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Simultaneous self-monitoring comparison of a supine algorithm-equipped wrist nocturnal home blood pressure monitoring device with an upper arm device

Kazuomi Kario MD, PhD[1] | Naoko Tomitani BSc[1] | Chie Iwashita BA[1] | Tomoko Shiga BA[1] | Hiroshi Kanegae BSc[1,2]

[1]Division of Cardiovascular Medicine, Department of Medicine, Jichi Medical University School of Medicine, Tochigi, Japan

[2]Genki Plaza Medical Center for Health Care, Tokyo, Japan

Correspondence
Kazuomi Kario, Division of Cardiovascular Medicine, Department of Medicine, Jichi Medical University School of Medicine, 3311-1 Yakushiji, Shimotsuke, Tochigi 329-0498, Japan.
Email: kkario@jichi.ac.jp

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Abstract

A nocturnal home blood pressure (BP) monitoring device that measures nighttime BP levels accurately with less sleep disturbance is needed for the 24-h management of hypertension. Here we conducted the first comparison study of simultaneous self-monitoring by both a supine position algorithm-equipped wrist nocturnal home BP monitoring device, the HEM-9601T (NightView; Omron Healthcare) with a similar upper arm device, the HEM-9700T (Omron Healthcare) in 50 hypertensive patients (mean age 68.9 ± 11.3 years). Both devices were worn on the same non-dominant arm during sleep over two nights. The patients self-measured their nighttime BP by starting nocturnal measurement mode just before going to bed. In total, 694 paired measurements were obtained during two nights (7.2 ± 1.5 measurements per night), and the mean differences (±SD) in systolic BP between the devices was 0.2 ± 10.2 mmHg (p = .563), with good agreement. In the comparison of nighttime BP indices, the difference in average SBP at 2:00, 3:00, and 4:00 AM and the average SBP of 1-h interval measurements was −0.5 ± 5.5 mmHg (p = .337), with good agreement. The HEM-9601T substantially reduced sleep disturbance compared to the upper arm-type device. The newly developed HEM-9601T (NightView) can thus accurately measure BP during sleep without reducing the wearer's sleep quality.

1 | INTRODUCTION

Recent guidelines recommend the importance of out-of-office blood pressure (BP) measurements throughout the 24 h for the management of hypertension.[1-3] Nighttime BP has been reported to be closely associated with cardiovascular events and organ damage in both studies using an ambulatory blood pressure monitoring (ABPM) device[4,5] and studies using a nocturnal home blood pressure monitoring (HBPM) device.[6-9] Although ABPM has been the gold standard to monitor out-of-office BP (including nighttime BP), evidence of the usefulness of nighttime BP measurements by a nocturnal HBPM device equipped with a timer function for automatic BP measurement during sleep is accumulating with the recent advances in device technology. Nocturnal HBPM is superior in terms of reproducibility and less discomfort,[10] but it still has disadvantages such as the sleep disturbance induced by

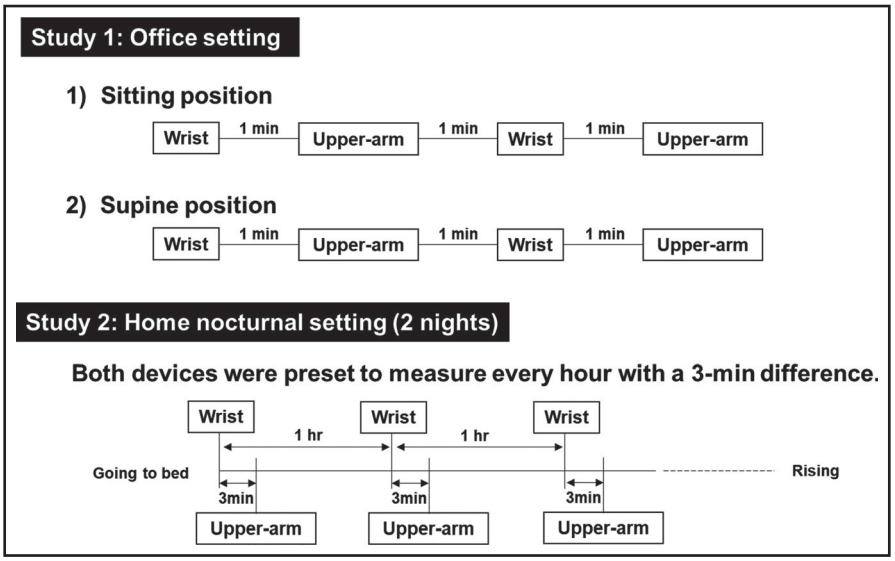


FIGURE 1 The BP measurement procedure. The BP measurement procedure consisted of two parts: Study 1 in the office and Study 2 in the home nocturnal setting

the device's cuff inflation, measurement noise, and frequency of measurements.

