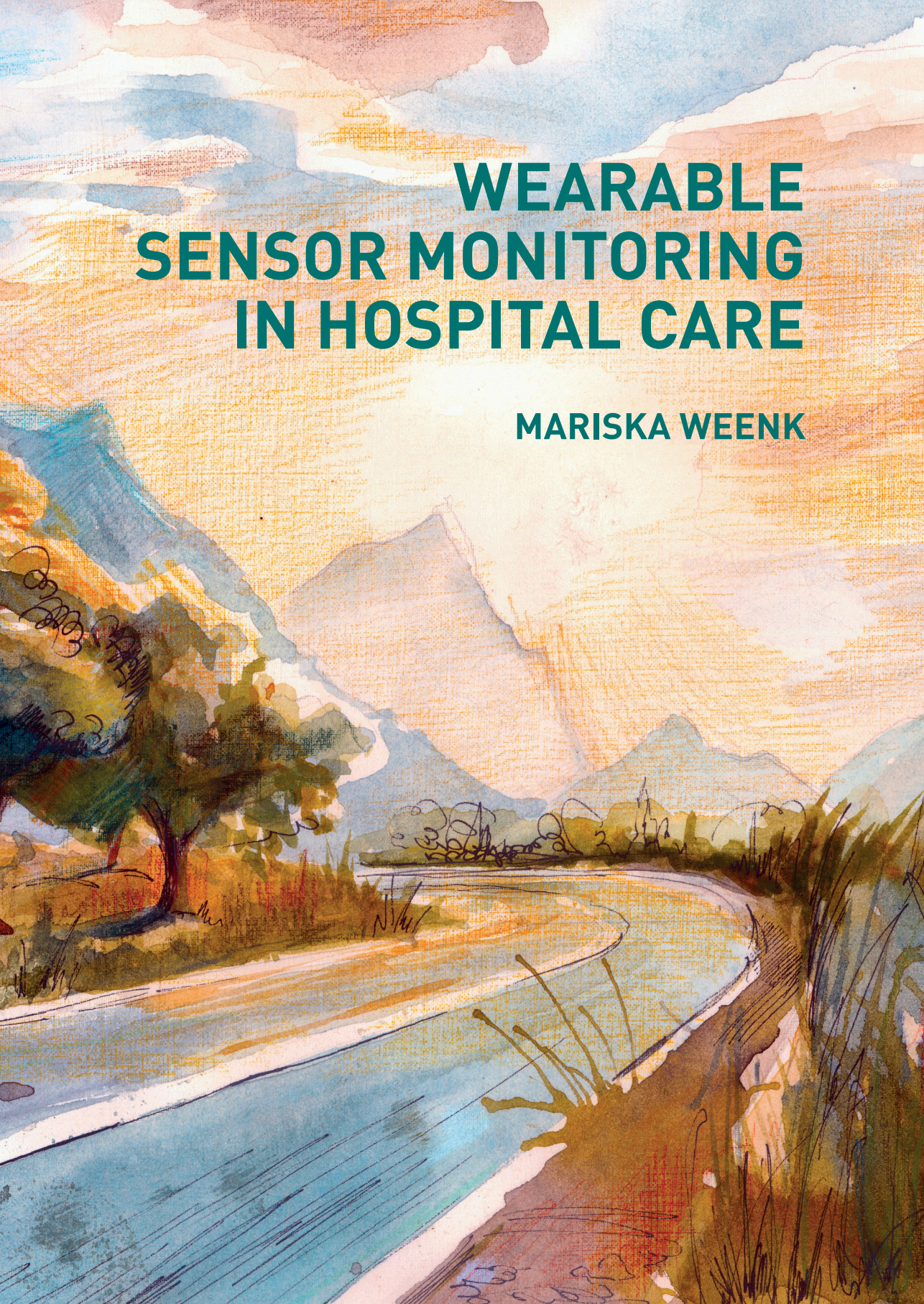
WEARABLE SENSOR MONITORING IN HOSPITAL CARE

MARISKA WEENK



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Mariska Weenk

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1.
General Introduction

GENERAL INTRODUCTION

Vital sign monitoring at the general ward

Measurements of vital signs such as heart rate, respiratory rate, blood pressure, temperature and oxygen saturation are common in hospitalized patients and provide insight in the patients' clinical condition.[1] Nowadays, many vital signs can be measured (semi-)continuously with the possibility of remote monitoring. This is usual practice in high care environments such as the Intensive Care Unit (ICU), the Operating Theatre and the Emergency Department. In these care locations, care givers are immediately informed about deterioration of the patients' vital signs. At the general ward, however, vital signs are measured discontinuously and manually and are registered by nurses on average three times in 24 hours, which basically means one time every work-shift. As a result, vital signs are 'monitored' via the electronic health record (EHR).

Early warning scores

Clinical deterioration regularly occurs in hospitalized patients, which may lead to life threatening events or death.[2,3] To assist care givers in the early identification of deteriorating patients at the general ward, scores have been developed based on vital signs. These scores are called Early Warning Scores (EWS) and were first reported in 1997 by Morgan and associates.[4] The Modified Early Warning Score (MEWS) is an example of an EWS and is commonly used.[5-7] A higher MEWS is associated with a worse clinical condition of the patient and an increased number of ICU admissions and cardiac arrests.[8-10] A recent review shows that the predictive value of EWS is high and that use of EWS benefits patient outcome.[11] However, significant limitations of EWS are also reported. Vital signs underlying the scores are not regularly measured, documented or interpreted at the general ward, sometimes due to unfamiliarity with the locally used EWS system.[12-16] Also, routine measurement of vital signs is subjected to inaccuracy and incompleteness.[3,17,18] For example, respiratory rate, an important predictor of sepsis and mortality,[19,20] is often incorrectly measured and underestimated by nurses.[21] Furthermore, many nurses consider the measurements as time-consuming.[21] The intermittent and manual measurements of vital signs at the ward harbor serious safety risks.[22] Patients may deteriorate in between measurements which is unnoticed by nurses. This is particularly the case during night hours when they are less attended by nurses.[23] A delayed detection of deterioration leads to unplanned ICU admissions, which are associated with higher mortality ranging between 20% and 65%, a longer hospital stay,[24-26] and a 60% increase of hospitalization costs.[27] More frequent measurements such as intensified periodic and continuous monitoring may result in earlier detection of significant changes in vital signs, that can predict life threatening events.[28] This is why patients at high risk of deterioration are often admitted to higher care units with continuous monitoring of vital signs at admission or immediately after surgery.[29]

Increase in vulnerable groups for deterioration at wards

The median age of hospitalized patients increases due to an ageing population and more elderly patients are eligible for complex medical and surgical treatments.[30] Particularly the frail older patients may deteriorate more often, suffer from more complications and increased mortality associated with hospital admissions.[31] There is an increasing desire to monitor these patients more intensively regarding vital signs at the general ward, also because of limited high care capacity.[32, 33]

Continuous monitoring and prediction

Intensified periodic or continuous monitoring at the general ward may be useful to detect changes in patients' vital signs earlier in comparison with discontinuous assessment of an EWS. Combined with predictive analytics, early detection followed by early activation of a rapid response team (RRT) and early intervention[34] potentially leads to improved survival and a decrease in hospital length of stay.[35] There are more possible advantages of continuous and remote monitoring at the general ward. Nurses do not have to enter patients' room for vital sign measurements, which reduces workload. Less disturbances improves patient's comfort and sleep at night, and ultimately can enhance recovery.[36-38] Data transmission from the continuous monitoring device to the EHR can be automated, reducing human errors of reporting. Patients can have better insight in their own medical data, which supports patient participation and self-management in hospital care.[39]

Wearable devices for continuous monitoring

In contrast with high care units where most patients are monitored lying in bed, continuous monitoring of vital signs at the general ward should facilitate patient mobilization. In comparison with patients in high and medium care units, patients at the ward more often change posture in bed, sit in a chair or walk in or outside their room. These posture changes and mobilization demand specific requirements of the monitoring devices. Furthermore, devices have to transmit data wirelessly, contain non-invasive and unobtrusive sensors and preferably can be worn on clothes or placed directly on the skin of an easily accessible part of the body.[40]

Most wearable devices are initially developed by the life style industry for fitness and wellness and include smart watches, patches or tattoos.[41-43] Some devices are potentially suitable to be used in medical practice, particularly those that measure heart rate, respiratory rate, oxygen saturation, blood pressure and temperature.[43] However, devices have to meet several demands for safe and effective introduction in healthcare and have to be approved by regulatory authorities for medical devices. Devices have to be reliable and accurate in measuring vital signs in a broad range of normal and abnormal values. Important is the property to set individual thresholds of vital signs or scores for alarming.[40] Many investigators have already claimed reliability and accuracy, however, these are proven in healthy volunteers with a normal range of values. Furthermore, unbiased reporting is questionable since researchers are often involved in the

development of the device.[41] Devices should also be able to transmit medical data wireless and remotely to a place where care givers can have real-time insight in data. Preferably devices are connectable to the EHR system for frequent storage of (aggregated) vital sign data which connection needs to be secured for privacy reasons.[44] The device characteristics should comply with long-term and continuous measurement. Thus, devices need to be comfortable and hypo-allergenic, they should be small, flexible and wireless[40,44] and have sufficient battery life time.[36,44] Also, they should be water proof. A high user-friendliness of the wearable device will also allow for patients measuring themselves at home or in the hospital with or without remote supervision. When given the opportunity to easily collect vital signs at home after discharge from hospital, patients obtain more insight in their own health data,[45] which may lead to better health outcome or behavioral change in chronic diseases.[46-49] Even a reduced length of hospital stay and decreased costs are possible when patients continue using a wearable device for vital sign monitoring after discharge from hospital to home.[35,50]

A few wearable devices meet the requirements as described above.[34,41,51] However, routine use of these devices for (continuous) monitoring of vital signs in healthcare, specifically at the general ward, is still limited.[41] From a healthcare perspective there are several explanations for the limited use:

- Wearable device has not received approval from regulatory bodies as a medical device
- Wearable device misses important vital sign(s) deemed mandatory for use in patient care[40]
- Wearable device has not been tested in patients[43,52]
- Wearable device has not been adopted by patients and their informal and formal care givers e.g. nurses[52]
- Wearable device is very expensive and not expected to be (cost)effective[41]
- Wearable device use has not been embraced or funded by healthcare providers, insurance companies and policy makers
- Adequate software analyzing the data stream in order to reduce false alarming and predict clinical deterioration is lacking[40,41,44]

Wearable devices used in this thesis

ViSi Mobile

The ViSi Mobile (Sotera Wireless, CA, USA) system (Figure 1) has received CE mark and is FDA-cleared for continuously monitoring of 5-lead electrocardiogram, heart rate, blood oxygen saturation, respiratory rate, skin temperature, and blood pressure (cuff-based and cuff-less on beat-to-beat based). Patients can see their own vital signs, which are displayed on a patient-worn wrist device. ViSi Mobile is able to send all vital sign data to a stand-alone laptop or to a server from where care givers have real time insight in patients' data. The ViSi Mobile can be connected with a predictive analytic scoring system and data can be automatically stored in the EHR.

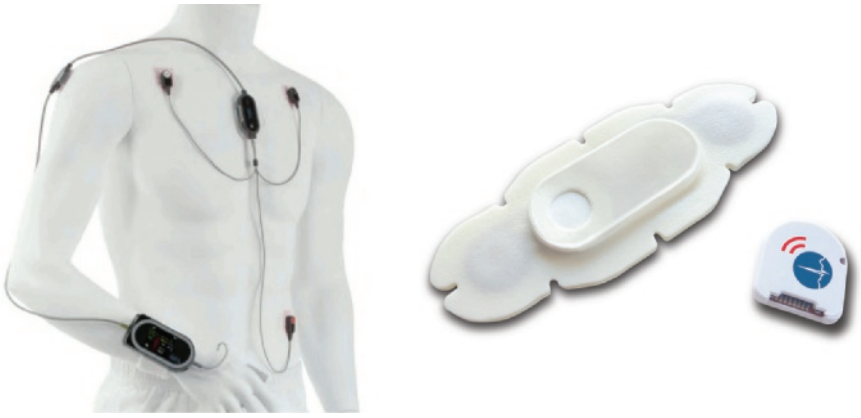

Figure 1 ViSi Mobile system (left) and HealthPatch (right)

HealthPatch

The HealthPatch (Vital Connect, CA, USA; Figure 1) is a flexible and self-adhesive patch containing two ECG electrodes, a battery and a reusable sensor. The HealthPatch has received CE mark and is FDA-cleared for continuous measurement of single-lead ECG, heart rate, respiratory rate, skin temperature, body posture, fall detection, and activity. Furthermore, the patch is able to measure heart rate variability which can be converted into a psychological stress percentage. Data can be transmitted to a secured cloud server from where patients and care givers have insight in the data e.g. smartphone via an app.

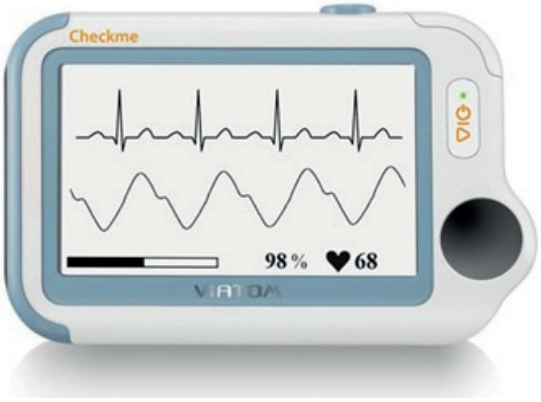

Figure 2 CheckMe

CheckMe

The CheckMe (Viatom Technology, Shenzhen, People's Republic of China; Figure 2) can be held between patients' hands and measures one or two lead ECG, body temperature, heart rate, oxygen saturation and systolic blood pressure in a cuff less manner based on pulse transit time. The device also includes a pedometer and a sleep monitor. Data can be transferred via Bluetooth to a mobile device using the CheckMe app.

Main objectives of this thesis

1. To evaluate the (technical) feasibility and accuracy of continuous monitoring using ViSi Mobile and HealthPatch at the internal medicine and surgical ward
   - Frequency, duration and cause of artifacts in monitoring data by ViSi Mobile and HealthPatch
   - Comparison of accuracy between regular nurse, ViSi Mobile and HealthPatch vital sign measurements
   - Alarming situations identified by ViSi Mobile and HealthPatch particularly during evening and nights shifts

2. To evaluate the using experiences of ViSi Mobile and HealthPatch by patients, relatives, nurses and physicians
   - Positive and negative effects of continuous monitoring at the general ward
   - Facilitators and barriers for the use of ViSi Mobile and HealthPatch at the general ward

3. To evaluate the accuracy of self-measurements by patients using the CheckMe in the outpatient clinic and at the internal medicine ward for chronic vascular disease e.g. hypertension.

Thesis outline

In **chapter 2** the initial experiences of continuous monitoring on the surgical and internal medicine ward using ViSi Mobile and HealthPatch are collected. In this pilot study the technical feasibility of continuous monitoring and the artifacts in data produced by ViSi Mobile and HealthPatch are evaluated and vital signs measured by both devices are compared with regular nurse measurements. Furthermore, first experiences of patients and nurses are documented.
Chapter 3 describes the user experiences of continuous monitoring using ViSi Mobile and HealthPatch by patients, relatives, nurses and physicians from a randomized controlled trial. Positive and negative effects, facilitators and barriers are extracted from in-depth semi-structured interviews, which are held on the surgical and internal medicine ward.
In **chapter 4** the accuracy of vital sign data by ViSi Mobile and HealthPatch is compared with regular nurse measurements, and alarming events based on ViSi Mobile or HealthPatch data

in time between nurse observations are evaluated. Also, the frequency, duration and cause of artifacts in data by both devices are studied in more detail.
The performance of the handheld device CheckMe regarding blood pressure measurement is evaluated in **chapter 5**. Blood pressure values of patients on the internal medicine outpatient clinic are measured with the CheckMe and data are compared with a validated, oscillometric reference blood pressure monitor. Influence of patients' posture on blood pressure is investigated.
Chapter 6 addresses the accuracy of the CheckMe on the internal medicine ward as blood pressure self-measurement tool. Self-measurements of patients are analyzed and compared with regular nurse measurements and measurements performed by a trained investigator.
In **chapter 7**, the HealthPatch is tested in a pilot study of health care providers regarding the usability of the stress sensor. Continuous stress measurements using heart rate variability and 'stress percentage' are performed during daily work and comparison is made between surgeons and residents and between different work activities.
Chapter 8 contains the general discussion and future perspectives, **chapter 9** the summary in English and **chapter 10** the summary in Dutch

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2.

Continuous monitoring of vital signs using wearable devices on the general ward: pilot study

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JMIR mHealth and uHealth 2017; 5 (7): e91

ABSTRACT

Background

Measurement of vital signs in hospitalized patients is necessary to assess the clinical situation of the patient. Early warning scores (EWS), such as the modified early warning score (MEWS), are generally calculated 3 times a day, but these may not capture early deterioration. A delay in diagnosing deterioration is associated with increased mortality. Continuous monitoring with wearable devices might detect clinical deterioration at an earlier stage, which allows clinicians to take corrective actions.

Objective

In this pilot study, the feasibility of continuous monitoring using the ViSi Mobile (VM; Sotera Wireless) and HealthPatch (HP; Vital Connect) was tested, and the experiences of patients and nurses were collected.

Methods

In this feasibility study, 20 patients at the internal medicine and surgical ward were monitored with VM and HP simultaneously for 2 to 3 days. Technical problems were analyzed. Vital sign measurements by nurses were taken as reference and compared with vital signs measured by both devices. Patient and nurse experiences were obtained by semistructured interviews.

Results

In total, 86 out of 120 MEWS measurements were used for the analysis. Vital sign measurements by VM and HP were generally consistent with nurse measurements. In 15% (N=13) and 27% (N=23) of the VM and HP cases respectively, clinically relevant differences in MEWS were found based on inconsistent respiratory rate registrations. Connection failure was recognized as a predominant VM artifact (70%). Over 50% of all HP artifacts had an unknown cause, were self-limiting, and never took longer than 1 hour. The majority of patients, relatives, and nurses were positive about VM and HP.

Conclusions

Both VM and HP are promising for continuously monitoring vital signs in hospitalized patients, if the frequency and duration of artifacts are reduced. The devices were well received and comfortable for most patients.

INTRODUCTION

In hospitalized patients, vital signs are measured to assess the clinical situation of the patient and to identify clinical deterioration.[1] Monitoring of these vital signs is usually done by nurses, and includes blood pressure (BP), heart rate (HR), respiratory rate (RR), blood oxygen saturation, and core temperature. Early warning scores (EWS) are physiological track-and-trigger systems, which use a multiparameter or aggregate weighted scoring system that assists in detecting physiological changes and thereby identify patients at risk for further deterioration.[2,3] The modified early warning score (MEWS) is a commonly used and validated EWS system (see Supplementary file 1).[4-6] A higher MEWS is associated with admissions to the intensive care unit (ICU), cardiac arrest, and mortality.[7-9] Since the introduction of EWS, a trend was seen toward a decrease in unplanned admissions to the ICU and a decrease in hospital mortality.[10-16] Although the EWS provides relevant data on patients' health status, the interval measurements may not capture early deterioration of vital signs,[17] particularly during the night when clinical deterioration may remain undetected until the next day.[18] This could explain why the majority of the unplanned ICU admissions take place between 8 am and 4 pm.[19] Unplanned ICU admissions are associated with an increased mortality rate, a longer hospital stay,[20-22] and a 60% increase in hospitalization costs.[23] Continuous monitoring of vital signs could be a useful tool to detect clinical deterioration in an earlier phase, which allows clinicians to take corrective interventions, particularly since subtle changes in vital signs often are present 8 to 24 hours before a life-threatening event such as ICU admission, cardiac arrest, and death.[13,24-27] Nowadays, wearable devices that facilitate remote continuous monitoring of vital signs exist.[28] These wireless devices could reduce patient discomfort due to fewer measurements by nurses,[29-31] allow patient mobility,[31] and might reduce workload for nurses.[30] Moreover, wearable devices are promising for safe patient transports between wards, the operating room, and the radiology department.[32] However, these devices are still underutilized in health care, even though they have been shown to be accurate,[17,33] and may reduce costs.[34] Despite many potential advantages, wearable devices may have disadvantages regarding technical dysfunction and adverse psychological effects increasing anxiety of patients for disturbances of vital signs.[33]

Recently, ViSi Mobile (VM; Sotera Wireless) and HealthPatch (HP; Vital Connect), two new devices approved by the US Food and Drug Administration (FDA) for wireless remote monitoring of vital signs, were introduced in health care. At present, little is known about the feasibility of continuous monitoring and experiences of patients and caregivers. The objective of this pilot study was to assess the technical feasibility of continuous monitoring with these new devices and to evaluate the experiences of patients and nurses with this method of monitoring on the general ward.

METHODS

Setting and Recruitment

Patients hospitalized in the internal medicine and surgical ward of the Radboud University Medical Center were included between December 2014 and March 2015. All consecutively admitted patients were approached for participation if they were hospitalized for at least 48 hours, and MEWS measurements were ordered at least three times a day by their medical doctor. Patients had to be 18 years or older and able to speak, read, and understand the local language. At the internal medicine ward, both VM and HP were attached to the patient after signed informed consent was obtained. At the surgical ward, patients signed informed consent before an elective surgical procedure. Both devices were attached to the patients after surgery and arrival at the ward. Patients were excluded from further analyses if they unexpectedly participated for a duration shorter than 24 hours in the study. To determine the technical feasibility and practical usability, the two wearable devices were used to continuously measure vital signs in patients, which were compared with regular data collected in the same patients. Since a formal power calculation was not feasible due to the lack of preliminary data with these monitoring systems, a sample size of 20 was estimated to obtain sufficient data for analysis. After reviewing the study protocol, the institutional review board waived the need for formal review and approval (number 2014-1434).

ViSi Mobile

The VM system has received Conformité Européenne (CE) mark and is FDA-cleared for continuously monitoring of 3- or 5-lead electrocardiogram (ECG), heart and pulse rate, blood oxygen saturation, RR, skin temperature, and BP (cuff-based and cuff-less on beat-to-beat basis; Figure 1). All vital signs are displayed on a patient-worn wrist device, which can be locked by an authentication code. This wrist device is connected to a thumb sensor, which measures blood oxygen saturation and BP. A chest sensor measures RR and skin temperature, and is connected with 3 or 5 ECG cables and sensors. In this pilot study, VM was wirelessly connected to a stand-alone Toughbook (Panasonic) pre-installed with VM software, from where the investigators received real-time insights on patients' vital signs and where all the data were stored. This Toughbook also showed alarms as soon as vital signs dropped out of normal ranges. The VM wrist device was powered by rechargeable batteries, which needed to be replaced every 12 to 14 hours.

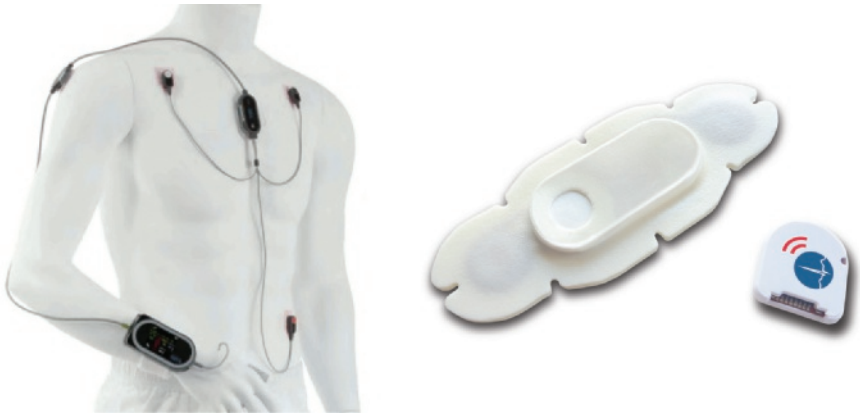

Figure 1 ViSi Mobile system (left) and HealthPatch (right).

HealthPatch

The HP consists of a reusable sensor and a disposable adhesive patch with 2 ECG electrodes at the bottom of the patch and a reusable sensor (see Figure 1). The HP has received CE mark and is FDA-cleared for continuous measurement of single-lead ECG, HR, heart rate variability (HRV), RR, skin temperature, body posture, fall detection, and activity. This small and lightweight patch can be attached to the patient's chest, from where the data is transmitted to a mobile device (eg, mobile phone, via Bluetooth). Wi-Fi connection facilitates data transmission from the mobile device to a secured cloud server. The patch is powered by a coin-cell battery that lasts 3 to 4 days.

Study Procedures

Patients gave verbal and written consent after being informed about the study protocol. Demographics including gender, age, reason for admission, and type of surgery were collected. At the surgical ward, VM and HP were attached to the patient after surgery and arrival at the ward. At the internal medicine ward, both devices were attached to the patient directly after signed informed consent was obtained. Vital signs were continuously measured during 2 or 3 days. This time frame was chosen to obtain enough vital sign data for analysis and to allow patients to get familiar with the devices. Nurses measured vital signs three times daily according to the protocol. Trained medical students additionally observed time-related vital signs monitored by VM at the Toughbook and HP on the cloud server. They marked the time points where vital signs were taken by the nurse and manually selected the results for vital signs measured by both devices at these time points for comparison. They also registered the cause and duration of technical problems and fixed them when necessary. In case of a VM alarm, the student warned the nurse. After 2 to 3 days, the enrolled patients and their relatives were interviewed about their experiences regarding continuous monitoring and both wearable devices. Nurses involved in the care of included patients were interviewed as well.

Data Collection and Analysis

Technical Feasibility

All registered data from VM and HP were retrieved for analysis in the Statistical Package for the Social Sciences version 20.0 (SPSS, Inc). Data of both devices were compared with measurements by nurses at the same time points. For each variable, the accepted discrepancy between nurse measurements and both devices was determined, which are listed in Table 1. These thresholds were defined as the maximum possible discrepancy in vital signs between the nurse measurements and both devices that would not lead to a change in medical treatment. A difference in MEWS score of 1 point or more between the nurse measurements and both devices was defined as a clinically relevant difference. The MEWS scores were calculated using vital signs measured by the nurses, VM, and HP. As VM and HP did not measure all required vital signs to calculate the MEWS score, such as level of consciousness, these vital signs were taken from the electronic health records (EHR). Bland-Altman plots[35] were created to assess the agreement between MEWS measurements by nurses and corresponding values of VM and HP. All artifacts ≥1 minute were analyzed, since we reasoned that artifacts of less than one minute would not be clinically relevant for a patient's situation. An artifact had occurred if no or an invalid value was recorded. Since trained medical students were not present all the time (primarily not during out-of-office hours), artifacts were divided into two groups, depending on the presence of a student.

Table 1 Accepted discrepancies between nurse measurements, ViSi Mobile, and HealthPatch

Vital sign	Accepted discrepancy
Heart rate	5 beats/min
Respiratory rate	2 breaths/min
Oxygen saturation	2%
Temperature[a]	0.5°C
Blood pressure	5 mm Hg
MEWS	1

[a]ViSi Mobile and HealthPatch measure skin temperature.

Practical Usability

User experiences were obtained by means of semistructured face-to-face interviews, after the patients had used the devices for 2 to 3 days. Patients' relatives and nurses were also interviewed. Interviews lasted approximately 10 minutes and the following topics were discussed: feelings of unsafety or safety, user friendliness, adverse events, and detection of clinical deterioration. One researcher (MW) performed a thematic content analysis to determine perceived positive and negative effects, and facilitators and barriers, which was critically reviewed by a second researcher (TB). Perceived positive and negative effects were presented according to the

Donabedian framework for the quality of health care,[36] which includes three main domains: structure, process, and outcome. Facilitators and barriers were divided into four domains: characteristics related to the patient, professional, intervention, and context.[37]

RESULTS

Demographics

A total of 25 patients were invited, of which 20 participated in the study—10 patients at the surgical ward and 10 patients at the internal medicine ward. The other 5 patients refused participation because they thought it would be too much of a mental or physical burden (see Figure 2). The study population included 13 males and 7 females with a mean age (standard deviation, SD) of 49.9 (13.4) years, ranging between 33 and 82 years. At the surgical ward, most patients were admitted for an elective gastrointestinal operation. Patients at the internal medicine ward were admitted for several conditions such as sepsis, arthritis, and blood pressure control.

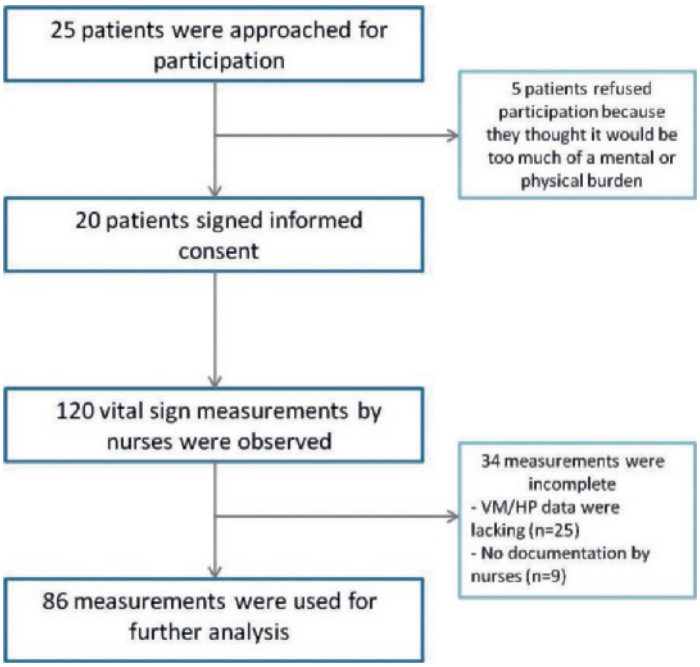

Figure 2 Included patients and vital sign measurements.

Table 2 ViSi Mobile and HealthPatch data in comparison with corresponding nurse measurements.

Vital signs	Nurse	ViSi Mobile		HealthPatch	
	Mean (SD)[j]	*Mean (SD)*	*Mean difference (SD) versus nurse*	*Mean (SD)*	*Mean difference (SD) versus nurse*
HR[f] (beats/min)	81.81 (13.12)	81.62 (12.23)	–0.20 (5.54)	84.34 (12.24)	–1.52[c] (5.63)
RR[g] (breaths/min)	17.38 (3.89)	16.20 (4.57)	1.19[a] (3.43)	18.02 (5.82)	–0.64 (4.94)
Saturation (%)	97.00 (96.00 to 98.00)[d]	97.00 (95.00 to 98.00)[d]	0.10 (1.65)	n.a.[k]	n.a.
Temperature (°C)	37.01 (0.60)	33.61(1.25)[e]		34.16 (1.16)[e]	
BP[h], systolic (mm Hg)	127.93 (19.33)	127.49 (18.68)	0.44 (11.99)	n.a.	n.a.
BP, diastolic (mm Hg)	73.17 (10.25)	81.17 (11.24)	–8.00[b] (9.93)	n.a.	n.a.
MEWS[i]	0.99 (1.13)	1.38 (1.30)	–0.40[a] (1.13)	1.59 (1.54)	–0.60[b] (1.22)

[a]*P*=.002. [b]*P*<.001. [c]*P*=.01. [d]Oxygen saturation was reported as median with interquartile range. [e]Skin temperature. [f]HR: heart rate. [g]RR: respiratory rate. [h]BP: blood pressure. [i]MEWS: modified early warning score. [j]SD: standard deviation. [k]n.a.: Not applicable.

Technical Feasibility

In total, 120 vital sign measurements by nurses were observed by the trained medical students (see Figure 2). In 40 measurements, one or more vital signs were missing. In 6 measurements, data were completed by consulting the EHR. As a result, 86 measurements were used for further analysis. For the remaining 34 measurements, VM and HP data were lacking (25 measurements), or vital signs were not documented by nurses (9 measurements). In 8 patients, data from the Toughbook was not available for further analysis due to accidental deletion of data; in 2 patients, no HP data were saved at the cloud server due to technical failures (eg, WiFi failures, disconnection between HP and its mobile device). In total, 742.8 hours of VM data and 1033.6 hours of HP data were collected; on an average 61.9 hours of VM and 57.5 hours of HP data were collected per patient.

Vital signs

Bland-Altman plots showing the mean of the two devices and the differences between the two devices (y-axis) with limits of agreement (1.96 SD) are displayed in Figures 3 and 4. Comparing the results for vital signs and MEWS score measured by nurses and VM, the mean differences were all within range with the predefined accepted discrepancies in Table 1, although wide limits of agreement were found (see Table 2). The largest discrepancy in the mean difference was found for diastolic BP. In 13 (15%) cases, the MEWS difference between nurse and VM was 2 points or higher, indicating important clinical differences between VM and nurse measurements (see Table 3). In four cases, this was related to differences in RR alone. In the remaining cases, the combination of RR and oxygen saturation, or RR and systolic BP caused the difference. Moreover, in six of these cases, VM measured a higher RR than nurses

(range: 1-6 breaths/min), and in the four other cases, nurses measured a higher RR than VM (difference: 2-6 breaths/min). In the three remaining cases that resulted in a different MEWS, there was a difference in systolic BP (difference: 14 mm Hg) or oxygen saturation (difference: 1%-5%) between VM and the nurse. The mean differences between nurse measurement and HP were all in agreement with accepted discrepancies, although wide limits of agreement were found (see Table 2). In 23 (27%) cases, MEWS differed 2 or 3 points between HP and nurse measurements (see Table 3). In 17 cases, HP measured higher RR compared with nurses. In 16 cases, differences were in the range of 3 to 8 breaths/minute. However, in one case, nurses measured 16 breaths/minute and HP measured 42 breaths/minute, indicating possible measurement errors in HP. In the remaining six cases, nurses measured a higher RR than HP (difference: 4-12 breaths/min).

Artifacts

ViSi Mobile

In total, 306 artifacts were found, with a total time of 121 hours. In 111 (36.3%) of 306 artifacts, a trained medical student was present, and 86 of 111 (77.5%) were identified and reported. A cause was found in 82 (95.1%) of 86 artifacts. Almost 70% of all reported artifacts were caused by connection failure between Toughbook and VM. Other artifact causes were motion of the sensors due to patient movements (n=21, 25.6%) and required calibration of blood pressure (n=2, 2.3%). Over 74% of all artifacts lasted less than 5 minutes. Almost 20% lasted less than 1 hour, and approximately 7% lasted longer than 1 hour.

