


## ORIGINAL PAPER

# Diagnostic accuracy of an algorithm for detecting atrial fibrillation in a wrist-type pulse wave monitor

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## Abstract

We evaluated the diagnostic value of atrial fibrillation (AF) measured by a wrist-type pulse wave monitor in this case-control study. Six serial pulse wave values (three in the left and three in the right wrist) were measured using a wrist-type monitor in 29 AF patients and 30 subjects with sinus rhythm. We defined “monitor AF in irregular pulse peak (IPP) 15/20/25” as follows: (a) IPP:  $|\text{interval of pulse peak} - \text{the average of the interval of the pulse peak}| \geq \text{the average of the interval of the pulse peak} \times 15/20/25\%$ ; (b) irregular heartbeat (IHB):  $\text{beats of IPP} \geq \text{total pulse} \times 20\%$ ; and (c) monitor AF:  $\geq 4$  IHBs of the six pulse wave measurements. In IPP 15, the sensitivity and specificity were 0.97 and 1.00, respectively. Pulse wave analysis by a wrist-type monitor was shown to have high sensitivity and specificity for the diagnosis of AF.

## 1 | INTRODUCTION

Atrial fibrillation (AF) is a common disease whose incidence increases with age<sup>1-3</sup> and is a major risk factor for stroke and thrombosis.<sup>4-6</sup> Hypertension increases the risk of thrombosis,<sup>7,8</sup> and the prevalence of hypertension is high.<sup>9-12</sup>

Paroxysmal AF is often asymptomatic, and the prognosis of asymptomatic AF is worse than that of symptomatic AF.<sup>13</sup> AF can be detected by self-examination of pulse,<sup>14</sup> but the accuracy of this approach is dependent on the skill of the patient.

Recent studies have reported the usefulness of a wrist-type monitor that uses a fingertip or thumb-on method to detect AF.<sup>15-17</sup> As an alternative approach, we recently developed a wrist-type pulse wave monitor to detect AF.<sup>18,19</sup> In this study, we evaluate the usefulness of our wrist-type pulse wave monitor for diagnosing AF.

## 2 | METHODS

We enrolled 29 outpatients with AF and 30 outpatients with sinus rhythm. Electrocardiography (ECG) showed AF during all six pulse

wave measurements in the AF subjects and sinus rhythm during all six measurements in the 30 subjects with sinus rhythm.

For each subject, six pulse wave measurements (25 seconds) were taken at 60-second intervals in the sitting position (alternating the left and right wrists, for a total of 3 left and 3 right wrist measurements), using a wrist-type pulse wave monitor (UW-330BLE; A&D; Figure 1A,B). We confirmed the concordance between the interval of the pulse wave and QRS wave in the ECG in all patients (total 1180 beats; Figure 1C). We evaluated the accuracy of the AF detection algorithm separately for the left and right wrist (Figure 1D).

### 2.1 | Photoplethysmography

Photoplethysmography (PPG) is an optical measurement technique that can be used to detect blood volume changes in the microvascular bed of the tissue.<sup>20</sup> It is a noninvasive method that makes measurements at the surface of the skin.

The PPG sensor system consists of green light-emitting diodes and photodetectors. Light traveling through biological tissue can be absorbed by different substances, including pigments in the skin, bone, arteries, and veins. Changes in blood flow occur mainly in the

arteries.<sup>21</sup> For example, the arteries contain more blood volume during the systolic phase of the cardiac cycle than during the diastolic phase. Photoplethysmography sensors optically detect changes in the blood flow volume in the microvascular bed of tissue via reflection from or transmission through the tissue. The PPG waveform features of the peripheral pulse were synchronized to each heartbeat. Undersensing and oversensing of the pulse waves were observed in 2.6% and 1.4% of the total beats in patients with sinus rhythm (11 800 beats), and 11.6% and 1.5% of the total beats in AF patients (13 440 beats).

