Atrial fibrillation future clinic. Novel platform to integrate smart device electrocardiogram into clinical practice

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BACKGROUND Direct-to-consumer devices allow patients to record electrocardiograms (ECG) and detect atrial fibrillation (AF). Clinical adoption of these devices has been limited owing to the lack of efficient workflow.

OBJECTIVE To assess a new care model for following patients after AF ablation that uses a smartphone ECG coupled with a novel cloud-based platform.

METHODS This was a pilot study to describe AF detection, healthcare utilization, use of additional ECGs and cardiac monitors, and changes in anxiety after AF ablation. Patients presenting 3–4 months after early successful AF ablation were randomized into a control group with standard clinical follow-up or a self-monitoring group using smartphone ECG (Kardia Mobile, KM) coupled with a cloud-based platform (KardiaPro, KP) that alerted the physician when AF was detected and followed for 6 months

RESULTS A total of 100 patients were randomized: 51 to the KM/KP group and 48 to the control group (1 withdrew). AF was detected in 18 patients (18.2%), 11 (21.6%) in the KM/KP group and 7 (14.6%) in the control group ($P = .42$). AF detection occurred at a median of 68 and 91 days in the KM/KP and control groups, respectively ($P = .93$). These differences were not statistically significant. Healthcare utilization and changes in anxiety were similar between the groups. More patients required additional ECGs or cardiac monitors in the control group (27.1%) compared to the KM/KP group (5.9%) ($P = .004$).

CONCLUSIONS Smartphone ECG with a cloud-based platform can be incorporated into the care of post–AF ablation patients without increasing anxiety and with less need for additional traditional monitors.

KEYWORDS Atrial fibrillation; Digital health; ECG monitoring; mHealth; Remote monitoring; Telehealth

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Introduction

Atrial fibrillation (AF) affects millions of patients and accounts for 450,000 hospitalizations and 150,000 deaths each year in the United States.[1] With an aging population, the incidence and prevalence of AF are expected to increase, leading to a significant economic impact on the healthcare system.[2–5] Long-term management of AF patients is complex and involves risk factor modification, stroke prevention, and rate and rhythm control.[6]

Advancement in digital health has led to the development of multiple direct-to-consumer devices that enable the user to record a rhythm strip on demand. These products have signaled a transformation of AF patient management and promised the provision of better and more effective care at a lower cost.[7,8] However, adoption in clinical practice has remained limited. A major hurdle is the lack of a clear workflow for triaging and managing data,[9] especially at a time when physician burden is becoming a common problem.[10] The majority of these devices allow the user to share their electrocardiogram (ECG) recordings with their healthcare providers as an e-mail attachment. These individual correspondences represent a logistical challenge to the healthcare providers.

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KEY FINDINGS

- Smartphone-based electrocardiography (ECG) using a cloud-based platform can be integrated successfully into the care of post–atrial fibrillation (AF) ablation patients.
- In a group of patients who had previously undergone successful AF ablation, rates of AF detection were similar between groups randomized to a smartphone-based ECG device (18.2%) and the standard of care (21.6%).
- Compared to patients randomized to monitoring using the smartphone-based ECG device, patients in the standard-of-care group required more additional ECGs or traditional cardiac monitors during the follow-up.
- Smartphone-based ECG monitoring can be incorporated into the care of post–AF ablation patients without increasing patient anxiety. Data from this study suggest the cloud-based platform can provide this increased level of monitoring without overburdening the caring clinician.

Kardia Mobile (KM) (AliveCor, Mountain View, CA) is a smartphone monitor enabling patients to record their heart rhythm. Recordings are 30 seconds in duration and analogous to a lead I rhythm strip. The KM device is coupled with an application that provides automated instant rhythm interpretation with the ability to detect possible AF (Figure 1). The KM received U.S. Food and Drug Administration clearance in November 2012 and the AF automated algorithm received clearance in August 2014.

The Kardia Pro (KP) platform was developed to allow patients' ECG recordings to be securely and seamlessly uploaded to the cloud. Once uploaded, these strips can be accessed by the care team without the need for direct e-mail communication. Importantly, the platform can be programmed to alert the caring physician if abnormal strips (AF detected or abnormal heart rates) are recorded by a patient. While many studies have examined the accuracy of the KM device and its automated algorithm for diagnosing AF,[11,12] there are no studies addressing how the data are managed by an arrhythmia clinic. Additionally, it remains unknown whether the adoption of this technology in clinical practice would lead to better outcomes or less use of resources. In fact, many direct-to-consumer devices rely on the model of patients e-mailing their recordings to their physicians, transforming the care into concierge medicine and limiting wider use. The primary objective of our study was to describe whether the adoption of KM through the use of the novel KP customized platform could be used for long-term AF detection after a successful AF ablation procedure compared to routine follow-up that is based on symptoms and intermittent cardiac monitoring as needed.