HealthPatch

In total, 648 artifacts were found in 18 patients, with a total time of 135 hours. More than 50% (n=354) of all artifacts lasted less than 1 minute and were excluded from further analysis. In the remaining 294 artifacts, a trained medical student was present in 60% (n=176) of the artifacts, and identified and reported the artifact in 53 (30%) cases. A cause was found in 24 (45%) artifacts such as HealthPatch losing skin contact (n=13, 54%), Bluetooth (n=4, 17%) or Wi-Fi problems (n=3, 13%), and patients leaving the ward without their mobile device (n=3, 13%). Around 43% of all artifacts lasted less than 5 minutes. Over 95% of all artifacts lasted less than 1 hour.

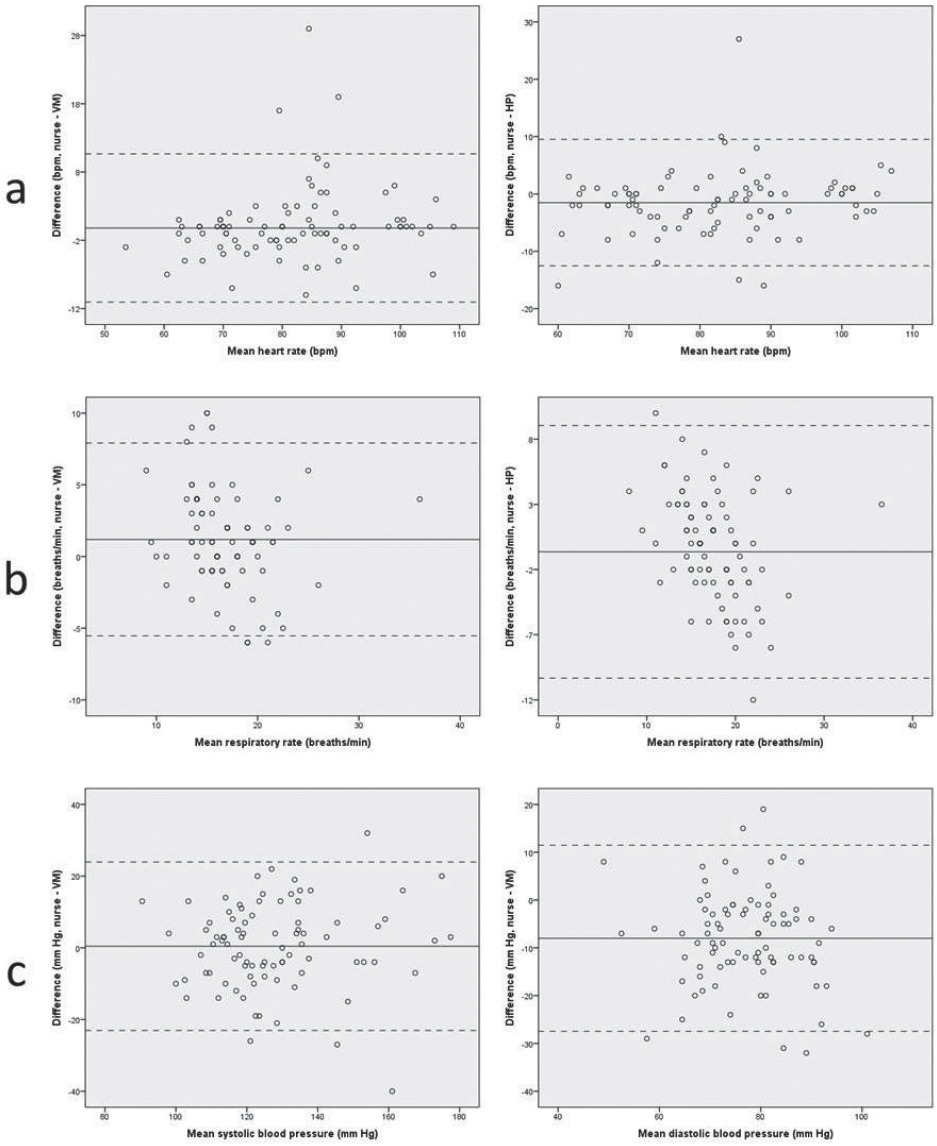

Figure 3 Bland-Altman plots: (a) heart rate (VM and HP), (b) respiratory rate (VM and HP), (c) systolic and diastolic blood pressure (VM). Solid lines indicate mean difference and dotted lines indicate limits of agreement.

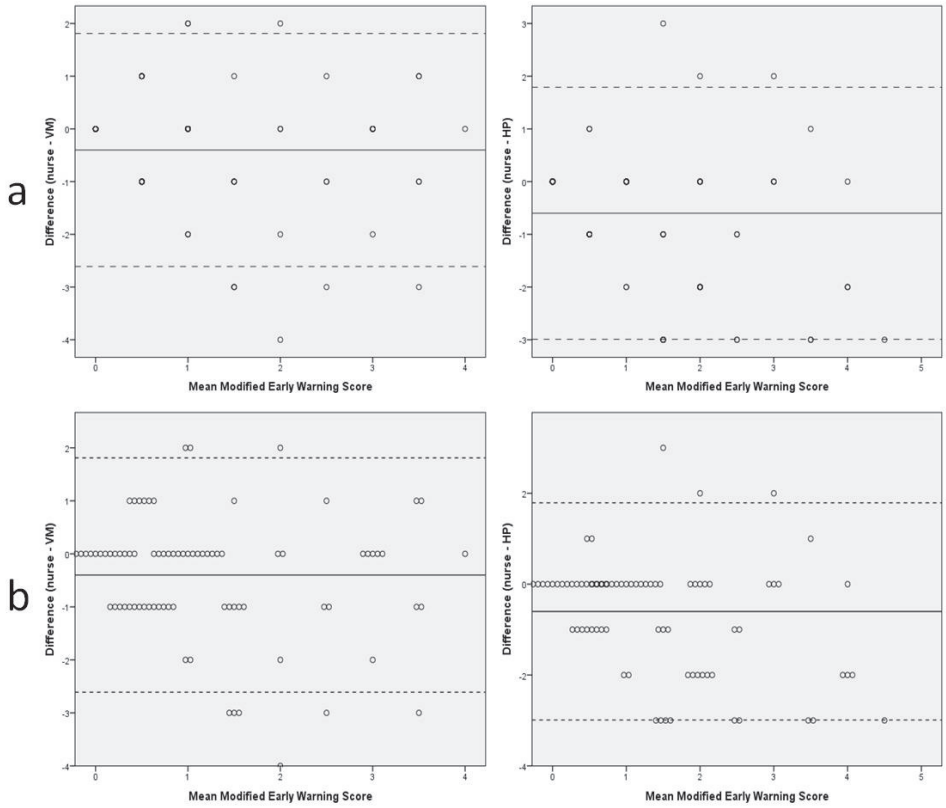

Figure 4 Bland-Altman plots showing modified early warning score: (a) VM and HP, (b) VM and HP (jittered). Solid lines indicate mean difference and dotted lines indicate limits of agreement.

Table 3 ViSi Mobile and HealthPatch data in comparison with corresponding nurse measurements.

	ViSi Mobile	**HealthPatch**
	Difference; nurse – VM (%)	*Difference; nurse - HP (%)*
HR[a] (beats/min)	≤ 5: 71 (82.5)	≤ 5: 65 (75.6)
	6-10: 12 (14.0)	6-10: 16 (18.6)
	> 10: 3 (3.5)	> 10: 5 (5.8)
RR[b] (breaths/min)	≤ 2: 50 (58.2)	≤ 2: 36 (41.9)
	3-5: 26 (30.2)	3-5: 31 (36.0)
	> 5: 10 (11.6)	> 5: 19 (22.1)
Saturation (%)	≤ 2: 76 (88.4)	n.a.[e]
	3-4: 9 (10.5)	
	≥ 5: 1 (1.1)	
BP[c] systolic (mm Hg)	≤ 5: 36 (41.9)	n.a.
	6-14: 33 (38.4)	
	≥ 15: 17 (19.7)	
BP[c] diastolic (mm Hg)	≤ 5: 27 (31.4)	n.a.
	6-14: 40 (46.5)	
	15: 19 (22.1)	
MEWS[d]	-4: 1 (1.2)	-3: 9 (10.5)
	-3: 5 (5.8)	-2: 11 (12.8)
	-2: 4 (4.7)	-1: 13 (15.1)
	-1: 23 (26.7)	0: 47 (54.7)
	0: 40 (46.5)	1: 3 (3.5)
	1: 10 (11.6)	2: 2 (2.3)
	2: 3 (3.5)	3: 1 (1.2)

[a]HR: heart rate. [b]RR: respiratory rate. [c]BP: blood pressure. [d]MEWS: modified early warning score. [e]n.a.: Not applicable.

Practical Usability

Evaluations were performed with all 20 patients, 7 relatives, and 4 nurses (see Table 4).

Perceived Positive and Negative Effects

Processes

One positive effect was identified in this dimension. Patients stated that nurses could keep an eye on the vital signs from a distance (n=3); this was also mentioned by one relative. No negative effects were identified.

Outcomes

Two positive effects were identified in this dimension. Eight patients and 66 relatives mentioned increased feelings of safety by being monitored continuously in comparison with the MEWS measurements by nurses only. A patient described:

Being monitored continuously is a very pleasant experience; I felt very safe.
(Translated from Dutch)

Earlier interventions were deemed possible in case of clinical deterioration (n=3). One negative effect was identified; one patient complained about having redness and itching while wearing the devices.

Facilitators and Barriers

Intervention

Seven facilitators were identified. Eight patients said they were not aware of the HP while it was attached to their chest. Other facilitators included not being restricted by the devices during daily activities such as bathing and putting on clothes (n=3), more freedom of movements compared with conventional devices (n=2), the small size of the HP (n=1), the good adhesive properties of the patches (n=1), and the invisibility of the devices under clothes (n=1). One patient described:

I have used a holter monitor at home several times. These devices are much smaller and they do not limit mobility to the same extent.
(Translated from Dutch)

One patient experienced great advantage of having an insight on his own vital signs. One barrier was noted 15 times. Patients mentioned that the VM wrist device was big or heavy (n=10); patches came off very quick (6 VM; 2 HP); VM had many cables (n=4); and VM had a short battery life (n=2).

Professional

Two facilitators and one barrier were identified in this domain. Two nurses stated that the patches did not lose skin contact while washing the patient, and one nurse said that it was very easy to attach the devices to the patient. One nurse mentioned that Wi-Fi connection was poor between Toughbook and the VM device.

Additional Findings

During the study, clinical deterioration was detected with the VM in one patient 3 days postoperatively after elective colorectal surgery. The device alerted the nurse who cared for the patient because he developed a tachycardia and tachypnea. This situation occurred between two regular measurements. He underwent relaparotomy after an anastomotic leak was confirmed by computer tomography.

Table 4 Users' experiences

	Nurse	Patient	Relatives
Perceived positive and negative effects			
Processes[a]			
- Nurse could keep eye on vital signs more easily		+	+
Outcomes			
- Feelings of safety		+	+
- Earlier interventions		+	
- Adverse events (redness and itching)		-	
Barriers and facilitators			
Intervention			
- Not aware of HP[b]		+	
- Small size of HP		+	
- Good adhesive properties		+	
- Not being restricted during daily activities		+	
- More freedom of movements		+	
- Invisibility under clothes		+	
- Better insight in own vital signs		+	
- VM[c] wrist device too big/heavy		-	
- Patches came of very quickly		-	
- VM has too many cables		-	
- Short VM battery life		-	
Professional			
- Good adhesive properties	+		
- Very easy to attach the devices	+		
- Bad Wi-Fi connection VM and Toughbook	-		

[a]No positive or negative effects in the "Structure" or "Context" fields were found. [b]HP: HealthPatch.
[c]VM: ViSi Mobile

DISCUSSION

Principal Findings

This study describes a unique approach in which we continuously measured vital signs on the ward using two recently released wireless devices. In general, data obtained by these devices correlated well with predefined accepted discrepancies and MEWS calculated on the basis of these devices correlated to a larger extent. Patients and nurses were mainly positive about the two devices. Both VM and HP are promising devices for continuous patient monitoring on the general ward. However, the number of artifacts should be reduced and the barriers mentioned by the users could be addressed to further improve both devices.

Vital Signs

The largest discrepancy in mean difference was found in VM diastolic blood pressure, which is unlikely to be directly clinically meaningful since it is not a component of the MEWS. Additionally, clinical decisions are mainly based on systolic blood pressure and other vital signs. Wide limits of agreement were found for almost all vital signs and MEWS. Although more than 70% of all MEWS differed 0 or only 1 point between devices and nurse measurements, larger differences in MEWS were found in a few cases, which may have important clinical consequences (eg, additional diagnostic procedures or change in treatment). In most of these cases, VM and HP measured a higher RR when nurses did not. Although most differences between nurse and device measurements were small (<5 breaths/min), in one case, difference between nurse and HP measurements was large (26 breaths/min). These findings are important as abnormal RR has been shown to be an important predictor of cardiac arrest[38] and an indicator of sepsis, pneumonia and respiratory depression;[39] therefore, it could under- or overestimate a clinical condition of a patient. Inaccurate RR measurements by nurses could explain the discrepancy. Direct measurement of RR is usually done by visually observing chest movement or by manual observations. Reproducibility may be limited by significant interobserver variability.[40] Conversely, ECG-derived RR measurements by HP and VM may be inaccurate. In case of HP, RR is estimated by ECG using the respiratory sinus arrhythmia method, which derives RR from HRV. Since this method has some limitations, an accelerometer was added to measure RR more accurately.[41] In VM, RR is derived from impedance pneumography, measuring respiratory volume and rate through the relationship between respiratory depth and thoracic impedance rate.[42] ECG-derived RR may not be accurate when there is excessive patient motion or during lower respiratory rates.[43,44] More research is required to gain a deeper insight in the different methods of measuring RR by devices and nurses.

Artifacts

Most reported VM artifacts concerned connectivity failure between VM and Toughbook. This was caused by a restricted Wi-Fi connection of approximately 15 meters between VM and

Toughbook, which explains why more artifacts were found in mobile patients. These artifacts were not deemed relevant since more stable Wi-Fi connections, such as by using multiple access points and 5 GHz networks, would be used to implement VM in a hospital setting. This would also facilitate continuous monitoring during patient transport between different wards. However, it is important to consider that a wireless connection can always fail, thus proper backup power and Internet connections are always demanded. Most HP artifacts were of unknown cause. However, most artifacts lasted less than one hour and were self-limiting.
Although HP could not measure all vital signs that are currently used to monitor patients and to calculate the MEWS, it may still provide more patient data than interval measurements by nurses, resulting in a more continuous dataflow and more specific trends. This may be of significance, in particular, since literature shows important lack of documentation of vital signs before a life-threatening event.[27] Besides that, several studies show that HR and RR change significantly before ICU transfer, cardiac arrest, and mortality and therefore, HP can have a valuable contribution to the prediction of life-threatening events.[24,27]

Practical Usability

The majority of patients, relatives, and nurses were positive about VM and HP. Whereas HP is able to administer vital signs in real time to patient's mobile phone, VM shows vital signs in real time on the wrist device; these devices could therefore increase insight on patient's health status and potentially influence their behaviors.[45,46] Although patients mentioned that the VM wrist device was heavy and VM consisted of many cables, they were not restricted during daily activities or mobility. This is important as hospitalized patients benefit from mobility, resulting in increased recovery and reduced risk of complications.[47,48] Another benefit of VM and HP is that nurses are able to see patients' vital signs from a distance. A review by Ulrich et al[49] has shown that sleep deprivation in patients is a common problem that is associated with hindrance of the healing process and an increase in morbidity and mortality. Using VM and HP, patients could continue sleeping during the night and did not have to be disturbed by vital sign measurements.
Possible negative aspects of continuous monitoring should also be taken into consideration. Wearable devices generate a large quantity of data each day. The workload of nurses and physicians withholds them from inspecting all these data, which means that the predictive value of continuous monitoring is lost.[17] Validated devices are available to process all these data and to send an alert when patient's vital signs drop out of normal ranges. A large number of alerts and even false-positive alerts could cause alarm-fatigue in nurses.[17,50] Algorithms using machine learning could be utilized to reduce false-positive alarms.[51-53] The VM battery has a battery life of 12 to 14 hours, which means that nurses have to change batteries twice a day. This might outweigh the fact that nurses no longer need to perform the standard MEWS measurements three times a day.

Comparison With Prior Work

A few studies about continuous monitoring at the general ward have been published. A wireless sensor was successfully used in pregnant women in an inpatient obstetric unit, which was able to monitor HR, RR, and temperature.[30] Recently, the SensiumVitals digital patch was tested in hospitalized patients.[54] This patch is able to measure HR and RR and was compared with a commonly used clinical monitor. A satisfactory agreement, comparable with the result in our study, was shown. The drawback of the study design was that the patients were monitored for only 2 hours, which prevented the authors from detecting trends in vital signs and lowered predictive value. The use of an implantable device for continuous monitoring has been described in the ambulatory setting. Abraham et al[55] described the use of a wireless implantable hemodynamic monitoring system in heart failure patients, which has shown to reduce hospitalization. Wireless technology systems in which patients measure vital signs at home have been described, such as for patients with chronic obstructive pulmonary disease,[56] patients with hypertension,[57] and patients with diabetes mellitus.[58,59] These systems were often well received by patients and health care providers, showing improvement of blood values such as glucose,[58,60] patients' disease management,[56,61] and better connection between the patient and the health care provider.[59] Particularly, the HP might be suitable for home monitoring, although its current version lacks the possibility to measure all vital signs. Though VM measures all vital signs, its size and cables might demand much from patients to enable monitoring at home.

Strength and Limitations

An important strength of the study is that we were able to monitor patients in a clinical setting instead of healthy participants in controlled settings. The study had a small sample size, and we missed some VM and HP data, particularly since VM data of 8 patients were automatically deleted from the Toughbook and could not be used for artifact analysis. This was due to wrong Toughbook settings and was changed with support from the manufacturer. The VM vital signs observed by students were used for the comparison with nurse measurements, and we were therefore able to draw conclusions about the feasibility of both VM and HP. However, data saturation in patient, nurse, and relative interviews may not have been reached. Selection bias could have occurred as not all patients who were approached did agree to participate. A further limitation of VM and HP is that both devices measure skin temperature instead of body temperature. Although it is not yet clear whether or not all vital signs are necessary for proper clinical judgment of ill patients, an algorithm should be developed to convert skin temperature into body temperature.

Conclusions

The VM and HP are promising devices for wireless continuous patient monitoring in the hospital and were very well received by both patients and nurses. The frequency and duration of artifacts

should be reduced and the barriers mentioned could be addressed to further improve VM and HP. An ongoing follow-up study focuses on the different effects of VM or HP compared with routine MEWS measurements on patient comfort and safety and nurse workload, and on early detection of deterioration. Future studies should focus on the effect of continuous monitoring on clinical outcome.

SUPLEMENTAL MATERIAL

Supplementary File 1 Modified Early Warning Score.

Score	3	2	1	0	1	2	3
Oxygen administration				Room air	< 5L O_2/min	< 10L O_2/min	
Oxygen saturation, %	≤ 91	92-93	94-95	≥ 95			
Respiratory rate, breaths/min	≤ 8		9-11	12-20		21-24	≥ 25
Heart frequency, beats/min	≤ 40		41-50	51-90	91-110	111-130	≥ 130
Systolic blood pressure, mm Hg	≤ 90	91-100	101-110	111-219			
Consciousness				A		Delirium	V/P/U
Core temperature, °C	≤ 35.0		35.1-36.0	36.1-38.0	38.1-39.0	≥ 39.1	

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3.

Continuous monitoring of vital signs at the general ward using wearable devices: patients' and healthcare professionals' view

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ABSTRACT

Background

Wearable devices are eligible for continuous patient monitoring at the general ward, increasing patient safety. Little is known about experiences and expectations of patients and health care professionals regarding continuous monitoring with these devices.

Objective

We sought to identify positive and negative effects, and barriers and facilitators for use of two wearable devices: ViSi Mobile (VM; Sotera Wireless) and HealthPatch (HP; Vital Connect).

Methods

In this randomized controlled trial study, 90 patients admitted to the internal medicine and surgical wards of a university hospital in the Netherlands were randomly assigned to continuous vital sign monitoring using VM or HP, and a control group. User experiences and expectations were addressed using semi-structured interviews. Nurses, physician assistants and medical doctors were interviewed as well. Interviews were analyzed using thematic content analysis. Psychological distress was assessed using State Trait Anxiety Inventory (STAI) and Pain Catastrophizing Scale (PCS). The System Usability Scale (SUS) was used to assess the usability of both devices.

Results

Sixty patients, 20 nurses, 3 physician assistants, and 6 medical doctors were interviewed. We identified 47 positive and 30 negative effects, and 19 facilitators and 36 barriers for the use of VM and HP. Most mentioned topics regarded earlier identification of clinical deterioration, increased feelings of safety, and VM lines and electrodes. No differences related to psychological distress and usability were found between randomization groups or devices.

Conclusions

Both devices were well received by most patients and healthcare professionals and the majority encouraged the idea of monitoring vital signs continuously at the general ward. This comprehensive overview of barriers and facilitators of using wireless devices may serve as a guide for future researchers, developers and healthcare institutions that consider implementing continuous monitoring at the ward.

INTRODUCTION

Today's technology is increasingly influencing healthcare.[1] Numerous wearable devices such as patches, smart watches and even tattoos exist that can register vital signs such as heart rate (HR), respiratory rate, oxygen saturation (SpO_2), and blood pressure (BP).[2-5] These devices are becoming more accurate and reliable,[2,6] and are smaller and more user friendly than current hospital monitoring devices which may facilitate patients' mobility and recovery during admission.[7,8] Additionally the devices can improve health outcomes such as hypertension and can be used as diagnostic tool in the identification of several diseases or clinical deterioration during admission.[2,9-11]

Vital signs of patients at general wards are usually monitored periodically by nurses, primarily during daytime.[12] Clinical deterioration in between two measuring moments may not always be detected and can result in unplanned admission to the intensive care unit (ICU) which is associated with longer hospital stay, increased mortality rate[13-15] and higher costs.[16] Particularly during the night, when less medical personnel is available and clinical deterioration may remain undetected until the next morning.[17] Wearable devices have the opportunity to monitor patients more frequently or continuously in order to provide additional information during the periods in which patients are not being seen by nurses.[4] By implementing continuous monitoring, clinical deterioration can be detected in an earlier phase, particularly since changes in vital signs are often present 8-24 hours before a life threatening event occurs.[18-22] Additional benefits of wearable device-based continuous monitoring are a reduced work load in nurses,[23] improved patient comfort due to fewer vital sign measurements[8,24] and safe patient transport between wards.[25] Besides positive effects of wearable devices, continuous monitoring can lead to false alarms, resulting in unnecessary additional diagnostic procedures and possible alarm-fatigue in healthcare professionals.[26,27]

Recently, ViSi Mobile Mobile (VM) and the HealthPatch (HP) entered hospital care. These two wearable devices are FDA approved for continuous vital sign monitoring and have shown to be as accurate as nurse measurements in admitted patients.[6] Several studies describing the opportunities of wearable devices, such as VM and HP have been published focused on the accuracy of data.[11] However, in order to be used for long term monitoring in hospitals, devices should be comfortable and user-friendly for both patients and healthcare professionals. Besides, they should be willing to use them and see the benefit of these wearable devices and of being monitored continuously. A complete overview of experiences and expectations of patients regarding continuous monitoring with wearable devices is lacking. This study aims to identify experiences of patients, nurses, physician assistants and medical doctors about the use of VM and HP in daily practice for continuous monitoring of vital signs at the general ward.

METHODS

Setting, participants and sampling

This randomized controlled trial was conducted in an university hospital between April 2015 and August 2016. The target population consisted of hospitalized patients, nurses, physician assistants, and medical doctors at the internal medicine and surgical ward and medical doctors from the intensive care unit. All consecutively admitted patients were invited to participate if they had to be hospitalized for at least three days. Surgical patients were included when they were scheduled for an elective abdominal surgical procedure. Patients were excluded and replaced when they were monitored less than 24 hours. A sample size of 90 patients (45 surgical and 45 internal medicine patients) was estimated to be sufficient to obtain data saturation based on our pilot study.[6] Patients' relatives were involved if they attended the interview. We aimed to interview all nurses, physician assistants and medical doctors who were involved in the care for included patients to obtain a complete overview of user experiences and expectations. The institutional review board decided that formal approval was not required after they reviewed the study protocol extensively (local CMO number 2015-1717). The study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

Wearable devices

VM (Sotera Wireless, CA, USA) is a patient monitoring system developed to enhance patient safety and early detection of clinical deterioration at a general ward. VM continuously measures five-lead ECG, HR, respiratory rate, SpO_2, BP and skin temperature. It transmits all data wireless to a platform with Sotera's analytic software such as desktop PCs or tablet PCs from where healthcare professionals have real time insight in patients' vital sign data. VM consists of a wrist device with touch screen display that shows vital signs, a thumb sensor that measures SpO_2 and BP. Five ECG cables are attached to the patient's chest, as well as a chest sensor that measures skin temperature and respiratory rate. The battery in the wrist device has to be changed every 12-16 hours.

The HP (Vital Connect, CA, USA) is a small and lightweight disposable adhesive patch that consists of two ECG electrodes and a reusable module, which contains a sensors and a Bluetooth transmitter. It contains a battery that has a wear cycle of approximately 3-4 days. The patch continuously measures one-lead ECG, HR, respiratory rate, heart rate variability (HRV), skin temperature, steps, and body posture.[28] The patch is attached to the patient's chest, from where it sends data via Bluetooth to a mobile device where patients can see their own vital signs. Data is transmitted to a secured Vital Connect cloud on the Internet via Wi-Fi.

Study procedures and data collection

Patients at the surgical and internal medicine ward provided written informed consent after being informed about the study protocol. All interviewed nurses, physician assistants and

medical doctors also signed informed consent. Patients were randomly assigned to 1) VM, 2) HP or 3) control group (no device) (1:1:1). This was done to equalize individual factors between groups and minimize bias. The control group only received the regular nurse measurements. They were interviewed about their current experiences and their expectations of continuous monitoring, without being influenced by wearing a device. At the internal medicine ward, patients were randomized immediately after signing informed consent. Surgical patients signed informed consent prior to an elective surgical procedure and were randomized after surgery on arrival at the ward. Vital signs were continuously measured for 2-3 days in the VM and HP group. Regular vital sign measurements three times a day by nurses continued according to the hospital protocol in all patients. To determine psychological distress, all patients completed the short version of the State Trait Anxiety Inventory (STAI)[29,30] at baseline, and on each day of the study period. On day 3, they completed the Pain Catastrophizing Scale (PCS), which provided a valid index about the extent to which people catastrophize.[31] STAI and PCS scores were compared between randomization groups since psychological distress can be a confounding factor. Furthermore, this allowed us to assess whether the devices affected psychological distress. Additionally, nurses who took care for participating patients and who were involved in e.g. attachment of the devices and changing batteries, completed the System Usability Scale (SUS),[32] which is a reliable tool for assessing usability. At the end of the study, patients and their relatives were interviewed face-to-face for approximately 45 minutes by one trained investigator. Nurses, physician assistants and medical doctors who were involved in the care for included patients were interviewed as well. For each semi-structured interview, an interview guide was used that consisted of predetermined themes based on the model for implementation of Grol and Wensing[33] enriched with findings of a recent pilot study about monitoring with similar wearable devices.[6] Themes concerned attitude towards continuous monitoring and the wearable devices, experiences with both wearables in clinical practice, future expectations of the devices, and perception on changes in clinical care using the devices. Questions focused on e.g. feelings of safety, user experiences with the devices, expected effect of continuous monitoring on patient safety and quality of care, and effect on nurse-patient interaction. The interview guide is available on request. The interviews were done by two researchers with a (bio)medical background, trained in interviewing.

Analysis

All interviews were audio-recorded and transcribed verbatim. Subsequently, two researchers (MW, TB) individually performed a thematic content analysis to determine facilitators and barriers, and positive and negative effects.[34,35] The researchers discussed the results until consensus was reached. The Donabedian framework for the quality of healthcare was used to present all positive and negative effects.[36] This framework distinguishes structure (context in which the care is delivered), process (all actions that make up health care), and outcome (all effects on patients' health). Facilitators and barriers were categorized according to an existing

framework concerning determinants of adoption of mobile health.[37,38] New determinants regarding use of VM and HP were added to the framework. Interviews were analyzed during the study and saturation was assessed using histograms, in which all new factors per interview were presented. Quotes and striking issues were documented as well. Once data saturation was reached, no further interviews were analyzed since it was expected that no new factors would be identified. STAI, PCS and SUS scores were analyzed using SPSS package version 20.0 (SPSS, Inc, Chicago, IL). STAI scores ranged from 6 to 24 and a higher score indicated more psychological distress. SUS scores ranged from 0-100 and a score above 68 was considered above average.[32]

Descriptive statistics were presented as mean with standard deviation (SD). Statistical significance between patient groups regarding demographics and PCS was calculated using the ANOVA or Pearson's chi-square test. ANOVA for repeated measures was used to assess differences in STAI score between days and randomization groups. An independent-samples T-test was used to calculate difference between HP and VM regarding SUS. STAI and SUS results were not correlated with the interview results. A p-value less than 0.05 was considered significant.

RESULTS

Demographics

165 patients were invited to participate, 89 patients at the surgical ward and 76 patients at the internal medicine ward. At each ward, 58 patients signed informed consent, 45 eventually participated in the study. Reasons for refusal were expectation of large mental (N=37) or physical burden (N=10) and expected discharge within 24 hours (N=2). At the surgical ward, 13 patients were excluded due to rescheduling of the surgery (N=5), withdrawal of informed consent (N=4), early death (N=2), prolonged ICU stay (N=1) and a delirium (N=1). Reasons to exclude patients at the internal medicine ward were monitoring shorter than 24 hours due to unexpected discharge (N=11) or physical burden by VM (N=2). No differences were found between randomization groups regarding age (p=0.740) and gender (p=0.549). Demographics are shown in Table 1. Relatives of 6 patients attended the interview. Six medical doctors (2 surgeons, 2 internists, 2 intensivists), 3 physicians assistants and 20 nurses were interviewed.

Questionnaires

Psychological distress

No significant effect between the three randomization groups was found on STAI score (p=0.330) and no significant within-subject effect was found in STAI score between days (p=0.780) (Table 2). Data of surgical and internal medicine patients were calculated separately; no significant effect between the randomization groups was found on STAI score (p=0.859 and p=0.170

respectively). No significant differences were found between the three randomization groups regarding PCS (p=0.573) (Table 2).

Table 1 Patient demographics.

	ViSi Mobile (n=30)	HealthPatch (n=30)	Control group (n=30)
Gender			
- Male (%)	18 (60.0)	22 (73.3)	20 (66.7)
- Female (%)	12 (40.0)	8 (26.7)	10 (33.3)
Age	63	56	62
(median, min-max)	(26-76)	(27-88)	(34-77)
measurement period (days)			
participated in study	3 (1-4)	3 (1-5)	3 (2-3)
(median, min-max)			
Reason for admission (%)			
- Colorectal disease	8 (26.7)	8 (26.7)	5 (16.7)
- Malignant	7	8	5
- Benign	1		
- Hepatobiliary disease	5 (16.7)	5 (16.7)	5 (16.7)
- Malignant	5	2	5
- Benign		3	
- Upper gastrointestinal disease			2 (6.7)
- Malignant			2
- Neuroendocrine tumors		1 (3.3)	2 (6.7)
- Malignant		1	2
- Herniation	1 (3.3)	1 (3.3)	1 (3.3)
- Hematological diseases		1 (3.3)	2 (6.6)
- Autoimmune diseases	4 (13.3)	2 (6.7)	
- Infectious diseases	3 (10.0)	7 (23.3)	6 (20.0)
- Other	9 (30.0)	5 (16.7)	7 (23.3)

Usability

The SUS was filled in by six nurses (3 internal medicine and 3 surgical nurses), one for each device. Both devices scored above average, indicating good usability. No significant difference was found between VM and HP (mean (SD) 77.9 (18.5) and 82.5 (18.6) respectively; p=0.678).

Table 2 State Trait Anxiety Inventory and Pain Catastrophizing Scale.

	STAI[c] baseline	STAI +1	STAI +2	STAI +3	PCS[d]
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*
VM[a]	11.8 (2.7)	11.3 (2.9)	10.6 (2.6)	10.6 (3.0)	14.2 (11.2)
HP[b]	11.4 (2.7)	11.2 (2.8)	11.5 (2.8)	11.2 (3.3)	15.7 (11.6)
Control	11.0 (3.1)	11.1 (3.1)	11.2 (3.3)	11.7 (3.5)	17.4 (10.9)

[a]VM, ViSi Mobile; [b]HP, HealthPatch; [c]STAI, State Trait Anxiety Inventory; [d]PCS, Pain Catastrophizing Scale.

Interview data

Data saturation occurred after 60 patients were interviewed (19 VM group, 21 HP group, 20 control group), indicating that it was considered unlikely that new factors would be identified in additional interviews (Figure 1). All interviews of healthcare professionals were analyzed. A total of 33 unique positive effects by patients and 56 positive effects by healthcare professionals, and 14 negative effects by patients and 31 negative effects by healthcare professionals were identified. Patients reported 13 facilitators and 22 barriers and healthcare professionals reported 13 facilitators and 36 barriers.

Positive effects

In the structure, process and outcome domains, 1, 23 and 23 positive effects were identified respectively (Supplementary file 1) by patients, their relatives and healthcare professionals. Six patients and two nurses mentioned alarms as positive effect of continuous monitoring using wearable devices. A nurse stated:

> *"We should all receive a mini-Ipad. It can show us patients' vital signs during our shift and will send us an alert in case the vital signs drop outside the normal ranges."* [Nurse ID 4]

Seventeen patients, two relatives and 17 healthcare professionals expected to be able to detect clinical deterioration in an earlier phase using continuous monitoring. Five patients, three nurses and one medical doctor mentioned that earlier detection can result in earlier interventions. Six patients, one relative and five nurses thought that the implementation of continuous monitoring can lead to less patient disturbances. Seven patients and 11 healthcare professionals thought that continuous monitoring can save time. We asked all nurses how to spend the saved time. A nurse mentioned:

> *"Just talking to the patient. To have more time for the story of the patient."* [Nurse ID 7]

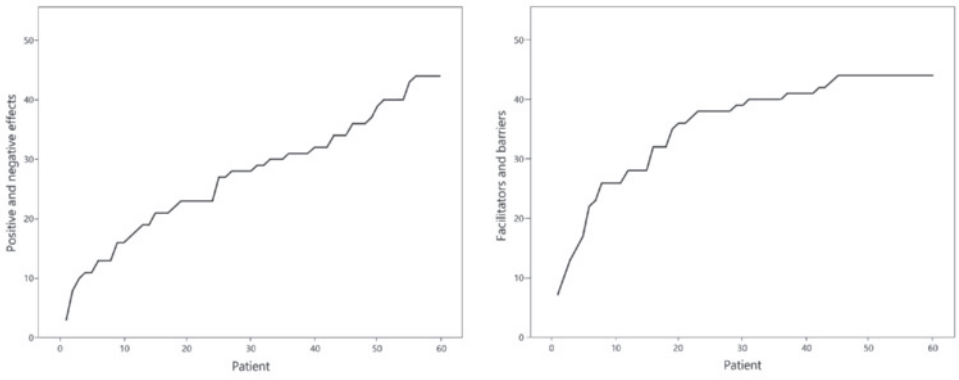

Figure 1 Saturation of positive and negative effects and facilitators. X-axis represents patient numbers; Y-axis represents each new item per interview that was mentioned by patients.