To overcome these problems, a wrist-type home nocturnal HBPM device that provides less discomfort and low measurement noise (Omron HEM-9600T) was developed and validated. In the validation study of the HEM-9600T, the BP values obtained by the wrist-type device were higher than those measured by a mercury sphygmomanometer, and the study authors concluded that this difference was caused by hydrostatic pressure and anatomic features of the wrist.[11] Following those results, a new wrist-type nocturnal HBPM device with two different algorithms for the sitting and supine positions and an improved cuff (Omron HEM-9601T) was developed. The validation study demonstrated that the HEM-9601T was able to measure reliable BP values in the laboratory setting.[12] However, there are no data regarding the evaluation of self-measured nighttime BP values obtained under real-world sleeping conditions at home.

This is the first study to compare nighttime BP simultaneously monitored by a supine position algorithm-equipped wrist-type HBPM device with an upper arm-type HBPM device in a self-measurement setting under real-world sleeping conditions.

2 | SUBJECTS AND METHODS

2.1 | Study population

Adult hypertensive patients who were taking antihypertensive medication 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 (rinA19-241). The study protocol was registered on a clinical trials registration site (University Hospital Medical Information Network Clinical Trials Registry, UMIN000041540). All participants provided written informed consent.

2.2 | BP measurement devices

The HEM-9601T (NightView; Omron Healthcare, Kyoto, Japan) is an automatic oscillometric device for self-measuring BP at the wrist. The HEM-9601T has two different buttons for BP measurements made in two different body positions, that is, sitting and supine positions (Figure S1). When BP is measured in the sitting position, the wrist should be at the heart level. A position sensor built into the HEM-9601T tells the wearer the correct measurement position. When BP is measured in the supine position (the nocturnal BP measurement mode), the device determines the SBP and DBP values by using the algorithm for the supine position. The cuff size can be used for wrist circumferences in the range of 13.5-21.5 cm.[12]

The HEM-9700T (Omron Healthcare, Kyoto, Japan) is an automatic upper arm-type device for the self-measurement of BP, and the validation study of this device was successfully conducted according to the ANSI/AAMI/ISO81060-2:2013 guidelines.[13] The HEM-9700T with a standard cuff can adapt to upper arm circumferences of 22-32 cm. Both the NightView wrist device and the upper arm device can be preset at bedtime to measure the wearer's BP during sleep for nighttime automatic measurements. The default preset timings of BP measurement on these devices are 2:00 AM, 4:00 AM and 4 h after pushing the "NIGHT" button. In the present study, the preset timings were changed to hourly measurements and used for the measurements. All BP readings were stored in the devices' memories.

TABLE 1 Comparison of blood pressure parameters measured by the wrist-type and upper arm-type devices in the office setting (100 pairs of measurements from 50 patients)

	Wrist device	Upper arm device	Difference (Wrist—upper arm)	*p* for difference
Sitting position				
SBP, mmHg	129.7 ± 16.1	130.2 ± 14.1	−0.5 ± 9.7	.607
DBP, mmHg	76.5 ± 12.1	78.9 ± 10.4	−2.4 ± 5.9	<.001
Heart rate, bpm	72.0 ± 12.1	72.1 ± 11.8	−0.1 ± 4.1	.753
Supine position				
SBP, mmHg	129.6 ± 14.9	127.8 ± 12.4	1.8 ± 8.5	.042
DBP, mmHg	74.9 ± 10.0	77.9 ± 8.9	−3.0 ± 5.4	<.001
Heart rate, bpm	67.4 ± 10.6	67.5 ± 10.5	−0.1 ± 2.2	.655

Note: Values are mean ± SD.

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

2.3 | BP measurement protocol

The BP measurement procedure consisted of two parts: Study 1 in the office and Study 2 in the home nocturnal setting (Figure 1). In both settings, the wrist-type and the upper arm-type BP monitoring devices were worn simultaneously on the same non-dominant arm.

2.3.1 | Study 1: Office setting

(1) Sitting position

The patient was seated and wearing the wrist-type and upper arm devices. BP readings were taken twice by each device (total of 4 readings, alternating between devices) with the wrist device first. Each BP measurement was taken by research staff at 1-min intervals.

