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Experience of a smartphone ambulatory ECG clinic for Emergency Department patients with palpitation: a single centre cohort study.

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**Author contributions:** MJR, JC & AM conceived the study. MJR, RM, VP & PH designed the trial. MJR obtained research funding. MJR, JC & AM supervised the conduct of the trial and data collection. RM, VP, GZ, SK, SA, PH & LD undertook recruitment of participants. JC, AM, & MJR managed the data including quality control. MJR provided statistical advice on study design and MJR, JC & AM analyzed the data; JC and MJR drafted the manuscript, and all authors contributed substantially to its revision. MJR takes responsibility for the paper as a whole.
Abstract and Keywords:

**Background and Importance:** Palpitation is one of the commonest presenting complaints to the emergency department (ED). Diagnosis depends on capturing an ECG during the episode. Unlike in syncope, patients retain consciousness and therefore their ability to activate an ECG event recorder. The IPED study demonstrated the FDA/CE approved AliveCor/Kardia that links to a smartphone app was safe and effective and a Smartphone Palpitation and Pre-syncope Ambulatory Care Clinic were therefore established.

**Objective(s):** To review the first year of patients attending the service to determine the number and cost-effectiveness of cardiac dysrhythmias diagnosis.

**Design:** Single-centre cohort study.

**Settings and participants:** Royal Infirmary of Edinburgh, UK. All patients (over 16 years) presenting consecutively to the ED with palpitation or pre-syncope, whose ECG was normal, who had a compatible device and in whom an underlying cardiac dysrhythmia was possible were enrolled.

**Intervention:** Ambulatory Care Clinic utilizing the AliveCor/Kardia device.

**Outcome measures and analysis:** Number diagnosed with cardiac dysrhythmia and mean cost per diagnosis.
Main results: Between 24 July 2019 and 23 July 2020, 290 consecutive patients were referred aged between 16 and 80 years (mean 43.3, SD 15.0). 120 (41.4%) were male. 237 (81.7%) were fitted with the device and 220 (75.9%) underwent full investigation. Seventeen of 237 (7.2%) patients had a cardiac diagnosis (12 atrial fibrillation/flutter, 5 SVT and 1 atrial tachycardia).

Conclusions: There were 17 cardiac diagnoses (7.2%). Cost per symptomatic rhythm diagnosis was 358 GBP (~415 Euro) and cost per cardiac dysrhythmia diagnosis was 4570 GBP (~5298 Euro). A smartphone-based event recorder clinic should be considered for ED palpitation patients.

Keywords: Emergency Department, Diagnosis, ECG monitoring, Cardiac dysrhythmias
Introduction

Smartphone medical technology has improved dramatically over recent decades with the number of users expected to exceed 3.8 billion in 2021. This health monitoring revolution [1] will allow better diagnosis of acute medical events such as palpitation, responsible for 300,000 presentations to UK Emergency Departments (ED) per year, and 16% of attendances to General/Family practice [2].

Diagnosis and subsequent management are dependent on capturing the underlying cardiac rhythm via Electrocardiogram (ECG) during the episode. This is difficult because symptoms often settle by the time an ECG can be recorded and conventional ambulatory monitoring, such as Holter, has a poor yield due to infrequency of symptoms and lack of compliance [3].

Unlike in syncope which renders the patient unconsciousness (and which requires investigation with continuous ECG), palpitation and pre-syncope patients retain consciousness and therefore their ability to activate an ECG event recorder. AliveCor/Kardia is FDA-cleared and the most clinically validated ambulatory ECG event recorder available worldwide [5-11]. Minimal training is required for the patient to place two fingers on the device and record a single lead I ECG on their smartphone, and in a subsequent version, a 6-lead ECG [4].

The multi-centre, randomised controlled IPED trial [12] showed use of AliveCor/Kardia increased the number of diagnostic ECGs captured during symptoms five-fold, the number of captured cardiac dysrhythmias eleven-fold, and reduced mean time to symptomatic rhythm detection to 9.5 days (SD 16.1) compared to standard care (42.9 days; SD 16.0; p<0.0001 [12]. These findings
resulted in the establishment of a Smartphone Palpitation and pre-syncope Ambulatory Care Clinic at the Royal Infirmary Edinburgh (RIE) in 2019.

This study reports the first ever real-world clinical implementation of a smartphone-based event recorder in the ED for patients with palpitation. We have published previously the first three month’s experience of establishing the service [13]. The aim of this study is to review the first year of patients attending the Smartphone Palpitation and Pre-Syncope Ambulatory Care Clinic service, to determine the number of cardiac dysrhythmias diagnosed and the cost effectiveness of the service.

