ORIGINAL RESEARCH

Non-invasive monitoring using photoplethysmography technology

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Abstract

We evaluated the accuracy and precision of a novel non-invasive monitoring device in comparison with conventional monitoring methods used in intensive care units (ICU). The study device was developed to measure blood pressure, pulse rate, respiratory rate, and oxygen saturation, continuously with a single sensor using the photoplethysmographic technique. Patients who were monitored with arterial pressure lines in the ICU were enrolled. Systolic and diastolic blood pressure, pulse rate, respiratory rate, and arterial oxygen saturation were measured continuously for 30 min at 5-min intervals using the conventional methods and the study device. The primary outcome variable was blood pressure. Blood pressure measured by the study device highly correlated with the arterial pressure line values (correlation coefficients > 0.95). Percent errors for systolic, diastolic and mean blood pressures were 2.4% and 6.7% and 6.5%, respectively. Percent errors for pulse rate, respiratory rate and oxygen saturation were 3.4%, 5.6% and 1.4%, respectively. The non-invasive, continuous, multi-parameter monitoring device presented high level of agreement with the invasive arterial blood pressure monitoring, along with sufficient accuracy and precision in the measurements of pulse rate, respiratory rate, and oxygen saturation.

Keywords Non-invasive · Continuous monitoring · Blood pressure · Photoplethysmography · Critically ill patients · Single sensor

1 Introduction

Monitoring physiological parameters—including blood pressure, heart rate, respiratory rate and oxygen saturation—is fundamental in intensive care units (ICUs) and operating rooms [1–3]. Multiple sensors are currently required for the continuous monitoring of these parameters in critically ill patients. Arterial pressure monitoring by the intra-arterial catheter is the standard method for continuous blood pressure monitoring in critically ill or high-risk patients [4–6]. However, arterial puncture and catheter placement are invasive procedures and carry the risk of complications, such as hemorrhage, infection, nerve damage, pseudoaneurysm formation, blood flow disturbance due to arterial obstruction, and residual cannulas [7–9], which justifies the development of a non-invasive continuous blood pressure monitoring device [10–13].

Non-invasive continuous blood pressure monitoring devices have been investigated based on the volume clamp method or arterial tonometry methods [14, 15]; however, a meta-analysis pointed out that these devices did not have sufficient accuracy and precision [16]. We previously developed a tabletop continuous blood pressure monitoring device based on the photoplethysmography technique which demonstrated comparable accuracy and precision to arterial line blood pressure measurements in a healthy subject [17]. Recent investigation into critically ill patients reported that the photoplethysmography technique is a promising technology for continuous blood pressure monitoring [13]. However, the accuracy and precision of the device remained insufficient when compared to invasive intra-arterial catheter blood pressure measurements [18].

In this study, we developed a continuous monitor using the photoplethysmographic technique with improved computational algorithm to be: (1) compact, (2) wireless, (3) single-sensor, and (4) able to continuously monitor four physiological parameters (blood pressure, pulse rate, respiratory rate and oxygen saturation). We tested the accuracy

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and precision of this system to ensure it was comparable to conventional continuous monitoring methods used for critically ill patients. The primary outcome variable was blood pressure, and secondary outcome variables were pulse rate, respiratory rate, and arterial oxygen saturation.

2 Materials and methods

2.1 Patients

This was a single-center, prospective, non-randomized, open-label study to evaluate a non-invasive continuous monitoring device (Fig. 1, μ-BPX model [sensor: RBP-100SPWCBS] co-developed with K&S Co., Ltd, Aichi, Japan). Patients who were admitted to the medical/surgical ICU in Chiba University Hospital from May 2016 to April 2017 and had arterial pressure lines inserted for monitoring were enrolled in this study. Patients were excluded if they (1) were supported by intra-aortic balloon pumping or extracorporeal membrane oxygenation, (2) had burns or other skin lesions on the location of the sensor application, (3) required magnetic resonance imaging (MRI) examination, (4) required hyperbaric oxygen therapy, (5) had hypersensitivity to infrared or transmitted light, or (6) were otherwise considered unsuitable for enrollment by investigators or test sharing physicians.

