Original Article

Identifying the Prevalence of the Life-threatening Atrial Fibrillation Using a Smartphone-Based Wireless Electrocardiography Device: An Observational Study

Esha Dyundi, Prashant Gupta, Robin Choudhary

Department of Research and Development, Agatsa Software Pvt. Ltd, Noida, Uttar Pradesh, India

Abstract

Background: Atrial Fibrillation (AF) is one of the most common types of arrhythmia across the world. Yet, many cases remain undiagnosed making it difficult to estimate the exact prevalence of AF. **Aims:** This observational study was done to understand the feasibility of a hand-held electrocardiography (ECG) device – SanketLife – in detecting AF cases. **Materials and Methods:** In the study, ECG data collected from the device for a period of 2 months were evaluated to detect AF cases. The device took 12-lead and single-lead ECG recordings in various health-care settings including self-monitoring done by patients at their homes and in diagnostic laboratories using the device for screening as well as hospitals using the device in their outpatient departments. The reports were saved in SanketLife Cloud and evaluated anonymously by a certified ECG expert and the findings were further confirmed by a cardiologist to evaluate AF or any other findings in the ECG. **Results:** SanketLife effectively captured AF cases and demonstrated the feasibility of using such a device in any care setting being clinical or home monitoring. **Conclusion:** The study concluded that the device can be used for regular monitoring by patients suffering from chronic AF. In health-care settings ranging from primary care to tertiary care, the device can be beneficial.

Keywords: Arrhythmias, atrial fibrillation, electrocardiography device, intraventricular conduction delay, SanketLife, smartphone-based wireless electrocardiography device

Introduction

Atrial fibrillation (AF) is one of the most common types of arrhythmias that can lead to major health consequences. There are nearly 33.5 million individuals living with AF; the estimated global age-adjusted prevalence was 0.5% in 2010.[1,2] It is estimated that the prevalence of AF will be doubled by 2030.[1] Early detection is very important in managing the cases of AF, but it is equally difficult to detect, especially paroxysmal AF.[3] The sensitivity of standard diagnostic tools such as ambulatory electrocardiography (ECG) and Holter monitoring remains low, especially in detecting short AF episodes.[3,4] Current guidelines advocate that "all patients who present with symptoms of AF should have their pulse checked for irregularities as well as 12-lead ECG."[5] Prolonged ECG monitoring may be especially useful in patients with heart failure and poststroke in order to enhance detection and reduce health resource utilization and costs.[2]

Videos Available on: www.j-pcs.org

Access this article online

Quick Response Code:

Website: www.j-pcs.org

DOI: 10.4103/jpcs.jpcs_42_19

This observational study evaluated the prevalence of AF in the user population and the ability of the Smartphone-based wireless ECG device SanketLife to effectively capture the AF which can be reported by a doctor upon interpreting the ECG.

Methods

A total of n = 8005 reports was recorded using SanketLife portable device during a period of 2 months (March–May 2019).

Address for correspondence: Dr. Esha Dyundi, P214, Sector 23, Sanjay Nagar, Ghaziabad - 201 002, Uttar Pradesh, India.
E-mail: edyundi@yahoo.com

Date of Submission: 16-Jul-2019 **Date of Acceptance:** 25-Nov-2019
Date of Revision: 26-Sep-2019 **Date of Web Publication:** 20-Dec-2019

How to cite this article: Dyundi E, Gupta P, Choudhary R. Identifying the prevalence of the life-threatening atrial fibrillation using a smartphone-based wireless electrocardiography device: An observational study. J Pract Cardiovasc Sci 2019;5:186-90.

This cross-sectional study analyzed the data collected using SanketLife ECG device stored in SanketLife Cloud and reviewed ECG reports taken in various health-care settings on an outpatient basis [Figure 1]. The medical conditions of users were not available as the study did not include any participation from the users. This study further provides the information on the prevalence of cardiac arrhythmia in the user population of SanketLife ECG device, people taking ECGs in a home care setting, and people performing quick screening in a health-care setting.

