Diagnostic Value of Atrial Fibrillation by Built-in Electrocardiogram Technology in a Blood Pressure Monitor

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Background: Hypertension in patients with atrial fibrillation (AF) is a known independent risk factor for stroke. The Complete blood pressure (BP) monitor (Omron Healthcare, Kyoto, Japan) was developed as the first BP monitor with electrocardiogram (ECG) capability in a single device to simultaneously monitor ECG and BP readings. This study investigated whether the Complete can accurately differentiate sinus rhythm (SR) from AF during BP measurement.

Methods and Results: Fifty-six consecutive patients with persistent AF admitted for catheter ablation were enrolled in the study (mean age 65.8 years; 83.9% male). In all patients, 12-lead ECGs and simultaneous Complete recordings were acquired before and after ablation. The Complete interpretations were compared with physician-reviewed ECGs, whereas Complete recordings were reviewed by cardiologists in a blinded manner and compared with ECG interpretations. Sensitivity, specificity, and κ coefficient were also determined. In all, 164 Complete and ECG recordings were simultaneously acquired from the 56 patients. After excluding unclassified recordings, the Complete automated algorithm performed well, with 100% sensitivity, 86% specificity, and a κ coefficient of 0.87 compared with physician-interpreted ECGs. Physician-interpreted Complete recordings performed well, with 99% sensitivity, 85% specificity, and a κ coefficient of 0.85 compared with physician-interpreted ECGs.

Conclusions: The Complete, which combines BP and ECG monitoring, can accurately differentiate SR from AF during BP measurement.

Key Words: Atrial fibrillation; Blood pressure; Digital health; Electrocardiogram (ECG)

Hypertension is highly prevalent in adults with atrial fibrillation (AF), especially those aged >60 years, and affects 1 billion adults worldwide.1 Stroke prevention is one of the top priorities of principal management in patients with AF.2–4 The presence of hypertension in patients with AF is an independent risk factor for stroke, with these individuals at a 1.8- to 2-fold higher risk of stroke than those without hypertension.4,5 Thus, it is important to refine personalized predictions of AF in hypertensive patients with sinus rhythm (SR).

The Complete blood pressure (BP) monitor (Omron Healthcare, Kyoto, Japan) is an upper arm BP monitor that allows users to simultaneously monitor ECG and BP at home (Figure 1). The ability to measure both risk factors simultaneously with a single device is an easy way for AF patients to track their condition and to know when to seek treatment to prevent stroke. The Complete was developed by AliveCor (Mountain View, CA, USA) and uses an advanced algorithm for improved detection of AF.6

The aim of this study was to investigate whether the Complete can differentiate SR from AF accurately and reliably while measuring BP compared with 12-lead ECGs acquired nearly simultaneously and interpreted by physicians. Correlations between Complete automated algorithm detection and physician-interpreted 12-lead ECGs, as well as between physician-interpreted Complete recordings and physician-interpreted 12-lead ECGs were assessed to characterize the quality of the Complete recordings.
Subjects were informed about the study and provided written informed consent. Patients who consented to take part in the study were provided with a Complete device paired with an iPhone at the time of their admission to hospital.

Patients were instructed to perform 2 BP measurements and a 30-s ECG recording of bipolar Lead I rhythm strip by touching the electrodes located on the top face and both sides of the monitor. If a recording could not be interpreted as “normal” or “possible AF”, patients were instructed to perform another measurement. Within 2h of the measurements made using the Complete device, 12-lead ECG recordings were obtained. This series of processes was performed before and after ablation during a patient’s hospitalization (Figure 2). The rhythm strip was automatically analyzed by the Complete algorithm, which labels a recording as “normal” or “possible atrial fibrillation” using a machine learning model. The algorithm uses a collection of approximately 50 specific parameters calculated from the rhythm strip, including RR interval statistics, morphological characteristics, signal quality, and frequency domain features. The algorithm classifies rhythm irregularity and the absence of a P wave as “possible AF” and regular rhythms with P waves as “normal” if the rate is between 50 and 100 beats/min. If the rate is <50 beats/min (“bradycardia”) or >100 beats/min (“tachycardia”), or if the recording is noisy or shorter than 30s (“unreadable”), then it is labeled as “unclassified”. After analysis, the recorded rhythm strips were automatically transferred to Omron Healthcare’s compliant cloud server, which conforms to the Health Insurance Portability and Accountability Act of 1996, and were downloaded and printed for review. All 12-lead ECGs and Complete recordings were independently reviewed in a blinded manner by cardiologists who classified the rhythm as SR, AF, or “uninterpretable” (due to baseline artifact, wander, or drift).

