International Journal of Research in Medical Sciences
Mahajan S et al. Int J Res Med Sci. 2023 Apr;11(4):1165-1169
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20230855

Original Research Article

Accuracy of smartphone based electrocardiogram for the detection of rhythm abnormalities in limb lead: a cross sectional study, non-randomised, single blinded and single-center study

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Received: 09 March 2023
Accepted: 24 March 2023

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ABSTRACT

Background: For the identification of arrhythmia and abnormal instances, researchers are examining the reliability of the interpretation offered by smartphone-based portable ECG monitors. The indicator of an unclear alteration in the electrical activity of the heart is a cardiac abnormality. As a result, its early and accurate identification can avoid myocardial infarction and even sudden cardiac death. Objectives of this study were to evaluate and validate the Spandan 12 lead ECG interpretation for accuracy in detection of the cardiac arrhythmias in comparison to the cardiologist diagnosis, and to evaluate the accuracy of the arrhythmia detection of Spandan ECG in comparison to the 12 lead ECG machine.

Methods: This cross-sectional study, non-randomised, single blinded and single-center study was carried out at Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India from 1st August 2022 to 31st January 2023. All patients (n=312) visiting the electrocardiogram (ECG) room at the department of cardiology of the SMIH, Dehradun with the prescription of ECG screening during the study period were included in the study were included in the study.

Results: In total, 1528 patients with or without a history of cardiovascular disease were enrolled from outpatient and emergency departments of cardiology. A final total of 312 participants considered for accuracy of interpretation of cardiac arrhythmias detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists' diagnosis. Mean age (SD) was 53.90±14.52 years. The male gender (68.78%) showed the maximum frequency than female gender. True Positive cases derived from confusion matrix for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis was 264 as compared to 273 from 12 lead gold standard. Sensitivity of smartphone Spandan ECG (81.23%) was comparable to gold standard 12 Lead ECG (81.49%). And, specificity, PPV and NPV of smartphone Spandan ECG was recorded to be better than gold standard 12 Lead ECG. Arrhythmia was detected correctly in 403 (70.8%) cases and 431 (61.86%) cases by smartphone ECG and 12 lead gold standards, respectively.

Conclusions: Spandan ECG device scored a high accuracy and sensitivity and high specificity. The overall accuracy of smartphone ECG in detecting the rhythm abnormalities increase by 9%, the significance rises in accuracy of computer interpretation when compared to the cardiologist's diagnosis.

Keywords: Cardiac arrhythmia, Smartphone, Specificity, Sensitivity, Accuracy, Validation

INTRODUCTION

People routinely seek medical attention from their primary care provider for symptoms that might be caused by heart arrhythmias.[1] Palpitations, dizziness, and (near) fainting are manifestations that cause patients to see their primary care physician. Common ECG findings like ectopic beats are cardiac rhythm irregularities that typically don't need treatment.[2] Others, like atrial fibrillation (AF) or atrial flutter (AFL), are present in 2% to 3% of the population and require additional testing and management to lower the risk of stroke and heart failure that are associated with them.[3]

The diagnosis and treatment of these frequent medical conditions have undergone a revolution as a result of the recent commercial availability of smartphone-based gadgets and wearable technologies with arrhythmia detection capabilities, which have given patients control over arrhythmia detection.[4] There are currently several commercially accessible mobile health (mHealth) devices that use electrocardiogram (ECG) and photoplethysmography (PPG)-based technologies to detect, record, and automatically interpret anomalies in heart rhythm and sudden changes in heart rate.[5-7] These devices are less costly and enable longer-term monitoring than prescription-based external rhythm monitoring techniques, enhancing their sensitivity for arrhythmia diagnosis, especially for patients who experience irregular symptoms that might be caused by heart arrhythmias.[8-10]

The Spandan smartphone ECG, created by Sunfox Technologies Private Limited, makes the claim that it can identify 21 distinct types of arrhythmia patterns in individuals with atrial fibrillation who have received a clinical diagnosis. After this technology had been clinically shown to deliver reliable and accurate diagnosis, non-medical persons may be able to utilise it anywhere in the globe. This technology may make it possible for even skilled medical staff in resource-constrained nations like India, where standard ECG equipment are not often accessible, to obtain a solid 12-lead ECG trace at a low cost.

Considering the foregoing, the study's goals were to assess and validate the Spandan 12 lead ECG interpretation for accuracy in detecting cardiac arrhythmias in comparison to cardiologist diagnosis; and to assess the accuracy of Spandan ECG's arrhythmia detection in comparison to the 12 lead ECG machine.

