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Clinical paper

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

Mariska Weenk[a,*], *Mats Koeneman*[b], *Tom H. van de Belt*[b], *Lucien J.L.P.G. Engelen*[b], *Harry van Goor*[a], *Sebastian J.H. Bredie*[b,c]

[a] *Department of Surgery, Radboud University Medical Center, Nijmegen, the Netherlands*
[b] *Radboud REshape Innovation Center, Radboud University Medical Center, Nijmegen, the Netherlands*
[c] *Department of Internal Medicine, Radboud University Medical Center, Nijmegen, the Netherlands*

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.

Keywords: Remote sensing technology, Wireless technology, Vital signs/physiology, Wearable electronic devices, Humans, Monitoring, Physiologic

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

* Corresponding author at: Dept. Surgery 618, P.O. Box 9101, 6500 HB, Nijmegen, the Netherlands.
E-mail address: Mariska.Weenk@radboudumc.nl (M. Weenk).

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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 min 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).

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.

Table 1 – Patient demographics. MEWS = Modified Early Warning Score.

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[a]	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)

[a] 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. BP = blood pressure. MEWS = Modified Early Warning Score.

Nurse		MEWS[a]	ViSiMobile	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]

[d]Core temperature.
[e]Skin temperature.
[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 Mean difference ± SD	Nurse - HealthPatch 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 ($p < 0.05$).
[b] Significant linear regression (proportional difference) ($p < 0.05$).
[c] Core temperature vs. skin temperature.

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.

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 which 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

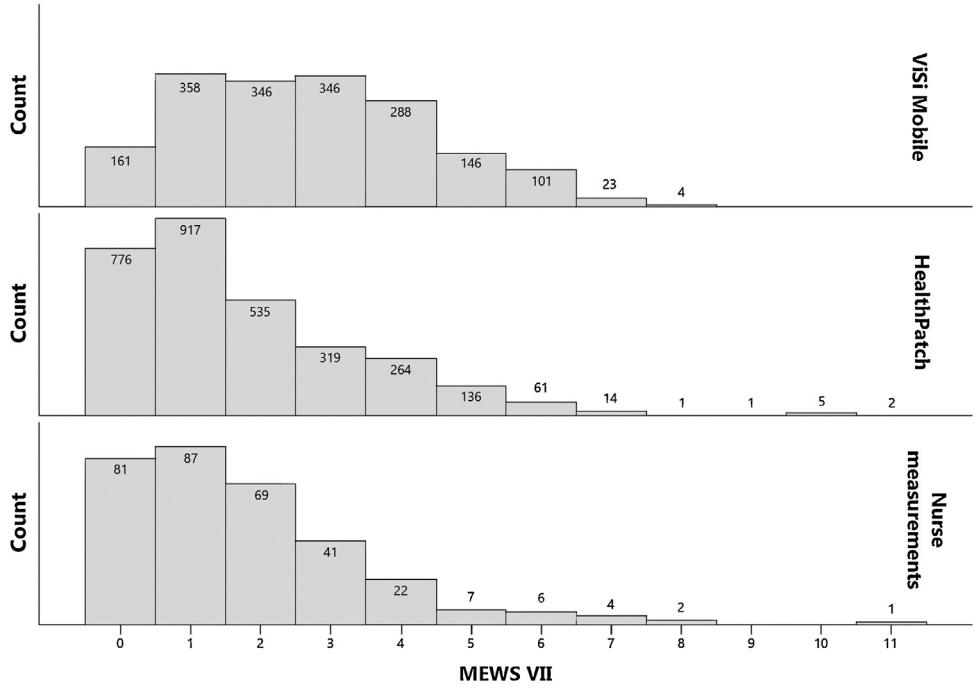

Fig. 1 – Modified Early Warning Scores VII frequencies for devices. Veranderen in 'Number of extra MEWS measured by ViSi Mobile and HealthPatch during non-observed periods by nurses'.
MEWS = Modified Early Warning Score.

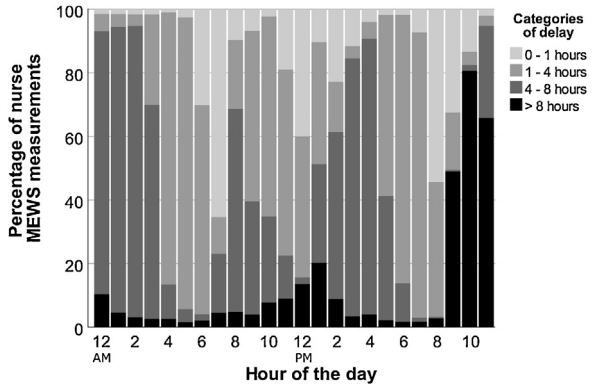

Fig. 2 – Time between high MEWS measured by a device and next regular MEWS measurement by a nurse. The X axis depicts the hour of the day; the Y axis depicts the percentage of nurse measurements with their delay (see box).

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 was 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.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.resuscitation.2019.01.017.

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