Smartphone application-supported validation of three automatic devices for self-measurement of blood pressure according to the European Society of Hypertension International Protocol revision 2010: the Omron HEM-7120, Yuwell YE680A and Cofoe KF-65B

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Background Accurate measurement of blood pressure (BP) is crucial to hypertension control and prevention of future stroke and heart attack. All BP measuring devices must be validated independently in the clinical setting.

Objective To validate the accuracy of three automatic upper arm devices (Omron HEM-7120, Yuwell YE680A and Cofoe KF-65B) for self-measurement of BP in Chinese adults with arm size of 22–32 cm.

Methods The validation was conducted independently for each of the three devices according to the European Society of Hypertension International Protocol revision 2010 (ESH-IP revision 2010), with the facilitation of a designated smartphone application. Subjects were recruited from those attending Beijing Anzhen Hospital for routine physical examination and clinic visits. For each device, BP was measured sequentially in 33 adults using a mercury sphygmomanometer (two observers) and the test device (one supervisor) with seven measurements alternating between observers and the device, which generated a total of 99 before/after paired values for SBP and DBP separately. The judgments were made based on the distribution of the paired difference among the 99 measurements (Part 1) and among the 33 subjects (Part 2). To pass, a device must achieve all the minimum Pass requirements in Part 1 and Part 2 for both SBP and DBP (Part 3).

Results Only HEM-7120 achieved the part 1 and part 2 targets for both SBP and DBP. KF-65B achieved the DBP targets of part 1 and part 2 but failed for SBP. YE680A only achieved the DBP targets of part 2 but failed for all others. The findings also indicated that the devices had higher SBP readings (1.3 mmHg, 1.0 mmHg and 4.1 mmHg higher for HEM-7120, YE680A and KF-65B, respectively) and lower DBP readings (2.0 mmHg, 1.1 mmHg and 3.3 mmHg lower, respectively) when compared to the mercury sphygmomanometer.

Conclusions The Omron HEM-7120 passed the requirements of the ESH-IP 2010 revision, while the Yuwell YE680A and Cofoe KF-65B failed (part 3). *Blood Press Monit* 26: 435–440 Copyright © 2021 The Author(s). Published by Wolters Kluwer Health, Inc.

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Introduction

Blood pressure (BP) can be measured by the oscillometric method, which works through the identification and record of a slight change of cuff pressure caused by arterial wall pressure because of the heart beating. Compared with a mercury sphygmomanometer, an electronic sphygmomanometer is well tolerated without mercury pollution, more convenient for BP monitoring, and less prone to observers' error or bias. For these reasons, mercury sphygmomanometers are gradually being supplanted by automated devices [1]. Accurate BP measurement is essential to BP management and cardiovascular disease prevention. All BP measuring devices must be validated independently in the clinical setting. Although ambulatory BP monitoring is the gold standard for BP measurement, it is invasive and not realistic to be used to validate so many sphygmomanometers on the market. A number of verification protocols have been developed worldwide to standardize the accuracy evaluation of electronic sphygmomanometer [2,3]. However, there are still many brands of devices already available on the market but not validated yet.

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The present study aimed to evaluate the accuracy of three self-measuring devices at home (Omron HEM-7120, Yuwell YE680A and Cofoe KF-65B) which have been on sale in China, according to the European Society of Hypertension International Protocol revision 2010 (ESH-IP revision 2010) [2].

Methods

Devices

The Omron HEM-7120 (OMRON Healthcare Co. Ltd, China), Yuwell YE680A (Jiangsu Yuwell Medical Equipment Co. Ltd.) and Cofoe KF-65B (Hunan Cofoe Medical Technology Development Co. Ltd.) are automatic oscillometric devices for self-measurement of BP at upper arm at home. The devices require four 1.5 V AA (LR06) alkaline batteries as a power supply. The dimension is 103 × 80 × 129 mm (width × height × depth) for HEM-7120, 133 × 100 × 83 mm for YE680A and 105 × 140 × 65 mm for KF-65B. The original arm cuffs are all designed for arm circumferences of 22–32 cm and not for smaller or larger ones. The three devices have semiconductive pressure sensors designed to measure BP values in the range of 0–299, 0–280 and 0–300 mmHg and a heart rate range of 40–180, 40–200 and 40–150 beats/min, respectively. The SBP, DBP and heart rate are displayed on a liquid crystal digital display.

The declared specific accuracy of the Omron HEM-7120 and Yuwell YE680A is ±3 mmHg for BP and ±5% for pulse rate and ±4% for both BP and pulse rate of Cofoe KF-65B.

