


Smartphone ECG Monitoring System Helps Lower Emergency Room and Clinic Visits in Post-Atrial Fibrillation Ablation Patients

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ABSTRACT

AIM: To evaluate the effectiveness of using a smartphone-based electrocardiography (ECG) monitoring device (ECG Check) on the frequency of clinic or emergency room visits in patients who underwent ablation of atrial fibrillation (AF).

METHODS: Two groups of patients were identified and compared: The conventional monitoring group (CM group) included patients who were prescribed conventional event monitoring or Holter monitoring systems. The ECG Check group (EC group) included patients who were prescribed the ECG Check device for continuous monitoring in addition to conventional event monitoring. The primary outcome was the number of patient visits to clinic or emergency room. The feasibility, accuracy, and detection rate of mobile ECG Check were also evaluated.

RESULTS: Ninety patients were studied (mean age: 66.2 ± 11 years, 64 males, mean CHA₂DS₂-VASc score: 2.6 ± 2). In the EC group, forty-five patients sent an average of 52.8 ± 6 ECG records for either routine monitoring or symptoms of potential AF during the follow-up period. The rhythm strips identified sinus rhythm (84.7%), sinus tachycardia (8.4%), AF (4.2%), and atrial flutter (0.9%). Forty-two EC transmissions (1.8%) were uninterpretable. Six patients (13%) in the EC group were seen in the clinic or emergency room over a 100-day study period versus 16 (33%) in the standard care arm (P value < 0.001).

CONCLUSIONS: Use of smartphone-based ECG monitoring led to a significant reduction in AF-related visits to clinic or emergency department in the postablation period.

KEYWORDS: Mobile ECG, atrial fibrillation, atrial ablation

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Introduction

Atrial fibrillation (AF) is the most commonly encountered arrhythmia in clinical practice.¹ Its prevalence increases with advancing age, affecting around 10% of the general population by the age of 80 years.^{2,3} Atrial fibrillation carries an increased risk for long-term cardiovascular complications including cerebrovascular accidents, heart failure, dementia, and even death.^{4–8} Radiofrequency ablation is a very commonly performed procedure for rhythm control in patients who have already failed antiarrhythmic drug therapy.^{9–12} However, it is not uncommon for AF episodes to occur asymptotically in the postablation

period.^{13–15} Arrhythmia monitoring in the postablation period is important to assess for ablation efficacy and early recurrence, which identifies patients at higher risk for requiring repeat ablation, anticoagulation therapy, and antiarrhythmic therapy.^{16,17} Yet, limited data are available regarding the optimal duration of cardiac monitoring after AF ablation.¹⁸ The current ambulatory monitoring devices used in AF management are basically divided into 2 groups: noncontinuous monitoring system and continuous monitoring systems.¹⁹ Despite the various tools that are currently used for detecting AF recurrences, they are expensive, time-limited, and sometimes involve invasive procedures to be implanted. Continuous monitoring tools are more sensitive in detecting AF recurrences, especially in patients who undergo an ablation procedure due to a higher incidence of

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Figure 1. Transmission of ECG Check device ECG recordings. ECG indicates electrocardiography.

asymptomatic recurrences.^{20,21} Nonetheless, the sensitivity of noncontinuous monitoring improves significantly with higher frequency and longer duration of monitoring.^{22,23} Data from implantable electronic devices have shown earlier detection of AF episodes and improved quantification of AF burden with remote monitoring.²⁴⁻²⁷ Recently, there has been a rapid change in the field of AF monitoring, particularly with the introduction of smartphone-based electrocardiography (ECG) technology. In addition to its accuracy in detecting arrhythmia, using smartphone-based ECG technology has been shown to be an attractive option for patients due to its ease of use.²⁸

The ECG Check device (Cardiac Designs Inc, San Francisco, CA) is an over-the-counter smartphone-based ECG monitor that is FDA 510k cleared (K170506) and is CE Marked (0086).²⁹ The device uses 2 metal pads which measure a single-lead electrical tracing and wirelessly transmits this transmission to the paired smart device via the Bluetooth protocol (Figure 1).

In this study, we evaluated the sensitivity and specificity of the ECG Check device as well as its impact on the frequency of visits to the emergency department (ED) and outpatient clinic.

