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Research article

Reliability of smartphone measurements of peripheral oxygen saturation and heart rate in hypotensive patients measurement of vital signs with smartphones

Arman Totuk [a], Burcu Bayramoglu [b], Ismail Tayfur [b,*]

[a] Simav Doc. Dr. Ismail Karakıyu State Hospital, Kütahya, Turkey
[b] University of Health Sciences, Sancaktepe Sehit Prof. Dr. Ilhan Varank Training and Research Hospital, Department of Emergency Medicine, Istanbul, Turkey

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ABSTRACT

Objective: With the increasing use of wearable technologies (smartphones and smartwatches), it has become possible to measure vital signs outside healthcare institutions without the need for an additional medical device. With the advancement in technologies, the accuracy of vital signs measured by smartphones and smartwatches has also increased. In this study, the accuracy of smart devices in the measurement of heart rate and saturation, which are two vital signs that are difficult to detect in conditions such as hypotension were investigated.

Materials and methods: The study was prospectively conducted in a tertiary healthcare center. In hypotensive patients who presented to the emergency department (ED) and required an arterial blood gas evaluation, oxygen saturation and heart rate values measured by a smartphone, those measured with a vital signs monitor (VSM) at the time of admission to the ED and oxygen saturation values measured by a blood gas analyzer (BGA) were compared.

Results: A total of 200 patients, 117 women and 83 men, were included in the study. It was determined that the correlation coefficients of the heart rate values measured by the vital signs monitor and smartphone were in a high statistical agreement. When the saturation values measured by the vital signs monitor, smartphone, and blood gas analyzer were compared, it was found that the intra-class correlation coefficients of the saturation values measured by the smartphone with reference to the blood gas analyzer and vital signs monitor were 0.957 and 0.949, respectively, indicating an excellent agreement.

Conclusion: Smartphones have as high efficiency as reference devices in measuring heart rate and saturation in hypotensive patients. In this way, hypotensive patients who need medical help can also have the opportunity to measure their vital parameters with their smartphones, without the need for any other medical device, before applying to the hospital or emergency health system. This may contribute to the improvement of the quality of life of the patients and the early and accurate information of the health care providers about the patient's health parameters.

* Corresponding author.
E-mail address: ismail.tayfur@sbu.edu.tr (I. Tayfur).

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1. Introduction

At the time of presentation to the emergency department (ED), vital signs, including fever, heart rate (HR), blood pressure (BP), respiratory rate, and peripheral oxygen saturation (SaO_2) are used to determine the general condition of patients and perform triage. As non-invasive methods producing rapid results, pulse oximetry stands out in the initial evaluation of patients presenting to the ED. There are some difficulties in measuring SaO_2 and HR with pulse oximeters. For example, inaccurate results can be obtained in cases such as vasoconstriction, carbon monoxide poisoning, improper placement of the probe, use of nail polish, and presence of anemia, hypotension or hypovolemia [1]. Despite all these limitations, pulse oximetry is still routinely used for saturation measurement.

With the advances in technology HR and SaO_2 can be measured by smartphones and smartwatches equipped with the necessary hardware and software. Smartphones are becoming more and more popular across the world and allow these vital signs to be measured quickly with their software capabilities without the need for an additional device. Smartphones use the same working principle (photoplethysmography-PPG) as saturation measuring devices when performing measurements [2]. Therefore, limitations in measurements performed with pulse oximetry also apply to smartphones.

In asthma, chronic obstructive pulmonary disease (COPD) and other diseases that make the person dependent on a respiratory support device, patients should also monitor their oxygen saturation values outside the hospital. In addition, although saturation monitoring is important during the ongoing COVID-19 pandemic, it is even more important in case of silent hypoxia. Silent hypoxia is a condition described in patients with COVID-19 and refers to the presence of severe hypoxemia without shortness of breath [3]. Saturation measurement via smartphones allows for early presentation to the ED through the identification of silent hypoxia among patients with COVID-19, thus mortality can be prevented. Furthermore, since patients who monitor their vital signs will visit the hospital in the case of an emergency, the transmission of the disease to health workers or healthy individuals during transportation to the hospital is minimized. This can prevent the loss of workforce due to COVID-19 among healthcare workers and ensure that they work under less risky conditions. In addition, using telemedicine, the data provided by smart devices and applications can help people that are under quarantine due to COVID-19 to communicate with their doctors from their homes. This can also decrease costs by reducing unnecessary hospital admissions. Xie et al. suggested that smartphones could be used for triage and reduce unnecessary hospital admissions, and thus provide savings on health services [4].

