JMIR Perioperative Medicine

Electronic, mobile, digital health approaches in cardiology and for cardiovascular health. Official partner journal of the European Congress on eCardiology and eHealth
Volume 4 (2021), Issue 1 ISSN: 2561-9128 Editor in Chief: Gunther Eysenbach, MD, MPH

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Review

Relationship Between Mobile Digital Sensor Monitoring and Perioperative Outcomes: Systematic Review

Ali Memon[1], BSc; Patrick Lec[2], MD; Andrew Lenis[2], MSc, MD; Vidit Sharma[2], MD; Erika Wood[2], MD; George Schade[1], MD; Wayne Brisbane[2], MD

[1]Department of Urology, University of Washington, Seattle, WA, United States

[2]Department of Urology, University of California, Los Angeles, Los Angeles, CA, United States

Corresponding Author:
Ali Memon, BSc
Department of Urology
University of Washington
1959 NE Pacific St
Seattle, WA, 98195
United States
Phone: 1 425 658 9467
Email: almemon98@gmail.com

Abstract

Background: Monitoring surgical recovery has traditionally been confined to metrics measurable within the hospital and clinic setting. However, commercially available mobile sensors are now capable of extending measurements into a patient's home. As these sensors were developed for nonmedical applications, their clinical role has yet to be established. The aim of this systematic review is to evaluate the relationship between data generated by mobile sensors and postoperative outcomes.

Objective: The objective of this study is to describe the current use of mobile sensors in the perioperative setting and the correlation between their data and clinical outcomes.

Methods: A systematic search of EMBASE, MEDLINE, and Cochrane Library from inception until April 2019 was performed to identify studies of surgical patients monitored with mobile sensors. Sensors were considered if they collected patient metrics such as step count, temperature, or heart rate. Studies were included if patients underwent major surgery (≥1 inpatient postoperative day), patients were monitored using mobile sensors in the perioperative period, and the study reported postoperative outcomes (ie, complications and hospital readmission). For studies including step count, a pooled analysis of the step count per postoperative day was calculated for the complication and noncomplication cohorts using mean and a random-effects linear model. The Grading of Recommendations, Assessment, Development, and Evaluation tool was used to assess study quality.

Results: From 2209 abstracts, we identified 11 studies for review. Reviewed studies consisted of either prospective observational cohorts (n=10) or randomized controlled trials (n=1). Activity monitors were the most widely used sensors (n=10), with an additional study measuring temperature, respiratory rate, and heart rate (n=1). Low step count was associated with worse postoperative outcomes. A median step count of around 1000 steps per postoperative day was associated with adverse surgical outcomes. Within the studies, there was heterogeneity between the type of surgery and type of reported postoperative outcome.

Conclusions: Despite significant heterogeneity in the type of surgery and sensors, low step count was associated with worse postoperative outcomes across surgical specialties. Further studies and standardization are needed to assess the role of mobile sensors in postoperative care, but a threshold of approximately 1000 steps per postoperative day warrants further investigation.

(JMIR Perioper Med 2021;4(1):e21571) doi:10.2196/21571

KEYWORDS

mobile sensors; perioperative; sensor monitoring; perioperative outcomes

Introduction

Of the 234.2 million patients who undergo major surgery every year globally, around 7 million will experience a postoperative complication [1]. These events are difficult for patients and clinicians and costly for hospitals and third-party payers [2]. Enhanced recovery after surgery (ERAS) protocols have reduced complication and readmission rates among various surgical

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specialties [3,4]. ERAS protocols assist patients to return to their preoperative baseline by minimizing opiate analgesia, promoting nutrition, and encouraging early ambulation. This has been shown to speed recovery and avoid hospital-acquired infections and complications [5]. However, these programs rely on interventions within hospitals and clinics and thus fail to extend recovery measurements into a patient's home.

It is now possible to track patient health metrics using commercially available mobile sensors. It may be possible to use these sensors to optimize patient recovery outside of the hospital. Commercial sensors are ubiquitous and relatively inexpensive, with almost 20% of American adults owning one [6]. Among the many options for sensor output, it is unclear which metrics are most clinically useful or hold promise for future research. For example, step count monitors are common and physical activity has been tied to favorable postoperative outcomes [7,8]. However, it is difficult to know exactly how step count modifies variables other than length of stay [9,10] or if length of stay can serve as a surrogate for impending complications [11]. As investigators seek to incorporate mobile sensors into ERAS pathways, there is a need for a synthesized evaluation of how mobile sensor output data correlate to postoperative outcomes.

Synthesizing the current literature may shed light on the validity of employing these devices in future prospective studies and guide efforts to improve perioperative care. While another recent meta-analysis reported the association between perioperative mobile sensor step count and length of stay, no study has compiled data on other important perioperative outcomes, such as 30- and 90-day morbidity and mortality and readmission [7]. Therefore, the aim of this systematic review is to describe the current use of mobile sensors in the perioperative setting and the correlation between their data and clinical outcomes.

Methods

Literature Search

A literature search was performed using MEDLINE, EMBASE, and the Cochrane Library from inception until April 2019 to identify studies of surgical patients monitored with mobile sensors. Searches included whole-field terms without quotations to maximize results. Medical subject headings for the literature search included surgery (subheading), activity tracker, and heart rate. A total of 13 search combinations were used, with "surgery" as the anchor followed by one or more of the following search terms: activity, tracker, fitness, heart, rate, Fitbit, Garmin, Apple Watch, Actigraph, Misfit, Huawei, Moov, Motiv, Sensewear, Omron, and wearable. Two reviewers (AM and WB) independently reviewed abstracts for inclusion and exclusion criteria and identified studies for full-text manuscript review. Manuscript review was performed independently, and disagreements in article selection for qualitative analysis were resolved by discussion or by a third blinded reviewer (GS). Although the literature search was conducted over a year prior to the publication of this systematic review, we believe that it is likely not an issue for the validity of the data, considering that many Cochrane reviews have been found to take similar lengths of time for submission, highlighting the lengthy process associated with submitting a systematic review [12].

Inclusion Criteria

Only studies reporting on major surgery, defined as any surgery requiring a postoperative hospitalization of at least one day, were included. Patients were required to have perioperative measurements with a mobile sensor and correlative clinical outcome measures reported. Any sensor type was included, provided it was mobile and capable of evaluating patients while at home. We did not require any particular reporting mechanism for documenting complications, such as the Clavien-Dindo classification. Both randomized trials and observational cohorts were included. While important, studies with a primary outcome of hospital length of stay were not included, as this outcome has been addressed in a recent meta-analysis [7]. The search was restricted to English-language articles.

Exclusion Criteria

Upon full-text review, studies were excluded if they evaluated patients younger than 18 years, sensors were not mobile (eg, continual electrocardiogram with a stationary receiver), patients were discharged without hospitalization, they lacked reported perioperative outcomes (ie, only reporting sensor output over time without a correlated perioperative outcome), or they represented a redundant patient population from an earlier study. Meta-analyses, case studies, and conference abstracts without an associated manuscript were reviewed for primary references but not directly included.

Study Quality

The quality of each selected article was assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system [13]. The GRADE system classifies the quality of evidence into high, moderate, low, or very low. This tool can be applied to both randomized controlled trials and observational studies. Disagreements between the reviewers (AM and WB) over the risk of bias were resolved by discussion or with involvement of a third reviewer (GS).

Data Extraction

Data from the reviewed manuscripts were extracted according to the PICO (population, intervention, comparison, and outcome) model for data extraction [14] using a standardized template modified to capture information regarding perioperative complications and sensor information [2]. The following data were extracted: (1) study features, including study design, type of surgery, number of patients, and patient demographics; (2) mobile sensor details, including type of sensor and sensor output measures (eg, number of steps, energy expenditure); (3) author-defined surgical outcomes, including readmission, 30- and 90-day complications, skilled nursing facility (SNF) discharge, and mortality.

Results

Search Results and Study Selection

Our literature search identified 2199 records using the protocol described above. An additional 10 manuscripts were identified

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by review of references. Using a priori exclusion criteria, 2130 records were removed, as shown in Multimedia Appendix 1. We evaluated 79 full-text articles, of which 11 manuscripts met inclusion criteria. The most common reason for manuscript exclusion was failure to report perioperative surgical outcomes (n=44). All authors whose studies used accelerometers were contacted by email up to two times to obtain patient-level step count and complications for meta-analysis. One author replied to our request but could not provide these data secondary to the interval since the study's completion. Due to the lack of patient-level data, meta-analysis of step count and complication rate was not performed. A forest plot was completed with the limited step count data available from 4 studies, and its results are summarized in Multimedia Appendix 2. Prior to performing a literature search, the study protocol was prospectively registered with the PROSPERO (International Prospective Register of Systematic Reviews) international database of systematic reviews (ID No. CRD42020134656).

Study Aims and Outcomes

As reported in Multimedia Appendix 3, a total of 10 of 11 studies evaluated physical activity. Of these, 7 specified the evaluation of activity and perioperative outcomes as a specific aim [15-21]. A total of 3 studies evaluated complications but did not mention if it was a primary or secondary end point [22-24]. One study evaluated temperature, heart rate, and respiratory rate as they related to interventions for sepsis and overall survival along with the secondary outcome of readmission [25].

Study Characteristics

This review encompassed 949 patients with activity data (step count: n=838; other: n=111). The included studies spanned publication from 2007 to 2019. Of the 11 surgical cohorts, 3 consisted of cardiothoracic cases (coronary artery bypass graft or coronary valve replacement: n=2; pulmonary wedge resection: n=1). A total of 6 studies evaluated patients recovering from general surgery procedures, including gastrointestinal surgery, colorectal surgery, hepatic resection, esophagectomy, and peritoneal cancer debulking with heated intraperitoneal chemotherapy. Finally, 1 study followed patients after lumbar spine fusion, and 1 evaluated patients following open vascular bypass grafting of the extremities. The largest study cohort consisted of 226 patients [25], while the smallest included 11 patients [16]. Surgical outcome variables were author defined and included Clavien-Dindo graded surgical complications, pulmonary and cardiovascular complications, sepsis, hospital readmission, and SNF discharge. A summary of study characteristics is available in Multimedia Appendix 3.

Sensor Characteristics

Sensors were located on the wrist (n=3), hip (n=3), thigh (n=2), upper arm (n=1), ankle (n=1), and chest (n=1). Within the 10 studies measuring physical activity, outputs included steps (n=6), length of time being physically active or upright (n=3), and daily caloric expenditure (n=1). A single study used a sternal sensor to record temperature, heart rate, and respiratory rate [25].

Physical Activity Output

As reported in Multimedia Appendix 4, a total of 9 of the 11 studies recorded physical activity using data from a triaxial accelerometer. Output from the accelerometer was reported as step counts in 6 of 9 studies. Alternatively, 3 of 9 studies reported accelerometer output as metabolic equivalents or time spent in activity. The earliest published study utilized an in-house uniaxial accelerometer that provided the duration of time that the patient was lying supine versus upright. When combining the reported mean step count per postoperative day for the 6 studies providing these data, we found that the average step count associated with postoperative complications was a mean of 1099 (SD 561) steps, while the step count associated with recovery without perioperative outcomes was a mean of 2184 (SD 1090) steps.

We performed a meta-analysis of how step count related to complications using a random-effects linear model adjusting for study size. A total of 4 of the 6 studies reporting mean step counts were included. Adjusting for number of participants, patients in the high-complication cohorts took 963 fewer daily steps than those in the low-complication cohorts (P=.38), as shown in Multimedia Appendix 1.

Non–Physical Activity Output

A single study evaluated temperature, heart rate, and respiratory rate for continuous vital sign measurements after surgery [25]. This system of evaluation was found to be superior to standardized vital sign measurements to inform an early warning score [26]. This resulted in earlier identification of sepsis and improved time to antibiotic administration, shortened length of stay, and decreased 30-day readmission rate.

Study Quality

Of the included studies, 8 were rated as low quality by GRADE criteria secondary to major differences between surgical groups, low participant number, high variability in results, and perception of bias (Multimedia Appendix 3) [13,15-20,22,23]. Two studies were rated as moderate quality due to medically homogenous participants and the lack of preoperative ambulatory information [21,24]. One study was rated as high quality due the results being obtained in a well-designed randomized controlled trial [25].

Discussion

Summary of Findings

This systematic review evaluated surgical patients monitored with a mobile sensor and correlated sensor output with postoperative outcomes. We identified 11 studies, of which 10 used physical activity tracking, with steps being the most common sensor output. There was heterogeneity between studies, yet our systematic review of the published data shows that lower step count was associated with increased adverse postoperative outcomes. This will require further prospective validation, but our evaluation suggests that a step count cutoff of around 1000 steps per day may be prognostic. We found limited evidence for other mobile sensors, such as heart rate, respiratory rate, and temperature sensors. However, the available

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data are promising. Going forward, an effort is needed to standardize reporting for mobile sensor output and postoperative outcomes to aid integration into ERAS protocols and the development of prognostic markers.

It has long been postulated that higher levels of postoperative activity are associated with improved outcomes. It is also likely that baseline activity represents a surrogate marker of overall patient health. Prior evaluation of physical activity and length of stay demonstrated that increased physical activity was associated with decreased length of stay [9]. It is likely that mobile digital sensors can also improve postoperative recovery as an adjunct to ERAS protocols by providing continuous patient data that providers can use to intervene early before complications occur [27]. Such sensors enable providers to monitor patients after the patient has departed from the hospital. There is early evidence that implementing home monitoring can result in postoperative improvement. However, it remains unclear which sensors and outputs should be the focus of such programs [28]. It is likely that a surgery-specific step count would be able to produce better predictions on patients needing enhanced recovery care [10]. Our study demonstrates that increased activity is associated with a broad set of improved postsurgical outcomes. In its current state, this information can inform postoperative risk stratification and with future work could be integrated into ERAS protocols.

While the benefits of activity are consistent with clinical experience, it is unclear to what extent these findings can be clinically implemented. We found that step counts of around 1000 steps per day are associated with adverse surgical outcomes. We hypothesize that in future studies, a step count below 1000 steps per day will be specific for a high risk of complication, while step counts greater than 2000 steps per day will be sensitive for ruling out complications. Such thresholds could inform when patients should be assigned more intensive postoperative care or be allowed early discharge.

Although physical activity represents an objective metric for health, an important limitation of this study is the broad inclusion of outcome definitions. Prior work has focused on length of stay, as it offers a common metric for postoperative recovery [9]. However, length of stay does not necessarily correlate with postoperative outcomes [11]. In fact, there is concern that shortening length of stay for certain surgeries may increase adverse events once the patient returns home [29]. A barrier to implementation will be the heterogeneity in sensor types [30,31]. This was well demonstrated in our evaluation, as the only 2 studies to use the same sensor involved the same author and institution [19,21]. However, despite differences in sensor type and outcomes, there were generally more favorable postsurgical outcomes with increased activity and continuous monitoring. Future studies should standardize reporting and possibly the type of sensors used in order to strengthen the pooled data analysis. It is likely that surgical specialties will need to define the most salient outcomes, but they must also report on standard outcomes, such as readmission and 30- and 90-day mortality rates.

Taken as a whole, this summary identifies that low activity and step count are associated with a heterogenous increase in adverse outcomes. Additionally, there is high-quality evidence that continuously tracking heart rate, respiratory rate, and temperature is also useful for early identification of sepsis. Mobile sensors will increasingly be implemented into postoperative convalescence in an effort to improve surgical outcomes. Such implementation has the potential to provide granular patient data on health and recovery before and after the index hospitalization. A major clinical barrier that merits considerable research is which sensors should be used and which output thresholds warrant clinical concerns. With sensor standardization and integration into the electronic health records, there is a potential to create predictive algorithms with considerable predictive power [32]. However, there will also be barriers to integrating these predictions into the clinical workflow [33]. Going forward, clinicians and industries should partner to validate how commercially available sensors can augment patient and clinician decision making. Additionally, collaborative efforts, such as those suggested by the mobile sensor data-to-knowledge program, should be used by investigators to pool resources and improve data and usability [34].

The main limitation of this study is that the number of studies that make up the systematic review is small and that within this review, 8 of 11 studies were low quality when using the GRADE tool, which is likely a reflection of the nascent state of this investigation but also underscores the potential for future study. While we were not able to find a statistically significant difference between step count and postoperative complications, we did find an association between lower step count and lower postoperative complications, which needs prospective evaluation. Additionally, the mean step counts associated with postoperative complications or recovery were quite different, and the fact that step count is a continuous variable should not completely discredit the merits of our findings.

Conclusions

Digital mobile sensors enable real-time postoperative monitoring of step count, activity, heart rate, respiratory rate, and temperature and have now been used in initial clinical studies. While significant heterogeneity between sensor type, measured output, and reported outcomes limit the generalizability and interpretation of the presented body of literature, several studies successfully demonstrate the potential for mobile sensors to measure clinically relevant metrics. High-quality prospective studies are required to establish the most clinically relevant metrics and threshold values to incorporate into care algorithms.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Study selection process.
[PNG File , 25 KB - periop_v4i1e21571_app1.png]

Multimedia Appendix 2
Forest plot utilizing available step count data from four studies.
[PNG File , 253 KB - periop_v4i1e21571_app2.png]

Multimedia Appendix 3
Characteristics of the studies included.
[PNG File , 254 KB - periop_v4i1e21571_app3.png]

Multimedia Appendix 4
Mobile sensor monitoring characteristics for the studies included.
[PNG File , 230 KB - periop_v4i1e21571_app4.png]

References

1. Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. The Lancet 2008 Jul;372(9633):139-144. [doi: 10.1016/S0140-6736(08)60878-8]
2. Healy M, Mullard A, Campbell D, Dimick J. Hospital and Payer Costs Associated With Surgical Complications. JAMA Surg 2016 Sep 01;151(9):823-830. [doi: 10.1001/jamasurg.2016.0773] [Medline: 27168356]
3. Tyson MD, Chang SS. Enhanced Recovery Pathways Versus Standard Care After Cystectomy: A Meta-analysis of the Effect on Perioperative Outcomes. Eur Urol 2016 Dec;70(6):995-1003 [FREE Full text] [doi: 10.1016/j.eururo.2016.05.031] [Medline: 27297680]
4. Greco M, Capretti G, Beretta L, Gemma M, Pecorelli N, Braga M. Enhanced recovery program in colorectal surgery: a meta-analysis of randomized controlled trials. World J Surg 2014 Jun;38(6):1531-1541. [doi: 10.1007/s00268-013-2416-8] [Medline: 24368573]
5. Liu VX, Rosas E, Hwang J, Cain E, Foss-Durant A, Clopp M, et al. Enhanced Recovery After Surgery Program Implementation in 2 Surgical Populations in an Integrated Health Care Delivery System. JAMA Surg 2017 Jul 19;152(7):e171032 [FREE Full text] [doi: 10.1001/jamasurg.2017.1032] [Medline: 28492816]
6. McCarthy J. One in Five U.S. Adults Use Health Apps, Wearable Trackers. Gallup News. URL: https://news.gallup.com/poll/269096/one-five-adults-health-apps-wearable-trackers.aspx [accessed 2020-04-20]
7. Oldmeadow LB, Edwards ER, Kimmel LA, Kipen E, Robertson VJ, Bailey MJ. No rest for the wounded: early ambulation after hip surgery accelerates recovery. ANZ J Surg 2006 Jul;76(7):607-611. [doi: 10.1111/j.1445-2197.2006.03786.x] [Medline: 16813627]
8. Lawrence VA, Hazuda HP, Cornell JE, Pederson T, Bradshaw PT, Mulrow CD, et al. Functional independence after major abdominal surgery in the elderly. J Am Coll Surg 2004 Nov;199(5):762-772. [doi: 10.1016/j.jamcollsurg.2004.05.280] [Medline: 15501119]
9. Abeles A, Kwasnicki RM, Pettengell C, Murphy J, Darzi A. The relationship between physical activity and post-operative length of hospital stay: A systematic review. Int J Surg 2017 Aug;44:295-302 [FREE Full text] [doi: 10.1016/j.ijsu.2017.06.085] [Medline: 28689861]
10. Daskivich TJ, Houman J, Lopez M, Luu M, Fleshner P, Zaghiyan K, et al. Association of Wearable Activity Monitors With Assessment of Daily Ambulation and Length of Stay Among Patients Undergoing Major Surgery. JAMA Netw Open 2019 Feb 01;2(2):e187673 [FREE Full text] [doi: 10.1001/jamanetworkopen.2018.7673] [Medline: 30707226]
11. Mujagic E, Marti WR, Coslovsky M, Soysal SD, Mechera R, von Strauss M, et al. Associations of Hospital Length of Stay with Surgical Site Infections. World J Surg 2018 Dec;42(12):3888-3896. [doi: 10.1007/s00268-018-4733-4] [Medline: 29978247]
12. Henderson LK, Craig JC, Willis NS, Tovey D, Webster AC. How to write a Cochrane systematic review. Nephrology (Carlton) 2010 Sep;15(6):617-624. [doi: 10.1111/j.1440-1797.2010.01380.x] [Medline: 20883282]
13. Atkins D, Eccles M, Flottorp S, Guyatt GH, Henry D, Hill S, GRADE Working Group. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches The GRADE Working Group. BMC Health Serv Res 2004 Dec 22;4(1):38 [FREE Full text] [doi: 10.1186/1472-6963-4-38] [Medline: 15615589]
14. Evidence Based Medicine. University of Illinois at Chicago. URL: https://researchguides.uic.edu/c.php?g=252338&p=3954402 [accessed 2020-04-20]
15. Wolk S, Linke S, Bogner A, Sturm D, Meißner T, Müssle B, et al. Use of Activity Tracking in Major Visceral Surgery-the Enhanced Perioperative Mobilization Trial: a Randomized Controlled Trial. J Gastrointest Surg 2019 Jun;23(6):1218-1226. [doi: 10.1007/s11605-018-3998-0] [Medline: 30298422]

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16. Iida H, Shimizu T, Maehira H, Kitamura N, Mori H, Miyake T, et al. A pilot study: The association between physical activity level using by accelerometer and postoperative complications after hepatic resection. Exp Ther Med 2018 Dec;16(6):4893-4899 [FREE Full text] [doi: 10.3892/etm.2018.6816] [Medline: 30542445]
17. Feeney C, Reynolds JV, Hussey J. Preoperative physical activity levels and postoperative pulmonary complications post-esophagectomy. Dis Esophagus 2011 Sep;24(7):489-494. [doi: 10.1111/j.1442-2050.2010.01171.x] [Medline: 21309920]
18. Agostini PJ, Naidu B, Rajesh P, Steyn R, Bishay E, Kalkat M, et al. Potentially modifiable factors contribute to limitation in physical activity following thoracotomy and lung resection: a prospective observational study. J Cardiothorac Surg 2014 Sep 27;9:128 [FREE Full text] [doi: 10.1186/1749-8090-9-128] [Medline: 25262229]
19. Matsuo T, Sakaguchi T, Ishida A, Yuguchi S, Saito K, Nakajima M, et al. Effect of in-hospital physical activity on cardiovascular prognosis in lower extremity bypass for claudication. J Phys Ther Sci 2015 Jun;27(6):1855-1859 [FREE Full text] [doi: 10.1589/jpts.27.1855] [Medline: 26180335]
20. Browning L, Denehy L, Scholes RL. The quantity of early upright mobilisation performed following upper abdominal surgery is low: an observational study. Aust J Physiother 2007;53(1):47-52. [doi: 10.1016/s0004-9514(07)70061-2]
21. Takahashi T, Kumamaru M, Jenkins S, Saitoh M, Morisawa T, Matsuda H. In-patient step count predicts re-hospitalization after cardiac surgery. J Cardiol 2015 Oct;66(4):286-291 [FREE Full text] [doi: 10.1016/j.jjcc.2015.01.006] [Medline: 25728798]
22. Low C, Bovbjerg D, Ahrendt S, Choudry M, Holtzman M, Jones HL, et al. Fitbit step counts during inpatient recovery from cancer surgery as a predictor of readmission. Ann Behav Med 2018 Jan 05;52(1):88-92 [FREE Full text] [doi: 10.1093/abm/kax022] [Medline: 29538623]
23. Gilmore SJ, Hahne AJ, Davidson M, McClelland JA. Physical activity patterns of patients immediately after lumbar surgery. Disabil Rehabil 2020 Dec;42(26):3793-3799. [doi: 10.1080/09638288.2019.1610512] [Medline: 31088180]
24. Cook DJ, Thompson JE, Prinsen SK, Dearani JA, Deschamps C. Functional recovery in the elderly after major surgery: assessment of mobility recovery using wireless technology. Ann Thorac Surg 2013 Sep;96(3):1057-1061. [doi: 10.1016/j.athoracsur.2013.05.092] [Medline: 23992697]
25. Downey C, Randell R, Brown J, Jayne DG. Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial. J Med Internet Res 2018 Dec 11;20(12):e10802 [FREE Full text] [doi: 10.2196/10802] [Medline: 30538086]
26. Goldhill D, McNarry A. Physiological abnormalities in early warning scores are related to mortality in adult inpatients. Br J Anaesth 2004 Jun;92(6):882-884 [FREE Full text] [doi: 10.1093/bja/aeh113] [Medline: 15064245]
27. Downey C, Tahir W, Randell R, Brown J, Jayne D. Strengths and limitations of early warning scores: A systematic review and narrative synthesis. Int J Nurs Stud 2017 Nov;76:106-119. [doi: 10.1016/j.ijnurstu.2017.09.003] [Medline: 28950188]
28. Lee T, Kaiser T, Alloway R, Woodle E, Edwards M, Shah S. Telemedicine Based Remote Home Monitoring After Liver Transplantation: Results of a Randomized Prospective Trial. Ann Surg 2019 Sep;270(3):564-572. [doi: 10.1097/SLA.0000000000003425] [Medline: 31356267]
29. Pascal L, Polazzi S, Piriou V, Cotte E, Wegrzyn J, Carty MJ, et al. Hospital Length of Stay Reduction Over Time and Patient Readmission for Severe Adverse Events Following Surgery. Ann Surg 2020 Jul;272(1):105-112. [doi: 10.1097/SLA.0000000000003206] [Medline: 30676380]
30. Taraldsen K, Chastin SFM, Riphagen II, Vereijken B, Helbostad JL. Physical activity monitoring by use of accelerometer-based body-worn sensors in older adults: a systematic literature review of current knowledge and applications. Maturitas 2012 Jan;71(1):13-19. [doi: 10.1016/j.maturitas.2011.11.003] [Medline: 22134002]
31. Montoye AHK, Moore RW, Bowles HR, Korycinski R, Pfeiffer KA. Reporting accelerometer methods in physical activity intervention studies: a systematic review and recommendations for authors. Br J Sports Med 2018 Dec;52(23):1507-1516. [doi: 10.1136/bjsports-2015-095947] [Medline: 27539504]
32. Tomašev N, Glorot X, Rae JW, Zielinski M, Askham H, Saraiva A, et al. A clinically applicable approach to continuous prediction of future acute kidney injury. Nature 2019 Aug;572(7767):116-119 [FREE Full text] [doi: 10.1038/s41586-019-1390-1] [Medline: 31367026]
33. Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T, et al. Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation. N Engl J Med 2019 Nov 14;381(20):1909-1917. [doi: 10.1056/nejmoa1901183]
34. Kuhn B. Advancing biomedical discovery and improving health through mobile sensor Big Data. Center of Excellence for Mobile Sensor Data-to-Knowledge. URL: https://md2k.org/ [accessed 2020-09-10]

Abbreviations

ERAS: enhanced recovery after surgery
GRADE: Grading of Recommendations Assessment, Development, and Evaluation
PICO: population, intervention, comparison, and outcome
PROSPERO: International Prospective Register of Systematic Reviews
SNF: skilled nursing facility

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Edited by R Lee; submitted 29.06.20; peer-reviewed by C Forbes, D Goyal, I Contreras; comments to author 13.08.20; revised version received 07.01.21; accepted 29.01.21; published 25.02.21.

Please cite as:
Memon A, Lec P, Lenis A, Sharma V, Wood E, Schade G, Brisbane W
Relationship Between Mobile Digital Sensor Monitoring and Perioperative Outcomes: Systematic Review
JMIR Perioper Med 2021;4(1):e21571
URL: https://periop.jmir.org/2021/1/e21571
doi:10.2196/21571
PMID:33629966

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Original Paper

Expectations of Continuous Vital Signs Monitoring for Recognizing Complications After Esophagectomy: Interview Study Among Nurses and Surgeons

Mathilde van Rossum[1,2,3], MSc; Jobbe Leenen[4,5], MSc; Feike Kingma[6], MD; Martine Breteler[3], MSc; Richard van Hillegersberg[6], MD, PhD; Jelle Ruurda[6], MD, PhD; Ewout Kouwenhoven[7], MD, PhD; Marc van Det[7], MD, PhD; Misha Luyer[8], MD, PhD; Grard Nieuwenhuijzen[8], MD, PhD; Cor Kalkman[3], MD, PhD; Hermie Hermens[2], PhD

[1]Department of Cardiovascular and Respiratory Physiology, University of Twente, Enschede, Netherlands
[2]Department of Biomedical Signals and Systems, University of Twente, Enschede, Netherlands
[3]Department of Anesthesiology, University Medical Center Utrecht, Utrecht, Netherlands
[4]Department of Surgery, Isala, Zwolle, Netherlands
[5]Connected Care Centre, Isala, Zwolle, Netherlands
[6]Department of Surgery, University Medical Center Utrecht, Utrecht, Netherlands
[7]Department of Surgery, ZGT Hospital, Almelo, Netherlands
[8]Department of Surgery, Catharina Hospital, Eindhoven, Netherlands

Corresponding Author:
Mathilde van Rossum, MSc
Department of Cardiovascular and Respiratory Physiology
University of Twente
Technical Medical Centre
PO Box 217
Enschede, 7500 A
Netherlands
Phone: 31 53 489 4152
Email: m.c.vanrossum@utwente.nl

Abstract

Background: Patients undergoing esophagectomy are at serious risk of developing postoperative complications. To support early recognition of clinical deterioration, wireless sensor technologies that enable continuous vital signs monitoring in a ward setting are emerging.

Objective: This study explored nurses' and surgeons' expectations of the potential effectiveness and impact of continuous wireless vital signs monitoring in patients admitted to the ward after esophagectomy.

Methods: Semistructured interviews were conducted at 3 esophageal cancer centers in the Netherlands. In each center, 2 nurses and 2 surgeons were interviewed regarding their expectations of continuous vital signs monitoring for early recognition of complications after esophagectomy. Historical data of patient characteristics and clinical outcomes were collected in each center and presented to the local participants to support estimations on clinical outcome.

Results: The majority of nurses and surgeons expected that continuous vital signs monitoring could contribute to the earlier recognition of deterioration and result in earlier treatment for postoperative complications, although the effective time gain would depend on patient and situational factors. Their expectations regarding the impact of potential earlier diagnosis on clinical outcomes varied. Nevertheless, most caregivers would consider implementing continuous monitoring in the surgical ward to support patient monitoring after esophagectomy.

Conclusions: Caregivers expected that wireless vital signs monitoring would provide opportunities for early detection of postoperative complications in patients undergoing esophagectomy admitted to the ward and prevent sequelae under certain circumstances. As the technology matures, clinical outcome studies will be necessary to objectify these expectations and further investigate overall effects on patient outcome.