## 2.2 | AF detection algorithm

The interval of pulse waves was analyzed, and the average pulse wave interval was calculated in 6 measurements (3 measurements each for the left and right wrist). We defined “monitor AF in irregular pulse peak (IPP) 15/20/25” as follows: (a) IPP: |interval of pulse wave - the average of the interval of the pulse wave|  $\geq$  the average of the interval of the pulse wave  $\times$  15/20/25%; (b) irregular heartbeat (IHB): beats of IPP  $\geq$  total pulse  $\times$  20%; and (c) the “monitor AF (IPP 15/20/25)”:  $\geq$  4 IHBs of the six pulse wave measurements according to a past report.<sup>22</sup>

Simultaneously during the deflation phase of each pulse wave measurement (when the AF detector of the device was operating), the ECG was recorded continuously in the I lead (Figure 1C). We confirmed the concordance between the interval of the pulse wave and QRS wave in the ECG in all patients (total 1180 beats).

## 2.3 | Ethical issues

The internal review board of the Jichi Medical University School of Medicine approved this study. Written informed consent for the study was obtained individually from all of the subjects.

## 2.4 | Statistical analysis

Data are shown as the mean  $\pm$  SD or a percentage. Student's *t* test was used to analyze the continuous data of the sinus rhythm and AF patients. Comparisons of parameters among the groups were made

using the chi-square test. The association between the RR interval in ECG and the pulse wave interval in the wrist-type monitor was assessed using Pearson's correlation coefficient and a Bland-Altman graph. The sensitivity, specificity, and kappa statistic for the AF diagnosis were assessed for each of the individual measurements made by the monitor. SPSS version 20.0 software (IBM Inc) was used for the statistical analysis. A probability value  $<0.05$  was considered statistically significant.

## 3 | RESULTS

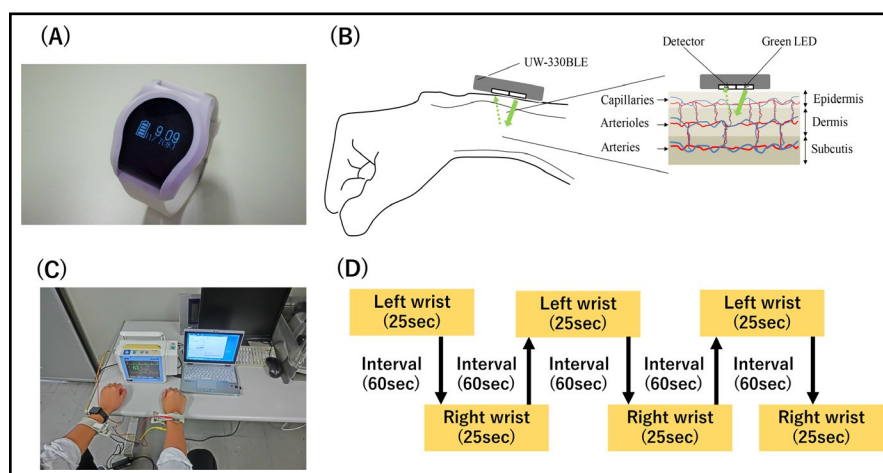
The clinical characteristics of the AF patients and sinus rhythm subjects are summarized in Table 1. The ages, gender distributions, CHADS<sub>2</sub> score, and CHA<sub>2</sub>DS<sub>2</sub>-VASc score of the two groups were similar.

The association between the pulse wave interval in the wrist-type monitor and the RR interval in ECG is demonstrated in Figure 2. The pulse wave interval was strongly associated with the RR interval in patients with sinus rhythm ( $R = 0.95$ ,  $P < .001$ ). Figure 3 is the Bland-Altman plot of the pulse wave interval and the RR interval in ECG. Even in AF patients, more than 95% of the values were within average  $\pm$  1.96SD.

The distribution of IHBs in the 6 measurements is shown in Figure 4. We defined monitor AF as more than 4 IHBs of 6 measurements (ie, 4/6, 5/6, or 6/6).

