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# A Digital Patient-Led Hospital Checklist for Enhancing Safety in Cataract Surgery: Qualitative Study

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# Abstract

**Background:** Surgery holds high risk for iatrogenic patient harm. Correct and sufficient communication and information during the surgical process is a root solution for preventing patient harm. Information technology may substantially contribute to engaging patients in this process.

**Objective:** To explore the feasibility of a digital patient-led checklist for cataract surgery, we evaluated the experiences of patients and nurses who have used this novel tool with a focus on use, appreciation, and impact.

**Methods:** A multidisciplinary team, including cataract surgeons, nurses, pharmacists and administrative representatives developed a 19-item digital patient-led checklist for cataract patients who underwent surgery in an ambulatory setting. This "EYEpad" checklist was distributed to patients and their companions during their hospital visit via an application on a tablet. It contained necessary information the patient should have received before or during the surgical preparation (8 items), before anesthesia (2 items), and before discharge (9 items). Patients and their companions were invited to actively indicate the information they received, or information discussed with them, by ticking on the EYEpad. Our qualitative research design included semi-structured individual interviews with 17 patients and a focus group involving 6 nurses. The transcripts were analyzed by 2 independent coders using both deductive and inductive coding.

**Results:** All but one of the 17 patients used the EYEpad, occasionally assisted by his or her companion (usually the partner). In several cases, the checklist was completed by the companion. Most patients felt positively about the usability of the EYEpad. Yet, for most of the patients, it was not clear why they received the checklist. Only 4 of them indicated that they understood that the EYEpad was used to determine if there were sufficient and correct information discussed or checked by the nurses. Although most nurses agreed the EYEpad was easy to use and could be a useful tool for improving patient engagement for improving safety, they felt that not all elderly patients were willing or capable of using it and it interfered with the existing surgical process. They also anticipated the need to spend more time explaining the purpose and use of the EYEpad.

**Conclusions:** Our results showed that a digital patient-led checklist is a potentially valid way to increase patient participation in safety improvement efforts, even among elderly patients. It also illustrates the crucial role nurses play in the implementation

and diffusion of technological innovations. Increased patient participation will only improve safety when both healthcare workers and patients feel empowered to share responsibility and balance their power.

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#### **KEYWORDS**

patient participation; checklist; cataract; surgery; patient safety; handheld computers; health information management; health communication; information technology

## Introduction

Health care delivery is too often not "free from accidental injuries," according to the Institute of Medicine definition of patient safety [1]. In Dutch hospitals, about 2.6% patients die and 1.6% are harmed annually due to preventable, unnecessary actions [2]. The associated costs are estimated at 0.5% of the national hospital care budget and, since only direct costs were considered, this calculation is likely an underestimation of the real costs [2].

Surgery is a high-risk area for iatrogenic patient harm [3,4]. Iatrogenic harm is the unintended or unnecessary harm or suffering arising from any aspect of the health care delivery besides the patient's condition [3]. Errors that cause iatrogenic harm to patients should be mitigated before they can cause harm [3].

The last decade has seen increasing awareness and focus on patient safety [5-9]. Traditionally, patient safety has been viewed as the sole responsibility of health professionals with patients as passive recipients. Nowadays, patient participation is increasingly being recognized as a key component in the improvement of health care since, in contrast to health care staff, patients are around during all steps of the care pathway [10-13]. However, few studies show patients as active participants in safety efforts, and these studies mostly focus on listening well and speaking up when concerned [14-17].

Communication between patients and professionals is a major issue in safety [18]. The handover of information from professional to patient is critical for successful recovery after surgery and compliance with postsurgical instructions [19]. Studies have shown that a lack of communication between patients and professionals in surgical care resulted in less optimal outcomes [18,20]. Insufficient and contradictory postsurgical information on health status and patient behavior requests are major safety issues.

Although it is known that communication of the "right things" at the "right moment" is important for preventing iatrogenic patient harm, it is difficult to optimize this process because patients are concerned with many things during their care pathways. Information technology may substantially contribute to engaging patients in activities to improve patient safety [21,22].

To increase patient participation in enhancing safe care, we developed an online checklist called the EYEpad for cataract patients to be used during their admission. Cataract surgery involves removal of opaque lens and replacement with an implanted artificial intraocular lens (IOL) is the most frequently

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performed surgery in the world [23]. The feasibility of this checklist—in terms of utilization, appreciation, and impact—according to patients and nurses has not yet been determined. To explore the feasibility of the digital checklist for cataract surgery, we evaluated the experiences of patients and nurses who have used the checklist at the Rotterdam Eye Hospital in the Netherlands.

### Methods

#### Design

We used a qualitative approach to explore patients' and nurses' experiences with the digital EYEpad checklist. The definition of semistructured interviews by Green and Thorogood is "In a semistructured interview, the researcher sets the agenda in terms of the topics covered but the interviewee's responses determine the kinds of information produced about those topics, and the relative importance of them" [24]. At appointments, we conducted semistructured interviews with patients and their companions, and a focus group with nurses.

#### Setting

Participants were recruited at the Rotterdam Eye Hospital, the only eye hospital in the Netherlands providing secondary and tertiary eye care. The hospital has a specialized ambulatory cataract pathway where about 6500 cataract surgeries are performed annually.

#### Intervention: The EYEpad

Patients often had questions about how to care for their treated eyes after discharge from the hospital. To prevent this, initially a paper card was designed to relay information to patients before their discharges. The card served as a memory aid for nurses to inform patients about these points, but was rarely used. Subsequently, a checklist for patients was designed. A multidisciplinary team, including cataract surgeons, nurses, pharmacists, and administrative representatives developed a 19-item patient-led checklist for cataract patients who underwent surgery in an ambulatory setting. The items were based on a review of nurses' current, often inconsistent, and not formally acknowledged, check moments. An initial gross-list of more than 30 items was reduced to 19, all of which were agreed upon by the multidisciplinary team. The checklist was first tested on paper by patients and later modernized into an application for the tablet called EYEpad. This checklist was distributed to patients and their companions via the application EYEpad, on a tablet, during their hospital visits. It contained 3 lists with necessary information the patient should have received during three contact moments with medical professionals on the day of their surgery: before or during surgical preparation (8 items),

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before anesthesia (2 items), and before discharge (9 items; see Figure 1 for the screenshot of the subchecklist and Textbox 1 for all 19 items).

The EYEpad is handed to the patient on the day of the surgery. The patient is supposed to indicate whether the predefined information on the checklist was discussed with the nurse. Based on this checklist, the patient is expected to address the nurse regarding the missing items. The checklist is also used by the nurse, to confirm whether all information has been addressed in a consistent manner. While the nurse checks the list, he or she can provide missing information for the patient and perform a formal acknowledgment ("check"). Finally, the patient can add his or her own questions to ensure that these questions are addressed during the dismissal conversation. Patients could also use the tablet for other general, educational, or entertainment functions, such as news services and games.

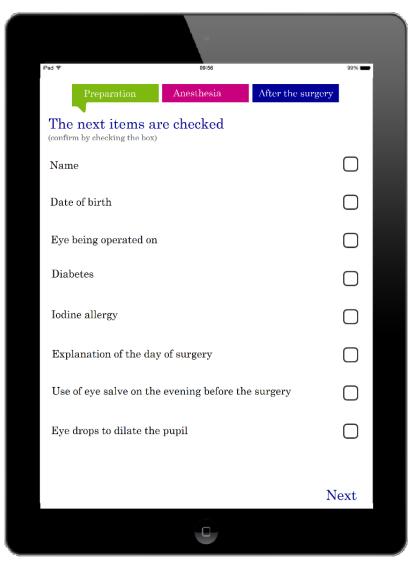
#### **Participants**

#### Patients

During a period of two weeks, patients who were scheduled first and last in the morning and in the afternoon were approached to participate in the study. A registered nurse recruited participants according to the following inclusion criteria: (1) age older than 18 years, (2) first cataract surgery, (3) ability to understand Dutch, (4) absence of severe comorbidities, and (5) absence of mental or cognitive disorders.

The selected patients were approached by phone one day before their hospital visit. Patients were given information about the study and asked whether they wished to participate. It was emphasized that participation was voluntary and their decision about participating in the study would have no effect on their treatment. When patients agreed to participate, the researcher fixed a time for a short interview at the hospital immediately after the patient's discharge.

Figure 1. Overview of the first subchecklist (preparation), containing information on specific events in the care pathway.



Textbox 1. Overview of the 19-item checklist.

#### I Preparation phase (8 items):

- Patient name
- Patient date of birth
- Eye to be operated on
- Diabetes status
- Iodine allergy status
- Explanation on day of surgery proceedings
- Explanation on eye balm application on eve of surgery
- Explanation of dilatation drops

#### II Anesthesia phase (2 items):

- Time-out
- Anesthetic eye drops

#### **III Postsurgical phase (9 items):**

- Review of surgical proceedings
- Pain assessment
- Postsurgical patient flyer
- Availability and application of eye drops at home
- Postsurgical telephone review (date and time)
- Removal of eye bandage
- Checking of pupil size and form
- Photo surgical team
- Eye drop application information and training

#### Nurses

The ambulatory surgical center (ASC) manager invited all nurses to a regular department meeting and allowed the researcher to use a part of the meeting for a focus group.

#### Measurements

#### **Participant Interviews**

Prior to the interview, the participants provided informed consent for participation and for tape recording of the interview. All interviews were conducted by a trained psychologist (JVDS). Interviews took an average of 10 minutes and took place in a separate room, behind closed doors, to preserve the patient's privacy.

During the interviews, an interview guide with 24 open-ended questions, derived from published literature and in consultation with staff members of the hospital and the University of Twente, was used. The interview questions focused on (1) EYEpad utilization: "Did you use the EYEpad?"; (2) appreciation of the EYEpad: "What did you like/dislike in the EYEpad?"; and (3) impact of the EYEpad: "What does feeling safe in a hospital mean to you?" Patients were asked explicitly to motivate and support their answers. All interviews were audiotaped. Ethical approval was obtained from the ethics committee of the University of Twente (#13196).

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#### Focus Group with Nurses

Prior to the focus group session, the nurses were asked to complete a 10-item questionnaire. This questionnaire was intended to stimulate the participants to think about the topics discussed during the focus group. We chose this approach to prevent group thinking by the participants.

All nurses were asked to provide consent for participation and tape recording of the focus group. The focus group lasted 60 minutes. During the focus group session, a script with open-ended questions, derived from published literature and in consultation with staff members of the hospital and the University of Twente, was used. The questions focused, as they did during the patient interviews, on (1) EYEpad utilization: "What instructions did you give to patients during handover of the EYEpad?"; (2) appreciation of the EYEpad: "What do you consider to be positive and negative aspects of the EYEpad?"; and (3) impact of the EYEpad: "What do you consider as benefits of the EYEpad?". Finally, the focus group addressed (4) the future of the EYEpad?" The minutes of the meeting were included in the analysis.

#### **Data Analysis**

The audiotaped data from the interviews was transcribed verbatim. Transcripts were deductively coded into one of the



three main categories: utilization, appreciation, and perceived impact. Next, the fragments in each category were further divided into subcategories, using inductive analysis, meaning the categories were inferred from the data, rather than from the existing literature. Coding was conducted by 2 coders (JVDS, AS). Differences were discussed until a consensus was achieved [24].

# Results

#### **Description of Participants**

From the 32 selected patients, 19 patients met the inclusion criteria. Seventeen patients accepted the invitation to participate in the study. Two patients refused to participate because they did not feel well enough to be interviewed after their surgeries. Eleven out of 17 (65%) patients were female. The average age was 69 years, ranging from 58 to 88. Almost all patients were accompanied by their partner (n=12) and others by their daughter (n=2), son (n=1), or another relative (n=1). One patient was not accompanied by a companion.

Six of the 18 registered nurses participated in the focus group. All nurses were female (n=6). The average age of the nurses was 46 years, ranging from 20 to 57. Most nurses (n=4) worked at the ASC for at least 5 years.

#### **Description of Themes**

Three themes emerged from the data analysis: utilization, appreciation and impact. The subthemes that belong to these themes can be found in Multimedia Appendix 1.

#### Utilization of the EYEpad

#### Patients

All but one patient used the EYEpad. In several cases (n=9), the EYEpad checklist was completed by the companion as the patients could not clearly see because their eyes were dilated or their reading glasses were stored in a locker. The companions only entered the patients' answers.

*I have completed it, but yes, actually I have only pressed the buttons. You have completed the answers.* [Companion 3]

Three patients completed the EYEpad on their own because they were more familiar with a tablet than their companion was. One patient and his companion did not use the EYEpad because they were not familiar with the use of a tablet device.

Most did not completely understand why they received the EYEpad. They took the EYEpad without further enquiries and assumed it was part of the hospital administration or it was for quality improvement. In only four cases, respondents indicated that the EYEpad was meant to validate if all necessary information was given to the patients and if nurses checked important information for patients' safety.

[Silence] No, I assume things automatically; they need to know who you are, and they repeat that often. [Silence] I think that's part of the administration. [Patient 1] Besides using the EYEpad application, patients and their companions could use other functionalities on the tablet, like the web browser, playing a game, or watching movies. One patient read the news on the internet, to relax, before her surgery.

Yes, I have checked the news that was available, so I had something to read...That killed the waiting time, so I enjoyed it. [Patient 17]

The others did not use the other functionalities on the tablet because they were unfamiliar with tablet functions or did not feel a need for it.

...And I was afraid that there was just one application [the EYEpad app], so I thought, yes [laughs], keep it like this, it is functioning well now, and I should not peddle someone else's tablet. [Patient 2]

During the surgery, I have watched the [intraocular live viewing] monitor, so you don't need the iPad [tablet] at that time. [Companion 3]

Fourteen participants, who already knew how to use a tablet, reported that the EYEpad was easy to use. However, some difficulties were experienced. First, some respondents reported that it was hard to fill in their birth date because the scroll menu moved fast. Second, some respondents did not understand the jargon used in the EYEpad, for example, "*time-out*." Further, it was not clear to all respondents when to use specific checklist tabs, considering there were 3 different tabs. Lastly, one respondent reported there was little time between the nurses' explanation and the use of the EYEpad; this patient did not have sufficient time to open the EYEpad and get used to it before he had to use it.

Yes, especially for that age, it was taking an aim. [Companion 2]

Yes, that's right [laughing], a kind of roulette, as it kept on rotating. [Patient 2]

When asked whether the participants preferred the version of the EYEpad on the tablet or on paper, 14 participants preferred the digital version because of the usability and ability to save data.

# *It is easy to complete, briefly touch and a checkmark appears.* [Patient 11]

Two participants preferred a paper questionnaire above a tablet; both reported low eHealth literacy. Both participants were females. One female was aged 82 and was accompanied by her daughter, and the other female was 72 years old and accompanied by her partner.

#### Nurses

Five of the 6 nurses provided the EYEpad to all patients, except when the patient did not have a companion or when the patient was very old. However, during the focus group, there was a discussion as to whether a patient could be "too old".

When someone is very old, I don't offer him an EYEpad. [Nurse]

But some elderly are very good with tablets, so I think that's no reason to not give it to an elderly patient. [Nurse]



Yes, indeed, some elderly are able to handle the EYEpad, and like it very much, so age should not be a discriminator. [Nurse]

Some see you approaching them with the piece, and they don't look very happy. [Nurse]

Another reason for not providing the EYEpad was the workload experienced by the nurses. The nurses were unanimous that the EYEpad was subordinate to their primary work: treating patients.

Sometimes you need to assist a colleague, or sometimes you are very busy, or something else needs your attention; the EYEpad is then the first to neglect or skip. [Nurse]

Five nurses mentioned that they found it hard to give the correct explanation when they provided the EYEpad to a patient. This was caused by different reasons. They referred to the busy schedule and the number of patients around during the provision of the EYEpad. Also, the perceived patient knowledge of the tablet played a role.

If it's very busy, it's difficult to give a proper explanation. You have less time. [Nurse]

If the patient is familiar with an iPad, the instructions can be done fast because you don't have to explain how an iPad works. [Nurse]

Although nurses were generally positive about the EYEpad usability, they noticed, just like the patients, a few difficulties. First, it was not clear which action was related to the term "*anesthetic drops*" on the second tab of the checklist.

I just still do not understand fully what must be ticked at "anesthetic drops." Is that the moment that we tell the patient they receive anesthetic drops and show which ones? Or is it the moment that we give the anesthetic drops? [Nurse]

Second, it was unclear why only "iodine allergy" was in the checklist because other allergies of the patients were also important to know. Finally, they noticed it was not always easy to go back to the top of the checklist when the checklist was finished.

#### Appreciation of the EYEpad

#### Patients

The EYEpad was well appreciated by patients and companions. Most of the respondents reviewed the EYEpad as "good" or "fine" (n=12). They especially appreciated the checkpoints. Both patients and companions indicated they felt more involved in the health care process on using the EYEpad.

Well, I thought it is an extra check, for you can't check these things (eg, eye to be operated on) often enough. [Patient 2]

We now need to think ourselves, and that was, ehh, you are more involved at least. [Companion 13]

#### Nurses

Most nurses did not appreciate the EYEpad for two reasons. The first reason was that the EYEpad caused some agitation for both patients and nurses. According to the nurses, some elderly

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patients were scared they had to use a tablet. Agitation was also experienced when the patients' companions moved from the waiting room to the preparation room to complete the second checklist.

What I have experienced as troublesome is that the companions of the patients now more often move to the preparation room taking their entire possessions, because they have to complete over there a second list. This is not really the intention and creates a lot of agitation. [Nurse]

Yes, indeed, previously the companion came just along to the preparation [room] as a patient had some degree of anxiety, but now they all come in to complete the checklist. [Nurse]

The second reason why not all nurses appreciated the EYEpad was because it was time-consuming.

The provision and explanation of the EYEpad still just takes a lot of extra time. It is not always the case that you are there with a short explanation, because most of the patients have several questions about it, such as how it exactly works. [Nurse]

They also mentioned positive aspects of the EYEpad. First, the use of the EYEpad improved the reputation of the day center.

It seems luxurious and very modern. [Nurse]

Second, they thought it was nice that younger patients were fine with the EYEpad. Third, they were generally positive about the usability. Most of the nurses (n=4) mentioned that the EYEpad was easy to use. Two mentioned that, although they were not completely familiar with a tablet, they always resolved it together with a colleague.

I think it is sometimes still quite a bit of a search, even though I know how an iPad works, but fortunately, you will always bring it to an end. [Nurse]

#### Impact of the EYEpad

#### Patients

Most patients saw no safety benefits associated with using the EYEpad (n=10). They did not know the purpose of the EYEpad. Six patients, however, thought the EYEpad could contribute to safety because of all the extra data checks.

*Uh, that the EYEpad would help for safer care, here, in the hospital? Well, no, I really don't see that link directly.* [Patient 5]

Yes, that would be possible, I think, or yes, I do not really know. What do you [companion] think? [Patient 10]

Yes, you know, it certainly can, as long as the nurse still take[s] care of those points [unchecked items on the checklists]. [Patient 4]

#### Nurses

According to the nurses, the contribution of the EYEpad to safety is not yet known. They felt time they spent on the EYEpad was too short to evaluate its contribution to patient safety. They were still uncomfortable with the EYEpad and felt their

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explanation to the patients was still suboptimal. The nurses named several impact factors associated with the EYEpad. First, they reported that the EYEpad had a positive influence on the empowerment of patients. The patients were more involved in their care process, more alert, and more conscious of their own responsibility.

The patient is more involved in his or her surgery process by the EYEpad. [Nurse]

By the EYEpad the patient becomes more alert and sees more things during the care process. [Nurse]

With the EYEpad you make the patient and his or her companion more aware of their own responsibility. [Nurse]

Second, the EYEpad had a positive impact on the patients' companions because the companions could use the other functionalities of the tablet to relax. Further, the EYEpad influenced the interaction between patients in a positive manner.

If a patient does not understand the EYEpad or encounters a problem, patients help each other. This creates more contact between patient and companion. Perhaps this also reduces the patient's anxiety. [Nurse]

Next, the EYEpad could have a negative impact on patients and their companions because they could get distracted by the EYEpad during intake, get surprised following presentation of the EYEpad, and companions could feel obligated to the patient.

If you give the tablet, people go straight to work with the tablet, therefore people pay less attention to the nurse. [Nurse]

Patients do not yet know anything about the EYEpad when they arrive at the day center on the day of their surgery. It can overwhelm them. [Nurse]

Some patients often do not dare to say they do not like it [tablet], because we [nurses] offer them from the hospital, and therefore they think that it is obligatory. [Nurse]

Companions are more concerned with the iPad [tablet] than with the patient, making the guidance or support falls away. [Nurse]

Lastly, the EYEpad may worsen the supportive role of the companion if the companion gives more attention to the tablet than to the patient.

