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EDITORIAL COMMENT

Mobile Health Technology

(Smart)Watch and Wait*

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Mobile device ownership has increased broadly, irrespective of age, race, and income.[1] An estimated 85% of Americans owned a mobile device in 2021 and 46% owned a wearable device (ie, smartwatch) in 2022.[1,2] The meteoric rise in device ownership has been accompanied by a parallel rise in the diversity of data types collected. Data collection has now expanded from more traditional measures, such as step count and exercise minutes, to electrocardiography (ECG) and arrhythmia monitoring as well as pulse oximetry. In light of the rising number of mobile device users and data types collected, there has been growing interest in leveraging mobile health (mHealth) technology and artificial intelligence for monitoring and managing users' health longitudinally, outside of episodic clinical encounters. In cardiovascular disease specifically, mHealth technology has been used to diagnose,[3] monitor,[4] and treat[5] diverse cardiovascular conditions.

In this issue of *JACC: Case Reports*, Sung et al[6] describe a novel application of mHealth technology for cardiovascular disease diagnosis—using a personal ECG monitoring device to diagnose vasospastic angina. In this vignette, the investigators report on a 48-year-old woman who presented with a non-ST-segment elevation myocardial infarction in the setting of traditional cardiovascular disease risk factors as well as immune thrombocytopenic purpura, suggesting a possible hypercoagulable state. Coronary angiography showed distal thrombosis of 2 coronary arteries, raising concern for coronary emboli or thrombosis, though symptoms failed to improve with medical therapies, including anticoagulation. Following discharge, the patient used a KardiaMobile 6L (AliveCor) 6-lead personal ECG monitor to obtain a 6-lead personal ECG that captured transient ST-segment elevations, establishing the diagnosis of vasospastic angina. Symptoms resolved with the initiation of verapamil.

Although this is the first case report in which mHealth technology was used to diagnose vasospastic angina, there has been exponential growth in the use of mHealth-based tools for arrhythmia detection and ECG monitoring. In 2019, Perez et al[3] published on the accuracy of irregular pulse notifications from the Apple Watch smartwatch app for atrial fibrillation detection. Among participants who received an irregular pulse notification and returned an ECG patch monitor, 34% had atrial fibrillation on their ECG patch. Similar results were observed in the Fitbit Heart Study.[7] Importantly, both studies relied on photoplethysmography to detect an irregular pulse with neither using a smartwatch-based ECG, and participants in both studies were sent a medical-grade ECG patch monitor to confirm the diagnosis. Since that time, additional studies have evaluated mHealth-based ECGs for arrhythmia detection as well as for the assessment of QT interval duration, with the latter accelerated by the early use of QTc-prolonging medications for the treatment of COVID-19.[8-10] In one study of 100 patients, the Apple Watch smartwatch ECG worn on the left wrist, which records the electrocardiographic equivalent of lead I, adequately measured QTc interval prolonging medications in 85% of patients, with performance improved when the smartwatch was moved to alternate positions.[9] Other studies have shown that the 6-lead personal ECG monitor can enable accurate measurements of the QT interval,[10] an application for

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which it has received Food and Drug Administration clearance, and screen for both acquired and congenital long QT syndrome when combined with artificial intelligence algorithms.[11]

In the current case report, Sung et al[6] report on an expanded use of mHealth technology—the detection of cardiac ischemia. Although case reports have described the use of smartwatch ECG technology for detection of ST-segment elevation myocardial infarction,[12] recent studies have evaluated use of these devices for ischemia detection in expanded patient populations. Between April 2019 and January 2020, Spaccarotella et al[13] collected a standard 12-lead ECG and multiple Apple Watch series 4 ECGs from 100 patients, including 54 with ST-segment elevation myocardial infarction and 27 with non-ST-segment elevation myocardial infarction. Rather than relying on a single recording from patients' left wrists, the smartwatch was placed in a series of different positions in order to obtain 9 bipolar ECG tracings corresponding to Einthoven leads I, II, and III and Wilson's precordial leads. With the 12-lead ECG as the reference standard, the smartwatch ECG was 93% sensitive and 95% specific for detecting ST-segment elevation and 94% sensitive and 92% specific for detecting non-ST-segment elevation ECG changes. In total, however, it took a mean of 5.80 minutes for the attending physician of the day to record the 9 ECG tracings, with none of the ECGs recorded by patients. In a second study of 256 patients who self-recorded a single-lead ECG from an Apple Watch series 4 or 5 smartwatch placed on their left wrist, pathological Q waves and ST-segment/T-wave abnormalities were commonly missed, with a sensitivity of 34% and specificity of 100% for ST-segment/T-wave abnormalities.[8] In a third study designed to compare the diagnostic accuracy of the KardiaMobile 6-lead personal ECG monitor against a standard 12-lead ECG, the 6-lead personal ECG monitor performed well for rhythm recognition and QT interval measurement though poorly for ischemia.[10] The kappa statistic for intermodality reliability was lowest for ST-segment depression ($\kappa = 0.340$), followed by ST-segment elevation ($\kappa = 0.421$), as compared with near-perfect agreement for many cardiac arrhythmias.

Taken in totality, the evidence supports the use of many commercial-grade mobile devices for the detection of arrhythmias and QT interval prolongation, though not as a tool for the routine detection of ischemia. Importantly, none of the commercial-grade devices are currently cleared by the Food and Drug Administration for ischemia detection. Smartwatch-based devices record only a single Einthoven lead (lead I), though they have the ability to record leads II and III and well as the precordial leads with alternative placement. Data collection from these alternative configurations, however, is performed asynchronously and requires significant time and expertise. Additionally, differences exist in the reference terminal used for the smartwatch-based precordial ECGs when compared with standard electrodes from a 12-lead ECG, suggesting the need for potential alternative diagnostic thresholds (ie, the precordial leads on a 12-lead ECG use the Wilson Central Terminal, which is the average potential of the 3 limb potentials, whereas the smartwatch uses the right or left arm as a reference point). Although the 6-lead personal ECG monitor overcomes many of these challenges by simultaneously generating a 6-lead ECG consisting of the limb and augmented vector leads, its sensitivity for ischemia diagnosis is limited in the absence of the precordial leads, and all devices require clinician interpretation.

As we enthusiastically embrace mHealth technology for its ability to disrupt traditional health care delivery models by empowering users and enabling longitudinal data collection, caution must be exercised. Alarms from many mHealth devices are of unproven value, have the potential to evoke user anxiety, and require downstream, clinician-directed testing. Thus, although these devices are quite powerful for generating data with multiple clinical applications, we must ensure that they are validated in diverse populations and consider appropriate protocols for downstream testing that minimize the use of scarce resources, most importantly clinician time. We are thus in an era in which the most powerful tool with which we can equip both patients and clinicians is not mHealth technology, but rather is the knowledge to use these devices appropriately.

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