Medical Devices: Evidence and Research

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ORIGINAL RESEARCH

Validation of BP devices QardioArm® in the general population and Omron M6 Comfort® in type II diabetic patients according to the European Society of Hypertension International Protocol (ESH-IP)

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Background: Following the European Society of Hypertension International Protocol (ESH-IP) Revision 2010, QardioArm® and Omron M6 Comfort IT® oscillometric devices were evaluated in the general population and in patients with type II diabetes, respectively, for self-blood pressure (BP) measurement.

Methods: Both devices, QardioArm® and Omron M6 Comfort®, measure BP at the brachial level. The ESH-IP Revision 2010 includes a total number of 33 subjects. For each measure, the difference between observer and device BP values was calculated. In all, 99 pairs of BP differences are classified into three categories (≤5, ≤10, and ≤15 mmHg). The protocol procedures were followed precisely.

Results: QardioArm® and Omron M6 Comfort® fulfilled the requirements of the ESH-IP and passed the validation process successfully. For QardioArm®, a total of 69 out of 99 comparisons for systolic blood pressure (SBP) showed an absolute difference within 5 mmHg and 82 out of 99 for diastolic blood pressure (DBP). As for Omron M6 Comfort®, a total of 83 out of 99 comparisons for SBP showed an absolute difference within 5 mmHg and 77 out of 99 for DBP. The mean differences between the device and mercury readings were 0.7±5.9 mmHg for SBP and 0.3±4.1 mmHg for DBP for QardioArm® and −1.4±4.7 mmHg for SBP and −2.1±4.3 mmHg for DBP for Omron M6 Comfort®. With regard to part 2 of ESH-IP 2010, 27 out of 33 subjects had a minimum of two out of three measurements within 5 mmHg difference for SBP and 31 out of 33 subjects for DBP for the QardioArm®, and 29 out of 33 patients had a minimum of two out of three measurements within 5 mmHg difference for SBP and 26 out of 33 patients for DBP for Omron M6 Comfort®.

Conclusion: QardioArm® and Omron M6 Comfort® readings differing from the mercury standard by <5, 10, and 15 mmHg fulfill the ESH-IP Revision 2010 requirements. Consequently, these two devices are suitable for use in the general population and non-insulin-dependent type II diabetic patients, respectively.

Keywords: QardioArm®, Omron M6 Comfort®, validation, blood pressure measurement, type II diabetes, International Protocol

Introduction

Over the last years, many automated blood pressure (BP) measuring devices have been developed to gradually supplant the standard mercury sphygmomanometer due

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to mercury limitations.[1,2] A validation process for these devices is therefore needed to verify their accuracy following different protocols, such as the European Society of Hypertension International protocol (ESH-IP),[3] the British Hypertension Society (BHS) protocol,[4] and the Association for the Advancement of Medical Instrumentation (AAMI) protocol.[5] This validation process is required in the general population and in specific populations such as type II diabetic patients, for example, where accurate BP measurement is crucial, so the effective management of hypertension can delay disease complications.

Type II diabetes is a major health problem that has higher prevalence in the older population.[6,7] It is well known that atherosclerotic disease is the major complication of type II diabetes.[8,9] Atherosclerosis leads to the degeneration of arterial elasticity and subsequent arterial wall stiffening which is a strong risk factor for early mortality in patients with type II diabetes.[8–10] Arterial wall stiffening is exacerbated with diabetes[11] and hypertension.[10,12,13] It is estimated that high BP occurs in over two-thirds of patients with type II diabetes.[14] Recent evidence has showed that BP control decreases the risk of developing diabetes-related microvascular, and microvascular complications.[15] Knowing that arterial stiffness is more critical in type II diabetic patients with hypertension than those without hypertension,[16] and that increase in arterial stiffness may affect the accuracy of automatic BP measurements,[17,18] accurate BP measurements in such populations is therefore crucial for the diagnosis and management. However, only a limited number of studies have tested the accuracy of automated BP monitors in the type II diabetic population,[19–22] and the majority of these validations did not adhere to existing validation standards according to specific protocols cited above.[3–5] Therefore, the issue of BP measurements accuracy remains controversial.[23] Because of the high prevalence of type II diabetes, and the importance to reduce morbidity and mortality associated to hypertension, it is important to assess the accuracy of automatic BP measurements in this specific population. Most importantly, measuring BP accurately will facilitate the establishment of a threshold level of BP above which antihypertensive treatment can be recommended especially in type II diabetic patients, highly prone to developing hypertension and its complications if misdiagnosed.

