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Evaluation of Spandan Smartphone-Based Electrocardiogram for Arrhythmia Detection: A Cross-Sectional Study in a Large Patient Cohort

ABSTRACT

Background: To assess the diagnostic accuracy of the Spandan Lead II smartphone-based electrocardiogram (ECG) device regarding cardiac arrhythmia, compared with that of the only lead II ECG strip from the gold-standard ECG machine (BPL ECG machine) and the diagnosis by a cardiologist.

Methods: The study, conducted from August 2, 2022, to June 2, 2023, in the local hospital, included 2799 participants aged 20 years and above. This was a single-blinded, cross-sectional study comparing the Spandan ECG device against the Gold Standard ECG and was diagnosed by a cardiologist. Participants referred for ECG testing by a cardiologist were included, and those with a pacemaker and/or ECG artifacts were excluded. To avoid any bias, the diagnosis was blinded to the cardiologist. Sensitivity, specificit , predictive values, *F*-score, and Matthew's correlation coefficie t of the Spandan device were the parameters on which accuracy was studied.

Results: Among 2799 participants (843 females, 1,956 males), the Spandan ECG system demonstrated high accuracy compared to the gold standard ECG machine, with sensitivity (95.5%), specificity (96.3%), positive predictive value (93.2%), negative predictive value (97.6%), *F*-Score (0.94), and a $P = .913$, for $P > .001$. It identified all arrhythmias without discrepancies and closely aligned with the gold standard ECG, which had slightly lower performance metrics. The study concluded that the Spandan Lead II ECG system is clinically applicable, especially in resource-limited settings.

Conclusion: The Spandan lead II smartphone-based ECG device offers high accuracy in diagnosing cardiac arrhythmias, comparable to standard ECG machines. Its portability, affordability, and ease of use make it a valuable tool for timely diagnosis in almost all clinical and non-clinical settings.

Keywords: Cardiac arrhythmia detection, lead II ECG, portable ECG devices, real-time monitoring, smartphone-based ECG, Spandan ECG

ORIGINAL INVESTIGATION

INTRODUCTION

A cardiac arrhythmia is an irregular heartbeat. The most common way of classifying them is based on the rate of conduction: bradyarrhythmia with a heart rate of less than 60 beats per minute (bpm) and tachyarrhythmia with a heart rate greater than 100 bpm.[1] It may lead to a life-threatening stroke, heart failure, or cardiac arrest. It is anticipated that 1.5%-5% of the general population would experience arrhythmias, with atrial fibrillation being the most prevalent.[2] It may be difficult to determine the true prevalence of arrhythmias because they can be paroxysmal and develop with or without symptoms at all. The overall presence of arrhythmia is associated with a higher degree of morbidity and mortality.[1] Accurate detection is related to the prevention of severe outcomes, and thus electrocardiogram (ECG) is an essential tool in clinical practice.

Electrocardiogram is one of the non-invasive diagnostic means that provides rapid identifi cation for many heart diseases, especially the electro-cardiac arrhythmias and acute coronary syndrome.[3-5] Diagnosis of any cardiac arrhythmia requires ECG confirmation to determine the severity, implications, and available treatments. Traditional short-term cardiac monitors cannot provide adequate information

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for patients who have infrequent and temporary symptoms or who suffer from paroxysmal atrial fibrillation (AF) with or without symptoms.[6] The standard 12-lead ECG has a major limitation in that it needs exact electrode placement, which makes it challenging for patients to record at home without medical assistance. A method for home ECG recording without professional help would be highly beneficial [7]

However, with the emergence of smartphone-based electrocardiogram devices in recent times, this field has been revolutionized by offering a portable, inexpensive, and practical solution for the detection of arrhythmias in real time. Continuous monitoring, ease of use, and broad accessibility offered by these devices are essential for effective arrhythmia management. These smartphone ECG devices are useful in the detection of various cardiac rhythm abnormalities. The use of the AliveCor Kardia smartphone ECG device was demonstrated by Jewson et al[8] for diagnosing exercise-related arrhythmias in athletes, with their obtained ECG traces during highly vigorous exercise, where traditional monitors would fail. Issa et al[9] presented a deep neural network model for the classifi ation of ECG beat classes, achieving high levels of accuracy and thus being one of the advanced machine learning techniques to show potential for improvement in diagnostic capabilities using single-lead mobile ECG devices.