The accuracy for detecting AF was as follows (Table 2). The sensitivity and specificity were 0.97 and 1.00 in IPP 15, and the sensitivity and specificity were 0.93 and 1.00 in IPP 20. In IPP 25, the specificity was also 1.00, but the sensitivity was relatively low (0.79). The positive predictive value was 1.00 in IPP 15, 20, and 25. The negative predictive value was 0.97 in IPP 15, 0.94 in IPP 20, and 0.83 in IPP 25 (Table 2).

We also evaluated the diagnostic accuracy of the IHB value for AF (354 measurements; AF: 174 measurements, sinus rhythm: 180 measurements). In IPP 15, the sensitivity and specificity were 0.92 and 0.83, and in IPP 20, the sensitivity and specificity were 0.91 and 0.92. In IPP 25, the specificity was 0.93, but the sensitivity was relatively low (0.78, Table 2).



**FIGURE 1** The measurement of pulse wave. A, A wrist-type pulse wave monitor (UW-330BLE; A&D), B, photoplethysmography, C, real measurement of pulse wave and electrocardiogram, D, protocol of this study

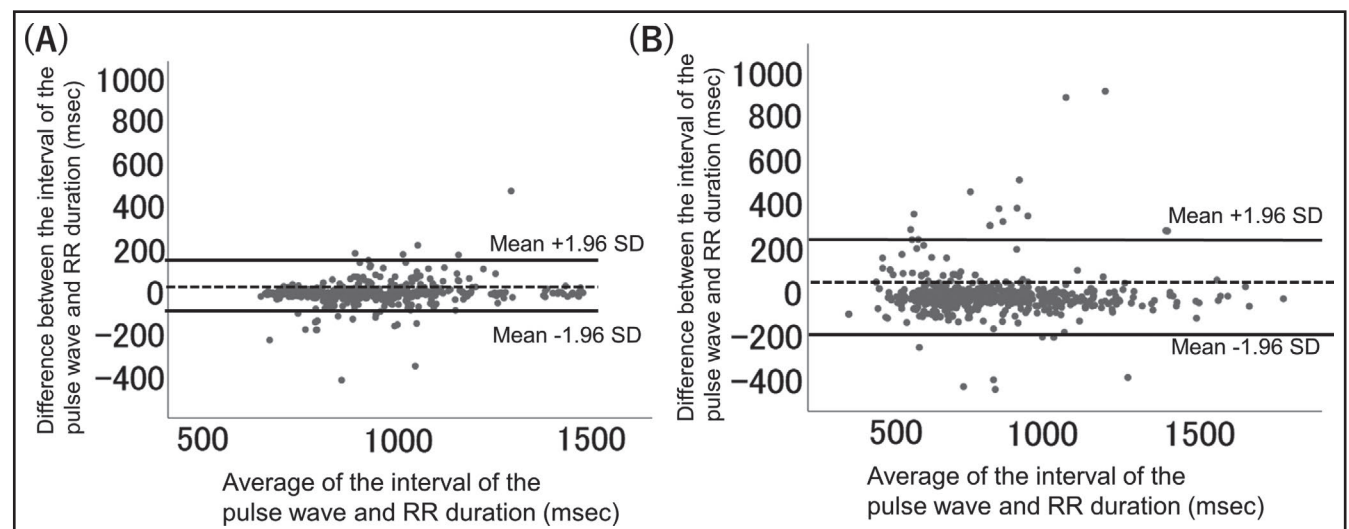
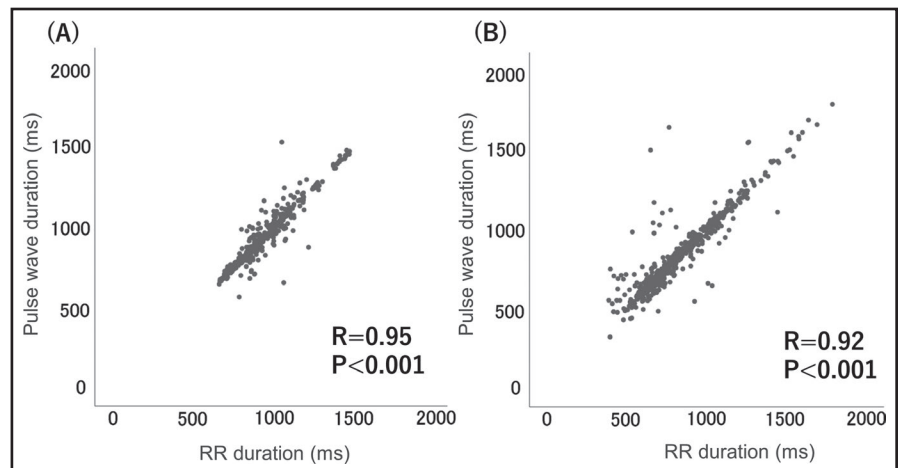
## 4 | DISCUSSION