Fig. 1 **a** Appearance of the developed device. Arrow 1: transmitter (size: 50 mm×57 mm×20 mm; weight: 65 g). Arrow 2: sensor (size: 35 mm×20 mm×3 mm; weight: 5 g). Arrow 3: charging cord (Detachable). **b** Image of monitor (connected to the transmitter via Bluetooth)
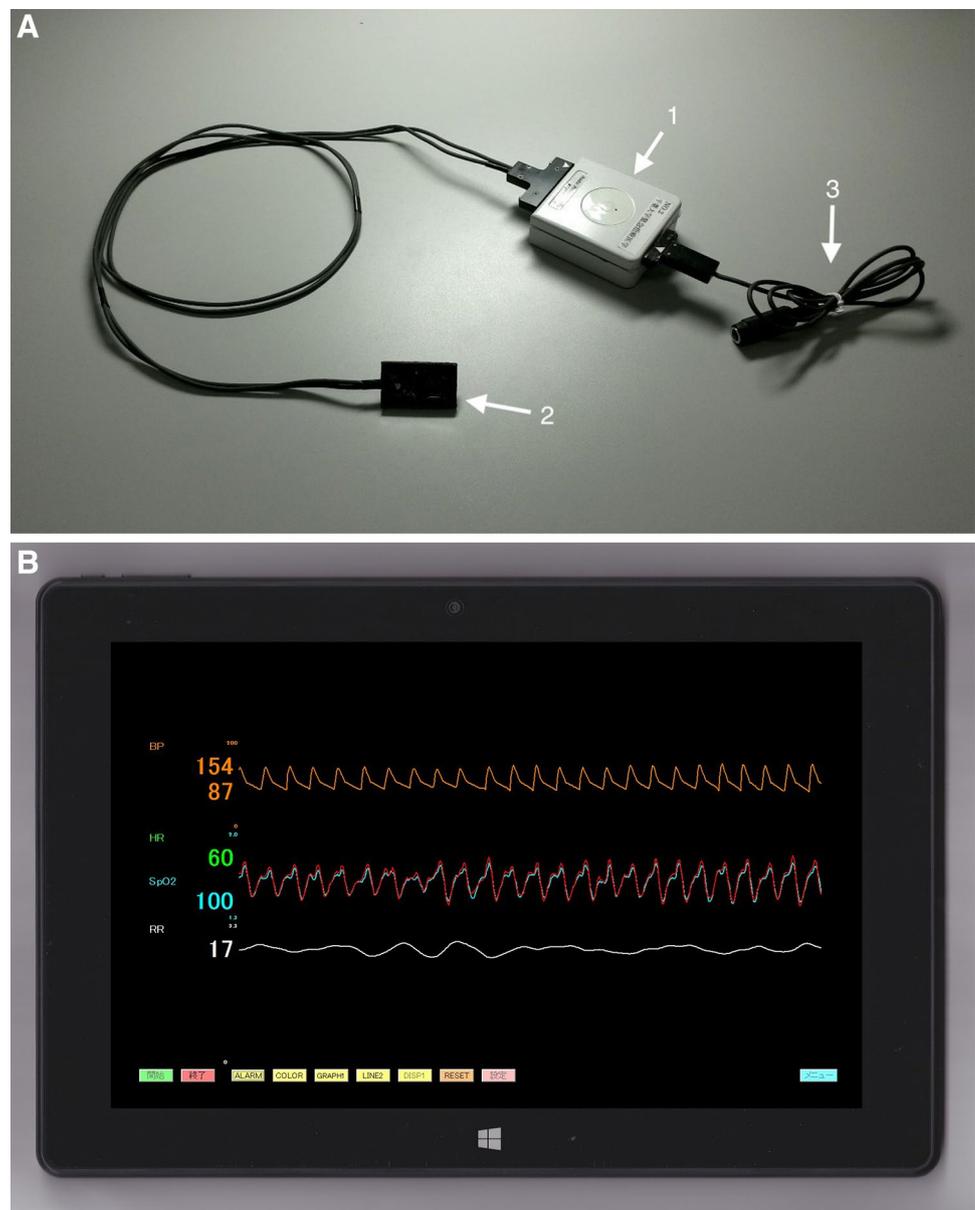
An international standard for sphygmomanometers—"European Society of Hypertension International Protocol revision 2010" for medical use permission of novel measurement devices [19]—recommends evaluating the validity of new measurement instruments by a comparison with conventional measurement systems in at least 33 cases. Accordingly, 66 cases (33 cases each for general and cardiac ICUs) were enrolled in this study.

The Institutional Review Board at Chiba University Hospital approved this study (approved number: G27048), and written informed consent was obtained from all patients or their authorized representatives.

2.2 Device

The study device is composed of a single reflective sensor to be used in contact with the skin surface to measure blood pressure, pulse rate, respiratory rate and oxygen saturation. Projected light captures the displacement of the blood vessel surface during expansion and contraction. This mechanism enables the sensor to receive a photoplethysmographic wave. Blood pressure is continuously computed based on this signal; the method for converting a photoplethysmographic wave into the value of blood pressure has been previously reported [17].

The study device converts the measured photoplethysmographic wave into blood pressure values, after calibration with a reference blood pressure. The reference blood pressure can either be measured by arterial pressure line or sphygmomanometer; arterial line pressure was used in the current study to evaluate the validity of the device as a continuous monitoring tool. We chose the approximations below for the blood pressure (systolic blood pressure, SBP, diastolic blood pressure, DBP) (Eqs. 1, 2) and photoplethysmographic signal (Eqs. 3, 4).

