



Accuracy and reliability of wrist-cuff devices for self-measurement of blood pressure

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Object Self-measurement of blood pressure (BP) might offer some advantages in diagnosis and therapeutic evaluation and in patient management of hypertension. Recently, wrist-cuff devices for self-measurement of BP have gained more than one-third of the world market share. In the present study, we validated wrist-cuff devices and compared the results between wrist- and arm-cuff devices. The factors affecting the accuracy of wrist-cuff devices were also studied.

Method The research group to assess the validity of automated blood pressure measuring device consisted of 13 institutes in Japan, which validated two wrist-cuff devices (WC-1 and WC-2) and two arm-cuff devices (AC-1 and AC-2). They used a crossover method, where the comparison was done between auscultation, by two observers by means of a double stethoscope on one arm and the device on the opposite arm or wrist.

Results There was good inter-observer agreement for the auscultation method in each institute (systolic blood pressure (SBP), -0.1 ± 2.8 mmHg; diastolic blood pressure (DBP), -0.1 ± 2.6 mmHg, $n = 498$). The mean difference between auscultation and the device was minimal both in arm-cuff devices (mean difference for AC-1, $2.2/1.9$ mmHg, $n = 97$ and for AC-2, $5.1/2.9$ mmHg, $n = 136$, SBP/DBP) and wrist-cuff devices (mean difference for WC-1, $-2.1/1.2$ mmHg, $n = 173$ mmHg and for WC-2, $-2.3/-5.6$ mmHg, $n = 92$). The standard deviation of the difference (SDD) in wrist-cuff devices, however (SDD for WC-1, $9.7/7.3$ mmHg and for WC-2, $10.2/8.6$ mmHg), was larger than that of the arm-cuff devices (SDD for AC-1, $5.6/6.6$ mmHg and for AC-2, $6.3/5.1$ mmHg). Grading of AC-1 and AC-2 based on criteria of British Hypertension Society was A/A and B/A, respectively, while that of WC-1 and WC-2 was C/B and D/

B, respectively. Using the same validation protocol, the results of validation for one device were divergent in each institute. In wrist-cuff devices, the BP value obtained in palmar flexion was significantly higher and that obtained in palmar dorsiflexion was significantly lower than that in palmar extension. In some cases, finger plethysmogram did not disappear during maximum inflation of the wrist-cuff (≥ 250 mmHg), even in palmar extension and especially in palmar flexion, suggesting incomplete obstruction of radial and/or ulnar arteries during inflation.

Conclusion The results suggest that wrist-cuff devices in the present form are inadequate for self-measurement of blood pressure and, thus, are inadequate for general use or clinical and practical use. However, there is much possibility in wrist-cuff device and the accuracy and reliability of wrist-cuff device are warranted by an improvement of technology. *J Hypertens* 20:629–638 © 2002 Lippincott Williams & Wilkins.

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Introduction

Self-measurement of blood pressure (BP) might offer some advantages in diagnosis and therapeutic evaluation and in patient management. Previous reports indicate that self-measured BPs are better predictors for prognosis of hypertension [1–3] than office BP and provide a more accurate evaluation of the effect of treatment [3–6]. One advantage of self-measured BP is that, from the greater number of readings averaged, a

person can obtain his/her inherent BP levels. The World Hypertension League [7], the Sixth Joint National Committee of Prevention and Treatment of Hypertension [8], and the 1999 WHO/ISH guidelines [9] recognize the value of self-measured BP. Each report, however, emphasizes the limitation of self-measurement of BP. The critical problem of self-measurement is the value provided by the device *per se*. So far, several automatic devices for self-measurement

have been validated. According to these validation studies, many automatic devices have a poor record for accuracy [3,10–14]. Furthermore, the majority of automated devices distributed have not yet been properly validated. Inaccurate self-measured BP inevitably leads to an incorrect diagnosis in practice and an erroneous conclusion in hypertension research [3].

The gold-standard for indirect BP measurement is the Riva–Rocci–Korotkoff sound method using the arm-cuff and mercury sphygmomanometer. Therefore, an automated device for self-measurement should essentially be based on the arm-cuff method. Surprisingly, however, it is estimated that wrist devices for self-measurement have gained 50% of the market share of the 1.2 million BP measuring devices sold annually in Germany [15] and 30% of the 2 million BP measuring devices sold in annually in Japan (unpublished data totalled by Y.I.). These automated devices sold not only in Germany, but also in other European countries and the USA, are mostly made in Japan (Table 1). Some of them are sold under the names of European and US manufacturers; i.e., Original Equipment Manufacturing (OEM). The annual production of the top five manufacturers in Japan, proportion of export, proportion of wrist-cuff devices, and trade name such as OEM, are shown in Table 1. The table shows that more than one-third of the devices recently sold in the world are wrist-cuff devices. If BP values provided by wrist-cuff devices are inaccurate, the adverse influence on practice and hypertension research could be serious [3]. In the present study, wrist-cuff devices are validated and the result of the validation of wrist-cuff devices is compared with that of arm-cuff devices in the multicenter study for validation of automated devices, which was supported by the Ministry of Health and Welfare, Japan. We also studied the factors affecting the accuracy and reliability of wrist measuring devices.

Methods

The research group to assess the validity of automated BP measuring devices was established in 1993 and is

supported by the Ministry of Health and Welfare, Japan. The research group consists of 13 institutes. Three kinds of automated devices were validated; the arm-cuff device, the wrist-cuff device, and the finger-cuff device. Because the purpose of the present study was to validate the wrist-cuff device and to compare the performance between wrist-cuff and arm-cuff devices, the data on finger-cuff devices has been omitted. Two wrist-cuff devices (Omron HEM 601, WC-1; Kyoto, Japan, and Matsushita Denko EW series (270, 271 and 278); WC-2, Tokyo, Japan) and seven arm-cuff devices (Omron HEM 707; AC-1; Kyoto, Japan and A & D UA series (743, 751 and 830); AC-2; Tokyo, Japan), more than three institutes participated in the validation study. Although the models of the Matsushita Denko EW series and A & D UA series were different, information from the manufacturers confirms that the essential machinery and algorithm of a series of the devices are the same. Therefore, the results of the validation for a series of the devices were combined. Participants for validation in each device were as follows; WC-1: *n* = 173 (18–84 years, 52.2 ± 17.0 years), WC-2: *n* = 92 (21–80 years, 56.8 ± 15.4 years), AC-1: *n* = 97 (21–84 years, 56.9 ± 17.6 years), AC-2: *n* = 136 (18–80 years, 50.7 ± 17.7 years).

