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Continuous monitoring of vital signs in surgical patients on a general ward: an observational cohort study

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TITLEPAGE

Title

Continuous monitoring of vital signs in surgical patients on a general ward: an observational cohort study.

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ABSTRACT

Objectives

To determine feasibility, in terms of acceptability and system fidelity, of continuous vital signs monitoring in major abdominal surgery patients on a general ward.

Design

Observational cohort study.

Setting

Tertiary teaching hospital.

Participants

Postoperative abdominal surgical patients (N=30) and nurses (N=23) at a surgical ward.

Interventions

Patients were continuously monitored with the SensiumVitals® wearable device until discharge in addition to usual care, which is intermittent Modified Early Warning Score measurements once a day. Heartrate, respiratory rate and axillary temperature were monitored every two minutes. Values and trends were visualized and alerts sent to the nurses.

Outcomes

System fidelity was measured by analysis of the monitoring data. Acceptability by patients was assessed by a 4-item questionnaire and acceptability of nurses by the USE-questionnaire.

Results

Thirty patients were monitored for a median duration of 81.3 h per patient resulting in 115,217 measurements per parameter. In total, 18.5% of heartrate, 51.4% of respiratory rate an 8.9% of temperature measurements showed artifacts. The system algorithm sent 972 alerts (median alert rate of 4.5 per patient per day) of which 90.3% were system alerts and 9.7% vital sign alerts. 93% of patients rated the patch as comfortable, 67% felt safer and 89% would like to wear it next time in the hospital. Nurses were neutral about usefulness (median 3.5 on a 7-point Likert scale), ease of use (3.7) and satisfaction (3.7) but agreed on ease of learning (5). Neutral scores were mostly related to the limited fidelity of the system.

Conclusions

Continuous monitoring of vital signs with a wearable device was well accepted by patients. Nurses ratings were highly variable, resulting in on average neutral attitude towards remote monitoring. Our results suggest it is feasible to monitor vital signs continuously on general wards, although acceptability of the device to nurses needs further improvement.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Both acceptability and fidelity of continuous vital sign monitoring system on the general ward were thoroughly investigated for both patients and nurses, establishing the feasibility of this intervention.
- Fidelity of the system was assessed based up a large dataset of 115,217 measurements of heart rate, respiratory rate and temperature.
- Our results provide relevant insights for the design of future larger-scale studies evaluating effectiveness and implementation strategies of continuous vital signs monitoring at the general ward.
- The study population was limited to surgical patients and the realtime monitoring data registration was not seamlessly integrated into the electronic medical record.

MAIN TEXT

Introduction

The post-operative complication rate after major abdominal surgery is 20-44%[1] which may result in re-interventions, prolonged hospital stay, Intensive Care Unit (ICU) admissions and mortality[2–4], and eventually to lower life expectancy, lower quality of life, and higher costs.[5–7] Early detection of postoperative clinical deterioration on the ward may allow for early intervention and better outcomes.[8] Currently, the optimal frequency of vital sign measurements remains unknown. On most surgical wards they are monitored no more than 1-3 times a day.[9,10] Early Warning Scores, such as the Modified Early Warning Score (MEWS) are then used to help identify patients at risk.[11–13] A higher MEWS is associated with admission to the ICU, cardiac arrest, and mortality.[14–16] However, a critical limitation of current monitoring practice is its infrequent and intermittent nature,[17,18] which may result in delayed detection of clinical deterioration, in particular during night shifts with lower staffing per patient rates.[19]

Recent advances in wearable, wireless sensor technology now facilitate continuous monitoring of vital signs.[20,21] Emerging evidence shows that these monitoring sensors are accurate, may improve outcomes and reduce costs by allowing earlier detection of changes in vital signs in clinical practice.[22] A previous study about continuous monitoring of abdominal surgical patients, resulted in earlier antibiotics administration, decreased hospital stay and readmissions within 30 days.[23] Another study by Subbe et al. (2017) reported more rapid response teams interventions, decreased cardiac arrests, reduced overall mortality, reduced illness severity and reduced mortality in those patients admitted to ICU, and an increase in pro-active decision-making on end-of-life care.[24] In addition, Weenk et al (2017) studied two continuous monitoring devices, and reported that continuous monitoring was feasible if frequency and duration of artifact measurements would be reduced.[25] Several other studies with wearable monitoring devices reported potential benefits such as less patient disturbance and improved sleep, reduced work load of nurses and improved safety during patient transport between departments.[26–29]

A new wearable device for wireless remote monitoring of vital signs has recently been tested in several hospitals, the SensiumVitals®. The first published reports have shown it to be valid and safe.[23,30,31] However, there is still insufficient insight regarding the feasibility of using such a continuous monitoring device at a general ward, especially because continuous monitoring can be defined as a complex intervention with many interacting components and behavior change of healthcare professionals.[32] As recommended by the Medical Research Council framework, feasibility testing and piloting are needed before larger scale clinical

implementation of such an intervention can be undertaken.[33] The aim of the study was to determine feasibility, in terms of acceptability and system fidelity, of continuous vital signs monitoring with the SensiumVitals® device among abdominal surgery patients on a general surgery ward.

Methods

Design

An observational cohort study was conducted from October until December 2019 at a surgical ward of a large tertiary teaching hospital. This study is reported in concordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[34]

Participants

Patients scheduled for elective colorectal or pancreatic resection were recruited through convenience sampling. Inclusion criteria were: age >= 18years, no cognitive impairments, expected hospitalization time three days or longer and fluent in the Dutch language. Exclusion criteria were: surgery for a palliative or emergency indication, a cardiac pacemaker in situ, a known allergy for any of the materials of the device or participating in another conflicting study. For nurses, eligibility criteria were: nursing registration, active involvement in the continuous monitoring system for at least three days during the study, and able to speak and read the Dutch language.

Intervention

Current standard of care was intermittent monitoring (once daily) using the Modified Early Warning Score (MEWS) according to the hospital policy.[35] In addition to standard care, patients included in the study were continuously monitored by the SensiumVitals® system *(Sensium, Abingdon, United Kingdom)*. This wireless monitoring device is Conformité Européene–(CE) marked, approved by the Food Drug Administration and worn as a patch on the patient's chest. It continuously monitors heart rate (HR) in beats per minute (bpm), respiratory rate (RR) in breaths per minute (brm), and – via a secondary sensor - axillary temperature (T_{ax}) in degrees Celsius (°C).[36] The patch is attached to the skin by two electrocardiogram stickers *(Skintact, Leonard Lang GmbH, Innsbruck, Austria)* as shown in Figure 1.

Every two minutes, the data were transmitted wirelessly through ceiling-mounted bridges to a dedicated server, and from there to a mobile device carried by the nurses and to

their desktop. There were two types of alerts: vital sign and system alerts. Vital sign alerts were sent when the parameter value passed the threshold (50 bpm < HR < 120 bpm, 8 brm < RR < 24 brm or 34.5°C < T_{ax} < 38.5°C). System alerts were sent when the connection was interrupted or when no valid measurement could be conducted. Both type of events had to occur continuously for a period of at least 14 minutes before an alert was sent out to the nurse. For each alert an acknowledgement of the alert by the nurse was required by pressing a button on their mobile device. After receiving a vital signs alert, the nurses were asked to immediately measure the patient's vital parameters manually in accordance with the applicable hospital policy (MEWS). When the nurse did not acknowledge the alert, reminders were sent every 14 minutes until acknowledgment was confirmed.

Procedures

Before start of the study, we tested if the system functioned properly and the nurses were trained in using the system and interpreting the data. Among the nurses there were ten key users, who received additional training for attaching the patch. Together with the investigators, they provided bed-side teaching to other nurses at the general ward during data collection.

From October until December 2019 electively scheduled surgical patients were screened for eligibility by the nurse during pre-operative admission on the ward. When patients agreed to participate, informed consent forms were signed. The SensiumVitals® patch was attached postoperatively when patients arrived at the ward from the recovery or the intensive care unit. Continuous monitoring by the patch was continued until discharge. The day before discharge, patients' experiences were obtained by a questionnaire. After completion of enrollment of all 30 patients, nurses were asked to complete their questionnaires.