For blood pressure (Fig. 2a).

$$S1 = (SBP - DBP) \times t/2 \tag{1}$$

$$S2 = DBP \times t \tag{2}$$

For photoplethysmographic signal (Fig. 2b)

$$ps1 = (p1 - p2) \times t/2 \tag{3}$$

$$ps2 = p2 \times t \tag{4}$$

Based on the approximations below (Eqs. 5, 6), we estimated SBP and DBP using photoplethysmographic value (Eqs. 7, 8).
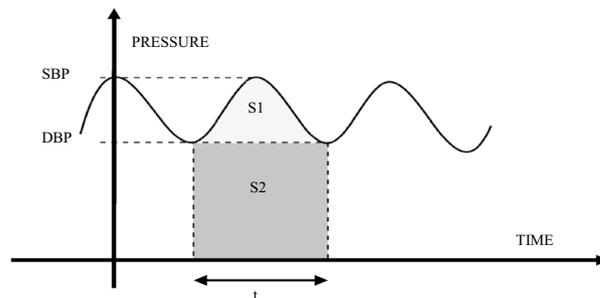
$$k2 = S2/ps2 \tag{5}$$

$$k1 = S1/ps1 \tag{6}$$

$$DBP = fDBP(ps2 \times k2) + f(S2) \tag{7}$$

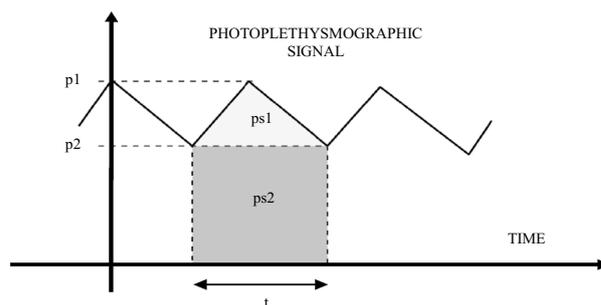$$SBP = fSBP(ps1 \times k1) + f(DBP) \tag{8}$$

Fig. 2 a A schema of the blood pressure pulsation and time course. **b** A schema of the photoplethysmographic pulsation and time course

Calibration was performed to calculate the conversion factors k1 and k2 to formulate the conversion functions, according to Eqs. (1–8) above. For instance, substituting arterial line data (ex: SBP = 130 mmHg, DBP = 60 mmHg, Heart rate = 80/min) in Eqs. (1, 2) and photoplethysmographic wave signal data (ex: p1 = 300, p2 = 100, Heart rate = 80/min) in Eqs. (3, 4) provide k1 and k2 (ex: 0.35 and 0.6, respectively) by Eqs. (5, 6). The calculated values can then be substituted into the conversion functions (Eqs. 7, 8), to enable the conversions from the observed photoplethysmographic wave signal values (ex: p1 = 310, p2 = 95, HR = 85/min) to estimated blood pressure (ex: SBP = 132 mmHg, DBP = 57 mmHg). Blood pressure measurements were obtained and recorded for every heartbeat.

The oxygen saturation of arterial blood was calculated using a previously reported algorithm based on the photoplethysmographic wave [20]. Respiratory rate was computed using the oscillation of the signal in the photoplethysmographic wave, which originated from the respiratory cycles of the patients.

2.3 Measurements

The study device was attached either to the upper arm, the precordium, or the temple, depending on the patient situation and the validity of the photopletysmographic signal.

After calibrating the device using the systolic and diastolic blood pressure from the arterial pressure line, parameters (systolic and diastolic blood pressure, pulse rate, respiratory rate, and arterial oxygen saturation) were measured continuously for 30 min at 5-min intervals (a total of 7-time points). Simultaneously, data were obtained from the arterial pressure line, an electrocardiogram (ECG) sensor, and a pulse oximeter (BSM-9101, Nihon Kohden, Tokyo, Japan), which are used in clinical practice. The skin at sensor attachment sites was checked after each measurement for irritation to evaluate the safety of the developed device.

