (the quantity dispensed by the pharmacy was sufficient for 5 days). In both groups, information concerning the systematic administration of analgesics was indicated on the prescription.

General anesthesia was standardized in the operating theatre with the use of propofol for induction (2 mg/kg), total intravenous anesthesia of propofol (target between 2 µg/mL and 6 µg/mL) or sevoflurane (fraction of expired sevoflurane 2%) for the maintenance of hypnosis, and total intravenous anesthesia of remifentanil (target between 3 ng/mL and 6 ng/mL). Hyperalgesia was prevented using ketamine (0.15 mg/kg) during general anesthesia. Intraoperative analgesia was performed with routine administration of paracetamol (1 g), nefopam (20 mg), and ketoprofen (100 mg) in the absence of respective contraindications. Tramadol (50 mg) or morphine (0.1 mg/kg) administration was possible at the end of the procedure at the anesthesiologist's discretion. During the patient's hospitalization (postanesthesia care unit and outpatient surgery unit), pain was assessed using NRS. Morphine titration was performed in the postanesthesia care unit if necessary (NRS>3/10). Postoperative nausea and vomiting was prevented, as per the Apfel score, with perioperative dexamethasone (4 mg) and droperidol (1.25 mg). Intraoperative analgesia was also homogeneous with the administration of systematic paracetamol (1 g), nefopam (20 mg), and ketoprofen (100 mg) in the absence of contraindication and ropivacaine infiltration as soon as it was possible. In the local anesthesia group, local anesthesia protocols were standardized, including xylocaine (10 mg/mL) or ropivacaine (2 mg/mL) infiltration for all surgeries and oxybuprocaine eye drops for ophthalmology.

The process of the semi-intelligent platform of SMS text messaging has been previously described [17]. Messaging started 2 days before the surgery with an SMS text message reminder and the possibility of alerting the medical staff if the patient was unable to attend the surgery. The patient could respond ALERT if there was a medical problem or if assistance was required. A response different to ALERT was categorized as an unexpected response. There was no obligation to respond to the SMS text message reminder. On the day before the surgery, the patient received 3 messages informing about the required time of arrival and location of the outpatient unit, fasting recommendations, and hygiene rules. After surgery, patients received several SMS text message reminders with the possibility to answer. These were sent at 11 AM on the day after the ambulatory surgery in which the patient was asked successively if everything was fine, the intensity of pain determined by the NRS between 0 and 10, the presence of postoperative nausea and vomiting, or other medical-surgical complications. On the seventh day, the patient received another SMS text message asking about satisfaction with the management by using a numerical scale from 0 to 10, the need to have consulted the general practitioner, an emergency service, or to be rehospitalized in the context of the ambulatory surgery performed, as well as the pain felt and communicated using the numerical scale. The patients' answers were centralized by Calmedica and then analyzed in an Excel spreadsheet software (version 2019, Microsoft).

Primary and Secondary End Points

The primary end point was the incidence of maximum pain experienced by the patient whether at rest or on mobilization, defined by NRS>3 on a scale of 0 to 10 (0=no pain, 10=maximum pain) on the seventh day following ambulatory surgery. Secondary end points were the incidence of severe pain on day 7 (NRS>6), moderate (NRS>3) or severe pain (NRS>6) on day 1, the presence of postoperative nausea and vomiting on day 1, the incidence of emergency consultation or rehospitalization within 7 days after surgery as well as the risk factors for this variable, and overall satisfaction with the management on a scale of 0 to 10. Demographic data such as age and sex as well as the type of surgery were also collected.

Statistical Analysis

Because of the retrospective and cohort nature of this study, we did not perform an a priori calculation of the sample size. The results are expressed as median and first and third quartile for quantitative data and as percentages for qualitative variables. The different data were compared with a chi-square test using the Prism software (version 6, GraphPad) for the qualitative variables. An overall analysis and then a subgroup analysis differentiating the "general or regional anesthesia" group and the "local anesthesia" group was performed. Univariate and multivariate analyses were performed with logistic regression models using the R software (version 3.0, R Core Team and the R Foundation for Statistical Computing). The variables included in the multivariate model were those clinically relevant, consistent with the literature, and with $P<.90$ in the univariate model. We performed simple imputation of the missing data by random draw with discounts for patients with consistent data. The only data transformation was the realization of age range to refine the fitting model. The evaluation of the model is represented by a figure representing the expected risk according to the observed risk of having the study criterion.

Results

In this study, we analyzed the data of 6099 patients. The demographic, anesthesia regimen, and the surgical data of these patients are presented in Table 1.

On the day after the surgery, 5.2% (318/6099) of the patients presented with moderate-to-severe pain: 5.9% (248/4187) in the general or regional anesthesia group and 3.7% (70/1912) in the local anesthesia group. In the whole cohort, 1.4% (87/6099) of the patients expressed severe pain, whereas 1.5% (64/4187) of the patients in the general or local regional anesthesia group and 1.2% (23/1912) in the local anesthesia group expressed severe pain. Seven days after the surgery, 18.6% (1135/6099) of the patients presented with moderate-to-severe pain at 7 days after the day surgery: 21.3% (892/4187) of the patients in the general or regional anesthesia group and 12.7% (243/1912) in the local anesthesia group. In this cohort, 4.3% (265/6099) of

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the patients expressed severe pain (expressed by an NRS>6): 4.8% (201/4187) in the general or regional anesthesia group and 3.3% (64/1912) in the local anesthesia group. The results of the univariate analysis and the adjusted multivariate model are shown in Table 2 (the calibration of the multivariate model is shown in Figure 1).

The incidence of emergency consultation/rehospitalization at 7 days after the surgery was 11.1% (679/6099). The results of the univariate analysis and the adjusted multivariate model for the risk factors are shown in Table 3 (the calibration of the multivariate model is shown in Figure 2).

The median global satisfaction was 9/10 [IQR 8-10] in the general or regional anesthesia group and 10/10 [IQR 8-10] in the local anesthesia group, with no significant difference between the 2 groups.

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Table 1. Demographic, surgical, and anesthesia regimen data of the study population (N=6099).

Characteristics	Value
Sex, n (%)	
Female	3004 (49.3)
Male	2508 (41.1)
Missing data	587 (9.6)
Age (years)	
Mean (SD)	51 (19)
Median (IQR)	54 (13)
Age range (years), n (%)	
0-18	135 (2.2)
18-40	1551 (25.4)
40-60	1663 (27.3)
60-70	1110 (18.2)
70-80	736 (12.1)
80-90	284 (4.7)
>90	33 (0.5)
Missing data	587 (9.6)
Anesthesia procedure, n (%)	
General or regional anesthesia	4187 (68.7)
Local anesthesia	1912 (31.3)
Surgical discipline, n (%)	
Pneumology	372 (6.1)
General surgery	424 (7)
Ophthalmology	1620 (26.6)
Orthopedic surgery	1172 (19.2)
Plastic surgery	590 (9.7)
Urology surgery	142 (2.3)
Vascular surgery	339 (5.6)
Gynecologic surgery	344 (5.6)
Medical surgery	33 (0.5)
Electroconvulsive therapy	365 (6)
Otorhinolaryngology	105 (1.7)
Missing data	593 (9.7)
Postoperative nausea and vomiting , n (%)	
PONV[a] D1[b]	57 (0.9)
Pain NRS[c]>3 D1	318 (5.2)
Pain NRS>6 D1	87 (1.4)
Pain NRS>3 D7	1135 (18.6)
Pain NRS>6 D7[d]	265 (4.3)
Satisfaction scale at day 7 after the surgery, n (%)	
0-2	55 (0.9)
3-5	169 (2.8)

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Characteristics	Value
6-8	1221 (20)
9-10	3711 (60.8)
Missing data	943 (15.5)
Emergency consultation/hospitalization at 7 days after surgery, n (%)	679 (11.1)

[a]PONV: postoperative nausea and vomiting.

[b]D1: day 1 after surgery.

[c]NRS: numeric rating scale.

[d]D7: 7 days after surgery.

Table 2. Univariate and multivariate analysis of pain (pain numeric rating scale >3) at 7 days after surgery.

	Univariate		Multivariate adjusted	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sex				
Female	1.00	N/A[a]	1.00	N/A
Male	0.77 (0.61-0.8)	<.001	0.66 (0.57-0.76)	<.01
Age (years)				
<18	1.00	N/A	1.00	N/A
18-40	1.31 (0.86-2.09)	.23	1.36 (0.87-2.19)	.19
40-60	1.39 (0.91-2.22)	.15	1.48 (0.94-2.41)	.10
60-70	0.82 (0.53-1.33)	.40	1.05 (0.66-1.74)	.83
70-80	0.75 (0.47-1.23)	.24	1.17 (0.72-1.97)	.53
80-90	0.57 (0.33-1.01)	.05	1.02 (0.57-1.86)	.95
>90	0.42 (0.10-1.30)	.18	0.63 (0.14-2.00)	.48
Anesthesia procedure				
Local anesthesia	0.54 (0.46-0.63)	<.001	1.00	N/A
General or regional anesthesia	1.00	N/A	1.18 (0.99-1.42)	.07
Surgical discipline				
Pneumology	0.53 (0.38-0.75)	<.001	0.97 (0.74-1.25)	.80
General surgery	1.00	N/A	1.54 (1.23-1.92)	<.01
Ophthalmology	0.23 (0.17-0.30)	<.001	0.51 (0.42-0.62)	<.01
Orthopedic surgery	1.02 (0.80-1.31)	.87	1.66 (1.42-1.94)	<.01
Plastic surgery	0.57 (0.43-0.77)	<.001	0.99 (0.80-1.23)	.94
Urology surgery	0.64 (0.40-0.99)	.05	0.86 (0.58-1.23)	.41
Vascular surgery	0.47 (0.33-0.67)	<.001	0.93 (0.69-1.24)	.62
Gynecologic surgery	0.54 (0.38-0.77)	.001	0.67 (0.50-0.88)	.01
Medical surgery	0.79 (0.33-1.73)	.58	1.33 (0.60-2.67)	.44
Electroconvulsive therapy	0.77 (0.56-1.07)	.12	1.23 (0.97-1.56)	.08
Otorhinolaryngology	0.51 (0.29-0.87)	.02	0.92 (0.58-1.42)	.73

[a]N/A: not applicable

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Figure 1. Multivariable calibration of pain risk (pain visual analog score >3) at 7 days after surgery. D7: 7 days after surgery.

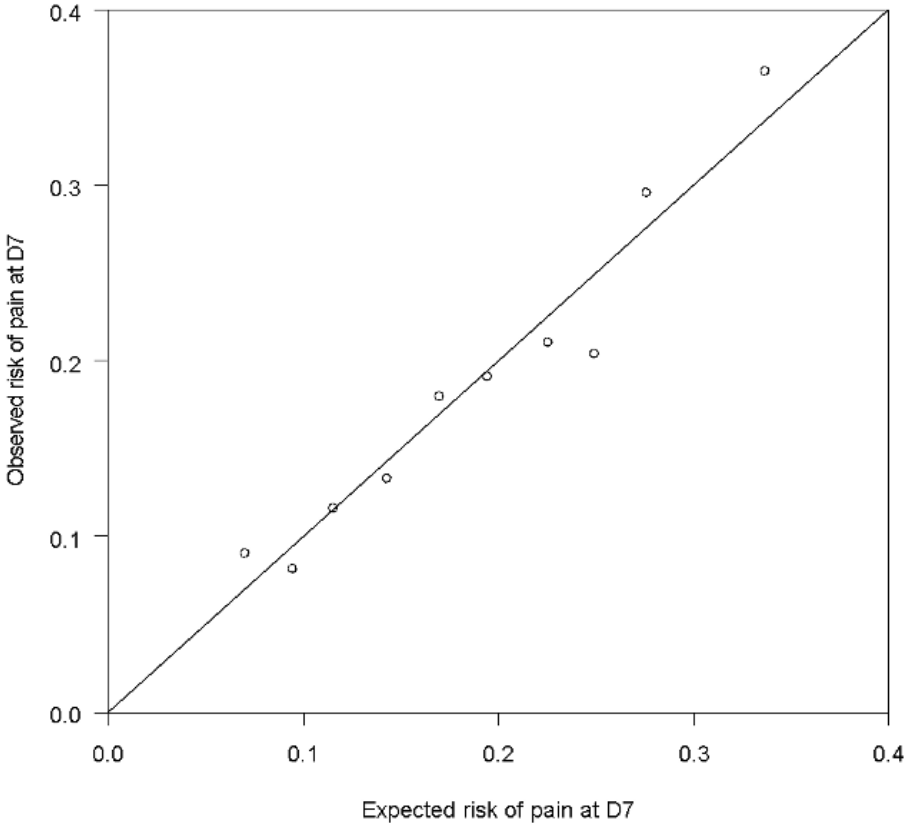

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Table 3. Univariate and multivariate analysis of emergency/rehospitalization risk at 7 days after surgery.

	Univariate		Multivariate adjusted	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Sex				
Female	1	N/A[a]	1	N/A
Male	0.82 (0.70-0.96)	.02	0.87	.14
Age (years)				
<18	1	N/A	1	N/A
18-40	0.88 (0.54-1.51)	.63	1.15 (0.70-1.99)	.60
40-60	0.77 (0.48-1.32)	.32	1.22 (0.73-2.13)	.47
60-70	0.51 (0.30-0.88)	.01	0.82 (0.48-1.49)	.50
70-80	0.81 (0.48-1.41)	.43	1.35 (0.78-2.46)	.30
80-90	0.88 (0.54-1.51)	.63	1.56 (0.83-3.00)	.17
>90	0.84 (0.23-2.45)	.77	1.41 (0.70-1.99)	.57
Anesthesia procedure				
Local anesthesia	0.82 (0.69-0.98)	.03	0.93 (0.73-1.17)	.54
General or regional anesthesia				
Surgical discipline				
Pneumology	0.87 (0.48-1.63)	.64	1.00 (0.54-1.96)	.99
General surgery	2.01 (1.57-2.55)	<.001	2.15 (1.65-2.81)	<.001
Ophthalmology	0.85 (0.70-1.03)	.09	0.82 (0.65-1.04)	<.10
Orthopedic surgery	0.77 (0.62-0.96)	.02	0.79 (0.63-0.99)	.04
Plastic surgery	0.87 (0.67-1.13)	.30	0.87 (0.65-1.15)	.33
Urology surgery	1.54 (1.02-2.27)	.03	1.62 (1.06-2.43)	.02
Vascular surgery	0.84 (0.59-1.16)	.30	0.87 (0.59-1.25)	.45
Gynecologic surgery	1.04 (0.76-1.40)	.79	0.99 (0.69-1.40)	.96
Medical surgery	1.03 (0.34-2.42)	.94	1.04 (0.34-2.45)	.93
Electroconvulsive therapy	0.49 (0.32-0.71)	<.001	0.43 (0.27-0.65)	<.001
Otorhinolaryngology	1.22 (0.72-1.96)	.64	1.00 (0.54-1.96)	.99
PONV[b] at day 1 after surgery	1.50 (0.69-2.93)	.26	N/A	N/A
Pain NRS[c] >3 at day 7 after surgery	3.66 (2.98-4.39)	<.001	2.54 (1.98-3.32)	<.001

[a]N/A: not applicable.

[b]PONV: postoperative nausea and vomiting.

[c]NRS: numeric rating scale.

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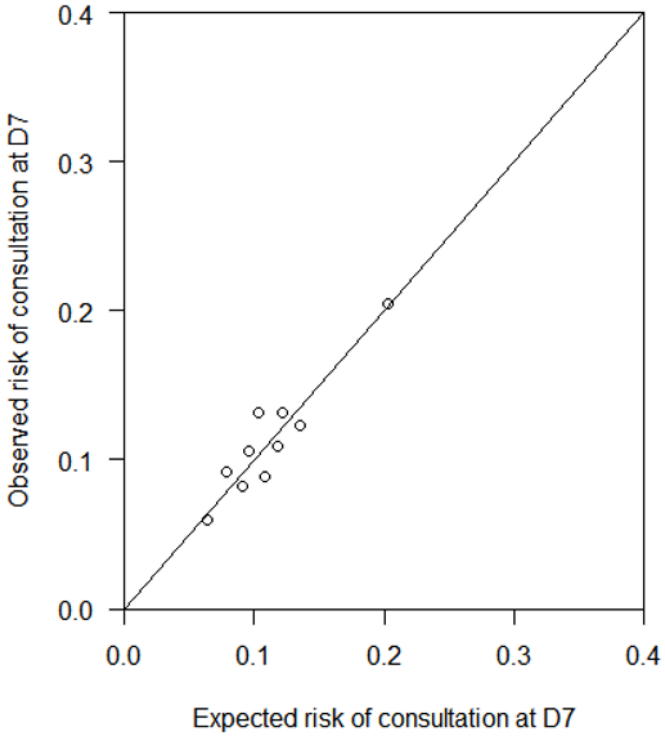
Figure 2. Multivariable calibration of emergency/rehospitalization risk at 7 days after surgery. D7: 7 days after surgery.



Discussion

Principal Findings

In this study on 6099 patients, on the day after surgery, 5.2% (318/6099) of the patients presented with moderate-to-severe pain: 5.9% (248/4187) in the general or regional anesthesia group and 3.7% (70/1912) in the local anesthesia group. At 7 days after the surgery, 18.6% (1135/6099) of the patients presented with moderate-to-severe pain, including 21.3% (892/4187) of the patients in the general or regional anesthesia group and 12.7% (243/1912) in the local anesthesia group. General surgery (odds ratio [OR] 1.54, 95% CI 1.23-1.92) or orthopedic surgery (OR 1.66, 95% CI 1.42-1.94) were associated with more late postoperative pain risk. The rate of emergency consultation or rehospitalization at 7 days after the surgery was 11.1% (679/6099) in this study. Late postoperative pain increased the risk of emergency consultation or rehospitalization (OR 2.54, 95% CI 1.98-3.32).

Comparison With Prior Work

In this retrospective study, the prevalence of pain on the day after day surgery (318/6099, 5.2%) was similar to that found in a previous study (7%) [17] but much lower than that reported in the majority of the older studies. In a review published in 2002, the incidence of acute postoperative pain was 45% and ranged from 6% to 95% in 13 studies that included mixed surgical procedures [8]. McGrath et al [12] in 2004 found an acute postoperative pain incidence rate of 30% in a cohort of 5703 patients. In that work, the proportion of types of surgery was different from ours, with almost half of them being ophthalmologic surgery, which does not cause much postoperative pain. In a 2007 study, the mean visual analog scale scores were greater than 40 mm in 21% (119/648) of the patients at postoperative day 1 [11]. Our study included more than 50% of general and orthopedic surgery cases. In a very recent work that included 1691 patients, 35.5% of the patients reported moderate-to-severe pain at postoperative day 1 [20]. The low rate observed in our work could be explained by the high proportion of patients receiving local anesthesia for minor surgery (1912/6099, 31.3%). Indeed, in our study, 5.9% (248/4187) of the patients in the general or regional anesthesia group and 3.7% (70/1912) of the patients in the local anesthesia group presented with moderate-to-severe pain. The decrease in the proportion of patients with acute postoperative pain is probably related to the improvement in pain management. The new advancements in the analgesia strategy used in our day surgery unit combine 3 main key components when not contraindicated: regional/local analgesia, acetaminophen, and nonsteroidal anti-inflammatory drugs [21]. This approach combined with education about postoperative pain integrated in enhanced recovery programs has been shown to improve surgical outcomes [22]. In our previous study of a randomized controlled trial in 186 patients, preoperative analgesic instruction and prescription during anesthesia consultation was found to reduce the incidence of early postoperative home pain in outpatient surgery from 48% to 24% on postoperative day 1 for surgery that generally results in severe postoperative pain [14].

Surprisingly, the prevalence of pain in this study increased from 5.2% (318/6099) to 18.6% (1135/6099) at 7 days after surgery in the general or regional anesthesia group (892/4187, 21.3%) more frequently than after that in the local anesthesia group (243/1912, 12.7%). This result is in agreement with 29.1% of the patients reporting moderate-to-severe pain at postoperative day 7 in the study of Carlier et al [20]. In another study on 1490 surgical inpatients, 41% of the patients reported moderate or severe pain on the day of surgery, with a declining rate of 14% after 4 days [19]. In the study of Gramke et al [11] on outpatients, the mean visual analog scale scores were greater

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than 40 mm in 21% of the patients on postoperative day 1, 13% on postoperative day 2, 10% on postoperative day 3, and 9% of the patients on postoperative day 4. In a previous work, we observed the passage from a rate of 7% at postoperative day 1 to 2.60% at postoperative day 7 [17]. The main difference between that work and this study is the surgical specialties included. Our previous work included more gynecological surgeries, which seemed to result in less postoperative pain in our multivariate analysis (OR 0.67, 95% CI 0.50-0.88), whereas in accordance with literature [9,12], general (OR 1.54, 95% CI 1.23-1.92) or orthopedic surgery (OR 1.66, 95% CI 1.42-1.94) is associated with more late postoperative pain risk. These 2 surgery disciplines represent more than 25% of the patients in our study. Barry et al [23] found that rebound pain (defined as an increase from well-controlled to severe pain typically within 12-24 hours of resolution of the nerve block) occurred in 49.6% of the cohort of 972 patients. In our study, 19.2% (1172/6099) of the orthopedic surgery cases could explain in part this higher prevalence of the late postoperative pain observed. Male gender was found to be a protective factor in our work (OR 0.66, 95% CI 0.57-0.76). This result is comparable with that of other studies that have identified female gender as a postoperative pain risk factor in both inpatient and outpatient settings. A very recent study [8] showed that the pain trajectory was more dependent on patient-related parameters than on those associated with the surgery, with young age and female sex being found as risk factors, as well as higher anxiety (OR 1.08, 95% CI, 1.01-1.14) and more pain behaviors (OR 1.10, 95% CI 1.02-1.18).

The emergency consultation or rehospitalization rate found in this study (679/6099, 11.1%) is higher than that reported in our previous work (6.7%) [17] but is comparable to that found by McIsaac et al in 2015 [24], wherein in their population-based cohort of 296,497 outpatients in Canada, 10.5% returned to the emergency unit or were readmitted to hospital within 30 days after the surgery. In another study [18], 2% of 744 patients were admitted to the hospital on an unplanned basis, returned to the hospital, or visited their general practitioner during the postoperative course, but the study was performed on 4 postoperative days only. Further, in a Danish multicenter study of morbidity after 57,709 day surgery procedures, the overall rate of return hospital visits was only 1.21% [25]. In the United Kingdom and Ireland pediatric units, the percentages of unplanned admissions varied from 0% to 16.3% in 93 participating centers [26]. The type of surgery could explain those results. In our study, general (OR 2.15 95% CI 1.65-2.81) and urology surgery (OR 1.62 95% CI 1.06-2.43) were identified as risk factors, whereas orthopedic surgery seemed to be a protective factor (OR 0.79, 95% CI 0.63-0.99). In our unit, patients were systematically reviewed in consultation by an orthopedic surgeon in the week following surgery, a process which probably makes the postoperative course safer. Finally, we observed that postoperative pain increases the risk of emergency consultation or rehospitalization (OR 2.54, 95% CI 1.98-3.32). McGrath et al [12] showed that postoperative pain is one of the reasons for nurse or physician consultation, unplanned consultation, or hospital readmission. Pain was the most commonly reported reason for return, occurring in 38% of the patients who had an unanticipated admission or in 20,817 patients requiring readmission. The general surgery service had the highest rate of unanticipated admissions or readmissions (3.2%), followed by otorhinolaryngology (3.1%) and urology (2.9%) clinics [27].

Strengths and Limitations

There are several limitations in this study. First, this study had a retrospective single-center design. However, the standardized organization of care teams was ensured because it was conducted in an outpatient surgery unit of a university hospital center. Second, we have no data on the different parameters. Patients were not identified as per the anesthesia regimen between general or regional anesthesia. Ophthalmology is also an important contributor to the number of local anesthesia cohorts, thereby leading to possible bias. The postdischarge medical adherence was not assessed in our study and may have contributed to the postoperative pain scores. Third, we did not measure patient perceptions with an adapted skill instrument. Multidimensional scales have now been developed and appear to be more relevant than a simple numerical scale [28,29]. Recent developments in the assessment of quality parameters after surgery have led to the implementation of quality of recovery as a principal end point after day case surgery. The quality of recovery is related to various aspects of patients' daily living after discharge to home.

In conclusion, this work shows that postoperative pain at 7 days after ambulatory surgery, integrated with new advancements in the management of postoperative analgesia (using infiltrations and peripheral blocks in addition to multimodal analgesia, including the use of nonsteroidal anti-inflammatory drugs), was reported in more than 18% of the cases, which is also associated with an increase in the emergency consultation or rehospitalization rates.

Acknowledgments

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Authors' Contributions

VC helped in the study conception and design, acquisition of data, statistical analysis and interpretation of data, and manuscript drafting. AM helped in the study conception and design, acquisition of data, analysis and interpretation of data, and in manuscript drafting. EA helped in interpretation of data and manuscript revision. TC helped in the interpretation of data and manuscript revision. JS helped in interpretation of data and manuscript revision. EB helped in the study conception and design, resident

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recruitment, study coordination, interpretation of data, and in manuscript revision. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

NRS: numeric rating scale
OR: odds ratio

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Original Paper

Determining the Reliable Measurement Period for Preoperative Baseline Values With Telemonitoring Before Major Abdominal Surgery: Pilot Cohort Study

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Abstract

Background: Preoperative telemonitoring of vital signs, physical activity, and well-being might be able to optimize prehabilitation of the patient's physical and mental condition prior to surgery, support setting alarms during in-hospital monitoring, and allow personalization of the postoperative recovery process.

Objective: The primary aim of this study was to evaluate when and how long patients awaiting major abdominal surgery should be monitored to get reliable preoperative individual baseline values of heart rate (HR), daily step count, and patient-reported outcome measures (PROMs). The secondary aim was to describe the perioperative course of these measurements at home.

Methods: In this observational single-center cohort study, patients used a wearable sensor during waking hours and reported PROMs (pain, anxiety, fatigue, nausea) on a tablet twice a day. Intraclass correlation coefficients (ICCs) were used to evaluate the reliability of mean values on 2 specific preoperative days (the first day of telemonitoring and the day before hospital admission) and randomly selected preoperative periods compared to individual reference values. Mean values of HR, step count, and PROMs per day were visualized in a boxplot from 14 days before hospital admission until 30 days after surgery.

Results: A total of 16 patients were included in the data analyses. The ICCs of mean values on the first day of telemonitoring were 0.91 for HR, 0.71 for steps, and at least 0.86 for PROMs. The day before hospital admission showed reliability coefficients of 0.76 for HR, 0.71 for steps, and 0.92-0.99 for PROMs. ICC values of randomly selected measurement periods increased over the continuous period of time from 0.68 to 0.99 for HR and daily step counts. A lower bound of the 95% CI of at least 0.75 was determined after 3 days of measurements. The ICCs of randomly selected PROM measurements were 0.89-0.94. Visualization of mean values per day mainly showed variable preoperative daily step counts (median 2409, IQR 1735-4661 steps/day) and lower postoperative daily step counts (median 884, IQR 474-1605 steps/day). In addition, pain was visually reduced until 30 days after surgery at home.

Conclusions: In this prospective pilot study, for patients awaiting major abdominal surgery, baseline values for HR and daily step count could be measured reliably by a wearable sensor worn for at least 3 consecutive days and PROMs during any preoperative day. No clear conclusions were drawn from the description of the perioperative course by showing mean values of HR, daily step count, and PROM values over time in the home situation.

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(JMIR Perioper Med 2022;5(1):e40815) doi:10.2196/40815

KEYWORDS

telemonitoring; major abdominal surgery; preoperative; wearable sensor; vital signs; patient-reported outcome measure; PROM; surgery; major surgery; abdominal surgery; observational study; pain; anxiety; fatigue; nausea; heart rate; step count

Introduction

The use of telemonitoring has been associated with improved clinical outcomes and cost-effectiveness of care in several fields of medicine [1,2]. Telemonitoring may be of great value in the preoperative phase, where telemonitoring at home may give a good indication of patients' individual baseline values, such as vital signs, physical activity, and the level of experienced pain and anxiety [3,4]. This information is expected to assist in clinical decision-making (ie, by risk assessment), optimize prehabilitation of the patient's physical and mental condition prior to surgery [3], support setting alarms during in-hospital monitoring, and allow personalization of the postoperative recovery process.

Despite these potential advantages, vital signs, physical activity, and patient-reported outcome measures (PROMs) of patients undergoing major abdominal surgery are not routinely monitored at home. Preoperative vital signs are often only measured in-hospital as part of the preoperative anesthetic screening and at hospital admission prior to surgery. Disadvantages of current practice are preoperative assessments being labor intensive and performed up to 12 weeks before surgery [5], and measurements during admission potentially being less representative because of increased psychological stress. Only a few studies describe baseline values before major abdominal surgery by telemonitoring at home. These studies mainly investigated the association between preoperative physical activity level and postoperative complications, readmissions, or functional recovery as a percentage of baseline values at 2 to 30 days before surgery [3,6-8]. It is currently unknown what period is sufficient to measure reliable baseline values for vital signs, steps, or PROMs in the time period that patients are on the waiting list for major abdominal surgery.

The primary aim of this study is to evaluate when and how long patients should be monitored at home to get reliable preoperative individual baseline values of heart rate (HR), step count, and PROMs (pain, anxiety, fatigue, nausea) before major open abdominal surgery. The secondary aim was to describe the course of HR, step count, and PROMs measured by telemonitoring at home before and after major abdominal surgery. This study was part of a prospective pilot study to evaluate the feasibility and patient experiences with perioperative telemonitoring (published separately [9]) to inform future study design.

Methods

Ethics Approval

The ethical committee of the University Medical Center Groningen approved the protocol (Telemonitoring in the Peri-operative Phase of Patients Undergoing Open Abdominal Surgery in a University Medical Center: A Pilot Study [PROMISE-study], research register number #201900432), and the study was conducted in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [10] and the Declaration of Helsinki.

Study Design and Participants

Between January 2020 and January 2021, a prospective observational cohort pilot study was performed at the University Medical Center Groningen, a large tertiary referral hospital in The Netherlands.

Patients were recruited if they were planned for elective major open abdominal surgery (vascular, hepato-pancreato-biliary, or lower gastrointestinal) at the outpatient clinic based on procedure codes in the electronic health record during the aforementioned study period. Eligible patients were expected to be on the waiting list for at least 2 weeks and have access to Wi-Fi at home. Exclusion criteria were being mentally incapable of participation, not able to walk without an aid, or unable to wear a sensor on the upper arm. The sample size for this pilot study was set at 20 patients. Study participation of a patient was paused if surgery was significantly delayed or ended if surgery was cancelled, or if a patient had severe postoperative complications.

Telemonitoring

After giving informed consent, patients received the telemonitoring devices and instructions at home from one of the executing researchers (MEH and RvM). The telemonitoring devices consisted of a wearable sensor (Everion, Biovotion AG, Zürich, Switzerland) and a tablet (Samsung Galaxy Tab A 10.1 2019). Patients were instructed to wear the sensor on the upper arm of their choice during waking hours and charge it during the night (sensor battery life was up to 40 hours, which required charging every 24 hours in practice). The Everion is a CE class IIa-certified wearable sensor that monitors vital signs based on photoplethysmography and physical activity (ie, step count) using an accelerometer with a sampling frequency of 1 Hz for vital signs and activity (raw data mode 51.2 Hz). The storage frequency for vital signs was once per minute and once per hour for step count. Data were transferred to the HealthyChronos application (HealthyChronos, Alphen aan den Rijn, Netherlands) on the tablet through Bluetooth and to the in-hospital database using Wi-Fi.

Based on previous validation studies with the Everion sensor [11,12], only HR was considered in this study. It has been shown that Everion underestimated HR by up to 5.3 beats per minute (bpm) and had a median absolute percentage error of 2.3% during daily activities compared to Holter measurements in volunteers [11]. Besides, HR had a moderate relationship (r=0.52) with nurse measurements in the surgical ward [12]. Respiration rate, blood oxygen saturation, and skin temperature measured by Everion had lower reliability and accuracy during

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daily activities in volunteers [11], and a poor relationship with nurse measurements in surgical patients [12]. To our best knowledge, the accuracy of Everion for daily step count is still unknown.

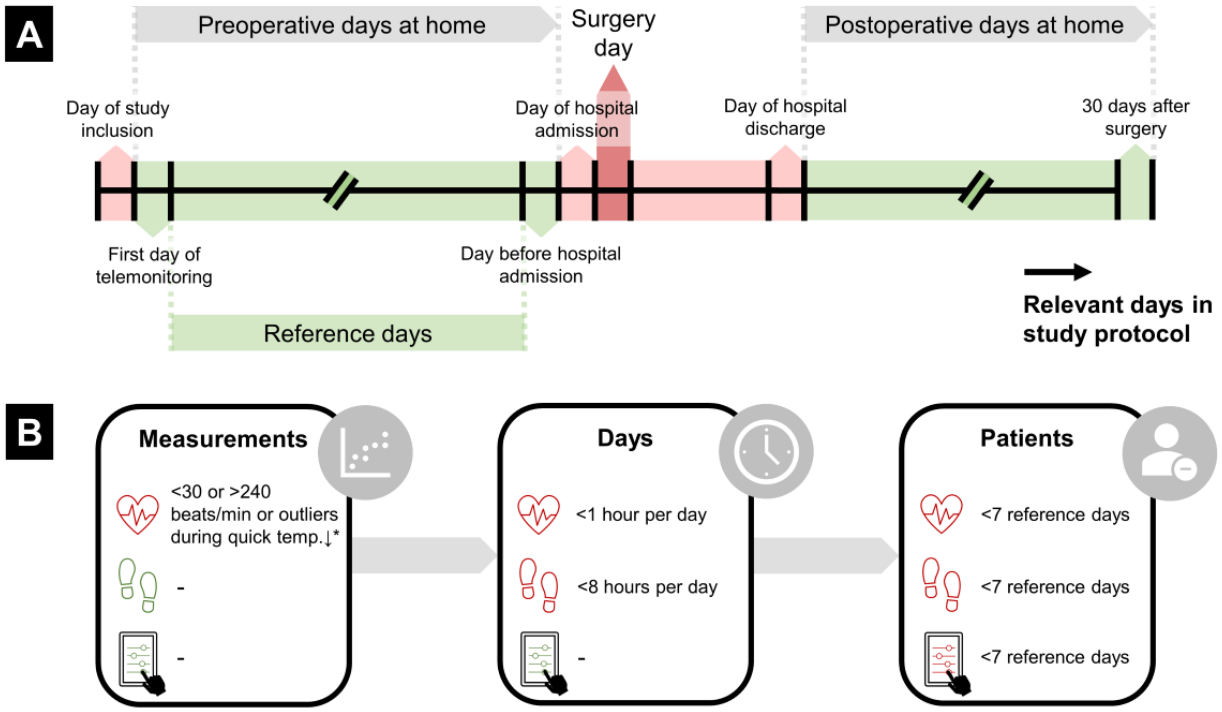
Patients received a notification to report PROMs twice a day: once in the morning (at random between 9 AM and 1 PM) and once at 8 PM in the mobile app on the tablet running on the Roessingh Research and Development eHealth platform (Activity Coach, Roessingh Research and Development, Enschede, The Netherlands [13]). PROMs included pain, anxiety, nausea, and fatigue on a visual analog scale (VAS) from 0 (no pain, anxiety, etc) to 10 (worst pain, anxiety, etc) imaginable.

Since this was an observational study without intervention, patients, and health care personnel were blinded to the telemonitoring data, and they did not receive feedback from the used technology.

Data Selection

Outcome measures were continuous data of HR and step count measured with the wearable sensor, and PROMs reported in the mobile app on the tablet, both preoperatively and postoperatively at home. Figure 1A shows a schematic overview of the preoperative and postoperative periods.

Figure 1. Schematic overview of (A) included (green) and excluded (red) preoperative and postoperative days at home, and (B) exclusion criteria at the level of measurements, days, and patients per parameter: heart rate, daily step count, and patient-reported outcome measures. See text for further explanation of measurement error removal.



Data from telemonitoring were retrieved from the databases and processed and analyzed in Matlab R2021b (Mathworks, Inc). To minimize bias in statistical analyses, the research team defined exclusion criteria at the level of measurements, days, and patients per parameter, as shown in Figure 1B. First, measurements were excluded if they met one of the following criteria [12]: (1) if HR was measured outside the technical ranges as stated by the manufacturer (30 to 240 bpm), or (2) if temperature decreased by 0.5 °C or more and HR was above its median plus 3 times its median absolute deviation [14,15] during 5 minutes at the end of a measurement period. The latter indicates that the sensor was removed and not directly put on the charger. Evaluation of the quality of measurement data was not part of this study, although earlier work on Everion measurements at the surgical ward showed that 1.2% of HR measurements were excluded for these reasons [12]. Second, a day of HR measurements was excluded from the analysis when less than 1 hour was available on that day. For the daily step count, the minimum available hours were set at 8 hours. Third, patients with less than 7 days of preoperative telemonitoring were excluded from data analyses.

Statistical Analysis

For each patient, the mean values of HR, step count, and PROMs measured on all included preoperative days were used as individual reference values. Two specific preoperative days were of interest: the first day of telemonitoring and the last day before hospital admission. We hypothesized that the behavior of patients might be different these days, resulting in lower reliability. The intraclass correlation coefficient (ICC) was used to assess the reproducibility between the 2 specific preoperative moments on the one hand and the reference values on the other hand. In addition, mean values of randomly selected measurement periods during the preoperative phase (excluding the first day of telemonitoring and the day before hospital admission) were used to determine the degree to which these measurements provide results similar to the reference values. Randomly selected contiguous periods ranged from 1 to 7 days

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for both HR and daily step counts, for days with at least 8 hours of HR measurements. For HR, randomly selected periods of 1 hour and 4 hours were used as well. For PROMs, ICCs were computed for one single randomly selected measurement.

The ICC, with its 95% CI based on absolute agreement, two-way random, and average measures, was used to evaluate the reliability. An ICC of ≤0.5 indicated poor, between 0.5 and 0.75 moderate, between 0.75 and 0.9 good, and >0.9 excellent reliability [16]. In addition, Bland-Altman plots with the difference against the average of paired values of HR and daily step count from the 2 specific preoperative moments were used to quantify the agreement between these measurements and the reference values. The mean difference (consistent bias) and the 95% limits of agreement (LoA) were estimated as well.

To describe the perioperative course of HR, daily step count, and PROM values over time in the home situation, the mean value per outcome per day was calculated for each patient. A boxplot was used to visualize these values for all patients from 14 days before hospital admission until 30 days after surgery.

Results

Study Participants

A total of 20 patients planned for major open abdominal surgery participated in this study and started telemonitoring at home with a median of 25 (IQR 18-45) days before surgery. The median time between being put on the waiting list and study inclusion was 11 (IQR 5.8-24.4) days. In total, 16 patients had at least 7 days of preoperative measurements and were included in the data analyses. Patient characteristics are shown in Table 1.

Table 1. Preoperative patient characteristics (n=16).

Descriptive	Values
Age (years), median (IQR)	69 (62.8-73.0)
Gender, n (%)	
Man	13 (81)
Woman	3 (19)
American Society of Anesthesiologists' classification, n (%)	
II	8 (50)
III	8 (50)
Comorbidities, n (%)	
Cardiovascular disease	8 (50)
Hypertension	5 (31)
Chronic pulmonary disease	2 (13)
Renal insufficiency	2 (13)
Nonsurgery related malignancy	1 (6)
Surgical procedure, n (%)	
Open abdominal aortic aneurysm repair	7 (44)
Hepatobiliary surgery	4 (25)
Gastrointestinal surgery	5 (31)

Individual Reference Values

For the 16 patients, the median number of reference days was 21 (IQR 14.5-38.5) for HR, 18 (IQR 13.5-35.5) for steps, and 18 (IQR 14-40) for PROMs. The number of hours of sensor data per day and reference values per parameter is summarized in Table 2, which also shows this information for the 2 specific preoperative days: the first day of telemonitoring and the day before hospital admission. Individual reference values and mean values on the 2 specific days are shown in Multimedia Appendix 1.

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Table 2. Information about measurements on the first day of telemonitoring, reference days, and the day before hospital admission, including measured values.

Parameter	First day of telemonitoring	Reference days	Day before hospital admission
Patients with sensor data, n	15	16	11
Number of hours with sensor data per day, median (IQR)	15 (14-15.8)	12.6 (11.6-14.1)	14 (10.8-14.8)
Mean HR[a] in bpm[b], median (IQR)	76.2 (65.5-79.6)	73.3 (66.6-80.4)	73.7 (70.6-83.9)
Standard deviation HR in bpm, median (IQR)	7.9 (7-10.4)	9.7 (8.4-11.7)	10.4 (8.9-10.7)
Daily step count by total number, median (IQR)	1645 (662-3696)	2763 (1576-6320)	2819 (1148-5218)
Mean pain on VAS[c] 0-10, median (IQR)	0.3 (0-2.4)	0.3 (0.1-4.5)	2.1 (0.1-5)
Mean anxiety on VAS 0-10, median (IQR)	0.4 (0.1-2.6)	0.7 (0-2.3)	1.3 (0.2-4.7)
Mean fatigue on VAS 0-10, median (IQR)	0.82 (0.1-2.3)	0.5 (0.1-3.9)	0.8 (0.1-5)
Mean nausea on VAS 0-10, median (IQR)	0.2 (0-2.1)	0.2 (0-1.3)	0.7 (0.1-2.3)

[a]HR: heart rate.

[b]bpm: beats per minute.

[c]VAS: visual analog scale.

Reliability

Table 3 shows the ICCs (and 95% CI) between the reference values and the mean values of the 2 specific preoperative days for HR, daily step count, and PROMs. The ICCs of the first day of telemonitoring were 0.91 for HR, 0.71 for steps, and at least 0.86 for PROMs (pain, anxiety, fatigue, and nausea), indicating good to excellent reliability. Good to excellent reliability coefficients (ie, ICC>0.75) were also found between these measurements on the day before hospital admission and the reference values, except for daily step count (ICC 0.71, 95% CI 0.21-0.92).

With regard to the mean values of randomly selected measurement periods during the preoperative phase, ICC values ranged from 0.68 to 0.99 for HR and daily step counts (Table 4). As expected, the ICCs increased over a continuous period of time for both. Good reliability point estimates were achieved after measuring at least 1 day. However, a lower bound of the 95% CIs of at least 0.75 (indicating good reliability) was determined using periods of at least 3 days (Table 4).

Randomly selected PROM measurements compared to the reference values resulted in an ICC of 0.93 (95% CI 0.82-0.97) for pain, 0.94 (95% CI 0.84-0.98) for anxiety, 0.91 (95% CI 0.77-0.97) for fatigue, and 0.89 (95% CI 0.73-0.96) for nausea, indicating good to excellent reliability.

Table 3. Intraclass correlation coefficients (ICC and 95% CI) between individual reference values and mean values on the first day of telemonitoring and the day before hospital admission.

Parameter	First day of telemonitoring		Day before hospital admission	
	Patients, n	ICC (95% CI)	Patients, n	ICC (95% CI)
Heart rate	15	0.91 (0.76-0.97)	11	0.76 (0.35-0.93)
Daily step count	13	0.71 (0.30-0.90)	10	0.71 (0.21-0.92)
Pain	14	0.86 (0.64-0.95)	10	0.99 (0.95-1.00)
Anxiety	14	0.90 (0.72-0.97)	10	0.92 (0.74-0.98)
Fatigue	14	0.94 (0.83-0.98)	10	0.97 (0.89-0.99)
Nausea	14	0.87 (0.64-0.95)	10	0.89 (0.64-0.97)

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Table 4. Intraclass correlation coefficients (ICC and 95% CI) between individual reference values and mean values of randomly selected periods for heart rate (HR) and daily step count.

Period	HR		Daily step count	
	Patients, n	ICC (95% CI)	Patients, n	ICC (95% CI)
1 hour	16	0.68 (0.30-0.87)	N/A[a]	N/A
4 hours	16	0.74 (0.41-0.90)	N/A	N/A
1 day	16	0.86 (0.65-0.95)	16	0.78 (0.49-0.92)
2 days	16	0.87 (0.68-0.95)	16	0.85 (0.63-0.94)
3 days	16	0.90 (0.75-0.96)	16	0.92 (0.80-0.97)
4 days	16	0.92 (0.80-0.97)	15	0.97 (0.92-0.99)
5 days	15	0.99 (0.96-0.99)	15	0.97 (0.91-0.99)
6 days	15	0.97 (0.91-0.99)	14	0.97 (0.90-0.99)
7 days	13	0.99 (0.95-1.00)	13	0.99 (0.96-1.00)

[a]N/A: not applicable.

Agreement

Bland-Altman plots for HR and daily step count using the reference values and the mean values of the first day of monitoring as well as the day before hospital admission are shown in Figure 2. While there was no bias in the mean HR values on the first day of monitoring (mean difference –0.1, 95% LoA –7.8 to 7.6 bpm), the mean difference (bias) of HR values measured on the day before hospital admission was 4 (95% LoA –5.4 to 13.5) bpm.

The mean difference in daily step counts measured on the first day of telemonitoring was –546 steps with a 95% LoA ranging from –3897 to 2805 steps. This mean difference changed to 270 steps with a broader 95% LoA of –5383 to 5923 steps on the day before hospital admission.

