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Corrigenda and Addenda

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

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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

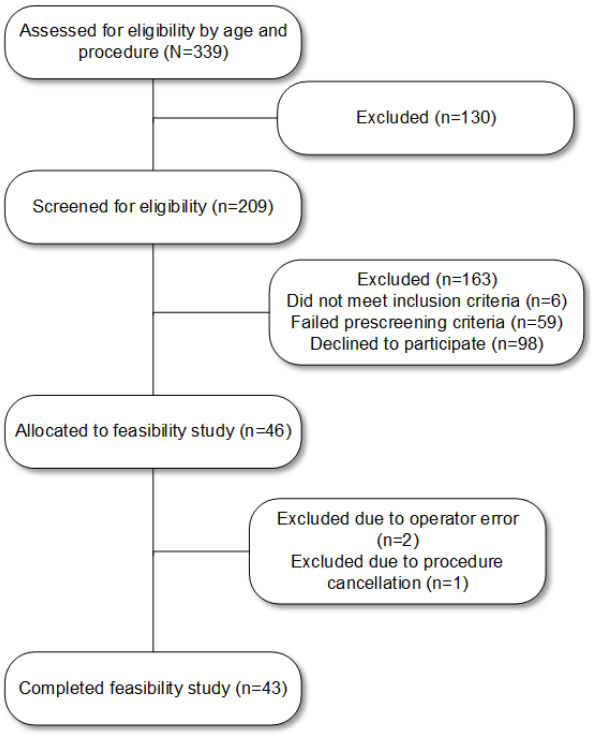
This study was performed in accordance with the principles of the Declaration of Helsinki. Approval was granted by the Yale University Institutional Review Board (IRB#2000033885). Informed consent was obtained from all participants included in the study. All provided data were deidentified prior to analysis 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.

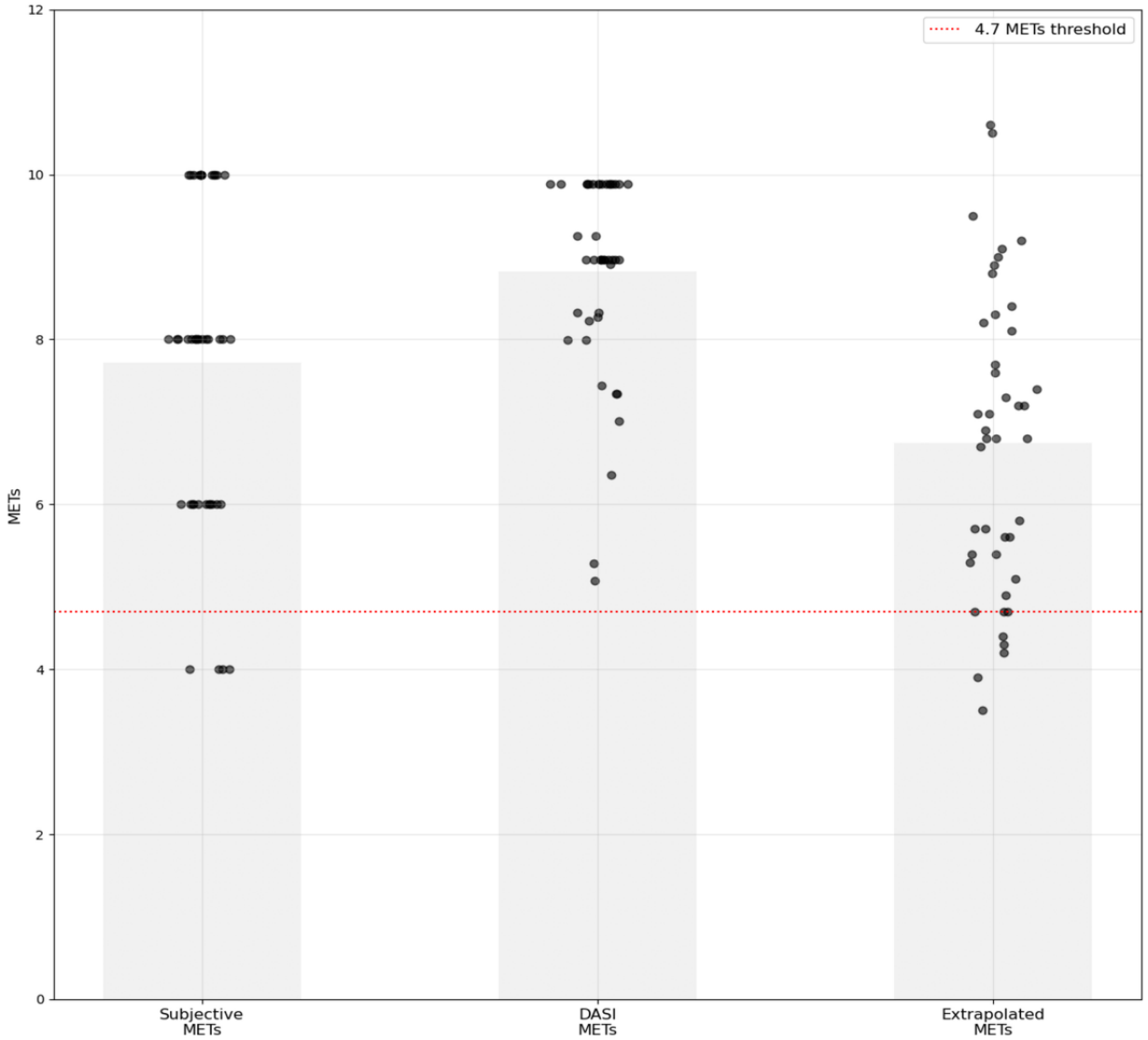
Primary End Points

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]

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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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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

(JMIR Perioper Med 2025;8:e58998) doi:10.2196/58998

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.

