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Title: AF Clinic of The Future

Using KardiaPro Platform for chronic care of patients with AF after ablation procedure

Principle Investigator: Khaldoun G. Tarakji, MD MPH

Sponsor: AliveCor

Background:

Pulmonary vein isolation (PVI) is a widely used strategy for the treatment of patients with symptomatic atrial fibrillation (AF). After ablation, patients are usually discharged with transtelephonic monitor. Patients are encouraged to send their electrophysiologist transmissions of their heart rhythm at least once a week or anytime they have symptoms. After 3-4 months of remote monitoring, patients come for their first visit after the ablation. At this visit, the electrophysiologist reviews the heart rhythm transmissions since the ablation and based on the findings, decisions are made regarding anticoagulation or antiarrhythmic drug therapy. If all transmissions show sinus rhythm and the patient is doing well, he or she is normally followed clinically based on symptoms without any rhythm monitors. Usually, these patients follow up in another 6 months with an ECG at the time of the visit with the caring electrophysiologist. During these 6 months, patients might experience palpitations or recurrent arrhythmias. These episodes usually trigger phone encounters with the provider and this can trigger additional testing. Sometimes it might lead to clinic or emergency room encounters.

Kardia Mobile is an FDA approved device that allows one lead ECG recording for 30 seconds using the patient's smart phone. The device has a built-in algorithm that detects AF. KardiaPro is a secure platform that allows the physician to access the patient's recording at any time. The platform can also be programmed to send a notification to the healthcare provider if AF is detected by the software. The goal of our study is to determine whether detection of AF with Kardia Mobile is different than the current standard approach and to assess the value of using Kardia Mobile and the KardiaPro platform in decreasing health care utilization and reducing patient anxiety following AF ablation.

Study Center: Cleveland Clinic

Study Objectives:

1. Determine whether detection of AF differs between standard of care (routine clinic visit with ECG) and the Kardia Mobile device for patients after initial successful AF ablation.

2. Determine whether the number of clinical encounters decreases with the use of Kardia Mobile compared to standard monitoring.
3. Evaluate the effect of using Kardia Mobile in reducing patient's anxiety (Using GAD-7 anxiety scale)

Study Design:

This single center study will enroll approximately 100 patients with AF after successful AF ablation. A successful AF ablation is defined as no documented AF episodes by ECG or ambulatory transtelephonic monitor after the first three weeks (blanking period) following AF ablation. Patients typically see their electrophysiologist 3-4 months after the ablation. At the time of this visit, eligible patients who provide informed consent will be randomized in 1:1 fashion (standard of care vs Kardia Mobile Device). Randomization will be stratified by the type of atrial fibrillation at initial presentation (paroxysmal or persistent). Each patient is expected to participate for approximately 6-8 months post randomization. Both groups will participate in a standardized assessment of anxiety (GAD7) at the time of enrollment and at the 6 month visit.

The 2 groups into which patients will be randomized include:

1) Group 1 (Control) Standard of Care (SOC) monitoring: This is our current standard of care for following patients after successful AF ablation. Patients will be followed clinically based on symptoms (no monitor is provided). They will be seen for follow up 6 months after enrollment into the study. During these 6 months, patients can call if they have symptoms. The caring team will order any additional testing or monitors as deemed necessary by the patient's primary electrophysiologist. At the 6 months follow up visit with the patient's primary electrophysiologist, a 12 lead ECG is performed. The GAD7 will be administered at this visit.

2) Group 2 (Treatment) Kardia Mobile device: Patients randomized to the Kardia mobile device will be enrolled in the Kardia platform. They will be educated about the use of the device and instructed to record at least once weekly or when they have symptoms. The recordings are not reviewed routinely. However, the automated software provides an initial interpretation of the rhythm. The software will be programmed to send a notification to an EP nurse practitioner if the algorithm detects AF. This will be shared with the primary electrophysiologist. If the patient calls with symptoms, the EP nurse practitioner or the caring electrophysiologist can access the recordings for review. At the 6 months follow up visit, a report of the Kardia recordings will be provided to the primary electrophysiologist along with a standard 12 lead ECG. The GAD7 will be administered at this visit.

Number of subjects: 100 patients

Target Population: Patients with atrial fibrillation (paroxysmal or persistent) presenting 3-4 months after successful AF ablation procedure. (Successful AF ablation is defined as maintaining sinus rhythm after the first 3 weeks blanking period)

Inclusion Criteria:

1. 18-85 years old
2. Have smartphone with data plan
3. History of AF (paroxysmal or persistent)
4. In sinus rhythm at the 3-4 month post-procedure visit and no evidence of AF during the interval starting after the 3 week blanking period and ending at the appointment time.
5. On Anticoagulation if CHADS VASC score is ≥ 1 and will continue to be on anticoagulation or CHADS VASC of Zero
6. Willing to follow up with their Cleveland Clinic electrophysiologist in 6 months

Exclusion Criteria

1. Patients without smartphone
2. Unwilling to provide consent
3. Unwilling to follow up in 6 months
4. CHADS VASC ≥ 1 and anticoagulation will be stopped
5. Presence of a cardiac implantable electronic device
6. If the primary electrophysiologist decides the patient still needs monitoring through traditional monitors due to any reason

Randomization:

Patients will be randomized in a 1:1 treatment allocation ratio to either standard of care or monitoring using the Kardia Mobile device. Randomization will be stratified by the type of atrial fibrillation at initial presentation (paroxysmal or persistent).

Primary Endpoint

The primary endpoint is time to atrial fibrillation detection during the study period. Time zero is defined as the time of randomization.

Secondary Endpoints

The following are considered secondary endpoints:

1) Incidence of atrial fibrillation within 6 months after successful AF ablation.
2) Average number of atrial fibrillation episodes detected after ablation procedure
3) Average number of clinical encounters within 6 months after successful ablation.
4) Use of alternative monitoring devices during the follow up interval (Holter, Ziopatch)
5) Change in level of anxiety from baseline to 6 months as measured by the Generalized Anxiety Disorder 7-item (GAD-7) scale

Data Analysis:

This is a descriptive pilot study and will enroll 100 patients meeting the inclusion and exclusion criteria. The expected duration of follow-up for each patient is approximately 6 months. The general statistical methodology will provide descriptive summaries and statistics on the entire cohort. Categorical variables will be summarized using frequencies and percentages. Continuous variables will be summarized as mean, standard deviation, median, interquartile range and minimum and maximum values. Only non-missing values will be reported. Missing data will not be imputed.

Data Collection and Storage:

All data will be entered into RedCap on a secured Cleveland Clinic server. Only investigators, research coordinators and statisticians involved in the study will have access to the data. Data will be collected mainly from the electronic medical record system, the EP lab database. Kardia Pro is a secure website and privacy statement will be provided to patients upon enrollment

Study Design Schematic: