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Clinical Validation of the Saadat Non-Invasive Blood Pressure Module According to the British Standard EN ISO 81060-2 Protocol

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Abstract

This study was conducted according to the British Standard EN ISO 81060-2 guidelines. The aim was to validate the Saadat non-invasive blood pressure (NIBP) module accuracy and reliability against manual auscultatory general practitioners (GP), readings. A total of 298 measurements and comparison procedures were performed on 95 adults without heart disease under the supervision of two GPs. In order to represent the relationships between the test device and the reference method, the Bland-Altman graphical plotting method was used. The mean differences and standard deviations (mean ± SD differences) between the readings of the Saadat NIBP module and determination of GPs as the reference method for systolic and diastolic were exceptionally close with: -2.22 ± 6.51 mmHg and -3.31±6.27 mmHg respectively. The Saadat NIBP module fulfilled the BS EN ISO 81060-2 requirements, which states that the mean ± SD of lower than 5±8 mmHg can be recommended for clinical use.

Keywords: Saadat NIBP, Validation, BS EN ISO 81060-2, Manual Auscultatory.

1. INTRODUCTION

Blood pressure is an important daily bio-signal, but the continuous monitoring of blood pressure is not an easy task [1-3]. Blood pressure is the force of blood pushing against the walls of the arteries [4-6]. Close monitoring of blood pressure is of great importance to the identification and treatment of hypotension and hypertension at the early stages. Both hypotension and hypertension can impair the function of vital organs, such as the heart, brain, and kidneys [7,8].

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Measuring blood pressure is important in determining the health status of an individual [9-11]. It serves medical treatment and foresees health concerns [12,13]. There are multiple techniques for determining blood pressure [14,15]. Blood pressure is measured using two numbers: systolic blood pressure and diastolic blood pressure [16,17].

An oscillometric means arterial pressure estimation method based on the dependence of pulse transit time on cuff pressure which is proposed in [18], the performance of which is compared with the maximum amplitude and zero-crossing methods in terms of mean error, mean absolute error, and standard deviation of error. An automatic blood pressure measurement based on the deep learning method is presented and the effects of stethoscope position and skin contact pressure on measured BPs were confirmed by applying this method [19]. The objectives of another study are to quantify concordance among blood pressure measurement methods and define the diagnostic sensitivity, specificity, and predictive value of automated office blood pressure. They are monitored in a population of hypertensive patients, which shows that the 4 measurement strategies provide similar average blood pressure estimates but generate many discordant results and the automated office blood pressure device can be very valuable as a replacement for the sphygmomanometer [20].

A patient-specific oscillometric blood pressure measurement is proposed in [21] and shown to be more accurate than the conventional method; therefore, the patient-specific method may improve automatic cuff blood pressure measurement accuracy.

Measurement can be completed through either the invasive or non-invasive method [22,23]. Invasive blood pressure measurements provide the beat to beat signals from the body [24]. Nevertheless, there are still disadvantages such as invasive inherency, arterial line infection, and expensive equipment which cause an increase in the usage of non-invasive devices as routine techniques in clinical practices [25,26].

Internationally, multiple companies manufacture non-invasive blood pressure sphygmomanometers. In order for the non-invasive sphygmomanometers to be approved, they have to be processed by a clinical investigation since they will be used on the general population indifferent to age, weight, or any special conditions of use. The automated oscillometric devices generally function based on linear deflation or step deflation [27,28].

The automated oscillometric is a common method for measuring blood pressure non-invasively. There are difficulties in choosing an accurate oscillometric device due to the abundance of this equipment in the market and only a few of which have published evidence indicating studies to test the reliability and validation of their techniques. Validation ensures the accuracy of technology as it is upheld and compared to a certain standard.