Methods

Study design and participants

This was a single-center, unblinded, randomized pilot study (ClinicalTrials.gov number NCT03557034) describing the impact of using KM with KP for long-term follow-up of patients after successful AF ablation. We targeted consecutive patients presenting to our center for their first outpatient follow-up 3 to 4 months after successful AF ablation. For this study, successful AF ablation was defined as freedom from documented AF episodes by ECGs or ambulatory

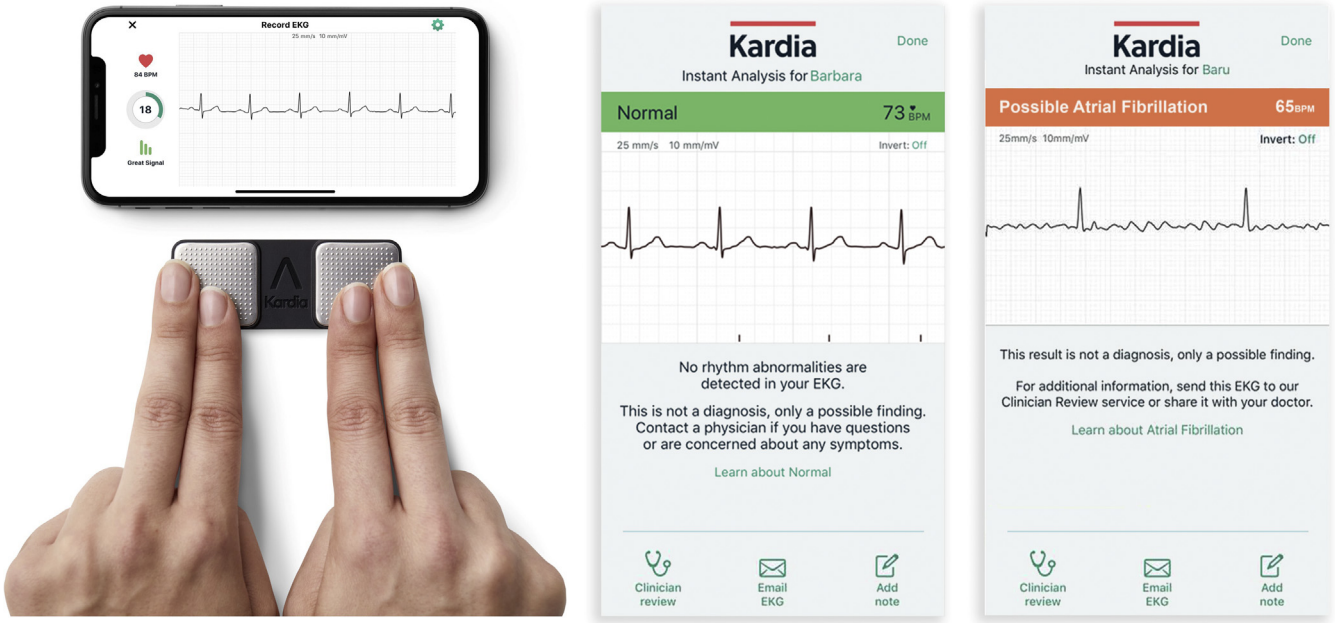

Figure 1 Example of a patient recording rhythm strip using a Kardia Mobile (AliveCor, Mountain View, CA) device paired with a smartphone app that provides instant interpretation of the rhythm as normal or possible atrial fibrillation.