In 2014, the Omron M6 Comfort® BP device was only validated in the general population following the ESH-IP;[24] and QardioArm® device has never been validated previously in any population. The aim of this study is to check the validity of the QardioArm® BP measurement device in the general population and Omron M6 Comfort® oscillometric BP measurement device in non-insulin-dependent type II diabetic patients, following the ESH-IP 2010.

Materials and methods

Ethical information

The study was approved by the local ethic committees, namely National Institute of Health, Ministry of Health, Republic of Armenia and Institutional Review Board and Ethical Committee Geitaoui Hospital, Beirut, Lebanon.

All eligible subjects included in this study signed an informed consent form prior to any BP measurement.

Tested devices

The QardioArm® device

The QardioArm® device, provided by Qardio Inc (San Francisco, CA, USA), is a home BP measurement automatic device at the arm level. It needs a device with Bluetooth 4.0, iOS 7.0 (or later), Android 4.4 "KitKat" (or later), and is compatible with iPhone, iPod, iPad, and Apple Watch as well as with Android phones and tablets. In order to operate the device, a specific free Qardio application can be downloaded from the Apple App Store or Google Play (or www.getqardio.com). The unit records BP using the oscillometric method, with an automatic inflation and a controlled pressure release valve, with a pressure range of 40–250 mmHg and pulse rate range of 40–200 beats/min. The unit weighs ~310 g including batteries. Four 1.5 V AAA batteries are needed. The included single cuff is easy-fit Lycra, applicable to arm circumferences ranging from 22 to 37 cm. The dimensions are 140×68×38 mm, when closed.

The Omron M6 IT Comfort® device

This device (HEM-7322U-E) was provided and randomly selected by the manufacturer (Omron Healthcare, Kyoto, Japan). It is a home BP measurement digital automatic device at the arm level. The monitor uses a Fuzzy-logic inflation system controlled by an electric pump and an automatic pressure release valve for the deflation. BP is recorded using the oscillometric method with a pressure range of 0–299 mmHg and pulse rate range of 40–180 beats/min. A digital LCD screen displays the measured BP and pulse rate. The unit weighs ~380 g without batteries. The device requires four AA alkaline batteries with an approximate capacity of 1000 measurements. A semirigid nylon/polyester single cuff is included with dimensions of 145 mm ×532 mm (air tube: 750 mm) and weights ~163 g; it is applicable to arm circumferences ranging from 22 to 42 cm.

Study protocol

Subjects and patients who were included fulfilled the main criteria (age, gender, and recruitment BP requirements) of the ESH-IP with age ≥25 years, at least 10 men and 10 women, with 10–12 participants in each of the three BP recruitment ranges (Tables 1–4).

General population

A total of 33 participants fulfilled the ESH-IP recruitment criteria and were included in the validation of the QardioArm® device. All participants' arm circumference was between 22 and 37 cm and none of them had atrial fibrillation or any other arrhythmia. Subjects were preselected from the general population in Yerevan, Armenia.

Non-insulin-dependent type II diabetic population

A total of 33 participants fulfilled the ESH-IP recruitment criteria and were included in the validation of the Omron M6 IT Comfort® device. All participants' circumference was between 22 and 42 cm and none of them had atrial fibrillation or any other arrhythmia or used insulin as treatment for type II diabetes. Patients were preselected from outpatient clinics and from inpatients at the Lebanese University affiliated hospitals (Mount-Lebanon, Lebanese Hospital Geitaoui, Rafik Hariri University Hospital, Governmental Hospital of Baabda, Rasoul el-Aazam Hospital, and Bahman Hospital).

For BP measurement, three persons were included in the validation team: two observers trained in accurate BP measurement and a supervisor, all of them having completed a training based on a CD-ROM specifically developed by the French Society of Hypertension to certify observers involved in clinical studies and to familiarize them with the use of tested devices.

Each device validation study was assessed in different populations (general population/type II diabetic populations), separately from the other device validations and at another time. Therefore, each patient participated in only one study device validation. Evaluation of the devices was done according to the ESH-IP Revision 2010.