Data collection

Primary outcomes were acceptability and fidelity of the continuous monitoring system. Acceptability was measured cross-sectionally and fidelity prospectively. Baseline characteristics of patients were obtained from the EMR data. Patient postoperative complications were reported according to the Clavien-Dindo Classification.[37,38] This scale classifies complications as I) no intervention needed, II) requiring pharmacological treatment, IIIa) requiring surgical, endoscopic or radiological intervention not under general anesthesia, IIIb) requiring surgical, endoscopic or radiological intervention under general anesthesia, IV) requiring admission the ICU and V) death of patient.

Acceptability was measured as recruitment and retention rates and experiences of patients and nurses.[39] First, patient acceptability was measured by four questions using a 5-point Likert scale (strongly agree to strongly disagree) about comfort, safety and recommendation on future use, as shown in Appendix A. Second, for nurses the Usefulness, Satisfaction, and Ease of use (USE) questionnaire was used for measuring acceptability.[40] This instrument is intended to identify the usefulness, satisfaction, ease of use and ease of learning of the intervention and consists of 30 statements on the beliefs about the monitoring system measured on a 7-point Likert scale (Appendix B). The USE questionnaire was translated by two researchers (JL and ED) to Dutch. Both questionnaires had a free text space for remarks.

Fidelity focused on the functioning of the SensiumVitals® system and was obtained by analysis of the collected data.[41] Outcomes were total monitoring time, total number of artifacts and total number of (system and vital sign) alerts. An artifact was registered if no valid measurement was recorded. Invalid values were identified by the algorithm of the system. All vital signs alerts were retrospectively categorized by two researchers (JL and ED) as true positive (TP), false positive (FP) or unclear based upon clinical condition, nurse MEWS measurements and reports in the EMR.

Statistical analysis

Since a formal power calculation was not possible due to the lack of preliminary data with the SensiumVitals® device, a sample size of 30 patients and 20 nurses was estimated to yield sufficient data for determination of feasibility.

All data were analyzed by descriptive statistics. For continuous data, medians and interquartile ranges (IQR) or means and standard deviations (SD) were calculated based upon normal distribution. Every parameter was checked for normality by the Shapiro-Wilk test and visually by a histogram.[42] For categorical data, frequencies and percentages were reported.

The questionnaire on patient acceptability was presented as categorical data. The USE questionnaire for nurses was reported as continuous data and was divided in the constructs: usefulness, ease of use, ease of learning and satisfaction. To determine reliability of the translated version of the USE, a Cronbach's alpha was determined for each construct. An α of >0.7 was considered consistent and therefore reliable. The remarks patients made were classified as positive, neutral or negative by two researchers and remarks of nurses were categorized within the constructs of the USE questionnaire. Finally, fidelity of the system was analyzed at patient level. All analyses were performed with IBM SPSS Statistics 24.0 for Mac *(IBM Armork, New York, USA)*.

Ethical considerations

The Medical Ethics Review Committee of Isala waived the need for ethical approval (protocol no. 190606). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient to participate in the study.

Patient and Public Involvement

While we did not directly involve patients in the design or conduct of our study, our analyses were motivated by the belief that the patient acceptability outcomes were relevant for patients.

Results

Study characteristics

A total of 36 patients were eligible to participate in the study. Of them, one patient was excluded due to a cognitive impairment, one patient declined to participate and four patients were lost to follow-up due to postoperative admittance at a technically unprepared part of the ward. This resulted in a recruitment rate of 94% (n=34) and dropout rate of 11% (n=4). Eventually, 30 patients (male: n=17) participated in the study with a mean age of 66 ± 10 years old. They underwent either colon (n=20), rectal (n=8) or pancreatic resections (n=2). Eleven patients (36.7%) developed sixteen complications in total. Of these, twelve were classified as grade I and II according to the Clavien-Dindo Classification. An overview of the patient characteristics is given in Table 1.

Acceptability: patient perspective

Twenty-seven patients (response: 90%) returned the questionnaire (Table 2 ; Figure 2). Of these, 25 patients (93%) rated wearing the patch as comfortable. Moreover, 18 patients (67%) felt safer during hospitalization although eight patients (30%) were neutral about this statement. For a future admission in the hospital, 24 patients (89%) would like to wear it and 20 patients (80%) of the patients would be willing to wear the patch for postsurgical home monitoring. Patient experiences are quoted in Table 3. There were no missing data in the returned questionnaires.

Acceptability: nurses' perspective

Thirty-five nurses were approached of whom 23 nurses (response: 66%) returned the questionnaire as shown in Table 4 and Figure 2. Median age of nurses was 28 years old (IQR

24 – 39) and they had a median working experience of five years (IQR 3 – 13). There were no missing data in the returned questionnaires. Quotes of remarks are given in Table 3.

Median score of usefulness was 3.5 (IQR 3.1–4.0; Cronbachs α = .916). Out of 23 nurses, n (61%) agreed that continuous monitoring by the patch was useful. However, seventeen nurses (74%) did not think the patch would save time and 16 (70%) disagreed about the statement it does everything they expected. One nurse reported she recognized the added value for the patient (Table 3).

Median score of ease of use was 3.7 (IQR 3.2–4.8 ; Cronbachs α = .937). Out of 23 nurses, 61% (N=14) disagreed with the statement that using it was effortless and 65% could not use it without consulting the written instructions. Nurses stated it was easy when the system operated accordingly but thought it could increase workload (Table 3).

Median score of ease of learning was 5.0 (IQR 4.0–5.8 ; Cronbachs α = .965). Out of 23 nurses, 15 nurses (65%) agreed they easily remembered how to use it and quickly became skillful with it. No remarks were reported considering this construct.

Median score of satisfaction was 3.7 (IQR 2.9–4.4 ; Cronbachs α = .931). Twelve of 23 nurses (52%) stated it was fun to use and 11 (48%) disagreed it was pleasant to use. 61% (N=14) disagreed the need to add the device to the routine work flow. There were no missing data in the returned questionnaires. Several remarks were made considering satisfaction. Predominantly about malfunction of the system, frequency of alarms and the discrepancy with nurse measurements (Table 3).

System fidelity

Total monitoring time was 3853 hours with a median of 81 hours (IQR 47–143) per patient. This resulted in a total of 115,217 measurements of the three vital signs. 18.5% (N=21 311) of HR measurements, 51% (N=59 184) of RR measurements and 9% (N=10 269) of T_{ax} measurements were artifacts.

In total, 972 alerts (median per patient: 18; IQR 8.75–41.75) were sent by the SensiumVitals® system, of which 90.3% (N=878) were system alerts and 9.7% (N=94) were about deviating vital signs. Although just three subjects were responsible for nearly half (41.4%) of all alerts, a direct cause for the artifacts and related system alerts was not found. The median alert rate was 4.5 per patient per day. The system alerts were generated because: HR was not registered (N=180; 20.5%), RR was not registered (N=145; 16.5%), T_{ax} was not registered (N=151 ; 17.1%), leads were off (N=281 ; 32.0%) or the patch was being replaced because of an empty battery (N=28 ; 3.9%). Of all 94 vital sign alerts, 35% were true positives,

44% were false positive and 21% uncategorized, as shown in Table 5. The percentage of true positive alerts was the highest for HR with 60% (n=9) followed by RR with 40% (n=16) and 20.5% for T_{ax}. T_{ax} had the most false positive alerts with 77% (n=30) versus 13% for HR and 22.5% for RR. False positive T_{ax} was mostly caused by registration of sub-temperature.

DISCUSSION

In this study we aimed to determine feasibility in terms of acceptability and fidelity of continuous wireless vital signs monitoring of abdominal surgery patients at the general ward. Patient acceptability of the patch sensor was high. Wearing the patch for several days was well tolerated and made patients feel safer. Most patients indicated they wished to be remotely monitored during a possible future hospital stay. However, a significant proportion of nurses was not yet convinced of the added value of continuous monitoring on the general ward.

