Validation of the FF680 upper-arm blood pressure monitor according to the AAMI/ESH/ISO universal standard (ISO 81060-2:2018) for use in clinical and self/home blood pressure monitoring among adults

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Abstract: This study evaluated the accuracy of blood pressure measurement in adults using FF680 electronic blood pressure monitors with the Korotkoff-Sound method, in accordance with the AAMI/ESH/ISO universal standards (ISO 81060-2:2018). The study was conducted at Shijiazhuang People's Hospital and lasted 56 days, from May 26 to July 21, 2023. Participants, drawn from an adult demographic, underwent data verification and analysis with strict adherence to the trial protocol. For the FF680 electronic blood pressure monitor using the Korotkoff-Sound method, data from 85 valid participants were analyzed. The findings revealed mean differences (standard deviations) of -0.66 mmHg (2.45 mmHg) for systolic blood pressure and -0.28 mmHg (2.09 mmHg) for diastolic blood pressure. Systolic and diastolic blood pressure had standard deviations of ≤6.9 mmHg and ≤6.95 mmHg, meeting the standard requirements. FF680 devices are recommended for adult blood pressure monitoring because they meet the AAMI/ESH/ISO universal requirements (ISO 81060-2:2018).

Keywords: Blood Pressure Measuring Device Validation, Korotkoff-Sound Method, Blood Pressure Measurement, Non-invasive Sphygmomanometer, Universal Standard

Introduction

Hypertension prevalence is rising due to improved living standards and dietary changes [1]. Accurate blood pressure (BP) measurement is crucial for diagnosing and managing hypertension [2, 3], with inaccuracies potentially leading to overtreatment or undertreatment of the condition [4]. The Korotkoff-Sound technique [5], as a non-invasive approach, remains the gold standard in BP measurement. FF680 is an electronic blood pressure monitor using this principle. The AAMI/ESH/ISO universal standards (ISO 81060-2:2018 [6]) currently serve as benchmarks for validating noninvasive BP measurement devices. This study aimed to confirm the efficacy of FF680 electronic blood pressure monitoring using the Korotkoff-Sound method in an adult population in accordance with these standards, to ensure its accuracy and reliability in real-world applications.

Method

This clinical trial commenced on May 26, 2023, following the receipt of approval from the Shijiazhuang People's Hospital drug/Medical device clinical trial Ethics Committee (Ethics Approval No.: SJZSRMYY-2023-19-01).

Participants

Participants were recruited from Shijiazhuang People’s Hospital. The inclusion criteria were as follows:

(1) Age over 12 years, ensuring at least 30% representation from each gender.

(2) Provision of informed consent and willingness to participate.

(3) Effective communication with the research team, high compliance, and adherence

to the study protocol.

The exclusion criteria were as follows:

(1) Individuals whose BP could not be accurately measured, with replacements made to maintain the sample size.

(2) Individuals with severe circulatory compromise, in shock, on cardiopulmonary bypass, with upper limb infections or catheters, excluding neonates and children;

(3) Individuals deemed unsuitable for inclusion by the researchers. According to the AAMI/ESH/ISO universal standards (ISO 81060-2:2018), a general population validation study requires ≥ 85 individuals aged >12 years. Data were collected from at least three sets per subject, totaling 255. Demographics, including age, sex, height, weight, hypertension history, and arm circumference, were recorded. Informed consent was obtained from all the participants.

Instruments

FF680 electronic blood pressure monitors utilize the Korotkoff-Sound method to measure human systolic blood pressure (SBP), diastolic blood pressure (DBP), and pulse rate. **Fig. 1** shows the product images of the FF680. FF680 devices have a measurement range of 0-299 mmHg, detect pulse rates of 40-200 bpm, and fit arm circumferences of 22-36 cm. Additional features include cuff wear self-checking, irregular pulse alerts, multi-user capabilities, and NB data transmission. Validation was done using a Yuwell mercury sphygmomanometer meeting ISO 81060 standards with auscultation for accurate BP measurements.

