

Accuracy of Single-Lead ECG Device for Diagnosis of Cardiac Arrhythmias Compared Against Cardiac Electrophysiology Study

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September 27, 2023

Abstract

Background Single-lead ECG devices may allow detection and diagnosis of cardiac rhythms. However, data on their accuracy for detecting cardiac arrhythmias beyond atrial fibrillation are limited. **Objectives** To determine the accuracy of the AliveCor KardiaMobile (AC; AliveCor Inc, Mountain View, CA) for the diagnosis of arrhythmias against gold standard cardiac electrophysiology study (EPS). **Methods** Patients undergoing clinically indicated EPS underwent simultaneous rhythms recording with an infraclavicular-placed AC, standard 12-lead ECG and EP catheters for intracardiac electrograms. Rhythms recorded during EPS were classified based on electrogram, 12-lead ECG and clinical findings. Blinded reviewers provided differential diagnoses for the single-lead AC tracings; a separate reviewer compared diagnoses made between the AC tracings and EPS findings. **Results** From 49 patients, 843 cardiac rhythms were captured during 502 AC recordings. Analysis of tracings containing sinus rhythm (n=273) returned overall accuracy of 92%, with sensitivity and specificity values of 93% and 92%, respectively. Accuracy for tracings per rhythm were atrial fibrillation 91% (n=51); supraventricular tachycardia accuracy was 89% (n=191), ventricular tachycardia 91% (n=198), ventricular fibrillation 98% (n=11), asystole 100% (n=5). Accuracy for supraventricular ectopy was 93% (n=28) and premature ventricular complexes was 91% (n=86). Overall accuracy was 94% for uninterrupted rhythms and 93% in tracings from patients with baseline bundle branch block. **Conclusions** When compared against the gold standard EPS diagnosis, interpretation of arrhythmias recorded by an AliveCor single-lead ECG device had reasonable diagnostic accuracy.

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Short Title: AliveCor Validation Against EPS for Cardiac Arrhythmias

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Conflict of Interest Disclosures

Dr Kumar has received funding and/or consulting fees from Abbott Medical, Biosense Webster, Biotronik and Medtronic, and has received honoraria from Abbott Medical, Biosense Webster, Biotronik, and Sanofi Aventis. Dr Mahajan has served on the advisory board of Abbott and Medtronic. The University of Adelaide reports receiving, on behalf of Dr Mahajan, research funding from Abbott, Bayer, and Medtronic, and lecture and/or consulting fees from Abbott, Bayer, Biotronik, Medtronic, and Pfizer. The remaining authors have nothing to disclose.

Sources of Funding

This study was funded by the National Heart Foundation Vanguard Grant (award ID 103056), the CSANZ-Bayer Young Investigator Research Grant, and the Research and Education Network Grant awarded to Dr Saurabh Kumar. Dr Saurabh Kumar is supported by the NSW Early-Mid Career Fellowship. Dr Clara Chow is supported by a NHMRC Investigator grant APP1195326. Dr Mahajan is supported by the Mid-Career Fellowship by The Hospital Research Foundation. Dr Kasun De Silva is supported by an NHMRC Postgraduate Research Scholarship.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics Approval Statement: Approval for this study was granted by the Western Sydney Local Health District Human Research Ethics Committee .

Patient Consent Statement: Informed consent was obtained from all participant I this study prior to their enrolment\

Word count: 5,441

ABSTRACT

Background

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To determine the accuracy of the AliveCor KardiaMobile (AC; AliveCor Inc, Mountain View, CA) for the diagnosis of arrhythmias against gold standard cardiac electrophysiology study (EPS).

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Patients undergoing clinically indicated EPS underwent simultaneous rhythms recording with an infraclavicular-placed AC, standard 12-lead ECG and EP catheters for intracardiac electrograms. Rhythms recorded during EPS were classified based on electrogram, 12-lead ECG and clinical findings. Blinded reviewers provided differential diagnoses for the single-lead AC tracings; a separate reviewer compared diagnoses made between the AC tracings and EPS findings.

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ventricular complexes was 91% (n=86). Overall accuracy was 94% for uninterrupted rhythms and 93% in tracings from patients with baseline bundle branch block.

Conclusions

When compared against the gold standard EPS diagnosis, interpretation of arrhythmias recorded by an AliveCor single-lead ECG device had reasonable diagnostic accuracy.

