Research Article

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Accuracy of the WBP-02A Device for Ambulatory Blood Pressure Measurement According to the Universal Protocol

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Abstract

Objective: To determine the accuracy of the Hingmed WBP-02A monitor, an ambulatory blood pressure monitoring device, according to the new ISO81060-2 2018/Amd 1/Amd 2 (Universal) protocol.

Methods: The WBP-02A device was tested in 95 subjects from the general population using four cuffs of different size and in 36 subjects who underwent a bicycle ergometric test.

Results: In the general population, the mean device–observer blood pressure difference was 3.98±3.77 mmHg for systolic blood pressure and 3.53±3.37 mmHg for diastolic blood pressure. The mean and standard deviation were below the maximum values required by the protocol (≤ 5 ± 8 mmHg) and thus criterion 1 was satisfied. Also criterion 2 of the protocol was satisfied being the standard deviations (3.71/3.31 mmHg) well below those required by the protocol (5.64/5.97 mmHg). During the ergometric test the mean device–observer difference was 3.84±2.97 mmHg for systolic blood pressure and 3.30±3.06 mmHg for diastolic blood pressure satisfying the protocol requirement.

Conclusions: The WBP-02A monitor satisfied the ISO 81060-2:2018/Amd 1/Amd 2 standard requirements for a general population study and also the protocol criterion for ambulatory blood pressure monitoring devices.

Keywords

Ambulatory Blood Pressure Monitoring (ABPM), WBP-02A device, Hypertension.

INTRODUCTION

The accuracy of blood pressure (BP) measurement is of paramount importance for the correct diagnosis of hypertension and the choice of appropriate antihypertensive treatment. To this end a well standardized procedure should be followed using reliable BP measurement devices [1,2]. Thus, as recommended by all international guidelines, only automatic BP monitors validated according to the requirements of international protocols should be used. With the old validation protocols, arm size was not included among the patient selection criteria [3-5]. In addition, the requirements for devices intended for ambulatory BP monitoring were the same as those for office or home BP monitors and the validation test was performed only in a stationary condition.

The recent ISO protocol 81060-2:2018/Amd1/Amd 2 (ISO), which represents the joint action of the Association for the Advancement of Medical Instrumentation, European Society of Hypertension International Protocol and International Organization for Standardization [6,7], established more stringent criteria for the validation of BP measuring devices including arm size distribution among the criteria for subject recruitment to ensure an even representation of all cuffs [8]. In addition, for the validation of monitors intended for ambulatory BP measurement (ABPM) an additional clinical investigation was required. In fact, the accuracy of the monitor has to be tested also during exercise on a bicycle ergometer to obtain an increase in heart rate of at least 15% of baseline level [8].

The aim of this study was to verify the accuracy and reliability of the WBP-02A device, intended for ABPM. The WBP-02A was first validated in a general population study and then tested in a subgroup of participants who performed bicycle ergometry.

SUBJECTS AND METHODS

Participants

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 for the WBP-02A general population and ambulatory BP studies

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are reported in table 1 and 2, respectively. The distribution of upper arm circumference was in accordance with the ISO requirements for a device provided with 4 cuffs (Table 3). 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 WBP-02A general population study. Protocol requirements and study results.

	Standard	Result		Judgement
Number of subjects	85 people or more	95 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	48 people	50.5%	PASS
		47 people	49.5%	
Age	>12 years old: 100%	95 people (mean, 40.2, range 19-78 years)	100%	PASS

Table 2: Characteristics of the subjects participating in the WBP-02A Ambulatory BP Monitoring study. Protocol requirements and study results.

Criterion	Standard	Results		Judgement
Number of subjects	35 people or more	36 people		PASS
Number of Measurement	7 times or more	7 times		PASS
Observer	2 people	2 people		PASS
Observer difference	±4mmHg or less	±4mmHg or less		PASS
Gender	Exempt	20 men	55.6%	PASS
		16 women	44.4%	
Age	>12 years old: 100%	36 people (mean, 36.7 ys Range, 19-78 ys)	100%	PASS
Heart rate increase during ergometry	>15% resting heart rate:	100% people (mean, 20.1% range, 16.0%-28.2%)		PASS

Table 3: WBP-02A general population study. Participants' arm size distribution, blood pressure range and cuff type.