Recent advancements have increased the scope of these devices. For instance, Haseeb et al[10] investigated the integration of artificial intelligence with smartphone ECG devices and observed signifi ant improvements in the accuracy of arrhythmia detection and predictive analytics. Similarly, benefits from real-time monitoring for patients with chronic cardiac conditions have been reviewed by Hossain et al[11], underscoring a reduction in emergency room visits and hospitalization due to timely interventions. Further, Zimetbaum and Nguyen[12] discussed the implications of mobile health technologies in chronic disease management, highlighting their role in patient empowerment and engagement.

The predictive capabilities of these devices were also demonstrated by some research. Gadaleta et al[13] developed a deep-learning model for the prediction of near-term AF from ambulatory single-lead ECG recordings using AF-free ECG intervals, improving the accuracy of prediction by a signifi ant margin over demographic metrics alone. More generally, Baman et al[6] discussed the impact of mobile health (mHealth) devices, including smartphone ECGs, on the accessibility and lowering of costs associated with arrhythmia detection, despite limitations like motion artifact and the need to confirm the d tected arrhythmias by ECG.

A smartphone-based ECG device's accuracy in monitoring horse cardiac rhythms was demonstrated by Hothersall et al[14] in veterinary medicine, indicating a wider range of applications beyond human medicine. Various large-scale screening studies, like Gruwez et al[15] in Belgium, have demonstrated the therapeutic implications and viability of using smartphone-based devices for AF screening in the general population. Similarly, Rajakariar et al[16] evaluated the AliveCor KardiaBand's diagnostic accuracy for AF and emphasized the need for physician involvement to ensure proper diagnosis.

Portable ECG devices, such as the Apple Watch and Alivecor, are used for lead I testing, which assesses rhythm abnormalities like atrial fibrillation. To prevent false positives, high specificity and sensitivity are required. The Lead II or a rhythm strip is sufficie t for diagnosing any cardiac arrhythmia. A smartphone-based portable ECG device (Spandan) that is capable of taking lead II and also 12 lead ECGs by using derived ECG methods. The Spandan portable ECG (Sunfox Technologies Pvt. Ltd.) device connects to a smartphone via an application interface, as shown in Figure 1. The test ECG device claims to evaluate cardiac arrhythmias.[17,18]

In the context of smartphone-based electrocardiographic devices, Mahajan et al[19] assessed the accuracy of the Spandan 12-lead smartphone ECG device in rhythm abnormality detection. Their study demonstrated that the Spandan ECG device had high sensitivity and specificit , like the standard 12-lead electrocardiogram, which opens a potential role for this tool to increase diagnostic accuracy in routine clinical practice. Their finding , therefore, provided a base for smartphone electrocardiographic devices in improving arrhythmia detection and management in clinical and non-clinical settings.[20]

Various case reports illustrate the Spandan ECG device's ability to detect early disease stages and prompt medical intervention. Singh et al[21] reported a 54-year-old patient with chest heaviness and palpitations, for which Spandan ECG revealed anteroseptal and lateral wall ischemia, thus helping in ischemic heart disease management. Another case involved an 84-year-old female with several comorbidities who became confused as a result of ventricular premature contractions and AF. The device facilitated AF detection, leading to pacemaker implantation.[22] Similarly, Spandan detected sinus rhythm with ventricular premature complexes in a 63-year-old patient with dyspnea, later diagnosed with atrial septal defect.[23] Chandola[24] reported Spandan ECG's role in monitoring ventricular tachycardia and cardiac sarcoidosis, guiding timely defibrilla or implantation. Additionally, Singh et al[25] identified Wolff-Parkinson-White syndrome during a routine health check-up. These cases underscore Spandan's value as a point-of-care modality in enhancing cardiac diagnosis and management.

