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Feasibility and Usability of a Mobile Application to Assess Symptoms and Affect in Patients with Atrial Fibrillation: A Pilot Study

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Abstract

Background : Atrial fibrillation (AF) is the most prevalent arrhythmia leading to hospital admissions. The majority of patients with AF report symptoms that are believed to be associated with the arrhythmia. The symptoms related to AF traditionally are collected during a clinic visit that is influenced by biases associated with recalling the experience over a limited period of time.

Purpose: We designed this pilot study to assess the usability and feasibility of a mobile application to assess symptoms in patients with AF.

Methods : We designed a mobile application (miAfib) to assess symptoms (chest pain, palpitation, shortness of breath, fatigue, dizziness/lightheadedness), positive affect (happy, excited, content) and negative affect (worried, angry, sad) on multiple occasions throughout the day based on iOS platform. We performed a four-week feasibility trial to examine user adherence, acceptance and experiences with the mobile application. We administered questionnaires to assess factors affecting usage and self-reported acceptance of the application based on a five-point Likert scale with zero representing strongly disagree and 5 representing strongly disagree with.

Results : We included ten patients with paroxysmal and persistent AF. The mean number of completed assessments each day was 2.81 ± 1.59 with 94.7% of days with at least one assessment. The users found the application easy to use (4.75±0.46), intended to use it in the future (4.37±1.06) and found it easy to integrate into daily routine (4.5±1.07).

Conclusions : In this pilot study, we found participants in this four-week trial reliably used the application and were able to use the app to report their daily symptoms and affect regularly. Participants reported that they found the application easy to use and would consider using the application in the future.

Introduction

Atrial fibrillation (AF) is the most prevalent arrhythmia leading to hospital admissions.[1] Its incidence is associated with an increase in the risk of stroke, congestive heart failure and overall mortality.[2] The national incremental cost of AF to the health care system has been estimated to be as high as $26.0 billion.[3] The number of patients diagnosed with AF is projected to increase to more than 15 million by 2050.[4] The majority of patients with AF report symptoms believed to be associated with the arrhythmia.[5] The most common symptoms reported are dyspnea, chest pain, dizziness, fatigue and palpitations.[6] These symptoms can lead to a decrease in functional status and quality of life in many patients with AF. [7]

Symptoms related to AF are traditionally collected via recall measures that require participants to summarize their experiences over some time period (i.e. since the last clinic visit). Current approaches to the assessment of symptoms during clinical visits is problematic for several reasons. They are susceptible to several factors including recall bias, retroactive reconstruction, effort after meaning, and affect-related bias.[8] Another concern is that the assessments of symptoms, affect and functional status are not performed in patients natural settings, therefore limiting their generalizability and ecological validity.[9] This emphasis on retrospective assessment also precludes examination of the dynamic changes in symptoms over time and their interaction with heart rhythm, affect and functional status. There is a need for development of tools that allow real-time repeated assessments of symptoms and affect to capture the daily variability in symptoms and understand the potentially dynamic daily interactions between symptom and affect.

Mobile applications("apps")are software designed to operate on a smartphone or other mobile devices. In the United States, smartphones are owned by 73% of adults who use these devices in a diverse range of activities in daily life.[10] Mobile applications have become increasingly important in the management of patients across a range of medical problems. They provide a unique opportunity to collect clinically-relevant data from a patient population through collection of data in patients natural environment. As such, we developed a novel mobile application (miAfib) to assess AF-relevant symptoms and affect on multiple occasions throughout the day. This

Key Words

Atrial Fibrillation, Mobile Application, Feasibility Study.

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Figure 1: miAfib mobile application

study aimed to evaluate the feasibility and usability of this mobile application for a four-week use period in a sample of individuals with AF.

Methods

We designed a mobile application (miAfib) to assess symptoms (chest pain, palpitation, shortness of breath, fatigue, dizziness/ lightheadedness), positive (happy, excited, content) and negative (worried, angry, sad) affect on multiple occasions throughout the day based on iOS platform for iPhone available through the app store for download by study participants [Figure 1]. The beta version of the mobile application was tested extensively for user experience, data recording and transfer prior to release of the final product to the app store. We designed a study website (www.miAfib.com) to assist participants with mobile application set up and study details. For self-reported measures, we utilized the mobile application to collect the severity of AF related symptoms and affect on multiple occasions throughout the study period. Patients were identified by a unique login, which allowed for authorization with the server and tracking of their responses. The users were prompted with notifications to remind them to complete the symptoms and affect assessments four times per day every three hours starting at 9AM. When the user opened the application, it displayed the assessments to the user. The application captured the users input, which was transferred back to University of Michigan Medical School (UMMS). These web services were designed to retrieve the data and store it at a University of Michigan HIPAA compliant server. The study team performed the initial setup of the application for all participants. The research coordinator performed the background and baseline clinical measurements during the initial encounter. Data security, patient privacy and HIPPA requirements were given a premium consideration. These were addressed through using data encryption, HIPPA compliant servers and password-protected files. We included patients with paroxysmal and persistent AF who presented to University of Michigan for the management of their cardiac arrhythmia. We also included patients with persistent AF undergoing electrical cardioversion. These patients recorded their heart rhythm using an event recorder before and after the electrical cardioversion.