Using SanketLife electrocardiography device

Device description

SanketLife ECG device is a lead-less device approximately size of a keychain, and the device easily fits into the palms and has the ability to take single-lead, chest-lead, and full 12-lead ECG. The device comprises three sensors – left sensor, right sensor, and side sensor [Figure 1].

The device is battery operated and using a coin cell (CR2032). Bluetooth connectivity is required for the device to get connected with the smartphone and be able to relay the heart electrical activity on the smartphones through the SanketLife App.

How to take electrocardiography with SanketLife

SanketLife uses sensors to take ECG unlike a traditional ECG machine that uses lead cables and electrodes to capture the ECG readings. To take a long recording of ECG using SanketLife device, the user has to touch their right and left thumb on the right and left sensors, respectively, and hold the position for 60 s to take the readings [Videos 1 and 2].

For a full 12-lead ECG, the user has to keep their right thumb on the right sensor and then has to place the side sensor on the specific position on the chest to capture ECG [Figure 2].

How reports are generated with SanketLife

This electrical activity of a person's heart captured using the SanketLife device is then relayed to a smartphone application via Bluetooth, and reports are generated on the smartphone in an easily shareable format. These reports can then be shared with a specialist for correlating with the clinical symptoms.

Electrocardiography data acquisition, recording, and review process

For the study, the recorded ECG reports that were saved to the SanketLife Cloud were taken and analyzed to understand the presentation of AF in the user population. The ECG stored in the SanketLife Cloud was sent to ECG analyst with the help of SanketLife ECG review portal which allowed him to view the report and mark the ECG findings on the portal [Figure 3]. The reports were then reviewed by a cardiologist to confirm the presence of AF in the reports. He then categorized the report into two categories of AF and potential AF. The reports marked as potential AF were due to the unavailability of a patient's clinical data or contact with the patient to cross-examine the report or do a repeat full 12-lead ECG in case of single long recording ECG reports to confirm the finding of AF.

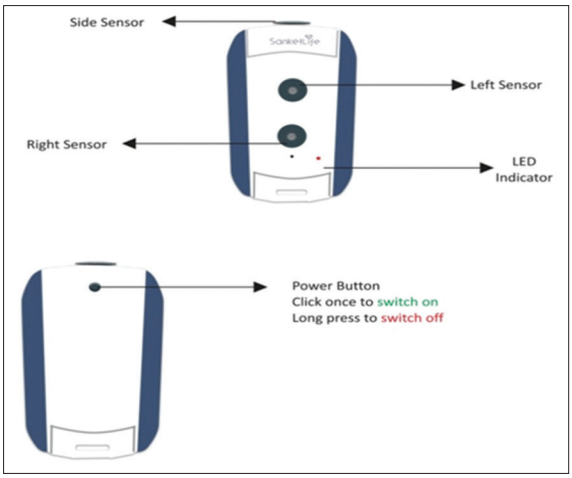

Figure 1: Device description.

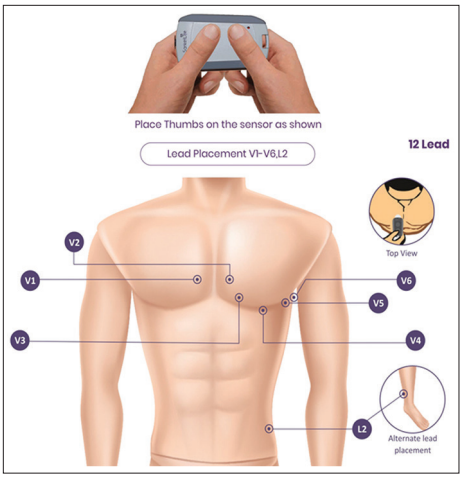

Figure 2: Electrocardiography lead positions by SanketLife electrocardiography device.

