

Development of Small and Lightweight Beat-By-Beat Blood Pressure Monitoring Device Based on Tonometry

Yuki Ota, Ayako Kokubo, Shingo Yamashita, and Kazuomi Kario

Abstract—Blood pressure (BP) variability (BPV) is one of the important risk factors of cardiovascular (CV) disease. Particularly, nocturnal short-term BPV, characterized as acute transient BP elevation over several tens of seconds (BP surge), can trigger CV events. To accurately detect BP surge, it is necessary to monitor BP at each heartbeat. Although continuous BP monitors have been developed and validated, they are too large to measure beat-by-beat (BbB) BP at home. Therefore, we developed a small and lightweight BbB BP monitoring device (BbB device) based on tonometry. In this study, the BbB device was evaluated in terms of size, weight, and performance compared with a validated conventional continuous BP monitoring device based on tonometry (conventional device). The performance was evaluated using the correlation coefficient of pulse wave signals and the difference in BbB BP values between the two devices. Measurement data obtained from 30 subjects with a total of 81 sets, including short-term BPV by the Valsalva maneuver, was used for the evaluation of the performance. The results showed that the conventional device consists of two units (a control unit and a sensor unit), while the BbB device has integrated them into a single unit, with a weight of 150 g (approximately 1/45th of the conventional device). The BbB device was significantly smaller and more lightweight than the conventional device. The correlation coefficient of pulse wave signals between the two devices was 0.98 ± 0.02 . The BbB systolic BP and diastolic BP differences were -0.3 ± 4.7 mmHg and 0.7 ± 3.4 mmHg, respectively. The developed BbB device was demonstrated to have an almost equivalent performance as the validated conventional device. In conclusion, we realized a small and lightweight continuous BP monitor that can evaluate the BP for each heartbeat using the BbB device without limitations regarding measurement location. Our device can monitor changes in BP at each heartbeat and short-term BPV, which would be important index for preventing CV events.

I. INTRODUCTION

Twenty-four-hour blood pressure (BP) monitoring is important for preventing hypertensive target organ damage and the onset of cardiovascular (CV) disease, such as stroke and heart disease [1], [2]. As home BP monitoring devices are increasingly used by consumers, it has become easier to monitor and manage morning and evening BP. However, there is still a risk of masked uncontrolled BP, such as at night. A previous study showed that mean nocturnal BP measured using ambulatory BP monitoring was more significantly related to CV disease than daytime and office BP measurements [3]. Moreover, an increase in nocturnal BP variability (BPV) was found to be associated with CV disease

[4]. Nocturnal short-term BPV is caused by obstructive sleep apnea, micro-awakenings, and so on [5] and is characterized as acute transient BP elevation over several tens of seconds. We defined it as BP surge in seconds that would trigger CV events. Thus, monitoring BP surge is important for preventing CV events. To detect BP surge caused by sleep apnea, an oxygen-triggered BP monitor was developed in a previous study [6]. However, BP surge might be underestimated because the oxygen-triggered BP monitor is based on the oscillometric method. Therefore, it is necessary to monitor the BP for each heartbeat to detect BP surge.

Three methods are used to monitor BP changes at each heartbeat: tonometry, volume clamp, and pulse transit time (PTT). These methods are used for noninvasive continuous BP monitoring. To monitor overnight continuous BP at home, the device needs to be small and able to measure for long periods. Moreover, to obtain continuous BP values accurately, it is necessary to obtain a pulse wave and a BP value for each heartbeat. The tonometry method satisfies these conditions compared with the other methods. Although a validated conventional continuous BP monitoring device based on tonometry (conventional device) has been developed and validated as a medical device, the conventional device cannot be used at home because it is immobile and large.

Therefore, based on tonometry, we developed a beat-by-beat (BbB) BP monitoring device. Our BbB BP monitoring device (BbB device) is sufficiently small and lightweight for use at home during the night. In this study, we describe the development of the BbB device, and the evaluation of its performance compared with the conventional device.