Fig. 1.FF680 product image.

Observer training and assessment

BP measurements were conducted using the Korotkoff-Sound method. Two observers monitored the BP readings using a mercury sphygmomanometer, employing the Korotkoff-Sound method and simultaneously auscultating using a dual stethoscope (Y-tube). The mercury blood pressure monitor was calibrated before commencing the study. Upon identifying Korotkoff sounds indicative of systolic and diastolic pressures, the observers independently recorded their readings. The two observers were blinded to each other's readings, whereas a third observer served as a supervisor to verify the BP readings of the other two observers. The observers received standard protocol-compliant training for mercury sphygmomanometer and practiced extensively.

Procedures

Participants were advised to abstain from smoking, caffeine, and vigorous activity for

30 minutes prior to BP measurement. They were instructed to void bladders and relax in quiet for 10-15 minutes. Participants were seated with feet flat and arms at heart level. During measurement, they remained silent, arms flat, palms up, fists relaxed. The same arm sequence method was employed, and the average of the readings of the two observers was used as the reference BP for each measurement.

Analysis

In accordance with the AAMI/ESH/ISO universal standards (ISO 81060-2:2018), the testing device must satisfy two main criteria. Criterion 1: The differences in SBP and DBP readings between the testing and reference devices were determined for each valid dataset. The mean and standard deviation of these differences across all the datasets were computed. Criterion 2: The average BP readings for each subject from both the testing and reference devices for each trial were averaged and the standard deviation of these averages across all subjects was calculated.

Results

The FF680 clinical study initially enrolled 90 participants; however, 5 were excluded because of significant variability in their BP readings, specifically deviations exceeding 12 mmHg for SBP or 8 mmHg for DBP across the entire dataset, in accordance with the AAMI/ESH/ISO universal standards. The analysis ultimately included 255 valid measurement sets from 85 participants. The cohort comprised 47 males (55.3%) and 38 females (44.7%), with ages ranging from 25 to 83 years old. Arm circumferences: 22-36 cm, and BP readings spanned from 79.0 to 187.0 mmHg for SBP and 51.0 to 111.0 mmHg for DBP, meeting the standard criteria. Table 1 presents the detailed data.

According to Criterion 1, the 255 valid paired measurements exhibited mean differences of -0.66 mmHg for SBP and -0.28 mmHg for DBP, with standard deviations of 2.45 mmHg and 2.09 mmHg, respectively. Both the mean differences and standard deviations for SBP and DBP were within acceptable limits, satisfying Criterion 1. For Criterion 2, the average of 85 valid paired individuals revealed an SBP standard deviation (SD) of 1.24 mmHg, which was less than 6.90 mmHg, and a DBP SD of 1.11 mmHg, which was less than 6.95 mmHg, thus satisfying Criterion 2.

111 **Table 1**.Characteristics of the study participants (FF680 n = 85).

Variable	the ISO 81060-2:2018 (n, %)	FF680 (%)
Age, y (range)		60.12±12.14 years (25-83 years)
Men: Women, n (%)	Men(≥26,≥30%);Women(≥26,≥30%)	47 (55.3%): 38 (44.7%)
Arm circumstance, cm(range)		28.66 ± 3.80 cm (22.0–36.0 cm)
≥22.0and<29.0cm	≥34,≥40%	46 (54.1%)
≥29.0and≤36.0cm	≥34,≥40%	39 (45.9%)
≥22.0and≤25.5cm	≥17,≥20%	20(23.5%)
≥32.5and≤36cm	≥17,≥20%	17(20%)
≥22.0and≤23.75cm	≥9,≥10%	10 (11.8%)
≥34.25and≤36cm	≥9,≥10%	9 (10.6%)
SBP, mmHg(range)		
≤100 mmHg	≥5%	21(8.2%)
≥160 mmHg	≥5%	18(7.1%)
≥140 mmHg	≥20%	59(23.1%)
DBP, mmHg(range)		
≤60 mmHg	≥5%	19(7.5%)
≥100 mmHg	≥5%	14(5.5%)

≥85 mmHg	≥20%	82(32.2%)

112 Data are expressed as the means ± SD or percentages or number.

Fig. 2(a) and **Fig. 2**(b) depict the distribution of differences in SBP and DBP between FF680 and the reference device across 255 datasets. **Fig. 2**(c) and **Fig. 2**(d) demonstrate the relationship between these differences and the arm circumference.