(JMIR Perioper Med 2021;4(1):e22387) doi:10.2196/22387

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KEYWORDS

telemedicine; physiological monitoring; vital signs; esophagectomy; postoperative complications

Introduction

Surgical treatment of esophageal cancer is highly complex and associated with considerable postoperative morbidity. Although the centralization of care and introduction of minimally invasive surgery have improved clinical outcomes, complications still occur in approximately 60% of patients undergoing esophagectomy [1,2]. These postoperative complications contribute to mortality, prolonged hospitalization, and increased costs [3-6].

To prevent severe sequelae of complications after esophagectomy, early recognition of clinical deterioration is essential [7-9]. As complications are often preceded by detectable signs, such as atrial fibrillation or hemodynamic instability [10,11], patients are usually admitted to high-care units in the first days after surgery for close monitoring of vital signs (eg, heart rate, respiratory rate, blood pressure, body temperature) and other clinical markers. However, with the introduction of enhanced recovery pathways, patients tend to be transferred to surgical wards earlier [12,13]. Consequently, clinical signs of complications after esophagectomy present more often at the ward. Since the level of patient monitoring is typically lower in a ward setting, where vital signs are only measured a few times per day, this poses a risk of missing important early signs of deterioration.

As the market for wearable medical technologies grows, unobtrusive tools for wireless vital signs monitoring are emerging. By allowing continuous vital signs monitoring even while mobilizing, these technologies may aid early recognition of clinical deterioration in ward patients [14-18] and could therefore be of interest for patients undergoing esophagectomy. However, despite the potential promises, the technology is still immature, and further developments are needed to facilitate optimal implementation [19,20]. Furthermore, it is as of yet unclear how continuous monitoring should be integrated in current routines to promote effective care escalation. Accordingly, acceptance of the new technology and adoption by caregivers is uncertain, while this is crucial for effective implementation. Lastly, to date, there is still only scant evidence of the clinical value in specific patient populations [21]. Therefore, the aim of this study was to gain insight into nurses' and surgeons' expectations of the potential effectiveness and clinical impact of continuous vital signs monitoring in patients admitted to the surgical ward after esophagectomy.

Methods

Participants

We performed semistructured interviews with nurses and surgeons involved in the postoperative care of patients undergoing esophagectomy, which allowed thorough discussion of research topics from different perspectives. The study focused on surgical practice in the Netherlands, and interviewees were recruited from 3 Dutch high-volume centers for esophageal surgery (University Medical Center Utrecht, Catharina Hospital Eindhoven, ZGT Hospital Almelo). Purposive sampling [22] was applied to obtain a sample of care professionals with a high level of relevant expertise, aiming to promote in-depth discussion and informed judgements of the interview topics. Accordingly, in each participating center, the chair of the surgical (ward) team proposed candidates with the most knowledge and experience of postoperative monitoring of patients undergoing esophagectomy. Candidates were invited to participate in the study through email and gave written consent for the interview.

Interview Setup

The interview setup and scheme (Multimedia Appendix 1) was developed by a group of 5 researchers and care professionals with expertise in the field of telemonitoring, clinical patient monitoring, esophageal surgery, and qualitative research. The interview included structured and open questions within 5 main themes. First, current approaches to patient monitoring after esophagectomy and factors influencing early recognition of postoperative complications were investigated. Subsequently, the participant's expectations regarding the effectiveness and clinical impact of continuous vital signs monitoring were discussed. Last, considerations regarding the implementation of continuous monitoring were explored. As anastomotic leak and pneumonia are the most prevalent complications that can seriously affect clinical outcome in patients undergoing esophagectomy [1,3,23], these complications were used as case examples to discuss the topics and elicit concrete predictions.

Two pilot interviews were conducted—one with an experienced nurse (working experience: 9 years) and one with a surgeon (working experience: 2 years)—within one of the participating centers to verify whether questions were interpreted correctly and whether the research goals were obtained. Based on these test interviews, visual aids described below were added to further improve clarification of questions and structuration of the interview. Furthermore, the test interview led to the removal of questions regarding potential effect size, since the test participants indicated that the validity of such expert-based judgments would be questionable given the many uncertainties involved.

A researcher from an independent institute with a background in technical medicine and wireless patient monitoring performed all interviews in private workplaces within the hospital. The interviewer was guided by the interview scheme but was allowed to change the sequence of questions within main topics or to add questions for emerging topics. Rephrasing of questions and probing was used to encourage detailed answering. The interviews were audiotaped, and no notes were taken.

Materials

The interviewer used visual aids for clarification of theoretical concepts and structured collection of information (Multimedia Appendix 1). The concept of continuous vital signs monitoring was introduced as the ability to constantly track heart rate,

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respiratory rate, body temperature, and oxygen saturation by means of unobtrusive wearable sensors that allow patient mobilization within the hospital. In addition, it was stated that automatic threshold alarms or (variations of) early warning scores could be integrated to assist detection of abnormalities.

To support and anchor estimations of potential clinical effects and minimize the possible influence of differences in preknowledge between participants, descriptive data of the local patient population were collected for each center and presented as the prior situation to the corresponding participants during the final part of the interview. Data included population characteristics, complication rates, and clinical outcome measures for all patients that underwent elective esophagectomy for nonrecurrent esophageal cancer between January 2015 and December 2016. All data were registered according to definitions by the Dutch Upper Gastrointestinal Cancer Audit [6,24] and collected prior to the interviews. Multimedia Appendix 2 summarizes the baseline characteristics of the pooled patient populations of the 3 participating centers.

Analysis

The interviewer transcribed the interview recordings. Next, all transcripts were coded using Atlas.ti software (version 8.3.2; Atlas.ti Scientific Software Development) for content analysis [25]. Coding was performed independently by the interviewer and a second researcher with expertise in nursing and wireless patient monitoring. In this process, content was categorized according to the predefined interview topics, after which the results of structured questions were summarized and emerging themes within categories were coded. Codes were refined as analysis progressed and added when new themes emerged. Any discrepancies in coding by the 2 researchers were mutually discussed to obtain consensus for all codes and themes. The transcripts were not returned to the participants for correction to avoid censoring, and study findings were member checked after completion of the analysis. To evaluate the level of data saturation that was obtained, we assessed the number of new themes that were elicited across the inclusion of participants. In addition, we explored the number of themes mentioned exclusively by either nurses or surgeons or by participants of 1 center only. The results were reported following the Standards for Reporting Qualitative Research guidelines [26].

Results

Participants

All candidates that were invited for the interview participated in the study. The recruited nurses (n=6) had a median working experience of 7.5 years (range 2-25 years), of which they worked 4 years (range 1-25 years) with patients undergoing esophagectomy. The participating surgeons (n=6) had a median working experience of 11 years (range 6-21 years) in upper gastrointestinal surgery. Interviews had an average duration of 44 minutes (range 25-63 minutes).

Data Saturation

Content analysis resulted in identification of 40 themes (Multimedia Appendix 3), of which 14 themes were described by participants in 2 centers and 25 themes were discussed in all included centers. In each center, at least 75% of all themes were described by at least one of the participants. In total, 85% of all themes were described by both nurses and surgeons. Analysis of the interviews from the last included participants did not result in elicitation of new themes (Multimedia Appendix 3); hence, sufficient data saturation was assumed.

Current Monitoring Routine

Current protocols for patient monitoring during ward stay were similar among the 3 hospitals. Typically, a physician visited the patient during daily rounds and performed physical examination on indication. Chest radiography, blood tests of infection parameters, and drain amylase tests were performed daily in the first days after surgery. Each hospital used an early warning score system (similar to the Modified or National Early Warning Score [27,28]) to evaluate the patient's status 3 to 4 times per day. As part of these early warning scores, standard vital sign measurements of heart rate, respiratory rate, blood pressure, oxygen saturation, and temperature were performed. This set was complemented by routine measurements of urine output and evaluation of mental status. However, participants of one hospital described that urine output and mental status were not assessed routinely for each patient but specifically in patients with suspected instability.

In case deterioration was suspected based on routine measurements and subjective nurse observations, additional physical examination, vital signs measurements, blood tests, or diagnostic imaging were performed to confirm findings and for further diagnosis. However, the approach of diagnostic confirmation seemed to vary between hospitals, as participants from one hospital promoted early activation of diagnostic imaging, while other participants advocated a wait-and-see policy to prevent overdiagnosis.

Early Recognition of Complications

All participants underlined that early recognition of complications is important for rapid recovery and minimization of adverse clinical outcomes. Furthermore, all participants were confident that the current monitoring routine supports early complication recognition but recognized that the time to identification and treatment of complications depends on various factors.

The majority of participants reported that signs of anastomotic leak and pneumonia typically present first in vital signs measurements and subjective nurse observations (Multimedia Appendix 4). In a later phase, abnormalities often present in lab tests and physical examinations, followed by medical imaging. However, several participants pointed out that the presentation of clinical deterioration varies per patient and complication type. As one nurse explained:

> *The presentation of a complication differs between patients. Some patients are able to compensate for a long time, while other patients deteriorate immediately.* [Participant 3]

Participants noted that clinical deterioration is not always visible in an early stage or for a mild degree of complications, where physiology is still unaffected or impairment is too small to be captured by routine observations or diagnostic tests.

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Furthermore, compensatory mechanisms or medication may suppress signs of deterioration. As such, abnormalities may remain undetected.

Conversely, abnormal diagnostic test results or physical symptoms, for example, tachycardia, could relate to various complication types, which hampers differentiation in an early phase. Moreover, abnormalities can be caused by the surgical stress response, comorbidities, or normal variations. For these reasons, identification of deterioration relies on the combination of subjective observations and diagnostic tests. Accordingly, caregivers often wait to see whether the observed abnormalities persist or present in other diagnostic tests before acknowledging a (potential) complication. Last, half of the participating surgeons mentioned that routine test results are often assessed statically according to standard thresholds, while temporal changes are more indicative of deterioration.

Participants explained that late detection of clinical deterioration can be caused by incomplete or delayed routine examinations. Nurse observations and vital signs measurements may be skipped or postponed if the patient appears stable, in particular when workload is high. Additionally, vital signs are not always measured in patients who are asleep to avoid sleep deprivation. Lastly, the interval between the onset of deterioration and evaluation of test results depends on the timing of routine measurements and clinical rounds, which leads to variable response times.

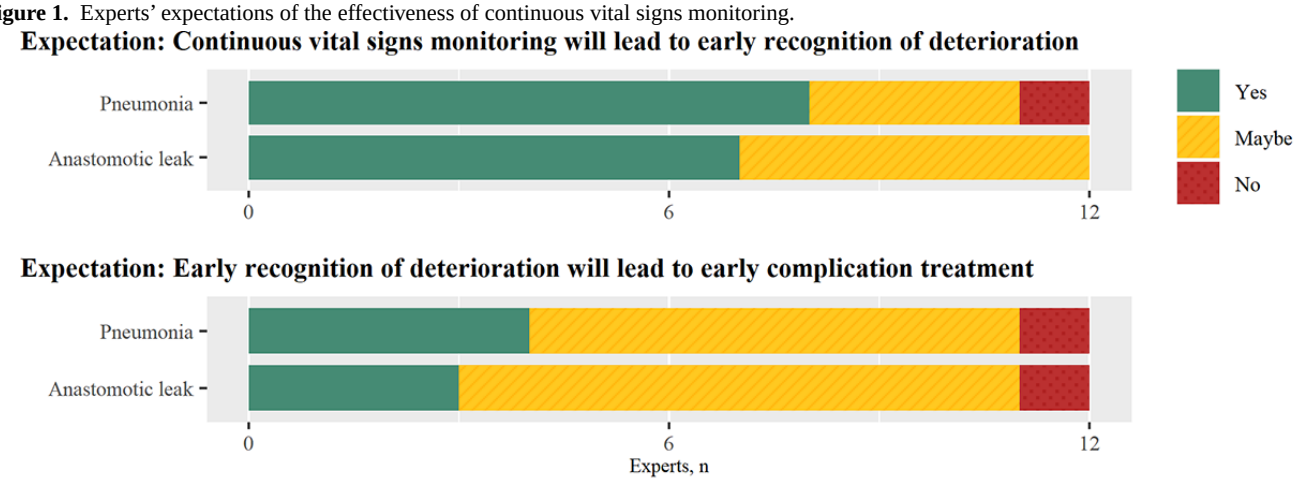
A total of 6 participants mentioned that the level of expertise of the treating physician and nurse influences how fast deterioration is recognized and acted upon, as this impacts the ability to observe and interpret physical signs and identify abnormalities in diagnostic results. This mainly concerns weekend, evening, and night shifts, which are typically occupied by less experienced staff.

Effectiveness of Continuous Vital Signs Monitoring

The majority of participants expected that continuous vital signs monitoring could support early recognition of deterioration related to anastomotic leak and pneumonia (Figure 1). A total of 6 participants estimated a maximal time gain of 1 to 8 hours, deduced from the fact that continuous availability of data can facilitate direct notification of (acute) abnormalities and hence fill the gap between current intermittent measurements, which are typically obtained every 8 hours. Conversely, 5 participants argued that the time gain could be higher and might reach 12 to 48 hours, mainly supported by the increased ability to identify time trends or abnormal patterns. As one surgeon described:

> *With the availability of continuous data, we can better observe trends, which are more important than spot-checks.…These patterns influence our judgement of the patient's status.* [Participant 4]

Figure 1. Experts' expectations of the effectiveness of continuous vital signs monitoring.



This can be of particular benefit for patients with slowly developing complications or in cases where deterioration is not suspected due to unspecific or absent physical signs. Lastly, 3 participants also described that it is likely that continuous monitoring promotes early identification by increasing the awareness of potential abnormalities. Next to pneumonia and anastomotic leak, participants mentioned that continuous monitoring could contribute to early detection of arrhythmias, such as atrial fibrillation, infections, and severe acute events, such as pulmonary embolism and myocardial infarction.

The participants who were more doubtful about the ability to recognize deterioration early mostly ascribed this to the limited sensitivity and specificity of vital signs measurements and the importance of full clinical assessment. A nurse stated:

> *These numbers don't tell the whole story.* [Participant 2]

Furthermore, it was argued that early warning does not just rely on vital signs, since first signs of complications could be observed in other measurements at the same time or even earlier depending on presentation (Multimedia Appendix 4). Last, several participants stated that it is unlikely that deterioration can be identified earlier, as current routines are already effective and caregivers are constantly alert to potential complications.

Most participants expected that early notification of deterioration effected by continuous vital signs monitoring would lead to earlier treatment of the underlying complication in (a subset of) patients (Figure 1). Participants pointed out that continuous monitoring would also promote earlier activation of therapy by increasing the certainty that abnormalities persist or providing

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an objective description of the patient status that could be used to justify escalation of care. The overall effect on time to treatment might, however, be limited, as clinical progress or diagnostic confirmation is often awaited first. A nurse explained:

> *There are cases where we have to wait and follow-up the measurements. Then we can identify whether the patient is indeed deteriorating or stabilizes.* [Participant 2]

Six participants stated that the implementation of active alarms is crucial for effective monitoring, as these could raise the awareness of abnormal vital signs. One of the surgeons mentioned:

> *Alarms will trigger caregivers to actively search for abnormalities….I think this will specifically improve the continuity of early recognition.* [Participant 11]

By supporting identification of abnormalities, automated alarms can reduce nurse workload and minimize the dependency on nurse expertise. However, it was also mentioned that alarm-based response systems may have unintended consequences, such as neglecting subjective patient observation, which should be prevented, as this is important for adequate patient assessment. Furthermore, it is crucial that notifications are given at the right time and that the number of false alerts is minimal to prevent alarm fatigue. A total of 3 surgeons stated it would be valuable to complement the static assessment of vital sign values by automatic trend detection.

Most participants mentioned that implementation of continuous monitoring requires training for nurses and physicians in the practical use of the monitoring system or interpretation of continuous vital signs. In addition, 10 participants underlined the need for a clear protocol that defines the responsibilities of clinical staff and describes when and how to act in case of vital sign abnormalities. However, it was also noted that it is first needed to gain more insight into patterns of deterioration that require escalation of care and that it would take time to find out and establish effective monitoring routines.

Impact of Continuous Vital Signs Monitoring

The combined data from the 3 participating hospitals (Figure 2) showed that patients who developed postoperative pneumonia, anastomotic leak, or both had a considerably longer length of hospital stay and increased risk of intensive care unit (ICU) or medium care unit (MCU) readmission. Furthermore, the data suggest that anastomotic leak strongly increases mortality. Overall, a minority of participants expected that early recognition and treatment of pneumonia and anastomotic leak effected by continuous monitoring would improve these outcome measures, as shown in Figure 3.

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Figure 2. Clinical outcome of patients undergoing esophagectomy. Outcomes are reported for the pooled patient population that underwent elective esophagectomy between 2015 and 2016 in one of the 3 participating centers (n=280). Subgroups reflect patients with or without pneumonia, anastomotic leak, or both within 30 days after surgery. ICU: intensive care unit; MCU: medium care unit.

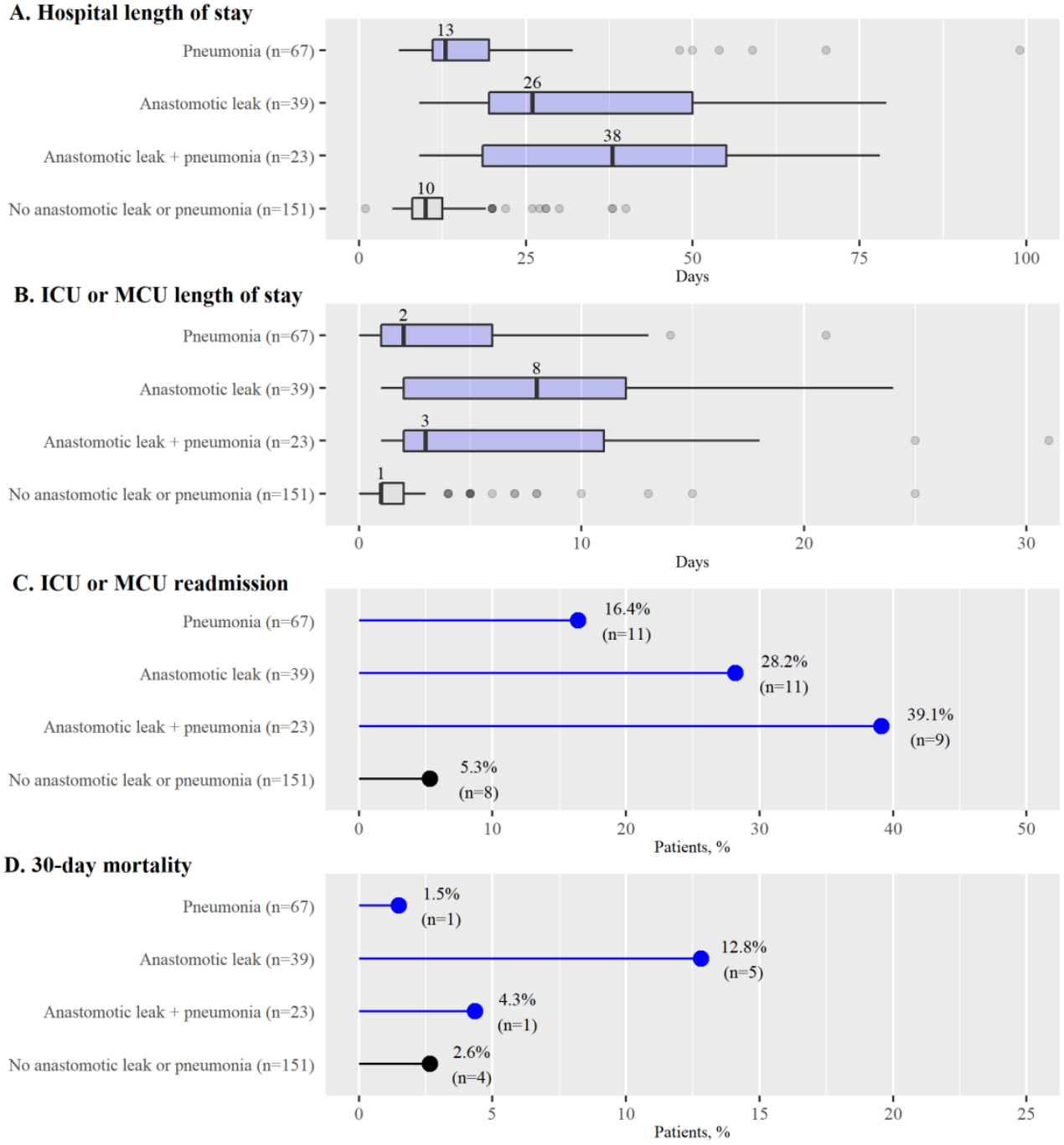

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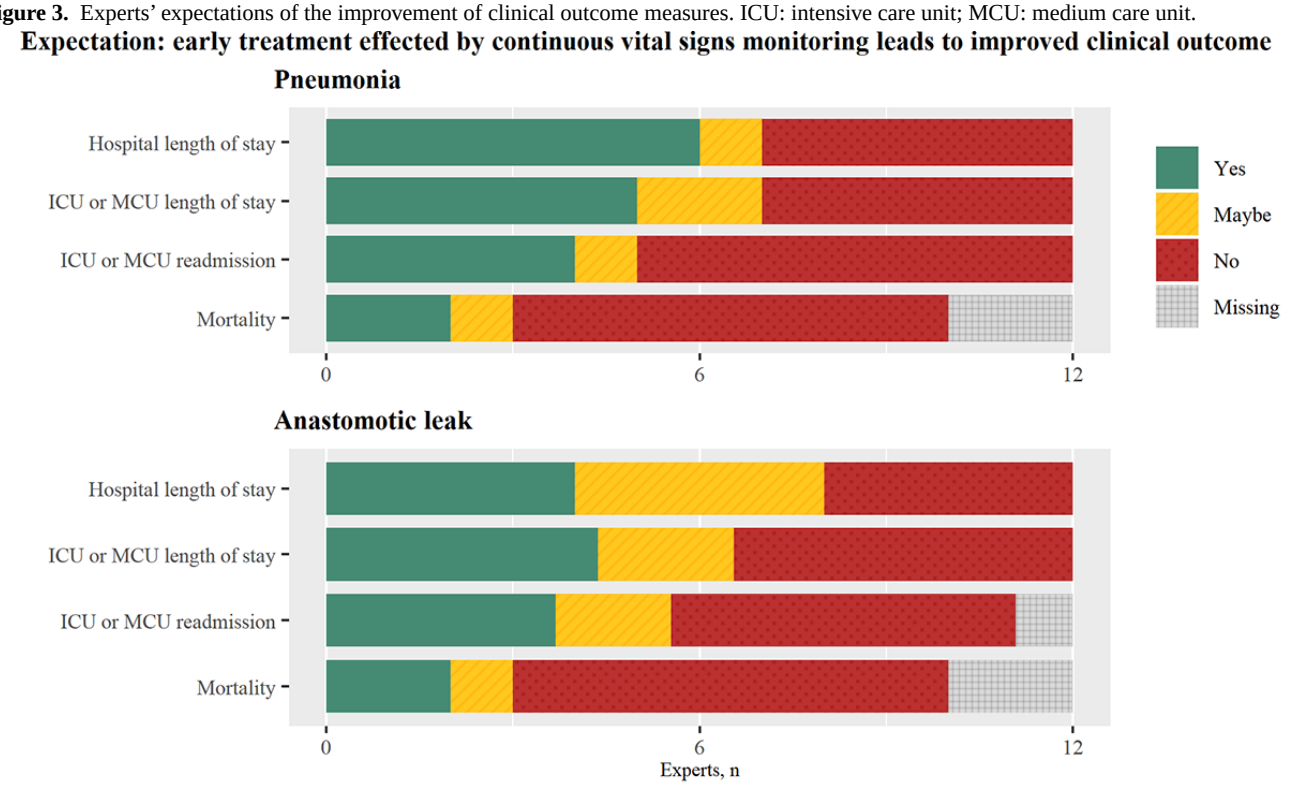
Figure 3. Experts' expectations of the improvement of clinical outcome measures. ICU: intensive care unit; MCU: medium care unit.



Participants who expected a reduced hospital and ICU or MCU length of stay assigned this either to a shortened recovery and treatment period or to earlier onset and hence completion of the treatment period. Improvement in ICU or MCU readmission rate and mortality was attributed to a potential reduction in complication severity. Two participants stated that early recognition is of the highest value in patients with mild complications, as prevention of further deterioration would still be relatively easy. In contrast, 2 other participants expected the most impact in cases of severe complications because there would be more room to reduce the degree of illness. Furthermore, it was mentioned that the largest benefits could be expected in patients with a poor preoperative condition, as these have a higher risk of severe deterioration.

A total of 5 participants mentioned that the time gain that could be obtained with continuous monitoring is insufficient for notable improvement of clinical outcome. One nurse stated:

> *The hours that we could possibly gain on top of our current protocol are not enough to impact the progress or severity of the complication.* [Participant 6]

Participants who were doubtful indicated that the minimal time gain required for significant reduction of adverse effects caused by complications would range from 12 to 48 hours. Lastly, it was pointed out that adverse effects of some complications cannot be minimized at all because early onset of treatment does not reduce the duration of hospitalization or change patient outcomes.

Considerations for Implementation

Taking all potential effects into account, 10 participants would consider implementing continuous monitoring on their ward for early detection of deterioration. Most of these participants (n=6) would monitor all patients undergoing esophagectomy, while others preferred preselection of older patients (n=1) or patients with a poor preoperative condition (n=1). Several participants considered applying continuous monitoring only during the first days of ward stay (n=2) or in case of nurse concerns (n=1).

The main argument against implementation included the expectation that continuous monitoring would not bring sufficient benefit on top of current monitoring protocols due to limited clinical effects. Furthermore, 5 participants mentioned that improvement in patient monitoring is becoming less relevant, as the prevalence and severity of complications is reducing over the years. A surgeon said:

> *Patients have a lower risk of developing complications than a few years ago.…Also, the effects of complications are less severe. So, we now have more room to await clinical progress.* [Participant 5]

Participants described additional risks and benefits related to patient experience, nurse workload, and financial consequences but were divided on these topics. Several participants suspected that continuous monitoring would create a feeling of safety for patients. On the other hand, other participants expected worry related to false alarms and the feeling of being at risk. Furthermore, it was noted that the sensor placement and potential overdiagnosis could increase patient burden.

While most participants expected a reduction of nurse workload from (partial) automated vital signs measurement, others warned of increased workload related to vital sign interpretation and management of alarms. Moreover, 3 nurses suspected that the implementation of continuous monitoring would also create increased expectations of the level of care. One of these nurses stated:

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> *In case you monitor patients continuously, you will also need to be able to provide continuous response.* [Participant 6]

However, they feared that this level of care could not be met, as the available time and expertise of the ward nurse staff is currently insufficient.

Lastly, participants reported that cost might be saved as a result of reduced hospital length of stay and reduced intensive care readmissions but also noted that expenditures might increase due to the costs of monitoring systems.

Discussion

Principal Findings

This study identified perceptions of surgeons and nurses on the potential clinical effects of continuous vital signs monitoring by means of wearable sensors in patients admitted to the ward after esophagectomy. Caregivers suspected that continuous vital signs monitoring could promote early recognition of clinical deterioration in this population and setting and contribute to early treatment of prevalent complications. However, there were varying expectations regarding whether continuous monitoring would lead to notable improvements in hospital length of stay, ICU readmission, and mortality. Despite an as of yet uncertain clinical impact, most caregivers are positive toward future implementation of continuous vital signs monitoring to support patient monitoring in the surgical ward, provided that their concerns are adequately addressed.

Previous Studies

The perioperative management of patients undergoing esophagectomy has evolved over the years, and there is growing attention to the importance of early complication recognition [8,11]. According to current study results, however, there is still room to improve early detection of complications in a ward setting, which conforms to findings of previous studies [17,29]. Vital signs and related early warning systems have been found to be good predictors of ICU transfer, cardiac arrest, and mortality [16,30,31]. Therefore, there are high expectations of the potential value of continuous wireless vital signs monitoring, which allow more accurate and constant risk evaluation [14,32,33].

Although evidence is still scarce, previous studies have described how continuous vital signs monitoring using wearable sensors could promote early identification of patient deterioration in a ward setting [21,34-37], which was also expected by these study participants. Furthermore, wireless monitoring has been proposed as a promising aid in other settings, for example, to assist in- or out-of-hospital monitoring of isolated patients during the current COVID-19 pandemic or surgical patients with restricted access to medical services [38].

However, previous studies have reported variable effects of continuous monitoring on patient outcomes and cost efficiency [21,36], which is in line with the mixed expectations regarding clinical impact found in our study. Part of this inconclusive evidence can be explained by the fact that most studies so far have included small or heterogeneous study populations and used different monitoring strategies. Furthermore, continuous monitoring has often not been implemented at its full potential, restricted by the constraints of current available technology or limited compliance to the monitoring or response protocols. Moreover, the monitoring protocols have often adopted a classical approach to vital signs assessment based on static vital signs levels. However, as described by current participants and in previous research [39], continuous and automated monitoring creates additional opportunities for trend evaluation and integration with context data, which may improve identification of deterioration. Accordingly, further investigation of adequate methods for trend-based and personalized assessment of vital signs data is encouraged.

On the other hand, these discrepant expectations regarding the possible clinical impact of continuous monitoring may also represent the complexity of managing postoperative surgical complications, where the ability to minimize adverse outcomes depends not only on early detection and treatment but also on the effects of the selected interventions. As the implementation of continuous monitoring introduces a risk of alarm fatigue and patient discomfort [21], studies that identify patients that would benefit most from continuous remote monitoring and early treatment are desired. Correspondingly, our study participants underlined the importance of establishing feasible but effective protocols for escalation of care. Furthermore, the responsibilities of caregivers and work processes should be adjusted with care to encourage adoption by caregivers and promote the effective implementation of continuous monitoring. The results of this interview study indicate that even if vital signs monitoring triggers early suspicion of deterioration, clinical observation as well as complementary diagnostic tests are imperative for the correct interpretation and actual diagnosis of complications. However, the introduction of continuous monitoring could also lead to overreliance in monitoring technology [29,33]. Therefore, careful implementation is required to balance the risks of missed events and overdiagnosis.

Strengths and Limitations

The qualitative design of this study allowed us to obtain estimations from professionals caring for patients undergoing esophagectomy, a highly complex surgical procedure associated with considerable risk, regarding the effectiveness of continuous monitoring technology. By using expert elicitation, the potential of continuous monitoring in the postoperative setting could be evaluated in the early development phase, where technology is evolving rapidly and the reliability, accuracy, and usability of these systems still need to be demonstrated [14]. Another advantage of this theoretical approach is that the results were not affected by the local implementation of technology or compliance of patients and caregivers, which could distort evaluation in clinical studies [21]. Furthermore, the interviews allowed stepwise investigation of individual components of the monitoring and response chain, which is challenging in a clinical setting.

However, as reflected by current findings, there are many patient-related or situational factors that might influence the effectiveness and impact of continuous patient monitoring and also challenge theoretical effect estimation. To promote the

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validity of estimates from caregivers, we therefore focused on a highly specific patient population and used case examples to minimize uncertainty. Furthermore, we purposely included only experienced caregivers from specialized centers within a single country to participate in the study to compose a homogeneous group of experts (ie, information-rich cases). Last, historical data of the local patient population were used to describe current clinical outcomes and create a consistent anchor point for effect evaluation. Nevertheless, current estimations can only be used hypothetically, and the overall impact on clinical outcome measures requires confirmation in clinical practice.