(2) Supine position

The patient rested on a bed in a relaxed supine position, wearing the wrist and upper arm devices. BP values in the supine position were measured with the patient's palm facing upward. A BP reading was taken twice with each device by research staff, using the same BP measurement procedure as that used for the sitting measurements.

2.3.2 | Study 2: Home nocturnal setting (2 nights)

After the measurements in Study 1 (office setting), all patients were asked to measure their nighttime BP during sleep at home for two consecutive nights. They were instructed to wear the wrist and upper arm devices on the same non-dominant arm and to start the nocturnal measurement mode (by pushing the nocturnal measurement button) just before going to bed each night. Both devices were preset to measure BP every 60 min with a 3-min difference between the devices' readings, during the nocturnal measurement mode (Figure 1, lower).

2.4 | Questionnaire on nocturnal blood pressure measurement

The patients were asked to complete a questionnaire after performing the 2-night nocturnal BP measurement. The questions asked (1) whether there was nocturnal awakening caused by the nocturnal measurements; (2) if so, whether it was caused by a the wrist device or the upper arm device; and (3) the reason for the awakening (measurement noise, cuff compression, etc).

2.5 | Statistical analyses

All statistical analyses were performed using the SAS ver. 9.4 software program (SAS Institute, Cary, NC). Pairwise differences between the wrist-type and the upper arm-type BP monitoring devices in-office and home nocturnal 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 home nocturnal measurements (Study 2). The mixed-effects repeated measures model included the device, the measurement time, and the interaction between the device and measurement time as fixed effects. All of the data processing and analyses were independently conducted at 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 study participants are summarized in Table S1. All 50 participants were hypertensive patients with antihypertensive treatment. The mean age was 68.9 ± 11.3 years (25-91 years old), 54% were male, and the average body mass index (BMI) was 25.8 ± 3.4 kg/m^2.

3.2 | Comparison in the office setting (Study 1)

According to the office BP measurement procedure, two alternating pairs of BP readings (wrist device followed by upper arm device) were taken for each participant in the sitting position and in the supine position: 100 paired BP readings from 50 patients were thus available for the analysis of BP values obtained in the sitting and supine positions, respectively.

In the sitting position, the mean SBP values measured by the wrist and upper arm devices were 129.7 ± 16.1 mmHg and 130.2 ± 14.1 mmHg, respectively, with no significant difference between devices (−0.5 ± 9.7 mmHg, $p = .607$; Table 1). The mean DBP values measured by the wrist and upper arm devices were 76.5 ± 12.1 mmHg and 78.9 ± 10.4 mmHg, respectively; the DBP measured by the wrist device was significantly lower (−2.4 ± 5.9 mmHg, $p < .001$).

In the supine position, the mean SBP values measured by the wrist and upper arm devices were 129.6 ± 14.9 mmHg and 127.8 ± 12.4 mmHg, respectively: A slight but significant difference was observed between the devices (1.8 ± 8.5 mmHg, $p = .042$; Table 1). The mean DBP values measured by the wrist and upper arm devices were 74.9 ± 10.0 mmHg and 77.9 ± 8.9 mmHg, respectively, and the wrist-measured DBP was significantly lower (−3.0 ± 5.4 mmHg, $p < .001$).

3.3 | Comparison in the home nocturnal setting (Study 2)

In total, 694 paired measurements from the 50 patients were obtained during the two nights. The average number of measurements per night was 7.2 ± 1.5 times, and the average number of measurements per participant for two nights was 13.9 ± 3.2 times.

In our comparison of all 694 paired readings, the SBP values measured by the wrist and upper arm devices were similar (116.4 ± 16.2 mmHg and 116.2 ± 16.3 mmHg, p for difference = .563; Table 2). Similar results were observed in the comparison of individual SBP averages per night (116.5 ± 12.2 mmHg vs. 116.3 ± 12.7 mmHg, p for difference = .764) and individual SBP averages per two nights (116.9 ± 11.6 mmHg vs. 116.5 ± 12.2 mmHg, p for difference = .603).

According to Bland-Altman plots, the mean difference (wrist device minus upper arm device) was 0.2 mmHg with 95% limits of agreement at −20.2 and 20.7 in the analysis using all 694 measurements. The mean difference was 0.2 mmHg with 95% limits of agreement (−10.5 and 10.9) in the analysis using the averaged SBP values per night ($n = 96$ pairs of averaged SBP values from the 50 patients) (Figure 2).

