Long-term Intermittent Versus Short Continuous Heart Rhythm Monitoring for the Detection of Atrial Fibrillation Recurrences After Catheter Ablation

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Background

In patients with symptomatic atrial fibrillation (AF), catheter ablation is a widely recommended treatment option

Monitoring for recurrence of AF in the post-ablation period is important to determine whether symptoms of palpitations are due to recurrent AF, to guide treatment options in asymptomatic AF, and to assess outcomes associated with catheter ablation

Short-term scheduled or symptom-initiated continuous electrocardiogram (ECG) monitors (ie, Holter or event recorders), commonly used to detect recurrent AF post-ablation, are limited by the risk of missing recurrent arrhythmias, especially in asymptomatic AF. Long-term monitoring (with implantable loop recorders) is limited by invasiveness, practicality, and cost

Smartphone-based external handheld rhythm recorders have been developed to overcome these limitations

Objectives

The objectives of this prospective observational study were to evaluate the effectiveness and usability of a long-term intermittent heart rhythm monitoring approach using a single-lead ECG monitor (AliveCor KardiaMobile [KM]) compared with a short continuous heart rhythm monitoring approach using a Holter monitor for the detection of AF recurrences after AF ablation and to evaluate KM accuracy for AF detection

PRIMARY ENDPOINT: Assess the difference in the proportion of patients with AF recurrences detected by using the KM monitor compared to using a Holter monitor

SECONDARY ENDPOINTS:

a. Evaluate the usability and user-friendliness of both the KM and Holter monitors

b. Assess the sensitivity and specificity of the KM algorithm for the detection of AF

Methods

- The study included adult patients (≥18 years of age) who underwent AF catheter ablation at a single medical center in the Netherlands and were able to operate a smartphone
- Baseline characteristics and demographics were collected from patients' medical records
- Holter monitor recordings were collected at 3-, 6-, and 12-month follow-up post-ablation
- At 1 of these timepoints, patients were provided the KM monitor and instructed on its use, and were asked to record a 30-second ECG trace 3 times daily and in the presence of symptoms for a 4-week period. KM ECG recordings were sent via email to the research team for analysis
  - KM ECG recordings were analyzed by 2 researchers (adjudicated by a third in case of conflicts) to assess the sensitivity and specificity of the KM algorithm
- A 10-item questionnaire (System Usability Scale [SUS]) evaluated the usability and user-friendliness of both the KM and Holter monitoring devices. An additional 4 questions on user-friendliness and device preference were added by the investigators

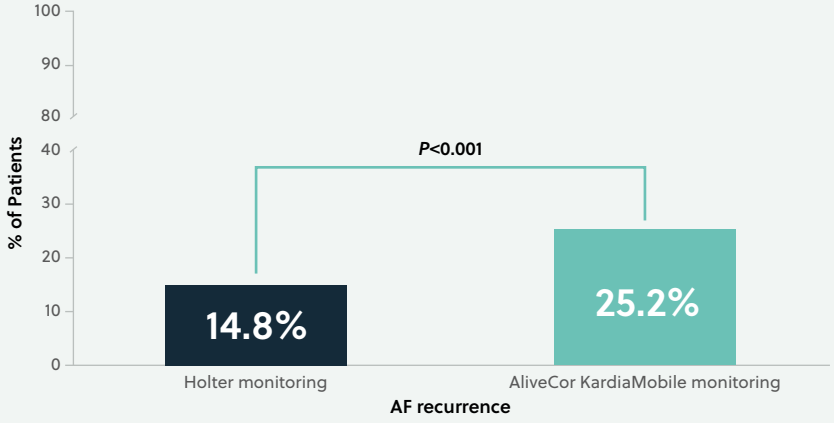
Results

- Out of 126 post-AF ablation patients, 115 (91.3%) patients (35 females, median age 64.0 [58.0–68.0] years) transmitted their KM recordings and were included in the analysis

PRIMARY ENDPOINT: Evaluate the proportion of patients with AF recurrences detected by using KM compared to Holter monitoring

1. Significantly more post-ablation patients with recurrent AF were detected with KM monitoring (n=29) compared with Holter monitoring (n=17; *P*<0.001) after the 4-week study period (**Figure 1**)