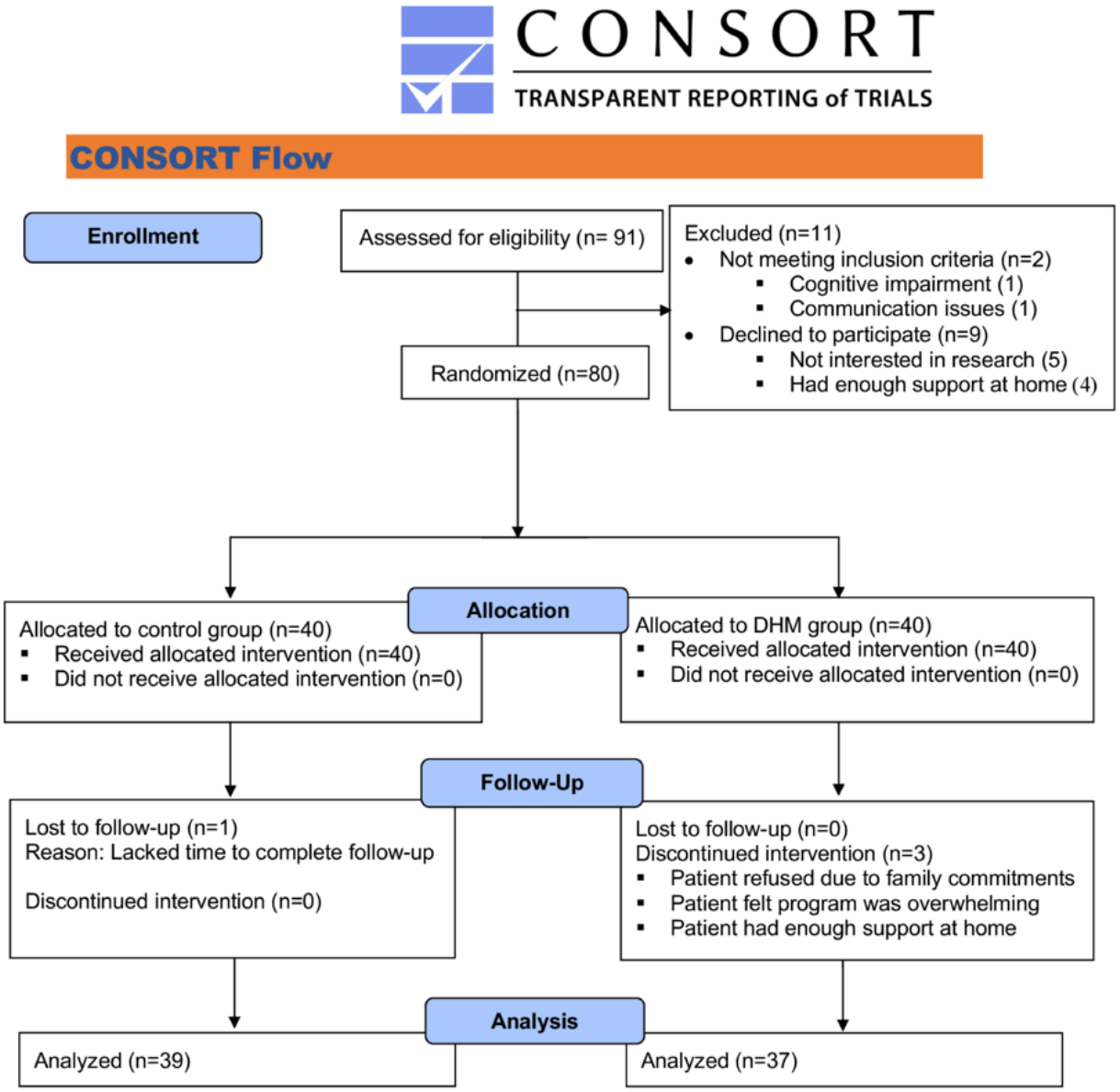


Table 1. Patient demographic and clinical characteristics.

	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.