In our study, the two observers used two parallel connected mercury sphygmomanometers and a teaching stethoscope as

Table 1 Screening and recruitment (**A**) and recruitment ranges (**B**) for the QardioArm® BP device according to the ESH-IP 2010

(A) Screening and recruitment: QardioArm®		
Total screened	36	
Total excluded	3	
• Ranges complete		0
• Ranges adjustment		0
• Arrhythmias		0
• Device failure		0
• Poor quality sounds		0
• Cuff size unavailable		0
• Distribution		0
• Other reasons		3
Total recruited	33	

(B) Recruitment ranges: QardioArm®			
		mmHg	**All**
		<90	0
	Low	90–129	11
SBP	Medium	130–160	11
	High	161–180	11
		>180	0
		<40	0
DPB	Low	40–79	11
	Medium	80–100	11
	High	101–130	11
		>130	0

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; ESH-IP, European Society of Hypertension International Protocol; SBP, systolic blood pressure

Table 2 Subjects' details (**A**) and observer measurement in each recruitment range (**B**) for the QardioArm® BP device according to the ESH-IP 2010

(A) Subject details: QardioArm®			
Sex	Male:female	18:15	
Age (years)	Range (low:high)	30:68	
	Mean (SD)	48.1 (10.5)	
Arm circumference (cm)	Range (low:high)	24:37	
	Mean (SD)	31.6(3.0)	
Mercury Cuff	Small	0	
	Standard	20	
	Large	13	
Recruitment		SBP	DBP
BP (mmHg)	Range (low:high)	101:180	49:129
	Mean (SD)	143.2 (27.4)	91.2 (20.3)

(B) Observer measurement in each recruitment range: QardioArm®	
SBP (mmHg)	
Overall range (low:high)	96:198
Low (<130)	33
Medium (130–160)	42
High (>160)	24
Maximum difference	18
DBP (mmHg)	
Overall range (low:high)	50:139
Low (<80)	36
Medium (80–100)	35
High (>100)	28
Maximum difference	8

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; ESH-IP, European Society of Hypertension International Protocol; SBP, systolic blood pressure; SD, standard deviation.

Table 3 Screening and recruitment (**A**) and recruitment ranges (**B**) for the Omron M6 IT Comfort® BP device according to the ESH-IP 2010

(A) Screening and recruitment: Omron M6 IT Comfort®		
Total screened	58	
Total excluded	25	
• Ranges complete		16
• Ranges adjustment		0
• Arrhythmias		0
• Device failure		0
• Poor quality sounds		1
• Cuff size unavailable		0
• Distribution		0
• Other reasons		8
Total recruited	33	

(B) Recruitment ranges: Omron M6 IT Comfort®			
		mmHg	**All**
		<90	0
	Low	90–129	11
SBP	Medium	130–160	11
	High	161–180	11
		>180	0
		<40	0
DPB	Low	40–79	11
	Medium	80–100	11
	High	101–130	11
		>130	0

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; ESH-IP, European Society of Hypertension International Protocol; SBP, systolic blood pressure.

Table 4 Patients' details (**A**) and observer measurement in each recruitment range (**B**) for the Omron M6 IT Comfort® BP device according to the ESH-IP 2010

(A)Patients' details:Omron M6 IT Comfort®			
Sex	Male:female	14:19	
Age (years)	Range (low:high)	43:85	
	Mean (SD)	60.8 (11.0)	
Arm circumference	Range (low:high)	24:36	
(cm)	Mean (SD)	30.5 (3.0)	
Mercury cuff	Small	0	
	Standard	19	
	Large	14	
Recruitment BP		SBP	DBP
(mmHg)	Range (low:high)	99:178	48:121
	Mean (SD)	143.8 (24.0)	86.4 (18.0)

(B) Observer Measurement in each Recruitment Range: Omron M6 IT Comfort®	
SBP (mmHg)	
Overall Range (low:high)	98:175
Low (<130)	36
Medium (130–160)	32
High (>160)	31
Maximum Difference	5
DBP (mmHg)	
Overall range (low:high)	49:124
Low (<80)	33
Medium (80–100)	35
High (>100)	31
Maximum difference	4

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; ESH-IP, European Society of Hypertension International Protocol; SBP, systolic blood pressure; SD, standard deviation.

a reference standard. They also measured the circumference of the arm to make certain that the cuff size being used is adequate for the subject. The agreement between the two observers, blinded from each other's result, was checked all over the evaluation period by the supervisor to ensure that the difference between the two observers is ≤4 mmHg for systolic and diastolic BP values. Otherwise, the measurement was repeated. Measurements through the mercury sphygmomanometer were performed according to the "same arm, consecutive measurements" supported at the heart level. Measurements by both devices were on the same arm supported at the heart level, as recommended by the manufacturers asking the subject to relax for 5–10 minutes, while making sure that the subject is seated with uncrossed legs and supported back. Two cuffs were used for the standard mercury sphygmomanometer measurements: standard cuff for 22–32 cm and large cuff for 32–42 cm arm circumference. In total, in each patient, nine consecutive BP measurements were performed using the mercury sphygmomanometers (five times) and the tested device (four times), and were recorded as follows:

- BPA: entry BP, observers 1 and 2 each with the mercury standard
- BPB: device detection BP, supervisor
- BP1: observers 1 and 2 with mercury standard
- BP2: supervisor with the test instrument
- BP3: observers 1 and 2 with mercury standard
- BP4: supervisor with the test instrument
- BP5: observers 1 and 2 with mercury standard
- BP6: supervisor with the test instrument
- BP7: observers 1 and 2 with mercury standard

Certainly, the interval between one BP measurement and the next one was 30–60 seconds.