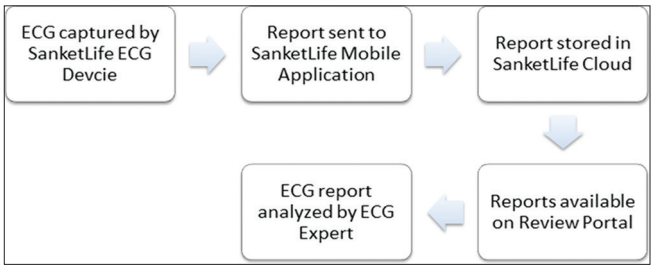

Figure 3: Process flow of SanketLife electrocardiography device from electrocardiography capture to electrocardiography review.

Study protocols and study enrollment

This study evaluated the prevalence of AF among the population of SanketLife users for a period of nearly 2 months. The study is designed in a way to anonymously screen the ECG reports taken using the SanketLife device. Each report was segregated as per the way they were recorded, i.e., one full 12-lead

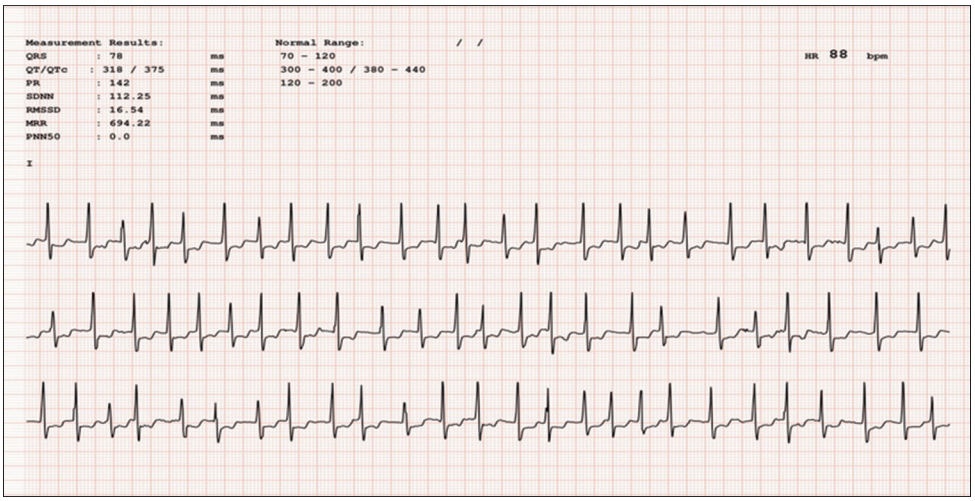

Figure 4: Electrocardiography sample report of long recording (60 s) taken by SanketLife electrocardiography device.

position report similar to the reports taken by conventional ECG machine and another report of long recording of any one-lead position for 60 s [Figure 4]. Each report was then screened initially by an ECG analyst, and the second level of review was done by a cardiologist. The study had no direct human participant involved, and clinical conditions were also unknown, so the inclusion criteria involved the reports taken and recorded from March to May 2019.

Results

Out of all the reports (n = 8005) screened for this study, 30 (0.37%) showed evidence of cardiac arrhythmias such as AF and AF with intraventricular conduction delay (n = 15) based on the graphical representation of the report [Figure 4]. The medical conditions and symptoms of users were not available as the study did not include any participation from the user, due to which the report categorization made by a cardiologist included categories AF and potential AF [Figure 5]. The reports categorized as potential AF were due to unavailability of any other evidence supporting the conclusion. This study provided the general information on the prevalence of AF in the user population of SanketLife ECG device.