## Discussion

#### **Principal Findings**

This study showed that the use of the EYEpad as a digital patient-led checklist in cataract surgery is feasible. Feasibility has been demonstrated in three ways. First, the EYEpad was well appreciated by patients. Patients were positive about the additional checks and felt more involved in their care processes. Second, we found the EYEpad, beside some practical difficulties, was easy for patients and nurses to use. Third, we found that the EYEpad helped patients feel empowered.

However, there remains room for improvement. The EYEpad, with its current instructions, can increase nursing workload. Furthermore, an improved introduction on the rationale and use of the digital checklist is needed because the purpose of the EYEpad was not always clear to the participants. Improved instructions are likely to further enhance patient experience, increasing patients' abilities to understand and influence their own care. This was suboptimal in this study because some patients participated just because the EYEpad was handed to them and not because they were motivated to use it.

#### Limitations

This study had several limitations. One limitation was that we held just one focus group with nurses. More focus groups could have yielded more information about the nurses' viewpoints. Moreover, participation in the focus groups was voluntary and in the end, only 6 of the 18 nurses participated. The nurses who participated likely held viewpoints that differed from nurses who did not participate.

Another limitation was that the purpose of the EYEpad was not clear to all patients and nurses at the start of the study. Only 4 patients indicated they understood the purpose of the EYEpad. This may be due to the limited explanation the nurses gave about the checklist. Apparently, a more elaborate explanation is needed to better understand the purpose of the EYEpad, both for patients and nurses. Previous work has suggested the success of checklist implementation largely depends on a clear explanation of the "why" and "how" [22]. A better understanding of the "why" in this study could further improve the feasibility.

Further, although we inquired as to patients' general experiences with the EYEpad; we did not explicitly address electronic health (eHealth) or health literacy during this study. Therefore we cannot be sure that needs related to EYEpad use were specifically addressed.

#### **Comparison with Prior Work**

In our study, the checklist was patient-led instead of team-led. We found this helped to empower the patients in their own care pathways. We suggested two possible explanations for why patients felt more empowered by using the EYEpad. First, patients may feel more engaged in their own care process. Using health technology makes patients feel more involved in their own care [25]. As indicated by Horwitz and Greysen et al, knowledge alone is not sufficient for proper self-care after surgery [26,27]. Hospitals need to facilitate a good transition, and recovery at home will improve, if patients and caregivers jointly explore patient-centered strategies.

Aujoulat et al described the success factors for patient empowerment. They found that the basics of patient empowerment were to provide reassurance and opportunities for self-exploration on how to manage illness [14]. Second, patients may experience a smaller gap between care professional and patient, which could help them discuss personal questions or issues that may interfere with their treatment.

Besides empowerment, we also found that the EYEpad increased patient participation. Checklists are supplementary tools that



encourage critical thinking and conversation [22]. The EYEpad may help patients engage in their own care. It can ease barriers to preventing harm—for example, not speaking up in the case of suspected errors. A study has shown that communication problems are the root causes of wrong IOL implants in cataract surgery [28]. In New York State, wrong implant-related errors account for 63% of the total number of malpractice claims, and data from Veterans Health Administration showed that approximately half of surgical errors were attributed to the use of the wrong implant [29]. Increased patient empowerment and participation using the checklist can prevent IOL-related errors and thereby improve patient safety.

A surprising finding was that nurses experienced the checklist as "extra work" instead of as a supportive tool for their daily tasks. This may be because the goal of the checklist was not clearly explained. Furthermore, not all nurses were involved in the development of the checklist, which may have made them feel less engaged.

#### **Learning Points**

Before further development of the EYEpad, some hurdles should be addressed. These include providing clear instruction on the rationale for the professionals involved and an improved introduction and explanation of the purpose of the checklist for patients. Communication about the objective of the new digital technology, both with health care staff and patients, is a vital element for successful implementation. It is important to include nurses and other health care professionals from the early idea generation stage, into development and iteration, to generate support and interest. Communication about the objective of the EYEpad must be clear, both to nurses and to patients. Further, our study showed that the practical implication involved listening closely to the care pathway: Which moments are best for the digital EYEpad checklist to be distributed given the planning of the surgical treatment flow? In the current process the use of the EYEpad sometimes disrupted the existing flow, when it should have contributed to a smoother and high-quality care process.

After these hurdles have been considered, the EYEpad can be further developed and implemented. We found that the EYEpad could encourage learning, for example by conscious information acquisition by patients. We did not give specific attention to eHealth and health literacy of participants. More attention to eHealth and health literacy may improve the level of learning.

Further, the checklist should relate to the various steps of the current care process. The better the checklist is implemented, the more structural value it will add toward patient participation in enhancing safe care. It would be useful to make a connection between the checklist and the patients' records to give the professionals insight into the data in a more accessible way. In addition, future studies should make a connection between the checklist and other patient tools to give patients a more complete overview of their care process.

#### Conclusion

In conclusion, we showed that a digital patient-led checklist during surgery was a feasible instrument in cataract care. Our findings suggest that a digital checklist could increase health literacy and provide enhanced guidance on the day of surgery. Our results also demonstrated the crucial role nurses play in the logistics of technological innovations. Increased patient participation will only improve safety as both health professionals and patients feel empowered to share responsibility and balance power.

#### Acknowledgments

We thank the patients, their companions, and the nurses who participated in this study for sharing their experiences with the EYEpad.

#### **Conflicts of Interest**

None declared.

Multimedia Appendix 1 Themes and subthemes. [PDF File (Adobe PDF File), 30KB - periop v1i2e3 app1.pdf]

Multimedia Appendix 2 19-item checklist (in Dutch). [PDF File (Adobe PDF File), 225KB - periop\_v1i2e3\_app2.pdf]

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#### Abbreviations

ASC: ambulatory surgical center eHealth: electronic health IOL: intraocular lens

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**Original Paper** 

# Postoperative Home Monitoring After Joint Replacement: Feasibility Study

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# Abstract

**Background:** We conducted a prospective observational study of patients undergoing elective primary hip or knee replacements to examine the feasibility of a postoperative home monitoring system as transitional care to support patients following their surgery in real time.

**Objective:** The primary outcome was the mean percentage of successful wireless transmissions from home of blood pressure levels, heart rate, oxygen saturation levels, and pain scores until postoperative day 4 with a feasibility target of  $\geq$ 90%.

**Methods:** Patients with an expected length of stay  $\leq 1$  day, age 18-80 years, Revised Cardiac Risk Index  $\leq$  class 2, and caretakers willing to assist at home were eligible. Patient satisfaction, as a secondary outcome, was also evaluated. Wireless monitoring equipment (remote patient monitoring, Telus Canada) was obtained and a multidisciplinary care team was formed.

**Results:** We conducted the study after obtaining Research Ethics Board approval; 54 patients completed the study: 21 males, 33 females. In total, we evaluated 9 hips, 4 hip resurfacing, 26 total knees, and 15 hemi-knees. The mean transmission rate was 96.4% (SD 5.9%; 95% CI 94.8-98.0). The median response to "I would recommend the Remote Monitoring System program to future patients" was 4.5 (interquartile range 4-5), with 1 being "strongly disagree" and 5 "strongly agree." At 30 days postop, there was no mortality or readmission.

**Conclusions:** This is an evolving new paradigm for postoperative care and the first feasibility study on monitoring biometrics after primary hip or knee replacement. Postoperative home monitoring combines current technology with real-time support by a multidisciplinary transitional care team after discharge, facilitating postsurgical care with successful wireless transmission of vitals. The postoperative home monitoring implementation is, therefore, generalizable to other surgical discharges from hospitals.

**Trial Registration:** ClinicalTrials.gov NCT02143232; https://clinicaltrials.gov/ct2/show/NCT02143232 (Archived by WebCite at http://www.webcitation.org/71ugAhhIk)

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#### **KEYWORDS**

postoperative home monitoring; postoperative transitional care; surgical length of stay; postoperative wireless monitoring; patient confidentiality during wireless monitoring; mobile phone

### Introduction

#### Background

For a number of reasons, including the impetus to increase surgical throughput, the median length of stay in Canada has been decreased from 6 days in 2006-2007 to 4 days in 2012-2013 for total hip replacements and from 5 days in 2006-2007 to 3 days in 2013-2014 for total knee replacements [1,2]. Nevertheless, the Canadian Institute of Health Information data (on hip or knee arthroplasty) suggest that "demand is rising at a rate that is outpacing the ability of health systems to keep up" [3].

The literature shows that although most patients have no surgical "returns" such as emergency department (ED) visits or readmissions within 30 days of surgical discharge, 6.5% are readmitted and 18.7% return to the ED within this period in Canada [4]. In one study in the United States, the 30-day readmission rate after total knee replacement was reported to be 5.6% [5]. In another study, the 30-day complication rate after hip or knee replacement was reported to be 2%, with complications including myocardial infarctions, deep vein thrombosis, pulmonary embolism, and death [6]. It is important to note the corollary that 98% of patients did not have complications and that 95.4% were not readmitted within 30 days of hip or knee replacements. The statistics, therefore, support the concept of earlier discharge in spite of a small proportion of patients requiring readmission.

Data from the Canadian Institute of Health Information also show that 1.9%, 9.4%, and 18.7% of postsurgical patients visited the ED within 1, 7, and 30 days of discharge, respectively (based on Ontario, Alberta, and Yukon data) [4]. Of the postsurgical patients who visited the ED within 7 days of discharge, 28.3% (8363/29,552) were evaluated to be at Canadian Triage and Acuity Scale (CTAS) level IV or V, that is, nonlife-threatening or emergent conditions. Such ED visits were potentially preventable or manageable at home.[4] In contrast, 24.4% and 47.2% of postsurgical visits to the ED were emergent and urgent (CTAS I, II, and III), respectively. Delay in taking such patients to the original index hospital results in increased mortality and costs [7,8]. The challenge is, thus, to decide which patients need to be repatriated expeditiously after discharge versus the ones with lesser complications to be managed at home. The postoperative home monitoring (POHM) solution allows remote wireless transmission of blood pressure (BP) levels, heart rate (HR), oxygen saturation (SpO<sub>2</sub>) levels, and pain scores using a tablet, noninvasive blood pressure cuff, and Bluetooth saturation monitor. We hypothesize that using this monitoring system, patients could be wirelessly monitored at home and their concerns after discharge may be addressed to appropriately. This is a report of an outpatient hip and knee replacement pathway at our institution using POHM.

#### Objectives

The objectives of this study were to demonstrate the feasibility of wireless home monitoring after elective primary hip or knee replacements with a primary feasibility target of  $\geq 90\%$ successful transmission of BP levels, HR, and SpO<sub>2</sub> levels and to collect pain scores 4 times a day from home until postoperative day (POD) 4. Secondary outcome included patient satisfaction.

# Methods

Approval from the Ottawa Hospital Research Ethics Board was obtained for a prospective observational study (NCT02143232) of patients undergoing elective primary hip or knee replacements with an expected length of stay  $\leq 1$  day (same day discharge), age between 50 and 80 years, Revised Cardiac Risk Index ≤Class 2, and caretakers to assist at home. As the study progressed, a younger age group was found to present for primary hip or knee replacements, which prompted a change in our age inclusion criterion from 50-80 years to 18-80 years, and we obtained an additional Research Ethics Board supplemental approval. Exclusion criteria included the presence of American Society of Anesthesiology Class IV, chronic obstructive pulmonary disease with forced expiratory volume 1 second  $\leq 1$ , obstructive sleep apnea, patient or family reluctance to participate in early discharge, prior enrollment in POHM, and a disease process that was unstable or undiagnosed. A sample size of 54 was sufficient to yield a one-sided 95% CI estimate around our primary outcome measure (proportion of successful transmissions) with a lower bound exceeding the cut-off point for feasibility of 90%, assuming a proportion of 95% successful transmissions. Consent was obtained in the Preadmission Unit (PAU) starting in March 2014 as per the Ottawa Hospital Research Institute standard operating procedures. The choice of anesthetic was left at the discretion of the anesthesiologist assigned to the case. Surgical approach was as per standard practice of minimally invasive technique: direct anterior in the hip or subvastus in the knee. Patients followed the standard postanesthetic recovery unit's hip and knee replacement clinical pathways.

Prior to discharge on the same day of surgery, remote patient monitoring (RPM, Telus Canada) hardware with cellular connectivity to the patient's home, alerts to the research team's smartphones, and data storage behind the hospital firewall were set up. A care path for primary hip or knee replacement was defined, with acetaminophen, celecoxib, an opioid (tapentadol, tramadol, or hydromorphone), pregabalin, and an anticoagulant (apixaban or rivaroxaban) prescribed on discharge unless otherwise contraindicated. Monitoring of BP, HR, SpO<sub>2</sub>, and pain scores was performed 4 times a day for 4 days postoperatively, and the data obtained were transmitted to the hospital server behind the firewall. Specific alert protocols were set up within the software (Telus, Canada), and a primary responder from within the research team was designated to

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receive the alerts at all times. Otherwise, the primary responder would check the Web-based monitoring dashboard once a day.

A patient questionnaire using a 5-point Likert scale (1: "strongly disagree," 3: "neutral," and 5: "strongly agree") was administered using the hardware (RPM, Telus Canada) without any research personnel present at the end of each monitoring period. Patients were followed up on POD 5 and via phone call on POD 30. Descriptive statistics (mean and SD or frequency and percentage) were used to describe the preoperative and predischarge characteristics of participants. Mean, SD, and median transmission rates were used to describe the actual transmissions over the total daily possible transmissions. Mean and SD were used to describe responses to the patient questionnaire. We followed the Strengthening the Reporting of Observational Studies in Epidemiology statement in reporting this study.

# Results

The target sample size of 54 patients was achieved between April 2014 and September 2015. Patients' demographic characteristics and comorbidities are presented in Table 1. Patients' eligibility, recruitment, and participation in the study

Table 1. Patient demographics.

are shown in the flowchart (Figure 1). Surgical procedures, anesthetic type, and medications received are reported in Table 2. The overall mean transmission rate was 96.4% (SD 5.9%; 95% CI 94.8-98.0), and the median transmission rate was 97.9% (interquartile range [IQR] 97.8%-98.8%; Table 3). There were 6 alerts of BP>140 mm Hg, 7 of BP<90 mm Hg; 7 alerts of HR>120 beats per minute, 0 of HR<50 beats per minute; and 1 alert of SpO<sub>2</sub> 88% (ie, SpO<sub>2</sub><90%). "Unsatisfied with pain control" alerts were sent by patients on 7 occasions and "pain limiting movement" alerts on 13 occasions. Apart from the courtesy phone call made on the evening of discharge, the median number of phone calls to patients during the 4 days of monitoring was 1.0 (IQR 1-3), with 11 and 21 patients with 0 or 1 phone call, respectively; 8 patients required 5 phone calls during the 4 days of monitoring. There was no mortality in the 30-day postoperative period.

Table 4 shows the patient responses to the questionnaire at the completion of the home monitoring. The median response to "I would recommend the Remote Monitoring System program to future patients" was 4.5 (IQR 4-5), with 5 being "strongly agree" (Figure 2). At the end of the monitoring questionnaire, patients were provided the opportunity to provide further comments (Table 5).

Variable	Patients (N=54)	
Age (years), mean (SD)	61.4 (8.3)	
Sex, n (%)		
Female	33 (61)	
Male	21 (39)	
Body mass index (kg/m <sup>2</sup> ), mean (SD)	27.51 (4.0)	
American Society of Anesthesiology Class, n (%)		
Ι	5 (9)	
П	40 (74)	
III	9 (17)	
IV	0 (0)	
High blood pressure on treatment, n (%)	15 (28)	
Type II diabetes mellitus on treatment, n (%)	3 (6)	
Hypercholesterolemia on treatment, n (%)	14 (26)	
Preoperative nonsteroidal anti-inflammatory drug use, n (%)	23 (43)	
Current smoker, n (%)	3 (6)	



Figure 1. Recruitment diagram for postoperative home monitoring (POHM) part 1. OSA: obstructive sleep apnea.

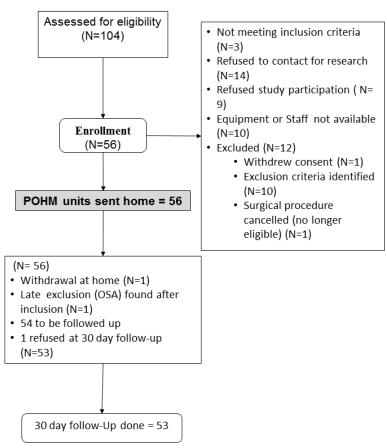


Table 2. Surgical procedures, anesthetic type, and medications received.

Variable	Patients (N=54), n (%)
Surgical procedure	
Total hip	9 (17)
Hip resurfacing	4 (7)
Total knee	26 (48)
Hemi knee	15 (28)
Anesthesia type	
Spinal	50 (93)
General anesthesia	4 (7)
Medication received	
Nonsteroidal anti-inflammatory drug on discharge	40 (74)
Tapentadol or tramadol on discharge	14 (26)
Acetaminophen on discharge	49 (91)
Pregabalin on discharge	54 (100)
Opioid on discharge	38 (72)
Anticoagulant on discharge	51 (94)



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 Table 3. Transmission rates during the first 4 days postoperatively.

Transmission	Percent mean (SD)
Transmission on day of Sx <sup>a</sup>	99.5 (0.03)
Transmission on postoperative day 1	98.3 (0.06)
Transmissions on postoperative day 2	97.9 (0.06)
Transmissions on postoperative day 3	97.8 (0.06)
Transmissions on postoperative day 4	90.9 (0.24)
Transmission per day overall <sup>b</sup>	96.4 (5.9)

<sup>a</sup>Day of Sx: Four transmissions (blood pressure [BP], heart rate [HR], oxygen saturation [SpO<sub>2</sub>], and pain); postoperative days 1-4: (BP, HR, SpO<sub>2</sub>, pain) × 4 per day × 4 days; total possible transmissions: 68 per patient during the study. <sup>b</sup>95% CI 94.8-98.0.

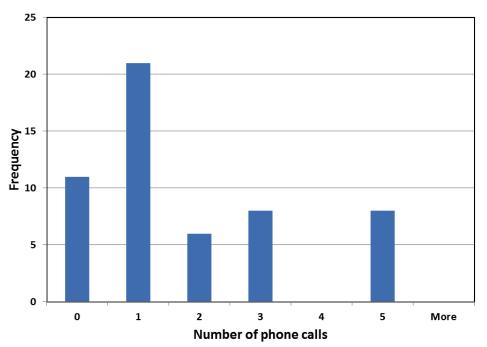
Table 4. Patient satisfaction survey (postoperative day 5).

Variable	Mean (SD) <sup>a</sup>	Number of patients answering the question <sup>b</sup>
"The information provided, told me what to expect about the Remote Monitoring System at home."	4.57 (0.54)	51
"The instructions on how to set up and use the Remote Monitoring System were easy to understand."	4.61 (0.57)	51
"The Remote Monitoring System was difficult to use."	1.82 (0.87)	51
"I felt safe at home during the four days of monitoring."	4.33 (1.01)	51
"During the 4 day monitoring, the response by the Clinician was efficient."	4.46 (0.89)	50
"There was too much to manage at home including the Remote Monitoring System."	2.22 (1.19)	51
"The length of four days for the actual monitoring was just right."	4.14 (0.72)	51
"During the 4 day monitoring, I would have liked more feedback from the Clinician."	2.41 (1.1)	51
"I would recommend the Remote Monitoring System program to future patients."	4.36 (0.8)	50

<sup>a</sup>1: "strongly disagree," 5: "strongly agree."

<sup>b</sup>Not every patient answered every question.

Figure 2. Frequency of phone calls during the 4 days of monitoring, part 1.



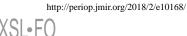


Table 5. Patient comments.

Patient	Comment
#1	"Excellent wonderful."
#2	"Excellent, godsend."
#10	"Comforting-monitoring remotely triggered interaction when at home as he had event. He had event, low BP. He would like comment section at each evaluation time to express how one feels."
#26	"Very good - reassuring that clinician sees the results entered BP monitor should have been demonstrated more with husband."
#40	"very good. Pain episode was managed,,hard to remember the time but by Day 2 ok, Preop stressed and at discharge but having wife shown equip was good."
#44	"concerned how pills affect you .wonderful, very safe, good to check blood pressure."

# Discussion

Our results demonstrate the feasibility of POHM at a transmission rate of >96% supported by a response team. Early data transmission and clear communications between the patients and response team led to alteration in the postoperative course. This is clearly demonstrated from a patient's comment:

"i had a pain crisis on day 2 and this programme allowed me to speak directly with [the nurse] and receive instructions and her rechecking on me I am immensely grateful to her and her initiative. [M]y only other re course would have been a trip to emergency and wait in line. This programme provides an indispensable safety net for major surgery day patient well done."

