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Are current wireless monitoring systems capable of detecting adverse events in high-risk surgical patients? A descriptive study

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ABSTRACT

Background: Adverse events are common in high-risk surgical patients, but early detection is difficult. Recent innovations have resulted in wireless and 'wearable' sensors, which may capture patient deterioration at an early stage, but little is known regarding their ability to timely detect events. The objective of this study is to describe the ability of currently available wireless sensors to detect adverse events in high-risk patients.

Methods: A descriptive analysis was performed of all vital signs trend data obtained during an observational comparison study of wearable sensors for vital signs monitoring in high-risk surgical patients during the initial days of recovery at a surgical step-down unit (SDU) and subsequent traumatology or surgical oncology ward. Heart rate (HR), respiratory rate (RR) and oxygen saturation (SpO₂) were continuously recorded. Vital sign trend patterns of patients that developed adverse events were described and compared to vital sign recordings of patients without occurrence of adverse events. Two wearable patch sensors were used (SensiumVitals and HealthPatch), a bed-based mattress sensor (EarlySense) and a patient-worn monitor (Masimo Radius-7).

Results: Twenty adverse events occurred in 11 of the 31 patients included. Atrial fibrillation (AF) was most common (20%). The onset of AF was recognizable as a sudden increase in HR in all recordings, and all patients with new-onset AF after esophagectomy developed other postoperative complications. Patients who developed respiratory insufficiency showed an increase in RR and a decrease in SpO₂, but an increase in HR was not always visible. In patients without adverse events, temporary periods of high HR and RR are observed as well, but these were transient and less frequent.

Conclusions: Current systems for remote wireless patient monitoring on the ward are capable of detecting abnormalities in vital sign patterns in patients who develop adverse events. Remote patient monitoring may have potential to improve patient safety by generating early warnings for deterioration to nursing staff.

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Introduction

Adverse events are common in high-risk patients within the hospital. In surgical patients, the incidence of complications after major surgery is reported between 17 and 44 percent, with a sig-

nificant associated mortality [1–3]. Obviously, complications have a negative effect on patient health and outcome, but a delay in detection of adverse events frequently aggravates the patient's condition. In the majority of adverse events, early signs of deterioration are present up to 48 h prior to admission to the Intensive Care Unit (ICU) [4–7]. The poor condition of patients upon arrival in the ICU reflects such a delay [8,9]. Early recognition of adverse events could lead to better outcomes, as adequate treatment of complications can be initiated before failure-to-rescue events occur [10,11].

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During rounds on the ward vital signs are usually measured and documented by nurses. The frequency of measurements is increased when this is deemed necessary and in case of aberrant signs the medical staff is informed. Although nurses have been manually checking patient’s vital signs dating back to the 19th century, this routine monitoring practice has several potential flaws. First, the frequency of monitoring is low, generally once per nurse shift. Second, relevant changes in vital signs may remain undetected, specifically when the changes are subtle or still within the normal range of physiology. Third, compliance from nurses to vital sign monitoring protocols is often poor, resulting too often in incomplete or incorrect documentation of data [12–14]. These drawbacks of monitoring are in part responsible for the delay in detection of adverse events or complications.

With the introduction of wearable sensors that allow wireless continuous vital signs monitoring, substantial improvement in patient safety might be achieved [15]. Various manufacturers recently developed systems for this purpose, some of which are FDA or CE approved, claiming to enhance patient safety. Ideally, wireless vital signs monitoring should be reliable, unobtrusive, and provide input to a clinical decision support system that alerts nursing staff early in case of patient deterioration. Importantly, the false alarm rate should be as low as possible in order to prevent ‘alarm fatigue’, a dangerous phenomenon which results in desensitization to alarms and missed alarms. In particular, such systems might benefit from the use of ‘intelligent’ alarms to identify relevant changes in physiological state when an adverse event develops. To date, however, no system meets all these requirements.

We recently critically validated the accuracy of four wireless systems with different sensing principles to study whether they can reliably measure heart rate and respiratory rate continuously in high-risk surgical patients [16]. While validating these sensors, several adverse events occurred in some of these patients. In this overview we aim to describe the ability of currently available sensors to detect vital signs changes prior to and during these events in a group of high-risk surgical patients.

Materials and methods

Study design and setting

We performed a descriptive analysis of all vital signs trend data obtained during an observational methods comparison study of wearable sensors for vital signs monitoring. A subset of patients developed adverse events during these vital signs recordings. In this study, vital sign trend patterns of patients with adverse events are described in more detail and compared to vital sign recordings of patients without occurrence of adverse events.

Heart rate and respiratory rate were continuously recorded in high-risk surgical patients with two wearable patch sensors (SensiumVitals: Sensium Healthcare Ltd, Oxford, UK, and HealthPatch: VitalConnect, California San Jose, CA), a bed-based mattress sensor (EarlySense; EarlySense Ltd, Ramat Gan, Israel) and a patient-worn monitor (Masimo Radius-7: Masimo Corporation, Irvine, CA, USA) simultaneously during the initial days of recovery at a surgical step-down unit (SDU) and subsequent stay on the traumatology or surgical oncology ward of the University Medical center Utrecht, the Netherlands. Besides heart and respiratory rate, oxygen saturation was continuously recorded with a SpO₂ finger probe (Masimo Radius-7). No alarms were generated and sent to nurses. A description and image of each sensor is shown in Table 1 and Fig. 1, respectively. Formal approval for this study was obtained from the local ethical committee (nr 16/062).

