Diagnostic Accuracy Study

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A new automatic blood pressure kit auscultates for accurate reading with a smartphone

A diagnostic accuracy study

Hongjun Wu, MD[a], Bingjian Wang, MD[b], Xinpu Zhu, MD[c], Guang Chu, MD[d], Zhi Zhang, PhD[d,*]

Abstract

The widely used oscillometric automated blood pressure (BP) monitor was continuously questioned on its accuracy. A novel BP kit named Accutension which adopted Korotkoff auscultation method was then devised. Accutension worked with a miniature microphone, a pressure sensor, and a smartphone. The BP values were automatically displayed on the smartphone screen through the installed App. Data recorded in the phone could be played back and reconfirmed after measurement. They could also be uploaded and saved to the iCloud. The accuracy and consistency of this novel electronic auscultatory sphygmomanometer was preliminarily verified here. Thirty-two subjects were included and 82 qualified readings were obtained. The mean differences ± SD for systolic and diastolic BP readings between Accutension and mercury sphygmomanometer were 0.87 ± 2.86 and −0.94 ± 2.93 mm Hg. Agreements between Accutension and mercury sphygmomanometer were highly significant for systolic (ICC = 0.993, 95% confidence interval (CI): 0.989–0.995) and diastolic (ICC = 0.987, 95% CI: 0.979–0.991). In conclusion, Accutension worked accurately based on our pilot study data. The difference was acceptable. ICC and Bland–Altman plot charts showed good agreements with manual measurements. Systolic readings of Accutension were slightly higher than those of manual measurement, while diastolic readings were slightly lower. One possible reason was that Accutension captured the first and the last korotkoff sound more sensitively than human ear during manual measurement and avoided sound missing, so that it might be more accurate than traditional mercury sphygmomanometer. By documenting and analyzing of variant tendency of BP values, Accutension helps management of hypertension and therefore contributes to the mobile heath service.

Abbreviations: AAMI = Association for the Advancement of Medical Instrumentation, AF = atrial fibrillation, ANSI = American National Standards Institute, App = Application, BPMs = BP monitors, CHEP = Canadian Hypertension Education Program, CI = confidence interval, CPU = central processing unit, DBP = diastolic blood pressure, ESH = European Society of Hypertension, ICC = intraclass correlation coefficients, iOS = iPhone operating system, ISO = International Organization for Standardization, SBP = systolic blood pressure, SD = standard deviation.

Keywords: auscultation, blood pressure monitor, hypertension, smartphone, sphygmomanometer

1. Introduction

For many years, mercury sphygmomanometer has been the standard instrument for measuring blood pressure (BP). Recently, for the reason of environmental concerns, clinical institutions have begun phasing out the mercury devices.[1]

Besides a potential for environmental contamination, manual office BP measurement has other important limitations in diagnosis and management of hypertension. First, the accuracy of the method could be compromised by observer bias, particularly terminal digit preference. Second, it might cause "white coat hypertension."[2,3]

For the convenience and cleaness of the automated oscillometric BP monitor (BPM), it has become very popular and is widely used in BP self-measurement recent years especially in developed countries.[4] In 2015, CHEP (Canadian Hypertension Education Program) recommends that measurement using validated electronic (oscillometric) upper arm devices is preferred over auscultation for accurate office BP measurement.[5,6]

However, the controversy about the accuracy of oscillometric sphygmomanometer has never stopped.[1,7] The maximal-amplitude algorithm is used by conventional oscillometry.[8,9] The hazards of so-called fixed ratio algorithms were illustrated in a mathematical study in which arterial rigidity was modelled by adapting different values for Young's modulus. They found that with the increasing of the vessel wall's rigidity in their model, the cuff pressure point at which maximal oscillation occurred was significantly increased, hence overestimating systolic and mean BP measurments.[10,11] Thus in the clinical setting, the technique was supossed to be less accurate when the arteries were less

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compliant, as was seen in the elderly.[8] So among different subgroups, the results require careful interpretations.

Although a number of devices have now passed both the AAMI (Association for the Advancement of Medical Instrumentation) and ESH (European Society of Hypertension) criteria, the technique is yet premature.[12,13] Data showed that almost all of the automated oscillometric BPMs suffered from the problem of inaccuracy. Landgraf et al[14] warned that patients whose BP appeared to be under control using the oscillometric technique might not be at their goal BP and might have been undertreated. Stergiou et al[7] found that 18% of the participants had unreliable oscillometric BP measurement (with >10 mm Hg difference between the 2 methods.) in their first but not their second visit, or the reverse.

Modern recognition algorithms are improved constantly, but have yet not produced convincing results. However, as we knew that automated oscillometric BPM was not the only chioce for us to measure BP values.

It has been proved for more than 100 years that classic BP measurement method of Korotkoff sounds auscultation is so far irreplaceable. With the fast development of mobile phone CPU (central processing unit), sound processing capabilities got a substantial growth. A novel automatic auscultation sphygmomanometer named Accutension emerges now.