Validation method

The most fallible component for the validation of autonomic device is the human observer [16]. Thus, the British Hypertension Society (BHS) protocol takes particular care to ensure that observers are trained to a very high standard [16]. A major difficulty with the BHS protocol, however, is the training process of observers. Therefore, in the present study, two doctors in each institute skilled in auscultation of Korotkoff sounds participated in simultaneous auscultation using a double stethoscope [10]. To guarantee the accuracy of the auscultation, agreement of the two observer's values obtained from auscultation in each institute was estimated as the mean difference and standard deviation (SD) between the two observers' auscultation

Table 1 State of production of automated blood pressure measuring devices in 1998, in the top five manufacturers in Japan and those in Korea and Taiwan

	Total production (thousand)	Proportion of export (%)	Proportion of wrist device (%)	OEM brand
Omron Life Science (Japan)	3500	72	29	
Matsushita Denko (Japan)	670	53	8	
Nissei (Japan)	1200	100	70	Braun, Hestia
A&D (Japan)	1500	87	20	Phillips, BO-SO, Artsana, Sunbeam
Terumo (Japan)	300	0	0	
Sein Electronics (Korea)	500	97	41	B. Braun, Medisana
Jawon Medical (Korea)	350	≈95	57	Samsung USA, Samsung Deuth
Taiwan	≈1500	≈95	≈80	
Rossmax (Taiwan)	800	95	100	?

Estimated values are shown in the Table for production in Taiwan. Microlife Medical Science Asia (Taiwan) did not provide information. All information was provided directly from each manufacturer.

(observer 1 – observer 2). The reference (observer 1) to obtain the difference between the two observers was arbitrarily set in each institute but the reference observer (observer 1) was always the same in each institute. The difference between the two observers in all institutes was determined and is illustrated in a Bland–Altman plot [17].

A simultaneous measurement from a wrist-cuff device and the auscultatory method is not possible. In the present study, sequential same arm comparison was not done, but rather a crossover comparison, which was a comparison between auscultation against the mercury standard in one arm and the device in the opposite arm or wrist. This crossover method was applied for all devices. Therefore, the mean difference and distribution of difference among devices were comparable and the mean difference and SD reflect the agreement with the standard auscultation. The arm and wrist were kept at heart level using a stand or pillow during validation. The wrist was extended during validation. In each subject, simultaneous standard auscultation in one arm and measurement by the devices on the other side were performed eight times reciprocally. The two observers' measurements were averaged and used as a reference value. The average of eight differences in each subject was used as a difference for the subject. The mean difference and SD from auscultation to the device was calculated in each device in each institute. All data for one device from all institutes are illustrated as a Bland–Altman plot.

The effect of the angle of the hand joint on blood pressure value using the wrist device

For the wrist-cuff device, correction of hydrostatic pressure to maintain the hand at heart level is necessary. The question arises whether hydrostatic pressure is the sole factor to influence BP when the wrist-cuff device is used. Therefore, the device was tested with different angles of the hand joint, i.e., palmar extension, palmar flexion, and palmar dorsiflexion. The WC-1 or WC-2 was attached 1 cm below the hand joint. This study was performed in 89 subjects (43 men, 59.0 ± 11.6 years of age and 46 women, 59.7 ± 9.9 years of age) for the WC-1 and 47 subjects (22 men, 60.4 ± 11.4 years of age and 25 women, 59.8 ± 10.5 years of age) for the WC-2. In each subject, wrist BPs were measured in each position. The order of the hand position was randomly assigned.

Determination of finger plethysmogram during blood pressure measurement by the wrist-cuff device

In the standard arm-cuff method, a procedure which indicates whether the cuff pressure completely occludes the brachial artery is recommended before auscultation, i.e., palpation of radial artery. To test whether the wrist cuff can completely occlude radial

and ulnar arteries, we measured the finger plethysmogram (DE Hokanson, EC5R, Bellevue, Washington, USA) before and during cuff inflation and during cuff deflation. This test was performed in 29 subjects (16 men, 56.8 ± 8.6 years and 13 women, 58.1 ± 12.2 years) using WC-1 in palmar extension, palmar flexion, and palmar dorsiflexion, respectively.

Statistical analysis

Values are represented by mean \pm standard deviation. The individual BP values obtained using the two different methods or by two observers were evaluated for mean difference at a given BP level as described by Bland and Altman [17]. The group means were compared by Student's *t*-test.

Results

Agreement of blood pressure values obtained by the two observers

The mean differences of BP (SD) between the two observers in each institute were minimal (Table 2). Bland–Altman plots demonstrated that Korotkoff sounds were determined by the two observers with minimal difference along with a wide range of BP (Fig. 1). An overall mean difference (SD) between two observers was $-0.1 \pm 2.8/-0.1 \pm 2.6$ mmHg for SBP/DBP, respectively ($n = 498$).

Validation of arm- and wrist-cuff devices

The mean difference (SD) of BP between auscultation and each device in each institute are shown in Table 3. The mean difference (SD) of each device was different among institutes. An overall mean difference between auscultation and each device was minimal in arm-cuff devices (AC-1: $2.2/1.9$ mmHg, $n = 97$ and AC-2: $5.1/2.9$ mmHg, $n = 139$) and wrist-cuff devices (WC-1: $-2.1/1.2$ mmHg, $n = 173$ and WC-2: $-2.3/-5.6$ mmHg, $n = 92$). The SD of differences in wrist-cuff devices (WC-1: $9.7/7.3$ mmHg and WC-2: $10.2/8.6$ mmHg) was larger than that of arm-cuff devices (AC-1: $5.6/6.6$ mmHg and AC-2: $6.3/5.1$ mmHg). The difference among institutes was larger with wrist-cuff devices than with arm-cuff devices.

The Bland–Altman plot clearly demonstrated that the distribution of the difference in the AC-1, an arm-cuff device, was apparently small when compared with that in the WC-1 or the WC-2, wrist-cuff devices (Figs 2 and 3). In the AC-1, an arm-cuff device, 2.1% of systolic measurements and 10.3% of diastolic measurements were 10 and 5 mmHg higher than auscultation, respectively, and 6.2% of systolic measurements and 22.7% of diastolic measurements were 10 and 5 mmHg lower than auscultation, respectively. In the AC-2, an arm cuff device, 18.4% of the systolic measurements and 30.1% of the diastolic measurements were 10 and 5 mmHg higher than auscultation, respectively, and

Table 2 Agreement of blood pressure values obtained by two observers in each institute

Devices validated	Institute No.	n	Age (years)	Observer 1		Observer 2		Δ SBP	Δ DBP
				SBP	DBP	SBP	DBP		
WC-1	1	222	54.8 \pm 15.9	134.0 \pm 23.6	79.4 \pm 12.8	134.1 \pm 23.6	80.0 \pm 12.8	-0.1 \pm 2.6	-0.7 \pm 2.3
	2	176	40.7 \pm 16.6	125.4 \pm 20.5	80.6 \pm 14.7	125.1 \pm 20.4	80.4 \pm 14.3	0.4 \pm 3.3	0.2 \pm 2.8
	3	232	46.4 \pm 16.4	124.6 \pm 18.3	72.6 \pm 14.7	124.0 \pm 18.5	71.6 \pm 14.4	0.6 \pm 2.7	1.0 \pm 2.8
	5	191	47.8 \pm 18.1	123.7 \pm 20.0	78.1 \pm 14.2	123.5 \pm 19.4	78.4 \pm 14.1	0.2 \pm 2.6	-0.3 \pm 2.5
	6	176	58.4 \pm 13.2	134.0 \pm 23.7	82.1 \pm 11.6	134.0 \pm 22.9	82.6 \pm 11.6	0.0 \pm 4.3	-0.4 \pm 2.7
	11	240	63.5 \pm 11.0	148.3 \pm 21.2	81.7 \pm 12.0	148.6 \pm 21.2	82.2 \pm 11.8	-0.3 \pm 3.7	-0.4 \pm 3.1
	12	80	52.9 \pm 11.6	129.5 \pm 21.1	81.3 \pm 13.9	129.9 \pm 20.7	81.2 \pm 13.6	-0.4 \pm 3.0	0.0 \pm 2.9
WC-2	6	192	60.3 \pm 9.1	132.1 \pm 20.4	80.5 \pm 10.3	132.3 \pm 20.1	81.4 \pm 10.3	-0.3 \pm 3.5	-1.0 \pm 2.9
	7	232	54.3 \pm 19.7	124.0 \pm 21.4	75.8 \pm 13.2	124.5 \pm 21.7	75.9 \pm 13.3	-0.5 \pm 1.8	-0.1 \pm 1.8
	8	136	54.8 \pm 17.2	145.0 \pm 26.4	86.6 \pm 18.1	145.8 \pm 26.5	86.5 \pm 18.5	-0.7 \pm 2.1	-0.9 \pm 2.9
	9	152	61.2 \pm 7.3	150.0 \pm 16.8	88.8 \pm 8.8	150.0 \pm 16.7	88.4 \pm 8.6	-0.1 \pm 0.9	0.4 \pm 1.4
AC-1	2	263	43.7 \pm 16.7	125.8 \pm 22.6	81.2 \pm 12.5	125.9 \pm 21.6	80.0 \pm 12.2	-0.1 \pm 3.3	0.2 \pm 2.3
	10	264	63.6 \pm 15.5	135.4 \pm 22.4	74.8 \pm 13.0	135.4 \pm 22.3	74.9 \pm 12.7	0.0 \pm 2.3	0.0 \pm 2.3
	11	248	64.1 \pm 11.3	153.3 \pm 23.5	82.3 \pm 12.2	153.8 \pm 23.3	82.1 \pm 12.0	-0.5 \pm 3.2	0.2 \pm 2.8
AC-2	1	240	55.7 \pm 15.8	138.5 \pm 25.3	78.9 \pm 12.9	138.9 \pm 25.5	79.8 \pm 12.7	-0.4 \pm 2.6	-0.9 \pm 2.8
	3	240	45.8 \pm 16.5	125.7 \pm 20.4	73.2 \pm 14.8	125.0 \pm 20.4	72.4 \pm 15.1	0.7 \pm 2.3	0.8 \pm 2.6
	5	185	47.2 \pm 17.4	127.8 \pm 21.5	81.8 \pm 13.3	127.8 \pm 21.2	81.3 \pm 12.9	0.0 \pm 2.6	0.5 \pm 2.4
	7	229	54.3 \pm 19.8	125.1 \pm 22.9	76.3 \pm 13.1	125.8 \pm 23.0	76.8 \pm 13.4	-0.7 \pm 1.8	-0.5 \pm 1.9
	8	112	51.8 \pm 15.5	139.3 \pm 26.7	87.9 \pm 18.4	139.7 \pm 26.9	88.1 \pm 18.8	-0.4 \pm 2.3	-0.3 \pm 2.9

SBP, systolic blood pressure; DBP, diastolic blood pressure; Δ BP, observer 1–observer 2; WC, wrist-cuff device; AC, arm-cuff device; WC-1, Omron HEM 601; WC-2, Matsushita Denko EW series; AC-1, Omron HEM 707; AC-2, A & D UA series; n, all measurement number.

