Validation of the TRANSTEK blood pressure monitor TMB-986 for home blood pressure monitoring according to the International Protocol

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Objective **To test the accuracy of the TRANSTEK home blood pressure monitor TMB-986 using the International Protocol of the European Society of Hypertension.**

Method **Device evaluation was performed on 33 participants (15 men and 18 women) with a mean ± standard deviation age of 56.2 ± 12.8 years (range: 35–80 years). Blood pressures (systolic blood pressure; SBP and diastolic blood pressure; DBP) were sequentially measured using mercury sphygmomanometer (two trained observers) and alternately measured by the test device (one supervisor).**

Results **In phase 1, 35, 44, 45 of SBP measurements and 41, 45, 45 of DBP measurements were within 5, 10, 15 mmHg. In phase 2.1, 70, 94, 99 of SBP measurements and 78, 93, 99 of DBP measurements were within 5, 10, 15 mmHg. In addition, the difference between the device and the mean of two observers was 2.2 ± 5.0 and 1.7 ± 4.8 mmHg for SBP and DBP, respectively. In phase 2.2, for SBP and DBP, respectively, 25 and 26 of 33 participants had at least two of their three differences with 5 mmHg and there were two and one participants who did not have any difference within 5 mmHg.**

Conclusion **The TRANSTEK blood pressure monitor TMB-986 passed all the phases of the International Protocol both for SBP and DBP and is recommended for home use.** ***Blood Press Monit*** **15:278–280 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

High blood pressure is one of the most readily preventable causes of stroke and other cardiovascular complications [1]. The American Society of Hypertension [2], American Heart Association and other organizations [3,4] recommend anyone with high blood pressure monitor his or her blood pressure at home. Home monitoring can help to quantify blood pressure variability, to obtain a more stable and consistent estimation of participant's actual blood pressure level and to assess the degree of coverage offered by antihypertensive drugs [5]. In the meantime, many automatic devices that measure blood pressure have become commercially available [6]. The accuracy and reliability of automatic blood pressure monitor used by patients has been of some concern [7]. This study mainly assesses the accuracy and reliability of TRANSTEK TMB-986 for home blood pressure monitoring according to the protocol of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) [8] in adults.

Methods

The TRANSTEK TMB-986 device

The TRANSTEK TMB-986 device (Transtek Electronics Co., Ltd, ZhongShan, GuangDong, China) is an automated electronic digital upper-arm blood pressure monitor. The device operates through oscillometric technique and is designed for home blood pressure monitoring. The applied cuff is suitable for arm circumferences ranging from 22–42 cm (standard: 22–32 cm; large: 32–42 cm). It has two users for choices and maximum 60 records per user. Systolic blood pressure (SBP) (ranging from 0–300 mmHg), diastolic blood pressure (DBP) (ranging from 0–300 mmHg), and pulse rate (ranging from 40–199 bpm) are displayed on a liquid crystal digital display. The inflation is performed by using a fuzzy logic electric pumping system and deflation by an automatic pressure release valve. Especially the device can measure SBP and DBP during inflation. The size is about 180 (length) × 100 (width) × 39 (height) mm and the weight is 300 g (without batteries). The device is powered by four batteries (1.5 V, type AAA) or an AC adaptor.

Participants

The 47 consecutive participants were recruited in the validation. Only three participants were opted out of the study before a complete measurement. With regard to sex and systolic and diastolic entry blood pressure ranges of the protocol, the first 33 participants (15 men

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and 18 women) were selected for analysis. A standard size cuff was used in 28 participants and larger cuff in five participants. All participants agreed to participate in the protocol and gave informed consent. The characteristics of the 33 participants are shown in Table 1.

Validation procedure

All blood pressure measurements were taken on the left arm or wrist, which was supported at the heart level. Participants had to rest in sitting position for at least 15 min in a quiet, warm room. Mercury blood pressure measurements [Home sphygmomanometer & stethoscope case (A type), Yuyue Medical Equipment Inc., Dan Yang, Jiang Su, China] were taken simultaneously by two observers blinded from each other using a Y-tube stethoscope with an observer variability of no more than 4 mmHg. Device detection measurement was followed by the supervisor, to ensure that the device was able to measure blood pressure of each participant.

Sequential measurements comparing the test devices and the standard mercury sphygmomanometer were obtained in the following sequences: the two observes took readings BP1, BP3, BP5 and BP7 and the supervisor took readings BP2, BP4 and BP6 using the test device. These measurements (BP1–BP7) were used in the validation analysis.

Each pair of observer measurements was averaged and then subtracted from the device measurement. The absolute differences between BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated and paired according to the device reading. For each pair, the one with the smaller difference was classified into three zones (within 5, 10 and 15 mmHg), separately for SBP and DBP, for 15 participants in phase 1 and for all 33 in phase 2.1. For each individual participant, the number of readings with a difference within 5 mmHg was also calculated (phase 2.2).

Data analysis

The measurements were used for analysis in Microsoft Excel according to the International Protocol (IP) of the ESH.

Result

The results of the validation analysis were shown in Table 2. In phase 1, the analysis was performed in a group of 15 participants (seven men and eight women) for a total of 45 readings. As the ESH protocol requirements, this phase was passed. In the phase 2, the analysis was performed in all 33 participants (15 men and 18 women). According to ESH rules, this phase was, thus, successfully completed. The differences between the two observers and the device were 2.2 ± 5.0 and 1.7 ± 4.8 mmHg for SBP and DBP, respectively. In addition, the second part of phase 2 (phase 2.2) of ESH protocol was passed by the device.

