Kardia

Clinical Research
On-Label & Off-Label
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Kardia

AliveCor®

Accuracy of Algorithm

Screening for atrial fibrillation during influenza vaccinations by primary care nurses using a smartphone electrocardiograph (iECG): a feasibility study.

Kardia Mobile was used to identify asymptomatic AF at the time of influenza vaccination in 5 practices in Sydney, Australia. Nurses used the automated algorithm to screen 973 patients aged ≥ 65 years between April-June 2015. Screening took on average 5 minutes (range 1.5 -10 minutes); abnormal recordings required additional time. Newly identified AF was found in 0.8% (8) of patients, and the overall prevalence of AF was 3.8% (37). The sensitivity and specificity of the automated algorithm for detecting AF was 95% and 99%, respectively. Screening by practice nurses was well accepted by practice staff. Key enablers were the confidence and competence of nurses and a 'designated champion' to lead screening at the practice. Barriers were practice specific, and mainly related to staff time and funding.

Orchard J, Lowres N, Freedman SB, Ladak L, Lee W, Zwar N et al.
Eur J Prev Cardiol. 2016; 23(2S):13-20.

Feasibility and cost-effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH-AF study.

One thousand pharmacy customers (mean age 76 ± 7 years, 44% male) were screened with Kardia Mobile. Newly identified AF was found in 1.5% (95% CI, 0.8-2.5%), and AF prevalence was 6.7%. The automated algorithm showed 98.5% sensitivity and 91.4% specificity for detecting AF. Using cost and outcome data from a United Kingdom study for AF screening, the incremental cost-effectiveness ratio of extending screening into the community with Kardia Mobile, based on 55% warfarin prescription adherence, would be $USD4,066 per quality-adjusted life-year gained, and $USD20,695 for preventing one stroke. In summary, screening for AF with Kardia Mobile is feasible and cost-effective.

Lowres N, Neubeck L, Salkeld G, Krass I, McLachlan AJ, Redfern J, et al.
Thromb Haemost. 2014;111(6):1167-76.

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

Kardia Mobile was used in a community screening of 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 Kardia Mobile 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.

Lau JK, Lowres N, Neubeck L, Brieger DB, Sy RW, Galloway CD, et al.
Int J Cardiol. 2013;165(1):193-4.

A smartphone-based ECG recorder is non-inferior to an ambulatory event monitor for diagnosis of palpitations.

This oral presentation reported results from a trial evaluating the diagnostic yield of Kardia Mobile versus a 14-day event monitor, with the use of both devices simultaneously. All recordings were interpreted by cardiologists. All Kardia Mobile recordings were triggered by patients at symptom onset, while 44.5% of event monitor recordings were symptom-triggered. Among 32 patients with palpitations, the diagnostic yield for Kardia Mobile was non-inferior to an event monitor for overall rhythm disturbances, ectopy, and AF (21.9% vs. 15.6%, p<0.01, for AF). The authors concluded that Kardia Mobile can be used as a first approach for the diagnosis of palpitations.

Narasimha D, Hanna N, Beck H, Chaskes M, Glover R, Gatewood R, et al.
Heart Rhythm Society's Annual Scientific Sessions (2016). Presentation.

Excellent symptom rhythm correlation in patients with palpitations using a novel smartphone based event recorder.

The diagnostic yield, arrhythmia detection, ECG quality, and patient experience between Kardia Mobile (12 weeks) and Holter monitoring (7 days) of 20 patients with palpitations was assessed. Symptom correlation was higher with Kardia Mobile than Holter (85% vs. 30%, p=0.003). The number of patients detecting an arrhythmia was higher with Kardia Mobile than Holter (45% vs. 10%, p=0.021). 96% of 966 ECGs from Kardia Mobile were interpretable. Kardia Mobile was associated with high levels of patient satisfaction. Provider workload for Holter vs. Kardia Mobile was comparable (39 vs. 43 minutes, p=0.352).

Begg GA, Newham W, Muzahir HT.
Heart Rhythm Society's Annual Scientific Sessions (2016). Abstract.

Ubiquitous wireless ECG recording: a powerful tool physicians should embrace.