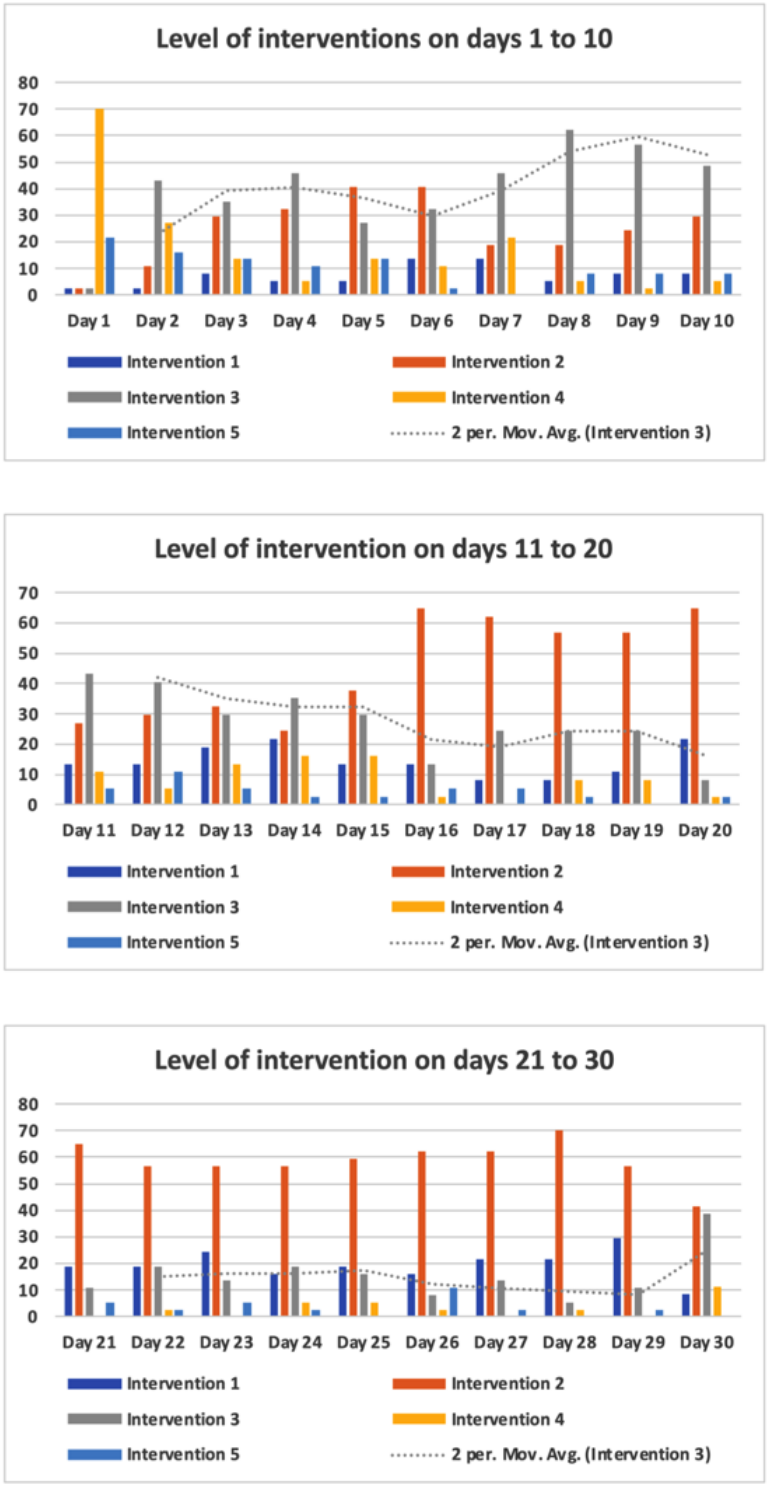
[c]ED: emergency department.

[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.

Acknowledgments

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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]

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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]

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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.

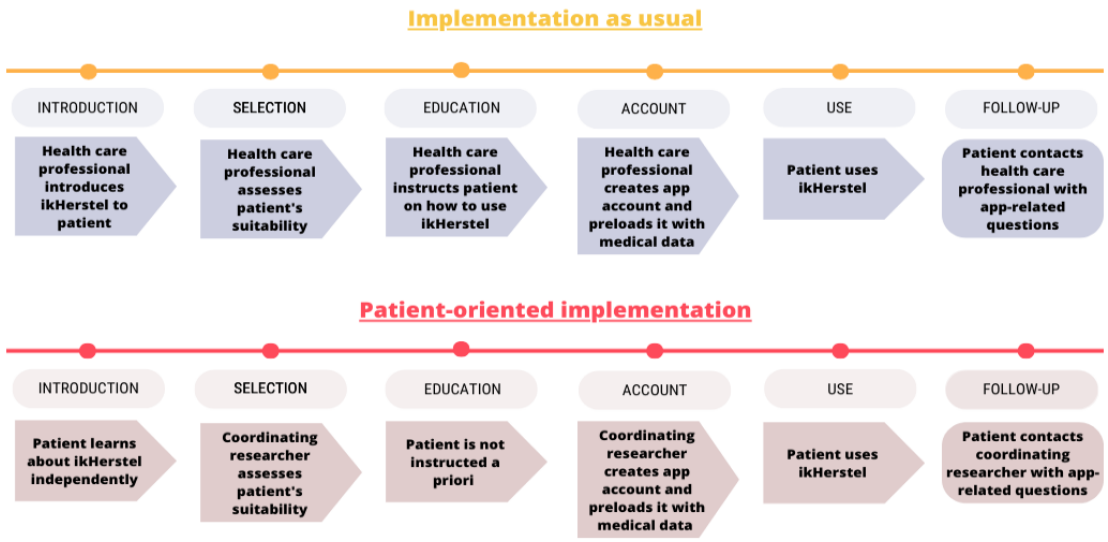

Table 1. Materials used for study recruitment and the frequency of their use, split into hospital-dependent and -independent tools.

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.