Comparison with other literature

The high acceptability by patients of this wearable wireless monitoring device, both in terms of 'wearability' and feeling safe, is in line with previous studies.[25,43–47] Nonetheless, one patient expressed skepticism about the reliability of the system. A similar concern was reported in the qualitative study of Downey et al.[44]

The lower acceptability by nurses could be related to the large number of system alerts, which can be considered as clinically irrelevant and thus as disturbing. This was well reflected in the remarks of nurses and is in agreement with a previous study by Progmet et al. about perceptions of nurses before implementation of a continuous monitoring device.[48] The cause of these alerts is the large number of artifacts and the relatively short time frame of 14 minutes before an alert is generated by the system. As a result, this has likely resulted in increased workload for nurses, which decreases their willingness to fully rely on the system as yet and may lead to alert fatigue.[49]

When considering system fidelity, the number of artifacts encountered in the present study was still considerably lower for all three parameters in comparison to a previous study with the SensiumVitals® system: HR: 19% vs. 41%; RR: 51 % versus 66%; T_{ax}: 9% versus 27%, respectively.[30] The high percentage of RR measurement artifacts is most likely due to the fact RR was measured by impedance which is affected by motion of the patient and rejected by the strict algorithm of the SensiumVitals®. Although temperature measurements had the least number of artifacts (14%), this was the parameter with most false positive alerts (77%). This is probably due to dislocation of the sensor generating a low temperature and thereby

sending a false alert. Overall, the number of alerts was experienced as unacceptably high which is in agreement with previous studies with these devices.[25,43] In these previous studies, the alarm thresholds were adjusted and the time intervals increased, to decrease the number of alerts.

Besides frequency and false alarm rate, lower acceptability by nurses can also be explained by the fact that nurses on general wards are not used to working with and interpreting trend data of monitoring devices.[20] Therefore, we believe that the frequency and false alarm rate and acceptability of such remote wireless monitoring systems by nurses might be dramatically improved with the inclusion of a reliable clinical decision support algorithm that takes the vital signs trends, as well as the relationship between various vital signs, into account instead of only generating alarms based on absolute values.[20]

Limitations

Several limitations should be considered, when interpreting our results. First, our study population was limited to patients undergoing major abdominal surgery and therefore may not be representative for other patient populations. Second, the acceptability by healthcare professionals may be influenced by several factors we did not account for in this study. The relatively short study duration and limited number of patients allowed for limited experience with remote wireless vital signs monitoring, in particular recognition of a life-threatening condition with the system. Besides, it was a standalone platform without integration in the EMR. Access to the data required many additional time consuming steps resulting in potentially lower commitment and acceptability. Also, this feasibility study was run in parallel with standard EWS measurements leading to a higher total nurse work load for monitoring of vital signs. Lastly, categorizing vital signs alerts was done retrospectively which may have introduced a bias in categorizing true and false positives alerts because in some cases adequate documentation was lacking.

Conclusion

Continuous monitoring of vital signs in abdominal surgery patients by the SensiumVitals® wearable device was well accepted by patients, and moderately by nurses. Use of this system is feasible on the surgical ward, but to improve nurse acceptability the system needs to be further improved by significantly reducing artifacts and alerts, and preferably by providing validated decision support software and smooth integration into the EMR. These results may provide helpful insights for larger scale implementation and effect studies of continuous monitoring at the general ward.

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Table 1: Patient characteristics

N = 30	
Sex (n, %)	
Male	17 (56.7)
Female	13 (43.3)
Age (mean ± SD)	66.3 ± 10.2
BMI (mean ± SD)	25.6 ± 3.9
ASA-class (n, %)	
1	9 (30.0)
2	20 (66.7)
3	1 (3.3)
Type of surgery (n, %)	
Pancreatic resection	2
Rectal resection	8
Colon resection	20
Oncological indication (n, %)	26 (86.7)
Postoperative ICU admission (n, %)	
Yes	2 (6.7)
No	28 (93.3)
Length of stay (median, IQR)	4.0 (3.75-13.0)
Complications (n)	16
Grade I	9
Grade II	3
Grade IIIa	1
Grade IIIb	3

Abbrevations: ASA=American Society of Anesthesiologists

Table 2: Patient acceptability

	Disagree (1-2)	Neutral (3)	Agree (4-5)
I found the patch comfortable (n, %)	0 (0)	2 (7.4)	25 (92.6)
I felt safer with the patch (n, %)	1 (3.7)	8 (29.6)	18 (66.7)
I would like to wear the patch in the hospital next time (n, %)	1 (3.7)	2 (7.4)	24 (88.9)
I would also like to wear the patch at home after surgery (n, %)	3 (11.1)	2 (7.4)	22 (81.5)

Table 3: remarks of patients and nurses (translated from Dutch)

Patients
Positive experiences:
'It provided a safe feeling for family also'
'I knew my limits through the system'
Negative experiences:
'It doesn't look reliable to me'
'The patch is comfortable, but glue residues from the stickers remain behind'
'Patch often changed because it was not working'
Neutral experiences:
'I forgot that the patch was there, therefore also neutral in terms of feeling safe.'

Nurses
Usefulness
'I see the added value for the patient'
Ease of use
'It is easy for the patients where it works'
'I found the product promising, but at the moment I think it costs us more work than it saves'
Ease of learning
None
Satisfaction
'I often had different values with the patient that did not match when I started to do manual measurements. This meant that I didn't get so much faith in the device'
'You are always at his bedside because there is no proper image of vital functions.'
'Receiving all alarms from all patients in the nursing ward. This is annoying due to continuous alarms but also for patients.'
'Very often there was no clear picture of breathing and heartbeat.'
'Frequency of alarms was high due to malfunctions'
'The mobile app regularly operates slow'

Table 4 : USE questionnaire among nurses (N=23)

	Median + IQR	Disagree (1-3)	Neutral (4)	Agree (5-7)
Usefulness (α = .916)	3.5 (3.1-4)			
It helps me be more effective.	4 (3-4)	9 (39.1)	10 (43.5)	4 (17.4)
It helps me be more productive.	3 (3-4)	13 (56.5)	8 (34.8)	2 (8.7)
It is useful.	5 (4-5)	3 (13.0)	6 (26.1)	14 (69.6)
It gives me more control over the activities in my work.	4 (3-5)	9 (39.1)	7 (30.4)	7 (30.4)
It makes the things I want to accomplish easier to get done.	3 (3-4)	12 (52.2)	8 (34.8)	3 (13.0)
It saves me time when I use it.	3 (2-4)	17 (73.9)	3 (13.0)	3 (13.0)
It meets my needs.	3 (3-5)	12 (52.2)	5 (21.7)	6 (26.1)
It does everything I would expect it to do.	3 (2-4)	16 (69.6)	4 (17.4)	3 (13.0)
Ease of use (α = .937)	3.7 (3.2-4.8)			
It is easy to use	4 (3-5)	6 (26.1)	6 (26.1)	11 (47.8)
It is simple to use	4 (3-6)	6 (26.1)	7 (30.4)	10 (43.5)
It is user friendly	4 (3-5)	8 (34.8)	4 (17.4)	11 (47.8)
It requires the fewest steps possible to accomplish what I want to do with it	4 (3-5)	11 (47.8)	4 (17.4)	8 (34.8)
It is flexible	4 (3-5)	8 (34.8)	7 (30.4)	8 (34.8)
Using it is effortless	3 (3-4)	14 (60.9)	5 (21.7)	4 (17.4)
I can use it without written instructions	4 (2-5)	15 (60.9)	1 (4.4)	7 (30.4)
I don't notice any inconsistencies as I use it	3 (2-4)	13 (56.5)	7 (30.4)	3 (13.0)
Both occasional and regular users would like it	4 (3-5)	8 (34.8)	7 (30.4)	8 (34.8)
I can recover from mistakes quickly and easily	4 (3-5)	8 (34.8)	9 (39.1)	6 (26.1)
I can use it successfully every time	3 (3-5)	13 (56.5)	4 (17.4)	6 (26.1)
Ease of learning (α = .965)	5 (4-5.8)			
I learned to use it quickly.	5 (4-6)	4 (17.4)	7 (30.4)	12 (52.2)
I easily remember how to use it.	5 (4-6)	5 (21.7)	3 (13.0)	15 (65.2)
It is easy to learn to use it.	5 (4-6)	8 (34.8)	4 (17.4)	11 (47.8)
I quickly became skillful with it.	5 (4-6)	4 (17.4)	4 (17.4)	15 (65.2)
Satisfaction (α = .931)	3.7 (2.9-4.4)			
I am satisfied with it.	4 (3-5)	9 (39.1)	6 (26.1)	8 (34.8)
I would recommend it to a friend.	4 (3-4)	8 (34.8)	10	5 (21.7)