Table 1
Overview of wireless monitoring solutions.

Sensor (manufacturer)	Sensor type	Vital signs measured	Update rate vital signs
Masimo Radius-7 (Masimo Corporation, Irvine, CA, USA)	Patient-worn monitor connected to a pulse oximeter and acoustic adhesive sensor in the neck (RRa)	Heart rate (pulse rate) Respiration rate Saturation	Every 2 s (storage)
SensiumVitals (Sensium Healthcare Ltd, Oxford, UK) ^a	Wireless adhesive patch sensor on chest	Heart rate Respiration rate	Every 120 s
HealthPatch MD (VitalConnect, San Jose, California, USA) ^b	Wireless adhesive patch sensor on chest	Heart rate Respiration rate	Every 4 s
EarlySense system (EarlySense Ltd, Ramat Gan, Israel)	Contactless piezoelectric sensor under the patient's mattress	Heart rate Respiration rate	Every 60 s

^a The Sensium system measures axillary temperature too.

^b The HealthPatch MD measures skin temperature too.



Fig. 1. Overview of the four wearable sensors: (A) Masimo Radius-7; (B) SensiumVitals; (C) HealthPatch MD; (D) EarlySense system.

Study population

For elective cases between February and September 2017, consecutive patients scheduled for major surgery with an indication for postoperative monitoring at the step-down unit were asked to participate at the pre-operative screening clinic. Acute cases were asked for participation upon admission to the step-down unit. These patients were considered for enrolment because they represent a population that is more prone for deterioration as compared to patients on the general ward only. Patients with an implantable cardiac device, patients who were allergic for any adhesives, or who had a wound or irritation near the sensor application site on the thorax, were excluded. After written informed consent was obtained from the patient, the four sensor systems (Table 1) were applied simultaneously to the patient and vital signs recording started.

Data selection and analysis

All vital sign recordings were divided into two groups: recordings of patients that developed adverse events and patients without occurrence of adverse events. For both groups, vital sign trend patterns were compared and described in detail. A median filter over a 120 s period was applied to the raw sensor data of Masimo Radius-7, HealthPatch MD and the EarlySense system to be able to evaluate the trend data among all sensors with the same up-

date rate. The update rate of SensiumVitals was unchanged (see Table 1). Adverse events were defined as any complication that may or may not have been preventable which required intervention.

We summarized and evaluated all adverse events. An example of this would be the description of vital sign patterns during periods of atrial fibrillation or an anastomotic leak. Furthermore, we studied to what extent such vital sign patterns were observable in patients who did not develop adverse events. All vital sign trends were visualized using Matlab R2017b (The Mathworks, Natick, Massachusetts, USA).

Results

During the study period, 31 patients were included for continuous vital signs recording with wearable sensors. Twenty adverse events occurred in 11 patients, of which 9 (45%) during SDU stay and 11 (55%) at the surgical ward. Six out of these 11 patients developed multiple adverse events (two events; $n = 4$ or three events; $n = 2$). In total, 2607 h of vital signs recording were available for analysis, with a median duration of 88 h per patient. Table 2 summarizes patient characteristics. An overview of adverse events is summarized in Table 3.

Descriptive analysis of vital signs recordings in patients who developed one or more adverse events

