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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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ABSTRACT

Objective 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. Heart rate, respiratory rate and axillary temperature were monitored every 2 min. Values and trends were visualised 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 hours (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 artefacts (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) were 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, with a median score of 3.5 (IQR 3.1–4) on a 7-point Likert scale, ease of use 3.7 (IQR 3.2–4.8) and satisfaction 3.7 (IQR 3.2–4.8), but agreed on ease of learning at 5.0 (IQR 4.0–5.8). 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 among 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 among nurses was extensively assessed.
- Fidelity of the system was assessed in a clinical ward setting for a large monitoring period.
- Real-time monitoring data registration and trends were not yet integrated into the electronic medical record.

INTRODUCTION

The postoperative complication rate after major abdominal surgery is 20%–44%,[1] which may result in reinterventions, 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 one to three 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*[24] 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 proactive decision-making on end-of-life care. In addition, Weenk *et al*[25] studied two continuous monitoring devices and reported that continuous monitoring was feasible if frequency and duration of measurements with artefact would be reduced.[25] Several other studies with wearable monitoring devices reported potential benefits such as less patient disturbance and improved sleep, reduced workload among 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 on a general ward, especially because continuous monitoring can be defined as a complex intervention with many interacting components and behaviour 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 the 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–December 2019) on 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 guidelines.[34]

Participants

Patients scheduled for elective colorectal or pancreatic resection were recruited through convenience sampling. Inclusion criteria were age ≥18 years, no cognitive impairments, expected hospitalisation time of 3 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 3 days during the study, and able to speak and read the Dutch language.

Figure 1 The SensiumVitals patch. The SensiumVitals patch 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.

Intervention

Current standard of care was intermittent monitoring (once daily) using the MEWS according to hospital policy.[35] In addition to standard care, patients included in the study were continuously monitored by the SensiumVitals system (Sensium, Abingdon, UK). This wireless monitoring device is CE (Conformité Européenne)-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 degree Celsius.[36] The patch is attached to the skin by two adhesive ECG electrodes (Skintact, Leonhard Lang, Innsbruck, Austria), as shown in figure 1.

Every 2 min, 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 preset 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 on 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 min 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 acknowledgement was confirmed.

Procedures

Before the 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 10 'key users', who received additional training in correctly applying the patch. Together with the researchers, they provided bedside teaching to other nurses on the general ward during data collection.

From October to December 2019 electively scheduled surgical patients were screened for eligibility by the nurse during preoperative 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 unit or ICU. Continuous monitoring by the patch was continued until discharge. The day before discharge, patients' experiences were obtained using a questionnaire. After completion of enrolment of all 30 patients, nurses were asked to complete their questionnaires.

Data collection

The 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 electronic medical record (EMR). Patients' postoperative complications were reported according to the Clavien-Dindo classification.[37 38] This scale classifies complications according to the following: grade I, no intervention needed; grade II, requiring pharmacological treatment; grade IIIa, requiring surgical, endoscopic or radiological intervention not under general anaesthesia; grade IIIb, requiring surgical, endoscopic or radiological intervention under general anaesthesia; grade IV, requiring admission to the ICU; and grade V, death of the 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 online supplemental appendix A. Second, for nurses the Usefulness, Satisfaction, and Ease of use (USE) questionnaire was used to measure 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 (online supplemental appendix B). The USE questionnaire was translated by two researchers (JPLL and EMD) 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 artefacts, total number of (system and vital sign) alerts and the acknowledgement rate of the vital signs alerts. An artefact was registered if no valid measurement was recorded. Invalid values were identified by the algorithm of the system. All vital signs alerts were retrospectively categorised by two researchers (JPLL and EMD) as true positive, false positive or unclear based on clinical condition, nurse MEWS measurements and reports on 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 analysed by descriptive statistics. For continuous data, median and IQR or mean and SD were calculated based on normal distribution. Every parameter was checked for normality using 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 into constructs: usefulness, ease of use, ease of learning and satisfaction. To determine the reliability of the translated version of the USE, a Cronbach's α 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 the remarks of nurses were categorised within the constructs of the USE questionnaire. Finally, the fidelity of the system was analysed at the patient level. All analyses were performed with IBM SPSS Statistics V.24.0 for Mac.

