

Impact of digital monitoring on compliance and outcome of lifestyle-change measures in patients with coexistent atrial fibrillation and obesity



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INTRODUCTION Obesity, a known risk factor for atrial fibrillation (AF), is potentially reversible through lifestyle changes, including diet and physical activity. However, lack of compliance is a major obstacle in attaining sustained weight loss. We investigated the impact of patient engagement using a digital monitoring system on compliance for lifestyle-change measures and subsequent outcome.

METHODS A total of 105 consecutive patients with coexistent AF and obesity (body mass index ≥ 28) were classified into 2 groups based on the monitoring method: group 1, use of digital platform (n = 20); group 2, conventional method (n = 85). Group 1 used the RfMx digital monitoring platform (smartphone app) that sets weekly goals for exercise and weight loss, tracks patient compliance data continuously, and sends regular text reminders. Conventional method included monitoring patients' adherence to diet and change in weight during in-person clinic visits or monthly phone calls from staff.

RESULTS Baseline characteristics of groups 1 and 2 were comparable. At 6 months of follow-up, 12 (60%) and 28 (33%) from group 1 and 2, respectively, were compliant with the physician instructions regarding diet and exercise ($P = .025$). Weight loss was observed in 9 of 12 (75%) from group 1 and 11 of 28 (39%) from group 2 ($P = .038$) and mean reduction in weight was 9.9 ± 8.9 lb and 4.0 ± 2.1 lb ($P = .042$).

CONCLUSION In this series, continuous digital monitoring was seen to be associated with significant improvement in compliance through better patient engagement, resulting in more weight loss compared to the conventional method.

KEYWORDS Digital monitoring; App; Lifestyle change; Weight loss; Atrial fibrillation

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Introduction

Several studies in the last few years have reported the benefits of weight reduction in patients with atrial fibrillation (AF).^{1–4} A randomized trial by Abed and colleagues¹ demonstrated reduction in AF symptom burden and severity and favorable cardiac remodeling with weight reduction and risk factor management. The ARREST-AF trial² observed significantly higher ablation success rate after efficient risk factor and weight management. The LEGACY study³ reported the same advantages at 5 years of follow-up in patients with sta-

ble weight loss. Finally, the CARDIOFIT study⁴ documented beneficial effects of improvement in cardiorespiratory fitness on AF burden and symptom severity. Of note, study participants with $>5\%$ weight fluctuation in the LEGACY trial were observed to have significantly higher risk of AF recurrence.³ Patient involvement and regular interaction with the clinical staff played a key role in plan adherence and persistence.³

Poor compliance to lifestyle changes, including diet and exercise, is a well-known challenge encountered by physicians worldwide. Thus, the search to find a better solution to maintain patient engagement has been escalated in recent years, with the primary focus on digital platforms, as these are widely accessed by the global population and provide an easy means of delivering health interventions.⁵ In the

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KEY FINDINGS

- Utilization of the digital app in the smartphone was associated with higher compliance to weight loss measures (diet and exercise) compared to the conventional methods.
- Weight loss was more pronounced in patients using the digital application.
- In nonparoxysmal atrial fibrillation patients, weight loss did not show a correlation with ablation outcome.

current pilot study, we investigated the impact of patient engagement using a digital monitoring system on compliance for lifestyle-change measures and subsequent outcome.