Data analysis

The accuracy of a device according to the ESH-IP is based on a comparison between the device and reference (mercury) measurements. Results were analyzed and expressed according to the ESH-IP requirements to conclude if the device passed or failed to pass the validation protocol. Part 1

and part 2 of the validation process concern the number of differences in the requested ranges for individual measurements (99 measurements) and for individual subjects (33 subjects), respectively.[3] A detailed explanation is provided in the "Results" section.

A specific analysis software developed by the International Society for Vascular Health was used for the statistical analysis. Bland–Altman plots were used to represent the relation between delta systolic blood pressure (SBP; device – reference) and mean SBP (device and reference) or delta diastolic blood pressure (DBP; device – reference) and mean DBP (device and reference). BP1, BP3, BP5, and BP7 were the means of the two observer measurements. To calculate the means, for each subject, the device measurements BP2, BP4, and BP6 were first compared to observer measurements BP1, BP3, and BP5, respectively, and then to observer measurements BP3, BP5, and BP7, respectively. Comparisons more favorable to the device were used, which means that since there were two means of observers' measurements that might be used, only the observers' mean that was the closest to the device measurements value was used. To calculate the differences, the observer measurement was subtracted from the device measurement. Differences were classified, separately for both SBP and DBP, according to whether their values were within 5, 10, or 15 mmHg. Data were expressed as mean ± standard deviation.

Results

The QardioArm® device

Subjects' details

A total of 36 subjects were screened to recruit 33 participants who met the ESH-IP criteria and three were excluded for reasons mentioned in Table 1A. The 33 remaining participants were recruited following the three different BP ranges, such as 11 subjects in each of the ranges in Table 1B. There were 18 males and 15 females; the mean age of the participants was 48±10.5 years (from 30 to 68 years). Their arm circumference ranged from 24 to 37 cm, with a total of 13/33 participants having an arm circumference ≥32 cm, where one easy-fit Lycra cuff (22–37 cm) with the QardioArm® device was used, and the standard (22–32 cm) and large (32–42 cm) cuffs were used with the mercury sphygmomanometer, according to patients' arm size. The mean recruitment SBP was 143.2±27.4 mmHg (101–180 mmHg) and the mean recruitment DBP was 91.2±20.3 mmHg (49–129 mmHg). More details about the participants' characteristics are described in Table 2A.

BP requirements

Observer measurements in each recruitment range are described in Table 2B. The number of observer test measurements in each pressure range is, as required by the ESH-IP, between 22 and 44; more specifically, it is between 24 and 42 measurements. The difference between the range with the highest count and that with the lowest count is, as required by the ESH-IP, ≤19; more specifically, it is 18 for SBP and 8 for DBP. The overall SBP range is, as required by the ESH-IP, from ≤100 to ≥170 mmHg; more specifically, it ranges from 96 to 198 mmHg. The overall DBP range is, as required by the ESH-IP, from ≤50 to ≥120 mmHg; more specifically, it varies from 50 to 139 mmHg.

BP measurements

The difference between two observers was −0.3±1.7 and −0.3±1.7 mmHg for SBP and DBP, respectively (−4 to +4 mmHg). The mean differences between the observers and the tested device were 0.7±5.9 mmHg for SBP and 0.3±4.1 mmHg for DBP. The numbers of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 5. Indeed, a total of 69 out of 99 comparisons for SBP showed an absolute difference within 5 mmHg and 82 out of 99 for DBP (vs at least 73 for SBP and 65 for DBP following ESH-IP requirements). In addition, a total of 91 out of 99 comparisons for SBP showed an absolute difference within 10 mmHg and 97 out of 99 for DBP (vs at least 87 for SBP and 81 for DBP following ESH-IP requirements). Furthermore, a total of 98 out of 99 comparisons for SBP showed an absolute difference within 15 mmHg and 98 out of 99 for DBP (vs at least 96 for SBP and 93 for DBP following ESH-IP requirements). Since "two" out of these three absolute differences of 5 or 10 or 15 mmHg for SBP are within the required range mentioned above and "all" (three out of three) of them for DBP, part 1 device validation was successfully completed.

