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Original Paper

Gamified Mobile App (MobERAS) for Telemonitoring Patients in the Postoperative Period Based on the Enhanced Recovery after Surgery Program: Development and Validation Study

Aline Evangelista Santiago[1*], PhD; Victor Pezzi Gazzinelli Cruz[2*], MSc; Rafaela Souza Furtado[3*], MD; Eduardo Batista Cândido[3*], PhD; Wladmir Cardoso Brandão[2*], PhD; Agnaldo Lopes Silva Filho[1,3*], PhD

[1]Department of Gynecology, Obstetrics and Mastology, Faculdade de Medicina de Botucatu, Universidade Estadual Paulista "Júlio de Mesquita Filho", Botucatu, Brazil

[2]Department of Computer Science, Pontifícia Universidade Católica de Minas Gerais, Belo Horizonte, Brazil

[3]Department of Gynecology and Obstetrics, Universidade Federal de Minas Gerais, Belo Horizonte, Brazil

[*]all authors contributed equally

Corresponding Author:
Aline Evangelista Santiago, PhD
Department of Gynecology, Obstetrics and Mastology
Faculdade de Medicina de Botucatu
Universidade Estadual Paulista "Júlio de Mesquita Filho"
Avenue Professor Mário Rubens Guimarães Montenegro
Botucatu, 18618-687
Brazil
Phone: 55 11975998003
Fax: 55 143880 1134
Email: alinevajf@gmail.com

Abstract

Background: Digital technology and gamified apps can be useful in the health care context. Gamification uses technology to influence users' actions and motivations through experiences that resemble games. Patient adherence to the enhanced recovery after surgery (ERAS) program is crucial for achieving early recovery after surgery and continuous monitoring is essential for obtaining good results.

Objective: This study aimed to describe the development and validation of a mobile app for enhanced recovery after surgery (MobERAS), a gamified mobile health app for telemonitoring patients in the postoperative period based on the ERAS program, and to evaluate its functionality and usability and the experience of patients, health care professionals, and computer professionals with its use.

Methods: We developed MobERAS for postoperative telemonitoring, with active participation of patients in the process, and offering availability of real-time information for the health team. The app development process included idealization, interdisciplinary team formation, potential needs assessment, and product deployment. Usability tests were conducted throughout the development process with improvements, technical adjustments, and updates. After finalization, comprehensive verification tests were performed. The parameters evaluated are those that can influence the length of hospital stay, such as nausea, vomiting, pain scales, return to normal gastrointestinal function, and thromboembolic events. MobERAS was designed to be downloaded by users on their phones, tablets, or other mobile devices and to provide postoperative data. The app has a GPS that monitors the patient's walking time and distance and is connected to a virtual database that stores the collected data.

Results: Women undergoing medium and major gynecologic oncologic surgeries were included. We included 65 patients with an average age of 53.2 (SD 7.4, range 18-85) years. The time of use ranged from 23.4 to 70 hours (mean 45.1, SD 19.2 hours). Regarding adherence to the use of MobERAS, the mean fill rate was 56.3% (SD 12.1%, range 41.7%-100%), and ambulation data were obtained for 60 (92.3%) of the 65 patients. The researcher had access to the data filled out by the patients in real time. There was good acceptance of the use of MobERAS by the patients, with good evaluation of the app's usability. MobERAS was easy to use and considered attractive because of its gamified design. The app was rated as good or very good in all items by health care professionals (n=20) and professionals specializing in technological innovation (n=10).

Conclusions: MobERAS is easy to use, safe, well accepted by patients, and well evaluated by experts. It can be of great use in clinical surgical practice and an important tool for greater engagement of patients and health care professionals with the ERAS program.

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KEYWORDS

handheld computer; mobile phone; postoperative period; mHealth; mobile health; telemedicine; postoperative; perioperative; recovery; surgery; surgical; gamify; gamified; gamification; app; apps; application; applications; design; develop; development; gynecology; gynecological; oncology; oncological; women's health; usability

Introduction

The usefulness of digital technology in the health field has been well recognized for its great potential to aid in the prevention, diagnosis, and management of diseases [1,2]. Moreover, given that the COVID-19 pandemic has promoted digital disruption worldwide, further incorporation of technology into health care practices can be expected [3].

Through mobile apps, patients can access health-related data, schedule medical appointments, manage medication dosages, improve well-being, and perform other health-related activities [1]. Many of these apps are aimed at patients with chronic illnesses, such as diabetes mellitus, obesity, mental disorders, malignant neoplasms, smoking, and alcoholism, leading to apparent improvements in self-management of the disease and aiding in promoting health [4-11]. Therefore, the use of technology to improve health is promising [12].

A *mobile medical app* incorporates the functionality of the device's software or transforms a mobile platform into a regulated medical device [13]. In this scenario, there is gamification, which consists of using technology to influence users' actions and motivations through experiences that resemble games [14]. Gamified apps have several purposes in the context of health care, including managing comorbidities, preventing disease, encouraging the practice of healthy lifestyle habits, providing information, and building character [12]. Associating the gamification proposal to stimulate some practices and the need for better adoption of medical recommendations, we proposed the development of a gamified medical app, which represents 1 strategy for adopting the measures recommended by the enhanced recovery after surgery (ERAS) program and for promoting greater patient engagement.

The ERAS program comprises multimodal perioperative assistance designed to achieve early recovery of patients undergoing surgery, with the objective of reducing hospitalization time and accelerating the return of patients to regular activities without increasing complications, hospital readmission rates, or costs. For better recovery, the program focuses mainly on reducing perioperative stress, satisfactory pain control, return to normal gastrointestinal function, and early mobilization. Adherence to the program is crucial, and continuous monitoring is essential for obtaining good results. Among the program's postoperative recommendations, patients are encouraged to follow some steps that can help them achieve good postoperative results, such as encouraging early mobilization, as well as early oral intake [15,16]. For example, it is known that the incentive to walk early exerts a positive impact on the incidence of thromboembolic events [17].

Aiming at optimized postoperative recovery and using the current concept of mobile technology in health, we developed an app (mobile app for enhanced recovery after surgery [MobERAS]) for postoperative telemonitoring, with active participation of the patients in this process and the availability of real-time information for the health team. MobERAS is used as a tool to simultaneously guide and encourage patients to follow medical recommendations through the use of gamification. This study aimed to describe the development and validation of MobERAS, evaluating its functionality and usability and the experience of patients, health care professionals, and computer professionals with its use.

Methods

Development Process

Development Approach and Regulatory Context

Determining the most appropriate development strategy was challenging, given the existence of different sources of guidance and few well-established regulations. To establish the app's development strategies, we followed the recommendations of the Regulation of the European Parliament, which set high quality and safety standards for medical devices. According to the Regulation of the European Parliament, MobERAS can be defined as a "medical device, because it is a software designed for specific medical purposes, such as diagnosis, prevention, and monitoring, without the use of pharmacological, immunological, or metabolic means." The device must be safety and efficacious, without compromising the clinical condition of patients. Risks must be managed such that they are minimized and considered acceptable. According to the European Regulation classification rules, MobERAS belongs to the class IIa category or moderate risk, as it is a noninvasive app designed to provide information for decision-making, diagnostic purposes, or therapeutic purposes without causing any immediate danger to the patient [18].

Under the specific definitions, MobERAS can be classified as an "active device intended for diagnosis and monitoring," as it is an active device for monitoring physiological processes and health conditions in the postoperative period. To meet the regulatory requirements of the class IIa category, general safety and performance adjustments are required, in addition to delivery of clinical evidence. To deal with general security and performance requirements, it is necessary to describe the

software design and validation process with information that allows the project stages to be understood [18].

To comply with these regulations, a MobERAS validation study was performed. The app development process included (1) idealization; (2) interdisciplinary team formation; (3) assessments of potential needs, feasibility, user population, and concept finalization; (4) app construction and product development; and (5) validation.

Apps, in general, must be usable in different countries; therefore, cultural and linguistic differences must be considered during their development [19]. Thus, MobERAS was developed in Portuguese for validation in Brazil using internationally validated scales, such as the visual analog scale for pain, as well as figures representative of the respective health status, enabling translation into other languages and interpretation by different cultures. A new version in English and Spanish has already been planned.

Concept Development and the Use of Gamification

The concept of MobERAS emerged from the need to encourage patients to comply with medical recommendations in the postoperative period. According to the ERAS program, active participation of patients in their recovery process is essential for obtaining good outcomes [16]. Accordingly, the app was designed such that patients could receive guidance on recommendations to follow in the postoperative period and be monitored and encouraged to adopt the targeted measures. In this context, the development of a gamified app was initiated.

By combining gameplay mechanics and experiences, gamification creates situations that resemble games, such as reward systems, using points, achievement badges, and leaderboards. The idea was to increase participation and promote the engagement and commitment of patients in their postoperative care through gamification. Encouraging measures such as early ambulation and oral intake improves the return to normal gastrointestinal function, decreases thromboembolic event risks, promotes early hospital discharge, and reduces complication rates [16]. To improve patient adherence to medical recommendations, the artifice of gamification was added. For example, when a patient positively fills in an item or walks for more time (>5 minutes) or a longer distance (>10 steps), they earn a bonus represented by stars or an incentive animation, similar to that in a game. Accordingly, goals are established with a reward-based strategy to obtain results, encouraging the patient to comply with medical recommendations.

Interdisciplinary Research Team

Interdisciplinarity in research involves sharing scientific knowledge among research team members [19]. In this study, intercommunication of the health and information technology areas was important. Researchers with training in information technology and those with experience in postoperative care were involved. The research team included a computer science professor, a computer science graduate student, a medical gynecologist oncology professor, a doctoral student in oncological gynecology, and a medical student.

All the researchers studied the ERAS program. After several meetings by the professionals involved in the project, the app's focus was reached. Goals to be achieved by patients were also defined. Subsequently, the app's functions, interface, and design were determined.

Assessments of Potential Needs, Feasibility, User Population, and Concept Finalization

According to ERAS program recommendations, the parameters evaluated in postoperative monitoring—simple interventions, such as early feeding, early ambulation, and multimodal analgesia—have shown to decrease the rate of postoperative ileus [20]. In the 1990s, Kehlet [21] introduced the idea of a multimodal approach to enhance functional rehabilitation postoperatively. One study suggested that avoiding limiting procedures (eg, using a urinary catheter or excessive venous hydration), implementing practices involving the use of local analgesia, and encouraging early nutrition can lead to faster postoperative recovery, as well as reduced morbidity and costs [22]. The recommendations are summarized in Table 1.

Table 1. Recommendations of the ERAS[a] program considered during app conceptualization.

Item	ERAS recommendations
Venous catheter	• Remove venous catheter when patient tolerates 500 cc of oral diet
Diet	• Regular diet in immediate postoperative period • Oral hydration
Ambulation	• Walk 8 times a day • Have all meals sitting in a chair • Stay out of bed for 8 hours a day
Bladder catheter	• Remove on first postoperative day
Nausea and vomiting/pain	• Multimodal approach • Avoid opioids

[a]ERAS: enhanced recovery after surgery.

Thus, these parameters were defined as those to be assessed in the first version of the product (Figure 1). Through frequent and intermittent alerts triggered by the app, patients are encouraged to follow medical instructions, such as walking and

moving their legs, and to complete assessments in the form of scales evaluating pain, nausea, and vomiting. Moreover, the app has a GPS that monitors the patient's walking time and distance.

The ERAS program and, therefore, MobERAS are applicable to patients undergoing elective surgeries in general, and MobERAS was developed for use in the postoperative period. Patients can download the app on their phones, tablets, or other mobile devices. There is an easy-to-understand login that requests the user's name, individual registration (in Brazil, the "Cadastro de Pessoas Físicas"), and date of birth. The information provided by the patient can be accessed remotely in real time by the assistant health care team through cell phones (Figure 2). Thus, the app functions as a health care tool for patients.

After a detailed elaboration of the product concept, an app development plan was generated, including issues such as design, usability, validation, and integration with the online database, in addition to assessment of possible risks. The product concept and development plan included functional and nonfunctional design requirements based on stakeholder specifications, such as architecture documentation, software integration, and unit test specifications.

For attractiveness, mobile device technology needs to be easy to navigate, be self-explanatory, and not contain much screen text [23]. Moreover, user instructions must be written for easy understanding and, when appropriate, supplemented with figures and diagrams [18]. Thus, an app was designed with multiple playful resources, such as symbols and images, with the minimal use of words. The texts were written using a language as close as possible to the popular colloquial language, without the use of many technical terms that could make it difficult for patients to understand. Furthermore, there was significant focus on developing an app that was easy to navigate, as some target patients were elderly and possibly unfamiliar with advanced and complex technologies.

As the app was designed with several playful resources, it can be translated and applicable in other countries without the need for additional programming. The app was built using the backend system and the Flutter framework. The app is connected to a virtual database (Firestore) to store the collected data. Every answer provided by the patient and all walking times are stored in this database on the internet for further analysis. The text used by the graphical user interface is managed separately to ensure easy software upgrades (eg, providing the ability to add new languages by simply translating the source text without additional programming).

The source code of the MobERAS system is available at Ref. [24].

Figure 1. Summary of postoperative parameters assessed by MobERAS created for this study based on the ERAS protocol. ERAS: enhanced recovery after surgery; MobERAS: mobile app for enhanced recovery after surgery.

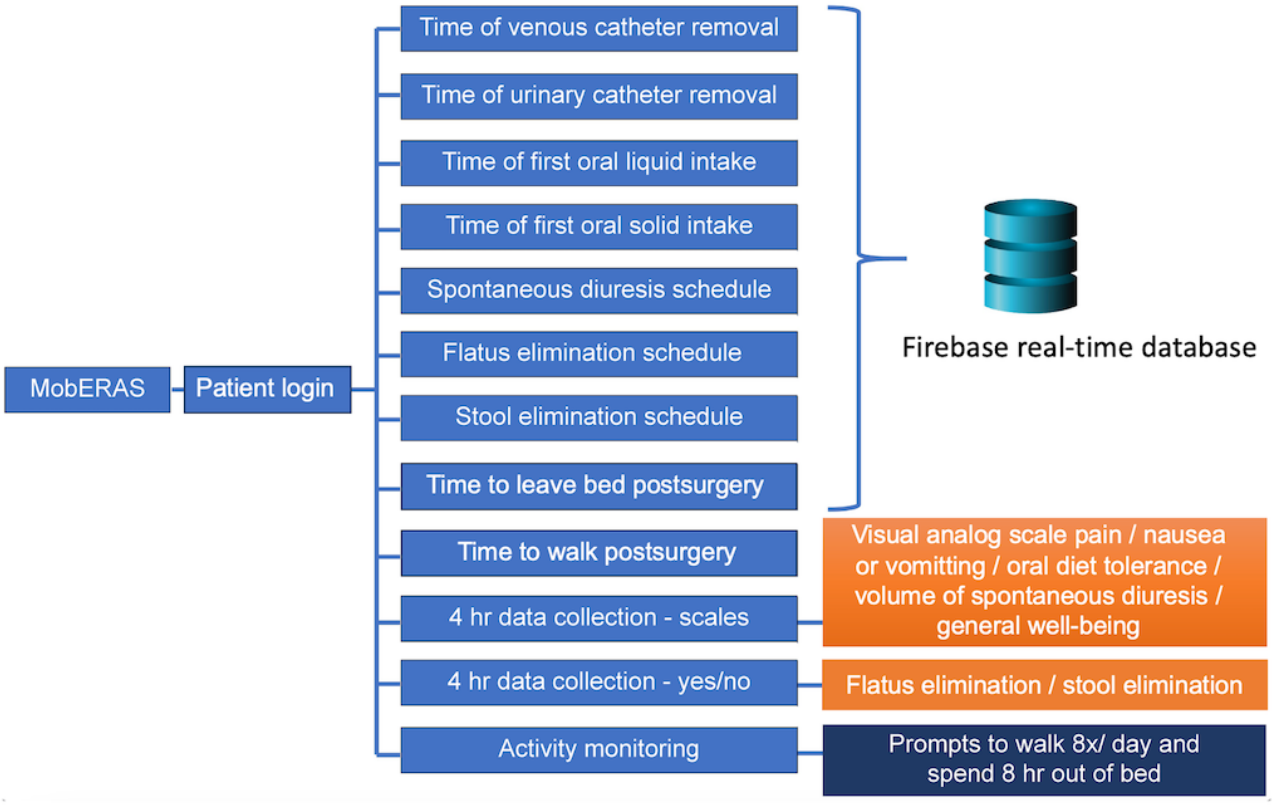
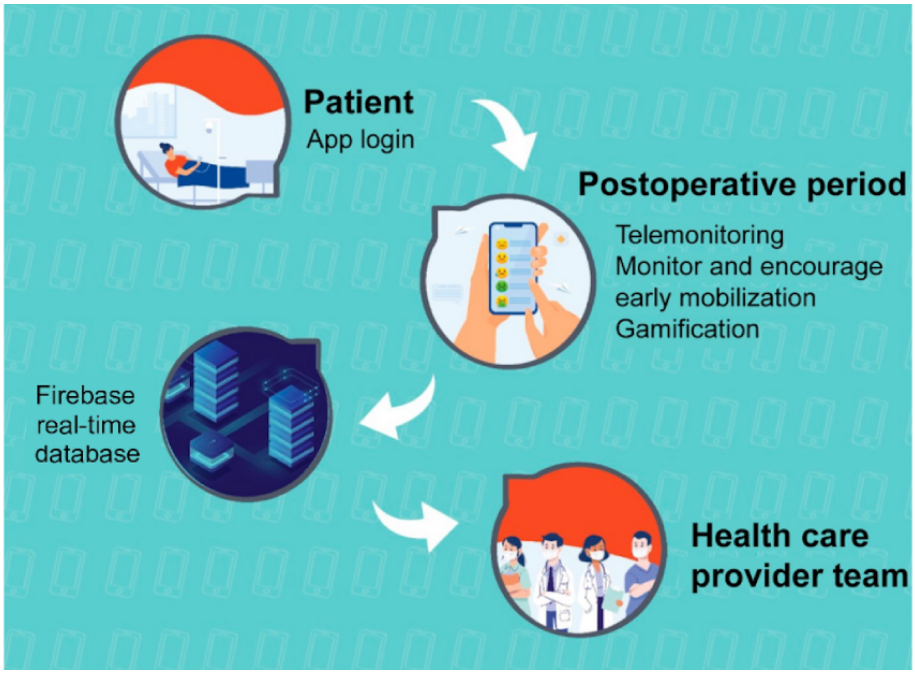


Figure 2. MobERAS enables real-time telemonitoring of the postoperative course and aims to improve patients' adherence to medical recommendations using gamification tools. MobERAS: mobile app for enhanced recovery after surgery.



Validation Process

To validate MobERAS, the study included the participation of a multidisciplinary team, including physicians and nurses from the health care team, computer professionals, and patients who used the app.

Study Population

Although the app is applicable to several surgical specialties, it was validated in the patient population attended by the physicians participating in the study. Patients with proposed medium and major gynecologic oncologic surgeries were invited to participate in the study. The patients were recruited from a public teaching hospital and a private hospital, both in Brazil and references in the care of women with gynecological cancer.

In total, 69 patients were invited to participate in the study, all of whom were undergoing medium and major gynecologic oncologic surgery. Of these, 4 (5.8%) patients refused to participate in the study: 2 (50%) of these 4 patients argued that they had no contact with any mobile device. These were an 83-year-old and a 72-year-old patient, the first one with no educational background and family income of 1 minimum wage and the second with incomplete primary education and family income between 1 and 2 minimum wages. Thus, 65 (94.2%) patients were included in the study, 35 (53.8%) patients from the public teaching hospital and the other 30 (46.2%) from the private hospital.

MobERAS Functioning

MobERAS was tested in the postoperative period as soon as patients arrived in the postanesthetic recovery room. The time of use was determined by the length of hospitalization of patients in the postoperative period. We evaluated adherence to the use of the app through the percentage of completion of the requested topics and through data collection regarding mobility and ambulation.

Patients' Evaluation of MobERAS

Aiming at evaluating the usability of MobERAS and its acceptance by users, at the end of its use by patients, at the time of hospital discharge, the patients were invited to fill out a survey, evaluating their experience with using the app and providing their opinion about it (Table 2). For this evaluation, we used the System Usability Scale (SUS), a usability scale developed by Brooke [25] in 1986. The SUS is a simple scale that offers a global view of subjective evaluations of usability [25].

The SUS is composed of 10 statements that are scored on a 5-point agreement strength scale, where 1 means "I totally disagree" and 5 means "I totally agree." The final scores range from 0 to 100, where higher scores indicate better usability. The statements alternate between positive and negative [25] because there are features in the statements that tend to result in generally positive or negative evaluations [26].

The SUS produces a single number (SUS score) that represents a measure of the overall usability of the system. Individual item scores are not meaningful in isolation. To calculate the SUS score, 1 is subtracted from the score that the user provides to the odd items (1, 3, 5, 7, and 9) and the user's score provided to the even items (2, 4, 6, 8, and 10) is subtracted from 5. For example, if the user scores an even item 2, the item score is 5 – 2 = 3. Thus, the contribution score for each item ranges from 0 to 4. After this, all the scores of the 10 questions are added, and the total value is multiplied by 2.5, resulting in the final score [25]. A score above 68 is considered above average, and a value below 68 is below average. However, Despite the wide use of the SUS, there is little guidance on the interpretation of SUS scores [27].

Table 2. MobERAS[a] evaluation questionnaire answered by the patients[b].

Item #	Item	I totally disagree	I disagree	I neither agree nor disagree (indifferent)	I agree	I totally agree
1	I would use MobERAS again.					
2	I found MobERAS unnecessarily complex.					
3	I found MobERAS easy to use.					
4	I would need help from a person with technical knowledge to use MobERAS.					
5	I think MobERAS functions are very well integrated.					
6	I think MobERAS is too inconsistent.					
7	I imagine that people will learn how to use MobERAS quickly.					
8	I found MobERAS confusing to use.					
9	I felt confident using MobERAS.					
10	I had to learn several new things before I could use MobERAS.					

[a]MobERAS: mobile app for enhanced recovery after surgery.

[b]Adapted from Brooke [25].

Evaluation of MobERAS by Health Care and Computer Professionals

To evaluate the quality of the information contained and provided by MobERAS, we used a multidimensional scale developed by Stoyanov et al [28] to rate and evaluate the quality of mobile health (mHealth) apps [28]. According to the Mobile App Rating Scale (MARS), the app quality was evaluated in 4 dimensions (engagement, functionality, aesthetics/design, and information) by 20 health care professionals (physicians and nurses) and 10 professionals with a computer science background working in technological innovation. All items were evaluated on a 5-point scale, from 1 for "inadequate" to 5 for "excellent." The minimum-possible score for each item was 30 and the maximum was 150 (1 and 5 points for each professional, respectively).

Ethical Considerations

The study was approved by the Ethics Committee of both hospitals (Women's Hospital Prof. Dr. José Aristodemo Pinotti and Vera Cruz Hospital), in addition to the ethics committee of São Paulo State University "Júlio de Mesquita Filho" (approval number 98361118.0.0000.5411), the proponent institution of the research, and all participants signed an informed consent form.

Results

Constructing a Mobile App: Product Development

The Initial Product (Prototype)

An initial product (prototype) was developed to run on the Android operating system, based on Figures 1 and 2. Usability tests were performed throughout the development process, with improvements, technical adjustments, and updates. Usability problems were verified using Nielsien's heuristics [29]. Usability tests were performed using this preliminary version of MobERAS in 10 women undergoing gynecological oncological surgery. Patients were interviewed to verify the difficulties in app use and obtain suggestions for app improvement. In this preliminary phase, system failures were analyzed and the necessary corrections and improvements were made. After the finalization of app development, comprehensive verification tests of the final product were conducted and validation tests were performed.

The Final Product

The final product complies with General Data Protection Regulations (GDPR), guaranteeing preservation of patient privacy. The patient account registers the patient's name, date of birth, and nationality (Figure 3A). After the patient logs in, a text with instructions on how the app works is displayed. The patient is then shown a video that uses drawings and visual animations to convey guidelines from the ERAS program aiming to improve recovery time and postoperative outcomes (Figure 3B). No intervention that causes changes in the treatment planning of the patient is proposed. The ERAS program guidelines are recommended for routine clinical and surgical practice.

After the end of the video, MobERAS displays a screen containing the first questionnaire, which refers to the occurrence of events usually monitored in the postoperative period, such as removal of the venous access and bladder catheter. The patient answers each question when the respective intervention occurs. The patient is also asked to record the first occurrence of certain events, such as the time of the first oral intake or spontaneous diuresis (Figure 4C-E). The events recorded by the questionnaire are presented in Textbox 1.

Figure 3. Sequence of MobERAS operation created for this study. (A) Login, (B) a video describing ERAS guidelines using drawings and visual animations, (C) the first questionnaire referring to the occurrence of events usually monitored in the postoperative period, and (D and E) the date and time of events recorded in (C). ERAS: enhanced recovery after surgery; MobERAS: mobile app for enhanced recovery after surgery.

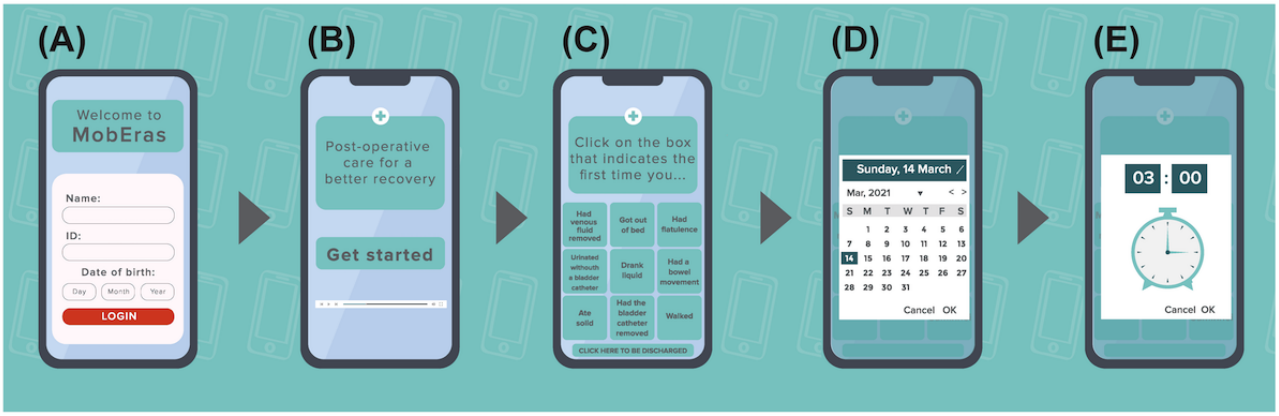
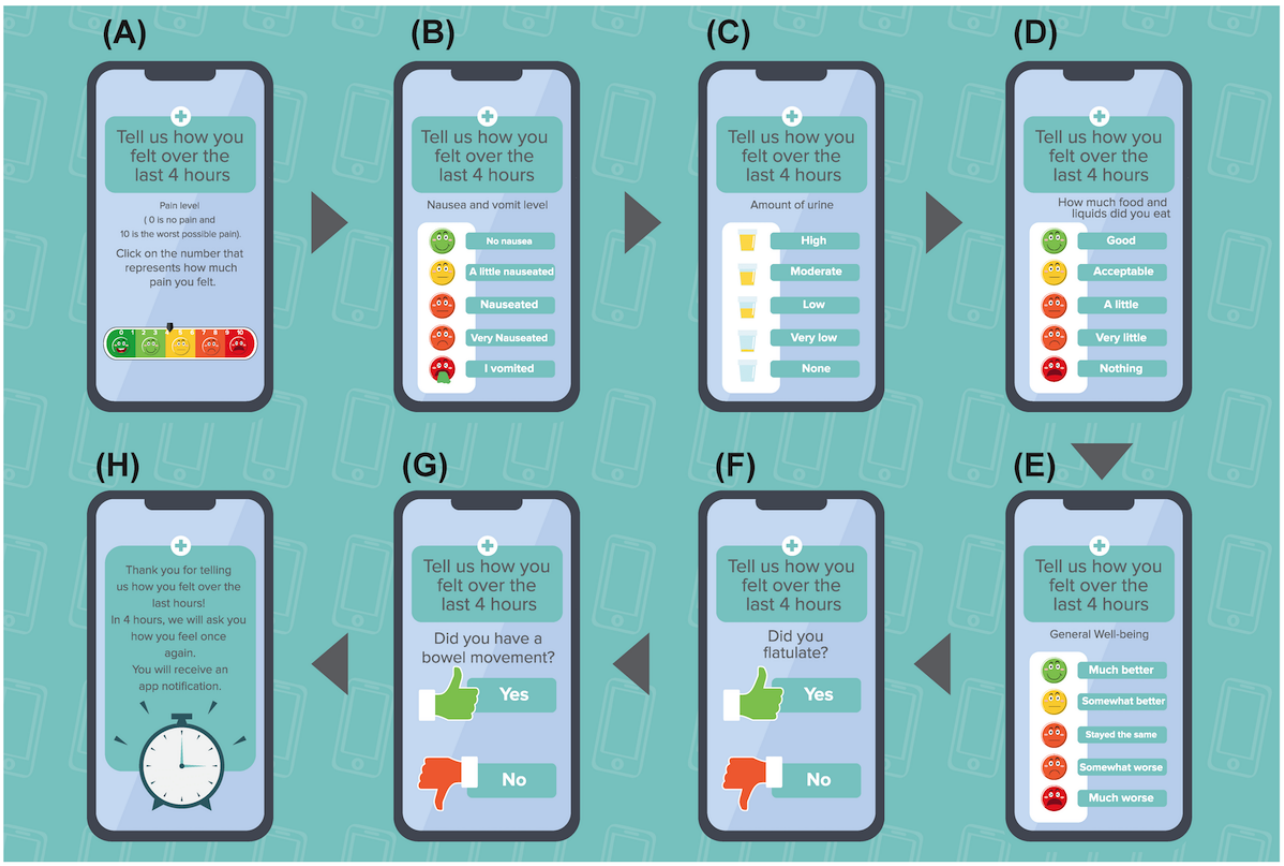


Figure 4. The second questionnaire, which the patient completes every 4 hours, when prompted by MobERAS. The patient is invited to click the number or figure that best represents their health status in the past 4 hours. (A) Pain level, (B) nausea and vomiting level, (C) amount of urine, (D) amount of food and liquid ingested, (E) general well-being, (F) occurrence of flatus, (G) whether bowels were opened, and (H) notice that a new notification to complete the questionnaire will be sent in 4 hours. MobERAS: mobile app for enhanced recovery after surgery.



Textbox 1. Questionnaires and parameters monitored by the mobile app for enhanced recovery after surgery (MobERAS).

First Questionnaire

Click on the box that indicates the first time you:

- Drank liquid
- Ate solid
- Had the bladder catheter removed
- Urinated without a bladder catheter
- Had flatulence
- Had a bowel movement
- Had venous fluid removed
- Got out of bed
- Walked

Second Questionnaire

Tell us how you felt over the last 4 hours. Click on the figure or number that best represents your last 4 hours.

- Visual analog scale for pain (Figure 4A): pain level (0: no pain; 10: worst-possible pain). Click on the number that represents how much pain you felt.
- Nausea and vomiting level: 5 levels of intensity (Figure 4B). No nausea, a little nauseated, nauseated, very nauseated, or vomited.
- Amount of urine: 5 levels of intensity (Figure 4C). High, moderate, low, very low, or none.
- How much food and liquids did you eat: 5 levels of intensity (Figure 4D). Good, acceptable, a little, very little, or nothing.
- General well-being: 5 intensity levels (Figure 4E). Much better, somewhat better, stayed the same, somewhat worse, or much worse.
- Did you flatulate? (Figure 4F): yes or no.
- Did you have a bowel movement? (Figure 4G): yes or no.

Simultaneously, the app screen continuously displays motivational messages on the upper scroll bar: “Try to eat all meals at the table and not in bed,” “Try to stay at least 8 hours out of bed,” “Try to walk at least 6 times throughout the day,” “Try to move your legs when you are lying down,” “Get moving! It is the best way for your recovery to be faster,” “Have you answered the questions of how you are today?” “Remember to answer the questions!”, and “Remember: your participation is essential for your recovery!”

At 4-hour intervals, alerts are triggered to complete a second questionnaire. Through this questionnaire, the patient is asked to score some scales and provide information on parameters to be monitored in the postoperative period. The patient is invited to click the number or figure that best represents their health status in the past 4 hours. These alerts are not triggered during the night (sleep period). The basic questions and scales are listed in Textbox 1, and examples of how the questions appear within the app are illustrated in Figure 4. With each positive note, the patient receives emojis or animations of recognition and congratulations to show that the event that occurred is desired for better recovery. Here, the use of gamification, through the reward system, is evident. Conversely, with each negative note, the patient receives emojis or animations to encourage improvement.

During app usage, the mobile device captures, through the GPS attached to it, the walking time and distance covered by the patient. At the time of hospital discharge, the patient confirms the date and time of the surgery and hospital discharge and then receives a final text with the guidelines to be followed at home in the postoperative period. All information recorded by the patient is sent to an online database connected to the attending physician’s cell phone, with the possibility of accessing the information in real time. This enables fast and targeted telemonitoring of patients.

Validation of the Final Product

MobERAS Functioning

MobERAS was used by all 65 (100%) patients in the study. The age of the women ranged from 18 to 85 years (mean 53.2, SD 7.4) years. Regarding the level of education, 29 (44.6%) women reported a medium level, and only 2 (3.1%) said they had no education. The number of women with elementary school and higher education was similar (n=18, 28.3%, and n=16, 24%, respectively). Regarding family income, most (n=51, 78.5%) reported an income of more than 4 minimum wages, with only 1 (1.5%) woman reporting an income below 2 minimum wages.

The average time of use was 45.1 (SD 19.2) hours, ranging from 23.4 to 70 hours. All patients completed the static questionnaire. Regarding the dynamic questionnaire, a completion rate ranging from 41.7% to 100% was observed (mean 56.3%, SD 12.1%).

There was a failure to capture data related to mobility and ambulation in 5 (7.7%) patients. Of these 5 patients, 3 (60%) did not move with the mobile device, and in the other 2 (40%) cases, there was a GPS malfunction. After expert evaluation,

GPS connection failure was identified. Thus, mobility and ambulation data were obtained for 60 (92.3%) of 65 patients.

Patients' Evaluation of MobERAS

The average SUS score of studies available in scientific databases is 68. In this study, the patients' perceived usability was found to be of a satisfactory level, with a mean SUS score of 81.3 (SD 9.4). Individual scores ranged from 70 to 100. The SUS score was calculated individually for each patient using MobERAS, and then, the scores were averaged. Of the 65 patients participating in the study, the majority (n=60, 92.3%) answered the final MobERAS usability evaluation questionnaire (SUS).

Evaluation of MobERAS by Health Care and Computer Professionals

In the evaluation of MobERAS by health care professionals and professionals specialized in technological innovation, it was possible to observe good general compliance with the proposed requirements for app evaluation. Considering a score of less than 70 as bad or very bad, from 70 to 110 as average, and higher than 110 as good or very good, the app was rated on all items evaluated according to MARS as good or very good, as shown in Table 3.

Table 3. MARS[a] used in the evaluation of the quality of information contained in or provided by MobERAS[b,c].

Dimension of MARS and assessments	Score
Engagement	
Entertainment (1: dull; 2: mostly boring; 3: OK; 4: moderately fun; 5: highly fun)	137
Interest (1: not interesting at all; 2: mostly uninteresting; 3: OK; 4: moderately interesting; 5: very interesting)	145
Customization (1: does not allow any customization; 2: allows insufficient customization; 3: allows basic customization; 4: allows numerous options for customization; 5: allows complete customization to the individual's characteristics)	128
Interactivity (1: no interactive features; 2: insufficient interactivity; 3: basic interactive feat; 4: offers a variety of interactive features; 5: very high level of interactive features)	119
Target group (1: completely confusing; 2: mostly confusing; 3: acceptable; 4: well targeted; 5: perfectly targeted)	147
Functionality	
Performance (1: inaccurate response; 2: major technical problems; 3: some technical problems; 4: mostly functional with minor problems; 5: perfect response)	111
Ease of use (1: no instructions; 2: usable after a lot of effort; 3: usable after some effort; 4: easy to learn how to use, clear instructions; 5: immediate use; intuitive)	143
Navigation (1: disconnected and random sections/navigation difficult; 2: usable after a lot of effort; 3: usable after some effort; 4: easy to use; 5: perfectly logical and intuitive screen flow throughout)	145
Gestural design (1: completely confusing; 2: often confusing; 3: OK, with some confusing elements; 4: intuitive, with negligible problems; 5: perfectly intuitive)	144
Aesthetics/design	
Layout (1: very bad design, some options impossible to select; 2: bad design, some options difficult to select; 3: satisfactory, few problems with selecting; 4: mostly clear, able to select; 5: professional, clear device display)	118
Graphics (1: amateurs; 2: lowqality / resolution; 3: moderate quality; 4: high quality; 5: very high quality)	122
Visual appeal (1: no visual appeal; 2: little visual appeal; 3: some visual appeal; 4: high level of visual appeal, professionally designed; 5: very attractive, memorable, stands out)	115
Information	
Accuracy of app description (1: has no description; 2: inaccurate; 3: OK; 4: accurate; 5: highly accurate description of app components/functions)	145
Goals (N/A[d]: app goals irrelevant to research goal; 1: has no chance of achieving its stated goals; 2: has very little chance of achieving goals; 3: clear goals, which may be achievable; 4: clearly specified goals and achievable; 5: specific and measurable goals, which are highly likely to be achieved)	140
Quality of information (N/A: no information within the app; 1: irrelevant/incoherent; 2: barely relevant/coherent; 3: moderately relevant/coherent; 4: relevant/coherent; 5: highly relevant/coherent)	144
Quantity of information (N/A: no information within the app; 1: minimal; 2: insufficient; 3: OK but not comprehensive; 4: broad range of information, some gaps; 5: comprehensive and concise, contains links to more information and resources)	117
Visual information (N/A: no visual information within the app; 1: completely confusing; 2: mostly confusing; 3: OK but often confusing; 4: mostly clear; 5: perfectly clear)	147
Credibility (1: legitimacy worthiness of source questionable; 2: legitimate source but cannot be verified; 3: developed by small nongovernmental organization/institution/specialised commercial business/funding body; 4: developed by government, university, or as above but larger in scale; 5: developed using nationally competitive government or research funding)	120
Evidence base (N/A: app not tested; 1: app not working; 2: trialled and partially positive outcomes in studies that are not RCTs[e]; 3: trialled and positive outcomes in studies that are not RCTs; 4: trialled and positive outcomes in 1-2 RCTs; 5: trialled and positive outcomes in >3 high-quality RCTs)	N/A

[a]MARS: Mobile App Rating Scale.

[b]MobERAS: mobile app for enhanced recovery after surgery.

[c]Adapted from Stoyanov et al [28].

[d]N/A: not applicable.

[e]RCT: randomized controlled trial.

Discussion

Principal Findings

This study described the development and validation process of an app (MobERAS) for telemonitoring, guiding, and encouraging the adoption of medical recommendations for use in the postoperative period. To the best of our knowledge, this is the first study to describe such an app for telemonitoring patients in the postoperative period using gamification. There are few apps developed to be used in the perioperative period, and most of these apps are intended to provide information to patients. An example is the Heal Better app [30], which aims to help educate and empower patients to comply with a recovery care plan after abdominal surgery by providing clinical information. The difference between MobERAS and these other apps is the real-time monitoring of the patient in the postoperative period and the use of gamification as a tool to encourage recommended medical practices. By combining telemonitoring with gamification, MobERAS aims to (1) monitor the postoperative course using data provided by patients; (2) evaluate the incorporation of the ERAS program recommendations into clinical and surgical practice and patients' responses to the adopted recommendations; (3) promote greater participation of patients in their postoperative recovery process and better adherence to medical recommendations, aiming to achieve faster recovery, early discharge from the hospital, and lower rates of complications; and (4) enable remote and real-time access of health data and postoperative evolution by physicians.

Worldwide, over 300,000 health apps are currently under development. Both the US Food and Drug Administration (FDA) and the European Medicine Agency of the European Union (EU) have recognized the importance of the software in diagnostic and therapeutic devices. Guidelines related to the use of digital tools in health were published by the World Health Organization in 2018, organizing the different digital and mobile interventions and their use in favor of the health system [31]. Significant progress has been made in app development, building an evidence base, validating functionality, and creating standards for development and design structures for app reviews. Nonetheless, even if an app is well developed, with evident quality, its ability to improve the health and well-being of patients can only be achieved if the app is actually used [1]. Features such as gamification can significantly increase users' attention and involvement. The most accepted definition of gamification is "the use of game design elements in nongame contexts." There are many gamification strategies that increase engagement, such as narrative structure, symbols, or avatars based on self-image, as well as integration tutorials. Resources present in smartphones, such as sensors and GPS services, have been useful for gamified health care interventions [15]. Considering this, gamification strategies were used to develop MobERAS, including the use of figures representing the health status of patients, a reward system, avatars, and motivational figures, as well as a GPS attached to the system to monitor walking. We believe that this will motivate patients to fulfill their goals and consequently follow medical recommendations, thus reaching the desired postoperative objectives.

It is known that walking 10 m (or 30 steps) without interruption can reduce the risk of thromboembolic phenomena by up to 50% [32]. It is also known that mobile device tools, such as sensors, can be useful in the delivery of health care resources [28]. Mobile devices have sensors integrated into them, and this type of resource can assist health care professionals in treating their patients with permanent connectivity [33]. In this context, the GPS integrated into MobERAS is used for continuous monitoring of mobility time and walking distance.

MobERAS was designed to start being used in the postoperative period for patients still in the hospital, showing the first signs of occurrence of important events, such as bladder catheter removal or the first oral intake, in addition to collecting postoperative data at short intervals, considering the need for more frequent monitoring during the hospital stay, such as monitoring pain, diet acceptance, or diuresis volume. For this reason, the app was validated in the hospital in the postoperative period within less than 72 hours of use. Nonetheless, the app can be programmed to collect information at longer intervals (eg, once or twice a day), and its domestic use can be evaluated in another study.

MobERAS collects self-reported data from patients just as if they were having an appointment with a doctor. The idea is for the app to become a tool to help with postoperative monitoring and not a replacement for regular supervision by the health care team. All information received by health care professionals in real time enables the early diagnosis of possible postoperative complications, resulting in better patient supervision after surgery being able to prevent more serious complications.

Postoperative adverse events are associated with longer hospital stays and increased mortality rates. The ERAS program represents a paradigm shift in conventional perioperative care, replacing some traditional practices with better evidence-based practices, minimizing overall health care spending, allowing for faster and safer rehabilitation, and improving well-being and patient satisfaction [15,16]. With this objective, the program focuses mainly on a decrease in perioperative stress, adequate pain control, return to normal gastrointestinal function, and early mobilization [22]. The app developed and described in this study was based on recommendations of the ERAS program. The parameters evaluated are those that can influence the length of hospital stay, such as nausea, vomiting, pain, return to normal normal gastrointestinal function, and thromboembolic events.

Thus, according to the guidelines recommended by the ERAS program and because MobERAS is gamified, we believe that the app can encourage longer walking times, with a consequent faster return to normal gastrointestinal function, and fewer thromboembolic events, resulting in benefits such as faster postoperative recovery, shorter hospital stay, and a lower rate of postoperative complications. Through the continuous collection of data from patients and the sharing of this knowledge with the doctor in real time, better pain control and better management of nausea and vomiting are expected with the use of the app. Moreover, the hospital will benefit from lower hospitalization costs without increasing the rate of complications.

Although mobile device ownership is widespread, its use in disease management and self-care is still in its early stages, and there is limited knowledge about its use in the perioperative setting [12]. MobERAS has as some of its objectives the collection of postoperative data and the telemonitoring of patients undergoing surgery. Using validation tests, these objectives were achieved, with the collection of clinical data and the monitoring of patients' health status, sharing information with health care professionals in real time. Objective symptoms are traditionally monitored as part of care and treatment, but patients' subjective descriptions are considered a key element of monitoring [15]. Through the app, patient self-reported information was collected, both regarding symptoms, such as pain, nausea, and vomiting, and objective parameters, such as serum and catheter withdrawal times.

Most health apps for smartphones have simple functions and do a little more than providing basic information. However, there is great potential for developing more effective gamified apps, depending on the repertoire and combinations of techniques used that are appropriate for a gamified platform. This development requires multidisciplinary collaboration between game developers, behavior change specialists, and public health experts [34]. In response to this need, this study involved health care professionals and experts in innovation technology in both the development and evaluation of MobERAS. As a result, we developed an app that, in addition to collecting data, uses gamification as a tool to guide and encourage patients to engage in their postoperative recovery process and comply with medical recommendations.

Given the rapid proliferation of smartphone apps, it is increasingly difficult for users, health care professionals, and researchers to identify and evaluate high-quality apps. Little information about the quality of apps is available [29]. One of the critical issues is the lack of evaluation of the reliability of mHealth monitoring systems [33]. In addition, there is little evidence that health care professionals and users participate in the design of health apps, and most apps do not contain theoretically consistent behavior change techniques. Few apps are compliant with the regulatory processes or have had their effectiveness formally evaluated, leading to concerns about the lack of benefits or even potentially harmful apps [34]. For this reason, we chose to perform a comprehensive validation of our app in this study, with quality assessment both from a subjective point of view, using the SUS answered by patients using the app, and from a technical point of view, using MARS and expert assessments.

Through the SUS answered by the patients, good evaluation was observed regarding usability, which suggests good acceptance of the use of the app by the patients. The SUS was chosen because of its widely recognized use in assessing product usability and its flexibility to adapt, because it is quick and easy to use, and because it offers a unique score that is easily understood by people who are involved in product and service development [26]. In addition, MobERAS was rated by the experts as good or very good on all MARS parameters, which also suggests a well-developed app with regard to engagement, functionality, design, and information. This leads us to conclude that this is a safe app with potential benefits and possible applicability in clinical practice.

Limitations and Strengths

One limitation of this work is that no case-control study was conducted to assess the impact of using the software on the occurrence of postoperative complications and the length of hospital stay. Furthermore, the use of MobERAS depends on an internet connection and active patient participation, and there may be changes in the level of awareness, pain, and other parameters that limit the correct use of MobERAS during the early postoperative period. The gamification process and app design also require further improvement. Although the app involved participation of patients during initial construction of the product and validation tests were performed with the participation of patients and professionals, the app was not codesigned with patients and health care professionals. In addition, the difficulty or ease of use of the app according to different age groups and socioeconomic levels was not analyzed.

However, the study also highlights the strengths of the app and its usefulness, which include the contribution of a multidisciplinary team and international applicability. Moreover, the technology used is compatible with current trends in health practices, and the app is compatible with cell phones and devices present in the daily life of the population. Another important point is that MobERAS was examined by experts, with good evaluation. In addition, the app's good functionality was proven, with postoperative data capture and its potential clinical applicability, in addition to good acceptance of its use by the patients.

Challenges

Challenges in the field of digital health care include issues related to development, validation, and use [35]. Despite such challenges, it is expected that these obstacles will be overcome by a growing number of apps that will become increasingly suitable for use in clinical practice. However, the first challenge in the dissemination of apps for clinical use is to increase awareness of the technologies available to doctors [1]. We believe that MobERAS can be of great help in the health care of patients, with possible early detection of postoperative complications, in addition to better monitoring of patients. We believe that the app can contribute to the health team acting immediately and more effectively when facing complications. Moreover, because the app is easy to navigate and attractive through the use of gamification tools, the patient can be stimulated to follow medical recommendations for better recovery. The app will work as a "virtual companion" during the patient's postoperative stay in the hospital. A subsequent randomized clinical trial will help us understand better the impact of MobERAS on postoperative clinical practice.

Conclusion

In conclusion, MobERAS can be used to orient patients, obtain postoperative data, and monitor patients in real time. The app is easy to use and attractive, given its gamified design. MobERAS is well accepted by patients and well evaluated by experts. Overall, MobERAS can be of great use in clinical practice, promoting the engagement and commitment of patients

in their postoperative care. We believe that the app can contribut to better postoperative assistance and outcomes. Further studies are required to verify the clinical applicability of MobERAS in a greater number of patients and the impact of its use on postoperative recovery.

Acknowledgments

This manuscript is the result of a doctoral thesis (for data for this thesis see [36]) at the Universidade Estadual Paulista “Júlio de Mesquita Filho” (UNESP) and is part of a research project that aims to develop and test software that encourages and monitors the adoption of ERAS program principles by patients undergoing surgery.

Authors' Contributions

Data collection was managed by EBC, AES, and ALSF; data analysis by AES and ALSF; technical application development by VPGC; manuscript writing by AES, ALSF, and RSF; and overseeing of app technical development by WCB.

Conflicts of Interest

None declared.

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Abbreviations

ERAS: enhanced recovery after surgery
MARS: Mobile App Rating Scale
mHealth: mobile health
MobERAS: mobile app for enhanced recovery after surgery
RCT: randomized controlled trial
SUS: System Usability Scale

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Original Paper

Impact of Consumer Wearables Data on Pediatric Surgery Clinicians' Management: Multi-Institutional Scenario-Based Usability Study

Michela Carter[1], MD; Samuel C Linton[1], MD, MS; Suhail Zeineddin[1], MD, MS; J Benjamin Pitt[1], MD, MS; Christopher De Boer[1], MD, MS; Angie Figueroa[1], MS; Ankush Gosain[2], MD, PhD; David Lanning[3], MD, PhD; Aaron Lesher[4], MD, MS; Saleem Islam[5], MD, MPH; Chethan Sathya[6], MD, MS; Jane L Holl[7], MD, MPH; Hassan MK Ghomrawi[8], MPH, PhD; Fizan Abdullah[1], MD, PhD

[1]Division of Pediatric Surgery, Department of Surgery, Ann and Robert H Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, IL, United States

[2]Division of Pediatric Surgery, Department of Surgery, Children's Hospital Colorado, University of Colorado School of Medicine, Aurora, CO, United States

[3]Division of Pediatric Surgery, Department of Surgery, Children's Hospital of Richmond at Virginia Commonwealth University, Richmond, VA, United States

[4]Division of Pediatric Surgery, Department of Surgery, Medical University of South Carolina, Charleston, SC, United States

[5]Division of Pediatric Surgery, Department of Surgery, University of Florida College of Medicine, Gainesville, FL, United States

[6]Division of Pediatric Surgery, Department of Surgery, Cohen Children's Medical Center, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, New Hyde Park, NY, United States

[7]Department of Neurology and Center for Healthcare Delivery Science and Innovation, University of Chicago, Chicago, IL, United States

[8]Department of Orthopaedic Surgery, Heersink School of Medicine, University of Alabama at Birmingham, Birmingham, AL, United States

Corresponding Author:
Fizan Abdullah, MD, PhD
Division of Pediatric Surgery, Department of Surgery
Ann and Robert H Lurie Children's Hospital of Chicago
Northwestern University Feinberg School of Medicine
225 East Chicago Avenue
Box 63
Chicago, IL, 60611
United States
Phone: 1 312 227 4210
Email: Fabdullah@luriechildrens.org

Abstract

Background: At present, parents lack objective methods to evaluate their child's postoperative recovery following discharge from the hospital. As a result, clinicians are dependent upon a parent's subjective assessment of the child's health status and the child's ability to communicate their symptoms. This subjective nature of home monitoring contributes to unnecessary emergency department (ED) use as well as delays in treatment. However, the integration of data remotely collected using a consumer wearable device has the potential to provide clinicians with objective metrics for postoperative patients to facilitate informed longitudinal, remote assessment.

Objective: This multi-institutional study aimed to evaluate the impact of adding actual and simulated objective recovery data that were collected remotely using a consumer wearable device to simulated postoperative telephone encounters on clinicians' management.

Methods: In total, 3 simulated telephone scenarios of patients after an appendectomy were presented to clinicians at 5 children's hospitals. Each scenario was then supplemented with wearable data concerning or reassuring against a postoperative complication. Clinicians rated their likelihood of ED referral before and after the addition of wearable data to evaluate if it changed their recommendation. Clinicians reported confidence in their decision-making.

Results: In total, 34 clinicians participated. Compared with the scenario alone, the addition of reassuring wearable data resulted in a decreased likelihood of ED referral for all 3 scenarios (P<.01). When presented with concerning wearable data, there was an increased likelihood of ED referral for 1 of 3 scenarios (P=.72, P=.17, and P<.001). At the institutional level, there was no difference between the 5 institutions in how the wearable data changed the likelihood of ED referral for all 3 scenarios. With the addition of wearable data, 76% (19/25) to 88% (21/24 and 22/25) of clinicians reported increased confidence in their recommendations.

Conclusions: The addition of wearable data to simulated telephone scenarios for postdischarge patients who underwent pediatric surgery impacted clinicians' remote patient management at 5 pediatric institutions and increased clinician confidence. Wearable devices are capable of providing real-time measures of recovery, which can be used as a postoperative monitoring tool to reduce delays in care and avoidable health care use.

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KEYWORDS

postoperative care; telehealth; consultation; remote; appendectomy; pediatric hospital; children; wearable device; minimally invasive surgery; pediatric surgery; remote simulation study

Introduction

When children are discharged from the hospital after surgery, clinicians depend on caregivers' surveillance of the patient and analysis of their recovery to initiate communication with the health care team. When a caregiver contacts the surgical team with concerns, clinicians rely on the caregiver's narrative of the patient's experience after discharge in order to triage the patient. Currently, caregivers lack objective methods to evaluate recovery after discharge. As a result, they are dependent upon their subjective assessment of the child's well-being and the child's ability to communicate their symptoms. It has been shown that the subjective nature of home monitoring contributes to both avoidable health care use and delays in treatment [1-4].

In the United States, laparoscopic appendectomy is the most common inpatient procedure in children, with approximately 80,000 to 100,000 performed annually [5]. Nearly 20% of appendectomies result in emergency department (ED) visits or readmissions within 90 days postoperatively, and greater than 40% of these ED presentations are potentially avoidable [6]. Clinician access to objective recovery data offers the potential for improved patient triage in the postoperative setting and would serve to reduce delays in care and unnecessary health care use. Consumer wearable devices, for example, Fitbit (Google), have the ability to provide continuous objective measurements of recovery, which include heart rate, step count, and sleep assessment (ie, "wearable data"). Furthermore, these data can be made available to clinicians in near real time. With such features, wearable devices have the potential to assist clinicians in the remote evaluation and triage of postoperative patients after discharge [7-10].

Within our institution, we previously demonstrated that the addition of wearable data to simulated scenarios of unplanned postoperative episodes of health care use impacted pediatric surgery clinicians' decision-making, including a significant difference in the likelihood of recommending immediate presentation to the ED and increased confidence in clinicians' decision-making [10]. However, the results may not be generalizable to other institutions that are not as familiar with the use of wearable devices in the postoperative setting. Therefore, the objective of this multi-institutional study was to evaluate whether the addition of actual and simulated objective data derived from a consumer-grade wearable device to telephone encounters derived from actual postoperative patient encounters impacted the decision-making of a diverse cohort of pediatric surgery clinicians when presented in a simulation environment.

Methods

Study Design

To evaluate the clinical use of wearable data, we presented 3 simulated, postdischarge telephone scenarios to pediatric surgery clinicians. The 3 scenarios were based on actual patients who underwent laparoscopic appendectomy for acute appendicitis at an urban, tertiary children's hospital. All 3 patients had worn the Fitbit Inspire, a consumer-grade wearable device, for 21 days after surgery as part of a previous study [8]. Surgeon authors (SL, CDB, and FA) selected these 3 patients to feature the most common postoperative complications following laparoscopic appendectomy, surgical site infections, and clinical scenarios, which could have been clarified with the addition of wearable data [11]. The three scenarios presented were as follows: (1) a 13-year-old female patient who underwent laparoscopic appendectomy for complicated appendicitis, and on a postoperative day 7, her caregiver called reporting 2 days of abdominal pain, loose stools, and incisional drainage; (2) a 10-year-old female patient who underwent laparoscopic appendectomy for simple appendicitis, and on postoperative day 3, her caregiver called with report of 2 days of fevers, abdominal pain, and periumbilical erythema; and (3) a 9-year-old male patient who underwent laparoscopic appendectomy for complicated appendicitis, and on postoperative day 10, his caregiver called with report of 2 days of purulent drainage from one of his surgical incisions.