Other positive effects regarding efficiency in health care were a reduced workload, shorter hospital length of stay, prevention of ICU admission, reduced costs and lower amount of required nursing staff. A patient described:

"You can stay shorter in the hospital and can go home with a wearable device. They can inspect your data in the hospital while you are at home. I would like that, it would feel more safe." [Patient ID 40]

Seventeen patients, one relative and nine healthcare professionals expected increased feelings of safety in patients on the general ward. Also, patients' relatives and nurses mentioned to feel safer. A nurse explained:

"Postoperative patients have been monitored continuously at the ICU. Some do feel unsafe after return at the general ward because of a lower number of vital sign measurements." [Nurse ID 1]

All nurses and most patients encouraged implementation of wearable devices for continuously monitoring of patients. A nurse and a patient mentioned:

"This is the future. We have to deal with it and the sooner we start working with those wearable devices, the more profit we will have." [Nurse ID 16]

"The future.. I think only 30% of the patients will be hospitalized by then. Patients will be monitored from home with this kind of smart devices." [Patient ID 50]

Negative effects

Twelve and 18 negative effects were identified in the process and outcome domain respectively by patients, their relatives and healthcare professionals (Supplementary file 2). One patient and five healthcare professionals thought that continuous monitoring can generate an overload of information. An internist mentioned:

"Sometimes you just do not want to know, making yourself crazy with too much data. Particularly when data does not influence your decision in patient's treatment." [Medical doctor ID 5]

Particularly nurses at the surgical ward were afraid that their ward would become like an ICU; three nurses and one medical doctor thought that this can lead to reluctance for transfer to the ICU. The alarm system was mentioned as negative effect by three nurses and three medical doctors, leading to false positive alarms, irrelevant alarms and alarm-fatigue. Nine patients, one relative and five nurses were afraid that interaction between patient and healthcare professionals would be reduced. A patient mentioned:

"You need the confidence from the nurses, I would miss that. However, quantity time might become quality time." [Patient ID 58]

Seven nurses and one medical doctor mentioned that continuous monitoring would cost more time and one nurse, one physician assistant and one medical doctor thought it would increase work load. A nurse said:

*"Maybe it will increase work load. What if you receive an alarm every time a patient falls asleep and the oxygen saturation decreases a little bit?" [*Nurse ID 6]

Twelve patients, two relatives and two healthcare professionals mentioned that patients can become worried by being able to see their own vital signs. A patient explained:

"Some people are very anxious. Like my wife… like she already said: she would overreact. I would like to know my vital signs, but she would panic." [Patient ID 54]

Facilitators

Eight facilitators were found in the domain 'Factors related to device' (Supplementary file 3). One nurse and one medical doctor mentioned that using continuous monitoring healthcare professionals are able to see trends in vital signs. A surgeon stated:

"Last night we saw a patient with an Early Warning Score of 3 and in the morning it suddenly was 13. Using continuous monitoring, we would have been able to see the Early Warning Score slowly increasing during the night." [Medical doctor ID 6]

Two patients, two nurses and one medical doctor mentioned the small size of the HP. Three patients said they thought it was easy to view al vital signs on the VM wrist device or the mobile device of the HP. Two patients and one nurse said they think both devices are reliable.

Three facilitators were found in the domain 'Individual factors'. Two patients, two nurses and two medical doctors thought that continuous monitoring will lead to earlier detection of clinical deterioration and two patients mentioned they think that patient safety will be improved. In the Human environment domain, eight facilitators were identified. Five patients mentioned that the devices were invisible under their clothes and seven patients said they were not aware of the device. One patient, two nurses and one medical doctor mentioned fewer actions during vital sign measurements as facilitator, such as putting on the upper arm cuff for BP measurements.

Barriers

In the domain 'Factors related to the devices', 22 barriers were identified (Supplementary file 3). Two patients, three nurses and one medical doctor mentioned the VM battery change as barrier. VM wrist device was thought to be too big or heavy by five patients, three nurses and one medical doctor. Furthermore, VM cables and the patches and electrodes were mentioned as barriers as well. A patient said:

"Yesterday I felt very ill. I noticed that when you do not feel very well, every line, every device is just too much." [Patient ID 40]

Three patients mentioned that devices are not able to measure patient experiences, such as pain. A patient described:

"The devices are not able to register pain. When the nurse does not visit me, I cannot tell her I am having a headache. The device will not register that." [Patient ID 55]

Two patients and five nurses said that it is a barrier that the HP is not able to measure all vital signs. Furthermore, it was also mentioned that VM and HP both are not able to measure core temperature.

Four barriers were identified in the domain Individual factors. One medical doctor mentioned the risk of overtreatment by identifying abnormalities in vital signs that cannot be ignored. One medical doctor and one patient said that the VM wrist device is stigmatizing. In the domain 'Human environment', six barriers were identified. Three patients thought it was a burden to

carry the HP mobile device. One medical doctor feared that there will be too much attention for the vital signs and less attention for the individual patient. One nurse mentioned that patients were worried that patches would come off. Four barriers were identified in the Organizational environment. Two medical doctors mentioned that nurses do not have adequate training to interpret continuous data. Four nurses and one medical doctor thought that there would not be enough personnel to monitor all data.

"At this moment it is not feasible to monitor all patients 24 hours a day and to anticipate adequately to clinical deterioration with the amount of nursing staff we have." [Nurse ID 6]

DISCUSSION

Main findings

In this study we successfully investigated non-ICU patients with a wide spectrum of clinical conditions and healthcare professionals regarding their experiences and expectations during the use of two wearable devices for continuous monitoring of vital signs. We showed that continuous monitoring at the ward was not only well received by patients and their relatives, but also by their healthcare professionals. We found that using wearable devices did not affect stress levels. The majority of participants favored the use of these devices in daily practice. Both patients and healthcare professionals expected that continuous monitoring of vital signs would lead to earlier identification of clinical deterioration and to an improvement of quality, safety and efficiency in healthcare.

Our semi-structured interviews revealed a primarily positive attitude towards continuous monitoring and both used devices from patients, relatives and healthcare professionals. A recent study by Abelson et al. also confirms that surgical patients have a positive attitude towards wearable devices and mobile apps and that they are willing to use them.[39] Earlier detection of clinical deterioration was frequently mentioned by patients and healthcare professionals corresponding with findings in a recent review by Cardona-Morrell et al. They showed that continuous monitoring of vital signs at the general ward leads to earlier detection of clinical deterioration.[10] Continuous monitoring can lead to saved time and reduced work load for nurses. All nurses mentioned they would use this time for the patient, such as mobilization, washing/showering patients, providing information and being a listening ear for the patient. This might solve the problem for less nurse-patient interaction, which was frequently feared of by patients. Future research should shed light on changes in nurses' workload after implementation of continuous monitoring. One of the most frequently reported barriers was the wrist device and cables of VM. Particularly surgical patients mentioned that the VM cables were a burden in combination with other lines, such as abdominal drains

and urinary catheters. However, patients did not feel restricted during daily activities. This is important since early appropriate mobilization improves recovery and reduces the risk of complications.[40,41] STAI and PCS scores revealed no differences in psychological distress between patients in the intervention and control group, indicating that nor the VM or HP caused additional stress or reduced stress. According to SUS scores, the 'larger' VM wrist device and cables did not influence the overall usability of the VM in comparison with the 'smaller' HP. It is expected that future devices will become smaller while being able to wirelessly monitor all vital signs continuously. The amount of data that will become available by continuous monitoring was mentioned as a negative effect by healthcare professionals, as it was expected that they can never review all data. Big data analytics are available for effective storage and processing of large amount of data.[42,43] Alarms can alert the nurse when patient's vital signs drops out of normal ranges, resulting in a high number of false-positive or irrelevant alarms or even alarm-fatigue.[27,44] Machine learning algorithms can prevent unnecessary diagnostic procedures and overtreatment due to a reduced number of irrelevant and false-positive alarms.[45-47]

Other research

Few studies regarding continuous monitoring at the general ward exist. Brown et al. compared continuous monitoring using the EarlySense system with intermittent monitoring at a medical-surgical ward.[48] This system includes a flat sensor that is placed under the patient's bed and monitors HR and respiratory rate continuously. They found a reduced number of days at the ICU and shorter overall hospital stay due to earlier interventions in patients who were monitored continuously. However, the system is not able to monitor other vital signs such as BP, SpO_2 and temperature and not when patients are out of bed. Using HP and VM, patients are able to mobilize throughout the hospital while being monitored continuously for relevant vitals. VM measures almost all vital signs, which are required to calculate the MEWS and judge the clinical situation of the patient.

Strengths and limitations

An important strength is that we were able to monitor patients admitted for various reasons for a longer period of time in a clinical setting. We collected a large number of semi-structured interviews from both patients and healthcare professionals and were able to reach data saturation in patients about all pre-defined categories, resulting in a comprehensive overview of the positive and negative effects of continuous monitoring and facilitators and barriers regarding VM and HP. The control group allowed us to collect current experiences from patients that were not yet influenced by using wearable devices. Regarding interviews with healthcare providers, data may not have saturated. Selection bias can have occurred since not all approached patients signed informed consent, particularly at the surgical ward. However, we randomized all patients to VM, HP or a control group and no significant differences were found between randomization groups for example gender, which minimized bias. Patients mainly did

not agree with participation because they feared the mental or physical burden, particularly severely ill patients or patients with psychological distress. No differences were found in experienced stress between different randomization groups. Although the STAI questionnaire is validated for measuring psychological distress, many other stressful factors can have had impact on patients and potentially influence the outcomes (stress prior to surgical procedures or complications during hospitalization).

Future perspectives

Implementation of wearable devices for continuous monitoring is expected to influence health care in multiple ways. Patient safety can be improved since trained and experienced personnel can be warned during an earlier phase of deterioration and perform early interventions. This can prevent unnecessary ICU admission and shorten hospitality stay. Nurses will have to be taught how to operate wearable devices and continuous vital sign data at the general ward. It is expected that nurses will have more time for other needs of a patient during admission. Data transmission via Wi-Fi between device and the EHR should be safe and accurate. Potential alarms in vital signs can be processed using predictive analytics and machine learning techniques to prevent false positive alarming. Furthermore, patients can benefit from continuation of monitoring using the same or comparable wearable devices. Vital signs data collected at home can be shared with trained nurses or physicians. With continuous monitoring patients can be more actively involved in their own treatment. To stimulate this, the facilitators and barriers reported in this study are of great value when planning to implement wearable devices at the general ward.

Conclusion

According to patients and healthcare professionals, VM and HP have great potential for continuous monitoring of vital signs at the general ward and almost all encouraged the idea of monitoring vital signs continuously at the general ward. The comprehensive overview of barriers and facilitators of using wireless devices should be taken into consideration when choosing the device for implementing continuous monitoring. Continuous monitoring may provide the ability of predictive analytics for clinical deterioration and early interventions. Further studies should explore the effect of continuous monitoring on clinical outcomes of patients at the general ward.

SUPPLEMENTAL MATERIAL

Supplementary file 1 Positive effects.

	Patient	Group	Relatives	Nurse	PA[a]	MD[b]
Structure						
1. Monitoring patients from a distance	2	HP[c]/Co[d]		2		
Process						
2. Vital sign monitoring	**23**			**18**	**4**	**4**
2.1 Monitoring patients with high MEWS				1		
2.2 Monitoring patients who don't call for help				1		
2.3 More information about patients						
2.3.1 Availability of historical data	4	HP/Co		2	1	1
2.3.2 Insight in effect of medication				1		
2.3.3 Could assist with differential diagnosis						1
2.3.4 Trends	1	VM[e]		5	2	1
2.3.5 Improved communication between physicians	1	Co				
2.3.6 From home	1	HP				
2.3.7 Not specified	7	VM/HP/Co		3		1
2.4 Alarms	6	VM/HP/Co		2		
2.5 Data automatically in EHR				2	1	
2.6 More reliable data						
2.6.1 No measuring error between nurses	1	HP				
2.6.2 Measurements at fixed time points	1	HP				
2.6.3 Not specified	1	HP		1		
3. Detection of clinical deterioration	**22**		**2**	**16**	**2**	**5**
3.1 Earlier detection of abnormal vital signs						
3.1.1 During the night	1	HP				
3.1.2 Not specified	16	VM/HP/Co	2	12	2	3
3.2 Earlier interventions						
3.2.1 Earlier ICU admission				1		1
3.2.2 Not specified	5	VM/HP		3		1
4. Patient-professional interaction	**9**		**1**	**12**		**1**
4.1 Less patient disturbances	6	VM/HP/Co	1	5		
4.2 More contact between nurse and patient	2	VM		2		
4.3 Less actions during MEWS measurements						
4.3.1 More hygiene by not touching the patient				1		
4.3.2 Not specified	1	VM		4		1
5. Increased patient mobility				2	1	2

	Patient	Group	Relatives	Nurse	PA[a]	MD[b]
Outcome						
6. Quality and safety	**8**			**10**		
6.1 Improvement of quality of care	1	Co		3		
6.2 Improvement of patient safety	7	VM/HP/Co		7		
7. Efficiency in health care	**14**			**17**	**3**	**7**
7.1 Time saving						
7.1.1 Time for other activities	1	HP			1	1
7.1.2 Particularly during evening and night shifts				1		1
7.1.3 Not specified	6	VM/HP/Co		7		
7.2 Reduced work load	3	HP		5	1	1
7.3 Shorter hospital length of stay						
7.3.1 Earlier discharge with HP	1	HP				
7.3.2 Shorter ICU length of stay						1
7.3.3 Not specified					1	1
7.4 Prevention of ICU admission				4		
7.5 Reduced costs	2	HP/Co				1
7.6 Less nursing staff needed	1	HP				
7.7 Not specified						1
8. Psychosocial domains/well being	**24**		**4**	**9**	**1**	**3**
8.1 Feelings of safety patient	17	VM/HP/Co	1	5	1	3
8.2 Feelings of safety nurse	1	Co		1		
8.3 Feelings of safety relatives	1	Co	3			
8.4 More privacy				1		
8.5 More rest in the room	2	HP/Co				
8.6 Better sleep at night	3	HP/Co		2		
9. Insight in own vital sign monitoring	**4**		**1**	**2**		
9.1 Patients are more involved in own treatment	1	Co		1		
9.2 To be relieved	2	VM	1			
9.3 Specified	1	Co		1		
10. No restriction in daily activities	1	HP				

[a]PA, Physician assistant; [b]MD, Medical doctor; [c]HP, HealthPatch; [d]Co, Control group; [e]VM, ViSi Mobile.

Supplementary file 2 Negative effects.

	Patient	Group	Relatives	Nurse	PA[b]	MD[c]
Process[a]						
1. Vital sign monitoring	**1**			**12**	**1**	**5**
1.1 Overkill information						
1.1.1 Things that cannot be ignored				2		
1.1.2 Less attention for vital signs				1		
1.1.3 Not specified	1	HP[d]		1		1
1.2 More similarities with ICU						
1.2.1 Delayed admission to ICU				3		1
1.2.2 Not specified				2	1	
1.3 Alarms						
1.3.1 False positive alarms, e.g. movements				1		1
1.3.2 Irrelevant alarms, particularly during night				2		1
1.3.3 Alarm-fatigue						1
2. Interaction between professionals and patients	**9**		**1**	**5**	**1**	
2.1 Less nurse-patient contact						
2.1.1 Less use of clinical eye				2		
2.1.2 Not specified	9	VM[e]/HP/Co[f]	1	3		
2.2 More nurse-physician contact					1	
3. Reduced patient mobility	1	Co			1	
Outcome						
4. Efficiency in health care	**1**			**9**	**1**	**2**
4.1 Costs more time						
4.1.1 More time with computer				4		1
4.1.2 To connect patients with devices				2		
4.1.3 Interns need more explanations				1		
4.2 Increased workload						
4.2.1 More questions from patients				1	1	
4.2.2 Not specified						1
4.3 Unnecessary treatments	1	Co		1		
5. Psychosocial domains/well-being	**16**		**3**	**9**	**1**	**1**
5.1 Obsessed patient	1	VM	1	5		
5.2 Worried patient						
5.2.1 Wrong interpretation of vital signs	1	HP	1		1	
5.2.2 Certain patient groups (e.g. anxiety)	1	VM				
5.2.3 By hearing alarms	1	HP				
5.2.4 That nobody is watching vital signs	1	Co				
5.2.5 Not specified	8	VM/Co	1	1		

	Patient	Group	Relatives	Nurse	PA[b]	MD[c]
5.3 Increased feelings of illness				1		
5.4 False sense of safety	1	HP		1		1
5.5 Feelings of unsafety	1	Co				
5.6 Worried family				1		
6. Restriction in daily activities	1	Co				
7. Reduced patient empowerment	1	Co				

[a]No positive or negative effects in the "Structure" field were found; [b]PA, Physician assistant; [c]MD, Medical doctor; [d]HP, HealthPatch; [e]VM, ViSi Mobile; [f]Co: Control group.

Supplementary file 3 Facilitators and barriers

	Fac	Bar	Device	Patient	Nurse	PA	MD
1. Factors related to devices							
1.1 Design and technical concerns							
1.1.1 WiFi connection between VM and Toughbook[a]		2	VM[d]		1	1	
1.1.2 Artifacts in data[a]		3	VM/HP[e]	1	1		1
1.1.3 Data too much/unclear[a]		2	VM/HP				2
1.1.4 Able to see trends[a]	2		VM/HP		1		1
1.1.5 Able to see vital signs from a distance[a]	1		VM/HP		1		
1.1.6 Small size[a]	5		HP	2	2		1
1.1.7 Battery change[a]		5	VM	2	3		
1.1.8 Wrist device[a]							
1.1.8.1 Too big/heavy		9	VM	5	3		1
1.1.8.2 Not easy to read vital signs		1	VM		1		
1.1.8.3 Light turns on during the night		3	VM	3			
1.1.8.4 Too loose		1	VM	1			
1.1.8.5 Too tight		1	VM	1			
1.1.9 Cables[a]		14	VM	8	6		
1.1.10 Patches/electrodes[a]		16	VM/HP	9	6		1
1.1.11 No upper arm cuff[a]	1		VM/HP		1		
1.1.12 Restriction during daily activities[a]		7	VM	2	5		
1.1.13 Alarms (irrelevant/false-positive)[a]		12	VM/HP	2	7	1	2
1.2 Characteristics of the innovation							
1.2.1 Perceived usefullness							
1.2.1.1 Devices have no clinical eye[a]		3	VM/HP	1			2
1.2.1.2 Not able to measure with devices during diagnostic procedures[a]		3	VM/HP	1	2		
1.2.1.3 Devices are not able to measure patient experience (e.g. pain)[a]		3	VM/HP	3			
1.2.2 Perceived ease of use							
1.2.2.1 Connecting patients[a]	1	2	VM		3		
1.2.2.2 Display/interface (VM wrist device/HP mobile device)[a]	3		VM/HP	3			
1.3 System reliability	3		VM/HP	2	1		
1.4 Legal issues							
1.4.1 Confidentiality – privacy concerns		2	VM/HP	2			
1.5 Validity of the resources							
1.5.1 Satisfaction about content available (completeness)							
1.5.1.1 Not able to measure all vital signs[a]		7	HP	2	5		
1.5.1.2 Measures skin temperature instead of core temperature[a]		1	VM	1			
1.5.2 Accuracy	4	2	VM/HP	4	2		
1.6 Cost issues		1	VM/HP				1

	Fac	Bar	Device	Patient	Nurse	PA	MD
2. Individual factors: knowledge, attitude, socio-demographic characteristics							
2.1 Attitude							
2.1.1 Agreement with the devices							
2.1.1.1 Time consuming/time saving							
2.1.1.1.1 Battery change[a]		2	VM		2		
2.1.1.1.2 Too much data (reviewing all the data take too much time)[a]		2	VM/HP		1	1	
2.1.1.2 Outcome expectancy (use leads to desired outcome)							
2.1.1.2.1 Earlier detection of abnormal vital signs[a]	6		VM/HP	2	2		2
2.1.1.2.2 Earlier discharge with HP[a]	2		VM/HP	1		1	
2.1.1.2.3 Improvement of patient safety[a]	2		VM/HP	2			
2.1.1.2.4 Overtreatment of patients[a]		1	VM/HP				1
2.1.1.3 Motivation/resistance to use							
2.1.1.3.1 Wrist device is stigmatizing[a]		2	VM	1			1
3. Human environment							
3.1 Factors associated with patients							
3.1.1 Patients' attitudes and preferences regarding devices							
3.1.1.1 Able to see own vital signs[a]	3		VM/HP	3			
3.1.1.2 Device invisible under clothes[a]	5		VM/HP	5			
3.1.1.3 Not aware of device[a]	7		VM/HP	7			
3.1.1.4 Extra device with HP[a]		3	HP	3			
3.1.1.5 Wanted to stop wearing VM, my wrist are not that well[a]		1	VM	1			
3.1.1.6 Short battery life[a]		1	VM	1			
3.1.1.7 Increased patient comfort (vitals measured with one device)[a]	1		VM	1			
3.1.2 Patient/health professional interaction							
3.1.2.1 Less attention for patient[a]		1	VM/HP				1
3.1.2.2 Less nurse-patient contact[a]		1	VM/HP	1			
3.1.2.3 Less patient disturbances during the night[a]	3		VM/HP	2			1
3.1.2.4 Less actions during vital sign measurements[a]	4		VM/HP	1	2		1
3.1.3 Other factors associated with patients							
3.1.3.1 Patients were worried that patches would come off[a]		1	VM		1		
3.2 Factors associated with healthcare providers[a]							
3.2.1 Device localized at chest[a]	1		HP		1		
3.2.2 Feelings of safety[a]	1		VM/HP		1		

	Fac	Bar	Device	Patient	Nurse	PA	MD
4. Organisational environment							
4.1 Internal environment							
4.1.1 Work (nature of work)							
4.1.1.1 Time constraints and workload		1	VM/HP		1		
4.1.2 Skill – Staff							
4.1.2.1 Staff issues (stability, shortage)							
4.1.2.1.1 Not enough personel to monitor all data[a]		5	VM/HP		4		1
4.1.3 Organisational factors							
4.1.3.1 Training/lack of or inadequate training							
4.1.3.1.1 Nurses are not able to anticipate to deteriorating vital signs[a]		1	VM/HP				1
4.1.3.1.2 Nurses cannot handle fluctuations in vital signs[a]		1	VM/HP				1

[a]These items are added to the Gagnon framework. [b]PA, Physician assistant; [c]MD, Medical doctor; [d]VM, ViSi Mobile; [e]HP, HealthPatch.

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4.

Wireless and continuous monitoring of vital signs in patients at the general ward

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ABSTRACT

Background

Clinical deterioration regularly occurs in hospitalized patients potentially resulting in life threatening events. Early warning scores (EWS), like the Modified Early Warning Score (MEWS), assist care givers in assessing patients' clinical situation, but cannot alert for deterioration between measurements. New devices, like the ViSi Mobile (VM) and HealthPatch (HP) allow for continuous monitoring and can alert deterioration in an earlier phase. VM and HP were tested regarding MEWS calculation compared to nurse measurements, and detection of high MEWS in periods between nurse observations.

Methods

This quantitative study was part of a randomized controlled trial. Sixty patients of the surgical and internal medicine ward with a minimal expected hospitalization time of three days were randomized to VM or HP continuous monitoring in addition to regular nurse MEWS measurements for 24–72 h.

Results

Median VM and HP MEWS were higher than nurse measurements (2.7 vs. 1.9 and 1.9 vs. 1.3, respectively), predominantly due to respiratory rate measurement differences. During 1282 h VM and 1886 h HP monitoring, 71 (14 patients) and 32 (7 patients) high MEWS periods were detected during the non-observed periods. Time between VM or HP based high MEWS and next regular nurse measurement ranged from 0 to 9 (HP) and 10 (VM) hours.

Conclusions

Both VM and HP are promising for continuous vital sign monitoring and may be more accurate than nurses. High MEWS can be detected in hospitalized patients around the clock and clinical deterioration at an earlier phase during unobserved periods.

INTRODUCTION

Hospitalized patients may suffer from clinical deterioration due to their underlying condition or adverse events, leading to life threatening events or death.[1,2] Frequently, these patients require treatment at the Intensive Care Unit (ICU) to prevent further deterioration.[3,4] Patients transferred from a general ward to an ICU need more resources, have a longer hospital stay and are more likely to die.[5–7] Earlier identification and treatment of threatening conditions lead to lower mortality rates.[8,9] To assist care givers in early identification, Early Warning Scores (EWS), such as the Modified Early Warning Score (MEWS) have been developed based on an aggregated vital sign scores[10] and are used to identify patients at risk for further deterioration and to deliver faster supportive care.[11] However, studies show conflicting results about the value of EWS in relation to patient outcomes.[12,13] Identification of early deterioration depends on the quality and frequency of measurements by nurses.[14] The optimal frequency of vital sign measurements is unknown,[15,16] but should be high enough to detect early changes in vital signs prior to life threatening events.[14] New developments in technology allow wireless and continuous monitoring of vital signs, which may lead to earlier detection of clinical deterioration at the general ward.[17,18] Additional benefits can be reduced work load for nurses[19] and less patient disturbances.[19–21] In a recent study we demonstrated that continuous monitoring by two different wearable devices was as accurate as nurse measurements and both devices were well received by patients and nurses.[22] In this study the use of ViSi Mobile (VM; Sotera Wireless, San Diego, CA, USA) and HealthPatch (HP; Vital Connect, Campbell, CA, USA) was examined in a setting of hospitalized non ICU patients. Differences in MEWS results between regular periodic measurements by nurses and device measurements were compared, and high MEWS periods in between nurses' measurements were identified.

METHODS

Participants and Setting

This study was part of a randomized controlled trial (RCT) on patient and care giver reported outcomes regarding smart devices for continuous monitoring vital signs at the internal medicine and surgical ward of the Radboud university medical center in the Netherlands. Patients who were 18 years or older and able to speak Dutch were eligible for participation. Vital sign measurements had to be ordered for at least three times a day by the care giver and expected hospitalization time had to be three days or longer. In case of an unexpected admission time of less than 24 h, a patient was excluded. Since a formal power calculation was not possible due to lack of preliminary data with these devices, a sample size of 60 patients was estimated to obtain sufficient data. In the RCT consisting of three groups, 30 patients were controls without continuous monitoring. These were excluded for further analysis.

The institutional review board decided that formal ethical review was not required after they reviewed the study protocol extensively (local CMO number 2015– 1717), because continuous monitoring using both devices did not interfere with regular treatment, privacy of the patients was guaranteed and all patients were asked to sign informed consent after they were informed about the study.

Wearable devices

ViSi Mobile (VM) is FDA approved and received CE mark for monitoring five vital signs continuously.[22] The wrist-worn device works with a number of sensors measuring blood pressure (BP), heart rate (HR), respiratory rate, blood oxygen saturation (SpO_2), skin temperature, and 5-lead ECG. BP can be measured cuff-less by a thumb sensor after twice daily calibration with an upper arm cuff. Vital signs are visible for patients on a wrist device and can be locked by an authentication code. In this study all vital signs were transmitted via Wi-Fi to a laptop. Battery in the wrist device had to be recharged after 12–16 h.

The HealthPatch (HP) is a small and lightweight disposable patch, containing two ECG electrodes, a reusable sensor and a disposable battery lasting 3–5 days.[22] It received FDA clearance and CE mark for continuously measuring one-lead ECG, HR, respiratory rate, skin temperature, steps, body posture and falls.[23] HP can be attached to the patient's chest from where it transmits all data via Bluetooth to a mobile device (iPod or smart phone) and via Wi-Fi connection to a secured internet cloud.

Study procedures

Patients gave written informed consent and were randomized for connection with VM or HP. Demographics including age, gender, MEWS at day 1, reason for admission and type of surgery were registered. At the surgical ward, patients signed informed consent before surgery and received VM or HP on arrival at the ward. At the internal medicine ward, patients were connected to the VM or HP immediately after signing informed consent. All patients participated between 24–72 h and they received regular MEWS measurements by nurses. Nurses were formally blinded for the device results; they had no insight in the device data during their regular measurement moments. The VM data collector, a preconfigured Panasonic Toughbook, was set at the nurse' post and showed alarms when vital signs fell out of normal ranges. Normal ranges were configured per individual patient based on current situation and clinical history. Technical issues, such as connectivity failures, were registered and repaired.

Data collection and analysis

Registered data were retrieved from the Toughbook (VM) and the Vital Connect secured cloud server (HP) for analysis. Nurse measurements were extracted from the Electronic Health Record (EHR) for the period of inclusion. Nurse measurements with missing vital signs, except oxygen administration and AVPU (Level of consciousness. A: Alert; V: Verbal; P: Pain; U:

Unresponsive), were excluded. Artefacts in VM and HP data, defined as no or an invalid value for more than one minute, were retrospectively determined and excluded.

Device data versus nurse measurements

Mean values for each vital sign obtained by either VM or HP were calculated from a five minute period of continuous registration prior to each nurse measurement and was compared to the nurses' results. Oxygen administration and AVPU were imputed as 0 l/min and as 'Alert' in case of a missing value in the EHR assuming that a deviating value would have been documented. Vital signs outside physiological realistic ranges defined as SpO_2 50–100%, respiratory rate 2– 50 breaths/min, HF 20–250 beats/min, temperature 32–42 °C, systolic BP 50–300 mmHg, were considered measuring errors and excluded. Because VM measures 5 vital signs (HR, respiratory rate, SpO_2, BP, skin temperature) and HP 3 (HR, respiratory rate, skin temperature), we introduced three variants of the MEWS calculation, to be able to compare VM and HP based MEWS with nurses' MEWS: (1) a regular MEWS-VII (all seven parameters were used in the calculation); (2) MEWS-IV based on SpO_2, HR, respiratory rate and systolic BP, measured by VM; (3) MEWS-II based on HR and respiratory rate which were measured in all groups. Vital signs not captured by VM or HP were taken from nurses' measurements to complete the MEWS calculation in all situations. Since VM and HP both are not able to measure core temperature, these measurements were taken from the EHR.

High MEWS measurements by VM and HP between periodical nurse measurements

For every 30 minutes of continuous VM and HP data, a mean or median value was calculated for each vital sign and the MEWS. In case of HP, the value of BP and SpO_2 were taken from the periodic nurse measurement prior to the device measurement. A high MEWS was defined as a calculated MEWS ≥ 6. In case of more than one consecutive MEWS ≥ 6 during a non-observed period by nurses, only the first high MEWS during such a non-observed period was counted.

Statistical analysis

All analyses were performed using SPSS 20.0 (SPSS, Inc, Chicago, IL). Descriptive statistics are presented as mean with standard deviation (SD) or median with interquartile range, depending on skewness of data distribution. To test for skewness, the Shapiro-Wilk test was used. Bland–Altman plots, showing mean differences with corresponding limits of agreement, were created to assess the agreement between vital signs measured by nurses and both devices. Selection bias between groups regarding age and MEWS at time of admission was analyzed using Student's t-test (normally distributed data) or Mann–Whitney U test (non-normally distributed data). The Chi-Square test was used to test for selection bias regarding gender. A P-value below 0.05 was considered significant.

RESULTS

Demographics

At the surgical ward, 59 patients were informed about the study (Supplementary file 1). Thirty-nine patients signed informed consent, of whom 30 participated. Nine patients were excluded because the surgical procedure was re-scheduled (N = 1), patient withdrew consent (N = 4), patient deceased (N = 2), ICU stay was extended (N = 1), or patient had a major immediate postoperative complication (N = 1). Twenty patients refused because they expected a mentally (N = 16) or physically (N = 4) burden. At the internal medicine ward, 46 patients were informed. Thirty-six patients signed informed consent, of whom 30 participated. Six patients were excluded because their admission time appeared shorter than 24 h (N = 4), or the use of VM was deemed physically heavy (N = 2). Ten patients refused participation because they expected mental (N = 7) or physical (N = 2) burden or discharge within 24 h (N = 1). Demographics are shown in Table 1. No differences were found between the VM and HP groups regarding age (p = 0.520), gender (p = 0.273), or median MEWS at time of admission (p = 0.217).

Device data versus nurse measurements

In total, 1282 h of VM and 1886 h of HP data were recorded, on average 49 h of VM and 63 h of HP data per patient. The amount of missing VM data was 10.1 percent (129 h), mainly due to connection failures and errors in data storage. 8.4 percent (158 h) of HP data was missing due to connection failures or unknown cause. The removed artifacts were mainly due to connection failures and errors in data storage, and would have led to so called 'blue alarms'. These blue alarms indicate technical issues and are strongly reduced in an ongoing study in which we were able to connect ViSi Mobile to the hospital wide-range Wi-Fi system (instead of the Toughbook). 'Red alarms' are alarms indicating change in vital signs and alert nurses. In this study, the blue alarm did not affect any reported result. In total, 150 MEWS measurements were performed by nurses during the time the VM was connected to patients. Of these measurements, 113 (75%) were used for further analysis and 25 percent could not be calculated due to missing vital signs. In the HP group, 199 of the 206 (96%) MEWS measurements by nurses were used. Table 2 shows the absolute values and contribution to the MEWS per vital sign. All MEWS IV and II values corresponded well with nurses' MEWS. Median MEWS measured by VM and HP were higher than nurses' MEWS. Compared to nurse measurements, VM SpO_2 and respiratory rate and HP respiratory rate measurements contributed more to the MEWS due to higher variability in respiratory rate measurements by both devices (Table 3; Supplementary file 2).

Table 1 Patient demographics.