Accutension (Accutension, Shanghai Zhihu Co. Ltd, Shanghai, China) was primarily devised as the first BP measure kit for home and clinical office use that attempted to provide the results as accurate as doctor's measurements, which employing a smartphone and App (Application) software. Doctors directly determine the BP by listening (auscultating) to the sounds of blood vessels. So did Accutension: it provides readings based directly on the sounds, not algorithms, resulting in accurate, consistent, and reliable BP measurements. The sounds from the tube of the stethoscope are fed into the phone through a microphone plugged into the jack. The pressure from the cuff is transferred to the phone by a pressure sensor via Bluetooth. Through the well-designed App software installed in the cell phone, each auscultation sound has a corresponding BP value. The final BP values are then displayed on the smartphone screen (Fig. 1A). Besides working as an independent BP kit with its own cuff, Accutension could also work with the traditional sphygmomanometer or any of the automatic BPMs. It could acquire a second reading simultaneously from 1 oscillometric device. So, Accutension could be used to proof the oscillometric BPM's readings (Fig. 1B).

Table 1

Advantages of Accutension over mercury sphygmomanometer.

Accutension	Mercury sphygmomanometer
The auscultation sounds are recorded by a mobile phone	By ears
High coordination with hands, eyes, ears, and brain is not required	Required
The korotkoff sounds are determined by graphics	Just by ears
The auscultation sounds are rarely missed	Often missed
The measurements can be reviewed by several people	Cannot
Deflation rate is under control	Deflating upon personal experiences
Objective (with raw data)	Subjective

Theoretically, Accutension is probably more accurate than manual mercury sphygmomanometer. One of the main reasons lies in the fact that during the manual auscultation, even the most skilled physicians might have the chance to miss the first or last auscultation sound, which leads to underestimated systolic BP or overestimated diastolic BP. However, Accutension could grasp each auscultation sounds perfectly, ensuring the accuracy of BP measurement. Table 1 compares the Accutension and mercury sphygmomanometer in many features. In order to assess the accuracy of Accutension, we designed a preliminary study here.

2. Materials and methods

2.1. Subject selection

All of the participants in the preliminary study were regular Chinese participants randomly recruited from outpatients or hospitalized patients of Shanghai General Hospital. A total of 32 consecutive patients during a routine clinic visit with their cardiologist (male 16 and female 16) were eligible to participate in this pilot study. The overall mean age of the study participants was 36.7 years (age range 24–83 years). The term "observer" was used throughout this paper to denote a physician or nurse trained to measure BP values accurately using the mercury sphygmomanometer[15] (ANSI/AAMI/ISO 81060-2:2013(E)) (ANSI: American National Standards Institute; ISO: International Organization for Standardization).

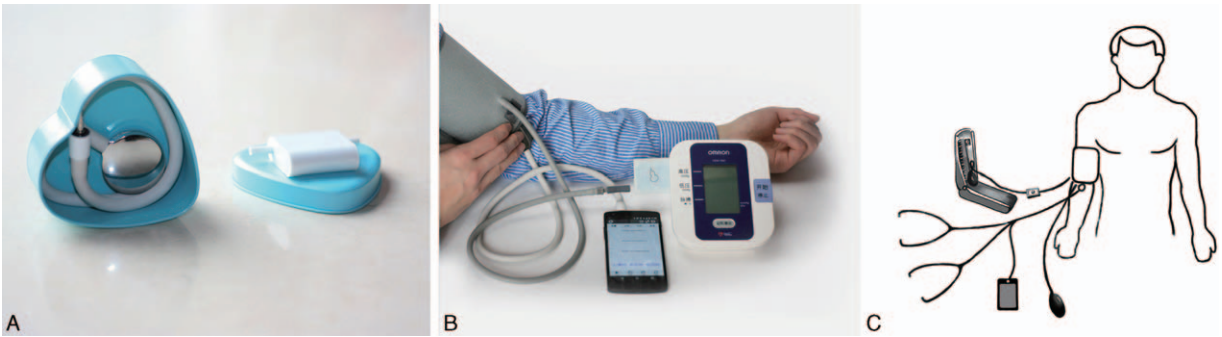

Figure 1. Monitor photograph: The main components of the Accutension are shown in (A). The component in the left is auscultation head equipped with a microphone which collects Korotkoff sounds and transfers them to the smartphone. The component in the right is pressure sensing and Bluetooth communication module. (B) By seamlessly accessing to the Omron oscillometric BP monitor, Accutension can acquire a second reading simultaneously from it. (C) Accutension works with mercury sphygmomanometer by incorporating into it. Two observers and Accutension share 1 stethoscope head by 2 Y-tube connectors.

Table 2

Screening and recruitment details.

Screening and recruitment				Recruitment ranges	
Total screened	40			mm Hg	All
Total excluded	8			<90	1
Ranges complete	0	SBP	Low	90–129	20
Range adjustment	0		Medium	130–160	11
Arrhythmias	1		High	161–180	0
Device failure	2			>180	0
Poor quality sounds	3				
Cuff size unavailable	0		Low	<40	0
Observer disagreement	1			40–79	20
Distribution	0	DBP	Medium	80–100	11
Other reasons*	1		High	101–130	1
Total recruited	32			>130	0

DBP = diastolic blood pressure, SBP = systolic blood pressure.