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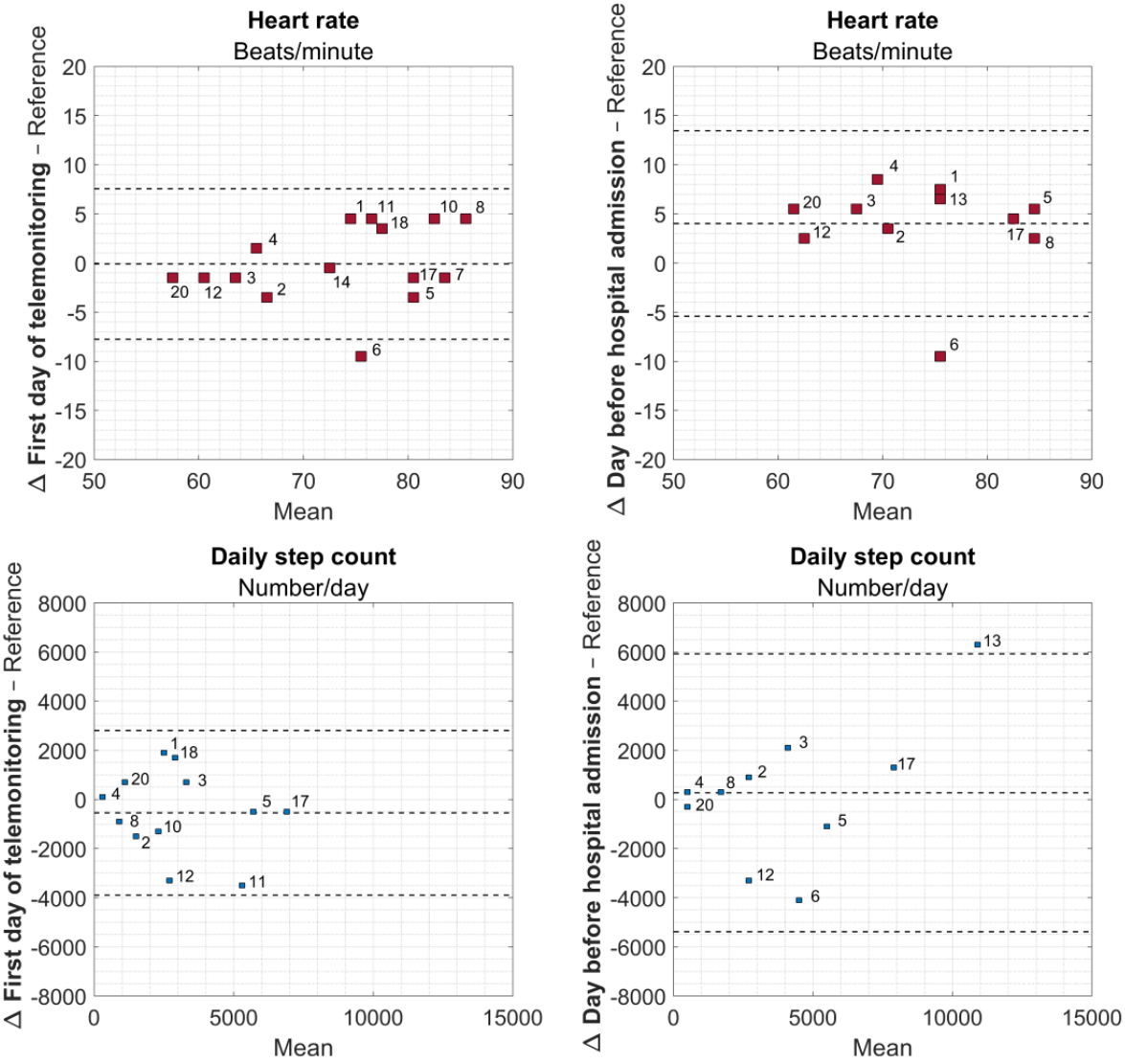
Figure 2. Bland-Altman plots for the mean values per patient for heart rate (upper row) and daily step count (bottom row) on the first day of telemonitoring (left column) and the day before hospital admission (right column). The middle dotted line represents the mean difference and the outer dotted lines the 95% limits of agreement. Numbers represent individual patients.



The Perioperative Course

Figure 3 shows the mean values per day measured by telemonitoring at home in the 14 days before and 30 days after surgery for HR, the number of daily steps, and PROMs. Postoperative telemonitoring data at home was available in 13 patients for a median of 17 (IQR 9-21) days. Noticeable is the variability of daily measurements of preoperative steps with a median of 2409 (IQR 1735-4661) steps/day and the lower postoperative step count with a median of 884 (IQR 474-1605) steps/day. In addition, it can be observed that pain reduces over time after surgery at home (not statistically tested).

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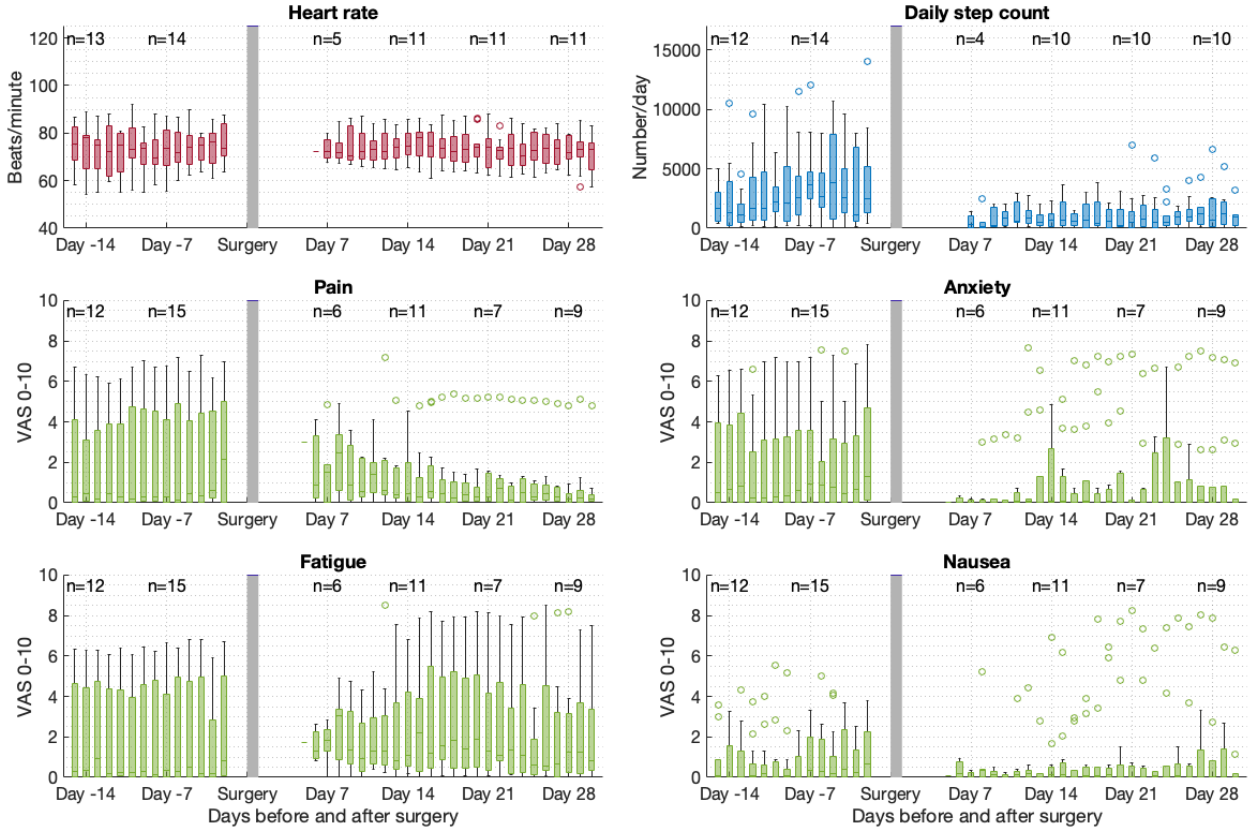
Figure 3. Boxplot of mean values of patients per day for each parameter in the 14 days before hospital admission and 30 days after surgery at home. Boxplots show the median values (bold lines), IQRs (limits of boxes), ranges (whiskers), and outliers (circles). VAS: visual analog scale.



Discussion

Principal Findings

The primary aim of this study was to evaluate during which period patients should be monitored minimally to obtain reliable preoperative baseline values before major open abdominal surgery. Based on the results from this pilot study, a period of 3 days seems to be sufficient for reliable baseline values for HR and daily step count. PROMs had good to excellent reliability on any day, including the first day of telemonitoring and the last day before hospital admission.

The secondary aim was to describe the perioperative course of HR, daily step count, and PROMs measured at home. Visualization of mean values per day mainly showed variable preoperative daily step counts and lower postoperative daily step counts. In addition, pain was visually reduced until 30 days after surgery at home.

Comparison to Prior Work

Preoperative continuous monitoring of HR in the home environment is currently hardly used or investigated. In a recent study, the resting HR of patients undergoing elective major colorectal surgery was measured during 30 preoperative days with a wearable sensor (Fitbit Charge 2, Fitbit Inc) [8]. The authors found no differences between the mean preoperative HR in patients with or without readmission within 30 days after surgery. Gräfitsch et al [4] asked 16 patients to measure HR twice a day for 7 days before abdominal wall hernia surgery (minor surgery) to generate a baseline. They only reported that the median HR remained stable over the perioperative period. Based on our results, a minimum of 3 days would be sufficient to measure reliable baseline values for HR. However, the clinical implications of these baseline values should be further investigated in future studies.

The daily step count has been mainly objectively measured after surgery and associated with postoperative outcomes [17,18]. Studies that monitored steps before major abdominal surgery show median numbers of 4151 to 4526 [8], 6209 [6], and 6562 [3] daily steps during 30 days, 2 days, and 3 to 7 days preoperatively, respectively. The higher median number of steps compared to our findings (median 2409 steps/day) might be due to the fact that patients in our study were older: median 69 (IQR 62.8-73.0) years versus median 55.5 (IQR 25.5-61.5) years and 58.0 (IQR 42.0-65.0) years [8], mean 55.2 (SD, 11.9) years [6], and median 55.5 (range 22-74) [3] years. Interestingly, we found a mean difference of minus 545 steps between the first day of telemonitoring and the reference values. Although patients were aware of the observational nature of the study, it was expected that the effect of being monitored (due to reactivity [19] and the novelty effect) would have led to a higher step count during the first period of telemonitoring. Optimizing physical activity preoperatively is part of enhanced recovery after surgery and prehabilitation programs, in which wearable sensors are very promising to assist in informing and supporting the patient and clinician [8,20].

PROMs are mostly applied in telemonitoring studies to detect changes during postoperative recovery [21-24]. One study reported a mean VAS of 2.2 (SD 3.1) for pain, 3.1 (SD 2.4) for

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fatigue, and 0.5 (SD 1.2) for nausea before major abdominal surgery without further use of these values [3]. Preoperative VAS for pain and fatigue reported in our study were lower with median reference values of 0.3 (IQR 0.1-4.5) for pain and 0.5 (IQR 0.1-3.9) for fatigue, while VAS for nausea was comparable with a median of 0.2 (IQR 0-1.3). Even though PROMs are subjective, especially relevant within context (eg, diagnosis and comorbidities), and are moment dependent, our results show that PROMs can be reliably measured on any preoperative day. This creates possibilities for their future use as baseline values, for example, to assess patients' resilience before surgery and for prehabilitation.

Technological developments enable preoperative evaluation in a patient's own environment and over a longer period to get more representative individual values. Despite this, practicality and organizational flexibility are also important for application in clinical practice. Although the literature is inconclusive about the minimum period for physical activity measurement, accelerometers are usually worn for up to 7 days, and it is common to include 4 out of 7 days with 10 hours/day wear time, including one weekend day [25]. Moreover, both the first and last measurement days are often omitted [25]. The minimum measurement period of 3 consecutive days of 8 hours to measure HR and daily step count found in our study indicates that effects from daily life activities on sensor measurements are sufficiently averaged during this period.

Strengths and Limitations

This study provides the first step toward the clinical application of preoperative telemonitoring. One of the strengths of this study is the random selection of measurements to find a reliable period for baseline values. Another strength of this study is the heterogeneity of the patients, which reflects the diversity of the surgical population for which perioperative telemonitoring may be of added value. First, an important limitation of this study is the small number of included patients. Four patients were excluded from data analyses due to the short period of preoperative measurements. The main reasons for this were that patients were scheduled for surgery earlier due to program dropout or connectivity problems. However, the choice of the minimum length of the reference period as well as the exclusion criteria for the minimum number of available data points per day was arbitrary as this is one of the first times preoperative baseline values derived by telemonitoring have been investigated. In the future, this could be improved by using a larger study population and refining the criteria to exclude data periods. Second, another limitation is that of all the vital signs measured by the wearable sensor, only HR was included in this study because the validity and reliability of the sensor for respiratory rate, blood oxygen saturation, and temperature were low [11,12]. Third, the validity and reliability of the sensor for daily step count are still unknown, which limits the translatability of the current results to other wearable sensors that measure daily step count.

Future Directions

Resting HR and HR during physical activity were not investigated in this study because activity parameters were stored once per hour and the sensor was not worn during the night due to charging. This could provide additional information and may be taken into account in future research.

Preoperative measurements of vital signs, physical activity, and PROMs may be used in future studies regarding prehabilitation or personalized monitoring of the entire perioperative period. In general, knowledge about the association between these parameters at home is scarce. For example, it is known that HR is highly affected by physical activity, and pain has been associated with decreases in daily steps [26]. A larger observational study monitoring vital signs, physical activity, and PROMs in surgical patients might be useful in understanding these associations since they are relevant for the interpretation of the telemonitoring data in clinical practice.

The generalizability of these results is limited due to the small sample size and limitations of the used sensor. However, this was a pilot study to assess the feasibility of perioperative telemonitoring [9] and to get an idea of the required period to measure preoperative values to inform future study design. The used method in this study could be applied to find a measurement period for reliable estimation of baseline values of other continuously monitored vital signs, patient populations, and wearable sensors as well.

Conclusions

In patients awaiting major abdominal surgery, baseline values for HR and daily step count could be measured reliably by a wearable sensor worn for at least 3 consecutive days in this study. PROMs could be measured with good to excellent reliability on any given day, including the first day of telemonitoring and the day before hospital admission. Visualization of mean values of HR, step count, and PROMs on the days before and after major abdominal surgery at home provided insight into the perioperative course of [these parameters in] our study population, although no clear conclusions could be drawn from this. Future work should focus on the clinical implications of these baseline values.

Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

MEH, RCLS, HJH, MT, and JPPMdV conceptualized the study. MEH, MEM, RCLS, HJH, MT, and JPPMdV were involved in methodology and interpretation of data. MEH and RvM carried out the data acquisition. MEH and MEM performed the data

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analyses, and MEH drafted the manuscript and visualized the data. RvM, MEM, RCLS, HJH, MT, and JPPMdV revised and edited the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Mean values on the first day of telemonitoring, the reference values, and mean values on the day before hospital admission for each parameter per patient. Each color corresponds with an individual patient. VAS: visual analog scale.
[PNG File , 336 KB - periop_v5i1e40815_app1.png]

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Abbreviations

bpm: beats per minute
HR: heart rate
ICC: intraclass correlation coefficient
LoA: limits of agreement
PROM: patient-reported outcome measure
PROMISE-study: Telemonitoring in the Peri-operative Phase of Patients Undergoing Open Abdominal Surgery in a University Medical Center: A Pilot Study
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
VAS: visual analog scale

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Original Paper

Personal Devices to Monitor Physical Activity and Nutritional Intake After Colorectal Cancer Surgery: Feasibility Study

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Abstract

Background: The use of self-monitoring devices is promising for improving perioperative physical activity and nutritional intake.

Objective: This study aimed to assess the feasibility, usability, and acceptability of a physical activity tracker and digital food record in persons scheduled for colorectal cancer (CRC) surgery.

Methods: This observational cohort study was conducted at a large training hospital between November 2019 and November 2020. The study population consisted of persons with CRC between 18- and 75 years of age who were able to use a smartphone or tablet and scheduled for elective surgery with curative intent. Excluded were persons not proficient in Dutch or following a protein-restricted diet. Participants used an activity tracker (Fitbit Charge 3) from 4 weeks before until 6 weeks after surgery. In the week before surgery (preoperative) and the fifth week after surgery (postoperative), participants also used a food record for 1 week. They shared their experience regarding usability (system usability scale, range 0-100) and acceptability (net promoter score, range –100 to +100).

Results: In total, 28 persons were included (n=16, 57% male, mean age 61, SD 8 years), and 27 shared their experiences. Scores regarding the activity tracker were as follows: preoperative median system usability score, 85 (IQR 73-90); net promoter score, +65; postoperative median system usability score, 78 (IQR 68-85); net promotor score, +67. The net promoter scores regarding the food record were +37 (preoperative) and–7 (postoperative).

Conclusions: The perioperative use of a physical activity tracker is considered feasible, usable, and acceptable by persons with CRC in this study. Preoperatively, the use of a digital food record was acceptable, and postoperatively, the acceptability decreased.

(JMIR Perioper Med 2022;5(1):e40352) doi:10.2196/40352

KEYWORDS

eHealth; fitness trackers; diet records; colorectal neoplasm; colorectal cancer; surgery; self management; patient care; physical activity; tracking; activity tracking; self-monitoring; feasibility; usability

Introduction

There is a growing body of literature that recognizes the importance of physical fitness in colorectal cancer (CRC) surgery. Higher levels of physical activity have been associated with improved outcomes such as decreased cancer mortality and recurrence rates [1,2]. After surgery, activity levels are low, and a decline in physical function and the incidence of psychological distress can negatively impact recovery [3,4]. A higher level of preoperative physical activity is associated with health-related quality of life and reduced adverse perioperative outcomes, such as complications, length of hospital stay, and readmissions [5-8].

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Given the potential to optimize physical fitness during the waiting period before surgery, the focus has shifted from rehabilitation to prehabilitation. Prehabilitation comprises the process of enhancing the functional and mental capacity of persons to buffer against potential adverse effects of a major stressor, such as surgery [9]. Prehabilitation programs incorporate exercise training with enhanced medical and psychological status [10]. Another important component of prehabilitation is the optimization of nutritional status with a focus on adequate protein intake [11]. Several studies have shown that multimodal prehabilitation can improve the physical fitness of persons with surgical CRC, although the effect on clinical outcomes remains less clear [12-15]. Persons feel the need to physically prepare for surgery and enjoy the experience of prehabilitation [16]. However, such programs could be time-consuming and labor-intensive, and most have suboptimal participant adherence rates [16,17].

In the last decade, interest in the use of physical activity trackers (PATs) in health care has increased. PATs provide automatic dynamic data tracking and can be linked to smartphones and other relevant fitness applications such as digital food records (DFRs). This ensures immediate availability of point-of-care data, such as steps per day and protein intake, with the ability to generate automated goal-directed alerts to users. PATs are used in persons with chronic diseases to improve physical fitness and are increasingly popular in oncology practice [18].

Several studies conclude that the use of PATs is feasible to objectively assess physical activity in CRC surgery [19-29]. Preliminary evidence suggests that physical activity measured by PATs is associated with postoperative outcomes after surgery [30-32]. However, questions have been raised about the suitability of PATs for this population and not much is known about persons' experiences. Furthermore, the combined monitoring of physical activity and protein intake with digital appliances is understudied.

Through this feasibility study, we aimed to assess the usability and persons' satisfaction regarding a robust commercially available PAT (Fitbit Charge 3; Fitbit, Inc.) in CRC surgery. We also examined the person's experience with a digital food record (DFR) to monitor nutritional intake. Additionally, we sought to obtain data on physical activity and protein intake in the perioperative period. Clinical outcomes were compared based on whether or not physical activity and protein intake goals were achieved.

Methods

Study Design and Setting

This observational cohort study was conducted at a large nonacademic training hospital (the Jeroen Bosch hospital, 's-Hertogenbosch) in The Netherlands from November 2019 to November 2020. In 2018, more than 250 new persons with CRC were treated at this hospital, nearly 180 of whom were eligible for curative surgery. In this hospital, the perioperative care in CRC surgery is embedded in the enhanced recovery after surgery pathways. All persons with CRC received written information about physical activity and nutrition during the perioperative period from the clinical nurse specialist. To support the usual care, participants in this study were provided a Fitbit Charge 3 to wear up to 4 weeks prior to surgery until 6 weeks after surgery on the wrist of the nondominant hand. The Fitbit was paired with the person's smartphone or tablet, or with a borrowed tablet from the hospital if the person does not have the compatible equipment, by the Fitbit app. This app automatically provides daily statistics on physical activity and sends a weekly report to the participants by email. Participants were asked to share these weekly reports with the researcher. To monitor their nutritional intake, participants filled in a DFR, 1 week prior to surgery and the last week of the study 5 weeks after surgery.

Participants

The study population consisted of persons with colorectal carcinoma scheduled to undergo elective surgery with curative intent. Persons between 18 and 75 years of age were included if they were able to use a smartphone or tablet that is compatible with the tracker. Persons were excluded if they were not proficient in Dutch or following a protein-restricted diet on the advice of a medical specialist.

Recruitment

Convenience sampling was used in which the clinical nurse specialist screened the eligibility of persons with CRC scheduled for elective and curative surgery during her consultation. Those eligible were given a study information sheet and asked permission to share contact details with the researcher. The researcher contacted people by telephone to discuss the content of the study. If a person was interested, eligibility was confirmed by the researcher and an information and consent form, approved by the local medical ethics committee, was sent. An appointment was planned with the researcher at a mutually convenient time, preferably in combination with other hospital appointments for the person. Written consent was obtained and the PAT was programmed and demonstrated in person by the researcher. Figure 1 shows the flow of participants.

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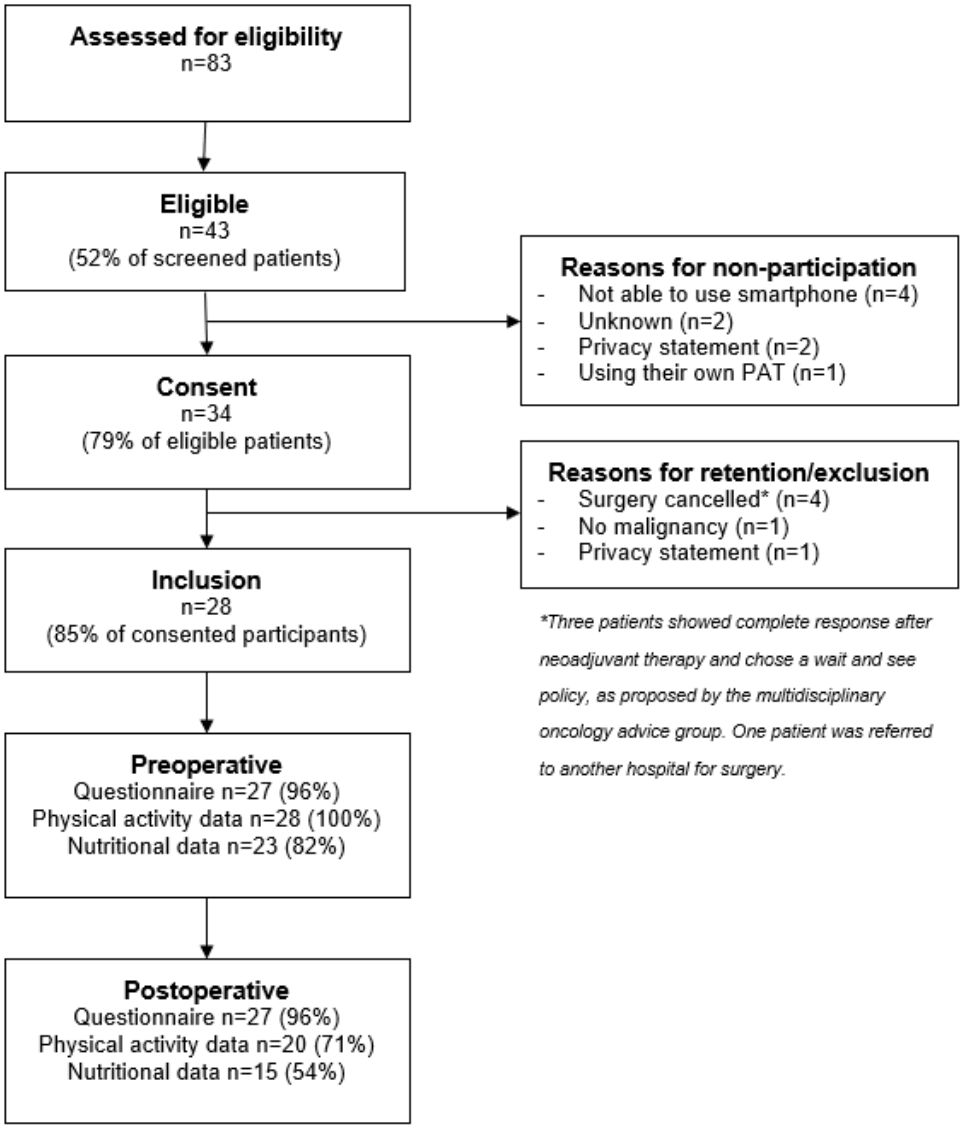
Figure 1. The flow of patients with colorectal cancer participating in the study. PAT: physical activity tracker.



Variables

Feasibility, Usability, and Acceptability

Rates on screening, eligibility, consent, inclusion, and completion were collected. In an online questionnaire, persons were asked to share their views on the usability and acceptability of the Fitbit and the DFR. The usability of the Fitbit was assessed by the system usability scale (SUS), consisting of 10 statements regarding the usability of an electronic device or system that participants can rate on a 5-point Likert scale. The Fitbit was considered usable if the mean SUS were higher than 68 [33]. Acceptability regarding the Fitbit and the DFR was measured using the customer satisfaction score (CSAT) and the net promotor score (NPS). The CSAT is a score where respondents indicate acceptability using a 5-point Likert scale answering the question: “How satisfied were you with your experience?” This score focuses mainly on short-term acceptability, whereas the NPS focuses more on the long term. The NPS is calculated based on responses to the question: “How likely is it that you would recommend our company/product/service to a friend or colleague?” using a scale of 0-10. The percentage of detractors (answering with 1-6) was subtracted from the percentage of promoters (answering with 9 or 10). Passive scores (answering with 7 or 8) were not counted. An NPS could be as low as –100 or as high as +100. A positive total NPS was considered acceptable [34].

Physical Activity

Physical activity was monitored using the Fitbit Charge 3, which has a visual display on the bracelet for monitoring activity progress. The weekly number of steps provided by the reports of the Fitbit app was monitored up to 4 weeks prior to surgery until 6 weeks after surgery. Other information regarding physical activity such as the number of floors climbed, calories burned, and active minutes was visible to participants but outside the scope of this study. This wrist-worn commercially available activity tracker is an objective person-generated measure of physical activity, as it has generally high validity and reliability for measuring daily step count [35-37]. At inclusion, persons were instructed to achieve at least 7500 steps per day, which seems to be a relevant goal as reflected upon research in this

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population [38,39]. No additional advice or incentives were given by researchers or caregivers during the study concerning physical activity other than within usual care. There were no implications on whether or not daily step goals were achieved.

Protein Intake

Protein intake in grams per day was measured using a DFR of The Netherlands Nutrition Centre called "Mijn Eetmeter." In this tool, users select and log foods from the Netherlands Food Information Resource (NethFIR) database, maintained and updated regularly by the Dutch National Institute for Public Health and the Environment (RIVM), containing macronutrient and micronutrient data of over 90,000 food items. This DFR is freely available to the public and is featured with a barcode scanner, options to add new foods, and remember favorite foods, and the ability to export nutritional data. Participants filled in their daily consumed foods and monitored their protein intake twice for 7 consecutive days. This method has similar validity and reliability when compared to conventional methods to assess dietary protein intake [40-42]. The DFR provided a weekly overview of consumed foods including daily protein intake. Other data on macronutrient and micronutrient levels were visible for participants but outside the scope of this study.

Participants were instructed to consume 1.2-1.5 g of protein per kilogram of body weight per day, with correction for underweight (BMI<20 kg/m^2) and overweight (BMI>27.5 kg/m^2), if necessary. This is considered the optimal amount for persons with CRC in the perioperative period [43,44]. All persons received an example daily menu from the clinical nurse specialist, which approximates individual protein requirements. Participants were advised to consume foods available in food stores that are, per definition, considered safe; no protein supplements were advised. No additional advice or incentives were given by researchers or caregivers during the study concerning protein intake other than within usual care. There were no implications on whether or not protein intake was adequate. Protein intake was considered adequate when participants ingest at least 1.2 g per kilogram body weight.

Person Characteristics and Clinical Outcomes

Person characteristics such as age (in years), sex (male/female), BMI (in kg/m^2), tumor location (rectum/colon), tumor stadium (I/II/III/IV), neoadjuvant therapy (non/chemotherapy/chemo-radiation/other), and surgical technique (laparoscopic/open) were collected. All participants are Dutch residents; further information regarding ethnicity is unknown. Clinical outcomes, measured 90 days after discharge, included the length of hospital stay (in days) in comparison with the expected number of hospital days in the care paths for colon (4 days) or rectal (6 days) cancer surgery. Data have been dichotomized (expected or longer than expected hospital stay compared with the care paths). The occurrence of complications (yes or no) and unplanned readmissions (yes or no) after hospital discharge was measured. Finally, "Textbook Outcome" was used as a composite measure of clinical process indicators [45]. Textbook outcome is realized for persons for whom all desired short-term health indicators (expected hospital stay, no complications, and no unplanned readmissions) are met.

Study Size

The aim of the study was not to provide an estimate of the treatment effect, so there was no formal sample size calculation. The estimation was made to recruit 30 persons over 6 months, based on the number of persons with CRC eligible for curative surgery in the previous year, clinical estimates of the number of persons eligible for inclusion (50%), and the estimated recruitment rate (80%). Due to the COVID-19 pandemic, nonmedically necessary care was delayed, and the inclusion period was extended to a total of 12 months.

Statistical Methods

Descriptive statistics have been used to summarize all variables using SPSS Statistics v25 (IBM Corp). To test for differences in baseline characteristics and clinical outcomes between persons who achieved their goals on protein intake and physical activity and persons who did not achieve their goals, the Fisher exact test for categorical data and the Mann-Whitney *U* test for not normally distributed continuous data were used. A 2-sided *P* value of <.05 was considered statistically significant. Reporting is consistent with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement for observational research [46].

Ethics Approval

This study was submitted for approval to the Medical Research Committee Brabant, who confirmed that the Medical Research Involving Human Subjects Act did not apply. The data were prospectively collected by applying the most recent version (version 7, October 2013) of the Declaration of Helsinki and the Guidelines for Good Clinical Practice.

Results

Participants

From November 2019 to November 2020, 144 persons with CRC underwent elective curative surgery. Inclusion for participation in this study was halted between March 16 and July 1 due to the measures surrounding COVID-19.

Figure 1 shows the flow of participants. A total of 28 persons were included. Although not statistically significant, the persons who declined tended to be older (*P*=.05) compared to included persons. There was no difference in gender (*P*=.45).

Table 1 displays the baseline characteristics, divided into whether or not participants reached their goals. In 5 (18%) cases, this division could not be made because of missing dietary food record data. Persons who reached their goals achieved a mean daily number of steps ≥7500 and ≥1.2 gram of protein per kilogram (adjusted) body weight per day. The participants who reached both goals preoperatively were more often female (n=9, 69% vs n=2, 20%; *P*=.04) and had lower BMI (24 kg/m^2, IQR 22-27 vs 27 kg/m^2, IQR 24-28; *P*=.03) compared to participants who did not reach their goals.

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Table 1. Baseline characteristics and clinical outcomes.

Characteristics	Total (N=28)	Goals[a] achieved (n=13)	Goals not achieved (n=10)	*P* value
Age (years), median (IQR; min-max)	61 (15; 47-73)	57 (15; 49-73)	59 (14; 49-73)	.95
Sex (male), n (%)	16 (57)	4 (31)	8 (80)	.04[b]
BMI, kg/m^2, median (IQR; min-max)	26 (4; 19-37)	24 (5; 19-30)	27 (4; 24-37)	.03[b]
ASA[c] index, n (%)				.49
I	4 (14)	2 (15)	0 (0)	
II	23 (82)	10 (77)	10 (100)	
III	1 (4)	1 (8)	0 (0)	
Tumor location				.67
Colon	19 (68)	8 (62)	8 (80)	
Rectum	7 (25)	3 (23)	2 (20)	
Both	2 (7)	2 (15)	0 (0)	
TNM[d] classification				.63
I	4 (14)	2 (15)	2 (20)	
II	8 (29)	5 (39)	2 (20)	
III	14 (50)	6 (46)	5 (50)	
IV	2 (7)	0 (0)	1 (10)	
Neoadjuvant treatment				.67
None	21 (75)	11 (85)	6 (60)	
Chemotherapy	2 (7)	1 (8)	1 (10)	
Radiotherapy	1 (4)	0 (0)	1 (10)	
Chemo-radiation	4 (14)	1 (8)	2 (20)	
Surgical technique				.44
Laparoscopic	27 (97)	13 (100)	9 (90)	
Open	1 (4)	0 (0)	1 (10)	
LOS[e] longer than expected	12 (43)	4 (31)	5 (50)	.42
Complications	6 (21)	1 (8)	4 (40)	.13
Unplanned readmissions	2 (7)	0 (0)	1 (10)	.44
Textbook outcome	16 (57)	9 (69)	5 (50)	.42

[a]Goals based on 1.2 grams of protein/kilogram of body weight/day and ≥7500 steps per day.

[b]A 2-sided *P* value of <.05 was considered statistically significant.

[c]ASA: American Society of Anesthesiologists.

[d]TNM: Tumor, Node, Metastasis classification

[e]LOS: length of hospital stay.

Usability and Acceptability

The usability of the Fitbit was assessed in the week prior to surgery and 5 weeks after surgery, with a median SUS of 85 (IQR 73-90) and 78 (IQR 68-85), respectively. Acceptability of the Fitbit was scored on the NPS with preoperative having 69% (n=18 answering with 9 or 10) promotors and 4% (n=1 answering with 6) detractors. Postoperatively, the percentage of promotors was 74% (n=20 answering with 9 or 10) and 7% detractors(n=2 answering with 3 or 4). Therewith, the NPS was preoperative +65 and postoperative +67. Acceptability of the DFR was scored on the NPS with a preoperative score of +37 based on 52% (n=14 answering with 9 or 10) being promotors and 15% (n=4 answering with 5 or 6) being detractors. Postoperatively, the NPS score was –7 based on 30% (n=8 answering with 9 or 10) promotors and 37% (n=10 answering with 2 to 6) detractors. Other scores regarding the acceptability of the Fitbit and DFR are presented in Table 2. There was room for free comments in the web-based questionnaire, and 22 (79%) participants used this option. In 14 cases, the feedback focused on the DRF, with most participants (n=12) identifying

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drawbacks or areas for improvement. In particular, the complexity of the app used was frequently mentioned.

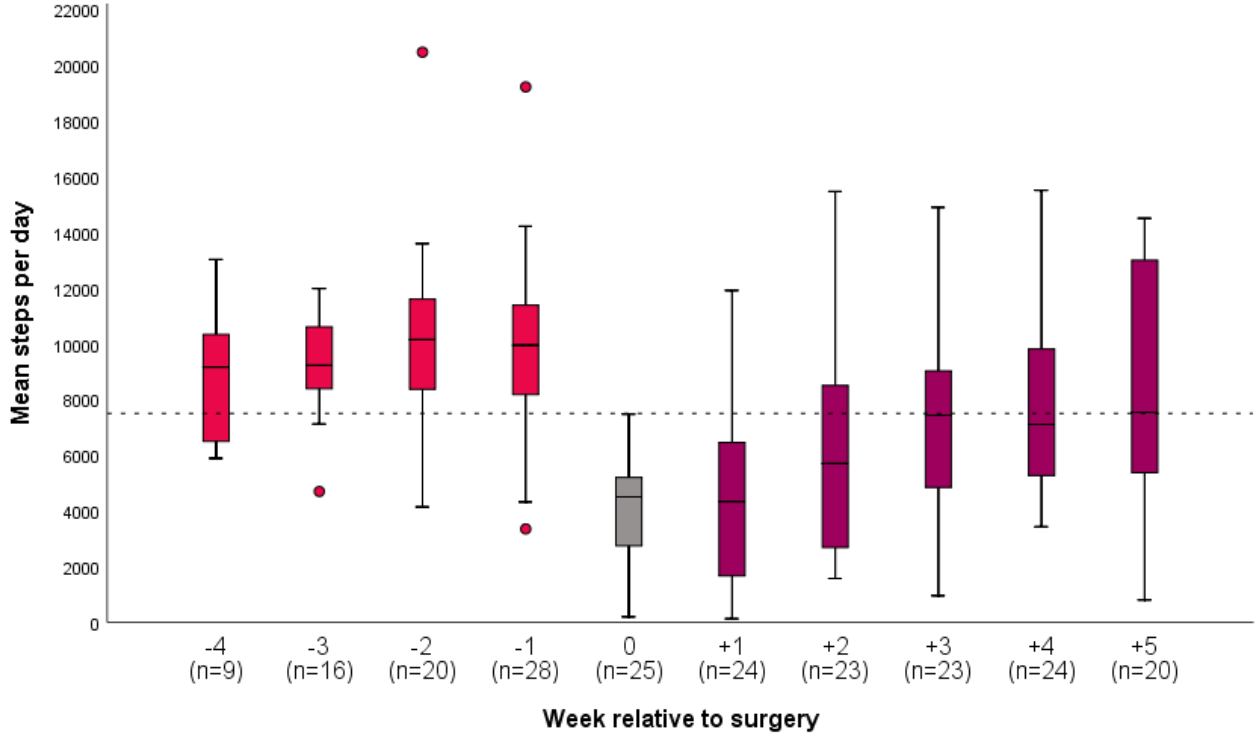
Table 2. Acceptability scores for the use of a physical activity tracker and digital food record.

	Physical activity tracker		Digital food record	
	Preoperative	Postoperative	Preoperative	Postoperative
Scores (range 1-5), median (IQR; min-max)				
Customer satisfaction score	5 (1; 3-5)	4 (1; 2-5)	4 (0; 3-5)	3 (2; 2-5)
The tool provides insight	5 (1; 3-5)	5 (1; 2-5)	5 (1; 2-5)	4 (1; 2-5)
The tool stimulates to reach goal	4 (2; 1-5)	4 (2; 1-5)	4 (2; 3-5)	4 (2; 2-5)

Physical Activity

Due to surgery planning, not all participants started measuring their physical activity 4 weeks before the surgery. In the week before surgery (preoperative), all participants had complete data on physical activity, and 79% (n=22) reached a mean number of steps ≥7500. A total of 14 (50%) participants provided data on physical activity in all postoperative weeks. Figure 2 shows the perioperative course of physical activity, expressed in the median number of steps per day.

Figure 2. Perioperative course of physical activity in patients with colorectal cancer using a physical activity tracker. The dotted line represents the daily goal of 7500 steps per day.



Protein Intake

Preoperatively, 23 (82%) participants provided data on their mean protein intake during the week before surgery, and 16 (70%) participants reached ≥100% of their individual protein intake goal. Postoperatively, 15 (54%) participants provided data on their mean protein intake during the fifth week after surgery, and 10 (67%) participants reached their goal. Figure 3 shows the median protein intake of participants relative to their minimal individual goal based on 1.2 g per kilogram body weight per day.

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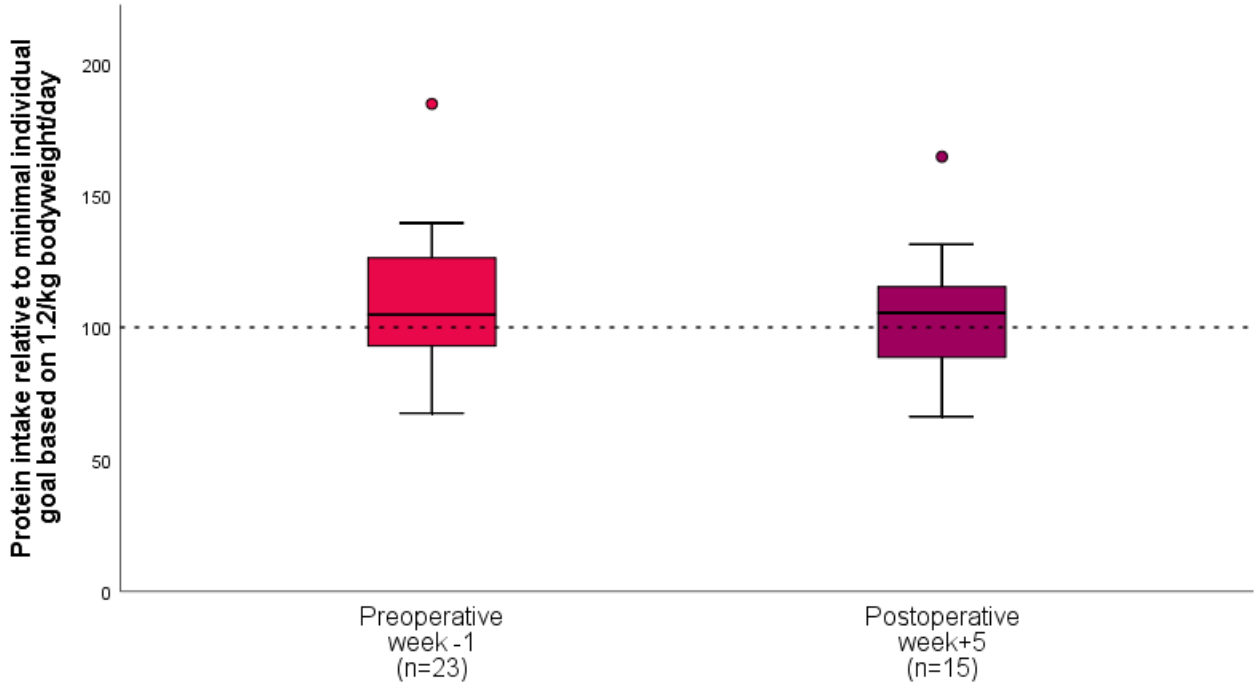
Figure 3. Perioperative course of protein intake in patients with colorectal cancer using a digital food record. The dotted line represents the daily protein goal.



Clinical Outcome

Table 1 summarizes clinical outcomes, divided into whether or not participants reached their goals. Persons who achieved ≥7500 steps per day and ≥1.2 g protein per kilogram body weight per day appeared to have lower rates of prolonged hospital stay (n=4, 31% vs n=5, 50%), complications (n=1, 8% vs n=4, 40%) and unplanned readmissions (n=0, 0% vs n=1, 10%). However, the differences were not statistically significant. The product of all clinical indicators resulted in the number and proportion of persons for whom all desired outcomes were realized and thereby a "Textbook Outcome" was achieved. The proportion of persons with a "Textbook Outcome" tended to be higher for persons who achieved their goals (n=9, 69% vs n=5, 50%; *P*=.42).

Discussion

Principal Findings

This study describes the feasibility, usability, and acceptability of a commercially available PAT and DFR in CRC surgery. Persons reported high scores for usability and acceptability of a PAT using the SUS, NPS, and CSAT scales. We found high compliance and high adherence rates to daily step goals in the perioperative period. The acceptability regarding the DFR was lower compared to the PAT; it was found acceptable in the preoperative setting only. The compliance rate for using the DFR was acceptable in the preoperative period with adequate protein intake in most persons, but the compliance rate dropped after surgery. Although not statistically significant, clinical outcomes appeared to benefit persons who achieved ≥7500 steps per day and ≥1.2 g protein per kilogram body weight per day.

Comparison to Prior Work

Few studies have examined persons' experiences regarding PATs in people who have received surgery. In a perioperative eHealth program with multiple components, den Bakker et al [21] used qualitative person feedback as well as a scale ranging from 0 to 10 to assess persons' with CRC attitudes. Participants were positive about the use of a PAT and stated that it was a good way to reflect on their level of activity, and the use motivated them to be physically active. Grimes et al [22] found high acceptability of wearing a wrist-worn accelerometer in 35 perioperative older adults, measured using a visual analogue scale questionnaire. Jonker et al [24] determined the feasibility, usability, and acceptability of the perioperative use of their mobile app and activity tracker in older persons with surgical cancer. Their scores on usability (SUS) and acceptability (NPS) were lower compared to the scores in our population, which might be related to a higher mean age of participants in their study.

The preoperative median step count in our study is comparable with other studies using PATs in persons with CRC [19,23,28]. In free-living, healthy, older adults, the reported daily number of steps ranges from around 2000 to 9000 [47]. For persons with cancer, and persons with other chronic conditions or those living with a disability, the expected range lowers to 1200-8800 steps per day [48]. Most persons in our study met the daily step goal comparable with recommended physical activity levels for persons with cancer [1] and the general population [49] prior to surgery. As expected, postoperatively, the median number of steps dropped to approximately 4300 steps/day 1 week after surgery, which is comparable to habitual steps/day in persons with heart and vascular diseases [48]. In the phase of recovery, physical activity increased, and 35% of the persons returned to the preoperative daily number of steps. In our study, the majority of persons underwent laparoscopic surgery. Functional recovery

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may differ between traditional open surgery and minimally invasive surgery. Due to the small number of participants (n=1) who underwent an open procedure (n=1), this could not be sufficiently explored in this study. A randomized blinded study on this topic found no difference in functional recovery after open versus laparoscopic colonic resection [50]. In line with our results, Nakajima et al [31] noted that persons with CRC with a low activity level were significantly older and had a higher rate of major complications.

Participants in our study considered the use of a DFR acceptable in the preoperative setting. This is comparable with other nutritional apps to promote a healthy lifestyle, with better scores for apps with options to memorize recent and favorite foods and a range of household and metric measures that increased the ease of self-monitoring of food intake [51]. In our study, the compliance rate was 82% (n=23) in the week prior to surgery with 70% (n=16) of participants reaching the recommended daily protein intake. After surgery, only 54% (n=15) completed their food record, of whom 67% (n=10) reached their goal. In addition to the compliance rate, the acceptability scores (CSAT and NPS) were also higher in the preoperative phase compared to the postoperative scores. This endorses the hypothesis of Grimes et al [22], who suggest that the preoperative setting may be a unique period in which behavioral interventions are more likely to be successful, possibly due to the well-defined end point (surgical procedure) and the motivation that good nutritional status can affect the surgical outcome. Although the compliance for both tools is higher in the preoperative period compared to the postoperative period, it is striking that the difference is more pronounced for the DFR. This may partly be explained by the fact that data on nutritional intake must be entered by the participants in the DFR, as opposed to the automatically generated data on physical activity through the PAT. Keeping a DFR can be time-consuming and burdensome, which could result in noncompliance or inadequate food logging and inadequate estimations of nutritional intake. Moreover, the complexity of the DFR used could impact compliance, since many persons reported on this topic in the online questionnaire. Finally, the tool used for assessing nutritional intake must be in line with the eating habits of the users to ensure compliance. In this case, the tool matched the eating habits of the Dutch study population but would be less suitable for a population with other eating habits.

Strengths and Limitations

Strengths of this study include its prospective design and follow-up period with digital support in both the preoperative as well as the postoperative period for up to 10 weeks total. Moreover, we combined monitoring of physical activity and dietary protein intake. Both could be considered relevant for maintaining or building muscle mass and are thus related to clinical outcomes [11]. Since low-cost commercially available personal devices were used, they could be easily applied in similar circumstances by others.

Both an advantage and limitation to our study was the homogenous study population of persons with CRC up to 75 years of age. Selection bias has likely occurred as persons who have agreed to participate are more likely to find the self-monitoring tools acceptable and useful. Given the nature of our study's population, bias could have occurred in selecting participants since our population is fairly young, technologically literate, and possibly more health conscious. This limits the generalizability of our findings. Finally, due to the small sample size, findings are preliminary and limited to usability and acceptability.

Conclusions and Future Directions

The results of this study show that the use of a commercially available PAT is feasible, acceptable, and usable for the self-monitoring of physical activity in the perioperative setting. The use of a DFR to monitor protein intake was acceptable before surgery. A less extensive tool or a DFR with only a 4-day registration as an alternate [52] might increase compliance with protein intake monitoring. To our knowledge, this is the first study combining the monitoring of physical activity and dietary protein intake using low-cost commercially available tools in persons with surgical CRC. Future research should focus on integrating both monitoring tools and could include monitoring vital signs to give a complete picture of a person's perioperative course. A large-scale data collection is necessary to validate the effects on clinical outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

CRC: colorectal cancer
CSAT: customer satisfaction score
DFR: digital food record
NPS: net promotor score
PAT: physical activity tracker

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Original Paper

Automated Intraoperative Short Messaging Service Updates: Quality Improvement Initiative to Relieve Caregivers' Worries

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Abstract

Background: Undergoing a surgical procedure is anxiety provoking for patients and their caregivers. During the intraoperative period, caregivers seek out informational updates from health care professionals, a situation complicated by COVID-19 health measures that require caregivers to wait outside the hospital. Short messaging service (SMS)-based communication that allows caregivers to follow their loved ones through surgery has shown promise in relieving anxiety and improving satisfaction with overall care. This form of communication is also well accepted by health care professionals and may be effective at relieving staff burden.