2.9% of the systolic measurements and 5.9% of diastolic measurements were lower than auscultation, respectively. In the WC-1, a wrist-cuff device, 19.7% of the systolic measurements and 16.2% of diastolic measurements were 10 and 5 mmHg higher than auscultation, respectively, and 11.6% of the systolic measurements and 25.4% of the diastolic measurements were 10 and 5 mmHg lower than auscultation, respectively. In the WC-2, a wrist device, 25.0% of systolic measurements and 42.4% of diastolic measurements were 10 and 5 mmHg higher than auscultation, respectively, and 7.6% of systolic measurements and 7.6% of diastolic measurements were 10 and 5 mmHg lower than auscultation, respectively. If BHS protocol criteria [16] is applied to these data to give only an impression for the level of device accuracy in comparison to previous results, AC-1 is graded as A/A, AC-2 as B/A, WC-1 as C/B and WC-2 as D/B. In the AC-2, an arm-cuff device, the mean difference was significantly larger ($P < 0.001$) than that in the AC-1. However, the distribution of difference in AC-2 was similar to that in AC-1 and apparently small when compared with that in WC-1 or WC-2 (Figs 2 and 3).

Effect of angle of hand joint on blood pressure obtained using wrist-cuff devices

In the WC-1, a wrist-cuff device, BP measured in palmar flexion was significantly higher ($n = 84$, flexion-extension, SBP, 4.1 ± 7.9 mmHg; DBP, 0.5 ± 5.8 mmHg) than that measured in palmar extension (SBP, $P < 0.001$), whereas the BP measured in palmar dorsiflexion was significantly lower than that in palmar extension ($n = 88$, dorsiflexion-extension, SBP, -4.2 ± 10.7 mmHg; DBP, -6.3 ± 6.6 mmHg) (Fig. 4, SBP,

$P < 0.01$; DBP, $P < 0.001$). Such result was also observed in the WC-2 ($n = 47$, flexion-extension: SBP, 10.9 ± 13.9 mmHg; DBP, 5.0 ± 12.1 mmHg, $P < 0.001$, dorsiflexion-extension: SBP, -2.6 ± 12.8 mmHg; DBP, -5.2 ± 8.2 mmHg, $P < 0.001$).

Determination of the finger plethysmogram during blood pressure measurement by the wrist-cuff device

In palmar extension, the finger plethysmogram did not disappear during maximum inflation of cuff pressure ($\cong 250$ mmHg) in two of 29 subjects. In palmar flexion, the finger plethysmogram did not disappear during maximum inflation of cuff pressure in six of 29 subjects, whereas in palmar dorsiflexion the finger plethysmogram did not disappear in only one of 29 subjects.

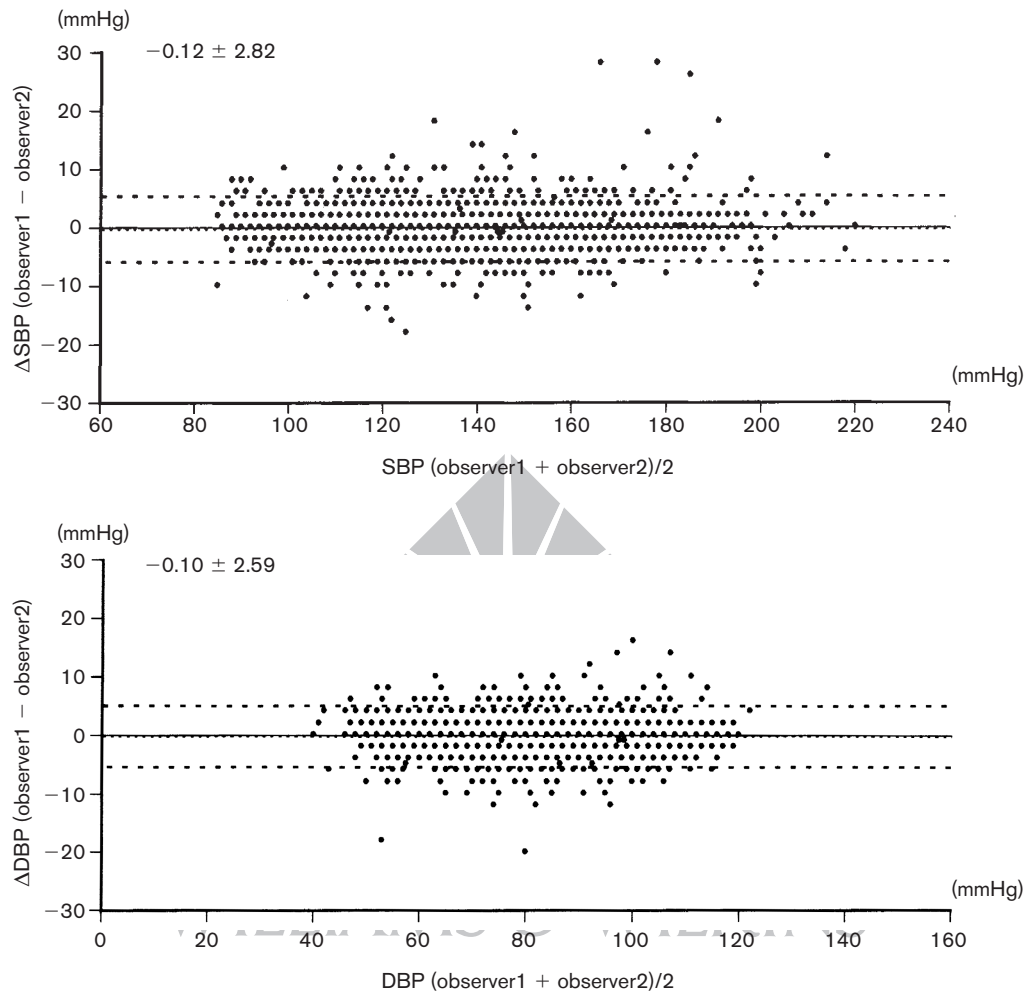
Discussion

Under stringently controlled validation conditions, wrist-cuff devices for self-measurement of BP were determined to be inaccurate and unreliable when compared to arm-cuff devices.

Validation procedure

Simultaneous same arm validation is not possible with wrist devices. Thus, in the present study, a crossover method was used. A sequential method may improve the finding of all tested devices. A possible cause of bias or error is the validation procedure (crossover method) *per se*. If such factors influence the results of the validation, all devices validated would be influenced equally because all devices were validated using the same protocol. Thus, comparison among devices is possible.

Fig. 1



Agreement of blood pressure values obtained by two observers. Δ BP: observer 1 – observer 2, horizontal line: (observer 1 + observer 2)/2. Dashed lines represent mean \pm 2 SD ($n = 498$).

Accuracy of wrist-cuff devices

The present study demonstrated that the SD of the mean difference between auscultation and the wrist-cuff device was extremely large when compared [18] with that between auscultation and arm-cuff device. On the basis of Association for the Advancement of Medical Instrumentation (AAMI) and BHS criteria, both arm-cuff devices were appropriate for clinical use but both wrist-cuff devices were not. This large SD was observed both for the WC-1 and WC-2 wrist-cuff devices. As shown in Table 1, the number of wrist-cuff devices in use is rapidly increasing. This tendency is serious for clinical practice, clinical science, and public health. BP obtained by auscultation was higher by more than 10/5 mmHg (SBP/DBP) than that obtained by wrist-cuff devices in 10.1/19.2% of subjects, respectively, and was lower by more than 10/5 mmHg than that obtained by wrist-cuff devices in 21.5/25.2% of

subjects, respectively. If subjects define their BP level on the basis of a wrist-cuff device, a large proportion of subjects were judged to be as hypertensive and normotensive, although they are actually normotensive and hypertensive, respectively. Such an inappropriate definition of hypertension and normotension, as determined using wrist-cuff devices, is a serious public health problem, e.g. the unnecessary burden of medical cost, side-effect of drug treatment, and deterioration of quality of life by overestimation, while unresolved risk for cardiovascular complications and target organ damage due to underestimation. Probably the influence on clinical pharmacologic, epidemiologic, and physiologic research could be serious.

Institutional differences in the validation results

Even under the stringently controlled protocol of the present study, the results of the validation for each

Table 3 Agreement of blood pressure values obtained by observer and devices in each institute

Devices validated	Institute No.	n	Average of two observer		Device			
			SBP	DBP	SBP	DBP	Δ SBP	Δ DBP
WC-1	1	222	134.4 \pm 23.7	79.8 \pm 12.6	133.7 \pm 23.1	75.5 \pm 11.8	0.7 \pm 8.4	4.2 \pm 5.5
	2	176	125.3 \pm 19.9	80.5 \pm 14.2	123.5 \pm 18.8	75.7 \pm 13.5	1.8 \pm 10.1	4.8 \pm 8.0
	3	232	124.3 \pm 18.2	72.1 \pm 14.0	126.8 \pm 19.6	70.9 \pm 13.3	-2.5 \pm 7.1	1.2 \pm 6.1
	5	191	123.6 \pm 19.0	78.4 \pm 13.7	130.1 \pm 19.6	78.4 \pm 13.7	-6.4 \pm 7.5	0.1 \pm 5.6
	6	176	134.0 \pm 22.1	82.4 \pm 10.1	142.8 \pm 17.6	90.1 \pm 10.2	-8.8 \pm 8.9	-7.8 \pm 7.0
	11	240	148.4 \pm 20.7	82.0 \pm 11.4	147.6 \pm 21.9	79.9 \pm 12.3	0.9 \pm 12.6	2.1 \pm 6.7
	12	80	129.7 \pm 21.3	81.2 \pm 14.2	127.0 \pm 19.4	76.4 \pm 12.7	2.7 \pm 3.7	4.8 \pm 3.3
WC-2	6	192	132.2 \pm 18.3	81.0 \pm 9.6	140.7 \pm 18.3	94.0 \pm 12.9	-8.5 \pm 9.9	-13.1 \pm 8.7
	7	232	123.1 \pm 20.9	74.7 \pm 13.5	120.4 \pm 20.0	78.4 \pm 15.0	2.7 \pm 7.0	-3.7 \pm 4.9
	8	136	145.4 \pm 26.4	86.1 \pm 18.0	150.1 \pm 25.6	87.3 \pm 22.9	-4.7 \pm 12.2	-1.2 \pm 10.3
	9	152	149.6 \pm 16.8	88.6 \pm 8.6	150.3 \pm 20.9	91.8 \pm 9.9	-0.7 \pm 8.9	-3.2 \pm 5.9
AC-2	2	263	125.7 \pm 21.0	80.0 \pm 11.3	121.9 \pm 19.8	73.4 \pm 12.2	3.8 \pm 6.5	6.7 \pm 7.8
	10	264	135.4 \pm 22.2	74.8 \pm 12.6	135.0 \pm 23.9	75.3 \pm 13.1	0.4 \pm 5.0	-0.4 \pm 4.4
	11	248	153.5 \pm 22.6	82.2 \pm 11.6	151.2 \pm 22.0	82.9 \pm 11.3	2.3 \pm 4.6	-0.7 \pm 4.1
AC-2	1	240	138.7 \pm 25.3	79.3 \pm 12.7	131.5 \pm 23.0	75.9 \pm 12.2	7.2 \pm 5.1	3.4 \pm 6.3
	3	240	125.4 \pm 20.1	72.8 \pm 14.5	119.0 \pm 21.9	69.8 \pm 13.0	6.3 \pm 7.2	3.0 \pm 4.4
	5	185	127.7 \pm 19.5	81.4 \pm 12.9	124.9 \pm 19.6	78.3 \pm 12.6	2.8 \pm 5.8	3.0 \pm 4.8
	7	229	123.8 \pm 22.2	75.0 \pm 13.7	119.2 \pm 22.0	73.2 \pm 12.8	4.7 \pm 3.3	1.8 \pm 3.6
	8	112	139.5 \pm 26.8	88.0 \pm 18.6	135.8 \pm 22.0	84.8 \pm 18.6	3.7 \pm 10.2	3.2 \pm 7.0

