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Correction: A Patient-Oriented Implementation Strategy for a Perioperative mHealth Intervention: Feasibility Cohort Study

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Related Article:

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In "A Patient-Oriented Implementation Strategy for a Perioperative mHealth Intervention: Feasibility Cohort Study" JMIR Perioper Med 2025;8:e58878) the authors noted one error.

The affiliations were incorrectly published as:

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These have been revised as follows:

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The correction will appear in the online version of the paper on the JMIR Publications website on February 12, 2025 together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Original Paper

Implementation of Brief Submaximal Cardiopulmonary Testing in a High-Volume Presurgical Evaluation Clinic: Feasibility Cohort Study

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Abstract

Background: Precise functional capacity assessment is a critical component for preoperative risk stratification. Brief submaximal cardiopulmonary exercise testing (smCPET) has shown diagnostic utility in various cardiopulmonary conditions.

Objective: This study aims to determine if smCPET could be implemented in a high-volume presurgical evaluation clinic and, when compared to structured functional capacity surveys, if smCPET could better discriminate low functional capacity (≤4.6 metabolic equivalents [METs]).

Methods: After institutional approval, 43 participants presenting for noncardiac surgery who met the following inclusion criteria were enrolled: aged 60 years and older, a Revised Cardiac Risk Index of ≤2, and self-reported METs of ≥4.6 (self-endorsed ability to climb 2 flights of stairs). Subjective METs assessments, Duke Activity Status Index (DASI) surveys, and a 6-minute smCPET trial were conducted. The primary end points were (1) operational efficiency, based on the time of the experimental session being ≤20 minutes; (2) modified Borg survey of perceived exertion, with a score of ≤7 indicating no more than moderate exertion; (3) high participant satisfaction with smCPET task execution, represented as a score of ≥8 (out of 10); and (4) high participant satisfaction with smCPET scheduling, represented as a score of ≥8 (out of 10). Student's *t* test was used to determine the significance of the secondary end points. Correlation between comparable structured surveys and smCPET measurements was assessed using the Pearson correlation coefficient. A Bland-Altman analysis was used to assess agreement between the methods.

Results: The mean session time was 16.9 (SD 6.8) minutes. The mean posttest modified Borg survey score was 5.35 (SD 1.8). The median patient satisfaction (on a scale of 1=worst to 10=best) was 10 (IQR 10-10) for scheduling and 10 (IQR 9-10) for task execution. Subjective METs were higher when compared to smCPET equivalents (extrapolated peak METs; mean 7.6, SD 2.0 vs mean 6.7, SD 1.8; t_{42}=2.1; P<.001). DASI-estimated peak METs were higher when compared to smCPET peak METs (mean 8.8, SD 1.2 vs mean 6.7, SD 1.8; t_{42}=7.2; P<.001). DASI-estimated peak oxygen uptake was higher than smCPET peak oxygen uptake (mean 30.9, SD 4.3 mL kg^{-1} min^{-1} vs mean 23.6, SD 6.5 mL kg^{-1} min^{-1}; t_{42}=7.2; P<.001).

Conclusions: Implementation of smCPET in a presurgical evaluation clinic is both patient centered and clinically feasible. Brief smCPET measures, supportive of published reports regarding low sensitivity of provider-driven or structured survey measures for low functional capacity, were lower than those from structured surveys. Future studies will analyze the prediction of perioperative complications and cost-effectiveness.

Trial Registration: ClinicalTrials.gov NCT05743673; https://clinicaltrials.gov/study/NCT05743673

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KEYWORDS

preoperative evaluation; submaximal cardiopulmonary exercise test; risk stratification; perioperative medicine; anesthesiology

Introduction

Background

Assessment of functional capacity or exercise tolerance, as measured by self-reported metabolic equivalents (METs), remains a cornerstone of preoperative risk stratification. METs are defined as multiples of the basal metabolic rate (1 MET=3.5 mL kg^{-1} min^{-1}), and self-reported ability to climb 1 flight of stairs has a general consensus of 4 METs [1]. A threshold of ≤4.6 METs (self-reported inability to climb 2 flights of stairs) has been associated with major adverse cardiac events, all-cause mortality, and increased perioperative complications [2-4]. Despite its importance, published reports have cast doubt on the accuracy of provider-driven and self-reported assessment of functional capacity [5,6]. Thus, reliable and efficient methods to precisely characterize functional capacity continue to be of importance in preoperative risk stratification.

Cardiopulmonary exercise testing (CPET) precisely characterizes exercise tolerance by analyzing cellular respiration at rest and during exercise challenges. By measuring resting gas exchange followed by maximal exercise to expose pathophysiological impairments, CPET exploits a symptom-limited approach with a 3-minute resting stage, 3 minutes of unloaded cycling, and a 10- to 12-minute ramp stage with increasing resistance until terminated by the participant [7]. Abnormal CPET measures have been frequently associated with perioperative morbidity, with a peak oxygen uptake (VO_2) of <15 mL kg^{-1} min^{-1} reported as a threshold for elevated cardiopulmonary risk after thoracic and major noncardiac surgery [8-12]. In addition, peak VO_2 impairment predicts an increased risk of surgical site infection, postoperative respiratory failure, and critical care readmission [13]. However, CPET has not been widely adopted in preoperative testing, likely due to limited availability, required technical skills, necessity of maximal patient effort, complexity of task, and cost. Yet, conventional preoperative care, usually comprised of subjective or structured, survey-based, clinician estimation of preoperative functional capacity, has demonstrated poor sensitivity in the identification of patients with low functional capacity (≤4 METs), when compared to CPET [13,14].

In contrast to a conventional symptom-limited approach, submaximal cardiopulmonary exercise testing (smCPET) uses a time-limited approach and predictive analytics to provide estimates of peak cardiopulmonary performance [7]. A maximal exercise effort is not required since it analyzes the VO_2 efficiency slope to predict peak cardiopulmonary performance [15-17]. Of note, the VO_2 efficiency slope has a strong correlation with peak VO_2 (r=0.941), permitting effort-independent prediction of conventional CPET measures [16]. Brief smCPET has demonstrated diagnostic utility in predicting postoperative length of stay, complications, and prognosis in heart failure, pulmonary hypertension, and other conditions [18-23].

Objectives

These advantages suggest that time-limited smCPET may be useful for rapid preoperative assessment of exercise tolerance. Therefore, the primary objective was to determine the logistic feasibility of smCPET integration within a high-volume presurgical evaluation clinic. Our measured feasibility end points were (1) operational efficiency, based on the experimental session length being <20 minutes; (2) modified Borg survey of perceived exertion, with a score of ≤7 indicating no more than moderate exertion; (3) high participant satisfaction with smCPET task execution, with a score of >8 (out of 10); and (4) high patient satisfaction with smCPET scheduling, with a score of >8 (of 10). Our secondary objective was to determine if comparable smCPET measures were significantly different from structured survey findings. The secondary end points were a comparison of (1) self-reported subjective METs from a survey versus smCPET equivalents (extrapolated peak METs), (2) Duke Activity Status Index (DASI) [24] estimates versus smCPET equivalents (extrapolated peak METs), and (3) estimated DASI maximal oxygen consumption (estimated peak VO_2) versus smCPET equivalents (extrapolated peak VO_2). This study hypothesized that brief smCPET would achieve two objectives: first, meet feasibility end points indicating successful implementation, and second, similar to prior published reports regarding provider-driven functional capacity assessments, identify lower peak METs and VO_2, when compared to structured surveys.

Methods

Trial Design

This is an ongoing prospective open-label clinical device study approved by the Yale University Institutional Review Board (IRB#2000033885; ClinicalTrials.gov: #NCT05743673 [25]; principal investigator: ZJC; date of registration: December 5, 2023). This clinical trial was registered prior to participant enrollment.

Study Population

Inclusion criteria for study enrollment included age of 60 years and older, a Revised Cardiac Risk Index (RCRI) [26] of ≤2, self-endorsed subjective METs of ≥4 (endorses reliably climbing 2 flights of stairs), and presenting for noncardiac surgery. The aim was to recruit 40 participants for the feThis number was estimated to be adequate to identify any study-related logistic process problems or patient-centered outcome deficiencies and to determine the operational efficiency of this novel system process. The RCRI≤2 criterion was selected given the novelty of smCPET in preoperative evaluation.

Given that participants were screened prior to surgical procedures, exclusion criteria were adapted to maintain current

standard-of-care practices in preoperative evaluation, which includes mandatory subspecialty evaluation of select cardiopulmonary conditions. Participants with recorded severe or critical heart valve disease, active exertional angina, nonambulation, gait abnormalities, end-stage renal disease, severe peripheral vascular disease, and neurological motor deficits were excluded. Additionally, non–English-speaking participants, those under legal guardianship, and participants documented to not have personal health care decision-making capacity were also excluded. After prescreening, a phone call was placed by a study team member, and eligible participants were invited for in-person written informed consent, preoperative evaluation, questionnaire assessment of METs, and a 6-minute smCPET experimental session.

Testing Environment

Testing was performed at the presurgical evaluation (PSE) clinic at Yale New Haven Hospital, which is responsible for more than 40,000 preoperative evaluations per year. On a daily basis, the PSE clinic is staffed by an anesthesiologist, 2 resident physicians, 3 certified nurse practitioners, and 6 nursing staff and contains 6 exam rooms.

Study Apparatus

The US Food and Drug Administration–approved Shape II is a compact, cardiopulmonary, breath-by-breath, exercise testing system that uses brief submaximal exercise effort (3 minutes) to generate multiple quantitative measures of actual and predicted peak cardiopulmonary performance measurements (Figure 1). Predicted peak exercise values are automatically calculated by the device using oxygen efficiency slope equations [16,17]. Furthermore, the device has been previously validated to conventional CPET measurements [27,28]. The compact design allows all the necessary equipment to be placed on a standard rolling cart and was deployed in a PSE clinic examination room (2.4 × 2.4 m). A stairstep (14-cm height) was used for the graded exercise portion. The graded exercise was performed with a device prompt (“begin exercise”), with auditory prompts at 1-minute intervals to increase step frequency if possible. A metronome is used to provide cadence. The device provides an option for either timed or symptom-limited assessment. The timed session was selected for all participants. The timed device session requires a total of 6 minutes: 2 minutes of seated baseline resting data, 3 minutes of escalating exercise using the stairstep, and 1 minute of seated recovery data to generate a variety of individual measures of cardiac and pulmonary physiological data (Multimedia Appendix 1).

Figure 1. Performance of submaximal cardiopulmonary exercise testing requires (A) 2 minutes of calibration data in the seated position with a disposal mouthpiece connected to the device, (B) 3 minutes of graded exercise using a stair step, and 1 minute of recovery data in the seated position. The submaximal cardiopulmonary device (white and blue box) is visible on the cart, attached to a laptop with calculation software. Coauthor JF gave express permission for the use of his likeness in this simulated participant session.

Data Collection

Participants received height, weight, and vital sign measurements (heart rate, blood pressure, and pulse oximetry). Informed written consent was performed, and participants were instructed on smCPET (approximately 5 minutes).

Session time was measured from the beginning of pretest METs questionnaires until the termination of the smCPET recovery phase. A session time of ≤20 minutes would indicate that 24 high-risk participants could be screened per day per machine, permitting high-volume assessment. Session components included (1) a 7-question subjective METs assessment, (2) a 12-question DASI survey, and (3) a timed smCPET (6 minutes).

The modified Borg survey of perceived exertion was performed at session termination. After study interventions, a standard preoperative evaluation was completed, and the participant was discharged. A 24-hour postexperiment survey of minor and major complications and patient satisfaction was performed by

telephone (Multimedia Appendix 2). With the exception of the patient satisfaction survey, all survey instruments were adapted from prior publications [29-31]. DASI-estimated peak METs and peak VO_2 were calculated from individual participants' DASI scores using the recommended formula.

Statistical Analysis

End points were reported as continuous variables, described as mean (SD); ordinal variables, as median (IQR and range); and categorical variables, as number (%). Secondary end points were first analyzed using the Student *t* test (2-tailed) to compare differences in comparable measurements. Agreement between structured survey findings and smCPET comparable measurements was assessed using 2 approaches. First, a Pearson correlation coefficient was calculated to evaluate the strength and direction of the linear relationship, followed by a Bland-Altman analysis to assess agreement between methods, where differences between paired measurements were plotted against their means. Mean difference (MD) and 95% limits of agreement (LOAs) were calculated. All analyses were carried out on R (version 4.1.1; R Foundation for Statistical Computing). To reduce the introduction of bias, a complete case analysis for missing data was performed, where participants with missing data were excluded from the analysis of the respective end point. Similarly, dropouts were removed from the analysis. A *P* value of <.05 was accepted for significance.

Ethical Considerations

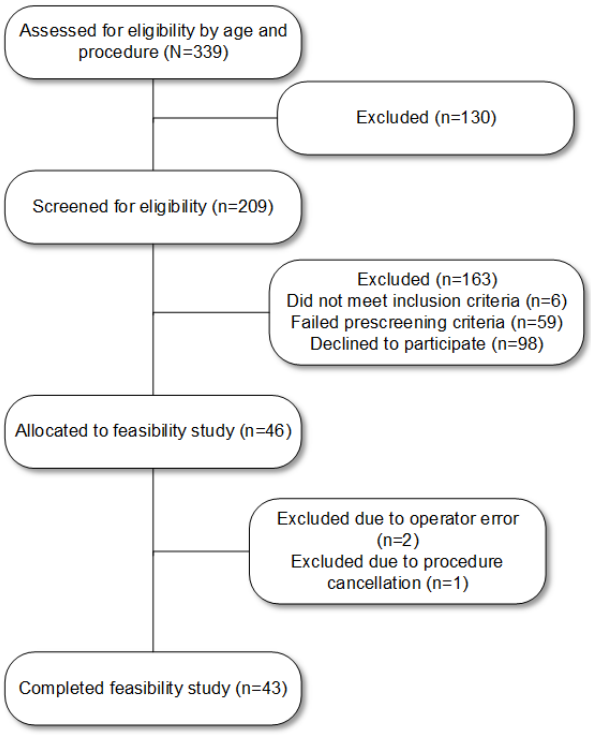
This study was performed in accordance with the principles of the Declaration of Helsinki. Approval was granted by the Yale University Institutional Review Board (IRB#2000033885). Informed consent was obtained from all participants included in the study. All provided data were deidentified prior to analysis to maintain participant privacy. No monetary compensation was provided to the participants. JF has given express written informed consent for the publication of his image in Figure 1.

Results

Participant Recruitment

We identified 209 (61.6%) out of 339 potential participants that met eligibility criteria; 6 (1.8%) did not meet the inclusion criteria, 59 (17.4%) failed the prescreening criteria, and 98 (28.9%) declined study participation (Figure 2). Initially, 46 participants were enrolled but 3 (7%) were excluded (operator error: n=2; surgery cancellation: n=1), for a final cohort of 43 participants.

Figure 2. A flow diagram of participant enrollment.



Baseline Characteristics

Trial participants had a median age of 68 (IQR 66-73, range: 60-86 years), 20 (47%) of 43 were female, and the mean BMI was 27.5 (SD 6.0) kg/m^2. Preoperative RCRI score was a median of 1 (IQR 1-1; range 1-2). Essential hypertension (22/43, 51%), hyperlipidemia (17/43, 39%), and solid tumor (25/43, 58%) were the most common premorbid conditions. A total of 22 (51%) out of 43 participants were former or active smokers. Major abdominal surgeries comprised 27 (63%) out of the 43 surgical procedures (Table 1).

All participants completed the smCPET session components. The mean peak respiratory exchange ratio was 0.88 (SD 0.12), consistent with submaximal effort (respiratory exchange ratio<1.05). The ventilatory threshold was achieved in 22 (51%) of 43 participants (mean 227.9, SD 21.9 seconds in those that achieved ventilatory threshold).

Table 1. Baseline demographical data of the study cohort (n=43).

Variable	Values
Age (years), median (IQR; range)	68 (66-73; 60-86)
Sex, n (%)	
Male	23 (54)
Female	20 (47)
BMI (kg/m^2), mean (SD)	27.5 (6.0)
Revised Cardiac Risk Index score, median (IQR; range)	1 (1-1; 1-2)
Preoperative comorbidities, n (%)	
Essential hypertension	22 (51)
Hyperlipidemia	17 (40)
Ventricular dysrhythmia	1 (2)
Congestive heart failure	1 (2)
Myocardial infarction	3 (7)
Cerebrovascular disease	1 (2)
Chronic obstructive pulmonary disease	3 (7)
Asthma	4 (9)
Obstructive sleep apnea	3 (7)
History of prior lung resection	1 (2)
Diabetes mellitus	7 (16)
Thyroid disorders	7 (16)
Solid tumor	25 (58)
Anemia	1 (2)
Social history, n (%)	
Smoking	
Ever	22 (51)
Active	4 (9)
Former	18 (42)
Never	21 (49)
Marijuana use (active)	4 (9)
Alcohol use	
Active	24 (56)
Former	16 (37)
Never	3 (7)
Cardiovascular medication use, n (%)	
Beta-blocker	14 (33)
Calcium channel antagonist	9 (21)
ACE/ARB[a] antagonist	16 (37)
Diuretic	12 (28)
Surgical categories, n (%)	
Abdominal major	27 (63)
Musculoskeletal major	4 (9)
Neurosurgical major	2 (5)

Variable	Values
Thoracic major	5 (12)
Other major	5 (12)

[a]ACE/ARB; angiotensin converting enzyme inhibitor/angiotensin receptor blockers.

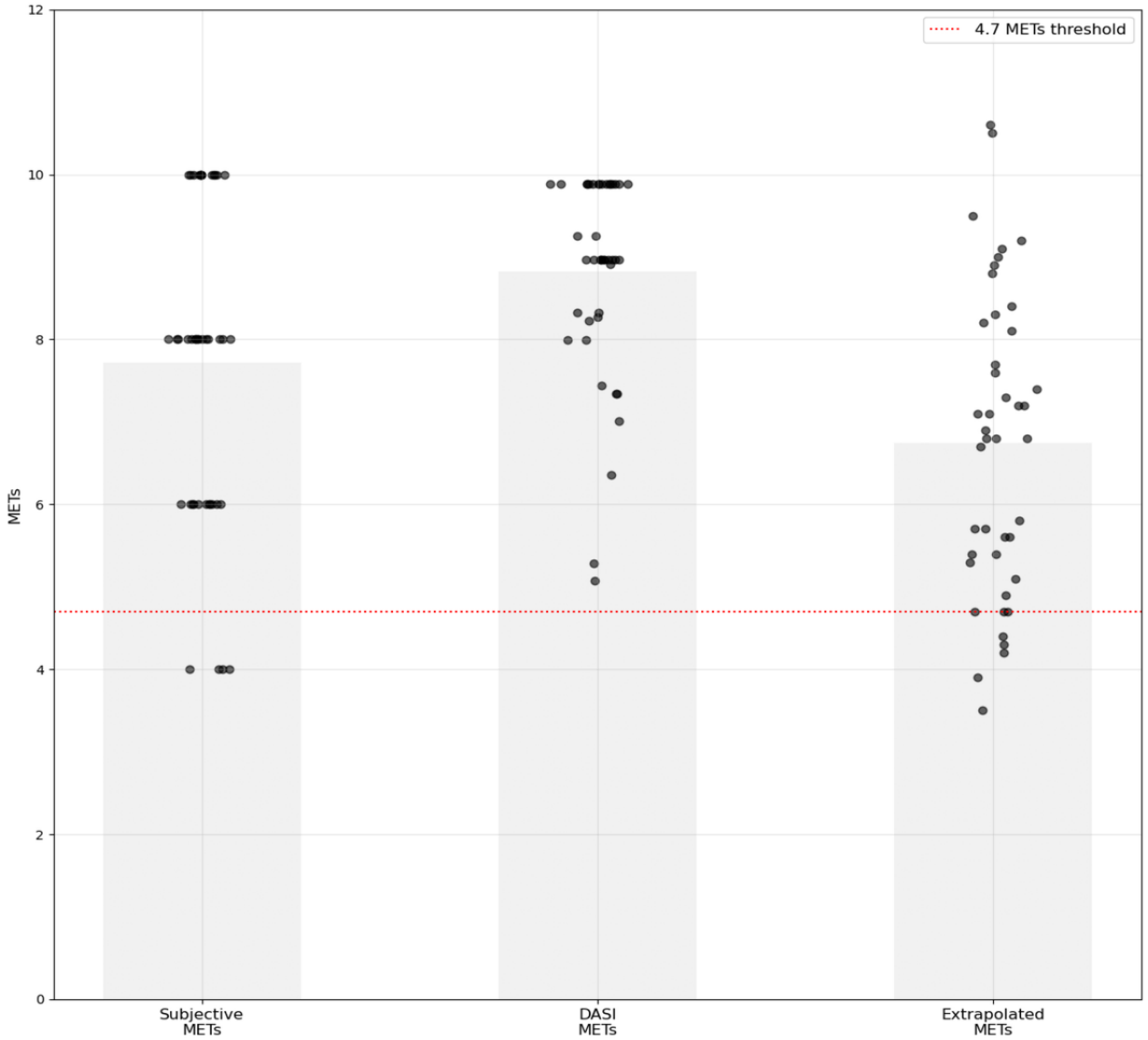
Primary End Points

The mean experimental session time was 16.9 (SD 6.8) minutes. The modified Borg survey score after experimental sessions was mean 5.35 (SD 1.8), corresponding to moderate perceived exertion. All 43 participants were reached for the 24-hour postexperiment survey. The median patient satisfaction (on a scale of 1=worst to 10=best) was 10 (IQR 10-10) for scheduling and 10 (IQR 9-10) for task execution. No major or minor complications associated with study testing were reported by participants. Operational efficiency was achieved within 15 experimental sessions among 4 study team members (3 physicians and 1 undergraduate researcher).

Secondary End Points

Average self-reported peak METs were higher when compared to smCPET equivalents (extrapolated peak METs; mean 7.6, SD 2.0 vs mean 6.7, SD 1.8; t_{42}=2.1; P<.001). DASI-estimated peak METs were higher when compared to the smCPET equivalents (extrapolated peak METs; mean 8.8, SD 1.2 vs mean 6.7, SD 1.8; t_{42}=7.2; P<.001). DASI-estimated peak VO_2 was higher than the smCPET equivalent (extrapolated peak VO_2; mean 30.9, SD 4.3 mL kg^{-1} min^{-1} vs mean 23.6, SD 6.5 mL kg^{-1} min^{-1}; t_{42}=2.1; P<.001). Figure 3 provides a comparison of values obtained from smCPET compared to structured survey–estimated peak METs and DASI-estimated peak METs.

Figure 3. Comparison of elicited METs from 2 structured survey instruments (subjective METs and DASI) compared to predicted peak METs from submaximal cardiopulmonary exercise testing (dotted line represents 4.7 METs). DASI: Duke Activity Status Index; MET: metabolic equivalent.



To analyze the congruency between the 3 study instruments, correlation and Bland-Altman analyses were performed. DASI-estimated METs showed a moderate positive correlation versus subjective METs (r=0.63; P<.001). Weaker correlations were observed with smCPET-derived extrapolated peak METs versus DASI and subjective METs (r=0.29; P=.06 and r=0.144; P=.36, respectively). DASI versus subjective METs showed an MD of 1.1 (SD 1.49; 95% LOAs –1.82 to 4.02) METs, while DASI versus smCPET-derived extrapolated peak METs showed larger discrepancies with an MD of 2.07 (SD 1.86; 95% LOAs –1.58 to 5.73) METs. The comparison between subjective METs and smCPET-derived extrapolated peak METs showed intermediate systematic bias with the widest LOAs (MD 0.97, SD 2.43 METs; 95% LOAs –3.80 to 5.75). When comparing DASI and smCPET-derived extrapolated peak VO_2 values, a positive MD was observed, indicating that DASI estimates were consistently higher (MD 7.23, SD 6.54 mL kg^{-1} min^{-1}; 95% LOA –8.11 to 21.12) and showed poor agreement (r=0.28; Multimedia Appendix 3).

Discussion

Principal Findings

Integration of brief smCPET in a high-volume PSE clinic was feasible as measured by the primary end points of session time, patient satisfaction with smCPET task execution, perceived exertion, and session scheduling. The operational efficiency of study team members was acceptable within 15 experimental sessions. Finally, smCPET measures of peak METs and VO_2 were significantly lower, when compared to comparable structured survey results.

Mean session time, which included the subjective METs survey, DASI, and 6-minute smCPET session, was 16.9 (SD 6.8) minutes, with progressive improvement over the study time period as operators (n=4) became facile with the study instrument (Multimedia Appendix 4). It is important to note that smCPET comprised 6 minutes of the session time, shorter than reported times with conventional CPET (15-20 min/session) [32]. In high-volume PSE, this may be advantageous, as patients are often seen on short notice for preoperative evaluation. Participants were able to flexibly arrange smCPET around other clinic appointments, decreasing study participants' time constraints. This likely enhanced our high satisfaction score for scheduling. High patient satisfaction was observed with task execution and perceived exertion during smCPET. The tested device uses a stationary stairstep for graded exercise, which was frequently familiar to participants. The short duration of graded exercise (3 minutes) was not perceived by any participant as maximum exertion by the Borg survey, likely contributing to the high level of patient satisfaction. Second, the Borg score of <7 after smCPET suggests a reasonable probability of success when transitioning its use to patients with more severe comorbidities, or preoperative deconditioning. It is important to note that the ventilatory threshold, or anaerobic threshold, was not measurable in 50% of our cohort, suggesting that the brief graded exercise contributed to the reported exertion level and high participant satisfaction.

One of the goals of smCPET is to make precise cardiopulmonary evaluation more widely available and patient centered, advantages that are acknowledged by its increasing adoption in the routine assessment of heart failure and pulmonary hypertension. Consistent with large-scale CPET application in cardiovascular clinical trials, smCPET did not result in findings of major or minor complications despite encouraging participants to safely provide their best effort within the timed and graded exercise component [33]. This is reassuring, as early termination of preoperative CPET trials, due to participant fatigue, safety, or other considerations, has been reported to be approximately 11% [13]. However, we purposefully selected functionally independent participants with self-reported ≥4.6 METs, and expansion to patients who are less functionally independent may result in higher smCPET session failure rates. Regardless, the safety of smCPET has been suggested by its routine application to high-risk and frail populations with severe cardiopulmonary disease, suggesting that a wide spectrum of preoperative populations can be safely tested using smCPET [20,22,34].

The structured survey estimated METs were, on average, significantly higher than their smCPET equivalents. Using the subjective METs structured survey, 8 (19%) of 43 participants reported peak METs within 10% of smCPET extrapolated peak METs, 12 (28%) were underestimated by >10%, and 23 (53%) were overestimated by >10%, when compared to smCPET values. Brief smCPET identified that 8 (19%) out of 43 study participants had ≤4.6 extrapolated peak METs (peak VO_2 equivalent: 14 mL kg^{-1} min^{-1}), corresponding to a METs threshold associated with higher perioperative cardiovascular risk [1,4]. Furthermore, smCPET identified 9 (21%) out of 43 participants with an age-adjusted peak VO_2 of less than 20 mL kg^{-1} min^{-1}, corresponding to poor aerobic capacity, and 2 (5%) with an extrapolated peak VO_2 less than 15 mL kg^{-1} min^{-1}, a measure frequently associated with higher perioperative risk [35]. These findings support prior descriptions of provider-driven and structured survey overestimation bias, highlighting the challenge of obtaining an accurate preoperative functional capacity assessment. Clinicians, when compared to CPET, had a 19.2% sensitivity in identifying low functional capacity (≤4 METs) [13,36]. Other investigations have also observed that preanesthesia evaluation calculation of self-reported METs overestimate functional capacity when compared to CPET assessment [6]. DASI was also found to poorly predict participants with lower peak VO_2 [13,24,36]. In a cohort of participants that would not necessarily receive extensive preoperative assessment, given that 100% reported the ability to reliably climb 2 flights of stairs, this may suggest opportunities to identify and preemptively optimize unexpected cardiopulmonary impairments prior to surgical intervention.

Worldwide, value-based health care has been a significant priority, and conventional preoperative evaluation may increase overall testing costs without improving perioperative outcomes [37-39]. Implementing brief smCPET for individualized preoperative cardiovascular evaluation may improve the precision of preoperative cardiovascular risk assessment and may potentially curb excess preoperative cardiovascular testing

commonly associated with older age and patients with higher comorbidities [40-42]. However widespread adoption of this technology in the perioperative space will require (1) further evidence of smCPET predictive validity for perioperative outcomes, (2) characterization of optimal system processes for patient selection, and (3) justification of cost-benefit.

Study Limitations

Several study limitations limit generalizability to other populations. Selection bias should be acknowledged given that participants who volunteered for the study are likely to be more health-conscious than usual patients who undergo PSE. A measurement bias may be introduced into the study given that researchers may unconsciously influence participant performance on smCPET or interpret results differently based on unconscious expectations. Similarly, a recall bias is often introduced when using structured, interview-style questionnaires such as those used in our study. Instrument bias may similarly impact smCPET findings; however, this is substantially reduced by routine device calibration.

Confounding factors are similar, where participants with higher fitness levels would find it easier to adapt to the stairstep exercise challenge. Our inclusion criteria purposely selected participants with lower comorbidities to ensure successful participation rates for this feasibility study. We acknowledge that certain premorbid conditions and chronic medication usage may influence smCPET participants' performance, but we did not balance this factor in this exploratory study. Although CPET and smCPET predictive performance with cardiovascular perioperative morbidity and mortality has been previously published, our cohort is not yet powered for the assessment of perioperative outcomes with this device [19,23,43,44]. Finally, the finding of no device-related adverse events should be cautiously interpreted given the small sample size and the possibility of rare exercise-induced adverse events.

Conclusions

In summary, we observed that smCPET implementation was well accepted into the workflow of a high-volume PSE clinic. Operator efficiency with the smCPET instrument was rapid and achieved relative parity at 15 participant sessions. smCPET, when compared to usual session times for conventional CPET of 15-20 minutes, uses less than half the time (6 minutes), making it attractive for the purposes of precise but time-efficient preoperative evaluation of exercise tolerance. This feasibility analysis has (1) reinforced the operational integrity of our active study protocol assessing smCPET findings with perioperative outcomes and (2) affirmed satisfactory patient-centered outcomes with study procedures. Studies should further expand smCPET predictive validity to postoperative cardiopulmonary complications, assess cost-effectiveness, and develop optimal system processes for patient selection.

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Data Availability

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

Authors' Contributions

Study conception and design were performed by ZJC, PH, and RBS. The first draft of the manuscript was performed by ZJC, JC, JZ, and ABB. Data collection was performed by ZJC, JF, JL, and DA. Statistical analysis was performed by ZJC. Further manuscript editing was performed by all coauthors. All authors read and approved the final manuscript.

Conflicts of Interest

ZJC receives partial funding from Shape Medical Systems, Inc related to this work. RBS reports owning stock in Johnson and Johnson unrelated to this work. RBS reports that Yale University has received funding from Merck for a study in which he was involved, unrelated to this work. PH reported receiving research support grants from Edwards Lifesciences and consulting and/or royalty fees from Baudax Bio, Fire1Foundry, Cardiage LLC, and Edwards Lifesciences. All other authors have no competing interests.

Multimedia Appendix 1
A detailed description of the submaximal cardiopulmonary exercise testing device and its measures.
[DOCX File , 18 KB - periop_v8i1e65805_app1.docx]

Multimedia Appendix 2
Adapted subjective METs survey questions and 24 hour postsession minor and major adverse events survey. MET: metabolic equivalent.
[PDF File (Adobe PDF File), 237 KB - periop_v8i1e65805_app2.pdf]

Multimedia Appendix 3
Bland-Altman plots for the compared measures: (A) subjective METs versus smCPET-extrapolated peak METs showed a mean difference of 0.97 METs but the widest LOAs; (B) DASI–estimated peak METs versus smCPET-extrapolated peak METs showed a mean difference of 2.07 METs, the largest discrepancy; (C) DASI-estimated peak METs versus subjective METs showed a mean difference of 1.1 METs but narrower LOAs; and (D) DASI-estimated peak VO2 versus smCPET-extrapolated peak VO2 showed that DASI had consistently higher estimates, with a mean difference of 6.5 mL kg–1 min–1. DASI: Duke Activity Status Index; LOA: limit of agreement; mean diff: mean difference; MET: metabolic equivalent; smCPET: submaximal cardiopulmonary exercise testing; VO2: peak oxygen uptake.
[PDF File (Adobe PDF File), 136 KB - periop_v8i1e65805_app3.pdf]

Multimedia Appendix 4
Operator efficiency as a function of session time (y-axis), defined as performance of two structured functional capacity survey instruments and submaximal cardiopulmonary exercise testing, versus session number (x-axis).
[PNG File , 98 KB - periop_v8i1e65805_app4.png]

References

1. Fleisher LA, Fleischmann KE, Auerbach AD, Barnason SA, Beckman JA, Bozkurt B, et al. 2014 ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing noncardiac surgery: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. J Am Coll Cardiol 2014;64(22):e77-137 [FREE Full text] [doi: 10.1016/j.jacc.2014.07.944] [Medline: 25091544]
2. Lurati Buse GAL, Puelacher C, Gualandro DM, Genini AS, Hidvegi R, Bolliger D, et al. Association between self-reported functional capacity and major adverse cardiac events in patients at elevated risk undergoing noncardiac surgery: a prospective diagnostic cohort study. Br J Anaesth 2021;126(1):102-110 [FREE Full text] [doi: 10.1016/j.bja.2020.08.041] [Medline: 33081973]
3. Reilly DF, McNeely MJ, Doerner D, Greenberg DL, Staiger TO, Geist MJ, et al. Self-reported exercise tolerance and the risk of serious perioperative complications. Arch Intern Med 1999;159(18):2185-2192. [doi: 10.1001/archinte.159.18.2185] [Medline: 10527296]
4. Biccard BM. Relationship between the inability to climb two flights of stairs and outcome after major non-cardiac surgery: implications for the pre-operative assessment of functional capacity. Anaesthesia 2005;60(6):588-593 [FREE Full text] [doi: 10.1111/j.1365-2044.2005.04181.x] [Medline: 15918830]
5. Weinstein AS, Sigurdsson MI, Bader AM. Comparison of preoperative assessment of patient's metabolic equivalents (METs) estimated from history versus measured by exercise cardiac stress testing. Anesthesiol Res Pract 2018;2018:5912726 [FREE Full text] [doi: 10.1155/2018/5912726] [Medline: 30250484]
6. Nieves-Alonso JM, Méndez Hernández RM, Ramasco Rueda F, Planas Roca A. Estimated metabolic equivalents of task do not correlate with the maximal oxygen consumption of patients undergoing lung resection surgery. Rev Esp Anestesiol Reanim 2022;69(7):437-441. [doi: 10.1016/j.redare.2021.01.006] [Medline: 35869005]
7. Glaab T, Taube C. Practical guide to cardiopulmonary exercise testing in adults. Respir Res 2022;23(1):9 [FREE Full text] [doi: 10.1186/s12931-021-01895-6] [Medline: 35022059]
8. Loewen GM, Watson D, Kohman L, Herndon JE, Shennib H, Kernstine K, et al. Preoperative exercise Vo2 measurement for lung resection candidates: results of Cancer and Leukemia Group B Protocol 9238. J Thorac Oncol 2007;2(7):619-625 [FREE Full text] [doi: 10.1097/JTO.0b013e318074bba7] [Medline: 17607117]
9. Benzo R, Kelley GA, Recchi L, Hofman A, Sciurba F. Complications of lung resection and exercise capacity: a meta-analysis. Respir Med 2007;101(8):1790-1797 [FREE Full text] [doi: 10.1016/j.rmed.2007.02.012] [Medline: 17408941]
10. Hartley RA, Pichel AC, Grant SW, Hickey GL, Lancaster PS, Wisely NA, et al. Preoperative cardiopulmonary exercise testing and risk of early mortality following abdominal aortic aneurysm repair. Br J Surg 2012;99(11):1539-1546. [doi: 10.1002/bjs.8896] [Medline: 23001820]
11. Older P, Hall A, Hader R. Cardiopulmonary exercise testing as a screening test for perioperative management of major surgery in the elderly. Chest 1999;116(2):355-362. [doi: 10.1378/chest.116.2.355] [Medline: 10453862]
12. Argillander TE, Heil TC, Melis RJF, van Duijvendijk P, Klaase JM, van Munster BC. Preoperative physical performance as predictor of postoperative outcomes in patients aged 65 and older scheduled for major abdominal cancer surgery: a systematic review. Eur J Surg Oncol 2022;48(3):570-581 [FREE Full text] [doi: 10.1016/j.ejso.2021.09.019] [Medline: 34629224]
13. Wijeysundera DN, Pearse RM, Shulman MA, Abbott TEF, Torres E, Ambosta A, et al. Assessment of functional capacity before major non-cardiac surgery: an international, prospective cohort study. Lancet 2018;391(10140):2631-2640. [doi: 10.1016/S0140-6736(18)31131-0] [Medline: 30070222]
14. Struthers R, Erasmus P, Holmes K, Warman P, Collingwood A, Sneyd JR. Assessing fitness for surgery: a comparison of questionnaire, incremental shuttle walk, and cardiopulmonary exercise testing in general surgical patients. Br J Anaesth 2008;101(6):774-780 [FREE Full text] [doi: 10.1093/bja/aen310] [Medline: 18953057]

15. Ferguson M, Shulman M. Cardiopulmonary exercise testing and other tests of functional capacity. Curr Anesthesiol Rep 2022;12(1):26-33 [FREE Full text] [doi: 10.1007/s40140-021-00499-6] [Medline: 34840532]
16. Baba R, Nagashima M, Goto M, Nagano Y, Yokota M, Tauchi N, et al. Oxygen uptake efficiency slope: a new index of cardiorespiratory functional reserve derived from the relation between oxygen uptake and minute ventilation during incremental exercise. J Am Coll Cardiol 1996;28(6):1567-1572 [FREE Full text] [doi: 10.1016/s0735-1097(96)00412-3] [Medline: 8917273]
17. Hollenberg M, Tager IB. Oxygen uptake efficiency slope: an index of exercise performance and cardiopulmonary reserve requiring only submaximal exercise. J Am Coll Cardiol 2000;36(1):194-201 [FREE Full text] [doi: 10.1016/s0735-1097(00)00691-4] [Medline: 10898434]
18. Snowden CP, Prentis JM, Anderson HL, Roberts DR, Randles D, Renton M, et al. Submaximal cardiopulmonary exercise testing predicts complications and hospital length of stay in patients undergoing major elective surgery. Ann Surg 2010;251(3):535-541. [doi: 10.1097/SLA.0b013e3181cf811d] [Medline: 20134313]
19. Prentis JM, Manas DMD, Trenell MI, Hudson M, Jones DJ, Snowden CP. Submaximal cardiopulmonary exercise testing predicts 90-day survival after liver transplantation. Liver Transpl 2012;18(2):152-159 [FREE Full text] [doi: 10.1002/lt.22426] [Medline: 21898768]
20. Oakland HT, Joseph P, Elassal A, Cullinan M, Heerdt PM, Singh I. Diagnostic utility of sub-maximum cardiopulmonary exercise testing in the ambulatory setting for heart failure with preserved ejection fraction. Pulm Circ 2020;10(4):2045894020972273 [FREE Full text] [doi: 10.1177/2045894020972273] [Medline: 33282205]
21. Joseph P, Savarimuthu S, Zhao J, Yan X, Oakland HT, Cullinan M, et al. Noninvasive determinants of pulmonary hypertension in interstitial lung disease. Pulm Circ 2023;13(1):e12197 [FREE Full text] [doi: 10.1002/pul2.12197] [Medline: 36814586]
22. Bernstein EJ, Mandl LA, Gordon JK, Spiera RF, Horn EM. Submaximal heart and pulmonary evaluation: a novel noninvasive test to identify pulmonary hypertension in patients with systemic sclerosis. Arthritis Care Res 2013;65(10):1713-1718 [FREE Full text] [doi: 10.1002/acr.22051] [Medline: 23740875]
23. Woods PR, Bailey KR, Wood CM, Johnson BD. Submaximal exercise gas exchange is an important prognostic tool to predict adverse outcomes in heart failure. Eur J Heart Fail 2011;13(3):303-310 [FREE Full text] [doi: 10.1093/eurjhf/hfq187] [Medline: 21036777]
24. Hlatky MA, Boineau RE, Higginbotham MB, Lee KL, Mark DB, Califf RM, et al. A brief self-administered questionnaire to determine functional capacity (the Duke Activity Status Index). Am J Cardiol 1989;64(10):651-654. [doi: 10.1016/0002-9149(89)90496-7] [Medline: 2782256]
25. A feasibility study of the SHAPE™ test of aerobic fitness in older adults presenting for moderate to high-risk surgery. ClinicalTrials.gov. 2023. URL: https://clinicaltrials.gov/study/NCT05743673 [accessed 2025-01-21]
26. Ford MK, Beattie WS, Wijeysundera DN. Systematic review: prediction of perioperative cardiac complications and mortality by the revised cardiac risk index. Ann Intern Med 2010;152(1):26-35. [doi: 10.7326/0003-4819-152-1-201001050-00007] [Medline: 20048269]
27. Miller AD, Woods PR, Olson TP, Hulsebus ML, O'Malley KA, MacCarter D, et al. Validation of a simplified, portable cardiopulmonary gas exchange system for submaximal exercise testing. Open Sport Med J 2010;4(1):34-40. [doi: 10.2174/1874387001004010034]
28. Kim CH, Hansen JE, MacCarter DJ, Johnson BD. Algorithm for predicting disease likelihood from a submaximal exercise test. Clin Med Insights Circ Respir Pulm Med 2017;11:1179548417719248 [FREE Full text] [doi: 10.1177/1179548417719248] [Medline: 28757799]
29. Borg GA. Psychophysical bases of perceived exertion. Med Sci Sports Exerc 1982;14(5):377-381. [Medline: 7154893]
30. McAuley P, Myers J, Abella J, Froelicher V. Evaluation of a specific activity questionnaire to predict mortality in men referred for exercise testing. Am Heart J 2006;151(4):890.e1-890897. [doi: 10.1016/j.ahj.2005.09.017] [Medline: 16569555]
31. Bell EC, Cox NS, Goh N, Glaspole I, Westall GP, Watson A, et al. Oxygen therapy for interstitial lung disease: a systematic review. Eur Respir Rev 2017;26(143):160080 [FREE Full text] [doi: 10.1183/16000617.0080-2016] [Medline: 28223395]
32. Albouaini K, Egred M, Alahmar A, Wright DJ. Cardiopulmonary exercise testing and its application. Heart 2007;93(10):1285-1292 [FREE Full text] [doi: 10.1136/hrt.2007.121558] [Medline: 17890705]
33. O'Connor CM, Whellan DJ, Lee KL, Keteyian SJ, Cooper LS, Ellis SJ, et al. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA 2009;301(14):1439-1450 [FREE Full text] [doi: 10.1001/jama.2009.454] [Medline: 19351941]
34. Woods PR, Frantz RP, Taylor BJ, Olson TP, Johnson BD. The usefulness of submaximal exercise gas exchange to define pulmonary arterial hypertension. J Heart Lung Transplant 2011;30(10):1133-1142 [FREE Full text] [doi: 10.1016/j.healun.2011.03.021] [Medline: 21622009]
35. Kaminsky LA, Arena R, Myers J, Peterman JE, Bonikowske AR, Harber MP, et al. Updated reference standards for cardiorespiratory fitness measured with cardiopulmonary exercise testing: data from the Fitness Registry and the Importance of Exercise National Database (FRIEND). Mayo Clin Proc 2022;97(2):285-293 [FREE Full text] [doi: 10.1016/j.mayocp.2021.08.020] [Medline: 34809986]

36. Wijeysundera DN, Beattie WS, Hillis GS, Abbott TEF, Shulman MA, Ackland GL, Measurement of Exercise Tolerance before Surgery Study Investigators, et al. Integration of the Duke Activity Status Index into preoperative risk evaluation: a multicentre prospective cohort study. Br J Anaesth 2020;124(3):261-270 [FREE Full text] [doi: 10.1016/j.bja.2019.11.025] [Medline: 31864719]
37. World Economic Forum. Value in Healthcare: Laying the Foundation for Health System Transformation. Geneva, Switzerland: World Economic Forum; 2017.
38. Mahajan A, Esper SA, Cole DJ, Fleisher LA. Anesthesiologists' role in value-based perioperative care and healthcare transformation. Anesthesiology 2021;134(4):526-540. [doi: 10.1097/ALN.0000000000003717] [Medline: 33630039]
39. Beckerleg W, Kobewka D, Wijeysundera DN, Sood MM, McIsaac DI. Association of preoperative medical consultation with reduction in adverse postoperative outcomes and use of processes of care among residents of Ontario, Canada. JAMA Intern Med 2023;183(5):470-478 [FREE Full text] [doi: 10.1001/jamainternmed.2023.0325] [Medline: 36972037]
40. Ellenbogen MI, Drmanovic A, Segal JB, Kapoor S, Wagner PC. Patient, provider, and system-level factors associated with preoperative cardiac testing: a systematic review. J Hosp Med 2023;18(11):1021-1033. [doi: 10.1002/jhm.13206] [Medline: 37728150]
41. Kumar M, Wilkinson K, Li YH, Masih R, Gandhi M, Saadat H, et al. Association of a novel electronic form for preoperative cardiac risk assessment with reduction in cardiac consultations and testing: retrospective cohort study. JMIR Perioper Med 2024;7:e63076 [FREE Full text] [doi: 10.2196/63076] [Medline: 39269754]
42. Ferré F, Laurent R, Furelau P, Doumard E, Ferrier A, Bosch L, et al. Perioperative risk assessment of patients using the MyRISK digital score completed before the preanesthetic consultation: prospective observational study. JMIR Perioper Med 2023;6:e39044 [FREE Full text] [doi: 10.2196/39044] [Medline: 36645704]
43. Bédat B, Koliakos E, Demarchi MS, Perentes J, Licker MJ, Triponez F, et al. Ventilatory efficiency slope is associated with cardiopulmonary complications after thoracoscopic anatomical lung resection. Interact Cardiovasc Thorac Surg 2022;35(1):ivac039 [FREE Full text] [doi: 10.1093/icvts/ivac039] [Medline: 35157073]
44. Kallianos A, Rapti A, Tsimpoukis S, Charpidou A, Dannos I, Kainis E, et al. Cardiopulmonary exercise testing (CPET) as preoperative test before lung resection. In Vivo 2014;28(6):1013-1020 [FREE Full text] [Medline: 25398794]

Abbreviations

CPET: cardiopulmonary exercise testing
DASI: Duke Activity Status Index
LOA: limit of agreement
MD: mean difference
MET: metabolic equivalent
PSE: presurgical evaluation
RCRI: Revised Cardiac Risk Index
smCPET: submaximal cardiopulmonary exercise testing
VO_2: oxygen uptake

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Quantification of Metamorphopsia Using a Smartphone-Based Hyperacuity Test in Patients With Idiopathic Epiretinal Membranes: Prospective Observational Study

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Abstract

Background: Quality of vision in patients with idiopathic epiretinal membranes (iERMs) is closely linked to distorted vision (metamorphopsia), which is often underestimated in clinical settings. Current surgical decision-making relies heavily on visual acuity and optical coherence tomography findings, which do not adequately reflect the patient's functional vision or the severity of metamorphopsia. There is a clinical need for tools that can reliably quantify this symptom to improve patient outcomes and streamline care pathways.

Objectives: This study is the first to assess the use of a novel smartphone-based hyperacuity test (SHT) in quantifying metamorphopsia before and after surgical intervention for iERMs, comparing it with a conventional printed chart.

Methods: This prospective observational study included 27 patients with iERMs with symptomatic metamorphopsia detected on the Amsler grid scheduled for vitrectomy with membrane peeling. The SHT (Alleye, Oculocare Medical Inc) and the horizontal (MH) and vertical (MV) M-chart (Inami & Co, Ltd) tests were performed 3 times before and 3 months after surgery. Pre- and postoperative metamorphopsia scores, changes in distance-corrected visual acuity, optical coherence tomography biomarkers, and subjective perception of metamorphopsia were evaluated.

Results: The mean SHT score significantly (r=0.686; P<.001) improved from 55.2 (SD 18.9) before surgery to 63.5 (SD 16.3) after surgery while the improvement of the M-chart scores were insignificant (MH r=0.37, P=.06; MV r=0.18, P=.36). Pre- and postoperative SHT scores showed very weak and insignificant correlations with the MH, MV, and MH+MV scores. Both metamorphopsia tests showed good reliability (intraclass correlation coefficients >0.75).

Conclusions: The SHT showed a significant improvement in postoperative metamorphopsia scores, indicating that it could be a valuable tool for quantifying visual distortion in patients with iERMs. While discrepancies with M-chart results were observed, both tests demonstrated good reliability. Clinically, the SHT may offer a practical solution for monitoring metamorphopsia and guiding complex surgical decision-making, particularly in telemedicine settings. Its accessibility could improve patient management, potentially enhancing preoperative triaging and reducing unnecessary visits.

Trial Registration: ClinicalTrials.gov NCT05138315; https://clinicaltrials.gov/study/NCT05138315

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KEYWORDS

mobile health; smartphone; telemedicine; Alleye; M-chart; metamorphopsia; epiretinal membrane; vitrectomy with membrane peeling; visual acuity; home monitoring; hyperacuity test; hyperacuity; surgical intervention; distorted vision; vision; ocular pathology; ocular; retinal; retina; surgery; macular degeneration; tomography; vitrectomy; ophthalmology

Introduction

An epiretinal membrane (ERM) is a common disorder leading to a decrease in visual acuity and distorted vision, called "metamorphopsia" in later stages [1,2]. ERMs in the majority of cases are idiopathic with no identifiable cause; however, they may be secondary due to an already existing ocular pathology. Metamorphopsia, one of the leading symptoms of ERM, can

be detected with the Amsler grid or the metamorphopsia chart (M-chart; Inami & Co, Ltd); however, these tools, including the M-chart, are often not routinely used in clinical practice despite metamorphopsia's importance in surgical decision-making. Clinicians often do not routinely assess metamorphopsia despite its impact on surgical decisions, relying instead on visual acuity, which often fails to reflect the subjective and functionally significant experience of metamorphopsia. Visualization of the membrane and evaluation of microstructural retinal alterations are best achieved with optical coherence tomography (OCT) but do not fully capture the functional visual disturbances experienced by patients [3]. ERMs are surgically treated via vitrectomy and membrane peeling. The degree of postoperative metamorphopsia is difficult to predict and the quantification of metamorphopsia may be helpful to identify patients who may benefit the most from surgery.

Recently, the emergence of digital health solutions, particularly smartphone-based apps, has introduced new possibilities for accessible and practical tools to assess metamorphopsia. The Alleye app (Oculocare Medical Inc), a smartphone-based hyperacuity test (SHT) with Food and Drug Administration 510 (k) clearance, is the first mobile app to provide a quantitative metamorphopsia result. It is already in use for monitoring the progression of metamorphopsia in retinal diseases such as age-related macular degeneration [4,5]. Compared with the conventional printed M-chart for metamorphopsia quantification, the SHT provides a unified score that supports longitudinal monitoring, examines more retinal axes for a comprehensive assessment, and incorporates gamification to improve patient adherence [4,5]. This may make it a practical tool for continuous care, especially as patients with ERM require long-term monitoring with frequent checkups. The SHT's remote testing capability may reduce the need for in-person visits and support telemedicine pathways, aligning with modern trends in patient-centered health care. Its relevance in the presence of ERM has yet to be evaluated.

This study represents the first attempt to evaluate the SHT in patients with idiopathic epiretinal membranes (iERM) by correlating the SHT (Alleye app) to the conventional printed chart (M-chart) for metamorphopsia quantification before and after iERM surgery. It aims to explore whether the SHT can serve as a reliable, efficient tool for metamorphopsia measurement in a clinical setting. In addition, the study also investigated the correlation between the metamorphopsia scores and retinal OCT biomarkers as well as subjective perception of metamorphopsia.

Methods

Ethical Considerations

The study was approved by the ethics committee of the City of Vienna (approval no. EK21-027-0321) and the Austrian Agency for Health and Food Safety. All research activities were conducted in accordance with institutional and national guidelines and complied with the Declaration of Helsinki and the Good Clinical Practice guidelines of the European Union. This study was registered at ClinicalTrials.gov with the identification number NCT05138315. Written informed consent was obtained from all participants before their enrollment in the study. All participants were fully informed about the nature of the study, and they had the opportunity to opt out at any time. Participant data were pseudonymized and deidentified to ensure confidentiality. Strict protective measures were in place to safeguard all participant information throughout the study. No financial compensation was provided to participants for their involvement in the study and participation was entirely voluntary. No images of identifiable individuals are included in the manuscript.

Study Design and Patients

This prospective observational study was conducted at the department of ophthalmology of the Hanusch Hospital, Vienna, Austria. The study included 30 eyes of 30 patients who met the inclusion criteria and were scheduled for membrane peeling with vitrectomy for iERM. Eligibility criteria included the presence of iERM, age above 18 years, written informed consent, best distance-corrected visual acuity (DCVA) ≤1.0 logMAR and metamorphopsia detected on the Amsler grid. Patients diagnosed with other macular disorders including age-related macular degeneration or participants who had undergone previous intraocular surgery except for uncomplicated cataract surgery were excluded from the study.

Preoperative examinations and the 3 months postoperative follow-up were performed by the team of the Vienna Institute for Research in Ocular Surgery, including an ophthalmologist (CL). Study-related ophthalmic examinations included slit lamp biomicroscopy, retinal examination, DCVA Early Treatment Diabetic Retinopathy Study (ETDRS), metamorphopsia testing (Amsler grid, SHT, and M-charts), and spectral-domain (SD)-OCT with the CE-certified Spectralis OCT (Heidelberg Engineering). The SD-OCT images were obtained using the fast scan protocol (25 sections, 240 µm, 30° angle, 0.75 D focus, AUTO 71 sensitivity, 100% IR power, OCT Volume mode, and high-speed rate of 8.8/s). Apart from these examinations, slit lamp biomicroscopy and SD-OCT were routinely performed in the outpatient department 1 week and 1 month after surgery.

Surgical Procedure

All patients included into this study were operated by the same surgeon. Surgery included a 23-gauge pars plana vitrectomy and membrane peeling in all cases. For visualization of the ERM and internal limiting membrane (ILM), chromovitrectomy was performed with a trypan blue and brilliant blue G-based dye (MembraneBlue Dual; DORC). The ERM peeling was performed using an end-gripping forceps. Peeling of the ILM was performed as a second step in all cases where it had not been removed en bloc with the ERM. A restaining has been performed in all patients to identify and peel ILM residues. If air tamponade was needed, a complete fluid-to-air exchange was performed at the end of surgery and patients were advised to postoperative prone positioning for 24 hours. Gas tamponade (SF6 or C3F8) was used only in cases with coexistent peripheral retinal breaks.

Metamorphopsia Tests

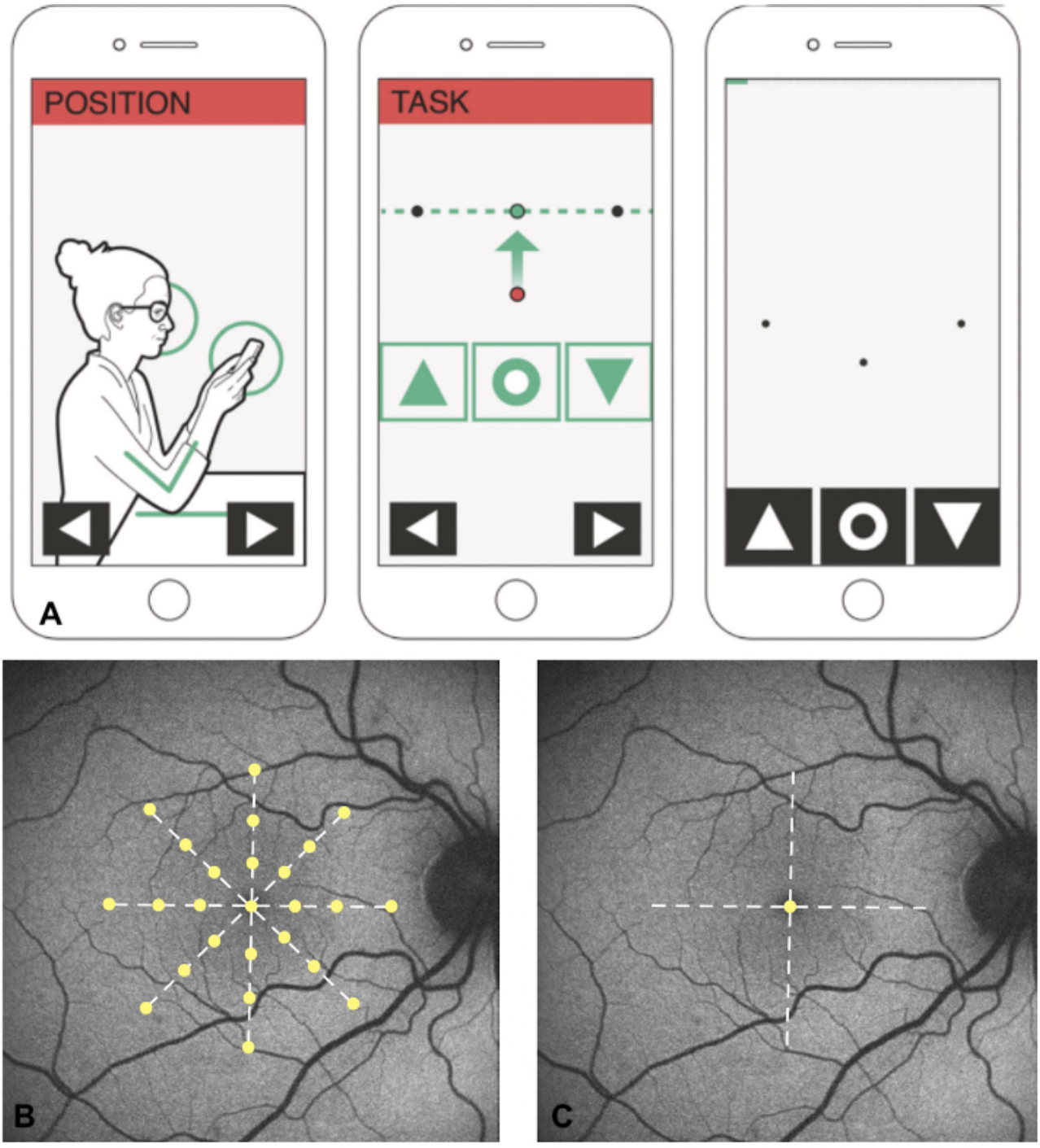
The main outcome variables in this study are the preoperative and 3 months postoperative mean SHT scores and mean M-chart scores. Both the M-chart and the SHT were consecutively performed 3 times before surgery and 3 months after surgery. The mean scores were used for statistical analysis and reliability of the 3 test repetitions was assessed. Detection of metamorphopsia on the Amsler grid was also included. The Amsler test was performed only once before and after surgery, as it provides a simple yes or no answer and was used as an inclusion criterion for the study. During the metamorphopsia examinations the eye not being tested was covered. In case patients needed reading glasses for near vision, they were asked to wear their own glasses or received a suitable near addition. All metamorphopsia examinations were tested with about 30-cm distance from the face and iPad rotation was standardized to a horizontal alignment.