Methods

The current study evaluated a novel software application (app) (RFMx; RFMx, Inc, Austin, TX) to track and monitor compliance in overweight and obese AF patients. Consecutive AF patients attending our clinic were screened and those with body mass index (BMI) of $>28 \text{ kg/m}^2$ that used a smartphone with cellular service, were willing to adhere to study restrictions, and consented to participate were included in this pilot trial. Patients with inability to participate in the exercise program secondary to physical disabilities or heart failure and those with structural or rheumatic heart disease were excluded. All of them received written and verbal advice on heart-healthy diet and moderate-intensity exercise from the RFMx health coach at baseline. The primary objective of the study was to evaluate the software platform in the clinic setting to track and stratify patients with AF based on the biometrics. Additionally, the study also evaluated the efficacy of the RFMx platform in intervening with health coaching and monitoring compliance for the lifestyle change recommendations. Patients who met the study criteria were given a fitness tracker to track sleep, activity, and heart rate; Bluetooth-enabled weight scale, and blood pressure cuff paired to the RFMx app on their smartphone. They were teamed up with a health coach who created a tailored 12-week diet and exercise program using telehealth- and text-based interventions to help patients achieve at least a 10% reduction of body weight over the training period that was tracked via the app. The study was approved by the institutional review board and all participants signed an informed consent.

Weight loss and adherence to lifestyle recommendations in the study participants (group 1) was compared with a control group of contemporary consecutive AF patients that were monitored by conventional method (group 2).

Group 1 used the RFMx digital monitoring platform, a HIPAA-secure cloud-based smartphone app that can connect to all Bluetooth-enabled wearable fitness devices. System

flow of the RFMx app is shown in the schematic in [Figure 1](#). The app set weekly goals for calorie intake, exercise, and weight loss based on the BMI; tracked patient compliance and health data continuously; and sent periodic text reminders.

Group 2 used the conventional method, which included monitoring patients' adherence to diet and change in weight during in-person clinic visits or monthly phone calls from staff.

All of these patients received catheter ablation for AF. Standard institutional protocol was followed to perform electrical isolation of the pulmonary veins (PV) and left atrial posterior wall. PV antrum isolation was performed guided by circular mapping catheter and intracardiac echocardiography using an irrigated-tip catheter (temperature: 42°C , lesion duration: 30–40 seconds, and power: 45–50 W). Posterior wall isolation was accomplished using multiple ablation points covering the whole posterior wall. A temperature probe was routinely placed in the esophagus. Radiofrequency applications were limited to 20 seconds at a single location over the esophagus and immediately halted if the temperature reached 39°C or rapidly rose. Complete abolition of all PV potentials rather than decrease in the amplitudes was the endpoint and confirmed by entrance and/or exit block.

Follow-up

All patients were followed up for 6 months with office visits, cardiology evaluation, 12-lead electrocardiogram, and 7-day Holter monitoring at 1 and 6 months. Additionally, patients were provided with event recorders for the first 5 months following the procedure and were asked to transmit their rhythm every time they had symptoms compatible with arrhythmias and at least 3–4 times a week even if asymptomatic.

Previously ineffective antiarrhythmic drugs (AAD) were prescribed to the patients during the 12-week blanking period, after which all AAD were discontinued. Ablation success was defined as absence of arrhythmia off AAD.

The research reported in this article adhered to the Helsinki Declaration as revised in 2013 guidelines.

Statistical analysis

Continuous variables were reported as mean (standard deviation) and categorical data were presented as absolute frequencies (percentage). Descriptive analysis was performed summarizing age, sex, risk factors, presenting symptoms, and comorbidities. The Student *t* test was used to compare continuous data and the χ^2 test was used to compare categorical data. All tests were 2-sided and $P < .05$ was considered as statistically significant. The analysis was performed using SPSS Statistics 25.0 (IBM SPSS Inc, Chicago, IL).

Results

A total of 20 patients were included in group 1 and 85 in group 2. Digital app monitoring was offered to 31 consecutive patients, of which 20 (64.5%) accepted. Patients declined majorly because either they were not familiar with or they did not feel comfortable about using apps in their phone.

