VIEWPOINT

Wearable Devices for Cardiac Rhythm Diagnosis and Management

James E. Ip, MD
Division of Cardiology, Department of Medicine, Cornell University Medical Center, New York Presbyterian Hospital, New York, New York.

＋

Author Audio Interview

＋

Supplemental content

With the increasing use of direct-to-consumer medical devices, it is paramount for clinicians to recognize the potential utilization for patient management. The increasing adoption of this new class of consumer-grade wearable devices that monitor heart rate and activity as well as smartphone technology that integrates information from devices (blood pressure monitors, digital scales, pedometers) can prove useful in the diagnosis and management of some patients. Devices and applications that are specifically designed to measure heart rate and electrocardiographic signals are particularly useful for determining if an arrhythmia is present (such as atrial fibrillation, paroxysmal supraventricular tachycardia, or ectopic beats). An example of this appears in **Figure 1**.

A patient in his 70s had intermittent palpitations and his fitness activity tracker (Fitbit Charge 2 HR) showed paroxysms of tachycardia at rest (Figure 1). The patient obtained an AliveCor Kardia device (approved by the US Food and Drug Administration [FDA]) for smartphones to obtain single-channel electrocardiographic recordings (typically lead I using the patient's right and left hands). This device recorded the tracings of long RP supraventricular tachycardia with retrograde P waves (**Figure 2**). The patient's diagnosis was confirmed by 12-lead electrocardiographic recordings (eFigure in the Supplement) and the patient was subsequently treated with catheter ablation for atypical (fast-slow) AV nodal reentrant tachycardia.

Similar wearable devices that result in the diagnosis and treatment of arrhythmias are likely to become more common as the use of consumer health-based technology expands. It is estimated that more than 50 million people in the United States wear a connected device to track activity and that number is expected to increase to more than 160 million with the introduction of smart watches.[1] The information generated by these devices could lead to false-positive results or potentially life-saving interventions such as initiation of anticoagulation for thromboembolism prophylaxis if atrial fibrillation (AF) is detected.

The accuracy of these devices for arrhythmia detection depends on the technology being used. The photoplethysmographic (PPG) sensors found in smart watches and fitness trackers estimate the heart rate based on the transmission and absorption of light applied against the skin.[2] Changes in tissue blood volume caused by peripheral pulses can be measured by dedicated photodetectors and light-emitting diodes emitted from wrist-worn bands or smartphone cameras. Their accuracy may be affected by ectopic beats, patient or device movement, environmental conditions (such as ambient lighting and temperature), skin color, and conductivity.

Combining data from PPG sensors with accelerometers can help identify some arrhythmias. Tachycardia detection at rest may indicate the presence of an arrhythmia such as AF or supraventricular tachycardia. The Apple Watch can notify the user based on programmable settings and its latest version has the capability to continuously evaluate heart rate and variability in the background to detect inappropriate bradycardia and AF.

Although PPG-based sensors can detect tachycardia or irregular rhythms, they may not easily distinguish between AF and premature beats unless the devices are combined with dedicated algorithms that analyze beat-to-beat variability. Therefore, it is essential to validate abnormal findings with direct electrocardiographic recordings. KardiaMobile (previously AliveCor Heart Monitor) received FDA 510(K) approval in 2012 and over-the-counter approval in 2014 as a single-lead cardiac event monitor. An alternative configuration of this technology that integrates with Apple Watch, called the KardiaBand, became available in November 2017. Apple Watch series 4 incorporates electrocardiographic recording capability with the back of the device and the watch bezel serving as the lead I electrocardiographic bipoles (software released on December 6, 2018) and it is designed to detect occult AF.

Compared with standard 12-lead electrocardiographic recordings, the Kardia device has been shown to detect atrial rate and rhythm, AV block, and QRS delay with similar accuracy.[3] When used to screen patients at risk for AF, this device showed a higher positive predictive value vs a PPG-based application mainly because ectopic beats resulted in false-positive results in PPG devices.[4] An evaluation of the Kardia device for AF screening in 204 patients reported a sensitivity of 98%, a specificity of 97%, and an overall accuracy level of 97% for detecting AF using an optimized algorithm in a community setting.[5] However, the US Preventive Services Task Force recently concluded that the current evidence is insufficient to assess the balance of benefits and harms of electrocardiographic screening for AF in adults aged 65 years or older based on the lack of supportive trials that show clinical benefit.[6] In addition, a recent study by Steinhubl et al[7] that included 2659 patients who were randomized to active monitoring of a self-applied continuous electrocardiographic patch for up to 4 weeks found a higher rate of AF diagnosis after 4 months, greater initiation of anticoagulants, increased health care use at 1 year, and no difference in AF-related emergency department visits or hospitalizations.