Key words: arrhythmia, single-lead ECG, ventricular tachycardia, atrial fibrillation, electrophysiology, AliveCor, wearable

ABBREVIATIONS

AC AliveCor

AF atrial fibrillation

BBB bundle branch block

BMI body mass index

BPM beats per minute

CI confidence interval

ECG electrocardiogram

EGM intracardiac electrogram

EPS electrophysiology study

LVEF left ventricular ejection fraction

IQR interquartile range

MSEC millisecond

PVC premature ventricular complex

SD standard deviation

sECG single-lead electrocardiogram

SR sinus rhythm

SVE supraventricular ectopy

SVT supraventricular tachycardia

VF ventricular fibrillation

VT ventricular tachycardia

INTRODUCTION

Cardiac arrhythmias are associated with decreased quality of life, increased morbidity and mortality, and have a considerable impact on healthcare systems.¹⁻⁴ Timely diagnosis of arrhythmias is essential, and ambulatory cardiac monitoring is commonly used to detect episodic arrhythmias.^{5,6} However, the transient nature of arrhythmias and symptoms may limit the diagnostic yield of ambulatory monitoring, which is reported to be as low as 15% for patients with unresolved palpitations.⁶⁻⁸ The past decade has witnessed surge in the prevalence and popularity of cardiovascular health devices, including those capable of recording single-lead electrocardiograms (sECG).⁹⁻¹³ One such device is the AliveCor KardiaMobile ([AC] AliveCor Inc, Mountain View, California, USA), a handheld sECG device has emerged as an alternative option for outpatient arrhythmia investigations.^{7,8} While its accuracy for detecting sinus rhythm (SR) and atrial fibrillation (AF)

is established against 12-lead ECGs, there is limited data on its accuracy for non-AF arrhythmias, nor for validation against gold standard cardiac electrophysiology studies (EPS).¹⁴⁻¹⁷ We therefore aimed to determine the accuracy of the AC in diagnosing a variety of arrhythmias against the gold standard cardiac EPS, through comparison of blinded AC interpretations to “gold standard” diagnoses derived from intracardiac electrograms (EGMs) and a 12-lead ECG during a clinically indicated EPS. In this report, we describe the overall accuracy, sensitivity and specificity of interpretations of cardiac rhythms recorded using the AC. We further aimed to assess the influence of the number of rhythms within the recording as well as the presence of baseline bundle branch block (BBB) upon tracing interpretability.

METHODS

This was a prospective study whereby 50 patients undergoing routine, clinically indicated EPS \pm radiofrequency ablation for previous diagnosed or suspected cardiac arrhythmias at Westmead Hospital, Sydney, Australia, were recruited between August 2019 and November 2020. Other data from this study, in its abbreviated form, combined with two other studies, has recently been published as a brief communication (800 words) (Turnbull, et al. JACC).¹⁸ This manuscript presents full data of the study including detailed rhythm specific analysis of the performance of the AC device. Written informed consent was obtained from all patients prior to the commencement of the study. The study was approved by Western Sydney Local Health District Human Research Ethics Committee. Patients that had a poor baseline sECG performed at the time of recruitment were excluded.

Study Workflow

A detailed study workflow is shown in Central Illustration. An independent data collector (S.T), blinded to the patient history, recorded the AC tracings simultaneously with the recording of EGMs and 12-lead ECG stored on the EPS continuous recording system (CardioLab EP Recording System, General Electric, Boston, Massachusetts, USA). The data collector provided three blinded, electrophysiology-trained reviewers (R.G.B, T.G.C, Y.K) with de-identified AC tracings for analysis. A fourth reviewer (S.K) was provided with EGMs and 12-lead surface ECGs for adjudication of the gold standard diagnosis. The presence of heart rhythm stability, or changes in rhythm or rate (either as a result of arrhythmia, pacing or medication) were used for determination of rhythms selected for analysis. Where possible, examples of all differing rhythms present for each patient were obtained for analysis. Diagnoses made by the blinded reviewers for AC tracings were classified as correct or incorrect, from which overall accuracy, sensitivity and specificity values were obtained. For total rhythms, overall accuracy was a composite of blinded reviewers’ interpretations. Inter-and intra-observer analysis was performed using a randomly selected sample of AC tracings, with interpretations compared.

Electrophysiology Study

The EPS was conducted as per the clinical indication, under either local sedation or general anaesthesia. Diagnostic catheters were positioned at the high right atrium, coronary sinus, His bundle, and the right ventricular apex as required. Standard electrophysiologic evaluation of anterograde and retrograde conduction, myocardial and nodal refractory periods, Wenckebach cycle lengths and sinus node recovery time were performed. Programmed electrical stimulation with up to four extra-stimuli from the right ventricular apex, sensed extra-stimuli, burst pacing down to the refractory cycle length, and arrhythmia entrainment with overdrive pacing were performed as indicated. Pharmacological provocation using beta-adrenergic agents, including isoprenaline, were administered as per the operator’s clinical discretion, and diagnostic adenosine was administered where indicated.

Twelve-lead ECGs and EGMs were recorded on CardioLab EP Recording System (GE), with bandpass filtering performed between 30-500Hz. Each induced or spontaneously occurring rhythm during the EPS was documented on the EP recording system by a member of the clinical team, and copies of EGMs and ECG obtained for analysis.

AC Application

The AC sECG device records tracings correlating with lead I vector of a 12-lead ECG when held in the user's hands or with finger application (manufacturer recommendations), for up to 300 seconds, using propriety application software. In patients undergoing EPS under sedation or general anaesthesia, handheld-operation is not feasible. Therefore, in this study, the AC was applied to the patient's chest (infraclavicular), correlating with a pseudo-lead I, given the reduced vector magnitude between points of skin-electrode contact. To capture and store the sECG recordings, a smartphone was placed nearby within the AC communication field.