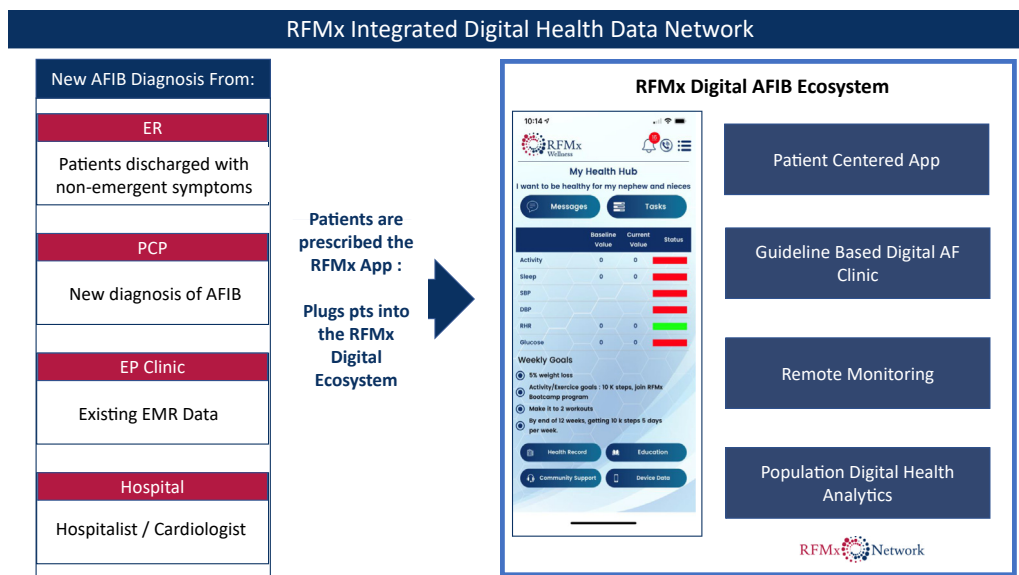


Figure 1 Schematic showing RFMx app (RFMx, Inc, Austin, TX) system flow. AF = atrial fibrillation; AFIB = atrial fibrillation; EMR = electronic medical record; EP = electrophysiology; ER = emergency room; PCP = primary care physician.

Baseline characteristics of the study population are provided in Table 1. None of the parameters were significantly different between groups. Nineteen of 20 (95%) patients in group 1 and 78 of 85 (91.8%) in group 2 had the baseline BMI $>30 \text{ kg/m}^2$ ($P = .62$).

At 6 months of follow-up, 12 (60%) and 28 (33%) patients from group 1 and 2, respectively, were compliant with the physician instructions regarding diet and exercise ($P = .025$). Weight loss was observed in 9 of 12 (75%) from group 1 and 11 of 28 (39%) from group 2 ($P = .038$) and mean reduction in weight was $9.9 \pm 8.9 \text{ lb}$ and $4.0 \pm 2.1 \text{ lb}$ ($P = .042$) (Figure 2).

One patient from group 1 (1/20, 5%) and 4 from group 2 (4/85, 4.7%) experienced arrhythmia recurrence off AAD during the 6-month follow-up ($P = .95$). Of these 5 patients, 3 had persistent AF and 2 had long-standing persistent AF (LSPAF) at baseline. Both patients with LSPAF and 1 of the 3 with persistent AF (all from group 2) had lost $>10\%$ of the body weight at the end of the follow-up. The remaining 2 patients (1 each from groups 1 and 2) were not compliant with the weight loss instructions and app use.

Discussion

Obesity, a known risk factor for AF, is potentially reversible through lifestyle changes, including diet and physical activity. However, poor health behaviors and resistance to lifestyle interventions are commonly observed worldwide, making weight loss and maintenance of healthy habits challenging. In the current pilot study, we investigated the impact of digital monitoring in improving compliance to weight loss measures. Our main findings were the following: (1) higher compliance was observed in patients that were monitored using the phone app, (2) weight loss was more prevalent and pronounced in the same group compared to those receiving

the conventional monitoring method, and (3) weight loss did not seem to impact arrhythmia recurrence in nonparoxysmal AF cases.