2.4 Statistical analysis

We evaluated the accuracy and precision of our device by comparing with conventional standard methods for measuring each parameter. The accuracy of a measurement system is defined as the degree of closeness of measurements of a quantity to its actual (true) value. The precision of a measurement system, also called reproducibility or repeatability, refers to the degree to which repeated measurements under unchanged conditions show the same results. The primary outcome variable was blood pressure, and the secondary outcome variables were pulse rate, respiratory rate, and arterial oxygen saturation. According to previous reports [21], two measurement systems are interchangeable when the percent error is under 28.3% [15]. In this study, percent error was calculated as [2 × standard deviation (SD)]/(average value measured by the methods), where SD is the standard deviation of the differences between the values measured by the two devices. Mean, SD, absolute difference, and 95% limits of agreement, were calculated for the developed device and conventional method [22]. Pearson's correlation coefficient (R) between measurements from the developed device and the conventional method was calculated. Bland–Altman plots were used to evaluate the agreement between the values measured by the developed device and those from conventional methods [22]. We also analyzed the accuracy of our device with respect to trending using concordance and polar plot techniques [23]. We set the exclusion zone of $\leqq 15\%$. Statistical analysis was performed with the GraphPad Prism 7 (GraphPad Software, San Diego, CA, USA) and the Matlab software package (Mathworks, Inc., Natick, MA, USA).

3 Results

Sixty-eight patients who were admitted to the medical/surgical ICU were enrolled in the study. Two patients, who were on a left ventricular assist system, were excluded due to a failure in detecting pulse waves, leaving a total of 66 cases (33 general ICU cases and 33 cardiac ICU cases) enrolled

(baseline characteristics, Table 1). Measurements were obtained for seven-time points, for a total of 462 measured values.

For the conventional method, systolic blood pressure ranged from 85 to 228 mmHg, diastolic blood pressure from 39 to 99 mmHg, mean blood pressure from 55 to 140 mmHg, pulse rate from 54 to 132 per minute, respiratory rate from 7 to 41 per minute, and oxygen saturation from 87 to 100%. The R values between the conventional method and photoplethysmography device were 0.993 for systolic blood pressure, 0.985 for diastolic blood pressure, 0.998 for mean blood pressure, 0.996 for pulse rate, 0.995 for respiratory rate, and 0.963 for oxygen saturation (Fig. 3).

In the primary analysis, percent errors for systolic blood pressure, diastolic blood pressure and mean blood pressure were 2.4%, 6.7% and 6.5% respectively, which are less than the predefined threshold of 28.3% (Table 2). As shown in Bland–Altman plots, the 95% limits of agreement ranged from −6.0 to 5.7 mmHg for systolic blood pressure (slope = −0.0093, P = 0.10) (Fig. 4a), −3.8 to 4.2 for diastolic pressure (slope = 0.0081, P = 0.32) (Fig. 4b) and −5.3 to 5.1 for mean blood pressure (slope = −0.0050, P = 0.55) (Fig. 4c). For the secondary outcome variables, percent error was 3.4% for pulse rate, 5.6% for respiratory

Table 1 Baseline characteristics of study patients

Baseline characteristics	
Age (year)	64.6 ± 17.5
Gender (% male)	69.7
Body mass index (kg/m²)	23.0 ± 4.5
Measurement site	
Arterial catheter (radial/femoral/dorsal) (n)	60/5/1
Developed device (temple/precordium/axilla/brachium) (n)	55/4/1/6
General ICU (n)	33
Cardiac arrest	11
Sepsis	9
Respiratory failure	6
Trauma	4
Others	3
Cardiac ICU (n)	33
Post cardiac surgery	26
Congestive heart failure	3
Arrhythmia	3
Others	1
Inotropes and vasopressor (n)	17
Dopamine	11
Dobutamine	7
Adrenaline	0
Noradrenaline	7