This study included surgeons and well as nurses from 3 centers. This allowed us to investigate topics and viewpoints from both the nursing and surgical professions and possible local perspectives within the Netherlands. According to national registries, these high-volume centers were responsible for 17% of all esophagectomies performed in the Netherlands in 2015 to 2016, and they reported similar population characteristics as those described for the national population [40]. Furthermore, except for some variation in the frequency and type of routine vital signs measurement, the overall clinical routines and escalation protocols were largely comparable between centers. Therefore, it is likely that the research sample is representative of the situation in the Netherlands. Although we conducted a limited number of interviews, viewpoints of participants or themes that were described by participants did not vary considerably within or between centers or between nurses and surgeons. In addition, as no new themes emerged from the interviews of the last included participants, sufficient saturation was assumed. Still, since the patient population and clinical routines may differ in other centers or countries, careful translation of findings for other settings is required.

Implications

As our study reflects that caregivers see opportunities to improve postoperative care after esophagectomy using wireless continuous vital signs monitoring, future studies that verify this potential in a ward setting are encouraged. By explicating factors that define the need for and ability of early complication recognition, current results may guide stepwise investigation of the effective time gain and corresponding clinical and economic effects of various monitoring strategies. As such, the optimal implementation of continuous wireless vital signs monitoring can be further evaluated as the technology matures.

Conclusions

Despite routine monitoring, identification of postoperative complications in patients undergoing esophagectomy admitted to the ward may be delayed due to limited frequency and diagnostic value of diagnostic measurements and the variable experience and skills of clinical staff. Surgeons and nurses expect that continuous vital signs monitoring by means of emerging wearable sensor technology would provide opportunities for early detection of clinical deterioration, which could promote rapid complication treatment. However, the effective time gain and impact on clinical outcome are yet uncertain and depend on patient and situational factors. Further investigation of the overall benefits and risks and optimal implementation of continuous vital signs monitoring is desired as technology matures.

Acknowledgments

The authors thank all surgeons and nurses who participated in the interviews and are grateful to all people within the participating centers who contributed to the collection and sharing of the local patient population data.

Conflicts of Interest

MvR, JL, FK, RH, JR, EK, MD, ML, GN, CK, and HH have no conflicts of interest to declare. MB is a part-time employee of Luscii Healthtech BV (health information and communications technology company in Amsterdam, the Netherlands). No competing financial interests exist.

Multimedia Appendix 1
Interview guide.
[PDF File (Adobe PDF File), 330 KB - periop_v4i1e22387_app1.pdf]

Multimedia Appendix 2
Baseline characteristics of patient population undergoing esophagectomy.
[PDF File (Adobe PDF File), 40 KB - periop_v4i1e22387_app2.pdf]

Multimedia Appendix 3
Themes elicited during context analysis.
[PDF File (Adobe PDF File), 117 KB - periop_v4i1e22387_app3.pdf]

Multimedia Appendix 4
Typical order of early signs observed for pneumonia and anastomotic leak.
[PDF File (Adobe PDF File), 20 KB - periop_v4i1e22387_app4.pdf]

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References

1. Low DE, Kuppusamy MK, Alderson D, Cecconello I, Chang AC, Darling G, et al. Benchmarking Complications Associated with Esophagectomy. Ann Surg 2019 Feb;269(2):291-298. [doi: 10.1097/SLA.0000000000002611] [Medline: 29206677]
2. Schmidt HM, Gisbertz SS, Moons J, Rouvelas I, Kauppi J, Brown A, et al. Defining Benchmarks for Transthoracic Esophagectomy: A Multicenter Analysis of Total Minimally Invasive Esophagectomy in Low Risk Patients. Ann Surg 2017 Nov;266(5):814-821. [doi: 10.1097/SLA.0000000000002445] [Medline: 28796646]
3. Goense L, Meziani J, Ruurda JP, van Hillegersberg R. Impact of postoperative complications on outcomes after oesophagectomy for cancer. Br J Surg 2019 Jan;106(1):111-119. [doi: 10.1002/bjs.11000] [Medline: 30370938]
4. Grimminger PP, Goense L, Gockel I, Bergeat D, Bertheuil N, Chandramohan SM, et al. Diagnosis, assessment, and management of surgical complications following esophagectomy. Ann N Y Acad Sci 2018 Dec;1434(1):254-273. [doi: 10.1111/nyas.13920] [Medline: 29984413]
5. Goense L, van Dijk WA, Govaert JA, van Rossum PSN, Ruurda JP, van Hillegersberg R. Hospital costs of complications after esophagectomy for cancer. Eur J Surg Oncol 2017 Apr;43(4):696-702. [doi: 10.1016/j.ejso.2016.11.013] [Medline: 28012715]
6. Busweiler LA, Henneman D, Dikken JL, Fiocco M, van Berge Henegouwen MI, Wijnhoven BP, Dutch Upper GI Cancer Audit group. Failure-to-rescue in patients undergoing surgery for esophageal or gastric cancer. Eur J Surg Oncol 2017 Oct;43(10):1962-1969. [doi: 10.1016/j.ejso.2017.07.005] [Medline: 28797755]
7. Paul S, Bueno R. Section VI: complications following esophagectomy: early detection, treatment, and prevention. Semin Thorac Cardiovasc Surg 2003 Apr;15(2):210-215. [Medline: 12838491]
8. Griffin SM, Shaw IH, Dresner SM. Early complications after Ivor Lewis subtotal esophagectomy with two-field lymphadenectomy: risk factors and management. J Am Coll Surg 2002 Mar;194(3):285-297. [doi: 10.1016/s1072-7515(01)01177-2] [Medline: 11893132]
9. Weledji EP, Verla V. Failure to rescue patients from early critical complications of oesophagogastric cancer surgery. Ann Med Surg (Lond) 2016 May;7:34-41 [FREE Full text] [doi: 10.1016/j.amsu.2016.02.027] [Medline: 27054032]
10. Seesing MFJ, Scheijmans JCG, Borggreve AS, van Hillegersberg R, Ruurda JP. The predictive value of new-onset atrial fibrillation on postoperative morbidity after esophagectomy. Dis Esophagus 2018 Nov 01;31(11):doy028. [doi: 10.1093/dote/doy028] [Medline: 29635398]
11. Oxenberg J. Prevention and Management of Complications from Esophagectomy. In: Chai J, editor. Esophageal Cancer and Beyond. London, United Kingdom: IntechOpen; 2018. [doi: 10.5772/intechopen.78757]
12. Gemmill EH, Humes DJ, Catton JA. Systematic review of enhanced recovery after gastro-oesophageal cancer surgery. Ann R Coll Surg Engl 2015 Apr;97(3):173-179 [FREE Full text] [doi: 10.1308/003588414X14055925061630] [Medline: 26263799]
13. Findlay JM, Gillies RS, Millo J, Sgromo B, Marshall REK, Maynard ND. Enhanced recovery for esophagectomy: a systematic review and evidence-based guidelines. Ann Surg 2014 Mar;259(3):413-431. [doi: 10.1097/SLA.0000000000000349] [Medline: 24253135]
14. Joshi M, Ashrafian H, Aufegger L, Khan S, Arora S, Cooke G, et al. Wearable sensors to improve detection of patient deterioration. Expert Rev Med Devices 2019 Feb;16(2):145-154. [doi: 10.1080/17434440.2019.1563480] [Medline: 30580650]
15. Taenzer AH, Pyke JB, McGrath SP. A review of current and emerging approaches to address failure-to-rescue. Anesthesiology 2011 Aug;115(2):421-431. [doi: 10.1097/ALN.0b013e318219d633] [Medline: 21587063]
16. DeVita MA, Smith GB, Adam SK, Adams-Pizarro I, Buist M, Bellomo R, et al. "Identifying the hospitalised patient in crisis"--a consensus conference on the afferent limb of rapid response systems. Resuscitation 2010 Apr;81(4):375-382. [doi: 10.1016/j.resuscitation.2009.12.008] [Medline: 20149516]
17. Kellett J, Sebat F. Make vital signs great again - A call for action. Eur J Intern Med 2017 Nov;45:13-19. [doi: 10.1016/j.ejim.2017.09.018] [Medline: 28941841]
18. Boer C, Touw HR, Loer SA. Postanesthesia care by remote monitoring of vital signs in surgical wards. Curr Opin Anaesthesiol 2018 Dec;31(6):716-722. [doi: 10.1097/ACO.0000000000000650] [Medline: 30095483]
19. Khanna AK, Hoppe P, Saugel B. Automated continuous noninvasive ward monitoring: future directions and challenges. Crit Care 2019 May 30;23(1):194 [FREE Full text] [doi: 10.1186/s13054-019-2485-7] [Medline: 31146792]
20. Leenen JPL, Leerentveld C, van Dijk JD, van Westreenen HL, Schoonhoven L, Patijn GA. Current Evidence for Continuous Vital Signs Monitoring by Wearable Wireless Devices in Hospitalized Adults: Systematic Review. J Med Internet Res 2020 Jun 17;22(6):e18636 [FREE Full text] [doi: 10.2196/18636] [Medline: 32469323]
21. Downey CL, Chapman S, Randell R, Brown JM, Jayne DG. The impact of continuous versus intermittent vital signs monitoring in hospitals: A systematic review and narrative synthesis. Int J Nurs Stud 2018 Aug;84:19-27. [doi: 10.1016/j.ijnurstu.2018.04.013] [Medline: 29729558]
22. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Adm Policy Ment Health 2015 Sep;42(5):533-544 [FREE Full text] [doi: 10.1007/s10488-013-0528-y] [Medline: 24193818]

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23. Blencowe NS, Strong S, McNair AGK, Brookes ST, Crosby T, Griffin SM, et al. Reporting of short-term clinical outcomes after esophagectomy: a systematic review. Ann Surg 2012 Apr;255(4):658-666. [doi: 10.1097/SLA.0b013e3182480a6a] [Medline: 22395090]
24. Busweiler LAD, Wijnhoven BPL, van Berge Henegouwen MI, Henneman D, van Grieken NCT, Wouters MWJM, Dutch Upper Gastrointestinal Cancer Audit (DUCA) Group. Early outcomes from the Dutch Upper Gastrointestinal Cancer Audit. Br J Surg 2016 Dec;103(13):1855-1863. [doi: 10.1002/bjs.10303] [Medline: 27704530]
25. Zhang Y, Wildemuth BM. Qualitative analysis of content. In: Applications of Social Research Methods to Questions in Information and Library Science, Second edition. Santa Barbara, CA: Libraries Unlimited; 2017:318-329.
26. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 2014 Sep;89(9):1245-1251 [FREE Full text] [doi: 10.1097/ACM.0000000000000388] [Medline: 24979285]
27. Subbe CP, Kruger M, Rutherford P, Gemmel L. Validation of a modified Early Warning Score in medical admissions. QJM 2001 Oct;94(10):521-526. [doi: 10.1093/qjmed/94.10.521] [Medline: 11588210]
28. Smith GB, Prytherch DR, Meredith P, Schmidt PE, Featherstone PI. The ability of the National Early Warning Score (NEWS) to discriminate patients at risk of early cardiac arrest, unanticipated intensive care unit admission, and death. Resuscitation 2013 Apr;84(4):465-470. [doi: 10.1016/j.resuscitation.2012.12.016] [Medline: 23295778]
29. Mok WQ, Wang W, Liaw SY. Vital signs monitoring to detect patient deterioration: An integrative literature review. Int J Nurs Pract 2015 May;21(Suppl 2):91-98. [doi: 10.1111/ijn.12329] [Medline: 26125576]
30. Downey CL, Tahir W, Randell R, Brown JM, Jayne DG. Strengths and limitations of early warning scores: A systematic review and narrative synthesis. Int J Nurs Stud 2017 Nov;76:106-119. [doi: 10.1016/j.ijnurstu.2017.09.003] [Medline: 28950188]
31. Bleyer AJ, Vidya S, Russell GB, Jones CM, Sujata L, Daeihagh P, et al. Longitudinal analysis of one million vital signs in patients in an academic medical center. Resuscitation 2011 Nov;82(11):1387-1392. [doi: 10.1016/j.resuscitation.2011.06.033] [Medline: 21756971]
32. Watkins T, Whisman L, Booker P. Nursing assessment of continuous vital sign surveillance to improve patient safety on the medical/surgical unit. J Clin Nurs 2016 Jan;25(1-2):278-281 [FREE Full text] [doi: 10.1111/jocn.13102] [Medline: 26531215]
33. Prgomet M, Cardona-Morrell M, Nicholson M, Lake R, Long J, Westbrook J, et al. Vital signs monitoring on general wards: clinical staff perceptions of current practices and the planned introduction of continuous monitoring technology. Int J Qual Health Care 2016 Sep;28(4):515-521. [doi: 10.1093/intqhc/mzw062] [Medline: 27317251]
34. Brown H, Terrence J, Vasquez P, Bates DW, Zimlichman E. Continuous monitoring in an inpatient medical-surgical unit: a controlled clinical trial. Am J Med 2014 Mar;127(3):226-232. [doi: 10.1016/j.amjmed.2013.12.004] [Medline: 24342543]
35. Weenk M, van Goor H, Frietman B, Engelen LJ, van Laarhoven CJ, Smit J, et al. Continuous Monitoring of Vital Signs Using Wearable Devices on the General Ward: Pilot Study. JMIR Mhealth Uhealth 2017 Jul 05;5(7):e91 [FREE Full text] [doi: 10.2196/mhealth.7208] [Medline: 28679490]
36. Cardona-Morrell M, Prgomet M, Turner RM, Nicholson M, Hillman K. Effectiveness of continuous or intermittent vital signs monitoring in preventing adverse events on general wards: a systematic review and meta-analysis. Int J Clin Pract 2016 Oct;70(10):806-824. [doi: 10.1111/ijcp.12846] [Medline: 27582503]
37. Breteler MJM, KleinJan E, Numan L, Ruurda JP, Van Hillegersberg R, Leenen LPH, et al. Are current wireless monitoring systems capable of detecting adverse events in high-risk surgical patients? A descriptive study. Injury 2020 May;51(Suppl 2):S97-S105 [FREE Full text] [doi: 10.1016/j.injury.2019.11.018] [Medline: 31761422]
38. Massaroni C, Nicolò A, Schena E, Sacchetti M. Remote Respiratory Monitoring in the Time of COVID-19. Front Physiol 2020;11:635 [FREE Full text] [doi: 10.3389/fphys.2020.00635] [Medline: 32574240]
39. Petit C, Bezemer R, Atallah L. A review of recent advances in data analytics for post-operative patient deterioration detection. J Clin Monit Comput 2018 Jun;32(3):391-402. [doi: 10.1007/s10877-017-0054-7] [Medline: 28828569]
40. Dutch upper gastrointestinal cancer audit (year report 2019). Dutch Institute for Clinical Auditing. URL: https://dica.nl/jaarrapportage-2019/duca [accessed 2021-01-22]

Abbreviations

ICU: intensive care unit
MCU: medium care unit

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Edited by G Eysenbach; submitted 10.07.20; peer-reviewed by M Joshi; comments to author 24.08.20; revised version received 18.12.20; accepted 16.01.21; published 12.02.21.

Please cite as:
van Rossum M, Leenen J, Kingma F, Breteler M, van Hillegersberg R, Ruurda J, Kouwenhoven E, van Det M, Luyer M, Nieuwenhuijzen G, Kalkman C, Hermens H
Expectations of Continuous Vital Signs Monitoring for Recognizing Complications After Esophagectomy: Interview Study Among Nurses and Surgeons
JMIR Perioper Med 2021;4(1):e22387
URL: http://periop.jmir.org/2021/1/e22387/
doi:10.2196/22387
PMID:33576743

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Original Paper

Hospital Costs and Long-term Survival of Patients Enrolled in an Enhanced Recovery Program for Open Liver Resection: Prospective Randomized Controlled Trial

Chris N Jones[1*], MBBS, MD, BSc, FRCA; Ben L Morrison[1*], MBBS, BSc, FRCA; Leigh JS Kelliher[1*], MBBS, BMedSci, MD, FRCA; Matthew Dickinson[1*], MBBS, JP BSc (Hons), MSc, FRCA, FFICM; Michael Scott[1*], MB, ChB, FRCA, FRCP, FFICM; Claudia Cecconi Ebm[2*], MD, MSc; Nariman Karanjia[1*], MS, FRCS (Gen); Nial Quiney[1*], MBBS, FRCA

[1]Royal Surrey NHS Foundation Trust, Guildford, United Kingdom

[2]Humanitas University, Milan, Italy

[*]all authors contributed equally

Corresponding Author:
Chris N Jones, MBBS, MD, BSc, FRCA
Royal Surrey NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
Phone: 44 01483464116
Email: chrisjones9@nhs.net

Abstract

Background: The clinical benefits of enhanced recovery programs (ERPs) have been extensively researched, but few studies have evaluated their cost-effectiveness. Our ERP for open liver resection is based closely on the guidelines produced by the Enhanced Recovery After Surgery Society (2016). This study follows on from a previous randomized controlled trial. We also undertook a long-term follow-up of the patients enrolled in the original trial alongside an analysis of the associated health economics.

Objective: We aimed to undertake a health economic and long-term survival analysis as part of a trial investigating the implementation of an ERP for open liver resection.

Methods: The enhanced recovery elements utilized included extra preoperative education, carbohydrate loading, oral nutritional supplements, postresection goal-directed fluid therapy (LiDCOrapid), early mobilization, and physiotherapy (twice a day compared with once per day in the standard care group). A decision-analytic model was used to compare the study endpoints for ERP versus standard care provided to patients undergoing open liver resection. Outcomes obtained included costs per life-years gained. Resource use and costs were estimated from the perspective of the National Health Service of the United Kingdom. A decision tree and Markov model were constructed using results from our earlier trial and augmented by external data from other published clinical trials. Long-term follow-up was also undertaken for up to 5 years after the surgery, and data were analyzed to ascertain if the ERP conferred any benefit on long-term survival.

Results: Patients receiving ERP had an average life expectancy of 6.9 years versus 6.1 years in the standard care group. The overall costs were £9538.279 (£1=US $1.60) for ERP and £14,793.05 for standard treatment. This results in a cost-effectiveness ratio of –£6748.33/QALY. Patients receiving ERP required fewer visits to their general practitioner (P=.006) and required lesser help at home with day-to-day activities (P=.04) than patients in the standard care group. Survival was significantly improved at 2 years at 91% (42/46) for patients receiving ERP versus 73% (33/45) for the standard care group (P=.03). There was no statistically significant difference at 5 years after the surgery.

Conclusions: ERPs for patients undergoing open liver resection can improve their medium-term survival and are cost-effective for both hospital and community settings.

(JMIR Perioper Med 2021;4(1):e16829) doi:10.2196/16829

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KEYWORDS

enhanced recovery after surgery; enhanced recovery; liver resection; enhanced recovery program; health economics; survival

Introduction

Liver resection is the preferred treatment option for many primary and secondary liver tumors. Despite advances in surgery and anesthesia and a corresponding reduction in mortality, liver resection is still associated with a high rate of postoperative morbidity ranging from 15% to 45% [1,2]. Enhanced recovery programs (ERPs) have been shown to reduce this morbidity as well as hospital length of stay following colorectal surgery [3]. Only a small number of cohort studies have compared an ERP with standard care in patients who had undergone a liver resection [4-8]. Prior to the clinical trial associated with this study [9], only 1 randomized clinical trial had been conducted; however, that study examined the use of laxatives and nutritional supplements within an ERP and did not compare this treatment with that of standard care [10]. Several systematic reviews, including meta-analyses with some overlap between the included studies, have concluded that ERPs can be successfully implemented for liver resection and can reduce the length of stay without affecting morbidity, mortality, or readmission rates [11-13]. None of the other liver resection trials measured any markers of quality of life (QoL) and only 1 included any economic analysis, showing a reduction in the hospital charges associated with ERP, but not reporting community costs [6].

A systematic review of economic evaluations of ERPs for colorectal surgery concluded that the current evidence is limited but tends to support the cost-effectiveness of ERPs; moreover, it acknowledges a need for further well-designed trials incorporating both hospital and community costs [14]. A broader systematic review looking into ERPs for several specialties agreed that the implementation of ERPs was cost-effective but more trials are needed to examine out-of-hospital costs [15]. Again, with regard to colorectal surgery, one trial has shown reduced community cost with improved QoL following the implementation of an ERP. This study included both open and laparoscopic surgeries, with the ERP group having a significantly higher proportion of laparoscopic surgeries; however, the results remain encouraging in suggesting an economic benefit with ERPs [16].

We performed a full economic evaluation alongside a randomized clinical trial [9], which incorporated QoL outcomes. Our timeframe was the first 4 weeks after the surgery based on a previous review that showed no difference in the QoL after that period [17]. We also conducted a separate 5-year follow-up of patients enrolled in the original randomized controlled trial to ascertain any significant difference in the long-term mortality between the ERP and standard care groups. Our intentions in this study were to establish whether any health economic benefit could be achieved, both in the hospital and in the community as a result of the introduction of an ERP for open liver resection and to investigate whether any survival benefit was seen over a 5-year postoperative period.

Methods

Study Design and Ethical Approval

The economic study was undertaken alongside an randomized clinical trial conducted between March 2011 and May 2012 at a regional hepatobiliary unit in southern England. The trial was ethically approved by the National Health Service (NHS) Research Ethics Committee and monitored by the Trust Research and Development Department. The trial was registered at controlled-trials.com (ISRCTN03274575).

Participants and Recruitment

All patients presenting for open liver resection were eligible. Patients were excluded if they underwent an entirely laparoscopic operation, needed a second concomitant procedure (eg, bile duct repair), were found to be inoperable at the time of surgery, or were unable to provide consent. Patients were first approached in the outpatient clinic and given a trial information sheet. A second, more comprehensive, discussion took place in the preassessment unit before trial consent was obtained. Patients were then randomized either to treatment within the ERP or standard care. The randomization sequence of group allocation by means of brown opaque envelopes was generated by an independent statistician.

Perioperative Care

Patients in both groups underwent a standardized anesthetic and surgical technique with thoracic epidurals for postoperative analgesia. The enhanced recovery elements utilized included extra preoperative education, carbohydrate loading, oral nutritional supplements, postresection goal-directed fluid therapy (LiDCOrapid), early mobilization, and physiotherapy (twice a day compared with once per day in the standard care group). Epidurals were removed on postoperative day 2 in the ERP group and on postoperative days 3-4 in the standard care group. The perioperative care is described in more detail in the associated clinical paper [9].

Quality-Adjusted Life Expectancy

Data from the original trial were used for the clinical outcomes, including survival and complication rates, utility, and costs during the observation period [9]. Utility values for the postoperative period were taken from international published literature and based on the standardized EQ-5D (EuroQoL-5 dimension, EuroQol Group) questionnaire [18] completed in the preassessment clinic after giving informed consent and on postoperative days 2, 3, 5, 7, 10, 14, and 28. The mean age and gender-specific life expectancy for our study population were extracted from UK mortality tables and adjusted for an increased relative risk of mortality in high-risk surgical survivors [19]. We then assigned a utility value to various stages of the disease process to derive the quality-adjusted life expectancy.

Resources and Costs

We explored a number of health economic outcomes—our primary outcome being the incremental cost-effectiveness of

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implementing an ERP. In order to estimate long-term outcomes, we created a Markov model (Figure 1). This model uses a mathematical algorithm to calculate outcomes based on actual data from the original trial and assumptions based on external evidence [17,18,20,21]. As the model also calculates the lifetime cost-effectiveness, we used the data available on UK health care standard life tables to calculate the life expectancy of our cohort and multiplied with the utility per life year [19]. We ran this simulation model over 10 years, whereby each individual had a possibility to annually transit between the various health states (alive without complications, alive with complications, developed complications, remain in the current state, or die). These data were checked against international literature [17,18]. The calculated time span of our cost-effectiveness model was 10 years, whereby the model was fed with survival trial data for up to 5 years and complemented with a predicted lifetime survival based on the UK life expectancy data. For the purpose of analysis, an episode of care was defined using in-hospital costs (up to discharge) or long-term follow-up costs (10 years).

For the cost-effectiveness analysis, we used trial input data to calculate the mean costs and mean quality-adjusted life expectancy for each treatment arm. These were determined by calculating the expected remaining mean life years per population and multiplying these with the utility of being in these states (mean values). The EQ-5D data were converted into a country-specific utility index value using UK-specific value sets (with values taken from 2014). In a subsequent Monte Carlo simulation, incremental costs and outcomes were computed using repeated random sampling to generate simulated data to use with a mathematical model. The simulation was repeated 10,000 times to calculate the costs, effects, and the incremental cost-effectiveness ratio and its 95% confidence intervals.

Subsequently, a cost-effectiveness acceptability curve (Figure 2) was plotted to graphically illustrate the outcome with different thresholds for one's willingness-to-pay for additional benefits gained (eg, willingness-to-pay for gaining an extra life year). The long-term outcomes assessed were costs and quality-adjusted life years (QALYs) gained. Our primary health economic outcome was the incremental cost-effectiveness of the ERP versus that of standard care, which was measured as the ratio of the differences in the costs and differences in the QALYs between the 2 patient groups.

Figure 1. Markov model. After surgery, a patient is either scheduled for standard treatment or an enhanced recovery program. If a patient is discharged, he/she has a certain risk to live with/without complications or die within the subsequent 15 years. ERP: enhanced recovery program.

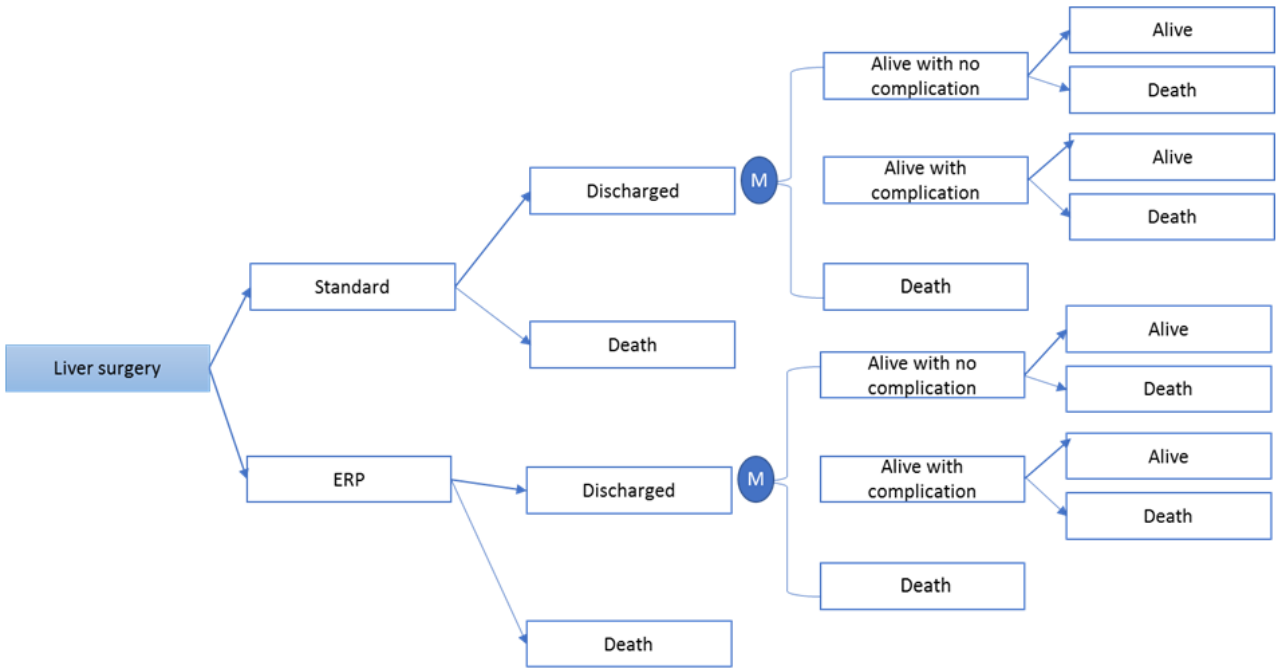

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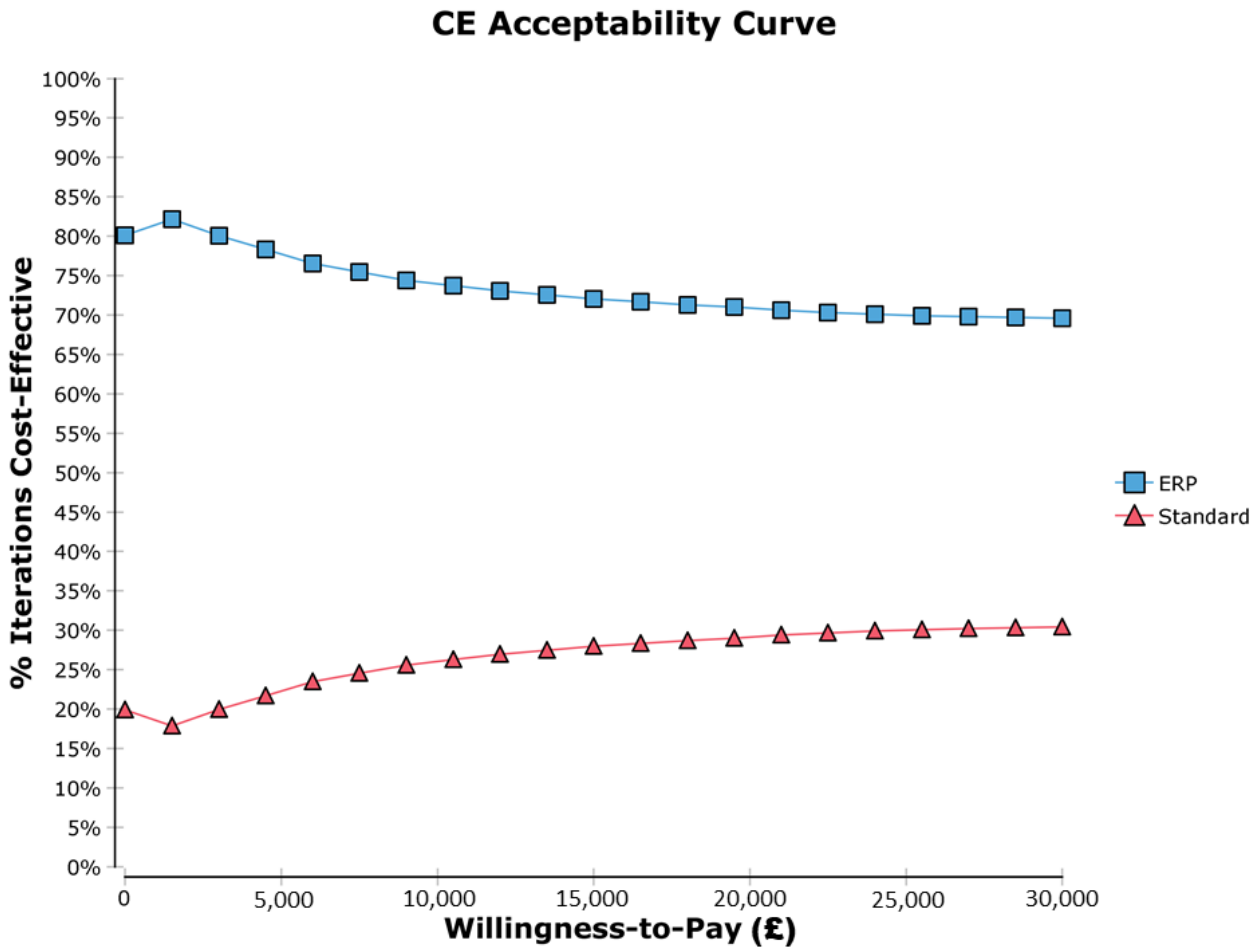
Figure 2. Cost-effectiveness acceptability curve. Throughout a wide range of varying willingness-to-pay, the enhanced recovery program pathway remains the dominant strategy. CE: cost-effectiveness; ERP: enhanced recovery program; £1= US $1.60.