It is fun to use.	5 (4-5)	5 (21.7)	6 (26.1)	12 (52.2)
It works the way I want it to work.	3 (2-4)	12 (52.2)	9 (39.1)	2 (8.7)
It is wonderful.	3 (2-4)	12 (52.2)	7 (30.4)	4 (17.4)
I feel I need to have it.	3 (2-4)	14 (60.9)	7 (30.4)	2 (8.7)
It is pleasant to use.	4 (2-5)	11 (47.8)	6 (26.1)	6 (26.1)

Abbrevations: IQR: Interquartile range; SD: standard deviation; α: Cronbach's Alpha

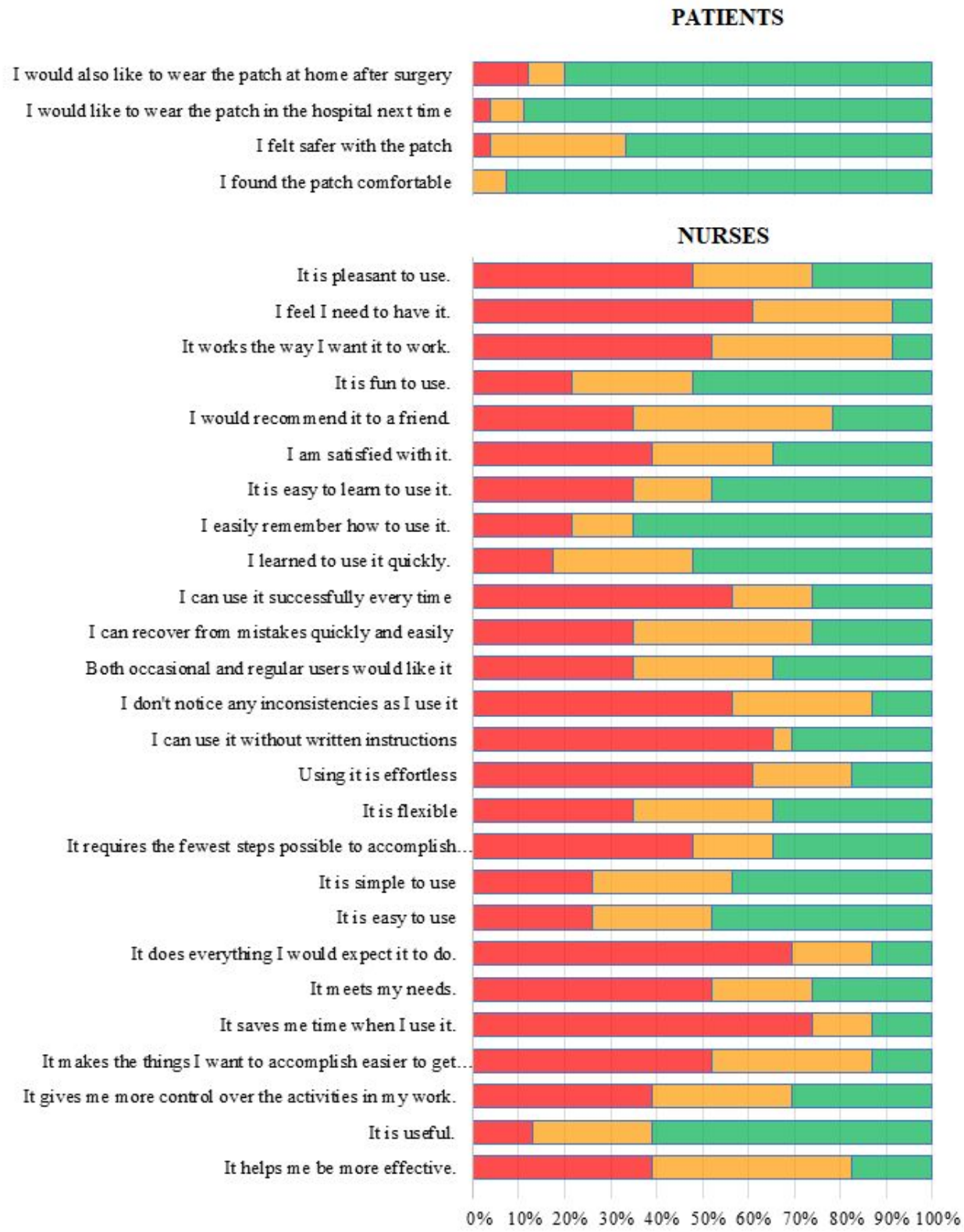
Table 5: Classification of vital signs alerts

	True positives	False positives	N/A	Total
Total alerts (n, %)	33 (35.1)	41 (43.6)	20 (21.3)	94
HR alerts (n)	9	2	4	15
RR alerts (n)	16	9	15	40
T_{ax} alerts (n)	8	30	1	39

Figure 1: The SensiumVitals® patch

The SensiumVitals® patch which is attached to the patient's chest and monitors heart rate and respiratory rate. The black 'wire' sensor is the external axillary temperature monitoring device.

Figure 2: Diagram of patient and nurses acceptability



: % agree (score 5-7)
: % neutral (score 4)
: % disagree (score 1-3)

APPENDIX A: QUESTIONNAIRE FOR PATIENTS

I found the patch comfortable

1	2	3	4	5
Strongly disagree				Strongly agree

The patch made me feel safer

1	2	3	4	5
Strongly disagree				Strongly agree

I would like to wear the patch in the hospital next time again.

1	2	3	4	5
Strongly disagree				Strongly agree

I would like to wear the patch at home after surgery.

1	2	3	4	5
Strongly disagree				Strongly agre

APPENDIX B: USE QUESTIONNAIRE (translated from Dutch)

Usefulness

1. It helps me be more effective.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

2. It helps me be more productive.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

3. It is useful.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

4. It gives me more control over the activities in my life.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

5. It makes the things I want to accomplish easier to get done.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

6. It saves me time when I use it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

7. It meets my needs.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

8. It does everything I would expect it to do.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

Ease of Use

9. It is easy to use.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

10. It is simple to use.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

11. It is user friendly.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

12. It requires the fewest steps possible to accomplish what I want to do with it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

13. It is flexible.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

14. Using it is effortless.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

15. I can use it without written instructions.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

16. I don't notice any inconsistencies as I use it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

17. Both occasional and regular users would like it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

18. I can recover from mistakes quickly and easily.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

19. I can use it successfully every time.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

Ease of Learning

20. I learned to use it quickly.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

21. I easily remember how to use it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

22. It is easy to learn to use it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

23. I quickly became skillful with it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

Satisfaction

24. I am satisfied with it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

25. I would recommend it to a friend.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

26. It is fun to use.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

27. It works the way I want it to work.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

28. It is wonderful.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

29. feel I need to have it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

30. It is pleasant to use.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1,2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	5,6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6,7
Bias	9	Describe any efforts to address potential sources of bias	4,5,6
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	7
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	8,9
Outcome data	15*	Report numbers of outcome events or summary measures over time	8,9

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	8,9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10,11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10,11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Feasibility of continuous monitoring of vital signs in surgical patients on a general ward: an observational cohort study

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TITLEPAGE

Title

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Physiologic Monitoring [MeSH], Feasibility Studies [MeSH], clinical deterioration, continuous monitoring, wireless wearable devices

Word count
3462

ABSTRACT

Objectives

To determine feasibility, in terms of acceptability and system fidelity, of continuous vital signs monitoring in abdominal surgery patients on a general ward.

Design

Observational cohort study.

Setting

Tertiary teaching hospital.

Participants

Postoperative abdominal surgical patients (N=30) and nurses (N=23).

Interventions

Patients were continuously monitored with the SensiumVitals® wearable device until discharge in addition to usual care, which is intermittent Modified Early Warning Score measurements. Heartrate, respiratory rate and axillary temperature were monitored every two minutes. Values and trends were visualized and alerts sent to the nurses.