The main objective of this paper is to validate the Saadat NIBP module as an automated oscillometric device against the auscultatory technique following the BS EN ISO 81060-2. BS EN ISO 81060-2 criteria are divided into different populations, such as

healthy adults, cases with some specified heart disease, and also pregnant women. This research was done for healthy volunteer adults according to EN ISO 81060-2 guidelines. This paper is structured as follows. In the section 1 of the paper, the whole subject of the study is mentioned. In section 2, materials and methods are shown. Discussion and explanation of the paper is in section 3. The results using the template is shown in section 4.

2. MATERIALS AND METHODS

According to the BS EN ISO 81060-2 criteria, the automated non-invasive sphygmomanometers must be validated with an auscultatory sphygmomanometer. The two GPs tried to ease the participants into a state of rest by talking to them in order to accurately record their blood pressure.

General practitioners trained in using a proper methodology for performing a resting blood pressure determination by utilizing an accepted clinical protocol for blood pressure measurement. This study was conducted on 95 randomly selected adult volunteers who wanted to check their health status. Subjects were recruited from the Feiz Hospital in Isfahan, Iran. Each subject was considered clinically stable and suitable. The average of the means, that the GPs came to after examining the results of the audible blood pressures, were considered a reference sphygmomanometer determination and the conclusions that the Saadat NIBP oscillometric module introduced was considered a sphygmomanometer under test. Cases with heart disease, no palpable brachial pulses for blood pressure, atrial fibrillation or other sustained arrhythmias, were excluded.

Cases with no clear phase 5 Korotkoff sound signaling diastolic or no audible Korotkoff sounds at all, were also excluded [29]. The whole clinical investigation procedure was performed under the supervision of two experienced GPs.

All participants received written informed consent prior to testing. It is important to say that this study has adopted an ethics commission in the medical science committee of Islamic Azad University, Najafabad branch with an approval id of IR.IAU.NAJAFABAD.REC.1397.56.

2.1.Validation Procedure

As per the criteria mentioned by the BS EN ISO 81060-2, the sphygmomanometer under the test cuff and the reference cuff are placed on opposite arms and will be altered with each trial. In order to measure the blood pressure of a participant, the GPs used the 3M Littman Master Classic II Teaching Stethoscope 40-inch Model 2139 alongside the Reister Big Ben Square Sphygmomanometer which has an error tolerance +/- 2 mmHg. The device is set on an adjustable stand where the GPs can change the height from 70 to 120 cm so that the reading is at their eye level. All recorded data and signals relating to the NIBP were stored via data collecting software which is written in Visual C# by the R&D department of Saadat Co. The GPs using the reference sphygmomanometer and sphygmo-manometer under test simultaneously determined the subject's blood pressure in opposite arms and interchanged arm sides between the two.

This was repeated until at least three pairs or at most six paired determinations were

completed. In the case that the determination was not successfully completed, it was redone without changing arm sides. As stated by protocol, the GP's recordings of their observations were not visible and remained unknown to each other.

Between each determination, the research group cleared the memory of the previous NIBP determination and waited at least 60 seconds. During the span of the examination, the subjects were advised not to move and talk. Participants were put in a stable position in which their back, forearm, and elbow were supported. The GPs placed the middle of the cuff at the level of the right atrium of the heart, placed the stethoscope over the brachial artery, and waited 5 minutes before the first recording.

According to BS EN ISO 81060-2, any pair, recorded by the GPs with a difference greater than 4mmHg, were excluded. In order to standard criteria the event that : 1) any two reference systolic blood pressure determinations on the same arm differed by more than 12 mmHg or any two references diastolic blood pressure determination on the same arm differed by more than 8 mmHg; 2) the lateral difference of the reference systolic blood pressure determinations was more than 15 mmHg or the lateral difference of the reference diastolic blood pressure determination was more than 10 mmHg, all data from a subject were excluded. The target population must meet the specified requirement from different aspects such as the subject population, gender, limb size distribution, and blood pressure distribution. This study of 95 adult volunteers without heart diseases resulting in 298 pairs of data, has an age average of 43, 61.75% (184/298)

male and 38.25% (114/298) female. All cuffs used in this evaluation were manufactured by Saadat Co. Since the sphygmomanometer under test has two cuff sizes following the BS EN ISO Protocol, at least 25% of the data has to use each cuff size, in which size 04 was used 71.47% (213/298) and size 05 was used 28.53% (85/298). The BS EN ISO requirements and the blood pressure distributions are more thoroughly explained in Table 1 provided in the results section.