Fifty-three attendees at a computing conference (mean age 43 ±11 years, 77% male) transmitted Kardia Mobile recordings weekly for eight weeks. Transmission interpretation was normal sinus rhythm (68%); sinus bradycardia or tachycardia (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. Use of the device caused 24% of subjects to reach out to see a physician for a consultation.

Saxon LA.
J Cardiovasc Electrophysiol. 2013;24(4):480-3.

Crowd-sourcing syncope diagnosis: mobile smartphone ECG apps.

This case report documents a 76-year-old gentleman with witnessed syncope. When he regained consciousness, a bystander cardiologist used Kardia Mobile on the patient, which showed sinus tachycardia with complete heart block and a narrow complex escape rhythm. The patient later underwent pacemaker implantation. Although Kardia Mobile is patient triggered, it can be used in syncope if applied by bystanders. The authors conclude there is a potential for widespread use of Kardia Mobile to usher in a new era of democratized, crowd-sourced, syncope diagnostic capability.

Nyotowidjojo I, Erickson RP, Lee KS.
Am J Med. 2016;129(4):e17-8.

Arrhythmia Assessment

Living with the handheld ECG.

This review paper discusses the evolution of the ECG and highlights the rise of digital health devices and wearable technologies. It identifies Kardia Mobile 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 Kardia Mobile is described for narrow complex tachycardia in a patient with palpitations, complete heart block in a patient with intermittent giddiness, arrhythmia in a patient following catheter ablation, and AF in an asymptomatic individual.

Mitchell AR, Le Page P.
BMJ Innov. 2015;0:1-3.

Smartphone ECG aids real time diagnosis of palpitations in the competitive college athlete.

Six college athletes presented to their athletic trainers complaining of palpitations during exercise. A single lead ECG was performed using Kardia Mobile and sent wirelessly to the team cardiologist who confirmed an absence of dangerous arrhythmia. Kardia Mobile has the potential to enhance evaluation of symptomatic athletes by allowing trainers and team physicians to make diagnoses in real-time and facilitate faster return to play.

Peritz DC, Howard A, Ciocca M, Chung EH.
J Electrocardiol. 2015;48(5):896-9.

Diagnosing symptomatic arrhythmia via mobile phone.

This is a 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 Kardia Mobile and used this device to record when symptomatic. A consultant cardiologist reviewed recordings to diagnose probable atrioventricular nodal re-entrant tachycardia. Treatment reviewed.

Richley D, Graham A.
Br J Cardiac Nurs. 2015;10(3):130.

Wide complex tachycardia recorded with a smartphone cardiac rhythm monitor.

This case report discusses the use of Kardia Mobile to diagnose RVOT ventricular tachycardia in diagnosis of a 62-year old man experiencing frequent, sudden episodes of exertional near-syncope and syncope with monomorphic RVOT VT. Kardia Mobile 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.

Waks JW, Fein AS, Das S.
JAMA Intern Med. 2015;175(3):437-9.

Arrhythmia Assessment

An observational study in the diagnostic utility of Kardia Mobile [formerly AliveCor] recorders for the investigation of symptomatic arrhythmias.

In this prospective observational study, Kardia Mobile was used to assess yield of diagnosis of symptomatic arrhythmias. 70 patients (mean age 38 years) without a history of syncope used Kardia Mobile when symptomatic, and a cardiologist or cardiac physiologist reviewed the ECG. Over a median 145 days, 69% submitted symptomatic recordings, which included sinus rhythm (48%), sinus tachycardia (21%), ventricular ectopy (15%), AF (10%), and supraventricular tachycardia (6%). Kardia Mobile enabled a symptom-rhythm correlation in the majority of patients.

Onwordi E, Dimarco AD, Walters EJ, Willis L, Mullan NJ, Tanner MA.
Heart Rhythm Society's Annual Scientific Sessions (2016). Abstract.

Managing Patients with AF: Post-Ablation

Using a novel wireless system for monitoring patients after the atrial fibrillation ablation procedure: the iTransmit study.

