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Research Article

A Single Blinded, Cross-Sectional, Single-Center Study for the Validation of Atrial Fibrillation Detection using Spandan Smartphone ECG

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ABSTRACT

The atrial fibrillation prevalence is found between 0.1% and 4% in community-based research and between 2.8% and 14% in studies conducted in hospitals; nevertheless, a large portion of AF is still misdiagnosed. Smartphone applications for diagnosing AF have been proposed given that a big portion of Indians own smartphones, although it is unknown how accurate these programs would be. The study's objectives were as follows: a) To evaluate the diagnostic efficacy of the Spandan ECG in detecting AF in a single center trial that took place in SMIH Dehradun under the supervision of the cardiologist, and b) to investigate arrhythmia detection through a smartphone-based and monitoring. This single-blinded, cross-sectional, single-center study was conducted at Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India from August 2022 to December 2022. Patients (n=32) undergoing the electrocardiogram (ECG) at the Department of Cardiology of the SMIH, Dehradun during the study period and diagnosed with atrial fibrillation. Mean age (SD) was 59.93±13.81 years. Males (n=17/32, 53.1%) show more frequency than females. Most patients had a medical history of coronary artery disease (21.8%). True positive cases derived from confusion matrix of atrial fibrillation detected using smartphone based ECG and 12 lead standard ECG along with the cardiologist's diagnosis was 29/32 on smartphone-based as compared to 19/32 from 12 lead gold standard. Atrial fibrillation was detected correctly in 29/32 cases and 19/32 cases by smartphone ECG and 12 lead gold standard, respectively. The study hypotheses that Spandan's ability of real-time ECG monitoring will be useful in evaluating whether a patient's discomfort is caused by recurrent arrhythmia.

Introduction

Atrial fibrillation (AF), the most prevalent arrhythmia, has affected more than 37 million individuals worldwide and is expected to upsurge by 2030 [1]. The risk of mortality and hospitalization for patients with AF is two times greater, and the high frequency of hospital admissions is a major factor in the high cost of AF-related medical care [2]. About 15% of ischaemic strokes are caused by untreated AF, which is also independently linked to heart failure, cognitive decline, and mortality [3]. Early detection of this arrhythmia has advantages such as tailored risk factor modification, accurate classification and assessment, and the use of early treatment techniques in a comprehensive or integrated care setting [4].

Delays in identification also frequently impair the management of patients with debilitating symptoms of AF, such as shortness of breath, syncope, and exercise intolerance. Although there is a significant burden of recognized AF in the community, studies have shown that AF identification can be enhanced with more regular monitoring [5]. Thus, it is imperative to create techniques for precise AF identification and monitoring to enhance patient care and lower the expenses of treating AF-related problems.

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The potential utility of smartphone-based ECGs for identifying AF has just been acknowledged by recommendations [6-8]. Mass screening for AF via smartphone-based technologies may occur soon because of the pervasive and expanding usage of this technology, with the results requiring clinical judgment on the part of healthcare experts. Thus, it is crucial to evaluate the relative diagnostic advantages and disadvantages of commercially accessible smartphone technology.

Sunfox Technologies Private Limited claims that the Spandan smartphone ECG can identify 14 different kinds of arrhythmia rhythms in people with atrial fibrillation who have received a clinical diagnosis. Following clinical demonstrations that this technology provides reliable and accurate diagnoses, non-medical people may be able to use it anywhere on the planet. This approach may allow even qualified medical personnel in resource-constrained countries like India, where standard ECG equipment is not always available, to produce a good 12-lead ECG trace at a minimal cost.

Given the foregoing, the purpose of this study is a) to evaluate the diagnostic efficacy of the Spandan ECG in detecting AF in a single-center trial that took place in SMIH Dehradun under the supervision of the cardiologist, and b) to examine the legitimacy of the smartphone-based arrhythmia detection and monitoring.

Materials And Methods

After obtaining their written informed consent, individuals visiting the Department of Cardiology of Shri Mahant Indresh Hospital (SMIH), Dehradun between August 2022 and December 2022 were given brief about the purpose of the study followed by their inclusion. There were 32 individuals in the final research population, who might be either male or female. After obtaining their written agreement and outlining the study's objectives, patients were included in the trial.

Patients who had been diagnosed with atrial fibrillation at the ECG room were included in the study, whereas patients with diagnoses other than atrial fibrillation, loose skin, ECGs recorded with electrical disturbances, surgical use of a radial artery, cardiac pacemakers, chronic heart rhythm abnormalities, or who were unable to give informed consent were excluded. This research received approval from the Department of Cardiology at SMIH.

