Validation of the iHealth BP3 upper-arm blood pressure monitor, for clinic use and self-measurement, according to the European Society of Hypertension International Protocol revision 2010

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Objective **This study aimed to evaluate the performance of the iHealth BP3 upper-arm blood pressure monitor, which is designed for clinic use and self-measurement of blood pressure using Apple touch devices as an interface.**

Methods **The European Society of Hypertension International Protocol (ESH-IP) revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely. Ninty-nine couples of test device and reference blood pressure measurements were obtained during the study (three pairs for each of the 33 participants).**

Results **The 33 participants, age 47.1±12.3 years (age range 27–69 years) and arm circumference 30.0±4.4 cm, had a mean systolic blood pressure (SBP) of 143.9±27.4 mmHg and a mean diastolic blood pressure (DBP) of 90.1±18.3 mmHg. The device passed all of the requirements fulfilling the standards of the protocol, and the mean±SD device–observer difference was 2.8±4.2 mmHg for SBP and −0.4±3.5 mmHg for DBP.**

Conclusion **According to the results of the validation study on the basis of the ESH-IP revision 2010, the iHealth BP3 can be recommended for clinic use and self-measurement in an adult population. *Blood Press Monit* 17:253–256 © 2012 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

Self-monitoring of blood pressure (BP) is recommended and is well accepted by hypertensive patients as a common part of hypertension management [1–3]. With the development of technology, many different types of electric BP devices are available for self-monitoring and clinical use. However, the accuracy of BP measuring devices is the most important factor beyond other functions. Recently, the Andon Health Co. Ltd developed an automatic upper-arm monitor for BP measurement, the iHealth BP3, which is a dock for Apple touch devices using the app of a BP monitoring system with several new features. In this study, we aimed to validate the iHealth BP3 upper-arm BP monitor according to the European Society of Hypertension International Protocol (ESH-IP) revision 2010 [4].

Methods

Device

The iHealth BP3 automatic upper-arm BP measurement device includes a monitor dock, connect cable, a standard cuff (or a large cuff), and a user guide. Through the free downloaded iHealth app, it turns any iOS device (3.0 or later) into a powerful BP monitor that is compatible with iPhone, iPod Touch, and iPad (Apple Inc. 1 Infinite Loop, Cupertino, California, USA). The iHealth BP3 has a size of 115 mm × 115 mm × 66.5 mm, with a weight of 215 g. It is equipped with a battery of 3.7 V Li-ion 400 mAh, which is rechargeable; meanwhile, it can run with a connect cable at a power of DC 5 V 1 A. The device can also measure pulse rate range from 40 to 180 beats/min (±5% accuracy). It records systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate, measure time, and pulse wave graphs with a visualized measurement process. Furthermore, years of data can be stored in iOS devices with a little space (Fig. 1). Detailed information on the iHealth BP3 is available from the webpage (*http://www.ihealth99.com*).

Familiarization

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

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Fig. 1

Brand	iHealth	Model	BP3
Manufacturer	Andon Health Co. Ltd		
Location	Upper arm		
Method	Oscillometry		
Purpose	Clinic and self/home measurement		
Operation	Automatic		
Arm cuffs	Standard adult: 22 – 30 cm Large adult: 30 – 42 cm		

Device photograph

Device details.

Recruitment

Hypertensive patients were recruited from among inpatients and outpatients in the Tandu Hospital of Fourth Military Medical University in Xi'an of China. Some participated immediately and without an appointment. Others attended the hospital specially. Normotensive individuals were recruited from among accompanying relatives or friends and hospital staff.

All participants provided informed consent to participate in this study, which was approved by the Ethics Committee of Tandu Hospital of Fourth Military Medical University. This study was registered in the Chinese Clinical Trial Registry (ChiCTR-DDT-11001731).

Procedure

The ESH-IP revision 2010 for the validation of BP measuring devices in adults was followed precisely [4,5]. Overseen by an independent supervisor, measurements were recorded by two nurses blinded to both each other's readings and the device readings.

Results

Among the total 54 participants screened, finally, 33 participants were recruited (18 men and 15 women), age 47.1 ± 12.3 years, after excluding 21 participants according to the ESH-IP revision 2010. The numbers of participants in different SBP and DBP recruitment ranges were also in agreement with the requirements of the protocol (Table 1). The arm circumference of all participants was 30.0 ± 4.4 cm with 17 standard and 16 large cuffs for the test device. The SBP and DBP of the 33 participants at the time of recruitment was 143.9 ± 27.4 and 90.1 ± 18.3 mmHg, respectively (Table 2).