Throughout the duration of the EPS, new AC recordings were commenced every 5 minutes, to maximise recording volume and to minimise selection bias. To ensure simultaneous comparisons, clocks on all systems were synchronised prior to each procedure. Recordings on the AC were stored locally within the AC smartphone application and transmitted to a secure web-based folder for analysis.

Patient Demographics

Baseline patient demographics were collected including patient's age, sex, body mass index (BMI), previous arrhythmia history, echocardiographic indices (left ventricular ejection fraction [LVEF]), baseline ECG features and co-morbidities.

Classification of Arrhythmias

Gold standard diagnoses were based on evaluation of EGMs, 12-lead ECG and clinical findings from the EPS. They were classified into the following differentials: sinus rhythm (SR); atrial fibrillation (AF); supraventricular tachycardia (SVT); supraventricular ectopy (SVE); ventricular tachycardia (VT); premature ventricular complexes (PVC); ventricular fibrillation (VF); and asystole. Rhythms encompassed under these classifications included pacing manoeuvres that visibly resemble these rhythms on 12-lead ECG, as described below. Examples of these are shown in Central Illustration and Supplementary Figures.

The Gold Standard Diagnoses were classified as:

- SR: encompassing sinus rhythm, sinus bradycardia and atrial pacing >600msec.
- AF: encompassing atrial fibrillation, atrial flutter with variable conduction, atrial pacing with irregular conduction and supraventricular tachycardias with irregular conduction.
- SVT: encompassing (sustained and non-sustained) supraventricular tachycardias demonstrating typical His-Purkinje system conduction including sinus tachycardia (>100bpm), focal atrial tachycardia, atrial pacing at cycle length >600msec, atrioventricular nodal re-entry tachycardia, atrioventricular re-entry tachycardia.
- SVE: encompassing spontaneous or provokable SVEs and atrial paced extrastimuli.
- VT: encompassing spontaneous or provokable ventricular tachycardia (sustained and non-sustained), programmed ventricular stimulation and ventricular pacing >600msec.
- PVC: encompassing spontaneous or provokable premature ventricular complexes and ventricular paced extra-stimuli.
- VF: encompassing ventricular fibrillation and polymorphic VT.
- Asystole: encompassing asystolic pauses >3 seconds.

For consistency in comparison between sECG and the gold standard diagnoses from the EPS, the reviewers were asked to use the same classification for labelling their interpretation, however, were permitted to include rationale.

Statistical Analysis

SPSS version 28 (IBM Corp., Armonk, NY) was used for analysis. Continuous variables were expressed as mean and standard deviation (SD) if there was a normal distribution and as a median (25%-75%) interquartile range (IQR) if there was skewed data. Interpretations were reported in terms of overall accuracy (overall probability that a patient is correctly classified), sensitivity (true positive rate) and specificity (true negative rate) and described as percentages with confidence intervals. For intra- and inter-observer analyses, a random number generator was utilised to extract a near-equivalent number of tracings from each reviewer for repeat

analysis. The Kappa statistic, a measure of inter-observer reliability, was utilised with Cohen’s Kappa (for two reviewers) and the Fleiss Kappa (adaptation of Cohen’s for three reviewers), with percentage agreement additionally reported. The Kappa result can be interpreted as such: Values [?]0 indicate no agreement, 0.01-0.20 as none to slight, 0.21-0.40 as fair, 0.41-0.60 as moderate, 0.61-0.80 as substantial, and 0.81-1.00 as almost perfect agreement.¹⁹ For inter-observer analysis, reviewers’ first interpretation of an AC tracing was compared between individual reviewers and to the three reviewers as an entity. For the intra-observer analysis, comparison was performed between reviewer’s original interpretations to their repeat interpretation of the same AC tracing.

RESULTS

A total of 50 patients undergoing clinically indicated EPS +- radiofrequency ablation were recruited for this study, from which infraclavicular AC rhythm recordings were acquired in 49 patients. One patient was removed from the study due to an isoelectric infraclavicular AC sECG, regardless of rhythm and despite normal 12-lead ECG and satisfactory screening. A total of 502 AC tracings containing 843 rhythms were recorded and analysed. Examples of different arrhythmias recorded on the AC are shown in Central Illustration.

Baseline Characteristics

Baseline characteristics are described in Table 1. Overall mean age was 58+-19 years, mean LVEF was 52+-12%, mean BMI was 28+-4 kg/m² and 71% of patients were male. History of an arrhythmia was present in 47 patients (96%) including AF (n=21; 43%); VT (n=20; 41%), SVT (n=18; 37%) and PVC (n=15; 31%). Baseline rhythm BBB was present in 12 (25%) as a result of conduction system disease or ventricular pacing from an underlying pacemaker/defibrillator. Co-morbidities included hypertension (n=25, 51%), hyperlipidaemia (n=22, 45%), structural heart disease (n=22, 45%) and ischaemic heart disease (n=11, 22%).