For the Amsler examination, the participants were asked to fixate on the central dot of the grid and evaluate whether the lines are straight and parallel and whether the squares are regular and equal in size. If any of these characteristics were mentioned, the Amsler test was positive.

The M-chart was performed 3 times both in horizontal (MH score) and vertical (MV score) planes. The examiner alternated between the 2 positions to get more objective scores. The test has 19 dotted lines with dot intervals between 0.2º and 2.0º visual angles. The patients were shown these dotted lines beginning with 0º until the minimum visual angle needed to cause the metamorphopsia to disappear being the score.

The SHT (Alleye app) software can be downloaded on Apple iOS devices or Google Play. The SHT was consecutively performed 3 times and the testing procedure before and after surgery was the same. The patients received an oral explanation of the examination aided by the “training” option on the app. The eye not being tested was covered. The patient held the iOS device (iPad) and the task of the SHT was to align the central dot on an imaginary straight line between the paracentral points by tapping the arrow keys (Figure 1). This assignment was repeated 12 times in 4 different axes until the test was completed and the patient received a score between zero and 100. A higher score should be indicative of less metamorphopsia in contrast to the M-chart where a higher score should indicate more pronounced metamorphopsia. The SHT covers 4 axes with fixation dots at different positions while the M-chart covers 2 axes with a central single fixation dot (Figure 1).

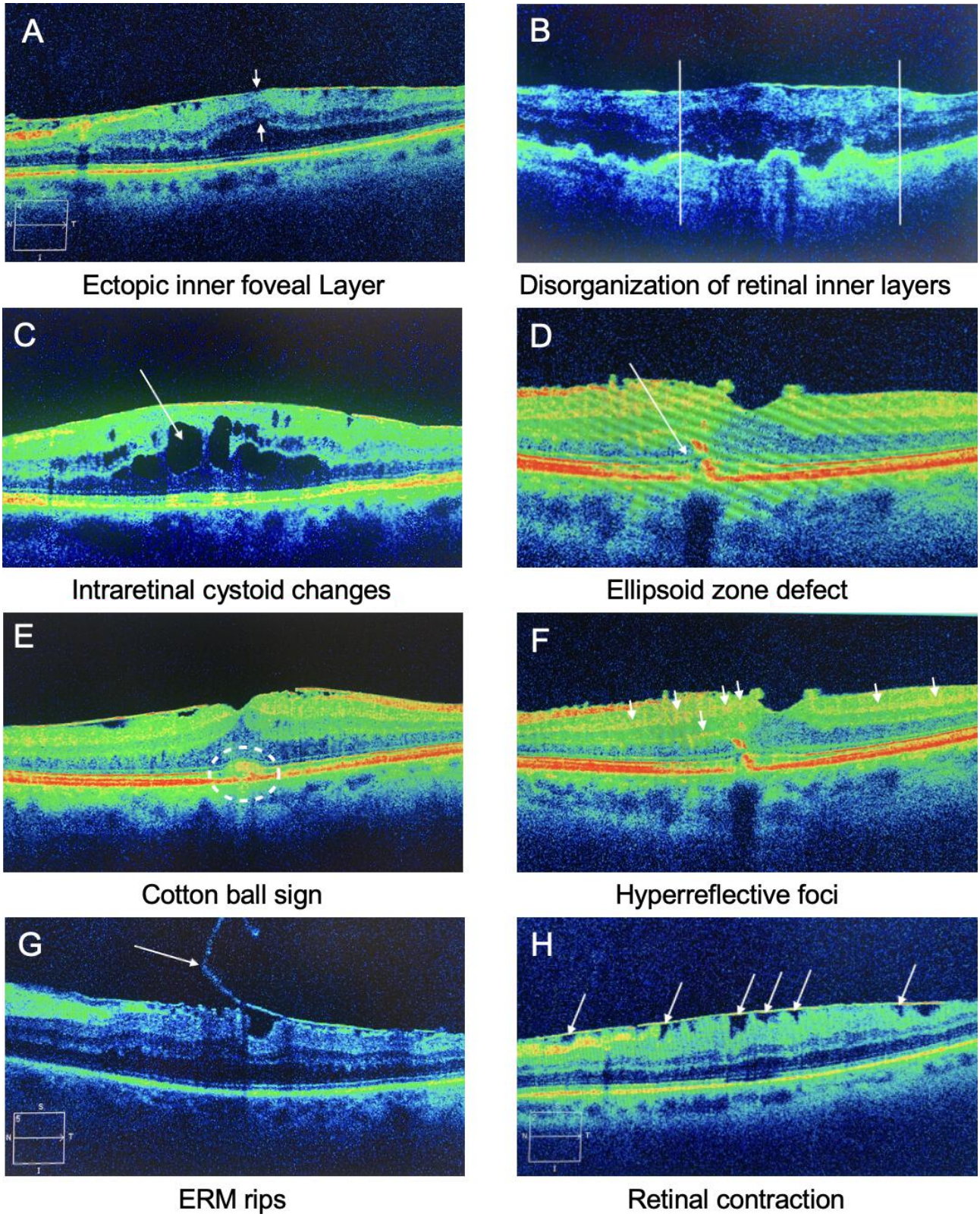
Figure 1. Correct positioning of the smartphone-based hyperacuity test (SHT) and alignment of the central dot on an imaginary straight line between the paracentral points (A) [6]. Four axes examined 3 times by the SHT with the target dot placed at different positions (B) compared with the M-chart with the horizontal and vertical axis and a central fixation dot (C) [7].



SD-OCT Biomarker Evaluations

As a secondary outcome this study evaluated the correlation of metamorphopsia scores and OCT biomarkers. OCT biomarkers are specific changes in retinal morphology with possible influence on postsurgical outcome. The preoperative SD-OCT images were evaluated by 2 independent graders (AD and SA) who were ophthalmology residents trained for OCT diagnosis. The readings of the 2 readers were compared and in case of discrepancies, the third reader, an experienced retina specialist made a final decision. The images were screened regarding the presence or absence of the following SD-OCT biomarkers: ectopic inner foveal layer, disorganization of retinal inner layers, intraretinal cystoid changes, ellipsoid zone defect, cotton ball sign, hyperreflective (HR) foci, ERM rips, and retinal contraction (Figure 2). Central macular thickness was also included in the analysis.

Figure 2. Spectral-domain optical coherence tomography (SD-OCT) biomarkers A–H (pictures taken and modified by Amon D). (A) Ectopic inner foveal layer is the presence of a continuous hypo- or hyperreflective lamina expanding from the inner nuclear layer and inner plexiform layer over the foveal zone as indicated by the arrows. (B) Disorganisation of retinal inner layers is present when the borders between the inner retinal layers are not recognisable as indictated between the two lines. (C) Intraretinal cystoid changes are fluid accumulations within the retina that can be recognised as hyporeflective spaces on OCT scans as indicated by the arrow. (D) The ellipsoid zone (EZ) is a hyperreflective region built between the interface of inner and outer photoreceptor segments and disruption can be seen as discontinuation of the hyperreflective EZ band as indicated by the arrow. (E) Cotton ball sign is defined as a round or diffuse hyperreflective area between the EZ and the interdigitation zone within the centre of the fovea as indicated by the circle. (F) Hyperreflective foci appear as small, highly reflective dots scattered within different layers of the retina as indicated by the arrows. (G) Epiretinal membrane rips are depicted as a torn edge of the ERM with a scrolled flap as indicated by the arrow. (H) Retinal contraction appears as wrinkling of the underlying retina caused by contraction of the ERM as indictaed by the arrows. ERM: epiretinal membrane.



Subjective Perception of Metamorphopsia

This study additionally tried to quantify the subjective perception of metamorphopsia using a telephone questionnaire. We postoperatively asked patients to grade their pre- and postoperative perception of metamorphopsia on a scale ranging from "0" indicating no distortion to "5" indicating severe distortion. Correlations between the subjective grades and standardized metamorphopsia scores were evaluated.

Statistical Analysis

Statistical analyses were conducted using SPSS (version 28; IBM SPSS Statistics). Level of significance was defined as a *P* value below .05. The Shapiro-Wilk test was used to test for normality. Reproducibility for the SHT and M-chart test was evaluated using intraclass correlation coefficients (ICCs) between 3 consecutive measurements pre- and postoperatively. We used the interpretation by Koo and Li [8] suggesting that ICC values below 0.5 are indicative of poor reliability, values between 0.5 and 0.75 are indicative of moderate reliability, values between 0.75 and 0.9 are indicative of good reliability, and values greater than 0.90 are indicative of excellent reliability. Correlations between the mean (mean of 3 examinations) SHT scores, mean MH, mean MV, the sum of mean MH and mean MV (MH+MV mean), and DCVA were calculated with a bivariate correlation. Paired 2-tailed *t* tests were applied to analyze the potential difference between preoperative and postoperative SHT and M-chart scores as well as DCVA. The *t* tests and bivariate correlation were used for the evaluation of the relationship between metamorphopsia scores and postoperative positive Amsler test, OCT biomarkers, and subjective metamorphopsia scores. Correlation coefficients were calculated using the Pearson correlation (*r*). Classification of the magnitude of correlation by Wuensch and Evans [9] was used interpreting an *r* value below 0.20 as very weak, *r* values between 0.20 and 0.39 as week, *r* values between 0.40 and 0.59 as moderate, *r* values between 0.60 and 0.79 as strong, and *r* value above 0.80 as very strong correlation.

Results

Demographic Data and Visual Acuity

A total of 30 patients were included into this study. Three of the 30 patients who had undergone preoperative examinations and surgery for iERM were lost to postoperative follow-up as they did not wish to participate in the postoperative study examinations and were therefore excluded from the final analysis. The mean age of our patient cohort was 71.2 (SD 8.2) years (Table 1). Regarding lens status, 12 patients were pseudophakic preoperatively and 15 were phakic preoperatively. Of the 15 preoperative patients with phakia, 12 patients underwent combined phacovitrectomy. Surgery resulted in a mean DCVA change of 15.3 (SD 9.3) ETDRS letters, with a minimum of −7 letters and a maximum change of 35 letters (*P*<.001; Table 2). The mean preoperative DCVA was 62.3 (SD 11.6) ETDRS letters compared with the mean postoperative DCVA with 77.6 (SD 8.2) letters. No significant correlations between the metamorphopsia scores and change in DCVA were found (Table 3).

Table . Demographic data (N=27).

Characteristics	Values
Age (years)	
Mean (SD)	71.2 (8.2)
Maximum	88
Minimum	54
Sex, n (%)	
Female	9 (33)
Male	18 (66)
Eye, n (%)	
Right eye	12 (44)
Left eye	15 (55)
Lens status, n (%)	
Preoperative phakia	15 (56)
Preoperative pseudophakia	12 (44)
Combined phacovitrectomy	12 (44)

Table . Visual acuity outcomes (Early Treatment Diabetic Retinopathy Study letters).

	Preoperative DCVA[a]	Postoperative DCVA	Change in DCVA
Mean (SD)	62.3 (11.6)	77.6 (8.2)	15.3 (9.3)
Maximum	82	90	35
Minimum	40	60	–7

[a]DCVA: distance-corrected visual acuity.

Table . Correlations between metamorphopsia scores and change in distance-corrected visual acuity.

	Pearson *r*	*P* value
SHT[a] mean preoperative	–0.17	.40
MH[b] mean preoperative	–0.16	.41
MV[c] mean preoperative	0.03	.87
MH+MV mean preoperative	–0.11	.59
SHT mean postoperative	–0.26	.18
MH mean postoperative	0.14	.49
MV mean postoperative	0.25	.22
MH+MV mean postoperative	0.20	.32

[a]SHT: smartphone-based hyperacuity test.

[b]MH: horizontal M-chart.

[c]MV: vertical M-chart.

Metamorphopsia Test Results

Change of Metamorphopsia After Surgery

Patients had significantly higher (r=0.69; P<.001) postoperative SHT scores compared with scores before surgery and a strong correlation between the 2 variables was found (Figure 3). The preoperative mean SHT score was 55.2 (SD 18.9) compared with 63.5 (SD 16.3) postoperatively resulting in a difference of 8.30 points. The improvement of M-chart scores, however, did not prove to be significant and the preoperative and postoperative values showed a weak correlation. The mean preoperative MH changed from 0.58 (SD 0.39) to 0.43 (SD 0.42) (r=0.37; P=.06) with a difference of 0.15, mean preoperative MV from 0.50 (SD 0.24) to 0.43 (SD 0.36) (r=0.18; P=.36) with a difference of 0.07, and mean preoperative MH+MV from 1.08 (SD 0.52) to 0.87 (SD 0.73) (r=0.25; P=.20) with a difference of 0.21 (Table 4).

Figure 3. Scatter plot depicting dots above the 45° line indicate patients who had improved smartphone-based hyperacuity test scores after epiretinal membrane surgery.

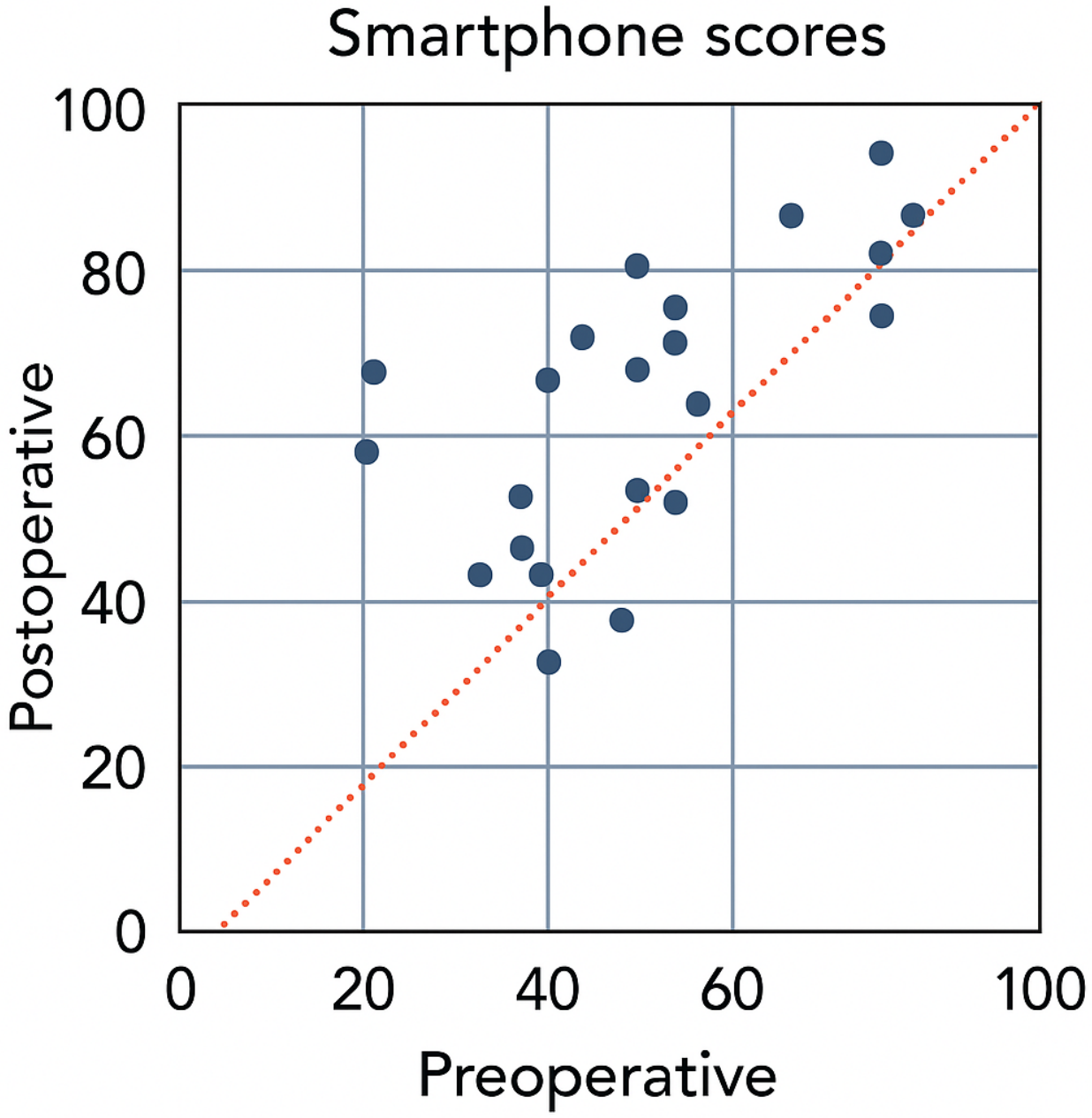


Table . Correlations between metamorphopsia scores.

Pairs of metamorphopsia scores	Mean (SD)	Pearson *r*	*P* value
Pair 1			
SHT[a] mean preoperative	55.22 (18.85)	0.69	<.001
SHT mean postoperative	63.52 (16.26)		
Pair 2			
MH[b] mean preoperative	0.58 (0.39)	0.37	.06
MH mean postoperative	0.43 (0.42)		
Pair 3			
MV[c] mean preoperative	0.50 (0.24)	0.18	.83
MV mean postoperative	0.43 (0.36)		
Pair 4			
MH+MV mean preoperative	1.08 (0.52)	0.25	.21
MH+MV mean postoperative	0.87 (0.73)		
Pair 5			
SHT mean preoperative	55.22 (18.85)	−0.18	.369
MH mean preoperative	0.58 (0.39)		
Pair 6			
SHT mean preoperative	55.22 (18.85)	0.01	.97
MV mean preoperative	0.50 (0.24)		
Pair 7			
SHT mean preoperative	55.22 (18.85)	−0.13	.51
MH+MV mean preoperative	1.08 (0.52)		
Pair 8			
MH mean preoperative	0.58 (0.39)	0.32	.10
MV mean preoperative	0.50 (0.24)		
Pair 9			
SHT mean postoperative	63.52 (16.26)	−0.14	.48
MH mean postoperative	0.43 (0.42)		
Pair 10			
SHT mean postoperative	63.52 (16.26)	−0.20	.32
MV mean postoperative	0.43 (0.36)		
Pair 11			
SHT mean postoperative	63.52 (16.26)	−0.18	.37
MH+MV mean postoperative	0.87 (0.73)		
Pair 12			
MH mean postoperative	0.43 (0.42)	0.74	<.001
MV mean postoperative	0.43 (0.36)		

[a]SHT: smartphone-based hyperacuity test.

[b]MH: horizontal M-chart.

[c]MV: vertical M-chart.

Reproducibility of Metamorphopsia Tests

The ICCs of all the metamorphopsia measurements showed good reliability (Table 5). The horizontal and vertical M-chart tests achieved higher scores than the SHT showing excellent reliability before and after surgery.

Table . Intraclass correlation coefficients of metamorphopsia tests.

Metamorphopsia test	Intraclass correlation coefficient
SHT[a] preoperative	0.87
MH[b] preoperative	0.96
MV[c] preoperative	0.94
SHT postoperative	0.82
MH postoperative	0.97
MV postoperative	0.93

[a]SHT: smartphone-based hyperacuity test.

[b]MH: horizontal M-chart.

[c]MV: vertical M-chart.

Correlations Between SHT and M-Chart

Correlations between the SHT and the M-chart were found to be very weak and not significant preoperatively as well as postoperatively. The correlation coefficients of the metamorphopsia scores and the corresponding levels of significance are listed in Table 4.

Correlation Between Metamorphopsia Scores and Amsler Grid

In 7 patients, metamorphopsia was not detected on the Amsler grid after surgery compared with 20 patients who still showed a positive postoperative Amsler test. The group of patients with a positive Amsler test after surgery showed significantly (r=−0.46; P=.02) worse postoperative SHT scores than the group without (Table 6). The mean SHT score of the patients with metamorphopsia detected on the Amsler grid after surgery was 59.2 (SD 15.3) compared with 75.7 (SD 12.9) of the patients with a negative Amsler test resulting in a difference of 16.7 between these groups. The group of patients with a postoperative positive Amsler test also showed significantly worse MV (r=0.39; P=.04) and MH+MV (r=0.39; P=.047) scores while the MH score was not significantly different between the groups (r=0.33; P=.09).

Table . Correlations between metamorphopsia scores and Amsler grid.

Postoperative	Amsler +	N	Mean (SD)	Pearson *r*	*P* value
SHT[a] score	Negative	7	75.9 (12.9)	−0.46	.02
	Positive	20	59.2 (15.3)		
MH[b] score	Negative	7	0.2 (0.3)	0.33	.09
	Positive	20	0.5 (0.4)		
MV[c] score	Negative	7	0.2 (0.3)	0.39	.04
	Positive	20	0.5 (0.4)		
MH+MV score	Negative	7	0.4 (0.5)	0.39	.047
	Positive	20	1.0 (0.7)		

[a]SHT: smartphone-based hyperacuity test.

[b]MH: horizontal M-chart.

[c]MV: vertical M-chart.

Correlation Between Metamorphopsia Scores and SD-OCT Biomarkers

Central macular thickness (r=−0.44; P=.02; r=−0.46; P=.02) and intraretinal cysts (r=−0.72; P<.001; r=−0.65; P<.001) proved to be significantly associated with pre- and postoperative SHT scores and HR foci showed a significant correlation with the postoperative SHT score (r=0.44; P=.02). Regarding the M-chart scores, the disorganization of retinal inner layers (r=0.68, P<.001; r=0.58, P=.002) and ellipsoid zone defect (r=0.49, P=.01; r=0.48, P=.01) showed significant associations with the preoperative vertical M-chart score (r=0.68; P<.001) and the preoperative MH+MV score (r=0.58; P=.002). The other biomarkers were not significantly associated with any of the metamorphopsia scores and correlations proved to be very weak to weak. Detailed results of the biomarker readings can be found in the Multimedia Appendix 1.

Correlation Between Metamorphopsia Scores and Subjective Metamorphopsia Perception

Out of 21 patients surveyed, 19 reported a subjective improvement in metamorphopsia after surgery. The mean subjective scores improved by 2.2 points from 3.7 (SD 0.9) preoperatively to 1.5 (SD 1.3) postoperatively, showing a significant correlation (r=0.55; P=.01;). The preoperative (r=0.58; P=.01) and postoperative (r=0.81; P<.001) subjective metamorphopsia scores correlated significantly with postoperative M-Chart scores, but not significantly with SHT scores. Patients with postoperative positive Amsler tests reported significantly more severe subjective metamorphopsia scores (r=0.49; P=.02).

Discussion

Principal Findings

The aim of this study was to estimate the correlation between the SHT (Alleye app) and a conventional printed chart (M-chart) for metamorphopsia quantification before and after vitrectomy with membrane peeling for patients with iERM.

The SHT has mainly been studied for other retinal diseases and this study is the first to ever investigate the SHT in patients with iERM. It is the first mobile app to provide a quantitative metamorphopsia result. Contrary to the vertical and horizontal scores of the M-chart, the SHT provides a single quantitative score including 4 axes instead of 2.

The SHT scores significantly (r=0.69; P<.001) improved from 55.2 (SD 18.9) preoperatively to 63.5 (SD 16.3) after surgery resulting in an improvement of 8.3 points. The mean postoperative M-chart scores also improved after surgery, but were not statistically significant. The significant improvement of postoperative SHT scores suggests that patients with metamorphopsia due to iERM may benefit from surgery and the SHT can potentially be a software to quantify these results. Clinicians routinely do not test for metamorphopsia, despite its relevance for surgical decisions. Kinoshita et al [3,10] found a significant correlation between preoperative and postoperative M-chart scores proposing the consideration of surgery before severe worsening of metamorphopsia and a stage where it cannot be completely resolved. Testing macular function with visual acuity alone is often insufficient, as it fails to capture metamorphopsia, a subjective perception that is challenging to measure objectively. In our study, both the SHT and the M-chart demonstrated good reliability, as shown by their ICCs. However, the SHT may offer a more comprehensive assessment by covering 4 retinal axes, whereas the M-chart evaluates only 2. It is important to note that this study did not aim to test the superiority of the SHT over the M-chart but was a first attempt to evaluate the SHT in patients with iERM aiming to identify a practical tool that enables efficient and reliable measurement of metamorphopsia in clinical practice. The tests provide complementary but distinct insights into the severity of metamorphopsia, and their scores should not be considered directly comparable. The SHT is primarily used for detecting macular edema. This was the first attempt to evaluate the SHT in patients with ERM, providing initial insights into its potential use for this condition. In addition, the SHT, being a more practical and digital tool, could offer significant advantages in clinical practice. The SHT's ability to provide a unified score, enable remote monitoring, and incorporate gamification may improve patient engagement and reduce unnecessary clinic visits.

Of interest, the results of our analysis showed a very weak and not significant association between the SHT and the M-chart. Since the M-chart includes only 2 axes, horizontal and vertical, while the SHT includes the horizontal, vertical, and oblique axes, there is a discrepancy between the examined retinal axes. A key limitation of this study is the inability to analyze individual horizontal, vertical, and oblique axes measured by the SHT, which could allow for a more direct comparison with the M-chart, which evaluates horizontal and vertical axes separately. To minimize the discrepancy between the examined axes, we combined the 2 M-chart axes and calculated the sum of the mean vertical M-chart score and mean horizontal M-chart score. The 2 axes included in 1 score, however, also did not significantly correlate with the SHT score. Analyses of the SHT's individual axes might help clarify whether the weak correlation observed between the 2 tests is due to differences in the retinal areas examined. However, this was not feasible due to the proprietary design of the SHT, which provides only a combined score rather than axis-specific data. This limitation has been communicated to the developers, and we recommend incorporating functionality for individual axis analysis in future updates to enhance the SHT's scientific use. Despite this constraint, studies have demonstrated the reliability and practicality of the SHT. Studies reported high ICCs, diagnostic reliability for monitoring macular function, good patient adherence and usability for remote monitoring, and a low threshold for use, making it accessible and effective in real-world settings [4,11-13]. These advantages position the SHT as a practical alternative for assessing metamorphopsia in clinical practice, even without detailed axis-specific data. In addition, the SHT's combined score approach may simplify the interpretation of metamorphopsia as a general symptom of macular dysfunction, supporting its use in patient-centered care. Nevertheless, the mapping of distorted vision to a specific axis may additionally be of use since the horizontal M-chart score tends to improve to a larger extent than the vertical score that arises in later stages suggesting that once the vertical distortion is present, it is less likely to resolve compared with horizontal metamorphopsia [10]. Our study as well as the study by Kinoshita et al [3,10] showed that the baseline MH score was higher than the MV score. The vertical plasticity may be greater than that for the horizontal retina since the axons of the retinal ganglion cells run horizontally rather than vertically in the posterior pole in addition to the optic disc that might also reduce horizontal displacement in the posterior pole. Since vertical contraction is perceived as horizontal metamorphopsia and vice versa, the horizontal M-chart scores might be higher than the vertical scores [14,15]. The prognostic properties of individual metamorphopsia axes may be of importance in advising patients and giving them a realistic prognosis for postoperative outcomes. Schmid et al [4] claimed that when using the SHT, patients actively need to align a central point on an imaginary straight line and the outer points remain stable in the paracentral visual

field thereby ensuring that patients fixate on the moving dot and avoiding saccades to the outer areas. This should ensure a proper fixation for metamorphopsia testing. In passive tests such as the M-chart or the Amsler grid, where patients are shown different lines or grids and asked about their perception of them, fixation on paracentral areas is more likely, which may lead to the conclusion of lower reproducibility. In our study, however, all metamorphopsia tests showed a good reliability (Table 5) and the M-chart even achieved higher scores than the SHT proving excellent reliability before and after surgery. This underlines the findings by Matsumoto et al [16] reporting good reliability of M-charts and intraindividual variation to be within 1 line (±0.1 score).

Regarding associations of metamorphopsia scores with the Amsler grid, almost a third of the patients had improved metamorphopsia after surgery when testing with the Amsler grid. The group of patients with a positive Amsler test after surgery showed significantly worse postoperative SHT scores (r=−0.46; P=.02), MV scores (r=0.40; P=.04), and MH+MV scores (r=0.39; P=.047) than the group without. The results suggest that a persistent positive Amsler test may be a reliable predictor of poor SHT scores and therefore outcome.

Postoperative mean visual acuity improved by 3 lines and no significant correlation between DCVA and metamorphopsia was found which is in accordance with literature [3,17-19]. Lens status revealed that 12 patients were pseudophakic preoperatively, while 15 were phakic, of whom 12 underwent combined phacovitrectomy. Since visual acuity was not the main focus of this study, the lens status was not further emphasized in the analysis. Metamorphopsia seems to be independent of visual acuity and an important symptom contributing to quality of vision.

Regarding the OCT biomarkers, a larger central macular thickness, the presence of intraretinal cysts, and HR foci were significantly associated with postoperative SHT scores. These findings suggest that these biomarkers may have prognostic properties for metamorphopsia outcomes after ERM surgery. This is particularly relevant in clinical decision-making, as identifying OCT biomarkers associated with postoperative visual distortion could help guide surgical timing and set realistic patient expectations. To validate our findings, larger studies and longer follow-up periods are necessary. These studies should further investigate the relationship between objective metamorphopsia scores, OCT biomarkers, and subjective metamorphopsia perception. Such research could refine the prognostic use of OCT findings and contribute to the development of comprehensive assessment tools that integrate objective measures with subjective experiences. Ultimately, this could lead to more tailored surgical interventions and improved patient outcomes in ERM management.

During the postoperative follow-up visits of our study, we frequently examined content patients stating that their visual distortion had highly improved and asking whether their scores had improved in an objective manner. This observation underlined the importance of an individual's perception of vision. Our study demonstrated that subjective perception of metamorphopsia in patients with iERM can improve with surgery and patients with a higher preoperative degree of metamorphopsia also suffer from more severe metamorphopsia postoperatively. Detailed results on the subjective outcomes are given in Multimedia Appendices 2 and 3.

An important aspect to consider with the SHT is the possibility for patients to quantitatively monitor the progression of metamorphopsia at home in a comfortable setting and compare their results with their last examinations. Interactive tests and the gamification of home-monitoring tasks can lead to a higher patient motivation to take ownership of their eye health as well as better protection of sight [20,21]. Smartphone apps can also serve as a tool for patients to remotely view their health record information [22]. The newest version of the SHT is designed to serve as a digital companion for patients to have a better overview of their retinal disease and keep them motivated to follow the treatment program. The novel features of the SHT enable patients and clinicians to collect data, manage appointments, and document diagnoses, medical results, visual acuity, injections, and subjective visual impairment [23]. Since many people already own a smartphone, the implementation of the SHT is rather straightforward. In our study, we included a large age range between 54 and 88 years and none of the patients needed extra help to perform the SHT after a short introduction at the beginning of the test. It is important, however, that patients who do not qualify for home monitoring are not disadvantaged and do not receive insufficient care for their eye health. Research suggests that smartphone-based vision monitoring is accessible across diverse population groups with varying levels of digital proficiency and social deprivation, making it a viable and reliable tool for monitoring clinical progression [24].

Currently, no established thresholds exist to define clinically significant changes in SHT scores or to determine when patients should seek medical advice. Further studies are necessary to address these gaps and to establish evidence-based benchmarks for the SHT's use in clinical decision-making. Previous research has provided M-chart–based thresholds for surgical indications; however, these cutoff values have not been adopted in clinical practice. Kinoshita et al [3] suggested that preoperative MH scores between 0.5 and 1.7 or MV scores between 0.5 and 0.9 could indicate the need for surgery. While strict cutoff values may be challenging in individual cases, quantifying metamorphopsia can enhance the decision-making processes. The SHT can complement traditional tools by providing additional, objective data to support surgical planning, facilitate triaging, and monitor disease progression.

Compared with the conventional printed M-chart for metamorphopsia quantification, the SHT offers several advantages that align with modern, patient-centered health care approaches. The SHT provides a unified score that supports longitudinal monitoring and examines more retinal axes, offering a more comprehensive assessment of metamorphopsia. In addition, the incorporation of gamification enhances patient engagement and adherence, transforming a clinical task into an interactive and motivating experience for patients. These features may make the SHT a practical tool for continuous care, particularly for patients with ERM who require long-term monitoring with frequent checkups. Patients with ERM undergo follow-ups spanning several years, with frequent visits to

monitor disease progression or assess the need for surgical intervention. A reliable and easily accessible tool such as the SHT could serve as a valuable monitoring score to detect changes or dynamics in metamorphopsia over time. Its capability for remote testing can further reduce the need for in-person visits, supporting telemedicine pathways and addressing the increasing demand for accessible health care solutions. Moreover, the SHT can be particularly beneficial for patients in underserved areas, those with mobility limitations, or in regions with limited physician availability, ensuring broader access to effective disease monitoring. While the SHT has demonstrated its use in other retinal conditions, its relevance in the context of ERM has yet to be fully evaluated. These attributes suggest that the SHT could play a key role in the evolution of digital health tools for monitoring metamorphopsia and guiding complex surgical decision-making in patients with ERM.

This study represents a foundational step in evaluating the SHT's app in ERM, emphasizing the need for further research to validate its clinical relevance and establish its role in patient-centered ophthalmologic care.

Limitations

Limitations of this study include the small sample size and the limited follow-up time as metamorphopsia tends to improve for a longer period of about 12 months after ERM surgery and a small number of patients is a limitation for the validity of the test [3,10]. To date, it has unfortunately not been possible to retrieve the results of the individual axes of the SHT separately as it would be of great interest to depict what the diagonal planes measure and calculate their correlations with the horizontal and vertical planes of the M-Chart. Without this breakdown of SHT results, the hypothesis that the discrepancy in examined retinal axes may be a reason why the scores of the 2 tests did not significantly correlate with each other cannot be fully proven. Due to the exploratory nature of this study, we could not perform a formal sample size calculation. Another confounder of this study may be patient motivation and character as well as a learning effect with repeated testing. The potential influence of learning effects on repeated testing with the SHT and M-chart is an important consideration for interpreting the study findings. While we assessed test-retest reliability for both tools, we did not explicitly analyze learning effects. Previous research on the SHT, including a study by Faes et al [12], demonstrated its excellent usability with a median system usability score of 90. This indicates that most users found the app intuitive and easy to learn, suggesting that the influence of learning on SHT results may be minimal. Furthermore, the digital nature of the SHT, combined with its interactive and standardized testing process, reduces the likelihood of variability due to user fatigue or concentration, issues that are more likely to affect manual tools such as the M-chart. Incorporating design elements that prioritize user-friendly interfaces, as seen with the SHT, can help maintain adherence and reduce the impact of learning effects in mobile health tools. Future studies could further investigate the influence of learning on SHT performance. As not all patients were pseudophakic after surgery, the improvement of DCVA may have been influenced by concomitant cataract surgery; however, visual acuity was not a main outcome of this study. Our study was conducted at a single center and all surgeries were performed by the same retina surgeon thereby increasing reproducibility.

Conclusions

The study was the first to ever investigate the SHT in patients with iERM. We showed that quantitative data provided by the SHT significantly improved after membrane peeling suggesting that patients with metamorphopsia due to iERM can benefit from surgery, and this application may potentially be a software to quantify metamorphopsia in patients with iERM. The metamorphopsia scores of the SHT showed a very weak and insignificant association with the M-chart scores. It would be of great interest to depict what the diagonal planes of the SHT measure and calculate their correlations with the horizontal and vertical planes of the M-chart to validate whether the poor correlation between the 2 tests may be explained by their discrepancy in examined retinal areas. The SHT may serve as a practical, accessible, and patient-centered tool for monitoring metamorphopsia, supporting long-term care and decision-making for patients with ERM, particularly in telemedicine and underserved settings. While this study lays the groundwork for future research, further studies including the breakdown of metamorphopsia axes of the SHT as well as a larger sample size and longer follow-up period are required to validate our results.

Authors' Contributions

All authors collectively contributed to the conception of the study. JH was responsible for study design, methodology, data interpretation, and review of the manuscript. CL operated all patients and was responsible for data recruitment. OF co-designed the study and contributed to the manuscript. DA was involved in literature search, data recruitment, data analysis, and drafted the manuscript. MR, CP, NB, and AS were responsible for patient and data recruitment. All authors read, contributed to, and approved the final manuscript. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Spectral-domain optical coherence tomography biomarker readings of the pilot study.

[DOCX File, 15 KB - periop_v8i1e60959_app1.docx]

Multimedia Appendix 2
Correlations between preoperative spectral-domain optical coherence tomography biomarkers and preoperative metamorphopsia scores.
[DOCX File, 16 KB - periop_v8i1e60959_app2.docx]

Multimedia Appendix 3
Correlations between preoperative spectral-domain optical coherence tomography biomarkers and postoperative metamorphopsia scores.
[DOCX File, 16 KB - periop_v8i1e60959_app3.docx]

References

1. Mao J, Wu H, Liu C, et al. Changes in metamorphopsia, visual acuity, and central macular thickness after epiretinal membrane surgery in four preoperative stages classified with OCT B-scan images. J Ophthalmol 2019;2019:7931654. [doi: 10.1155/2019/7931654] [Medline: 31316825]
2. Díaz-Valverde A, Wu L. To peel or not to peel the internal limiting membrane in idiopathic epiretinal membranes. Retina (Philadelphia, Pa) 2018 Sep;38 Suppl 1:S5-S11. [doi: 10.1097/IAE.0000000000001906] [Medline: 29068917]
3. Kinoshita T, Imaizumi H, Okushiba U, Miyamoto H, Ogino T, Mitamura Y. Time course of changes in metamorphopsia, visual acuity, and OCT parameters after successful epiretinal membrane surgery. Invest Ophthalmol Vis Sci 2012 Jun 14;53(7):3592-3597. [doi: 10.1167/iovs.12-9493] [Medline: 22589432]
4. Schmid MK, Thiel MA, Lienhard K, Schlingemann RO, Faes L, Bachmann LM. Reliability and diagnostic performance of a novel mobile app for hyperacuity self-monitoring in patients with age-related macular degeneration. Eye (Lond) 2019 Oct;33(10):1584-1589. [doi: 10.1038/s41433-019-0455-6]
5. Brucker J, Bhatia V, Sahel JA, Girmens JF, Mohand-Saïd S. Odysight: a mobile medical application designed for remote monitoring-a prospective study comparison with standard clinical eye tests. Ophthalmol Ther 2019 Sep;8(3):461-476. [doi: 10.1007/s40123-019-0203-9] [Medline: 31346977]
6. Faes L, Islam M, Bachmann LM, Lienhard KR, Schmid MK, Sim DA. False alarms and the positive predictive value of smartphone-based hyperacuity home monitoring for the progression of macular disease: a prospective cohort study. Eye (Lond) 2021 Nov;35(11):3035-3040. [doi: 10.1038/s41433-020-01356-2] [Medline: 33414531]
7. Portugal T. Figure 3: normal fundus autofluorescence: uniform grayish signal in the fundus and a marked dark appearance in the optic nerve (absence of RPE) and retinal vessels (absorption of fluorescence by hemoglobin and other blood contents). URL: https://amdbook.org/content/figure-3-normal-fundus-autofluorescence-uniform-grayish-signal-fundus-and-marked-dark-appear [accessed 2023-06-04]
8. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. J Chiropr Med 2016 Jun;15(2):155-163. [doi: 10.1016/j.jcm.2016.02.012] [Medline: 27330520]
9. Wuensch KL, Evans JD. Straightforward statistics for the behavioral sciences. J Am Stat Assoc 1996 Dec;91(436):1750. [doi: 10.2307/2291607]
10. Kinoshita T, Imaizumi H, Miyamoto H, Katome T, Semba K, Mitamura Y. Two-year results of metamorphopsia, visual acuity, and optical coherence tomographic parameters after epiretinal membrane surgery. Graefes Arch Clin Exp Ophthalmol 2016 Jun;254(6):1041-1049. [doi: 10.1007/s00417-015-3147-3] [Medline: 26319984]
11. Schmid MK, Faes L, Bachmann LM, Thiel MA. Accuracy of a self-monitoring test for identification and monitoring of age-related macular degeneration: a diagnostic case-control study. Open Ophthalmol J 2018;12(19–28):19-28. [doi: 10.2174/1874364101812010019] [Medline: 29619125]
12. Faes L, Golla K, Islam M, et al. System usability, user satisfaction and long-term adherence to mobile hyperacuity home monitoring-prospective follow-up study. EYE (Lond) 2023 Mar;37(4):650-654. [doi: 10.1038/s41433-022-01959-x] [Medline: 35292773]
13. Gross N, Bachmann LM, Islam M, et al. Visual outcomes and treatment adherence of patients with macular pathology using a mobile hyperacuity home-monitoring app: a matched-pair analysis. BMJ Open 2021 Dec 23;11(12):e056940. [doi: 10.1136/bmjopen-2021-056940] [Medline: 34949632]
14. Arimura E, Matsumoto C, Okuyama S, Takada S, Hashimoto S, Shimomura Y. Retinal contraction and metamorphopsia scores in eyes with idiopathic epiretinal membrane. Invest Ophthalmol Vis Sci 2005 Aug;46(8):2961-2966. [doi: 10.1167/iovs.04-1104] [Medline: 16043872]
15. Kuroyanagi K, Gunji H, Kato H, Gekka T, Arai K, Ito Y. Use of M-charts® in the evaluation of metamorphopsia after surgical removal of epiretinal membrane. Jpn J Clin Ophthalmol 2010;64:1551-1554.
16. Matsumoto C, Arimura E, Okuyama S, Takada S, Hashimoto S, Shimomura Y. Quantification of metamorphopsia in patients with epiretinal membranes. Invest Ophthalmol Vis Sci 2003 Sep;44(9):4012-4016. [doi: 10.1167/iovs.03-0117] [Medline: 12939323]

17. Leisser C, Amon DL, Huemer JC, Findl O. Diagnostic reliability of optical coherence tomography biomarkers for postsurgical success in visual acuity in patients with idiopathic epiretinal membranes. Klin Monbl Augenheilkd 2023 Oct;240(10):1207-1213. [doi: 10.1055/a-1756-5243] [Medline: 35426108]
18. Crincoli E, Savastano MC, Savastano A, et al. New artificial intelligence analysis for prediction of long-term visual improvement after epiretinal membrane surgery. Retina (Philadelphia, Pa) 2023 Feb 1;43(2):173-181. [doi: 10.1097/IAE.0000000000003646] [Medline: 36228144]
19. Nowomiejska K, Oleszczuk A, Brzozowska A, et al. M-charts as a tool for quantifying metamorphopsia in age-related macular degeneration treated with the bevacizumab injections. BMC Ophthalmol 2013 Apr 15;13(1):13. [doi: 10.1186/1471-2415-13-13] [Medline: 23587218]
20. Razavi H, Baglin E, Sharangan P, et al. Gaming to improve vision: 21st century self‐monitoring for patients with age‐related macular degeneration. Clin Exp Ophthalmol 2018 Jul;46(5):480-484. [doi: 10.1111/ceo.13097] [Medline: 29131493]
21. Kaiser PK, Wang YZ, He YG, Weisberger A, Wolf S, Smith CH. Feasibility of a novel remote daily monitoring system for age-related macular degeneration using mobile handheld devices: results of a pilot study. Retina (Philadelphia, Pa) 2013 Oct;33(9):1863-1870. [doi: 10.1097/IAE.0b013e3182899258] [Medline: 23609122]
22. NHS digital. Online access to GP health records. 2025 Mar 5. URL: https://digital.nhs.uk/services/nhs-app/nhs-app-guidance-for-gp-practices/guidance-on-nhs-app-features/online-access-to-gp-health-records [accessed 2023-06-12]
23. Alleye. Alleye becomes a digital companion for patients with retinal disease. : Medium; 2023. URL: https://medium.com/@technology_11408/alleye-becomes-a-digital-companion-for-patients-with-a-retinal-disease-f98e234929c5 [accessed 2023-06-12]
24. Mendall J, Islam M, Wong K, et al. Digital exclusion, social deprivation, and clinical outcomes of patients undergoing hyperacuity home monitoring. Ophthalmol Ther 2024 Oct;13(10):2759-2769. [doi: 10.1007/s40123-024-01020-y] [Medline: 39181973]

Abbreviations

DCVA: distance-corrected visual acuity
ERM: epiretinal membrane
HR: hyperreflective
ICC: intraclass correlation coefficient
iERM: idiopathic epiretinal membrane
ILM: internal limiting membrane
MH: horizontal M-chart
MV: vertical M-chart
OCT: optical coherence tomography
SD-OCT: spectral-domain optical coherence tomography
SHT: smartphone-based hyperacuity test

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Original Paper

Enhancing Quadruple Health Outcomes After Thoracic Surgery: Feasibility Pilot Randomized Controlled Trial Using Digital Home Monitoring

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Abstract

Background: Surgical recovery after hospital discharge often presents challenges for patients and caregivers. Postoperative complications and poorly managed pain at home can lead to unexpected visits to the emergency department (ED) and readmission to the hospital. Digital home monitoring (DHM) may improve postoperative care compared to standard methods.

Objective: We conducted a feasibility study for a randomized controlled trial (RCT) to assess DHM's effectiveness following thoracic surgical procedures compared to standard care.

Methods: We conducted a 2-arm parallel-group pilot RCT at a single tertiary care center. Adult patients undergoing thoracic surgical procedures were randomized 1:1 into 2 groups: the DHM group and the standard of care (control group). We adhered to the intention-to-treat analysis principle. The primary outcome was predetermined RCT feasibility criteria. The trial would be feasible if more than 75% of trial recruitment, protocol adherence, and data collection were achieved. Secondary outcomes included 30-day ED visit rates, 30-day readmission rates, postoperative complications, length of stay, postdischarge 30-day opioid consumption, 30-day quality of recovery, patient-program satisfaction, caregiver satisfaction, health care provider satisfaction, and cost per case.

Results: All RCT feasibility criteria were met. The trial recruitment rate was 87.9% (95% CI 79.4%-93.8%). Protocol adherence and outcome data collection rates were 96.3% (95% CI 89.4%-99.2%) and 98.7% (95% CI 92.9%-99.9%), respectively. In total, 80 patients were randomized, with 40 (50%) in the DHM group and 40 (50%) in the control group. Baseline patient and clinical characteristics were comparable between the 2 groups. The DHM group had fewer unplanned ED visits (2.7% vs 20.5%; *P*=.02), fewer unplanned admission rates (0% vs 7.6%; *P*=.24), lower rates of postoperative complications (20% vs 47.5%, *P*=.01) shorter hospital stays (4.0 vs 6.9 days; *P*=.05), but more opioid consumption (111.6, SD 110.9) vs 74.3, SD 71.9 mg morphine equivalents; *P*=.08) compared to the control group. DHM also resulted in shorter ED visit times (130, SD 0 vs 1048, SD 1093 minutes; *P*=.48) and lower cost per case (CAD $12,145 [US $ 8436.34], SD CAD $8779 [US $ 6098.20] vs CAD $17,247 [US $11,980.37], SD

CAD $15,313 [US $10,636.95]; *P*=.07). The quality of recovery scores was clinically significantly better than the controls (185.4, SD 2.6 vs 178.3, SD 3.3; *P*<.001). All 37 patients who completed the intervention answered the program satisfaction survey questionnaires (100%; 95% CI 90.5%-100%). Only 36 out of 80 caregivers responded to the caregiver satisfaction questionnaires at the end of the fourth week post hospital discharge (47.7%; 95% CI 35.7%-59.1%). Health care providers reported a 100% satisfaction rate.

Conclusions: This pilot RCT demonstrates the feasibility of conducting a full-scale trial to assess DHM's efficacy in improving postoperative care following thoracic surgery. DHM shows promise for enhancing continuity of care and warrants further investigation.

Trial Registration: ClinicalTrials.gov NCT04340960; https://clinicaltrials.gov/study/NCT04340960

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KEYWORDS

remote monitor; digital home monitoring; continuity of care; quadruple health outcomes; patient satisfaction; caregivers satisfaction; healthcare provider satisfaction; feasibility; RCT; thoracic surgery; postoperative monitoring; surgical recovery; perioperative medicine; patient care; questionnaire

Introduction

Recovery following surgical discharge poses significant challenges for patients and their caregivers. This challenge is compounded by the growing practice of discharging patients earlier after surgical procedures, intensifying the postoperative care demands. Moreover, the health care system often operates within a framework of fragmented and poorly integrated services, exacerbating the difficulties faced by patients transitioning from hospital to home after surgery, which can lead to complications and inadequately managed pain, resulting in returns to the hospital or visits to the emergency department (ED) [1-5].

Numerous studies underscore the critical role of postdischarge continuity of care in reducing ED visits and readmission rates (RRs) [6-11]. For instance, Shargall et al [12] successfully implemented an “Integrated Comprehensive Care” program involving allied health care professionals, significantly reducing 30-day RRs among thoracic surgery patients. Similar reductions in RRs have been attributed to patient education, well-coordinated discharge planning, physician follow-up, and in-home visits [13]. Data from Canada highlight that within the first 7 days following surgical discharge, 28.3% of ED diagnoses fell under the Canadian Emergency Department Triage and Acuity Scale (CTAS) IV or V, indicating less urgent or nonurgent cases [14]. It is reasonable to assume that many of these patients could have avoided ED visits by providing appropriate transitional care [15].

To address the needs of patients at a higher risk of postdischarge complications, the concept of continuity of care through digital home monitoring (DHM) emerges as a promising avenue to enhance education, modify behavior, and ultimately achieve improved patient outcomes [9]. With this approach, care teams gain insights into each patient's condition daily or weekly, eliminating the reliance on sporadic office visits, typically occurring only once or twice a year [16]. This continuous and comprehensive view of patient health empowers care teams to make timely adjustments to care plans and proactively engage patients in self-managing care [17]. A virtual care option that extends postdischarge continuity of care offers a viable solution [18-21].

Given the intricacies of providing continuity of care through DHM and the challenges associated with conducting a well-designed randomized controlled trial (RCT) in this context, a pilot study emerges as an essential preliminary step. The primary aim of this pilot study is to assess acceptability, identify logistical requirements, optimize the study design and data collection process, and evaluate readiness for a full-scale trial [22]. Undertaking an RCT that involves continuity of care with a DHM solution is resource-intensive. It raises practical concerns for all stakeholders, including hospital administrators, nurses, clinicians, and patients. Although the primary objective of this pilot study is to examine the feasibility of conducting a comprehensive RCT, this research specifically aims to investigate the feasibility of continuity of care using DHM on postoperative outcomes in patients following thoracic surgery. We hypothesize that continuity of care facilitated by DHM will reduce 30-day ED visits compared to standard care practices.

Methods

Overview

A parallel-group, 2-arm pragmatic pilot feasibility RCT was conducted from September 2022 to January 2023 at the London Health Sciences Centre. Participants were allocated 1:1 to receive continuity of care with DHM or standard of care (control) following the discharge after their thoracic surgical procedures. All participants provided written or electronic informed consent using the REDCap (Research Electronic Data Capture) tool hosted at the London Health Sciences Centre (REDCap e-consent). The analyses and reporting adhered to the CONSORT (Consolidated Guidelines of Reporting Trials) guidelines for pilot trials and the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist [23,24].

To execute the components of the DHM interventions, the health care team was trained from May 2021 to August 2022 using the Plan-Do-Study-Act cycle. Inclusion criteria were patients aged 18 years or older, undergoing a thoracic surgical procedure

(eg, elective anatomic lung resection or any major foregut procedure, such as an esophagectomy), and the surgeon in agreement with patient enrollment. Accredited thoracic surgeons performed all surgeries. Exclusion criteria were patients with unstable disease processes in the postoperative period (eg, postoperative intensive care unit stay) or those with factors that could impact outcome assessment (eg, cognitive impairment, inability to understand English, and limited access to a telephone, computer, or internet services). Patients were also excluded postoperatively if they had intraoperative or immediate postoperative complications requiring an intensive care unit stay.

Upon enrollment, eligible participants were randomized using the simple randomization feature of REDCap. No stratification factors or blocking were applied. The assignment of groups was concealed until the moment of randomization, at which point REDCap automatically allocated participants to the study arms [25]. All consecutive postoperative patients were approached to participate in the study. The randomization occurred on the day of discharge so that in-hospital care was not biased. Due to the pragmatic nature of the trial, patients, surgeons, clinical navigators (CNs), and other health care providers were not masked in the group allocation.

Preoperative, intraoperative, and postoperative patient management followed standard practices and were similar in both groups. A standardized care pathway for postthoracic surgical procedures was implemented for postoperative pain control involving acetaminophen, nonsteroidal anti-inflammatory drugs, hydromorphone, and adjunct medications, such as pregabalin. These were also prescribed on discharge unless otherwise contraindicated. Patients were monitored continuously after surgery while still in the postanesthesia care unit. While on the surgical ward, routine nursing assessments were conducted per the thoracic unit's standard of care. Patients in the control group were discharged home without any monitoring, per the current standard of care. Patients who experienced postdischarge complications were instructed to contact their surgeon's office or visit the hospital ED.

Patients in the DHM group received the same in-hospital care as the control group. In addition, DHM patients signed up for the cloud-based technology platform Vivify Health (Plano, Texas) digital portal with a unique username and password. Through the digital portal, the patient would connect with the CN, who guided the patient through every recovery step. The CN connected, engaged, and educated the patients regarding the recovery pathway. The CN also established clear expectations for patients. Before patients were ready for discharge, patients in the DHM group were given a DHM kit and shown how to use it to maintain continuity of care through the digital care platform. The DHM kit contained a noninvasive blood pressure (NIBP), hemoglobin oxygen saturation (SpO_2), and heart rate (HR) monitor. The data was transferred to a secured digital care platform through the app. DHM patients had access to speak to one of the health care providers at any time of day (CN or virtual care physician). The CN monitored the dashboard from 8 AM to 4 PM After 4 PM, the CN handed over the monitoring dashboard to one of the preassigned physicians (ie, virtual care physicians). Both the CN and physicians were trained in the platform. The health care provider used the digital platform to communicate, engage, and manage patients remotely and efficiently.

Patients measured their vital signs for 2 weeks. The patient also had daily scheduled video calls on days 1-15 after hospital discharge and on an as-needed basis from days 16-30. During the video calls, patients interacted with the CN and responded to symptom questionnaires. The CN organized unscheduled video visits on days without planned virtual visits if they detected changes in patient vital signs or recovery symptom questionnaires requiring follow-up. During virtual visits, the CN discussed any symptoms the patient was experiencing, evaluated their wounds, and obtained a picture if needed. The CN monitored the digital care platform dashboard from the provider side, with an alert for NIBP, HR, SpO_2, wound concerns, home medications, and pain. Alerts were displayed in a color-coded fashion on the dashboard. The CN also monitored the patient's symptoms and identified any changes from the patient's baseline. The CN called a preassigned clinician (ie, the patient's surgeon, a study physician, or a nurse practitioner) if any of the patient's symptoms required medical attention. Physicians could add or modify treatments as needed, and if required, they could have the patient come to an outpatient or ED facility for evaluation or management. Instructions were provided for the patient to call an emergency number (ie, 911) in collaboration and consultation with a physician if appropriate if any symptom indicated immediate distress. The CN and patients were just one button or "mouse click" away from each other, with multiple options to communicate by phone, SMS text message, email, or the virtual care platform (video chat). All these modes of communication were through a secured platform. The CN monitored and intervened by providing patients with advice and next steps if they had health concerns. Self-help educational videos were also available for patients.

This RCT was conducted as a pilot study, with a primary emphasis on assessing feasibility outcomes, which include trial recruitment, protocol adherence, and data collection. We followed the traffic light approach criteria for reporting feasibility outcomes [25-27]. This approach defined (1) feasible (green, 75%-100%) where all feasibility outcomes were met and no protocol modifications were needed; (2) feasible with modification (amber, 50%-75%) where all feasibility outcomes were met or could be met with protocol modifications; and (3) not feasible (red, <50%) where even with protocol modifications, feasibility outcomes could not be met. The clinical outcomes were assessed secondarily to inform the measurement strategy and sample size requirements for a future RCT (ie, by estimating variability, SDs, and prevalence of critical clinical outcomes). Our quadruple health outcome measurement strategy included (1) postoperative outcomes like 30-day ED visits, 30-day RRs, postoperative complications, in-hospital length of stay, 30-day quality of recovery (QoR-40) [28], and postdischarge 30-day opioid consumption; (2) patient-program satisfaction and caregiver satisfaction [29]; (3) health care provider satisfaction; and (4) financial sustainability like cost per case analysis.

Patient-reported outcomes were collected up to 30 days post hospital discharge. Daily data was collected using automatic electronic questionnaires completed digitally and transmitted directly to the REDCap database. Patients also had the option to complete daily questionnaires by video or telephone with a CN. The questionnaires were completed on a smartphone, tablet, or personal computer. Masked assessors verified the data in the REDCap database. Information regarding the 30-day ED visits, 30-day RRs, postoperative complications, postdischarge 30-day opioid consumption, and in-hospital length of stay was obtained from electronic medical records. The patient-program satisfaction survey consisted of 9 questions collected by the research assistant at the end of the 30 days in the DHM group. Patient agreement or satisfaction with statements was recorded on a 5-point scale (from 1=strongly disagree to 5=strongly agree) using a checkmark (✓), with a higher score indicating a higher level of patient agreement or satisfaction. The caregiver survey consists of 17 "Yes" or "No" questions collected by the research assistant at the end of the 30 days in the RPM program in both the DHM and control groups. The satisfaction survey for health care providers comprised 9 questionnaires, addressed at the project's conclusion through the Microsoft Teams survey link and disseminated via electronic mail. Case costing data consisting of the average direct surgical and nonsurgical inpatient costs was obtained for the DHM group and control groups according to the Ontario case costing initiative methodology for 2019-2020 data [30].

The following factors were considered in creating the 5 grades of interventions during the postoperative follow-up using RPM programs: phone calls, video calls, asynchronous messages, self-help educational materials, the amount of time the CN spent addressing the patient's concerns, and escalation to the virtual care physician. The definition of levels of digital health intervention: (1) no intervention and no assessment; (2) no intervention, but the automatic collection of signs, symptoms, and vital signs questionnaires; (3) mild intervention, wherein the CN spends less than 15 minutes with the patient; (4) moderate intervention, characterized by the CN spending 15-30 minutes with the patient; and (5) severe intervention, involving either the CN spending more than 30 minutes with the patient or the situation being escalated to a virtual care physician for further management.

Based on previous data, at least 70 measured participants were required to estimate SD with enough precision for future sample size calculations [31]. We aimed to recruit and obtain outcome data from 80 patients (40 per group), allowing for an attrition rate of approximately 15%. This sample size was also consistent with recommendations regarding the minimum number of participants required to identify feasibility issues [32]. We used "intention-to-treat" analysis. No formal comparison between the study arms was undertaken for outcomes, given that this is a feasibility study. Quantitative secondary outcome measures were summarized descriptively using appropriate summary statistics in the result section and by the trial arm in the tabular column. Continuous variables were reported as mean, standard deviation, and median (range), as appropriate. Categorical variables were reported as counts and percentages. Statistical analyses were performed using GraphPad Prism (GraphPad) software.

Ethical Considerations

This study was formally registered with ClinicalTrials.gov (NCT04340960) and received full board review and approval from the institutional research ethics board at Western University (HSREB 114886). All individual participants involved in the study provided informed consent. Furthermore, appropriate measures were implemented to maintain the confidentiality and anonymity of patient data throughout the research. The study posed no significant risks to the participants, who kept the right to withdraw without facing repercussions regarding their standard of care. Ultimately, no financial compensation was offered to the participants involved in the study.