II. METHODS AND MATERIALS

A. Conventional BbB BP monitor

A conventional continuous BP monitoring device based on tonometry, called JENTOW (approved model name is JENTOW-7700 in Japan; Nihon Colin, Japan), has been developed, which was validated as a medical device. JENTOW consists of a sensor unit and a control unit. The sensor unit has a multi-element pressure sensor, automatic position adjustment (APA) mechanism, and a mechanism for pressing the pressure sensor. The control unit is equipped with a mechanism to control the sensor unit, and it also consists of a CPU, a pump, and a valve. These units were connected by a cable and worked on an AC battery. JENTOW monitors BP at each heartbeat and short-term BPV, such as BP surge [7]. This

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(A) Block diagram of the BbB BP monitoring system

(B) BbB BP monitoring device

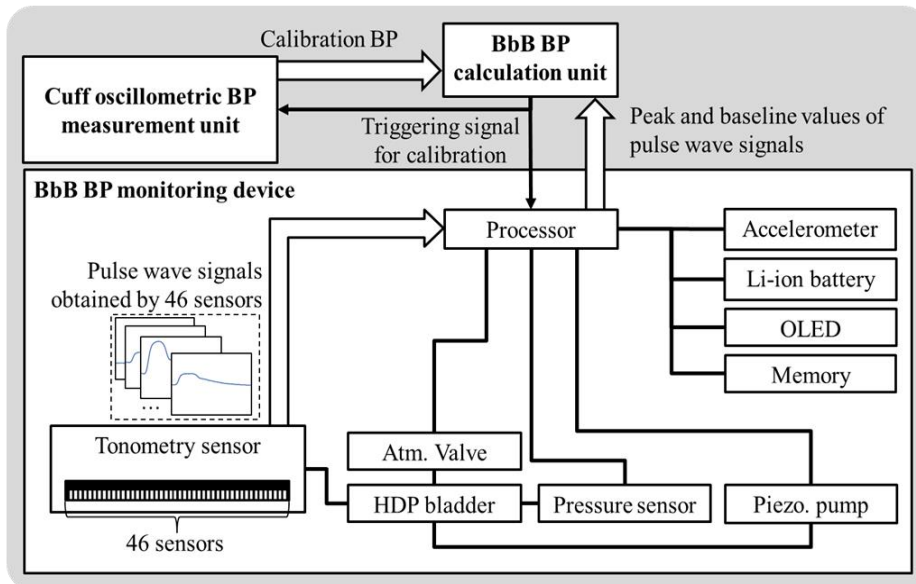


Figure 1. Overview of the BbB BP monitoring system, consisting of a BbB BP monitoring device, a BbB BP calculation unit, and a cuff-oscillometric measurement unit. (A) A block diagram of the BbB BP monitoring system. (B) A BbB BP monitoring device. BP, blood pressure; BbB, beat-by-beat; Tonometry sensor, multi-element MEMS pressure sensor; HDP, hold-down pressure; Li-ion, lithium ion; Atm., atmospheric release; OLED, organic light-emitting diode; Piezo., piezoelectric.

device can be clinically used in operating room and clinical research. However, JENTOW cannot be used at home because of its immobility and large size.

B. Development of new BbB BP monitoring device

To monitor short-term BPV overnight at home, we developed a small and lightweight BbB device that could be worn on the left wrist and could continuously monitor pulse waves. To calculate the BbB BP, a BbB BP monitoring system was constructed that used a cuff-oscillometric BP measurement unit, a BbB BP calculation unit, and the BbB device. The cuff-oscillometric BP measurement unit was used to measure calibration BP. The BbB BP calculation unit was an application for calculating BbB BP using the pulse wave signals and calibration BP, which are obtained by the other two units.