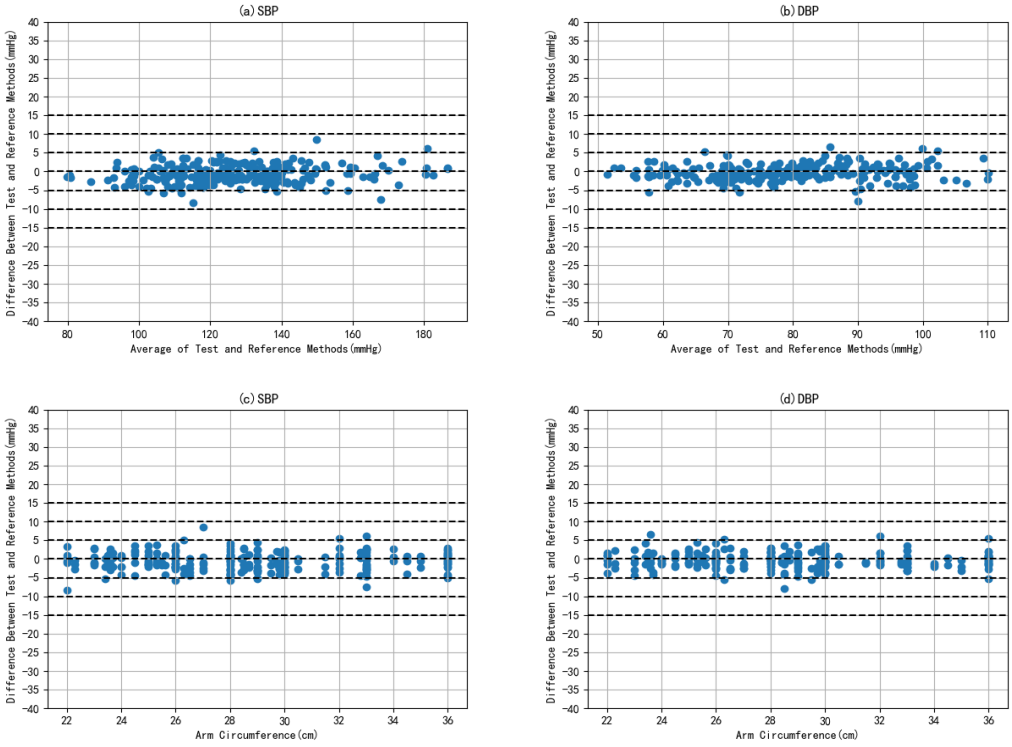

Fig. 2.Distribution of BP Differences and Arm Circumference Correlation for FF680 Device.

Discussion

This study validated the accuracy of FF680 against the AAMI/ESH/ISO universal standards (ISO 81060-2:2018) in an adult population. Its Korotkoff-Sound method aligned with test and reference devices, fulfilling all criteria. FF680, renowned for user-friendliness and precision, includes cuff-fit check, irregular heartbeat detection, multi-user measurement, NB-IoT data transfer, and smart device integration. All additional features excelled during validation.

The study findings demonstrated that FF680 comply with the two criteria outlined in

the AAMI/ESH/ISO universal standards. The test devices demonstrated exceptional stability, operated flawlessly, and were user friendly.

Conclusion

FF680 has been approved in accordance with the AAMI/ESH/ISO universal standards (ISO 81060-2:2018) for use in clinical and self/home blood pressure monitoring among adults.

Conflicts of interest

There are no conflicts of interest.

References

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