Validation of the TMB-2296-BT blood pressure monitor in adults according to the ISO 81060-2:2018 + Amd.1:2020.

Bin Peng[a], Jia Hua, Xind[a] Wanga, Zijian Xie[a], Xiaoqin Dua, Chaoya Li[a], Jiahui Liang[b]

[a]Department of Cardiology VI, Chenzhou No.1 people's hospital, Hunan, China,

[b]Guangdong Transtek Medical Electronics, Zhongshan, China,

Correspondence to: Bin Peng,PhD, Department of Cardiology VI, Chenzhou No.1 people's hospital, 102 Luojiajing, Chenzhou City, Hunan Province, China.

Tel:0735- 0735-2343666 e-mail: Pbboshi@163.com

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Abstract

This study aimed to validate the effectiveness and safety of the test device (TMB-2296-BT) blood pressure (BP) monitor in adults according to ISO 81060-2:2018 + Amd.1:2020, which is a digital monitor. Three trained observers used the same arm sequential method to compare the SBPs and DBPs measured by the test device with those measured by the reference device (mercury sphygmomanometer). For the test device with cuff ranging from 22 to 32cm, there are 88 adults, with a male-to-female ratio of 35:53. The mean differences and SD between reference BPs and test device BPs readings were 0.21± 2.59/0.66±2.12mmHg for systolic BP (SBP)/diastolic BP (DBP) for criterion 1, and 0.21± 2.07/0.66± 1.76 mmHg for SBP/DBP for criterion 2. For test device with cuff ranging from 22 to 42cm, there are

87 adults, with a male-to-female ratio of 49:38. The mean differences and SD between reference BPs and test device BPs readings were -1.62± 2.80/0.12±3.01mmHg for systolic BP (SBP)/diastolic BP (DBP) for criterion 1, and -1.62± 2.35/0.12± 2.60 mmHg for SBP/DBP for criterion 2. Test device fulfilled both validation criterion 1 and 2 of the ISO 81060-2:2018+A1:2020 guidelines.

Keywords: accuracy, blood pressure monitor, validation, clinical trial

Introduction

According to the WHO, approximately 1.28 billion adults aged 30-79 years worldwide suffer from hypertension. As a chronic disease, hypertension may increase the risk of heart and kidney or other disease[1,2], so prevention and early detection of blood pressure abnormalities are essential. Therefore, ensuring accurate measurement of BP values is of utmost importance. TMB-2296-BT, manufactured by Guangdong Transtek Medical Electronics Co., Ltd, is a non-invasive, digital BP monitor intended for use in measuring BP and pulse rate.. This device uses the Oscillometric Measuring method to detect blood pressure. This study aimed to validate its effectiveness and safety according to the ISO 81060-2:2018+A1:2020 guidelines.

Methods

Recruit at least 85 subjects to measure BP using both the test device and the reference device. Throughout the trial, investigators should comply with CIP and regulatory requirements, enroll eligible subjects and record demographic information about subjects[3,4]. Before measuring the BP, subject should empty the bladder, sit

comfortably and relax for about 5 minutes with legs uncrossed and feet flat on floor, bare arm resting on table with mid-arm at heart level. The BP was measured by two observers who received training on clinical investigation plan (CIP). Each observer independently recorded the BP readings from the reference device, ensuring that their respective recordings were not visible to each other. The BPs of the test device were recorded by supervisor and should not be visible to the observers. The Korotkoff sound [fifth phase (K5)] should be used by the observers for determining the reference DBP, if the Korotkoff sound [fifth phase (K5)] is not audible, the subject shall be excluded.

The same arm sequential method was adopted. The observer inflated the bladder until the pressure reached a range of 80-100 mmHg, palpated the radial artery every 20mmHg per pressurization until the radial artery tube was flattened by the cuff, and then pressurized 30 mmHg, released the air and the outgassing rate should not exceed 2-4 mmHg/s to measure the reference device's BP. After recording the BPs, wait at least 1minuteand use the test device to measure the subject's BPs of arm on the same side. Record the BPs and continue to measure the BPs using the reference device. Repeat the two procedures until 9 data sets have been collected.

Data analysis

Table 1 showed the distribution of data on age, gender, arm circumference and BP that all met the requirements of ISO 81060-2:2018 + Amd.1:2020.

