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The first study comparing a wearable watch-type blood pressure monitor with a conventional ambulatory blood pressure monitor on in-office and out-of-office settings

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Abstract

Wearable blood pressure (BP) monitoring devices which measure BP levels accurately both in and out of the office are valuable for hypertension management using digital technology. The authors have conducted the first comparison study of BPs measured by a recently developed wrist-worn watch-type oscillometric BP monitoring (WBPM) device, the "HeartGuide," versus BPs measured by an ambulatory BP monitoring (ABPM) device, A&D TM-2441, in the office (total of 4 readings alternately measured in the sitting position) and outside the office (30-minutes interval measurements during daytime) in 50 consecutive patients (mean age 66.1 ± 10.8 years). The 2 BP monitoring devices were simultaneously worn on the same non-dominant arm throughout the monitoring period. The mean difference (±SD) in systolic BPs (average of 2 readings) between WBPM and ABPM was 0.8 ± 12.8 mm Hg (P = .564) in the office and 3.2 ± 17.0 mm Hg (P < .001) outside the office. The proportion of differences that were within ±10 mm Hg was 58.7% in the office and 47.2% outside the office. In a mixed-effects model analysis, the temporal trend in the difference between the out-of-office BPs measured by the two devices was not statistically significant. In conclusion, the difference between the WBPM and ABPM device was acceptable both in and out of the office.

1 | INTRODUCTION

Recent guidelines recommended increased use of out-of-office blood pressure (BP) measurement to aid the management of hypertension.[1-3] Ambulatory BP monitoring (ABPM) and home BP monitoring (HBPM) are 2 accepted out-of-office BP measurement methods available in clinical practice. However, the number of BP measurements that can be collected using these two methods is limited. A wearable BP monitoring device which could measure BP levels both in and out of the office would be valuable for the long-term management of hypertension, particularly in an era of digital communications. Recently, there has been increased interest in the development of cuffless BP monitoring devices, and a few such devices are currently sold on the market.[4-9] However, these devices indirectly estimate BP but do not directly measure BP.[4-9] The reliable direct measurement of BP is critically important for hypertension management in clinical practice.

A wearable wrist-type BP monitoring device, the "HeartGuide," was developed to directly measure BP values using the oscillometric method. This device has a position sensor which assesses and ensures that the

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wrist is appropriately positioned within a range around the heart level during BP measurement (Figure 1). The HeartGuide device was recently validated in the laboratory environment according to the protocol from the American National Standards Institute, Inc/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 guideline.[10] However, no study has previously compared the HeartGuide device, or any other wrist-worn watch-type oscillometric BP monitoring (WBPM) device, with ABPM, the reference standard, for both office and out-of-office settings.

We have conducted this first study to compare WBPM using the HeartGuide device and traditional ABPM in-office and out-of-office settings among adult 50 outpatients.

2 | METHODS

2.1 | Study population

Adult outpatients (24-87 years old) who were scheduled to conduct ABPM in their clinical practice were consecutively recruited at Jichi Medical University Hospital. The study protocol was approved by the institutional review board of Jichi Medical University School of Medicine (rin-B18-030). The study protocol was registered on a clinical trial registration site (University Hospital Medical Information Network Clinical Trials Registry, UMIN000036689). All participants provided written informed consent.

2.2 | BP measurement devices

The HeartGuide device (Omron Healthcare Co., Ltd.) is a patient-self-initiated automatic oscillometric device for measuring BP at the wrist. We used the HeartGuide device cuff size that is appropriate for those with wrist circumferences in the range of 16.0-19.0 cm (HEM-6410T), or a larger cuff (HEM-6410T-ZL) suitable for those with a wrist circumference of 18.0-21.5 cm is also available. The "HeartGuide" device was previously validated in the laboratory setting.[10] ABPM was measured by using the TM-2441 (A&D Company), an automatic oscillometric device with a BP cuff worn on the upper arm. The TM-2441 was previously validated in accordance with the ISO810602:2013 protocol.[11] The HeartGuide device is self-activated, and the wrist should be at the heart level when BP is measured to reduce hydrostatic effects (Figure 1).