Results

A total of 91 consecutive patients were considered for inclusion in our study. In total, 80 patients met the inclusion criteria, consented to participate, and were randomized to either the control (n=40) group or the DHM (n=40) group (Figure 1). The 2 groups' patient demographics and clinical characteristics were similar (Table 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. DHM: digital home monitoring.

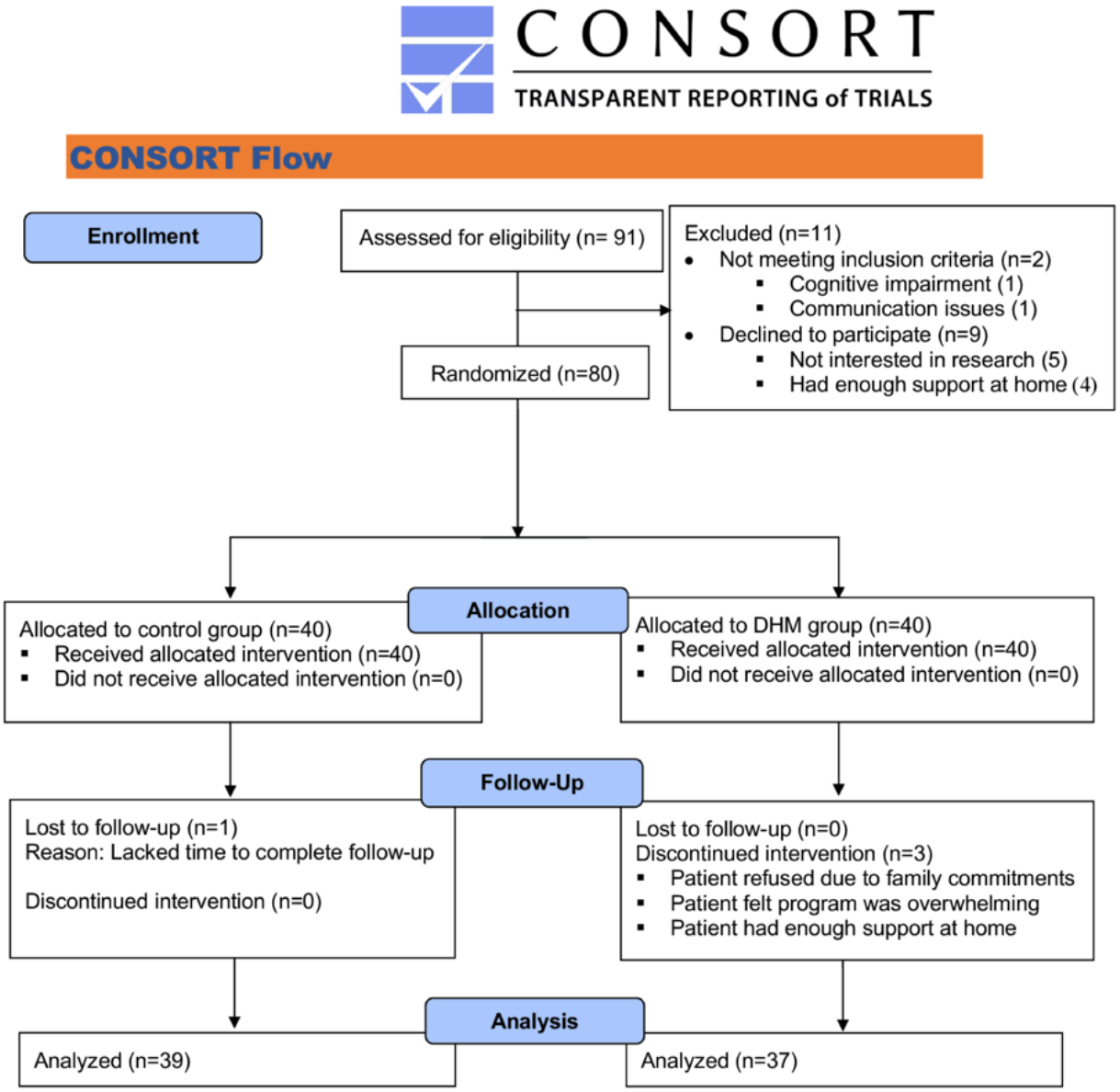


Table 1. Patient demographic and clinical characteristics.

	Control group	DHM[a] group	Total	*P* value
Age (years), mean (SD)	65.5 (14.7)	63.3 (15.0)	64.4 (14.8)	.51
Gender, n (%)				.36
Female	25 (62.5)	20 (50)	45 (56.2)	
Male	15 (37.5)	20 (50)	35 (43.7)	
BMI (kg/m^2), mean (SD)	30.1 (12.3)	27.8 (5.0)	28.9 (9.40)	.28
Outside the London area, n (%)				.48
Yes	23 (57.5)	27 (67.5)	50 (62.5)	
No	17 (42.5)	13 (32.5)	30 (37.5)	
Disease type, n (%)				.99
Primary lung cancer	17 (42.5)	17 (42.5)	34 (42.5)	
Secondary lung cancer	7 (17.5)	7 (17.5)	14 (17.5)	
Others	16 (40)	16 (40)	32 (40)	
PFT, mean (SD) (n)				
FEV1[b]	85.8 (18.2) (16)	88.5 (21.1) (19)	87.3 (19.6) (35)	.69
DLCO[c]	74.6 (19.6) (16)	77.6 (17.1) (18)	76.2 (18.1) (34)	.64
Cancer type, n (%)				.40
Malignant	24 (60)	23 (57.5)	47 (58.7)	
Benign	2 (5)	0 (0)	2 (2.5)	
Others	14 (35)	17 (42.5)	31 (38.7)	
Side of surgery, n (%)				.06
Right	17 (42.5)	8 (20)	25 (31.2)	
Left	10 (25)	18 (45)	28 (35)	
N/A[d]	13 (32.5)	14 (35)	27 (33.7)	
Type of resection, n (%)				.30
Wedge	13 (32.5)	11 (27.5)	24 (30)	
Segmentectomy	4 (10)	1 (2.5)	5 (6.2)	
Lobectomy	8 (20)	12 (30)	20 (25)	
Pneumonectomy	0 (0)	0 (0)	0	
Pleural	3 (7.5)	0 (0)	3 (3.7)	
Mediastinal	1 (2.5)	2 (5)	3 (3.7)	
Foregut procedure	11 (27.5)	14 (35)	25 (31.2)	
Surgical approach, n (%)				.17
Thoracotomy	12 (30)	7 (17.5)	19 (23.7)	
Laparotomy	8 (20)	5 (12.5)	13 (16.2)	
VATS[e]	18 (45)	21 (52.5)	39 (48.7)	
Laparoscopic	2 (5)	7 (17.5)	9 (11.2)	
Staging (pTNM[f]), n (%)				.66
IA/IB	14 (35)	9 (22.5)	23 (28.7)	
IIA/IIB	4 (10)	8 (20)	12 (15)	
IIIA/IIIB	3 (7.5)	2 (5)	5 (6.2)	
IV	2 (5)	1 (2.5)	3 (3.7)	

	Control group	DHM[a] group	Total	*P* value
Metastatic disease	1 (2.5)	2 (5)	3 (3.7)	
N/A	16 (40)	18 (45)	34 (42.5)	
Histology, n (%)				.95
Adenocarcinoma	13 (32.5)	12 (30)	25 (31.2)	
Small cell carcinoma	2 (5)	1 (2.5)	3 (3.7)	
Metastasis	2 (5)	2 (5)	4 (5)	
Others	1 (2.5)	0 (0)	1 (1.2)	
Carcinoid	0 (0)	1 (2.5)	1 (1.2)	
N/A	22 (55)	24 (60)	46 (57.5)	
Smoking history, n (%)				.76
Quit smoking	21 (52.5)	21 (52.5)	42 (52.5)	
Active smokers	5 (12.5)	3 (7.5)	8 (10)	
Nonsmokers	14 (35)	16 (40)	30 (37.5)	

[a]DHM: digital home monitoring.

[b]FEV1: forced expiratory volume at the end of 1 second.

[c]DLCO: diffusing capacity of lung for carbon monoxide.

[d]N/A: not applicable.

[e]VATS: video-assisted thoracoscopy.

[f]pTNM: tumor (T), lymph nodes (N), metastasis (M).

Among the eligible patients who declined enrollment, the most common reason was not being interested in participating in research while receiving care (5.4%), followed by patients having enough support at home for recovery after hospital discharge (4.3%). In total, 3 patients from the DHM group withdrew in the second week after hospital discharge. The first patient withdrew due to family commitments, the second patient felt the program was overwhelming, and the last patient had enough support at home during recovery and decided to withdraw from the program. Only one patient from the control group was lost at the end of the 30-day follow-up period. In total, 76 patients—39 in the control group and 37 in the DHM group—completed the study. Out of 80 caregivers who provided consent for enrollment, only 36 caregivers (16 in the control group and 20 in the DHM group) responded to the caregiver satisfaction questionnaires at the end of the fourth week (47.7%; 95% CI 35.7%-59.1%).

Our study met all green feasibility criteria (Table 2). All 5 thoracic surgeons agreed to have their patients consecutively recruited and adhere to the study protocol. The recruitment rate was 87.9% (95% CI 79.4%-93.8%), and protocol adherence was 96.3% (95% CI 89.4%-99.2%). Data were collected for outcomes in 98.7% (95% CI 92.9%-99.9%) of participants.

Table 2. Feasibility outcomes.

	Not feasible (red)[a]	Feasible with modification (amber)[b]	Feasible (green)[c]	Study results
Trial recruitment	<50%	50%-74%	75%-100%	87.91%
Protocol adherence	<50%	50%-74%	75%-100%	96.25%
Outcome data collection	<50%	50%-74%	75%-100%	98.70%

[a]Not feasible (red) <50%: even with protocol modifications, some feasibility outcomes cannot be met.

[b]Feasible with modification (amber) 50%-75%: all feasibility outcomes are met or can be met with protocol modifications.

[c]Feasible (green) 75%-100%: all feasibility outcomes are met; no protocol modifications are needed.

The mean age of the sample was 64.4 (SD 14.8) years, with 56.2% being female, and the mean BMI was 28.9 (SD 9.4) kg/m^2. Most patients had malignant cancer (58.7%) and primary lung cancer (42.5%). Patients most commonly underwent wedge resection (30%), lobectomy (25%), or foregut procedures (31.2%). The most common surgical approach was video-assisted thoracoscopy (48.7%), followed by thoracotomy (23.7%), and then laparotomy (16.2%).

The mean total length of stay in the hospital was 5.4 (SD 6.6) days (control vs DHM: 6.9, SD 8.8 vs 4.0, SD 2.7), and the incidence of postoperative complications was 33.7% (control vs DHM: 47.5% vs 20%). The total number of ED visits in this sample was 11.2% (control vs DHM: 20.5% vs 2.7%). All these ED visits were unplanned, and the mean time spent in the ED was 894 (SD 1047) minutes (control vs DHM: 1048, SD 1093 vs 130, SD 0). One patient from the DHM group presented to

the ED with testicular pain. Patients from the control group presented with abdominal bloating or distension, wound concerns, dysphagia, or pain crises. The total hospital RR for the sample was 6.5% (control vs DHM: 7.6% vs 5.4%). The unplanned hospital RR was 3.9% (control vs DHM: 7.6% vs 0%), and the planned hospital RR was 2.6% (control vs DHM: 0% vs 5.4%), respectively. The mean 30-day morphine equivalent dose opioid consumption was 92 (SD 94.2) mg (control vs DHM: 74.3, SD 71.9 vs 111.6, SD 110.9), and the mean in-hospital cost per case was CAD $14,729 (US $10,227.96; SD CAD $12,702 [US $8820.40]; control vs DHM: CAD $17,247 [US $11,976.49], SD CAD $15,313 [US $10,633.50] vs CAD $12,145 [US $8433.61], SD CAD $8779 [US $6096.23]; Table 3).

Table 3. Postoperative outcomes.

	Control group	DHM[a] group	Total	*P* value
LOS[b] (days), mean (SD)	6.9 (8.8)	4.0 (2.7)	5.4 (6.6)	.05
Postoperative complications, n (%)	19 (47.5)	8 (20)	27 (33.75)	.01
Unplanned ED[c] visits, n (%)	8 (20.5)	1 (2.7)	9 (11.25)	.02
Planned ED visits, n (%)	0	0	0	—[d]
Time spent in ED (min), mean (SD)	1048 (1093)	130 (0)	894 (1047)	.48
Unplanned RR[e], n (%)	3 (7.6)	0	3 (3.9)	.24
Planned RR, n (%)	0	2 (5.4)	2 (2.6)	.23
Total RR, n (%)	3 (7.6)	2 (5.4)	5 (6.5)	.99
30-Day morphine equivalent dose consumption (mg), mean (SD)	74.3 (71.9)	111.6 (110.9)	92.4 (94.2)	.08
Cost per case (CAD $; CAD $1=US $0.69), mean (SD)	17,247 (15,313)	12,145 (8779)	14,729 (12,702)	.07

[a]DHM: digital home monitoring.

[b]LOS: length of hospital stay.

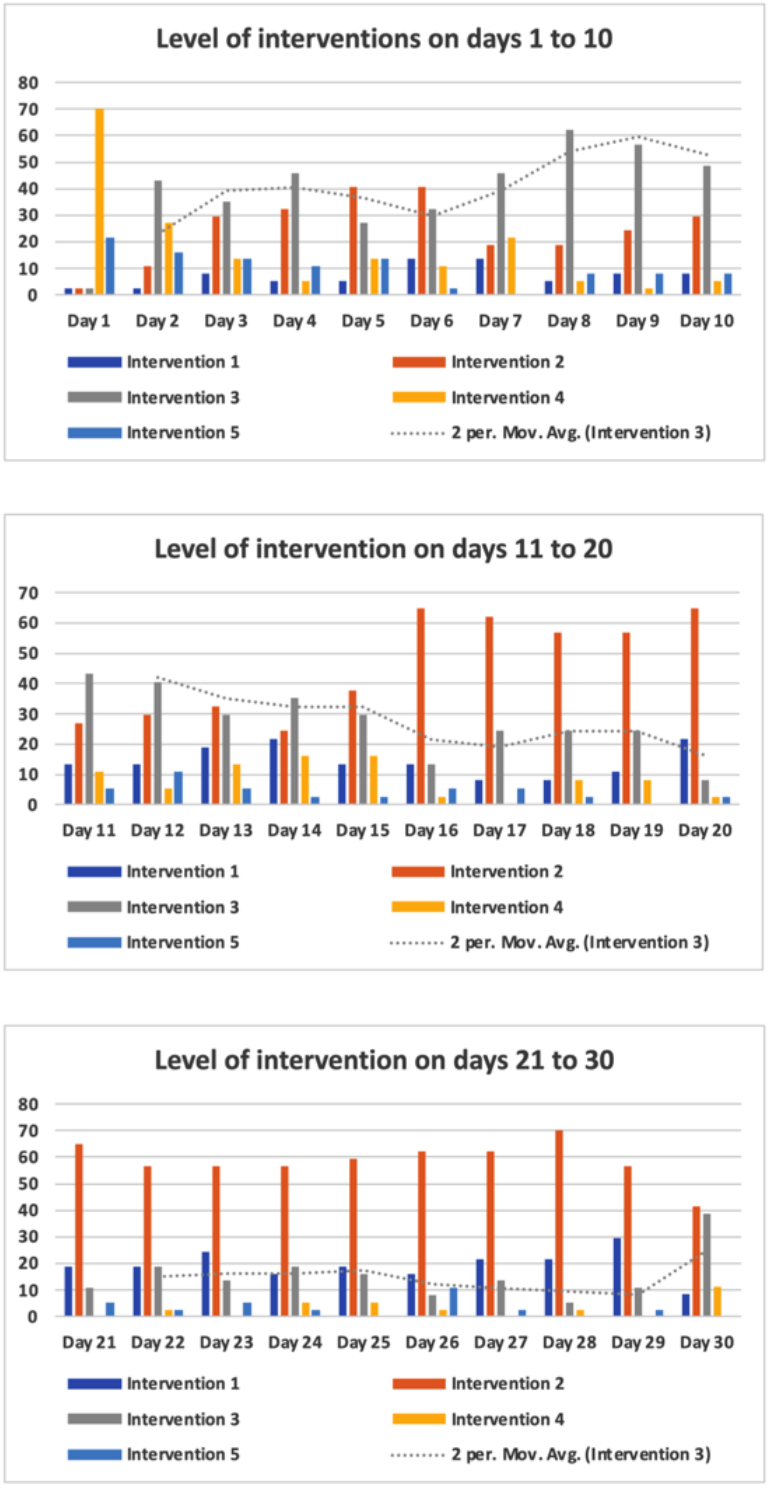
[c]ED: emergency department.

[d]Not applicable.

[e]RR: readmission rate.

The remote monitoring team most often used level 2 or 3 interventions, except for postdischarge day 1, where intervention level 4 was the most common (Figure 2). Comparing interventions over 0-15 days and 16-30 days revealed that level 2 interventions rose significantly from 26.6% to 59.5% (P<.001). In contrast, level 3, 4, and 5 interventions dropped substantially from 38.5% to 16.6%, 15.8% to 3.4%, and 8.6% to 3.2%, respectively (P<.001). The most common issues addressed through the digital platform included pain (23%), surgical wound concerns (11%), shortness of breath (10%), diarrhea (7%), medication management (7%), nausea or vomiting (5%), and dizziness (5%; Multimedia Appendix 1).

Figure 2. Levels of digital health intervention.



At 30 days postoperatively, the mean global QoR-40 score for the sample was 181.9 (SD 5.0). The scores for individual domains included emotional status (39.3, SD 1.4), physical comfort (53.5, SD 0.6), psychological support (33.1, SD 1.7), physical independence (22.7, SD 0.6), and pain (33.1, SD 0.4; Table 4).

Table 4. Quality of recovery.

	Control group (n=39)	DHM[a] group (n=37)	Total (N=76)	*P* value
Global QoR-40[b], mean (SD)	178.3 (3.3)	185.4 (2.6)	181.9 (5.0)	<.001
Emotional status, mean (SD)	38.3 (0.8)	40.4 (0.6)	39.3 (1.4)	<.001
Physical comfort, mean (SD)	53.0 (0.7)	53.9 (0.7)	53.5 (0.6)	<.001
Psychological support, mean (SD)	31.9 (0.5)	34.3 (0.2)	33.1 (1.7)	<.001
Physical independence, mean (SD)	22.2 (0.5)	23.2 (0.4)	22.7 (0.6)	<.001
Pain, mean (SD)	32.7 (0.6)	33.4 (0.5)	33.1 (0.4)	<.001

[a]DHM: digital home monitoring.

[b]QoR-40: 30-day quality of recovery.

Responses from the patient and caregiver satisfaction surveys administered at the end of the fourth week postoperatively were recorded (Multimedia Appendices 2 and 3, respectively). All 37 patients who completed the intervention answered the program satisfaction survey questionnaires (100%; 95% CI 90.5%-100%). More than 95% of patients agreed or strongly agreed that the instructions for setting up the remote monitoring system were easy to understand. All 37 patients in the DHM group agreed or strongly agreed that they felt safe at home and that the CN and physicians responded promptly and efficiently. All patients in the DHM group either agreed or strongly agreed that they would recommend the remote monitoring system program to future patients. Out of 80 caregivers who provided consent for enrollment, only 36 caregivers responded to the caregiver satisfaction questionnaires at the end of the fourth week post hospital discharge (47.7%; 95% CI 35.7%-59.1%). While taking care of the family members at home after the hospital discharge, our sample caregivers reported less burden on family members (8.5%), less interference with personal activities (28.5%), feeling less confined to staying at home (37.1%), and less physical strain (14.2%). However, caregivers reported taking more time off work than initially anticipated (14.2%), employment activities being affected (14.2%), educational activities being affected (8.5%), increased demand on time (31.4%), changes in personal plans (51.4%), and family adjustments (62.8%). Health care providers reported a 100% satisfaction rate (Multimedia Appendix 4).

Discussion

The findings from this trial support the feasibility of conducting a full-scale RCT to compare DHM with the current standard of care after thoracic surgery. The study showed excellent feasibility, achieving a recruitment rate of 87.9%, protocol adherence of 96.3%, and collecting outcome data for 98.7% of participants. These results indicate significant engagement and compliance, reinforcing the study's viability for broader implementation.

The most common barrier to participation among eligible patients in this study was a lack of willingness to participate in research while receiving care (n=5, 5.4%). Other reasons included patients who felt they had enough support at home to recover after hospital discharge (n=4, 4.3%). However, all patients consented to randomization due to the preconception that the care team would connect with them after hospital discharge to aid their recovery. This finding suggests that recruitment for a full-scale trial may be facilitated by addressing implicit biases and emphasizing the importance of continuous connection with the care team to improve postoperative outcomes. Most patients preferred being assigned to the continuity of care with a DHM group rather than the standard care group (70%). In comparison, 25% of the patients did not express any preference.

Using smartphone technology for postoperative follow-up and patient communication has significantly minimized the chances of ED visits and RRs [33,34]. In the United Kingdom, a remote monitoring initiative for 900 colorectal patients reduced costs by 63% while achieving high patient satisfaction [35]. Likewise, a quality improvement study involving 48 thoracic patients with robotic lobectomies found that home monitoring effectively enabled safe early discharges and demonstrated possible economic benefits [36]. Conversely, in an RCT that included 292 postsurgical patients, there was no notable difference between the home monitoring and control groups in ED visits post surgery. Patients in the remote patient monitoring group had an average adherence rate of 86% for daily vital sign logging and 78% for daily question logging [37]. Still, home monitoring was well-received by both patients and physicians, although technological challenges diminished its benefits. Many of these studies relied on automatic data collection methods. Our research yields similar findings but is a prospective RCT focused on thoracic surgical patients. We incorporated more pragmatic inclusion criteria with the caregivers' surveys and used Vivify technology. Our intervention is labor-intensive, differing from other studies, including educational resources, automated questionnaires, vital sign data collection, 2-way communication, and daily CN calls.

This pilot RCT examined the feasibility and clinical impact of continuous DHM on postoperative outcomes in patients undergoing major thoracic surgery. The DHM group had fewer postoperative complications, unplanned ED visits, and unplanned RRs. A potential explanation may be the increased continuity of care and the clinician's ability to monitor a patient's

clinical status to implement necessary interventions before the progression of postoperative complications or ED visits [38-41]. Moreover, the global QoR-40 score and all individual domains were rated higher in the DHM group. This may have resulted from increased patient surveillance and clinician intervention to ensure patients remain on an acceptable path to recovery [42]. However, this trial was not powered or designed with the QoR-40 scores as a primary outcome; thus, these findings must be interpreted cautiously. The satisfaction survey results indicate that patients and health care providers highly value the remote monitoring program. However, caregivers have shown mixed responses. Our findings imply that while patients and providers regard the program positively, further support for caregivers could improve their experience and address the reported increased time demands and schedule adjustments. This can be explored further in the full-scale RCT.

A potential barrier to implementing a DHM system is the difficulty of setting it up and using it by the patient. However, in our study, most patients reported that setup instructions were easy to understand and did not find the system difficult to use. Overall, satisfaction with the program was excellent, and all participants would recommend the remote monitoring system to future patients. Of note, caregivers of patients in the DHM group reported that caregiving affected their personal, educational, and work activities more than the control group. This may be explained by the need to assist the patient in recording vitals and concerns and uploading this information to the digital care platform.

One strength of our study was the diverse patient population regarding gender, age, and BMI. Pathologies such as primary malignancies, secondary malignancies, and nonmalignant diseases were also included. Surgical procedures were diverse, with various types of resections and surgical approaches. The heterogeneity of the study patients indicates that this can be universally implemented in other surgical populations. Patients and their caregivers were adequately trained to record vital signs and upload concerns online, reducing the workload of the home care team. Furthermore, extensive remote patient monitoring was implemented, including HR, NIBP, SpO_2, and daily assessment measurements.

The limitations of this study include the fact that it was not statistically powered to detect postoperative outcome differences. As such, any between-group comparison should be interpreted with caution. Additionally, patients were only followed for 4 weeks postoperatively, so data on the efficacy of continuous DHM on postoperative outcomes beyond this time point remain unknown. Since January 2023, Vivify technology has not been available in Ontario, Canada, and we will be using different technology in our next project to explore these promising results. The potential threats to this feasibility may be reproducibility and scalability associated with the entirely new platform and the maintenance of labor-intensive resource intervention. Further, the cost of the intervention should have been evaluated in this study. Finally, this study was performed at a single center in patients undergoing major thoracic surgery and may need exploration to implement in other surgical populations at different institutions.

In conclusion, the VivifyHealth digital health platform provides a user-friendly interface to extend continuity of care. DHM effectively improved the quality of patients' recovery while decreasing postoperative complications, unplanned ED visits, and hospital RRs. Effective implementation of these platforms may reduce the utilization of scarce health care resources while maintaining excellent patient outcomes and satisfaction. Findings from this pilot trial support the feasibility of conducting a robust full-scale trial to explore these promising results.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Health problems addressed via a digital home monitoring program.
[PNG File , 130 KB - periop_v8i1e58998_app1.png]

Multimedia Appendix 2
Patient/Program Satisfaction Questionnaires.
[DOCX File , 34 KB - periop_v8i1e58998_app2.docx]

Multimedia Appendix 3
Caregivers Satisfaction.
[DOCX File , 34 KB - periop_v8i1e58998_app3.docx]

Multimedia Appendix 4
Healthcare Provider satisfaction.
[DOCX File , 33 KB - periop_v8i1e58998_app4.docx]

Multimedia Appendix 5
CONSORT eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 431 KB - periop_v8i1e58998_app5.pdf]

References

1. Dickinson KJ, Taswell JB, Allen MS, Blackmon SH, Nichols FC, Shen R, et al. Unplanned readmission after lung resection: complete follow-Up in a 1-year cohort with identification of associated risk factors. Ann Thorac Surg 2017;103(4):1084-1091. [doi: 10.1016/j.athoracsur.2016.09.065] [Medline: 27993376]
2. Konstantinidis K, Woodcock-Shaw J, Dinesh P, Brunelli A. Incidence and risk factors for 90-day hospital readmission following video-assisted thoracoscopic anatomical lung resection†. Eur J Cardiothorac Surg 2019;55(4):666-672. [doi: 10.1093/ejcts/ezy345] [Medline: 30364954]
3. Lee AJ, Liu X, Borza T, Qin Y, Li BY, Urish KL, et al. Role of post-acute care on hospital readmission after high-risk surgery. J Surg Res 2019;234:116-122 [FREE Full text] [doi: 10.1016/j.jss.2018.08.053] [Medline: 30527462]
4. Kidane B, Higgins S, Hirpara DH, Kaaki S, Shen YC, Allison F, et al. From emergency department visit to readmission after esophagectomy: analysis of burden and risk factors. Ann Thorac Surg 2021;112(2):379-386. [doi: 10.1016/j.athoracsur.2020.11.020] [Medline: 33310147]
5. Nelson DB, Lapid DJ, Mitchell KG, Correa AM, Hofstetter WL, Mehran RJ, et al. Perioperative outcomes for stage I non-small cell lung cancer: differences between men and women. Ann Thorac Surg 2018;106(5):1499-1503. [doi: 10.1016/j.athoracsur.2018.06.070] [Medline: 30118712]
6. Yang H, Dervin G, Madden S, Beaulé PE, Gagné S, Crossan ML, et al. Postoperative home monitoring after joint replacement: feasibility study. JMIR Perioper Med 2018;1(2):e10168 [FREE Full text] [doi: 10.2196/10168] [Medline: 33401364]
7. Yang H, Dervin G, Madden S, Fayad A, Beaulé P, Gagné S, et al. Postoperative home monitoring after joint replacement: retrospective outcome study comparing cases with matched historical controls. JMIR Perioper Med 2018;1(2):e10169 [FREE Full text] [doi: 10.2196/10169] [Medline: 33401365]
8. van Walraven C, Mamdani M, Fang J, Austin PC. Continuity of care and patient outcomes after hospital discharge. J Gen Intern Med 2004;19(6):624-631 [FREE Full text] [doi: 10.1111/j.1525-1497.2004.30082.x] [Medline: 15209600]
9. Minervini F, Taylor J, Hanna WC, Agzarian J, Hughes K, Pinkney P, et al. Can a mobile app technology reduce emergency department visits and readmissions after lung resection? A prospective cohort study. Can J Surg 2022;65(6):E798-E804 [FREE Full text] [doi: 10.1503/cjs.000122] [Medline: 36418065]
10. Leppin AL, Gionfriddo MR, Kessler M, Brito JP, Mair FS, Gallacher K, et al. Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. JAMA Intern Med 2014;174(7):1095-1107 [FREE Full text] [doi: 10.1001/jamainternmed.2014.1608] [Medline: 24820131]
11. Young JM, Butow PN, Walsh J, Durcinoska I, Dobbins TA, Rodwell L, et al. Multicenter randomized trial of centralized nurse-led telephone-based care coordination to improve outcomes after surgical resection for colorectal cancer: the CONNECT intervention. J Clin Oncol 2013;31(28):3585-3591. [doi: 10.1200/jco.2012.48.1036]
12. Shargall Y, Hanna WC, Schneider L, Schieman C, Finley CJ, Tran A, et al. The integrated comprehensive care program: a novel home care initiative after major thoracic surgery. Semin Thorac Cardiovasc Surg 2016;28(2):574-582. [doi: 10.1053/j.semtcvs.2015.12.003] [Medline: 28043480]
13. Fox JP, Suter LG, Wang K, Wang Y, Krumholz HM, Ross JS. Hospital-based, acute care use among patients within 30 days of discharge after coronary artery bypass surgery. Ann Thorac Surg 2013;96(1):96-104 [FREE Full text] [doi: 10.1016/j.athoracsur.2013.03.091] [Medline: 23702228]
14. Book. All-Cause Readmission to Acute CareReturn to the Emergency Department. Ottawa, ON: Canadian Institute for Health Information; 2012.
15. Cleeland CS, Wang XS, Shi Q, Mendoza TR, Wright SL, Berry MD, et al. Automated symptom alerts reduce postoperative symptom severity after cancer surgery: a randomized controlled clinical trial. J Clin Oncol 2011;29(8):994-1000. [doi: 10.1200/jco.2010.29.8315] [Medline: 21282546]
16. Sun V, Dumitra S, Ruel N, Lee B, Melstrom L, Melstrom K, et al. Wireless monitoring program of patient-centered outcomes and recovery before and after major abdominal cancer surgery. JAMA Surg 2017;152(9):852-859 [FREE Full text] [doi: 10.1001/jamasurg.2017.1519] [Medline: 28593266]
17. Cheng X, Yang Y, Shentu Y, Ding Z, Zhou Q, Tan Q, et al. Remote monitoring of patient recovery following lung cancer surgery: a messenger application approach. J Thorac Dis 2021;13(2):1162-1171 [FREE Full text] [doi: 10.21037/jtd-21-27] [Medline: 33717589]

18. Avery KNL, Richards HS, Portal A, Reed T, Harding R, Carter R, et al. Developing a real-time electronic symptom monitoring system for patients after discharge following cancer-related surgery. BMC Cancer 2019;19(1):463 [FREE Full text] [doi: 10.1186/s12885-019-5657-6] [Medline: 31101017]
19. Keng CJS, Goriawala A, Rashid S, Goldstein R, Schmocker S, Easson A, et al. Home to stay: an integrated monitoring system using a mobile app to support patients at home following colorectal surgery. J Patient Exp 2020;7(6):1241-1246 [FREE Full text] [doi: 10.1177/2374373520904194] [Medline: 33457571]
20. Hong TH, Kim MK, Ryu DJ, Park JS, Bae GC, Jeon YS. The reliability of remote patient-reported outcome measures via mobile apps to replace outpatient visits after rotator cuff repair surgery: repetitive test-retest comparison study for 1-year follow-up. J Med Internet Res 2021;23(3):e20989 [FREE Full text] [doi: 10.2196/20989] [Medline: 33646133]
21. Subramani Y, Querney J, Singh P, Zhang Y, Fochesato L, Fatima N, et al. Preoperative anesthesia virtual video consultations in a preadmission clinic: quality improvement study. JMIR Perioper Med 2024;7:e57541 [FREE Full text] [doi: 10.2196/57541] [Medline: 39052992]
22. Kistin C, Silverstein M. Pilot studies: a critical but potentially misused component of interventional research. J Am Med Assoc 2015;314(15):1561-1562 [FREE Full text] [doi: 10.1001/jama.2015.10962] [Medline: 26501530]
23. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, PAFS Consensus Group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasibility Stud 2016;2(1):64 [FREE Full text] [doi: 10.1186/s40814-016-0105-8] [Medline: 27965879]
24. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res 2011;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
25. Singh J. Randomization and online databases for clinical trials. J Pharmacol Pharmacother 2014;5(2):173-174. [doi: 10.4103/0976-500x.130155]
26. Thabane L, Lancaster G. A guide to the reporting of protocols of pilot and feasibility trials. Pilot Feasibility Stud 2019;5(1):37 [FREE Full text] [doi: 10.1186/s40814-019-0423-8] [Medline: 30858987]
27. Avery KNL, Williamson PR, Gamble C, O'Connell Francischetto E, Metcalfe C, Davidson P, et al. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. BMJ Open 2017;7(2):e013537. [doi: 10.1136/bmjopen-2016-013537] [Medline: 28213598]
28. Gornall B, Myles P, Smith C, Burke J, Leslie K, Pereira M, et al. Measurement of quality of recovery using the QoR-40: a quantitative systematic review. Br J Anaesth 2013;111(2):161-169 [FREE Full text] [doi: 10.1093/bja/aet014] [Medline: 23471753]
29. Nagappa M, Querney J, Martin J, John-Baptiste A, Subramani Y, Lanting B, et al. Perioperative satisfaction and health economic questionnaires in patients undergoing an elective hip and knee arthroplasty: a prospective observational cohort study. Anesth Essays Res 2021;15(4):413-438 [FREE Full text] [doi: 10.4103/aer.aer_5_22] [Medline: 35422546]
30. OCC. Ontario Case Costing Initiative. URL: http://www.occp.com/mainPage.htm? [accessed 2015-07-18]
31. Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. Trials 2014;15(1):264 [FREE Full text] [doi: 10.1186/1745-6215-15-264] [Medline: 24993581]
32. Viechtbauer W, Smits L, Kotz D, Budé L, Spigt M, Serroyen J, et al. A simple formula for the calculation of sample size in pilot studies. J Clin Epidemiol 2015;68(11):1375-1379. [doi: 10.1016/j.jclinepi.2015.04.014] [Medline: 26146089]
33. Lu K, Marino NE, Russell D, Singareddy A, Zhang D, Hardi A, et al. Use of short message service and smartphone applications in the management of surgical patients: a systematic review. Telemed J E Health 2018;24(6):406-414. [doi: 10.1089/tmj.2017.0123] [Medline: 29111887]
34. Dawes AJ, Lin AY, Varghese C, Russell MM, Lin AY. Mobile health technology for remote home monitoring after surgery: a meta-analysis. Br J Surg 2021;108(11):1304-1314. [doi: 10.1093/bjs/znab323] [Medline: 34661649]
35. Siddika A, Tolia-Shah D, Pearson TE, Richardson NGB, Ross AHM. Remote surveillance after colorectal cancer surgery: an effective alternative to standard clinic-based follow-up. Colorectal Dis 2015;17(10):870-875. [doi: 10.1111/codi.12970] [Medline: 25851058]
36. Mangiameli G, Bottoni E, Tagliabue A, Giudici VM, Crepaldi A, Testori A, et al. Early hospital discharge on day two post-robotic lobectomy with telehealth home monitoring. J Clin Med 2024;13(20):13 [FREE Full text] [doi: 10.3390/jcm13206268] [Medline: 39458218]
37. Spaulding A, Loomis E, Brennan E, Klein D, Pierson K, Willford R, et al. Postsurgical remote patient monitoring outcomes and perceptions: a mixed-methods assessment. Mayo Clin Proc Innov Qual Outcomes 2022;6(6):574-583. [doi: 10.1016/j.mayocpiqo.2022.09.005] [Medline: 36304524]
38. Costantino ME, Frey B, Hall B, Painter P. The influence of a postdischarge intervention on reducing hospital readmissions in a Medicare population. Popul Health Manag 2013;16(5):310-316 [FREE Full text] [doi: 10.1089/pop.2012.0084] [Medline: 23537154]
39. Hu Y, McMurry TL, Isbell JM, Stukenborg GJ, Kozower BD. Readmission after lung cancer resection is associated with a 6-fold increase in 90-day postoperative mortality. J Thorac Cardiovasc Surg 2014;148(5):2261-2267.e1 [FREE Full text] [doi: 10.1016/j.jtcvs.2014.04.026] [Medline: 24823283]

40. Van Haren RM, Correa AM, Sepesi B, Rice DC, Hofstetter WL, Roth JA, et al. Hospital readmissions after pulmonary resection: post-discharge nursing telephone assessment identifies high risk patients. J Thorac Dis 2020;12(3):184-190 [FREE Full text] [doi: 10.21037/jtd.2020.02.08] [Medline: 32274083]
41. Varela G, Aranda JL, Jiménez MF, Novoa N. Emergency hospital readmission after major lung resection: prevalence and related variables. Eur J Cardiothorac Surg 2004;26(3):494-497. [doi: 10.1016/j.ejcts.2004.05.035] [Medline: 15302041]
42. Gordon WJ, Henderson D, DeSharone A, Fisher HN, Judge J, Levine DM, et al. Remote patient monitoring program for hospital discharged COVID-19 patients. Appl Clin Inform 2020;11(5):792-801 [FREE Full text] [doi: 10.1055/s-0040-1721039] [Medline: 33241547]

Abbreviations

CN: clinical navigator
CONSORT: Consolidated Standards of Reporting Trials
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
CTAS: Canadian Emergency Department Triage and Acuity Scale
DHM: digital home monitoring
ED: emergency department
HR: heart rate
NIBP: noninvasive blood pressure
QoR-40: 30-day quality of recovery
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
RR: readmission rate
SpO2: hemoglobin oxygen saturation

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Original Paper

Reducing Greenhouse Gas Emissions and Modifying Nitrous Oxide Delivery at Stanford: Observational, Pilot Intervention Study

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Abstract

Background: Inhalational anesthetic agents are a major source of potent greenhouse gases in the medical sector, and reducing their emissions is a readily addressable goal. Nitrous oxide (N_2O) has a long environmental half-life relative to carbon dioxide combined with a low clinical potency, leading to relatively large amounts of N_2O being stored in cryogenic tanks and H cylinders for use, increasing the chance of pollution through leaks. Building on previous findings, Stanford Health Care's (SHC's) N_2O emissions were analyzed at 2 campuses and targeted for waste reduction as a precursor to system-wide reductions.

Objective: We aimed to determine the extent of N_2O pollution at SHC and subsequently whether using E-cylinders for N_2O storage and delivery at the point of care in SHC's ambulatory surgery centers could reduce system-wide emissions.

Methods: In phase 1, total SHC (Palo Alto, California) N_2O purchase data for calendar year 2022 were collected and compared (volume and cost) to total Palo Alto clinical delivery data using Epic electronic health records. In phase 2, a pilot study was conducted in the 8 operating rooms of SHC campus A (Redwood City). The central N_2O pipelines were disconnected, and E-cylinders were used in each operating room. E-cylinders were weighed before and after use on a weekly basis for comparison to Epic N_2O delivery data over a 5-week period. In phase 3, after successful implementation, the same methodology was applied to campus B, one of 3 facilities in Palo Alto.

Results: In phase 1, total N_2O purchased in 2022 was 8,217,449 L (33,201.8 lbs) at a total cost of US $63,298. Of this, only 780,882.2 L (9.5%) of N_2O was delivered to patients, with 7,436,566.8 L (90.5%) or US $57,285 worth lost or wasted. In phase 2, the total mass of N_2O use from E-cylinders was 7.4 lbs (1 lb N_2O=247.5 L) or 1831.5 L at campus A. Epic data showed that the total N_2O volume delivered was 1839.3 L (7.4 lbs). In phase 3, the total mass of N_2O use from E-cylinders was 10.4 lbs or 2574 L at campus B (confirming reliability within error propagation margins). Epic data showed that the total N_2O volume delivered was 2840.3 L (11.5 lbs). Over phases 2 and 3, total use for campuses A and B was less than the volume of 3 E-cylinders (1 E-cylinder=1590 L).

Conclusions: Converting N_2O delivery from centralized storage to point-of-care E-cylinders dramatically reduced waste and expense with no detriment to patient care. Our results provide strong evidence for analyzing N_2O storage in health care systems that rely on centralized storage, and consideration of E-cylinder implementation to reduce emissions. The reduction in N_2O waste will help meet SHC's goal of reducing scope 1 and 2 emissions by 50% before 2030.

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KEYWORDS

anesthetic gases; emissions; green house gas; sustainability; pilot study; electronic health record; implementation; nitrous oxide; global warming

Introduction

Reducing greenhouse gas (GHG) emissions is a priority that must be addressed to reduce climate change and its negative impacts on earth and its inhabitants. The US Environmental Protection Agency (EPA) classifies GHG emissions into different categories, with scope 1 emissions defined as direct GHG emissions from sources that are controlled by organizations, including health care systems, and scope 2 emissions being indirect GHG emissions associated with the purchase of electricity, heat, steam, or cooling [1]. Stanford Health Care (SHC) has signed on to the US Department of Health and Human Services' pledge to reduce its scope 1 and 2 emissions by 50% by 2030 [2]. Within the medical sector, inhalational anesthetic gases that are directly released into the atmosphere are a major source of potent GHGs. Thus, there is a fertile opportunity to reduce GHGs by reducing the emission of anesthetic gases [3]. By collecting annual emissions data within the SHC system, improvements to sustainability and infrastructure could be explored.

Global warming potential (GWP) represents the energy a gas is able to absorb relative to carbon dioxide (CO_2), with a larger GWP representing increased planetary warming [4]. The environmental impacts of 2 inhaled anesthetic gases over a 100-year period (ie, global warming potential of GHGs over a 100-year period [GWP100]) are particularly relevant: desflurane, a volatile halogenated agent with particularly high GWP100 of 2540, and nitrous oxide (N_2O) with a lower GWP100 of 298 but used in much higher volumes than other anesthetic gases, and with longer half-life compared to CO_2, leading to lasting environmental consequences [5]. Further, because of its low clinical potency, large amounts of N_2O must be stored for use, increasing the chance of pollution through leaks. Centrally piped cryogenic liquid, centrally piped gas, and portable E-cylinders are the standard options for delivering N_2O [6]. Miles of pipes and innumerable valves in centrally piped systems lead to an abundance of leaks, contributing to excessive loss and waste [6]. While desflurane has already been discontinued from routine clinical use at SHC, we aimed to determine the degree to which N_2O emissions could be reduced and waste prevented, building on prior studies highlighting the waste of N_2O in other institutions [7].

Methods

Phase 1

To begin investigating N_2O emissions, purchase data (volume and cost) were collected and compared to total use data (clinical delivery) using the Epic SlicerDicer tool, part of the Epic electronic health record (EHR) [8]. Epic yearly clinical use data for N_2O are available per clinical service in the SHC's operating rooms. Gas losses in the system can be estimated by comparing documented gas delivery at the point of care with the volume of N_2O purchased. Initial data analysis revealed a drastic amount of lost N_2O, leading us to perform a pilot study (phase 2, E-cylinder implementation) to enable remediation aimed at reducing N_2O emissions.

Phase 2

Using the Institute for Healthcare Improvement framework of "Plan, Do, Study, Act" for performance improvement [9], a pilot study was conducted in the 8 operating rooms of the SHC campus in Redwood City, California (campus A). E-cylinder canisters were deployed in each operating room and all central N_2O pipelines were disconnected. EHR documentation of gas delivered in liters (volume) was compared to measured E-cylinder mass. To verify use and track N_2O leaving each tank, the E-cylinders were weighed before and after use on a weekly basis with the difference in mass converted to volume (liters). Since the measured pressure remains the same as long as liquid remains in the cylinders, pressure differences cannot be used for measuring N_2O flow until only gas is left (at which point the pressure drop correlates with the amount of gas being removed) [10]. By using the conversion of 1 lb (0.45 kg) of N_2O being equal to 247.5 L [6], the volume of N_2O dispensed could be calculated. Total calculated volume leaving the E-cylinders based on measured mass was compared to total volume delivered according to Epic data.

Phase 3

Following the results of phase 2, a secondary study was conducted in 16 operating rooms at Blake Wilbur Drive Palo Alto, California (campus B). Phase 3 used the same methodology as phase 2 over a 3-week period.

Ethical Considerations

Due to the nature of the research and institutional approval, no IRB approval was necessary. No identifying patient data was used as we only measured nitrous oxide gas delivery and utilization.

Results

Phase 1

According to the Stanford Medicine Sustainability Program Office [2], the annual Palo Alto SHC 2022 Scope 1 emissions were 19,374 $MTCO_2e$ (metric ton of CO_2 equivalent, the standard unit for comparing different GHGs to quantify their environmental impact and GWP) of which medical gases (including N_2O, CO_2, sevoflurane, and isoflurane) represented 4862 $MTCO_2e$. N_2O contributed 4590 $MTCO_2e$ of the medical gases. Thus, medical gases account for 25.1% of all SHC scope 1 emissions, and N_2O alone accounts for 94.4% of those emissions (or 23.7% of the total).

Annual clinical usage of N_2O in 2022 per Epic data (Table 1) was 780,882.2 L (3155.1 lbs or 1431.1 kg), with the greatest use being for orthopedic surgery, general surgery, and neurosurgery cases. However, the total amount of N_2O purchased was 8,217,449 L (33,201.8 lbs or 15,060.1 kg), at a total cost of US $63,298. Thus, only 9.5% of the total purchased N_2O was actually delivered to patients, and 90.5% (or US $57,285 worth) was wasted.

Table 1. Annualized data comparing centralized N_2O system to hypothetical E-cylinders for Stanford Health Care (SHC; all campuses).

	Amount purchased (L)	Cost (US $)	Amount used (L)	Amount lost as waste (L)
Centralized system	8,217,449	63,298	780,882.2	7,436,566.8
E-cylinders	780,882.2[a]	6015	780,882.2	0[b]

[a]Amount needed to purchase with zero surplus based on use data under experimental conditions.

[b]Annualized E-cylinder data are extrapolated from experimental conditions; real-world conditions may vary.

With these data indicating a loss of greater than 90% between storage tanks and clinical use, a highly inefficient storage and pipeline system was recognized. The proposed solution (for phase 2 of the study) was to decommission the storage tanks and pipelines and switch to portable E-cylinders that stored and delivered N_2O at the point of care.

Phase 2

The change in mass of the E-cylinders indicated that N_2O use at campus A totaled 7.4 lbs (3.4 kg), or a volume of 1831.5 L, over the 5-week study period. Epic data showed total N_2O volume delivered to be 1839.3 L calculated to 7.4 lbs (3.4 kg; consistent with the measured 7.4 lbs). Using the standard of 1 E-cylinder=1590 L or 6.4 lbs (2.9 kg) [11], total use equaled 1.16 E-cylinders.

Phase 3

The E-cylinder change in mass indicated that N_2O use at campus B totaled 10.4 lbs (4.7 kg), or 2574 L, over the 3-week data collection period. Epic data showed total N_2O volume delivered to be 2840.3 L calculated to 11.5 lbs (5.2 kg; compared to the measured 10.4 lbs, which would be equivalent to 1.63 E-cylinders) [11].

Discussion

Principal Findings

Results from phase 1 corroborate findings from previous studies in the United Kingdom and Portland, Oregon [12,13], which reveal excessive waste from centralized storage of N_2O and pipe systems for delivery. Phases 2 and 3 of this study, from 2 different SHC campuses, demonstrate the efficient, cost-effective elimination of waste through substitution of E-cylinders with storage and delivery at the point of care. In phases 2 and 3, avoidable N_2O emissions were almost completely eliminated (Multimedia Appendix 1). The discrepancy between actual weighed N_2O and Epic-reported use for campus A was 7.8 L, or <0.1 lb (<0.1 kg). Campus B had a greater discrepancy with the difference in actual weighed N_2O and Epic-reported use being 266.3 L, or 1.1 lbs (0.45 kg). The amount of gas delivered according to the EHR was greater than the amount actually measured at the source, potentially accounted for by limited precision of the scales used to weigh the E-cylinders (only to 0.1-lb increments), or accidental reconnection of N_2O pipelines in one operating room during phase 3. This issue was detected after 1 week and immediately rectified.

E-cylinders provide an efficient and effective solution, but they hold limitations. E-cylinders must be stored properly to ensure that they do not present a catalyst in the event of a fire [14]. However, no policy implementation is required as E-cylinders are already in use in operating rooms and costs associated with storage can be offset by the N_2O saved. Ready accessibility, lower cost, reduced supply chain issues, and efficiency of E-cylinders far outweigh the abovementioned disadvantages.

Limitations

The limitations of this study include the fact that real-world use and waste may vary from our experimental conditions, likely incurring greater losses. If e-cylinder valves are accidentally left open, losses may simulate those from centralized pipelines until the valve is closed [6] or the E-cylinder is emptied. The amount of N_2O to be purchased would need to be greater than the amount used in our example (Table 1), to provide surplus in the E-cylinders as well as spare E-cylinders. Prospective estimates of volume when making a purchase order would likely exceed actual use. Both recording and documentation of N_2O readings and the scale measurements are susceptible to error.

Conclusions

Converting the delivery of N_2O from centralized storage to point-of-care E-cylinders has dramatically reduced waste and expense with no detriment to patient care. Stanford's pledge to reduce scope 1 and 2 emissions by 50% can be achieved and even surpassed if this practice is changed in all SHC locations. The introduction of E-cylinders will provide a nondisruptive means for immediately decreasing emissions while continuing to provide optimal anesthetic care. Pilot studies throughout Stanford's campuses continue, with the goal of removing the centralized N_2O system and switching to E-cylinders at other sites, thereby significantly reducing anesthetic GHG emissions. Efforts to reduce GHG emissions may begin locally but have applications globally. Reducing the anesthetic carbon footprint of health care organizations is necessary for our planet and can begin with the reduction of wasteful emissions.

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Authors' Contributions

EPK conducted the data analysis and drafted and edited the manuscript. DC conducted the data analysis and edited the manuscript. SK collected and analyzed the data. PK conceptualized the study, conducted and analyzed the data, and edited the manuscript. PK and SK (SaadatKhan@stanfordhealthcare.org) are co-corresponding authors.

Conflicts of Interest

PK is an associate editor for *JMIR Perioperative Medicine*.

Multimedia Appendix 1
Reduction in N_2O emissions per metric ton of CO_2 equivalents by switching from the original central supply to portable supply E-cylinder storage.
[PNG File , 58 KB - periop_v8i1e64921_app1.png]

References

1. Scope 1 and Scope 2 Inventory Guidance. United States Environmental Protection Agency. 2020. URL: https://www.epa.gov/climateleadership/scope-1-and-scope-2-inventory-guidance [accessed 2024-12-16]
2. Stanford Medicine. Our Sustainability Commitment. Stanford Health Care. URL: https://stanfordhealthcare.org/sustainability-program-office/sustainability-program-office/what-we-do/our-sustainability-commitment.html [accessed 2024-12-16]
3. Chesebro BB, Gandhi S. Mitigating the systemic loss of nitrous oxide: a narrative review and data-driven practice analysis. Br J Anaesth 2024 Dec;133(6):1413-1418. [doi: 10.1016/j.bja.2024.08.028] [Medline: 39322471]
4. Understanding Global Warming Potentials. United States Environmental Protection Agency. 2016. URL: https://www.epa.gov/ghgemissions/understanding-global-warming-potentials [accessed 2024-12-16]
5. Sulbaek Andersen MP, Nielsen OJ, Wallington TJ, Karpichev B, Sander SP. Medical intelligence article: assessing the impact on global climate from general anesthetic gases. Anesth Analg 2012 May;114(5):1081-1085. [doi: 10.1213/ANE.0b013e31824d6150] [Medline: 22492189]
6. Collaborating to prevent nitrous oxide waste in medical gas systems. Practice Greenhealth. URL: https://practicegreenhealth.org/tools-and-resources/collaborating-prevent-nitrous-oxide-waste-medical-gas-systems [accessed 2024-12-16]
7. Seglenieks R, Wong A, Pearson F, McGain F. Discrepancy between procurement and clinical use of nitrous oxide: waste not, want not. Br J Anaesth 2022 Jan;128(1):e32-e34 [FREE Full text] [doi: 10.1016/j.bja.2021.10.021] [Medline: 34802695]
8. Our Software. Epic Systems Corporation. URL: https://www.epic.com/software/ [accessed 2024-12-16]
9. How to Improve: Model for Improvement. Institute for Healthcare Improvement. URL: https://www.ihi.org/resources/how-to-improve [accessed 2024-12-16]
10. Medical Gases: Storage and Supply. Anesthesia Key. 2019. URL: https://aneskey.com/medical-gases-storage-and-supply-2/ [accessed 2024-12-16]
11. Rose G, McLarney J. Pneumatic Systems. In: Anesthesia Equipment Simplified. New York, NY: McGraw-Hill Education; 2014.
12. Devlin-Hegedus JA, McGain F, Harris RD, Sherman JD. Action guidance for addressing pollution from inhalational anaesthetics. Anaesthesia 2022 Sep 21;77(9):1023-1029 [FREE Full text] [doi: 10.1111/anae.15785] [Medline: 35729804]
13. Sherman J. It's time hospitals abandon nitrous oxide pipes. ASA Monitor 2024;88:33 [FREE Full text] [doi: 10.1097/01.ASM.0001006828.24359.cd]
14. Nitrous oxide. CAMEO Chemicals. URL: https://cameochemicals.noaa.gov/chemical/8909#:~:text=It%20is%20noncombustible%20but%20it,to%20rupture%20violently%20and%20rocket [accessed 2024-12-11]

Abbreviations

EHR: electronic health record
EPA: Environmental Protection Agency
GHG: greenhouse gas
GWP: global warming potential
GWP100: global warming potential of GHGs over a 100-year period
$MTCO_2e$: metric ton of carbon dioxide equivalent
N_2O: nitrous oxide
SHC: Stanford Health Care

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Original Paper

A Patient-Oriented Implementation Strategy for a Perioperative mHealth Intervention: Feasibility Cohort Study

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Abstract

Background: Day surgery is being increasingly implemented across Europe, driven in part by capacity problems. Patients recovering at home could benefit from tools tailored to their new care setting to effectively manage their convalescence. The mHealth application ikHerstel is one such tool, but although it administers its functions in the home, its implementation hinges on health care professionals within the hospital.

Objective: We conducted a feasibility study of an additional patient-oriented implementation strategy for ikHerstel. This strategy aimed to empower patients to access and use ikHerstel independently, in contrast to implementation as usual, which hinges on the health care professional acting as gatekeeper. Our research question was “How well are patients able to use ikHerstel independently of their health care professional?”

Methods: We investigated the implementation strategy in terms of its recruitment, reach, dose delivered, dose received, and fidelity. Patients with a recent or prospective elective surgery were recruited using a wide array of materials to simulate patient-oriented dissemination of ikHerstel. Data were collected through web-based surveys. Descriptive analysis and open coding were used to analyze the data.

Results: Recruitment yielded 213 registrations, with 55 patients ultimately included in the study. The sample was characterized by patients undergoing abdominal surgery, with high literacy and above average digital health literacy, and included an overrepresentation of women (48/55, 87%). The implementation strategy had a reach of 81% (63/78), with 87% (55/67) of patients creating a recovery plan. Patients were satisfied with their independent use of ikHerstel, rating it an average 7.0 (SD 1.9) of 10, and 54% (29/54) of patients explicitly reported no difficulties in using it. A major concern of the implementation strategy was conflicts in recommendations between ikHerstel and the health care professionals, as well as the resulting feelings of insecurity experienced by patients.

Conclusions: In this small feasibility study, most patients were satisfied with the patient-oriented implementation strategy. However, the lack of involvement of health care professionals due to the strategy contributed to patient concerns regarding conflicting recommendations between ikHerstel and health care professionals.

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KEYWORDS

perioperative care; recovery; feasibility; convalescence; patient-oriented; surgery; perioperative; eHealth; mHealth; tailor; customize; patient care; digital intervention; health intervention; patient education; surgical care; hospital care; digital health; perioperative medicine; elective surgery; technology; caregiver; mobile app; digital care

Introduction

Day surgery—defined as admittance to and discharge from a hospital within 24 hours following surgery—has seen a marked increase in Organisation for Economic Co-operation and Development member countries over the past decades [1]. The appeal of day surgery derives from multiple factors, including its reduced cost, decreased morbidity and mortality, and high levels of patient satisfaction [2-6]. When it comes to postsurgical recovery, however, the reports are more nuanced. Tran et al [7] showed how 1 in 3 patients exhibit suboptimal recovery trajectories following day surgery. Patients recovering at home describe feelings of insecurity, an experience moderated by the timely provision of information, professional support, and expectation management [4,8-12]. mHealth interventions have been shown to be effective when it comes to targeting these domains and their use in the perioperative setting is well appreciated by patients [13,14]. In the Netherlands specifically, the Patient Journey app has been shown to improve postoperative outcomes for patients with musculoskeletal disorders [15].

Similarly, the mHealth intervention ikHerstel (meaning "I recover" in Dutch) is a tool designed to support patients undergoing abdominal surgery during their perioperative period. The intervention's ability to speed up postoperative recovery, reduce pain, and improve patients' quality of life has been established in previous studies [12,16-18]. However, its implementation occurs on the level of the hospital ward, and it hinges on the involvement of health care professionals within the ward, who act as both distributors of the intervention and instructors of patients. This strategy features benefits as well as challenges: health care professionals are well situated to select eligible patients and can improve adherence to treatment when they use effective communication strategies [19,20]. However, at the time of publishing, the intervention has been implemented in only 10% of hospitals in the Netherlands. Wider implementation is hampered by, among other factors, financial barriers present in the Dutch health care system that make upscaling of telemonitoring interventions in general a difficult enterprise [21]. This limits ikHerstel's reach, leaving patients bereft of its aforementioned benefits.

In this feasibility study, we explored a patient-oriented implementation strategy for ikHerstel that aimed to circumvent this hospital-level barrier by targeting patients directly. If successful, this strategy could operate in addition to implementation as usual, with reimbursement flowing from health insurers to patients. We therefore aimed to evaluate whether it would be successful in increasing the intervention's reach and whether patients, once reached, were able to use ikHerstel independently from their health care professional.

Methods

Ethical Considerations

Approval for the study was granted by the medical ethics committee of Amsterdam University Medical Center on May 31, 2022 (2022.0224). Informed consent was obtained through postal mail and patients were informed of their ability to opt out of participation in the study at any time. Patients were provided with access to ikHerstel free of charge but were not offered any remuneration for their participation in the study. Data were deidentified by the coordinating researcher, and patients were labeled using random strings. The patient identification keys were kept in a separate location from the data.

Study Setting

We conducted a prospective study assessing the feasibility of a patient-oriented implementation strategy for the ikHerstel mHealth intervention. Our assessment was performed based on the model of Steckler and Linnan [22]; its outcomes were reach, dose delivered, dose received, fidelity, and recruitment. In consultation with health insurers and a patient interest group, we aimed to include 100 perioperative patients representing the theoretical user base of the ikHerstel app, that is, any patients who were theoretically able to access the app and use it in such a way as to manage their own recovery, regardless of age, gender, nationality, literacy, digital literacy, or health literacy. Recruitment started in September 2022 and lasted through September 2023.