Methods

Study design

This is a single-center retrospective study of patients with AF who underwent ablation in the University of Utah hospital between 2015 and 2017. An ethical exemption review was obtained from the University of Utah Institutional Review Board before the study commenced. Two study groups were defined in our study, conventional monitoring group (CM group) and ECG Check group (EC group). All patients in the EC group received an ECG Check device compatible with iPhone (Apple Inc, Cupertino, CA) or Android in addition to the conventional ambulatory ECG monitor (external cardiac event monitor, mobile cardiac monitor, or Holter monitor) as part of the routine clinical management. Patients in the CM group were monitored exclusively via a conventional ambulatory ECG monitor.

EC group inclusion criteria included the following: (1) Patients aged > 18 years who underwent atrial ablation, (2) Patients who own and can operate a smartphone and the ECG

Check device, (3) Patients who underwent at least 1 atrial ablation procedure, (4) Patients who underwent at least 30 consecutive days of continuous conventional monitoring, and (5) Patients who attended at least 2 follow-up clinic visits. We excluded the following: (1) Patients unwilling to send daily ECG transmissions and declined the use of the ECG Check device, (2) Patients who did not own or could not operate a smartphone, and (3) Patients who were lost to follow-up.

Postablation management and follow-up

In our center, the standard of postablation care requires patients to be seen in an outpatient setting at least once in the first 3 months after ablation and every 6 months for 2 years thereafter. In addition, patients routinely receive cardiac event monitors for 30 days after ablation.

ECG Check monitoring protocol

In the EC group, ECG transmissions were obtained using the ECG Check device and its corresponding application found in the iTunes App Store or Google Play. The application measures a 30-second strip when it detects an adequate signal and subsequently saves the ECG strip. It then automatically tags the rhythm strip with either a red button in the setting of arrhythmic rhythm or a green button in case of sinus rhythm. It also provides an option to either transmit the recording to the server where it can be reviewed by a health care provider from the website or send to a secure e-mail account of the University of Utah Hospital to be reviewed by a health care provider.

Patients transmitted ECG transmissions for any reason they judged appropriate. All patients were asked to send daily ECG transmissions, regardless of their symptoms. Patients were also instructed to send ECG transmissions if experiencing any AF symptoms.

The protocol used in this study is described in Figure 2. Patients were instructed to call the cardiovascular center at the University of Utah if their obtained rhythm strip was tagged with a red button or they experienced symptoms related to the AF or the ablation procedure. Figure 3 demonstrates an example of a patient-provider communication to

Protocol of ECG Transmission Triage

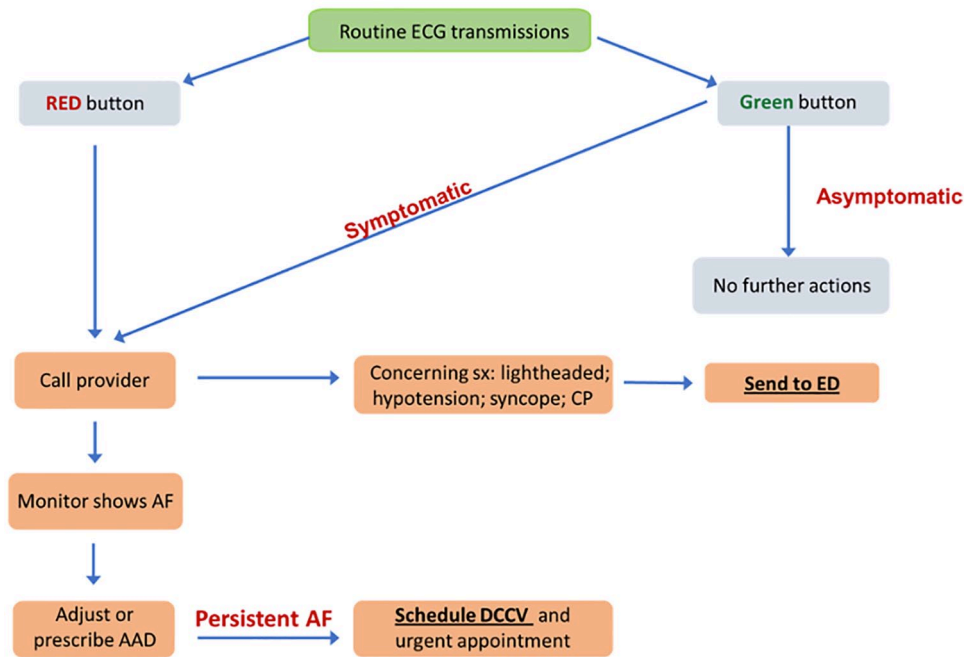


Figure 2. ECG Check clinical algorithm. AAD indicates antiarrhythmic drug; AF, atrial fibrillation; CP, chest pain; DCCV, DC cardioversion; ED, emergency department.