Although wearable devices and patient-activated intermittent nonlooping ambulatory electrocardiographic monitors have the potential to improve the

Corresponding Author: James E. Ip, MD, New York Presbyterian Hospital, 525 E 68th St, Starr 4, New York, NY 10021 (jei9008@med.cornell.edu).

Figure 1. Example of Supraventricular Tachycardia Diagnosed by Wearable Device (Fitbit)

Shows sudden increase in heart rate to 110 to 120 beats/min on 2 occasions (pink arrows) for 1 to 2.5 hours each time in the absence of physical activity.

Figure 2. Kardia Device Tracings Showing Single-Lead Electrocardiographic Recordings During Normal Sinus Rhythm vs During Supraventricular Tachycardia

A, Obtained using both hands (right arm to left arm), generating a lead I tracing. B, Obtained from right arm and left leg. The generated lead II electrocardiogram reveals retrograde P waves (pink arrows) during a long RP tachycardia that were not apparent in the lead I tracing.

diagnosis of sporadic or occult arrhythmias, it is important to recognize the potential implications of their widespread use. When patients bring this information to their physicians, it can be challenging to interpret and analyze. A recent study of 100 patients undergoing cardioversion for AF showed that 34% of KardiaBand recordings, despite being obtained under direct observation, were categorized as "unclassified" by the device algorithm due to unclear reasons or baseline artifact and low amplitude recordings.[8] Poor electrocardiographic signal quality and false AF or tachycardia alarms can result in misinterpretation and inappropriate results, which may lead to unnecessary medical referrals and testing. This can especially be problematic if devices are used in a population with low prevalence of disease.

Wearable devices are further ushering in a new era of remote monitoring and telemedicine, which is still evolving in regard to data management, cybersecurity, regulation, and reimbursement. Patients who are engaged in their medical management have improved adherence to medical therapy and ostensibly better health outcomes. However, when the mantra of "your data belongs to you" (from Fitbit) becomes an expectation that is extrapolated to cardiac implantable electronic devices such as pacemakers or implantable cardioverter-defibrillators, problems may arise and such data should be interpreted and managed by a qualified clinician.

Although the use of consumer-based devices may be more affordable than traditional ambulatory electrocardiographic monitoring, it is essential to understand the limitations of these technologies to avoid inappropriate reliance on them for diagnostic purposes. Even though these devices may aid in the detection of arrhythmias (such as AF or supraventricular tachycardia), it remains to be seen how to best integrate these devices to improve health care.

REFERENCES

1. Steinberg JS, Varma N, Cygankiewicz I, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. Heart Rhythm. 2017;14(7): e55-e96. doi:10.1016/j.hrthm.2017.03.038

2. Allen J. Photoplethysmography and its application in clinical physiological measurement. Physiol Meas. 2007;28(3):R1-R39.

3. Haberman ZC, Jahn RT, Bose R, et al. Wireless smartphone ECG enables large-scale screening in diverse populations. J Cardiovasc Electrophysiol. 2015;26(5):520-526. doi:10.1111/jce.12634

4. Chan PH, Wong CK, Poh YC, et al. Diagnostic performance of a smartphone-based photoplethysmographic application for atrial fibrillation screening in a primary care setting. J Am Heart Assoc. 2016;5(7):e003428. doi:10.1161/JAHA. 116.003428

5. Lau JK, Lowres N, Neubeck L, et al. iPhone ECG application for community screening to detect silent atrial fibrillation: a novel technology to prevent stroke. Int J Cardiol. 2013;165(1):193-194. doi:10.1016/j.ijcard.2013.01.220

6. US Preventive Services Task Force. Screening for atrial fibrillation with electrocardiography: US Preventive Services Task Force recommendation statement. JAMA. 2018;320(5):478-484. doi:10.1001/jama.2018.10321

7. Steinhubl SR, Waalen J, Edwards AM, et al. Effect of a home-based wearable continuous ECG monitoring patch on detection of undiagnosed atrial fibrillation. JAMA. 2018;320(2):146-155. doi:10.1001/jama.2018.8102

8. Bumgarner JM, Lambert CT, Hussein AA, et al. Smartwatch algorithm for automated detection of atrial fibrillation. J Am Coll Cardiol. 2018;71(21):2381-2388. doi:10.1016/j.jacc.2018.03.003