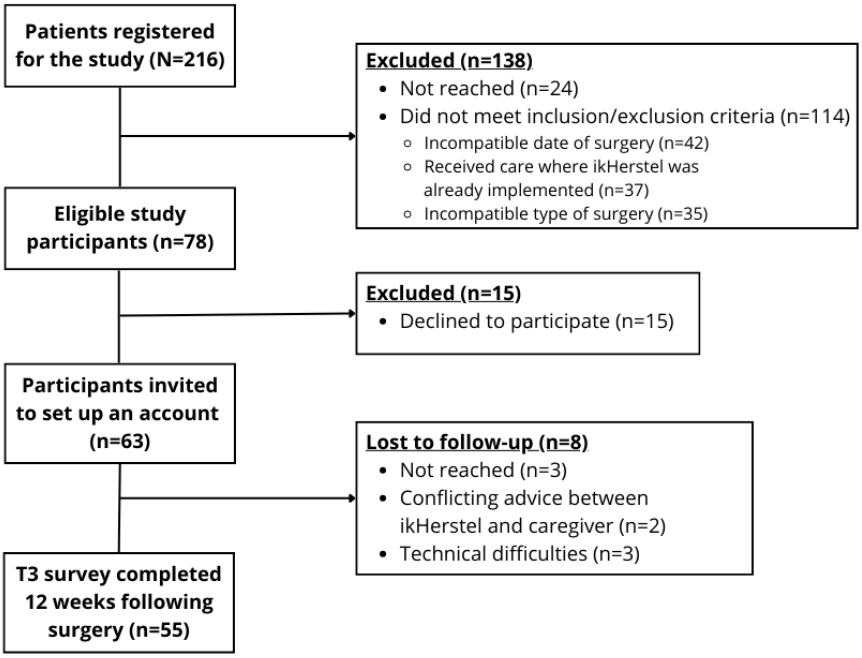

Table 3. Sample characteristics (n=55).

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.

Acknowledgments

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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]

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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.

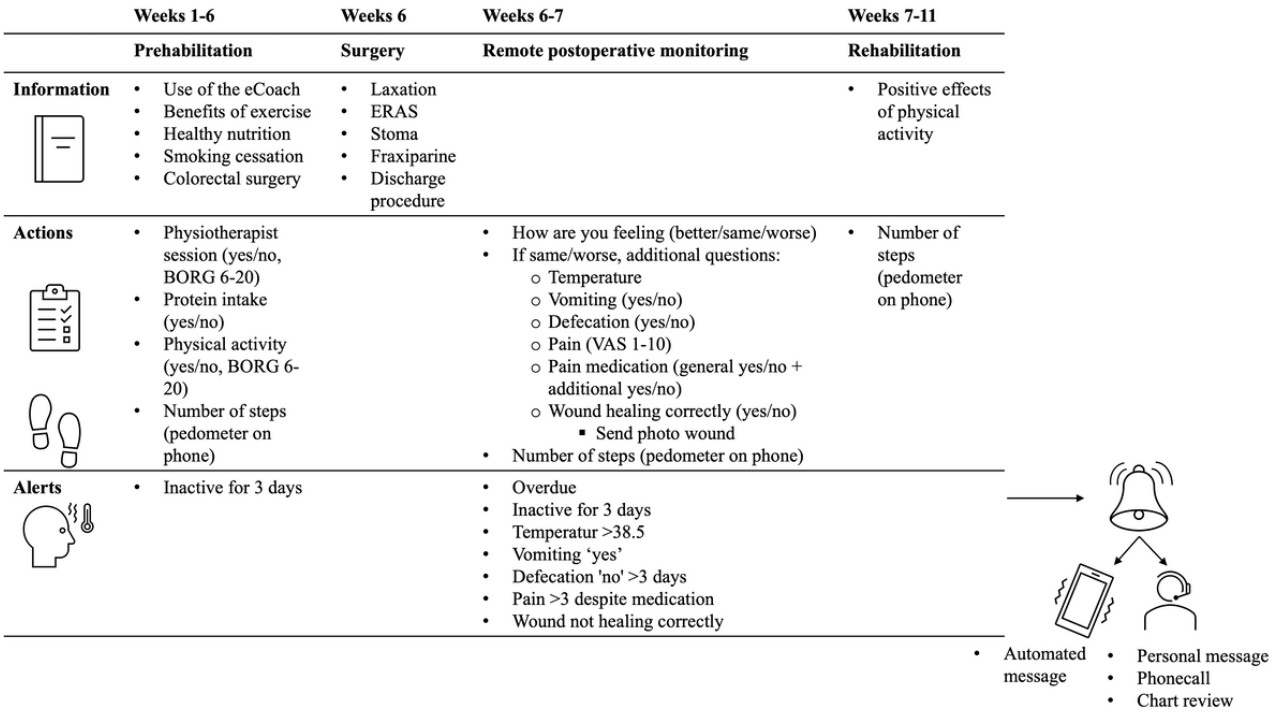
The nurse coordinator checked for eligibility right after the appointment with the surgeon by asking, “do you have a smartphone?” and “are you good at using your smartphone?” Patients were excluded if they were unable to use the app because they did not own a smartphone, did not have web connection, 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