SBP, systolic blood pressure; DBP, diastolic blood pressure; Δ BP, average of two observers - device; WC, wrist-cuff device; AC, arm-cuff device; WC-1, Omron HEM 601; WC-2, Matsushita Denko EW series; AC-1, Omron HEM 707; AC-2, A & D UA series; n, all measurement number.

device were different among institutes. Such inconsistency among institutes might be derived from different observers and different subjects in each institute. In the present study, the agreement of BP values by auscultation between two observers in each institute was excellent, suggesting that the influence of observer bias on the institutional difference would be minimal, although the possibility remains that some of the differences with agreement lie in technical difficulties with observers, rather than the differences with devices. Furthermore, a certain systematic error is assumed in some institutes. The most possible explanation is an inappropriate correction of difference in hydrostatic pressure between heart and cuff. A 10 cm difference between heart and cuff is equivalent to 7 mmHg difference. Although the study protocol strictly regulated the arm cuff level to keep at heart level using stand or pillow, a certain difference of hydrostatic pressure is possible to be remained among institutes. This difference may affect mean difference of BP between auscultation and wrist-cuff device among institutes. However, this difference of hydrostatic pressure does not affect the SD of difference. A correction of hydrostatic pressure is the most important issue when subjects use a wrist-cuff device properly. If a large institutional difference is mediated by an inappropriate correction of hydrostatic pressure, BP provided using a wrist-cuff device would become larger in daily use than in the validation study. Thus, it is possible that this difference of hydrostatic pressure seriously affects BP value.

It is assumed that the subjects' characteristics in each institute, influence the result of validation. The BHS protocol and AAMI guideline, however, strictly controls

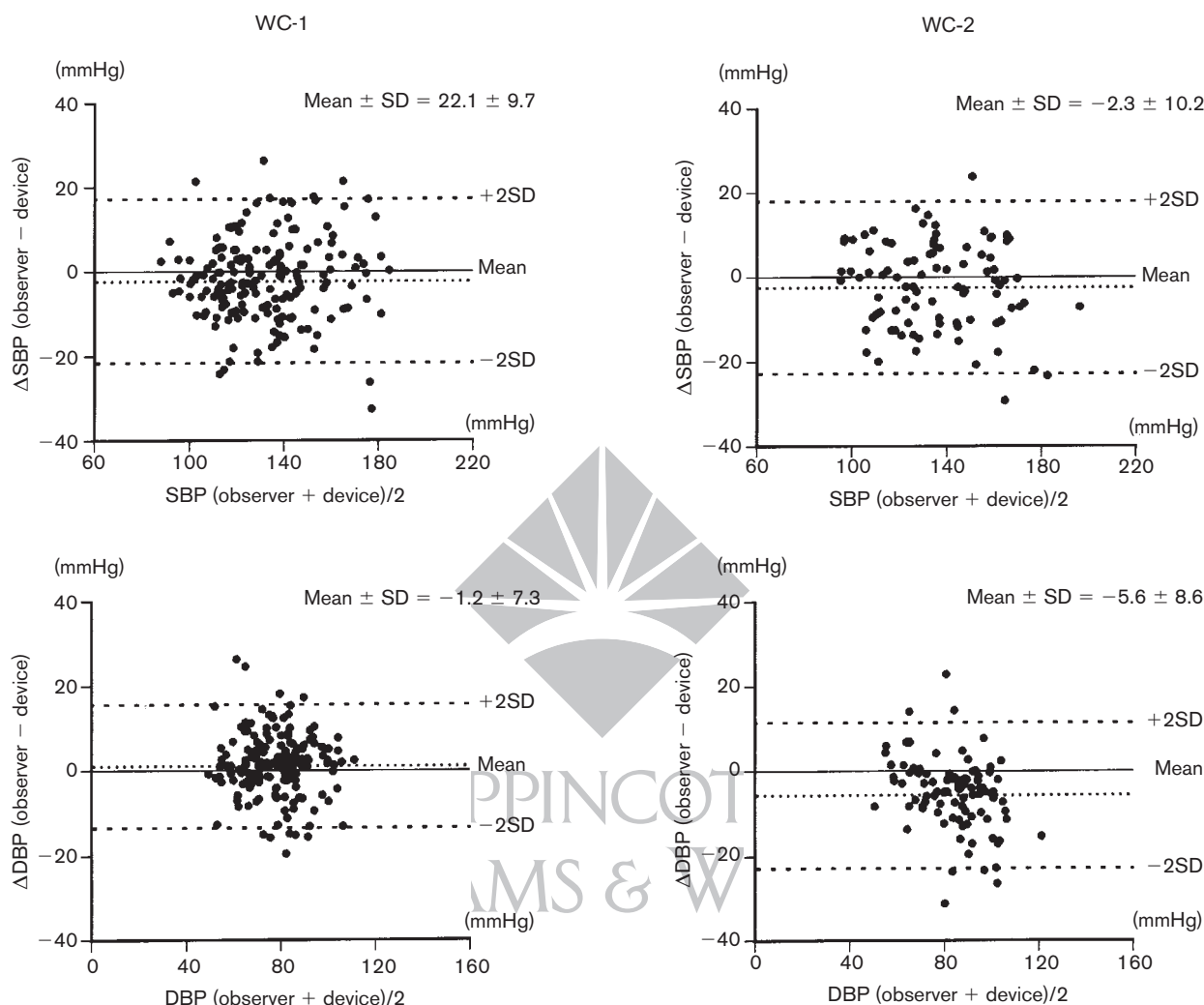
the age, number of subjects, and BP range of subjects validated [16,18]. Actually in the present validation study, the BP range validated was rather narrow, especially in DBP. The accuracy of the device has been shown to deteriorate with increasing BP [12]. Since less than 10% of study participants had SBP \geq 180 mmHg and DBP \geq 100 mmHg in the present study, this deviation of study participants may have affected the results in favour of the device, while this is an important bias for the validation to be considered.

After following a strict protocol, the results of validation from one institute may reflect the accuracy of the device. At present, however, it is recommended that a device should be validated by different institutes according to an authorized protocol, such as BHS, where the training of observers has great emphasis. Manufacturers are responsible for this validation process and should publish it for consumers as well as practitioners.