Compared to the upper arm device, the DBP values measured by the wrist device were significantly lower in all of the analyses using all 694 measurements, the per night average, and the two-night average (−4.1 ± 7.9 mmHg, $p < .001$; −4.0 ± 4.4 mmHg, $p < .001$; −3.9 ± 3.8 mmHg, $p < .001$, respectively) (Table 2).

When we compared the average BP values obtained at 2:00, 3:00, and 4:00 AM, no significant difference was detected in the SBP average (115.8 ± 13.4 mmHg vs. 116.4 ± 14.9 mmHg, p for difference = .420), but there was a significant difference in the DBP average (66.8 ± 8.0 mmHg vs. 71.3 ± 9.4 mmHg, p for difference < .001) (Table 2).

3.4 | Mixed-effects analysis of the temporal trend in self-measured nocturnal BP

The mean number of paired (ie, wrist device followed by upper arm device) measurements per night per participant was 7.2 ± 1.5

TABLE 2 Comparison of blood pressure parameters measured by the wrist-type and upper arm-type device in the 2-night home nocturnal setting (Total 694 pairs of measurements from 50 patients)

	Wrist device	Upper arm device	Difference (Wrist—upper arm)	p for difference
All measurements ($n = 694$ pairs of measurements)				
SBP, mmHg	116.4 ± 16.2	116.2 ± 16.3	0.2 ± 10.2	.563
DBP, mmHg	66.8 ± 10.8	70.9 ± 10.9	−4.1 ± 7.9	<.001
Heart rate, bpm	60.6 ± 7.9	60.5 ± 7.8	0.1 ± 3.9	.571
Individual averages of BPs per night ($n = 96$ pairs of average BP [mean 7.2 ± 1.5 measurements/night])				
SBP, mmHg	116.5 ± 12.2	116.3 ± 12.7	0.2 ± 5.4	.764
DBP, mmHg	67.2 ± 8.0	71.2 ± 8.3	−4.0 ± 4.4	<.001
Heart rate, bpm	60.8 ± 6.6	60.7 ± 6.6	0.1 ± 1.7	.624
Individual averages of BPs measured at 2:00, 3:00, and 4:00 AM per night ($n = 93$ pairs of average BP [mean 2.8 ± 0.5 measurements/night])				
SBP, mmHg	115.8 ± 13.4	116.4 ± 14.9	−0.6 ± 7.6	.420
DBP, mmHg	66.8 ± 8.0	71.3 ± 9.4	−4.4 ± 5.8	<.001
Heart rate, bpm	59.9 ± 6.7	59.9 ± 6.6	0.1 ± 2.6	.838

Abbreviations: BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.
Values are mean ± SD.