As for part 2 of ESH-IP 2010, 27 out of 33 subjects had a minimum of two out of three measurements within 5 mmHg difference for SBP and 31 out of 33 subjects for DBP (vs at least 24 out of 33 subjects for SBP and DBP following ESH-IP requirements). In addition, three out of 33 subjects had a minimum of zero out of three measurements within 5 mmHg difference for SBP and two out of 33 subjects for DBP (vs a maximum of three subjects for SBP and DBP following ESH-IP requirements). Since these two conditions mentioned above were validated, part 2 device validation was successfully completed. Therefore part 3 of the QardioArm® device validation passed, since parts 1 and 2 were both validated.

Table 5 Validation results for the QardioArm® BP device according to the ESH-IP 2010

Validation results qardioArm®							
Part 1		**≤5 mmHg**	**≤10 mmHg**	**≤15 mmHg**	**Grade 1**	**Mean (mmHg)**	**SD (mmHg)**
Pass req	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	69	91	98	Pass	0.7	5.9
	DBP	82	97	98	Pass	0.3	4.1
Part 2		**2/3≤5 mmHg**	**0/3≤5 mmHg**		**Grade 2**		**Grade 3**
Pass req		≥24	≤3				
Achieved	SBP	27	3		Pass	Pass	
	DBP	31	2		Pass	Pass	
Part 3							Result
							Pass

Notes: Pass Req: as required by the IP; achieved: as recorded by the device. Refer to the text for more explanations about parts 1–3.
Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; IP, International Protocol; ESH-IP, European Society of Hypertension International Protocol; SBP, systolic blood pressure; SD, standard deviation.

Bland–Altman plots of the differences between BP measurements obtained with the QardioArm® device and the sphygmomanometer are shown for SBP (Figure 1A) and for DBP (Figure 1B). These results are in concordance with the requested criteria of the ESH-IP and the device succeeded in fulfilling the validation criteria of the ESH-IP Revision 2010.

The Omron M6 IT Comfort® device

Patients' details

In all, 58 non-insulin-dependent type II diabetic patients were screened to recruit 33 participants who met the ESH-IP criteria and 25 were excluded for reasons mentioned in Table 3A. The 33 remaining participants were recruited following the three different BP ranges, such as 11 subjects in each of the ranges in Table 3B. There were 14 males and 19 females; the mean age of the participants was 61±11 years. Their arm circumference ranged from 24 to 36 cm, with a total of 14/33 participants having an arm circumference ≥32 cm, where one universal rigid cuff (22–42 cm) with the Omron M6 IT Comfort® device was used, and the standard (22–32 cm) (n=19 patients) and large (32–42 cm) (n=14 patients) cuffs were used with the mercury sphygmomanometer, according to patients' arm size. The mean recruitment SBP was 143.8±24 mmHg (99–178 mmHg) and the mean recruitment DBP was 86.4±18 mmHg (48–121 mmHg). More details about participants' characteristics are described in Table 4A.

BP requirements

Observer measurements in each recruitment range are described in Table 4B. The number of observer test measurements in each pressure range is, as required by the ESH-IP, between 22 and 44; more specifically, it is between 31 and 36 measurements. The difference between the range with the highest count and that with the lowest count is, as required by the ESH-IP, ≤19; more specifically, it is 5 for SBP and 4 for DBP. The overall SBP range is, as required by the ESH-IP, from ≤100 to ≥170 mmHg; more specifically, it varies from 98 to 175 mmHg. The overall DBP range is, as required by the ESH-IP, from ≤50 to ≥120 mmHg; more specifically, it ranges from 49 to 124 mmHg.

BP measurements

The difference between the two observers was −0.2±2.2 and +0.3±2.1 mmHg for SBP and DBP, respectively (−4 to +4 mmHg). The mean differences between the observers and the tested device were −1.4±4.7 mmHg for SBP and −2.1±4.3 mmHg for DBP. The numbers of measurements differing from the mercury standard by 5, 10, and 15 mmHg or less are shown in Table 6. Indeed, a total of 83 out of 99 comparisons for SBP showed an absolute difference within 5 mmHg and 77 out of 99 for DBP (vs at least 73 for SBP and 65 for DBP following ESH-IP requirements). In addition, a total of 94 out of 99 comparisons for SBP showed an absolute difference within 10 mmHg and 93 out of 99 for DBP (vs at least 87 for SBP and 81 for DBP following ESH-IP requirements). Furthermore, a total of 97 out of 99 comparisons for SBP showed an absolute difference within 15 mmHg and 99 out of 99 for DBP (vs at least 96 for SBP and 93 for DBP following ESH-IP requirements). Since "two" out of these three absolute differences of 5 or 10 or 15 mmHg for SBP are within the required range mentioned above and "all" (three out of three) of them for DBP, part 1 device validation was successfully completed.