Fifty-five patients (mean age 60 ± 12 years) with AF undergoing ablation recorded their rhythm using Kardia Mobile and a traditional transtelephonic monitor (TTM) whenever they had symptoms, or at least once a week, for 3-4 months following ablation. All were interpreted by electrophysiologists. There were 831 Kardia Mobile recordings, and 7 were noninterpretable. Of the 389 simultaneous recordings with Kardia Mobile and TTM, there was excellent agreement (K statistic 0.82). Kardia Mobile detected sinus rhythm 97% of the time and correctly detected AF and atrial flutter 100% of the time, with 3% false-positive results. For manual review of Kardia Mobile versus TTM for detection of AF, Kardia Mobile had 97% specificity and 100% sensitivity. P waves could be difficult to discern, and occasionally this resulted in mislabeling sinus rhythm with atrial ectopy as AF. Kardia Mobile is an alternative method for monitoring patients after AF ablation, with patients agreeing on ease of use.

Tarakji KG, Wazni OM, Callahan T, Kanj M, Hakim AH, Wolski K, et al.
Heart Rhythm. 2015;12(3):554-9.

Managing Patients with AF: Post-Cardioversion

Detection of recurrent atrial fibrillation using novel technology.

This is a case study of a 58-year-old patient with AF 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 Kardia Mobile 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.

Hickey KT, Dizon J, Frulla A.
JAFIB. 2013;6(4):50-1.

Managing Patients with AF: Monitor Symptoms and Rhythm

Atrial fibrillation self-monitoring: patients versus algorithms.

The feasibility of twice-daily self-monitoring with Kardia Mobile was evaluated in 18 patients with paroxysmal AF and rhythm control management. Patients were instructed to recognize and notate sinus or AF. Over 3 months, the mean sensitivity of patient detection was 85% and the specificity was 98%; the Kardia Mobile AF algorithm sensitivity was 100% and specificity was 97%. Adherence to the twice-daily monitoring program declined over time, from median 83% to 58%.

Ross HM, Smith AJ.
Heart Rhythm Society's Annual Scientific Sessions (2016). Abstract.

Managing Patients with AF: Monitor Symptoms and Rhythm

A single-center randomized, controlled trial investigating the efficacy of a mHealth ECG technology intervention to improve the detection of atrial fibrillation: the iHEART study protocol.

The iHEART study is a single center, prospective, randomized controlled trial. A total of 300 participants with a recent history of AF will be enrolled. Participants will be randomized 1:1 to receive the iHEART intervention, receiving an iPhone® equipped with a Kardia Mobile and behavioral altering motivational text messages or usual cardiac care for 6 months. This will be the first study to investigate the utility of a mobile health intervention in a "real world" setting. This study will assess the impact of Kardia Mobile on clinical outcomes, quality of life, quality-adjusted life-years and disease-specific knowledge.

Hickey KT, Hauser NR, Valente LE, Riga TC, Frulla AP, Masterson Creber R, et al.
BMC Cardiovasc Disord. 2016;16:152.

Diagnosing AF Early in High Risk Patients: Post-Cardiac Surgery

Self-monitoring for atrial fibrillation recurrence in the discharge period post-cardiac surgery using an iPhone electrocardiogram.

This study aimed to determine the feasibility of patients self-monitoring with Kardia Mobile to identify recurrence of post-operative AF (POAF) in the post-discharge period following cardiac surgery. Forty-two participants with no prior history of AF, and discharged home in stable sinus rhythm, used Kardia Mobile 4 times per day for 4 weeks post-discharge. Self-monitoring for POAF recurrence using Kardia Mobile was feasible and acceptable, and participants felt empowered. Self-monitoring identified 24% (95% CI 12–39%) with an AF recurrence within 17 days of hospital discharge. 80% of patients with recurrence were at high enough stroke risk to warrant consideration of anticoagulation. The study concluded that Kardia Mobile is a non-invasive, inexpensive, convenient and feasible way to monitor for AF recurrence in post-cardiac surgery patients. It also provides a mechanism to provide knowledge about the condition and also potentially reduces anxiety.

Lowres N, Mulcahy G, Gallagher R, Freedman B, Marshman D, Kirkness A, et al.
Eur J Cardiothorac Surg. 2016;50(1):44-51.

Diagnosing AF Early in High Risk Patients: Screening

Screening for atrial fibrillation in 13,122 Hong Kong citizens with smartphone electrocardiogram.