Objective: Here, we describe a quality improvement initiative of a standardized and integrated intraoperative SMS-based system to improve communication between surgical teams and caregivers. The main goal was to improve satisfaction with care, while the secondary goal was to reduce caregiver anxiety.

Methods: The initiative followed the framework of the Model for Improvement. A large tertiary care hospital offered the SMS to caregivers who were waiting for loved ones undergoing surgery. SMS messages were integrated into the clinical information system software and sent at key points during the surgical journey to phone numbers provided by caregivers. A satisfaction survey was sent to caregivers 1 business day after surgery. Data were collected between February 16 and July 14, 2021.

Results: Of the 8129 surgeries scheduled, caregivers waiting for 6149 (75.6%) surgeries agreed to receive SMS messages. A total of 34,129 messages were sent. The satisfaction survey was completed by 2088 (34%) of the 6149 caregivers. Satisfaction with messages was high, with the majority of respondents reporting that the messages received were adequate (1476/2085, 70.8%), clear (1545/2077, 74.4%), informative (1488/2078, 71.6%), and met their needs (1234/2077, 59.4%). The overall satisfaction score was high (4.5 out of 5), and caregivers reported that receiving text messages resulted in a reduction in anxiety (score=8.2 out of 10). Technical errors were reported by 69 (3.3%) caregivers. Suggestions for improvements included having messages sent more often; providing greater patient details, including the patient's health status; and the service being offered in other languages.

Conclusions: This digital health initiative provided SMS messages that were systematically sent to caregivers waiting for their loved ones undergoing surgery, just as COVID-19 restrictions began preventing waiting onsite. The messages were used across 15 surgical specialties and have since been implemented hospital-wide. Digital health care innovations have the capacity to

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improve family-centered communication; what patients and their families find useful and appreciate will ultimately determine their success.

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KEYWORDS

COVID-19; surgery; intraoperative; OR nurse; communication; technology; short messaging service; SMS; text message; caregiver; anxiety; perioperative; surgical; surgical procedure; mHealth; mental health; digital health; digital health care

Introduction

Background

Surgery, whether elective or emergent, is a distressing medical procedure that evokes high levels of anxiety in both patients and caregivers [1-3]. More than 1 million surgical interventions were performed in Canada in 2020 [4]; these procedures implicate family members and caregivers as requisite accompaniers. Separated from their loved ones during the intraoperative period, caregivers experience distress, helplessness, fear, loneliness, frustration, and uncertainty, as well as physiological responses, such as increased heart rate, impaired sleep, and restlessness [5-7]. Although caregivers previously waited in the surgical waiting area, with the arrival of the COVID-19 pandemic and mandatory hygiene measures, most are now required to wait off-site with only remote access to surgical staff for updates [8].

Family members anxiously seek informational updates about their loved one's status [7,9], but the intraoperative time frame is often the most difficult moment to provide such details. Progress reports are effective at relieving the distress felt by caregivers during surgery and contribute to overall satisfaction with care [10,11]. In fact, surgeons consider the main purpose of their intraoperative communication with family members to be the reduction in anxiety [12]. During these moments, surgeons report that the surgical details are not remembered by family members and caregivers, whose primary concern is to know whether their loved one is alive and awake.

The importance of including caregivers in the surgical conversation reflects *information sharing*, 1 of the core concepts of patient- and family-centered care (PFCC) [13]. PFCC has been shown to lead to improved patient health outcomes, a better overall experience of care, and a wiser allocation of resources [13]. Fostering effective intraoperative communication to fulfill PFCC has become a priority in the surgical setting, where surgeons, anesthetists, nurses, and receptionists are often solicited for information. Surgical nurse liaisons are described in the scientific literature as being the link between family and the operating room (OR) and are often responsible for providing specific, ongoing, and predictable information on the day of surgery [14-18].

Hospitals have supplemented face-to-face perioperative consultations with other modes of information provision. These include using volunteers for support with navigating the hospital, providing informational cards [19], installing electronic patient status boards in waiting rooms [20], showing videos that describe the surgery [21,22], and allowing a 5-minute postanesthesia care unit (PACU) visit between caregivers and patients [23]. Although speaking with a member of the surgical team remains the gold standard, a 2016 study by Heath et al [18] found that families receiving intraoperative updates from a nurse were equally satisfied if they received them in person or by telephone. Indeed, the authors suggested that telephone calls provided more individualized care and privacy for family members. As a result, they could wait and receive news wherever they preferred.

Mobile health (mHealth) solutions in the field of surgery have grown as the use of mobile phones has become nearly universal [24,25]. Recent reviews examine mobile app–based and short messaging service (SMS)-based interventions in the management of surgical patients [26-28]. The overall findings reveal that SMS-based perioperative communication is acceptable, efficient, and effective for patients, caregivers, and health care providers. Furthermore, the interventions demonstrate positive results, including reduced anxiety, increased adherence to treatment, improved symptom monitoring, better pain management, increased satisfaction with care, and lower postoperative readmission rates [26,27]. Importantly, they also provide continuity of care in the preoperative-to-postoperative window [11,29-31].

Studies that use SMS-based communication to update family members and other caregivers during the intraoperative period are limited yet offer compelling evidence of their value as they produce positive outcomes [32-36]. Gordon et al [32] carried out a multicenter prospective study that connected surgical patients to any number of individuals designated as a contact. This person received 7 emails or SMS updates. Two days postoperatively, patients, message recipients, and surgical staff completed a satisfaction survey. A large majority of patients (74%) endorsed the program as being an "improved hospital experience," while 96% of the message recipients claimed they "felt more connected to their loved ones during surgery." For the surgical team, 87% found it to be "useful and efficient." Wieck et al [35] describe the integration of pager-based SMS updates in a children's hospital as part of an effort to streamline communication with families. Families were paged with 4 updates during surgery. Satisfaction with information increased over 30% for families, and 96% of nurses felt that "patients' families were getting the information that they desired." In contrast, Howe et al [36] tested the effect of pager-based updates using a randomized controlled trial of adults admitted for orthopedic surgery. The families in the control group received care as usual, while the intervention group received a text message at the beginning, middle, and end of surgery. The intervention group experienced lower levels of anxiety and higher levels of satisfaction with the information provided compared to the control group. In 2016, Kwan et al [33], in a

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nonrandomized prospective survey, measured the perioperative level of anxiety in parents whose children were undergoing spinal surgery. In the intervention group, parents received 10 SMS updates every 10-20 minutes during surgery, while the control group received treatment as usual. The intervention group had significantly lower measures of anxiety both during surgery and postoperatively. Similarly, Poudel et al [34], using a randomized single-blinded prospective study, measured anxiety in family members who were waiting for loved ones undergoing oncologic surgery. The control group received care as usual, while the intervention group was provided with intraoperative SMS updates at 5 times points during surgery. The SMS group had significantly lower anxiety scores at 1 hour into surgery and at surgery completion compared to the control group.

Patients, health care providers, and message recipients find SMS-based updates of surgical milestones to be acceptable, useful, and anxiolytic. In the context of the COVID-19 pandemic, mobile apps that allow caregivers to follow their loved ones through surgery are beginning to be offered commercially and are being integrated into medical centers [37]. However, commercially available apps raise concerns surrounding privacy, security, and reliability. Furthermore, context-specific mobile apps are not suited to provide a standardized system of messaging that translates into sustainable interventions.

Objectives

This paper describes a quality improvement initiative that consisted of the implementation of a standardized and sustainable intraoperative SMS-based system that improves communication between surgical teams and caregivers [38]. Specifically, this initiative aims to improve caregiver satisfaction with care and reduce caregiver anxiety during the intraoperative period.

Methods

Clinical Setting

This quality improvement initiative was undertaken at the Centre hospitalier de l'Université de Montréal (CHUM) in Montreal, Quebec, Canada. This newly constructed hospital represents the modernization and centralization of 3 separate hospitals where, between 2015 and 2020, an average of 24,000 surgeries occurred each year. The hospital runs a total of 36 surgery rooms spread over 2 floors, and 16 surgical specialties are practiced in the new center. For this project, most specialties were involved; only ophthalmology, obstetrics, the burn center, and emergent surgeries were not included in this initial phase. Approval for the initiative was obtained from the director of professional services and the associate director of academic and university affairs of the hospital. This quality improvement initiative followed the framework set out by the Model for Improvement originally described by the Associates in Process Improvement [39,40]. The process involves forming a team; setting an aim; selecting measures and changing them as required or suggested; pilot-testing the initiative; implementing changes; and spreading the change more globally. CHUM supports this cycle of innovation for creating value in health care (eg, improving patient care as well as staff and team experiences, optimizing resources, collaborating with educators) [41].

Ethical Considerations

This quality improvement initiative did not require CHUM Institutional Research Board review. All caregivers who participated in this study were treated in accordance with the Declaration of Helsinki (7th revision 2013). Participants provided verbal consent that their caregiver receive SMS messages from the digital platform and were able to opt out at any time without affecting the standard of care. Participant (caregiver) information was not associated with the data collected for the purpose of this initiative, and personal patient information was not collected, transferred, or published. These measures were put in place to maintain the right to privacy and confidentiality.

Procedures

A member of the surgical team described the SMS system to caregivers and how they could receive intraoperative messages if they so desired. This was done during surgery scheduling or at admission for surgery. Messages were provided as a parallel system to standard care and were not included in the medical health record of the patient. Caregivers provided a phone number to the staff and were told that unidirectional updates would be sent during specific points during surgery and that the last update would indicate the unit where their loved one was recovering or when they would be discharged. Caregivers were required to wait off the hospital premises during surgery due to COVID-19 restrictions. A final message was sent to the caregivers 1 business day after surgery to invite them to complete a survey using the online platform Lime Survey. No reminders were sent.

The system (including messages and the satisfaction survey) was pilot-tested for reliability and acceptability between January 11 and February 14, 2021. The research team and 2 staff members reviewed the patient intake process, the functionality of the digital platform, and the content of the caregivers' responses. From a total of 884 participating caregivers, 404 (45.7%) completed the questionnaire. Refinement of the initiative occurred at this stage. One SMS message was removed from the surgical updates as it was deemed unnecessary. As caregivers noted (in open-ended questions of the satisfaction questionnaire) that the SMS messages reduced their anxiety, a single question on anxiety was added, as has been done by others [42,43]. Finally, 1 question that provided an open-ended choice for improvements on the SMS messages was made into a drop-down menu for commonly noted suggestions from this pilot phase, with 1 additional open comment box. Data collection of survey responses took place between February 16 and July 14, 2021.

Development of the SMS System and Messages

SMS messages and their send times were integrated into the clinical information system software Centricity Opera (General Electric Healthcare) [44]. These modifications to Centricity Opera were made by working in close collaboration with the company that provides the software. Messages were sent from

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Centricity Opera to the Application Programming Interface company Twilio [45], which then transmitted the messages to caregivers.

The wording of all SMS messages was developed by the surgical staff working group (the research team). For the initial phase, messages were only offered in French. The text was then reviewed in collaboration with the hospital's communication department and edited to consider privacy and to ensure messages were written in clear, concise, and accessible language. SMS messages provided resources, including a link to the hospital's appointment center and a telephone help line with a 24-hour-a-day nurse available to discuss patient concerns. Wording for 2 additional SMS messages was prepared: (1) in the event caregivers needed to come to the hospital during the time of COVID-19-mandated curfew hours, the message provided the necessary medical authorization to travel during curfew, and (2) in the case of a power failure, a customizable message was created such that it could be sent once the system functioning returned, noting that messages may have been interrupted. All SMS messages are presented in Table 1.

The timing of SMS message delivery was decided upon by the research team. Updates were sent out as patients traveled through checkpoints considered key times in the surgical trajectory (see Figure 1). Although the messages were labeled for internal identification using numbers, these were not seen by caregivers. In fact, each surgical journey differed by patient, depending on their condition. For example, a patient may have come to surgery from within the hospital, been operated upon, gone through the PACU, and then been sent to the care unit. The appropriate and relevant messages received by their caregivers would be identified internally as message 2, followed by message 4 and then message 6.

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Table 1. SMS[a] messages sent to caregivers during key times during surgery.

Message	Content
Message 1	CHUM[b] Day Surgery One of your loved ones wishes to keep you informed of their progress during their day of surgery. The patient has just arrived at the day surgery department. This is the first in a series of messages intended to keep you informed of the progress of his or her surgery. Please note that for reasons of confidentiality we do not transmit any medical information via the text messaging system. CHUM day surgery +1 (514) XXX-XXXX https://repertoire.chumontreal.qc.ca/fiches/chirurgie-dun-jour
Message 2	CHUM OR[c] Your loved one is presently in the surgery room. Surgery will begin shortly. You will receive an SMS once the surgery is complete.
Message 3	CHUM PACU[d] Your loved one's surgical procedure is complete. He or she is now on their way to the care unit. This is the last message you will receive from the OR team.
Message 4	CHUM PACU The surgery is complete. Your loved one is currently in the PACU. You will receive the next SMS when he/she has completed the post-surgery safety monitoring period. Please note that since the PACU is a sterile area, visits are not permitted.
Message 5	CHUM Day Surgery Your loved one has returned to the day surgery unit. You will receive a message when he or she has met the discharge criteria. COVID-19 restrictions: you must wait for the nurse's call before coming to pick up your loved one.
Message 6	CHUM PACU The surgical procedure of your loved one is complete, and he or she is now on their way to the care unit. This is the last message you will receive from the OR team.
Message 7	For travel during COVID curfew: CHUM authorization After receiving the call from the nurse, use the attached authorisation to justify your trip to the CHUM.
Authorization for discharge	Accompanying a patient admitted at the CHUM during the curfew decreed by the Quebec government. You will find below an authorization from the Centre hospitalier de l'Université de Montréal authorizing you to travel during curfew hours for the sole purpose of picking up your loved one at the hospital when he or she is ready to go home. Be sure to keep this message until you return home. To whom it may concern, this message certifies that the bearer is the escort authorized by a CHUM patient who was discharged from the hospital following surgery today. To verify the authenticity of this discharge certificate, contact the hospital department at +1 514-XXX-XXXX. CHUM, 1051 Sanguinet Street, Montreal, QC H2X 3E4.
Message 8	CHUM Day Surgery Your loved one has completed his or her surgical journey and has met the criteria for discharge. He or she can now leave the hospital. Report to the Departure Lounge (Pavilion C - Ground Floor) or to the pickup area as directed by the nurse. This is the last message you will receive from the OR team. Health file: https://www.chumontreal.qc.ca/en/fiche/who-can-i-ask-if-i-have-questions-about-my-health Are you worried or do you need advice following your visit to the CHUM? Dial: +1 (514) XXX-XXXX.
Message 9	CHUM Day Surgery Your loved one's surgical procedure is complete, and he or she has met all discharge criteria. He or she is now being transferred to the referring center. This is the last message you will receive from the OR team. Health Sheet: https://www.chumontreal.qc.ca/en/fiche/who-can-i-ask-if-i-have-questions-about-my-health Are you worried or do you need advice following your visit to the CHUM? Dial: +1 (514) XXX-XXXX. To reach the appointment centre at the CHUM: +1 (514) XXX-XXXX or +1 (855)-XXX-XXXX.
Notice of disruption	Notice of Disruption of CHUM Text Messaging Service Due to a disruption in our text messaging system, you may have experienced difficulties in receiving messages from the CHUM concerning your loved one. We apologize for the inconvenience. The messaging service has now been restored. Thank you for your understanding. The CHUM OR team
CHUM survey	Hello Our files indicate that you received SMS updates of your loved one during their surgical journey. We are sending you a survey regarding your satisfaction with the different SMS you received. The survey is confidential. Thank you for your time. CHUM Team - Client satisfaction team

[a]SMS: short messaging service.

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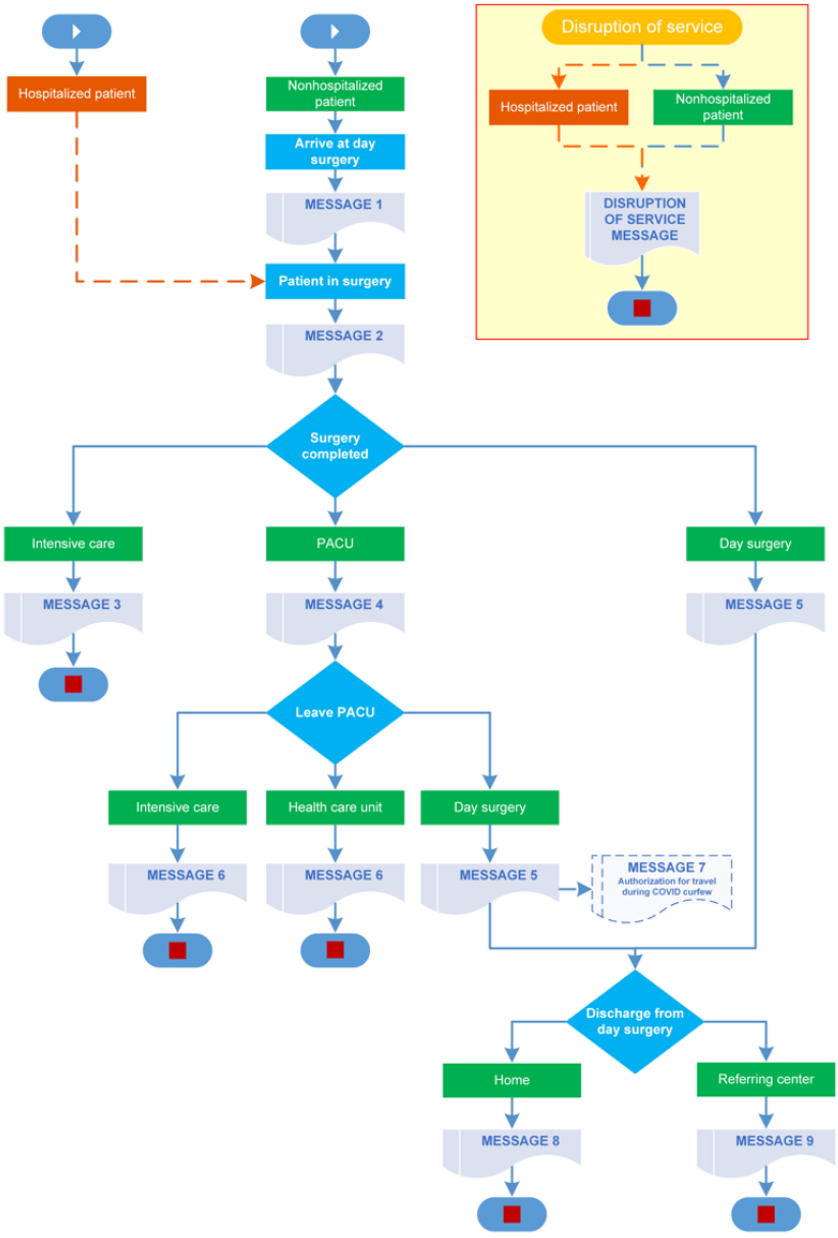
[b]CHUM: Centre hospitalier de l'Université de Montréal.

[c]OR: operating room.

[d]PACU: postanesthesia care unit.

Figure 1. SMS Messages sent during patient's surgical trajectory.



Questionnaire

A satisfaction survey was developed by our team consisting of 10 self-reported items, 9 (90%) of which were used in this analysis.

One question asked whether respondents noticed that the day surgery contact number was included in their first message, to which they were able to answer either yes or no. This question was included to see whether caregivers were able to absorb the information provided and make effective use of resources.

Four items measured satisfaction with the messages and asked whether (1) the number of SMS messages received was adequate, (2) the messages delivered were clear, (3) the messages delivered kept respondents informed about the progress of their loved ones' operation, and (4) the information provided in the messages during the day met the respondent's needs and expectations. Response choices consisted of a 4-point forced Likert scale: 1=completely agree, 2=agree, 3=disagree, and 4=completely disagree.

To verify the adequacy of the information included in SMS updates, 1 item queried whether respondents needed to contact the day surgery service despite having received SMS messages; response items were either yes or no. Those who responded yes were offered a menu of reasons why they contacted the service, including "To find out a room number," "For information about the length of the operation," "For additional information about the operation," "For information about the condition of my loved one's health," "For information concerning discharge

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time," "For the address of the hospital," and 1 open field to describe "Other."

In line with Howe et al [36], overall satisfaction was assessed with the question "On a scale of 1 to 5, how would you rate your overall satisfaction with the SMS application? (with 1 being completely dissatisfied and 5 being completely satisfied)?" One open-ended question asked respondents whether they had any suggestions or comments following their experience with the messaging system.

Anxiety was measured by the single question "On a scale of 1 to 10, to what level did receiving text messages reduce your anxiety about your loved one's surgical journey? (with 1 being not at all reduced and 10 being greatly reduced)?"

Data Analysis

Anonymized data were exported from Lime Survey into Microsoft Excel for analysis. Results are expressed using descriptive statistics, frequencies, percentages, and mean scores. Spearman correlation was used to measure the association between total satisfaction and reduction in anxiety. "Other" reasons for having to contact the day surgery were described. Responses to the open-ended question that asked for comments or suggestions about the platform were analyzed by the team; similar items were coded and grouped into unique categories; frequencies are reported for these categories. Missing data were approximately 1%, and thus case-wise deletion was used to obtain all descriptive statistics [46,47].

Results

Users and Communication

Of the 8129 surgeries scheduled between January 14 and July 13, 2021, caregivers waiting for 6149 (75.6% participation rate) surgeries agreed to use the SMS system. A total of 34,129 messages were sent, resulting in an average of 5.6 messages per user. From 2088 respondents, 69 (3.3%) errors were considered technical issues (ie, software malfunction). Negative feedback included messages sent at a time that did not correspond with the surgical schedule, were missing, or were repeated. The staff may have incorrectly entered the time of surgery in the software; at other times, the origin of the error was not known. A few caregivers reported they did not receive SMS messages, an error that was determined to be due to incorrect phone numbers being linked to the caregivers, due to either caregiver or staff error in providing or recording the phone numbers. Information technology network downtime and power outages occurred twice; caregivers received the message drafted for this purpose, although some respondents noted the delay and a lack of communication in the open-ended question on satisfaction with the service. Other errors were determined to be a lack of human care coordination with the SMS messages. Caregivers reported mistimed instructions for pick-up of patients (too early) or an absence of expected communication from the nurse postoperatively.

Level of Caregiver Satisfaction and Anxiety

The satisfaction questionnaire was sent to all 6149 respondents 1 working day after surgery, of which 2088 (34%) completed it. A majority of respondents (1511/2054, 73.6%) endorsed yes (they had seen the phone number provided in the first SMS sent) versus no (543/2054, 26.4%).

Satisfaction with messages was high, with the majority of respondents claiming they completely agreed that the number of messages received was adequate (1476/2085, 70.8%), clear (1545/2077, 74.4%), informative (1488/2078, 71.6%), and met their needs (1234/2077, 59.4%); see Table 2.

Approximately 1 (20%) in 5 caregivers (425/2055, 20.7%) needed to contact the day surgery unit. Reasons for this communication are described in Table 3.

Other reasons (78/425, 18.4%) for contacting the OR included questions or comments pertaining to surgery cancellations or delays, longer-than-normal perceived length between SMS messages, permission to visit the patient, planning of travel for patient transport home, clarification of messages or the SMS process, worry and stress about the patient, and trouble with the SMS system. Overall satisfaction with the app had an average score of 4.5 out of 5 (2041/2088, 97.7%).

In response to how SMS messages reduced anxiety in relation to the patient's surgical journey, caregivers reported an average score of 8.2 out of 10 (2046/2088, 98%), where 10 represented "greatly reduced." Spearman correlation revealed that the overall score in satisfaction was highly correlated with the reduction in anxiety (r_s=0.608, P<.001).

Table 2. Caregiver satisfaction with SMS[a] messages.

Item	Completely agree, n (%)	Agree, n (%)	Disagree, n (%)	Completely disagree, n (%)	Total, N
The number of SMS messages received was adequate.	1476 (70.8)	501 (24.0)	73 (3.5)	35 (1.7)	2085
The messages delivered were clear.	1545 (74.4)	468 (22.5)	45 (2.2)	19 (0.9)	2077
The messages delivered kept caregivers informed about the progress of their loved one's operation.	1488 (71.6)	475 (22.9)	89 (4.3)	26 (1.2)	2078
The information provided in the messages during the day met the caregiver's expectations and needs.	1234 (59.4)	651 (31.3)	147 (7.1)	45 (2.2)	2077

[a]SMS: short messaging service.

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Table 3. Reasons caregivers contacted day surgery despite having received SMS[a] messages (N=425).

Reason	Caregivers, n (%)[b]
To find out a room number	56 (13.2)
For information about the length of the surgery	89 (20.9)
For additional information about the surgery	126 (29.6)
For information about the condition of my loved one's health	217 (51.1)
For information concerning discharge time	113 (26.6)
For the address of the hospital	7 (1.6)
Other	78 (18.4)

[a]SMS: short messaging service.

[b]Categories are not mutually exclusive, and thus percentages do not add up to 100%.

Caregiver Comments

The majority of respondents (1360/2088, 65.1%) answered the open-ended question regarding their experience; comments were subsequently collapsed into 7 unique categories and 20 subcategories to obtain a total of 2078 comments (see Table 4). Caregivers provided feedback not only for the SMS service but also for their experience worldwide.

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Table 4. Subcategories of commentary provided by caregivers (N=2078).

Category	Caregivers, n (%)
Positive feedback (n=1293, 62.2%)	
Positive comments, thanks, and congratulations	492 (38.0)
Specific positive feedback on the SMS[a] system	633 (49.0)
Positive feedback on the surgical experience	87 (6.7)
Reduced anxiety	81 (6.3)
Desire for more information (n=352, 17.0%)	
Would have liked to know the room number of their loved one	43 (12.2)
Would like to know state of health of the patient	152 (43.2)
Surgeon's call important	15 (4.3)
Would like to know how long each segment of wait is	93 (26.4)
Discharge information not detailed or precise enough	49 (13.9)
Negative feedback (n=139, 6.7%)	
Was stressful	12 (8.7)
Mistimed SMS	64 (46.0)
Delays between SMS messages too long	48 (34.5)
Dissatisfied with the message system	15 (10.8)
Software error (n=69, 3.3%)	
Number or delivery of texts incorrect	69 (100.0)
Constructive criticism (n=58, 2.8%)	
Messages need to be clarified.	27 (46.6)
Messages feel impersonal in their tone.	21 (36.2)
The SMS should also be provided in English.	10 (17.2)
Dissatisfied with experience at the OR[b] (n=38, 1.8%)	
Surgery delayed or cancelled	38 (100.0)
Incomplete comments or other issues (n=129, 6.2%)	
Unclear or incomplete messages	55 (42.6)
Comments about other issues or departments (eg, security)	74 (57.4)

[a]SMS: short messaging service.

[b]OR: operating room.

Discussion

Principal Findings

The purpose of this paper was to describe an SMS-based digital health initiative that aims to improve communication between surgical teams and caregivers during the time of surgery. The SMS platform was specifically designed to improve caregiver satisfaction with care and to reduce caregiver anxiety. Caregiver reports of satisfaction with the messages and the initiative were high. Caregivers also reported a positive effect on anxiety reduction and offered constructive feedback on how to improve the quality, content, and method of delivery of information.

The results of this study confirm that integrating a standardized system of intraoperative messages in the clinical information system of an OR can enable SMS updates that can be sent in real time to those waiting for loved ones undergoing surgery. Unlike other context-specific innovations, this initiative was integrated with the existing hospital's software infrastructure and was thus generalizable to other settings using clinical information system management software. SMS communication for surgical updates is now a permanent service being offered throughout the CHUM.

This project and its outcomes support the vision of the World Health Organization (WHO) Global Strategy on Digital Health for 2020-2025 [48], which states that digital innovations will be valued and adopted if they are accessible and sustainable, increase efficiency in the delivery of care, and protect the privacy of patient health information. This initiative was piloted and then implemented for testing just as COVID-19 restrictions were rendering access to hospital wait areas impossible. Thousands of caregivers were able to receive SMS

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communication about their loved ones, in addition to care as usual. To the best of our knowledge, this study has the largest sample size to date for intraoperative messaging.

Satisfaction With Messages

Overall, caregiver satisfaction was high. Due to the wide range of surgical specialties involved in this project, there were many combinations of patient trajectories and timing (see Figure 1), and thus, the number and frequency of messages differed. Despite this, over 90% of respondents agreed or completely agreed that the information provided was clear and adequate, kept them informed about their loved one's progress, and met their expectations. Of the caregivers who needed to contact the day surgery, many had concerns with regard to the evolution of surgery and the condition of their loved one's health (see Table 3). The SMS messages did not contain individualized health information in order to avoid a breach of patient privacy.

Caregiver worries were addressed by talking with a staff member, providing insight into avenues for future modifications to the timing and content of updates. Updates may be better received if they can be provided more frequently and with more patient-specific content. This recommendation was specifically noted by caregivers in their suggestions for improvements. In line with this commentary are those suggestions made by caregivers participating in an intervention that provided intensive care unit patients' families with daily updates by SMS [31]. In 32.3% of participants, feedback regarding the updates was that they contained "sparse and not very concrete" information about their loved ones [31]. Patient information that is curated was described by Globus et al [49]. Parents of infants in neonatal intensive care—who undergo extremely stressful separations from their babies daily—received SMS updates once a day that included information that was both nonmedical (eg, location of crib) and medical (eg, babies' weight, procedures performed). As a result, parents reported feeling more at ease in approaching medical staff and more satisfied with regular information provision concerning their infant's medical status. Thus, without dehumanizing the patient-provider experience, SMS messages have the power to contribute to the continuum of care and empower caregivers with information.

Anxiety

Those who wait are heavily emotionally invested in the information they seek and report the wait as being a time of constant anxiety and exhausting vigilance, which is diminished slightly by human interaction and, then, the end of surgery [6,50]. Overall, caregiver anxiety was reduced to a large extent (score=8.2 out of 10) by receiving communication from the OR, suggesting that the messages were effective at reducing intraoperative stress. This was the second goal of the initiative. This effect was confirmed in the commentary that was freely provided in open-ended answers and was part of the reason a measure of anxiety was included after the pilot phase. The positive effect of reducing anxiety using SMS intraoperative updates has been demonstrated in a range of surgical specialties using controlled studies [33,34,36]; here, we confirmed their findings. It is important to address anxiety to reduce adverse outcomes seen in caregivers that persist postoperatively. These include fear of death of a loved one, frustration, anger, guilt, and other lasting psychological and physical disturbances [7,51-53].

Global Satisfaction

The reduction in anxiety seen in this project may have been an essential driver in the overall satisfaction scores of 90% (or 4.5 out of 5), as the 2 were highly correlated. This level of satisfaction is in line with Gordon et al [32], where 94.3% of caregivers responded they "enjoyed this software" in response to receiving 7 email or SMS customized intraoperative updates. Receiving mobile-based messages also offers caregivers the freedom to better plan their wait and may thus influence their overall experience. Prior to COVID-19-mandated off-site waiting, leaving the hospital was reported as a coping strategy used by parents of oncology patients who could not bear to sit in a waiting room during their child's surgery [7]. Instead, while waiting for news, they filled "unoccupied" time with "occupied" time [54] and fared better in terms of anxiety and distress, as reported by parents who stayed at the hospital.

Future Directions

Evidence from future controlled and qualitative studies may result in intraoperative text-based communication systems such as this one becoming a permanent adjunct to the standard of care. Aside from clinical applications, the platform may also serve as a skeleton upon which other perioperative communication interventions can extend their research capacity. For example, Farias et al [29] tested a perioperative communication and support system that delivered messages by SMS to parents of children undergoing tonsillectomy. Parents were contacted both before and after, but not during, the surgery. Interviews with parents revealed that even though the messages were automated, parents felt continuously supported and that they would have appreciated receiving more information and more messages. Adding the intraoperative period using a system such as the one installed at the CHUM may have been well received by the parents.

Limitations

This initiative had a few notable limitations. First, for caregivers who waited for surgeries that spanned many hours, receiving messages at strategic trajectory-related time points may not have satisfied the desire to know how the surgical procedure itself was evolving. Future iterations should include updates that are sent at a minimal interval in order to prevent delay-related anxiety and concern in those who are waiting. Second, caregivers were required to understand written French and own and be comfortable using a network-supported mobile phone capable of receiving text-based messages. However, a quarter of those approached opted not to use the SMS platform. It may have been that among those caregivers who declined, some were not able to communicate in French or at ease with digital technology. To attain *digital health equity* for patient health initiatives, designs should consider socioeconomic determinants of health [55]. For example, not all health care users have access to technology or the eHealth literacy needed to navigate digital tools. There were no demographic and socioeconomic data collected from caregivers that may have provided insight into how the technology was received and

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appreciated. Collecting this data in the future will allow for more nuanced analyses to identify predictors of acceptability, satisfaction, and anxiety reduction. Third, our response rate was 34% (n=2088), which is approximately 10% lower than average controlled studies with surgical patients and health care providers [56] and online surveys generally [57]. A higher response rate from a future study using the same platform will help inform the outcomes reported by this cohort [58]. Fourth, no control group was used, nor were health care providers or administrators included at this stage. Future assessments of this service would benefit from a control group as well as professionals to help assess degrees of effect and acceptability and to gather feedback for improvement. Future research planned by the team should include a 2-armed randomized prospective study to determine the impact of this innovation. Finally, errors in message delivery were reported by 69 (3.3%) of 2088 caregivers. Regulatory agencies require that hospitals maintain mechanisms to protect against accidental disclosure or loss of patient health information [59,60]. Thus, although the SMS messages did not reveal any personal information, careful staff training and system checks should be put in place to help eliminate instances of messages being sent at the wrong surgical time, to an incorrect number, or not at all.

Conclusions

Due to the increasing prevalence of smartphone ownership, text-based messaging has become an indispensable tool in patient and caregiver surgical care [26]. Here, we described an innovative SMS-based communication system to keep caregivers, family members, and friends up to date on the surgical trajectory of their loved ones. This initiative has informed best practices for hospital-wide implementation and has provided evidence-based data for a scaled-up version of SMS communication in a surgical setting in any hospital. Feasible and acceptable, SMS messages are likely to be a vital adjunct to in-person communication, as they have the potential to reduce the burden of health care professionals and increase efficiency. Importantly, they can also satisfy the tenets of PFCC and contribute to improved overall health care. In the context of COVID-19, adapting to technologically supported methods of safely sharing patient information will be paramount.

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Authors' Contributions

AM, É Maillet, É Matetsa, and SD were responsible for the conception, design, and data collection for this initiative. SR and ETN analyzed and interpreted the data. SR and ETN drafted the initial manuscript, while SD created the algorithm graphic. All authors made critical revisions to the intellectual content and gave their final approval of the version to be published.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Satisfaction survey: original French.
[PDF File (Adobe PDF File), 4320 KB - periop_v5i1e36208_app1.pdf]

Multimedia Appendix 2
Satisfaction survey: English translation.
[DOCX File , 20 KB - periop_v5i1e36208_app2.docx]

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Abbreviations

CHUM: Centre hospitalier de l'Université de Montréal
OR: operating room
PACU: postanesthesia care unit
PFCC: patient- and family-centered care
SMS: short messaging service

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Original Paper

The Impact of a Text Messaging Service (Tonsil-Text-To-Me) on Pediatric Perioperative Tonsillectomy Outcomes: Cohort Study With a Historical Control Group

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Abstract

Background: Tonsillectomy is a common pediatric surgical procedure performed in North America. Caregivers experience complex challenges in preparing for their child's surgery and coordinating care at home and, consequently, could benefit from access to educational resources. A previous feasibility study of *Tonsil-Text-To-Me,* an automated SMS text messaging service that sends 15 time-sensitive activity reminders, links to nutrition and hydration tips, pain management strategies, and guidance on monitoring for complications, showed promising results, with high levels of caregiver satisfaction and engagement.

Objective: This study aimed to pilot-test *Tonsil-Text-To-Me* in a real-world context to determine whether and how it might improve perioperative experiences and outcomes for caregivers and patients.

Methods: Caregivers of children aged 3 to 14 years undergoing tonsillectomy were included. Data from a historical control group and an intervention group with the same study parameters (eg, eligibility criteria and surgery team) were compared. Measures included the Parenting Self-Agency Measure, General Health Questionnaire-12, Parents' Postoperative Pain Measure, Client Satisfaction Questionnaire-8, and engagement analytics, as well as analgesic consumption, pain, child activity level, and health service use. Data were collected on the day before surgery, 3 days after surgery, and 14 days after surgery. Participants in the intervention group received texts starting 2 weeks before surgery up to the eighth day after surgery. Descriptive and inferential statistics were used.

Results: In total, 51 caregivers (n=32, 63% control; n=19, 37% intervention) who were predominately women (49/51, 96%), White (48/51, 94%), and employed (42/51, 82%) participated. Intervention group caregivers had a statistically significant positive difference in Parenting Self-Agency Measure scores (P=.001). The mean postoperative pain scores were higher for the control group (mean 10.0, SD 3.1) than for the intervention group (mean 8.5, SD 3.7), both of which were still above the 6/15 threshold for clinically significant pain; however, the difference was not statistically significant (t_{39}=1.446; P=.16). Other positive but nonsignificant trends for the intervention group compared with the control group were observed for the highest level of pain (t_{39}=0.882; P=.38), emergency department visits (χ^2_2=1.3; P=.52; Cramer V=0.19), and other measures. Engagement with

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resources linked in the texts was moderate, with all but 1 being clicked on for viewing at least once by 79% (15/19) of the participants. Participants rated the intervention as highly satisfactory across all 8 dimensions of the Client Satisfaction Questionnaire (mean 29.4, SD 3.2; out of a possible value of 32.0).

Conclusions: This cohort study with a historical control group found that *Tonsil-Text-To-Me* had a positive impact on caregivers' perioperative care experience. The small sample size and unclear impacts of COVID-19 on the study design should be considered when interpreting the results. Controlled trials with larger sample sizes for evaluating SMS text messaging interventions aimed to support caregivers of children undergoing tonsillectomy surgery are warranted.

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KEYWORDS

tonsillectomy; otorhinolaryngology; text messaging; caregivers; surgery; perioperative; patient discharge; aftercare; short messaging service; pain management; mobile phone

Introduction

Tonsillectomy is one of the most common pediatric surgical procedures performed in North America, comprising 16% of all ambulatory surgeries performed on the pediatric population [1]. As the surgery is frequently performed on an outpatient basis, most of the perioperative care is undertaken by caregivers at home [2]. Caregivers can become confused, anxious, or overwhelmed because of a lack of knowledge about how to prepare for their child's surgery; how to monitor for complications such as postoperative pain, nausea, or reduced oral intake; and how to administer appropriate pain medication [3,4]. These uncertainties can contribute to the 33% of caregivers who make unscheduled health care visits to the clinic or emergency department (ED) after surgery [5]. In a study evaluating >36,000 tonsillectomies with or without adenoidectomies, 7% of patients revisited the hospital, and 1% of patients revisited a second time. Acute pain accounted for 18% of the first revisits and 11% of the second revisits, whereas fever and vomiting or dehydration were the primary diagnoses in 28% and 18% of the revisits, respectively [6]. A large proportion of return visits to hospitals are treat-and-release visits that may have been avoided through more adequate symptom control at home [7].

Efforts to support families through this perioperative period typically include health care providers offering verbal instructions or sharing web-based and printed resources and pamphlets. Studies have shown that caregivers typically correctly recall only parts of the information explained to them at the clinic [8], and almost half of this information is remembered incorrectly [9,10]. With >90% of adults in North America owning internet-enabled devices, it is common for caregivers to use the internet to learn about their child's health issues or seek alternative treatment options [11,12]. However, the reliability, quality, and readability of the evidence found in these web-based resources, particularly for tonsillectomy, may be questionable or difficult to understand [13-15]. By following outdated or inaccurate information, caregivers risk making decisions that can negatively affect recovery, such as underdosing their child's postoperative analgesics [16]. Improving timely access to quality perioperative education might help to better prepare families and reduce these potential negative effects [17].

SMS text messages are convenient, cost-effective, asynchronous (ie, can be read by participants at times they prefer), and do not require labor-intensive face-to-face contact. SMS text messaging interventions have been shown to improve not only medical appointment adherence but also treatment compliance for a range of clinical contexts [18,19]. Leveraging clinical recommendations from our previous Delphi study [20] and results of the early feasibility study [21], our team developed an automated SMS text messaging service, *Tonsil-Text-To-Me* (TTTM), to provide just-in-time support to caregivers across the perioperative pathway. The results of the feasibility and usability study showed that caregivers viewed the TTTM system as an improvement over the standard model of information delivery with no safety or security concerns, and although the SMS text messages were fully automated, participants saw them as reinforcing a sense of support from their health care team.

The objectives of this study were to investigate whether TTTM was effective at decreasing caregivers' level of preoperative anxiety and distress, reducing postsurgery health care use, improving pain management, and having a positive impact on child outcomes (eg, hydration, level of activity, and pain-related behavior). We expected that caregivers receiving TTTM would report high satisfaction levels consistent with the feasibility study results.

Methods

Study Design

After receiving institutional review board approval, we conducted a prospective quasi-experimental pilot study to compare data from a historical usual care group (control) with a group receiving TTTM (intervention) in addition to usual care. Although not involving random allocation, the historical control group data offer a useful comparator for early pilot studies where researchers are interested in refining parameter estimates for larger controlled trials [21]. The original study plan aligned with criteria for when a historical control group would have less risk to validity (eg, precisely defined standard treatment, same participant eligibility for both groups, same methods of evaluation, and performed in the same organization) [22,23]. As this was an exploratory study with limited funding, we set a sample size goal based on guidelines [24] for 30 participants in each group. Data collection occurred at time point 1 (T1; the

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day before the surgery), time point 2 (T2; 3 days after surgery), and time point 3 (T3; 14 days after surgery).

Setting and Population

The study took place at a pediatric otolaryngology clinic within a teaching hospital in Nova Scotia, Canada (IWK Health Centre). More than 300 tonsillectomies were performed at this clinic in 2017, the year preceding this study. Surgeries were often scheduled 3 to 6 months after the consultation visit, resulting in a large time gap in which usual care instruction booklets could be misplaced or critical information forgotten. Caregivers of children aged 3 to 14 years who received a surgical referral at the IWK Health Centre for tonsillectomy with or without adenoidectomy were approached. Caregivers aged ≥18 years, with a cell phone, and who were able to understand the SMS text messages in English were eligible. We excluded families from the study if the child had complex medical needs beyond routine tonsillectomy surgical care; a peritonsillar abscess or suspicion of malignancy; nonelective indications; and complex chronic conditions, craniofacial abnormalities, diabetes, or a disorder in hemostasis. The inclusion criteria for the control and intervention groups were the same. Informed consent was obtained from all participants.

Intervention

The TTTM service sent 15 texts to caregivers over a 3-week period, including 8 before surgery, 1 on the day of surgery, and 6 during the week after surgery (Textbox 1). The automated service sent messages timed to the surgery date so that time-sensitive information (eg, what to bring to the hospital on the day of surgery) arrived at the right time (eg, the evening before surgery). The message content was based on evidence-based recommendations [15] and included reminders on when to start or stop activities, tips on pain management, and recommendations on when to follow up with a provider. To support active engagement with the content of the brief messages (122-135 characters), 8 texts also included a link to an external resource (eg, web-based tour of the day surgery unit, map of directions to the hospital, and a list of soft food). Of the 15 messages, 10 (67%) were set to be delivered in the morning, and 5 (33%) were set to be delivered in the evening.

Textbox 1. Tonsil Text-to-Me SMS text messaging and data collection schedule. ENT: ear, nose, and throat.

Before surgery

- 14 days before: Acknowledge sign-up, clinic contact number, and how to stop receiving texts
- 10 days before: Link to a coloring book story about day surgery for the child
- 7 days before: Information on stopping medication
- 6 days before: Link to the day surgery web-based tour video
- 4 days before: Link to the checklist for what to bring to the hospital
- 3 days before: Link to a list of soft food ideas
- 2 days before: Link to pain management tips, how to cancel surgery, and reminder that it is okay for the child to eat as usual that day
- 1 day before: Reminder on when to stop solid foods and link to parking instructions for hospital

Time point 1 data collection (day before surgery)

Day of surgery

- Link to checklist for what to bring to the hospital and tips on how to ask their child about their pain

After surgery

- 1 day after: Link to tips on encouraging food and fluid intake and clinic contact number
- 2 days after: Information on physical symptoms typical of peak pain period and guidance on resumption of physical activity
- 3 days after: Information on typical peak pain, pain occurrences, and tips on pain management

Time point 2 data collection (3 days after surgery)

- 5 days after: Information on when the child might return to school
- 7 days after: Information on resuming physical activities
- 8 days after: Provided information on the ENT Clinic helpline in case of continued pain and discomfort.

Time point 3 data collection (14 days after surgery)

Measures

Demographics

Several demographic measures were collected at baseline: age, gender, ethnicity, employment status, education level, current use of technology, and preferences for using technology in different health-related capacities.

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Caregiver Self-efficacy

Preoperative caregiver self-efficacy was measured at T1 using 3 problem-solving items from the Parenting Self-Agency Measure (PSAM) [25] (ie, "I feel sure of myself as a parent," "I can solve most problems between my child and me," and "when things are going badly between my child and me, I keep trying until things begin to change"). The PSAM is a self-report measure of general self-efficacy for parents of children aged 3 to 12 years. Respondents rated each of the 3 items using a 5-point Likert scale ranging from 1=never to 5=always. A total score between 3 and 15 was computed.

Caregiver Distress

Preoperative caregiver distress was measured at T1 using the well-validated short form of the General Health Questionnaire-12 (GHQ-12) [26]. The GHQ-12 covers several domains associated with a person's level of distress and is worded in such a way as to comprise 6 positive and 6 negative items. Response items are scored on a 4-point scale (ranging from 0 to 3), and a global score between 0 and 36 is calculated, with higher scores indicating higher levels of distress.

Child's Pain

At T2 and T3, caregivers were asked to report their child's average level of pain in the past 24 hours and the highest level of pain in the past 24 hours on a scale of 0 (no pain) to 10 (worst pain). The well-established 15-item Parents' Postoperative Pain Measure (PPPM) [27] was used to measure caregiver-reported pain-related behavior of their child at T2. A sum score was computed by tallying the number of *yes*=1 and *no*=0 responses for a total score of 15. As per guidelines, a score of 6/15 signified clinically significant pain [28].

Child's Activity

As a proxy measure of fluid intake, we asked caregivers at T2 to report "yes" or "no" as to whether their child had urinated at least twice in the previous 24-hour period. The child's activity level was measured at T2 and T3 by asking caregivers to report the level of physical activity on a 4-item scale (ie, bedridden, sluggish but walking, easily tired but active, or normal) during the past 24 hours.

Analgesic Therapy

Caregivers reported the number of doses per type of analgesic (eg, acetaminophen, ibuprofen, and morphine) administered within the past 24-hour period at T2 and T3.

Health Care Use

At T3, caregivers were asked to report on the number of postoperative ED visits; hospitalizations; family physician visits; calls to ear, nose, and throat (ENT) nurses or surgeons; acute or unplanned clinic visits; calls to 811 (local nonurgent health care advice line); and the number of antibiotic courses prescribed in relation to the tonsillectomy since surgery day.