Fig. 1(A) shows a block diagram indicating the constitution of the BbB BP monitoring system. Continuous pulse wave signals were obtained by a multi-element MEMS pressure sensor (tonometry sensor) in the BbB device directly placed on the skin above the radial artery and were transmitted to the processor. The tonometry sensor was developed by us [8]. When the piezoelectric pump received a control signal from the processor, it inflated the hold-down pressure bladder. The calibration BP was measured when the cuff-oscillometric BP measurement unit wirelessly received a triggering signal from the processor. The calibration timing was automatically judged by the processor of the BbB device or the BbB BP calculation unit when contact between the tonometry sensor and skin significantly changed because of body motion.

The BbB device consisted of a tonometry sensor, a circuit board, a battery, and other components integrated into a single small unit (Fig. 1(B)). To integrate these components into one small unit, the following features were equipped. First, this device was equipped with a developed guide function, which

is the estimated position of the radial artery from the pressure values of the tonometry sensor. This function can manually adjust the position of the tonometry sensor instead of the APA mechanism. The APA mechanism was one of the factors that JENTOW was large. Second, the circuit size of the device was reduced by installing the tonometry sensor which was improved noise resistance by incorporating peripheral circuits [8]. Third, by reducing current consumption, current consumption of this device was approximately 60 mA during BbB BP measurement. This device could be equipped with a lithium-ion battery and realized the measurement of BbB BP for approximately 10 hours. Therefore, we realized a BbB device that can measure BbB BP overnight and was easy to wear on the wrist.

C. Evaluation

The BbB device was evaluated for its size, weight, and performance compared with JENTOW. The width, depth, and height of the BbB device were measured using a digital caliper (Mitutoyo CD-15APX; Mitutoyo, Japan), and the weight was measured using a digital scale (KD-200; TANITA, Japan). The size and weight of JENTOW were confirmed from the instruction manual. The performance of the BbB device was evaluated using the correlation coefficient of the pulse wave signals and the difference of BbB BP values with JENTOW. These signals and values were stored in the memory, and a computer analyzed them after the measurement. To evaluate the performance of the BbB device, 30 subjects were recruited for this study. Their characteristics are shown in Table I. This study was approved by the Examination Review Committee (IRB-1831) of OMRON Healthcare Co., Ltd.

The BbB device was worn on the left wrist and JENTOW was worn on the right wrist, performing three times simultaneous measurements per subject. An entry BP value was measured using the cuff-oscillometric BP attached at the

upper right arm. Each measurement was performed for approximately 1 min in a supine position and divided into three states: 1) calibration state (10 s), 2) resting state (approximately 20 s), and 3) BP elevation state (approximately 30 s). The performance of the BbB device was evaluated, excluding the calibration state. After the resting state, the Valsalva maneuver was conducted for 15 s to induce BP surge in the BP elevation state. In the calibration state, the measured BP values of JENTOW were used for calibration to remove the differences between the calibration value of the BbB device and that of JENTOW.

TABLE I. SUBJECT CHARACTERISTICS (N = 30)

Characteristics	
Age (yr)	38.6 ± 8.1
Male:female (n)	25:5
Left wrist size (cm)	15.5 ± 1.1
Entry BP measured by cuff-oscillometric method^a	
Systolic BP (mmHg)	118.6 ± 10.0
Diastolic BP (mmHg)	70.8 ± 7.2

a. Entry systolic BP and diastolic BP were measured with the right arm using the cuff-oscillometric BP monitor before BbB BP measurement.

The performance of the BbB device in each measurement was evaluated as follows. To assess the amount of BP elevation by the Valsalva maneuver, we calculated the difference between the maximum and minimum BbB BP (MMD) at each measurement. In addition, the correlation coefficient of the pulse wave signals between the two devices was expressed as average ± standard deviation (SD) in all subjects. The difference in the BbB BP compared with that of JENTOW was evaluated using the Bland–Altman analysis [9]. The difference was calculated as the BbB BP measured by the BbB device minus that measured by JENTOW and expressed as average ± SD in all subjects.

The performance of the BbB device was evaluated using 81 sets of data, and 9 data were excluded. For 7 sets of data, measurement errors occurred in JENTOW, and for 2, the measurement time did not last 1 min.