METHODS

Individuals visiting the ECG room at the department of cardiology of Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India with the prescription of ECG screening between 1 August 2022 to 31 January 2023 were invited to participate and were included in this cross sectional study, non-randomised, single blinded and single-center study after obtaining their written informed consent. The final selected study population was composed of 312 participants of either gender.

Patients were enrolled in the study by taking their written consent and explaining the purpose of the study. Patients at ECG room with or without a history of cardiovascular disease were enrolled from outpatient and emergency departments of cardiology were included in the study whereas patients with loose skin, ECGs recorded with electrical disturbances or who could not provide informed consent were excluded from the study. The Institutional Ethics Committee of SMIH approved this study.

Analysis of arrhythmias

The arrhythmias that were considered under this study were sinus tachycardia, sinus bradycardia, atrial tachycardia, atrial flutter, atrial fibrillation, junctional rhythm, ventricular tachycardia, AV-block, high degree av-block, supraventricular ectopic, ventricular ectopic, WPW syndrome and superventricular tachycardia. ECGs were generated and viewed according to instructions provided by Sunfox Technologies Private Limited. The patients were in a resting position when the ECGs were taken. The patients were subsequently given permission to lie down and followed the research nurses' instructions. The digital data including the 12-lead recording were transferred to a Google cloud-based server for further analysis using a Spandan smartphone ECG-based application.

12-lead ECG recordings

Both the Spandan 12L and 12 lead ECG devices were used to record the 12-lead ECGs at a sampling frequency of 500 Hz. The participants' ECGs were taken over a 10-second period while the patients were in resting positions by the nurse using a 12-lead standard and Spandan ECG. The patient's Spandan smartphone ECG is loaded with an application that connects the device through micro USB, allowing the patient to submit the ECG records to Google cloud-based servers.

A blinded team of cardiologist’s independently evaluated all 12-lead ECGs from standard ECG machine and smartphone 12-lead ECG machine for detection of arrhythmias. ECGs were classified for true positive if the detection was correct and false negative if the detection was wrong.

Statistical analysis

The data was collected on an excel sheet and descriptive statistical analysis was performed. Evaluation of the accuracy of arrhythmia detection was done by evaluation of specificity, sensitivity, NPV and PPV of the overall screening.

RESULTS

In total, 1528 patients with or without a history of cardiovascular disease were enrolled from outpatient and emergency departments of cardiology. A final total of 312 participants considered for accuracy of interpretation of ischemia detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists diagnosis.

Table 1 summarizes the baseline characteristics of the study population. Mean age was 53.90±14.52 years (range in years: 25 and above) and 1051 subjects (68.78%) were males while remaining 477 subjects (31.22%) were females.

Table 1: Baseline characteristics of study population.

Parameters	Overall patients with atrial fibrillation	Standard 12 lead ECG	12 lead smartphone ECG	Cardiologist's diagnosis
Age (mean±SD) years	53.90±14.52			
Female, N (%)	477 (31.22)			
Male, N (%)	1051 (68.78)			
BMI (mean) (kg/m^2)	23.48			
Arrhythmic ECG	NA	431	403	312
Non arrhythmic ECG	NA	1097	1127	1222
Bradycardia	NA	97	91	85
Tachycardia	NA	85	105	74
Atrial fibrillation	NA	28	55	34
Atrial flutter	NA	8	24	5
Ectopy	NA	41	40	24
Other arrhythmias	NA	172	88	90

Table 2: Confusion matrix of ECG interpretation for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis for overall evaluation.

Parameters	12 lead gold standard	Smartphone ECG
True positive	273	264
True negative	1022	1057
False positive	171	146
False negative	62	61

Table 3: The sensitivity, specificity, PPV, and NPV of the standard ECG and 12 lead smartphone ECG for interpretation in comparison to cardiologist diagnosis.

Parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Goldstandard 12 lead ECG	81.49	85.67	94.28	61.49
Smartphone Spandan ECG	81.23	87.86	94.54	64.39

Table 4: Accuracy of interpretation of Arrhythmias detected by the Standard 12 lead ECG and smartphone ECG in comparison to cardiologist's diagnosis (n=312).

Parameters	12 lead gold standard	Smartphone ECG
Arrhythmia detected correctly	431	403
Accuracy of detection (%)	61.86	70.8

Table 2 summarizes the confusion matrix of ECG interpretation for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis for overall evaluation. True positive cases derived from confusion matrix for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis was 264 as compared to 273 from 12 lead gold standard.

Table 3 summarizes the sensitivity, specificity, PPV, and NPV of the standard ECG and 12 lead smartphone ECG for interpretation in comparison to cardiologist diagnosis.