Standard	Result			Judgement
	Arm circumference			
	Upper 50%	at least 40%	43.2% (31-42 cm)	PASS
	Lower 50%	at least 40%	56.8% (18-30 cm)	
	Upper 25%	at least 20%	20.0% (38-43 cm)	
	Lower 25%	at least 20%	25.3% (18-23 cm)	
	Upper 12.5%	at least 10%	10.5% (41-43 cm)	
	Lower 12.5%	at least 10%	10.5% (18-20 cm)	
	Range of blood pressure in mmHg			
	SBP>=160	at least 5%	18.9%	PASS
	SBP>=140	at least 20%	50.5%	
	SBP<=100	at least 5%	14.7%	
	DBP>=100	at least 5%	21.1%	
	DBP>=85	at least 20%	47.4%	
	DBP<=60	at least 5%	10.2%	
Type of cuff				
	SA cuff (18-26 cm) 16 people or more		22 people	PASS
	A cuff (22-32 cm) 20 people or more		21 people	
	LA cuff (22-36 cm) 27 people or more		27 people	
	XLA cuff (30-43 cm) 25 people or more		25 people	

SBP indicates systolic blood pressure; DBP, diastolic blood pressure; SA, small adult; A, adult standard; LA, large adult; XLA, extra-large adult.

Devices

The WBP-02A ambulatory BP model is an oscillometric fully automatic device for ABPM at the upper arm, manufactured by Shenzhen Hingmed Medical Instrument Co.,Ltd (Shenzhen, China). The device's memory allows for 300 BP and heart rate data storage, and these data can be transferred to PC software by USB wire. The device can automatically take measurements at fixed intervals ranging from 5 to 120 minutes. The four cuffs used in the present study are suitable for arm circumferences ranging from 18.0 to 43.0 cm (small adult cuff, 18-26 cm; middle adult cuff, 22-32 cm; large adult cuff, 26-36 cm; extra-large adult cuff, 30-43 cm).

Procedures

Both validation studies were 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 [8]. Validation of the devices was carried out performing sequential same-arm measurements strictly following the ISO protocol [8]. 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.

During the ergometric study on the bicycle, the cuff was supported and kept at the level of the heart. During the BP measurements, the subjects continued to pedal in order to keep their heart rate level always at least 15% higher than at baseline. The heart rate was recorded during the exercise for each observer and device BP measurement.

Data analysis

For the general population study, the required criteria 1 and 2 of the ISO protocol were used, and the device-observer BP differences were expressed as mean ±SD [6-8]. 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. Only criterion 1 is required for ABPM studies. 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 [9].

RESULTS

General Population Study

Ninety-five participants were enrolled to satisfy the minimum number of subjects per cuff and were categorized on the basis of the BP and arm size ranges (Table 1). The participants' arm size distribution, BP range and cuff type are reported in table 3. All participants' characteristics satisfied the requirements of the ISO protocol. In the general population, the mean device–observer difference in the 285 separate BP data pairs was 3.98±3.77 mmHg for systolic BP and 3.53±3.37 mmHg for diastolic BP in agreement with criterion 1 of the protocol standard requirements (≤ 5 ± 8 mmHg) (Table 4). Also criterion 2 was satisfied being the standard deviations of the 95 participants well below the maximum values required by the protocol (Table 4)**.** Plots of the device-observer BP differences according to BP level are shown in figure 1 and according to arm circumference in figure 2.

Ambulatory BP measurement study

Thirty-six participants were enrolled. Their characteristics are reported in table 2. The average heart rate increase during bicycle ergometry was 20.1% (range 16.0% to 28.2%). The mean device–observer difference in the 108 separate BP data pairs and their standard deviation were 3.84 ± 2.97 mmHg for systolic BP and 3.30 ± 3.06 mmHg for diastolic BP, in agreement with criterion 1 of the protocol standard requirements. Plots of the device-observer BP differences according to systolic BP and diastolic BP distribution are shown in figure 3.