In an analysis mainly on chronic disease management in a pan-Canadian study on RPM in 2014, acute care was considered and thought to be the most complex of the RPM initiatives, at level 5 [9]. In the risk stratification framework, RPM deployment should ensure that technological complexity, patient acuity, and risk of hospitalization (rehospitalization in our case) are aligned. A patient profile with moderate to high risk of (re)hospitalization should be known to one or more services to ensure multidisciplinary case management. We concur with the conclusion and having a multidisciplinary team; our care model involved surgery, anesthesia, acute pain service, and nursing.

The importance of the POHM is that it does not rely only on the availability of software and hardware but also on the infrastructure to support the home monitoring, including patient safety, secure transmissions, and team response while maintaining privacy. Potential data security and privacy breaches are an increasing concern in mobile medicine [10,11]. One study identified potential data security and privacy breaches in 95.63% (17,193/17,979) of mobile iOS apps [12]. In our project, patient confidentiality and data security were built into the design from the beginning, starting with the hospital firewall for data repository and the use of protected institutional emails. We believe it to be of paramount importance, and since the study completion, we have continued the project in partnership with the Ontario Telehealth Network, which has data infrastructure in compliance with the provincial Office of the Information and Privacy Commissioner of Ontario.

In addition, a primary responder should be designated at the originating hospital to review patients' surgical and anesthetic

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histories whenever alerts are received. The protocols for alerts include algorithms to allow an escalation of severity. The immediate transmission of alerts to the primary responder's smartphone allows the primary responder not to be tied to a monitor but be able to carry out other duties during the monitoring period. In addition, as demonstrated in our feasibility study, most of the patients, in fact, only required 0 or 1 phone call over the 4 days apart from the initial courtesy call on the day of discharge. Nevertheless, 8 of 54 patients required 5 phone calls over the 4 days for support and management. The escalating alert algorithm allows the primary responder to focus on the patients who require more attention at home after discharge.

There have been studies on postsurgical RPM; however, all but one study were on the monitoring of activity levels at home using mobile devices such as smartphones [13-15]. The one study in which bio signs were monitored at home was on 20 patients who had undergone liver transplantation [16]. We present here the first feasibility results on POHM of bio signs after primary hip or knee replacements.

There are some limitations to the current study. It was a prospective, observational trial without interventions. The primary outcome was collected using actual digital transmissions to the hospital server as an objective count. The patient questionnaire was administered at the end of the monitoring period using POHM hardware at the patients' home without any researcher being present. It is unlikely that a bias would have influenced patients' responses. The actual data on 30-day mortality and any other adverse events were collected by the research team via phone calls, and being a numerical count, the data were objective and unbiased. We believe, therefore, that the feasibility and reliability of POHM were demonstrated without bias.

Any surgical population with low surgical readmission or ED visit rates would be an excellent candidate for earlier discharge and POHM. In other surgical specialties, initiatives such as Early Recovery after Surgery have been implemented to achieve earlier discharge [17]. With the advent of minimally invasive surgery, improved anesthetic techniques, and postoperative pain management modalities, earlier postsurgical discharge is increasingly possible and appropriate; POHM is, therefore, generalizable to other surgical populations.

Our study demonstrated that a wireless system is feasible for monitoring patients at home postoperatively. Combining

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real-time interactive support by the health care team and the rapidly evolving monitoring technologies such as wearables, POHM systems hold great promise for even more advanced monitoring at home. The automated system with escalating alerts is a monitoring system with built-in intelligence and allows the primary responder to monitor patients without being tied to a monitor. We believe that POHM is a new paradigm of transitional care for surgical recovery in the postacute care period.

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#### **Conflicts of Interest**

None declared.

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#### Abbreviations

BP: blood pressureED: emergency departmentHR: heart ratePOD: postoperative dayPOHM: postoperative home monitoringRPM: remote patient monitoring

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**Original Paper** 

# Postoperative Home Monitoring After Joint Replacement: Retrospective Outcome Study Comparing Cases With Matched Historical Controls

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# Abstract

**Background:** A retrospective cohort study was conducted in patients undergoing postoperative home monitoring (POHM) following elective primary hip or knee replacements.

**Objective:** The objectives of our study were to compare the cost per patient, readmissions rate, emergency room visits, and mortality within 30 days to the historical standard of care using descriptive analysis.

**Methods:** After Research Ethics Board approval, patients who were enrolled and had completed a POHM study were individually matched to historical controls by age, American Society of Anesthesiology class, and procedure at a ratio 1:2.

**Results:** A total of 54 patients in the study group and 107 in the control group were eligible for the analysis. Compared with the historical standard of care, the average cost per case was Can \$5826.32 (SD 1418.89) in the POHM group and Can \$9198.58 (SD 1513.59) for controls. After 30 days, there were 2 emergency room visits (3.7%) and 0 readmissions in the POHM group, whereas there were 8 emergency room visits (7.5%) and 2 readmissions (1.9%) in the control group. No mortalities occurred in either group.

**Conclusions:** The POHM study offers an early hospital discharge pathway for elective hip and knee procedures at a 38% reduction of the standard of care cost. The multidisciplinary transitional POHM team may provide a reliable forum to minimize readmissions, and emergency room visits within 30 days postoperatively.

**Trial Registration:** ClinicalTrials.gov NCT02143232; https://clinicaltrials.gov/ct2/show/NCT02143232 (Archived by WebCite at http://www.webcitation.org/73WQ9QR6P)

(JMIR Perioper Med 2018;1(2):e10169) doi:10.2196/10169



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#### **KEYWORDS**

postoperative care; postoperative home monitoring; postoperative emergency department visit; postoperative readmissions; continuity of care; cost reductions; length of stay

# Introduction

#### Background

Postsurgical emergency department (ED) visits and readmissions within 30 days after surgical discharge led to a marked increase in expenditures [1]. In a retrospective database study of 152,783 patients undergoing major joint replacements, 5.81% (8883/152,783) patients returned to ED within 30 days, more common than 30-day readmissions of 3.42% (5229/152,783), and pain was the most frequent single diagnosis (25.75%) [2]. Often, patients return to a nonindex hospital, which is not the hospital where surgery was performed originally [3]. The costs in such cases are higher [4], as is the mortality [5]. Data on 667,796 surgical patients from the Canadian Institute for Health Information show that 18.7% of postsurgical patients visited ED within 30 days of discharge (based on Ontario, Alberta, and Yukon data) [1]. An innovative, safe clinical pathway to provide continuity of care or transitional care after surgical discharge would seem ideal both from the patient safety and cost containment perspectives. The postoperative home monitoring (POHM) pathway is feasible and provides the transitional care team to maintain direct communication with their patients after surgery. However, the cost associated with this clinical pathway or the rate of ED visits or readmissions postoperatively have not been studied previously. In this study, we hypothesize that the outcomes of POHM are comparable to historical controls and the costs are lower.

#### Objectives

This study aims to descriptively compare the rates of 30-day readmissions, number of ED visits, and total costs between POHM patients and historical controls.

# Methods

This study protocol was approved by the Research Ethics Board. Data from patients who completed the POHM study were collected, and historical controls were selected, matched in 2:1 ratio to POHM cases by age in deciles, American Society of Anesthesiology class, and procedure. Then, potentially matched controls between January 2010 and December 2012 were identified by Medical Records, and the actual control charts were selected by the RANDBETWEEN function in Microsoft Excel. The cost analysis was conducted by the hospital Finance Department as per the provincial protocols for case costing.

Outcomes were predefined and unchanged during the trial. We compared the rates of postoperative 30-day mortality, readmissions, ED visits, and the total costs between the groups.

We used descriptive statistics (mean [SD] or n [%]) to describe the preoperative and predischarge characteristics of participants. Furthermore, cases and controls were compared using descriptive statistics.

# Results

A total of 54 POHM patients (recruited between April 17, 2014 and August 31, 2015) and 107 control patients (January 2010 and December 2012) were eligible for this study. Table 1 shows the demographic characteristics and outcomes for the 2 groups. For one of the cases, an American Society of Anesthesiologists class 1, only one control was found. No 30-day postoperative mortality occurred in the controls or cases. The 30-day postoperative ED visits were 3.7% (2/54) and 7.5% (8/107) in the POHM group and controls, respectively. There were two 30-day postoperative readmissions among the controls and none among the POHM cases. Table 2 shows the direct, indirect, and total costs between the cases and controls. The average total costs were Can \$5826.32 (SD 1418.89) for cases and Can \$9198.58 (SD 1513.59) for controls.



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Table 1. The case-control demographics and 30-day outcomes, postoperative home monitoring Part 2.

Variables	Postoperative home monitoring, (n=54)	Controls, (n=107)
Age, mean (SD)	61.4 (8.3)	61.9 (8.5)
Body mass index, mean (SD)	27.5 (4.0)	30.7 (6.2)
High blood pressure, n (%)	15 (27.8)	38 (35.5)
Type II diabetes mellitus, n (%)	3 (5.6)	12 (11.2)
Hypercholesterolemia, n (%)	14 (25.9)	28 (26.2)
Pain >3 mo requiring treatment, n (%)	54 (100)	96 (89.7)
Current smoker, n (%)	3 (5.8)	10 (9.4)
Anesthesia type, n (%)		
Spinal	50 (92.6)	91 (85.0)
General	4 (7.4)	16 (15.0)
30-day emergency room visit, n (%)	2 (3.7)	8 (7.5)
30-day readmissions, n (%)	0	2 (1.9)
30-day mortality, n (%)	0	0

Table 2. Indirect and direct costs in cases and controls, postoperative home monitoring Part 2.

Type of cost <sup>a</sup>	Postoperative home monitoring (n=54), Mean (SD)	Controls (n=107), Mean (SD)
Variable direct labor <sup>b</sup>	1277.79 (152.78)	2586.62 (601.84)
Variable direct material-general supplies <sup>c</sup>	563.22 (58.37)	637.26 (120.47)
Variable direct other <sup>d</sup>	101.90 (26.88)	162.94 (44.19)
Variable direct material, patient-specific supplies <sup>e</sup>	2373.63 (1368.88)	2724.86 (1170.15)
Fixed direct labor <sup>f</sup>	192.44 (21.98)	372.46 (117.92)
Fixed direct other—sundry <sup>g</sup>	12.02 (0.94)	6.05 (16.95)
Fixed direct building, equipment, and grounds <sup>h</sup>	450.05 (30.43)	247.61 (47.11)
Variable indirect <sup>i</sup>	626.2 (57.86)	1764.3 (412.77)
Fixed indirect <sup>j</sup>	229.07 (23.5)	696.48 (190.96)

<sup>a</sup>Cost structure in use in the province of Ontario.

<sup>b</sup>Nurses, lab technicians, social workers, etc.

<sup>c</sup>Food, dressings, etc.

<sup>d</sup>Contracted laundry service.

<sup>e</sup>Nonward stock drugs, prostheses, etc.

<sup>f</sup>Clerical and management staff in clinical areas.

<sup>g</sup>Insurance, travel expenses.

<sup>h</sup>Renovation, equipment maintenance contracts, including software.

<sup>i</sup>Clerical human resources, records, housekeeping etc.

<sup>j</sup>Staff in overhead areas.

# Discussion

This study shows that the 30-day readmission or ED visit rates were comparable, if not lower, between POHM and historical cohorts. Conversely, the costs were lower. Based on the current literature, for hip or knee replacements, one would expect 2%-5% postoperative complication or readmission rates [6,7].

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In other words, 95%-98% of patients would be safe to be discharged when surgically ready. With the advances in surgical techniques, anesthetic management, and postoperative analgesia, we believe that earlier discharge after surgery is becoming more feasible and acceptable. As the technology evolves, the POHM infrastructure will be able to capitalize on more sophisticated monitoring, including the rapidly evolving "wearables." The

POHM solution is not expected to change complication rates but with reliable wireless connectivity, real-time interactions with patients are feasible. Such continuity of care would allow a clinician to determine when a patient could be managed at home, return to a nonindex hospital, or return to the index hospital expeditiously, thereby making earlier postsurgical discharge safer with better patient satisfaction.

Postoperative follow-up phone calls have been implemented in many centers. However, little evidence exists that follow-up phone calls by themselves reduce postdischarge readmission rates or ED visits [8-10]. Of various measures that mitigate postdischarge readmissions, continuity of care by physicians who treated patients prior to admission is the most important factor in reducing readmissions [11,12]. The model of care in this study supported the patient after discharge with a multidisciplinary team, including surgeons who had operated on patients. We believe that the model of care is a crucial element in supporting patients after discharge.

The results of this study were viewed by the hospital as an important finding and led our hospital to partner with the Ontario TeleHealth Network. The cost associated with the POHM technology (hardware and software) is expected to drop further in the future. In addition, the ability to scale up; to maintain updates, patient privacy, confidential data repository; to add other devices onto the system; and to negotiate pricing by bulk has increased the ease of application of POHM.

This study has some limitations. Retrospective historical data were used as controls but conducting a concurrently controlled

study was not feasible. Because the sample size was small, we could not draw the statistical significance of differences in 30-day ED visits or readmissions, although a trend of higher rates in the control group was observed. There is potential of missing the 30-day returns in the control group if a patient did not return to our hospital or was readmitted at another hospital. Nevertheless, the trend being already higher in the control group would suggest that if there were a bias, it would have been an underdocumenting of the 30-day mortality, readmissions, or ED visits in the control group. In addition, the cost tracking over the 2 periods in the chart audit was based on the same provincial methodology and with a relatively stable inflation rate, we believe the true cost differences are reflected in our comparisons. The physician costs both in terms of consults, both in patients with longer length of stay and in patients with 30-day ED visits or readmissions, were not tracked. As alluded to earlier, 30-day ED visits or readmissions in the control group to nonindex hospitals were not tracked and their costs, therefore, are not included. Nevertheless, the bias would have been in favor of the control group.

In conclusion, we believe that POHM is a new paradigm of postacute care model for surgical recovery, providing better surgical access by further reducing the length of stay, 30-day ED visits by providing continuity of care and addressing patient concerns, and 30-day readmission rates by stratifying postdischarge management at home, at a nonindex hospital, or return to the index hospital.

#### Acknowledgments

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#### **Conflicts of Interest**

None declared.

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#### Abbreviations

**ED:** emergency department **POHM:** postoperative home monitoring

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### **Original Paper**

# Web-Based Learning for Children in Pediatric Care: Qualitative Study Assessing Educational Challenges

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# Abstract

**Background:** Hospitalization is a significant and stressful experience for children, which may have both short-term and long-term negative consequences. Anaesthesia-Web is a Web-based preparation program that has been well received and is being used worldwide to reduce stressful experiences, increase understanding, and exchange information in pediatric care. A deeper theoretical and educational understanding encompassing children's learning processes on Anaesthesia-Web may optimize and support the development and design of similar websites for children in pediatric care.

**Objective:** The objective of this study was to elucidate key educational principles in the development and design of websites for children in pediatric care.

**Methods:** A directed qualitative content analysis was applied to analyze the content and design of Anaesthesia-Web from a theoretical and educational perspective. preunderstanding, motivation, learning processes, and learning outcome were used to analyze the learning possibilities of Anaesthesia-Web for children prior to contact with pediatric care.

**Results:** We found 4 themes characterizing children's learning opportunities on Anaesthesia-Web in the analysis: "In charge of my learning"; "Discover and play"; "Recognize and identify"; and "Getting feedback". The analysis showed that Anaesthesia-Web offers children control and enables the use of the website based on interest and ability. This is important in terms of motivation and each child's individual preunderstanding. Through discovery and play, children can receive, process, and apply the information on Anaesthesia-Web cognitively, emotionally, and by active participation. Play stimulates motivation and is very important in a child's learning process. When facing pediatric care, children need to develop trust and feel safe so that they can focus on learning. On Anaesthesia-Web, children can recognize situations and feelings and can find someone with whom to identify. Several features on the website promote feedback, which is necessary to judge learning achievements, confirm understanding, and embody the need for repetition.

**Conclusions:** Web-based preparation programs are important learning resources in pediatric care. Content and design needs to change from simply providing information to embracing the importance of a child's need to process information to learn and fully understand. By developing Web-based preparation programs that include educational principles, Web-based technology can be used to its fullest advantage as a learning resource for children. The 4 educational themes described in this study should help future similar website developments within pediatric care.

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#### **KEYWORDS**

child; parents; learning; education; internet; information; preparation; preoperative; anesthesia; risk; delivery of health care; mobile phone

# Introduction

# Web-Based Technology to Prepare Children for Anesthesia and Surgery

The internet is a rapidly emerging source of health service and health care information [1]. Web-based technology has been shown to efficiently convey information in a number of health areas [2-7]. Hospitalization is an important area where children require preparation because the event constitutes a significant and stressful experience, which may cause psychological and behavioral consequences and complicate cooperation and treatment as well as future dealings with medical services [8-11]. Anesthesia and surgery are some of the most stressful events for children while in hospital [12,13]. In terms of impact, children with preoperative anxiety and stress are at higher risk of developing postoperative excitement, distress, nausea, increased levels of pain and analgesic exposure, and delayed hospital discharge during the early postoperative period. Many children also show late reactions in the form of nightmares, separation anxiety, eating disorders, and temper tantrums within the weeks following anesthesia and surgery [9,10,12,14,15]. Preparation for a forthcoming hospitalization is important to decrease children's distress and anxiety for medical procedures [13,16-18]. Adequate preparation is also important to generate accurate expectations and to reduce uncertainties and inconsistencies between fantasy and reality [11,16-18].

The digital age is upon us and is, to varying degrees, integrated into everyday life in most countries around the world. In Sweden, 92% of the population has a computer, 93% has access to the internet, 56% owns a tablet, and 77% owns a smartphone. Most families with children (87%) have multiple computers, tablets, and smartphones. The age at which children start using the internet is notably earlier nowadays (67% of 3-year olds), and the proportion of children using it daily increases with age (32% at the of age 2 years, 50% at 6 years, 75% at 10 years, and 96% in teenage) [19]. The use of Web-based technology to prepare children for pediatric care is increasing, and it provides almost unlimited opportunities for the development and design of such programs. However, preparation of children involves more than delivery of information. Receiving information does not mean one has learned and understood. Learning is a process of constructing one's own understanding [20,21]. Children need to process information about their illness and health to learn about and fully understand their condition [22,23]. Focus on the design and development of preparation programs for children prior to contact with the health care system, therefore, has to change from only providing information to encompassing children's learning processes.

Anaesthesia-Web [24] exemplifies a well-received and worldwide used website to prepare children for hospitalization, anesthesia, and surgery. Even though the development of Anaesthesia-Web was based on children's experiences, a comprehensive pedagogical perspective on the website is

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lacking. In this study, we analyzed the content and design of Anaesthesia-Web based on a theoretical pedagogical framework. A deeper theoretical and pedagogical understanding encompassing children's learning processes on Anaesthesia-Web may optimize and support the development and design of similar websites for children in pediatric care.

#### The Development of Anaesthesia-Web

The content and design of Anaesthesia-Web was developed and produced by a multidisciplinary team of around 150 persons including health care professionals, computer programmers, Web designers and Web design students, journalists, authors, television producers, advertising agencies, and photographers recruited from children's magazines and television shows. The adolescent parts of the website were created together with a popular Swedish author, and the design was both modern and stylish to suit the age group. The team also included parents and children aged 4-16 years with different ethnic backgrounds and experiences of hospitalization, anesthesia, and surgery. The aim of including people with different perspectives in the developmental process was to explore the need for preparation as well as to understand how the content could be best presented and understood among different groups of users. The multilingual work played a central role during the development of Anaesthesia-Web. Native speakers of all available languages on the website were included in the development team. Translations of all manuscripts were completed by authorized translators who were experienced in translating text from the medical context. All text was proofread by native speakers with medical knowledge who were also translating for the web programmers during the implementation of the text to the website. The recordings of all text involved around 25 native speaking actors per language in appropriate ages for all the characters.

#### **Previous Evaluations of Anaesthesia-Web**

In order to understand the usage and distribution of website data on total numbers and geographical distribution of the visitors, the most visited parts of the website and visitor's interactions on notice boards were registered continuously and analyzed descriptively over a period of 5 years (2009-2013). Visitors were registered through their internet protocol addresses. Search engines and websites with a ping back were also registered. All statistics were collated using a log analyzer, generating advanced Web, streaming, file transfer protocol, or mail server statistics graphically. Anaesthesia-Web had an average of 120,000 visitors from approximately 100 different countries annually. The number of visitors was equally distributed over the years, months of the year, and days of the week. Around 300 different websites link to Anaesthesia-Web. Most visitors find the website via the Web address (62,040/120,000, 51.7%) and search engines (50,760/120,000, 42.3%) and the rest via other websites (7200/120,000, 6%). The most common keyword combinations for finding Anaesthesia-Web on search engines were: anaesthesia and children, anaesthesia and risks, and risks with

*anaesthesia*. Analysis of the "Top 5" most visited parts of Anaesthesia-Web during November each year between 2009 and 2013 showed that the most popular parts of the website have stayed quite stable during the years. The most frequently visited parts of Anaesthesia-Web were the "playful" parts and the written part of the website describing general information about anesthesia.