Daily step counts and heart rate data were measured by Fitbit and recorded in Fitabase, a third-party, Health Insurance Portability and Accountability Act (HIPAA)–compliant database, designed to track data provided by an enrolled Fitbit device. The Fitbit data, in addition to information from the patient's electronic medical record, including actual documented encounters between the caregiver and pediatric surgery clinicians

and the documented descriptions of the patient's symptoms as reported by the caregiver, were used to generate the simulated telephone scenarios. For each scenario, the patient's wearable data were used to create a daily heart rate graph and a daily step count graph, both of which included data from postoperative day 1 through the date of the telephone encounter. In addition, the patient's average, minimum, and maximum heart rate in the 5 minutes, 1 hour, 4 hours, and 24 hours leading up to the encounter were displayed in a table. Using Fitbit data collected during our previously published study, the age- and sex-adjusted step counts collected from patients with an uncomplicated postoperative course after the same surgery were included as a normative reference for the clinician evaluating the patient's scenario [8].

The study team evaluated the patient's actual data at the time of the telephone encounter and classified it as concerning if the patient's heart rate was elevated and physical activity reduced relative to the normative reference data. Contrarily, wearable data were classified as reassuring if the heart rate and physical activity were approximate to the normative reference data. The study team then created simulated wearable data for each scenario that were opposite to the actual data, that is, simulated wearable data were concerning (elevated heart rate and low step count) when the patient's actual wearable data were reassuring (heart rate and step count within normal range for age). The source of the wearable data and the classification as concerning or reassuring were not shared with the clinicians who participated in the study. Representative concerning and reassuring wearable data for the 24 hours preceding the time of encounter for the 3 scenarios are demonstrated in Table 1.

Table 1. Concerning and reassuring wearable data for the 24 hours preceding the simulated telephone encounter for scenarios 1-3.

Patient and wearable data	Concerning	Reassuring
Scenario 1: 13-year-old female patient, POD[a] 7		
Average heart rate (bpm)	86	86
Minimum heart rate (bpm)	63	63
Maximum heart rate (bpm)	121	103
Step count	1100	6100
Scenario 2: 10-year-old female patient, POD 3		
Average heart rate (bpm)	80	80
Minimum heart rate (bpm)	60	60
Maximum heart rate (bpm)	142	105
Step count	650	5100
Scenario 3: 9-year-old male patient, POD 10		
Average heart rate (bpm)	109	92
Minimum heart rate (bpm)	93	78
Maximum heart rate (bpm)	144	113
Step count	2100	5050

[a]POD: postoperative day.

A total of 5 pediatric institutions, located throughout the United States, elected to participate in this study. The institutions that participated were diverse in practice settings; however, all were associated with an academic institution. Pediatric surgery clinicians, including attending surgeons, resident surgeons, and advanced practice providers, were recruited from the 5 participating institutions. Poll Everywhere audience response software was used for survey participation. At the start of the survey, the participants were oriented to wearable data from a patient with an uncomplicated postoperative course following laparoscopic appendectomy. The 3 telephone scenarios were then presented to the clinician participants in 3 formats. First, the scenario was presented without wearable data and participants were asked to triage the patient and determine the urgency for follow-up care, including seeking care immediately, prescribing a medication with outpatient follow-up, outpatient follow-up alone, and providing reassurance without the need for follow-up. Clinicians were then asked to rate their "likelihood to recommend the patient present to the ED immediately" using a 10-point Likert scale, with 1 representing "not at all likely to recommend ED presentation" and 10 representing "definitely would recommend ED presentation."

The participants were then shown the telephone scenario with concerning and reassuring wearable data in random sequence and without revealing the classification to the respondents. Participants were asked about their likelihood of recommending ED presentations using the same 10-point Likert scale for both sets of wearable data. They were then asked to report if the wearable data increased their confidence in their recommendation and, if provided the wearable data alone, they would initiate contact with the patient and caregiver to assess their recovery. Participants were only offered the opportunity to respond to each multiple-choice question once. In total, the participants were asked to score their likelihood of

recommending ED presentation for all 3 scenarios without wearable data, with concerning wearable data, and with reassuring wearable data for a total of 9 recommendations for ED presentation.

Statistical Analysis

Survey responses were determined to be nonparametric by Shapiro-Wilk testing. Descriptive analyses were performed and included frequencies of response and median (IQR). Wilcoxon rank sum test was performed comparing the clinician's recommendation for ED presentation without wearable data to their recommendation with concerning wearable data and reassuring wearable data. The likelihood of ED referral without wearable data was then subtracted from the likelihood of ED referral with wearable data to evaluate how a clinicians' management recommendation changed. A positive change was consistent with an increased likelihood of ED referral while a negative change was consistent with a decreased likelihood of ED referral. No difference indicated no change in the likelihood of ED referral. To evaluate for institutional variation, the proportion of survey respondents at each institution who were more likely to refer, were less likely to refer, and did not change their likelihood of ED referral with the addition of wearable data was determined for each scenario and compared by Fisher exact test. Statistical significance was defined as $P<.05$.

Ethical Considerations

This study received ethics exemption from Ann and Robert H Lurie Children's Hospital (IRB #2022-5553). The relevant guideline which supports exemption status is based on Lurie guidelines: the disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

Results

Study Participants

In total, 34 clinicians voluntarily participated in the study (Table 2). Site 3 contributed the greatest complement with 12 participants, accounting for 35% (12/34) of the study cohort. The smallest contributing site was site 1 with 4 participants, accounting for 12% (4/34) of the study cohort. In total, 65% (22/34) of the participants were attending surgeons, 15% (5/34) were advanced practice providers, 15% (5/34) were surgery residents, and 6% (2/34) did not report clinician type. Response rates ranged from 68% (23/34) to 85% (29/34) responses per survey question.

Table 2. Survey participants by institution and clinician type.

Institution	Attending, n (%)[a]	Advanced practice providers, n (%)[a]	Resident, n (%)[a]	Not reported, n (%)[a]	Total (N=34), n (%)
Site 1	4 (100)	0 (0)	0 (0)	0 (0)	4 (12)
Site 2	4 (67)	2 (33)	0 (0)	0 (0)	6 (18)
Site 3	4 (33)	1 (8)	5 (42)	2 (17)	12 (35)
Site 4	5 (100)	0 (0)	0 (0)	0 (0)	5 (15)
Site 5	5 (71)	2 (29)	0 (0)	0 (0)	7 (21)
All sites	22 (65)	5 (15)	5 (15)	2 (6)	34 (100)

[a]Percentage values are calculated using the values in the "Total" column as the denominators.

Scenario 1

When scenario 1 was presented without wearable data, 17 (61%) of 28 respondents recommended outpatient follow-up, while 10 (36%) recommended they seek care immediately and 1 (4%) recommended reassurance without follow-up. When asked to rank the likelihood of recommending ED presentation, the median recommendation was 5 (IQR 3-7). When presented with reassuring wearable data, the median recommendation for ED presentation was 2 (IQR 1-3) with a median change from when no wearable data were available of –2 (IQR –4 to –1; $P<.001$). ED referral was less likely for 24 (86%) of 28 respondents in response to the reassuring wearable data while 2 (7%) did not change their recommendation and 2 (7%) were more likely to recommend ED presentation. In total, 22 (85%) of 26 respondents reported increased confidence in their recommendation with the addition of the reassuring wearable data, while 6 (24%) of 25 reported that if they had been presented with the reassuring wearable data alone, they would have initiated contact with the patient or caregiver in order to evaluate for a postoperative complication.

When the scenario was presented with concerning wearable data, the median recommendation for ED presentation was 5 (IQR 3-7) with a median change of 0 (IQR 0-2; $P=.72$). A total of 9 (36%) of 25 respondents were more likely to recommend ED referral in response to the concerning wearable data, while 12 (48%) had no change in their recommendation and 4 (16%) were less likely to recommend ED referral. In total, 21 (88%) of 24 participants reported increased confidence in their recommendation, and 22 (85%) of 26 reported they would reach out to the patient or caregiver if presented the wearable data alone. Survey responses for scenario 1 are summarized in Table 3 and Figure 1. Response to the addition of reassuring and concerning wearable data by institutions is demonstrated in Figure 2. There was no difference between institutions in how they responded to the addition of reassuring ($P=.10$) or concerning wearable data ($P=.18$).

Figure 1. Recommendation for emergency department presentation provided by pediatric surgery clinicians at 5 institutions when presented with 3 simulated telephone scenarios: (1) without wearable data, (2) with concerning wearable data, and (3) with reassuring wearable data. Likelihood of emergency department referral reported on a 10-point Likert Scale with 1 representing “Not at all likely” and 10 representing “Definitely”. *Significant change by Wilcoxon rank sum test.

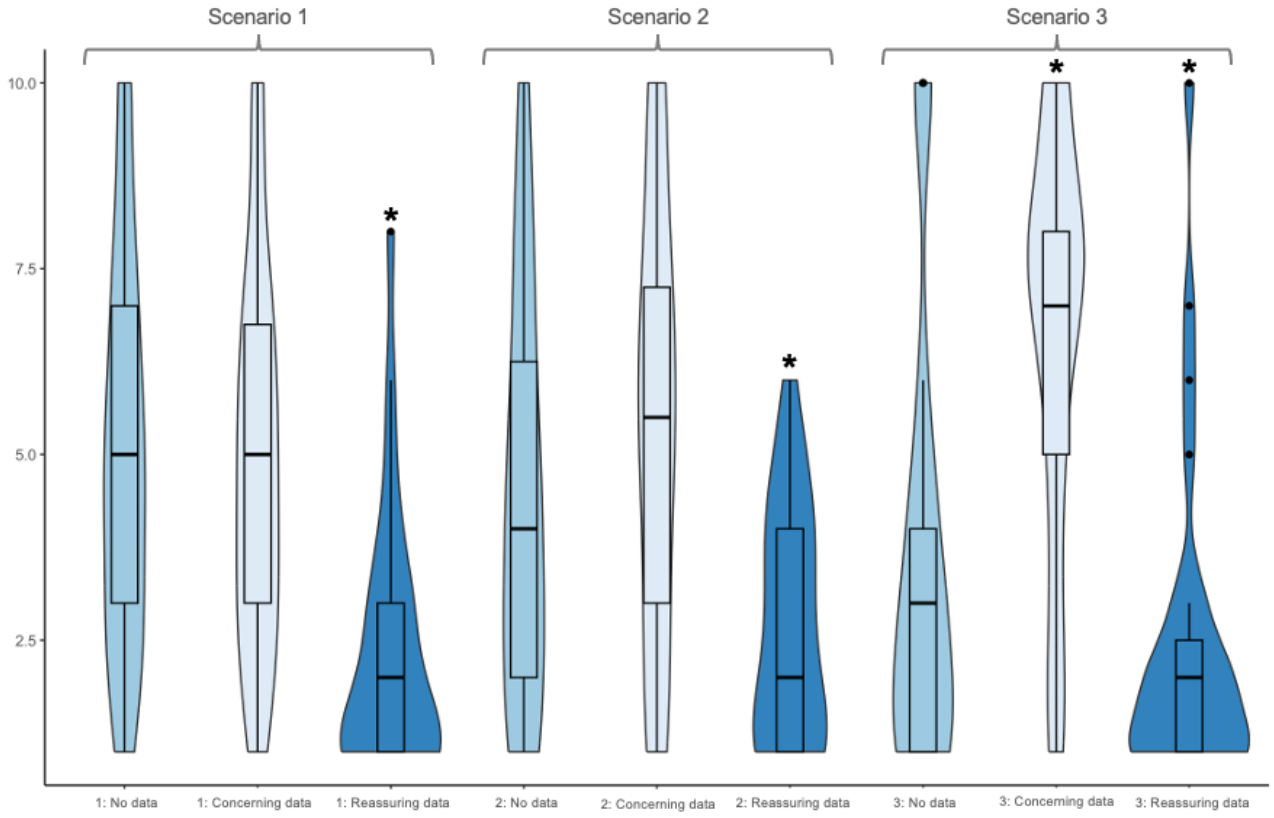


Figure 2. How the likelihood of emergency department referral changed at each institution with the addition of reassuring and concerning wearable data to scenario 1. ED: emergency department.

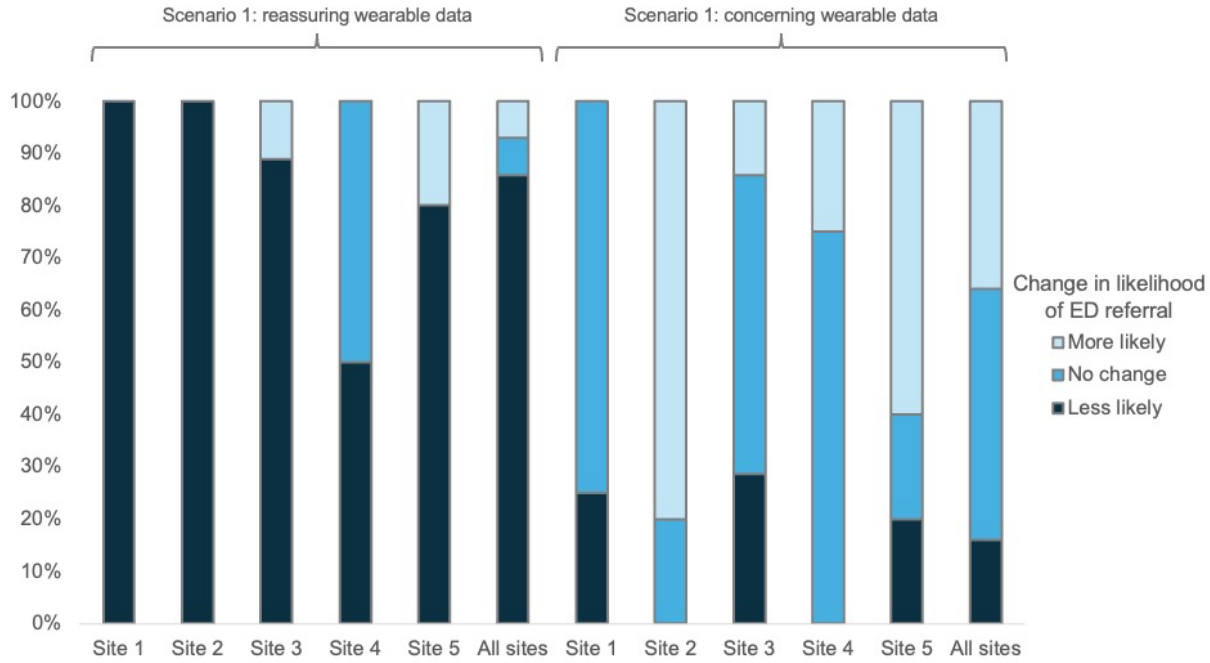


Table 3. Simulated remote management recommendations from pediatric surgery clinicians at 5 institutions in response to telephone scenario 1 presented without wearable data, then with reassuring and concerning wearable data. Scenario 1: 13-year-old female patient on postoperative day 7 following laparoscopic appendectomy for complicated appendicitis, now with 2 days of abdominal pain, loose stools, and incisional drainage.

	No wearable data	Reassuring wearable data	Concerning wearable data
Initial recommendation (n=28), n (%)			
Seek care immediately	10 (36)	—[a]	—
Prescription and outpatient follow-up	0 (0)	—	—
Outpatient follow-up	17 (61)	—	—
Reassurance and no follow-up	1 (4)	—	—
Likelihood of ED[b] referral, median (IQR)	5 (3 to 7)	2 (1 to 3)	5 (3 to 7)
Change in the likelihood of ED referral, median (IQR)	—	–2 (–4 to –1)	0 (0 to 2)
P value	—	<.001	.72
Increased confidence, n/N (%)	—	22/26 (85)	21/24 (88)
Would reach out to patient or caregiver, n/N (%)	—	6/25 (24)	22/26 (85)

[a]Not applicable.

[b]ED: emergency department.

Scenario 2

When scenario 2 was presented without wearable data, 14 (50%) of 28 respondents recommended outpatient follow-up, while 7 (25%) recommended a prescription and outpatient follow-up and 7 (25%) recommended the patient should seek care immediately. The median likelihood of recommending ED presentation was 4 (IQR 2-6.75). When reassuring wearable data was presented with the patient scenario, the median likelihood of recommendation for ED presentation decreased to 2 (IQR 1-4). This represented a median change in score of –1 (IQR –2.5 to 0; *P*<.001). ED referral was less likely for 16 (62%) of 26 respondents in response to the reassuring wearable data, while 7 (27%) did not change and 3 (12%) were more likely to recommend ED presentation. In total, 23 (85%) of 27 respondents reported increased confidence in their recommendation when the reassuring wearable data were added. Only 7 (30%) of 23 reported they would initiate contact with the patient or caregiver in response to the reassuring wearable data alone.

When concerning wearable data were presented with the scenario, the median recommendation for ED presentation was 5.5 (IQR 3-7.75) representing a median change of 0 (IQR 0-2; *P*=.17). With the addition of concerning wearable data, 12 (44%) of 27 respondents were more likely to recommend ED referral, while 14 (52%) had no change in their recommendation and 1 (4%) was less likely to recommend ED referral. In addition, 19 (76%) of 25 reported increased confidence with this recommendation, and 18 (80%) of 25 reported they would reach out to the patient or caregiver if presented the concerning wearable data alone. Survey responses for scenario 2 are summarized in Table 4 and Figure 1. Response to the addition of reassuring and concerning wearable data for scenario 2 by institution is demonstrated in Figure 3. There was no significant difference between institutions in their response to the addition of reassuring (*P*=.90) or concerning wearable data (*P*=.05).

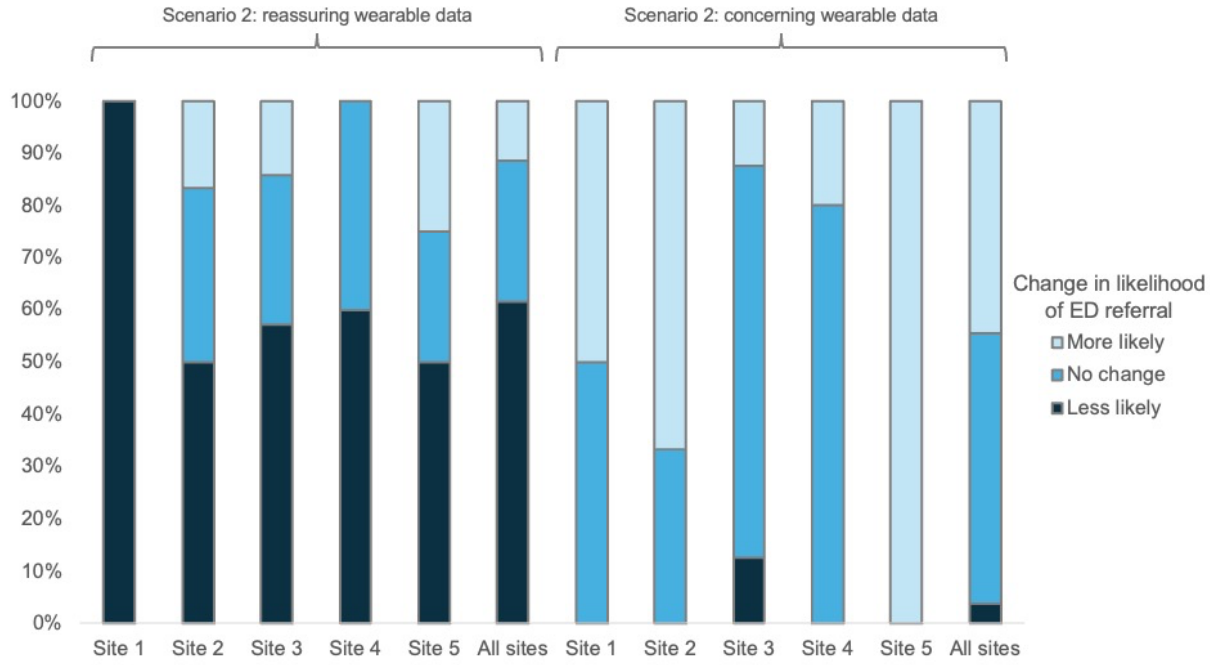
Table 4. Simulated remote management recommendations from pediatric surgery clinicians at 5 institutions in response to telephone scenario 2 presented without wearable data, then with reassuring and concerning wearable data. Scenario 2: 10-year-old female patient on postoperative day 3 following laparoscopic appendectomy for simple appendicitis, now with 2 days of fevers, abdominal pain, and periumbilical erythema.

	No wearable data	Reassuring wearable data	Concerning wearable data
Initial recommendation (n=28), n (%)			
Seek care immediately	7 (25)	—[a]	—
Prescription and outpatient follow-up	7 (25)	—	—
Outpatient follow-up	14 (50)	—	—
Reassurance and no follow-up	0 (0)	—	—
Likelihood of ED[b] referral, median (IQR)	4 (2 to 6.75)	2 (1 to 4)	5.5 (3 to 7.75)
Change in likelihood of ED referral, median (IQR)	—	–1 (–2.5 to 0)	0 (0 to 2)
P value	—	<.001	.17
Increased confidence, n/N (%)	—	23/27 (85)	19/25 (76)
Would reach out to patient or caregiver, n/N (%)	—	7/23 (30)	20/25 (80)

[a]Not applicable.

[b]ED: emergency department.

Figure 3. How the likelihood of emergency department referral changed at each institution with the addition of reassuring and concerning wearable data to scenario 2. ED: emergency department.



Scenario 3

When scenario 3 was presented without wearable data, 18 (64%) of 28 recommended outpatient follow-up, while 6 (21%) recommended the patient seek care immediately and 4 (14%) recommended a prescription with outpatient follow-up. When asked about the likelihood of recommending ED presentation, the median score was 3 (IQR 1-4.5). When reassuring wearable data were added, the median recommendation dropped to 2 (IQR 1-3) representing a median decrease in recommendation of 0 (IQR –2 to 0; *P*=.002). ED referral was less likely for 13 (48%) of 27 in response to the reassuring wearable data, while 13 (48%) did not change and 1 (4%) was more likely to recommend ED presentation. In total, 23 (85%) of 27 clinicians reported increased confidence in their recommendation when the reassuring wearable data were added, while 6 (24%) of 25 reported they would reach out to the patient or caregiver if presented the reassuring wearable data alone.

When presented concerning wearable data, the median recommendation for presentation to the ED increased to 7 (IQR 5-8), a median increase of 3 (IQR 0.5-5; *P*<.001). With the addition of concerning wearable data, 22 (76%) of 29

respondents were more likely to recommend ED referral, while 5 (17%) had no change in their recommendation and 2 (7%) were less likely to recommend ED referral. In total, 22 (88%) of 25 reported increased confidence in their recommendation when concerning wearable data were present. In addition, 23 (96%) of 24 reported they would initiate contact with the patient or caregiver if presented the concerning wearable data alone.

Survey responses for scenario 3 are summarized in Table 5 and Figure 1. Institutional response to the addition of reassuring and concerning wearable data for scenario 3 is demonstrated in Figure 4. There was no significant difference between institutions in their response to the addition of reassuring (P=.20) or concerning wearable data (P=.57).

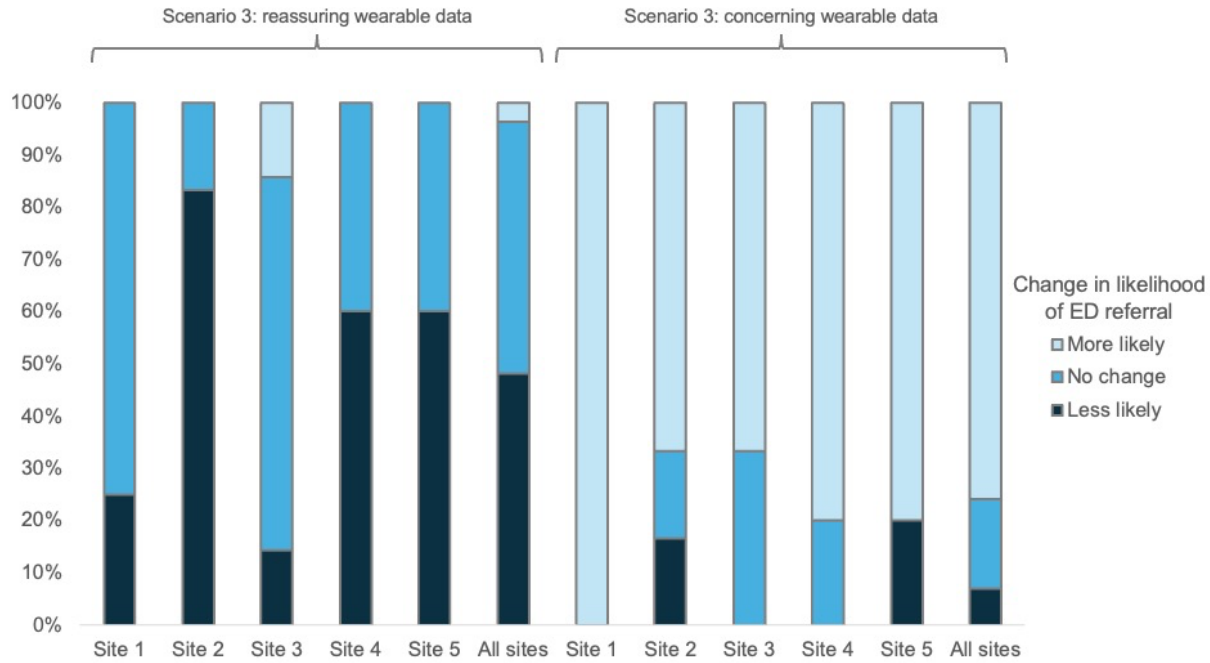
Table 5. Simulated remote management recommendations from pediatric surgery clinicians at 5 institutions in response to telephone scenario 3 presented without wearable data, then with reassuring and concerning wearable data. Scenario 3: a 9-year-old male patient on postoperative day 10 following laparoscopic appendectomy for complicated appendicitis, now with 2 days of purulent drainage from the surgical port site.

	No wearable data	Reassuring wearable data	Concerning wearable data
Initial recommendation (n=28), n (%)			
Seek care immediately	6 (21)	—[a]	—
Prescription and outpatient follow-up	4 (14)	—	—
Outpatient follow-up	18 (64)	—	—
Reassurance and no follow-up	0 (0)	—	—
Likelihood of ED[b] referral, median (IQR)	3 (1 to 4.5)	2 (1 to 3)	7 (5 to 8)
Change in likelihood of ED referral, median (IQR)	—	0 (–2 to 0)	3 (0.5 to 5)
P value	—	.002	<.001
Increased confidence, n/N (%)	—	23/27 (85)	22/25 (88)
Would reach out to patient or caregiver, n/N (%)	—	6/25 (24)	23/24 (96)

[a]Not applicable.

[b]ED: emergency department.

Figure 4. How the likelihood of emergency department referral changed at each institution with the addition of reassuring and concerning wearable data to scenario 3. ED: emergency department.



Discussion

Principal Findings

This study investigated the potential impact that postoperative objective measures of recovery collected by a consumer-grade wearable device, the Fitbit, may have on the decision-making of pediatric surgery clinicians from 5 children's hospitals in the United States. We found significant changes in recommendation for ED presentation when simulated telephone scenarios were supplemented with heart rate and step count data derived from Fitbit. Clinicians reported increased confidence with their decision-making when supplemented with wearable data. In addition, the majority of clinicians reported they would initiate contact with the patient and caregiver if they were presented with concerning wearable data in isolation. How wearable data impacted clinicians' likelihood of ED referral did not differ between institutions. These findings support consumer wearables as a generalizable clinical tool and provide further impetus for their adoption as a low-cost and efficient postoperative postdischarge remote monitoring technology with the potential to decrease the burden of unnecessary health care use and delays in seeking care.

Our study demonstrates that when clinicians are supplied with objective data from a wearable device, they are able to interpret these data and incorporate them into their decision-making with significant changes in their recommendations for ED presentation compared with when no wearable data were provided. In the current practice model, a "worst-case" mindset is assumed. The clinician is blinded to any objective measure of recovery and is solely dependent on the subjective narrative provided to them by the caregiver and patient. Patient safety and the medicolegal system necessitate this practice; however, it perpetuates health care saturation and associated costs as it often results in referral for an in-person evaluation. The addition of objective data has the potential to reassure the clinician or reinforce, and even augment, clinical concern. For example, in scenarios 1 and 2, there was no change in recommendation for ED presentation when concerning wearable data were added; therefore, the subjective information alone was concerning and the addition of objective data only strengthened confidence in this recommendation. However, when reassuring wearable data were supplied, the clinicians were significantly less likely to recommend ED presentation. As the subjective information for these scenarios did not change, this highlights the use of objective measures of recovery and their value in clinical decision-making. Alternatively, when scenario 3 was presented with concerning wearable data, the clinicians' recommendation for ED presentation significantly increased; therefore, augmenting clinical concern for a postoperative complication. This demonstrates how delays in care may be avoided with the addition of wearable data.

Not only did the wearable data change the clinicians' assessment of postoperative, postdischarge patients, but the data also gave the clinicians more confidence in their decisions. Greater than three-fourths of clinicians reported increased confidence in their recommendations when wearable data were added for all scenarios. This increase in confidence was reported regardless of whether wearable data were reassuring or concerning; it points to the incomplete information practitioners currently experience after discharge, upon which practitioners are asked to make clinical decisions. Clinicians experience uncertainty regarding caregivers' ability to assess their child's recovery, and simple interventions to improve communication between the health care system and the caregiver reduce postoperative ED presentation by up to 50% [4,10]. Furthermore, with an enriched form of communication between the health care system, caregiver, and patient, it is anticipated that unnecessary ED presentation could be reduced even further.

It is important to note that while these results indicate the influence of wearable data on decision-making, it is not possible to determine, with certainty, from this study whether the addition of wearable data influenced the clinicians' decision-making in a manner that can be delineated as correct. However, the changes seem to make clinical sense. Likewise, it is general practice for the institutions included in our study, and many others, that hemodynamically stable minor postoperative complications, such as a surgical site infection without systemic manifestations, be seen in the outpatient clinic if feasible to avoid the significant health care expenditure associated with the ED [6,12]. Moreover, how the likelihood of ED referral changed in response to the addition of concerning or reassuring wearable data did not differ between institutions. This supports consistency in wearable data interpretation across diverse practice settings and despite expected variation in institutional practice patterns.

Avoidable ED use has become an important focus of quality improvement initiatives to decrease unnecessary health care expenditures and health care saturation [6,13-15]. These initiatives were propagated by the adoption of digital health technology into clinical care. The momentum for this was largely propelled by the COVID-19 pandemic, during which the US Centers for Medicare and Medicaid (CMS) equated reimbursement of in-person and telemedicine visits, which was accompanied by the alignment of third-party payers [16]. As a result, many surgical departments implemented digital health platforms for postoperative patient care, which have been shown to be effective and efficient means of delivering care to children in the perioperative setting [17-24]. However, the objective data obtained during an in-person encounter remains largely absent; there are no vital signs available to interpret and the physical exam is limited to visual inspection [17]. Consumer-grade wearable devices, such as Fitbit, have been shown to supplant this absent objectivity by delivering measures of postoperative recovery including measures of heart rate, physical activity, and sleep [7,8].

Consumer wearable devices are unique in that they allow continuous capture and real-time transmission of health care measures which enables recovery trends to be examined [17]. When our survey participants were asked, 80% (20/25) to 96% (23/34) of clinicians reported they would reach out to the patient in response to concerning wearable data while only 24% (6/25) to 30% (7/23) would do so in response to reassuring wearable data. This demonstrates heart rate and step count data derived from wearable devices can be accurately analyzed and interpreted with ease by clinicians and can be integrated as a monitoring tool if wearable data are presented in real time. The

integration of wearable data from Apple Health and Fitbit into the electronic health system has begun at several institutions [25]. Therefore, the practicality of wearables for postdischarge monitoring must be determined. This includes how data should be presented to optimize efficiency and how it will be incorporated into clinical workflow. Previous work has shown that clinicians favor data metrics familiar to them, such as heart rate, over those unique to wearable devices, such as step count [10]. Advances in wearable technology have continued to expand the range of measures available with the newest models including measures routinely used in practice, such as respiratory rate and oxygen saturation, which would further enhance clinician comfort and desirability of use.

Limitations

This study has a number of limitations. First, the clinicians were responding to simulated patient scenarios. Although they were derived from actual patients, 1 set of wearable data was constructed for each scenario to create a pair of concerning and reassuring data. Second, clinicians respond to these questions in a simulation environment and survey format, which is low stakes and low stress in comparison with the high-demand workflow experienced by clinicians in daily practice. Prospective studies using actual patients are necessary to determine how wearable data change clinical decision-making in practice and their impact on postoperative outcomes and health care use. In addition, the Likert scales used for the survey were developed for the purposes of this study and have not been externally validated limiting the generalizability of our findings beyond this setting. Furthermore, the sites included in the study were all high-volume, academic children's hospitals, and the study participants may not be representative of all clinicians caring for children after an appendectomy throughout the United States. Finally, the majority of respondents were attending surgeons. Although use in practice requires further elucidation, system patterns suggest it is more likely that nurse clinicians, advanced practice providers, and surgeons-in-training will field an initial postoperative telephone call. This further suggests the need to define the platform upon which wearable data will be implemented.

Conclusion

Wearable data enhance the communication between caregivers, patients, and the health care team. The addition of objective measures of recovery to simulations of postoperative telephone scenarios impacts the recommendations made by pediatric surgery clinicians from diverse practice settings and improves clinician confidence when making remote patient assessments. Augmenting remote patient assessment offers the potential for improved triage of pediatric patients and could serve to reduce avoidable health care use. Furthermore, wearable devices, such as Fitbit, have the capability of providing real-time measures of recovery, which can be used as a postoperative monitoring tool to avoid delays in care for pediatric patients with postoperative complications.

Authors' Contributions

Study conception and design by FA, HMKG, SCL, SZ, and CDB. Acquisition of data performed by SCL, SZ, CDB, AF, AG, DL, AL, SL, and CS. Analysis and interpretation of data performed by SCL, MC, SZ, and JBP. Drafting of manuscript performed by MC. Critical revision was performed by all authors.

Conflicts of Interest

None declared.

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Abbreviations

CMS: Centers for Medicare and Medicaid
ED: emergency department
HIPAA: Health Insurance Portability and Accountability Act

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Review

The Effectiveness of Patient Education on Laparoscopic Surgery Postoperative Outcomes to Determine Whether Direct Coaching Is the Best Approach: Systematic Review of Randomized Controlled Trials

Bhagvat Maheta[1], BS; Mouhamad Shehabat[1], BS; Ramy Khalil[1], BS; Jimmy Wen[1], BA; Muhammad Karabala[1], MS; Priya Manhas[1], MS; Ashley Niu[1], MS; Caroline Goswami[1], MS; Eldo Frezza[1], MBA, MD

California Northstate University College of Medicine, Elk Grove, CA, United States

Corresponding Author:
Eldo Frezza, MBA, MD
California Northstate University College of Medicine
9700 W Taron Dr
Elk Grove, CA, 95757
United States
Phone: 1 (916) 378 3491
Email: eldo.frezza@cnsuedu.onmicrosoft.com

Abstract

Background: As of 2022, patient adherence to postoperative guidelines can reduce the risk of complications by up to 52.4% following laparoscopic abdominal surgery. With the availability of various preoperative education interventions (POEIs), understanding which POEI results in improvement in patient outcomes across the procedures is imperative.

Objective: This study aims to determine which POEI could be the most effective on patient outcomes by systematically reviewing all the POEIs reported in the literature.

Methods: In total, 4753 articles investigating various POEIs (eg, videos, presentations, mobile apps, and one-on-one education or coaching) were collected from the PubMed, Embase, and Scopus databases. Inclusion criteria were adult patients undergoing abdominal laparoscopic surgery, randomized controlled trials, and studies that provided postoperative outcomes. Exclusion criteria included studies not published in English and with no outcomes reported. Title and abstract and full-text articles with POEI randomized controlled studies were screened based on the above criteria through a blinded, dual review using Covidence (Veritas Health Innovation). Study quality was assessed through the Cochrane Risk of Bias tool. The included articles were analyzed for educational content, intervention timing, intervention type, and postoperative outcomes appropriate for a particular surgery.

Results: Only 17 studies matched our criteria, with 1831 patients undergoing laparoscopic cholecystectomy, bariatric surgery (gastric bypass and gastric sleeve), and colectomy. In total, 15 studies reported a statistically significant improvement in at least 1 patient postoperative outcome. None of these studies were found to have an overall high risk of bias according to Cochrane standards. In total, 41% (7/17) of the included studies using direct individual education improved outcomes in almost all surgery types, while educational videos had the greatest statistically significant impact for anxiety, nausea, and pain postoperatively (P<.01). Direct group education demonstrated significant improvement in weight, BMI, exercise, and depressive symptoms in 33% (2/6) of the laparoscopic gastric bypass studies.

Conclusions: Direct education (individual or group based) positively impacts postoperative laparoscopic surgery outcomes.

Trial Registration: PROSPERO CRD42023438698; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=438698

(JMIR Perioper Med 2024;7:e51573) doi:10.2196/51573

KEYWORDS

patient; education; surgeries; laparoscopic; postoperative; outcomes; systematic review

Introduction

Background

Adherence to postoperative guidelines can impact the risk of complications by up to 52.4% after laparoscopic surgery, as shown by a 2022 prospective study [1]. The enhanced recovery after surgery (ERAS) protocol is a systematic approach to minimize postoperative pain, complications, and duration of hospital stay in patients undergoing surgical procedures [2-4]. The protocol, established by the ERAS Society, a not-for-profit multiprofessional multidisciplinary medical-academic society, aims to determine the optimal approach for delivering care to patients undergoing surgical procedures, with the goal of facilitating quicker postoperative recovery [4]. The ERAS protocol consists of patient education, preemptive analgesia, and other practical procedures to improve patient outcomes [4,5]. The ERAS protocol continues to be implemented in a wide range of surgical fields and has been shown to significantly decrease patient complications from 35.7% to 16.4% in a prospective cohort study in 2016 [6].

As the ERAS protocol demonstrates, patient compliance after laparoscopic abdominal surgery is essential to reducing postoperative complications [7]. Nonadherence to the recommendations set by the surgical team, such as medication consumption or general lifestyle suggestions, can have a significant impact on postoperative recovery and patient complications [1,8]. For instance, studies have documented that poor compliance in patients undergoing gastric banding surgeries results in poorer outcomes, including reduced weight loss postoperatively [9]. Educating patients on their surgical procedure, potential postoperative consequences, and preventive steps to minimize complications has improved patient compliance and reduced hospital stays following laparoscopic surgery [5,10]. These preemptive measures may play a profound role in mitigating the psychological burden of pain, anxiety, and fear during recovery [11].

Objectives

As the laparoscopic approach in surgical procedures is considered to be newer, the research following its patient education for postoperative care is limited [12]. To adapt to these novel approaches, modernized educational formats that have been shown to improve surgical patient outcomes include verbal, written, multimedia, mobile apps, and one-on-one or group counseling [11,13,14]. As intervention types continue to be explored, there is no gold standard preoperative education intervention (POEI) that has shown consistent improvement in patient outcomes across the procedures. The aim of this study is to systematically review the literature on POEIs to ascertain which POEI is more effective in improving outcomes in patients undergoing laparoscopic abdominal surgery.

Methods

Our review adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement and EQUATOR (Enhancing the Quality and Transparency of Health Research) guidelines This protocol is registered in the PROSPERO database (CRD42023438698) [15].

Search Strategy

A systematic search was performed using 3 databases: PubMed, Embase, and Scopus. The search strategy was developed through an iterative process, using the methodology recommended by the Study Center of the German Society of Surgery, and included key terms related to laparoscopic abdominal surgeries and patient education [16]. The full search algorithm was used to identify potential articles in all 3 databases (Multimedia Appendix 1).

Article Selection

A total of 4753 articles investigating POEI were collected from the 3 databases after the removal of duplicates. Inclusion criteria were inclusion of a patient education intervention, adult patients undergoing abdominal laparoscopic surgery, randomized controlled trials (RCTs), and articles including postoperative outcomes (Figure 1). Exclusion criteria were articles not published in English, no patient education intervention included, nonabdominal laparoscopic procedures, pediatric patients, and articles without outcomes reported. Eligibility criteria are described using the population, intervention, comparator, outcomes, timing, and setting framework (Table 1). Title and abstract and full-text articles were screened using the inclusion and exclusion criteria via a blinded, dual review with 2 independent reviewers using Covidence (Veritas Health Innovation). If the decision was not unanimous, discrepancies were resolved after further review until a consensus was reached to determine final article inclusion or exclusion.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart illustrating the process of selecting articles.

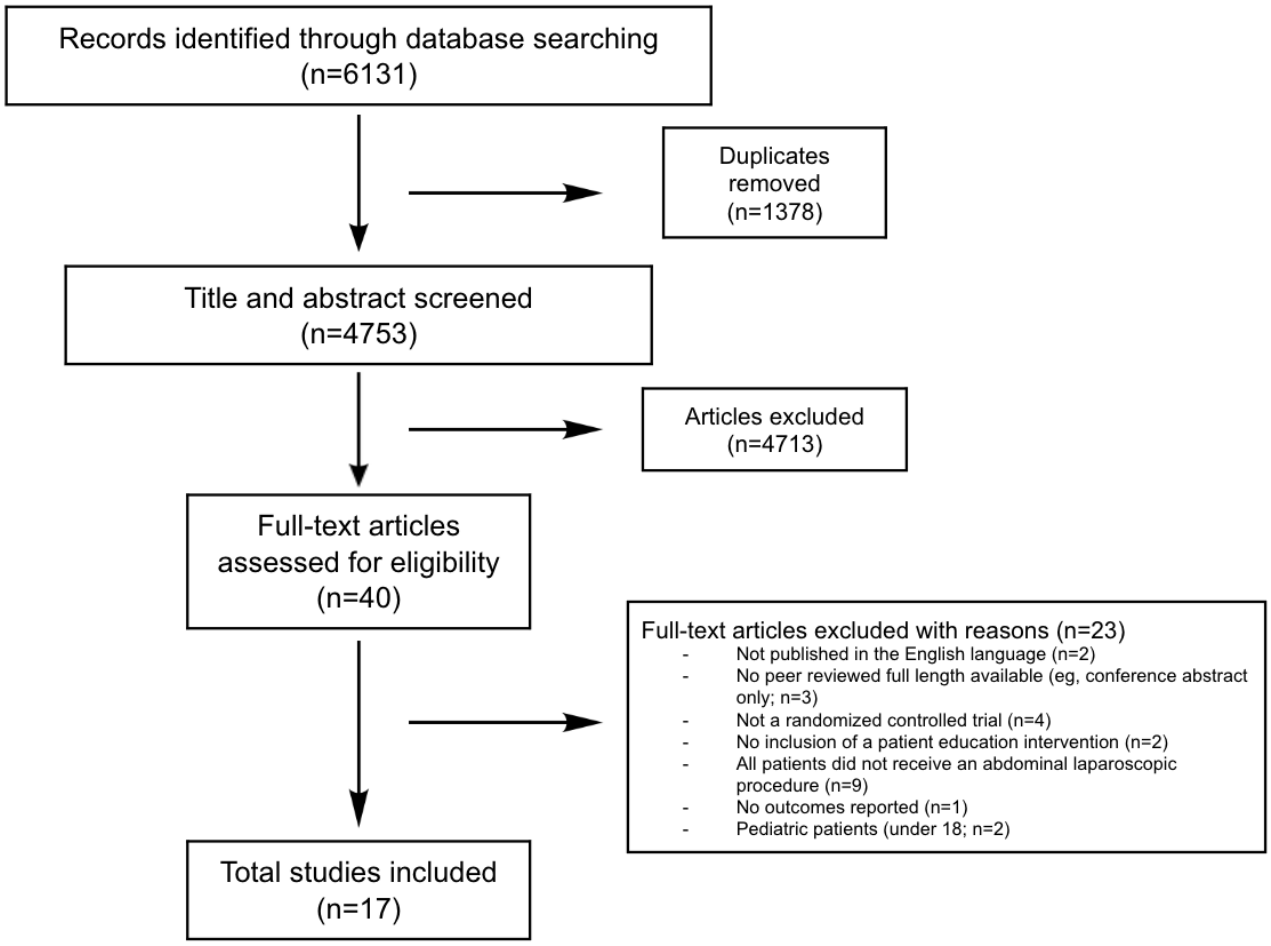

Table 1. Population, intervention, comparator, outcomes, timing, and setting eligibility criteria.

Domain	Description

Population	• Inclusion
	  • Adults (ie, aged >18 years) undergoing an abdominal laparoscopic procedure
	• Exclusion
	  • Pediatric (ie, aged <18 years) patients
	  • Not an abdominal laparoscopic procedure

Intervention	• Inclusion
	  • Inclusion of a patient education intervention preoperatively including direct individual education (7 studies), direct group education (2 studies), educational video (4 studies), multimedia presentation (2 studies), and mobile app (2 studies). Some education interventions continued postoperatively.
	• Exclusion
	  • No inclusion of a patient education intervention

Comparator	• Randomized controlled trial • Usual preoperative care (eg, surgeon consult and required presurgical routine before bariatric surgery) was the control group. Some interventions included the usual preoperative care along with the education intervention • If applicable, preoperative measures were compared to postoperative measures in the intervention group and between intervention and control group

Outcomes	• Inclusion
	  • Outcomes analyzed
	  • Varied between intervention type (ie, nausea, pain, anxiety, fatigue, percentage of unexpected hospitalizations, quality of life, weight, caloric intake, complication rate, first exhaust time, first defecation time, intensive care unit admissions, BMI, exercise, depressive symptoms, Self-Care Mean Agency scores, Body Image Scale scores, and postoperative patient compliance)
	• Exclusion
	  • Articles without outcomes reported
	• Outcomes were categorized into 3 categories: patient discomfort, surgical outcomes, and quality of life

Timing	• Interventions with any follow-up period were included
Setting	• Any care setting (including in-patient clinics or outpatient and ambulatory care)

Data Extraction and Analysis and Study Quality

Study quality was assessed through the Cochrane Risk of Bias tool as all included studies were RCTs [17]. Each domain assessed (ie, sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias) were evaluated as “high,” “low,” or “unclear” risk of bias. An abstraction form was developed through an iterative process to standardize the data extraction process (Multimedia Appendix 1). Data extraction was performed via a blinded, dual review with 2 independent reviewers on Covidence, with any discrepancies resolved after further review. Study variables analyzed in this systematic review included educational content, intervention timing and duration, intervention type, surgery type, and postoperative outcomes related to a particular surgery. POEIs included educational videos, multimedia presentations, mobile apps, direct individual education, and direct group education. All extracted data were compiled for analysis using Google Sheets (Google Drive; Google, LLC).

Results

Literature Selection

Using PubMed, Embase, and Scopus, the initial search yielded 6131 articles, of which 1378 (22.5%) duplicates were removed, leaving 4753 (77.5%) articles. Of the 4753 articles, during the title and abstract screening, we excluded 4713 (99.2%) and included 40 (0.8%). During the second phase, after a full-text review of the 40 articles, 17 (42.5%) were included in this systematic review. From the 17 studies that matched the inclusion criteria, 15 (88.2%) reported a statistically significant improvement in ≥1 patient postoperative outcomes (Table 2) [18-34].

Table 2. Summary of the included articles.

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
Abbasnia et al [18]	Laparoscopic cholecystectomy	145 patients (average age 43.54 years) with cholecystitis undergoing laparoscopic cholecystectomy	Educational video (animation 1 shown 2 hours before the surgery and animation 2 shown after the surgery; preoperative and postoperative)	• Content • Animation 1 was used before surgery to reduce anxiety. • "A 40-year-old man entered the operating room with a nurse. History-taking was carried out by an anesthesiologist, and the patient entered the operating room. The equipment and devices that were connected to the patient for monitoring and the method of general anesthesia were shown to the patient. After anesthesia, the recovery room and dressings of the operation site were displayed to the patient. Subsequently, the anatomy of the gall- bladder and its function, as well as the gallbladder surgery by laparoscopy, were demonstrated. Moreover, the patient observed the advantages of the laparoscopy method compared with open surgery." • Animation 2 was used after surgery to manage pain. • "A 40-year-old man was seated in a semisitting position, and the narrator states that this condition made it easier to breathe and reduce the pressure inside the abdomen, thereby reducing the pain. Deep breathing and effective coughing were displayed to the patient step by step, and an emphasis was put on the importance of causing faster CO2 (carbon dioxide) gas release from the abdominal cavity and secretions. In addition, the method of fixing the surgical incision with the help of a hand or a small pillow, which helps to reduce pain during coughing, deep breathing, and movement in bed, was demonstrated to the patient. Thereafter, movement in bed was shown to prevent blood clots and encourage faster expulsion of gas from the abdominal cavity. These movements included exercising the sole of the feet, ankles, and thighs. Finally, the patient was shown how to get out of bed step by step." • Modality: virtual reality headsets	There was a statistically significant improvement in preoperative state anxiety, the Bonferroni test for anxiety and patient distraction, pain reported by the VAS[a], and quality and intensity of subjective pain reported by the McGill Pain Questionnaire.

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome

Bollschweiler et al [20]	Laparoscopic cholecystectomy	76 patients (average age 55.16 years) with cholecystitis undergoing laparoscopic cholecystectomy	Multimedia presentation (preoperative education session was provided)	• Content
				  • Chapters with disease features, therapeutic alternatives, and the hospital stay, including a description of the operation itself. Certain pages are mandatory for the procurement of informed consent.
				• The chapters focus on the following:
				  • Why does the operation need to be performed? The risks of gallstones are presented.
				  • Preoperative examinations are described in detail. Complex examinations are presented with videos of each procedure.
				  • The chapter explaining that the operative procedure is divided into different sections. The cholecystectomy is clarified using an animated graphic of the operation with a parallel description of the procedure by the surgeon. For interested patients, video from an actual operation is also available.
				  • Potential complications from surgery or postoperative risks are related objectively, without focusing on emotional aspects. All risks are shown with rates of occurrence (as described in the literature) and a severity index. Each topic is shown on a navigation bar. By clicking on a risk, background information appears.
				  • "The next 4 weeks" chapter includes practical information regarding the length of hospital stay, postoperative nutrition, and aspects of wound treatment for the first 4 weeks after the operation.
				• Modality: in-person with a combination of documents, presentations, and videos
					There was a statistically significant improvement in perceived information; however, no statistically significant improvement was found in the Knowledge and Skills Acquisition for anxiety.

da Silva Schulz et al [21]	Laparoscopic cholecystectomy	43 patients (average age 69.35 years) with cholecystitis undergoing laparoscopic cholecystectomy	Direct individual education (ie, fourth, eighth, 12th, 18th, and 25th day postoperative)	• Content • "The experimental group received the 'Telephone Consultation' intervention from a researcher on the 4th (D4), 8th (D8), 12th (D12), 18th (D18) and 25th (D25) postoperative day; a total of 5 telephone consultations were attempted for each participant in the experimental group. During the patient's follow-up, we used the guidelines developed by NIC standardization and a literature review (e.g., questions about mobility at home, food intake and wound care)." • Modality: telephone consultation intervention from a researcher	There was a statistically significant decrease from first to second evaluation and from first to third evaluation for loss of appetite with nausea in the experimental group. Both groups saw a significant decrease from first to third evaluation for pain and reduction was observed in the experimental group for postoperative expectations.
Stergiopoulou et al [30]	Laparoscopic cholecystectomy	60 patients (average age 51.5 years) with cholelithiasis undergoing laparoscopic cholecystectomy	Educational video (20-minute preoperative session was performed in the patient ward; information leaflet and MCD[b] was available to patients for as long as they wished for)		Groups A, B, and C showed a statistically significant increase in knowledge score regarding laparoscopic cholecystectomy when compared to group D. Furthermore, there was a statistically significant decrease in postoperative pain and nausea during the first 16 hours across all interventional groups when compared to control.

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
				• Content • "Multimedia CD contains animation, narration, and photographs with six sections: fundamental elements of bile anatomy and physiology, aspects of the disease, details on the procedure and alternative options, possible complications and duration of hospital stay, and advice about recovery and life after laparoscopic cholecystectomy. Each section has pages, with a total of 28 pages, six of which contained extra photographs and animations. Each page had text fields and the same layout and background graphics. Content was selected in collaboration with surgeons and was written in simple Greek at a senior high school grade level. Leaflet and personalized presentation was developed using the exact contents of MCD." • Modality: multimedia CD with a laptop or leaflet	
Subirana Magdaleno et al [31]	Laparoscopic cholecystectomy	62 patients (average age 46.8 years) with cholelithiasis undergoing laparoscopic cholecystectomy	Direct individual education (15-30 days before the scheduled surgery; preoperative)	• Content • Intensified preoperative education with personalized oral and written information of the entire surgical and anesthetic process from a specialized nurse. They were informed about the following points of the process: type of operation, symptoms to be treated in the postoperative period, probable complications, wound care, and diet. • Modality: oral and informative brochure	No statistically significant differences were found in terms of pain levels or postoperative nausea, morbidity, percentage of unexpected hospitalizations, quality of life, or degree of satisfaction.
Toğaç and Yılmaz [32]	Laparoscopic cholecystectomy	124 patients (average age 48.72 years) with cholelithiasis undergoing laparoscopic cholecystectomy	Educational video (30- to 45-minute session in 4 stages; preoperative)	• Content • The first stage included providing information about cholelithiasis, including its causes, preoperative preparation, exercises, surgery, complications, wound care, nutrition, and medicines. Then, a video of laparoscopic cholecystectomy was played on a notebook. Finally, a leaflet about laparoscopic cholecystectomy was shown. In the second stage, knowledge about transfer to the operating room, its physical ambience and waiting room, surgical instruments, and explanations about anesthesia and surgical team were ensured. Information concerning what was expected of the patient before and during general anesthesia and how to join, recovery period, and how the patient is transferred were told. Besides, operating room pictures and surgical instruments were shown via the notebook. In the third stage, photographs and leaflets were used to train patients regarding postoperative care, both in the clinic and at home, such as how to mobilize and change dressing. In the fourth stage, any questions on different issues about laparoscopic cholecystectomy that were not mentioned by the researchers in patient's education were answered. Afterward, the patients were provided with a leaflet prepared by the researcher to reinforce what they had learned. • Modality: photographs, leaflets, and videos	

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
					There was a statistically significant decrease in the VAS-pain and VAS-nausea scores of the intervention group at postoperative hours 0, 2, 4, 6, and 8. In addition, the 24-hour VAS-pain score of the intervention group was significantly lower than that of the control group. The VAS-vomiting scores of the control group were higher than those of the intervention group at postoperative hours 6 and 8. Moreover, a significant difference was noted between the intervention and control groups in terms of changes in the VAS-pain, nausea, and vomiting scores over time. Before the intervention, there was no significant difference between the groups in terms of the STAI[c]-I scores; however, a statistically significant difference was determined before surgery and at the postoperative hour 24. There was also a significant difference between the groups in terms of the changes in the STAI-I scores over time. No significant difference was observed between the 2 groups in relation to the STAI-II scores obtained before the intervention, before surgery, and at postoperative hour 24. When the patient learning needs subscale scores were compared before education, there was a significant difference between the 2 groups in terms of activities of living, community and follow-up, feelings related to condition, and enhancing quality of life.
Udayasankar et al [33]	Laparoscopic cholecystectomy	50 patients (average age 40.14 years) undergoing laparoscopic cholecystectomy	Multimedia presentation (preoperative)	• Content • Information about the surgical procedure and planned anesthetic was given via a PowerPoint presentation on a mobile phone or tablet. The information was a customized collection of graphical representations of surgical and anesthetic procedures that were limited but appropriate. • Modality: PowerPoint presentation on a mobile phone or tablet.	Statistically significant reduction was observed in anxiety in ERAS[d] group compared to control on the day before surgery and 6 hours postoperatively. In addition, there was a statistically significant reduction in hunger, thirst, fatigue, and overall perioperative experience.
	Laparoscopic gastric bypass				

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
Deniz Doğan and Arslan [22]		51 patients (average age 38.78 years) undergoing laparoscopic gastric bypass or sleeve gastrectomy	Mobile app (before the operation and first, second, and third months after the operation; preoperative and postoperative)	• Content • "The app includes care, nutrition, and exercise training for patients undergoing bariatric surgery, starting from the preoperative period, and covering the first 3 months after surgery, as well as a food and an exercise diary, and weight tracking interfaces that will help patients develop healthy lifestyle behaviors while adapting to their new lives. In addition to these, there is a live consultation where patients can communicate with researchers and interfaces with questionnaires and answers to frequently asked questions by patients." • Modality: mobile app and live consultation with researchers and interfaces	There was a statistically significant decrease in the first, second, and third month BMI (kg/m^2) mean scores of the experimental group; no statistically significant difference was found between Self-Care Mean Agency scores and mean scores of the Body Image Scale.
Kalarchian et al [23]	Laparoscopic gastric bypass	40 patients (average age 46.9 years) undergoing laparoscopic gastric bypass	Direct individual education (4 months of meal plans with monthly individual telephone calls with dietary coach consisting of 4 calls of 15 minute each; postoperative)	• Content • "That patient intervention included 4 monthly deliveries of portion controlled foods and a personalized menu plan for grocery store items. The participants also received menus that included 3 small meals and 1-2 snacks per day to maintain their portion sizes." • Modality: delivered meal and menu plans	There was a statistically significant improvement in improved weight trajectory and reduced caloric intake relative to a control group.
Kalarchian et al [24]	Laparoscopic gastric bypass	143 patients (average age 44.9 years) with obesity undergoing Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding	Direct individual education (24 weekly contacts, including 12 face-to-face and 12 telephone sessions; postoperative)	• Content • "consisted of participation in any physician-supervised diet program, in promoting post-surgery weight loss and minimizing complications in comparison with usual care." • Modality: face-to-face and telephone education sessions	There was a statistically significant weight loss from enrollment to postintervention follow-up compared to control. However, at 24 months, the intervention group lost less compared to control.
Mata et al [26]	Laparoscopic gastric bypass	97 patients (average age 59.95 years) undergoing laparoscopic gastric bypass	Mobile app (education intervention was given preoperatively, daily during hospital stay, and at 4 weeks; postoperative)		There was no statistically significant improvement of this app on mean adherence to a bundle of 5 postoperative interventions (ie, mobilization, GI motility stimulation, breathing exercises, and consumption of oral liquids and nutritional drinks) that are dependent on patient participation.