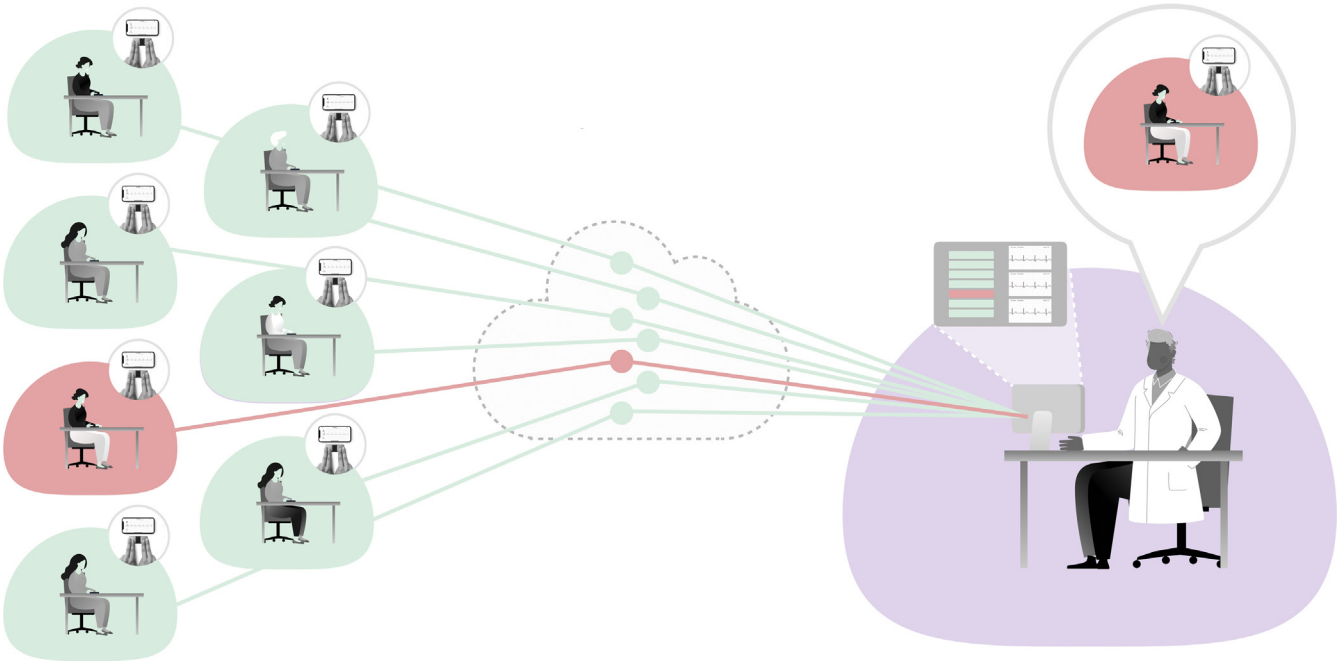

Figure 2 Patients in the Kardia Mobile (KM) (AliveCor, Mountain View, CA) / Kardia Pro (KP) arm were advised to record tracings at least once a week or any time they experienced symptoms. The automated algorithm provided immediate feedback to the patient with interpretation including "Normal" (represented in green) or "Possible AF" (represented in red). Recordings were automatically uploaded to the KP cloud-based platform, which was programmed to triage all abnormal recordings to the primary electrophysiologist's in-basket. All other recordings were accessible at any time on demand by the caring team.

transtelephonic monitor after the first 3 weeks blanking period following an AF ablation procedure. Potential participants were then screened and informed consent was obtained before enrollment. The research reported in this paper adhered to the Helsinki Declaration as revised in 2013 for human research, and to CONSORT guidelines for clinical trials.

To be included in the study, patients had to be between 18 and 85 years of age, have a compatible smartphone or tablet with internet access, have a history of paroxysmal or persistent AF, be presenting for their 3-to 4-month follow-up after successful AF ablation as defined in the study protocol, and be willing to follow up in 6–8 months. Patients with CHA_2DS_2-VASc score ≥ 1 had to stay on anticoagulation. We excluded patients with cardiac implantable electronic devices (pacemaker, defibrillator, loop recorder) or if the primary electrophysiologist decided the patient still needed cardiac rhythm monitoring through traditional monitors. Patients who were already using KM or other direct-to-consumer ECG recording devices were also excluded. Enrolled patients were then randomized in a 1:1 fashion into 2 groups: the standard-of-care (SOC, control) group, where patients were followed clinically based on symptoms and were not provided with a cardiac monitor at the time of randomization; and the self-monitoring (intervention) group, where patients were provided with the KM device and enrolled in the KP platform. Randomization was stratified based on the type of AF (paroxysmal or persistent). For patients in both arms and throughout the follow-up period, 12-lead ECGs or ambulatory cardiac monitors could be ordered as needed at the discretion of the primary electrophysiologist. Subjects in the KM/KP arm were provided with a KM device, which was paired with their smartphone device. They were advised to record tracings at least once a week or any time they experienced symptoms. All the recordings were automatically uploaded to the KP cloud-based platform. All caring electrophysiologists and arrhythmia clinic team members were given a user name and password to access the secure web-based KP platform. The KP software was programmed to triage abnormal recordings or recordings with possible AF to the primary electrophysiologist's in-basket in the KP dashboard. In addition, the KP platform was programmed to send the caring physician a weekly e-mail reminder if they had new abnormal recordings to review in their KP in-basket. All other recordings were accessible at any time on demand by the caring team (Figure 2). The follow-up duration was 6 months. Patients in both arms had the ability to contact the caring physician for any questions or symptoms. At the 6-month follow-up visit, all KM recordings were reviewed by the primary electrophysiologist. Additionally, at baseline and at the 6-month follow-up visit, participants were asked to answer the Generalized Anxiety Disorder 7-item scale questionnaire. The study design is illustrated in Supplemental Figure S1.