Demographics	ViSi Mobile (n=30)	HealthPatch (n=30)
Gender		
- Male (%)	18 (60.0)	22 (73.3)
- Female (%)	12 (40.0)	8 (26.7)
Median age	63	56
(min-max)	(26-76)	(27-88)
Median time		
participated in study	3	3
(min-max; in days)	(1-4)	(1-5)
Median MEWS at day 1*	0 (0-1)	1 (0-2)
- Median saturation	97 (96-98)	98 (96-99)
- Median respiratory rate	16 (16-18)	16 (16-18)
- Median heart rate	83 (74-97)	82 (72-98)
- Median systolic blood pressure	139 (123-159)	138 (126-148)
- Median core temperature	37.3 (36.7-37.6)	37.2 (36.7-37.8)
Reason for admission (%)		
- Colorectal disease	8 (26.7)	8 (26.7)
- Malignant	7	8
- Benign	1	
- Hepatobiliary disease	5 (16.7)	5 (16.7)
- Malignant	5	2
- Benign		3
- Neuroendocrine tumors		1 (3.3)
- Malignant		1
- Herniation	1 (3.3)	1 (3.3)
- Hematological diseases		1 (3.3)
- Autoimmune diseases	4 (13.3)	2 (6.7)
- Infectious diseases	3 (10.0)	7 (23.3)
- Other	9 (30.0)	5 (16.7)

MEWS = Modified Early Warning Score.

*First MEWS measurement determined at time of admission.

Table 2 Vital signs and calculated MEWS VII, IV and II in patients with VM or HP, compared to nurses' measurements.

Nurse		MEWS[a]	ViSi Mobile	MEWS
Saturation (%)	97 (95 – 98)	0.4	95.6 (94.0 – 97.1)	0.7
Respiratory rate (breaths/min)	16 (16 – 16)	0.1	15.7 (12.9 – 18.1)	0.4
Heart rate (beats/min)	82 (72 – 90.5)	0.3	79.9 (70.6 – 91.1)	0.3
Systolic BP (mmHg)	123 (106 – 140.5)	0.6	117.7 (103.0 – 134.9)	0.7
MEWS-II		0.4		0.8
MEWS-IV		1.4		2.1
MEWS-VII		1.9		2.7[c]

Nurse		MEWS[a]	HealthPatch	MEWS
Saturation (%)	96 (96 – 98)	0.3		
Respiratory rate (breaths/min)	16 (16 – 18)	0.1	18.6 (16.5 – 21.3)	0.7
Heart rate (beats/min)	84 (73 – 91)	0.3	83.8 (74.4 – 92.0)	0.3
Systolic BP (mmHg)	130 (118 – 145)	0.2		
MEWS-II		0.4		1.0
MEWS-IV		0.9		1.6[b]
MEWS-VII		1.3		1.9[c]

BP = Blood pressure. MEWS = Modified Early Warning Score.
[a]Partial score of total MEWS. [b]Completed with saturation and systolic blood pressure from concurring nurse measurement. [c]Completed with oxygen administration, AVPU score and temperature from concurring nurse measurement.

Table 3 Differences in vital signs and calculated Modified Early Warning Score between nurses and patients with ViSi Mobile or HealthPatch.

Vital sign	Nurse – ViSi Mobile	Nurse - HealthPatch
	Mean difference ± SD	*Mean difference ± SD*
Saturation (%)	0.94 ± 2.65[a]	-
Respiratory rate (breaths/min)	0.84 ± 3.43[a,b]	-1.94 ± 3.56[a,b]
Heart rate (beats/min)	0.69 ± 9.27	-1.00 ± 6.18[a]
BP systolic (mm Hg)	5.42 ± 14.27[a]	-
BP diastolic (mm Hg)	-5.57 ± 9.80[a]	-
Temperature (°C)	2.96 ± 1.13[a,b,c]	2.76 ± 0.89[a,b,c]
MEWS II	-0.38 ± 0.89[a]	-0.65 ± 1.14[a]
MEWS IV	-0.80 ± 1.64[a]	-0.65 ± 1.14[a]
MEWS VII	-0.80 ± 1.64[a]	-0.65 ± 1.14[a]

SD = Standard deviation. BP = Blood pressure. MEWS = Modified Early Warnings Scores.
[a]Significant one-sample T-test ($p < .05$). [b]Significant linear regression (proportional difference) ($p < .05$).
[c]Core temperature vs. skin temperature.

High MEWS measured by VM and HP in between nurse measurements

Fig. 1 shows the number of extra MEWS measured by VM and HP during non-observed periods by nurses: 71 in 14 VM patients and 32 in 7 HP patients. Time between high MEWS measured by a device and next regular MEWS measurement by a nurse is depicted in Fig. 2. Delay between these measurements ranged from 0 up to 10 h. In 57 of 71 (80%) VM and 30 of 32 (94%) HP cases of high MEWS, the consecutive MEWS calculated by nurses was not alarming (MEWS < 6). Thirty-four times (48%) with VM and 14 times (44%) with HP, the high MEWS occurred between 6 PM–8 AM.

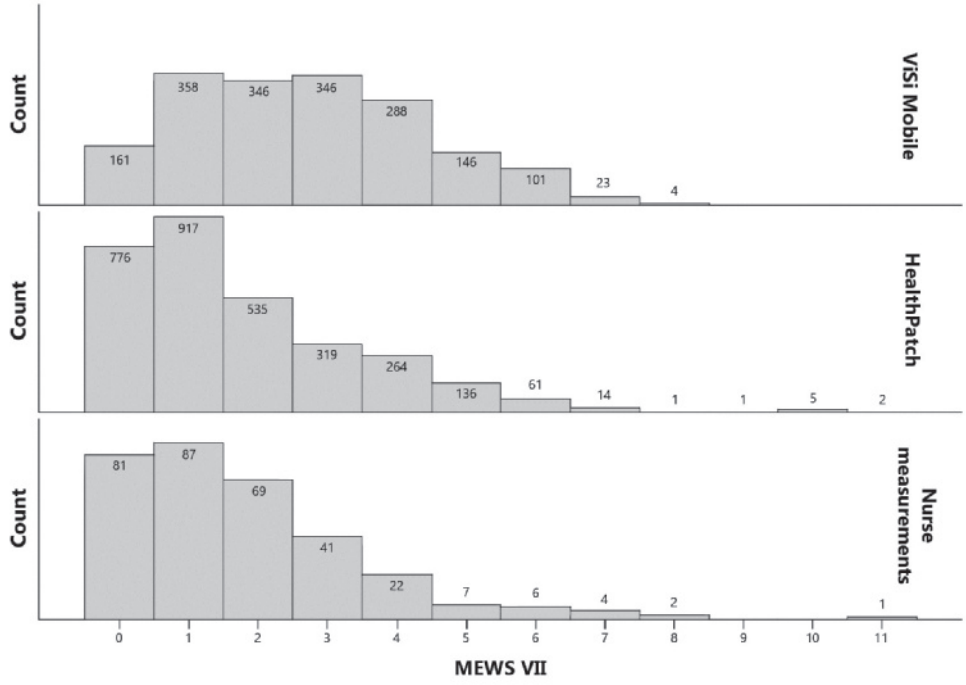


Figure 1 Number of extra MEWS measured by ViSi Mobile and HealthPatch during non-observed periods by nurses'.
MEWS = Modified Early Warning Score.

DISCUSSION

Main findings

VM and HP measurements resulted in higher MEWS compared to observations by nurses, due to higher median and more variable respiratory rate measurements registered by both devices. Over 100 periods of high MEWS, based on continuous device measurements, were

found during unobserved periods, half of them during evening and night shifts, indicating missed potentially alarming situations. Regarding high MEWS, delay before the next regular nurse MEWS measurement was up to 10 h.

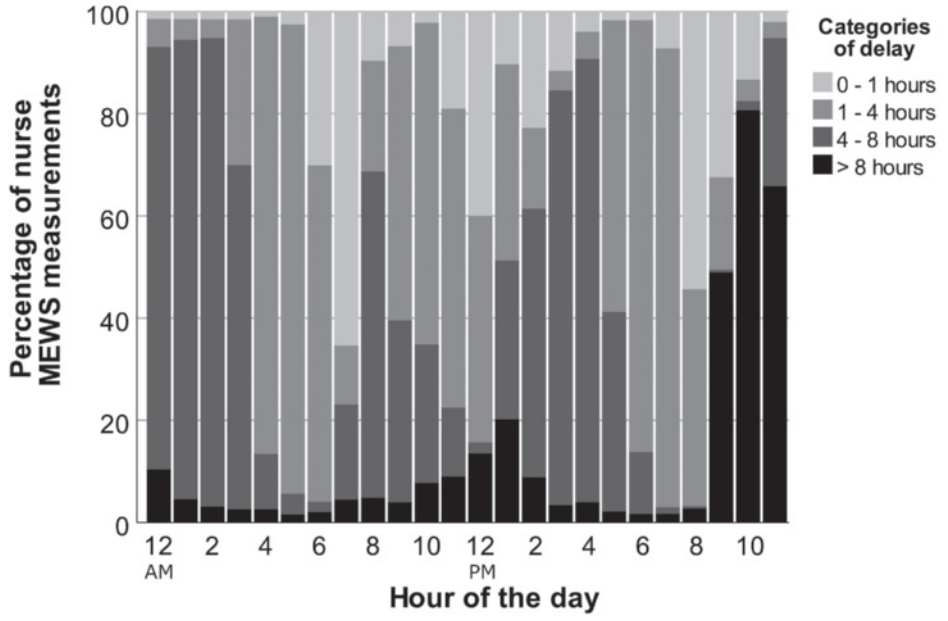


Figure 2 Time between high MEWS measured by a device and next regular MEWS measurement by a nurse. The X axis depicts the hour of the day; the Y axis depicts the percentage of nurse measurements with their delay (see box).

Discrepancies in respiratory rate measurements

Both devices measured higher MEWS values compared to nurses' measurements due to more variable respiratory rate measurements. Differences in median respiratory rate measurements between devices and nurses' measurements have been found in previous studies.[19,24] These differences are relevant since respiratory rate is an important predictor for severe complications, such as sepsis[25] and cardiac arrest.[26] Despite different methods to measure respiratory rate by the devices (e.g. heart rate variability plus accelerometer, versus impedance pneumography), the results did not differ between ViSi Mobile and HealthPatch. Respiratory rate seems difficult to measure accurately with an inter-observer variation up to 35%.[27] Visual chest movements should be observed for 1 min to calculate respiratory rate, but is often done for only 15 s, which may result in inaccurate measurements.[15] In this study, most nurses calculated respiratory rate

from a 15 s observation or, in some cases, by just estimating the number of chest movements, resulting in a median respiratory rate of 16 breaths/min, with a very small interquartile range of 16–18 breaths/min. Inaccurate respiratory rate measurement by nurses potentially lead to underestimation of the patients' clinical condition and can be improved by monitoring patients using these devices.

High MEWS measurements

The overall intention is detecting high MEWS earlier than measured by nurses in order to improve the timeliness of clinical actions ("true positives"), and do so without unnecessarily alarming too many ("false positives"). In this study we did not focus on clinical end-points. Many high MEWS were found in patients based on VM or HP without care givers being aware of these potentially alarming and unsafe situations. In three patients in this study, nurses were alarmed by VM between two regular nurse measurements and warned a physician. The patients were later diagnosed with a pneumonia, atrial fibrillation and an anastomotic leakage. Almost 50% of all high MEWS calculated on VM and HP measurements occurred during evenings and nights, when patients are less attended and more vulnerable to unnoticed deterioration.[28] High MEWS could also be generated due to physiological noctural changes in vital signs, such as lower BP and respiratory rate.[29] Potential drawbacks of these 'false-positive' alarms are increased work load and alarm-fatigue.[30–32] Algorithms based on machine learning can reduce these false alarms.[33–35] The effect of these high MEWS on clinical outcome and nurses' workload and alarm fatigue will be further explored in ongoing studies.

Previous research

Cardona-Morrell et al. showed that continuous monitoring of vital signs enabled the detection of clinical deterioration in an earlier phase than intermittent measurements.[17] The frequency of the Rapid Response Teams (RRT) activations increased, and complete and timely vital sign documentation improved. The effects on clinical outcome, such as ICU transfers and length of stay were less evident. Most studies had small sample sizes and a non-randomized design. We randomized patients to reduce the risk of selection bias. In a multicenter study using an electronic automated system, an increase in RRT calls, improved survival and a decrease in length of stay was demonstrated, and time to complete and record vital signs was reduced.[36] The monitors in this study contained cables reducing patient mobility. Also, monitors could not measure respiratory rate, meaning additional nurse measurements, documentation and likely underestimation of the EWS.

Limitations

Selection bias may have occurred because one third of all patients refused to participate, particularly at the surgical ward and mainly due to negative expectations regarding the VM device. Since VM and HP do not measure all vital signs needed to calculate the MEWS,

registrations of nurses were used with potential to be inaccurate or missing. It is unknown whether all vital signs are necessary for proper clinical judgment. Other EWS, such as the standardized early warning score, reduce patient mortality without scoring oxygen administration.[37] Literature shows that HR and respiratory rate change significantly before cardiac arrest and mortality, indicating that HP derived data may be enough to predict life threatening events.[1,2] Both devices measure skin temperature, which is recommended to be converted to core temperature for clinical use. The accuracy, however, should be questioned particularly in certain disease circumstances such as shock. For this reason we took nurse core temperature measurements in the VM and HP calculations of the MEWS. The potential of skin temperature for use in prediction of clinical deterioration will be further explored in future studies. VM artefacts mostly concerned connectivity failures between VM and its Toughbook due to a restricted Wi-Fi connection of 15 meters. Most artefacts were found in patients who were able to move around. With routine and scaled up use in a hospital, VM is connected with the hospital Wi-Fi system which reduces the number of artefacts and can provide safe transfer between wards or during diagnostic procedures, such as a CT scan.

Impact and future research

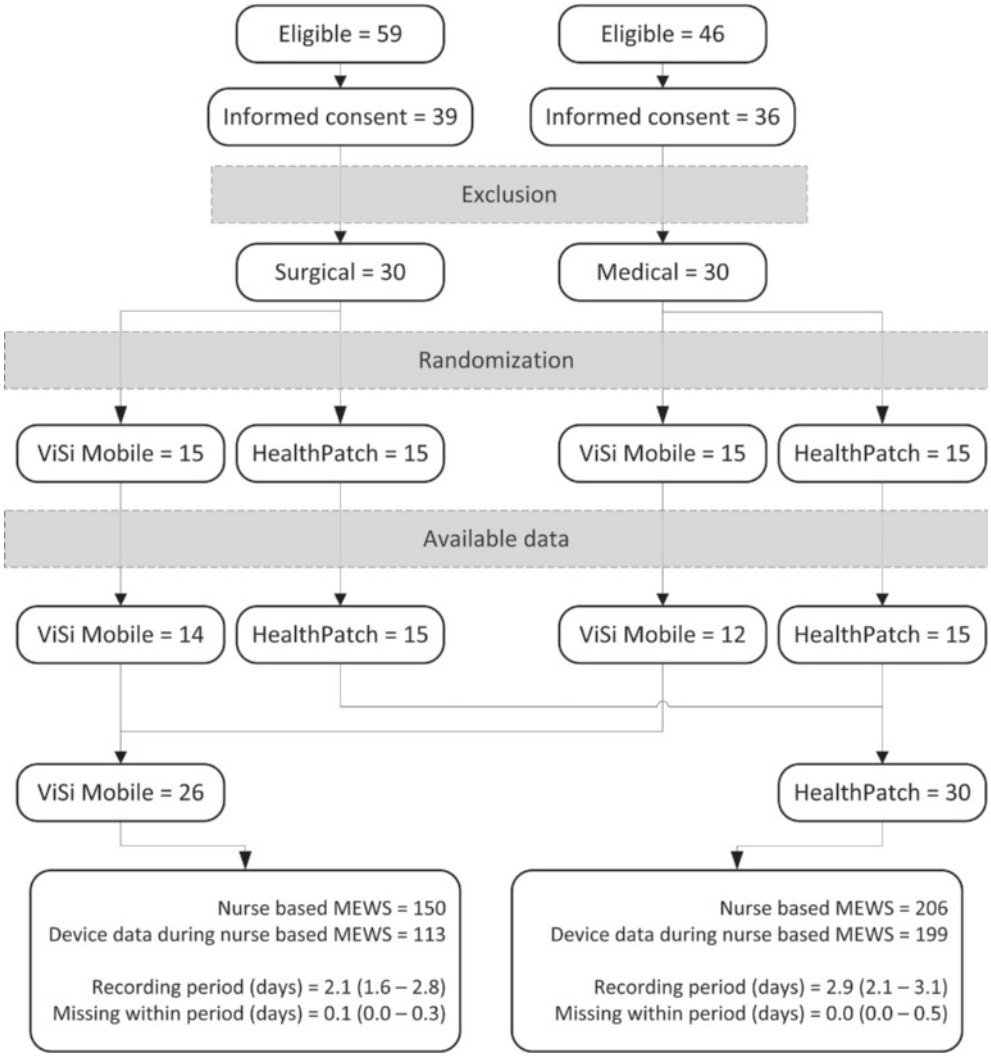
Earlier identification of clinical deterioration with continuous monitoring may prevent serious adverse events and reduce mortality at the general ward and during transport[38] and hospital costs.[6,39] Continuous monitoring may improve patient wellbeing by reducing sleep disturbances due to nurse measurements.[40-42] Further studies should focus on the clinical and socioeconomic outcomes of continuous monitoring with these wearable devices and the reduction of nurse workload. The nature and severity of alarming situations have to be explored.

Conclusions

Both VM and HP are promising for continuous vital signs monitoring at the general ward. Both measure respiratory rate more accurately than nurses. High MEWS can be detected in hospitalized patients around the clock and detect clinical deterioration in unobserved periods at an earlier phase. The availability of continuous monitoring may pave the way for adequate predicting upcoming clinical deterioration and early interventions.

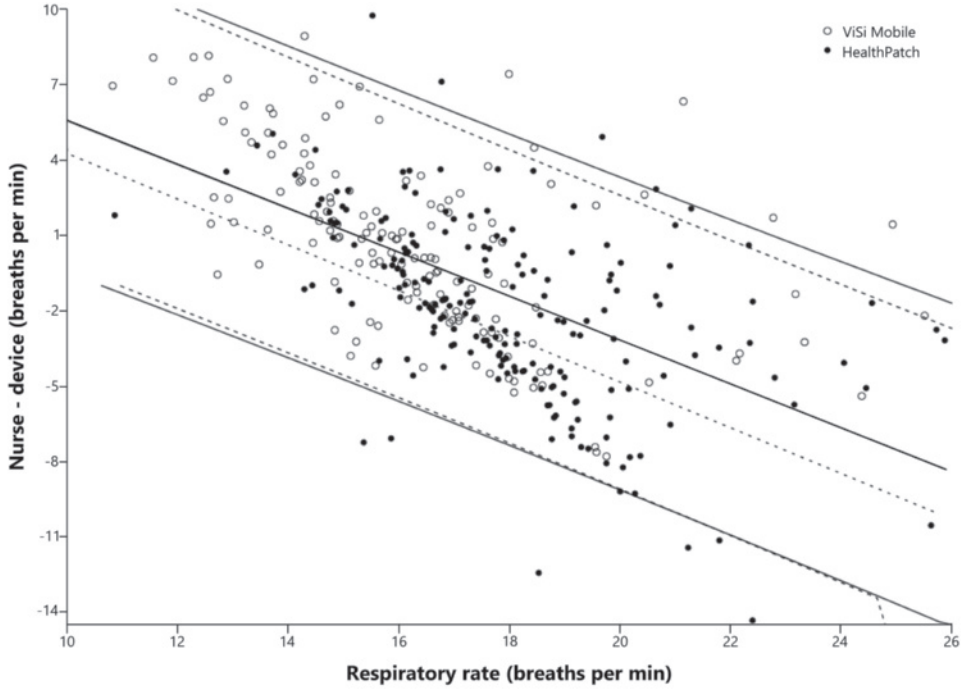
SUPPLEMENTAL MATERIAL

Supplementary file 1 Flowchart of patients' recruitment and inclusion in the study. Number of Modified Early Warning Scores performed by nurses and calculated by ViSi Mobile and HealthPatch. Duration of recording data and missing periods with median and ranges.



MEWS = Modified Early Warning Score.

Supplementary file 2 Bland-Altman plot showing respiratory rate.



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5.

A new cuffless device for measuring blood pressure: A real-life validation study

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ABSTRACT

Background

Cuffless blood pressure (BP) monitoring devices, based on pulse transit time, are being developed as an easy-to-use, more convenient, fast, and relatively cheap alternative to conventional BP measuring devices based on cuff occlusion. Thereby they may provide a great alternative to BP self-measurement.

Objective

The objective of our study was to evaluate the performance of the first release of the Checkme Health Monitor (Viatom Technology), a cuffless BP monitor, in a real-life setting. Furthermore, we wanted to investigate whether the posture of the volunteer and the position of the device relative to the heart level would influence its outcomes.

Methods

Study volunteers fell into 3 BP ranges: high (>160 mmHg), normal (130–160 mmHg), and low (<130 mmHg). All requirements for test environment, observer qualification, volunteer recruitment, and BP measurements were met according to the European Society of Hypertension International Protocol (ESH-IP) for the validation of BP measurement devices. After calibrating the Checkme device, we measured systolic BP with Checkme and a validated, oscillometric reference BP monitor (RM). Measurements were performed in randomized order both in supine and in sitting position, and with Checkme at and above heart level.

Results

We recruited 52 volunteers, of whom we excluded 15 (12 due to calibration failure with Checkme, 3 due to a variety of reasons). The remaining 37 volunteers were divided into low (n=14), medium (n=13), and high (n=10) BP ranges. There were 18 men and 19 women, with a mean age of 54.1 (SD 14.5) years, and mean recruitment systolic BP of 141.7 (SD 24.7) mmHg. BP results obtained by RM and Checkme correlated well. In the supine position, the difference between the RM and Checkme was >5 mmHg in 17 of 37 volunteers (46%), of whom 9 of 37 (24%) had a difference >10 mmHg and 5 of 37 (14%) had a difference >15 mmHg.

Conclusions

BP obtained with Checkme correlated well with RM BP, particularly in the position (supine) in which the device was calibrated. These preliminary results are promising for conducting further research on cuffless BP measurement in the clinical and outpatient settings.

INTRODUCTION

Noninvasive blood pressure (BP) monitors based on cuff occlusion are used widely in and outside of care facilities. These devices measure systolic (SBP) and diastolic blood pressure (DBP) by auscultation[1] or oscillometry.[2] Disadvantages of these measurements are discomfort for the patient because of painful cuff inflation, which may influence BP outcome, and the impossibility of continuous or semicontinuous BP monitoring due to the necessity of cuff inflation and deflation. Measurements can also vary between users, for example, patients or health care workers, due to interindividual differences in use. Although self-measurement of BP using noninvasive BP monitors has been shown to produce significantly greater BP reduction in patients with hypertension than standard care using clinic-based BP measurements,[3] it is not common practice because it is time consuming and has high overall costs because of expensive equipment and technologies.[4]

To overcome the disadvantages of BP measurements based on cuff occlusion and to provide easy-to-use devices for reliable self-measurement, pocket-sized BP monitoring devices without the need of a pressure cuff have been developed and are entering the consumer market. The majority of the cuffless devices indirectly measure BP by determining pulse transit time, the time interval required for a pressure wave in the arterial tree to travel between 2 sites (ie, a proximal and a distal point). Pulse transit time is closely related to BP via arterial compliance. Not only are these devices able to measure BP quickly and conveniently, but some of them also measure other modalities such as pulse rate, oxygenation, respiratory rate, and skin temperature. Furthermore, with respect to BP measurement, correct cuff size and cuff position are no longer important issues to take into account for obtaining reliable results. Altogether, these new cuffless devices could be an excellent alternative to BP measuring devices based on cuff occlusion, especially for the purpose of self-measurement.

The Checkme Health Monitor (Viatom Technology, Shenzen, People's Republic of China) is a newly released Conformité Européenne-approved cuffless BP monitoring device. Checkme is a IIa category medical device compliant with directive 93/42/European Economic Community. As it is aimed at the consumer market, it has been defined as a screening device for primary medical checking and not for diagnostic use. However, for its use in a clinical setting, especially during monitoring of hypertension treatment, the device's accuracy in persons with BPs outside the normal range has to be determined as well.

To ensure the accuracy of new BP monitoring devices, several protocols have been established, such as the European Society of Hypertension International Protocol (ESH-IP) revision 2010[5] and protocols of the Association for the Advancement of Medical Instrumentation.[6,7] However, a single unified protocol for all types of BP monitoring devices is still under development. For example, the ESH-IP and Association for the Advancement of Medical Instrumentation protocols stipulate the use of a mercury sphygmomanometer as the reference device, whereas the International Organization for Standardization protocol allows use of any type of reference

manometer, as long as it meets the accuracy requirement. Furthermore, the protocols that have been developed for validating noninvasive BP devices are designed primarily for monitors that are intrinsically able to give absolute BP readings in a single measurement.

Other category devices, such as Checkme, require patient-specific calibration by a secondary measurement method or device before they can give absolute BP readings. A protocol for validating such a monitor must include provisions to assess the monitor's accuracy in tracking intrapatient BP changes, relative to the calibrated level, after a patient-specific calibration or between calibrations.[8]

Another issue in daily practice is that oscillometric devices for the noninvasive estimation of BP have progressively become the clinical standard because of the need to train staff in determining BP by auscultation, cost, and the banning of mercury in many states and countries.[2] Therefore, it is conceivable that new devices are being evaluated in comparison with the easy-to-use automated oscillometric BP devices used in daily practice.

Finally, with classic BP devices, a correct BP can only be determined with the detection point (eg, the arm) at heart level. Because of the assumed method of BP measuring with cuffless devices, it is still unclear whether the device's position relative to the heart may influence the results of the measurement.

The aim of this study was to evaluate the performance of the first release of the Checkme cuffless BP monitor in a real-life patient setting. To this purpose, we compared Checkme BP measurements with measurements from a validated oscillometric reference BP monitor (RM) according to ESH-IP requirements. Our second aim was to investigate whether the posture of the volunteer and the position of the device relative to the heart level would affect outcomes.

METHODS

Checkme

Checkme is a cuffless BP monitoring device, which only determines SBP. It can be used both in clinical settings and for self-measurement (Figure 1).

This biometrical device can also measure skin temperature, heart rate, oxygen saturation, and 1-lead electrocardiogram, and it can be used as a sleep monitor. Before being able to measure SBP with Checkme, a personal profile containing sex, age, weight, and height has to be created, and the device has to be calibrated with an RM. Calibration is performed by simultaneously measuring SBP with Checkme and with RM and entering the SBP of the RM into Checkme after each measurement. After both calibration measurements, the Checkme is ready to use. SBP, heart rate, and oxygen saturation can then be measured by putting the right index finger beneath the lid on top, the right thumb on the metal plate on front, and the right middle finger on the metal plate on the back. Simultaneously, the metal plate on the left side of the device has to be pressed against the palm of the left hand (Figure 2, Figure 3).

Figure 1 Checkme Health Monitor (Viatom Technology) device.

Figure 2 Checkme position during measurement (front).

Figure 3 Checkme position during measurement (back).

Checkme has to be held still at heart level during a measurement. Performing one measurement takes about 20 seconds. To evaluate the result, data can be transferred via Bluetooth to a mobile phone or tablet (supported operating systems are iOS or Android) with the Checkme app (Figure 4). Details by which the Checkme measures BP have not been described in the public domain.

Reference Device

We used the validated Vital Signs Monitor 300 series (Welch Allyn, Skaneateles Falls, NY, USA) as RM. This automatic device measures SBP and DBP in the upper arm by oscillometry. The normal adult cuff size is suitable for people with an arm circumference of 25.3–34.4 cm. We used the small adult cuff when arm circumference was lower (range 20.0–27.0 cm) and the large adult cuff when arm circumference was higher (range 40.7–55.0 cm).

Familiarization

Before the validation procedure, we took a multiple series of test measurements using the Checkme and RM to familiarize ourselves with the devices. To test the study procedure and familiarize ourselves with it, we measured 2 volunteers accordingly. We encountered no problems. Experienced technicians of the Radboud University Medical Center maintained and calibrated the RM according to the manufacturer's protocol.

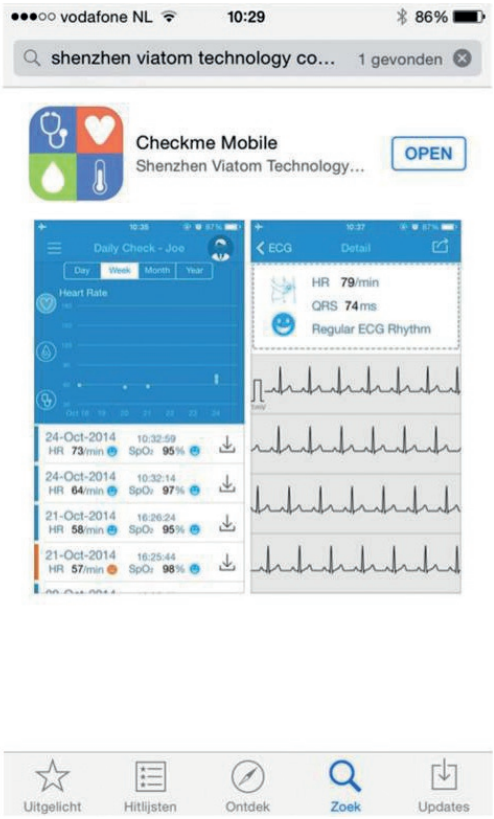

Figure 4 The Checkme app, showing heart rate (HR), electrocardiogram (ECG), and oxygen saturation (SpO_2).

Recruitment

We recruited study volunteers from patients who visited the hypertension outpatient services of the Radboud University Medical Center Department of Internal Medicine. To cover inclusion in all BP categories in this study, we also recruited patients with hypertension admitted to the hospital (highest BP range) and healthy employees (lowest BP range). We stopped recruitment after obtaining valid measurements of 37 volunteers with baseline BP measurements in the required ranges. Exclusion criteria were cardiac arrhythmias, upper-arm circumference outside the cuff range, and age <25 years. Information on age, sex, and use of antihypertension medication was collected and height, body weight, and arm circumference were measured. All volunteers gave written informed consent. The institutional review board gave permission for this study (Medical Research Ethics Committee CMO no. 2015-1717).

Protocol

This study followed the ESH-IP requirements for test environment, observer qualification, volunteer recruitment, and BP measurements for the validation of BP measurement devices.[5] Because device readings are digital, 1 researcher performed all measurements. In addition to the ESH-IP requirements, we took measurements in different positions to establish the influence of posture on device readings.

Each volunteer was seen individually in a quiet, temperature-controlled room. Appropriate cuff size (in the case of RM) was chosen based on upper-arm circumference. For each individual volunteer, a new profile was created on the Checkme device, with input of sex, date of birth, height, and weight. Volunteers were given oral instructions regarding proper use of the Checkme device before measurements were taken.

Baseline measurements were performed with the volunteer in the supine position after resting for 10 minutes. BP was measured 3 times at the right upper arm with the RM. The mean of the last 2 values was used as the baseline value, on the basis of which volunteers were divided into 1 of 3 BP categories: high (SBP >160 mmHg), normal (SBP ≥130 and ≤160 mmHg), or low (SBP <130 mmHg) BP, according to ESH-IP, with at least 10 volunteers in each BP category.

Next, we calibrated the Checkme device with the volunteer in the supine position with hands resting on the lower abdomen. The last measured baseline SBP with the RM was used as the input value for calibration. After calibration, we randomized the order of measurements. In the first series of measurements, BP was measured in the supine position with Checkme at heart level (arms resting on lower abdomen), Checkme above heart level (arms stretched above the head at a 90° angle with the body), and the RM (right upper arm) according to the randomization order. After the first series of measurements in the supine position, volunteers were asked to sit up. After 5 minutes of rest, the volunteer's BP was again measured in random order with the Checkme at heart level and RM, both in the upright position. All of the above measurements were executed 3 times successively. According to ESH-IP, the interval between consecutive measurements was between 30 and 60 seconds. Failed measurements were repeated up to a maximum of 3 times.

Statistical Analysis

All statistic calculations were performed with IBM SPSS version 20 (IBM Corporation). To evaluate the influence of the volunteer's position on the device readings, we compared the means of 3 consecutive measurements with a device in the supine or sitting position by paired samples *t* -test. A difference with $P<.05$ was considered to be significant.

RESULTS

We excluded 15 of 52 recruited volunteers: 12 due to repeated BP calibration failures with Checkme, 2 because they appeared to have low BP (SBP <130 mmHg) with already sufficient data, and 1 who declined to continue after inclusion. None of the volunteers had arrhythmias. In <3% of all measurements, BP had to be measured again due to failure during the first attempt of both the RM and the Checkme readings.

Study Population

Of the 37 volunteers who completed the study, 14 were in the low range (SBP <130 mmHg), 13 were in the medium range (SBP between 130 and 160 mmHg), and 10 were in the high range (SBP >160 mmHg). Table 1 shows their baseline characteristics. There were 18 men and 19 women with a mean age of 54.1 (SD 14.5) years. The mean baseline SBP was 141.7 (SD 24.7) mmHg. For 31 of the 37 volunteers (84%) we used the normal cuff size of the RM. Due to an arm circumference above than normal range, the remaining 6 volunteers (16%) required the large cuff.

Table 1 Study population characteristics.

Characteristics	All volunteers (n=37)
Male:female	18:19
Age in years, mean (SD)	54.1 (14.5)
White, n (%)	36 (97)
Black, n (%)	1 (3)
Height in m, mean (SD)	172.2 (7.5)
Weight in kg, mean (SD)	83.3 (18.4)
Use of blood pressure-lowering drugs, n (%)	22 (60)
Normal cuff size, n (%)	31 (84)
Baseline systolic blood pressure in mmHg, mean (SD)	141.7 (24.7)

Feasibility

In 22 of 52 volunteers (42%), calibration with Checkme failed the first time (error message: "unstable measure, calibration failed"). We repeated the procedure up to a maximum of 5 times. In 5 of 52 volunteers (10%), calibration succeeded after the second attempt, in 4 (8%) after the third attempt, and in 1 (2%) after the fifth attempt. Calibration continued to fail in 12 of 52 volunteers (23%), whereupon they were excluded from further measurements. In 2 of 37 volunteers who completed the study, the SBP measurement could not be determined in the upright position.

Comparing BP Results (Primary Aim)

Table 2 shows the BP results for RM and Checkme. Table 3 shows the proportion of patients with differences between RM and Checkme of >5, >10, and >15 mmHg. We constructed Bland-Altman scatter plots of BP differences between RM and Checkme against the mean BP of the RM and Checkme in the supine (Figure 5) and upright positions (Figure 6). BP results correlated with the position of Checkme relative to the heart level.

Table 2 Systolic blood pressure measurements (mmHg) taken by the reference monitor and Checkme in the supine and upright positions.