Inclusion and Exclusion Criteria

Patients were eligible for inclusion if they were older than 18 years, proficient in the Dutch language, and prospective recipients of one of the following elective surgical procedures: laparoscopic or abdominal hysterectomy, laparoscopic cholecystectomy, open or laparoscopic inguinal hernia surgery, or laparoscopic adnexal surgery. Patients were excluded if the date of their surgery was ≥14 days prior to inclusion, they were undergoing a combination of surgeries, they had comorbidities that invalidated the convalescence recommendations provided by ikHerstel, they were undergoing oncological surgery, or they were receiving care from a hospital that had already implemented ikHerstel.

Intervention and Procedure

ikHerstel was developed in collaboration with health care professionals of a diverse background. Its development process has been described previously [23]. An overview of the current functions and layout of ikHerstel is provided in Multimedia Appendix 1. Its aim is to prepare patients and manage their expectations preoperatively and to support them in recovery of the daily functions of life postoperatively [23]. Each patient received the ikHerstel intervention in addition to usual care. Patients were able to interact with the intervention in the form of a mobile app, which they used up to the point of their total recovery. They were provided with personal accounts in which they constructed their recovery plan through goal attainment by selecting 8 personal activities from a list of 31 to constitute their most important recovery goals. In this way, one patient might create a plan focused on performing tasks around the house while another might create one centered on regaining the ability to run long distances. Patients monitored their recovery plan through the mobile app: they were asked to indicate when they were able to perform each of the activities in their plan. The total postoperative recovery was visible as a percentage within the app. Additionally, educational material about recovery

was provided to patients in the form of text and video animations through the app's library screen.

Implementation Strategy as Usual

In its current form, ikHerstel's implementation strategy hinges on health care professionals, who recruit eligible patients, introduce them to the app and its potential benefits, and provide them with access by creating a personal account. This final step is particularly crucial, as patients cannot access ikHerstel without an account, and health care professionals preload each account with recovery-related data specific to the patient's surgical procedure. Implementation occurs at the level of the hospital ward. A medical liaison associated with ikHerstel trains the ward's staff in the app's use and goals and in carrying out support tasks like creating patient accounts. The hospital ward is also provided with a web portal that mediates these administrative functions, allows for monitoring of each patient's recovery, and provides health care professionals with organizational support.

Patient-Oriented Implementation Strategy

The patient-oriented implementation strategy piloted in this study circumvented health care professionals, relying instead on patients to sign up and use ikHerstel independently. Health care professionals did not have access to the app or the web portal. Instead, these responsibilities were assigned to the coordinating researcher as a placeholder for the support staff of the ikHerstel spinoff company. During the course of the study, the coordinating researcher created patients' accounts and loaded them with surgery-related data based on information provided by the patients. Patient monitoring through the web portal was not performed. In case of questions concerning ikHerstel, patients were directed to the coordinating researcher, whose contact details were provided. Patients with medical questions were directed by the researcher to consult their health care professional. This highlights the key role still reserved for health care professionals in this patient-oriented implementation, as they retained responsibility for care of their patients, including monitoring for adverse outcomes. Accordingly, patients were informed that their health care professional held final authority over the content and provision of care. Figure 1 illustrates the differences between the implementation strategies. Table 1 presents an overview of the recruitment tools that were used, distinguishing between hospital-independent and -dependent tools.

With the exception of the magazine advertisements, all advertisements followed the same basic design, created with low-literacy patients in mind. An example is provided in Multimedia Appendix 2. These materials were distributed to patients in hospitals, on patient fora, on webpages of patient interest groups, in patient magazines, through internet search engine advertisements, and within patient groups on social media. Each advertisement linked to a web portal where patients were informed of the study and asked to leave their contact details. Patients were subsequently contacted via telephone by the coordinating researcher, who provided further information and performed screening on the basis of the inclusion and exclusion criteria.

Figure 1. Schematic representation of the differences between implementation as usual and the patient-oriented implementation.

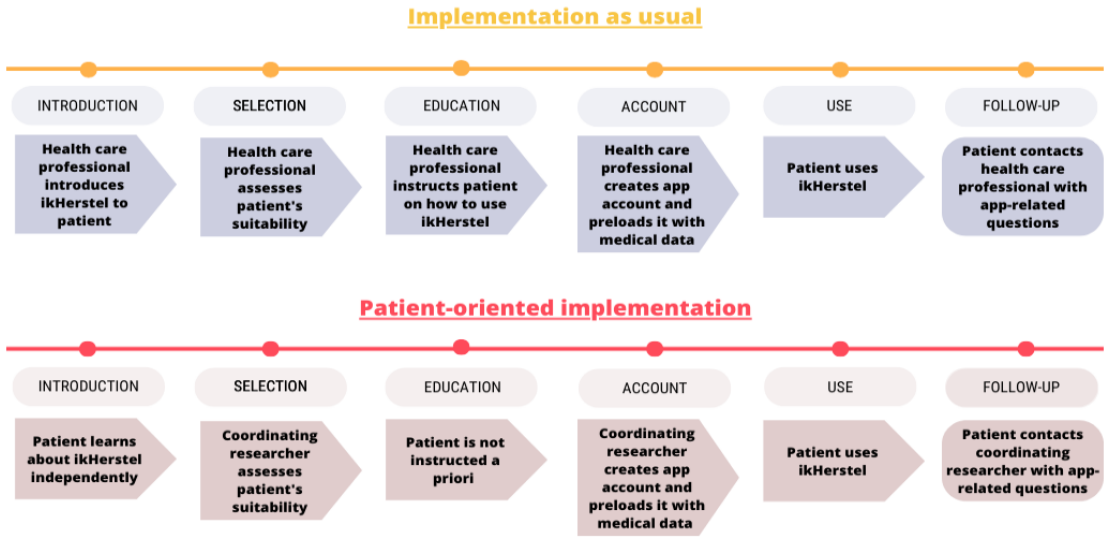

Table 1. Materials used for study recruitment and the frequency of their use, split into hospital-dependent and -independent tools.

Materials	Frequency of use, n
Hospital-independent	
Forum advertisements	15
Webpage advertisements	2
Internet search engine advertisements	1
Social media advertisements	4
Magazine advertisements	2
Hospital-dependent	
Flyers	11
Posters	10
Business cards	6
Electronic displays	5
Hospital staff	2

Data Collection

Data were collected through a set of 4 digital surveys constructed, distributed, and maintained through Survalyzer (Survalyzer AG). A baseline survey (T_0) was used to collect demographic data. Follow-up surveys were distributed to patients at T_1 (3 weeks), T_2 (6 weeks), and T_3 (12 weeks) after surgery to collect data on the user experience.

Background Factors and Implementation Outcomes

Demographic data included socioeconomic factors like age, sex, and education level, which is aligned with a previous study by van der Meij et al [24]. Demographics also included a measure of patients' traditional literacy, operationalized on the basis of the Diagnostic Illiteracy Scale, where a score of 14 points or higher constitutes a risk of the individual being illiterate [25]. Digital literacy was operationalized using patient self-assessment and a scanning tool (Quickscan) developed for physicians by the Dutch patient advocate organization Pharos, which characterizes patients as digitally unskilled with a score of 10 points or higher [26].

The model by Steckler and Linnan [22], commonly used in public health, describes the evaluation of implementation outcomes as a concatenated appraisal of an intervention's context, reach, dose delivered, dose received, fidelity, and recruitment. Operationalization of these outcomes was performed similarly to previous process evaluations of ikHerstel to facilitate comparison [24,27]. We omitted the aspect of fidelity, as the app does not deviate from protocol in its delivery of the intervention. We also omitted context, as this is described in earlier publications, as well as the aspect of implementation, as we judged its transformation of the other aspects into a summative score to be a bad fit for our study. We also evaluated the recruitment tools and their channels (hospital dependent vs independent) in terms of their effectiveness in recruiting eligible patients to use the app. To compute this count, we asked patients to state how they were informed about the study.

We measured patient attitudes in alignment with the patient-oriented character of the implementation strategy and for comparison with previous research [24,27]. We operationalized patient attitudes as patients' self-reported satisfaction rating and their experienced barriers to use. We additionally measured patient attitudes using the unified theory of acceptance and use of technology 2 (UTAUT2), developed by Venkatesh et al [28]. Briefly, this framework describes an individual's intention to use a technology as being determined by 7 constructs: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation, price value, and habit. Social influence and hedonic motivation were deemed less relevant to ikHerstel's context and thus were not included. Relevant UTAUT2 survey items were selected by the researchers, adapted to the research context, and translated into Dutch. Response categories followed a 4-point Likert scale centered on agreement. The resultant survey is provided in Multimedia Appendix 3. A full overview of the study's outcomes and their operationalization is presented in Table 2.

Table 2. Operationalization of implementation outcomes and patient attitudes.

	Description	Operationalization
Implementation outcomes[a]		
Reach	The proportion of the intended target audience that participated in the study	Numerator: number of patients who met the inclusion criteria and signed an informed consent form; denominator: number of patients who met the inclusion criteria, regardless of their eventual participation in the study
Dose delivered	The number or amount of intended units of the intervention provided to the study population	Numerator: number of patients who were provided with an account for the ikHerstel app; denominator: number of patients who met the inclusion criteria and signed an informed consent form
Dose received	The extent to which participants actively engaged with, interacted with, were receptive to, or used the intervention	Numerator: number of patients who activated their ikHerstel account, created a recovery plan, and used the app on a weekly basis; denominator: number of patients who were provided with an account for the ikHerstel app
Recruitment	The effectiveness of the procedures used to attract participants	An appraisal of the effectiveness of each recruitment medium (hospital dependent vs independent) and tool in terms of the number of inclusions versus registrations they produced
Patient attitudes		
Patient satisfaction	—[b]	Patient satisfaction, assessed through a self-reported score between 0 and 10
Barriers to use	—	Five open questions: • What did you like about using ikHerstel? • What makes using ikHerstel easy? • What did you dislike about using ikHerstel? • What makes using ikHerstel difficult? • Do you have any other comments about the ikHerstel app?
Performance expectancy[c]	The degree to which using the technology will provide benefits to consumers	The degree to which patients view ikHerstel as being able to beneficially affect their postsurgical recovery; operationalized as 3 self-reported items, scored using a 1-4 Likert scale
Effort expectancy[c]	The degree of ease associated with consumers' use of the technology	The degree to which patients feel using ikHerstel is simple and straightforward; operationalized as 3 self-reported items, scored using a 1-4 Likert scale
Facilitating conditions[c]	Consumers' perceptions of the resources and support available to perform a behavior	The degree to which patients feel they are supported in their use of ikHerstel; operationalized as 2 self-reported items, scored using a 1-4 Likert scale
Price value[c]	Consumers' cognitive tradeoff between the perceived benefits of the technology and the monetary cost for using it	The degree to which patients are willing to pay for their use of ikHerstel; operationalized as 1 self-reported item, scored using a 1-4 Likert scale
Habit[c]	The extent to which consumers tend to perform behaviors automatically because of learning	The degree to which patients feel their use of ikHerstel has become habitual; operationalized as 1 self-reported item, scored using a 1-4 Likert scale

[a]Based on the model by Steckler and Linnan [22].

[b]Not applicable.

[c]Based on the unified theory of acceptance and use of technology 2 by Venkatesh et al [28].

Data Analysis

Descriptive statistics were used to summarize the study's findings according to each process outcome as well as the UTAUT2 dimensions. Open-ended patient attitude items were assessed and categorized by the coordinating researcher, and the resultant categories were subsequently reviewed by another researcher from the research team.

Results

Reach

In the period between September 2022 and September 2023, 216 patients registered for the study. A schematic representation of the inclusion process is presented in Figure 2. Initial screening via telephone resulted in 148 exclusions. A major reason for exclusion was timing, as many patients only signed up for ikHerstel once their surgery had already taken place. The exclusion criteria were revised to account for this unexpected result, allowing patients to participate up to 14 days following their surgery. This nevertheless still led to 42 exclusions due to

timing. A total of 68 patients were identified as eligible for participation and were subsequently sent informed consent forms. Among these 42 patients, 5 were excluded due to incompatible types of surgery that had not been identified as such prior to telephone screening. This resulted in a total of 63 included patients, which constitutes a reach of 81% (63 / (216 – (109 + 5 + 24)).

Baseline characteristics of these respondents are presented in Table 3. A majority of respondents were female, corresponding to one half of the included surgery types being gender specific for women. All the respondents had Dutch nationality and close to two-thirds (35/55) had a high level of education. All patients scored full points on the Quickscan test, and only one respondent gave a categorical self-description as being not very digitally skilled. The same held true for traditional literacy, with none of the respondents scoring in a range that would put them at risk of having low literacy skills [29].

Figure 2. Flow chart for inclusion in the study.

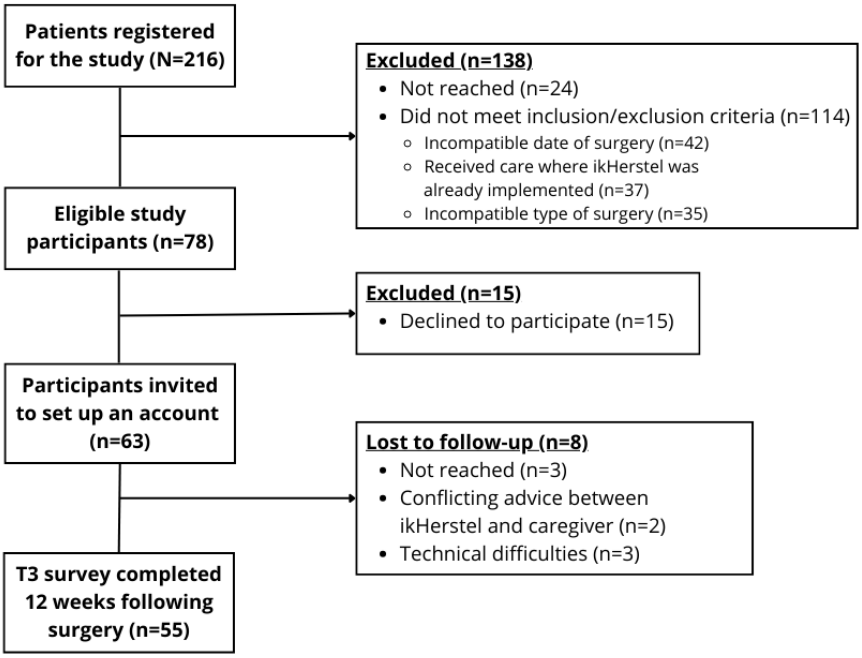

Table 3. Sample characteristics (n=55).

Variables	Values
Age (years), mean (SD)	48.6 (12.4)
Sex, n (%)	
Male	7 (13)
Female	48 (87)
Nationality, n (%)	
Dutch	55 (100)
Education, n (%)	
Low	7 (13)
Intermediate	13 (24)
High	35 (64)
Type of surgery, n (%)	
Laparoscopic uterus extirpation	21 (38)
Abdominal uterus extirpation	8 (15)
Vaginal uterus extirpation	6 (11)
Laparoscopic adnexal surgery	5 (9)
Laparoscopic cholecystectomy	10 (18)
Laparoscopic inguinal hernia surgery	4 (7)
Open inguinal hernia surgery	1 (2)
Digital skills—Quickscan, mean (SD)	6 (0)
Digital skills—self-scan (categorical), n (%)	
Very digitally skilled	29 (53)
Of average skill	25 (46)
Not or not very digitally skilled	1 (2)
Digital skills—self-scan (numeric), mean (SD)	7.9 (1.5)
Literacy score, mean (SD)	8.5 (2.6)

Dose Delivered

Of the 63 patients who signed the informed consent form and met the inclusion and exclusion criteria, 63 were provided with an account in the ikHerstel app. The dose-delivered fraction therefore computes to a percentage of 100%.

Dose Received

Of the 63 patients who were provided with an account, 55 activated their account and created a personalized recovery plan. Of these 55 patients, 34 reported using the app on a weekly or more frequent basis. The dose received fraction (34/63) therefore computes to a percentage of 54%.

Recruitment

An overview of the number of registrations and inclusions per recruitment tool is provided in Table 4. Most of the registrations (87/216, 40%) originated from tools that were dependent on hospitals, like posters, waiting room electronic displays, and hospital staff. Tools outside of the hospital yielded 36% (77/216) of registrations. However, they yielded more eligible patients (32 vs 31), as well as a higher proportion of eligible patients (32/77) compared to hospital-dependent tools (31/87).

Table 4. Overview of the number of registrations and eligible patients per recruitment tool.

Tools	Registrations, n (N=216)	Eligible patients, n (n=63)
Hospital-independent		
Forum advertisements	14	8
Webpage advertisements	1	0
Internet search	17	7
Social media	18	13
Magazine advertisements	21	2
Other[a]	6	2
Subtotal	77	32
Hospital-dependent		
Flyers	11	6
Posters	10	6
Business cards	2	2
Electronic displays	11	7
Hospital staff	24	8
Unspecified[b]	27	0
Other[c]	2	2
Subtotal	87	31
Unknown[d]	52	0

[a]This category included person-to-person contacts (n=5) and receiving an email of unknown origin (n=1).

[b]These respondents stated that the hospital was the source of their contact with ikHerstel.

[c]This category included patient-to-patient contacts in the convalescence room (n=1) and the webpage of the hospital (n=1).

[d]These respondents did not state how they came into contact with ikHerstel, mostly due to a lack of communication or stated interest on their part.

Patient Attitudes

Patients rated their overall satisfaction with ikHerstel an average 7.0 (SD 1.9) of 10. One patient did not answer the open-ended questions. A substantial proportion of patients (14/54) explicitly stated not having any dislikes about using ikHerstel, and an even greater proportion (29/54) explicitly reported no difficulties in using it. Most patients (49/54) reported positive experiences with ikHerstel. The most frequently stated (17/49) positive experience with ikHerstel related to its provision of perspective when it came to recovery. Patients furthermore found the app was clear in its presentation of information (10/49) and easy to use (8/46). Other stated likes related to the app's motivating power (6/49), its function as a source of information (3/49), its comforting effect (2/49), the patients' ability to benchmark their recovery (2/49), and a general statement of satisfaction (1/49). A majority of patients (50/54) reported on aspects that made using ikHerstel easy. The most frequently stated aspect was its clarity in presenting information (23/50). Patients also found it easy to navigate through the app (20/50) and praised its round-the-clock availability as a mobile phone app (6/50). One patient simply affirmed its ease of use, and others (4/50) found nothing about it easy. One patient stated, "Easy to use and provides motivation to start exercising and pick up activities again."

The most striking dislikes reported by patients were those concerning its recommendations. In some cases, what the app prescribed was misaligned with what patients felt they could handle. This mismatch ran both ways, as some patients felt the app was too ambitious, while others reported it was holding them back: "..that you [ikHerstel] go much faster than my recovery. That feels like failure because it repeatedly says you are behind on your recovery. It became more and more frustrating."

Another frequently stated mismatch was between ikHerstel and health care professionals. Of the 45 patients who reported receiving recovery recommendations from their health care professional, 33 stated that the recommendations provided by ikHerstel conflicted "sometimes" or more frequently. The majority of these (n=17) described the health care professional as conservative when it came to performing activities compared to the app. Others (n=8) reported that the app's recommendations were more elaborate and covered a wider slice of their daily life. Some patients (n=6) explicitly stated a dislike of the mismatch. In these cases as well, health care professionals' prescriptions were more conservative, and as a result, these patients reported feelings of frustration and insecurity: "[T]he recommendations from both the hospital and the GP [general practitioner]'s assistant were so much more conservative regarding when you should try and pick up activities that it made me feel insecure."

Other dislikes related to difficulties with inputting data (n=14), a lack of personalization (n=7), a lack of functionalities (n=5), the demotivating effect of the app (n=3), accessibility (n=1), technical failures (n=1), and miscellaneous difficulties (n=3); 14 patients found nothing to dislike. One patient stated, “After altering one of the activities, I had to redo all the input I had previously provided.”

UTAUT2 Dimensions

Among UTAUT2 survey dimensions, respondents rated their performance expectancy an average of 2.7 (SD 0.8) of 4 points. Effort expectancy was rated at 3.3 (SD 0.8) of 4 points and facilitating conditions at 3.4 (SD 0.7) of 4 points. The dimension of price value was scored an average 1.7 (SD 0.7) of 4 points, corresponding to 6 of 55 patients confirming that they would be agreeable to paying for the services provided by ikHerstel. A substantial proportion of patients (20/52) stated their use of ikHerstel had become habitual, resulting in an average score of 2.3 (SD 0.9) of 4 points for the dimension of habit.

Discussion

Principal Findings

In this feasibility study, we aimed to evaluate a patient-oriented implementation strategy for the mHealth intervention ikHerstel. We included 55 patients undergoing abdominal surgery among 216 registrations, and we investigated whether direct distribution of ikHerstel was a feasible addition to its implementation through hospitals. Hospital-dependent recruitment yielded slightly more registrations, while hospital-independent recruitment produced more eligible patients. The patient-oriented strategy constituted a reach of 81% (63/78), and 100% of reached patients were sent the intervention, after which 54% (34/63) engaged with it. Patients reported general satisfaction with ikHerstel, scoring it an average 7.0 (SD 1.9) of 10 points.

Other studies have examined user experiences with mHealth apps in the perioperative setting. To illustrate, a cross-sectional study on the Patient Journey app yielded higher levels of satisfaction compared to this study [15]. Patients were likewise positive about the app’s ease of use and its clear provision of useful information. A systematic review of patient experiences with mHealth confirms that this is a main benefit of these interventions [13]. The finding that patients regretted losing the possibility of communicating with their health care professional through the app was not replicated in our study. A previous process evaluation concerning a version of ikHerstel that did feature this function found that patients appreciated it, but that it should not replace a telephone appointment with their health care professional [24].

We hypothesized that the patient-oriented implementation strategy would increase ikHerstel’s reach. However, in terms of absolute scale, this expectation proved incorrect. Over the span of a year, only 216 registrations were generated, compared to the 1031 and 673 reported in previous studies, where hospitals played a central role in recruitment through their waiting lists [24,27]. Despite lower registration numbers, the reach of the patient-oriented implementation strategy was better, or at least comparable to, previous studies, at 81%, compared to 40% and 60%, respectively [24,27]. In addition to scale, an advantage of recruitment through hospitals was apparent when comparing the rate of and reasons for exclusion. Only 5% of patients were excluded due to ineligibility in the study by van der Meij et al [24], compared to our study’s exclusion rate of 53%. Poor timing (n=42, 37%), double registration (n=37, 32%), and ineligible types of surgery (n=35, 31%) make up the reasons for exclusion. In fact, poor timing proved such a barrier to participation that we were forced to revise our exclusion criteria halfway through the study to include patients up to 14 days after their surgery. Our assumption that patients would start looking for tools to support them through their perioperative journey prior to surgery proved false. In practice, this means that a substantial proportion of patients missed out on ikHerstel’s preoperative functions designed to enhance preparation and manage expectations.

The mismatch between ikHerstel’s recommendations and those of health care professionals also points to the strategic position of these professionals in perioperative care. Patients listed this mismatch not only as a source of dislike but also as one of feelings of insecurity. Other studies have reported similar findings [13,15]. The conflict itself may arise due to the conservative character of many health care professionals, as some studies indicate [30,31]. Complications that arose may likewise have caused mismatches by altering patients’ needs and invalidating the care provision of ikHerstel. Both cases advocate for the integral role of health care professionals in mHealth implementation strategies, as they are ideally situated to select patients and to adjust care provision when complications arise. By replacing these agents with a researcher, we effectively placed a part of our intervention outside of the broader system of care. Despite this, most patients had no trouble using ikHerstel independently. More than half of patients reported no difficulties and a quarter of patients explicitly found nothing to dislike.

Patients find value in mHealth apps in their provision of information that would otherwise not be readily available, and find even more value if that information is tailored to the patients’ individual situation [32]. In light of our own findings, it seems vital that health care professionals are involved in how mHealth is implemented to provide this function: as gatekeepers, selecting the right patients; as anchors, integrating an intervention into the broader system of care; but not as tech support, as patients seem able to navigate mHealth independently. Health care professionals could be involved through professional training, introducing them to the mHealth evidence base, or it may take the form of colleagues operating as implementation champions [33].

Limitations

A number of limitations need to be addressed, the first being the absence of health care professionals’ perspectives in our evaluation of the implementation strategy’s feasibility. The patient-oriented character of the study was chosen in dialogue with patient interest groups and health insurers, and aligns with the study’s aim of empowering patients to access ikHerstel even if their hospital has not implemented it. Health care professionals’ assessments of our strategy may nevertheless have yielded important insights, as they may have shed light

on conflicting recovery recommendations that were received by the participants.

Another limitation is the study's lack of a diverse sample of patients. We disproportionately included highly educated women of Dutch nationality. While an overrepresentation of women was expected due to the overrepresentation of gynecological types of surgery in our study, this does not explain the sample's high level of education or the lack of international patients. In the case of the latter, the use of the Dutch language in our recruitment material may well have discouraged any international patients from engaging with the study. For the former, the multimedia recruitment strategy we used, emphasizing access to a medical innovation, may have selected for highly educated patients, as some studies have reported on the association between educational level and the use of health services [34-37]. Here too, we may see a reflection of the absence of a health care professional, whose prompting influence might have worked to transcend such barriers. A study on sex differences regarding intention to use mHealth apps in the Netherlands found that women had a more negative attitude of mHealth, perceiving it as being less useful than did men [38]. This may have driven the difference in overall satisfaction scores between this study and the previous study by van der Meij et al [24], who included a more equal distribution of male versus female patients. Stratification by sex provides some weight to this argument, producing an average satisfaction score of 8.3 for men versus 6.8 for women, although these figures lack reliability precisely due to our sample's low representation of men.

Conclusions

The patient-oriented implementation strategy evaluated in this study was an equivocal success. One of its main hypothesized advantages of more easily reaching a wide audience of patients was not demonstrated. However, its method of recruitment has low costs, and most patients were satisfied and engaged with the mHealth app. Lack of involvement of health care professionals, rather than usability issues on the patients' side, contributed to patients' concerns regarding conflicting recommendations between ikHerstel and health care professionals. Given patient engagement, satisfaction, and improvement in outcomes [12,16-18] with use of such apps, hospitals should consider strategies where health care professionals are involved in selecting patients that may benefit from mHealth apps for postoperative recovery after day surgery and guiding patients' care.

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Conflicts of Interest

EvdM, JAFH, and JRA are the developers of the mHealth care program under study. JAFH and JRA are consultants and certificate holders of a spinoff company for implementation of the mobile app component of the IkHerstel intervention in the Netherlands (ie, the intervention under study). This spinoff company had no impact on the submitted work. JAFH received grants from Nederlandse Organisatie voor Wetenschappelijk Onderzoek, ZonMw, and Samsung during the conduct of the study and received a fee from Olympus outside the submitted work. JRA holds a chair in insurance medicine paid by the Dutch Social Security Agency and has received grants from ZonMw, Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Instituut Gak, Uitvoeringsinstituut Werknemersverzekeringen, Sociale Zaken en Werkgelegenheid, VWS (Volksgezondheid, Welzijn en Sport), Pfizer, Achmea, CVZ (College Voor Zorgverzekeringen), and Zorginstituut; all outside the submitted work. EvdM declares no competing interests.

Multimedia Appendix 1
Screening structure and content of ikHerstel.
[DOCX File , 316 KB - periop_v8i1e58878_app1.docx]

Multimedia Appendix 2
Advertisement design.
[DOCX File , 796 KB - periop_v8i1e58878_app2.docx]

Multimedia Appendix 3
Unified theory of acceptance and use of technology survey items.
[DOCX File , 22 KB - periop_v8i1e58878_app3.docx]

References

1. Health at a glance: Europe. Organisation for Economic Co-operation and Development/European Union. 2018. URL: https://www.oecd.org/en/publications/health-at-a-glance-europe-2018_health_glance_eur-2018-en/full-report.html [accessed 2025-01-07]

2. Madsen H, Henderson W, Dyas A, Bronsert M, Colborn K, Lambert-Kerzner A, et al. Inpatient versus outpatient surgery: a comparison of postoperative mortality and morbidity in elective operations. World J Surg 2023 Mar;47(3):627-639. [doi: 10.1007/s00268-022-06819-z] [Medline: 36380104]
3. Friedlander DF, Krimphove MJ, Cole AP, Marchese M, Lipsitz SR, Weissman JS, et al. Where is the value in ambulatory versus inpatient surgery? Ann Surg 2021 May 01;273(5):909-916. [doi: 10.1097/SLA.0000000000003578] [Medline: 31460878]
4. Lemos P, Pinto A, Morais G, Pereira J, Loureiro R, Teixeira S, et al. Patient satisfaction following day surgery. J Clin Anesth 2009 May;21(3):200-205. [doi: 10.1016/j.jclinane.2008.08.016] [Medline: 19464614]
5. Martin AD, Nunez RN, Andrews JR, Martin GL, Andrews PE, Castle EP. Outpatient prostatectomy: too much too soon or just what the patient ordered. Urology 2010 Feb;75(2):421-424. [doi: 10.1016/j.urology.2009.08.085] [Medline: 19969327]
6. Mathis MR, Naughton NN, Shanks AM, Freundlich RE, Pannucci CJ, Chu Y, et al. Patient selection for day case-eligible surgery: identifying those at high risk for major complications. Anesthesiology 2013 Dec;119(6):1310-1321 [FREE Full text] [doi: 10.1097/ALN.0000000000000005] [Medline: 24108100]
7. Tran TT, Kaneva P, Mayo NE, Fried GM, Feldman LS. Short-stay surgery: what really happens after discharge? Surgery 2014 Jul;156(1):20-27. [doi: 10.1016/j.surg.2014.03.024] [Medline: 24856316]
8. Berg K, Arestedt K, Kjellgren K. Postoperative recovery from the perspective of day surgery patients: a phenomenographic study. Int J Nurs Stud 2013 Dec;50(12):1630-1638. [doi: 10.1016/j.ijnurstu.2013.05.002] [Medline: 23726224]
9. Gilmartin J. Contemporary day surgery: patients' experience of discharge and recovery. J Clin Nurs 2007 Jun;16(6):1109-1117. [doi: 10.1111/j.1365-2702.2007.01548.x] [Medline: 17518885]
10. Larsson F, Strömbäck U, Rysst Gustafsson S, Engström Å. Postoperative recovery: experiences of patients who have undergone orthopedic day surgery. J Perianesth Nurs 2022 Aug;37(4):515-520 [FREE Full text] [doi: 10.1016/j.jopan.2021.10.012] [Medline: 35279387]
11. Mottram A. 'They are marvellous with you whilst you are in but the aftercare is rubbish': a grounded theory study of patients' and their carers' experiences after discharge following day surgery. J Clin Nurs 2011 Nov;20(21-22):3143-3151. [doi: 10.1111/j.1365-2702.2011.03763.x] [Medline: 21762418]
12. Vonk Noordegraaf A, Anema JR, van Mechelen W, Knol DL, van Baal WM, van Kesteren PJM, et al. A personalised eHealth programme reduces the duration until return to work after gynaecological surgery: results of a multicentre randomised trial. BJOG 2014 Aug;121(9):1127-35; discussion 1136. [doi: 10.1111/1471-0528.12661] [Medline: 24511914]
13. De La Cruz Monroy MFI, Mosahebi A. The use of smartphone applications (apps) for enhancing communication with surgical patients: a systematic review of the literature. Surg Innov 2019 Apr;26(2):244-259. [doi: 10.1177/1553350618819517] [Medline: 30602332]
14. Timmers T, Janssen L, Kool RB, Kremer JA. Educating patients by providing timely information using smartphone and tablet apps: systematic review. J Med Internet Res 2020 Apr 13;22(4):e17342 [FREE Full text] [doi: 10.2196/17342] [Medline: 32281936]
15. Willems SJ, Coppieters MW, Pronk Y, Diks MJF, van der Heijden KWAP, Rooker S, et al. A clinical journey mobile health app for perioperative patients: cross-sectional study. JMIR Hum Factors 2021 Feb 08;8(1):e20694 [FREE Full text] [doi: 10.2196/20694] [Medline: 33555262]
16. den Bakker CM, Schaafsma FG, Consten ECJ, Schraffordt Koops SE, van der Meij E, van de Ven PM, et al. Personalised electronic health programme for recovery after major abdominal surgery: a multicentre, single-blind, randomised, placebo-controlled trial. Lancet Digit Health 2023 Aug;5(8):e485-e494 [FREE Full text] [doi: 10.1016/S2589-7500(23)00084-5] [Medline: 37419843]
17. Bouwsma EVA, Bosmans JE, van Dongen JM, Brölmann HAM, Anema JR, Huirne JAF. Cost-effectiveness of an internet-based perioperative care programme to enhance postoperative recovery in gynaecological patients: economic evaluation alongside a stepped-wedge cluster-randomised trial. BMJ Open 2018 Jan 21;8(1):e017782 [FREE Full text] [doi: 10.1136/bmjopen-2017-017782] [Medline: 29358423]
18. van der Meij E, Anema J, Leclercq W, Bongers M, Consten E, Schraffordt Koops S, et al. Personalised perioperative care by e-health after intermediate-grade abdominal surgery: a multicentre, single-blind, randomised, placebo-controlled trial. Lancet 2018 Jul 07;392(10141):51-59. [doi: 10.1016/S0140-6736(18)31113-9] [Medline: 29937195]
19. Ha JF, Longnecker N. Doctor-patient communication: a review. Ochsner J 2010;10(1):38-43 [FREE Full text] [Medline: 21603354]
20. Kvarnström K, Westerholm A, Airaksinen M, Liira H. Factors contributing to medication adherence in patients with a chronic condition: a scoping review of qualitative research. Pharmaceutics 2021 Jul 20;13(7):1100 [FREE Full text] [doi: 10.3390/pharmaceutics13071100] [Medline: 34371791]
21. Praatplaat belemmeringen opschaling telemonitoring. Nederlandse Vereniging van Ziekenhuizen. URL: https://nvz-ziekenhuizen.nl/sites/default/files/2022-12/Belemmeringen%20opschaling%20telemonitoring.pdf [accessed 2024-02-19]
22. Steckler A, Linnan L. Process Evaluation for Public Health Interventions and Research. Hoboken, NJ: Jossey-Bass; 2002.
23. den Bakker CM, Schaafsma FG, van der Meij E, Meijerink WJ, van den Heuvel B, Baan AH, et al. Electronic health program to empower patients in returning to normal activities after general surgical and gynecological procedures: intervention

mapping as a useful method for further development. J Med Internet Res 2019 Feb 06;21(2):e9938 [FREE Full text] [doi: 10.2196/jmir.9938] [Medline: 30724740]
24. van der Meij E, Huirne JA, Ten Cate AD, Stockmann HB, Scholten PC, Davids PH, et al. A perioperative eHealth program to enhance postoperative recovery after abdominal surgery: process evaluation of a randomized controlled trial. J Med Internet Res 2018 Jan 02;20(1):e1 [FREE Full text] [doi: 10.2196/jmir.8338] [Medline: 29295808]
25. Greef M, Deursen A, Tubbing M, Bohnenn E. Development of the Diagnostic Illiteracy Scale in order to reveal illiteracy among adults. Andragogic Stud J Stu Adult Edu Learn 2013;1(1):1-48 [FREE Full text]
26. Quickscan digitale vaardigheden. Pharos. URL: https://www.pharos.nl/wp-content/uploads/2024/08/Quickscan_digitale-vaardigheden_082024.pdf [accessed 2022-05-02]
27. Bouwsma EVA, Vonk Noordegraaf A, Szlávik Z, Brölmann HAM, Emanuel MH, Lips JP, et al. Process evaluation of a multidisciplinary care program for patients undergoing gynaecological surgery. J Occup Rehabil 2014 Sep;24(3):425-438 [FREE Full text] [doi: 10.1007/s10926-013-9475-4] [Medline: 24057871]
28. Venkatesh V, Thong JYL, Xu X. Consumer acceptance and use of information technology: extending the unified theory of acceptance and use of technology. MIS Q 2012;36(1):157-178. [doi: 10.2307/41410412]
29. van Deursen A, van Dijk J. Modeling traditional literacy, internet skills and internet usage: an empirical study. Interact Comput 2014 Jul 16;28(1):13-26. [doi: 10.1093/iwc/iwu027]
30. Clayton M, Verow P. Advice given to patients about return to work and driving following surgery. Occup Med (Lond) 2007 Oct;57(7):488-491. [doi: 10.1093/occmed/kqm063] [Medline: 17906266]
31. Nygaard IE, Hamad NM, Shaw JM. Activity restrictions after gynecologic surgery: is there evidence? Int Urogynecol J 2013 May;24(5):719-724 [FREE Full text] [doi: 10.1007/s00192-012-2026-2] [Medline: 23340879]
32. Peng W, Kanthawala S, Yuan S, Hussain SA. A qualitative study of user perceptions of mobile health apps. BMC Public Health 2016 Nov 14;16(1):1158 [FREE Full text] [doi: 10.1186/s12889-016-3808-0] [Medline: 27842533]
33. Santos WJ, Graham ID, Lalonde M, Demery Varin M, Squires JE. The effectiveness of champions in implementing innovations in health care: a systematic review. Implement Sci Commun 2022 Jul 22;3(1):80 [FREE Full text] [doi: 10.1186/s43058-022-00315-0] [Medline: 35869516]
34. Groeneveld PW, Sonnad SS, Lee AK, Asch DA, Shea JE. Racial differences in attitudes toward innovative medical technology. J Gen Intern Med 2006 Jun;21(6):559-563 [FREE Full text] [doi: 10.1111/j.1525-1497.2006.00453.x] [Medline: 16808736]
35. National Academies of Sciences, Engineering, and Medicine. Health-Care Utilization as a Proxy in Disability Determination. Washington, DC: The National Academies Press; 2018.
36. Salganicoff A, Ranji U, Beamesderfer A, Kurani N. Women and health care in the early years of the ACA: key findings from the 2013 Kaiser Women's Health Survey. KFF. 2014 May 15. URL: https://www.kff.org/womens-health-policy/report/women-and-health-care-in-the-early-years-of-the-aca-key-findings-from-the-2013-kaiser-womens-health-survey/ [accessed 2025-07-01]
37. Hopman P, Heins M, Rijken M, Schellevis F. Health care utilization of patients with multiple chronic diseases in the Netherlands: differences and underlying factors. Eur J Intern Med 2015 Apr;26(3):190-196 [FREE Full text] [doi: 10.1016/j.ejim.2015.02.006] [Medline: 25704328]
38. van Elburg FRT, Klaver NS, Nieboer AP, Askari M. Gender differences regarding intention to use mHealth applications in the Dutch elderly population: a cross-sectional study. BMC Geriatr 2022 May 24;22(1):449 [FREE Full text] [doi: 10.1186/s12877-022-03130-3] [Medline: 35610577]

Abbreviations

UTAUT2: unified theory of acceptance and use of technology 2

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Original Paper

Feasibility of a Comprehensive eCoach to Support Patients Undergoing Colorectal Surgery: Longitudinal Observational Study

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Abstract

Background: The mainstay of colorectal cancer care is surgical resection, which carries a significant risk of complications. Efforts to improve outcomes have recently focused on intensive multimodal prehabilitation programs to better prepare patients for surgery, which make the perioperative process even more complex and demanding for patients. Digital applications (eCoaches) seem promising tools to guide patients during their care journey. We developed a comprehensive eCoach to support, guide, and monitor patients undergoing elective colorectal surgery through the perioperative phase of the care pathway.

Objective: The primary aim of this study was to determine its feasibility, in terms of recruitment rate, retention rate, and compliance. Also, usability and patient experience were examined.

Methods: A single-center cohort study was conducted from April to September 2023 in a tertiary teaching hospital in the Netherlands. All elective colorectal surgery patients were offered an eCoach that provided preoperative coaching of the prehabilitation protocol, guidance by giving timely information, and remote monitoring of postoperative recovery and complications. Recruitment and retention rate, as well as compliance for each part of the care pathway, were determined. Secondary, patient-reported usability measured by the Usefulness, Satisfaction, and Ease of Use questionnaire and patient experiences were reported.

Results: The recruitment rate for the eCoach was 74% (49/66). Main reasons for exclusion were digital illiteracy (n=10), not owning a smartphone (n=3), and the expected burden of use being too high (n=2). The retention rate was 80% (37/46). Median preoperative compliance with required actions in the app was 92% (IQR 87-95), and postoperative compliance was 100% (IQR 100-100). Patient-reported usability was good and patient experiences were mostly positive, although several suggestions for improvement were reported.

Conclusions: Our results demonstrate the feasibility of a comprehensive eCoach for guiding and monitoring patients undergoing colorectal surgery encompassing the entire perioperative pathway, including prehabilitation and postdischarge monitoring. Compliance was excellent for all phases of the care pathway and recruitment and retention rates were comparable with rates reported in the literature. The study findings provide valuable insights for the further development of the eCoach and highlight the potential of digital health applications in perioperative support.

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KEYWORDS

eCoach; telehealth; remote monitoring; home monitoring; virtual; eHealth; colorectal surgery; colorectal cancer; prehabilitation; ERAS; rehabilitation; care pathway; patient journey; feasibility; coaching; mobile phone

Introduction

Background

Colorectal cancer is the third leading cause of cancer deaths worldwide and is mainly diagnosed at an advanced age [1]. The mainstay of colorectal cancer care is surgical resection, which carries a significant risk of complications [2,3]. During hospital admission, enhanced recovery after surgery programs have been adopted widely, resulting in shorter hospital lengths of stay [4,5]. More recently, focus has shifted to optimizing patients preoperatively through multimodal prehabilitation programs, including physical training programs, improving nutritional status, and ameliorating medical comorbidities, thereby reducing postoperative complications [6,7]. After discharge, patients are encouraged to actively rehabilitate to full functional recovery. The entire care pathway from diagnosis to full functional recovery generally takes several months or longer when patients need to receive (neo)adjuvant chemo(radiation) therapy.

For many patients, the perioperative journey can be overwhelming and increasingly complex, as they need to manage a lot of information and perform various tasks at different times [8]. This highlights the need for a broader approach to health care that focuses not just on treating the disease but also on overall well-being, long-term recovery, and self-management. To support patients better, digital tools such as eCoaches are being used more in clinical practice [9]. These tools offer timely information, reminders, and remote monitoring to help patients stay on track and detect complications early. By promoting self-management, eCoaches also reduce the burden on health care systems, which is crucial as resources become more limited [10].

Many health apps for perioperative guidance are available, but the content is often narrow and applied to only one aspect of the care pathway, such as prehabilitation or postoperative monitoring [11-14]. An eCoach for colorectal surgery was reported, but did not include prehabilitation, for which digital coaching can be particularly helpful [15]. Furthermore, clear reporting of feasibility for older surgical patients in real-life clinical practice is often missing [16,17]. A recent study described feasibility of an intervention that combined digital guidance with intensive one-on-one human health coaching, but this is a health professional labor-intensive protocol [18]. More comprehensive digital coaching applications are needed that minimize health care resource usage while optimally informing and engaging patients, ultimately enhancing the quality of care.

A comprehensive eCoach was implemented to guide the patient throughout the perioperative colorectal pathway, providing timely information and monitoring prehabilitation adherence. In addition, immediately after discharge, patients were monitored remotely (vital signs, vomiting, stools, pain, and wound healing with automated alert identification and handling) to allow early detection of postoperative complications and thereby potentially prevent emergency readmissions and improve outcomes. To our knowledge this is the first eCoach for elective colorectal surgery encompassing the entire care pathway, including prehabilitation as well as postdischarge postoperative monitoring. This study explores the feasibility of a digital health application by assessing whether it works as intended in a given context, emphasizing key factors for implementation success while also considering user experience and system demands.

Aim

The primary aim of this study was to determine the feasibility, in terms of recruitment rate, retention rate, and compliance, of a comprehensive eCoach in support of the perioperative care pathway for colorectal surgical patients. The secondary aim was exploring usability, patient experiences and feedback, and evaluating app-induced workload.

Methods

Study Design and Setting

A single-center longitudinal observational study was conducted from April 2023 until September 2023 in a 1200-bed tertiary teaching hospital (Isala, Zwolle) in the Netherlands. Annually, approximately 350 colorectal resections are performed by a team of 5 specialized general surgeons. In April 2023, the eCoach application was implemented into the colorectal surgery pathway at the same time as the implementation of a standardized multimodal prehabilitation program (Fit4Surgery [19]). The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guideline for reporting observational studies was followed [20].

Ethical Considerations

The Medical Ethics Committee of the Isala Hospital reviewed the protocol (20230403) and declared that the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO) did not apply for this study, as the study involves an evaluation of usual care data. The study was conducted in accordance with the Declaration of Helsinki. After onboarding in the eCoach, each patient provided informed consent for use of their personal health information for research purposes in the app.

Participants and Procedures

Patients (older than 18 years) who were preparing for elective colorectal surgery and following the prehabilitation program were included when they were able to communicate in Dutch. The application was integrated into “usual care,” whereby the surgeon explicitly advised patients during their preoperative visit to enroll in the prehabilitation program and to use the app.

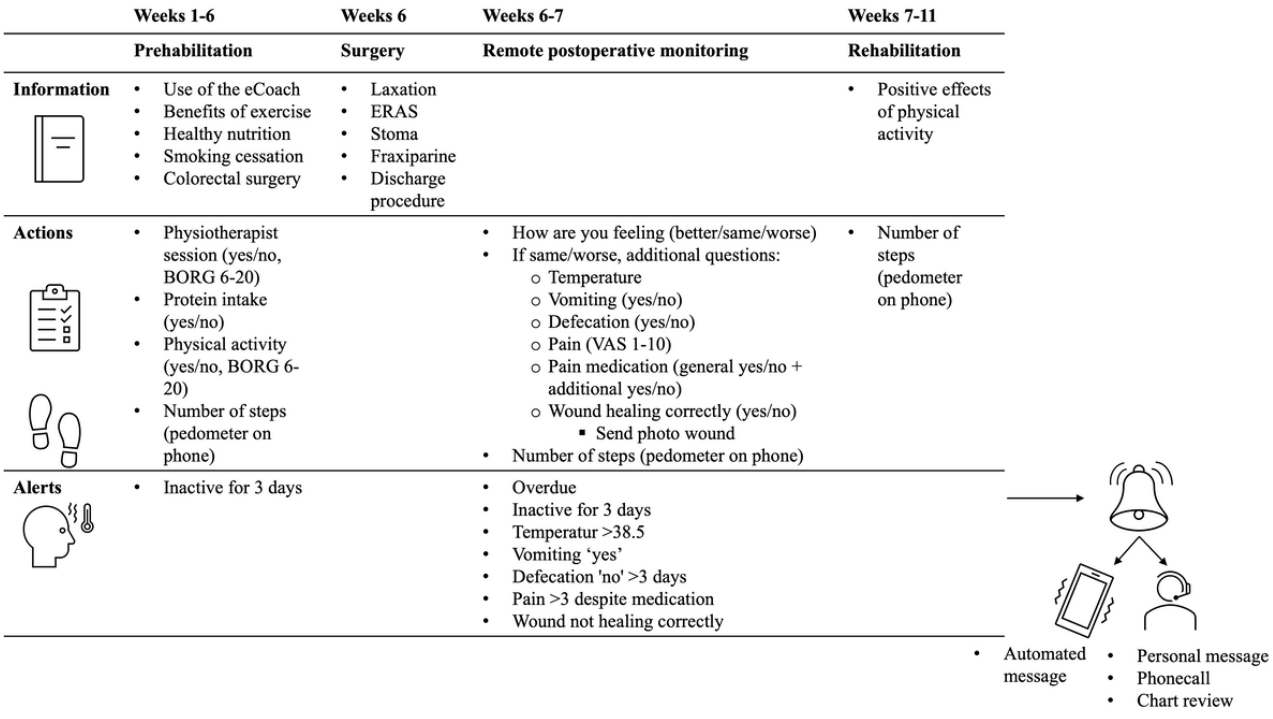
The nurse coordinator checked for eligibility right after the appointment with the surgeon by asking, “do you have a smartphone?” and “are you good at using your smartphone?” Patients were excluded if they were unable to use the app because they did not own a smartphone, did not have web connection, did not possess sufficient digital literacy skills, or had preexistent physical or mental limitations. The onboarding process was completed during an appointment with the case manager (a specially trained nurse who performs the screening and coordination of prehabilitation), who explained the use of the eCoach and evaluated the patient’s ability to use it effectively. Patients who underwent emergency surgery during the care pathway, prior to the planned colorectal resection (eg, due to bowel obstruction), were excluded from the study. When patients received neoadjuvant treatment (radiotherapy or chemoradiotherapy), they were included only after completion and restaging (response evaluation) and definitive acceptance for surgery by the colorectal multidisciplinary team meeting. Health care professionals registered in the electronic patient files if patients were eligible, reasons for nonparticipation, and all usual care data.

Intervention Description

The mobile app eCoach (Luscii Healthtech BV) was developed by health care professionals (clinicians, physiotherapists, dieticians, and nurse practitioners) with expertise on perioperative care in collaboration with the Isala Connected Care team and Luscii Healthtech BV (Multimedia Appendix 1).

Figure 1 illustrates the perioperative care pathway and the integration of the eCoach into this process, including the phases of prehabilitation, surgery, remote postoperative monitoring, and rehabilitation. The eCoach provided tailored information and action prompts specific to each phase. Automated alerts were configured and managed by specialized virtual care nurses at the Isala Virtual Care Center. If required actions were not completed, an automated reminder was sent in the evening. Inactivity for more than 3 consecutive days triggered an alert to the virtual care nurse, who could then take appropriate action, such as sending a personal message, making a phone call, or reviewing the patient’s chart and deciding that no action was necessary. The eCoach acts as a gatekeeper, with all processes being highly standardized and objective. The virtual care nurse reviews the situation when an alert is triggered and determines the appropriate action based on the specific circumstances. This ensures that patient management is consistent and reliable, while allowing for personalized intervention when necessary.

Figure 1. Overview of the eCoach intervention in the colorectal care pathway. BORG: Borg Rating of Perceived Exertion Scale; ERAS: enhanced recovery after surgery protocol; VAS: visual analogue scale.



In the prehabilitation phase (weeks 1-6), the eCoach monitored adherence to the multimodal prehabilitation program and provided timely information on relevant aspects of the care pathway. This involved prompting patients to report whether they attended a physiotherapy session that day and to record their Borg Rating of Perceived Exertion (BORG 6-20) as soon as possible afterward. To support adherence to the nutritional component, the eCoach inquired whether patients had taken their prescribed protein supplement.

During the surgery phase (week 6), the eCoach provided information on key topics such as preparing for surgery, bowel preparation (if applicable), anticoagulant therapy, and discharge procedures.

In the remote postoperative monitoring phase (weeks 6-7), patients completed a daily questionnaire assessing how they felt compared with the previous day (better, the same, or worse). If they reported feeling the same or worse, the eCoach prompted additional questions about body temperature, pain, vomiting, defecation, and wound healing. If responses exceeded set thresholds, an alert was generated, and an automated message advised the patient to contact the hospital. The virtual care nurse checked the alerts and took action when necessary. This included validating the alerts (eg, requesting wound details and photographs and forwarding them to the responsible department) and ensuring that patients followed the app's advice to contact the hospital.

In the rehabilitation phase (weeks 7-11) the eCoach provided information about the positive effect of physical activity in recovery after surgery and monitoring of physical activity. Although the care pathway transitions into long-term cancer follow-up, in this feasibility study, it was considered to end at 30 days post surgery.

Variables and Measurements

Primary Outcomes

The primary outcome of this study was the feasibility of the eCoach app. Feasibility explores whether a digital health system works as intended in a given context and was measured by the recruitment rate, retention rate, and compliance [21]. Recruitment rate was calculated as the proportion of eligible patients, relative to the total elective colorectal surgery patient cohort during the study period. Retention rate was defined as the proportion of patients who completed the use of the eCoach until the end of the eCoach care pathway (30 days after surgery), with reasons for dropout documented. Compliance was defined as the extent at which patients followed the prescribed actions (as shown in Figure 1) within the app, as presented in the intervention description. Since the rates reported in previous literature range between 53% and 95%, we deemed the eCoach feasible when the recruitment rate, retention rate, and compliance were all above 70% [17].

Secondary Outcomes

The secondary outcomes were patient experiences (usability and feedback), app-induced nursing activities, and preliminary effectiveness parameters. A full description of the operationalization of the secondary outcomes can be found in Multimedia Appendix 2.

Usability was evaluated using the Usefulness, Satisfaction, and Ease of Use (USE) questionnaire, which consists of 30 statements rated on a 7-point Likert scale [22]. These statements pertain to 4 key constructs: usefulness, satisfaction, ease of use, and ease of learning regarding the interventions. The questionnaire had been translated into Dutch and used in prior research, with Cronbach a per construct from 0.916 to 0.965 [23,24]. It was gathered using an automatic message in the eCoach, which included a link to the questionnaire.

Feedback on the app's use was collected at the end of the telemonitoring process by the virtual care nurse through a phone call, which was documented in the electronical patient dossier. During the call, patients were asked open-ended questions such as, "How did you experience this process?" and "What improvements would you suggest?" Patient feedback was coded and the themes were categorized into "positive experiences" and "proposed improvements" applying the principles of content analysis [25]. Coding and thematizing was performed by 2 researchers (ADT and JPLL) who discussed differences until consensus was reached. The number of times a theme was mentioned by a patient was reported.

App-induced nursing activities were determined by describing the number of alerts per action item as described in Figure 1 and type of nurse actions that were initiated by alerts of the eCoach.

Preliminary effectiveness parameters consisted of preoperative outcomes after prehabilitation (Steep Ramp Test, 1 repetition maximum tests, and Patient-Generated Subjective Global Assessment Short Form), perioperative functional outcomes (quality of recovery, physical functioning, and quality of life), and postoperative parameters (postoperative complications, length of stay, and time to functional recovery). The Quality of Recovery-15 (QoR-15), Patient-Reported Outcomes Measurement Information System (PROMIS)–Physical Function (PF), and PROMIS-10 questionnaires were administered preoperatively (1 day before surgery) and postoperatively (2 days, 7 days, and 30 days) automatically in the eCoach app. The virtual care nurse made a scheduled call to all patients to remind them about the 30-day questionnaires and asked their feedback on the process. Patient characteristics and postoperative parameters of the study population were gathered (Table 1).

Table 1. Patients' characteristics.

Characteristics	Study population (n=37)
Sex (female), n (%)	17 (46)
Age (year), median (IQR)	65 (60-77)
BMI, median (IQR)	26 (24-32)
ASA[a], n (%)	
I	3 (8)
II	24 (65)
III	9 (24)
IV	1 (3)
CCI[b], median (IQR)	5 (4-6)
Type of surgery (laparoscopic), n (%)	36 (97)
Tumor location, n (%)	
Colon	27 (73)
Rectum	10 (27)
Tumor sort (malignant), n (%)	36 (97)
Surgery procedure, n (%)	
Right hemicolectomy	14 (38)
Left hemicolectomy	5 (14)
Sigmoid resection	8 (22)
LAR[c]	7 (19)
APR[d]	2 (5)
Stoma	1 (3)
Smoking (yes), n (%)	4 (11)
VSAQ[e], median (IQR)	8 (6-10)
HADS[f], median (IQR)	5 (3-8.5)
Hemoglobin (mmol), median (IQR)	
Baseline (n=33)	8.2 (7.0-9.2)
Preoperative (n=17)	7.6 (6.0-9.1)
Complications (yes), n (%)	8 (22)
Clavien-Dindo, n (%)	
I-II	4 (11)
III	3 (8)
IV	1 (3)
Length of stay in days, median (IQR)	4 (3-5)
Time to functional recovery, median (IQR)	1 (0-2)
Care after discharge, n (%)	
Independent	28 (76)
Home care	9 (24)
Rehabilitation center	N/A[g]
Readmissions (yes), n (%)	3 (8)
SRT[h] (W[i]/kg), median (IQR)	2.61 (2.10-3.68) before prehabilitation[j]; 2.82 (2.16-4.10) after prehabilitation[k]

Characteristics	Study population (n=37)
1 RM[l] tests, median (IQR)	
Row	30 (24-35) before prehabilitation; 35 (28-43) after prehabilitation
Chest press	40 (26-56) before prehabilitation; 53 (35-60) after prehabilitation
Leg press	210 (183-323) before prehabilitation; 235 (188-299) after prehabilitation
Lat pulldown	32 (26-38) before prehabilitation; 35 (29-42) after prehabilitation
PG-SGA sf[m], median (IQR)	1 (0.5-4) before prehabilitation; 1 (0-2) after prehabilitation

[a]ASA: American Society of Anesthesiologists.
[b]CCI: Charlson Comorbidity Index.
[c]LAR: low anterior resection.
[d]APR: abdominal perineal resection.
[e]VSAQ: Veteran Specific Activity Questionnaire.
[f]HADS: Hospital Anxiety and Depression Scale.
[g]N/A: not applicable.
[h]SRT: Steep Ramp Test.
[i]W: wattage.
[j]Before prehabilitation: n=34.
[k]After prehabilitation: n=26.
[l]RM: repetition maximum.
[m]PG-SGA sf: Patient-Generated Subjective Global Assessment Short Form.

Statistical Analysis

Formal sample size calculation was challenging given the observational feasibility study design, but a sample in the range of 20-25 is considered adequate for this type of study [26,27]. We determined to include all patients during 3 months. Given the expected number of surgeries (n=85) and dropout rate of previous studies (50%), we expected to include 40 patients.

Descriptive statistics were used to evaluate patient demographics and to assess the feasibility. Continuous data were checked for normality by a Shapiro-Wilk test and visually by a histogram. Based on normality, median and IQR or mean and SD were presented. For categorical data, frequencies and percentages were calculated. All data were analyzed using SPSS Statistics (version 24; IBM Corp) for Windows. The answers on the open-ended questions were coded and categorized by 2 researchers (ADT and JPLL) by content analysis based with predefined categories: positive experiences and proposed improvements. Categories were quantified.

