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SHORT REPORT

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Assessment of a new algorithm to detect atrial fibrillation in home blood pressure monitoring device among healthy adults and patients with atrial fibrillation

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Abstract

The authors evaluated the diagnostic accuracy of a new algorithm for detecting atrial fibrillation (AF) using a home blood pressure (BP) monitor. Three serial BP values were measured in 205 subjects with sinus rhythm and 75 subjects with AF confirmed by electrocardiogram. Irregular pulse peak (IPP) 15 was defined as follows: |interval of pulse peak - the average of the interval of the pulse peak| ≥ the average of the interval of the pulse peak × 15%. Irregular heartbeat (IHB) was defined as follows: beats of IPP ≥ total pulse × 20%. The sensitivities of IPP15 for diagnosing AF defined as two or three IHBs of three readings were 1.0 and 0.99, and the corresponding specificities were 0.97 and 0.99, respectively. The algorithm using two or more IHBs of three readings in the setting of IPP15 had the highest diagnostic accuracy for AF.

1 | INTRODUCTION

Atrial fibrillation (AF) is one of the major factors associated with embolic stroke and heart failure.[1] The diagnosis of new onset of AF and management for AF is important. However, the ability to detect paroxysmal AF is limited even when using long-term electrocardiographic monitoring. Pulse self-examination is useful for detecting one's own AF, but almost 40% of AF patients are asymptomatic.[2]

Hypertension is one of the major etiologic factors for coexisting AF, and blood pressure (BP) control is important for the prevention of AF.[3,4] Aging can increase the risk of developing both hypertension and AF, and coexisting AF and hypertension can increase stroke risk.[5] A new method for diagnosing AF in hypertensive patients is thus urgently needed.

We previously evaluated a new algorithm for home BP monitoring and demonstrated its high diagnostic accuracy for detecting AF among 36 outpatients who were previously diagnosed with AF.[6] In the present study, we assessed the accuracy of the algorithm in 280 subjects consisting of patients with AF and healthy adults.

2 | METHODS

2.1 | Study subjects

A total of 280 subjects, including 100 patients with AF and 180 annual health check-up examinees, were analyzed in the present study. The data for the 100 patients with AF were taken from a previous study conducted at Jichi Medical University to evaluate a new algorithm designed for the detection of AF using a home BP-monitoring device (approved by the institutional review board of the Jichi Medical University School of Medicine, Tochigi, Japan). The data for the 180 check-up examinees were collected at A&D Co., the makers of the BP-monitoring device, for product quality evaluation and verification. Written informed consent was obtained from all subjects.

2.2 | Pulse wave analysis and ECG

In a previous study, we collected three BP measurements for each of the current patients after ≥ 5 minutes of rest in the supine position with at least 30 seconds between measurements, using a validated home BP monitor (UA-1020; A&D).[7] The three BPs were measured by inflating the cuff to a point over the patient's systolic BP and then gradually deflating it. The pulse wave was extracted by changing each pulse pressure after cuff deflation in each of the three BP measurements. The intervals of pulse waves were analyzed automatically by the UA-1020 during the decompression phase (Figure S1). As in our previous study,[6] irregular pulse peak (IPP) 15 was defined as follows: |interval of pulse peak - the average of the interval of the pulse peak| ≥ the average of the interval of the pulse peak × 15%. Irregular heartbeat (IHB) was defined as follows: beats of IPP ≥ total pulse × 20% (shown in Figure S2). We confirmed the diagnostic accuracy for each of three IPP cutoffs: 25% (IPP25), 20% (IPP20), and 15% (IPP15). We defined "monitor AF" as the AF detected by this home BP monitor equipped with this algorithm. This study also investigated how many IHBs out of the three measurements should be defined as "monitor AF" to increase the diagnostic accuracy.

Simultaneous ECG monitoring was performed continuously during the deflation phase of each BP measurement (when the AF detector of the device was operating). We evaluated the accuracy of "monitor AF" confirming the concordance between "monitor AF" in the home BP monitor and AF detected in the ECG.

TABLE 1 Baseline data of patients with sinus rhythm and AF rhythm

	Sinus rhythm n = 205	AF rhythm n = 75	*P* value
Age, yrs	53 ± 10	68 ± 10	<.001
Male sex, %	69.0	76.0	.24
Systolic BP, mmHg	125 ± 15	124 ± 16	.58
Diastolic BP, mmHg	83 ± 11	81 ± 12	.18
Pulse rate, ppm	69 ± 10	78 ± 13	<.001

Note: Abbreviation: AF, atrial fibrillation; BP, blood pressure; ppm, pulse per minute.

TABLE 2 Accuracy of the "monitor AF" defined by the frequency of IHB at each IPP cutoff

IPP	Monitor AF +/−	Sensitivity	Specificity	κ
(a) Monitor AF is defined as 1 IHB of 3 readings				
IPP 25%	77/203	0.95	0.98	0.92
IPP 20%	86/194	0.99	0.95	0.95
IPP 15%	100/180	1.00	0.88	0.80
(b) Monitor AF is defined as 2 IHBs of 3 readings				
IPP 25%	67/213	0.85	0.99	0.87
IPP 20%	75/205	0.96	0.99	0.95
IPP 15%	81/199	1.00	0.97	0.95
(c) Monitor AF is defined as 3 IHBs of 3 readings				
IPP 25%	49/231	0.66	1.00	0.73
IPP 20%	64/216	0.86	1.00	0.89
IPP 15%	74/206	0.99	0.99	0.97

Note: Abbreviations: AF, atrial fibrillation; IHB, irregular heartbeat; IPP, irregular pulse peak.

