Development of a Novel Algorithm to Detect Atrial Fibrillation Using an Automated Blood Pressure Monitor With an Irregular Heartbeat Detector

Makoto Ishizawa, MD, PhD; Takahisa Noma, MD, PhD; Takahiro Izumi, MD; Ryosuke Tani, MD; Tomoko Inoue, MD; Eriko Nasu, MD; Atsushi Tobiume, MD; Yusuke Hasui, MD; Shota Yokoyama, MD; Hideyuki Hamaya, MD; Shohei Ishikawa, MD, PhD; Keiji Matsunaga, MD; Ryo Kawakami, MD; Kumi Konishi, MD; Yuichi Miyake, MD, PhD; Kaori Ishikawa, MD, PhD; Teppei Tsuji, MD, PhD; Kazushi Murakami, MD, PhD; Naoki Nishimoto, PhD; Hiroyuki Kitajima, PhD; Tetsuo Minamino, MD, PhD

Background: Atrial fibrillation (AF), which contributes to an increased risk of stroke, frequently remains undetected, suggesting an unmet need for easier and more reliable AF screening. The reports on screening AF using an Omron blood pressure (BP) monitor with an irregular heartbeat (IHB) detector show inconsistent results, so the aim of this study was to develop a novel algorithm to accurately diagnose AF with 3 BP measurements using an Omron automated BP monitor with IHB detector.

Methods and Results: In total, 303 general cardiac patients were included. Real-time single-lead ECG revealed AF in 44 patients. BP measurement was performed 3 times per patient using the Omron BP monitor HEM-907, and the number of IHBs detected was recorded. Based on these data, we developed the following algorithm: ≥1 IHB is detected during at least 2 of 3 BP measurements and the maximum number of IHBs detected is ≥2. Using this algorithm, we achieved a sensitivity of 95.5% and specificity of 96.5%, for diagnosing AF.

Conclusions: The novel algorithm with 3 BP measurements using the Omron automated BP monitor with IHB detector showed high sensitivity and specificity for diagnosing AF in general cardiac patients.

Key Words: Algorithms; Atrial fibrillation; Blood pressure monitors; Irregular heartbeats
**Procedure**

The automated oscillometric BP monitor used for this study was an Omron HEM-907 (OMRON Healthcare, Kyoto, Japan), which is designed for clinical use in a physician’s office or in hospital. This device has an additional function that detects the number of IHBs (as defined earlier). When the BP monitor detects 1, 2 or ≥3 IHBs during BP measurement, the monitor shows 1, 2 or 3 dots, respectively. This device has passed the Association for the Advancement of Medical Instrumentation validation protocol and has been used in other clinical studies.  

BP measurement was performed 3 times for each patient with the Omron HEM-907 in accordance with the Japanese Society of Hypertension Guidelines for the Management of Hypertension 2014. After at least 5 min of seated rest, the 1st BP measurement was performed, and subsequent measurements were taken at 1 min intervals. The systolic BP, diastolic BP, pulse rate, and the number of IHBs detected were recorded for each BP measurement. Real-time single-lead ECG was recorded continuously during all BP measurements using the HealthPatch MD (VitalConnect Inc., CA, USA), ReadMyHeart (TRYTECH Co. Ltd., Tokyo, Japan), or Duranta (ZAIKEN Co. Ltd., Tokyo, Japan). The recorded ECGs were analyzed by 2 board-certified cardiologists who were blinded to the results of the BP measurements. The patients with AF were classified into the “AF” group and all patients without AF were classified into the “Non-AF” group. Patients in the “Non-AF” group were further classified into an “Other arrhythmias” group with arrhythmias except AF and the “Sinus” group with normal sinus rhythm. All patients diagnosed with sinus arrhythmia were classified as “Sinus” group because respiratory sinus arrhythmia was judged as being effectively harmless; 2 patients required additional reference to their medical records and a 12-lead ECG to diagnose their rhythm.