2.3 | Definition of "expected difference" in the comparison study

There is the international ANSI/AAMI/ISO 81060-2:2013 guideline for the validation study (Criterion 1: Mean and standard deviation (SD) for the difference of the device minus the observer BP measurements ≤±5 and ≤8 mm Hg, respectively). However, there is no definition of what is acceptable when comparing two different devices. Thus, we propose the new definition of the "expected difference" between the two devices in the comparison study is calculated as $(SD^2 \text{ of device } 1 + SD^2 \text{ of device } 2)^{0.5}$, where SD is the same SD for the difference between a device and observer BP measurements. In the first validation study of the HeartGuide, performed according to the international ANSI/AAMI/ISO 81060-2:2013 guideline, the difference in the systolic BP (SBP) between WBPM and the standard auscultation method was −0.9 ± 7.6 mm Hg for the medium-sized cuff (Criterion 1).[10] In the validation study of the TM-2441 (A&D) used in this comparison study, the accuracy was also acceptable (the difference in the SBP between TM-2441 and the standard auscultation method was −0.8 ± 6.46 mm Hg) (Criterion 1).[11] If auscultatory reading is the gold standard, and the SD of differences scores of the two devices is 7.6 and 6.46 mm Hg, then the expected SD of the difference between WBPM and ABPM would be $(7.6^2 + 6.46^2)^{0.5} = 9.97$. Thus, in this study, we calculated the proportion of the difference within ±10 mm Hg.

2.4 | BP measurement protocol

WBPM and ABPM were worn on the same non-dominant arm. The BP measurement procedure consisted of two parts: Study 1 in the office and Study 2 in the out-of-office condition (Figure 2).

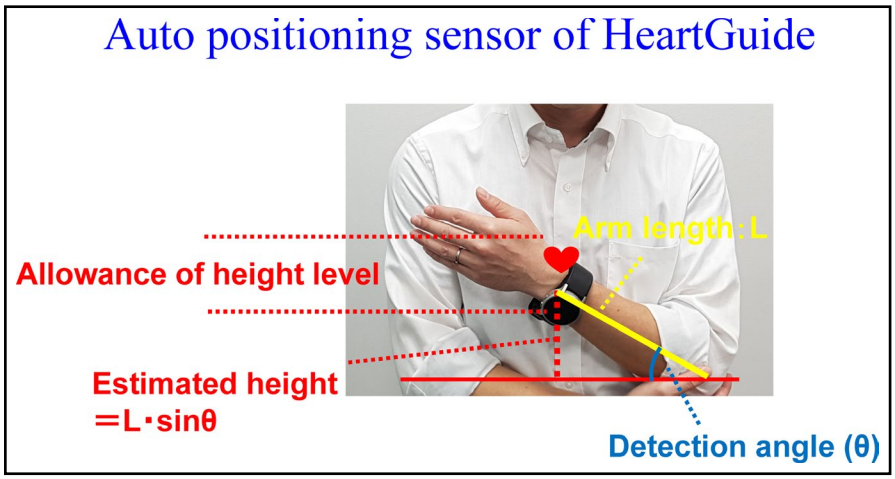


FIGURE 1 Auto-positioning sensor of HeartGuide. HeartGuide will vibrate automatically when the device is set within same height level to heart (within allowance of height level range defined by the upper and lower detection angles)

2.4.1 | Study 1 (office condition)

Patients were seated and wearing the WBPM and ABPM devices. BP readings were taken twice by each device (total of 4 readings, alternating between devices) with the ABPM device first; readings were triggered by trained research staff at 30- to 60-second intervals.

2.4.2 | Study 2 (ambulatory condition)

After the measurements in Study 1 (office condition), all participants were instructed on how to use the WBPM device according to a standardized protocol (Figure S1A, B). Then, 24-hour ABPM, with measurements taken every 30 minutes, was initiated. Patients were instructed to self-measure WBPM just after automatic ABPM measurement at least 10 times while awake.

2.5 | Self-report diary

Patients were provided a diary in which they were asked to answer questions about their situation, activities, feelings, and body position at the time of each awake BP measurement during the 24-hour monitoring period. Sitting and non-sitting conditions are separated by this self-reported diary.

2.6 | Statistical analysis

All statistical analyses were performed using SAS version 9.4 (SAS Institute). Pairwise differences between WBPM and ABPM in-office BP readings were tested using a paired *t* test. Mixed-effects repeated-measures models were used to compare the BP readings measured by the two devices for the out-of-office BP measurements (Study 2). The mixed-effects repeated-measures model included the device, reading (1st, 2nd, 3rd,..., 15th), and the interaction between the device and reading as fixed effects.

All the data processing and analysis were independently conducted in the Global Analysis Center of BP (GAP) at the Jichi Medical University COE Cardiovascular Research and Development (JCARD) Center.

3 | RESULTS

3.1 | Participant characteristics

The characteristics of the participants are shown in Table 1. The mean age was 66.1 ± 10.8 years, 60% were male, and the average body mass index (BMI) was 23.4 ± 4.8 kg/m^2. The prevalence of regular alcohol use, current smoking, hypertension, and antihypertensive medication use was 30%, 4%, 98%, and 94%, respectively.

3.2 | Comparison in the office setting

According to the office BP measurement procedure, two alternating pairs of BP readings (ABPM followed by WBPM) were taken for each participant: 92 paired BP readings from 50 patients were available for analysis, as there were 8 instances for which either ABPM or WBPM failed to obtain a valid reading.

The mean SBP measured by WBPM and ABPM was 132.8 ± 17.4 and 132.0 ± 17.1 mm Hg, respectively, and there was no significant difference between WBPM and ABPM in mean SBP (0.8 ± 12.8 mm Hg, P = .564) (Table 2). The proportion of paired readings for which the SBP difference was within ±10 mm Hg was 58.7% of the total readings.

The mean diastolic BP (DBP) measured by WBPM and ABPM was 78.9 ± 10.3 and 82.1 ± 9.7 mm Hg, respectively. The difference between WBPM and ABPM in mean DBP was −3.2 ± 8.7 mm Hg (P < .001). The proportion of paired readings for which the DBP difference was within ±10 mm Hg was 75.0% of the total readings.

The correlation between WBPM and ABPM was strong for both SBP and DBP (0.73 and 0.63, respectively) in the data of 92 pairs. When comparing the average of the 2 WBPM readings to the average of the 2 ABPM readings, the correlations were 080 and 0.70 for SBP and DBP, respectively, for the 50 patients.

3.3 | Comparison in the out-of-office setting

In total, the 50 participants triggered 1509 WBPM BP measurements, of which 1283 were successfully obtained and stored in the device: The mean percentage of successful measurements per participant was 86.7%. A total of 956 paired measurements of ABPM followed by WBPM were successfully obtained from the 50 participants.

The difference in BP between matched WBPM and ABPM readings was 3.2 ± 17.0 mm Hg (P < .001) for SBP and −3.2 ± 11.3 mm Hg for DBP (P < .001) (Table 3). The proportion of differences that were within ±10 mm Hg was 47.2% for SBP and 70.3% for DBP of the total readings.

As determined by participant diary, 635 paired readings were taken in the sitting position. The BP differences between WBPM and ABPM were comparable in both sitting (n = 635) and non-sitting (n = 321: standing [n = 151], supine [n = 36], unknown [n = 134]) conditions (Table 3, Table S1).

3.4 | Mixed-effects analysis of temporal trend in out-of-office BP data

The mean number of paired (ABPM following by WBPM) measurements per participant was 19.1 ± 7.5. A mixed-effects repeated-measures analysis using the first 15 pairs of readings per participant was performed in order to compare the difference between WBPM and ABPM at each time point (Figure 3, Figure S2). The SBP