Outcomes

System fidelity was measured by analysis of the monitoring data. Acceptability by patients and nurses was assessed using questionnaires.

Results

Thirty patients were monitored for a median duration of 81 h(IQR 47–143) per patient resulting in 115,217 measurements per parameter. In total, 19%(N=21,311) of heart rate, 51%(N=59,184) of respiratory rate and 9% of temperature measurements showed artifacts (N=10,269). The system algorithm sent 972 alerts (median alert rate of 4.5 per patient per day) of which 90.3%(N=878) were system alerts and 9.7%(N=94) vital sign alerts. 35%(N=33) of vital sign alerts were true positives. 93%(N=25) of patients rated the patch as comfortable, 67%(N=18) felt safer and 89%(N=24) would like to wear it next time in the hospital. Nurses were neutral about usefulness; a median score 3.5(IQR3.1-4) on a 7-point Likert scale, ease of use 3.7(IQR3.2-4.8) and satisfaction 3.7(IQR3.2-4.8) but agreed on ease of learning 5.0 (IQR4.0-5.8). Neutral scores were mostly related to the perceived limited fidelity of the system.

Conclusions

Continuous monitoring of vital signs with a wearable device was well accepted by patients. Nurses ratings were highly variable, resulting in on average neutral attitude towards remote monitoring. Our results suggest it is feasible to monitor vital signs continuously on general wards, although acceptability of the device to nurses needs further improvement.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Abdominal surgical patients are a population likely to benefit from continuous physiological monitoring.
- The study population was limited to elective major abdominal surgical patients.
- Acceptability of the system to nurses was extensively assessed.
- Fidelity of the system was assessed in a clinical ward setting for a large monitoring period.
- The realtime monitoring data registration and trends were not yet integrated into the electronic medical record.

MAIN TEXT

Introduction

The post-operative complication rate after major abdominal surgery is 20-44%[1] which may result in re-interventions, prolonged hospital stay, Intensive Care Unit (ICU) admissions and mortality[2–4], and eventually to lower life expectancy, lower quality of life, and higher costs.[5–7] Early detection of postoperative clinical deterioration on the ward may allow for early intervention and better outcomes.[8] Currently, the optimal frequency of vital sign measurements remains unknown. On most surgical wards they are monitored no more than 1-3 times a day.[9,10] Early Warning Scores, such as the Modified Early Warning Score (MEWS) are then used to help identify patients at risk.[11–13] A higher MEWS is associated with admission to the ICU, cardiac arrest, and mortality.[14–16] However, a critical limitation of current monitoring practice is its infrequent and intermittent nature,[17,18] which may result in delayed detection of clinical deterioration, in particular during night shifts with lower staffing per patient rates.[19]

Recent advances in wearable, wireless sensor technology now facilitate continuous monitoring of vital signs.[20,21] Emerging evidence shows that these monitoring sensors are accurate, may improve outcomes and reduce costs by allowing earlier detection of changes in vital signs in clinical practice.[22] A previous study about continuous monitoring of abdominal surgical patients, resulted in earlier antibiotics administration, decreased hospital stay and readmissions within 30 days.[23] Another study by Subbe et al. (2017) reported more rapid response teams interventions, decreased cardiac arrests, reduced overall mortality, reduced illness severity and reduced mortality in those patients admitted to ICU, and an increase in pro-active decision-making on end-of-life care.[24] In addition, Weenk et al (2017) studied two continuous monitoring devices, and reported that continuous monitoring was feasible if frequency and duration of measurements with artifact would be reduced.[25] Several other studies with wearable monitoring devices reported potential benefits such as less patient disturbance and improved sleep, reduced work load of nurses and improved safety during patient transport between departments.[26–29]

A new wearable patch device for wireless remote monitoring of vital signs has recently been tested in several hospitals, the SensiumVitals®. The first published reports have shown it to be valid and safe.[23,30,31] However, there is still insufficient insight regarding the feasibility of using such a continuous monitoring device at a general ward, especially because continuous monitoring can be defined as a complex intervention with many interacting components and behavior change of healthcare professionals.[32] As recommended by the Medical Research Council framework, feasibility testing and piloting are needed before larger scale clinical

implementation of such an intervention can be undertaken.[33] The aim of the study was to determine feasibility, in terms of acceptability and system fidelity, of continuous vital signs monitoring with the SensiumVitals® device among abdominal surgery patients on a general surgery ward.

Methods

Design

An observational cohort study was conducted for a 3 month period (October to December 2019) at a surgical ward of a large tertiary teaching hospital. This study is reported in concordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[34]

Participants

Patients scheduled for elective colorectal or pancreatic resection were recruited through convenience sampling. Inclusion criteria were: age >= 18years, no cognitive impairments, expected hospitalization time three days or longer and fluent in the Dutch language. Exclusion criteria were: surgery for a palliative or emergency indication, a cardiac pacemaker in situ, a known allergy for any of the materials of the device or participating in another conflicting study. Emergency surgical patients were excluded because it was deemed not possible to obtain true informed consent. For nurses, eligibility criteria were: nursing registration, active involvement in the continuous monitoring system for at least three days during the study, and able to speak and read the Dutch language.

Intervention

Current standard of care was intermittent monitoring (once daily) using the Modified Early Warning Score (MEWS) according to the hospital policy.[35] In addition to standard care, patients included in the study were continuously monitored by the SensiumVitals® system *(Sensium, Abingdon, United Kingdom)*. This wireless monitoring device is Conformité Européene–(CE) marked, approved by the Food Drug Administration and worn as a patch on the patient's chest. It continuously monitors heart rate (HR) in beats per minute (bpm), respiratory rate (RR) in breaths per minute (brm), and – via a secondary sensor - axillary temperature (T_{ax}) in degrees Celsius (°C).[36] The patch is attached to the skin by two adhesive electrocardiogram electrodes *(Skintact, Leonard Lang GmbH, Innsbruck, Austria)* as shown in Figure 1.

Every two minutes, the data were transmitted wirelessly through ceiling-mounted bridges to a dedicated server, and from there to a mobile device carried by the nurses and to their desktop. There were two types of alerts: vital sign and system alerts. Vital sign alerts were sent when the parameter value passed the pre-set thresholds (50 bpm < HR < 120 bpm, 8 brm < RR < 24 brm or 34.5°C < T_{ax} < 38.5°C). These low and high thresholds were based upon the MEWS' lower and upper thresholds.[10] For the upper threshold the parameters correspond with the median value of MEWS 2. System alerts were sent when the connection was interrupted or when no valid measurement could be obtained. Each type of event had to occur continuously for a period of at least 14 minutes before an alert was sent out to the nurse. This time frame was based on previous clinical experience of the manufacturer, researchers and in consensus with the ward nurses. Literature about an optimal time frame for alerts is still lacking. Nurses were required to acknowledge each alert by pressing a button on their mobile device. After receiving a vital signs alert, the nurses were asked to measure the patient's vital parameters manually in accordance with the applicable hospital policy (MEWS). When the nurse did not acknowledge the alert, reminders were sent until acknowledgment was confirmed.

Procedures

Before start of the study, we tested if the system functioned properly and the nurses were trained in using the system and interpreting the data. Among the 35 nurses who had received training were ten 'key users', who received additional training in correctly applying the patch. Together with the researchers, they provided bed-side teaching to other nurses at the general ward during data collection.

From October to December 2019 electively scheduled surgical patients were screened for eligibility by the nurse during pre-operative admission on the ward. When patients agreed to participate, informed consent forms were signed. The SensiumVitals® patch was attached postoperatively when patients arrived at the ward from the recovery or the intensive care unit. Continuous monitoring by the patch was continued until discharge. The day before discharge, patients' experiences were obtained by a questionnaire. After completion of enrollment of all 30 patients, nurses were asked to complete their questionnaires.

Data collection

Primary outcomes were acceptability and fidelity of the continuous monitoring system. Acceptability was measured cross-sectionally and fidelity prospectively. Baseline characteristics of patients were obtained from the EMR data. Patient postoperative

complications were reported according to the Clavien-Dindo Classification.[37,38] This scale classifies complications as I) no intervention needed, II) requiring pharmacological treatment, IIIa) requiring surgical, endoscopic or radiological intervention not under general anesthesia, IIIb) requiring surgical, endoscopic or radiological intervention under general anesthesia, IV) requiring admission the ICU and V) death of patient.

