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Letter to the Editor

iPhone ECG application for community screening to detect silent atrial fibrillation: A novel technology to prevent stroke

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Atrial fibrillation (AF) is the most common sustained arrhythmia, and its prevalence increases with age. In those aged 65 or older, screening studies reveal the prevalence (in AF at time of screening) to be 4.4%, with 1.4% of those having previously undiagnosed AF [1]. In our own study of ambulant patients, 6.7% of those ≥65 years were in AF and in 10% of these, AF was incidentally detected, most without symptoms of palpitations or the elevation of resting heart rate [2].

AF is associated with increased morbidity and mortality including a 5-fold increased risk of stroke. Since many with AF are asymptomatic, presentation with a complication such as stroke may be the first manifestation of this arrhythmia. In up to one quarter of cases of ischemic stroke, a cause is not found and subclinical AF is a likely aetiological factor. A recent pacemaker study revealed a significant association between device-detected silent AF and the risk of stroke or systemic embolization [3].

With temporal trends showing an increasing AF incidence, in part due to the aging population, a community screening program to detect silent AF could have a significant impact on stroke prevention. However, until now, community screening with ECGs has not been thought cost-effective for AF detection [4].

The development of new technology, such as an iPhone application which records a high quality single lead ECG (Fig. 1), makes mass ECG screening feasible. We assessed the accuracy of the iPhone ECG as a diagnostic screening tool for the detection of AF by comparing it with a contemporaneous 12-lead ECG interpreted by a cardiologist.

We recorded iPhone ECGs in two cohorts of patients. Each AliveCor iPhone ECG was easily recorded in patients in only 1 min. Recording commences with finger placement of right and left hands on the two electrodes at the back of the iPhone case (Fig. 1), and instructions to relax arms and hands to reduce noise and artifact. Finger contact activates ECG recording of bipolar lead I (right hand to left hand). Cardiac electrical activity in lead I is transmitted from the case to the iPhone by frequency modulation of an ultrasound signal using a 19,000 Hz center frequency and a modulation index of 200 Hz/mV (FMECG). The ultrasonic FMECG received by the iPhone microphone is digitized at 44.1 kHz, 24-bit resolution. The application in the iPhone demodulates the signal to a digital ECG trace (300 samples/s, 16-bit resolution), which can be viewed in real-time or stored, and instantly transmitted by the iPhone to a secure server which is Health Insurance Portability and Accountability Act (US HIPAA) confidentiality/privacy standards compliant. The file is stored as a PDF file for physician interpretation accessible through a password-protected website. An automated algorithm, developed to interpret rhythm, produces noise-filtered traces and a computer-averaged complex for AF diagnosis based on criteria of p-wave absence and R–R interval irregularity.

In order to assess the initial algorithm and further enhance it, 109 patients (39 in AF), were recruited from a single center (the learning set). Within 6 h of a 12-lead ECG, each patient had a single lead (Lead I) iPhone ECG recorded and later presented to two independent cardiologists (DB and RS) blinded to the 12-lead diagnosis. ECGs were also interpreted by the automated algorithm. The actual rhythm was determined from the 12-lead ECG interpreted by a third cardiologist (SBF). Following unblinding, the algorithm was optimized by increasing the weighting of absence of P waves, and applied to the same dataset.

The sensitivity, specificity, overall accuracy and Kappa (a measure of agreement between the cardiologist or algorithm and the actual

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Fig. 1. iPhone single lead (Lead I) ECG showing AF. Electrodes are part of the AliveCor iPhone case on the reverse of the phone and correspond to the positive and negative poles of lead I.

12-lead ECG rhythm) for iPhone ECG AF diagnosis were calculated for each cardiologist, and both algorithms (original and optimized).

The validation set comprising another 204 patients, 48 in AF, was recruited to validate the optimized algorithm, again with blinding to the 12-lead diagnosis, and analyzed in the same way.

The study was approved by our IRB and all patients gave written informed consent. The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology.

Sensitivity, specificity, overall accuracy and Kappa for diagnosis of AF from iPhone ECGs in the learning set are shown in Table 1. Accuracy and Kappa were similar for cardiologists A and B but lower for the initial automated algorithm. After algorithm optimization, sensitivity, specificity, overall accuracy and Kappa improved.

The optimized algorithm performed extremely well in the validation set with high sensitivity, specificity, overall accuracy and Kappa (95% CI) of 98% (89%–100%), 97% (93%–99%), 97% (94%–99%) and 0.92 (0.86–0.98) respectively. There was only one false negative. All 5 false positives were associated with small voltage P waves in lead I, and 2 also had multiple atrial ectopics giving rise to irregularity.

This technology enables a high quality single lead ECG to be recorded quickly and easily on a standard iPhone. The high sensitivity, specificity and accuracy of the algorithm, and widespread distribution of smartphones, make this device ideal for community screening. We are currently utilizing this device, with only manual reading by a cardiologist, in an ongoing study in community pharmacies with pharmacists trained in the use of the iPhone ECG. This study will determine the feasibility of this approach to screen for undiagnosed AF in customers aged ≥65 [5]. Ideally, in future studies, AF diagnosis would be made automatically within seconds by the automated algorithm residing on the secure server. Given the high rates of undetected AF in the aging population at risk and the effectiveness of anticoagulation in reducing stroke, widespread screening to detect subclinical AF using a smartphone and an automated algorithm could have a substantial impact on reducing the stroke burden.

Table 1
Performance of single lead iPhone ECG for the detection of AF in the learning set and the validation set.

	Sensitivity	Specificity	Accuracy	Kappa
Learning set (n = 109)				
Cardiologist A	100%	90%	94%	0.87
Cardiologist B	95%	94%	95%	0.88
Original algorithm	87%	97%	94%	0.86
Optimized algorithm	100%	96%	97%	0.94
Validation set (n = 204)				
Optimized algorithm	98%	97%	97%	0.92

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