HIGHLIGHTS

- The Spandan device is handy in resource-constrained places because it is portable, affordable, and easy to use in various clinical and non-clinical settings.
- A reliable alternative for the Lead II ECG strip from the Gold Standard ECG machines, the study demonstrated that the Spandan lead II ECG device delivers outcomes that match comparable devices.
- Spandan's effi acy in identifying arrhythmias like ventricular ectopic beats and atrial fibrillation emphasizes its usefulness in managing cardiac conditions.

Figure 1. Spandan portable electrocardiogram, developed by Sunfox Technologies Pvt. Ltd., is a smartphone-based portable ECG device capable of taking lead II and also 12 lead ECGs by using derived ECG methods to evaluate cardiac arrhythmias.

The study was designed to assess and validate Spandan lead II ECG interpretation in detecting cardiac arrhythmia accuracy by comparing its diagnostic performance with only lead II ECG strips from the Gold Standard ECG machines and diagnoses made by a cardiologist. This was done by evaluating the sensitivity, specificit , and overall accuracy of Spandan.

METHODS

Study Design

The study has been designed with meticulous care: a single-blinded, cross-sectional, and observational inquiry. It is aimed at validating the accuracy of only Lead II of the Spandan 12 Lead ECG Machine interpretation for detecting cardiac arrhythmias, compared with a cardiologist's diagnosis, and assessing the accuracy of Spandan ECG in the detection of arrhythmias when compared with only the lead II strip from the 12 Lead gold standard ECG machines.

Participants

The study cohort comprised 3000 individuals aged 20 years or older who had been selected from patients referred by doctors for ECG investigation in the ECG room. Patients with implanted pacemakers and those who reported baseline wandering and artifacts in the ECG reports were excluded from this analysis. Following the application of exclusion criteria, 2799 individuals were eligible for inclusion, ensuring a cohort representative of the target population.

Lead II Electrocardiogram Strips for Arrhythmia Detection

The comparison was performed between the Lead II ECG strip from the gold standard ECG machine and the Lead II ECG strip of the Spandan ECG device. While both devices are capable of recording a full 12-lead ECG, the analysis focused especially on the Lead II rhythm strip, which is capable of arrhythmia detection, including conditions such as AF, atrial ectopic beats, and other arrhythmias.[9] Lead II acquisition is straightforward and can be performed even by untrained personnel, enhancing its practicality in diverse settings. To address potential discrepancies caused by dynamic ECG changes, the time interval between recordings from the 2 devices was strictly limited to no more than 10 minutes, thereby minimizing the risk of evaluation errors and ensuring a robust comparison.

Ethical Considerations

Although this study primarily evaluates the device's diagnostic capabilities rather than making direct clinical decisions, it has been recognized that data from this study could inform future diagnostic or decision-support tools. The institution's ethics board has been consulted, and while formal ethics approval was deemed unnecessary for this phase, ethical standards such as obtaining signed informed consent without recording patient names, anonymizing and encoding patient names on ECG reports, and Case Report Forms during data collection to ensure participant confide tiality will be adhered to. If the scope of the study evolves to involve clinical decision-making directly, ethics committee approval will be sought as appropriate.

Ethical Approval

Ethical considerations for this study were conducted under the guidance of the head of the Cardiology Department due to the non-interventional nature of the research and no clinical decisions or medications were administered based on the smartphone ECG device results. All clinical decisions were made by cardiologists using the gold standard ECG. As a result, local institutional ethics committee approval was not sought. The study was carried out in accordance with the principles of the Declaration of Helsinki.

Informed Consent

Before being included in the study, each participant provided their informed consent. Both verbally and in writing,

participants received comprehensive information on the purpose, procedures, potential risks, and benefits associated with the study. Consent forms were designed to be easily understandable and included statements ensuring participants' right to withdraw from the study at any time without any consequences to their medical care. Signed consent forms were collected and securely stored according to ethical guidelines.

Settings

This research was carried out in the ECG room at the local hospital from August 2, 2022 to June 2, 2023.