Volunteers' position	Mean[a]	SD	Range (min; max)[a]
Supine position			
Reference monitor	136.6	21.8	84.7 (106.3; 191.0)
CheckMe at heart level	138.4	25.2	94.5 (94.5; 189.0)
CheckMe above heart	130.7[b]	27.7	101.0 (86.0; 187.0)
Upright position			
Reference monitor	139.2	22.3	100.7 (102.3; 203.0)
Checkme at heart level	136.6[c]	25.9	87.7 (102.3; 190.0)

[a]The average or range of 3 consecutive blood pressure measurements. [b]P<.001 compared with Checkme at heart level. [c]P=.01 compared with Checkme at heart level in the supine position.

Influence of Posture on the Device Readings (Secondary Aim)

Table 2 summarizes the results of the SBP measurements obtained with RM and Checkme in the various positions. In the supine position, SBP measured with Checkme above heart level was significantly lower than SBP measured supine at heart level. SBP obtained with Checkme in the upright position was significantly lower than in the supine position, in which the device is just above heart level. Table 3 summarizes differences in SBP readings between RM and Checkme in both the supine and upright positions. The SBP measurement with Checkme in the upright position was significantly lower than the SBP measurement with Checkme in the supine position.

Table 3 Differences in systolic blood pressure readings between the reference monitor and Checkme in various postures and the proportion of volunteers with differences >5, >10, and >15 mmHg between the reference monitor and Checkme.

Reading differences	Supine at heart level (n=37)	Upright at heart level (n=35)
Difference between the devices (mm Hg)		
Mean (SD)	−1.8 (8.5)	2.6 (12.1)[a]
Min; max of range	−19.3; 18.2	−35.5; 20.3
Degree of difference		
>5 mmHg, n (%)	17 (46)	23 (66)
>10 mmHg, n (%)	9 (24)	15 (43)
>15 mmHg, n (%)	5 (14)	6 (17)

[a] *P*=.02 compared with measurements in the supine position.

DISCUSSION

The results of this comparative study show that the first version of the Checkme device yields BP results that are to a large extend comparable with BPs obtained by a validated oscillometric BP monitor. We observed this for a predefined wide range of BP levels under well-controlled circumstances. Furthermore, BP results correlated with the position of Checkme relative to the heart level. Compared with a reference BP, Checkme recorded a higher BP below heart level and a lower BP above heart level.

Due to the lack of a uniform international protocol that includes provisions to assess intrapatient BP changes relative to the calibrated level, it was not possible to conduct a formal device validation study. As the Checkme requires patient-specific calibration by a secondary measurement device before it can measure absolute BP, we consider such a protocol to be necessary.

The strength of this study is that it met all ESH-IP requirements for test environment, observer qualification, volunteer recruitment, and BP measurements. Measurements were conducted in a quiet, temperature-controlled room and the manufacturer's guidelines on use of the test device were followed. Furthermore, we used a validated RM device and randomized the order of measurements with Checkme and RM to eliminate the influence of changes in BP over time on the study results.

Checkme is one of the first cuffless devices to be launched, indicating that cuffless BP measurement is in its infancy. Notably, Checkme has outgrown its developmental phase. As the technique of cuffless devices is continuously being improved, future generations of Checkme may be even more suitable for measuring BP in the clinic.

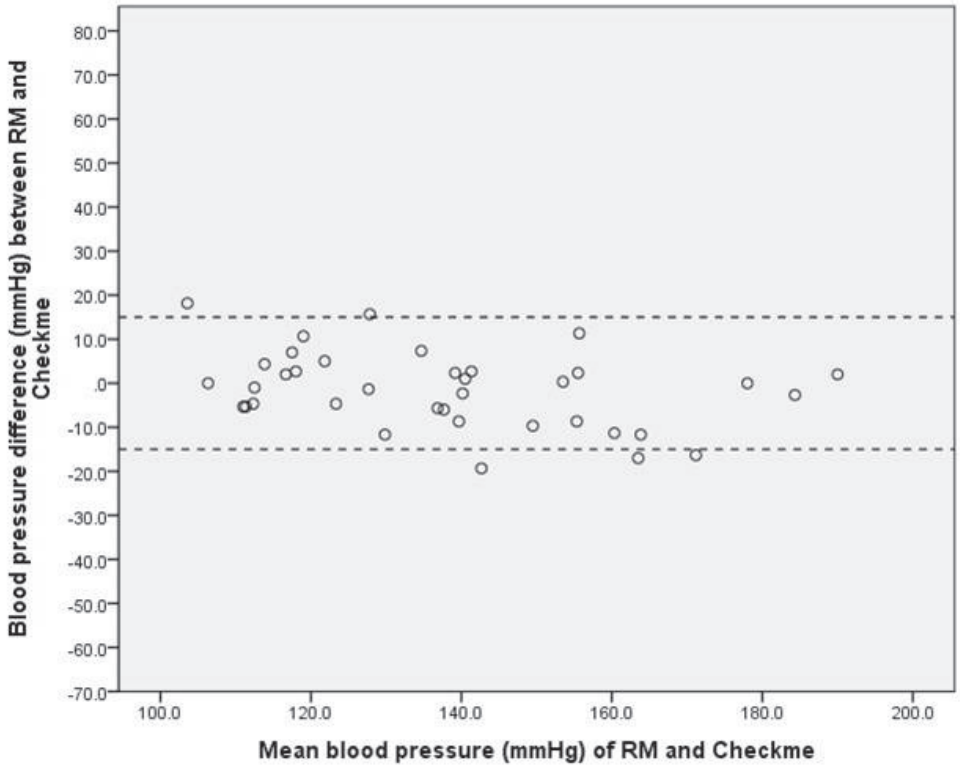

Figure 5 Bland-Altman plot of the difference in systolic blood pressure readings between the reference monitor (RM) and the Checkme Health Monitor (at heart level) in the supine position.

One disadvantage of Checkme is the inability to measure DBP, because DBP can be used to calculate pulse pressure and adds to the overall cardiovascular risk profile. Based on the underlying method of measuring, a subsequent version of Checkme may expected to have this ability. Another issue with the Checkme version used in this study was the inability to calibrate the device in a substantial number of volunteers. Repeated attempts to calibrate Checkme after warming volunteers' hands and further instructing them to hold still or change their position were not effective in some of them and thus further BP measurements were not possible. According to the manufacturer, a new software release has resolved this problem.
Ideally, Checkme is calibrated by taking simultaneous BP measurement with the RM. In this study, we calibrated Checkme after baseline measurements with the RM. However, as the time interval between taking the 2 measurements was a maximum 2 minutes (depending on the number of attempts during calibration), we can assume that BP had not significantly altered. Calibration parameter stability over longer periods of time has yet to be established in further

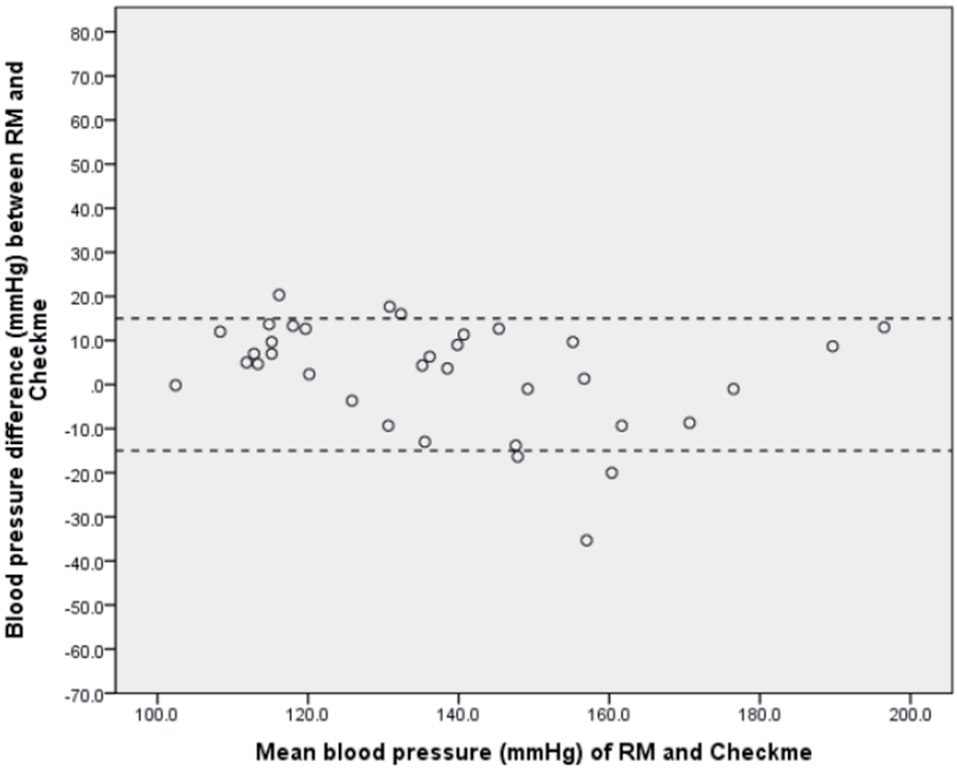

Figure 6 Bland-Altman plot of the difference in systolic blood pressure readings between the reference monitor (RM) and the Checkme Health Monitor (at heart level) in the upright position

research. After the completion of this study, Viatom updated the Checkme software to reduce calibration failures and has provided additional instructions for positioning Checkme against a lower limb during the calibration measurements. Therefore, the process of calibration can be expected to be more successful in future studies.

Checkme's BP measuring algorithm has not been made public, probably for commercial reasons. Most cuffless devices measure BP indirectly by determining pulse transit time, the time interval required for a pressure wave in the arterial tree to travel between 2 sites (ie, a proximal and a distal point). Pulse transit time is closely related to BP via arterial compliance. For example, if arterial BP increases, arterial wall tension will increase. Subsequently, arterial compliance and pulse transit time will decrease.[9] Most cuffless devices calculate pulse transit time by using the electrocardiogram as the proximal timing reference and the arterial waveform in an extremity as the distal reference.[10] Recent research has shown a significant relationship between BP measured with pulse transit time and BP measured with conventional devices based on cuff occlusion.[11-13]

Differences in BP depending on posture and position of the device suggest that cuffless BP measurement by Checkme, and probably in general, is influenced by the position of the device relative to heart level. This may suggest an inherent error in Checkme's algorithm when BP is measured in a position other than that indicated by the manufacturer. Therefore, it is important that future users of Checkme conduct all measurements in the position stipulated in the user manual. Furthermore, we observed 1 outlier (with SBP difference between RM and Checkme >40 mmHg), which we could explain.

If Checkme will be able to fulfill formal international validation protocol requirements, which include provisions to assess the monitor's accuracy in tracking intrapatient BP changes relative to the calibrated level, after a patient-specific calibration or between calibrations, we expect increased use of this device. Especially promising is such devices' ability to measure BP faster and more conveniently than conventional BP monitoring devices based on cuff occlusion. This implies not only that BP can be measured more efficiently in the clinic, but also that patients can easily self-monitor their BP at home. Because self-measurement of BP has been shown to have a positive effect on reducing BP,[3] this easy-to-use BP device will probably find a place in the management of hypertension. The low costs of cuffless devices relative to cuff occlusion devices will also contribute to their implementation in and outside the clinic.

We believe the market of wearable BP sensors will develop in the areas of self-measurement and remote monitoring. In this context, device validation may be accelerated if development of techniques, calculation, and feedback on the basis of clinical data would take place in an open source environment.

CONCLUSION

Checkme SBP correlated well with reference SBP, in particular in the supine position. Although we did not perform a formal validation study at this preliminary stage, these preliminary results are most promising and warrant further research on cuffless BP measurement in the hospital, the clinic, and at home.

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6.

A smart all-in-one device to measure vital signs in admitted patients

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ABSTRACT

Background

Vital sign measurements in hospitalized patients by nurses are time consuming and prone to operational errors. The Checkme, a smart all-in-one device capable of measuring vital signs, could improve daily patient monitoring by reducing measurement time, inter-observer variability, and incorrect inputs in the Electronic Health Record (EHR). We evaluated the accuracy of self measurements by patient using the Checkme in comparison with gold standard and nurse measurements.

Methods and findings

This prospective comparative study was conducted at the Internal Medicine ward of an academic hospital in the Netherlands. Fifty non-critically ill patients were enrolled in the study. Time-related measurement sessions were conducted on consecutive patients in a randomized order: vital sign measurement in duplicate by a well-trained investigator (gold standard), a Checkme measurement by the patient, and a routine vital sign measurement by a nurse. In 41 patients (82%), initial calibration of the Checkme was successful and results were eligible for analysis. In total, 69 sessions were conducted for these 41 patients. The temperature results recorded by the patient with the Checkme differed significantly from the gold standard core temperature measurements (mean difference -0.7± 0.6). Obtained differences in vital signs and calculated Modified Early Warning Score (MEWS) were small and were in range with predefined accepted discrepancies.

Conclusions

Patient-calculated MEWS using the Checkme, nurse measurements, and gold standard measurements all correlated well, and the small differences observed between modalities would not have affected clinical decision making. Using the Checkme, patients in a general medical ward setting are able to measure their own vital signs easily and accurately by themselves. This could be time saving for nurses and prevent errors due to manually entering data in the EHR.

INTRODUCTION

The Early Warning Score (EWS) was developed in the United Kingdom in 1997.[1] The EWS is a physiological scoring system that assists caregivers in detecting physiological changes and clinical deterioration in hospitalized non-critically ill patients.[2,3] Since then, the EWS has been modified, which has resulted in the now commonly-used Modified Early Warning Score (MEWS). The MEWS includes systolic blood pressure (BP, mmHg), heart rate (HR, beats per minute), respiratory rate (RR, breaths per minute), temperature (Celsius), oxygen saturation (SpO_2, %), amount of administrated oxygen (L/min), and the AVPU (Alert, responsive to Verbal stimulation, responsive to Painful stimulation and Unresponsive).[4–6] A higher MEWS is associated with more ICU admissions and increased mortality.[7–9] Generally, the MEWS is determined for each patient at least three times per day to provide a general assessment of their clinical condition during hospitalization.

Although early warning scoring has been widely adopted and aims to create a safe, controlled situation, several issues have been raised about its practicability and efficacy. Measuring vital signs is time consuming, and frequently results in incomplete data input.[4,10] A complete MEWS calculation takes approximately six minutes in total when accounting for measurements with several devices, data processing, and calculation of the MEWS. Inter-observer variation in measurements may exist, leading to a different MEWS in identical situations.[11] Further, results of the measurements are frequently entered in the Electronic Health Record (EHR) manually, and are therefore prone to mistakes.[12,13] Finally, there is often no automatic alarm produced by the EHR to trigger a nurse to a higher level of surveillance or to call the Rapid Response Team (RRT). This makes MEWS monitoring rather subjective, and dependent on care professionals who may react differently to comparable situations.

The Checkme Pro Health Monitor™ (Viatom Technology, Shenzhen, People's Republic of China) is a newly released Conformite´ Européenne (CE)-approved smart all-in-one device, which measures four of the five MEWS vital signs in less than 25 seconds (Figure 1) and can easily be handled by patients. Given its capabilities, the Checkme could represent a significant improvement in daily patient monitoring given its potential to reduce measurement time, inter-observer variability, and incorrect EHR inputs, without increasing costs. Moreover, the device enables patients to measure vital signs themselves, providing them greater insight into their health situation and increases patient empowerment in an in-hospital setting. Recent research showed promising results for BP measurements using the Checkme, however, evidence for its performance for other vital signs is limited.[14]

In this prospective comparative study, we evaluated the Checkme for accuracy in assessing the individual vital signs used to calculate the MEWS in hospitalized non-critically ill patients on an Internal Medicine ward. Vital signs and calculated MEWS based on patient-operated Checkme measurements were compared with vital signs and calculated MEWS obtained by nurses and by a well-trained investigator (gold standard).

METHODS

Setting and participants

Participants in this study were consecutive patients admitted to the General Internal Medicine ward of the Radboud University Medical Centre between March 2016 and May 2016. Patients were included if they were in a stable clinical condition, aged 18–75 years, mentally competent and able to understand instructions, and able to provide written informed consent. After reviewing the study protocol, the institutional review board waived the need for formal review and approval (local Ethical Committee Number 2016–2519).

The Checkme

The study device, the Checkme, measures one or two lead ECG, body temperature, heart rate (HR), SpO_2 and systolic blood pressure (BP) in a cuffless manner based on pulse transit time. The device also includes a pedometer and a sleep monitor. The Checkme has a "Daily Check" measuring mode, which measures all vital signs in less than 25 seconds. Before being able to conduct measurements with Checkme, a personal profile inclusive of gender, age, weight, and height is created on the device, and the systolic BP is calibrated once. This calibration is performed by measuring systolic BP simultaneously with a reference device, and by entering the reference systolic BP into Checkme. Systolic BP, HR, and SpO_2 can then be measured by placing the right index finger beneath the lid on top of the device, the right thumb on the metal plate in the front, and the right middle finger on the metal plate on the back. Simultaneously, the metal plate on the left side of the device is then pressed against the palm of the left hand (Figure 1). Temperature can be measured separately via a sensor pressed against the forehead. The Checkme is not able to measure diastolic BP, RR or AVPU. To evaluate the results, data can be transferred via Bluetooth to a mobile phone or iOS/Android tablet with the Checkme app.

Study procedures

After written informed consent was obtained, four measurement sessions were conducted in randomized order: a gold standard measurement in duplicate by a well-trained investigator, a measurement with the Checkme by the patient, and a regular vital sign measurement taken by a nurse. The gold standard measurements were performed to check for intra-observer variability. To obtain an accurate MEWS calculation from mixed data input, the investigator measurements were always carried out shortly before or after the Checkme measurement. The measurement sessions were conducted in the morning (6:30 AM), afternoon (2:00 PM) or evening (8:00 PM), always as close as possible to a regular nurse measurement, within a maximal time window of 30 minutes for all measurements. All measurements were done in the supine position in bed with patients in stable clinical condition. Patients were not allowed to leave their beds during the measurements. The investigator was blinded to the nurse's measurement

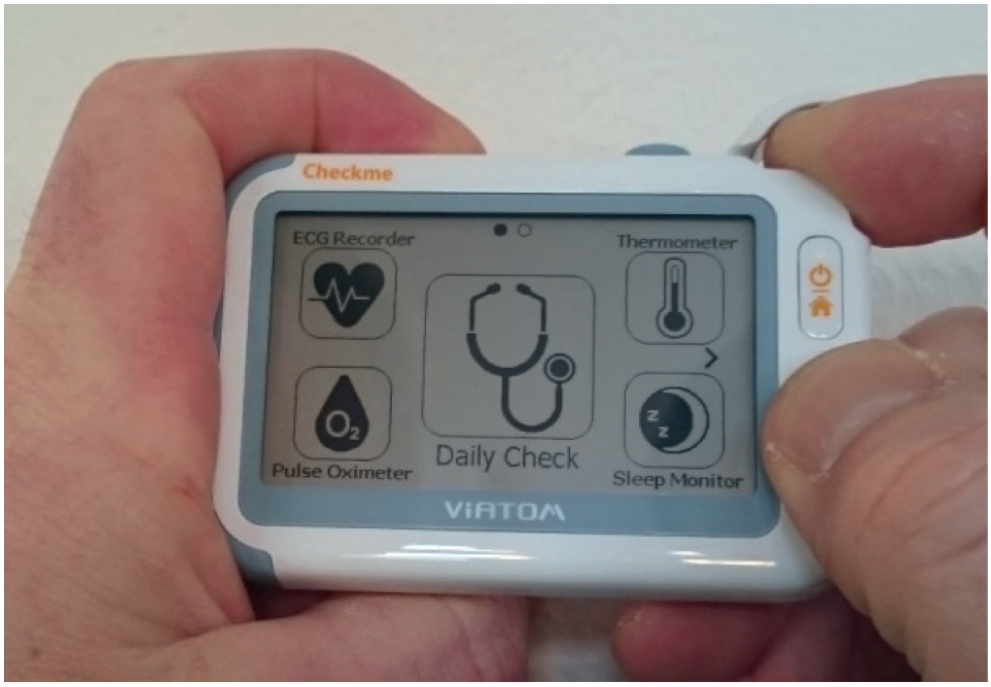

Figure 1 Viatom Checkme held in measuring position.

results to avoid confounding. Measured vital signs were HR, systolic BP, temperature, RR, SpO_2, oxygen administration, and AVPU. A MEWS calculation was then performed according to established protocol. Gold standard and nurse vital signs were measured using an automated BP measuring device (Dinamap, GE Healthcare, Germany), a pulse oximeter (Dinamap, GE Healthcare, Germany) and a tympanic thermometer (Genius 2, Medtronic, USA). The BP calibration of the Checkme was conducted as a separate measurement in the morning, using the same Dinamap blood pressure measuring device. Following a calibration attempt, the device would display either "calibration succeed", "calibration failed", or "unstable measurement". If the calibration failed or was unstable on three consecutive attempts, the patient was excluded from the study. Because the RR and AVPU cannot be measured with the Checkme, the values of the repeated investigator's measurements were used for MEWS calculation in conjunction with Checkme vital signs.

Methods of analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (IBM SPSS Statistics version 20.0, SPSS inc., Chicago, Illinois, USA). The vital signs were described using mean with standard deviation (SD). Bland-Altman plots were created to assess intra-observer variability and differences in vital signs and calculated MEWS measured by the investigator,

the nurse, and the patient (Checkme). In the plot, every data point represents the difference between two measurement methods. The solid line represents the mean difference, and the dotted lines represent the limits of agreement (1.96 SD). A one-sample t-test was performed on the difference between two measuring methods. A p-value < 0.05 was considered to be significant. For each vital sign, the clinically acceptable discrepancy between the three methods of measurements was predetermined. Clinically relevant differences were considered as follows: 5+ beats/min (HR); 5+ mm Hg (systolic BP); 0.5+°C (temperature); 2+ breaths/min (RR); 2+ % SpO_2. A difference in MEWS score of 1 point or more between different measurement sets was additionally considered to be clinically relevant.

RESULTS

Study population

Fifty consecutive patients were included in the study for at least one set of vital sign measurements and MEWS calculations. Patients' demographics and results of the Checkme calibrations are depicted in Table 1. In 41 of 50 patients (82%), initial calibration of the Checkme was successful and results were eligible for analysis. Two sets of measurements were performed in the morning (6:30 AM), 49 sets in the afternoon (2:00 PM) and 18 sets in the evening (8:00 PM). This resulted in a total of 69 measurement sets in 41 patients. Nine measurements performed by nurses (13.0%) were not complete (vital sign missing or not correctly entered in the EHR).

Table 1 Demographics of study population and results of calibration procedure.

		Total	Men	Women
Gender (%)		50 (100.0)	31 (62.0)	19 (38.0)
Age (years)		56.7 ± 15.8	58.7 ± 14.0	53.4 ± 17.8
Weight (kg)		79.5 ± 18.8	84.0 ± 16.5	72.2 ± 20.5
Length (cm)		171.9 ± 26.7	180.0 ± 7.1	158.7 ± 39.5
Calibration of Checkme				
Successful calibration (%)		41 (82.0)	25 (80.6)	16 (84.2)
Number of successful attempts (%)	1	30 (73.2)	18 (72.0)	12 (75.0)
	2	7 (17.1)	6 (24.0)	1 (6.2)
	3	4 (9.7)	1 (4.0)	3 (18.8)

General results

Patient measurements using the Checkme took approximately 30 seconds per patient, and an additional 6–7 minutes were needed to calibrate the device. A successful first attempt BP calibration was obtained in 30 (73.2%) patients (Table 1). Repeated calibration attempts were needed in the other patients, and calibration eventually failed in 9 patients. Most failures were presumed to be due to shivering or cold hands. Calibration failure was not found to correlate with patient gender, age, or weight.

Intra-observer variability

Table 2 depicts the vital signs and MEWS obtained via the well-trained investigator (gold standard) and the mean values of these measures in duplicate. Intra-observer variability was found to be significant for temperature measurements; measurements for other parameters were comparable for both attempts. Depending on the vital sign, 67.7 to 98.5% of the obtained results were less than the predefined clinically relevant differences. Sixty-two (91.1%) calculated MEWS measurements fell within the predefined limits of agreement.

Differences in vital signs

Table 2 depicts the results of vital signs measured by nurses and patients (Checkme) in comparison with the gold standard. Data were equally distributed, and all mean differences were less the predefined clinically relevant limits for acceptable differences. Compared with the gold standard, the vital sign measurements recorded by the nurse showed a slightly but significantly higher temperature. Measurements of RR were additionally found to be somewhat discordant, with 14 (24.1%) of all measurements differing by 3–4 breaths/min and 17 (29.3%) of all measurements differing more than 5 breaths/min. Figure 2 shows the Bland-Altman plots of nurse and gold standard measurements.

Figure 3 shows the Bland-Altman plots for Checkme in comparison with the gold standard. The results recorded by the Checkme for HR and SpO_2 were largely in line with the gold standard measurements. Checkme temperature readings did differ significantly from the gold standard for temperature, with 17 (25.7%) of all measurements differing more than 1.0 °C from the gold standard. Further, for systolic BP, 17 (25.0%) of all measurements differed by more than 15 mmHg. Mean differences for all vital signs were, however, within the predefined limits of agreement.

Differences in calculated MEWS

MEWS calculations on the basis of vital signs obtained by the gold standard measurements differed significantly from the MEWS based on nurse measurements, but were comparable to the MEWS derived from Checkme measurements. Compared with gold standard MEWS, the nurses' MEWS differed by two points or more in 15 (25.8%) cases. By contrast, in 10 (15.4%) cases MEWS differed two points or more between gold standard MEWS and Checkme. Most

Table 2 Mean values and differences for vital signs measured by gold standard, nurse and Checkme.

	Heart Rate (beats/ min)	Systolic Blood pressure (mm Hg)	Temperature (˚C)	Respiratory Rate (breaths/ min)	Saturation (%)	MEWS
Gold standard:						
Mean of measure 1 and 2 ± SD	74.1 ± 11.9	127.4 ± 17.4	36.9 ± 0.6	17.9 ± 4.2	95.9 ± 1.6	1.5 ± 1.4
Measure 1 vs measure 2:						
Mean difference ± SD[a]	-0.5 ± 3.8	0.4 ± 6.4	0.1 ± 0.3[b]	-0.2 ± 1.7	0.1 ± 0.9	0.1 ± 0.8
Categories n (%)	≤5: 59 (86.8)	≤5: 46 (67.7)	≤0.5: 65 (95.6)	≤2: 60 (88.2)	≤2: 67 (98.5)	≥+2: 5 (7.4)
	6–9: 8 (11.7)	6–14: 20 (29.4)	0.5–0.9: 1 (1.5)	3–4: 7 (10.3)	3–4: 1 (1.5)	0–1: 62 (91.1)
	≥10: 1 (1.5)	≥15: 2 (2.9)	≥ 1.0: 2 (2.9)	≥5: 1 (1.5)	≥5: 0 (0)	≥-2: 1 (1.5)
Nurse:						
Mean ± SD	73.5 ± 10.8	128.0 ± 18.3	37.1 ± 0.5	17.2 ± 2.2	96.3 ± 1.5	0.7 ± 1.1
Nurse vs Gold Standard:						
Mean difference ± SD)[a]	-0.8 ± 5.8	0.8 ± 9.7	0.2 ± 0.3[b]	-0.8 ± 4.3	0.4 ± 1.6	-0.8 ± 1.2[b]
Categories n (%)	≤5: 38 (65.5)	≤5: 27 (46.6)	≤ 0.5: 48 (82.8)	≤ 2: 27 (46.6)	≤2: 50 (86.2)	≥ +2: 1 (1.7)
	6–9: 16 (27.6)	6–14: 26 (44.8)	0.6–0.9: 9 (15.5)	3–4: 14 (24.1)	3–4: 7 (12.1)	0–1: 43 (74.1)
	≥10: 4 (6.9)	≥15: 5 (8.6)	≥ 1.0: 1 (1.7)	≥5: 17 (29.3)	≥ 5: 1 (1.7)	≥-2: 14 (24.1)
Checkme:						
Mean ± SD	74.6 ± 11.6	125.0 ± 19.2	35.7 ± 4.4	18.5 ± 4.5	96.8 ± 3.8	1.4 ± 1.6
Checkme vs Gold Standard:						
Mean difference ± SD[a]	0.7 ± 4.0	-2.7 ± 15.2	-0.7 ± 0.6[b]	n.a.	0.9 ± 4.2	0.1 ± 1.2
Categories n (%)	≤5: 57 (83.8)	≤5: 25 (36.8)	≤0.5: 25 (37.9)		≤2: 47 (69.1)	≥+2: 8 (12.3)
	6–9: 10 (14.7)	6–14: 26 (38.2)	0.6–0.9: 24 (36.4)		3–4: 16 (23.5)	0–1: 55 (84.6)
	≥10: 1 (1.5)	≥15: 17 (25.0)	≥1.0: 17 (25.7)		≥5: 5 (7.4)	≥-2: 2 (3.1)

[a]Positive (negative) value indicates higher (lower) mean value in measure 1 than in measure 2 of gold standard, and in nurse or Checkme measure than gold standard; [b]$p < 0.01$ compared with gold standard

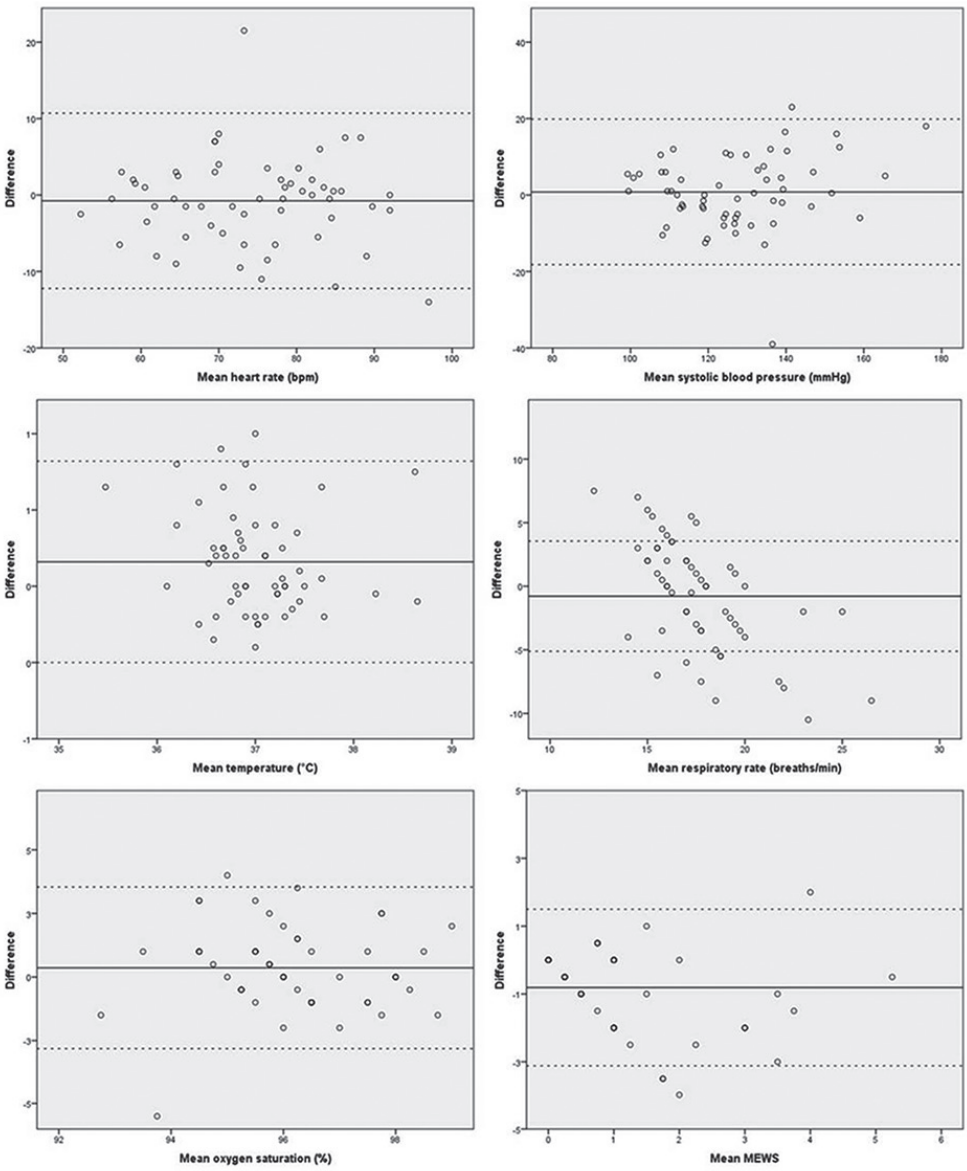

Figure 2 Bland-Altman plots of nurse and gold standard results.

MEWS calculations differed by 0–1 points between two methods. Mean differences of calculated MEWS were in range with the predefined accepted discrepancies. Three of 69 MEWS calculations by gold standard and nurses fell outside the limits of agreement (Figure 2). Bland-Altman plots are shown in Figure 3.

Other

Patients reported their experiences about the use of the Checkme. In general, they found the device to be user-friendly, and described being able to measure their own vital signs with ease. Some elderly patients experienced difficulty holding the device firmly during measurement.

DISCUSSION

For the first time, the Checkme all-in-one device was tested in clinical practice in a significant number of hospitalized non-critically ill Internal Medicine patients to determine 4 of 5 vital signs necessary for early warning scoring. This study shows that after initial calibration of the Checkme to measure systolic BP, patients were able to easily and reliably measure their own vital signs. The results obtained by the Checkme were, to a large extent, comparable to the measurements obtained by nurses and by those of a gold-standard well-trained investigator. Measurement differences had a minimal effect on the aggregated MEWS.