Problem on the cuff-oscillometric principle

In the validation of the automated devices, we should be concerned about how SBP and DBP are defined in the cuff-oscillometric principle. The cuff-oscillometric method detects the mean arterial pressure [18,19] and essentially cannot provide the SBP and DBP. During the cuff deflation, the pulse wave transmitted to the cuff gradually increases and peaks at the mean arterial pressure [18,19] and then decreases again during further deflation. The SBP and DBP are approximately estimated as the points where the profile of differentiated pulse wave rises and falls, respectively, although no theoretically approved algorithm has been estab-

Fig. 2



Agreement of blood pressure values obtained by observer and the wrist-cuff device. WC-1: Omron HEM 601, WC-2: Matsushita Denko EW series. Δ BP, observer – device; horizontal line, (observer + device)/2.

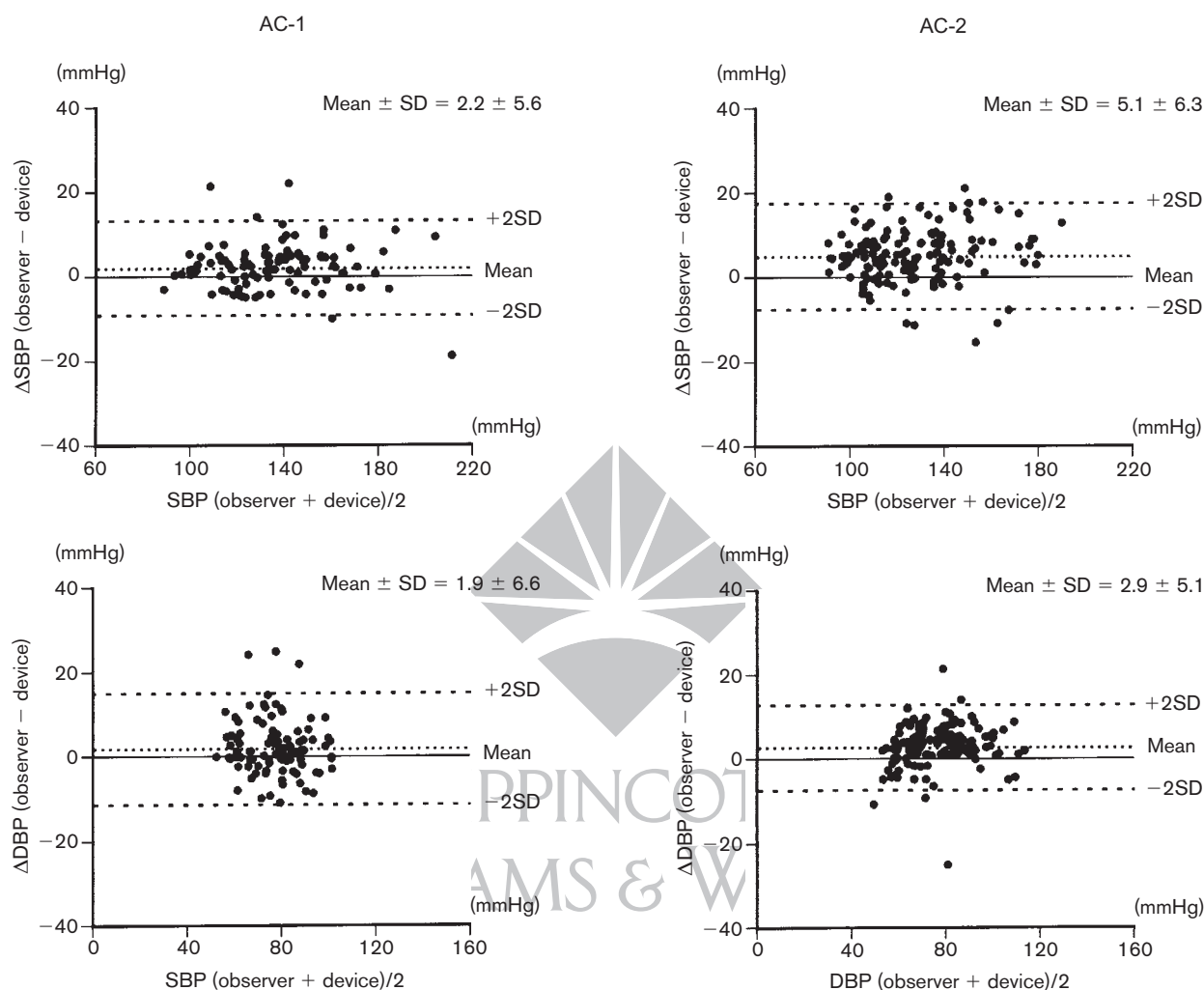
lished. Each manufacturer modifies the algorithm on the basis of Korotkoff sounds to make the SBP and DBP by cuff-oscillometric principles. Therefore, the mean difference of BP between auscultation method and the cuff-oscillometric device is minimal, even when using the wrist-cuff device.

Mechanism underlying the inaccuracy of wrist-cuff devices

Why do wrist-cuff devices provide such a wide range of distribution of differences? The present multi-center study was performed under the same protocol for each device and in each institute. The correction of hydrostatic pressure (the position of the wrist in relation to the heart) in the wrist-cuff device was strict. Therefore, it seems that factors other than hydrostatic pressure, influence the difference between auscultation and

wrist-cuff devices. One of the possible mechanisms depends on the anatomy of the wrist. In the present study, the wrist-cuff did not necessarily occlude the radial and/or ulnar artery, even with enough cuff pressure. This might be due to the relation among the longitudinal palmar tendon, wrist arteries, and radius and ulna. Because in cuff-oscillometric devices, arterial pressure is defined on the basis of an algorithm (see the discussion on the problem of cuff-oscillometric principle), BP values would be provided if radial and/or ulnar arteries were insufficiently occluded. In the present study, all SBP values recorded by wrist-cuff devices in nine cases, in whom incomplete occlusion of wrist arteries was supposed, were higher than those by the auscultatory method. Insufficient occlusion of wrist arteries depends on the subjects and frequently on the

Fig. 3



Agreement of blood pressure values obtained by observer and the arm-cuff device. AC-1: Omron HEM 707, AC-2: A & D UA series. Δ BP, observer - device; horizontal line, (observer + device)/2.

