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Validation of four automatic devices for self-measurement of blood pressure according to the International Protocol: The Pic Indolor Personal Check, Comfort Check, My Check and Travel Check

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Abstract

Objective. Four oscillometric devices for self-measurement of blood pressure (SBPM) were evaluated according to the International Protocol of the European Society of Hypertension (ESH) in four separate studies. The Pic Indolor Personal Check, Comfort Check and My Check measure blood pressure (BP) at the brachial level; the Travel Check measures radial BP at the wrist level. *Methods.* The International Protocol includes a total number of 33 subjects. In each study and for each subject, four BP measurements were performed simultaneously by two observers using mercury sphygmomanometers alternately with three measurements by the tested device. The difference between the observers and the device BP values (99 pairs) were classified into three categories ($\leq$5, $\leq$10, $\leq$15 mmHg). *Results.* All four tested devices passed the validation process. The mean differences between the device and mercury readings were 0.1 ± 2.9 and -0.1 ± 3.8 mmHg for systolic and diastolic BP respectively for the Personal Check; -1.0 ± 3.7 and 0.2 ± 3.2 mmHg for the Comfort Check; -0.6 ± 4.5 and -1.5 ± 4.3 mmHg for the My Check; -0.1 ± 2.0 and 0.6 ± 1.7 mmHg for the Travel Check. *Conclusion*. Readings of the Pic Indolor Personal Check, Comfort Check, My Check and Travel Check devices differing by less than 5, 10 and 15 mmHg fulfill the International Protocol requirements and therefore can be used by patients for SBPM.

Key Words: *Comfort Check, European Society of Hypertension, home blood pressure, International Protocol, My Check, Personal Check, Pic Indolor, Travel Check, validation*

Introduction

Advantages of blood pressure (BP) self-measurement have been well documented (1,2). Indeed, self-BP measurement (SBPM) not only provides valuable information for hypertension diagnosis but also on BP control of the treated patient, and it improves patient's compliance with antihypertensive therapy (1–3). Therefore, it is appropriate to encourage the widespread use of SBPM as an important adjunct to the clinical care of patients with hypertension (2). Clinical indications of the SBPM have been recently highlighted in several guidelines and consensus conferences (1–6). Obviously, SBPM is only practicably useful if the devices are user-friendly and accurate. Recommended devices for SBPM should have been submitted to independent validation procedures. Currently, only few of available devices on the market have been validated and are recommended for the patient use (7). Validation has to be performed according to recognized protocols specifically designed for this purpose, such as the British Hypertension Society (BHS) protocol (8), the Association for the Advancement of Medical Instrumentation (AAMI) protocol (9) and the International Protocol (10) published by the European Society of Hypertension (ESH). In this study, four devices for SBPM were validated according to the international protocol in four separate studies.

Methods

Devices

Pic Indolor Personal Check: The Pic Indolor Personal Check device records brachial BP using the

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oscillometric method with a pressure range of 30–260 mmHg and pulse rate range of 40–199 beats/min. Systolic BP (SBP), diastolic BP (DBP) and pulse rate are displayed on a liquid crystal digital (LCD) display. It includes 60 memories for each zone, two zones. Deflation is automatic by a constant air release solenoid valve. The unit weighs approximately 360 g without batteries. Three sizes of cuffs, small, standard and large are available. The small cuff is adapted to arm circumference less than 24 cm, the cone cuff to arm circumference of 24–36 cm and the large cone cuff to arm circumference >36 cm.

Pic Indolor Comfort Check: The Pic Indolor Comfort Check device records brachial BP using the oscillometric method with a pressure range of 30–260 mmHg and pulse rate range of 40–199 beats/min. It includes 60 memories for each zone, two zones. The inflation is performed using electric pumping system and the deflation by an automatic pressure release valve. At the end of each measurement, SBP, DBP and pulse rate are displayed on a LCD screen. The unit weighs approximately 360 g without batteries. This device uses a pre-formed cuff designed to improve the patient comfort and to enlarge the possible range of usage, from 22 cm to 46 cm of arm circumference. The cuff is easier to be wrapped around the arm because of a special performed shape.

