Recurrent Atrial Fibrillation/Flutter Detection After Ablation or Cardioversion Using the AliveCor KardiaMobile Device: iHEART Results

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Background

Atrial fibrillation (AF) is the most common arrhythmia in clinical practice, affecting up to 6.1 million people in the United States and approximately 10 million patients in Europe[1]

However, these rates likely underestimate the true impact of AF as it is frequently asymptomatic, untreated, and undiagnosed

Untreated AF increases the risk of thromboembolic events, most notably, a 5-fold increase in the risk of stroke

Direct current cardioversion (DCCV) and radiofrequency catheter ablation (RFA) are commonly used methods to restore normal sinus rhythm; however, postprocedure recurrence of AF/atrial flutter (AFL) is common

Conventional electrocardiogram (ECG) and ambulatory devices are suboptimal for the diagnosis of recurrent AF/AFL as they can only capture episodes over a limited period of time. This can delay diagnosis, potentially prolonging time in AF and increasing the risk of complications

Objectives

To compare the AliveCor KardiaMobile (KM) ECG monitor versus standard care on:

1. Time from enrollment to detection of AF/AFL recurrence
2. Time from detection of AF/AFL recurrence to treatment

Methods

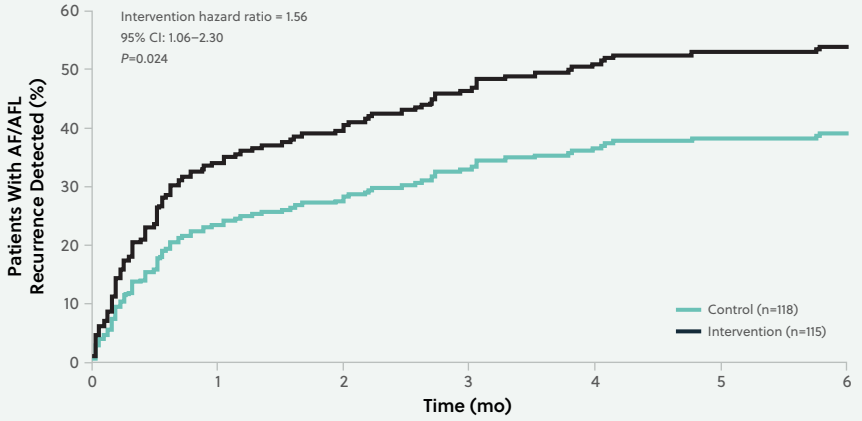
- Single-center, prospective, randomized clinical trial of 262 adults (≥18 years of age) with a history of documented AF/AFL and ≥1 risk factor for AF/AFL
- 233 randomized patients (intervention group [n=115]; control group [n=118]) underwent DCCV or RFA, were in normal sinus rhythm, and were eligible for analysis at 6-month follow-up
- Patients in the intervention group were instructed to self-record a daily ECG and also additional ECGs if they experience symptoms associated with an arrhythmia
- Patients in the control group received guideline-directed care as defined by the 2014 American College of Cardiology/American Heart Association/Heart Rhythm Society AF treatment guidelines and the treating cardiologist.[2] There was no additional monitoring for the control group

Results

OBJECTIVE 1: Compare the AliveCor KM ECG monitor versus standard care on time from enrollment to detection of recurrent AF/AFL

- The likelihood of atrial arrhythmia recurrence detection was significantly greater in the KM group compared with the control group (*P*=0.024) (**Figure 1**), regardless of procedure (DCCA or RFA)

FIGURE 1. Kaplan-Meier Analysis of Time to First Detection of Recurrent Atrial Arrhythmia



The *P* value shown is for control group vs intervention group after adjusting for procedure at enrollment (RFA or DCCV).
AF, atrial fibrillation; AFL, atrial flutter; CI, confidence interval; DCCV, direct current cardioversion; RFA, radiofrequency ablation.

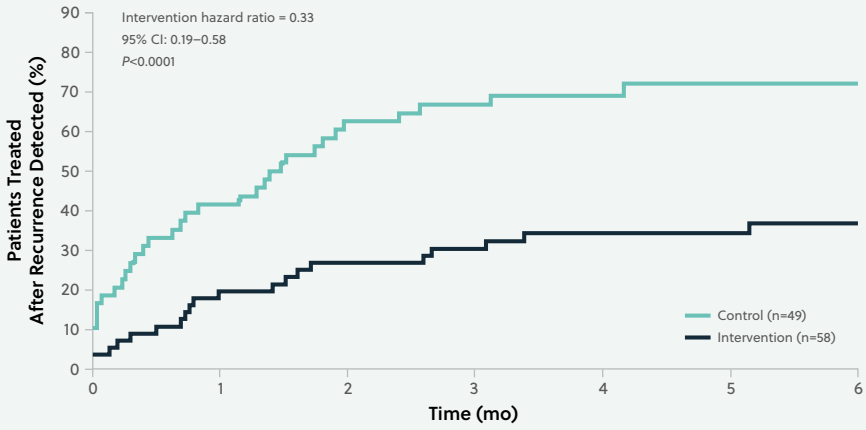
Results (cont'd)

- After the first month (late recurrence), there was no significant difference in time to detection of arrythmia recurrence (*P*=0.54)
- Early recurrence of atrial arrythmia (within 1 month post-RFA) was a strong predictor of later recurrence (within 6 months of RFA)
  - 52% of RFA patients who experienced early recurrence of arrythmia also experienced a later recurrence compared with 16% of those who did not experience early recurrence (*P*=0.0006)

OBJECTIVE 2. Compare the AliveCor KM ECG monitor versus standard care on time from detection of AF/AFL recurrence to treatment

- Patients with recurrent AF/AFL in the KM group were less likely to be treated than those in the control group (*P*<0.0001) (**Figure 2**)

FIGURE 2. Kaplan-Meier Analysis of Time From Detection of Recurrent AF/AFL to First Treatment of Recurrent Arrhythmia



AF, atrial fibrillation; AFL, atrial flutter; CI, confidence interval.

PATIENT COMPLIANCE

- There was a wide range in patient compliance with the KM monitor among patients in the intervention group (n=115), with 40% (n=46) of patients recording an average of <1 ECG every 2 days, 36% (n=41) of patients recording an average of >1 ECG per day, and 13% (n=15) of participants recording an average of >2 ECG recordings per day

Conclusions

Use of the AliveCor KM ECG monitor shortened the time to detection of recurrent arrhythmias compared with standard care; this was most evident for early (first-month) recurrences

Early recurrence after RFA was a strong predictor of later recurrence

However, the KM group did not have a shorter time from documentation of a recurrence to treatment

Possible reasons for this include a higher rate of concurrent diagnosis and treatment of arrhythmia in the same clinical episode, higher rates of DCCV in the control group, and reluctance to immediately treat paroxysmal recurrences within 30 days following the procedure

Early detection of recurrent arrhythmia using the AliveCor KM ECG monitor may help engage patients and inform health care providers to initiate anti-arrhythmic measures more appropriately

Importance to AliveCor

This study demonstrates that use of the AliveCor KM monitoring device facilitates the early detection of recurrent AF/AFL in post-RFA and post-DCCV patients; this in turn may help expedite treatment and reduce the risk of future complications

References:

1. Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S. Epidemiology of atrial fibrillation: European perspective. *Clin Epidemiol*. 2014;6:213-220.

2. Hickey KT, Hauser NR, Valente LE, et al. 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. *BMC Cardiovasc Disord*. 2016;16:152.