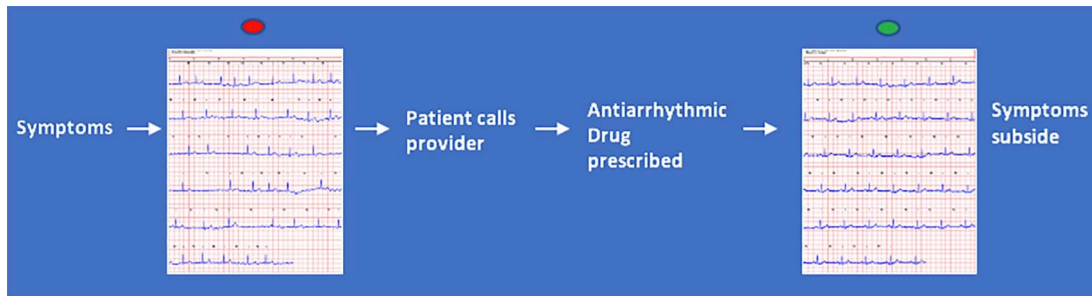


Figure 3. Patient-provider communication to manage AF episode detected on ECG Check device. AF indicates atrial fibrillation; ECG, electrocardiography.

convert an AF episode and avoid an ED visit. Two independent experienced ECG readers (W.C. and B.Z.) reviewed all ECG transmissions.

Statistical analysis

Clinical data are reported as means and standard deviations for continuous variables and as frequencies for categorical variables. Multivariable analyses were performed adjusting for potentially confounding risk factors such as age, gender, diabetes mellitus, hypertension, congestive heart failure, reablation, smoking, medications, body mass index, and most importantly the duration of continuous arrhythmia monitoring. Differences in AF detection rates between the study groups were assessed using Cox proportional hazards models. Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC). A *P* value of less than 0.05 was used for significance in all analyses.

Results

Patient characteristics

Ninety patients were enrolled in our study between March 2015 and April 2017 (45 patients were enrolled in the CM group and 45 patients were enrolled in the EC group). The average age of the patient population was 66 years. Sixty-four patients were males. Sixty-six patients (73%) had repeat AF ablations. The clinical characteristics of the patient population are summarized in (Table 1). There were no significant differences between the 2 groups in baseline characteristics.

Electrocardiography transmissions

In the EC group, the average ECG transmissions per patient sent via a smartphone-based monitor was 52.8 for either routine monitoring or symptoms of potential AF. A total of 2378 transmissions were received during a 100-day follow-up period.

Table 1. Baseline clinical characteristics.

	EC GROUP (N=45)	CONVENTIONAL GROUP (N=45)	P VALUE
Age (years)	61.3 ± 7.7	60.9 ± 7.4	0.803
Female, % (n)	37.8 (17)	42.2 (19)	0.667
BMI (Kg/m ²)	29.9 ± 2.8	30.0 ± 2.9	0.970
CHA ₂ DS ₂ -VASc	3.1 ± 1.2	2.4 ± 1.6	0.056
Reablation, % (n)	60.0 (27)	68.9 (31)	0.378
Coronary artery disease, % (n)	26.7 (12)	24.44 (11)	0.809
Mitral valve disease, % (n)	6.7 (3)	6.7 (3)	1.000
Diabetes mellitus, % (n)	62.2 (28)	53.3 (24)	0.393
Hypertension, % (n)	53.3 (24)	48.9 (22)	0.673
Ejection fraction (%)	53.5 ± 7	50.5 ± 8.4	0.071
Hyperlipidemia, % (n)	66.7 (30)	60.0 (27)	0.512
Long-term obstructive pulmonary disease, % (n)	8.9 (4)	11.1 (5)	0.725
Obstructive sleep apnea, % (n)	22.2 (10)	15.6 (7)	0.417
Pulmonary hypertension, % (n)	11.1 (5)	11.1 (5)	1.000
History of stroke/TIA, % (n)	8.9 (4)	6.7 (3)	0.694
Thyroid disease, % (n)	8.9 (4)	11.1 (5)	0.725
Smoker, % (n)	24.4 (11)	33.3 (15)	0.352
AF type			
Paroxysmal, % (n)	51.1(23)	53.33 (24)	0.833
Persistent, % (n)	48.9 (22)	44.4 (20)	0.673

Abbreviations: AF, atrial fibrillation; BMI, body mass index; EC, ECG Check; ECG, electrocardiography; TIA, transient ischemic attack.