Pic Indolor My Check: The Pic Indolor My Check device records brachial BP using the oscillometric method with a pressure range of 30–260 mmHg and pulse rate range of 40–199 beats/min. It includes memory for 120 measurements. The inflation is performed using electric pumping system and the deflation by an automatic pressure release valve. At the end of each measurement, SBP, DBP and pulse rate are displayed on a LCD screen. The unit weighs approximately 340 g without batteries. This device uses a cone cuff, adult type, designed for an arm circumference ranging from 24 to 36 cm. The cuff is easy to be wrapped around the arm because of a special cone form.

Pic Indolor Travel Check: The Pic Indolor Travel Check device is an automatic oscillometric device for SBPM, measuring radial BP at the wrist level. The inflation is performed using electric pumping system and the deflation by an automatic pressure release valve. This device can be used for wrist circumferences ranging from 13.5 to 22 cm, it measures BP range from 30–260 mmHg and pulse rate from 40–199 beats/min; at the end of each measurement, SBP, DBP and pulse rate are displayed on a LCD screen. It includes 60 memories for each zone, two zones. The unit weighs approximately 145 g without batteries.

Blood pressure measurements: For each study, manufacturer was asked to provide two or three complete devices, declared by the manufacturer as standard production models. Before the validation study *per se*, a familiarization period of about 2 weeks took place in an outpatient clinic. During this period, the investigators familiarize themselves with the use of the tested device.

The validation team of each study consisted of three persons experienced in BP measurement. Investigators followed training on the basis of a CD-ROM specifically developed by the French Society of Hypertension for the certification of observers involved in clinical studies. Two of the

Table I. Results of the Pic Indolor Personal Check device.

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	37	45	45	Continue		
	DBP	33	42	45	Continue		
Phase 2.1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.	Mean diff.	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	91	99	99	Pass	0.1	2.9
	DBP	87	96	99	Pass	−0.1	3.8
Phase 2.2		2/3≤5 mmHg	0/3≤5 mmHg		Recomm.		
Required		≥22	≤3				
Achieved	SBP	32	0		Pass		
	DBP	29	2		Pass		

Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

three observers have simultaneously measured BP using a teaching stethoscope for simultaneous measurements (Y tube) and two standard mercury sphygmomanometers, the components of which have been carefully checked before the study; the third observer was the supervisor that checked the agreement of BP values obtained by the two observers who were blinded from each other's readings. All BP measurements of the four validation studies were performed by the team 1 (under the supervision of G. Germano) and data analysis was performed by team 2 (R. Asmar).

Population

According to the International Protocol, in phase 1, a total of 15 treated or untreated participants are included who fulfill the age, gender and entry BP range requirements (age ≥30 years, at least five men and five women, five participants with entry BP within each of the ranges 90–129, 130–160 and 161–180 mmHg for SBP and 40–79, 80–100 and 101–130 mmHg for DBP. Arm circumference is distributed by chance. If analysis of these data is successful, additional participants are recruited until a total of 33 participants fulfill the age, gender and entry BP requirements for phase 2 (age ≥30≥years, at least 10 men and 10 women, 11 participants with entry BP within each of the BP ranges for SBP and DBP). In order to optimize recruitment, it is recommended that subjects for the high diastolic and low systolic groups should be recruited first, then those with high systolic and low diastolic, finally the remaining gaps should be field.