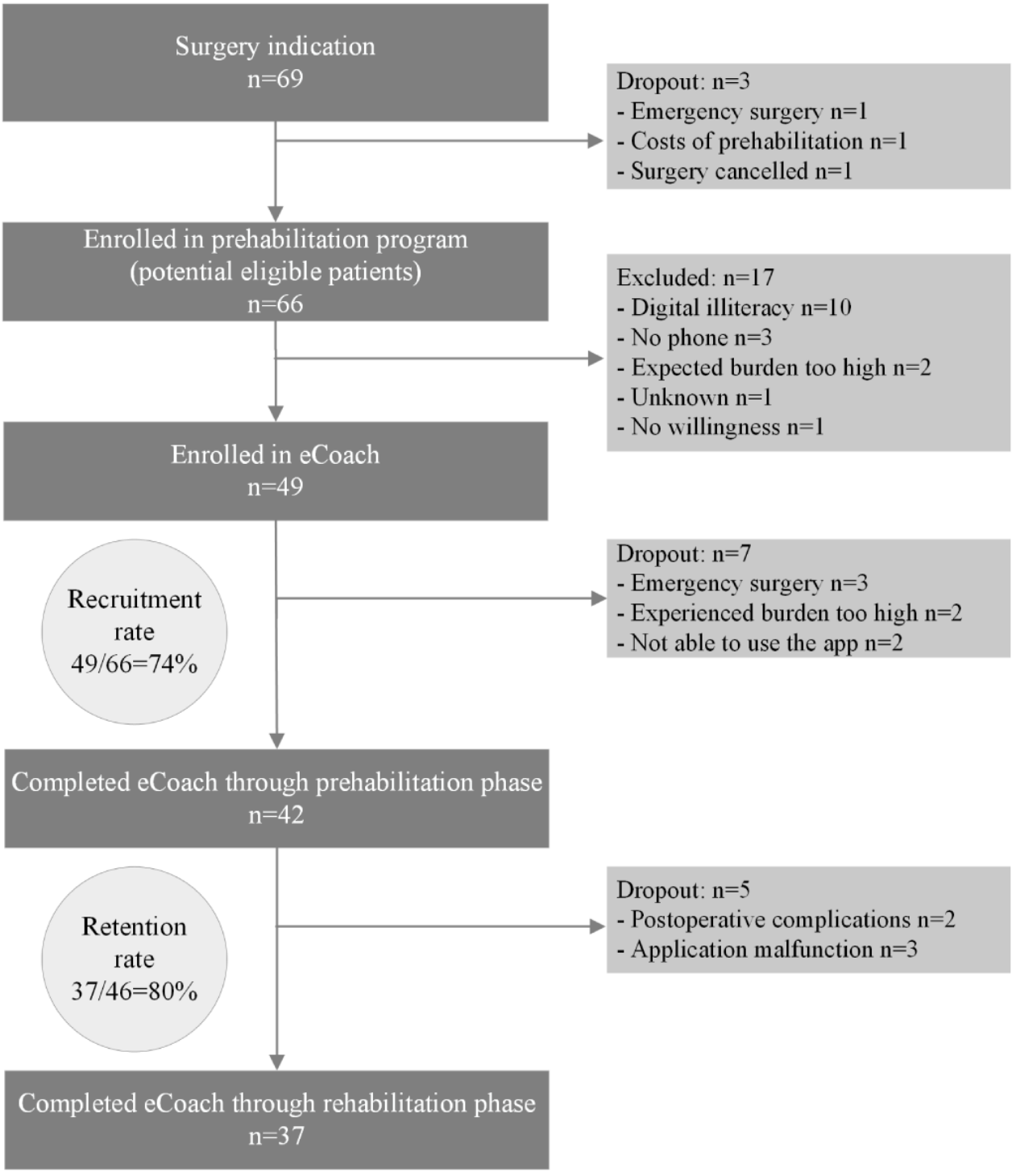
A total of 37 patients completed the study, of which the patient characteristics are shown in Table 1. Median age was 65 (IQR 60-77) years and median Charlson Comorbidity Index score was 5 (IQR 4-6). Four patients experienced minor complications (Clavien Dindo I-II), such as issues with ileostomy production 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

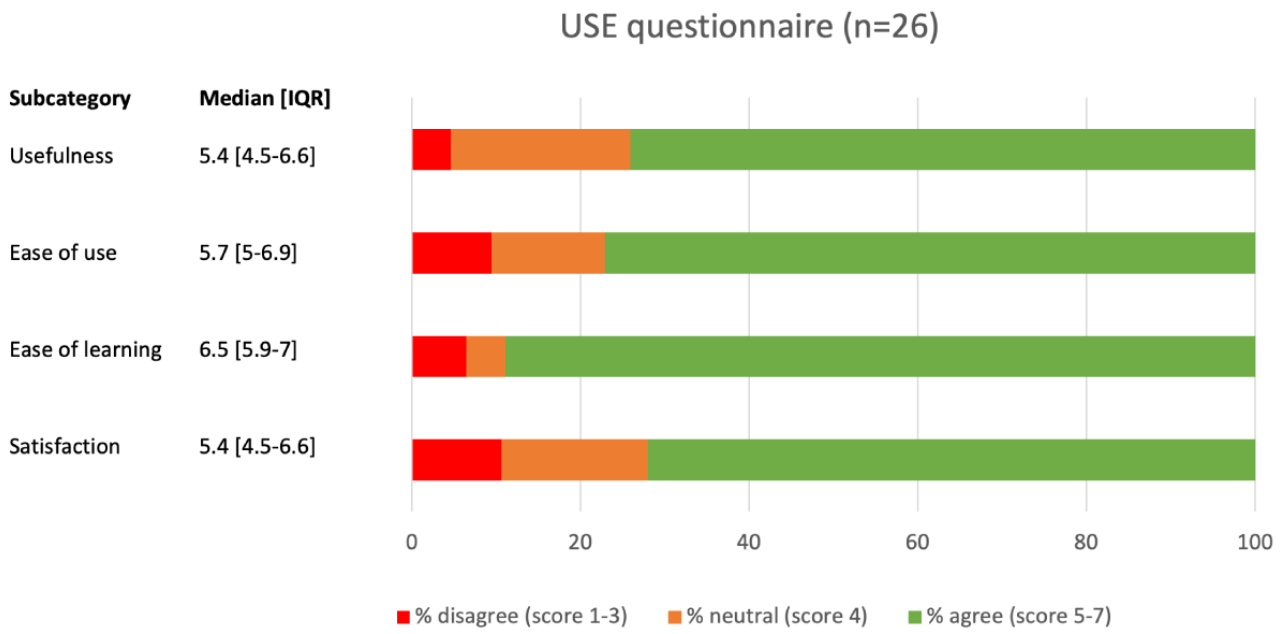
Median compliance was 95% (IQR 82%-96%), preoperative compliance was 92% (IQR 87%-95%), and postoperative compliance was 100% (IQR 100%-100%). Preoperative compliance was highest with 98% (IQR 90%-100%) with "physiotherapist session." Compliance with the number of steps was lowest with 86% (IQR 72%-93%). 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]