Data on all NHS health care resources used in the treatment for both groups during the first 4 weeks after the surgery, including those relating to the operation, hospital stay, and postdischarge community care, was collected prospectively at the individual patient level. Indirect (societal) costs associated with lost productivity were not calculated due to the short observation period of the study and the technical and conceptual problems associated with assessing them.

The anesthetic and operation techniques were the same for all participants. Operation costs were calculated using the fully absorbed costs obtained locally (see Multimedia Appendix 1). The operation start and finish times were recorded for each patient. Likewise, the anesthetic start and finish times were recorded; thus, anesthetic costs could similarly be calculated using fully absorbed costs obtained from the finance department (£9.16 per minute for anesthesia and £15.70 per minute of theater time, £1=US $1.60). The fully absorbed hospital costs relating to the length of the postoperative hospital stay and use of ward beds, high dependency units, and intensive care units (in days) were obtained locally (intensive care unit £1652.80 per day, high dependency unit £502.08 per day, and ward £151.68 per day). Additional costs for the ERP group included the preoperative carbohydrate drink (Nutricia Clinical Care: 6 cartons £8.40), oral nutritional supplements (Fortisip Compact, Nutricia Clinical Care: contract price £0.14 per bottle), and use of LiDCOrapid (total fixed and variable costs £91.20 per patient). The community health care costs incurred by NHS health care providers in the month after the discharge, including consultations at a general practitioner surgery and home visits by district nurses, were assessed by a questionnaire given to the patient on discharge. They were asked to complete this on postoperative day 14 and repeated on postoperative day 28. Unit costs for community health care resources were obtained from the "Unit Costs of Health and Social Care 2011" compiled by Lesley Curtis (Multimedia Appendix 2) [22]. The costs for patients requiring readmission for overnight stays were included in the hospital costs using the appropriate fully absorbed daily rate.

In order to estimate the long-term costs, we added direct postdischarge health care costs for the follow-up management of high-risk surgical patients and used a 3% discount rate as recommended by the National Institute of Clinical Excellence. In our analysis, we assumed daily costs in hospital to be linear, meaning that the first day has the same monetary value as all subsequent days. This does not reflect the real-world scenario, and therefore, we performed a sensitivity analysis around these values. We ran Monte Carlo simulations to account for variances in model inputs. Mean data were used for the cost-effectiveness acceptability curve to plot the threshold for when a society is unwilling to pay for any additional life gained.

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Five-Year Survival Rates

Patients were followed up at 5 years from the date of their operation by using the NHS Spine data portal. If the patient had died during this period, his or her date of death was recorded and survival after the surgery was calculated. A Kaplan-Meier survival curve was created for each group and statistical significance was calculated at set intervals using chi-square or Fisher exact tests depending upon sample size.

Results

Patient Demographics and Care After Surgery

A total of 104 consecutive patients were enrolled in the trial. Thirteen patients were withdrawn after randomization because of changes to their original oncological staging. Ninety-one patients completed the study; 45 received standard care and 46 were treated within the ERP. Patients in the ERP group had significantly higher P-POSSUM (Portsmouth modification of the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity) scores and a significantly higher proportion of malignant disease (see Table 1). The median anesthetic time was similar in both groups (52 [IQR 45-60] minutes in the ERP group vs 55 [IQR 40-60] minutes for the standard care group, *P*=.64) as was surgical time (189 [IQR 163-236] minutes vs 207 [IQR 150-255] minutes, *P*=.54, respectively). The median total theater cost was, therefore, similar in both groups (£3457 [IQR £3073-£4125] vs £3618 [IQR £2898-£4507], *P*=.55, respectively).

Intensive care unit stays were on average half a day shorter in the ERP group when compared to those of the standard care group; however, this was not significant (1.5 [IQR 1-2] days vs 2 [IQR 1-2] days, *P*=.15). For this level two care, there was a median £827 cost saving in the ERP group; however, this did not reach statistical significance (ERP: £2479 [IQR £1563-£3306] vs standard care: £3306 [IQR £1653-£3306], *P*=.18). High dependency unit care was also 1 day shorter in the ERP group when compared to that in the standard care group but was not statistically significant (1 [IQR 0-2] day vs 2 [IQR 0-3] days, *P*=.08); similarly, there was a median £502 cost saving in the ERP group but this did not reach statistical significance (ERP: £502 [IQR £0-£1004] vs standard care: £1004 [IQR £0-£1506], *P*=.09). There was a 1-day reduction from 3 days to 2 days in normal ward stay in the ERP group versus standard care (*P*<.001). Patients in the ERP group were discharged home, on average, 3 days earlier than the standard care group (median 4 [IQR 3-5] days vs 7 [IQR 6-8] days). Similarly, there was a reduction of £151.68 in the costs between groups that did reach statistical significance (£303 [IQR £0-£341) vs £455 [IQR £303-£758], respectively, *P*<.001).

Patients in the ERP group had, on average, 3.9 physiotherapy sessions per hospital episode compared to 4.3 sessions in the standard care group. Overall, the cost per number of bed days between the groups showed an average saving of £654 in favor of the ERP group (*P*=.01). However, when we compared the overall hospital costs, we observed a median cost saving of £864 per patient in favor of the ERP group (ERP: £6826 [IQR £5804-£8124] vs standard care: £7690 [IQR £6880-£9763], *P*=.007). The overall hospital cost for each group showed a £113,476 difference in favor of the ERP group (£344,147 vs £457,623, respectively).

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Table 1. Patient demographics and operation details (N=91).

Characteristics	Enhanced recovery program group (n=46)	Standard care group (n=45)
Age (years), median (IQR)	64 (27-83)	67 (27-84)
Sex ratio (Male:Female)	31:15	23:22
Body mass index (kg/m^2), mean (SD)	25.6 (5.0)	26.9 (4.4)
American Society of Anesthesiologists fitness grade (n)		
I	0	2
II	43	38
III	3	5
Diagnosis (n)		
Colorectal metastases	35	26
Other metastases	10	10
Benign disease	1	9
Neoadjuvant chemotherapy	36	25
P-POSSUM[a], mean (SD)		
Physiological score	16.4 (3.4)	16.8 (3.6)
Operative severity score	19.4 (3.7)	17.1 (4.8)
Operation (n)		
Major resection (3 segments)	21	12
Minor resection	25	33
Specimen weight (g), median (IQR)	373.3 (156.3-780.5)	179.5 (69.6-606.3)
Blood loss (mL), median (IQR)	350 (174-900)	340 (150-645)
Need for blood transfusion (n)	7	3
Death	1	1

[a]P-POSSUM: Portsmouth modification of the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity.

Community Care After Discharge

Overall, there was no increase in community or primary care health use after discharge in the ERP group (see Table 2). Despite being discharged, on average, 3 days sooner, fewer patients in the ERP group required visits to their general practitioner, with 15 visits in the ERP group compared with 38 in the standard care group (*P*=.006). Similarly, only 33 patients in the ERP group required visits to a practice nurse compared with 48 in the standard care group during the same period, but again, this did not reach statistical significance (*P*=.12). Significantly fewer patients in the ERP group required help with day-to-day activities at home from friends and family (25 patients vs 33 patients in the standard care group, *P*=.04). There were no significant differences between the groups with regard to outpatient visits (ERP: 5 [11%] vs standard care: 10 [22%], *P*=.17) or emergency department attendances (ERP: 2 [4%] vs standard care: 0 [0%], *P*=.49). Average community care costs based on per patient basis were similar in both groups (median £90 [IQR £21-£156] vs £73 [IQR £47-£203] in the standard care group, *P*=.49). Overall costs of community care showed a £2542 cost saving in favor of the ERP group (£6723 in the ERP group vs £9265 for the standard care group).

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Table 2. Data of community care and primary care usage by the patients from the day of discharge to postoperative day 28 (N=91).

Postoperative data of patients	Enhanced recovery program group (n=46)	Standard care group (n=45)	*P* value[a]
Visit to general practitioner, n (%)	14 (30)	25 (56)	.01[b]
Total visits to general practitioner (n)	15	38	.006[c]
Home visit from general practitioner, n (%)	0 (0)	1 (2)	.49
General practitioner practice nurse visits, n (%)	20 (43)	28 (62)	.052[b]
Total visits to nurse (n)	33	48	.12[c]
Home visit from nurse, n (%)	17 (37)	17 (38)	.87[b]
Total nurse home visits (n)	42	49	.86
Outpatient visit, n (%)	5 (11)	10 (22)	.16
Emergency department/walk-in center, n (%)	2 (4)	0 (0)	.49
Help from friends and family, n (%)	25 (54)	33 (73)	.04[b]
Total friends and family events (n)	132	188	.02[c]

[a]Statistical significance tested with Fisher exact test. The statistical test chosen was based upon sample size.

[b]Chi-square test.

[c]Mann-Whitney *U* test.

Incremental Cost-effectiveness Ratio

There was a significant difference in the QoL between the 2 groups during the 28 days after surgery, as measured by the multidimensional health value index EQ-5D. The median area under the curve was 37.2 for the ERP group compared with 35.6 for the standard care group (*P*=.002). When this was annualized, it resulted in an overall QALY gain of 0.004 for the ERP group (*P*=.002). Costs were £9538.3 in the ERP versus £14,793.1 in the standard care group, and life expectancy was calculated to be 6.9 years in the ERP group versus 6.1 years in the standard care group. The incremental cost-effectiveness ratio was £–6748.3/QALY gained, meaning that the new pathway is the dominant strategy (more effective and less expensive) and should be recommended to decision makers (Table 3 and Figure 3).

Table 3. Results of the incremental cost-effectiveness analysis.

Type of care	Costs (£)[a]	Life years (QALY)[b]	Incremental cost-effectiveness (£/QALY)
Enhanced recovery program	9538.30	6.9	0.0
Standard care	14,793.10	6.1	–6748.30

[a]£1= US $1.60.

[b]QALY: quality-adjusted life year.

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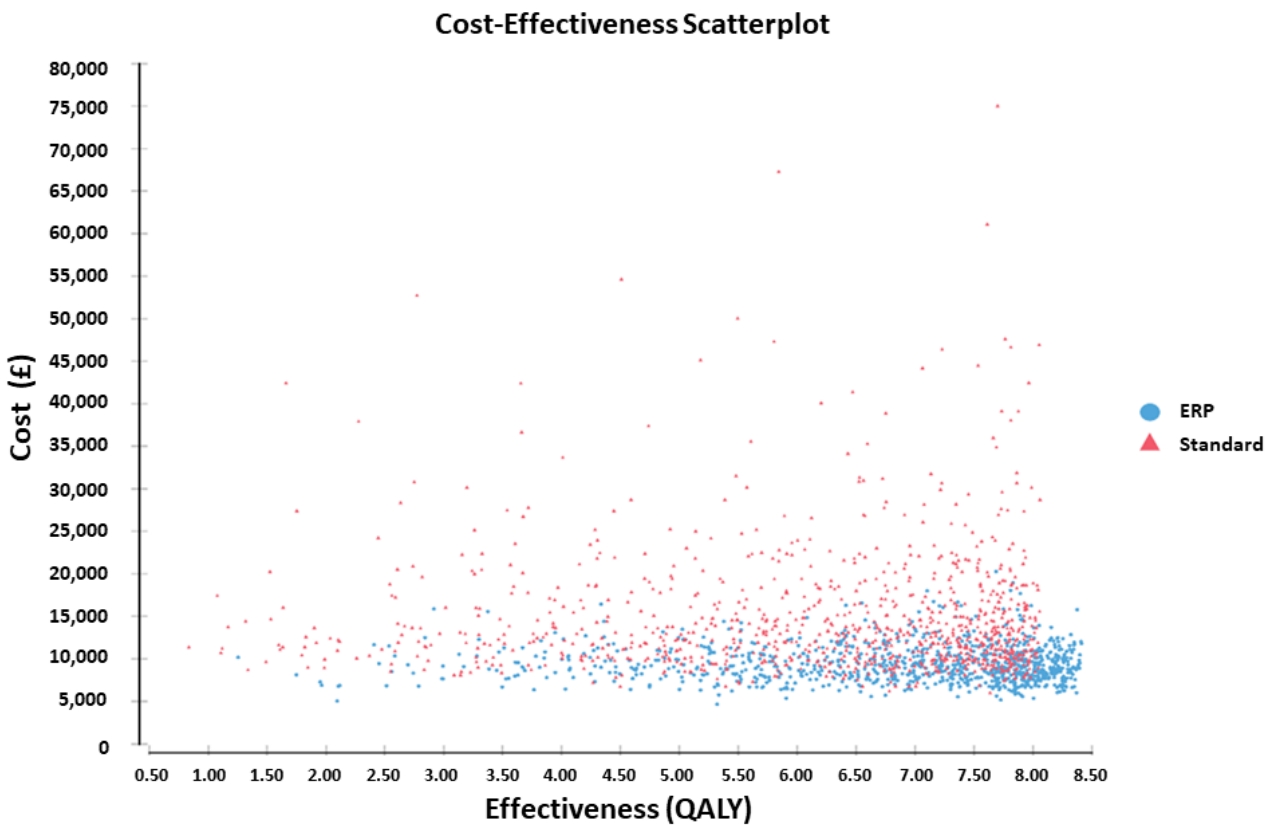
Figure 3. Scatter plot of 10,000 Monte Carlo simulations for the enhanced recovery program demonstrating the costs per quality-adjusted life years for 10,000 independent replications of a patient pathway. ERP: enhanced recovery program; QALY: quality-adjusted life year.



Long-term Mortality

All patients who underwent surgery were followed up at 5 years and data were analyzed at 1-, 2-, and 5-year intervals. Data are shown in Table 4, Table 5, and Table 6 below. Owing to different sample sizes over the 5-year period, Fisher exact test was used at 1 and 2 years and chi-square test at 5 years to determine statistical significance. Overall mortality was not significantly different between the ERP and standard care groups at 1 and 5 years (survival: 41/45, 91% in standard care group vs 45/46, 98% in ERP group at 1 year, *P*=.20, and 23/45, 51% in standard care group vs 24/46, 52% in ERP group at 5 years, *P*=.92). Patient survival at 2 years was found to be significantly improved (standard care group: 33/45, 73% vs ERP group: 42/46, 91%; *P*=.03), and on subgroup analysis, this difference was more profound in patients with malignant disease (standard care group: 24/36, 67% vs ERP group, 41/45, 91%; *P*=.01), which remained the case when isolating patients with colorectal metastases (standard care group: 18/26, 69% vs ERP group: 32/35, 91%; *P*=.04). Kaplan-Meier survival curves for all patients (Figure 4) and patients with malignant disease (Figure 5) are shown below.

Table 4. Long-term survival data of all patients.

Term	Survival of standard care group (n=45), n (%)	Survival of enhanced recovery program group (n=46), n (%)	*P* value
1 year	41 (91)	45 (98)	.20[a]
2 years	33 (73)	42 (91)	.03[a]
5 years	23 (51)	24 (52)	.92[b]

[a]Fisher exact test.

[b]Chi-square test. Choice of statistical test dependent upon the sample size.

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Table 5. Long-term survival of all patients with malignant disease.

Term	Survival of standard care group (n=36), n (%)	Survival of enhanced recovery program group (n=45), n (%)	*P* value
1 year	32 (89)	44 (98)	.17[a]
2 years	24 (67)	41 (91)	.01[a]
5 years	16 (44)	23 (51)	.55[b]

[a]Fisher exact test.
[b]Chi-square test. Choice of statistical test dependent upon the sample size.

Table 6. Long-term survival of patients with colorectal metastases.

Term	Survival of standard care group (n=26), n (%)	Survival of enhanced recovery program group (n=35), n (%)	*P* value
1 year	23 (88)	34 (97)	.30[a]
2 years	18 (69)	32 (91)	.04[a]
5 years	14 (54)	16 (46)	.53[b]

[a]Fisher exact test.
[b]Chi-square test. Choice of statistical test dependent upon the sample size.

Figure 4. Kaplan-Meier survival curves for all patients. ERP: enhanced recovery program.

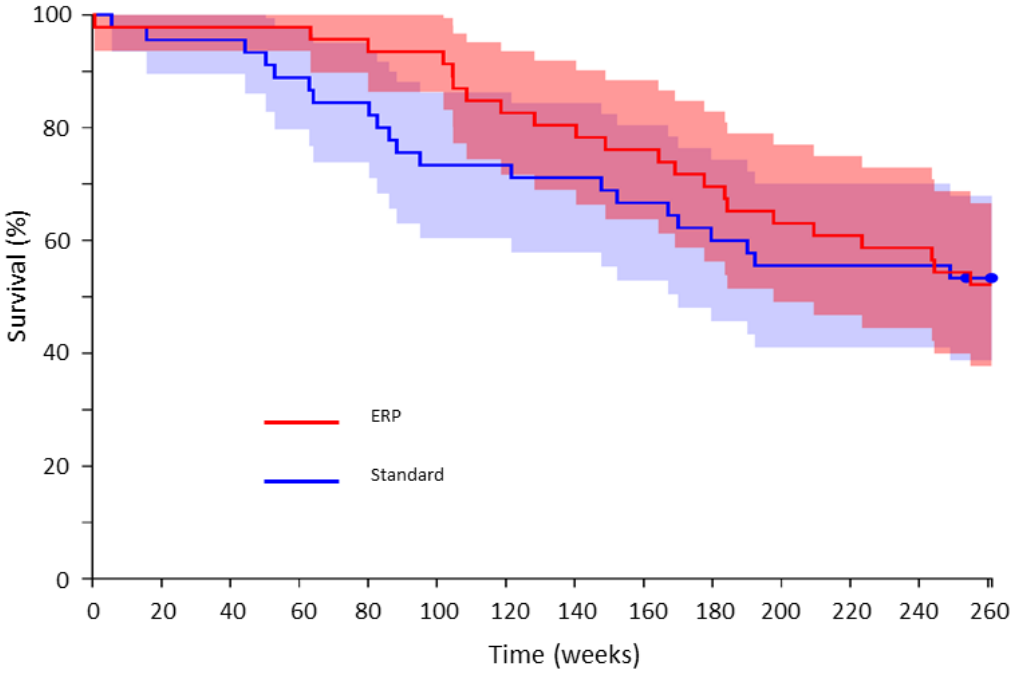

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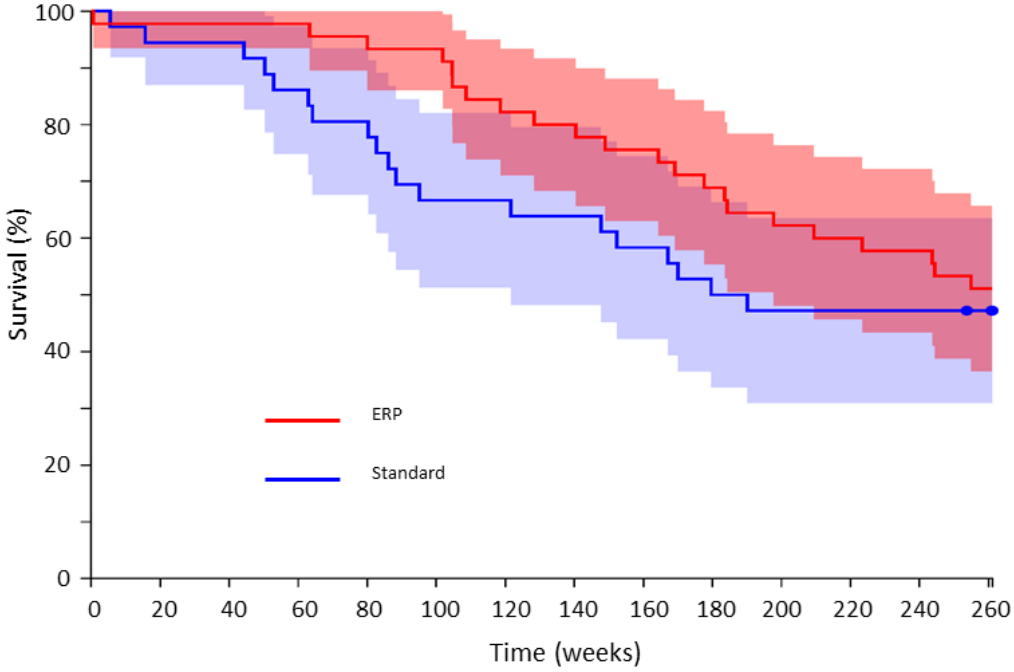
Figure 5. Kaplan-Meier survival curves for patients with malignant disease. ERP: enhanced recovery program.



Discussion

Analysis of both in-hospital and community costs showed significant savings for patients in the ERP group, despite inherent cost implications of the pathway itself, alongside reduced mortality at 2 years and the previously demonstrated reduced morbidity and hospital length of stay. Regarding the costs of implementation, the pathway includes a preoperative patient education meeting with a clinical specialist nurse. This was built into their routine preassessment hospital visit, thereby not increasing the burden upon the patient in terms of transport or time off work and not requiring additional nursing staff or appointments. After the surgery, patients in the ERP group received 2 physiotherapy visits per day as opposed to just 1. However, due to the reduced length of hospital stay, this equated to the same number of physiotherapy visits overall. Visits from the acute pain team were reduced due to routine removal of the epidural on postoperative day 2, thereby saving an average of 4 visits.

Importantly, there was no increase in community or primary care costs and having demonstrated an in-hospital cost saving following the implementation of ERP for liver resection, it is reassuring to conclude that costs and burdens have not simply been transferred into the community. In fact, patients in the ERP group required significantly fewer visits to their general practitioner in the first 4 weeks after their discharge, despite being home 3 days earlier. Patients also reported requiring significantly less help at home from friends and family in the first 2 weeks, thus also conferring secondary economic benefits on the part of those who would otherwise have potentially sacrificed time at work themselves.

This is the first time a paper comparing ERP versus standard care for open liver resection has reported on informal caregiver burden. Previous studies have included an economic analysis but did not include any community cost or burden analysis [6,23]. A recent study from Alberta, Canada demonstrated reduced community health service utilization following implementation of an ERP for colorectal surgery [24]. Interestingly, they did not show a significant reduction in primary care visits. Our study does not include any economic benefit from earlier return to work or variation in working days lost due to family or friend assistance, which may result from the ERP. The overall total group costs showed a significant £111,367.60 difference between the groups. However, much of this can be explained by 2 patients in the standard care group who experienced extended hospital stays and contributed over £97,500 of this cost difference. One patient stayed for 39 days with a total hospital cost of £34,623.30. The second patient unfortunately died from liver failure following a prolonged stay in level 2 with hospital costs of £62,921.40. If we exclude these 2 patients from our final analysis, there remains a significant median cost difference of £796.81 per patient between the 2 groups (£7823.88 vs £7027.07, P=.02). Note that hospital charges are not the same as direct costs. They serve as a proxy for cost as they are easy to collect but may not accurately resemble true economic cost. Differences between the economic cost, the accounting cost, and the charges to the patient may be different from actual resource use [25]. Being able to demonstrate cost-effectiveness of the ERP should be encouraging to decision makers, considering the implementation of such a program and the financial impact. At the current NHS-recommended threshold of £30,000 per QALY, the probability of the pathway being cost-effective is 73% based upon our analysis.

The ERP group had a significant improvement in survival at 2 years when compared with the standard care group—a finding that is perhaps more noteworthy, given the relatively small number of subjects in the study. The original trial was powered to detect a difference in the length of the hospital stay and thus, it was not anticipated that sufficient patients be recruited to demonstrate any difference in survival with an ERP. Although

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it is beyond the scope of this analysis to establish why there was improved survival in the ERP group, one possible contributing factor could be the different complication profile between the two groups. In concordance with previous studies, overall complications were significantly reduced in the ERP group [3]. Khuri et al demonstrated a link between the occurrence of postoperative complications and reduced survival time following a major surgery [26]. It follows that if patients experience fewer complications as a result of an ERP, then they may be expected to have improved long-term survival—a hypothesis supported by the findings of a recent systematic review that showed a relationship between postoperative morbidity and worse cancer outcomes following gastrointestinal surgery [27]. In our study, the ERP appears to confer a benefit for roughly the first 2 years following surgery but by 5 years, survival becomes equivalent to those who received standard care. This is contrary to the findings in the study by Khuri et al [26], where the survival benefit was sustained. It could be suggested that the convergence of the curves is a result of the natural history of the overall disease process experienced by patients who require liver resection, but little difference is seen between the groups at 5 years whether patients with benign disease are excluded or not. Only 10 patients of the 91 patients were found to have benign disease of whom 2 died within the 5-year follow-up period. Both were in the standard care group and both died after 2 years (3.7 and 4.8 years). This suggests a 5-year mortality of 20% for patients with benign disease compared to nearer 50% for those with malignant disease although it must be remembered the sample size here is very small. Another factor that may explain the disappearance of the survival benefit at 5 years is the significantly higher P-POSSUM scores in the ERP group, indicating that due to their premorbid health and severity of their surgery, these patients were at higher risk than those in the standard care group.

Overall, this study has shown that an ERP for open liver resection can improve medium-term survival, is cost-effective in both the hospital and community setting, and has the potential to further improve clinical outcomes and incur lower costs to society. In a climate searching for means to increase efficiency and simultaneously improve patient care, enhanced recovery offers the opportunity to achieve both. Initial investment in both money and time will likely be required but the returns have been shown, by this and other studies, to be worth the expense. As more studies are performed, the cost implications are likely to become clearer. For long-term survival rates, more studies would be required to help further establish the ongoing survival benefits, which may be incurred through the implementation of an ERP.

Acknowledgments

The authors thank Laura Spring, the hepatobiliary clinical nurse specialist who was instrumental in organizing the patient diary and helped with patient follow-up, Heather Gage who helped design the QoL analysis and the area under the curve calculation, Professor William Fawcett and Dr Pradeep Prabhu who provided anesthesia for a significant number of trial patients, and Tushna Vandrevala and Chris Fry who are supervisors from the University of Surrey.

Conflicts of Interest

MS has received travel reimbursement and speaker fees from Baxter and Edwards Lifescience and is on the advisory board of Deltex and Trevena.

Multimedia Appendix 1
Operation costs.
[DOCX File , 17 KB - periop_v4i1e16829_app1.docx]

Multimedia Appendix 2
Unit costs for community health care resources and quality-adjusted life years.
[DOCX File , 14 KB - periop_v4i1e16829_app2.docx]

References

1. Benzoni E, Molaro R, Cedolini C, Favero A, Cojutti A, Lorenzin D, et al. Liver resection for HCC: analysis of causes and risk factors linked to postoperative complications. Hepatogastroenterology 2007;54(73):186-189. [Medline: 17419257]
2. Jarnagin W, Gonen M, Fong Y, DeMatteo R, Ben-Porat L, Little S, et al. Improvement in perioperative outcome after hepatic resection: analysis of 1,803 consecutive cases over the past decade. Ann Surg 2002 Oct;236(4):397-406; discussion 406. [doi: 10.1097/01.SLA.0000029003.66466.B3] [Medline: 12368667]
3. Varadhan KK, Neal KR, Dejong CHC, Fearon KCH, Ljungqvist O, Lobo DN. The enhanced recovery after surgery (ERAS) pathway for patients undergoing major elective open colorectal surgery: a meta-analysis of randomized controlled trials. Clin Nutr 2010 Aug;29(4):434-440. [doi: 10.1016/j.clnu.2010.01.004] [Medline: 20116145]
4. van Dam RM, Hendry P, Coolsen M, Bemelmans M, Lassen K, Revhaug A, Enhanced Recovery After Surgery (ERAS) Group. Initial experience with a multimodal enhanced recovery programme in patients undergoing liver resection. Br J Surg 2008 Aug;95(8):969-975. [doi: 10.1002/bjs.6227] [Medline: 18618897]

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5. Stoot J, van Dam RM, Busch O, van Hillegersberg R, De Boer M, Olde Damink SWM, Enhanced Recovery After Surgery (ERAS) Group. The effect of a multimodal fast-track programme on outcomes in laparoscopic liver surgery: a multicentre pilot study. HPB (Oxford) 2009 Mar;11(2):140-144 [FREE Full text] [doi: 10.1111/j.1477-2574.2009.00025.x] [Medline: 19590638]
6. Lin D, Li X, Ye Q, Lin F, Li L, Zhang Q. Implementation of a fast-track clinical pathway decreases postoperative length of stay and hospital charges for liver resection. Cell Biochem Biophys 2011 Nov;61(2):413-419 [FREE Full text] [doi: 10.1007/s12013-011-9203-7] [Medline: 21556940]
7. MacKay G, O'Dwyer PJ. Early discharge following liver resection for colorectal metastases. Scott Med J 2008 May;53(2):22-24. [doi: 10.1258/rsmsmj.53.2.22] [Medline: 18549066]
8. Koea JB, Young Y, Gunn K. Fast track liver resection: the effect of a comprehensive care package and analgesia with single dose intrathecal morphine with gabapentin or continuous epidural analgesia. HPB Surg 2009;2009:271986 [FREE Full text] [doi: 10.1155/2009/271986] [Medline: 20029637]
9. Jones C, Kelliher L, Dickinson M, Riga A, Worthington T, Scott M, et al. Randomized clinical trial on enhanced recovery versus standard care following open liver resection. Br J Surg 2013 Jul;100(8):1015-1024. [doi: 10.1002/bjs.9165] [Medline: 23696477]
10. Hendry P, van Dam RM, Bukkems S, McKeown DW, Parks R, Preston T, Enhanced Recovery After Surgery (ERAS) Group. Randomized clinical trial of laxatives and oral nutritional supplements within an enhanced recovery after surgery protocol following liver resection. Br J Surg 2010 Aug;97(8):1198-1206. [doi: 10.1002/bjs.7120] [Medline: 20602497]
11. Coolsen M, Wong-Lun-Hing E, van Dam RM, van der Wilt AA, Slim K, Lassen K, et al. A systematic review of outcomes in patients undergoing liver surgery in an enhanced recovery after surgery pathways. HPB (Oxford) 2013 Apr;15(4):245-251 [FREE Full text] [doi: 10.1111/j.1477-2574.2012.00572.x] [Medline: 23458424]
12. Hughes M, McNally S, Wigmore S. Enhanced recovery following liver surgery: a systematic review and meta-analysis. HPB (Oxford) 2014 Aug;16(8):699-706 [FREE Full text] [doi: 10.1111/hpb.12245] [Medline: 24661306]
13. Ni T, Yang H, Zhang H, Meng H, Li B. Enhanced recovery after surgery programs in patients undergoing hepatectomy: A meta-analysis. World J Gastroenterol 2015 Aug 14;21(30):9209-9216 [FREE Full text] [doi: 10.3748/wjg.v21.i30.9209] [Medline: 26290648]
14. Lee L, Li C, Landry T, Latimer E, Carli F, Fried GM, et al. A systematic review of economic evaluations of enhanced recovery pathways for colorectal surgery. Ann Surg 2014 Apr;259(4):670-676. [doi: 10.1097/SLA.0b013e318295fef8] [Medline: 23673770]
15. Stowers M, Lemanu D, Hill A. Health economics in Enhanced Recovery After Surgery programs. Can J Anaesth 2015 Feb;62(2):219-230. [doi: 10.1007/s12630-014-0272-0] [Medline: 25391739]
16. Lee L, Mata J, Ghitulescu GA, Boutros M, Charlebois P, Stein B, et al. Cost-effectiveness of Enhanced Recovery Versus Conventional Perioperative Management for Colorectal Surgery. Ann Surg 2015 Dec;262(6):1026-1033. [doi: 10.1097/SLA.0000000000001019] [Medline: 25371130]
17. Khan S, Wilson T, Ahmed J, Owais A, MacFie J. Quality of life and patient satisfaction with enhanced recovery protocols. Colorectal Dis 2010 Dec;12(12):1175-1182. [doi: 10.1111/j.1463-1318.2009.01997.x] [Medline: 19594603]
18. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy 1990 Dec;16(3):199-208. [doi: 10.1016/0168-8510(90)90421-9] [Medline: 10109801]
19. National life tables: UK. Period life expectancy by age and sex for the UK. URL: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesunitedkingdomreferencetables [accessed 2020-10-02]
20. Straatman J, Cuesta MA, de Lange-de Klerk ESM, van der Peet DL. Long-Term Survival After Complications Following Major Abdominal Surgery. J Gastrointest Surg 2016 May;20(5):1034-1041 [FREE Full text] [doi: 10.1007/s11605-016-3084-4] [Medline: 26857591]
21. King P, Blazeby J, Ewings P, Franks P, Longman R, Kendrick A, et al. Randomized clinical trial comparing laparoscopic and open surgery for colorectal cancer within an enhanced recovery programme. Br J Surg 2006 Mar;93(3):300-308. [doi: 10.1002/bjs.5216] [Medline: 16363014]
22. Unit costs of health and social care 2011. URL: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2011/ [accessed 2020-10-12]
23. Page A, Gani F, Crowley K, Lee K, Grant M, Zavadsky T, et al. Patient outcomes and provider perceptions following implementation of a standardized perioperative care pathway for open liver resection. Br J Surg 2016 Apr;103(5):564-571. [doi: 10.1002/bjs.10087] [Medline: 26859713]
24. Thanh NX, Chuck AW, Wasylak T, Lawrence J, Faris P, Ljungqvist O, et al. An economic evaluation of the Enhanced Recovery After Surgery (ERAS) multisite implementation program for colorectal surgery in Alberta. Can J Surg 2016 Dec 01;59(6):415-421 [FREE Full text] [doi: 10.1503/cjs.006716] [Medline: 28445024]
25. Williams SV, Finkler SA, Murphy CM, Eisenberg JM. Improved cost allocation in case-mix accounting. Med Care 1982 May;20(5):450-459. [doi: 10.1097/00005650-198205000-00002] [Medline: 6808255]
26. Khuri S, Henderson W, DePalma R, Mosca C, Healey N, Kumbhani D, Participants in the VA National Surgical Quality Improvement Program. Determinants of long-term survival after major surgery and the adverse effect of postoperative

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complications. Ann Surg 2005 Sep;242(3):326-41; discussion 341. [doi: 10.1097/01.sla.0000179621.33268.83] [Medline: 16135919]

27. Shimada H, Fukagawa T, Haga Y, Oba K. Does postoperative morbidity worsen the oncological outcome after radical surgery for gastrointestinal cancers? A systematic review of the literature. Ann Gastroenterol Surg 2017 Apr;1(1):11-23 [FREE Full text] [doi: 10.1002/ags3.12002] [Medline: 29863169]

Abbreviations

ERP: enhanced recovery program
EQ-5D: EuroQoL-5 dimension
NHS: National Health Service
QALY: quality-adjusted life year
QoL: quality of life

Edited by R Lee; submitted 29.10.19; peer-reviewed by M Das, T Bergmo, J Banks; comments to author 05.01.20; revised version received 15.12.20; accepted 10.01.21; published 01.02.21.