AC Rhythm Interpretation vs. Gold Standard Diagnosis

The overall accuracy, sensitivity, specificity and 95% confidence intervals (CI) of blinded AC rhythm interpretations compared to the gold standard diagnosis is shown in Figures 1-3. Reviewers were able to accurately identify 94.3% (93.1–95.3%) of uninterrupted rhythms (defined as tracings containing a solitary rhythm) (n=224), with sensitivity of 94.6% (90.8–97.2%) and specificity of 94.2% (92.9–95.3%). In tracings from patients with BBB (n=202), overall accuracy (92.7% [90.8–94.3%]), sensitivity (87.6% [82.3–91.8%]) and specificity (94.1% [92.1–95.7%]) were also reasonable (Table 2).

Sinus Rhythm

Overall accuracy for identification of SR (n=273) returned a value of 92.4% (89.8–94.6%); sensitivity was 92.7% (88.9–95.5%) and specificity 92.1% (87.9–95.3%). Accuracy for uninterrupted SR (n=65) was 93.3% (89.2–96.2%), sensitivity and specificity 98.5% (91.7–100.0%) and 91.2% (85.7–95.1%) respectively (Table 2). The single misinterpreted uninterrupted tracing was labelled as SVT (Supplementary Table 1). In tracings with BBB, results for SR (n=60) were slightly lower, returning accuracy of 91.4% (84.7–95.8%), sensitivity 93.3% (83.8–98.2%), and specificity 89.3% (78.1–96.0%).

Atrial Fibrillation

Overall accuracy was for AF (n=51) diagnoses was 91.0% (88.2–93.4%), sensitivity 86.3% (73.7–94.3%) and specificity 91.6% (88.6–94.0%). Uninterrupted AF (n=34) returned an accuracy of 92.9% (88.7–95.9%), sensitivity of 88.2% (72.6–96.7%) and specificity of 93.7% (89.2–96.7%) (Table 2). Where misinterpreted, uninterrupted AF was labelled as either SR or SVT with accompanying SVEs (n=4; Supplementary Table 1). In tracings with baseline BBB and AF (n=27), interpretability remained, with accuracy 92.2% (85.8–96.4%), sensitivity 88.9% (70.8–97.7%) and specificity 93.3% (85.9–97.5%).

Supraventricular Tachycardia

Analysis of tracings containing SVT (n=191) demonstrated overall accuracy of 89.4% (86.4–92.0%), sensitivity 92.2% (87.4–95.5%), specificity 87.8% (83.6–91.2%). The majority of recordings containing uninterrupted SVT (n=73) were identified correctly, with the single misdiagnosed instance interpreted as VT (Supplementary Table 1). Overall accuracy for uninterrupted SVT 88.8% (84.0–92.7%), sensitivity 98.6% (92.6–100.0%) and specificity 84.1% (77.3–89.5%). The presence of BBB in SVT recordings (n=24) returned accuracy (91.4% [84.7–95.8%]) and specificity (94.6% [87.8–98.2%]), however with notably reduced sensitivity (79.2% [59.5–90.8%]) (Figure 1).

Supraventricular Ectopics

Overall accuracy for identification of SVEs (n=28) was 93.0% (90.4–95.1%). Sensitivity was notably reduced at 75.0% (55.1–89.3%), with specificity at 94.1% (91.6–96.0%). Reduced sensitivity was attributed to common misinterpretation as AF (Supplementary Table 2), and omission from interpretation. In tracings with BBB (n=19), interpretation of SVEs returned improved values with accuracy 94.0% (88.0–97.5%), sensitivity 89.5% (66.9–98.7%), and specificity 94.9% (88.4–98.3%) (Figure 1).

Ventricular Tachycardia

Results of interpretations for tracings containing VT (n=198) returned overall accuracy of 91.2% (88.4–93.6%), sensitivity 92.4% (87.8–95.7%) and specificity 90.5% (86.6–93.5%). Uninterrupted VT (n=51) returned accuracy of 90.2% (85.5–93.7%), sensitivity 88.2% (76.1–95.6%), specificity 90.8% (85.4–94.6%). Interpretations of tracings containing VT in patients with baseline BBB (n=44) returned results comparative to overall VT analysis, with accuracy 91.4% (84.7–95.8%), sensitivity of 93.2% (81.3–98.6%), and specificity of 90.3% (81.0–96.0%) (Figure 1). In the recordings that uninterrupted VT was misdiagnosed, the most common interpretation provided was SVT (n=5; Supplementary Table 1).

Premature Ventricular Complexes

From tracings containing PVCs (n=86), analysis returned an overall accuracy of 90.8% (88.0–93.2%). Sensitivity was notably reduced at 73.3% (62.6–82.2%), but specificity preserved at 94.5% (91.8–96.5%). Presence of BBB on tracings with PVCs (n=25) returned further reduced values, with overall accuracy 84.5% (76.6–90.5%), sensitivity 68.0% (46.5–85.1%) and specificity 89.0% (80.7–94.6%) (Figure 1). Interpretations provided by reviewers commonly included coexisting rhythms accurately, but where missed, PVCs were most commonly not differentiated (Supplementary Tables 2-4)

Ventricular Fibrillation and Asystole

Both VF (n=11) and asystole (n=5) were correctly identified on all tracings, reflected by sensitivity values of 100% (71.5–100%) and 100% (47.8–100%) respectively. Overall accuracy for VF was 98.4% (96.9–99.3%) and specificity 98.4% (96.8–99.3%), whilst overall accuracy for asystole was 99.8% (98.9–100.0%) and specificity 99.8% (98.9–100.0%): Results for both rhythms were affected by false positive diagnoses for other rhythm types (Supplementary Table 2).