2.2. Data Analysis

Taking the data collected by the mentioned software, the mean ±SD differences between the test device and the reference method must be lower than 5±8 mmHg for systolic, diastolic and referring to the BS EN ISO criteria.

As the data was being recorded, it was constantly stored in an Excel file, followed by a data analysis completed through the MATLAB version R2018b software.

The sphygmomanometer under test error was calculated by taking the difference between the sphygmomanometer under test blood pressure and the reference sphygmomanometer blood pressure and adding by the lateral difference. In order to showcase the relationship between the auscultatory method and NIBP, as recommended by BS EN ISO, Bland-Altman plots were used.

2.3. Results

After analyzing the data of this study collected from 95 adults and 298 pairs of data, the conclusion reached was that the blood pressure distribution is 23.82% above

140 mmHg (71), 19.12% below 100 mmHg (57) and 06.04% above 160mmHg (18) for systolic. The blood pressure distribution for diastolic were 20.80% above 85 mmHg (62), 17.11% below 60 mmHg (51) and 05.70% above 100mmHg (17). Through examining the results of the study and comparing them to the BS EN ISO requirements, it is apparent that they are completely in line with one another and that the mean differences between the GP's and test device technology readings were exceptionally close as displayed in Table 1.

The Bland-Altman plots are used to present the discrepancies between the test device and the reference method for systolic and diastolic in Fig. 1 and Fig. 2 respectively. The x-axis represents the average of both techniques while the y-axis is the difference between the test device and reference method, both are displayed in mmHg. The mean ± SD differences between the readings of test device and determination of GPs as the reference method for systolic and diastolic were: -2.22±6.51 mmHg and -3.31±6.27 mmHg respectively. As shown in the plot, only a few of the data are scattered out of the limits of agreement.