* Explanation summary: 1 subject had to leave for personal reasons before completing the sequence.

The inclusions criteria include: More than 18 years old, male or female; the subjects agree to participate in this study and fill in the informed consent; in a stable clinical phase. The exclusion criteria include (the subjects who meet one of the following items should not be enrolled): suffering from acute pain or in clinically unstable phase; upper arm missing or upper arm wounds not healed; bilateral upper arterial occlusion. The dropout criteria (withdraw from the test in the midway): subjects who want to withdraw; researchers believe that the subject is unsuitable to continue. The study population is a consecutive series of participants defined by the selection criteria.

Most of the participants had 3 valid mercury and Accutension measurements for systolic and diastolic BP readings. For more details about the subject selection, see Table 2. Data collection was planned before the test was performed. Among them, there were 8 subjects had hypertension history, 4 had diabetes mellitus, and 5 smokers.

The present study was approved by the Ethics Committee of Shanghai Jiao Tong University, Shanghai, China. Written informed consent was obtained from all of the participants.

2.2. Study design

The side of arms and the main observer (who inflated and deflated the mercury sphygmomanometer) were determined by random numbers. In order to minimize the bias, same arm simultaneous method was employed here. One measurement yielded 3 simultaneously BP readings. Once measurements were finished, BP values were recorded by observes. Observers must be blinded from each other's measurements and the device measurements throughout the study. This specific design approach was taken for 3 reasons: first, to minimize the observer bias; second, to eliminate the order effect encountered in sequential method (i.e., first reading being always higher)[16]; and third, to minimize the possibility that Accutension readings might affect the mercury readings.

2.3. Device

The Accutension is an upper-arm electronic BPM designed to be used in clinical settings and at home. As in our initial design stage, it is semi-automatic: BP determination is performed automatically but cuff inflation and deflation needs manual operation. In this study, Accutension worked with mercury sphygmomanometer by incorporating into it as shown in Fig. 1C. The medical mercury sphygmomanometer (Jiangsu Yuyue Medical Equipment & Supply Co., Jiangsu, China) was used as the standard comparison device to Accutension. The standard mercury cuffs [small adult (17–21 cm), adult (22–31 cm), large adult (32–41 cm), and extra-large adult (42–50 cm)] were used to perform all BP measurements.

The calibration technique performed to check the Accutension involved connecting the mercury sphygmomanometer and the Accutension device via a Y-tube connector.

It works like this: First, touch CONNECTION icon on the upper right corner of the operation interface. Once the connection is established, touch MEASURE icon to start measuring and the device picks up sounds and pressure signals during cuff deflation. Data would be displayed on the screen when the measurement is finished. Touch the SAVE icon if you want to save the values. Touch the SHARE icon if you want to upload the data to the iCloud for storage. In the ANALYSIS interface, a BP fluctuation tendency for a period of time (e.g., 1 week, 1 month, or 1 year, etc.) is available, which contributes to long-term BP monitoring and management (Fig. 2).

It addition to the automatic mode, when uncertain measurements are occurred due to noise disturbance, the measure process can be recalled by using the manual mode. By rechecking the measure process and then resetting the red lines on the screen, observers may have accurate BP readings ultimately (Fig. 2B).

The sensitivity of the microphone can largely affect the accuracy. Therefore, we have designed a high-sensitivity microphone here.

2.4. BP measurement

2.4.1. Subject preparation. Comfortably seated with legs uncrossed and feet flat on the floor. Has the back, elbow, and forearm supported. Has the middle of the cuff at the level of the right atrium of the heart.

2.4.2. Observer preparation. Observers had been trained in using a proper methodology for performing a resting BP determination by utilizing an accepted protocol for BP measurement.[12]

2.4.3. Reference determination. Two observers and Accutension shared 1 stethoscope head by 2 Y-tube connectors (Fig. 1C). Measurements were acquired simultaneously and three BP readings were yielded. If either observer detected significantly irregular heart rhythm, that determination would be excluded.