**Materials and Methods**

**Design:** Single centre cohort study.

**Setting:** Emergency Department (ED) and Acute Medicine Unit (AMU) of the RIE, UK

**Patients:** From 24 July 2019, all patients aged 16 years or older presenting consecutively to the Emergency Department (ED) or Acute Medicine Unit (AMU) of the RIE, UK with palpitation or pre-syncope, whose ECG was normal, had a compatible Apple/Android phone, tablet or watch and a possibility of underlying cardiac dysrhythmia, were offered an appointment at the Smartphone Palpitation and Pre-Syncope Ambulatory Care Clinic based in Ambulatory Care, adjacent to the ED. Exclusion criteria included the patient being non-ambulant, requiring hospital admission, having a prior diagnostic ECG, multiple frequent episodes or recent acute myocardial infarction (AMI), severe heart failure, unstable angina, experiencing chest pain or syncope, unwilling or unable to use the AliveCor/Kardia Heart Monitor and ECG App and possessing a cardiac pacemaker or other implanted electronic device. Patients having a likely non-cardiac cause for
their palpitation (e.g., anxiety, sepsis) were also excluded as these patients were likely to have sinus tachycardia secondary to an identified underlying cause for which the management was already clear (e.g. antibiotics, fluids, anxiolytics).

**Intervention:** A clinical Standard Operating Procedure (SOP) was devised, and funding secured through a business case for the purchase of 40 AliveCor/Kardia single lead devices which were cleaned and reused multiple times. The patient’s smartphone was checked for compatibility and patients were asked to bring their app store password to the ambulatory appointment. Prior to clinic attendance, patients were asked to download the AliveCor/Kardia app but set-up and device training/demonstration was completed at the clinic. The AliveCor/Kardia device is small and rectangular shaped with two metal squares at each end upon which the patient places two fingers. The device connects to a smartphone through the phone’s microphone which allows an ECG recording to commence once the AliveCor/Kardia smartphone app is opened (see Supplemental Digital Content). Whilst the AliveCor/Kardia App give the patient a diagnosis foe each recorded ECG, in this study, we did not rely on the AliveCor/Kardia diagnoses and all tracings were reported by a physician in the clinic.

Routine blood tests, thyroid function tests, full blood count, urea and electrolytes, magnesium levels were taken, and patients were provided an advice leaflet and planned to be seen in clinic on the next available day. History of the event was revisited, and further details around the episode were recorded in the Electronic Patient Record (EPR). The IPED study [12] showed that 93% of participants recording a symptomatic rhythm during the 90 days, did so in the first 28
days. It was decided to review patients at 4 weeks to enable efficient device usage and timely treatment. However, patients without a symptomatic recording at 4 weeks could be re-reviewed if necessary.

Other components of the SOP included a list of compatible devices, patient symptom diary, patient instruction manual, clinic checklist and clinician advice on incorporating a patient ECG into the RIE EPR. Our hospital data controller recommended anonymising and standardising patient information in the AliveCor/Kardia application (i.e. first name ‘ambulatory’, last name ‘care’, date of birth ‘01/01/1980’). The study was deemed by the local ethics service to be a service evaluation and therefore ethical approval was not required. The study was registered on the RIE ED Quality Improvement Project (QIP) database.

The clinic protocol was reviewed with clinic staff at 3-months and improvements were made to increase clinic efficiency. Issues identified included refining clinic referral criteria, addressing patient expectations and embedding electronic ECGs into the EPR. Clinic review times were reduced to 2 weeks, but patients could defer the appointment and keep the device longer if there were no recordings by that time.

**Data Collection:** A specially designed database was created using REDCap, a secure electronic database (http://www.project-redcap.org) for anonymised data entry [14-15], funded by a grant from the Royal College of Emergency Medicine (RCEM). Data was collected from EPRs of sequential ED and AMU patients who were referred to the Smartphone Palpitation and Pre-
Syncope Ambulatory Care Clinic during a 12-month period. Data input occurred from August 2020 through November 2020 by two medically trained abstractors. Chart elements were coded based on information detailed in the patient EPRs from two separate patient encounters, one in the ED or AMU and the second in the clinic setting. Pre-defined rules were designed to handle ambiguous elements.

**Primary outcomes:** Number of patients diagnosed with a cardiac dysrhythmia. Mean cost of a cardiac dysrhythmia diagnosed through the service.

**Analysis:** Analysis of the data was conducted using RedCap. Unless otherwise stated, data are presented as median with interquartile range (IQR) (25th to 75th percentile) for non-parametric continuous variables and as simple frequencies, proportions and percentages for categorical variables. Parametric continuous variables are presented as mean with Standard Deviation (SD).

**Healthcare economic analysis:** Overall and mean healthcare utilisation costs (primary/community/secondary care and intervention costs) were calculated for both groups. Costing scope included primary care, secondary care and community NHS costs obtained from 2017/18 NHS reference cost data [16].