Please cite as:
Jones CN, Morrison BL, Kelliher LJS, Dickinson M, Scott M, Cecconi Ebm C, Karanjia N, Quiney N
Hospital Costs and Long-term Survival of Patients Enrolled in an Enhanced Recovery Program for Open Liver Resection: Prospective Randomized Controlled Trial
JMIR Perioper Med 2021;4(1):e16829
URL: http://periop.jmir.org/2021/1/e16829/
doi:10.2196/16829
PMID:33522982

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Viewpoint

An Online Calculator to Better Understand the Impact of False-Negative COVID-19 Polymerase Chain Reaction Test Results in the Context of Anesthesia Providers

Sean Runnels[1], MD; John Frederick Pearson[1], MD; Jon Dean Samuels[2], MD; Rohan Kirit Panchamia[2], MD

[1]Department of Anesthesiology, University of Utah School of Medicine, Salt Lake City, UT, United States

[2]Department of Anesthesiology, Weill Cornell Medical College, New York, NY, United States

Corresponding Author:
Rohan Kirit Panchamia, MD
Department of Anesthesiology
Weill Cornell Medical College
525 E 68th St
New York, NY, 10065
United States
Phone: 1 2127462755
Email: rkp9004@med.cornell.edu

Abstract

What does the COVID-19 false-negative exposure problem mean in the context of a local anesthesia practice? We present a customizable online calculator designed to quantify and better understand individual and aggregate provider exposure risk.

(JMIR Perioper Med 2021;4(1):e26316) doi:10.2196/26316

KEYWORDS

COVID-19; testing; false-negative rate; calculator; provider exposure; airway management; anesthesia; exposure; false negative; risk; transmission; infectious disease

Recently, Van Zundert et al [1] provided an excellent summary of the state of affairs concerning airway management and the Coronavirus Disease (COVID-19). One piece of the risk puzzle is a better understanding of the risk anesthesia providers face during the pandemic. A joint statement by the American Society of Anesthesiologists and the Anesthesia Patient Safety Foundation references a Centers for Disease Control and Prevention document recommending that patients scheduled for surgery should be screened for SARS-CoV-2 by polymerase chain reaction (PCR) testing, and if negative, the operating room staff can perform the surgery using only contact and droplet precautions [2,3].

The low sensitivity of SARS-CoV-2 PCR testing can lead to a high rate of false negatives [4,5]. These false-negative results—patients who are infected but test negative—may be most consequential to operating room staff, especially if donned in protective gear recommended for droplet precautions and not in gear recommended for aerosolizing procedures in COVID-19–positive patients. This is especially important as detection of the virus is unlikely prior to symptom onset [6].

Appreciating the true false-negative rate is an important start in determining provider-specific risk. An excellent online calculator is available to illustrate the impact of test sensitivity and pretest probability on the rate of false negatives [7]. We recommend this as a resource that may enhance one's understanding of this issue in general. The obvious next step is to ask, "What does the false-negative rate mean in the local context of anesthesia to an individual provider or a group practice?" Perhaps a better way to state this is, "What does it mean to me and my practice?"

To allow dynamic, contextualized, and accessible understanding of the magnitude of risk posed by the false-negative problem in the context of an anesthesia provider, we have developed an online COVID-19 false-negative exposure risk calculator specifically for anesthesia providers. The Runnels & Pearson online calculator includes variable inputs of (1) SARS-CoV-2 prevalence, (2) PCR test sensitivity (estimated at 70%), (3) airways managed per day by an individual provider, and (4) number of airways managed by group per day. Each of these inputs is customizable, allowing inputs to reflect current local conditions or even model past or potential future scenarios. The calculator can be accessed online [8]. Calculated statistical outputs are (1) the false-negative rate; (2) cases performed per false-negative encounter; (3) individual provider workdays per

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false-negative exposure; and (4) number of providers encountering a false negative per day, week, and month. The University of Utah tests all patients within 3 days prior to elective surgery. On November 15, 2020, prevalence was 1.5% (49,575 active cases/3,280,000 people) [9]. Outputs are displayed for sensitivities of 70% and 90% in Figures 1 and 2.

Figure 1. False-negative exposure risk calculator outputs for the University of Utah Department of Anesthesiology for November 15, 2020, at a COVID-19 test sensitivity of 70%. PCR: polymerase chain reaction.

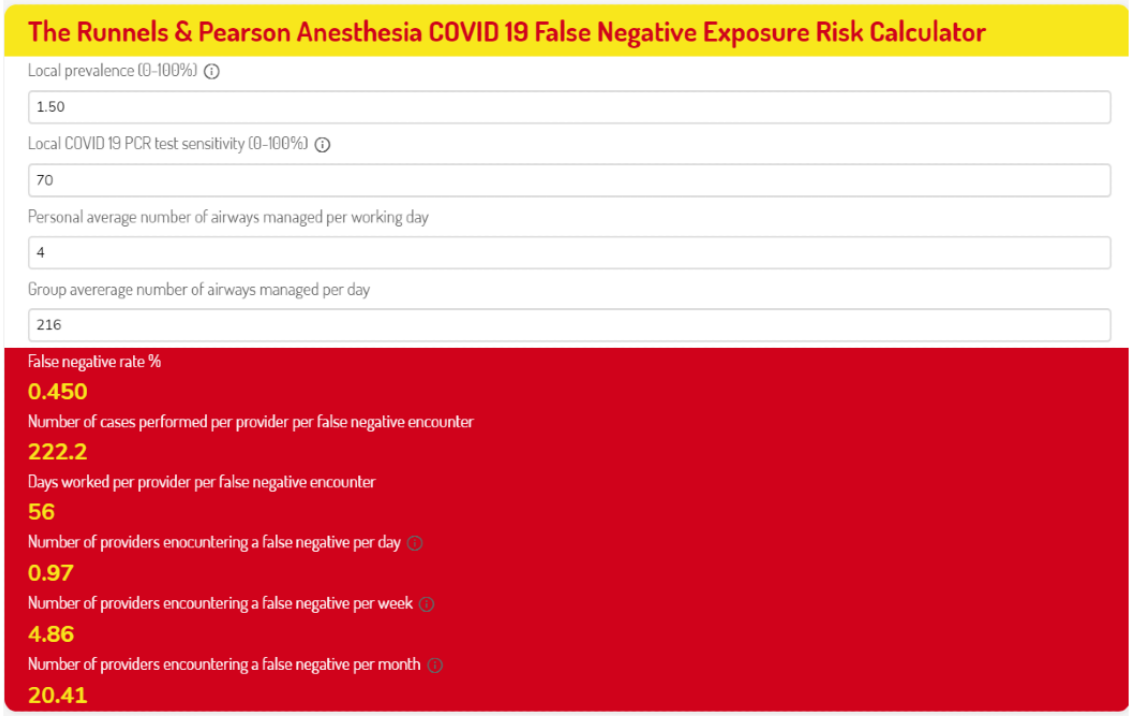
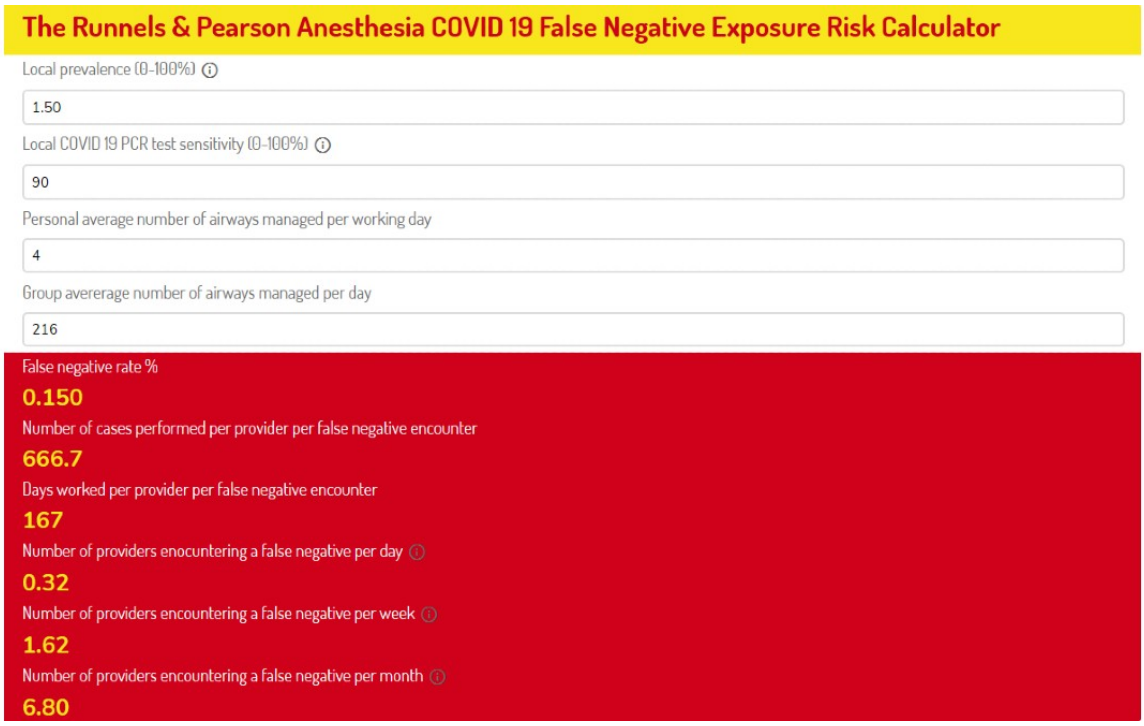


Figure 2. False-negative exposure risk calculator outputs for the University of Utah Department of Anesthesiology for November 15, 2020, at a COVID-19 test sensitivity of 90%. PCR: polymerase chain reaction.



Our goal is to create indices that have real meaning to providers and decision makers across disparate health care systems. This risk calculator can offer real-time, contextualized information that may offer part of a solution to the conundrum of uniform guidelines for heterogeneous risk. Perhaps guidelines of the future may be based on quantifiable risk thresholds, allowing guidelines to better fit the local situation on the ground. In addition, the Runnels & Pearson calculator may be used as a retrospective research tool to better understand how individual hospital or system guidelines concerning personal protective

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equipment (PPE) were made. For instance, a timeline comparing anesthesia provider risk and PPE guideline issuance might help us understand if these guidelines were data driven in nature.

Care must be taken to ensure that inputs into this calculator accurately reflect the data on the ground. We make no recommendations about sources for data inputs. Even with imprecise data inputs, this tool may be useful in generating a general understanding of risk in the context of anesthesia and operating rooms. We believe a general understanding can help facilitate better policy, guidelines, and allocation of resources in the service of improving the safety of patients and providers.

Authors' Contributions

SR and JFP were responsible for conception and design of the work. All authors contributed to the drafting, revising, and approval of the final version of the manuscript.

Conflicts of Interest

SR is the CEO of Through The Cords LLC as well as an associate professor of anesthesiology at the University of Utah. The other authors have no conflicts of interest. Calconic.com is an online calculator host company that enables the creation of online calculators disseminated on the web. No data or metadata pertaining to users are collected by any of the authors of this work or any entity associated with these authors. Hosting of the online calculator is currently free of charge and should remain so to users in the long term. Any fees associated with Calconic hosting in the future, should those arise, will be paid for directly by the authors.

References

1. Van Zundert TC, Barach P, Van Zundert AA. Revisiting safe airway management and patient care by anaesthetists during the COVID-19 pandemic. Br J Anaesth 2020 Dec;125(6):863-867 [FREE Full text] [doi: 10.1016/j.bja.2020.09.004] [Medline: 32972715]
2. The ASA and APSF joint statement on perioperative testing for the COVID-19 virus. American Society of Anesthesiologists. 2020. URL: https://www.apsf.org/news-updates/asa-and-apsf-joint-statement-on-perioperative-testing-for-the-covid-19-virus/ [accessed 2020-08-29]
3. Interim infection prevention and control recommendations for healthcare personnel during the coronavirus disease 2019 (COVID-19) pandemic. Centers for Disease Control and Prevention. 2020. URL: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html [accessed 2020-11-04]
4. Kucirka LM, Lauer SA, Laeyendecker O, Boon D, Lessler J. Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction-Based SARS-CoV-2 Tests by Time Since Exposure. Ann Intern Med 2020 Aug 18;173(4):262-267 [FREE Full text] [doi: 10.7326/M20-1495] [Medline: 32422057]
5. Arevalo-Rodriguez I, Buitrago-Garcia D, Simancas-Racines D, Zambrano-Achig P, Del Campo R, Ciapponi A, et al. False-negative results of initial RT-PCR assays for COVID-19: A systematic review. PLoS One 2020;15(12):e0242958 [FREE Full text] [doi: 10.1371/journal.pone.0242958] [Medline: 33301459]
6. Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA 2020 Jun 09;323(22):2249-2251. [doi: 10.1001/jama.2020.8259] [Medline: 32374370]
7. Watson J, Whiting PF, Brush JE. Interpreting a covid-19 test result. BMJ 2020 May 12;369:m1808. [doi: 10.1136/bmj.m1808] [Medline: 32398230]
8. The Runnels & Pearson anesthesia COVID 19 false negative exposure risk calculator. Calconic. URL: https://www.calconic.com/calculator-widgets/anesthsia-provider-covid-false-negative-riskcalulator/5f295910a67f460029bccc70?layouts=true [accessed 2020-11-15]
9. COVID-19 surveillence. Utah Department of Heath. 2020. URL: https://coronavirus.utah.gov/case-counts/# [accessed 2020-11-15]

Abbreviations

PCR: polymerase chain reaction
PPE: personal protective equipment

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Edited by R Lee; submitted 06.12.20; peer-reviewed by K Lee, T Quinn; comments to author 01.02.21; revised version received 07.03.21; accepted 15.03.21; published 14.04.21.

Please cite as:
Runnels S, Pearson JF, Samuels JD, Panchamia RK
An Online Calculator to Better Understand the Impact of False-Negative COVID-19 Polymerase Chain Reaction Test Results in the Context of Anesthesia Providers
JMIR Perioper Med 2021;4(1):e26316
URL: https://periop.jmir.org/2021/1/e26316
doi:10.2196/26316
PMID:33851930

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Original Paper

Utilization of the iOS Shortcuts App to Generate a Surgical Logbook Tool: Feasibility Study

Daniel Thompson[1], MBBS

Department of Vascular Surgery, St Vincent's Hospital Melbourne, Fitzroy, Australia

Corresponding Author:
Daniel Thompson, MBBS
Department of Vascular Surgery
St Vincent's Hospital Melbourne
41 Victoria Pde
Fitzroy, 3065
Australia
Phone: 61 92312211
Email: Daniel.thompson@svha.org.au

Abstract

Background: Surgical audit is an essential aspect of modern reflective surgical practice and is key to improving surgical outcomes. The surgical logbook is an important method of data collection for both personal and unit audits; however, current electronic data collection tools, especially mobile apps, lack the minimum recommended data fields.

Objective: This feasibility study details the creation of a free, effective surgical logbook tool with the iOS Shortcuts app and investigates the time investment required to maintain a surgical logbook with this tool. In addition, we investigate the potential utility of the Shortcuts app in creating medical data collection tools.

Methods: Using the iOS Shortcuts app, we created a shortcut "Operation Note," which collects surgical logbook data by using the minimum and extended audit data sets recommended by the Royal Australasian College of Surgeons. We practically assessed the feasibility of the tool, assessing the time requirement for entry, accuracy, and completeness of the entered data.

Results: The shortcut collected accurate and useful data for a surgical audit. Data entry took on average 65 seconds per case for the minimum data set, and 135 seconds per case for the extended data set, with a mean difference of 68 seconds ($P<.001$; 95% CI 61.6-77.7).

Conclusions: This feasibility study demonstrates the utility of the iOS Shortcuts app in the creation of a surgical logbook and the time-consuming nature of data collection for surgical audit. Our iOS Operation Note shortcut is a free, rapid, and customizable alternative to currently available logbook apps and offers surgical trainees and consultants a method for recording surgical operations, complications, and demographic data.

(JMIR Perioper Med 2021;4(1):e24644) doi:10.2196/24644

KEYWORDS

app; audit; data collection; data; feasibility; medical education; mHealth; surgery; surgical audit; surgical education; utility

Introduction

Surgical audit is one of the mainstays of reflective practice and improving patient outcomes. Audit allows for the capture of operative results, operation numbers, billing information, and complications. In Australia, it is mandatory to maintain a logbook when undertaking surgical training with the Royal Australasian College of Surgeons (RACS); RACS provides a minimum and extended suggested data set for both trainee and consultant logbooks [1].

Owing to the increasing complexity of health care, electronic information systems are recommended to be utilized to capture clinical data. The use of hospital medical record systems relies heavily on accurate data being captured by staff and may not include the required fields or enough detail to facilitate successful audit of practice [1]. Hence, RACS recommends that surgeons maintain personal logbooks [1]. Many surgeons utilize technology, such as mobile phones, to collect these data; however, on recent review, the applications available in the Australian market fall short of both the suggested minimum and extended data set, highlighting the need for a better surgical logbook tool [2].

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The most commonly reported barrier to successful logbook-keeping is the time required for data entry and maintenance [3]. A key difficulty is navigating the balance between increased data capture for more complete and useable information and the extended amount of time required to enter such data. Data overload is "a danger to a successful audit" and this balance must be carefully considered when designing an audit tool [1]. The RACS minimum data set consists of 12 data points, and the extended data set contains 24 data points [1].

In Australia, the primary surgical audit tool for trainees and consultants is the Morbidity Audit and Logbook Tool (MALT) and is mandatory for surgical trainees in certain colleges [4]. MALT contains both the minimum and extended data set and is a useful tool in audit and reflective practice. However, there are some barriers to mobile access to MALT, including a multistep login process, reliance on an internet connection, and the absence of a mobile app, which may limit its use in prospective data capture [2].

It is unclear what proportion of surgeons prospectively maintain a logbook versus those who carry out a retrospective review prior to a regular audit. Prospective record-keeping has the added advantage of being more accurate and resolves issues regarding the evaluation of operative volumes due to computerized or paper-based medical record systems, which may be missed if coded incorrectly, or in procedures with multiple surgeons or specialties [5]. Mobile apps offer an accessible, rapid, and easy-to-use method of prospective record keeping.

Electronic data capture tools have been widely adopted by researchers in medicine and provide an effective way of prospectively collecting data for storage and tabulation [6]. More than 100 different data capture tools are currently available, ranging from those specifically designed for capturing clinical data, such as REDCap, to informal survey software, such as SurveyMonkey and Google Forms [7]. Formal data collection tools such as REDCap and Open Data Kit are usually compliant with established national data security regulations; however, they often have a requirement for some knowledge of computer programming, with an associated learning curve [8]. Nonclinical tools such as SurveyMonkey and Google Forms require an active internet connection and lack end-to-end encryption [8]. Despite these concerns, many institutions have utilized simple data capture tools owing to the simplicity of their implementation and their cost-effectiveness [9].

While RACS provides a guideline regarding the minimum and extended criteria required for a logbook, certain surgeons and specialties may benefit from customization, allowing for further categorization of operative data for personal or research purposes and more efficient data entry [3].

The iOS Shortcuts app (hereinafter referred to as "Shortcuts") was released in 2019 and allows users to create custom macros allowing for data entry, manipulation, and storage on any iOS-compatible devices [10]. Rather than computer programming, Shortcuts provides the user with a list of tasks to select, which are then customized and transformed to a workflow to be activated by the user. The software utilizes end-to-end encryption when transmitting data and is stored on an encrypted and secure iCloud server.

There is currently no literature describing the potential use of Shortcuts in the collection of clinical data. This feasibility study highlights the utility of the application and demonstrates its functionality in the creation of a surgical logbook tool.

Methods

A custom shortcut was designed using the freely available iOS Shortcuts app on an iPad Pro (11-inch) device running on iOS 13.7.

A Numbers (Apple, Cupertino) Spreadsheet document was created in a suitable folder of the iPad storage with the address "/Shortcuts/Logbook/Logbook.numbers" (Multimedia Appendix 1). A sheet and table-titled logbook were created (Multimedia Appendix 1, Sheet 1). An additional file and table were created for the extended data sheet (Multimedia Appendix 2). These files have been provided as a Microsoft Excel spreadsheet to facilitate review from both Windows and Apple devices; however, the shortcut tool requires the Apple Numbers file format to operate successfully.

Using Shortcuts, we generated a workflow macro for the logbook. The workflow consists of multiple data entry blocks, consisting of a prompt for the user with a question, followed by the appearance of a text box accepting the user-entered data, and finally storage as a variable (Figure 1). There are three ways this system is used: a free text entry (Figure 2) and 2 menu choice operations; that is, list or menu (Figures 2 and 3). An agile software development approach was utilized with iterative design, development, testing, and refinement [11].

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Figure 1. Example of a shortcut in operation with a user prompt to enter the operation name.

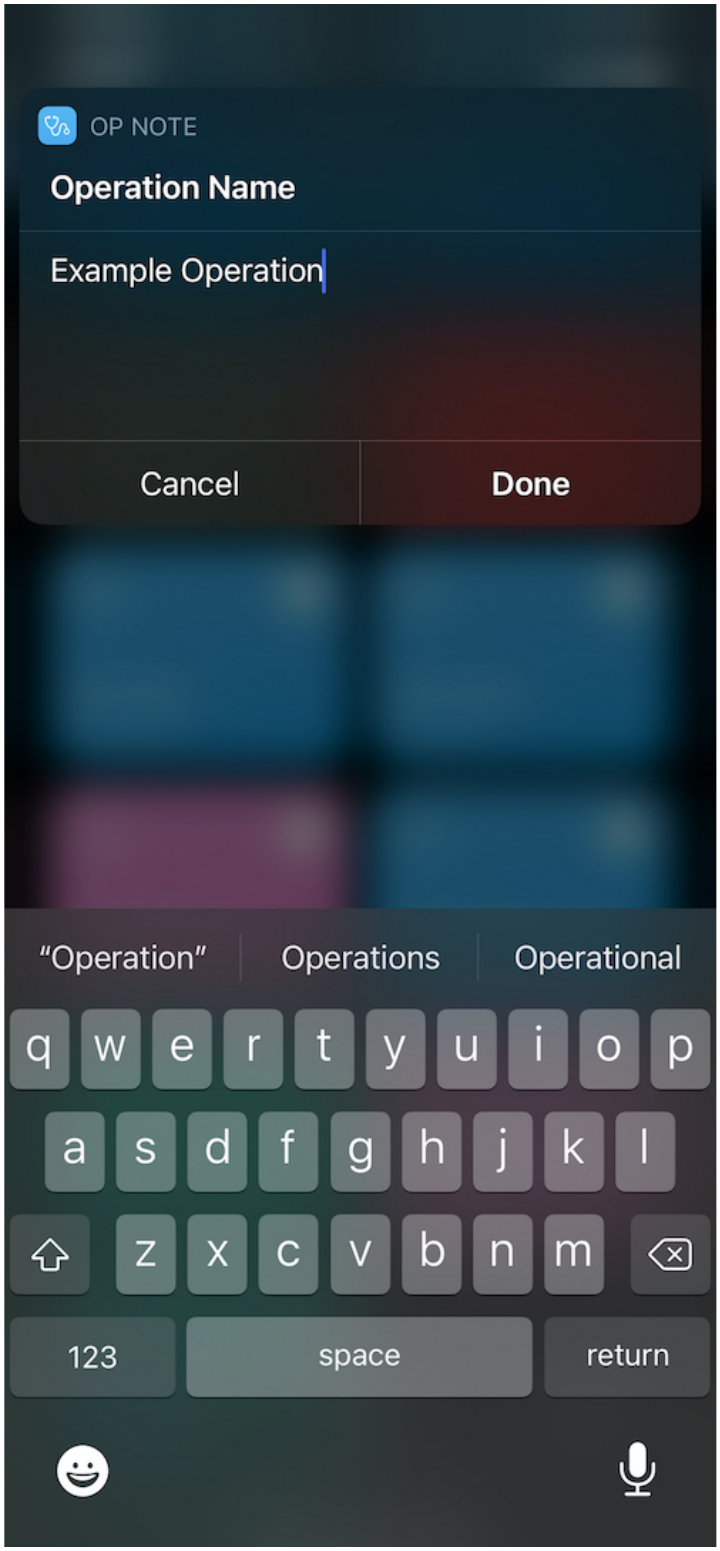

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Figure 2. Workflow, free text, and "Choose from list" data entry shortcuts in the iOS Shortcuts app.

