Validation of the Beneware model ABP-021 ambulatory blood pressure monitor according to the revised 2010 European Society of hypertension international protocol

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Objectives **This study aimed to evaluate the accuracy of the Beneware model ABP-021 oscillometric blood pressure monitor in the general population according to the European Society of Hypertension International Protocol (ESH-IP). The accuracy of the device was assessed in relation to various clinical variables, including age, sex, BMI, and arm circumference.**

Methods **Thirty-three individuals (18 men and 15 women), with a mean age of 36 ± 14 years (age range: 20–68 years), were studied according to the recommendations of the ESH-IP. Sequential same-arm blood pressure measurements were performed, alternating between a mercury standard and the automatic device. The differences among the test–control measurements were assessed and divided into categorization zones of 5, 10, and 15 mmHg discrepancy.**

Results **The device complied with the quality requirements of the ESH-IP. The device–observer disagreement was − 1.2 ± 4.7 mmHg for systolic blood pressure (SBP) and − 1.7 ± 4.3 mmHg for diastolic blood pressure (DBP). The device produced 77, 93, and 98 measurements, respectively, within the 5, 10, and 15 mmHg discrepancy limits for SBP. For DBP, 80, 97, and 99 measurements were observed within the 5, 10, and 15 mmHg discrepancy limits. The number of participants with two or three of the device–observer differences within 5 mmHg was 26 for SBP and 29 for DBP, whereas there were only two participants with no device–observer differences within 5 mmHg for DBP.**

Conclusion **These data show that the Beneware model ABP-021 monitor meets the requirements of the ESH-IP, in static conditions, indicating its suitability for measuring blood pressure in the general adult population. *Blood Press Monit* 23:210–213 Copyright © 2018 Wolters Kluwer Health, Inc. All rights reserved.**

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Keywords: ambulatory blood pressure monitoring, arterial hypertension, blood pressure, validation

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Introduction

Cardiovascular diseases are the leading cause of mortality and morbidity worldwide, and arterial hypertension (HT) is one of the most significant contributors to the epidemiological burden of cardiovascular diseases [1]. Given this well-known concern, HT needs to be studied thoroughly in all its aspects, including one of the major problems involved, that of blood pressure measurement. Considering that the diagnosis and management of HT is primarily dependent on the noninvasive brachial blood pressure (BP) measurement, the accuracy of the procedure is essential for a proper clinical decision as small errors can have major public health implications [2]. This is of particular concern, considering the proliferation of BP-measuring monitors, particularly automatic devices, as a consequence of the need to limit the use of mercury [3] and the need to surpass the limitations of office BP measurement [4]. These in turn have led to new problems, given the need for quality control, which culminated in the development of validation protocols [3] and the publication of standards governing such equipment (European Community Directive 93/42/EEC) [5]. At the same time, the advent of ambulatory blood pressure monitoring (ABPM) has led to improved characterization of BP patterns and hence cardiovascular risk. ABPM has clear merits, supported by extensive scientific evidence, and has been validated thoroughly [6–9]. Nonetheless, its reliance on automatic devices indicates the need for some form of control in terms of both quality and suitability for users [10].

The Suzhou Beneware Medical Equipment Co. Ltd (Hangzhou, China) has recently developed an automatic upper-arm ABPM device, the Beneware Model ABP-021. In this study, we aimed to validate the device for use in the general population according to ESH-IP [3].

Methods

Device

The Beneware Model ABP-021 automatic upper-arm ABPM device (Fig. 1) includes a monitor dock, connect cable, a standard cuff (or a large cuff), and a user guide. The monitor has a size of 113 × 75 × 26 mm and a weight

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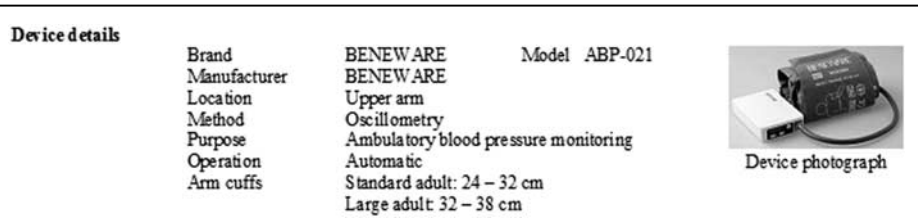
Fig. 1



Details of the device.