Assessments

The primary outcome of interest was AF detection within the 6-month follow-up period. Healthcare utilization related to AF was measured by the number of outpatient clinic visits, phone encounters, emergency room visits, hospitalization, or cardioversions occurring during follow-up. The study also assessed the use of additional 12-lead ECGs and

ambulatory cardiac monitors and changes in patient anxiety using the validated Generalized Anxiety Disorder 7-item anxiety scale.

Statistical analysis

Patients were analyzed according to their randomly assigned group (intention-to-treat principle). A sensitivity analysis was also conducted using the "as-treated" population to account for control patients that obtained a recording device on their own, or intervention patients that never used their assigned KM device. Categorical variables are reported as numbers and percentages of the total within each treatment group and compared using the χ^2 statistic. Continuous variables are reported as means and standard deviations and compared using the Student *t* test.

Kaplan-Meier methods were used to estimate the rate of AF detection and the log-rank statistic compared rates between the control and intervention arm.

Funding

The study was supported through an unrestricted research grant from AliveCor. AliveCor provided the KM devices but was not involved in the design or conduct of the study, the analysis of the data, or the writing of the manuscript.

Results

One hundred patients were enrolled and randomized in this study from April 2018 to July 2019. After enrollment and randomization, 1 patient withdrew consent. A summary flow chart is presented in Supplemental Figure S2.

Demographics and clinical characteristics were similar and are summarized in Table 1. The mean age was 64 ± 10 years and the majority were male (71%). The mean CHA_2DS_2-VASc score was 1.95 ± 1.328 among study participants and the majority were on apixaban for anticoagulation (51.5%). Subjects were randomized to SOC (control) group (n = 48) and KM/KP group (n = 51). Patients were followed for a mean of 5.6 ± 1.9 months, with 69% completing at least 6 months follow-up.

On average, patients in the KM/KP group transmitted 1.8 ± 2.2 tracings per week. Within 6 months of follow-up, 18 patients in the study (18.2%) had AF detected and confirmed after randomization. Seven (14.6%) of these were in the control group and 11 (21.6%) of these were in the KM/KP group (P = .42) (Figure 3).

Detection of AF occurred at a median of 91 days after randomization among the control group compared to 68 days among the KM/KP group (P = .93). Of note, there were 2 participants in each randomization group that crossed over to the alternative study group. In the as-treated analysis, AF was detected in 12.5% (n = 6/48) of the control group patients compared to 23.5% (n = 12/51) among the KM/KP patients (P = .16). This detection of AF occurred at a median of 106 days after randomization in the control group compared to 71.6 days for the KM/KP group (P = .89).

Healthcare utilization was similar between groups (Table 2). The mean number of phone encounters was 2.90 ± 6.2 in the control group and 1.96 ± 2.7 in the KM/KP group (P = .33). The average number of hospitalizations (0.17 ± 0.4 in SOC vs 0.25 ± 0.7 in KM/KP group, P = .48) and emergency room visits (0.19 ± 0.5

Table 1 Baseline patient characteristics

	All	Standard-of-care control group	Kardia Mobile / Kardia Pro[†] intervention group
Total number of patients	99	48	51
Age (mean ± SD)	64.0 ± 10.2	64.3 ± 11.8	63.8 ± 8.5
Female, n (%)	29 (29.3)	13 (27.1)	16 (31.4)
Race, n (%)			
White	95 (96.9)	44 (93.6)	51 (100)
Black	2 (2.0)	2 (4.3)	0
Asian	1 (1.0)	1 (2.1)	0
Highest educational level, n (%)			
High school	13 (13.7)	4 (8.7)	9 (18.4)
Some college	18 (18.9)	9 (19.6)	9 (18.4)
Associate's degree	13 (13.7)	7 (15.2)	6 (12.2)
Bachelor's degree	29 (30.5)	14 (30.4)	15 (30.6)
Master's degree	10 (10.5)	6 (13.0)	4 (8.2)
Doctoral/professional degree	12 (12.6)	6 (13.0)	6 (12.0)
Type of atrial fibrillation, n (%)			
Paroxysmal	49 (49.5)	23 (47.9)	26 (51.0)
Persistent	33 (33.3)	17 (35.4)	16 (31.4)
CHA_2DS_2-VASc, median (IQR)	2 (1, 3)	2 (1, 3)	2 (1, 3)
Anticoagulant, n (%)			
Apixaban	51 (51.5)	25 (52.1)	26 (51.0)
Dabigatran	4 (4.0)	1 (2.1)	3 (5.9)
Rivaroxaban	28 (28.3)	14 (29.2)	14 (27.5)
Warfarin	11 (11.1)	5 (10.4)	6 (11.8)

[†]AliveCor, Mountain View, CA.