Participants selection

The participants were recruited from the physical examination center and clinics in the Beijing Anzhen Hospital, Capital Medical University from 22 January 2018 to 12 February 2018. People attending the physical examination center and hypertension outpatient clinics, including hospital staff or their acquaintances, were selected after screened for recruitment requirements. Although the number of hypertension outpatient visits is large in Beijing Anzhen Hospital, there was some difficulty in recruiting subjects with BP at

Table 1 Participant recruitment details of three devices

		Recruitment ranges				
Screening and recruitment	*N*	BP range and level (mmHg)			*N*	n on Rx
Omron HEM-7120						
Total screened	44	SBP	Low	<90	0	4
Total excluded	11			90–129	10	
Ranges complete	1		Medium	130–160	12	9
Range adjustment	0		High	161–180	8	8
Arrhythmias	0			>180	3	
Device failure	0					
Poor quality sounds	0		Low	<40	0	4
Cuff size unavailable	0			40–79	10	
Observer disagreement	2	DBP	Medium	80–100	12	8
Distribution	6		High	101–130	9	7
Other reasons	2			>130	2	
Total recruited	33					
Yuwell YE680A						
Total screened	44	SBP	Low	<90	0	4
Total excluded	11			90–129	11	
Ranges complete	1		Medium	130–160	10	7
Range adjustment	0		High	161–180	9	10
Arrhythmias	0			>180	3	
Device failure	0					
Poor quality sounds	1	DBP	Low	<40	0	6
Cuff size unavailable	2			40–79	11	
Observer disagreement	3		Medium	80–100	11	5
Distribution	2		High	101–130	11	10
Other reasons	2			>130	0	
Total recruited	33					
Cofoe KF-65B						
Total screened	41	SBP	Low	<90	0	0
Total excluded	8			90–129	12	
Ranges complete	1		Medium	130–160	10	8
Range adjustment	0		High	161–180	9	10
Arrhythmias	1			>180	2	
Device failure	0					
Poor quality sounds	1	DBP	Low	<40	0	2
Cuff size unavailable	2			40–79	10	
Observer disagreement	2		Medium	80–100	12	6
Distribution	1		High	101–130	9	10
Other reasons	0			>130	2	
Total recruited	33					

Table 2 Subject details for device validation

Characteristics	Omron HEM-7120 N=33	Yuwell YE680A N=33	Cofoe KF-65B N=33
Sex			
Male:female	19:14	18:15	18:15
Age (years)			
Range (low: high)	30:80	26:83	25:80
Mean ± SD	50.0 ± 11.2	49.5 ± 13.7	48.8 ± 15.0
Arm circumference (cm)			
Range (low:high)	22:31	24:32	22:32
Mean (SD)	27.0 ± 2.2	27.6 ± 2.6	26.9 ± 2.8
Recruitment SBP (mmHg)			
Range (low:high)	100:199	91:196	94:216
Mean (SD)	144.5 ± 25.0	143.6 ± 26.2	143.3 ± 31.6
Recruitment DBP (mmHg)			
Range (low:high)	49:140	40:129	57:145
Mean (SD)	92.2 ± 19.6	88.3 ± 21.1	91.2 ± 21.3
Antihypertensive treatment			
N	19	21	18
%	57.6	63.7	54.6

No statistical significance ($P < 0.05$) was found among the three device groups. Comparison of binary data was conducted using the chi-square test, and ANOVA was used for continuous data.

high ranges as the study proceeded. It was also not rare that the patients fulfilled the BP condition at clinics, but excluded at entry measurements. However, all the barriers were subjugated finally by encouraging more professionals at the clinic to participate in the subject screening and 33 participants meeting the protocol requirements for subjects and BP were successfully recruited for each device.

Procedure

The ESH-IP revision 2010 for the validation of BP measuring devices in adults was followed. Before formal validation, 12 test measurements were carried out without any problems for each device.

Overseen by an independent supervisor, measurements were recorded by two observers blinded from each other's readings and from the device readings. The BP measurements were alternated between the mercury sphygmomanometer and the test device. Simultaneous auscultations were performed by two observers using a double stethoscope (Y tube) when the BP was measured using a mercury sphygmomanometer. Starting with the observers, measurements are recorded sequentially alternating between observers and the device in the order BPA, BPB, BP1, BP2, BP3, BP4, BP5, BP6 and BP7.