Analysis of Atrial Fibrillation

The ECG test was taken only one time from both gold standard ECG and Spandan ECG devices. According to guidelines offered by Sunfox Technologies Private Limited, ECGs were created and examined. The ECGs were collected while the patients were lying down. The patients were then allowed to lie down in a supine position and follow the research nurses' instructions. The digital data was collected which included the case reports of the subjects including the ECG recordings. Spandan smartphone ECG-based application data is transmitted to a cloud-based server for further analysis.

12-lead ECG Recordings

The 12-lead ECGs were recorded at a sampling frequency of 500Hz using both the Spandan 12L and conventional 12-lead ECG machine. The nurses used a 12-lead standard and Spandan ECG to take the participants' ECGs throughout a 10-second interval while the patients were in resting positions. The programme on the patient's Spandan smartphone ECG links the device via micro USB connecting cable, this allows the data of ECG recording of patients to upload to Google cloud-based servers. A blinded team of cardiologists analysed all ECGs from conventional ECG machines and smartphone lead II ECG devices for atrial fibrillation detection. ECGs were labeled as true positive if the detection was valid and false negative if it was incorrect.

Statistical Methods

The data was entered into a spreadsheet, and a detailed statistical analysis was carried out. The efficacy of arrhythmia detection was evaluated by estimating the inaccuracy in detecting atrial fibrillation in comparison to the cardiologist's diagnosis.

Results

In total, 1337 subjects enrolled for the study and were screened for ECG out of which 1305 subjects later either withdrew consent or missed to qualify the inclusion criteria. A final total of 32 participants diagnosed with atrial fibrillation were recruited from the cardiology OPD and emergency department for the study. The baseline characteristics of the study population are outlined in (Table 1) below. The average age was 59.93 13.81 (range in years: 40 or above) where 17 patients (53.1%) were males and 15 patients (46.9%) females.

Table 1: Baseline characteristics of study population.

Parameters	Overall patients with Atrial Fibrillation (n =32)(%)
Age (Mean±SD) years	59.93±13.81
Female	15 (46.9)
Male	17 (53.1)
Body Mass Index (Mean) (Kg/m2)	24.25
Medical History	
Chest Pain	3 (9.3)
Palpitations	6 (18.8)
Shortness of Breath	3 (9.3)
Hypertension	5 (15.6)
Smoker	3 (9.3)
COVID-19 patients	2 (6.2)

Diabetic	3 (9.3)
Coronary Artery Disease	7 (21.8)
History of Medications	
Subjects on Anti-Coagulant Drugs	16 (50)
Subjects on Diuretics Drugs	12 (37.5)
Subjects on Antacid	9 (28.1)
Subjects on Anti-Hypertensive Drugs	13 (40.6)
Subjects on Anti-Anginal Drugs	3 (9.3)
Subjects on Anti-Hyperlipidemic Drugs	8 (25)
Subjects on Hyperglycemic Drugs	3 (9.3)

Below (Table 2) summarizes the ventricular arrhythmia detection matrix for 12 lead conventional ECG and smartphone ECG as compared to the cardiologist's diagnosis. In comparison to cardiologist diagnosis, the number of true positive instances determined for atrial fibrillation by the confusion matrix for 12 lead standard ECG and smartphone ECG was 29/32, compared to 19/32 for 12 lead gold standards.

Table 2: Confusion matrix of atrial Fibrillation detection for conventional 12 lead ECG and Smartphone-based ECG diagnosed by a cardiologist.

Parameters	**12 lead Gold standard**	**Smartphone ECG**
True Positive	19/32	29/32
True Negative	0	0
False Positive	0	0
False Negative	13/32	3/32

Table 3 below lists rhythm detection by Spandan portable ECG in 32 cases with cardiologist-confirmed AF. The Spandan ECG was used to analyse rhythm in two different ways: offline interpretation of the PDF of the rhythm waveform recorded in the Spandan ECG App by the cardiologists, and notification/display on the smartphone user's screen. In all 32 (100%) rhythm examinations, the Spandan ECG app produced a downloadable PDF of the ECG waveform. The Spandan ECG app always produce a PDF copy of the ECG report; this never happened in any of the situations.

Table 3: Rhythm detection by Spandan ECG in 32 instances of cardiologist-confirmed AF.