Sensitivity of smartphone Spandan ECG (81.23%) was comparable to gold standard 12 lead ECG (81.49%). And, specificity, PPV and NPV of smartphone Spandan ECG was recorded to be better than gold standard 12 lead ECG.

Table 4 depicts the accuracy of interpretation of arrhythmia detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists' diagnosis. Arrhythmia was detected correctly in 403 (70.8%) cases and 431 (61.86%) cases by smartphone ECG and 12 lead gold standards, respectively.

DISCUSSION

In this study, the diagnostic efficacy of a conventional 12-lead ECG equipment and a cutting-edge smartphone ECG device were evaluated. The findings were in consistence with the results of previous studies and demonstrated that both devices had diagnostic accuracies for both regular and irregular beats that were equivalent.[11-17] These results corroborated Lau et al findings that the S-ECG-R had a 98% sensitivity and 97% specificity.[21] Although the present study encompassed both normal and varied aberrant rhythms, their analysis was restricted to AF. In a similar vein, Haberman et al discovered that the rate, rhythm, and atrioventricular blocks could be detected with comparable diagnostic accuracy using conventional ECG and S-ECG-R.[18] Nonetheless, due to the stringent inclusion criteria in our study, our analysis revealed a greater diagnosis accuracy that may be explained.

Those who were unable to steadily grasp the accessory in both hands were disqualified. We may have overestimated our findings since we removed persons because of the poor recording quality, which affected about 4% of the overall population. Cardiologists' and smartphone application algorithm evaluations of the 1L-ECG device's positive diagnostic qualities for AF/AFL were consistent with a number of earlier investigations. The investigations by Chan et al and Desteghe et al which obtained sensitivities of 71.4%, 66.7%, and 65.9%, respectively, using the KardiaMobile algorithm to identify AF, stood out as notable outliers.[19,20] The low sensitivity of the AF-detection algorithm in the authors' individual studies, all of which were carried out with chosen older patients, wass not adequately explained.

The most prevalent arrhythmias were considered in this study, including supraventricular tachycardia, sinus bradycardia, premature complexes, and AF. They may provide a clinical problem and induce palpitations. A new theme of diagnosing and monitoring these arrhythmias, particularly those that are challenging to diagnose using other conventional methods, may emerge from research into the usefulness and diagnostic accuracy of such devices. This might have an impact on the level of treatment provided, the cost, patient involvement in their care, and their happiness.

In contrast to previous techniques, the confirmation of rhythmic irregularities detection utilising Spandan allowed the user's smartphone to view ECG data in real-time. To allow real-time monitoring, the user's smartphone must have the application loaded on it, and Spandan must be linked to it through micro USB cable. As a result, it offered benefits for real-time ECG monitoring but may also carried a risk of data loss from bluetooth disconnecting. The benefit of Spandan was its low weight (15 g). Because it employed interchangeable electrodes and a coin cell battery, the gadget was simple to reuse. This study hypothesises that Spandan's real-time ECG monitoring made it likely to be helpful when determining if a patient's ailment was related to intermittent arrhythmia. Furthermore, because of the Spandan's light weight and small size, increased patient compliance with utilising the device was anticipated.

Limitations

This study used a single device and a single centre. Prior to receiving each recording, participants received instructions on how to utilise the smartphone application, and their capacity to capture each trace was immediately assessed. Without this guidance, the recorded tracings' accuracy in an ambulatory situation may suffer. The study's average population age, which was greater than the average age of the Indian population at 54 years old, was another possible weakness. Hence, it's possible that the results don't accurately reflect what the broader population would experience.

CONCLUSION

Spandan is a user-friendly, stand-alone smartphone app that has shown good results for detecting rhythm irregularities. Spandan ECG device received great marks for accuracy, sensitivity, and specificity. The overall accuracy of smartphone ECG in detecting the rhythm abnormalities increase by 9%, the significance rises in accuracy of computer interpretation when compared to the cardiologist's diagnosis. Hence, we can conclude that of the smartphone-based ECG will not only bring the convenience to the primary healthcare provider but also enhance the patient experience. These results make the app a potential candidate for inclusion in next rhythm abnormality screening or case-finding programmes. Before acting on electrocardiographic diagnosis produced by this smartphone-based 12-lead ECG equipment, doctors should use care.

Funding: Funded by Sunfox Technologies for validation of Spandan ECG device
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mahajan S, Garg S, Sharma R, Singh Y, Chandola N, Bhatia T, et al. Accuracy of smartphone-based electrocardiogram for the detection of rhythm abnormalities in limb lead: a cross sectional study, non-randomised, single blinded and single-center study. Int J Res Med Sci 2023;11:1165-9.