Satisfaction and Intervention Engagement

Intervention group participants were asked to rate their satisfaction with the TTTM service at T3 using the Client Satisfaction Questionnaire [29], which is a unidimensional, 8-item measure used worldwide to assess client or patient satisfaction with health services. Responses are scored from 1 to 4, and thus, the possible total scores ranged from 8 to 32. Higher scores indicate greater satisfaction. Engagement with the TTTM messages was operationalized as the number of texts received, number of clicks on embedded links, and number of caregivers who opted out of the service by texting "STOP" before all texts were received. Aggregate engagement analytics were compiled at T3 through the SMS text messaging platform.

Recruitment and Enrollment

The original study plan was to begin recruitment for the intervention group immediately after data collection for the historical control group. However, institutional IT approval and the privacy process related to technical infrastructure caused significant delays, further compounded by the COVID-19 pandemic's impacts on clinical research [30].

Control group cohort data was collected over a 10-month period starting in 2017. A 4-month period was used for active recruitment, there was a 3- to 4-month wait for surgery, and the postsurgery follow-up period lasted for ≥2 weeks. Control group participants (ie, caregivers) were recruited through advertisements displayed at the clinic and through clinic nurses who introduced the study to caregivers. In addition, caregivers were able to self-enroll by visiting our web-based recruitment site and completing a 5-minute guided screening and web-based consent process. Once enrollment was confirmed, the research coordinator generated a study ID in REDCap (Research Electronic Data Capture; Vanderbilt University) [31], and an automated questionnaire schedule sent surveys to caregivers on the day before the surgery (T1), during the peak pain period on day 3 (T2), and 14 days after surgery (T3). REDCap also sent 2 reminder emails for surveys that were not completed.

Intervention group data collection ran from May 2021 to December 2021. Recruitment flow was adjusted for the intervention group to allow for flexibility in changing COVID-19 pandemic precautions and hospital restrictions; for example, as in-clinic recruitment was not possible, distance-delivered recruitment materials were developed. Potential participants were identified by screening the surgical wait-list for families whose surgery dates fell within the study timeline. A postcard with study details was mailed, and a follow-up phone call was made. After informed consent was confirmed, the research coordinator generated a study ID in REDCap, and an automated questionnaire schedule sent surveys to caregivers on the day before the surgery (T1), during the peak pain period on day 3 (T2), and 14 days after surgery (T3). A booking clerk entered the participant's information into the surgery booking interface, where they flagged the study participant to receive the texts. Using a secure file transfer protocol, we sent a daily report for those enrolled in the TTTM intervention to the SMS text messaging service vendor SimplyCast. SimplyCast's secure SMS text messaging service sent SMS text messages with periodic embedded links per the defined schedule to caregivers based on surgery data outlined in the SMS text message schedule (see the *Results* section).

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Statistical Analysis

We used SPSS software (IBM Corp) [32] and Jeffreys's Amazing Statistics Program [33] for data analysis. Standard descriptive statistics, including means, SDs, frequencies, and percentages, were used to summarize the continuous preoperative and postoperative measures as appropriate. Differences between the 2 groups were tested with paired-sample *t* tests (2-tailed) or chi-square tests where appropriate. Where assumptions of normal distribution and equality of variance were violated, Mann-Whitney *U* tests were used. Effect sizes were extracted (ie, Cohen *d*, Cramer V, odds ratios [ORs], and rank-biserial correlation) where applicable. All statistical tests were performed using 2-tailed tests at the 0.05 level of significance. Analysts were not blinded to group allocation.

Ethics Approval

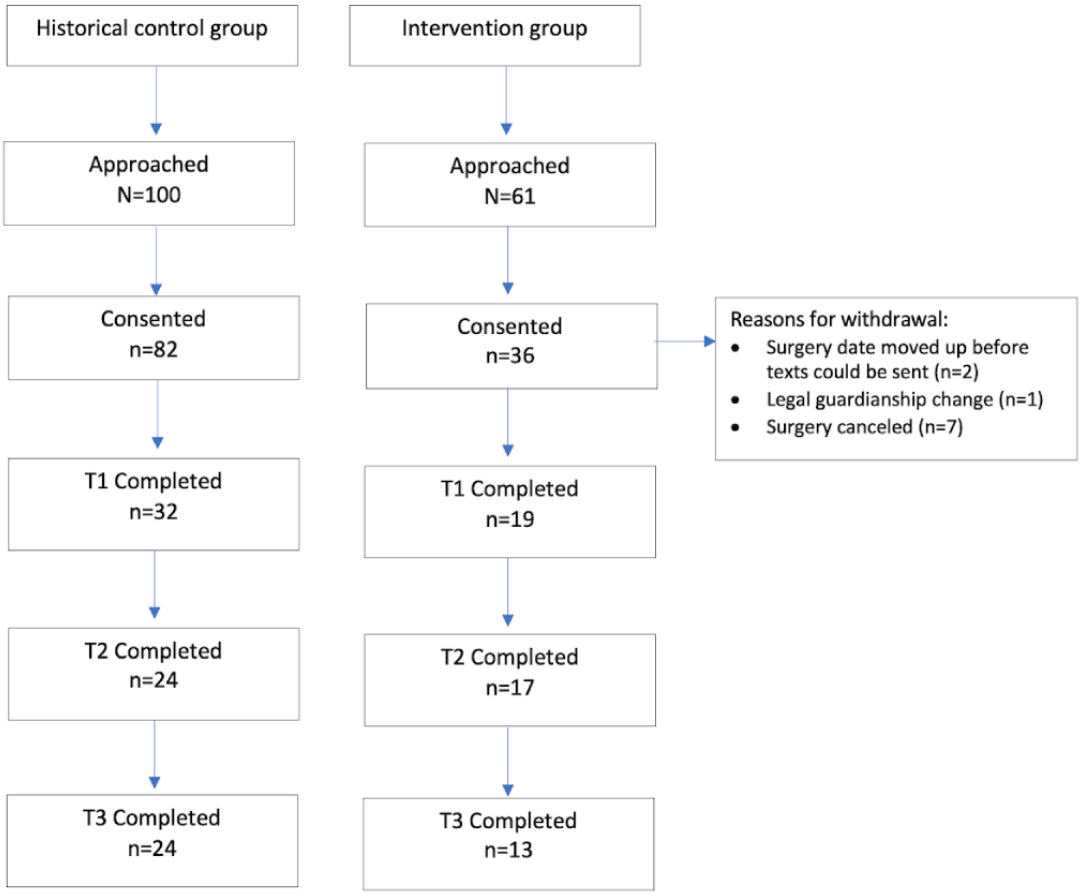
This study has been funded by an IWK Health Centre Translating Research Into Care grant and has been approved by the IWK Health Centre Research Ethics Board (1021845).

Results

Overview

An overview of recruitment and enrollment is presented in the Figure 1 flow diagram. A total of 100 caregivers were approached during control group data collection and 61 during intervention group data collection. Approximately 82% (82/100) consented to participate in the historical control group, and 59% (36/61) consented to participate in the intervention group. Approximately 28% (10/36) of intervention group participants withdrew before T1 data collection for reasons that included changed or canceled surgery dates and changes in legal guardianship status.

Figure 1. Flowchart of study participants in the historical control and intervention groups.



Demographics

An overview of baseline demographics is presented in Table 1. All but 1 participant were women caregivers. Most were White, employed with a university degree, and living in a household with ≥2 children. There were no significant group differences at baseline regarding the age of the caregiver (χ^2_3=3.3; *P*=.35), gender (χ^2_2=3.5; *P*=.17), education level (χ^2_3=5.8; *P*=.12), ethnicity (χ^2_2=1.9; *P*=.39), employment status (χ^2_2=3.0; *P*=.28), or number of children in the household (χ^2_2=1.0; *P*=.60).

Preferences for using SMS text messages for different health care service use contexts are reported in Table 2. Respondents in both groups reported high use of SMS text messaging in daily life, with 98% (50/51) reporting that they send SMS text messages at least once a day. When asked to rank the top 3 reasons for using their mobile phones, respondents in both control and intervention groups indicated that receiving and

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sending SMS text messages was the number 1 reason (32/32, 100%, and 19/19, 100%, respectively), followed by receiving and making phone calls (22/32, 69%, and 17/19, 90%, respectively). Being able to receive appointment reminders (49/51, 96%) and consult with health care professionals (36/51, 71%) were among the top ways that respondents wanted to use their mobile phones.

Table 1. Baseline demographic characteristics of caregivers (N=51).

Characteristics	Control group (n=32), n (%)	Intervention group (n=19), n (%)
Age (years)		
18 to 25	0 (0)	1 (5)
26 to 35	11 (34)	9 (47)
36 to 45	20 (63)	9 (47)
≥46	1 (3)	0 (0)
Gender		
Woman	32 (100)	17 (90)
Man	0 (0)	1 (5)
Other or prefer not to say	0 (0)	1 (5)
Ethnicity		
White	31 (97)	17 (90)
Middle Eastern	1 (3)	1 (5)
African Canadian, African American, or Caribbean	0 (0)	1 (5)
Highest educational level		
High school or less	3 (9)	4 (21)
College diploma	10 (31)	2 (10)
University degree	18 (56)	10 (53)
Other	1 (3)	3 (16)
Employment		
Unemployed	3 (9)	5 (26)
Employed	28 (87)	14 (74)
Prefer not to say	1 (3)	0 (0)
Number of children in the household		
1	7 (22)	5 (26)
2	18 (56)	8 (42)
≥3	7 (22)	6 (32)

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Table 2. Baseline technology use and preferences of caregivers (N=51).

Technology uses and preferences	Control group (n=32), n (%)	Intervention group (n=19), n (%)
Number of texts sent per week		
At least once a day	32 (100)	18 (95)
More than once a week but less than once a day	0 (0)	1 (5)
Less than once per week	0 (0)	0 (0)
Would you like to use your mobile phone for the following		
Receive appointment and vaccination reminders		
Yes	30 (94)	19 (100)
No	2 (6)	0 (0)
Consult with physicians and nurses		
Yes	23 (72)	13 (68)
No	9 (28)	6 (32)
Get help sticking with a medication regimen		
Yes	12 (37)	4 (21)
No	20 (63)	15 (79)
Receive test results		
Yes	23 (72)	13 (68)
No	9 (28)	6 (32)
Talk with a professional about health concerns		
Yes	16 (50)	9 (47)
No	16 (50)	10 (53)
Access emergency services		
Yes	20 (63)	7 (37)
No	12 (37)	12 (63)

Caregiver Self-efficacy and Distress

Out of a possible total score of 15, at T1, the mean scores on the 3 PSAM items were 12.5 (SD 1.1) for the control group and 13.7 (SD 1.1) for the intervention group. A Mann-Whitney *U* test indicated that the mean scores on parenting self-efficacy were significantly higher for the intervention group, with a small effect size (U=136.50; P=.002; r_{rb}=0.53, 95% CI –0.73 to –0.24). Overall, on the GHQ-12, both control (mean 2.53, SD 0.57) and intervention group (mean 2.42, SD 0.61) participants reported challenges in feeling "capable of making decisions" and in feeling that they were "playing a useful part in things" (Table 3). The effect size for mean differences on the GHQ-12 in this analysis was small (Cohen d=0.32, 95% CI –0.26 to 0.88), and the independent-sample t test indicated a nonsignificant difference (t_{49}=1.090; P=.28).

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Table 3. Caregivers' GHQ-12[a] scores at time point 1 (N=51).

GHQ-12 items (have you done the following)	Control group (n=32), mean (SD)[a]	Intervention group (n=19), mean (SD)[a]
Been able to concentrate on what you were doing	2.09 (0.86)	2.16 (0.83)
Lost much sleep over worry	1.16 (1.02)	1.84 (0.96)
Felt that you are playing a useful part in things	2.31 (0.69)	2.32 (0.67)
Felt capable of making decisions about things	2.53 (0.57)	2.42 (0.61)
Felt constantly under strain	1.37 (0.91)	1.32 (1.20)
Felt you could not overcome your difficulties	0.72 (0.77)	1.05 (1.08)
Been able to enjoy your normal day-to-day activities	2.16 (0.57)	2.16 (0.83)
Been able to face your problems	2.25 (0.62)	1.06 (0.80)
Been feeling unhappy or depressed	1.06 (0.80)	1.21 (1.08)
Been losing confidence in yourself	0.72 (0.73)	0.84 (1.02)
Been thinking of yourself as worthless	0.31 (0.54)	0.84 (1.02)
Been feeling reasonably happy	2.09 (0.69)	1.74 (0.93)
Overall score	18.78 (3.02)	20.37 (3.34)

[a]GHQ-12: General Health Questionnaire-12.

Child's Pain

At T2, on a scale of 0 (no pain) to 10 (worst pain), the control group reported a slightly lower average level of pain (mean 4.38, SD 1.76) than the intervention group (mean 4.65, SD 2.26). The mean score for the highest level of pain at T2 was 7.37 (SD 1.88) for the control group and slightly lower at 6.70 (SD 2.97) for the intervention group. Independent-sample *t* tests did not indicate a significant difference between the groups, and only small effects were observed on the average level of pain (t_{39}=–0.433; *P*=.67; Cohen *d*=0.14, 95% CI –0.76 to 0.49) and the highest level of pain (t_{39}=0.882; *P*=.38; Cohen *d*=0.28, 95% CI –0.34 to 0.90).

The most frequently reported pain-related change in behavior at T2 in the control group was eating less than usual (22/24, 92%). In the intervention group, the most common behavior change was wanting to be close to their caregiver more than usual (14/17, 82%) and eating less (14/17, 82%; Table 4). The least frequently reported pain-related change in behavior for the control group was acting more worried than usual (8/24, 33%), and for the intervention group, it was the child taking medication when they normally refuse (3/17, 18%). The mean PPPM score was higher for the control group (mean 10.0, SD 3.1) than for the intervention group (mean 8.5, SD 3.7), both of which were still above the 6/15 threshold for clinically significant pain. An independent-sample *t* test did not report a significant difference in PPPM scores (t_{39}=1.446; *P*=.16), although a small effect size was found (Cohen *d*=0.46, 95% CI –0.02 to 1.08).

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Table 4. Frequency of caregivers' endorsement of PPPM[a] items at time point 2 (N=41).

PPPM items (when your child was recovering from surgery, did she or he do the following?)	Control group (n=24), n (%)	Intervention group (n=17), n (%)
Whine or complain more than usual	17 (71)	10 (59)
Cry more easily than usual	15 (63)	9 (53)
Play less than usual	21 (88)	12 (71)
Not do the things she or he normally does	15 (63)	12 (71)
Act more worried than usual	8 (33)	6 (35)
Act more quiet than usual	17 (71)	11 (65)
Have less energy than usual	18 (75)	11 (65)
Refuse to eat	12 (50)	10 (59)
Eat less than usual	22 (92)	14 (82)
Hold the sore part of his or her body	13 (54)	7 (41)
Try not to bump the sore part of his or her body	15 (63)	6 (35)
Groan or moan more than usual	16 (67)	8 (47)
Look more flushed than usual	16 (67)	11 (65)
Want to be close to you more than usual	21 (88)	14 (82)
Take medication when she or he normally refuses	14 (58)	3 (18)

[a]PPPM: Parents' Postoperative Pain Measure.

Analgesic Therapy

Analgesic therapy was consistent across the groups. At T2, caregivers in both the control and intervention groups reported administering on average 3.75 (SD 0.61) and 3.59 (SD 1.73) doses of acetaminophen, respectively, and 3.46 (SD 1.06) and 3.59 (SD 1.73) doses of ibuprofen, respectively, within the previous 24 hours (range 0-8; Table 5). Across both groups at T3 (14 days after surgery), only one of the caregivers reported offering analgesics within the previous 24-hour period. Chi-square group difference tests on use or nonuse of medication did not indicate a significant association, although small effects were demonstrated at both T2 (χ^2_1=0.9; *P*=.32; OR 0.33, 95% CI 0.01-8.79) and T3 (χ^2_1=0.8; *P*=.36; OR 0.39, 95% CI 0.01-10.37).

Table 5. Average analgesic doses administered in the previous 24 hours (T2[a] and T3[b]; N=76).

Dosages	Control group	Intervention group
T2 (3 days after surgery)[c]		
Acetaminophen, mean (SD; range)	3.75 (0.61; 2-4)	3.59 (1.73; 0-8)
Ibuprofen, mean (SD; range)	3.46 (1.06; 0-4)	3.59 (1.73; 0-8)
Morphine, mean (SD; range)	1.12 (1.15; 0-4)	0.59 (1.06; 0-4)
T3 (14 days after surgery)[d]		
Acetaminophen, mean (SD; range)	0.05 (0.21; 0-1)	0 (0; 0)
Ibuprofen, mean (SD; range)	0.05 (0.21; 0-1)	0 (0; 0)
Morphine, mean (SD; range)	0 (0; 0)	0 (0; 0)

[a]T2: time point 2.

[b]T3: time point 3.

[c]Control group: n=24; intervention group: n=17.

[d]Control group: n=22; intervention group: n=13.

Child's Activity

In terms of fluid intake, all caregivers reported that their children had urinated at least twice in the past 24 hours. In addition, at T2, caregivers in the control group reported that 13% (3/24) of the children were at their normal level of activity in the past 24 hours compared with 24% (4/17) in the intervention group. A caregiver in each group reported that their child was bedridden. Most caregivers in the control group reported that their child was "easily tired but active" (16/24, 67%), whereas caregivers in the intervention group reported that their child was "sluggish

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but walking" (6/17, 35%) or "easily tired but active" (6/17, 35%). By T3, most (21/23, 91% control group; 13/13, 100% intervention group) of the caregivers reported that their children had returned to normal activity levels. We created a dichotomous variable of normal activity versus reduced activity (ie, easily tired, sluggish, or bedridden). The chi-square group difference for normal activity and reduced activity showed no significant differences at T2 (χ^2_1=0.8; *P*=.35; OR 2.15, 95% CI 0.41-11.20).

Health Service Use

Hospital admissions were reported by 13% (3/23) of the respondents in the control group and 8% (1/13) of those in the intervention group, with visits to the ED reported by 17% (4/23) and 8% (1/13), respectively. The number of calls to the ENT clinic, family physicians, or 811 (local health information phoneline) was higher in the control group (8/23, 35%) than in the intervention group (4/13, 31%). Antibiotic prescriptions were reported by 9% (2/23) of the caregivers in the control group and 15% (2/13) of the caregivers in the intervention group. However, chi-square and Cramer V tests showed no significant differences and only small associations for hospital admissions lasting for <24 hours (χ^2_1=0.01; *P*=.92; Cramer V=0.02), lasting for >24 hours (χ^2_1=0.6; *P*=.45; Cramer V=0.13), ED visits (χ^2_2=1.3; *P*=.52; Cramer V=0.19), visits to outpatient walk-in clinics (χ^2_1=1.2; *P*=.27; Cramer V=0.18), calls to the ENT clinic (χ^2_2=2.1; *P*=.35; Cramer V=0.24), or calls to 811 or family physician (χ^2_1=1.85; *P*=.17; Cramer V=0.23).

Satisfaction and Engagement

The results of the Client Satisfaction Questionnaire-8 showed high levels of satisfaction with TTTM across all 8 dimensions (Table 6). The mean total satisfaction score, out of a possible 32, was 29.4 (SD 3.6, range 24.0-32.0).

All caregivers engaged with the full TTTM intervention, and none texted "STOP" to cease the messages. Engagement with the linked resources within the texts was moderate, with 90% (9/10) of the embedded links within the texts being viewed at least once by 79% (15/19) of the participants. All participants (19/19, 100%) viewed the web-based tour video and both checklists of what to bring to the hospital. Approximately 79% (15/19) viewed the presurgery tips on nonpharmacological postsurgery pain management; however, only 58% (11/19) viewed the postsurgery link regarding how to ask their child about their level of pain (Table 7).

Table 6. Results of the CSQ-8[a] (N=13).

CSQ-8 dimensions	Values, mean[b] (SD)
Quality of service	3.62 (0.51)
Kind of service you wanted	3.69 (0.48)
The extent to which the program met your needs	3.69 (0.48)
Recommend the program to a friend	3.69 (0.48)
Satisfaction with the amount of help received	3.77 (0.44)
Services helped you to deal with problems	3.54 (0.52)
Overall satisfaction with the service	3.69 (0.48)
Return to the program for help	3.69 (0.48)

[a]CSQ-8: Client Satisfaction Questionnaire-8.

[b]Highest possible score=4.

Table 7. Participants' engagement with the linked resources within the SMS text messages.

Embedded links topic	Intervention group (n=19), n (%)
Coloring book	11 (58)
Web-based tour	19 (100)
Checklist	19 (100)
Soft food list	15 (79)
Postsurgery pain	15 (79)
Parking	13 (69)
Eating and drinking	9 (48)
Asking about pain	11 (58)

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Discussion

Principal Findings

In this study, a brief 15-message TTTM intervention that was delivered adjunct to usual care during the COVID-19 pandemic revealed high uptake and engagement. A positive, significant difference in preoperative caregiver self-efficacy was found, suggesting that SMS text messages may have helped caregivers to develop positive expectations regarding their ability to handle postoperative activities with their child. Furthermore, caregivers receiving the texts reported improvements over usual care related to the highest level of child's pain intensity, child's pain-related behavior, health care use, and child's return to normal activity levels, although statistical significance was not noted. These results are not unlike other SMS text messaging intervention studies that target the perioperative experiences of adults [34,35] and suggest that pediatric perioperative pathways are a rich area for further research. In the following sections, we detail the strengths and limitations of this study, as well as future lines of inquiry.

The study has several strengths. First, research on the use of technology to support perioperative education for pediatric tonsillectomy is nascent, despite being one of the most frequently performed pediatric surgeries. A systematic review [36] of phone- and internet-based pain and recovery support programs for pediatric tonsillectomy found only 4 relevant randomized controlled trials. Only 1 clinical trial of an SMS text messaging intervention for perioperative pediatric tonsillectomy has been published; it was conducted outside of North America [19] and had a high risk of bias [36]. Contributing our preliminary cohort study findings to this emerging academic literature can inform future trial designs for research teams facing similar pragmatic limitations and help to refine outcomes of interest to maximize translational research potential [37]. Second, TTTM is designed to support caregivers across the full perioperative period (ie, before, day of, and for 2 weeks after their child's surgery) and was assessed using multiple measures (eg, analgesic use, caregiver self-efficacy, child pain levels, and health service use). Among technology-based pediatric-related intervention studies, most have measured only child and system outcomes [38] or measured them at only 1 postoperative time point [39,40]. Our comprehensive findings suggest that patient-level (eg, child pain) and system-level (eg, hospital visits) outcomes should be complemented with an assessment of the quality-of-care measures that help us to understand caregiver experiences (eg, caregiver distress) and behaviors across the perioperative period. Given the volume of tonsillectomy surgeries performed each year in North America [1], even modest individual-level improvements in pain management or improved perceptions of self-efficacy for managing care at home derived from brief SMS text messages could have significant real-world benefits. Finally, as caregivers' role in pediatric perioperative care is vital [41], and they increasingly expect and prefer to receive information about surgical procedures through their smartphones [42], our study offers some of the earliest findings into how SMS text messaging as a modality might meet that need. Participants in our study, as well as other studies [43], report high satisfaction with health service–related SMS text messages, an even less intensive and complex technology than mobile apps. Caregivers actively engaged in learning about the skills and strategies offered through the texts. Given the large and potentially permanent migration to web-based supports and services during the COVID-19 pandemic, the need to support caregivers in using relevant technologies that can tailor what information they receive, when, and in what way may be even more pressing.

The early stage of research in this field presents numerous lines of future inquiry. Both groups in our study reported clinically significant levels of pain 3 days after surgery, and the embedded links to pain management strategies were engaged with the least. A better understanding of how SMS text messaging interventions might be optimized to improve adherence to best practice pain management strategies and promote the use of nonpharmacological pain management strategies could help to ensure that the most minimally invasive technology is used to produce optimal outcomes. Drawing from persuasive system design frameworks [44] and behavior change theories [45], there may be both content and functionality improvements that can be made to the intervention that might support improved pain management in particular. Second, monitoring and reporting on participant recruitment, satisfaction, feasibility, and outcome efficacy in demographically diverse populations will help to determine the utility and cultural relevance of these interventions. Our study, based in an east coast Canadian organization context, adds to the knowledge base but used a demographically homogenous sample. As concepts of pain, pain management [46], and caregiving [47] are deeply influenced by culture and ethnicity, it is critical, especially during this period of early evidence building, to expand our understanding of whether and how interventions such as TTTM should be tailored to be more culturally affirming [48].

Limitations

Several study limitations should be noted. Our ability to conduct more robust analyses was limited because of sampling. Unforeseen delays occurred because of IT infrastructure approvals, and the COVID-19 pandemic limited the time frame for completing research activities. The use of historical control group data is prone to type I errors [21]; however, baseline demographic equivalence, no significant changes to the surgery itself, and the postoperative recommendations for parents between group conditions likely limited potential impacts. Given differences observed in recruitment and follow-up rates, some consideration of the external validity of the research is warranted; for example, changes to clinic and research staff may have introduced selection bias, and different recruitment and consent pathways (ie, the historical control group had a web-based consent option, whereas, for the intervention group, it was phone based) may confound the findings in ways we did not measure. It would be important for future research to be powered sufficiently to detect group differences and trial TTTM as a stand-alone intervention, not just as an adjunct to usual care. Data derived from this pilot study can be used to calculate the sample size for a future randomized controlled trial. The extent to which pandemic-related environmental factors for families (eg, caregivers spending more time at home with their children and children's normal activities affected by public

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health restrictions) and health care organizations (eg, hospital visit requirements and physical distancing guidelines) affected the study results is unclear.

Conclusions

Preliminary results from this prospective cohort intervention study with a historical control group revealed that TTTM had a positive impact on caregivers' perioperative care experience. The results should be viewed with caution, given the unclear impacts of the COVID-19 pandemic on preoperative levels of caregiver distress, health service use, and typical caregiver-child interactions. Continued research into SMS text messaging interventions targeting pediatric perioperative experience is warranted, especially given caregivers' high satisfaction with TTTM and high rates of texting in their everyday lives.

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Conflicts of Interest

None declared.

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Abbreviations

ED: emergency department
ENT: ear, nose, and throat
GHQ-12: General Health Questionnaire-12
OR: odds ratio
PPPM: Parents' Postoperative Pain Measure
PSAM: Parenting Self-Agency Measure
REDCap: Research Electronic Data Capture
T1: time point 1
T2: time point 2
T3: time point 3
TTTM: *Tonsil-Text-To-Me*

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Original Paper

Identifying Risk Factors, Patient-Reported Experience and Outcome Measures, and Data Capture Tools for an Individualized Pain Prediction Tool in Pediatrics: Focus Group Study

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Abstract

Background: The perioperative period is a data-rich environment with potential for innovation through digital health tools and predictive analytics to optimize patients' health with targeted prehabilitation. Although some risk factors for postoperative pain following pediatric surgery are already known, the systematic use of preoperative information to guide personalized interventions is not yet widespread in clinical practice.

Objective: Our long-term goal is to reduce the incidence of persistent postsurgical pain (PPSP) and long-term opioid use in children by developing personalized pain risk prediction models that can guide clinicians and families to identify targeted prehabilitation strategies. To develop such a system, our first objective was to identify risk factors, outcomes, and relevant experience measures, as well as data collection tools, for a future data collection and risk modeling study.

Methods: This study used a patient-oriented research methodology, leveraging parental/caregiver and clinician expertise. We conducted virtual focus groups with participants recruited at a tertiary pediatric hospital; each session lasted approximately 1 hour and was composed of clinicians or family members (people with lived surgical experience and parents of children who had recently undergone a procedure requiring general anesthesia) or both. Data were analyzed thematically to identify potential risk factors for pain, as well as relevant patient-reported experience and outcome measures (PREMs and PROMs, respectively) that can be used to evaluate the progress of postoperative recovery at home. This guidance was combined with a targeted literature review to select tools to collect risk factor and outcome information for implementation in a future study.

Results: In total, 22 participants (n=12, 55%, clinicians and n=10, 45%, family members) attended 10 focus group sessions; participants included 12 (55%) of 22 persons identifying as female, and 12 (55%) were under 50 years of age. Thematic analysis identified 5 key domains: (1) demographic risk factors, including both child and family characteristics; (2) psychosocial risk factors, including anxiety, depression, and medical phobias; (3) clinical risk factors, including length of hospital stay, procedure type, medications, and pre-existing conditions; (4) PREMs, including patient and family satisfaction with care; and (5) PROMs, including nausea and vomiting, functional recovery, and return to normal activities of daily living. Participants further suggested

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desirable functional requirements, including use of standardized and validated tools, and longitudinal data collection, as well as delivery modes, including electronic, parent proxy, and self-reporting, that can be used to capture these metrics, both in the hospital and following discharge. Established PREM/PROM questionnaires, pain-catastrophizing scales (PCSs), and substance use questionnaires for adolescents were subsequently selected for our proposed data collection platform.

Conclusions: This study established 5 key data domains for identifying pain risk factors and evaluating postoperative recovery at home, as well as the functional requirements and delivery modes of selected tools with which to capture these metrics both in the hospital and after discharge. These tools have been implemented to generate data for the development of personalized pain risk prediction models.

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KEYWORDS

patient-oriented research; patient-reported outcome measures; patient-reported experience measures; risk prediction; pain; individualized risk; surgery; anesthesia; focus groups; thematic analysis; perioperative; participatory medicine; digital health tool; postsurgical pain; children; opioid use; virtual focus group; postoperative; pediatrics; risk prediction; health outcome

Introduction

Background

Persistent postsurgical pain (PPSP) is common in children [1] and is associated with detrimental consequences [2-4]. Although up to half of the variance in PPSP is attributable to genetic factors [5], modifiable factors have also been identified, such as psychosocial factors, such as anxiety, poor pain-coping mechanisms, and pain catastrophizing [1,6-8]. Although these risk factors are known, these findings have not yet been widely translated into algorithmic decision-making to guide personalized interventions, which could improve clinical outcomes, such as acute postoperative pain.

The perioperative period is a data-rich environment with potential for innovation through digital health tools and predictive analytics [9,10]. One such domain ripe for transformational change is the opportunity to use the preoperative period to optimize a patient's health by performing targeted prehabilitation, which is a process of improving the functional capability of a patient prior to surgery to withstand the surgical insult and facilitate a return to preoperative conditions. Prehabilitation programs for adults [11,12] focusing on healthy eating and nutritional supplementation [12,13], improving physical function and exercise capacity [12,14], providing psychosocial interventions [15,16], and presurgical opioid weaning [17] can reduce the length of hospital stay; postoperative complication rates, such as pneumonia or wound infection [18]; and postoperative pain [19]. In pediatrics, similar concepts are being introduced in children with muscular and neurologic disease undergoing surgery [20] and are being developed for use in children undergoing spinal surgery [21].

To help develop strategies to improve family-centered care, patient-reported outcome measures (PROMs) are being implemented as standardized and validated questionnaires to systematically quantify patient perceptions regarding their health status [22], such as pain/discomfort and mobility. Furthermore, patient-reported experience measures (PREMs) can be used to quantify patient opinions regarding their health care encounter [22]. PROMs and PREMs are fundamental to personalization of care and should be ideally suited to developing risk prediction models targeting family-relevant experiences and outcomes.

Objectives

Our long-term goal is to reduce the incidence of PPSP, and consequently chronic long-term postoperative opioid use, by developing personalized pain risk prediction models that can guide clinicians and families in identifying and selecting prehabilitation strategies to reduce acute postoperative pain. To develop such a system, our first steps were (1) to use patient-oriented research principles [23] and clinical expertise to identify risk factors for pediatric postoperative pain, as well as identify the PROMs and PREMs that are most meaningful in evaluating postoperative recovery, and (2) to select the appropriate tool(s) to capture these metrics both in the hospital and after discharge so that we can collect data for future pain risk modeling.

Methods

Study Design

We conducted a semistructured qualitative study through focus groups with parents of children who had previously undergone surgery, adults with lived pediatric surgical experience, and clinicians who work at BC Children's Hospital (BCCH) in Vancouver, BC, Canada.

Ethical Considerations

Approval was obtained from the University of British Columbia/Children's & Women's Health Centre of British Columbia Research Ethics Board (H21-00658; date of approval July 12, 2021; principal investigator: author MG).

Participant Recruitment and Eligibility

Allied health professionals at BC Children's Hospital were approached via departmental email distribution lists. To ensure our sample was representative and included a range of surgical procedures, parents were recruited in person in 2 surgical clinics within BC Children's Hospital (orthopedics and otorhinolaryngology), during their child's hospital visit, or in the anesthetic care unit (ACU), which provides perioperative care for children of all ages undergoing a variety of elective surgical procedures. Adults with previous childhood surgery were recruited via provincial research networks (Reach BC and the BC Children's Hospital patient experience office e-network). Informed consent was obtained by research staff in person or

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electronically using Research Electronic Data Capture (REDCap, Vanderbilt University) [24,25] hosted at the BC Children's Hospital Research Institute. Due to the small sample size and its consequent privacy concerns, parents and participants with pediatric lived experience will not be differentiated and will be collectively referred to as family members, as guided by the advice of our research ethics board.

As the focus groups were conducted virtually, participants without an internet connection and access to an electronic device were ineligible for recruitment. To encourage participation, participants were remunerated CA $25 (approximately US $18.35) per session for their expertise and time. Mixed panels of approximately 2-3 family members and 2-3 clinicians were targeted for each focus group.

Data Collection

A brief prestudy questionnaire was administered using REDCap to collect participants' demographic information. Two research team members with expertise in qualitative methods conducted 10 virtual focus groups between October 2021 and April 2022 using Zoom (Zoom Video Communications): one researcher facilitated each session (authors MDW or RS), while another took notes (author MDW or RS or Kim Correa [KC]). At the start of each focus group, a brief overview of our research program was provided, and we indicated that our objective was to identify (1) preoperative variables that may be associated with pain following surgery as well as PREMs and PROMs to collect postoperatively and (2) potential tools/instruments that could be implemented for data collection in the hospital and following discharge. Two sessions were conducted: The first was focused on objective 1; these participants were later contacted to return for a second session, in which we reviewed the major findings from the previous session and discussed objective 2.

In session 1, an open-ended discussion was structured around 4 themes: (i) *presurgical* variables that might be relevant to poor surgical outcomes; (ii) whether each of the identified presurgical variables related specifically to the patient, the parent/caregivers, or both; (iii) *postsurgical* PREMs and PROMs that represent a meaningful evaluation of the recovery process; and (iv) a discussion of additional relevant features of the perioperative and recovery periods.

In session 2, 3 themes were discussed: (i) potential instruments (if known) that could be used for data collection, (ii) potential functional requirements and delivery mode considerations for surveys to capture these data, and (iii) how to achieve effective implementation of these data collection tools both in the hospital and after discharge.

Each session lasted approximately 1 hour, was audio-recorded, and was digitally transcribed using the live transcription function in Zoom. Transcripts were verified by a member of the research team (KC) and participant names replaced by sequential identifiers.

Data Analysis

Focus group transcripts were analyzed using NVivo (QSR International), and results were summarized using thematic analysis [26]. Two research team members (MDW and KC) independently reviewed two transcripts and used inductive coding to organize the data by theme, subtheme, and participant type [27]. These researchers then compared interpretations and developed consistent codes, which were applied to the remaining 4 transcripts (deductive coding); the 2 researchers discussed additional themes that emerged, resolved any further discrepancies, and modified the coding framework iteratively to ensure that key concepts were not overlooked and that the coding framework remained consistent. Due to the qualitative nature of the study, we did not estimate a target sample size and instead applied a saturation criterion, which indicated that once similar comments and concerns were repeatedly discussed across focus groups, saturation had occurred, and participant recruitment could conclude.

Tool Selection for Future Data Capture

Following the focus group thematic analysis, the research team used a combination of these findings and targeted literature reviews to identify specific data capture tools and questionnaires that satisfied the key requirements arising from the focus group discussions. In brief, we searched the literature, using the terms given by our participants, as well as using related terms or synonyms, to identify tools that (1) most closely matched our participants' meaning, (2) were feasible to implement, and (3) had been validated in a similar population or setting. This selection was further guided by multiple team meetings to gain expert consensus among researchers, clinicians, and patient partners. Finally, tools for implementation in a future data collection and risk modeling study were proposed.

Results

Focus Group Participant Demographics

In total, 22 participants were included. Participant demographics were as follows: 12 (55%) clinicians (n=2, 17%, registered nurses, n=2, 17%, nurse practitioners, n=1, 8%, surgeon, and n=7, 42%, anesthesiologists) and 10 family members attended 10 focus group sessions: 2 (20%) of the 10 sessions included 2 participants per session, and the 8 (80%) remaining sessions included 3-4 participants per session; 4 (40%) of the 10 sessions were mixed groups (combining clinicians and family members). When approached in the clinic, 5 family members declined due to a lack of interest and 2 clinicians declined due to limited availability; 2 family members declined to participate following informed consent due to limited availability. Participants included 12 (55%) of 22 persons identifying as female, and 12 (55%) were under 50 years of age. Clinicians worked in surgery, anesthesiology, and pain management (n=8, 67%) and perioperative/perianesthesia nursing (n=4, 33%). Family member participants included 9 (90%) of 10 with either a certificate (university/nonuniversity) or a university degree and 1 (10%) with a high school diploma (or equivalent).

Key Domains for Data Capture

Comments from focus group participants were grouped into 5 domains, described in the following sections, with a list of quantifiable metrics summarized in Table 1.

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Table 1. Key metrics identified from focus groups with clinicians, allied health professionals, and family members to be used for future data collection.

Domain	Metrics to capture
Demographic risk factors	• Child factors: age, sex at birth, weight • Family factors: level of education, household income, ethnicity, primary language
Psychosocial risk factors	• Anxiety; (pain) catastrophizing, depression, medical phobia(s), obsessive compulsive disorder, posttraumatic stress disorder, coping strategies (stressful situations), support network availability
Clinical risk factors	• Type of surgery, number of previous surgeries, pre-existing conditions (eg, chronic pain and previous response to anesthetics), history of narcotic/analgesic use or abuse, administered medications (eg, multimodal pain management) during the perioperative period
PREMs[a]	• Coordination of care, access to care, clarity of discharge instructions, satisfaction with care
PROMs[b]	• Functional recovery: eating and drinking, nausea or vomiting, bowel movements and urination, mobility, return to school and play activities, length of hospital stay, prescribed medications at hospital discharge • Undesired postprocedural side effects: surgical site infection, bleeding, pain severity and duration, number of readmissions or seeking of urgent care

[a]PREM: patient-reported experience measure.

[b]PROM: patient-reported outcome measure.

Demographic Variables

Clinicians noted that adolescents tend to experience increased pain following surgery, whereas younger children recover more quickly; families largely agreed but also indicated that younger children are “a lot more nervous” about undergoing surgery (family member 1), whereas teenagers have “more control over the situation and decision-making power” (family member 2) to decrease potential anxiety. The child with an increased BMI may be “underdosed on pain medications” (clinician 1), and optimizing a “patient’s nutrition and fitness level” (clinician 2) may improve outcomes. Some clinicians recommended capturing socioeconomic aspects that may impact the child’s recovery (clinician 1) and indicated that language barriers may cause “difficulties for health care professionals to explain and set realistic expectations for families and prepare them for the postoperative period” (clinician 3).

Psychosocial Factors

Most clinicians and family members indicated that we should quantify both parent and patient anxiety. Increased anticipation of surgery-induced pain may lead to catastrophizing, where the parent has the potential to “excessively fuel the emotional state of the child” (family member 3). Children “can sense the anxiety and the changes in behavior of their parents,” which may increase postoperative complications when compared to children observing “parents that are calm and understanding” (clinician 3). Due to their association with anxiety, capturing information about depression, medical phobias (specifically needle phobia), obsessive compulsive disorder, and posttraumatic stress disorder was also suggested. Some family members and clinicians believed that patients who do not cope well with “stress or with new situations” (clinician 7) may struggle following surgery. Finally, families and clinicians indicated that assessing the availability for a family’s support network following discharge may also be imperative to ensuring optimal recovery.

Clinical Characteristics

Clinicians noted that the type of surgery is associated with varying levels of expected postoperative pain, depending on extent and location, with multiple surgeries potentially “leading to chronic pain syndromes” (clinician 5), which may increase pain following surgery. The patients’ pre-existing conditions, including chronic or prolonged pain following a previous surgery, or an atypical response to anesthetics or a history of opioid analgesic use or substance abuse “may [also] affect the amount of analgesia that is required to achieve [optimal] pain control” (clinician 6). Clinicians further indicated that the class and dose of medications administered during the perioperative period, as well as any multimodal pain management, will be imperative to capture due to their beneficial effect in managing intra- and postoperative pain. Finally, clinicians suggested that we quantify the planned length of hospital stay as a surrogate for medical complexity, as well as unplanned readmission(s) or seeking urgent care.

Patient-Reported Experience Measures

Some family members indicated that poor coordination of postoperative care results in “a distinct contrast in the experiences of people who are [connected with] primary care for follow-up compared to those who are not” (family member 3). Several participants suggested that a negative experience with health care can create stress and adversely impact both recovery and the attitudes toward subsequent medical procedures. Furthermore, although care may be easily acquired within the hospital, access becomes more difficult once discharged back into the family’s community. Family members further indicated that discharge instructions are meant to educate and set realistic expectations, but worried that ambiguity could produce “a lack of confidence” (family member 4) and may compromise effective pain management.

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Patient-Reported Outcome Measures

Clinicians and family members primarily indicated the importance of returning to normal physical function, such as capturing whether patients are eating and drinking, vomiting or feeling nauseated, having "normal" bowel movements and urination, or experiencing undesired procedural side effects, such as surgical site infection(s) or postoperative bleeding. In addition, family members believed it would be imperative to ask questions such as "Are you playing?" (family member 4), "Are you able to go to school?" (family member 4), and "Are you capable of managing stairs?" (family member 1), which represent common activities of daily living and functional recovery for children and adolescents. Finally, participants believed that we should continually capture "the severity, duration, and trajectory of postoperative pain" with "developmentally appropriate [pain scales]" (clinician 4).

Requirements and Modes for Data Capture Tools

The second iteration of focus groups identified key functional requirements and delivery modes considerations for future data capture tools and questionnaires (Table 2).

Table 2. Key functional requirements and delivery modes for data collection tools, identified from the second iteration of focus groups with clinicians and family members.

Domain	Considerations
Functional requirements	• Using primarily standardized and validated scale-based tools, including Likert scales and multiple-choice questions • Sparingly using open-ended questions (to ensure the patient's voice is heard) • Collecting repeated measurements (eg, postoperative days 1, 2, 3, 7) • Ensuring brief survey completion times (no longer than 15 minutes) • Using binary questions and branching logic to create dynamic surveys asking only relevant questions • Providing save (and resume) functionalities • Enabling notifications and reminders • Having an opt-out option
Delivery modes	• Primarily electronic • Providing an alternate paper-and-pencil or telephone option • Having both parent proxy and self-report versions
Compensation requirement	• Remunerating participants for their time, expertise, and lived experience

Functional Requirements

Clinicians and family members indicated that standardized and validated scale-based tools should be implemented to streamline administration of multiple surveys and optimize comparability across studies and hospitals. Participants further indicated that surveys should be "quick and easy," increase "accessibility," and ensure "a representative sample" (clinician 9), for example, Likert scales and multiple-choice questions. Open-ended questions should be used sparingly but should be included to ensure patients "have their voice heard" (family member 6). Clinicians and family members further suggested repeating surveys, such as postoperative days 1, 2, 3, and 7, which should take less than 10-15 minutes each and should stop at 3 months, as survey fatigue/attrition may be a potential barrier. Binary "yes/no" questions and branching logic could substantially reduce survey completion times with future questions, depending on choices made by participants. Some family members and clinicians indicated that the survey should be savable (and resumable) and include notifications to ensure survey completion. Family members also suggested that having an opt-out feature would allow participants an opportunity to stop participating at any time. Finally, participants indicated that patients should receive monetary incentives to encourage survey completion and reward participants for their time.

Delivery Modes

Most participants believed that we should "collect information as seamlessly as possible" (family member 5), principally via electronic survey administration. However, both family members and clinicians also indicated that we should "provide multiple options" (clinician 9) so families can choose their preferred format, whether paper and pencil, electronic, or a telephone call, to go through the survey with a research team member and ask clarification questions. Some participants indicated that parent proxy surveys should be used to assess children under 13 years of age, whereas adolescents could self-report questionnaires with parental/guardian consent. Parents largely agreed and further indicated that self-report measures would be valuable to assist in understanding the child's perspective as "they're not always forthcoming to their parents" (family member 5).

Design of a Perioperative Data Collection Platform

Based on the proposed key metrics, the functional requirements, and delivery modes identified by participants, as well as a brief literature review, we designed a perioperative data collection platform to gather preoperative risk factors, intraoperative and in-patient data for hospitalized patients, and postoperative PREMs/PROMs (Figure 1).

PROMs will be collected using the Patient-Reported Outcomes Measurement Information System (PROMIS) [28] due the extensive library of standardized, validated, and Likert scale–based questionnaires, brief administration times, and the ability to evaluate and monitor multiple patient-oriented domains in parallel via repeated application (on postoperative days 1, 2, 3, 7, 15, 30, and 90). This will also allow for multiple data capture methods (electronic, telephone, or paper and pencil) as well as different modes of administration, such as self-reporting (patient age>12 years) and parent proxy (patient age≤12 years).

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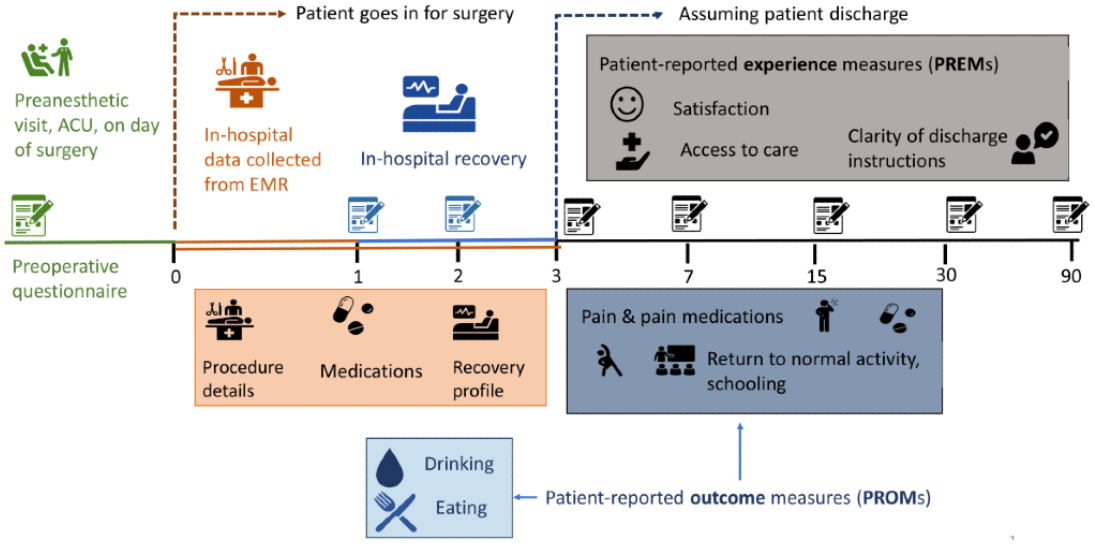
Figure 1. Proposed perioperative data collection timeline. ACU: anesthetic care unit; EMR: electronic medical record.