Methods

Study Design and Study Participants

The present multicenter, non-randomized, and adjudicator-blinded study evaluated the accuracy of the Complete device in detecting AF during BP measurement. Omron Healthcare provided the Complete coupled to a WiFi-enabled smart device (iPhone; Apple Inc., Cupertino, CA, USA) for use in the study. Omron Healthcare was not involved in study design, implementation, data analysis, or manuscript preparation. This study was approved by all institutional review boards of the participating institutions, including the Kyoto Prefectural University of Medicine, and was performed in accordance with the Declaration of Helsinki.

Patients with persistent AF who were admitted for catheter ablation were screened for study eligibility. To be eligible for inclusion, patients had to be >20 years of age and to have a history of persistent AF. Patients with pacemakers or defibrillators were excluded from the study. All

statistical analysis

Sensitivity and specificity were calculated for comparisons

Figure 2. Flow chart of study participants. AF, atrial fibrillation; ECG, electrocardiogram.
between: (1) Complete automated interpretation and physician-interpreted 12-lead ECGs; (2) physician-interpreted Complete recordings and physician-interpreted 12-lead ECGs; and (3) Complete automated interpretation and physician-interpreted Complete recordings. Kappa (κ) coefficients for interobserver agreement were calculated, and κ coefficients >0.8 were considered to indicate excellent agreement. Independence was tested using Chi-squared tests. Statistical analyses were performed using JMP Pro 15 (SAS Institute, Cary, NC, USA).

### Results

In all, 56 patients were enrolled in the study from May 2019 to March 2020. The baseline characteristics and measurement data of the study population are listed in Table 1. Acute recurrence before postablation measurements was observed in 7 of 56 patients (12.5%). There were 164 simultaneous 12-lead ECGs and Complete recordings, and 8 Complete recordings (4.9%) were labeled as “unclassified” by the Complete algorithm.

To test the accuracy of the Complete automated algorithm for detecting possible AF, Complete automated rhythm interpretation and physician-interpreted 12-lead ECG readings were compared. Of the 156 interpretable recordings, the sensitivity and specificity for detecting possible AF by the Complete automated algorithm were 99% (95% CI 0.97–1.00) and 85% (95% CI 0.76–0.93), respectively, with a κ coefficient of 0.85 (95% CI 0.76–0.93; Table 2).

To assess the fidelity and overall quality of Complete recordings and transmission, physician-interpreted Complete recordings and 12-lead ECGs were compared. Of the 164 simultaneous 12-lead ECGs and Complete recordings, 3 Complete recordings were “uninterpretable” by the physicians. Of the remaining 161 recordings, the sensitivity and specificity for detecting AF by physician-interpreted Complete recordings were 99% (95% CI 0.97–1.00) and 85% (95% CI 0.76–0.93), respectively, with a κ coefficient of 0.85 (95% CI 0.76–0.93; Table 3).

To measure the quality of the Complete recordings, the interpretations provided by the Complete automated algorithm and physicians were compared. As noted, 8 recordings were labeled as “unclassified” by the Complete algorithm. Of the remaining 156 recordings, the sensitivity and specificity for detecting possible AF by Complete automated algorithm interpretation were 99% (95% CI 0.97–1.00) and 97% (95% CI 0.92–1.00), respectively, with a κ coefficient of 0.96 (95% CI 0.91–1.00).

Of the 8 recordings labeled “unclassified” by the Complete algorithm, 1 (12.5%) was due to a heart rate of <50 or >100 beats/min, 4 (50%) were due to baseline artifact and a low amplitude of the recordings, and 1 (12.5%) was due to a recording <30 s in duration. The reasons why the remaining 2 recordings (25%) were classified as “unclassified” were unclear. Of the 8 “unclassified” recordings, 1 was considered “uninterpretable” by the physicians. The remaining 7 Complete recordings were interpreted by the physicians with 100% sensitivity and 100% specificity (5 in AF, 2 in SR). All 10 false-positive AF recordings were associated with small-voltage P waves and frequent supraventricular premature contractions (SVPCs) giving rise to irregularity, as shown in Figure 3.

### Discussion

Digital medical technology has revolutionized medical examinations, especially in the field of cardiology. Modern applications are becoming available with advances in technology that enable more advanced ad hoc monitoring. These range from new devices to mobile phone applications. These options allow for more advanced screening with
detectors have been available for some time. Several clinical studies examining the accuracy of IHB in detecting AF have shown high specificity (range 0.92–0.97) for IHB, but with variable sensitivity (range 0.30–0.97), suggesting that IHB detectors should not be used for AF screening.¹¹

In contrast to IHB detection, according to the US Food and Drug Administration (FDA), detection of AF repre-

| Method for interpreting the recording | % of patients with interpretable results | Accuracy of AF diagnosis compared to 12-lead ECG |
|---------------------------------------|-----------------------------------------|---------------------------------------------|
| Algorithm interpretation             | 95%                                     | 100% sensitivity; 86% specificity            |
| Physician interpretation             | 98%                                     | 99% sensitivity; 85% specificity             |

Figure 3. Examples of false-positive recordings.