From May 1, 2014, to April 30, 2015, adults aged 18 and above were informed by media promotion for a community-wide AF screening program in Hong Kong. A group of non-medical volunteers used Kardia Mobile to screen 13,122 Hong Kong citizens (mean age 65.5 ± 13.3 years). All recordings were overread by a cardiologist within 1 month of the recording, and all participants with AF detected were referred for medical consultation. Fifty-six (0.4%) out of 13,122 Kardia Mobile recordings were uninterpretable. Newly diagnosed AF was discovered in 101 (0.8%) participants. The overall prevalence for AF was 1.8% (239/13,122, 95% CI 1.6-2%). Systematic population-based ECG screening for AF with Kardia Mobile was feasible and identified a proportion of Hong Kong citizens with AF that was comparable with that of contemporary US and European populations.

Chan NY, Choy CC.
Heart. 2017;103(1):24-31.

Diagnosing AF Early in High Risk Patients: Screening

Feasibility and cost-effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH-AF study.

One thousand pharmacy customers (mean age 76 ± 7 years, 44% male) were screened with Kardia Mobile. Newly identified AF was found in 1.5% (95% CI, 0.8-2.5%), and AF prevalence was 6.7%. The automated algorithm showed 98.5% sensitivity and 91.4% specificity for detecting AF. Using cost and outcome data from a United Kingdom study for AF screening, the incremental cost-effectiveness ratio of extending screening into the community with Kardia Mobile, based on 55% warfarin prescription adherence, would be $USD4,066 per quality-adjusted life-year gained, and $USD20,695 for preventing one stroke. In summary, screening for AF with Kardia Mobile is feasible and cost-effective.

Lowres N, Neubeck L, Salkeld G, Krass I, McLachlan AJ, Redfern J, et al.
Thromb Haemost. 2014;111(6):1167-76.

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

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Lau JK, Lowres N, Neubeck L, Brieger DB, Sy RW, Galloway CD, et al.
Int J Cardiol. 2013;165(1):193-4.

Smartphone based photoplethysmograph as a screening solution for atrial fibrillation: a digital tool to detect AFib?

This abstract compared the accuracy of photoplethysmography (PPG) with Kardia Mobile for the diagnosis of AF in a national incentivized screening campaign of 1056 individuals in Belgium (mean age 59 years, 41% male). Screening resulted in identification of 8 AF cases and 22 other irregular rhythms. Kardia Mobile had 3.8% unreadable ECGs. Kardia Mobile had a sensitivity of 100% and a specificity of 99.6%. The PPG device had comparable performance.

Grieten L, Van Der Auwera J, Vandervoort P, Rivero-Ayerza M, Van Herendael H, De Vusser, P, et al.
American College of Cardiology Scientific Sessions (2017). Abstract.

Feasibility of using mobile ECG recording technology to detect atrial fibrillation in low-resource settings.

This study used Kardia Mobile to screen 50 adults in Kenya (mean age 54 years, 66% women) attending Kijabe Hospital outpatient internal medicine or diabetes clinics; 44% had hypertension, 32% had diabetes, and 4% had stroke. ECG tracings in 4 of the 50 patients (8%) showed AF, and none had been previously diagnosed with AF. The authors concluded that Kardia Mobile can be used to screen for AF in low-resource settings.

Evans GF, Shirk A, Muturi P, Soliman EZ.
Glob Heart. Published online first: 13 Mar 2017. doi:10.1016/j.gheart.2016.12.003.

High burden of unrecognized atrial fibrillation in rural India: an innovative community-based cross-sectional screening program.

Residents from 6 villages in Gujarat, India, were screened for AF using Kardia Mobile. A total of 235 participants aged 50 years and older (half female) used Kardia Mobile for 2 minutes on 5 consecutive days. Community health workers helped to screen participants. The prevalence of AF increased by the number of screenings, from 3.0% with 1 screening to 5.1% with 5 screenings.

Soni A, Earon A, Handorf A, Fahey N, Talati K, Bostrom J, et al.
JMIR Public Health Surveill. 2016;2(2):e159.

Screening for atrial fibrillation during influenza vaccinations by primary care nurses using a smartphone electrocardiograph (iECG): a feasibility study.

Kardia Mobile was used to identify asymptomatic AF at the time of influenza vaccination in 5 practices in Sydney, Australia. Nurses used the automated algorithm to screen 973 patients aged ≥ 65 years between April-June 2015. Screening took on average 5 minutes (range 1.5 -10 minutes); abnormal recordings required additional time. Newly identified AF was found in 0.8% (8) of patients, and the overall prevalence of AF was 3.8% (37). The sensitivity and specificity of the automated algorithm for detecting AF was 95% and 99%, respectively. Screening by practice nurses was well accepted by practice staff. Key enablers were the confidence and competence of nurses and a 'designated champion' to lead screening at the practice. Barriers were practice specific, and mainly related to staff time and funding.