Table 1. *Validation results and BS EN ISO requirements*

| Result Investigation & BS EN ISO Requirement			
Criteria		BS EN ISO Requirement	Result Investigation
Number	Subject	85	95
	Blood pressure test	255	298
Gender	Male	30%	61.75% (184/298)
	Female	30%	38.25% (114/298)
Limb Size	Cuff 04	25%	71.47% (213/298)
	Cuff 05	25%	28.53% (85/298)
Blood Pressure Distribution	Systolic	5% below 100mmHg	19.12% below 100mmHg (57/298)
		20% above 140mmHg	23.82% above 140mmHg (71/298)
		5% above 160mmHg	6.04% above 160mmHg (18/298)
	Diastolic	5% above 100mmHg	5.70% above 100mmHg (17/298)
		5% below 60mmHg	17.11% below 60mmHg (51/298)
		20% above 85mmHg	20.80% above 85mmHg (62/298)
Mean ± SD	Systolic	≤ 5 ± 8 mmHg	-2.22 ± 6.51
	Diastolic		-3.31 ± 6.27
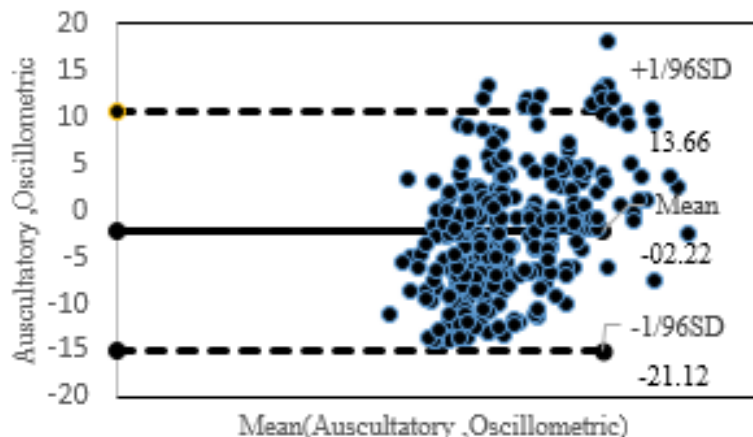
Fig. 1. Systolic pressure Reference value minus Test value mean of Reference & Test value for 298 pairs of measurement (n=95) limits of agreement (Mean ± 1.96SD): (-21.12 to 13.66).
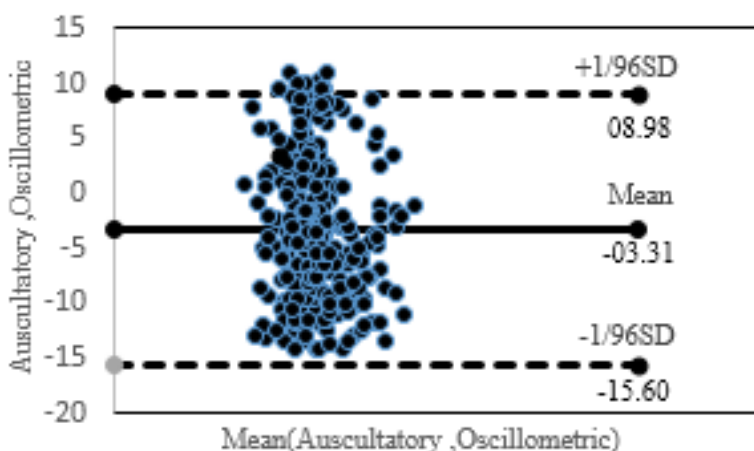

Fig. 2. Diastolic pressure Reference value minus Test value mean of Reference & Test value for 298 pairs of measurement (n=95) limits of agreement (Mean ± 1.96SD): (-15.60 to 08.98).

3. DISCUSSION

As mentioned earlier, the intention of this study was to validate the Saadat NIBP module. Hence, the oscillometric method was used and a total of 298 pairs of data were collected from 95 average healthy adults. In order to meet the criteria mentioned by BS EN ISO 81060-2, collecting high and low blood pressure points where required. Since our target group was "everyday healthy adult" individuals with blood pressure above 160mmHg for systolic and 100mmHg for diastolic, as stated by the ISO criteria, data were rare. This is the same limitation affiliated with using the invasive blood pressure method [30].

Considering individuals with extreme blood pressures were under medical supervision, using the invasive blood pressure method possibly was harmful. This is overcome by the auscultation method.

Nevertheless, the auscultation method also had complications. In order to have accurate data and minimize human error during listening, GPs were tested and persons

with similar hearing ability had to be chosen. Another noteworthy point is that the subjects needed to be calm and at ease. Taking into consideration any factor that could influence blood pressure such as smoking, stress and nervousness, subjects were placed into a state of stability so that the data collected would be as accurate as possible [31].

This also made sure that all subjects were tested in equal circumstances of stability so that the data collected would be as accurate as possible. Despite the complications we faced, the Saadat team was able to successfully conduct this study following the BE EN ISO 81060-2 criteria and thus validated the Saadat NIBP module that published the results.

In future work, we can also study the recorded signals from cases and, for example, compare the shape of cases' blood profiles with each other in terms of accuracy.

4. USING THE TEMPLATE

The Saadat Patient Care Monitor Alborz B9 that includes the NIBP module fulfilled the BS EN ISO 81060-2 validation requirements of the automated oscillometric devices. This was proven according to the analyzed results of the NIBP measurements and it is recommended to be used for clinical or research purposes.

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