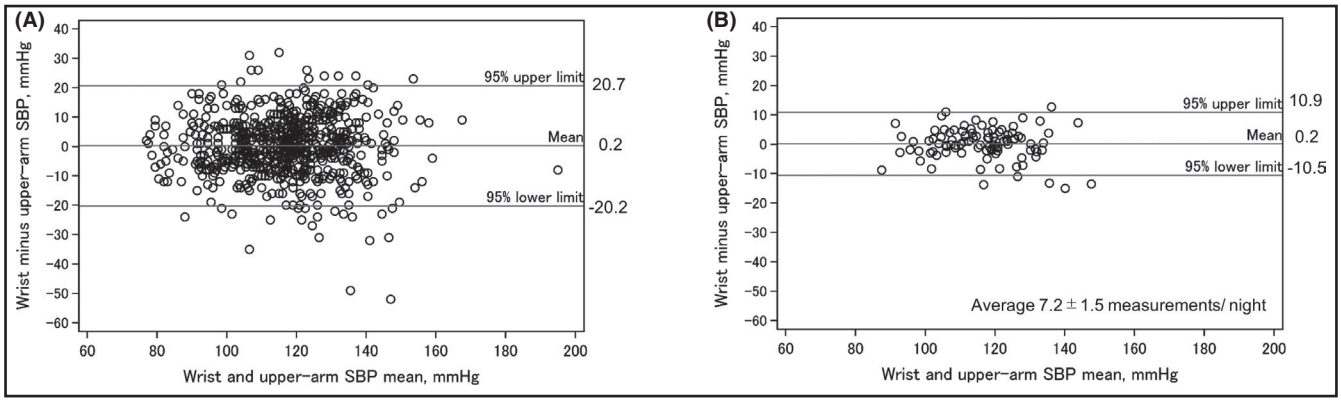
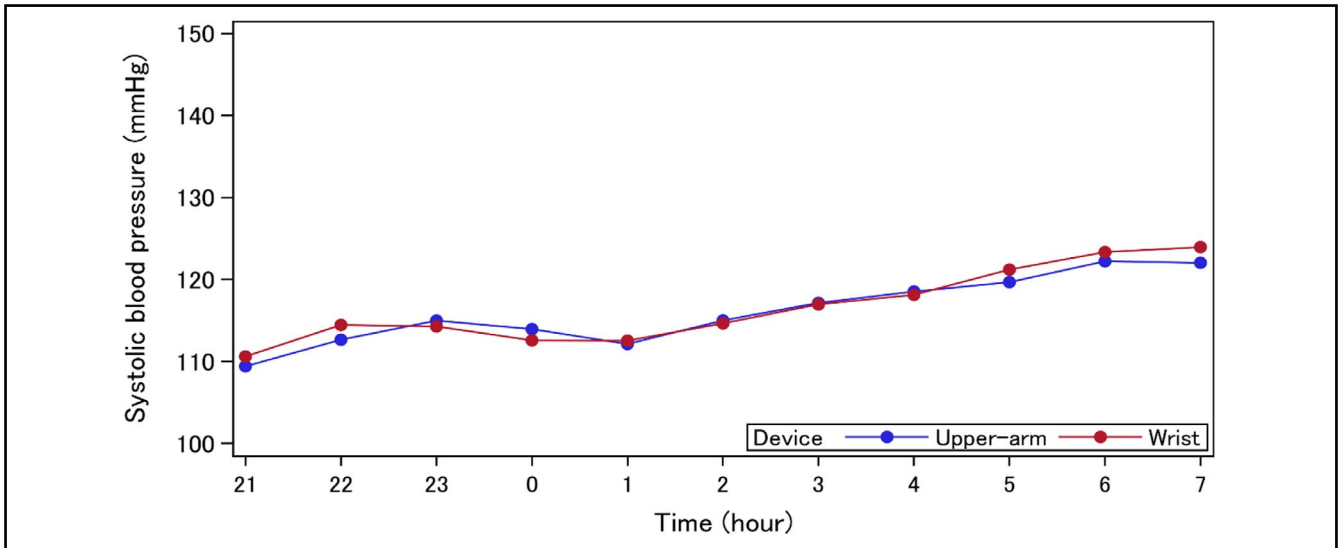


FIGURE 2 Bland-Altman plots of the differences between the wrist-measured systolic blood pressure (SBP) and upper arm-measured SBP in the 2-night home nocturnal setting. A, Plots of all SBP measurements (n = 694 pairs of SBP readings from 50 patients). B, Plots of averaged SBP values per night (n = 96 pairs of averaged SBP from 50 patients). Abbreviation: SBP, systolic blood pressure.



Time, hr	21:00	22:00	23:00	0:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00
No. of measurements	10	30	60	75	85	89	86	84	82	57	21
Wrist SBP, mmHg	110.6	114.5	114.3	112.6	112.5	114.7	117.0	118.1	121.2	123.3	123.9
Upper-arm SBP, mmHg	109.4	112.7	115.0	114.0	112.1	115.0	117.2	118.5	119.7	122.2	122.0
Difference at each time, mmHg	1.2	1.8	−0.7	−1.4	0.4	−0.4	−0.2	−0.4	1.5	1.1	1.9
P for difference	0.806	0.524	0.720	0.442	0.806	0.826	0.991	0.816	0.369	0.584	0.573

FIGURE 3 Mixed-effects analysis of the time trend in SBP measured by the wrist device and the upper arm device (n = 679). Plots represent the estimated SBP values calculated by a mixed-effect model that included the device, measurement time, and the interaction between the device and measurement time as fixed effects. There was no significant interaction between the two measures across the measurement time points

between 9:00 PM and 11:00 AM A mixed-effects repeated measures analysis using the 679 pairs of readings was performed in order to compare the SBP difference between the wrist device and the upper arm device at each time point (Figure 3). The data measured at 8:00, 9:00, 10:00, and 11:00 AM were excluded from the mixed-effect analysis because the numbers of measurements were below 10 at each time point. There was no significant difference in the estimated SBP values between the two devices at any of the time

points. Regarding DBP, the differences between devices were significant or marginally significant at each time point (Figure S2). In addition, the interaction between device and time points was not significant for either SBP or DBP.