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 to 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 a 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 (n=2) resections. Eleven patients (36.7%) developed 16 complications in total. Of these, 12 were classified as grade I and II according to the Clavien-Dindo classification. An overview of the patient characteristics is given in table 1.

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

ASA, American Society of Anesthesiologists; BMI, body mass index; ICU, intensive care unit.

Acceptability: patients' perspectives

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 hospitalisation, although 8 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%) would be willing to wear the patch for postsurgical home monitoring. Patient experiences are quoted in box 1. There were no missing data in the returned questionnaires.

Table 2 Patient acceptability

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

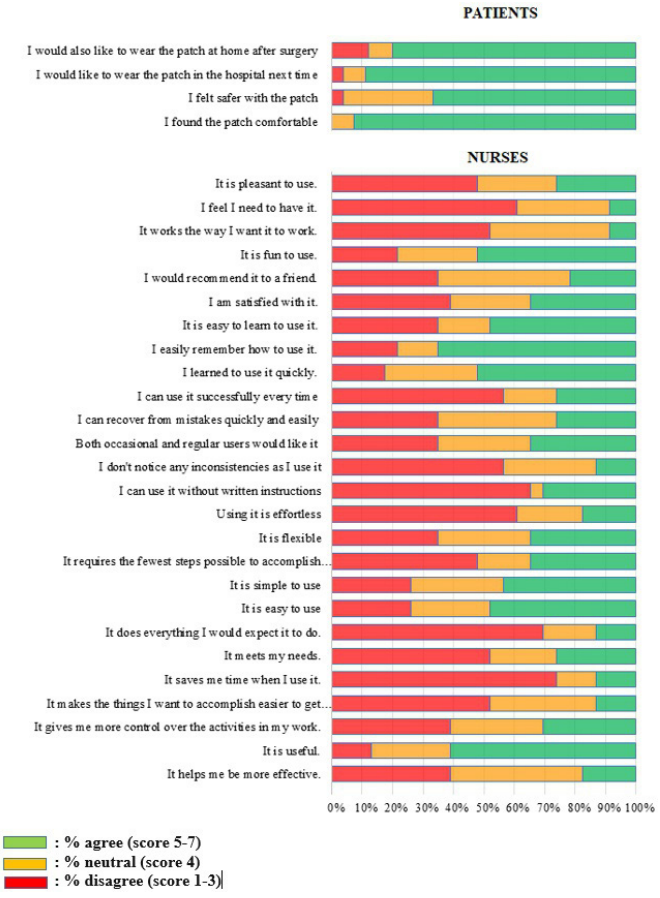

Figure 2 Diagram of patients' and nurses' acceptability.

Acceptability: nurses' perspectives

Thirty-five nurses were approached, of whom 23 (response: 66%) returned the questionnaire, as shown in table 3 and figure 2. The median age of nurses was 28 years old (IQR 24–39) and they had a median working experience of 5 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 box 1.

The median score of usefulness was 3.5 (IQR 3.1–4.0; Cronbach's α=0.916). 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 recognised the added value for the patient (box 1).

The median score for ease of use was 3.7 (IQR 3.2–4.8; Cronbach's α=0.937). 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 (box 1).

The median score of ease of learning was 5.0 (IQR 4.0–5.8; Cronbach's α=0.965). Out of 23 nurses, 15 (65%) agreed they easily remembered how to use it and quickly

Box 1 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.'

became skilful with it. No remarks were reported considering this construct.

The median score of satisfaction was 3.7 (IQR 2.9–4.4; Cronbach's α=0.931). 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 routine workflow. There were no missing data on the returned questionnaires. Several remarks were made considering satisfaction, predominantly about malfunction of the system, frequency of alarms and the discrepancy with nurse measurements (box 1).

System fidelity

The 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. In total, 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 artefacts.