Results

Overview

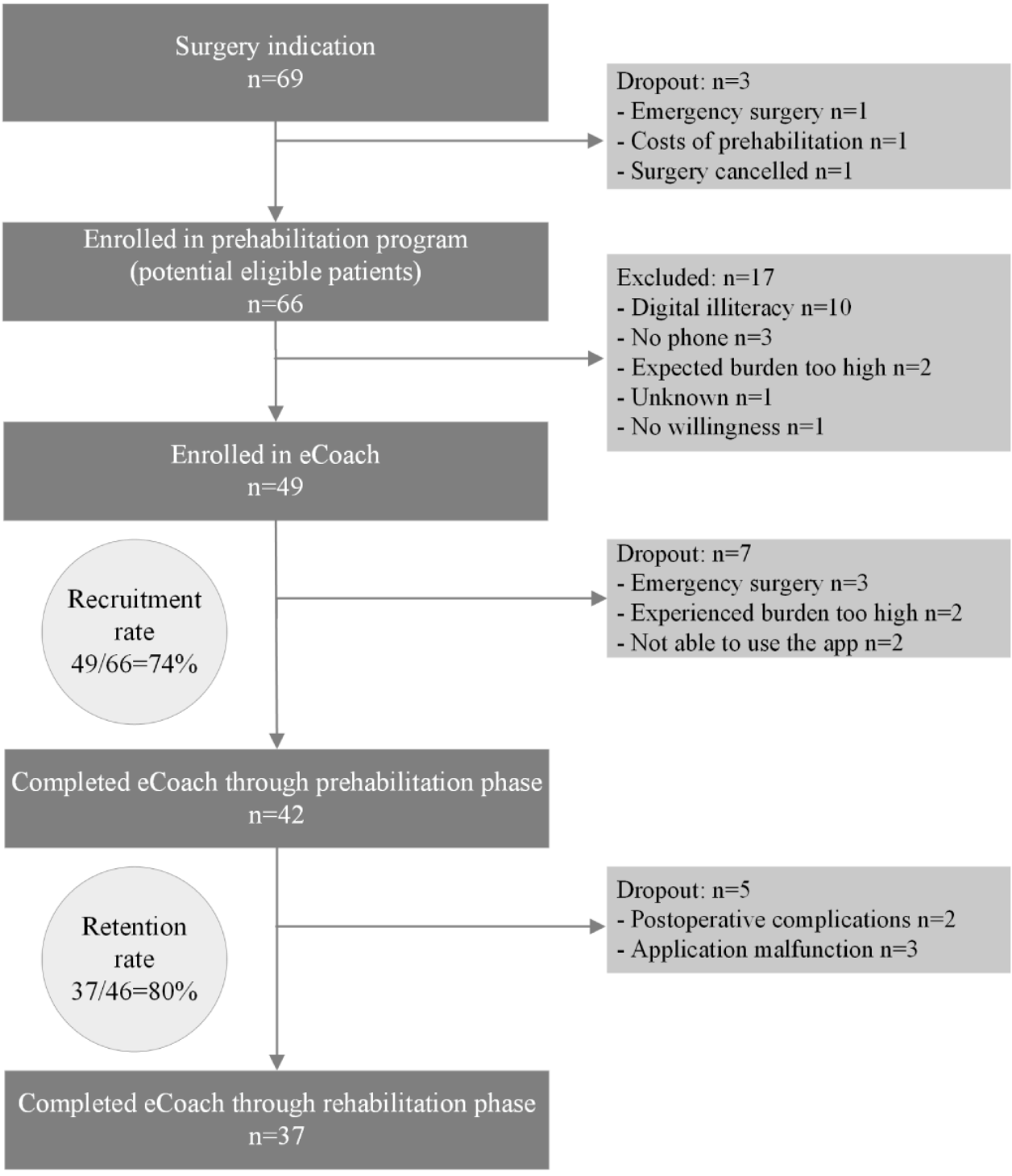
A total of 37 patients completed the study, of which the patient characteristics are shown in Table 1. Median age was 65 (IQR 60-77) years and median Charlson Comorbidity Index score was 5 (IQR 4-6). Four patients experienced minor complications (Clavien Dindo I-II), such as issues with ileostomy production and atrial fibrillation. The other 4 patients had major complications (Clavien Dindo III-IV), including abscess, anastomotic leakage, and systemic inflammatory response syndrome, with 1 patient requiring intensive care unit admission.

Primary Outcomes

Recruitment Rate and Retention Rate

During the study period 66 patients were eligible for the colorectal surgery pathway. Of the 66 included patients, 49 enrolled in the eCoach, resulting in a recruitment rate of 74% (49/66; Figure 2). Main reasons for exclusion were digital illiteracy (n=10), not having a phone (n=3), and expected extra burden of the app being too high (n=2). Of the 49 enrolled patients, 4 (92%) dropped out preoperatively during the prehabilitation phase and 5 (88%) postoperatively during the close monitoring or rehabilitation phase, resulting in a retention rate of 80%. Two patients dropped out due to the significant burden imposed by postoperative complications, leading them to discontinue using the eCoach. The 3 patients who underwent emergency surgery were excluded from the calculations of recruitment and retention rates.

Figure 2. Flowchart of study population, including recruitment rate and retention rate.



Compliance

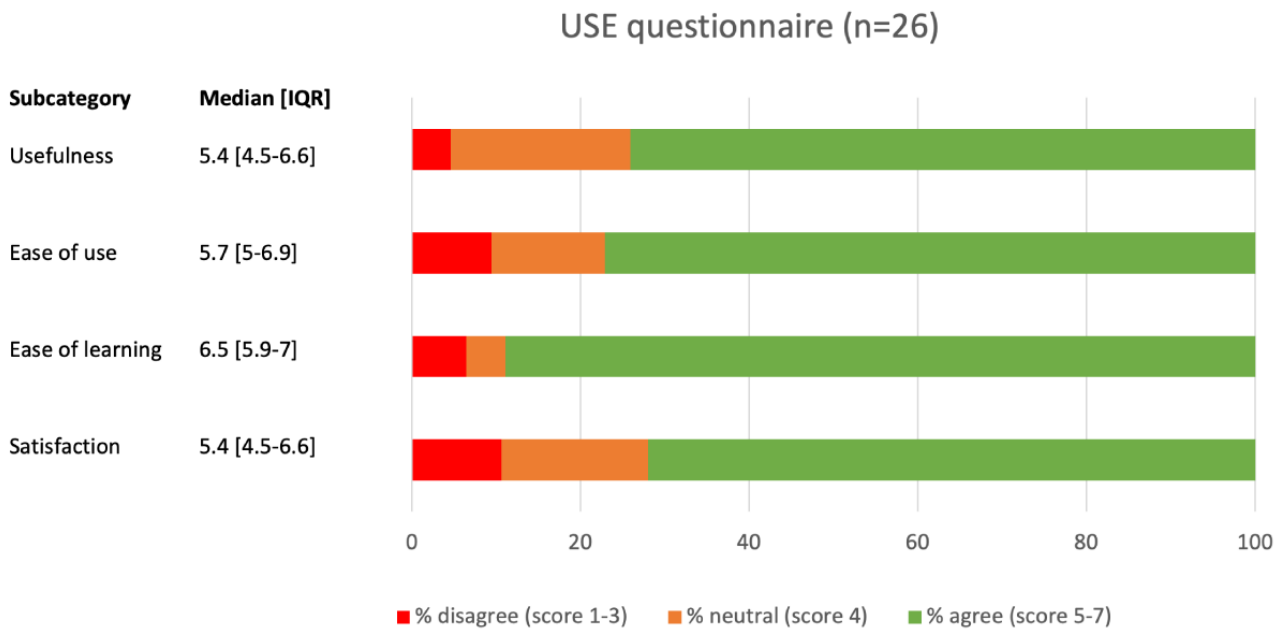
Median compliance was 95% (IQR 82%-96%), preoperative compliance was 92% (IQR 87%-95%), and postoperative compliance was 100% (IQR 100%-100%). Preoperative compliance was highest with 98% (IQR 90%-100%) with "physiotherapist session." Compliance with the number of steps was lowest with 86% (IQR 72%-93%). Compliance with "protein intake" was 90% (IQR 84%-97%), on which patients reported "yes" 97% of the time. Of the 37 patients, 34 patients responded. The median compliance to the postoperative questions "Well-being compared to yesterday" was 100% (IQR 100%-100%), and patients reported feeling better 60% of the times. Compliance for the additional questions was 100% (IQR 100%-100%), where "Wound healing correctly" resulted in a negative response most of the times. A comprehensive presentation of compliance with various components of the eCoach is shown in Multimedia Appendix 3.

Secondary Outcomes

Patient Experiences: Usability

Twenty-six patients (response rate: 70%) completed the USE questionnaire (Figure 3) at day 30 postoperatively. Median scores for usefulness, ease of use, ease of learning, and satisfaction were 5.4, 5.7, 6.5, and 5.4, respectively, on a 1-7 Likert scale, all of which are considered good outcomes. Scores and IQRs to individual questions and categories are described in detail in Multimedia Appendix 4.

Figure 3. Usefulness, Satisfaction, and Ease of Use questionnaire. USE: Usefulness, Satisfaction, and Ease of Use.



Patient Experiences: Content Analysis

In total, 89% (33/37) of patients answered the questions about their experiences with the eCoach. Forty-eight positive experiences were reported. One patient said, “I especially valued the motivation to stay physically active. I feel like this made me healthier and stronger.” Other patients called it “a good incentive,” or “a helpful reminder for the protein intake.” Twenty-four patients reported 41 proposed improvements. These areas of improvement were diverse, but rigidity of the app was most frequently mentioned (Textbox 1 and Multimedia Appendix 5).

Textbox 1. Content analysis of experiences reported by patients.

Positive experiences (n=48)

- General positive experiences (n=18)
- Providing support and engagement (n=15)
- Informative (n=7)
- Stimulating motivation and incentives (n=4)
- Mental support (n=2)
- Continuous connection (n=2)

Proposed improvements (n=41)

- Limited usability (n=9)
- Rigidity of the app (n=14)
- Problems with the pedometer (n=6)
- Length of postoperative monitoring was unclear or insufficient (n=6)
- Missed features in the app (n=3)
- Engagement difficulties and mental burden (n=3)

App-Induced Nursing Activities

Out of 1752 preoperative alerts, 99.9% (n=35) were processed automatically by the eCoach, with only 2 alerts needing manual interventions for protein intake. Of the 222 alerts for protein intake across 30 patients, 99% (n=29) were processed automatically by the system. Two alerts required manual interference, so 2 messages were sent by the nurse to remind patients about their protein intake. The number of postoperative alerts was 126 (n=10), of which 43% (54/126) were processed automatically. The remaining alerts led to 21 phone calls and 19 messages in the app. The alerts for "Wound healing correctly" resulted in the most alerts with actions necessary. A detailed summary of nursing activities induced by the app is shown in Multimedia Appendix 6.

Preliminary Effectiveness Parameters

The median physical fitness was preoperatively 2.61 (IQR 2.10-3.68) W/kg and postoperatively 2.82 (IQR 2.16-4.10) W/kg on the Steep Ramp Test (Table 1). Eight patients developed complications after surgery (8/37, 22%) and 4 of them severe (Clavien Dindo III or IV) (4/37, 11%). Median length of stay was 4 days (IQR 3-5) and median time to functional recovery was 1 day (IQR 0-2).

Quality of recovery at 30 days postsurgery was rated comparable with preoperative scores, whereas quality of life and physical functioning at 30 days were not completed back to preoperative levels (Table 2).

Table 2. Preliminary effectiveness parameters.

	–2 days (n=22)	+1 day (n=23)	+7 days (n=24)	+30 days (n=26)
Quality of recovery score, median (IQR)	134.5 (105-144)	112.0 (83-120)	119.5 (102-133)	135 (115-143)
PROMIS[a]-10 (quality of life) score, median (IQR)	28 (25-34)	26 (23-29)	N/A[b]	26 (25-32)
PROMIS of Physical Functioning score, median (IQR)	38.5 (23.8-40)	13 (11-16)	N/A	28.5 (20-34)

[a]PROMIS: Patient-Reported Outcomes Measurement Information System.

[b]N/A: not applicable.

Discussion

Principal Findings

Our results demonstrate the feasibility of a comprehensive eCoach that was developed for elective colorectal surgery patients incorporating all phases of the care pathway, including prehabilitation, enhanced recovery after surgery components, and postoperative monitoring. Recruitment (49/66, 74%) and retention (37/46, 80%) rates were comparable with rates reported in the literature, whereas the compliance (overall 95%) was excellent. Patient-reported usability was good, and patients not only reported to value the eCoach as a beneficial addition to the patient journey but also reported some areas of improvement that need to be addressed in future iterations of the eCoach.

Recruitment and Retention

We found that a significant number of eligible patients were unable to use the eCoach. Nineteen patients (19/66, 29%) were excluded at baseline due to digital illiteracy, not owning a smartphone, or finding the eCoach mentally burdensome. Only 1 patient was excluded due to unwillingness to participate. Given the study population of unselected patients with colorectal cancer, including a significant proportion of older adult and frail patients, this finding is, however, not unexpected and in line with recruitment rates reported in the literature [11,18,28-31]. Older age groups are known to have lower digital proficiency and lower smartphone ownership, and using a digital application may provide a high perceived burden for frail older adult patients, who are facing the challenges of a recent cancer diagnosis and an upcoming high-risk surgery [17]. Although our study did not quantify frailty, the reasons for nonparticipation, such as digital illiteracy and lack of smartphone ownership, suggest that excluded patients were more likely to be older adults and vulnerable. This aligns with findings from a digital prehabilitation study, which reported that patients with insufficient digital skills were older and had a more unfavorable risk profile [32].

Retention was comparable or slightly better than rates reported in the literature. Dropouts were disease related, technical, or due to a perceived heavy burden of using the eCoach. The reported technical issues (malfunction) had not been encountered during initial beta testing and were promptly solved by the development team. When dropping out in the preoperative phase due to emergency surgery (eg, bowel obstruction), these patients could no longer participate for external reasons and were thus excluded from the retention assessment.

Our findings show that there is a subset of patients unable to participate or dropping out for various reasons, confirmed by previous studies. Thus, in clinical practice we cannot relying solely on digital coaching. Hybrid approaches including nondigital and personalized coaching and guidance will remain necessary in order to reach all patients. Furthermore, these results highlight the need for more inclusive design in health care technology, ensuring that the development process considers vulnerable groups and digital illiteracy.

Compliance

Overall compliance (adherence) was excellent in our study. It was slightly lower during the preoperative phase (92%) than postoperatively (100%), probably because there were more preoperative actions to comply with. Median compliance for monitoring physiotherapy visits, physical activity, and protein intake varied between 90% and 98%, where in other studies compliance ranged from 53% to 86% [17]. Possible reasons for

the high compliance rates are the user-friendly app design, the seamless integration into routine care, the onboarding meeting with a dedicated case manager, and the explicit encouragement to enroll and adhere from the surgeons. Our results underscore the high potential value of digital applications for encouraging patient engagement and self-management, which may help improve quality of care and reduce the number of unplanned patient-provider contacts.

Usability and Patient Satisfaction

Most of the patients were positive about the guidance by the eCoach, as shown in the high median scores of the USE questionnaire and in the qualitative feedback. Patient feedback has shown that the eCoach also provides implicit psychological support, helping them feel more connected, confident, and mentally prepared for surgery. The qualitative evaluation of a comparable app reported similar responses [33]. Assistance by trained staff is known to increase perceived usability, which might have contributed to our favorable outcomes [17]. Some areas of improvement were reported, including missing features and lack of personalization, which will need to be addressed in future iterations of the eCoach. To further improve patient experiences in real-life practice, the suggested areas of improvement in the feedback should be addressed. Some of these are technical issues, such as links not working correctly, the inability to fill in missed actions a day later, or problems with the pedometer. The problems with the pedometer seem more consistent, since the compliance is structurally lower than the other preoperative actions and the number of alerts, which were all automatically processed, was large. One explanation maybe that some patients did not have a pedometer installed on their smartphone, so often just filled in an estimated number of steps. Furthermore, patients reported inadequate personalization of the eCoach. For instance, patients who were unable to walk (but able to use a bike trainer) felt like the eCoach was not always fitting to their personal situation.

Strengths and Limitations

The key strength of this study is the comprehensive evaluation of the eCoach in real-life clinical practice, covering the entire perioperative pathway for colorectal surgery patients. This practical implementation allows for efficient assessment of feasibility, addressing both patient needs and implementation challenges early on, with high generalizability within the standardized Dutch health care system. The eCoach platform is commercially available and has been adopted by several centers in the Netherlands. In our center, it has become the standard of care and expanded to include complex surgical patients. To support broader implementation, we are committed to training virtual care nurses, sharing our experiences, and establishing virtual care centers. Ensuring that the necessary infrastructure and expertise are in place is essential, and we are actively working toward this to facilitate the expansion of virtual care services [34].

The results of this observational feasibility study have to be interpreted in the light of some limitations, including its single-center design in which the intervention was accessible only to Dutch-speaking people with a web-connected device, and the relatively small cohort. Another limitation of this study is that we included the first group of patients after implementation of the eCoach, potentially resulting in the technical errors experienced by patients. Although these errors were readily addressed during the initial phase of the study, 3 patients had dropped out as a result. It is important to note that these technical issues were part of the initial learning curve and are expected to be minimized in future iterations of the eCoach, ensuring a smoother experience for subsequent patient groups. Furthermore, more alerts were generated initially as we opted to err on the side of caution to ensure patient safety.

Future Directions

Further studies in larger cohorts are needed to assess the potential role of an eCoach in improving clinical effectiveness and cost-efficiency, such as its impact on readmission rates and length of stay, by comparing it with a matched historical control group or randomization [34]. eCoaches may help reduce the burden on the health care system by promoting self-management and compliance and thereby reduce the number of unplanned patient-health care provider contacts. The integration of eCoaches into complex care pathways facilitates comprehensive health management, including approaches that extend beyond traditional disease treatment. Combining the eCoach with an objective measurement device, such as an accelerometer or a continuous vital signs monitoring device, may help reliably measure physical activity and assess time to full recovery [35]. The value of the reported additional secondary end points (QoR, PROMIS-10, and PROMIS-PF) measuring preliminary effectiveness and patient-reported functional parameters were of limited value for this study but will be valuable in future follow-up studies.

As recruitment in virtual eCoach applications will remain suboptimal in older adult or frail patients, studies are needed to develop protocols to better triage patients at baseline to select who are eligible and suitable for inclusion. The complexity of health needs and potential cognitive or physical limitations in older adult, frail, and high-risk patients underscore the need for alternative methods of perioperative support. One way to improve recruitment, retention, and intervention efficacy is designing more personalized and tailored digital health applications [36]. Future iterations of the eCoach may facilitate individual exercise mode by personal choice and tailored communication to the individual level of health literacy and education. Adding a web-based interface or the ability to add a caregiver could reduce the technological barrier for some patients.

Current prehabilitation protocols for colorectal surgery include frequent physical training sessions by physiotherapist. Given the excellent compliance of the eCoach, eligible lower-risk patients may well follow an unsupervised virtual prehabilitation program by using the eCoach. A study to determine the value of unsupervised virtual prehabilitation is planned to start at our institution.

Conclusions

Our results demonstrate the feasibility of using a comprehensive eCoach for guidance and monitoring of elective colorectal surgery patients through all phases of the care pathway.

Compliance was excellent and recruitment and retention rates were comparable with rates reported in the literature. Patient-reported usability was good, and patients reported to value the eCoach as a beneficial addition to the patient journey. The study findings provide valuable insights for the further development of the eCoach and highlight the potential of digital health applications in perioperative support.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Examples of the eCoach interface, showing daily actions for patients on the left and a small part of the available information on the right.
[PNG File , 286 KB - periop_v8i1e67425_app1.png]

Multimedia Appendix 2
Description of secondary outcomes.
[DOCX File , 19 KB - periop_v8i1e67425_app2.docx]

Multimedia Appendix 3
Compliance of the different items of the eCoach.
[DOCX File , 17 KB - periop_v8i1e67425_app3.docx]

Multimedia Appendix 4
USE outcomes.
[DOCX File , 22 KB - periop_v8i1e67425_app4.docx]

Multimedia Appendix 5
Quotes of patient experiences.
[DOCX File , 26 KB - periop_v8i1e67425_app5.docx]

Multimedia Appendix 6
App-induced nursing activities.
[DOCX File , 18 KB - periop_v8i1e67425_app6.docx]

References

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin 2021;71(3):209-249 [FREE Full text] [doi: 10.3322/caac.21660] [Medline: 33538338]
2. Sharp SP, Malizia R, Skancke M, Arsoniadis EG, Ata A, Stain SC, et al. A NSQIP analysis of trends in surgical outcomes for rectal cancer: what can we improve upon? Am J Surg 2020;220(2):401-407. [doi: 10.1016/j.amjsurg.2020.01.004] [Medline: 31964524]
3. Dharap SB, Barbaniya P, Navgale S. Incidence and risk factors of postoperative complications in general surgery patients. Cureus 2022;14(11):e30975 [FREE Full text] [doi: 10.7759/cureus.30975] [Medline: 36465229]
4. Gustafsson UO, Scott MJ, Hubner M, Nygren J, Demartines N, Francis N, et al. Guidelines for perioperative care in elective colorectal surgery: enhanced recovery after surgery (ERAS) society recommendations: 2018. World J Surg 2019;43(3):659-695. [doi: 10.1007/s00268-018-4844-y] [Medline: 30426190]
5. Lassen K, Soop M, Nygren J, Cox PBW, Hendry PO, Spies C, Enhanced Recovery After Surgery (ERAS) Group. Consensus review of optimal perioperative care in colorectal surgery: enhanced recovery after surgery (ERAS) group recommendations. Arch Surg 2009;144(10):961-969. [doi: 10.1001/archsurg.2009.170] [Medline: 19841366]

6. Wilson RJT, Davies S, Yates D, Redman J, Stone M. Impaired functional capacity is associated with all-cause mortality after major elective intra-abdominal surgery. Br J Anaesth 2010;105(3):297-303 [FREE Full text] [doi: 10.1093/bja/aeq128] [Medline: 20573634]
7. Molenaar CJL, Minnella EM, Coca-Martinez M, Ten Cate DWG, Regis M, Awasthi R, PREHAB Study Group. Effect of multimodal prehabilitation on reducing postoperative complications and enhancing functional capacity following colorectal cancer surgery: the PREHAB randomized clinical trial. JAMA Surg 2023;158(6):572-581 [FREE Full text] [doi: 10.1001/jamasurg.2023.0198] [Medline: 36988937]
8. Chan RJ, Milch VE, Crawford-Williams F, Agbejule OA, Joseph R, Johal J, et al. Patient navigation across the cancer care continuum: an overview of systematic reviews and emerging literature. CA Cancer J Clin 2023;73(6):565-589 [FREE Full text] [doi: 10.3322/caac.21788] [Medline: 37358040]
9. Tsiouris KM, Tsakanikas VD, Gatsios D, Fotiadis DI. A review of virtual coaching systems in healthcare: closing the loop with real-time feedback. Front Digit Health 2020;2:567502 [FREE Full text] [doi: 10.3389/fdgth.2020.567502] [Medline: 34713040]
10. Aapro M, Bossi P, Dasari A, Fallowfield L, Gascón P, Geller M, et al. Digital health for optimal supportive care in oncology: benefits, limits, and future perspectives. Support Care Cancer 2020;28(10):4589-4612 [FREE Full text] [doi: 10.1007/s00520-020-05539-1] [Medline: 32533435]
11. Scheper H, Derogee R, Mahdad R, van der Wal R, Nelissen RGHH, Visser L, et al. A mobile app for postoperative wound care after arthroplasty: ease of use and perceived usefulness. Int J Med Inform 2019;129:75-80. [doi: 10.1016/j.ijmedinf.2019.05.010] [Medline: 31445292]
12. van der Linden MJW, Nahar van Venrooij LMW, Verdaasdonk EGG. Personal devices to monitor physical activity and nutritional intake after colorectal cancer surgery: feasibility study. JMIR Perioper Med 2022;5(1):e40352 [FREE Full text] [doi: 10.2196/40352] [Medline: 36512385]
13. Lambert G, Drummond K, Tahasildar B, Carli F. Virtual prehabilitation in patients with cancer undergoing surgery during the COVID-19 pandemic: protocol for a prospective feasibility study. JMIR Res Protoc 2022;11(5):e29936 [FREE Full text] [doi: 10.2196/29936] [Medline: 35522464]
14. Yi J, Yoon JY, Won CW, Kim M, Lee KS. The roles of health literacy and social support in the association between smartphone ownership and frailty in older adults: a moderated mediation model. BMC Public Health 2024;24(1):1064 [FREE Full text] [doi: 10.1186/s12889-024-18163-z] [Medline: 38632509]
15. Smithson M, McLeod MC, Theiss L, Shao C, Kennedy G, Hollis R, et al. Ileostomy patients using patient engagement technology experience decreased length of stay. J Gastrointest Surg 2022;26(3):635-642 [FREE Full text] [doi: 10.1007/s11605-021-05158-z] [Medline: 34618324]
16. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: a scoping review. Int J Med Inform 2019;126:95-104. [doi: 10.1016/j.ijmedinf.2019.03.018] [Medline: 31029270]
17. Jonker LT, Haveman ME, de Bock GH, van Leeuwen BL, Lahr MMH. Feasibility of perioperative eHealth interventions for older surgical patients: a systematic review. J Am Med Dir Assoc 2020;21(12):1844-1851.e2 [FREE Full text] [doi: 10.1016/j.jamda.2020.05.035] [Medline: 32694000]
18. Esper SA, Holder-Murray J, Meister KA, Lin HS, Hamilton DK, Groff YJ, et al. A novel digital health platform with health coaches to optimize surgical patients: feasibility study at a large academic health system. JMIR Perioper Med 2024;7:e52125 [FREE Full text] [doi: 10.2196/52125] [Medline: 38573737]
19. Sabajo CR, Dieleman JP, Dekker JW, Heuvel B, Klaas JM, Slooter GD. Multimodal prehabilitation for colorectal cancer patients: study protocol of a nationwide multicentre study with uniform prehabilitation protocols. Res Square 2024. [doi: 10.21203/rs.3.rs-4000534/v1]
20. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ 2007;335(7624):806-808 [FREE Full text] [doi: 10.1136/bmj.39335.541782.AD] [Medline: 17947786]
21. Johns Hopkins University. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. 2016. URL: https://iris.who.int/bitstream/handle/10665/252183/9789241511766-eng.pdf?sequence=1&isAllowed=y [accessed 2025-01-18]
22. Lund AM. Measuring usability with the USE questionnaire. Usability Interface 2001;8(2):3-6.
23. Leenen JPL, Dijkman EM, van Dijk JD, van Westreenen HL, Kalkman C, Schoonhoven L, et al. Feasibility of continuous monitoring of vital signs in surgical patients on a general ward: an observational cohort study. BMJ Open 2021;11(2):e042735 [FREE Full text] [doi: 10.1136/bmjopen-2020-042735] [Medline: 33597138]
24. Gao M, Kortum P, Oswald F. Psychometric evaluation of the USE (Usefulness, Satisfaction, and Ease of use) questionnaire for reliability and validity. Proc Hum Factors Ergon Soc Annu Meet 2018;62(1):1414-1418. [doi: 10.1177/1541931218621322]
25. Bengtsson M. How to plan and perform a qualitative study using content analysis. NursingPlus Open 2016;2:8-14. [doi: 10.1016/j.npls.2016.01.001]

26. Totton N, Lin J, Julious S, Chowdhury M, Brand A. A review of sample sizes for UK pilot and feasibility studies on the ISRCTN registry from 2013 to 2020. Pilot Feasibility Stud 2023;9(1):188 [FREE Full text] [doi: 10.1186/s40814-023-01416-w] [Medline: 37990337]
27. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. Am J Prev Med 2009;36(5):452-457 [FREE Full text] [doi: 10.1016/j.amepre.2009.02.002] [Medline: 19362699]
28. Abdelfatah E, Ramos-Santillan V, Cherkassky L, Cianchetti K, Mann G. High risk, high reward: frailty in colorectal cancer surgery is associated with worse postoperative outcomes but equivalent long-term oncologic outcomes. Ann Surg Oncol 2023;30(4):2035-2045. [doi: 10.1245/s10434-022-12970-7] [Medline: 36648616]
29. Low CA, Danko M, Durica KC, Kunta AR, Mulukutla R, Ren Y, et al. A real-time mobile intervention to reduce sedentary behavior before and after cancer surgery: usability and feasibility study. JMIR Perioper Med 2020;3(1):e17292 [FREE Full text] [doi: 10.2196/17292] [Medline: 33393915]
30. Jonker LT, Plas M, de Bock GH, Buskens E, van Leeuwen BL, Lahr MMH. Remote home monitoring of older surgical cancer patients: perspective on study implementation and feasibility. Ann Surg Oncol 2021;28(1):67-78 [FREE Full text] [doi: 10.1245/s10434-020-08705-1] [Medline: 32602060]
31. Haveman ME, van Melzen R, Schuurmann RC, Hermens HJ, Tabak M, de Vries JPPM. Feasibility and patient's experiences of perioperative telemonitoring in major abdominal surgery: an observational pilot study. Expert Rev Med Devices 2022;19(6):515-523 [FREE Full text] [doi: 10.1080/17434440.2022.2108703] [Medline: 35975601]
32. Scheenstra B, Bongers BC, Broeders B, Imkamp M, Van Susante L, Kietselaer B, et al. Reasons and predictors of non-participation in a personalized digital prehabilitation care trial for patients undergoing elective cardiothoracic surgery. Interdiscip Cardiovasc Thorac Surg 2023;37(2):ivad123 [FREE Full text] [doi: 10.1093/icvts/ivad123] [Medline: 37486278]
33. van der Velde M, Valkenet K, Geleijn E, Kruisselbrink M, Marsman M, Janssen LM, et al. Usability and preliminary effectiveness of a preoperative mHealth app for people undergoing major surgery: pilot randomized controlled trial. JMIR Mhealth Uhealth 2021;9(1):e23402 [FREE Full text] [doi: 10.2196/23402] [Medline: 33410758]
34. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of medical research council guidance. BMJ 2021;374:n2061 [FREE Full text] [doi: 10.1136/bmj.n2061] [Medline: 34593508]
35. Leenen JPL, Ardesch V, Patijn G. Remote home monitoring of continuous vital sign measurements by wearables in patients discharged after colorectal surgery: observational feasibility study. JMIR Perioper Med 2023;6:e45113 [FREE Full text] [doi: 10.2196/45113] [Medline: 37145849]
36. O'Connor S, Hanlon P, O'Donnell CA, Garcia S, Glanville J, Mair FS. Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. BMC Med Inform Decis Mak 2016;16(1):120 [FREE Full text] [doi: 10.1186/s12911-016-0359-3] [Medline: 27630020]

Abbreviations

BORG 6-20: Borg Rating of Perceived Exertion
PROMIS: Patient-Reported Outcomes Measurement Information System
QoR-15: Quality of Recovery-15
STROBE: STrengthening the Reporting of OBservational studies in Epidemiology
USE: Usefulness, Satisfaction, and Ease of Use

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Use of Virtual Reality in the Pediatric Perioperative Setting and for Induction of Anesthesia: Mixed Methods Pilot Feasibility Study

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Abstract

Background: Children commonly experience high levels of anxiety prior to surgery. This distress is associated with postoperative maladaptive behaviors. Virtual reality (VR) is an innovative tool for reducing anxiety and pain during various medical procedures. Previous randomized controlled trials have demonstrated its efficacy in reducing children's anxiety in the preoperative waiting room or during induction.

Objective: The primary aim of this study was to examine the feasibility of VR distraction throughout the perioperative period, from the waiting room until the induction of general anesthesia (GA). Secondary aims were to assess its clinical utility, tolerability, and initial clinical efficacy.

Methods: A mixed methods, concurrent triangulation feasibility trial was piloted at the Shriners Hospitals for Children–Canada. Participants played an interactive VR game throughout the perioperative period, starting from the waiting room until induction. Feasibility was examined with the duration of the VR intervention, recording the number of interruptions, and taking field notes. Clinical utility was assessed using a perception questionnaire. Tolerability was evaluated by the Child Simulator Sickness Questionnaire (CSSQ). Initial clinical efficacy was assessed by the Faces Pain Scale–Revised, Faces Anxiety Scale, Graphic Rating Scale for multidimensional pain, the Induction Compliance Checklist, and the Pediatric Anesthesia Emergence Delirium scale. Quantitative data were supported with field notes and semistructured interviews with patients and parents. Quantitative and qualitative themes were compared via the triangulation protocol to produce final themes.

Results: A total of 39 patients, with a mean age of 11.9 (SD 2.8) years, undergoing elective surgery under GA participated in the study. Stakeholders, including patients, parents, and health care providers, were receptive and willing to adapt to VR. Of the 39 patients, 19 (49%) continued to use VR during transportation and 6 (15%) were induced with VR. Barriers to feasibility included (1) interruptions to VR in 92% (36/39) of patients by health care professionals, (2) unpredictable surgery delays prolonging the duration of the VR intervention (mean 23.1, SD 24.4 minutes; range 5 - 150 minutes), and (3) discontinuation of VR before induction due to mask seal (n=3) and discomfort with supine positioning (n=2). Patients were generally satisfied with VR, deemed it acceptable and easy to use, and would recommend it to others. VR was tolerable with no self-reported simulator sickness (CSSQ: mean 0.01, SD 0.1). The mean Faces Anxiety Score was 1.5 (SD 1.1) at baseline and 0.7 (SD 0.9) during VR.

Conclusions: While VR demonstrated good clinical utility and was well tolerated in the broad perioperative setting, this study highlighted important feasibility barriers in the waiting room and especially during induction of anesthesia, both at the organizational and technical levels. This study highlights several considerations that should be carefully addressed for the successful implementation of perioperative VR.

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KEYWORDS

virtual reality; augmented reality; mixed reality; extended reality; computer-generated simulation; digital world; virtual environment; anxious; pediatrics; anesthetics; preoperative; feasibility; artificial intelligence; digital health technology; surgery; child care

Introduction

Virtual reality (VR) is an innovative tool for managing anxiety and pain during medical procedures, such as needle insertion, dressing changes, and dental care [1]. Up to 60% of children experience high levels of anxiety at induction of general anesthesia (GA) [2,3]. This distress is associated with a greater risk of postoperative emergence delirium [4,5], disturbed sleep, and behavioral and emotional disturbances [6]. Previous studies and a meta-analysis have demonstrated the efficacy of preoperative operating room (OR) tours by VR in reducing anxiety [7-18]. With regard to VR use during induction of anesthesia, 2 randomized controlled trials (RCTs) by Jung et al [19] and Samnakay et al [20] have demonstrated the efficacy of a VR game for distraction and anxiety reduction compared to standard care or noninferiority to the use of a 2D tablet. The perioperative period is a continuum of multiple moments that can cause anxiety, including awaiting surgery in the waiting room, being transported to the OR, and undergoing induction of anesthesia in the OR. Understanding the VR feasibility for distraction across these different moments would be fundamental to determining if and where VR can be integrated into the overall perioperative patient flow. Integrating VR into the induction of anesthesia may be more technically complex than in other studied settings, such as intravenous (IV) insertions. Hence, the primary objective of this study was to determine the feasibility of using VR for distraction in the perioperative setting, from the preoperative waiting room to induction. Secondary aims were to assess the clinical utility, tolerability, and initial effectiveness of VR in the same time frame.

Methods

Study Design and Setting

A mixed method [21], concurrent triangulation feasibility study was piloted on the OR floor of the Shriners Hospitals for Children–Canada, a university-affiliated, not-for-profit, bilingual, pediatric orthopedic hospital located in Montreal, Quebec, Canada. The OR floor consisted of a preoperative waiting room, 4 ORs, and a postanesthesia care unit (PACU). In this study, 14 anesthesiologists, 17 surgeons, 14 nurses, 3 respiratory therapists, and 4 orderlies were involved in VR use. The study commenced during the COVID-19 pandemic, resulting in parents no longer being allowed in the OR during the anesthesia induction, with recruitment starting in May 2021 and ending in June 2022.

VR-CORE Outcomes for VR2 Trials

The VR Clinical Outcomes Research Experts (VR-CORE) methodological framework guided this VR2 trial, of which the aim is to produce an "initial assessment in the target patient population within a representative clinical setting" [22]. The primary outcome was the feasibility of perioperative VR, consisting of barriers and facilitators to this intervention [22]. Secondary outcomes consisted of: (1) clinical utility, defined as acceptability, ease of use and understanding, satisfaction, and recommendation of the VR intervention; (2) tolerability, which entailed the absence of physical or emotional adverse effects related to VR; and (3) initial clinical efficacy, defined as patients' outcomes of anxiety, pain, and compliance at induction.

Participants

Convenience sampling was used to prospectively recruit participants in the preoperative evaluation clinic. Patients were eligible if they (1) were aged between 5 and 21 years, (2) had a scheduled elective surgery under GA, and (3) could understand French or English. Patients were excluded if they (1) had a cognitive, auditory, or visual impairment preventing VR use or (2) had a history of seizures or epilepsy. Parents or legal guardians were eligible if they were present with the child and were willing to share their perspectives. A sample size of approximately 40 patients was based on a prior feasibility study including at the study site [23] and a similar setting [24]. The sample size aligned with the VR-CORE recommendations [22].

VR Intervention

Participants played a pretested [23,25,26], interactive game with sound, DREAM (Paperplane Therapeutics, Inc) [27], via the Pico Neo 3 headset. DREAM entails patients throwing red balls at balloons, diamonds, and trolls in a fantastical landscape. The game was developed with input from medical professionals and tested at pediatric sites, including the study site [23,25,26]. DREAM was designed for health care use, allowing for (1) reduced speed to prevent VR sickness, (2) one hand for play, (3) head movement to orient the character, (4) aesthetic appeal, and (5) a no "loss" state. One headset was available for this study. The game was not mirrored onto a tablet for parents or clinicians to view to avoid internet connection-related interruptions to gameplay.

Study Procedure

Nursing staff in the preoperative clinic helped identify eligible participants. A member of the research team explained the study to parents and patients and, if agreeable, obtained informed consent and assent during their preoperative appointment, days or weeks before their surgery. On the day of surgery, game instructions were provided, and the headset was fitted to the patient by a researcher in the preoperative waiting room. The VR intervention was offered within the workflow of the study site (Figure 1). At least 5 minutes of gameplay for VR immersion was encouraged before transfer to the OR; however, gameplay was allowed to extend for longer durations if there were OR delays. Patients were encouraged to pause after 30 minutes of screen time to avoid VR sickness. The researcher remained on standby and troubleshooted VR issues. Patients could pause or discontinue VR at any point. Nurses, orderlies, surgeons, and anesthesiologists usually visited patients in the waiting room to perform preoperative tasks and assessments before transfer to the OR. At the study site, patients routinely received Tylenol and did not routinely receive anxiolytics unless deemed necessary. EMLA cream was routinely applied 30 minutes prior to awake IV insertions. Patients were verbally notified when it was time for their surgery and were asked if they wanted to continue VR for transfer to the OR and induction. Patients were preoxygenated with an age-appropriate mask. The method of induction, usually inhalational with sevoflurane at

the study site, was left to the anesthesiologist's discretion. After induction, the headset was removed.

Figure 1. Virtual reality intervention at various perioperative time points: in the waiting room (top), during transport (middle), and during induction (bottom).

Data Collection

After informed consent, baseline sample characteristics were collected from patients and hospital charts. Patient-reported anxiety, pain, and VR sickness were subsequently collected in the waiting room using the Faces Anxiety Scale (FAS) [28], the Faces Pain Scale–Revised (FPS-R) [29], and the Child Simulator Sickness Questionnaire (CSSQ) [30], respectively. During the VR intervention, field notes were taken by a researcher [23]. In the OR, induction compliance was assessed by a researcher via the Induction Compliance Checklist (ICC) [31]. In the PACU, as part of standard practice, the nurses recorded the emergence delirium using the Pediatric Anesthesia Emergence Delirium (PAED) scale [4]; the scores were retrieved

from the chart. Following the surgery, patients retrospectively reported anxiety, pain, and VR sickness experienced during VR use using the FAS, FPS-R, and CSSQ, as well as the Graphic Rating Scale (GRS) [32]. Patient perception was assessed using a modified version of the Patient Perception Questionnaire [33]. These data were collected either immediately after surgery in the PACU, a few days later in the inpatient unit, or weeks to months later at the follow-up appointment. Finally, if agreeable, the patient and their parent (if present) participated in an audio-recorded, semistructured interview, using a previously used interview guide created by the study team [23].

Data Analysis

Descriptive statistics were used to summarize the sociodemographic and instrument data using Microsoft Excel (2016) measures of central tendency and variance, generating a list of key findings set aside for triangulation. Qualitative data analysis was conducted separately through directed content analysis [34] of the field notes and interviews. The themes identified were supported by quotes, observations, and field notes. Triangulation analysis of qualitative and quantitative data led to the identification of meta-themes, which resulted from qualitative and quantitative sources, and themes drawn from one data source [23,35]. Through this process, qualitative and quantitative data were compared and contrasted, resulting in “agreement,” “disagreement,” “silence,” or “complementarity” between the two data source.

Ethical Considerations

This study was performed in accordance with the principles of the Declaration of Helsinki. Approval was granted by the McGill Institutional Review Board (A06-M31-19B). Informed consent was obtained from all participants and legal guardians included in the study. All data were deidentified prior to analysis to maintain participant privacy. Participants received no monetary compensation.

Results

Sample Characteristics

In total, 61 eligible patients were approached for study participation, of which 49 consented or assented to participate. Two patients withdrew on the morning of their scheduled surgery before the VR intervention, as they were no longer interested in using VR. Eight patients were lost to follow-up as their surgery was canceled, and their rescheduled date conflicted with other participants (Figure 2). Overall, 39 patients, with a mean age of 11.9 (SD 2.8) years and a median age of 12 (IQR 10-13.5) years, used VR in the perioperative setting, for a participation rate of 64% (39/61; Table 1). A total of 11 participants and 9 parents agreed to participate in the interview following their surgery. The remaining patients were lost to follow-up after their surgery.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. OR: operating room; VR: virtual reality.

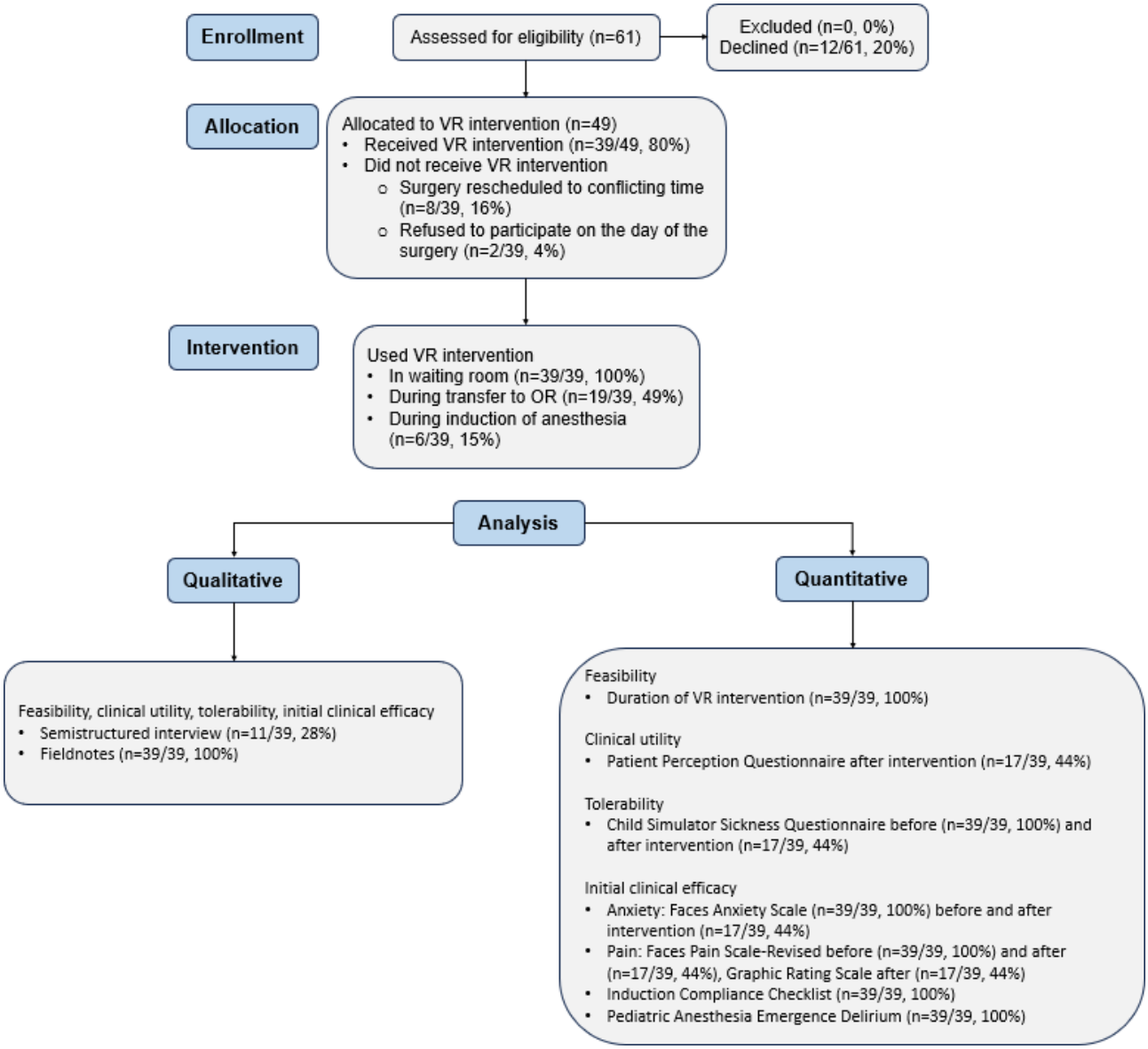


Table . Patient demographics (n=39).

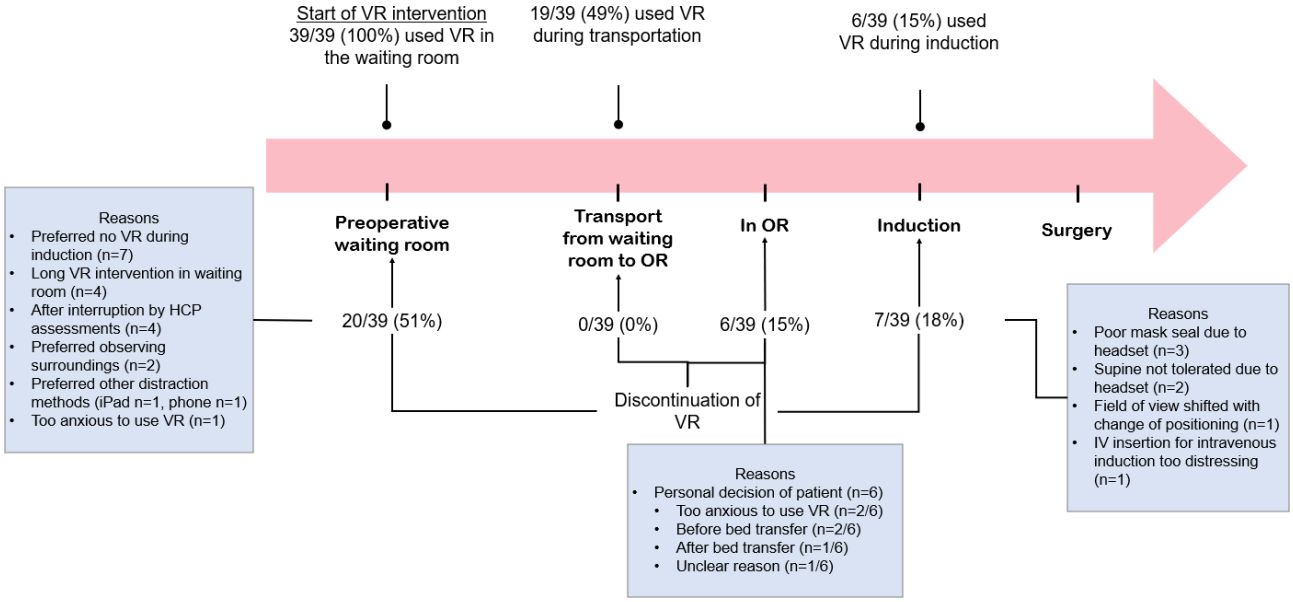
Characteristics	Values
Age (years)	
Mean (SD)	11.9 (2.8)
Median (IQR)	12 (10 - 13.5)
Sex, n (%)	
Male	18 (46)
Female	21 (54)
Race, n (%)	
White	30 (77)
Black	5 (13)
Hispanic	1 (3)
Other	3 (8)
Patients receiving preoperative medications, n (%)	
Tylenol	39 (100)
Midazolam	2 (5)
Diagnosis, n (%)	
Hip and leg disorders	10 (26)
Sports injuries	7 (18)
Foot and ankle disorders	5 (13)
Scoliosis	4 (10)
Abdominal	3 (8)
Bone and soft tissue tumors	2 (5)
Neuromuscular	2 (5)
Other	6 (15)
Surgery, n (%)	
Orthopedic	
Hip and knee	15 (38)
Hardware removal or ablation	8 (21)
Foot and ankle	5 (13)
Spine	4 (10)
Other	4 (10)
General surgery	
Hernia repair	2 (5)
Urology	
Excision of penile cyst	1 (3)

Feasibility

Overview

Of the 39 patients, 6 (15%) used VR across the entire perioperative period, with 20 (51%) discontinuing VR in the preoperative waiting room, 6 (15%) inside the OR before induction, and 7 (18%) during induction (Figure 3). Transportation to the OR proceeded smoothly with no discontinuations. Most inductions were inhalational (37/39, 95%). Two (5%) IV inductions were attempted with VR, one of which was discontinued due to anxiety.

Figure 3. Timeline of VR intervention and reasons for discontinuation of VR. HCP: health care professional; OR: operating room; VR: virtual reality.



Facilitator: Receptiveness and Adaptability

Health care professionals appeared enthusiastic about the VR intervention, encouraging the patients during gameplay and offering implementation suggestions to the research team. On 6 occasions, the clinician adapted their preoperative evaluation in the waiting room to minimize interruption to the VR intervention by speaking to the parents or by discretely performing the task while the patient continued playing. After explaining the VR intervention and its implications for induction, all anesthesiologists attempted to integrate VR into their workflow. For example, the head of the OR table was raised, or extra pillows were placed under a patient's head for comfort while wearing the headset during induction. Only 2 (14%) of the 14 anesthesiologists in this study had prior VR experience.

Facilitator: Communication

Communication among patients, parents, and clinicians was maintained during the VR intervention. Clinicians explained what they were doing and notified the patient before important time points, such as leaving the waiting room for the OR. Clinicians and parents were actively involved in the VR intervention, asking children what they were seeing. Their involvement fostered a positive environment for patients to be immersed in VR. Patients could easily notify their clinicians about discomfort or desire to pause VR. Patients generally appreciated being informed of what was happening when using VR. One patient who was induced with VR reflected, "I would have liked to be notified when they were going to put on the induction mask. They didn't tell me! And I was surprised!" [Participant 29].

Barrier: Interruptions to the VR Intervention

Most patients (36/39, 92%) experienced at least one interruption during their entire VR intervention (from waiting room to induction), causing most patients (34/39, 87%) to remove their headset at least once. In the preoperative waiting room, the most common reason for interruption was preoperative assessments by clinicians (34/39, 87%), after which few patients (4/39, 10%) discontinued VR altogether. One mother stated, "[My daughter] was saying that she was so relaxed, and that VR helped her think about other things. And you could see that she was immersed in the game. And then, at one point, the effect was kind of lost because doctors came to see her" [Mother of participant 32].

Barrier: Duration of VR Use

The average total duration of the VR intervention was 23.1 (SD 24.4) minutes, ranging from 5 to 150 minutes. Most patients (37/39, 95%) had sufficient VR playtime in the preoperative waiting room to achieve immersive distraction for induction. However, due to frequent, unpredictable delays in the OR schedule, playtime in the waiting room was often extended for longer durations. Hence, some patients (15/39, 38%) took breaks in the middle of VR, and a few patients (4/39, 10%) became tired or bored, discontinuing VR altogether in the waiting room (Figure 3). One parent shared, "[…] at one point he stopped playing because it was always the same thing. After a while, it was enough" (parent of participant 10). In contrast, on one occasion, a patient [Participant 16] arrived late, leading clinicians to prioritize preoperative evaluations and reducing VR playtime to only 2 minutes before transfer to the OR. Nevertheless, this patient did not exhibit anxiety behaviors and had excellent compliance during induction (ICC=0).

Barrier: Induction With VR

Some challenges were noted in integrating VR into the intraoperative workflow. Among the 13 patients who attempted induction with VR, 6 (46%) inductions, including one IV induction, were completed with VR (Figure 3). VR was discontinued during 7 attempted VR inductions (7/13, 54%), including one IV induction, revealing challenges such as poor mask seal with the headset (n=3) and discomfort with supine positioning due to the headset structure (n=2; Figure 3). Achieving a good mask seal and ensuring a quick induction were prioritized by anesthesiologists over VR use, sometimes leading to VR discontinuation. Additionally, even when the

patient kept the headset during inhalational induction, one anesthesiologist explained that it was somewhat difficult to maintain a good mask seal. Additionally, 3 patients discontinued VR during the transfer from the stretcher to the OR table, and 2 temporarily paused VR. One patient explained that it felt like they were falling during the transfer from the stretcher to the OR bed with the headset.

Barrier: Technical Issues

VR-related technical issues, namely loss of audio (5/39, 13%), headset adjustments (5/39, 13%), and changes in the field of view when the patient changed orientation (4/39, 10%), were other sources of interruptions, at which point the researcher was able to quickly troubleshoot the issue, allowing for the patient to resume playing. On one occasion, the headset ran out of battery in the OR due to extended preoperative play time, causing a delay while the charger was retrieved, after which the patient continued to play.

Clinical Utility

Acceptability

VR was accepted by patients and parents. Almost all patients (38/39, 97%) were initially willing to use VR. Many patients looked forward to playing VR, asking the front desk personnel and nurses to commence upon arrival at the hospital. Parents supported the integration of VR in their child's care, asking them about the game and inquiring about hospital implementation efforts.

Satisfaction

Overall, all patients found VR fun (Table 2) and were happy to use VR perioperatively for distraction (Table 3), particularly in the preoperative waiting room. Several parents remarked their child was "gone in another world." One patient said, "I hope this never ends. Oh my god, this is so much fun" [Participant 20]. In contrast, adolescents primarily discontinued VR in the waiting room despite acknowledging the distraction it provided due to the game's repetitive and puerile nature. A few patients (3/39, 8%) opted to use other nonpharmacological means of distraction, such as their phone.

Table . Mean Graphic Rating Scale score for each item.

	Score, mean (SD)[a]
Pain	
Time spent thinking about pain	0 (0)
Unpleasant pain	0.1 (0.5)
Worst pain	0.4 (1.5)
Fun	7.8 (1.6)
Nausea	0 (0)

[a]Each item is rated on a 10 cm line, from 0 to 10. Along the line, descriptive markers "mild," "moderate" and "severe" are present.

Table . Patient perceptions of the clinical utility of the virtual reality intervention (n=17).

Scale and items	Responses, n (%)				Quotes
	1	2	3	4	
1=Not at all, 2=A little bit, 3=Some, and 4=A lot					
How much did the virtual reality game distract you during your medical procedure?	1 (5.9)	2 (11.8)	6 (35.3)	8 (47.1)	• "When they put me to sleep, I didn't even feel like I was being put to sleep. All I remember is having the mask on my face, being told to breathe, and then I was gone" [Participant 27].
How much did the virtual reality game help lower your pain during your medical procedure?	11 (64.7)	1 (5.9)	2 (11.8)	3 (17.6)	• "I didn't have pain to begin with." [Participant 32] • "Since I was focused on [VR], I would say that my pain [behind my knees] decreased." [Participant 1]
1=Very unlikely, 2=Unlikely, 3=Likely, and 4=Very likely					
Would you ask to play a virtual reality game for your next medical procedure?	0 (0)	0 (0)	9 (52.9)	8 (47.1)	• N/A
Would you recommend playing a virtual reality game to another patient like you?	0 (0)	0 (0)	5 (29.4)	12 (70.6)	• "This game would be good even for people my age who don't know much about video games. […] There are some more anxious, or who are having trouble coping, or for who it's their first surgery. VR would help them." [Participant 1]
1=Very unhappy, 2=Unhappy, 3=Happy, and 4=Very happy					

Scale and items	Responses, n (%)				Quotes
	1	2	3	4	
How happy were you with playing the virtual reality game during your medical procedure?	0 (0)	0 (0)	10 (58.8)	7 (41.2)	• "I hope this never ends! Can I have this for my birthday?" [Participant 20] • "Mom, I won 2585 points!" [Participant 44] • "It was okay for my age. It's not the best thing ever, but […] to distract me, it's pretty good." [Participant 27]

Ease of Use and Understanding

All patients, regardless of age and previous experience with VR or video games, rapidly understood how to play the game easily. Older patients were pre-emptively instructed by the researcher on troubleshooting certain technical issues, such as shifts in the field of view during position changes.

Recommendation of the VR Intervention

All patients would request and recommend VR if they or another patient needed another surgery under anesthesia (Table 3). One patient aged 17 years explained, "This game would be good even for people my age who don't know much about video games. […] There are some more anxious, or who are having trouble coping, or for whom it's their first surgery. VR would help them" [Participant 1].

Tolerability

Physical Adverse Events

All patients who used VR, regardless of duration, experienced no VR sickness at baseline, or during VR, as per the CSSQ (Table 4) and the GRS (Table 2). Two patients felt that their eyes were tired and took a break. One patient felt "a little bit dizzy," prompting him to take multiple short breaks in VR use in the waiting room. For the majority of children, the VR headset was comfortable. One patient found the headset "a little bit heavy on [her] head," which resolved when it was loosened. For another, the headset sometimes slid down his face. Discomfort was felt at the back of the head with 4 patients when asked to lay supine for induction with VR. One patient described a sensation of falling when being transferred from one bed to another with VR.

Table . Anxiety, pain, and virtual reality (VR) sickness: baseline versus during VR intervention.

Scale	Score, mean (SD)	
	Baseline (n=39)	During VR (n=17)
Faces Anxiety Scale[a]	1.5 (1.1)	0.7 (0.9)
Faces Pain Scale–Revised[b]	0.3 (0.9)	0.3 (1.2)
Child Simulator Sickness Questionnaire[c]		
Nausea	0 (0)	0 (0)
Oculomotor	0 (0)	0.02 (0.14)
Disorientation	0 (0)	0.02 (0.14)
Total	0 (0)	0.01 (0.13)

[a]The Faces Anxiety Scale for children is scored from 0 to 4, showing 5 faces with increasing levels of anxiety. A score of 0 means "no anxiety," a score of 4 means "extreme anxiety."

[b]The Faces Pain Scale–Revised is scored from 0 to 10, showing 6 faces with increasing pain. A score of 0 means "no pain," a score of 10 means "very much pain."

[c]A score of ≥3 of the Child Simulator Sickness Questionnaire indicates the presence of simulator sickness.

Emotional Adverse Events

The use of VR generated minimal adverse emotions. One patient [Participant 36], initially reluctant to use the headset due to a desire to see his surroundings, became immersed and distracted with reassurance.

Initial Clinical Efficacy

Anxiety

At baseline, the mean FAS score was 1.5 (SD 1.1), and many patients (24/39, 62%) demonstrated anxiety-related behaviors such as restlessness, crying, maintaining proximity to parents, and tense body language. Of the 39 patients, 2 (5%) were premedicated with midazolam prior to using VR due to particularly elevated anxiety (Table 1). During the VR intervention, the FAS score was 0.7 (SD 0.9) (Table 4), and some patients visibly relaxed as they became immersed, laughing and making exclamations about the game: “Wow! There’s lots of big balloons!” Patients expressed VR helped them cope: “It was fun, it made me stop thinking about the surgery completely” [Participant 27]. Parents echoed the sentiment, saying “[VR] definitely worked,” [Mother of participant 15]. Others viewed VR more pragmatically, describing VR as a tool that “allows [them] to pass time” [Participant 1] rather than management of anxiety. Patients who used VR during induction overall agreed that it distracted them, “I don’t remember what [health care professionals] were doing [during induction]” [Participant 25], “When they put me to sleep, I didn’t even feel like I was being put to sleep. All I remember is having the mask on my face, being told to breathe, and then I was gone” [Participant 27].

Spikes of anxiety, displayed as crying, verbal expressions of fear, tense body language, and withdrawing, were observed before transport to the OR and before initiating induction. Signs of poor immersion included decreased head movement and letting go of the controller. Due to increased anxiety, 1 patient discontinued VR in the waiting room before leaving for the OR, and 2 patients discontinued VR in the OR.