Following the validation process of ESH-IP revision 2010 accurately, a total of 99 couples of test device and reference BP measurements were obtained during the study (three pairs for each of the 33 participants). The observer measurements in each recruitment range were 31, 35, and 33 for SBP and 29, 34, and 36 for DBP, respectively (Table 3). The observer differences for SBP and DBP were within −4 to 4 mmHg, 0.1 ± 2.3 and 0.2 ± 2.0 mmHg, respectively (Table 4).

The device produced 72, 94, and 99 measurements within 5, 10, and 15 mmHg for SBP and 85, 99, and 99 for DBP, respectively. The device–observer disagreement

Table 1 Screening and recruitment details

Screening and recruitment		Recruitment ranges			
Total screened	54	SBP (mmHg)		All	On Rx[a]
Total excluded	21	Low	<90	0	1
			90–129	11	
Ranges complete	16	Medium	130–160	11	5
Range adjustment	5				
Arrhythmias	0	High	161–180	10	7
Device failure	0		>180	1	
Poor quality sounds	0	DBP (mmHg)			
Cuff size unavailable	0	Low	<40	0	3
			40–79	11	
Observer disagreement	0	Medium	80–100	10	3
Distribution	0				
Other reasons	0	High	101–130	12	7
Total recruited	33		>130	0	

DBP, diastolic blood pressure; Rx, treatment; SBP, systolic blood pressure.
[a]Number of patients on prescription.

Table 2 Participant details

Sex		
Male : female	18 : 15	
Age (years)		
Range (low : high)	27 : 69	
Mean (SD)	47.1 (12.3)	
Arm circumference (cm)		
Range (low : high)	22 : 38	
Mean (SD)	30.0 (4.4)	
Cuff for the test device		
Standard	17	(22–30 cm)
Large	16	(30–42 cm)
Recruitment BP (mmHg)	SBP	DBP
Range (low : high)	89 : 190	46 : 121
Mean (SD)	143.9 (27.4)	90.1 (18.3)

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

was 2.8±4.2 mmHg for SBP and −0.4±3.5 mmHg for DBP. The number of participants with two or three of the device–observer differences within 5 mmHg was 24 for SBP and 29 for DBP, whereas there was only one participant with none of the device–observer differences within 5 mmHg for DBP (Table 5 and Fig. 2). The validation results fulfilled the criteria of the ESH-IP revision 2010 for the general population.

Discussion

The iHealth BP3 is a fully automatic device for upper-arm BP measurement, which doubles as a charging station and a dock for iPod Touch, iPhone, and iPad. The device uses Apple touch devices as an interface and measures BP through a BP monitoring system that can be downloaded freely from the Apple app store. It helps users to manage records using simple tools: interactive graphs, average calculation, and smart WHO classification, which is simple, easy to use, and very effective. Through the Wi-Fi, the current BP status and historical results can be shared through e-mail with friends or family members to keep them notified, as well as doctors or other medical professionals as part of an analysis of the user's health. As an affiliated BP measurement product of Apple touch devices, the producer makes the iHealth BP3 a BP measurement device with fashion appearance which caters for requirements of customers and telemedicine.

As an automatic BP measurement device, an accurate BP measurement is of utmost importance [6]. From the validation performance, the iHealth BP3 passed all phases of ESH-IP revision 2010 that showed accuracy of BP measurement for self-monitoring in the general population [4]. Along with the iHealth BP3, although the iPod Touch (Apple Inc.) was used as a visualized operation interface in the validation study, the use of iPhone and iPad (Apple Inc.) can also yield the same or even a better visualized effect and measurement experience. For the telemedicine of BP monitoring with the iHealth BP3, the effect of hypertension management needs to be evaluated in future studies.

Table 3 Observer measurements in each recruitment range

SBP (mmHg)		DBP (mmHg)	
Overall range (low : high)	91 : 192	Overall range (low : high)	46 : 122
Low (<130)	31	Low (<80)	29
Medium (130–160)	35	Medium (80–100)	34
High (>160)	33	High (>100)	36
Maximum difference	4	Maximum difference	7

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

Table 4 Observer differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – observer 1			
Range (low : high)	−4 : +4	−4 : +4	3
Mean (SD)	+0.1 (2.3)	+0.2 (2.0)	

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

Conclusion

According to the results of the validation study on the basis of the ESH-IP revision 2010, the iHealth BP3 upper-arm BP monitor can be recommended for clinic use and self-measurement in an adult population.

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Conflicts of interest

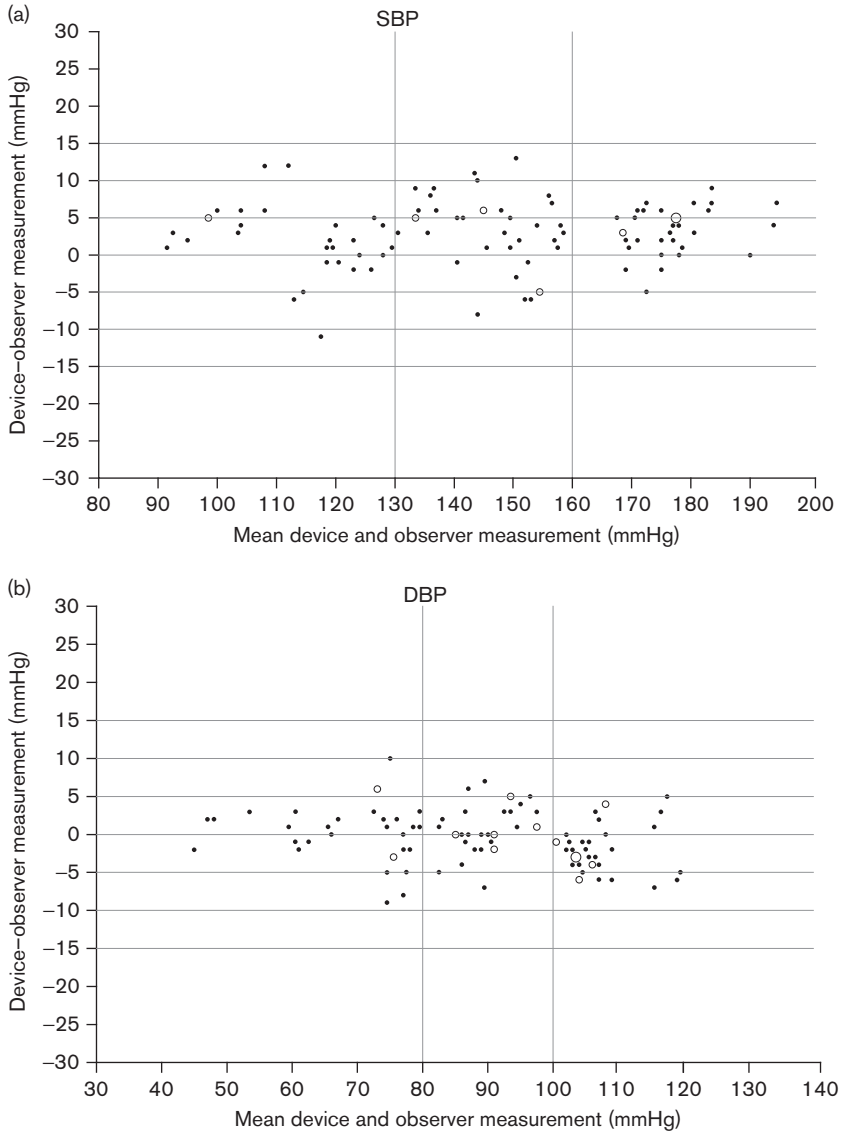
There are no conflicts of interest.

Table 5 Validation results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade1	Mean (mmHg)	SD (mmHg)
Pass requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
SBP	72	94	99	Pass	2.8	4.2
DBP	85	99	99	Pass	−0.4	3.5
Part2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Pass requirements	≥ 24	≤ 3				
Achieved						
SBP	24	0		Pass		Pass
DBP	29	1		Pass		Pass
Part3						Pass

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

Fig. 2



(a) Systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP) differences between the test device and the observer, and the mean pressure of device and observer values. The plot is shown with small dots, medium, and large bubbles. The small dots represent single points, the medium bubbles represent two superimposed points, and the large bubbles represent three superimposed points.

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