In a previously published randomized controlled trial, including 125 children and parents undergoing outpatient surgery, Anaesthesia-Web was compared with conventional printed brochure material. A set of 6 questions was assembled for children as well as for parents. A prerequisite was that a complete answer to the chosen questions should be available both in the Web-based option and the brochure material. All questions should be relevant to anesthesia. The primary endpoint was to compare the total question score of correctly answered questions by children prepared using the Anaesthesia-Web or conventional printed brochure material.

Secondary endpoints were the total question score for parents and the influence of age, gender, and time between the preoperative visit and day of surgery. The main conclusion was that Web-based interactive preoperative preparation results in higher total question scores in children aged 3-12 years and in their parents compared with conventional brochure material [25].

#### Objective

The objective of this study was to elucidate key educational principles in the development and design of websites for children in pediatric care.

## Methods

#### **Research Approach**

A directed qualitative content analysis [26] was applied to illuminate and explain prerequisites for children's learning on a website preparing children for hospitalization. The chosen approach of content analysis is signified by applying predetermined variables or concepts to interpret a text or content. A directed qualitative content analysis is used when existing theoretical or empirical knowledge about a subject is judged to enhance the understanding of a certain research question. The aim is to describe the common themes characterizing the object being studied. In this case, the design and the coherent content of Anaesthesia-Web constituted the data being analyzed. The predetermined concepts applied in this analysis were derived from a theoretical pedagogical framework.

#### Anaesthesia-Web: Content of the Analysis

Anaesthesia-Web (Figure 1) represents a comprehensive, interactive, age-appropriate, multimedia, Web-based portal to prepare and educate children and families prior to contact with the health care system. On Anaesthesia-Web, children can learn about the body and how it works; what it is like to be hospitalized; and what happens before, during, and after anesthesia and surgery.

Figure 1. The front page of the Anaesthesia-Web website. Copyright: Anaesthesia-Web.





#### The Content and Design of Anaesthesia-Web

The content of the information provided on Anaesthesia-Web is based on evidence and clinical experience from different contexts including medicine, children's cognitive developmental science, and Web-based technology. Common concerns from children and parents before hospitalization include uncertainty and outcome of procedures, separation, loss of control, needle sticks, pain, and risks associated with anesthesia and surgery [27-30]. The website aims to provide learning possibilities as preparation for these scenarios with information for toddlers (1-3 years), pre-school children (3-5 years), school children (5-12 years), adolescents (12-18 years), and parents. Anaesthesia-Web comes in two different parts, which map on to the traditional "For Children" and "For Adults" distinction, but are in practice labeled: "Read" and "Experience." Anaesthesia-Web contains a wide range of communication modalities such as films, cartoons, Web books, games, blogs, videos, and interviews with children of different ages. Two characters, Doctor Safeweb (Figure 2) and Hilding Vilding

(Figure 3), are key features of Anaesthesia-Web. Doctor Safeweb is available all over the website to guide visitors and to answer frequently asked questions. He conveys all information in both writing and with recorded narration. Hilding Vilding works as a curious spy scout in the hospital. He is as tiny as the palm of the hand, which means he can be present everywhere and investigate everything without being discovered. Two notice boards are available on Anaesthesia-Web, one for younger children and one for adolescents. On the notice boards, children can ask each other questions and share experiences using text and drawings (Figure 4).

The information on Anaesthesia-Web is generally applicable, which means that the website can be used regardless of the health care setting to which the family presents. Anaesthesia-Web is available in Swedish and 3 major world languages (English, Arabic, and Spanish) and contains written information in 27 languages. Anaesthesia-Web has open access with different URL addresses.

Figure 2. Doctor Safeweb is available all over the Anaesthesia-Web to guide visitors and to answer frequently asked questions. Copyright: Tintin Timén and Stefan Wahlberg.



Figure 3. The curious spy-scout Hilding Vilding helps visitors to investigate the hospital on the Anaesthesia-Web. Copyright: Tintin Timén and Stefan Wahlberg.



Figure 4. The Anaesthesia-Web has notice boards where children can ask each other questions and share experiences in text and drawings. Copyright: Anaesthesia-Web.



#### **Directed Theoretical Content Analysis**

The theoretical framework is based on a combination of learning theories and especially considered in relation to research on children's learning. Please see the Multimedia Appendix 1 for further explanation. In the theoretical pedagogical framework, learning is regarded as an active construction process and an individual's life-world is the basis for his or her understanding, thinking, and action [20,22]. Learning involves the whole person and is defined as a meaning-making-construction process about new or modified interpretations of perceptions and experiences [20,21]. The educational concepts of *preunderstanding, motivation, learning processes,* and *learning outcome* (Multimedia Appendix 1) were used to analyze the learning possibilities with Anaesthesia-Web for children prior to contact with pediatric care.

#### Preunderstanding

Preunderstanding is a significant part of learning built on emotional, cognitive, and practical live experiences; knowledge acquisition; and reflections, which are more or less conscious. Preunderstanding is a prerequisite, and constitutes the basis, for the interpretation of new experiences and thoughts and for understanding and appraisal of what is seen, heard, and experienced [20,31,32]. The individual interpretation of the world always starts with what is already known, which helps to not only understand but also react if something seems odd, different, or frightening. Although there is awareness of preunderstanding, it is often not apparent that it will direct

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individual attention and action. Preunderstanding can thereby be a barrier for learning when thinking is obstructed and the ability to see and consider other perspectives decreases [22].

#### Motivation

Motivation to learn is vital to stimulate the start and maintenance of a learning process [22,32-34]. Motivation can be triggered not only by the experiences of something being fun and exciting [35] and by internal and external factors but also when previously used approaches to solve problems are not working and when new questions arise that need to be answered and investigated [22,32-34]. Motivation is stimulated both by the challenge and experience of having to master something, as well as by the feeling of succeeding [36].

#### Learning Processes

An individual's processing of information is central and constitutes the essence of the learning process. A learner not only receives information but also interprets and connects it to the existing knowledge, thereby constructing new understanding. Feedback on learning achievements is very important in the learning process [37,38]. All senses are needed to capture new information and to process the existing knowledge cognitively, emotionally, and by active participation. By processing new information and analyzing the old and new understanding, new understanding and knowledge can be developed [20,31].

#### Learning Outcome

Learning processes are meant to result in understanding, ability to perform skills, and, maybe, changed attitudes and behaviors depending on the learning situation [20,22,39]. In this case, the learning goals are related to children and parents being prepared for hospitalization and more specifically for anesthesia and surgery. This means for the child to understand what is going to happen and be able to cope with the situation. Moreover, it is important that both children and parents experience safety and confidence. Feedback on learning achievements is important to support the learner to be confident that the message is understood correctly or to clarify that the information should be repeated for improved understanding [38,40].

In the first phase of the analysis, the predetermined concepts to be applied on Anaesthesia-Web were chosen and described according to the basic theoretical pedagogical framework. In the second phase, the learning concepts were systematically applied on Anaesthesia-Web to identify salient learning opportunities such as how to get access to information, different kinds of multimedia, and possibilities for interaction and guidance. In the third phase, the salient learning opportunities were analyzed using a combination of learning concepts and knowledge about children's learning in the context of health care and especially relating the analysis to the features of Web-based learning. This iterative, analytic process, based on the theoretical pedagogical framework, helped identify themes that mirrored children's opportunities to learn on a website prior to a hospitalization.

The research group comprised different perspectives including Web-based learning, medical education, technology-enhanced learning, pediatrics, and anaesthesia. Two researchers (GL and CS) performed the initial analysis, and the whole group negotiated and agreed on the results to ensure trustworthiness [41,42].

# Results

#### Themes

In the analysis of Anaesthesia-Web related to the central learning concepts *preunderstanding*, *motivation*, *learning processes*, and *learning outcome* (see Multimedia Appendix 1) we found 4 themes related to children's learning: *In charge of my learning*; *Discover and play*; *Recognize and identify*; and *Getting feedback*. The correspondence between the concepts and the themes is presented in Table 1.

#### Theme 1: In Charge of My Own Learning

This theme involves the central learning concepts *preunderstanding* and *motivation*. Based on their level of knowledge, interest, and interpretation, children themselves can decide where to start and how to use Anaesthesia-Web. This allows them to be in charge of their own learning, which is an important motivational factor [22,32-34]. Instead of classifying children as one equal group, Anaesthesia-Web acknowledges children as a diverse group in which the need and format for information differ. All information on Anaesthesia-Web is adapted to children's different cognitive and developmental

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stages. This includes, for example, the vocabulary, the length of stories and films, and the configuration and design of characters and their expressions. However, there are no signs connected to age on Anaesthesia-Web, and thus, it is up to everyone to choose what and how to use the content provided.

Children's past experiences of sickness and health care vary, and Anaesthesia-Web enables children to put their previous experiences into a new frame of reference and enhance their thinking and learning. Anaesthesia-Web contains a wide range of multimedia such as films, cartoons, Web books, games, blogs, videos, and interviews with children of different ages. Here, children are able to take part in a hospital adventure together with the hospital's clowns, potter around and paint, create their own operating theater, watch a film, and meet children with different experiences of hospitalization. On the notice boards, children can ask each other questions and express and share experiences in texts, drawings, paintings, or photos. In addition, there is information on different forms of anesthesia, sedation, pain alleviation, and answers to frequently asked questions from children and adults. Parents receive suggestions on how to prepare both themselves and their children prior to hospitalization.

Anaesthesia-Web can extend children's ability to learn by enabling exposure to ideas and experiences that otherwise would be inaccessible. In "My own Operating Room" (Figure 5), children can construct their own reality by taking command and choosing what procedures they want to experience and what professions they want to play. Maybe they want to change roles being nurses or doctors. Anaesthesia-Web provides children with tools to imagine and explore what it is like to be in authentic situations. They get the opportunity to experience roles in a real-life setting and, at the same time, learn about the setting itself.

Doctor Safeweb and Hilding Vilding, the central characters on Anaesthesia-Web, support the children to take charge of their own learning. By conveying all content in both writing and with recorded narration, children with special needs, hearing and visual impairments, and reading difficulties are given equal access to preparation and learning. For immigrant children, all information on Anaesthesia-Web is available in Swedish and 3 major world languages (English, Spanish and Arabic). Doctor Safeweb, Hilding Vilding, all characters, and animated animals are fluent in these languages.

#### Theme 2: Discover and Play

This theme involves the central learning concepts *motivation* and *learning process*. The content on Anaesthesia-Web is mediated by playful interactive elements to stimulate children's natural curiosity, knowledge seeking, and motivation, factors which are all crucial to initiate and maintain the learning process. Children can use play to seek new knowledge and make events possible to understand. The interactive parts of Anaesthesia-Web enable children to not only prepare for upcoming events but also process what has happened. On Anaesthesia-Web, children can learn and experience how to give an injection, how to bandage a wound, and plaster a broken leg. They can monitor the heartbeat and measure the blood pressure.

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Learning concepts	Themes				
	In charge of my own learning	Discover and play	Recognize and identify	Getting feedback	
Preunderstanding	✓		✓		
Motivation	$\checkmark$	✓	$\checkmark$	✓	
Learning Process		$\checkmark$	$\checkmark$		
Learning Outcome				✓	

Figure 5. The Anaesthesia-Web's "My own operating room" gives children the opportunity to play and explore what it is like to be in an authentic hospital situation. Copyright: Anaesthesia-Web.



In "My own Operating Room," children can decorate and furnish an operating room to their taste. They might want the operating room to have flowered walls and grass on the floor, with a pink operating table with comfortable pillows or a table that looks like a space rocket. They can also try various technical functions such as using different monitors or operating the suction, surgical lights, and tables. Anaesthesia-Web's main characters Doctor Safeweb and Hilding Vilding play significant roles in stimulating children's motivation for learning. Hilding Vilding is filled with questions and does not stop asking them until he has found the answers. With the answers on hand, Hilding Vilding is a master at explaining difficult and complex things in an easy and understandable way. Children can follow Hilding Vilding through an exciting adventure inside the body, playing and learning from his coloring and craft book (Figure 6).

At Anaesthesia-Web, children can design and create their own bandage, email it to a friend, or print and frame it. When playing the "X-ray" game or the "body memory game," they can learn about the body and how it works. In the "Intravenous game,"

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they can give injections and start intravenous infusions. In the "Pain quiz," children can learn how to estimate the level of pain as well as strategies to cope with pain. Multimedia formatting offers choices of interfaces (text, images, sounds, and animations) as the use of all senses for processing and interpreting information is known to be beneficial for children's learning.

#### Theme 3: Recognize and Identify

This theme involves the central learning concepts *preunderstanding, motivation,* and *learning process.* The learning process depends on a will to be engaged, interested, and experience the effort as meaningful. Children's preunderstanding can stimulate their motivation to learn about what is going to happen to them in the hospital, but the Web-based information can also be a hindrance if the information is frightening or if children do not perceive that it is directed toward them. Recognition and identification are the important factors for children to experience the visit as meaningful and to maintain the motivation to learn.

Figure 6. Children can play and learn from Hilding Vilding's coloring and craft book on the Anaesthesia-Web. Copyright: Anaesthesia-Web.



The diversity of characters available on Anaesthesia-Web offers children with different backgrounds the possibility to find someone with similar experiences they can recognize and identify with. The content on Anaesthesia-Web is nontime sensitive and without time-dependent factors such as hairstyles, clothing, and accessories. Characters and their appearance are neutralized and deidentified. A number of characters consist of sick animals and teddy bears undergoing examination and treatments (Figure 7). Toddlers can identify with cuddly toys, and the information for school children is adapted for this age group's curiosity. Adolescents can gain information from others who have blogged about their experiences while hospitalized.

Anaesthesia-Web does not contain any hospital-specific or procedure-specific information, and all interiors are created with generalizable features to help children identify with the information regardless of where and why the child presents for health care. Hilding Vilding plays a key role in fostering this: he is afraid but, at the same time, is curious to explore the hospital, has a lot of questions, and wants to understand and learn. He gets answers to almost all questions, including the ones children probably would never dare to ask. Since Hilding Vilding always makes himself exhausted by asking even the dumbest questions, he allows children to feel that they are always doing better than himself. Hilding Vilding confirms that it is natural to be afraid and clarifies that being curious, asking questions, and searching for answers is the only way to learn something new and that when you have learned something new, you often become a little less frightened. In the Web-based magazine "Lucas's adventure," (Figure 8) children are gradually

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introduced to steps associated with anesthesia and surgery. By following someone who experiences the same procedures as they themselves will, children are given the opportunity to recognize situations and gain insight and understanding in advance.

The notice boards on Anaesthesia-Web help recognize and identify others in the same situation. Children focus on their own fears and experiences associated with different medical conditions, hospitalization, anesthesia, and surgery and those of their siblings and friends. They discuss symptoms; treatments; and side effects, especially their fear of needles, injections, and painful procedures. Fasting routines before and after anesthesia and preoperative and discharge procedures are also commonly discussed. On the notice boards for adolescents, discussions are most often about fear of exposing themselves during examinations and treatments and anxiety about losing consciousness and control.

#### **Theme 4:** Getting Feedback

This theme involves the central learning concepts *motivation* and *learning outcome*. From an educational perspective, feedback is crucial in giving the visitors the opportunity to not only test their level of knowledge but also reduce fear and generate trust and confidence. On Anaesthesia-Web, children get immediate feedback on their performance and progress without any delay, which increases motivation and concentration and retains attention. Doctor Safeweb has a central role in giving advice and feedback when children explore Anaesthesia-Web. He is available all over the website to guide and to give

confirmation, feedback, and answers to frequently asked questions. By getting an immediate feedback on the failure of an idea, children have a chance to correct, learn from errors, improve performance, and achieve goals. On the notice boards, children can participate in discussions and get feedback to questions from peers facing similar experiences. On a website dealing with sickness and hospitalization, feedback that promotes trust and confidence is vital. In this, Doctor Safeweb has a warm, secure, and faithful personality that encourages children and parents to maintain their motivation for learning when encountering new and sometimes frightening situations.

Figure 7. Neutral and de-identified characters undergoing examinations and treatments on the Anaesthesia-Web. Copyright: Anaesthesia-Web.



Figure 8. In the web-magazine "Luca's adventure", children are gradually introduced to anaesthesia and surgery by following someone experiencing the same procedures as they will. Copyright: Anaesthesia-Web.





## Discussion

#### **Principal Findings**

Web-based information can be interactive and patient centered, but if it is not used with the consideration of children's learning processes, it might work only as another source of information. In this study, the content and design of Anaesthesia-Web were analyzed from an educational perspective. The concepts of *preunderstanding, motivation, learning processes,* and *learning outcome* were used to analyze the possibilities for children to learn on Anaesthesia-Web prior to contact with health care system. In the analysis of Anaesthesia-Web related to central learning concepts, we found 4 themes: *In charge of my learning; Discover and play; Recognize and identify;* and *Getting feedback.* 

Studies have shown that Web-based activities can be effective for reasoning, problem solving, and recognition of words, concepts, and situations at an earlier age than expected [43-46]. Therefore, the multimedia diversity in combination with the visitor's freedom on the website is of importance to stimulate children's learning based on their varied background, knowledge, abilities, and what they find as meaningful. Children need opportunities to learn in ways that work for them [28,45,47,48]. Preunderstanding will direct children's attention, which might be helpful when navigating on the website; however, it can also become an obstacle to learning. This complexity is important when designing a website for children within the health care context. For many children, the information on the website is their first meeting with the health care system, whereas others have a lot of experiences, which unfortunately are not always positive. Children with previous experience of hospitalization are not protected from fear. On the contrary, their concerns and anxiety are often increased because they know what to expect and because previous approaches to solve problems and answer questions may have failed [17,28]. Therefore, when designing Web-based learning opportunities, it is crucial to consider this group of children. With increasing cultural diversity and global mobility, it is important to be aware that hospitalization can be a very traumatic experience for migrant children; language, cultural and religious beliefs, and previous experiences of health care and hospitalization in these children demand specific prerequisites for preparation and learning [49]. By creating opportunities for migrant children to be in charge of their learning in their native language, the risk of unnecessary anxiety as well as misunderstandings will decrease.

Our analysis shows that Anaesthesia-Web provides crucial prerequisites for any visitor to take charge of their learning. The content is adapted to children with different experiences, backgrounds, ages, knowledge, culture, developmental stages, and abilities, aiming to provide information suitable for everyone. This is in line with educational research, which shows the importance of offering opportunities for meaningful learning [22]. The content is presented and designed to provide different kinds of learning opportunities, offering multimedia diversity and ease of access for the visitor to make individual choices. By designing multiple approaches to solve problems, answer

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questions, and investigate information, meaningfulness and motivation to learn can be triggered [35].

Research into children's learning with Web-based technology in schools has shown that computer programs offer children some control over learning activities and provide opportunities for choices or imaginative expressions, facilitate children's creative approaches to learning, and increase interest and engagement [50]. Children will need guidance and support to get interested and make choices because it is a great challenge for children to approach the frightening situation associated with preparation for a hospitalization. On Anaesthesia-Web, this is managed by the two central characters: "Doctor Safeweb," representing order and safety, and "Hilding Vilding," introducing fun and curiosity, initiating challenges, and confirming that it is possible to take different routes to learning and discovery.

The theme Discover and play represents the core of the content and layout on the website. Discovery and play are interrelated, but the concept "discover" contains important additional features for learning. Exploration and play are well documented as important factors in children's learning, and the theme highlights significant educational factors connected to the stimulation of motivation and processes involved in learning. The website helps children explore the hospital environment and what is going to happen to them while in hospital. The content and design are developed to stimulate and motivate children's curiosity, creativity, engagement, incidental learning, and active participation, and they can approach the situation playfully, asking questions and finding answers. Playing may reduce the pressure associated with achievements or need to learn [51], providing children with a minimum of risks for experiences related to mistakes and inadequacy in their preparation for hospitalization. Children's motivation has been shown to increase when they are involved with engaging and fun Web-based technology [50]. Computer learning activities can elicit high levels of interest in and focus on a learning task that does not tend to diminish over time [45,52]. These studies relate to learning in school, but it seems likely that this knowledge is applicable to our target population. On Anaesthesia-Web, visitors are given possibilities to prepare for and process hospitalization by accessing information; by practicing skills, functions, and procedures; and by experimenting with different roles in a real-life hospital setting while learning about the setting itself. Children, therefore, receive, process, and apply information cognitively, emotionally, and by active participation. By processing new information and analyzing the old, new understanding and knowledge can be constructed [20,31,45]. As a tool in the learning process, the computer gives the learner specific opportunities for information seeking, communication, and processing of information [50,51,53]. The use of visualization, modeling, and simulation have been proved to be powerful tools to increase children's understanding of scientific concepts and underlying phenomena [45]. By providing children with tools to help them understand and manage procedures, they may be able to transfer what they experience on the website to the real-world context [51]. This is extremely important when designing a website to prepare for a real event [45,50,53-55]. It has also been shown that Web-based technology is beneficial

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to engage children in collaborative learning, reasoning, and problem-solving activities that had been thought to be too sophisticated for them to understand and perform at very young ages [46].