Supervision and Oversight

All tests and procedures were undertaken under the supervision of a cardiologist or an ECG technician to ensure uniformity in following laid-down protocols, introducing the least bias. With such conscientious supervision maintained, the data collected becomes more reliable and accurate, and the integrity of the research study is preserved.

Reference Standard

In this study, the reference standard used for the assessment of both the Spandan smartphone-based ECG device and the Gold Standard ECG machine was the cardiologist's interpretation of arrhythmias. Sensitivity, specificit , positive predictive value (PPV), negative predictive value (NPV), and accuracy rates were calculated for reports of both devices to compare their diagnostic performance relative to the cardiologist's interpretation. This approach provides an unbiased assessment of their ability to detect arrhythmias accurately in the study population.

Data Collection

The study will be conducted in 2 stages. In the fir t stage, consent forms will be collected from participants verbally and in writing. Field data collectors will fill out the Case Report Format (CRF) according to study protocols, which will be submitted to the principal investigator. The CRF contains information on diabetes history, smoking, current symptoms, implanted pacemakers, and any history of coronary intervention. The CRF assists the cardiologist in diagnosing the case appropriately. In the second stage, the ECG will be performed by the Gold standard ECG machine, followed by the lead II ECG test using the Spandan smartphone-based ECG device. Both ECG machines are equipped with computerized interpretation, and printed reports will be obtained.

Data Interpretation

A cardiologist would be assigned to provide a diagnosis for both Spandan and Gold standard ECG reports. The cardiologist would be blind computerized interpretations to avoid bias.

Timing Considerations

To mitigate this potential bias, a time interval of not more than 10 minutes between the Spandan system report and the Gold Standard ECG report will be observed. This temporal demarcation ensures an impartial and stringent assessment of diagnostic accuracy.

Both the gold standard ECG and the Spandan device performed simultaneous recordings in the majority of cases. However, the cases listed below experienced time discrepancies between the recordings due to factors such as patient overload and challenges like improper electrode adhesion caused by hair or oily skin.

As understood, the note highlights specific considerations for interpreting the results:

a) If the gold standard indicates Sinus Tachycardia or Bradycardia while Spandan shows normal but the doctor deems it abnormal, it will be classified as a true positive. This occurrence may be attributed to time differences between the 2 ECGs.
In case 1, there was a time discrepancy of 1 minute between both reports. The 2 devices—the Gold Standard ECG machine and the Spandan lead II ECG device—show varying heart rates and arrhythmia conditions. The Gold Standard ECG machine shows a heart rate of 57 bpm coupled with sinus bradycardia. In contrast, the Spandan ECG device presents a heart rate of 65 bpm and a normal sinus rhythm but the doctors deem it as sinus bradycardia. So, it was classified as a true positi e, as shown in Figure 2A,B.

b) If premature atrial contractions (PAC) or premature ventricular complexes (PVC) are evident in only 1 ECG graph, it will also be regarded as a true positive. PAC and PVC can be episodic and, therefore, may not manifest in another ECG graph.
In case 2, there was a time discrepancy of 4 minutes between both reports. The Gold Standard ECG machine and the Spandan lead II ECG device both show varying heart rates and arrhythmic conditions. The Gold Standard ECG machine shows a heart rate of 75 bpm coupled with premature atrial contraction, while the Spandan lead II ECG device presents a heart rate of 78 bpm and a normal sinus rhythm but the doctor deems it to be a case of premature atrial contraction. Therefore, it was considered as a true positive, as shown in Figure 3A,B.

Statistical Analysis

The diagnostic accuracy of the 2 devices, Spandan and the gold standard, concerning recommending arrhythmia, was evaluated in this regard by sensitivity, specificit , PPV, NPV, *F*-Score, and Matthew's correlation coefficie t (MCC).