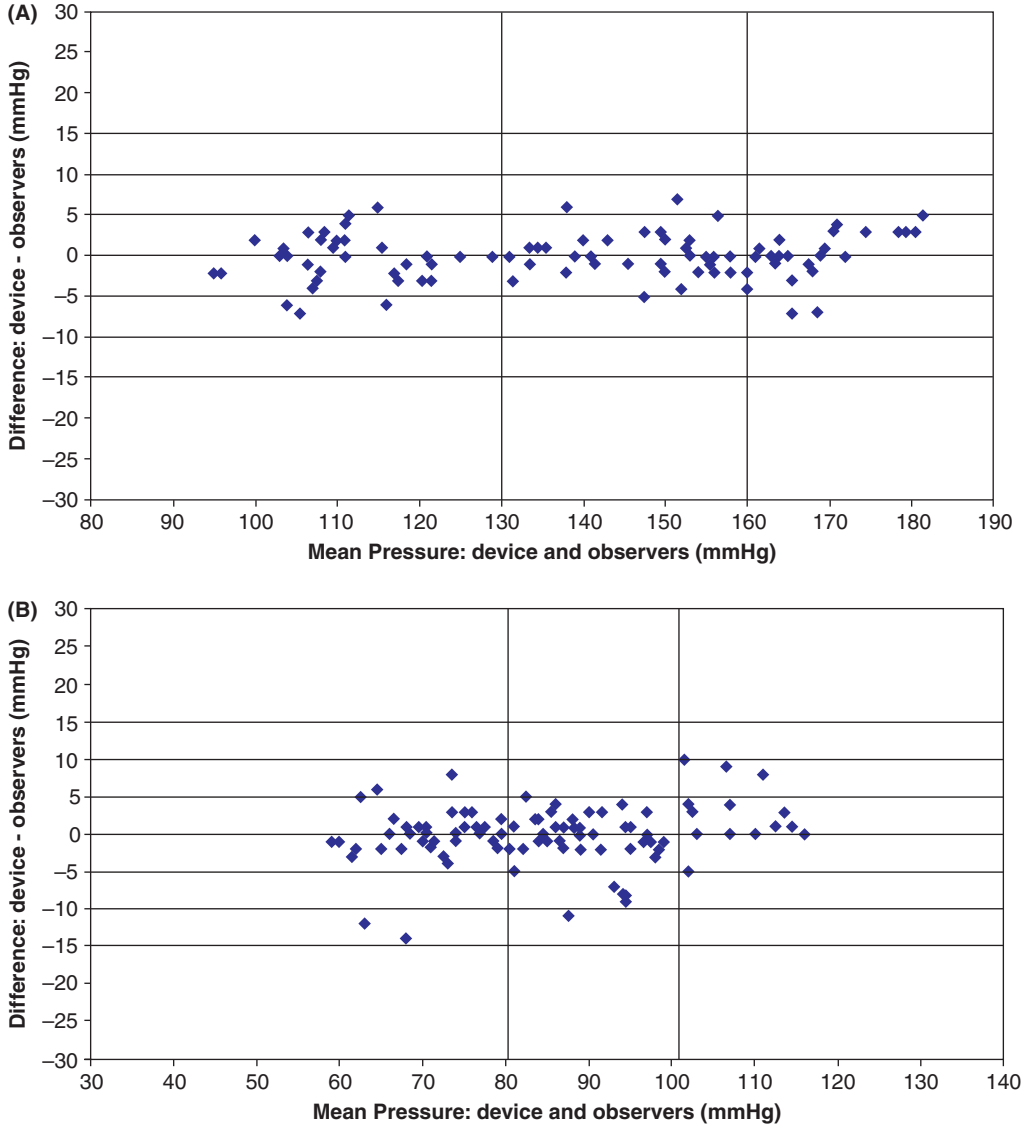

Figure 1. Plots of BP difference between the Pic Indolor Personal Check readings and the mean of the two observer readings in 33 participants (n=99). Systolic (A) and diastolic (B).

Table II. Results of the Pic Indolor Comfort Check device.

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	33	44	44	Continue		
	DBP	37	44	45	Continue		
Phase 2.1		**≤5 mmHg**	**≤10 mmHg**	**≤15 mmHg**	**Recomm.**	**Mean diff.**	**SD**
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	87	98	98	Pass	−1.0	3.7
	DBP	91	98	99	Pass	0.2	3.2
Phase 2.2		**2/3≤5mmHg**	**0/3≤5 mmHg**		**Recomm.**		
Required		≥22	≤3				
Achieved	SBP	31	0		Pass		
	DBP	31	0		Pass		

Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

Procedure

Subjects were seated in a quiet room and BP measurements started after a 10-min rest period. Arm circumference was measured and cuff size was adapted. All measurements were made on the left arm at the heart level. BP was measured simultaneously by the two observers alternately with the automatic device as mentioned above. Measurements were carried out in the following sequence:

- *BPA* – Entry BP, observers 1 and 2, the mean values of the two observers were used to categorize the subject into the low, medium or high range separately for SBP and DBP as described above.
- *BPB* – Device detection BP, observer 3. This BP was performed to allow the tested device to determine the BP characteristics of the subject and was not included in the analysis.
- *BP1* – Observers 1 and 2 with the mercury standard.
- *BP2* – Supervisor with the tested device.
- *BP3* – Observers 1 and 2 with the mercury standard.
- *BP4* – Supervisor with the tested device.
- *BP5* – Observers 1 and 2 with the mercury standard.
- *BP6* – Supervisor with the tested device.
- *BP7* – Observers 1 and 2 with the mercury standard.

Analysis

Differences between tested device and control measurements were classified according to whether they lay within 5, 10 or 15 mmHg. Differences are always calculated by subtracting the observer measurement from the device measurement. Differences were classified separately in this way for both SBP and DBP. For the accuracy assessment, only measurements BP1 to BP7 were used. The mean of each pair of observer measurements was calculated; this was denoted as observer measurement BP1, BP3, BP5 or BP7. Each device measurement was flanked by two of these observer measurements, and one of these was selected as the comparative measurement. Details of the analysis procedure have been previously published elsewhere (10).

The number of differences in each zone was calculated and compared with the number required by the International Protocol and a continue/fail grade for first phase and pass/fail grade for second phase (phase 2.1) was determined. Also, for the second phase, the number of measurements falling within 5 mmHg was determined for each of the 33 subjects and a pass/fail recommendation was determined according to the protocol (phase 2.2). To pass the validation, a device must pass both phase 2.1 and phase 2.2.

Results

Pic Indolor Personal Check

This study included 33 subjects (14 men and 19 women) with a mean age of 49 ± 13 years, their mean arm circumference was 28 ± 3 cm (range: 24–36 cm). Standard size cuff was used in 30 subjects and large cuff in three subjects. The difference between the two observers was 1.0 ± 1.8 and 0.6 ± 1.9 mmHg for SBP and DBP, respectively. The mean values of SBP and DBP were respectively 145 ± 24/92 ± 15 mmHg. The mean differences between the observers and the tested device were 0.1 ± 2.9 and −0.1 ± 3.8 mmHg for SBP and DBP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table I. The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are displayed in Figure 1. These results are in agreement with the International Protocol requirements for the primary and secondary phases. Thus the Pic Indolor Personal Check device fulfills the validation criteria of the International Protocol.

Pic Indolor Comfort Check

This study included 33 subjects (18 men and 15 women) with a mean age of 56 ± 17 years, their mean arm circumference was 28 ± 2 cm (range: 23–33 cm). Standard size cuff was used in 32 subjects and large cuff in one subject. The difference between the two observers was −0.4 ± 2.2 mmHg and 0.2 ± 2.0 mmHg for SBP and DBP, respectively. The mean values of SBP and DBP were respectively 145 ± 24/91 ± 13 mmHg. The mean differences between the observers and the tested device were −1.0 ± 3.7 and 0.2 ± 3.2 mmHg for SBP and DBP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table II. The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are displayed in Figure 2. These results are in concordance with the International Protocol requirements for the primary and secondary phases. Thus the Pic Indolor Comfort Check device fulfills the validation criteria of the International Protocol.

The Pic Indolor My Check

This study included 33 subjects (16 men and 17 women) with a mean age of 55 ± 17 years, their mean arm circumference was 29 ± 3 cm (range: 23–36 cm).