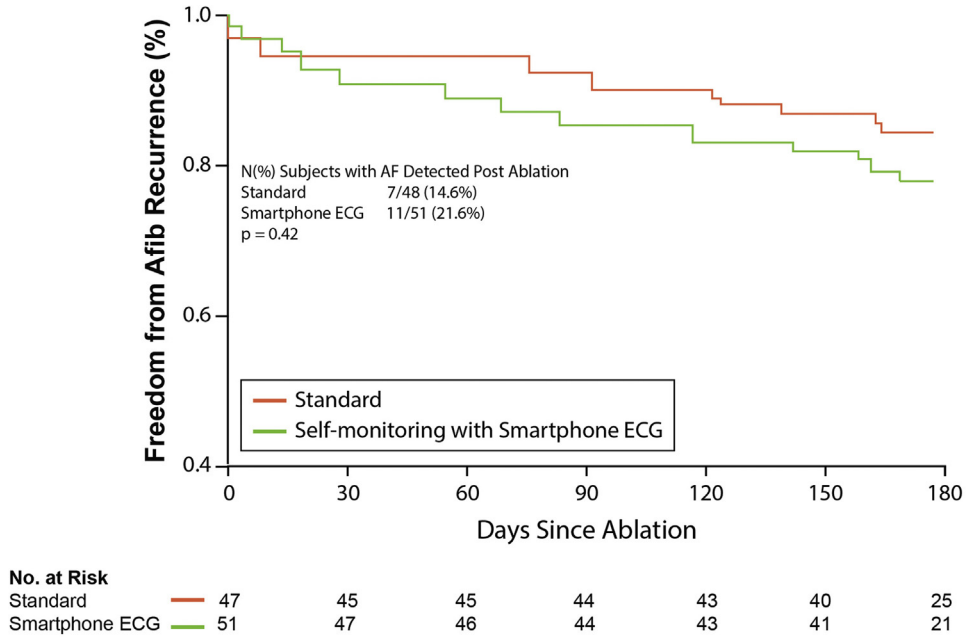

Figure 3 Kaplan-Meier curves for first atrial fibrillation atrial fibrillation detection between the standard-of-care control group and Kardia Mobile (KM) (AliveCor, Mountain View, CA) / Kardia Pro (KP) self-monitoring group. ECG = electrocardiogram.

in the control group vs 0.16 ± 0.4 in KM/KP group, $P = .74$) were also similar between study groups. More patients required additional ECGs and ambulatory heart rhythm monitors in the control group (27.1%) compared to the KM/KP group (5.9%) during the study period ($P = .004$). The change in anxiety level for the control group (-1.23 ± 4.52) and KM/KP group (0.00 ± 4.78) was similar ($P = .2$) over the study period (Table 3).

Discussion

Ablation is a well-established therapeutic option for symptomatic patients with AF.[13] After the procedure, patients are usually followed using arrhythmia transmitters; however, long-term follow-up after the first 3–4 months varies widely. The most recent consensus document for AF ablation recommends at least 3 visits (at 3, 6, and 12 months) with a 12-lead ECG at each visit and a 24-hour Holter monitor at 12 months. Additional event recorders can be used at regular periods or if the patient becomes symptomatic.[13] Follow-up beyond 1 year is encouraged and consists of periodic visits with ECG and Holters as needed. The consensus document also suggests the use of smartphone ECG for long-term follow-up but without clear guidance about the mechanism to handle or triage the data.[13]

In this single-center randomized pilot study, we examined the use of the patient's smart device for long-term follow-up after successful AF ablation that involves the use of a KM device combined with the use of a novel KP platform that allows the physician to access the patient's recordings remotely and on demand. We targeted patients who would have otherwise gone without additional cardiac monitoring, specifically those who presented for their first visit after successful ablation and were to remain on anticoagulation or had a CHA_2DS_2-VASc score of zero. This is a group of patients that usually does not require extensive additional monitoring.

Table 2 Healthcare utilization and electrocardiogram or cardiac monitor use among the control and Kardia Mobile / Kardia Pro groups

	Control group n = 48	Smartphone ECG KM/KP group n = 51	*P* value
Healthcare utilization			
Outpatient clinic visits	2.2 ± 2.7	3.3 ± 5.8	.23
Phone encounters	2.9 ± 6.2	2.0 ± 2.7	.33
Emergency room visits	0.19 ± 0.5	0.16 ± 0.4	.74
Hospitalizations	0.17 ± 0.4	0.25 ± 0.7	.48
Cardioversions, n (%)	1 (2.1)	1 (2.1)	.99
Additional ECGs or cardiac rhythm monitors	13 (27.1%)	3 (5.9%)	.004
ECG	2 (4.2)	0	
Kardia Mobile	2 (4.2)	0	
Extended rhythm monitor (patch)	6 (12.5%)	2 (3.9)	
Ambulatory continuous telemetry	3 (6.3)	1 (2.0)	

ECG = electrocardiogram; KM / KP = Kardia Mobile / Kardia Pro.