The ***F*-score**, or ***F1*-score**, measures a test's accuracy, focusing on the balance between correctly identified positive cases—true positives (TP)—and misclassified cases, including false positives (FP) and false negatives (FN). It is calculated as shown in equation (1).

$$F-score=\frac{TP}{TP+\frac{1}{2}(FP+FN)} \quad (1)$$

The *F*-score ranges from 0 to 1, where a value of 1 indicates perfect accuracy, meaning all true positives are identified without any false positives or false negatives, while a value of 0 represents the worst possible performance, with no true positives identified

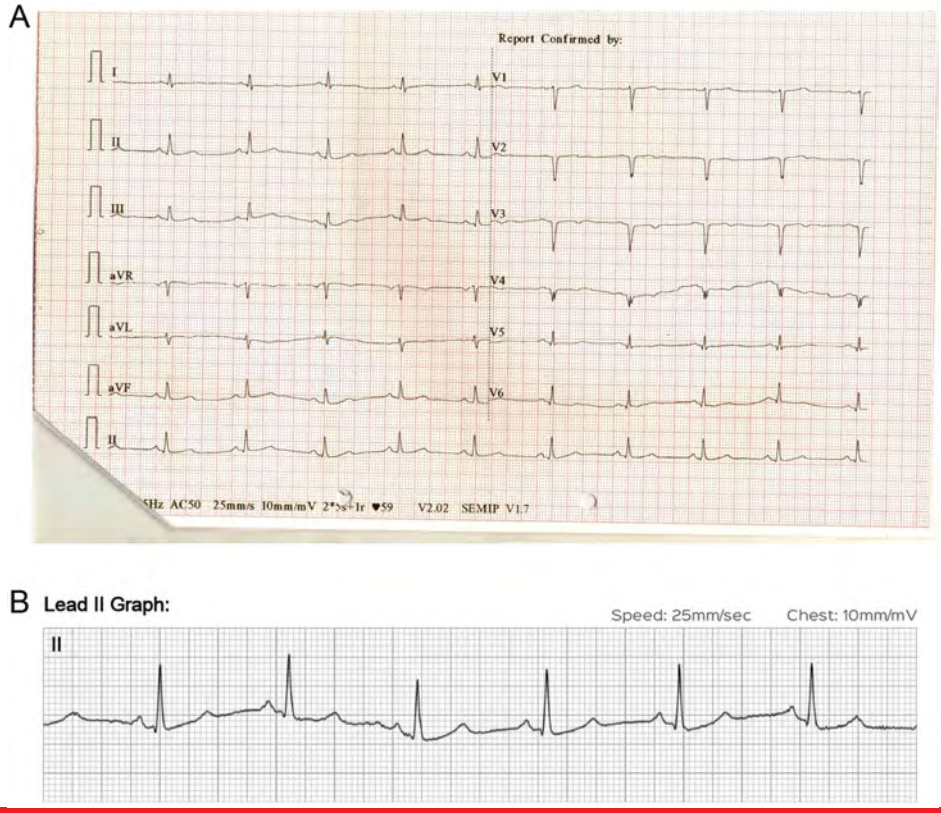

Figure 2. (A) Case 1 gold standard ECG: Patient showing sinus bradycardia as interpreted by computerized analysis of only lead II ECG strip from the gold standard ECG machine. (B) Case 1 Spandan lead II ECG: Patient showing normal sinus rhythm as interpreted by computerized analysis of Spandan device.

Matthew's correlation coefficie t is a metric for evaluating binary classifi ation performance, accounting for TP, true negatives (TN), FP, and FN. It is calculated as shown in equation (2).

$$MCC = \frac{TN \times TP - FN \times FP}{\sqrt{(TP + FP)(TP + FN)(TN + FP)(TN + FN)}} \quad (2)$$

P-value ranges from –1 to +1, where +1 represents perfect agreement, 0 indicates random guessing, and –1 signifies total disagreement between predictions and actual outcomes.

Artificial Intelligence–Assisted Technologies: QuillBot, Draw.io.

Data Privacy, Security, Confide tiality, and Storage

The hospital ensures that no data will be shared with any department, company, or third party, as protecting patient data privacy and security is the top priority. The study will adhere to strict data handling protocols: all data will be anonymized at the point of collection and securely stored on a 2-step authenticated local server of the hospital, with backup storage maintained through HIPAA-compliant cloud storage and spreadsheets, as well as printed sheets stored in the hospital. Access to the data will be restricted to authorized personnel from the hospital. No personally identifiable information will be linked to the data used for analysis. Furthermore, all data transfers will utilize secure, encrypted channels to maintain data integrity and confide tiality.