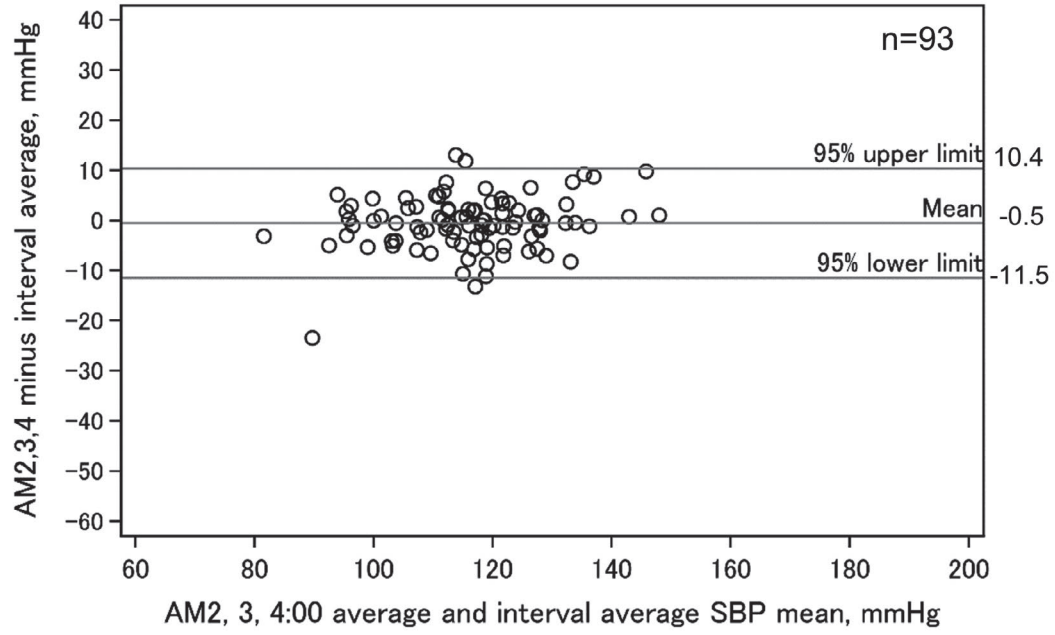
3.5 | Nocturnal measurement schedule

Of two-night nocturnal measurements from 50 patients, the 93 nights included the measurements at 2:00, 3:00, and 4:00 AM The individual SBP average per night of the wrist-measured BP at 2:00, 3:00, and 4:00 AM (mean 2.8 ± 0.5 measurements) and the SBP average of the 1-hr interval measurements throughout a night (mean 7.4 ± 1.3 measurements) were 115.8 ± 13.4 and 116.3 ± 12.3 mmHg, respectively (p = .337) (Figure 4B). The Bland-Altman plot shows good agreement between the two nighttime BP indices (Figure 4A). There was also no significant difference in the DBP average between the two indices (−0.2 ± 3.7 mmHg difference, p = .530).

3.6 | Questionnaire on nocturnal blood pressure measurement

All 50 study patients responded to the questionnaire on their experiences of nocturnal self-measurement (Table 3). The average (±SD) number of nocturnal awakenings caused by nocturnal

(A)



(B)

	Average of 2:00, 3:00 and 4:00	Average of interval measures	Difference	P for difference
Average per one night (n=93 average values from 50 patients)				
No. of measurements	2.8±0.5	7.4±1.3		
SBP, mmHg	115.8±13.4	116.3±12.3	−0.5±5.5	0.337
DBP, mmHg	66.8±8.0	67.1±8.0	−0.2±3.7	0.530
Heart rate, bpm	59.9±6.7	60.7±6.6	−0.8±2.7	0.007

FIGURE 4 Comparison of individual average SBP values by the wrist device measured at 2:00, 3:00, and 4:00 AM with those measured at 1-hr intervals throughout one night. A, Bland-Altman plots for the difference in nighttime indices of the average of 2:00, 3:00, and 4:00 AM measurements of SBP and average SBP measured at 1-hr intervals throughout a night. B, Comparison of nighttime SBP, diastolic blood pressure (DBP), and heart rate indices. Values are mean ± standard deviation. Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

measurements (not including awakenings due to nocturnal urination) was 1.4 ± 1.4 for the first measurement night and 0.8 ± 1.2 for the second night. Of the 50 patients, 60.0% were awakened by a nocturnal BP measurement on the first night and 46.0% on the second night. On both the first and second nights, the upper arm-device was more frequently reported as the cause of nocturnal awakening compared to the wrist device (Night 1:80.0% for upper arm, 3.3% for wrist, and 16.7% for both devices; Night 2:65.2% for upper arm, 17.4% for wrist, and 17.4% for both devices). The cuff compression of the upper arm device was the most frequently reported cause of sleep disturbance (Night 1:17 patients, Night 2:10 patients).