Intra-observer variability between investigator measurements was low, supporting the use of this measurement as a "gold standard". The differences in measured temperature between investigator measurements and between investigators' and nurses' measurements can be explained by the measuring error of 0.1°C of the tympanic thermometer used.[15] Significant differences for temperature were found between Checkme and the tympanic thermometer. Tympanic thermometers are often used in hospitalized patients, although the accuracy of tympanic temperature measurements for core body temperature measurement in the literature is mixed.[16–18] Checkme is able to measure infrared body temperature on the forehead and was recently validated.[19] A recent review by Geijer et al. showed that these methods of infrared body temperature measurement are not as accurate as invasive methods, but are comparable to tympanic thermometers.[20] Although absolute Checkme temperature measurements will be lower than core temperature measurements, the device is able to accurately monitor temperature changes in patients, which is often the primary finding of clinical interest.[16]

Although more extensive differences were found for systolic BP measurements between gold standard and Checkme, these were not statistically significant. Checkme is able to measure BP without cuffs using pulse transit time, which is closely related to BP via cuff based methods and arterial compliance.[21–23] Although a validation study has yet to be published, BP measurement by the Checkme has been shown to be reliable and accurate in an earlier study.[14] Additionally, BP differences in our study had a minimal effect on differences in calculated MEWS, without

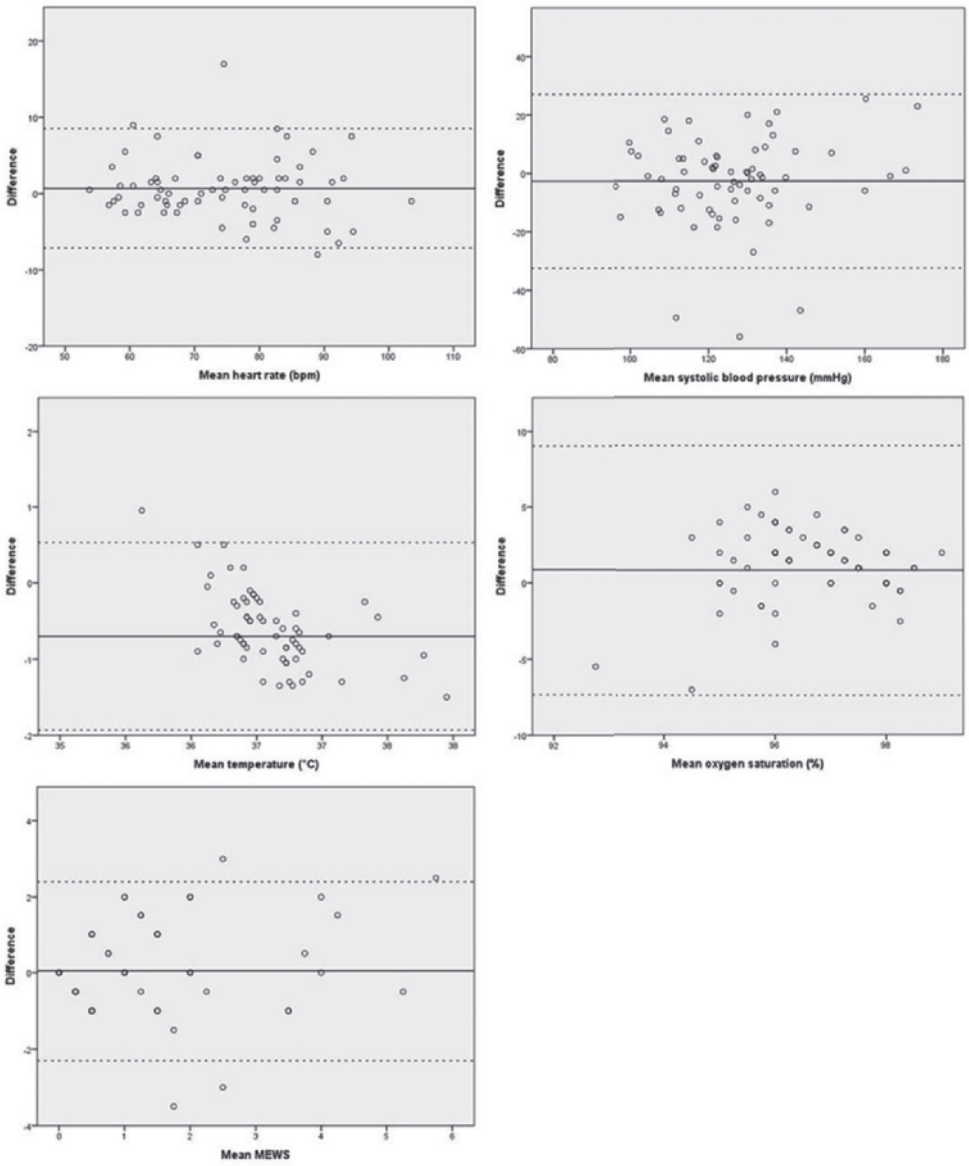

Figure 3 Bland-Altman plots of Checkme and gold standard results.

important clinical consequences. Although the measurements were randomized, the gold standard and Checkme measurements were always undertaken directly after one another, whereas the nurse measurements sometimes had a time difference of 5 to 30 minutes before or after the other measurements. This could explain the differences between nurses' and gold standard RR measurements. Inaccurate RR measurements by nurses and limited reproducibility as evidenced by significant inter-observer variability could further explain this discrepancy.[24]

The calculated MEWS derived from Checkme values corresponded more closely with the gold standard MEWS than did the MEWS calculated by nurses' measurements. The predominance of MEWS calculations by Checkme differed by one point or less from MEWS calculations obtained via the gold standard. Such differences had no important consequences for nurses' actions, such as increased frequency of vital sign measurements, additional diagnostic procedures, or rapid response team calls.

An additional important underlying finding in this study is that conscious and non-critically ill patients were able to measure their own vital signs easily and in an accurate and reliable way when compared to nurses. Furthermore, the Checkme measurements by the patient took less time after BP was calibrated successfully, and patient comfort was enhanced by avoiding the need for cuff BP measurements. It is unknown whether the Checkme data would be more accurate if the nurse had performed the measurements using the device, as this was not the focus of our study.

There may be additional benefits to patient self-monitoring of vital signs. For example, in the home setting, patient self monitoring of BP has been shown to have a positive effect on BP regulation,[25] and improves patients' insight into their own health status and recovery.[26] Early experience with a device continuously monitoring vital signs resulted in increased interest in health data by patients on the internal and surgical ward (unpublished own data).

One drawback of the Checkme is the troublesome calibration of the BP measurement in approximately one-fifth of our patients. Our research group evaluated the performance of the BP monitor of the Checkme and also studied whether the position of the device influenced the outcome.[14] Twenty-five percent of the participants experienced difficulties during calibration in supine position. This percentage is higher, by contrast, than the 18 percent of patients in our study in whom most calibration difficulties were presumed to be due to shivering or cold hands. The troublesome calibration could limit home monitoring of vital signs by patients. It is expected that the next version of the Checkme will have a more simplified calibration procedure. Until then, the calibration procedure could be performed by trained physicians or nurses at the outpatient clinic, while the patient receives instructions about the use of the Checkme. Also, a trained physician or nurse will be availabe for patients in case of technical problems using the Checkme at home.

A strength of this study is the comparison of three measurement methods by an investigator, a nurse, and a patient, with blinding for the results of measurements. It is additionally important

that we measured admitted patients in a clinical setting instead of healthy participants in a controlled setting. Time between gold standard and nurse measurements was mostly less than 10 minutes but could be 30 minutes. We cannot rule out slight changes in vital functions in a period of 30 minutes, however, due to the random order, the rigid protocol of nurse measurements in a patient group that is stable on the ward, comparison and interpretation of results seems justified. A limitation is that the Checkme is not able to measure diastolic BP and RR; RR is frequently used to inform clinical judgement in hospitalized patients.[27] Importantly, the next version of the Checkme will have the ability to measure RR. MEWS also includes oxygen administration and AVPU, which cannot be measured by the Checkme. Other EWS, such as the standardised early warning score, do not include oxygen admission but have still been shown to decrease inpatient mortality.[28] It could be possible that not all vital signs have a predictive value for clinical deterioration in different patient groups. Finally, critically ill or confused patients are not able to measure their own vital signs using the Checkme. Although the benefit of patients measuring their own vital signs is not attainable in this patient population, vital signs could still be collected reliably by nurses using the Checkme.

Future clinical research should focus on the use of Checkme and similar devices to predict clinical deterioration in various clinical settings, as well as patients' and caregivers' experiences using all-in-one devices. Furthermore, more frequent measurements and connections to hospital's EHR, including automated alarming, may further increase patient safety during admission through earlier detection of clinical deterioration. The Checkme is suitable for home monitoring and is able to send all data to secured platforms via telemonitoring. Vital sign data could be used to optimize a patient's home health or to identify underlying diseases such as atrial fibrillation prior to hospitalization and surgical procedures. It is expected that prehabilitated patients recover faster and with a lower complication rate postoperatively.[29] Cardiac patients could use the Checkme at home for 24-hour ECG registration and analysis, benefitting from a more comfortable method of monitoring than current holter monitors as well as from enhanced insight into their own health data.

In summary, our study demonstrates that patients in a general medical ward setting are able to measure their own vital signs easily and accurately by themselves, with comparable or even potentially superior accuracy to current nurse measurements. This could be time saving for nurses and prevent errors due to manually entering data in the EHR. While the rate of BP calibration failures limits Checkme applicability in certain patients at this time, it is anticipated that forthcoming versions of this device will address this shortcoming.

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Stress measurements in surgeons and residents using a smart patch

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ABSTRACT

Background

Stress may negatively affect surgeons' performance during surgical procedures, jeopardizing patient safety. For measuring stress, complex methods are used that cannot record stress real time. This study reports stress measurements in surgeons and residents using a novel patch sensor to identify activities and risk factors of stress.

Methods

In this explorative study, surgeons and residents wore the HealthPatch™ during all daily activities for 2-3 days. The patch recorded heart rate variability (HRV), and real time stress percentage using a validated algorithm of heart rate (HR) and HRV. The patch was compared with self perceived stress reporting using STAI.

Results

A significant increase in HRV and stress percentage was shown in twenty surgeons and residents during surgery in comparison with other activities. Consultants showed lower stress levels while operating compared to fellows and residents. Stress according to the patch did not correlate with STAI outcome.

Conclusions

Continuous stress monitoring using a wearable sensor patch reveals relevant data on actual stress of surgeons and residents. Stress was highest performing an operation, particularly in fellows and residents.

INTRODUCTION

Surgery is a stressful profession.[1] Long and continuous working hours, high workload, dealing with life and death,[1] and technically challenging procedures[2] are common contributors to stress in surgeons and surgical residents. Chronic stress can lead to relational issues, depression, and burnout,[3-5] and also increases the risk of cardiovascular disease and decreases life expectancy.[6-9]

Surgeons and residents spend a large part of their time in the operating room. Stress can both positively and negatively affect surgeon's performance in the operating room. While moderate levels of stress are necessary to improve alertness, focus, efficiency of action and thus overall performance ('good stress'),[10] excessive and long lasting stress is known to compromise technical[11-13] and non-technical skills ('bad stress').[13] During surgical procedures, excessive levels of stress are mainly caused by technical problems, complexity of the procedure, equipment failures, patient complications, interruptions, and high workload.[10,14,15] During laparoscopic procedures, stress is associated with a prolonged operation time,[11,12] poorer motion efficiency, and an increased number of errors.[12,16] Excessive levels of stress also impair non-technical skills such as communication,[10,17,18] teamwork, judgment, and decision making.[10,17] Loss of these abilities is associated with undesirable events in the operating room and could compromise patient safety.[13-15,18-22]

Research of surgical stress has been focused on the operating room environment and stress has rarely been studied during other activities.[23,24] However, ward rounds and seeing patients in the Emergency Room, the Intensive Care Unit and outpatient clinic may also elicit stress, of which the consequences for the quality of work are unknown.

Heart rate (HR), heart rate variability (HRV), skin conductance, eye blinks, and salivary cortisol[13] are objective markers for stress response. HRV in particular has shown to be a reliable and more time related measure for stress than the other markers.[25] Several studies showed changes in HRV recordings in surgeons during surgical procedures, indicating an increase in intra-operative stress.[24,26-31] Qualitative measurement of stress is commonly by self-reporting questionnaires, such as the State Trait Anxiety Inventory (STAI).[32] Arora et al.[33] developed a method to measure surgeons' stress during surgical procedures using the so-called Imperial Stress Assessment Tool (ISAT). By combining heart rate, salivary cortisol and STAI data, they were able to measure intraoperative stress in a reliable and valid manner. Drawbacks of this tool are the complexity, the time consuming and expensive cortisol analyses, and the inability to obtain real-time stress levels and for a longer period.

Recently, wearable sensors became available for use in healthcare, which can continuously measure vital signs such as HR in an easy and reliable way. The HealthPatch™ (Vital Connect, Campbell, CA, USA) is a small, lightweight and comfortable patch, which is attached to the chest. The patch is unique in measuring stress continuously and depicting stress real time, using a validated algorithm that computes stress as a combination of HRV and HR.[34,35] Because

of these features the patch has potential to be used in training situations and to assess chronic stress.

An exploratory study was conducted determining the value of the patch in continuously measuring stress levels in surgeons and surgical residents during all work activities in comparison to usual self perceived stress scoring. Important objective was to evaluate to what extent demographic and surgical factors, surgical experience level in particular, affect this stress.

METHODS

Participants

Consultants, fellows and residents were recruited from the surgical department of the Radboud university medical center in the Netherlands between July 2014 and December 2014. A sample size calculation was not deemed necessary because of the exploratory nature of this study. Demographics including gender, age, level of surgical experience and concurrent use of medication affecting heart rate were noted. Participants gave verbal consent after being informed about the study and the anonymous reporting of data. After reviewing the study protocol, the institutional review board waived the need for formal review and approval (2014-1603).

Patch details

The HealthPatch™ is a flexible self-adhesive patch containing two ECG electrodes and a battery (Figure 1). The patch is validated to measure nine items: single-lead ECG, HR, HRV, stress level in percentage, respiratory rate, skin temperature, body posture, activity and steps. Patch data are streamed to a smart phone via Bluetooth, from where they are transmitted to a secured online cloud for storage. Data can be downloaded from the individual accounts for analysis.

Procedure

Participants wore the patch for at least 48 h. In the morning of the first day, the patch was attached to the participant's chest and a connection was established between the patch and a smart phone via Bluetooth. Baseline patch data and STAI score were collected during 15 min of rest in which participants were instructed to sit comfortably, not performing any physical activity, not reading or speaking. Thereafter, data were continuously collected during all daily work activities for the next 48-72 h. Participants filled out the STAI before and immediately after each surgical procedure, not before and after other activities. This was decided because the other daily activities are more heterogeneous and more frequent e.g. administrative activity. All participants kept a personal logbook in which they documented the type and time of daily activities and also physical activity (e.g. running, taking stairs). At the end of each working

day one researcher (MW) debriefed participants with help of the personal logbook. Technical failures and side effects of the HealthPatch were documented.

Figure 1 HealthPatch™.

Stress measurements

HRV

The smart patch measures HRV, which is defined as the variation in time interval between heart beats (R-R interval). The R-R interval is the time between the peaks of two consecutive QRS complexes as recorded by the 125 Hz ECG.[36] According to the recommendations of the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology,[37] subsequent intervals of five minutes were used for automatic calculation of the HRV by the patch. This was done by using time domain and frequency domain analyses. For time domain, the standard deviation of the interval between two heart beats (SDNN) and square root of the mean R-R interval (RMSSD) were used as parameters reflecting HRV. Low SDNN or RMSSD indicate stress.[38] In the frequency domain, Fourier transformation was used by the patch to calculate the power spectral density. Three main spectral densities were distinguished: the very low frequency (VLF) component (0-0.04 Hz), the low frequency (LF) component (0.04-0.15 Hz) and the high frequency (HF) component (0.15-0.40 Hz). LF and HF represent two branches of the autonomic nervous system; LF is expected to be a marker of sympathetic modulation with some parasympathetic act and HF is a marker of

vagal modulation.[39,40] Stress is accompanied by an increase of sympathetic activity, resulting in an increase in LF and a decrease in HF.[38,40] The LF/HF ratio was calculated separately by a researcher to isolate sympathetic tone more precisely.

Real time stress percentage

The patch shows stress real time every four seconds.[34] This stress depicts the result of an algorithm that uses HR and SDNN: Stress (%) = HR + α * SDNN.[34] This stress algorithm was validated and has shown to be sensitive for acute changes in psychological stress.[35] When stress occurs, HR will increase and SDNN will decrease. According to the manufacturer α is usually a negative number. The stress percentage is calibrated to the individual baseline HR. This is done by mapping stress to a cumulative distributive function (Gaussian CDF), ranging between 0 and 1 and multiplied by 100. The stress shown is also adapted to the personal range of daily stress by adjusting the Gaussian CDF to new stress data. The lowest stress level is '0' and highest stress level is '100'. The patch stops measuring the stress percentage when physical activity e.g. walking stairs is undertaken. Thus, only mental stress is recorded by the stress percentage.

Stress perception

For stress perception, the short version of the STAI was used (Table 1).[41] This validated test consists of six items on a four-point scale and measures emotional, cognitive and physical stress. The STAI takes about 2 min to complete. Total STAI scores range from 6 to 24, whereby higher scores indicate an increase in perceived stress.

Table 1 State trait anxiety inventory.

	Not at all	Some-what	Moderately so	Very much
I feel calm	1	2	3	4
I feel tense	1	2	3	4
I feel upset	1	2	3	4
I am relaxed	1	2	3	4
I am content	1	2	3	4
I am worried	1	2	3	4

Data analysis

Participants were divided into groups according to gender and level of experience; consultants (two or more years of independent practice), fellows (surgeons with less than two years of independent practice), senior residents (postgraduate year (PGY) 5 or 6), and junior residents (PGY 4 or less). For analysis fellows and senior residents were grouped together. Daily activities

of participants were divided in baseline, surgical procedures, and non surgical activities (ward visits, outpatient clinic, and administrative work). Time with no clinical activities according to the personal logbook was excluded from further analysis. All surgical procedures performed by the participant during the day or evening were included. Surgical procedures were divided into short (<2 h) and long procedures (2 h) as a proxy for complexity of the operation and hypothetically a difference in stress. Only elective surgical procedures were included. All baseline, outpatient and ward activities were included in the analysis. For administrative work activities one representative period per participant was selected based on the logbook. Data were downloaded in *.CSV files (MS Excel 2007). Raw data were inspected for artifacts and further analyzed in SPSS version 20.0 (SPSS, Inc, Chicago, IL). A surgical procedure was defined as stressful when the postoperative STAI score was at least 1 point higher than the preoperative STAI score.[33]

Statistical analysis

All statistical data analyses were performed using MS Excel and SPSS. Descriptive statistics are presented as mean with standard deviation (SD) or median with range, depending on skewness of data distribution. To test for skewness, the Shapiro-Wilk test was used. Gender and duration of operation were compared using the Independent students' t-test or Mann-Whitney test for nonnormally distributed data. Statistical significance between the different activities, between levels of experience and STAI scores was calculated using the ANOVA or Kruskal Wallis test. Stressful surgical procedures according to an increase in STAI scores were compared with non-stressful procedures using the independent students' t-test or Mann Whitney U test. Pearson correlations were used to test for relationships between delta STAI scores and HRV and stress percentage. A p value less than 0.05 was considered significant.

RESULTS

Five consultants, seven fellows and senior residents, and eight junior residents (11 men and 9 women) participated. The mean age (±SD) of the consultants, fellows and senior residents, and junior residents were respectively 46.20 (±7.16) years, 35.43 (±4.44) years, 32.25 (±1.83) years. The mean (±SD) years of experience at consultant level was 11.80 (±6.91) years. At the time of data collection, one fellow and one junior resident were pregnant for six weeks. One male fellow used beta-blockers. In all participants, data were collected during baseline and administrative work. Measurements involved sixty-three elective surgical procedures, 22 long and 41 short procedures. Data of eight participants were collected at the outpatient clinic and data of seven participants when at the surgical ward.

In two participants data was missing due to connection failures. In one participant two hours were missing during a surgical procedure, in the other participant four hours were missing

Table 2 HR, SDNN, HRV and stress percentage during different daily activities.

	Heart rate (bpm) – median (min-max)	SDNN (ms) – mean ± SD	RMSSD (ms) – median (min-max)	LF/HF ratio – mean ± SD	Stress (%) – mean ± SD
Baseline (20 participants)	70.00 (48.65-84.69)[a]	81.03 ± 27.86[b]	38.97 (22.00-131.70)[c]	3.97 ± 2.50[d]	20.04 ± 13.48[e]
Surgery (63 procedures)	87.69 (62.32-120.38)[a, f, j, o]	51.00 ± 12.08[b, g, k, p]	23.50 (13.14-54.21)[c, h, l, q]	6.18 ± 3.04[d, m]	60.77 ± 24.20[e, i, n, r]
Outpatient clinic (8 participants)	74.30 (61.26-82.97)[f]	80.98 ± 9.14[g]	40.39 (25.25-45.63)[h]	4.31 ± 1.91	28.29 ± 14.31[i]
Ward (7 participants)	75.73 (63.98-83.44)[j]	77.30 ± 20.27[k]	34.94 (28.35-63.82)[l]	3.99 ± 1.20[m]	19.48 ± 8.92[n]
Administrative work (20 participants)	72.64 (57.74-88.07)[o]	74.22 ± 25.39[p]	33.52 (18.61-60.09)[q]	4.72 ± 1.92	29.25 ± 19.88[r]

[a]Baseline versus surgery, $p < 0.001$. [b]Baseline versus surgery, $p < 0.001$. [c]Baseline versus surgery, $p = 0.001$. [d]Baseline versus surgery, $p = 0.010$. [e]Baseline versus surgery, $p = 0.001$. [f]Surgery versus outpatient clinic, $p = 0.005$. [g]Surgery versus outpatient clinic, $p = 0.016$. [h]Surgery versus outpatient clinic, $p = 0.001$. [i]Surgery versus outpatient clinic, $p = 0.001$. [j]Surgery versus ward, $p = 0.007$. [k]Surgery versus ward, $p = 0.006$. [l]Surgery versus ward, $p = 0.006$. [m]Surgery versus ward, $p = 0.408$. [n]Surgery versus ward, $p < 0.001$. [o]Surgery versus administrative work, $p < 0.001$. [p]Surgery versus administrative work, $p < 0.001$. [q]Surgery versus administrative work, $p < 0.001$. [r]Surgery versus administrative work, $p < 0.001$.

during ward visits and administration. In two other participants, the patch lost complete skin contact after two days resulting in data interruptions on the third day. In two other participants, measurements were stopped after two days because of skin irritation. In 16 participants, baseline STAI scores were collected. In 42 of the 63 surgical procedures, STAI was completely filled in before and after the operation. In 21 procedures participants indicated time shortage completing the STAI preparing the next operation.

Stress measurement outcomes

A 40% decrease in SDNN, a 40% decrease in RMSSD, a 64% increase in the LF/HF ratio and a 300% increase in stress percentage were found during surgery in comparison with baseline, indicating increased stress (Table 2). SDNN and RMSSD were decreased and stress percentage increased during surgery in comparison with non-surgical activities (Figure 2). Stress measurement outcomes of non-operative activities did not differ between each other or from baseline.

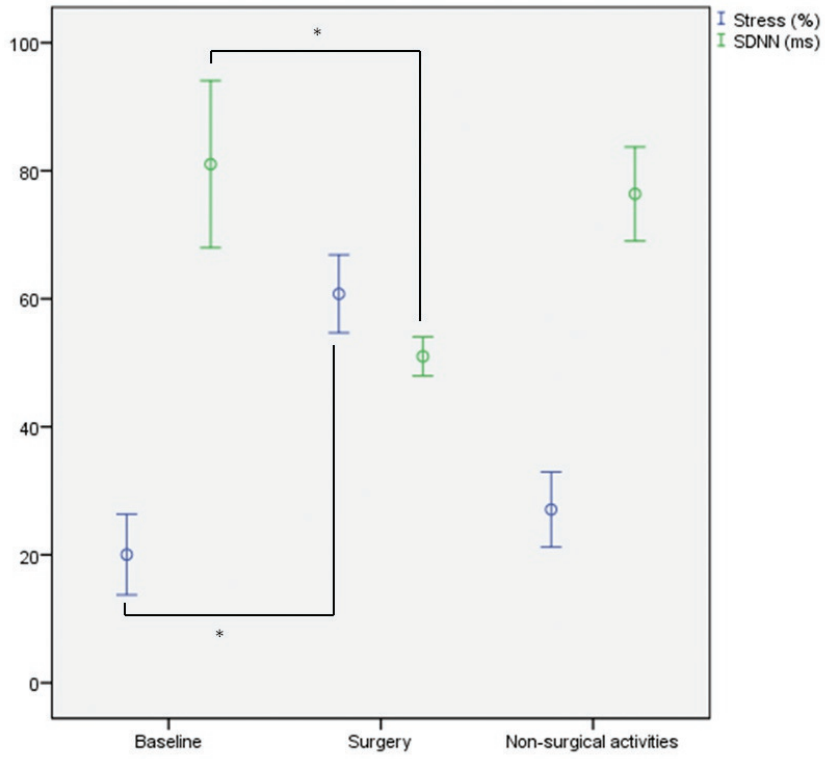

Figure 2 Mean stress percentage and SDNN with 95% confidence intervals between activities. *p < 0.001.

Demographic and surgical factors

Baseline stress measurements outcomes were comparable between men and women (Table 3). SDNN and RMSSD were significantly lower in women compared to men during surgery, also when excluding the two pregnant females and the male using betablockers. SDNN, RMSSD, LF/HF ratio, and stress percentage were comparable between long and short surgical procedures (50.58 ± 14.18 vs. 51.23 ± 10.97, p = 0.250; 25.94 (14.53-54.21) vs. 23.46 (13.14-51.70), p = 0.697; 6.33 ± 3.38 vs. 6.10 ± 2.89, p = 0.526; 63.43 ± 23.82 vs. 59.34 ± 24.58, p = 0.451, respectively). During surgery, fellows and senior residents had higher stress percentages and lower SDNN and RMSSD scores than consultants (Table 4; Figure 3). Lower RMSSD scores were also found in junior residents. These results indicate higher stress during surgery by less experienced participants. Three examples of the stress course of a day of operations and of outpatient clinic activities combined with debriefing data are given in Figure 4.

Stress perception

Baseline STAI score was higher in men than in women (9.67 ± 1.66 and 6.70 ± 0.95; p = 0.001). Levels of experience did not affect baseline STAI score. Significant difference was found between baseline STAI scores and preoperative STAI scores (8.38 ± 2.03 vs. 10.12 ± 2.85; p = 0.043). Fifteen of the 42 surgical procedures with complete STAI data were identified as stressful. Gender or level of experience did not differ between perceived stressful and non-stressful procedures. SDNN, RMSSD, LF/HF ratio and stress percentage did not differ between stressful and nonstressful procedures (48.05 ± 7.09 vs. 51.47 ± 11.86, p = 0.250; 25.34 (16.19-37.79) vs. 21.00 (13.14-54.21); p = 0.705; 6.13 ± 3.37 vs. 7.08 ± 3.32, p = 0.386; and 61.00 ± 22.93 vs. 61.98 ± 24.63, p = 0.898, respectively). Delta STAI scores did not correlate with SDNN (r = -0.212, p = 0.178), RMSSD (r = 0.022, p = 0.892), LF/HF ratio (r= 0.033, p = 0.835) and stress percentage (r = -0.046, p=0.771).

Table 3 HR, HRV and stress percentage between men and women

	Baseline		Surgery	
	Men	**Women**	**Men**	**Women**
Heart rate (bpm) – median (min-max)	68.57 (48.65-84.69)	70.61 (59.50-75.46)	86.18 (62.32-106.42)[a]	94.73 (68.98-120.38)[a]
SDNN (ms) – mean ± SD	87.94 ± 30.31	72.57 ± 23.41	54.69 ± 11.66[b]	46.67 ±11.26[b]
RMSSD (ms) – median (min-max)	47.98 (22.00-131.70)	31.29 (22.57-77.78)	27.75 (16.19-54.21)[c]	21.00 (13.14-42.69)[c]
LF/HF ratio – mean ± SD	3.95 ± 2.76	4.00 ± 2.31	6.22 ± 3.16	6.13 ± 2.96
Stress (%) – mean ± SD	16.63 ± 12.25	24.19 ± 14.45	55.35 ± 20.56	67.12 ± 26.86

SDNN = standard deviation of the R-R intervals; RMSSD = square root of the mean R-R interval; LF = low frequency; HF = high frequency. [a]p=0.050. [b]p=0.007. [c]p=0.001.

DISCUSSION

Continuous stress monitoring in surgeons and surgical residents using a new, small and light weighted, wearable sensor patch reveals relevant and almost complete data on stress levels of surgeons and residents during their workday. Performing an operation was more stressful than other daily activities, particularly for fellows and residents, and based on different stress calculations. The patch did not interfere with the activities and was well tolerated by most participants, and measured actual time-related stress levels differences during real life situations, whereas a common subjective stress evaluation (STAI) did not find any difference.

Table 4 Recordings during surgical procedures; divided by level of experience

	Consultants (n=5)	**Fellows and senior residents (n=7)**	**Junior residents (n=8)**
Heart rate (bpm) – median (min-max)	75.00 (62.32-97.17)[a, e]	93.53 (71.18-120.38)[a]	88.98 (71.54-107.10)[e]
SDNN (ms) – mean ± SD	59.47 ± 13.82[b]	48.05 ± 10.38[b]	50.36 ± 11.68
RMSSD (ms) – median (min-max)	31.55 (22.75-38.27)[c, f]	20.55 (13.14-54.21)[c]	22.54 (13.69-51.70)[f]
LF/HF ratio – mean ± SD	5.60 ± 1.61	6.59 ± 3.41	6.02 ± 3.16
Stress (%) – mean ± SD	42.76 ± 22.76[d]	70.56 ± 18.09[d]	58.60 ± 25.90

SDNN = standard deviation of the R-R intervals; RMSSD = square root of the mean R-R interval; LF = low frequency; HF = high frequency. [a]Consultants versus Fellows and senior residents, p=0.001. [b]Consultants versus Fellows and senior residents, p=0.024. [c]Consultants versus Fellows and senior residents, p=0.018. [d]Consultants versus Fellows and senior residents, p=0.003. [e]Consultants versus Junior residents, p=0.002. [f]Consultants versus Junior residents, p=0.036.

We used various calculations for determining stress levels based on heart rate and heart rate variability data and the real time depicted stress percentage. Stress percentage results compared well with the calculated data. This outcome favors the use of stress percentage level as indicator of stress with this patch because this parameter is real time depicted, easy to read, can show rapid changes and is independent of physical activity. For the first time continuous (self)monitoring of stress for a long period is possible which could not be achieved with existing methods such as the Imperial Stress Assessment Tool and saliva cortisol.[33] Parameters for parasympathetic and sympathetic activity (LF and HF) showed less significant differences and only between operations and baseline values. LF/HF ratio is more sensitive for artifacts and is less reliable over shorter periods.[42] However, results should be interpreted with caution due to low numbers in subgroup analyses and possible inaccuracy in LF and HF data with a relatively low sample frequency of the patch.

High stress levels during operations have been reported[24,26-30] but comparisons with other daily activities was not yet examined. Performing an operation gave more mental stress than activities at the ward and the outpatient clinic, or when doing administration. Interpretation of these differences should be done with caution. Less than half of the participants had outpatient clinic or ward activities during the days the patch was worn and there could have been a selection bias in other activities. Also one period of administrative activity per person was taken into account albeit representative for these activities. Previous studies also showed lower stress levels in experienced surgeons in comparison with younger colleagues.[13,29,43-48] This is possibly explained by differences in coping strategies.[10] Consultants seem more capable of recognizing internal signals indicating stress, such as

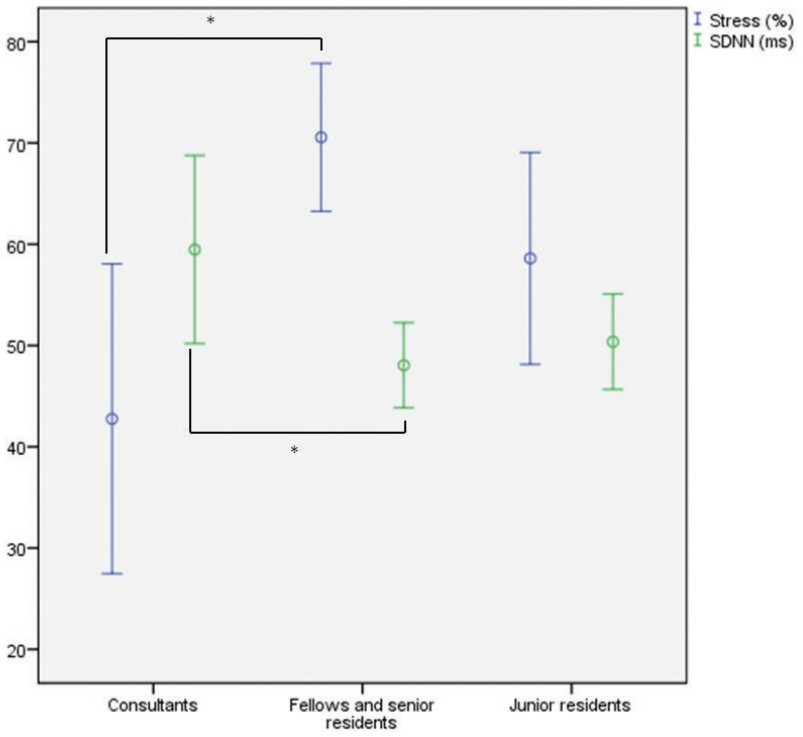

Figure 3 Mean stress percentage and SDNN with 95% confidence intervals between levels of experience. *p < 0.001.