Induction Compliance

The majority of patients (32/39, 82%) had a perfect anesthetic induction (ICC=0), 5/39 (13%) patients had a suboptimal induction (ICC=1 to 4), whereas 2/39 (5%) patients had a poor induction (ICC>4). One patient [Participant 37] with a poor induction (ICC=9) was immersed in VR in the preoperative waiting room but, upon removing his headset in the OR, became rapidly anxious and agitated during induction.

Emergence Delirium

Upon recovery in the PACU, there was no report of emergency delirium. All patients scored zero on the PAED scale.

Pain

The majority of patients (25/39, 64%) had low baseline pain scores (Table 4) and did not perceive VR to help with pain management at all (Table 3). In this study, patients were not subject to painful interventions except for a preinduction IV insertion in two cases, one of which was aborted due to anxiety (Figure 3). In contrast, patients with baseline pain associated with their condition agreed that VR helped decrease it, “Because I was concentrated on other things, the pain decreased” [Participant 1].

Discussion

Principal Findings

Overall, while VR showed good clinical utility and tolerability, our study demonstrated feasibility challenges with the implementation of VR in the waiting room and induction. Importantly, there was a 50% discontinuation rate prior to arrival at the OR. In the waiting room, notable challenges included interruptions to VR by health care professionals in almost all patients and OR scheduling delays leading to unexpectedly long durations of VR use in the waiting room. This issue was compounded by the fact that DREAM was designed for short procedural distraction, limiting its suitability for longer durations of use when ORs were delayed. In contrast to other studies, our study contained patients in the adolescent age group, up to 18 years old, who compared to younger children may find VR less “novel” and have preferences for more complex games than DREAM. Additionally, the discontinuation rate was likely influenced by the study design and philosophy of care, which advocates for patients deciding if and how they would like to use VR, and to encourage the integration of their other coping strategies to relieve their anxiety, which is reflective of the real-world use of VR in practice. In other studies using VR at induction, premature discontinuation rates for VR were much lower, around 10% or less [19,20,23,24,26,36]. However, these studies introduced VR right before transport to the OR, whereas in this study, VR was often started in the waiting room, more than 5 minutes before transport to the OR, whether intentionally at the request of the patient or unintentionally due to delays.

Despite these feasibility barriers in the waiting room, VR demonstrated good clinical utility, as patients and parents reported high satisfaction and enjoyment with the VR intervention. They all recommended VR for others to use and desired to use VR again in the health care setting. FAS was relatively low at baseline in our study population and did not appear to change “during intervention”, though statistical significance and causality were not assessed for in this feasibility study. Previous VR studies in the waiting room have yielded positive results for anxiety reduction [7-16]. However, since these studies did preoperative OR tours by VR, establishing comparisons with our study and game may be difficult. Overall, waiting room VR games can be a valuable tool for temporary immersion and distraction; however, the suitability of VR becomes limited in cases of prolonged wait times.

The interpretation of the feasibility and use of VR during induction is limited by the high discontinuation rate in the waiting room and the consequently small sample of participants (6/39, 15%) induced with VR. Nevertheless, we noted that while VR was beneficial for some patients, for others, the distraction afforded by VR became limited as their anxiety increased in the OR and during induction. Thirteen inductions were attempted with VR in our study, half of which were completed without interruption of VR. Difficulties with mask fit and supine positioning were major feasibility barriers. The Pico Neo 3 headset used in this study has a hard piece of plastic at the back of the head, which rendered supine positioning uncomfortable for some patients. Troubleshooting included additional pillows

for padding and raising the head of the bed. As for troubles with the mask seal, the headset had to be propped up to allow access to the nose and mouth. In another study, anesthesiologists rotated the mask 180 degrees, allowing for a better fit with the headset at the expense of the mask seal [20].

To our knowledge, 2 RCTs have assessed the efficacy of VR during induction of anesthesia. Samnakay et al compared a VR video to a 2D video tablet, demonstrating similar efficacy between both technologies in reducing anxiety during induction. While children had higher satisfaction ratings with VR than with 2D tablets, anesthesiologists favored the 2D tablet over VR for inhalational inductions [20]. This is somewhat consistent with our findings, as we found induction with VR to be a technically challenging task that requires further optimization in technique and hardware, while satisfaction ratings remained high among patients. The similar efficacy of tablets and VR in their study [20], combined with the relative complexity of VR use during inhalational induction, argues against the use of VR during induction, though further evidence is needed to support this conclusion. Jung et al [19] demonstrated that a VR game, similar in mechanics to DREAM, during induction significantly decreased anxiety compared to the standard of care. In their study, only 1 out of 81 discontinued VR due to battery depletion, and 2 out of 81 discontinued VR during induction to see their parents [19]. This success, in contrast to our study, may be partly attributable to the use of a different headset (ie, Samsung Gear VR), in which the head strap is made of a softer, thinner material, not hindering supine positioning, and potentially to the health care professionals' experience levels with using VR.

Most (32/39, 82%) patients displayed perfect induction compliance as per the ICC, the interpretation of which becomes limited by the low number of patients wearing the VR headset at induction (6/39, 15%). Of note, one patient displayed poor induction compliance (ICC=9) only once the headset was removed in the OR. This is probably explained by their known prior history of high anxiety and poor induction compliance in the perioperative setting and the limited benefits that VR may offer certain patients. Furthermore, we observed that conflicting stimuli from the "real" environment, such as transfers from stretcher to OR bed and exposure to volatile anesthetics, can remove patients from their immersion. Interestingly, Samnakay et al reported children with VR had lower odds of having a perfect induction compared to children with tablets. Because VR hides the real-world environment, it is possible that real-world stimuli generate unintended surprises [20]. OR tours by VR in the waiting room improved induction compliance in two studies at the same institution [9,10], whereas they did not in two other studies [7,19]. In this study, a subset of patients preferred observing the OR environment during induction. This brings into consideration a potential advantage of augmented reality (AR) for them, in which a digital image is overlaid in the real world. The use of AR may significantly reduce anxiety in pediatric patients [37] and improve mask acceptance in children undergoing induction of GA compared to children induced without [38].

Clinical Implications

VR offers an innovative approach to help patients manage their anxiety before surgery under GA, but it is not a one-size-fits-all solution, and patients should be thoughtfully selected, especially considering the technical challenges encountered during induction. Importantly, the institution must be well organized for a coordinated approach to VR implementation. For minimal workflow and VR interruption, the intervention should ideally be started after completing all preoperative assessments. Ongoing collaboration and cooperation with all the health care providers should be elicited to minimize interruptions during gameplay. Indeed, a policy and procedure should detail when to alert cases of potential VR use with the health care team, especially anesthesiologists and respiratory therapists, such that they may adapt their approach and determine if VR is medically contraindicated. Prior to starting VR, the health care team should clarify with the patient when they would like to use VR, establish a communication plan, and determine whether the patient prefers being immersed or aware of their surroundings. However, they may always change their mind. It would be crucial to determine how VR for induction can be coordinated with expected and unexpected surgery delays. Depending on context, one health care professional should be responsible for administering and monitoring the VR intervention from the waiting room to the OR. Child life specialists, anesthesiologists, or respiratory therapists may be best equipped with that task as they are closely involved with the patient before and during induction. To render VR more compatible with induction, the health care team should opt for a headset that is not bulky, does not cover the patient's nose or mouth, and has no counterbalance weight at the back. Anesthesiologists should be aware that mask fit with the headset may be suboptimal, and that access to eyes is limited. The feasibility of VR may improve as the institution and its clinicians become increasingly experienced with its use.

Limitations

Due to the high discontinuation rate of VR preinduction, either by choice, surgical delays, or other circumstances, more data are needed to elucidate the feasibility of VR during anesthesia induction. Furthermore, many patients were lost to follow-up after their surgery; hence, self-reported postoperative outcomes such as anxiety and pain were incomplete. FAS "during VR" were obtained postintervention, in the PACU at the earliest, relying on the recall of the patients. Further, interviews were not conducted with all patients, potentially missing important insights for discontinuing VR use before induction. As this was a pilot feasibility VR2 trial, only descriptive statistics were performed, establishing no causal links. While this study included the perspectives of patients and parents, clinicians' perspectives were obtained via field notes, limiting our ability to offer a complete picture of VR benefits and limitations. The VR game DREAM was designed for young children during acute medical procedures, with some of the older patients expressing boredom leading to discontinuation. Finally, the significant portion of the playtime taking place in the waiting room may have influenced the discontinuation of VR use for the OR transfer and induction.

Future Research

Future studies aiming to investigate the use or implementation of VR in the perioperative setting should assess the feasibility of the intervention tailored to their organizational context. As mentioned previously, the feasibility of VR during induction of anesthesia could not be well assessed in this study due to the discontinuation rate and feasibility challenges that occurred prior to induction. Future studies should test the effectiveness of various games or software adapted to patient age, interests, and psychological needs. Further practice and research are needed to determine the conditions that would render VR compatible with anesthesia induction. More RCTs would be beneficial to truly assert the efficacy of VR in the perioperative period in comparison to other available technology, including 2D screens and augmented reality.

Conclusion

In the perioperative setting, from the waiting room until induction, VR may be a valuable tool for temporary distraction to help cope with this setting. While VR demonstrated clinical utility and tolerability, our study found, in the current state of VR implementation at our institution, important feasibility barriers in the waiting room and especially during the induction of anesthesia. Several considerations must be made to address the peculiarities of induction. This study contributes to the growing body of literature about VR in the perioperative process, elucidating important clinical challenges.

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Conflicts of Interest

None declared.

References

1. Tas FQ, van Eijk CAM, Staals LM, Legerstee JS, Dierckx B. Virtual reality in pediatrics, effects on pain and anxiety: a systematic review and meta-analysis update. Paediatr Anaesth 2022 Dec;32(12):1292-1304. [doi: 10.1111/pan.14546] [Medline: 35993398]
2. Davidson AJ, Shrivastava PP, Jamsen K, et al. Risk factors for anxiety at induction of anesthesia in children: a prospective cohort study. Paediatr Anaesth 2006 Sep;16(9):919-927. [doi: 10.1111/j.1460-9592.2006.01904.x] [Medline: 16918652]
3. Perrott C, Lee CA, Griffiths S, Sury MRJ. Perioperative experiences of anesthesia reported by children and parents. Paediatr Anaesth 2018 Feb;28(2):149-156. [doi: 10.1111/pan.13300] [Medline: 29266767]
4. Mohkamkar MB, Farhoudi FM, Alam-Sahebpour AM, Mousavi SAM, Khani SP, Shahmohammadi SB. Postanesthetic emergence agitation in pediatric patients under general anesthesia. Iran J Pediatr 2014 Apr;24(2):184-190. [Medline: 25535538]
5. Kain ZN, Wang SM, Mayes LC, Caramico LA, Hofstadter MB. Distress during the induction of anesthesia and postoperative behavioral outcomes. Anesth Analg 1999 May;88(5):1042-1047. [doi: 10.1097/00000539-199905000-00013] [Medline: 10320165]
6. Fortier MA, Del Rosario AM, Rosenbaum A, Kain ZN. Beyond pain: predictors of postoperative maladaptive behavior change in children. Paediatr Anaesth 2010 May;20(5):445-453. [doi: 10.1111/j.1460-9592.2010.03281.x] [Medline: 20199608]
7. Park JW, Nahm FS, Kim JH, Jeon YT, Ryu JH, Han SH. The effect of mirroring display of virtual reality tour of the operating theatre on preoperative anxiety: a randomized controlled trial. IEEE J Biomed Health Inform 2019 Nov;23(6):2655-2660. [doi: 10.1109/JBHI.2019.2892485] [Medline: 30640637]
8. Ryu JH, Oh AY, Yoo HJ, Kim JH, Park JW, Han SH. The effect of an immersive virtual reality tour of the operating theater on emergence delirium in children undergoing general anesthesia: a randomized controlled trial. Paediatr Anaesth 2019 Jan;29(1):98-105. [doi: 10.1111/pan.13535] [Medline: 30365231]
9. Ryu JH, Park JW, Nahm FS, et al. The effect of gamification through a virtual reality on preoperative anxiety in pediatric patients undergoing general anesthesia: a prospective, randomized, and controlled trial. J Clin Med 2018 Sep 17;7(9):284. [doi: 10.3390/jcm7090284] [Medline: 30227602]
10. Ryu JH, Park SJ, Park JW, et al. Randomized clinical trial of immersive virtual reality tour of the operating theatre in children before anaesthesia. Br J Surg 2017 Nov;104(12):1628-1633. [doi: 10.1002/bjs.10684] [Medline: 28975600]
11. Wu Y, Chen J, Ma W, Guo L, Feng H. Virtual reality in preoperative preparation of children undergoing general anesthesia: a randomized controlled study. Anaesthesiologie 2022 Dec;71(Suppl 2):204-211. [doi: 10.1007/s00101-022-01177-w] [Medline: 35925196]

12. Eijlers R, Dierckx B, Staals LM, et al. Virtual reality exposure before elective day care surgery to reduce anxiety and pain in children: a randomised controlled trial. Eur J Anaesthesiol 2019 Oct;36(10):728-737. [doi: 10.1097/EJA.0000000000001059] [Medline: 31356373]
13. Dehghan F, Jalali R, Bashiri H. The effect of virtual reality technology on preoperative anxiety in children: a Solomon four-group randomized clinical trial. Perioper Med (Lond) 2019;8(5):5. [doi: 10.1186/s13741-019-0116-0] [Medline: 31171963]
14. Esposito C, Autorino G, Iervolino A, et al. Efficacy of a virtual reality program in pediatric surgery to reduce anxiety and distress symptoms in the preoperative phase: a prospective randomized clinical trial. J Laparoendosc Adv Surg Tech A 2022 Feb;32(2):197-203. [doi: 10.1089/lap.2021.0566] [Medline: 34962159]
15. Buyuk ET, Odabasoglu E, Uzsen H, Koyun M. The effect of virtual reality on children's anxiety, fear, and pain levels before circumcision. J Pediatr Urol 2021 Aug;17(4):567. [doi: 10.1016/j.jpurol.2021.04.008] [Medline: 34006462]
16. Castanys TF, Carrión AJ, Gómez FR, et al. Effects of virtual tour on perioperative pediatric anxiety. Paediatr Anaesth 2023 May;33(5):377-386. [doi: 10.1111/pan.14639] [Medline: 36700361]
17. Simonetti V, Tomietto M, Comparcini D, Vankova N, Marcelli S, Cicolini G. Effectiveness of virtual reality in the management of paediatric anxiety during the peri-operative period: a systematic review and meta-analysis. Int J Nurs Stud 2022 Jan;125:104115. [doi: 10.1016/j.ijnurstu.2021.104115] [Medline: 34781118]
18. Chen H, Chen L, Zhu C, Li S, Zhou J, Liu C. Immersive virtual reality versus video distraction for the management of emergence delirium in children: a randomized controlled study. J Perianesth Nurs 2025;40(2):318-325. [doi: 10.1016/j.jopan.2024.05.006] [Medline: 39140922]
19. Jung MJ, Libaw JS, Ma K, Whitlock EL, Feiner JR, Sinskey JL. Pediatric distraction on induction of anesthesia with virtual reality and perioperative anxiolysis: a randomized controlled trial. Anesth Analg 2021 Mar 1;132(3):798-806. [doi: 10.1213/ANE.0000000000005004] [Medline: 32618627]
20. Samnakay S, von Ungern-Sternberg BS, Evans D, et al. 3-Dimensional virtual reality versus 2-dimensional video for distraction during the induction of anesthesia in children to reduce anxiety: a randomized controlled trial. Anesth Analg 2024 Aug 23. [doi: 10.1213/ANE.0000000000007119] [Medline: 39178153]
21. Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. Ann Fam Med 2004;2(1):7-12. [doi: 10.1370/afm.104] [Medline: 15053277]
22. Birckhead B, Khalil C, Liu X, et al. Recommendations for methodology of virtual reality clinical trials in health care by an international working group: iterative study. JMIR Ment Health 2019 Jan 31;6(1):e11973. [doi: 10.2196/11973] [Medline: 30702436]
23. Addab S, Hamdy R, Le May S, Thorstad K, Tsimicalis A. The use of virtual reality during medical procedures in a pediatric orthopedic setting: a mixed-methods pilot feasibility study. Paediatr Neonatal Pain 2024 Sep;6(3):45-59. [doi: 10.1002/pne2.12078] [Medline: 39473832]
24. Gold JI, Annick ET, Lane AS, Ho K, Marty RT, Espinoza JC. "Doc McStuffins: Doctor for a Day" Virtual Reality (DocVR) for pediatric preoperative anxiety and satisfaction: pediatric medical technology feasibility study. J Med Internet Res 2021 Apr 19;23(4):e25504. [doi: 10.2196/25504] [Medline: 33730687]
25. Le May S, Hupin M, Khadra C, et al. Decreasing pain and fear in medical procedures with a pediatric population (DREAM): a pilot randomized within-subject trial. Pain Manag Nurs 2021 Apr;22(2):191-197. [doi: 10.1016/j.pmn.2020.10.002] [Medline: 33495093]
26. Osmanlliu E, Trottier ED, Bailey B, et al. Distraction in the emergency department using virtual reality for intravenous procedures in children to improve comfort (DEVINCI): a pilot pragmatic randomized controlled trial. CJEM 2021 Jan;23(1):94-102. [doi: 10.1007/s43678-020-00006-6] [Medline: 33683617]
27. Paperplane Therapeutics Virtual Reality. DREAM – virtual reality for pain & anxiety. YouTube. 2023 Jul 11. URL: https://www.youtube.com/watch?v=C0Y2dib7Hhg&ab_channel=PaperplaneTherapeutics [accessed 2025-04-10]
28. McKinley S, Coote K, Stein-Parbury J. Development and testing of a Faces Scale for the assessment of anxiety in critically ill patients. J Adv Nurs 2003 Jan;41(1):73-79. [doi: 10.1046/j.1365-2648.2003.02508.x] [Medline: 12519290]
29. Hicks CL, von Baeyer CL, Spafford PA, van Korlaar I, Goodenough B. The Faces Pain Scale-Revised: toward a common metric in pediatric pain measurement. Pain 2001 Aug;93(2):173-183. [doi: 10.1016/S0304-3959(01)00314-1] [Medline: 11427329]
30. Hoeft RM, Vogel J, Bowers CA. Kids get sick too: a proposed child simulator sickness questionnaire. Proc Hum Factors Ergon Soc Annu Meet 2003 Oct;47(20):2137-2141. [doi: 10.1177/154193120304702013]
31. Kain ZN, Mayes LC, Wang SM, Caramico LA, Hofstadter MB. Parental presence during induction of anesthesia versus sedative premedication: which intervention is more effective? Anesthesiology 1998 Nov;89(5):1147-1156. [doi: 10.1097/00000542-199811000-00015] [Medline: 9822003]
32. Tesler MD, Savedra MC, Holzemer WL, Wilkie DJ, Ward JA, Paul SM. The word-graphic rating scale as a measure of children's and adolescents' pain intensity. Res Nurs Health 1991 Oct;14(5):361-371. [doi: 10.1002/nur.4770140507] [Medline: 1891622]

33. Ford CG, Manegold EM, Randall CL, Aballay AM, Duncan CL. Assessing the feasibility of implementing low-cost virtual reality therapy during routine burn care. Burns 2018 Jun;44(4):886-895. [doi: 10.1016/j.burns.2017.11.020] [Medline: 29305105]
34. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov;15(9):1277-1288. [doi: 10.1177/1049732305276687] [Medline: 16204405]
35. Farmer T, Robinson K, Elliott SJ, Eyles J. Developing and implementing a triangulation protocol for qualitative health research. Qual Health Res 2006 Mar;16(3):377-394. [doi: 10.1177/1049732305285708] [Medline: 16449687]
36. Mosadeghi S, Reid MW, Martinez B, Rosen BT, Spiegel BMR. Feasibility of an immersive virtual reality intervention for hospitalized patients: an observational cohort study. JMIR Ment Health 2016 Jun 27;3(2):e28. [doi: 10.2196/mental.5801] [Medline: 27349654]
37. Chamberland C, Bransi M, Boivin A, Jacques S, Gagnon J, Tremblay S. The effect of augmented reality on preoperative anxiety in children and adolescents: a randomized controlled trial. Paediatr Anaesth 2024 Feb;34(2):153-159. [doi: 10.1111/pan.14793] [Medline: 37925608]
38. Yun R, He EM, Zuniga M, et al. Augmented reality improves pediatric mask induction: a prospective, matched case-control study. J Patient Exp 2024;11. [doi: 10.1177/23743735241241146] [Medline: 38549806]

Abbreviations

AR: augmented reality
CSSQ: Child Simulator Sickness Questionnaire
FAS: Faces Anxiety Scale
FPS-R: Faces Pain Scale–Revised
GRS: Graphic Rating Scale
ICC: Induction Compliance Checklist
IV: intravenous
OR: operating room
PACU: postanesthesia care unit
PAED: Pediatric Anesthesia Emergence Delirium
RCT: randomized controlled trial
VR: virtual reality
VR-CORE: VR Clinical Outcomes Research Experts

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Original Paper

Development and Validation of a Routine Electronic Health Record-Based Delirium Prediction Model for Surgical Patients Without Dementia: Retrospective Case-Control Study

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Abstract

Background: Postoperative delirium (POD) is a common complication after major surgery and is associated with poor outcomes in older adults. Early identification of patients at high risk of POD can enable targeted prevention efforts. However, existing POD prediction models require inpatient data collected during the hospital stay, which delays predictions and limits scalability.

Objective: This study aimed to develop and externally validate a machine learning-based prediction model for POD using routine electronic health record (EHR) data.

Methods: We identified all surgical encounters from 2014 to 2021 for patients aged 50 years and older who underwent an operation requiring general anesthesia, with a length of stay of at least 1 day at 3 Indiana hospitals. Patients with preexisting dementia or mild cognitive impairment were excluded. POD was identified using Confusion Assessment Method records and delirium International Classification of Diseases (ICD) codes. Controls without delirium or nurse-documented confusion were matched to cases by age, sex, race, and year of admission. We trained logistic regression, random forest, extreme gradient boosting (XGB), and neural network models to predict POD using 143 features derived from routine EHR data available at the time of hospital admission. Separate models were developed for each hospital using surveillance periods of 3 months, 6 months, and 1 year before admission. Model performance was evaluated using the area under the receiver operating characteristic curve (AUROC). Each model was internally validated using holdout data and externally validated using data from the other 2 hospitals. Calibration was assessed using calibration curves.

Results: The study cohort included 7167 delirium cases and 7167 matched controls. XGB outperformed all other classifiers. AUROCs were highest for XGB models trained on 12 months of preadmission data. The best-performing XGB model achieved a mean AUROC of 0.79 (SD 0.01) on the holdout set, which decreased to 0.69-0.74 (SD 0.02) when externally validated on data from other hospitals.

Conclusions: Our routine EHR-based POD prediction models demonstrated good predictive ability using a limited set of preadmission and surgical variables, though their generalizability was limited. The proposed models could be used as a scalable, automated screening tool to identify patients at high risk of POD at the time of hospital admission.

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KEYWORDS

delirium; machine learning; prediction; postoperative; algorithm; electronic health records; surgery; risk prediction

Introduction

Postoperative delirium (POD) is a common and serious surgical complication that affects 15%-50% of older surgical patients [1-3]. POD is characterized by acute fluctuations in consciousness and has a complex etiology thought to be caused by interactions between predisposing (eg, individual vulnerability) and precipitating (eg, acute illness or surgery) factors [4]. Common predisposing factors include older age, preexisting cognitive impairment, poor physical functioning, alcohol abuse, smoking, and depression [5-8]. Risk factors unique to surgical settings include the type of surgery (eg, major vascular procedures), emergent status, case complexity, and perioperative medications [6,7,9,10]. Despite being an acute condition, delirium is associated with long-term cognitive and physical impairment, institutionalization, and death [4,11]. However, up to 40% of cases may be preventable, and multicomponent, nonpharmacologic interventions may be effective in reducing incidence and health care costs [12,13].

Early and accurate POD risk prediction can inform prevention and enable targeted intervention and resource planning efforts. Fortunately, the widespread availability of electronic health record (EHR) data and advancements in machine learning offer an opportunity to develop accurate, low-cost, and scalable screening tools for POD risk. Several machine learning-based POD prediction models have been developed, reporting areas under the curve (AUROCs) ranging from 0.71 to 0.86 [14-26]. However, the models with the highest AUROCs have important limitations that hinder their practical application. First, they focus on specific patient subsets (ie, intensive care unit (ICU) patients, cardiac surgery), which restricts their generalizability to general surgical populations. Second, population-specific models necessitate separate models for each subpopulation, making implementation cumbersome and resource intensive. Finally, many of these models require inpatient data that take hours or days to accumulate, delaying risk assessment and potential interventions. A small number of studies have developed POD prediction models for general surgical populations; however, these models still incorporate nonroutine clinical data (eg, inpatient nursing assessments) that require time to collect and may not be universally available [14-18,27].

These limitations highlight the need for a model that can predict POD in a diverse surgical population using readily available preoperative data, as it could provide an early, inexpensive, and scalable prescreening tool to identify patients who may benefit from additional monitoring or preventative measures. In this study, we developed and externally validated a machine learning model that can accurately predict POD in surgical patients at the time of hospital admission using only routine EHR data. We also identified preoperative EHR-based predictors of POD and determined how preoperative surveillance length affected model performance.

Methods

Ethical Considerations

This study was approved by the Indiana University (IU) Institutional Review Board (#15767) and adhered to the reporting standards described in the Transparent Reporting of Individual Prognosis or Diagnosis (TRIPOD) guidelines [27].

Study Data and Cohort Selection

Diagnoses, medication orders, surgery, and other inpatient clinical records (eg, nursing assessments) were extracted from the IU Health electronic data warehouse. IU Health, a nonprofit health system with the largest physician network in the state of Indiana, includes 17 hospitals and dozens of outpatient facilities and performs approximately 115,000 surgeries per year [28]. We identified all surgical hospitalizations for patients aged 50 years and older who underwent surgery requiring general anesthesia at an IU Health facility between January 1, 2014, and December 31, 2021; had a length of stay of at least 1 day; and did not have preexisting dementia. Hospitalizations of patients with preexisting dementia (defined as having a dementia diagnosis code or an order for an antidementia medication before admission; see Table S1 in Multimedia Appendix 1) were excluded because dementia is known to be the single-strongest predictor of delirium [6]; models are not needed to forecast risk. For a hospitalization to be eligible, the patient had to have at least 1 IU Health encounter (defined as any interaction with an IU Health facility, eg, outpatient, inpatient, or emergency department visits) in the year before admission and have at least 1 diagnosis or medication record during that period. If no sex, race, or age data were available across all of a given patient's hospitalizations, that patient was excluded.

This study followed a retrospective case-control design where nondelirium (ie, control) hospitalizations were matched to delirium (ie, case) hospitalizations by sex, race, age within 3 years, and admission year within 3 years. We matched on these variables to ensure the age distribution for cases and controls was equalized across race and sex groups. As a result, age was less important to the model, and biases within strata of race and sex were minimized. Because matching was done at the hospitalization level rather than the patient-level, it was possible for case and control hospitalizations belonging to the same patient to be matched.

Hospitalizations where the patient developed POD were designated as cases. POD was defined as at least 1 positive Confusion Assessment Method (CAM) [29] nursing assessment or a delirium *International Classification of Diseases, Ninth Revision* (ICD-9)/*International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code (see Table S2 in Multimedia Appendix 1) recorded during the hospital stay. The CAM is a validated diagnostic algorithm with an overall sensitivity of 94% and a specificity of 89% [30]. Hospitalizations where delirium was present at the time of admission were excluded because the model is intended to predict POD. Hospitalizations without delirium or any nurse-documented confusion (ie, cognitive assessments reporting that the patient was disoriented, confused, or did not follow commands) were eligible to be selected as controls. Visits that did not have documented delirium (ie, delirium ICD code or positive CAM) but did have nurse-documented confusion were excluded from the control pool to ensure controls were not actually misclassified cases; confusion (without delirium) could possibly represent subsyndromal delirium. If a case had more

than 1 potential control, a control was randomly selected. For each eligible visit, the index date was defined as the date of hospital admission. We used the following set of sociodemographic, surgery, diagnosis, and medication variables to build our predictive models.

Variables

Sociodemographic variables included age, patient-reported sex, and patient-reported race (categorized as Black, White, Asian, other, or unknown for analytic purposes), and insurance type. The insurance type was ascertained during each index visit and categorized as commercial, government (Medicare or Medicaid), self-pay, or other/unknown. Smoking status at the time of surgery was extracted from the EHR and categorized as "current," "former," or "never smoker." The BMI was obtained from the visit nearest to the index. The initial American Society of Anesthesiologists (ASA) class and emergency surgery status (defined as operations with an ASA class of 5 or E) were also included. Surgical specialty was assigned based on National Surgical Quality Improvement Program inclusion and exclusion criteria [31]**.** If a patient underwent 4 or more procedures falling under 2 or more distinct specialties, the visit was categorized as "multispecialty."

Diagnosis variables were generated using ICD-9/ICD-10-CM codes. Binary variables were created for each of the 31 Elixhauser disease groups using Quan et al [32] coding scheme and Elixhauser mortality scores were calculated for each patient using van Walravan weights [32-34]. We also created binary variables for other diagnoses potentially associated with increased risk of delirium, including previous delirium, cerebrovascular disease (CVD), previous traumatic brain injury (TBI), and sensory impairment (Table S3 in Multimedia Appendix 1). We derived a composite variable representing the total comorbidity burden by calculating the sum of the number of unique ICD codes (at the 3-digit level) a patient had prior to each index date. Variables for the number of ICD codes belonging to the ICD-10 group Z00-Z99 (factors influencing health status and contact with health services) and their ICD-9 equivalents were also included based on prior literature [14], grouped as follows: Z00-Z13, Z16, Z17, Z18, Z20-29, Z30-39, Z40-53, Z55-65, Z69-76, and Z77-99.

Medication variables were generated using medication order data. Anticholinergic (ACh) medications were identified using the Anticholinergic Cognitive Burden (ACB) scale, a well-established tool that categorizes medications based on the strength of their ACh activity [35]. Three ACh medication variables were developed representing the total number of orders for drugs with an ACB score of 1, 2, and 3, respectively. We also included other non-ACh medication variables as predictors. Since medication orders were retrieved from multiple health care institutions, a unified mapping of medication names to a drug taxonomy was not available. Instead, we mapped each medication in the medication orders to the Anatomical Therapeutic Chemical (ATC) classification codes [36]. The ATC drug classification system is hierarchical with multiple sublevels and maintained by the World Health Organization. For this study, all 14 main groups (eg, A: alimentary tract and metabolism; B: blood and blood-forming organs; C: cardiovascular system) and the first-level subgroup were included (eg, A01: stomatological preparations; A02: drugs for acid-related disorders). For each patient, the count of medication orders (excluding AChs, which were derived separately, as described before) associated with a given ATC subgroup was calculated over the preindex assessment period. We also created a variable summing the total number of medication orders before each admission to capture polypharmacy.

Model Development and Evaluation

Three IU Health institutions were selected for this study. Institutions A, B, and C had the first-, second-, and third-greatest number of delirium cases, respectively. Institution-specific models were developed using data derived from the following preindex surveillance periods: 3 months before admission, 6 months before admission, and 1 year before admission. The purpose of training these separate models was to provide an understanding of how the training data and surveillance period impact the models' ability to predict POD and generalizability. Prior to training, each model's data were split into training (80%) and holdout (20%) sets, while maintaining a 1:1 ratio of cases and controls to avoid class imbalance. Imbalanced data are problematic in classification tasks because the model will focus on learning the characteristics of the majority class. As a result, the model may achieve high accuracy but fail to accurately identify the minority class.

In this study, 6 demographic variables, 4 surgical variables, 49 diagnosis variables, and 84 medication variables were included for a total of 143 features. Categorical variables were one-hot encoded (ie, converted into dummy variables), and continuous variables were standardized such that they each had a mean of 0 and an SD of 1. We initially explored several different machine learning models to predict whether patients would develop POD after surgery. In addition to traditional logistic regression, a parametric model, we also tried random forest, extreme gradient boosting (XGB), and a multilayer neural network because they can learn complex nonlinear relationships between variables. Optimal hyperparameters for each model were selected using a grid search with 5-fold cross-validation. Each candidate model was evaluated by calculating the area under the receiver operating characteristic curve (AUROC) on its holdout set using data from 1 year before hospital admission, and the model with the highest AUROC was selected as the final model. XGB outperformed the other candidate classifiers in all cases.

After model selection, XGB models trained on data from institution A (referred to as XGB_A) were internally validated on holdout data from institution A and externally validated using holdout data from institutions B and C. Similarly, models trained on data from institutions B and C (referred to as XGB_B and XGB_C, respectively) were internally validated on holdout data from institutions B and C and externally validated using data from institutions A and C and A and B, respectively. The predictive performance of each model was evaluated on the holdout and external validation data by creating 1000 bootstrapped samples without replacement, calculating the AUROC, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) in each sample and then

averaging them across all samples. We also generated predictions for nondelirium visits with nurse-documented confusion (which were excluded from training) to examine how the models handle patients with possible subsyndromal delirium. The default threshold of 0.50 was used for predictions. Shapley Additive Explanation (SHAP) [37] was used to determine the most important features, and model calibration was assessed using calibration curves. All analyses were completed using R version 4.3.2 (R Foundation for Statistical Computing).

Results

Study Cohort

Figure 1 depicts the workflow used for model development, internal validation, and external validation for the model trained on data from institution A. Between 2014 and 2022, at the 3 institutions of interest, there were 39,968 surgical visits for 30,131 unique patients aged 50 years and older. Of the identified visits, 431 (1.4%) were excluded for not having any previous diagnosis or medication order data, and 120 (0.4%) were excluded for missing sex, race, or the ASA class. The 6250 (20.7%) visits with nurse-documented confusion (but no delirium) were excluded from the training and holdout sets but reserved for later analyses. After matching, the final analytic sample included 7167 (23.8%) delirium cases and 7167 (23.8%) matched controls (Figure 2).

Figure 1. Workflow for the development and validation of the model using data from institution A. XGB: extreme gradient boosting.

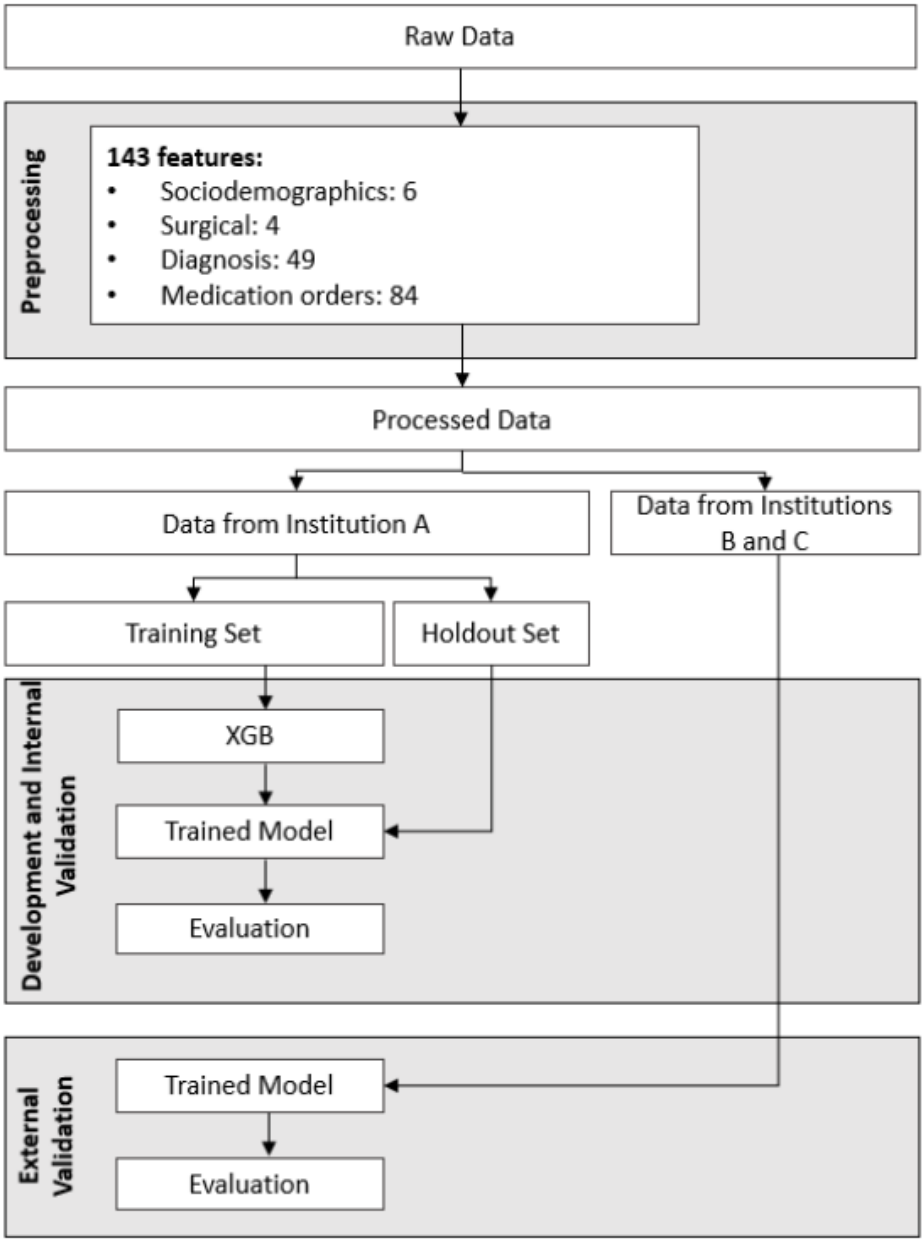
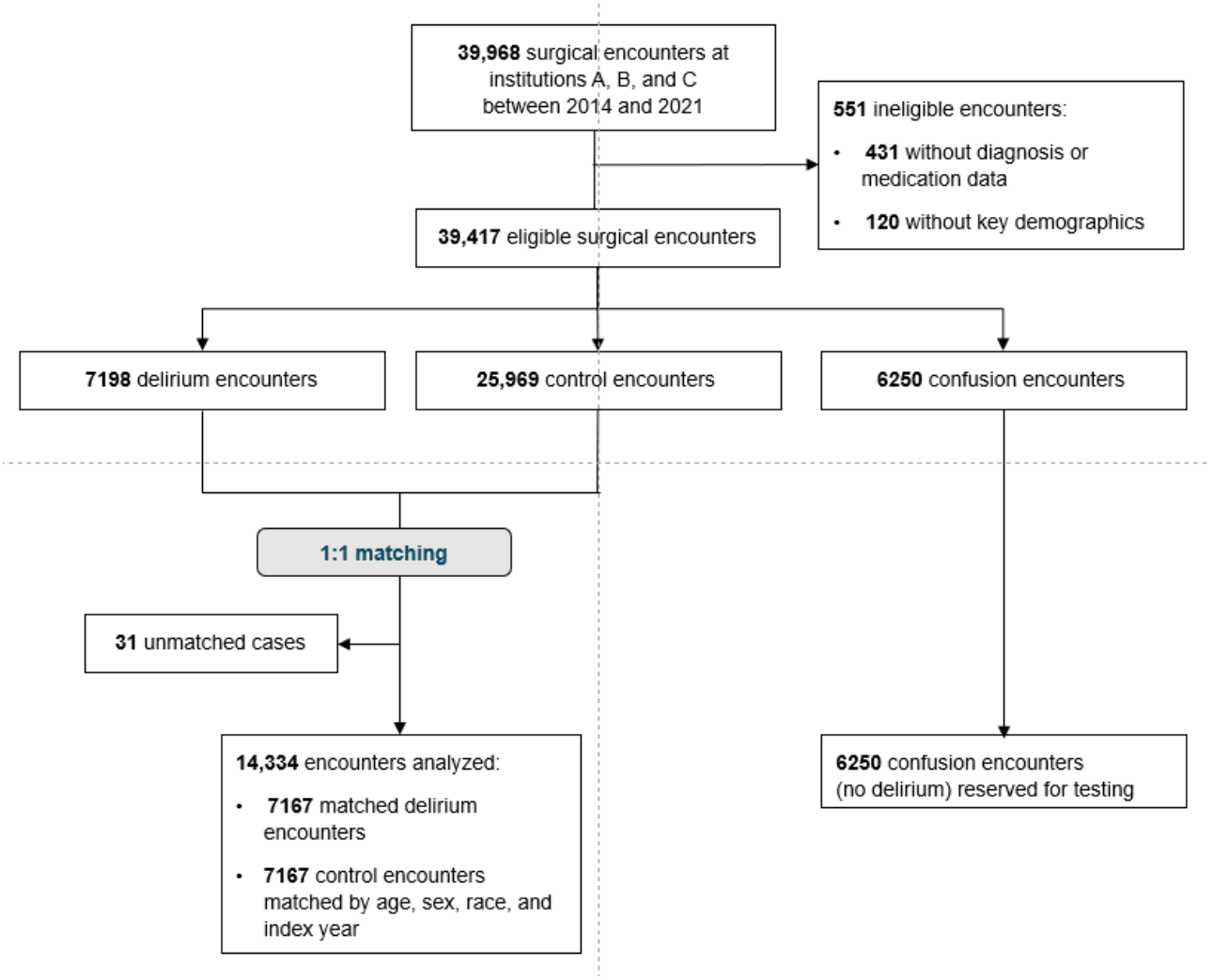


Figure 2. Patient inclusion flow diagram.



Pooling across institutions, the median age was 68 (IQR 61-76) years, and most patients were male (n=7412, 51.7%), White (n=12,276, 85.6%), and had public insurance (n=11,523, 80.4%). The most common surgical specialty was general surgery (n=3600, 25.1%), and 11.5% (n=1644) of operations were classified as emergencies (Table 1 and Table S4 in Multimedia Appendix 1).

As shown in Table 2, the 3 most common comorbidities in the general cohort were hypertension (n=9998, 69.8%), diabetes (n=5189, 36.2%), and nonmetastatic cancer (n=5222, 29.6%). Delirium cases differed from controls in several respects. Delirium cases had a greater comorbidity burden than controls and were more likely to have previous delirium (Table 2 and Table S5 in Multimedia Appendix 1).

Of the 6250 (20.7%) visits with nurse-documented confusion but without delirium, 3185 (51%) belonged to institution A, 1328 (21.2%) to institution B, and 1737 (27.8%) to institution C. Patients with confusion were more likely to have had delirium in the past year than controls but less likely than cases. Their comorbidity burden also fell in between that of cases and controls (Tables S6 and S7 in Multimedia Appendix 1).

Table 1. Characteristics of delirium cases and controls by institution.

Variables[a]	Institution A		Institution B		Institution C	
	Controls (n=3739)	Cases (n=3739)	Controls (n=1928)	Cases (n=1928)	Controls (n=1500)	Cases (n=1500)
Age (years), median (IQR)	68 (61-76)	68 (61-76)	66 (59-73)	66 (59-73)	72 (63-80)	72 (63-80)
Sex: female, n (%)	1840 (49.2)	1840 (49.2)	861 (44.7)	861 (44.7)	760 (50.7)	760 (50.7)
Race, n (%)						
Asian	12 (0.3)	12 (0.3)	13 (0.7)	13 (0.7)	1 (0.1)	1 (0.1)
Black	758 (20.3)	758 (20.3)	162 (8.4)	162 (8.4)	59 (3.9)	59 (3.9)
Other	4 (0.1)	4 (0.1)	3 (0.2)	3 (0.2)	4 (0.3)	4 (0.3)
White	2959 (79.1)	2959 (79.1)	1747 (90.6)	1747 (90.6)	1432 (95.5)	1432 (95.5)
Unknown	6 (0.2)	6 (0.2)	3 (0.2)	3 (0.2)	4 (0.3)	4 (0.3)
Insurance, n (%)						
Private	857 (22.9)	572 (15.3)	547 (28.4)	391 (20.3)	239 (15.9)	124 (8.3)
Public	2861 (76.5)	3137 (83.9)	1376 (71.4)	1530 (79.4)	1253 (83.5)	1366 (91.1)
Uninsured	21 (0.6)	30 (0.8)	5 (0.3)	7 (0.4)	8 (0.5)	10 (0.7)
BMI, median (IQR)	28.5 (24.3-33.7)	27.5 (23.1-32.7)	27.2 (23.2-32.0)	27.0 (22.7-32.0)	28.0 (23.9-33.6)	27.2 (22.9-33.2)
Smoking status, n (%)						
Current	505 (13.5)	561 (15.0)	173 (9.0)	263 (13.6)	213 (14.2)	280 (18.7)
Former	1609 (43.0)	1805 (48.3)	799 (41.4)	901 (46.7)	624 (41.6)	689 (45.9)
Never	1625 (43.5)	1373 (36.7)	956 (49.6)	764 (39.6)	663 (44.2)	531 (35.4)
ASA[b] class, n (%)						
1-2	421 (11.3)	143 (3.8)	126 (6.5)	37 (1.9)	250 (16.7)	81 (5.4)
3-4	3102 (83.0)	2875 (76.9)	1722 (89.3)	1649 (85.5)	1132 (75.5)	1152 (76.8)
5 or E	216 (5.8)	721 (19.3)	80 (4.1)	242 (12.6)	118 (7.9)	267 (17.8)
Surgical specialty, n (%)						
Cardiothoracic (CT)	536 (14.3)	577 (15.4)	183 (9.5)	160 (8.3)	72 (4.8)	142 (9.5)
Ears, nose, and throat (ENT)	48 (1.3)	80 (2.1)	76 (3.9)	98 (5.1)	17 (1.1)	77 (5.1)
General	498 (13.3)	490 (13.1)	952 (49.4)	981 (50.9)	309 (20.6)	370 (24.7)
Multiple	97 (2.6)	614 (16.4)	78 (4.0)	322 (16.7)	15 (1.0)	74 (4.9)
Neurology	666 (17.8)	672 (18.0)	3 (0.2)	10 (0.5)	169 (11.3)	128 (8.5)
Orthopedics	907 (24.3)	620 (16.6)	103 (5.3)	68 (3.5)	560 (37.3)	370 (24.7)
Other	28 (0.7)	28 (0.7)	57 (3.0)	61 (3.2)	11 (0.7)	22 (1.5)
Plastic surgery	165 (4.4)	111 (3.0)	31 (1.6)	17 (0.9)	77 (5.1)	95 (6.3)
Urology/gynecology	276 (7.4)	172 (4.6)	440 (22.8)	209 (10.8)	153 (10.2)	131 (8.7)
Vascular	518 (13.9)	375 (10.0)	5 (0.3)	2 (0.1)	117 (7.8)	91 (6.1)

[a]Continuous variables are summarized as the median (IQR) and categorical variables as n (%).

[b]ASA: American Society of Anesthesiologists.

Table 2. Clinical characteristics of cases and controls by institution.

Variable[a]	Institution A		Institution B		Institution C	
	Controls (n=3739)	Cases (n=3739)	Controls (n=1928)	Cases (n=1928)	Controls (n=1500)	Cases (n=1500)
ECI[b] score, median (IQR)	5 (0-13)	8 (2-18)	9 (4-17)	13 (5-22)	5 (0-12)	9 (2-18)
Number of ICD[c] codes, median (IQR)	21 (12-33)	24 (12-40)	21 (11-34)	26 (13-41)	17 (80-29)	22 (11-38)
Congestive heart failure (CHF), n (%)	713 (19.1)	1040 (27.8)	203 (10.5)	304 (15.8)	267 (17.8)	445 (29.7)
Arrhythmia, n (%)	969 (25.9)	1203 (32.2)	397 (20.6)	485 (25.2)	393 (26.2)	471 (31.4)
Valvular disease, n (%)	639 (17.1)	724 (19.4)	148 (7.7)	188 (9.8)	115 (7.7)	178 (11.9)
Peripheral vascular disorder (PVD), n (%)	977 (26.1)	1138 (30.4)	217 (11.3)	259 (13.4)	316 (21.1)	378 (25.2)
Hypertension, n (%)	2767 (74.0)	2696 (72.1)	1217 (63.1)	1255 (65.1)	997 (66.5)	1066 (71.1)
Chronic obstructive pulmonary disorder (COPD), n (%)	962 (25.7)	1227 (32.8)	444 (23.0)	506 (26.2)	398 (26.5)	542 (36.1)
Diabetes, n (%)	1295 (34.6)	1502 (40.2)	558 (28.9)	717 (37.2)	481 (32.1)	636 (42.4)
Hypothyroidism, n (%)	659 (17.6)	630 (16.8)	347 (18.0)	339 (17.6)	249 (16.6)	310 (20.7)
Renal failure, n (%)	891 (23.8)	1198 (32.0)	506 (26.2)	639 (33.1)	336 (22.4)	474 (31.6)
Liver disease, n (%)	266 (7.1)	336 (9.0)	415 (21.5)	573 (29.7)	73 (4.9)	129 (8.6)
Lymphoma, n (%)	69 (1.8)	85 (2.3)	75 (3.9)	71 (3.7)	33 (2.2)	26 (1.7)
Cancer, n (%)	986 (26.4)	1040 (27.8)	1273 (66.0)	1184 (61.4)	339 (22.6)	400 (26.7)
Coagulopathy, n (%)	264 (7.1)	393 (10.5)	164 (8.5)	336 (17.4)	100 (6.7)	153 (10.2)
Obesity, n (%)	720 (19.3)	758 (20.3)	303 (15.7)	372 (19.3)	333 (22.2)	374 (24.9)
Weight loss, n (%)	240 (6.4)	371 (9.9)	220 (11.4)	349 (18.1)	76 (5.1)	173 (11.5)
Fluid/electrolyte disorders, n (%)	761 (20.4)	1171 (31.3)	440 (22.8)	716 (37.1)	334 (22.3)	543 (36.2)
Deficiency anemia, n (%)	460 (12.3)	659 (17.6)	244 (12.7)	335 (17.4)	211 (14.1)	296 (19.7)
Alcohol abuse, n (%)	135 (3.6)	219 (5.9)	67 (3.5)	129 (6.7)	30 (2.0)	74 (4.9)
Drug abuse, n (%)	171 (4.6)	213 (5.7)	58 (3.0)	80 (4.1)	42 (2.8)	72 (4.8)
Psychoses, n (%)	20 (0.5)	84 (2.2)	13 (0.7)	34 (1.8)	12 (0.8)	38 (2.5)
Depression, n (%)	905 (24.2)	1022 (27.3)	343 (17.8)	514 (26.7)	275 (18.3)	406 (27.1)
CVD[d], n (%)	527 (14.1)	668 (17.9)	111 (5.8)	141 (7.3)	142 (9.5)	231 (15.4)
Previous TBI[e], n (%)	35 (0.9)	74 (2.0)	12 (0.6)	19 (1.0)	17 (1.1)	23 (1.5)
Sensory impairment, n (%)	212 (5.7)	203 (5.4)	81 (4.2)	91 (4.7)	75 (5.0)	118 (7.9)
Previous delirium, n (%)	215 (5.8)	615 (16.4)	103 (5.3)	304 (15.8)	85 (5.7)	278 (18.5)

[a]Continuous variables are summarized as the median (IQR) and categorical variables as n (%).

[b]ECI: Elixhauser comorbidity index.

[c]ICD: *International Classification of Diseases.*

[d]CVD: cerebrovascular disease.

[e]TBI: traumatic brain injury.

Model Evaluation

XGB had the highest AUROC out of the 4 candidate classifiers (AUROC=0.79), followed by the neural network (AUROC=0.78), the random forest (AUROC=0.78), and logistic regression (AUROC=0.72). Based on this AUROC evaluation, the XGB model was retained for further analysis. For institution A, the training set included 5234 visits (n=2617, 50%, cases and n=2617, 50%, controls) and the holdout set included 1503 visits (n=752, 50%, cases and n=751, 50%, controls). For institution B, the training and holdout data sets included 2699 visits (n=1350, 50%, cases and n=1349, 50%, controls) and 775 visits (n=387, 49.9%, cases and n=388, 50.1%, controls), respectively. The training and holdout data sets for institution C included 2100 visits (n=1050, 50%, cases and n=1050, 50%, controls) and 603 visits (n=302, 50.1%, cases and n=301, 49.9%, controls), respectively.

The models trained on institution A (ie, XGB_A) had the best performance, achieving AUROCs of 0.77-0.79 on institution A holdout data and 0.68-0.74 when externally validated on data from institutions B and C. Models trained on institution B (ie, XGB_B) were the least robust, achieving a maximum AUROC of 0.71 on holdout data from institution B and 0.72-0.74 when externally validated on data from institutions A and C. Models trained on institution C (ie, XGB_C) performed better than XGB_B but worse than XGB_A, with a maximum AUROC of 0.77 on holdout data from institution C and 0.64-0.75 when externally validated on data from institutions A and B (Table 3).

Table 3. XGB[a] model performance metrics[b] by surveillance period and holdout data.

Surveillance period, models, and institutions	AUROC[c], mean (SD)	Sensitivity, mean (SD)	Specificity, mean (SD)	PPV[d], mean (SD)	NPV[e], mean (SD)
1 year, XGB_A					
Institution A	0.79 (0.01)	0.70 (0.02)	0.72 (0.02)	0.72 (0.02)	0.71 (0.02)
Institution B	0.69 (0.02)	0.49 (0.03)	0.78 (0.02)	0.69 (0.03)	0.61 (0.02)
Institution C	0.74 (0.02)	0.70 (0.03)	0.66 (0.03)	0.67 (0.03)	0.69 (0.03)
1 year, XGB_B					
Institution A	0.74 (0.01)	0.76 (0.02)	0.57 (0.02)	0.64 (0.02)	0.70 (0.02)
Institution B	0.71 (0.02)	0.57 (0.03)	0.75 (0.02)	0.69 (0.03)	0.64 (0.02)
Institution C	0.73 (0.02)	0.65 (0.03)	0.68 (0.03)	0.67 (0.03)	0.66 (0.03)
1 year, XGC_C					
Institution A	0.75 (0.01)	0.75 (0.02)	0.60 (0.02)	0.66 (0.02)	0.71 (0.02)
Institution B	0.69 (0.02)	0.47 (0.03)	0.77 (0.02)	0.67 (0.03)	0.59 (0.02)
Institution C	0.77 (0.02)	0.66 (0.03)	0.69 (0.03)	0.69 (0.03)	0.67 (0.03)
6 months, XGB_A					
Institution A	0.78 (0.01)	0.56 (0.03)	0.73 (0.02)	0.67 (0.03)	0.62 (0.02)
Institution B	0.68 (0.02)	0.45 (0.03)	0.79 (0.02)	0.68 (0.03)	0.59 (0.02)
Institution C	0.74 (0.02)	0.67 (0.03)	0.66 (0.03)	0.67 (0.03)	0.67 (0.03)
6 months, XGB_B					
Institution A	0.73 (0.01)	0.78 (0.02)	0.54 (0.02)	0.63 (0.02)	0.71 (0.02)
Institution B	0.71 (0.02)	0.56 (0.03)	0.73 (0.02)	0.67 (0.03)	0.62 (0.02)
Institution C	0.74 (0.02)	0.66 (0.03)	0.68 (0.03)	0.68 (0.03)	0.67 (0.03)
6 months, XGC_C					
Institution A	0.73 (0.01)	0.76 (0.02)	0.55 (0.02)	0.63 (0.02)	0.70 (0.02)
Institution B	0.65 (0.02)	0.52 (0.03)	0.70 (0.02)	0.64 (0.03)	0.60 (0.02)
Institution C	0.76 (0.02)	0.71 (0.03)	0.66 (0.03)	0.68 (0.03)	0.69 (0.03)
3 months, XGB_A					
Institution A	0.77 (0.01)	0.70 (0.02)	0.70 (0.02)	0.70 (0.02)	0.70 (0.02)
Institution B	0.69 (0.02)	0.47 (0.03)	0.78 (0.02)	0.68 (0.03)	0.60 (0.02)
Institution C	0.74 (0.02)	0.68 (0.03)	0.67 (0.03)	0.67 (0.03)	0.68 (0.03)
3 months, XGB_B					
Institution A	0.72 (0.01)	0.75 (0.02)	0.55 (0.02)	0.63 (0.02)	0.69 (0.02)
Institution B	0.70 (0.02)	0.56 (0.03)	0.74 (0.02)	0.68 (0.03)	0.63 (0.02)
Institution C	0.74 (0.02)	0.65 (0.03)	0.68 (0.03)	0.67 (0.03)	0.66(0.03)
3 months, XGC_C					
Institution A	0.73 (0.01)	0.75 (0.02)	0.57 (0.02)	0.64 (0.02)	0.70 (0.02)
Institution B	0.64 (0.02)	0.50 (0.03)	0.71 (0.02)	0.63 (0.03)	0.58 (0.02)
Institution C	0.76 (0.02)	0.73 (0.03)	0.64 (0.03)	0.67 (0.03)	0.70 (0.03)

[a]XGB: extreme gradient boosting.

[b]Mean (SD) metrics presented were obtained using bootstrap resampling on the held-out patients from institutions A, B, and C.

[c]AUROC: area under the receiver operating curve.

[d]PPV: positive predictive value.

[e]NPV: negative predictive value.

Performance became marginally worse with shorter surveillance periods. All models were relatively well calibrated (Figures S1-S3 in Multimedia Appendix 1). The top 5 most important features for XGB_A, XGB_B, and XGB_C by evaluation data set and surveillance period are presented in Table 4 and Tables S8-S9 in Multimedia Appendix 1. The ASA class was frequently the most important predictor.

Across all surveillance periods, the models predicted between 40% and 60% of the patients with confusion as cases or controls (Table S10 in Multimedia Appendix 1).

Table 4. Top 5 most influential variables used by XGB[a] models (1-year surveillance period).[b]

Model and rank	Holdout data		
	Institution A	Institution B	Institution C
XGB_A			
1	ASA[c] class	ASA class	ASA class
2	ICD[d] group: Z00-Z13[e]	ICD group: Z00-Z13	ICD group: Z00-Z13
3	Multispecialty surgery	Multispecialty surgery	Service: hospitalist[f]
4	Service: hospitalist	Service: hospitalist	Multispecialty surgery
5	Emergency surgery	Previous delirium	Emergency surgery
XGB_B			
1	ASA class	ASA class	ASA class
2	Multispecialty surgery	Multispecialty surgery	Multispecialty surgery
3	Previous delirium	Previous delirium	Previous delirium
4	BMI	Urology/gynecology surgery	Service: orthopedics[g]
5	Emergency surgery	BMI	BMI
XGB_C			
1	ASA class	ASA class	ASA class
2	Service: hospitalist	Service: hospitalist	Service: orthopedics
3	Service: orthopedics	Service: orthopedics	Service: hospitalist
4	Previous delirium	Previous delirium	Previous delirium
5	Multispecialty surgery	Multispecialty surgery	ICD group: Z77-Z99[h]

[a]XGB: extreme gradient boosting.

[b]Feature importance measured using Shapley Additive Explanation (SHAP) values. XGB_A, XGB_B, and XGB_C were trained on data from institutions A, B, and C, respectively.

[c]ASA: American Society of Anesthesiologists.

[d]ICD: *International Classification of Diseases.*

[e]ICD group Z00-Z13: persons encountering health services for examinations.

[f]Admitted to hospitalist service.

[g]Admitted to orthopedics service.

[h]ICD group Z77-Z99: persons with potential health hazards related to family and personal history and certain conditions influencing health status.