All ECG Check ECG transmissions were obtained by patients outside of the health care setting. Most ECG transmissions obtained from the EC group were marked as sinus rhythm (84.7%). Two hundred ECG transmissions were sinus tachycardia (8.4%), 100 ECG transmissions were interpreted as AF (4.2%), 21 ECG transmissions were consistent with atrial flutter (AFL) (0.9%), and 42 ECG transmissions (1.8%) were uninterpretable (Figure 4).

Number of ED and outpatient department visits

Six patients (13%) in the EC group were seen for a nonscheduled outpatient department (OPD) or ED visit for AF-related complaints over a 100-day study period, whereas 16 patients (33%) in the CM group visited the OPD or ED for AF-related complaints (P value < 0.001). There was a statistically significant difference with respect to AF-related OPD visits (6 vs 16; $P=0.03$). Patients in the CM group visited the ED twice as much as those enrolled in the EC group for AF management (3 vs 6; $P=0.39$) (Figure 5). All OPD and ED visits by the EC group were directed by health care providers due to arrhythmia on ECG Check.

Total ECG transmissions received in 100 day study period

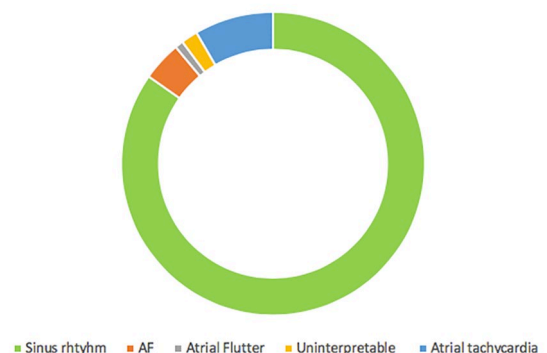


Figure 4. Total ECG recordings transmitted via ECG Check devices over 100 days. AF indicates atrial fibrillation; ECG, electrocardiography.

Sensitivity and specificity of ECG Check in detecting arrhythmias

ECG Check device detected AF/AFL rhythm 100% correctly. The sensitivity and specificity of the ECG Check device for detecting AF is 100% and 97%, respectively. All AFL cases (3) on conventional monitors were detected via ECG Check

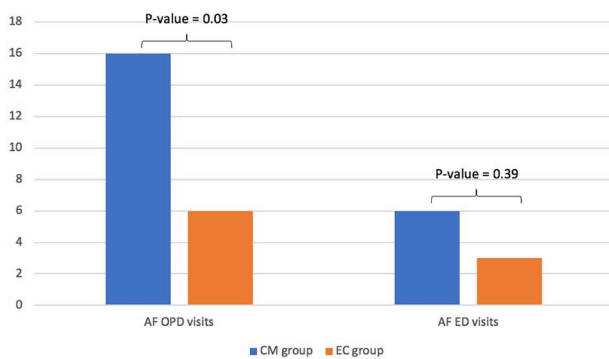


Figure 5. Number of AF-related outpatient department (OPD) and ED visits for EC group and conventional group. AF indicates atrial fibrillation; CM, conventional monitoring; EC, ECG Check; ECG, electrocardiography; ED, emergency department.

Table 2. κ statistic to assess agreement between simultaneous ECG Check and standard rhythm monitoring recordings (n=800).

ECG CHECK	TRADITIONAL MONITOR DEVICE (CEM, MCT, HOLTER)			
	SINUS	AF	ATRIAL FLUTTER	TOTAL
Sinus	737	0	0	737
AF	0	50	0	50
Atrial flutter	1	0	12	13
Total	738	50	12	800

Abbreviations: AF, atrial fibrillation; CI, confidence interval; ECG, electrocardiography; CEM, continuous event monitor; MCT, mobile cardiac telemetry. $\kappa = 0.78$ (95% CI 0.69-0.87).

device, indicating a 100% sensitivity and 100% specificity for detecting AFL. Overall, considering AF and AFL as a single rhythm state, the ECG Check device had a 100% sensitivity and 97% specificity for detecting AF/AFL (Table 2). The false-positive rate was 2.89%. Cohen's kappa coefficient (κ) was 0.78 (95% confidence interval [CI] 0.69-0.87), which indicates a substantial agreement between ECG Check device ECG transmission and the conventional ambulatory ECG monitor ECG transmission.