3 | RESULTS

Of the total 280 subjects in this analysis, 75 subjects exhibited AF in their ECG findings conducted in this study protocol and 205 subjects exhibited sinus rhythm at the timing of BP measurement. Baseline data of the subjects with AF and sinus rhythm are summarized in Table 1. The distribution of BP values was similar between the two groups. The patients with AF rhythm were older and had a higher pulse rate than those with sinus rhythm. The accuracies of IHB detection for all 840 readings at the three IPP cutoff values of 15% (IPP15), 20% (IPP20) and 25% (IPP25) are shown in Table S1. In keeping with the findings of our previous study,[6] the setting of IPP15 had higher accuracy for IHB detection than the settings of IPP20 or IPP25. The diagnostic accuracies of the "monitor AF" for each IPP cutoff value, which were defined by the frequency of IHB, are shown in Table 2. The accuracy of "monitor AF" in IPP15 defined by one IHB, two IHBs and three IHBs of three readings had sensitivities of 1.0, 1.0 and 0.99 and specificities of 0.88, 0.97 and 0.99, respectively. The definition of monitor AF as two IHBs or three IHBs of three readings using the setting of IPP15 had the highest sensitivity and specificity with a kappa-statistic suggesting almost perfect agreement.

In a sensitivity analysis of 70 patients over 65 years old, the definition of monitor AF as two IHBs of three readings using the setting of IPP15 had the highest sensitivity and specificity, with a high kappa-statistic in the patients over 65 years old as shown in Table S2.

4 | DISCUSSION

We examined the accuracy of a home BP-monitoring device equipped with our new algorithm for pulse wave analysis for the detection of AF among patients with AF and healthy adults, using settings similar to those in a real-world clinical environment. We previously demonstrated that the algorithm had high diagnostic accuracy for detecting AF among 36 patients with previously diagnosed AF.[6] The high diagnostic accuracy was found even in a larger population that included a large portion of subjects with sinus rhythm for diagnosing AF.

Our main findings were as follows. (a) The following definition of IHB was suitable for monitoring AF: beats of IPP ≥ total pulse × 20% based on the IPP. (b) Two or more IHBs of three readings in the setting of IPP cutoff values at 15% (IPP15) had the highest sensitivity and specificity for diagnosing AF. (c) A home BP-monitoring device equipped with the IHB algorithm could contribute to the total management of hypertensive patients in the future. The accuracy of monitor AF in IPP15 defined by two IHBs and three IHBs of three readings had high sensitivities of 1.0 and 0.99 and high specificities of 0.97 and 0.99, respectively.

Thirty-two of the total 840 readings were found to be false-positive readings for IHB because of arrhythmias. Our study indicated that patients with false-positive readings for IHB may have irregular heartbeat due to frequent premature contractions and sinus arrhythmia in ECG findings. However, the home BP-monitoring device had no error of BP measuring caused by any arrhythmias.

Previous meta-analyses and studies have similarly shown that AF detection algorithms using BP-monitoring required three consecutive measurements or at least two out of three consecutive measurements for accurate AF diagnosis.[8,9] Other study also suggested that a higher ventricular rate during AF could underestimate the oscillometric BP values even when using three measurements.[10] Our study had high specificity for detecting AF patients, and our AF patients had a mean pulse rate of 78 ± 13 pulses per minute. However, the ventricular rate during AF should be taken into account when determining the accuracy of oscillometric BP values in AF patients.

The prevalence of both hypertension and AF could increase with aging. It is recommended that patients over 65 years of age undergo an opportunistic screening for AF using pulse-taking followed by an ECG to detect asymptomatic AF.[11] In patients over 65 years old in present study, the definition of monitor AF as two or more IHBs of three readings using the setting of IPP15 also had the highest sensitivity and specificity with a high kappa-statistic suggesting almost perfect agreement.

We also developed a new information communication technology (ICT)-based multi-sensor ambulatory BP-monitoring device that stores the brachial intra-cuff pressure waveform data and each shape of the oscillometric curve.[12–14] This device could also be used for home BP monitoring. These devices for home and ambulatory BP monitoring of out-of-office BP measurements could help to clarify the relationship between AF onset and BP variability in daily life. Further, they could help to achieve an optimal management of hypertension as an "anticipation medicine" for zero cardiovascular events. Home BP-monitoring devices equipped with our new algorithm for detecting AF would contribute to the diagnosis of new-onset AF and to the prevention of cerebral-vascular embolic events in hypertensive patients by individualized optimal BP management over the long term.

5 | CONCLUSION

This study demonstrated that a new AF detection algorithm mounted on a home BP-monitoring device had high diagnostic accuracy for detecting AF, and could be used to monitor BP and heart rhythm every day and over a long term. Such monitoring could contribute to a worldwide reduction in the health care burden related to AF. Further investigations will be needed to establish the evidence of diagnosing AF and optimal BP control in hypertensive patients by the home BP-monitoring device.

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DISCLOSURES

K. Kario has received research funding from A&D Co. N. Yasui is an employee of A&D Co.

AUTHOR CONTRIBUTION

Kario K takes primary responsibility for this paper. Watanabe T wrote the manuscript and did the statistical analysis. Kabutoya T collected the patients' data. Kario K acquired research grants for the study. Watanabe T, Tomitani N, Yasui N, Kabutoya T, Hoshide S and Kario K reviewed/edited the manuscript.

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SUPPORTING INFORMATION

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

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