Archival

The scanned ECG reports and all study-related documents will be kept in cloud storage for transparency purposes and future reference. Archiving this way ensures proper scrutiny and verifi ation of the finding .

Technical Specifi ations of the Spandan Device

A description of the algorithms utilized by the device for arrhythmia detection (e.g., signal preprocessing, feature extraction, and decision logic), as outlined in Figure 4, was applied for analysis.

RESULTS

In this study, the STARD (Standards for Reporting Diagnostic Accuracy Studies) guidelines were followed (as shown in Figure 5). These guidelines are based on diagnostic accuracy studies, which are designed to assess the performance of a diagnostic test or tool (Spandan smartphone-based ECG) by comparing its results with a reference or gold standard. This approach ensures the reliability and validity of the findings by adhering to a standardized framework for reporting diagnostic accuracy.

The study initially enlisted the participation of 3000 individuals between August 2, 2022, and June 2, 2023. Only 2799 individuals who fulfilled the inclusion criteria of the present

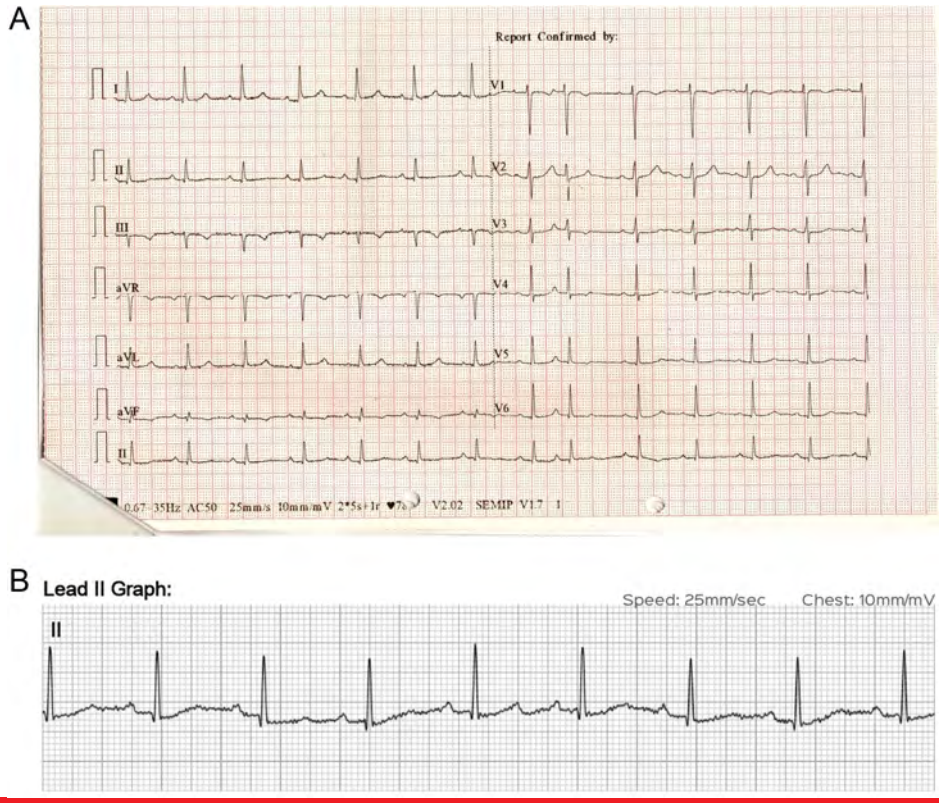

Figure 3. (A) Case 2 Gold Standard ECG: The patient is showing premature atrial contraction as interpreted by computerized analysis of only Lead II ECG strip from the gold standard ECG machine. (B) Case 2 Spandan Lead II ECG: The patient is depicting normal sinus rhythm as interpreted by computerized analysis of Spandan device.

study were invited to participate in the Arrhythmia screening study. Among them, 979 exhibited abnormalities, while 1820 displayed normal ECG readings. The cohort comprised 843 females and 1956 males, thus reflecting the gender distribution within the population. Adhering to hospital protocols, every patient referred by a doctor to the ECG room underwent an ECG procedure utilizing the Gold Standard ECG. In the specific context of this research endeavor, an additional ECG was recorded using a smartphone-based ECG device.