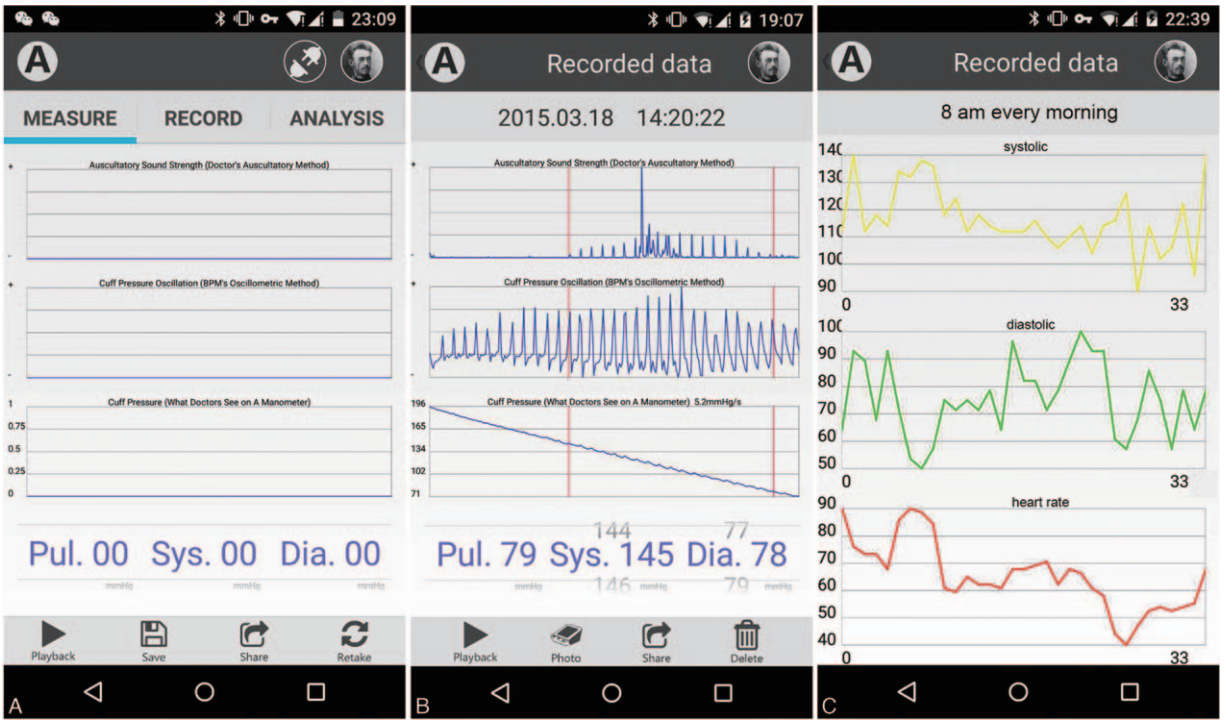

Figure 2. (A) Main interface of App software run on a smartphone. (B) BP measure process. Recorded Korotkoff sounds are displayed in the first row of (B), and the positions of red lines represent the systolic and diastolic BP value, respectively. The Korotkoff sounds could be played back on the phone and the red lines could be reset accordingly. Pulse rate, systolic, and diastolic BP value were listed in the bottom. (C) Three curves which represent fluctuation tendency of BP values and heart rates (yellow line for systolic, green line for diastolic, red line for heart rate) 8 AM every morning for 33 days.

Observer measurements should be recorded simultaneously by the observers on separate sheets. Any pair of observers' determinations with a difference greater than 4 mm Hg (0.53 kPa) should be excluded as recommended by AAMI procedure. And the measurements should be taken again.

2.4.4. Measurement. The maximum inflation pressure was determined as 30 mm Hg above the point when pulse disappeared. And then the cuff was deflated at a constant rate of 2 to 3 mm per second.[17] The appropriate BP cuff size (small adult, adult, large adult, extra-large adult) was selected according to the mid-arm circumference of the participant. Three qualified systolic and diastolic measurements were expected to be obtained. The observers were demanded to simultaneously determine the subject's BP in 1 inflation/deflation cycle. The determinations were repeated at 60-second intervals until the required number of valid determinations had been obtained.

Six observers were involved in the study. Three criteria were used to assess the observer effect on the BP readings of the devices: individual observer's mean difference of the between-device readings, end-digit preference, and mean deflation rate.

Mid-arm circumference was determined by making a horizontal mark at the midpoint at the posterior aspect of the arm and measured the arm circumference.

2.5. Statistical analyses

The between-device differences for systolic BP and diastolic BP were assessed separately. Differences were calculated as Accutension − mercury. The correlation of BP readings between the 2 devices was assessed using the Pearson correlation coefficient. The agreement of BP readings between the 2 devices was assessed using intraclass correlation (ICC). A Bland–Altman graph was also created to assess the agreement between the 2 devices, which displayed the differences of between-device readings (Accutension − mercury) compared with the corresponding averages [(Accutension + mercury/2)]. χ^2 test was used to test if the diagnosis rate of hypertension was equal between the 2 devices. The α-level for a significant test was considered to be $P < 0.05$. All statistical analyses were performed using the software product IBM SPSS22.0 for Windows.

3. Results

3.1. Performance of Accutension

The study was performed from January 23, 2015 to March 18, 2015. Measurement of BP was performed by Accutension successfully. Eighty-two valid systolic and diastolic blood pressure (DBP) values were obtained. There were no adverse events during the study. There were no indeterminate results and outliers of the index tests.

3.2. Measured BP values

The mean values (SD) for systolic and diastolic BP readings of Accutension were 120.45 (17.65) and 77.90 (10.93) mm Hg. The mean values (SD) for systolic and diastolic BP readings of observer measurements were 119.58 (16.60) and 78.84 (10.27) mm Hg. The mean (SD) differences for systolic and diastolic BP readings between Accutension and observers were 0.87 (2.86) (range from −4 to 10) and −0.94 (2.93) (range from −9 to 4) mm

Table 3

Subject details.