Tools for Data Capture

To decrease potential redundancy, patient factors, such as age and sex at birth, will be extracted from electronic medical records (EMRs), whereas family factors, such as household income and ethnicity, are appropriate for self-reporting. PROMIS anxiety, depression, and social relationship tools will capture patients' preoperative psychosocial data; parental pain catastrophizing will be captured using the pain-catastrophizing scale (PCS) [29] or its child version (PCS-C) [30] for adolescent self-reporting. The Car, Relax, Alone, Forget, Friends, Trouble (CRAFFT) [31] questionnaire will be used to *optionally* self-report the adolescents' history with substance abuse. The in-hospital data, including the type of surgery, length of hospital stay, and administered medications, can be collected from the EMRs, whereas pain intensity, pain interference, and physical function need to be captured via PROMIS tools as they continue to be collected past hospital discharge. Additionally, PREMs will be captured via parent proxy on postoperative days 15, 30, and 90 based on the pediatric care transitions measure [32], whereas PROMs will be gathered on postoperative days 1, 2, 3, 7, 15, 30, and 90 using PROMIS [28] tools. Finally, in-hospital outcomes, including nausea, vomiting, and pain, will be transcribed from EMRs and subsequently captured via parent proxy reporting following discharge.

Discussion

Principal Findings

Using the preoperative period to optimize patients' health by performing targeted prehabilitation is an opportunity to improve patient outcomes; specifically, digital health innovations might transform how perioperative care can be delivered in a personalized and family-centered way. Thematic analysis of focus groups identified 5 key domains for data capture to be used in risk modeling and to capture family-meaningful variables for pediatric postoperative recovery: (1) demographics, including age, sex, and weight; (2) psychosocial factors, including anxiety, depression, and medical phobias; (3) clinical characteristics, including pre-existing conditions, procedure type, and length of hospital stay; (4) PREMs, including patient and family satisfaction with care; and (5) PROMs, including nausea and vomiting, functional recovery, and return to normal activities of daily living. Participants further identified functional requirements, including the use of standardized and validated instruments, and repeated measures, to guide the selection of appropriate tools to capture these metrics, both in the hospital and following discharge, as well as specifying that data collection should be primarily electronic, with a paper-and-pencil option. The combination of well-established PREM/PROM questionnaires, PCSs, and substance use questionnaires for adolescents embodied these functional requirements in our proposed data collection platform.

Comparison With Prior Work

Studies have demonstrated that pediatric patients frequently develop PPSP, which may include patterns of persistent opioid use following surgery [1,4,33,34]. A wide range of risk factors have been identified, including some that may be amenable to preoperative [4,35-39] or perioperative [33] mitigation; these are broadly in line with the findings of this study and include pre-existing chronic pain and presurgical pain intensity, pain coping, child anxiety, preoperative opioid/substance use, depression, and poor sleep quality. There is, in the pediatric domain, also significant evidence that parental anxiety can impact a child's postoperative pain experience [40,41]. Although these risk factors can be modeled [42-44], a recent systematic review and meta-analysis indicated that there are few pediatric studies that have been conducted to model presurgical risk factors associated with PPSP [1]. Interestingly, preoperative demographic factors, including age, sex, and the BMI were not associated with PPSP, and preoperative pain intensity had only an inconsistent association [1]. In contrast, preoperative psychosocial factors were consistently associated with PPSP, including child anxiety, decreased efficacy of pain coping, and parental pain catastrophizing [1], which further highlights the importance of including these factors in predictive PPSP models.

Due to PPSP risk factors being well understood in adults, personalized predictive analytic frameworks and decision support tools have been developed and implemented in the adult perioperative domain [45-49]. Despite the potential value and

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benefits of listening to families when co-developing an eHealth tool, such as determining end-user preferences for content and feature considerations to effectively support patient self-management [50] and obtaining parents' feedback to efficiently design clinical trials in young children [51], patient-oriented research principles and methods [52,53] are rarely used to guide data collection platform development and results in PREMs and PROMs are not commonly included in predictive algorithms [45-49]. As our hospital has established that parents are keen to play a role in research across the pediatric care spectrum [54], conducting patient-oriented research [23] is paramount to addressing this substantial opportunity for improvement.

The Personalized Risk Evaluation and Decision Making in Preoperative Clinical Assessment app is 1 of the few platforms that involved patient partners with lived surgical experience in the initial development [55]. Although the study collected some PREM and PROM data, including satisfaction, length of hospital stay, and anxiety, these metrics were not used to predict long-term outcomes following discharge [55]. Furthermore, the failure to include comprehensive family-relevant long-term outcomes in national registries, such as the National Surgical Quality Improvement Program [56], results in risk prediction models derived from these data sets potentially lacking long-term patient-oriented outcomes. Our findings highlight the feasibility of including patient-oriented research principles, as well as PREMs and PROMs, in predictive modeling in an effort to improve long-term outcomes following surgery.

Limitations

First, our sample comprised a relatively small cohort of clinicians and family members, and only a small subset of our group provided specific feedback on our data collection instruments, both of which may limit the transferability (or generalizability) of our findings. Although our cohort did comprise a diverse cohort of health care team members and parents of children from multiple clinics in our hospital, and we extended their contributions with further review of the literature, broader engagement with patient representation organizations might be desirable in future work. Additionally, our findings may be biased due to the research team being affiliated with the same organization (BC Children's Hospital) where the patients and family members are being recruited and receiving care, instead of being recruited using a multi-institutional approach. Second, it would be ideal to add children and adolescents to future sessions and to potentially develop young persons' advisory groups [57] to ensure that risk factors, PREMs, and PROMs represent pediatric patient needs. Third, our focus groups comprised only English-speaking participants, which may also have limited transferability; language interpretation services and closed captioning were offered during recruitment, but the primary language may still have represented an obstacle to accessibility. Finally, capturing nonverbal data, such as kinetics, facial expressions, proxemics, and paralinguistics, was beyond the scope of this study but should be considered in future work, particularly if analyzing clinical, patient, or family requirements directly in a health care setting, or during evaluation of proposed solutions.

Conclusion

Our study identified key domains in which to capture data for targeting postoperative pain risk factors, such as demographics, psychosocial factors, clinical characteristics, and family-relevant outcomes during the recovery period, such as PREMs and PROMs. Clinician and family participants indicated functional requirements and preferred delivery modes; combined with a targeted literature review, these requirements allowed us to find tools with which to capture the identified metrics both in the hospital and after discharge. These tools will be implemented to generate data to inform the development of personalized pain risk stratification models.

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The data sets generated and analyzed during the study are not publicly available due to privacy and ethical requirements, but aggregated data may be made available from the corresponding author on reasonable request; individual transcripts will not be available as per guidance by our research ethics board.

The contributors associated with Pediatric Pain Prediction Collaboration are as follows: Kathleen Duddy, British Columbia Children's Hospital, Vancouver, BC, Canada; Jennifer C Park, British Columbia Children's Hospital, Vancouver, BC, Canada; and Michelle Groberman, British Columbia Children's Hospital.

Authors' Contributions

MDW participated in study design, data collection, qualitative analysis, and drafting and editing of the manuscript. NCW, RSS, KCL, LP, JR, PP, NC, EPC, and MG participated in study design, drafting, and critical revision of the manuscript.

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Conflicts of Interest

This study was supported, in part, by a University of British Columbia (UBC) Canada's Digital Technology Supercluster expansion research grant. MG holds a Michael Smith Health Research BC scholar award; MDW and RS hold Mitacs Elevate postdoctoral fellowships.

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Abbreviations

EMR: electronic medical record
PCS: pain-catastrophizing scale
PPSP: persistent postsurgical pain
PREM: patient-reported experience measure
PROM: patient-reported outcome measure
PROMIS: Patient-Reported Outcomes Measurement Information System
REDCap: Research Electronic Data Capture

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Original Paper

Assessing the Different Levels of Virtual Reality That Influence Anxiety, Behavior, and Oral Health Status in Preschool Children: Randomized Controlled Clinical Trial

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Abstract

Background: Compared with a traditional behavior management strategy and oral health training, virtual reality (VR) integrated with multisensory feedback possesses potential advantages in dentistry.

Objective: This study aimed to assess the impact of different levels of VR on anxiety, behavior, and oral health status.

Methods: This study was carried out in the Department of Pediatric Dentistry at the Tabriz University of Medical Sciences from December 2020 to June 2021. We randomly assigned 60 healthy children aged 4 years to 6 years to 4 groups, each consisting of 15 children. The study consisted of 2 consecutive sessions. During the first visit, the plaque index was calculated, and oral health education was carried out in all groups using Immersive VR (group I), Semi-immersive VR (group II), Nonimmersive VR (group III), and tell-show-do (TSD; group IV). In the second session, an amalgam restoration was performed in all groups. Participants' anxiety and behavior were recorded using the face version of the Modified Child Dental Anxiety Scale (MCDAS[f]) and Frankl scale. The plaque index was recorded in 2 follow-up sessions.

Results: The greatest prevalence of positive behavior (P=.004) and the lowest anxiety (P<.001) were recorded in group I, followed by group II, group III, and group IV. The plaque index scores showed a reduced trend between the first session and follow-up sessions (P<.001), but the values did not differ significantly between the 4 groups during the 3 sessions (P=.28, P=.54, P=.18).

Conclusions: The most positive behavior was observed in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups. Moreover, oral health education using VR resources can improve oral health status in children.

Trial Registration: Iranian Registry of Clinical Trials 20210103049926N1; https://www.irct.ir/trial/53475

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KEYWORDS

virtual reality; anxiety; behavior; oral health training

Introduction

Virtual reality (VR) is defined as a highly interactive, computer-based multimedia environment in which the user is involved in a computer-generated world [1]. A real or imagined environment can be delivered visually in the 3 dimensions of width, height, and depth, which could additionally provide an interactive experience visually in full real-time motion with sound and possibly with tactile and other forms of feedback [2]. The different types of VR systems that use various technology perform different functions.

Nonimmersive VR systems are the least implemented VR techniques. They involve implementing VR on a desktop computer. Using the desktop system, the virtual environment

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is observed through a portal by utilizing a standard monitor [3]. A semi-immersive VR system is comprised of a relatively high-performance graphics computing system along with a large screen monitor or multiple television projection systems that increase the depth of immersion [2]. An immersive VR system is the most direct experience of virtual environments in which the user wears a head-mounted display (HMD) to view the virtual environment. An HMD uses small monitors placed in front of each eye that provide stereo, bi-ocular or monocular images [2]. This type of VR system covers the audio and visual perception, cuts out all outside information, and therefore provides a fully immersive visual experience for the observer [4].

From a technological perspective, VR is a set of the following technologies: a helmet, trackers, and a 3D visualizing system. However, from a psychological point of view, VR is simultaneously a simulative technology, a cognitive technology, and an embodied technology. VR is a kind of reality simulation. Specifically, what distinguishes VR from other media is the sense of presence and immersion: the sense of “being there” inside the virtual environment produced by the technology. The simulative power of VR makes it a great tool for experiential learning. On the one hand, VR allows patients to learn through reflection on doing. On the other hand, VR can be described as an advanced imaginative system or an experiential form of imagery that is as effective as reality at inducing emotional responses [5].

A review of the literature revealed evidence of the usefulness of VR technologies for different medical procedures including traumatic injuries, injection or blood sampling, burn care, physiotherapy, and chemotherapy [6-9].

Numerous investigations have extensively addressed the use of immersive VR in dental settings to reduce anxiety and pain during the procedure [10-12]. Use of VR offers a theory-driven approach to educate and train health care providers. The application of a VR technique relies on psychological elements in pain perception. The redirection of attention away from the noxious stimulus, that is distraction, and sensory focusing reduce the severity of the physical injury [13].Moreover, it has been shown that VR engages the patient’s conscious attention and thereby, results in less pain perception [14]. Therefore, redirection of attention modifies internal thoughts by diverting from the real, external environment through immersion in a virtual world by introducing a pleasant experience while engaging higher cognitive and emotional centers of the nervous system.

In addition, current evidence shows that the oral health competency and practice of preschool children were less than adequate [15]. Oral hygiene instructions using educational lectures significantly improve oral health status [16]. However, current evidence suggests that the development of verbal command comprehension skills in preschool children continues for several years, which could explain the difficulty found in the training and practice of oral hygiene techniques using only verbal instructions in this age range [17]. As a result, play-based and audiovisual oral health education has been developed to modify behavioral change and promote tooth brushing skills in children [15].

To the best of our knowledge, there has been no study investigating the impact of different delivery systems of VR on anxiety level, behavior, and oral health education. Therefore, considering the promising profile reported in the literature on the potential impact of VR in children, this study aimed to assess the effect of different levels of VR including nonimmersive VR, semi-immersive VR, and immersive VR in comparison with a conventional behavior management and training strategy on behavior, anxiety, and oral health status of children aged 4 years to 6 years.

Methods

Ethical Review

This clinical trial was reported based on the CONSORT (Consolidated Standards of Reporting Trials) statement [18]. Ethical approval for the study was obtained from the Research Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1400.292).

Recruitment

This study was carried out and funded by the Department of Pediatric Dentistry, Tabriz University of Medical Sciences. The participants consisted of 60 healthy children between 4 years and 6 years of age who attended the Department of Pediatric Dentistry for routine dental treatment from December 2020 to June 2021.

Sample Size

In the study by Niharika et al [19], which showed a significant decrease in pain perception and state anxiety scores with the use of VR eyeglasses during dental treatment in children aged between 4 years and 8 years, the mean anxiety scores in the intervention and control groups were 14.72 (SD 3.57) and 19.56 (SD 3.74), respectively. Considering an α of .05 and power of 80%, a minimum sample size of 44 was determined. Assuming a dropout rate of about 25%, the minimum calculated sample size was at least 60 patients (15 in each group) to increase the validity of the study.

Eligibility Criteria

At the first attendance, the Screen for Child Anxiety Related Disorders (SCARED) questionnaire was used to identify patients with anxiety disorders. A total of 60 healthy children aged 4 years to 6 years with nonanxiety disorder was included in the study. Other inclusion criteria were children with no history of invasive medical and dental treatment and the presence of at least one carious mandibular primary molar requiring amalgam restoration.

Randomization and Blinding

Participants were randomly assigned to 4 groups using the RandList software (DatInf GmbH, Tübingen, Germany). Unique blind codes were used to identify the interventions to blind the outcome assessors and data statisticians.

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Clinical Procedure

Before starting the clinical procedure, written consent was obtained from the parents or legal guardians of the children. All dental procedures in all groups were carried out by a final-year postgraduate pediatric dentistry student. The study consisted of 2 consecutive treatment sessions and 2 follow-up sessions. In the first session, the instruments were introduced to the child using the conventional behavioral control technique (tell-show-do [TSD]) to efficiently establish the child's communication level. The plaque index was calculated using plaque disclosing tablets and recorded as the child's initial oral health status. Then, oral hygiene instructions were given in all groups. Oral hygiene instructions were provided using an HMD (Immersive VR group; i-glasses 920HR, Ilixco Inc, Menlo Park, CA) in group I, a large television (Semi-immersive VR group; webOS TV, LH590V, LG, Seoul, South Korea) in group II, a tablet (Nonimmersive VR group; Galaxy Tab A7 Lite, Samsung, Seoul, South Korea) in group III, and TSD in group IV. The oral hygiene instructions were provided using VR glasses, on which oral hygiene instructions were demonstrated. The VR used in this study was a passive environment where users were able to visualize in a virtual environment (static not dynamic) with which children could not interact. In the 3 VR groups, the same animation presenting the brushing technique was displayed to the corresponding groups, while moulage scenario training using TSD was used in group IV. A horizontal scrub brushing technique was taught to the children and their parents. Participants were required to brush their teeth twice a day, in the morning and at night before going to bed, for 2 minutes with their parent's supervision. New sets of toothpaste (Colgate Minions, 0.24% sodium fluoride) and toothbrush (Colgate Kids Toothbrush) were delivered to each parent/child pair. In addition, the parents were instructed to use a "pea-sized" amount of the toothpaste.

In the second session, which took place 1 week after the first session, dental treatment was performed in all 4 groups in addition to the oral hygiene instructions via immersive VR (HMD), semi-immersive VR (large television), nonimmersive VR (tablet), or TSD. In this session, the VR device was introduced to the participants in the VR groups before treatment, and once the VR device was placed on the child's eyes, the cartoon was started. Then, a topical anesthetic agent was placed on the injection site using a piece of cotton roll, and an inferior alveolar block injection was administered, followed by a class I or II amalgam restoration. Participants in the TSD group received similar procedures without the use of VR distraction.

During the second session, an episode of the Tom and Jerry cartoon was displayed for all 3 VR groups. The participants' anxiety was measured using the face version of the Modified Child Dental Anxiety Scale (MCDAS[f]), and overall behavior was recorded using the Frankl classification scale. Oral health status was re-examined in 2 follow-up sessions (1 month apart) using the plaque index.

Instruments

SCARED Questionnaire

The parent version of the SCARED questionnaire was designed to assess anxiety symptoms in children under 8 years of age. In this questionnaire, a total score higher than 25 indicated childhood anxiety disorders and therefore were excluded from the present study [20].

Face Version of the MCDAS(f) Questionnaire

This questionnaire is used to evaluate state anxiety in children during conventional dental procedures. This self-report scale consists of 8 questions with 5 pictorial answers for each question. Scores on the MCDAS(f) scale range from 8 to 40, with scores below 19 indicating no state anxiety, scores above 19 indicating state anxiety, and scores above 31 signifying severe phobic disorder (Figure 1) [21].

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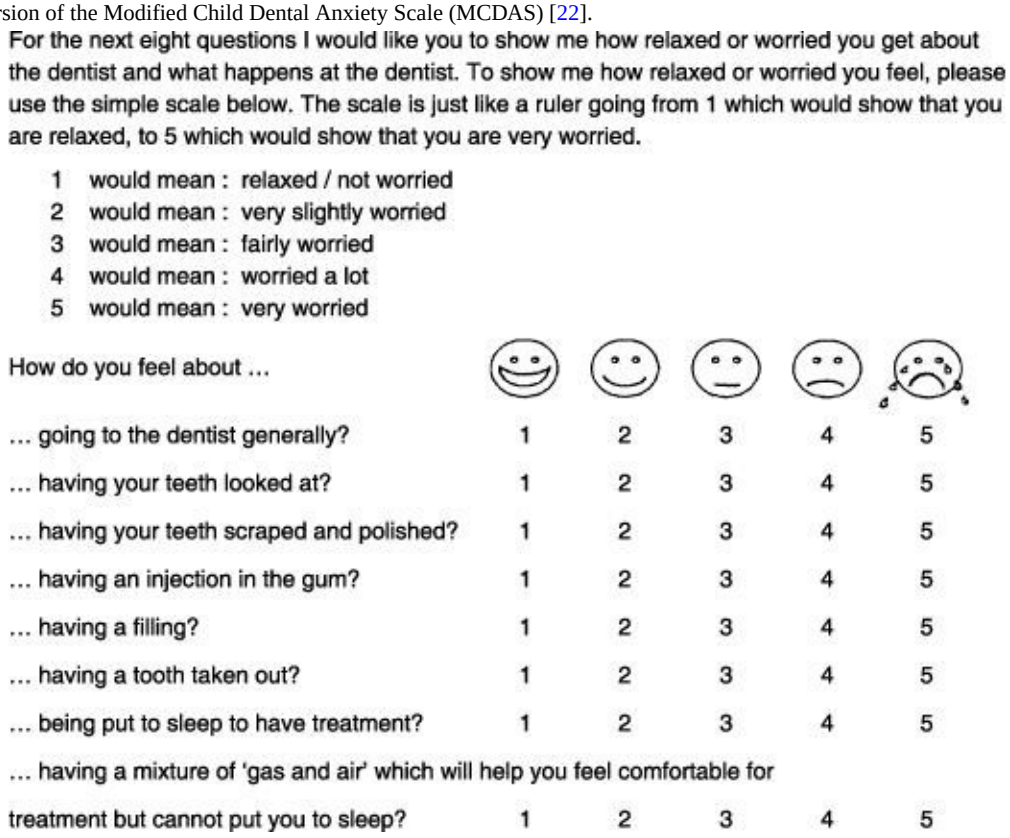
Figure 1. Face version of the Modified Child Dental Anxiety Scale (MCDAS) [22].



Frankl Behavior Rating Scale

This scale divides observed behavior into the following 4 categories: Rating 1, definitely negative (refusal of treatment, forceful crying, fearfulness, or any other overt evidence of extreme negativism); Rating 2, negative (reluctance to accept treatment, uncooperativeness, some evidence of negative attitude but not pronounced); Rating 3, positive (acceptance of treatment; cautious behavior at times; willingness to comply with the dentist, at times with reservation, but patient follows the dentist's directions cooperatively); and Rating 4, definitely positive (good rapport with the dentist, interest in the dental procedures, laughter and enjoyment) [23].

Statistical Analysis

All data were analyzed using SPSS (IBM Corp, Armonk, NY). The results are reported using descriptive statistical analysis (mean [SD] and percentages). Chi-square tests were used to assess gender differences and behaviors between the groups. A one-way analysis of variance (ANOVA) was used to compare the mean plaque index between groups. A Kruskal-Wallis test was used to compare mean MCDAS(f) anxiety scales, mean ages, and mean SCARED scores. A Mann-Whitney *U* test was used to compare mean MCDAS(f) anxiety scales between groups. Repeated measure analysis was performed to compare the mean plaque index in different groups and between different time intervals. The statistical significance was set to .05.

Results

Demographic and SCARED Score Results

The final sample consisted of 60 children in 4 groups. There were no statistically significant differences between groups regarding gender (*P*=.86) and age (*P*=.76). The SCARED scores also did not differ significantly between the 4 groups (*P*=.99; Table 1).

Table 1. Participants' gender, age, and Screen for Child Anxiety Related Disorders (SCARED) scores for the 4 groups (total n=60).

Characteristic	TSD[a] (n=15)	Immersive VR[b] (n=15)	Semi-immersive VR (n=15)	Nonimmersive VR (n=15)	*P* value
Gender, n (%)					
Female	8 (13)	9 (15)	7 (12)	7 (12)	.87
Male	7 (12)	6 (10)	8 (13)	8 (13)	
Age (years), mean (SD)	5.25 (0.77)	5.46 (0.63)	5.26 (0.79)	5.21 (0.81)	.76
SCARED score, mean (SD)	12.81 (7.79)	12.66 (7.09)	13.06 (7.88)	12.64 (7.41)	.99

[a]TSD: tell-show-do.

[b]VR: virtual reality.

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Children's Anxiety Assessment Results

The overall mean MCDAS(f) anxiety score of the participants was 12.68 (SD 4.18). The mean MCDAS(f) anxiety scores of the VR groups and control (TSD) group are shown in Table 2. A statistically significant difference was detected in mean MCDAS(f) scores between the 4 groups (P<.001). The lowest MCDAS(f) score was observed in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups.

Comparison of the mean MCDAS(f) anxiety scores between groups according to the Mann-Whitney U test showed statistically significant differences between the 3 VR groups and TSD group. Furthermore, statistically significant differences were detected among the VR groups (Table 3).

Table 2. Face version of the Modified Child Dental Anxiety Scale (MCDAS[f]) anxiety scores for the 4 groups.

MCDAS(f)	TSD[a], mean (SD)	Non-immersive VR[b], mean (SD)	Semi-immersive VR, mean (SD)	Immersive VR, mean (SD)	P value
Anxiety	16.93 (3.61)	14.20 (2.65)	11.33 (2.52)	8.26 (1.57)	<.001

[a]TSD: tell-show-do.

[b]VR: virtual reality.

Table 3. Comparison of the face version of the Modified Child Dental Anxiety Scale (MCDAS[f]) anxiety scores between the groups.

Group	Nonimmersive VR[a]	Semi-immersive VR	Immersive VR	TSD[b]
Nonimmersive VR				
U	—[c]	47	3.5	59.5
P value	—	.006	<.001	.03
Semi-immersive VR				
U	47	—	32.5	24.5
P value	.006	—	<.001	<.001
Immersive VR				
U	3.5	32.5	—	5.5
P value	<.001	<.001	—	<.001
TSD				
U	59.5	24.5	5.5	—
P value	.03	<.001	<.001	—

[a]VR: virtual reality.

[b]TSD: tell-show-do.

[c]Not applicable.

Children's Behavioral Assessment Results

Differences in Frankl scale scores were statistically significant between the 4 groups (P=.004; Table 4). The most positive behavior was observed in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups.

Table 4. Comparison of Frankl behavior scale scores between the 4 groups.

Behavior	TSD[a], mean (SD)	Nonimmersive VR[b], mean (SD)	Semi-immersive VR, mean (SD)	Immersive VR, mean (SD)	P value
Definitely negative	4 (6.7)	1 (1.7)	0	0	.004
Negative	5.8 (8.3)	6 (10)	3 (5)	2 (3.3)	
Positive	6 (10)	8 (13.3)	10 (16.7)	7 (11.7)	
Definitely positive	0	0	2 (3.3)	6 (10)	

[a]TSD: tell-show-do.

[b]VR: virtual reality.

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Oral Health Status Results

The overall mean plaque index scores were 0.71 (SD 0.14), 0.51 (SD 0.15), and 0.49 (0.16) in the first session and first and second follow-up visits, respectively. The mean plaque index scores for all groups are shown in Table 5. There were no statistically significant differences between groups in the first session or first and second follow-up visits (P=.28, P=.54, and P=.18, respectively).

In addition, repeated measures analysis was performed to compare mean plaque index scores between the different time intervals within each group. Differences in the plaque index scores were statistically significant between the initial session and follow-up sessions in all 4 groups due to the significant sphericity (P<.001). However, the interaction between time and group was not significant (P=.21; Table 5, Figure 2).

Table 5. Plaque index scores at each visit for the 4 groups.

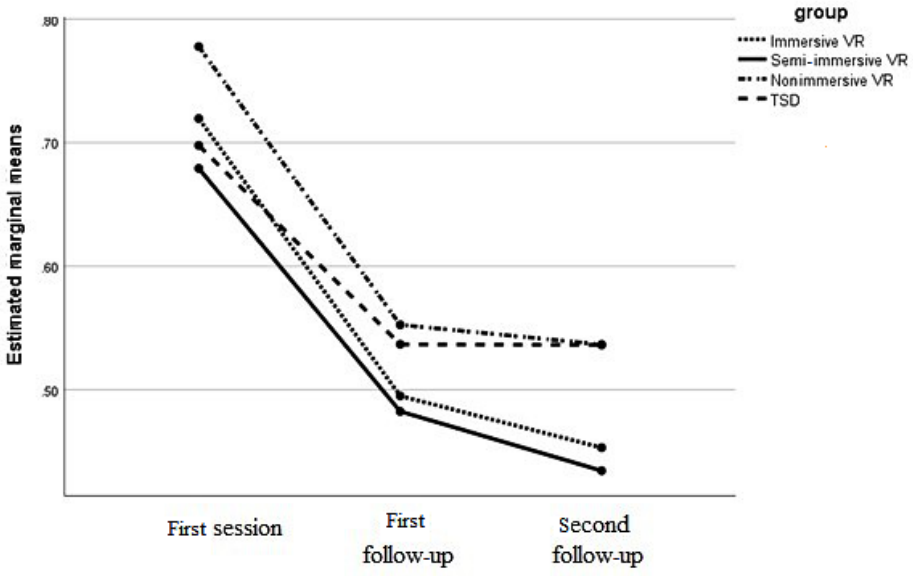
Plaque index	TSD[a,b], mean (SD)	Nonimmersive VR[b,c], mean (SD)	Semi-immersive VR[b], mean (SD)	Immersive VR[b], mean (SD)	*P* value
Initial session	0.69 (0.19)	0.77 (0.12)	0.67 (0.14)	0.71 (0.09)	.28
First follow-up visit	0.53 (0.17)	0.55 (0.14)	0.48 (0.15)	0.49 (0.12)	.54
Second follow-up visit	0.53 (0.19)	0.53 (0.15)	0.43 (0.16)	0.45 (0.11)	.18

[a]TSD: tell-show-do.

[b]Difference between visits: P<.001.

[c]VR: virtual reality.

Figure 2. Plaque index scores at each visit for the 4 groups. TSD: tell-show-do; VR: virtual reality.



Discussion

Principal Findings

This study showed that the lowest anxiety score and the most positive behavior were observed in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups. The results revealed that there were no statistically significant differences in mean plaque index scores between the 4 groups.

In this randomized clinical trial, we evaluated the impact of different levels (delivery systems) of VR on anxiety and behavior in children during the dental procedures. In addition, this study aimed to evaluate the impact of oral health education using different levels of VR on children's oral hygiene status.

All participants underwent a rigorous screening process using the parent version of the SCARED questionnaire to exclude the children with trait anxiety disorders, which is defined as a general predilection to respond with anxiety in threatening situations including dental procedures. Moreover, since a history of painful medical or dental experiences has been identified as an important determinant of anxiety and pain perception, in this study, participants with a history of any dental and surgical procedures were excluded [24]. Meanwhile, it has been suggested that using favorite, familiar, fantasy children's characters could prevent them from focusing on the anxiety-inducing appearance of dental equipment; therefore, a similar episode of the Tom and Jerry cartoon series was played for all patients [25].

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Effects of VR on Children's Anxiety and Behavior

The results of this study revealed that different VR delivery systems were effective in decreasing anxiety during the dental procedure. The lowest prevalence of anxiety was experienced by the children in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups. Furthermore, the VR application induced more positive behavior in children during routine dental procedures. These results represent significant practical improvements in behavioral outcomes in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups. These results suggest that, with increasing immersion depth, children's attention will be pulled more from the real world, and thereby, children experience lower levels of dental anxiety and more positive behaviors.

The application of VR is based on the psychological theories of pain perception in which anxiety and pain are the expressions of sensory inputs; therefore, the cognitive appraisal of emotions is important in the process and degree of stress experienced by the patients [26]. The hypothesis that distraction reduces distress is clearly relying on cognitive models, and it is assumed that the experience of distress depends on information processing. Anxiety is caused by paying attention to sensory inputs and processing them emotionally, thus distraction could interrupt this process and reduce pain perception [26].

Furthermore, as demonstrated by Kahneman's capacity model, individuals have a limited pool of information-processing resources, and using their capacity for one specific activity limits their availability for other activities [27]. Thus, engaging in an attention-grabbing activity confuses available attention and prevents the processing and accessing of other information. It seems that VR robs precious cognitive resources from other information-processing activities such as dental procedures. In a similar context, increasing the level of immersion using multisensory VR (visual, auditory, and sometimes tactile elements) creates significant cognitive demand on patients and therefore steals cognitive resources from other events. Thus, more immersive VR could exert a more distractive effect by diverting conscious attention away from painful and anxious stimulation, leading to reduced subjective pain and anxiety levels [13,14]. It is not surprising that complete blockage of the child's visual fields and providing audiovisual inputs via the VR eyeglasses in the Immersive VR group resulted in the lowest level of anxiety and the most positive behavior.

On the other hand, new research attempts to monitor brain changes using functional magnetic resonance imaging (fMRI) during VR device use [28]. This finding shows a strong relationship between the neurological and psychological components of pain; when a person pays less attention to pain, pain severity in the brain will decrease. With the use of VR devices, not only did the participants report reduced pain but their fMRI scans also showed a reduction in pain-related brain areas including the primary and secondary somatosensory cortex, insula, thalamus, and anterior cingulate cortex. Therefore, the users of VR devices not only experience audiovisual distraction but also exhibit decreased neural activity in pain-related brain regions [28].

In accordance with results of this study, a review of the literature revealed a reduction in pain and anxiety levels in the majority of studies using VR devices during dental procedures [10,11,28]. Moreover, findings of this study are also consistent with the evidence of prior studies on the relationship between VR and different medical procedures including intravenous (IV) placement, chemotherapy, and physiotherapy [29-31].

However, the results of this study differ from the study conducted by Alhalabi et al [10], in which using VR eyeglasses had no significant effect on anxiety and pain perception during inferior alveolar nerve block injection in 6 10-year-old children. Part of this inconsistency could be attributed to the different populations and parameters collected and analyzed. In the study by Alhalabi et al [10], discomfort was evaluated just after administering the inferior alveolar nerve block, while in other studies, anxiety and pain were recorded during the entire treatment procedure. Further, differences in the age ranges of the children could explain the underlying contradictory results. The findings of the study by Das et al [32] provide supportive evidence for our line of reasoning that older children suppose VR technology to be a simple game, while younger consumers are significantly captivated by VR's immersive power in engaging children and harnessing their emotions [32]. Since coping skills and cognitive ability are underdeveloped in preschool children, distraction techniques including VR is a crucial part of a behavior management strategy. Therefore, it is not surprising that a VR technique was more effective in preschool children in comparison with older children [32].

In addition, in the study by Alhalabi et al [10], a very large VR device was used. Therefore, the practitioner's vision was considerably blocked during the dental procedures and local anesthesia administration, which might explain the differences in the practitioner's understanding of the clinical situation. In this study, appropriately sized VR eyeglasses were used to accommodate the size of children while completely blocking the participant's vision.

In accordance with the results of this study, the findings of studies using a crossover design to test VR efficacy have confirmed reduced pain perception and anxiety levels in healthy children during 2 consecutive dental sessions [12,33]. The advantage of a crossover study is that each participant would be compared to themselves in both experimental and control situations.

It is worth noting that, although positive behaviors and reduced anxiety levels were observed in the Nonimmersive and Semi-immersive groups, the lowest anxiety level and the most positive behavior were seen in the Immersive VR group. These advantages are attributed to the complete blockage of the child's visual field and greater immersion of the child by application of immersive VR devices.

Effects of VR on Children's Oral Hygiene Status

The second aim of this study was to examine the effect of oral health education using different VR delivery systems on oral health promotion in 4–6-year-old children.

Although the result of this study revealed a reduced plaque index in all studied groups, the difference did not reach a

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statistically significant level. In contrast with the results of this study, Chang et al [15] suggested a digital design for tooth brushing with UbiComp technology to promote the brushing skills of kindergarten children. They reported that this technology promotes tooth brushing skills of children in a short training time and can significantly improve children's oral health status.

Nonsignificant differences between plaque indexes in the VR and control groups can be attributed to the fact that a mouth moulage was used to demonstrate tooth brushing to the participants in the control group, which was more effective than verbal commands and tangible for the child. However, using VR to educate about oral hygiene practices and tooth brushing in VR groups was also interesting for the children and their parents. It should be noted that virtual realism may be related with static or dynamic objects [34]. In this study, users were able to visualize in a virtual environment (static), but in the studies focused on digital methods, users were able to visualize and interact in a virtual environment (dynamic) [15]. Furthermore, virtual environments employ augmented reality (AR) as a learning tool and provide a more realistic experience for the participants. AR is a technology that superimposes a computer-generated virtual scenario atop an existing reality in order to create a sensory perception through the ability to interact with it; therefore, AR seems to be more effective in real operations than VR [35]. In this study, due to the application of audiovisual systems of VR without a haptic tracker or AR technique for oral health education, no difference was observed between the different VR delivery systems as well as between VR and the control group.

Despite reports of simulation sickness, nausea, and eye strain in young children using the VR technique, the participants in our study did not have any adverse effects nor discomfort using the VR [7].

Although this study offers a clear picture of the influence of different VR delivery systems on anxiety, behavior, and oral health education in preschool children, the findings should be considered in the context of some limitations. One of the limitations in this study is the age of the participants, which makes it difficult to generalize the findings to other age groups. Since different age groups exhibit different cognitive characteristics and behavioral patterns toward the VR technique, conducting prospective research studies utilizing different age groups is highly recommended for future studies. In addition, we suggest considering mediating factors influencing VR, including the different types of software and hardware of VR devices. Furthermore, our findings endorse the necessity of conducting studies using various medical and dental procedures and environments. Moreover, further studies addressing other preventive measures of oral hygiene practice are suggested.

Conclusion

Based on the obtained results, the lowest anxiety score and the most positive behavior were observed in the Immersive VR group, followed by the Semi-immersive VR, Nonimmersive VR, and TSD groups. However, the results did not show statistically significant differences in mean plaque index scores between the 4 groups at the first and second follow-up visits. Therefore, it can be concluded that different levels of VR can be effectively used to reduce anxiety and promote positive behavior during routine dental procedures. Moreover, oral health education using VR resources can improve oral health status in children; however, using traditional methods of education would result in a comparable rate of improvement in oral health condition.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 8966 KB - periop_v5i1e35415_app1.pdf]

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Abbreviations

ANOVA: analysis of variance
AR: augmented reality
CONSORT: Consolidated Standards of Reporting Trials
fMRI: functional magnetic resonance imaging
HMD: head-mounted display
IV: intravenous
MCDAS(f): face version of the Modified Child Dental Anxiety Scale
SCARED: Screen for Child Anxiety Related Disorders
TSD: tell-show-do
VR: virtual reality

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Original Paper

Outcomes With a Mobile Digital Health Platform for Patients Undergoing Spine Surgery: Retrospective Analysis

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Abstract

Background: Digital health solutions have been shown to enhance outcomes for individuals with chronic medical illnesses, but few have been validated for surgical patients. The digital health platform ManageMySurgery (MMS) has been validated for spine surgery as a feasible method for patients along their surgical journey through in-app education and completion of patient-reported outcomes surveys.

Objective: The aim of this study is to determine the rates of 90-day emergency room (ER) visits, readmissions, and complications in patients undergoing spine surgery using MMS compared to patients using traditional perioperative care alone.

Methods: Patients undergoing spine surgery at a US-based academic hospital were invited to use MMS perioperatively between December 2017 and September 2021. All patients received standard perioperative care and were classified as MMS users if they logged into the app. Demographic information and 90-day outcomes were acquired via electronic health record review. The odds ratios of having 90-day ER visits, readmissions, mild complications, and severe complications between the MMS and non-MMS groups were estimated using logistic regression models.

Results: A total of 1015 patients were invited, with 679 using MMS. MMS users and nonusers had similar demographics: the average ages were 57.9 (SD 12.5) years and 61.5 (SD 12.7) years, 54.1% (367/679) and 47.3% (159/336) were male, and 90.1% (612/679) and 88.7% (298/336) had commercial or Medicare insurance, respectively. Cervical fusions (559/1015, 55.07%) and single-approach lumbar fusions (231/1015, 22.76%) were the most common procedures for all patients. MMS users had a lower 90-day readmission rate (55/679, 8.1%) than did nonusers (30/336, 8.9%). Mild complications (MMS: 56/679, 8.3%; non-MMS: 32/336, 9.5%) and severe complications (MMS: 66/679, 9.7%; non-MMS: 43/336, 12.8%) were also lower in MMS users. MMS users had a lower 90-day ER visit rate (MMS: 62/679, 9.1%; non-MMS: 45/336, 13.4%). After adjustments were made for age and sex, the odds of having 90-day ER visits for MMS users were 32% lower than those for nonusers, but this difference was not statistically significant (odds ratio 0.68, 95% CI 0.45-1.02; *P*=.06).

Conclusions: This is one of the first studies to show differences in acute outcomes for people undergoing spine surgery who use a digital health app. This study found a correlation between MMS use and fewer postsurgical ER visits in a large group of spine surgery patients. A planned randomized controlled trial will provide additional evidence of whether this digital health tool can be used as an intervention to improve patient outcomes.

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KEYWORDS

digital health; spine surgery; surgical outcomes; mobile health; mobile application; surgery; postoperative; mobile health; mobile app; mHealth; recovery

Introduction

Approximately 35,000 cervical spine procedures and 200,000 lumbar spine surgeries are performed in the United States each year [1,2]. This high surgical volume is also associated with significant resource use in the health care system, with expenses averaging around US $20,000 for cervical cases and US $50,000 for lumbar cases.

Recent changes to the American Medicare and Medicaid insurance systems have rewarded hospitals for reducing 90-day postoperative emergency room (ER) visits and penalized them for unnecessary ER visits [3]. The rates of 90-day postoperative ER visits at 2 major medical centers were 9.4% and 13%, respectively, with postoperative discomfort being the most common reason [3,4]. According to one of these centers' economic analyses, the average postoperative spine ER visit costs around US $2000, whereas the average readmission costs US $7400. [3] Given the significant economic burden, improved patient follow-up and education about medical emergencies may help minimize health care resource utilization by reducing postoperative ER visits following spine surgery.

Furthermore, spine procedures are linked with high clinical morbidity. Postoperative morbidity rates for cervical fusion and cervical arthroplasty have been reported to be as high as 19%-20% [5,6], with common complications including wound infections, dysphagia, hematoma, and urine retention [5-7]. Lumbar procedures include laminectomies and discectomies, as well as more traditional posterior fusion techniques (transforaminal and posterior lumbar interbody fusions) and less invasive anterior and lateral interbody fusions [8-10]. Complication rates for lumbar techniques vary greatly, with some studies showing rates of 14% for anterior lumbar fusion [11], 30%-40% for severe lateral lumbar fusion [12], and 8%-17% for transforaminal and posterior lumbar fusion [9,11]. Many patients may be fearful about spine surgery due to the variety of surgical methods, the complexity of the anatomy, and the variety of possible postoperative outcomes. With the increasing number of outpatient procedures, there is an increasing unmet need to assist patients in navigating these complex spine therapies and achieving the best potential outcomes.

Prior research on postoperative ER visits has discovered that early postoperative phone calls and telehealth visits from clinical personnel can help minimize ER visits [13,14], implying that early patient engagement and communication can help alleviate the health care system's burden. Although telehealth visits and phone calls may alleviate some of the strain on health care resources, they are time-consuming and difficult to scale.

Mobile apps are being aggressively deployed as platforms for connecting care professionals and patients and for providing information outside of the hospital setting in today's increasingly digital environment where smartphone use is common. A review of mobile health solutions reveals an abundance of new apps for patient education, clinical diagnostics, treatment adherence, and behavioral change [15]. Mobile health apps have been shown to reduce patient visits and hospitalizations and to facilitate self-care in patients with chronic conditions such as diabetes and cardiovascular disease [16,17]. Certain mobile apps have been designed to serve as acute perioperative care tools for communicating pre- and postoperative instructions and concerns. Apps designed for abdominal and orthopedic procedures reduce follow-up visits [18-20].

Previously, our team proved the feasibility of ManageMySurgery (MMS), a perioperative mobile app, in educating patients across various interventional and surgical paths and in gathering patient-reported outcomes for spine and breast procedures [21,22]. MMS enables patients to access instructional content tailored to their procedure, receive notifications and reminders along standardized care pathways and from their provider teams, and complete pre- and postoperative questionnaires to inform and monitor their clinical team.

Although digital health is rapidly expanding, little research has been done on its quantifiable impact on patient outcomes. We anticipate that using a complete digital health platform specialized for spine surgery (MMS) can help patients undergoing elective spine surgery avoid emergency department visits, postoperative hospital readmissions, and postoperative problems. We specifically hypothesize that compared to patients using traditional perioperative care, those using MMS will have fewer ER visits, fewer hospital readmissions, and fewer postoperative complications in the 90 days after surgery. This would directly impact the health care cost placed on patients having these procedures and could also reduce the systemwide burden of excess health care resource utilization.

Methods

Ethics Approval

Ethics approval was obtained prior to beginning the study from the Duke University Institutional Review Board (protocol #Pro00074329).

Description of the MMS App

MMS is a cloud-based, HIPAA (Health Insurance Portability & Accountability Act)-compliant solution that provides a platform for patients and caregivers undergoing interventional or surgical procedures. It allows patients to prepare for procedures through in-app educational content specific to their surgery, access to frequently asked questions (FAQs), and communication with their surgical team. The MMS-Spine module supports the most commonly performed spine surgeries, with submodules available for lumbar laminectomy or discectomy, lumbar fusion, and anterior cervical discectomy and fusion. The app is available on mobile operating systems including Android (Google Inc) and iOS (Apple Inc), as well

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as through a web app to reach the widest patient population possible.

MMS was designed by an interdisciplinary team, and the spine module described in this study (MMS-Spine) uses evidence-based guidelines from national societies, including the North American Spine Society, American Association of Neurological Surgeons, and the American Association of Orthopedic Surgeons. The app phrases questions, responses, and other content at a sixth grade reading level. Literacy evaluation was performed by the Duke Patient Education Governance Council.

A nurse navigator creates an account for patients who are invited to use MMS-Spine, enters patient demographic information into the app, and assigns them to a submodule based on surgery type: Anterior Cervical Discectomy & Fusion (ACDF), Spinal Fusion, or Lumbar Discectomy. These function as care pathways that contain different sets of educational materials and tasks specific to the surgery type. As an example, some FAQs within the ACDF submodule are “What are the risks of ACDF?” and “What is the process for getting an ACDF?”. In the Spinal Fusion module questions include “How will a spinal fusion affect my flexibility or ability to move?” and “What are the risks of spinal fusion?” [21]. Patients can also view postoperative information, such as serious symptoms to watch for during recovery and restrictions on activity, eating, and drinking after surgery [4].

MMS also collects patient-reported outcomes via in-app surveys, specifically the commonly used and well-validated PROMIS-29 (Patient-Reported Outcomes Measurement Information System 29), Oswestry Back Disability Index, and Neck Disability Index [23-26]. Baseline surveys are collected 2 to 4 weeks prior to surgery, and postoperative surveys are automatically available to patients after discharge, with automatic reminders delivered to their smartphones to complete these surveys. Results from these surveys are analyzed and presented separately. Patients are also prompted with reminders to complete other tasks, such as checking into appointments and completing preoperative instructions.

Providers can view results of the MMS app as well as the responses and trends from the patient surveys. Furthermore, patients and providers can communicate within the application through a HIPAA-compliant messaging system. Multimedia Appendix 1 and Multimedia Appendix 2 contain screenshots of the app, including the patient and provider interfaces.

Participants and Setting

This project was conducted as a retrospective cohort study. Patients were eligible for the study if they were scheduled to undergo an elective spine surgery at Duke University Health System between December 2017 and September 2021, English was their primary language, they were at least 18 years old, they had a device capable of running MMS (iOS, Android, or desktop computer), they could consent, their surgeon had invited them to join MMS during a preoperative appointment, and if the patient had at least 90 days of follow-up after their surgical procedure. Patients without phones who wanted a family member or friend to proxy using the in-app caregiver function were also invited to use MMS and were included in the study. Patients were excluded if 90 days had not passed since their surgery date and if they had surgery at more than 6 spinal levels, as these surgeries were typically for scoliosis or other deformity procedures that were not supported by the MMS app at the time.

If the patients accepted their invitation by logging into the app, they were assigned to the MMS user cohort. Nonusers were considered to be those patients or their designated caregivers who had never logged into MMS.

Users of MMS downloaded and logged into the app 2 to 4 weeks before the elective spine surgery, received structured preoperative information, and completed baseline surveys. Patients could complete 6-week, 3-month, 6-month, and 12-month postoperative surveys after surgery. Patients received push notifications via the app to complete these surveys, check into appointments, and complete other tasks assigned to them by their provider team. Consent was obtained electronically and at the time of enrollment. Consent included permission to use MMS app and electronic health record outcomes and demographic data for research purposes. Each patient completed a brief, standardized, self-guided walk-through orientation within the app, which included instructions on how to access educational materials and complete tasks (such as completing surveys or checking into appointments). This procedure was also followed by proxies who used the caregiver function.