Inter-observer and Intra-observer Reliability Analysis

Inter-observer reliability analysis for AC tracings showed a Kappa coefficient between 0.38-0.54 for the reviewers and an agreement percentage between 85-94% (Supplementary Table 5). Intra-observer reliability analysis for AC tracings showed a Kappa between 0.35-0.79 and agreement percentage between 85-97% (Supplementary Table 6).

DISCUSSION

This study is the first of its kind to evaluate the accuracy of the AC sECG for the diagnosis of various cardiac arrhythmias against the gold standard cardiac EPS, where the diagnosis was based on evaluation of EGMs and 12-lead surface ECG.

It conveys the following important findings:

1. AC sECG tracings can be used to detect arrhythmias with consistently high level of accuracy, and >93% overall accuracy across all rhythms, when reviewed by clinicians.
2. Non-AF arrhythmias (SVT, VT, VF and asystole) are recognisable with a good-to-high degree of accuracy, whereas premature complexes may be underappreciated.
3. sECG devices present an opportunity to clinicians to incorporate an additional diagnostic tool into conventional practice.

Accuracy of AC sECG Across Rhythms

The documentation of various non-AF arrhythmias has been reported from several studies investigating the AC in clinical practices: Reed et al. demonstrated symptomatic arrhythmia detections with the AC in a cohort of 240 symptomatic patients presenting to an Emergency Department, who were randomised to either standard care plus the use of the AC (intervention, n=124), or standard care alone (control, n=116).⁸ Arrhythmias detected in the AC group included ectopics (n=8) and SVT (n=3). In another study, Nguyen et al.²⁰ described documentation of SVT in 16% (n=39) of transmitted AC tracings in a population of paediatric patients previously diagnosed with arrhythmias.

Additionally, Waks et al. demonstrated a symptom driven diagnosis of a wide-complex tachycardia in an active 62-year-old with presyncope. Subsequent EPS revealed right ventricular outflow tract tachycardia, leading to treatment with catheter ablation.²¹ Similarly, Roelle et al. reported the utilisation of an AC to track previously identified VT, leading to eventual EPS.²² Reports of SVT identification leading to EPS and treatments including beta-blocker therapy and catheter ablation are also growing.^{23,24} However, despite these reports, the large-scale evidence for VT and SVT diagnosis is limited, with our study establishing the validity of the AC utilisation for both. And whilst clinical implications may remain limited, this study incorporates demonstrable efficacy in identification of sinister VF and asystole.

Several studies have validated the use of the AC in the screening and diagnosis of patients with asymptomatic or symptomatic AF.^{14-17,25-28} Whilst this study has been able to reinforce the diagnostic yield of the AC for AF, large-scale validation of the AC in non-AF arrhythmias remains limited.

One previous study which has investigated the utility of the AC in the diagnosis of both AF and non-AF arrhythmias was performed by Rischard et al., comparing AC tracings to concomitant 12-lead ECGs presented to blinded cardiologist reviewers. Sensitivity and specificity of the reviewed tracings for AF (n=275) were 82% and 92%, similar to our findings of 86% and 92%. However, differing from our results, sensitivity and specificity of AC for other supraventricular tachycardia (n=94) were 26% and 98%, compared to 92% and 88% respectively; and for wide-QRS tachycardia (n=5) 60% and 100%, respectively.²⁹ Importantly the present study includes a much larger quantity of non-AF arrhythmia ECGs, gold standard diagnosis using EGMs and electrophysiology-trained reviewers. The notable difference in sensitivity values for SVT analysis may be attributable to differences in sample size and to tracing quality, in that patients in the present study were administered anaesthesia for their EPS and subsequently sECG tracings carried minimal motion artefact. It is also possible that differences in approach to tracing analysis may have impacted results; where Rischard employed a standardised reading flowchart for analysis by reviewing cardiologists, the present study required the electrophysiology-trained reviewers to use their clinical judgement, but also to broadly categorise perceived SVTs as such.

In a similar study, performed within a population of hospitalised patients, Essayagh et al. reported accuracy, sensitivity and specificity values of electrophysiologist-interpreted AC tracings containing a variety of arrhythmias.³⁰ The results that analysis returned values for accuracy (86-99%) and specificity (87-100%) comparable to the present study; however, sensitivity values were generally lower (10-89%), likely owing to a smaller sample size and arrhythmia grouping approach. The primary difference in between the two studies was the absence of a reported 12-lead ECG or similar to confirm arrhythmias as opposed to our study approach with comparison against the gold standard EPS. Additionally, whilst our study incorporated the approach of grouping SVT arrhythmias, a larger volume of arrhythmias was also acquired. Our study supports the existing literature and demonstrates the ability to diagnose both narrow- and broad-complex

arrhythmias, but further expands upon the existing diagnostic paradigm through the volume of arrhythmias explored and by comparison to the diagnostic gold standard.