Table 3 Results from Generalized Anxiety Disorder 7-item scale among the control and Kardia Mobile / Kardia Pro groups

	Control group		Difference from baseline	Smartphone ECG KM/KP group		Difference from baseline	Absolute difference between groups	
Question	Pre	Post	(Post − pre)	Pre	Post	(Post − pre)	Smartphone ECG vs standard	*P* value
Nervous or anxious or on edge	23 (47.9)	14 (29.2)	-18.7 (-32.5, -5.0)	21 (41.2)	15 (29.4)	-11.8 (-45.1, 21.6)	6.9 (-12.6, 26.6)	.49
Uncontrolled worrying	14 (29.2)	9 (18.8)	-10.4 (-20.8, -0.02)	16 (31.4)	10 (19.6)	-11.8 (-39.6, 16.1)	-1.4 (-18.8, 16.1)	.88
Worrying about different things	22 (45.8)	17 (35.4)	-10.4 (-24.8, 4.0)	22 (43.1)	19 (37.3)	-5.9 (-41.7, 29.9)	4.5 (-16.8, 25.9)	.68
Trouble relaxing	17 (35.4)	12 (25.0)	-10.4 (-26.0, 5.1)	15 (29.4)	16 (31.4)	2.0 (-34.4, 38.3)	12.4 (-8.4, 33.2)	.24
Restless	13 (27.1)	7 (14.6)	-12.5 (-27.4, 2.4)	10 (19.6)	14 (27.5)	7.8 (-27.6, 43.3)	20.3 (-0.2, 40.9)	.05
Annoyed or irritable	24 (50.0)	16 (33.3)	-16.7 (-32.3, -1.0)	24 (47.1)	18 (35.3)	-11.8 (-50.4, 26.9)	4.9 (-18.1, 27.9)	.68
Afraid somethng awful will happen	8 (16.7)	3 (6.3)	-10.4 (-23.6, 2.8)	10 (19.6)	9 (17.7)	-1.9 (-32.7, 28.8)	8.5 (-9.1, 26.0)	.35
Overall GAD-7 score	3.9 ± 4.8	2.7 ± 4.4	-1.23 (-2.6. 0.17)	3.2 ± 4.5	3.2 ±4.4	0.0 (-1.4, 1.4)	1.23 (-0.7, 3.2)	.21

GAD-7 = Generalized Anxiety Disorder 7-item scale.

After 6 months of follow-up, there were more patients with AF detection in the KM/KP than the control group; however, the difference was not statistically significant. Detection of AF occurred earlier among the KM/KP group at a median of 68 days after randomization, compared to 91 days in the control group, but was also not statistically significant. A common concern in the medical community with the use of direct-to-consumer devices is the potential increase in healthcare utilization. In our pilot study, we recorded no increase in phone calls, in-person visits, emergency room encounters, or hospital admissions in the KM/KP group. We recorded more ECGs and ambulatory cardiac monitors ordered for patients in the control group compared to the KM/KP group, indicating that these smart device ECG tracings coupled with physician review are reliable and decrease the need for additional traditional monitoring. Another concern is whether the use of these devices with the direct visualization of the automated rhythm interpretation would increase anxiety instead of providing reassurance. In our small study, the 2 groups were similar in their responses to a generalized anxiety disorder questionnaire administered before and after the study period, and there was no difference in the change of anxiety scale score between the 2 groups (Table 3).

The majority of previous studies looking into direct-to-consumer devices enabling ECG rhythm recording have focused on validation of the technology or screening the general public.[11,12,14–16] Despite the hype about these devices, little is known about embedding these technologies into clinical practice. One of the obstacles slowing wider adoption is the lack of innovative solutions for healthcare providers to wade through the deluge of biometric data.[9] Our study was designed to assess a new platform that would facilitate the triage of these recordings, by combining the use of artificial intelligence in providing the preliminary interpretation through the device with the support of the physician's over-read of abnormal recordings. False-positive and false-negative results in these devices are not uncommon, and for any finding that could lead to a change in management, a physician review is needed.[12,14] In our study, there were 4 patients in the KM/KP group in whom a recording was labeled as possible AF by the algorithm, yet upon review by the caring physician through the KP platform were found to be sinus rhythm with premature atrial contractions. On the other hand, it is important to note that among the 40 patients in the KM/KP group who did not have any recordings interpreted as possible AF by the algorithm, none had AF upon the final direct review of all these recordings by their caring physicians.