Statistical analysis

65 According to ISO 81060-2:2018 + Amd.1:2020, the mean error and SD of the
66 differences between the test device and the reference device were needed to meet the
67 requirements. In this study, the results were showed on table 2.
68

69 Table 1 Distribution of baseline statistics

Cuff range:22-32cm		Cuff range:22-42cm	
Age (year)	51.9±16.3(18-82)	Age (year)	59.3±11.7(18-77)
Gender	male: female=35:53 (39.8%:60.2%)	Gender	male: female=49:38 (56.3%:43.7%)
arm circumference(cm)		arm circumference(cm)	
upper 25%	27.3%	upper 25%	26.4%
upper 50%	21.6%	upper 50%	25.3%
lower 25%	28.4%	lower 25%	25.3%
lower 50%	22.7%	lower 50%	23.0%
upper 12.5%	22.7%	upper 12.5%	11.5%
lower 12.5%	14.8%	lower 12.5%	11.5%
SBP(mmHg)		SBP(mmHg)	
≤100	14.9%	≤100	10.5%
≥140	34.4%	≥140	33.6%
≥160	6.9%	≥160	9.8%
DBP(mmHg)		DBP(mmHg)	
≤60	6.9%	≤60	14.1%
≥85	41.2%	≥85	36.3%
≤100	12.6%	≤100	20.3%

70

71 Table 2 mean error and SD of the differences between the test device and the reference device

		Criterion 1				Criterion 2	
	BP	Mean error	Requirement	SD	Requirement	SD	Requirement
Cuff for 22-32cm	SBP	0.21	≤5	2.59	≤8	2.07	≤6.95
	DBP	0.66	≤5	2.12	≤8	1.76	≤6.90
Cuff for 22-42cm	SBP	-1.62	≤5	2.80	≤8	2.35	≤6.73
	DBP	0.12	≤5	3.01	≤8	2.60	≤6.95

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Results

88 subjects were enrolled in trial using a cuff ranging from 22 to 32cm, 87subjects were enrolled in trial using a cuff ranging from 22 to 42cm. As the table 1 show, the distribution of subject's age, gender, arm circumference BPs met the requirements of the ISO 81060-2:2018 + Amd.1:2020.

Discussion

This test device establishes a "zero pressure" equivalent to the atmospheric pressure before every measurement. When the cuff begins to inflate, the test device derives a blood pressure value by measuring the vibrations against the walls of the blood vessels as the blood flows. This is a common measurement method for electronic blood pressure which is oscillometric method. Since different processes may result in variations in the accuracy of the blood pressure monitor, we conducted this study to verify its accuracy.

In existing clinical practice guidelines, blood pressure measurement techniques include intermittent automatic blood pressure measurement and non-automatic blood pressure measurement, etc. This study compared automatic blood pressure with auscultation method to measure the accuracy of the TMB-2296-BT.

For the test device with a cuff ranging from 22 to 32cm, the mean difference of SBP and DBP was 0.21mmHg and 0.66mmHg, which were less than 5mmHg. The standard deviations corresponding to them were 2.59 and 2.12mmHg respectively, which were less than 8mmHg. Bland-Altman plots was showed on Fig. 1. On criterion

2, the SD was 2.07 and 1.76mmHg respectively corresponding to mean difference 0.21 and 0.66mmHg. According to clause 5.2.4.1.2 of ISO 81060-2:2018+A1:2020, the SD should be less than 6.95 and 6.90mmHg respectively. Therefore, the results obtained from this study met the requirements specified by the standard.

For the test device with a cuff ranging from 22 to 42cm, the mean difference of SBP and DBP was -1.62mmHg and 0.12mmHg, which were less than 5mmHg. The standard deviations corresponding to them were 2.80 and 3.01mmHg respectively, which were less than 8mmHg. Bland-Altman plots was showed on Fig. 2. On criterion 2, the SD was 2.35 and 2.60mmHg respectively corresponding to mean difference -1.62 and 0.12mmHg. According to clause 5.2.4.1.2 of ISO 81060-2:2018+A1:2020, the SD should be less than 6.73 and 6.95mmHg respectively. Therefore, the results obtained from this study met the requirements specified by the standard.

Furthermore, there isn't any adverse event or device failure during the trial.

Conclusion

TMB-2296-BT blood pressure monitor manufactured by Guangdong Transtek Medical Electronics Co., Ltd. meets the requirements of ISO 81060-2:2018+A1:2020 and the device is effective and safety.

Thus, TMB-2296-BT is qualified to measure the BP for adults in home.