Application Beyond AC Devices

These findings suggest that the AC may prove a useful tool in the diagnosis of cardiac arrhythmias, and whilst clinical utilization has been investigated in a number of sECG devices, generalisability of results remains unclear.⁹⁻¹³ Notably, a recent systematic review evaluating detection of arrhythmias beyond AF using smartwatches, as opposed to the AC, described 14 case reports/series and 4 cohort studies which included a spectrum of arrhythmias detected by sECGs, including VT, various SVTs, second- and third-degree atrioventricular block, Wolff-Parkinson White syndrome, sinus bradycardia and sinus tachycardia.³¹

In a study by Mehta et al., when comparing four sECG devices on inpatients and with tracings analysed by a mixed group of clinicians, described differences between sECG device tracings interpretability possibly attributable to inherent differences in hardware and software features.³² Conversely, in another study by Mannhart et al., comparable sensitivity and specificity of automated algorithms was demonstrated in five commonly used sECG devices (including AC). Mannhart also demonstrated a consistently high level of interpretation sensitivity and specificity between devices when tracings were reviewed by cardiologists, suggesting minimal differences in sECG quality when reviewed by trained clinicians.³³ Given the findings of the present study were acquired through sECG analysis by electrophysiology-trained clinicians, they may arguably be applied to other sECG devices, reaffirming the reliability of other widely used sECG devices.

Limitations

Strengths of this study include it being an investigator-initiated analysis of AC sECG against gold standard EPS with a large sample size of analysed rhythms. However, some limitations need to be acknowledged.

1) The AC sECG was acquired with the AC to the patient's infraclavicular chest, as opposed to the standard approach of finger application to the AC electrodes, resulting in attenuation of P and R wave amplitudes in selected patients. We acknowledge this is not the routine method of sECG acquisition, and our results may have altered with standard application of the AC, or use of the 6-lead model the same vendor. However, all patients in this study were under general anaesthesia or sedation, and unable to hold the device independently. It is possible that the patients' hands may have been bound together to hold the device, however this would have hindered access to arterial lines, risked preservation of sterile fields, exposed tracings from respiration artefacts and rendered physical adjustments to the device (such as repositioning, or removal for cardioversions) difficult and disruptive to the patients' procedure. Importantly, the clinician interpretations demonstrated a preserved minimum quality for sECGs compatible with interpretability. 2) Interpretation of sECG tracings was performed by reviewers blinded to patients' clinical histories; clinical data would likely assist clinicians in making accurate diagnoses. These limitations indicate the need for further large-scale studies that may expand upon our findings, despite observable diagnostic efficacy for a large volume of arrhythmias.

CONCLUSION

This study demonstrates that an sECG acquired using the AliveCor KardiaMobile application may be used by clinicians to diagnose arrhythmias with reasonable accuracy when compared against the gold standard of rhythm diagnosis in the cardiac EPS. The findings suggest that the AliveCor may be a reasonably useful tool for the investigation of cardiac arrhythmias and supports the use of sECG for selected patients; however, validation of interpreted rhythms should be performed with 12-lead ECG or cardiac EPS where clinically indicated.

Supplementary Material

Tables ST1-ST6

Figures SF1-SF7

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TABLES

Table 1. Baseline Characteristics. Displays baseline clinical characteristics of study participants.

Patient characteristics	n = 49
Female, n (%)	14 (29%)
Age, mean±SD, years	58.3±18.9
Body mass index, mean±SD	28.3±4.2
LVEF %, mean±SD (%)	51.6±12.2
Previous arrhythmia, n (%)	47 (96%)
Atrial Fibrillation, n (%)	21 (43)
Supraventricular Tachycardia, n (%)	18 (37)
Ventricular Tachycardia, n (%)	20 (41)
Premature Ventricular Complexes, n (%)	15 (31)
Baseline BBB, n (%)	12 (25)
Left BBB n (%)	6 (12)
Right BBB n (%)	6 (12)
Hypertension, n (%)	25 (51)
Hyperlipidaemia, n (%)	22 (45)
Diabetes, n (%)	5 (10)
Structural Heart Disease, n (%)	22 (45)
Ischaemic Heart Disease, n (%)	11 (22)
Congenital Heart Disease, n (%)	2 (4)

Abbreviations: BBB-bundle branch block; LVEF-left ventricular ejection fraction; SD-standard deviation.

Table 2. EPS vs AliveCor interpretation by the three reviewers' overall accuracy. Displays the gold standard diagnosis derived from the EPS, number of each rhythm type, and the overall accuracy, sensitivity and specificity of the comparative interpretation provided by the blinded reviewers for the AliveCor tracings.