Sex			
Male/female	16:16		
Age, y			
Range (low/high)	24:83		
Mean (SD)	36.72 (13.08)		
Arm circumference, cm			
Range (low/high)	20:38		
Mean (SD)	30.06 (4.53)		
Cuff for test device			
Small adult	3		17–21 cm
Adult	21		22–31 cm
Large adult	8		32–41 cm
Extra large	0		42–50 cm
		SBP	DBP
Automatic measurements (mm Hg)			
Range (low/high)		85:175	56:110
Mean (SD)		120.45 (17.65)	77.90 (10.93)
Observer measurements (mm Hg)			
Range (low/high)		84:168	64:109
Mean (SD)		119.58 (16.60)	78.84 (10.27)
Between-observer differences (Observer 2 – Observer 1)			
Range (low/high)		−4:4	−4:4
Mean (SD)		0.29 (2.37)	0.10 (2.34)
Absolute mean (SD)		1.93 (1.39)	1.90 (1.37)

DBP = diastolic blood pressure, SBP = systolic blood pressure, SD = standard deviation.

Hg (Table 3). As recommended by AAMI, the mean difference between the *reference sphygmomanometer (mercury sphygmomanometer here)* and the *sphygmomanometer-under-test (Accutension here)* should <5 mm Hg with SD <8 mm Hg. Although it was not a validation trial here, the statistic results clearly fulfilled the criteria.

3.3. Comparisons of measured BP values (Accutension – mercury)

Figure 3A is a bar graph that showed the percent distribution of the absolute differences between the 2 device measurements within 0 to 2, 3 to 5, 6 to 10 mm Hg categories (There was no difference >10 mm Hg.) Absolute agreement within 5 mm Hg was considered the acceptable threshold for between-device agreement.[15] In our study, 92.68% of systolic BP readings and 96.34% of diastolic BP readings had between-device difference <5 mm Hg. As recommended by ESH, at least 66% of subjects should have difference (*mercury sphygmomanometer between Accutension here*) <5 mm Hg, 82% of subjects have difference <10 mm Hg and 94% of subjects have difference <15 mm Hg. Although it was not a validation trial here, the statistic results obviously fulfilled the criteria. Actually, 59.75% of systolic readings and 69.51% of diastolic readings had difference <2 mm Hg here.

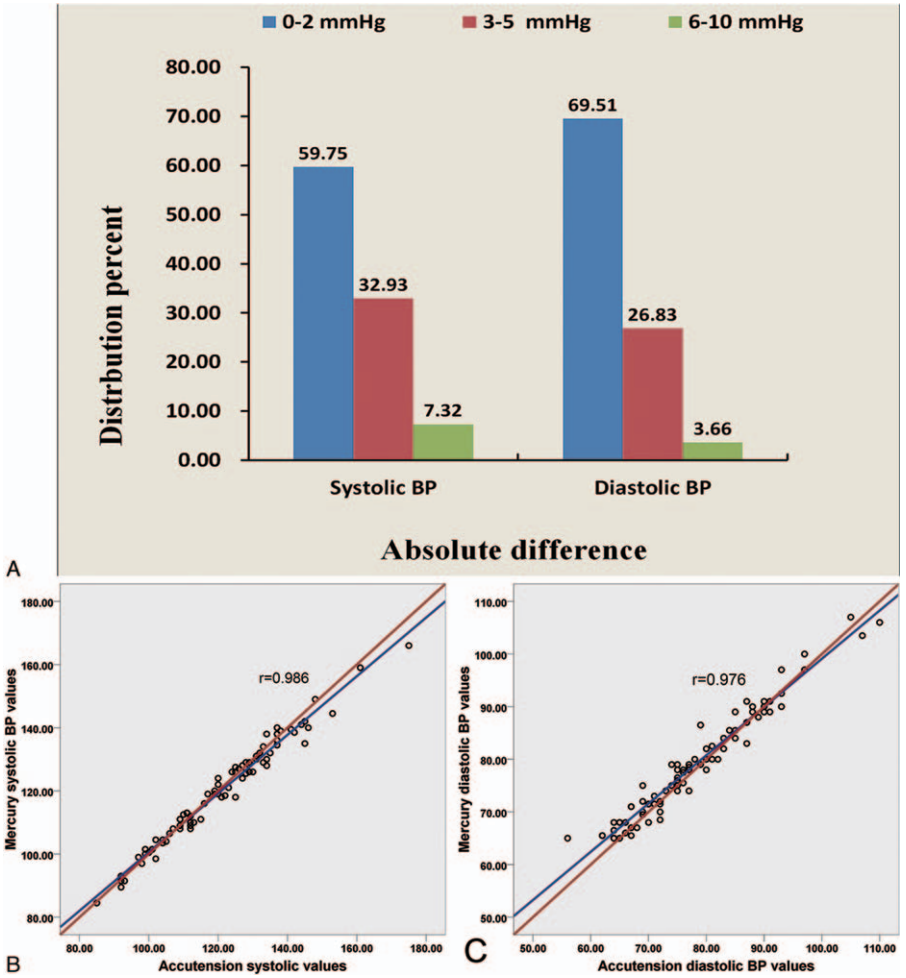

Figure 3. (A) A bar graph shows the percent distribution of the absolute differences between the 2 device measurements within 0 to 2, 3 to 5, 6 to 10 mm Hg categories. (B and C) The correlations of mercury and Accutension BP readings (systolic and diastolic) are shown. Red lines is the reference line ($y = x$).