Taking the single-lead ECG as the reference method for definitive diagnosis of AF, the diagnostic values (sensitivity, specificity, and accuracy) for diagnosing AF were calculated in every case, with both the number of IHBs detected and the number of BP measurements in which IHBs were detected. Furthermore, we analyzed the data based on the rhythm that is ≤25% or ≥25% than the average rhythm of a pulse wave detected during BP measurement. There are several reports examining the utility of the Omron BP monitor with an IHB detector in screening for AF, but the results have not been consistent, possibly because all past studies used only 1 BP measurement. In this study, we evaluated the ability to diagnose AF in general cardiac patients when 3 BP measurements were performed with an Omron automated BP monitor equipped with IHB detector. Furthermore, we developed a novel algorithm to accurately diagnose AF with an Omron BP monitor based on data from the number of IHBs detected during 3 BP measurements.

**Methods**

**Subjects**

Patients who were hospitalized or visited outpatient clinics at Kagawa University Hospital or who entered welfare-based nursing homes for the elderly in Kagawa were recruited. The exclusion criteria were age under 20 years, the presence of a pacemaker, and/or an implanted defibrillator and refusal to participate. Patients who could not remain at rest while seated, who could not have BP measured in the upper arm, such as dialysis patients, and any who were judged unsuitable for the study by their doctor were also excluded. If the Omron BP monitor stopped automatically and showed an error sign while measuring BP, we did not perform additional BP measurements in order to avoid unnecessary pain and thus also excluded those patients from the analysis.

In total, 345 consecutive patients were recruited; 9 patients were excluded because a medical history of pacemaker implantation was found after they provided informed consent; 31 patients (including 9 AF patients) showed an error sign during BP measurements; 2 patients whose data could not be collected because of technical or mechanical difficulties were excluded. Therefore, data from the remaining 303 patients were analyzed (Figure 1). Medical information of all patients was collected from their medical records.

![Figure 1. Flow chart of patient recruitment and participation. BP, blood pressure.](image-url)
Diagnosing AF With Automated BP Monitor

Diagnosing AF With Automated BP Monitor

The association between the RR intervals on the real-time single-lead ECG and the pulse wave intervals detected by the Omron BP monitor was checked with 50 intervals from the first 3 AF patients in the same way as reported by Kabutoya et al.6

The protocol was approved by the Kagawa University Ethics Committee, and signed informed consent was given by all patients.

Statistical Analysis

The baseline characteristics data are expressed as the mean±standard deviation (SD). The association between the RR intervals on ECG and the pulse wave intervals recorded by the Omron BP monitor was assessed using Pearson’s product-moment correlation coefficient. The sensitivity, specificity, and accuracy for the diagnosis of AF were calculated by generating 2 contingency tables with the single-lead ECG diagnosis as the reference. A significant association between 2 variables on a contingency table was determined using the Chi-square test, and P<0.05 was considered significant. The 95% confidence intervals for the sensitivity, specificity and accuracy were calculated using the Agresti-Coull method.16 All calculations were performed with SAS software (University Edition; SAS Institute Inc., Cary, NC, USA).

Results

Among the 303 patients, 252 (83%) visited the hospital’s outpatient clinics or were hospitalized in Kagawa University Hospital, and 51 patients (17%) were admitted to welfare-based nursing homes for the elderly. The mean age of the subjects was 72.2 years; 124 patients (40%) were over 75 years old, 23 patients (7%) were over 90 years old, and the oldest patients were 99 years old (Table 1).

Based on the results of the ECG diagnosis, 44 patients (14%) had AF and were classified as the “AF” group. Among the 259 patients in the “Non-AF” group, 211 (70%) were classified as the “Sinus” group and 48 (16%) were classified as the “Other arrhythmias” group. The “Sinus” group included 15 patients with sinus arrhythmias. Among the 48 patients in the “Other arrhythmias” group, 29 had atrial premature contractions, 15 had ventricular premature contractions, 2 had both atrial and ventricular premature contractions, 1 had an atrial flutter and 1 had an atrial tachycardia.