Table 4: Results of the validation for the WBP-02A general population study according to the ISO protocol.

Criterion 1, Standard		**Criterion 1, Result**		**Judgement**
Mean value	± 5mmHg or less	SBP	3.98 mmHg	PASS
		DBP	3.53 mmHg	PASS
Standard deviation	8mmHg or less	SBP	3.77 mmHg	PASS
		DBP	3.37 mmHg	PASS
Criterion 2, Standard		**Criterion 2, Result**		
Standard Deviation	<5.64 mmHg	SBP	3.71 mmHg	PASS
	<5.97 mmHg	DBP	3.31 mmHg	PASS

SBP indicates systolic blood pressure; DBP, diastolic blood pressure

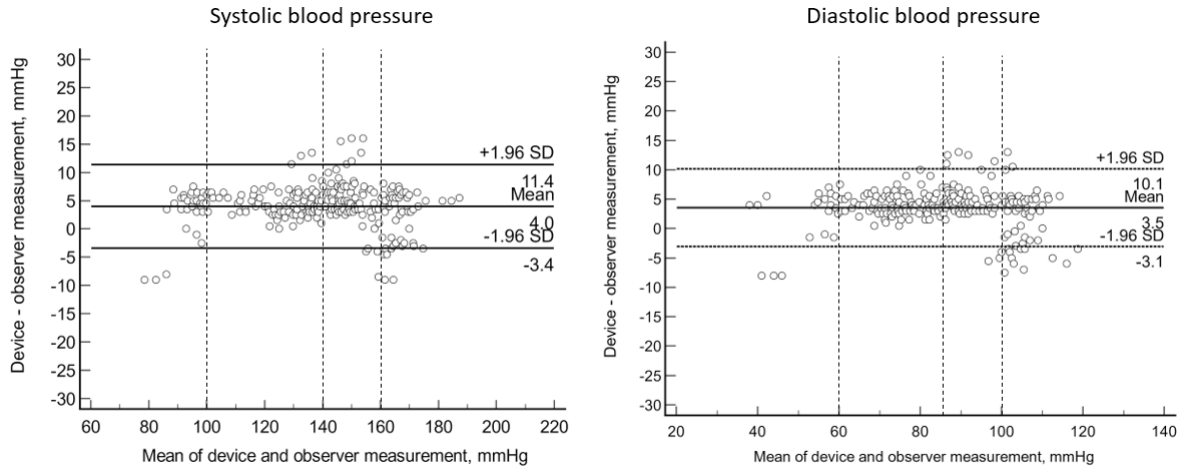

Figure 1: Scatter plots of systolic and diastolic blood pressure differences between the WBP-02A device and the observers (y-axis) against the average of the test device and observer pressure values (x-axis) in the General Population study (N=95).