All continuous variables are shown as mean ± standard deviation

Fig. 3 The physiological parameters estimated by the photoplethysmography device versus the values monitored by the conventional method. The Pearson's correlation coefficients (R) was 0.993 for systolic blood pressure (**a**), 0.985 for diastolic blood pressure (**b**), 0.998 for mean blood pressure (**c**), 0.996 for pulse rate (**d**), 0.995 for respiratory rate (**e**), and 0.963 for oxygen saturation (**f**)
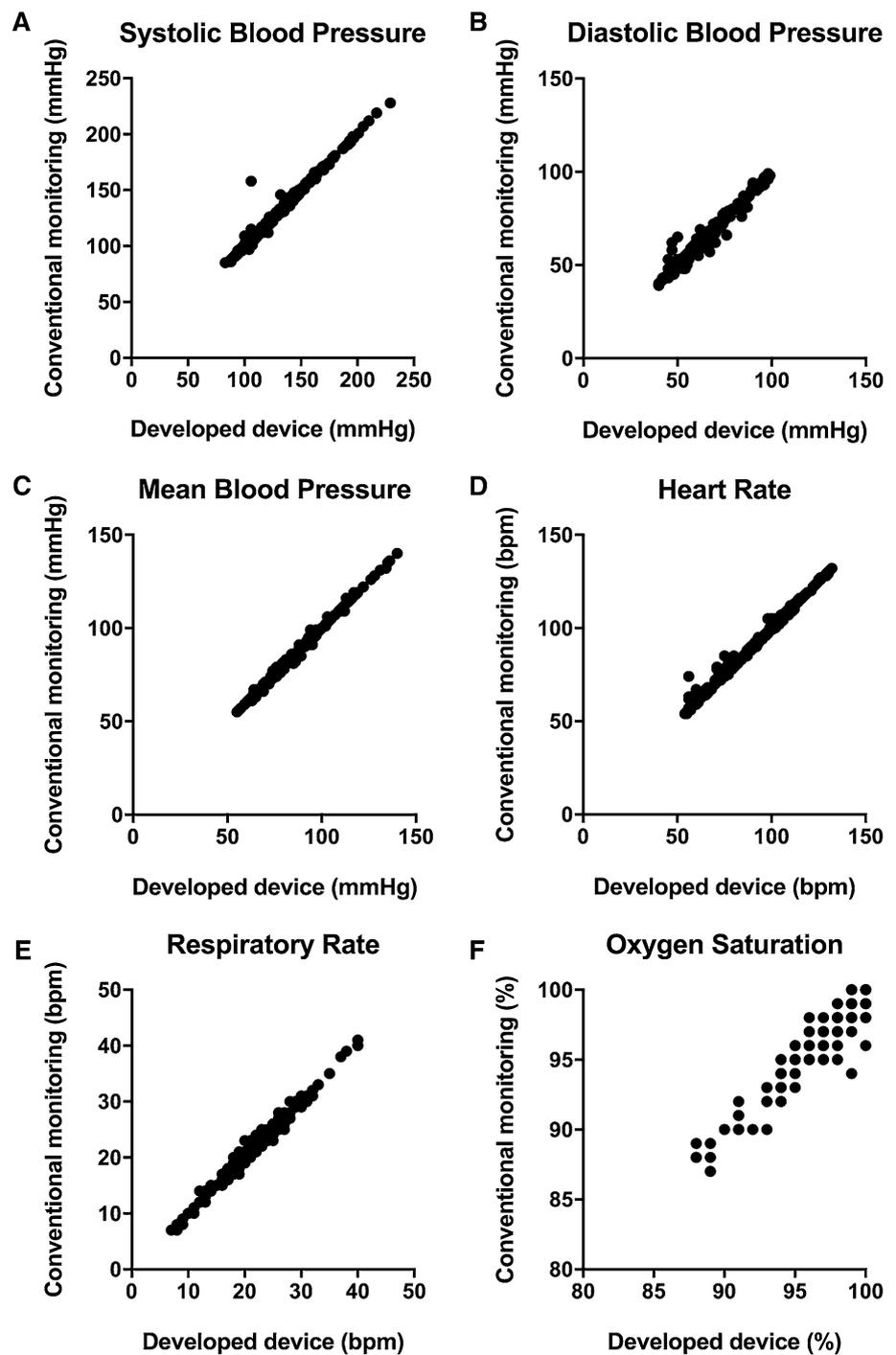
rate, and 1.4% for oxygen saturation (Table 2), and the 95% limits of agreement ranged from −3.3 to 2.7 per minute for heart rate (slope = 0.014, $P = 0.0007$) (Fig. 4d), −1.2 to 1.1 per minute for respiratory rate (slope = −0.0087, $P = 0.076$) (Fig. 4e), and −1.0 to 1.7% for oxygen saturation (slope = −0.029, $P = 0.027$) (Fig. 4f). The polar plots presented concordance rates of 94.0%, 84.4%, and 89.7% for systolic, diastolic, and mean blood pressures, 85.8% for heart rate, 86.1% for respiratory rate, and 54.3% for

oxygen saturation (Fig. 5). No skin irritation was observed at the sites of sensor attachment.

4 Discussion

In this study of a non-invasive continuous monitoring device based on the photoplethysmographic technique in ICU patients, the developed device had a high level of agreement