BPA was the mean values of entry measurement by the two observers and used to categorize the participants into low, medium or high BP range, separately for SBP and DBP. The BP ranges of a subject were categorized as LL: <90, L: 90–129, M: 130–160, H: 161–180, HH: >180 for SBP, and LL: <40, L: 40–79, M: 80–100, H: 101–130, HH: >130 for DBP. The LL and L together and HH and H together were counted as the low and high, respectively.

BP1 to BP7 were validation measurements. As reference BP1, BP3, BP5 and BP7, a repeated measurement would be required if the difference between the two observers was more than 4 mmHg.

Table 3 Observer measurements in each recruitment range

BP range	Omron HEM-7120 N=33	Yuwell YE680A N=33	Cofoe KF-65B N=33
SBP (mmHg)			
Overall range (low:high)	96:191	88:200	90:203
Low (<130)	38	34	33
Medium (130–160)	39	34	35
High (>160)	22	31	31
Maximum difference	17	3	4
DBP (mmHg)			
Overall range (low:high)	49:132	54:129	49:124
Low (<80)	30	33	39
Medium (80–100)	38	42	36
High (>100)	31	24	24
Maximum difference	8	18	15

The major procedures including subject recruitment, BP measurements, data entry and judgments were conducted with the facilitation of a smartphone application designated for this work for both observers and supervisors. The app had been well tested in advance to make sure it was convenient for use with no conflict with the protocol, and with better quality control. For example, when a reference BP measurement is finished, the BP values will be uploaded by the two observers separately without communication, the app will judge then immediately if the measurements by the two observers differ by more than 4 mmHg and a repeated measurement is needed. To improve the quality, a picture of the BP reading shown on the screen of the test device will be taken for each measurement, and a 50 s countdown function was designed to make sure the interval between two measurements is not too long or too short. Each time a patient completing all the tests, a message was immediately shown to instruct what kinds of subjects should be recruited next. Three smartphones without SIM cards but with internet access through WIFI were used to avoid interruption from the phone call and short message.

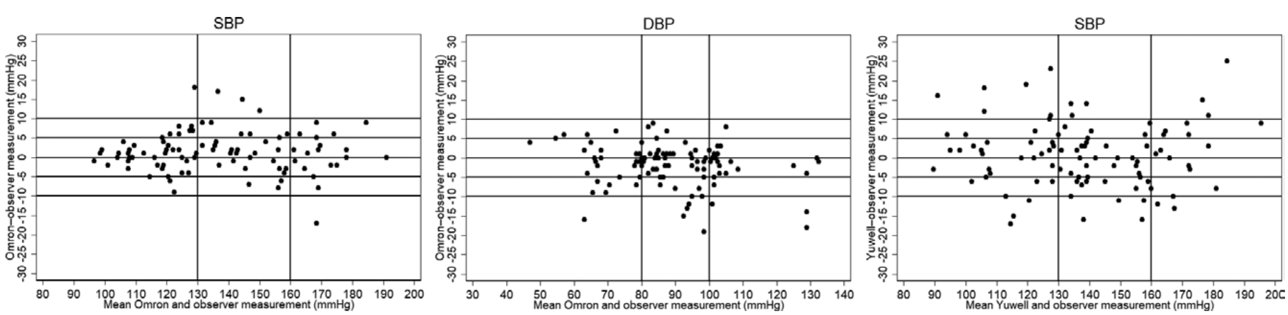
Analysis

The accuracy of a device according to the ESH-IP 2010 is based on a comparison between the device and reference (mercury) measurements. Each of the three SBP and three DBP readings recorded by the device is compared to the nearer of the previous and next observer measurement. Two differences were calculated by subtracting, respectively, the preceding and following observer mean taken with the mercury sphygmomanometer. The smaller one of the two difference values in absolute terms was categorized into four bands (≤5, ≤10, ≤15 and >15 mmHg) according to its rounded value. The observer mean with smaller absolute difference value among two measurements was identified as observer value of this device measurement. Accuracy is determined by the number differences in three requested ranges (≤5, ≤10 and ≤15 mmHg) among 99 individual measurements (Part 1) and by the numbers of subjects whose BP measurements