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome

				• Content:
				  • "Postoperatively, participants randomized to the intervention group received a tablet computer (Apple iPad, Cupertino, USA) containing a novel mobile app. In brief, it included three sections:
				  • (1) Milestones checklist: A checklist was always visible in the app's home page listing the day's recovery goals with a brief description of the requirements to achieve each one. Next to each description, a button icon was available for the patients to press when the milestone was achieved, and an overall score of the number of milestones achieved compared to the total number for that day was constantly visible in the app's main dash-board.
				  • (2) Daily clinical questionnaires: A brief questionnaire assessing adherence and outcomes for the previous day. In contrast with the milestones checklist, which assessed progress for the present day, the clinical questionnaire assessed the previous day to give an overall summary. Items regarding bowel function and passage of gas were modified for the group of patients with a stoma (i.e., Did you pass stool? Or, did your bag have stool?). After submitting the information, the app displays a total score of the number of 'milestones met' (one for every enhanced recovery pathway element of interest they achieved), with a brief phrase of encouragement for goals that were achieved and advice for how to reach the mile-stones that were not yet achieved. Patients could review this feedback at any time in the app's home page.
				  • (3) Education: access to educational material was always available in the app's home page. Accessing one of the modules produced a detailed description of the milestones for each postoperative day. An exact replica of the education booklet received in their preoperative visit was also included in the educational module."
				• Modality: novel mobile app on a tablet computer (Apple iPad)	

Nijamkin et al [28]	Laparoscopic gastric bypass	144 patients (mean age 44.8 years) with obesity undergoing Roux-en-Y gastric bypass surgery.			

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
			Direct group education (intervention was given 7 months postoperatively, education was received for 90 minutes every other week for a total of 6 sessions in small groups and frequent contact with a registered dietician; patients were reassessed at 12 months following surgery)	• Content • "The first session of the education intervention addressed the daily meal planning guide and the maintenance diet. It provided recommendations on identifying and avoiding unhealthful foods, tips to promote proper nutrition by controlling portion size, new routine eating habits, and using an exchange list for weight management. This session was based on the Dietary Guidelines for Americans due to their reliable science-based advice on promoting health and lowering risk for chronic diseases via diet and physical activity. Daily energy intake was limited to 1,000-1,400 kcal and the minimum daily protein intake was 60-70 g with the goal of preserving lean tissue and prevent nutritional deficiencies. Additionally, the session also emphasized characteristics of typical Hispanic diets and the dietary changes that come with acculturation. The session also emphasized traits of typical Hispanic diets and the dietary changes that come with acculturation. Throughout the program, the importance of physical activity and a healthy diet were stressed in the postoperative life. The following session was designed to guide sedentary individuals to begin a regular exercise program and understanding how physical activity can aid in keeping weight off after bariatric surgery. Sessions 3 through 6 focused on emotional support interventions. These include behavior change strategies, stress relief without food, self-motivation, and relapse prevention. Overall, the intervention provided strategies that could facilitate change, increase self-esteem, help establish a consistent exercise program, recognize binge eating problems, and other motivational strategies." • Modality: comprehensive nutrition and lifestyle educational intervention with a registered dietician	At preoperative and 6 months postoperatively, there were no significant differences between intervention and control groups. However, at 12 months, both groups lost significant weight, with the intervention group losing significantly greater weight and significantly greater BMI reduction. Walking mean time, intensity of exercise, and involvement in physical activity was also significantly increased compared to control group at 12 months. No significant difference was found in daily energy intake and number of meals between groups.
Petasne Nijamkin et al [29]	Laparoscopic gastric bypass	144 patients (average age 44.5 years) with obesity undergoing laparoscopic Roux-en-Y gastric bypass	Direct group education (preoperative baseline, 6 months, and 12 months postoperatively)	• Content • "Those in the comprehensive support intervention received a total of 6 educational sessions focused on behavior change strategies and motivation along with nutrition counseling in groups of up to 12 participants, in addition to the postbariatric standard care. Sessions were conducted every other week in English or Spanish, according to participants' preference, in a nonjudgmental and nonconfrontational approach, expressing empathy and accepting participants' unwillingness to change. Group meetings started immediately after the randomization at 6 months after surgery. A psychologist and a registered dietitian guided the educational sessions. Every meeting lasted approximately 90 minutes." • Modality: educational support interventions	Statistically significant decrease of depressive symptoms and greater excess body weight loss were found 12 months after surgery in the interventional group.
	Laparoscopic sleeve gastrectomy				

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
Yayla and Menevşe [34]		66 patients (average age 37.09 years) with obesity undergoing laparoscopic sleeve gastrectomy	Educational video (3 times a day at 09 AM, 3 PM, and 9 PM the day before surgery [preoperative] and every postoperative day [days 1-5])	• Content • "The 9-minute animation education, which was prepared for postoperative sleeve gastrectomy patients, was written and directed by the researchers. The nurse explained how the deep breathing exercise was done using the benefits of respiration exercises (2 minutes) in the first part and the diaphragmatic breathing exercises and incentive spirometry (4 minutes) in the second part. In the third part, the researcher first showed how to do the exercises and then repeated the exercises with the patients (3 minutes)." • Modality: animated video sequences	There was a statistically significant difference between the mean postoperative fifth-day pain scores of the experimental and control groups. There was a statistically significant difference between the mean postoperative fifth-day scores of the experimental and control groups.
Li et al [25]	Laparoscopic colectomy	200 patients (average age 55.75 years) undergoing laparoscopic radical resection of colorectal cancer.	Direct individual education (unspecified preoperative or perioperative length, but education continued until discharge)	• Content • "The preoperative issues were communicated to the patients in ERAS group through face-to-face communication, written notice, or multimedia. Preoperative education includes anesthesia and surgical procedure, encouragement of early postoperative feeding and activity, promotion of pain management and respiratory therapy, presetting discharge criteria, and notification of follow-up and readmission pathway. The education continues through the entire process of the perioperative period until the patient is discharged." • Modality: face-to-face communication, written notice, or multimedia	There were statistically significant differences in complication rate, first exhaust time, and first defecation time between the 2 groups.
Molenaar et al [27]	Laparoscopic colectomy	251 patients (average age 70 years) with colorectal cancer undergoing colorectal cancer resection	Direct individual education (assessments were performed at baseline, preoperatively [approximately 4 weeks after baseline, except for CPET[e]], and 8 weeks postoperatively. Surgical outcomes were evaluated 30 days after surgery)		There was a statistically significant reduction in the rate of severe complications and fewer medical complications observed in patients undergoing prehabilitation compared with standard care. Secondary outcomes regarding admission to intensive care unit were significantly reduced.

Study	Surgery type	Patient demographics	Intervention type (timing+duration)	Content and modality of patient education	Outcome
				• Content • "The supervised training consisted of a 1-hour session of aerobic and strength exercises 3 times per week with resting days in between. The aerobic part, preferably performed on a bicycle, consisted of a high-intensity interval training using baseline CPET-derived variables. It consisted of 4 intervals of 2-minute high-intensity bouts conducted at 85% to 90% of peak power, alternated with 4 intervals of 4-minute moderate intensity bouts at 30% of peak power. Resistance exercise consisted of 2 series of 10 repetitions targeting major muscle groups. The intensity was set at 65% to 70% of the calculated baseline indirect 1 repetition maximum (1 RM). Professional strength equipment, body weight, elastic bands, or calibrated dumbbells were used. Based on nutritional assessment and dietary habits, a registered dietitian provided a full nutritional intervention. The program aimed to balance macronutrients and to achieve a daily amount of proteins of 1.5g per kg. Additionally, participants were provided with a whey protein supplement and were instructed to ingest 30g within 1 hour after the in-hospital training session and 1 hour before sleeping daily. Vitamin D and multivitamin supplements were also provided. Anxiety-coping interventions consisted of relaxation techniques and deep breathing exercises provided by psychology trained personnel in a 1-to-1 session. If a high risk of mental distress was detected by medical history or baseline scores of the Generalized Anxiety Disorder 7-item scale of 10 or higher or Patient Health Questionnaire 9-item of 15 or higher, participants were additionally referred to a medical psychologist. A smoking cessation program was offered, if indicated. The program consisted of individual counseling and nicotine replacement therapy." • Modality: 4-week multimodal personalized in-hospital supervised preoperative program	
Aydal et al [19]	Mixed laparoscopic abdominal surgery	135 patients (average age 43.96 years) undergoing laparoscopic cholecystectomy (n=77, 57%), appendectomy (n=27, 20%), hernia repair (n=15, 11.1%), colon resection (n=7, 5.2%), or gastrectomy (n=6, 4.5%)	Direct individual education (20- to 30-minute preoperative education session)	• Content • "For the standardization of patient education, an education booklet was prepared in consultation with academic nursing experts. The content included information on the operating room environment and surgical team, anesthesia process, postoperative care, and surgical process. The patient education was not given by the researchers in order to prevent research bias. To avoid any differences between the educators, all education was carried out by one voluntary service nurse and one operating room nurse. About two hours of education was given to the nurses to ensure they adopted a similar approach in patient education and to prevent bias caused by individual factors." • Modality: in-person by a voluntary service nurse and an operating room nurse	There was a statistically significant improvement in anxiety levels (Spielberger State-Trait Anxiety Inventory) directly after the intervention; however, no statistically significant difference was found in anxiety or pain (ie, VAS) levels in the postoperative period.

[a]VAS: Visual Analog Scale.

[b]MCD: multimedia CD.

[c]STAI: State-Trait Anxiety Inventory.

[d]ERAS: enhanced recovery after surgery.

[e]CPET: cardiopulmonary exercise test.

A total of 1831 patients undergoing laparoscopic cholecystectomy, bariatric surgery (ie, gastric bypass and gastric sleeve), and colectomy were included. There were a wide range of patient postoperative outcomes reported in the included studies, including nausea, complication rate, and weight loss (Table 3). These patient outcomes were categorized into *patient discomfort, surgical outcomes, and quality of life.* No included studies had an overall high risk of bias (Table 4). The PRISMA flowchart illustrates the process of selecting articles in Figure 1 [35].

Table 3. Patient education interventions and patient outcomes.

Intervention type (number of studies)	Surgery type	Patient outcomes
Direct individual education (n=7)	Laparoscopic cholecystectomy	• Nausea[a] • Pain[a] • Percentage of unexpected hospitalizations • Quality of life
Direct individual education (n=7)	Bariatric surgery: laparoscopic gastric bypass	• Weight[b] • Caloric intake[a]
Direct individual education (n=7)	Laparoscopic colectomy	• Complication rate[a] • First exhaust time[a] • First defecation time[a] • Intensive care unit admission[a]
Educational video (n=4)	Laparoscopic cholecystectomy	• Anxiety[b] • Pain[b] • Nausea[a]
Educational video (n=4)	Bariatric surgery: laparoscopic gastric sleeve	• Pain[b]
Direct group education (n=2)	Bariatric surgery: laparoscopic gastric bypass	• Weight[b] • BMI[b] • Exercise[b] • Depressive symptoms[b]
Multimedia presentation (n=2)	Laparoscopic cholecystectomy	• Anxiety[b] • Fatigue[b]
Mobile app (n=2)	Bariatric surgery: laparoscopic gastric bypass	• BMI[a] • Self-Care Mean Agency Scores • Body Image Scale scores • Postoperative patient compliance

[a]$P<.05$.

[b]$P<.01$.

Table 4. Risk of bias of the included studies.

Study	Sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors	Incomplete outcome data	Selective outcome reporting	Other source of bias
Abbasnia et al [18]	Low	Low	Unsure	Unsure	Low	Low	Low
Aydal et al [19]	High	High	High	High	High	Unsure	Low
Bollschweiler et al [20]	Low	Low	High	Low	Low	Low	Low
da Silva Schulz et al [21]	Low	Low	High	Low	High	Low	Low
Deniz Doğan and Arslan [22]	Low	High	High	Low	Low	Low	Low
Kalarchian et al [23]	Low	Low	High	Low	Low	Low	Low
Kalarchian et al [24]	High	High	High	Low	High	Low	Low
Li et al [25]	Unsure	Low	Low	Low	High	Unsure	Low
Mata et al [26]	Low	Low	High	Low	Low	Low	Low
Molenaar et al [27]	Low	Low	High	Low	Low	Low	Low
Nijamkin et al [28]	Low	Low	High	Low	Low	Low	Low
Petasne Nijamkin et al [29]	Low	Low	High	Low	Low	Low	Low
Stergiopoulou et al [30]	High	High	Low	Low	Low	Low	Low
Subirana Magdaleno et al [31]	High	High	High	High	Low	Low	Low
Toğaç and Yılmaz [32]	Low	Low	High	Low	Low	Low	Low
Udayasankar et al [33]	Low	Low	Low	Low	Low	Low	Low
Yayla and Menevşe [34]	Low	Low	High	Low	Low	Low	Low

Patient Discomfort

The *Patient Discomfort* category consisted of nausea, pain, and anxiety as patient's postoperative outcomes.

Nausea was significantly ($P<.05$) reduced in 2 intervention types. Following laparoscopic cholecystectomy, 43 patients who received direct individual education demonstrated a decrease in postoperative nausea, as measured by the Mini Nutritional Assessment test and the simplified Apfel scale [21]. Educational videos preoperatively also proved to decrease patients' reporting of nausea [30,32]. The educational video study by Toğaç and Yılmaz [32] was conducted on 124 patients, and the results were obtained using the Visual Analog Scale (VAS). The study by Stergiopoulou et al [30] was conducted on 60 patients, and the results were obtained using the Numerical Rating Scale ranging from 0 to 10. These 2 studies demonstrated statistical significance.

Pain was reduced postoperatively following 2 main interventions: direct individual education [21] and educational videos [18,30,32,34]. Direct individual education and educational videos displayed a statistically significant reduction in pain ($P<.05$ and $P<.01$, respectively). The educational video study conducted by Abbasnia et al [18] included 145 patients, and results were obtained with the VAS and McGill Pain Questionnaire. Yayla and Menevşe [34] analyzed 66 patients via the VAS.

Anxiety was shown to be statistically decreased ($P<.01$) in POEIs that incorporated both educational videos [18,30] and presentations [33]. The educational video intervention used by Abbasnia et al [18] included 145 patients and collected data via the State-Trait Anxiety Inventory. While Stergiopoulou et al [30] collected data via the Amsterdam Preoperative Anxiety Scale and Information, Udayasankar et al [33] focused on 50 patients and reported a reduction in preoperative anxiety ($P=.003$) and postoperative anxiety after 6 hours ($P=.001$).

Surgical Outcomes

Surgical outcomes category consisted of *percentage of unexpected hospitalizations, complication rate, intensive care unit (ICU) admission, first exhaust time,* and *first defecation time.* These varying patient outcomes provide insight into the patient's condition after surgery. *Percentage of unexpected hospitalizations* postoperatively was not significantly reduced when direct individual education intervention type was introduced [31]. *Complication rate, ICU admission, first exhaust time,* and *first defecation time* were all reduced postoperatively when patients were debriefed via individual education or coaching intervention [25,27]. Molenaar et al [27] included 251 patients and measured their results via Comprehensive Complication Index (P=.02). Li et al [25] obtained their results via observation indicators.

Quality of Life

Factors that affect *quality of life* were also considered to have a detrimental effect on a patient's long-term well-being. This category consisted of patient outcome factors such as *weight, BMI, caloric intake, exercise, depressive symptoms, fatigue, Self-Care Mean Agency scores,* and *Body Image Scale scores*. Patient *weight* was found to be statistically significantly decreased in both direct individual and group education POEIs (P<.01) [23,24,28,29]. Petasne Nijamkin et al [29] and Nijamkin et al [28] included 144 patients in a group education setting and reported weight loss in patients who received a POEI 12 months postoperatively (P<.001). Kalarchian et al [23,24], using a structured intervention, included 40 patients in a direct individual education method and had patients lose weight in the POEI arm at 4 months (P=.003).

BMI was also found to be statistically significantly decreased in patients provided with direct group education or coaching (P<.01) [28] and in patients provided with a POEI using a mobile app (P<.05) [22]. Deniz Doğan and Arslan [22] included 51 patients in the mobile app intervention and recorded a reduced BMI (P<.05) in the first 3 months postoperatively.

Caloric intake was statistically decreased (P<.05) when patients received a direct individual education POEI [24]. An increase in *exercise* and a decrease in *depressivesymptoms* was found to be statistically significant (P<.01) when patients received a direct group education POEI [28,29]. In the study by Nijamkin et al [28], exercise was measured via the Short Questionnaire to Assess Health Enhancing Physical. In the study by Petasne Nijamkin et al [29], depression was measured via the Beck Depression Inventory questionnaire and demonstrated a decrease in depression incidence after 12 months (P<.001).

Patient *fatigue* postoperatively was decreased when patients were given an educational presentation (P=.008) [33]. *Self-Care Mean Agency* scores and *Body Image Scale* scores had no significant increase in patients when provided with a POEI via a mobile app [22]. Deniz Doğan and Arslan [22] assessed *Self-Care Mean Agency scores* via a Likert-type Scale ranging from 0 to 4 with 35 items and *Body Image Scale* via a Likert-type scale ranging from 1 to 5 with 40 items. The direct group education intervention had a significant positive effect on *weight, BMI, exercise,* and *depressive symptoms* for patients after laparoscopic bariatric surgery, suggesting potential future physician consideration as a preferred intervention choice [28,29].

Direct Individual and Direct Group Education

POEIs included direct individual education, direct group education, video education, multimedia presentations, and mobile apps. Direct individual education methods included supervised and personalized training programs lasting from 1 to 3 months postoperatively as well as nutritional guidance delivered by nurses and physicians via in-person sessions or telehealth [19,27]. POEIs that incorporated personalized training programs led to a decrease in the rate of severe complications (P<.05) and anxiety (P<.05) [19,27]. Direct individual education also involved personalized preoperative education brochures and advice given by the patient's surgeon, which reduced nausea postoperatively (P<.05) [21]. In addition, patients received postoperative portion-controlled meal deliveries and counseling over 4 weeks, provided by a registered dietitian, leading to weight loss (P<.01) and reduced caloric intake (P<.05) [24]. Direct group education POEIs for bariatric surgeries involved 4 to 6 comprehensive lifestyle and behavioral or motivational sessions with the research teams and registered dieticians, and it resulted in a significant decrease in weight, BMI, and depressive symptoms (P<.01) and a significant increase in exercise (P<.01) [28,29].

Educational Videos and Multimedia Presentations

Video education modalities involved short animations that served the goal of assuaging anxiety and operative fear. These animations were shown to the patient up to 3 times preoperatively and daily postoperatively for 1 week, which led to decreases in anxiety, pain, and nausea (P<.01) [18,34]. Likewise, preoperative multimedia presentations administered by registered nurses in the form of CDs and additional animations or brochures provided additional material to the patient before surgery, educating patients about the primary purpose of the surgery, preoperative examinations, and potential complications [20,30,33]. These POEIs led to statistically significant decreases in anxiety and fatigue in patients undergoing laparoscopic cholecystectomy (P<.01) [20,30,33].

Mobile App

Finally, mobile app POEIs developed by the research teams allowed patients to access educational resources on their own time, and it included information about postsurgical care, weight tracking, nutrition, and exercise regimens with recovery goals during the first 3 months of surgery [22,26]. Patients receiving this POEI experienced a decrease in BMI (P<.05); however, there was no statistically significant decrease in Self-Care Mean Agency scores, Body Image Scale scores, or postoperative patient compliance [22,26].

Discussion

Principal Findings

In this systematic review of RCTs, 17 studies were included, analyzing a total of 1831 patients. Approximately 38% (3/8) of the laparoscopic cholecystectomy studies tested an educational

video, which led to a statistically significant decrease in postoperative anxiety, pain, and nausea [18,30,32,34]. Nearly 50% (7/17) of the studies included in this review found that direct individual education improved outcomes for a variety of surgical procedures. Educational videos were most effective at reducing anxiety, nausea, and pain after surgery [18,30]. In about 33% (2/6) of the studies on laparoscopic gastric bypass, direct group education was shown to be effective in improving weight, BMI, exercise, and depressive symptoms. To decrease postsurgery complication rates, ICU admission, as well as first exhaust and defecation time for patients, direct individual education POEIs can be implemented before surgery [25,27].

Direct Individual Education and Direct Group Education

Direct individual education was the most effective POEI across all included procedure types: laparoscopic cholecystectomy, bariatric surgery, and colectomy [19,21,23-25,27,31]. Direct individual education has been shown to be effective in other surgical procedures as it provides patients with a personalized intervention tailored to their specific needs, which allows for patients to freely communicate and better understand their condition, treatment plan, and postoperative care [36,37]. For example, in hip or knee arthroplasty, patient education led to a significantly shorter length of stay ($P<.001$), suggesting that the effectiveness of one-on-one education or coaching found in this review is not only limited to abdominal laparoscopic procedures [10]. Direct group education had significantly improved outcomes across laparoscopic gastric bypass for weight, BMI, exercise, and depressive symptoms ($P<.01$) [28,29]. A group setting allows for bonding with others and building a support system, which can be a critical influence toward lifestyle changes necessary for improved outcomes after bariatric surgery [38,39]. In a prior systematic review analyzing POEIs in patients undergoing major surgery, the authors found that increased frequency of message exposure improved outcomes; however, this review suggests that the frequency of message exposure may not be as important as POEI type since all frequencies of one-on-one and group education or coaching POEIs had similar effectiveness across all procedure types [13]. Although the included studies incorporated in-person direct individual and group education, there are emerging technologies, such as virtual reality, that offer a new avenue to provide patients with individual or group education and coaching through a distanced modality [40,41].

Educational Videos and Multimedia Presentations

POEIs with educational videos or a presentation had the most statistically significant improvements on anxiety, pain, and fatigue after laparoscopic cholecystectomy ($P<.01$) [18,20,30,32-34]. The use of videos to educate patients allowed for increased standardization, cost-effectiveness, and accessibility due to the prerecorded nature of this intervention that can be applied broadly throughout multiple disciplines of medicine [42,43]. Incorporation of educational videos also allows for patients to receive the POEI from the convenience of their own home and reduces health care inequity related to access to transportation and proximity to the hospital [44-46]. Preoperative video education has been shown to improve physical symptoms in the literature, as suggested by this review; however, this POEI has also been shown to improve knowledge, preparedness, satisfaction, psychological well-being, quality of life, and health care use in other surgery types [47]. Presentations allow for patients and caregivers to engage with the material and ask questions to better understand the content [48]. Both forms of POEI have demonstrated effectiveness in improving specific patient outcomes based on the content of the education; if the content is tailored toward focusing on additional aspects of the patient's postoperative recovery, more patient outcomes may be improved [49].

Mobile Apps

Newer forms of technology are also being tested for POEIs; however, more development is required within this area. In the 2 interventions that leveraged a mobile app for their POEI, there was improvement in BMI ($P<.01$); however, no statistically significant improvement was observed in Self-Care Mean Agency scores, Body Image Scale scores, or postoperative patient compliance [22,26]. Although there were limited significant improvements in patient outcomes while using mobile apps, coupling newer technology with aspects of tested POEIs, such as in-person education, educational videos, or presentations, may be a feasible option to optimize patient outcomes after laparoscopic abdominal surgery. Use of mobile apps in plastic surgery has been shown to significantly improve understanding of the surgery and postoperative patient compliance; this suggests that this modality of POEI has the potential to also improve patient quality outcomes for abdominal laparoscopic procedures if researched further [14]. Benefits of using technology through mobile apps, virtual reality, or artificial intelligence may provide increased accessibility to populations with limited mobility or access to clinical settings. These forms of communication can serve as a vital platform for enhancing the patient-physician rapport [50-53]. There are challenges associated with implementing these tools as the technology of these POEIs encompasses the associated expenses, accessibility, and maintenance. In addition, these platforms will require extensive training to ensure a user-friendly platform for different patient populations [54,55].

Limitations

This study can be considered in light of the following limitations. First, the tools to report patient outcomes were not consistent across the included studies, thus a meta-analysis or further synthesis is not possible. Second, only laparoscopic cholecystectomy, bariatric surgery (ie, gastric bypass and gastric sleeve), and colectomy surgeries were included because these were the only available surgery types with RCTs published regarding POEI. The heterogeneity of the included studies within the review provides a more diverse and holistic review of the published POEIs, which allows a narrative analysis of the pros and cons of individual interventions in each type of surgery included; however, it limits the ability to statistically compare the interventions to determine the most efficacious POEI in laparoscopic abdominal surgery. There are numerous types of abdominal laparoscopic surgeries where POEI may be beneficial, but they were not included in this systematic review due to a lack of published RCTs. Some included studies did not

report all aspects of the POEI, such as information regarding the process of developing the education content or the provision of training, supervision, or assistance with the POEI, including if there was any prototype testing or stakeholder feedback through co-design sessions. This limited the quantification of the effects of these features and their relationship with outcomes as there was significant variability in the published literature. Furthermore, the included studies may have been used for a more comprehensive, multidisciplinary intervention, confounding their direct impact on patient outcomes. However, this study provides informative insights into the current knowledge base pertaining to POEI and its applications in the field of abdominal laparoscopic surgeries.

Conclusions

This systematic review analyzed 17 RCTs that demonstrated the effect of POEIs on postoperative patient outcomes after abdominal laparoscopic surgeries. A total of 1831 patients undergoing laparoscopic cholecystectomy, bariatric surgery (ie, gastric bypass and gastric sleeve), or colectomy were included in this analysis, and 15 studies reported a statistically significant improvement in at least 1 patient postoperative outcome. Overall, direct individual education was the most effective POEI across all included procedure types; direct group education had the most significantly improved outcomes primarily among bariatric surgeries. POEIs that incorporated educational videos or presentations demonstrated the most statistically significant improvements in anxiety, pain, and fatigue following laparoscopic cholecystectomy. Direct education, whether individual or group based, has been shown to have a more positive impact on postoperative outcomes than newer POEIs, such as mobile apps. The practicality of this allows surgeons to personalize the health care delivered to each patient and provide the appropriate POEI based on which outcomes are more important for that patient. Future directions include expanding the use of POEIs to additional surgical procedures and further testing POEIs that incorporate more recent technology.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy and abstraction guide.
[DOCX File , 213 KB - periop_v7i1e51573_app1.docx]

Multimedia Appendix 2
PRISMA Checklist.
[PDF File (Adobe PDF File), 284 KB - periop_v7i1e51573_app2.pdf]

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Abbreviations

EQUATOR: Enhancing the Quality and Transparency of Health Research
ERAS: enhanced recovery after surgery
ICU: intensive care unit
POEI: preoperative education intervention
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
VAS: Visual Analog Scale

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Original Paper

A Novel Digital Health Platform With Health Coaches to Optimize Surgical Patients: Feasibility Study at a Large Academic Health System

Stephen Andrew Esper[1*], MD, MBA; Jennifer Holder-Murray[2*], MD; Katie Ann Meister[1*], BS, CPM; Hsing-Hua Sylvia Lin[3], MS, PhD; David Kojo Hamilton[4], MD; Yram Jan Groff[5], MD; Brian Scott Zuckerbraun[2], MD; Aman Mahajan[1], MD, MBA, PhD

[1]Department of Anesthesiology and Perioperative Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA, United States

[2]Department of Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA, United States

[3]Department of Anesthesiology and Perioperative Medicine, University of Pittsburgh, Pittsburgh, PA, United States

[4]Department of Neurosurgical Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA, United States

[5]Department of Orthopedic Surgery, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

[*]these authors contributed equally

Corresponding Author:
Stephen Andrew Esper, MD, MBA
Department of Anesthesiology and Perioperative Medicine
University of Pittsburgh Medical Center
A-1305 Scaife Hall
3550 Terrace Street
Pittsburgh, PA, PA/15213
United States
Phone: 1 412 647 2994
Fax: 1 412 647 2993
Email: espersa@upmc.edu

Abstract

Background: Pip is a novel digital health platform (DHP) that combines human health coaches (HCs) and technology with patient-facing content. This combination has not been studied in perioperative surgical optimization.

Objective: This study's aim was to test the feasibility of the Pip platform for deploying perioperative, digital, patient-facing optimization guidelines to elective surgical patients, assisted by an HC, at predefined intervals in the perioperative journey.

Methods: We conducted an institutional review board–approved, descriptive, prospective feasibility study of patients scheduled for elective surgery and invited to enroll in Pip from 2.5 to 4 weeks preoperatively through 4 weeks postoperatively at an academic medical center between November 22, 2022, and March 27, 2023. Descriptive primary end points were patient-reported outcomes, including patient satisfaction and engagement, and Pip HC evaluations. Secondary end points included mean or median length of stay (LOS), readmission at 7 and 30 days, and emergency department use within 30 days. Secondary end points were compared between patients who received Pip versus patients who did not receive Pip using stabilized inverse probability of treatment weighting.

Results: A total of 283 patients were invited, of whom 172 (60.8%) enrolled in Pip. Of these, 80.2% (138/172) patients had ≥1 HC session and proceeded to surgery, and 70.3% (97/138) of the enrolled patients engaged with Pip postoperatively. The mean engagement began 27 days before surgery. Pip demonstrated an 82% weekly engagement rate with HCs. Patients attended an average of 6.7 HC sessions. Of those patients that completed surveys (95/138, 68.8%), high satisfaction scores were recorded (mean 4.8/5; n=95). Patients strongly agreed that HCs helped them throughout the perioperative process (mean 4.97/5; n=33). The average net promoter score was 9.7 out of 10. A total of 268 patients in the non-Pip group and 128 patients in the Pip group had appropriate overlapping distributions of stabilized inverse probability of treatment weighting for the analytic sample. The Pip cohort was associated with LOS reduction when compared to the non-Pip cohort (mean 2.4 vs 3.1 days; median 1.9, IQR 1.0-3.1 vs median 3.0, IQR 1.1-3.9 days; mean ratio 0.76; 95% CI 0.62-0.93; *P*=.009). The Pip cohort experienced a 49% lower risk of 7-day readmission (relative risk [RR] 0.51, 95% CI 0.11-2.31; *P*=.38) and a 17% lower risk of 30-day readmission (RR

0.83, 95% CI 0.30-2.31; *P*=.73), though these did not reach statistical significance. Both cohorts had similar 30-day emergency department returns (RR 1.06, 95% CI 0.56-2.01, *P*=.85).

Conclusions: Pip is a novel mobile DHP combining human HCs and perioperative optimization content that is feasible to engage patients in their perioperative journey and is associated with reduced hospital LOS. Further studies assessing the impact on clinical and patient-reported outcomes from the use of Pip or similar DHPs HC combinations during the perioperative journey are required.

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KEYWORDS

digital health solution; feasibility; length of stay reduction; patient engagement; patient satisfaction; perioperative medicine

Introduction

The annual surgical volume in the United States is estimated at 48.4 million procedures [1]. Though heart disease and stroke may be the 2 leading causes of worldwide mortality (25% or 15 million deaths) [2,3], before the SARS-CoV-2 pandemic, postoperative surgical mortality was the third leading contributor to death in the United States [2]. Furthermore, the occurrence of postoperative 30-day complications is expected to rise to 15% among all patients and cost over US $11,000 per case, or US $31.35 billion nationally, on an annual basis [4,5]. Improving surgical quality of care to reduce mortality, complications, readmissions, and emergency department (ED) visits represents an enormous opportunity for the health care system. To reduce surgical complications and improve postoperative outcomes, focus has shifted to optimizing patients preoperatively and postoperatively through strategies such as prehabilitation, improvement in medical comorbidity, and enhanced recovery after surgery protocols [6]. Because mobile and wireless technologies have become increasingly accessible and capable on a global scale [7], digitization of protocols and other health interventions is being developed as a means to improve quality of care while reducing cost.

The field of digital health has grown over the past several years with advances in digital health platforms (DHPs) or telemedicine services, which have allowed deployment in select patient populations to improve chronic health conditions [8]. Several mobile apps have been developed and used as tools to help provide perioperative instructions as well as protocol guidance for patients. Feasibility studies have shown these DHP are convenient for patients to use in orthopedic surgery [9,10] and gastrointestinal surgery [11-13]. Yet, outcomes results have been mixed [14,15] or not yet studied to date. Furthermore, the DHP content is often narrow and applied to one surgery type or a specific problem, such as activity or pain management, rather than more holistic prehabilitation and curated to each patient's needs based on patient comorbidity, activity level or ability, or nutritional status. Additionally, these DHPs did not use a one-on-one health coach (HC) in addition to the DHP to assist patients in achieving their goals. Finally, there continues to be a significant unmet need within health care to provide patients undergoing surgery with high-quality education, optimization, and care coordination throughout the complex preoperative and postoperative journey. Our hospital desired to pilot an integrated DHP with human digital HCs to improve patient preoperative optimization, surgical care coordination, and outcomes. To address this need, we partnered with a novel perioperative DHP company, Pip Care, to create digitized perioperative patient-facing optimization guidelines and surgical instructions for our surgical population. Pip simplifies the patient's health care plan into definable, easy-to-understand, and complete daily tasks and uses regular HC contact to improve outcomes, thus setting Pip apart from other DHPs. The aim of this study was to test the feasibility and acceptability of the novel Pip platform in deploying perioperative patient-facing optimization guidelines to elective surgical patients both digitally and with the assistance of an HC at predefined intervals in the perioperative journey and to report clinical outcomes and patient satisfaction with the use of Pip.

Methods

Overview

We partnered with Pip Care to develop perioperative content and test the deployment of Pip perioperatively. Pip is a HIPAA (Health Insurance Portability and Accountability Act)-compliant, personalized, and interactive DHP that functions on both iOS (Apple Inc) and Android (Google Inc) operating systems.

Design of Clinical Pathways and Pip Functionality

A multidisciplinary team in perioperative care at our academic medical center from anesthesiology, surgery, and nursing defined the pathway content and patient tasks to be digitized on the Pip platform. These perioperative clinical pathways included preoperative nutrition, preoperative fitness, smoking cessation, preparation for surgery, day-before surgery planning, home preparation, and recovery after surgery. Patients were digitally assigned the appropriate clinical pathways by the human HC following the initial HC-patient intake and the HC's review of the patient's comorbidities from the electronic medical record. The tasks were prompted to the patient at appropriate intervals. Certified human HCs employed by Pip Care received education regarding the clinical pathways and were trained to interact with the electronic medical record for data collection and communication. HCs were responsible for motivating patients to reach their pre- and postsurgery goals through at least weekly one-on-one video or audio sessions; during these sessions, HCs would also answer any questions, provide educational content, track patient-reported outcomes (PROs), communicate patient progress to the provider, and facilitate referrals and resources if needed, in coordination with the perioperative clinical team members (Table 1). In addition to HC follow-up, patients were invited to explore a host of educational multimedia resources on disease processes and why optimization of said diseases is important before surgery.

Pip contains 4 key features, which are represented by separate pages within the DHP user experience. The first is Pip My Plan, which displays the assigned personalized care plans and tasks by their HC (Figure 1). The second is Pip Appointments. Patients were asked to schedule weekly digital HC sessions through the Appointments page. The HC also populated the patient's surgery-related appointments into this section for easy patient viewing (Figure 2). Third, patients have access to unlimited engagement with their HC through the Pip Messages page (Figure 3). Finally, patients have further unlimited access to a library of health system-approved education content, including articles and videos, to assist with their surgery preparation and recovery (Figure 3).

Table 1. Pip health coach (HC) tasks.

Category and tasks	Task description
Referral management	
Review the EMR[a] Pip List for newly added patients.	HC reviews the EMR to identify and validate referred patients.
Referred patient data transfer	HC transcribes the appropriate patient information into the Pip database.
Pilot enrollment and activation	
Execute the enrollment conversion plan.	HC executes a time-cadence enrollment conversion plan until the patient has enrolled in the pilot study or until the enrollment conversion plan ends.
Execute the patient activation conversion plan.	HC executes a time-cadence activation conversion plan until the patient has scheduled an "Initial HC Session" or until the activation conversion plan ends.
Surgery coaching and care plan management	
Weekly health coaching sessions.	For an estimated 4 weeks before surgery and 4 weeks postsurgery, HC conducts 30-minute weekly coaching sessions with patients to assist with surgery preparation and recovery.
Coaching session documentation	HC documents "encounter notes" from each coaching session.
Coaching session scheduling	HC schedules the subsequent coaching session.
Midweek patient check-in	In between weekly sessions, the HC sends at least 1 message (in-app or SMS text message) to the patient.
Patient communication through the in-app message	HC responds to the patients' messages when they are received.
Distribution of surgery-related educational materials	HC sends patients applicable educational content on best practices for surgery preparation and recovery.
Patient care plan assignment and management	HC assigns and manages the patient's care plans, including fitness, nutrition, smoking cessation, and discharge planning.
Provider communication	
Weekly patient progress report sent through EMR Encounter Note	HC's encounter note in the EMR is sent to the clinical provider, detailing the patient's status and adherence to protocols.
EMR InBasket communication	When an HC receives an out-of-scope question from a patient or learns of an escalated clinical issue, the HC messages the provider through EMR InBasket to escalate the clinical issue.
Provider synchronization calls	HC participates in daily and weekly synchronization calls with the provider team to ensure good communication and proper workflows.
Care coordination	
Surgery-related appointments	HC reviews the EMR and ensures all surgery-related clinical appointments are properly displayed within the Pip app. The HC encourages attendance at these appointments through messaging and during coaching sessions.
Facilitating health system resources for patients	HC facilitates health system-specific surgery-related resources for the patient as needed.
Patient-reported outcome and satisfaction data collection	
Collecting patient satisfaction surveys	HC sends an anonymous patient satisfaction survey to patients.
Collecting PROs[b]	HC collects PROs upon the patient's completion of the pilot program.
Service recovery	
Digital platform trouble shooting	HC assists with any issues with the technology.

[a]EMR: electronic medical record.

[b]PRO: patient-reported outcome.

Figure 1. Screenshots of Pip with personalized protocols and daily tasks in My Plan.

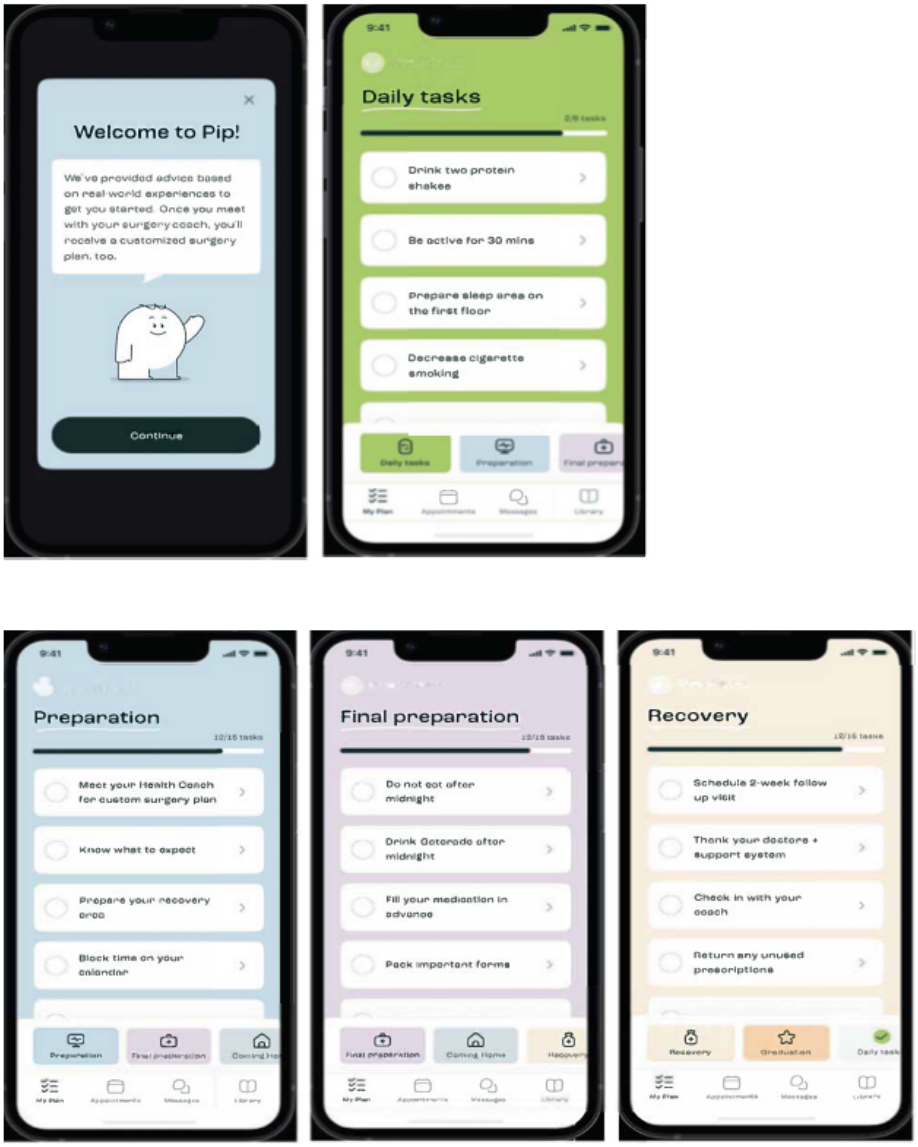


Figure 2. Pip patient engagement map. HC: health coach.

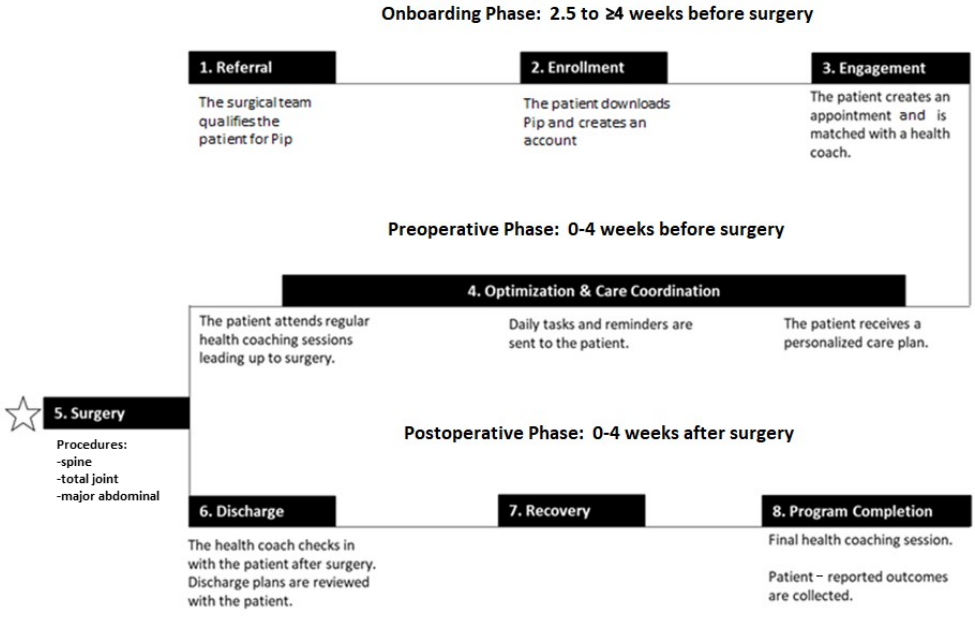
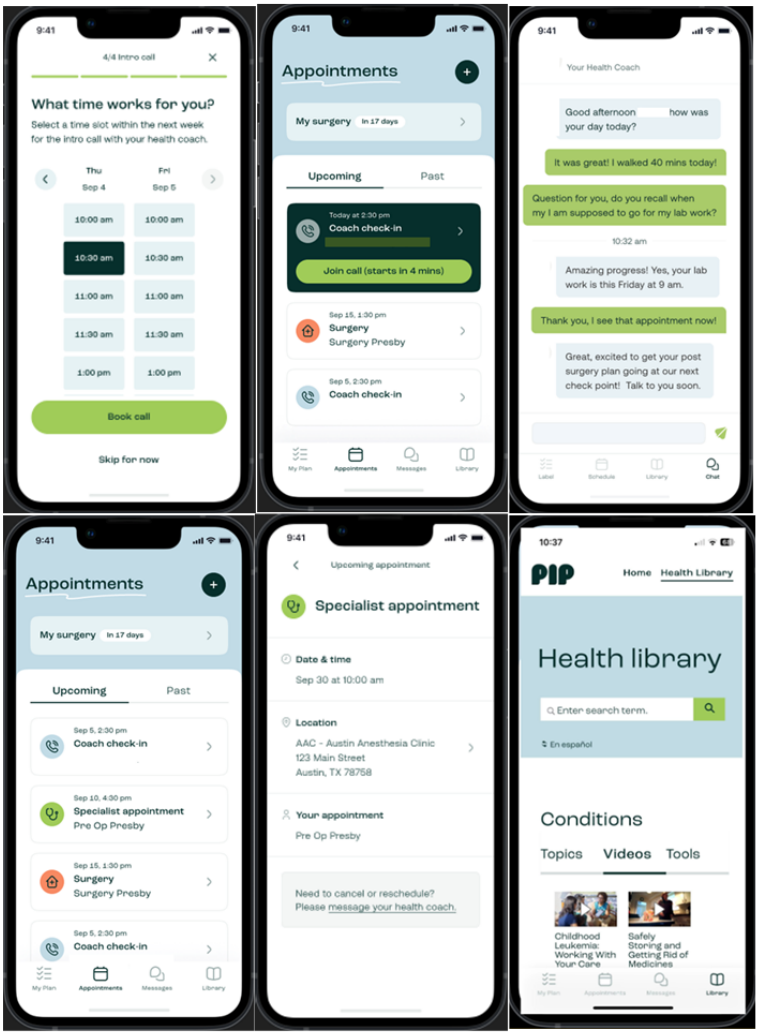


Figure 3. Screenshot examples of the Pip Appointments section, messaging, and entry into the Pip Library.



Feasibility Study

This study is an institutional review board/quality improvement review committee–approved (ID 3949) descriptive and prospective feasibility study of patients scheduled for elective abdominal, spine (cervical, lumbar, thoracic, and combined), and total joint replacement (hip or knee) surgery, invited to enroll in Pip from 2.5 to 4 weeks preoperatively through 4 weeks postoperatively at a single academic medical center from November 22, 2022, to March 27, 2023. Inclusion criteria were being aged 18 years or older; ability to speak and understand English; scheduled elective abdominal, spine, or joint replacement surgery; having more than 1 comorbidity linked to increased surgery risk (eg, type 2 diabetes, being aged 70 years or older, having a BMI greater than 40 kg/m^2, high blood pressure, and smoking history); no recent hospitalization for medical comorbidity that may impact surgical timing, such as heart failure (in order to ensure surgical date was likely); daily access to a tablet or smartphone; and technological literacy (ability to navigate digital devices with oversight or perioperative team assistance). Exclusion criteria include surgery not scheduled, canceled or delayed, or a change in scheduled surgery type.

Patients were recruited continuously from our perioperative clinic until the desired pilot sample size of approximately 150 patients was reached. All patients received our standard perioperative risk assessment, optimization, and educational content from our perioperative clinic. After enrollment, patients downloaded and enrolled in Pip. Patients scheduled their first digital one-on-one session with the HC through the Pip platform after enrollment, and this first HC visit was typically scheduled within 1 week or less. HC visits were offered weekly preoperatively and weekly following hospital discharge. If at any time the patient desired to leave the study, they were able to withdraw (Figure 2).

The number of patients who were invited, enrolled, activated, and completed the program was collected. The number of health coaching sessions attended and the time from enrollment to surgery were collected. Patient-specific characteristics included age, institutional perioperative risk score (low being less than 2%, intermediate being between 2% and less than 5%, and high being 5% or more risk of mortality or major adverse cardiac or cerebrovascular events) [16], type of surgery, length of stay (LOS), readmission, and ED visits. Primary end points include patient satisfaction, patient engagement, and Pip HC evaluations. We used industry benchmarks to compare our DHP enrollment rate [17,18], surgery completion with enrollment [18], and

postsurgery engagement rates [17,18]. Patients' overall satisfaction was assessed by the topline patient satisfaction surveys with score ratings from 1 to 5, with 1 denoting the lowest satisfaction and 5 denoting the highest satisfaction [19]. Pip HCs were evaluated based on a scaled numerical response to the question, "How much do you agree with the statement: My Pip Health Coach Helped Me Prepare for and Recover from Surgery?" using a score rating scale of 1 to 5, with 1 denoting "strongly disagree" and 5 denoting "strongly agree." The Pip experience was evaluated for acceptability using the net promoter score with the question, "Using a scale of 1 to 10, how likely are you to recommend Pip to a friend or colleague?" with 1 denoting "least likely" and 10 denoting "most likely."

Secondary end points included LOS, 7- and 30-day readmission rates, and ED use within 30 days. In order to evaluate the effect of Pip, patients receiving the Pip program were compared with a non-Pip group of patients. This control group of patients included patients who were aged 18 years or older and underwent elective surgery of the same type from January 1, 2022, to December 31, 2022.

Statistical Analysis

The primary end points are descriptive. Secondary end points required further statistical analysis. Continuous variables were summarized using the mean (SD) or median (IQR) when appropriate. Categorical variables were summarized by frequencies and percentages. The chi-square test was used for differences in proportions for categorical variables, and the Student *t* test or nonparametric Kruskal-Wallis test was used to determine the differences in the distribution of continuous data between the Pip and non-Pip groups. Stabilized inverse probability of treatment weighting (SIPTW) was created to reduce selection bias and balance the patient characteristics (ie, age, procedures, and perioperative risk score) in the Pip and non-Pip groups [20,21]. A marginal structural model with log-linked gamma distribution and SIPTW was used to estimate the mean ratios of the LOS between the Pip and non-Pip groups. Marginal structural models with log-binomial distribution and SIPTW were used to estimate the relative risk of 7-day hospital readmission, 30-day hospital readmission, and 30-day ED use [21]. All tests were two-sided and a *P* value of less than .05 was used to indicate statistical significance. SAS (version 9.4; SAS Institute) was used for statistical analyses.

Ethical Considerations

The study was granted a waiver of consent as the risk to the patient was considered to be minimal and was considered to be a quality improvement study. All patient participation was voluntary, and no patient received compensation.

Results

Engagement Outcomes

Out of 283 patients invited to participate in Pip, 172 (60.8%) were enrolled, compared to industry benchmarks (5%-30%). A total of 5 patients who enrolled were excluded from this analysis due to surgery delay, cancellation, or alternative surgery scheduled. Of those enrolled, 83.1% (143/172) had ≥1 HC session. Of the patients who had ≥1 HC session, 97.2% (138/142) proceeded to surgery, an improvement compared to industry benchmarks (90%-93%) [17,18]. After surgery, 70.3% (97/138) patients engaged with Pip postoperatively, compared to the industry benchmarks (31%-52%; Figure 4). Pip demonstrated an 82% weekly engagement rate, defined as repeat attendance at HC sessions. There was an average of 27 (range 7-108) days of lead time from enrollment to surgery, and patients attended an average of 6.7 (range 3-19) HC sessions. Pip received a total of 95 patient satisfaction survey submissions. Patients reported an overall high level of satisfaction based on the topline survey (mean 4.8/5; n=95; Table 2). Patients strongly agree that HC helped them throughout the perioperative process based on the Pip HC evaluation (mean 4.97/5; n=33). To measure acceptability, the net promotor score rating score was obtained; of the 33 respondents, the mean score was 9.7 out of 10.

Figure 4. Pip patient engagement map. *Data set does not include 2 patient referrals who were out of scope of pilot parameters. ** Exclusions to analysis are as follows: patient did not need surgery (n=1); patients referred for alternative lower-risk therapy (n=2); surgery delayed and patient rescheduled (n=1); surgery delayed and Pip could not access the patient's chart (n=1).

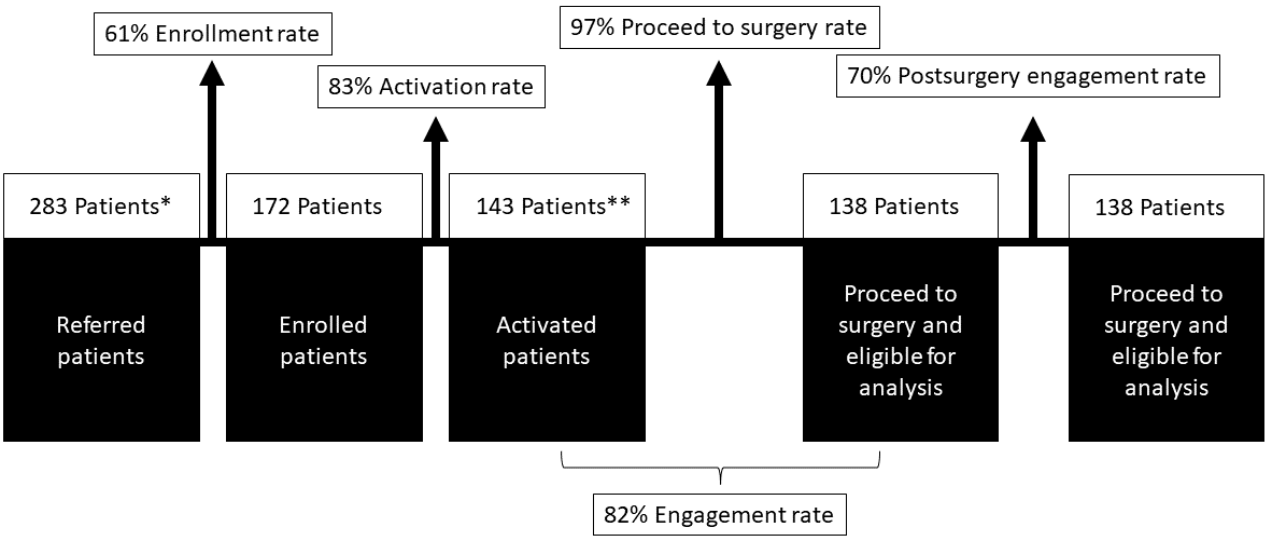


Table 2. Aggregate patient satisfaction scores (average score rating was 4.8 out of 5).

Score	Surveys completed (n=95), n (%)
1	0 (0)
2	1 (1)
3	1 (1)
4	16 (17)
5	77 (81)

Clinical Outcomes

There were a total of 367 patients in the non-Pip group and 138 patients in the Pip group. After creating SIPTW based on age, procedures, and perioperative risk score, a total of 268 patients in the non-Pip group and 128 patients in the Pip group had appropriate overlapping distributions of SIPTW for the analytic sample. Before SIPTW, age and preoperative risk score were shown to be significantly different between the Pip and non-Pip groups (Table S1 in Multimedia Appendix 1). Baseline patient characteristics weighted by SIPTW showed a balanced age, procedure type, and preoperative risk score between the 2 groups (Table 3). The Pip cohort was associated with both mean and median reductions in LOS when compared to the non-Pip cohort (mean 2.4 vs 3.1; median 1.9 IQR 1.0-3.1 vs median 3.0, IQR 1.1-3.9). Pip was significantly associated with a 24% reduction in postoperative LOS (mean ratio 0.76; 95% CI 0.62-0.93; *P*=.009 Table 4). Pip care was associated with a 49% lower risk of 7-day readmission (relative risk [RR] 0.51; 95% CI 0.11-2.31; *P*=0.38) and a 17% lower risk of 30-day readmission (RR 0.83; 95% CI 0.30-2.31; *P*=.73), though not statistically significant. Pip and non-Pip groups had similar risk in 30-day ED returns (RR 1.06; 95% CI 0.56-2.01; *P*=.85).