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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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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.

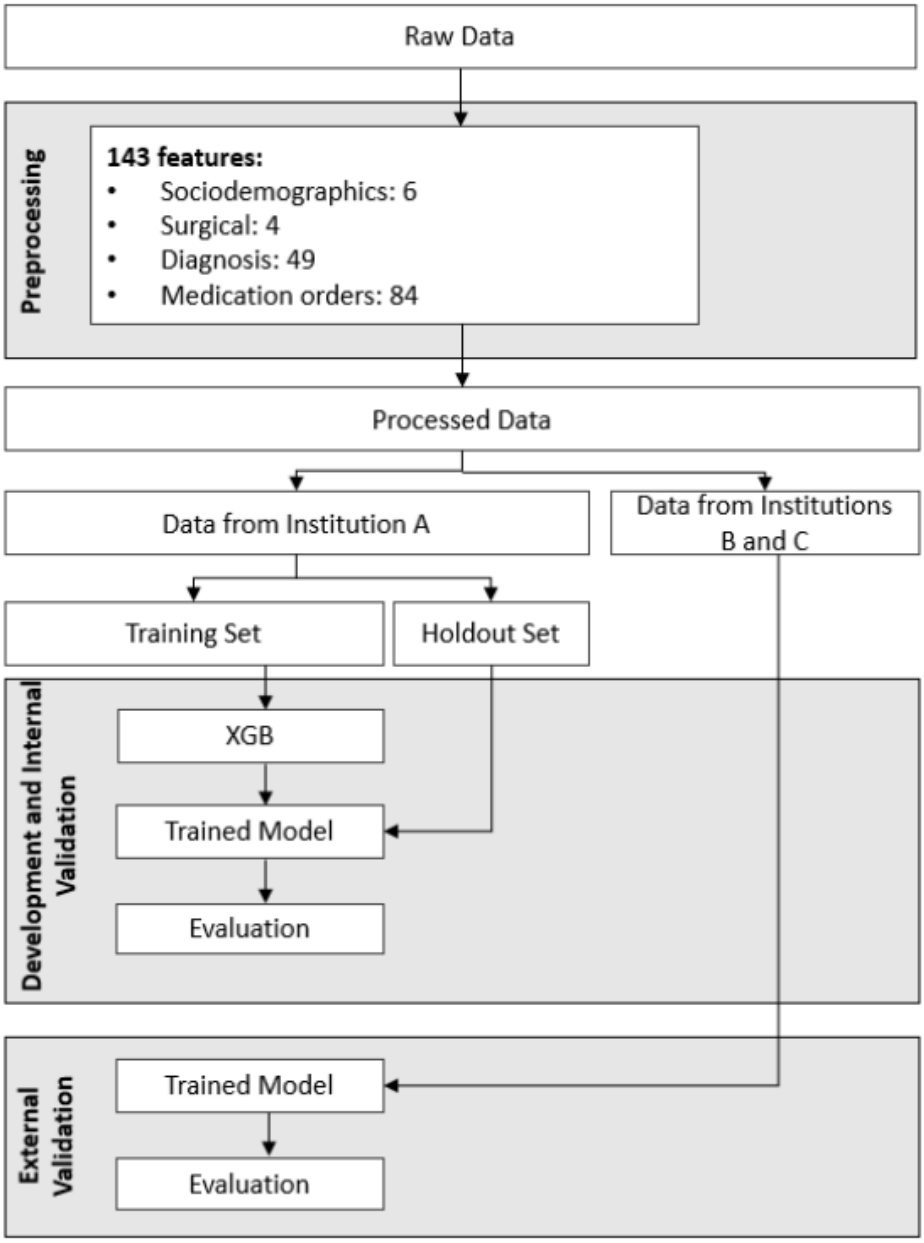
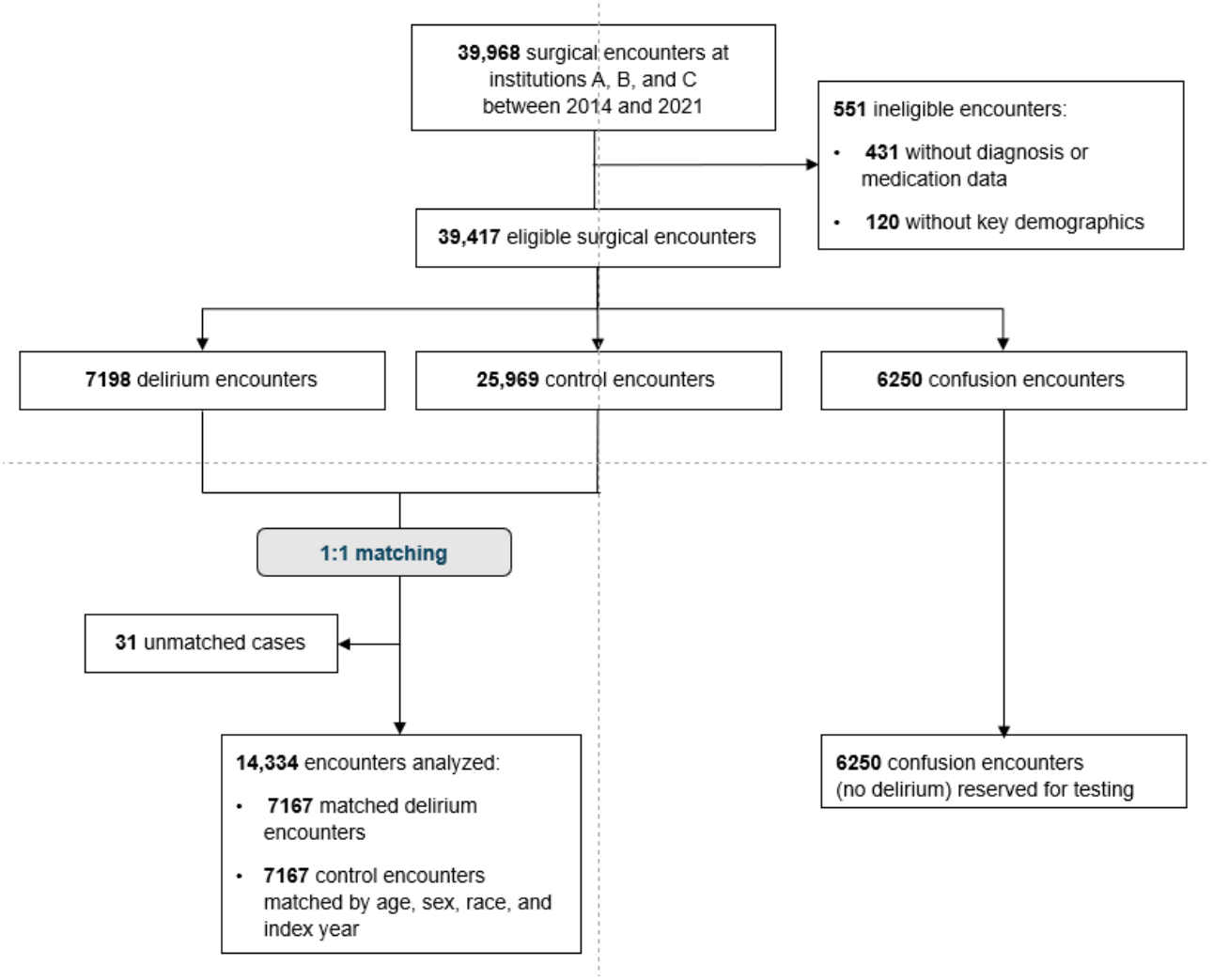