Orchard J, Lowres N, Freedman SB, Ladak L, Lee W, Zwar N et al.
Eur J Prev Cardiol. 2016; 23(2S):13-20.

Medical outpatient clinics is an ideal setting for atrial fibrillation screening using a handheld single-lead ECG with automated diagnosis.

This study evaluated the feasibility of Kardia Mobile to screen for undiagnosed AF in 9,046 consecutive patients ≥ 65 years attending medical clinics between Dec 2014 to Jan 2016. All ECGs were over-read by a cardiologist. Approximately 10% of patients underwent repeated screening. Newly identified AF was found in 1.5% on a single screen, and an additional 1.2% was detected in those screened on multiple occasions. About 21% of newly diagnosed patients had a history of stroke, and 10% were taking oral anticoagulation for reasons other than AF. Overall AF prevalence was 9.4% (850/9,046). Single-time point screening with Kardia Mobile is feasible and identified a significant number of patients at high risk of stroke. Repeated screening increased diagnostic yield.

Yan BP, Chan LL, Lee VW, Freedman B.
European Society of Cardiology 2016 Congress. Abstract.

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

Kardia Mobile was used to screen 954 participants aged 12-99. There were 54 (5.6%) people noted to have a potential abnormality (conduction defect, increased voltage, rhythm abnormality); of these 23 (43%) were abnormal with two confirming AF and 2 showing atrial flutter. Other abnormalities detected included atrial and ventricular ectopy, bundle branch block, and left ventricular hypertrophy. One patient with increased voltages was later diagnosed with hypertrophic cardiomyopathy. In conclusion, Kardia Mobile was quick and easy to use and led to new diagnoses of arrhythmia, bundle branch block, left ventricular hypertrophy and cardiomyopathy.

Le Page P, McLachlan H, Anderson L, Penn L, Moss A, Mitchell A.
Br J Cardiol. 2015;22:31-3.

Diagnosing AF Early in High Risk Patients: Screening

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

Ninety-five patients, 29 with AF and 66 in sinus rhythm, were assessed with Kardia Mobile and a standard 12-lead EKG by two physicians in clinic. For one practitioner's review, the sensitivity of Kardia Mobile was 90% and the specificity was 86%; for the other practitioner, the sensitivity was 93% and the specificity was 76%. The high sensitivity of Kardia Mobile suggests this test is a good 'rule-out' for AF. A positive test should be combined with a 12-lead EKG to confirm the diagnosis of AF.

Williams, J, Pearce K, Benett I.
Br J Cardiol. 2015;22:70-2.

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

Receptionists and practice nurses screened patients aged ≥65 years using Kardia Mobile. 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). Kardia Mobile was well accepted by GPs, nurses and patients. Receptionists were reluctant, whereas nurses were confident in using the device to explain and provide screening.

Orchard J, Freedman SB, Lowres N, Peiris D, Neubeck L.
Aust Fam Physician. 2014;43(5):315-9.

Pharmacy-based screening for atrial fibrillation in high-risk Maori and Pacific populations.

One hundred twenty-one Maori and Pacific people age ≥ 55 years were screened for AF with Kardia Mobile in New Zealand community pharmacies; if the automatic algorithm was positive, participants were referred to primary care for confirmatory 12-lead ECG. Two of the 121 participants screened had a new diagnosis of AF (1.7%), and two known AF cases appeared to not be receiving warfarin, giving a total of four people (3%) that could benefit from initiation of anticoagulation. There were 2 false positives, which were thought to occur due to incorrect handling of the device, which was corrected through further training of the pharmacists. The study determined that Kardia Mobile is highly acceptable to patient populations as well as health professionals in this environment.

Walker N, Doughty R, Parag V, Harrison J, Bennett M, Freedman B.
N Z Med J. 2014;127(1398):128-31.

Patient Management of Cardiac Risk Factors

Supporting Literature

Effect of weight reduction and cardiometabolic risk factor management on symptom burden and severity in patients with atrial fibrillation: a randomized clinical trial.