Pulse wave analysis of wrist-type monitor was precisely reflected RR duration of ECG. The IPP 15 and IPP 20 algorithms exhibited more than 90% sensitivity and more than 90% specificity for the diagnosis of AF.

**TABLE 1** Patient characteristics

	Sinus rhythm (N = 30)	Atrial fibrilla- tion (N = 29)	P
Age (y)	67.7 ± 8.0	66.5 ± 12.2	.67
Men (%)	70.0	72.4	.84
Hypertension (%)	50.0	37.9	.19
Diabetes (%)	6.7	6.9	.95
Stroke (%)	3.3	3.5	.96
Vascular disease	6.7	10.3	.32
CHADS <sub>2</sub> score	0.9 ± 0.8	1.1 ± 0.9	.37
CHA <sub>2</sub> DS <sub>2</sub> -VASc score	2.0 ± 1.4	2.1 ± 1.3	.78

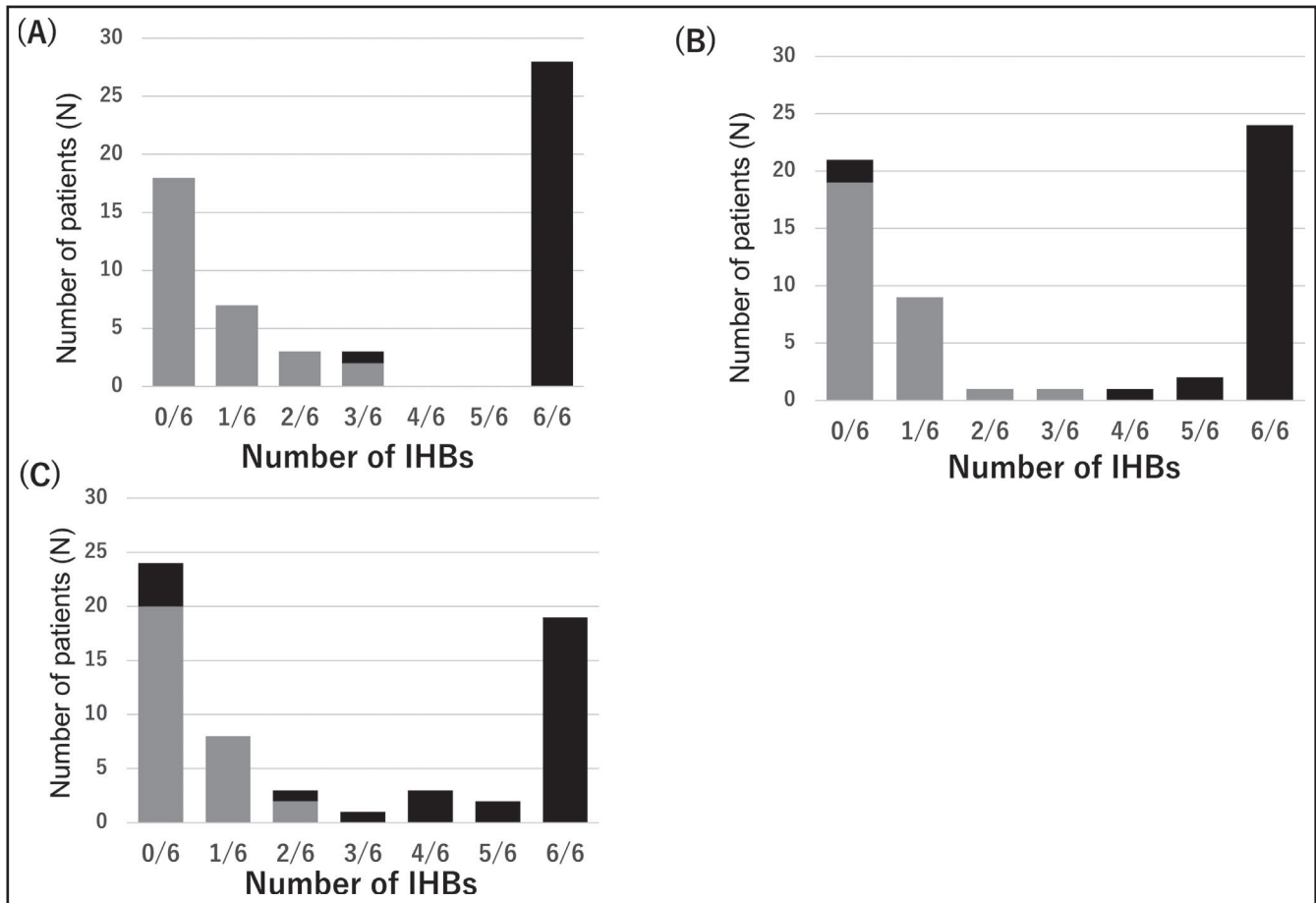
**FIGURE 2** The association between the interval of the pulse wave and heart rate. A, Patients with sinus rhythm, B, patients with atrial fibrillation