The third theme Recognize and identify is crucial when preparing children for contact with the health care system. To find it meaningful to enter and use the website, children first need to recognize and identify with the content and characters. Second, they need to recognize and identify themselves as persons needing to learn and prepare prior to a hospitalization. Building on children's view of their own thoughts, concerns, and experiences of sickness and hospitalization has been shown to be essential in the development of Web-based preparation programs in health care settings [56,57]. When developing Anaesthesia-Web, a panel of 15 children, aged 4-16 years, with different experiences of sickness and health care were involved. The development of the content together with the target group is important for children's need to not only identify with others facing similar situations [48] but also increase the acceptance and use of the information provided. On Anaesthesia-Web, children can interact with a diversity of characters and find someone to identify with. Accompanied by the safe and trustful character Doctor Safeweb, children are guided and supported to explore step-by-step the strange and maybe frightening situations at the hospital. The fantasy character Hilding Vilding acknowledges the feelings of fear and worry to help overcome barriers for learning. The presence of notice boards on the website helps identifying with others facing the same situation. A child's identity is enhanced by participating in a community or becoming member of a group [58] and can be a powerful motivator for learning. Identification with others increases interest and engagement, enhances meaning, and results in an increased motivation to learn.

The fourth theme *Getting feedback* highlights the possibilities to verify and confirm that the learner has managed, understood, made progress, and received acknowledgment for achievements and performances. Feedback is crucial for keeping up the motivation to learn and is necessary to enable the judgment of what has been learned. The best forms of feedback supporting learning involve interactive processes [37,38]. This is a challenge to accomplish on a website concerning preparation for hospitalization accessed in advance at home. Features promoting feedback on Anaesthesia-Web include quiz games, answers to frequently asked questions, and performance feedback for practical skills with guidance by Doctor Safeweb. The notice board offers the possibility to discuss, share experiences, receive feedback, and learn from others facing similar situations. Studies of children's learning using Web-based technology have indicated that learning proceeds most rapidly when learners are provided with different levels of challenge, when they have frequent opportunities to apply the ideas they encounter, and when feedback on the success and failure is received immediately [45]. When designing games, it is important to ensure that the game structure suits the learning objectives. Children seem to like unpredictability, audio effects, and games with scoring opportunities where the speed of an answer counts [51]. An improvement suggested by our analysis could be for children to have the possibility to chat and receive

immediate feedback on questions and concerns from the hospital.

#### Implications for Designing Health Care-Related Websites for Children

By developing preparation programs based on pedagogical knowledge and experience of children's learning processes, we believe that Web-based technology can be used to its fullest advantage as a health care learning resource. The themes found in the analysis of Anaesthesia-Web provide a basic structure that captures the key educational features needed to prepare children for contact with health care system. Communication with health professionals is an area for further development, but opportunities for children to communicate with others facing similar health challenges and experiences is an important advancement [50]. Learning using Web-based technology is most effective when there is active engagement, participation in groups, frequent interactions, feedback, and connections to the real world [45]. Identification with others creates interest and engagement, which, in turn, lead to meaningfulness and an increased motivation to learn about one's own situation. Web-based technology can also be a solution for children with special needs for social interaction, communication, and learning [43,59-61], allowing them to participate in reality-based activities that would otherwise not be possible for them [62]. According to social learning theories, certain behaviors can be learned and reproduced, under similar conditions, by observing the actions performed by others [63].

The abovementioned research about improvements in children's problem-solving abilities as well as abilities to abstract and engage in reflective thinking using Web-based learning activities is well worth looking into to increase the learning opportunities for children prior to a hospitalization [45,46,50,51]. The development of sophisticated computer games has resulted in new approaches to learning principles, emphasizing the role of elaboration, playing, and engagement [51,64]. Through interactive learning using games, pictures, and sounds, children receive several associations that help them remember and assimilate new information [62].

For adolescents, the internet has become an important, valued, and frequently accessed information source for a range of sensitive health issues [2]. When designing prerequisites for adolescent's learning, it is of highest importance to consider how to meet this group's preunderstanding by providing the information at an appropriate level, balancing between childhood and the adult world. It is a challenge to develop and iteratively refine systems that are attractive enough to catch children's and young people's interest, are useful, and keep the visitor engaged to the website [56,57,65,66]. We would argue that a website has only one chance to catch a visitor's attention, and therefore, it is important to carefully consider how to develop the content and design to be serious and trustworthy as well as secure an active updating [56]. The phenomenon of attrition applies to a varying extent to most eHealth interventions [67]. Active updating is an important task that can be seen as the continued existence of a website in terms of keeping visitors interested through continuous adjustments to maintain presence, interest, and the website as a living tool [56]. Another factor to be aware

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of is that children of all ages are extensive media consumers, which may have resulted in a distorted picture of sickness and hospitalization. Providing children with reality-based information is, therefore, important to help them regulate their expectations and allay their fears [56,68].

#### **Methodological Limitations**

The choice of learning theories and the assumptions about learning they mirror has influenced the analysis and the result. To ensure credibility and make it possible for researchers and readers of the paper to transfer the results to other contexts, the theoretical perspectives on learning were described in detail (see Multimedia Appendix 1) and were applied systematically [41] by an experienced multidisciplinary group.

#### Acknowledgments

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#### **Conflicts of Interest**

GL is the initiator and current owner of the nonprofit website Anaesthesia-Web.

Multimedia Appendix 1 Supplementary Appendix. [PDF File (Adobe PDF File), 418KB - periop\_v1i2e10203\_app1.pdf]

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# Implementation of an Enhanced Recovery Pathway for Minimally Invasive Pectus Surgery: A Population-Based Cohort Study Evaluating Short- and Long-Term Outcomes Using eHealth Technology

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# Abstract

**Background:** Pectus excavatum and pectus carinatum are the most common chest wall deformities. Although minimally invasive correction (minimally invasive repair of pectus, MIRP) has become common practice, it remains associated with severe postoperative pain. Preoperative psychosocial factors such as anxiety and low self-esteem can increase postsurgical pain. Early detection of psychological symptoms, effective biopsychosocial perioperative management of patients, and prevention of pain chronification using an enhanced recovery pathway (ERP) may improve outcomes. However, the incidence of the latter is poorly described in adolescents undergoing MIRP.

**Objective:** The objective of our study was to evaluate the implementation of an ERP containing early recovery goals and to assess persistent postsurgical pain 3 months postoperatively in pediatric patients undergoing MIRP. The ERP consists of a Web-based platform containing psychological screening questionnaires and extensive telemonitoring for follow-up of patients at home.

**Methods:** A population-based cohort study was conducted with prospectively collected data from patients undergoing pectus surgery between June 2017 and December 2017. An ERP was initiated preoperatively; it included patient education, electronic health-based psychological screening, multimodal pre-emptive analgesia, nausea prophylaxis as well as early Foley catheter removal and respiratory exercises. After hospital discharge, patients were followed up to 10 weeks using a Web-based diary evaluating pain and sleep quality, while their rehabilitation progress was monitored via Bluetooth-connected telemonitoring devices.

**Results:** We enrolled 29 adolescents using the developed ERP. Pre-emptive multimodal analgesia pain rating scores were low at hospital admission. Optimal epidural placement, defined by T8-9 or T9-10, occurred in 90% (26/29) of the participants; thus, no motor block or Horner syndrome occurred. Mean bladder catheterization duration was 3.41 (SD 1.50) days in ERP patients. Numeric rating scale (NRS) scores for pain and the incidence of nausea were low, contributing to a fluent rehabilitation. Mean NRS scores were 2.58 (SD 1.77) on postoperative day (POD) 1, 2.48 (SD 1.66) on POD 2, and 3.14 (SD 1.98) on POD 3 in ERP-treated patients. Telemonitoring at home was feasible in adolescents after hospital discharge despite adherence difficulties.

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Although the pain scores at the final interview were low (0.81 [SD 1.33]), 33% (9/27) long-term follow-up ERP patients still experienced frequent disturbing thoracic pain, requiring analgesic administration, school absenteeism, and multiple doctor (re)visits.

**Conclusions:** Allocating patients to the appropriate level of care preoperatively and immediately postoperatively may improve long-term outcome variables. Internet-based technologies and feasible, objective monitoring tools can help clinicians screen surgical patients for risk factors and initiate early treatment when indicated. Future research should focus on improving risk stratification and include a psychological assessment and evaluation of the effect of perioperative care pathways in children undergoing major surgery.

**Trial Registration:** ClinicalTrials.gov NCT03100669; https://clinicaltrials.gov/ct2/show/NCT03100669 (Archived by WebCite at http://www.webcitation.org/72qLB1ADX)

(JMIR Perioper Med 2018;1(2):e10996) doi:10.2196/10996

## **KEYWORDS**

enhanced recovery; pectus carinatum; funnel chest; telemedicine; persistent postsurgical pain; mobile phone; eHealth; pediatric surgery; thorarcic surgery

## Introduction

Funnel chest (pectus excavatum, PE) occurs in 1 out of 400-1000 live births and is the most common chest wall deformity (80%-90% incidence rate); additionally, it affects 4 times more males than females. Pectus carinatum (PC) is the second most common anterior chest deformity (15%), with an even more pronounced male predominance [1]. Surgery, frequently during childhood, is often planned for esthetic reasons rather than as a necessary correction due to compression of underlying organs. Although minimally invasive correction (minimally invasive repair of pectus, MIRP) has become common practice because of the reduced surgical stress response, lower blood loss, and smaller incisions [2], it remains associated with severe acute and persistent postoperative pain. Psychosocial factors, including preoperative anxiety and low self-esteem, are identified as risk factors for increased postoperative pain [3-5]. Furthermore, evidence has revealed that patients undergoing thorax surgery are prone to the development of persistent postsurgical pain (PPSP) [6,7], which is often neuropathic and, therefore, more difficult to treat. However, little is currently known about the precise incidence of PPSP in children after pectus surgery. Despite the increased scientific interest in pain management after pectus surgery [8,9], the provision of adequate pain management and the necessary antiemetic and psychological treatments during the whole perioperative period remain a challenge for health care providers.

Recently, enhanced recovery pathways (ERPs) have been implemented worldwide as evidence-based standardized perioperative approaches. ERPs became the standard of care for patients undergoing colorectal surgery [10]. By introducing enhanced recovery programs, multidisciplinary teams began working together, and the traditional care model was shifted to a more holistic approach, improving many patient-related outcome measurements by reducing the variation of care. The implementation of such ERPs for children and adolescents undergoing MIRP may not only reduce postoperative acute pain and increase overall satisfaction but also provide early alerts to caregivers regarding potential risk factors for increased postoperative pain or PPSP, allowing early treatment that may further improve patient outcomes. The use of one of the most rapidly growing health care innovations [11], electronic health (eHealth) technology (smartphone apps, individual Web-based platforms, and medical devices), may facilitate biopsychosocial follow-up, especially in the long term after hospital discharge [12].

In this study, we aimed to evaluate the implementation of a newly developed holistic ERP for adolescents undergoing elective MIRP surgery utilizing eHealth technology for preoperative psychological screening and long-term postoperative patient follow-up.

## Methods

## **Recruitment Enhanced Recovery Pathway-Treated Patients**

Between June 2017 and December 2017, 29 patients scheduled for MIRP were managed via the implemented multidisciplinary perioperative care pathway after obtaining written informed consent. All surgical procedures were performed by one attending pediatric thoracic surgeon. The technique used has been described by Nuss et al for PE [2] and by Abramson et al for PC [13]. Patients with a history of psychiatric disease, chronic opioid use (>3 months), or revision surgery were excluded from this implementation study. All patients were recruited by the Department of Thoracic and Vascular Surgery and, subsequently, selected for this study by the Anesthesiology Department, Antwerp University Hospital, Belgium. Notably, 2 patients refused preoperative psychological screening via Web-based questionnaires and long-term follow-up via individual eHealth technology. None of the patients reported preoperative pain symptoms. Questionnaire reports and medical data obtained before and after hospital admission were recorded by patients via a specifically designed electronic medical record, supporting an individualized approach.

This population-based cohort study was performed in accordance with the ethical standards of International Conference on Harmonisation-Good Clinical Practice and the Declaration of Helsinki after obtaining study approval from the Institutional Review Board (IRB) and Ethics Committee of the Antwerp University Hospital, Belgium (study identifier: 17/08/082) and

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trial registration (ClinicalTrials.gov NCT03100669). No additional specific IRB approval was requested for the retrospective control cohort as such retrospective use of patient data is already fully covered by a waiver granted by the general IRB that is applicable within the hospital for all research-related activities. The existence of this general IRB was made known to each patient upon admission to hospital, and approval was obtained from each patient. The specifics of the data extraction performed within this retrospective cohort were submitted to the EC for acknowledgment and filing.

## **Historical Controls**

This paper reports initial findings after the implementation of an ERP in patients undergoing pectus surgery in the Antwerp University Hospital, Belgium. Results of this implementation study were analyzed and compared with retrospective acquired administrative data collected from medical charts and hospital records. The retrospectively derived control patient cohort at our hospital underwent identical pectus procedure by the same surgeon without an ERP and were selected by age ( $\leq 18$  years) and pathology (PE and PC).

## **Multidisciplinary Enhanced Recovery Pathway**

Figures 1 and 2 present the components of the multidisciplinary ERP.

## **Preoperative Study Phase**

A clinical study interview was executed 1-2 weeks preoperatively. A preoperative psychological inventory [14]

was performed by patients after activation of the personal Web-based Antwerp Personalized Pain Initiative (APPI; Appi@Home, a European Union registered trademark under registration #017610627) platform; Figure 3; Multimedia Appendix 1). Validated Web-based Dutch questionnaires (Multimedia Appendix 2) included screening for anxiety and depressive symptoms (Hospital Anxiety and Depression Scale, HADs [15]), or trait characteristics (State-Trait Anxiety Inventory, STAI [16]) and self-esteem (Rosenberg Self-Esteem Scale, RSES [17]). Self-assessment through the abovementioned Web-based questionnaires were used in this Web-based trial part. If deviating or alarming questionnaire scores were recorded, an appointment with the psychologist was scheduled preoperatively. In addition, alarming scores were defined on normative data and described cutoffs, as previously described [14]. If present, the appropriate treatment was performed by a specialized psychologist.

The routine preanesthetic assessment included taking patient history and performing clinical examination, blood collection, and technical cardiac and pulmonary investigations if necessary, supplemented by an extensive information session regarding the anticipated surgical trajectory. Key features regarding postoperative pain, pain management with patient-controlled thoracic epidural analgesia (PCEA), and the Foley catheter were included in a procedure-specific information leaflet. Preoperative assessment included the administration of a 7-day regimen of oral gabapentin 1 week preoperatively and alignment of patients' expectations.

Figure 1. Protocol design—timeline. ERP: enhanced recovery pathway; APPI: Antwerp Personalized Pain Initiative; PPSP: persistent postsurgical pain.

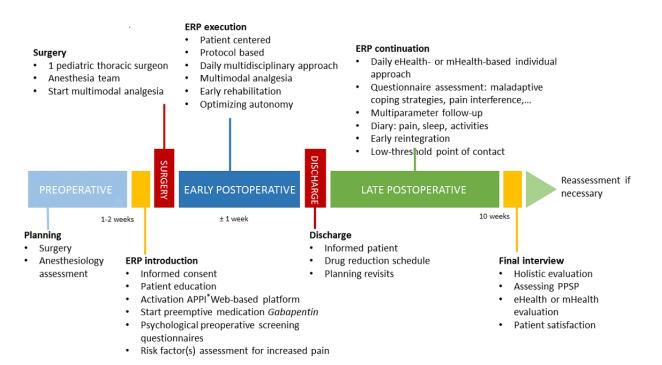
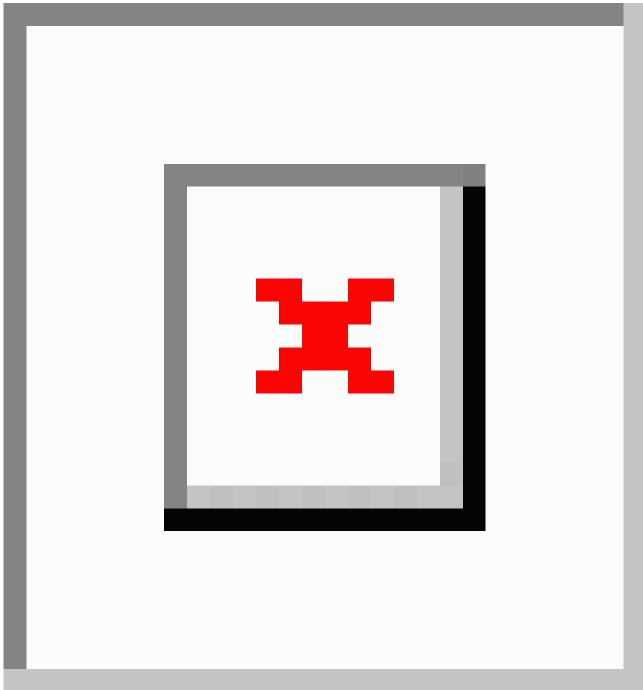
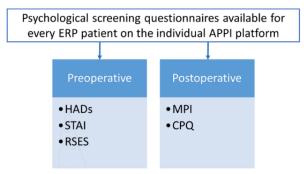


Figure 2. Timeline of the conducted surveys. T0: day of surgery; T1: day of hospital discharge; HADs: Hospital Anxiety and Depression Scale; STAI: State-Trait Anxiety Inventory; RSES: Rosenberg Self-Esteem Scale; NRS: Numeric Rating Scale; MPI: Multidisciplinary Pain Inventory; CPQ: Coping Pain Questionnaire.





**Figure 3.** Multidisciplinary enhanced recovery pathway—psychological elements. ERP: enhanced recovery pathway; APPI: Antwerp Personalized Pain Initiative; HADs: Hospital Anxiety and Depression Scale; STAI: State-Trait Anxiety Inventory; RSES: Rosenberg Self-Esteem Scale; MPI: Multidimensional Pain Inventory; CPQ: Coping with Pain Questionnaire.



### **Early Postoperative Study Phase**

Multimedia Appendix 3 provides a complete overview of the used ERP protocol during hospital admission. In brief, the intraoperative treatment included multimodal analgesia using a thoracic epidural opioid-local anesthetic mixture, ketorolac, and acetaminophen based on patient weight. Additionally, the ERP featured a maximal multimodal antiemetic strategy including dexamethasone, ranitidine, dehydrobenzperidol, and propofol for anesthesia maintenance. Immediately after surgery, patients were admitted to the postanesthesia care unit and were transferred to the ward when postanesthesia care unit discharge criteria were fulfilled. Postoperatively, oral gabapentin was continued for ERP patients in addition to PCEA, nonsteroidal anti-inflammatory drugs, and acetaminophen around-the-clock. The use of intravenous morphine or tramadol was strictly avoided, and a rigorous antiemetic strategy included ondansetron administration during the PCEA regimen. If necessary, escape analgesia for breakthrough pain and antiemetic rescue was available. In the subsequent days, PCEA settings were decreased in a stepwise fashion according to the protocol. Implementation of a programmed intermittent bolus regimen was applied to diminish rebound pain during the reduction of the PCEA dose. Under the protocol, PCEA was discontinued on postoperative day (POD) 6, or, if possible, on POD 5. Urinary catheters were removed as quickly as possible. During hospital admission, daily pain scores, respiratory rehabilitation, and vomiting were recorded in a multidisciplinary fashion. Nausea was noted when persistent. Patients were discharged on acetaminophen, a fixed combination of tilidine and naloxone (Valtran Retard), and gabapentin. Upon discharge from the hospital, patients were provided with a reduction scheme for the analgesic intake over a period of 2 weeks (Multimedia Appendix 4).

#### Late Postoperative Study Phase

The extended ERP included a follow-up period of 10 weeks postoperatively to meet the PPSP working definition proposed by Werner and Kongsgaard [18]. After hospital discharge, 2 Web-based questionnaires were provided for completion within the first week after hospital admission to screen for maladaptive coping strategies and pain-rehabilitation interference using their individual Appi@Home platform.