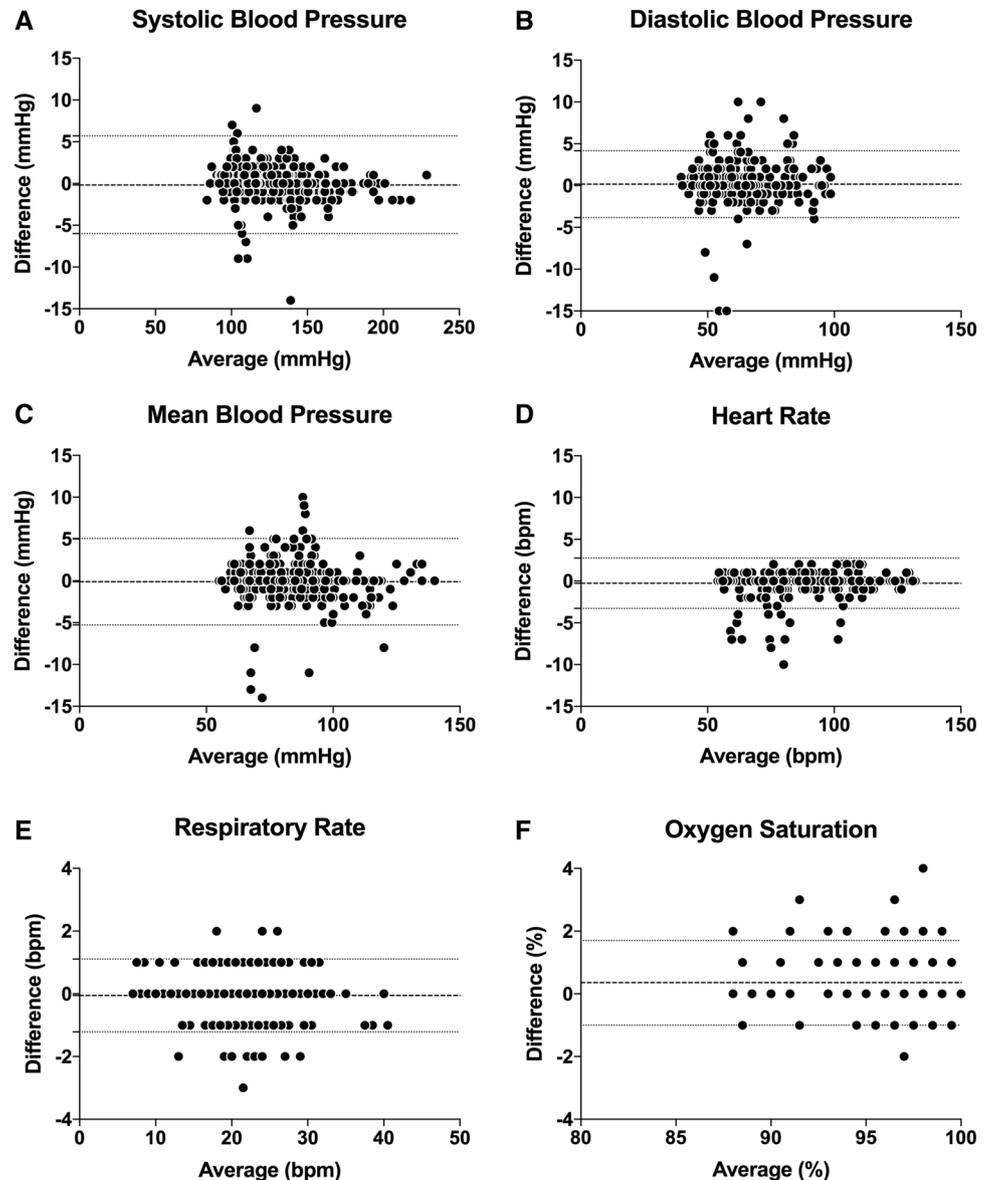**Table 2** Blood pressure, pulse rate, respiratory rate and oxygen saturation

	Developed device	Conventional device	Difference	Percent error (%)
Systolic blood pressure	126.9 ± 24.3	127.1 ± 24.5	− 0.2 ± 3.0	2.4
Diastolic blood pressure	60.9 ± 11.9	60.8 ± 11.8	0.2 ± 2.0	6.7
Mean blood pressure	81.2 ± 14.5	81.3 ± 14.6	− 0.1 ± 2.6	6.5
Pulse rate	90.2 ± 17.0	90.4 ± 16.8	− 0.3 ± 1.5	3.4
Respiratory rate	21.0 ± 5.6	21.1 ± 5.6	− 0.1 ± 0.6	5.6
Oxygen saturation	97.8 ± 2.5	97.4 ± 2.6	0.3 ± 0.7	1.4

Difference: the difference between the values measured by the developed device and those measured by conventional methods

Percent error: [2 × standard deviation (SD) of the differences between the values measured by the two devices]/(average value measured by the methods)