Acceptability was measured as recruitment and retention rates and experiences of patients and nurses.[39] First, patient acceptability was measured by four questions using a 5-point Likert scale (strongly agree to strongly disagree) about comfort, safety and recommendation on future use, as shown in Appendix A. Second, for nurses the Usefulness, Satisfaction, and Ease of use (USE) questionnaire was used for measuring acceptability.[40] This instrument is intended to identify the usefulness, satisfaction, ease of use and ease of learning of the intervention and consists of 30 statements on the beliefs about the monitoring system measured on a 7-point Likert scale (Appendix B). The USE questionnaire was translated by two researchers (JL and ED) to Dutch. We asked nurses to assess the concept of continuous monitoring, and not just the SensiumVitals® technology. Both questionnaires had a free text space for remarks.

Fidelity focused on the functioning of the SensiumVitals® system and was obtained by analysis of the collected data.[41] Outcomes were total monitoring time, total number of artifacts, total number of (system and vital sign) alerts and the acknowledgment rate of the vital signs alerts. An artifact was registered if no valid measurement was recorded. Invalid values were identified by the algorithm of the system. All vital signs alerts were retrospectively categorized by two researchers (JL and ED) as true positive (TP), false positive (FP) or unclear based upon clinical condition, nurse MEWS measurements and reports in the EMR.

Statistical analysis

Since a formal power calculation was not possible due to the lack of preliminary data with the SensiumVitals® device, a sample size of 30 patients and 20 nurses was estimated to yield sufficient data for determination of feasibility.

All data were analyzed by descriptive statistics. For continuous data, medians and interquartile ranges (IQR) or means and standard deviations (SD) were calculated based upon normal distribution. Every parameter was checked for normality by the Shapiro-Wilk test and visually by a histogram.[42] For categorical data, frequencies and percentages were reported.

The questionnaire on patient acceptability was presented as categorical data. The USE questionnaire for nurses was reported as continuous data and was divided in the constructs:

usefulness, ease of use, ease of learning and satisfaction. To determine reliability of the translated version of the USE, a Cronbach's alpha was determined for each construct. An α of >0.7 was considered consistent and therefore reliable. The remarks patients made were classified as positive, neutral or negative by two researchers and remarks of nurses were categorized within the constructs of the USE questionnaire. Finally, fidelity of the system was analyzed at patient level. All analyses were performed with IBM SPSS Statistics 24.0 for Mac *(IBM Armork, New York, USA)*.

Ethical considerations

The Medical Ethics Review Committee of Isala waived the need for ethical approval (protocol no. 190606). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient to participate in the study.

Patient and Public Involvement

While we did not directly involve patients in the design or conduct of our study, our analyses were motivated by the belief that the patient acceptability outcomes were relevant for patients.

Results

Study characteristics

A total of 36 patients were eligible to participate in the study. Of them, one patient was excluded due to a cognitive impairment, one patient declined to participate and four patients were lost to follow-up due to postoperative admittance at a technically unprepared part of the ward. This resulted in a recruitment rate of 94% (n=34) and dropout rate of 11% (n=4). Eventually, 30 patients (male: n=17) participated in the study with a mean age of 66 ± 10 years old. They underwent either colon (n=20), rectal (n=8) or pancreatic resections (n=2). Eleven patients (36.7%) developed sixteen complications in total. Of these, twelve were classified as grade I and II according to the Clavien-Dindo Classification. An overview of the patient characteristics is given in Table 1.

Acceptability: patient perspective

Twenty-seven patients (response: 90%) returned the questionnaire (Table 2 ; Figure 2). Of these, 25 patients (93%) rated wearing the patch as comfortable. Moreover, 18 patients (67%) felt safer during hospitalization although eight patients (30%) were neutral about this statement. For a future admission in the hospital, 24 patients (89%) would like to wear it and 20 patients

(80%) of the patients would be willing to wear the patch for postsurgical home monitoring. Patient experiences are quoted in Table 3. There were no missing data in the returned questionnaires.

Acceptability: nurses' perspective

Thirty-five nurses were approached of whom 23 nurses (response: 66%) returned the questionnaire as shown in Table 4 and Figure 2. Median age of nurses was 28 years old (IQR 24 – 39) and they had a median working experience of five years (IQR 3 – 13). There were no missing data in the returned questionnaires and there was no difference in median age in the non-response group. Quotes of remarks are given in Table 3.

Median score of usefulness was 3.5 (IQR 3.1–4.0; Cronbachs α = .916). Out of 23 nurses, 61% (N=14) agreed that continuous monitoring by the patch was useful. However, 74% of the nurses (N=17) did not think the patch would save time and 70% (N=16) disagreed about the statement "it does everything I expected". One nurse reported she recognized the added value for the patient (Table 3).

Median score for ease of use was 3.7 (IQR 3.2–4.8 ; Cronbachs α = .937). Out of 23 nurses, 61% (N=14) disagreed with the statement that using it was effortless and 65% (N=15) could not use it without consulting the written instructions. Nurses stated it was easy when the system operated without too many artefacts and alerts which could increase workload (Table 3).

Median score of ease of learning was 5.0 (IQR 4.0–5.8 ; Cronbachs α = .965). Out of 23 nurses, 15 nurses (65%) agreed they easily remembered how to use it and quickly became skillful with it. No remarks were reported considering this construct.

Median score of satisfaction was 3.7 (IQR 2.9–4.4 ; Cronbachs α = .931). Twelve of 23 nurses (52%) stated it was fun to use and 11 (48%) disagreed it was pleasant to use. Fourteen nurses (61%) disagreed with the need to add this device to the routine work flow. There were no missing data in the returned questionnaires. Several remarks were made considering satisfaction. Predominantly about malfunction of the system, frequency of alarms and the discrepancy with nurse measurements (Table 3).

System fidelity

Total monitoring time was 3853 hours with a median of 81 hours (IQR 47–143) per patient. This resulted in a total of 115,217 measurements of the three vital signs. 18.5% (N=21,311) of

HR measurements, 51.4% (N=59,184) of RR measurements and 8.9% (N=10,269) of T_{ax} measurements were artifacts.

In total, 972 alerts (median per patient: 18; IQR 8.75–41.75) were sent by the SensiumVitals® system, of which 90.3 % (N=878) were system alerts and 9.7% (N=94) were about deviating vital signs. Although just three subjects were responsible for nearly half (41.4%) of all alerts, a direct cause for the artifacts and related system alerts was not found. The median alert rate was 4.5 per patient per day. The system alerts were generated because: HR was not registered (N=180; 20.5%), RR was not registered (N=145; 16.5%), T_{ax} was not registered (N=151 ; 17.1%), leads were off (N=281 ; 32.0%) or the patch was being replaced because of an empty battery (N=28 ; 3.9%).

Of the 94 vital sign alerts, 12 (12.8%) were not acknowledged by the nurses. No downward trend during the study was seen in the acknowledgment rate. Of the alerts, 35% were true positives, 44% were false positive and 21% uncategorized, as shown in Table 5. The percentage of true positive alerts was the highest for HR with 60% (n=9) followed by RR with 40% (n=16) and 20.5% for T_{ax}. T_{ax} had the most false positive alerts with 77% (n=30) versus 13% for HR and 22.5% for RR. False positive T_{ax} were caused by registration of sub-temperature.

DISCUSSION

In this study we aimed to determine feasibility in terms of acceptability and fidelity of continuous wireless vital signs monitoring of abdominal surgery patients at the general ward. Patient acceptability of the patch sensor was high. Wearing the patch for several days was well tolerated and made patients feel safer. Most patients indicated they wished to be remotely monitored during a possible future hospital stay. However, a significant proportion of nurses was not yet convinced of the added value of continuous monitoring on the general ward.