III. RESULT

Table II shows the size and weight of the BbB device compared with JENTOW. The BbB device was significantly

smaller and lighter than JENTOW. The examples of the pulse wave signals obtained by the BbB device and JENTOW are shown in Fig. 2. The measurement BP values were elevated during and after the Valsalva maneuver. The MMD and mean of measurement BP values that were measured by each device for the 81 sets of data are shown in Table III. The correlation coefficient between the pulse wave signals obtained by the BbB device and those of JENTOW was 0.98 ± 0.02 . The difference in BbB BP values was shown in Fig. 3, as determined using the Bland–Altman analysis. The difference in the measured systolic BP (SBP) was -0.3 ± 4.7 mmHg and that of the measured diastolic BP (DBP) was 0.7 ± 3.4 mmHg.

TABLE II. COMPARISON OF THE BbB DEVICE AND JENTOW

		JENTOW		
		BbB device	Control unit	Sensor unit
Size (cm)	Width	9.3	28.0	5.8
	Depth	7.5	29.0	3.3
	Height	7.1	12.5	3.4
Weight (g)		150	7000	
Power source		Lithium-ion battery		AC battery

Comparison of the size, weight, and power source of the two devices. The size and weight of JENTOW were confirmed from the instruction manual of “JENTOW-7700.”

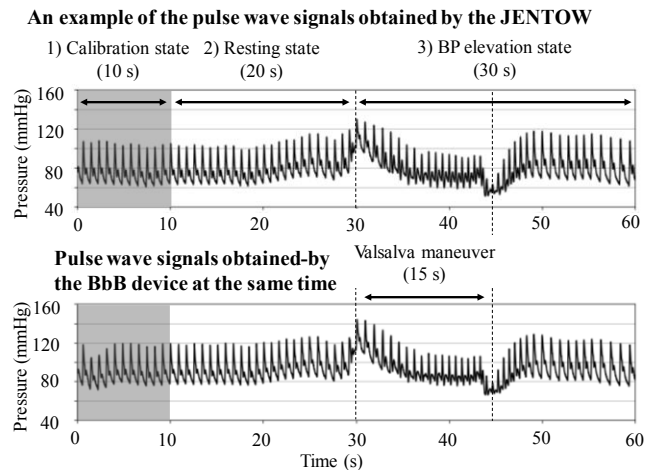


Figure 2. Example of the relationship between the pulse wave signals simultaneously obtained by the BbB device worn on the left wrist and JENTOW worn on the right wrist.

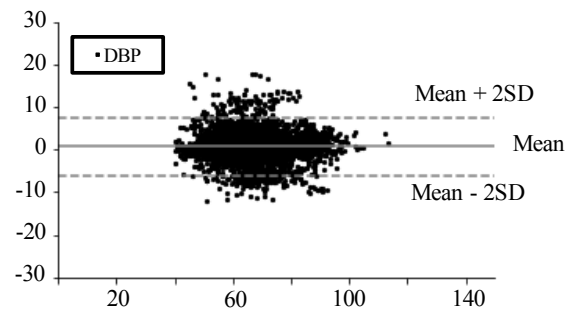
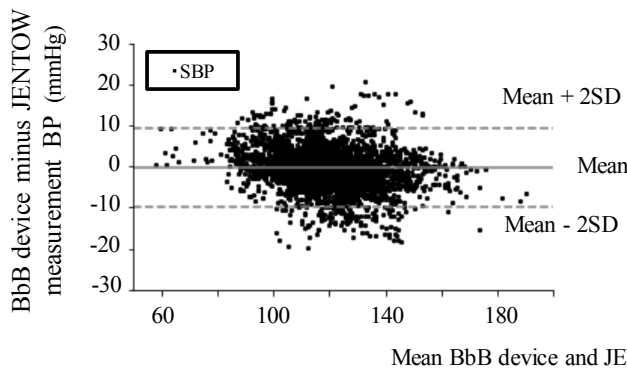


Figure 3. The scatterplots indicate the difference in the BbB BP values measured by the BbB device minus those measured by JENTOW using the Bland–Altman analysis (4234 beats of BbB BP obtained with 81 sets of data are plotted). These plots include BbB BPs obtained in the resting and BP elevation states. Solid lines indicate between-method means, while broken lines indicate between-method means ± 2 SD in all data.