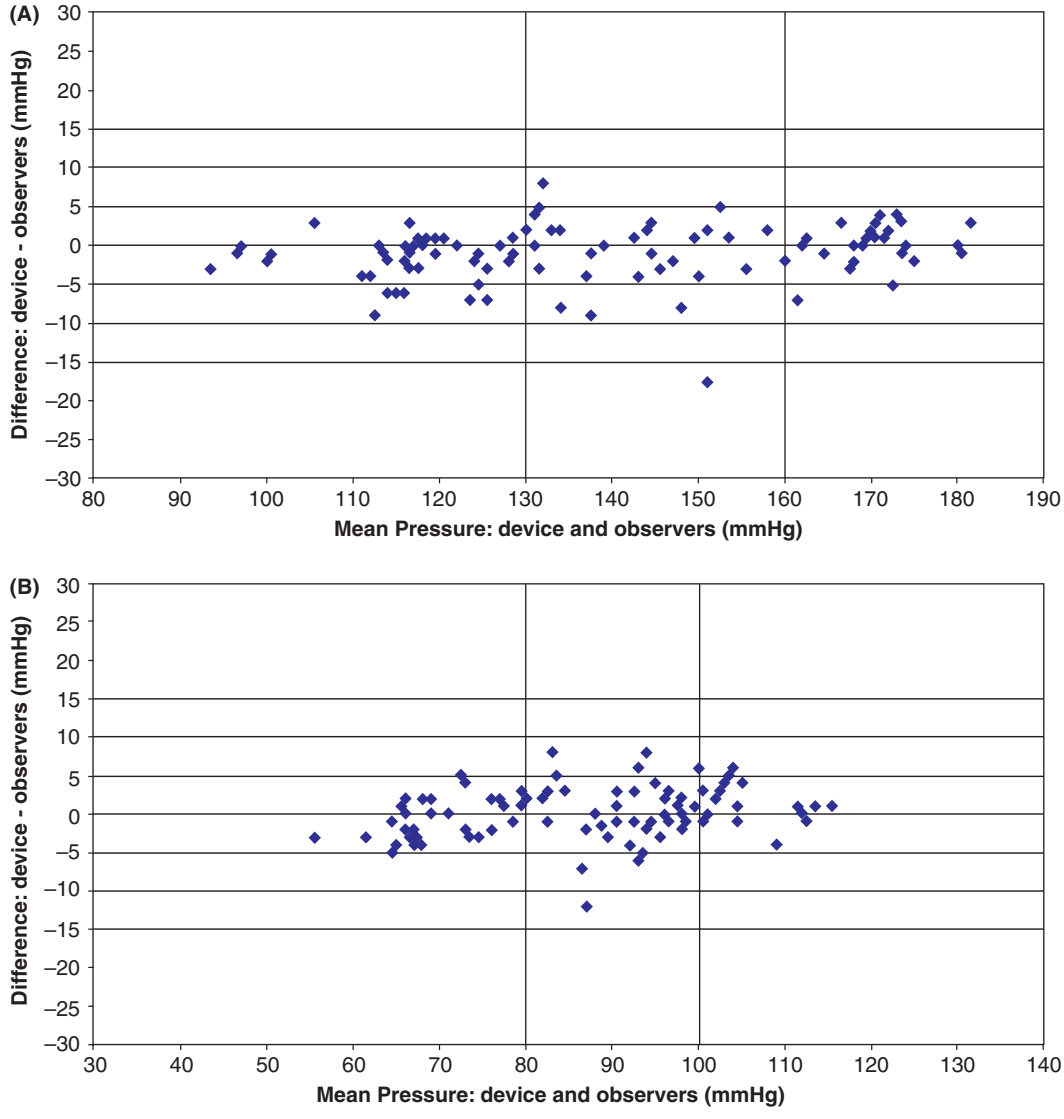

Figure 2. Plots of BP difference between the Pic Indolor Comfort Check readings and the mean of the two observer readings in 33 participants (n=99). Systolic (A) and diastolic (B).

Table III. Results of the Pic Indolor My Check device.

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	32	42	43	Continue		
	DBP	26	40	45	Continue		
Phase 2.1		**≤5 mmHg**	**≤10 mmHg**	**≤15 mmHg**	**Recomm.**	**Mean diff.**	**SD**
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	86	96	97	Pass	−0.6	4.5
	DBP	80	94	99	Pass	−1.5	4.3
Phase 2.2		**2/3≤5 mmHg**	**0/3≤5 mmHg**		**Recomm.**		
Required		≥22	≤3				
Achieved	SBP	31	0		Pass		
	DBP	28	2		Pass		

Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

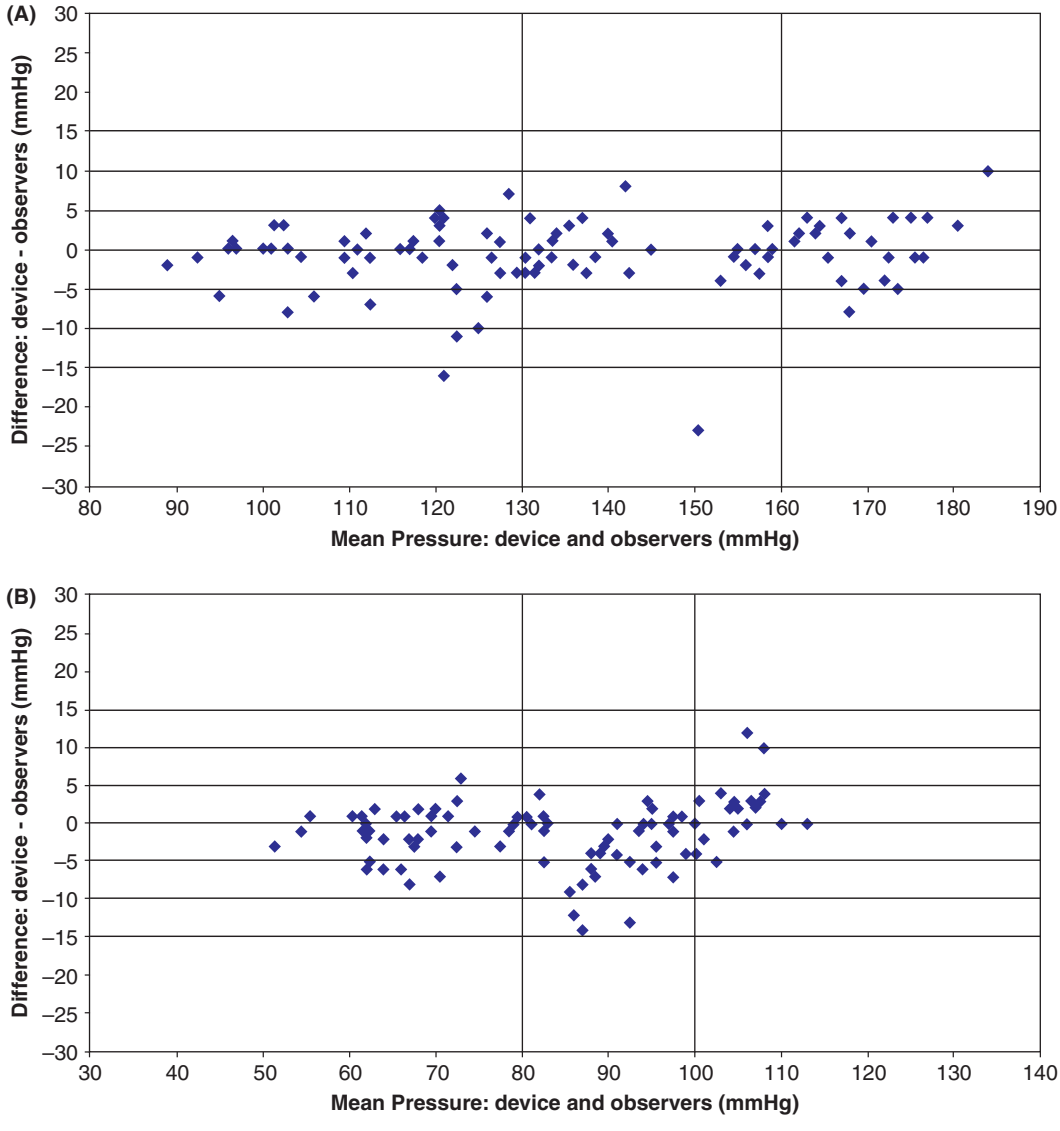

Figure 3. Plots of BP difference between the Pic Indolor My Check readings and the mean of the two observer readings in 33 participants (n=99). Systolic (A) and diastolic (B).

Table IV. Results of the Pic Indolor Travel Check device.