Figure 2. Patient inclusion flow diagram.



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]

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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.

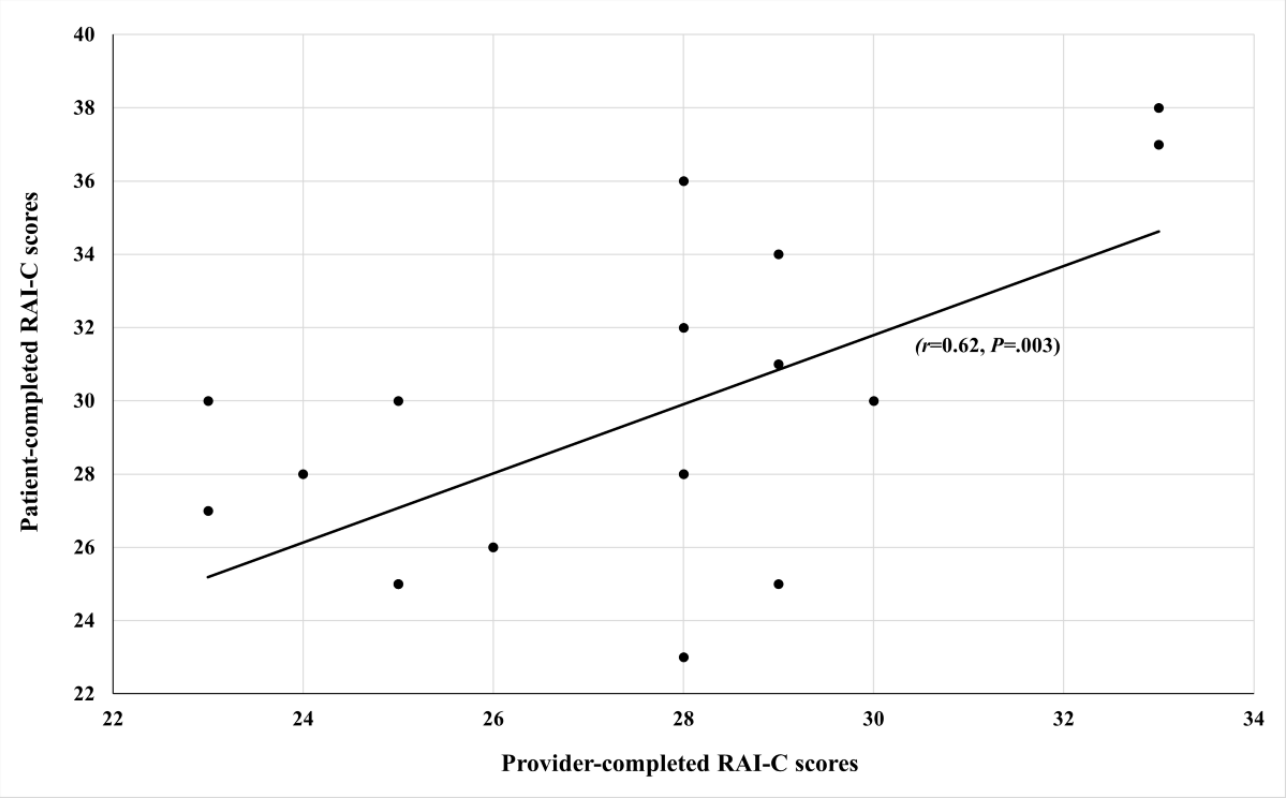
[b]Two participants declined to respond.

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.

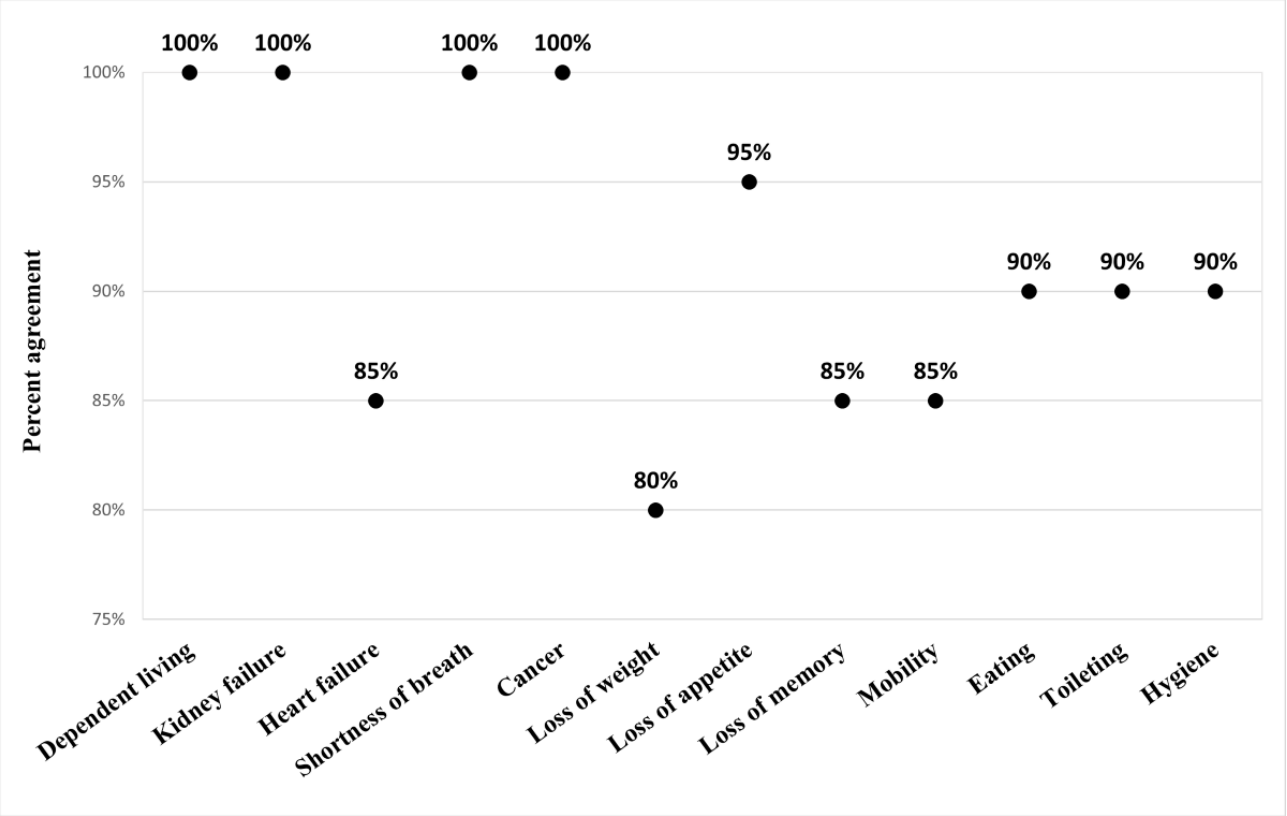
Figure 1. Correlation between provider-completed and patient-completed total RAI-C scores (N=20). RAI-C: Clinical Risk Analysis Index.



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]

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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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