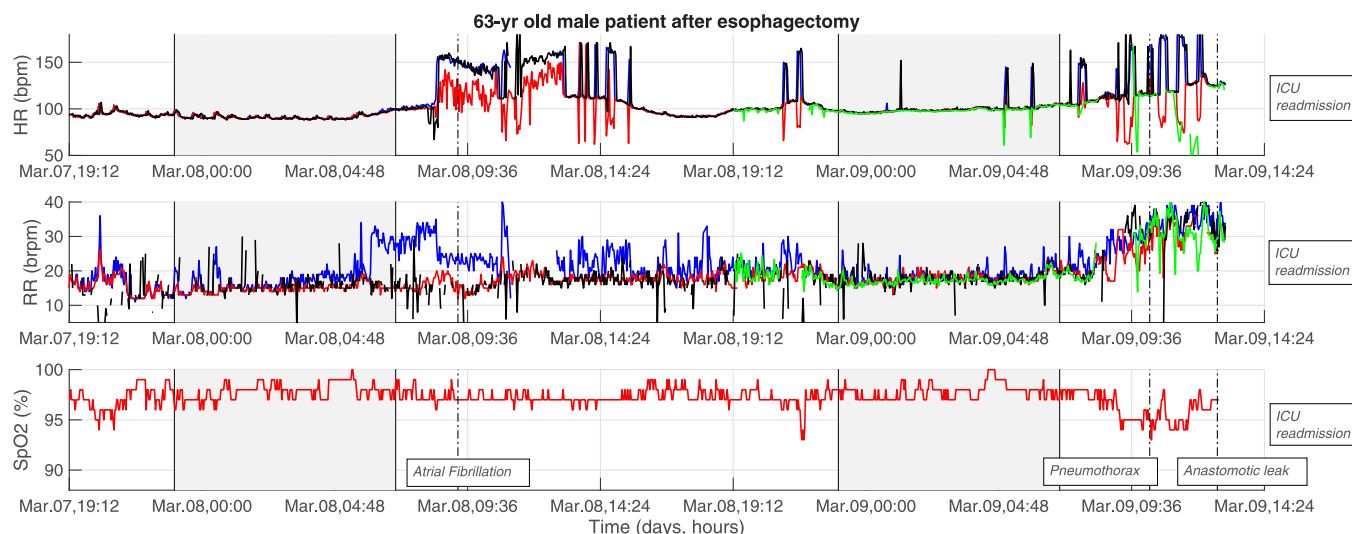


Fig. 2. Example of a patient who developed adverse events, while vital signs were recorded continuously on the surgical ward with the two wireless patch sensors (SensumVitals: black, HealthPatch MD: blue), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas.

Table 2
Patient characteristics (N = 31).

Male, n (%)	21 (68)
Age (years) Median (IQR)	62 (20)
Specialty	
Surgical oncology, n (%)	16 (52)
Trauma, n (%)	15 (48)
Comorbidities	
Hypertension, n (%)	5 (16)
Diabetes, n (%)	3 (1)
COPD, n (%)	3 (10)
Cardiovascular disease, n (%)	2 (6)
Length of stay (days) Median (IQR)	12 (9)
Readmission within 30 days, n (%)	2 (6)
Length of vital sign recording (hours) Median (IQR)	88 (74)

Table 3
overview adverse events.

Type AE	n (%)
Atrial fibrillation	4 (20)
Pneumonia	4 (20)
Pneumothorax	3 (15)
Anastomotic leak	2 (10)
Gastroparesis	2 (10)
Pulmonary Embolism	1 (5)
Atelectasis	1 (5)
Diaphragmatic hernia	1 (5)
Pancreatic leak	1 (5)
Chyle leak	1 (5)
Total	20
Number of AEs at the SDU	9 (45)
Number of AEs at the ward	11 (55)
Other	
SDU readmission	3 (16)
ICU readmission	1 (5)

Fig. 2 shows HR, RR and SpO₂ measurements during the fifth and sixth day postoperatively of a 63-year-old male patient after esophagectomy at the SDU. Three events occurred before the patient was readmitted to the ICU. The first event shows a sudden HR increase on March 8th, diagnosed as new-onset atrial fibrillation, which started after patient mobilization. The next morning, on March 9th, this patient developed a pneumothorax (second event) and anastomotic leak (third event); he rapidly developed respiratory insufficiency and was diagnosed with sepsis, followed

by urgent ICU readmission. The following changes in vital signs can be seen in Fig. 2, before these two events were diagnosed: a slowly increasing HR from 100 to 130 bpm, an increasing RR from 18 to > 35 brpm and a more subtle decrease in oxygen saturation, from 97% to 93%.

Fig. 2 also illustrates that both Masimo Radius-7 and the EarlySense system underestimate HR during periods of AF.

Fig. 3 shows the vital sign trends of a 68-year old male patient after esophagectomy from the 2nd to 8th day postoperatively. In the afternoon of June 18th, the patient complained of chest pain and acute dyspnea after. Subsequently, pulmonary embolism was diagnosed. In the hours before and after this event, an increase in HR from 75 to 110 bpm was seen and a more subtle increase in RR from 14 to 21 brpm. Oxygen saturation frequently decreased below 90% (Fig. 3). In the evening of June 19th, the nurse palpated the pulse of the patient and was unsure whether it was irregular. A subsequent ECG did not show AF. The diagnosis of new-onset AF was not confirmed until another ECG early in the morning of June 21st. In addition, the patient also complained of intolerable epigastric pain. Subsequently, a pancreatic fistula was diagnosed.

Although new-onset AF was not diagnosed before June 21st, the HR pattern frequently showed sudden increases or decreases of HR (Fig. 3). In addition, both Masimo Radius-7 and EarlySense underestimate the ventricular rate during rapid AF.

Fig. 4 shows HR, RR and SpO₂ trends on day 6, 7 and 8 of a 54-year male patient admitted with multiple rib fractures, grade IV liver laceration and a hemopneumothorax after a fall from height. In the morning of May 10th, the chest drain was removed, but after an attempt to reduce oxygen administration oxygen therapy had to be increased. In the afternoon of May 10th, a recurrent pneumothorax was diagnosed, for which conservative treatment with patient-controlled analgesia was initiated. On May 11th, the patient complained of increasing pain, despite adequate pain treatment, after which the patient was readmitted to the SDU with respiratory insufficiency. In the hours before and after this event, HR gradually increased from 70 to 100 bpm. At the same time, RR increased from 16 to 30 brpm. Oxygen saturation frequently decreased below 90%, despite oxygen therapy.

