Research Article

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Validation of the DBP-20I Monitor for Self Blood Pressure Measurement According to the Universal Protocol

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Abstract

Objective: To determine the accuracy of the Hingmed DBP-20i monitor, a device intended for oscillometric self blood pressure (BP) measurement according to the new ISO81060-2 2018/Amd 1/ Amd 2 (Universal) protocol.

Methods: The DBP-20i monitor was tested in 90 subjects from the general population aged from 19 to 78 years (mean 41 years). The device was provided with a single wide-range cuff suitable for arm circumferences ranging from 17 to 42 cm. The validation was carried out performing sequential same-arm measurements strictly following the universal protocol.

Results: The mean device–observer difference was 3.71±3.44 mmHg for systolic BP and 3.21±3.54 mmHg for diastolic BP. Both mean and standard deviations were below the maximum values required by the protocol (≤ 5 ± 8 mmHg) and thus criterion 1 was satisfied. The device performance satisfied also criterion 2 of the protocol being the standard deviations (3.38/3.45 mmHg) well below those required by the protocol (5.83/6.03 mmHg).

Conclusions: The Hingmed DBP-20i device satisfied the ISO 81060-2:2018/Amd 1/Amd 2 standard requirements for a general population study and is suitable for BP measurement in people with arm size ranging from 17 to 42 cm.

Keywords

DBP-20I monitor, Self blood pressure measurement, Blood Pressure.

INTRODUCTION

A number of studies indicate that a large number of the upper arm devices sold in medical markets and electronic stores do not report any information about cuff size and suitability [1]. Yet, appropriate cuff size is crucial for accurate blood pressure (BP) measurement [2,3]. Obesity is an emerging problem worldwide [4] and obese patients often require the use of large-sized cuffs [5,6]. Indeed, a body of evidence has shown that the use of a standard size cuff in people with large arms may lead to inaccurate readings [2,3,7]. The regular adult cuff width and length are often inappropriate for individuals with large arms and many people will have inaccurate BP measurement if BP monitors are not provided with large cuffs [8,9]. However, in patients with very large arms, measurement with a cuff of appropriate size may be difficult in the presence of short upper-arms because the elbow end of the cuff may extend past the elbow.

The accuracy of blood pressure (BP) measurement devices should be assessed with a well standardized procedure as recommended by all international guidelines [5,6]. With the old validation protocols arm circumference was not included among the patient selection criteria [10]. The recent ISO protocol 81060-2:2018/ Amd1/Amd 2 (ISO), which represents the joint action of several International Organizations for Standardization [11,12], established more stringent criteria for the validation of BP measuring devices including arm size distribution among the requirements for subject recruitment.

To facilitate the measurement of BP in subjects with a wide range of arm sizes, some companies developed so-called wide-range cuffs which are able to measure BP accurately over a wide range of arm circumferences [9,13]. However, it is crucial that monitors provided with these cuffs are validated on a wide range of arm sizes testing also subjects with arm circumferences at the extremes of the declared range. This paper reports on the accuracy and reliability of the Hingmed DBP-20i monitor, an oscillometric device intended for BP measurement in hospital or other medical establishments, which was tested in a general population using a single wide-range cuff suitable for arm circumferences ranging from 17 to 42 cm.

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SUBJECTS AND METHODS

Participants

Study participants older than 12 years of age were recruited from among the outpatients or the staff of the Poliambulatorio Arcella, Padua, Italy. Gender and BP distributions are reported in table 1 and 2. The distribution of upper arm circumference was in accordance with the ISO requirements (Table 2). The study was approved by the Institutional Review Board of the Poliambulatorio Arcella and performed according to the Declaration of Helsinki. A written informed consent was given by all the participants.

Table 1: Characteristics of the participants enrolled in the DBP-20i general population study. Protocol requirements and study results.

	Standard	Result		Judgement
Number of subjects	85 people or more	90 people		PASS
Number of measurements	7 times or more 3 valid test/ reference BP pairs	7 times 3 valid test/reference BP pairs		PASS
Observer	2 people	2 people		PASS
Observer difference	±4mmHg or less	±4mmHg or less		PASS
Gender	Male 30% or more Female 30% or more	45 people	50%	PASS
		45 people	50%	
Age	>12 years old: 100%	90 people (mean, 41.3, range 19-78 years)	100%	PASS

Devices

The DBP-20i monitor is an oscillometric upper-arm BP monitor manufactured by Shenzhen Hingmed Medical Instrument Co.,Ltd (Shenzhen, China), designed for BP measurement in hospital or other medical establishments. The memory allows for 1000 BP and heart rate data storage. The wide-range cuff used in the present study was suitable for arm circumferences ranging from 17 to 42 cm.