Comparison with previous work

The high acceptability by patients of this wearable wireless monitoring device, both in terms of 'wearability' and feeling safe, is in line with previous studies.[25,43–47] Nonetheless, one patient expressed skepticism about the reliability of the system. A similar concern was reported in the qualitative study of Downey et al.[44]

The lower acceptability by nurses could be related to the large number of system alerts, which can be considered as clinically irrelevant and thus as disturbing. This was well reflected in the remarks of nurses and is in agreement with a previous study by Progmet et al. about

perceptions of nurses before implementation of a continuous monitoring device.[48] The cause of these alerts is the large number of artifacts and the relatively short time frame of 14 minutes before an alert is generated by the system. As a result, this has likely resulted in increased workload for nurses, which decreases their willingness to fully rely on the system as yet and may lead to alert fatigue.[49]

When considering system fidelity, the number of artifacts encountered in the present study was still considerably lower for all three parameters in comparison to a previous study with the SensiumVitals® system: HR: 19% vs. 41%; RR: 51 % versus 66%; T_{ax}: 9% versus 27%, respectively.[30] The high percentage of RR measurement artifacts is most likely due to the fact RR was measured by impedance which is affected by motion of the patient and rejected by the strict algorithm of the SensiumVitals®. Although temperature measurements had the least number of artifacts (14%), this was the parameter with most false positive alerts (77%). This is probably due to transient dislocation of the sensor generating an apparent low axillary temperature and thereby sending a false alert. Overall, the number of alerts was experienced as unacceptably high which is in agreement with previous studies with these devices.[25,43] In these previous studies, the alarm thresholds were adjusted and the time intervals increased, to decrease the number of alerts.

Besides frequency and false alarm rate, lower acceptability by nurses can also be explained by the fact that nurses on general wards are not used to working with and interpreting trend data of monitoring devices and the lack of literature about optimal thresholds and a clinically relevant time frame for alerts.[20] Therefore, we believe that the frequency and false alarm rate and acceptability of such remote wireless monitoring systems by nurses might be dramatically improved with the inclusion of a reliable clinical decision support algorithm that takes the vital signs trends, as well as the relationship between various vital signs, into account instead of only generating alarms based on absolute values.[20]

Limitations

Several limitations should be considered, when interpreting our results. First, the study population was limited to patients undergoing major abdominal surgery and therefore may not be representative for other patient populations. Emergency surgical patients are more prone to complications and may thus derive more benefit from continuous vital signs monitoring.[50] However, they were not included because of the need for informed consent.

In addition, acceptability of remote wireless vital signs monitoring to healthcare professionals may be influenced by several factors we were unable to account for in this study.

The study duration was relatively short, and the intervention was not yet fully integrated into standard care pathways and workflows in the ward. The limited number of patients and exclusion of emergency surgery may account for the fact that we did not observe any life-threatening conditions with the system. Lack of integration with the EMR may have negatively influenced nurses' experiences with the system. Access to the vital signs trend data required many additional - time consuming - steps resulting in potentially lower commitment and acceptability. Also, during this feasibility study nurses still had to calculate routine EWS scores, leading to increased total nurse workload. In addition, the results are based on this specific continuous monitoring system while other systems are also available. Lastly, categorizing vital signs alerts was done retrospectively which may have introduced a bias in categorizing true and false positives alerts because in some cases adequate documentation was lacking.

Conclusion

Continuous monitoring of vital signs in abdominal surgery patients by the SensiumVitals® wearable device was well accepted by patients, but only moderately by nurses. Use of this system was feasible on the surgical ward, but to increase acceptability for nurses the system needs improvements, in particular a significant reduction of artifacts and alerts. One desirable development would be the addition of a well-validated system for clinical decision support and smooth integration into the hospital EMR. These results may provide helpful insights for larger scale implementation and (cost)effectiveness studies of continuous monitoring at the general ward.

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CONTRIBUTORS

JL conceived of the presented idea. JL, ED, JvD, HvL, GP: conception or design of the work.

JL: data collection. JL, ED: data analysis and interpretation. JL, ED, JvD, HvL, CK, LS, GP: drafting the article. JL, ED, JvD, HvL, CK, LS, GP: critical revision of the article All authors: final approval of the version to be published

DATA AVAILABILITY STATEMENT

No data are available.

COMPETING INTEREST STATEMENT

None.

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Table 1: Patient characteristics

N = 30	
Sex (n, %)	
Male	17 (56.7)
Female	13 (43.3)
Age (mean ± SD)	66.3 ± 10.2
BMI (mean ± SD)	25.6 ± 3.9
ASA-class (n, %)	
1	9 (30.0)
2	20 (66.7)
3	1 (3.3)
Type of surgery (n, %)	
Pancreatic resection	2
Rectal resection	8
Colon resection	20
Oncological indication (n, %)	26 (86.7)
Postoperative ICU admission (n, %)	
Yes	2 (6.7)
No	28 (93.3)
Length of stay (median, IQR)	4.0 (3.75-13.0)
Complications (n)	16
Grade I	9
Grade II	3
Grade IIIa	1
Grade IIIb	3

Abbrevations: ASA=American Society of Anesthesiologists

Table 2: Patient acceptability

	Disagree (1-2)	Neutral (3)	Agree (4-5)
I found the patch comfortable (n, %)	0 (0)	2 (7.4)	25 (92.6)
I felt safer with the patch (n, %)	1 (3.7)	8 (29.6)	18 (66.7)
I would like to wear the patch in the hospital next time (n, %)	1 (3.7)	2 (7.4)	24 (88.9)
I would also like to wear the patch at home after surgery (n, %)	3 (11.1)	2 (7.4)	22 (81.5)

Table 3: remarks of patients and nurses (translated from Dutch)

Patients
Positive experiences:
'It provided a safe feeling for family also'
'I knew my limits through the system'
Negative experiences:
'It doesn't look reliable to me'
'The patch is comfortable, but glue residues from the stickers remain behind'
'Patch often changed because it was not working'
Neutral experiences:
'I forgot that the patch was there, therefore also neutral in terms of feeling safe.'

Nurses
Usefulness
'I see the added value for the patient'
Ease of use
'It is easy for the patients where it works'
'I found the product promising, but at the moment I think it costs us more work than it saves'
Ease of learning
None
Satisfaction
'I often had different values with the patient that did not match when I started to do manual measurements. This meant that I didn't get so much faith in the device'
'You are always at his bedside because there is no proper image of vital functions.'
'Receiving all alarms from all patients in the nursing ward. This is annoying due to continuous alarms but also for patients.'
'Very often there was no clear picture of breathing and heartbeat.'
'Frequency of alarms was high due to malfunctions'
'The mobile app regularly operates slow'

Table 4 : USE questionnaire among nurses (N=23)

	Median + IQR	Disagree (1-3)	Neutral (4)	Agree (5-7)
Usefulness (α = .916)	3.5 (3.1-4)			
It helps me be more effective.	4 (3-4)	9 (39.1)	10 (43.5)	4 (17.4)
It helps me be more productive.	3 (3-4)	13 (56.5)	8 (34.8)	2 (8.7)
It is useful.	5 (4-5)	3 (13.0)	6 (26.1)	14 (69.6)
It gives me more control over the activities in my work.	4 (3-5)	9 (39.1)	7 (30.4)	7 (30.4)
It makes the things I want to accomplish easier to get done.	3 (3-4)	12 (52.2)	8 (34.8)	3 (13.0)
It saves me time when I use it.	3 (2-4)	17 (73.9)	3 (13.0)	3 (13.0)
It meets my needs.	3 (3-5)	12 (52.2)	5 (21.7)	6 (26.1)
It does everything I would expect it to do.	3 (2-4)	16 (69.6)	4 (17.4)	3 (13.0)
Ease of use (α = .937)	3.7 (3.2-4.8)			
It is easy to use	4 (3-5)	6 (26.1)	6 (26.1)	11 (47.8)
It is simple to use	4 (3-6)	6 (26.1)	7 (30.4)	10 (43.5)
It is user friendly	4 (3-5)	8 (34.8)	4 (17.4)	11 (47.8)
It requires the fewest steps possible to accomplish what I want to do with it	4 (3-5)	11 (47.8)	4 (17.4)	8 (34.8)
It is flexible	4 (3-5)	8 (34.8)	7 (30.4)	8 (34.8)
Using it is effortless	3 (3-4)	14 (60.9)	5 (21.7)	4 (17.4)
I can use it without written instructions	4 (2-5)	15 (60.9)	1 (4.4)	7 (30.4)
I don't notice any inconsistencies as I use it	3 (2-4)	13 (56.5)	7 (30.4)	3 (13.0)
Both occasional and regular users would like it	4 (3-5)	8 (34.8)	7 (30.4)	8 (34.8)
I can recover from mistakes quickly and easily	4 (3-5)	8 (34.8)	9 (39.1)	6 (26.1)
I can use it successfully every time	3 (3-5)	13 (56.5)	4 (17.4)	6 (26.1)
Ease of learning (α = .965)	5 (4-5.8)			
I learned to use it quickly.	5 (4-6)	4 (17.4)	7 (30.4)	12 (52.2)
I easily remember how to use it.	5 (4-6)	5 (21.7)	3 (13.0)	15 (65.2)
It is easy to learn to use it.	5 (4-6)	8 (34.8)	4 (17.4)	11 (47.8)
I quickly became skillful with it.	5 (4-6)	4 (17.4)	4 (17.4)	15 (65.2)
Satisfaction (α = .931)	3.7 (2.9-4.4)			
I am satisfied with it.	4 (3-5)	9 (39.1)	6 (26.1)	8 (34.8)
I would recommend it to a friend.	4 (3-4)	8 (34.8)	10	5 (21.7)

