Can a Patch Electrocardiographic Device Be a Leading Actor for Detecting Atrial Fibrillation?

— Diversifying Electrocardiographic Monitoring Devices —

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It is well known that atrial fibrillation (AF) is among the most important arrhythmias requiring therapeutic intervention for stroke prevention.¹ A recent issue is the detection of paroxysmal AF (PAF), which is an important cause of cryptogenic or embolic stroke of undetermined source, by using electrocardiographic (ECG) devices capable of long-term recording.² It has been reported that the longer the duration of ECG monitoring, the higher the detection rate of PAF.^{3,4} In the past decade, the numbers of commercially available devices, including patch-type ECG devices, wristwatch-type healthcare products and implantable ECGs that are smaller and detect PAF for longer periods of time, have increased.^{3,5,6} Notably, 40% of

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PAF cases are reported to be asymptomatic.⁷ False-negative results can occur if the device is incapable of recording the ECG for a long period or the test has no auto-trigger function. Here, we will discuss the advantages and disadvantages of the currently diversified ECG devices, focusing on efficient PAF detection. The future requirements for ECG devices will also be discussed.

The currently available patch-type ECG devices are well-balanced in terms of PAF detection accuracy and patient burden for the study (**Figure 1**). A patch ECG

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Figure 2. Typical examples of each ECG device. **(A)** Patch-type ECG: eMemo® (Fukuda Denshi, Co., Ltd., Tokyo, Japan). **(B)** Subcutaneous implantable cardiograph: REVEAL LINQ® (Medtronic, Co., Ltd., Minneapolis, MN, USA). ECG, electrocardiography. All rights reserved. The devices were used with the permission of Fukuda, Denshi, Co., Ltd., and Medtronic, Co., Ltd.

device is usually used to detect ECG with a single channel of bipolar induction over the heart. Compared with ambulatory ECG (AECG), patch-type devices are simpler and less burdensome for the patient because of the small number of electrodes and absence of electrode leads. Another advantage is that such devices are not subject to lead motion artifacts. Some patch-type models can be replaced daily. A patch ECG can record waveforms for 5–14 days. eMemo® (Fukuda Denshi, Co., Ltd., Tokyo, Japan) (**Figure 2A**) and Duranta® (ZAIKEN, Co. Ltd., Tokyo, Japan) can record ECG waveforms for 14 and 7 days, respectively. The Zio Patch monitor® (iRhythm Technologies, San Francisco, CA, USA) stores continuous ECG waveforms for 48 h; it can then detect PAF for 3–14 days with an auto-trigger function.⁵ However, the use of eMemo® and Duranta® may be burdensome to medical staff, because they must manually analyze all ECG waveforms for 7–14 days.

In this issue of the Journal, Okubo et al test⁸ an algorithm for detecting AF and estimate the calculation duration based on the R-R interval (RRI) distribution using a novel patch-type ECG device (MyBeat®) in a multicenter prospective study. The advantage of this system is that the algorithm is based on the RRI distribution, and it automatically calculates the presence of PAF using software, which is more efficient and much easier to analyze than the conventional patch ECG devices. However, MyBeat® detects peak R-R measurement from the ECG, so it recognizes arrhythmia based only on RRI variation, subsequently leading to AF recognition only. Furthermore, it is difficult to distinguish complete atrioventricular block with AF from frequent premature atrial contraction and AF. Presently, MyBeat® is not approved as a medical device and more evidence has to be accumulated.

Recently, healthcare products, including the Apple Watch® (Apple, Inc., Cupertino, CA, USA) have become capable of detecting PAF. The Apple Watch® Series 3 and later models occasionally check heart rhythm in the background using a photoplethysmography sensor and can send a notification if an irregular heart rhythm appearing to be PAF is identified.⁶ Users can also record an ECG directly on Apple Watch® Series 4, 5 and 6 by holding their finger on the digital crown for 30s. The device's advantage is that, because it is worn all the time, it can monitor the heart rhythm throughout the day. However, the limitations

include the following: the ECG application on the Apple Watch® does not monitor heart rhythm continuously or passively, and although the ECG application and irregular rhythm notification have been cleared by regulatory authorities, they cannot be used alone to diagnose AF. Because Apple Watch® uses a photoplethysmography sensor to determine PAF when it checks heart rhythm in the background, it does not have approved accuracy compared with prescriptive ECG devices. However, it has the potential to screen many asymptomatic and symptomatic patients.

Insertable cardiac monitors (ICMs) are currently the most reliable devices for long-term monitoring of arrhythmic events. The REVEAL LINQ® (Medtronic, Minneapolis, MN, USA) was successfully miniaturized (44.8×7.2×14 mm; 2.5 g) in 2016³ (**Figure 2B**). The other 2 manufacturers have released the same type of ICM (**Figure 1**). Event occurrence can be confirmed by periodic device check. The disadvantages of these devices are as follows: they are small but invasive and the P-wave amplitude cannot be detected largely due to their short interelectrode distance.⁹ The detection rate of AF was reported to increase from 6.2% in 30-day ICM recordings to 40% in 30-month ICM recordings.³ There is no dispute that this device should be used as a last resort when noninvasive ECG devices fail to diagnose arrhythmias.

Among all ECG devices, AECG has the largest number of electrodes and the greatest distance between electrodes. Therefore, theoretically, its AF diagnostic accuracy is the highest. The disadvantage of the conventional models is that they can only record for 24 h. Currently, models that can be used for up to 14 days are commercially available. However, it is impossible to change the electrodes throughout the observation period, which could last even up to 2 weeks, leading to an increased risk of developing skin rashes in patients, as compared with other devices. Thus, the device may be burdensome to the patient.

In conclusion, medical professionals should understand the advantages and disadvantages of the diverse range of ECG devices and use them clinically for their specific purpose. A method for reducing the burden of long-term ECG data analysis of patch ECG devices needs to be developed in the future. If this issue is addressed, the patch-type ECG device has the potential to become the mainstream tool for detecting AF that requires immediate treatment. Artificial intelligence assisting deep learning may be a possible solution.

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Data Availability

The deidentified participant data will not be shared.

Disclosures

None.

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