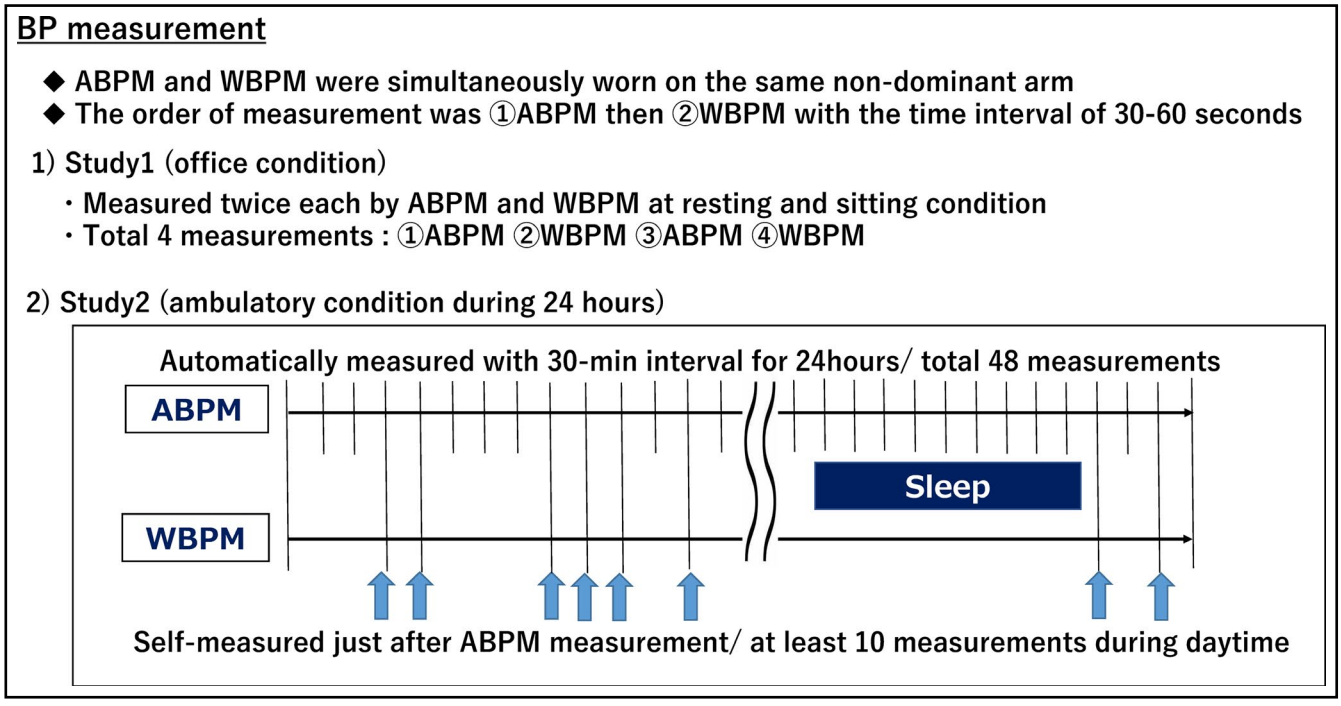


FIGURE 2 Study protocol

difference between WBPM and ABPM was 9.90 mm Hg higher in WBPM for the first pair ($P < .001$) and 5.62 mm Hg for the 2nd pair ($P = .056$). The estimated mean SBP difference, across all time points, was 3.1 mm Hg ($P < .001$), consistent with the result of the *t* test reported in Table 3. The lower DBP by WBPM than ABPM remained significant (Figure S2). The interaction between device and time points was not statistically significant for either SBP (after ignoring the first two pairs) or DBP.

TABLE 1 Patient characteristics

Variables	N = 50
Age, years	66.1 ± 10.8
Male, %	60
Body mass index, kg/m^2	23.4 ± 4.8
Current smoker, %	4
Regular drinker, %	30
Hypertension, %	98
Antihypertensive medication, %	94
Cardiovascular disease, %	
Angina	10
Myocardial infarction	4
Aortic dissection	4
Stroke	2
Heart failure	6

Note: Values are mean ± standard deviation or % patients.

4 | DISCUSSION

To our knowledge, this is the first study to compare WBPM using an oscillometric device (HeartGuide) and traditional ABPM. The results indicate that the mean difference between the WBPM and ABPM was acceptable in both the office and out-of-office settings.

