Validation of a Portable ECG Monitoring Device in Diagnosing Atrial Fibrillation

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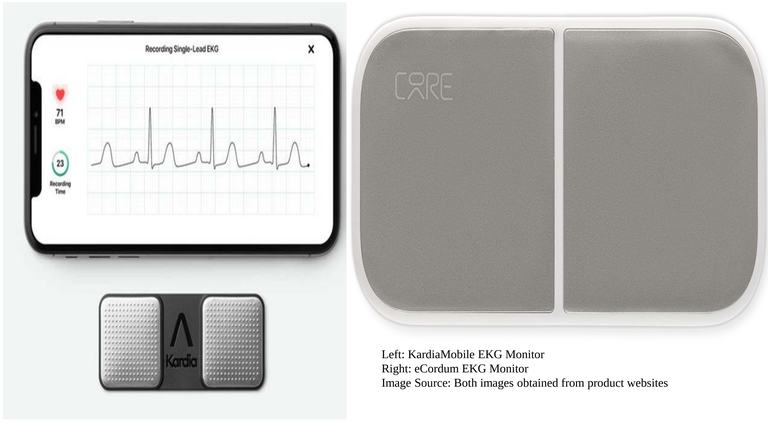
Background

- The underlying cause of AF is believed to be high frequency excitation of the atrium that results in dyssynchrony in atrial contraction and irregular ventricular excitation
- As portable and wearable medical technology advances, we have been able to make diagnosis of AF more easily, and more people have become aware of the medical condition. In fact, more than 454,000 people are admitted to a hospital with a primary or secondary diagnosis of AF each year in the United States
- AF contributes to about 158,000 deaths each year, and the death rate from AF as the primary or secondary diagnosis of death has been rising for more than 20 years
- One of the biggest consequences of AF is its concomitant risk for stroke events resulting in significant economic burden and rising morbidity and mortality
- The mainstay of treatment for most patients with AF is long-term oral anticoagulants (OAC). Although the use of OAC improves longevity and decreases morbidity in patients with AF, it is associated with the possibility of life-threatening bleeding complications. Because of these perceived risks, many patients with AF will not take OAC continuously although they may be exposed to a greater risk of getting a stroke
- Since AF symptoms are often transient, fleeting or silent, many patients at risk for stroke won't know when their risk is highest, and they are unable to document clinical arrhythmia when the symptoms occur. A hand-held monitor with high accuracy for AF detection could change our current treatment of AF by delivering a patient-centered technology solution facilitating improved patient understanding of disease processes, engagement, and compliance with therapy to promote overall health and desired medical outcomes
- Currently, ubiquitous cardiac monitoring systems that promise accurate detection of AF are emerging in the market. eCordum Core-Care Handheld Monitor and KardiaMobile ECG monitor by AliveCor are two examples of such systems that are currently available in the market
- The present study is intended to confirm the efficacy of utilizing the above-mentioned devices to improve the delivery of care in patients with AF
- The availability of a new and exciting light-weight non-obtrusive hand-held monitor with high diagnostic accuracy and specificity for AF promises to provide clinicians with succinct, timely, quality reports on patients being monitored and, therefore, be able to more effectively care for the lives of patients with AF, their friends and families
- Our study will help to validate the ability of two contemporary hand-held devices to reliably detect AF with a high specificity and sensitivity

Research Question/hypothesis

- The primary question of this research is whether an ECG recorded with a contemporary handheld cardiac monitors, such as eCordum Core-Care and KardiaMobile is accurate and noninferior to the gold-standard, dual chamber pacemaker for the diagnosis of atrial fibrillation (AF)
- We hypothesize that commonly available handheld monitors such as eCordum Core-Care and KardiaMobile are noninferior to the gold-standard, dual chamber pacemaker in making a diagnosis of atrial fibrillation



Left: KardiaMobile EKG Monitor
Right: eCordum EKG Monitor
Image Source: Both images obtained from product websites

Discussion

- Atrial fibrillation is a very common medical condition which has the potential for high levels of morbidity and mortality as well as high levels of burden on patients, families, and the medical system
- AF symptoms can often be transient or otherwise unnoticed, which can lead to delay in receiving needed medical care, increasing patient's risk for harmful sequelae such as stroke or heart failure
- This study is intended to determine the efficacy of two non-invasive, handheld cardiac monitoring systems in detecting atrial fibrillation
- The availability of a new, light-weight, non-invasive, portable and handheld cardiac monitor with high diagnostic accuracy and specificity for detecting atrial fibrillation promises to provide clinicians with succinct, timely and quality monitoring reports on this large and expanding patient population
- Timely, accurate and more frequent monitoring will allow clinicians to more effectively care for the lives of patients with AF, as well as their friends and family

Methods

- Project Status
  - SRB approved. IRB approval pending. Continuing data collection until 12/1/2021
- Study Design
  - Prospective observational cohort study of subjects that will consist of established patients at Arnot Ogden Medical Center (AOMC) Heart and Vascular Institute with a known history of atrial fibrillation and an implanted dual chamber device
  - Subjects will undergo brief and completely noninvasive cardiac recordings using the AliveCor Kardia and eCordum Core-Care handheld devices for 30 seconds each.
  - Recordings from handheld devices will later be compared to a "gold standard" concomitant recording from the subjects own implanted device by two board-certified cardiologists who will be blinded to the patients identity
- Inclusion Criteria
  - Established patients at AOMC Heart and Vascular Institute with a known history of Afib and an implanted dual chamber device who present to the clinic for a routine, previously scheduled device check from 12/1/2015 - 12/1/2021
  - Age >= 18 and <= 99
- Exclusion Criteria
  - Age < 18 and > 99
  - Unable to provide consent
  - No documented follow up
- Outcome Measures
  - Primary: Sensitivity and specificity regarding the detection of atrial fibrillation based on algorithms used in the handheld devices to be studied
- Interventions
  - Brief, completely noninvasive cardiac recordings by the AliveCor Kardia and eCordum Core-Care handheld devices for 30 seconds each
  - A comparison between the cardiac recordings generated by the handheld devices being tested and the patient's own implanted device will be made by two board-certified cardiologists who are blinded to the patients identity
  - Sensitivity and specificity will be determined for the handheld devices to detect the presence of paroxysmal/persistent atrial fibrillation
  - A determination on the feasibility of using either the AliveCor Kardia or eCordum Core-Care handheld devices to detect atrial fibrillation will be made

References

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