Table 3. Weighted patient characteristics by Pip versus non-Pip.

Variable	Non-Pip (n=268; 68%)	Pip (n=128; 32%)	*P* value
Age (years)			.85
Mean (SD)	63.8 (13.1)	63.6 (10.7)	
Median (IQR)	66 (56-73)	65 (59-71)	
Minimum-maximum	19-88	20-84	
Sex, n (%)			.14
Female	155 (57.8)	64 (50)	
Male	113 (42.2)	64 (50)	
Race, n (%)			.78
White	235 (87.7)	114 (89.1)	
Black	25 (9.3)	11 (8.6)	
Other	4 (1.5)	3 (2.3)	
Unknown or declined	4 (1.5)	1 (0.78)	
Risk level, n (%)			.69
Low	224 (83.6)	109 (85.2)	
Intermediate	40 (14.9)	16 (12.5)	
High	4 (1.5)	3 (2.3)	
Procedure, n (%)			.99
Major abdominal	31 (11.6)	15 (11.7)	
Spine	69 (25.7)	35 (27.3)	
TJR[a] hip	75 (28)	36 (28.1)	
TJR knee	93 (34.7)	42 (32.8)	

[a]TJR: total joint replacement.

Table 4. Comparison of secondary end points between non-Pip and Pip patients using marginal structural models with stabilized inverse probability of treatment weighting (SIPTW).

Secondary end points	Non-Pip (n=268; 68%)	Pip (n=128; 32%)	*P* value
Length of stay (days)			.009
Mean (SD)	3.1 (2.8)	2.4 (2.4)	
Median (IQR)	2.9 (1.1-3.9)	1.9 (1.0-3.1)	
Minimum-maximum	0-27.8	0-14.2	
Mean ratio (95% CI)	Reference	0.76 (0.62-0.93)	
7-day readmission			.38
Patients, n (%)	9 (3.4)	2 (1.7)	
Relative risk (95% CI)	Reference	0.51 (0.11-2.31)	
30-day readmission			.73
Patients, n (%)	13 (4.9)	5 (4.1)	
Relative risk (95% CI)	Reference	0.83 (0.30-2.31)	
30-day emergency department return			.85
Patients, n (%)	26 (9.7)	13 (10.3)	
Relative risk (95% CI)	Reference	1.06 (0.56-2.01)	

Discussion

Primary Result and Comparison With Previous Work

Our results demonstrate that Pip, a novel mobile DHP that combines both human HCs and technology, is feasible to use to engage patients during their perioperative journey. Pip engagement was also associated with reduced hospital LOS. Of the patients who attended ≥1 HC session, over two-thirds completed the program, which is far better than industry benchmarks. As the mean age of our Pip cohort was 63 (range 20-84) years, this demonstrates great engagement and feasibility across many ages.

There are multiple DHPs that have been developed in recent years, some focusing on chronic medical conditions or symptom monitoring [8,22]. There are also other mobile DHPs that are designed to provide enhanced recovery after surgery protocol guidance, presurgical instructions, and patient adherence to said protocols to help improve outcomes for both patient and hospital [13,23-25]. However, this is one of the first perioperative DHPs to involve a human-HC interaction to help allay patients' anxiety, alleviate clinical and administrative burden, and digitize perioperative protocols and instructions, not only through the preoperative period but also in the postoperative setting.

Our primary outcomes focused on human-technology and human-human engagement [26], that is, how the user interacts with both the technology and the emotional response to the human interaction. The excellent short-term user experience patient satisfaction scores and net promotor scores demonstrate high patient satisfaction and the commercializability of the product. Over 95% (93/95) of patients were satisfied with Pip and would recommend it. Pip generated impressive patient satisfaction scores when discussing patient-HC interaction, and nearly all respondents agreed that they would refer a friend or colleague going through surgery to use Pip. Furthermore, the patient capture rate and DHP use are far in excess of industry benchmarks. As 70% (97/138) of the patients who proceeded to surgery completed the program, this is also an advantage to health systems for cost reduction with shorter LOS and decreased complications with improved optimization.

Positive comments on the use of Pip in the perioperative journey supported that both the HC and the DHP, in concert with the HC, helped to relieve anxiety, hold patients accountable using encouragement, and empower patients to take responsibility for their care. These comments reflect observations that high-level engagement, representing a partnership for shared leadership, is very important [27]. Furthermore, the patients' desire to be not only heard (as a token of involvement) but listened to (reflecting a deeper conversation addressing the core issues at the center of the patient's thoughts) is essential to continued patient engagement with the platform [28].

An interesting finding was the significant LOS reduction with Pip use. While impressive, we acknowledge that this is a small cohort and the study was not powered for this outcome. Nevertheless, using a marginal structural model with SIPTW, the sample size is preserved close to the original data and produces an appropriate estimation of the main intervention effect while maintaining an appropriate type I error rate. Pip was significantly associated with a 24% reduction in postoperative LOS (mean ratio 0.76; 95% CI 0.62-0.93), and Pip was associated with 49% and 17% lower risk in readmissions at 7 and 30 days (though not statistically significant). Though we have matched for age, procedure, and perioperative risk score and feel that the likely effect is the Pip intervention, further studies powered for these outcomes are necessary. As all patients in the Pip and standard of care cohorts attended our perioperative risk stratification and optimization clinic, these findings may be even more pronounced when a robust perioperative clinic is not readily available in smaller health systems or when patients have limited access to care.

Furthermore, we feel that the personalized contact from the HC offers advantages over other content-only DHPs. The DHP and HC combination, personalized optimization protocols, and high satisfaction correlate with positive patient outcomes. Further studies examining the type and frequency of Pip DHP or HC interaction based on patient comorbidity would offer interesting insights into more widespread deployment of the DHP and HC resources for those most likely to benefit.

Limitations

This study has several limitations. Because all patients were computer literate and had ready access to smartphones, there may have been a participation bias that influenced this feasibility study. Adding a web-based interface or the ability to add a caregiver could reduce the technological barrier for some patients. Additionally, those patients who chose to participate in Pip may have contributed to selection bias for patients who are more motivated to optimize before surgery. Our patient satisfaction data are limited to descriptive statistics, and further information will be collected in the future. Additionally, the satisfaction question assessing the HC was framed positively, and this may have skewed the patient rating. Regarding secondary end points, while the LOS reduction is significant and the readmission rate reduction trends reasonably, this study was neither designed nor powered for these outcomes. Additionally, because many referrals took place within the health system network, there may have been other factors contributing to these outcomes. Further study is required with a larger cohort designed to examine both clinical outcomes and PROs.

Conclusions

In summary, Pip is a novel mobile health care digital platform that combines human HCs and preoperative optimization content that is feasible to engage surgical patients during their perioperative journey, with high patient enrollment and very high engagement with the HCs. Patient satisfaction was high for those participating in Pip. When compared to a similar cohort without Pip, surgical patients that participated in Pip experienced a reduced LOS in our feasibility study. Further studies are required to better assess the clinical and PRO impacts of the use of Pip or similar DHPs combined with HCs during the perioperative journey, as the use of an HC may offer improved patient-centered outcomes.

Acknowledgments

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Conflicts of Interest

Authors SAE and AM serve as consultants for Pip Care. All other authors have no conflicts of interest.

Multimedia Appendix 1
Baseline characteristics and outcomes before weighting by Pip versus non-Pip.
[DOCX File , 16 KB - periop_v7i1e52125_app1.docx]

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Abbreviations

DHP: digital health platform
ED: emergency department
HC: health coach
HIPAA: Health Insurance Portability and Accountability Act
LOS: length of stay
PRO: patient-reported outcome
RR: relative risk
SIPTW: stabilized inverse probability of treatment weighting

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Original Paper

Use of Biofeedback-Based Virtual Reality in Pediatric Perioperative and Postoperative Settings: Observational Study

Zandantsetseg Orgil[1], BS; Anitra Karthic[2,3], BA; Nora F Bell[4], MD; Lisa M Heisterberg[2], MD, PhD; Sara E Williams[5], PhD; Lili Ding[4,6], PhD; Susmita Kashikar-Zuck[4,7], PhD; Christopher D King[4,7], PhD; Vanessa A Olbrecht[8], MD

[1]Abigail Wexner Research Institute, Nationwide Children's Hospital, Columbus, OH, United States

[2]Department of Anesthesiology, The Ohio State University College of Medicine, Columbus, OH, United States

[3]Department of Anesthesiology & Pain Medicine, Nationwide Children's Hospital, Columbus, OH, United States

[4]Department of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH, United States

[5]Department of Anesthesiology, Perioperative and Pain Medicine, Stanford University School of Medicine, Palo Alto, CA, United States

[6]Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, United States

[7]Pediatric Pain Research Center, Division of Behavioral Medicine and Clinical Psychology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, United States

[8]Department of Anesthesiology and Perioperative Medicine, Nemours Children's Health, Delaware Valley, Wilmington, DE, United States

Corresponding Author:
Vanessa A Olbrecht, MD
Department of Anesthesiology and Perioperative Medicine
Nemours Children's Health, Delaware Valley
1600 Rockland Road
Wilmington, DE, 19803
United States
Phone: 1 3022987443
Fax: 1 3026514185
Email: Vanessa.Olbrecht@nemours.org

Abstract

Background: Biofeedback-based virtual reality (VR-BF) is a novel, nonpharmacologic method for teaching patients how to control their breathing, which in turn increases heart rate variability (HRV) and may reduce pain. Unlike traditional forms of biofeedback, VR-BF is delivered through a gamified virtual reality environment, increasing the accessibility of biofeedback. This is the first study to systematically integrate VR-BF use in the pediatric perioperative setting, with the ultimate goal of evaluating the efficacy of VR-BF to reduce pain, anxiety, and opioid consumption once feasibility and acceptability have been established.

Objectives: The primary objective was to develop a clinical trial protocol for VR-BF use in the pediatric perioperative setting, including preoperative education and training, and postoperative application of VR-BF in children undergoing surgery. A secondary objective was to evaluate the patient and parent experience with VR-BF.

Methods: A total of 23 patients (12-18 years of age) scheduled for surgery at Nationwide Children's Hospital were recruited using purposive sampling. Following training, participants independently completed a daily, 10-minute VR-BF session for 7 days before surgery and during their inpatient stay. Participants could use VR-BF up to 2 weeks after hospital discharge. Patient- and session-level data of VR-BF usage and achievement of target HRV parameters were measured to identify the optimal frequency and duration of sessions before and after surgery for this population. Standardized questionnaires and semistructured interviews were conducted to obtain qualitative information about patients' experiences with VR-BF.

Results: Patient-level data indicated that the highest odds of achieving 1 session under target HRV parameters was after 4 sessions (odds ratio [OR] 5.1 for 4 vs 3 sessions, 95% CI 1.3-20.6; OR 16.6 for 3 vs 2 sessions, 95% CI 1.2-217.0). Session-level data showed that a session duration of 9 to 10 minutes provided the greatest odds of achieving 1 session under target HRV parameters (OR 1.3 for 9 vs 8 min, 95% CI 1.1-1.7; OR 1.4 for 8 vs 7 min, 95% CI 1.1-1.8; OR 1 for 10 vs 9 min, 95% CI 0.9-1.2). Qualitative data revealed patient satisfaction with the VR-BF technology, particularly in managing perioperative stress (17/20, 85%). Few patients reported VR-BF as beneficial for pain (8/20, 40%).

Conclusions: Children and adolescents undergoing surgery successfully learned behavioral strategies with VR-BF with 10-minute sessions once daily for 5 days. To integrate VR-BF as a therapeutic intervention in a subsequent clinical trial, patients will be instructed to complete three 10-minute sessions a day for 7 days after surgery.

Trial Registration: ClinicalTrials NCT04943874; https://clinicaltrials.gov/ct2/show/NCT04943874

(JMIR Perioper Med 2024;7:e48959) doi:10.2196/48959

KEYWORDS

virtual reality; biofeedback; biofeedback-based virtual reality; acute pain; postoperative pain; pediatrics; postoperative; pain; anxiety; children; adolescents; perioperative management; acceptability; feasibility; pain reduction

Introduction

For many patients, the postoperative period is associated with significant and sometimes uncontrolled pain [1-4]. Not only can these circumstances lead to higher morbidity, increased hospital costs, and longer recovery times, but uncontrolled postoperative pain also increases the risk of exposure to and persistent use of opioids [4-8]. Despite greater emphasis on the use of multimodal, opioid-sparing analgesic regimens for postoperative pain, the percentage of patients experiencing severe pain after surgery has not changed significantly since the early 2000s, and narcotics remain the primary treatment for pain management [9-11]. Thus, the demand for nonpharmacologic alternative therapies for pain control has never been greater for children and adolescents [12].

One nonpharmacologic alternative is biofeedback, a mind-body therapy that provides sustained pain relief [13,14] in various clinical settings [15-26]. Biofeedback reduces pain by teaching patients behavioral modifications (eg, decreasing respiratory rate) to change their physiological status (eg, increasing heart rate variability [HRV]) [27], characterized as the increase and subsequent decrease in heartbeats during inhalation and exhalation, respectively [28]. Higher HRV downregulates the sympathetic nervous system and activates the parasympathetic nervous system, increasing vagal tone and reducing pain [29,30]. However, many barriers exist to the routine use of biofeedback [31], including the need for trained personnel and specialized equipment, and the lack of patient engagement and motivation for session repetition [32]. Thus, alternative strategies to deliver this effective therapy at point-of-care are needed in children and adolescents.

As technological advances have allowed for greater use of virtual reality (VR), VR has been implemented in many clinical situations to minimize pain during acutely painful procedures [33-42]. The sense of immersion created by VR can complement the therapeutic effects of distraction therapy during short, painful procedures by redirecting attention [43,44] and engaging the patient in simple mind-body therapies such as guided relaxation and slow breathing [45,46]. However, to date, VR-based delivery of distraction- and relaxation-based therapies have shown only transient reductions in pain that are insufficient to assist with more prolonged pain experiences, including postoperative pain [45,47-49].

To fill the unmet critical need for accessible, nonpharmacologic analgesia, we are exploring the integration of biofeedback with VR (VR-BF) as a promising new therapy that may be effective for postoperative pain management and may overcome the challenges of existing mind-body interventions [50]. However, VR-BF has yet to be systematically used in the perioperative period; thus, no defined treatment protocols exist for its application [51]. This study aimed to refine a treatment protocol for preoperative education and training and postoperative application of VR-BF in children and adolescents undergoing surgery requiring management by the Acute Pain Service by assessing the impact of VR-BF use on HRV parameters. To gain additional qualitative acceptability data of this technology, standardized questionnaires were used to assess patient and parent perceptions of their experience with VR-BF.

Methods

Overview

This single-center, prospective observational study of pediatric surgical patients aimed to refine a VR-BF protocol consisting of a preoperative education and training period to identify the optimal frequency and duration of VR-BF sessions to achieve target physiological parameters. Findings from this study will inform the design of a clinical trial to assess the ability of a VR-BF intervention to reduce postoperative pain, anxiety, and opioid consumption in children and adolescents.

Ethical Considerations

This study was approved by the institutional review board (#STUDY00002080) at Nationwide Children's Hospital (NCH) and conducted per the rules and regulations for ethical clinical research. This study was registered with ClinicalTrials.gov on May 17, 2021 (NCT04943874) and adhered to the CONSORT (Consolidated Standards of Reporting Trials) guidelines. Written consents from parents (and assent for patients younger than 12 years) were obtained from all participants before the first study visit. A stipend of up to US $100 per patient was given for completing all pre- and postsurgical study procedures.

Patients

A total of 23 patients scheduled for surgery anticipated to cause moderate to severe pain were recruited using purposive sampling between March 2022 and September 2022. Patients at NCH undergoing surgical procedures associated with moderate to severe pain (eg, laparotomy and spine surgery) are managed by the Acute Pain Service and receive intravenous opioids for pain management. All patients received standard postoperative care and were not withheld from medications during study participation.

Patients were identified up to 2 months in advance of their surgery for recruitment. Eligibility criteria can be found in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- 12-18 years old (all inclusive)
- Able to read, understand, and speak English
- Scheduled to undergo surgery at Nationwide Children's Hospital anticipated to cause moderate to severe pain with 1-night postoperative hospital admission
- Require postoperative pain management by the Acute Pain Service
- Own or have access to a mobile device or computer

Exclusion criteria

- Younger than 12 years or older than 18 years
- Non–English-speaking
- History of significant developmental delay, psychiatric conditions associated with hallucinations or delusions, or significant neurological disease, especially epilepsy or seizure disorder
- History of significant motion sickness
- History of chronic pain
- Chronically using opioids or benzodiazepines for the management of pain preoperatively
- Actively experiencing nausea or vomiting
- Any conditions that preclude their ability to use the VR headset, such as craniofacial deformities or surgeries of the head and neck

Equipment

All participants in this study used the Meta Quest2 VR headset (Meta Platforms Inc) and the guided relaxation-based VR app, Mindfulness Aurora, developed by the Stanford Chariot program. Mindfulness Aurora encourages relaxation practice by being focused on slow breathing. Patients are transported to an alpine meadow, where visual and auditory cues associated with the changing environment prompt participants to mirror and synchronize their breathing to the app. These changes include floating butterflies, swaying trees, and cloud movements as the 3-dimensional world transitions from day to night over a period of 10 minutes (Figure 1).

Patient physiological parameters were recorded during VR-BF sessions using HeartMath Inner Balance (HeartMath Institute), a commercially available heart rhythm monitoring device used to teach patients biofeedback. HRV is collected using an ear-clip sensor and integrated directly with the Inner Balance mobile app through Bluetooth. Data were then stored in an online data cloud accessible by the study team using HeartMath's emWave Pro software. HeartMath uses a method of quantifying heart rhythms derived from spectral power analysis, and the ideal fluctuations in the HRV waveform over time are depicted as a sine wave on a power spectrum [28]. The degree of how sine-wave-like the user's HRV pattern was scored into low (poor), medium, and high (good) states of coherence. Each coherence state is then assigned a numerical value depicting the proportion of time the user was in each state of low, medium, and high coherence (displayed as red, blue, and green, respectively, in emWave Pro).

Figure 1. Snapshots of the Mindfulness Aurora app. (A) Daytime scene as patients are verbally instructed to sync their breathing with the wings of a floating butterfly. (B) The Mindfulness Aurora app transitioning from day to night. (C) Night scene in the Mindfulness Aurora app in which patients are verbally instructed to sync their breathing with the Northern Lights.

Biofeedback-Based VR Sessions

Before Arrival for Surgery

Participants underwent a single in-person or virtual training session, up to 2 weeks before surgery. During this visit, participants watched a prerecorded video on the benefits of HRV biofeedback and received a scripted device and content tutorial from a trained clinical research coordinator. Participants were instructed to independently complete a daily, 10-minute session at home for 7 days before their procedure. Session frequency and duration were determined in line with the standard protocol for mind-body therapies [29,52]. Participants were asked to record each session (date, time, and duration) directly

into a web-based data capture tool, REDCap (Research Electronic Data Capture; Vanderbilt University).

Day of Surgery and Post Surgery

Participants were instructed to bring the devices to the hospital on the day of surgery and to resume daily sessions for the duration of hospital admission starting on postoperative day 0. Patients also had the opportunity to use VR-BF as needed outside of the daily 10-minute session while admitted to the hospital, particularly when in pain. A study team member provided technical assistance as needed.

A final study visit was conducted before discharge to obtain patient feedback using investigator-derived questionnaires. For those who opted to continue independent pain management with VR-BF for up to 14 additional days after hospital discharge, the final study visit was scheduled after the additional time or when participants decided to stop, whichever came first. The same web-based data capture tool was used for recording postoperative sessions. The final study visit occurred in person (in the clinical research department or at a surgery follow-up visit) or by phone.

Measures

The primary outcome of this study was the development of a VR-BF treatment protocol, including the frequency and duration of sessions before and after surgery for children and adolescents to be applied in a future efficacy trial.

Patient Information

Before surgery, the patient's age, sex, race, ethnicity, comorbidities, and current pain or anxiety medications were collected. Following surgery, the patient's American Society of Anesthesiologists (ASA) status [53], diagnosis at surgery, surgery type, and anesthesia type and duration were also collected.

Biofeedback-Based VR and Heart Rate Variability

The patient's ability to complete at least 1 session in which 50% or more of the session time achieved high HRV coherence (target parameter) was recorded. Changes in the frequency (number of sessions) and duration (time in minutes) of VR-BF sessions completed during the preoperative and postoperative periods were measured. The target parameter was selected based on the clinical experience of what constitutes a relaxing breathing training session for youth and youth with pain using the metrics available through the HeartMath program indicating success (eg, achieving "green" when in high HRV coherence).

Patient Experience

Patient experience was measured with a questionnaire (patient experience questionnaire—child [PEQ-C]; Multimedia Appendix 1) created by the study investigators. A similar survey (patient experience questionnaire—parent [PEQ-P]; (Multimedia Appendix 2) was given to the participant's parent or guardian to understand their experience and perspective with their child using VR-BF; PEQ-P was optional for parents of adult patients. Patients and parents used a 5-point Likert scale to rank the extent to which they agree to statements on the PEQ-C and PEQ-P from "strongly agree" to "strongly disagree." Responses to each questionnaire item provided feedback for making iterative protocol refinements on 5 domains of VR-BF acceptability, that are VR content and usability, preoperative education and training, postoperative application, perceived efficacy, and acceptability and satisfaction.

Participants completed surveys at the final study visit on paper or electronically with an iPad (Apple, Inc).

Statistical Analysis

Overview

Statistical analysis was conducted using SAS 9.4 (SAS Institute). A *P* value of .05 was the cutoff for statistical significance. Although no confirmatory hypothesis testing was done, exploratory analyses were conducted to investigate the association, if any, between VR-BF and HRV parameters. Any missing data were examined, and all available data were used in the statistical analyses.

Descriptive Analysis

Descriptive statistics (categorical variables: frequency and percentage; continuous variables: mean and SD or median and IQR) were generated for study variables, including baseline characteristics and perioperative VR-BF use (adjusted and nonadjusted for preoperative, postoperative, and home sessions).

Associations Between Biofeedback-Based VR Use and Achievement of Target Heart Rate Variability

Logistic and spline regression with and without adjustment for preoperative, postoperative, or home VR-BF applications were used to explore relationships between different frequencies and durations of VR-BF sessions and patients' ability to achieve a high HRV coherence for 50% or more of a session time. Patient-level and session-level data were used to determine the appropriate VR-BF dosing and to refine the treatment protocol.

Analysis of Patient-Level Data

A total of 2 outcomes were separately derived at the patient level by preoperative, postoperative, or home use. One is the percentage of sessions achieving target parameters: n_1/n, where n_1 is the number of sessions achieving target parameters, and n is the total number of sessions. The other is a binary outcome of any session achieving the target parameter, which equals 1 if $n_1>0$, 0 otherwise.

Patient-level number of sessions and average session duration were also derived separately by preoperative, postoperative, or home use. Comparisons in the number of sessions and average session duration between patients completing at least 1 session with 50% or more of session time under target HRV coherence versus those that did not (miss) were conducted using Wilcoxon rank-sum tests. Nonlinear regression and nonlinear logistic regression with spline (for the number of sessions and average session duration) were used for the 2 outcomes, the percentage of sessions, and any session achieving the target HRV parameter, respectively. This allowed us to examine the impact of frequency and duration of VR-BF use on the outcomes while adjusting for preoperative, postoperative, or home use. Random participant effect was included in the models when significant.

Analysis of Session-Level Data

A binary outcome of a session achieving or failing to achieve the target HRV parameter was derived at the session level. Its association with session number and duration was examined using logistic regression with spline for session-level outcomes while adjusting for preoperative, postoperative, or home use. Random participant effect was included in the models when significant.

Sample Size

Due to the nature of this pilot study, no statistical power analysis was done to determine the sample size. Instead, the sample size was based on findings from this team's work in a previous pilot clinical trial [45,49,54,55], the investigators' clinical experiences with the patient population, and existing literature on protocol refinements in intervention development [56,57]. Purposive sampling was used for a representative patient population. Patient enrollment and data review were carried out in groups of 4 to allow for iterative protocol refinements between patients.

Results

Participant Characteristics

Over 8 months, 23 patients were enrolled in this study. Data from 22 (96%) patients were included in the final analysis; 1 (4%) dropped out on the second day of study participation. The education and training session was conducted preoperatively for 22 (96%) participants, and 1 participant completed the education and training session on postoperative day 1. Although this patient deviated from protocol due to noncompliance with the study protocol, the patient's data are included in the analysis as data were obtained. Missing data resulted from challenges in patient adherence, including compliance to study protocol, experiencing pain and other negative symptoms due to surgery, and inability to contact the patients' families.

Most participants were female (16/23, 70%) and Caucasian (19/23, 83%), consistent with the demographics of our surgical population (Table 1). Of the 23 patients, 9 (39%) underwent abdominal, bariatric, colorectal, or urological surgeries; 2 (9%) underwent chest procedures; and 12 (52%) underwent orthopedic surgery. Most patients (14/23, 61%) were classified as ASA physical status I or II, and 39% (9/23) were classified as ASA physical status III or IV (Table 1).

In the preoperative period, 87% (20/23) out of the total number of enrolled patients completed ≥1 session (median 6, IQR 4-7; Figure 2) with an average duration of 9.6 (SD 2.3) minutes. In this group, 95% (19/20) achieved the target HRV (eg, high HRV coherence) for 50% or more of session time in at least 1 completed session. During the postoperative (eg, inpatient stay) period, 70% (16/23) participants completed at ≥1 session (median 2, IQR 1-2.5) with an average duration of 9.5 (SD 2.3) minutes; of which 81% (13/16) successfully achieved the target parameters. Following hospital discharge, 43% (10/23) participants opted to continue VR-BF therapy at home and completed ≥1 session (median 2.5, IQR 2-4) lasting on average 9.2 (SD 1.9) minutes; 80% (8/10) participants were able to achieve the target HRV (Figure 2). More than half of the total participants declined further participation in the study following hospital discharge as they considered Mindfulness Aurora to be "boring."

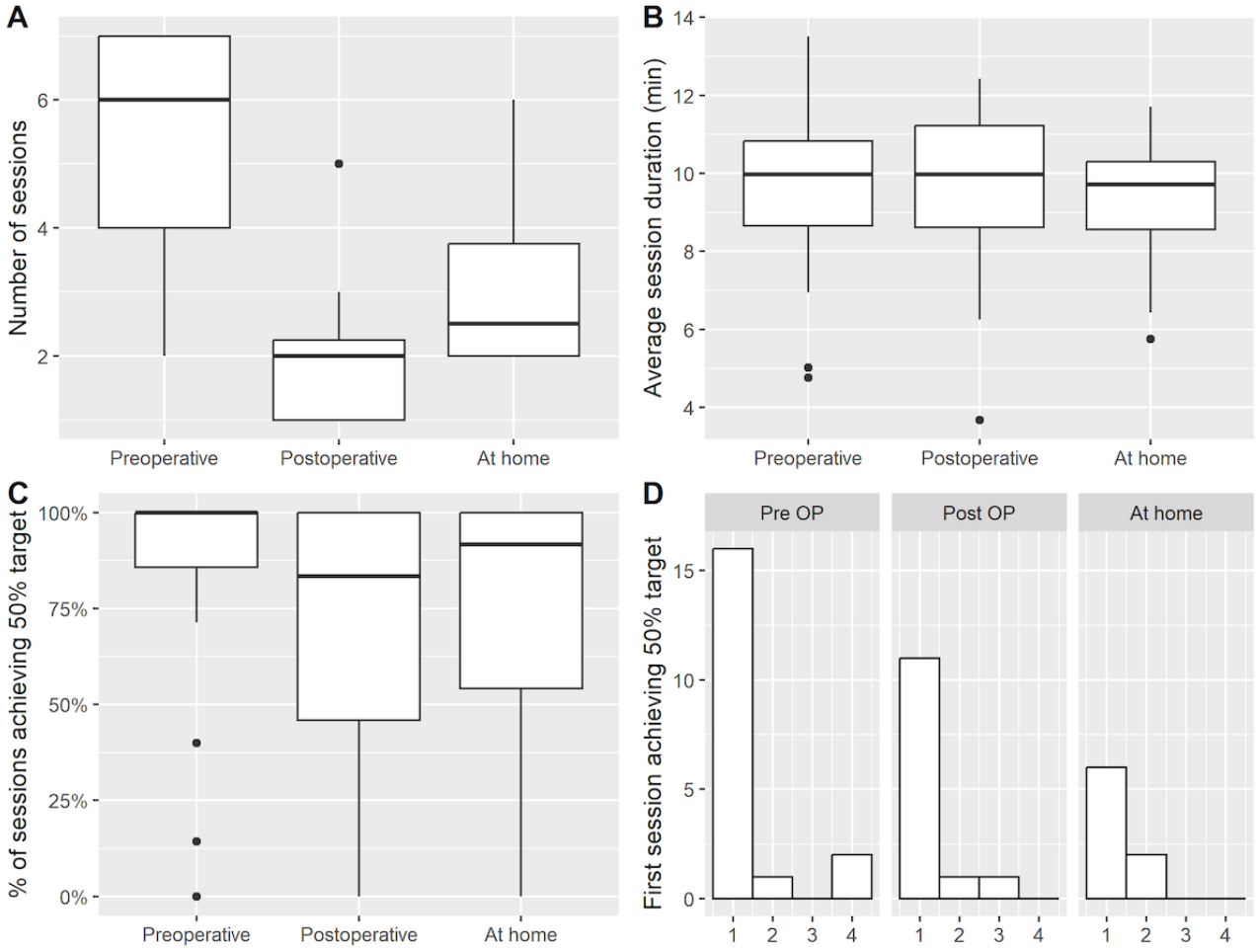
Overall, 91% (21/23) of participants completed a session throughout the observational period combined. Of these, 95% (20/21) achieved the target HRV for 50% or more of session time in at least 1 completed session. During the interviews, participants shared that they did not find the contents of Mindfulness Aurora engaging or entertaining enough for them to undergo daily sessions, resulting in reduced completion of postoperative sessions and a small number of patients continuing home use following discharge.

Table 1. Participant demographics and medical data.

Variable	Value
Total number of participants, N	23
Age (years), mean (SD)	15.5 (1.8)
Length of hospital stay (nights), mean (SD)	3.1 (4.4)
Sex, n (%)	
Male	7 (30)
Female	16 (70)
Race, n (%)	
African American or Black	3 (13)
White	19 (83)
Asian	1 (4)
Ethnicity, n (%)	
Hispanic	1 (4)
Non-Hispanic	22 (96)
Surgery type, n (%)	
Abdominal	3 (13)
Bariatric	2 (9)
Chest	2 (9)
Colorectal	3 (13)
Orthopedic	12 (52)
Urology	1 (4)
ASA[a] status, n (%)	
I or II (healthy or mild systemic disease)	14 (61)
III or IV (severe or life-threatening disease)	9 (39)

[a]ASA: American Society of Anesthesiologists.

Figure 2. Boxplots of (A) number of sessions, (B) average session duration, (C) percentage of session achieving target, and (D) histogram of the first session number to achieve target using patient-level data.



Biofeedback-Based VR Dosing

Number of Sessions

The Wilcoxon rank-sum test showed that the number of sessions completed by patients who achieved target HRV (median 4, IQR 2-6) was significantly higher than those who did not reach the target HRV in any of the sessions (median 1.5, IQR 1-2, *P*=.003; Table 2).

Table 2. Median (IQR) average duration and the number of biofeedback-based virtual reality sessions of patients completing one or more sessions with 50% or more of session time under target heart rate variability coherence versus those that did not (miss). The Wilcoxon rank-sum test was used to compare the 2 groups.

Patient level outcome	Median (IQR)	*P* value
Number of sessions		.003
Miss	1.5 (1-2)	
Achieve target HRV[a]	4 (2-6)	
Average session duration (minutes)		.55
Miss	9.5 (5-11.3)	
Achieve target HRV	10 (8.6-10.7)	

[a]HRV, heart rate variability

Nonlinear logistic regression analysis of patient-level outcomes of any session achieving target parameters adjusted for the duration when the perioperative period the sessions were completed showed that participants who completed 4 sessions had the highest odds of having at least 1 session achieving target parameters (odds ratio [OR] 5.1 for 4 vs 3 sessions, 95% CI 1.3-20.6; OR 16.6 for 3 vs 2 sessions, 95% CI 1.2-217.0; Tables 3 and 4). A nonlinear relationship was observed between the patient-level number of sessions and the percentage of sessions resulting in target outcomes. The percentage of sessions resulting in target outcomes increased, then peaked between 4 and 6 sessions (*P*=.04; Figure 3A). However, session-level analysis

using nonlinear logistic regression with the outcome of a session achieving target HRV parameters and adjustment for preoperative, postoperative, or home sessions did not show significant associations between session number and achieving target parameters (Table 5). In all analyses, sessions occurring in the preoperative, postoperative, or home periods did not impact any outcomes at either the patient or session level (results not shown).

Table 3. Patient-level analysis of nonlinear regression with spline for the number of sessions and average session duration with adjustments for preoperative, postoperative, or home sessions. Logistic regression with outcome—patients achieving target heart rate variability parameters in at least one session.

Session	Odds ratio (95% CI[a])
Number of sessions	
3 vs 2	16.43 (1.24-217.00)
4 vs 3	5.13 (1.28-20.62)
5 vs 4	1.89 (0.49-7.34)
6 vs 5	1.15 (0.19-6.79)
Average session duration	
8 vs 7 minutes	1.30 (0.68-2.48)
9 vs 8 minutes	1.25 (0.68-2.29)
10 vs 9 minutes	0.75 (0.45-1.25)

[a]CI: Wald CI.

Table 4. Patient-level analysis of nonlinear regression with spline for the number of sessions and average session duration with adjustments for preoperative, postoperative, or home sessions. Regression with outcome—percentage of sessions achieving target heart rate variability parameters.

Effect	Least square mean (95% CI[a])
Number of sessions	
3	0.49 (–0.15 to 1.12)
4	0.59 (–0.08 to 1.25)
5	0.60 (–0.08 to 1.28)
6	0.58 (–0.12 to 1.28)
Average session duration	
7 minutes	0.21 (–0.22 to 0.63)
8 minutes	0.26 (–0.17 to 0.69)
9 minutes	0.31 (–0.13 to 0.76)
10 minutes	0.27 (–0.19 to 0.73)
11 minutes	0.10 (–0.38 to 0.58)

[a]CI: Wald CI.

Figure 3. Spline fit of (A) number of sessions and (B) percentage of sessions achieving target parameters.

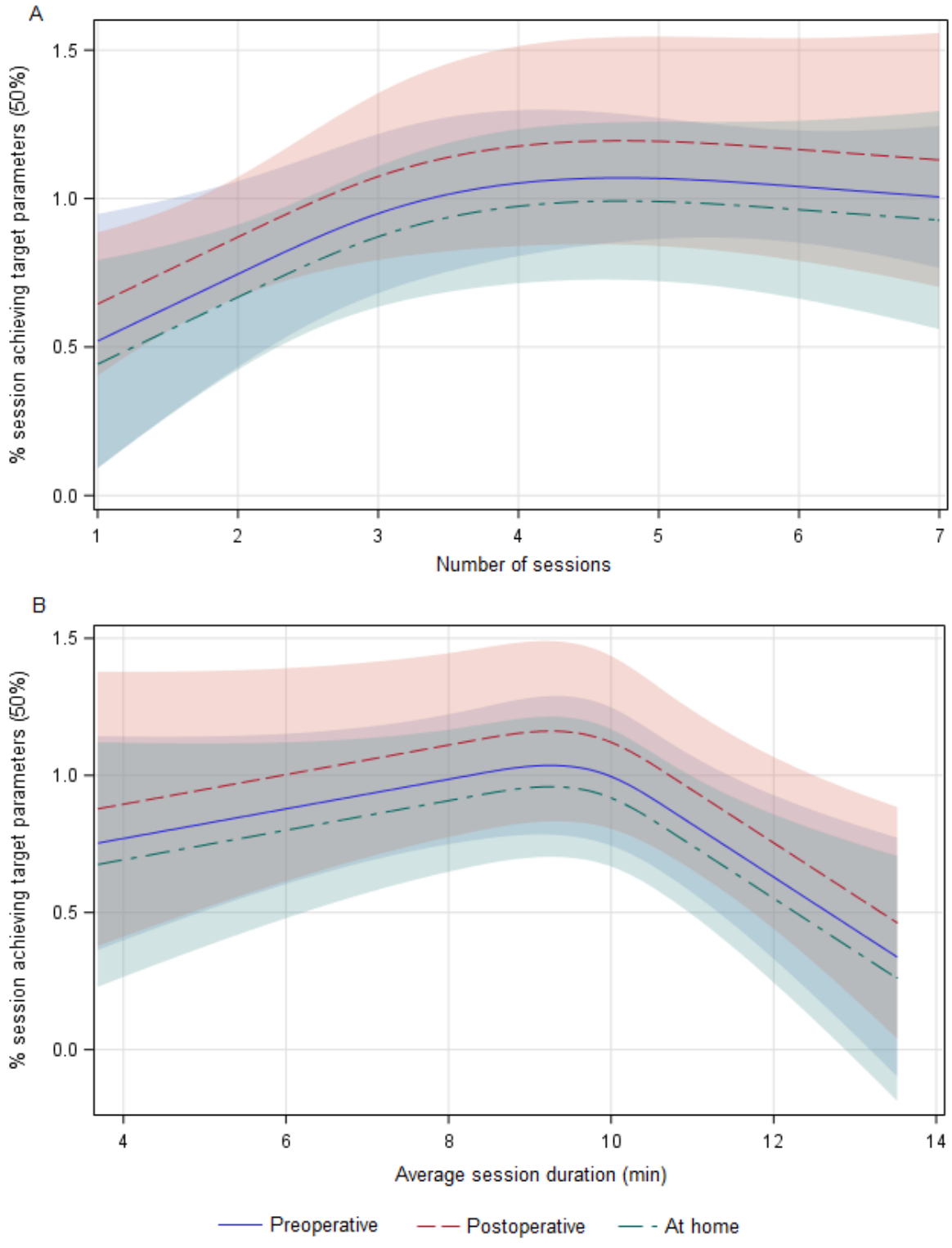


Table 5. Session-level analysis of nonlinear regression with spline for the number of sessions and average session duration with adjustments for preoperative, postoperative, or home sessions. Logistic regression with outcome—session achieving target heart rate variability parameters.

Session	Odds ratio (95% CI[a])
Session number	
3 vs 2	1.33 (0.88-2.02)
4 vs 3	0.81 (0.57-1.15)
5 vs 4	0.72 (0.46-1.13)
6 vs 5	0.72 (0.46-1.13)
Session duration (minutes)	
8 vs 7	1.41 (1.09-1.81)
9 vs 8	1.35 (1.07-1.70)
10 vs 9	1.04 (0.90-1.21)
11 vs 10	0.65 (0.51-0.82)
12 vs 11	0.52 (0.37-0.73)

[a]CI: Wald CI.

Session Duration

The Wilcoxon rank-sum test between patients achieving target HRV (median 10, IQR 8.6-10.7 min) versus those that did not (median 9.5, IQR 5-11.3 min) showed that regardless of when the sessions occurred, the average session duration was not associated with HRV concordance (P=.55; Table 2).

Nonlinear logistic regression of patient-level outcomes from any session achieving target parameters with adjustment for when the sessions were completed in the perioperative period showed the average session duration did not impact target HRV achievement (Tables 3 and 4). A nonlinear relationship existed between the average session duration and the percentage of sessions resulting in target outcomes at the patient level. The percentage of sessions resulting in target outcomes increased and peaked between an average session duration of 9-10 minutes (P=.01; Figure 3B).

Session-level analysis using nonlinear logistic regression with the outcome of a session achieving target HRV parameters and adjustment for preoperative, postoperative, or home sessions showed that session duration is nonlinearly associated with the outcome (spline of session duration P<.001) and sessions with a duration of 9 or 10 minutes had the highest odds of achieving target parameters (OR 1.3 for 9 vs 8 min, 95% CI 1.1-1.7; OR 1.4 for 8 vs 7 min, 95% CI 1.1-1.8; OR 1 for 10 vs 9 min, 95% CI 0.9-1.2; Table 5).

Patient Experience

The PEQ-C and PEQ-P were completed by 87% (20/23) patients and 83% (19/23) parents. Overall, patients and parents both expressed high satisfaction with VR-BF, reporting that they "would recommend VR therapy to friends and family" (15/20, 75% patients; 12/19, 63% parents) and "would use VR again" (12/20, 60% patients; 11/19, 58% parents) if given the opportunity. Patients reported that they "received good preoperative instructions" (18/20, 90%), they "understood how to use the devices" (20/20, 100%), and "the VR technology was easy to use" (19/20, 95%). Similarly, parents agreed that their child "received good instructions" (18/19, 95%) and "could easily use the technology" (15/19, 79%). Few patients "wished the VR experience was more realistic" (8/20, 40%).

During the postoperative period, many patients were "happy to have tried the VR therapy" (16/20, 80%). However, 10% (2/20) of patients reported having "experienced adverse side effects from the VR-BF sessions." The interviews revealed that 1 participant experienced a mild headache during a session late at night. The second participant reported experiencing nausea due to not wearing prescription glasses during the session. From the parents' perspectives, nearly half reported that "VR therapy helped them feel better about managing their child's pain" (9/19, 48%).

Furthermore, 85% (17/20) of patients and 63% (12/19) of parents believed "VR-BF helped with stress and feeling calmer." In terms of pain reduction, patients (8/20, 40%) and parents (6/19, 32%) reported lower levels of perceived efficacy with VR-BF, and only 5% (1/20) of patients and 11% (2/19) of parents "believed VR-BF helped to reduce consumption of pain medications." However, the majority of patient (16/20, 80%) and parent (13/19, 68%) responses were neutral on whether they "believed something other than VR-BF would have made the participant feel better."

Discussion

This pilot study aimed to develop a future protocol for perioperative VR-BF use in children and adolescents undergoing surgery. Because this technology is novel, assessing its feasibility and acceptability and creating a treatment protocol are essential before designing an efficacy trial. The findings from this work provide preliminary support for the feasibility and acceptability of a perioperative VR-BF intervention for children and adolescents and lay the foundation for the next step in the work to assess the ability of this technology to reduce pain and anxiety in children and adolescents undergoing surgery.

Quantitative results indicated that independent of when sessions occurred, completing between 4 and 6 VR sessions of 9 and 10 minutes was most significantly associated with patients achieving and maintaining target physiological parameters in at least 1 session [27,29]. Qualitative results revealed that perioperative use of VR-BF was well-received by patients and families, particularly in terms of an increase in patient calmness. These findings align with previous literature indicating that mind-body therapies delivered through a gamified virtual world may be viable options for managing pain and anxiety [58]. However, our work also emphasizes the need to tailor content to children's interests. Because of the lack of variety and type of content (eg, guided relaxation), many patients considered the VR intervention to be boring. As a result, their engagement with the intervention was not as high, which can give rise to a lack of compliance with the intervention [50].

In addition to establishing key parameters for protocol development, the results of the study also identified a number of directions for future research. Due to limited data points from the postoperative periods, the adjusted analysis combined all sessions during the pre-, post-, and home periods. Patients may have been less likely to feel motivated to complete postoperative sessions as many participants reported experiencing elevated pain and stress after surgery, often for the first time, and this may provide insight to why most completed sessions were observed during the preoperative period. Additional research is necessary to determine optimal dosing for postoperative VR-BF application, which may support a different frequency and duration [59]. In addition, participants did not find VR-BF effective for pain reduction, with daily once postoperative use. It is possible that "dosing" VR-BF 3 times daily after surgery could strike a balance between enough uses to achieve target physiologic parameters yet not too onerous to decrease adherence. This regimen is consistent with a study reporting significant transient decreases in pain among hospitalized patients (18 years) using VR versus in-room televisual relaxation programs, a standard of care for all patients [43]. Redesigning the protocol that instructs patients to complete 3 sessions per day after surgery will allow for evaluation of the impact of this frequency and duration on pain reduction in phase 2.

Mind-body therapies, such as yoga, meditation, acupuncture, and even hypnosis, are widely used for chronic pain management. [60]. Only recently, mind-body therapies, including biofeedback, and their relevance to treating acute pain in the perioperative setting have been empirically studied. However, there is insufficient information to establish parameters for efficient HRV-focused biofeedback treatment protocols regarding breathing duration, inhalation/exhalation ratio, body position, or breathing control [61]. A systematic review analyzed protocols implementing HRV-focused biofeedback in 143 studies from the last 20 years and found that many sessions lasted 20 minutes for adults [62], in contrast to 9-10 minutes in our study. Especially in a pediatric population, a shorter session length may be preferred, given the possibility of low motivation for session repetition [50,63] and that younger patients may display an intrinsic apt to master and achieve HRV coherence more quickly and by the first training session in comparison to older patients [64].

To our knowledge, few studies have investigated daily biofeedback use, and even fewer have tried to systematically integrate such interventions into perioperative acute pain care in children and adolescents. In addition, 1 study examined the potential for HRV biofeedback to support self-regulation training in 4 adolescents participating in a chronic pain rehabilitation program and demonstrated improved cardiopulmonary functioning during active training without active feedback, suggesting self-regulation [32]. These results are promising for using HRV biofeedback for children with chronic pain. Still, it requires more extensive research studies with more rigorous methodologies and detailed protocols to support the benefits and implementation of HRV biofeedback in children and adolescents.

With the increasing use of HRV biofeedback therapies in adults, companies like HeartMath have begun developing noninvasive devices to measure HRV for calmness and meditation across the lifespan. This has allowed some critical differences between adults and younger patients to emerge. A pilot study of patients (13-55 years) with eating disorders using the same HeartMath technology as in this study found that younger patients were better at achieving 100% HRV coherence by the first session than older patients [64]. Another study investigating biofeedback and relaxation in children (8-14 years) receiving chemotherapy treatment found significant improvements in HRV coherence by the third and fourth 60-minute sessions [65]. Treatment protocols investigating HRV-focused biofeedback in children and adolescents have ranged from 3 to 36 sessions, each lasting as little as 3 minutes to up to 1 hour [66]. Although there has not been a consensus on the optimal protocol for HRV-focused biofeedback, there is growing acceptance of this therapy, applied independently or as an adjunct to other conventional treatments, in routine medicine for pre- and postsurgical care [24-26].

The immersive environment and sense of awareness created by VR technology are thought to improve patient's motivation and adherence to a treatment protocol [67], enhancing the therapeutic benefits of complementary medicine. Our previous pilot work using distraction-based VR [49] and guided relaxation-based VR [45] on postoperative pain and anxiety paved the way for combining biofeedback with VR to treat pediatric postoperative pain in a novel and innovative integration of therapies. Distraction-based VR redirects patients' attention away from the source of their pain. However, without VR, distraction alone yields minimal benefits without any lasting or significant impact on pain relief [42,44,68]. Guided relaxation-based VR, similar to VR-BF, teaches patients relaxation techniques like slow breathing and mindfulness, which can engage parasympathetic or vagal responses to decrease pain [46]. Unlike VR-BF, neither provides patients with instantaneous feedback nor teaches them pain-reducing strategies. A VR-based delivery method may effectively overcome challenges that often hinder the widespread dissemination of conventional mind-body therapies, particularly biofeedback [50]. VR-BF provides an affordable and engaging nonpharmacologic means to safely reduce pain for longer than a brief VR session. Furthermore, as a self-directed tool, VR-BF can potentially reach more patients than biofeedback interventions that rely on clinical instructions and specially trained personnels. The combination of an effective pain and

anxiety-reducing tool like biofeedback combined with an immersive technology like VR has the potential to be a very powerful, engaging, and efficacious novel therapy that could be particularly well suited to children and adolescents.

This study has some limitations. The study design prioritized feasibility and acceptability outcomes; therefore, it was not designed as a randomized clinical trial with a control group. A power calculation was not conducted before patient enrollment, and the sample size was established based on the work of previous pilot studies. In addition, the effects on pain, anxiety, and opioid consumption were not measured as this was outside of the scope of this work. The largest limitation with this work was that Mindfulness Aurora and HeartMath do not provide immediate feedback to patients while they are undergoing the VR-BF experience. While the VR game provides a voice-guided narrative to patients telling them how to breathe, and HeartMath captures HRV parameter accomplishment; patients cannot modify or alter their breathing during the experience as they do not receive feedback from the system to help with these modifications. Ultimately, a true VR-BF system would best optimize training in and use of biofeedback in the perioperative period. Having real-time physiological feedback is likely essential to biofeedback learning and will guide patients to improve their performance while progressing through VR-BF sessions.

In summary, this study guided protocol development for the use of VR-BF in the perioperative setting in children and adolescents undergoing surgery. Critically, we found that preoperative VR-BF training that incorporated between 4 and 6 once-per-day sessions, each with a duration of 9-10 minutes, was associated with the highest probability of achievement of target HRV parameters. To enhance protocol adherence and increase the perception of VR-BF as an intervention in the postoperative period, in the next phase of the study, patients will be instructed to complete three 10-minute VR-BF sessions for a total of 7 days after surgery. Our future research plan is to conduct a randomized control trial using the developed protocol [51] to investigate the efficacy of VR-BF in reducing postoperative pain, anxiety, and opioid consumption. Ultimately, this study is essential to developing a nonopioid pain management base in children and adolescents experiencing pain and anxiety.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient experience questionnaire – Child (PEQ-C).
[DOC File , 77 KB - periop_v7i1e48959_app1.doc]

Multimedia Appendix 2
Patient experience questionnaire – Parent (PEQ-P).
[DOC File , 73 KB - periop_v7i1e48959_app2.doc]

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Abbreviations

ASA: American Society of Anesthesiologists
CONSORT: Consolidated Standards of Reporting Trials
HRV: heart rate variability
NCH: Nationwide Children's Hospital
OR: odds ratio

PEQ-C: patient experience questionnaire—child
PEQ-P: patient experience questionnaire—parent
REDCap: Research Electronic Data Capture
VR: virtual reality
VR-BF: biofeedback-based virtual reality

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Original Paper

Postsurgical Pain Risk Stratification to Enhance Pain Management Workflow in Adult Patients: Design, Implementation, and Pilot Evaluation

Matthias Görges[1,2], PhD; Jonath Sujan[2], MEng; Nicholas C West[2], MSc; Rama Syamala Sreepada[1,2], PhD; Michael D Wood[1,2], PhD; Beth A Payne[2,3], PhD; Swati Shetty[4], BSc, MD; Jean P Gelinas[5,6], MD; Ainsley M Sutherland[1,7], MD, PhD

[1]Department of Anesthesiology, Pharmacology & Therapeutics, The University of British Columbia, Vancouver, BC, Canada

[2]Research Institute, BC Children's Hospital, Vancouver, BC, Canada

[3]School of Population and Public Health, The University of British Columbia, Vancouver, BC, Canada

[4]MD Undergraduate Program, The University of British Columbia, Vancouver, BC, Canada

[5]Department of Anesthesiology & Pain Medicine, University of Alberta, Edmonton, AB, Canada

[6]Department of Anesthesiology, Surrey Memorial Hospital, Surrey, BC, Canada

[7]Department of Anesthesiology, St. Paul's Hospital, Vancouver, BC, Canada

Corresponding Author:
Matthias Görges, PhD
Department of Anesthesiology, Pharmacology & Therapeutics
The University of British Columbia
Rm V3-324, 950 West 28th Avenue
Vancouver, BC, V5Z 4H4
Canada
Phone: 1 6048752000 ext 5616
Email: mgoerges@bcchr.ca

Abstract

Background: Exposure to opioids after surgery is the initial contact for some people who develop chronic opioid use disorder. Hence, effective postoperative pain management, with less reliance on opioids, is critical. The Perioperative Opioid Quality Improvement (POQI) program developed (1) a digital health platform leveraging patient-survey-reported risk factors and (2) a postsurgical pain risk stratification algorithm to personalize perioperative care by integrating several commercially available digital health solutions into a combined platform. Development was reduced in scope by the COVID-19 pandemic.

Objective: This pilot study aims to assess the screening performance of the risk algorithm, quantify the use of the POQI platform, and evaluate clinicians' and patients' perceptions of its utility and benefit.

Methods: A POQI platform prototype was implemented in a quality improvement initiative at a Canadian tertiary care center and evaluated from January to September 2022. After surgical booking, a preliminary risk stratification algorithm was applied to health history questionnaire responses. The estimated risk guided the patient assignment to a care pathway based on low or high risk for persistent pain and opioid use. Demographic, procedural, and medication administration data were extracted retrospectively from the electronic medical record. Postoperative inpatient opioid use of >90 morphine milligram equivalents per day was the outcome used to assess algorithm performance. Data were summarized and compared between the low- and high-risk groups. POQI use was assessed by completed surveys on postoperative days 7, 14, 30, 60, 90, and 120. Semistructured patient and clinician interviews provided qualitative feedback on the platform.

Results: Overall, 276 eligible patients were admitted for colorectal procedures. The risk algorithm stratified 203 (73.6%) as the low-risk group and 73 (26.4%) as the high-risk group. Among the 214 (77.5%) patients with available data, high-risk patients were younger than low-risk patients (age: median 53, IQR 40-65 years, vs median 59, IQR 49-69 years, median difference five years, 95% CI 1-9; *P*=.02) and were more often female patients (45/73, 62% vs 80/203, 39.4%; odds ratio 2.5, 95% CI 1.4-4.5; *P*=.002). The risk stratification was reasonably specific (true negative rate=144/200, 72%) but not sensitive (true positive rate=10/31, 32%). Only 39.7% (85/214) patients completed any postoperative quality of recovery questionnaires (only 14, 6.5%

patients beyond 60 days after surgery), and 22.9% (49/214) completed a postdischarge medication survey. Interviewed participants welcomed the initiative but noted usability issues and poor platform education.

Conclusions: An initial POQI platform prototype was deployed operationally; the risk algorithm had reasonable specificity but poor sensitivity. There was a significant loss to follow-up in postdischarge survey completion. Clinicians and patients appreciated the potential impact of preemptively addressing opioid exposure but expressed shortcomings in the platform's design and implementation. Iterative platform redesign with additional features and reevaluation are required before broader implementation.

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KEYWORDS

patient-oriented research; patient-reported outcome measures; risk prediction; pain; individualized risk; surgery; anesthesia; opioid analgesia; short-term opioid use; care planning; digital health platforms

Introduction

Background

The ongoing opioid overdose epidemic has contributed to unprecedented and unnecessary deaths, with an estimated 100,306 deaths from prescription and illegal opioid use in the United States in the 12 months before April 2021 [1] and 5360 deaths in Canada in the first 9 months of 2022 [2]. For many patients with an opioid use disorder, the perioperative period represents the source of initial exposure (>6% compared to 0.4% in a control cohort without surgery in the United States) [3]. Hence, effective postoperative pain management, with less reliance on the prescription of opioids, could be a valuable mechanism to reduce the development of subsequent opioid use disorder. Postsurgical opioids are most frequently prescribed by the surgeon and followed up by the patient's primary care physician [4]. Anesthesiologists are uniquely positioned to manage acute postoperative pain effectively with multimodal analgesia to decrease perioperative opioid exposure and prevent subsequent persistent opioid use [3].

Perioperative health care is being optimized through enhanced recovery after surgery (ERAS) pathways [4-6], multimodal analgesic plans [5,7,8], and regional anesthesia techniques [9]. Further opportunities to improve postsurgical pain trajectories are offered by prehabilitation programs [10-12], our developing understanding of the risks of persistent postsurgical pain [13-17], and the feasibility of accessing and analyzing large volumes of data. A critical step is identifying patients at high risk of significant postsurgical pain and long-term opioid use.

The Perioperative Opioid Quality Improvement (POQI) program was designed to address the ongoing opioid use epidemic in British Columbia, where opioid use disorder continues to be one of the most pressing public health concerns. Recent studies have highlighted the scale of the local opioid problem and highlighted the case for addressing opioid risk during routine clinical care, including surgery: 12% of our population received an opioid prescription in 2017, with the number of people who receive a high dose (>90 morphine milligram equivalents [MME]/day) increasing during the period from 2013 to 2017 [18]; patients with opioid overdose have often had previous clinical encounters for pain (50%) and surgery (5%) [19].

The POQI program was funded in 2019 by DIGITAL, Canada's Global Innovation Cluster for digital technologies, as a consortium between digital health companies, health care organizations, and university partners. It aimed to develop and implement a postsurgical pain risk stratification algorithm by integrating several commercially available digital health solutions into a combined POQI digital health platform for prehabilitation and postsurgical care planning. The COVID-19 pandemic adversely impacted the ability to engage clinicians and patients in co-designing and testing the solution iteratively. Hence, the project faced significant delays, and the scope of the POQI platform development was reduced. Specifically, planned features for 2-way communication and personalization of educational information for patients were not included in the prototype tested in this study.

Objectives

The specific objectives of the pilot deployment of the POQI platform were to assess (1) the screening performance of the risk stratification algorithm to facilitate subsequent risk score optimization and (2) the use, utility, and perceived benefit of the POQI platform among end users (clinicians and patients).

Methods

Study Design and Approval

The study involved the design, implementation, and pilot evaluation of the POQI digital health platform at Providence Health Care's (PHC's) St. Paul's Hospital in Vancouver, British Columbia, Canada. The target users were clinicians and patients. The patient population for pilot-testing had undergone a designated set of colorectal surgeries; this population was selected because the colorectal surgical clinic was an early adopter of an electronic health history questionnaire (HHQ) upon which the platform expanded. As a result of this initiative, the Department of Anesthesiology and Pain Medicine at PHC established a new Transitional Pain Clinic for patients at risk of persistent postoperative pain or opioid use after surgery. It held weekly clinics during the study period and continued to serve St. Paul's Hospital patients after the study concluded.

The POQI platform incorporated an algorithm [20] that classified patients as low risk or high risk for persistent postsurgical pain and long-term opioid use. Clinicians used this classification to assign patients to low-risk or high-risk pathways for personalized prehabilitation, patient education, and care planning. Specifically, patients were told that there were resources that they could use to learn about pain and nonpharmacologic strategies for pain management and that they

could keep track of their medication use and pain scores over time in the system. The performance of this risk stratification was evaluated based on observed postoperative inpatient opioid use. The clinician and patient user experiences were evaluated using mixed methods.

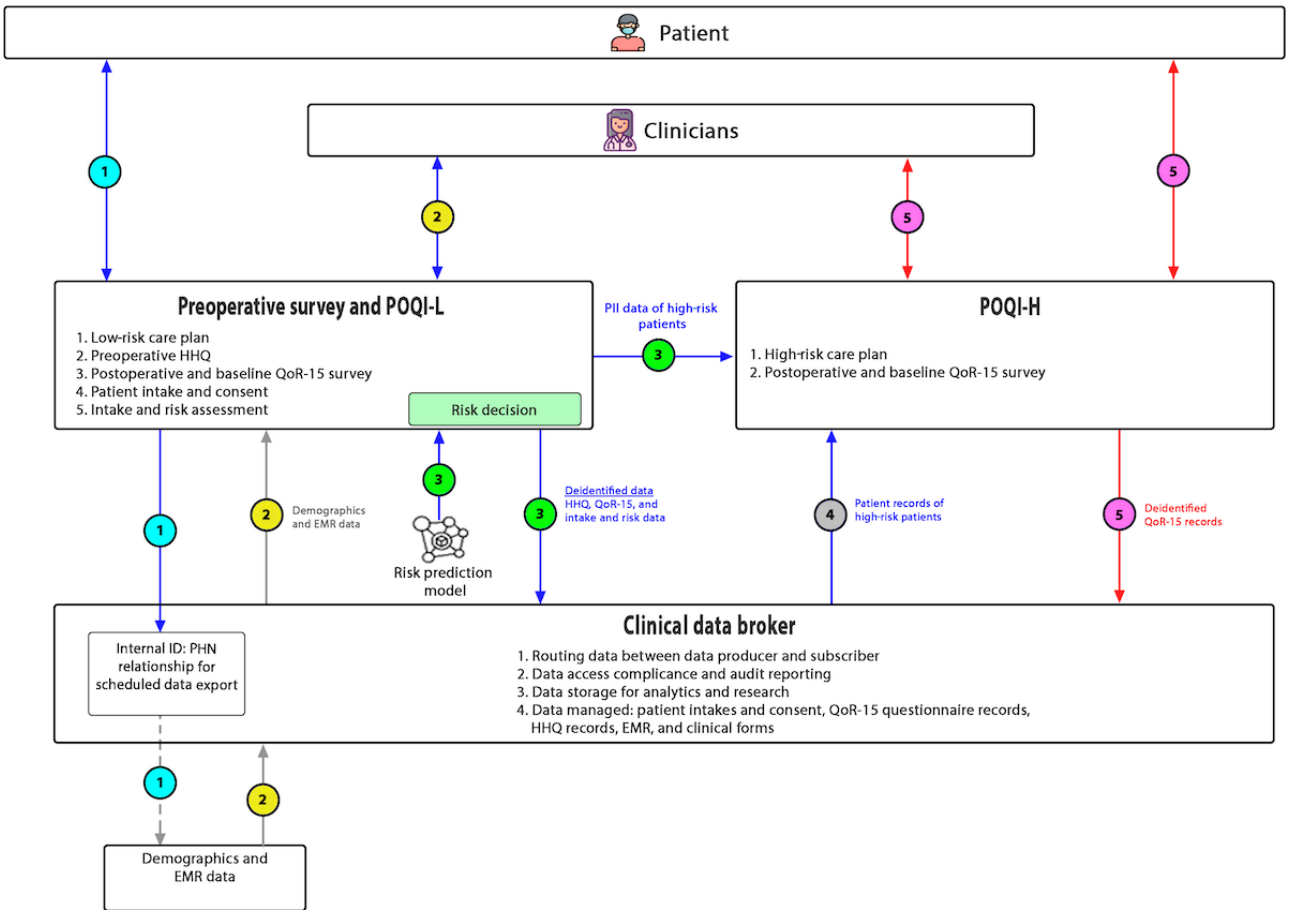
Ethical Considerations

The University of British Columbia PHC Research Ethics Board determined this work to be a quality improvement project (reviewed on October 13, 2020), for which they do not require ethical review under Article 2.5 of the Canadian Tri-Council Policy Statement [21]. Hence, this project was run as a quality improvement pilot project governed by Privacy Impact Assessment and Security Threat and Risk Assessment. This manuscript adheres to the SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) reporting guidelines [22].

The POQI Digital Health Platform

Development of the POQI platform combined existing technologies from 3 industry partners (Figure 1): a preoperative survey and POQI platform for low-risk patients (POQI-L), supplied by Thrive Health; a POQI platform for high-risk patients (POQI-H), supplied by Careteam Technologies; and a data broker, supplied by Excelar Technologies (also incorporating Xerus Medical from 2021). Additional components were identified and developed based on the needs of the clinical implementation partners (the anesthesiologists and perioperative care team at St. Paul's Hospital). The platform's original scope of development work was scaled back due to resource and time constraints during the COVID-19 pandemic. The resultant POQI platform used in this study should be considered an initial prototype. Original development plans included (1) additional iterations of user testing and design refinement; (2) additional features, such as 2-way communication between patients and clinicians; and (3) personalization of educational materials to meet patients' needs optimally.

Figure 1. Workflow in the perioperative quality improvement (POQI) platform showing the integration of clinical and patient-reported data from patient-facing components and the electronic medical record (EMR) integrated by a data broker. PHN: personal health number; PII: personally identifiable information; POQI-H: POQI platform for high-risk patients; POQI-L: POQI platform for low-risk patients; QoR: quality of recovery.



The prototype POQI platform allowed for the collection of patient-specific data, including a presurgical HHQ (questions selected as risk factors for modeling are presented in Multimedia Appendix 1) and patient-reported outcome measures (PROMs) at baseline. Furthermore, data were collected postoperatively using quality of recovery-15 (QoR-15) questionnaires [23] and additional PROM surveys to collect self-reported medication use and pain (scores). The platform was linked to an automated export from the Cerner electronic medical record (EMR) system (Cerner Corp), which allowed for collecting surgery details and oral and intravenous opioid use data from inpatient medication administration records.

Initial HHQ data were used to stratify patients for risk of persistent postsurgical pain and opioid use, using a previously

developed risk score, which was based on the data collected from 122 patients who underwent colorectal surgery; 22 (18%) of them had high postoperative opioid use, which was strongly associated with a history of chronic pain, substance use disorder, and open surgery [20]. Patients were categorized into high-risk and low-risk groups using a point-based prediction model that considered 11 risk factors with different weights [20]: substance use disorder (risk score weight=5); current prescription of opioid (risk score weight=5), benzodiazepine (risk score weight=4), or antidepressant (risk score weight=4); recreational drug use (risk score weight=4); history of chronic pain (risk score weight=4), anxiety or panic attacks (risk score weight=2), depression (risk score weight=2), or poorly controlled pain after surgery (risk score weight=2); female sex (risk score weight=2); and age <40 years (risk score weight=1; refer to relevant HHQ questions in Multimedia Appendix 1). The algorithm flagged a patient as high risk if the risk score was >7 out of 35, after which a clinician manually onboarded the patient to the POQI-H platform or confirmed that they should remain on the POQI-L platform. The clinician could override the algorithm's proposed risk label if they deemed it clinically appropriate. In addition, clinicians could use their clinical judgment to manually onboard patients directly to POQI-H after the St. Paul's Hospital Transitional Pain Clinic consultation, even when no electronic HHQ data were available.

High-risk patients were given a care plan that provided them with education about pain and opioid management and prompted them to record their medication use and pain scores (refer to the *Study Design and Approval* section for details). Some high-risk patients were also seen preoperatively in St. Paul's Hospital Transitional Pain Clinic for prehabilitation, education, and pain management planning when the responsible clinician deemed it appropriate. Postoperatively, high-risk patients were flagged by St. Paul's Hospital Transitional Pain Clinic providers for closer follow-up by the Acute Pain Service clinicians in the hospital.

Regardless of the risk categorization, patients who used a significant quantity of opioids postoperatively (>90 MME) were also followed by St. Paul's Hospital Transitional Pain Service for optimization of their postdischarge pain management and opioid weaning; 90 MME was chosen as the threshold for referral, as it is recommended in the 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain that patients using >90 MME per day be weaned to the lowest effective dose, potentially including discontinuation [24].

Participants and Recruitment

Pilot use of the POQI platform was initiated at St. Paul's Hospital in December 2021 and formally adopted on January 1, 2022. The target population for pilot-testing included patients undergoing a designated set of colorectal surgeries during the active enrollment period (Multimedia Appendix 2) and excluded patients who underwent screening and minimally invasive diagnostic procedures such as endoscopies. Patients who had a surgery that was not included in the designated set or had undergone procedures with a surgical time of <20 minutes were excluded. Furthermore, patients who underwent surgery before January 1, 2022, were excluded, as the complete POQI platform implementation was not available for clinical use until then. Only the surgical encounter closest to the most recently recorded HHQ was considered when patients had multiple procedures. Eligible patients were enrolled for the pilot through routine clinical care by the medical office assistant in surgical clinics (Figure 2). Postoperative data collection continued for up to 120 days after surgery, with surveys potentially completed on postoperative days 7, 14, 30, 60, 90, and 120.

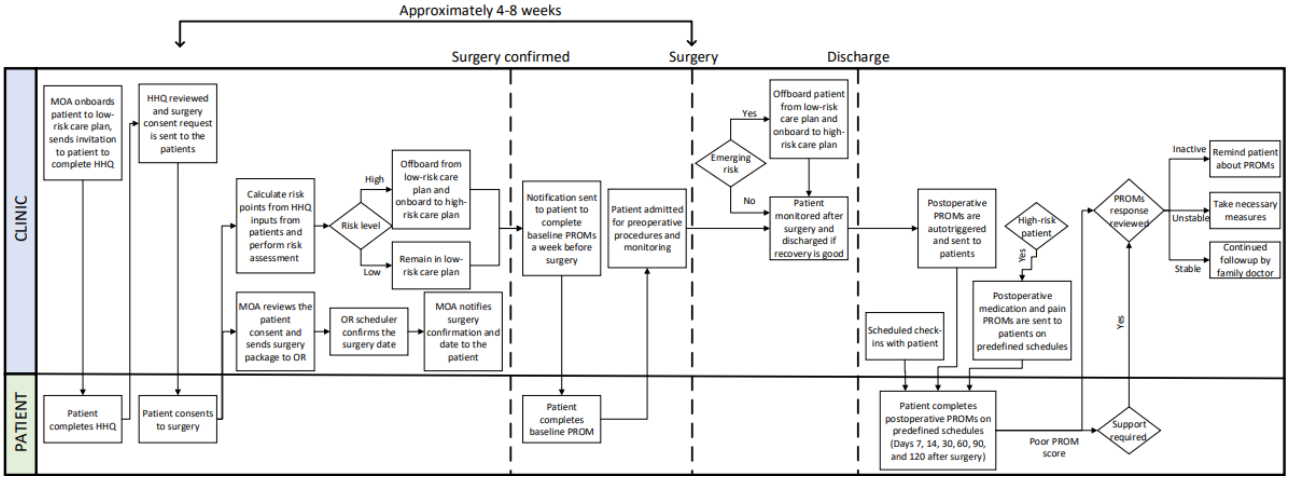


Figure 2. Clinical workflow of the perioperative quality improvement platform as piloted at St. Paul's Hospital. This figure illustrates the flow of patients through their perioperative care journey and delineates which pieces the system performs and when the patient is involved in this process; it shows key decision points, such as when the patient is risk stratified before their procedure and whether patients require enhanced follow-up after discharge. A poor patient-reported outcome measure (PROM) score (bottom right) was indicated if the patient reported having an unplanned hospital admission for pain, having to seek urgent care for pain, or if they were still taking opioids beyond postoperative day 7. HHQ: health history questionnaire; MOA: medical office assistant; OR: operating room.

Data Collection and Management

The patient-specific data, including preoperative baseline HHQ, QoR-15 questionnaires, and PROM surveys, were fed directly to the data broker from the respective POQI-L or POQI-H platforms. The surgery details and opioid use data from the medication administration record were extracted from the EMR. These data were made available in a data lake by the Excelar

data broker for analysis. The unifying variables used to link the multiple platforms were the patient's personal health number and the ThriveID, assigned at the initial onboarding for HHQ completion. Data for this evaluation were aggregated and deidentified (Figure 2). The deidentified data sets were then exported to the research team for analysis.

Outcomes

Risk Stratification

To evaluate the risk stratification, we elected to focus on inpatient opioid use. Analyzing long-term opioid use was not possible: records of opioids dispensed from the provincial medication system (PharmaNet) were not made available due to provincial policy constraints at the time, and patient self-report was deemed to be unfeasible and incomplete or biased. Therefore, the primary outcome used to evaluate the accuracy of the risk stratification was based on inpatient daily opioid use, using a threshold of >90 MME per day to indicate high opioid use, in line with the recommendations for opioid therapy and chronic noncancer pain [24]. MME was computed by multiplying the dosage of opioids delivered to the patient with the MME conversion factor of the corresponding drug and route of administration (Multimedia Appendix 3). For oral methadone, the MME conversion factor varies with the dosage administered per day; consequently, an aggregation algorithm was used to calculate the total methadone administered per day.

Patient-controlled analgesia was typically used for in-hospital intravenous opioid administration. Nurses regularly recorded the number of doses delivered to the patient, and the patient-controlled analgesia pump was reset every 12 hours at the end of their shift. The net amount of drug delivered to the patient was computed using the number of doses and the amount of drug in each dose. The MME values from intravenous and oral administration were then summed for every patient over a 24-hour period, starting at 6 AM and ending at 6 AM the following day.

EMR data structures and export limitations prevented us from including MMEs of drugs delivered through continuous opioid infusion or boluses; these patients were excluded from MME evaluation. Intraoperative opioids were not included when computing MME/day; that is, on the day of surgery, only opioids administered after the surgery up to 6 AM the following day were included for the MME/day calculation.

Use, Utility, and Perceived Benefit

The user experience outcomes of use, utility, and perceived benefit were evaluated using mixed methods.

Use was measured quantitatively by evaluating both uptake and attrition with the platform. Uptake was measured by the number of patients completing the HHQ survey and the number completing the preoperative baseline QoR-15. Attrition was evaluated by measuring continued use of the system postoperatively, that is, by the number of patients completing at least 1 postoperative QoR-15 survey, at least 1 PROM survey, and their postoperative data collection period up to the 90-day mark.

Utility and perceived benefit were evaluated through a series of semistructured interviews with both patients and clinicians via Zoom (Zoom Video Communications). To obtain a representative sample, a randomly selected group of 10 patients deemed high risk for significant postsurgical pain and a random group of 10 patients deemed low risk for significant postsurgical pain were contacted approximately 1 week after hospital discharge and invited to participate. For clinicians, we included anesthesiologists and nurses in St. Paul's Hospital Transitional Pain Clinic and aimed for a sample of 5 clinicians.

Brief (approximately 10-15 minutes) interviews focused on three domains: (1) experience with the platform technologies, (2) perceived benefit of the platform for the health care experience, and (3) feedback or concerns about the platform (Multimedia Appendix 4). Interviews were conducted in a safe environment of mutual respect and facilitated by a medical student (SS) assisting with the project. Transcripts were automatically obtained from Zoom and downloaded from the videoconferencing platform for all interviews. A research team member (MDW) thematically analyzed the transcripts using NVivo (QSR International).

Additional Secondary Outcomes

Additional secondary outcomes included emergent readmissions; pain scores over the first 3 postoperative days; and continued opioid use at 30, 60, and 90 days, collected through the additional PROM surveys. To determine the number of patients who had emergent readmissions, we filtered the inpatient and emergency department visit data sets for patients with prior surgery. We confirmed that the admission time in the new visit was after the discharge time following the surgery. As inpatients could have had nonemergent readmissions for scheduled procedures and not all emergent visits require admissions, only the inpatient visits categorized as "urgent/emergent" and the patients admitted after emergency visits were included. The data set was split into readmissions within 30 days and readmissions within 180 days after discharge.

Statistical Analysis

The available data were summarized for high- and low-risk patients, including patient count, age distribution, surgical wait time (time to surgery after referral for surgical care), procedure duration, length of hospital stay, the identified risk factors from the HHQ (refer to *The POQI Digital Health Platform* section), preoperative and postoperative QoR-15 scores, the proportion of the population that completed the QoR-15, length of follow-up, the number of emergent readmissions, in-hospital opioid use in MME/day, and most prevalent surgeries. Frequency data are reported as n/N (%); the denominator N changes due to data linking issues and loss of follow-up during the study period.

Due to the small sample size, data for low- and high-risk groups were compared using nonparametric statistical tests: the Fisher exact test for counts and the Mann-Whitney *U* test for continuous data. A logistic regression of all risk factors for high in-hospital opioid use was performed to generate adjusted odds ratios (ORs), reported with 95% CIs. Analyses were performed using Python (version 3.10; Python Software Foundation):

Pandas (version 1.5.0; Wes McKinney), SciPy (version 1.9.3; Enthought), and NumPy (version 1.23.3) were used for data cleaning, processing, and analysis; Matplotlib (version 3.6.0) was used to generate plots; and Openpyxl (version 3.0.10) was used to create analysis reports. R software (version 4.2.2; The R Foundation) was used for statistical comparisons.

The accuracy of the risk stratification was assessed to determine if the algorithm was sensitive enough to categorize patients based on their health history. This was achieved by constructing confusion matrices using the high- and low-risk labels generated by the risk prediction algorithm (using HHQ data, not POQI-L or POQI-H enrollment labels) and the outcome, that is, high (>90 MME/day) and low (≤90 MME/day) opioid use. These data were used to estimate sensitivity, specificity, false negative rate, false positive rate, and positive and negative likelihoods.

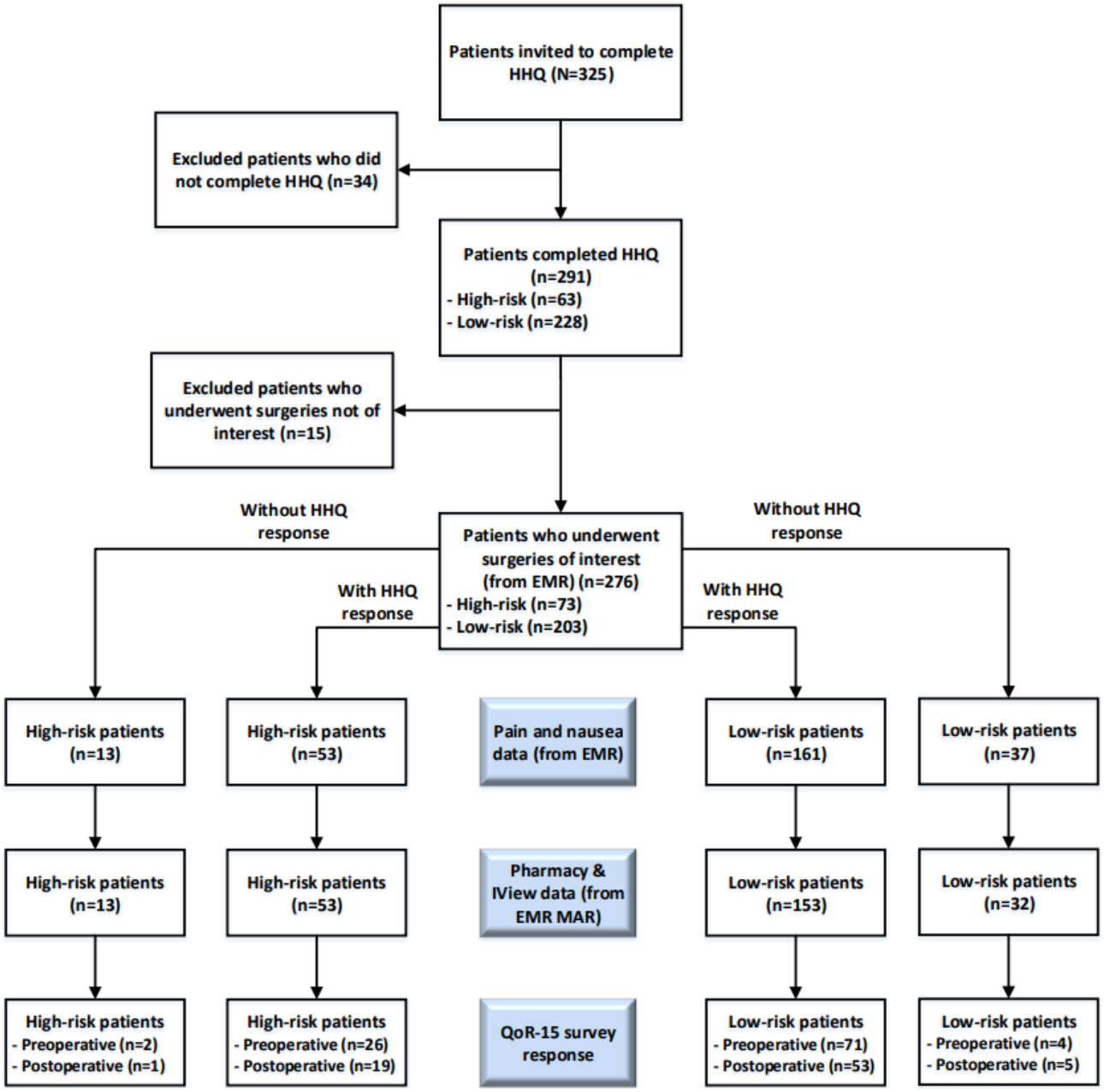
Scatter with line (median) plots and box plots were created to determine the trend of opioid use by patients on postoperative days 0 to 10 and to compare the trend between low- and high-risk patients.

Results

Population

A total of 276 eligible patients were admitted for one of the colorectal procedures selected for inclusion in the study at St. Paul's Hospital between January 01, 2022, and September 30, 2022, and completed the HHQ before surgery (Figure 3). The denominators vary in the result tables due to the selective completion of surveys and the availability of linked data.

Figure 3. Platform uptake, attrition, and data completeness in high-risk and low-risk patients. EMR: electronic medical record; HHQ: health history questionnaire; MAR: medication administration record; QoR: quality of recovery.



Risk Stratification Characteristics

Of the 276 patients, the risk stratification algorithm identified 203 (73.6%) patients as low risk and 73 (26.4%) as high risk. The most common surgeries for low-risk patients were laparoscopic resection of the anterior colon, transanal resection of a rectal lesion by assisted microsurgery, and laparoscopic resection of the bowel. The most common surgeries for high-risk patients were laparoscopic resection of the anterior colon, laparoscopic resection of the bowel, and lysis of adhesions.

The most substantial differences in risk factors between the high-risk and low-risk groups were history of depression (OR 29.4, 95% CI 9.2-125; risk score weight=2), antidepressant prescription (OR 23.4, 95% CI 7.9-85.2; risk score weight=4), current opioid prescription (OR 20.4, 95% CI 4.2-196.4; risk score weight=5), and history of chronic pain (OR 19.4, 95% CI 6.9-63.3; risk score weight=4; Table 1).

Table 1. Risk factor distribution among cohort and risk groups, with odds ratios for being in the high-risk group. While risk factor details were not available in all cohort patients, the label from the calculation was available.

Risk factor	Total sample (N=214), n (%)	Low-risk group (n=161), n (%)	High-risk group (n=53), n (%)	Odds ratio (95% CI)
Substance use disorder	9 (4.2)	3 (1.9)	6 (11.3)	6.6 (1.4-42.6)
Current opioid prescription	13 (6.1)	2 (1.2)	11 (20.8)	20.4 (4.2-196.4)
Benzodiazepine prescription	9 (4.2)	3 (1.9)	6 (11.3)	6.6 (1.4-42.6)
Antidepressant prescription	28 (13.1)	5 (3.1)	23 (43.4)	23.4 (7.9-85.2)
Recreational drug use	29 (13.6)	10 (6.2)	19 (35.8)	8.3 (3.3-22.0)
History of chronic pain	29 (13.6)	6 (3.7)	23 (43.4)	19.4 (6.9-63.3)
History of anxiety	46 (21.5)	18 (11.2)	28 (52.8)	8.8 (4.0-19.7)
History of depression	27 (12.6)	4 (2.5)	23 (43.4)	29.4 (9.2-125.0)
History of poorly controlled pain	26 (12.1)	11 (6.8)	15 (28.3)	5.3 (2.1-14.0)
Female sex	90 (42.1)	59 (36.6)	31 (58.5)	2.4 (1.2-4.8)
Age (<40 years)	32 (15.0)	20 (12.4)	12 (22.6)	2.1 (0.8-4.9)

High-risk patients were younger than low-risk patients (age: median 53, IQR years, vs median 59, IQR years, median difference [MD] 5 years, 95% CI 1-9; *P*=.02) and were more often female (45/73, 62%, vs 80/203, 39.4%; OR 2.5, 95% CI 1.4-4.5; *P*=.002; Table 2). Furthermore, high-risk patients reported lower baseline (preoperative) QoR scores (median 122, IQR 91-136, vs median 131, IQR 116-140, MD 12, 95% CI 2-23; *P*=.02).

Table 2. Preoperative and surgical characteristics of the overall cohort and separate risk groups.

	Total sample (N=276)	Low-risk group (n=203)	High-risk group (n=73)	*P* value	Median difference (95% CI)	Odds ratio (95% CI)
Age (y), median (IQR)	59 (47-68)	59 (49-69)	53 (40-65)	.02	5 (1 to 9)	—[a]
Sex, n (%)				.002	—	2.5 (1.4 to 4.5)
Male	151 (54.7)	123 (60.6)	28 (38.4)			
Female	125 (45.3)	80 (39.4)	45 (61.6)			
Surgery type, n (%)				.15	—	1.5 (0.9 to 2.8)
Closed	183 (66.3)	140 (69.0)	43 (58.9)			
Open	93 (33.7)	63 (31.0)	30 (41.1)			
Time to surgery (days), median (IQR)[b]	30 (18-68)	29 (16-54)	34 (19-86)	.21	–4.9 (–13.3 to 2.7)	—
Length of surgery (hours), median (IQR)	2.1 (1.2-3.1)	2.1 (1.1-3.0)	1.9 (1.2-3.3)	.85	0.0 (–0.3 to 0.4)	—
Preoperative QoR-15[c] score, median (IQR)[d]	129 (104-139)	131 (116-140)	122 (91-136)	.02	12 (2 to 23)	—

[a]Not applicable.

[b]Data available: total, n=267; low-risk patients, n=195; high-risk patients, n=75. This indicates the number included in the analysis (eg, surgical decision time is not available for all patients).

[c]QoR-15: quality of recovery-15.

[d]Data available: total, n=110; low-risk patients, n=77; high-risk patients, n=33. This indicates the number included in the analysis.

Postoperative Outcomes

Overall inpatient opioid use was not significantly different between the 2 risk groups, with a median of 20 IQR (10-45) MME/day in low-risk cases versus a median of 25 IQR (10-50) MME/day in high-risk cases (MD –2, 95% CI –5 to 0; *P*=.10; Table 3). Similarly, no significant difference was observed in opioid use across the recovery profile of low- versus high-risk patients over the first 10 postoperative days (Figure 4). Our risk factors were not strong predictors for high MME/day: none of the ORs from logistic regression were significant (ie, 95% CI range included 1 for all predictors), which differs from our original model building cohort [20] (Table 4, right column).

Table 3. Inpatient opioid use in patients with patient-controlled analgesia or oral opioid medications (n=231)[a].

	Total (n=231)	Low-risk group (n=165)	High-risk group (n=66)	*P* value	Median difference (95% CI)	Odds ratio (95% CI)
MME[b]/day (mg), median (IQR)	24 (10-47)	20 (10-45)	25 (10-50)	.10	–2 (–5 to 0)	—[c]
Total MME (mg), median (IQR)	48 (15-145)	43 (15-130)	65 (18-237)	.09	–10 (–38 to 1)	—
Patients using >90 MME/day, n (%)	31 (13.4)	21 (12.7)	10 (15.1)	.67	—	1.2 (0.5 to 2.9)

[a]Some patients, not included here, had continuous opioid infusion only or no opioid medications.

[b]MME: morphine milligram equivalent.

[c]Not applicable.

Figure 4. Box plots of morphine milligram equivalents (MME) per day comparing high-risk and low-risk patients.

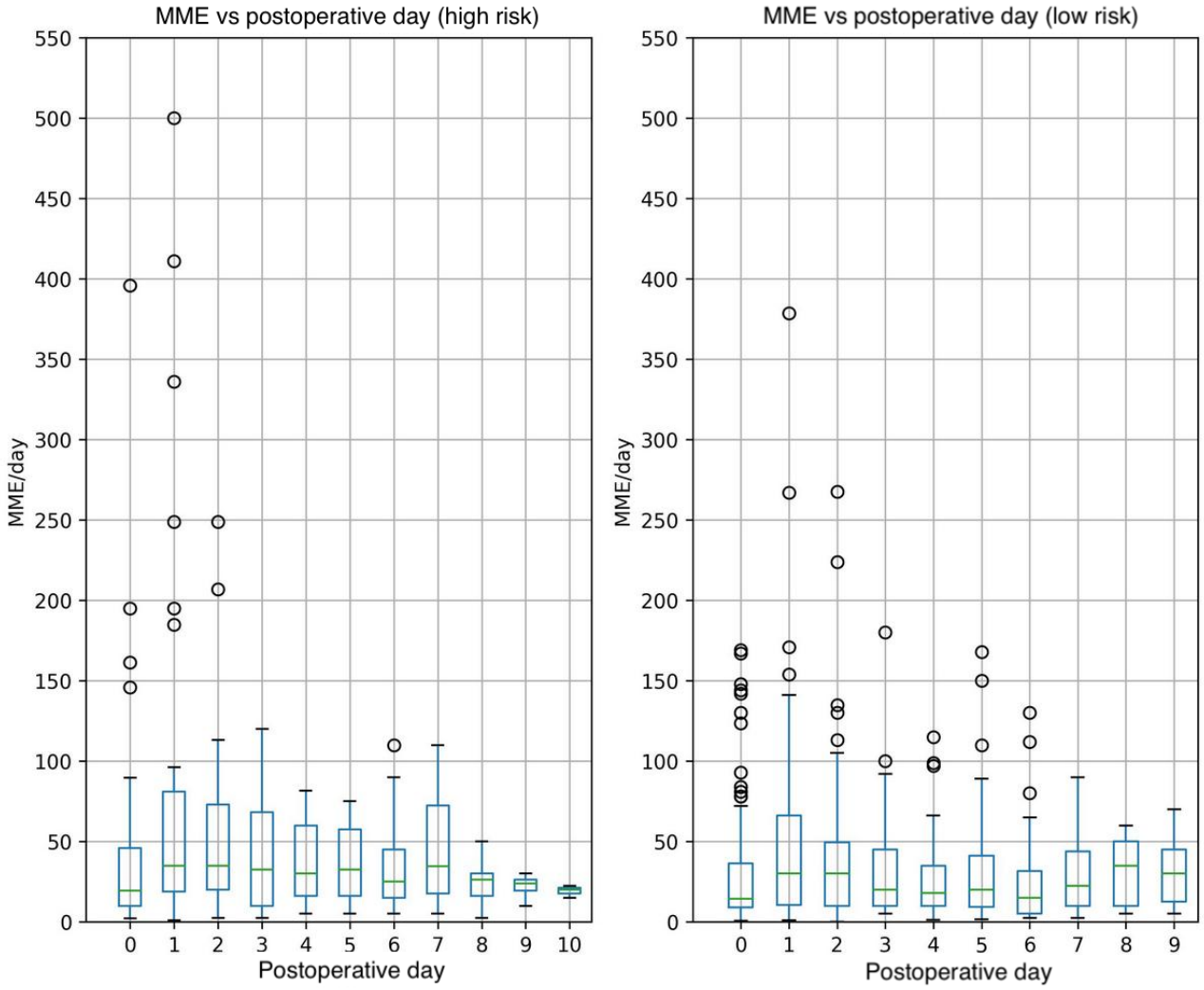


Table 4. Risk factor distribution among cohort and outcome groups, with the odds ratios for patients using >90 morphine milligram equivalent (MME) per day for which the presurgical health history questionnaire details were available. The adjusted odds ratios from the derivation cohort [20] are provided for reference.

Risk factor	Total sample (n=201), n (%)	≤90 MME/day (n=177), n (%)	>90 MME/day (n=24), n (%)	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)[a]	Adjusted odds ratio in the derivation cohort [20] (95% CI)
Substance use disorder	9 (4.5)	7 (4.0)	2 (8.3)	2.2 (0.2-12.6)	1.8 (0.2-9.5)	1.6 (1.0-2.3)
Current opioid prescription	12 (6.0)	9 (5.1)	3 (12.5)	2.6 (0.4-11.8)	2.9 (0.5-12.4)	1.1 (0.7-1.6)
Benzodiazepine prescription	9 (4.5)	8 (4.5)	1 (4.2)	0.9 (0.0-7.4)	0.6 (0.0-4.4)	1.0 (0.8-1.3)
Antidepressant prescription	28 (13.9)	23 (13.0)	5 (20.8)	1.8 (0.5-5.5)	1.6 (0.4-6.2)	1.2 (0.7-1.8)
Recreational drug use	28 (13.9)	25 (14.1)	3 (12.5)	0.9 (0.2-3.2)	0.7 (0.1-2.5)	1.1 (0.6-1.7)
History of chronic pain	28 (13.9)	24 (13.6)	4 (16.7)	1.3 (0.3-4.3)	0.9 (0.2-3.1)	1.6 (1.0-2.6)
History of anxiety	44 (21.9)	35 (19.8)	9 (37.5)	2.4 (0.9-6.5)	2.5 (0.8-7.3)	0.8 (0.5-1.2)
History of depression	26 (12.9)	22 (12.4)	4 (16.7)	1.4 (0.3-4.8)	0.8 (0.2-3.2)	0.9 (0.6-1.3)
History of poorly controlled pain	25 (12.4)	23 (13.0)	2 (8.3)	0.6 (0.1-2.8)	0.5 (0.1-2.1)	1.1 (0.6-1.7)
Female sex	82 (40.8)	72 (40.7)	10 (41.7)	1.0 (0.4-2.7)	0.8 (0.3-2.0)	1.0 (0.6-1.6)
Age (<40 years)	30 (14.9)	26 (14.7)	4 (16.7)	1.2 (0.3-3.9)	1.2 (0.3-4.0)	1.0 (0.9-1.0)
Open surgery	—[b]	—	—	—	—	1.2 (0.7-2.0)

[a]Values derived from multivariate logistic regression, including all other risk factors.

[b]Not applicable.

Readmissions and other postoperative outcomes did not differ between high- and low-risk groups, although the overall median postoperative QoR-15 score was higher in the low-risk group than in the high-risk group (MD 11, 95% CI 4-19; *P*=.002; Table 5).

Table 5. Postoperative outcomes.

	Total (n=231)	Low-risk group (n=165)	High-risk group (n=66)	*P* value	Median difference (95% CI)	Odds ratio (95% CI)
Total readmissions, n (%)	75 (32.5)	51 (30.9)	24 (36.4)	.22	—[a]	1.5 (0.8 to 2.7)
Emergent readmissions (within 30 days of surgery), n (%)	20 (8.7)	13 (7.8)	7 (10.6)	.43	—	1.5 (0.5 to 4.4)
Emergent readmissions (30 to 180 days following surgery), n (%)	7 (3.0)	4 (2.4)	3 (4.5)	.39	—	2.1 (0.3 to 12.9)
Length of hospital stay (days), median (IQR)	4 (2-6)	4 (2-6)	5 (1-7)	.56	0 (–1 to 0)	—
Overall postoperative QoR-15[b] score, median (IQR)[c]	118 (100-133)	121 (107-134)	108 (89-128)	.002	11 (4 to 19)	—

[a]Not applicable.

[b]QoR-15: quality of recovery-15.

[c]Data available: total, n=85; low-risk patients, n=59; high-risk patients, n=26. This indicates the number included in the analysis.

Risk Stratification Performance

In terms of performance, with an incidence of opioid use of >90 MME/day as the primary outcome, the pilot risk stratification algorithm was reasonably specific (true negative rate=144/200, 72%) but not sensitive (true positive rate=10/31, 32%). These equate to a high false negative rate of 68% (21/31), with a false positive rate of 28% (56/200), a positive likelihood of 1.15, and a negative likelihood of 0.94.

Postoperative Use of the POQI Platform

Data are available for 214 (77.5%) of the 276 patients who completed the HHQ and were risk stratified by the POQI platform (low-risk patients: 161/203, 79.3%; high-risk patients: 53/73, 73%). Of the 276 patients, 85 (30.8%) completed any

postoperative QoR-15 questionnaire (low-risk patients: 59/203, 29.1%; high-risk patients: 26/73, 36%). Similarly, 31 (15.3%) of the 203 low-risk patients and 3 (4.1%) of the 73 high-risk patients reported any postoperative opioid use (Table 6).

Table 6. Postoperative use of the perioperative quality improvement (POQI) platform.

	Total sample (n=276)	Low-risk group (n=203)	High-risk group (n=73)	*P* value	Median difference (95% CI)	Odds ratio (95% CI)
Data available from preoperative HHQ[a], n (%)	214 (77.5)	161 (79.3)	53 (72.6)	.26	—[b]	0.7 (0.4 to 1.4)
Completed at least 1 postoperative questionnaire, n (%)	85 (30.8)	59 (29.1)	26 (35.6)	.62	—	0.9 (0.4 to 1.7)
Length of follow-up postsurgery (days), median (IQR)[c]	25 (11-54)	24 (11-53)	29 (11-57)	.80	–1 (–9 to 10)	—
Completed follow-up questionnaires at POD[d] 31 to 60, n (%)	15 (5.4)	11 (5.4)	4 (5.5)	.99	—	1.0 (0.3 to 4.4)
Completed follow-up questionnaires beyond POD 90, n (%)	3 (1.1)	0 (0)	3 (4.1)	.57	—	0 (0 to 6.8)
Patients reporting postoperative medication use, n (%)	34 (12.3)	31 (15.3)	3 (4.1)	.01	—	4.2 (1.2 to 22.1)

[a]HHQ: health history questionnaire.

[b]Not applicable.

[c]Data available: total, n=85; low-risk patients, n=59; high-risk patients, n=26. This indicates the number included in the analysis.

[d]POD: postoperative day.

Qualitative Interviews

We conducted feedback interviews with 3 (15%) patients (2 POQI-L users and 1 POQI-H user) of the 20 invited patients; most patients (17/20, 85%) approached declined to participate in this portion of the study. We interviewed all 4 clinicians (anesthesiologists and nurses who used both platforms) involved in the platform deployment in St. Paul's Hospital Transitional Pain Clinic.

Perceived Benefit of the Platforms for the Health Care Experience

Patients recognized that the POQI-L had improved their health care experience by making them mindful of their behavior, such as "stating how I was feeling, anxiety about things, etc," which gave them "a sense of agency" over their care. It also provided a sense of reassurance that the health care team was continually monitoring their health status after they returned home following hospital discharge. Similarly, the POQI-H user believed there was a potential benefit:

> *[T]his will help me keep track of things and have some kind of two-way communication*

However, they did not feel that the potential had been met with the current version.

The clinical users perceived minimal benefits of the POQI-H, such as improving their workflows and allowing them to manage their patients better. However, they recognized potential patient benefits, including access to educational information:

> *[F]or the patients, there is good access to many resources.*
>
> *[The platform] provided people with resources to manage their pain well while they're at home [with] an option to access further information* [as needed]

The clinical users identified benefits of the POQI-L, which administered the HHQ to all patients as a screening and triage tool: clinicians reported that it was helpful to display the pain risk score and "to see whether they're a high or low risk as a quick way to screen patients." Integrating patient information in a single document was also helpful:

> *[It was] also useful as a way to gather all the patient's medical history.*

User Experience With the Platforms

Patients experienced issues using both platforms, although this may have resulted from poor communication of the purpose of the application and potential benefits for them:

> *I'm not sure what that tool is trying to be.* [POQI-L user]
>
> *[...] I didn't feel like I had much guidance in using [it].* [POQI-H user]

Furthermore, there was a lack of clarity in instructions for using both platforms; for example, the POQI-L users expressed frustration about redundant emails or SMS text messages, which were unclear about "what was supposed to be completed and when," and the POQI-H user said as follows:

> *I wasn't sure if I was supposed to initiate certain things, or if like somebody from my care team would go in.*

Furthermore, the 2 POQI-L participants were unaware of their postoperative risk score and its details and viewed this as a

missed opportunity to benefit from understanding their personalized risk for significant postsurgical pain.

Similarly, usability issues during the initial deployment contributed to attrition among clinical users; for example, 1 clinician admitted that they had not signed patients up on the POQI-H for 4 months, as they did not find it easy to use, were not satisfied with the functionality, and could not quickly locate necessary information; another clinician had "*stopped using [POQI-L] as a method to look up patients and filter them out to see who should be put on [POQI-H].*" The clinicians who had used both platforms expressed concerns with quality assurance and usability:

I think both platforms have much potential when they're working... [but]there have been many [issues] to deal with in the development of the programs, which have been both challenging and frustrating.

Both patients and clinicians expressed a desire for greater platform integration. One patient stated as follows:

> *[I] would have hoped that there would have been things populated in it [to] show the integration of services that I was accessing post-surgery.*

Clinicians indicated that there should be a single platform with a unified vision; for example, a clinician stated as follows:

> *I want to be able to do everything from one platform; I don't want to have to be on multiple different platforms. So that's my ideal scenario.*

Discussion

Principal Findings

A pragmatic risk prediction algorithm was used to categorize 276 patients who underwent colorectal surgery into high-risk or low-risk groups for significant postoperative pain. The algorithm's performance was evaluated using a primary outcome threshold of >90 MME/day during in-hospital recovery: it was found to be reasonably specific (true negative rate=14/200, 72%) but not sensitive (true positive rate=10/31, 32%). Furthermore, the risk categorization was used to drive dedicated preoperative and postoperative patient surveys using the high-risk (POQI-H) or low-risk (POQI-L) platforms. Preoperative surveys, including HHQ, were completed by 214 (77.5%) of the 276 patients, but there was a significant loss to follow-up with postoperative surveys, including QoR-15, completed by only 85 (39.7%) of the 214 patients. Qualitative feedback from clinician and patient users indicated shortcomings in the design and implementation of the patient- and clinician-facing components of the POQI platform.

Comparison With Prior Work

The motivation was that POQI would establish a platform to support personalized multimodal pain management techniques and patient preparation or education to reduce reliance on opioids (both in-hospital and postdischarge opioid use) during recovery from surgery. Identifying those at most significant risk of postoperative pain and providing tailored care plans based on their risk levels may help reduce initial opioid consumption. A recent systematic review suggested that a higher risk of developing persistent postsurgical pain is associated with younger age, female sex, and preoperative pain [25], which are consistent with the characteristics observed in the patients classified as high risk by our algorithm (Table 2). Furthermore, a recent multicenter study in the United States identified preoperative opioid use as the most significant predictor of prolonged opioid use after surgery [26]. Again, this factor was a significant distinguishing characteristic of our high-risk patients, along with a history of depression, antidepressant use, and chronic pain (Table 2).

Virtual care solutions for patients in the postsurgical period, including web-based tools and mobile apps, can support tracking various postoperative outcomes, including prescription drug use. Although the development of perioperative eHealth or mobile health solutions for telemonitoring is still maturing [27], these technologies show promise as not only their implementation is feasible but they can also streamline clinical workflow and improve patient outcomes [28,29]. Web-based patient portals integrated with the EMR can improve patient satisfaction, enable more effective health care use [30], and improve outcomes such as glycemic control in patients with diabetes [31]. However, there are several barriers to successful implementation, as our experience with poor patient retention indicates (Figure 3). To improve patient engagement through an EMR portal, it is essential to avoid high attrition rates, which requires addressing the requirements of diverse patients, focusing on usability and functionality, and adopting implementation science approaches [32]; using apps can also have a positive impact [33]. Perioperative solutions must be designed with frequent and meaningful clinician and patient input and evaluated in large, robust clinical trials [27,29]. Particular attention is needed when developing and evaluating tools for vulnerable populations, such as patients with chronic pain issues and older patients, although a recent systematic review reported generally positive results from 7 studies on patients aged ≥65 years [34]. In contrast, our population was relatively younger, with a median age of 59 (IQR) (47-68) years. Furthermore, an evaluation of a patient-centric digital pain management app reported acceptable patient engagement and improved anxiety and pain catastrophizing in similarly aged patients who had experienced chronic pain of moderate to severe intensity for at least 3 months [33].

The lack of follow-up data prevented us from effectively evaluating or optimizing the risk stratification algorithm we implemented. The risk model was reasonably specific, based on in-hospital MME, but with poor sensitivity and a subsequent high false negative rate, as it failed to identify patients who may have benefited from the POQI-H platform. None of our 11 patient-reported preoperative risk factors had a significant adjusted OR for high in-hospital opioid use (>90 MME/day), in which the 95% CI range excluded 1 (Table 4). This indicates that by themselves, none of the risk factors would have predicted high postoperative opioid use in this cohort, although these are recognized risk factors. This contradicts the findings from our retrospective study in the same hospital, which found that a history of chronic pain and substance use disorder was associated with high postoperative opioid requirements [20]. The small sample sizes in both our retrospective and prospective

cohorts may have limited our ability to detect these associations reliably in the chosen population. Alternatively, despite being evidence based [24], our selected threshold of >90 MME/day may not be optimal. Future work should explore other potentially self-reportable risk factors, such as open surgery, pain catastrophizing, or lack of planned regional anesthesia, as well as interactions between synergistic or antagonistic risk factors. Finally, data science approaches show promise in predicting postsurgical outcomes, with generally positive findings in a recent systematic review [35]. Such technology has been used to predict prolonged opioid use after orthopedic surgery [36] or estimate the risk of an adverse outcome within 30 days of an opioid dispensation [37]. These techniques may help refine local models, such as our algorithm, but we need more data at this stage.

Importantly, our platform was an amalgamation of various existing (or slightly adapted) technologies that lacked adequate workflow integration and did not adapt to varying clinical or patient needs to allow evaluation when there were any deviations from the predefined workflow. For example, we could not access clinically relevant long-term outcomes for many high-risk patients. Improving access to available administrative and clinical data could facilitate improved prediction performance using machine learning techniques [37].

Lessons Learned

We cannot report a fully realized solution due to a lack of integration with the provincial medication system and the reduced scope of the platform in light of the COVID-19 pandemic. However, the problems that we encountered and the lessons learned during our implementation can benefit other research, specifically clinical and industry teams endeavoring to build perioperative virtual care solutions to improve postoperative opioid use after discharge. Any work addressing this critical public health problem should ensure frequent engagement of patient and clinical partners, including co-design [38], to confirm that the design addresses patient and provider needs and delivers meaningful benefits to patient care and health care practice.

Next, when including a research component in health care system technical development and implementation, it is essential to ensure that research end points are integrated into project plans. This ensures that industry partners and clinical teams contribute to and approve evaluation plans so that the teams understand and support each other's priorities. We also suggest including all partners in frequent data quality assessments and using an objective committee to oversee project activities, focusing on system-level goals while enabling each partner to achieve their respective objectives.

Given the likelihood that the requirement for virtual care solutions in the perioperative setting will grow, preparing for the transition to a long-term sustainable implementation is essential [39,40]. This should leverage experiences from stakeholders; focus on user experience; and ensure data are collected, validated, and delivered to the right people at the right time to improve the quality of care. Feedback is essential to a learning health system [41]: process metrics, patient trajectories, and benchmarking tools will enable clinicians to learn from their patients. PROMs and patient-reported experience measures [42] will be fundamental to improving the quality of care provided, focusing on patient-relevant outcomes rather than only system-relevant ones and enabling the personalization of care.

Limitations

In addition to the implementation issues already discussed, we must acknowledge many limitations in the data that we have presented. First, restrictions to hospital access due to the COVID-19 pandemic care considerations leading up to and during the pilot recruitment period likely caused significant delays. It also hampered effective engagement between patients, the research team, clinical teams, and industry partners and disrupted the opportunity to refine the software solution through further design iterations.

Second, it is unclear from our data how patients used the information provided through the platform. The qualitative results from a limited number of patients willing to be interviewed and clinicians suggest that some patients glimpsed the potential value of the tool. However, they did not use or benefit from the educational materials and saw the platform as a survey tool rather than a virtual care platform. This may have contributed to the observed attrition rate and lack of interest in participating in usability interviews. Further design iterations were needed to respond to end user concerns and improve engagement in the platform. The lack of long-term follow-up was further compounded by technical issues and the lack of completed PROM survey data from patients. To prevent this from happening in the future, it may be better to engage and support patients' needs through a prospective approach that uses a near real-time data pipeline and integrated interfaces directly into workflows at the point of care. The lack of bidirectional EMR integration is a limitation of our implementation. It likely contributed to our high attrition rates and compromised the quality of the data we could report on. As discussed, improving patient engagement through an EMR portal requires a more robust implementation approach than we could apply here.

Third, the primary aim of the algorithm to identify persistent postoperative opioid requirements could not be determined without access to prescription data to verify dispensed medications after discharge. Gaining such access using patient-directed or authorized access through the British Columbia Health Gateway was a project goal, and implementation was explored. However, it was found to be impossible due to provincial policy constraints. Hence, we cannot know whether the intervention impacted prolonged opioid use after surgery. Future studies should explicitly include long-term follow-up but may have to augment it with self-reports to capture the difference between dispensed and taken medications.

Finally, this analysis is limited due to a small sample size from a single center (including only 24, 11.9% of the 201 patients who used opioids >90 MME/day) and missing follow-up outcomes from many patients designated as high risk for significant postsurgical pain and opioid use. This is partly due to low engagement during the COVID-19 pandemic and

challenges in achieving the project's objectives within a limited funding period. Similarly, we planned to recruit 10 patients from the POQI-L group, 10 from the POQI-H group, and 5 clinicians to participate in semistructured interviews. However, we only obtained feedback from 3 patients (2 POQI-L users and 1 POQI-H user) and 4 clinicians. A broader sample would have provided more insight into the shortcomings and potential benefits of the system and should be built into any future evaluation.

Again, this final limitation was, at least in part, due to the COVID-19 pandemic. On the other hand, the COVID-19 pandemic created a greater motivation for developing and implementing systems that support virtual care through the perioperative process. This may be particularly relevant in a hospital such as St. Paul's Hospital, a tertiary care academic hospital with patients from all over British Columbia, a geographically vast Canadian province with a widely distributed population. Finally, pain management requires multidisciplinary care that may not be available in rural communities. A well-designed platform could fill this gap and enable patients to benefit from personalized risk prediction and virtual prehabilitation while overcoming potential resource constraints.

Conclusions

Our POQI platform categorized patients who underwent colorectal surgery into high-risk or low-risk groups for significant postoperative pain and opioid use, using a pragmatic risk prediction algorithm. The algorithm's performance was reasonably specific but not sensitive in predicting in-hospital opioid requirements. However, a significant loss in follow-up with postdischarge surveys suggested shortcomings in the design and implementation of the platform, which may have been improved with additional development work and the opportunity to engage patients more comprehensively. Important lessons learned during implementation included the early and frequent engagement of patients and clinical partners in the design and evaluation process. Finally, POQI platform users appreciated its potential impact on reducing opioid exposure, streamlining perioperative care, and improving patient outcomes, suggesting a redesign and evaluation before wider implementation is desirable.

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Conflicts of Interest

JPG is a consultant for Excelar Technologies. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Risk factors and relevant questions from health history questionnaire.
[DOCX File , 25 KB - periop_v7i1e54926_app1.docx]

Multimedia Appendix 2
List of included colorectal surgeries in pilot implementation.
[DOCX File , 24 KB - periop_v7i1e54926_app2.docx]

Multimedia Appendix 3
Morphine milligram equivalent conversion factors.
[DOCX File , 21 KB - periop_v7i1e54926_app3.docx]

Multimedia Appendix 4
Interview guides.
[DOCX File , 25 KB - periop_v7i1e54926_app4.docx]

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Abbreviations

EMR: electronic medical record
ERAS: enhanced recovery after surgery
HHQ: health history questionnaire
MD: median difference

MME: morphine milligram equivalents
OR: odds ratio
PHC: Providence Health Care
POQI: Perioperative Opioid Quality Improvement
POQI-H: Perioperative Opioid Quality Improvement platform for high-risk patients
POQI-L: Perioperative Opioid Quality Improvement platform for low-risk patients
PROM: patient-reported outcome measure
QoR-15: quality of recovery-15
SQUIRE: Standards for Quality Improvement Reporting Excellence

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Original Paper

Association of a Novel Electronic Form for Preoperative Cardiac Risk Assessment With Reduction in Cardiac Consultations and Testing: Retrospective Cohort Study

Mandeep Kumar[1,2,3], MD; Kathryn Wilkinson[2], BS; Ya-Huei Li[4], PhD; Rohit Masih[3], MD; Mehak Gandhi[3], MD; Haleh Saadat[5,6], MD; Julie Culmone[1], DNP, APRN-BC

[1]Pre-Admission Testing Center, Perioperative Medicine, Hartford HealthCare, Hartford, CT, United States

[2]University of Connecticut, Storrs, CT, United States

[3]Hartford HealthCare Medical Group, Hartford, CT, United States

[4]Research Program, Hartford HealthCare, Hartford, CT, United States

[5]Integrated Anesthesia Associates-Fairfield Division, Hartford Healthcare, Hartford, CT, United States

[6]Frank H Netter MD School of Medicine, Quinnipiac University, North Haven, CT, United States

Corresponding Author:
Mandeep Kumar, MD
Pre-Admission Testing Center
Perioperative Medicine, Hartford HealthCare
85 Seymour St, Suite 601
Hartford, CT, 06106
United States
Phone: 1 860 972 2334
Email: mandeep.kumar@hhchealth.org

Abstract

Background: Preoperative cardiac risk assessment is an integral part of preoperative evaluation; however, there is significant variation among providers, leading to inappropriate referrals for cardiology consultation or excessive low-value cardiac testing. We implemented a novel electronic medical record (EMR) form in our preoperative clinics to decrease variation.

Objective: This study aimed to investigate the impact of the EMR form on the preoperative utilization of cardiology consultation and cardiac diagnostic testing (echocardiograms, stress tests, and cardiac catheterization) and evaluate postoperative outcomes.