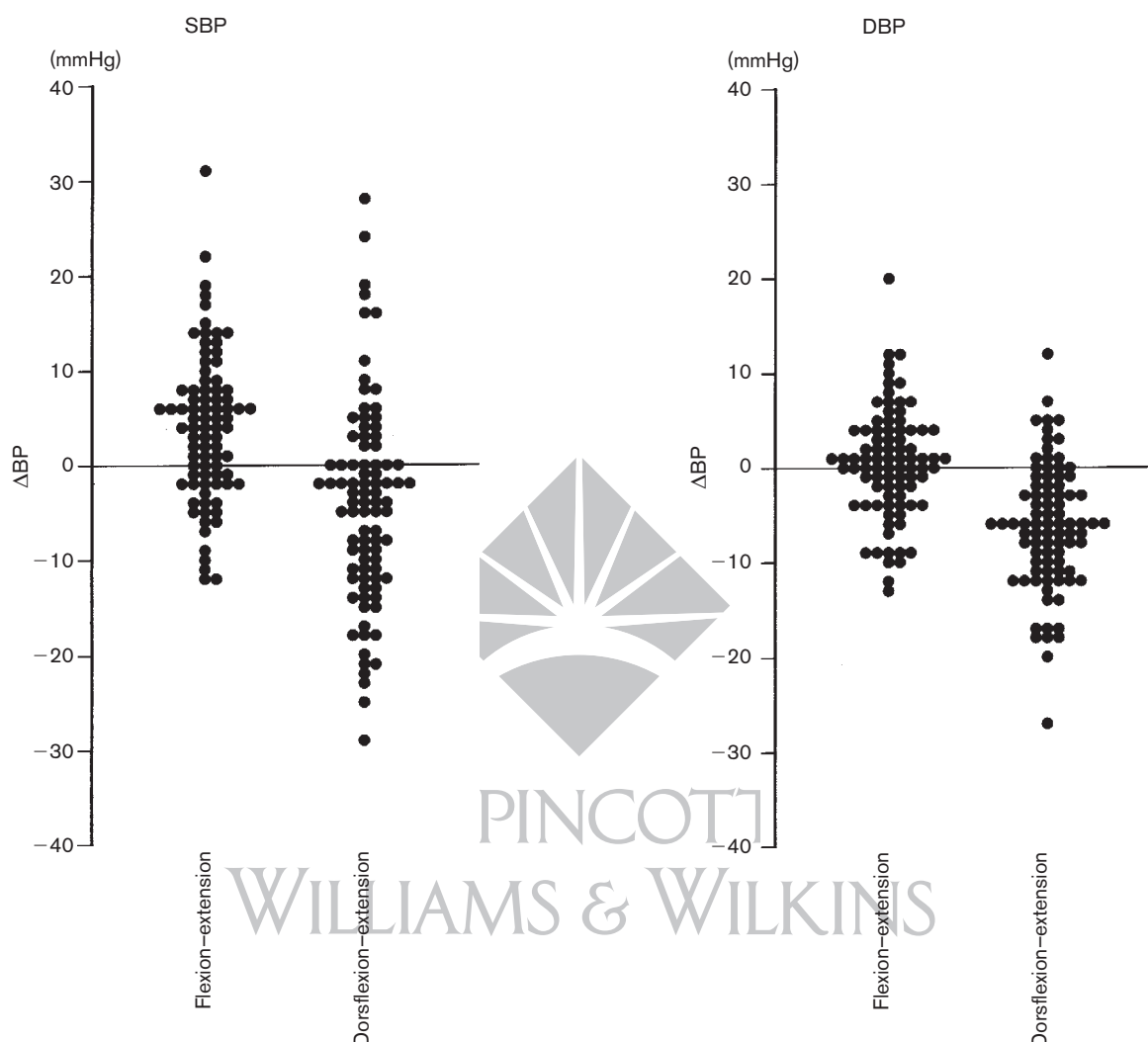
angle of the hand joint. The arteriosclerotic vascular changes in radial and ulnar arteries might be the remaining possible mechanism for the large difference between auscultation and the wrist-cuff device [19,20]. Furthermore, the relation between cuff and thickness of wrist and fitness of cuff still seems to be a factor affecting BP levels measured by wrist-cuff devices. Such factors, in addition to the position of the wrist in relation to the heart, can induce a large SD of the difference between auscultation and wrist-cuff devices.

Recommendation and conclusion

In a certain proportion of subjects, wrist-cuff devices provide BP values equivalent to those obtained using arm-cuff devices. Under stringently controlled conditions, however, BP values provided by wrist-cuff devices differed by more than $\pm 10/\pm 5$ mmHg from auscultation in a large proportion of subjects. Further-

more, it is doubtful that users can strictly control the measurement conditions during measurements by wrist-cuff devices, such as the position of the wrist, angle of the hand joint and fitness of cuff. Thus the divergence between BP estimated by auscultation and BP provided using a wrist-cuff device would become larger in daily use than that in the validation study. Therefore, it is concluded that wrist-cuff devices for self-measurement of BP in the present form are inadequate for self-measurement of BP and, thus, are inadequate for general use or clinical and practical use. There are some positive aspects of wrist-cuff devices however, e.g. in patients with obese arms; they may actually give more accurate readings than arm devices. We must refer to the limitation of this multicenter validation study, e.g. incomplete application of BHS protocol and AAMI guidelines, including the limited range of BP values validated. However, there are many

Fig. 4



Effect of angle of hand joint on blood pressure obtained using wrist-cuff device. Δ BP: palmar flexion or dorsiflexion – palmar extension.

possibilities for the wrist-cuff device and the accuracy and reliability of the wrist-cuff device will be warranted by an advancement of technology.

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Appendix

Research Group to Assess the Validity of Automated Blood Pressure Measurement Devices in Japan.

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