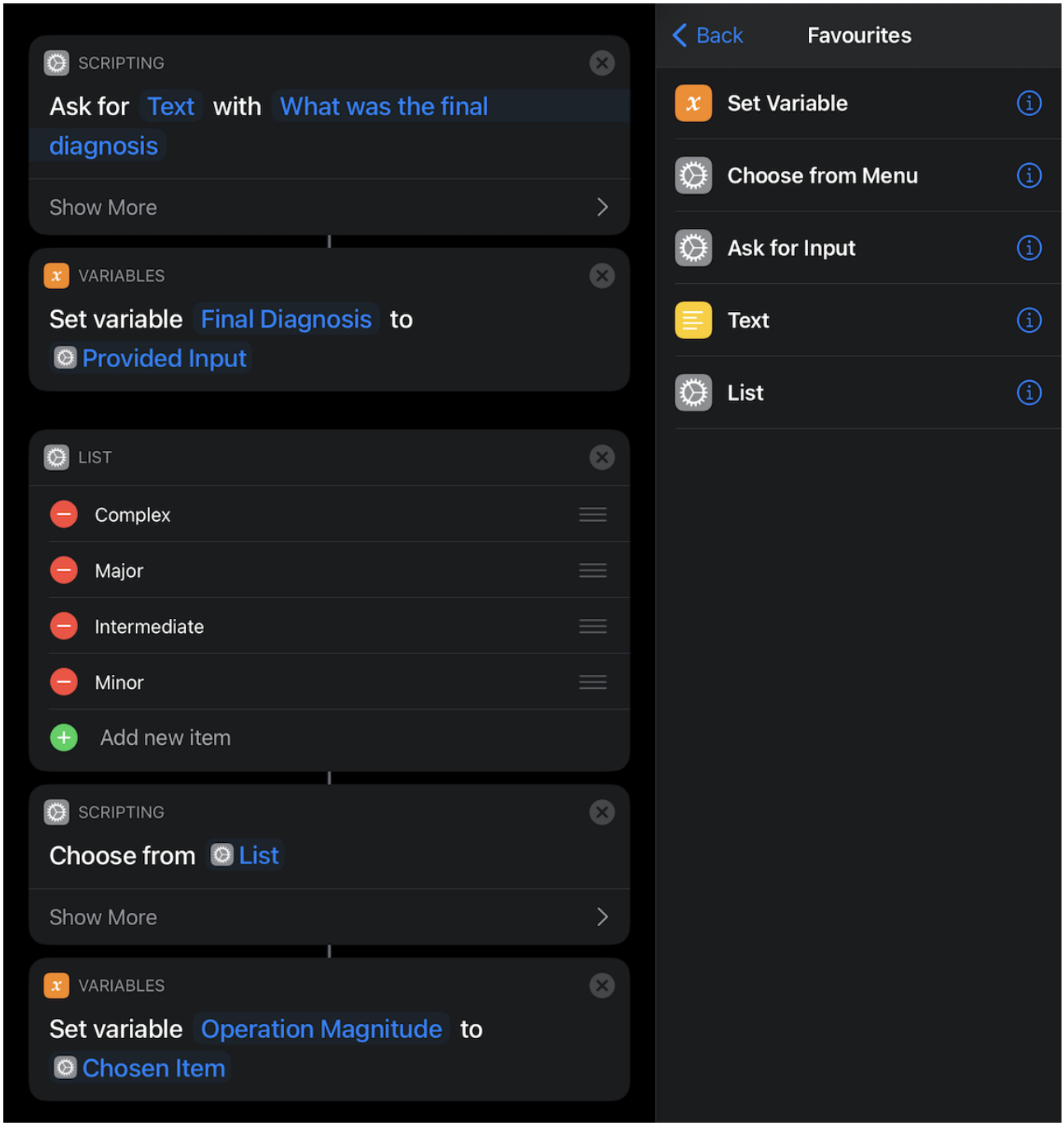

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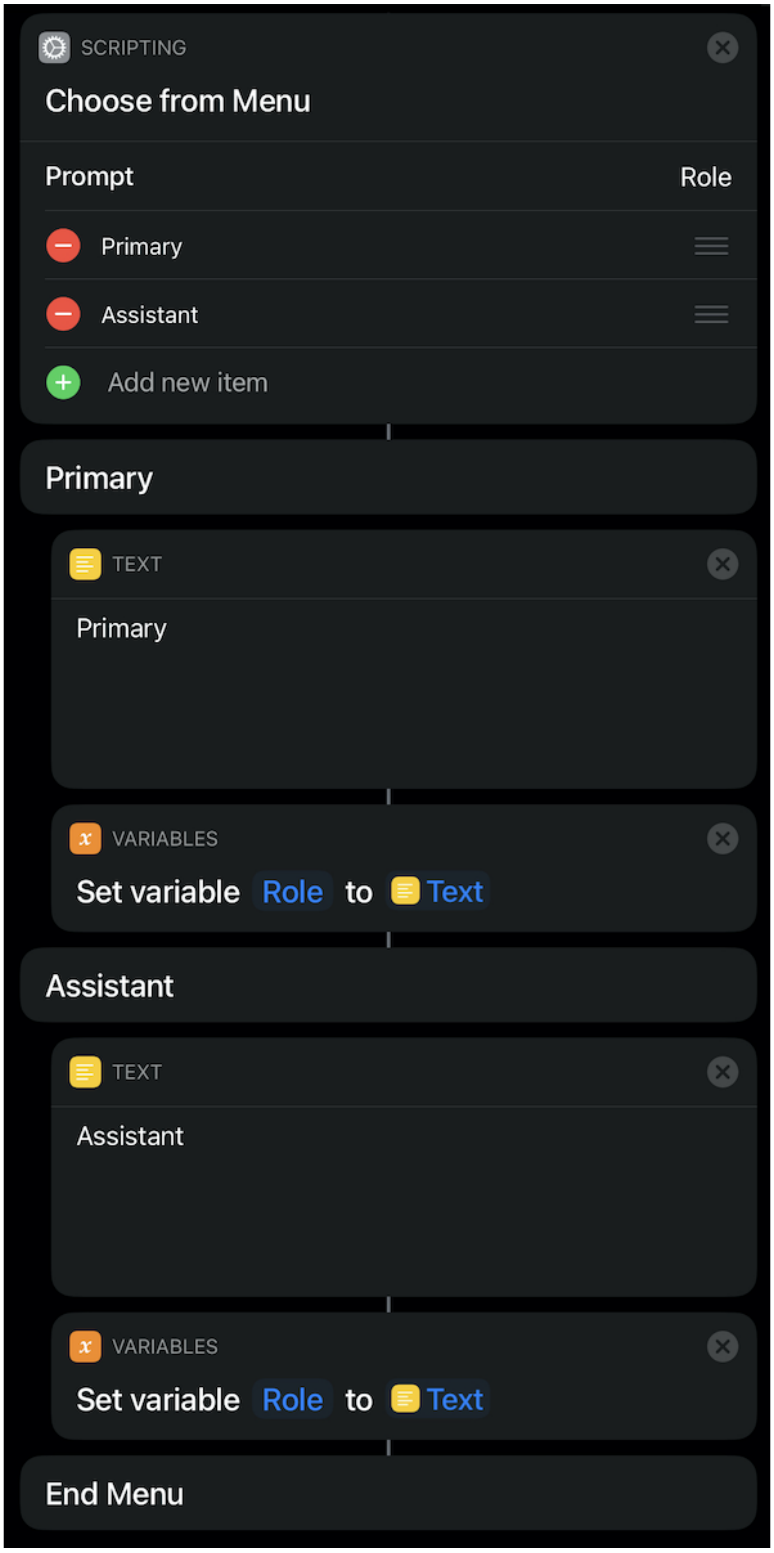
Figure 3. Workflow and "Choose from menu" data entry shortcut in the iOS Shortcuts app.



In total, 2 shortcuts were designed with 2 separate receiving spreadsheets, first with the minimum RACS recommended data set, both of which are freely available through the iCloud service [12,13].

For the purpose of evaluation, a timer was started at the initiation of the shortcut and stopped upon data storage, in order to determine the time taken to use this tool. This timer was excluded for the provided example shortcuts and spreadsheets.

Upon conclusion of the shortcut, the Numbers spreadsheet was opened, and the listed variables were stored as a new row with variables entered into each subsequent column.

A second spreadsheet was created to demonstrate the analytical capability of the logbook tool for audit purposes. This example data analysis tool is provided in Multimedia Appendix 1 (Sheet 2). Prefilled formulas were created for case numbers, operation categories, patient gender, complications and grades, and length of stay, and automatically updated as new cases were entered.

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The tool was practically assessed for feasibility, with a surgical registrar entering 20 mock operations into the minimum and extended data field shortcuts. The operation notes were created randomly by computer software with a selection of common operations, indications, and demographic data. Feasibility was assessed by assessing the time required for data entry, the completeness of the entered data, and the accuracy of the filled spreadsheet with the required clinical data.

Results

Shortcuts performed well during testing and has been shown to collect both complete and useful data. The average data entry time for an operation across both minimum and extended data sets was 100 seconds.

In total, 20 cases were recorded with the minimum and extended data sets. The average time for completion of the minimum data set was 65 seconds, with a total time of 21 minutes 43 seconds for 20 cases. The average time for completion of the extended data set was 135 seconds, with a total time of 46 minutes 58 seconds for 20 cases. There was a mean difference of 68 seconds per case between the minimum and extended data sets compared to the minimum data set (P<.001; 2-tailed t_{19}=17.52; 95% CI 61.6-77.7). Table 1 summarizes the time requirements for data entry with the Shortcut.

Table 1. Time requirement for data entry in the minimum and extended data sets.

Week	Cases (n)	Average time to complete data entry (seconds)	Total time spent entering cases, minutes (seconds)
1 (minimum data set)	20	65	21 (43)
2 (extended data set)	20	135	46 (58)

The built-in example data analysis table functioned well, having captured the entered data and presented basic statistical analysis in real time. Multimedia Appendix 1 (Sheet 2) summarizes the data fields used. On analyzing the spreadsheet, 100% of the required fields were filled successfully, since the shortcut design does not allow incomplete data to be entered.

Discussion

Principal Findings

Surgical audit is key for modern successful surgical practice, allowing for reflection on case numbers, outcomes, complications, and deaths. A surgical logbook is a key tool for collecting these data and can be utilized in both personal and unit audits. Surgeons are increasingly turning to technology to complete tasks more efficiently and accurately; however, mobile logbook offerings in the Australian setting still do not meet the recommended minimum requirements [2]. The main barrier for the completion of a prospective surgical logbook is the time required for completion, and mobile apps hold the potential for a tool that is portable, accurate, and time saving.

The most commonly reported barrier to the maintenance of a surgical logbook is time [1]. Collection of such a wide range of data points, as exemplified by the extended data set, requires an easy-to-use, rapid, and efficient tool to accurately record data in a timely manner. Retrospective data collection may be less accurate owing to time elapsed since the operation date, and automatic audit from hospital-recorded data may not include all required fields. Our tool provides an accurate, customizable system for collecting audit data.

MALT is a surgical auditing tool available to trainees and consultants as part of their college membership and is also available to resident medical officers as part of the JDocs Framework of the RACS (costing AU $345=US $268.14 annually) [14]. This cost may be a barrier to its use. This is especially relevant as previous studies have demonstrated that residents who complete a logbook are more likely to complete surgical procedures; as such, an accessible and free logbook app (eg, Shortcuts developed herein) may be of use in junior physicians' reflective practice and potentially increase their motivation to be involved in the operating theater [5].

Ahmadi et al [2] explored a number of available logbook tools in their recent review and reported that none of them collected sufficient data to meet the minimum and extended data sets recommended by the RACS. Shortcuts collects all required fields for either the minimum or extended data sets. While custom data collection tools such as REDCap and Open Data Kit could be utilized to create a surgical logbook tool, they would require extensive coding and app development skills to create a mobile interface [15].

Our app was created without the use of code, utilizing Shortcut's "drag and drop" interface, which allowed for accessible and easy creation of a data collection tool on a mobile device. This software is well suited for an app such as the surgical logbook, and the provided example files can be utilized as a framework to create a specialty-specific logbook with user customization. Our shortcut program is freely available on the internet [12,13] and can be used quickly after installation (Multimedia Appendices 1 and 2) in a Numbers spreadsheet file format.

Shortcuts has been designed to allow for easy end user modification, and it provides a framework from which surgeons, trainees, and residents can create a surgical logbook that suits their needs. For example, in vascular surgery, a categorical field may be added for arterial, venous, or renal access fields, as found in the Australasian Vascular Audit [16]. The tool allows for audit data to be generated from a spreadsheet, like with many other data collection tools, and users can design their own analysis spreadsheet to provide relevant summary statistics and graphs. An example of basic statistical analysis is provided in Multimedia Appendix 1 (Sheet 2), which allows for rapid review of a number of summary statistics.

Further improvements to our app could include integration with a web-based system such as MALT, importing and saving operation notes for future reference, and barcode scanning for universal record number entries in hospitals that use compatible

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barcode labels. At present, no logbook apps that allow integration with MALT are available [2].

Limitations

A primary limitation of this tool in some jurisdictions is the use of iCloud storage. This is necessitated by the design limits of Shortcuts, which, at present, prevents local iOS storage. This limitation is shared among many currently available apps and is a challenge for mobile data collection tools in general; these tools often have advanced security features but lack official data regulation accreditation [17-19]. The iCloud service is highly secure, requiring 2-factor authentication and utilizing end-to-end encryption; these features are not shared by more informal survey tools such as SurveyMonkey. iCloud's security potentially meets the regulatory specifications for protocols such as the Health Insurance Portability and Accountability Act or General Data Protection Regulation; however, the lack of signed industrial agreements has limited formal accreditation [20].

Australia does not have a formal health information act such as Health Insurance Portability and Accountability Act or General Data Protection Regulation; rather, organizations and clinicians are required to take "reasonable steps" to protect the privacy of patient data [19]. Accordingly, the RACS MALT service utilizes 2048-bit key encryption to secure connections but has no formal data protection regulatory agreements in place [21]. Shortcuts potentially meets the minimum standards for data protection; however, it is the responsibility of users to ensure that data are collected in line with the data protection regulations within their jurisdictions.

Another limitation of both this app and other audit tools, including MALT, is that prospectively entering operation details at the time of the operation may result in nonrecording of delayed complications [1]. Shortcuts allows for immediate postoperative complications to be entered, such as hemorrhage or death; however, complications that occur in the days and weeks following an operation need to be entered manually and retrospectively upon their occurrence, in the data spreadsheet. Further development of this app and the inclusion of an additional complications shortcut may allow for automation of data entry related to complications.

Conclusions

This study shows the feasibility of utilizing the iOS Shortcuts app as a data collection tool, as revealed through the creation of a surgical logbook. Shortcuts is highly customizable and has a wide range of potential applications including data collection; moreover, it can be used as an interactive medical algorithm tool that allows for the creation of clinical interaction guidelines based on user input in the future.

Acknowledgments

I acknowledge the valuable contribution of Dr Peter Hingston, St Vincent's Hospital (Melbourne, Australia).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Minimum data set spreadsheet.
[XLSX File (Microsoft Excel File), 13 KB - periop_v4i1e24644_app1.xlsx]

Multimedia Appendix 2
Extended data set spreadsheet.
[XLSX File (Microsoft Excel File), 10 KB - periop_v4i1e24644_app2.xlsx]

References

1. Royal Australasian College of Surgeons. 2013. URL: https://umbraco.surgeons.org/media/1350/surgical_audit_and_peer_review_guide_2014.pdf [accessed 2020-09-19]
2. Ahmadi N, Sritharan N, Aruliah E. A Critical review of surgical logbook applications for the android and iOS platforms in the Australian setting. AMJ 2018;11(3):195-201 [FREE Full text] [doi: 10.21767/AMJ.2018.3354]
3. Boult M, Maddern GJ. Clinical audits: why and for whom. ANZ J Surg 2007 Jul;77(7):572-578. [doi: 10.1111/j.1445-2197.2007.04140.x] [Medline: 17610696]
4. Royal Australasian College of Surgeons. 2013. URL: https://umbraco.surgeons.org/media/1048/2020-guide-to-set-booklet.pdf [accessed 2020-09-19]
5. Harrington CM, Kavanagh DO, Ryan D, Dicker P, Lonergan PE, Traynor O, et al. Objective scoring of an electronic surgical logbook: Analysis of impact and observations within a surgical training body. Am J Surg 2017 Nov;214(5):962-968. [doi: 10.1016/j.amjsurg.2017.07.028] [Medline: 28781101]
6. El Emam K, Jonker E, Sampson M, Krleza-Jerić K, Neisa A. The use of electronic data capture tools in clinical trials: Web-survey of 259 Canadian trials. J Med Internet Res 2009 Mar 09;11(1):e8 [FREE Full text] [doi: 10.2196/jmir.1120] [Medline: 19275984]

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7. Best Survey Software | 2020 Reviews of the Most Popular Tools and Systems. Capterra. URL: https://www.capterra.com/electronic-data-capture-software/ [accessed 2020-09-19]
8. Patridge EF, Bardyn TP. Research Electronic Data Capture (REDCap). J Med Libr Assoc 2018 Jan 12;106(1):142. [doi: 10.5195/jmla.2018.319]
9. Yoldi-Negrete M, Morales-Cedillo I, Navarro-Castellanos I, Fresán-Orellana A, Panduro-Flores R, Becerra-Palars C. Combining Adobe Forms and Dropbox to Obtain a Low-Cost Electronic Data Collection System. Telemed J E Health 2019 Mar;25(3):250-256. [doi: 10.1089/tmj.2018.0029] [Medline: 29932811]
10. Shortcuts app release notes. Apple Inc. 2019 Apr 29. URL: https://support.apple.com/en-us/HT209087 [accessed 2020-09-19]
11. Highsmith J, Cockburn A. Agile Software Development: The Business of Innovation. Computer 2001;34(9):120.
12. Operation Note - Minimum Data Sheet. iCloud. URL: https://www.icloud.com/shortcuts/24ab2d21cff64d74abbe58ebc6d52b95 [accessed 2021-04-26]
13. Operation Note - Extended Data Sheet. iCloud. URL: https://www.icloud.com/shortcuts/26c234e567ce46b4b2f94c5f2fc4181e [accessed 2021-04-26]
14. What is JDocs? JDocs Framework - Royal Australasian College of Surgeons. URL: https://jdocs.surgeons.org/ [accessed 2021-04-27]
15. Maduka O, Akpan G, Maleghemi S. Using Android and Open Data Kit Technology in Data Management for Research in Resource-Limited Settings in the Niger Delta Region of Nigeria: Cross-Sectional Household Survey. JMIR Mhealth Uhealth 2017 Nov 30;5(11):e171 [FREE Full text] [doi: 10.2196/mhealth.7827] [Medline: 29191798]
16. Bourke BM, Beiles CB, Thomson IA, Grigg MJ, Fitridge R. Development of the Australasian vascular surgical audit. J Vasc Surg 2012 Jan;55(1):164-169 [FREE Full text] [doi: 10.1016/j.jvs.2011.06.102] [Medline: 21906906]
17. Yetisen AK, Martinez-Hurtado JL, da Cruz Vasconcellos F, Simsekler MCE, Akram MS, Lowe CR. The regulation of mobile medical applications. Lab Chip 2014 Mar 07;14(5):833-840. [doi: 10.1039/c3lc51235e] [Medline: 24425070]
18. Tovino S. Privacy and Security Issues with Mobile Health Research Applications. J Law Med Ethics 2020 Mar;48(1_suppl):154-158. [doi: 10.1177/1073110520917041] [Medline: 32342741]
19. Kelly JM. Australia Would Benefit from US-Style Health Information Security Regulation. ANU J Law Technol 2020;1(2):1-24 [FREE Full text]
20. Alder S. Is iCloud HIPAA Compliant? HIPAA Journal. 2019 Aug 01. URL: https://www.hipaajournal.com/icloud-hipaa-compliant/ [accessed 2020-09-28]
21. System security: Information about MALT's data safety and security. Royal Australasian College of Surgeons. URL: https://www.surgeons.org/research-audit/morbidity-audits/morbidity-audit-and-logbook-tool/accessing-using-malt/system-security [accessed 2020-09-28]

Abbreviations

MALT: Morbidity Audit and Logbook Tool
RACS: Royal Australasian College of Surgeons

Edited by G Eysenbach, L Buis; submitted 09.12.20; peer-reviewed by R Lundin, S Tierney, J Shenson, S Reis; comments to author 04.01.21; revised version received 04.01.21; accepted 17.04.21; published 13.05.21.

Please cite as:
Thompson D
Utilization of the iOS Shortcuts App to Generate a Surgical Logbook Tool: Feasibility Study
JMIR Perioper Med 2021;4(1):e24644
URL: https://periop.jmir.org/2021/1/e24644
doi:10.2196/24644
PMID:33983132

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Original Paper

Short-Term Wearable Sensors for In-Hospital Medical and Surgical Patients: Mixed Methods Analysis of Patient Perspectives

Meera Joshi[1,2], MBBS, PhD; Stephanie Archer[1*], PhD; Abigail Morbi[1*], BSc, MBBS; Sonal Arora[2*], PhD; Richard Kwasnicki[1], PhD; Hutan Ashrafian[1], PhD; Sadia Khan[2], DM; Graham Cooke[3], PhD, FRCP; Ara Darzi[1], FRCS

[1]Department of Surgery and Cancer, Imperial College London, London, United Kingdom
[2]Chelsea and Westminster Hospital NHS Foundation Trust, London, United Kingdom
[3]Department of Infectious Disease, Wright-Fleming Institute, London, United Kingdom
[*]these authors contributed equally

Corresponding Author:
Meera Joshi, MBBS, PhD
Department of Surgery and Cancer
Imperial College London
South Kensington Campus
London
United Kingdom
Phone: 44 0207589
Email: meera.joshi03@imperial.ac.uk

Abstract

Background: Continuous vital sign monitoring using wearable sensors may enable early detection of patient deterioration and sepsis.

Objective: This study aimed to explore patient experiences with wearable sensor technology and carry out continuous monitoring through questionnaire and interview studies in an acute hospital setting.

Methods: Patients were recruited for a wearable sensor study and were asked to complete a 9-item questionnaire. Patients responses were evaluated using a Likert scale and with continuous variables. A subgroup of surgical patients wearing a Sensium Vital Sign Sensor was invited to participate in semistructured interviews. The Sensium wearable sensor measures the vital signs: heart rate, respiratory rate, and temperature. All interview data were subjected to thematic analysis.

Results: Out of a total of 500 patients, 453 (90.6%) completed the questionnaire. Furthermore, 427 (85.4%) patients agreed that the wearable sensor was comfortable, 429 (85.8%) patients agreed to wear the patch again when in hospital, and 398 (79.6%) patients agreed to wear the patch at home. Overall, 12 surgical patients consented to the interviews. Five main themes of interest to patients emerged from the interviews: (1) centralized monitoring, (2) enhanced feelings of patient safety, (3) impact on nursing staff, (4) comfort and usability, and (5) future use and views on technology.

Conclusions: Overall, the feedback from patients using wearable monitoring sensors was strongly positive with relatively few concerns raised. Patients felt that the wearable sensors would improve their sense of safety, relieve pressure on health care staff, and serve as a favorable aspect of future health care technology.

(JMIR Perioper Med 2021;4(1):e18836) doi:10.2196/18836

KEYWORDS

patient feedback; patient evaluation; questionnaire; interview; qualitative

Introduction

Delayed detection of patient deterioration in hospitals is a major cause of morbidity and mortality and is mostly caused by human-related monitoring failure [1-3]. Patients' psychological parameters are altered during deterioration, particularly their vital signs, which are recognized early on [4,5]. Vital sign changes measured as part of routine clinical care for hospitalized patients may be present several hours prior to the onset of clinical events such as cardiac arrest, death, and intensive care unit admission [6]. Unfortunately, existing systems are unable to detect patient deterioration rapidly, and 39% of acute emergency patients admitted to critical care units are referred late [1].

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In the United Kingdom, the National Early Warning Scoring (NEWS) System is used to detect clinical deterioration and improve patient safety. This is an aggregate scoring system that measures vital signs [3]. A score is allocated to each vital sign parameter, and high scores indicate patient deterioration [3]. If a patient has an NEWS of 0, a minimum of 12 hourly observations are recommended [3]. Among most patients in a general ward, observations are made 4-6 hours apart, but the frequency is increased for patients in a more critical condition [3]. Continuous invasive monitoring is only feasible in high-dependency units and not in the general ward setting where better noninvasive monitoring methods are needed. The latest lightweight sensors offer the potential for continuous monitoring of in-hospital patients.

Some previous studies have reviewed the reliability of wearable devices [4,5]. However more studies are needed to elucidate the performance of wearable devices [6] and to understand the perspectives of patients using them. The last few years have seen a drastic increase in wearable sensors in various clinical contexts from continuous monitoring during pregnancy [7] and assessment of patients with sleep apnea [8] and multiple sclerosis [9]. More studies have reviewed the patient adherence to and satisfaction with new technologies, with greater emphasis on patient feedback [9].

This study aimed to explore patient experiences with wearable sensor technology and carry out continuous monitoring through questionnaire and in-depth semistructured interviews in an acute hospital setting.

Methods

Study Design

A mixed methods approach was adopted to evaluate the breadth and depth of patient experience with a wearable sensor technology. To evaluate the breadth, patients recruited in a wearable patch study were asked to complete a questionnaire; semistructured interviews were held for a subgroup of patients to explore their experience with the sensor in detail.

Ethics

Ethical approval was granted by Yorkshire & The Humber - Leeds East Research Ethics Committee (reference number 17/YH/0296).

Patient Recruitment

All patients were recruited in a wearable patch study performed at West Middlesex University hospital—a busy hospital located in northwest London serving an ethnically diverse population. For recruited patients not understanding English (written or spoken), efforts were made to identify an appropriate translator to enable informed consent.

Sensium Sensor

Acutely unwell patients admitted to hospital were provided the Sensium Vital Sign Sensor (The Surgical Company) in addition to undergoing standard monitoring of vital signs by nurses.

The Sensium wearable sensor measures the vital signs: heart rate (HR), respiratory rate (RR), and temperature. The sensor is a one-off sensor with a battery life of 5 days; for longer hospitalization periods, an additional sensor is required. This sensor is lightweight, disposable, and waterproof. It transmits data wirelessly via low-power radio frequency signals to engineered bridges, which further transmit the data to a server. The data flow from the sensor to the virtual server via a bridge before being transmitted via Wi-Fi to smartphone apps. Figure 1 shows the sensor placement on a patient's chest. The sensor was placed by either trained health care professionals looking after the patient or the research team. The patch was attached to the anterior chest wall, using two standard disposable electrocardiography (ECG) electrodes (Red-Dot2560, 3M Co). Surgical tape was used to secure the temperature probe in the axilla.

A previously reported predictive strategy is used to calculate the HR based on the RR interval [10]. The RR is derived from changes in thoracic impedance. A very small current is injected through the ECG electrodes. Changes in thoracic impedance are detected as variations in voltage (V) measured at the ECG electrodes. Inhalation (peak resistance) and exhalation (trough resistance) are detected from a 60-second segment of an IP waveform to calculate the median RR. Temperature is measured using a calibrated thermistor placed in the patient's axilla. Individual vital sign parameters are measured and processed in a time-dependent manner.

Once the vital signs are measured, it is transmitted to a microchip in the sensor, which has an inbuilt processing unit that transmits the average HR values as beats per minute and RR as breaths per minute, to the nearest bridge. These data are then transmitted to the central server [10], allowing digital alerts to be sent to health care staff through smartphones or electronic health records (Figure 2).

Data security is critical when using wearable technology. The Sensium system is ISO 27001 compliant, safe, and secure. The Sensium patches are uniquely identified through a machine-readable serial number, which can be matched to a patient ID band on the Sensium server with the use of a bar code scanner. No patient-identifiable information is communicated from the Sensium patch to the Sensium bridge, except for the device serial number and the HR, RR, and temperature values. After information transfer from the Sensium bridge to the secure Sensium server, the values derived from the patch are contextualized with patient-identifiable demographic information, which is usually obtained from the Patient Administration System. The Sensium patch transmits data to the Sensium bridge every 2 minutes and receives positive feedback from the Sensium server that the data have been received. If the Sensium bridge is out of range or the server yields no positive feedback, the patch continuously attempts communication until successful. The Sensium patch stores up to 3 hours of data locally and transmits this information to a Sensium bridge once back in range.

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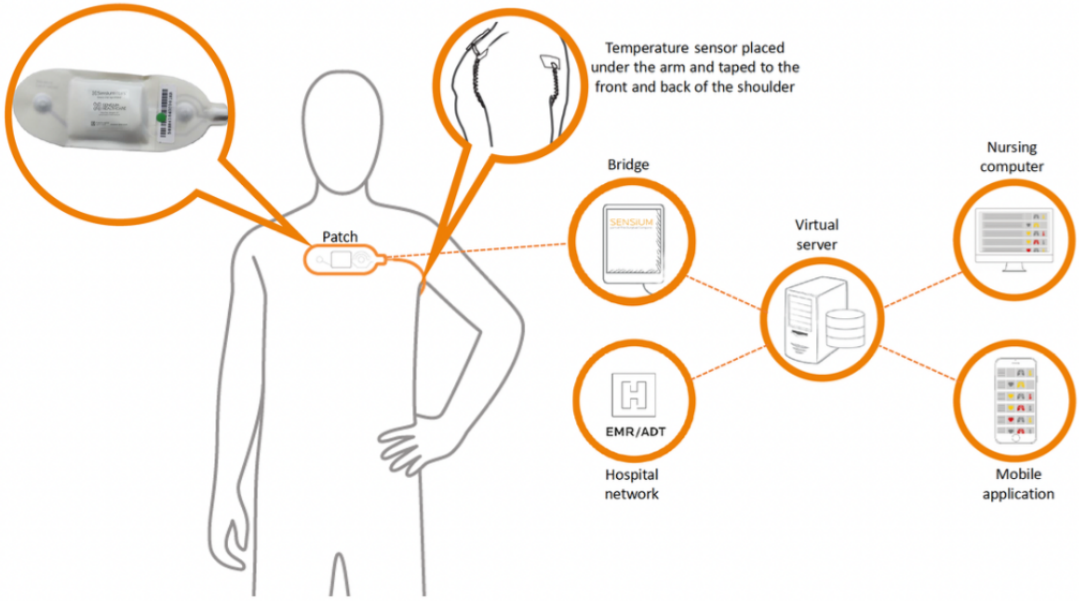
Figure 1. The Sensium wearable sensor being placed on a patient's chest. The image was reproduced with permission from Sensium, Abingdon, UK.

Figure 2. The Sensium wearable sensor demonstrating data transmission to the server and then to the mobile apps or computers. The image was reproduced with permission from Sensium, Abingdon, UK.



Questionnaire

All patients who had worn the sensor during the wearable patch study were invited to complete a questionnaire, which was previously piloted with volunteers. The questionnaire was adapted from the Systems Usability Scale—a reliable tool for assessing the reliability of a device [11]. This 9-item questionnaire was scored on a 5-point Likert scale ranging from strongly agree, agree, neutral, disagree, and strongly disagree (1=strongly agree, 2=agree, 3=neutral, 4=disagree, 5=strongly disagree, and 6=no data). The questionnaire encompassed five main themes: patient comfort, understanding, safety, and whether patients would wear the device again in the hospital or at home. A copy of the questionnaire can be found in Multimedia Appendix 1. The questionnaire was a paper-based questionnaire completed after the hospitalization period on sensor removal.

Semistructured Interviews

A subgroup of the recruited patients was invited to participate in an in-depth semistructured interview. All interviews were conducted by the lead researcher (MJ), using a prepared topic guide, which was previously evaluated by healthy volunteers. The questions were open-ended and focused on the following aspects: patient understanding, continuous monitoring, comfort, problems of any kind, potential future changes, and patient perception of potential future home monitoring technologies. An example of an interview question is "How do you feel about being monitored with the wearable sensor?" Interviews were audio-recorded and transcribed verbatim.

Analysis

Questionnaire Data

Data were analyzed using SPSS (version 25, IBM Corp). Consistent with previous similar studies [12-14], the scores for

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each question were considered continuous variables. Means (SD) values were calculated per question.

Semistructured Interviews

Interview data were subjected to thematic analysis [15]. Thematic analysis facilitates the identification, analysis, and determination of reporting patterns (themes) within data sets and the organization and provision of depth. Initial codes were developed by MJ and were independently reviewed by a second coder (AM); these codes were discussed and refined until final themes were generated.

Results

Patient Demographics

In total, 453 of 500 (90.6%) patients who had worn the wearable sensor completed the questionnaire, of whom 231 (51%) were female, and the mean age was 57 (range 18-95) years. The sample was representative of the overall study population. All patients wore the sensor throughout their stay of 2 days on average.

A total of 12 patients (male: n=6, 50%) participated in the semistructured interviews. Patients were recruited from various medical and surgical admitting wards, and their mean age was 49 (range 23-73) years. Detailed patient information is provided in Table 1.

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Table 1. Patient demographics.

Patient #	Specialty	Sex	Age (years)	Employment status	Ethnicity	Presenting complaint	Frailty	Residence	Past medical history	Infection
1	Surgical	M	71	Retired	White, British	Deranged renal function, high stoma output	Independent	Own home	Laparotomy, gall bladder and ascending colon removed 11/2017, post op leak and further laparotomy 3 weeks later	N
2	Surgical	M	25	Student	White, British	Perforation, had a laparotomy	Independent	Own home	N/A[a]	Y
3	Surgical	M	20	Employed	White, British	Appendicitis	Independent	Own home	Cyst removed from Jaw	Y
4	Surgical	F	33	Self-employed	Other White background	Acute cholecystitis	independent	Own home	N/A	Y
5	Surgical	F	27	Employed	Mixed background	Terminal ileal Crohn disease	Independent	Own home	N/A	Y
6	Surgical	F	48	Employed	White, British	Appendicitis, had a laparotomy, thought to be Meckel's	Independent	Own home	N/A	Y
7	Surgical	F	73	Retired	White, British	ERCP[b] pancreatitis	Independent walks with crutches (amputee has prosthesis)	Own home	N/A	N
8	Surgical	M	66	Employed	White, British	Cholecystitis/biliary colic	Independent	Own home	N/A	N
9	Surgical	M	70	Employed	Other White background	Irreducible paraumbilical hernia, abdominal pain	Independent	own home	N/A	Y
10	Surgical	F	54	Employed	White, British	Unwell and diarrhea	Independent	Own home	Appendicectomy, hysterectomy, breast lump removal	Y
11	Surgical	M	74	Unknown	White, British	Rib fracture falling off a ladder	Independent	Own home	N/A	N
12	Surgical	F	40	Employed	Black/Black, British African	Subacute bowel obstruction	Independent	Own home	Several bowel operations, repeated bowel obstructions	N

[a]N/A: not applicable.

[b]ERCP: endoscopic retrograde cholangiopancreatography.