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 only three subjects were responsible for nearly half (41.4%) of all alerts, a direct cause for the artefacts 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 due to 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 acknowledgement rate. Of the alerts, 35% were true positives, 44% were false positives and 21% uncategorised, as shown in table 4. 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) vs 13% for HR and 22.5% for RR. False positive T_{ax} was caused by registration of subtemperature.

DISCUSSION

In this study we aimed to determine the feasibility in terms of acceptability and fidelity of continuous wireless vital signs monitoring of abdominal surgery patients on 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 were 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 scepticism 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 clinically irrelevant and thus disturbing. This was well reflected in the remarks of nurses and is in agreement with a previous study by Prgomet *et al*[48] about the perceptions of nurses before implementation of a continuous monitoring device. The cause of these alerts is the large number of artefacts and the relatively short time frame of 14 min 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 artefacts encountered in the present study was still considerably lower for all three parameters in comparison with a previous study with the SensiumVitals system: HR: 19% vs 41%; RR: 51% vs 66%; T_{ax}: 9% vs 27%, respectively.[30] The high percentage of RR measurement artefacts is most likely due to the fact RR was measured by impedance, which is affected by the motion

Table 3 USE questionnaire among nurses (n=23)

	Median (IQR)	Disagree (1–3)	Neutral (4)	Agree (5–7)
Usefulness (α=0.916)	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=0.937)	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=0.965)	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=0.931)	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)

α, Cronbach's α; USE, Usefulness, Satisfaction, and Ease of use questionnaire.

of the patient and rejected by the strict algorithm of the SensiumVitals. Although temperature measurements had the least number of artefacts (14%), this was the parameter with the most false positive alerts (77%). This is probably due to transient dislocation of the sensor generating an apparent low T_{ax} 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, as well as the lack of literature on optimal thresholds and a clinically relevant time frame for alerts.[20] Therefore, we believe that the frequency and false alarm rate and

Table 4 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: uncategorised.
HR, heart rate; RR, respiratory rate; T_{ax}, axillary temperature.

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 of 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 among 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 early warning 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, categorising vital signs alerts was done retrospectively, which may have introduced bias in categorising true and false positive 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 among nurses the system needs improvements, in particular a significant reduction in artefacts and alerts. One desirable development would be the addition of a well-validated system for clinical decision support and smooth integration into hospital EMR. These results may provide helpful insights for larger scale implementation and (cost-)effectiveness studies of continuous monitoring on the general ward.

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Contributors JPLL conceived of the presented idea. JPLL, EMD, JDvD, HLvW, GAP: conception or design of the work. JPLL: data collection. JPLL, EMD: data analysis and interpretation. JPLL, EMD, JDvD, HLvW, CK, LS, GAP: drafting the article. JPLL, EMD, JDvD, HLvW, CK, LS, GAP: critical revision of the article. All authors: final approval of the version to be published.

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Patient consent for publication Not required.

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REFERENCES

1 International Surgical Outcomes Study group. Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries. *Br J Anaesth* 2016;117:601–9.
2 Findlay G, Goodwin A, Protopappa K, *et al*. *Knowing the risk: a review of the peri-operative care of surgical patients*. London: National Confidential Enquiry into Patient Outcome and Death, 2011.
3 Jhanji S, Thomas B, Ely A, *et al*. Mortality and utilisation of critical care resources amongst high-risk surgical patients in a large NHS trust. *Anaesthesia* 2008;63:695–700.
4 Pearse RM, Harrison DA, James P. Identification and characterisation of the high-risk surgical population in the United Kingdom. *Crit Care* 2006;10:10R81.
5 Pearse RM, Holt PJE, Grocott MPW. Managing perioperative risk in patients undergoing elective non-cardiac surgery. *BMJ* 2011;343:d5759.
6 Scally CP, Thumma JR, Birkmeyer JD, *et al*. Impact of surgical quality improvement on payments in Medicare patients. *Ann Surg* 2015;262:249–52.