More than 60% of the patients included in the analysis

Table 1. Baseline Characteristics of the Study Patients

<table>
<thead>
<tr>
<th></th>
<th>All patients (n=303)</th>
<th>AF (n=44)</th>
<th>Sinus (n=211)</th>
<th>Other arrhythmias (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>72.2±13.5</td>
<td>76.3±10.3</td>
<td>71.1±14.5</td>
<td>73.6±11.2</td>
</tr>
<tr>
<td>Male (%)</td>
<td>61.7</td>
<td>77.3</td>
<td>58.8</td>
<td>60.4</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>23.5±4</td>
<td>22.7±3.4</td>
<td>23.7±4.2</td>
<td>23.5±3.3</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>61.7</td>
<td>54.0</td>
<td>60.7</td>
<td>70.8</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>29.0</td>
<td>15.9</td>
<td>31.3</td>
<td>29.2</td>
</tr>
<tr>
<td>Congestive heart failure (%)</td>
<td>21.5</td>
<td>45.5</td>
<td>15.2</td>
<td>25.0</td>
</tr>
<tr>
<td>TIA/cerebral infarction (%)</td>
<td>15.5</td>
<td>11.4</td>
<td>14.7</td>
<td>20.8</td>
</tr>
<tr>
<td>Vascular disease (%)</td>
<td>28.7</td>
<td>18.2</td>
<td>32.2</td>
<td>22.9</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>131.0±18.8</td>
<td>124.8±14.3</td>
<td>132.3±19.0</td>
<td>129.6±20.0</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>71.9±13.1</td>
<td>70.4±14.3</td>
<td>72.6±12.6</td>
<td>69.9±13.9</td>
</tr>
<tr>
<td>Pulse pressure (mmHg)</td>
<td>59.0±14.6</td>
<td>54.4±12.4</td>
<td>59.6±14.9</td>
<td>59.6±13.8</td>
</tr>
<tr>
<td>Pulse rate (beats/min)</td>
<td>71.0±12.0</td>
<td>77.4±12.8</td>
<td>70.4±11.1</td>
<td>68.4±13.5</td>
</tr>
</tbody>
</table>

Data are expressed as mean±SD. AF, atrial fibrillation; BP, blood pressure; TIA, transient ischemic attack.
had hypertension. Compared with the patients in the “Non-AF” group, those in the “AF” group were older, had a higher prevalence of compensatory heart failure and a lower prevalence of diabetes and vascular disease. No differences in BP were observed between the “AF” and “Non-AF” groups, but the pulse rate was higher in the “AF” group than in the “Non-AF” group (Table 1).

A representative pulse wave detected by the Omron BP monitor and the real-time ECG recorded at the same time are shown in Figure 2, showing clearly the good association (r=0.991, P<0.01) between the RR interval on ECG and the pulse wave interval detected by the Omron BP monitor. The number of IHBs detected during the 1st, 2nd, and 3rd BP measurement using the Omron BP monitor HEM-906 with an IHB detector was analyzed, and the diagnostic values (sensitivity, specificity, and accuracy) for diagnosing AF were calculated in each case (Supplementary Table). When at least 1 IHB was detected during a BP measurement (1st, 2nd or 3rd), the diagnosis of AF had a sensitivity within the range of 86.4–88.6% and a specificity within the range of 90.3–93.8% (Table 2, Supplementary Table). When at least 1 IHB was detected during 3 BP measurements, the sensitivity for diagnosing AF reached 100% but specificity was only 79.5% (Table 3). When at least 1 IHB was detected during at least 2 of 3 BP measurements, the diagnosis of AF had a sensitivity of 95.5% and a specificity of 93.8%. Furthermore, when at least 1 IHB was detected during at least 2 of 3 BP measurements and the maximum number of IHBs during 3 BP measurement was ≥2, the diagnosis of AF using the novel algorithm had sensitivity, specificity and accuracy of 95.5%, 96.5% and 96.4%, respectively. Importantly, all patients in the “Sinus” group were excluded by this novel algorithm. In the “Non-AF” group, 39 of 48 patients were also excluded by this algorithm, and the remaining 9 patients, who had frequent premature beats, were not distinguished from patients with AF.

