



ALIVECOR CLINICAL RESEARCH

ACCURACY

Accuracy and Novelty of an Inexpensive iPhone-based Event Recorder

Paul Garabelli et al. Heart Rhythm. May 2012 : SP23. Innovation Poster Session II. Presentation IA02-1.

<http://tinyurl.com/lfds7qw>

This study compared the accuracy between an ECG lead I from a conventional 12-lead ECG and the AliveCor Mobile ECG in 62 patients. The QRS morphology was found to be the same, though the ECG from the AliveCor Mobile ECG had more baseline noise than the standard ECG. The mean/SD of the R-wave amplitudes for the standard and iPhone recordings respectively were 0.77/0.24 (mV) and 0.78/0.24 (mV), $P < 0.0001$. In the five patients with pacemakers, pacing spike artifacts were clearly identified enabling verification of pacing capture.

SCREENING

The effectiveness of a mobile ECG device in identifying AF: sensitivity, specificity and predictive value

Jonathan Williams et al. Br. J. Cardiol., Vol. 22, Issue 2, April 2015.

<http://tinyurl.com/ogv6ghx>

This study determined the AliveCor Mobile ECG to be a simple and non-invasive option for early identification of unknown atrial fibrillation (AF) in primary care. AliveCor ECG traces were compared with a gold-standard 12-lead ECG on a population known to have AF and one that did not have AF at the time of recording. The AliveCor Mobile ECG has a high negative-predictive value and is sufficiently sensitive in the hands of experienced clinicians to be useful in detecting AF a general practice population, but does not replace the need for a diagnostic 12-lead ECG in suspected cases of AF.

Wireless Smartphone ECG Enables Large-Scale Screening in Diverse Populations

Zachary Haberman et al. J. Cardiovasc. Electrophysiol., Published online: March 2015.

<http://tinyurl.com/prcqsh7>

This study compared the 12-lead ECG to the AliveCor Mobile ECG for 381 healthy young adults, elite athletes and cardiology clinic patients. AliveCor accurately detects baseline intervals, such as AV block and QRS delay, atrial rate, and rhythm and enables screening in diverse populations.

The efficacy of a smartphone ECG application for cardiac screening in an unselected island population

Pierre Le Page et al. Br. J. Cardiol., Vol. 22, Issue 1, Pages 31-33, March 2015.

954 participants aged 12 to 99 were screened with the using the AliveCor Mobile ECG. Fifty-four (5.6%) people were noted to have a potential abnormality requiring further evaluation with a 12-lead ECG. Of these, 23 (43%) were abnormal.

The AliveCor Mobile ECG led to new diagnoses of arrhythmia, bundle branch block, LVH and cardiomyopathy. Due to its highly portable nature and ease of use, this application could be used as a rapid screening tool for cardiovascular abnormalities, minimizing the resource, time and cost burdens associated with a 12-lead ECG for community screening.

Pharmacy-based screening for a trial fibrillation in high-risk Maori and Pacific populations

Natalie Walker et al. N. Z. Med. J., Vol. 127, Issue 1398, pages 128-31, July 2014.

<http://tinyurl.com/obdvosb>

The feasibility of having a community pharmacist use the AliveCor Mobile ECG to screen a high-risk primary care population, Māori and Pacific people aged ≥55 years, for AF was examined. An ECG was undertaken using the AliveCor Mobile ECG; patients were informed immediately of the result and, if AF positive, referred back to their usual GP for a 12-lead confirmatory ECG. Two of the 121 people screened had a new diagnosis of AF, and two known AF cases appeared not to be receiving warfarin, giving a total of four people (3%) that could benefit from an intervention. The study determined that the AliveCor Mobile ECG is highly acceptable to patient populations as well as health professionals in this environment.

iPhone ECG screening by practice nurses and receptionists for atrial fibrillation in general practice: the GP-SEARCH qualitative pilot study

Jessica Orchard et al. Aust Fam Physician. Vol. 43, No.5, pages 315-319, May 2014.

<http://tinyurl.com/kgoce22>

Receptionists and practice nurses screened patients aged ≥65 years using an AliveCor Mobile ECG. General practitioner (GP) review was then provided during the patient's consultation. Eighty-eight patients (51% male; mean age 74.8 ± 8.8 years) were screened: 17 patients (19%) were in AF (all previously diagnosed). The AliveCor Mobile ECG was well accepted by GPs, nurses and patients. Receptionists were reluctant, whereas nurses were confident in using the device to explain and provide screening.

Feasibility and cost effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies

Nicole Lowres et al. Thromb Haemost., Vol. 111, Issue 6, pages 1167-1176, April 2014.

<http://tinyurl.com/l2fq96b>

This study investigated community screening for unknown AF using the AliveCor Mobile ECG in pharmacies. Screening with the AliveCor Mobile ECG in pharmacies with an automated algorithm is both feasible and cost-effective. Sensitivity analysis indicated cost-effectiveness improved with increased treatment adherence.

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

Jerrett Lau et al. Int. J. Cardiol., Vol. 165, Issue 1, pages 193-194, 30 April 2013.

<http://tinyurl.com/porqbav>

The AliveCor Mobile ECG was used in 109 patients (70 in sinus rhythm and 39 in AF) soon after a 12-lead ECG had been performed. The ECGs were interpreted by two cardiologists blinded to the rhythm diagnosis, and were processed to provide an automated diagnosis of sinus rhythm or AF. Results were compared with the 12-lead ECG diagnosis by a third cardiologist. An 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. This study concluded that the AliveCor Mobile ECG can be used to simply and rapidly record a high quality single-lead ECG to accurately detect AF, making it an ideal technology for community screening programs to detect silent AF.