As for part 2 of ESH-IP 2010, 29 out of 33 subjects had a minimum of two out of three measurements within 5 mmHg

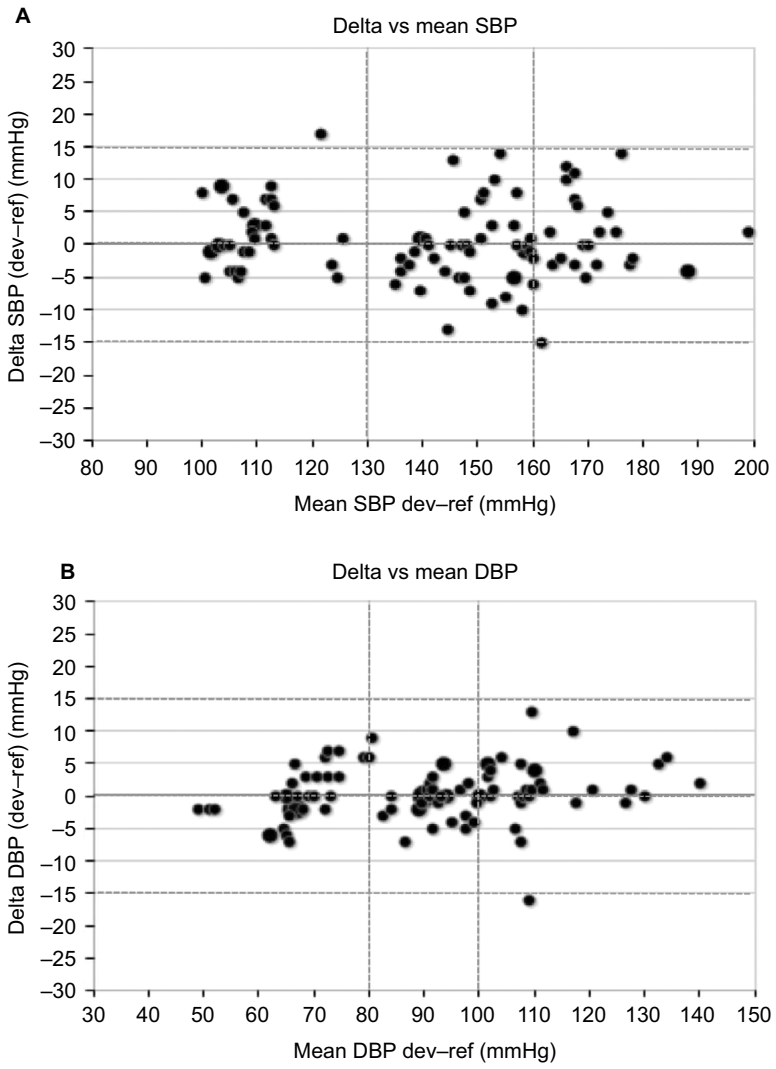

Figure 1 Plots of systolic (**A**) and diastolic (**B**) BP differences between the QardioArm® BP device and the mean of two observers' readings in 33 subjects (n=99 measurements).

Notes: Delta SBP dev–ref: systolic difference between the QardioArm® and mercury sphygmomanometer; mean SBP dev–ref: mean systolic average values of the QardioArm® and the mercury sphygmomanometer. Delta DBP dev–ref: diastolic difference between the QardioArm® and mercury sphygmomanometer; mean DBP dev–ref: mean diastolic average values of the QardioArm® and the mercury sphygmomanometer.

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; dev, device; ref, reference; SBP, systolic blood pressure.

Table 6 Validation results for the Omron M6 IT Comfort® BP device according to the ESH-IP 2010

Validation Results Omron M6 IT Comfort®							
Part 1		**≤5 mmHg**	**≤10 mmHg**	**≤15 mmHg**	**Grade 1**	**Mean (mmHg)**	**SD (mmHg)**
Pass req.	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	83	94	97	Pass	–1.4	4.7
	DBP	77	93	99	Pass	–2.1	4.3
Part 2		**2/3≤5 mmHg**		**0/3≤5 mmHg**	**Grade 2**		**Grade 3**
Pass req.		≥24		≤3			
Achieved	SBP	29		0	Pass	Pass	
	DBP	26		2	Pass	Pass	
Part 3							Result
							Pass

Notes: Pass Req: as required by the IP; achieved: as recorded by the device. Refer to the text for more explanations about parts 1–3.