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Reference

1. https://www.who.int/news-room/fact-sheets/detail/hypertension

2. ISO 81060-2:2018+A1:2020 Non-invasive sphygmomanometers —Part 2: Clinical investigation of intermittent automated measurement type

3. EN ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

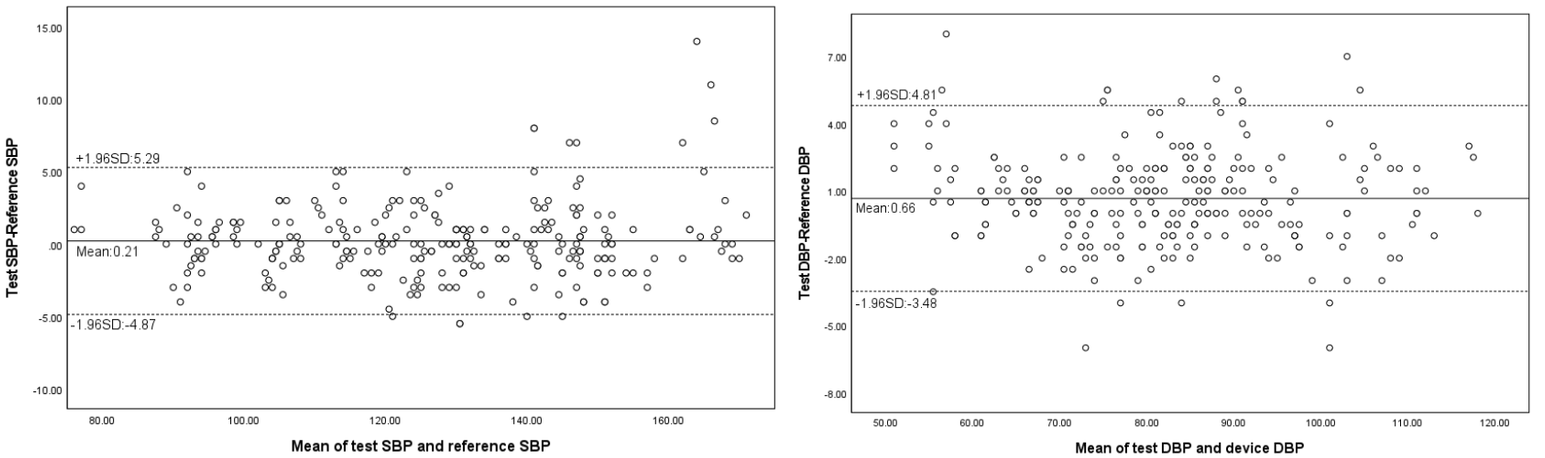

Fig.1 Scatter plot for difference value of SBP and DBP (mmHg) measured by the test device and the reference device (262 sets of data).

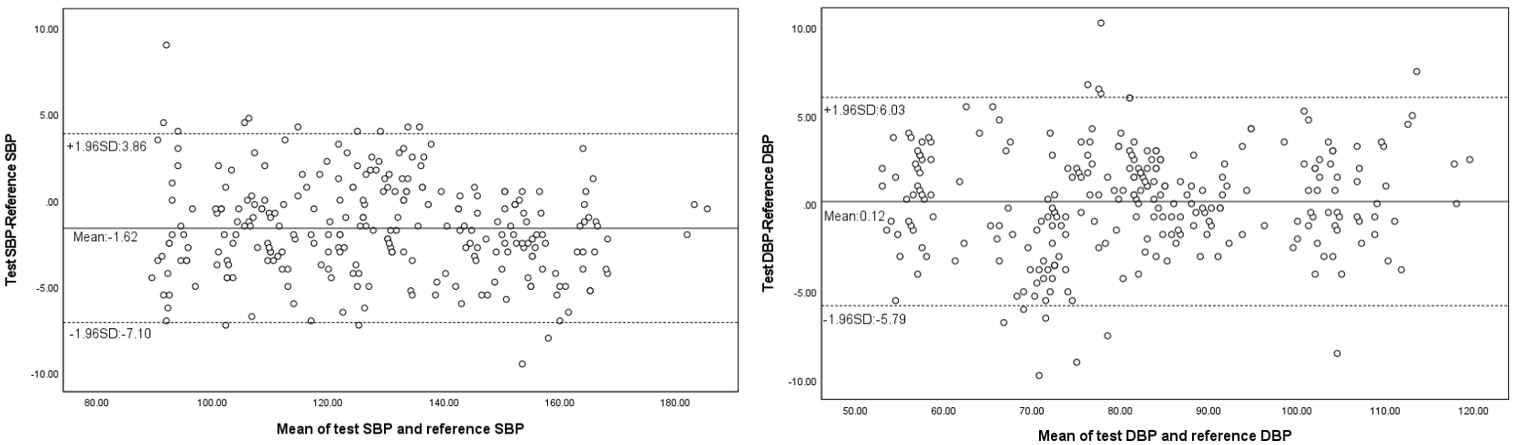

Fig.2 Scatter plot for difference value of SBP and DBP (mmHg) measured by the test device and the reference device (259 sets of data).