7 Head J, Ferrie JE, Alexanderson K, *et al*. Diagnosis-specific sickness absence as a predictor of mortality: the Whitehall II prospective cohort study. *BMJ* 2008;337:a1469.
8 Churpek MM, Yuen TC, Edelson DP. Predicting clinical deterioration in the hospital: the impact of outcome selection. *Resuscitation* 2013;84:564–8.
9 Lockwood C, Conroy-Hiller T, Page T. Vital signs. *JBI Libr Syst Rev* 2004;2:1–38.
10 Evans D, Hodgkinson B, Berry J. Vital signs in hospital patients: a systematic review. *Int J Nurs Stud* 2001;38:643–50.
11 van Zanten ARH, Brinkman S, Arbous MS, *et al*. Guideline bundles adherence and mortality in severe sepsis and septic shock. *Crit Care Med* 2014;42:1890–8.
12 Young MP, Gooder VJ, McBride K, *et al*. Inpatient transfers to the intensive care unit: delays are associated with increased mortality and morbidity. *J Gen Intern Med* 2003;18:77–83.
13 NICE. Acutely ill adults in hospital: recognising and responding to deterioration. National Institute for Health and Clinical Excellence: guidance 2007.
14 Smith MEB, Chiovaro JC, O'Neil M, *et al*. Early warning system scores for clinical deterioration in hospitalized patients: a systematic review. *Ann Am Thorac Soc* 2014;11:1454–65.
15 Quarterman CPJ, Thomas AN, McKenna M, *et al*. Use of a patient information system to audit the introduction of modified early warning scoring. *J Eval Clin Pract* 2005;11:133–8.
16 Goldhill DR, McNarry AF. Physiological abnormalities in early warning scores are related to mortality in adult inpatients. *Br J Anaesth* 2004;92:882–4.
17 Downey CL, Tahir W, Randell R, *et al*. Strengths and limitations of early warning scores: a systematic review and narrative synthesis. *Int J Nurs Stud* 2017;76:106–19.
18 Clifton L, Clifton DA, Pimentel MAF, *et al*. Predictive monitoring of mobile patients by combining clinical observations with data from wearable sensors. *IEEE J Biomed Health Inform* 2014;18:722–30.
19 Beckett D, Gordon C, Paterson R, *et al*. Assessment of clinical risk in the out of hours Hospital prior to the introduction of hospital at night. *Acute Med* 2009;8:33–8.
20 Cardona-Morrell M, Prgomet M, Turner RM, *et al*. Effectiveness of continuous or intermittent vital signs monitoring in preventing adverse events on general wards: a systematic review and meta-analysis. *Int J Clin Pract* 2016;70:806–24.
21 Watkins T, Whisman L, Booker P. Nursing assessment of continuous vital sign surveillance to improve patient safety on the medical/surgical unit. *J Clin Nurs* 2016;25:278–81.
22 Appelboom G, Camacho E, Abraham ME, *et al*. Smart wearable body sensors for patient self-assessment and monitoring. *Arch Public Health* 2014;72:28.
23 Downey C, Randell R, Brown J, *et al*. Continuous versus intermittent vital signs monitoring using a wearable, wireless patch in patients admitted to surgical wards: pilot cluster randomized controlled trial. *J Med Internet Res* 2018;20:e10802.
24 Subbe CP, Duller B, Bellomo R. Effect of an automated notification system for deteriorating ward patients on clinical outcomes. *Crit Care* 2017;21:52.
25 Weenk M, van Goor H, Frietman B, *et al*. Continuous monitoring of vital signs using wearable devices on the general ward: pilot study. *JMIR Mhealth Uhealth* 2017;5:e91.
26 Breteler MJM, KleinJan E, Numan L, *et al*. Are current wireless monitoring systems capable of detecting adverse events in high-risk surgical patients? A descriptive study. *Injury* 2020;51:S97–105.
27 Boatin A, Wylie B, Goldfarb I. Wireless maternal vital sign monitoring in inpatient full-term pregnant women: a feasibility and acceptability study. *Int J Gynecol Obstet* 2015;131:E492 http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L72070358
28 Sahandi R, Noroozi S, Roushan G, *et al*. Wireless technology in the evolution of patient monitoring on General Hospital wards. *J Med Eng Technol* 2010;34:51–63.