After 100 days of monitoring, all patients in the EC group reported using the device easily. In addition, there was no difference in the rate of hospitalizations between the EC group and the CM group; no deaths occurred during follow-up.

Discussion

This study has shown that the ECG Check device is highly sensitive and specific in detecting atrial arrhythmias in the postablation period. In addition, we have shown for the first time that the use of ECG Check device in the outpatient setting has led to a remarkable reduction in OPD and ED visits for post-AF ablation patients.

These findings are highly important because early AF recurrence can be used to predict the long-term success of AF ablation, and hence, appropriate monitoring during the blanking

period may help physicians identify patients who are at a higher risk of treatment failure. Recent data have shown significant association between early post-AF ablation arrhythmia burden and AF recurrence, mortality, and hospitalization.³⁰⁻³² Moreover, early recurrences, mainly after 1 month of ablation has been shown to predict long-term procedural failure and promote early reablation.³³ Also, early arrhythmia monitoring after ablation can aid in initiating and adjusting antiarrhythmic and atrioventricular nodal blocking medications after ablation.¹⁶⁻¹⁸

Among patients in the EC group, a significant reduction in the number of AF-related OPD visits was observed compared with patients in the CM group. Also, the number of AF-related ED visits was lower among patients in the EC group patients compared with patients in the CM group. Patients in the EC group had access to instant feedback from their health care providers regarding their symptoms and ECG transmissions as health care providers were able to guide management upon reviewing ECG transmissions by reassuring the patient, modifying therapy, or asking the patient for an OPD or ED visit. In addition, instant feedback enabled health care providers to, remotely, distinguish between symptoms related to AF/AFL or symptoms related to other benign causes, which reduced the need for unnecessary OPD or ED visits. This is an important part of postablation management as patient-reported symptoms have been shown to poorly correlate with AF recurrence; it has been shown that 40% of patients reporting AF-related symptoms did not have evidence of AF recurrence on their implantable device monitor memory.³⁴

Implications for clinical practice

Smartphone-based ECG monitoring devices have been shown to be accurate in AF and AFL rhythm detection.^{28,35,36} Two previous studies have shown that the usage of smartphone-based ECG monitors is actually cost-effective in diagnosing AF and preventing complications, such as stroke.^{35,36} Tarakji et al²⁸ have demonstrated that smartphone-based ECG monitoring improves patient compliance by almost 39% compared with patients monitored with conventional ECG monitors. Recently, Hickey et al^{37,38} published pilot cohort data from within the iHEART randomized clinical trial, which is assessing the efficacy of mobile health technology on AF detection, clinical outcomes, and patient's quality of life. The preliminary data have shown that over a 6-month follow-up period, patients who were given smartphone-based ECG monitors had more than double the detection rate of AF/AFL recurrence compared with patients monitored via conventional ECG monitors (61% vs 30%).³⁷ In addition, patients using smartphone-based ECG monitors had a significant improvement in quality of life over the 6-month follow-up period.³⁷ Our study has shown that smartphone-based ECG monitoring devices improve health care usage. We think that expanding the use of smartphone-based ECG monitoring devices would lead to more accurate assessment of patients' postablation condition and

procedural success, which in turn would allow earlier change in management to prevent dreadful AF complications, such as stroke. Earlier detection of arrhythmia has been shown to improve survival rates.^{25,26} In addition, we believe that implementing smartphone-based ECG monitoring technology in daily clinical practice would improve patients' satisfaction and compliance. More studies are needed to further assess the impact of smartphone-based ECG monitoring technology on AF clinical outcomes.

Limitations

One limitation of this study is that it is a retrospective study conducted in a single institution. ECG Check is a smartphone-based device, and the population included in this study solely comprised patients able to operate a smartphone, which might not be representative of the general AF patient population.

Conclusions

Smartphone-based ECG monitoring can potentially lower the burden of OPD and ED AF-related visits in the postablation period. ECG Check device is highly sensitive and specific in detecting AF and AFL in a postablation population.

Authors' Note

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Author Contributions

M.A. and Q.M. collected data, performed statistical analysis, analysed data, contributed to study design, and wrote the paper. I.T., J.A., M.B., and R.B. contributed to data collection and paper review. B.Z. and W.C. reviewed all ECG transmissions. N.F.M. conceived the original idea and study design. M.G.C. and N.F.M. supervised the research project, reviewed data collection and analysis, and edited the manuscript. All authors discussed the results and commented on the manuscript.

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