A comparative analysis of ECG tracings from both the Gold Standard machine and the Spandan smartphone-based lead II ECG device for the lead II test revealed substantial concordance. Most tracings displayed an excellent resemblance, with only minor differences that lacked diagnostic significance. Figures 6 and 7 visually exemplify this alignment, showcasing the Gold Standard ECG and the Spandan ECG of the same patient.

For instance, the computerized analysis of the Gold Standard ECG revealed atrial fibrillation. Next, the computerized interpretation by Spandan also showed atrial fibrillation, aligning the result with the Gold Standard ECG. A cardiologist, blinded to the computerized interpretations and origin of the reports, reviewed both sets of ECG tracings independently to avoid bias. This clinical interpretation was confirmed by the cardiologist as evidence of atrial fibrillation in the patient and further highlighted the potential diagnostic utility of the Spandan ECG device.

Among 979 abnormal cases, premature ventricular complexes (11.6%), sinus bradycardia (33.6%), and sinus tachycardia (41.2%) were most prevalent, and other different types of detected arrhythmias were outlined in Table 1.

Hypertension (24.7%) and CAD (36.37%) dominated participant comorbidities, highlighting a diverse clinical profile, as shown in Table 2.

Spandan ECG showed comparable accuracy to the gold standard ECG, with higher true positives and fewer false positives detected, as demonstrated in Table 3.

Spandan ECG had more specificity than the gold standard ECG (96.3% vs. 94.8%) and had a higher PPV (93.2% vs. 90.3%) while having equivalent sensitivity and negative predictive value, as presented in Table 4 and Figure 8.

The Spandan Lead II ECG performed better by achieving 96.0% accuracy, 93.2% precision, an *F*-score of 0.94, and a $P = .913$, for $P > .001$; it outperformed the Gold Standard ECG in all aspects, as shown in Figure 9 and Tables 5 and 6.

Among 2799 subjects, the prevalence of diabetes, hypertension, and smoking was analyzed. Higher male representation in both normal and abnormal groups is reported in Table 7.

Confounding Factors: Analysis of demographic variability (age, gender, comorbidity) and its influen e on the results were described in Table 8. Environmental factors, such as