The ability of the patient to visualize the recordings with the instant automated interpretation provides reassurance to the patient when it is normal, an advantage that other traditional cardiac rhythm monitors, including implantable loop recorders, do not provide. With traditional monitors, the patient becomes a passive element in their care rather than an active participant. The immediate and instantaneous access to the patient's data did not lead to increases in healthcare utilization or anxiety in our study.

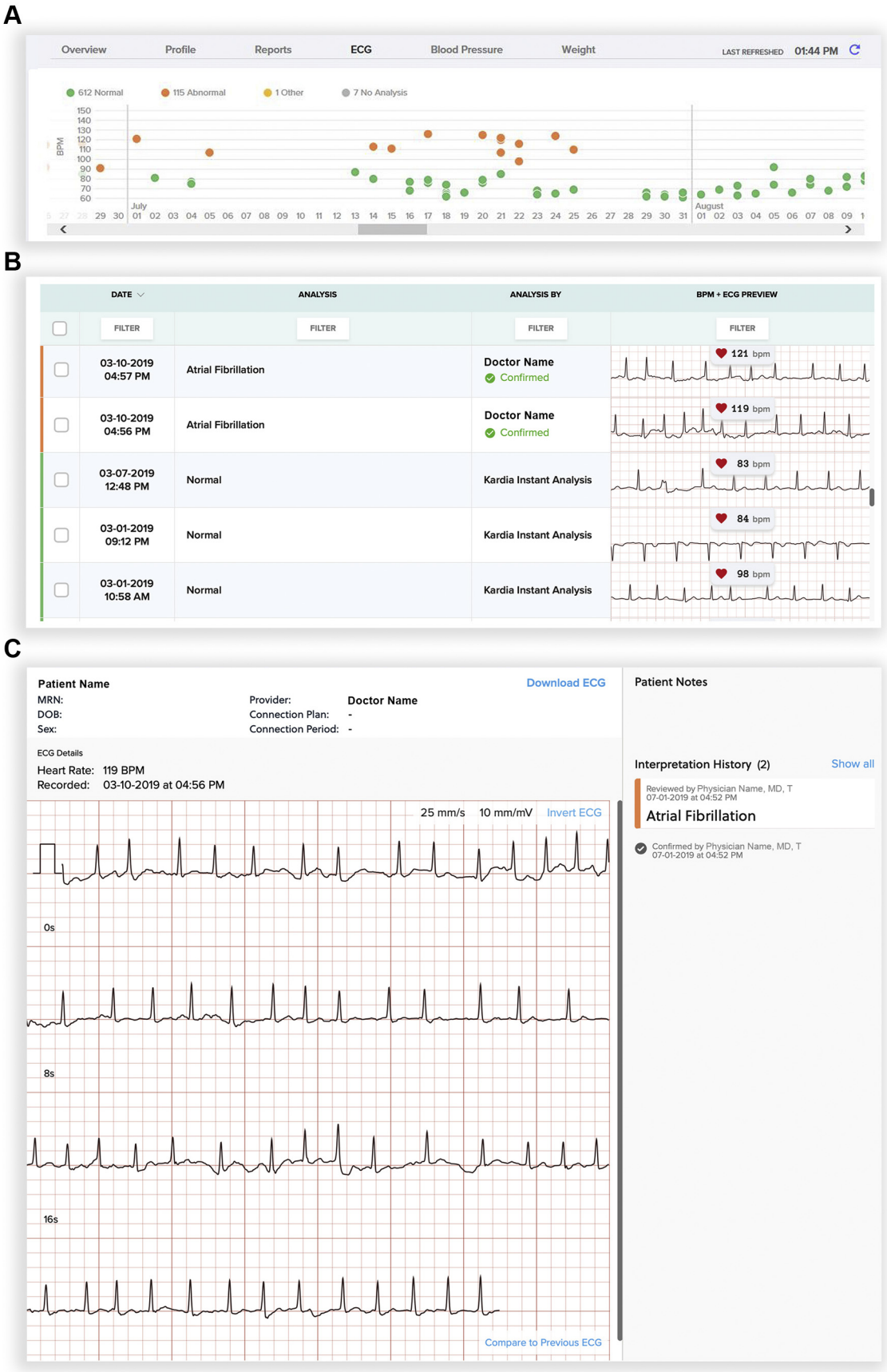

Figure 4 Example of a patient using Kardia Mobile (KM) (AliveCor, Mountain View, CA) / Kardia Pro (KP) platform. Recordings of normal sinus rhythm are labeled as green dots in the KP platform. Recordings of possible atrial fibrillation are labeled in orange and get triaged to the caring physician in-basket for confirmation. Clicking the recording will open up the recording of 30 seconds.