Methods: A retrospective cohort study was conducted. Patients who underwent outpatient preoperative evaluation prior to an elective surgery over 2 years were divided into 2 cohorts: from July 1, 2021, to June 30, 2022 (pre–EMR form implementation), and from July 1, 2022, to June 30, 2023 (post–EMR form implementation). Demographics, comorbidities, resource utilization, and surgical characteristics were analyzed. Propensity score matching was used to adjust for differences between the 2 cohorts. The primary outcomes were the utilization of preoperative cardiology consultation, cardiac testing, and 30-day postoperative major adverse cardiac events (MACE).

Results: A total of 25,484 patients met the inclusion criteria. Propensity score matching yielded 11,645 well-matched pairs. The post–EMR form, matched cohort had lower cardiology consultation (pre–EMR form: n=2698, 23.2% vs post–EMR form: n=2088, 17.9%; P<.001) and echocardiogram (pre–EMR form: n=808, 6.9% vs post–EMR form: n=591, 5.1%; P<.001) utilization. There were no significant differences in the 30-day postoperative outcomes, including MACE (all P>.05). While patients with "possible indications" for cardiology consultation had higher MACE rates, the consultations did not reduce MACE risk. Most algorithm end points, except for active cardiac conditions, had MACE rates <1%.

Conclusions: In this cohort study, preoperative cardiac risk assessment using a novel EMR form was associated with a significant decrease in cardiology consultation and testing utilization, with no adverse impact on postoperative outcomes. Adopting this approach may assist perioperative medicine clinicians and anesthesiologists in efficiently decreasing unnecessary preoperative resource utilization without compromising patient safety or quality of care.

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KEYWORDS

preoperative; cardiology consultations; decrease low value care; cardiology; cardiac; cohort; surgery; surgical; EMR; EMRs; EHR; EHRs; electronic medical record; electronic medical records; electronic health record; electronic health records; form; forms; assessment; assessments; risk; risks; referral; consultation; consultations; testing; diagnosis; diagnoses; diagnostic; diagnostics

Introduction

Approximately 17.2 million surgeries are performed annually in the United States [1], with an estimated 3% combined risk of perioperative mortality, myocardial infarction (MI), and ischemic stroke [2]. Clinicians must estimate the probability of perioperative adverse events for shared decision-making and risk mitigation. This includes evaluating preexisting cardiac conditions, performing risk assessment with tools such as the Revised Cardiac Risk Index (RCRI), and using an algorithm to determine if a stress test is indicated [3]. The *American College of Cardiology /American Heart Association (ACC/AHA) Perioperative Cardiac Evaluation 2014 Guideline* [4] provides a widely accepted preoperative evaluation algorithm.

Preoperative workup may include a referral to a cardiologist, and appropriate indications for such consultations have been described [3,5]. Inappropriate cardiac testing or cardiology referrals are considered low-value care because they rarely change perioperative management, cause surgical delays, and increase costs [5-12]. Low-value preoperative cardiac stress testing is estimated to cost US $102 to US $238 million [9]. Potential causes include nonspecific referral requests or the assumption that a cardiology consultation may decrease legal risk in the event of a postoperative cardiac complication [5,13,14]. A preoperative referral to a cardiologist is an independent risk factor for low-value cardiac testing [8,14,15]. Pappas et al [16] noted significant variation in stress test orders among 118,552 patients that persisted even after adjusting for patient risk factors. Additionally, the average wait time to see a cardiologist is 26.6 days according to a 2022 AMN/Merritt Hawkins survey [17]. Studies of simulated patient scenarios have demonstrated that it is challenging for anesthesia residents [18] and practicing anesthesiologists [19] to consistently follow a preoperative cardiac algorithm. In summary, variation in requesting cardiology consultations and stress testing, unnecessary costs, and potential for surgical delays make a compelling case for an intervention to assist clinicians. However, we are not aware of any electronic medical record (EMR) process for the structured completion of a preoperative cardiac algorithm or its association with preoperative resource utilization and postoperative outcomes.

Our hospital system adapted the ACC/AHA algorithm in 2020 to standardize indications for preoperative cardiology evaluation and created an EMR form in 2022 to streamline its completion. The objective of this study was to investigate the impact of the EMR form on the preoperative utilization of cardiology consultation and cardiac diagnostic testing (echocardiograms, stress tests, and cardiac catheterization) and to evaluate postoperative outcomes.

Methods

Study Design, Setting, and Population

We performed a retrospective cohort analysis of patients aged ≥18 years who underwent an outpatient preoperative evaluation between July 1, 2021, and June 30, 2023, followed by an elective surgical procedure. Exclusion criteria were urgent and emergent surgical procedures, duplicate visits, and incomplete data. Hartford Healthcare is a 7-hospital integrated health care system in Connecticut. The preoperative evaluation centers are staffed by advanced practice providers, in collaboration with internal medicine hospitalist physicians. The data of interest were collected as part of routine clinical care. The study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guideline [20].

Ethical Considerations

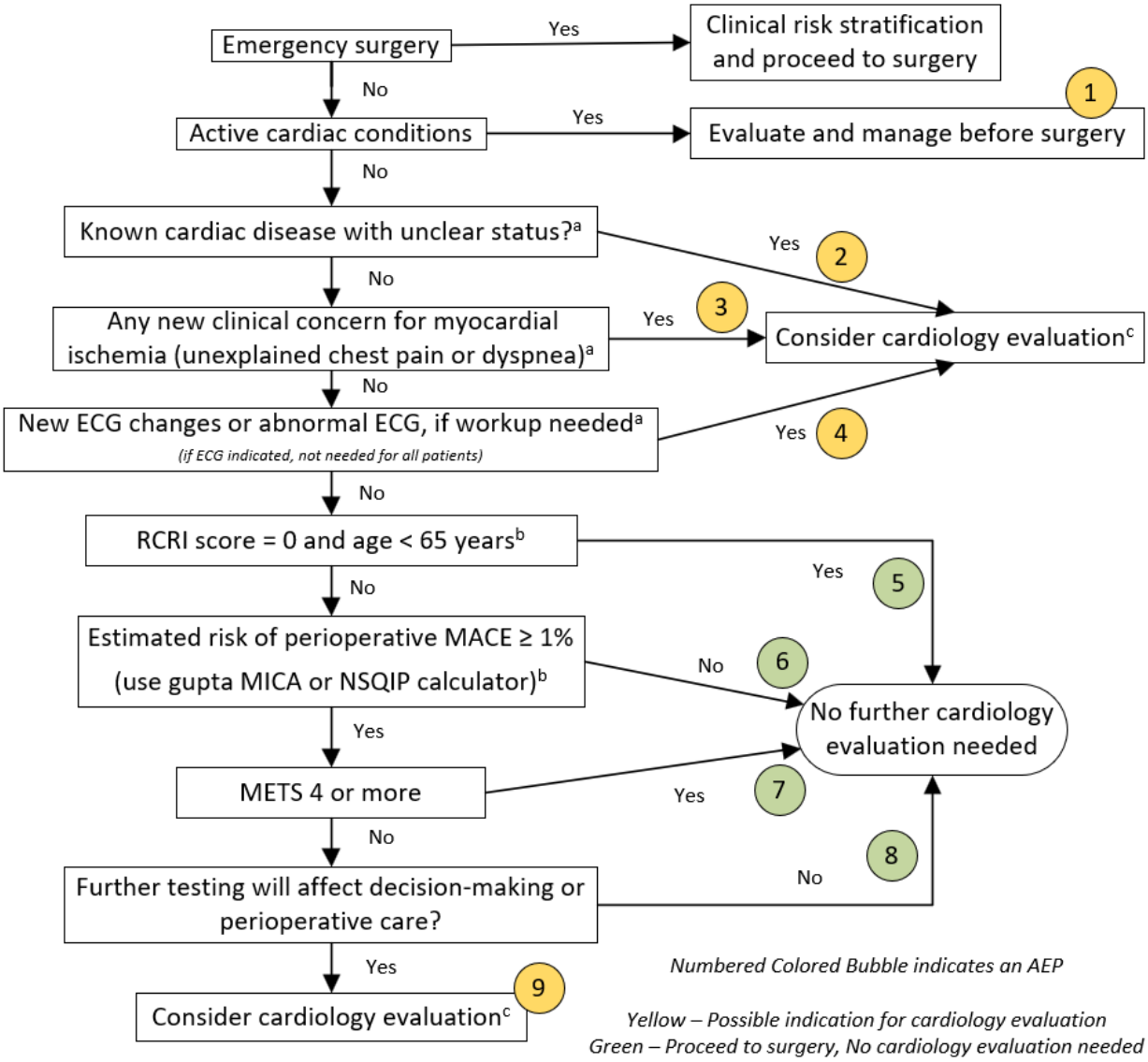
This study was approved by the Institutional Review Board of Hartford Healthcare (HHC-2023-0113; approved on May 18, 2023), which waived the requirement for written informed consent. The data were deidentified before study analysis was performed. No compensation was provided to study participants.

Preoperative Cardiac Risk Algorithm Used in This Study

Overview

Our institution's preoperative cardiac risk algorithm is adapted from the 2014 ACC/AHA perioperative cardiovascular evaluation guideline [4] with modifications to address nonacute cardiovascular symptoms, timing of intervention for coronary artery disease (CAD), stability of preexisting cardiac disease, and a nuanced consideration of major adverse cardiac events (MACE) risk, as detailed below and represented in Figure 1.

Figure 1. Preoperative cardiac risk assessment algorithm used in this study. a: Nonacute cardiovascular symptoms or known cardiac disease with unclear status, reasonable to consider cardiology input before surgery. b: Estimated MACE risk: those with an RCRI score of zero and age <65 years are considered low risk. The MACE risk % is calculated using the Gupta MICA or ACS NSQIP surgical risk calculator. c: Consider cardiology evaluation: our institution determined that it was optimal to defer the ordering of noninvasive stress testing to a cardiologist. ACS: American College of Surgeons; AEP: algorithm end point; ECG: electrocardiogram; MACE: major adverse cardiac events; METS: metabolic equivalents; MICA: Myocardial Infarction or Cardiac Arrest; NSQIP: National Surgical Quality Improvement Program; RCRI: Revised Cardiac Risk Index.



Nonacute Cardiovascular Symptoms or Known Cardiac Disease

The 2014 ACC/AHA algorithm does not include an assessment of nonacute cardiovascular symptoms. However, in clinical practice, potential evidence of new myocardial ischemia, such as unexplained chest pain, dyspnea, new ischemic electrocardiogram (ECG) changes, or abnormal ECG findings without prior workup, may warrant further evaluation [3,21,22]. Additionally, patients with CAD require consideration of the timing of surgery relative to the time elapsed since coronary revascularization. Finally, if the stability of preexisting cardiac disease is unclear, a cardiologist's input can be valuable [3].

Estimated MACE Risk

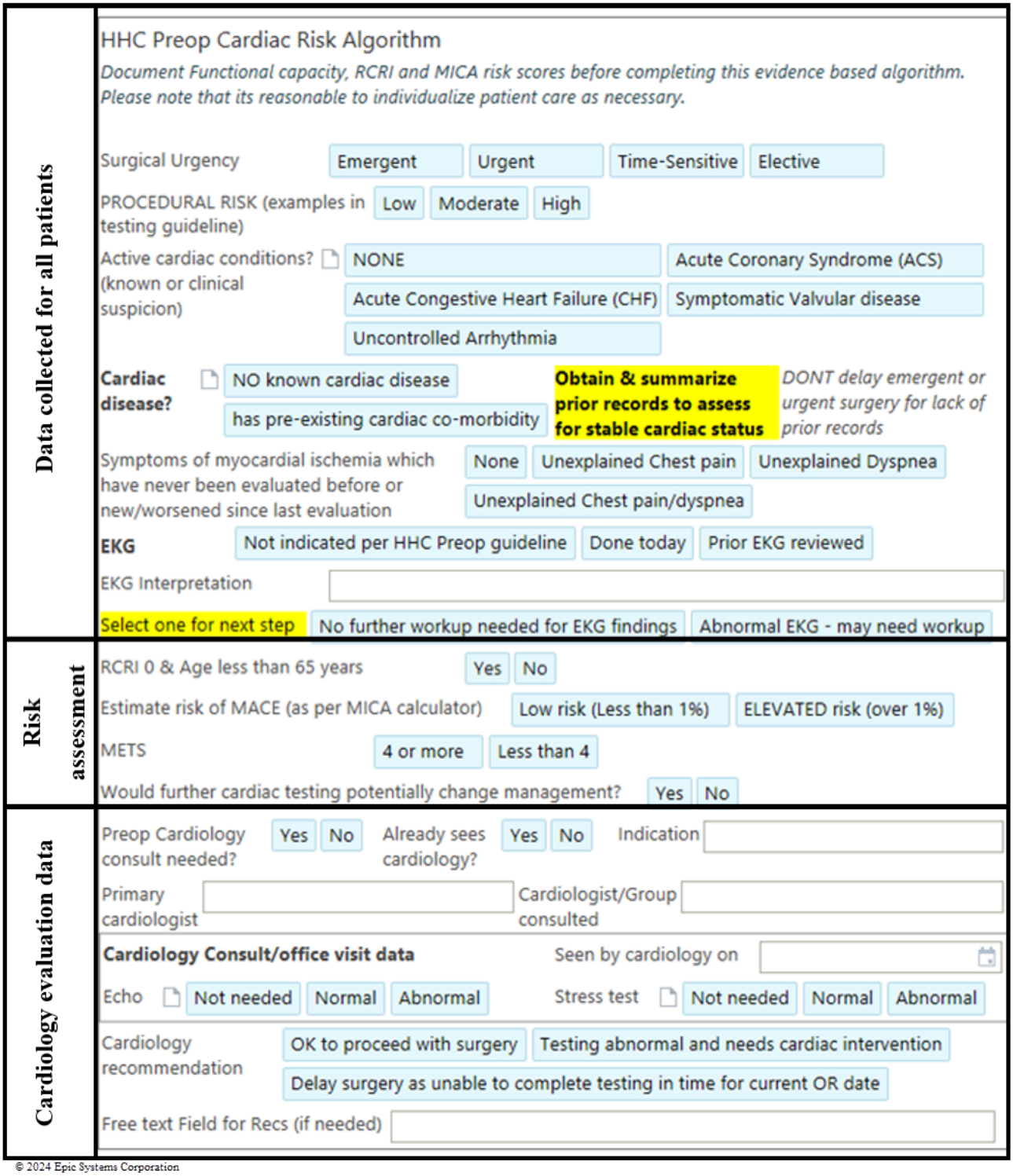
The ACC/AHA algorithm suggests using the RCRI, Gupta Myocardial Infarction or Cardiac Arrest (MICA), or the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) surgical risk calculators. The RCRI calculator helps select low-risk patients only if RCRI score is zero and the age is <65 years, as noted in the Canadian Cardiovascular Society 2017 guideline [23], based on the Vascular Events In Noncardiac Surgery Patients Cohort Evaluation (VISION) study [24], showing increased MACE risk in patients older than 65 years, even in the absence of other risk factors. Hence, *RCRI score of 0 and age <65 years* is our algorithm's initial step for MACE assessment [21]. The Gupta MICA and ACS NSQIP surgical risk calculators provide a more specific assessment [25] of the patient's risk since they combine surgical and patient risk factors. Consequently, their use is in better alignment with the ACC/AHA algorithm, categorizing MACE risk <1% as low risk.

EMR Form for Consistent Algorithm Completion

In busy clinical practice, consistently completing a multistep algorithm can be challenging. To address this issue, we

developed an EMR form (Epic) to assist clinicians in performing preoperative assessments (Figure 2). This takes less than 1 minute to complete; displays suggestions when preoperative cardiac testing may be unnecessary (an example is shown in Multimedia Appendix 1); and tracks the completed steps of the algorithm and the point at which it ends, referred to as the algorithm end point (AEP). The electronic form was implemented on July 1, 2022, as a standard part of outpatient preoperative evaluations performed at Hartford Healthcare preoperative evaluation centers. The form has 3 components: basic clinical information (completed for all patients), risk assessment (these steps use the preoperative risk tool results to guide the clinician through the steps of the algorithm), and cardiology consultation data (if performed). The AEPs are shown in Figure 1.

Figure 2. The Preop Cardiac Risk Algorithm smart form with all possible variables. HHC: Hartford Healthcare; MACE: major adverse cardiac event; MICA: Myocardial Infarction or Cardiac Arrest; RCRI: Revised Cardiac Risk Index.



Exposure, Variables, and Outcomes

The primary exposure was the completion of the EMR form. The 2 study cohorts were dichotomized based on the date of preoperative evaluation: from July 1, 2021, to June 30, 2022 (pre–EMR form cohort), and from July 1, 2022, to June 30, 2023 (post–EMR form cohort). The following variables were collected: demographic data (age, sex, race, ethnicity, date of the preoperative center visit, and date and type of surgery), comorbidities (atrial fibrillation, CAD, congestive heart failure, cerebrovascular accident, transient ischemic attack, chronic kidney disease, or diabetes mellitus), perioperative risk scores (functional capacity, see Multimedia Appendix 2; American Society of Anesthesiologists physical status; RCRI score; and Gupta MICA score), and surgical risk level (categorized as low, moderate, or high risk, with standard definitions used at our institution; see Multimedia Appendix 3).

The primary preoperative resource utilization outcomes were the completion of preoperative cardiology consultations and cardiac diagnostic testing (echocardiography, stress tests, or cardiac catheterization). These must have occurred within 60 days before the surgery to be considered preoperative (The 60-day timeframe was selected to account for instances where surgery is rescheduled due to delays in obtaining testing, although preoperative evaluations typically occur 30 days before surgery). The primary 30-day postoperative outcome collected were as follows: MACE (defined as a composite measure of acute MI, cardiac revascularization, acute congestive heart failure [CHF], or all-cause mortality), acute MI (as defined by the Standardized Endpoints in Perioperative Medicine initiative; see Multimedia Appendix 4) [26], cardiac revascularization (percutaneous coronary intervention or coronary artery bypass graft surgery), acute CHF (defined as clinical or radiographic evidence of volume overload treated with diuretics), and all-cause mortality. Secondary outcomes were intensive care unit (ICU) utilization, all-cause emergency department visits, and all-cause readmissions within 30 days after surgery. Mortality data were obtained from the Connecticut Department of Public Health [27]. All deaths in Connecticut are reported to the Department of Public Health; hence, we consider this a reliable measure. All other data and outcomes were extracted from EMR reporting.

The appropriateness of cardiology consultations was evaluated in the post–EMR form cohort. Possible cardiology consultation indications were defined as the presence of an active cardiac condition (AEP 1); known cardiac disease with unclear status (AEP 2); concern for myocardial ischemia (AEP 3); new ECG changes or abnormal ECG with no prior workup (AEP 4); and elevated MACE risk with poor functional capacity, for which further testing may change management (AEP 9). All other AEPs were considered “no clear indications” (Figure 1).

Statistical Analysis

The study population was depicted with frequencies and percentages for binary or categorical information and the median and IQR for the numerical data. Group comparisons for binary or categorical information were performed using the chi-square or Fisher exact test if the sample size was small for binary variables. If $P<.05$ was observed for the first test for categorical variables (>2 classes), a post hoc test was carried out with Bonferroni adjustment. The independent-samples Mann-Whitney *U* test was used for age comparison between the groups.

Propensity score matching was performed to identify comparable subpopulations. The predictive probability of assigning patients to the pre– versus post–EMR form cohort was generated using the demographics and patient characteristics listed in the *Methods* section. Propensity score–matched, pre– and post–EMR form cohorts were identified using a 1:1 case-control match on propensity score [28], and baseline characteristics were evaluated to determine whether the 2 subpopulations were comparable. A sensitivity analysis was conducted using the E-value approach to assess the magnitude of the unmeasured confounding bias [29,30]. The lowest E-value is 1, suggesting that no unmeasured confounding exists to explain the current association between the predictor and outcome. A higher E-value indicates a stronger unmeasured confounder association that may explain the current effect [29]. A subanalysis was performed in the post–EMR form cohort to evaluate the association of appropriate cardiology consultation indications versus not with completed cardiology consultations and 30-day MACE. Hypothesis testing was performed with a 2-sided α of .05, and all analyses were performed using IBM SPSS Statistics for Windows (version 29).

Results

Between July 1, 2021, and June 30, 2023, a total of 26,583 sequential outpatient preoperative evaluations met the inclusion criteria. Duplicate visits (n=442) and patients with missing preoperative risk scores (n=657) were excluded. The final study population comprised 25,484 patients: 13,365 before and 12,119 after the EMR form implementation. Unadjusted analysis showed that the 2 cohorts were significantly different in terms of several baseline characteristics. A higher proportion of patients in the preintervention group were male (5987/13,365, 44.8% vs 5279/12,119, 43.6%; $P=.047$), were White (10,613/13,365, 79.4% vs 9407/12,119, 77.6%; $P=.02$), had a higher baseline incidence of atrial fibrillation (1170/13,365, 8.8% vs 976/12,119, 8.1%; $P=.04$), and had CAD (1516/13,365, 11.3% vs 1246/12,119, 10.3%; $P=.006$) compared to the postintervention group. Additionally, the pre–EMR form group had a higher number of patients with poor functional capacity (2187/13,365, 16.4% vs 1770/12,119, 14.6%; $P<.001$) and patients who were undergoing high-risk surgery (3071/13,365, 23% vs 2527/12,119, 20.9%; $P<.001$). Propensity score matching resulted in 11,645 matched pairs (23,290/25,484, 91.4% of the full cohort) with similar pre– and post–EMR form cohorts in terms of demographics, comorbidities, perioperative risk tool results, and surgical risk levels, as there were no statistically significant differences (all $P>.05$; Table 1).

Table 1. Characteristics of unmatched and propensity score–matched cohorts by electronic medical record (EMR) form implementation status.

Variables	Unmatched cohort		*P* value[a]	Propensity score cohort		*P* value[a]
	Pre–EMR form (n=13,365)	Post–EMR form (n=12,119)		Pre–EMR form (n=11,645)	Post–EMR form (n=11,645)	
Demographics						
Age (years), median (IQR)	64 (53-72)	64 (53-72)	.39	64 (53-72)	64 (53-72)	.72
Sex, n (%)			*.047*[b]			.62
Male	5987 (44.8)	5279 (43.6)		5115 (43.9)	5077 (43.6)	
Female	7377 (55.2)	6839 (56.4)		6530 (56.1)	6568 (56.4)	
Race, n (%)			*.02*			.96
Asian	143 (1.1)	149 (1.2)		134 (1.2)	145 (1.2)	
African American	989 (7.4)	976 (8.1)		911 (7.8)	925 (7.9)	
White	10,613 (79.4)	9407 (77.6)		9245 (79.4)	9223 (79.2)	
American Indian	42 (0.3)	43 (0.4)		42 (0.4)	41 (0.4)	
Others	1578 (11.8)	1544 (12.7)		1313 (11.3)	1311 (11.3)	
Hispanic or Latino, n (%)	1540 (11.8)	1418 (12)	.50	1374 (11.8)	1391 (11.9)	.73
Comorbidities, n (%)						
Atrial fibrillation	1170 (8.8)	976 (8.1)	*.04*	930 (8)	949 (8.1)	.65
Coronary artery disease	1516 (11.3)	1246 (10.3)	*.006*	1203 (10.3)	1210 (10.4)	.88
Congestive heart failure	465 (3.5)	407 (3.4)	.60	384 (3.3)	388 (3.3)	.88
CVA[c] or TIA[d] history	576 (4.3)	489 (4.0)	.27	452 (3.9)	465 (4)	.66
Chronic kidney disease	1499 (11.2)	1215 (10)	*.002*	1173 (10.1)	1187 (10.2)	.76
Diabetes mellitus	2735 (20.5)	2445 (20.2)	.57	2334 (20)	2357 (20.2)	.71
Any cardiac comorbidites[e]	5133 (38.4)	4442 (36.7)	*.004*	4266 (36.6)	4298 (36.9)	.66
Perioperative risk tool results, n (%)						
Metabolic equivalents			*<.001*			.49
Less than 4	2187 (16.4)	1770 (14.6)		1687 (14.5)	1724 (14.8)	
4 or more	11,178 (83.6)	10349 (85.4)		9958 (85.5)	9921 (85.2)	
ASA[f] physical status classification			.79			.27
ASA 1 or 2	8675 (64.9)	7847 (64.7)		7618 (65.4)	7538 (64.7)	
ASA 3 or 4	4690 (35.1)	4272 (35.3)		4027 (34.6)	4107 (35.3)	
Revised Cardiac Risk Index			.38			.71
0 or 1	12,642 (94.6)	11,433 (94.3)		11,010 (94.5)	10,997 (94.4)	
2 or more	723 (5.4)	686 (5.7)		635 (5.5)	648 (5.6)	
Gupta MICA[g]			.93			.76
Low risk (less than 1%)	12,700 (95)	11,519 (95)		11,062 (95)	11,072 (95.1)	
Elevated risk (over 1%)	665 (5)	600 (5)		583 (5)	573 (4.9)	
Surgical risk level			*<.001*			.89
Low	2995 (22.4)	2838 (23.4)		2693 (23.1)	2720 (23.4)	
Moderate	7299 (54.6)	6754 (55.7)		6519 (56)	6486 (55.7)	
High	3071 (23)	2527 (20.9)		2433 (20.9)	2439 (20.9)	

[a]*P* value compares pre– vs post–EMR form implementation.

[b]Italics indicates a statistically significant difference (*P*<.05).

[c]CVA: cerebrovascular accident.

[d]TIA: transient ischemic attack.

[e]Any cardiac risk comorbidities is a composite measure of the presence of either of the following: atrial fibrillation, coronary artery disease, congestive heart failure, CVA or TIA, chronic kidney disease, or diabetes mellitus.

[f]ASA: American Society of Anesthesiologists.

[g]MICA: Myocardial Infarction and Cardiac Arrest.

In the matched cohort, cardiology consultation utilization was lower in the post–EMR form cohort (pre–EMR form: 2698/11,645, 23.2% vs post–EMR form: 2088/11,645, 17.9%; *P*<.001). Echocardiograms were completed less often in the post–EMR form cohort (pre–EMR form: 808/11,645, 6.9% vs post–EMR form: 591/11,645, 5.1%; *P*<.001). The rates of stress tests and cardiac catheterization were lower in the post–EMR form cohort; however, these differences were not statistically significant (*P*=.38 and .41, respectively). The E-values for preoperative cardiology consultation and testing ranged from 1.42 to 2.14, suggesting a low likelihood of unmeasured confounding (Table 2). Monthly trends in preoperative resource utilization are presented in Figure 3.

The 30-day postoperative outcomes were compared between the matched cohorts. No statistically significant differences were observed in the occurrence of acute MI, cardiac revascularization, acute CHF, ICU utilization, emergency department visits, readmission, or mortality (all *P*>.05; Table 3).

Preoperative cardiology consultation indications were dichotomized into “possible indications” and “no clear indications.” A higher number of patients in “possible indication” group experienced MACE as compared to those in “no clear indication” group (28/3749, 0.7% vs 18/7896, 0.2%; *P*<.001). However, the completion of preoperative cardiology consultation was not associated with a decrease in MACE risk in either group (Table 4).

The MACE count was analyzed for each AEP in the post–EMR form cohort. Active cardiac conditions were associated with 3.9% (2/51) MACE. All other AEPs had either zero or <1% MACE. Of note, *RCRI score=0 and age <65 years* was associated with 0.1% (2/3826) MACE, and MICA low risk was associated with 0.5% (16/3111) MACE. Statistical significance was noted (*P*<.001) but with low confidence, as the MACE rate was zero for several AEPs (Multimedia Appendix 5).

Table 2. Preoperative cardiology consultation and testing within 60 days before surgery in propensity score–matched, pre– and post–electronic medical record (EMR) form implementation cohorts.

Variables	Total (n=23,290)	EMR form implementation		*P* value[a]	E-value
		Pre–EMR form (n=11,645)	Post–EMR form (n=11,645)		
Preoperative cardiac consultation, n (%)	4786 (20.5)	2698 (23.2)	2088 (17.9)	*<.001*[b]	1.63
Preoperative echocardiogram, n (%)	1399 (6)	808 (6.9)	591 (5.1)	*<.001*	2.14
Preoperative stress test, n (%)	379 (1.6)	198 (1.7)	181 (1.6)	.38	1.42
Preoperative cardiac catheterization, n (%)	96 (0.4)	52 (0.4)	44 (0.4)	.41	1.65

[a]*P* value compares pre– vs post–EMR form implementation using the Pearson chi-square test.

[b]Italics indicates a statistically significant difference (*P*<.05).

Figure 3. Preoperative cardiology consultations and testing percentages over the 2-year study period. "0" represents July 1, 2022 (the date of the implementation of the electronic medical record form).

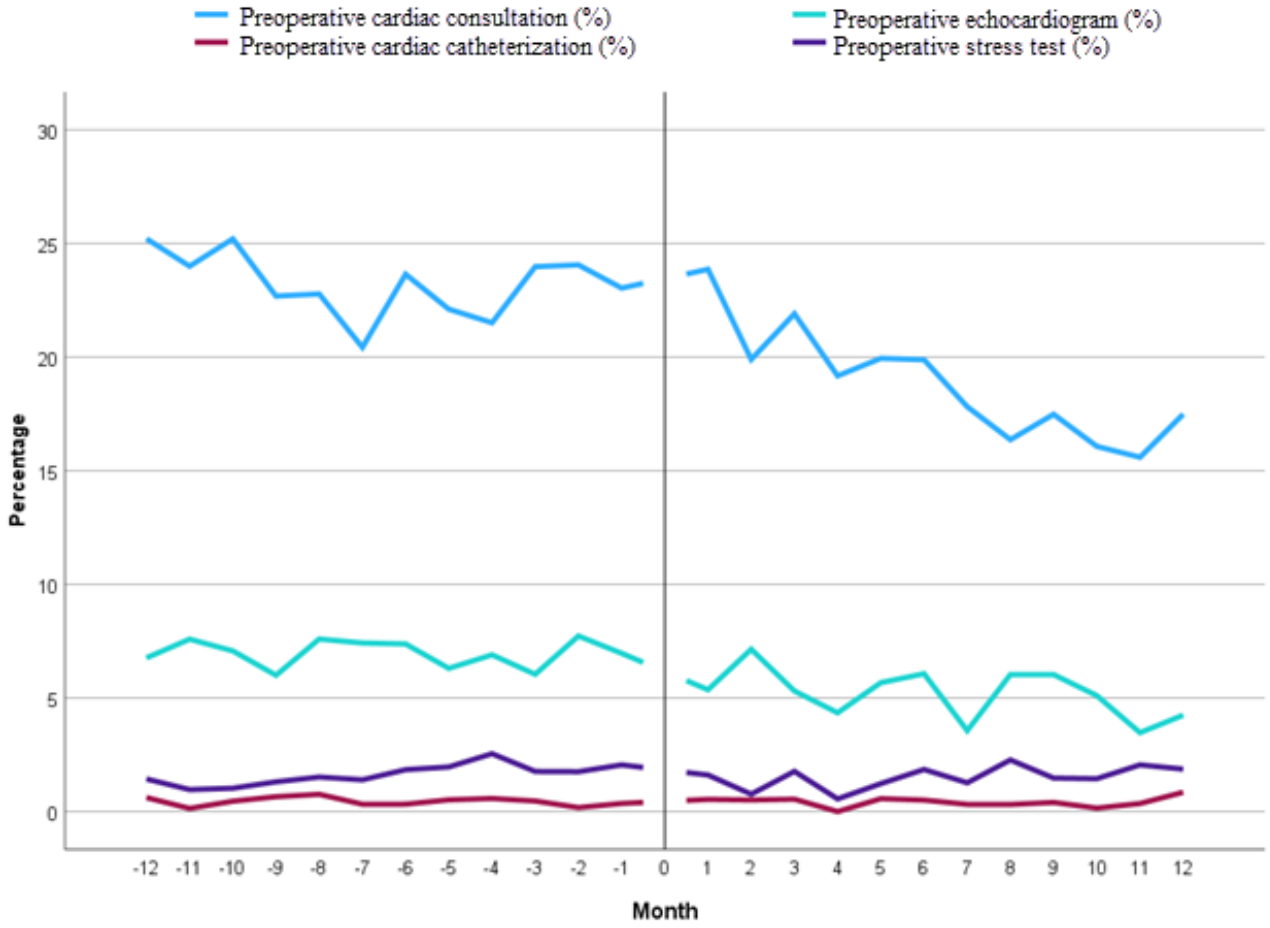


Table 3. 30-Day postoperative outcomes in propensity score–matched, pre– vs post–electronic medical record (EMR) form implementation cohorts.

Variables	Total (n=23,290)	EMR form implementation		*P* value[a]
		Pre–EMR form (n=11,645)	Post–EMR form (n=11,645)	
Acute MI[b], n (%)	28 (0.1)	14 (0.1)	14 (0.1)	>.99
Cardiac revascularization, n (%)	7 (0)	2 (0)	5 (0)	.45
Acute CHF[c], n (%)	46 (0.2)	22 (0.2)	24 (0.2)	.77
Mortality, n (%)	32 (0.1)	16 (0.1)	16 (0.1)	>.99
MACE[d,e], n (%)	91 (0.4)	45 (0.4)	46 (0.4)	.92
ICU[f] utilization, n (%)	352 (1.5)	169 (1.5)	183 (1.6)	.45
Emergency department visit, n (%)	1308 (5.6)	676 (5.8)	632 (5.4)	.21
Readmission, n (%)	1505 (6.5)	747 (6.4)	758 (6.5)	.77

[a]*P* value compares pre– vs post–EMR form implementation using the Pearson chi-square test.

[b]MI: myocardial infarction.

[c]CHF: congestive heart failure.

[d]MACE: major adverse cardiac events.

[e]30-Day MACE is a composite measure of acute MI, cardiac revascularization, acute CHF, or all-cause mortality occurring within 30 days of the index procedure. Some patients had more than 1 event; hence, the composite total does not equal a simple addition of the 4 individual components.

[f]ICU: intensive care unit.

Table 4. 30-Day major adverse cardiac events (MACE) in the post–electronic medical record (EMR) form cohort, stratified by consultation indication and preoperative cardiology consultations.

Algorithm end point composite	Preoperative cardiac consultation, n (%)		*P* value[a]
	No (n=9557)	Yes (n=2088)	
No clear consultation indications (n=7896)	7180 (90.9)	716 (9.1)	—[b]
MACE	14 (0.2)	4 (0.6)	.052
Possible indication for consultation (n=3749)	2377 (63.4)	1372 (36.6)	—
MACE	16 (0.7)	12 (0.9)	.49

[a]*P* value compares with vs without preoperative cardiac consultation using the Pearson chi-square test.

[b]Not applicable.

Discussion

Principal Findings

In this cohort study of patients presenting for outpatient preoperative evaluations before surgery, completion of a structured, EMR-based preoperative cardiac algorithm was associated with a decreased frequency of preoperative cardiology consultations and echocardiograms without an increase in postoperative MACE and other adverse outcomes.

Our study was observational; however, several factors support the validity of our results. We studied a considerable surgical population over 2 years and used propensity score matching to balance several potential confounders of perioperative risk between cohorts, including age, sex, race, comorbidities, perioperative risk tool results, and inherent surgery-specific risks. Both cohorts had a substantial burden of comorbidities (~36%), and a high proportion of patients underwent moderate- or high-risk surgical procedures (~76%). The postoperative outcomes were similar between the pre– and post–EMR form cohorts, with a cumulative low risk of postoperative MACE of 0.4% (pre–EMR form: 45/11,645, 0.4% vs post–EMR form: 46/11,645, 0.4%; *P*=.92), suggesting that our initiative decreased unnecessary consultations and testing while maintaining an excellent quality of care. Consistent with our results, several other studies also show that inappropriate cardiology consultations and stress tests do not lower the risk of postoperative MACE [5-8,10-12].

A subanalysis of “appropriate” versus “no clear indications” for cardiology consultation in the postintervention cohort showed that many consultations were still requested without a clear indication, highlighting an opportunity to improve the process. Interestingly, the MACE rates did not differ regardless of whether a cardiology consultation was completed, even when there was an appropriate reason for the consultation (Table 4). Similar findings have been reported in the context of preoperative cardiology consultations in patients hospitalized for hip fracture surgery [8]. We suggest that preoperative cardiology consultations should be requested only if required for clinical management and not just because a surgical procedure is planned.

Our study provides a template to guide clinicians in adhering to preoperative algorithms to reduce low-value care. Since the EMR form data can be used to determine the algorithm steps completed, future research could use a similar process to evaluate the ACC/AHA algorithm [4], which has not been prospectively validated despite its wide use.

Our study had several limitations. Due to the retrospective design, the possibility of selection bias and residual confounding remains despite balancing the measured baseline characteristics using propensity scoring. However, we also calculated the E-value, which suggests a low likelihood of unmeasured confounders. The high baseline rate of preoperative cardiology consultations in our study population (23%) may not reflect clinical practice elsewhere. However, our literature review shows a significant variation with rates of 8.7% in low-risk gastrointestinal endoscopic procedures [7], 51.8% in a population undergoing low-risk bariatric surgery [15], and from 6.9% to 87.5% in a study of patients undergoing vascular surgery across 29 hospitals [31]. Our study observed a lower rate of complications compared to NSQIP data [32]; however, NSQIP uses random sampling [33] as compared to all consecutive patients in our study, including approximately 25% of patients undergoing low-risk surgical procedures. Lastly, our data are from a single health care system and thus may not be generalizable to other care settings.

Conclusion

The use of a novel electronic form for the preoperative cardiac risk algorithm is associated with decreased cardiology consultations and testing without an increase in postoperative cardiac complications.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Example of algorithm ending when Myocardial Infarction or Cardiac Arrest (MICA) risk is <1%.
[PDF File (Adobe PDF File), 50 KB - periop_v7i1e63076_app1.pdf]

Multimedia Appendix 2
Functional capacity assessment.
[PDF File (Adobe PDF File), 58 KB - periop_v7i1e63076_app2.pdf]

Multimedia Appendix 3
Risk classification of surgical procedures.
[PDF File (Adobe PDF File), 26 KB - periop_v7i1e63076_app3.pdf]

Multimedia Appendix 4
Acute myocardial infarction determination methodology.
[PDF File (Adobe PDF File), 67 KB - periop_v7i1e63076_app4.pdf]

Multimedia Appendix 5
30-Day major adverse cardiac events (MACE) for each algorithm end point (AEP), post-EMR cohort only. EMR: electronic medical record.
[PDF File (Adobe PDF File), 111 KB - periop_v7i1e63076_app5.pdf]

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Abbreviations

ACC: American College of Cardiology
ACS: American College of Surgeons
AEP: algorithm end point
AHA: American Heart Association
CAD: coronary artery disease
CHF: congestive heart failure
ECG: electrocardiogram
EMR: electronic medical record
ICU: intensive care unit
MACE: major adverse cardiac events
MI: myocardial infarction
MICA: Myocardial Infarction or Cardiac Arrest
NSQIP: National Surgical Quality Improvement Program
RCRI: Revised Cardiac Risk Index
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
VISION: Vascular Events In Noncardiac Surgery Patients Cohort Evaluation

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Original Paper

Preoperative Anesthesia Virtual Video Consultations in a Preadmission Clinic: Quality Improvement Study

Yamini Subramani[1*], MD; Jill Querney[1*], MD; Priyanka Singh[1*], MD; Yifan Zhang[1*], MD; Lee-Anne Fochesato[1*], MSc; Nida Fatima[1*], MBBS; Natasha Wood[2*], MSc; Mahesh Nagappa[1*], MD

[1]Department of Anesthesia and Perioperative Medicine, London Health Sciences Centre, St. Joseph Health Care, Schulich School of Medicine and Dentistry, Western University, London, ON, Canada

[2]Department of Nursing, London Health Sciences Centre, Western University, London, ON, Canada

[*]all authors contributed equally

Corresponding Author:
Mahesh Nagappa, MD
Department of Anesthesia and Perioperative Medicine
London Health Sciences Centre, St. Joseph Health Care, Schulich School of Medicine and Dentistry
Western University
339 Windermere Road
London, ON, N6A 5A5
Canada
Phone: 1 5196858500 ext 34436
Email: Mahesh.Nagappa@lhsc.on.ca

Abstract

Background: The preadmission clinic (PAC) is crucial in perioperative care, offering evaluations, education, and patient optimization before surgical procedures. During the COVID-19 pandemic, the PAC adapted by implementing telephone visits due to a lack of infrastructure for video consultations. While the pandemic significantly increased the use of virtual care, including video appointments as an alternative to in-person consultations, our PAC had not used video consultations for preoperative assessments.

Objective: This study aimed to develop, implement, and integrate preoperative video consultations into the PAC workflow.

Methods: A prospective quality improvement project was undertaken using the Plan-Do-Study-Act (PDSA) methodology. The project focused on developing, implementing, and integrating virtual video consultations at London Health Sciences Centre and St. Joseph Health Care (London, Ontario, Canada) in the PAC. Data were systematically collected to monitor the number of patients undergoing video consultations, address patient flow concerns, and increase the percentage of video consultations. Communication between the PAC, surgeon offices, and patients was analyzed for continuous improvement. Technological challenges were addressed, and procedures were streamlined to facilitate video calls on appointment days.

Results: The PAC team, which includes professionals from medicine, anesthesia, nursing, pharmacy, occupational therapy, and physiotherapy, offers preoperative evaluation and education to surgical patients, conducting approximately 8000 consultations annually across 3 hospital locations. Following the initial PDSA cycles, the interventions consistently improved the video consultation utilization rate to 17%, indicating positive progress. With the onset of PDSA cycle 3, there was a notable surge to a 29% utilization rate in the early phase. This upward trend continued, culminating in a 38% utilization rate of virtual video consultations in the later stages of the cycle. This heightened level was consistently maintained throughout 2023, highlighting the sustained success of our interventions.

Conclusions: The quality improvement process significantly enhanced the institution's preoperative video consultation workflow. By understanding the complexities within the PAC, strategic interventions were made to integrate video consultations without compromising efficiency, morale, or safety. This project highlights the potential for transformative improvements in health care delivery through the thoughtful integration of virtual care technologies.

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KEYWORDS

preoperative evaluation; preadmission clinic; telemedicine; remote; virtual care; remote consultation; video consultation; telehealth; online health; digital health; perioperative medicine; preoperative; eMedicine; surgery; consultation; safety; assessment; virtual care; workflow; implementation; integration; hospital

Introduction

Amid the COVID-19 pandemic, many in-person consultations in the preadmission clinic (PAC) at our tertiary academic centers of London Health Sciences Centre (LHSC) and St. Joseph's Health Care in London, Ontario, Canada, shifted to telephone consultations. Telephone consultations were instrumental in reducing unnecessary hospital visits and in-person interactions, thereby mitigating the risk of COVID-19 transmission. While phone consultations facilitate thorough patient history–taking and chart review, they inherently lack the capability for a physical examination, which is essential in preanesthesia evaluations. Specifically, an airway assessment, which is critical for anesthesia planning, cannot be conducted effectively over the phone. By integrating a telemedicine model that includes audio and visual components in the PAC, several significant advantages emerge, including (1) an enhanced physical assessment, as the visual capability over video calls ensures a more accurate and comprehensive evaluation than phone consultations; (2) improved patient interaction given that nonverbal communication plays a crucial role in interpreting patient concerns and responses, which is lost in phone consultations; (3) increased diagnostic accuracy, since visual examinations can aid in identifying physical signs that might indicate underlying health issues, which may not be apparent through phone calls; and (4) enhanced patient engagement and education, as visual tools can be used to educate patients about their procedure and anesthesia plan, making it easier for them to understand complex information [1,2].

Telehealth involves electronic video communication between patients and health care providers to improve patient health remotely [3,4]. While telemedicine has long been used in rural areas without access to specialists, its prevalence increased widely during the COVID-19 pandemic [5,6]. When strategically deployed, virtual care enhances the quality and effectiveness of patient care and enables dynamic risk stratification through big data and machine learning [7].

LHSC and St. Joseph's Health Care collectively handle approximately 50,000 surgical cases annually across various subspecialties. The PAC is a designated setting for multidisciplinary preoperative assessments and optimization of operating room efficiency. Notably, not all patients receive preoperative assessments in the PAC, as limitations in time, office space, and human resources restrict the number of patients seen. The PAC team, comprising professionals from medicine, anesthesia, nursing, pharmacy, occupational therapy, and physiotherapy, offers preoperative evaluation and education to surgical patients, totaling approximately 8000 consultations annually across 3 hospital locations.

Over the years, the PAC has undergone alterations in office location, size, caseload, and staffing. The PAC team's preoperative consultations often include internal medicine and/or anesthesiology consultations and cover all surgical subspecialties. Some consultations are time-sensitive or involve mandatory in-person visits due to combined procedures such as x-rays, electrocardiograms, echocardiography, surgical team consultations, and blood work. Therefore, implementing video consultations requires meticulous planning and decision-making to ensure smooth clinic operations [8].

On a national and global level, virtual care video appointments have become a popular alternative to in-person and phone appointments during the COVID-19 pandemic [9,10]. Patients benefit from time and cost savings, increased communication with providers, improved access to care, and involvement of family members or caregivers [1,11]. Telemedicine has been shown to reduce missed appointments, wait times, and readmissions; enhance office efficiency with fewer front desk phone calls; and increase medication adherence. The ability of health care providers to make eye contact, assess body language, discuss sensitive topics, and conduct a limited physical examination over a virtual video platform can improve the patient-physician relationship [12]. This approach aligns with the trend toward digital health care solutions and ensures that patient safety and care quality are maintained at the highest standards.

During the COVID-19 pandemic, the PAC adapted by implementing telephone visits due to a lack of infrastructure for video consultations. While the pandemic significantly increased the use of virtual care, including video appointments as an alternative to in-person consultations, our PAC had not used video consultations for preoperative assessments. A preliminary assessment indicated room for development and improvement of video consultations before routine integration. The initiative focused on enhancing preoperative care without direct patient participation or using identifiable data, potentially offering valuable insights to the broader health care community. This project aimed to develop, implement, and integrate structured steps and process changes using Cisco DX80 Webex devices, measuring the impact on the number or percentage of video consultations through validated continuous quality improvement Plan-Do-Study-Act (PDSA) cycles.

Methods

Ethical Considerations

Ethics approval was not obligatory for this initiative; however, we secured Western Research Ethics Board approval (project ID: 118733) before commencing the quality improvement project, conducted between May 2021 and December 2023. No data or personal identifiers from participants were collected. Only information related to the process, such as patient selection, the percentage of successful video consultations, and issues encountered, were documented in a patient-independent manner.

Study Objective

The primary objective of this study was to develop, implement, and integrate virtual video consultations within the PAC, offering surgical patients the option of a virtual video consultation as an alternative to in-person visits in collaboration with our institution's multidisciplinary team.

Participants and Data Sources

Initial data collection covered 4 weeks, from the first to the last day of the month, following the implementation of the March 2021 video consultations. Following the initiation of changes, repeat data were gathered for up to 1 month to evaluate the sustainability and ongoing enhancement of the revised practice. Daily video consultations in each PAC were systematically documented throughout the project to facilitate continuous quality improvement.

In the project's initial phase, the data supported the suitability of virtual video consultations for patients undergoing bariatric surgery. Our workgroup decided to pilot the project with this population as these patients were already familiar with the Cisco Webex platform. Notably, the acceptance rate for preoperative video consultations among patients undergoing bariatric surgery reached 100% owing to their preexisting use in the bariatric program for preoperative education. This success among this group of patients catalyzed the broader expansion and implementation of video consultations across PACs.

Approximately 100 virtual video consultations were conducted to streamline preoperative video consultation steps. PAC nursing teams held small group meetings to assess the strengths and weaknesses of telephone and video consultations, documenting opinions shared during the discussions. However, no participant-specific information was collected. Stakeholders were briefed on the results of this preliminary assessment.

To identify areas for expansion and improvement, we sought feedback through an audit and a series of PDSA cycles to facilitate change and monitor progress. A key theme emerging from baseline information and staff feedback was enhancing communication between the PAC, patients, and surgeons' secretaries to offer the option of virtual video consultations postsurgical diagnosis. Additionally, patients' emails were collected to enable sending invitation links for video consultations. A unique shared mailbox was established for this purpose.

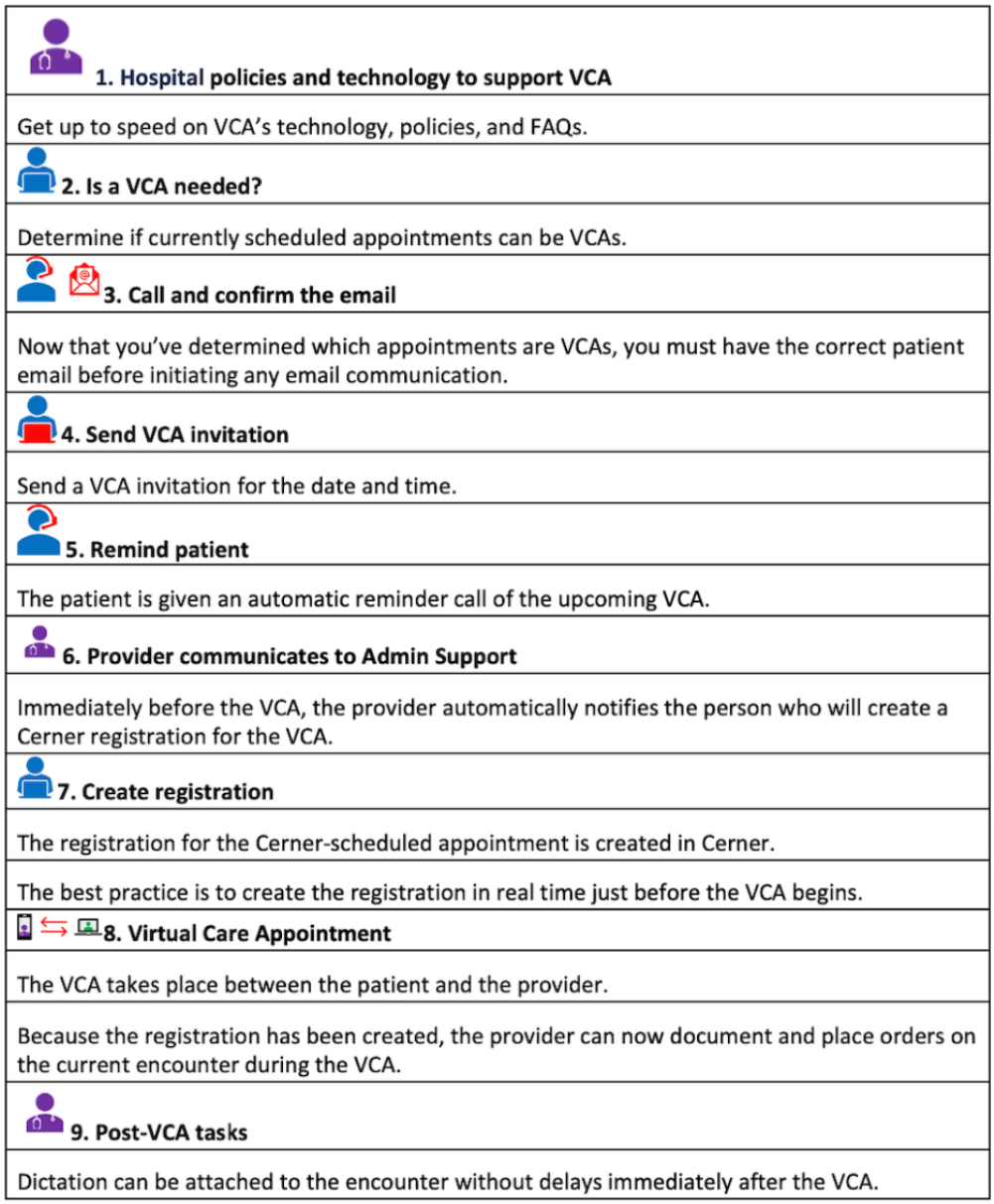
We enlisted champions from each stakeholder group to garner support for our rapid cycle changes. Leveraging data and stakeholder feedback, we used the PDSA methodology to shape our quality improvement strategy over 3 years, abstaining from formal statistical analyses for before-and-after comparisons.

Strategy

Overview

We carried out 3 PDSA test cycles over the 3 years. Figure 1 outlines the steps involved in establishing and implementing virtual care appointments.

Figure 1. Steps involved in a virtual care appointment (VCA).



First Intervention: PDSA Cycle 1

Approval from the hospital for the secure Cisco Webex platform prompted the use of cameras for the Cisco DX80 Webex devices in dedicated PAC rooms for video consultations. Collaborative group meetings involving PAC nurses, anesthesiologists, hospital IT staff, and the hospital virtual care team, were held to implement process improvements. Repeated data collection occurred several weeks later using the same preliminary assessment questionnaire after this intervention. The hospital invested in computer-integrated cameras (Cisco DX80 Webex devices) through the virtual care funding program, which were installed in PAC rooms. PAC nurses received 4 training sessions, and video virtual appointment scheduling and registration was established. A common email was created with a shared folder/inbox and regular updates were implemented to enhance virtual care.

Second Intervention: PDSA Cycle 2

A dedicated video consultation booking clerk was appointed at the PAC, aiming to boost the percentage of video consultations and simplify the process. Several weeks after the intervention, a reaudit was conducted on the various steps of video consultations.

Third Intervention: PDSA Cycle 3

The objective of this stage was to increase the percentage of video consultations further and streamline the process. This involved improving the booking process, routinely collecting patients' email IDs into electronic records, easing connection to the meeting link (web-based) for patients and health care providers, and integrating them into the patient's electronic record. With integration of Cisco Webex in Cerner health information technology software, the booking clerk clicks a single button to send the invitation to the patient for a video link. The automatic reminders are sent to the patient to prepare for the video consultation. Once the booking is confirmed, a

Webex video link appears in the patient's electronic chart under the "Virtual Care Appointments" section. The other health care providers can connect with the patient at the scheduled time by clicking the hyperlink "Click here to join." This prevents clerical errors in sending email invitations and avoids steps for sharing the PINs for the video connections. Training sessions were conducted for the PAC clinic team, including nurses, medicine and anesthesia staff, clinical fellows, and residents. This served as a brief introduction to the initiative and familiarization with the new video consultation process. Changes in provincial rules and regulations for video consultations increased physicians' acceptance rate, addressing persistent improvement opportunities identified in previous implementation cycles.

Results

Our initial workup indicated that our PAC did not have a video consultation platform before initiating this project. Following the first and second PDSA cycles, the interventions consistently enhanced this metric to a 17% utilization rate, signaling positive developments. As PDSA cycle 3 commenced, there was a substantial increase to a 29% utilization rate during the initial phase. This trend continued, reaching a 38% utilization rate of virtual video consultations in the later phase of the cycle. Utilization was persistently maintained at a high level throughout the entirety of 2023, highlighting the sustained success of our interventions (Figure 2).

Figure 3 provides a comprehensive flow diagram detailing the steps and communication pathways involved in patients' video consultations. Additionally, this figure highlights the specific changes introduced during the PDSA cycles within the project.

Figure 2. Run chart showing the percentage of patients who completed the video consultation. PDSA: Plan-Do-Study-Act.