Gold Standard Diagnosis	n	Overall Accuracy (%) (95% CI)	Sensitivity (95% CI)	Specificity
Sinus Rhythm	273	92.4 (89.8-94.6)	92.7 (88.9-95.5)	92.1 (87.9-
Atrial Fibrillation	51	91.0 (88.2-93.4)	86.3 (73.7-94.3)	91.6 (88.6-
Supraventricular Tachycardia	191	89.4 (86.4-92.0)	92.2 (87.4-95.5)	87.8 (83.6-
Supraventricular Ectopy	28	93.0 (90.4-95.1)	75.0 (55.1-89.3)	94.1 (91.6-
Ventricular Tachycardia	198	91.2 (88.4-93.6)	92.4 (87.8-95.7)	90.5 (86.6-
Premature Ventricular Complexes	86	90.8 (88.0-93.2)	73.3 (62.6-82.2)	94.5 (91.8-
Ventricular Fibrillation	11	98.4 (96.9-99.3)	100.0 (71.5-100.0)	98.4 (96.8-
Asystole	5	99.8 (98.9-100.0)	100.0 (47.8-100.0)	99.8 (98.9-
All Uninterrupted Rhythms Combined	224	94.3 (93.1-95.3)	94.6 (90.8-97.2)	94.2 (92.9-
Sinus Rhythm Only	65	93.3 (89.2-96.2)	98.5 (91.7-100.0)	91.2 (85.7-
Atrial Fibrillation Only	34	92.9 (88.7-95.9)	88.2 (72.6-96.7)	93.7 (89.2-
Supraventricular Tachycardia Only	73	88.8 (84.0-92.7)	98.6 (92.6-100.0)	84.1 (77.3-
Ventricular Tachycardia Only	51	90.2 (85.5-93.7)	88.2 (76.1-95.6)	90.8 (85.4-
Ventricular Fibrillation Only	1	100.0 (98.4-100.0)	100.0 (2.5-100.0)	100.0 (98.4-
All Rhythms + Baseline BBB Combined	202	92.7 (90.8-94.3)	87.6 (82.3-91.8)	94.1 (92.1-
Sinus Rhythm	60	91.4 (84.7-95.8)	93.3 (83.8-98.2)	89.3 (78.1-
Atrial Fibrillation	27	92.2 (85.8-96.4)	88.9 (70.8-97.7)	93.3 (85.9-
Supraventricular Tachycardia	24	91.4 (84.7-95.8)	79.2 (59.5-90.8)	94.6 (87.8-
Supraventricular Ectopy	19	94.0 (88.0-97.5)	89.5 (66.9-98.7)	94.9 (88.4-
Ventricular Tachycardia	44	91.4 (84.7-95.8)	93.2 (81.3-98.6)	90.3 (81.0-

Gold Standard Diagnosis	<i>n</i>	Overall Accuracy (%) (95% CI)	Sensitivity (95% CI)	Specificity
Premature Ventricular Complexes	25	84.5 (76.6-90.5)	68.0 (46.5-85.1)	89.0 (80.7-
Ventricular Fibrillation	1	97.4 (92.6-99.5)	100.0 (2.5-100.0)	97.4 (92.6-
Asystole	2	99.1 (95.3-100.0)	100.0 (15.8-100.0)	99.1 (95.2-

Abbreviations: AF-atrial fibrillation; CI-confidence interval; PVC-premature ventricular complex; SR-sinus rhythm; SVE-supraventricular ectopy; SVT-supraventricular tachycardia; VT-ventricular tachycardia

FIGURE LEGENDS

Central Illustration. Study Workflow

Study workflow including recruitment, data collection and analysis with depiction of infraclavicular chest placement of the AliveCor during cardiac EPS, recording of single-lead ECGs using the associated smartphone application and examples of various recorded arrhythmias.

Abbreviations: *AC-AliveCor; AF-atrial fibrillation; EPS-electrophysiology study; PVC-premature ventricular complex; SVE-supraventricular ectopy; SVT-supraventricular tachycardia; VF-ventricular fibrillation; VT-ventricular tachycardia*

Figure 1. Overall Accuracy of Single-Lead ECG Interpretations

Comparison of Overall Accuracy values from blinded reviewer interpretations of the AliveCor single-lead ECGs, defined by each of the gold standard diagnosis differential and for all rhythms combined.

Abbreviations: *AF-atrial fibrillation; PVC-premature ventricular complex; SR-sinus rhythm; SVE-supraventricular ectopy; SVT-supraventricular tachycardia; VF-ventricular fibrillation; VT-ventricular tachycardia*

Figure 2. Sensitivity of Single-Lead ECG Interpretations

Comparison of Sensitivity values from blinded reviewer interpretations of the AliveCor single-lead ECGs, defined by each of the gold standard diagnosis differential and for all rhythms combined.

Abbreviations: *AF-atrial fibrillation; PVC-premature ventricular complex; SR-sinus rhythm; SVE-supraventricular ectopy; SVT-supraventricular tachycardia; VF-ventricular fibrillation; VT-ventricular tachycardia*

Figure 3. Specificity of Single-Lead ECG Interpretations

Comparison of Specificity values from blinded reviewer interpretations of the AliveCor single-lead ECGs, defined by each of the gold standard diagnosis differential and for all rhythms combined.

Abbreviations: *AF-atrial fibrillation; PVC-premature ventricular complex; SR-sinus rhythm; SVE-supraventricular ectopy; SVT-supraventricular tachycardia; VF-ventricular fibrillation; VT-ventricular tachycardia*

FIGURES

Central Illustration. Study Workflow

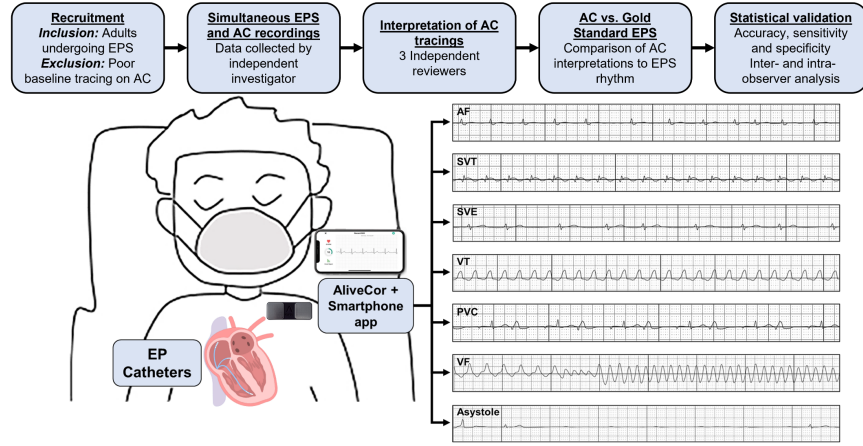


Figure 1. Overall Accuracy of Single-Lead ECG Interpretations

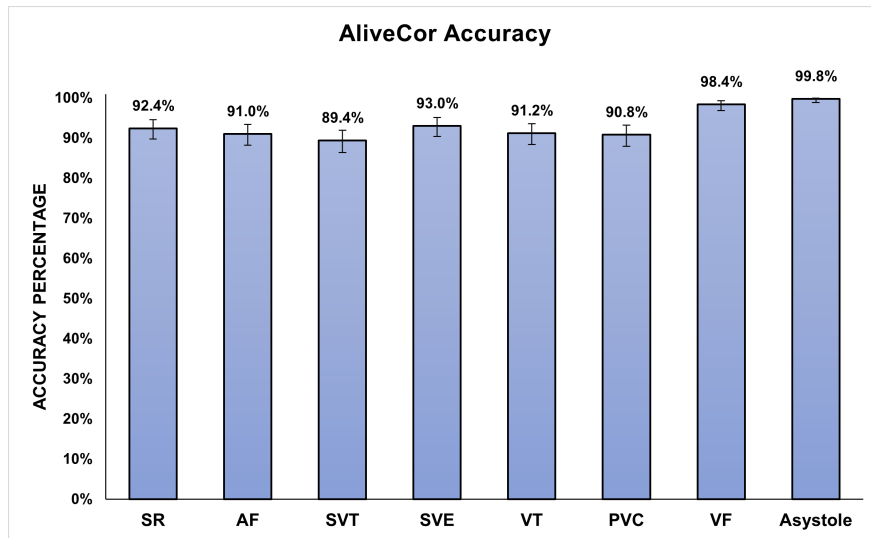


Figure 2. Sensitivity of Single-Lead ECG Interpretations

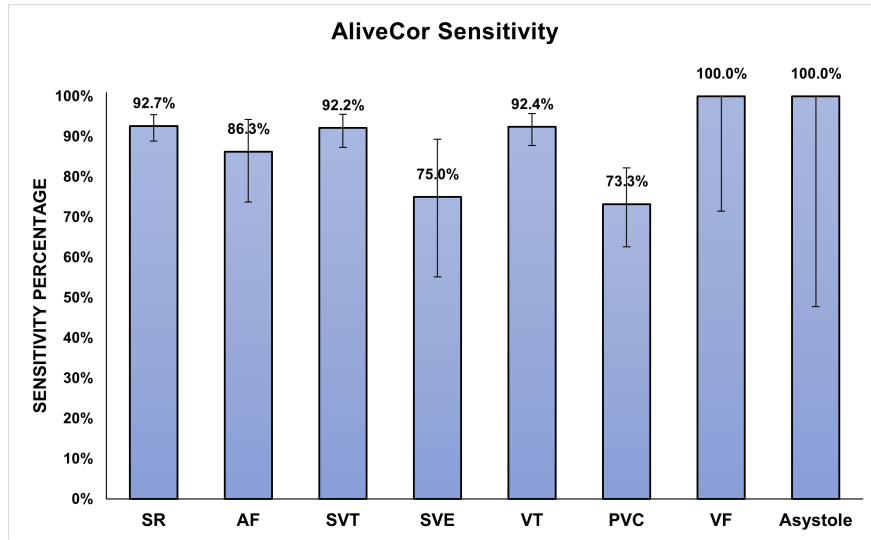


Figure 3. Specificity of Single-Lead ECG Interpretations