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; IP, International Protocol; ESH-IP, European Society of Hypertension International Protocol; SBP, systolic blood pressure; SD, standard deviation.

difference for SBP and 26 out of 33 subjects for DBP (vs at least 24 out of 33 subjects for SBP and DBP following ESH-IP requirements). In addition, none of the 33 subjects had a minimum of zero out of three measurements within 5 mmHg difference for SBP and two out of 33 subjects for DBP (vs a maximum of three subjects for SBP and DBP following ESH-IP requirements). Since these two conditions mentioned above were validated, part 2 device validation was successfully completed. Therefore, part 3 of the Omron M6 IT Comfort® validation passed since parts 1 and 2 were both validated.

Bland–Altman plots of the differences between BP measurements obtained with the Omron M6 IT Comfort® device and the sphygmomanometer are shown for SBP (Figure 2A)

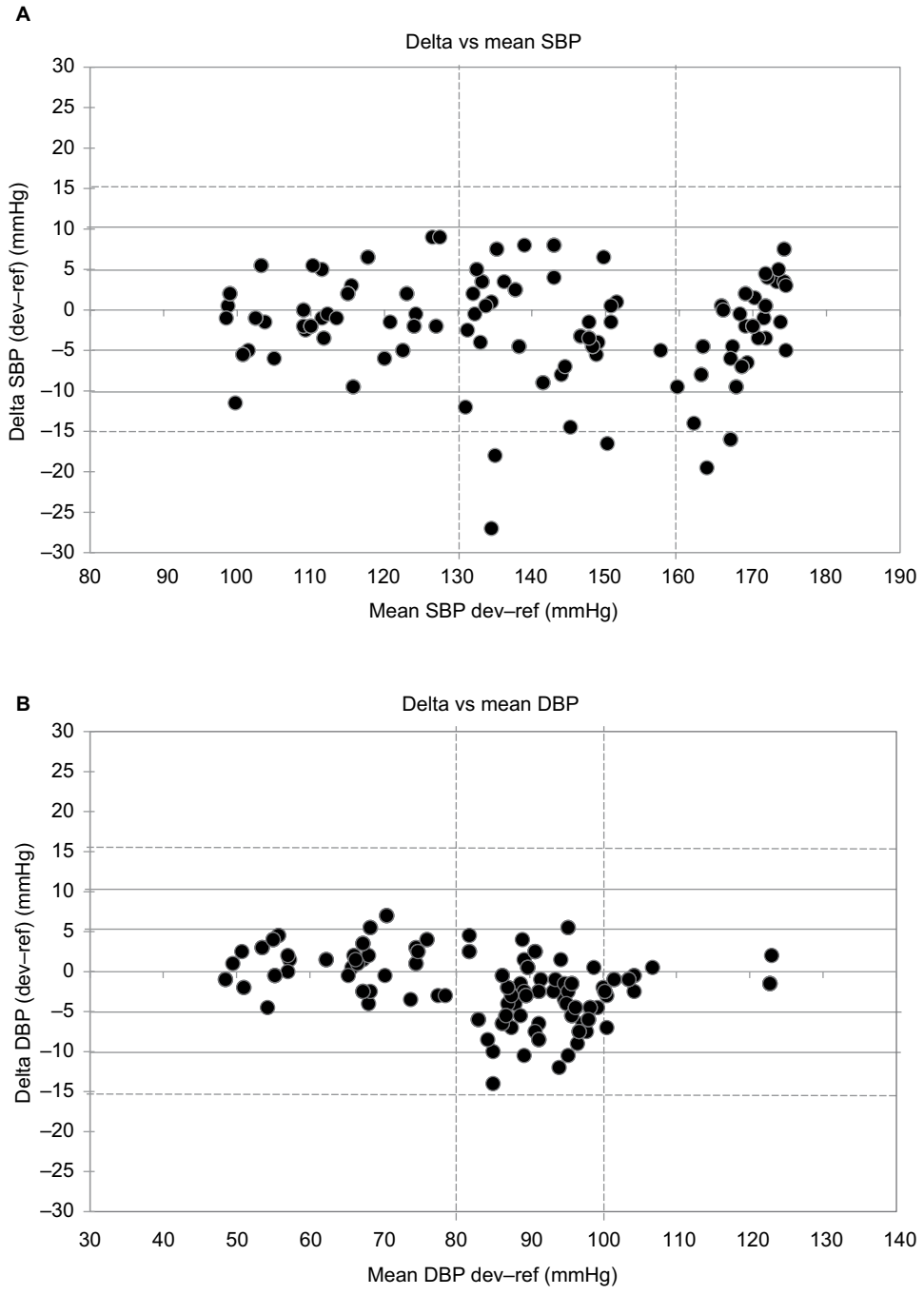

Figure 2 Plots of systolic (**A**) and diastolic (**B**) BP differences between the Omron M6 IT Comfort® BP device and the mean of two observers' readings in 33 subjects (n=99 measurements).