Fig. 5 shows the vital sign trends from the 3d to 5th day postoperatively of a 51-year male trauma patient admitted with fractures of the transverse processes of the lumbar vertebrae, sacral fractures and a dislocated femur fracture for which he received

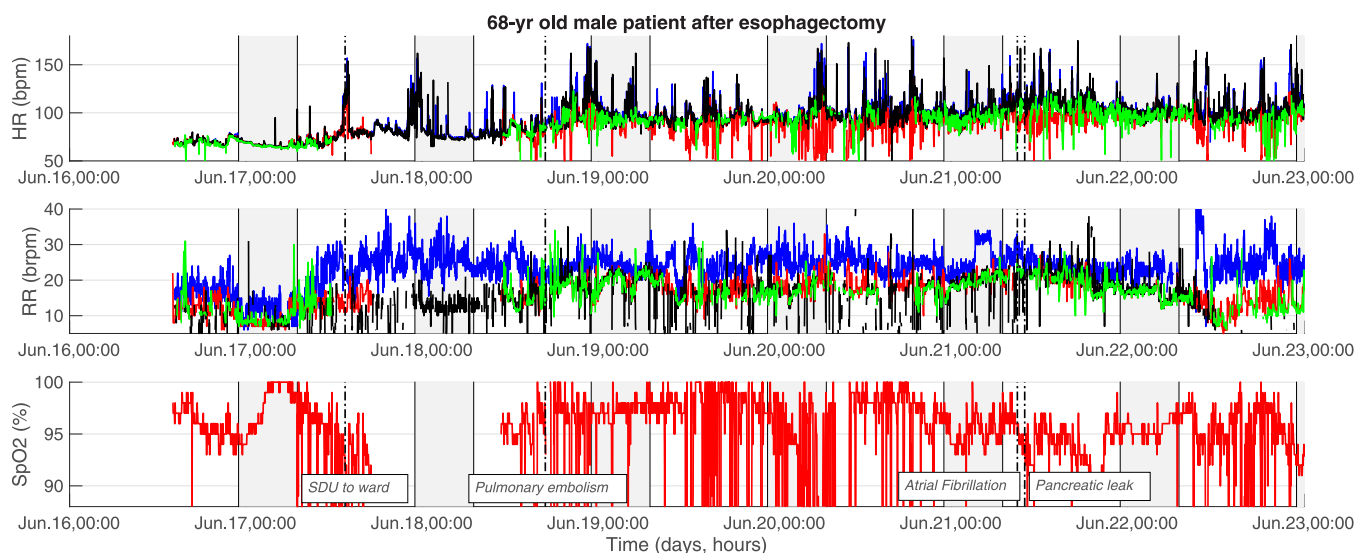


Fig. 3. Example of a patient who developed an adverse event, while vital signs were recorded continuously on the surgical ward with the wireless patch sensor (SensiumVitals: black), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas.

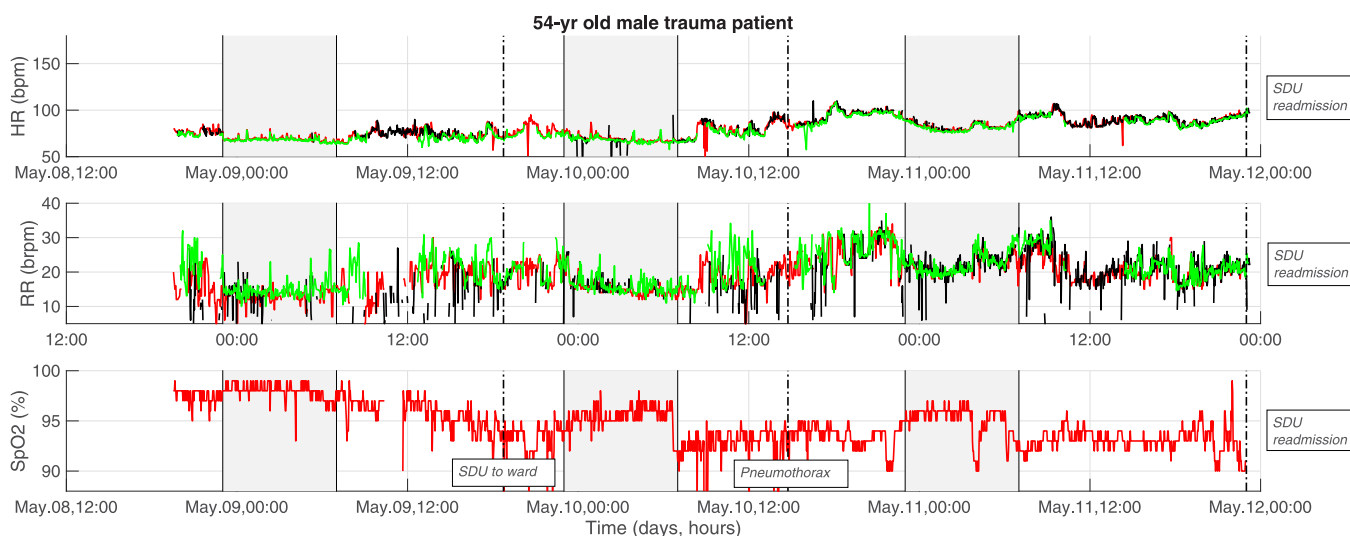


Fig. 4. Example of a patient who developed an adverse event, while vital signs were recorded continuously on the surgical ward with the wireless patch sensor (SensiumVitals: black), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas.