Discussion

Principal Findings

We developed and externally validated 3 models to predict POD with routine EHR data available at the time of hospital admission. In our experiments, XGB outperformed all other classifiers and demonstrated good discriminative ability on holdout data, achieving a maximum AUROC of 0.79. Generalizability varied by model and the institution used for external validation.

Our models demonstrated good predictive accuracy, with XGB_A outperforming XGB_B and XGB_C across all surveillance periods. Interestingly, longer surveillance periods did not appear to significantly benefit model performance. This is likely because the most important features were surgery-related variables, which were fixed across all surveillance durations. Additionally, surveillance duration did not impact how the models classified patients with confusion but no delirium (ie, potential subsyndromal delirium); approximately half were predicted to be cases, and the other half were predicted to be controls, regardless of the surveillance period. Given that subsyndromal delirium is thought to be on the spectrum between healthy

controls and delirium [38], it was expected that the models would have trouble classifying those patients.

Generalizability varied by model and institution. XGB_A performed relatively well when externally validated using data from institution C, as did XGB_C when validated using data from institution A. However, the AUROCs for both models decreased substantially when validated on data from institution B. In contrast, XGB_B had higher AUROCs when externally validated on institutions A and C than it did on holdout data from the same institution it was trained on. We hypothesize that the observed variation in performance could be due to institution B having a substantially different patient population than institutions A and C. Institutions A and C are trauma centers that perform a comparatively large number of orthopedic surgeries, and their populations have fewer comorbidities. Institution A also cares for complex vascular and cardiac patients, while the other 2 institutions generally do not. Conversely, institution B is not a trauma center and performs mostly general and urologic/gynecologic surgeries. It also largely services frail, high-acuity patients with chronic illnesses, and the general surgical complexity is higher. The comparatively low AUROC of XGB_B could reflect the model having difficulty discriminating between cases and controls, because it was trained on patients who were more ill, regardless of delirium status. These results highlight the importance of selecting an appropriate training population when a generalizable prediction model is desired; if a hospital has a patient population that differs significantly from the training data set, a localized model may be needed, even within the same hospital system.

The ASA class, a subjective measure of a patient's physiologic status [39], was frequently the most important feature. This supports previous literature linking a higher ASA class to a greater risk of POD [40]. The Elixhauser comorbidity index (ECI) did not appear in the list of top features despite the strong association of comorbidities with delirium, possibly because the ASA class summarizes health information beyond mortality risk and additionally identifies emergency cases. However, the subjectivity of the ASA class [41] may harm model generalizability compared to more objective measures, such as comorbidity scores. Other surgical variables, including admitting service and surgical specialty, were frequently among the top 5 features. Notably, both these variables have been associated with an increased risk of POD, particularly surgical specialty [6]. Multispecialty surgery was particularly important across models, suggesting that surgical complexity may be an important risk factor for delirium. The type of admitting service and individual surgical specialties that were most predictive differed by model, potentially because the distributions were different between institutions. For example, urologic/gynecologic surgery was frequently a top predictor in XGB_B models but not in others. This could be because proportionally more controls had that type of surgery than cases at institution B but not at institutions A and C. Reducing the cardinality of these variables is likely to improve generalizability but potentially at the cost of reduced discriminative ability. For XGB_A, the number of ICD codes belonging to ICD-10 group Z00-Z13 ("persons encountering health services for examinations") was a top feature, and higher values negatively influenced model predictions. This may be because this ICD group captures routine health examinations, which are often undertaken by healthier individuals. The fact that the top features are supported by the literature suggests that the models are clinically explainable.

Several delirium prediction models have been developed, reporting AUROCs ranging from 0.56 to 0.94 [42]. The models with the highest AUROCs focus on specific patient subsets (ie, ICU patients, cardiac surgery) and include variables collected during the hospital stay, such as the APACHE score (which must be calculated), surgery duration (often not reliably recorded), and inpatient laboratory values. In-hospital variables may, indeed, be the strongest predictors of delirium and explain why our model failed to outperform previous ones; however, they were intentionally excluded from this study as that would preclude our models from being used at the time of hospitalization. Fewer models have been developed that are both her based and intended to be used at or shortly after admission. In their 2022 paper, Bishara et al [14] developed a POD prediction model for the general surgical population using different machine learning approaches and preoperative EHR data. They found that an XGB model outperforms other classifiers, similar to our findings, and reported an internal validation AUROC of 0.85 [14]. In contrast to our study, matching was not performed, and patients with dementia were included in the study population. Fifty-nine variables derived from inpatient (but preoperative) nursing assessments were also included as predictors. Some of these assessments (eg, Braden Scale score [43]) captured patients' functional status, which is highly correlated to delirium [5,6] and may explain why their model had a higher AUROC. Wong et al [44] developed a model to predict delirium in a general inpatient population without known cognitive impairment using an XGB model and reported an AUROC of 0.86. Their model used 796 features collected within 24 hours of admission and included inpatient neurologic examination data, which were highly predictive of delirium. These factors could explain, at least in part, the difference in performance between these previous models and our models.

In summary, our findings suggest that a machine learning model trained on routine EHR data can achieve clinically useful accuracy when predicting POD. Unlike previous models, the models presented in this study can be used to make predictions at the time of hospital admission, which could quickly inform preventive and resource-planning efforts. The models were also externally validated, providing critical information about generalizability when using a limited set of prehospital and surgery variables. These models can be readily integrated into EHR systems to provide a scalable, automated prescreening tool to flag patients who are at risk of developing POD and would benefit from targeted preventative measures.

Strengths and Limitations

Our study has several strengths. First, we used both the CAM method and ICD codes to maximize case identification; because delirium ICD codes are extremely specific but less sensitive [45], false negatives are unlikely. Second, we compared different surveillance periods to determine how surveillance duration influences accuracy. Third, we examined how the models

classify patients with confusion but no delirium, which could potentially capture subsyndromal delirium. Finally, we trained our models on data from 3 different institutions and externally validated them against each other to determine their transportability.

This study also has several limitations. Although we attempted to maximize delirium detection by using both the CAM method and ICD codes, a small number of patients did not have any CAM data available. As mentioned previously, delirium ICD codes tend to have high specificity but lower sensitivity [45], so some cases may have been missed. Patients were intentionally matched on age, sex, and race to limit biases related to these variables; however, discriminative ability was likely reduced as a result. Because patients with preexisting dementia or confusion during the inpatient visit (but no documented delirium) were excluded, the models may not generalize well to those types of patients. However, we chose to exclude those patients because their high risk of delirium was evident; our models focused on patients with a less clear delirium risk, which could partially explain the lower performance compared to previous models. Finally, although the models were externally validated, the hospitals were within the same health care system, which may present more optimistic generalizability relative to uses of the models in outside systems.

Conclusion

Routine EHR data can be used for early delirium prediction in a diverse cohort of surgery patients without dementia. Although our models slightly underperformed relative to some of the previously published classifiers that use inpatient data, our routine EHR-based models serve a distinct purpose of enabling predictions at the time of admission, while being highly scalable. Generalizability varied depending on the training data, so institution-specific models may be necessary when using only a limited set of preadmission and surgery variables with distributions that substantially differ between institutions. The proposed models could be used in clinical practice as an automated prescreening tool for the early identification of high-risk patients, enabling clinicians to immediately adjust their care strategies and inform targeted delirium prevention measures and resource planning.

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Authors' Contributions

All authors contributed to study conception and design. EH performed all analyses and drafted the manuscript. All authors critically revised and reviewed the final manuscript.

Conflicts of Interest

ZBM has a financial interest in DigiCare Realized and could benefit from the results of this research. MB serves as a chief scientific officer and cofounder of BlueAgilis; and the chief health officer of DigiCare Realized, Inc. He has equity interest in Blue Agilis, Inc DigiCare Realized, Inc; Preferred Population Health Management LLC; and MyShift, Inc (previously known as RestUp, LLC). He serves as an advisory board member for Acadia Pharmaceuticals; Eisai, Inc; Biogen; and Genentech. These conflicts have been reviewed by Indiana University and have been appropriately managed to maintain objectivity. The remaining authors declare no competing interests.

Multimedia Appendix 1
Calibration curves for XGB; ICD codes for preexisting Alzheimer's disease, related dementias, delirium, and additional variables; sociodemographic and surgical characteristics of patients and controls; clinical characteristics of patients and controls; XGB model predictions for confusion encounters; and top 5 most influential variables used by XGB models. ICD: International Classification of Diseases; XGB: extreme gradient boosting.
[DOCX File , 271 KB - periop_v8i1e59422_app1.docx]

References

1. Marcantonio ER, Goldman L, Mangione CM, Ludwig LE, Muraca B, Haslauer CM, et al. A clinical prediction rule for delirium after elective noncardiac surgery. JAMA 1994 Jan 12;271(2):134-139. [Medline: 8264068]
2. Marcantonio ER, Flacker JM, Wright RJ, Resnick NM. Reducing delirium after hip fracture: a randomized trial. J Am Geriatr Soc 2001 May;49(5):516-522. [doi: 10.1046/j.1532-5415.2001.49108.x] [Medline: 11380742]
3. Rudolph JL, Jones RN, Levkoff SE, Rockett C, Inouye SK, Sellke FW, et al. Derivation and validation of a preoperative prediction rule for delirium after cardiac surgery. Circulation 2009 Jan 20;119(2):229-236 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.108.795260] [Medline: 19118253]
4. Inouye SK, Westendorp RGJ, Saczynski JS. Delirium in elderly people. Lancet 2014 Mar 08;383(9920):911-922 [FREE Full text] [doi: 10.1016/S0140-6736(13)60688-1] [Medline: 23992774]
5. Marcantonio ER. In the clinic. Delirium. Ann Intern Med 2011 Jun 07;154(11):ITC6-1, ITC6. [doi: 10.7326/0003-4819-154-11-201106070-01006] [Medline: 21646553]

6. Vasilevskis EE, Han JH, Hughes CG, Ely EW. Epidemiology and risk factors for delirium across hospital settings. Best Pract Res Clin Anaesthesiol 2012 Sep;26(3):277-287 [FREE Full text] [doi: 10.1016/j.bpa.2012.07.003] [Medline: 23040281]
7. Brouquet A, Cudennec T, Benoist S, Moulias S, Beauchet A, Penna C, et al. Impaired mobility, ASA status and administration of tramadol are risk factors for postoperative delirium in patients aged 75 years or more after major abdominal surgery. Ann Surg 2010 Apr;251(4):759-765. [doi: 10.1097/SLA.0b013e3181c1cfc9] [Medline: 20224380]
8. Greene NH, Attix DK, Weldon BC, Smith PJ, McDonagh DL, Monk TG. Measures of executive function and depression identify patients at risk for postoperative delirium. Anesthesiology 2009 Apr;110(4):788-795 [FREE Full text] [doi: 10.1097/aln.0b013e31819b5ba6] [Medline: 19326494]
9. Noimark D. Predicting the onset of delirium in the post-operative patient. Age Ageing 2009 Jul;38(4):368-373. [doi: 10.1093/ageing/afp024] [Medline: 19297372]
10. Koebrugge B, van Wensen RJA, Bosscha K, Dautzenberg PLJ, Koning OHJ. Delirium after emergency/elective open and endovascular aortoiliac surgery at a surgical ward with a high-standard delirium care protocol. Vascular 2010;18(5):279-287. [doi: 10.2310/6670.2010.00052] [Medline: 20822723]
11. Witlox J, Eurelings LSM, de Jonghe JFM, Kalisvaart KJ, Eikelenboom P, van Gool WA. Delirium in elderly patients and the risk of postdischarge mortality, institutionalization, and dementia: a meta-analysis. JAMA 2010 Jul 28;304(4):443-451. [doi: 10.1001/jama.2010.1013] [Medline: 20664045]
12. Inouye SK, Bogardus ST, Charpentier PA, Leo-Summers L, Acampora D, Holford TR, et al. A multicomponent intervention to prevent delirium in hospitalized older patients. N Engl J Med 1999 Mar 04;340(9):669-676. [doi: 10.1056/NEJM199903043400901] [Medline: 10053175]
13. Hshieh TT, Yang T, Gartaganis SL, Yue J, Inouye SK. Hospital elder life program: systematic review and meta-analysis of effectiveness. Am J Geriatr Psychiatry 2018 Oct;26(10):1015-1033 [FREE Full text] [doi: 10.1016/j.jagp.2018.06.007] [Medline: 30076080]
14. Bishara A, Chiu C, Whitlock EL, Douglas VC, Lee S, Butte AJ, et al. Postoperative delirium prediction using machine learning models and preoperative electronic health record data. BMC Anesthesiol 2022 Jan 03;22(1):8 [FREE Full text] [doi: 10.1186/s12871-021-01543-y] [Medline: 34979919]
15. Hu X, Liu H, Zhao X, Sun X, Zhou J, Gao X, et al. Automated machine learning-based model predicts postoperative delirium using readily extractable perioperative collected electronic data. CNS Neurosci Ther 2022 Apr;28(4):608-618 [FREE Full text] [doi: 10.1111/cns.13758] [Medline: 34792857]
16. Davoudi A, Ebadi A, Rashidi P, Ozrazgat-Baslanti T, Bihorac A, Bursian AC. Delirium prediction using machine learning models on preoperative electronic health records data. Proc IEEE Int Symp Bioinformatics Bioeng 2017 Oct;2017:568-573 [FREE Full text] [doi: 10.1109/BIBE.2017.00014] [Medline: 30393788]
17. Racine AM, Tommet D, D'Aquila ML, Fong TG, Gou Y, Tabloski PA, RISE Study Group. Machine learning to develop and internally validate a predictive model for post-operative delirium in a prospective, observational clinical cohort study of older surgical patients. J Gen Intern Med 2021 Feb;36(2):265-273 [FREE Full text] [doi: 10.1007/s11606-020-06238-7] [Medline: 33078300]
18. Xue B, Li D, Lu C, King CR, Wildes T, Avidan MS, et al. Use of machine learning to develop and evaluate models using preoperative and intraoperative data to identify risks of postoperative complications. JAMA Netw Open 2021 Mar 01;4(3):e212240 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.2240] [Medline: 33783520]
19. Zhao H, You J, Peng Y, Feng Y. Machine learning algorithm using electronic chart-derived data to predict delirium after elderly hip fracture surgeries: a retrospective case-control study. Front Surg 2021;8:634629 [FREE Full text] [doi: 10.3389/fsurg.2021.634629] [Medline: 34327210]
20. Matsumoto K, Nohara Y, Sakaguchi M, Takayama Y, Fukushige S, Soejima H, et al. Temporal generalizability of machine learning models for predicting postoperative delirium using electronic health record data: model development and validation study. JMIR Perioper Med 2023 Oct 26;6:e50895 [FREE Full text] [doi: 10.2196/50895] [Medline: 37883164]
21. Mufti HN, Hirsch GM, Abidi SR, Abidi SSR. Exploiting machine learning algorithms and methods for the prediction of agitated delirium after cardiac surgery: models development and validation study. JMIR Med Inform 2019 Oct 23;7(4):e14993 [FREE Full text] [doi: 10.2196/14993] [Medline: 31558433]
22. Jung JW, Hwang S, Ko S, Jo C, Park HY, Han H, et al. A machine-learning model to predict postoperative delirium following knee arthroplasty using electronic health records. BMC Psychiatry 2022 Jun 27;22(1):436 [FREE Full text] [doi: 10.1186/s12888-022-04067-y] [Medline: 35761274]
23. Luo Y, Wu X, Song Y, Wang X, Liu K, Shi C, et al. Development and validation of a nomogram to predict postoperative delirium in older patients after major abdominal surgery: a retrospective case-control study. Perioper Med (Lond) 2024 May 16;13(1):41 [FREE Full text] [doi: 10.1186/s13741-024-00399-3] [Medline: 38755693]
24. Geßele C, Saller T, Smolka V, Dimitriadis K, Amann U, Strobach D. Development and validation of a new drug-focused predictive risk score for postoperative delirium in orthopaedic and trauma surgery patients. BMC Geriatr 2024 May 13;24(1):422 [FREE Full text] [doi: 10.1186/s12877-024-05005-1] [Medline: 38741037]
25. Fan Y, Yang T, Liu Y, Gan H, Li X, Luo Y, et al. Nomogram for predicting the risk of postoperative delirium in elderly patients undergoing orthopedic surgery. Perioper Med (Lond) 2024 May 04;13(1):34 [FREE Full text] [doi: 10.1186/s13741-024-00393-9] [Medline: 38702728]

26. Nagata C, Hata M, Miyazaki Y, Masuda H, Wada T, Kimura T, et al. Development of postoperative delirium prediction models in patients undergoing cardiovascular surgery using machine learning algorithms. Sci Rep 2023 Nov 30;13(1):21090 [FREE Full text] [doi: 10.1038/s41598-023-48418-5] [Medline: 38036664]
27. Collins GS, Reitsma JB, Altman DG, Moons K. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD statement. BMC Med 2015 Jan 06;13(1):1 [FREE Full text] [doi: 10.1186/s12916-014-0241-z] [Medline: 25563062]
28. IU Health: about our system. Indiana University Health. URL: https://iuhealth.org/about-our-system [accessed 2024-04-15]
29. Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: the Confusion Assessment Method. A new method for detection of delirium. Ann Intern Med 1990 Dec 15;113(12):941-948. [doi: 10.7326/0003-4819-113-12-941] [Medline: 2240918]
30. Wei LA, Fearing MA, Sternberg EJ, Inouye SK. The Confusion Assessment Method: a systematic review of current usage. J Am Geriatr Soc 2008 May;56(5):823-830 [FREE Full text] [doi: 10.1111/j.1532-5415.2008.01674.x] [Medline: 18384586]
31. Khuri SF, Henderson WG, Daley J, Jonasson O, Jones RS, Campbell DA, Principal Investigators of the Patient Safety in Surgery Study. Successful implementation of the Department of Veterans Affairs' National Surgical Quality Improvement Program in the private sector: the Patient Safety in Surgery study. Ann Surg 2008 Aug;248(2):329-336. [doi: 10.1097/SLA.0b013e3181823485] [Medline: 18650645]
32. Quan H, Sundararajan V, Halfon P, Fong A, Burnand B, Luthi J, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. Med Care 2005 Nov;43(11):1130-1139. [doi: 10.1097/01.mlr.0000182534.19832.83] [Medline: 16224307]
33. Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. Med Care 1998 Jan;36(1):8-27. [doi: 10.1097/00005650-199801000-00004] [Medline: 9431328]
34. van Walraven C, Austin PC, Jennings A, Quan H, Forster AJ. A modification of the Elixhauser comorbidity measures into a point system for hospital death using administrative data. Med Care 2009 Jun;47(6):626-633. [doi: 10.1097/MLR.0b013e31819432e5] [Medline: 19433995]
35. Campbell N, Maidment I, Fox C, Khan B, Boustani M. The 2012 update to the anticholinergic cognitive burden scale. J Am Geriatr Soc 2013 Apr;61(S1):S142-S143. [doi: 10.1111/JGS.2013.61.ISSUE-S1]
36. Anatomical therapeutic chemical (ATC) classification. World Health Organization. URL: https://www.who.int/tools/atc-ddd-toolkit/atc-classification [accessed 2023-09-04]
37. Lundberg SM, Lee LSI. A unified approach to interpreting model predictions. arXiv. Preprint posted online 2012. [doi: 10.48550/arXiv.1705.07874] . [doi: 10.48550/arXiv.1705.07874]
38. Ouimet S, Riker R, Bergeron N, Cossette M, Kavanagh B, Skrobik Y. Subsyndromal delirium in the ICU: evidence for a disease spectrum. Intensive Care Med 2007 Jun 3;33(6):1007-1013. [doi: 10.1007/s00134-007-0618-y] [Medline: 17404704]
39. Doyle DJ, Hendrix JM, Garmon EH. American Society of Anesthesiologists Classification. Treasure Island, FL: StatPearls Publishing; 2023.
40. Oh E, Li M, Fafowora T, Inouye S, Chen C, Rosman L, et al. Preoperative risk factors for postoperative delirium following hip fracture repair: a systematic review. Int J Geriatr Psychiatry 2015 Sep;30(9):900-910 [FREE Full text] [doi: 10.1002/gps.4233] [Medline: 25503071]
41. Sankar A, Johnson SR, Beattie WS, Tait G, Wijeysundera DN. Reliability of the American Society of Anesthesiologists physical status scale in clinical practice. Br J Anaesth 2014 Sep;113(3):424-432 [FREE Full text] [doi: 10.1093/bja/aeu100] [Medline: 24727705]
42. Lindroth H, Bratzke L, Purvis S, Brown R, Coburn M, Mrkobrada M, et al. Systematic review of prediction models for delirium in the older adult inpatient. BMJ Open 2018 Apr 28;8(4):e019223 [FREE Full text] [doi: 10.1136/bmjopen-2017-019223] [Medline: 29705752]
43. Bergstrom N, Braden BJ, Laguzza A, Holman V. The Braden Scale for predicting pressure sore risk. Nurs Res 1987;36(4):205-210. [Medline: 3299278]
44. Wong A, Young AT, Liang AS, Gonzales R, Douglas VC, Hadley D. Development and validation of an electronic health record-based machine learning model to estimate delirium risk in newly hospitalized patients without known cognitive impairment. JAMA Netw Open 2018 Aug 03;1(4):e181018 [FREE Full text] [doi: 10.1001/jamanetworkopen.2018.1018] [Medline: 30646095]
45. Kim D, Lee J, Kim C, Huybrechts K, Bateman B, Patorno E, et al. Evaluation of algorithms to identify delirium in administrative claims and drug utilization database. Pharmacoepidemiol Drug Saf 2017 Aug;26(8):945-953 [FREE Full text] [doi: 10.1002/pds.4226] [Medline: 28485014]

Abbreviations

ACB: Anticholinergic Cognitive Burden
ACh: anticholinergic
ASA: American Society of Anesthesiologists
ATC: Anatomical Therapeutic Chemical

AUROC: area under the receiver operating characteristic curve
CAM: Confusion Assessment Method
CVD: cerebrovascular disease
ECI: Elixhauser comorbidity index
EHR: electronic health record
ICD: International Classification of Diseases
ICD-9: International Classification of Diseases, Ninth Revision
ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification
IU: Indiana University
NPV: negative predictive value
POD: postoperative delirium
PPV: positive predictive value
SHAP: Shapley Additive Explanation
TBI: traumatic brain injury
XGB: extreme gradient boosting

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Original Paper

Agreement Between Provider-Completed and Patient-Completed Preoperative Frailty Screening Using the Clinical Risk Analysis Index: Cross-Sectional Questionnaire Study

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Abstract

Background: Frailty is associated with postoperative morbidity and mortality. Preoperative screening and management of persons with frailty improves postoperative outcomes. The Clinical Risk Analysis Index (RAI-C) is a validated provider-based screening tool for assessing frailty in presurgical populations. Patient self-screening for frailty may provide an alternative to provider-based screening if resources are limited; however, the agreement between these 2 methods has not been previously explored.

Objective: The objective of our study was to examine provider-completed versus patient-completed RAI-C assessments to identify areas of disagreement between the 2 methods and inform best practices for RAI-C screening implementation.

Methods: Orthopedic physicians and physician assistants completed the RAI-C assessment on veterans aged 65 years and older undergoing elective total joint arthroplasty (eg, total hip or knee arthroplasty) and documented scores into the electronic health record during their preoperative clinic evaluation. Participants were then mailed the same RAI-C form after preoperative evaluation and returned responses to study coordinators. Agreement between provider-completed and patient-completed RAI-C assessments and differences within individual domains were compared.

Results: A total of 49 participants aged 65 years and older presenting for total joint arthroplasty underwent RAI-C assessment between November 2022 and August 2023. In total, 41% (20/49) of participants completed and returned an independent postvisit RAI-C assessment before surgery and within 180 days of their initial evaluation. There was a moderate but statistically significant correlation between provider-completed and patient-completed RAI-C assessments (r=0.62; 95% CI 0.25-0.83; P=.003). Provider-completed and patient-completed RAI-C assessments resulted in the same frailty classification in 60% (12/20) of participants, but 40% (8/20) of participants were reclassified to a more frail category based on patient-completed assessment. Agreement was the lowest between provider-completed and patient-completed screening questions regarding memory and activities of daily living.

Conclusions: RAI-C had moderate agreement when completed by providers versus the participants themselves, with more than a third of patient-completed screens resulting in a higher frailty classification. Future studies will need to explore the differences between and accuracy of RAI-C screening approaches to inform best practices for preoperative RAI-C assessment implementation.

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KEYWORDS

Risk Analysis Index; preoperative screening; questionnaire; frailty; self-reported; veteran; hip; knee; arthroplasty; elective surgery; cross-sectional; quality improvement

Introduction

Frailty is a multidimensional syndrome characterized by decreased physiological reserve reducing recovery from stressors including surgery and is associated with increased postoperative morbidity and mortality [1]. Frailty screening and multidisciplinary management of persons with frailty before elective surgery improve perioperative functional performance, decrease postoperative mortality, and may improve postoperative morbidity [2,3]. While numerous patient-completed frailty screening tools (eg, FRAIL Scale, Edmonton Frail Scale, and Vulnerable Elders Survey) have been used to predict surgical morbidity and mortality in different surgical populations, few have undergone as extensive validation in the presurgical population as the Clinical Risk Analysis Index (RAI-C) [4,5]. The RAI-C is a validated 14-item health and functioning questionnaire developed to distinguish between frail and robust persons in the preoperative setting. It calculates a score between 0 and 81 from information provided by a person or surrogate with scores ≥37 indicating frailty [5-7]. Higher RAI-C scores have been associated with postoperative mortality across surgical specialties suggesting its use as an easily administered preoperative risk-stratification tool [6-8]. RAI-C has been adopted by the Veterans Health Administration (VHA) as the preferred tool for presurgical frailty assessment with the goal to optimize the care of at-risk persons [9].

Validation studies suggest that persons can complete the RAI-C independently, which is advantageous if provider time is limited [6-8]. However, review of study methods indicates that providers modified participant responses as needed, suggesting that screening was not entirely patient-led [6,7]. It is uncertain how often providers changed participant responses, which domains were modified, and how modifications affected frailty classifications. Therefore, we sought to examine provider-completed versus patient-completed RAI-C assessments to identify areas of disagreement between the 2 methods and inform best practices for RAI-C screening implementation.

Methods

Screening Procedures

Overview

As part of a quality improvement initiative, we designed and implemented a cross-sectional pilot examination to screen participants aged 65 years and older referred to an outpatient, VHA orthopedic clinic for elective total joint arthroplasty (TJA; eg, total hip or knee arthroplasty) for frailty between November 2022 and August 2023. The primary aim was to examine the agreement between provider-completed and patient-completed RAI-C assessments to inform frailty screening practices at our institution.

Orthopedic physicians and physician assistants underwent training on the use of an electronic health record (EHR)–embedded web-based RAI-C questionnaire. During preoperative evaluations, providers screened participants for frailty using the EHR-embedded assessment and recorded the RAI-C scores. Robust (RAI-C <30), prefrail (RAI-C 30-36), and frail (RAI-C ≥37) classifications were based on cutoffs defined in a large recalibration and external validation study of patients undergoing major elective noncardiac surgery. In that study, the 180-day postoperative mortality rate for RAI-C ≥30 was 2.0%, surpassing the overall mean mortality rate of 1.8%, and 4.3% for RAI-C ≥37, which is greater than twice the mean mortality rate of the population [5]. All participants also underwent screening for dementia with the Mini-Cog, a validated cognitive screen combining 3-item word memory and clock drawing [10]. Scores range from 0 to 5, with scores <3 indicating significant risk for dementia [11]. After the visit, participants were mailed a paper version of the RAI-C with a letter explaining the purpose of the screening tool and instructions on how to send back completed forms to study coordinators.

Participants were excluded from the study if surgery was performed before the participant responses to the RAI-C were received for analysis to mitigate possible confounding effects of surgery on patient-completed RAI-C responses. In addition, we excluded participant responses that were received more than 180 days from the date of provider-completed RAI-C to avoid confounding effects of progressive loss of function and osteoarthritis-related pain on the patient-completed RAI-C results. We chose an exclusion cutoff of 180 days based on findings that in individuals awaiting TJA for more than 180 days, worsening patient-reported outcome measures (ie, joint-specific function and health-related quality of life) were associated with increased levels of clinical frailty [12].

Analysis of Intervention and Measures

Patient-completed RAI-C responses were compared with provider-completed EHR-RAI-C results and analyzed for discrepancies between their total RAI-C and individual domain scores. The study authors performed a detailed EHR review to verify accuracy of provider and participant responses pertaining to health conditions (ie, presence of renal failure, heart failure, weight loss, or cancer). The provider completing the RAI-C also performed Mini-Cog screening for dementia to identify persons who would benefit from geriatric consultation (eg, scores <3), but results of this screening did not inform the subjective participant responses to the RAI-C question on loss of memory. The accuracy of participant responses to subjective questions (ie, limitations in activities of daily living [ADLs], loss of appetite, or memory problems) was not verified.

The primary outcome measure was the degree of concordance between provider-completed and patient-completed total RAI-C scores. Secondary outcome measures were degree of concordance between the responses for individual domains and

the effect of time elapsed between provider-completed and patient-completed responses on the degree of concordance between scores. The Pearson product-moment correlation coefficient (r) was used to determine the linear relationship between provider-completed and patient-completed total RAI-C and individual RAI-C domain scores and time elapsed in days from provider to participant completion of the RAI-C and the absolute difference in scores obtained, respectively. Quantile-quantile plots and histograms of both the provider-completed and patient-completed total RAI-C scores indicated that the distributions of both variables were approximately normal. All analyses were performed in R (version 4.3.1; R Foundation for Statistical Computing).

Ethical Considerations

The Human Research Protection Program, Associate Chief of Staff for Research and Development, and Quality, Safety, and Values department reviewed this project in accordance with the Veterans Health Administration Program Guide 1200.21 and determined that it was a nonresearch, operations activity. Thus, approval by an institutional review board and consent to participate were not needed. Participant data were anonymized to ensure privacy and confidentiality. Participants were not offered compensation.

Results

Forty-nine participants aged 65 years and older presenting for TJA underwent RAI-C screening between November 2022 and August 2023. In total, 61% (30/49) of participants returned a postvisit RAI-C assessment, but 9 participants underwent surgery before completion and were excluded from analysis. An additional participant who returned a postvisit RAI-C assessment more than 180 days from orthopedic clinic evaluation was excluded. Therefore, 41% (20/49) of participants who returned a completed postvisit RAI-C assessment before surgery within 180 days from their initial evaluation were included in our analysis and their characteristics are summarized in Table 1. The number of positive responses to RAI-C questions reported in Table 2 show all responses. Identical result counts between provider and patient responses do not necessarily indicate agreement between their respective responses.

We used RAI-C score without cancer in our analysis since none of the participants met RAI-C definition of cancer (ie, unresectable cancer, metastatic cancer with poor prognosis, chemotherapy within 30 days, or radiotherapy within 90 days). There was statistically significant, moderate correlation between provider-completed and patient-completed RAI-C (N=20, r=0.62, 95% CI 0.25-0.83; P=.003; Figure 1).

Table 1. Participant characteristics (N=20).

Characteristics	Values
Gender, n (%)	
Men	19 (95)
Average age, years (range)	74 (66-83)
Race, n (%)[a]	
White	17 (85)
Black	2 (10)
Preferred language, n (%)[b]	
English	18 (90)
Mini-Cog score ≥3, n (%)	19 (95)

[a]One participant declined to respond.

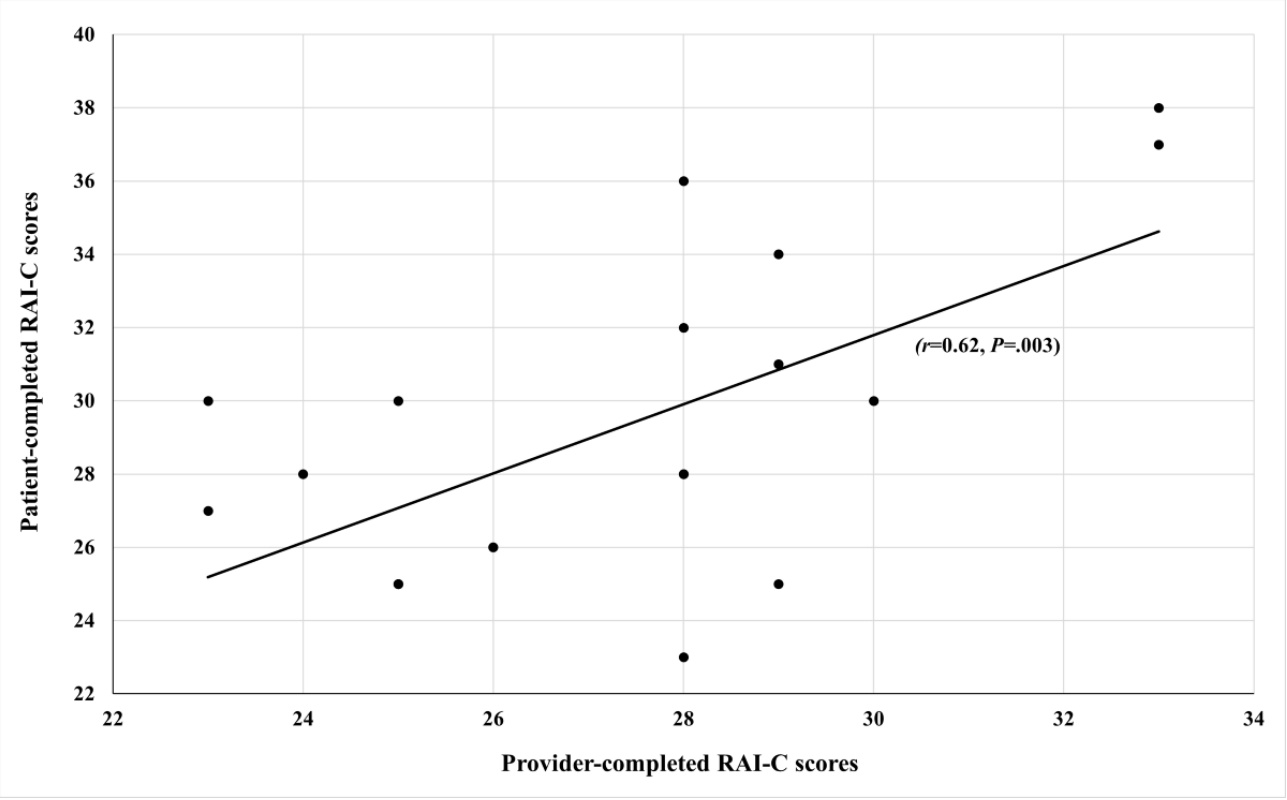
[b]Two participants declined to respond.

Table 2. Patients' and providers' responses.

Factors	Patient-completed	Provider-completed
Medical conditions per RAI-C[a] definition, n (%)		
Kidney disease	0 (0)	0 (0)
Heart failure	3 (15)	0 (0)
Shortness of breath	0 (0)	0 (0)
Cancer within 5 years	0 (0)	0 (0)
Nutrition, n (%)		
Loss of weight	3 (15)	1 (5)
Loss of appetite	1 (5)	0 (0)
Cognition, n (%)		
Loss of memory	4 (20)	3 (15)
Limitations in activities of daily living, n (%)		
Mobility	10 (50)	10 (50)
Eating	3 (15)	1 (5)
Toileting	2 (10)	0 (0)
Personal hygiene	2 (10)	0 (0)
Total RAI-C score, n (%)		
RAI-C <30 (Robust)	11 (55)	17 (85)
RAI-C 30-36 (Prefrail)	7 (35)	3 (15)
RAI-C ≥ 37 (Frail)	2 (10)	0 (0)

[a]RAI-C: Clinical Risk Analysis Index.

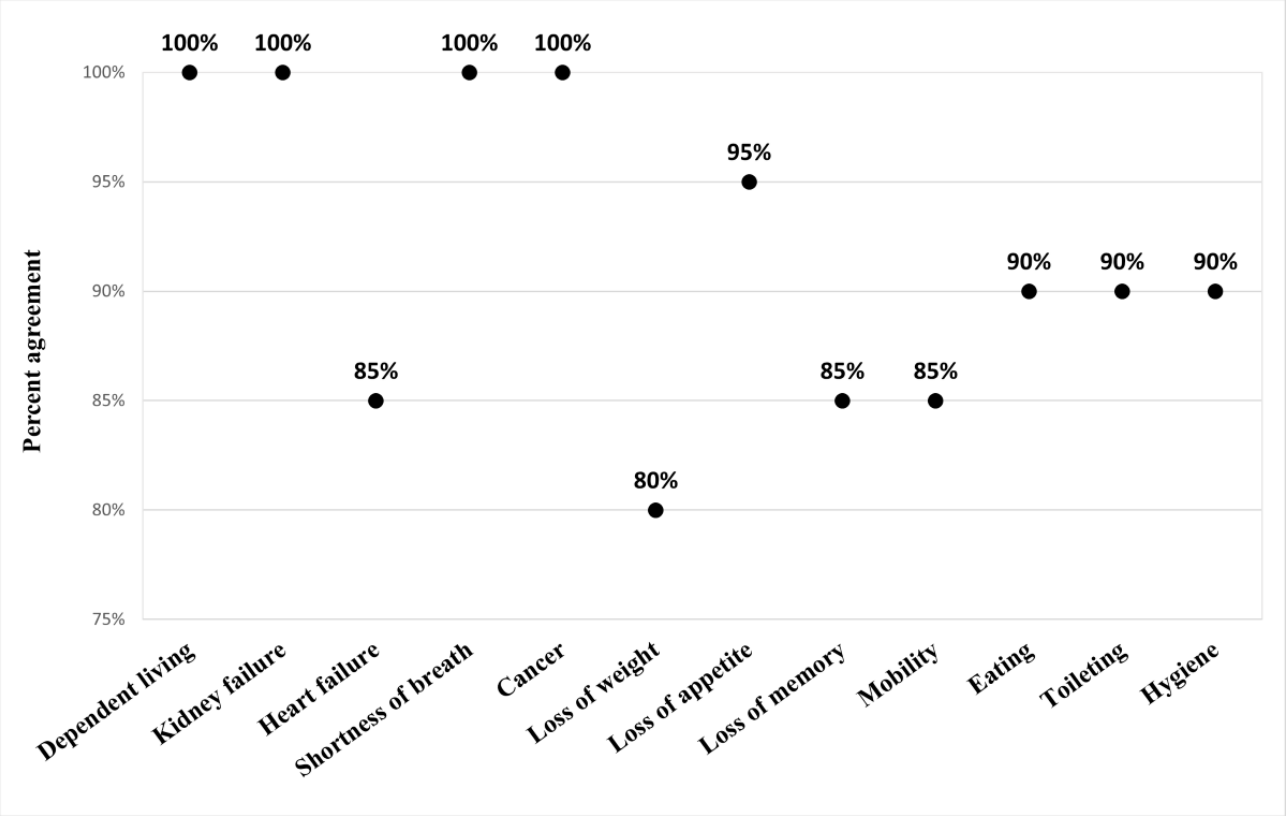
Figure 1. Correlation between provider-completed and patient-completed total RAI-C scores (N=20). RAI-C: Clinical Risk Analysis Index.



Frailty classification was identical in 60% (12/20) of participants. The remaining 40% (8/20) of participants were reclassified to a higher level of frailty based on patient-completed RAI-C scores. In addition, 30% (6/20) of participants were reclassified from robust to prefrail and 10% (2/20) from prefrail to frail (Multimedia Appendix 1).

Agreement between questions concerning chronic health conditions such as kidney disease and cancer was relatively high (Figure 2).

Figure 2. Percentage agreement between provider-completed and patient-completed responses to individual domains of the Clinical Risk Analysis Index (N=20).



The domains with lowest agreements included heart failure, loss of weight, loss of memory, and the mobility subcategory of ADLs. Neither participant nor provider responses to weight loss (ie, loss of ≥10 lb in the past 3 months without trying) were accurate as they were not supported by EHR-documented weights. Although participant responses to weight loss compared with provider responses differed in 20% (4/20) of participants, this disagreement did not affect their respective frailty classification.

In responding to questions on loss of appetite, loss of memory, and limitations in ADLs, 45% (9/20) of participants assigned lower scores than providers, which reclassified 6 of these participants to a higher level of frailty. Therefore, participant responses to questions pertaining to loss of appetite, loss of memory, and ADLs accounted for 75% (6/8) of observed reclassifications to a higher level of frailty. The remaining 2 observed reclassifications to a higher level of frailty were based on participant responses indicating presence of heart failure, which was supported on review of EHR documentation of heart failure symptoms or consistent findings on transthoracic echocardiography.

On average, participants returned self-assessments within 41 days of the date the forms were mailed to them (median 28, range 21-68 days) with an average time between completion of provider and participant RAI-C forms of 65 (median 65, range 25-118) days. Time elapsed between assessments did not correlate with the differences observed between RAI-C scores (N=20, r=0.38; P=.10).

Discussion

Principal Findings

The RAI-C is preferred for preoperative frailty screening in VHA and has been validated in presurgical populations [5-7]. These prior validation studies have not fully explored the relationship between provider and patient-completed assessments as a method to increase screening efficiency. We showed that our population of older veterans with low concern for cognitive impairment presenting for elective orthopedic TJA could complete RAI-C assessments independently. However, the correlation between provider-completed and patient-completed RAI-C scores was only moderate and more than a third of participants were reclassified to higher levels of frailty based on self-assessment. While other studies comparing provider versus participant perceptions of frailty also observed moderate correlation between the 2 methods, their study populations and settings were different (emergency room vs preoperative setting), they used a different screening tool (Clinical Frail Scale vs RAI-C), and they found that providers

assigned higher levels of frailty than participants [13,14]. Our study is one of the first to highlight areas of discrepancy between provider-completed and patient-completed RAI-C, suggesting challenges to the predictive validity of this tool and considerations for clinical implementation.

We found that disagreement between provider and participant responses and reclassifications were mainly based on participant-perceived decline in appetite, memory, and performance of ADLs, or heart failure. Notably, all participants accurately recognized their heart failure diagnosis, while providers missed the diagnosis in 3 cases. Disagreement between provider and participant responses to these domains (ie, heart failure, loss of appetite, memory loss, and limitations in ADLs) and provider underclassification of frailty has potentially significant clinical ramifications. Although optimal management of frailty is ill-defined, expert consensus suggests that persons with frailty should undergo comprehensive assessments to identify and address rehabilitative, nutritional, and psychosocial needs preoperatively [15]. Emerging data suggest that multimodal interventions can improve postsurgical outcomes for persons with frailty undergoing elective surgeries [3,16,17]. High-risk surgical candidates with frailty should have exploration of their health care priorities, postsurgical goals, and care preferences to avoid potentially deleterious postoperative outcomes [18]. Clarification of goals of care in the context of surgical risk and expected clinical outcomes, termed “surgical pause,” increases receipt of goal-concordant care and avoids unwanted surgery [19]. Thus, adequately and accurately identifying level of functional ability, cognition, and ultimately frailty of preoperative persons is important for unbiased care planning and resource allocation.

However, disuse or incorrect use of frailty screening tools can contribute to misclassification of frailty, potentially limiting access to interventions and significantly impacting quality of life and function. Elective TJA is rarely lifesaving but significantly impacts functional ability and preservation of independence [20]. Without consistent use of validated tools to screen for frailty, ageism and other implicit biases may contribute to overclassification of frailty by health care professionals and increase their reluctance to offer therapies simply based on biological age or “old” appearance [21]. Alternatively, concerns about surgical candidacy, unaddressed pain, and further loss of function may contribute to social desirability and response biases that encourage underclassification of frailty by participants who are reluctant to report functional or other limitations when responding to provider questions assessing for presurgical frailty [22,23]. Similar to responses to sensitive questions, where perceptions of anonymity and privacy increase the accuracy of self-reported answers, written responses to questions on performance of ADLs may be more accurate than verbal responses to providers, especially during the first encounter when participants have not yet built rapport with their providers [24,25].

In addition, the lived experiences of older adults and their perception of health may influence frailty classification and related health outcomes [26]. The person’s perception of decline in one domain (eg, performance of ADLs) may affect performance in other domains (eg, decline in appetite or memory) with a cumulative effect on level of frailty [26]. Therefore, the participants’ responses could be considered a more accurate reflection of subjective symptoms or functional ability, as they represent the individuals’ perceptions of their health.

When participants respond to the same questions without provider oversight, the effect of these biases may be minimized, and the accuracy of the screening tool might improve.

Limitations

Our evaluation was limited to a small population of mainly English-speaking men with low concern for cognitive impairment within 1 VHA orthopedic surgery clinic which may not relate to other presurgical populations (eg, peripheral vascular surgery or general surgery) with different prevalences of frailty and cognitive impairment. In addition, worsening joint-specific function and health-related quality of life with longer wait times before TJA or surgical intervention between provider and patient-completed RAI-C can influence participants’ responses. Therefore, we attempted to mitigate possible confounding effects of prolonged wait times before surgery by excluding participant-completed RAI-C results that were completed more than 180 days from provider-completed surveys. We attempted to mitigate the effect of surgery on patient-completed RAI-C by excluding those participants who underwent surgery before completing the self-reported RAI-C. Nonetheless, our study was strengthened by the high participant response rate of more than 40%. In most cases of disagreement (ie, cognition and limitations in ADLs), participants’ responses resulted in a higher frailty classification, which could not be verified for accuracy. Furthermore, we could not assess for the role of selection bias on our findings. It is possible that self-reported responses to the RAI-C were predominantly completed and returned by participants who disagreed with provider-completed responses to the RAI-C. Finally, participant completion of the RAI-C relies on the ability to read and understand the questions. We were unable to assess the effects of health literacy or educational level on assessment disagreements.

Conclusions

Frailty screening with the RAI-C can be done by providers or patients before elective orthopedic TJA. The level of disagreement observed between provider-completed and patient-completed assessments suggests that these methods are not interchangeable. Future studies exploring screening methods in larger, more diverse populations who are undergoing a variety of surgeries may clarify challenges to screening accuracy and validity of patient-completed screening approaches.

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Authors' Contributions

MK, AT, and KR contributed to the concept and design of the project; MK and KR took the lead in drafting the manuscript; and MK and KB conducted the data analysis. All authors provided critical feedback and helped shape this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Frailty classification based on provider-completed versus patient-completed RAI-C scores (N=20). RAI-C: Clinical Risk Analysis Index.
[PNG File , 51 KB - periop_v8i1e66440_app1.png]

References

1. Shinall MC, Arya S, Youk A, Varley P, Shah R, Massarweh NN, et al. Association of preoperative patient frailty and operative stress with postoperative mortality. JAMA Surg 2020;155(1):e194620 [FREE Full text] [doi: 10.1001/jamasurg.2019.4620] [Medline: 31721994]
2. Hall DE, Arya S, Schmid KK, Carlson MA, Lavedan P, Bailey TL, et al. Association of a frailty screening initiative with postoperative survival at 30, 180, and 365 Days. JAMA Surg 2017;152(3):233-240 [FREE Full text] [doi: 10.1001/jamasurg.2016.4219] [Medline: 27902826]
3. Hall DE, Youk A, Allsup K, Kennedy K, Byard TD, Dhupar R, et al. Preoperative rehabilitation is feasible in the weeks prior to surgery and significantly improves functional performance. J Frailty Aging 2023;12(4):267-276 [FREE Full text] [doi: 10.14283/jfa.2022.42] [Medline: 38008976]
4. Nidadavolu LS, Ehrlich AL, Sieber FE, Oh ES. Preoperative evaluation of the frail patient. Anesth Analg 2020;130(6):1493-1503 [FREE Full text] [doi: 10.1213/ANE.0000000000004735] [Medline: 32384339]
5. Arya S, Varley P, Youk A, Borrebach JD, Perez S, Massarweh NN, et al. Recalibration and external validation of the risk analysis index: a surgical frailty assessment tool. Ann Surg 2020;272(6):996-1005 [FREE Full text] [doi: 10.1097/SLA.0000000000003276] [Medline: 30907757]
6. Hall DE, Arya S, Schmid KK, Blaser C, Carlson MA, Bailey TL, et al. Development and initial validation of the risk analysis index for measuring frailty in surgical populations. JAMA Surg 2017;152(2):175-182 [FREE Full text] [doi: 10.1001/jamasurg.2016.4202] [Medline: 27893030]
7. Shah R, Borrebach JD, Hodges JC, Varley PR, Wisniewski MK, Shinall MC, et al. Validation of the risk analysis index for evaluating frailty in ambulatory patients. J Am Geriatr Soc 2020;68(8):1818-1824 [FREE Full text] [doi: 10.1111/jgs.16453] [Medline: 32310317]
8. George EL, Hall DE, Youk A, Chen R, Kashikar A, Trickey AW, et al. Association between patient frailty and postoperative mortality across multiple noncardiac surgical specialties. JAMA Surg 2021;156(1):e205152 [FREE Full text] [doi: 10.1001/jamasurg.2020.5152] [Medline: 33206156]
9. The surgical pause practice adopted as national program. US Department of Veterans Affairs. 2024 Feb 13. URL: https://www.hsrd.research.va.gov/impacts/surgical-pause.cfm [accessed 2024-07-13]
10. Borson S, Scanlan JM, Chen P, Ganguli M. The mini-cog as a screen for dementia: validation in a population-based sample. J Am Geriatr Soc 2003;51(10):1451-1454 [FREE Full text] [doi: 10.1046/j.1532-5415.2003.51465.x] [Medline: 14511167]
11. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The mini-cog: a cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. Int J Geriatr Psychiatry 2000;15(11):1021-1027. [doi: 10.1002/1099-1166(200011)15:11<1021::aid-gps234>3.0.co;2-6] [Medline: 11113982]
12. Bayram JM, Wickramasinghe NR, Scott CEH, Clement ND. Clinical frailty is independently associated with joint-specific function and health-related quality of life in patients awaiting a total hip or knee arthroplasty. Bone Jt Open 2023 Apr 7;4(4):241-249. [doi: 10.1302/2633-1462.44.bjo-2023-0020.r1]
13. Shah SP, Penn K, Kaplan SJ, Vrablik M, Jablonowski K, Pham TN, et al. Comparison of bedside screening methods for frailty assessment in older adult trauma patients in the emergency department. Am J Emerg Med 2019;37(1):12-18. [doi: 10.1016/j.ajem.2018.04.028] [Medline: 29728285]
14. Dresden SM, Platts-Mills TF, Kandasamy D, Walden L, Betz ME. Patient versus physician perceptions of frailty: a comparison of clinical frailty scale scores of older adults in the emergency department. Acad Emerg Med 2019;26(9):1089-1092 [FREE Full text] [doi: 10.1111/acem.13825] [Medline: 31265194]

15. Alvarez-Nebreda ML, Bentov N, Urman RD, Setia S, Huang JC, Pfeifer K, et al. Recommendations for preoperative management of frailty from the Society for Perioperative Assessment and Quality Improvement (SPAQI). J Clin Anesth 2018;47:33-42. [doi: 10.1016/j.jclinane.2018.02.011] [Medline: 29550619]
16. Pouwels S, Stokmans RA, Willigendael EM, Nienhuijs SW, Rosman C, van Ramshorst B, et al. Preoperative exercise therapy for elective major abdominal surgery: a systematic review. Int J Surg 2014;12(2):134-140 [FREE Full text] [doi: 10.1016/j.ijsu.2013.11.018] [Medline: 24325942]
17. Cabilan CJ, Hines S, Munday J. The effectiveness of prehabilitation or preoperative exercise for surgical patients: a systematic review. JBI Database System Rev Implement Rep 2015;13(1):146-187. [doi: 10.11124/jbisrir-2015-1885] [Medline: 26447015]
18. Reuben DB, Jennings LA. Putting goal-oriented patient care into practice. J Am Geriatr Soc 2019;67(7):1342-1344 [FREE Full text] [doi: 10.1111/jgs.15885] [Medline: 30882888]
19. Oyekan AA, Lee JY, Hodges JC, Chen SR, Wilson AE, Fourman MS, et al. Increasing quality and frequency of goals-of-care documentation in the highest-risk surgical candidates: one-year results of the surgical pause program. JB JS Open Access 2023;8(2):e22.00107 [FREE Full text] [doi: 10.2106/JBJS.OA.22.00107] [Medline: 37101601]
20. Neuprez A, Neuprez AH, Kaux JF, Kurth W, Daniel C, Thirion T, et al. Total joint replacement improves pain, functional quality of life, and health utilities in patients with late-stage knee and hip osteoarthritis for up to 5 years. Clin Rheumatol 2020;39(3):861-871 [FREE Full text] [doi: 10.1007/s10067-019-04811-y] [Medline: 31720892]
21. Chang ES, Kannoth S, Levy S, Wang SY, Lee JE, Levy BR. Global reach of ageism on older persons' health: a systematic review. PLoS One 2020;15(1):e0220857 [FREE Full text] [doi: 10.1371/journal.pone.0220857] [Medline: 31940338]
22. Bispo JP. Social desirability bias in qualitative health research. Rev Saude Publica 2022;56:101 [FREE Full text] [doi: 10.11606/s1518-8787.2022056004164] [Medline: 36515303]
23. Tay Swee Cheng R, Klainin-Yobas P, Hegney D, Mackey S. Factors relating to perioperative experience of older persons undergoing joint replacement surgery: an integrative literature review. Disabil Rehabil 2015;37(1):9-24. [doi: 10.3109/09638288.2014.906663] [Medline: 24689440]
24. Durant LE, Carey MP. Self-administered questionnaires versus face-to-face interviews in assessing sexual behavior in young women. Arch Sex Behav 2000;29(4):309-322. [doi: 10.1023/a:1001930202526] [Medline: 10948721]
25. Ong AD, Weiss DJ. The Impact of Anonymity on Responses to Sensitive Questions. J Applied Social Pyschol 2006 Jul 31;30(8):1691-1708. [doi: 10.1111/j.1559-1816.2000.tb02462.x]
26. Khalil AH, Gobbens RJJ. What If the clinical and older adults' perspectives about frailty converge? A call for a mixed conceptual model of frailty: a traditional literature review. Healthcare (Basel) 2023;11(24):3174 [FREE Full text] [doi: 10.3390/healthcare11243174] [Medline: 38132064]

Abbreviations

ADLs: activities of daily living
EHR: electronic health record
RAI-C: Clinical Risk Analysis Index
TJA: total joint arthroplasty
VHA: Veterans Health Administration

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Evaluating Large Language Models for Preoperative Patient Education in Superior Capsular Reconstruction: Comparative Study of Claude, GPT, and Gemini

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Abstract

Background: Large language models (LLMs) are revolutionizing natural language processing, increasingly applied in clinical settings to enhance preoperative patient education.

Objective: This study aimed to evaluate the effectiveness and applicability of various LLMs in preoperative patient education by analyzing their responses to superior capsular reconstruction (SCR)–related inquiries.

Methods: In total, 10 sports medicine clinical experts formulated 11 SCR issues and developed preoperative patient education strategies during a webinar, inputting 12 text commands into Claude-3-Opus (Anthropic), GPT-4-Turbo (OpenAI), and Gemini-1.5-Pro (Google DeepMind). A total of 3 experts assessed the language models' responses for correctness, completeness, logic, potential harm, and overall satisfaction, while preoperative education documents were evaluated using DISCERN questionnaire and Patient Education Materials Assessment Tool instruments, and reviewed by 5 postoperative patients for readability and educational value; readability of all responses was also analyzed using the cntext package and py-readability-metrics.

Results: Between July 1 and August 17, 2024, sports medicine experts and patients evaluated 33 responses and 3 preoperative patient education documents generated by 3 language models regarding SCR surgery. For the 11 query responses, clinicians rated Gemini significantly higher than Claude in all categories (P<.05) and higher than GPT in completeness, risk avoidance, and overall rating (P<.05). For the 3 educational documents, Gemini's Patient Education Materials Assessment Tool score significantly exceeded Claude's (P=.03), and patients rated Gemini's materials superior in all aspects, with significant differences in educational quality versus Claude (P=.02) and overall satisfaction versus both Claude (P<.01) and GPT (P=.01). GPT had significantly higher readability than Claude on 3 R-based metrics (P<.01). Interrater agreement was high among clinicians and fair among patients.

Conclusions: Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro effectively generated readable presurgical education materials but lacked citations and failed to discuss alternative treatments or the risks of forgoing SCR surgery, highlighting the need for expert oversight when using these LLMs in patient education.

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KEYWORDS

superior capsular reconstruction; massive rotator cuff tear; large language models; preoperative patient education; informed consent process

Introduction

Large language models (LLMs) are extensive neural network models based on deep learning [1,2]. These models learn the grammar, semantics, and contextual information of a language by training on vast amounts of textual data, enabling them to perform various natural language processing tasks [1,2]. Due to the powerful text processing, text generation capabilities, and immense knowledge training of LLMs, researchers have begun to continually explore the potential of LLMs in clinical application scenarios, including professional licensing examinations in various countries and regions [3-5], answering public health questions [6,7], analyzing radiological images [8], disease screening [9], disease diagnosis [10], and discipline education [11]. As the versions and functions of LLMs are constantly updated and upgraded, these models have a low usage threshold and are convenient to use. It is particularly important for professionals in various disciplines to assess the accuracy and completeness of LLMs in their respective fields. This assessment not only provides a strong basis for the application of LLMs in various disciplines but also identifies their shortcomings, serving as a warning for nonprofessional users [3,8,10,11].

Superior capsular reconstruction (SCR) was initially proposed by Mihata et al [12] in 2012 as a technique to restore the superior restraint of the humeral head passively, thereby restoring force couples and improving shoulder joint kinematics. Over the past decade, SCR has become one of the commonly used treatment methods for massive and irreparable rotator cuff tears among clinicians [13,14]. However, the surgical techniques for SCR are highly variable [15]. For example, contrary to the results of earlier studies, further research suggests using dermal allograft instead of fascia lata autograft, leading to a current lack of sufficiently effective long-term follow-up data with high levels of evidence [16-18]. Moreover, as SCR is a reconstructive surgery rather than a repair surgery [15], it is challenging to provide patients with a standardized and effective explanation and communication during the preoperative informed consent process. An effective preoperative informed consent process is one of the essential steps in alleviating patients' perioperative anxiety and improving treatment efficacy [19,20].

Rational and effective preoperative patient education is one of the critical components in developing standardized diagnosis and treatment processes for clinical surgery departments [21]. The main difficulty lies in the professional knowledge gap between medical staff and patients [22]. Previous studies have shown that using multimedia as patient education materials can better help patients understand surgical procedures and alleviate perioperative anxiety [23,24]. However, in most cases, doctors still primarily use verbal responses to address patients' individualized questions [25]. This might probably because preparing personalized educational materials and providing oral education requires a significant investment of time and effort, leading to high time and economic costs. Furthermore, there is a vast difference in the sources of medical information accessed by doctors and patients [26]. Doctors primarily obtain medical information from clinical guidelines, research literature, and textbooks, while patients often acquire medical information through simple search engines and social media software, which may contain false and overly embellished content [26-28]. Patients often lack the ability to think independently when faced with this information.

With the development of LLMs in recent years, researchers have discovered that the disciplinary knowledge possessed by these LLMs can pass professional examinations in multiple disciplines [3,10,29]. Their powerful text processing capabilities not only allow them to polish complex text content to enhance readability but also enable them to independently generate text content that is more comprehensive and empathetic compared to health care professionals [6,7,30]. The quality of their answers is also significantly better than the search results from search engines [27,28]. Researchers have also pointed out that when using LLMs as patient education assistive tools, the primary task of doctors is to determine the accuracy of the information and make necessary clarifications [5,31]. Furthermore, researchers believe that LLMs can present information in a way that is understandable to most patients, making them a valuable supplement for orthopedic surgeons in obtaining informed consent and shared decision-making [4,5].