Technological innovations continue to become exceedingly ingrained into everyday life and increasing numbers of consumers are beginning to use software and hardware devices to manage their health.⁵ Approximately 90% of adults in the United States and United Kingdom use the internet and 91% of millennials in these countries own smartphones.⁶ Given the nearly universal accessibility of digital media and the affordability of programs using these platforms, it is not surprising that there is now considerable interest in developing digital interventions for behavior change.⁶

In this pilot study, remote guidance and support by the diet and exercise coach and periodic reminders to follow lifestyle recommendations were seamlessly delivered through the app

Table 1 Baseline characteristics of study population

	Group 1 N = 20	Group 2 N = 85	P value
Age (years)	65.7 ± 10.8	67.4 ± 8.6	.45
Male	12 (60%)	48 (57%)	.77
Body mass index (kg/m^2)	34.5 ± 3.4	35.0 ± 3.7	.58
Hypertension	12 (60%)	45 (52.9%)	.74
Diabetes	8 (40%)	37 (43.5%)	.78
Dyslipidemia	16 (80%)	65 (76.5%)	.78
Coronary artery disease	5 (25%)	11 (12.9%)	.30
Congestive heart failure	4 (20%)	16 (18.8%)	1.00
Body weight (lb)	226.4 ± 37.5	219.7 ± 23.5	.90
Obstructive sleep apnea	9 (47.4%)	36 (42.3%)	.83
Paroxysmal AF	12 (63.2%)	49 (57.6%)	.95
Persistent AF	5 (25%)	24 (28.2%)	.77
Long-standing persistent AF	3 (15%)	12 (14.1%)	.91

Values are mean $\pm$ SD or n (%).

AF = atrial fibrillation.

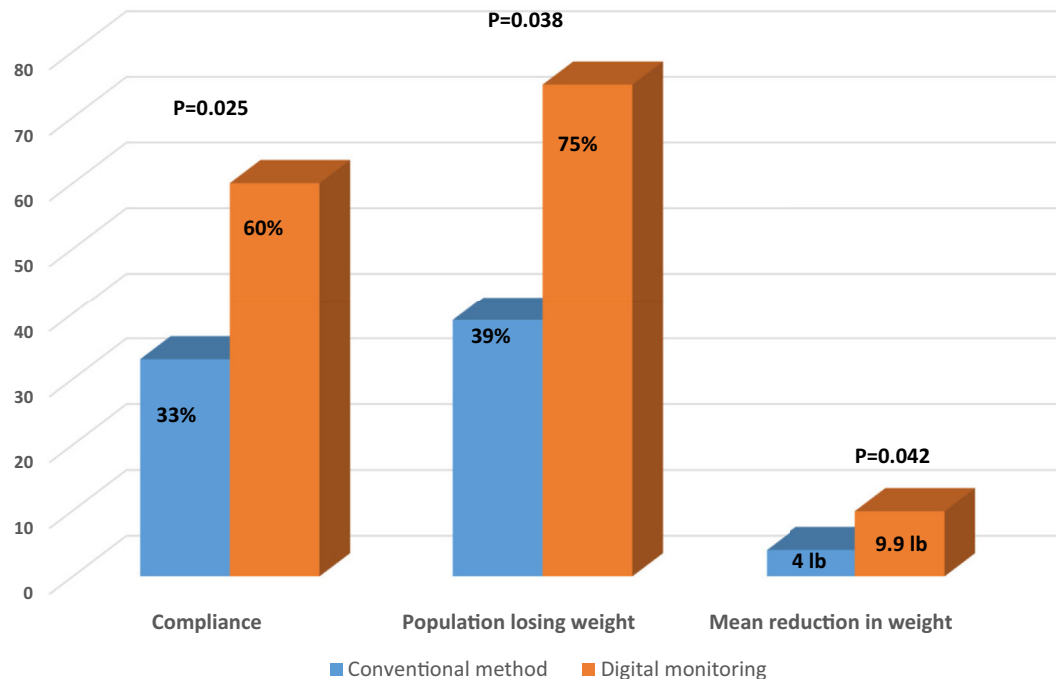


Figure 2 Bar diagram showing patient compliance and weight loss measures at 6 months. At 6 months of follow-up, 12 (60%) and 28 (33%) patients from group 1 and 2, respectively, were compliant with the physician instructions regarding diet and exercise ($P = .025$). Weight loss was observed in 9 of 12 (75%) from group 1 and 11 of 28 (39%) from group 2 ($P = .038$) and mean reduction in weight was 9.9 ± 8.9 lb and 4.0 ± 2.1 lb ($P = .042$).

