CLINICAL RESEARCH STUDY

THE AMERICAN JOURNAL of MEDICINE®

Mobile Health Technology for Atrial Fibrillation Management Integrating Decision Support, Education, and Patient Involvement: mAF App Trial

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ABSTRACT

BACKGROUND: Mobile Health technology for the management of patients with atrial fibrillation is unknown.
METHODS: The simple mobile AF (mAF) App was designed to incorporate clinical decision-support tools (CHA_2DS_2-VASc [Congestive heart failure, Hypertension, Age ≥75 years, Diabetes Mellitus, Prior Stroke or TIA, Vascular disease, Age 65–74 years, Sex category], HAS-BLED [Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol concomitantly], SAMe-TT_2R_2 [Sex, Age <60 years, Medical history, Treatment, Tobacco use, Race] scores), educational materials, and patient involvement strategies with self-care protocols and structured follow-up. Patients with atrial fibrillation were randomized into 2 groups (mAF App vs usual care) in a cluster randomized design pilot study. Patients' knowledge, quality of life, drug adherence, and anticoagulation satisfaction were evaluated at baseline, 1 month, and 3 months. Usability, feasibility, and acceptability of the mAF App were assessed at 1 month.
RESULTS: A total of 113 patients were randomized to mAF App intervention (mean age, 67.4 years; 57.5% were male; mean follow-up, 69 days), and 96 patients were randomized to usual care (mean age, 70.9 years; 55.2% were male; mean follow-up, 95 days). More than 90% of patients reported that the mAF App was easy, user-friendly, helpful, and associated with significant improvements in knowledge compared with the usual care arm (P values for trend <.05). Drug adherence and anticoagulant satisfaction were significantly better with the mAF App versus usual care (all $P < .05$). Quality of life scores were significantly increased in the mAF App arm versus usual care, with anxiety and depression reduced (all $P < .05$).
CONCLUSIONS: The pilot mAFA Trial is the first prospective randomized trial of Mobile Health technology in patients with atrial fibrillation, demonstrating that the mAF App, integrating clinical decision support,

Funding: This research project was funded by Chinese PLA Healthcare Foundation (13BJZ40), Beijing Natural Science Foundation (7142149), Beijing Natural Science Foundation (Z141100002114050), and National Natural Science Foundation of China (H2501).

Conflicts of Interest: GYHL: Consultant for Bayer/Janssen, BMS/Pfizer, Biotronik, Medtronic, Boehringer Ingelheim, Microlife, and Daiichi-Sankyo. Speaker for Bayer, BMS/Pfizer, Medtronic, Boehringer Ingelheim, Microlife, Roche, and Daiichi-Sankyo. No fees are received personally.

Authorship: All authors had access to the data and played a role in writing this manuscript.

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http://dx.doi.org/10.1016/j.amjmed.2017.07.003

education, and patient-involvement strategies, significantly improved knowledge, drug adherence, quality of life, and anticoagulation satisfaction.
 • The American Journal of Medicine (2017) ■■, ■■–■■

KEYWORDS: Atrial fibrillation; Drug adherence; Mobile health; Patient education

INTRODUCTION

Atrial fibrillation is the most common cardiac arrhythmia, with a global health burden of approximately 33.5 million individuals with atrial fibrillation worldwide.[1] The lifetime risk for developing atrial fibrillation is 21% to 23% in women and 17% to 26% in men.[2-4] In the past 5 decades, age-adjusted atrial fibrillation prevalence globally has increased 5-fold[5] and is expected to double by 2050.[1] Atrial fibrillation–related stroke is devastating, which has been described as an "atrial fibrillation–related stroke tsunami" without proper treatment with oral anticoagulants.[6]

The underuse or inappropriate use of oral anticoagulants is common in the population with atrial fibrillation, particularly so in many Asian countries.[7] Even in the new era of non–vitamin K antagonist oral anticoagulants,[5] many patients remain undertreated.[8] Also, 28% of high-risk patients (defined as a CHA_2DS_2-VASc [Congestive heart failure, Hypertension, Age ≥75 years, Diabetes Mellitus, Prior Stroke or TIA, Vascular disease, Age 65–74 years, Sex category] score ≥2) are not anticoagulated, whereas 51% of very low-risk patients are inappropriately anticoagulated.[9]

Nonadherence to atrial fibrillation guidelines is common across all risk strata, ranging from 33% to 68% among the high-risk population.[10] On the other hand, patients' preferences are another important reason for nonadherence to therapy.[11] Thus, efforts to streamline decision-making for stroke prevention in patients with atrial fibrillation and to improve patients' knowledge are important in the era of non–vitamin K antagonist oral anticoagulants.[12]

Novel strategies that incorporate eHealth or Mobile Health encompass the use of information and communication technologies in the management of disease, providing innovative solutions to the problem of long-term management after discharge.[13,14] However, there are limited data on the implementation of Mobile Health technology for the management of patients with atrial fibrillation, particularly in relation to its feasibility, efficacy, and safety.

CLINICAL SIGNIFICANCE

- Mobile Health technology is increasingly proposed for cardiovascular disease management.
- The feasibility, efficacy, and safety of Mobile Health technology for the management of patients with atrial fibrillation are unknown.
- The pilot mAFA Trial demonstrated that an approach integrating clinical decision support, education, and patient-involvement strategies using the mAF App would translate to significantly improved knowledge, drug adherence, anticoagulant satisfaction, and quality of life.

Our aim was to perform a randomized, controlled trial (mAFA; Clinical Trials Registry Number: ChiCTR-IOR-17010436) of a Mobile Health technology–supported atrial fibrillation management model, integrating clinical decision support tools, guideline-based treatment, and patient involvement. The mAFA Trial is the first prospective randomized trial of Mobile Health technology in patients with atrial fibrillation.

MATERIALS AND METHODS

A user-friendly mAF App was developed for smart phones based on the Android Operating System (Google Inc., Mountain View, Calif) and Apple iOS (Cupertino, Calif), which incorporated clinical decision support (clinical risk scores, ie, CHA_2DS_2-VASc, HAS-BLED [Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol concomitantly], and SAMe-TT_2R_2 [Sex, Age < 60 years, Medical history, Treatment, Tobacco use, Race] score), patient educational programs, patient involvement self-care components, and structured follow-up components.

Patients with atrial fibrillation were randomized to 2 groups (mAF App vs usual care) in a cluster randomized design based in 2 hospitals, Chinese PLA General Hospital and Meishan City People's Hospital, between January 1, 2017, and May 1, 2017. Inclusion criteria included adult patients aged >18 years with atrial fibrillation diagnosed with electrocardiogram and 24-hour Holter. We excluded individuals aged <18 years, those with valvular atrial fibrillation (eg, prosthetic), and those unable to provide written informed consent (Supplementary Figure 1, available online).

Patients' knowledge, quality of life, drug adherence, and anticoagulation satisfaction were evaluated at baseline, 1 month, and 3 months. Usability, feasibility, and acceptability of the mAF App were assessed at 1 month.

Design of mAF App

The mAF App was designed with versions for patients and doctors respectively. The mAF App incorporates details such