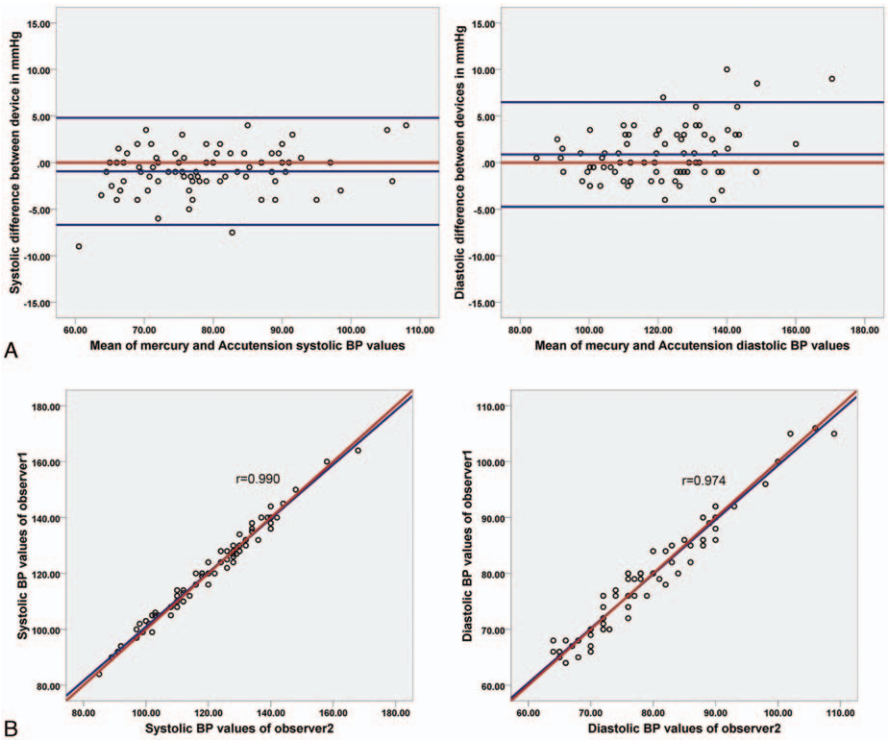

Figure 4. (A) The mean-difference Bland–Altman plots were used here to show the agreement of the between-device differences with the BP levels. The mean of device pressure and its corresponding observer pressure was plotted against their difference with a point. The *y*-axes represented errors from −15 to +15 mm Hg. The *x*-axis of these plots represented BPs in the systolic ranging from 80 to 180 mm Hg and the diastolic ranging from 60 to 110 mm Hg. Horizontal reference line was drawn at 0 mm Hg (red). The mean difference (SD) of systolic was 0.87 (2.86) (95% reference range: −4.74 to 6.48) and diastolic was −0.94 (2.93) (95% reference range: −6.68 to 4.80). The corresponding lines of above values were both drawn from the *y*-axes. (B) The correlations of between-observers BP readings (systolic and diastolic) are shown. Red lines is the reference line ($y=x$).

The correlations of mercury and Accutension BP readings were tested for systolic and diastolic separately. They were significantly correlated ($r=0.986$ for systolic, $r=0.976$ for diastolic) ($P<0.05$) (Fig. 3B and C).

Agreements between the mercury and Accutension BP measurement were highly significant (ICC > 0.9) for systolic (ICC = 0.993, 95% confidence interval (CI): 0.989–0.995) and diastolic (ICC = 0.987, 95% CI: 0.979–0.991).

Figures 4A shows the relationship of the between-device differences with the BP levels. The mean-difference Bland–Altman plots were used here. In general, Accutension red a little higher than mercury for systolic BP, while a little lower for diastolic BP. It showed a good agreement between mercury and Accutension measurements. Some extreme values beyond 1.96 SDs were seen in both figures. The percent of values outside the boundaries were 2.4% and 4.8% for systolic and diastolic, respectively.

As to the cuff size selection, nobody was given an extra-large adult cuff size. Eight subjects were given a large adult cuff size. Twenty-one subjects were given an adult cuff size. Three subjects were given a small adult cuff size (Table 3). The mean deflation rate was 3.67 mm Hg/s (from 2.20 to 5.86 mm Hg/s).

3.4. Comparisons of measured BP values (between-observers)

The correlations of between-observers BP readings were tested for systolic and diastolic separately. They were significantly correlated ($r=0.990$ for systolic, $r=0.974$ for diastolic) (Fig. 4B).

Agreements between observers assessing BP measurement using 1 stethoscope head were highly significant for systolic (ICC = 0.990, 95% CI: 0.984–0.993) and diastolic (ICC = 0.974, 95% CI: 0.960–0.983).