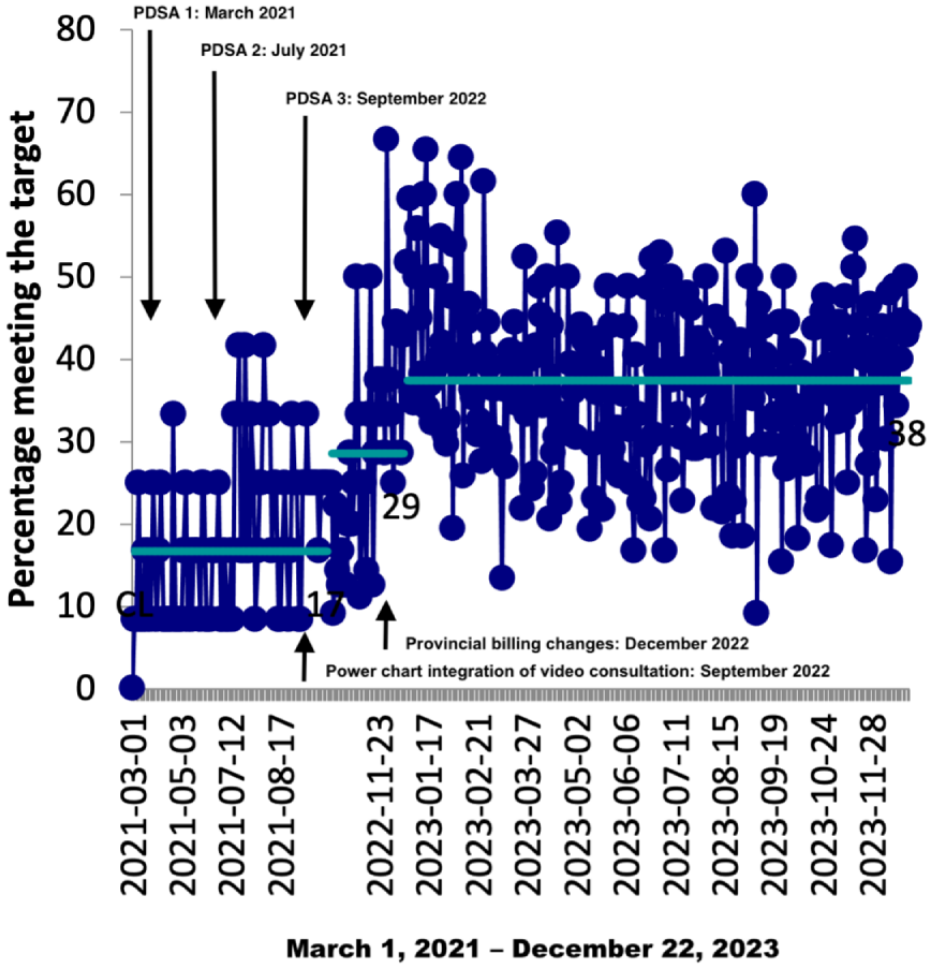
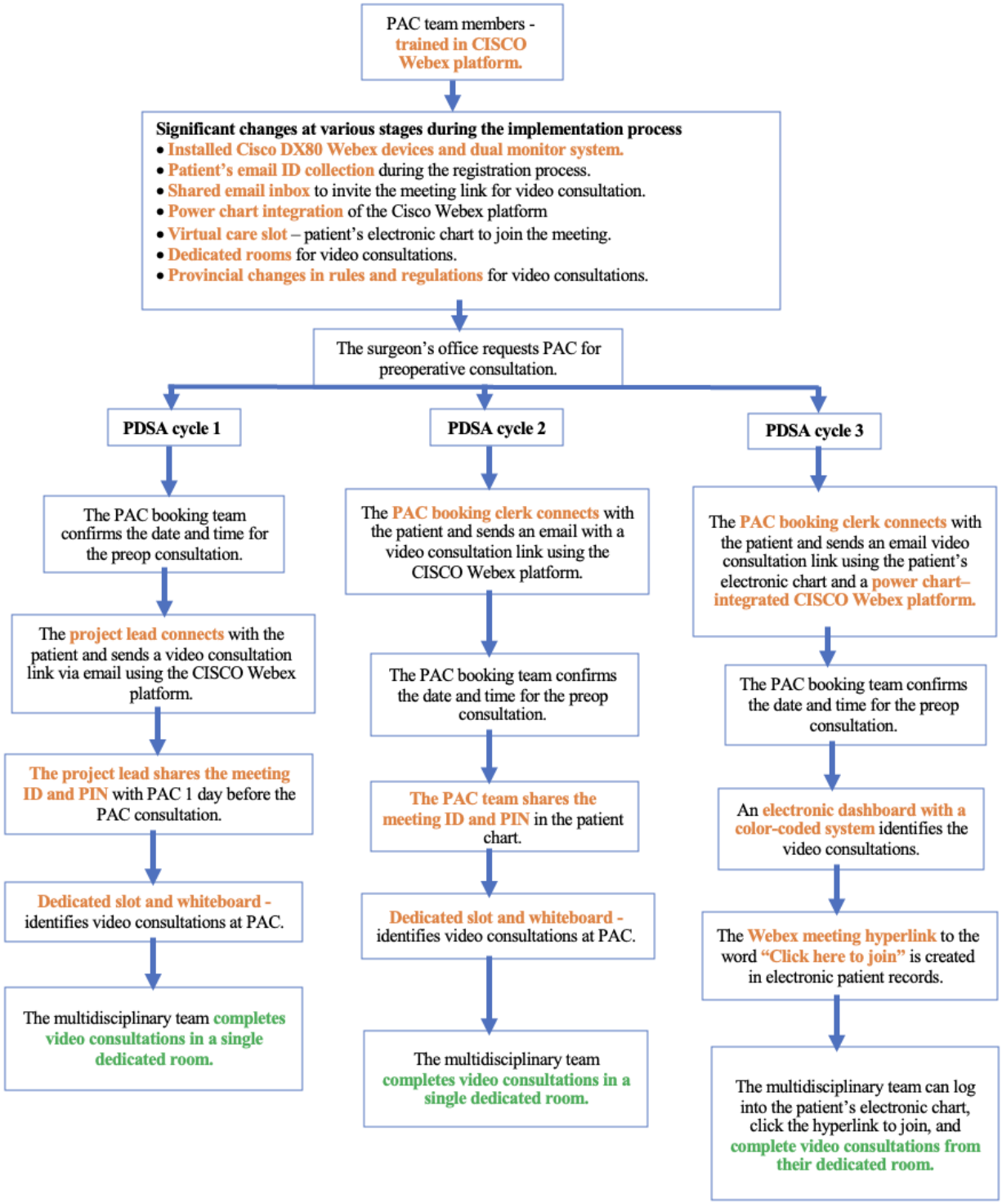


Figure 3. Comprehensive flow diagram detailing the steps and communication pathways involved in patients' video consultations during the PDSA cycles. PAC: preadmission clinic; PDSA: Plan-Do-Study-Act.



Discussion

Our results demonstrated that following the interventions through 3 successive PDSA cycles, the utilization rate of video consultations increased to 17% and then to 29% and finally to 38%, maintaining this high level throughout 2023, confirming the sustained success of our quality improvement project.

The PAC under study is part of the perioperative process in a Canadian academic tertiary health sciences center within a publicly funded health care system. While this quality improvement program may have limited applicability to other institutions due to variations in staffing, office space, equipment, technology, expertise, scheduling, communication, patient volumes, and guidelines, the lessons learned here may still offer valuable insights into enhancing patient satisfaction through the introduction of video consultations during the perioperative period of care.

The primary objective of this quality improvement project was to explore, develop, implement, and integrate virtual video consultations within the PAC, ensuring that patient-centered care remains timely, efficient, and safe while preserving the importance of in-person consultations. Key to the project's success was enhancing communication among PAC staff, patients, and surgeons' offices; incorporating OneChart Video Webex Appointments; and aligning with provincial changes in rules and regulations. The surgeon's office electronically communicated patients' preference for video consultation to the PAC staff while requesting a preoperative consultation. This decentralized the work for the PAC booking clerk. Significant clinical enhancements in video consultations were achieved throughout the preoperative journey without compromising patient care, as evidenced by the increase of video consultations in the PAC from 0% to 38%. The sustainability of said video consultations was confirmed over the past 12 months, indicating enduring improvement and garnering ongoing support and acceptance from the staff. The groundwork for video consultations positions them for long-term continuation, providing a compelling case for improved staffing, IT support, and physical space. This successful implementation of innovative methods empowers stakeholders to advocate for PAC maintenance and further enhancement.

One prominent observation in our project stems from significant variability observed across PACs and within the same clinic on different days, resulting in total virtual video consultation fluctuations. Various factors contribute to this variability, including the volume of patients referred to the PAC from surgical specialties, medical comorbidities of patients rendering them ineligible for video consultations, specific surgical procedures necessitating in-person consultations, variations in the booking staff at the PAC responsible for sending email invitations for video consultations, the number of surgeries conducted during specific slow-down periods such as holidays, and fluctuations in the overall caseload seen in the PAC. Notably, certain days, labeled as "Super Wednesdays" and "Super Tuesdays" in our PAC, presented twice as many patients, leading to increased video consultations on those days. To mitigate the inconsistency in scheduling personnel, a specialized team member was assigned to facilitate clear communication between patients and surgeons' offices, focusing on effectively organizing video consultations. Some of the other challenges that may be experienced while implementing the video consultations are (1) poor patient internet connectivity, (2) challenges in implementing hardware accessibility in all PAC rooms, and (3) lack of digital literacy among older patients and health care providers.

While the patient information system facilitated data collection, manual data collection remains necessary. Working closely with the hospital's IT and virtual care teams and their resources proved essential in enhancing patient flow throughout the project by seamlessly integrating video calls into electronic records. In the continuous improvement process, communication options such as "virtual care appointments using Webex" were incorporated into electronic record views, enhancing the efficiency of joining video consultations for the multidisciplinary team in the PAC.

Changes in the PAC were noted during the project, coinciding with broader system and provincial changes. Increased acceptance rates among patients, PAC staff, and physicians led to higher numbers of video consultations. Workforce issues were addressed by assigning additional clerks to assist with the booking process, although no increase in medical and nursing staff occurred. These modifications underscored the clinic's significance within larger hospitals and the provincial system, emphasizing the need for innovative methods to enhance patient flow, efficiency, and satisfaction without compromising safety.

A key limitation of our study is the lack of consideration for total virtual care usage, as we did not monitor the number of phone visits during the implementation period. Without this information, it is challenging to grasp the impact on overall virtual care usage fully. Another significant limitation is the provincial billing changes that disincentivized phone use, which occurred simultaneously with PDSA cycle 3. These changes substantially affected the PDSA cycle and should be considered when interpreting the results.

Virtual care video appointments offer a reasonable alternative to in-person and phone consultations, gaining prominence during the COVID-19 pandemic and likely continuing to play a significant role in health care [13]. Future directions involve advancing the newly implemented video consultation by integrating an app-based preoperative education system already used at our hospital. Additionally, expanding electronic communication options such as asynchronous preoperative messages will deliver real-time, crucial, and up-to-date information and education about the preoperative journey without interrupting a phone call. This approach aims to empower patients and enhance their compliance with preoperative instructions.

Conflicts of Interest

None declared.

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Abbreviations

LHSC: London Health Sciences Centre
PAC: preadmission clinic
PDSA: Plan-Do-Study-Act

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Original Paper

Comparing Anesthesia and Surgery Controlled Time for Primary Total Knee and Hip Arthroplasty Between an Academic Medical Center and a Community Hospital: Retrospective Cohort Study

Thy B Nguyen[1], BA; Nathaen Weitzel[2], MD; Craig Hogan[3], MD; Rachel M Kacmar[2], MD; Kayla M Williamson[4], MS; Jack Pattee[4], PhD; Vesna Jevtovic-Todorovic[2], MD, MBA, PhD; Colby G Simmons[2], DO, MBA; Adeel Ahmad Faruki[2,5], MD, MBA

[1]University of Colorado School of Medicine, Aurora, CO, United States

[2]Department of Anesthesiology, University of Colorado Anschutz Medical Campus, Aurora, CO, United States

[3]Department of Orthopaedic Surgery, University of Colorado Anschutz Medical Campus, Aurora, CO, United States

[4]Department of Biostatistics and Informatics, Colorado School of Public Health, University of Colorado - Anschutz Medical Campus, Aurora, CO, United States

[5]Department of Anesthesiology and Perioperative Medicine, MD Anderson Cancer Center, Houston, TX, United States

Corresponding Author:
Adeel Ahmad Faruki, MD, MBA
Department of Anesthesiology and Perioperative Medicine
MD Anderson Cancer Center
Faculty Center, Floor 13, FC13.2000
1400 Holcombe Blvd, Unit 409
Houston, TX
United States
Phone: 1 713 792 6911
Email: aafaruki@mdanderson.org

Abstract

Background: Osteoarthritis is a significant cause of disability, resulting in increased joint replacement surgeries and health care costs. Establishing benchmarks that more accurately predict surgical duration could help to decrease costs, maximize efficiency, and improve patient experience. We compared the anesthesia-controlled time (ACT) and surgery-controlled time (SCT) of primary total knee (TKA) and total hip arthroplasties (THA) between an academic medical center (AMC) and a community hospital (CH) for 2 orthopedic surgeons.

Objective: This study aims to validate and compare benchmarking times for ACT and SCT in a single patient population at both an AMC and a CH.

Methods: This retrospective 2-center observational cohort study was conducted at the University of Colorado Hospital (AMC) and UCHealth Broomfield Hospital (CH). Cases with current procedural terminology codes for THA and TKA between January 1, 2019, and December 31, 2020, were assessed. Cases with missing data were excluded. The primary outcomes were ACT and SCT. Primary outcomes were tested for association with covariates of interest. The primary covariate of interest was the location of the procedure (CH vs AMC); secondary covariates of interest included the American Society of Anesthesiologists (ASA) classification and anesthetic type. Linear regression models were used to assess the relationships.

Results: Two surgeons performed 1256 cases at the AMC and CH. A total of 10 THA cases and 12 TKA cases were excluded due to missing data. After controlling for surgeon, the ACT was greater at the AMC for THA by 3.77 minutes and for TKA by 3.58 minutes (P<.001). SCT was greater at the AMC for THA by 11.14 minutes and for TKA by 14.04 minutes (P<.001). ASA III/IV classification increased ACT for THA by 3.76 minutes (P<.001) and increased SCT for THA by 6.33 minutes after controlling for surgeon and location (P=.008). General anesthesia use was higher at the AMC for both THA (29.2% vs 7.3%) and TKA (23.8% vs 4.2%). No statistically significant association was observed between either ACT or SCT and anesthetic type (neuraxial or general) after adjusting for surgeon and location (all P>.05).

Conclusions: We observed lower ACT and SCT at the CH for both TKA and THA after controlling for the surgeon of record and ASA classification. These findings underscore the efficiency advantages of performing primary joint replacements at the

CH, showcasing an average reduction of 16 minutes in SCT and 4 minutes in ACT per case. Overall, establishing more accurate benchmarks to improve the prediction of surgical duration for THA and TKA in different perioperative environments can increase the reliability of surgical duration predictions and optimize scheduling. Future studies with study populations at multiple community hospitals and academic medical centers are needed before extrapolating these findings.

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KEYWORDS

anesthesia controlled time; surgery-controlled time; total joint arthroplasty; healthcare operations; efficiency; total joint replacement; knee; hip; arthroplasty; anesthesia; surgery; surgical duration; community hospital; surgeon; reliability; operating room; anesthesiology; orthopedics; perioperative; medicine

Introduction

Hip and knee osteoarthritis (OA) are pervasive causes of disability and pain globally, and the burden of OA is expected to increase due to population aging and the rising prevalence of obesity [1]. Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are 2 of the most common and well-accepted surgical interventions to improve quality of life for patients with end-stage joint deterioration [2]. Therefore, a considerable increase has been projected for TKA and THA cases (673% and 174%, respectively) from 2005 to 2030 in the United States [3]. The anticipated demand for joint replacements combined with the importance of the operating room (OR) in hospital revenue and margins emphasize the importance of identifying factors that decrease cost and maximize efficiency in the OR [4,5]. One such process is establishing benchmarks that are accurate predictors of surgical duration in order to improve hospital operations, optimize OR schedule modeling and management, reduce health care costs, and improve patient satisfaction and experience.

Prior efforts have been made to assess OR efficiency using mean anesthesia-controlled time (ACT) and surgery-controlled time (SCT) values [6]. ACT is defined as the sum of the time starting when the patient enters the OR until the patient is ready for surgical positioning, added to the time starting when the incision is closed and ending when the patient leaves the OR [7]. SCT is defined as the time from when the patient is ready for positioning to when the surgical sites are closed. Studies examining SCT for TKA found that computer-based estimations of historical performance were a better predictor of actual SCT than the estimates provided by surgeons, while assessments of heterogeneity of ACT and SCT based on current procedural terminology (CPT) codes have also highlighted the need for more granular prediction models [8,9]. Moreover, ACT and SCT at academic institutions may be increased because of teaching responsibilities for anesthesia and surgery trainees and may not reflect mean ACT and SCT for the same procedures in other settings. Furthermore, a spectrum of clinical and nonclinical factors could contribute to significant variation in case duration between surgeons [10,11]. This study will compare the ACT and SCT of THA and TKA between an academic medical center (AMC) and a community hospital (CH) for 2 orthopedic surgeons.

We hypothesize that after adjusting for surgeon, the ACT and SCT between an AMC and a CH will have a statistically significant difference for both knee and hip procedures.

Methods

Design

This retrospective 2-center observational cohort study was conducted at an AMC—the University of Colorado Hospital—and a university-affiliated CH—UCHealth Broomfield Hospital. Prior to the COVID-19 pandemic, hip and knee replacement surgeries were primarily performed at the AMC. However, during the pandemic, these surgeries were relocated to the CH from March 2020 through August 2020 and again in November 2020. Both orthopedic surgeons work with the same team of orthopedic surgery physician assistants and trainees (residents and fellows) at both locations. The University of Colorado Department of Anesthesiology staffs both the AMC and CH with an anesthesia care-team model consisting of supervising attending physicians and anesthesia providers such as certified registered nurse anesthetists, anesthesiology assistants (AAs), or anesthesiology resident physicians-in-training. The academic center also has student AAs who often work alongside certified registered nurse anesthetists and AAs. The CH does not have anesthesiology residents or student AAs present for any procedure. The practice for anesthesiology at both locations includes primarily performing neuraxial anesthesia on both TKA and THA if patients are appropriate and amenable to this type of anesthetic. For TKA, single-shot adductor canal blocks were performed in the preoperative area before the patient was brought to the OR. In the OR, the neuraxial anesthetic or a general anesthetic was performed.

Eligibility Criteria

Inclusion criteria for the study included participants undergoing primary THA and TKA. These cases were performed by 2 fellowship-trained adult reconstructive orthopedic joint surgeons who operated at both the AMC and CH. The time frame for cases performed was from January 1, 2019, to December 31, 2020. Inclusion criteria included being aged older than 18 years and the procedure type was determined based on CPT codes billed for the case. Only CPT codes 27130 (THA) and 27447 (TKA) were assessed in this study. Exclusion criteria included cases with missing data required to calculate ACT and SCT.

Data Collection and Storage

Demographic data and time stamps for each case were collected from electronic medical records and stored securely on the AMC's cloud drive.

ACT and SCT Calculation

The time stamps for *In Room Time*, *Ready for Positioning and Prep Time*, *Incision Time*, *Close Time*, and *Out of Room Time* were collected for each case. *Ready for Positioning* is defined as the point when the anesthesia team has completed their activities, signifying that the patient was prepared for surgical positioning. *Ready for Positioning and Prep Time* indicated that all presurgical anesthesia-related activities were completed and the surgical team could begin positioning the patient and performing surgical preparation. ACT was calculated based on *([Ready for Positioning and Prep Time] – [In Room Time]) + ([Out of Room Time] – [Close Time])*. SCT was calculated based on *([Close Time] – [Ready for Positioning and Prep Time])*.

Statistical Analysis

Descriptive statistics were performed using means and SDs for continuous variables, whereas counts and percentages were used for categorical variables. The primary outcome was the duration of ACT and SCT. Several independent variables were investigated for association with ACT and SCT in TKA and THA procedures. These independent variables include the location (AMC vs CH), surgeon identity (1 of 2 surgeons), American Society of Anesthesiologists (ASA) classification (dichotomized into ASA class I/II, representing mild to moderate systemic disease, vs ASA class III/IV, representing severe systemic disease), and anesthesia type (general vs neuraxial). Several multiple regressions were fit to assess relevant associations. The first tested association describes 4 multivariable linear regressions; for each outcome (ACT or SCT), separate multivariable linear regressions were fit for each surgery type (TKA or THA). Location and surgeon identity were included as independent variables. The second tested association is of 4 separate multivariable regressions; however, the set of modeled independent variables changes including location, surgeon identity, and ASA classification as covariates. The third tested association is of 4 separate multivariable regressions using location, surgeon identity, and anesthetic type as covariates.

Associations were considered statistically significant if the *P* values were less than α at the .05 level. R^2 and adjusted R^2 are reported for multivariable regressions. R^2 characterizes the proportion of variability in the outcome explained by model covariates, thus providing an estimate of the predictive utility of the model. Adjusted R^2 likewise estimates the model's predictive usefulness, with a correction for the number of independent variables. R (version 4.0.4; R Core Team) was used for all analyses.

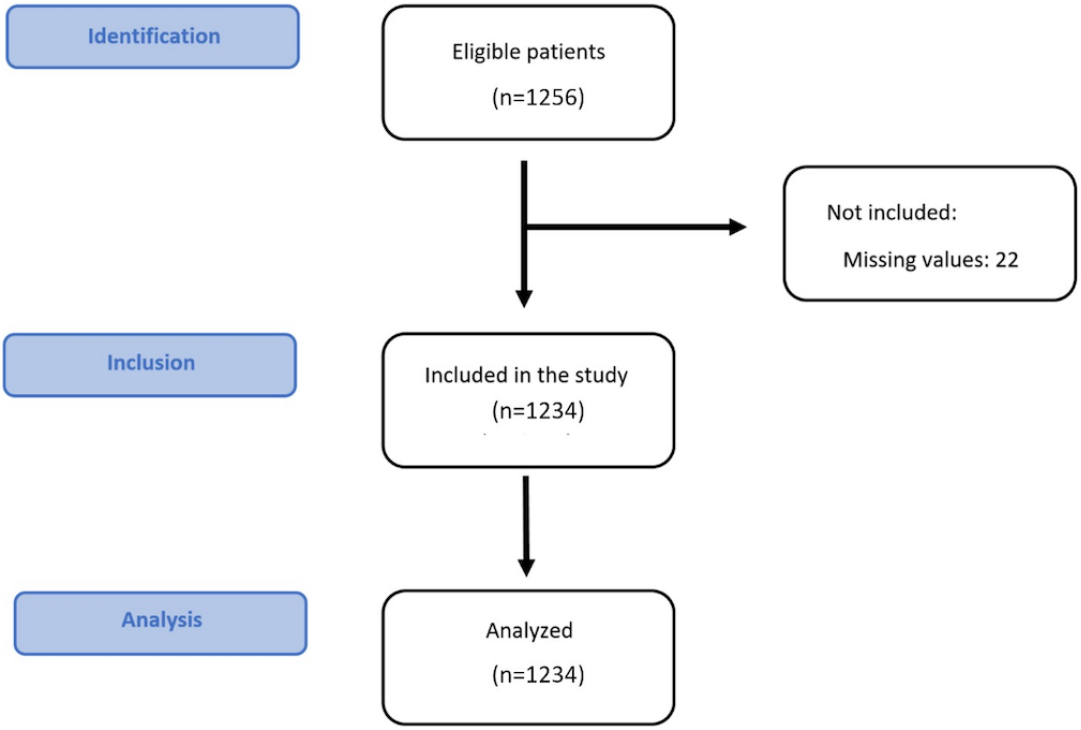
Ethical Considerations

The study was reviewed by the University of Colorado Denver Institutional Review Board and the study was approved for exempt status (Colorado Multiple Institutional Review Board Protocol 20-2987), as it involved an observational retrospective analysis of existing medical records and therefore did not require additional interventions or the collection of new data from human research participants. Given the exempt status of the study, the written consent requirements of participants were waived for this Colorado Multiple Institutional Review Board Protocol. The original informed consent for the primary data collection allowed for secondary analyses without additional consent, as approved by the institutional review board. This study was designed and executed following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cohort studies (Multimedia Appendix 1). To ensure the confidentiality and privacy of human research participant data, all patient records used in this study were deidentified prior to analysis. As there were no interactions or additional interventions with the participants, compensation was not applicable, and therefore not provided.

Results

There were 1256 observations for the 2 surgeons at the AMC and CH from January 1, 2019, to December 31, 2020. There were 619 THA observations and 637 TKA observations. A total of 10 (1.6%) out of 619 THA cases and 12 (1.8%) out of 637 TKA cases had missing values and were excluded from the analyses (Figure 1). One TKA case was missing ASA classifications and was omitted for regression controlling for this variable. The data set included 21 bilateral procedures at the AMC and 3 bilateral procedures at the CH. Secondary CPT codes were documented for a total of 5 cases including 1 cystoscopy, 1 tendon repair, 2 arteriograms, and 1 total hip liner exchange. All of the cases with secondary CPT codes documented occurred at the AMC.

Figure 1. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) flow diagram.



There were no significant differences between the AMC and CH patient groups for age, sex, and ASA classification (all *P*>.05; Table 1). For THA, 29.2% (130/445) of the cases performed at the AMC used general anesthesia, while 7.3% (12/164) of the cases performed at the CH used general anesthesia, despite no statistically significant difference in ASA classification. Results were similar for TKA, as 23.8% (109/457) of the cases performed at the AMC used general anesthesia, while 4.2% (7/168) of the cases performed at the CH used general anesthesia, despite no statistically significant difference in ASA classification. The observed average SCT was 14.61 minutes longer for surgeon 1 and 9.31 minutes longer for surgeon 2 at the AMC in comparison to the CH for THA procedures. Furthermore, the observed average SCT was 18.01 minutes longer for surgeon 1 and 14.37 minutes longer for surgeon 2 at the AMC in comparison to the CH for TKA procedures (Table 2). The values for ACT also consistently showed increased time at the AMC for both THA and TKA cases for both surgeons (Table 2).

Table 1. Patient demographics and case characteristics.

Characteristics	Cases performed at AMC[a] (n=902)	Cases performed at CH[b] (n=332)	*P* value[c]
Patient demographics			
Age (years), mean (SD)	63.1 (12.5)	63.5 (10.4)	.59
Female sex, n (%)	n (59.1)	n (60.5)	.70
Procedure and its ASA[d] classification, n (%)			
THA[e] (AMC: n=445; CH: n=164)			
I/II	266 (59.8)	110 (67.1)	.12
III/IV	179 (40.2)	54 (32.9)	N/A[f]
TKA[g] (AMC: n=457; CH: n=168)			
I/II	261 (57.1)	107 (63.7)	.17
III/IV	195 (42.7)	61 (36.3)	N/A
Procedure and its anesthetic classification, n (%)			
THA (AMC: n=445; CH: n=164)			
General anesthesia	130 (29.2)	12 (7.3)	<.001
Neuraxial anesthesia	315 (70.8)	152 (92.7)	N/A
TKA (AMC: n=457; CH: n=168)			
General anesthesia	109 (23.8)	7 (4.2)	<.001
Neuraxial anesthesia	348 (76.2)	161 (95.8)	N/A
Missing documentation	1 (0.2)	0 (0)	N/A

[a]AMC: academic medical center.

[b]CH: community hospital.

[c]*P* values correspond to a hypothesis test for the association of the study variable with surgical location. Continuous variables are assessed via 2-tailed *t* test and dichotomous variables via a difference of proportions test.

[d]ASA: American Society of Anesthesiologists.

[e]THA: total hip arthroplasty.

[f]N/A: not applicable.

[g]TKA: total knee arthroplasty.

Table 2. Comparison of the mean (SD) ACT[a] and SCT[b] for total hip arthroplasty and total knee arthroplasty between surgeons and between operative settings.

Outcome and variable	Total hip arthroplasty		Total knee arthroplasty	
	AMC[c], mean (SD)	CH[d], mean (SD)	AMC, mean (SD)	CH, mean (SD)
ACT (min)				
Surgeon 1	27.03 (12.97)	24.07 (8.01)	24.91 (11.34)	20.29 (7.72)
Surgeon 2	25.18 (10.69)	20.98 (8.67)	22.71 (8.34)	20.51 (7.42)
SCT (min)				
Surgeon 1	116.46 (27.03)	101.85 (25.08)	116.49 (25.56)	102.63(18.45)
Surgeon 2	111.96 (31.7)	102.61 (23.03)	106.26 (43.72)	91.99 (16.28)

[a]ACT: anesthesia-controlled time.

[b]SCT: surgery-controlled time.

[c]AMC: academic medical center.

[d]CH: community hospital.

Location and surgeon identity were included as independent variables. After adjusting for surgeon, the mean ACT for THA at the AMC was 3.77 (95% CI 1.83-5.71) minutes longer than for the CH and 3.58 (95% CI 1.91-5.26) minutes longer for TKA (both *P*<.001; Table 3). After adjusting for surgeon, the mean SCT at the AMC was 11.14 (95% CI 6.02-16.26) minutes

longer for THA and 14.04 (95% CI 8.43-19.65) minutes longer for TKA (both P<.001; Table 3) in comparison to the CH. Having a moderate to severe systemic disease (ASA class III/IV) increased the ACT by 3.76 (95% CI 2.00-5.51; P<.001) minutes and SCT by 6.33 (95% CI 1.66-10.99; P=.008) minutes for THA after adjusting for location and surgeon (Table 4). Having an ASA classification of III/IV did not significantly increase the ACT time for TKA (P=.08; Table 4). There was no significant difference noted for ACT and SCT between neuraxial anesthesia and general anesthesia (all P>.05; Table 5). For all models, the adjusted R^2 was less than 10%, indicating that a significant amount of the variation in ACT and SCT is not explained by hospital, surgeon, ASA classification, or anesthetic used.

Table 3. Multivariable linear regression coefficients for the association of ACT[a] and SCT[b] with hospital and surgeon.

Outcome and variable	Total hip arthroplasty[c]			Total knee arthroplasty[d]		
	Estimates (min)	95% CI	*P* value	Estimates (min)	95% CI	*P* value
ACT						
Coefficient intercept	23.47	21.42 to 25.51	<.001	21.03	19.47 to 22.58	<.001
AMC[e]	3.77	1.83 to 5.71	<.001	3.58	1.91 to 5.26	<.001
Surgeon 1	–2.18	–3.98 to –0.38	.02	–1.57	–3.06 to –0.08	.04
SCT						
Coefficient intercept	104.43	99.04 to 109.83	<.001	102.50	97.29 to 107.71	<.001
AMC	11.14	6.02 to 16.26	<.001	14.04	8.43 to 19.65	<.001
Surgeon 1	–3.12	–7.87 to 1.63	.20	–10.34	–15.33 to –5.35	<.001

[a]ACT: anesthesia-controlled time.

[b]SCT: surgery-controlled time.

[c]ACT for total hip arthroplasty had 609 observations and an R^2/R^2 adjusted value of 0.033/0.030; and total knee arthroplasty had 625 observations and an R^2/R^2 adjusted value of 0.033/0.029.

[d]SCT for total hip arthroplasty had 609 observations and an R^2/R^2 adjusted value of 0.032/0.029; and total knee arthroplasty had 625 observations and an R^2/R^2 adjusted value of 0.058/0.055.

[e]AMC: academic medical center.

Table 4. Multivariable linear regression coefficients for the association of ACT[a] and SCT[b] with ASA[c], hospital, and surgeon.

Outcome and variable	Total hip arthroplasty[d]			Total knee arthroplasty[e]		
	Estimates (min)	95% CI	*P* value	Estimates (min)	95% CI	*P* value
ACT						
Coefficient intercept	22.13	20.02 to 24.24	<.001	20.53	18.87 to 22.18	<.001
ASA class III/IV	3.76	2.00 to 5.51	<.001	1.33	–0.18 to 2.84	.08
AMC[f]	3.50	1.58 to 5.42	<.001	3.50	1.82 to 5.18	<.001
Surgeon 1	–2.03	–3.81 to –0.25	.03	–1.53	–3.02 to –0.03	.045
SCT						
Coefficient intercept	102.18	96.56 to 107.80	<.001	101.56	96.02 to 107.11	<.001
ASA class III/IV	6.33	1.66 to 10.99	.008	2.61	–2.46 to 7.67	.31
AMC	10.69	5.58 to 15.79	<.001	13.82	8.19 to 19.44	<.001
Surgeon 1	–2.87	–7.60 to 1.86	.23	–10.36	–15.36 to –5.36	<.001

[a]ACT: anesthesia-controlled time.

[b]SCT: surgery-controlled time.

[c]ASA: American Society of Anesthesiologists.

[d]ACT for total hip arthroplasty had 609 observations and an R^2/R^2 adjusted value of 0.061/0.056; and total knee arthroplasty had 624 observations and an R^2/R^2 adjusted value of 0.037/0.003.

[e]SCT for total hip arthroplasty had 609 observations and an R^2/R^2 adjusted value of 0.043/0.039; and total knee arthroplasty had 624 observations and an R^2/R^2 adjusted value of 0.060/0.055.

[f]AMC: academic medical center.

Table 5. Multivariable linear regression coefficients for the association of ACT[a] and SCT[b] with anesthesia, hospital, and surgeon.

Outcome and variable	Total hip arthroplasty[c]			Total knee arthroplasty[d]		
	Estimates (min)	95% CI	*P* value	Estimates (min)	95% CI	*P* value
ACT						
Coefficient intercept	22.15	19.29 to 25.01	<.001	19.35	16.91 to 21.78	<.001
Neuraxial anesthesia	1.38	–0.71 to 3.47	.92	1.75	–0.21 to 3.70	.11
AMC[e]	4.08	2.08 to 6.07	<.001	3.83	2.21 to 5.64	<.001
Surgeon 1	–2.12	–3.92 to –0.32	.02	–1.56	–3.05 to –0.07	.04
SCT						
Coefficient intercept	105.56	98.01 to 113.11	<.001	103.01	94.93 to 111.20	<.001
Neuraxial anesthesia	–1.18	–6.71 to 4.35	.68	–0.53	–7.09 to 6.03	.87
AMC	10.88	5.62 to 16.15	<.001	13.93	8.17 to 19.70	<.001
Surgeon 1	–3.17	–7.93 to 1.59	.19	–10.34	–15.34 to –5.35	<.001

[a]ACT: anesthesia-controlled time.

[b]SCT: surgery-controlled time.

[c]ACT for total hip arthroplasty had 609 observations and an R^2/R^2 adjusted value of 0.036/0.031; and total knee arthroplasty had 625 observations and an R^2/R^2 adjusted value of 0.037/0.033.

[d]SCT for total hip arthroplasty had 609 observations and an R^2/R^2 adjusted value of 0.033/0.028; and total knee arthroplasty had 625 observations and an R^2/R^2 adjusted value of 0.058/0.054.

[e]AMC: academic medical center.

Discussion

Overview

A paucity of literature exists for benchmarking operative times in different surgical settings, and our study therefore aimed to refine the prediction of surgical case duration for THA and TKA between an academic center and a CH for the same orthopedic surgeons. Our results showed that both SCT and ACT were statistically significantly longer for primary hip and knee arthroplasty at the AMC compared with the CH. The mean ACT was higher at the AMC by less than 4 minutes for THA and TKA for both surgeons, and this modest increase in ACT when trainees are present is consistent with previous reports [12,13]. Therefore, although the participation of anesthesia trainees at the AMC may elongate the ACT, these results are not clinically meaningful in the context of OR efficiency—decreases in ACT have not been shown to permit the scheduling of another OR case in a workday but may be relevant for patient satisfaction and experience [14]. In addition, it is crucial to recognize the value of surgical training and its pivotal role in preparing the next generation of health care providers. Finding a balance between providing trainees with comprehensive experiences while maintaining operational efficiency is crucial.

The mean SCT was greater at the academic center for THA and TKA procedures compared with the CH. Our results may have clinically significant implications, as a 16-minute difference in 4 cases can result in an extra hour of operating time per day, allowing for the scheduling of another short case during a normal surgical block or relieving staff in the OR earlier to reduce overtime call coverage pay. Previous studies have shown that operative time significantly increases when procedures are performed with surgical resident or surgical fellow participation [15,16]. The R^2 values in our results (<10%, Tables 3-5) also indicate the existence of other covariates that were not adjusted for in our multiple linear regression modeling such as the presence of scrub technician trainees, anesthesia trainees, surgical trainees, or traveling nursing staff who are not regularly participating in orthopedic surgery cases at the hospital. Therefore, understanding this cost of training surgical residents, nursing, and scrub technician staff can help OR managers find a balance between achieving scheduling and financial targets while exploring strategies to provide adequate educational opportunities.

Furthermore, it is pragmatic to identify other factors that could affect OR efficiency (ie, type of anesthesia, performing secondary procedures during the joint replacement, or performing bilateral procedures). In this study, we observed no significant differences between the ACT or SCT for both surgical centers when comparing general anesthesia versus neuraxial anesthesia. The current literature offers mixed results about the effect of anesthesia type on surgical time. A meta-analysis comparing the use of neuraxial anesthesia versus general anesthesia found no significant differences in surgical time for a variety of cases [17]. Contrastingly, a different study found that spinal anesthesia significantly reduced the duration of TKA surgery and resulted in decreases in the rates of thromboembolic events, infections, blood transfusion rates, and hospital length of stay [18]. Another study also found significant decreases in ACT when regional anesthesia was used [19-21]. Furthermore, there is limited literature exploring the implication of ASA classification on SCT or ACT. Previous studies propose a positive correlation between ASA classification and perioperative complication rates for patients undergoing fixation

of hip fractures [22]. ASA classification is also a significant predictor of length of stay cost for patients undergoing TKA [23,24]. In our study, there was an increase in ACT and SCT by approximately 4 and 6 minutes respectively for both surgical centers when the patient had moderate to severe systemic disease (ASA class III or IV) compared with patients with mild or no systemic disease (ASA class I or II). With over 3700 primary joint arthroplasty cases performed across the AMC's hospitals per year, a 10-minute decrease in ACT and SCT per case could result in 37,000 available OR minutes, equating to greater than 200 additional orthopedic cases (at an average of 155 minutes per case).

Limitations

Our study has several limitations. One of the limitations of this study is the sample size. Even with 1234 cases, there was still an underrepresentation of patients with ASA classifications of I and IV. While we feel this sample represents the patient population that normally receives primary joint replacement surgery, a larger cohort would allow for a more granular analysis of each ASA classification group. A second limitation is associated with the generalizability of this study. Our analysis was performed at 1 AMC and 1 CH. Only 2 surgeons were tracked for this study due to their unique movement between the 2 clinical sites. A larger cohort of surgeons with a similar multisite practice pattern could provide data that would be more generalizable. Furthermore, the perioperative environment and considerations at other academic and CHs could lead to different results. Therefore, the increased difference seen in SCT in our study could be a result of differences in OR culture between academic institutions and CHs, along with increased time required for on-the-job education for trainees in nursing and scrub technicians. Individual variation in the documentation of the surgery process could also be a confounding variable for the calculation of ACT and SCT. In addition, the decision-making process regarding the choice of surgical center involves a complex interplay of patient and surgical factors, some of which may not have been captured in our analysis. For example, the selection of cases for the academic center hospital may be influenced by factors such as case complexity, patient comorbidities, or surgeon preference. These potential biases could introduce uncontrolled variability into the ACT or SCT. Last, we define *Ready for Positioning* as the time point when anesthesia had completed its activities and when the patient was prepared for surgical positioning including completion of any additional intravenous lines or invasive monitoring if required for the procedure. However, other logistical factors may influence the actual commencement of surgery. Therefore, although our definition represents the point when anesthesia activities were complete, it does not imply the presence and readiness of the surgical team. Future directions of this study include assessing the effect of different levels of trainee and surgical nursing team involvement in our analysis, in addition to comparisons of cost and clinical outcomes between the 2 hospital locations and postoperative outcomes including complication rates.

Conclusions

OA is 1 of the 10 leading causes of disability in developed countries and the consequential growth in the volume of hip and knee replacement surgeries to manage end-stage OA will contribute to substantial and rising health expenditure [25,26]. Therefore, it is critical to optimize OR scheduling and management to maximize efficiency and decrease costs for both health systems and patients. As the demand for THA and TKA grows, it will be increasingly important to optimize OR efficiency for those surgeries. This study aims to validate and compare benchmarking times for ACT and SCT in a single patient population in both an academic center and a CH. One major application of these findings is that there is an efficiency benefit of performing primary joint replacements in our CH, as demonstrated by an average 16-minute reduction of SCT and a 4-minute reduction of ACT per case. This equates to a savings of approximately 80 minutes over the course of 4 surgical cases in a day, which could allow for the scheduling of another case. Such data can help to increase the reliability of surgical duration predictions and optimize scheduling to ultimately improve OR use, reduce cost, and improve patient experience.

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Data Availability

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

Authors' Contributions

TBN, KMW, NW, CH, RMK, VJT, CS, and AAF drafted the manuscript. TBN, KMW, NW, CH, RMK, VJT, CS, and AAF revised the manuscript. TBN, KMW, and AAF performed data analysis and interpretation. AAF was the principal investigator, performed the study design, and drafted the study protocol.

Conflicts of Interest

None declared.

Multimedia Appendix 1
STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist.
[PDF File (Adobe PDF File), 89 KB - periop_v7i1e45126_app1.pdf]

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Abbreviations

AA: anesthesiology assistant
ACT: anesthesia-controlled time
AMC: academic medical center
ASA: American Society of Anesthesiologists
CH: community hospital
CPT: current procedural terminology
OA: osteoarthritis
OR: operating room
SCT: surgery-controlled time
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
THA: total hip arthroplasty
TKA: total knee arthroplasty

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Original Paper

Factors Influencing Neuromuscular Blockade Reversal Choice in the United States Before and During the COVID-19 Pandemic: Retrospective Longitudinal Analysis

Vladimir Turzhitsky[1], PhD; Lori D Bash[1], PhD; Richard D Urman[2*], MBA, MD; Michael Kattan[3*], PhD; Ira Hofer[4*], MD

[1]Merck & Co, Inc, Rahway, NJ, United States

[2]College of Medicine, The Ohio State University, Columbus, OH, United States

[3]Cleveland Clinic, Cleveland, OH, United States

[4]Icahn School of Medicine at Mount Sinai, New York, NY, United States

[*]these authors contributed equally

Corresponding Author:
Vladimir Turzhitsky, PhD
Merck & Co, Inc
126 E Lincoln Avenue
Rahway, NJ, 07065
United States
Phone: 1 781206642
Email: vladimir.turzhitsky@merck.com

Abstract

Background: Neuromuscular blockade (NMB) agents are a critical component of balanced anesthesia. NMB reversal methods can include spontaneous reversal, sugammadex, or neostigmine and the choice of reversal strategy can depend on various factors. Unanticipated changes to clinical practice emerged due to the COVID-19 pandemic, and a better understanding of how NMB reversal trends were affected by the pandemic may help provide insight into how providers view the tradeoffs in the choice of NMB reversal agents.

Objective: We aim to analyze NMB reversal agent use patterns for US adult inpatient surgeries before and after the COVID-19 outbreak to determine whether pandemic-related practice changes affected use trends.

Methods: A retrospective longitudinal analysis of a large all-payer national electronic US health care database (PINC AI Healthcare Database) was conducted to identify the use patterns of NMB reversal during early, middle, and late COVID-19 (EC, MC, and LC, respectively) time periods. Factors associated with NMB reversal choices in inpatient surgeries were assessed before and after the COVID-19 pandemic reached the United States. Multivariate logistic regression assessed the impact of the pandemic on NMB reversal, accounting for patient, clinical, procedural, and site characteristics. A counterfactual framework was used to understand if patient characteristics affected how COVID-19–era patients would have been treated before the pandemic.

Results: More than 3.2 million inpatients experiencing over 3.6 million surgical procedures across 931 sites that met all inclusion criteria were identified between March 1, 2017, and December 31, 2021. NMB reversal trends showed a steady increase in reversal with sugammadex over time, with the trend from January 2018 onwards being linear with time (R^2>0.99). Multivariate analysis showed that the post–COVID-19 time periods had a small but statistically significant effect on the trend, as measured by the interaction terms of the COVID-19 time periods and the time trend in NMB reversal. A slight increase in the likelihood of sugammadex reversal was observed during EC relative to the pre–COVID-19 trend (odds ratio [OR] 1.008, 95% CI 1.003-1.014; *P*=.003), followed by negation of that increase during MC (OR 0.992, 95% CI 0.987-0.997; *P*<.001), and no significant interaction identified during LC (OR 1.001, 95% CI 0.996-1.005; *P*=.81). Conversely, active reversal (using either sugammadex or neostigmine) did not show a significant association relative to spontaneous reversal, or a change in trend, during EC or MC (*P*>.05), though a slight decrease in the active reversal trend was observed during LC (OR 0.987, 95% CI 0.983-0.992; *P*<.001).

Conclusions: We observed a steady increase in NMB active reversal overall, and specifically with sugammadex compared to neostigmine, during periods before and after the COVID-19 outbreak. Small, transitory alterations in the NMB reversal trends

were observed during the height of the COVID-19 pandemic, though these alterations were independent of the underlying NMB reversal time trends.

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KEYWORDS

neuromuscular blockade; sugammadex; neostigmine; rocuronium, vecuronium, intubation, counterfactual; anesthesia; anesthetic; anesthesiologist; anesthesiologists; surgery; surgical; preference; preferences; retrospective; utilization; pattern; patterns; trend; trends; national; healthcare database; healthcare databases; COVID-19; time-trend analysis; neuromuscular; longitudinal analysis; longitudinal; neuromuscular blockade agent; clinical; surgical procedure; inpatient; inpatient surgery; retrospective analysis; USA; United States

Introduction

The neuromuscular blockade (NMB) agents rocuronium and vecuronium help achieve and maintain optimal levels of muscle paralysis to facilitate intubation and ensure patient immobility during surgery. Following surgery, recovery of neuromuscular function is accomplished via spontaneous recovery or through active pharmacologic reversal. Spontaneous recovery can be slow and unpredictable and can result in residual neuromuscular blockade (rNMB) associated with deleterious consequences, including muscle weakness, impaired respiration, and postoperative pulmonary complications [1-4]. The incidence of rNMB with spontaneous recovery can vary widely but can reach and exceed 50% [3,5-7].

Additionally, 2 pharmacologic agents, neostigmine and sugammadex, are available for active NMB reversal. Neostigmine is an anticholinesterase inhibitor, while sugammadex acts as a selective direct inhibitor of rocuronium and vecuronium that allows for rapid, predictable reversal, even at deep NMB levels. Following the approval of sugammadex in the United States in 2016, the proportion of procedures using active reversal (vs spontaneous reversal) steadily increased through mid-2019. This coincided with the growing use of sugammadex for reversal, though significant practice variability has been observed based on patient, procedural, and environmental factors [8,9].

At the start of the COVID-19 pandemic, hospitals rapidly adopted measures to reduce viral exposure and reallocated resources to emergency departments and intensive care units. For surgical units, elective procedures were largely postponed while recommendations favored anesthetic techniques aimed to minimize aerosolization and contamination of the environment [10-12]. For example, the use of rapid sequence intubation became common if not standard, and interventions to shorten postanesthesia care unit (PACU) stay duration, such as using efficient NMB reversal strategies, would be advantageous in minimizing exposure risk. However, initial studies during the early COVID-19 period had not revealed the long-lasting impacts of the pandemic on surgical practice [13-15]. A more in-depth assessment may reveal subtle changes in anesthesia practice as hospitals transitioned from early to late COVID-19 eras.

This study analyzes NMB reversal agent use patterns for US adult inpatient surgeries before and after the COVID-19 outbreak to determine whether pandemic-related practice changes affected use trends established before COVID-19. By understanding these trends, we can gain insight into how NMB management has evolved following COVID-19 and potentially recognize patient, procedural, and institutional factors that were associated with these changes. We hypothesize that the use of sugammadex for NMB reversal would accelerate in the post–COVID-19 period given the evidence demonstrating decreased PACU time and, potentially, diminished exposure to COVID-19 [16,17]. We make use of methods such as counterfactual analysis, which have been introduced as an effective approach for inferring causality on retrospective health care data in general [18-25] and impacts of the COVID-19 pandemic in particular [26,27].

Methods

Data Source

A retrospective analysis was conducted on US adult inpatient surgical procedures occurring between March 1, 2017, and December 31, 2021, within the PINC AI Healthcare Database (PHD) [28]. The PHD is a large, US hospital–based, service-level, all-payer database that contains information on inpatient discharges, primarily from geographically diverse nonprofit, nongovernmental, and community and teaching hospitals and health systems from rural and urban areas. Hospitals or health care systems submit administrative, health care use, and financial data from patient encounters. Inpatient admissions include over 108 million visits with more than 8 million per year since 2012, representing approximately 25% of annual US inpatient admissions.

Ethical Considerations

This study used preexisting data with no identifiable information and therefore does not require institutional review board review per Federal Regulations for the Protection of Human Research Subjects (45CFR 46.102(e)) or patient consent [29]. All patient-related study data (eg, demographics, disease state, and information on billed services such as medications, laboratory tests, diagnostics, and therapeutic services) were accessed in compliance with the Health Insurance Portability and Accountability Act of 1996. This analysis was conducted and reported per the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

Patient Selection

US adults aged ≥18 years and who received rocuronium or vecuronium during an inpatient surgical procedure were

included. Exclusion criteria were a diagnosis of myasthenia gravis or renal failure, receiving pyridostigmine therapy, NMB reversal with both sugammadex and neostigmine, pregnancy (proxied by women undergoing obstetrical procedures), or those diagnosed with COVID-19 (for encounters occurring in 2020 and 2021). For any hospitalized patient undergoing multiple surgeries during a calendar 30-day period or a given inpatient stay, only the first surgery was included in the analysis.

For each eligible patient, information on demographics, clinical characteristics (eg, age, gender, anthropometrics, and comorbidities), insurance status, admission status (eg, elective, emergency, or trauma), site characteristics (eg, hospital size and geographic region), and anatomic location of the surgery were collected. Additionally, the type of NMB agent administered (rocuronium or vecuronium) as well as the reversal strategy (eg, neostigmine, sugammadex, or no active pharmacologic reversal) were recorded. The use of rocuronium or vecuronium for NMB was the inclusion criteria for this study due to the aim of quantifying NMB reversal practice changes in the sugammadex-eligible population. Data were categorized by time period in the following manner: baseline period (BP, March 1, 2017, to February 29, 2019); before COVID-19 era (BC, March 1, 2019, to February 29, 2020); early COVID-19 era (EC, April 1, 2020, to July 31, 2020); middle COVID-19 era (MC, August 1, 2020, to December 31, 2020); and late COVID-19 era (LC, January 1, 2021, to December 31, 2021). For this study, the post–COVID-19 period encompasses EC, MC, and LC time periods. The month of March 2020 was omitted in these analyses to account for a transition period and due to the unavailability of COVID-19 diagnostic information. The EC period was predominated by the early part of the breakout, the lack of information beyond testing for COVID-19 and implementing strict measures to reduce viral exposure within the hospital setting; the MC period correlated with the initial availability of COVID-19 vaccination for health care workers, thus (theoretically) lessening the impact of the pandemic on health care decisions; the LC period reflects when vaccines were available to the general public and restrictive infection control measures were loosened.

Statistical Analyses

NMB use was summarized by characteristics using descriptive statistics. Similarly, NMB reversal strategies (ie, sugammadex, neostigmine, or no reversal) were summarized by time period, patient, site, and procedural characteristics using descriptive statistics.

Multivariable Analysis

To identify factors related to NMB reversal choice during the COVID-19 and pre–COVID-19 eras, 2 multivariable logistic regression models were developed similarly to previous studies that modeled NMB reversal choices using PHD through June 2019 [8,9]. The first logistic regression models (model 1a and model 1b) aimed to test the effect of the COVID-19 time period on reversal choices by accounting for patient, hospital, and procedural characteristics. Encounters spanning both time periods (pre– and post–COVID-19) were included in these models to test for the overall effect of the COVID-19 era on reversal patterns, after accounting for all the covariates. Model 1a evaluated the effect of active (pharmacological) versus no (nonpharmacological) NMB reversal while model 1b evaluated sugammadex versus neostigmine reversal. Model 1 takes into account the trend in reversal over time by modeling the changes in NMB reversal as a linear trend over the period of January 1, 2018, to December 31, 2021. The effect of EC, MC, and LC eras are modeled as an interaction of the corresponding time period flag with the time-trend variable. For example, a positive interaction term coefficient between a post–COVID-19 period and time-trend variable in model 1b indicates a more rapidly increasing likelihood of sugammadex being used in the post–COVID-19 era as compared to the trend in the pre–COVID-19 time periods. The results from model 1 provide an overall estimate of the effect of the COVID-19 time period but do not provide insight into the effects for various population subtypes.

Counterfactual Analysis

Model 2 was constructed and used in a counterfactual analysis to address model 1's inability to evaluate changes in NMB reversal over time within patient subgroups. Models 2a (active vs no NMB reversal) and 2b (sugammadex vs neostigmine) were constructed using pre–COVID-19 data (January 1, 2018, to February 29, 2020) to be able to predict how a patient would have their NMB reversed (or not) based on their encounter characteristics. These models also include a continuous time variable that accounts for a linear trend to the log likelihood of the NMB reversal choice, to extrapolate this trend to the COVID-19 eras. Model accuracy, such as the receiver operating characteristic curve, is reported to help gauge the utility of these models for counterfactual analysis.

Counterfactual analysis was conducted to predict how COVID-19–era patients would have been reversed had they been treated during the pre–COVID-19 era based on their demographic, clinical, and institutional characteristics. The differences between the observed sugammadex reversal in the COVID-19 eras (actual) and the hypothetical or predicted reversal had each of those patients been seen pre–COVID-19 based on model 2 (counterfactual) were calculated. The differences in actual versus counterfactual reversal choices were then compared for each of the patient demographic, clinical, and institutional characteristics (eg, age group, comorbidities, surgery type, or hospital size). The counterfactual model was calibrated by adjusting the cutoff probability threshold to result in the same number of predicted classes (eg, sugammadex and neostigmine) as were actually observed in the combined COVID-19 eras. The odds ratios (OR) were also normalized such that the total patient-weighted OR was 1, which removed any residual time-dependent drift from the counterfactual model. The NMB reversal was compared between actual and counterfactual for each demographic, clinical, and institutional characteristic by obtaining ORs and CIs based on contingency tables for each covariate.

All statistical analyses were performed using SAS software (version 9.4; SAS Institute Inc).

Results

Study Population

Among the nearly 39.4 million inpatient encounters evaluated between March 1, 2017, and December 31, 2021, in the PHD, a total of 3,289,747 patients and 3,602,887 procedures involved the use of rocuronium or vecuronium and met all inclusion and exclusion criteria. The number of encounters included 1,644,370 during BP, 820,078 during BC, and 1,138,439 during the 3 post–COVID-19 periods (Table S1 in Multimedia Appendix 1). Patient demographics and characteristics were generally similar across the time periods despite attaining statistical significance driven by the large sample size (Table 1). Mean age (SD) ranged from 58.5 (16.76) years in the EC period to 59.0 (16.35) years during BC. A slightly higher percentage of patients were women (range 108,541/209,451, 51.8% in EC to 890,910/1,644,370, 54.2% in BP), and most patients identified as White (range 477,774/628,197, 76.1% in LC to 1,287,545/1,644,370, 78.3% in BP) throughout the study.

The percentage of patients with at least 1 comorbidity trended higher during this study's period, increasing from 80.4% (1,321,911/1,644,370) during BP to 85.2% (535,076/628,197) by LC. The largest increases in comorbidity rates (>2% increase from BP to LC) were observed in cardiac arrhythmias, fluid or electrolyte disorders, and obesity or overweight conditions. The percentage of admissions due to elective procedures decreased between BC and EC (from 451,190/820,078, 55%, to 98,637/209,451, 47.1%) and there was a corresponding rise in the percentage of emergency or urgent admissions during these time periods (from 348,840/820,078, 42.5%, during BC to 104,123/209,451, 49.7% during EC).

Among the 3.6 million patient encounters included in this analysis, a majority involved teaching hospitals (range 885,068/1,644,370, 53.8%, in BP to 358,262/628,197, 57% in LC) and approximately 90% occurred in urban institutions (range 188,028/209,451, 89.8% in EC to 571,412/828,197, 91% in LC, Table S2 in Multimedia Appendix 1). The largest proportion of encounters (1,516,497/3,602,887, 42.1%) involved hospitals with 500 or more beds, while institutions with fewer than 200 beds accounted for approximately 15.5% (559,884/3,602,887) of encounters. Nearly half (1,736,173/3,602,887, 48.2%) of the encounters involved institutions in the South, 23% (828,275/3,602,887) from the Midwest, 14.6% (525,401/3,602,887) from the West, and the remaining 14.2% (513,038/3,602,887) from the Northeast.

Table 1. Patient characteristics.