pelvic fracture surgery. In the night of May 24th, the patient suddenly developed respiratory insufficiency and was diagnosed with atelectasis, for which he was readmitted to the SDU. The following changes in vital signs can be seen before this event was diagnosed: the existing tachycardia further increased from 100 to 120 bpm. At the same time, RR increased from 20 to 30 brpm and his oxygen saturation rapidly decreased below 88%.

Descriptive analysis of vital signs recordings of patients without occurrence of adverse events

Fig. 6 shows the vital signs of a 64-year old female patient 2 days after hepatectomy surgery without development of adverse events. A short period of tachycardia can be noticed early in the morning on April 23. This corresponds with a brief period of patient mobilization, since no measurements of the bed-based EarlySense system are present. In addition, no sustained tachypnea can be recognized. SpO₂ slowly decreased over time, but remained stable.

Fig. 7 shows HR, RR and oxygen saturation of a 36-year-old male patient admitted with multiple rib fractures and a pneumothorax after a

motorcycle accident. This patient did not develop complications during hospital stay. Frequent short periods of tachycardia can be seen in Fig. 7, which correspond with periods of mobilization. During mobilization, respiration rate increased slightly too, but no sustained periods of tachypnea were observed. In the morning of April 27th, oxygen administration was stopped. During this period, oxygen saturation decreased to 95%, but it remained stable over time.

Fig. 8 shows vital sign recordings of a 70-year-old male patient admitted with multiple rib fractures and hemothorax after a fall from height. No adverse events occurred during hospital stay. There were no episodes with sustained tachycardia. Respiration rate slowly decreased during the night and slightly increased in the morning during periods of mobilization. Oxygen saturation remained stable around 94–96% over time.

Summary of adverse events

An overview of adverse events is summarized in Table 3. All four patients that developed new-onset AF after esophagectomy

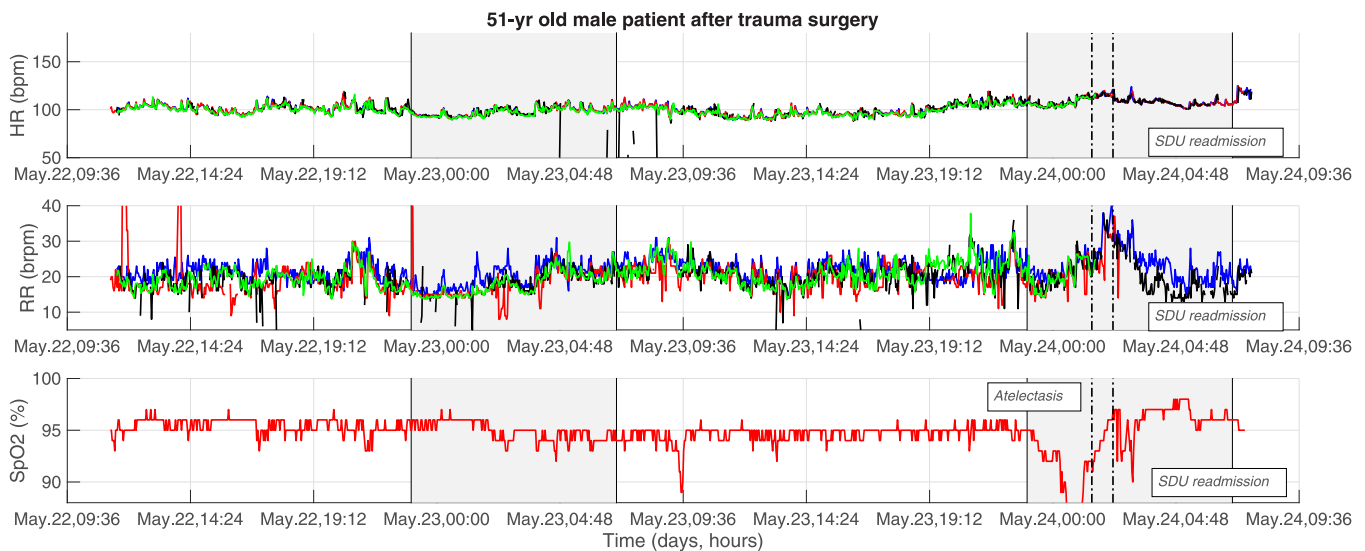


Fig. 5. Example of a patient who developed an adverse event, while vital signs were recorded continuously on the surgical ward with the two wireless patch sensors (SensiumVitals: black, HealthPatch MD: blue), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas.