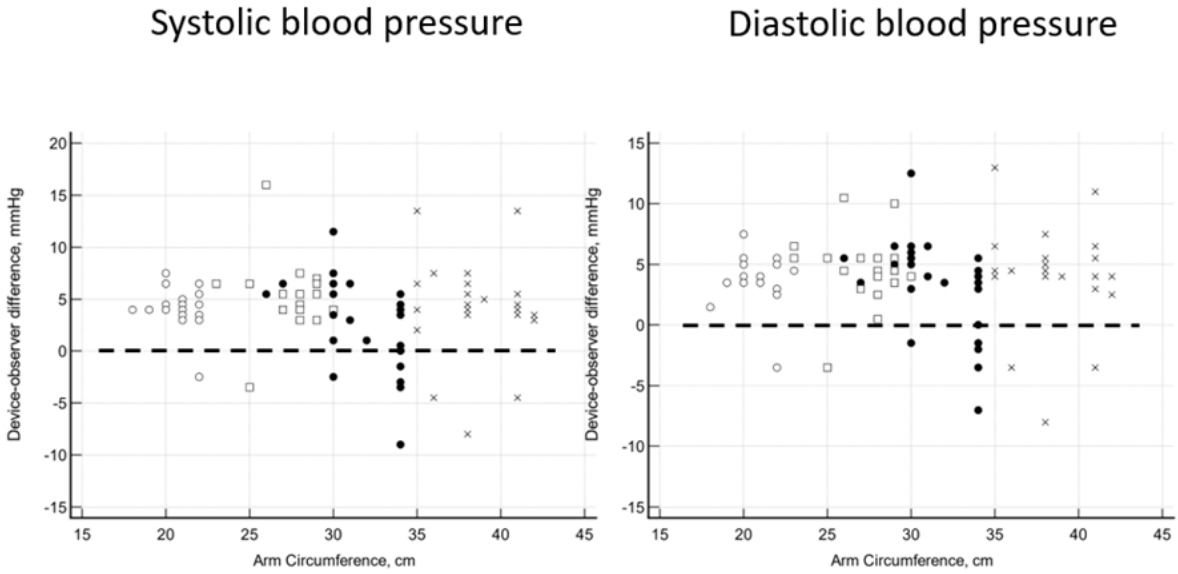

Figure 2: Scatter plots of systolic and diastolic blood pressure differences between the WBP-02A device and the observers (y-axis) against the arm circumference in the General Population study (N=95). Four different cuffs were used according to arm size, as indicated by the symbols. SA indicates small adult; A, adult standard; LA, large adult; XLA, extra-large adult.

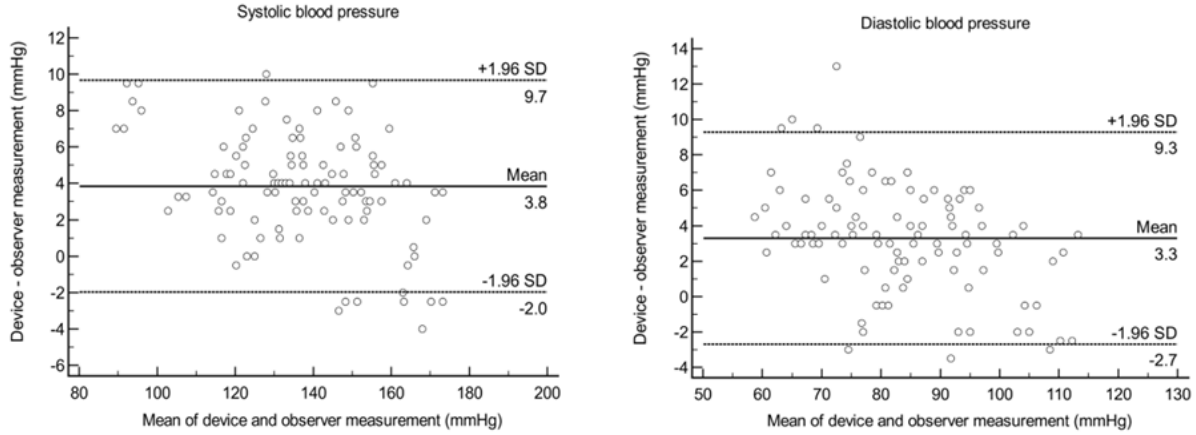

Figure 3: Scatter plots of systolic and diastolic blood pressure differences between the WBP-02A device and the observers (y-axis) against the average of the test device and observer pressure values (x-axis) during the ergometric test in the Ambulatory BP Monitoring study (N=36).

DISCUSSION

Before 2018, for the validation of ABPM devices all international protocols used the same criteria as those used for devices measuring BP in resting conditions [3-5]. However, during ABPM BP is measured with the subject performing his/her routine activities and not only in stationary conditions. With the advent of the recent ISO protocol in 2018 [6-8], an additional ergometric investigation was requested in at least 35 subjects with the purpose of obtaining a steady increase in heart rate during the BP measurements. However, only a few automatic devices have been validated using this new modality. The present results showed that the WBP-02A monitor not only fulfilled the validation criteria in the static study performed in 95 participants from the general population but also satisfied criterion 1 in the dynamic study indicating that the monitor performance was not affected by the hemodynamic changes during exercise.

CONCLUSIONS

The present results show that the Hingmed WBP-02A monitor satisfied both the ISO standard requirements for a general population and the protocol requirement for validation of devices intended for ABPM. In fact, the accuracy of the WBP-02A remained substantially unchanged during stress testing.

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