Notes: Delta SBP dev–ref: systolic difference between the Omron M6 Comfort® and mercury sphygmomanometer; mean SBP dev– ref: mean systolic average values of the Omron M6 Comfort® and the mercury sphygmomanometer. Delta DBP dev–ref: diastolic difference between the Omron M6 Comfort® and mercury sphygmomanometer; mean DBP dev–ref: mean diastolic average values of the Omron and the mercury sphygmomanometer.

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; dev, device; ref, reference; SBP, systolic blood pressure.

and for DBP (Figure 2B). These results are in concordance with the requested criteria of the ESH-IP and the device succeeded in fulfilling the validation criteria of the ESH-IP Revision 2010.

Discussion

This study is the first to provide information on the accuracy of both the QardioArm® device for BP measurement in the general population and the Omron M6 IT Comfort® device for BP measurement in the non-insulin-dependent type II diabetic population. Omron M6 Comfort® BP device was previously validated by our team in the general population following ESH-IP[24]; however, the QardioArm® device has never been validated previously in any population. The results of the study showed that QardioArm® and Omron M6 Comfort® device successfully passed the validation requirements in the general population and in non-insulin-dependent type II diabetic patients, respectively, according to the ESH-IP Revision 2010.

There are two important points related to both the devices (QardioArm® and Omron M6 Comfort®) and the validation protocol (ESH-IP) that need to be discussed.

First, QardioArm® has never been validated in any type of population and Omron M6 Comfort® has only been validated previously in the general population.[12] In this study, QardioArm® has been validated successfully in the general population and Omron M6 Comfort® has been validated successfully in a specific population (type II diabetic patients). However, other specific populations such as obese, elderly, and pregnant women have not been addressed. Therefore, the results of our study cannot be extrapolated to other specific populations.

Second, in the present study, regarding the type II diabetic population, the patients recruited were known to have non-insulin-dependent type II diabetes; however, this was regardless of checking the presence of microalbuminuria (MAU). Whether the presence of MAU may affect the BP measurement[25] accuracy remains questionable.

Third, we presumed that diabetes type II measurements involve stiffer arteries; however, this has not been investigated as it was not the main objective of our study. Certainly, measuring arterial stiffness would have been an added value to analyze the accuracy of the BP monitor accordingly.

In terms of the validation protocol, ESH-IP was used in this study. It has been published in 2002 and revised in 2010.[3] The aim of this protocol was to simplify the previous protocols (BHS[4] and AAMI[5]) without violating their integrity.[3] Its main advantage is that the sample size required is smaller (n=33) compared to the two other protocols (n=85). However, some limitations were noted.

First, the ESH-IP does not specify the number of validation studies needed to approve the accuracy of the device although experts agreed that a device should be validated in two different centers separately, at least. Therefore, it is important to check the validity of BP measuring devices in specific populations as an add-on step in the validation process before widespread application in clinics/homes.

Second, there are specific requirements needed for the subjects recruited; their age should be at least 25 years and children and young adults are excluded from being studied. Moreover, since adult population is a part of a larger heterogeneous population affected by hypertension, extrapolation of the validation studies' results in this selected population to a more specific population is risky and may negatively affect clinical practice. However, in our study, standard and large arm circumferences were covered.

Finally, there is no explicit criteria mentioned for a validation process in specific populations in the ESH-IP, and this is highly recommended to be taken into consideration in its next revision. Actually, the presence of several protocols for validation such as AAMI,[5] BHS,[4] ESH-IP[3] is problematic for several reasons: 1) manufacturers cannot perform all three protocols; 2) experts are recognizing mainly their national protocols; for example, AAMI in the USA, ESH-IP in Europe; 3) impossibility to compare various studies; therefore, there is an ultimate need for a unified international protocol.[26]

Conclusion

This study showed that the QardioArm® device and Omron M6 Comfort® device successfully passed the validation requirements in the general population and in type II diabetic patients, respectively, according to the ESH-IP Revision 2010.

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Disclosure

The authors report no conflicts of interest in this work.

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