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

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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.

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 [12]. 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 audiorecorded, 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,
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 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.
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.

**Expectation: Continuous vital signs monitoring will lead to early recognition of deterioration**

- **Pneumonia**
  - Yes: 6
  - Maybe: 6
  - No: 0

- **Anastomotic leak**
  - Yes: 6
  - Maybe: 6
  - No: 0

**Expectation: Early recognition of deterioration will lead to early complication treatment**

- **Pneumonia**
  - Yes: 6
  - Maybe: 6
  - No: 0

- **Anastomotic leak**
  - Yes: 6
  - Maybe: 6
  - No: 0

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
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.
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.
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:
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
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.

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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 ]
References


Abbreviations

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

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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.

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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Enhanced recovery program group (n=46)</th>
<th>Standard care group (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median (IQR)</td>
<td>64 (27-83)</td>
<td>67 (27-84)</td>
</tr>
<tr>
<td>Sex ratio (Male:Female)</td>
<td>31:15</td>
<td>23:22</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD)</td>
<td>25.6 (5.0)</td>
<td>26.9 (4.4)</td>
</tr>
<tr>
<td>American Society of Anesthesiologists fitness grade (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>II</td>
<td>43</td>
<td>38</td>
</tr>
<tr>
<td>III</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Diagnosis (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colorectal metastases</td>
<td>35</td>
<td>26</td>
</tr>
<tr>
<td>Other metastases</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Benign disease</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Neoadjuvant chemotherapy</td>
<td>36</td>
<td>25</td>
</tr>
<tr>
<td>P-POSSUM⁴, mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiological score</td>
<td>16.4 (3.4)</td>
<td>16.8 (3.6)</td>
</tr>
<tr>
<td>Operative severity score</td>
<td>19.4 (3.7)</td>
<td>17.1 (4.8)</td>
</tr>
<tr>
<td>Operation (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major resection (3 segments)</td>
<td>21</td>
<td>12</td>
</tr>
<tr>
<td>Minor resection</td>
<td>25</td>
<td>33</td>
</tr>
<tr>
<td>Specimen weight (g), median (IQR)</td>
<td>373.3 (156.3-780.5)</td>
<td>179.5 (69.6-606.3)</td>
</tr>
<tr>
<td>Blood loss (mL), median (IQR)</td>
<td>350 (174-900)</td>
<td>340 (150-645)</td>
</tr>
<tr>
<td>Need for blood transfusion (n)</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Death</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

⁴P-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).
Table 2. Data of community care and primary care usage by the patients from the day of discharge to postoperative day 28 (N=91).

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

<sup>a</sup>Statistical significance tested with Fisher exact test. The statistical test chosen was based upon sample size.

<sup>b</sup>Chi-square test.

<sup>c</sup>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.

<table>
<thead>
<tr>
<th>Type of care</th>
<th>Costs (£)&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Life years (QALY)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Incremental cost-effectiveness (£/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhanced recovery program</td>
<td>9538.30</td>
<td>6.9</td>
<td>0.0</td>
</tr>
<tr>
<td>Standard care</td>
<td>14,793.10</td>
<td>6.1</td>
<td>–6748.30</td>
</tr>
</tbody>
</table>

<sup>a</sup>£1= US $1.60.

<sup>b</sup>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 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>
<thead>
<tr>
<th>Term</th>
<th>Survival of standard care group (n=45), n (%)</th>
<th>Survival of enhanced recovery program group (n=46), n (%)</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>41 (91)</td>
<td>45 (98)</td>
<td>.20(^a)</td>
</tr>
<tr>
<td>2 years</td>
<td>33 (73)</td>
<td>42 (91)</td>
<td>.03(^a)</td>
</tr>
<tr>
<td>5 years</td>
<td>23 (51)</td>
<td>24 (52)</td>
<td>.92(^b)</td>
</tr>
</tbody>
</table>

\(^a\)Fisher exact test.

\(^b\)Chi-square test. Choice of statistical test dependent upon the sample size.
Table 5. Long-term survival of all patients with malignant disease.

<table>
<thead>
<tr>
<th>Term</th>
<th>Survival of standard care group (n=36), n (%)</th>
<th>Survival of enhanced recovery program group (n=45), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>32 (89)</td>
<td>44 (98)</td>
<td>.17a</td>
</tr>
<tr>
<td>2 years</td>
<td>24 (67)</td>
<td>41 (91)</td>
<td>.01a</td>
</tr>
<tr>
<td>5 years</td>
<td>16 (44)</td>
<td>23 (51)</td>
<td>.55b</td>
</tr>
</tbody>
</table>

aFisher exact test.  
bChi-square test. Choice of statistical test dependent upon the sample size.

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

<table>
<thead>
<tr>
<th>Term</th>
<th>Survival of standard care group (n=26), n (%)</th>
<th>Survival of enhanced recovery program group (n=35), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>23 (88)</td>
<td>34 (97)</td>
<td>.30a</td>
</tr>
<tr>
<td>2 years</td>
<td>18 (69)</td>
<td>32 (91)</td>
<td>.04a</td>
</tr>
<tr>
<td>5 years</td>
<td>14 (54)</td>
<td>16 (46)</td>
<td>.53b</td>
</tr>
</tbody>
</table>

aFisher exact test.  
bChi-square test. Choice of statistical test dependent upon the sample size.

Figure 4. Kaplan-Meier survival curves for all patients. 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

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


Abbreviations

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

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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

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

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

\(^a\)ASA: American Society of Anesthesiologists.

\(^b\)PACU: postanesthesia care unit.
Table 2. Mean and range of the symptom scores on postoperative day 1 (n=95).

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

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

<table>
<thead>
<tr>
<th>Day</th>
<th>Response rate, %</th>
<th>SwQoR-LA, mean (SD)</th>
<th>SwQoR-LA, minimum-maximum</th>
<th>SwQoR-LA floor effect, n (%)</th>
<th>Cronbach α</th>
<th>Split-half coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 7</td>
<td>72.9</td>
<td>4.8</td>
<td>84.0 - 91.0</td>
<td>4 (4.4)</td>
<td>.88</td>
<td>0.86</td>
</tr>
<tr>
<td>Day 6</td>
<td>71.5</td>
<td>5.1</td>
<td>83.2 - 92.0</td>
<td>6 (6.7)</td>
<td>.87</td>
<td>0.80</td>
</tr>
<tr>
<td>Day 5</td>
<td>70.6</td>
<td>5.7</td>
<td>82.0 - 92.0</td>
<td>8 (8.9)</td>
<td>.87</td>
<td>0.81</td>
</tr>
<tr>
<td>Day 4</td>
<td>69.7</td>
<td>6.2</td>
<td>82.2 - 92.0</td>
<td>6 (6.7)</td>
<td>.89</td>
<td>0.82</td>
</tr>
<tr>
<td>Day 3</td>
<td>68.8</td>
<td>6.8</td>
<td>81.5 - 92.0</td>
<td>7 (8.9)</td>
<td>.88</td>
<td>0.86</td>
</tr>
<tr>
<td>Day 2</td>
<td>67.9</td>
<td>7.4</td>
<td>81.0 - 92.0</td>
<td>8 (8.9)</td>
<td>.88</td>
<td>0.86</td>
</tr>
<tr>
<td>Day 1</td>
<td>66.0</td>
<td>7.9</td>
<td>80.3 - 92.0</td>
<td>6 (6.7)</td>
<td>.88</td>
<td>0.86</td>
</tr>
</tbody>
</table>

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.

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

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
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.

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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


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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