Discussion

AF presents itself as a major health concern worldwide associated with a considerable risk of heart attacks and stroke.[1,2] It increases long-term morbidity, mortality, and health-care costs and reduces the quality of life.[4] For the majority of patients, AF progresses from a silent paroxysmal form to a more permanent arrhythmia with complications.[4] Various studies have confirmed that the severity and the chances of arrhythmias increase with advancing age.[6-8] The need for early detection in cases of AF can help in improving the outcomes, but this approach is hindered with the silent nature of many AF cases. Silent AF or paroxysmal AF is diagnosed incidentally during routine physical or electrocardiographic examination and in many cases revealed after complications such as stroke or heart failure.[9,10] The need

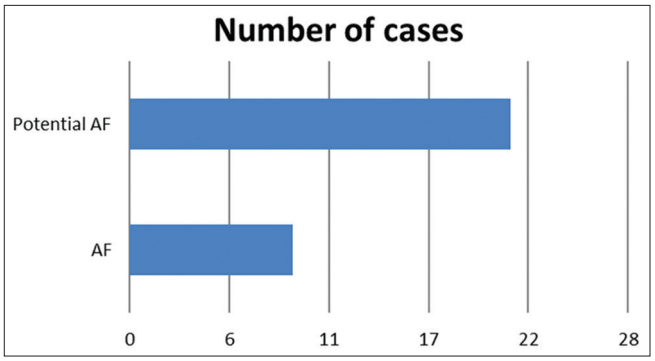

Figure 5: Total electrocardiography report findings of atrial fibrillation by SanketLife electrocardiography device, as categorized by cardiologist into atrial fibrillation and potential atrial fibrillation.

to emphasize on the detection of such silent AF cases is that they rapidly progress to a permanent form of AF as they are left untreated because of being missed.

The market presently has many remote monitoring solutions available that offer heart monitoring solution that comes with similar features although affordability of such devices varies [Table 1].

The study fairly concluded that the device can effectively perform as a tool for monitoring of heart activity and taking ECG in any clinical or home setting. The evaluated reports also concluded that the device can effectively capture AF upon being clinically correlated with physicians and the diagnosis can be further confirmed through symptoms presented by the patient. The golden standard of detecting AF remains the ECG, but the available options are cumbersome, costly, and not easy to handle. SanketLife, on the other hand, provides a more convenient way to record ECG by being a leadless, compact and portable alternative to any traditional ECG machine. The study further elaborates on the sensitivity of the device in capturing the ECG irrespective of the care setting and the user. In cases of paroxysmal AF, the slightest symptom experienced

Table 1: Comparison between handheld electrocardiogram devices available in the market

Device	ECG characteristics	Dimensions	Weight	Power input	Mobile App connectivity	In-App doctor review	Manufacturer	Price (approximately) (₹)
BARC handheld 12-lead ECG machine	Capture full 12-lead ECG using cable Rhythm recording Connects with mobile/PC	3.5”(L) ×2.5”(B) ×0.5”(H) inches	100 g	Standard Li-ion mobile battery	Bluetooth/ LAN connectivity	No	India	35,000
SanketLife ECG device	Capture full 12-lead ECG, wireless Rhythm recording Easily shareable report formats In-App doctor review	7.2 cm × 4.3 cm × 1.55 cm Three electrodes	25 g	CR2032 batteries	Bluetooth	Yes	India	3999
Mobmon 12.0 resting ECG recorder with telemedicine	Capture full 12-lead ECG, wireless Shareable report formats	NA	<2 kg	Battery	3.5 mm audio jack	Yes	India	75,300
Omron HCG-801 Heartscan ECG monitor	Captures single-lead ECG with display	12 cm × 6.5 cm × 2 cm	106 g	Batteries (2 × LR03 - AAA)	NA	NA	NA	26,000
Philips Efficia ECG 100	Capture full 12-lead ECG using cable Rhythm recording Connects with mobile/PC	15 cm × 9 cm × 3 cm	<300 g	Li-ion rechargeable battery	Wi-Fi connectivity	No	India	80,000
KardiaMobile	Captures single-lead ECG Shareable report format	8.2 cm × 3.2 cm × 0.35 cm Two 3 cm × 3 cm stainless steel electrodes	18 g	3V CR2016 coin cell battery	Ultrasound	Yes	Designed in USA, manufactured in China	15,000
BPL Cardiart 6108 T ECG machine	Captures 12-, 5-, 3-lead ECG using cable Single-channel print	27 (L) ×18 (H) ×6 (D) cm	<2.6 kg	NiMH rechargeable battery (built-in)	NA	No	India	24,000