DIAGNOSIS

Diagnosing symptomatic arrhythmia via mobile phone

Dave Richley et al. BJCN, Published online: 20 March 2015.

<http://tinyurl.com/noachl3>

This is a single case study of a 22-year old admitted to the hospital for an episode of tachycardia at a rate of 150 BPM. Upon discharge from the hospital, the patient had an exercise ECG test in attempt to provoke the arrhythmia, then wore a 24-hour ambulatory ECG, and finally was issued a patient-activated event recorder for two weeks. None of these methods captured abnormalities despite symptoms recurring approximately every three months. The patient then purchased an AliveCor Mobile ECG and used this device to record a lead II ECG upon a subsequent attack of palpitations. A consultant cardiologist used this recording to diagnose probable atrioventricular nodal re-entrant tachycardia. Treatment followed.

Living with the handheld ECG

Andrew R. J. Mitchell et al. BMJ Innov. Published online: 5 March 2015.

<http://tinyurl.com/nltbuxs>

This paper discusses the evolution of the ECG and highlights the rise of digital health devices and wearable technologies. It identifies the AliveCor Mobile ECG as a useful tool to reduce clinic visits and lower the cost of monitoring while increasing the speed and accuracy of diagnoses. Clinical usability of the AliveCor Mobile ECG is described for narrow complex tachycardia in a patient with palpitation, complete heart block in a patient with intermittent giddiness, arrhythmia in a patient following catheter ablation, and atrial fibrillation in an asymptomatic individual.

Wide Complex Tachycardia Recorded With a Smartphone Cardiac Rhythm Monitor

Jonathan Waks et al. JAMA Intern. Med. Vol. 175, Issue 3, pages 437-439. January 2015.

This study discusses the diagnosis of a 62-year old man experiencing frequent, sudden episodes of exertional near-syncope and syncope with monomorphic RVOT VT. The AliveCor Mobile ECG is found to be easy to use and may improve diagnostic yield in patients with symptoms of palpitations, light-headedness, or near-syncope. However, the lack of adhesive electrodes and variable contact between the patient and the device can lead to superimposed noise and artifact that may, in some cases, obscure the correct electrocardiographic diagnosis. Further, the device records cardiac rhythms only upon proper activation. Understanding these limitations, an implantable cardiac rhythm monitor is recommended as an alternative in the case of rapid-onset syncope or very short-lived symptoms.

Ubiquitous Wireless ECG Recording: A Powerful Tool Physicians Should Embrace

Leslie A. Saxon. *J. Cardiovasc. Electrophysiol.*, Vol. 24, Issue 4, pages 480-483, April 2013.

<http://tinyurl.com/op6sasy>

Fifty-four participants transmitted AliveCor Mobile ECG recordings weekly for eight weeks. Without training, subjects used the device to record ECG's for themselves and others. Transmission interpretation was normal sinus rhythm (68%); sinus brady or tachy (16%); extra atrial or ventricular systoles (2%); QRS delay (1%); and noise (13%). Symptomatic ventricular tachycardia and asymptomatic ST segment depression were detected in two participants, suggesting that early detection of abnormalities provides a window of diagnostic and therapeutic opportunity for intervention to prevent significant cardiac events.

The majority of participants (82%) reported that the device was beneficial, 33% felt that they were more health conscious after participating in the study, and 88% thought that the device was transmitting accurate information. Participants indicated that they found the portability, ease of use, and the form factor to be the design aspects of the device that were most conducive to use. Use of the device caused 24% of subjects to reach out to see a physician for a consultation and 16% felt that they discovered a health condition unknown to them because they were able to correlate a symptom of rapid heart rate or palpitations to an event recorded that they recognized in the tracing and felt needed medical consultation.

MONITORING

Using a Novel Wireless System in Monitoring patients After Atrial Fibrillation Ablation Procedure. The iTransmit Study

Khaldoun G. Tarakji et al. *HeartRhythm*. In Press. Published online: November 2014.

<http://tinyurl.com/q7oppz9>

AF patients undergoing ablation (60 enrolled, 55 completed study) were provided an AliveCor Mobile ECG and traditional transtelephonic monitor. Patients were asked to record their rhythm using both monitors simultaneously whenever they had symptoms and at their weekly scheduled transmissions. AliveCor Mobile ECG recordings had blinded reviews by an independent electrophysiologist. Transtelephonic monitor recordings were reviewed by the primary electrophysiologist. The kappa coefficient was 0.82, indicating excellent agreement between the two methods. The AliveCor Mobile ECG had 100% sensitivity and 97% specificity for detection of AF/atrial flutter compared to the transtelephonic monitor. The AliveCor Mobile ECG can provide an alternative method for monitoring AF patients after ablation procedure. Most patients found the AliveCor Mobile ECG easy to use and preferred it to the transtelephonic monitor.

Detection of recurrent atrial fibrillation utilizing novel technology

Kathleen Hickey et al. *JAFIB*, Vol. 6, Issue 4, Dec 2013 - Jan 2014.

<http://tinyurl.com/l7gu475>

This is a single case study of a 58-year-old AF patient with multiple cardiac risk factors who failed to remain in normal sinus rhythm after two ablations and one cardioversion. Following a second cardioversion, the patient was given an AliveCor Mobile ECG for mobile monitoring of any symptomatic events. Within days, the patient began feeling symptomatic again and used his device to transmit an ECG to his healthcare provider. The novel technology led to more timely detection of recurrent AF. Since approximately one-third of patients with AF are asymptomatic, a daily ECG transmission in those who have undergone a prior cardioversion or AF ablation may prove useful in detecting silent AF.