Table 4 Validation results for the three devices

Part 1	≤5 mmHg	≤10 mmHg	≤15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass required						
Two of	73	87	96			
All of	65	81	93			
Omron HEM-7120 achieved						
SBP	73	94	96	Pass	1.3	5.3
DBP	73	91	96	Pass	-2.0	5.6
Yuwell YE680A achieved						
SBP	50	79	91	Fail	1.0	9.0
DBP	67	87	95	Fail	-1.1	6.5
Cofoe KF-65B achieved						
SBP	53	79	91	Fail	4.1	7.0
DBP	65	89	96	Pass	-3.3	5.3
Part 2	**2/3 ≤5 mmHg**	**0/3 ≤5 mmHg**		**Grade 2**		**Grade 3**
Pass required	≥24	≤3				
Omron HEM-7120 achieved						
SBP	27	2		Pass		Pass
DBP	24	2		Pass		Pass
Yuwell YE680A achieved						
SBP	16	4		Fail		Fail
DBP	24	2		Pass		Fail
Cofoe KF-65B achieved						
SBP	16	4		Fail		Fail
DBP	24	2		Pass		Pass
Part 3						**Result**
Omron HEM-7120						Pass
Yuwell YE680A						Fail
Cofoe KF-65B						Fail

Fig. 1



Bland–Altman plots of the differences among three devices' readings and the observer measurements for SBP.

satisfy certain standard (Part 2). To pass, a device must achieve all the minimum Pass Requirements in Part 1 and Part 2 for both SBP and DBP (Part 3). A detailed explanation is provided in the '*Results*' section.

Bland–Altman plots were used to present the relationship between device-reference differences and device-reference means for SBP and DBP to show the trend of differences with increasing BP levels.

Results

The details of participant recruitment, subject details and distribution of recruitment measurements are shown in Tables 1, 2 and 3, respectively. To sum up, 33 subjects were successfully recruited for each device (Table 1). Except that the lowest DBP of subjects for Omron HEM-7120 (57 mmHg) did not meet the requirement (≤50 mmHg), all the requirements for device validation were achieved, including at least 10 male and 10 female; all subjects should be at least 25 years of age with sinus rhythm; with 10–12 subjects in each of the three SBP and three DBP recruitment ranges; the number of recruitment measurements in each pressure range must be between 22 and 44; the difference between the range with the highest count and that with the lowest count cannot exceed 19; the overall SBP range must be from ≤100 to ≥170 mmHg and the overall DBP range must be from ≤50 to ≥120 mmHg. Other findings and validation result together with pass requirements are described below and in Table 4.

Omron HEM-7120

The differences between the two observers were 0.23 ± 2.53 and 0.06 ± 2.48 mmHg for SBP and DBP, respectively (−4 to +4 mmHg). The mean differences between the observers and the test device were 1.3 ± 5.3 mmHg for SBP and −2.0 ± 5.6 mmHg for DBP. The number of BP differences between observer and device measurements falling within 5, 10 and 15 mmHg were 73/99, 94/99 and 96/99 for SBP and 73/99, 91/99 and 96/99 for DBP, respectively (passed Part 1 for both SBP and DBP). There were 27 and 24 subjects with two or three of the absolute differences within 5 mmHg for SBP and DBP, respectively, and 2 subjects with none of the absolute differences within 5 mmHg for both SBP and DBP (passed Part 2 for both SBP and DBP). In the end, the Omron HEM-7120 device passed ESH-IP2.

Yuwell YE680A

The differences between the two observers were 0.71 ± 2.36 and 0.51 ± 2.32 mmHg for SBP and DBP, respectively (−4 to +4 mmHg). The mean differences between the observers and the test device were 1.0 ± 9.0 mmHg for SBP and −1.1 ± 6.5 mmHg for DBP. The number of BP differences between observer and device measurements falling within 5, 10 and 15 were 50/99, 79/99 and 91/99 for SBP and 67/99, 87/99 and 95/99 for DBP, respectively (failed Part 1 for either SBP or DBP). There were 16 and 24 subjects with two or three of the absolute differences within 5 mmHg for SBP and DBP, respectively, and 4 and 2 subjects with none of the absolute differences within 5 mmHg for SBP and DBP, respectively (passed Part 2 for DBP, but failed for SBP). In the end, the Yuwell YE680A device failed ESH-IP2.

Cofoe KF-65B

The differences between the two observers were 0.68 ± 2.33 and 0.15 ± 2.29 mmHg for SBP and DBP, respectively (−4 to +4 mmHg). The mean differences between the observers and the test device were 4.1 ± 7.0 mmHg for SBP and −3.3 ± 5.3 mmHg for DBP. The number of BP differences between observer and device measurements falling within 5, 10 and 15 mmHg were 53/99, 79/99 and 91/99 for SBP and 65/99, 89/99 and 96/99 for DBP, respectively. There were 16 and 24 subjects with two or three of the absolute differences within 5 mmHg for SBP and DBP, respectively, and 4 and 2 subjects with none of the absolute differences within 5 mmHg for SBP and DBP, respectively (passed Part 2 for DBP, but failed for SBP). In the end, the Cofoe KF-65B device failed ESH-IP2.