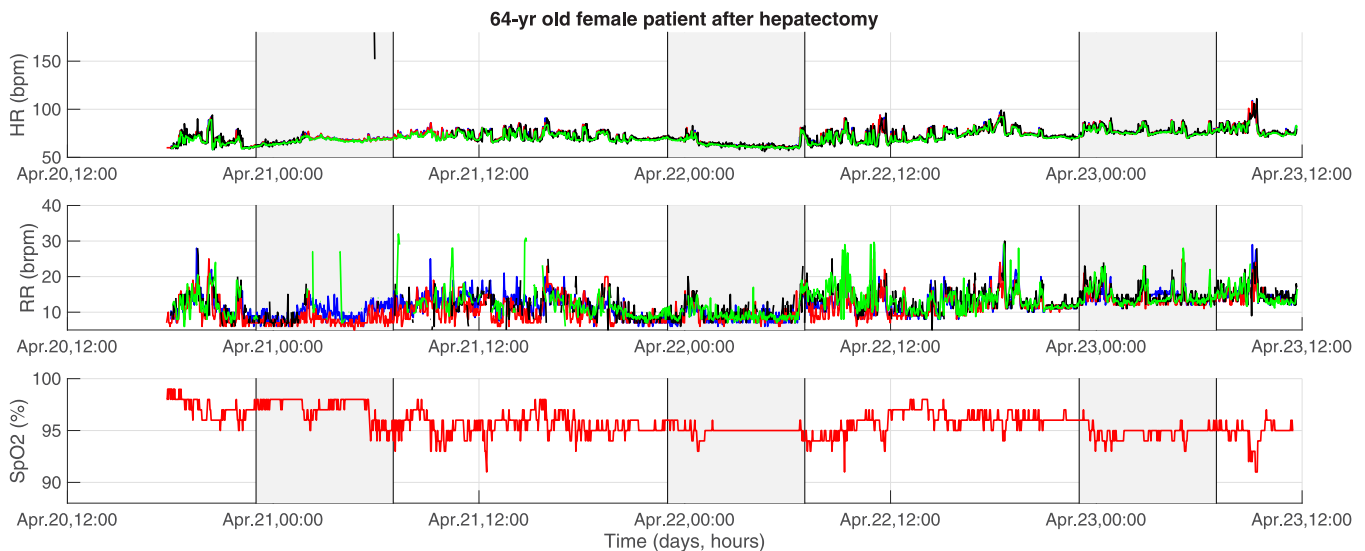


Fig. 6. Example of a patient in whom vital signs were recorded continuously on the surgical ward with the two wireless patch sensors (SensiumVitals: black, HealthPatch MD: blue), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas. No adverse events occurred during the measurement period.

also developed other postoperative complications, such as an anastomotic leak, pneumonia or pneumothorax. During AF, a sudden increase in HR or gradual increase in HR was recognized in all four vital sign recordings. However, differences exist among sensors to capture AF with rapid ventricular rate. Both Masimo-Radius 7 and EarlySense underestimate the actual heart rate during periods of AF whereas HealthPatch MD and SensiumVitals did not.

Patients that became respiratory insufficient showed an increase in RR and a decrease in SpO₂. Most patients showed an increase in HR as well, although this was not always clearly visible. In patients with mild pneumonia, who did not develop respiratory insufficiency, changes in vital signs were often minor or ambiguous.

In vital sign recordings of patients without adverse events, temporary periods of high HR and RR can be observed as well. However, these periods occurred less frequent, were often transient and less severe when compared to patients who subsequently devel-

oped an adverse event. In addition, none of the patients without adverse events showed substantial simultaneous changes in HR and RR, except for short episodes during mobilization.

Discussion

The ability of currently available wireless vital signs sensors to detect adverse events in a group of high-risk surgical patients and also vital sign trend patterns in patients who did not develop adverse events during the measurement period were evaluated in this study. The current first generation of wireless sensors were shown to detect abnormalities in vital sign trend patterns before adverse events were diagnosed. In patients without adverse events, periods of tachycardia and tachypnea did occur, but these changes occurred less frequently and were often transient. Furthermore, none of the patients without adverse events showed simultaneous increases in HR, RR and SpO₂, except during periods of mobilization.