Figure 4. The Appi@Home toolbox and smartphone app-the medical devices for patient monitoring after hospital discharge.



Scores of the validated Dutch questionnaires (Multimedia Appendix 5) from the Multidimensional Pain Inventory (MPI) [19] and the Coping Pain Questionnaire (CPQ) [20] were assessed. Using eHealth technology, adolescents used their smartphones to log in to the Appi@Home smartphone app for the direct transmission of the derived objective parameters of 3 medical-rated telemonitoring devices (activity tracker, blood pressure monitor, and oxygen saturation measurement device) in the ubiquitous health monitoring system Appi@Home (Figure



4; Multimedia Appendix 1). In addition, the objective data were supplemented by subjective personal diary answers, including daily pain, sleep, and activity assessments on an 11-level scale, which was asked to be filled in daily via the Appi@Home app on patients' smartphones. When no (objective or subjective) data were obtained for 1 week, patients received a single reminder via the platform. If no response was provided, patients were contacted via telephone and asked about their well-being; furthermore, measurement instructions were repeated and

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patients were noted as nonadherent. Adherence is referred to as the capacity of a patient to abide by mutually agreed recommendations regarding daily monitoring [20,21]. Patients presented for postoperative evaluation visits 1-2 weeks after surgery and 2-3 months after surgery at the Department of Thoracic Surgery according to surgeon preference.

The final study interview was planned 3 months postoperatively for patients on an ERP. In-hospital reassessments were scheduled earlier if necessary. An integrated final assessment was executed by a study physician or team member from the multidisciplinary pain center. Furthermore, the intake of medication and side effects, the presence of sleep disturbances, presence of PPSP, school absenteeism, and overall satisfaction were recorded. Moreover, a thorough evaluation of the Web-based platform was performed.

## **Data Analysis**

All data were recorded using a specific designed, multidisciplinary registration tool ("PectusBoek") and Microsoft Excel for Windows 2016 (Microsoft Corporation, Redmond, WA). Patient characteristics were extracted from the electronic patient record (C-medical record, Cegeka, Vienna, Austria) during the hospital stay. In addition, questionnaire scores, diary answers, and medical devices data were derived from their individual eHealth APPI platforms and described. Data were analyzed using SPSS Statistics software, version 21.0 for Windows (IBM Corp, Armonk, NY, United States).

Numeric Rating Scale scores (NRS) for pain and nausea symptoms and subjective sleep scores were summarized and described. When multiple pain scores were assessed in a single day, the day's scores were averaged. A supplementary NRS was recorded by a specialized pain nurse, as were PCEA-related side effects or complications. Furthermore, rehabilitation measures, including flow-oriented spirometry and posture exercises, were evaluated and recorded by a specialized physiotherapist.

Values for the postoperative length of hospital stay (LOS), days of PCEA, and urinary catheterization of patients on an ERP were compared with the corresponding values in the cohort of the previous 93 (ratio 1:3 to reduce selection bias) adolescent pectus procedure patients at our institution before the ERP transition period. The relationships between patient characteristics and outcome variables were analyzed using the independent sample t test and chi-square test after normality control.

# Results

## **Patient Characteristics**

Overall, 28 males and 1 female (age range 12-18 years) underwent MIRP via the ERP protocol. Of them, 23 were treated

for a PE deformity. The mean Haller Index was 3.53 (range 2.5-6.8); however, this outcome was measured in only 9 of 23 patients with PE. Mean body length and body mass index were 174.28 (SD 9.14) cm and 18.37 (SD 2.30) kg/m<sup>2</sup>, respectively.

## Early Recovery: Pain Assessment and Related Outcome Variables

Nausea symptoms were reduced in ERP patients on POD 1 compared with previously operated patients undergoing the same procedure at our hospital, as indicated by their data (5/29, 17%, ERP participants vs 37/93, 40%, non-ERP-treated patients; P=.03). Of the 29 ERP-treated patients, 1 (3%) reported nausea symptoms more than once the day after surgery. The highest incidence of postoperative nausea among patients using the ERP was recorded on POD 3 in 24% (7/29) participants, and 10% (3/29) of them reported nausea symptoms more than twice that day, despite multimodal antiemetic strategies. In 2 ERP patients, nausea was associated with vomiting.

If other side effects were present during the ERP treatment, pruritus was most frequent (25/29, 86%) during the PCEA administration, followed by dizziness (4/29, 14%) within the first 3 PODs. Not unexpectedly, ERP patients had a significantly less neuraxial analgesia side effect (1/29, 0.3%, ERP patients vs 20/93, 22%, non-ERP patients; P=.03) after the standardized thoracic catheter insertion; furthermore, accurate pain reduction was reflected in a longer PCEA administration period for ERP patients (5.76 [SD 1.02] days vs 4.67 [SD 1.20] days; P<.001]. Enrolled ERP patients followed the PCEA weaning protocol, and PCEA was discontinued in 38% (11/29) patients on POD 5 and in 90% (26/29) patients on POD 6. PCEA characteristics were compared with previous non-ERP-treated patients at our hospital (Table 1). Using the 11-level NRS pain scale (0: no pain to 10: worst pain), average pain scores given by the educated patients are shown in Table 2.

Of all ERP participants, 64% (18/29) were able to maximally execute flow-oriented incentive spirometry on POD 1, 93% (25/29) on POD 2, and all of them on POD 3. In addition, 30% (8/29) patients were able to execute physical exercises while standing upright on POD 2; this number increased during the consecutive days to 67% (18/29) on POD 3, 77% (20/29) on POD 4, and 96% (26/29) on POD 5. Moreover, patients were stimulated to increase mobilization and walk from POD 3 onward. Furthermore, 26% (7/29) patients were able to walk on POD3, 58% (15/29) on POD 4, and 82% (22/29) on POD 5. However, no rehabilitation data were available for patients treated without a standardized perioperative protocol.



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Table 1. Patient-controlled epidural analgesia (PCEA) characteristics in patients undergoing minimally invasive repair of pectus with and without an enhanced recovery pathway (ERP).

Postoperative day	ERP-treated patients (n=29)	Non-ERP-treated patients (controls; n=93)	P value	
Thoracic-level PCEA, n (%)			<.001	
T8-10	26 (90)	0 (0)		
Other	3 (10)	93 (100)		
Problem <sup>a</sup> , n (%)			.03	
Yes: no	1:28 (0.3)	20:73 (22)		
Horner syndrome	0 (0)	12 (60)		
Motor blockade	0 (0)	3 (15)		
Prematurely removed	1 (0.3)	5 (25)		
Length of PCEA, mean (SD)	5.76 (1.02)	4.67 (1.20)	<.001	

<sup>a</sup>Problem defined as Horner syndrome, motor blockade, or unforeseen premature PCEA discontinuation.

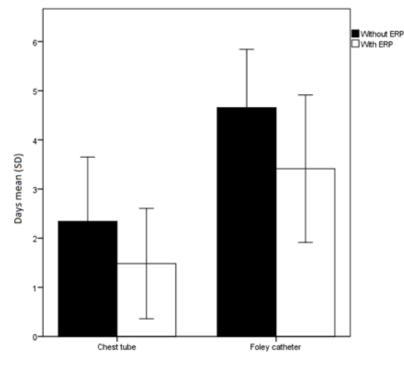
Table 2. Average pain scores assessed by a specialized pain care provider in patients treated with and without an enhanced recovery pathway (ERP).

Postoperative day (POD)	ERP-treated patients (n=29),	Non-ERP-treated patients (controls; n=93),	P value	
	mean (SD)	mean (SD)		
POD 1				
At rest	1.26 (1.43)	1.24 (1.40)	.94	
During exercise	2.58 (1.77)	2.84 (1.60)	.50	
POD 2				
At rest	1.08 (1.38)	1.41 (1.62)	.36	
During exercise	2.48 (1.66)	3.24 (1.70)	.05 <sup>a</sup>	
POD 3				
At rest	1.58 (2.15)	1.16 (1.16)	.37	
During exercise	3.14 (1.98)	2.66 (1.40)	.19	
POD 4				
At rest	1.73 (1.76)	1.29 (1.74)	.26	
During exercise	3.71 (2.16)	2.70 (1.79)	.02 <sup>a</sup>	
POD 5				
At rest	1.52 (1.87)	1.00 (1.59)	.16	
During exercise	2.84 (1.70)	2.23 (1.69)	.12	

<sup>a</sup>Significant at *P*<.05.



Figure 5. The chest tube and urinary catheter duration (mean [SD]) in patients treated with and without an enhanced recovery pathway (ERP).



ERP-treated patients had a significantly reduced Foley catheterization period (3.41 [SD 1.50] vs 4.66 [SD 1.18] days; P<.001) with a much sooner removal of the chest tube (1.48 [SD 1.12] vs 2.34 [SD 1.31] days; P=.002; Figure 5) compared with non-ERP-treated patients, as indicated by their retrospective data, at our hospital. However, the LOS was longer in the ERP-treated group (7.66 [SD 2.01] vs 6.32 [SD 1.26] days; P<.001]. ERP-treated patients could have been discharged after 6.59 (SD 1.99) days (P=.40), but they stayed in the hospital for diverse nonmedical reasons.

## Early Psychological Screening in Surgical Patients Treated With the Enhanced Recovery Pathway

The implementation of psychological screening tools is an innovative feature of the ERP protocol. The PPSP-defined risk factors for anxiety, depression, and low self-esteem were identified using 3 Web-based questionnaires before surgery. Table Questionnaire scores and normative "control" data are summarized in Table 3.

The HADS has been developed for detecting states of depression and anxiety in a hospital setting [22,23]; it contains 2 subscales to assess the presence of an anxiety or depressive disorder. The overall mean score for "fear" was 6.00 (SD 3.20; range: 1-12), indicating the absence of anxiety states prior to surgery. In addition, 71% (17/29) patients scored between 0 and 7 (no anxiety), and 21% (5/29) patients scored between 8 and 10 (possible anxiety); 8% (2/29) patients scored ≥11 (probable anxiety). Screening for depressive disorders showed a mean score of 3.33 (SD 2.76; range: 0-10) and indicated the absence of depressive states prior to surgery. Moreover, 92% (22/29) patients scored 0-7 (no depression), and 8% (2/29) patients scored 8-10 (possible depression). No patient with an alarming score was identified by either subscale. Additionally, trait anxiety was measured using the STAI-DY-2. The overall mean score of the study sample (38.67 [SD 7.99]) was compared with

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available control data of a group of 18-year-old male military recruits (decile 6) [24], which indicated a mean level of trait anxiety in the enrolled ERP patients.

For evaluation of global self-esteem in patients undergoing MIRP with an ERP, the RSES was used. The RSES is a screening instrument for negative body image perception [25]. The mean score of the overall patient sample was 21.25 (SD 3.49), which was above the theoretically defined cutoff score of 15 [26]. No single patient scored beneath this cutoff. On comparing mean self-esteem levels across 53 nations, we found higher self-esteem among our patients than among Belgian patients with a mean score of 19.66 (SD 5.28) [26].

The MPI measures various pain-relevant aspects. We focused on the "pain severity" and "interference" subclasses; therefore, the Dutch version of the MPI questionnaire was used [19]. The mean score of the study sample was compared with the available normative data (mean and SD) of the "IASP Primary Site: Thoracic Region" [27]. The overall mean "pain severity" score in our patients was 2.27 (SD 1.09), which was lower than that of the normative sample (5.01 [SD 0.82]). The overall mean "pain interference" score in our patients was 3.41 (SD 0.81), which was also lower than that of the normative sample (5.01 [SD 0.80]).

For assessing various pain-coping strategies, the CPQ was used [28]. CPQ active and passive coping indices were calculated according to the method described by Soares and Grossi [29] and Nicholas et al [30]. The mean raw subscale scores were compared with those of the normal group of patients with chronic low back pain or neck pain because an identical control group was missing [31]. The decile scores are written in parentheses below. The overall mean "diverting attention" score was 21.32 (SD 12.89; decile 4). The overall mean "reinterpret pain sensation" score was 8.18 (SD 6.41; decile 2). The overall mean "catastrophizing" score was 10.45 (SD 8.96; decile 2).

Table 3. Detailed questionnaire scores from Web-based psychological screening.

Questionnaire variables	Questionnaire outcome	Available data <sup>a</sup>
Hospital Anxiety and Depression Scale		
Fear, mean (SD)	6.00 (3.20)	b
No anxiety, n (%)	17 (71)	Cutoff: ≤7
Possible anxiety, n (%)	5 (21)	Cutoff: $\geq 8$ , but <10
Probable anxiety, n (%)	2 (8)	Cutoff: ≥10
Depression, mean (SD)	3.33 (2.76)	_
No depression, n (%)	22 (92)	Cutoff: ≤7
Possible depression, n (%)	2 (8)	Cutoff: $\geq 8$ , but <10
Probable depression, n (%)	0 (0)	Cutoff: ≥10
State-Trait Anxiety Inventory, mean (SD)		
Trait anxiety	38.67 (7.99)	Decile 6
Rosenberg Self-Esteem Scale, mean (SD)	21.25 (3.49)	Midpoint cutoff: 15
Multidimensional Pain Inventory, mean (SD)		
Pain severity	2.27 (1.09)	5.01 (0.82)
Pain interference	3.41 (0.81)	5.01 (0.80)
Coping Pain Questionnaire, mean (SD)		
Diverting attention	21.32 (12.89)	Decile 4
Reinterpret pain sensation	8.18 (6.41)	Decile 2
Catastrophizing	10.45 (8.96)	Decile 2
Ignore pain sensation	23.09 (12.44)	Decile 3
Praying or hoping	20.00 (15.37)	Decile 5
Coping self-statements	38.09 (11.52)	Decile 5
Increased behavioral activities	19.95 (10.26)	Decile 3
Perceived pain control	10.65 (5.69)	Decile 7

<sup>a</sup>Normative data and cutoff scores from previous literature, see text for references.

<sup>b</sup>No data available.

The overall mean "ignore pain sensation" score was 23.09 (SD 12.44; decile 3). The overall mean "praying or hoping" score was 20.00 (SD 15.37; decile 5). The overall mean "coping self-statements" score was 38.09 (SD 11.52; decile 5). The overall mean "increased behavioral activities" score was 19.95 (SD 10.26; decile 3). The overall mean "perceived pain control" score was 10.65 (SD 5.69; decile 7). Note that these scores represent the pain-coping ability of the study sample. The mean postoperative pain during the first week after discharge was low (NRS: 3.68 [SD 0.22]; MPI pain severity: 2.27 [SD 1.09]), reflecting the need to develop strategies to cope with pain.

# Long-Term Rehabilitation: Subjective and Objective Variables

There was a large variability in the use of the telemonitoring devices in the study sample. As patients were asked to use the devices every day during the 10-week follow-up period, we would theoretically receive, at least, 70 results from each patient's monitoring tool when the patients' adherence was maximal. On average, patients used the devices half as much as expected—only 38 times (Table 4).

There was very little evidence of vital sign problems in the study group (Multimedia Appendix 6), even during the first week when opioids were prescribed. Mean oxygen saturation, heart rate, and systolic blood pressure were 97.85% (SD 1.06%; range: 93%-100%), 81.69 (SD 12.60) beats per minute (range: 55-112), and 111.72 (SD 9.99) mm Hg (range: 90-159), respectively, during the first week after discharge. No alarming vital signs, defined as a systolic blood pressure <95 mm Hg or >140 mm Hg, oxygen saturation <95%, tachycardia >140 beats per minute, bradycardia <45 beats per minute, or >10% deviation from the last parameter control before hospital discharge, were recorded during the long-term study follow-up. These findings further indicate the overall wellness of patients after their discharge from the hospital.

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Table 4. Per patient use of coupled telemonitoring devices that were asked to be actively used once a day and use of an eDiary in the follow-up period.

Parameter	Times used per patient, range	Mean (SD)
Oxygen saturation monitor	8-77	38.00 (21.93)
Blood pressure monitor	7-78	38.50 (23.12)
Diary	1-67	19.88 (16.03)

Table 5. Mean Numeric Rating Scale (NRS) scores for pain, rehabilitation, and sleep quality of enhanced recovery pathway patients after hospital discharge.

Weeks at home <sup>a</sup>	Results, n <sup>b</sup>	Pain <sup>c</sup> , mean (SD)	Daily activity <sup>d</sup> , mean (SD)	Sleep quality <sup>e</sup> , mean (SD)
Week 1 (≤7 days)	97	3.68 (0.22)	4.54 (0.19)	6.10 (0.22)
Week 2 (day 8-14)	70	3.14 (2.34)	5.29 (2.57)	5.29 (2.54)
Week 3 (day 15-21)	58	2.62 (1.92)	4.43 (2.42)	5.93 (2.26)
Week 4 (day 22-28)	52	2.71 (2.39)	5.54 (2.36)	6.40 (2.33)
Week 5 (day 29-35)	50	1.92 (1.88)	5.52 (3.13)	6.80 (2.52)
Week 6 (day 36-42)	38	1.89 (1.57)	6.03 (2.92)	6.50 (2.85)
Week 7 (day 43-49)	35	1.91 (2.37)	5.51 (3.04)	5.77 (3.26)
Week 8 (day 50-56)	25	2.60 (2.55)	5.40 (2.83)	6.36 (2.77)
Week 9 (day 57-63)	25	2.24 (2.28)	5.24 (2.79)	6.16 (2.78)
Week 10 (day 64-70)	17	2.18 (1.38)	6.06 (2.14)	7.41 (2.60)

<sup>a</sup>Results were collected using the Web-based platform during the defined follow-up period of 10 weeks postoperatively.

<sup>b</sup>Number of recorded measurements.

<sup>c</sup>0: no pain; 10: worst pain.

<sup>d</sup>0: worst activity execution possible; 10: ideal activity execution.

<sup>e</sup>0: worst sleep quality; 10: optimal sleep quality.

Mean NRS scores for pain intensity, daily activity execution, and subjective sleep quality within the first week of hospital discharge were 3.68 (SD 0.22), 4.54 (SD 0.19), and 6.10 (0.22), respectively. Table 5 gives an overview of the overall mean pain scores, daily activity execution capabilities, and subjective sleep quality during out of the hospital follow-up. All of these parameters favorably evolved in each patient during the postoperative phase (Multimedia Appendix 7), with decreasing pain scores and increasing scores for sleep quality and satisfaction with the performance of daily activities.

Mean results from daily patient activity generated by the objective activity tracker are shown in Figure 6. The expected long-term postoperative rehabilitation is given in Figure 7, which is shown by the activity tracker data from patient YJ.

Overall, 24 patients used the activity tracker monitoring tool (Table 6). Results were registered in 6 different categories: lying, sitting, standing, walking, running, and cycling. The patients were able to track their activity during 39.79 (SD 5.12) days after surgery, with a large range in the patient individual monitoring use (minimum 1 day, up to maximal use during the study period). Theoretically, the 29 included ERP patients carried the activity tracker during, at least, 70 days, generating activity measurements during a total of 1890 days. During this ERP implementation study, the activity of ERP patients was tracked solely for 955 days (955/1890, 51%). Moreover, only

873 tracked days were evaluated as representative data; that is, activity day logs containing 24 hours of "lying" were interpreted as "tracker not used" and were excluded for data analysis. Patients were registered as "lying down" most frequently during the day. Moreover, "lying down" frequency did not decrease during the consecutive weeks after hospital discharge. Not surprisingly, patients seldom performed more intense activities such as running or cycling during the follow-up period.

No single patient-reported side effect from the perioperative intake of oral gabapentin was observed. In addition, 77% (20/26) patients did not report any side effects from the oral opioid administration on the final interview. When asked about symptoms, 4 patients reported drowsiness, and all others reported dizziness. All of these symptoms disappeared after dose reduction during the first 2 weeks after their hospital discharge.

Although mean pain scores were extremely low at the final interview (NRS: 0.81 [SD 1.33]), 11% (3/27) participants continued to use analgesics on a routine basis. Moreover, 37% (10/27) MIRP operated patients still experienced frequent disturbing pain 10 weeks postoperatively, leading to sporadic intake of analgesic drugs, school absenteeism, and multiple doctor (re)visits. All patients located the pain in the midaxillary thoracic region (5 patients even reported bilateral pain) and all described neuropathic pain characteristics.



Figure 6. Study population mean objective activity variables during postoperative rehabilitation after hospital admission. Data are shown as mean percentages of daily activity evaluated in 6 categories: lying (blue), sitting (green), standing (dark yellow), walking (purple), running (yellow), and cycling (red).