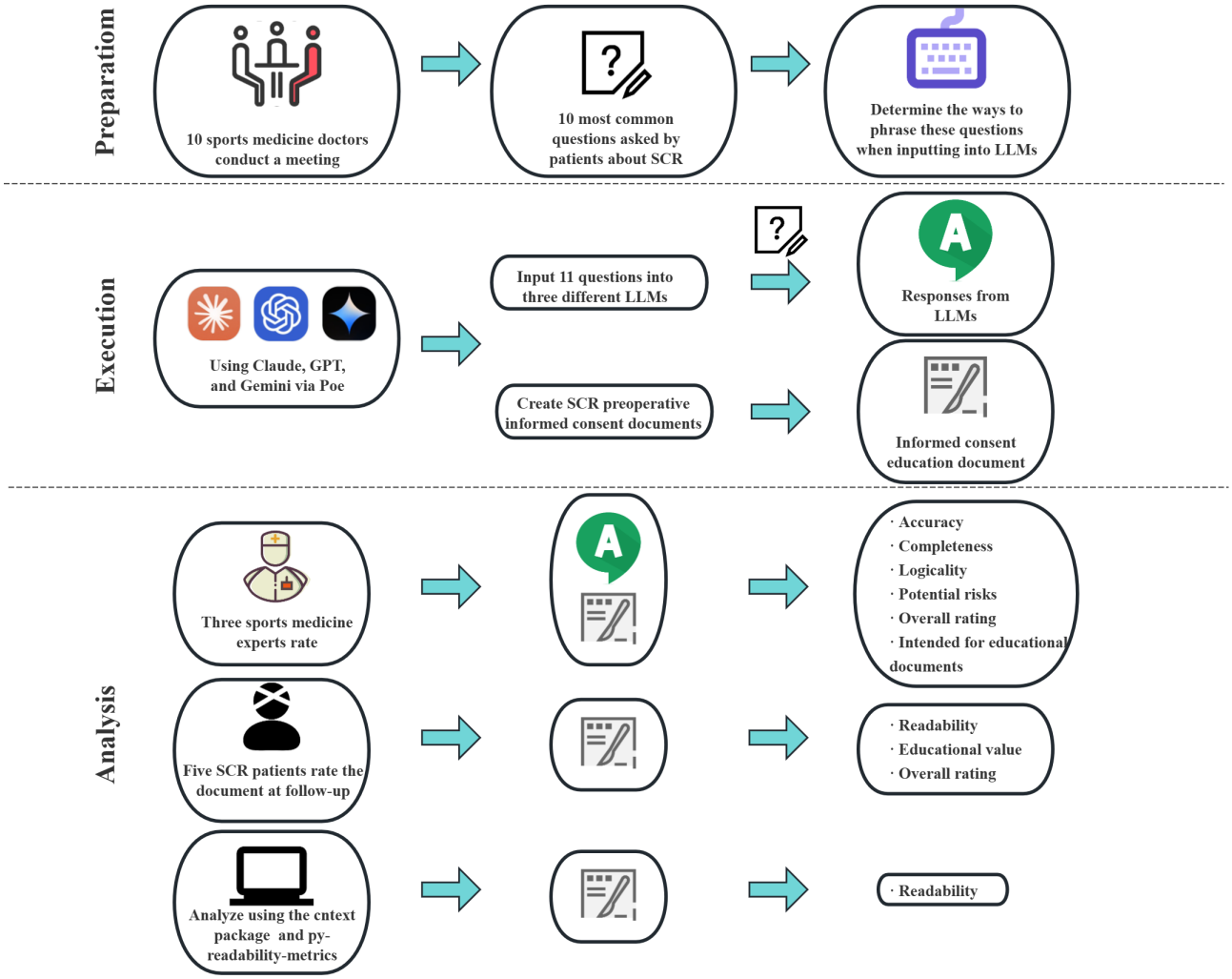
This cross-sectional study aims to assess the capability and application potential of different LLMs in preoperative patient education by evaluating the responses of 3 LLMs—GPT-4-Turbo, Claude-3-Opus, and Gemini-1.5-Pro—to SCR-related patient inquiries. In addition, the study will evaluate patient education documents generated by the LLMs for the informed consent process, which will be jointly assessed by health care professionals and patients. We hypothesize that LLMs can generate readable patient education materials for SCR, but the accuracy, completeness, and patient-assessed readability of the content will require expert review before clinical application.

Methods

Study Design Overview

This cross-sectional analysis, conducted from July 1 to August 17, 2024, evaluated the quality of responses generated by different LLMs in the context of preoperative patient education for SCR. The study design assessed Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro (accessed via Poe) on their ability to answer SCR-related patient questions and generate educational materials. The specific study flow is shown in Figure 1. All LLM prompts and responses, as well as expert and patient evaluations, were conducted in Chinese. Screenshots of Poe website operations are available in Mendeley (Mendeley Data, V1), with English translations generated by GPT-4-Turbo (via Poe) in Multimedia Appendix 1.

Figure 1. Flow diagram of the study process. LLM: large language model; SCR: superior capsular reconstruction.



Ethical Considerations

This study was approved by the Ethics Committee of our organization and was eligible for exemption from ethical review considering that this cross-sectional study involved no interventions or potential risks to patients.

Questions and Prompts Development

The research team for this study consists of 12 members, including 10 experienced sports medicine clinicians and 2 doctoral students specializing in LLMs, who collaborated to create patient education materials about SCR. The clinicians include 3 senior-level experts (2 of whom are subject matter experts from external institutions), 2 associate senior-level experts, and 5 intermediate-level experts, with each clinician having at least 5 years of clinical experience.

The 2 doctoral students first collected a total of 100 questions by having each of the 10 clinical experts propose 10 questions daily that patients frequently asked about SCR, covering aspects like etiology, treatment principles, methods, complications, rehabilitation, and hospitalization costs. After removing duplicates and combining some of the questions, they included only the effective questions that all experts agreed were meaningful. This process resulted in the inclusion of 11 questions. Along with these questions, the doctoral students provided instructions (Table 1) requiring LLMs to draft a standardized preoperative informed consent patient education document. After the drafted prompts were reviewed and approved by the aforementioned 10 clinical experts, doctoral students created standardized prompts for each question, consisting of unified “Background+ Question” formats (Table 1). These standardized prompts were then used to generate a comprehensive patient education document addressing most concerns of SCR patients using LLMs.

Table . Content and strategies for asking questions to large language models.

Subject	Theme	Content
Background	Clinical case	The patient was diagnosed with a massive rotator cuff tear due to supraspinatus muscle injury. The doctor plans to perform a superior capsular reconstruction surgery on the shoulder joint.
Question 1	Muscle injury	The imaging report says that I have a supraspinatus muscle injury. What is the supraspinatus muscle, and what causes this type of injury?
Question 2	Surgical principles and indications	What is the reconstruction of the superior capsule of the shoulder joint, what is the therapeutic principle of the surgery, and what are the indications for the surgery?
Question 3	Graft materials	What are the commonly used graft materials in the reconstruction of the superior capsule of the shoulder joint, and what are the differences between these grafts?
Question 4	Surgical hardware	Besides grafts, does the reconstruction of the superior capsule of the shoulder joint require the use of screws, and do these screws need to be removed in a second surgery?
Question 5	Surgical complications	What are the surgical complications of superior capsule reconstruction of the shoulder joint?
Question 6	Recovery time	How long is the typical recovery time after superior capsule reconstruction surgery of the shoulder joint?
Question 7	Healing issues	What situations can lead to poor healing or failure of the superior capsule reconstruction surgery of the shoulder joint?
Question 8	Autograft risks	In superior capsule reconstruction surgery of the shoulder joint, if an autograft is chosen, what are the impacts and risks to the area from which the autologous tissue is harvested?
Question 9	Surgical costs	What are the chargeable items during the superior capsule reconstruction surgery of the shoulder joint, and what surgical consumables are needed?
Question 10	Graft longevity	If the superior capsule reconstruction surgery of the shoulder joint is successful, how long is the lifespan of the implanted graft, and what are the differences between different types of grafts?
Question 11	Anesthesia and hospitalization	What type of anesthesia is required for superior capsule reconstruction surgery, how long does the surgery take, and how long is the hospital stay required?
Document generation request	Education document	Please generate a comprehensive educational document about superior capsule reconstruction surgery of the shoulder joint. This document is to be provided to patients for reading during the preoperative informed consent process.

LLM Selection and Prompt Execution

Both ChatGPT 4 and Claude 3 are among the most popular language models today, with Gemini (formerly known as Bard) also gaining significant traction [32]. Studies suggest potential discrepancies in the functionalities of GPT-4 models used on the OpenAI official website [33]. To mitigate potential systematic errors arising from these discrepancies, we access Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro through the Poe website. Poe, created by Anthropic, is a platform that aggregates multiple AI chatbots, enabling users to engage with different AI assistants within a single interface and compare their responses [34].

To ensure that each interaction is independent and unbiased by previous exchanges, the doctoral students perform a “clear context” operation after each query. This approach ensures that

each question and response are treated independently, preventing information carryover from previous interactions, and is informed by other research [7,11]. Since the purpose of our study was to evaluate the ability of pretrained LLMs to handle new tasks, we used LLMs in Zero-shot mode. Before input, the generated content has no specific setting (ie, suppose you are a doctor or speak like a doctor). The input provided to the LLMs follows a "background+ question/request" format (human message) and the output answers (assistant message) were collected then, ensuring clarity and relevance within each independent interaction.

Evaluation of LLM Response Quality

This study evaluates the quality of patient informed consent documents generated by LLMs from 3 perspectives: physicians' assessment, patients' assessment, and readability analysis.

In total, 3 senior doctors evaluated the LLMs' responses to 11 specific questions related to a specific medical procedure, assessing them for correctness, completeness, logic, and potential harm using a 5-point Likert scale [35]. Physicians also provided an overall satisfaction score using a 10-point Likert scale. In addition, to evaluate the quality of health care information provided by each LLM, 2 validated instruments were also used to assess the generated documents: DISCERN (score ranging from 1=low to 5=high for overall information quality) and the Patient Education Materials Assessment Tool (PEMAT) for printable materials (scores of 0% - 100% for understandability) [6]. The PEMAT assessment tool was able to assess printable and audiovisual understandability, while the DISCERN instrument could review the quality of information for the consumer particularly with a focus on treatment choices in health information.

In total, 5 patients who underwent the specific medical procedure reviewed the LLM-generated patient education documents, rating their readability and educational value on a 5-point Likert scale and overall satisfaction on a 10-point Likert scale. This aimed to assess the documents' clarity and educational value from nonprofessional readers' perspectives.

Finally, a readability analysis of all LLMs' responses was conducted using the cntext package [36] in R (version 4.4.1), examining sentence structure and evaluating readability via 3 indices: readability 1 (average characters per clause), readability 2 (proportion of adverbs and conjunctions), and readability 3, based on the Fog Index and calculated as half the sum of readability 1 and readability 2. Besides, we also applied the "py-readability-metrics" to evaluate the readability, which includes metrics such as the Flesch Reading Ease Score, Flesch-Kincaid Grade Level, and Gunning Fog Index.

Data Analysis

Statistical analysis used SPSS (version 26.0; IBM Corp) using nonparametric tests due to nonnormally distributed data (Kolmogorov-Smirnov test). Mann-Whitney *U* test compared scoring between groups, with significance at $P<.05$. Interrater reliability, assessed using Fleiss kappa value, was interpreted as follows: poor agreement (<0.01); slight agreement (0.01 - 0.20); fair agreement (0.21 - 0.40); moderate agreement (0.41 - 0.60); substantial agreement (0.61 - 0.80); almost perfect agreement (0.81 - 1.00) [7]. GraphPad Prism 8 generated bar charts for visualizing results.

Results

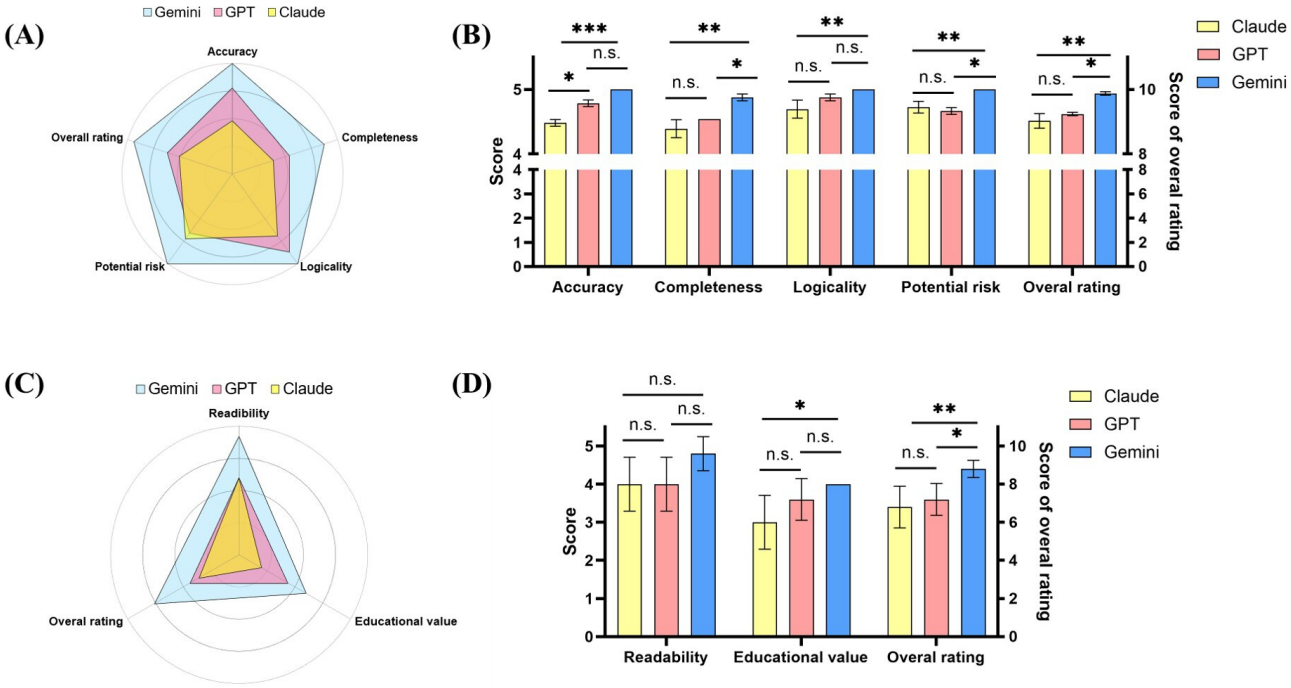
Overview

Between July 1 and July 14, 2024, we sent invitations to sports medicine experts at various hospitals in the South China region for a webinar held on July 18. During this meeting, we discussed 11 key issues and formulated 12 strategies for sending inquiry requests as part of our study. From July 20 to August 1, 2024, we posed 11 surgery-related questions about SCR and requested the creation of preoperative patient education documents through the Poe website to 3 different LLMs: Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro. These models collectively produced 33 responses and 3 preoperative patient education documents. From August 10 to August 17, 2024, three experienced sports medicine clinicians, who are not from the same institution, along with 5 patients who had undergone SCR surgery, evaluated the responses and documents provided by the LLMs.

Evaluations From the Subjective Perspective of Doctors

In total, 3 professional sports medicine doctors first evaluated the responses of 3 different LLMs to 11 inquiries. The evaluations focused on accuracy, completeness, logicality, potential risk, and overall rating. The results showed that Gemini's responses were significantly superior to Claude's in all evaluated categories including accuracy (mean 5.00, SD 0.00 vs mean 4.48, SD 0.83; $P<.001$), completeness (mean 4.88, SD 0.33 vs mean 4.39, SD 0.70; $P=.001$), logicality (mean 5.00, SD 0.00 vs mean 4.70, SD 0.59; $P<.01$) potential risk (mean 5.00, SD 0.00 vs mean 4.73, SD 0.57; $P<.01$), and overall rating (mean 9.88, SD 0.42 vs mean 9.03, SD 1.31; $P=.001$; Figures 2A and 2B). Compared to GPT, Gemini's responses were superior in all categories, with significant differences noted in completeness (mean 4.88, SD 0.33 vs mean 4.55, SD 0.67; $P=.02$), potential risk (mean 5.00, SD 0.00 vs mean 4.67, SD 0.82; $P=.01$), and overall rating (mean 9.88, SD 0.42 vs mean 9.24, SD 1.30; $P=.01$; Figures 2A and 2B. GPT's responses, when compared to Claude's, were superior in accuracy ($P=.03$), completeness ($P=.34$), logicality ($P=.11$), and overall rating ($P=.42$); however, Claude was rated higher in potential risk ($P=.85$; Figures 2A and 2B). Of these differences, only the accuracy presented a statistically significant difference (Figures 2A and 2B).

Figure 2. Quality evaluation results from doctors and patients for 11 questions generated by 3 large language models. (**A-B**) Evaluation from the doctor's perspective; (**C-D**) evaluation from the patient's perspective. n.s. not significant; *P<.05, **P<.01, ***P<.001.



In terms of the PEMAT scores for the preoperative patient education materials generated by each LLM, Gemini scored higher than GPT (mean 1.00, SD 0.00 vs mean 0.91, SD 0.09; P=.12), and GPT scored higher than Claude (mean 0.91, SD 0.09 vs mean 0.79, SD 0.10; P=.18), with only the difference between Gemini and Claude (mean 1.00, SD 0.00 vs mean 0.79, SD 0.10; P=.03) being statistically significant (Figure 3). Regarding the DISCERN scores, Claude achieved the highest overall score, followed by Gemini and then GPT, though these differences were not statistically significant (Table 2). In the item of the DISCERN which represents overall satisfaction (the 16th question presented in Table 2), Gemini scored the highest, while GPT and Claude scored the same, with no statistical significance in the differences. The consistency among the 3 evaluators was high, with no instances of "Poor agreement" or "Slight agreement" in their assessments (Multimedia Appendix 2).

Figure 3. PEMAT scoring percentage for the patient education document generated by three large language models. n.s.: not significant; *P<.05, **P<.01, ***P<.001.

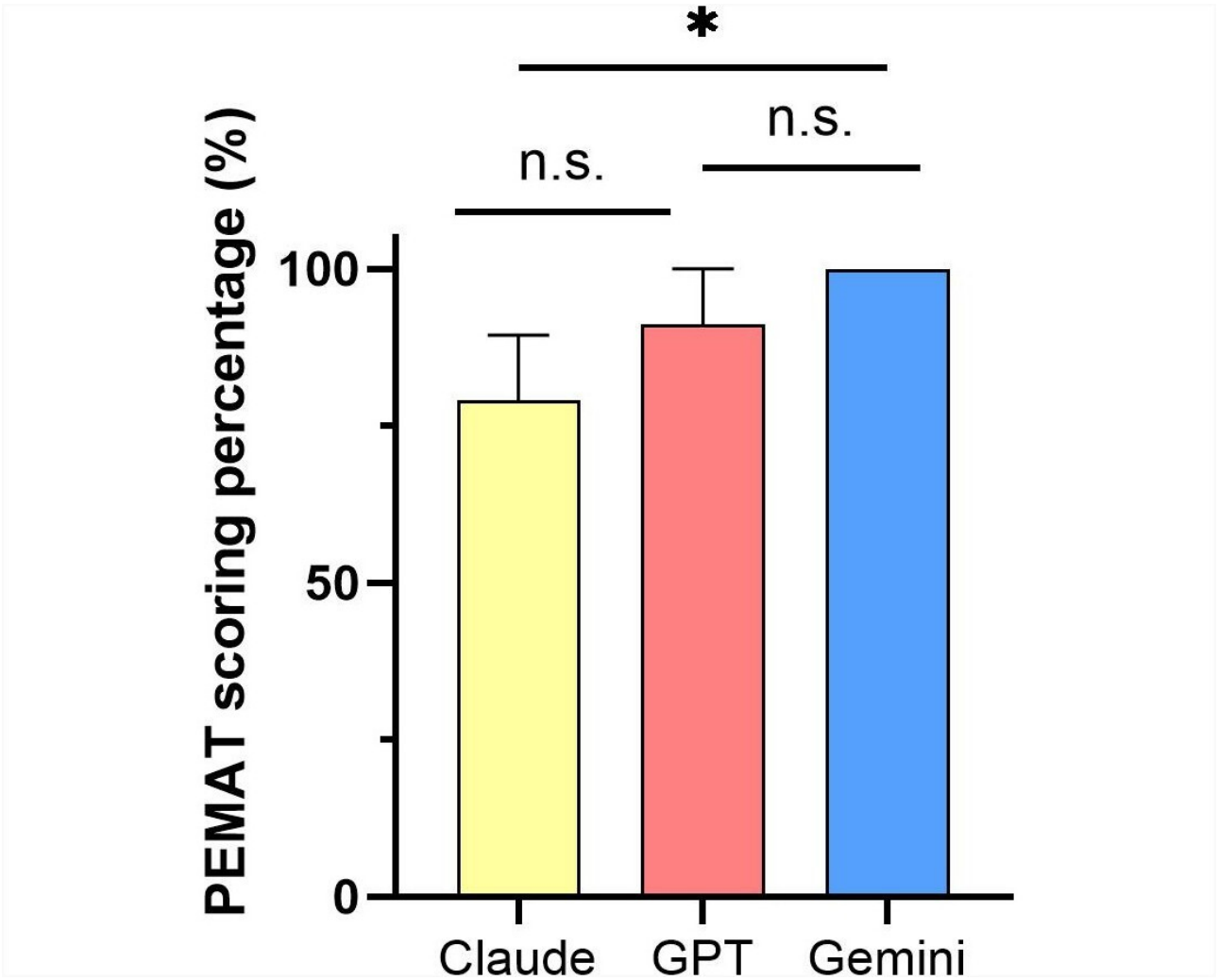


Table . Quality grades for section 2 of the DISCERN Tool.

Section 2. How good is the quality of information on treatment choices ?	Claude-3-Opus, Median (IQR)	GPT-4-Turbo, Median (IQR)	Gemini-1.5-Pro, Median (IQR)	Claude versus GPT, *P* value	Claude versus Gemini, *P* value	GPT versus Gemini, *P* value
Does it describe how each treatment works?	4 (3-4)	4 (3-4)	5 (4-5)	—[a]	.09	.09
Does it describe the benefits of each treatment?	4 (3-5)	4 (3-4)	1 (1-1)	.64	.04	.03
Does it describe the risks of each treatment?	4 (3-4)	3 (2-3)	5 (4-5)	.09	.09	.04
Does it describe what would happen if no treatment is used?	1 (1-1)	1 (1-1)	1 (1-1)	—	—	—
Does it describe how the treatment choices affect overall quality of life?	1 (1-1)	1 (1-1)	1 (1-1)	—	—	—
Is it clear that there may be more than one possible treatment choice?	1 (1-1)	1 (1-1)	1 (1-1)	—	—	—
Does it provide support for shared decision-making?	3 (3-4)	3 (2-3)	3 (2-3)	.32	.20	—
Based on the answers to all of the above questions, rate the overall quality of the publication as a source of information about treatment choices.	3 (3-4)	3 (3-4)	4 (3-4)	—	.46	.46

[a]Not applicable.

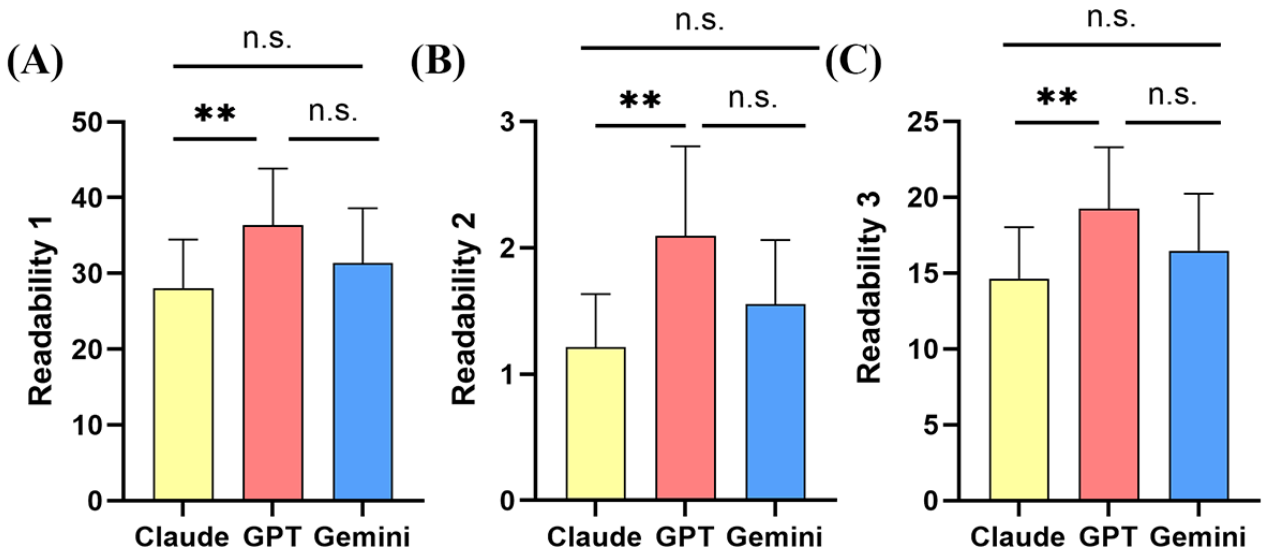
Evaluations From the Subjective Perspective of Patients

In the ratings provided by 5 follow-up patients for the preoperative patient education materials generated by the LLMs, Gemini scored higher than GPT and Claude across all parameters, including readability, educational quality, and overall rating (Figures 2C and 2D). Among these, the difference in educational quality between Gemini and Claude (mean 4.00, SD 0.00 vs mean 3.60, SD 0.55; *P*=.02) was statistically significant (Figures 2C and 2D). Furthermore, Gemini's advantage in overall satisfaction when compared to both Claude (mean 8.80, SD 0.45 vs mean 6.80, SD 1.10; *P*<.01) and GPT (mean 8.80, SD 0.45 vs mean 7.20, SD 0.84; *P*=.01) also showed statistical significance (Figures 2C and 2D). The consistency of all ratings given by the 5 follow-up patients was evaluated as "Fair agreement" (Multimedia Appendix 2).

Objective Evaluations of Readability

Based on the analysis methods of the context package, readability is assessed from 3 perspectives, namely readability 1, readability 2, and readability 3. Under these assessments, GPT's readability is higher than that of Gemini (readability 1: mean 36.38, SD 7.47 vs mean 31.39, SD 7.20, *P*=.18; readability 2: mean 2.09, SD 0.71 vs mean 1.55, SD 0.51, *P*=.09; readability 3: mean 19.24, SD 4.07 vs mean 16.47, SD 3.77, *P*=.17) and Claude (readability 1: mean 36.38, SD 7.47 vs mean 28.05, SD 6.43, *P*<.01; readability 2: mean 2.09, SD 0.71 vs mean 1.21, SD 0.42, *P*<.01; readability 3: mean 19.24, SD 4.07 vs mean 14.63, SD 3.40, *P*<.01), with the difference between GPT and Claude being statistically significant (Figure 4). Although Gemini's readability is higher than Claude's, the difference is not statistically significant (Figure 4). However, when readability was assessed using py-readability metrics, there was no statistical difference between the 3 LLM models (Multimedia Appendix 3).

Figure 4. Comparison of the results of text readability analysis from three analytical perspectives using the cntext package in R software. n.s.: not significant; *P<.05, **P<.01, ***P<.001.



Discussion

Principal Findings

The main findings of our study are as follows: (1) the three LLMs (Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro) demonstrated good overall potential for application in patient education for SCR surgery. They were able to generate answers to 11 SCR-related questions and create standardized preoperative informed consent patient education documents. (2) In the subjective evaluations by professional sports medicine clinicians and patients who had undergone SCR surgery, Gemini slightly outperformed GPT and Claude in multiple dimensions, including accuracy, completeness, logic, potential risks, and overall satisfaction. (3) In this study, the 3 LLMs did not proactively provide evidence sources when answering questions and generating patient education documents. If LLMs are to be used to assist with patient education in clinical applications, it may be necessary to specifically require LLMs to cite information sources to enable doctors and patients to judge the authority and reliability of the content. (4) Although Gemini performed best in the ratings for SCR patient education-related tasks, considering the complexity and potential risks of LLMs in medical applications, clinicians still need to carefully review and make necessary corrections to the content generated by LLMs to ensure the professionalism and reasonableness of patient education materials. LLMs should be positioned as assistive tools rather than decision-making entities in clinical applications.

LLMs have proven to be reliable sources of information for orthopedic surgery-related questions, creating patient education documents that enhance the understanding of diagnostic and therapeutic processes for nonprofessionals and improve the readability of educational materials [28,37,38]. However, evaluating the quality of responses from LLMs is not straightforward. Researchers assessed ChatGPT 3.5's medical knowledge by using clinical standards and licensing examination questions to evaluate its theoretical understanding and practical application [39]. With the advent of ChatGPT 4.0 and the iterative upgrades of various LLMs from different companies, there has been a growing recognition and exploration of the expanded pretraining data and enhanced text processing capabilities of the latest LLM versions in different clinical scenarios [40,41]. Scholars have realized that the quality of LLM responses is influenced by multiple factors, including the amount of information in the query [42], the questioning strategy [43], and many unpredictable elements [44]. These unpredictable elements are evident when, under controlled conditions with all variables constant, the same question yields different answers and shows varying styles of text presentation. Consequently, while researchers have acknowledged the capabilities of LLMs in diagnosing, treating, and creating educational documents across disciplines, they continue to reject the idea of LLMs performing independent medical actions, affirming their role solely as an auxiliary tool in the hands of professionals [45,46].

This study aims to assess the feasibility of using three popular LLMs as auxiliary tools for sports medicine physicians during the informed consent process for patients undergoing SCR. In this study, physicians use LLMs primarily to assess the accuracy and comprehensiveness of the information and to clarify content. Unlike previous studies that evaluated answer readability solely through software analysis of word and sentence structure [4,6,47], this study also included follow-up visits with SCR patients post surgery, where patients subjectively assessed the readability and educational significance of the information. Patient ratings primarily focused on the presurgical educational materials generated by LLMs, excluding the evaluation of 11 specific questions, as the answers to these questions required physician assessment of accuracy and comprehensiveness and clarification before clinical use. Without this step by physicians, patients, who are not medical professionals, might not be able to accurately assess the details of the questions. Although all 3 models performed satisfactorily in evaluating "potential risks," this does not imply that patients can rely on LLMs as their sole source of medical advice. We believe that the SCR medical decision-making process, which does not involve extensive use of medications and auxiliary treatments pre- and post-surgery

and follows a "surgery-rehabilitation" model, does not necessitate the phase-wise, continuous assessments and patient education required for conditions like cancer.

Despite the potential benefits of using LLMs in patient education, several ethical and privacy issues need to be addressed before their widespread application. The accuracy and reliability of the information generated by LLMs are critical, especially in sensitive medical contexts. To enhance their accuracy, strategies such as retrieving pertinent information from credible, external data sources before generating text can be incorporated into subsequent versions of LLMs. And patient privacy is a fundamental concern when using LLMs in medical settings. LLMs may require access to patient data to generate personalized and relevant information. However, this access must be strictly regulated to prevent unauthorized use or disclosure of sensitive patient information.

In addition, our "Prompt Execution" phase revealed that without background information, LLMs occasionally misidentify SCR as a supraspinatus repair surgery under patch bridging, leading to content generation biases. We consider such biases to be system errors caused by human operational mistakes, which can be avoided by adjusting prompt strategies under the guidance of subject matter experts. Therefore, using LLMs for specialist information retrieval is not without its challenges, and we believe that merely relying on LLM-generated disclaimers like "I am not a medical professional; if you feel unwell, please seek medical attention immediately" at the end of responses is insufficient [28]. The mitigation of these errors can be facilitated through the use of techniques such as fine-tuning and retrieval-augmented generation. Fine-tuning entails training the LLM on a smaller, highly specialized dataset that has been meticulously curated to capture the intricate details of the medical domain and retrieval-augmented generation can address issues of hallucinations by first retrieving pertinent information from credible, external data sources before generating text. Incorporating these strategies into subsequent versions of LLMs has the potential to enhance their accuracy and reliability, particularly in sensitive applications such as patient education. A thorough examination would offer valuable insights into refining these models to deliver precise and trustworthy information within medical contexts.

Our study meanwhile discovers critical gaps in LLMs are used in medical settings, particularly in presurgical patient education. LLMs often do not provide sources for their information, and their responses can include inaccuracies or fabricated sources, known as "hallucinations" [48]. This issue is exacerbated when users do not specifically ask for sources, leading LLMs to sometimes provide outdated or irrelevant information [48,49]. Furthermore, the LLMs in the study failed to discuss alternative treatments, benefits, and risks associated with not undergoing specific surgeries like SCR. This omission is significant as discussing these elements is essential for informed medical decision-making and respects patient rights to understand all available options. Given these limitations, LLMs should not independently manage diagnosis or patient education. Instead, they should serve as supplementary tools, aiding health care professionals who can provide the necessary context, accuracy, and depth in patient interactions. This approach ensures that patient education remains thorough, accurate, and ethically conducted, aligning with medical standards and patient rights. This challenge can be tackled through the application of more advanced prompt engineering methodologies, the integration of contextual reasoning capabilities, and the implementation of step-by-step guidance mechanisms. By engaging in multiple iterative interactions with the model, it becomes possible to refine its responses and produce more comprehensive information, encompassing alternative treatment options, based on the specific inputs provided by the user. Such an approach would empower the LLM to deliver content that is more personalized, well-informed, and balanced. Moreover, the development of LLM-Agents offers a compelling solution to the limitations of LLMs in sensitive domains like medical decision-making. By integrating planning, memory, tool use, and agent or brain components, these agents can enhance their ability to provide accurate, verified information. This not only supports human expertise but also ensures that the information presented is transparent and evidence-backed. As research continues, the full potential of integrating citation capabilities within LLM-Agents should be explored to further improve their reliability and trustworthiness in high-stakes contexts.

With the evolution of internet technology, we have witnessed a transition from Web1.0 to Web2.0, and the ways we access information have dramatically changed—from relying on traditional media to accessing massive amounts of information anytime and anywhere via the internet, social media, and personal media platforms [50,51]. Particularly on social media and personal media platforms, we can find questions similar to our own and the corresponding responses [6,50,51]. However, the accuracy and comprehensiveness of information obtained in this manner can be uncertain [51]. Online responses vary greatly in quality, lacking systematic organization and authority, and the response time and outcomes of further inquiries are unpredictable. Studies have shown that answers from ChatGPT 3.5 are not only more comprehensive and empathetic than those from certified physicians on Reddit forums but, despite demonstrating high quality in assessing dementia care issues, they fall slightly short in predicting potential future problems [52,53]. When comparing responses from ChatGPT 4.0, 3.5, and those on Reddit, ChatGPT 4.0's responses significantly surpassed the others, reaching a new level of excellence [54]. In responding to patient inquiries, LLMs also perform more accurately than Google searches and are easier to read [27]. However, they also share a common drawback: the use of LLMs in medical consultations is best accompanied by professional medical personnel to "clarify" the responses [31]. Therefore, LLMs are not suitable for independently handling any part of the diagnostic or treatment process within the medical system, but they are better suited as tools to enhance the efficiency of professional medical personnel or as mediums for personalized patient communication and education [55,56].

As technology continues to advance, hospitals are consistently innovating in all aspects of clinical diagnosis and treatment to enhance diagnostic accuracy, treatment outcomes, and patient satisfaction, representing an unstoppable trend in health care innovation [57,58]. However, balancing standardized processes with personalized patient needs often presents a challenge [59].

LLMs present an opportunity to potentially maintain standardized quality in their responses while also accommodating personalized requests. LLMs, encompassing both free and paid versions, are generally accessible to the public as open platforms [60]. Although current research does not support its use in guiding clinical decisions [61], using ChatGPT in doctor-patient communication benefits both doctors and patients [7]. Doctors can interpret and supplement ChatGPT's responses based on their clinical experience, offering more personalized consultations to patients [31]. In addition, patients reduce their need to search for information on the internet, and their trust in physicians may be enhanced with the objective evidence provided by AI. Under the joint oversight of doctors and patients, the advantages of artificial intelligence can be fully used [62]. Nevertheless, the widespread adoption and application of LLMs still face technical and policy limitations. Technical limitations include differences in handling inputs in various languages [63], performance discrepancies between proprietary and open-source models [64], and the occurrence of "hallucinations" when faced with biased questions [65]. Since commonly used LLMs like GPT, Gemini, and Claude are proprietary, and these models are trained with significantly more data than open-source models, we can only continue to explore ways to avoid "hallucinations" instead of fixing the root cause of such issues [66,67]. In addition, policy restrictions cannot be ignored [68]. Health systems and hospitals need to develop detailed policies to regulate the clinical auxiliary use of LLMs, including ensuring patient informed consent, standardized user training, and the preservation of usage records [7]. Sound policies are essential to ensure the appropriate and efficient use of tools [65,68]. Through these measures, the safety of LLM applications in the medical field can be effectively enhanced, protecting patient rights while improving the efficiency and quality of doctor-patient communication [47,69].

Limitations

This study has several limitations. First, both the linguistic input and the analyzed responses were in Chinese. On one hand, this choice was made to facilitate assessments by Chinese-speaking clinical experts and patients during follow-ups. On the other hand, input in different languages could introduce potential errors and biases. Second, this research only explores the feasibility of using LLMs to generate content related to SCR for patient education. The variability in surgical procedures and specialties could pose distinct challenges in patient education, which means the conclusions drawn from this study cannot be simply generalized to other disciplines. Finally, during the "Prompts Development" phase, it was found that without additional background information, SCRs are prone to be misidentified by LLMs as bridge suture repairs of the supraspinatus muscle. However, since all 3 models used were proprietary, we opted for a "Background+ Question" approach to mitigate this systematic error, without being able to investigate the reasons behind such occurrences.

Conclusions

Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro effectively addressed patient queries and generated readable presurgical education materials. However, they lacked citations and failed to explore alternative treatments, benefits, and potential risks of forgoing SCR surgery. While these LLMs can serve as valuable aids for physicians, they should not be used as standalone tools for patient education without expert oversight to ensure comprehensive and accurate information is provided.

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Data Availability

All data included in this study are available upon request by contact with the corresponding author.

The subjects of this study are LLMs (large language models). Besides being used as operational models, LLMs also serve as tools for translating Chinese content into English, as detailed in Multimedia Appendix 1. The specific types of models used, the websites they are accessed through, and their methods of use are all mentioned in the relevant sections. Beyond these functions, LLMs do not influence the generation of the article's content in any other way.

Authors' Contributions

Conceptualization: WY Gan, H Li, JF Ouyang
Methodology: WY Gan, H Li, JF Ouyang
Supervision: XF Zheng
Visualization: YK Liu
Writing—original draft: WY Gan, H Li, JF Ouyang, YK Liu
Writing—reviewing and editing: WY Gan, H Li, JF Ouyang, YK Liu, ZW Xue, M Wang, HB He, B Song, XF Zheng

Conflicts of Interest

None declared.

Multimedia Appendix 1

All Questions and Answers for Claude-3-Opus, GPT-4-Turbo, and Gemini-1.5-Pro (Use GPT-4-Turbo for Chinese to English translation).
[DOCX File, 71 KB - periop_v8i1e70047_app1.docx]

Multimedia Appendix 2
Table S1: Consistent evaluation of Fleiss kappa among raters.
[DOCX File, 14 KB - periop_v8i1e70047_app2.docx]

Multimedia Appendix 3
Comaprison of readability by py-readability-metrics.
[DOCX File, 19 KB - periop_v8i1e70047_app3.docx]

References

1. Flaharty KA, Hu P, Hanchard SL, et al. Evaluating large language models on medical, lay-language, and self-reported descriptions of genetic conditions. Am J Hum Genet 2024 Sep 5;111(9):1819-1833. [doi: 10.1016/j.ajhg.2024.07.011] [Medline: 39146935]
2. Rengers TA, Thiels CA, Salehinejad H. Academic Surgery in the Era of Large Language Models: A Review. JAMA Surg 2024 Apr 1;159(4):445-450. [doi: 10.1001/jamasurg.2023.6496] [Medline: 38353991]
3. Chow R, Hasan S, Zheng A, et al. The Accuracy of Artificial Intelligence ChatGPT in Oncology Examination Questions. J Am Coll Radiol 2024 Nov;21(11):1800-1804. [doi: 10.1016/j.jacr.2024.07.011] [Medline: 39098369]
4. Eng E, Mowers C, Sachdev D, et al. Chat Generative Pre-Trained Transformer (ChatGPT) – 3.5 Responses Require Advanced Readability for the General Population and May Not Effectively Supplement Patient-Related Information Provided by the Treating Surgeon Regarding Common Questions About Rotator Cuff Repair. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2025 Jan;41(1):42-52. [doi: 10.1016/j.arthro.2024.05.009]
5. Mika AP, Martin JR, Engstrom SM, Polkowski GG, Wilson JM. Assessing ChatGPT Responses to Common Patient Questions Regarding Total Hip Arthroplasty. Journal of Bone and Joint Surgery 2023;105(19):1519-1526. [doi: 10.2106/JBJS.23.00209]
6. Pan A, Musheyev D, Bockelman D, Loeb S, Kabarriti AE. Assessment of Artificial Intelligence Chatbot Responses to Top Searched Queries About Cancer. JAMA Oncol 2023 Oct 1;9(10):1437-1440. [doi: 10.1001/jamaoncol.2023.2947] [Medline: 37615960]
7. Xue Z, Zhang Y, Gan W, Wang H, She G, Zheng X. Quality and Dependability of ChatGPT and DingXiangYuan Forums for Remote Orthopedic Consultations: Comparative Analysis. J Med Internet Res 2024 Mar 14;26:e50882. [doi: 10.2196/50882] [Medline: 38483451]
8. Gertz RJ, Dratsch T, Bunck AC, et al. Potential of GPT-4 for detecting errors in radiology reports: Implications for reporting accuracy. Radiology 2024 Apr;311(1):e232714. [doi: 10.1148/radiol.232714] [Medline: 38625012]
9. Maida M, Ramai D, Mori Y, et al. The role of generative language systems in increasing patient awareness of colon cancer screening. Endoscopy 2025 Mar;57(3):262-268. [doi: 10.1055/a-2388-6084] [Medline: 39142348]
10. Ebel S, Ehrengut C, Denecke T, Gößmann H, Beeskow AB. GPT-4o's competency in answering the simulated written European Board of Interventional Radiology exam compared to a medical student and experts in Germany and its ability to generate exam items on interventional radiology: a descriptive study. J Educ Eval Health Prof 2024;21:21. [doi: 10.3352/jeehp.2024.21.21] [Medline: 39161266]
11. Gan W, Ouyang J, Li H, et al. Integrating ChatGPT in orthopedic education for medical undergraduates: Randomized controlled trial. J Med Internet Res 2024 Aug 20;26:e57037. [doi: 10.2196/57037] [Medline: 39163598]
12. Mihata T, McGarry MH, Pirolo JM, Kinoshita M, Lee TQ. Superior capsule reconstruction to restore superior stability in irreparable rotator cuff tears: a biomechanical cadaveric study. Am J Sports Med 2012 Oct;40(10):2248-2255. [doi: 10.1177/0363546512456195] [Medline: 22886689]
13. E. Cline K, Tibone JE, Ihn H, et al. Superior Capsule Reconstruction Using Fascia Lata Allograft Compared With Double- and Single-Layer Dermal Allograft: A Biomechanical Study. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2021 Apr;37(4):1117-1125. [doi: 10.1016/j.arthro.2020.11.054]
14. Mihata T, Lee TQ, Hasegawa A, et al. Arthroscopic superior capsule reconstruction for irreparable rotator cuff tears: Comparison of clinical outcomes with and without subscapularis tear. Am J Sports Med 2020 Dec;48(14):3429-3438. [doi: 10.1177/0363546520965993] [Medline: 33104385]
15. Claro R, Fonte H. Superior capsular reconstruction: current evidence and limits. EFORT Open Rev 2023 May 9;8(5):340-350. [doi: 10.1530/EOR-23-0027] [Medline: 37158430]
16. Mihata T, Lee TQ, Watanabe C, et al. Clinical results of arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2013 Mar;29(3):459-470. [doi: 10.1016/j.arthro.2012.10.022]

17. Hirahara AM, Andersen WJ, Panero AJ. Superior capsular reconstruction: Clinical outcomes after minimum 2-year follow-up. Am J Orthop (Belle Mead NJ) 2017;46(6):266-278. [Medline: 29309442]
18. Snyder SJ, Arnoczky SP, Bond JL, Dopirak R. Histologic evaluation of a biopsy specimen obtained 3 months after rotator cuff augmentation with GraftJacket Matrix. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2009 Mar;25(3):329-333. [doi: 10.1016/j.arthro.2008.05.023]
19. Edwards PK, Mears SC, Lowry Barnes C. Preoperative education for hip and knee replacement: Never stop learning. Curr Rev Musculoskelet Med 2017 Sep;10(3):356-364. [doi: 10.1007/s12178-017-9417-4] [Medline: 28647838]
20. Alattas SA, Smith T, Bhatti M, Wilson-Nunn D, Donell S. Greater pre-operative anxiety, pain and poorer function predict a worse outcome of a total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 2017 Nov;25(11):3403-3410. [doi: 10.1007/s00167-016-4314-8] [Medline: 27734110]
21. Krebs ED, Hoang SC. Informed consent and shared decision making in the perioperative environment. Clin Colon Rectal Surg 2023 May;36(03):223-228. [doi: 10.1055/s-0043-1761158]
22. Noble PC, Fuller-Lafreniere S, Meftah M, Dwyer MK. Challenges in outcome measurement: Discrepancies between patient and provider definitions of success. Clin Orthop Relat Res 2013;471(11):3437-3445. [doi: 10.1007/s11999-013-3198-x]
23. Villanueva C, Talwar A, Doyle M. Improving informed consent in cardiac surgery by enhancing preoperative education. Patient Educ Couns 2018 Dec;101(12):2047-2053. [doi: 10.1016/j.pec.2018.06.008] [Medline: 29937111]
24. Bollschweiler E, Apitzsch J, Obliers R, et al. Improving informed consent of surgical patients using a multimedia-based program? Results of a prospective randomized multicenter study of patients before cholecystectomy. Ann Surg 2008 Aug;248(2):205-211. [doi: 10.1097/SLA.0b013e318180a3a7] [Medline: 18650629]
25. Sceats LA, Morris AM, Narayan RR, Mezynski A, Woo RK, Yang GP. Lost in translation: Informed consent in the medical mission setting. Surgery 2019 Feb;165(2):438-443. [doi: 10.1016/j.surg.2018.06.010] [Medline: 30061041]
26. Neubauer PD, Tabaee A, Schwam ZG, Francis FK, Manes RP. Patient knowledge and expectations in endoscopic sinus surgery. Int Forum Allergy Rhinol 2016 Sep;6(9):921-925. [doi: 10.1002/alr.21763] [Medline: 27028979]
27. Hristidis V, Ruggiano N, Brown EL, Ganta SRR, Stewart S. ChatGPT vs Google for queries related to dementia and other cognitive decline: Comparison of results. J Med Internet Res 2023 Jul 25;25:e48966. [doi: 10.2196/48966] [Medline: 37490317]
28. Oeding JF, Lu AZ, Mazzucco M, et al. ChatGPT-4 Performs clinical information retrieval tasks using consistently more trustworthy resources than does google search for queries concerning the Latarjet procedure. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2025 Mar;41(3):588-597. [doi: 10.1016/j.arthro.2024.05.025]
29. Nicikowski J, Szczepański M, Miedziaszczyk M, Kudliński B. The potential of ChatGPT in medicine: an example analysis of nephrology specialty exams in Poland. Clin Kidney J 2024 Aug;17(8):sfae193. [doi: 10.1093/ckj/sfae193] [Medline: 39099569]
30. Bernstein IA, Zhang YV, Govil D, et al. Comparison of ophthalmologist and large language model chatbot responses to online patient eye care questions. JAMA Netw Open 2023 Aug 1;6(8):e2330320. [doi: 10.1001/jamanetworkopen.2023.30320] [Medline: 37606922]
31. Li LT, Sinkler MA, Adelstein JM, Voos JE, Calcei JG. Chatgpt responses to common questions about anterior cruciate ligament reconstruction are frequently satisfactory. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2024 Jul;40(7):2058-2066. [doi: 10.1016/j.arthro.2023.12.009]
32. Nwachukwu BU, Varady NH, Allen AA, et al. Currently available large language models do not provide musculoskeletal treatment recommendations that are concordant with evidence-based clinical practice guidelines. Arthroscopy: The Journal of Arthroscopic & Related Surgery 2025 Feb;41(2):263-275. [doi: 10.1016/j.arthro.2024.07.040]
33. Chen L, Zaharia M, Zou J. How is chatgpt's behavior changing over time? . Preprint posted online on Jul 1, 2023 URL: https://ui.adsabs.harvard.edu/abs/2023arXiv230709009C [accessed 2025-06-06]
34. Menz BD, Kuderer NM, Bacchi S, et al. Current safeguards, risk mitigation, and transparency measures of large language models against the generation of health disinformation: repeated cross sectional analysis. BMJ 2024 Mar 20;384:e078538. [doi: 10.1136/bmj-2023-078538] [Medline: 38508682]
35. Yalamanchili A, Sengupta B, Song J, et al. Quality of large language model responses to radiation oncology patient care questions. JAMA Netw Open 2024 Apr 1;7(4):e244630. [doi: 10.1001/jamanetworkopen.2024.4630] [Medline: 38564215]
36. Li HQ, Yang Y, Xue FW, Liu ZY. Annual report readability and trade credit financing: Evidence from China. Research in International Business and Finance 2024 Apr;69:102220. [doi: 10.1016/j.ribaf.2024.102220]
37. Draschl A, Hauer G, Fischerauer SF, et al. Are chatgpt's free-text responses on periprosthetic joint infections of the hip and knee reliable and useful? J Clin Med 2023 Oct 20;12(20):6655. [doi: 10.3390/jcm12206655] [Medline: 37892793]
38. Kaarre J, Feldt R, Keeling LE, et al. Exploring the potential of ChatGPT as a supplementary tool for providing orthopaedic information. Knee surg sports traumatol arthrosc 2023 Nov;31(11):5190-5198. [doi: 10.1007/s00167-023-07529-2]
39. Sumbal A, Sumbal R, Amir A. Can ChatGPT-3.5 pass a medical exam? A systematic review of ChatGPT's performance in academic testing. J Med Educ Curric Dev 2024;11(23821205241238641):23821205241238641. [doi: 10.1177/23821205241238641] [Medline: 38487300]

40. Deng L, Wang T, et al. Evaluation of large language models in breast cancer clinical scenarios: a comparative analysis based on ChatGPT-3.5, ChatGPT-4.0, and Claude2. Int J Surg 2024 Jan;110(4):1941-1950. [doi: 10.1097/JS9.0000000000001066]
41. Jarry Trujillo C, Vela Ulloa J, Escalona Vivas G, et al. Surgeons vs ChatGPT: Assessment and feedback performance based on real surgical scenarios. J Surg Educ 2024 Jul;81(7):960-966. [doi: 10.1016/j.jsurg.2024.03.012] [Medline: 38749814]
42. Zhu L, Mou W, Lai Y, et al. Step into the era of large multimodal models: a pilot study on ChatGPT-4V(ision)'s ability to interpret radiological images. Int J Surg 2024 Jul 1;110(7):4096-4102. [doi: 10.1097/JS9.0000000000001359] [Medline: 38498394]
43. Lim ZW, Pushpanathan K, Yew SME, et al. Benchmarking large language models' performances for myopia care: a comparative analysis of ChatGPT-3.5, ChatGPT-4.0, and Google Bard. EBioMedicine 2023 Sep;95(104770):104770. [doi: 10.1016/j.ebiom.2023.104770] [Medline: 37625267]
44. Chervenak J, Lieman H, Blanco-Breindel M, Jindal S. The promise and peril of using a large language model to obtain clinical information: ChatGPT performs strongly as a fertility counseling tool with limitations. Fertil Steril 2023 Sep;120(3 Pt 2):575-583. [doi: 10.1016/j.fertnstert.2023.05.151] [Medline: 37217092]
45. Thirunavukarasu AJ, Ting DSJ, Elangovan K, Gutierrez L, Tan TF, Ting DSW. Large language models in medicine. Nat Med 2023 Aug;29(8):1930-1940. [doi: 10.1038/s41591-023-02448-8] [Medline: 37460753]
46. Tan S, Xin X, Wu D. ChatGPT in medicine: prospects and challenges: a review article. Int J Surg 2024 Jun 1;110(6):3701-3706. [doi: 10.1097/JS9.0000000000001312] [Medline: 38502861]
47. Haver HL, Gupta AK, Ambinder EB, et al. Evaluating the use of ChatGPT to accurately simplify patient-centered information about breast cancer prevention and screening. Radiol Imaging Cancer 2024 Mar;6(2):e230086. [doi: 10.1148/rycan.230086] [Medline: 38305716]
48. Chelli M, Descamps J, Lavoué V, et al. Hallucination rates and reference accuracy of ChatGPT and Bard for systematic reviews: Comparative analysis. J Med Internet Res 2024 May 22;26:e53164. [doi: 10.2196/53164] [Medline: 38776130]
49. Burnette H, Pabani A, von Itzstein MS, et al. Use of artificial intelligence chatbots in clinical management of immune-related adverse events. J Immunother Cancer 2024 May 30;12(5):38816231. [doi: 10.1136/jitc-2023-008599] [Medline: 38816231]
50. Terrasse M, Gorin M, Sisti D. Social media, e-health, and medical ethics. Hastings Cent Rep 2019 Jan;49(1):24-33. [doi: 10.1002/hast.975] [Medline: 30790306]
51. Ho A, McGrath C, Mattheos N. Social media patient testimonials in implant dentistry: information or misinformation? Clin Oral Implants Res 2017 Jul;28(7):791-800. [doi: 10.1111/clr.12883] [Medline: 27279455]
52. Ayers JW, Poliak A, Dredze M, et al. Comparing physician and artificial intelligence chatbot responses to patient questions posted to a public social media forum. JAMA Intern Med 2023 Jun 1;183(6):589-596. [doi: 10.1001/jamainternmed.2023.1838] [Medline: 37115527]
53. Aguirre A, Hilsabeck R, Smith T, et al. Assessing the quality of chatgpt responses to dementia caregivers' questions: Qualitative analysis. JMIR Aging 2024 May 6;7:e53019. [doi: 10.2196/53019] [Medline: 38722219]
54. Girton MR, Greene DN, Messerlian G, Keren DF, Yu M. ChatGPT vs medical professional: Analyzing responses to laboratory medicine questions on social media. Clin Chem 2024 Sep 3;70(9):1122-1139. [doi: 10.1093/clinchem/hvae093] [Medline: 39013110]
55. La Bella S, Attanasi M, Porreca A, et al. Reliability of a generative artificial intelligence tool for pediatric familial Mediterranean fever: insights from a multicentre expert survey. Pediatr Rheumatol Online J 2024 Aug 23;22(1):78. [doi: 10.1186/s12969-024-01011-0] [Medline: 39180115]
56. Cavnar Helvaci B, Hepsen S, Candemir B, et al. Assessing the accuracy and reliability of ChatGPT's medical responses about thyroid cancer. Int J Med Inform 2024 Nov;191(105593):105593. [doi: 10.1016/j.ijmedinf.2024.105593] [Medline: 39151245]
57. Pallett AC, Nguyen BT, Klein NM, Phippen N, Miller CR, Barnett JC. A randomized controlled trial to determine whether A video presentation improves informed consent for hysterectomy. Am J Obstet Gynecol 2018 Sep;219(3):277. [doi: 10.1016/j.ajog.2018.06.016] [Medline: 29959929]
58. Zhang MH, Haq ZU, Braithwaite EM, Simon NC, Riaz KM. A randomized, controlled trial of video supplementation on the cataract surgery informed consent process. Graefes Arch Clin Exp Ophthalmol 2019 Aug;257(8):1719-1728. [doi: 10.1007/s00417-019-04372-5] [Medline: 31144057]
59. McCollough CH. Standardization versus individualization: how each contributes to managing dose in computed tomography. Health Phys 2013 Nov;105(5):445-453. [doi: 10.1097/HP.0b013e31829db936] [Medline: 24077044]
60. Vaid A, Duong SQ, Lampert J, et al. Local large language models for privacy-preserving accelerated review of historic echocardiogram reports. J Am Med Inform Assoc 2024 Sep 1;31(9):2097-2102. [doi: 10.1093/jamia/ocae085] [Medline: 38687616]
61. Balla Y, Tirunagari S, Windridge D. Machine learning in pediatrics: Evaluating challenges, opportunities, and explainability. Indian Pediatr 2023 May 14. [Medline: 37179470]
62. Yeo YH, Samaan JS, Ng WH, et al. Assessing the performance of ChatGPT in answering questions regarding cirrhosis and hepatocellular carcinoma. Clin Mol Hepatol 2023 Jul;29(3):721-732. [doi: 10.3350/cmh.2023.0089] [Medline: 36946005]

63. Shao CY, Li H, Liu XL, et al. Appropriateness and comprehensiveness of using ChatGPT for perioperative patient education in thoracic surgery in different language contexts: Survey study. Interact J Med Res 2023 Aug 14;12:e46900. [doi: 10.2196/46900] [Medline: 37578819]
64. Sandmann S, Riepenhausen S, Plagwitz L, Varghese J. Systematic analysis of ChatGPT, Google search and Llama 2 for clinical decision support tasks. Nat Commun 2024 Mar 6;15(1):2050. [doi: 10.1038/s41467-024-46411-8] [Medline: 38448475]
65. Rao A, Pang M, Kim J, et al. Assessing the utility of ChatGPT throughout the entire clinical workflow: Development and usability study. J Med Internet Res 2023 Aug 22;25:e48659. [doi: 10.2196/48659] [Medline: 37606976]
66. Masters K. Medical Teacher 's first ChatGPT's referencing hallucinations: Lessons for editors, reviewers, and teachers. Med Teach 2023 Jul 3;45(7):673-675. [doi: 10.1080/0142159X.2023.2208731]
67. Hatem R, Simmons B, Thornton JE. A call to address AI "Hallucinations" and how healthcare professionals can mitigate their risks. Cureus 2023 Sep;15(9):37809168. [doi: 10.7759/cureus.44720]
68. Bukar UA, Sayeed MS, Razak SFA, Yogarayan S, Amodu OA. An integrative decision-making framework to guide policies on regulating ChatGPT usage. PeerJ Comput Sci 2024;10:e1845. [doi: 10.7717/peerj-cs.1845] [Medline: 38440047]
69. Platt J, Nong P, Smiddy R, et al. Public comfort with the use of ChatGPT and expectations for healthcare. J Am Med Inform Assoc 2024 Sep 1;31(9):1976-1982. [doi: 10.1093/jamia/ocae164]

Abbreviations

LLM: large language model
PEMAT: Patient Education Materials Assessment Tool
SCR: superior capsular reconstruction

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