Validation of Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol revision 2010

Huiyong Tian[a], Sijian Zeng[a], Xiaoyan Zhong[a], Wei Gong[b] and Wenjun Liu[a]

Objective **Transtek blood pressure monitor TMB-1491 is an automatic upper arm device designed for self/home measurement in adult populations. This study aimed to evaluate its accuracy according to the European Society of Hypertension International Protocol revision 2010.**

Methods **The protocol requirements were followed precisely with the recruitment of 33 adult individuals on whom same-left-arm sequential systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured. According to the validation protocol, 99 pairs of test device and reference blood pressure measurements were obtained in this study (three pairs for each of the 33 participants).**

Results **The device produced 74, 95 and 99 measurements within 5, 10, and 15 mmHg for SBP and 85, 97, and 99 for DBP, respectively. The mean ± SD device–observer difference was − 0.6 ± 4.4 mmHg for SBP and − 0.6 ± 3.4 mmHg for DBP. The number of participants with two or three device–observer difference within 5 mmHg was 24 for SBP and 29 for DBP. In addition, none of the participants had a device–observer difference within 5 mmHg for SBP, and three of the participants had the same for DBP.**

Conclusion **Transtek TMB-1491 has passed all phases of European Society of Hypertension International Protocol revision 2010 and can be recommended for self/home measurement in adult populations.** *Blood Press Monit* **20:280–282**

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[a]Biomedical Engineering Laboratory, School of Biomedical Engineering and [b]Department of Cardiovascular Medicine, Nanfang Hospital, Southern Medical University, Guangzhou, China

Correspondence to Wenjun Liu, PhD, Biomedical Engineering Laboratory, School of Biomedical Engineering, Southern Medical University, No. 1838, North Guangzhou Street, Baiyun District, Guangzhou City, GuangDong 510515, China Tel/fax: +86 020 61648278; e-mail: wenjunliu_smu@163.com

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Introduction

Hypertension is one of the most important preventable risk factors for stroke and other cardiovascular diseases [1–4]. Many scientific societies, such as the American Society of Hypertension [5], the American Heart Association, and the European Society of Hypertension [6,7], recommend that anyone with hypertension should monitor his or her blood pressure (BP) at home. Home monitoring can help to improve the overall management of hypertension, to obtain a more stable and consistent estimation of a participant's actual BP level, and to assess the degree of coverage offered by antihypertensive drugs [8]. Therefore, the accuracy and reliability of self/home measurement BP monitors used by patients has been of some concern [9]. In this study, we aimed to evaluate the accuracy and reliability of Transtek TMB-1491 according to the European Society of Hypertension International Protocol (ESH-IP 2010) [10].

Methods

Tested device

Transtek TMB-1491 (Guangdong Transtek Medical Electronics Co. Ltd, Zhongshan, China) is an automatic upper arm device designed for self/home measurement in adult populations. The device operates through oscillometric technology and by monitoring BP during inflation. The device has a measurement range of 40–230 mmHg for systolic blood pressure (SBP) and diastolic blood pressure (DBP) and 40–199 beats/min for pulse rate. The cuff applied is suitable for arm circumferences ranging from 22 to 42 cm (standard cuff: 22–32 cm; large cuff: 22–42 cm). It has two users for choice and a maximum of 60 records per user. Power is supplied by four AAA batteries.

Familiarization

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

Participants

Study participants were recruited from among hypertensive participants, accompanying relatives, and the staff at Nanfang Hospital of Southern Medical University in Guangzhou, China. The Ethics Committee of Nanfang Hospital approved this study and all participants signed informed consent. Patients on antihypertensive treatment were also recruited and recorded.

Procedure

The validation process strictly followed the ESH-IP 2010 and was performed by two observers and an independent supervisor experienced in BP measurement. A mercury sphymomanometer and a double-headed stethoscope were used as a reference device, which had been calibrated and

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checked carefully before this study. The two observers were blinded to each other's readings and tested device reading. Participants had to rest in a sitting position for at least 15 min in a quiet room. Sequential measurements of the reference mercury sphymomanometer and the tested device were performed on the left upper arm of the participants. The validation results were analyzed in Microsoft Excel according to the ESH-IP 2010.

Results

Thirty-three participants were recruited (20 men and 13 women), age 61.1 ± 21.0 years, after excluding 20 participants according to the ESH-IP 2010. The reasons for exclusion are listed in Table 1. The numbers of participants in different SBP and DBP recruitment ranges also fulfilled the requirements of the protocol (Table 1). The arm circumference of all participants was 27.6 ± 3.3 cm, with 19 participants using a standard cuff (22–32 cm) and 14 participants using a large cuff (22–42 cm) for the tested device. The SBP and DBP of the 33 participants were 140 ± 25.2 and 88 ± 14.6 mmHg, respectively (Table 2).

Following the validation process of ESH-IP 2010 precisely, a total of 99 couples measurements of the tested device and the reference mercury sphymomanometer were obtained during the study. The observer measurements in each recruitment range were 33, 37, and 29 for SBP and 37, 34, and 28 for DBP, respectively (Table 3). The mean differences between two observers were 0.86 ± 2.72 mmHg for SBP and 1.33 ± 2.49 mmHg for DBP, and all differences were in the range of −4 to 4 mmHg (Table 4). The tested device produced 74, 95, and 99 measurements within 5, 10, and 15 mmHg for SBP and 85, 97, and 99 for DBP, respectively. The mean ± SD of device–observer difference was −0.6 ± 4.4 mmHg for SBP and −0.6 ± 3.4 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. In addition, none of the participants had device–observer differences within 5 mmHg for SBP and three participants had the same values for DBP (Table 5).