In previous studies, oxygen saturations were measured with smartphones in normotensive patients, and it was found to be compatible with saturation values measured using pulse oximetry and arterial blood gas analysis [4, 5, 6, 7]. However, despite the availability of studies conducted with normotensive patients, no study has evaluated the measurement performance of smartphones in hypotensive cases. The study aims to investigate the accuracy rate of smartphones in SaO_2 and HR measurements in hypotensive patients and determine whether smartphones could be reliably used in the measurement of these vital signs.

2. Material and method

The study was prospectively conducted between November 2019 and January 2020 in a tertiary healthcare center. Ethical approval was obtained from the ethics committee of the same institution (HNEAH-KAEK 2019/KK/141).

2.1. Study design and setting

Patients who presented to the ED with the acute exacerbation of asthma and COPD, congestive heart failure, pneumonia, sepsis, cerebrovascular disease, and multiple trauma, received a diagnosis of hypotension, and required an arterial blood gas evaluation were included in the study. Written informed consent was obtained from the patients included in the study. Cases of cardiopulmonary arrest requiring an emergency intervention and other unstable patients, those who could not adapt to device measurements, those with hypothermia (body temperature below 35 °C), those using nail polish or prosthetic nails, and those who did not provide consent were excluded from the study.

The patient was placed in the supine position and BP was measured by an experienced healthcare professional using a mercury manometer three times at 3-min intervals in accordance with the standard protocol, and the average of these three measurements was recorded. Hypotension was diagnosed based on a systolic blood pressure value below 90 mmHg or a mean arterial pressure below 65 mmHg, or a 40 mmHg decrease in systolic blood pressure compared to normal blood pressure [8].

Data were simultaneously recorded by a smartphone and a vital signs monitor (VSM), and an arterial blood gas sample was taken

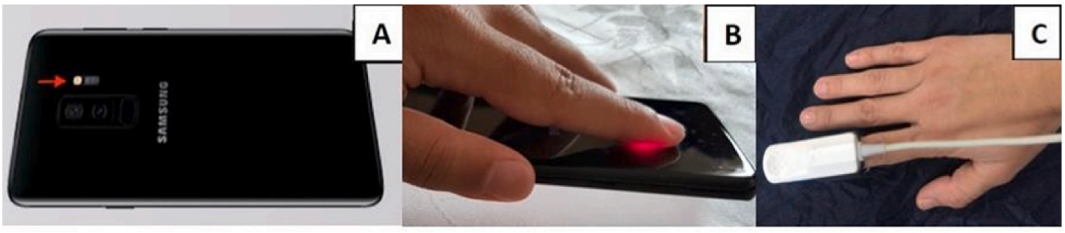

Fig. 1. Method of the measurement heart rate and peripheral oxygen saturation with the smartphone and vital signs monitor.

for analysis at the same time. The arterial blood gas analysis is accepted as the gold standard in the measurement of oxygen saturation. Before starting the study, the blood gas analyzer (BGA) and VSM were calibrated by the authorized service.

In this study, SaO_2 and HR values were measured using a Samsung Galaxy S9 Plus (SM-G965F) smartphone and Samsung Health application with the version number SM-G965F 6.10.5.031 installed on this smartphone. A single smartphone was used in all the patients after disinfection before each measurement. HR and SaO_2 measurements were undertaken by placing the patient's second finger of the right hand on the sensor designed for HR and SaO_2 measurements on the back of the smartphone, taking care that the finger completely covered the sensor (Figure 1A, B, C). Each measurement took 15 s and was repeated three times, and the results were averaged. The results were recorded by a doctor blinded to the patient's VSM results.

For the VSM measurements of the HR and SaO_2 values, the Welch Allyn, Connex Spot Monitor 71 WT device with a Nellcor probe were used in the ED. Each measurement was repeated three times, and the results were averaged. The data were recorded by a doctor blinded to the patient's smartphone measurement values.

Arterial blood gas samples taken under appropriate conditions were analyzed with the Radiometer ABL800 (754R0428N007) device in the ED, and the SaO_2 values were recorded by the doctor who took the blood gas sample.

The SaO_2 values measured by the VSM, BGA and smartphone were compared. In addition, the comparison of the HR values measured by the smartphone and VSM was undertaken. The patients' age, gender, presentation complaint and blood pressure were also evaluated.