**Results**

Between 24 July 2019 and 23 July 2020, 113,085 patients were seen in RIE ED and AMU, 1,845 presenting with palpitation (1.6%). Mean age was 54.0 (SD 20.8) and 55% were admitted to
Commonest reasons for an ED presenting complaint of palpitation were atrial fibrillation or flutter, non-specific chest pain, supraventricular tachycardia, anxiety disorder and recreational drug use. 290 patients (16%) seen in ED with palpitation or pre-syncope were discharged from the ED with an outpatient referral to the Smartphone Palpitation and Pre-Syncope Ambulatory Care Clinic. 120 (41.4%) were male and 170 (58.6%) females. Age ranged 16 to 80 years, with a mean of 43.3 years (SD 15.0). **Figure 1** is a flow chart of patients in the study, showing referrals and ultimate diagnosis. 75.9% (n=220) underwent full investigation, which includes initial assessment at clinic, training with the device and further follow up appointment to review any recordings. On first assessment, 15.5% (n=45) were unsuitable for the device due to incompatibility or refusal/inability to use the AliveCor/Kardia device.

282 patients attended during the first year of clinic operation. There were 236 (83.7%) non-cardiac diagnoses and 23 (8.2%) cardiac diagnoses. Of those fitted with the device and completed clinic follow-up (n=237, 81.7%), 17 had cardiac diagnoses (7.2%), 200 non-cardiac diagnoses (84.3%) and 20 undiagnosed (8.4%). 10 (58.8%) of the cardiac diagnoses were atrial fibrillation (AF) or paroxysmal AF, 5 (29.4%) were SVT or paroxysmal SVT, one (5.9%) atrial flutter and one (5.9%) likely atrial tachycardia. 2 patients had atrial flutter on KardiaMobile, but further review, diagnosed non-cardiac rhythm (sinus rhythm). All other patients had non-cardiac rhythms including sinus rhythm, ventricular extrasystoles and bigeminy. The majority of patients (166; 57.2%) described presenting symptom as ‘fluttering’ or ‘racing’. Other presenting features included chest pressure (7.9%), skipped beats (8.6%) and pounding (6.6%). Duration of symptoms varied with 10 minutes or less (33.1%) and 1 hour or less (32.8%) being most common. 20 patients
remained undiagnosed; 3 did not record a symptomatic ECG with the device and 17 failed to attend clinic follow-up.

The Smartphone Palpitation and Pre-Syncope Ambulatory Care Clinic service review 3-months after implementation adjusted this initial time to review to 14 days. Therefore, at one year, the median number of days device was fitted was 14 (IQR 7.0-16.8). 11 patients were admitted to hospital in relation to palpitation, with a median stay of 1 day (IQR 1.0-2.0) and a range of 1-3 days. 21 patients (7.2%) had management commence at clinic: 11 started beta-blockers (52.4%), 4 on an anticoagulant (19.0%), 4 a PPI (19.0%), 1 digoxin (4.8%), 1 ACE-inhibitor (4.8%) and 4 a change in drug dose (19.0%). At follow-up appointments, some patients underwent further investigations: 53 (18.3%) a 24-hour Holter, 38 (13.1%) an echocardiogram, 7 (2.4%) a 48-hour or longer Holter and 1 patient an implantable loop recorder (0.3%). Most of these tests were arranged by clinic (66.3%), 3 (3.8%) had tests organised by ED, 14 (17.5%) via GP and 16 (20.0%) by cardiology.

Overall healthcare utilisation costs (including clinic and personnel time, investigations, and devices) were 77,685 GBP [16]. Each symptomatic rhythm diagnosis cost 358.00 GBP (~415 Euro) and each cardiac rhythm diagnosis cost 4569.71 GBP (~5298 Euro).

**Discussion**

This study reports the first ever real-world clinical implementation of a smartphone-based event recorder in the ED for patients with palpitation and demonstrates similar results to the IPED trial,
the difference being that this study demonstrates real-world effectiveness outside the context of a research trial. The Smartphone Palpitation and Pre-Syncope Ambulatory Care Clinic led to a cardiac diagnosis in 7.2% of patients fitted with the device similar to the 8.8% in the IPED study [12]. These diagnoses translated into a change in clinical management with 7.2% of clinic patients having treatment instigated mainly around commencement of anti-arrhythmic or anticoagulant therapy.