Table 2. 2×2 Contingency Tables

<table>
<thead>
<tr>
<th></th>
<th>BP monitor reading</th>
<th>ECG reading</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>(A) At least 1 IHB detected during 3 BP measurements</td>
<td>44</td>
<td>53</td>
</tr>
<tr>
<td>(B) At least 1 IHB detected during 2 of 3 BP measurements</td>
<td>42</td>
<td>16</td>
</tr>
<tr>
<td>(C) Novel algorithm with 3 BP measurements</td>
<td>42</td>
<td>9</td>
</tr>
</tbody>
</table>

(A) Positive reading was defined as when at least 1 IHB was detected during 3 BP measurements. (B) Positive reading was defined as when at least 1 IHB was detected during at least 2 of 3 BP measurements. (C) Positive reading was defined as when at least 1 IHB was detected during at least 2 of 3 BP measurements and the maximum number of IHBs during 3 BP measurements was ≥2. AF, atrial fibrillation; BP, blood pressure.

Table 3. Diagnostic Values for AF

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(95% CI)</td>
<td>(95% CI)</td>
<td>(95% CI)</td>
</tr>
<tr>
<td>At least 1 IHB detected during 3 BP measurements</td>
<td>100% (95% CI 90.4–100)</td>
<td>79.5% (95% CI 74.2–84.0)</td>
<td>82.5% (95% CI 77.8–86.4)</td>
</tr>
<tr>
<td>At least 1 IHB detected during 2 of 3 BP measurements</td>
<td>95.5% (95% CI 84.0–99.6)</td>
<td>93.8% (95% CI 90.1–96.2)</td>
<td>94.1% (95% CI 90.8–96.3)</td>
</tr>
<tr>
<td>Novel algorithm with 3 BP measurements</td>
<td>95.5% (95% CI 84.0–99.6)</td>
<td>96.5% (95% CI 93.4–98.3)</td>
<td>96.4% (95% CI 93.5–98.0)</td>
</tr>
</tbody>
</table>

AF, atrial fibrillation; BP, blood pressure; CI, confidence interval; IHB, irregular heartbeat.

Discussion

The present study showed diagnostic values for AF when 3 sequential BP measurements using an Omron automated BP monitor with an IHB detector were performed. When these measurements using this monitor were performed and the novel algorithm was subsequently applied, the diagnosis of AF achieved a sensitivity of 95.5%, specificity of 96.5% and accuracy of 96.4% in general cardiac patients.

AF Detection Algorithm With Automated BP Monitor

Diagnostic performance for AF detection with an automated BP monitor has been demonstrated in recent years. Kabutoya et al reported that both the sensitivity and the specificity for diagnosing AF reached 100% when the definition of an IHB was changed from “25% variation” to “20%” or “15%” in 20 sinus and 16 AF patients using an automated BP monitor made by A & D. It was suggested that AF could be distinguished from sinus rhythm easily by tightening the criteria of an IHB, but their study subjects did not include patients with non-AF arrhythmias. There is concern that the more stringent the IHB criterion, the greater the number of false positives, especially in patients with non-AF arrhythmias.

Wiesel et al reported that the Microlife BP monitor could diagnose AF with 90–100% sensitivity and 89–99% specificity. The Microlife BP monitor had the original algorithm, which has a coefficient of variation (CV=SD/M) obtained from the mean (M) and standard deviation (SD) of the pulse wave interval, and CV ≥0.06 was a positive result for detecting AF. Interestingly, that algorithm attempts to prevent premature contractions from becoming false positives by excluding pulse waves that vary ≥25% from the mean RR interval; however, some AF patients with large variations in their RR intervals may become false positives.
negatives.\textsuperscript{18,19} This is the major difference with the Omron BP monitor, which only detects an IHB of $\leq 25\%$ or $\geq 25\%$ than the average rhythm during a BP measurement.