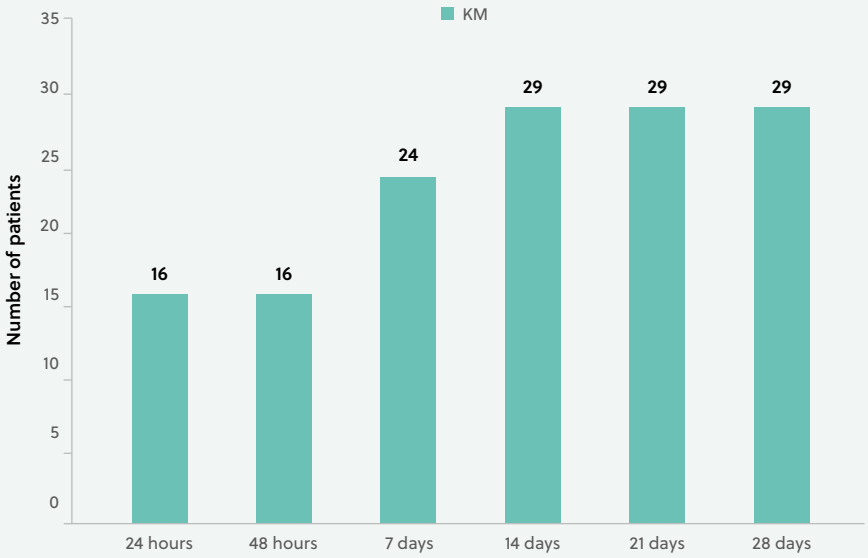
FIGURE 1. Proportion of Patients Diagnosed With Atrial Fibrillation Recurrences by AliveCor KardiaMobile vs Holter Monitoring



Results (cont'd)

- During the 3-, 6-, and 12-month follow-up visits, more patients with recurrent AF were detected by KM compared with Holter monitoring at each time point
  - 20 patients (27.0%), 2 (12.5%), and 7 (28.0%) with recurrent AF were detected by KM at 3, 6, and 12 months, respectively
  - 12 patients (16.2%), 1 (6.3%), and 4 (16.0%) with recurrent AF were detected by Holter ECG at 3, 6, and 12 months, respectively
- All patients with AF recurrences were detected within 14 days of long-term intermittent heart rhythm monitoring with KM
- More than 14 days of diagnostic monitoring with KM did not increase the detection rate of recurrent AF (**Figure 2**)

FIGURE 2. KM Monitoring Time Needed to Detect Recurrent AF in Post-Ablation Patients



Conclusions

The AliveCor KardiaMobile monitor identified more patients with recurrent AF after ablation compared with Holter monitoring

The AliveCor KardiaMobile monitor showed high sensitivity, specificity, and diagnostic accuracy for the detection of AF

Patients reported higher usability grades for the AliveCor KardiaMobile monitor than for Holter monitoring

Importance to AliveCor

This study demonstrated that the AliveCor KardiaMobile monitor provides a rapid, accurate, and user-friendly diagnostic tool for detecting post-ablation recurrence of AF that patients prefer over Holter monitoring

SECONDARY ENDPOINTS: Assess the usability and user-friendliness of both long-term intermittent heart rhythm monitoring by KM and short continuous heart rhythm monitoring by Holter and evaluate the sensitivity and specificity of KM to detect recurrent AF

- Usability and user-friendliness of KM compared with Holter monitor
  - Significantly more patients rated KM higher (SUS Grade A), more convenient, and more likely to recommend than a Holter monitor (**Table 1**)

TABLE 1. Usability and User-Friendliness of AliveCor KardiaMobile Compared With Holter Monitor

	AliveCor KardiaMobile	Holter	*P* Value
SUS* Grade ≥68%, n (%)	49 (80.4)	36 (59.1)	0.203
SUS* Grade A, n (%)	40 (65.6)	27 (44.3)	0.006
KM more convenient than Holter, n (%)	59 (79.8)	5 (6.8)	<0.001
Would recommend KM over Holter, n (%)	53 (73.7)	6 (8.4)	<0.001

*System Usability Scale (SUS) scores were converted into grades from A, which indicates superior performance, to F (for failing performance). Of 115 patients, 61 completed the 10-item SUS questionnaire and 72 answered the 4 questions on user-friendliness and device preference. The ranges of the SUS grades were: A (78.9%–100%), B (72.6%–78.8%), C (62.7%–72.5%), D (51.7%–62.6%) and F (0%–51.6%). Grade C was divided into C1 (62.7%–67.9%) and C2 (68.0%–72.5%). Devices scoring below the average SUS score of 68.0% are considered to cause a problem with usability.

- The KM monitor demonstrated high sensitivity and specificity for the detection of AF
  - For the detection of AF, the KM diagnostic algorithm was associated with a sensitivity of 95.3%, specificity of 97.5%, positive predictive value of 76.5%, and negative predictive value of 99.6%