2.2. Statistical analysis

Descriptive statistics were presented as number (%), mean ± standard deviation and median (min-max) values. The Shapiro-Wilk test was used to check the normality assumption. In the analysis of the differences between the measurement values of the groups, the Mann–Whitney U test was used in the absence of a normal distribution, and Student's t-test otherwise. The G*Power Version 3.1.6 program was used to calculate the sample size, and the sample size was calculated as at least 200 cases. The Bland–Altman method was used to evaluate the agreement between the measurements, and the intra-class correlation coefficients (ICCs) were calculated. ICC values were interpreted according to Portney's textbook. An ICC value below 0.50 was interpreted to indicate poor agreement; 0.50–0.75, moderate agreement; 0.75–0.90, good agreement; and above 0.90, excellent agreement [9]. For the evaluation of data obtained from the study, statistical analyses were performed using SPSS v. 23.0 software package. P values less than 0.05 were considered statistically significant.

3. Results

The study included a total of 200 patients, of whom 58.5% were women. The mean age of the patients was 59.02 ± 17.47 years. The mean systolic and diastolic BP values of the patients were found to be 80.68 ± 6.03 mmHg and 45.22 ± 4.98 mmHg, respectively. When the patients were evaluated according to the disease groups, 62 (31%) presented to the ED due to pulmonary complaints, 29 (14.5%) cardiac, 26 (13%) neurological, 28 (14%) urinary, 26 (13%) endocrinal and 29 (14.5%) other complaints.

The mean HR obtained from the VSM was 91.3 ± 23.7 bpm and the mean HR obtained from the smartphone was 90.11 ± 23.52 bpm. The ICC value for the HR measurements of the VSM and smartphone was 0.994 [95% confidence interval (CI): 0.987–0.997; $p < 0.001$], indicating an excellent agreement between the two devices (Table 1).

Using the Bland–Altman Method, the congruency between the HR values measured by the VSM and smartphone was evaluated. The mean value for the differences of the measurements was 1.19 (95% CI: 0.8656–1.5144), and the standard deviation value was 2.33. The limits of agreement at the 95% confidence level were calculated using the mean and standard deviation values of the differences between these measurements and determined as −3.37 and 5.75 (Fig. 2).

The mean SaO_2 values measured by the VSM, smartphone and BGA were determined as 92.6% ± 5.65, 92.72% ± 5.72, and 92.5% ± 5.69, respectively. The ICC values calculated for SaO_2 were 0.967 (95% CI: 0.956–0.975; $p < 0.001$) for the comparison of the VSM and BGA, 0.957 (95% CI:0.944–0.967; $p < 0.001$) for the comparison of the smartphone and BGA, and 0.949 (95% CI: 0.934–0.962; $p < 0.001$) for the comparison of the VSM and smartphone. The ICC values for the SaO_2 measurements obtained from the VSM, smartphone, and BGA showed an excellent agreement between the devices (Table 2).

The congruency between the SaO_2 measurements of the smartphone and BGA was also evaluated with the Bland-Altman plot. The mean difference of the measurements was determined as 0.22 (95% CI: −0.01188–0.4519), and the standard deviation value was 1.66.

Table 1
Comparison of the heart rate values measured by the VSM and smartphone.

	VSM heart rate	Smartphone heart rate
Mean ± SD	91.3 ± 23.7	90.11 ± 23.52
Median (min-max)	89 (39–166)	88 (38–164)
Regression equation	$y = 0.4889 + 0.007729$ x	
Intersection (95% CI)	0.4889 (−0.8026–1.7804)	
Curve (95% CI)	0.007729 (−0.006054–0.02151)	
ICC (95% CI)	0.994 (0.987–0.997)	
p value for ICC	<0.001	

VSM: Vital signs monitor, SD: standard deviation; ICC: Intra-class correlation coefficient, CI: Confidence interval.

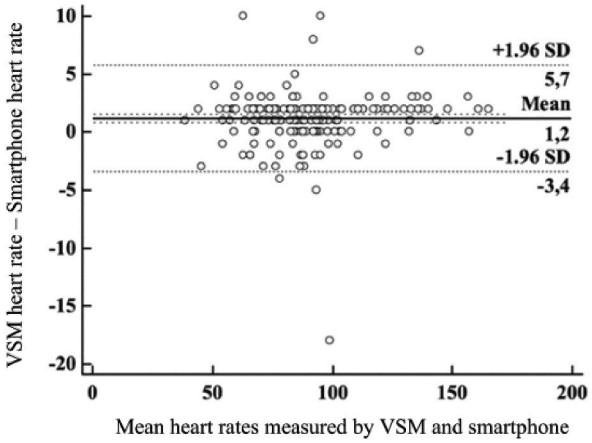

Fig. 2. Bland–Altman plot for the congruency between the heart rate values measured by VSM and smartphone.

Table 2
Comparison of the SaO_2 measurements of VSM, smartphone and BGA.

	VSM SaO_2	Smartphone SaO_2	BGA-SaO_2
Mean ± SD	92.6 ± 5.65	92.72 ± 5.72	92.5 ± 5.69
Median (min-max)	94 (72–99) 94	(72–99)	94 (72–100)
	VSM-BGA SaO_2	Smartphone-BGASaO_2	VSM-Smartphone SaO_2
Regression equation	$y = 0.7869 + -0.00748$ x	$y = -0.3632 + 0.0063$x	$y = 1.1597 + -0.0139$ x
Intersection (95% CI)	0.7869 (−2.5911–4.1649)	−0.3632 (−4.1927–3.4663)	1.1597 (−3.0247–5.3441)
Curve (95% CI)	−0.00748 (−0.0439–0.02896)	0.0063 (−0.03498–0.04757)	−0.0139 (-0.0589–0.0312)
ICC (95% CI)	0.967 (0.956–0.975)	0.957 (0.944–0.967)	0.949 (0.934–0.962)
p value for ICC	<0.001	<0.001	<0.001

SaO_2: Oxygen saturation, VSM: Vital signs monitor, SD: standard deviation; ICC: Intra-class correlation coefficient.

Using the mean and standard deviation values of the differences between these measurements, the limits of agreement at the 95% confidence level were calculated as −3.039 and 3.479 (Fig. 3).

Lastly, when the congruency between SaO_2 measurements of the VSM and smartphone was evaluated using the Bland–Altman method, the mean difference between the measurement values was calculated as −0.1250 (95% CI: −0.3770–0.1270) with a standard deviation of 1.81. Using the mean and standard deviation values of the differences between these measurements, the limits of agreement at the 95% confidence level were determined as −3.667 and 3.417 (Fig. 4).

4. Discussion

In this study, measurements of VSM with pulse oximetry probes, smartphones and BGA were compared. The ICC values of the SaO_2

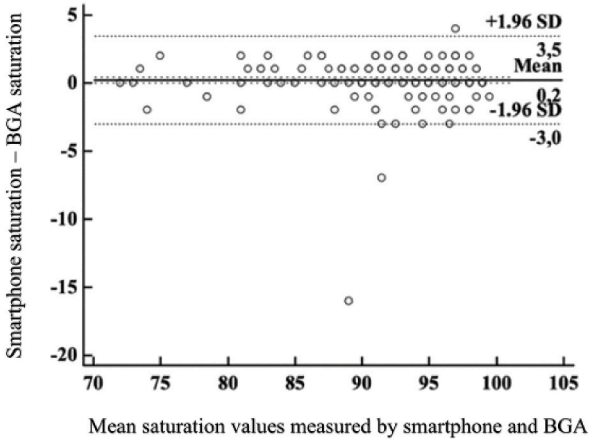

Fig. 3. Bland–Altman plot for the congruency between the SaO_2 values measured by smartphone and BGA.

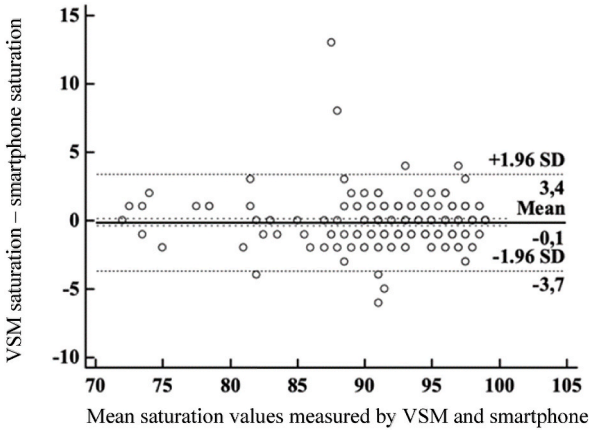

Fig. 4. Bland-Altman plot for the congruency between the SaO_2 values measured by VSM and smartphone.

measurements performed by the VSM, smartphone, and BGA indicated an excellent agreement between the devices. Similarly, the ICC value of the HR measurements showed an excellent agreement between the VSM and smartphone.