Data Collection

MMS collected and securely stored data gathered throughout the patient's engagement with the app using Amazon Web Services. The MMS database was used to collect app usage data. The app collects data such as the number of account sign-ins, task or survey completion, the addition of proxy caregiver(s), the device used to access MMS, and the number of FAQs viewed.

A chart review from the electronic health record was used to collect patient demographics (age at time of procedure, sex, insurance status), surgical details (specific procedure, number of spinal levels), and clinical outcomes within 90 days of surgery. The specific 90-day clinical outcomes collected in this study included postoperative unplanned readmissions to any hospital, excluding other preplanned admissions such as postoperative rehabilitation, colonoscopy, other elective surgeries, postoperative ER visits at any hospital, reasons for these postoperative ER visits, and postoperative complications.

Complications were ranked in severity using the Clavien-Dindo scale, which has been validated for spine surgery [27,28]. The Clavien-Dindo scale ranks postoperative complications from 1 to 5, with 1 indicating mild or no treatment needed, 2 indicating complications requiring pharmacologic treatments or blood transfusions, 3 indicating procedural treatment (surgery, interventional radiology, endoscopy), 4 indicating intensive care unit–level treatment or organ failure, and 5 indicating patient death [29]. For this study, the Clavien-Dindo score was further used to classify patients into the categories of mild complication (Clavien-Dindo score 1-2) or severe complication requiring intervention (Clavien-Dindo score 2-5)

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Statistical Analysis

Descriptive statistics are used to summarize patient demographics, surgical characteristics, MMS usage, and reasons for ER visits. Means, SDs, medians, first and third quartiles, and minimum and maximum values are reported for continuous variables. The number and percentage of nonmissing values for categorical variables are reported. The 90-day ER visit rate, 90-day readmission rate, 90-day mild complication rate, and 90-day severe complication rate, as well as their 95% CIs using a binomial distribution, are reported as primary outcomes. Along with adjustments for age and sex, multinomial logistic regression models were used to estimate the odds ratio of having a 90-day ER visit, 90-day readmission, 90-day mild complication, and 90-day severe complication in the MMS group versus the non-MMS group. All statistical tests were 2-sided, and test significance was determined at α=.05 without accounting for multiple testing. SAS version 9.4 (SAS Institute Inc) was used for statistical analysis.

Results

Patient Characteristics and MMS App Usage

A total of 1160 patients undergoing elective spine surgery at Duke University Medical Center were invited to use MMS between December 2017 and September 2021. After inclusion and exclusion criteria of age, minimum follow-up time, and number of surgical levels were applied, 1015 patients were included in the final study cohort. Of this cohort, 679 patients or their caregivers (66.90%) logged into MMS at least once and were considered MMS users, while 336 patients (33.10%) did not use MMS.

Table 1 shows the demographics of the patients. Patients in both groups were of similar age (non-MMS: mean 61.5 years, SD 12.7 years; MMS: mean 57.9 years, SD 12.5 years) and had equal proportions of uninsured patients (MMS: 12/679, 1.8%; non-MMS: 6/336, 1.8%). The MMS group had more males (MMS: 367/669 54.1%; non-MMS: 159/336, 47.3%). Patients in both groups most commonly underwent cervical fusion operations (559/1015, 55.07%) or single-approach lumbar fusions (231/1015, 22.75%). Additionally, 360 patients (360/1015, 35.46%) underwent single-level operations, and 341 patients (341/1015. 33.60%) underwent 2-level operations.

MMS usage is summarized in Table 2. The MMS app was used by 679 patients, with 397 (58.5%) using an iOS device and 253 (37.2%) using an Android device. The ACDF module was used by 387 (57%), the discectomy module by 65 (9.6%), and the spinal fusion module by 227 (33.4%). Patients and their caregivers logged onto MMS an average of 3.4 (SD 4) times; however, patients could access the app multiple times per login until they are logged out; thus, actual usage was likely higher. Moreover, 236 (34.8%) patients gave access to proxy caregivers, of whom 188 (79.7%) logged in to use the app, and 50.2% of patients viewed at least 1 FAQ.

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Table 1. Demographic and clinical characteristics of patients.

Patient characteristics	Non-MMS[a] (n=336)	MMS (n=679)	Total (N=1015)
Age at surgery (years), mean (SD)	61.5 (12.7)	57.9 (12.5)	59.1 (12.7)
Age at surgery (years), median (Q1, Q3[b])	62 (54, 71)	58 (49, 68)	60 (50, 69)
Age at surgery (years), range	19-88	22-88	19-88
Patient sex, n (%)			
Male	159 (47.3)	367 (54.1)	526 (51.8)
Female	177 (52.7)	312 (45.9)	489 (48.2)
Payor group, n (%)			
Commercial	129 (38.4)	336 (49.5)	465 (45.8)
Medicare	169 (50.3)	276 (40.6)	445 (43.8)
VA[c]/military/government employee/Medicaid	32 (9.5)	55 (8.1)	87 (8.6)
None	6 (1.8)	12 (1.8)	18 (1.8)
Procedure, n (%)			
360 lumbar fusion[d]	32 (9.5)	70 (10.3)	102 (10.0)
Cervical fusion[e]	166 (49.4)	393 (57.9)	559 (55.1)
Laminectomy/discectomy	40 (11.9)	64 (9.4)	104 (10.2)
Lumbar fusion[f]	90 (26.8)	141 (20.8)	231 (22.8)
Other[g]	8 (2.4)	11 (1.6)	19 (1.9)
Surgery levels, n (%)			
1	108 (32.1)	252 (37.1)	360 (35.5)
2	121 (36.0)	220 (32.4)	341 (33.6)
3	67 (19.9)	130 (19.1)	197 (19.4)
4	33 (9.8)	67 (9.9)	100 (9.9)
5	5 (1.5)	7 (1.0)	12 (1.2)
6	2 (0.6)	3 (0.4)	5 (0.5)
Surgery level, median (Q1, Q3)	2 (1, 3)	2 (1, 3)	2 (1, 3)

[a]MMS: ManageMySurgery app.

[b]Q1, Q3: first and third quartiles.

[c]VA: Veterans Affairs.

[d]Anterior approach to lumbar fusion + posterior approach to lumbar fusion.

[e]Includes both anterior and posterior cervical fusions.

[f]Includes singular approach to lumbar fusion, anterior or posterior.

[g]Includes cervical arthroplasty, thoracic fusion, sacroiliac fusion.

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Table 2. MMS app usage results (n=679).

Characteristic	Value
Patients and caregivers' total sign-in counts, n (%)	
1-3	470 (69.2)
4-6	137 (20.2)
7+	72 (10.6)
Patients and caregivers' total sign-in counts, mean (SD)	3.4 (4)
Patients and caregivers' total sign-in counts, median (Q1, Q3)	2 (1, 4)
Caregiver added, n (%)	236 (34.8)
Added caregivers that logged in (out of 236), n (%)	188 (79.7)
Device used, n (%)	
iOS	397 (58.5)
Android	253 (37.2)
Web app/other	29 (4.3)
MMS[a] submodule used, n (%)	
ACDF[b]	387 (57.0)
Lumbar discectomy	65 (9.6)
Spinal fusion	227 (33.4)
Number of FAQs[c] viewed, n (%)	
0	338 (49.8)
1-10	97 (14.3)
11-20	75 (11.0)
21-40	104 (15.3)
41+	65 (9.6)
Number of FAQs viewed, mean (SD)	12.1 (18.2)
Number of FAQs viewed, median (Q1, Q3[d])	1 (0, 20)
Number of FAQs viewed, range	0-93

[a]MMS: ManageMySurgery app.

[b]ACDF: Anterior Cervical Discectomy & Fusion.

[c]FAQs: frequently asked questions.

[d]Q1, Q3: first and third quartiles.

Ninety-Day Clinical Outcomes

Table 3 displays the 90-day ER visit rates, readmission rates, and postoperative complication rates. Of the 336 MMS nonusers, 30 (8.9%) had a readmission, 45 (13.4%) had an ER visit, 32 (9.5%) had a mild complication, and 43 (12.8%) had a severe complication within 90 days of their initial operation. Among the 679 patients who used MMS, there were 55 (8.1%) readmissions, 62 (9.1%) ER visits, 56 (8.3%) mild complications, and 66 (9.7%) severe complications.

As shown in Table 3, MMS patients were significantly less likely than non-MMS patients to have a 90-day ER visit with a univariable odds ratio of 0.65 (95% CI 0.43-0.98; *P*=.04). The odds ratio for an MMS patient having a 90-day readmission compared to a non-MMS patient having a 90-day readmission was 0.90 (95% CI 0.56-1.43; *P*=.65). The odds ratio for an MMS patient having a 90-day severe complication compared to a non-MMS patient was 0.72 (95% CI 0.48-1.09; *P*=.12), while the odds ratio for a mild complication was 0.82 (95% CI 0.52-1.3; *P*=.40).

When adjusted for age and sex, the odds ratio for an MMS patient having a 90-day readmission compared to a non-MMS user was 0.97 (95% CI 0.6-1.55; *P*=.88), the odds ratio for a 90-day severe complication was 0.78 (95% CI 0.52-1.19; *P*=.25), the odds ratio for a 90-day mild complication was 0.95 (95% CI 0.59-1.51; *P*=0.82), and the odds ratio for a 90-day ER visit was 0.68 (95% CI 0.45-1.02; *P*=.06).

Among the 107 patients in both groups who visited the ER, the most common reasons for an ER visit included syncope or falls (n=17, 15.9%), wound infections (n=13, 12.1%), and back pain (n=12, 11.2%). More detail on the reasons for ER visits is shown in Table 4. Of note, 25 of the 45 (56%) non-MMS patients had

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a visit reason involving pain, while 21 of the 62 (34%) MMS patients presented with pain as a concern. Note that a patient can have more than 1 reason for an ER visit.

Table 3. Ninety-day clinical outcomes.

90-day outcome	Non-MMS[a] (n=336)		MMS (n=679)		Total (n=1015)		Univariate MMS:non-MMS		Multivariate MMS:non-MMS	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	OR[b] (95% CI)	*P*	OR (95% CI)	*P*
ER[c] visit	45 (13.4)	9.8-17	62 (9.1)	7-11.3	107 (10.5)	8.7-12.4	0.65 (0.43-0.98)	.04	0.68 (0.45-1.02)	.06
Readmission	30 (8.9)	5.9-12	55 (8.1)	6.1-10.2	85 (8.4)	6.7-10.1	0.90 (0.56-1.43)	.65	0.97 (0.6-1.55)	.88
Mild complication	32 (9.5)	6.4-12.7	56 (8.3)	6.2-10.3	88 (8.7)	6.9-10.4	0.82 (0.52-1.3)	.40	0.95 (0.59-1.51)	.82
Severe complication	43 (12.8)	9.2-16.4	66 (9.7)	7.5-12	109 (10.7)	8.8-12.6	0.72 (0.48-1.09)	.12	0.78 (0.52-1.19)	.25

[a]MMS: ManageMySurgery app.

[b]OR: odds ratio.

[c]ER: emergency room.

Table 4. Reasons for 90-day postoperative ER visits.

Reason for the ER[a] visit	Non-MMS[b] (n=45), n (%)	MMS (n=62), n (%)	Total (n=107), n (%)
Syncope/fall	5 (11.1)	12 (19.4)	17 (15.9)
Wound infection	4 (8.9)	9 (14.5)	13 (12.1)
Back pain	7 (15.6)	5 (8.1)	12 (11.2)
Limb pain	6 (13.3)	5 (8.1)	11 (10.2)
Chest pain	6 (13.3)	5 (8.1)	11 (10.2)
Neurological symptoms	3 (6.7)	4 (6.5)	7 (6.5)
Dyspnea	4 (8.9)	5 (8.1)	9 (8.4)
Leg swelling/DVT[c]	5 (11.1)	3 (4.8)	8 (7.5)
Abdominal pain	5 (11.1)	3 (4.8)	8 (7.5)
Dysphagia	0 (0.0)	4 (6.5)	4 (3.7)
Pain: unspecified	2 (4.4)	2 (3.2)	4 (3.7)
Urinary symptoms	1 (2.2)	3 (4.8)	4 (3.7)
Neck pain	2 (4.4)	2 (3.2)	4 (3.7)
Palpitations	0 (0.0)	2 (3.2)	2 (1.9)
Other	8 (17.8)	9 (14.5)	17 (15.9)
Unknown	0 (0.0)	2 (3.2)	2 (1.9)

[a]ER: emergency room.

[b]MMS: ManageMySurgery app.

[c]DVT: deep vein thrombosis.

Discussion

Principal Results

We present a study analyzing the postoperative clinical outcomes of patients who were invited to use a mobile digital health tool (MMS) before their elective spine surgery at a large, US academic medical center. In our univariate analysis, we found that compared to patients using traditional perioperative care, those using MMS had 35% lower odds of postoperative ER visits than did the non-MMS group and fewer severe postoperative complications in the 90 days after surgery. After adjustments for age and sex, there was a marginal improvement in ER visits in the MMS user group, with the MMS group having 32% lower odds of an ER visit than the non-MMS group, but this result did not show statistical significance (*P*=.06).

Our findings suggest that digital health solutions may assist in lowering adverse patient outcomes following spine surgery and may help reduce unnecessary health care resource utilization

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associated with ER visits. This is one of the first studies to document tendencies in acute outcomes associated with the use of a mobile health tool for patients undergoing spine surgery. Previously published research on mobile health solutions for spine surgery demonstrated the viability of using apps to engage patients in their recovery process and documented one such app that resulted in decreased pain scores when compared to traditional rehabilitation alone [30]. However, very few spine surgery apps have been linked with ER visits or complications. As a result, our findings support efforts to incorporate digital health tools into clinical practice, as they might help enhance objective outcomes through mass patient education.

Comparisons With Prior Work

ER Visits

Postoperative pain has been blamed for the vast majority of unnecessary postoperative ER visits following spine surgery [4], which could cost billions of dollars per year. In orthopedic surgery, Kelly et al [31] discovered that the most prevalent reasons for ER visits following knee arthroplasty are pain and swelling. The authors then focused on pain and edema, changing discharge instructions to better educate patients and improve pain control, with the goal of lowering ER visits for these reasons [31]. Table 4 shows that of the 45 non-MMS patients who presented to the ER, 25 (56%) had a complaint of pain, compared to only 21 of the 62 (33.9%) MMS users with ER visits. Following spine surgery, postoperative discomfort in areas such as the neck, back, and limbs is a common and often benign occurrence. By establishing realistic expectations through patient education, digital health solutions such as MMS may remind patients of a normal postoperative course, potentially leading to fewer unnecessary postoperative pain visits. Such solutions may also encourage appropriate ER visits, as apps like MMS can educate patients about red flags that indicate a visit is necessary.

Additionally, patient engagement plays a role in reducing ER visits after various types of surgery. Close patient follow-up via scheduled phone calls or additional outpatient visits has been demonstrated to prevent avoidable ER utilization following surgery [32-34]. Improved patient education and awareness leads to lower emergency service utilization as patients' concerns are allayed by their health care providers. MMS keeps patients engaged throughout their surgical journeys by providing pre- and postoperative education, reminders, and surveys.

Readmissions and Postoperative Complications

There was no evidence of a significant reduction in readmissions among MMS users according to our analysis. Prior studies have found 90-day readmission rates of approximately 6%-10% following elective spine surgery [24,35]. Our study found that the MMS and non-MMS groups had readmission rates of 8.1% (55/679) and 8.9% (30/336), respectively.

Although our study did not reveal a statistically significant reduction in 90-day postoperative complications, it did find numerically fewer problems among MMS patients. Our complication rates are comparable to those reported in the literature for both MMS and non-MMS populations. Prior research on enhanced recovery after surgery pathways indicates that implementing these postoperative protocols has resulted in a reduction in the time of hospital stay following spine surgery but has not resulted in a reduction in complication rates [36,37]. Perhaps the numerically lower complication rates observed in our study cohort indicate that preoperative education provided by digital health, such as proper wound care and ambulation, may help patients prepare for surgery in such a way that they are less likely to experience preventable complications following surgery. Another possibility is that patients who used MMS were already healthier and more involved in their health, minimizing their susceptibility to problems; however, because we did not collect data on patient comorbidities, this will need to be investigated further in future studies.

Impact on Providers

Patient engagement strategies such as phone calls and more frequent follow-up visits place an increased burden on physicians and other health care practitioners, which is where mobile apps can help. MMS keeps patients involved in their surgical journeys by providing pre- and postoperative education, reminders, and surveys. Using a smartphone app can help relieve some of the strain on health care practitioners, allowing them to focus on more critical patient care responsibilities. For example, a practitioner having to administer the PROMIS-29 and Oswestry Disability Index at preoperative, 6-week, and 3-month timelines would have to administer 6 surveys per patient during the time period analyzed in this study. Instead, these can be completed automatically by patients without using limited provider time. Interestingly, it appears that while most patients did not view any FAQs, many logged into MMS 4 to 7 or more times, suggesting that they were spending time on the app completing surveys and other tasks when engaged with the platform. This suggests that MMS is helping to alleviate the time-intensive burden of survey completion from providers but that patients might prefer to receive information about their surgery directly from their providers.

A reduction in ER visits at large tertiary medical centers, such as the one where this study was conducted, may help alleviate ER overcrowding and enable more efficient workflows for emergency medicine providers, resulting in tangible benefits for both providers and other patients in need of emergency care. These benefits have been reported in other studies as well, with a systematic review of mobile health technologies for surgical patients reporting that mobile apps have been shown to reduce postoperative emergency visits, prevent inappropriate visits for wound checks, and improve adherence to postoperative rehabilitation [30]. In the realm of spine surgery, one study noted that many in-person follow-ups were avoided with the use of a mobile app, as it allowed issues such as pain control to be resolved remotely [38]. Our study thus expands on what other researchers have noted regarding the ability of digital health tools to reduce provider burden.

Limitations

First, although our study found links between digital health use and fewer ER visits, our sample size was insufficient to establish statistical significance with a multivariable model. To have 80% power to detect a .05 level of significance with ER visit rates of 9.1% and 13.4% (from our results), a sample size of about

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1700 patients would be required; this number would likely be higher for a multivariable study. Second, in our multivariable model, we did not account for patient comorbidities, which can affect outcomes. In a planned randomized controlled trial, we hope to address both of these limitations.

Third, rather than analyzing the level of engagement and its relationship to patient outcomes, we examined whether the patient used the app on a binary scale. This is a limitation of the app because we currently have no way of measuring the amount of time spent on it. Because it is impossible to predict when a patient will log out of MMS, a patient may open and use the app multiple times during a single login. We hope to address these issues in subsequent updates.

Finally, the findings are limited by the inherent biases of retrospective cohort studies. This demonstrates selection bias, as even nonusers of MMS were invited to download the app but never logged in or used it. Furthermore, the study is hampered by the inherent biases associated with electronic health record review, such as data entry errors, missing data from unconnected record systems, and discrepancies in chart review among reviewers. Future clinical research will be conducted to illustrate the impact of digital health technologies while addressing some of these possible constraints.

Future Directions

This preliminary retrospective study provides data to suggest that the use of a digital health tool could help improve patient outcomes. In order to establish a more definitive link between MMS use and reductions in negative postoperative outcomes, we are planning a randomized controlled trial with MMS as the primary intervention for patients undergoing spine surgery. This trial would have a larger sample size, control for patient comorbidities, and use an intention-to-treat analysis to see if digital health tools can play a role in improving patient outcomes. Other future studies will involve analyzing subjective patient measures, such as the PROMIS-29 surveys given to patients within MMS.

Conclusions

We have demonstrated the potential utility of a digital health platform (MMS) to improve health care utilization and patient outcomes in spine surgery, specifically demonstrating the tendency in reducing postoperative ER visits. Digital health platforms could prevent unnecessary ER visits by keeping patients engaged in their preparation for and recovery from major surgery as well as educating them on what a normal recovery looks like. This would relieve additional strain on patients, caregivers, providers, and the health care system as a whole. A randomized controlled trial is planned in the future to account for unmeasured confounders in this study.

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Data Availability

The data sets generated during and analyzed during this study are not publicly available in order to protect the patient health information found in the data but can be deidentified and shared by the corresponding author on reasonable request and with the approval of the institutional review board.

Conflicts of Interest

SPL and ZFG are cofounders and equity holders of Higgs Boson Health. MMH is an equity holder of Higgs Boson Health. MP is a consultant and equity holder of Higgs Boson Health. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Screenshot of the ManageMySurgery app with a description of the app's features.
[PNG File , 978 KB - periop_v5i1e38690_app1.png]

Multimedia Appendix 2
Screenshot of the ManageMySurgery app patient and provider interfaces.
[PNG File , 625 KB - periop_v5i1e38690_app2.png]

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Abbreviations

ACDF: Anterior Cervical Discectomy & Fusion
ER: emergency room
FAQs: frequently asked questions
HIPAA: Health Insurance Portability and Accountability Act
MMS: ManageMySurgery
PROMIS-29: Patient-Reported Outcomes Measurement Information System 29

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Original Paper

Evaluation of Telemedicine Use for Anesthesiology Pain Division: Retrospective, Observational Case Series Study

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Abstract

Background: An increasing number of patients require outpatient and interventional pain management. To help meet the rising demand for anesthesia pain subspecialty care in rural and metropolitan areas, health care providers have used telemedicine for pain management of both interventional patients and those with chronic pain.

Objective: In this study, we aimed to describe the implementation of a telemedicine program for pain management in an academic pain division in a large metropolitan area. We also aimed to estimate patient cost savings from telemedicine, before and after the California COVID-19 “Safer at Home” directive, and to estimate patient satisfaction with telemedicine for pain management care.

Methods: This was a retrospective, observational case series study of telemedicine use in a pain division at an urban academic medical center. From August 2019 to June 2020, we evaluated 1398 patients and conducted 2948 video visits for remote pain management care. We used the publicly available Internal Revenue Service’s Statistics of Income data to estimate hourly earnings by zip code in order to estimate patient cost savings. We estimated median travel time and travel distance with Google Maps’ Distance Matrix application programming interface, direct cost of travel with median value for regular fuel cost in California, and time-based opportunity savings from estimated hourly earnings and round-trip time. We reported patient satisfaction scores derived from a postvisit satisfaction survey containing questions with responses on a 5-point Likert scale.

Results: Patients who attended telemedicine visits avoided an estimated median round-trip driving distance of 26 miles and a median travel time of 69 minutes during afternoon traffic conditions. Within the sample, their median hourly earnings were US $28 (IQR US $21-$39) per hour. Patients saved a median of US $22 on gas and parking and a median total of US $52 (IQR US $36-$75) per telemedicine visit based on estimated hourly earnings and travel time. Patients who were evaluated serially with telemedicine for medication management saved a median of US $156 over a median of 3 visits. A total of 91.4% (286/313) of patients surveyed were satisfied with their telemedicine experience.

Conclusions: Telemedicine use for pain management reduced travel distance, travel time, and travel and time-based opportunity costs for patients with pain. We achieved the successful implementation of telemedicine across a pain division in an urban academic medical center with high patient satisfaction and patient cost savings.

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KEYWORDS

COVID-19; pain management; telemedicine; cost savings; patient satisfaction

Introduction

Background

Chronic pain is the most common reason for seeking medical care, with a prevalence of 50% and 10% of localized and generalized chronic pain, respectively, in the United States. Chronic pain is associated with significant occupational, functional, and psychological morbidity and accounts for an estimated annual US $61 billion in lost productivity in the United States [1]. Since the COVID-19 pandemic, chronic pain patients have experienced difficulties accessing pain care because of closures of pain clinics and limited access to in-person therapies needed for effective chronic pain management, such as psychological, medical, or physical interventions. Because of social distancing measures from the pandemic leading to inactivity and social isolation, many patients experienced additional exacerbation of their symptoms.

However, pandemic policies discouraging direct in-person contact forced pain practices to use alternative methods to deliver care to chronic and interventional patients, which led to the rapid adoption of telemedicine. To encourage telemedicine use, governments eased regulations, and Medicare [2] and other insurers temporarily established reimbursement parity with in-person visits, which commercial insurers emulated to help drive telehealth adoption and help health care providers maintain care continuity and avoid missed care [3,4]. In addition, the increasing availability of internet access and computer devices allows for greater viability of telemedicine services; 85% of households in the United States have an internet subscription and 92% have a device with computer capabilities, including smartphones [5]. Before the pandemic, telehealth was rarely used for pain management and was generally confined to pain care for military patients in remote settings [6] or trialed for a small number of patients [7-9].

Rationale

Clinical consultations using telemedicine have been associated with patient cost savings, without a difference in clinical outcomes compared to in-person visits [10], and with health system benefits [10]. In addition, clinical consultations using telemedicine have been associated with high levels of patient satisfaction and acceptance of telehealth services, both for patients with chronic disease states [11] and those requiring postprocedural follow-up [12]. Despite the progressive adoption of telemedicine to deliver pain care, there is limited literature that has helped in the understanding of patient satisfaction with telemedicine use for pain management and its associated patient-centered time and financial savings compared to in-person visits. While the future of clinical pain practice continues to evolve to include hybrid care delivery using both in-person and telemedicine visits, there is limited telemedicine literature to help inform wider adoption of telemedicine and its associated best practices for pain management.

Specific Objectives

Prior to the pandemic, we initiated telemedicine-enabled pain clinics for interventional patients with chronic pain at our academic medical center and community practices to reduce wait times and no-show rates and to increase patient satisfaction. During the onset of the pandemic, the majority of outpatient pain visits at the University of California, Los Angeles (UCLA) rapidly shifted to telemedicine visits. This paper focuses on the structure, implementation, and patient cost savings and satisfaction associated with our pain division's telemedicine program. We aimed to (1) describe the UCLA Comprehensive Pain Center's telemedicine implementation for comprehensive pain management; (2) estimate the travel time, travel distance, and time-based opportunity savings for patients using telemedicine; and (3) describe patient satisfaction using telemedicine.

Methods

Study Design

This was a retrospective, observational case series study of telemedicine use in a pain division at an urban academic medical center comprising the UCLA Comprehensive Pain Center and Community Pain Clinics.

Setting

The UCLA Comprehensive Pain Center is a multidisciplinary pain management practice in Santa Monica, California. The practice is staffed by four attending physicians, a physician assistant, and a licensed clinical social worker. In addition to performing consults and follow-up visits, providers can perform procedures without image guidance, including trigger point injections, joint injections, and nerve blocks. The UCLA Comprehensive Pain Center has 10 examination rooms equipped with an examination bed and a computer with a camera for electronic medical record (EMR) access via Epic (Epic Systems Corporation) and telemedicine use. The majority of procedures are done on an outpatient basis at the Santa Monica UCLA Outpatient Surgery Center. Typical outpatient procedures include epidurals, nerve blocks, radiofrequency ablations (ie, neurolysis), joint injections, kyphoplasties and vertebroplasties, and placement of spinal cord stimulators and intrathecal pain pumps.

The UCLA Community Pain Clinics are community extensions of the UCLA Comprehensive Pain Center. There are currently nine attending physicians operating out of six office locations in the Greater Los Angeles Metropolitan Area. The community sites provide the same quality of care at a variety of geographical locations distributed throughout the Los Angeles Metropolitan Area. Outpatient procedures are performed at nearby surgery centers within the community. Patient demographics, diagnoses, procedural interventions, and telemedicine use closely resemble those seen at the Santa Monica UCLA Comprehensive Pain Center.

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For both the Santa Monica UCLA Comprehensive Pain Center and the UCLA Community Pain Clinics, patients are generally referred from their primary care or surgical providers. All pain management providers perform a thorough evaluation, including a history and physical, and review all the labs, imaging, and other pertinent data. Management may involve additional diagnostic studies, medication, multidisciplinary therapy, and interventional procedures. Patients already on opioid medication constitute a significant portion of the referrals. Given the opioid epidemic and US Centers for Disease Control and Prevention guidelines for opioid management, many prescribing physicians emphasize weaning opioid usage, especially for patients on more than 60 morphine milligram equivalents. If the pain management provider agrees to manage the patient's opioid regimen, regular follow-up is usually required every 4 weeks.

Data Sources

We extracted demographic data from the EMR for all video visit encounters within the anesthesiology pain division from August 1, 2019, to June 30, 2020. Telemedicine visits for patients residing in California were included for analysis. During the COVID-19 pandemic in California, a "Safer at Home" directive was ordered on March 18, 2020. Before the COVID-19 era, patients used telemedicine prior to the "Safer at Home" directive; during the COVID-19 era, patients had their first telemedicine visit for pain management following the directive.

To measure patient satisfaction, we used data from a patient satisfaction survey sent to patients after their video visit. UCLA Connected Health emails each patient a patient satisfaction survey after completion of their video visit. The survey has 11 questions with responses on a 5-point Likert scale and a section for comments. From March 24 to April 22, 2020, UCLA Connected Health transitioned its survey platform from REDCap (Research Electronic Data Capture) to Qualtrics; during this period, patient satisfaction surveys were not distributed, and no patient satisfaction survey data are available for this period. All survey responses from August 1, 2019, to March 23, 2020, and from April 23 to June 30, 2020, were included for survey analysis.

Intervention

The UCLA Comprehensive Pain Center implemented telemedicine for use in clinical care in July 2019, and we report on the period from August 1, 2019, to June 30, 2020. The UCLA Pain Division uses telemedicine for initial consultations, medication management, and postprocedural follow-up visits. In Textbox 1, we list our institution's telemedicine eligibility criteria.

Textbox 1. Clinical use cases of patients with pain who are offered a telemedicine video visit.

Clinical use cases for telemedicine:

- New patients for postoperative pain medication management
- New patients that have been referred by a spine surgeon for a specific injection
- Posthospitalization follow-up of patients
- Patients on medication management who need a medication refill or adjustment in medication
- Patients who need to discuss imaging results and next steps in their management
- Patients with recurrent pain who may need a repeat injection
- Postprocedural (ie, pain injection) follow-up of patients

Our group's clinical experience thus far with telemedicine is that it offers a convenient care delivery option to the patient and that, generally, adequate clinical assessments can be made during a telemedicine visit. In all telemedicine use cases, the need for an in-person physical exam is made on a case-by-case basis. An abbreviated physical examination is documented in the EMR. If the source or nature of pain is unclear during the telemedicine visit, the clinician may request for the patient to come for an in-person evaluation. Other reasons the clinician may request an in-person evaluation include the following: if physical examination is required by the patient's insurance company for procedural authorization, though many, including Medicare, do not require authorization for procedures; if there are concerning lesions on a patient's magnetic resonance imaging scan necessitating a more comprehensive physical examination; and if urine drug screening is requested, for instance, if a substance misuse disorder is suspected. Overall, in our experience, about 10% of telemedicine visits are converted to in-person visits.

For initial telemedicine consultations, the physician elicits a history from the patient, and an abbreviated physical exam is performed remotely by asking the patient to do certain maneuvers and eliciting feedback on pain in response to these movements. Further management is decided based on the history and the abbreviated physical examination. Should a procedure be recommended, a complete physical examination is performed in the preoperative area on the day of the procedure.

The UCLA Anesthesiology Pain Division also offers the option for telemedicine visits for medication management as an alternative to in-person visits. During a telemedicine visit for medication management, the patient provides the physician with an update regarding pain levels and functionality while on the current medication regimen and reports any adverse side effects associated with the medication regimen. The physician may review pertinent imaging and diagnostic studies or order additional studies and referrals. The physician also assesses for any aberrant drug-related behaviors and checks CURES (Controlled Substance Utilization Review and Evaluation System) reports before prescribing scheduled medications.

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Prescriptions are primarily e-scripted to the patient's preferred pharmacy, and patients are generally prescribed up to a 30-day supply of medication, with additional refills as appropriate.

Our institution has also used telemedicine for postprocedural follow-up. Depending on the procedure, patients are offered the option to follow up with their pain physician using telemedicine as early as 2 to 3 days to 3 to 4 weeks after the procedure. For patients who seek radiofrequency ablation, most insurance payors require two diagnostic medial branch nerve blocks to be completed with significant improvement (ie, >80% improvement in functionality and pain scale) before proceeding with radiofrequency ablation. This requires a follow-up evaluation between these staged procedures, for which we offer a telemedicine follow-up visit. For most other nonstaged procedures, procedure follow-ups can also be completed via telemedicine. During a postprocedural follow-up telemedicine visit, the clinician will inquire about any improvement after the procedure and any adverse side effects associated with the procedure. The patient will be asked to comment on improvement in functionality, if any, as a result of the procedure. The patient and the physician would discuss the next steps in clinical management, including medications, the potential for repeat procedures, additional procedures, and referrals to other specialists.

UCLA Health uses Vidyo videoconferencing software (Vidyo, Inc) for its telemedicine video visits. Telemedicine visits are scheduled within Epic, and providers log in to the video visit from the Epic clinic schedule. UCLA Health uses a mobile-only option for patients who use the Epic MyChart app (Epic Systems Corporation) on their smartphone or tablet to log in to the myUCLAhealth patient portal. After logging in to the Epic MyChart app, patients are prompted with a "begin visit" button at the top of the opening webpage. Patients wait in a virtual "waiting room" until the provider logs on to the video interface. Figure 1 illustrates the video interface for the telemedicine visits.

Figure 1. Representative illustration of the interface used for pain telemedicine visits at the UCLA Comprehensive Pain Center (© 2021 Epic Systems Corporation). UCLA: University of California, Los Angeles.

Outcomes and Definitions

We evaluated patient cost savings and satisfaction associated with telemedicine use in our patient population. To calculate patient costs saved by using telemedicine for care as opposed to an in-person visit, the patient's total cost for an in-person visit was estimated by calculating and totaling the total fuel cost for travel by car to a clinic visit, parking cost, and time-based opportunity cost, based on previously published methods [12,13]. The round-trip travel time and round-trip travel distance were calculated using each patient's originating zip code to that of their pain management clinic using Google Maps' Distance Matrix application programming interface (Google). Travel time with traffic was estimated by assuming afternoon telemedicine encounters beginning at 2 PM. Given that driving is much more common than the use of public transportation in the Greater Los Angeles Area [14], driving time was used to estimate travel time. To calculate the total travel fuel cost, we used the median value for regular fuel cost in California during the time period included in this study (US $3.42/gal) [15] and fuel economy (24.9 miles/gal) [16] among California vehicles. Day parking costs at the UCLA Medical Center Westwood, Santa Monica, and the community practices were US $13, US $20, and US $0, respectively, at the time of the study. To estimate the time-based opportunity cost for travel to an in-person visit, we calculated the patient's estimated earnings per hour based on their zip code, and then multiplied their estimated earnings per hour by their estimated round-trip travel time. To estimate patient earnings per hour by zip code, we used the Internal Revenue Service's Statistics of Income (IRS SOI) program's Individual Income Tax Statistics–2017 ZIP Code Data [17], which was the most recent data set publicly available. We adjusted for inflation from 2017 to 2020 US dollars using January data from the US Bureau of Labor Statistics' (BLS) Consumer Price Index [18].

To estimate patient earnings per hour by zip code based on the IRS SOI, total annual earnings within a zip code were first calculated as the sum of two income categories: (1) business or professional income and (2) salaries and wages. We defined earnings to include wages and income from running a business, a more comprehensive definition of labor earnings. In contrast, wages listed in employer databases do not reflect patients' income from running a business. For individual returns, annual earnings per person can be calculated by dividing total annual earnings by the number of individual returns within the zip code. For joint filings, earnings per person must be calculated by dividing total earnings by twice the number of filings, since

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each filing reflects two people's combined earnings. Within each zip code, annual earnings per person are calculated using a denominator that reflects the share of filings that were individual versus joint returns [19,20]. In particular, we used the following calculation to estimate annual earnings per person within each zip code:

> Annual earnings = the sum of average annual earnings / ([(2 × % married filing jointly) + % individual returns] × the total number of returns)

Finally, to estimate earnings per hour, we divided the estimated annual earnings per person by 2000 hours per year. We assumed 2000 working hours per year, which equals 40 hours per week times 50 weeks per year. This is similar to the annual work hours assumption used by the BLS when it estimates hourly wages from surveys of employers: the BLS uses an estimate of 2080 hours per year [21]. Notably, our estimate allows for a larger fraction of the patient population to be unemployed, out of the workforce, or working part time. To the extent that patients both earn less annually and work fewer hours per year than average, these factors may offset each other with respect to hourly earnings calculations.

To estimate the time-based opportunity savings, we multiplied the round-trip travel time by the patient's estimated hourly earnings by zip code; for this pain population, the median hourly earnings were US $28 per hour. Sensitivity analyses were conducted by varying the fuel cost (US $3.20-$3.80/gal), the median round-trip distance (5-200 miles), and the fuel economy (15-60 miles/gal) to characterize the range of travel costs, round-trip travel distance, and hourly earnings. A subset of our patients had serial visits for chronic pain management, and we conducted a sensitivity analysis varying hourly earnings and number of visits to understand savings with telemedicine over chronic care management.

Patient characteristics and study variables were summarized using mean (SD), median (IQR), or frequency (%), unless otherwise noted, using the Python programming language (Python Software Foundation [22]). In order to summarize the distribution of each of our patient characteristic variables or outcome variables, we first assessed the distributions visually. For variables that were approximately normally distributed, we used mean and SD as our summary statistics. For variables that had a skewed distribution, we elected to use median and IQR. Statistical comparisons between groups (ie, patients from the pre–COVID-19 era and those from the COVID-19 era) were assessed using the independent-samples *t* test for continuous variables (2-tailed) and the chi-square test for categorical variables (eg, gender and race). *P* values less than .05 were considered statistically significant.

Ethical Considerations

Institutional Review Board (IRB) approval was obtained but given exempt status for the purposes of analyzing and retrospectively reporting our results for quality improvement (IRB #20-000573).

Results

Demographics

We completed 2948 telehealth video visits with 1398 patients. The mean age of the total patient sample was 56 (SD 16) years. Patients from the pre–COVID-19 era were, on average, younger than patients from the COVID-19 era (52 [SD 14] years vs 56 [SD 16] years, respectively; *P*<.001). There was no significant difference in the distribution of race between cohorts from the pre–COVID-19 era and the COVID-19 era. Additional patient demographic characteristics are presented in Table 1.

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Table 1. Demographic characteristics of patients who completed a video visit within the anesthesiology pain division between August 2019 and June 2020.

Characteristic	All patients from completed encounters (N=1398)	Patients from pre–COVID-19 era (n=219)	Patients from COVID-19 era (n=1179)	*P* value[a]
Video visits, n (%)[b]	2948 (100)	511 (17.3)	2120 (71.9)	N/A[c]
Age (years)				
Mean (SD)	56 (16)	52 (14)	56 (16)	<.001
Median (IQR)	57 (44-67)	53 (43-62)	58 (45-68)	N/A
Gender, n (%)				
Male	545 (39.0)	84 (38.4)	461 (39.0)	.84
Female	853 (61.0)	135 (61.6)	718 (60.9)	
Round-trip travel time (minutes), median (IQR)	69 (46-101)	81 (52-113)	68 (44-99)	.002
Round-trip travel distance (miles), median (IQR)	26 (13-55)	28 (13-54)	26 (13-57)	.07
Earnings (US $/hour), median (IQR)	28 (21-39)	31 (22-44)	28 (21-37)	.03
Total savings per video visit (US $), median (IQR)	52 (36-75)	66 (49-108)	51 (31-74)	<.001
Self-reported race, n (%)				
White or Caucasian	1012 (72.4)	169 (77.2)	843 (72.0)	.54
Other race	142 (10.2)	18 (8.2)	124 (10.5)	
Black	107 (7.7)	13 (5.9)	94 (8.0)	
Declined to specify	51 (3.6)	7 (3.2)	44 (3.7)	
Asian	50 (3.6)	9 (4.1)	41 (3.5)	
Unknown	22 (1.6)	2 (0.9)	20 (1.7)	
American Indian or Alaska Native	10 (0.7)	0 (0)	10 (0.8)	
Native Hawaiian or other Pacific Islander	4 (0.3)	1 (0.5)	3 (0.3)	

[a]*P* values were based on statistical comparisons between groups, which were assessed using the independent-samples *t* test for continuous variables (2-tailed) and the chi-square test for categorical variables. *P* values for categorical variables are reported in the top row of that group.

[b]Percentages in this row only are based on the total number of video visits (N=2948).

[c]N/A: not applicable; statistical comparisons were not performed for "video visits" or median "age."

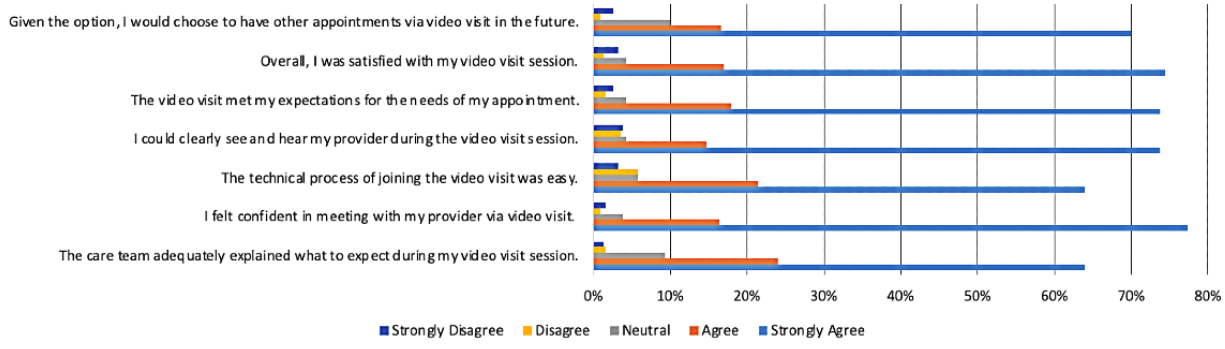
Telemedicine No-show Data

A total of 3006 telehealth video visits were scheduled for 1419 patients. Of 3006 scheduled telemedicine visits, there were 58 (1.9%) no-shows and 2948 (98.1%) successfully completed telehealth visits.

Patient Satisfaction Data

Of the 2192 video visit encounters for which a patient experience survey was emailed, there were 313 completed patient experience surveys (response rate of 14.3%). Patient satisfaction for using telehealth for pain management was high. Out of 313 survey responders, 286 (91.4%) either "agreed" or "strongly agreed" that they were satisfied with a video visit for care management, and 293 (93.6%) survey responders either "agreed" or "strongly agreed" that they felt confident in meeting with their provider via a video visit. Out of 313 survey responders, 271 (86.6%) said that they either "agreed" or "strongly agreed" that they would prefer future video visits for pain management care. We present the results of the patient experience survey in Figure 2.

Figure 2. UCLA Health telemedicine patient satisfaction survey results (n=313 surveys). UCLA: University of California, Los Angeles.



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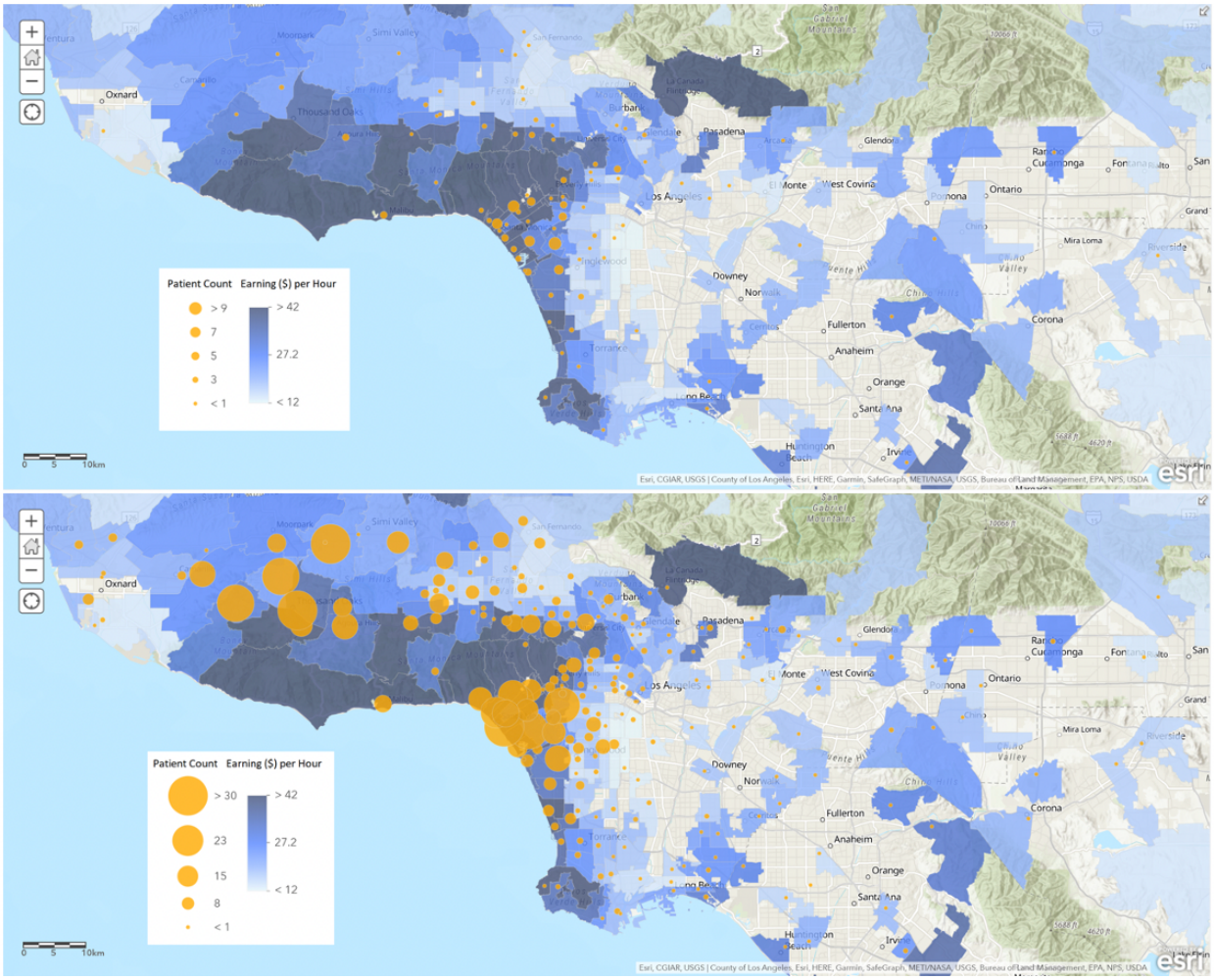
Travel Distance and Time Saved

As calculated from the patients' home zip codes to their pain providers' clinics, the median round-trip travel distance was 26 miles (IQR 13-51). The median round-trip travel time in afternoon traffic conditions was 69 minutes (IQR 46-101). Patients from the pre–COVID-19 era experienced longer travel times than patients from the COVID-19 era (P=.002). Figure 3 presents the geographical distribution of patients who participated in a telemedicine video visit.

Figure 3. Geographical distribution of patients from the pre–COVID-19 era (top image) and patients from the COVID-19 era (bottom image).



Patient Cost Savings With Telemedicine

We estimated direct and time-based opportunity savings that patients obtained from a telemedicine video visit. Patients experienced direct savings in fuel and parking costs. Our results suggest that patients experienced a median direct savings of US $22. Because differences in regional fuel cost, fuel economy, and distance traveled affect the total savings, we conducted sensitivity analyses by varying round-trip driving distance, fuel economy, and fuel prices per gallon (Figures S1 and S2 in Multimedia Appendix 1).

