THE IPED STUDY

Multi-centre Randomised Controlled Trial of a Smartphone-based Event Recorder Alongside Standard Care Versus Standard Care for Patients Presenting to the Emergency Department with Palpitations and Presyncope: The IPED (Investigation of Palpitations in the ED) study

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Background

Palpitations and presyncope are common causes of emergency department (ED) visits in the United Kingdom and the United States.

Capturing the underlying cardiac rhythm associated with these symptoms is difficult because many patients have fully recovered and the electrocardiograph (ECG) has frequently normalized by the time they are evaluated in the ED. The transient and often infrequent nature of these episodes limits the diagnostic utility of clinic-based 12-lead ECGs and conventional ambulatory monitors (eg, Holter monitor).

The AliveCor KardiaMobile (KM) ECG monitor (**Figure 1**) allows the patient to quickly (30 seconds) take a medical-grade ECG recording and detect atrial fibrillation, bradycardia, tachycardia, or normal heart rhythm. The trace can be stored on a smart phone/tablet and emailed to the healthcare provider.

Objectives

Compare participants with palpitations or presyncope with no obvious cause after the initial ED consultation receiving standard care and use of the AliveCor KM (intervention group) versus standard care alone (control group) on:

1. Symptomatic rhythm detection rate at 90 days (primary outcome).
2. Symptomatic cardiac arrhythmia detection rate at 90 days, time to detection of a symptomatic rhythm or cardiac arrhythmia, patient satisfaction, and cost-effectiveness (secondary outcomes).

Methods

This prospective, randomized, multicenter trial included 243 participants (age range, 17 to 74 years; mean age, 39.5 years) presenting to 10 EDs in the UK* with palpitations or presyncope with no obvious underlying cause after the initial consultation. Eligible participants were randomized to either the intervention group (n=124) or the control group (n=116) and followed for 90 days.

FIGURE 1. The AliveCor KardiaMobile ECG Monitor

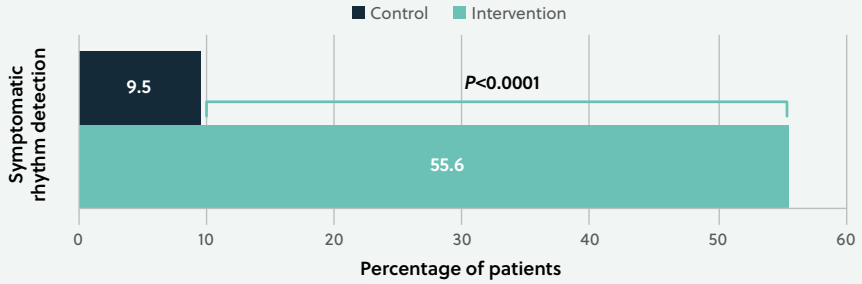
* Participating hospitals included Royal Infirmary of Edinburgh, Chesterfield, Royal Devon and Exeter Hospital, Leicester Royal Infirmary, Royal London Hospital, Barts NHS Trust, Whipps Cross Hospital, Barts NHS Trust, Nottingham University Hospital, Derriford Hospital, Royal Berkshire Hospital and Musgrove Park Hospital.
Photographs courtesy of AliveCor, Inc.

Results

OBJECTIVE 1: Compare the symptomatic rhythm detection rate at 90 days of the intervention group with the control group.

1. Significantly more symptomatic rhythms were detected at 90 days in the intervention group (69/124 participants; 55.6%) versus the control group (11/116 participants; 9.5%) (*P*<0.0001) (**Figure 2**).

FIGURE 2. Symptomatic Rhythm[a] at 90 Days



[a]Symptomatic rhythm was defined as any ECG recorded during an episode of palpitations or presyncope allowing symptom-rhythm correlation.

Results (cont'd)

OBJECTIVE 2: Compare the symptomatic cardiac arrhythmia detection rate at 90 days, time to detection of a symptomatic rhythm or cardiac arrhythmia, patient satisfaction, and cost-effectiveness of the intervention group versus the control group.

1. Significantly more symptomatic cardiac arrhythmias were detected at 90 days in the intervention group (11/124 participants; 8.9%) compared with the control group (1/116 participants; 0.9%) (*P*=0.006).

2. Atrial fibrillation was the most common symptomatic cardiac arrhythmia in the intervention group (n=8/124), while sinus bradycardia was the common symptomatic cardiac arrhythmia in the control group (n=1/116, **Table 1**).

TABLE 1. Symptomatic Cardiac Arrhythmias in Patients With Palpitations or Presyncope

	AliveCor KM (n=124)	SC Alone (n=116)
Symptomatic cardiac arrhythmia[a] (n, %)	11 (8.9%)	1 (0.9%)
Atrial fibrillation (n)	8	0
SVT (n)	3	0
Sinus bradycardia (<40) (n)	0	1
Atrial flutter (n)	1	0

[a]Some participants had more than 1 symptomatic rhythm recorded.
KM, KardiaMobile; SC, standard care; SVT, supraventricular tachycardia.

3. The mean time to symptomatic rhythm detection was significantly shorter in the intervention group (9.5 days) compared with the control group (42.9 days) (*P*<0.0001).

4. The mean time to symptomatic cardiac arrhythmia detection was significantly shorter in the intervention group (9.9 days) compared with the control group (48.0 days) (*P*=0.0004).

Patient Satisfaction

Patient satisfaction in the intervention group was high: 87% (80/92) of respondents reported the AliveCor KM was easy to use, 73% (66/91) reported it was always available when needed, 74% (67/91) reported no problem recording the heart tracing, and 65% (59/91) reported no problems sending the heart tracing.

Cost Analysis

The cost per symptomatic rhythm diagnosis was £921 (≈$1210 USD) less per patient in the intervention group (£474 [≈$623 USD]) compared with the control group (£1395 [≈$1834 USD]).

Conclusions

The AliveCor KM monitor and standard care increased the symptomatic rhythm detection rate over 5-fold compared with standard care alone at 90 days.

The symptomatic cardiac arrhythmia detection rate at 90 days was increased almost 10-fold with the AliveCor KM monitor and standard care compared with standard care alone, and the time to detection of a symptomatic rhythm or cardiac arrhythmia was decreased over 4-fold.

Participants were satisfied with the AliveCor KM monitor and there was a reduction in cost per symptomatic rhythm detection compared with standard care.

The AliveCor KM is safe and easy to use and should be considered part of the care paradigm in select patient populations.

Importance to AliveCor

This study demonstrates that the AliveCor KM monitor can overcome limitations of clinic-based and conventional ambulatory devices by rapidly detecting cardiac rhythms associated with palpitations and presyncope and should be part of on-going care of all patients presenting acutely with unexplained palpitations or presyncope.

References:

1. Probst MA, Mower WR, Kanzaria HK, Hoffman JR, Buch EF, Sun BC. Analysis of emergency department visits for palpitations (from the National Hospital Ambulatory Medical Care Survey). *Am J Cardiol.* 2014;113(10):1685-1690.

2. Thiruganasambandamoorthy V, Stiell IG, Wells GA, Vaidyanathan A, Mukarram M, Taljaard M. Outcomes in presyncope patients: a prospective cohort study. *Ann Emerg Med.* 2015;65(3):268-276.e266.