All continuous variables are shown as mean ± standard deviation

Fig. 4 Bland–Altman plots showing the measurement differences between the developed device and the conventional method against the average measurement with a mean bias (dashed horizontal line), 95% limits of agreement (dotted horizontal line), and regression line (solid line). **a** For systolic blood pressure, the mean bias is − 0.2, the 95% limits of agreement range from − 6.0 to 5.7 mmHg and slope of regression line is − 0.0093 ($P = 0.10$); **b** for diastolic blood pressure, the mean bias is 0.2, the 95% limits of agreement are ranged from − 3.8 to 4.2 mmHg and slope of regression line is 0.0081 ($P = 0.32$); **c** for mean blood pressure, the mean bias is − 0.1, the 95% limits of agreement are ranged from − 5.3 to 5.1 mmHg and slope of regression line is − 0.0050 ($P = 0.55$); **d** for heart rate, the mean bias is − 0.3, the 95% limits of agreement are ranged from − 3.3 to 2.7 per minute and slope of regression line is 0.014 ($P = 0.0007$); **e** for respiratory rate, the mean bias is − 0.1, the 95% limits of agreement are ranged from − 1.2 to 1.1 per minute and slope of regression line is − 0.0087 ($P = 0.076$); **f** for oxygen saturation, the mean bias is − 0.3, the 95% limits of agreement are ranged from − 1.0 to 1.7% and slope of regression line is − 0.029 ($P = 0.027$)
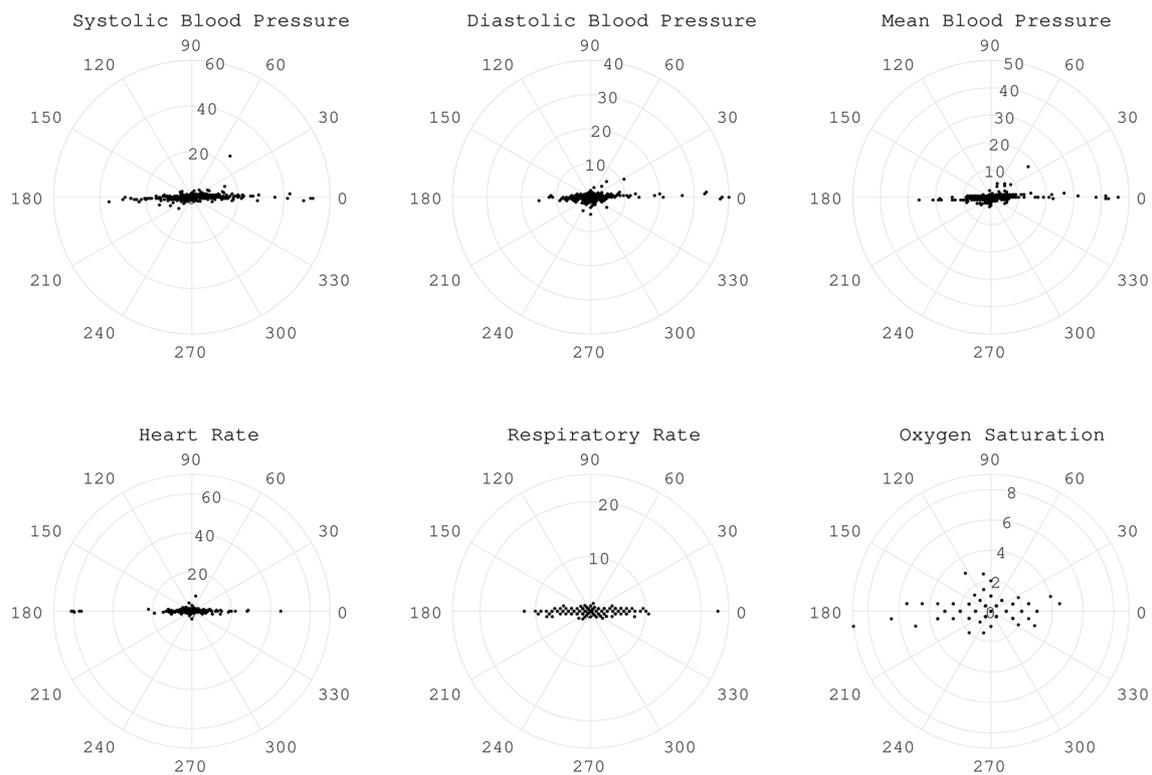
Fig. 5 The polar plot analysis showing the ability of tracking changes in the systolic blood pressure, diastolic blood pressure, mean blood pressure, pulse rate, respiratory rate, and oxygen saturation. The polar plot presented a concordance rates of 94.0%, 84.4%, and 89.7% for systolic, diastolic, and mean blood pressure, 85.8% for heart rate, 86.1% for respiratory rate, and 54.3% for oxygen saturation when applying an exclusion zone of 15%

with the conventional arterial line pressure monitoring for blood pressure measurement. In addition to blood pressure monitoring, the device could continuously monitor pulse rate, respiratory rate, and oxygen saturation with sufficient accuracy and precision using only the single sensor.

Recently, various non-invasive continuous devices have been developed to measure blood pressure, fueling enthusiasm that the new technology could replace the conventional invasive arterial pressure measurement in critical care settings [24]. Several non-invasive techniques—such as the volume clamp method, the volume compensation method, and arterial tonometry—have been implemented and tested for feasibility in clinical settings, but the accuracies of these devices have remained insufficient [14–16].