Patients also experienced time-based opportunity savings. Based on this cohort's zip code residence, their median hourly earnings were US $28 (IQR US $21-$39) per hour, with subsequent median time-based opportunity savings of US $32, bringing the estimated median total savings per telemedicine video visit to US $52 (IQR US $36-$75). Patients from the pre–COVID-19 era had higher hourly earnings (P=.03) and experienced greater estimated total savings than patients from the COVID-19 era (P<.001). Sensitivity analyses were conducted to reflect the value of a telemedicine encounter based on hourly earnings (Figure S3 in Multimedia Appendix 1). Patients who received serial telemedicine care had a median number of 3 visits and saved a median of US $156. We conducted a sensitivity analysis evaluating total savings for multiple telemedicine visits for chronic pain management care (Figure S4 in Multimedia Appendix 1).

Discussion

Principal Findings

This study examined telemedicine encounters within the anesthesiology pain division of an urban academic health care system and its affiliate community practices, both before and after implementing the COVID-19 "Safer at Home" order, focusing on patient savings and satisfaction. Patients who attended telemedicine visits avoided an estimated median round-trip driving distance of 26 miles and a median travel time of 69 minutes during afternoon traffic conditions. Within the sample, the median hourly earnings were US $28 per hour. Patients saved a median of US $22 on gas and parking and a

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total of US $52 per telemedicine visit based on estimated hourly earnings and travel time. Patients who were evaluated serially with telemedicine for medication management saved a median of US $156 over a median of 3 visits. Out of 313 patients surveyed, 91.4% (n=286) were satisfied with their telemedicine experience.

Study Strengths

We introduced our telemedicine program for all the patients seen in our health care system meeting our eligibility criteria, and not for a narrow subset of patients, improving the generalizability of our findings to a general pain management population. Inclusion in our study of patients seen in both academic and community-based practices also improved our findings' generalizability. Our study included a relatively high number of patients, making the findings more robust. Our use of IRS SOI data to estimate hourly earnings by zip code, rather than using citywide median incomes, likely strengthened the accuracy of our cost savings estimate.

Comparison With Prior Studies

Other studies have established the significant increase in telemedicine adoption since the beginning of the COVID-19 pandemic [23,24] as well as the high level of patient satisfaction with telemedicine visits [23]. Several studies have specifically examined the implementation of a telemedicine program for patients with chronic pain [7-9,25], some of which reported a high degree of patient satisfaction [7,8] and significant patient cost savings [8,9] as we found in our study, though measured in sample sizes totaling less than 50 patients. Pronovost et al [9] found a total patient cost savings per patient of US $310 more than we found in our study, though this was the cumulative savings that patients experienced longitudinally over months rather than with a single visit as we calculated; additionally, only patients with a travel distance greater than 100 kilometers were included, likely inflating travel costs for in-person visits. The telemedicine program introduced in Hanna et al [7] was only offered to a subset of patients living on an island, with the study's pain center only accessible by sea or air, possibly making patients more satisfied with telemedicine due to the lack of ease of access to in-person health care. Similarly, Peng et al [8] also reported satisfaction with telemedicine, but in a sample of patients with an average home-to-clinic travel distance of 314 kilometers, making the ease of telemedicine more pronounced in this population. Song et al [25] described telemedicine use for pain management during the COVID-19 pandemic as we did, but did not include any quantified metrics examining the benefit of telemedicine in this context. To our knowledge, ours was the only study that investigated differences in patient characteristics between those using telemedicine for chronic pain before and after the beginning of the COVID-19 pandemic.

Study Limitations

Our methods only took into account the use of cars as a transportation mode. We did not look at other means of transportation (eg, bus, ride-sharing, and flights) when calculating travel costs. Furthermore, ideally, our time-based opportunity cost analysis would quantify patient savings at the individual level. While our approach provided a more refined way of calculating time-based opportunity cost, our approach was limited in that even within a zip code, earnings varied for particular patients, and our method did not, therefore, perfectly capture patient earnings. Our time-based opportunity cost analysis also did not consider patients who may be unemployed, unable to work, or retired, which may represent hourly earnings of $0 per hour and for whom total savings may only reflect travel costs. We also compared the observational cohorts on a few characteristics that we could abstract from the EMR, leaving the potential for unmeasured confounding factors.

Study Implications

Patient savings are an essential component of the financial benefits of telemedicine. These savings should ideally be quantified at an individual patient level to reflect heterogeneous populations of patients with different opportunity costs associated with travel for in-person visits. Opportunity costs are typically estimated based on hourly wage rates or hourly earnings, but such individual income data are not collected by health systems. In this study, we estimated the earnings of our sample of patients with pain using a novel approach that used publicly available IRS SOI data, which allowed us to estimate hourly earnings by zip code. Earnings estimated based on patient zip codes are more accurate than using citywide or national median incomes or wages, which is the measure used in previous studies [12,26,27]. This is because earnings vary by geography, and people with similar incomes tend to cluster together geographically in particular zip codes. Medical centers in specific locations will often serve specific patient populations with higher or lower earnings than the citywide median wage or national averages; thus, a national or citywide median wage will tend to underestimate the earnings of a patient population living primarily in high-income areas and overestimate the earnings of a patient population living primarily in low-income areas. Our approach allows telemedicine's financial benefits to vary for different medical centers and different practice areas that serve populations with different income levels, facilitating a more accurate estimate of patient savings.

Our data suggest that patients who stood to benefit the most from adopting telemedicine—because they have higher hourly earnings and, therefore, higher time-based opportunity costs of in-person visits—were early adopters of telemedicine. Patients from the pre–COVID-19 era had higher total savings compared to the patients from the COVID-19 era ($P<.001$). Telemedicine offers value for patients in the form of time-based opportunity savings, especially for patients who must travel long distances, experience traffic, or have high time-based opportunity costs from missed work. A subset of patients had multiple video visits for medication management. Figure S4 in Multimedia Appendix 1 is a sensitivity analysis showing savings over serial telemedicine care, suggesting that telemedicine may provide a cost-effective means for obtaining continuity of pain management care.

Patient satisfaction as a measure of quality of care is also a key part of value-based care. It has been associated with the success of telemedicine initiatives [28], patient retention [29], and treatment plan adherence [30]. Our study revealed high patient satisfaction with telemedicine, with 86.6% of patients (271/313)

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responding that they would elect to use telemedicine again. As the pandemic abates, pain providers could consider developing a hybrid model of care using telemedicine and in-person visits.

Telehealth Sustainability for Pain Management and Future Challenges

Consensus recommendations from panels of adult chronic pain health professionals have identified the value of telemedicine to manage pain [31,32], but sustained telemedicine use by pain practices will be dependent on provider acceptance, a supportive reimbursement policy environment, and patient technical literacy. Pain clinicians will need to determine the right criteria for telemedicine and in-person care moving forward, and clinical practice guidelines and malpractice policies will need to be updated to incorporate telemedicine and remote monitoring [31]. The financial implications of telehealth for pain practices' overhead costs, including different staffing models and the need for office leases, will need to be understood in order to find areas for possible cost savings and revenue for practices [33]. Should telehealth continue to be a valued care delivery option for pain management, policy makers will need to expand reimbursement to promote high-volume telemedicine use, and quantifying patient cost savings could assist in policy development for reimbursement of telemedicine services [34]. Expanded reimbursement may include creating billing codes or payment models that take into account the additional work required to offer telemedicine visits, such as technical triage or having staff prepare patients for a telemedicine visit.

Finally, challenges with using telemedicine at the patient level have begun to come to light since the COVID-19 pandemic. Access to telemedicine involves different economic and social factors, and chronic and interventional patients will need access to telecommunications technologies [35] as well as the ability to use them effectively. Pain practices will need to understand their patients' technological literacy, their patients' limitations around access to the internet [36] and devices, and the characteristics of their patients who do not use telemedicine [37,38].

Conclusions

In this study, we aimed to describe the implementation and evaluation of our adult anesthesia pain division's standardized telemedicine practice guidelines for adult chronic and interventional patients with pain and to estimate total patient cost savings and satisfaction with telemedicine. We found that per visit, patients saved US $52, on average, taking into account both actual cost and time-based opportunity cost and that a high proportion of patients surveyed were happy with their telemedicine experience. Chronic pain causes significant suffering and a reduced quality of life, especially in the setting of a pandemic, but telemedicine provides efficient and cost-effective care to patients with chronic pain. Our telemedicine initiative was built on our academic hospital's comprehensive pain center and the community clinics' capacity to treat and care for patients with pain needs; our findings suggest that expanding the use of telemedicine for pain management may save patients time, reduce costs, and provide high patient satisfaction. Following the COVID-19 pandemic, we anticipate that telemedicine management for patients with pain will continue to evolve as health care systems strive to improve population health and improve care access for patients with pain needs.

Authors' Contributions

LJ created the study, wrote the IRB application, analyzed data, and wrote and reviewed the final manuscript. IW and JI created the study, obtained data, and wrote and reviewed the final manuscript. XD created figures for the manuscript. JS added supporting literature, created figures, and wrote and revised the final manuscript. GP obtained data and wrote and reviewed the final manuscript. HH and ET maintained the technical infrastructure of the program, obtained data, and helped write the final manuscript. TG provided methods guidance and statistical support and helped to write and review the final manuscript. MS provided methods guidance, helped write methodological sections of the manuscript, and helped to write and review the final manuscript. NK created the study and helped write the manuscript.

Conflicts of Interest

NK is a shareholder and medical advisor to HAI Solutions LLC and a shareholder and medical advisor to HeartCloud, Inc.

Multimedia Appendix 1
Sensitivity analyses.
[DOCX File , 197 KB - periop_v5i1e33926_app1.docx]

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Abbreviations

BLS: Bureau of Labor Statistics
CURES: Controlled Substance Utilization Review and Evaluation System
EMR: electronic medical record
IRB: Institutional Review Board
IRS SOI: Internal Revenue Service's Statistics of Income
REDCap: Research Electronic Data Capture
UCLA: University of California, Los Angeles

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Original Paper

A Canadian Weekend Elective Pediatric Surgery Program to Reduce the COVID-19–Related Backlog: Operating Room Ramp-Up After COVID-19 Lockdown Ends—Extra Lists (ORRACLE-Xtra) Implementation Study

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Abstract

Background: The COVID-19 pandemic caused by the SARS-COV-2 virus has resulted in unprecedented challenges for the health care system. A decrease of surgical services led to substantial backlogs for time-sensitive scheduled pediatric patients. We designed and implemented a novel pilot weekend surgical quality improvement project called Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).

Objective: Our overall goals are to increase patient access to surgery (and reduce the wait list), improve operating room efficiencies, and optimize parent and staff experience.

Methods: Using the DMAIC (define, measure, analyze, improve, control) framework, we implemented ORRACLE-Xtra in a tertiary care academic pediatric hospital during a quiescent period of the COVID-19 pandemic. We defined process and outcome measures based on provincial targets of out-of-window cases. Parental and staff satisfaction was tracked by surveys.

Results: ORRACLE-Xtra led to 247 patients receiving surgery during the pilot period, resulting in a 5% decrease in the total number of patients on our wait list with Paediatric Canadian Access Targets for Surgery IV (147/247, 59.5%), with 38.1% (94/247) out-of-window of provincial targets. Most of the process and outcome measures were met or exceeded. Overall parental satisfaction was at 95.8% (110/121), with 79% (64/81) of staff reporting satisfaction with working weekends.

Conclusions: Through the ORRACLE-Xtra pilot program, we have shown that hospitals impacted by COVID-19 can reduce the surgical backlog using innovative models of service delivery in a Canadian context. Sustained funding is critical to achieving more meaningful reductions in wait times for scheduled surgeries over the longer term and needs to be balanced with staff well-being.

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KEYWORDS

waiting lists; quality improvement; patient satisfaction; COVID-19; ambulatory surgery; pandemics; Canada

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Introduction

The COVID-19 pandemic caused by the SARS-COV-2 virus has resulted in unprecedented challenges for the health care system. In March 2020, the Canadian Province of Ontario's Ministry of Health (MoH) enacted a provincewide directive to decrease surgical services to preserve hospital capacity [1]. However, this directive led to significant backlogs for time-sensitive scheduled (elective) surgeries in adult and pediatric centers across Ontario with an impact on patients and families, similar to reports from other jurisdictions [2-5]. In children, surgical delays are a source of significant morbidity because of three key issues: timing of surgery has a critical impact on the growth and development of the child; treatable conditions may deteriorate over time because of the effects of growth; and excessive surgical wait times may result in the need to perform more complex surgeries than were initially planned, leading to an increase in avoidable complications [5-9].

Due to the mandated reduction in surgical activity, the surgical wait list at our institution increased by 29% from 3799 (December 2019) to 4915 patients by the end of December 2020. This increase was despite a successful increase in surgical activity from July 2020. The Paediatric Canadian Access Targets for Surgery (P-CATS) use diagnosis-based categories to define time-based targets (windows) for completing scheduled pediatric surgeries [10]. During the COVID-19 pandemic, between March and December 2020, PCATS-defined out-of-window rates for cases on our surgical wait list increased from an already high rate of 44% to 58%. Using novel machine learning algorithms, we demonstrated that even on resuming our usual level of surgical activity the surgical wait list would not decrease without a substantial increase in resources. In resource-constrained environments, more medically urgent procedures may gain preferential access to the operating room (OR), which leads to a virtual two-tiered wait list system where lower acuity day-case procedures have further increased in wait times. By December 2020, our out-of-window rates for day-case surgical procedures exceeded 60% and increased at a faster rate than those of higher complexity surgeries.

Following the resumption of scheduled care, the MoH provided additional targeted funding for 3 months (January to March 2021) to address the surgical backlog. At our institution, despite additional funding, limited health human resources and OR real estate prevented an increase in scheduled surgical activity hours during our typical Monday to Friday workweek. In addition, we calculated that any attempt to increase the proportion of day-case surgical activity during the weekday schedule would serve to overwhelm the limited postanesthesia care unit (PACU), causing bottlenecks. These bottlenecks would reduce OR access to more medically urgent and complex cases. Thus, we recognized that an innovative program would be required to increase surgical activity above historical norms, specifically target low-acuity day-case procedures, and ultimately reduce the surgical backlog. In response to the MOH funding initiative and respecting our human health resources and physical capacity limitations, we designed and implemented a novel pilot weekend surgical program called Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).

This pilot QI project aimed to assess the feasibility of efficiently reducing the number of patients on the surgical wait list by scheduling elective surgeries on the weekends with a high level of satisfaction among participating parents and providers.

Methods

Objectives and Aims

We aimed to efficiently reduce patients on the surgical wait list by scheduling elective surgeries on the weekends. By opening six dedicated ORs for scheduled surgery on each of the 12 weekends between January 9 and March 28, 2021, we targeted a 5% reduction in the surgical backlog (250 children) based on previous modelling using machine learning predicting anesthesia and surgical times along with nursing staff availability. In addition, the entire weekend scheduled surgery program was considered entirely separate from the regular emergency surgical service that ran in parallel within the same OR complex.

The secondary aim was to evaluate the process and outcome measures we defined as integral to the program's success and long-term establishment. Given that our institution had not previously performed scheduled weekend surgeries, this program also provided us with an opportunity to pilot novel processes that could potentially increase OR efficiencies during the typical weekday schedule. We aimed to compare process measures, including the number of scheduled cases completed, rate of same-day cancellations, rate of preanesthesia fasting violations, the proportion of on-time starts (8 AM and 8:15 AM), operational block use, and room turnover times. Finally, we aimed to assess caregiver satisfaction and provider satisfaction of participating in the weekend program.

The project was designed using the DMAIC (define, measure, analyze, improve, control) methodology of Lean QI. The DMAIC methodology is a Six-Sigma data-driven improvement cycle designed to identify and address inefficiencies in a process, improve process outcomes, and make these improvements more predictable over time [11-13]. We chose this technique as it allowed us to improve our processes rapidly and iteratively over the 12-week pilot phase.

Ethic Approval

We obtained institutional approval from the Hospital for Sick Children for this quality improvement project (QIP-2021-01-08).

Governance and Principles of ORRACLE-Xtra

The ORRACLE-Xtra steering committee was established and consisted of surgical, anesthesia, and OR nursing leadership who identified a series of guiding principles for the weekend program (Textbox 1) and patient selection criteria (Multimedia Appendices 1 and 2).

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Textbox 1. Guiding principles and rationale of the Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra) pilot program.

Maximize reduction in the number of patients on the wait list

Demonstrate beneficence and utility for efficient use of limited Ministry of Health funding

Target surgical divisions with the largest wait list, including high numbers of day cares

Demonstrate beneficence and utility for efficient use of the limited Ministry of Health fund

Target out-of-window cases

Aim for equity in case selection by prioritizing cases with longest waits as per standardized Paediatric Canadian Access Targets for Surgery–recommended wait times

Low acuity surgeries

Achieve high throughput per surgical list to minimize complex logistics and variability in case length, and reduce the likelihood of needing inpatient stay

Clearly defined case selection criteria

Equity in case selection, minimize day-of-surgery cancellations, increase operational efficiency

Minimize the need for inpatient admissions

Avoid increasing bed census over weekend in pandemic-related already resource-constrained environment, minimizing number of extra nursing staff required to run the weekend program

Separate ORRACLE staffing and logistics from the regular weekend emergency surgical team (no crossover of resources)

Reduce risk of scheduled surgery cancellations due to sharing or competing for same perioperative human health resources

Minimize number of required specialist technical services and staff (eg, pathology)

Ensure cost-effective program, minimizing the number of volunteer staff required to be present to run the weekend program

Promote an efficient team-based approach (same operating room nurse, anesthetist, recovery nurse, and support staff per each operating room)

Optimize surgical list efficiency and promote team well-being, camaraderie, and morale

Staff free to go home when the last case has finished

Provide an incentive for increased operating room efficiency

The steering committee met weekly and, using the DMAIC process, reviewed the operative cases, operational metrics, logistical challenges, and opportunities for improvement from the previous weekend (Multimedia Appendix 3). Due to pandemic restrictions on in-person meetings, we used a combination of online meetings and email for discussion, data analysis, and decision-making (Multimedia Appendix 4).

Following discussion and consensus, we identified process and outcome measures for the ORRACLE-Xtra program (Multimedia Appendix 5). To provide a data-driven approach as per DMAIC, we designed and implemented dashboards that summarized outcome measures in real time. We integrated the dashboards into our electronic health record system, Epic and Power BI (Microsoft Corporation). The Epic dashboard depicted patient health information linked to patient records, procedures, and date of surgery (Figure 1 and Multimedia Appendix 5). The PowerBI dashboards continually illustrated operational efficiency metrics such as OR start times, room turnover times, surgical case length, preanesthesia fasting violations, and tracked changes in the surgical wait list (Figure 1). We determined baseline using data from the prepandemic period. To collect caregiver and provider experience and satisfaction with the program, we used an online REDCap-based survey delivered by email within 24 to 48 hours after surgery [14].

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Figure 1. Dashboards used to inform data-driven decisions for Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra). Panel A shows the Epic dashboard depicting real-time patient and operational information. Panel B shows the PowerBI dashboard depicting ORRACLE-Xtra process outcome measures.

Staff Eligibility

Using regular department communication channels, we sent volunteer calls to anesthesiologists, nurses, surgeons, OR attendants, admission clerks, and equipment processing personnel to staff and support the weekend-scheduled surgical lists. As a result, we ran up to six ORs each weekend (three on Saturday, three on Sunday). Once we confirmed the required staff for each surgical list, we identified patients who met specific case selection criteria. All staff were compensated for their time.

Patient Eligibility

Patients suitable for the weekend program were identified from the existing surgical waitlist using clear selection criteria developed by the steering committee (Multimedia Appendix 2). The overarching principle used was to identify medically stable patients who required low-complexity short surgical procedures. These patients could be discharged home from the PACU without requiring an inpatient bed. In addition, these patients should have long surgical wait times as defined by P-CATS and the provincial out-of-window status. The case selection criteria were distributed to each surgical service to assist with patient selection.

Data Analysis

Using the Canadian Pediatric Perioperative Outcomes National Datalake dictionary, data was extracted from Epic and imported into Excel (Microsoft Corporation) for analysis. We used descriptive statistics to summarize the data. Continuous variables were depicted as mean (SD) values and categorical variables as numbers (proportions). This quality improvement project is

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reported according to the SQUIRE 2.0 (Revised Standards for Quality Improvement Reporting Excellence) checklist [15].

Results

Demographics

A total of 247 patients received surgery during the ORRACLE-Xtra pilot period, resulting in a 5% decrease in the total number of patients on our surgical wait list (Table 1). Of the 247 patients, 94 (38.1%) patients were female. The mean age was 5.9 (SD 4.6) years. Patients were most commonly American Society of Anesthesiologists 1 (n=209, 84.6%) and P-CATS IV priority (n=147, 59.5%), with 38.1% (n=94) being out-of-window per provincial targets. Patients travelled from across the province (Figure 2). Surgical teams from five surgical services—plastic surgery, urology, dentistry, ophthalmology, and otolaryngology (Table 2)—performed over 37 procedures (Table 3). A total of 228 hours of surgical time and 245.4 hours of anesthesia time were used. A total of 133 staff volunteered to work these extra weekend lists. The distribution of the staff working these shifts provided is shown in Multimedia Appendix 6.

Table 1. Patient characteristics.

	Plastics	Urology	Dentistry	Ophthalmology	Otolaryngology	Total
Age (years), mean (SD)	7.22 (5.5)	5.39 (3.4)	2.95 (1.2)	7.22 (5.0)	9.22 (5.3)	5.91 (4.6)
Sex, n (%)						
Female	50 (56.3)	0 (0.0)	26 (46.6)	23 (43.4)	5 (45.4)	95 (38.5)
Male	31 (43.7)	54 (100.0)	31 (53.4)	30 (56.6)	6 (54.5)	152 (61.5)
Cases performed, n	71	54	58	53	11	247
Blocks used, n	14	12	12	14	4	56
Surgical hours used, n	58.62	45.80	49.90	53.95	19.70	227.97
P-CATS[a], n (%)						
II[a]	0 (0.0)	0 (0.0)	0 (0.0	1 (1.9)	0 (0.0)	1 (0.4)
III	1 (1.4)	0 (0.0)	3 (5.2)	3 (5.7)	0 (0.0)	7 (2.8)
IV	11 (15.5)	39 (72.2)	55 (94.8)	38 (71.7)	4 (36.4)	147 (59.5)
V	57 (80.3)	6 (11.1)	0 (0.0)	11 (20.8)	0 (0.0)	74 (30.0
VI	2 (2.8)	9 (16.7)	0 (0.0)	0 (0.0)	7 (63.6)	18 (7.3)
ASA[b], n (%)[c]						
1	62 (88.6)	51 (94.4)	51 (87.9)	35 (66.0)	9 (81.8)	208 (84.6)
2	8 (11.4)	3 (5.6)	5 (8.6)	17 (32.1)	1 (9.1)	34 (13.8)
3	0 (0.0)	0 (0.0)	2 (3.4)	1 (1.9)	1 (9.1)	4 (1.6)
Provincial WTIS[d,e]						
Within target	57 (80.3)	14 (25.9)	52 (89.7)	22 (41.5)	8 (72.7)	153 (61.9)
Beyond target	14 (19.7)	40 (74.1)	6 (10.3)	31 (58.5)	1 (27.3)	94 (38.1)

[a]P-CATS: Paediatric Canadian Access Targets for Surgery.

[b]ASA: American Society of Anesthesiologists.

[c]Missing data: plastics n=1.

[d]WTIS: Wait Time Information System.

[e]Takes into consideration dates affecting readiness to treat (n=25).

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Figure 2. The provincewide distribution of patients presenting for Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).

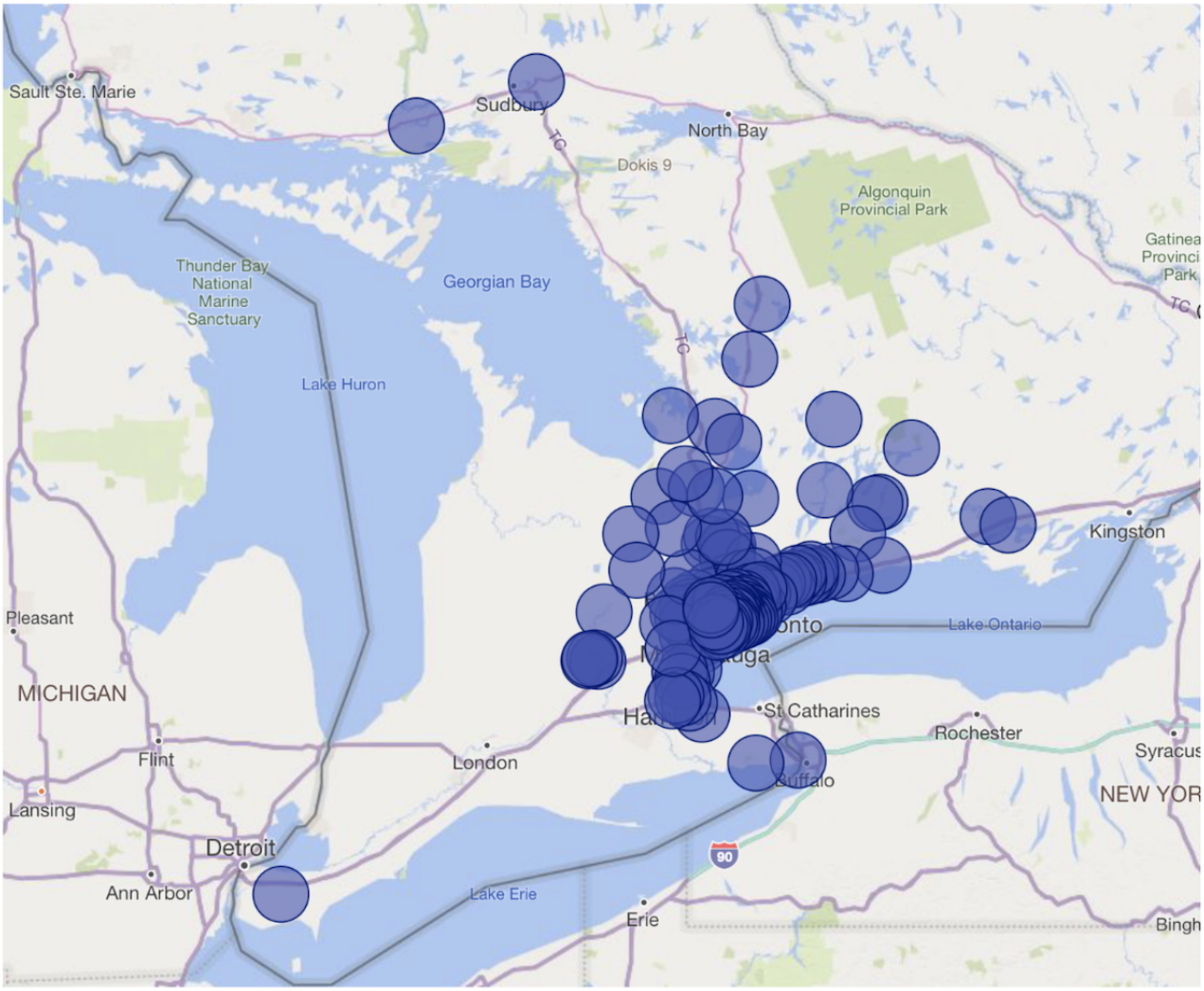

Table 2. Surgical services and cases performed during Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).

	Plastics	Urology	Dentistry	Ophthalmology	Otolaryngology	Total, n
Cases performed, n (%)	71 (28.7)	54 (21.9)	58 (23.5)	53 (21.5)	11 (4.5)	247
Surgical blocks used, n (%)	14 (24.6)	12 (21.1)	12 (22.8)	14 (24.6)	4 (7.0)	56
Surgical hours, n (%)	58.6 (25.7)	45.8 (20.0)	49.9 (21.9)	54.0 (23.7)	19.7 (8.6)	228.0
Postoperative destination, n (%)						
Home	71 (100.0)	54 (100.0)	58 (100.0)	53 (100.0)	7 (63.6)	243 (98.4)
Inpatient unit	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (36.3)	4 (1.6)
Room turnover time (minutes), mean (SD)	21.5 (13.9)	21.7 (14.0)	22.5 (13.8)	27.1 (14.1)	25.4 (12.0)	23.1 (13.8)

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Table 3. Procedures performed during the Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra) pilot program.

Procedure	Cases, n (%)
Plastics	
Amputation sixth digit/polydactyly excision	6 (8.5)
Coleman fat transfer/fat injection	2 (2.8)
Cyst/lesion/skin tag excision	30 (42.3)
Duplicated digit reconstruction	1 (1.4)
Excisional biopsy	3 (4.2)
Hemagioma/mixed capillary and lymphatic malformation excision	4 (5.6)
Nervus excision	2 (2.8)
Plate and screw removal	1 (1.4)
Scar tissue revision	4 (5.6)
Setback otoplasty (5 bilateral, 1 unilateral)	6 (8.5)
Subungual exostosis excision	1 (1.4)
Tongue tie release	1 (1.4)
Trigger finger/thumb release	10 (14.1)
Urology	
Hydrocele repair	7 (13.0)
Orchidopexy	45 (83.3)
Orchiectomy	1 (1.9)
Penoplasty	1 (1.9)
Dentistry	
Dental extraction	1 (1.7)
Dental extraction and restoration	32 (55.2)
Dental restoration	25 (43.1)
Ophthalmology	
Botulinum injection	1 (1.9)
Cataract extraction	2 (3.8)
Conjunctival biopsy	3 (5.7)
Corneal crosslinking/revision	4 (7.5)
Entropion repair	2 (3.8)
Electroretinogram/retcam/fluorescein angiogram	6 (11.3)
Eyelid dermoid excision	1 (1.9)
Myectomy	1 (1.9)
Nystagmus surgery	1 (1.9)
Orbital dermoid cyst excision	3 (5.7)
Ptosis repair	4 (7.5)
Strabismus repair, rectus recession (6 bilateral, 8 unilateral)	14 (26.4)
Tear duct probe	11 (20.8)
Otolaryngology	
Cochlear implant (1 bilateral, 2 unilateral)	3 (27.3)
Fess, polypectomy, maxillary enterostomy, ethmoidectomy, sphenoidotomies, frontal, sinusotomy (bilateral)	1 (1.9)
Tympanoplasty	7 (63.6)

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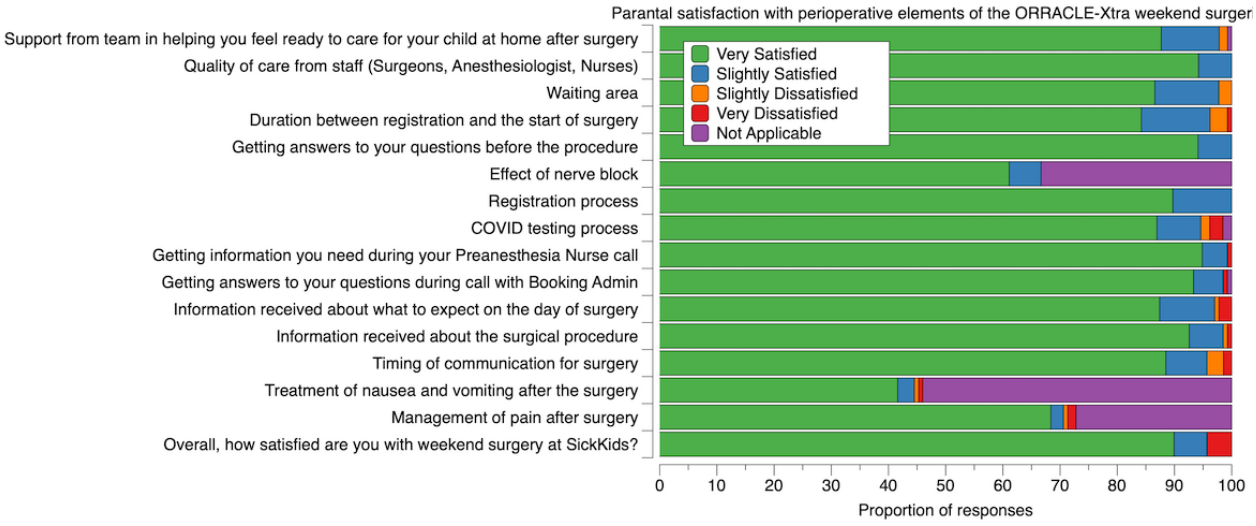
Outcome Measures

Outcome measures were met or exceeded in almost all instances (Table 4). Over 98% (247/250) of planned cases were completed. Preanesthesia fasting violations occurred at just 1.2% (target <15%) and lower than the concurrent monthly rate of 3.5%. Over 95.1% (235/247) of cases were completed in less than 100 minutes of surgical time (target >90%). Over 63% of blocks ended early (target 5%). In addition, 66.7%, (165/247) of surgical cases started on time (target of 85%). The mean room turnover time was 23.1 minutes (target of 31 minutes). Overall parental satisfaction was 95.8% (110/121 parent/guardian respondents; Figure 3). Challenges identified in the preprocedure areas from parental surveys led to immediate changes outlined in Multimedia Appendix 3. Of the 81 staff, 64 (79%) responding to the staff survey reported satisfaction from working on the weekend. All staff mentioned some concerns of potential burnout from working on the weekend.

Table 4. Process and outcome measures from the Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra) pilot program.

Measure	Expected	Actual
Completed cases, n	250	247
Scheduled cases completed (%)	97	95.74
Cancelled cases (%)	3	4.26
Cases under 100 minutes (%)	90	95.5
Preanesthesia fasting violation (%)	15	1.21
On-time starts (8 AM; %)	85	66.67
On-time starts (8:15 AM; %)	90	94.74
Operational block use (%)	75	79.17
Early block finish (%)	5	63.16
Late block finish (%)	10	1.75
Timely turnover (%)	90	88.66
Parental satisfaction (%)	80	95.87
Staff satisfaction (%)	80	79.01

Figure 3. Parental experiences and satisfaction from Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).



Discussion

We have shown that it is possible to establish a highly efficient weekend surgical day care model in a tertiary care pediatric hospital that can run alongside a regular weekend emergency service without interruption. ORRACLE-Xtra either met or exceeded all operational targets with low cancellation rates or preanesthesia fasting violations [16]. In addition, we found that case throughput per list and operational efficiencies were superior to those seen during the weekdays. As such, we believe that this pilot program lends itself favorably to being a sustainable model for health care delivery in the future.

The short surgical time and subsequent rapid turnover time were quicker than comparable lists during the week. However, this seemingly positive finding led to unintended consequences. The preoperative processes of each surgical list were broadly based on typical timings seen during weekday surgery. However, due to more rapid OR turnovers experienced on the weekend, the

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OR called subsequent patients on each list sooner than planned yet were not ready due to incomplete preoperative check-ins and fasting status. Using DMAIC, we were able to identify this problem early in the program and address it by using a preoperative flow coordinator to ensure timelier check-in of patients, particularly during the early part of the day when congestion was at its peak. As a result, predicted surgical booking times were adjusted in line with actual times, and more cases were scheduled for each list. Standard preanesthesia fasting times were also extended to account for a faster turnover of surgical cases.

In addition, due to the unexpected rapid OR throughput, the PACU was filled with postoperative patients. On occasion, the PACU could not accept subsequent patients who had completed surgeries resulting in further delays in subsequent surgeries on the list. We addressed this problem by altering the PACU staffing model to ensure more nursing availability earlier in the day to facilitate receiving more children at one time.

As operational efficiencies improved throughout this pilot program, many surgical lists finished well before the planned end-of-day allowing the surgical and nursing team to leave early (in contrast to our typical weekday workflow of reassigning teams to other areas). This had the effect of improving team morale, as reported on our provider satisfaction survey. We considered this an important finding, particularly as all staff joined the program voluntarily, and as such, we believe it helped stimulate further sign-up for future weekend lists. In addition, similar efficiencies could be realized on weekdays following similar staffing and scheduling approaches.

We also found that we could not schedule as many out-of-window cases as planned (only 38% of cases out-of-window). This meant that the overall out-of-window rate on our overall wait list did not appreciably change, given the small pilot and difficulties in bringing such children for surgery. Many families, already having waited a long time for surgery, were now reluctant to attend for surgery during the ongoing pandemic and elected to postpone until the pandemic was over. Alternatively, we found that those children who had participated in a primary assessment during the pandemic and were listed for surgery (in-window) were more willing to accept a surgical date [2]. This could be explained in part to a different risk tolerance for scheduled care during this unprecedented time. Further efforts need to be made to ensure equity of access to provide care for those children who have already experienced excessively long surgical wait times.

Over 95% of parents were satisfied with the care provided over the weekend with consistency across all surgical services. As a tertiary institution, our patient catchment area is spread across the entire province of Ontario and therefore is a sizable geographical area. However, the weekend surgeries did not appear to be a barrier to access for weekend surgery as patients from areas that are 6- to 8-hour drives away presented for a weekend surgery. Indeed, families who travelled from outside of the Greater Toronto Area commented that the hospital was more accessible on the weekend due to reduced transit time and reduced need for caregivers to take time away from work. Over 79% of staff reported being satisfied with working on the weekend. Working in this program on the weekends gave teams a sense of accomplishment and community by helping with the surgical backlog. However, some negative impact on workload and well-being was reported by nursing staff, particularly given that weekend work was in addition to the regular work schedule and thus impacted work-life balance. Administrators will need to carefully consider the overall effect of increased service from a finite pool of health care providers, with a focus on well-being.

An added benefit of using the DMAIC process to run a well-defined pilot scheduled weekend surgical project was that we were able to identify several critical improvements in service delivery. These improvements could be implemented on regular weekdays and lead to more substantial reductions in the surgical backlog:

- Fixed care teams using a designated anesthesiologist, surgeon, OR nursing, PACU nursing access, and support staff for each room improved room flow, efficiency, and throughput.
- The concept of the entire team being free to finish their shifts on completion of the list was an incentive for efficient case turnover.
- Performing more day-case surgery on the weekends may allow increased access for more medically complex surgical cases during the weekday, thus benefiting all surgical divisions and patients under the care of perioperative services.
- When provided more human resources, it will be possible to leverage empty OR complexes and unused inpatient capacity on the weekends. This allows us to scale the program to offer an even greater scope and volume of surgical activity to reduce the surgical wait list and backlog more rapidly.

In conclusion, through the ORRACLE-Xtra pilot program, we have shown that hospitals impacted by COVID-19 can use targeted MoH funding to reduce the surgical backlog associated with the COVID-19 pandemic via the use of innovative models of service delivery. In addition, sustained institutional funding to expand the perioperative workforce is critical to achieving more meaningful reductions in wait times for scheduled surgeries over the longer term. Our institution and other pediatric institutions may find the information herein helpful for regular weekday work and future pandemics.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Composition of the Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra) Steering Committee.
[DOCX File , 14 KB - periop_v5i1e35584_app1.docx]

Multimedia Appendix 2
Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra) patient selection criteria for weekend elective surgery.
[DOCX File , 14 KB - periop_v5i1e35584_app2.docx]

Multimedia Appendix 3
Decisions made throughout the 12-week pilot phase.
[DOCX File , 21 KB - periop_v5i1e35584_app3.docx]

Multimedia Appendix 4
Schedule of meetings held throughout the 12-week pilot of Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).
[DOCX File , 15 KB - periop_v5i1e35584_app4.docx]

Multimedia Appendix 5
Process and outcome measures for Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).
[DOCX File , 14 KB - periop_v5i1e35584_app5.docx]

Multimedia Appendix 6
Characteristics of staff volunteering for Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists (ORRACLE-Xtra).
[DOCX File , 14 KB - periop_v5i1e35584_app6.docx]

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Abbreviations

DMAIC: define, measure, analyze, improve, control
MoH: Ministry of Health
OR: operating room
ORRACLE-Xtra: Operating Room Ramp-Up After COVID Lockdown Ends—Extra Lists
PACU: postanesthesia care unit
P-CATS: Paediatric Canadian Access Targets for Surgery
SQUIRE 2.0: Revised Standards for Quality Improvement Reporting Excellence

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Original Paper

Influence of the COVID-19 Pandemic on Clinical Trial Discontinuation in Anesthesiology: Cross-sectional Analysis

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Abstract

Background: The COVID-19 pandemic drastically altered perioperative medical practice owing to safety concerns, postponing elective or nonemergent procedures, supply chain shortages, and reallocating perioperative staff to care for patients with COVID-19. However, the impact of the pandemic on the conduct on anesthesiology clinical research is unknown.

Objective: The primary objective was to quantify the magnitude of the COVID-19 pandemic's impact on anesthesiology clinical research.

Methods: We performed a systematic search using ClinicalTrials.gov to identify clinical trials related to the practice of anesthesiology. We screened trials with status updates from January 1, 2020, through October 1, 2021, to capture trials potentially affected by the COVID-19 pandemic by the time of our search. Investigators screened for relevant studies and extracted trial characteristics along with the reason for discontinuation reported on the clinical trial registry.

Results: A total of 823 clinical trials met inclusion criteria, and 146 clinical trials were discontinued within the designated date range. In total, 24 (16.4%) of the 146 clinical trials were halted explicitly owing to the COVID-19 pandemic. A significant association existed between trial enrollment numbers and the likelihood of discontinuation due to the COVID-19 pandemic, as larger trials were more likely to be disrupted (z=–2.914, P=.004).

Conclusions: The COVID-19 pandemic is reportedly associated with the discontinuation of anesthesiology-related clinical trials. With the uncertain course of the COVID-19 pandemic, developing anesthesia trial protocols to help minimize social interaction and prevent premature trial disruption are imperative.

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KEYWORDS

clinical trials; anesthesia; anesthesiology; COVID-19; pandemic; perioperative care; lockdown

Introduction

Clinical trials are at the forefront of modern medicine and evidence-based care, as they provide novel diagnostic tools and interventions for a variety of conditions [1-3]. Unfortunately, the COVID-19 pandemic has significantly disrupted clinical trial conduct and hindered trial accessibility and overall development owing to public safety measures including

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lockdowns and mandatory closures [4-6]. Moreover, updated guidelines from the US Food and Drug Administration (FDA) encouraged trialists to carefully consider whether to continue studies in light of risks associated with the COVID-19 pandemic and to either accommodate trial design to mitigate risk or to discontinue studies indefinitely [7,8]. Clinical trialists also faced recruitment difficulties during the pandemic, as referring physicians were reallocated to assist with pandemic efforts [9]. The surgical specialties have also been impacted, as many procedures deemed elective or nonemergent were canceled, thereby reducing time in the operating room [9]. Changes to clinical practice during the pandemic had direct consequences on the conduct of clinical trials [5].

Anesthesiologists have played a vital role in the COVID-19 pandemic response, specifically regarding airway management and ventilatory support [10]. Many patients with COVID-19 develop profound hypoxemia, pulmonary infiltrates, and altered lung function requiring intubation and ventilatory support [11]. A multicenter study conducted over 3 months reported that over 80% of patients with confirmed COVID-19 were intubated [11]. Owing to increased aerosolization of respiratory secretions during bag-mask ventilation, many institutions have implemented rapid sequence induction for all patients requiring ventilatory support to prevent the potential spread of COVID-19 [12,13]. As the pandemic continued, the number of patients requiring intubation—along with prolonged intubation times—increased significantly, leading to ventilator shortage [14]. Moreover, the increased demand for anesthetic equipment required for intubation has led to a downstream shortage of supplies for elective cases, placing patients who do not have COVID-19 at a disadvantage to receiving adequate care [15]. The clinical practice of anesthesiologists changed drastically during the pandemic [16], and together with the aforementioned changes in clinical trial conduct, it is likely that ongoing anesthesiology clinical trials were disrupted during the pandemic. Given the important role of perioperative medicine, anesthesiologists will continue to rely on findings from clinical trials to stay up to date with novel interventions and therapies, and interruptions to clinical research may have important implications. Therefore, the primary objective of this study is to highlight the impact of the COVID-19 pandemic on the progress of clinical trials related to anesthesiology.

Methods

Search Strategy

We conducted a systematic search of ClinicalTrials.gov, an international registry of both privately and publicly funded clinical studies, for trials related to anesthesiology on October 2, 2021 [17]. Our search string included the following terms: *Anesthesia*, *Anesthesiology*, *Anesthesiologist*, *General Anesthesia*, *Standard Induction of General Anesthesia*, *Mask Ventilation*, *Laryngeal Mask Airway*, *Monitored Anesthesia Care*, *Endotracheal Intubation*, *Awake Fiberoptic Intubation*, *Left-sided Double Lumen Tube*, *Wire Cricothyroidotomy*, *Spinal Anesthesia*, *Lumbar Epidural*, *Regional Anesthesia*, and *Peripheral Nerve Block*. To retrieve all trials potentially impacted by the COVID-19 pandemic, we used the date range of January 1, 2020, through October 1, 2021. The search string is presented in Textbox 1.

Textbox 1. Search string for clinical trials.

ClinicalTrials.gov:

Anesthesia OR Anesthesiology OR Anesthesiologist OR General Anesthesia OR Standard Induction of General Anesthesia OR Mask Ventilation OR Laryngeal Mask Airway OR Monitored Anesthesia Care OR Endotracheal Intubation OR Awake Fiberoptic Intubation OR Left-Sided Double Lumen Tube OR Wire Cricothyroidotomy OR Spinal Anesthesia OR Lumbar Epidural OR Regional Anesthesia OR Peripheral Nerve Block | Recruiting, Active, not recruiting, Enrolling by invitation, Suspended, Terminated, Withdrawn Studies | Interventional Studies | Phase Early Phase 1, 1, 2, 3, 4 | Last update posted from 01/01/2020 to 10/01/2021

Eligibility Criteria

Trials were included on the basis of the following criteria: (1) the study is relevant to the clinical practice of anesthesiologists for use in perioperative care including induction, sedation, emergence, analgesia, hemodynamic stability, oxygenation, pain management, and complications secondary to anesthetic methods; (2) the study is interventional in nature; (3) the study status is ongoing (recruiting, active but not recruiting, enrolling by invitation) or discontinued (suspended, withdrawn, or terminated); and (4) the study is in any phase (I, II, III, and IV). Trials that did not meet all of the inclusion criteria were excluded from the analysis.

Data Extraction

Resulting trials from the search strategy were extracted for trial status, condition treated, enrollment number, funding, study type, study design, last update posted date, and trial location. We screened trials for relevance to the field of anesthesiology in accordance with the "conditions treated." Any studies irrelevant to the field were excluded. Two authors (BT and BR) extracted reasons for discontinuation provided on the ClinicalTrials.gov website in a blinded, duplicate manner. Trials that explicitly stated "COVID-19" in the "Recruitment Status" box on ClinicalTrials.gov as a reason for discontinuation were coded as such. We additionally extracted trial intervention of these studies. Trials that failed to mention the COVID-19 pandemic as a reason for discontinuation were coded for the reason provided. Trials that did not specify a reason for discontinuation were coded as "not provided."