Phase 1		≤5 mmHg	≤10 mmHg	≤15 mmHg	Recomm.		
Required	One of	25	35	40			
Achieved	SBP	43	45	45	Continue		
	DBP	45	45	45	Continue		
Phase 2.1		**≤5 mmHg**	**≤10 mmHg**	**≤15 mmHg**	**Recomm.**	**Mean diff.**	**SD**
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	97	99	99	Pass	−0.1	2.0
	DBP	99	99	99	Pass	0.6	1.7
Phase 2.2		**2/3≤5mmHg**	**0/3≤5 mmHg**		**Recomm.**		
Required		≥22	≤3				
Achieved	SBP	32	0		Pass		
	DBP	33	0		Pass		

Recomm., recommendation; Mean diff., mean difference (mmHg); SD, standard deviation (mmHg); SBP, systolic blood pressure; DBP, diastolic blood pressure.

Standard size cuff was used in 30 subjects and large cuff in three subjects. The difference between the two observers was 0.3±2.2 mmHg and 0.7±1.9 mmHg for SBP and DBP, respectively. The mean values of SBP and DBP were respectively 142±25/89±15 mmHg. The mean differences between the observers and the tested device were −0.6±4.5 and −1.5±4.3 mmHg for SBP and DBP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table III. The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are displayed in Figure 3. These results are in concordance with the International Protocol requirements for the primary and secondary phases. Thus the Pic Indolor My Check device fulfills the validation criteria of the International Protocol.

The Pic Indolor Travel Check

This study included 33 subjects (17 men and 16 women) with a mean age of 54±14 years, their mean wrist circumference was 18±2 cm (range: 15–22 cm). The difference between the two observers was 0.5±1.6 and 0.3±1.8 mmHg for SBP and DBP, respectively. The mean values of SBP and DBP were respectively 146±24/91±14 mmHg. The mean differences between the observers and the tested device were −0.1±2.0 and 0.6±1.7 mmHg for SBP and DBP, respectively.

The numbers of measurements differing from the mercury standard by 5, 10 and 15 mmHg or less are shown in Table IV. The difference between the device readings and the mean BP of device and the two observers for all 99 points for SBP and DBP are displayed in Figure 4. These results are in concordance with the requested criteria of the International Protocol for the primary and secondary phases. Thus the Pic Indolor Travel Check device fulfills the validation criteria of the International Protocol.

Discussion

This study provides information on the accuracy of four devices for SBPM measurements. The Pic Indolor Personal Check, Comfort Check and My Check measure BP at the brachial level whereas the Travel Check measures radial BP at the wrist level. The results showed that all the four devices passed the validation requirements of the international Protocol of the ESH provided that they are used by well-trained observers and respecting the factors affecting the measurements accuracy described by the manufacturers. Before their widespread application, some clarifications may be helpful.

In this study, validation was performed according to the international protocol. This protocol has been published by the ESH (10) aiming to simplify the two other available protocols, the BHS (8) and AAMI (9) without sacrificing their integrity. The main advantage of this protocol is that it requires a lower number of subjects, 33 instead of 85 with the two other protocols. However, this protocol has some limitations. (i) The population requested in the international protocol is confined to adults >30 years with specifications in terms of age, gender, BP level, arm circumference, etc., since such selective population is only a part of the large heterogeneous population affected by hypertension; the extrapolation of the results to other specific populations may be hazardous and risky. Specific validation studies are needed if the devices will be used by specific populations, such as pregnant women, elderly, obese, children, etc., or with specific conditions such as arrhythmia. (ii) The number of validation studies requested to approve the device accuracy is an important issue. The international protocol does