to our study participants. Patients were asked to log in their daily diet intake and exercise intensity. The user-friendly application not only was very well accepted by the patients, but also motivated them to stay compliant with the suggested weight-management measures. The opportunity to connect with the remote lifestyle coach as needed and the text reminders were the most plausible reasons for increased patient engagement and improved compliance. In the mActive randomized trial,⁷ participants enrolled in the text-messaging group (positive reinforcement or boosting messages) increased their daily steps substantially compared to the no-texting group. In another study on real-world patients with obesity and diabetes, digital lifestyle change programs effectively supported in achieving weight loss.⁸ A systematic review with meta-analysis demonstrated the text-messaging interventions to be associated with improved physical activity.⁹

Reversal of obesity improves procedure outcome in AF patients undergoing catheter ablation. In a study conducted by our group, patients having sporadic AF recurrence with coexistent metabolic syndrome and obstructive sleep apnea received a personalized calorie-controlled diet plan and were asked to maintain moderate-intensity physical activity.¹⁰ At the end of the 20 ± 6 months follow-up period with diligent monitoring, 74% of the compliant patients remained arrhythmia-free and freedom from recurrence was significantly associated with weight loss.¹⁰ However, it is important to mention that we did not see a correlation between weight loss and arrhythmia recurrence in nonparoxysmal AF cases, especially LSPAF. This finding was in agreement with one of our earlier studies, where patients with rigorous weight loss interventions did not show

improvement in symptom severity and ablation outcome at 1-year follow-up after a single procedure, despite significant reduction in weight.¹¹ We believe that in LSPAF, considered as a “permanent” arrhythmia, the advanced degree of substrate remodeling is beyond reversal by the modulating effects of weight loss, especially within few months after initiation of weight loss accomplished by diet and exercise interventions without optimization of concomitant risk factors.¹¹

The significance of digital applications has become more prominent in the current era of the COVID-19 pandemic, when social isolation, limitations in outdoor activities, working from home, and reluctance to come to the hospital for in-person check-ups have boosted the need for remote monitoring and encouragement from healthcare workers to maintain a healthy lifestyle. Thus, the relevance of our study findings cannot be overemphasized in the present context. Moreover, it is a dynamic, ever-evolving, and widely utilized field that has the potential of getting better, establishing more real-time interactions between healthcare providers and receivers and encouraging people to maintain a healthy lifestyle.

Limitations

Small sample size was a major limitation of this study. However, participants were consecutively enrolled and the results were compared with a larger population (control group) that was not monitored using the app. Secondly, results were available at 6 months of follow-up and not longer. Therefore, our findings cannot be used to project long-term weight loss facilitated by frequent checking with the digital app.

Conclusion

In this series, using a digital network with a patient-centered app connected to digital devices tracking biometric data in AF patients was associated with significant improvement in compliance through patient engagement, resulting in significantly greater weight loss compared to the conventional method. Larger trials are warranted to validate our study findings.

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Disclosures

Dr Natale is a consultant for Boston Scientific, Biosense Webster, St. Jude/Abbott Medical, Biotronik, Baylis, and Medtronic. The remaining authors have nothing relevant to disclose.

Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

All patients provided written informed consent.

Ethics Statement

The authors designed the study and gathered and analyzed the data according to the Helsinki Declaration guidelines

on human research. The research protocol used in this study was reviewed and approved by the institutional review board.

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