Plots of the differences between the device readings and the mean blood pressure of the two observers against the mean blood pressure for all 99 measurements for SBP and DBP are displayed in Fig 1. These results are in agreement with the International Protocol requirements for the two phases. Thus the TRANSTEK TMB-986 device fulfills the validation criteria of the IP.

Table 1 Characteristics of the study participants ($n = 33$)

Characteristics	Mean ± SD	Range
Age (years)	56.2 ± 12.8	35–80
Arm circumferences (cm)	31.1 ± 4.9	24.5–38.6
Body mass index	25.1 ± 5.2	18–39
Pulse rate (beat per min)	75.3 ± 12.6	61–109
Mean systolic pressure (mmHg)	144.2 ± 19.8	92–178
Mean diastolic pressure (mmHg)	94.6 ± 15.7	62–126

Table 2 Accuracy of TRANSTEK TMB-986

Phase1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.		
Required						
One of	25	35	40			
Achieved						
SBP	35	44	45	Continue		
DBP	41	45	45	Continue		
Phase 2.1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recomm.	MD	SD
Required						
Two of	65	80	95			
All of	60	75	90			
Achieved						
SBP	70	94	99	Pass	2.2	5.0
DBP	78	93	99	Pass	1.7	4.8
Phase 2.2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recomm.		
Required	≥ 22	≤ 3				
Achieved						
SBP	25	2		Pass		
DBP	26	1		Pass		

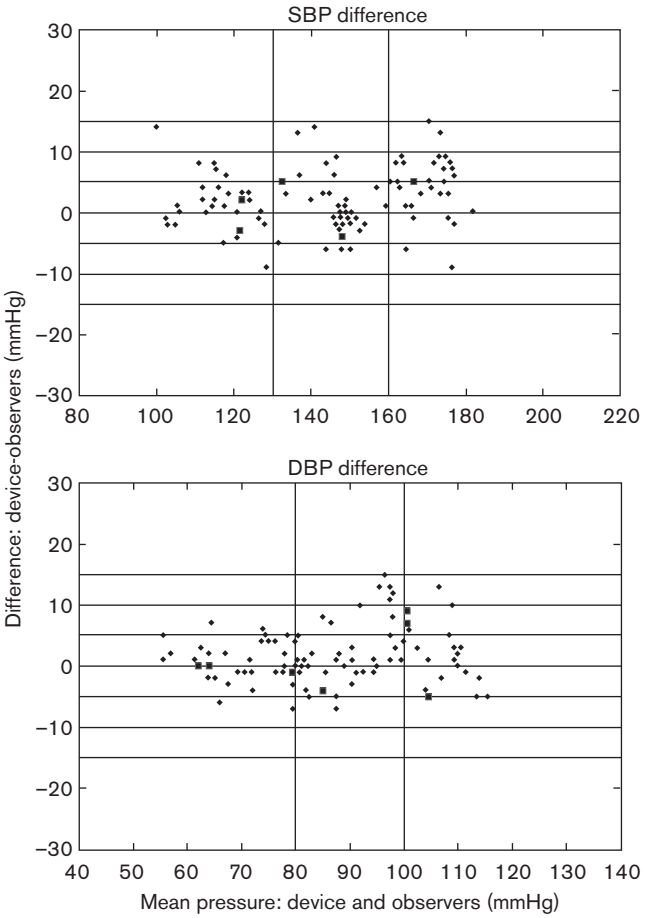
DBP, diastolic blood pressure; MD, mean difference (mmHg); Recomm., recommendation; SBP, systolic blood pressure; SD, standard deviation (mmHg).

Discussion

The study shows that TRANSTEK TMB-986 device met the ESH requirements for SBP and DBP and passed the validation. In addition, the device fulfilled the accuracy with 2.2 ± 5.0 and 1.7 ± 4.8 mmHg for SBP and DBP, respectively within the Association for the Advancement of Medical Instrumentation requirement [9] which requires the device to achieve a mean difference ± SD within 5 ± 8 mmHg. So it can be recommended for use in the adult population.

In this study, the graphical presentations of the device-observers differences in SBP and DBPs showed a good agreement between the mercury sphygmomanometer and TRANSTEK TMB-986. No points were outside the ± 15 mmHg limits but only a few data fell on the ± 15 mmHg limits maybe that the recruitment number (33 participants) is not as large as the number (a minimum of 85 participants) of Association for the Advancement of Medical Instrumentation [9] or British Hypertension Society [10]. Although the reduced sample

Fig. 1



Plot of the systolic blood pressure (upper plot) and diastolic blood pressure (lower plot) difference between the TMB-988 device and the mean of the observers (*y*-axis) against the mean pressure of the observers and the device (*x*-axis) in 33 participants ($n=99$). The square point in the plots represents two same data duplicated.

size results in a reduction in statistical power from 98 to 70%, which brings into question the applicability of the ESH-IP [11], the IP stated intention 'a simplified protocol that does not sacrifice the integrity of the earlier protocols' [8]. The measurements were not dependent on the blood pressure level. Mean differences between observer and devices and their standard deviations were somewhat smaller for DBP than SBP. Plot of the observer-device differences showed that there are at least 30 points included within each blood pressure range. It can indicate that the hardware and algorithms of the device have the capacity to work properly in blood pressure measurements over a wide range.

There is a new protocol [12] published in Feb 2010, which will supersede the old ESH from 1st July 2010 and there are many changes in the revised protocol such as age restriction, blood pressure level, accuracy criteria, etc. This validation study was performed before the revised IP publication. In next step, the devices are validated based on the revised IP.

In conclusion, the TRANSTEK blood pressure monitor TMB-986 device upper blood pressure monitor can be recommended for home use in adults.

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