4 | DISCUSSION

To the best of our knowledge, this is the first study to compare BP values obtained with simultaneous self-monitoring by a wrist home BP monitoring device and an upper arm home BP monitoring device in a nocturnal home setting. The results indicate that the differences between the wrist and upper arm devices were comparable in the self-measured nocturnal home setting.

4.1 | Blood pressure measured in the nocturnal home setting

In our comparison of 694 pairs of measurements obtained from the 50 patients, the difference in SBP between the wrist device and the upper arm device was 0.2 mmHg and 95% of the values were within ±20.4 mmHg, indicating good agreement. Our comparison of the averaged SBP values at the individual level revealed that the difference between devices showed good agreement; 95% of the values were within ±10.7 mmHg. Previous studies demonstrated that wrist-measured BP values in the supine position were different according to the palm position (downward, upward, and sideways).[11,12] In the real-world sleeping condition, the position of the wearer's wrist and the direction of the palm are not constant. However, we observed herein that the nighttime BP values measured by the wrist device were comparable to those measured by the upper arm-type device even in the self-measurement setting at home.

The present study was the first to evaluate the consecutive BP readings by a device worn on the wrist followed by readings taken by an upper arm device, both of which were worn on the non-dominant arm. In addition, a newly developed wrist device with an algorithm that can be used with the wearer in the supine position and an improved cuff for nocturnal measurement were used in this study. A previous investigation compared a wrist HBPM with an upper arm HBPM in the real-world sleep condition, but the measurements by each device were taken on separate nights.[14] In addition, because that investigation used a wrist device without a supine position algorithm, the SBP/DBP values measured by the wrist device in supine position were 5.6/6.4 mmHg higher than those measured by the upper arm device. Even after subtracting this difference from the actual measured values, the difference between devices was significant. That investigation[14] also demonstrated that the nocturnal BP measurements obtained with a wrist device produced less sleep disturbance and discomfort compared to an upper arm device.

TABLE 3 Questionnaire on nocturnal blood pressure measurement [Correction added on January 27, 2021, after first Online publication: The term "(n = 49 responses)" and "(% among 49 responses)" has been removed from Table 3.]

	Night 1	Night 2
No. of nocturnal awakenings* caused by nocturnal BP measurements	1.4 ± 1.4	0.8 ± 1.2
No. of patients awakened by nocturnal BP measurements, *n*	30 (60.0)	23 (46.0)
Causes of nocturnal awakening:		
(1) Upper arm-type device, *n* (%)	24 (80.0)	15 (65.2)
Measurement noise, *n*	6	5
Cuff compression, *n*	17	10
Others, *n*	1	0
(2) Wrist-type device, *n* (%)	1 (3.3)	4 (17.4)
Measurement noise, *n*	1	1
Cuff compression, *n*	1	3
Others, *n*	0	0
(3) Both devices, *n* (%)	5 (16.7)	4 (17.4)
Measurement noise, *n*	2	3
Cuff compression, *n*	4	4
Others, *n*	1	0

Abbreviations: BP, blood pressure.

Values are mean ± SD, number, or percentage.

*Not including awakenings due to nocturnal urination.

A study of individuals with obesity compared nighttime BP measured at the forearm with nearly simultaneous (with 1-2 min time lag) measurements at the upper arm using an ABPM device designed for upper arm measurement.[15] The agreement between the forearm readings and upper arm readings measured by the same ABPM for upper arm was sub-optimal. In order to measure BP at the wrist, it is necessary to use a specific cuff and device that are optimized and developed for specific wrist measurement. Obese patients who present difficulty measuring BP at the upper arm are more likely to have nocturnal hypertension, and their nighttime BP during sleep should be measured. A wrist HBPM device adapted for large wrist circumferences would be useful for the BP management of obese patients.

4.2 | Blood pressure measured in the office setting

In the present study's office sitting measurement, the SBP values measured by the wrist device were not significantly different from those measured by the upper arm device (difference: −0.5 mmHg, $p = .607$). However, the mean SBP measured by the wrist device in the supine position was 1.8 mmHg higher than the value measured by the upper arm device ($p = .042$).