Questionnaire Outcomes

The questionnaire results were positive overall. Descriptive statistics for each questionnaire item are provided in Table 2. In total, 427 of 500 (85.4%) patients agreed that the wearable sensor was comfortable to wear and 27 (5.4%) reported that the sensor was cumbersome. Only 11 (2.2%) patients thought the system was complex, while 416 (83.2%) agreed that they knew whom to contact if problems arose. Furthermore, 397 (79.4%) patients did not feel the need for extensive information before sensor use. The majority of patients (n=445, 89.0%) agreed that they understood the purpose of the wearable sensor and 347 (69.2%) felt safer being monitored. Regarding future use, most patients agreed that they would wear the sensor again when in the hospital (n=429, 85.8%) and at home (n=398, 79.6%).

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Table 2. Descriptive statistics for each questionnaire item.

Please rate your level of agreement with the following statements	Strongly agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly disagree, n (%)	No data, n (%)	Total number, n (%)
1. The wearable patch was comfortable to wear	224 (44.8)	203 (40.6)	14 (2.8)	11 (2.2)	1 (0.2)	47 (9.4)	500 (100)
2. I found this system unnecessarily complex	1 (0.2)	10 (2.0)	12 (2.4)	277 (55.4)	152 (30.4)	48 (9.6)	500 (100)
3. I understood what the wearable patch was for	213 (42.6)	232 (46.4)	4 (0.8)	3 (0.6)	0 (0.0)	48 (9.6)	500 (100)
4. I felt safer being monitored whilst wearing the wearable patch	132 (26.4)	214 (42.8)	90 (18.0)	16 (3.2)	0 (0.0)	48 (9.6)	500 (100)
5. I knew who to contact if I had any problems with the wearable patch	154 (30.8)	262 (52.4)	15 (3.0)	19 (3.8)	2 (0.4)	48 (9.6)	500 (100)
6. I would wear the wearable patch again when in hospital	175 (35.0)	254 (50.8)	12 (2.4)	9 (1.8)	0 (0.0)	50 (10.0)	500 (100)
7. I found this system very cumbersome to wear	4 (0.85)	23 (4.6)	19 (3.8)	263 (52.6)	142 (28.4)	49 (9.8)	500 (100)
8. I would wear the wearable patch in my home	163 (32.6)	235 (47.0)	17 (3.4)	30 (6.0)	6 (1.2)	49 (9.8)	500 (100)
9. I needed to learn a lot of things before I could get going with this system	11 (2.2)	32 (6.4)	11 (2.2)	263 (52.6)	134 (26.8)	49 (9.8)	500 (100)

Semistructured Interview Outcomes

Five main themes emerged from the interviews: (1) centralized monitoring, (2) safety, (3) impact on nursing staff, (4) comfort and usability, and (5) the future and views on technology. These themes and their contributing subthemes are summarized in Figure 3.

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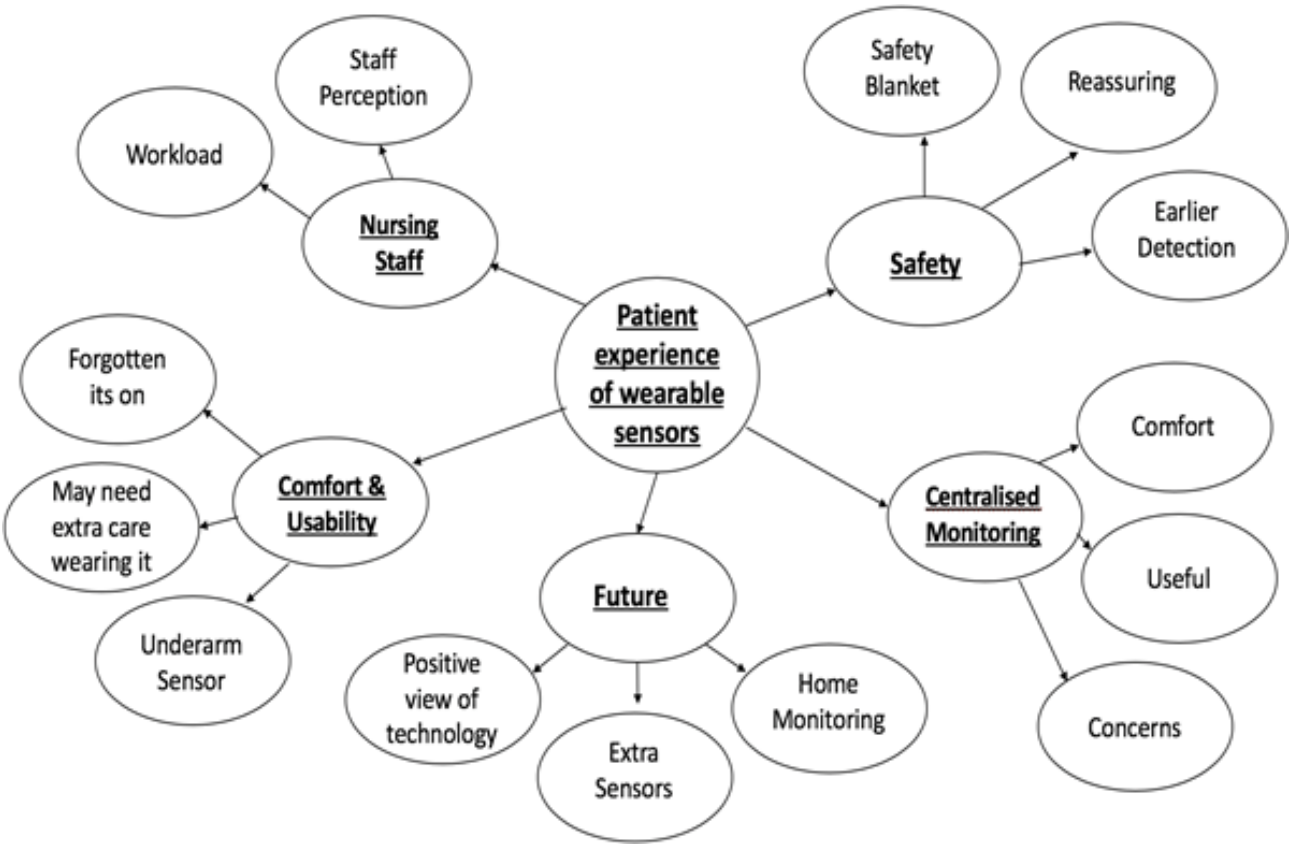
Figure 3. Themes and subthemes from thematic analysis.



Centralized Monitoring

Centralized monitoring was consistently described by patients and included many of the other themes. Centralized monitoring provided patients with greater peace of mind, and patients felt that health care staff were always around if a problem arose.

> *Remote monitoring so your doctor can sit at the desk and see his patients, how you're doing.* [Patient 9, male, aged 70 years]

Patients described feeling reassured knowing that they were being monitored even when health care staff were not at their bedside.

> *I think it would be really reassuring for people, especially as the data is centralized.* [Patient 10, female, aged 54 years]

However, one patient was concerned about the patch potentially not allowing for any monitoring as no feedback was provided to the patients.

> *I was worried it wasn't really recording when it needed to be recording.* [Patient 8, male, aged 66 years]

Central monitoring was discussed among all interviewed patients, which provided patients with greater peace of mind and reassurance. One patient was concerned about the lack of feedback to patients.

Safety

All interviewed patients commented on an enhanced feeling of patient safety while wearing the patch. The extra layer of support provided them a feeling of reassurance.

> *I felt like there was a second safety blanket around me, almost, and that I was constantly in amongst the nurses. I appreciate that the nurses do their obs as frequently as they can, but they're very busy. So, for this to be on constantly, it's reassuring.* [Patient 2, male, aged 25 years]

Problems with the current monitoring system were identified from their experiences in the ward. This was particularly noticeable overnight, where the perceived current monitoring by nurses was minimized.

> *Reassuring, an extra layer, particularly at night where they don't do obs.* [Patient 10, female, aged 54 years]

In some patients requiring indwelling lines (ie, nasogastric tube), a patient's speech ability seemed to prevent them from being able to raise concerns if there was a problem. Patients felt that the additional use of the wearable patch along with continuous monitoring could help provide patients with an additional "voice" if their condition suddenly exacerbated.

> *Some people can't talk like if they've got tubes in and stuff but that could talk for them, like if they can't say I'm feeling hot or feeling ill.* [Patient 12, female, aged 40 years]

Patient-identified high-risk groups that may benefit the most from the wearable sensors included the following: children, postoperative patients, and the elderly. Patients were concerned

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that current systems may cause a delay in identifying unwell patients, thus compromising patient safety. Conversely, patients believed that continuous monitoring for conditions such as infection would improve patient safety and facilitate earlier detection of patient deterioration.

Nursing Staff

The impact of continuous monitoring on staff workload was highlighted. Most patients believed that the technology would reduce the workload of nurses who were already perceived to be under considerable strain.

> *I missed my medication dose because they were so busy, and they didn't get to me. I know it's not about medicine but they would have been alerted on their, you know, say if my temperature had gone up or – It's just the fact that they're so busy and there's not enough of them, I think it's good, it can take some of the strain off of their workload.* [Patient 12, female, aged 40 years]

The patients understood the demanding nature of a nurse's role and that staff shortages add further pressure on an already stretched workforce. Patients felt that wearable sensors would improve the nursing workload and allow them time to take on other tasks.

> *Free nurses for an awful lot of routine stuff, you know they have been doing me every half an hour, am sure there are better things they can be doing in a busy place like this.* [Patient 9, male, aged 70 years]

While most patients agreed that the wearable sensors would ease the nursing workload, one patient was concerned that continuous monitoring may increase the demands placed on staff.

> *The nurses might be running away if they have got too much to do.* [Patient 8, male, aged 53 years]

Another concern of one patient was that if the sensors were too efficient, they would be used as a replacement for a regular check-up by a nurse.

> *Thought it was to see if it could replace the need to have regular nurse check-ups of heart rate and what not.* [Patient 3, male, aged 20 years]

In summary, all patients reported that wearable sensors and continuous monitoring would affect the nursing workload. Most patients believed that these would ease the nursing workload; however, one patient was concerned that the demands on the staff would be increased, and another patient was concerned that sensors may be used as a replacement for regular check-ups by nurses if they prove to be too efficient.

Comfort and Usability

All patients described the patch as being comfortable to wear. Many patients had forgotten about the existence of the patch on their person once it was on.

> *From about five minutes after it was on, I completely forgot it was there.* [Patient 2, male, aged 25 years]

One patient described the sensor as being very comfortable, but slightly irritating after a week.

> *I just find it a bit irritating now when I have to adjust it every now and then, but I had it on for a week.* [Patient 8, male, aged 66 years]

Certain everyday tasks, such as changing clothes and bathing required extra care to prevent dislodging the patch and reducing monitoring.

> *Only concern was when I wanted to get changed, I didn't want to sort of move it off too quickly, in case I caught on the sensor when I had a wash.* [Patient 6, female, aged 48 years]

During interviews, patients made some suggestions to enhance the comfort levels of the patch and to improve overall usability. A few patients indicated that the patch could be made smaller but were concerned that doing so would potentially reduce comfort levels. Other potential changes identified for both utility and comfort were changes to the fixings and the underarm temperature sensor.

> *The underarm sensor I managed to knock off in the shower so that might need some looking at, caught the spiral cable when towel drying, I knocked the patch off, fixings comparatively bulky.* [Patient 1, male, aged 71 years]

Overall, all patients agreed that the sensor was comfortable. Those patients who had worn the sensor for longer a period—up to 1 week—found it to be irritating at times. Certain everyday tasks such as bathing and changing clothes required additional care with the sensor on. Patients made several suggestions to improve the sensor further, which included a size reduction and changes to the underarm temperature sensor.

The Future

Patients described wearable sensors as the future and being a "step forward" [Patient 3, male, aged 20 years]. In future, all patients are likely to wear the sensor while at home. High-risk groups such as children and postoperative patients were identified to most benefit from home-based monitoring, and they agreed that this constituted an enhancement in medical care technology. Patient 1 (male, aged 71 years) stated, "I think it would be brilliant if we can extend early developments into the home environment," further stating that these developments would help in "flagging dangerous symptoms."

The use of sensors for home-based monitoring was particularly important because patients expressed their current concern of going home after an operation and becoming unwell. Moreover, one patient described how her friend developed an infection at home post surgery and died.

> *She developed an infection post her cancer surgery. But, so it wasn't even the actual surgery that killed her as such, but you know like these symptoms come on really quickly, you're starting to feel – because you get delirious when you get a temperature and you may not realise how sick you are, but if that was to send a message to somebody then I just think that's amazing.* [Patient 12, female, aged 40 years]

Patients felt that future sensors would be smaller and have additional features such as blood pressure monitoring and

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accelerometry, which would help detect falls, particularly for high-risk elderly individuals at home.

> *Yes, I would imagine for old people it could be very valuable, particularly if it detected movement as well.* [Patient 9, male, aged 70 years]

Patients suggested further sensor modalities such as implantable sensors for future use. They felt that this would be the natural evolution of sensor technology and would be beneficial.

Overall, patients expressed a positive opinion of technology in general and were reassured with the technological advancement in health care.

Discussion

Study Overview

A key determinant to the further use of wearable devices is end-user evaluation by patients. To date, limited qualitative data on patient evaluation are available within the wider literature, particularly from among patients in acute hospital settings. Researchers have reported that larger sample sizes are required for evaluating future wearable sensors [16]. To our knowledge, this is the largest questionnaire study of wearable sensors used in an acute hospital setting to date. The large questionnaire sample size coupled with in-depth patient interviews helped ensure diversity in the responses, providing future insights into patient perspectives.

Principal Findings

Safety

This study reported that most patients felt safe wearing the patch, describing it as an "extra safety blanket." Patients felt safer with centralized monitoring systems, concurrent with a previous study describing how sensors provide patients with a sense of added security [17].

Comfort

Most patients in this study found the wearable sensor comfortable, and many of them reported they had forgotten that they were wearing it. Similar findings were reported in a previous study on elective surgical patients using the Sensium sensor where the sensor was so comfortable that the patients had forgotten that it was on (10 of 12 patients) [18]. Patient comfort with wearable sensors was assessed through interviews, which has also been reported previously [18]. While this study reviewed the opinions of patients within an elective setting the opinion of patients in an acute setting have thus far remained unexplored. A questionnaire study on the use of wearable devices at home to assess seizures in patients reported that patient comfort levels are an important consideration [19].

Ease of Sensor Use and Design

Sensor design and simplicity of use are important. Most patients in this study did not require extensive information before using the technology, reflecting the ease of use among patients. Previous studies have revealed that technical problems and complicated designs can cause frustration and stress among patients [20]. A simple sensor design is an important end-user preference [8].

Potential for Further Use of Wearable Sensors Both in the Hospital and at Home

In this study, most patients would wear the wearable sensors again when in the hospital and at home. High demands among patients would potentially assist the future use of wearable sensors. Patients had a very positive view of the sensor technology overall and felt that wearable sensors facilitating continuous monitoring would certainly be used in the future. The concept of home-based monitoring using wearable sensors was welcomed by patients and is likely the next step in wearable sensing technology. A small study using a wearable sensor called Vital Connect in the home setting has been previously reported [20]. This study reports "encouraging positive feedback on wearability and usability" of the sensors for home use [20]. High-risk groups potentially benefiting the most were identified by patients in this study, including children, the elderly, and postoperative patients. Wearable sensor use by the elderly is gaining increasing interest [21]. Studies on the use of vital sign monitors coupled with additional monitoring sensors such as fall detectors and physical activity monitors are currently underway [22]. In cases of deterioration, alerts would be sent to family members or caregivers [10]. With a worldwide ageing population, wearable sensor technologies may help generate solutions to provide support to individuals at home to facilitate independent living.

Concerns for Wearable Sensor Use

On interviewing patients, few concerns were raised about wearable sensors, but these concerns were raised by only a few patients. One patient reported that while she welcomed the monitoring tool, she did not want it to be an excuse to discharge patients early from hospital. Another patient expressed concerns over data security, which has also been previously highlighted [18].

Ideas for Future Wearable Sensor Development

Patients reported numerous areas for future development. These included a reduction in sensor size and changes to the design of the underarm sensor. This is concurrent with the wider literature; a review of patient perspectives of wearable sensors reported that patients preferred small, compact devices that were not directly visible to others to reduce any stigmatization [6].

Strengths

This study lays the foundation for patients' perspectives on wearable sensors in an acute hospital setting. Until now, a limited number of studies have reviewed patient feedback on wearable sensors. Unlike this study, previous studies have reviewed patient feedback as a secondary, rather than primary, objective [6]. A key strength of this study is the high rates of questionnaire completion with feedback from 453 of 500 (90.6%) patients. This enhances the reliability of the feedback generated and helps reduce any potential bias. The themes and subthemes derived from the interviews remarkably overlapped with the outcomes of the questionnaire, encouraging the use of both methods. Multiple data collection methods offered a comprehensive view of patient feedback.

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Limitations

There is a potential bias in patient recruitment as we can only obtain feedback from patients agreeing to wear the sensor. As such, these patients may have a positive opinion of technology compared to others not recruited in this study (a total of 1398 patients were screened, 691 were ineligible for recruitment, and 207 did not consent to participate in the trial). The average number of days for sensor use in this study was 2 days. Those wearing the sensor for prolonged periods may yield different outcomes particularly regarding comfort and usability. Only one sensor device (Sensium wearable sensor) was used in the study. Though the broad themes of sensor technology and continuous monitoring also apply to other sensors, themes such as comfort may not be applicable to other sensor devices.

Future Perspectives

Further studies may reveal the opinions of patient's friends and relatives to understand their perspectives on the technology. This would be of great importance if the wearable sensors were being used at home and alerting the patients' family members. Future studies reviewing wearable sensor use over longer periods are required.

Conclusion

Overall, the feedback from patients was strongly positive. Wearable sensor technology continues to develop, and these data suggest that patients would welcome its use when acutely unwell and in an acute hospital setting.

Acknowledgments

This is an independent study funded by the National Institute for Health Research (NIHR) Imperial Biomedical Research Centre (BRC) and NIHR Imperial Patient Safety Translational Research Centre. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, NIHR, or Department of Health and Social Care. GC is supported in part by an NIHR research professorship.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient questionnaire.
[DOCX File , 1713 KB - periop_v4i1e18836_app1.docx]

References

1. Kause J, Smith G, Prytherch D, Parr M, Flabouris A, Hillman K, Intensive Care Society (UK), Australia and New Zealand Intensive Care Society Clinical Trials Group. A comparison of antecedents to cardiac arrests, deaths and emergency intensive care admissions in Australia and New Zealand, and the United Kingdom--the ACADEMIA study. Resuscitation 2004 Sep;62(3):275-282. [doi: 10.1016/j.resuscitation.2004.05.016] [Medline: 15325446]
2. Centre for Clinical Practice at NICE (UK). Acutely Ill Patients in Hospital: Recognition of and Response to Acute Illness in Adults in Hospital. London: National Institute for Health and Clinical Excellence (UK); Jul 2007.
3. National Early Warning Score (NEWS) 2: Standardising the assessment of acute-illness severity in the NHS Updated report of a working party Executive summary and recommendations. Royal College of Physicians. 2017 Dec. URL: https://www.rcplondon.ac.uk/file/8504/download [accessed 2021-02-10]
4. Breteler MJM, Huizinga E, van Loon K, Leenen LPH, Dohmen DAJ, Kalkman CJ, et al. Reliability of wireless monitoring using a wearable patch sensor in high-risk surgical patients at a step-down unit in the Netherlands: a clinical validation study. BMJ Open 2018 Feb 27;8(2):e020162 [FREE Full text] [doi: 10.1136/bmjopen-2017-020162] [Medline: 29487076]
5. Weenk M, van Goor H, Frietman B, Engelen LJ, van Laarhoven CJ, Smit J, et al. Continuous Monitoring of Vital Signs Using Wearable Devices on the General Ward: Pilot Study. JMIR Mhealth Uhealth 2017 Jul 05;5(7):e91 [FREE Full text] [doi: 10.2196/mhealth.7208] [Medline: 28679490]
6. Bergmann JHM, McGregor AH. Body-worn sensor design: what do patients and clinicians want? Ann Biomed Eng 2011 Sep;39(9):2299-2312. [doi: 10.1007/s10439-011-0339-9] [Medline: 21674260]
7. Grym K, Niela-Vilén H, Ekholm E, Hamari L, Azimi I, Rahmani A, et al. Feasibility of smart wristbands for continuous monitoring during pregnancy and one month after birth. BMC Pregnancy Childbirth 2019 Jan 17;19(1):34 [FREE Full text] [doi: 10.1186/s12884-019-2187-9] [Medline: 30654747]
8. Baty F, Boesch M, Widmer S, Annaheim S, Fontana P, Camenzind M, et al. Classification of Sleep Apnea Severity by Electrocardiogram Monitoring Using a Novel Wearable Device. Sensors (Basel) 2020 Jan 04;20(1):286 [FREE Full text] [doi: 10.3390/s20010286] [Medline: 31947905]
9. Midaglia L, Mulero P, Montalban X, Graves J, Hauser SL, Julian L, et al. Adherence and Satisfaction of Smartphone- and Smartwatch-Based Remote Active Testing and Passive Monitoring in People With Multiple Sclerosis: Nonrandomized Interventional Feasibility Study. J Med Internet Res 2019 Aug 30;21(8):e14863 [FREE Full text] [doi: 10.2196/14863] [Medline: 31471961]

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10. Lewy H. Wearable Devices: From Healthy Lifestyle to Active Ageing. 2015 Aug 25 Presented at: 2015 37th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC); 25-29 August 2015; Milan, Italy. [doi: 10.1109/embc.2015.7320188]
11. Brooke J. SUS-A quick and dirty usability scale. In: Jordan P, Thomas B, McClelland I, Weerdmeester B, editors. Usability Evaluation In Industry. London: CRC Press; 1996.
12. Davis R, Sevdalis N, Neale FG, Massey MR, Vincent C. Hospital patients' reports of medical errors and undesirable events in their health care. J Eval Clin Pract 2013 Oct;19(5):875-881. [doi: 10.1111/j.1365-2753.2012.01867.x] [Medline: 22691129]
13. Davis R, Sevdalis N, Vincent C. Patient involvement in patient safety: the health-care professional's perspective. J Patient Saf 2012 Dec;8(4):182-188. [doi: 10.1097/PTS.0b013e318267c4aa] [Medline: 23007240]
14. Kelley K, Clark B, Brown V, Sitzia J. Good practice in the conduct and reporting of survey research. Int J Qual Health Care 2003 Jun;15(3):261-266. [doi: 10.1093/intqhc/mzg031] [Medline: 12803354]
15. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
16. Fensli R, Pedersen P, Gundersen T, Hejlesen O. Sensor acceptance model - measuring patient acceptance of wearable sensors. Methods Inf Med 2008;47(1):89-95. [doi: 10.3414/me9106] [Medline: 18213434]
17. Olsson A, Persson A, Bartfai A, Boman I. Sensor technology more than a support. Scand J Occup Ther 2018 Mar;25(2):79-87. [doi: 10.1080/11038128.2017.1293155] [Medline: 28276963]
18. Downey C, Brown J, Jayne D, Randell R. Patient attitudes towards remote continuous vital signs monitoring on general surgery wards: An interview study. Int J Med Inform 2018 Jun;114:52-56. [doi: 10.1016/j.ijmedinf.2018.03.014] [Medline: 29673603]
19. Patel A, Moss R, Rust S, Patterson J, Strouse R, Gedela S, et al. Patient-centered design criteria for wearable seizure detection devices. Epilepsy Behav 2016 Nov;64(Pt A):116-121. [doi: 10.1016/j.yebeh.2016.09.012] [Medline: 27741462]
20. Selvaraj N. Long-term remote monitoring of vital signs using a wireless patch sensor. 2014 Oct 08 Presented at: 2014 IEEE Healthcare Innovation Conference (HIC); 8-10 October 2014; Seattle, WA, USA. [doi: 10.1109/hic.2014.7038880]
21. Azimi I, Rahmani A, Liljeberg P, Tenhunen H. Internet of things for remote elderly monitoring: a study from user-centered perspective. J Ambient Intell Human Comput 2016 Jun 20;8(2):273-289. [doi: 10.1007/s12652-016-0387-y]
22. Malwade S, Abdul S, Uddin M, Nursetyo A, Fernandez-Luque L, Zhu X, et al. Mobile and wearable technologies in healthcare for the ageing population. Comput Methods Programs Biomed 2018 Jul;161:233-237. [doi: 10.1016/j.cmpb.2018.04.026] [Medline: 29852964]

Abbreviations

ECG: electrocardiography
HR: heart rate
IP: impedance pneumography
NEWS: National Early Warning Scoring
RR: respiratory rate

Edited by G Eysenbach; submitted 03.04.20; peer-reviewed by A Tsanas, D Snider; comments to author 26.10.20; revised version received 18.12.20; accepted 13.01.21; published 22.04.21.

Please cite as:
Joshi M, Archer S, Morbi A, Arora S, Kwasnicki R, Ashrafian H, Khan S, Cooke G, Darzi A
Short-Term Wearable Sensors for In-Hospital Medical and Surgical Patients: Mixed Methods Analysis of Patient Perspectives
JMIR Perioper Med 2021;4(1):e18836
URL: https://periop.jmir.org/2021/1/e18836
doi:10.2196/18836
PMID:33885367

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Original Paper

Swedish Web Version of the Quality of Recovery Scale Adapted for Patients Undergoing Local Anesthesia and Peripheral Nerve Blockade (SwQoR-LA): Prospective Psychometric Evaluation Study

Ulrica Nilsson[1,2*], PhD; Karuna Dahlberg[3*], PhD; Maria Jaensson[3*], PhD

[1]Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Huddinge, Sweden
[2]Perioperative Medicine and Intensive Care, Karolinska University Hospital, Stockholm, Sweden
[3]School of Health Sciences, Faculty of Medicine and Health, Örebro University, Örebro, Sweden
[*]all authors contributed equally

Corresponding Author:
Ulrica Nilsson, PhD
Department of Neurobiology, Care Sciences and Society
Karolinska Institutet
Alfred Nobels Allé 23
Huddinge, 14183
Sweden
Phone: 46 70 420 34 95
Email: ulrica.nilsson@ki.se

Abstract

Background: The frequency and timing of assessing patient symptoms and discomfort during postoperative recovery are goals. Therefore, real-time recovery evaluation has been suggested to identify specific deficits in patient recovery.

Objective: This study aimed to psychometrically evaluate the Swedish Web Version of the Quality of Recovery (SwQoR) Scale adapted for patients undergoing local and peripheral nerve block (SwQoR-LA).

Methods: This was a secondary analysis of a psychometric evaluation of 107 patients aged ≥18 years undergoing day surgery under local or peripheral nerve block anesthesia at 4 different day surgery departments in Sweden. The SwQoR-LA, available through a mobile app called Recovery Assessment by Phone Points (RAPP), was completed daily on postoperative days 1-7.

Results: Some evidence of construct validity was supported, and discriminant validity was found in 7 of 8 items related to general anesthesia. The internal consistency was acceptable (.87-.89), and the split-half reliability was 0.80-0.86. Cohen d effect size was 0.98, and the percentage of change from baseline was 43.4%. No floor nor ceiling effects were found.

Conclusions: The SwQoR-LA is valid, reliable, responsive, and clinically feasible for digital real-time recovery assessment of patient recovery to identify specific deficits in patient recovery and detect those patients who might benefit from a timely intervention.

Trial Registration: ClinicalTrials.gov NCT02492191; https://clinicaltrials.gov/ct2/show/NCT02492191

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2015-009901

(JMIR Perioper Med 2021;4(1):e23090) doi:10.2196/23090

KEYWORDS

day surgery; local anesthesia; peripheral nerve blockade; postoperative recovery; psychometric evaluation

Introduction

Postoperative recovery is an individual process and a transformative journey to a new stable state [1]. It has a clear starting point [1], followed by a dynamic and individual process including physical, psychological, social, and habitual dimensions [1-3] that affect each other [1]. Due to advances in surgery, anesthesia, nursing care, and early mobilization, postoperative outcome and recovery have improved [4,5]. Inpatient surgery has decreased in favor of day surgery.

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Postoperative care at the hospital for day surgery patients is short, as the patients are discharged on the same day or within 24 hours [6]. This quick discharge implies that patients must take on great responsibility for their recovery process [7,8]. It is extremely important to follow up with and support patients in their recovery, both at the hospital and after discharge. Hence, several different patient-reported outcome questionnaires have been developed and tested and are recommended for use in clinical practice and clinical trials in surgery and anesthesia [9-11]. However, the frequency and timing of such assessment must be considered, and measurement at a single time point can be highly problematic [12]. Therefore, real-time recovery evaluation—that is, the simultaneous collection, analysis, and reporting of data occurring at different clinically relevant postoperative intervals—has been suggested to identify specific deficits in patient recovery [12-14].

To our knowledge, only one evidence-based questionnaire has been adapted for daily assessment for measuring patient-reported postoperative symptoms through an electronically assessed follow-up questionnaire: the Swedish web version of Quality of Recovery (SwQoR). The SwQoR questionnaire has been made available through an app called Recovery Assessment by Phone Points (RAPP) and includes 24 postoperative symptoms related to surgery and anesthesia [15-17]. Psychometric evaluation of the SwQoR has been performed and revealed high validity and reliability and a high degree of responsiveness; thus, the SwQoR was found to be clinically feasible for use in the systematic follow-up of patient postoperative recovery [18].

Based on experience from day surgery departments using RAPP in clinical practice, a short form for patients who have undergone day surgery under local anesthesia or peripheral nerve block has been requested. Some of the symptoms included in the SwQoR are related to general anesthesia and could therefore be excluded for the questionnaire to be more user-friendly for this group of patients. After discussion with the staff at the day surgery departments and based on our own experience, 8 symptoms related to general anesthesia were deleted from the SwQoR: sore throat, sore mouth, voice not sounding the same as usual, having trouble breathing, muscle pain, trouble urinating, diarrhea, and feeling constipated. The aim of this study was to undertake a psychometric evaluation of the real-time recovery questionnaire SwQoR-LA after adapting it for patients undergoing local anesthesia and peripheral nerve block.

Methods

Study Design

This study involved a psychometric evaluation of data originating from a multicenter, 2-group, parallel, single-blind, randomized controlled trial conducted from October 2015 to July 2016 at 4 day surgery departments in Sweden. The primary aim was to estimate the cost-effectiveness of using, vs not using, RAPP for follow-up on recovery after day surgery [19]. This study involves only those participants who were randomized into the intervention group and who underwent local or peripheral block anesthesia. This study followed the ethical standards of the Helsinki Declaration (6th revision) and was approved by the Uppsala Regional Ethics Committee (2015/262).

Sample

The data collection procedure was as follows. Information on the planned surgery was provided to the patients together with written information on the study. Upon their arrival at the day surgery department, a research nurse provided patients with oral information about the study and invited them to enroll. The inclusion criteria were age ≥18 years, undergoing day surgery, able to understand written and spoken Swedish, and access to a smartphone. Exclusion criteria were memory and visual impairment, undergoing surgical abortion, and ongoing substance abuse.

SwQoR-LA

The SwQoR-LA includes 16 of the 24 postoperative symptoms included in the SwQoR. The symptoms are scored on an 11-point numeric visual analogue scale from 0 (“none of the time”) to 10 (“all of the time”). Each question appears separately on the screen, and a dot on the visual analogue scale has to be moved to indicate an answer. The symptoms disappear from the screen immediately after a response is given, and each question on a symptom must be answered to submit the daily assessment [20].