Mobile questionnaires

The questions for the mobile application were designed to assess symptoms most commonly associated with AF, positive and negative affect. The questions assessing symptoms consisted of a ten-point scale with zero representing no symptoms at all and 10 representing severe symptoms. The questions used to assess symptoms were: "how severe is your shortness of breath", "what is your level of fatigue", "how severe are your palpitations", "how severe is your chest pain" and "how severe is your dizziness or lightheadedness". The questions assessing affect were rated using a five-point scale with zero representing absence and 5 representing complete presence of emotion. The questions used to assess positive affect were: "how happy are you at this time", "how excited are you at this time" and "how content are you at this time". The questions used to assess negative affect were: "how worried are you at this time", "how angry are you at this time" and "how sad are you at this time". Mean symptom, positive and negative affect scores were used to summarize the results obtained from the mobile application.

Survey

A final follow up session was arranged approximately four weeks from the first session. In the final session, the research coordinator conducted a semi-structured interview with the participant over the phone. The participants completed a self-report questionnaire, consisting of five-point Likert scaled questions (one, representing strongly disagree, to five, representing strongly agree) designed to measure ease of use ('by the end of four weeks I found the app easy to use'), convenience and integration into daily routine ('by the end of the four weeks I found the app easy to use'/ had fitted into my routine') and future intentions to use the application ('I intend to use the app in the future').[11] Mean score was used to summarize the results obtained from the surveys.

Table 1: Baseline Characteristics

Age	
Sex (Female %)	5 (50%)
Paroxysmal AF (%)	5 (50%)
Hypertension (%)	4 (40%)
Diabetes (%)	1 (10%)
Obstructive Sleep Apnea (%)	5 (50%)
Congestive Heart Failure (%)	1 (10%)
Chronic Kidney Disease (%)	0 (0%)
Peripheral Vascular Disease (%)	0 (0%)

Feasibility trial

We performed a four-week feasibility trial to examine user adherence, acceptance and experiences with the mobile application.

Patient Characteristics

Patients with a history of symptomatic persistent and paroxysmal AF seen at the University of Michigan Health Center (UMHS) were eligible to be included in the study. Identification and recruitment of eligible participants was based on the physician referral and use of ICD-10 codes. Potential patients were screened for initial eligibility by a research coordinator. Written informed consent was obtained prior to study enrollment. Baseline characteristics were obtained at the initial visit. Staff recruited patients between November 2015 and February 2017. Eligibility criteria were: age > 21, diagnosis of AF and stable medical regimen for at least 30 days prior to study

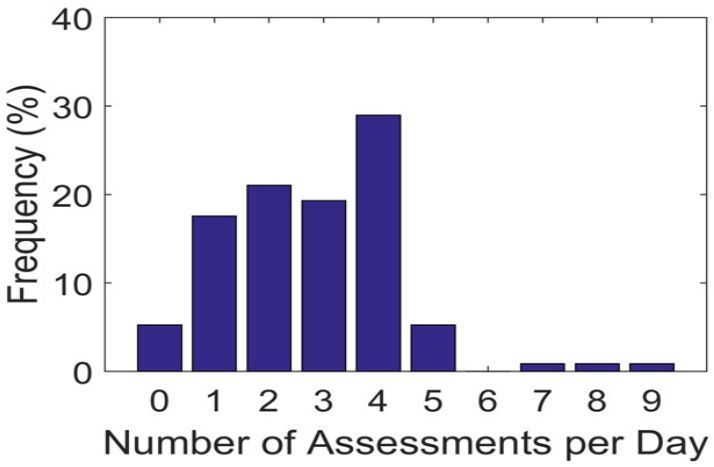

Figure 2: The distribution of completed assessments per day

inclusion. The exclusion criteria were: no symptoms associated with AF, psychiatric disorders, diagnosed neurological disorders associated with cognitive difficulties (stroke, dementia, Parkinson's disease, Multiple Sclerosis), cancer or brain tumors, chronic use of recreational drugs, alcohol abuse and moderate to severe traumatic injury, life expectancy less than one year, pregnancy, known allergic reaction to adhesives or family history of adhesive skin allergies and existing implantable cardiac rhythm devices and neuro-stimulators. The baseline characteristics of patients are summarized in [Table 1].