There are many patient-orientated benefits to our service. Patients are assessed in a quieter environment where questions and concerns are addressed, and the patient can be educated on using the device. Most clinic attendees were ultimately diagnosed with non-cardiac rhythms, which provided reassurance and avoided unnecessary tertiary cardiology referrals. Widespread use of the device will lead to more effective diagnosis of palpitation patients thought to be at risk of cardiac dysrhythmia, reduce healthcare and investigation costs, and minimise long-term consequences of untreated cardiac dysrhythmia. Expanding the service to community settings such as family/general practitioners or pharmacies [18], could enable patients to be investigated without them requiring hospital attendance. With ongoing concerns around COVID-19 and recurrent national lockdowns, the AliveCor/Kardia postal service can also be utilised to minimize patients’ attendance at hospital.

The IPED study reported a high usability score, with patients reporting the monitor to be simple and acceptable for monitoring their health [12]. Only 7 patients re-presented to the ED or phoned the clinic for further advice over the first year of the clinic. These patients did, however, re-
engage numerous times seeking further evaluation or reassurance. More work to understand the relationship between patients and healthcare apps is important to improve overall patient experience and reduce unnecessary re-attendances. Also determining those palpitation patients at most risk of cardiac dysrhythmia is a challenge, and no distinctive features from the presentation or history have yet been identified that may best select patients for follow-up in our service.

Technology and health monitoring is a developing field and improvements will enhance user experience and encourage more patients to take an active role in health management. As use of smartphones grows globally, access to applications such as the AliveCor/Kardia will become more universal, paving the route for personalised healthcare and enhanced preventative healthcare.

**Limitations:** The clinic was based at a single site. Subsequent patient presentations to acute settings could only be captured if the patient represented to the NHS Lothian healthcare system. Presentations to other health boards were not captured. It is noted that COVID-19 may have reduced the overall volume of patients referred and attending the clinic during lockdown periods as there was a general fall in numbers attending ED. Our study relied upon patient memory of symptoms being recorded accurately which may have introduced recall bias. Additionally, data collection was retrospective. Although there may be referral bias in our study due to us studying only participants that were referred to the clinic by the ED and AMU clinicians, the study looked at every consecutive attendance to the service and is therefore a robust real world, pragmatic implementation study of a healthcare device.
Conclusion: This is the first clinical implementation study of the AliveCor/Kardia in an ED setting and demonstrates similar detection rates to the IPED study. A smartphone-based event recorder clinic should be considered for ED patients presenting with palpitation or pre-syncope.

References


Table 1: Summary characteristics of patients attending the Smartphone Palpitation and pre-syncope Ambulatory Care Clinic.

<table>
<thead>
<tr>
<th>Gender: Male</th>
<th>120 (41.4%)</th>
</tr>
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<tbody>
<tr>
<td>Age in years /mean (SD)</td>
<td>43.3 (15.0)</td>
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</table>

<table>
<thead>
<tr>
<th>Primary Presenting Symptom</th>
<th></th>
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<tbody>
<tr>
<td>Fluttering or Racing</td>
<td>166 (57.2%)</td>
</tr>
<tr>
<td>Skipped/Missed beat(s)</td>
<td>25 (8.6%)</td>
</tr>
<tr>
<td>Chest pain or pressure</td>
<td>23 (7.9%)</td>
</tr>
<tr>
<td>Pounding</td>
<td>19 (6.6%)</td>
</tr>
<tr>
<td>Light-headed</td>
<td>16 (5.5%)</td>
</tr>
<tr>
<td>Irregular beating</td>
<td>15 (5.2%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>14 (4.8%)</td>
</tr>
<tr>
<td>Fainted</td>
<td>6 (2.1%)</td>
</tr>
<tr>
<td>Anxious</td>
<td>3 (1.0%)</td>
</tr>
<tr>
<td>Arm or Neck Pain</td>
<td>3 (1.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom Duration</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>1 minute or less</td>
<td>22 (7.6%)</td>
</tr>
<tr>
<td>10 minutes of less</td>
<td>96 (33.1%)</td>
</tr>
<tr>
<td>1 hour or less</td>
<td>95 (32.8%)</td>
</tr>
<tr>
<td>More than 1 hour</td>
<td>77 (26.6%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of days device fitted for /mean (SD)</th>
<th>13.8 (12.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non Index admissions in relation to palpitations</td>
<td>11 (3.8%)</td>
</tr>
<tr>
<td>Duration of admission /mean (SD)</td>
<td>1.5 (0.69)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Management commenced in SPACC</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Beta-blockers</td>
<td>11 (3.9%)</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>4 (1.4%)</td>
</tr>
<tr>
<td>Proton-Pump Inhibitor</td>
<td>4 (1.4%)</td>
</tr>
<tr>
<td>Change in drug dose</td>
<td>4 (1.4%)</td>
</tr>
<tr>
<td>Digoxin</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>ACE-inhibitor</td>
<td>1 (0.4%)</td>
</tr>
</tbody>
</table>
**Figure 1:** Flow chart of patients in the study showing those referred and their ultimate diagnosis.