Procedures

The validation study was performed by two trained observers (EM and DdF) who had each received adequate training by an expert in BP measurement (CF). BP was measured with a mercury sphygmomanometer at the upper arm using cuffs whose bladders had to cover 75 to 100% of the circumference of the arm [6]. The device was tested performing sequential same-arm measurements strictly following the ISO protocol [11]. A reference BP measurement was taken by the two observers, followed by a test device measurement. Then, four sequential readings were taken by observers 1 and 2 (BP1, BP3, BP5, and BP7), and three BP readings were taken by the supervisor (CF) with the test instrument (BP2, BP4, and BP6). The two observers were blinded to the measurements obtained by each other and to the device readings.

Data Analysis

The device-observer BP differences were expressed as mean ± SD and the required criteria 1 and 2 of the ISO protocol were used [11,12]. According to criterion 1, the mean device-observer BP difference should be ≤ 5 mmHg and the standard deviation ≤ ±8 mmHg. According to criterion 2, the maximum permissible standard deviation is a function of the mean device-observer BP difference, as reported in table 1 of the ISO protocol. Analyses were performed using Systat version 12 (SPSS Inc., Evanston, IL, USA). MedCalc version 19 (MedCalc Software, Ostend, Belgium) was used to generate the Bland-Altman plots [14].

RESULTS

Ninety participants were enrolled and were categorized on the basis of the BP and arm size ranges (Table 2). The mean device–observer difference was 3.71±3.44 mmHg for systolic BP and 3.21±3.54 mmHg for diastolic BP in agreement with criterion 1 of the ISO protocol requirements (Table 3). Also criterion 2 was satisfied being the standard deviations of the participants 3.38 mmHg for systolic BP and 3.45 mmHg for diastolic BP, well below the maximum values required by the protocol (Table 3). Plots of the device-observer BP differences according to BP level are shown in figure 1 and according to arm circumference in figure 2.

Table 2: Participants' arm size distribution and blood pressure range.

Standard	Result			Judgement
Arm circum-ference	Upper 50%	at least 40%	43.3% (31-42 cm)	PASS
	Lower 50%	at least 40%	56.7% (17-30 cm)	
	Upper 25%	at least 20%	26.7% (37-42 cm)	
	Lower 25%	at least 20%	26.7% (17-23 cm)	
	Upper 12.5%	at least 10%	12.2% (40-42 cm)	
	Lower 12.5%	at least 10%	12.2% (17-20 cm)	
Range of blood pressure (mmHg)	SBP>=160	at least 5%	18.1%	PASS
	SBP>=140	at least 20%	47.0%	
	SBP<=100	at least 5%	15.2%	
	DBP>=100	at least 5%	20.4%	
	DBP>=85	at least 20%	44.1%	
	DBP<=60	at least 5%	9.6%	

SBP indicates systolic blood pressure; DBP, diastolic blood pressure

Table 3: Results of the validation for the DBP-20i general population study according to the ISO81060-2 2018/Amd 1/Amd 2 protocol.

Criterion1	Standard	Criterion1	Result	Judgement
Mean value	±5mmHg or less	SBP	3.71 mmHg	PASS
		DBP	3.21 mmHg	PASS
Standard deviation	8mmHg or less	SBP	3.44 mmHg	PASS
		DBP	3.54 mmHg	PASS
Criterion2	**Standard**	**Criterion2**	**Result**	
Standard Deviation	<5.83 mmHg	SBP	3.38 mmHg	PASS
	<6.03 mmHg	DBP	3.45 mmHg	PASS

SBP indicates systolic blood pressure; DBP, diastolic blood pressure

DISCUSSION

Several studies have shown that miscuffing is common in clinical practice especially in people with large arms in whom too small cuffs are often used causing an overestimation of the true BP [7-9]. The use of cuffs containing bladders of inappropriate dimensions may be the source of substantial errors which leads to erroneous conclusions in clinical practice [5,6]. The majority of users are able to use the standard size cuff that comes with the device and get accurate readings. However, an increasingly larger portion of the general population has large arms [4] and a standard size cuff and bladder may produce inaccurate readings and spuriously increase the recorded BP leading