Figure 4. Accuracy of atrial fibrillation (AF) diagnosis by the Complete automated algorithm and physician interpretation compared with the 12-lead electrocardiogram (ECG). Patients were instructed to put their thumbs on the top electrodes of the device, and 2 or more fingers on each of the side electrodes, to record their ECG. Once the fingers were placed on the electrodes, the ECG recording started automatically. Automated Complete recordings detected AF with 100% (95% confidence interval [CI] 1.00–1.00) sensitivity and 86% (95% CI 0.78–0.94) specificity compared with physician-interpreted 12-lead ECGs. Physician-interpreted Complete recordings detected AF with 99% (95% CI 0.97–1.00) sensitivity and 85% (95% CI 0.76–0.93) specificity compared with physician-interpreted 12-lead ECGs.

improved specificity and sensitivity.⁸⁻⁹ For example, the detection of AF during periodic self-monitoring of BP using home automation devices by hypertensive patients has the advantage of being widely available in populations to screen for AF, and is a cost-effective alternative to current screening approaches.¹⁰

Several BP monitors with irregular heartbeat (IHB)
sents a diagnosis of the disease. To date, 6 published clinical trials have investigated the diagnostic accuracy of AF detection by automated BP measurements. All 6 studies compared the results of the BP monitor against a 12-lead ECG interpreted by cardiologists and reported sensitivity (range 0.89–1.00) and specificity (range 0.76–0.99). Furthermore, it has been suggested that the diagnostic accuracy (sensitivity and specificity) of the AF detection algorithm can be improved by increasing the number of measurements. However, because these devices are only designed to detect AF by assessing the consistency of pulse rate irregularities, physicians cannot use them as a diagnostic decision tool at the time of consultation.

Conversely, small hand-held ECG devices have now been developed that allow a "visible" rhythm recording using smartphone technology. In 2017, the Kardia Band (AliveCor) was introduced as the first FDA-approved Apple Watch accessory that can record a quick rhythm strip equivalent to Lead I for 30s for a patient. More recently, the Kardia Mobile Cardiac Monitor was paired with an automated rhythm adjudication algorithm for the detection of AF to offer simple and prompt AF detection. Now, an automated rhythm adjudication algorithm for the detection of AF has been added to the Complete BP device. Assessment of the accuracy of the Complete device in the present study shows excellent agreement with physician-interpreted simultaneously acquired 12-lead ECGs during BP measurement (Figure 4). In suspected paroxysmal AF, repeated automated home BP monitoring with ECG technology may increase the likelihood of diagnosing AF. Hypertension and AF are common chronic and recurrent conditions with an unmet need for disease tracing and diagnosis. In the near future, monitoring disease-related metrics through such multifunctional BP devices will be essential in assessing the effectiveness of treatment and disease management.

In the present study, a significant association was found between the frequency of SVPCs and that of false-positive AF detection (Figure 3). Despite high diagnostic accuracy, with sensitivity and specificity of 100% and 86%, respectively, false-positive findings may unnecessarily alarm users. However, excessive SVPCs have been linked not only to future risk of AF, but also to cardiovascular outcomes. False-positive findings may unnecessarily alarm users. However, excessive SVPCs have been linked not only to future risk of AF, but also to cardiovascular outcomes. However, excessive SVPCs have been linked not only to future risk of AF, but also to cardiovascular outcomes. However, excessive SVPCs have been linked not only to future risk of AF, but also to cardiovascular outcomes. However, excessive SVPCs have been linked not only to future risk of AF, but also to cardiovascular outcomes.

Conclusions

Complete, a combination BP and ECG monitor, can accurately differentiate SR from AF with good sensitivity and specificity and excellent interobserver agreement compared with 12-lead ECGs. Having the ability to measure both BP and AF simultaneously in a single device provides users with a simple way of keeping track of their condition and knowing when to seek treatment for stroke prevention.

Sources of Funding

Omron Healthcare provided the Complete and iPhone for this study, but was not involved in study design, data analysis, or article preparation.

Disclosures

K.S. has had university research contracts with Omron Healthcare. K.S. is also affiliated with an endowed department sponsored by Biotronik and Japan LifeLine.

The other authors have no conflicts of interest to declare.

IRB Information

This study was approved by the Institutional Clinical Research Review Board of Kyoto Prefectural University of Medicine (Reference no. ERB-C-1347).

Data Availability

The deidentified participant data will not be shared.

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