	BP[a] (n=1,644,370)	BC[b] (n=820,078)	EC[c] (n=209,451)	MC[d] (n=300,791)	LC[e] (n=628,197)
Age[f] (years)					
Mean (SD)	58.6 (16.31)	59.0 (16.35)	58.5 (16.76)	58.6 (16.57)	58.8 (16.85)
Minimum, Maximum	18, 89	18, 89	18, 89	18, 89	18, 89
Median (IQR)	61 (48-70)	61 (48-71)	61 (47-71)	61 (48-71)	61 (47-71)
Age category[f] (years), n (%)					
18-30	112,133 (6.8)	54,225 (6.6)	15,683 (7.5)	21,128 (7)	45,338 (7.2)
31-40	147,963 (9)	73,238 (8.9)	19,839 (9.5)	28,467 (9.5)	61,031 (9.7)
41-50	217,072 (13.2)	105,670 (12.9)	27,043 (12.9)	39,092 (13)	80,868 (12.9)
51-60	340,761 (20.7)	162,767 (19.8)	40,873 (19.5)	58,449 (19.4)	117,202 (18.7)
61-70	416,743 (25.3)	207,379 (25.3)	51,304 (24.5)	74,935 (24.9)	153,046 (24.4)
71-80	288,194 (17.5)	153,377 (18.7)	38,255 (18.3)	55,684 (18.5)	118,827 (18.9)
>80	121,504 (7.4)	63,422 (7.7)	16,454 (7.9)	23,036 (7.7)	51,885 (8.3)
Sex female[f], n (%)	890,910 (54.2)	440,317 (53.7)	108,541 (51.8)	159,893 (53.2)	333,931 (53.2)
Race[f], n (%)					
Asian	25,205 (1.5)	13,155 (1.6)	3811 (1.8)	5502 (1.8)	13,947 (2.2)
Black	172,317 (10.5)	86,619 (10.6)	22,820 (10.9)	34,421 (11.4)	74,791 (11.9)
White	1,287,545 (78.3)	634,056 (77.3)	163,018 (77.8)	232,506 (77.3)	477,774 (76.1)
Hispanic ethnicity[f], n (%)	141,183 (8.6)	73,837 (9)	18,426 (8.8)	27,853 (9.3)	68,885 (11)
Insurance[f,g], n (%)					
Commercial	665,441 (40.5)	317,972 (38.8)	79,909 (38.2)	115,013 (38.2)	231,540 (36.9)
Government	749,389 (45.6)	383,018 (46.7)	96,045 (45.9)	138,052 (45.9)	289,800 (46.1)
Low-income	212,173 (12.9)	108,509 (13.2)	30,647 (14.6)	43,737 (14.5)	97,210 (15.5)
Comorbidites ≥1[f], n (%)	1,321,911 (80.4)	676,491 (82.5)	175,939 (84)	252,355 (83.9)	535,076 (85.2)
Comorbidities[h], n (%)					
Cardiac arrhythmias[f]	278,499 (16.9)	148,374 (18.1)	39,801 (19)	56,421 (18.8)	124,456 (19.8)
Chronic pulmonary disease[f]	303,871 (18.5)	157,402 (19.2)	40,808 (19.5)	58,895 (19.6)	123,865 (19.7)
Congestive heart failure[f]	114,852 (7)	64,837 (7.9)	18,118 (8.7)	25,313 (8.4)	57,681 (9.2)
Depression[f]	216,235 (13.2)	115,225 (14.1)	29,414 (14)	44,250 (14.7)	91,828 (14.6)
Diabetes (complicated)[f]	131,594 (8)	74,660 (9.1)	21,230 (10.1)	29,410 (9.8)	65,836 (10.5)
Diabetes (uncomplicated)[f]	223,314 (13.6)	108,624 (13.2)	26,276 (12.5)	38,592 (12.8)	80,350 (12.8)
Fluid or electrolyte disorders[f]	325,819 (19.8)	174,481 (21.3)	52,486 (25.1)	70,018 (23.3)	152,579 (24.3)
Hypothyroidism[f]	200,129 (12.2)	103,612 (12.6)	25,704 (12.3)	37,537 (12.5)	78,411 (12.5)
Obesity or overweight[f]	394,421 (24)	210,688 (25.7)	54,282 (25.9)	82,251 (27.3)	173,667 (27.6)
Other neurological disorders[f]	117,534 (7.1)	63,352 (7.7)	18,501 (8.8)	25,511 (8.5)	55,371 (8.8)
Peripheral vascular disorders[f]	125,078 (7.6)	67,508 (8.2)	18,339 (8.8)	26,595 (8.8)	58,697 (9.3)
Sleep apnea[f]	147,851 (9)	81,705 (10)	19,498 (9.3)	30,259 (10.1)	65,179 (10.4)
Solid tumor without metastasis[f]	194,163 (11.8)	98,675 (12)	27,302 (13)	36,644 (12.2)	81,145 (12.9)
COVID-19 not present[f,i], n (%)	1,644,142 (100)	819,852 (100)	209,200 (99.9)	299,296 (99.5)	601,470 (95.7)

	BP[a] (n=1,644,370)	BC[b] (n=820,078)	EC[c] (n=209,451)	MC[d] (n=300,791)	LC[e] (n=628,197)
Admission type[f], n (%)					
Elective	932,608 (56.7)	451,190 (55)	98,637 (47.1)	156,479 (52)	307,003 (48.9)
Emergency or urgent	674,323 (41)	348,840 (42.5)	104,123 (49.7)	136,181 (45.3)	302,208 (48.1)
Trauma center	37,439 (2.3)	20,048 (2.4)	6691 (3.2)	8131 (2.7)	18,986 (3)

[a]BP: baseline period.

[b]BC: before COVID-19 era.

[c]EC: early COVID-19 era.

[d]MC: middle COVID-19 era.

[e]LC: late COVID-19 era.

[f]Statistically significant at the $P<.05$ level.

[g]Commercial category includes managed care, workers' compensation, and self-pay. The government category includes Medicare and other government insurance types. The low-income category includes Medicaid, charity, and indigent.

[h]Most frequently observed Elixhauser comorbidities shown.

[i]No history of COVID-19 within 2 months of encounter.

NMB Use Patterns

During the total study period, the vast majority of encounters involved rocuronium use with or without succinylcholine (3,229,651 encounters, 89.6%; Table S3 in Multimedia Appendix 1). A general trend of increasing rates of rocuronium only (with or without succinylcholine) was observed during this study's period, increasing from 87.1% during BP to 93% during LC. The use of succinylcholine with rocuronium or vecuronium was used in 5.3% of patient encounters overall. This rate increased from 4.8% during BP to a peak of 6.9% during the EC period, before falling to 5.4% during LC.

NMB Reversal Agent Use Patterns

Before the COVID-19 outbreak, the use of sugammadex for NMB reversal steadily increased following its approval in 2016, with approximately 1 in 4 encounters using this agent for reversal during BP (Table 2; Figure 1) [9]. This trend continued through the post–COVID-19 eras, reaching 51.1% (321,268/628,197) of encounters during LC. Consequently, reversal with neostigmine decreased from 47.1% from BP to 26.6% during LC. Overall, the rate of active NMB reversal with either sugammadex or neostigmine gradually increased over time. Spontaneous reversal steadily decreased from 27.5% (451,838/1,644,370) of encounters during BP to 22.3% (139,854/628,197) during LC. The trends in sugammadex, neostigmine, and active reversal were approximately linear from 2018 until the end of this study's period (R^2>0.99, for sugammadex and neostigmine, R^2=0.95 for active reversal).

When comparing patient characteristics by reversal type (ie, spontaneous, sugammadex, or neostigmine), the distribution by age, race, and ethnicity was similar, though statistical significance was achieved due to the large sample size (Tables S4-S6 in Multimedia Appendix 1). Encounters involving reversal with neostigmine or sugammadex tended to involve younger patients (mean 57.4, SD 17.15 to 58.2, SD 16.56 years for neostigmine and 58.7, SD 16.83 to 59.2, SD 16.43 years for sugammadex) compared to spontaneous reversal (mean 59.2, SD 16.28 to 59.9, SD 15.83 years). Women comprised a higher proportion of those reversed with sugammadex (49,534/92,709, 53.4%, to 231,852/417,266, 55.6%) or neostigmine (36,704/67,321, 54.5%, to 441,284/775,266, 56.9%) and a lower proportion of spontaneous reversal (22,303/49,421, 45.1%, to 217,774/451,838, 48.2%) compared to men. Those who underwent spontaneous reversal were more likely to have ≥1 comorbidity (379,136/451,838, 83.9% to 124,367/139,854, 88.9%) compared to those reversed with sugammadex (334,071/417,266, 80.1%, to 273,297/321,268, 85.1%) or neostigmine (608,704/775,266, 78.5%, to 137,412/167,075, 82.2%).

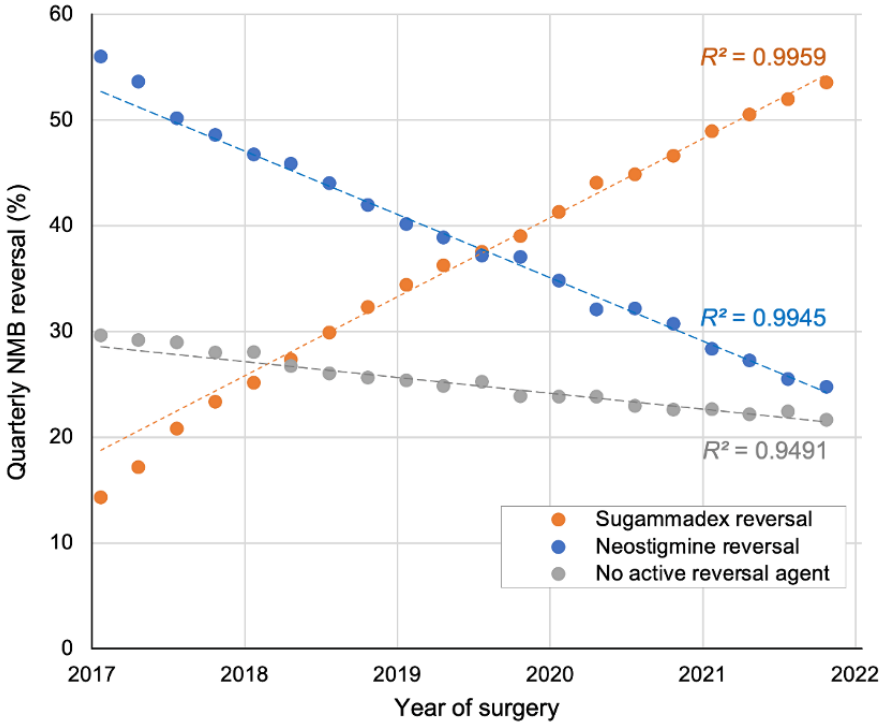
The use of NMB reversal agents was similar based on institution type. During BP, sugammadex was used in 24.8% (219,463/885,068) of encounters in teaching hospitals and 26.1% (197,803/759,302) in nonteaching hospitals. The use of sugammadex increased to 50.2% (179,721/358,262) among teaching hospitals and 52.4% (141,547/269,935) in nonteaching hospitals during the LC era.

Table 2. Pharmacological and nonpharmacological reversal of NMB[a] during COVID-19 time periods.

Reversal strategy	Total (n=3,602,887)	Baseline period (n=1,644,370)	Before COVID (n=820,078)	Early COVID (n=209,721)	Middle COVID (n=300,791)	Late COVID (n=628,197)
Neostigmine, n (%)	1,411,570 (39.2)	775,266 (47.1)	307,727 (37.5)	67,321 (32.1)	94,181 (31.3)	167,075 (26.6)
Sugammadex, n (%)	1,280,618 (35.5)	417,266 (25.4)	311,227 (38)	92,709 (44.3)	138,148 (45.9)	321,268 (51.1)
No active reversal, n (%)	910,699 (25.3)	451,838 (27.5)	201,124 (24.5)	49,421 (23.6)	68,462 (22.8)	139,854 (22.3)

[a]NMB: neuromuscular blockade.

Figure 1. Quarterly proportions of NMB reversal agent use during this study's period. Trend lines evaluate linearity after January 2018, the time period used for logistic regression models. NMB: neuromuscular blockade.



Multivariable Analysis

Multivariable regression analyses were used to identify time trends and their interaction terms with post–COVID-19 time periods for pharmacologic (active) versus no pharmacologic (spontaneous) reversal (model 1a), and for reversal with sugammadex versus neostigmine (model 1b; Table 3; Figures 2 and 3). The overall yearly time-trend throughout this study's period demonstrated an increase in the use of active reversal (using either sugammadex or neostigmine) compared to no pharmacologic reversal (OR 1.129; *P*<.001). However, there were variations in the interaction term coefficient when analyzing specific post–COVID-19 time periods (refer to the Multivariable Analysis section of the Methods section for details on the analysis approach). Active reversal did not show a significant association, or change in trend, during EC (OR 1.002, 95% CI 0.997-1.008; *P*=.44) or MC (OR 0.996, 95% CI 0.991-1.001; *P*=.12). A slight but statistically significant decrease in the active reversal trend (ie, there was a slowing of the trend toward increased use of active reversal) was observed in LC (OR 0.987, 95% CI 0.983-0.992; *P*<.001). Based on these observations, the counterfactual analysis (model 2a) was not evaluated.

Significant associations in the use of active reversal were also observed based on patient, procedure, and institutional factors (Table 3; Figure 2). Except for those aged 18-30 years, fewer older adults (aged 41 to 70 years) tended to show a decreased odds of active reversal (OR range 0.941-0.983; reference those aged 31-40 years), while older adults (aged >70 years) were more likely to use active reversal (OR range 1.094-1.349). Compared to elective surgical procedures (reference), emergency, trauma, and urgent admissions revealed significantly decreased use of active pharmacologic reversal (OR 0.641, 95% CI 0.637-0.645; 0.612, 95% CI 0.602-0.622; and 0.668, 95% CI 0.662-0.675; respectively; *P*<.001 for each).

When comparing the use of sugammadex versus neostigmine in model 1b (Table 3, Figure 3), the yearly time-trend from January 2018 onwards demonstrated a steady increase in the use of sugammadex over neostigmine (OR 1.388, 95% CI 1.381-1.396; *P*<.001). Analysis of the specific post–COVID-19 time periods revealed a small but statistically significant interaction with the time trend in NMB reversal (Table 3). A slight but statistically significant increase in sugammadex reversal was observed during EC (OR 1.008, 95% CI 1.003-1.014; *P*=.003), followed by negation of that trend during MC (OR 0.992, 95% CI 0.987-0.997; *P*<.001). There was no significant interaction identified in the LC period (OR 1.001, 95% CI 0.996-1.005; *P*=.81).

Other covariates in model 1b that were significantly associated with sugammadex reversal included older age categories, urgent or emergent and trauma admissions, cardiac comorbidities (including arrhythmias, peripheral vascular disorders, congestive heart failure), obesity, chronic pulmonary disease, and diabetes. Most surgical types were associated with higher rates of sugammadex reversal as compared to the reference (musculoskeletal surgeries or surgeries involving the nervous system) with the exception of female genitalia. Hospitals with fewer beds (0-199 or 200-399 vs 400+) were associated with a lower likelihood of sugammadex reversal. Hospitals in the Northeast and South geographic regions of the United States also had significantly lower odds of sugammadex reversal as compared to the West and Midwest.

Table 3. Logistic regression estimates from multivariate models (active vs spontaneous and sugammadex vs neostigmine).

	Model 1a: active vs spontaneous		Model 1b: sugammadex vs neostigmine	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Time trend (yearly)	1.129 (1.123-1.135)	<.001	1.388 (1.381-1.396)	<.001
Time trend×EC[a]	1.002 (0.997-1.008)	.44	1.008 (1.003-1.014)	.003
Time trend×MC[b]	0.996 (0.991-1.001)	.13	0.992 (0.987-0.997)	<.001
Time trend×LC[c]	0.987 (0.983-0.992)	<.001	1.001 (0.996-1.005)	.81
NMB group (reference=rocuronium+succinylcholine or vecuronium+succinylcholine)				
>1 class of long-acting NMB + succinylcholine	0.469 (0.455-0.483)	<.001	0.542 (0.517-0.567)	<.001
Rocuronium or vecuronium	1.501 (1.484-1.519)	<.001	1.421 (1.404-1.440)	<.001
Age (y; reference=31-40 y)				
18-30	1.057 (1.041-1.072)	<.001	0.917 (0.904-0.930)	<.001
41-50	0.959 (0.947-0.972)	<.001	1.042 (1.030-1.054)	<.001
51-60	0.941 (0.930-0.952)	<.001	1.095 (1.083-1.107)	<.001
61-70	0.983 (0.971-0.995)	.004	1.108 (1.095-1.120)	<.001
71-80	1.094 (1.080-1.108)	<.001	1.137 (1.123-1.150)	<.001
>80	1.349 (1.329-1.369)	<.001	1.251 (1.233-1.269)	<.001
Female vs male	1.110 (1.103-1.116)	<.001	0.989 (0.983-0.995)	<.001
Race (reference=White)				
Asian	0.905 (0.887-0.925)	<.001	0.929 (0.909-0.950)	<.001
Black	1.002 (0.993-1.012)	.62	0.897 (0.889-0.905)	<.001
Other	0.926 (0.916-0.937)	<.001	0.803 (0.794-0.812)	<.001
Unknown	0.938 (0.921-0.956)	<.001	0.686 (0.673-0.698)	<.001
Ethnicity (reference=not Hispanic)				
Hispanic	0.945 (0.935-0.955)	<.001	1.171 (1.159-1.184)	<.001
Unknown	0.910 (0.903-0.918)	<.001	1.096 (1.087-1.105)	<.001
Admission type (reference=elective)				
Emergency	0.641 (0.637-0.645)	<.001	1.158 (1.150-1.165)	<.001
Trauma center	0.612 (0.602-0.622)	<.001	1.652 (1.621-1.685)	<.001
Urgent	0.668 (0.662-0.675)	<.001	1.156 (1.145-1.168)	<.001
Low-income (reference=not low-income[d])	0.972 (0.964-0.981)	<.001	1.069 (1.060-1.079)	<.001
Comorbidities (present vs absent)				
Valvular disease	0.710 (0.702-0.718)	<.001	0.940 (0.927-0.953)	<.001
Diabetes (complicated)	0.870 (0.862-0.878)	<.001	1.019 (1.009-1.030)	<.001
Cardiac arrhythmias	0.766 (0.760-0.772)	<.001	1.020 (1.012-1.029)	<.001
Sleep apnea	1.034 (1.024-1.044)	<.001	1.034 (1.024-1.044)	<.001
Solid tumor without metastasis	1.124 (1.113-1.135)	<.001	1.057 (1.047-1.067)	<.001
Peripheral vascular disorders	1.443 (1.428-1.457)	<.001	1.071 (1.059-1.084)	<.001
Obesity or overweight	1.013 (1.006-1.020)	<.001	1.096 (1.089-1.104)	<.001
Congestive heart failure	0.810 (0.802-0.819)	<.001	1.100 (1.087-1.114)	<.001
Chronic pulmonary disease	1.012 (1.004-1.019)	.002	1.102 (1.094-1.110)	<.001
Surgical type (reference=MSK[e] and CNS[f])				
Female genital	1.877 (1.845-1.911)	<.001	0.980 (0.967-0.994)	.005

	Model 1a: active vs spontaneous		Model 1b: sugammadex vs neostigmine	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Cardiovascular	0.372 (0.369-0.376)	<.001	1.044 (1.033-1.055)	<.001
Urinary and male genital	1.408 (1.386-1.430)	<.001	1.101 (1.085-1.116)	<.001
Digestive	2.056 (2.040-2.072)	<.001	1.115 (1.107-1.123)	<.001
Integumentary hemic and lymphatic	0.906 (0.893-0.919)	<.001	1.237 (1.218-1.256)	<.001
Endocrine	0.794 (0.764-0.825)	<.001	1.326 (1.274-1.381)	<.001
Eye	1.226 (1.108-1.356)	<.001	1.531 (1.377-1.702)	<.001
Others, unknown, or missing	0.981 (0.912-1.056)	.614	1.596 (1.484-1.717)	<.001
ENT[g]	0.702 (0.680-0.724)	<.001	1.632 (1.572-1.695)	<.001
Respiratory	0.847 (0.835-0.858)	<.001	1.651 (1.627-1.676)	<.001
Bed size (reference=400+)				
0-199	0.828 (0.820-0.835)	<.001	0.823 (0.815-0.830)	<.001
200-399	0.858 (0.852-0.865)	<.001	0.864 (0.858-0.870)	<.001
Teaching vs not teaching	0.971 (0.964-0.977)	<.001	1.006 (0.999-1.012)	.09
Institution region (reference=West)				
Midwest	1.263 (1.250-1.275)	<.001	0.956 (0.947-0.966)	<.001
Northeast	1.013 (1.002-1.024)	.021	0.431 (0.426-0.435)	<.001
South	1.203 (1.192-1.213)	<.001	0.617 (0.612-0.623)	<.001
History of COVID-19 (reference=no COVID-19)	0.976 (0.947-1.005)	.10	1.018 (0.989-1.048)	.23

[a]EC: early COVID-19 era.

[b]MC: middle COVID-19 era.

[c]LC: late COVID-19 era.

[d]Low-income insurance types include Medicaid, charity, and indigent.

[e]MSK: musculoskeletal.

[f]CNS: central nervous system.

[g]ENT: ear nose throat.

Figure 2. Forest plot of odds ratio: active versus spontaneous reversal (model 1a). The time period between January 1, 2018, and February 29, 2020, was considered as a reference to evaluate the interaction of the time trend with EC, MC, and LC periods. Bars represent 95% CI. Low income includes Medicaid, charity, and indigent insurance types. CNS: central nervous system; EC: early COVID-19 (April 1, 2020, and July 31, 2020; the month of March 2020 was omitted to account for a transition period and due to the unavailability of COVID-19 diagnostic information); ENT: ear nose throat; LC: late COVID-19 (January 1, 2021, to December 31, 2021); MC: middle COVID-19 (August 1, 2020, to December 31, 2020); MSK: musculoskeletal; NMB: neuromuscular blockade; ROC: rocuronium; SUC: succinylcholine; VEC: vecuronium.

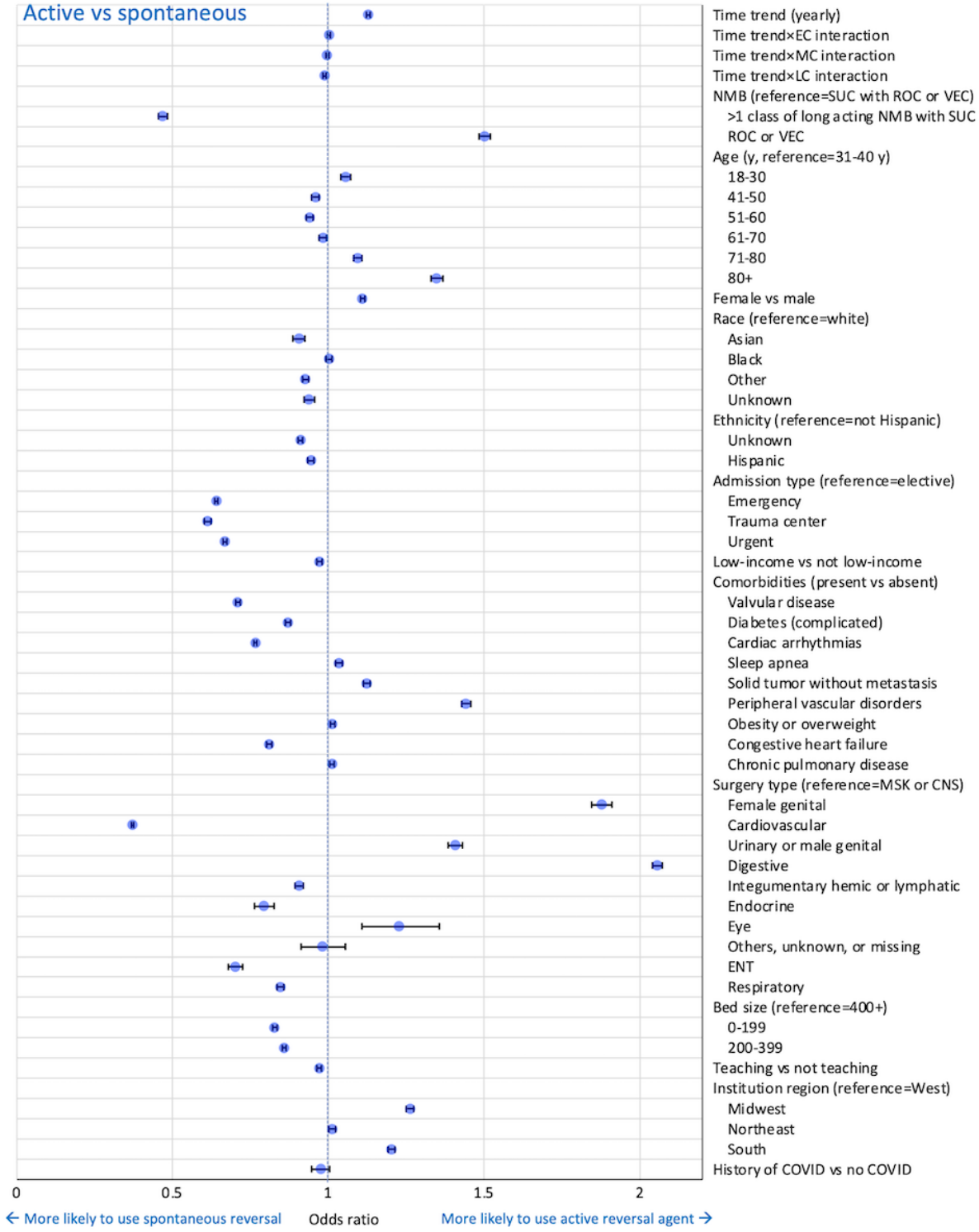
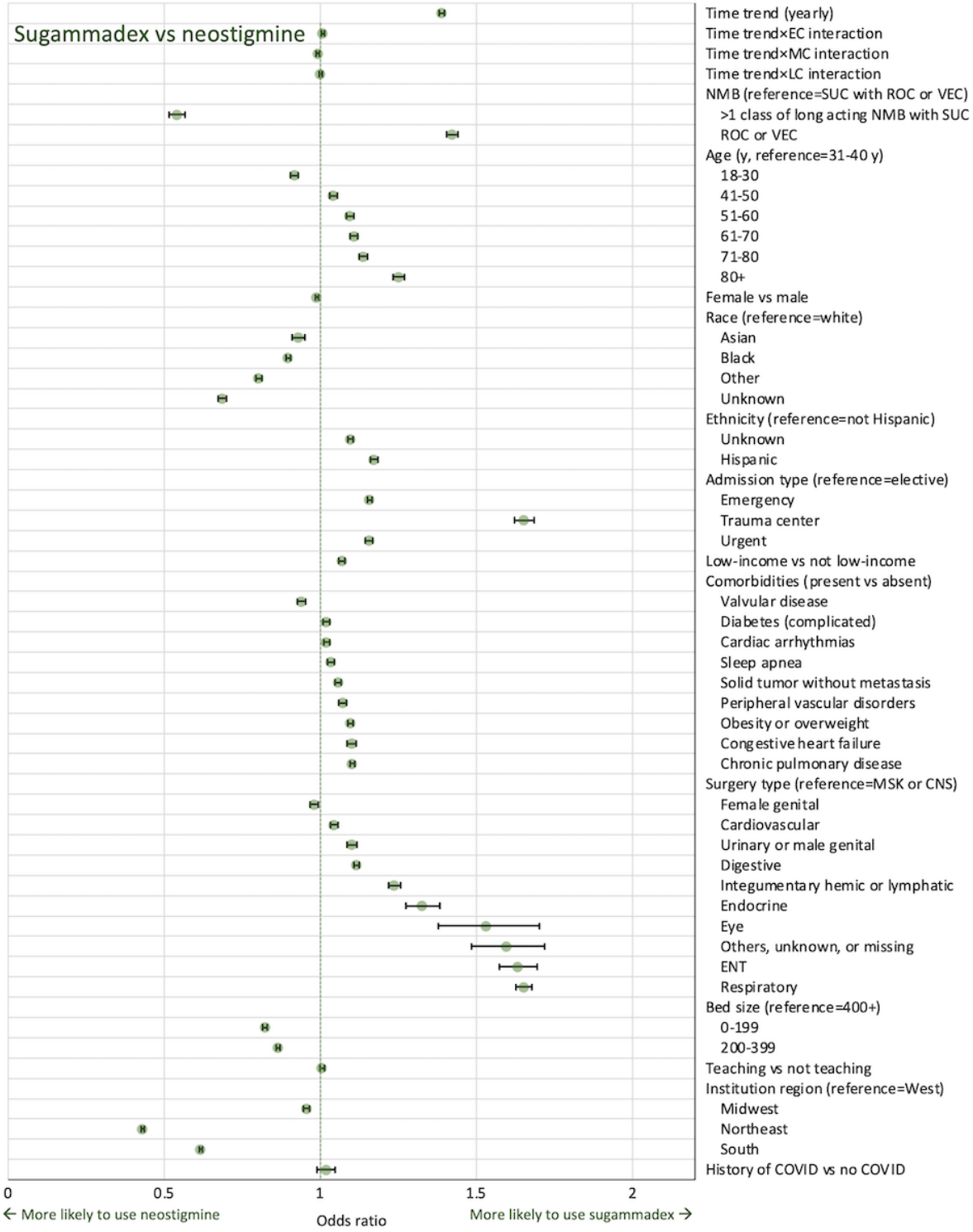


Figure 3. Forest plot of odds ratio: sugammadex vs neostigmine (model 1b). The time period between January 1, 2018, and February 29, 2020, was considered as a reference to evaluate the interaction of the time trend with EC, MC, and LC periods. Bars represent 95% CI. Low income includes Medicaid, charity, and indigent insurance types. CNS: central nervous system; EC: early COVID-19 (April 1, 2020, to July 31, 2020; the month of March 2020 was omitted to account for a transition period and due to the unavailability of COVID-19 diagnostic information); ENT: ear nose throat; LC: late COVID-19 (January 1, 2021, to December 31, 2021); MC: middle COVID-19 (August 1, 2020, to December 31, 2020); MSK: musculoskeletal; NMB: neuromuscular blockade; ROC: rocuronium; SUC: succinylcholine; VEC: vecuronium.



Counterfactual Analysis

When comparing EC, MC, and LC time periods within patient subgroups, only a few differences were observed in actual NMB reversal compared to expected use. Most differences were observed in LC among institution and multimodal NMB characteristics (Figure 4). After normalization, only a few patient and institutional characteristics showed a significant deviation from the expected trend of the sugammadex reversal rate. Of the patient characteristics that had an observable counterfactual difference, patients with Hispanic ethnicity were reversed with sugammadex less frequently in the LC era as compared to how they would have been reversed before COVID-19. Institutions

with 400 or more beds or classified as teaching institutions also had a relative decrease in sugammadex reversal rates as compared to expected trends from before COVID-19 data. On the other hand, small hospitals (0-199 beds), mid-sized hospitals (200-399), and those located in the south of the United States had higher rates of sugammadex reversal than expected from pre–COVID-19 trends, having relative actual or counterfactual ratios greater than 1.

Figure 4. Counterfactual analysis comparing actual sugammadex reversal odds relative to prepandemic multivariate model–based reversal odds (model 2b). Normalized ORs were calculated by dividing observed ORs with counterfactual ORs of sugammadex reversal and multiplied by a frequency-weighted scaling factor for relative comparison between time periods. Bars represent 95% CI. Low income includes Medicaid, charity, and indigent insurance types. CNS: central nervous system; ENT: ear nose throat; MSK: musculoskeletal; NMB: neuromuscular blockade; OR: odds ratio; ROC: rocuronium; SUC: succinylcholine; VEC: vecuronium.

Discussion

Principal Results

This study used a large health care database comprising 931 sites across the United States to identify changes in use trends for NMB and NMB reversal agents for inpatients before and after health care systems experienced the COVID-19 outbreak. Through multivariable regression analysis, we identified factors related to the patient, procedure, and institution that were associated with NMB reversal choices.

We originally hypothesized that the use of sugammadex for NMB reversal in the post–COVID-19 period would increase given the evidence demonstrating decreased PACU time and, thus, diminished potential exposure to COVID-19. When analyzing changes in the sugammadex use trend for NMB reversal, a slight, transient effect was observed during the post–COVID-19 time points. During EC, a small but statistically

significant increase in sugammadex use (compared to neostigmine) was revealed, though this trend was negated by an equivalent decrease during the MC period. However, the association with sugammadex use was small and short-lived, thus arguing that other factors in the complex process of NMB and NMB reversal selection are influencing these decisions. Logistic regression analysis showed that sugammadex use was favored in emergency and urgent admissions compared to elective admissions, and the number of emergency and urgent admissions increased from 42.5% (348,840/820,078) in the BC period to 49.7% (104,123/209,451) in the EC period (Table 1). However, this did not translate to an increase in sugammadex reversal in the counterfactual analysis (model 2b, Figure 4), which largely showed no significant difference in the sugammadex reversal rates of patients being treated in the COVID-19 eras relative to how they would have been treated before COVID-19. It is also important to point out that this study is attempting to identify an association or change in trend, beyond the currently established time-trend, which has observed a strong, steady increase in sugammadex before COVID-19, likely due to increasing evidence of the benefit of sugammadex in avoiding rNMB and in quicker time to reach a train-of-four (TOF) ratio of >0.9 [17,30]. To help account for this, the analysis used data starting in January 2018, which showed a more linear and predictable increase in sugammadex use leading to the start of the COVID-19 pandemic in March 2020. Given the strong association of sugammadex in the yearly time-trend (OR 1.388, 95% CI 1.381-1.396), it is possible that small but significant changes to the NMB reversal trend following COVID-19 are being masked by the existing time-trend.

The counterfactual analysis in this study was intended to identify trends in patient and institutional characteristics that deviated from overall sugammadex reversal patterns captured in the multivariate analysis, which assumes constant effects for all of the covariates. Most of the changes that deviated from the prepandemic trend, as observed from the significantly higher or lower actual or counterfactual ratio in Figure 4, were a reversal of the characteristics that were found to be associated with the early adoption of sugammadex [9]. For example, a lower-than-predicted use of sugammadex in trauma center patients and large hospitals in the peri–COVID-19 time periods may be explained as a renormalization caused by a higher-than-expected adoption of sugammadex in these settings in the initial years after sugammadex approval.

Limitations

Though this study used robust methodology and a large US database of over 3.5 million inpatient encounters, several limitations must be addressed. The PHD includes patients covered by all payer types from both teaching and nonteaching institutions of various bed sizes. However, it is not representative of geographic location, with the South region more heavily weighted, which could limit the generalizability of the results. The PHD did not include information on the depth of NMB block (moderate vs deep), use of quantitative neuromuscular monitoring, or detection of postoperative rNMB, which can impact NMB reversal selection. The PHD also did not provide individual hospital data on census or capacity limitations. Methods were proposed to account for controlling for the variability in experience between regions, sites, and time periods relative to this capacity. However, there was still a possibility that the impact of a burden on each hospital was either captured incorrectly in general or relative to the BC experience, though the burden was likely to be just as well or just as poorly, captured from one site to another. This study does not take into account reporting sites that were not continuously enrolled throughout this study's period. During this study's period extending over 4.5 years, practice and policy changes in surgery and anesthesiology were likely to occur that could have influenced the selection of NMB and NMB reversal agents. Additionally, variations in hospital protocols as well as access to reversal agents were not accounted for in this study. These could include external factors on anesthesia practice among institutions, such as adherence to enhanced recovery protocols, quantitative neuromuscular monitoring following surgery, budgetary constraints, and quality initiatives. Certain patient characteristics (eg, American Society of Anesthesiology physical status classification or smoking status) and procedure data (eg, drug dose or duration of procedure) were not available that could impact NMB reversal choice. By the nature of this study and data collection, there is a potential for recording errors. Lastly, the determination of early, mid, and late COVID-19 time periods was largely subjective. In the absence of nationwide, standardized protocols to guide surgical and anesthesia practices in the wake of the COVID-19 outbreak, each institution adapted independently to the pandemic based on available resources and local impacts of the pandemic, which can vary widely over time and location. Despite the limitations of the data source and our limited ability to identify certain details, our study provides an aggregate observation on the effect of the COVID-19 pandemic on NMB reversal practices in non–COVID-19 patients in the United States.

Comparison With Prior Work

Before COVID-19, rocuronium (with or without succinylcholine) was the predominant NMB used among US inpatient procedures, accounting for approximately 87% (1,432,947/1,644,370) of patient encounters during the BP. Preference for rocuronium over vecuronium continued through the post–COVID-19 time periods, with 93% (583,815/628,197) of encounters using rocuronium (with or without succinylcholine) in LC. These findings were consistent with prior studies on NMB use among US inpatients. Bash et al [9] demonstrated a trend in preference for rocuronium over vecuronium (with or without succinylcholine) from 2014 to 2019 among US inpatients, increasing from 84.3% in 2014 to 90.7% by the first half of 2019. This trend was even more pronounced among US outpatients, with rocuronium (with or without succinylcholine) accounting for over 96% of NMB use during the first half of 2019 [8].

Database studies revealed trends in NMB reversal favoring active over spontaneous (or no pharmacologic agent) reversal. Among US inpatients, the percentage of encounters using spontaneous reversal gradually decreased from 36.5% in 2014 to 34.3% in 2016 [9]. This decreasing trend accelerated in 2016 (with the approval of sugammadex) and reached 27.6% by the first half of 2019. This current study demonstrated that a decreasing trend in the use of spontaneous reversal continued

through the COVID-19 time periods. Logistic regression estimates did not reveal any significant association, or change in the trend, between active versus spontaneous reversal during the EC and MC time periods. During LC, a small but significant association was observed showing a decrease in the rate of active reversal change (effective change in OR of time trend from 1.129 to 1.115). Analyses revealed several patient, procedural, and institutional factors with significant associations with the choice of reversal approach. The most pronounced association identified was related to admission type, with emergency, trauma center, and urgent admissions strongly favoring the use of spontaneous reversal compared to elective procedures. The percentage of elective admissions decreased substantially from 55% (451,190/820,078) in BC to 47.1% (98,637/209,451) in EC, and only partially returned during the MC and LC periods. This was likely the result of a nationwide response to postpone nonessential, elective surgeries as a means to limit COVID-19 exposure in hospitals and focus health care resources on managing the pandemic [14,15].

Contrary to our hypothesis, this study suggests that the impact of COVID-19 on NMB reversal selection was generally limited during the post–COVID-19 era throughout the United States. Though the change in trend for sugammadex use was small and transient in the post–COVID-19 era, the steady trend of increasing sugammadex use over neostigmine that started before COVID-19 and continued in the post–COVID-19 era eclipsed the small transient effects of the pandemic. This trend may be attributed to evidence demonstrating certain benefits of sugammadex over neostigmine, including diminished reversal time, more rapid discharge from the PACU, and a lower incidence of rNMB [17,30-32]. However, the lack of an acceleration of sugammadex use during the post–COVID-19 periods may be attributed to several factors, including clinical inertia or a lack of evidence related to the potential reduction in viral exposure associated with quicker NMB reversal time (and earlier extubation in the operating room). Educational programs can help to ensure current standards of care are attained and maintained in the postoperative setting.

Nonetheless, neostigmine remains a reasonable alternative for NMB reversal in certain patients with minimal blockade. Recent guidelines from the American Society of Anesthesiologists and the European Society of Anesthesiology and Intensive Care (both guidelines released after the date of final data collection of this study) confirm neostigmine's place in therapy and offer recommendations on the appropriate use of this agent in NMB reversal when accompanied with quantitative neuromuscular monitoring [33,34]. American Society of Anesthesiologists recommends quantitative neuromuscular monitoring for all patients and prefers sugammadex over neostigmine at deep, moderate, and shallow depths (ie, TOF ratio <0.4) of NMB induced by rocuronium or vecuronium [33]. Yet, neostigmine is indicated as a reasonable alternative for patients with minimal blockade (ie, TOF ratio = 0.4 to <0.9) [31]. Similarly, the European Society of Anesthesiology and Intensive Care recommends sugammadex for deep, moderate, and shallow NMB (TOF ratio <0.4) induced by rocuronium or vecuronium, while neostigmine can be considered following advanced spontaneous recovery (ie, TOF ratio >0.2) [34]. Future research using databases that collect TOF information would be instrumental in understanding the impact of these guidelines on current trends and outcomes in NMB reversal selection.

Conclusions

This large, retrospective database study analyzed over 3.5 million inpatient encounters throughout the United States to identify changes in NMB use and reversal trends during the COVID-19 pandemic. We hypothesized that sugammadex use for NMB reversal would accelerate during the post–COVID-19 eras as a means to reduce PACU or operating room time and, subsequently, the risk of COVID-19 exposure. However, our findings demonstrated only a slight, transient acceleration of sugammadex use during the EC that was largely negated with time. This study did not attempt to investigate the reasons for the lack of change in the existing trend in the use of NMB reversal agents. Additional research is needed to better understand how pandemic-related practice changes have affected long-term NMB and reversal selection based on patient, procedural, or institutional factors, and potentially recognize patient subpopulations that experienced greater changes in anesthesia practice during this period.

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Authors' Contributions

VT helped design, analyze, and interpret the results, draft this paper, and critically review this paper for important intellectual content. IH, MK, LDB and RDU helped design this study, interpret the results, draft this paper, and critically review this paper for important intellectual content.

Conflicts of Interest

VT and LDB are full-time employees of Merck & Co, Inc, which manufactures and distributes sugammadex, and may own stock or hold stock options in Merck & Co, Inc. MK and IH receive consulting fees from Merck & Co, Inc. RDU receives consulting fees from Merck & Co, Inc and AcelRx.

Multimedia Appendix 1
Tables showing patient attrition, patient and institution characteristics by COVID era and NMB reversal mechanism. NMB: neuromuscular blockade.
[DOCX File , 82 KB - periop_v7i1e52278_app1.docx]

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Abbreviations

BC: before COVID-19 era
BP: baseline period
EC: early COVID-19 era
LC: late COVID-19 era
MC: middle COVID-19 era
NMB: neuromuscular blockade
OR: odds ratio
PACU: postanesthesia care unit
PHD: PINC AI Healthcare Database
rNMB: residual neuromuscular blockade
TOF: train-of-four

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Viewpoint

Blood Management: A Current Opportunity in Perioperative Medicine

Moises Auron[1,2,3], MD

[1]Department of Hospital Medicine, Cleveland Clinic, Cleveland, OH, United States

[2]Department of Pediatric Hospital Medicine, Cleveland Clinic Children's, Cleveland, OH, United States

[3]Outcomes Research Consortium, Cleveland, OH, United States

Corresponding Author:
Moises Auron, MD
Department of Hospital Medicine
Cleveland Clinic
9500 Euclid Ave
Cleveland, OH, 44195
United States
Phone: 1 2164458383
Fax: 1 2164448530
Email: auronm@ccf.org

Abstract

The purpose of this viewpoint is to provide awareness of the current opportunities to enhance a high-value care approach to blood product transfusion. It provides a historical context to the evolution of blood management, as well as of the patient safety and high-value care movement. Leveraging current technology for enhanced education, as well as clinical decision support, is also discussed.

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KEYWORDS

blood management; perioperative; anemia; plasma; transfusion

Origins of High-Value Care

The need to improve patient outcomes, with emphasis on patient safety, evidence-based decision-making, and a strong focus on high-value care, stemmed from the US Institute of Medicine's seminal publication *To Err Is Human* [1], which was very influential in enhancing awareness of the impact of individual human behavior and decision-making on patients' outcomes. It was a humbling and necessary perspective that spearheaded a movement toward more effective, efficient, cost-effective, and high-value–oriented practice of medicine.

Historical Perspective on Blood Management

Blood management is not an exception to this movement. Transfusional medicine underwent tremendous development during the second half of the 20th century, faced with specific challenges such as the need for bloodless surgery in patients who refused blood transfusions and the rise of transfusion-associated viral diseases [2]. In addition, there was growing evidence of the adverse consequences associated with liberal blood transfusion, including increased mortality, sepsis, and increased length of hospitalization. This led to an awareness of the need to focus efforts on developing blood product transfusion based on the individual need of the patient, and in 2005, Isbister [3] coined the term "patient blood management." This is a complex approach that focuses on three pillars: (1) optimizing patient hematopoiesis and enhancing red cell mass, (2) minimizing blood losses with improved source control and optimization of coagulopathy, and (3) enhancing patient tolerance to anemia [2]. In the past 30 years, substantial evidence grew to support a more restrictive transfusional approach once there was evidence that patients could tolerate lower hemoglobin values without major adverse effects; this evidence came from multiple patient populations, such as critically ill patients, older patients with high cardiovascular risk undergoing surgery, and patients with active gastrointestinal bleeding [4]. Another very important aspect that must be considered is the increasing cost associated with transfusion of blood products. Furthermore, procedures aimed to enhance patient safety (eg, pathogen reduction in platelets) substantially increase the overall cost of transfusion. A high-value care approach helps to gain insight

into nontransfusional alternatives to optimize underlying hematologic conditions, but also to be cost conscious and aware of the financial impact of indiscriminate use of blood [5,6].

Aim

The aim of this viewpoint is to allow physicians and clinicians caring for surgical patients who order blood products to reflect on the impact of the high-value care movement in blood management and transfusional medicine, as well as on the currently prevailing opportunities to enhance better decision-making; this is particularly relevant after considering the historical perspective. Ideally, the best scenario would be that patients undergo procedures and hospitalizations with minimal exposure to blood products, aiming to leverage nontransfusional correction of underlying hematologic processes. This requires enhanced awareness of current guidelines and standards of care, as well as leveraging current technology (eg, electronic health records) to help gain insight into current transfusion practices and to provide direct clinical decision-support tools that facilitate best practices in blood product ordering.

There is strong evidence of the increasing complexity of hospitalized and surgical patients [7]. It can be hypothesized that this complexity is also associated with anemia and coagulopathy as increasingly encountered comorbid conditions, especially in surgical patients. The physicians and health care professionals caring for these patients must have enhanced awareness to identify and recognize anemia and coagulopathy, with a subsequent diagnostic approach aiming to not just treat but to identify its etiology to optimize a nontransfusional approach (eg, the use of intravenous iron) [8]. A pharmacologic approach to anemia provides a more efficient and patient-centered optimization of these comorbidities with consequent enhanced treatment effectiveness and decreased adverse outcomes associated with unnecessary blood transfusion [4].

Current Challenges

The current 2023 Association for the Advancement of Blood & Biotherapies (AABB) red blood cell transfusion guidelines have reinforced this parsimonious approach to blood transfusion, with even more conservative and restrictive levels to trigger transfusion in patients with acute coronary syndromes and pediatric patients [9]. Nonetheless, more widespread enhanced adherence to the AABB guidelines in regard to red blood cell transfusion is a necessity. In addition, plasma transfusion offers a strong opportunity for improvement in health care delivery, especially as there is a need to minimize unnecessary plasma transfusion as well as its inappropriate dosing; plasma should be transfused with weight-based dosing and in appropriate clinical scenarios. Undertransfusion of plasma, by not using weight-based dosing, is a current challenge as this not only does not have a therapeutic corrective effect on coagulopathy but is a source of wastage [10]. Enhanced education efforts worldwide, as well as leverage of current technology, create awareness and encourage adoption of a high-value approach to plasma and red blood cell transfusion. Another element to consider as a balancing measure to enhanced patient safety is the increased associated cost; in the case of platelet transfusion, in the United States the current standard of care is the use of pathogen-reduced platelets; this approach increases costs of individual blood products substantially [6].

The perioperative continuum of care provides different stages to ensure that patients are properly evaluated and treated. In the preoperative setting, the optimization of anemia carries the most significant value through raising hemoglobin values to levels high enough to minimize reaching the transfusion threshold while also enhancing overall oxygen delivery [4]. In the intraoperative setting, the leverage of cell-saver technology, as well as optimization of coagulopathy, can mitigate the risk of blood product use; however, awareness of appropriate indications as well as of dosing of blood products promotes a high-value approach and minimizes wastage [9,10]. In the postoperative realm, it involves ensuring appropriate monitoring of ongoing blood losses, as well as monitoring the patient for potential complications associated with postsurgical anemia, such as myocardial ischemia in noncardiac surgery [11].

Potential Solutions and Opportunities

What can be done to mitigate the inappropriate overuse of blood products, inappropriate dosing, and lack of awareness of the associated costs? Appropriate data bank analysis and data-driven interventions, as well as the implementation of human factors engineering and newer technologies such as artificial intelligence within the current workflow (like the electronic health record), can enhance the effectiveness of patient blood management efforts [12]. This entails having a database of all patients being transfused in a hospital or health care system and being able to have granularity to drill down to data on the individual patient, ordering physician, and baseline and posttransfusion laboratory values (eg, complete blood count), as well as associated outcome metrics like readmissions, length of stay, and cost of care. In addition, short-cycle data, which allow immediate identification of patients who can benefit from further stratification and assessment of underlying anemia and coagulopathy, permits guiding clinicians to pursue real-time high-value care and evidence-based interventions supported by clinical decision support tools. Also, data governance of anemia and coagulopathy assessment, as well as blood transfusion practices, provides a platform for permit auditing, benchmarking best practices, and providing real-time feedback to individual physicians, increasing awareness of areas of success and opportunities [13].

The electronic health record also provides a strong platform for education, as clinical decision-support tools can be embedded in the orders [14]. For instance, in our institution, we default red blood cell transfusion orders to single units and have a formal indication: What is the current transfusion threshold? This allows the ordering health care professional to reflect and select a reason when the order does not follow the current AABB guidelines. Also, when plasma is ordered, there is an indication to use weight-based volumes to minimize undertransfusion, as well as education that transfusion for an international normalized ratio <1.8 will not have a meaningful impact. Order overriding

can occur, but with the need to provide a rationale. The more the orders are used and experience increases with blood product transfusion, the more exposure there will be to this workflow, allowing for enhanced education. Also, the electronic health record can facilitate improved documentation of blood product transfusions, allowing the development of increased insight into potential blood product overuse [15].

In this issue of *JMIR Perioperative Medicine*, we provide the opportunity to outline the evidence for evaluation and optimization of perioperative anemia in different surgical populations, as well as to discuss the opportunities for leverage of current technologies to enhance the effectiveness of approaches to improve patient outcomes and enhance the high-value care approach, minimizing not only financial costs, but more importantly, decreasing patient harm.

Conflicts of Interest

MA is an associate editor of *JMIR Perioperative Medicine*.

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Abbreviations

AABB: Association for the Advancement of Blood & Biotherapies

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Viewpoint

Blood Bonds: Transforming Blood Donation Through Innovation, Inclusion, and Engagement

Ankita Sagar[1], MD, MPH, FACP

Creighton University School of Medicine, CommonSpirit Health, Monmouth Junction, NJ, United States

Corresponding Author:
Ankita Sagar, MD, MPH, FACP
Creighton University School of Medicine
CommonSpirit Health
4 Interlaken Road
Monmouth Junction, NJ, 08852
United States
Phone: 1 9179136278
Email: Ankita.Sagar@commonspirit.org

Abstract

The journey of receiving blood as a patient with transfusion-dependent beta thalassemia has profoundly shaped my understanding of the life-saving power of blood donation. This personal experience underscores the critical importance of blood donors, not just for individual recipients but for the broader community, enhancing public health, productivity, and well-being. There are several challenges to securing a blood donor pool in current health care climate. Solutions that focus on the engagement of donors, clinicians, and patients are key to improving the donor pool and utilizing the blood supply in a judicious manner.

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KEYWORDS

blood donor; engagement; digital health; health technology; EBM; inclusive; inclusivity; shared decision-making; evidence-based medicine; blood shortage; blood product; transfusion; transfusions; donor; donation; hematology; perioperative medicine; surgery

Background

The journey of receiving 771 units of blood as a patient with transfusion-dependent beta thalassemia has profoundly shaped my perspective on the life-saving generosity of blood donors. The altruism of my blood donors has not only sustained my life to reach my 40th birthday but also serves as a poignant reminder of human compassion in our world for me, giving me hope as both a physician and a patient.

Beyond individual recipients, blood donors contribute to community-wide benefits, enhancing health, longevity, and productivity across diverse professions and lifestyles. Blood products represent a critical facet of medical treatment that has yet to be effectively revolutionized on a large scale. Despite advancements in various medical technologies and therapies, the fundamental process of blood donation and transfusion remains reliant on the altruism of donors. Despite the substantial volume of blood donated in the United States—13.6 million units annually—the supply remains precarious, with 25% of community blood centers reporting only 1 day or less of blood supply via America's Blood Centers [1,2]. The limited supply is a reflection of the changing dynamics and profiles of blood donors: donations from adults aged 18 to 25 years declined by 32%, while those from adults aged 25-64 years and 65 years or older increased by 14% and 41%, respectively [3]. This decline in younger donors signals a concerning trend, indicating potential challenges in engaging and retaining future blood donors, which could exacerbate supply issues in the years to come. This illustrates the critical challenges in securing blood supply within the United States. Addressing these challenges demands a coordinated effort to increase donations and optimize the use of blood products, involving stakeholders such as patients, clinical teams, and donors in a strategic framework aimed at securing a sustainable blood supply for all who depend on it.

Engaging Clinical Teams

Access to established guidelines or frameworks pertaining to blood product utilization can significantly enhance engagement among clinical teams and patients. Recent studies have identified considerable variability in intraoperative blood product administration guidelines across professional societies, particularly concerning indications, decision-making processes, and the underlying evidence base [4-6]. This underscores a

critical need for dedicated research into outcomes related to intraoperative and postoperative blood product use, with the aim of establishing standardized clinical guidelines.

Transfusion remains one of the most frequent procedures in surgical settings, with efforts focused on improving the judicious use of red blood cell products for surgical patients [7]. Despite initiatives such as updated clinical guidelines being available, implementation in the surgical continuum has been gradual, reflecting persistent self-identified knowledge gaps among physicians and advanced practice providers [7-9]. Furthermore, clinicians recognize the importance and applicability of transfusion medicine knowledge to their daily clinical practice and welcome further training and education [9]. Moreover, when a self-identified need is addressed via targeted educational interventions and implementation of an evidence-informed guideline, a positive impact on knowledge outcomes, patient outcomes, and enhancement in practice is often noted [10].

The use of technology offers promising methods to enhance clinician engagement and decision-making. Augmented intelligence and clinical decision support tools allow machine learning to assist in predicting bleeding risk and optimizing transfusion strategies, especially in settings such as treating gastrointestinal bleeding in the intensive care unit [11]. These and other advancements underscore the transformative potential of technology in augmenting clinical practice and improving patient outcomes [12]. Nevertheless, prior to vast use of such technology, potential harms caused by and biases within the algorithm of such technology needs to be further studied with due diligence [7].

Engaging Patients

Among patients requiring blood products, shared decision-making and incorporating patients' preferences and values are pivotal in determining individualized transfusion thresholds [13]. Interdisciplinary clinical teams regularly engage in shared decision-making processes that balance patient preferences and evidence-informed clinical protocols. This collaborative approach has proven successful in areas such as cancer prevention and screening, advance directive planning, statin therapy for primary prevention of coronary artery disease, and immunotherapy in oncology. By adopting similar strategies for transfusion needs, individualized plans for anticipated transfusion needs may successfully align with patients' values and clinical science to ensure the judicious use of blood products.

Engaging Blood Donors

Broadening the donor pool and enhancing retention efforts are essential to mitigating blood shortages. Revisiting restrictive policies, such as the Food and Drug Administration's recent lift on blood donation restrictions for LGBTQ+ (lesbian, gay, bisexual, transgender, queer) individuals in alignment with global scientific evidence and inclusive policies, promotes equity and significantly bolsters donor numbers [14]. Similarly, revisiting strategies to engaging younger generations in blood donation requires authentic, relatable approaches that highlight its altruistic impact. Engaging campaigns emphasizing the immediate life-saving potential of donations, rather than monetary incentives, resonate more deeply with younger donors who prioritize values and community impact [15]. Furthermore, combining campaigns with personal narratives from donors and recipients can further inspire community dialogue and encourage new and returning donors, reinforcing the vital role of blood donation in saving lives and fostering community solidarity [16].

Recent innovations, like virtual reality experiences during blood donation, have shown promise in enhancing donor engagement through positive emotional experiences. Studies have shown that involving mixed reality, a form of virtual reality, reduces donor anxiety and enhances satisfaction, making blood donation a mindful and positive experience [17]. Such applications are actively being employed given their transformative impact, by bolstering blood bank efforts or donor recruitment [18,19].

Technology and scientific advances can help ensure the sustainability of blood donation for years to come. Blood donors provide life-sustaining treatment for transfusion-dependent patients like me, and their significant contributions deserve the utmost commitment to ensuring a reliable blood supply. By leveraging evidence-based guidelines to optimize blood product utilization, fostering shared decision-making, enhancing clinical team engagement, and embracing impactful donor engagement strategies, we can effectively mitigate future blood shortages and secure a sustainable future for transfusion medicine. As both a patient and physician, I am hopeful about the potential of these advancements in ensuring that every person in need can rely on the life-saving generosity of blood donors.

Conflicts of Interest

None declared.

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Abbreviations

LGBTQ+: lesbian, gay, bisexual, transgender, queer

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Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
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