In this partially blinded study, 150 patients with symptomatic AF were randomized to weight management or general lifestyle advice to determine the effect of weight reduction on AF burden. For the intervention, participants were prescribed meal replacements for 2 of their daily meals, an exercise program, and face-to-face clinic visits every 3 months. Participants were required to maintain a diet, activity, and blood pressure diary. Over 15 months, the intervention group showed a significantly greater reduction in weight (14.3 and 3.6 kg, respectively; p <0.001), blood pressure (3 mmHg and 1 mmHg; p<0.001), AF symptom burden and severity scores, and in cumulative duration as measured by 7-day Holter recordings. These findings support therapy directed at weight and risk factors in the management of AF.

Abed HS, Wittert GA, Leong DP, Shirazi MG, Bahrami B, Middeldorp ME, et al.
JAMA. 2013;310(19):2050-60

Off-Label

Comparison of QT interval readings in normal sinus rhythm between a smartphone heart monitor and a 12-lead ECG for healthy volunteers and inpatients receiving sotalol or dofetilide.

This study sought to evaluate the accuracy of Kardia Mobile for assessing the QTc. Across 99 healthy volunteers and 25 hospitalized patients in sinus rhythm being loaded on dofetilide or sotalol, Kardia Mobile QTc had good agreement with the 12-lead ECG QTc. For patients receiving QT prolonging antiarrhythmics, Kardia Mobile is capable of detecting QTc prolongation, and lead-I is most accurate in measuring the QTc if < 500 milliseconds.

Garabelli P, Stavrakis S, Albert M, Koomson E, Parwani P, Chohan J, et al.
J Cardiovasc Electrophysiol. 2016;27(7): 827-32.

Surface 12-lead electrocardiogram recordings using smart phone technology.

The 12-lead ECG was reproduced using the bipolar arrangement of Kardia Mobile coupled to smart phone technology. In 5 individuals, recordings from both a standard 12-lead ECG and a Kardia Mobile-generated 12-lead ECG had the same interpretation. This study demonstrates the feasibility of creating a 12-lead ECG with a smart phone.

Baquero GA, Banchs JE, Ahmed S, Naccarelli GV, Luck JC.
J Electrocardiol. 2015;48(1):1-7.

QTc intervals can be assessed with Kardia Mobile [formerly AliveCor] heart monitor in patients on dofetilide for atrial fibrillation.

The feasibility of Kardia Mobile tracings for QTc assessment in 5 patients receiving dofetilide was assessed. There was no significant difference between Kardia Mobile QTc and standard ECG-QTc (all ± 20 msec). None of the patients required a dosage adjustment due to QT prolongation during their stay. Kardia Mobile can be used to monitor the QTc in patients receiving dofetilide for AF.

Chung EH, Guise KD.
J Electrocardiol. 2015;48(1):8-9.

The use of a smartphone-based ECG in the screening of QT intervals in children.

In this pilot study, the reliability of Kardia Mobile in measuring the QT interval in children was assessed. A total of 196 children (mean age 9.2 years ± 4.0 months) between September and November 2015 were included. The mean QT interval obtained from Kardia Mobile was strongly correlated with the mean QT interval from 12-lead ECG (correlation coefficient, 0.77, p <0.001). Kardia Mobile can accurately detect QT intervals and potentially be used for screening of congenital long QT syndrome in children.

Karacan M, Celik N, Akdeniz C, Gul EE, Tuzcu V.
Heart Rhythm Society's Annual Scientific Sessions (2016). Abstract.

A smartphone application to diagnose the mechanism of pediatric supraventricular tachycardia.

The utility of Kardia Mobile to record supraventricular tachycardia (SVT) and to distinguish atrioventricular reentrant tachycardia (AVRT) from atrioventricular nodal reentrant tachycardia (AVNRT) in pediatric patients was ascertained. Tracings were obtained by placing the smartphone in three different positions on the chest. Two blinded pediatric electrophysiologists jointly analyzed a pair of sinus and tachycardia tracings in each position. 37 patients (mean age 13.7 years) were enrolled. 128 pairs of tracings were obtained, and the correct diagnosis was made in 59-73% with the three-lead positions. Kardia Mobile can successfully record SVT in pediatric patients and can predict the SVT mechanism at least as well as previously published reports of Holter monitors.

