Validation of the TMB-2266 blood pressure monitor in adults according to the ISO 81060-2:2018 + Amd.1:2020.

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Abstract

This study aimed to validate the accuracy of the test device (TMB-2266) blood pressure (BP) monitor in adults according to ISO 81060-2:2018 + Amd.1:2020 universal standard protocol, which is a digital monitor. Three trained observers used the same arm sequential method to compare the systolic blood pressures (SBPs) and Diastolic blood pressures (DBPs) measured by the test device with those measured by the reference device (mercury sphygmomanometer). For the test device with cuff ranging from 16 cm to 36 cm and 22 cm to 42 cm, there are 102 subjects, with a children-to-adults ratio of 37:65. The mean difference (MD) and standard deviation (SD) between reference BPs and test device BPs readings were (0.94±4.36) /

(0.52±3.89) mmHg for SBP/DBP for criterion 1, and (0.94 ± 3.78) / (0.52 ± 3.52) mmHg for SBP / DBP for criterion 2. Test device with the cuff limb circumference size of 16-36 cm and 22-42 cm fulfilled both validation criterion 1 and 2 of the ISO 81060-2:2018 + Amd.1:2020 standard, hence, it can be recommended for both clinical and self / home BP measurement in adults.

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

Introduction

According to data from 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 diseases [1-2], so prevention and early detection of blood pressure abnormalities are essential. Therefore, ensuring accurate measurement of BP values is of utmost importance. In 2018, the ISO 81060-2:2018 was considered the universal standard protocol for the validation of noninvasive BP-measuring devices, when the members of the Association for the Advancement of Medical Instrumentation (AAMI), European Society of Hypertension (ESH), and the International Standard Organization (ISO) committees reached a consensus on an optimal validation standard [5].

TMB-2266, manufactured by Guangdong Transtek Medical Electronics Co., Ltd, is a non-invasive, automated 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 the accuracy according to the ISO 81060-2:2018+A1:2020

universal standard protocols [3-4] and execute in accordance with EN ISO 14155:2020 [6].

Methods

The study should recruit at least 85 subjects to measure BP using both the test device and the reference device in order to obtain at least 255 data pairs, as stipulated in ISO 81060-2:2018. Throughout the trial, investigators should comply with clinical investigation plan (CIP) and regulatory requirements, enroll eligible subjects and record demographic information about the 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 the mercury BP measurements according to the Universal Standard. Each observer independently recorded the BP readings from the reference device, ensuring that their respective recordings were invisible 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. Any pair of observers' SBP value or DBP value with a difference greater than 4 mmHg (0.53 kPa) was excluded.

The accuracy validation used the same arm sequential method. The observer inflated the bladder until the pressure reached a range of 80-100 mmHg, palpated the radial

artery every 20 mmHg 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 1 minute and 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. Test device and reference device were measured alternately on the same arm. Repeat the two procedures until sufficient valid BP data were collected. The first paired values were not used in the calculation of accuracy.

Data analysis

Data were analyzed using SPSS for Windows, IBM according to the criteria described in the protocols. The difference between the mean observer values and the test values was calculated according to the protocol and was displayed as Bland–Altman plots against the mean of reference BP values.

And the distribution of data on age, gender, arm circumference and BP was as shown on Table 1. Data was all met the requirements of ISO 81060-2:2018 + Amd.1:2020. According to ISO 81060-2:2018 + Amd.1:2020, the MD and SD of the differences between the test device and the reference device were needed to meet the requirements. In this study, the results were shown on table 2.

Results

102 subjects were enrolled in trial using a arm circumference ranging from 16 cm to 42cm（37 children / 65 adults, median ± SD age 37.9±25.0, range 6-87 years）.

For these two cuffs, each quarter of the total arm circumference lies at least 20% of subjects, and the highest octile and lowest octile of the total arm circumference lies at least 10% of subjects. For blood pressure distribution, both of the two cuffs at least 5% of the reference blood pressure readings have a SBP ≤100 mmHg, SBP ≥160 mmHg, and DBP ≤60 mmHg, ≥100 mmHg. At least 20% of the reference blood pressure readings have SBP≥140 mmHg and DBP ≥85 mmHg . As shown on the table 1, the distribution of subject's age, gender, arm circumference BPs met the requirements of the ISO 81060-2:2018 + Amd.1:2020.

According to Criterion 1, the TMB-2266 of the mean difference of SBP between the test device and the reference device was 0.94 mmHg, with an SD of 4.36 mmHg. The mean difference of DBP between the test device and the reference device was 0.52 mmHg, with an SD of 3.89 mmHg. The mean difference of the TMB-2266 between SBP and DBP was less than ±5 mm Hg, and the SD was less than 8 mmHg.

According to Criterion 2, the TMB-2266 of the mean difference of MD of SBP between the test device and the reference device was 0.94 mmHg, with an SD of 3.78 mmHg which less than 6.87 mmHg. The mean difference of DBP between the test device and the reference device was 0.52 mmHg, with an SD of 3.52 mmHg which less than 6.91 mmHg.

As shown on table 2, the criterion 1 and 2 met the requirements of the ISO 81060-2:2018 + Amd.1:2020.

According to criterion 1, draw the Bland-Altman plots for SBP and DBP. The MD,

MD + 1.96SD, and MD – 1.96SD denoted by the horizontal lines. The SBP of MD ± 1.96SD were 0.94 (9.49,- 7.60), the DBP of MD ± 1.96SD were 0.52(8.15, -7.12). As shown on figure 1.

For criterion 2, the SBP of MD ± 1.96SD were 0.94 (8.34, -6.47), the DBP of MD ± 1.96SD were 0.50 (7.40, -6.39). As shown on figure 2.

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.

In this study, the test device’s operation is simple, and the LED screen display provides a wider viewing angle for reading. In a blood pressure monitor used for measuring upper arm blood pressure, the test device is characterized by small dimensions and lightweight design, while also offering long battery life, allowing for 150 measurements on a full charge. It supports Bluetooth connection, allowing for viewing of the blood pressure history on a smartphone. In terms of display, it uses simple green or orange reminders to indicate normal blood pressure or blood pressure that exceeds the normal range. It comes with two cuff sizes:16-.36 cm and 22-42 cm, making it suitable for obese individuals as well. The accuracy of oscillometric devices is significantly affected by several factors such as cuff size [7]. The two cuffs, 16-36

cm and 22-42 cm, were validated by collecting data from 37 subjects and 65 subjects, respectively.

The study had several limitations. The enrolled subjects didn't include subjects younger than 3 years, pregnant women, and individuals with cardiac arrhythmia or arm circumference beyond the cuff size.

Since different measurement 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 standard, 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-2266.

Conclusion

TMB-2266 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-2266 is qualified to measure the BP for adults in home.

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