In a small-scale study conducted with nine patients to demonstrate the efficacy of pulse oximeters in measuring SaO_2 in hypotensive patients, Severinghaus et al. evaluated three different oximeter devices and found them to be unsuccessful [10]. Although smartphones and pulse oximeters use the same working principle, the reason why our study is not in agreement with that study may be that it was carried out in 1990 with the technical knowledge and facilities of that time and it was a small-scale study. With the developing technology and introduction of new methods, devices and software, these devices can now provide higher accuracy in the measurement of HR and SaO_2 in hypotensive patients.

Alexander et al. compared the HR and SaO_2 values measured by a VSM and a software application developed for the iPhone camera on healthy volunteers and found no correlation between the two measurements. However, as limitations of their study, the authors stated that the software application they used might have been inadequate and they performed the measurements only on healthy volunteers, and they emphasized the need for further studies to be conducted with patients [11]. Another limitation of that study was that the smartphone used did not have a special saturation probe integrated into the device, and saturation was attempted to be measured with the phone camera. Jordan et al. compared different software applications developed for iPhone 5S in 191 patients presenting with cardiopulmonary complaints or an SaO_2 value of $\leq$94%. The authors utilized two different applications using the camera and flashlight of iPhone 5S, an external device compatible with iPhone 5S, and a software application developed for this device. While the software applications using the camera and flashlight showed almost no agreement with the control group, the software application of the external device had a moderate level of agreement, but this device also misclassified patients at a rate of 1/4. As a result, the authors concluded that such software applications should not be trusted [12].

In a study conducted by Chan et al., HR and SaO_2 measurements with smartphones were undertaken in healthy volunteers and patients with chronic lung disease during exercise and at rest. In this study, measurements were made with the help of a probe connected to the audio jack of the smartphone. The saturation values measured both during exercise and at rest were evaluated to be reliable in the healthy volunteers. While the saturation values obtained at rest were found to be reliable in patients with chronic lung disease, they were not considered reliable during exercise [6]. Measurements during exercise not being reliable may be due to general measurement principles not being followed during this activity.

In contrast to Chan et al. and Alexander et al., Pipek et al. found that the HR and SaO_2 values were in agreement between the measurements performed using an Apple Watch Series 6 smartwatch and a pulse oximetry device among 100 volunteers with chronic lung disease [5]. Garde et al. in their study with the help of a probe connected to a smartphone, suggested that vital signs obtained from mobile devices might be useful in deciding on which patients to admit to the hospital [13]. Tayfur et al. used the integrated photoplethysmography (PPG) in the camera and flash of the Samsung Galaxy S8 smartphone in 101 patients, of whom 57 had cardiopulmonary diseases, and compared the HR and SaO_2 values with a VSM and an BGA. The authors reported that the HR values measured by the smartphone and VSM were highly correlated, and similarly the SaO_2 measurements of the smartphone and BGA were in high agreement. Tayfur et al. determined that the accuracy rates of vital signs increased with the development of smartphone technologies and software, and recommended further studies with different patient groups and a larger number of patients [7]. In another study, Browne et al., using the Samsung S9 Plus smartphone containing Maxim Integrated biosensors, reported that the results met the FDA/ISO accuracy certificate requirements for clinical pulse oximetry use [14]. Hoffman et al. used Google Nexus 6P in their study and they found in a wider range SaO2 values (70–100%) compared to the literature [15]. These studies show that more accurate results can be achieved through hardware and software developed as technology progresses.

In the current study evaluating hypotensive patients, in addition to a pulse oximeter, a smartphone based on the PPG technology, which is the main working mechanism of pulse oximeters was used. Comparison of the measurements performed by the pulse oximeter, smartphone using the PPG technology, and BGA, were found an excellent agreement between the SaO_2 values of all three devices, as well as the HR values measured by the VSM and smartphone. As a result, smartphones based on the PPG technology can be reliably

used in the measurement of vital signs, even in hypotensive patients according to results of this study. The widespread adoption of easily accessible mobile technologies that can be used at home without any additional device, especially in cases where patient-health personnel contact needs to be minimized, such as during pandemics will contribute to the early diagnosis of diseases, reduce the burden on the health system, and minimize the risk of disease transmission.

The most important limitations of our study include the single-center design and measurements being performed using a single smartphone. Multicenter studies to be conducted with larger and different patient groups using different models of smartphones, applications and software can better demonstrate the reliability of these devices in the evaluation of vital signs.

Declarations

Author contribution statement

Arman Totuk: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper. Burcu Bayramoğlu: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper. Ismail Tayfur: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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Data availability statement

Data will be made available on request.

Declaration of interest's statement

The authors declare no competing interests.

Additional information

No additional information is available for this paper.

Conflicts of interest

The authors declare that they have no conflict of interest.

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