ECG: Electrocardiogram, NA: Not available, LAN: Local area network, PC: Personal computer, Li-ion: Lithium-ion, AAA: Triple-A standard dry-cell battery, NiMH: Nickel-metal hydride, BARC: Bhabha Atomic Research Centre, HCG: Model Name, BPL: British Physical Laboratories group

by the patient can be immediately confirmed by taking an ECG by SanketLife and getting the reports evaluated. The device can be used for regular monitoring by patients suffering from chronic AF. In health-care settings ranging from primary care to tertiary care, the device can be beneficial. With the changing health-care scenario and the age of digital transformation, both patients and health-care professionals are looking for ways that can be cost-effective and innovative and easily monitor the patient conditions. The SanketLife device can be one of the viable options to provide clinical confidence to the doctors and improve the quality of life of patients using it.

Finally, although our study has proved very promising, we continue to collect more data to further consolidate the diagnostic capabilities of SanketLife ECG device. The real-world usability of the device to provide ECG diagnosis in the most remote locations will be the next possible approach for a ubiquitous health-care system.

Limitations

The limitations of this study include the unavailability of patient data such as medical history, present complaint, age, and gender to provide further analysis for the study.

Ethics clearance

Ethical approval for the study was provided by the Royal Pune Independent Ethics Committee on July 30, 2019.

Acknowledgment

We would like to express our particular gratitude to Dr. Paramjeet Singh (consultant physician and noninvasive cardiologist) for his expertise and for providing his full support with the reviewing process of reports while concluding the results.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Patel NJ, Atti V, Mitrani RD, Viles-Gonzalez JF, Goldberger JJ. Global rising trends of atrial fibrillation: A major public health concern. Heart 2018;104:1989-90.
2. Morillo CA, Banerjee A, Perel P, Wood D, Jouven X. Atrial fibrillation: The current epidemic. J Geriatr Cardiol 2017;14:195-203.
3. Kara K, Geisel M, Möhlenkamp S, Lehmann N, Kälsch H, Bauer M, *et al*. B-type natriuretic peptide for incident atrial fibrillation – The Heinz Nixdorf recall study. J of Cardiol 2015;65:453-8.
4. García-Fernández A, Roldán V, Marín F. Strategies for prediction and early detection of atrial fibrillation: Present and future. Europace 2017;19:515-7.
5. Davis M, Rodgers S, Rudolf M, Hughes M, Lip GY. Guideline Development Group for the NICE clinical guideline for the management of atrial fibrillation. Patient care pathway, implementation and audit criteria for patients with atrial fibrillation. Heart 2007;93:48-52.
6. Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: The Framingham Study. Stroke 1991;22:983-8.
7. Chugh SS, Havmoeller R, Narayanan K, Singh D, Rienstra M, Benjamin EJ, *et al*. Worldwide epidemiology of atrial fibrillation: A global burden of disease 2010 study. Circulation 2014;129:837-47.
8. Dilaveris PE, Kennedy HL. Silent atrial fibrillation: Epidemiology, diagnosis, and clinical impact. Clin Cardiol 2017;40:413-8.
9. Barbarossa A, Guerra F, Capucci A. Silent atrial fibrillation: A critical review. J Atr Fibrillation 2014;7:1138.
10. Ferreira C, Providência R, Ferreira MJ, Gonçalves LM. Atrial fibrillation and Non-cardiovascular diseases: A systematic review. Arq Bras Cardiol 2015;105:519-26.