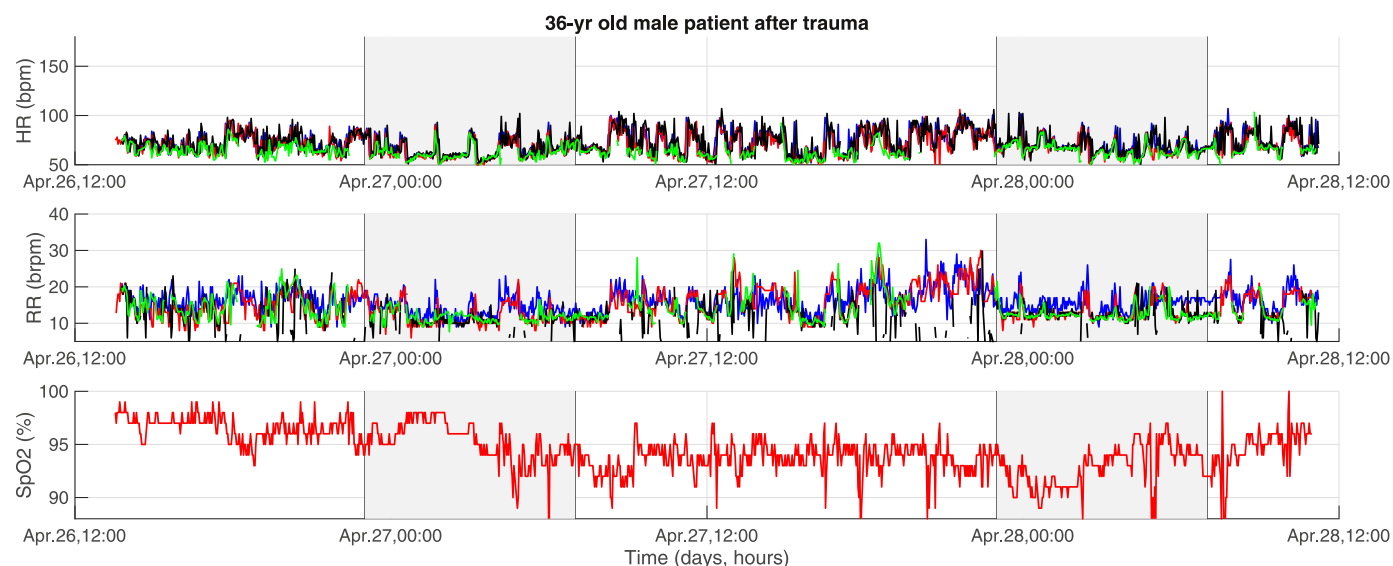


Fig. 7. Example of a patient in whom vital signs were recorded continuously on the surgical ward with the two wireless patch sensors (SensiumVitals: black, HealthPatch MD: blue), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas. No adverse events occurred during the measurement period.

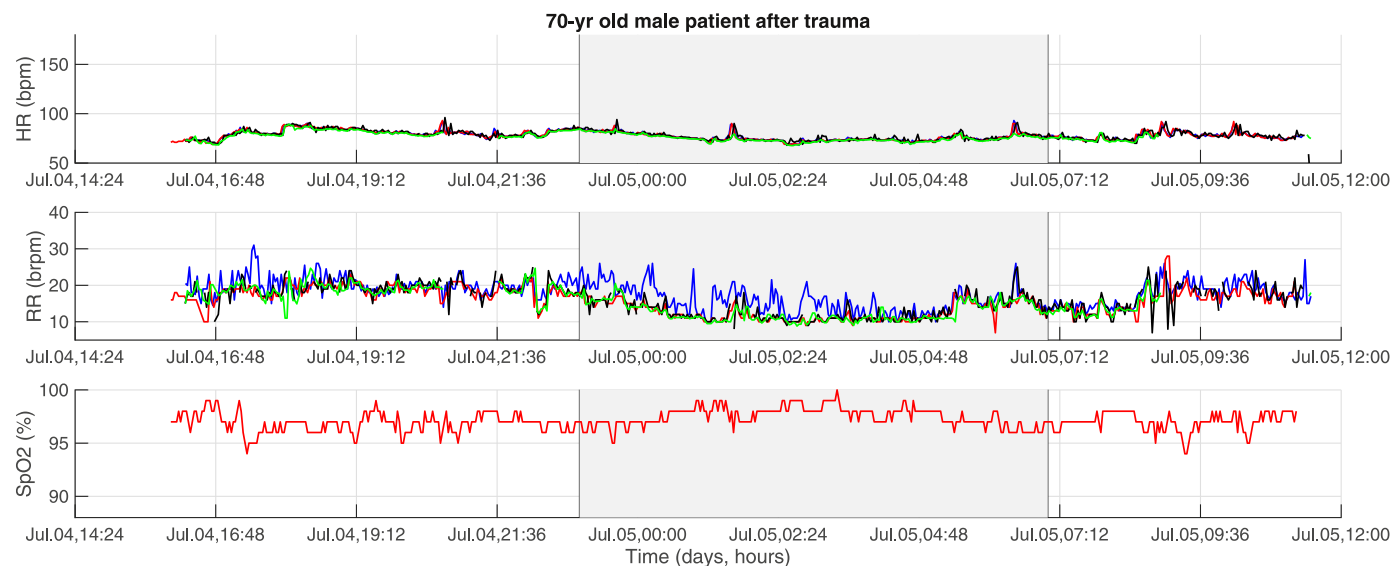


Fig. 8. Example of a patient in whom vital signs were recorded continuously on the surgical ward with the two wireless patch sensors (SensiumVitals: black, HealthPatch MD: blue), the bed-based system EarlySense (green) and a patient-worn monitor (Masimo Radius-7: red). The night from 11 p.m. to 7 a.m. is illustrated by shaded gray areas. No adverse events occurred during the measurement period.