It is fun to use.	5 (4-5)	5 (21.7)	6 (26.1)	12 (52.2)
It works the way I want it to work.	3 (2-4)	12 (52.2)	9 (39.1)	2 (8.7)
It is wonderful.	3 (2-4)	12 (52.2)	7 (30.4)	4 (17.4)
I feel I need to have it.	3 (2-4)	14 (60.9)	7 (30.4)	2 (8.7)
It is pleasant to use.	4 (2-5)	11 (47.8)	6 (26.1)	6 (26.1)

Abbrevations: IQR: Interquartile range; SD: standard deviation; α: Cronbach's Alpha

Table 5: Classification of vital signs alerts

	True positives	False positives	N/A*	Total
Total alerts (n, %)	33 (35.1)	41 (43.6)	20 (21.3)	94
HR alerts (n)	9	2	4	15
RR alerts (n)	16	9	15	40
T_{ax} alerts (n)	8	30	1	39

*N/A: uncategorized

Figure 1: The SensiumVitals® patch

The SensiumVitals® patch which is attached to the patient's chest and monitors heart rate and respiratory rate. The black 'wire' sensor is the external axillary temperature monitoring device.

Figure 2: Diagram of patient and nurses acceptability

The SensiumVitals® patch

160x119mm (300 x 300 DPI)

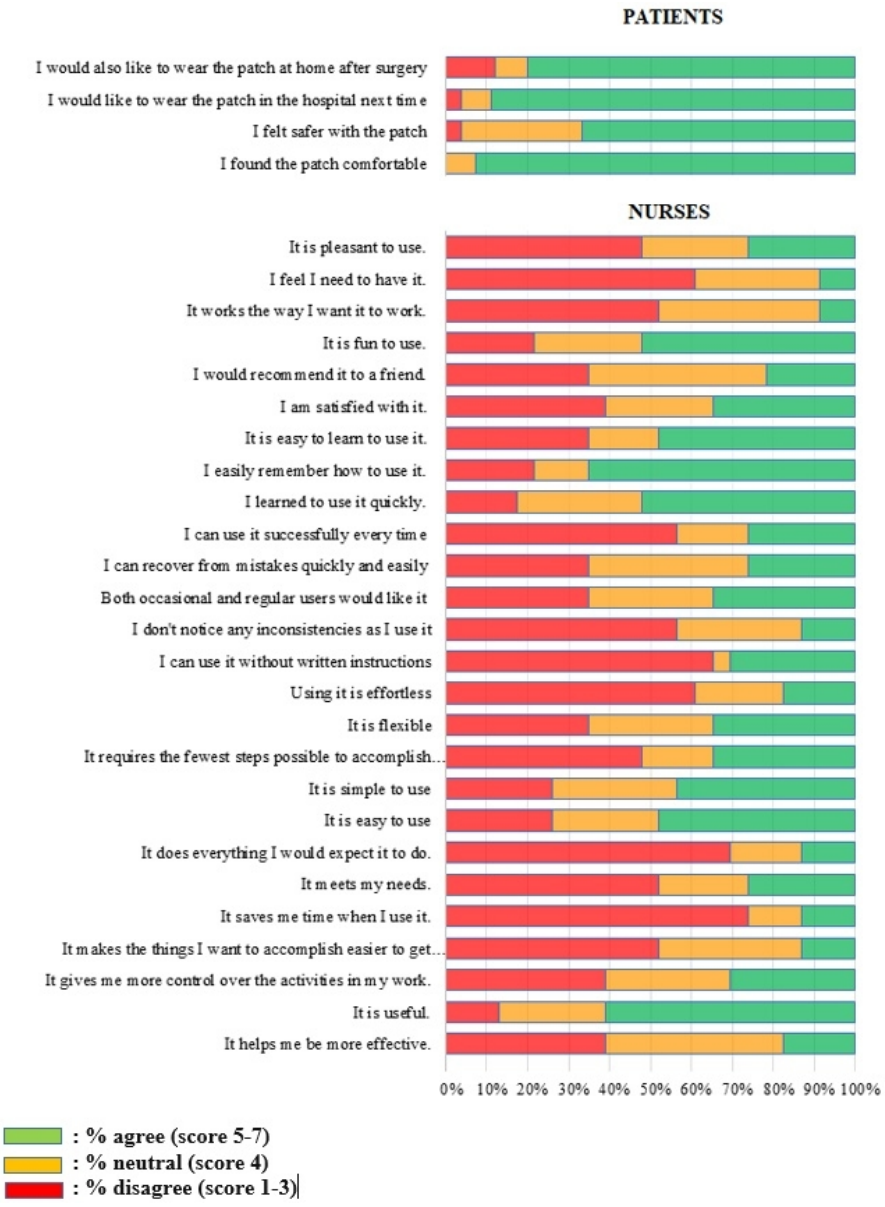

Diagram of patient and nurses acceptability

185x227mm (96 x 96 DPI)

APPENDIX A: QUESTIONNAIRE FOR PATIENTS

I found the patch comfortable

1	2	3	4	5
Strongly disagree				Strongly agree

The patch made me feel safer

1	2	3	4	5
Strongly disagree				Strongly agree

I would like to wear the patch in the hospital next time again.

1	2	3	4	5
Strongly disagree				Strongly agree

I would like to wear the patch at home after surgery.

1	2	3	4	5
Strongly disagree				Strongly agree

APPENDIX B: USE QUESTIONNAIRE (translated from Dutch)

Usefulness

1. It helps me be more effective.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

2. It helps me be more productive.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

3. It is useful.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

4. It gives me more control over the activities in my life.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

5. It makes the things I want to accomplish easier to get done.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

6. It saves me time when I use it.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

7. It meets my needs.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

8. It does everything I would expect it to do.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

Ease of Use

9. It is easy to use.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

10. It is simple to use.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

11. It is user friendly.

1 2 3 4 5 6 7
Strongly disagree Strongly agree

12. It requires the fewest steps possible to accomplish what I want to do with it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

13. It is flexible.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

14. Using it is effortless.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

15. I can use it without written instructions.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

16. I don't notice any inconsistencies as I use it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

17. Both occasional and regular users would like it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

18. I can recover from mistakes quickly and easily.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

19. I can use it successfully every time.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

Ease of Learning

20. I learned to use it quickly.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

21. I easily remember how to use it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

22. It is easy to learn to use it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

23. I quickly became skillful with it.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

Satisfaction

24. I am satisfied with it.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

25. I would recommend it to a friend.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

26. It is fun to use.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

27. It works the way I want it to work.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

28. It is wonderful.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

29. feel I need to have it.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

30. It is pleasant to use.

1	2	3	4	5	6	7
Strongly disagree					Strongly agree	

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1,2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	5,6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6,7
Bias	9	Describe any efforts to address potential sources of bias	4,5,6
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	7
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	8
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	8,9
Outcome data	15*	Report numbers of outcome events or summary measures over time	8,9

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	8,9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10,11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10,11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.