4.1 | Office condition

The mean difference in SBP between WBPM and ABPM was 0.8 mm Hg ($P = .564$) in the office condition. While the mean SBP difference between the two devices was quite good, the DBP measured by WBPM was 3.2 mm Hg lower than that by ABPM, probably due to the different BP algorithms used in the two devices. Another possibility is that the hyperemia induced by brachial cuff inflation may have affected the diastolic BP-dominant decrease in the distal portion of the same arm (wrist). This difference may also be partly explained by the amplification of pulse pressure between brachial and radial arteries.

4.2 | Ambulatory condition

The mean difference in SBP between WBPM and ABPM was 3.2 mm Hg (higher for WBPM than for ABPM, $P < .001$) in the ambulatory condition. In the mixed-effects analysis, this difference (after ignoring the first two pairs of readings) was almost the same 3.1 mm Hg. No out-of-office BP device has ever been validated against auscultatory readings in the ambulatory setting. Thus, we did not

know what difference between the device and auscultatory readings to expect. This difference may partly be due to lower positioning of the WBPM device during self-measurement in the ambulatory condition. Theoretically, being 5 cm below heart level would account for the 3.5 mm Hg higher SBP by WBPM (hydrostatic pressure). The self-BP measurement of the HeartGuide is only accurate when the device is positioned at heart level. In this study, participants were asked to shift WBPM device from the lower position to the upper position to set the position of WBPM device. Specifically, they were asked to raise their arm until the WBPM began vibrating, which is the lowest level at which the WBPM is allowed, by the auto-positioning sensor function to take a reading. However, during the taking of the reading patients may have lowered their arms involuntarily. We therefore recommend that patients be instructed to raise their arm to the upper limit of the range, relative to the heart, in which the device vibrates before initiating an ambulatory reading (Figure 1).

We used a mixed-effects analysis to evaluate the temporal trend in BP differences between the two devices. After ignoring the first two pairs of readings, there was no significant interaction for either SBP or DBP, indicating that the temporal trend in 2 BPs was essentially the same. However, the difference between WBPM and ABPM was greater for the 1st and 2nd self-measurements of SBP. Thus, it might be better to discard the first two self-measurements of WBPM (as is sometimes done for ABPM) in clinical practice.

In this study, the SBP difference between WBPM and ABPM was similar in the sitting and non-sitting positions. Increased number of BP measurements in the different conditions during real-world daily life will be the most important wearable concept of BP monitoring, which increases the accuracy (ie, reduces the standard error) of the estimates of mean BP and BP variability.[12] Daytime ambulatory BP measured by ABPM (which include BPs measured in both sitting and non-sitting

TABLE 2 Comparison of BP measured by WBPM and ABPM in the office (92 pairs of BP readings from 50 study patients)

	WBPM	ABPM	Difference (WBPM-ABPM)	*P* for difference[a]	Correlation coefficient
SBP, mm Hg	132.8 ± 17.4	132.0 ± 17.1	0.8 ± 12.8	.564	.726[b]
DBP, mm Hg	78.9 ± 10.3	82.1 ± 9.7	−3.2 ± 8.7	<.001	.627[b]
PR, bpm	73.3 ± 14.5	73.8 ± 12.6	−0.5 ± 4.9	.337	.922[b]

Abbreviations: ABPM, ambulatory blood pressure monitoring; DBP, diastolic blood pressure; PR, pulse rate; SBP, systolic blood pressure; WBPM, wearable blood pressure monitoring.

[a]By paired *t* test.

[b]*P* < .001.