Procedures

Preoperatively, the research nurse assisted with the installation of RAPP, including SwQoR, onto each participant’s smartphone for both participants who underwent general and local or peripheral block anesthesia. The participants were encouraged to do a test run of the app by putting in fake responses. The research nurse also explained other functionalities of the RAPP, such as how to move between the items and how to use the navigation keys.

The participants were instructed to complete the SwQoR in the RAPP every day until postoperative day 14. A daily reminder helped the participants to remember to send in their daily report on their recovery. The health care professionals at the day surgery department had access to all patient data via a web administrator interface.

This study includes data for the 16 symptoms (ie, SwQoR-LA) on postoperative days 1-7 from the participants that underwent local or peripheral block anesthesia. Based on the opinion of both patients and clinicians using RAPP in clinical practice, 7 days of assessment was considered appropriate, as a short recovery period after minor surgery with local or peripheral block anesthesia is expected. In addition to the SwQoR, other collected variables were age, gender, American Society of Anesthesiologists physical status, and type of anesthesia.

Psychometric Evaluation

The psychometric evaluation was guided by the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) [21] and a previous psychometric evaluation of the SwQoR [18]. Acceptability, which measures the clinical user friendliness, was assessed in terms of the successful response rate on postoperative days 1-7. Floor and ceiling effects (ie, the number of respondents who

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achieved the lowest or highest possible scores) were measured on days 1-7; it was considered a problem if more than 15% of the study population achieved the lowest or highest possible score [22]. Construct validity is the extent to which questionnaire scores are consistent with hypotheses, assuming that the questionnaire validly measures the construct being addressed. A correlation coefficient >0.4 was considered to be evidence of construct validity (ie, moderate to strong correlation). To analyze construct validity, a priori hypothesis testing was conducted, under the hypothesis that the SwQoR-LA, just as with the SwQoR [18], on day 1 would correlate positively with the duration of surgery, duration of stay at the postanesthesia care unit (PACU), and patient age. In addition, lower quality of recovery (ie, higher degree of postoperative symptoms) was not expected in women versus men, just as with the SwQoR [18]. Discriminant validity was tested on day 7, and it was expected that patients who underwent local anesthesia would have significantly lower scores on the symptoms related to general anesthesia that are not included in the SwQoR-LA: voice not sounding the same as usual, sore throat, sore mouth, having trouble breathing, muscle pain, trouble urinating, diarrhea, and feeling constipated. For example, sore throat and sore mouth are symptoms related to the endotracheal tub or laryngeal mask used under general anesthesia.

Reliability was assessed with (1) internal consistency, by measuring the average correlation between the SwQoR items on days 1-7, indicated by Cronbach α, and (2) split-half reliability, by measuring the correlation between randomly split segments of the SwQoR on days 1-7. Responsiveness, which was used to evaluate the SwQoR-LA's sensitivity and ability to detect clinically important changes, was measured with (1) Cohen *d* effect size, calculated as average changes in scores from days 1 to 7, divided by the pooled SD of all measurements (where 0.2-0.5 indicates a small effect, 0.5-0.8 a moderate effect, and 0.8-1.2 a large effect) [23], and (2) mean changes over time and percent changes from baseline on days 1-7.

Statistical Analysis

The sample size was calculated for the original randomized controlled trial [19]; therefore, no sample size was calculated for the SwQoR-LA. Descriptive statistics are presented as means, SDs, numbers and percentages, ranges or minimum-maximum, or 95% CI for the sake of clarity. In this study, when analyzing the overall level of recovery after local anesthesia, we used the global score of the SwQoR-LA, with a minimum value of 0 and a maximum value of 160.

To investigate differences between symptoms and gender, the Mann-Whitney U-test was performed. Associations were measured with Spearman rank coefficients (rho). Cronbach α and split-half reliability with the Spearman-Brown coefficient were used to assess the internal consistency. SPSS version 24 (IBM Corp, Armonk, NY) for Windows was used for the statistical analyses. The null hypothesis was rejected at a two-tailed $P<.05$.

Results

Acceptability

Of the 513 patients, 19 were excluded due to cancelled operations (n=15), refusal to participate (n=3), or technical issues (n=1), leaving 494 patients. Of the remaining patients, 107 underwent local or peripheral nerve block anesthesia, 362 underwent general anesthesia, and 25 had missing information about the type of anesthesia and were thereby excluded from the analysis. The results of this study only include the patients who underwent local anesthesia (n=107), except for the discriminant validity analysis. Patients' demographic variables and perioperative factors are presented in Table 1.

The response rate was 88.8% (95/107) on postoperative day 1 and 72.9% (78/107) on day 7. The global SwQoR-LA score decreased from 35.7 (SD 24.4) on day 1 to 15.5 (SD 15.5) on day 7 (Table 2).

Because the patients had to respond to each item in order to move on to the next item, there were no missing answers. Pain in the surgical wound was the symptom that occurred most frequently, starting with a value of 4.6 on day 1 and ending at 1.8 on day 7 (Figure 1).

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Table 1. Demographic variables and surgical and anesthetic factors (n=107).

Variables	Values
Gender n (%)	
Male	35 (33)
Female	72 (67)
Age (years), mean (SD)	49 (14)
Age (years), median (minimum-maximum)	55 (18-73)
ASA[a], n (%)	
I	31 (29)
II	19 (18)
Missing information	57 (53)
Type of anesthesia, n (%)	
Local infiltration	66 (62)
Intravenous regional anesthesia (IVRA)	24 (22)
Sciatic nerve block	17 (16)
Type of surgery, n	
Orthopedics	46
Hand	39
General	8
Ear, Nose, and Throat (ENT)	8
Gynecology	3
Urology	2
Dental	1
Duration of surgery (minutes), mean (SD)	34 (25)
PACU[b] stay (minutes), mean (SD)	82 (53)

[a]ASA: American Society of Anesthesiologists.

[b]PACU: postanesthesia care unit.

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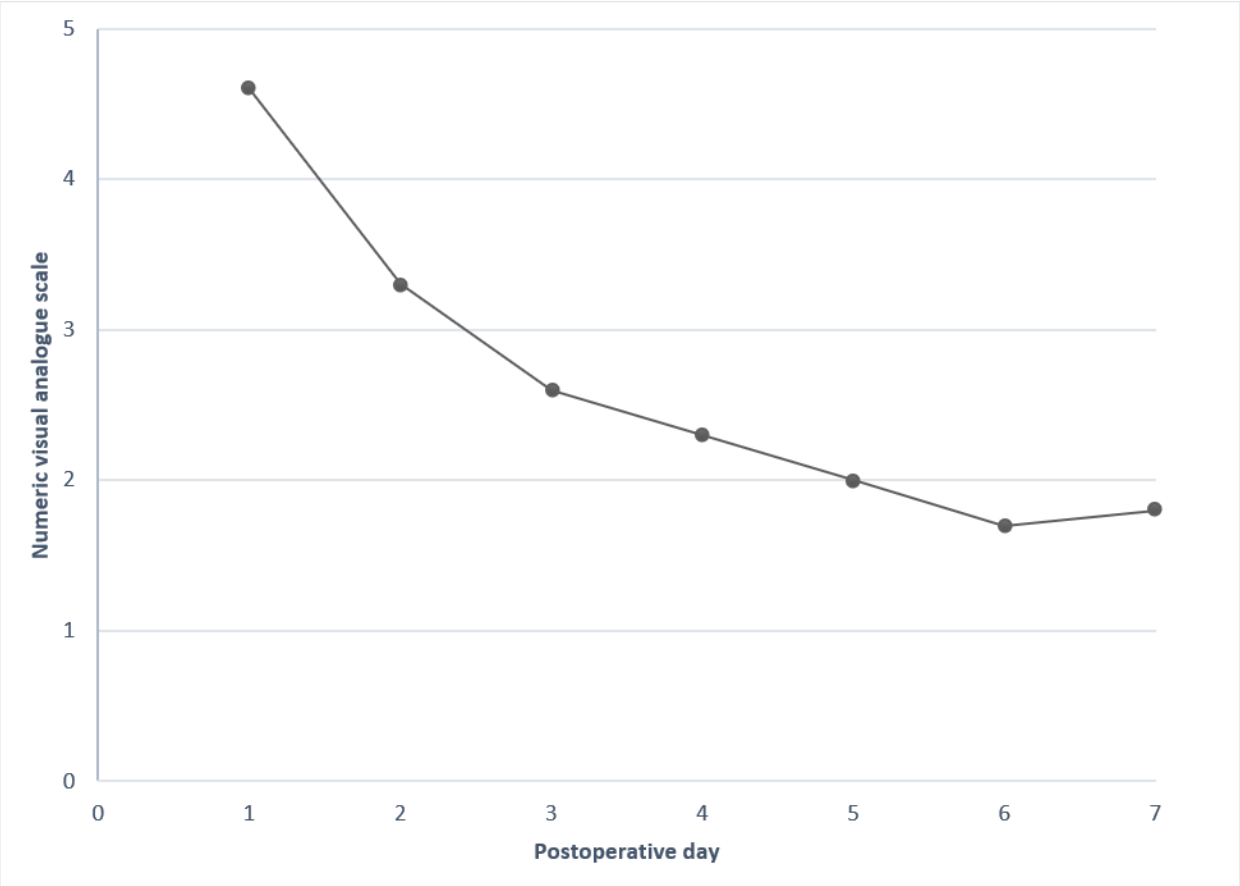
Table 2. Mean and range of the symptom scores on postoperative day 1 (n=95).

Item	Symptom score	
	Mean (SD)	Minimum-maximum
Sleeping difficulties	2.1 (2.8)	0-10
Not having a general feeling of well-being	2.9 (2.8)	0-9
Not feeling in control of my situation	2.4 (2.9)	0-10
Having difficulty feeling relaxed or comfortable	2.6 (2.6)	0-10
Depressed	1.3 (2.2)	0-10
Anxious	1.6 (2.4)	0-10
Difficulties concentrating	1.7 (2.5)	0-9
Having difficulty taking care of my personal hygiene	2.9 (2.9)	0-10
Having difficulty returning to work or usual home activities	6.6 (3.4)	0-8
Pain in the surgical wound	4.6 (3.0)	0-10
Reddened surgical wound	1.5 (2.4)	0-10
Swollen surgical wound	2.1 (2.8)	0-10
Fever	0.3 (0.9)	0-4
Nausea, vomiting, or both	0.9 (2.0)	0-8
Dizziness	1.2 (2.0)	0-8
Headache	1.1 (1.9)	0-8

Figure 1. Pain in the surgical wound on postoperative days 1-7.



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Floor or Ceiling Effects

The distributions of the SwQoR-LA scores on days 1-7 were skewed to the left and ranged between 0 and 101. No patient gave the maximum score (ie, there was no ceiling effect). No floor effects were present either (Table 3).

Table 3. Response rate, mean, minimum and maximum scores, floor effect, Cronbach α, and split-half coefficient of the Swedish Web Version of the Quality of Recovery Scale Adapted for Patients Undergoing Local Anesthesia and Peripheral Nerve Blockade (SwQoR-LA) on postoperative days 1-7.

	Day 1 (n=95)	Day 2 (n=90)	Day 3 (n=93)	Day 4 (n=89)	Day 5 (n=85)	Day 6 (n=80)	Day 7 (n=78)
Response rate, %	88.8	84.1	86.9	83.2	79.4	74.8	72.9
SwQoR-LA, mean (SD)	35.7 (24.4)	27.0 (21.7)	20.5 (18.6)	20.0 (18.1)	18.0 (18.2)	16.8 (17.1)	15.5 (15.5)
SwQoR-LA, minimum-maximum	0-99	0-101	0-83	0-85	0-92	0-91	0-84
SwQoR-LA floor effect, n (%)	2 (2.1)	4 (4.4)	6 (6.4)	6 (6.7)	4 (4.7)	6 (7.5)	7 (8.9)
Cronbach α	.88	.87	.87	.87	.89	.88	.88
Split-half coefficient	0.86	0.80	0.81	0.85	0.81	0.82	0.86

Validity

Construct validity analysis indicated low correlations between the SwQoR-LA on day 1 and PACU stay (rho=0.21, *P*=.05), duration of surgery (rho=0.28, *P*<.001), and patient age (rho=0.18, *P*=.11). There were no significant differences in global SwQoR-LA between the genders on day 1: women, 38.7 (SD 24.9) versus men, 29.8 (22.6).

Discriminant validity was determined by comparing 8 symptoms related to general anesthesia on postoperative day 1 between patients who had undergone general anesthesia and patients who had undergone local anesthesia. All symptoms except for "Diarrhea" were significantly lower in the patients who had undergone local anesthesia (Table 4).

Table 4. Discriminant validity of the Swedish Web Version of the Quality of Recovery Scale Adapted for Patients Undergoing Local Anesthesia and Peripheral Nerve Blockade (SwQoR-LA), as analyzed with Mann-Whitney U tests.

Item	General anesthesia (n=313), mean (SD)	Local anesthesia (n=95), mean (SD)	*P* value
Voice not sounding the same as usual	1.7 (2.7)	0.6 (1.7)	<.001
Sore throat	2.0 (2.8)	1.4 (1.2)	<.001
Sore mouth	1.0 (2.0)	0.1 (0.7)	<.001
Having trouble breathing	0.8 (1.7)	0.3 (1.2)	.02
Muscle pain	2.2 (2.8)	1.4 (2.2)	.01
Trouble urinating	1.0 (2.0)	0.4 (1.4)	.01
Feeling constipated	1.2 (2.3)	0.6 (1.6)	.01
Diarrhea	0.4 (1.2)	0.3 (1.0)	.32

Reliability

Regarding internal consistency, the Cronbach α for the sum score of the SwQoR-LA ranged between .87 and .89, while the split-half coefficient ranged between 0.82 and 0.90 (Table 3).

Responsiveness

Cohen *d* effect size between days 1 and 7 was 0.98. The mean change in the global SwQoR-LA score from day 1 to day 7 was –19.7 (SD 19.4) with a 95% CI of 15.2-24.2, *P*<.001. The percentage of change from baseline was 43.4%.

Discussion

The aim of this study was to perform a psychometric evaluation of the use of a real-time recovery questionnaire for a population of day surgery patients undergoing local and peripheral block anesthesia, namely, the SwQoR-LA. To our knowledge, the SwQoR-LA is the first real-time recovery questionnaire that has been developed and tested for this specific group of patients. The SwQoR-LA was shown to have high validity, reliability, responsiveness, and clinical user friendliness. The construct validity of the SwQoR-LA was supported for PACU stay and duration of surgery, although there were low correlations. However, no significant correlations were found between age and SwQoR-LA. Strong correlations have been reported previously for patients undergoing major surgery [10,24-26]. However, due to the minor nature of the surgery and anesthesia in the present study, low correlations were expected. We found no differences between genders, which is in line with a study from Iceland [27] and an earlier publication of ours [18,28]. However, gender differences in postoperative recovery have been reported in earlier studies with inpatients undergoing surgery from Denmark [29], Iran [26], and Australia [24,25].

Discriminant validity was confirmed in 7 of the 8 symptoms that are mainly related to general anesthesia. The symptom that was not significant was "Diarrhea," possibly due to the minor

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surgery procedures. However, a symptom that that seems to be missing in SwQoR-LA is postoperative fatigue. Postoperative fatigue has been reported as a common symptom after day surgery [30] and occurs in patients, irrespective of whether general or local anesthesia is used [1,30,31]. Postoperative fatigue has a large impact on patients' daily life [31,32]. Postoperative symptoms such as early postoperative cognitive decline, [33] pain, anxiety, depression, stress, and changes in sleep patterns [34] seem to influence the severity of fatigue. However, if the symptom "Diarrhea" should be removed from SwQoR-LA in favor of the symptom "Fatigue" has to be further investigated as well as psychometrically evaluated.

Postoperative pain in the surgical wound is an important symptom to measure repeatedly and thereby identify its progression. In this study, pain in the surgical wound was the symptom that occurred most frequently, with an average level of 4.6 at day 1. The levels decreased to 3.3 on day 2 and to <3 on day 3 and thereafter. In a recent study by Rodrigues et al [35], 3.8% of the patients undergoing peripheral block and 2.1% of the patients undergoing local anesthesia suffered from uncontrolled pain on days 1-2. However, they did not assess the levels of postoperative pain as well as the progression over time.

Internal consistency of the SwQoR-LA showed acceptable values, with a Cronbach α range of .87-.88 for days 1-7. This result is in line with the SwQoR, for which Cronbach α ranges from .91 to .93 for days 1-7 [18]. Cronbach α is directly affected by scale length and increases with an increasing number of items [22]. Nevertheless, the length of the scale is not the only accurate judgment [36]. Nunnally and Bernstein [37] are frequently quoted for the following cut-off values: Cronbach α of at least .70 in the early stages of research; Cronbach α of .80 in an applied setting when cut-off scores are used and for basic research; and Cronbach α of .90 for scales used for clinical purposes, with a desired standard of .95 in such cases [36,37]. The SwQoR-LA should be concentrated on individual items and global scores—a recommendation that has also been made for the SwQoR [18]. Therefore, and because the sample size was too small (ie, <10 participants per item) [22], no factor analysis of the SwQoR-LA was performed.

The response rate on day 1 was 88.8% and decreased over time, with a response rate of 72.9% observed on day 7. This decreased response rate may reflect the fact that the symptoms were low on day 7, as the changes from baseline were 43.4%, from 37.7 on day 1 to 15.5 on day 7. This finding indicates that the SwQoR-LA has the ability to detect clinically important changes [22] following day surgery in patients undergoing local and peripheral block anesthesia. In an earlier study by the same research group, the patients considered that a period of 9 days was acceptable for assessing postoperative recovery after day surgery [17]. However, that population included both patients undergoing local anesthesia and those undergoing general anesthesia [17]. As well, both patients and clinicians using RAPP in clinical practice have pointed out that 14 days of assessment is too long for the short recovery period after minor surgery with local or peripheral block anesthesia. We therefore suggest that 7 days of postoperative assessment with the SwQoR-LA is appropriate for this group of patients. Furthermore, the SwQoR-LA is a real-time recovery, electronic assessment, which is important to identify specific deficits in patient recovery [12,13]. As postoperative recovery is a dynamic and individual process that includes physical, psychological, social, and habitual aspects [1-3], recovery assessments should be multidimensional, be patient focused, and occur in real time at multiple clinically relevant postoperative time points [14]. The ability to identify symptom-specific recovery failure and implement targeted therapies to improve recovery is an important goal for perioperative care [12,14]. This requires a real-time recovery questionnaire such as the SwQoR-LA for early identification of recovery failure as well as for assessment of the outcomes following interventions in clinical practice and clinical trials [12]. If access to the web version of the SwQoR-LA is not possible, the paper version can be used instead, as there is equivalence between the web version and paper version [17].

Limitations

There are some limitations in our study. First, the sample size is relatively small, but considered sufficient for examining psychometric properties with 16 items. However, there is no consensus about the number of participants for each type of psychometric analysis. To analyze construct validity, responsiveness, and floor and ceiling effects, a sample size of at least 50 participants is recommended [22]. Second, no test-retest reliability was conducted. This feature could be improved in future studies by involving a larger pool of patients undergoing a wider range of peripheral nerve block. Third, the duration for data entry was not measured.

Conclusions

To our knowledge, this study is the first to evaluate a real-time recovery questionnaire, the SwQoR-LA, in patients undergoing local or peripheral nerve block anesthesia. The SwQoR-LA is valid, reliable, responsive, and clinically feasible for the real-time assessment of patient recovery in order to detect those patients who might benefit from timely follow-up and intervention.

Acknowledgments

This study is supported by FORTE (the Swedish Research Council for Health, Working Life and Healthcare), grant number 2013-4765, and Vetenskapsrådet (the Swedish Research Council), grant number 2015-02273.

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Conflicts of Interest

Author UN and the Örebro University Enterprise AB hold shares in RAPP-AB. None of the other authors have any potential conflicts of interest.

References

1. Nilsson U, Jaensson M, Hugelius K, Arakelian E, Dahlberg K. A journey to a new stable state-further development of the postoperative recovery concept from day surgical perspective: a qualitative study. BMJ Open 2020 Sep 23;10(9):e037755 [FREE Full text] [doi: 10.1136/bmjopen-2020-037755] [Medline: 32967881]
2. Allvin R, Berg K, Idvall E, Nilsson U. Postoperative recovery: a concept analysis. J Adv Nurs 2007 Mar;57(5):552-558. [doi: 10.1111/j.1365-2648.2006.04156.x] [Medline: 17284272]
3. Lundmark M, Lennerling A, Almgren M, Forsberg A. Recovery after lung transplantation from a patient perspective - proposing a new framework. J Adv Nurs 2016 Dec 19;72(12):3113-3124. [doi: 10.1111/jan.13058] [Medline: 27346667]
4. Nilsson U, Gruen R, Myles PS. Postoperative recovery: the importance of the team. Anaesthesia 2020 Jan 05;75 Suppl 1(S1):e158-e164 [FREE Full text] [doi: 10.1111/anae.14869] [Medline: 31903575]
5. Weiser TG, Haynes AB, Molina G, Lipsitz SR, Esquivel MM, Uribe-Leitz T, et al. Estimate of the global volume of surgery in 2012: an assessment supporting improved health outcomes. The Lancet 2015 Apr;385:S11. [doi: 10.1016/s0140-6736(15)60806-6]
6. Darwin L. Patient selection for day surgery. Anaesthesia & Intensive Care Medicine 2016 Mar;17(3):151-154. [doi: 10.1016/j.mpaic.2015.12.002]
7. Berg K, Arestedt K, Kjellgren K. Postoperative recovery from the perspective of day surgery patients: a phenomenographic study. Int J Nurs Stud 2013 Dec;50(12):1630-1638. [doi: 10.1016/j.ijnurstu.2013.05.002] [Medline: 23726224]
8. Dahlberg K, Jaensson M, Nilsson U, Eriksson M, Odencrants S. Holding It Together-Patients' Perspectives on Postoperative Recovery When Using an e-Assessed Follow-Up: Qualitative Study. JMIR Mhealth Uhealth 2018 May 25;6(5):e10387 [FREE Full text] [doi: 10.2196/10387] [Medline: 29802094]
9. Gornall B, Myles P, Smith C, Burke J, Leslie K, Pereira M, et al. Measurement of quality of recovery using the QoR-40: a quantitative systematic review. Br J Anaesth 2013 Aug;111(2):161-169 [FREE Full text] [doi: 10.1093/bja/aet014] [Medline: 23471753]
10. Kleif J, Waage J, Christensen K, Gögenur I. Systematic review of the QoR-15 score, a patient- reported outcome measure measuring quality of recovery after surgery and anaesthesia. Br J Anaesth 2018 Jan;120(1):28-36 [FREE Full text] [doi: 10.1016/j.bja.2017.11.013] [Medline: 29397134]
11. Bowyer A, Jakobsson J, Ljungqvist O, Royse C. A review of the scope and measurement of postoperative quality of recovery. Anaesthesia 2014 Nov 02;69(11):1266-1278 [FREE Full text] [doi: 10.1111/anae.12730] [Medline: 24888412]
12. Ladha K, Wijeysundera DN. Role of patient-centred outcomes after hospital discharge: a state-of-the-art review. Anaesthesia 2020 Jan;75 Suppl 1:e151-e157 [FREE Full text] [doi: 10.1111/anae.14903] [Medline: 31903568]
13. Bowyer AJ, Royse CF. Postoperative recovery and outcomes--what are we measuring and for whom? Anaesthesia 2016 Jan 01;71 Suppl 1:72-77 [FREE Full text] [doi: 10.1111/anae.13312] [Medline: 26620150]
14. Bowyer A, Royse C. The importance of postoperative quality of recovery: influences, assessment, and clinical and prognostic implications. Can J Anaesth 2016 Feb 16;63(2):176-183. [doi: 10.1007/s12630-015-0508-7] [Medline: 26475163]
15. Jaensson M, Dahlberg K, Eriksson M, Grönlund Å, Nilsson U. The Development of the Recovery Assessments by Phone Points (RAPP): A Mobile Phone App for Postoperative Recovery Monitoring and Assessment. JMIR Mhealth Uhealth 2015 Sep 11;3(3):e86 [FREE Full text] [doi: 10.2196/mhealth.4649] [Medline: 26362403]
16. Jaensson M, Nilsson U. Impact of changing positively worded items to negatively worded items in the Swedish web-version of the Quality of Recovery (SwQoR) questionnaire. J Eval Clin Pract 2017 Jun 21;23(3):502-507. [doi: 10.1111/jep.12639] [Medline: 27650792]
17. Dahlberg K, Jaensson M, Eriksson M, Nilsson U. Evaluation of the Swedish Web-Version of Quality of Recovery (SwQoR): Secondary Step in the Development of a Mobile Phone App to Measure Postoperative Recovery. JMIR Res Protoc 2016 Sep 28;5(3):e192 [FREE Full text] [doi: 10.2196/resprot.5881] [Medline: 27679867]
18. Nilsson U, Dahlberg K, Jaensson M. The Swedish Web Version of the Quality of Recovery Scale Adapted for Use in a Mobile App: Prospective Psychometric Evaluation Study. JMIR Mhealth Uhealth 2017 Dec 03;5(12):e188 [FREE Full text] [doi: 10.2196/mhealth.9061] [Medline: 29229590]
19. Nilsson U, Jaensson M, Dahlberg K, Odencrants S, Grönlund Å, Hagberg L, et al. RAPP, a systematic e-assessment of postoperative recovery in patients undergoing day surgery: study protocol for a mixed-methods study design including a multicentre, two-group, parallel, single-blind randomised controlled trial and qualitative interview studies. BMJ Open 2016 Jan 13;6(1):e009901 [FREE Full text] [doi: 10.1136/bmjopen-2015-009901] [Medline: 26769788]
20. Jaensson M, Dahlberg K, Eriksson M, Nilsson U. Evaluation of postoperative recovery in day surgery patients using a mobile phone application: a multicentre randomized trial. Br J Anaesth 2017 Nov 01;119(5):1030-1038 [FREE Full text] [doi: 10.1093/bja/aex331] [Medline: 29077818]

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21. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res 2010 May 19;19(4):539-549 [FREE Full text] [doi: 10.1007/s11136-010-9606-8] [Medline: 20169472]
22. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 2007 Jan;60(1):34-42. [doi: 10.1016/j.jclinepi.2006.03.012] [Medline: 17161752]
23. Sawilowsky SS. New Effect Size Rules of Thumb. J. Mod. App. Stat. Meth 2009 Nov 01;8(2):597-599. [doi: 10.22237/jmasm/1257035100]
24. Myles PS, Weitkamp B, Jones K, Melick J, Hensen S. Validity and reliability of a postoperative quality of recovery score: the QoR-40. Br J Anaesth 2000 Jan;84(1):11-15 [FREE Full text] [doi: 10.1093/oxfordjournals.bja.a013366] [Medline: 10740540]
25. Stark P, Myles P, Burke JA. Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15. Anesthesiology 2013 Jun;118(6):1332-1340 [FREE Full text] [doi: 10.1097/ALN.0b013e318289b84b] [Medline: 23411725]
26. Yaghoobi S, Hamidfar M, Lawson DM, Fridlund B, Myles PS, Pakpour AH. Validity and reliability of the Iranian version of the quality of recovery-40 questionnaire. Anesth Pain Med 2015 Apr 20;5(2):e20350 [FREE Full text] [doi: 10.5812/aapm.20350] [Medline: 25893185]
27. Sveinsdottir H, Borgthorsdottir T, Asgeirsdottir MT, Albertsdottir K, Asmundsdottir LB. Recovery After Same-Day Surgery in Patients Receiving General Anesthesia: A Cohort Study Using the Quality of Recovery-40 Questionnaire. J Perianesth Nurs 2016 Dec;31(6):475-484. [doi: 10.1016/j.jopan.2015.07.003] [Medline: 27931699]
28. Jaensson M, Dahlberg K, Nilsson U. Sex Similarities in Postoperative Recovery and Health Care Contacts Within 14 Days With mHealth Follow-Up: Secondary Analysis of a Randomized Controlled Trial. JMIR Perioper Med 2018 Mar 26;1(1):e2. [doi: 10.2196/periop.9874]
29. Kleif J, Edwards HM, Sort R, Vilandt J, Gögenur I. Translation and validation of the Danish version of the postoperative quality of recovery score QoR-15. Acta Anaesthesiol Scand 2015 Aug 13;59(7):912-920. [doi: 10.1111/aas.12525] [Medline: 25867135]
30. Mendy N, Moriceau J, Sacuto Y, Besnier E, Clavier T, Ndangang M, et al. Postoperative fatigue after day surgery: prevalence and risk factors. A prospective observational study. Minerva Anestesiol 2020 Dec;86(12). [doi: 10.23736/s0375-9393.20.14358-x]
31. Nilsson U, Jaensson M, Dahlberg K, Hugelius K. Postoperative Recovery After General and Regional Anesthesia in Patients Undergoing Day Surgery: A Mixed Methods Study. J Perianesth Nurs 2019 Jun;34(3):517-528 [FREE Full text] [doi: 10.1016/j.jopan.2018.08.003] [Medline: 30470465]
32. Gilmartin J. Contemporary day surgery: patients' experience of discharge and recovery. J Clin Nurs 2007 Jun;16(6):1109-1117. [doi: 10.1111/j.1365-2702.2007.01548.x] [Medline: 17518885]
33. Fan Y, Yuan L, Ji M, Yang J, Gao D. The effect of melatonin on early postoperative cognitive decline in elderly patients undergoing hip arthroplasty: A randomized controlled trial. J Clin Anesth 2017 Jun;39:77-81. [doi: 10.1016/j.jclinane.2017.03.023] [Medline: 28494914]
34. Zargar-Shoshtari K, Hill AG. Postoperative fatigue: a review. World J Surg 2009 Apr 3;33(4):738-745. [doi: 10.1007/s00268-008-9906-0] [Medline: 19189174]
35. Rodrigues NM, Ribeiro P, Jesus F, Caldeira M. Pain in Ambulatory Surgery: 4-Year Experience of an Ambulatory Surgery Unit in a Tertiary Hospital. Ambulatory Surgery 2020;26(1):14-16.
36. Yang Y, Green SB. Coefficient Alpha: A Reliability Coefficient for the 21st Century? Journal of Psychoeducational Assessment 2011 May 19;29(4):377-392. [doi: 10.1177/0734282911406668]
37. Nunnally J, Bernstein I. Psychometric theory, 3rd edition. New York, NY: McGraw-Hill; 1994:1994.

Abbreviations

COSMIN: COnsensus-based Standards for the selection of health Measurement INstruments
PACU: postanesthesia care unit
RAPP: Recovery Assessment by Phone Points
SwQoR-LA: Swedish Web Version of the Quality of Recovery Scale Adapted for Patients Undergoing Local Anesthesia and Peripheral Nerve Blockade

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Edited by G Eysenbach; submitted 31.07.20; peer-reviewed by K Li, J Odom-Forren; comments to author 01.12.20; revised version received 04.12.20; accepted 19.12.20; published 15.01.21.

Please cite as:
Nilsson U, Dahlberg K, Jaensson M
Swedish Web Version of the Quality of Recovery Scale Adapted for Patients Undergoing Local Anesthesia and Peripheral Nerve Blockade (SwQoR-LA): Prospective Psychometric Evaluation Study
JMIR Perioper Med 2021;4(1):e23090
URL: http://periop.jmir.org/2021/1/e23090/
doi:10.2196/23090
PMID:33448932

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