Table 1 Participant details

Sex (male : female)	18 : 15	
Age (years)		
Range (low : high)	20 : 68	
Mean (SD)	36 (14)	
Arm circumference (cm)		
Range (low : high)	24 : 35	
Mean (SD)	29 (4)	
Cuff for the test device		
Standard	20 (24–32 cm)	
Large	13 (32–38 cm)	
Recruitment BP (mmHg)	SBP	DBP
Range (low : high)	98 : 181	55 : 120
Mean (SD)	144 (27)	89 (15)

BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 2 Screening and recruitment details

		Recruitment ranges				
Screening and recruitment	*N*			mmHg	All	On Rx
Total screened	57	SBP	Low	< 90	0	0
Total excluded	24			90–129	11	
Ranges complete	19		Medium	130–160	11	2
Range adjustment	5		High	161–180	10	7
Arrhythmias	0			> 180	1	
Device failure	0					
Poor-quality sounds	0	DBP	Low	< 40	0	0
Cuff size unavailable	0			40–79	11	
Observer disagreement	0		Medium	80–100	11	2
Distribution	0		High	101–130	11	7
Other reasons	0			> 130	0	
Total recruited	33					

DBP, diastolic blood pressure; Rx, on treatment; SBP, systolic blood pressure.

Table 3 Observer measurements in each recruitment range

SBP (mmHg)		DBP (mmHg)	
Overall range (low : high)	97 : 182	Overall range (low : high)	52 : 121
Low (< 130)	32	Low (< 80)	31
Medium (130–160)	34	Medium (80–100)	34
High (>160)	33	High (>100)	34
Maximum difference	2	Maximum difference	3

Maximum difference: difference between the lowest and the highest absolute number of measurements respectively for SBP and DBP categories.
DBP, diastolic blood pressure; SBP, systolic blood pressure.

of 168 g without battery. It works with two 1.5 V AA (LR6) alkaline or two high-capacity Ni-HM batteries, with an overall measurement capacity of up to 400 measurements per battery. The measurement ranges are as follows: systolic blood pressure (SBP): 60–260 mmHg; diastolic blood pressure (DBP): 30–195 mmHg; and heart rate (HR): 30–200 beats/min. The estimated accuracy is ± 3 mmHg for BP and ± 5% for HR. The device uses an oscillometry with a linear deflation method to measure BP. The monitor has a build-in USB communication interface enabling connection with a PC operating the dedicated ABPM analysis software. The software provides all of the conventional ABPM statistical and graphical data, and also reports edition and storage capabilities. More information on the device is available from the webpage (*http://www.beneware.com.cn*). The Beneware Model ABP-021 complies with the European Community Directive 93/42/EEC for medical products and bears the corresponding CE 0197 mark.

Table 4 Observer differences.

Observer 2 to observer 1	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Range (low : high)	−4 : +4	−4 : +2	3
Mean (SD)	+0.8 (2.1)	+0.4 (1.7)	

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Familiarization

Twelve test measurements were carried out and no problems were encountered.

Recruitment

Thirty-three individuals (18 men and 15 women), recruited from a private care institution and from the community of a Superior Education Institution, with blood pressure values within the limits established by the ESH-IP [3] were assessed (Table 1). The mean age of the participants was 36 ± 14 years (range: 20–68); SBP was 144 ± 27 mmHg (range: 98–181) and DBP was 89 ± 15 mmHg (range: 55–120). BMI was 26 ± 4 kg/m^2 (range: 19–31) and arm circumference was 29 ± 4 cm (range: 24–35). Other clinically relevant factors assessed included smoking habits, personal history, current therapy, and physical activity. All the participants provided their informed consent to participate in the protocol.

Table 5 Validation results

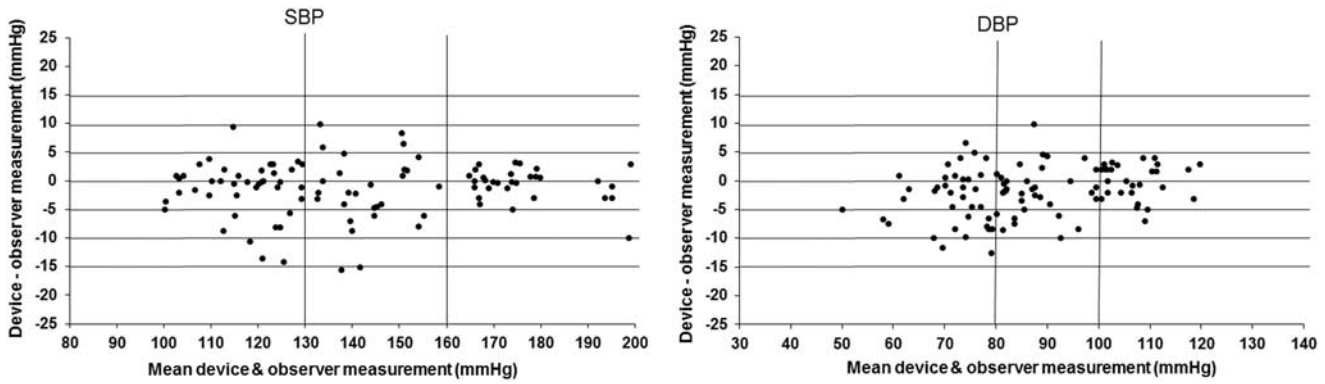
Part 1	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	77	93	98	Pass	−1.2	4.7
DBP	80	97	99	Pass	−1.7	4.3