TABLE 3 Comparison of BP measured by WBPM and ABPM in the ambulatory condition

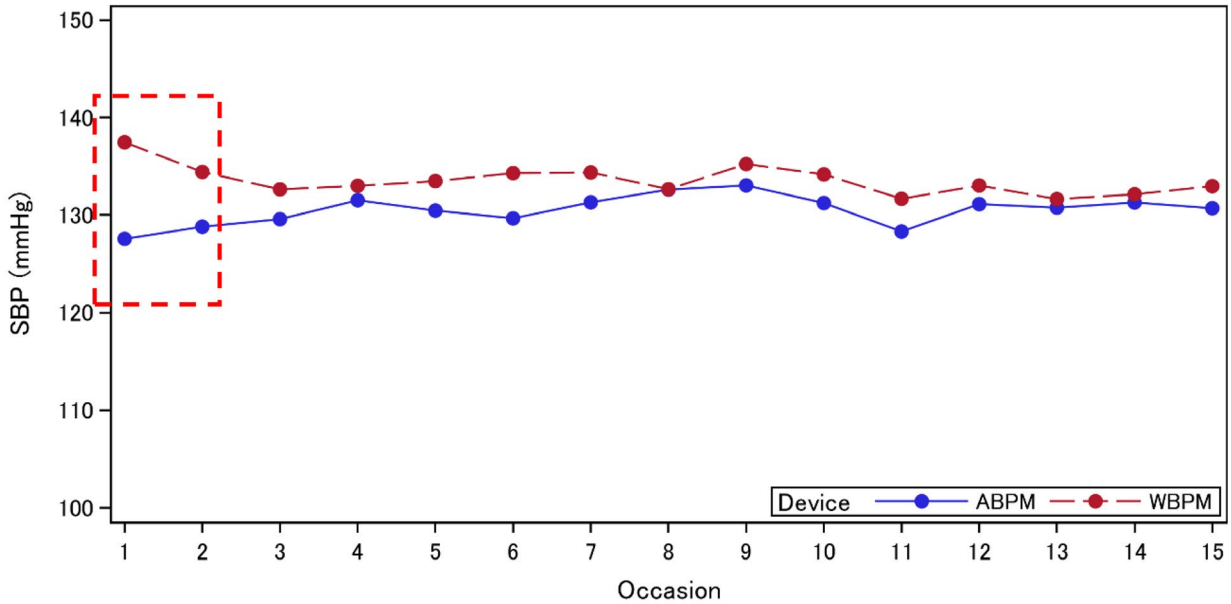
	WBPM	ABPM	Difference (WBPM-ABPM)	*P* for difference[a]	Correlation coefficient
All BPs (N = 956)					
SBP, mm Hg	132.1 ± 18.6	129.0 ± 21.1	3.2 ± 17.0	<.001	.640*
DBP, mm Hg	78.2 ± 12.6	81.4 ± 14.1	−3.2 ± 11.3	<.001	.646*
PR, bpm	73.0 ± 10.8	73.4 ± 12.2	−0.4 ± 6.5	.061	.846*
BPs measured in sitting condition (N = 635)					
SBP, mm Hg	133.5 ± 18.2	130.1 ± 19.9	3.4 ± 16.4	<.001	.633*
DBP, mm Hg	79.0 ± 12.3	82.2 ± 13.8	−3.2 ± 11.1	<.001	.642*
PR, bpm	72.3 ± 10.7	72.5 ± 11.7	−0.1 ± 6.1	.559	.870*
BPs measured in non-sitting conditions[b] (N = 321)					
SBP, mm Hg	129.4 ± 19.1	126.6 ± 23.2	2.8 ± 18.2	.006	.646*
DBP, mm Hg	76.6 ± 13.0	79.8 ± 14.7	−3.2 ± 11.8	<.001	.646*
PR, bpm	74.3 ± 10.9	75.1 ± 12.9	−0.9 ± 7.2	.027	.829*
BPs measured in standing conditions (N = 151)					
SBP, mm Hg	132.1 ± 20.8	129.7 ± 23.0	2.4 ± 18.8	.114	.638*
DBP, mm Hg	80.1 ± 13.4	81.4 ± 15.2	−1.3 ± 10.2	.116	.753*
PR, bpm	77.9 ± 10.7	80.0 ± 12.8	−2.1 ± 7.8	.002	.791*

Abbreviations: ABPM, ambulatory blood pressure monitoring; DBP, diastolic blood pressure; PR, pulse rate; SBP, systolic blood pressure; WBPM, wearable blood pressure monitoring.

[a]By paired *t* test.

[b]Non-sitting conditions are standing (n = 151), supine (n = 36), and unknown (n = 134).

*$P < .001$.



