

ArrhythmiaNews

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Consumer-Based ECG Technology: Potential and Pitfalls

Broadly defined, digital health describes the use of digital information, data, and communication technologies to collect, share, and analyze health information for purposes of improving patient health and health care delivery. Mobile health (mHealth) describes the delivery of health care via mobile communication devices, such as smartphones. These have their own sensors, such as accelerometers and cameras, which can be exploited for physiological measurements and patient monitoring.

mHealth efforts have concentrated on atrial fibrillation (AF), which often remains undiagnosed in the current clinical practice environment using conventional ECG detection methods. This can result in missed opportunities to initiate appropriate anticoagulation therapy in higher risk individuals. In addition, more than a third of AF patients have no attributable symptoms and many patients do not visit their physician routinely. Novel technologies are being developed to enhance the detection of AF and overcome the limitations of conventional methods.

A 12-lead ECG remains the gold standard for the detection of any arrhythmia. More specifically for AF, the detection ability is limited due to the short time frame of ECG acquisition. AF can be paroxysmal and brief in duration, especially in patients with recent onset, and can self-terminate by the time a 12-lead ECG is recorded. Several types of ambulatory ECG-based devices have been developed to overcome this limitation. Traditional lead-based devices have been increasingly displaced by solutions with electrodes embedded in adhesive patches that can be worn for 14-21 days. Although these recording systems have proven very valuable in practice, they are expensive to implement, and time-limited by definition.

More recently, non-wearable solutions coupled to the smartphone have emerged. These devices allow for the user to perform a “spot check” single-lead ECG strip, usually 30 seconds or longer. Clinicians may use such devices as a point-of-care device to obtain an interpretable rhythm strip in place of a 12-lead ECG. Patients may use these devices for ad hoc or routine evaluation of their rhythm. The ECG data can be instantaneously transmitted for automated interpretation with the ability of the consumer to request a physician overread, usually for a surcharge.

The greatest advantages are the ubiquity of the smartphone and thus the ECG recorder. Patients can spontaneously make ECG recordings for symptoms, or can be instructed to record based on a formal schedule or varied by location and activity. There is essentially no limit to the availability of the smartphone-based system. Further, there is no fixed duration for the recording period, and patients can record as long as they have the hardware (smartphone and electrodes) and the downloaded app.

AliveCor KardiaMobile (AliveCor Inc., USA) is an example of a smartphone-based device, with which a 30-second lead I ECG can be recorded by placing a finger of each hand on the two electrodes, usually placed on the phone case. The ECG electrical signal is then converted to an ultrasonic FM sound signal, and transmitted to a smartphone on which the app has been installed. The tracings can be reviewed on the smartphone, electronically stored or transmitted for review by the user’s provider if so desired.

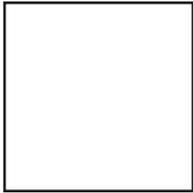
Automated algorithms provide instantaneous analysis to the user. The rhythm is labeled as “normal” when the patient’s heart rate is between 50 and 100 bpm, there are

no or very few abnormal beats, and the shape, timing and duration of each complex is considered normal. The algorithm can detect “possible AF” on the basis of the presence or absence of a P wave and the regularity of the RR interval. The rhythm is labeled as “unreadable” when the detector indicates there was too much interference for an adequate recording, whether from too much movement or poor contact between the electrodes and the patient’s skin. Several versions of the device’s automated algorithms have been evaluated and have performed well but imperfectly. In clinical practice, the automated rhythm diagnosis performs less well than in the published evaluations. Notably, AF is often overdiagnosed when there is ectopy or noise and/or significant sinus arrhythmia. Clinical management should never be based on these automated analyses without proper overreads.

KardiaBand (AliveCor Inc., USA) is an accessory device for the Apple smartwatch. This device records a 30-second single-lead ECG while the patient is wearing the Apple watch on their wrist and places the opposite thumb on the electrode in the KardiaBand. The tracing is stored and analyzed by the same algorithm as the AliveCor KardiaMobile installed on the Apple watch.

Other non-electrocardiographic options also exist. Automatic oscillometric blood pressure monitors with imbedded algorithms





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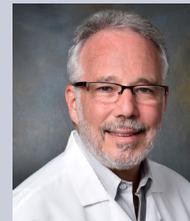
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can detect AF by assessing the regularity of pulses. Photoplethysmography (PPG) is an optical technology that detects AF by measuring and analyzing a peripheral pulse waveform by detecting changes in the light intensity, which reflects the tissue blood volume of a skin surface such as the fingertip, earlobe, or face. An automated algorithm to detect AF subsequently analyzes the generated pulse waveform. This technology has been applied to use with smartphones, where the phone's camera is used to measure fingertip pulse waveform. The PPG technology has also been incorporated in smartwatch technologies to measure heart rate. In addition, most wrist worn wearables depend on PPG to estimate heart rate and cardiac rhythm.

While several studies have established the sensitivity and specificity of novel devices for the detection of AF, no study to date has investigated the utility of an mHealth intervention positively affecting clinical outcomes. Future studies such as the Apple Heart Study and iHeart program are enrolling patients to address these shortcomings. In addition, patient acquired ECGs can potentially overwhelm caregivers' capacity to receive, interpret and integrate these self-generated clinical events. Finally, physician reimbursement is in its infancy regarding fees for these ECG interpretations, but progress is slowly being made.

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To learn more about Drs. Altman and Steinberg, visit arrhythmia.org.



Welcome Dr. Francesco Santoni-Rugiu

The Arrhythmia Center and electrophysiologists of Summit Medical Group have been growing by leaps and bounds. Indeed, the group now has the largest volume at Hackensack University Medical Center. We are pleased to announce that a very experienced electrophysiologist, Dr. Francesco Santoni, has joined the Arrhythmia Center and will be providing outpatient services at the Florham Park and Fair Lawn locations and performing procedures at neighboring institutions. Dr. Santoni-Rugiu previously lent his expertise at Mt. Sinai Medical Center and practiced electrophysiology in New York City.