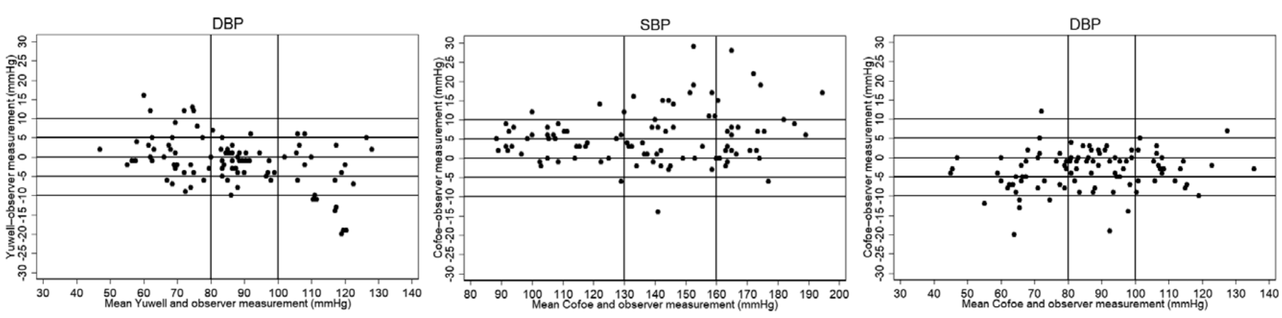
Bland–Altman plots of the device–observer differences against the average of device and observer values for the 99 pairs of comparisons are shown in Fig. 1 for SBP and Fig. 2 for DBP.

Discussion

This study is the first to provide accuracy information of the Omron HEM-7120, Yuwell YE680A and Cofoe KF-65B device for BP measurement in the general population in Chinese general population. It is also the first one to validate BP measuring devices with the support of a smartphone application. The results of the present study showed that only the Omron HEM-7120 passed the validation for SBPs and DBPs according to the ESH-IP revision 2010, whereas Yuwell YE680A and Cofoe KF-65B failed to reach the required standards.

Although hundreds of upper arm devices for self-measurement of BP have been validated and announced through the website www.dableducational.org, only a few products on the market have been evaluated for accuracy [4]. Considering two out of three home-use BP measuring devices already on sale failed in the ESH-IP validation, we strongly recommend doing more validation work for other devices available on the market. In addition, further validation for Omron HEM-7120, Yuwell YE680A and Cofoe KF-65B devices may also be needed for two reasons. First, the default cuffs of the three devices are only suitable for people with arm circumference of 22–32 cm. In this study, 4 out of 129 subjects screened were

Fig. 2



Bland–Altman plots of the differences among three devices' readings and the observer measurements for DBP.

excluded due to their arm circumferences were larger than 32 cm. These devices equipped with larger cuffs should be validated. Second, the requirement for the lowest DBP was not met among the subjects recruited for the Omron HEM-7120 device. It is required to be ≤50 mmHg, whereas it was 57 mmHg in this study.

It is not easy to follow the ESH-IP revision 2010 precisely. The smartphone application designated for this study can largely improve the adherence to the protocol through features, including process control, automatic data recording, immediate calculation and feedback, evidence collection and decision support. It could make the complex validation process smart, objective and simple. Here are some examples and explanations. When a reference BP measurement is finished, the BP values will be uploaded by the two observers separately without communication. The app can judge immediately whether the BP values measured by the two observers differ by more than 4 mmHg and a repeated measurement is needed, or this difference has happened twice, and the subject should be excluded. Each time a patient completing the measurements, a message will be immediately shown to instruct the supervisor what kinds of patients should be recruited next. All the procedures will be recorded by the app step by step. Any exclusion of subjects, failure in BP measurements and range adjustment will be recorded in the server. To improve the quality, the BP reading shown on the screen of a test device must be photographed for each measurement, and a 50 s countdown function can make sure the interval between two measurements is not too long or too short. However, further improvements for the app still exist. For example, a systematic report in PDF format should be developed by the app right after the measurement for the last subject is completed.

Conclusion

Although already on sale, only Omron HEM-7120 passed the validation according to the ESH-IP revision 2010, whereas Yuwell YE680A and Cofoe KF-65B failed, indicating that most BP measuring devices for home use need validation.

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Conflicts of interest

There are no conflicts of interest.

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