Time point	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
difference at each time point	9.90	5.62	3.06	1.48	3.02	4.64	3.06	0.04	2.18	2.94	3.36	1.91	0.88	0.84	2.26
P for difference	<0.001	0.055	0.296	0.613	0.303	0.113	0.301	0.989	0.461	0.326	0.266	0.536	0.786	0.802	0.524
P for interaction (reference: 3)	0.099	0.537	Ref	0.703	0.992	0.703	1.000	0.468	0.833	0.977	0.943	0.787	0.617	0.619	0.863

FIGURE 3 Mixed-effects analysis of temporal trend in systolic BP measured by the wearable BP monitoring (WBPM) and ambulatory BP monitoring (ABPM) in the ambulatory condition. Dotted square is the area of significant differences between the 2 measures. There was no significant interaction between the 2 measures across the 15 pairs of readings

conditions) is a well-known risk factor.[13] Thus, WBPM could be available to measure BP in various conditions as well as sitting condition.

4.2.1 | SD of the difference

The SD of the difference in SBPs between WBPM and ABPM was 12.8 mm Hg in the office condition. This value was a little bit greater than the calculated "expected difference" of 10 mm Hg. This SD of the difference increased to 17.0 mm Hg in the ambulatory condition. Thus, the difference between paired readings obtained by the two devices varies considerably from occasion to occasion. As we could not conduct a validation study using auscultation readings in the ambulatory conditions, the clinical value of the BPs of WBPM is not confirmed by their consistency with BPs measured by ABPM, but rather by their association with organ damage or clinical prognosis.

For example, we previously conducted a comparison study of the nighttime BPs measured by ABPM and home BP.[14] The nighttime BP measured by ABPM is a well-known cardiovascular risk factor.[15,16] In that study, nighttime SBP measured by home BP was slightly higher by 2.6 ± 13.4 mm Hg than nighttime BP measured by ambulatory BP (P < .001).14 Even with this relatively high SD (13.4 mm Hg) of the difference,14 we recently demonstrated that nighttime SBP measured by home BP monitoring was significantly and independently associated with organ damage at baseline[17] and with the risk of new-onset cardiovascular events during the follow-up period.[18]

4.3 | Study limitation

The consecutive measurements of ABPM followed by WBPM worn on the same arm may affect the absolute BP values. In the future, a randomized controlled study of ABPM-WBPM order vs WBPM-ABPM order would permit estimation of any "order effect." In addition, a study evaluating whether the positioning of the wrist WBPM device, relative to the heart, should be at the lowest, highest, or middle of the devices acceptable range could provide important information for the practical use of this device. Last, all patients in this study used the smaller-sized WBPM cuff; the present results may not generalize to those with wrist circumferences >19 cm.

4.4 | Conclusion and perspectives

The newly developed wearable BP monitoring has acceptable agreement with the ABPM. A key factor in determining the acceptability of out-of-office BP monitoring devices is the usability of the device. The HeartGuide might be preferable to traditional ABPM, because patients find it more comfortable, less intrusive, and less burdensome. Moreover, the WBPM device facilitates multiple readings of ambulatory BP in the sitting and non-sitting conditions, over multiple days, which may increase the reliability of BP measurement when compared to a single ABPM measurement session and, thus, may improve the reliability of the diagnosis of hypertension and facilitate the treatment of true hypertension. Clinical studies using WBPM in the wide range of setting that patients experience in various daily life conditions are likely to prove valuable for clinical practice in the future. In addition, nighttime BP measurement is clinically very important. The HeartGuide device is not yet optimized or validated for nighttime measurement, but if this could become available in the future, it would increase the utility of the wrist device, as would automatic activation, rather than reliance of self-activation.

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CONFLICT OF INTEREST

Dr Kario has received research grant from Omron Healthcare, A&D, and Fukuda Denshi. Dr Schwartz is a consultant for Atcor. This has no relationship to the present study. Dr Schwartz has not received any funding from Omron. Dr Shimbo is a consultant for Abbott Vascular, Edward Lifesciences, Medtronic, and Tryton Medical. He conducts event ascertainment for clinical trials that they are conducting. These studies have nothing to do with BP measurement and hypertension. Dr Shimbo did not receive any funding from Omron. Dr Williams has received honoraria for lectures on hypertension from Omron Healthcare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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