29 Posthuma LM, Downey C, Visscher MJ, *et al*. Remote wireless vital signs monitoring on the ward for early detection of deteriorating patients: a case series. *Int J Nurs Stud* 2020;104:103515.
30 Downey C, Ng S, Jayne D, *et al*. Reliability of a wearable wireless patch for continuous remote monitoring of vital signs in patients recovering from major surgery: a clinical validation study from the tracing trial. *BMJ Open* 2019;9:e031150 http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L628904217
31 Breteler MJM, KleinJan EJ, Dohmen DAJ. Vital signs monitoring with wearable sensors in high-risk surgical patients: a clinical validation study. *Anesthesiology* 2019.
32 Leenen JPL, Leerentveld C, van Dijk JD, *et al*. Current evidence for continuous vital signs monitoring by wearable wireless devices in hospitalized adults: systematic review. *J Med Internet Res* 2020;22:e18636.
33 Craig P, Dieppe P, Macintyre S, *et al*. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.
34 von EE, Altman DG, Egger M. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ [Internet]* 2007;335:806–8 https://www.bmj.com/content/335/7624/806
35 Duus CL, Aasvang EK, Olsen RM, *et al*. Continuous vital sign monitoring after major abdominal surgery-Quantification of micro events. *Acta Anaesthesiol Scand* 2018;62:1200–8.
36 Sensium Healthcare. Early detection of patient deterioration [online], 2019. Available: https://www.sensium.co.uk/_assets/media/documents/brochures/brochure.pdf [Accessed 11 Oct 2019].
37 Clavien PA, Barkun J, de Oliveira ML, *et al*. The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg* 2009;250:187–96.
38 Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004;240:205–13.
39 Bowen DJ, Kreuter M, Spring B, *et al*. How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.
40 Lund A. Measuring usability with the use questionnaire. *Usability User Exp Newslett* 2001;8.
41 Proctor E, Silmere H, Raghavan R, *et al*. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;38:65–76.
42 Ghasemi A, Zahediasl S. Normality tests for statistical analysis: a guide for non-statisticians. *Int J Endocrinol Metab* 2012;10:486–9.
43 Downey C, Randell R, Brown J. Continuous versus intermittent vital signs monitoring in patients admitted to surgical wards: a cluster-randomised, controlled trial. *Color Dis [online]* 2018;20:60 http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L624186281
44 Downey CL, Brown JM, Jayne DG, *et al*. Patient attitudes towards remote continuous vital signs monitoring on general surgery wards: an interview study. *Int J Med Inform* 2018;114:52–6.
45 Paul JE, Chong MA, Buckley N, *et al*. Vital sign monitoring with continuous pulse oximetry and wireless clinical notification after surgery (the VIGILANCE pilot study)-a randomized controlled pilot trial. *Pilot Feasibility Stud* 2019;5:36.
46 Hubner P, Schober A, Sterz F, *et al*. Surveillance of patients in the waiting area of the department of emergency medicine. *Medicine* 2015;94:e2322.
47 Izmailova ES, McLean IL, Bhatia G, *et al*. Evaluation of wearable digital devices in a phase I clinical trial. *Clin Transl Sci* 2019;12:247–56 http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L625914593
48 Prgomet M, Cardona-Morrell M, Nicholson M, *et al*. Vital signs monitoring on general wards: clinical staff perceptions of current practices and the planned introduction of continuous monitoring technology. *Int J Qual Health Care* 2016;28:515–21.
49 Sendelbach S, Funk M. Alarm fatigue: a patient safety concern. *AACN Adv Crit Care* 2013;24:378–88.
50 McCoy CC, Englum BR, Keenan JE, *et al*. Impact of specific postoperative complications on the outcomes of emergency general surgery patients. *J Trauma Acute Care Surg* 2015;78:912–9.