Statistical Analysis

To determine any significant differences in enrollment between trials discontinued owing to the COVID-19 pandemic versus all other discontinued trials, we used a Mann-Whitney *U* test, which was the preferred test because enrollment numbers were nonnormally distributed among our sample trials. Fisher exact tests were used to determine associations between trials halted owing to the COVID-19 pandemic with the funding source and trial location (US-based and non–US-based trials). Studies that

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listed multiple sites were coded as US-based if any of the sites were US locations. The funding source was coded as either *US Government* (US Federal agency, Veterans Affairs, Department of Defense, etc), *Industry* (if any industry involvement was reported), or *Other* for registered clinical trials receiving funding from neither industry nor government. *Other* is a "funded by" category that investigators can select on ClinicalTrials.gov, and we applied the term as defined on ClinicalTrials.gov. If a study included *US Government* and *Industry*, it was coded as *US Government* owing to superseding reporting guidelines, with the same hierarchy for studies with *Industry* and *Other*.

Statistical analyses were performed using Stata (version 16.1; StataCorp).

Ethical Considerations

Our study did not meet the criteria for human subject research according to the institutional review board [18]. ClinicalTrials.gov is an open source database that does not contain identifiable private information. Therefore, using the 2018 flow chart provided by the US Department of Health and Human Services [19], it was determined that our research did not involve human subjects and that the Protection of Human Subjects under United States Law (1974), the Code of Federal Regulations Title 45: Public Welfare, part 46 (45 CFR 46) did not apply.

Results

Study Characteristics

Our original search string returned 1595 trials, and 823 were included after screening for relevance to our search. Among the 823 included trials, the median enrollment was 80 (IQR 40-133) with a total of 160,021 participants (range 0-2000). By funding source, 52 (6.3%) were categorized as *Industry*, 20 (2.4%) as *US Government*, and 751 (91.3%) as *Other.* By trial status, 70 (8.5%) were categorized as active, 39 (4.7%) were enrolled by invitation, 568 (69.0%) were recruiting, 19 (2.3%) were suspended, 76 (9.2%) were terminated, and 51 (6.2%) were withdrawn. By the phase of trial conduction, 82 (10.0%) were in phase 1, a total of 108 (13.1%) and 185 (22.5%) were in phases 2 and 3, respectively, and 448 (54.4%) were in phase 4.

Discontinued Trials

Of the 823 included trials, 146 (17.7%) were discontinued between January 1, 2020, and October 1, 2021. Of the discontinued trials, the median enrollment was 7 (IQR 0-50) with a range of 0 to 407 participants. A total of 5816 participants were involved in prematurely discontinued studies. By funding source, 16 (11.0%) were categorized as *Industry*, 3 (2.1%) as *US Government*, and 127 (87.0%) as *Other*. A total of 54 (37.0%) trials were conducted in other countries and 92 (63.0%) were conducted in the United States. By study design, 16 (11.0%) were nonrandomized, while 130 (89.0%) were randomized, and 103 (70.6%) included masked study participants, while 43 (29.5%) included unmasked participants. Regarding study intervention, 3 (2.1%) were categorized as *Device*, 122 (83.6%) as *Drug*, 20 (13.7%) as *Procedure*, and 1 (0.7%) as *Other*. By trial status, 19 (13.0%) were categorized as suspended, 76 (52.1%) as terminated, and 51 (34.9%) as withdrawn. The reported reasons for discontinuation were as follows: recruitment and enrollment (n=39, 26.7%), sponsor-related (n=2, 1.4%), safety and efficacy (n=8, 5.5%), PI-related (n=15, 10.3%), funding and resources (n=10, 6.8%), design-related (n=23, 15.8%), lack of approval (n=7, 4.8%), not provided (n=10, 6.8%), other (n=8, 5.5%), and owing to the COVID-19 pandemic (n=24, 16.4%).

COVID-19–Related Discontinuation

Of the 146 discontinued trials, 24 (16.4%) were halted explicitly owing to the COVID-19 pandemic as stated on ClinicalTrials.gov. These trials had a median trial enrollment of 32.5 (IQR 19.5-85.5) with a range of 0-400. By trial status, 10 (41.7%) were suspended, 9 (37.5%) were terminated, and 5 (20.8%) were withdrawn. The majority of the trials (20, 83.3%) were found to have a primary intervention of *Drug* and 4 (16.7%) had *Procedure.* By study design, 23 (96.0%) were randomized, while 1 (4.0%) was nonrandomized. A total of 18 (75.0%) trials included masked participants, while 6 (25.0%) included unmasked participants. By funding source, 2 (8.3%) trials were funded by *Industry*, 1 (4.2%) was funded by the *US Government*, and 21 (87.5%) were funded by *Other* sources. A total of 6 (25.0%) were performed internationally, while 18 (75.0%) were performed in the United States.

Associations

We found significant associations between termination reasons (COVID-19 vs non–COVID-19) and trial status with 52.6% (10/19) of trials suspended owing to the COVID-19 pandemic, while 11.8% (9/76) of studies were terminated owing to the COVID-19 pandemic, and 9.8% (5/51) trials were withdrawn owing to the pandemic (Table 1). Furthermore, the Mann-Whitney *U* test showed a significant difference in enrollment between trials discontinued owing to the COVID-19 pandemic (median 32.5, IQR 19.5-85.5) and those discontinued owing to non–COVID-19 reasons (median 5, IQR 0-35; z=–2.914; P=.004).

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Table 1. Associations among reasons for discontinuation and trial characteristics.

Characteristics	Does not explicitly state COVID-19–related reasons (n=122)	Explicitly states COVID-19–related reasons (n=24)	Total	Chi-square (*df*)	*P* value
Status, n (%)				20.9 (2)	<.001
Suspended	9 (6.2)	10 (6.9)	19 (13.0)		
Terminated	67 (46.0)	9 (6.2)	76 (52.1)		
Withdrawn	46 (31.5)	5 (3.4)	51 (34.9)		
Intervention, n (%)				1.0 (3)	.81
Device	3 (2.1)	0 (0)	3 (2.1)		
Drug	102 (69.9)	20 (13.7)	122 (83.6)		
Procedure	16 (11.0)	4 (2.7)	20 (13.7)		
Other	1 (0.7)	0 (0)	1 (0.7)		
Randomization, n (%)				1.3 (1)	.26
Not randomized	15 (10.3)	1 (0.7)	16 (11.0)		
Randomized	107 (73.3)	23 (15.8)	130 (89.0)		
Study design, n (%)				0.3 (1)	.60
Masked	85 (58.2)	18 (12.3)	103 (70.6)		
Unmasked	37 (25.3)	6 (4.1)	43 (29.5)		
Funding, n (%)				0.8 (2)	.67
Industry	14 (9.6)	2 (1.4)	16 (11.0)		
Other	106 (72.6)	21 (14.4)	127 (87.0)		
Government	2 (1.4)	1 (0.7)	3 (2.1)		
Location, n (%)				1.8 (1)	.18
Non–US-based	48 (33.0)	6 (4.1)	54 (37.0)		
US-based	74 (50.7)	18 (12.3)	92 (63.0)		
Enrollment[a]				—[b]	.004
Median (IQR)	5 (0-35)	32.5 (19.5-85.5)	7 (0-50)		
Range	0-407	0-400	0-407		
Total	4284	1532	5816		

[a]Mann-Whitney U test, z=–2.914.

[b]N/A: not applicable.

Discussion

Principal Findings

Our study demonstrated over 1 in 6 anesthesiology-related clinical trials registered on ClinicalTrials.gov at the time of our search were prematurely discontinued as a direct result of the COVID-19 pandemic. Of note, we found a significant association between trial enrollment and the likelihood of reporting discontinuation owing to the COVID-19 pandemic, with larger trials being more likely to be have been discontinued owing to the COVID-19 pandemic. Indeed, over one-fourth of participants involved in discontinued anesthesia clinical trials during the pandemic were from trials that claimed the COVID-19 pandemic as the primary cause for discontinuation.

The considerable rise in social distancing efforts and quarantine guidelines could have limited participant–provider interactions, thus pushing larger trials to halt trial progress until safer conditions could be ensured. From a logistical standpoint, Sathian et al [5] described how the COVID-19 pandemic has disrupted operational planning, activity creation, and decision-making of major clinical trials, causing an overall operational burden to the clinical trial industry. However, properly maintaining clinical trials requires more than just participation. Investigation personnel at clinical sites consistently interact with trial participants, and multiple researchers, fellows, and scientists participate in data collection, some of whom may interact with patients or other members of the care team [20]. Thus, larger trials with more personnel could have been more at risk of premature cessation than smaller trials that were more likely to accommodate social distancing standards. Further, attempting to uphold a trial in a socially distanced world may have outweighed the potential benefit of the trial itself—more trial participants implies more potential exposures to COVID-19.

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In response to the heightened transmission of COVID-19, the FDA called on researchers and trial sponsors to "determine that the protection of a participant's safety, welfare, and rights is best served by continuing a study participant in a trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial" [7]. Discontinuing a study altogether could have been the only way to ensure participant safety among trials with high enrollment. The limitations of person-to-person contact during the pandemic as well as the potential threat of COVID-19 exposure may have predisposed larger anesthesia-related clinical trials to premature discontinuation.

Future Directions

The need for continued anesthesiology-related research is evident given our study findings. Under current circumstances, unprecedented shortages of ventilators, paralytics, and sedative medications have driven anesthesiologists to practice outside of previous standards of care [21]. For example, Beitler et al [14] proposed using "ventilator sharing" to improve ventilator treatment of patients with COVID-19. Treatment plans and quality care measures are actively evolving in the field of anesthesiology, further pressing the need for upholding anesthesia-related research. A potential solution to maintaining trial progression could be via the establishment of novel communication methods that are more able to withstand a socially distanced society. Wijesooriya et al [22] describes how certain trial activities, such as obtaining informed consent, clinical follow-up, and monitoring parameters such as blood glucose, pulmonary function, and electrocardiography can be performed remotely with new computer models and monitoring tools. Additionally, Bridges et al [23] present the benefits of telehealth for perioperative anesthetic care, as certain undertakings such as mobile phone–based videoconferencing for preoperative and postoperative consultation, at-home data monitoring of fluid status, and anticoagulation, and Bluetooth-connected cardiopulmonary sensors have led to quality improvements within health care systems [24]. However, standardizing data collection methods and maintaining data repositories for anesthesiologists to review remain as challenges to telehealth and should be further explored.

Over 2500 clinical trials were suspended between December 2019 and May 2020, and nearly half of these were suspended owing to the COVID-19 pandemic [25]. Moreover, the *British Journal of Surgery* reported that an estimated 2,367,050 operations per week would be canceled or postponed during the peak 12 weeks of disruption due to the COVID-19 pandemic [26]. Thus, the enormous number of surgeries canceled during the pandemic rendered the conduct of perioperative clinical trials incredibly difficult and may have led to discontinuation of some trials. Our findings reflect the extensive influence of the COVID-19 pandemic on perioperative anesthesia care and highlight an important impact, which may have repercussions on clinical trial progress going forward.

Strengths and Limitations

First, although over 1 in 6 halted trials from our study explicitly mentioned the COVID-19 pandemic as a reason for discontinuation, it is difficult to determine the exact reasons for discontinuation among the remaining halted trials beyond what was stated directly within the "Recruitment Status" box on ClinicalTrials.gov. Therefore, trials that did not explicitly mention the COVID-19 pandemic as a reason for discontinuation could have potentially been affected by the COVID-19 pandemic, thus underestimating the impact of the pandemic on the conduct of anesthesia-related clinical trials. Second, the nature of our study is cross-sectional and therefore cannot establish causality. Other factors could have contributed to the discontinuation of anesthesiology clinical trials during the pandemic, which were not directly related to the COVID-19 pandemic. Our results should be interpreted with this limitation in mind. Lastly, we did not assess the baseline discontinuation rate of anesthesiology clinical trials prior to the COVID-19 pandemic. Future studies are needed to observe discontinuation rates prior to the pandemic so that proper comparisons can be made. Although we can quantify the trials discontinued during the pandemic, we cannot determine whether the discontinuation differs from previous time intervals. The strengths of our study include the use of ClinicalTrials.gov, which is the largest clinical trial registry. Second, we performed data extraction in a blinded, duplicate manner, which served to reduce systematic error.

Conclusions

The COVID-19 pandemic has reportedly impacted the progress of anesthesia-related research. Therefore, it is critical to consider further efforts in maintaining trial conduct with the purpose of improving anesthetic care. The value of collective data curation and dissemination to researchers and anesthesia providers has been evident throughout the COVID-19 pandemic. Anesthesia-related research must continue even during difficult times, and the unforeseen end to the COVID-19 pandemic should spark an initiative to incorporate innovative methods for data retrieval and trial conduct within the breadth of anesthesiology.

Conflicts of Interest

None declared.

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Abbreviations

FDA: US Food and Drug Administration

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Original Paper

Understanding the Cognitive Demands, Skills, and Assessment Approaches for Endotracheal Intubation: Cognitive Task Analysis

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Abstract

Background: Proper airway management is an essential skill for hospital personnel and rescue services to learn, as it is a priority for the care of patients who are critically ill. It is essential that providers be properly trained and competent in performing endotracheal intubation (ETI), a widely used technique for airway management. Several metrics have been created to measure competence in the ETI procedure. However, there is still a need to improve ETI training and evaluation, including a focus on collaborative research across medical specialties, to establish greater competence-based training and assessments. Training and evaluating ETI should also incorporate modern, evidence-based procedural training methodologies.

Objective: This study aims to use the cognitive task analysis (CTA) framework to identify the cognitive demands and skills needed to proficiently perform a task, elucidate differences between novice and expert performance, and provide an understanding of the workload associated with a task. The CTA framework was applied to ETI to capture a broad view of task and training requirements from the perspective of multiple medical specialties.

Methods: A CTA interview was developed based on previous research into the tasks and evaluation methods of ETI. A total of 6 experts from across multiple medical specialties were interviewed to capture the cognitive skills required to complete this task. Interviews were coded for main themes, subthemes in each category, and differences among specialties. These findings were compiled into a skills tree to identify the training needs and cognitive requirements of each task.

Results: The CTA revealed that consistency in equipment setup and planning, through talk or think-aloud methods, is critical to successfully mastering ETI. These factors allow the providers to avoid errors due to patient characteristics and environmental factors. Variation among specialties derived primarily from the environment in which ETI is performed, subsequent treatment plans, and available resources. Anesthesiology typically represented the most ideal cases with a large potential for training, whereas paramedics faced the greatest number of constraints based on the environment and available equipment.

Conclusions: Although the skills tree cannot perfectly capture the complexity and detail of all potential cases, it provided insight into the nuanced skills and training techniques used to prepare novices for the variability they may find in practice. Importantly, the CTA identified ways in which challenges faced by novices may be overcome and how this training can be applied to future cases. By making these implicit skills and points of variation explicit, they can be better translated into teachable details. These findings are consistent with previous studies looking at developing improved assessment metrics for ETI and expanding upon their work by delving into methods of feedback and strategies to assist novices.

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KEYWORDS

knowledge elicitation; knowledge acquisition; medical simulation; medical training; medical assessment; critical care; cognitive task analysis; qualitative methods; qualitative; endotracheal intubation; preoperative; training; health care professional; medical education; cognitive skill

Introduction

Background

Proper airway management is an essential skill for hospital personnel and rescue services to learn [1-4]; it is the first priority in the management of patients who are critically ill [5]. Airway management includes a set of guidelines and clinical procedures performed to maintain or restore a patient's airflow to and from the lung [2,5-9]. Endotracheal intubation (ETI) is a widely used technique for airway management in which a laryngoscope is used to obtain a view of the patient's vocal cords to pass an endotracheal tube into the trachea to facilitate lung ventilation [5,7,10].

ETI is a lifesaving but complicated procedure. The success rate of prehospital intubation is approximately 69.8% and may be as low as 45% [11,12]. Failure to properly ventilate contributes to poor patient outcomes in patients with trauma [6,13,14] and may lead to life-threatening complications, such as hemorrhage, obstruction, tension pneumothorax, or fatality [9,11,13-16]. The risk of an adverse event increases with each subsequent intubation attempt, which can cause tissue damage, edema, or bleeding [9,11,16,17]. Therefore, it is critical that providers be properly trained and competent in performing this procedure. The difficulty of the procedure is determined by patient characteristics and unanticipated events [7,13]. These may include patient weight, atypical airway physiology, any unanticipated obstructions, hemodynamic instability, or compounding injury, which may necessitate cervical spine protection [7,10,11,14].

Despite it being a critical skill in airway management, there is variation in the method of training and way in which to measure competency [18]. Current training methods typically include practicing on cadavers or mannequins and in airway management rotations in clinical settings with live patients [5,9,17,19]. Airway management rotations typically begin by watching in the operating room, where intubation is more routine and easier, and moving to units within the hospital in which intubation is increasingly difficult, such as the intensive care unit [10,19]. However, due to variation in patient anatomy and the need for patient safety, medical residents do not always have the opportunity to practice difficult intubations on live patients [9]. Thus, mannequins and simulators are used instead. Mannequins have been shown to have no direct risk to patients, allow for repeated practice, and act as a bridge between classroom instruction and practical application [10,19].

Although the Accreditation Council for Graduate Medical Education (ACGME) mandates competency in ETI, there is still room for interpretation as to how to evaluate that competency [19]; these measures differ on the number of required procedures, the type of intubation experiences, and the nature of the training program itself. Several metrics have been developed to measure competence in the ETI procedure [12,17,19,20]. Binary item checklists are the most commonly used evaluation metric. However, these provide a summative, rather than formative, assessment of trainee skill [10,12,19]. A recent review of training methods by Brown et al [19] calls for a change to improve ETI training and evaluation. These include a focus on multispecialty research to establish criteria in airway management and establish training collaboration, longitudinal competence-based assessments rather than quantitative assessments, and the incorporation of modern, evidence-based procedural training methodologies [19].

Cognitive task analysis (CTA) is a framework from human factors engineering developed to identify cognitive demands and skills needed to proficiently perform a task; it seeks to describe performance differences between novices and experts and provides an understanding of the workload associated with a task [20]. Methods of CTA typically involve observation and interviews to elicit both explicit and implicit knowledge about a task that may be omitted during free recall [21,22]. Unlike hierarchical task analysis (HTA), which seeks to describe the procedure in terms of sequential tasks and subtasks required to complete a goal [23], CTA seeks to understand and characterize the procedural knowledge of experts to inform tool design and novice informational requirements and to understand potential errors to avoid or correct them [20,22]. An additional advantage of CTA is that it may be conducted with a limited number of subject-matter experts. Although there is little consensus as to exactly how many experts are needed to achieve the greatest knowledge elicitation, it is recommended to interview experts only until enough information is collected [24,25]. Owing to diminishing returns, wherein the amount of new information collected decreases with each new expert interviewed, an ideal number of participants is typically between 3 and 5 participants [24,25].

Objectives

This study seeks to apply the CTA framework toward the training of ETI. Findings from the CTA would highlight the learning needs of novices toward the development of task expertise and problem solving in adverse events. This work will focus on integrating perspectives from multiple specialties including anesthesiology, emergency medicine, and paramedicine to capture a broad view of task and training requirements. Finally, the results of the CTA will be used to inform a set of skills required to inform a more objective evaluation method for ETI.

Methods

Hierarchical Task Analysis

Before conducting the CTA, an HTA was completed to identify the key tasks that occur before, during, and immediately after ETI using direct laryngoscopy. An HTA breaks down the procedure into specific tasks and subtasks from the preparation

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of equipment and positioning the patient to securing the endotracheal tube in place once it has been inserted. The HTA was completed based on a review of previous studies into assessment of ETI [6,10,26] and gathering information from sources that included web-based videos, reference texts, and observation. Both Ryason et al [10] and Hart et al [26] described the validation of metrics for ETI assessment. These metric tools were used to create an HTA for this study. The HTA started with the following main tasks: (1) initiating the procedure and positioning the patient, (2) inserting the direct laryngoscopy blade, (3) achieving the optimal laryngeal view, (4) inserting the endotracheal tube, (5) verifying tube placement, and (6) securing the endotracheal tube. Subtasks were not explicitly described but were used to inform the creation of an interview guide.

CTA Interview Development

Interview questions were developed to capture a broad array of the steps required to complete an ETI and the necessary cognitive requirements to complete those activities. These included the specific goals of each step (and substep), the main challenges faced by novices and strategies used by experts to overcome these challenges, methods of feedback, and current measures of proficiency. The questions were organized by subtask. The HTA and previous assessment tools served as a guide for systematically developing CTA questions for each task in the ETI procedure.

The interviews were semistructured, beginning with broad questions about the task (eg, "What are the main goals and priorities during this step?") with subsequent questions based on the response for clarification or to increase the interviewer's understanding (eg, "Can you explain the difference between the use of a stylet versus a bougie as an assistance device?"). Further questions expanded on the differences between performing ETI across varying specialties (eg, anesthesiology in the operating room, emergency medicine in a hospital emergency department, or paramedicine in someone's home). Additional questions were used to help discern implicit aspects of the cognitive processes of the procedure, such as decisions involved and methods to determine proficiency (eg, "What visual or tactile feedback do you use to determine the [laryngoscopy] blade is positioned correctly?"). Example questions from the interviews of ETI are provided in Textbox 1.

Textbox 1. Exemplar questions from the cognitive task analysis interview with endotracheal intubation experts.

Cognitive task analysis interview questions

- Describe the sequence of actions necessary to complete this step.
- What are the main goals and priorities during this step?
- What tools do you gather to begin? What factors determine this choice?
- What do you look for to determine proficiency in this step?
- In what instances might you need to use additional strategies to gain better visualization or understanding of landmarks?
- What steps do novices seem to have problems learning or performing?
- What is the proper grip to hold the laryngoscopy blade?
- What visual or tactile feedback do you use to determine the blade is positioned correctly or needs to be adjusted?
- What is the optimal laryngeal view?
- What feedback measures do you use to determine correct placement of the endotracheal tube?
- What methods do you use to test the security of the endotracheal tube?
- What problems should an expert be able to solve if they have mastered endotracheal intubation?
- At what point do you intervene if a task is being performed incorrectly? What does this intervention look like?

Follow-up questions to prompt further discussion

- What alternative strategies could you use?
- What precautions or preventative measures do you use to overcome any risks?
- What skills are involved in completing this step?

Interviews were conducted using Zoom (Zoom Video Communications, Inc) video conferencing and in-person observation of the procedure on mannequins. Data were recorded through handwritten notes and audio and video recordings of the interviews. Zoom conferencing provided a transcription of each recording, which was reviewed against the audio recording for accuracy before the analysis. Each interview lasted approximately 60 minutes. Participants were briefed on the study objectives before meeting with the researcher conducting the interview.

Ethical Approval

The study was approved by the institutional review board at the University at Buffalo (STUDY00004879) and the Army Human Research Protection Office (ARL 21-007).

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Participants

Interviews were conducted with 6 participants from multiple specialties and work environments to gain diverse perspectives on the procedure. The participants were 2 anesthesiologists, 2 emergency medicine physicians, and 2 paramedics. The participants were from Florida, New York, and Ontario, Canada. The participants were all considered experts in their field, and each participant serves as an instructor in their respective setting.

These medical specialties were chosen based on their job descriptions and responsibilities and the nature of medical procedures they can perform. Anesthesiologists complete 12 to 14 years of formal education, including 12,000 to 16,000 hours of clinical training [27]. They are required to evaluate, monitor, and supervise patient care before, during, and after surgery and may assist in pain management [27,28].

Emergency medicine physicians complete 11 to 12 years of formal education, of which 3 to 4 years are residency in an emergency medicine program. Emergency medicine physicians must stabilize and treat patients until emergency care is no longer required. This includes completing a patient assessment, diagnosing illness or injuries, ordering appropriate medical exams and treatments, creating and communicating postemergency plans with the patient and other providers as necessary, and facilitating the patient transition to their home or living environment or to another department in the hospital [29,30]. Although education requirements may differ, the job responsibilities among emergency medicine physicians in the United States and Canada are comparable [30].

Finally, paramedics receive the least amount of formal school-based training. Paramedics must hold an emergency medical technician–basic (EMT-B) certification before applying for a paramedic program. The EMT-B program typically requires 150 to 180 hours of training. Paramedics must complete an additional 1200 to 1800 hours of training in a nationally accredited program and pass both written and practical examinations [31]. Paramedics are responsible for responding to emergency calls for medical assistance; must assess, triage, and treat patient physical and psychological needs; and facilitate referrals to a higher level of medical care when necessary [31]. Unlike an EMT-B, who can perform basic life support, a paramedic may perform more complex medical procedures and administer medication [31].

Analysis

A thematic analysis of the qualitative data from the interviews was conducted primarily by a single researcher (TK), a PhD student in human factors. Deductive coding was used to create the following high-level categories based on the interview guide: main goals, challenges, methods of feedback, strategies, and measures of proficiency. A deeper analysis using inductive coding was conducted to identify further themes related to the cognitive aspects of ETI. These themes were identified and organized within each high-level category for each task of the ETI procedure. Owing to variation in cognitive skills required across specialties, a separate analytic framework was developed to delineate competencies among the specialties examined in this study: anesthesiology, emergency medicine, and paramedicine. This allowed for further analysis of the differences between ideal and complicated cases; for example, in a hospital environment, the patient is typically in an accessible location, whereas outside the hospital, the patient may need to be moved to a location where the provider can perform ETI. The themes and subthemes were incorporated into a skills tree depicting the various cognitive skills and insights in each step of the procedure; this skills tree can then be used to develop training tools or provide greater insight into assessment metrics.

Results

Overview

A total of 6 participants were interviewed and observed. Of these 6 participants, 5 (83%) were interviewed over Zoom video conferencing, and 1 (17%) was interviewed in person. In addition, 33% (2/6) of the participants provided a demonstration of the ETI on a mannequin. Interviews were conducted by a single researcher (TK). Of the 6 participants, 2 (33%) were anesthesiologists, 2 (33%) were emergency medicine physicians, and 2 (33%) were paramedics. The participants had an average of 17 years of experience: anesthesiologists 18 years, emergency medicine physicians 17 years, and paramedics 16 years. All participants held educational roles in their respective facilities and were considered experts in their field.

The interviews elicited the cognitive demands and procedural skills required to complete ETI from the perspectives of practitioners across multiple specialties. These interviews further highlighted the training requirements, stumbling points, and measures of proficiency that novices experience when performing this procedure. Furthermore, the interviews showed the differences and similarities in cognitive requirements when performing ETI within different medical specialties and environments. The findings from these interviews were categorized according to each step of the ETI procedure and emergent themes, as shown in Table 1.

Five broad, high-level categories were identified for each step of the ETI procedure: main goals, challenges, methods of feedback, strategies to assist, and measures of proficiency. Emergent themes within each of the above categories were mapped to the various steps of the ETI procedure. This represents the interconnected nature of each category of cognitive insights, as they relate to a specific task or subtask within the procedure. For example, under the “Insertion of the Endotracheal Tube” task, the main goal is to successfully insert the tube. However, deviations in the patient’s anatomy, noted under challenges, may arise when the airway is smaller than anticipated, and it is difficult to actually pass the endotracheal tube past the vocal cords. A strategy that could be used is to advance a bougie past the vocal cords first, as it has a smaller diameter, and then insert the endotracheal tube over the bougie.

The content in each theme within the skills tree table can be elaborated based on the complexity of each case. However, the key insights represented here provide a level of detail sufficient to the design of new cross-specialty training methods and assessment tools.

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Table 1. Skills tree for endotracheal intubation.

	Main goals	Challenges	Methods of feedback	Strategies to assist	Measures of proficiency
Overall procedure	• Consistency • Timing (preoxygenation [5 minutes], equipment setup, and procedure [30-60 seconds])	• Provider-related: confidence in ability to perform a procedure and to lead medical team; maintain composure • Patient-related: atypical anatomy or unanticipated events, patient's medical conditions, and airway difficulty • Procedure-related: safety of the patient and provider and type of intubation (rapid-sequence or awake)	• Talk-aloud method (prior to real case, during real case, and contingency planning for simulated case) • Mannequins and simulators • Video laryngoscope	• Medical team (reassurance of expert to provide feedback and to take over procedure; other team members to provide assistance and to monitor patient vitals) • Procedure talk-through method (prior to real case and during real case)	• Planning for procedure (clear and concise, contingency for real or potential problems, and next steps [what comes after ETI[a]]) • Consistency (in each step) • Timing • Communication with medical team • Number of successful intubations (on a mannequin and person) • Lack of trauma to lips, teeth, or airway tissues • Accreditation Council for Graduate Medical Education Requirements
Step 1: preparation and positioning	• Ventilate and preoxygenate the patient • Ensure functionality of equipment (medical equipment and medication) • The patient is positioned correctly (supine, sniffing position and appropriate height for provider)	• Consistency (equipment is set up in the same manner each time and all equipment and materials are available) • Timing (insufficient preoxygenation) • Patient characteristics (facial hair, weight, anatomical challenges [eg, jaw size and neck mobility], and other injuries)	• Patient body position (supine, sniffing position and height of surface on which patient is laying) • Suitability of equipment (chosen tools are appropriate for the patient) • Indication for intubation	• Consistency • Use of additional equipment (to change equipment if needed and to reposition the patient)	• Correct indication for intubation • Consistency over multiple attempts • The patient is positioned correctly • Suitability of equipment (appropriate equipment sizes and medication)
Step 2: inserting the direct laryngoscopy blade	• Timing (approximately 30 seconds) • Visualization (keep airway clear to see while inserting laryngoscopy blade)	• Motor skills (rocking blade back instead of lifting, not sweeping tongue to the left, lifting blade too early, using excessive force to lift blade) • Patient-related factors (abnormal/atypical anatomy and obstructed view) • Movement speed (move too quickly, leading to additional challenges)	• Field of vision (can provider see vs can they not see)	• Talk-aloud method (slows down procedure to allow the provider to visualize and provides the instructor an opportunity to understand trainee's view) • Make a change (to equipment and technique)	• Talk-aloud method • Blade position • Pre-assessment determinations (airway difficulty determines timing and may influence repositioning and number of reattempts that are reasonable) • Lack of trauma to patient
Step 3: achieving the optimal view	• See tracheal opening (achieve a view in which the provider can pass the endotracheal tube through the vocal cords)	• Motor skill (blade in correct position and use of force rather than fine motor control) • Obstructed view (due to abnormal or atypical anatomy)	• Talk-aloud method (provides the instructor an opportunity to understand the trainee's view) • Video review (if available)	• Reposition the patient (body supports, pull on the right side of the mouth, and the BURP[b] technique) • Review patient history (maintain composure) • Change equipment • SALAD[c] technique	• Verbal review (of technique and landmarks) • Timing (5-10 seconds)

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	Main goals	Challenges	Methods of feedback	Strategies to assist	Measures of proficiency
Step 4: inserting the endotracheal tube	• Tube inserted correctly (into the trachea and at the correct depth) • Minimize trauma to airway tissues	• Incorrect positioning of endotracheal tube (into the esophagus, into only 1 bronchus, and too shallow) • Premature removal of equipment	• Stopping criteria (depth mark on tube at the teeth or lips and can tube continue to advance [likely in esophagus] or not [likely in trachea]) • Tactile sensation (feel of tracheal rings against bougie)	• Use of assistance device (stylet and bougie) • Tube adjustment (hold toward the end of the tube rather than hold the tube near the lips and bend the tube using a stylet into a hockey stick shape [≤45° angle]) • Change equipment (stylet to bougie; tube dimension) • SALAD technique	• Depth of tube • Number of attempts to insert tube • Timing
Step 5: verifying endotracheal tube placement	• Established airflow to the lungs (endotracheal tube is in the correct position for appropriate oxygenation)	• Verification methods (available tools for verification and objectivity of verification methods) • Position of endotracheal tube (in the esophagus rather than the trachea, in 1 bronchus rather than 2, and not far enough into the trachea)	• Visual methods (visualization of tube going through cords and tube changing color due to mist) • Auditory methods (auscultation of breath sounds) • Device-assisted methods (end-tidal CO_2, chest x-ray, and ultrasound) • Patient vital signs	• Readjustment of tube (to a different depth) • Reattempt to insert endotracheal tube	• Patient has airflow to both lungs
Step 6: securing the endotracheal tube	• Stability of endotracheal tube placement (ensure endotracheal tube will not move after placement)	• Available tools (tape and securement device) • Securing tube to another tube (eg, to NG[d] tube) • Failure to plan for postintubation activities	• Tug test (lightly pull on the endotracheal tube to test security) • Visual examination of tape or tube securement device	• Avoid unnecessary movement of tube • Tug test (excessive force during the tug test may extubate the patient prematurely)	• Endotracheal tube does not move or come out

[a]ETI: endotracheal intubation.

[b]BURP: backwards, upwards, right, pressure.

[c]SALAD: Suction-Assisted Laryngoscopy Airway Decontamination.

[d]NG: nasogastric.

Main Goals

Main goals refer to the overarching objective of each task within ETI. Achieving these goals determines if that task is considered successful and if the practitioner is ready to move to the next step. Themes in the main goals category provide a basis for the evaluation of trainee success. Achieving these goals, in conjunction with feedback received, as described in the "Methods of Feedback" section, allows the trainee to determine if they should proceed to the next step or make a corrective action at the current step.

The degree to which each goal is achieved may vary owing to differences in task complexity, patient characteristics, and the environment in which the ETI is being performed. For example, in achieving the optimal view, the main goal is to achieve a view of the patient's soft palate and tracheal opening through which the provider can pass the endotracheal tube. A provider mentioned:

> *...there are four views you can get...you can either see the vocal cords completely...or you can see only a very small part of the opening.*

In an ideal case, the provider would be able to see the epiglottis and the vocal cords in the center of the field of vision.

Although some variation results from patient or environmental characteristics, there may also be acceptable deviation in provider performance. This can be clearly seen in the first step of the procedure: positioning the patient. The patient should

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always be in a supine and sniffing position by which the patient's ears are at the level of their shoulders and it looks as if the patient is sniffing flowers. However, the amount of padding or the angle at which the patient is positioned (eg, in reverse Trendelenburg) are variable.

Challenges

Challenges are instances in which novices typically experience difficulty when performing ETI. These may be typical or routine obstacles that may occur during the procedure, unanticipated events, or barriers that arise from the provider's lack of experience. Typical challenges include anatomy- and physiology-related obstacles. For example, the patient may have a small mouth and jaw. As a result, the provider may need to use a smaller laryngoscopy blade or may experience difficulty in maneuvering the blade into position without causing damage to the patient's teeth or airway tissues. Problems or experiences that cannot be controlled or accounted for before the procedure are considered unanticipated events. The most commonly noted unanticipated event was an obstructed airway that was undetected in a preintubation airway assessment, such as a subglottic stenosis.

Challenges resulting from the provider's lack of experience include both behavioral- and skill-related barriers to ETI. The provider's confidence, or lack thereof, in their ability was frequently cited as a behavioral barrier. A provider noted:

> *...an older medic who's done this a bunch of times may spend longer...and know they're almost where they need to be whereas novices may get in there and spend 15 seconds...and give up on that.*

Another provider discussed the provider's confidence in leading the medical team; if the provider is not confident in their ability, the rest of the medical team may also feel anxious. Skill-related barriers are those related to the motor skill necessary to perform ETI, such as lifting the laryngoscopy blade to achieve the optimal view rather than rocking the blade back into the patient's teeth.

Addressing these challenges during training allows novices to develop decision-making strategies for anticipated and unanticipated barriers to ETI. This supports the provider in assessing the trainee's ability to plan for future cases. It also provides insight into cognitive and motor skills where additional training may be required. The specific challenges a novice faces may influence what additional strategies are used to assist the provider in completing the procedure. Finally, by addressing these challenges explicitly during training, the novice may feel a greater sense of accomplishment when overcoming these hurdles and thus boost their confidence.

Methods of Feedback

Methods of feedback refer to the external elements used by the provider to determine if they are performing the step correctly or if any adjustments are required. Feedback may be visual, tactile, or auditory. Visual methods of feedback include those that the provider can see. For example, when positioning the patient, the provider must also consider the height of the bed. The patient should be at a height "where [the provider's] elbows bend at about 90°." Some elements, such as this, are visible to both the novice performing the ETI and the trainer observing. Other visual elements are only seen by the novice, such as if the provider can see the patient's vocal cords or not. In this case, additional strategies to assist performance may also be necessary.

Auditory methods of feedback primarily include talk-through protocols. During training, and before real cases, novices may discuss the procedure and potential problems that may arise. This allows the novice to verbally demonstrate their knowledge of the procedure and problem-solving capabilities. Verbal protocols also provide the trainer with information on what the novice is seeing during steps where there is limited visual feedback, such as when attempting to achieve the optimal view. Auditory methods also include the use of auscultation to verify placement of the endotracheal tube. Using a stethoscope, the physician listens for breath sounds over the stomach and both lungs to ensure that there is appropriate airflow.

Finally, tactile methods of feedback encompass those that the novice can feel. For example, providers can use stopping criteria when inserting the endotracheal tube. If the endotracheal tube can continue to advance, it is an indicator that it is likely in the esophagus and a second attempt is required; however, if the endotracheal tube stops and cannot be advanced further, it is likely in the trachea.

Incorporation of these methods of feedback into training provides novices with additional tools by which to evaluate and adjust their performance. Not all methods may be necessary in each case owing to natural variation in complexity; however, these methods are translatable to all cases. Furthermore, these methods of feedback can be incorporated into training as evaluation criteria for each task within the ETI procedure.

Strategies to Assist

Strategies to assist are tools used by the provider to avoid or overcome complications presented during the ETI procedure. Commonly, these are used in response to a presented challenge or in conjunction with methods of feedback to adjust performance. The most commonly presented strategies were for the provider to make a change in how they are approaching the task. For example, when inserting the laryngoscopy blade, switching from a Miller blade to a MacIntosh blade may allow the provider to gain better visualization for later steps. Other reported physical strategies included the use of additional equipment, such as padding to reposition the patient or portable suction to remove blood or emesis obstructing the view of the airway. Additional strategies include talk-through protocols, which force the novice to slow down and take stock of what they are seeing and doing and how consistently the novice performs the procedure over multiple attempts. These strategies are cultivated by experts in order to assist trainees in developing their motor skills and build confidence in their ability. As such, it is critical to identify these strategies as requisite tools to successfully completing ETI.

Measures of Proficiency

Measures of proficiency refer to the assessment methods used by a trainer to determine if the novice is successfully performing the procedure. These measures of proficiency provide a baseline

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for evaluation at each step of the procedure. Thus, providers can use these measures to target specific steps for additional training. These also allow for insight into which additional strategies or feedback may be most beneficial to the trainee.

Examples of measures to evaluate motor skill proficiency include observer assessment of patient positioning, laryngoscopy blade position, and the depth measurement mark on the endotracheal tube after it is inserted. In addition, the trainer may use talk-through protocols to determine if the trainee is progressing appropriately during the procedure; for example, the trainee may announce landmarks within the mouth and throat as they are advancing the laryngoscopy blade. Talk-through protocols also provide insight into the trainee's problem-solving abilities, similar to what might be experienced during medical licensing examinations.

Other measures of assessment include the time taken to complete the ETI, not including preoxygenation, how consistently the provider performs over multiple intubations, and the number of successful intubations performed. Providers reported varying counts of successful intubations for proficiency; a provider from anesthesiology cited that 50 successful intubations would be sufficient to call someone proficient, whereas an emergency medicine physician cited over 100 intubations throughout 5 years of residency. Other providers referenced the ACGME requirements as the standard for measuring proficiency across intubation attempts, with a minimum requirement of 35 successful intubations. The ACGME defines 5 levels of competency in airway management. At level 1, novices are expected to describe the airway anatomy. By level 5, the novice should be able to teach airway management skills to other health care providers. Although the ACGME does not have specific evaluation metrics, the suggested methods of evaluation include airway management assessment cards, checklists, procedures logs, and simulations.

Themes by Specialty

The participants in this study were from various specialties. As such, differences were found in the learning requirements, strategies to assist, and methods of feedback and measures of proficiency used by trainers. These differences are listed in Table 2. The table distinguishes the following specialties: anesthesiology, emergency medicine, and paramedicine. Overall, there are a few key differences between the specialties. Variation among specialties primarily derived from the environment in which ETI is performed, subsequent treatment plans, and available resources.

Anesthesiology typically represented the most ideal cases for intubation; providers cited anesthesiology as the first specialty students are placed during airway management rotations. In anesthesiology, ETI is performed in an operating room with a full staff to assist. Presurgical assessments and patient review ensures the provider can select the appropriate equipment and medication for that patient. In emergency medicine, the patient may still be in the hospital, but there may not be time to conduct a full airway assessment or patient history before performing ETI. Thus, it may be more difficult to determine the correct equipment sizes or medication.

Paramedics are limited by the equipment and personnel available on a particular emergency call. In addition, a paramedicine trainer noted "if [the patient is] in a very small or a very dimly lit area, I will immediately try to see if we can move the patient." The provider must continue to perform basic life support while moving the patient to a new location to begin the ETI procedure without the assistance of a full medical team.

Finally, the postintubation plan is different among specialties. In anesthesiology, the patient is about to undergo a surgical procedure; therefore, the postintubation plan is to monitor the patient throughout the surgery. Likewise, paramedics have a known postintubation plan: transport the patient to a medical facility for further care. However, in emergency medicine, the next steps are not always obvious to novices. An emergency medicine physician noted "one thing [novices] forget about is having sedation ready for afterwards." Regardless of what is required after intubation, it is critical to provide sedation so that the patient does not attempt to remove the tube prematurely and without assistance.

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Table 2. Differences of endotracheal intubation among medical specialties.

	Anesthesiology	Emergency medicine	Paramedicine
Preparation and positioning			
Challenges	• Patient characteristics: patient undergoes presurgical assessment; typically, most ideal cases and patient characteristics that influence difficulty of ETI[a] are addressed before procedure • Environment: operating room with full staff to assist; easy access to equipment and medication	• Patient characteristics: patient may or may not have an airway assessment completed • Environment: clinical room with staff to assist; easy access to equipment and medication	• Patient characteristics: patient does not have an airway assessment • Environment: nonclinical setting; patient may need to be moved from a small space, such as a closet, to a location in which the provider has sufficient room to perform ETI; provider may be hunched over the patient rather than having elbows at 90° angle • Equipment: do not use medication, as there is insufficient patient history to administer the correct medication and limited storage in the ambulance
Inserting the direct laryngoscopy blade			
Challenges	• Patient-related factors: airway assessment allows provider to account for patient variability (eg, facial hair)	• Patient-related factors: airway assessment, if available, allows provider to account for patient variability (eg, facial hair)	• Patient-related factors: unable to account for patient variability
Strategies to assist	• Potential for video laryngoscope	• Potential for video laryngoscope	• Video laryngoscope not always available
Achieving the optimal view			
Strategies to assist	• Reposition patient: additional equipment and assistance available to maneuver patient into sufficient position for intubation • Suction: readily available	• Reposition patient: additional equipment and assistance available to maneuver patient into sufficient position for intubation • Suction: readily available	• Reposition patient: limited equipment and assistance available to maneuver patient into sufficient position for intubation • Suction: portable suction may or may not be available
Verifying the endotracheal tube			
Methods of feedback	• Available methods: availability of visual, auditory, and medical devices to verify placement of endotracheal tube	• Available methods: availability of visual, auditory, and medical devices to verify placement of endotracheal tube	• Available methods: limited verification methods available: end-tidal CO_2 monitor and visual and auditory methods which may be subject to human error
Securing the endotracheal tube			
Challenges	• Postintubation activities: postintubation activity is known and planned for other medical procedures	• Postintubation activities: may be a failure to plan for postintubation activities	• Postintubation activities: postintubation activity is known and planned for transportation to a medical facility • Environment: tube may be moved during transportation

[a]ETI: endotracheal intubation.

Discussion

Principal Findings

CTA interviews with experts in ETI discerned the five following cognitive skills and processes necessary to perform and evaluate the procedure: (1) the main goals, (2) challenges faced by novices when performing ETI, (3) methods of feedback by which the individual performing the procedure can gauge success, (4) strategies used by experts to assist performance, and (5) measures of proficiency by which novices are evaluated at each step. The skills tree depicts these various cognitive skills and processes, as well as the implicit subskills and areas of variation, at each step. This allows for the identification of challenges faced by novices and the ways in which these challenges may be overcome. Furthermore, the breakdown of skills by subtask allows these points to be better translated into teachable details.

Interviews with experts in ETI from various specialties assisted in identifying and systematically representing the cognitive processes and skills required to perform ETI tasks. These cognitive processes include the main goals, challenges novices face, methods of feedback, strategies used to assist performance, and measures of proficiency of each step, as defined by previous HTA and assessment metrics [6,10,26]. These insights are critical for the development of training and objective assessment tools. In addition, the CTA highlighted the complexity of the

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procedure arising from challenges providers may face because of environmental or patient-related variability.

Although the CTA did not capture the complexity and detail of all potential cases, it provided insight into the nuanced skills and training techniques used to prepare novices for the variability they may find in practice. Importantly, the CTA identified ways in which challenges faced by novices may be overcome and how this training can be applied to future cases. For example, the trainee may be asked to verbally dictate their contingency plan for inserting the endotracheal tube should the airway prove to be more difficult. During this process, the trainee could be continuously provided increasingly difficult or complex adverse events to assess their ability to solve problems at each potential pitfall.

The skills tree developed from the CTA interviews highlights the various subskills and areas of variation that are not always easily explicitly taught to novices. For example, patient variability may include neck mobility, other injuries, facial hair, and gender. Characteristics such as neck mobility, jaw size, or the presence of other injuries or medical conditions to monitor are routinely discussed. However, the presence of facial hair or gender may pose unique challenges that are not always explicitly discussed before a case where they become applicable. Facial hair may disrupt the ability of the bag mask to seal properly on the patient's face, resulting in poor preoxygenation, and women typically have breast tissue, which, depending on the patient's position, may add additional strain on the neck or chest, which increases the difficulty of the intubation. These subthemes in each step refer to the nuances of skills and maneuvers required to complete each task. By making these implicit themes explicit, they can be better translated into teachable details. These findings are consistent with previous studies looking at developing improved assessment metrics for ETI [10,13,19,26] and expand upon their work by delving into methods of feedback and strategies to assist novices.

Although CTA interviews are advantageous because they require a small number of participants, it is possible with a greater number of participants from all 3 disciplines that a greater number of cognitive processes and strategies would emerge. In addition, a greater number of experts could serve to highlight greater differences between medical specialties and discern additional aspects of training unique to those specialties.

Conclusions and Future Work

Findings from the CTA as depicted in this paper can only be validated through expert review and through the development of training systems. Future work may focus on the difference in cognitive skills between novices and experts performing ETI in simulated cases, error recognition and repair, and task switching in which cognitive skills developed in learning ETI are applied to a different procedure. The CTA also highlighted instances where cross-specialty training may provide a new dynamic to the training method and provide a wider application for training in various fields, such as military combat medic training.

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Authors' Contributions

BM, JN, SS, and LC participated in the development of the concept for the study. TK and LC developed the study materials and cognitive task analysis interview guide. LC led the recruitment of participants and oversaw the study. TK conducted the interviews, completed the data analysis, and developed the skills tree and medical specialty comparison tables. TK wrote the first draft of the manuscript and revised it first with input from LC and then all authors.

Conflicts of Interest

None declared.

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Abbreviations

ACGME: Accreditation Council for Graduate Medical Education
CTA: cognitive task analysis
EMT-B: emergency medical technician–basic
ETI: endotracheal intubation
HTA: hierarchical task analysis

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