Ferdman DJ, Liberman L, Silver, ES.
Pediatr Cardiol. 2015;36(7):1452-7.

Off-Label

SPEAR Trial: Smartphone Pediatric ElectrocARdiogram Trial.

This study aimed to assess the usefulness of pediatric ECG tracings generated by Kardia Mobile. Over a year, 20 patients with documented paroxysmal arrhythmia used Kardia Mobile, generating a total of 238 tracings. 96% of tracings were of diagnostic quality for sinus rhythm, sinus tachycardia, supraventricular tachycardia, and AF. 126 patient satisfaction surveys (64% from parents) were completed. 98% of the survey responses indicated that it was easy to obtain tracings, 93% found it easy to transmit the tracings, 98% showed added comfort in managing arrhythmia by having the device, and 93% showed interest in continued use of the device after the study period ended. In summary, Kardia Mobile generates tracings of diagnostic quality in children. User satisfaction was extremely positive.

Nguyen HH, Van Hare GF, Rudokas M, Bowman T, Silva JN.
PLoS ONE 10(8):e0136256. doi:10.1371/journal.pone.0136256.

Smartphone ECG for evaluation of STEMI: results of the ST LEUIS Pilot Study.

In this pilot study, a 12-lead ECG generated from electrodes attached to Kardia Mobile was compared to the 12-lead ECG in evaluation of in-hospital cardiac ischemia. 6 patients for whom the hospital ST elevation myocardial infarction (STEMI) was activated were evaluated. All tracings were taken prior to catheterization or immediately after revascularization while still in the catheterization laboratory. The 12-lead ECG generated from Kardia Mobile had excellent correlation with the gold standard 12-lead ECG in all patients. Four out of six tracings were judged to meet STEMI criteria on both modalities as determined by three experienced cardiologists, and in the remaining two, consensus indicated a non-STEMI ECG diagnosis. This study confirmed the potential of Kardia Mobile for evaluation of acute ischemia.

Muhlestein JB, Le V, Albert D, Moreno FL, Anderson JL, Yanowitz F, et al.
J Electrocardiol. 2015;48(2):249-59.

Intermittent versus continuous anticoagulation therapy in patients with atrial fibrillation (ICARE-AF), a pilot study.

Fifty-eight patients with paroxysmal AF and CHADS2 < 3 were randomized to intermittent anticoagulation based on daily Kardia Mobile monitoring (n=29), or continuous anticoagulation with a new oral anticoagulation medication (n=29). Over a median 20 months, 20 patients in the intermittent arm failed to submit a daily ECG at least once (median 3 failed submissions). 10 patients (35%) crossed over to continuous anticoagulation, either for failure to submit an ECG for 3 days, or for progression to persistent AF. Rates of death or stroke were not different between the groups (3 vs. 1, p=0.65). Major bleeding was not different. Gastrointestinal bleeding was more frequent in the continuous group.

Stavrakis S, Stoner JA, Kardokus J, Garabelli PJ, Po SS, Lazzara R.
J Interv Card Electrophysiol. 2017;48(1):51-60.

Wireless smartphone ECG enables large-scale screening in diverse populations.

The accuracy of Kardia Mobile for determining baseline ECG intervals and rate and rhythm was assessed in 381 healthy young adults, elite athletes, and cardiology clinic patients. Kardia Mobile accurately detected baseline intervals, atrial rate, and rhythm, and enabled screening in diverse populations.

Haberman ZC, Jahn RT, Bose R, Tun H, Shinbane JS, Doshi RN, et al.
J Cardiovasc Electrophysiol. 2015;26(5):520-6.

Other Supporting Literature

Mobile technology and the digitization of healthcare.

This review assesses current literature of mobile health and provides a framework for the advances in mobile health by understanding the various device, patient, and clinical factors as they relate to digital health, from device designs and patient engagement, to clinical workflow and device regulation.

Bhavnani SP, Narula J, Sengupta PP.
Eur Heart J. 2016;37(18):1428-38.

Defining a mobile health roadmap for cardiovascular health and disease.

This review outlines specific opportunities for mobile health, potential challenges to the development and adoption of solutions, and a framework for developing safe, effective, and evidence-based mobile health solutions for cardiovascular disease.

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