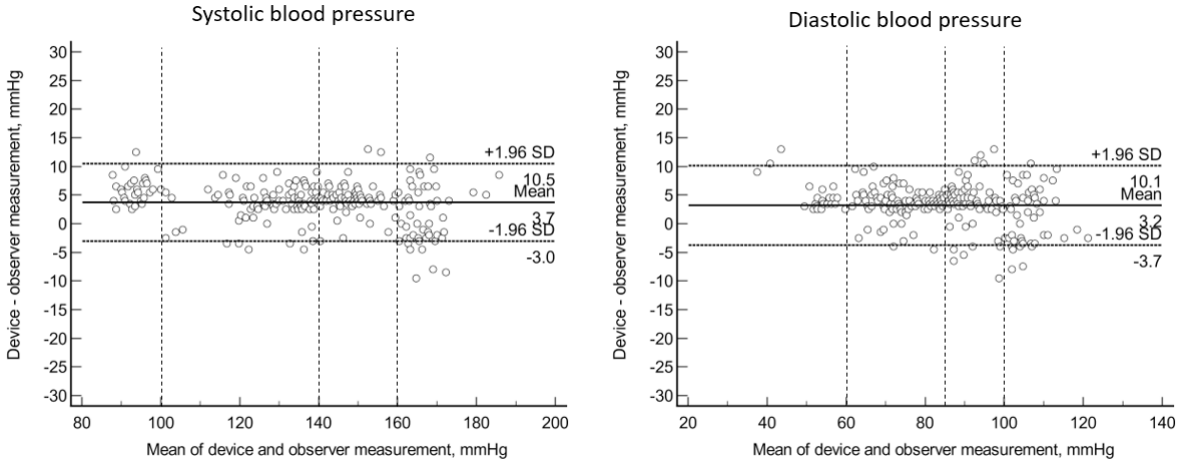

Figure 1: Scatter plots of systolic and diastolic blood pressure differences between the DBP-20i device and the observers (y-axis) against the average of the test device and observer pressure values (x-axis) in the General Population study (N=90).

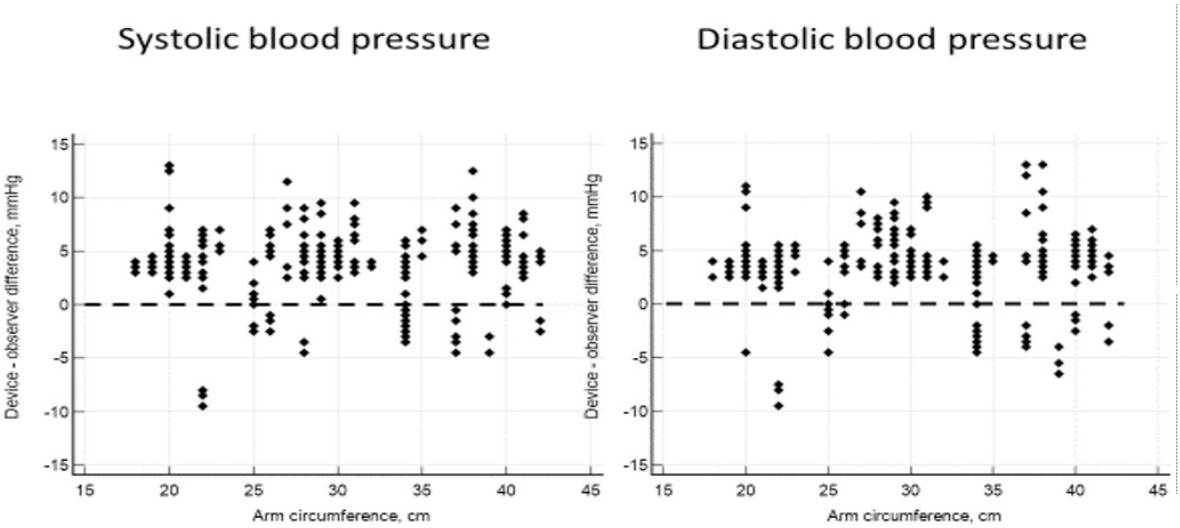

Figure 2: Scatter plots of systolic and diastolic blood pressure differences between the DBP-20i device and the observers (y-axis) against the mid-arm circumference (x-axis) in the General Population study (N=90).

to overdiagnosis of hypertension. For this reason, wide-range cuffs that can cover a broad range of arm sizes, thanks to a software that can adjust the device parameters based on the characteristics of the individual arm being tested, have been introduced into the market [9,13]. However, it is of paramount importance for the manufacturer to demonstrate that these cuffs, that have inappropriate bladder dimensions according to current standards, provide reliable results across the full range of arm circumferences.

In the present study, we tested the accuracy of a single wide-range cuff that may fit arms 17 cm to 42 cm in circumference. Our results in 90 subjects from the general population showed that the DBP-20i monitor using the wide-range cuff proved to be accurate for all arm circumferences. In fact, as shown in figure 2, the device-observer systolic and diastolic BP differences were unrelated to the arm size.

CONCLUSIONS

The present results show that the Hingmed DBP-20i monitor provided with a single wide-range cuff satisfied the ISO protocol requirements for a general population across a wide range of arm sizes. In addition, within our sample, we did not find any relationship between the device-observer systolic and diastolic BP discrepancies and the circumference of the arm.

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