During AF, a clear trend in HR was recognized in all recordings. All four patients that developed new-onset AF after esophagectomy also developed other adverse events. It may be as such of predictive value for developing other postoperative complications. This finding is consistent with previous studies that showed a high association between AF and various postoperative infectious complications [17,18].

Interestingly, this study also shows differences among the studied wireless sensors to capture AF with rapid ventricular rate. Masimo Radius-7 underestimates the actual heart rate since it calculates heart rate from the plethysmographic waveform obtained from the pulse oximeter probe. Similarly, the EarlySense system may underestimate the actual heart rate during periods of AF, since it derives HR from cardiac ballistic movement associated with ejection of blood with each heart cycle. During AF with rapid ventricular rate many beats will have had insufficient time for ventric-

ular filling as a result undetectable peripheral pulse. Both patch sensors SensiumVitals and HealthPatch MD derive heart rate from ECG and show therefore higher accuracy for HR during periods of AF [19,20].

The vital sign trends of the patients that became respiratory insufficient showed an increase in RR and a decrease in SpO₂. Most patients showed a simultaneous increase in HR, although this was not always clearly visible. In patients with mild pneumonia who developed no respiratory insufficiency for example, clear changes in vital signs were not always present.

Even during periods of hemodynamic and respiratory stability, decreases in SpO₂ (<90%) are recognized, although less frequent in patients who did not develop adverse events. With the current single parameter 'threshold' based alarms, this would have resulted in a high number of false-positive alerts which could lead to highly undesirable alarm fatigue among ward nurses [21]. However, if RR,

HR and SpO₂ patterns deteriorate simultaneously as shown in the present study, a much stronger predictive value for patient deterioration arises.

The present study provides a first glance of the capability of first-generation wireless monitoring systems. The fact that patient deterioration is often preceded by changes in vital signs is not new, but so far no studies have evaluated the ability of one or more wireless systems to detect deteriorating vital sign trend patterns in patients that deteriorate on a general ward. A few studies have demonstrated the potential of continuous vital signs monitoring systems on the ward. In a recent study of postsurgical patients of which blood pressure was continuously monitored with the ViSi Mobile system on the ward, Turan et al. [22] showed that nearly half of the patients experienced severe hypotension (mean arterial pressure < 65 mmHg) for more than 15 min which were missed by routine nursing rounds. In another study, the MEWS was calculated every 30 min with two remote monitoring solutions (ViSi mobile system and HealthPatch) and compared to regular MEWS measurements of nurses [23]. Recordings of these remote monitoring systems resulted in periods of high MEWS, most of them during the evening and night, indicating that potentially alarming situations were missed. Although both studies show potential advantages of continuous vital signs monitoring on the ward, these studies did not show to which extent periods of either severe hypotension or high MEWS was associated with patient deterioration. In addition, both studies did not evaluate the value of vital sign trends in predicting clinical deterioration.

A large number of studies have been published on the use of Modified Early Warning Scores (MEWS) to recognize patient deterioration early and initiate therapy, including Rapid Response team activation [12,24–26]. Until now, such studies only used intermittently recorded vital signs when calculating a score. Scores that include trends over time typically use the change since the last vital observation [27,28]. However, no studies are available yet that report on the ability of continuous wireless monitoring solutions to identify patient deterioration early.

This study was designed to validate the sensor accuracy of four different remote monitoring systems, not to clinically monitor surgical patients. As a result, the sample size and number of adverse events was too small to identify specific vital signs patterns for each type of adverse event. Nevertheless, despite a relatively low number of adverse events, these results do provide insight in the ability of the current generation of wireless sensors to assist in more timely detection of patient deterioration.

Although most of the adverse events in the present study occurred during ward admission, some of the complications were diagnosed during SDU stay where continuous surveillance monitoring was already in place. However, this study did not focus on the ability to recognize patient deterioration earlier, but to show to what extent current wireless monitoring systems are capable to detect vital sign patterns of patient deterioration.

The potential benefits of wireless patient monitoring on the ward with wearable sensors are increasingly being recognized in literature [23,29–31]. To succeed in developing reliable patient monitoring systems, wireless sensors need to be connected to sophisticated signal analysis and alarm notification systems to inform nursing staff on time, while at the same time minimizing false-positive alerts. Future large studies in high-risk patients are therefore needed to obtain sufficient amount of data to validate algorithms designed to reliably identify patient deterioration.

Conclusions

Current systems for wireless monitoring of patients on the ward are capable of recognizing vital signs abnormalities in surgical patients who develop adverse events. Remote patient monitoring

may have potential to generate early warnings for patient deterioration to nursing staff and could as such contribute to improved patient safety. To prevent unacceptably high false-positive alarm rates, future systems might benefit from improvements in the deterioration detection algorithms and alert systems to pave the way for predicting clinical deterioration and early interventions.

Declaration of Competing interest

MJMB is part-time employee of Luscii Healthtech BV (Health ICT company, Amsterdam, The Netherlands).

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