Our primary measures of interest were frequency of usage (measured via number of completed assessments), qualitative accounts of the effects of the application and factors affecting usage, as well as self-reported acceptance of the application (as measured in the questionnaire).

Results

The mean number of completed assessments each day was 2.81 ± 1.59 (median=3, Q1=2, Q3=4) with 94.7% of days with at least one assessment while in study. The frequency of assessments is demonstrated in [Figure 2]. The patients completed the full assessment at every instant of using the application. These results indicate that participants were able to routinely engage with the application during the trial period while also providing comprehensive data.

Descriptive statistics showed that users found the application easy to use (4.75±0.46) and intended to use it in the future (4.37±1.06). Convenience and integration into daily routinewas rated highly (4.5±1.07). While these data are supportive, these self-reported measures were obtained over a relatively brief trial period and additional measures may be needed for long term habitual use.

Four patients used the mobile application while wearing the event recorder (BodyGuardian Heart, Preventice Solutions). Patients completed mean of 3.89 ± 1.34 assessments while wearing the event recorder. Patients found that the application was easy to use (4.50±0.58) and intended to use it in the future (4.0±1.41). The participants found the application convenient and easy to integrate into daily their routine (4.0±1.41). [Figure 2] demonstrates an example of patient reported data in patients before and after an electrical cardioversion.

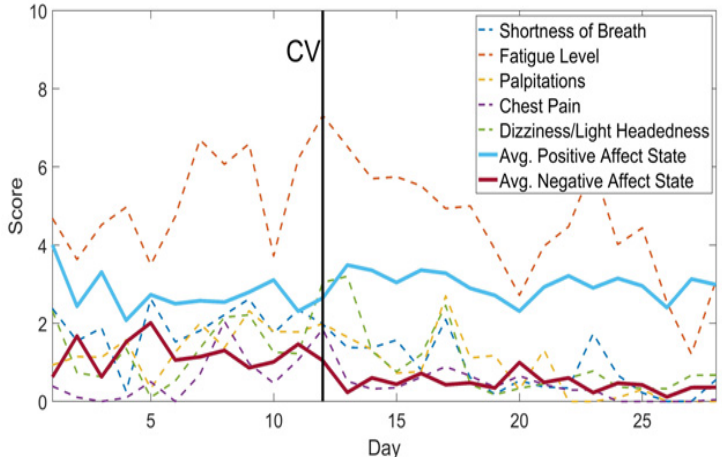

Figure 3: Symptoms and Affect Recorded by miAfib Mobile Application Before and After Electrical Cardioversion

Discussion

This was the first study to evaluate the feasibility and applicability of a mobile application to assess daily symptoms and affect in patients with AF. Participants in this four-week trial regularly used the application to report their daily symptoms and affect. Participants found the application easy to use and would consider using the application in the future.

There is growing evidence that affect is associated with cardiovascular health.[12] Negative emotional states have been associated with acute cardiac dysfunction, myocardial ischemia and increased long term cardiovascular mortality.[13] These negative emotional states and specifically anxiety and depression have also been linked to more severe symptoms in patients with AF.[12], [14]-[16] However, investigating the temporal sequence of affect and cardiac dysfunction represents significant methodological challenges that are not addressed with one-time assessments of affect during clinic visits. The prospective real-time assessments of how a person feels over a period of time have demonstrated an association between negative affect, acute cardiac dysfunction and poor long-term survival. Despite the evidence suggesting an association between affect and symptoms in cardiovascular disease, there have not been studies evaluating their relationship in patients with AF. Our mobile application allows for more accurate and time sensitive measurement of symptoms and affect in patients with AF, so that we can determine how within-subject changes in symptoms and affect influence functional status in individuals with symptomatic AF. These findings lay the foundation for future research evaluating the subjective symptoms and affect and their relationship with rhythm and functional status. This approach will provide an unparalleled window into the daily lives of patients with AF.

Limitations

Our pilot study included a limited number of patients to evaluate the feasibility of the mobile application. Larger studies are needed to determine its feasibility in a diverse group of patients with AF. Although the overwhelming majority of our patients found the mobile application easy to use, there is a need to evaluate its feasibility in different patient populations with both paroxysmal and persistent AF. Future research is also needed to determine the feasibility of personalization of the mobile application based on patient and physician preferences.

Conclusions

Our study demonstrates the feasibility of a mobile application designed to assess symptoms and affect in patients AF. Our mobile

application provides a unique opportunity to evaluate psychological and physiological correlates of symptoms in patients with AF.

Conflict Of Interests

None.

Disclosures

None.

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