Table 1 Screening and recruitment details and the BP distribution of participants for TMB-1491

Screening and recruitment			Recruitment range		
Total screened	53		mmHg	All	On prescription
		SBP			
Total excluded	20	Low	< 90	0	0
Ranges complete	14		90–129	12	
Range adjustment	4	Medium	130–160	11	4
Arrhythmias	1	High	161–180	8	8
Device failure	0		> 180	2	
Poor quality sounds	0				
		DBP			
Cuff size unavailable	1	Low	< 40	0	0
Observer disagreement	0		40–79	12	
Distribution	0	Medium	80–100	11	4
Other reasons	0	High	101–130	10	8
Total recruited	33		> 130	0	

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

Table 2 Participants' details

Sex	
Male : female	20 : 13
Age (years)	
Range (low : high)	27 : 92
Mean (SD)	61.1 (21.0)
Arm circumference (cm)	
Range (low : high)	22 : 39
Mean (SD)	27.6 (3.3)
Cuff for tested device (cm)	
22–42 (arm)	14
22–32 (arm)	19
BP range (low : high) (mmHg)	
SBP	93 : 187
DBP	58 : 122
Mean (SD)	
SBP	140 (25.2)
DBP	88 (14.6)

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

Table 3 Observer measurements distribution in each range

SBP (mmHg)		DBP (mmHg)	
Overall range (low : high)	95 : 186	Overall range (low : high)	56 : 119
Low (< 130)	33	Low (< 80)	37
Medium (130–160)	37	Medium (80–100)	34
High (>160)	29	High (>100)	28
Maximum difference	8	Maximum difference	9

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

Table 4 Differences in observers' measurements

Observer 2 − observer 1	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Range (low : high)	−4 : +4	−4 : +4	3
Mean (SD)	+0.86 (2.72)	+1.33 (2.49)	

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

Bland–Altman plots of SBP and DBP differences between the test device and observer measurements and the mean pressure values showed that all 99 BP differences were beyond the 15 mmHg range (Fig. 1). Thus, the accuracy of Transtek TMB-1491 fulfilled all the criteria of the ESH-IP 2010 for the general adult population.

Discussion

The study provided information on the accuracy of Transtek TMB-1491 for self/home BP measurement. Through this validation, Transtek TMB-1491 fulfilled the requirements of all phases of ESH-IP 2010. Two cuffs were used in this validation: a standard cuff for arm circumferences ranging from 22 to 32 cm and a large cuff for arm circumferences ranging from 22 to 42 cm to fulfill the requirements of various populations. All 99 points of the device–observer differences had a uniform distribution rather than being clustered within a range (Fig. 1). This indicates that the hardware and algorithms of the device have the capacity to work properly in BP measurements over a wide range.

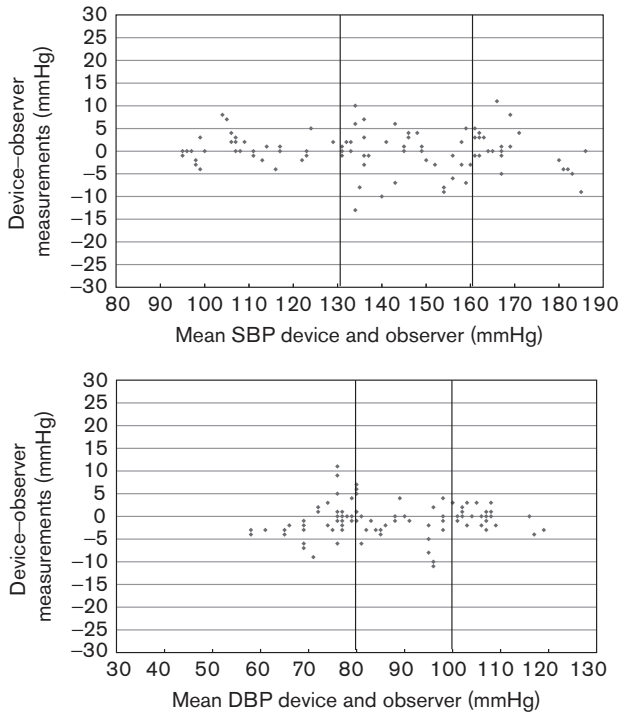
Table 5 Validation result

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	74	95	99	Pass	−0.6	4.4
DBP	85	97	99	Pass	−0.6	3.4

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

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

Fig. 1



Differences versus the mean pressure between the tested device and the observer values. DBP, diastolic blood pressure; SBP, systolic blood pressure.

This study has limitations. Although 33 participants were recruited, according to the protocol, the statistical power of the study may be at an increased risk of failing to reject an inaccurate device. Furthermore, BP measurement in a routine clinical setting is different from that in a validation process, especially for self-measurement. Thus, multiple readings are recommended to obtain accurate BP information on which to base diagnostic and treatment decisions in practice.

Conclusion

According to the results of this study on the basis of the ESH-IP 2010, Transtek TMB-1491 can be recommended for self/home measurement in a general adult population.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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