**FIGURE 3** Bland-Altman plot of the interval of the pulse wave and heart rate values. SD: standard deviation. A, Patients with sinus rhythm, B, patients with atrial fibrillation

We evaluated the accuracy of pulse wave measurement with the wrist-type monitor for the diagnosis of AF. The association between the pulse wave of the wrist-type monitor and the RR duration of ECG was good. We previously confirmed the diagnostic value of the AF algorithm using a home blood pressure monitor,<sup>22</sup> and here we found that pulse wave analysis using the wrist-type monitor also had good diagnostic value for AF. The wrist-type monitor is mobile and easy to carry. The frequency of onset of paroxysmal AF has diurnal variation.<sup>23</sup> In the elderly, AF onset occurs predominantly in the daytime in response to autonomic functions.<sup>24,25</sup> The wrist-type monitor is useful to detect AF during daytime and might be especially useful for elderly patients. Many patients with AF symptoms will be able to activate the wrist-type monitor themselves. In addition, it might be possible to diagnose paroxysmal AF by activating the wrist-type monitor at the appearance of symptoms.

In our experiments, the IPP 15 and IPP 20 algorithms achieved more than 90% sensitivity and more than 90% specificity for the diagnosis of AF. In past reports using a mobile AF monitor, the sensitivity was 93% and the specificity was 84% using an Apple watch



**FIGURE 4** The distribution of sinus rhythm and atrial fibrillation according to the number of IHBs of three measurements. A, IPP 15%, B, IPP 20%, C, IPP 25%. Black bars = patients with atrial fibrillation; gray bars = sinus rhythm patients. IHB, irregular heartbeat; IPP, irregular pulse peak

with a Kardia band,<sup>15</sup> the sensitivity was 93.1% and the specificity was 90.9% using an iPhone with finger pulse,<sup>16</sup> and the sensitivity was 94.7% and the specificity was 93% using fingertip PPG.<sup>17</sup> We achieved a high rate of detection of AF using an algorithm that considers 2 of the 3 available measurements in order to increase the

specificity according to the method described in our previous report.<sup>22</sup> The pulse wave may be disturbed by body motion, and AF may cause pulse deficits; thus, the RR interval and the pulse wave interval are not completely coincident. However, in our sinus rhythm patients, pulse wave analysis using a wrist-type monitor was well

**TABLE 2** Accuracy of the monitor for diagnosing AF

Threshold	Monitor AF + / Monitor AF -	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Kappa
(A) Patients (N = 59)						
IPP 15%	28/31	0.97	1.00	1.00	0.97	0.97
IPP 20%	27/32	0.93	1.00	1.00	0.94	0.93
IPP 25%	23/36	0.79	1.00	1.00	0.83	0.80
Threshold	IHB + / IHB -	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Kappa
(B) Measurements (N = 354)						
IPP 15%	190/164	0.92	0.83	0.84	0.91	0.75
IPP 20%	172/182	0.91	0.92	0.92	0.91	0.83
IPP 25%	147/207	0.78	0.93	0.92	0.81	0.71

Abbreviations: AF, atrial fibrillation; IHB, irregular heart beat; IPP, irregular pulse peak.

reflected the RR duration of ECG. For patients with a low fluctuation of pulse wave by the wrist-type monitor, our algorithm can still calculate a sinus rhythm with high accuracy.

Several methods are available for the detection of asymptomatic AF: pulse palpitation, standalone ECG recording devices, smartphone-based ECG recording devices, smartphone-based PPG, and BP monitors with an AF detection algorithm.<sup>26</sup> Our device is similar to the smartphone-based PPG and BP monitor with an AF detection algorithm. The PPG method usually requires that the patient places a finger in contact with the smartphone camera.<sup>27</sup> In this study, we did not equip our device with a screen for displaying the data, but we currently developing a screen that will be incorporated into the wrist band. By changing the wave form and position, we will be able to measure blood pressure by using the wrist band. In the future, further improvements to the wrist-type blood pressure monitor may lead to dramatically better detection of blood pressure variability than by an ambulatory blood pressure monitor, and it can be applied to information technology.<sup>18,19</sup> If this algorithm could be incorporated into the wrist-type blood pressure monitor, it would be able to detect AF earlier and could help to improve the prognosis of hypertensive patients. This device in this study was wearable and hence may be useful in a mass screening.

The main limitation of this study was that arrhythmias other than AF were not included. Healthy subjects with an irregular heart rhythm (ie, sinus arrhythmia), and frequent premature cardiac beats might be misdiagnosed with AF. The characteristics of AF are pulse irregularity and pulse loss. We have previously considered that irregularity of pulse, but not heartbeat, is a useful diagnostic tool for AF. However, to reduce the false-positive rate and evaluate the diagnostic value and accuracy of these parameters for AF, further studies including arrhythmias other than AF will be needed to further evaluate the AF detection algorithm of the wrist-type monitor. In the AF group, when the RR duration was short (ie, when tachycardia was present), the discrepancy between the RR duration and pulse wave seemed to be larger. Tachycardia might thus result in undersensing of pulse. Also, although we did not measure the wrist circumference, larger wrist circumference could have resulted in less accurate measurement. Body motion artifacts could have affected the oversensing and undersensing of pulse waves. Finally, this study was a case-control study with a very small number of cases. Further prospective studies with a larger number of enrolled subjects will be needed to evaluate the diagnostic value of this device.

## 5 | CONCLUSIONS

Pulse wave analysis by a wrist-type monitor was in good agreement with the RR duration by electrocardiography, and the IPP 15 and IPP 20 algorithms had high sensitivity and high specificity for the diagnosis of AF.

## ACKNOWLEDGMENT

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## CONFLICT OF INTEREST

K Kario received research grants from A&D Company Limited; N Yasui, S Takahashi, and K Uemoto are employees of A&D Company Limited; and all other authors report no potential conflict of interest in relation to this article.

## DISCLOSURES

This study was conducted as a joint research between Jichi Medical University School of Medicine and A&D Company, Limited.

## AUTHOR CONTRIBUTION

T. Kabutoya and K. Kario conceived and designed the study; analyzed and interpreted the data. T. Kabutoya, S. Takahashi, T. Watanabe, Y. Imai, K. Uemoto, N. Yasui, K. Kario drafted the manuscript or critically revised for important intellectual content; approved the final version of the submitted manuscript.

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