**Improvement in Diagnostic Performance for AF With Multiple BP Measurements Using Automated BP Monitor**

There are several studies that have evaluated the diagnostic performance for AF detection when BP measurement was performed 3 times with an automated BP monitor made by companies other than Omron.\textsuperscript{7,8,11} Those reports defined AF when positive results were found during at least 2 of 3 BP measurements, and in this way the best diagnostic performance for AF could be obtained. Consistent with previous reports, our study with the Omron BP monitor also showed similar optimal AF detection when positive results were found during at least 2 of 3 BP measurements. When IHBs were detected during at least 1 of the 3 BP measurements, the diagnosis of AF had high sensitivity but low specificity. In that case, patients with sinus arrhythmia or extra systoles easily became false positives. In contrast, when IHBs were detected in all 3 BP measurements, the diagnosis of AF had high specificity but low sensitivity. In that case, false negatives may easily occur, failing to diagnose AF with subtle fluctuations. The condition of “positive results detected during at least 2 of 3 BP measurements” may be appropriate for diagnosing AF, which has characteristic pulse wave irregularities that randomly increase or decrease.

**Novel Algorithm for Diagnosing AF Using Omron BP Monitor With IHB Detector**

In this study, we developed a novel algorithm that was defined as the condition of IHBs being detected during at least 2 of 3 BP measurements and the maximum number of IHBs was $\geq 2$ using an Omron automated BP monitor with an IHB detector. Using this novel algorithm, all 9 false-positive patients had non-AF arrhythmias, and none had respiratory sinus arrhythmia. In addition, even in patients with non-AF arrhythmias, only a minority showed a maximum value of $\geq 2$ IHBs detected during at least 2 of 3 BP measurements, because the pulse waves in patients with sporadic premature atrial or ventricular contractions are not as consistent as in AF. Thus, a certain number of patients with other arrhythmias could be distinguished from those with AF. The novel algorithm was limited in its ability to distinguish AF from some non-AF arrhythmias such as persistent bigeminy or trigeminy; however, the novel algorithm could be applied in clinical practice, given the high level of diagnostic accuracy for AF demonstrated in this study.

**Study Limitations**

Firstly, a total of 29 patients, including 9 AF patients, were excluded because of an “error” sign on the Omron automated BP monitor. Almost all automated BP monitors using the oscillometric method have a function to stop BP measurements when IHBs appear at the same time as the values of systolic and diastolic BP are being determined and will display an “error” sign. This function is needed to measure the correct BP, but might decrease the sensitivity and specificity to detect AF. Secondly, the pulse rate of the AF group was slightly high, and 106 of 303 patients including 12 AF patients were taking $\beta$-blockers for the treatment of hypertension, heart failure, and arrhythmia. As this study was an observational study under daily care, we were unable to make detailed evaluations about the effects of pulse rate or medications on the diagnostic detection of AF. However, it is likely that detecting AF was not influenced by pulse rate unless it was severe tachycardia, because the good association between the RR interval on ECG and the pulse wave interval detected by the automated Omron BP monitor was observed independently of the RR interval (Figure 2). Lastly, the number of AF patients was nearly equal to that of other arrhythmia patients, whereas the prevalence of other arrhythmia patients was overwhelmingly high compared with that of AF patients in society. Further study examining another population would be necessary to prove the usefulness of this method in the real world.

**Conclusions**

This study showed that a novel algorithm using 3 BP measurements by an Omron automated BP monitor equipped with an IHB detector had high sensitivity and specificity for the diagnosis of AF in general cardiac patients.

**Acknowledgments**

This work was supported by a research grant from the OMRON HEALTHCARE company (Kyoto, Japan). We appreciate the assistance of Tani Terue and Watanabe Satoko as clinical research coordinators. We also acknowledge Dr. Yoshihimi Takabatake, the director of Takabatake Hospital, and Dr. Takayoshi Matsui, the director of Matsu Hospital, for their cooperation in recruiting patients and providing as place for performing the measurements.

**References**

Omron M6 blood pressure monitors to detect atrial fibrillation in hypertensive patients. *Adv Ther* 2012; 29: 64–70.


**Supplementary Files**

Please find supplementary file(s);