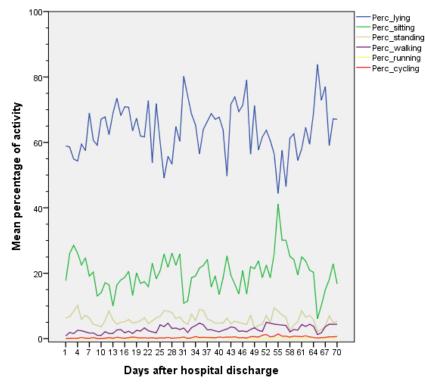
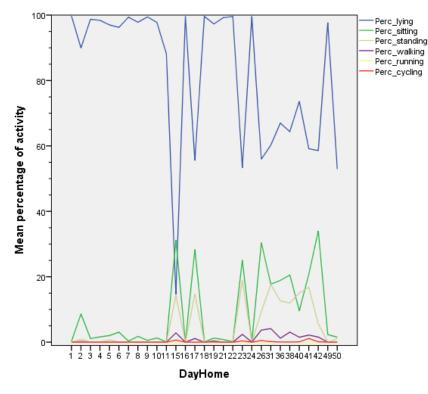


Figure 7. Evolution of daily activities during rehabilitation. Mean objective activity variables of patient Y.J. during postoperative rehabilitation after hospital admission. Data are given as mean percentages of daily activity evaluated in 6 categories; lying (blue), sitting (green), standing (dark yellow), walking (purple), running (yellow), and cycling (red).





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Table 6. Mean activity levels in 6 different intensity categories registered by the activity monitoring tool over 24 hours per week after hospital discharge.

Weeks at	Days, n <sup>b</sup>	Lying		Sitting		Standi	ng	Walki	ng	Runni	ng	Cyclin	ıg
home <sup>a</sup>		Day, %	Hours, mean (SD)										
Week 1	123	59.10	14.18 (6.30)	23.51	5.64 (4.21)	7.27	1.74 (1.65)	1.86	0.45 (0.46)	0.07	0.02 (0.12)	0.16	0.04 (0.06)
Week 2	121	65.44	15.71 (6.78)	15.29	3.67 (3.69)	5.08	1.22 (1.80)	1.65	0.40 (0.612)	0.05	0.01 (0.05)	0.21	0.05 (0.12)
Week 3	115	66.42	15.94 (5.91)	17.78	4.27 (3.86)	5.38	1.29 (1.31)	2.34	0.56 (0.72)	0.04	0.01 (0.03)	0.30	0.07 (0.14)
Week 4	80	60.01	14.40 (5.82)	21.47	5.15 (3.85)	6.76	1.62 (1.71)	3.07	0.74 (0.84)	0.12	0.03 (0.10)	0.23	0.05 (0.09)
Week 5	84	67.16	16.12 (5.57)	18.55	4.45 (3.90)	6.32	1.52 (1.50)	3.35	0.80 (0.82)	0.09	0.02 (0.09)	0.35	0.09 (0.17)
Week 6	79	64.25	15.42 (6.22)	19.51	4.68 (4.02)	5.79	1.39 (1.40)	2.81	0.67 (0.68)	0.16	0.04 (0.15)	0.39	0.09 (0.15)
Week 7	61	70.16	16.84 (7.01)	18.33	4.40 (4.56)	4.94	1.19 (1.53)	2.84	0.68 (0.77)	0.06	0.02 (0.72)	0.44	0.11 (0.17)
Week 8	51	57.68	13.84 (5.61)	25.35	6.08 (4.30)	6.25	1.50 (1.21)	3.76	0.90 (0.75)	0.12	0.03 (0.86)	0.86	0.21 (0.21)
Week 9	57	58.08	13.94 (6.92)	24.01	5.76 (5.45)	5.77	1.38 (1.49)	3.41	0.82 (0.83)	0.11	0.03 (0.07)	0.68	0.16 (0.21)
Week 10	46	70.37	16.89 (6.01)	15.69	3.76 (3.93)	4.62	1.11 (1.31)	3.41	0.82 (0.82)	0.12	0.03 (0.11)	0.44	0.11 (0.15)

<sup>a</sup>Results were collected using the Web-based platform during the defined follow-up period of 10 weeks postoperatively.

<sup>b</sup>Overall number of included measurement days.

Questions regarding Appi@Home satisfaction were asked at the final interview, 3 months postoperatively (Table 7) in this ERP implementation trial. In addition, 27 ERP-treated patients rated the smartphone app, the individual Web-based platform usability, and the platform accessibility as "good" or "excellent" in 78% (21/27), 85% (23/27), and 89% (24/27) cases, respectively. No individual scored the platform usability or accessibility as "insufficient." Regarding the time burden for psychological assessments, 56% (15/27) participants indicated a (rather) low effort for questionnaire completion, and 19% (5/27) patients mentioned that an average effort was required. Overall, 78% (21/27) ERP patients were able to complete the Web-based questionnaires within the imposed deadlines.

The overall satisfaction after ERP was high. Of note, 17 patients rated the in-hospital care as "very good" and 8 rated it as "good," and only 1 patient evaluated the overall care as "sufficient." The overall satisfaction with the long-term follow-up was rated as "very good" by 13 patients, "good" by 10 patients, and "sufficient" by 3 adolescent pectus patients.



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Table 7. Satisfaction with the eHealth technology for postoperative monitoring of patients at home.

Patient satisfaction of device or app <sup>a</sup>	Number of patients, n (%)
Smartphone	
Insufficient	5 (19)
Sufficient	6 (23)
Good	8 (31)
Excellent	7 (27)
Oxygen saturation monitor	
Insufficient	0 (0)
Sufficient	2 (8)
Good	5 (19)
Excellent	19 (73)
Blood pressure monitor	
Insufficient	6 (23)
Sufficient	6 (23)
Good	10 (39)
Excellent	4 (15)
Activity tracker	
Insufficient	5 (19)
Sufficient	3 (12)
Good	6 (23)
Excellent	12 (46)
Sleep monitor	
Insufficient	3 (11)
Sufficient	1 (4)
Good	10 (38)
Excellent	12 (46)
App (daily measurements)	
Insufficient	1 (4)
Sufficient	5 (19)
Good	12 (46)
Excellent	8 (31)
Web-based platform (questionnaires) <sup>b</sup>	
Insufficient	0 (0)
Sufficient	2 (8)
Good	8 (31)
Excellent	14 (54)
Main reason for nonadherence	
Time-consuming	1 (4)
Remembering	19 (73)
Empty battery	2 (8)
Device failure	4 (15)

<sup>a</sup>Patient satisfaction given by 26 enhanced recovery pathway patients at the final interview, 10 weeks postoperatively.

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<sup>b</sup>Two patients did not complete this questionnaire.

# Discussion

#### **Principal Findings**

This first implementation study evaluated different outcome variables of the implemented ERP postoperatively in early recovery and assessed the occurrence of PPSP 3 months postoperatively in pediatric patients undergoing MIRP using eHealth technology. We demonstrated the possibilities of eHealth screening and monitoring tools in a perioperative enhanced recovery program. Using Appi@Home, patients can be monitored during the entire (prolonged) rehabilitation period.

#### Acute Pain and Short-Term-Related Variables

Although surgical correction of pectus deformities has been considered a minimally invasive procedure, MIRP is still accompanied by severe postoperative pain [32]. Bogert et al [33] identified pain scores of 4.1, 4.0, and 3.5 in pectus patients in the first 3 PODs, even with the PCEA treatment. Several studies have shown that postoperative pain is often difficult to manage [8,9], and higher postoperative pain scores are associated with persistent or chronic pain [3,6]. Kristensen et al [6] collected adult reports of patients after thoracotomy, and 16% of them recalled pain >3 months postoperatively. Despite pain scores for which additional treatment is some sometimes required, some physicians succeeded in early hospital discharge after 4.9 (range 3-8) days [34] or 3.1 (range 2-6) days [35]. The use of ERPs has gained major attention in recent years. However, many clinicians struggle to appropriately describe and dose postoperative analgesics while tackling the real needs of patients in acute pain [33]. Litz et al [36] recently described the potential benefit of an in-hospital ERP in patients undergoing thoracic wall deformity repair. Optimal treatment using a pre-emptive multimodal management protocol covering biopsychosocial needs improved patient-related outcome measures, whereas undertreatment of acute pain increased the risk of pain chronification [3]. Possibly, more important than the ongoing debate on the optimal peroperative and immediate postoperative treatment in the ERP (eg, epidural vs intravenous analgesia) [37], novel research suggests a more structured holistic care pathway of routine elective major surgery, understanding the relation between medication initiation, dosage, and duration, focusing on early appropriate treatment of yellow and red flags[38,39]. This requires multidisciplinary follow-up of patients, maximizing patient and parent satisfaction. Our data showed that the implementation of the ERP positively affected early rehabilitation with low pain scores, even with thorough epidural analgesia administration. Pain scores were even lower when compared with data from Litz et al who also used gabapentin but preferred early systemic opioid administration instead of epidural analgesics [36]; the scores were 5.2 (SD 1.7), 3.8 (SD 2.1), and 3.8 (SD 2.2), on POD 0, 1, and 2, respectively. Furthermore, clinicians are urged to remove chest tubes and Foley and epidural catheters as soon as possible, so that the risk of potential urinary or epidural infections and delayed rehabilitation can be reduced.

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In this study, patients and their family members were instructed and educated very early in the perioperative trajectory, thereby reducing anxiety and identifying additional risk factors for increased or prolonged postsurgical pain as suggested by Williams et al using a management pathway including biopsychosocial formulation [7]. The establishment of a constructive relationship between caregiver, patient, and family, as recommended by Liossi et al [39], also provided a platform to provide perioperative context and explain interventions and expectation as indicated by patients and parents on the final interview. Furthermore, the implementation of such a holistic surgical care pathway was positively assessed by the adolescents and their parents during hospital admission as well as after discharge.

#### Persistent Pain and Long-Term Rehabilitation

Our study differs from other studies in terms of the biopsychosocial evaluation and the extended daily follow-up even after hospital discharge. To date, little data concerning subacute, persistent, or chronic postoperative pain in children have been collected, despite growing knowledge regarding risk factors [7]. Our project included the recording of objective parameters, such as vital signs, and subjective variables concerning pain, daily activities, and sleep quality after hospital discharge. Hence, medical intervention could be planned early if necessary. Despite the low pain scores in our study population 3 months postoperatively, 33% (9/27) adolescents reported continued daily intake of analgesics, repeated visits to general practitioners or specialized health care services, and even school absenteeism because of thoracic neuropathic pain symptoms. The dependency of children on their parents and school absenteeism during young vulnerable life increases the importance of these numbers. A possible explanation may be that the increased body length growth or surgical correction of an asymmetrical deformity may lead to consequent increased (unilateral) pressure after fixation with potential intercostal nerve damage as suggested by Wildgaard et al [40]. However, more research with long-term evaluation is necessary to decipher causal variables.

### Implementation of eHealth and Mobile Health Care

Digital apps are on the rise in health care. The need for such apps is apparent due to the increasing tendencies toward early postoperative recovery with reduced hospital stay lengths [36,37]. Through apps, mobile technology [41], and wearables, the health of patients can be monitored more accurately and faster [42]. Consistent with our data, efficient care using this technology was positively evaluated by various patient-related outcome measurements such as pain, daily activities, and overall satisfaction [43]. In fact, mobile health can be a facilitator of evolution toward a value-based approach to care. In this first implementation trial, patients reported the monitoring tools as feasible devices, and they indicated that a rather low effort was required for Web-based questionnaire completion. However, in addition to the need to optimize the performance of the individual wearables, research should be devoted to increasing patient adherence. The use of gamification techniques and other approaches could accelerate implementation [44]. The use of

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such game design elements can increase the motivation of people to adhere to telemonitoring actions and Web-based questionnaires as part of their individual follow-up and therapy.

Little is known about the possibilities of eHealth in this specific patient group of pectus adolescents; however, many of them could benefit from improved perioperative care. This ERP implementation project combines various suggestions reported in other target groups such as psychological screening, structured care, and PROM. Nevertheless, more detailed research through well-designed study protocols is necessary toward postoperative (long-term) application of eHealth modalities in adolescents after a major surgery.

## Limitations

We recognize that our implementation study has some limitations. First, we compared ERP-treated patients with retrospective data in our hospital before such protocols were used for MIRP patients. Therefore, data between 2010 and 2014 were used. It should be mentioned that the Abramson technique has only been introduced in recent years. Moreover, although recognized as the most important risk factor for pain, those historical controls have only been matched for age and pathology. Furthermore, additional research is needed to further clarify the differences in multiple patient-related outcome measurements among patients treated using the ERP protocol in the 2 MIRP categories, PE and PC. Second, the adherence to the different telemonitoring devices should be further

increased. The daily use of the devices is mainly diminished due to "forgot to use it"; this could be a possible explanation for the high reported activity tracker category "lying down." Third, the design of this study focused on adolescent pectus patients without a history of opioid use or psychiatric disease. Ideally, patients diagnosed with autistic spectrum disorders or other mental illnesses should be included in an ERP, as they could benefit the most from standardized care. Our findings must, therefore, be evaluated in larger comparative descriptive studies and randomized controlled trials.

## Conclusion

Our study results offer a potential approach for optimizing holistic patient care, consequently, improving patient-reported outcome measures. Early risk factor identification and structured individual medical (long-term) follow-up after discharge may further enhance rehabilitation. Health care providers should extend their knowledge of and embrace available eHealth technologies for biopsychosocial care.

Our platform provides a framework for optimizing patient- and procedure-specific psychological Web-based screening questionnaires, individual patient monitoring, and treatment (re)assessment. Furthermore, it may contribute to scientific research by offering reliable long-term data.

The implementation of holistic surgical care pathways using a multidisciplinary eHealth-based approach is a combination that merits further investigation in various surgical patient groups.

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#### **Conflicts of Interest**

None declared.

Multimedia Appendix 1 Appi@Home digital platform. [PDF File (Adobe PDF File), 19KB - periop\_v1i2e10996\_app1.pdf]

Multimedia Appendix 2 Preoperative Psychological Screening Questionnaires. [PDF File (Adobe PDF File), 12KB - periop v1i2e10996 app2.pdf]

Multimedia Appendix 3

Multidisciplinary Enhanced Recovery Pathway – Medication Components. PCEA, patient-controlled epidural anesthesia; TCA, target controlled anesthesia; PACU, post-anesthesia care unit; POD, postoperative day; IV, intravenous; PO, per os; PIB, programmed intermittent bolus regimen.

[PDF File (Adobe PDF File), 51KB - periop\_v1i2e10996\_app3.pdf]

#### Multimedia Appendix 4

Standard medication reduction scheme, recommended after hospital discharge. NSAID: nonsteroidal anti-inflammatory drug. All drugs are administrated taking into account the weight of the patient.

[PDF File (Adobe PDF File), 98KB - periop\_v1i2e10996\_app4.pdf]

Multimedia Appendix 5

Postoperative Psychological Questionnaires. [PDF File (Adobe PDF File), 12KB - periop v1i2e10996 app5.pdf]

Multimedia Appendix 6 Vital signs during patient follow-up at home. Note that patients did not use the devices when admitted to the hospital during the early postoperative period. [PNG File, 214KB - periop v1i2e10996 app6.png]

Multimedia Appendix 7

Subjective outcome variables per patient during postoperative rehabilitation at home (after hospital discharge). Note that patients did not use the individual diary when admitted to the hospital during the early postoperative period. NRS: Numeric Rating Scale. [PNG File, 142KB - periop\_v1i2e10996\_app7.png]

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## Abbreviations

APPI: Antwerp Personalized Pain Initiative **CPQ:** Coping Pain Questionnaire eHealth: electronic health **ERP:** enhanced recovery pathway HADS: Hospital Anxiety and Depression Scale **IRB:** institutional review board LOS: length of hospital stay MIRP: minimally invasive repair of pectus MPI: Multidimensional Pain Inventory NRS: Numeric Rating Scale PC: pectus carinatum PCEA: patient-controlled epidural analgesia PE: pectus excavatum **POD:** postoperative day **PPSP:** persistent postsurgical pain **RSES:** Rosenberg Self-Esteem Scale **STAI:** State-Trait Anxiety Inventory

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## **Original Paper**

# Evaluating the Variation of Intraocular Pressure With Positional Change During Colorectal Laparoscopic Surgery: Observational Study

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# Abstract

**Background:** The incidence of perioperative visual loss following colorectal surgery in the US is quoted as 1.24 per 10,000. Raised intraocular pressure (IOP) during extreme Trendelenburg position leading to reduced optic nerve perfusion is thought to be a cause.

**Objective:** To assess the effect of the degree of Trendelenburg tilt and time spent in Trendelenburg on IOP during laparoscopic colorectal surgery.

**Methods:** Fifty patients undergoing laparoscopic colorectal surgery were recruited. A Tonopen XL applanation tonometer was used to take IOP measurements hourly during surgery, and each time the operating table was tilted. A correlation coefficient for the degree of Trendelenburg tilt and IOP was calculated for each patient. Group 1 included patients undergoing a right-sided colonic procedure, and Group 2 included all left-sided colonic operations.

**Results:** The mean age of Group 1 participants (n=25) was 69 years (SD 14), and Group 2 (n=25) was 63 years (SD 16; P>.05). The average length of surgery for Group 1 was 142 minutes (SD 48), and Group 2 was 268 minutes (SD 99; P≤.05). The mean maximum degree of Trendelenburg tilt in Group 1 was 10 (SD 7) and Group 2 was 19 (SD 6; P≤.05). The mean IOP increase was 9 mm Hg (SD 5) for Group 1 and 15 mm Hg (SD 5) in Group 2 (P≤.05). An overall correlation coefficient for the degree of Trendelenburg tilt and IOP change (n=48) was .78.

**Conclusions:** There is a strong correlation between IOP elevation during laparoscopic colorectal surgery and the degree of Trendelenburg tilt. This may be significant for patients undergoing prolonged surgery and especially those with glaucoma.

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## **KEYWORDS**

laparoscopic; colorectal; intraocular pressure; Trendelenburg

# Introduction

## Background

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Trendelenburg positioning is commonly used during laparoscopic colorectal surgery to allow the use of gravity to move the small bowel out of the pelvis and provide the surgeon

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with adequate views. The degree of tilt and time spent in these positions varies depending on the type of resection, the complexity of the case, and the surgeon. Trendelenburg positioning and pneumoperitoneum used during laparoscopic surgery lead to an increase in central venous pressure (CVP). An increase in CVP leads to a rise in episcleral venous pressure which in turn increases intraocular pressure (IOP). As the eye

has limited distensibility, it only requires a small change in aqueous humor volume for IOP to change significantly. Problems in venous drainage can lead to a reduced arterial blood supply, reducing oxygen delivery to the optic nerve, and result in ischemia and neovascularization [1].

Postoperative vision loss (POVL) is a serious complication which significantly affects the quality of life. The incidence of POVL has gradually increased. The cause is thought to be multifactorial: (1) an increase in more complex surgeries being performed, and (2) patients with multiple comorbidities who are at higher risk of postoperative complications [2,3]. In cases where the cause is not identified (eg, foreign body in the eye), the most common explanation is optic nerve ischemia [2,4]. Ischemia may be the result of anemia, hypotension, blood loss, or raised IOP leading to optic nerve [2,5,6].

#### Objective

This study aimed to look at how the degree of Trendelenburg tilt during laparoscopic colorectal surgery affects IOP.

# Methods

## **Study Design**

This study was a clinically based prospective observational trial. The study was reviewed and approved by the Northampton Research Ethics Committee (protocol number: 11GA019, April 2012) and undertaken as per the tenets of the Council of Helsinki. All patients undergoing planned laparoscopic colorectal resection under the colorectal surgery service at Nottingham University Hospital were invited to participate in the study. Patients undergoing a right-sided colonic procedure were included in Group 1, and those undergoing left-sided colonic procedures (including subtotal resections) were included in Group 2. Participants were divided into these groups because left-sided colon procedures were hypothesized to spend longer in a steeper Trendelenburg tilt compared to those only undergoing right-sided procedures. Patients with a history of significant ocular disease other than glaucoma, or an allergy to latex were excluded from this study. Patients expressing an interest in participating were given an information leaflet and those who were willing to join signed a consent form before study intervention.

Demographic data (1) gender, (2) age, (3) smoking history, (4) comorbidities, and (5) medication history was collected from each patient. Baseline eye examinations were also performed including: (1) best corrected visual acuity, (2) gonioscopy, (3) central corneal thickness, (4) Goldmann applanation tonometry, (5) and Tonopen XL applanation tonometer. The Tonopen XL applanation tonometer measurements were repeated after lying the patient supine for 5 minutes. They were collected after administering 1% tetracaine eye drops and repeated to obtain an average of 3 readings at 5% accuracy.