	AF, n (%)	Inconclusive, n (%)	No Reading, n (%)	Sensitivity, %	Specificity, %
Spandan ECG notification/display	32	0 (%)	0 (%)	87.8	97%
PDF report Interpretation by Cardiologist	32	0 (%)	0 (%)	100%	100%

Table 4 shows the precision with which atrial fibrillation diagnosed by the conventional 12L ECG and smartphone- based ECG may be interpreted in contrast to a cardiologist's evaluation. Atrial fibrillation was accurately identified in 29/32 cases and 19/32 cases by smartphone ECG and 12 lead gold standard, respectively.

Table 4: Accuracy of interpretation of atrial fibrillation detected by the conventional 12 lead ECG and smartphone-based ECG in comparison to clinical diagnosis (n= 32).

Parameters	12 lead Gold standard	Smartphone ECG
Atrial Fibrillation detected correctly	19	29
Accuracy of detection (%)	59.37	87.8

Discussion

There have been reports of a variety of portable ECG monitoring devices due to the recent advancements in smartphone technology [9-11]. The most popular way to measure ECG among them has been double-lead monitoring. It is theoretically possible to detect AF with a commercially available smartphone, with extremely high diagnostic accuracy, and with moderately good sensitivity and specificity. According to this, smart devices generally have the capacity to screen for and monitor AF [12-14].

This study assessed a novel smartphone app's capacity to identify AF using two distinct assessment techniques. Based on the acquired double-lead ECG, the Spandan ECG clearly identified atrial fibrillation with good sensitivity and specificity. False positive findings were mostly caused by extrasystoles and poor signal quality that the filter failed to identify. The findings of our investigation are comparable to other screening techniques and equipment diagnostic accuracy. According to recent research and meta-analysis, the best approaches for identifying an irregular pulse and atrial fibrillation were 12-lead ECGs and blood pressure monitors. Moreover, the accuracy values for new smartphone applications are inconsistent in recent studies. Haberman *et al.* discovered that in patients in cardiology clinics, the AliveCor had a sensitivity of 94% and a specificity of 99% [13].

Hospitalized patients had lower readings with a sensitivity range of 55-79% and a specificity range of 97.5-97.9%, according to Desteghe *et al.* It is crucial to highlight the population variability amongst the studies

that were conducted: the majority of participants participated while being hospitalized, and the prevalence of AF varied greatly [15-16]. The validation of atrial fibrillation detection utilizing Spandan can monitor ECG data in real-time using the user's smartphone, as opposed to holter monitoring [17].

To enable instantaneous monitoring, the user's smartphone needs to have the Spandan ECG application installed. To interface the hardware ECG device with the smartphone a micro USB cable is used. This interface of less complex hardware to the smartphone leads to the recording of the ECG. The advantage of Spandan is its lightweight and portability. Being a single channel, 12 lead ECG device make Spandan smartphone ECG simple to reuse. This study hypotheses that real-time ECG monitoring by Spandan will be useful in diagnosing whether a patient's illness is caused by intermittent arrhythmia. Furthermore, because Spandan is light and compact, increased compliance among patients with using the device is expected.

Limitations

With 32 participants, this study used a single-channel ECG device at a single center. Participants were instructed about the methods to use the smartphone application prior to receiving each recording, and their ability to catch each trace was instantly assessed. Without this instruction, the accuracy of recorded tracings in an ambulatory setting may have decreased. The average age of the patient population in the study was approximately 59 years old, which was older than the average age when the Indian population is taken into consideration, which could be another shortcoming of this study. As a result, the results may not precisely reflect what the general population would experience.

Conclusion

A simple single channel 12 lead ECG along with standalone smartphone software called Spandan demonstrated encouraging AF detection performance. The Spandan app received great marks for accuracy, sensitivity, and specificity. These findings place the app in contention for inclusion in future AF monitoring or case-finding activities. Doctors should exercise caution before acting on electrocardiographic diagnoses generated by the 12-lead smartphone-based ECG equipment.

Funding

Funded by Sunfox Technologies for validation of Spandan ECG device.

Conflicts of Interest

None.

Ethical Approval

The study was approved by the Institutional Ethics Committee.

Consent to Participate

The written consent form was collected from the enrolled subjects.

Author Contributions

Sahil Mahajan: Principal investigator of the study and study conceptualizing. Salil Garg: Co-Principal investigator of study and study protocol designing. Yogendra Singh: Interpretation of the ECG reports and data evaluation. Richa Sharma: Interpretation of the ECG reports and data Evaluation. Nitin Chandola: Data statistics and research coordinator of the study. Tanuj Bhatia: Study methodology and protocol designing. Basundhara Bansal: Study trial co-ordinator and data management.

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