Part 2	2/3 ≤5 mmHg	0/3 ≤5 mmHg	Grade 2	Grade 3
Pass requirements	≥24	≤3		
Achieved				
SBP	26	0	Pass	Pass
DBP	29	2	Pass	Pass

Part 3	Result
	Pass

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 2



Bland–Altman plots of the automatic device–observer differences for systolic (a) and diastolic (b) blood pressures. The *x*-axis represents the mean of the device and observer measurements and the *y*-axis shows the discrepancy between the device and observer measurements.

Procedure

The ESH-IP for the validation of BP-measuring devices in adults was followed accurately [3]. Overseen by an independent supervisor, measurements were recorded by two observers blinded to each other's readings and from the device readings. All the observers underwent training before the start of the validation process. The protocol was begun after each participant had been resting for around 10 min.

Results

Among a total of 57 participants screened, 33 participants were recruited (Table 1), after excluding 24 participants according to the ESH-IP [3]. The numbers of participants in different SBP and DBP recruitment ranges were in agreement with the requirements of the protocol (Table 2).

A total of 99 pairs of test device and reference BP measurements were obtained during the study (three pairs for each of the 33 participants), as recommended in the ESH-IP [3]. The observer measurements in each recruitment range were 32, 34, and 33 for SBP and 31, 34, and 34 for DBP, respectively (Table 3).

The observer differences were within −4 to 4 mmHg for SBP (mean difference: 0.8 ± 2.1 mmHg) and within −4 to 2 mmHg for DBP (mean difference: 0.4 ± 1.7 mmHg) as shown in Tables 4 and 5.

The device produced 77, 93, and 98 measurements, respectively, within the 5, 10, and 15 mmHg discrepancy limits for SBP. For DBP, 80, 97, and 99 measurements were observed within the 5, 10, and 15 mmHg discrepancy limits. The device–observer disagreement was −1.2 ± 4.7 mmHg for SBP and −1.7 ± 4.3 mmHg for DBP. The number of participants with two or three of the device–observer differences within 5 mmHg was 26 for SBP and 29 for DBP, whereas only two participants

had no device–observer differences within 5 mmHg for DBP.

The differences among measurements are shown graphically in Fig. 2 as Bland–Altman plots [11], indicating that the test device slightly underestimated the mean of the observers' measurements as stated previously. Furthermore, visual inspection of the Bland–Altman plots allowed to exclude the existence of discrepancy bias in relation to the mean values of both SBP and DBP.

The overall validation results fulfilled the criteria of the ESH validation protocol for the general adult population.

Discussion

Blood pressure measurement is the cornerstone for HT clinical management, and therefore, its accuracy is of utmost importance [12]. To prevent the methodology itself from being a source of error, it is essential that the quality of the devices be rigorously evaluated as this point is central to the method's clinical validity. Several validation protocols are currently available that enable such reservations to be overcome by a simple and rigorous process, providing the guarantee of quality that is required for the inclusion of automatic BP devices in integrated programs of clinical surveillance. The present study used the protocol developed by the ESH [3], in which differences between control and test device measurements are divided into categorization zones (5, 10, and 15 mmHg discrepancy), the final classification of the device being based on the cumulative distribution of differences among these zones. The results clearly show that the Beneware Model ABP-021 monitor provides reliable and accurate measurements in adult participants in static conditions. The differences between the reference measurements and those of the device were minimal (below 2 mmHg) and the SD of device–observer discrepancy (4.7 and 4.3 mmHg for SBP and DBP, respectively) were within the limit of less than 8 mmHg required by the Association for the Advancement of Medical Instrumentation [13]. Nonetheless, a major limitation arises from the fact that the validation protocol was implemented under resting (static) conditions, not taking into account the ecological contexts in which an ABPM monitor operates under daily living circumstances.

From the overall validation performance, the Beneware Model ABP-021 met all the quality requirements of the ESH-IP protocol [3].

Conclusion

According to the results of the validation study and the levels of accuracy found in static conditions, the Beneware model ABP-021 upper-arm BP monitor can be recommended for ambulatory blood pressure monitoring in the general adult population.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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