The care of the AF patient is usually long-term and involves multiple interventions or procedures.[6] Management decisions are rarely urgent, but when needed, access to data in a timely fashion is paramount and can lead to a better patient experience. An example is provided in Figure 4 of a 60-year-old patient who was randomized to the KM/KP group. The patient developed lightheadedness and nausea after an outing with his wife. A rhythm strip was recorded and transmitted to the KP platform (Figure 4A). This strip was interpreted by the automated algorithm as possible AF (Figure 4B) and was triaged to the treating physician in-basket folder in the KP platform for review (Figure 4C), confirming the diagnosis of AF. The treating physician was able to expeditiously contact the patient to provide guidance in a timely manner.

This study also provides information about patients' behavior in using smart device ECG technology in their home environment. The ability to use the technology spanned age brackets and education levels. Overall, patients were reasonable with the amount of data they collected and transmitted. In our study cohort, the median number of recordings transmitted was 1.3 per week.

While we focused on the long-term follow-up post AF ablation in our study, the future applications of the technology and the platform in the care of the AF patient are many. A previous study assessed the accuracy of a smartwatch band in detecting AF among patients presenting for elective cardioversion and found that 8% of them were in sinus rhythm and did not need to present for the procedure.[14] The use of these devices with a platform that enables the caring team to access these recordings on demand could avoid scheduling unnecessary cardioversions. The synergistic relationship between instantaneous interpretation via the automated algorithm, digital platform, patient, and healthcare provider is key for successful adoption of digital technology into busy clinical practices and will turn the technology into an asset rather than a burden and transform the relationship between the AF patient and the physician into a partnership rather than a unidirectional process. This model of care is not limited to AF care and could be applied to multiple cardiovascular specialties in need of patient-recorded data.

While not the original intent of this pilot study, our results highlight the limitations in the traditional definition of a successful AF ablation. In the guidelines, any AF episode lasting more than 30 seconds is considered a recurrence of AF.[13] Recently, this concept was challenged and an alternative approach using AF burden was suggested.[17] The KP platform helps illustrate the shortcomings of our definition of success after AF ablation. Supplemental Figure S3 shows frequent recordings by an AF patient using KM/KP with evidence of almost daily episodes of paroxysmal AF prior to his AF ablation. For over a year after his ablation, he continued to record at a similar frequency, yet he only recorded 1 episode of AF 8 months after the procedure, surrounded by months of normal sinus rhythm. This will deem his AF ablation as unsuccessful using the guidelines' definition of AF recurrence. While AF burden can only be measured accurately using continuous monitoring, the impact of AF ablation on the frequency of AF episodes is clear The example also serves as a reminder that AF can still occur and can easily be missed by intermittent short-term ambulatory monitors.

Finally, telemedicine has been growing in multiple specialties. Our results highlight the opportunity for cardiovascular and arrhythmia patients to be effectively managed with virtual visits and telemedicine platforms.[18] The recent COVID-19 pandemic has reminded us about the importance of remote care. However, to improve the outcome of a virtual visit, it needs to be supported by data. For the AF patient, a virtual visit coupled with ECG recordings over time can lead to more informed and meaningful care than an in-person visit with a single ECG. Regulatory and reimbursement models are needed to support these new models of patient care.

Study Limitations

This was a single-center, randomized pilot study with a small sample size and therefore was not powered to make definitive conclusions between the 2 groups. Future larger studies with longer follow-up duration will be needed to show impact. We targeted patients with compatible smart devices, which might have led to selection bias. To minimize this bias, we excluded patients who were using a KM device or any other direct-to-consumer device capable of recording an ECG rhythm strip. There were variable subtypes of AF (paroxysmal and persistent) included in this study, but our randomization scheme stratified by AF type. Crossover between the study groups occurred, as 2 subjects randomized to the control arm purchased the KM on their own. This represents a challenge in conducting studies using direct-to-consumer devices in a randomized fashion when patients can independently purchase these devices. Our study utilized the KM single-lead monitor coupled with the KP platform. There are several smart ECG devices available on the market, which represents a challenge in creating different platforms for different devices used by patients.

Conclusions

The KM paired with the KP platform can be effectively incorporated into the care of post–AF ablation patients to assist in the detection of late AF recurrences, without increasing patient anxiety and with less need for additional cardiac monitors. The study provides an example of a new cardiovascular care model that utilizes digital health devices, supported by platforms that enable patients to generate, view, and share their data with their healthcare providers.

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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.

Patient Consent

All patients provided written informed consent.

Authorship

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

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.cvdhj.2021.02.002.

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