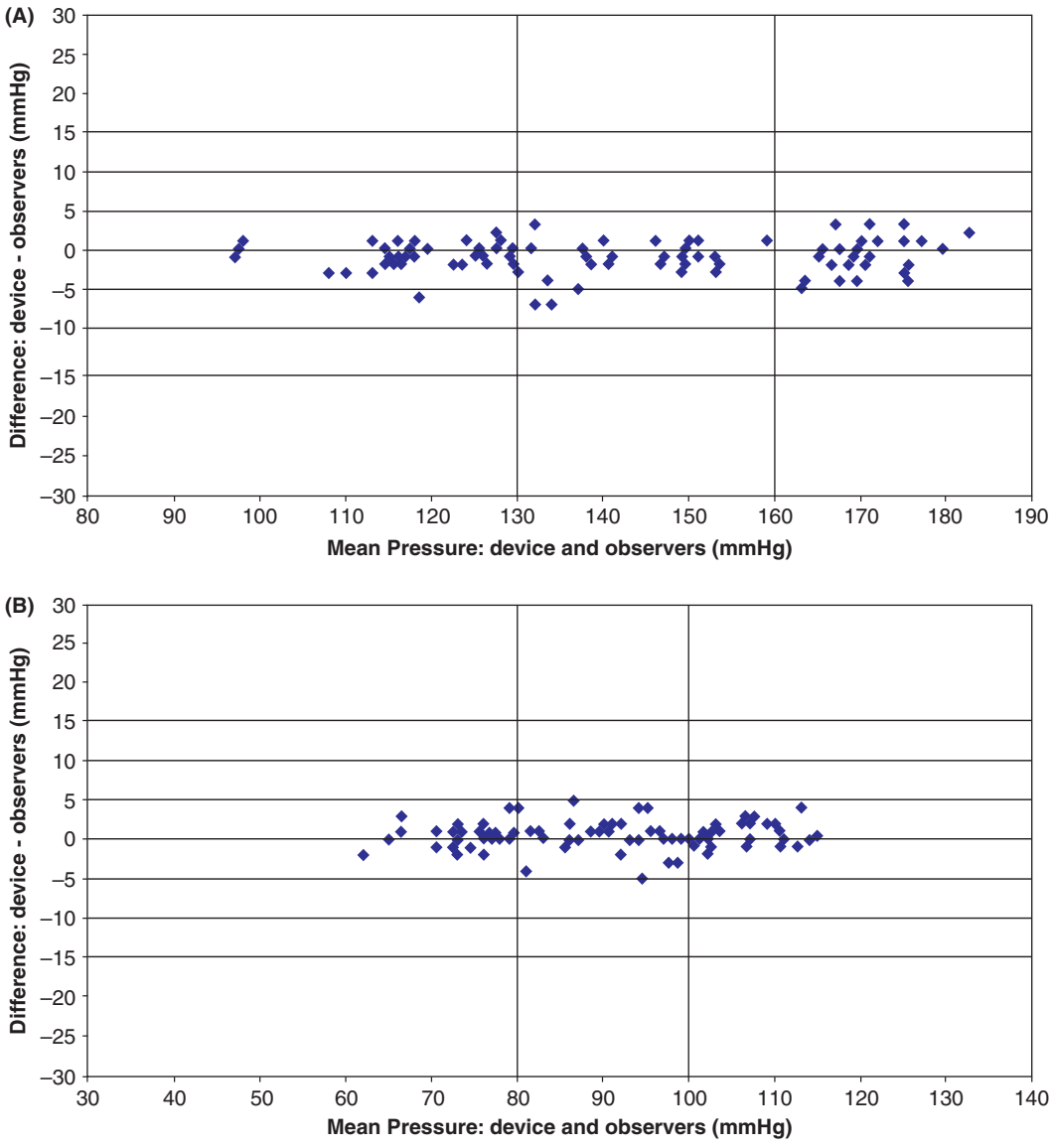

Figure 4. Plots of BP difference between the Pic Indolor Travel Check readings and the mean of the two observer readings in 33 participants ($n=99$). Systolic (A) and diastolic (B).

not specify the number of devices or study sites recommended to enhance the accuracy requirements. Experts agree that it would be important to have at least two validation studies conducted in different centers and various populations. In this regard, the AAMI protocol recommends more than one study but without specifying the number of studies or devices. Therefore, since none of the four tested devices in the present study went through prior validation, it would be important to achieve at least a second study in specific population before recommending their widespread use in clinic.

Conclusion

The results of the present study show that the four tested devices, the Pic Indolor Personal Check, Comfort Check, My Check and Travel Check meet the requirements of the international protocol in a general population and can be used by patient for SBPM. Because of certain limitations of the international protocol, it would be desirable to corroborate the present results by other studies performed in general or specific populations.

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Conflicts of interest: None.

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