The absolute mean deviation (SD) for systolic and diastolic BP readings of observer measurements were 1.93 (1.39) and 1.90 (1.37) (Table 3). It could be seen that both the means and absolute means between observers for systolic and diastolic were <2 mm Hg. 79.27% of between-observer differences were within 3 mm Hg for systolic, and 67.07% were within 3 mm Hg for diastolic (differences were in absolute values). For the BP determinations of Accutension, all of the end-digits were at or about 20% preferences, while for the mercury BP determinations there was a bit end-digit preference for zero (24%).

3.5. Comparisons of the high BP recognition agreement between devices

Table 4 shows the between-device agreement for the recognition of high BP (≥140/90 mm Hg). Mercury BP determination was assumed as the gold standard for the specificity and sensitivity analyses. χ^2 test showed that the diagnosis rates of hypertension had no significant difference between the 2 devices. Accutension correctly identified 88.89% of hypertensive individuals and 97.26% of normotensive individuals. The kappa value was 0.821.

4. Discussion

The present study was designed primarily to introduce a novel electronic auscultatory sphygmomanometer and preliminarily

Table 4

Recognition of high blood pressure in persons aged 18 and over, by mercury and Accutension.

Device and agreement*		High blood pressure	
		Mercury	
		Yes	No
Accutension	Yes	8	2
	No	1	71
	Percent of hypertensive		
Accutension	12.20%		
Mercury	10.98%		
	Agreement statistics		
Sensitivity	88.89		
Specificity	97.26		
Kappa	0.821		

Note: High blood pressure is systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg. Mercury is the mercury sphygmomanometer device.

* Mercury blood pressure readings are gold standard.

verify its accuracy. Until the beginning of this work, no similar product was available. It found here that auscultatory electronic sphygmomanometer (Accutension) accomplished the measurement and showed a good accuracy. Clinical trials for the validation of the mature products would be carried out in the near future.

This study found that the agreement between Accutension and mercury was very good. If the sample size had been enough, Accutension would meet the AAMI validation criteria, which demands the mean value (SD) of the differences between the reference sphygmomanometer and sphygmomanometer-under-test should be within or equal to ±5.0 mm Hg (SD ≤ 8.0 mm Hg).

Pearson correlation, ICC, and Bland–Altman plots were used to test the agreement of between-devices here. Theoretically, Pearson correlation could not be used to verify the consistency. It only showed the correlation of the 2 devices. So ICC and Bland–Altman plots were combined with Pearson correlation to afford extra evidences of the consistency.

In current test, simultaneous measurements became possible as we used 2 Y-type joints to connect the 2 observers and Accutension, which was the recommendation of AAMI standard. Simultaneous measurements could avoid errors between the measurements, reduce the number of measurements and finally lead to good consistency. Pruijm et al[18] has proved that the modified simultaneous test following ESH validation protocols was not only time-saving but also validated.

Comparisons of measured BP values (Accutension – mercury) in the present study show a good performance for both systolic and diastolic BP, which is better than most of the oscillometric automated BPM. One of the previous validation study comparing Omron HEM-7252G-HP (one of the newly and popular oscillometric automated BPM) with mercury, the results showed that the overall difference between the 2 devices was −1.5 mm Hg (SD = 5.1) for systolic and −1.2 mm Hg (SD = 3.9) for diastolic.[19] Why Accutension could be more accurate than oscillometric sphygmomanometer? It might owe to 3 main reasons. Firstly, as mentioned above, it employs direct measurements rather than statistical algorithms. In one of our simultaneous BP measurements for Omron, Accutension, and mercury sphygmomanometer, we found accidently that when the Omron finished the measurement, the Korotkoff sounds could still be heard. It finally caused a 20 mm Hg difference of diastolic BP between Omron and Accutension. The simultaneous manual reading was consistent with Accutension, indicating that the oscillometric sphygmomanometer adopting statistical algorithm based on a large sample might cause significant errors for certain individuals.

Secondly, obvious arrhythmias such as atrial fibrillation (AF) could affect the outcome of the oscilloscope sphygmomanometer. ESH 2003 recommended using auscultatory method for BP measurement when the subject had AF.[20] In one of the patients excluded for the reason of AF, it was found that arrhythmia did not affect the accuracy of Accutension. It might contribute to the auscultatory method employed by Accutension. Although arrhythmia could disrupt the algorithm and then affect the accuracy of oscillometric, it has no impact on Accutension.

Thirdly, as mentioned before, the maximal-amplitude algorithm of oscillometric BPM increasingly overestimated the mean arterial pressure when arterial stiffness increased. Thus, the technique would be less accurate when the arteries are less compliant especially in the elderly and hypertension subjects. However, arteriosclerosis would lead to Korotkoff sounds to be clearer in some degree, so the accuracy of Accutension might become higher instead.