Blood pressure measurements by a device based on the photoplethysmographic technique, however, were correlated to those measured by a sphygmomanometer in a small feasibility study of 25 healthy subjects (correlation coefficients: systolic blood pressure = 0.60; mean arterial pressure = 0.60) [25]. In addition, our previous study demonstrated that blood pressure measured by a tabletop non-invasive continuous monitoring device based on the photoplethysmographic technique had high correlation with measurements taken by the conventional arterial

line pressure monitoring in a healthy subject (correlation coefficients: systolic blood pressure = 0.90; diastolic blood pressure = 0.83), which suggests that devices based on the photoplethysmographic technique are potentially accurate and precise [17].

In this study, a compact device was developed and tested against arterial line pressure monitoring in critically ill patients. In the primary analysis, percent error of systolic, diastolic blood pressure, and mean blood pressure were 2.4%, 6.7% and 6.5%, respectively, which are considerably lower than the predefined threshold of 28.3% [21]. In a previous investigation, which compared blood pressure measured by the photoplethysmographic technique to arterial line pressure for 32 surgical patients, the differences in the measurements (mean ± SD) were $0.78 ± 13.1$ mmHg and $0.59 ± 10.2$ mmHg for systolic and diastolic blood pressure, respectively [26]. The differences in the present study were, $-0.2 ± 3.0$ mmHg, $0.2 ± 2.0$ mmHg and $-0.1 ± 2.6$ mmHg for systolic, diastolic and mean blood pressure, respectively (Table 2), which were considerably smaller than the previous investigation. The Association for the Advancement of Medical Instrumentation (AAMI) guidelines defined the acceptable measurement difference range for systolic and diastolic blood pressure to be within 5 mmHg for accuracy

(mean) and 8 mmHg for precision (SD) [27]; the developed device sufficiently satisfied both requirements.

Another investigation on a device based on the photoplethysmographic technique in critically ill patients suggested that the technique was potentially useful for non-invasive blood pressure monitoring, but had considerably wide 95% limits of agreement when compared with arterial line pressure (− 40.9 to 34.9 mmHg for systolic blood pressure and − 20.7 to 13.4 mmHg for diastolic). The study concluded that the insufficient accuracy and precision would need to be solved before the device could be used in the clinical setting [18]. The computational algorithm of the study device to convert the photoplethysmographic signal into blood pressure was optimized to achieve narrower 95% limits of agreement (− 6.0 to 5.7 mmHg for systolic blood pressure, − 3.8 to 4.2 for diastolic blood pressure, − 5.3 to 5.1 for mean blood pressure) to be sufficient for clinical application. Since the table-top non-invasive continuous monitoring device using the photoplethysmographic technique is approved by the Pharmaceuticals and Medical Devices Agency, the present product based on the same measurement principle would be labeled for the future clinical application according to the demonstrated results.

The ability to measure additional biometric parameters (pulse rate, respiratory rate, and arterial oxygen saturation) with only one probe broadens the clinical applications of the device. A potential application for this device could be monitoring during patient transportation, when multiple electrodes and probes could become tangled and problematic. The developed device demonstrated sufficient accuracy in the measurement of blood pressure and other biometric parameters. The accuracy of the measurements can be ensured with an initial calibration, and maintained with additional calibration as needed. It should be noted that although the device was calibrated using the arterial line pressure in the current study to confirm the accuracy of the system, it could also be calibrated non-invasively by using sphygmomanometer measurements in the clinical setting. The data processor has been designed to judge the cycle of the photoplethysmographic waves, adjusting for the signal noise due to factors such as body movements. These features have contributed to the accuracy and precision of the device.

Some limitations need to be addressed. First, the performance of the device was evaluated in accordance with an international standard for sphygmomanometers, which is a non-invasive device [19]. Second, the measurements were evaluated for 30 min according to the criteria of European Society of Hypertension International Protocol revision 2010. This may not seem long enough for the validation of a device designed for 24 h continuous monitoring in the ICU, especially if the blood pressure remained static during the 30 min evaluation. However, arterial blood pressure fluctuated more than 20 mmHg in 19 cases (28%), suggesting

the accuracy of the device in clinically relevant settings. In addition, the concordance rate of systolic blood pressure was 94.0% with exclusion zone of ≦ 15%, indicating reliable trending ability.

In conclusion, we developed and tested a non-invasive, continuous, multi-parameter monitoring device based on the photoplethysmographic technique on critically ill patients. The blood pressure measurements of the wireless single-sensor probe showed a high level of agreement with the measurements from the conventional invasive blood pressure monitoring method, as well as sufficient accuracy and precision in the measurements of pulse rate, respiratory rate, and oxygen saturation.

Compliance with ethical standards

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