On the day of surgery, baseline IOP was taken in the right eye using the Tonopen XL applanation tonometer. IOP measurements were repeated in the right eye at the following points during surgery: (1) after induction of general anaesthetic, (2) at the start of surgery, (3) 5 minutes after pneumoperitoneum

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was created, (4) every hour after the start of surgery, (5) 5 minutes after the table was tilted at any point during surgery, and (6) at the end of surgery. The timing of these readings was documented along with the angle of the table tilt, positive end expiration pressure (PEEP), expired carbon dioxide ( $CO_2$ ) level, mean arterial pressure (MAP), and pulse rate.

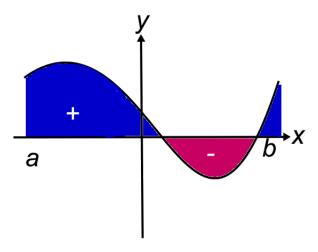
Spinal or thoracic anesthesia was administered at the start of each operation. Spinal anesthesia consisted of up to 500 µg of intrathecal diamorphine and up to 20 mg of bupivacaine. Epidural anesthesia was maintained with 0.125% levobupivacaine and 4 µg/mL of fentanyl. Induction of general anesthesia included 25-50 µg/kg of midazolam, remifentanil (0.5-1 µg/kg) or fentanyl (1-2 µg/kg), propofol (1-2.5 mg/kg), and neuromuscular blockade with either rocuronium or atracurium was given. Anesthesia was maintained with intraoperative target-controlled remifentanil infusion at (0.05-2.0 µg/kg per minute) in addition to oxygen, air, and desflurane.

#### Statistical Analysis

Data were analyzed with an unpaired t test for comparison of IOP change, length of surgery, and the degree of tilt used between the 2 groups. A paired t test was used for comparison of IOP before and after the induction of a pneumoperitoneum and maximum IOP increase with the maximum degree of Trendelenburg tilt during surgery. A Pearson's correlation coefficient between the degree of tilt measurements and IOP was calculated for each patient. The individual correlation coefficients were then pooled using a meta-analytic approach considering the different number of readings and potential heterogeneity between patients. The Stata code metan was used to perform meta-analysis modeling. All correlation coefficients were normally distributed into Fisher Z, and the pooled Fisher z scores (95% CI were then transformed back to a correlation coefficient with 95% CI using the z to r transformation equation.

Further analysis to incorporate the length of time spent at various degrees of Trendelenburg tilt was carried out by determining the area under the curve (AUC). This was calculated by plotting the time from the start of surgery against the degree of table tilt in either an upward (negative) or downward (positive) position. The Trendelenburg tilt was recorded as positive and reverse Trendelenburg as negative. The AUC was determined by multiplying the degree of table tilt by the time spent in that position in minutes. If the table was in the upward head position, this value would be negative (ie, the negative y-axis portion of graph Figure 1). All these were added up to give a cumulative tilt AUC by the product of degrees and minutes. For example, time spent in the upward head position gave a negative value which was effectively subtracted from the total AUC when added to the portion of the curve where the patient was in the Trendelenburg position. The change in IOP AUC was calculated similarly, with IOP change from baseline plotted on the y-axis, and the x-axis time in minutes from the start of surgery. The change in IOP was calculated by subtracting the baseline IOP from the IOP measurements taken during surgery. If the IOP went below the baseline IOP, this was plotted on the negative y-axis which effectively subtracted from the overall cumulative change in IOP AUC.

**Figure 1.** Tilt AUC calculation method= start of surgery, b= end of surgery, y-axis= degree of head down tilt, x-axis= time in minutes. For 'change in IOP' AUC: y-axis= change in IOP in mmHg, x-axis = time in minutes.



A multilevel mixed analysis was carried out comparing the following variables to the change in IOP AUC that occurred at each time point in each patient. The variables analyzed included: (1) time from the start of surgery (minutes), (2) AUC, (3) pneumoperitoneum pressure in millimeters of mercury (mm Hg), PEEP, (4)  $CO_2$ , and (5) MAP.

# Results

Fifty-five patients were enrolled in this study of which 5 withdrew their consent on the day of surgery. Group 1 and Group 2 each consisted of 25 patients. Twenty-six (52%) were male, and 24 (48%) were female with a mean of 66 (SD 16) years of age. Three (6%) of the patients were graded as American Society of Anesthesiologists (ASA) 1, 43 (86%) were ASA 2, and 4 (8%) were ASA 3. The mean body mass index (BMI) was 27 (SD 5) kilograms per meter squared (kg/m<sup>2</sup>). Table 1 summarizes the demographics of patients in each group. Table 2 details the operative procedures performed in each group.

# Correlation Between Tilt Area Under the Curve and Intraocular Pressure

Correlation between the degree of tilt AUC and IOP was analyzed for each patient. Meta-analysis of Pearson's correlation coefficient between the degree of tilt and IOP was estimated at r=.78 with heterogeneity chi-squared ( $X^2_{47}=72.9$ , P=.009) indicating there is a significant positive correlation between the IOP and the degree of Trendelenburg tilt (Figure 2). Two patients were excluded from this analysis as they remained supine (at degree zero) which did not allow for a Pearson's correlation.

## Comparison of Tilt and Intraocular Pressure Between Groups 1 and 2

Comparison between Group 1 and Group 2 was performed using an unpaired *t* test for maximum IOP increase and maximum Trendelenburg tilt. There was a significant difference between the 2 groups. For the maximum IOP increase from baseline, the *t* score was 3.89 with 95% CI –8.79 to –2.81, *P*<.001. For the maximum Trendelenburg tilt, the *t* score was 4.72 with 95% CI –12.64 to –5.09, *P*<.001 (Table 3).

## Multilevel Analysis of Factors That May Affect Intraocular Pressure

A multilevel mixed analysis compared the change in IOP AUC at each time point with each variable measured to include: (1) time from start of surgery, (2) tilt AUC, (3) pneumopressure, (4) PEEP, (5) CO<sub>2</sub> level, and (6) MAP. For this analysis, all patients were included. The output from this analysis is detailed in Table 4.

The statistical analysis carried out showed that the critical factors affecting IOP rise was the length of surgery, tilt AUC, and expired  $CO_2$ .

## Analysis of the Effect of Pneumoperitoneum on Intraocular Pressure

The effect of pneumoperitoneum on IOP was assessed by comparing the IOP measured 5 minutes after the induction of pneumoperitoneum to the maximum IOP rise that occurred intra-operatively. The surgeon would create the pneumoperitoneum and carry out a diagnostic laparoscopy while supine before tilting the patient, and an IOP measurement would be taken. A two-tailed t test was carried out with t=7.79, 95%CI 6.20 to 9.38,  $P \le .001$  (Table 5). In 1 patient, we were unable to measure IOP immediately after the induction of pneumoperitoneum as a central line was being placed, they were therefore excluded from the t test analysis.



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 Table 1. Patient demographic data comparison between Group 1 and Group 2.

Parameter	Group 1	Group 2	
Gender, n (%)			
Male	15 (30)	11 (22)	
Female	10 (20)	14 (28)	
Age (years), mean (SD)	69 (14)	63 (16)	
BMI <sup>a</sup> (kg/m <sup>2</sup> ), mean (SD)	26 (4)	28 (6)	
ASA <sup>b</sup> grade, n (%)			
Ι	1 (2)	2 (4)	
Π	20 (40)	23 (46)	
III	4 (8)	0 (0)	
Operative time (minutes), n (%)			
<100	5 (10)	0 (0)	
100-199	18 (36)	4 (8)	
200-299	3 (6)	11 (22)	
300-399	0 (0)	3 (6)	
400-499	0 (0)	4 (8)	
>500	0 (0)	2 (4)	
Length of stay (days), n (%)			
<3	2 (4)	0 (0)	
3-5	12 (24)	12 (24)	
6-10	7 (14)	8 (16)	
>10	3 (6)	5 (10)	
Deaths, n (%)	$1(2)^{c}$	0 (0)	
Trendelenburg tilt (degree), n (%)			
<14	18 (36)	5 (10)	
14-20	7 (14)	12 (24)	
>20	0 (0)	8 (16)	
Blood loss (mL), n (%)			
<100	15 (30)	17 (34)	
100-500	7 (14)	3 (6)	
>500	3 (6)	5 (10)	

<sup>a</sup>BMI: body mass index.

<sup>b</sup>ASA: American Society of Anesthesiologists.

<sup>c</sup>Day 2 from a chest infection.



Table 2. Operation details for all 50 patients.

Parameter	n (%)
Group 1	
Laparoscopic right hemicolectomy	24 (96)
Laparoscopic colotomy	1 (4)
Group 2	
Laparoscopic anterior resection	15 (60) <sup>a</sup>
Laparoscopic Hartmann's	3 (12) <sup>b</sup>
Laparoscopic subtotal colectomy	4 (16) <sup>a</sup>
Laparoscopic panproctocolectomy	1 (4)
Laparoscopic completion proctectomy and ileoanal pouch	1 (4) <sup>a</sup>
Extralevator abdominoperineal resection	1 (4)

<sup>a</sup>One converted to open.

<sup>b</sup>Two converted to open.

Figure 2. A graph of the intra-operative data collected for patient 1. It shows a strong correlation between the degree of tilt and the IOP measurements taken using the Tono-Pen XL.

Study			~
ID		ES (95% CI)	Weight
1		0.59 (0.12, 1.07)	3.08
2	•	0.20 (-0.34, 0.74)	2.35
3		0.99 (0.25, 1.74)	1.27
4	•	1.31 (0.69, 1.93)	1.81
5		0.18 (-0.48, 0.83)	1.63
6		1.22 (0.56, 1.87)	1.63
7		0.72 (0.10, 1.34)	1.81
• –		0.33 (-0.26, 0.93)	1.99
9	<b>.</b>	0.80 (0.14, 1.45)	1.63
10	*	0.33 (-0.55, 1.20)	0.91
11		0.60 (0.04, 1.17)	2.17
12		0.66 (-0.32, 1.64)	0.72
13		0.90 (0.16, 1.64)	1.27
14	•	0.95 (0.50, 1.40)	3.44
15 -		0.61 (-0.19, 1.41)	1.09
16		0.68 (-0.30, 1.66)	0.72
17		0.48 (-0.32, 1.28)	1.09
18		0.70 (-0.10, 1.50)	1.09
19		0.40 (-0.09, 0.89)	2.90
20		0.83 (0.24, 1.42)	1.99
21		1.14 (0.34, 1.94)	1.09
22		0.96 (0.60, 1.33)	5.25
23	•	0.63 (0.12, 1.13)	2.72
24 -		0.69 (-0.18, 1.57)	0.91
25		0.96 (0.39, 1.52)	2.17
26		0.98 (0.18, 1.78)	1.09
27		0.97 (0.51, 1.43)	3.26
28		1.35 (0.55, 2.15)	1.09
29		0.59 (0.13, 1.05)	3.26
30 -		0.37 (-0.22, 0.96)	1.99
31	•	1.35 (0.94, 1.76)	4.17
32	• • · ·	0.37 (-0.12, 0.86)	2.90
33		1.16 (0.36, 1.96)	1.09
34		1.31 (0.97, 1.66)	5.98
35 -		0.45 (-0.20, 1.11)	1.63
36	<u> </u>	-0.48 (-1.35, 0.40)	0.91
37		-0.07 (-1.05, 0.91)	0.72
38		0.47 (-0.41, 1.35)	0.91
39		0.58 (-0.04, 1.20)	1.81
40	-	1.61 (0.74, 2.49)	0.91
41		0.96 (0.59, 1.34)	4.89
42		0.80 (0.00, 1.60)	1.09
43	• ·	0.20 (-0.45, 0.86)	1.63
44		1.00 (0.51, 1.49)	2.90
45		0.74 (0.12, 1.36)	1.81
46		0.80 (0.41, 1.20)	4.53
47	• •	0.20 (-0.42, 0.82)	1.81
48		0.78 (0.29, 1.27)	2.90
Overall (I-squared = 35.5%, p = 0.009)	♦	0.78 (0.69, 0.86)	100.00



Table 3. Overall mean length of surgery, baseline, and mean rise in intraoperative pressure between Group 1 and Group 2.

Parameter	Group 1	Group 2	P value
Age (years), mean (SD)	69 (14)	63 (16)	.15
Baseline IOP <sup>a</sup> (mm Hg), mean (SD)	16 (4)	17 (2.9)	.64
Length of surgery (minutes), mean (SD)	142 (49)	268 (99)	<.001
Maximum Trendelenburg tilt (degree), mean (SD)	10 (5)	15 (5)	<.001
Maximum increase from baseline IOP intraoperatively (mm Hg), mean (SD)	9 (5)	15 (5)	<.001

<sup>a</sup>IOP: intraocular pressure.

Table 4. Regression analysis outcome for all 50 patients.

Change in intraocular pressure AUC <sup>a</sup>	Coefficient (SE)	z value	Coefficient (95% CI)	P value
Time from start of surgery	4.33 (0.49)	8.88	4.33 (3.37 to 5.28)	<.001
Tilt AUC	0.48 (0.04)	12.66	0.48 (0.41 to 0.56)	<.001
Pneumopressure	-2.46 (4.16)	-0.59	-2.46 (-10.62 to 5.69)	.55
PEEP <sup>b</sup>	25.05 (26.54)	0.94	25.05 (-26.97 to 77.07)	.35
CO <sub>2</sub> <sup>c</sup>	121.69 (47.06)	2.59	121.69 (29.45 to 213.93)	.01
MAP <sup>d</sup>	1.46 (1.84)	0.79	1.46 (-2.16 to 5.07)	.43

<sup>a</sup>AUC: area under the curve.

<sup>b</sup>PEEP: positive end-expiratory pressure.

<sup>c</sup>CO<sub>2</sub>: concentration of expired carbon dioxide.

<sup>d</sup>MAP: mean arterial pressure.

**Table 5.** Comparative data for maximum intraoperative pressure (IOP) increase during the operation and the increase following pneumoperitoneum induction.

Parameter	N	Mean (SD)
Maximum IOP increase	50	12 (6)
IOP rise following pneumoperitoneum	49	4 (6)

# Discussion

## **Principal Findings**

Laparoscopic surgery is the preferred approach for most colorectal resections. The advantages include (1) smaller incisions, (2) reduced blood loss, (3) less postoperative pain, and (4) reduced recovery time [7]. Trendelenburg positioning is used during laparoscopic colorectal surgery and other specialties including urology and gynecology to utilize gravity as a form of retraction. It allows the small bowel to fall out of the pelvis away from the operative field during left-sided resections. During a right hemicolectomy, the Trendelenburg position is used to help move the small bowel away during the cecal dissection. Our study found the degree of tilt used and the time spent in Trendelenburg is significantly lower in right-sided resections compared to left-sided resections. During a right hemicolectomy, we found that a reverse Trendelenburg position is often used when mobilizing the hepatic flexure. This was why we used tilt AUC as a measure for part of our analysis to consider the time spent in the reverse Trendelenburg as well as the Trendelenburg. As the reverse tilt was measured as a negative tilt, the amount of time spent in the reverse position

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reduced the overall AUC value. The maximum Trendelenburg tilt was significantly different between the 2 groups. For Group 1 the mean maximum Trendelenburg tilt was 9.70, and for Group 2 it was 15.10.

An IOP above 25 mm Hg is considered pathological [8]. Chauhan et al [9] looked at the effect of raised IOP in rats. Their data suggested changes were dependent on the peak increase in IOP. They found a peak increase of 15 mm Hg in IOP resulted in extensive axonal loss (mean loss of 69.2%), and a peak increase of 20 mm Hg in IOP resulted in profound axonal structural loss (mean reduction of 76.7%). They concluded that optic nerve axonal damage was related to the peak increase in IOP with a change of 10 mm Hg or more leading to damage of the optic nerve [9]. The length of time that IOP is raised has an additional cumulative effect [10,11]. Similar findings were also made by Morrison et al [12]. Our results showed a significant difference in the maximum change in IOP with a mean IOP rise of 9.3 mm Hg, versus 15.1 mm Hg in Group 1 and 2, respectively.

Grosso et al [10] compared 3 groups of patients: (1) those undergoing laparoscopic surgery supine, (2) laparoscopic

surgery in Trendelenburg position, and (3) open surgery in a supine position. They looked at the effect of pneumoperitoneum (12-14 mm Hg) on IOP and found a mean rise of 4 (range 0-11.2) mm Hg, which was comparable to our 4.43 mm Hg rise, following pneumoperitoneum. The mean increase following 45 minutes after the start of surgery was 5.05 mm Hg in the Trendelenburg group versus 4.23 mm Hg in the laparoscopic group not placed in Trendelenburg [10]. In our study, we compared the IOP rise that was measured 5 minutes following induction of pneumoperitoneum to the overall maximum IOP rise that occurred during surgery. This gave a mean rise of 4.43 mm Hg following pneumoperitoneum induction compared to an overall rise of 12.22 mm Hg. This too was statistically significant suggesting the creation of pneumoperitoneum alone (at 11-14 mm Hg) that was used on our patients does not cause a clinically significant increase in IOP.

Awad et al [13] also looked at the effect of steep Trendelenburg positioning on IOP during robotic prostatectomy [13]. Their analysis revealed PEEP, duration of surgery, end-tidal  $CO_2$ levels, and MAP were all significant predictors of IOP change during surgery. The Grosso et al [10] and Awad et al [13] dataset varied from our study as their patients were placed in Trendelenburg position at the same degree of tilt and IOP measurements were taken at specific time points. In our study, the degree of Trendelenburg varied as did the time spent in Trendelenburg. This allowed us to assess the effect of time and position steepness on IOP. Our analysis also showed that the length of surgery, time spent in Trendelenburg position, the degree of Trendelenburg tilt, and expired  $CO_2$  levels were significant factors for change in IOP during surgery.

Glaucoma affects 2% of the population over the age of 40 years and this increases with age [14]. However, only half of those with glaucoma know they have it, meaning 50% do not know. Also, another 3%-5% of the population over this age suffer from ocular hypertension which is a risk factor for the development of glaucoma. Therefore, potentially 1 in 50 patients undergoing a laparoscopic colorectal resection could have glaucoma, but only 50% of these would have been diagnosed.

Our study also showed the degree of Trendelenburg tilt was strongly correlated with IOP, with a coefficient value of .78 (P=.009). During the study, we also observed that by reducing the tilt even by a few degrees, the IOP would reduce almost immediately, which is of great clinical significance. This may be a useful mechanism to prevent sustained IOP elevation during surgery when prolonged surgery is being undertaken. It may

also benefit patients in whom there are concerns that optic nerve ischemia of prolonged IOP elevation may be risky such as patients known to have glaucoma.

#### Limitations

There were limitations to our study, including the use of Tonopen instead of the gold standard Goldmann applanation tonometer for IOP measurement [15]. Studies have shown that taking an average of 2 readings, the accuracy of the Tonopen is significantly increased. In our study, we took 3 measurements and used the average. Other studies have shown this improves the accuracy of Tonopen measurements and are similar to the Goldmann applanation tonometer [15-17]. Measuring IOP in only 1 eye can also be a potential limitation. However, Grosso et al [10] measured IOP in both eyes at each time point and found minimal difference between the left and right eye [10,18]. A further limitation to our study was due to the IOP measurements being available throughout surgery to the anesthetist and surgeon. If the IOP measurements were high (>30 mm Hg), it prompted the anesthetist to ask for a reduction in the Trendelenburg tilt. In the few patients in which this was done, this led to the observation that reducing the Trendelenburg tilt by only 2 degrees, there was a decrease in IOP. Also, by returning the patient to supine, the IOP returned to near baseline after only 5 minutes of moving the table.

Vision loss is a significant potential complication of steep Trendelenburg positioning. However, even where catastrophic vision loss does not occur, sustained IOP elevation may result in some subclinical optic nerve damage. This may increase the risk of later vision loss [9], particularly in those patients who have preexisting optic nerve damage or develop optic nerve pathology later in life.

## Conclusion

In conclusion, our results showed a strong correlation between the degree, duration of the Trendelenburg tilt, and IOP during laparoscopic colorectal surgery. Significant and prolonged IOP elevation occurred in a proportion of patients which is of clinical significance when operating on patients with glaucoma. By reducing the degree of Trendelenburg tilt during laparoscopic colorectal surgery, the IOP rise can be reduced. Additional studies to consider intraoperative breaks from Trendelenburg or IOP screening preoperatively with targeted therapy to prophylactically reduce IOP in patients undergoing a lengthy surgical procedure requiring Trendelenburg positioning would be of clinical value.

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#### **Conflicts of Interest**

None declared.

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## Abbreviations

AUC: area under the curve BMI: body mass index CO2: carbon dioxide CVP: central venous pressure IOP: intraocular pressure MAP: mean arterial pressure PEEP: positive end-expiratory pressure POVL: postoperative vision loss



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