What's more, in terms of sound recording and processing, Accutension was different from traditional automatic BPMs based on Korotkoff sounds. When automatic BPMs based on Korotkoff sounds determined BPs, the Korotkoff sounds were mostly not recorded. So the Korotkoff sounds after measurement were not available for a real person to auscultate and confirm. Different manufacturers might use their own criteria to judge the Korotkoff sounds. For example, the Korotkoff sounds could be analyzed only for certain frequency. Accutension was very different from these automatic Korotkoff sounds based BPMs. Firstly, it was designed to record the sounds with high fidelity and when it was played back the sounds were very close to the original sounds heard directly from the stethoscope. This could make sure the BP could be determined by listening to the playback of the sounds even without the aid of sound visualization. Secondly, the sound visualization showed the strength of the sounds, which had not been used in the automatic BPMs based on Korotkoff sounds. The sound visualization and BP marking lines could help identify the start and end of the Korotkoff sounds more accurately. (Operation video is available at the following URL: https://youtu.be/4x-FGf-b_iY.).

In this study, the smartphone used was Google Nexus and the operating system was Android 6.0. In future trials, iPhone6 or later versions with iOS (iPhone operating system) will be used. Their high-fidelity sound sampling function would contribute to more perfect auscultation. With the powerful sound sampling functions of iPhone, Accutension would stand "on the shoulders of giants" to perform much better than traditional electric auscultatory sphygmomanometer.

At the same time, as for the reasons listed in Table 1, Accutension might be more accurate than manual auscultation. It captures sounds more sensitive without sounds missing and records them objectively without instant forgetting encountered in manual measurements. Theoretically, the systolic BP would be underestimated when the first Korotkoff sound is missed, and the diastolic BP would be overestimated when the last Korotkoff sound is missed. Comparing with Accutension, the manual mercury sphygmomanometer in the present study underestimated systolic BP and overestimated diastolic BP. The results were consistent with the theoretical anticipation. One possible reason is that Accutension captured the first and the last korotkoff sound more sensitively than human ear during the measurement and avoided sound missing. It is justified that

Accutension might be more accuracy than the traditional mercury sphygmomanometer.

The consistency of between-observers was also good in this study. The BP observers were continuously monitored for between-observers agreement within 4 mm Hg, and they repeated measures when a difference was greater than 4 mm Hg. As for mercury BP values, the determinations had the largest end-digit preference for zero (24%). Mean deflation rate was 3.67 mm Hg/s and the highest rate was 5.86 mm Hg/s, while the AAMI required the continuous linear deflation rate should be between 2 and 3 mm Hg/s or between 2 and 3 mm Hg/pulse. Deflation control should be improved if a formal clinical trial begins. Owing to the real-time deflation rate displaying by the Accutension, further training of manual measurement could meet the above requirement. The cuff sizes were selected according to predetermined arm circumference values.

Our kappa statistic value for hypertension recognition in the present study was 0.821. One reason for the low sensitivity here was that less hypertension subjects were recruited. However, it was higher than the kappa value obtained in the previous oscillometric study, which was 0.72.[1] However, due to the high specificity, individuals who were measured with normal BP values by Accutension were more likely to be normal when measured by mercury.

There remain things to be improved in the later versions of Accutension. Two subjects were excluded for failing to obtain valid data, and this was caused by failing to obtain valid korotkoff sounds, which was witnessed by playing back the sounds recorded. The main factors influencing Accutension measure process are consist of noise disturbance, failing to put the stethoscope head in proper position of the brachial artery, weaker auscultation sounds, bigger arm circumference, and so on. More improvements should be made in the following aspects: being automatic, increasing the sensitivity of stethoscope head, analyzing sound more precisely, enhancing sound insulation and minimizing the size of the transmission pipes.

The mean between-device differences grouped by age, gender, race and ethnicity, BMI, cuff size, and irregular heart rate were failed to be test owing to the small sample size. It is suggested that those subgroup analyzes would be accomplished in the coming large-scale clinical trials.

There are some other limitations in the present study. First, people included were young and mostly not hypertensive. Therefore, the generalizability of these results in older populations with stiffer arteries and in hypertensive patients was limited. Also, since Accutension has been designed for home BP recording, a comparison with one of the validated ambulatory BP monitors would be more relevant.

However, Accutension could contribute more to the mobile heath service. For example, the BP data of the patients could be uploaded to the iCloud storage. By documenting and analyzing the variation of BP values, Accutension helps management of hypertension.

5. Conclusion

Accutension worked accurately based on our pilot study data. The difference was acceptable. Pearson correlation coefficient, intraclass correlation (ICC), and Bland–Altman plot graphs showed good agreements with manual mercury measurements. Systolic readings of Accutension were slightly higher than those of manual measurement, while diastolic readings were slightly lower. One possible reason is that Accutension captures the first and the last korotkoff sound more sensitively than human ear during the manual measurement and avoids sound missing, so that it might be more accuracy than traditional mercury sphygmomanometer. By documenting and analyzing variation of BP values, Accutension helps management of hypertension and therefore contributes to the mobile heath service. One of the most innovations of this product is making the process of auscultatory BP measurement recordable and reliable. With further developments in technologies, Accutension will inevitably bring about a breakthrough in the BP measurement.

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