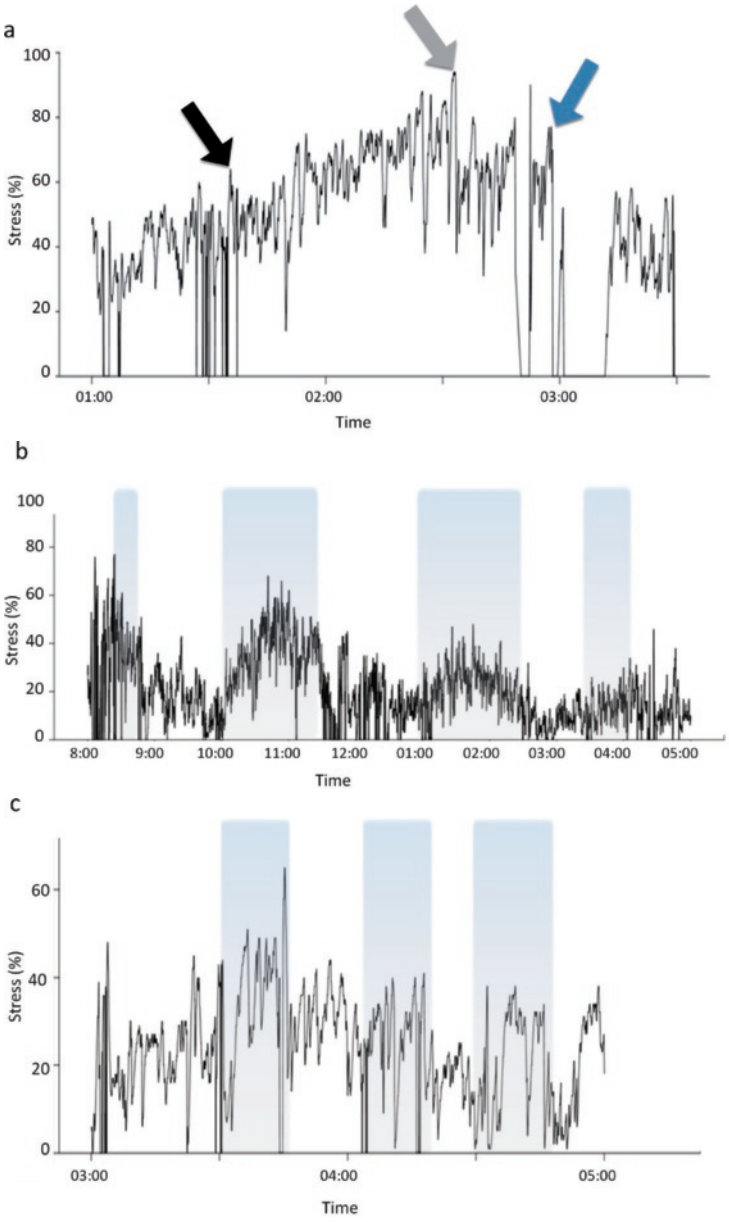

Figure 4 a: Stress pattern (%) of a fellow during a surgical procedure (hemihepatectomy). Black arrow indicates start of operation; grey arrow indicates when senior surgeon enters the OR for supervision; blue arrow indicates end of the hardest part of the operation. **b:** Stress pattern (%) of a consultant during four surgical procedures (blue areas). **c:** Stress pattern (%) of a consultant during an afternoon of outpatient clinic. Blue areas indicate administrative work in between patient contact using a newly introduced electronic medical record system. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

heart pounding and clouded judgment, and may have developed better coping strategies to deal with stress by for example physical relaxation methods, distancing techniques and self-talk. In contrast to senior residents and fellows, no significant difference in stress levels was found between consultants and junior residents. This could possibly be explained by the fact that junior residents operate under more supervision than senior residents and fellows.

The increased stress during operation may be considered as 'good stress', reflecting increased focus. We cannot rule out that some elevations of the stress are due to increased focus and excitement. Due to the small sample size we could not analyze stress data in relation to intra operative problems, which might indicate 'bad stress'. However, we observed long lasting stress levels during surgery corresponding with increased stress levels during other, potentially, more relaxing activities in some individuals, which may indicate 'bad (chronic) stress'.

It was not an aim of this study to validate objective stress measured by this device against a subjective self perceived stress by the STAI questionnaire. We, however, compared outcomes of these two different stress measurements to have an impression about their relationship. As shown in the results section no correlation was found between subjective and objective stress measurements. Underreporting of perceived stress in general and specifically in surgical specialists has been reported.[49] Perceived stress might have been affected by a short moment of the procedure and is dependent on recollection after the operation, whereas objective stress calculations encompassed the total operation and were expressed in mean or median. In contrast to STAI the device is potentially more suitable to pick up more and longer 'unnoticed' stress moments which is relevant for determination of chronic stress.

Strength of this study is the comparison of stress obtained by continuous registration, between all daily activities in a group of surgeons and residents and during two to three days in a row. Combining stress data with notes in the logbooks and daily debriefings also allowed for detailed insight in individual stress patterns. Frequent and long during high stress percentages were found in some individuals and at more than one daily activity (see Figure 4).

The small number of participants, the few demographics obtained and the missing patch and STAI data limited further subgroup analyses for stress risk factors. Measurements prematurely stopped in 20% participants due to patch dysfunction or irritation. The skin irritation in 10% participants would hamper use of the patch for more days in a row. Adhesive patches for sensitive skin are developed and may decrease skin irritation. Future studies should take the limitation of occasional patch dysfunction into account.

Regarding its ability to measure stress continuously and depict stress real time this sensor device has large potential in healthcare, both for healthcare workers and patients, both in daily practice and in a training environment, and both for an individual and a team effort. Particularly trainees may benefit recognizing stressors and stressful situations real time and learning to cope with or prevent stress. Operating room team simulation training using the patch in all participants would allow residents and consultants to train various crisis situations, to experience stress and to reflect on the consequences regarding quality and safety of the

operation. Other potential application is the early and simple assessment of chronic stress in patients and healthcare workers by computer analysis of continuous or serial time periods of patch data. Other means for chronic stress analysis such as hair analysis are costly and still need validation.[50,51] Ongoing studies focus on stress monitoring in trainees and faculty during surgical simulation training and in patients and nurses at the surgical ward.

CONCLUSION

Continuous stress monitoring in surgeons and residents using a simple, easy to wear sensor patch reveals real time data on different stress levels of surgeons and residents during the day. With this new technique we could demonstrate that performing an operation is more stressful than other daily activities in the hospital, particularly with less surgical experience. The stress percentage allows for real time feedback of the stress level making the sensor patch suitable for a widespread application in healthcare.

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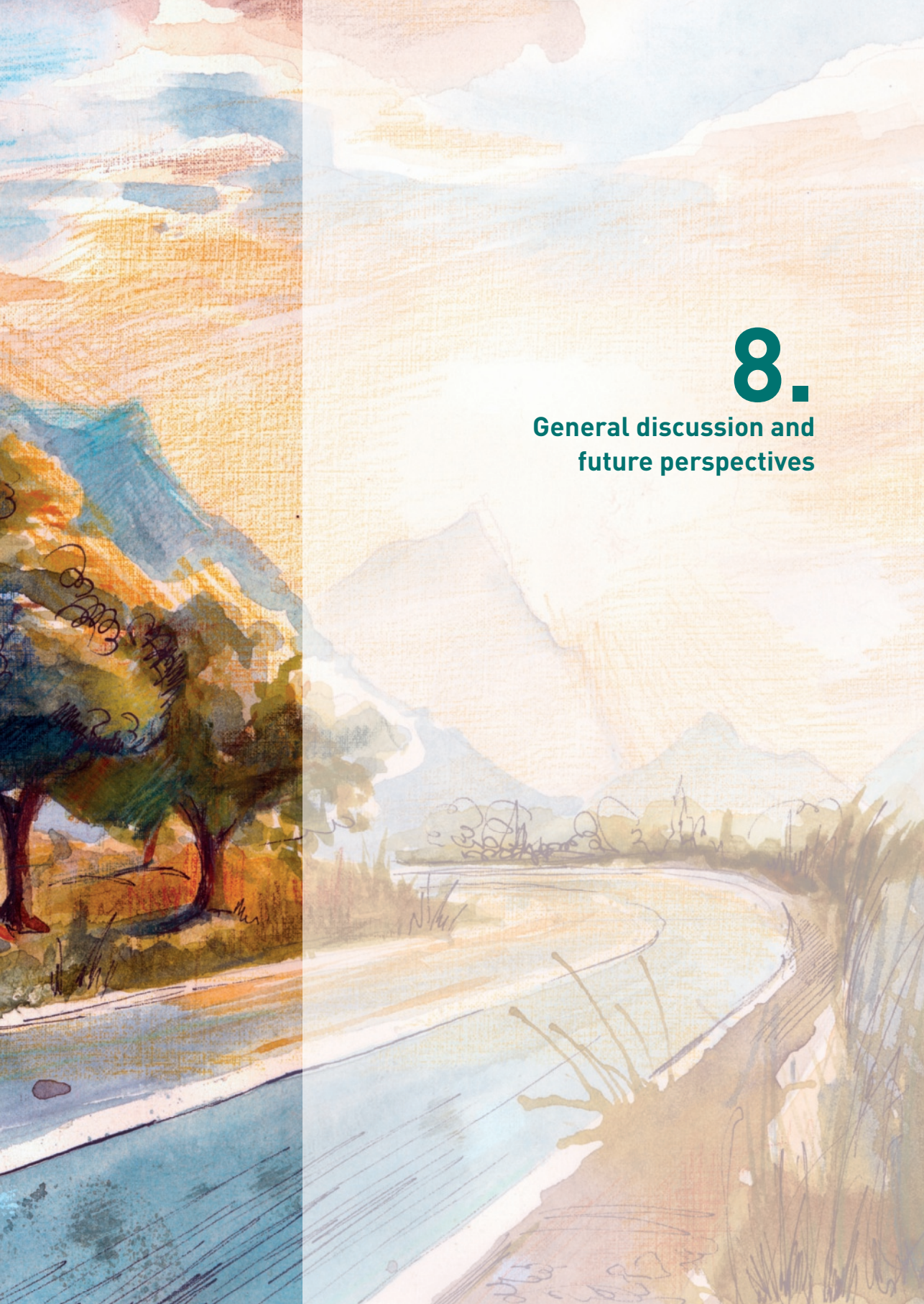

8.

General discussion and future perspectives

GENERAL DISCUSSION

Main findings

In this thesis, we showed that using wearable devices for continuous or intensified periodic monitoring in patients is feasible, that the devices are user friendly and have great potential for early and accurate detection of clinical deterioration in the individual patient. Most studies focused on continuous monitoring using ViSi Mobile and HealthPatch at a surgical and internal medicine ward. Vital sign data obtained by the two devices was comparable with measurements by nurses. MEWS values calculated from device data were more accurate, mainly the respiratory rates. Patient and care givers share a positive attitude towards continuous monitoring with both devices. They reported early identification of clinical deterioration and increased feelings of safety as benefits. Barriers for device use were different for HealthPatch and ViSi Mobile, for example the ViSi Mobile has several wires and a bulky wrist part. In two studies we showed promising results of the use of the CheckMe device for measuring and intensified periodic monitoring in hypertension. This device is accurate and suitable to be operated by patients, holding promise for use at home. However, some drawbacks were reported considering operability and accuracy that needs to be addressed before routine application in chronic disease management or during rehabilitation.

The HealthPatch was also studied for continuous stress monitoring in healthcare workers and identified meaningful variation in daily mental stress related to work activities and to the level of work experience.

Continuous monitoring at the general ward

Patient perspective

High user-friendliness of a wearable monitoring device is a prerequisite for sustainable use in- and outside the hospital by healthcare workers and by patients. Although patient acceptance is crucial for successful implementation of a new wearable device,[1] only few studies investigated this.[2] We showed that patients appreciate the ViSi Mobile and the HealthPatch, although several barriers regarding user friendliness still have to be addressed, such as the ViSi Mobile wires crossing the arm and chest, and the loss of skin contact of the HealthPatch in some individuals. Sotera Wireless (San Diego, USA) soon will launch a next version of the ViSi Mobile which is smaller, weighs less, and contains only one wire. Although the HealthPatch is small and often goes unnoticed by patients, it does not measure all vital signs which are at present deemed necessary for adequate in-hospital safety monitoring. However, it is expected that not all vital signs need to be measured continuously for proper clinical judgment in each patient or at any time.[3] The type of device and the number of vital signs to be monitored might be selected on the actual clinical condition and comorbidity of the patient, the (change in) severity of his condition and the type of the intervention. This may allow for more personalized and precise patient monitoring.

Continuous monitoring can result in earlier identification of clinical deterioration, improved survival and shorter hospital length of stay, but does not seem to affect the number of admissions to the Intensive Care Unit (ICU) and adverse events.[4,5] However, design, setting and methodology of the few studies performed show relevant flaws: small sample sizes, no randomized controlled trials,[4] use of devices without adequate alarming system[6] or devices with multiple wires and connections reducing patient mobility.[5,7] Good quality trials and large data base analyses may provide solid evidence for scaled up implementation of continuous monitoring at the general ward. Our group recently started to collect data of patients on 60 hospital beds (30 at the gastro-intestinal surgery and surgical oncology ward and 30 at the internal medicine ward), who are continuously monitored with the ViSi Mobile system, to provide answers to questions regarding relevant efficacy and safety outcomes. Initial experiences point into the direction that availability of continuous vital sign risk scoring improves awareness of deterioration of patients but is insufficient to early predict adverse events. Predictive analytics using artificial intelligence have potential to early identify a patient at risk for developing an adverse event.[8] Although the number of predictive analytic systems rapidly increases in healthcare, only few address the effect of early prediction on patient outcome.[9] Clearly, more research is needed in this field focusing not only on prediction of deterioration but also on improvement. The latter may have beneficial organizational and logistic impact for example appropriate and timely discharge from hospital to home and reduction of readmissions.

Availability of continuous (remote) monitoring at home could accelerate discharge and allow patients to rehabilitate in their own environment. However, ViSi Mobile will be less suitable for home monitoring due to its bulkiness and wires, and the necessity to daily calibrating. The HealthPatch is more comfortable and user friendly with potential for home monitoring as part of the continuously monitored patient journey from home to hospital and from hospital to home (see Figure 1). Obviously only selected patients may benefit from HealthPatch monitoring due to its limited features and impossibility to measure blood pressure. The whole concept of a continuously monitored patient journey with alternation of different wearable devices where appropriate is in its infancy and needs further clinical and socioeconomic exploration.

Nurse perspective

Success of continuous monitoring of vital signs strongly depends on nurses' engagement with the technology, starting with making them familiar with the technology and its purposes.[2,10,11] Lack of familiarity often leads to the perception of increased workload.[2] Our preliminary experience to achieve widespread acceptance is that nurses should be involved from the beginning in all phases of preparation and implementation and preferably take part in clinical validation of the technology. Nurses should be trained in a simulated setting before use in patients, with frequent evaluations of retention of knowledge and skills. Such approach ensures that nurses feel more confident using the technology.[2,12] New generation nurses are

expected to be intuitive and comfortable using new (digital) technology also as a result of new educational initiatives such as the 'Nursing and Technology' program.[13]

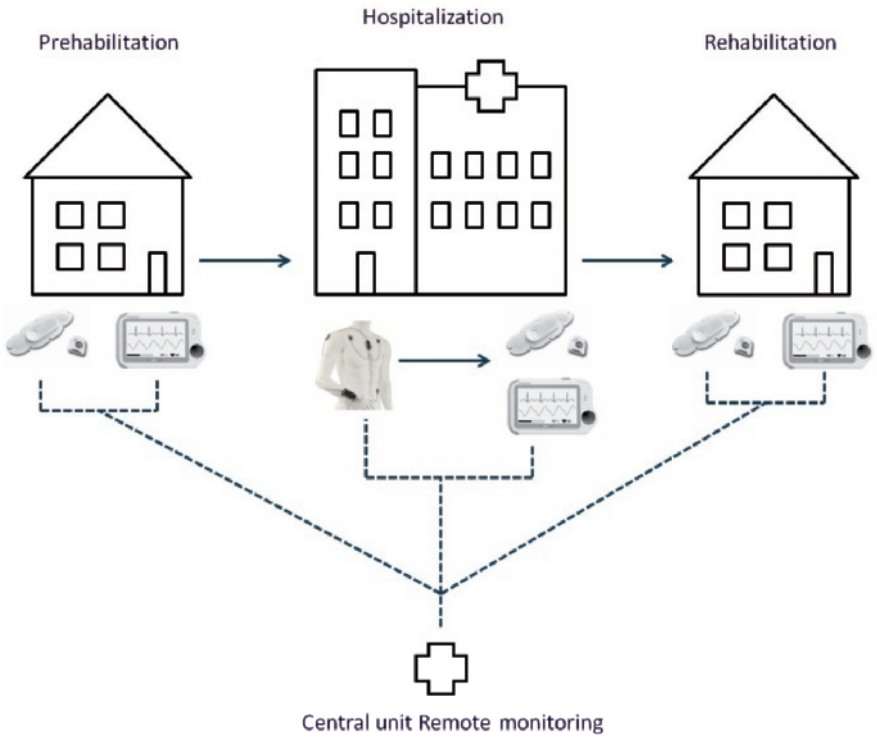

Figure 1 Patient journey.
Personalized vital sign monitoring in the hospital (example of elective surgical procedure): 'heavy' monitoring using the ViSi Mobile, 'light' monitoring using HealthPatch and CheckMe. Note, the original HealthPatch is shown here.

Manual vital sign measurement contributes to the workload of nurses. Monitoring with devices is expected to reduce workload, allowing nurses to spend time on other care tasks and important social interaction with patients. A specific type of workload that can be reduced by continuous monitoring with wearable devices is care of patients who stay in contact-isolation rooms e.g. MRSA, tuberculosis, stem cell transplantation. At present, a nurse has to dress up in a gown, cap, mask and gloves three times a day for only ten minutes of vital sign measurements.
The main barrier of continuous monitoring for nurses is the alarm burden which can result in alarm fatigue and unsafe care[2,12] An alarm can occur due to technical failure of the continuous monitoring system or due to real abnormalities of vital signs. Part of the technical failures is dealt with automatically by the device and used software. It is expected that this automatic

correction will increase with better devices and more intelligent software. Recently, machine learning algorithms have been reported reducing the number of clinically irrelevant alarms in high care patients.[14-16] The burden of 'real' alarms depends on the disease severity of the patients monitored and (the possibility of) individual alarm settings. There were on average 10 alarms per day per patient with ViSi Mobile at a combined medical surgical ward, which was considered acceptable regarding appropriate balance between number of alarms and risk of alarm fatigue.[17] For more elaborated patients with a higher prevalence of deterioration and complications at a general ward the alarm burden and (risk of) alarm fatigue needs to be established and is part of our future research on continuous monitoring. Nurses fear that continuous monitoring leads to a shift of more complex patients to the general ward than at present, specifically an earlier step down from high care. This fear should be addressed before implementing continuous monitoring at the general ward taking into account the significantly lower nurse/patient ratio compared to high care units and the lower educational and experience level regarding management of a critically ill patient. Less time for interaction with a patient due to a low nurse/patient ratio, particularly at night, carries the risk of overreliance on continuous monitoring, which has shown to be a risk factor for missing clinical deterioration.[18]

Hospital

Important considerations for implementing continuous monitoring by a hospital organization are the quality of care improvement and associated costs. Both are scarcely investigated particularly considering relevant patient outcomes. Slight et al. implemented a monitoring system at the general ward and found it to be cost-effective regarding hospital length of stay and ICU length of stay.[19] The system was installed at a 33-bed medical surgical ward and data were gathered for a 9-month period before and 9-month after implementation. The total hospital length of stay and ICU length of stay was reduced with 801 and 128 days, respectively. To be cost-effective, authors stated that it is essential that nurses promptly react to generated alarms for patients with signs of clinical deterioration and that a Rapid Response Team is available to treat these patients. Effect of the alarms on nurses' workload and alarm fatigue were not investigated, underestimating the drawbacks of monitoring in this paper.

A clear picture of the potential harm as well as the benefit is important for decision making regarding wearable device monitoring.[20] Harm can vary from skin allergy to false results of measurements. Approval of wearable devices by notifying bodies, such as the Food and Drug Agency (FDA), is mandatory to minimize the hazards and risks of a new wearable device and accessory software. Medical devices receive extensive scrutiny before FDA approval and manufacturers are obligated to report any adverse event regarding the device after approval, which could eventually result in device recall and great loss of investment. The costly undertaken of research, FDA approval and device performance surveillance could explain why particularly start-up companies primarily aim at the lifestyle market with devices that are potentially suitable for medical use.

The rapid development of devices makes it difficult for a hospital to purchase a device that is up to date for a longer period of time. In the studies, we used a Toughbook connected with the ViSi Mobile by Bluetooth which resulted in many disconnections and artifacts. At present there is a direct connection to our well-functioning and large capacity Wi-Fi network. The old version of ViSi Mobile is heavier in weight and has multiple wires connected to chest sensors compared to the new version. Also, the new version contains arrhythmia detection software which holds promise for use in cardiac patients. Present algorithms of ViSi Mobile are not robust enough for measuring (sudden changes in) body temperature and blood pressure, which drawback is announced to be dealt with in a next version.

The current battery life of ViSi Mobile of about 12 hours implies that at least two batteries are needed per patient for 24 hours continuous monitoring. This increases the purchase costs of the device and nurse's workload. Low power consumption and high energy efficiency are required for long-term monitoring devices.[21,22]

The data produced by the devices contains private and sensitive medical information. The Wi-Fi system must securely transmit data between patient and the location of storage, such as the electronic health record (EHR), according to current legislation.[23] All these barriers should be taken into account when hospitals aim at purchasing wearable devices for continuous monitoring. Some important barriers and solutions and/or requirements are listed in table 1.

Table 1 To be considered by a hospital before purchasing wearable devices for continuous monitoring at the general ward

Barrier	Solution / requirements
Transmission and storage of a large amount of sensitive patient information	Strong and secured Wi-Fi system and Electronic Health Record (EHR) System
Resistance of nurses and physicians to use new monitoring technology	- Formation of a team with super-users - Early engagement of personnel - Adequate training of medical personnel - Easy-to-use device
Short battery life time of device	- Low power consumption - Other energy techniques (e.g. body heat) - Battery change protocol
Storage and analysis of 'big data'	Selection of analyzed data for storage in the EHR
High purchase costs	- Cost-effectiveness analysis - Rental/lease options
Earlier patient discharge from ICU to general ward	Appropriate agreements and proper guidelines regarding patient transfer between wards
False positive alarms generated by devices; alarm fatigue	- Better software and algorithms - Possibility of individual thresholds

We learned that early installing a multidisciplinary team to prepare for implementing continuous monitoring with a wearable device at the general ward is crucial for adoption of this new technology by healthcare workers and patients. Table 2 shows the composition of such team and the general description of the activities of each team member.

Table 2 Multidisciplinary team composition before implementation of wearable devices for continuous monitoring at the general ward

Member	Activities
Super-user	- Training nurses and physicians for appropriate use of devices
IT specialist -CIO -CMIO -Data Security specialist	- Preparing and installing the IT infrastructure and data security measures - Preparing connection to EHR
Medical technology specialist	- Purchasing and testing hardware (server, monitors, adapters etc) - Support in case of technical issues
Physician and nurse	- Preparing care protocols e.g. alarm management - Sharing experiences with colleagues
Research team	- Preparing research protocols and IRB agreement
Project manager	- Project planning e.g. milestones, deliverables, meetings
Strategic buying department (e.g. lawyers)	- Preparing contracts e.g. purchase conditions
Patient	- Input on care and research protocols e.g. evaluation
Communication department	- Preparing internal/external communication plan

Intensified periodic monitoring

The CheckMe is a promising device for frequent measuring vital signs of and by patients inside and outside the hospital. Recovering patients at the general ward are able to reliably monitor their own vital signs, which leads to an increased number of observations, increased patient self-management and autonomy, and a reduced workload for nurses.

The CheckMe has potential as home self-measurement device by patients with chronic diseases. This could give a more authentic representation of the patient's condition and could reduce costs due to a shorter hospital length of stay.[24] An initial study of 12 patients with hypertension shows feasibility in blood pressure measurement at home and good comparison with available cuff dependent devices.[25] However, for full potential some serious limitations of the CheckMe have to be addressed and more research on accuracy in all conditions is needed, and research including cost-effectiveness. Calibration of blood pressure is cumbersome and may fail due to cold or shivering fingers. Other drawback is the inability to measure respiratory rate and diastolic blood pressure. Particularly respiratory rate seems important for prediction

of deterioration in chronic disease such as COPD exacerbation,[26] and prediction of sepsis[27] and cardiac arrest.[28,29] Although systolic blood pressure alone is a good predictor of risk of cardiovascular events, the combination of both systolic and diastolic blood pressure has shown to improve the risk prediction with subsequent treatment reducing cardiovascular events.[30] The next version of the CheckMe is announced to have a more simplified calibration protocol and addition of diastolic blood pressure measurement. With increased user friendliness and the added features, CheckMe favorably compares with several other home devices currently marketed for self-control by patients with hypertension,[31] diabetes mellitus,[32,33] and chronic obstructive pulmonary disease.[34] Possibility of connection with an online personal health record allows patients to upload their medical data and to share this with their care givers either in or outside a hospital. Access to own medical data has shown to improve self-management[35,36] and therapy adherence.[37] Furthermore, clinical outcome of several chronic diseases improves, such as better blood glucose levels in patients with diabetes mellitus.[32,33]

Stress monitoring in healthcare workers

We were able to continuously measure stress levels on the basis of heart rate variability in surgeons and surgical residents using the HealthPatch and to identify inter-individual and within person differences. Providing insight in (chronic) stress levels in surgeons and residents is important because the surgical professional is at high risk for the development of depression, burn out[38,39] and cardiovascular diseases.[40] Abnormal mental stress affects communication, team work and decision making[41,42] and is associated with undesirable events in the operating room and compromised patient safety.[43-46] We expect similar consequences of stress for other (para)medical and nurse professions. Taking into account the importance of the effect of stress on acquiring skills is reflected by stress and stress response adapted training procedures in the aviation and automotive industry.[47-49] Continuous objective stress measurement may benefit effective training and coaching of the healthcare professionals in stress awareness and coping, knowing that some (healthcare) professionals tend to underreport their perceived stress and endanger quality of care.[50] There are several other relevant areas in healthcare for researching and implementing continuous and reliable monitoring of stress for example in disease prevention, patient monitoring, skills training and fit to perform programs.

A change in vendor of the HealthPatch resulted in reduced availability of stress data impeding the repetition of studies regarding stress monitoring. Such actions as mentioned earlier hamper researchers, clinicians and policymakers to select a new device for safe, effective and sustainable use in healthcare. More transparency and open data access and collaboration between academic institutions and enterprises are needed to avoid waist of investments.

FUTURE PERSPECTIVES

The monitored patient journey

With devices becoming more user friendly and proven safe and effective, we foresee that various forms of continuous vital sign (and other parameter) monitoring becomes an important part of the patient journey starting at home, continuing in the hospital and remaining after discharge back at home.

At home

Before a planned hospitalization, for example prior to a major operation, patients need to visit the hospital often more than once and receive advices and treatments to improve their condition by several (para)medical specialties, e.g. physiotherapist, dietician, anesthesiologist, internist. Treatment of pre-existing disorders e.g. diabetes, hypertension and improving the patient' cardiovascular and respiratory condition by exercises prior to hospitalization may reduce the number of adverse events, particularly after complex surgical procedures.[51] These prehabilitation programs are time-consuming and costly and inherit the risk of adverse events during unsupervised exercises at home. Wearable devices embedded in virtual care initiatives such as by ForaHealthyMe Inc.[52] will allow for complete patient prehabilitation at home by remote monitoring and analyses of vital signs and physical parameters and performing virtual consults with physicians and paramedics (see Figure 2).

At the hospital

We expect that during hospitalization the choice of monitoring device and number of measured vital signs will depend on patient's actual disease (state), co-morbidity, type of treatment and predicted risk of adverse events. For example, patients staying at the general ward after complex surgery or after emergency admission and who are prone to deteriorate are monitored more intensively by devices including blood pressure and oxygen saturation. Patients in a better clinical condition and who are able to walk around can measure their own vital signs discontinuously using devices like the CheckMe. More simple devices such as the HealthPatch can be used for continuous monitoring of respiratory and heart rate for example in patients with exacerbation of COPD or during treatment of pneumonia. The selective use of a range of different wearable devices may allow for personalized, efficient, affordable and sustainable vital sign monitoring in a hospital.

When using various devices and software for vital sign monitoring it is mandatory to have one data platform and a connection with the EHR system. This allows for optimal integration with other patient data such as demographics, laboratory results, clinical notes and medication and enables more precise and personalized prediction of adverse events and appropriate actionsto prevent these events. In addition to vital signs, pain, stress, sleep, activity and body posture are clinically relevant parameters for continuous monitoring of disease state and recovery.

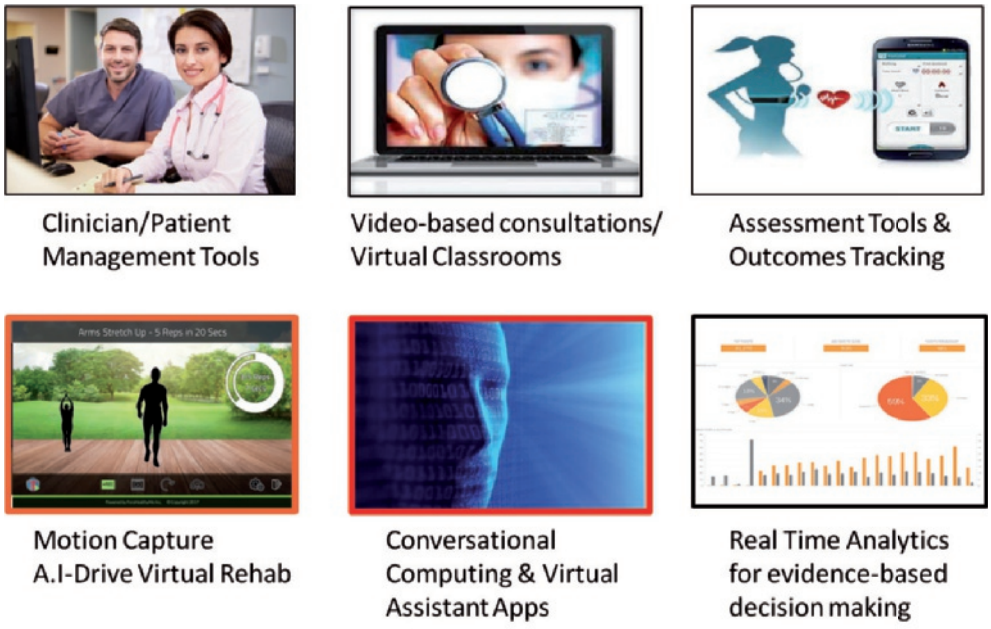

Figure 2 Dashboard Virtual Care pre-and rehabilitation. Courtesy of Courtney Cole, ForaHealthyMe Inc, Markham, Ontario, Canada

Monitoring, analyzing and responding on all these data is undoable for personnel at the general ward and requires a different in-hospital care model. The Radboud university medical center recently took the initiative for a central unit of remote monitoring to analyze and respond to all types of (dis)continuous data coming from (wearable) devices of patients at the general wards. First, the unit will install predictive analytics based on vital signs and focusing on prevention of deterioration.[53,54] A so-called Vital Risk Score (VRS) will be introduced with potential to indicate a trend in data towards deterioration. Second, the unit will direct the rapid response team to the ward based on VRS combined with centrally available other patient data. This central coordination is meant to efficiently organize and to improve quality of acute care of patients at general wards (see Figure 3). At present, the predictive value of the VRS for adverse events is assessed by various studies from our research group. A work protocol to diagnose and treat patients with increased risk of deterioration based on VRS will be drafted and the subsequently altered way of work by nurses and doctors at the ward and by rapid response team members will be explored. Obviously more evidence on safety, efficacy and (lean) organization of (remote) continuous monitoring and predictive analytics for deterioration in hospitalized patients is needed to start implement new care models for nurses and doctors.

Back at home

Small and user-friendly devices monitoring patients at home regarding vital signs and other physical parameters will possibly enable earlier hospital discharge and decrease hospital costs.[24] Moreover, patients will have the opportunity to recover in their own familiar environment, which may improve patients' sleep and reduce stress. The hospital can receive medical data from the patients and sent an alarm in case of deterioration in vital signs and before adverse events occur. For such a remote monitoring and alarming approach, collaboration between hospitals, patients and healthcare workers in primary care should be optimized. It should be clear in particular which professional has to be alerted first in case of deterioration. There is still little experience with organizing care of patients who are discharged from hospital and remain continuously monitored by a hospital when at home.[55,56] Hospitals can learn from existing independent medical service centers monitoring chronically ill patients with heart failure,[57] COPD,[34] hypertension,[31] diabetes mellitus[32] and dementia at home.[58]

Although still a few barriers have to be addressed, e.g. calibration and connection issues, the CheckMe and HealthPatch both might be suitable for home self-monitoring. For example, the HealthPatch could be used to predict hypoglycemia in diabetic patients using heart rate variability.[59] An online platform as mentioned earlier could allow patients to collect their own medical data and share this with their general practitioners and medical specialists.

Patients' access to their own medical data has shown to positively influence self-management,[34,35] improve health outcomes[60,61] and therapy adherence.[37] Furthermore, wireless technology which monitor patients at home could reduce the number of hospitalizations[57] and costs.[62]

For use at home, patients need to receive proper instructions regarding use and technical issues of devices and should be able to easily approach a trained health care worker in case of technical issues and other concerns. This could be a trained nurse in the hospital, but also a trained district nurse or nurse in a nursing home. Also a 24/7 helpdesk is warranted. It is expected that patient acceptance and easy handling of wearable devices will increase in the future since new generations will be more familiar with wearable technology from the lifestyle industry. Monitoring patients at home will also have implications from societal and ethical point of view. The balance should be made between patients' privacy versus the potential benefits of wireless monitoring, such as reduced number of hospital readmissions and early discharge. Sending data from home trough a wireless network might be a serious threat to the privacy of a patient. Also other reasons for privacy issues may arise, such as personal belief and cultural environment.[63] Furthermore, other issues such as the stigma of wearing a wearable device and impact on daily activity should be considered.[12]

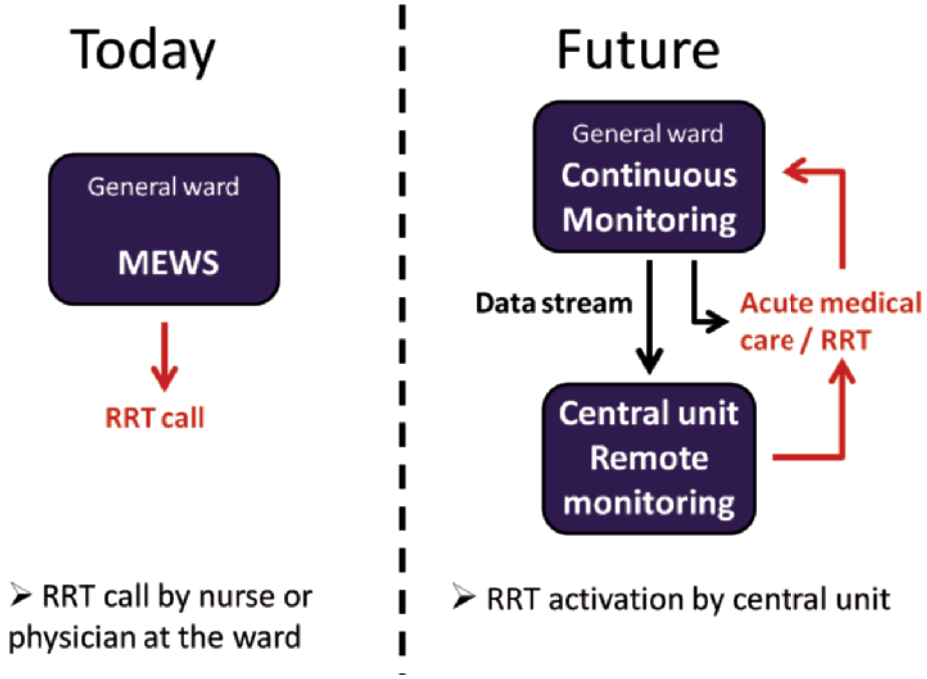

Figure 3 Today's versus future's situation of patient monitoring and RRT activation.