In the validation study of the wrist home BP monitoring device, the HEM-9601T, the mean difference in SBP measured by a mercury sphygmomanometer and the HEM-9601T was 0.1 mmHg.[12] This discrepancy may be caused by the different references of the BP measurements.

4.3 | Nocturnal measurement schedule and frequency

The mixed-effects analysis revealed no significant difference in SBP between the two devices at any time point, and no interaction between the devices and time points was observed. In other words, the BP values measured by the two devices were comparable at all time points. Notably, the SBP difference was <1.0 mmHg during the hours 1:00-4:00 AM

In the J-HOP Nocturnal BP study using a upper arm nocturnal HBPM device, nocturnal home BPs were measured at three preset times per night (2:00, 3:00, and 4:00 AM), and the average of the 2:00, 3:00, and 4:00 AM nighttime SBP values was a predictor of incident cardiovascular disease events, independent of office and morning home SBP.[7] In the present study, the average of the 2:00, 3:00, and 4:00 AM SBP values was almost identical, with a <1.0 mmHg-SBP difference between the wrist and upper arm-type devices, and it was comparable to the average of the 1-hr interval measurements throughout a night.

Frequent measurements of nighttime BP during one night might cause sleep disturbance. The J-HOP Nocturnal BP study demonstrated that even the less-frequent measurements of nighttime BP (only three measurements) per night on multiple nights provided prognostic power. Measurements at 2:00, 3:00, and 4:00 AM on multiple nights by a wrist device with less sleep disturbance would provide a more accurate measure of the wearer's BP during sleep. Further studies to evaluate the prognostic power of wrist-measured nighttime BP are needed.

4.4 | Sleep disturbance

Although the patients' nocturnal BP measurements were taken by the wrist device first followed by the upper arm device, our questionnaire revealed that the main reason for sleep disturbance in this study was the upper arm cuff compression. A study of a general elderly population demonstrated that decreased sleep quality determined by actigraphy was significantly associated with higher nighttime BP measured by ABPM.[16] Therefore, BP measurement with frequent sleep disturbance may not always capture the real nighttime BP of an individual. Our present results demonstrated that the wrist-worn HEM-9601T substantially reduced sleep disturbance compared to the upper arm device.

The average number of nocturnal awakenings caused by the nocturnal BP measurements decreased from the first night to the second night. The study participants might have felt more discomfort on the first night. Repeated nocturnal home BP measurements using wrist device might decrease the sleep disturbance.

5 | STUDY LIMITATIONS

In this nocturnal home BP monitoring study, the simultaneous monitoring by two different BP monitoring devices over two nights (especially the upper arm cuff inflation) might have disturbed the sleep of some patients. The impact of sleep disturbance by BP monitoring should be examined in a future study.

We did not compare the nighttime BP values measured by the wrist HBPM device with those measured by ABPM. In our previous comparison study of nighttime BP measured by an upper arm device and by ABPM, the nighttime home SBP (ie, the average of the nighttime SBP values measured at 2:00, 3:00, and 4:00 AM) was slightly higher than the nighttime ambulatory SBP (difference, 2.7 mmHg).[9]

Herein, the DBP values measured by the wrist device were significantly lower than those measured by the upper arm device, probably due to the different BP algorithms used in the two devices. Systolic blood pressure is a more important risk for organ damage and future cardiovascular events than DBP (especially in older patients, such as our study participants, with the mean age 68.9 years). A further comparison study using the wrist-worn HEM-9601T device is needed to clarify the difference in DBP in different populations with different demographics such as younger and/or obese patients.

6 | CONCLUSION AND PERSPECTIVES

The self-monitored nocturnal home BP values measured by the wrist HBPM device equipped with a supine position algorithm were

comparable to those measured by the upper arm HBPM device and have been shown to be clinically reliable. Our findings also indicate that the wrist-worn HEM-9601T device would be superior to ABPM and upper arm HBPM in term of patients' acceptance and preference, because it substantially reduced sleep disturbance compared to the upper arm device.

AUTHOR CONTRIBUTION

K. Kario and N. Tomitani wrote the manuscript. K. Kario collected the patients' data with support from C. Iwashita and T. Shiga. N. Tomitani and H. Kanegae analyzed the data. K. Kario supervised the conduct of the study.

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DISCLOSURES

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ORCID

Kazuomi Kario https://orcid.org/0000-0002-8251-4480
Naoko Tomitani https://orcid.org/0000-0002-1443-7073

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SUPPORTING INFORMATION

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

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