TABLE III. MMD AND MEAN OF BbB BPs

	BbB device	JENTOW
Mean of systolic BP (mmHg)	118.3 ± 10.6	118.6 ± 11.8
Mean of diastolic BP (mmHg)	67.6 ± 8.5	66.9 ± 8.9
MMD of systolic BP (mmHg)	37.7 ± 17.2	39.2 ± 18.4
MMD of diastolic BP (mmHg)	24.7 ± 10.5	24.3 ± 9.9

Comparison of BbB BP measured by the BbB device and JENTOW for each of 81 sets of measurement data.

IV. DISCUSSION

The developed BbB device was significantly smaller and lighter than the validated conventional device, JENTOW, and had an almost equivalent performance. The weight of this device was 150 g, which is approximately indicated as 1/45th of the conventional device. Moreover, this device was cableless and easily measured BbB BP at home without depending on the measurement environment. Performance evaluation was performed, including the BP elevation state, in which SBP is approximately elevated to 40 mmHg on average. The correlation coefficient of the pulse wave signals was 0.98 ± 0.02 , which shows a high correlation, and the difference in the BbB BP values was small.

Noninvasive continuous BP can be measured using tonometry, volume clamp and PTT methods. The volume clamp method requires servo control to adjust the cuff pressure in parallel with the arterial pressure of the finger [10]. The system based on the volume clamp consists of mechanical elements, such as a pump, a valve, and an air hose. To realize servo control by these elements, a pump and a valve are required to have high performance. It is difficult to realize the miniaturization of the device using this method. Because, in addition to the miniaturization of parts, it is necessary to satisfy the performance that enables servo control. Moreover, it is difficult to monitor continuous BP for long-term measurements because finger compression has led to ischemia of finger blood flow [7]. The PTT method calculates the BbB BP as an estimated value using the time delay for the pressure wave to travel between two arterial sites instead of pressure. The estimated BbB BP is affected by blood density, the average cross-sectional area of the arteries between the measurement sites, and arterial compliance [11]. It is necessary to optimize each parameter for each user. Therefore, the tonometry method is the most suitable for measuring overnight continuous BP at home.

Although the BbB device was small and lightweight, this device has usability limitations compared with a home BP monitor. First, palpation, which is difficult for non-medical workers, is required to adjust the location of the tonometry sensor on the skin above the radial artery. We will improve the guide function of this device, which is equipped for adjusting the position of the tonometry sensor so that non-medical workers can use it. Second, a contact between the tonometry sensor, skin changes such as body motion, and BbB BP cannot be accurately calculated. We will improve the function to calibrate at the appropriate timing and exclude abnormal values using the accelerometer signal. In this study, there are limitations such as the number of subject and the point of view in the evaluation. In order to realize a BbB device that is easy to use at home, we need to develop evaluation method based on the intended use.

Recently, several studies have progressed using our device based on tonometry. BP surge was successfully observed in patients with obstructive sleep apnea in a previous clinical study [1]. Moreover, we have developed an algorithm for automatically detecting BP surge from overnight BbB BP [12]. BP surge, which would trigger CV events, can be effectively evaluated using the algorithm. In another study, our device based on tonometry was used to develop a novel index for predicting the daily BP variations from 30 min of BbB BP [13]. The basic configuration of a device that is used in these studies is the same as the BbB device, which is better considering its ease of use. We will proceed with clinical research on the value of measuring BbB BP and improve this system so that it could be easily used at home.

V. CONCLUSION

We developed a BbB BP monitoring device based on tonometry, which can measure BP for each heartbeat. The BbB device was small and lightweight compared with the validated medical device using tonometry. Moreover, the pulse wave signals had a high correlation, and the BbB BP values were almost equivalent to those of the validated device.

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