Taken all together future research of continuous monitoring of vital signs and other physical parameters during the patient journey should be broad and in the several domains of healthcare innovation including technical innovation, social innovation and business innovation, in order to provide answers to the many questions existing and coming up in this emerging field of digital health technology.

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9.

Summary
Nederlandse samenvatting

SUMMARY

Introduction

Chapter 1 is the general introduction of this thesis. The focus of the thesis is to evaluate the feasibility of three wearable devices for vital sign monitoring and to give an overview of the user experiences. Measurement of vital signs in hospitalized patients is important to provide insight in the patients' condition and to detect clinical deterioration.[1] Clinical deterioration may lead to admission to the Intensive Care Unit (ICU), a longer hospital stay and mortality.[2,3] To identify deteriorating patients, Early Warning Scores (EWS), such as the Modified Early Warning Scores (MEWS), have been developed for use by care givers.[4,5] However, due to the intermittent nature of the MEWS measurements, clinical deterioration may occur between MEWS measurements and remain unnoticed, particularly during the night when less medical personnel is available.[6,7] Also, mistakes occur due to inaccurate and incomplete documentation in the Electronic Health Record (EHR).[8,9] Repetitive measurements are increasingly important because patients in the hospital become more at risk for deterioration; they are older and undergo more complex interventions.[10,11] Nowadays, continuous and remote monitoring is possible with wearable devices. Most devices are developed for fitness and wellness, but have the potential to monitor patients in and outside the hospital.[12,13] To be suitable for patient monitoring, devices have to meet several demands, such as being able to monitor vital signs accurately and reliably, and to transmit data wireless to the EHR. Furthermore, devices have to be small and comfortable for patients.[14] In this thesis, the use of ViSi Mobile (Sotera Wireless, CA, USA), HealthPatch (original version of VitalPatch; Vital Connect, CA, USA) and CheckMe (Viatom Technology, Shenzhen, People's Republic of China) was evaluated; three devices that entered the healthcare market for intermittent and continuous monitoring of vital parameters.

The following objectives of this thesis were formulated:

1. To evaluate the (technical) feasibility and accuracy of continuous monitoring using ViSi Mobile and HealthPatch on the internal medicine and surgical wards

2. To evaluate the using experiences of ViSi Mobile and HealthPatch by patients, relatives, nurses and physicians

3. To evaluate the accuracy of self-measurement by patients using the CheckMe in the outpatient clinic and on the internal medicine ward

The feasibility of continuous monitoring using ViSi Mobile and the HealthPatch was first tested. The results are described in **chapter 2**. In this pilot study, 20 hospitalized patients at the internal medicine ward and surgical ward were included and wore the ViSi Mobile and HealthPatch for two to three days. Monitored vital sign data by ViSi Mobile and HealthPatch was compared with regular nurse MEWS measurements. Patient and nurse experiences were evaluated.

In total, 86 out of 120 MEWS' measurements by nurses were used for detailed analysis. Vital sign measurements by ViSi Mobile and HealthPatch were generally consistent with nurse measurements. In 30% of the cases, clinically relevant differences in MEWS were found mainly due to inconsistent nurse respiratory rate registrations. The predominant ViSi Mobile artifact was a connection failure in 70% of cases. Over 50% of all HealthPatch artifacts had an unknown cause, were self-limiting and did not take longer than one hour.
It was concluded that ViSi Mobile and HealthPatch are promising for vital sign monitoring at the general ward. The devices were well received and comfortable for most patients.

Based on the results of this pilot study, we conducted a randomized controlled trial (RCT), of which the results are described in **chapter 3**. Focus of this RCT was to identify positive and negative effects, and barriers and facilitators for continuous monitoring using ViSi Mobile and HealthPatch. Ninety hospitalized patients at the internal medicine and surgical ward were included and randomly assigned to ViSi Mobile, HealthPatch or a control group with periodic vital sign monitoring by nurses. Patients' user experiences and expectations and those of their relatives if applicable were evaluated using semi-structured interviews. Nurses, physician assistants and medical doctors involved in care of included patients, were interviewed as well. Interviews were analyzed using thematic content analysis. Patients' stress levels during hospitalization were obtained using questionnaires and were compared between groups.
Data saturation was reached after 60 patients. We analyzed interviews of 20 nurses, 3 physician assistants, and 6 medical doctors. In total, 47 positive and 30 negative effects were identified and 19 facilitators and 36 barriers. Most mentioned topics regarded earlier identification of clinical deterioration, increased feelings of safety, and ViSi Mobile wires and electrodes. No differences were found in patients' stress levels between randomization groups.
The results show a mainly positive attitude towards continuous monitoring and ViSi Mobile and HealthPatch by patients, relatives and caregivers.

Part of this RCT was used to compare vital sign data by ViSi Mobile and HealthPatch with those by nurses. Results are presented in **chapter 4**. Sixty patients at the surgical and internal medicine ward were randomized to continuous monitoring with ViSi Mobile or HealthPatch for 24 to 72 hours in addition to regular nurse measurements of the MEWS. MEWS measurements by nurses were compared with the calculated MEWS based on the ViSi Mobile and HealthPatch data. Vital signs not captured by ViSi Mobile or HealthPatch, such as consciousness and oxygen administration, were taken from nurse registrations to allow for MEWS calculation. Since HealthPatch does not measure oxygen saturation and blood pressure, and both devices are not able to measure core temperature, these measurements were taken from the EHR. The number of high MEWS (defined as MEWS ≥ 6) by ViSi Mobile and HealthPatch in between regular MEWS measurements by nurses were recorded to obtain an impression of potential meaningful deteriorations remaining undetected by nurses.

Median MEWS, measured by ViSi Mobile (2.7 vs. 1.9) and HealthPatch (1.9 vs. 1.3) were higher than by nurse measurements mostly due to differences in respiratory rate measurements. During 1282 hours of ViSi Mobile and 1886 hours of HealthPatch monitoring, 71 (in 14 patients) and 32 (in 7 patients) high MEWS values were detected during the non-observed periods by nurses. Time between a ViSi Mobile and HealthPatch based high MEWS and the next regular nurse measurement ranged from 0 to 10 (ViSi Mobile) and 0 to 9 (HealthPatch) hours.
The results show that the calculated MEWS from vital sign measurements by ViSi Mobile and HealthPatch correspond well with those by nurses. Both devices measure respiratory rate more accurately than nurses. High MEWS based on device measurements are present in hospitalized patients at unobserved periods and may indicate deterioration at an early phase.

The CheckMe is a smart all-in-one device for intermittent vital sign measurement. The CheckMe records systolic blood pressure, oxygen saturation, skin temperature and a 1-lead electrocardiogram. The patient can handle the device himself with potential of better (more frequent measurements; automatic electronic health recording) daily patient monitoring and reduction of nurses' workload. In **chapter 5**, we evaluated the performance of the CheckMe regarding systolic blood pressure measurement in comparison to a reference blood pressure measurement device at the hypertension outpatient clinic. Furthermore, we wanted to investigate whether the posture of the patient and the position of the device relative to the heart level would influence its outcomes. Fifty-two patients were recruited falling into three systolic blood pressure ranges: high (>160 mmHg), normal (130–160 mmHg), and low (<130 mmHg), according to the European Society of Hypertension International Protocol (ESH-IP). All requirements for test environment, observer qualification, patient recruitment, and blood pressure measurements were met according to the ESH-IP for the validation of blood pressure measurement devices. After calibrating the CheckMe device, we measured systolic blood pressure using the CheckMe and using a validated, oscillometric reference blood pressure monitor (RM). Measurements were performed in randomized order both in supine and in upright position, and with CheckMe at and above heart level.
Of the 52 patients, we excluded 15 patients (12 due to calibration failure with Checkme, 3 due to other reasons). The remaining 37 patients fell into low (n=14), medium (n=13), and high (n=10) blood pressure ranges. There were 18 men and 19 women with a mean age of 54.1 (SD 14.5) years and a mean systolic BP at recruitment of 141.7 (SD 24.7) mmHg. The mean difference between the RM and CheckMe was -1.8 mmHg (SD 8.5) in the supine position and 2.6 mmHg (SD 12.1) in the upright position. Systolic blood pressure measured with Checkme above heart level was significantly lower than systolic blood pressure measured supine at heart level (mean 130.7 mmHg, SD 27.7; mean 138.4 mmHg, SD 25.2 respectively).
It was concluded that blood pressure obtained with CheckMe correlates well with RM, particularly in the supine position.

In **chapter 6**, we evaluated self-measurement of vital signs using the CheckMe device compared to trained investigator measurement (gold standard) and nurse measurement to assess if self-measurement is reliable and can replace nurse measurement in future hospital care. Patients admitted to the internal medicine ward were included in this prospective comparative study. Time-related measurement sessions were conducted on consecutive patients in a randomized order: vital sign measurement in duplicate by a trained investigator (gold standard) using an automated blood pressure measuring device, a CheckMe measurement by the patient, and a routine vital sign measurement using an automated blood pressure measuring device by a nurse. Vital signs and calculated MEWS based on patient-operated CheckMe measurements were compared with vital signs and calculated MEWS obtained by nurses and investigator.
In 41 of 50 patients (82%), initial calibration of the CheckMe was successful and results of 69 measurement sessions were eligible for analysis. The temperature results recorded by the patient with the CheckMe differed significantly from the gold standard core temperature measurements (mean difference 0.1 ± 0.3). Obtained differences in vital signs and calculated MEWS were small and were in range with predefined accepted discrepancies.
Patient-calculated MEWS using the CheckMe correlate well with investigator-calculated and nurse-calculated MEWS. The small differences observed between modalities seem insignificant for clinical decision making. Patients can accurately measure their own vital signs using the CheckMe, which may positively affect vital sign monitoring, patient's autonomy and nurse's workload at the general ward.

Surgeons have a stressful profession and excessive levels of stress can jeopardize patient safety and quality of surgical care. Real-time stress measurement may identify stressing situations and activities.
In **chapter 7** we explored stress patterns of surgeons and residents during daily work using the HealthPatch. Consultants and surgical residents wore the HealthPatch for two to three days. The patch measures heart rate variability (HRV) and calculates and displays a real-time stress percentage using a validated algorithm including heart rate (HR) and HRV. The 'patch stress', standard deviation of the interval between two heart beats (SDNN), square root of the mean R-R interval (RMSSD), and ratio between low frequency (LF) and high frequency (HF), and stress percentage, was compared with self perceived stress reporting using the State Trait Anxiety Inventory (STAI). Each participant filled in a logbook including daily activities.
A significant increase in HRV and stress percentage was shown in twenty surgeons and residents during surgery in comparison with other activities (outpatient clinic, ward, administrative work). Consultants showed lower stress levels while operating compared to fellows and residents. Stress according to the patch did not correlate with STAI outcome.
It is concluded that continuous stress monitoring using a wearable sensor patch reveals relevant data on actual stressors of surgeons and surgical residents.

Chapter 8 provides the general discussion and future perspectives.

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NEDERLANDSE SAMENVATTING

Inleiding

De inleiding van dit proefschrift is beschreven in **hoofdstuk 1.** In dit proefschrift vermeldden wij de resultaten van onderzoeken naar het gebruik van twee nieuwe wearable devices voor het continu monitoren van vitale parameters bij opgenomen patiënten en één all-in-one minimonitor voor zelfmetingen door patiënten. Tevens gaven wij een overzicht van de gebruikerservaringen van patiënten en zorgprofessionals.

Het meten van vitale parameters bij opgenomen patiënten in het ziekenhuis is van belang voor het inschatten van de klinische conditie en voor het detecteren van klinische achteruitgang.[1] Klinische achteruitgang kan leiden tot een dure opname op de Intensive Care (IC) met een langere opnameduur tot gevolg en is geassocieerd met een verhoogde kans op overlijden.[2,3] Early Warning Scores (EWS), zoals de Modified Early Warning Score (MEWS), worden doorgaans elke dienst berekend uit vitale parameters die handmatig zijn afgenomen door een verpleegkundige. Deze worden gebruikt om vitaal bedreigde patiënten tijdig te signaleren.[4,5] Echter, doordat de MEWS vaak met ruime tussenpozen wordt bepaald bestaat het risico dat de patiënt klinisch achteruitgaat tussen twee MEWS bepalingen. Hierdoor kan klinische achteruitgang op het moment van voorkomen gemist worden en mogelijk pas laat worden ontdekt. Het grootste risico hierop is gedurende de nacht, wanneer er minder verplegend personeel aanwezig is.[6,7] Een ander nadeel van handmatig meten van vitale parameters en berekenen van een MEWS is dat er fouten gemaakt kunnen worden, bijvoorbeeld tijdens het invoeren in het elektronisch medisch dossier.[8,9]

Het adequaat en frequent meten van vitale parameters in het ziekenhuis wordt steeds belangrijker omdat de huidige patiëntenpopulatie in het ziekenhuis een toenemend risico loopt op klinische achteruitgang. Dit komt door de vergrijzing, multimorbiditeit en doordat meer complexe (operatieve) ingrepen worden uitgevoerd.[10,11] Continue monitoring zou een mogelijke oplossing kunnen zijn voor bovenstaande problematiek en dit kan tegenwoordig met nieuw ontwikkelde en kleine 'wearable devices'. Een aantal van deze devices wordt primair ontwikkeld voor de consumentenmarkt maar zouden in een aantal gevallen ook gebruikt kunnen worden voor het monitoren van patiënten, zowel in het ziekenhuis als in de thuissituatie.[12,13] Devices moeten aan verscheidene eisen voldoen voordat ze geschikt zijn voor toepassing in het medische domein. Ze moeten nauwkeurig zijn, voldoen aan strenge kwaliteitseisen en data draadloos kunnen overbrengen naar het elektronisch patiënten dossier. Daarnaast moeten ze klein en comfortabel genoeg zijn om patiënten langdurig te kunnen monitoren.[14] In dit proefschrift evalueerden we het gebruik van drie wearable devices die in staat zijn vitale parameters continu en periodiek te meten: ViSi Mobile (Sotera Wireless, CA, USA), HealthPatch (doorontwikkeld naar de VitalPatch; Vital Connect, CA, USA) en CheckMe (Viatom Technology, Shenzhen, People's Republic of China).

De primaire doelen van de studies in dit proefschrift waren:

1. Evaluatie van de (technische) haalbaarheid en de nauwkeurigheid van continue monitoring van vitale parameters door ViSi Mobile en HealthPatch op twee reguliere verpleegafdelingen (interne geneeskunde en heelkunde)

2. Verzamelen en evalueren van de gebruikerservaringen van patiënten, verpleegkundigen en artsen met ViSi Mobile en HealthPatch

3. Evaluatie van de nauwkeurigheid van vitale parameter metingen met behulp van de CheckMe door patiënten zelf, zowel in een ambulante setting als tijdens een opname op een verpleegafdeling

In **hoofdstuk 2** evalueerden wij de haalbaarheid van continue monitoring door ViSi Mobile en HealthPatch op een reguliere verpleegafdeling. In een pilot studie werden 20 patiënten geïncludeerd op de verpleegafdeling interne geneeskunde en heelkunde. De patiënten droegen zowel de ViSi Mobile en de HealthPatch gedurende de eerste 2 tot 3 dagen van de opname. De gemeten vitale parameters door beide devices werd vergeleken met de handmatig gemeten waarden door de verpleegkundigen en de hieruit berekende MEWS. Ervaringen van verpleegkundigen en patiënten met beide devices werden geëvalueerd.
Van de 120 MEWS metingen door verpleegkundigen bleken 86 MEWS metingen compleet en bruikbaar voor verdere analyse. In het algemeen kwamen de resultaten van de vitale parameters gemeten met de ViSi Mobile en HealthPatch overeen met die van de handmatige metingen door de verpleegkundigen. In 30% van de gevallen bleek de berekende MEWS verschillend, voornamelijk door verschillen in gemeten ademhalingsfrequentie tussen verpleegkundigen en beide devices. Er traden gedurende het continu monitoren bij beide devices artefacten op. Bij de ViSi Mobile metingen werd 70% hiervan veroorzaakt door connectieproblemen tussen het device en het platform (laptop). Bij de HealthPatch werden kortdurende onderbrekingen (tot maximaal een uur) waargenomen. In meer dan 50% van de gevallen was dit van onbekende oorzaak en loste het probleem zich meestal vanzelf op. De meeste patiënten waren enthousiast over het gebruik van de ViSi Mobile en HealthPatch en vonden de devices comfortabel. Uit deze resultaten trokken we de conclusie dat ViSi Mobile en HealthPatch veelbelovend zijn voor het continue monitoren van vitale parameters op de verpleegafdeling.

Op basis van de resultaten van de pilotstudie ontwierpen we een randomized controlled trial (RCT), waarvan de resultaten worden beschreven in **hoofdstuk 3**. In deze studie evalueerden we gebruikerservaringen en verwachtingen ten aanzien van het gebruik van ViSi Mobile en HealthPatch voor continue monitoring. In totaal includeerden we 90 patiënten op de verpleegafdelingen interne geneeskunde en heelkunde. Deze patiënten werden gerandomiseerd in drie groepen, namelijk 1) monitoring met ViSi Mobile, 2) monitoring met HealthPatch en 3) een controlegroep (alleen reguliere MEWS bepaling door verpleegkundigen).

Positieve en negatieve effecten en belemmerende en bevorderende factoren voor het gebruik van beide devices voor continue monitoring werden in kaart gebracht door middel van semigestructureerde interviews. Behalve patiënten en eventuele familieleden interviewden we ook verpleegkundigen, physician assistants en artsen die betrokken waren bij de zorg van de geïncludeerde patiënten. De interviews werden geanalyseerd door middel van thematische inhoudsanalyse. De mate van ervaren stress door patiënten werd gemeten door middel van vragenlijsten en vergeleken tussen de drie groepen.
Dataverzadiging werd bereikt na analyse van 60 patiënten interviews. Tevens analyseerden we de interviews bij 20 verpleegkundigen, drie physician assistants en zes artsen. We identificeerden in totaal 47 positieve en 30 negatieve effecten, en 19 bevorderende en 36 belemmerende factoren. De meest genoemde onderwerpen waren het eerder ontdekken van klinische achteruitgang, gevoelens van veiligheid en de lijnen en elektrodes van de ViSi Mobile. We vonden geen verschillen in ervaren stress door patiënten tussen de verschillende groepen. De resultaten lieten zien dat patiënten, familieleden en zorgverleners overwegend positief staan tegenover het gebruik van ViSi Mobile en HealthPatch voor continue monitoring.

Deze RCT werd ook gebruikt om de kwantitatieve resultaten van gemeten vitale parameters door ViSi Mobile en HealthPatch te vergelijken met gemeten vitale parameters door verpleegkundigen. De resultaten van deze vergelijking zijn beschreven in **hoofdstuk 4**. Zestig patiënten van de verpleegafdelingen interne geneeskunde en heelkunde waren gerandomiseerd voor continue monitoring door middel van ViSi Mobile of HealthPatch gedurende 24 en 72 uur. Tevens werden bij hen de reguliere metingen en MEWS berekening door verpleegkundigen verricht. Uit de vitale parameters gemeten door ViSi Mobile en HealthPatch werd een MEWS berekend en vergeleken met de MEWS op basis van metingen door verpleegkundigen. De resultaten van vitale parameters die niet gemeten konden worden door ViSi Mobile en HealthPatch, zoals bewustzijn en zuurstoftoediening, werden uit het elektronisch patiëntendossier geëxtraheerd. Daarnaast meet de HealthPatch geen zuurstofsaturatie en bloeddruk en meten beide devices huidtemperatuur in plaats van kerntemperatuur. Derhalve werden ook de resultaten hiervan verkregen uit het elektronisch patiëntendossier. Het aantal hoge MEWS (gedefinieerd als een MEWS ≥ 6), gemeten door ViSi Mobile en HealthPatch tussen de reguliere metingen van de verpleegkundigen werden geregistreerd. Hiermee werd een indruk verkregen van het voorkomen van situaties van potentiële klinische achteruitgang in de periode tussen de reguliere verpleegkundige metingen die mogelijk ook langdurig onopgemerkt zouden zijn gebleven. De mediane MEWS, berekend op basis van de ViSi Mobile (2.7 vs. 1.9) en HealthPatch (1.9 vs. 1.3), was hoger dan de MEWS gemeten door verpleegkundigen. Dit kwam voornamelijk door verschillen in gemeten ademhalingsfrequenties. In totaal werd met ViSi Mobile 1282 uur en met HealthPatch 1886 uur gemeten. Hierbij vonden we respectievelijk 71 (bij 14 patiënten) en 32 (bij 7 patiënten) hoge MEWS waarden (≥ 6) tussen de reguliere MEWS metingen van verpleegkundigen. De tijd tussen zo'n hoge MEWS meting en de eerstvolgende reguliere meting door de verpleegkundige kon oplopen tot 10 uur.

Hieruit valt op te maken dat de MEWS, berekend uit vitale parameters gemeten door beide devices goed correleert met de MEWS berekening door verpleegkundigen op het moment van hun metingen. Wel varieerde de ademhalingsfrequentie gemeten met de devices veel meer dan de meting door verpleegkundigen, waardoor de MEWS op basis van de devices regelmatig hoger uitviel. De indruk bestaat dat de ademhalingsfrequentie door beide devices betrouwbaarder gemeten wordt dan door verpleegkundigen. Tevens werd geconcludeerd dat tussen de reguliere MEWS meetmomenten er met continue monitoring frequent hoge MEWS uitslagen zijn die aanleiding zouden hebben gegeven tot inschakelen van een IC-team indien opgemerkt. Mogelijk kan continue monitoring met de ViSi Mobile en HealthPatch klinische achteruitgang al in een vroegere fase detecteren.

The CheckMe is een klein 'all-in-one' device waarmee de patiënt zelf zijn eigen vitale parameters kan meten. Het device meet de systolische bloeddruk, zuurstofsaturatie, huidtemperatuur en maakt een eenvoudig electrocardiogram. Frequente zelfmeting door de ambulante patiënt met bijvoorbeeld de Checkme kan leiden tot betrouwbaardere meetresultaten dan eenmalige meting op een polikliniek. In **hoofdstuk 5** rapporteerden we de resultaten van een studie waarbij we de systolische bloeddruk, gemeten door de CheckMe, vergelijken met die van een referentie bloeddrukmeter op de polikliniek Interne Geneeskunde. Daarnaast onderzochten we de invloed van de houding van de patiënt en de Checkme op de gemeten bloeddruk. We includeerden 52 patiënten met hypertensie, die we onderverdeelden in drie subcategorieën volgens de European Society of Hypertension International Protocol (ESH-IP): hoge bloeddruk (>160 mmHg), normale bloeddruk (130-160 mmHg) en lage bloeddruk (<130 mmHg). Aan alle vereisten voor een vergelijkende studie van een bloeddrukmeter zoals beschreven in de ESH-IP werd voldaan, zoals studie omgeving, patiënt werving en wijze van bloeddrukmetingen. Na het calibreren van de CheckMe werd de bloeddruk gemeten zowel met de CheckMe als met een referentie bloeddrukmeter. Metingen werden verricht in zowel achteroverliggende als in zittende positie in willekeurige volgorde. Van de 52 potentieel geschikte patiënten werden 15 patiënten niet geïncludeerd (12 door calibratie problemen met de CheckMe en 3 om andere redenen). Van de overgebleven 37 patiënten hadden 14 patiënten een lage bloeddruk, 13 patiënten een normale bloeddruk en 10 patiënten een hoge bloeddruk. De studiepopulatie bestond uit 18 mannen en 19 vrouwen met een gemiddelde leeftijd van 54.1 (SD 14.5) jaar. De gemiddelde bloeddruk op moment van inclusie was 141.7 (SD 24.7) mmHg. Het gemiddelde verschil tussen de referentie monitor en CheckMe bedroeg -1.8 mmHg (SD 8.5) in achteroverliggende positie en 2.6 mmHg (SD 12.1) in zittende positie. Wanneer de CheckMe boven harthoogte werd gehouden bleek de systolische bloeddruk significant lager dan wanneer deze op harthoogte werd gehouden (gemiddelde 130.7 mmHg, SD 27.7; gemiddelde 138.4 mmHg, SD 25.2 respectievelijk).
Uit deze gegevens concludeerden we dat er een goede correlatie bestaat tussen de systolische bloeddrukmetingen gemeten door CheckMe en referentiemonitor, met name bij patiënten in achteroverliggende positie. Een formele validatiestudie van dit device konden we niet

verrichten omdat er nog geen protocol bestaat voor de validatie van de bloeddruk van cuffless bloeddrukmeters.

In **hoofdstuk 6** werden door de patiënt gemeten vitale parameters met de CheckMe vergeleken met metingen door een getrainde onderzoeker (gouden standaard) en verpleegkundigen. Doel was te beoordelen of de zelfmetingen met de CheckMe betrouwbaar zijn, zodat in de toekomst Checkme de reguliere metingen door verpleegkundigen kan vervangen. In deze prospectieve vergelijkende studie includeerden we patiënten die werden opgenomen op de verpleegafdeling interne geneeskunde. De verschillende metingen werden in willekeurige volgorde bij elke patiënt verricht: metingen door de getrainde onderzoeker in tweevoud (gouden standaard) met een elektronische bloeddrukmeter, meting met de CheckMe door de patiënt en reguliere meting door de verpleegkundige met een elektronische bloeddrukmeter. De vitale parameters gemeten door de CheckMe en de hieruit berekende MEWS werden vergeleken met de vitale parameters gemeten door de onderzoeker en verpleegkundige.
Calibratie met de CheckMe was succesvol bij 41 van de 50 (82%) geïncludeerde patiënten. Bij deze patiënten konden 69 metingen worden gebruikt voor verdere analyse. We vonden significante verschillen tussen de gemeten temperatuur door de CheckMe en door de onderzoeker (gemiddeld verschil -0.7 ± 0.6). Verschillen tussen de andere vitale parameters, gemeten met de verschillende meetmethoden, waren klein en binnen de van tevoren vastgestelde en geaccepteerde grenzen.
MEWS berekend uit vitale parameters door de CheckMe correleerde goed met de gemeten MEWS door onderzoeker en verpleegkundige. De kleine verschillen die we vonden tussen verschillende vitale parameters lijken niet relevant voor de klinische besluitvorming. We concludeerden dat patiënten met de CheckMe betrouwbaar hun eigen vitale parameters kunnen meten tijdens een opname. Dit kan een positieve invloed hebben op het autonomie gevoel van patiënten in (en buiten) een ziekenhuis en de werkdruk van verpleegkundigen verlagen.

Chirurgen hebben een stressvol beroep. Hoge stress levels, ervaren door chirurgen, kunnen een negatief effect hebben op de patiëntveiligheid en kwaliteit van zorg. Het real-time meten van het stressniveau kan meer inzicht geven in stressvolle situaties en activiteiten, waarop mogelijk geanticipeerd kan worden. In **hoofdstuk 7** hebben we stress gemeten door middel van de HealthPatch bij chirurgen en chirurgen in opleiding gedurende hun dagelijkse werkzaamheden. Alle deelnemers droegen de HealthPatch gedurende 2-3 dagen. Deze pleister berekent een stresspercentage met een gevalideerd algoritme op basis van hartslagvariabiliteit (HRV) en hartslag. Gemeten stress door de HealthPatch werd vergeleken met gerapporteerde subjectieve stress. Deze werd gestructureerd vastgelegd met een gevalideerde vragenlijst, de State Trait Anxiety Inventory (STAI). Daarnaast legde iedere deelnemer alle dagelijkse werkzaamheden vast in een dagboek.

In totaal includeerden we 20 chirurgen en chirurgen in opleiding. Bij beide groepen vonden we een significante verhoging van het stresspercentage tijdens het opereren in vergelijking met andere werkzaamheden (werk op de polikliniek en verpleegafdeling, administratie). Ervaren chirurgen toonden een lager stress percentage tijdens het opereren dan fellow chirurgen en chirurgen in opleiding. De gemeten stress door de HealthPatch correleerde niet goed met de subjectieve stressbeleving (STAI resultaten).
We concludeerden dat de HealthPatch gebruikt kan worden voor continue stress metingen bij chirurgen en chirurgen en in opleiding en dat dit inzicht geeft in stressoren tijdens dagelijkse werkzaamheden.

Hoofdstuk 8 bevat de discussie en toekomstperspectieven. In dit proefschrift hebben we laten zien dat het gebruik van wearable devices voor zowel continue als periodieke monitoring van patiënten in het ziekenhuis haalbaar is. De huidige devices zijn gebruiksvriendelijk en hebben potentie om klinische achteruitgang in een vroeger stadium te detecteren. Op dit moment zijn er nog een aantal belemmerende factoren zoals de batterijduur van de devices, artefacten en de bedrading en elektrodes van de ViSi Mobile. Hiervoor verwachten we een technische oplossing op korte termijn.
Op basis van de in dit proefschrift gepresenteerde resultaten werd recent besloten om continue monitoring standaard te gaan toepassen op twee reguliere verpleegafdelingen ter vervanging van routinemetingen door verpleegkundigen en de opbrengst hiervan voor het herstel van de patiënt te onderzoeken. Primair wordt geëvalueerd of continue monitoring een meerwaarde heeft op het gebied van voorspellen van klinische achteruitgang en patiënt veiligheid in het algemeen, ten opzichte van het huidige MEWS protocol. Tevens zal de mogelijkheid van centrale monitoring op afstand, waarbij het inschakelen van een IC-team vanuit één centraal punt in het ziekenhuis wordt aangestuurd, worden onderzocht. Doel hiervan is om de coördinatie van de acute zorg in het ziekenhuis efficiënter te laten verlopen en om de kwaliteit ervan te verhogen. Andere studies hebben als doel (dis)continue monitoring met wearable devices in de thuissituatie te evalueren, zowel voor als na een geplande ziekenhuisopname en bij patiënten met langdurige aandoeningen bijvoorbeeld hoge bloeddruk, hartfalen en COPD.

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APPENDICES

Curriculum vitae
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CURRICULUM VITAE

Mariska Weenk was born on the 31st of December 1987 in Doetinchem, the Netherlands. She graduated from high school in 2006 (Staring College, Lochem) and moved to Nijmegen to study Biomedical Sciences at the Radboud University. After obtaining her bachelor's degree in 2011 she started to study Medicine. During her study, she participated in several committees, such as StudentenOrganisatie voor Onderwijs en Studie (SOOS) and Facultaire StudentenRaad (FSR) and worked as a student-assistant for the department of Internal Medicine. She did a clinical internship in Cameroon (2011) and Nicaragua (2013-2014).

In May 2014, she obtained her medical degree (MD) and started as a PhD student at the department of Surgery at the Radboud University Medical Center, Nijmegen. For her research, she collaborated with the department of Internal Medicine and Radboud REshape Innovation Center. Up to June 2017 she performed the studies presented in this thesis under supervision of Prof. Dr. Harry van Goor, Dr. Bas Bredie and Dr. Tom van de Belt. In 2015 and 2016 she also worked as a resident in the department of Surgery at the Radboud University Medical Center.

In September 2017, she started as a general practitioner in training (Radboud University Medical Center) in Millingen aan de Rijn, under the supervision of Geert-Jan Janssen. She continued her training at the department of Geriatrics at the Radboud University Medical Center and is currently working at the Emergency Department at the Rijnstate hospital in Arnhem.

Mariska lives together with Sander Alken in Nijmegen.

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Alken APB, Fluit CRMG, **Weenk M**, Koeneman M, Luursema JM, van Goor H. Measuring stress and coaching behaviors during a highly realistic trauma surgery team training. Submitted.

Ogink PAM, de Jong JM, Koeneman M, **Weenk M**, Engelen LJLPG, van Goor H, van de Belt TH, Bredie SJH. Usability of a New Cuffless Device for Ambulatory Blood Pressure Measurement in Hypertension. Submitted.

A

RIHS PHD PORTFOLIO

Institute for Health Sciences
Radboudumc

Name PhD candidate:	**Mariska Weenk**	**PhD period:**	**01-01-2015 – 01-07-2017**
Department:	**Surgery**	**Promotor:**	**Prof. H. van Goor**
Graduate School:	**Radboud Institute for Health Sciences**	**Co-promotors:**	**Dr. T.H. van de Belt** **Dr. S.J.H. Bredie**

	Year(s)	ECTS
TRAINING ACTIVITIES		
a) Courses & Workshops		
- Laboratory Animal Science (artikel 9)	2014	3.0
- Introduction course for PhD students	2015	1.75
- Basiscursus Regelgeving en Organisatie van Klinische Trials (BROK)	2015	1.5
- Scientific Integrity	2016	0.4
- Biometrics	2016-2017	6.0
- Scientific writing	2017	3.0
b) Seminars & lectures		
- Nurses and E-health, Radboudumc (oral presentation)	2015	0.3
- Lunch meeting 'Continuous Monitoring' for employees Radboudumc (oral presentation)	2015	0.3
- Wetenschapsdag 'Continue monitoring', Radboud University (oral presentation)	2016	0.5
c) Symposia & congresses		
- WATCH conference, AMC Amsterdam	2015	0.5
- Hacking Health Reshape Innovation Center, Radboudumc, Nijmegen (oral presentation)	2015	0.4
- Chirurgendagen, NVvH (oral presentation)	2015	0.5
- Academic Surgical Congress, Jacksonville, USA (oral presentation)	2016	1.25
- Association for surgical education conference, Boston, USA (oral presentation)	2016	1.75
- Academic Surgical Congress, Las Vegas, USA (oral presentation)	2017	1.25
- International Forum on Quality and Safety in Healthcare (BMJ), London, UK (poster presentation)	2017	1.0
d) Other		
- Research meeting department of surgery	2014-2017	1.0
TEACHING ACTIVITIES		
e) Lecturing		
- Suturing course at medical faculty, Radboud University	2015	0.1
- Lecture 'Wearable devices' at medical faculty, Radboud University	2015	0.1
- Lecture 'Lichamelijk onderzoek: vitale functies' at medical faculty, Radboud University	2015	0.5
- 'Student meets patient' at medical faculty, Radboud University	2015-2016	0.9
f) Supervision of internships / other		
- Supervisor profielwerkstuk B. Fikkers and H. Chen, Stedelijk Gymnasium, Nijmegen: 'Invloed van een jurypanel op stresservaring van een leerling tijdens een presentatie'	2015	1.0
- Supervisor master thesis F. Beldman, Radboud University: 'Continuous monitoring of vital signs using wearable devices: patients' and healthcare professionals' view'	2016	2.0
- Supervisor scientific project P. Anvary and I. Smetsers, Radboud University: 'Difference in stress levels between kidney transplantations during day and night'	2017	1.0
TOTAL		30.0

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