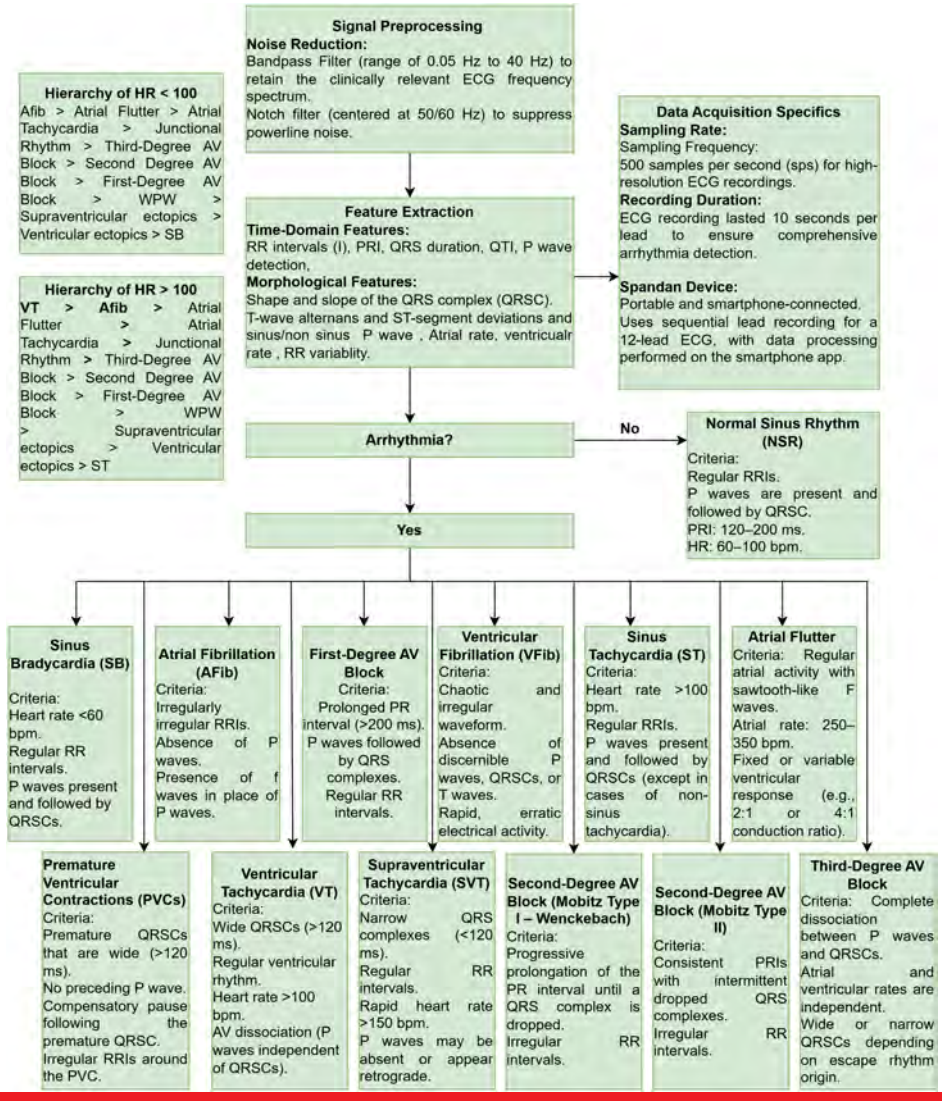

Figure 4. Algorithm of the device for cardiac arrhythmia detection.

patient movement, improper electrode placement, and electrical noise, can affect ECG recording quality in healthcare settings. Physical activity, like during stress tests, may introduce noise or arrhythmias, impacting device performance and interpretation accuracy.

A detailed comparison of the Spandan Smartphone ECG's diagnostic performance with outcomes from prior research on cardiac arrhythmia detection was presented in Table 9.

DISCUSSION

Principal Findings

To assess and validate the diagnostic performance of the Spandan lead II ECG device for the diagnosis of cardiac arrhythmias compared to the gold standard conventional ECG machine, diagnosis by the cardiologist. The Spandan ECG captured episodes of arrhythmias in the subject under continuous monitoring, each 10 seconds in duration. Data showed numerous forms of arrhythmic patterns; among the most common were Atrial Flutter, AF, Accelerated Junctional Rhythm, Atrial Tachycardia, Junctional Rhythm, Ventricular Ectopic, Sinus Bradycardia, and Sinus Tachycardia. The fin - ings of this study underscore the clinical validity and reliability of lead II-based arrhythmia testing using the Spandan smartphone-based ECG device. These results demonstrate high sensitivity and specificit , with Spandan ECG achieving a sensitivity of 95.5% and a specificity of 96.3% in detecting cardiac arrhythmias compared to the gold standard ECG. These results highlight the robustness of Spandan ECG in accurately identifying rhythm abnormalities, reaffirming its clinical utility and correctness in arrhythmia detection.

Atrial fibrillation is the most prevalent persistent heart rhythm disorder in the general population, with a global community prevalence ranging from 0.5% to 5.5%.[28-31] Research conducted in India has revealed signifi ant variations in AF prevalence, ranging from 0.1% to 1.6%.[32,33] This highlights the need for tools like the Spandan smartphone-based ECG, which can assist patients in early detection of arrhythmias in both clinical and non-clinical settings. In those with detected arrhythmias, timely intervention may help in altering treatment plans.

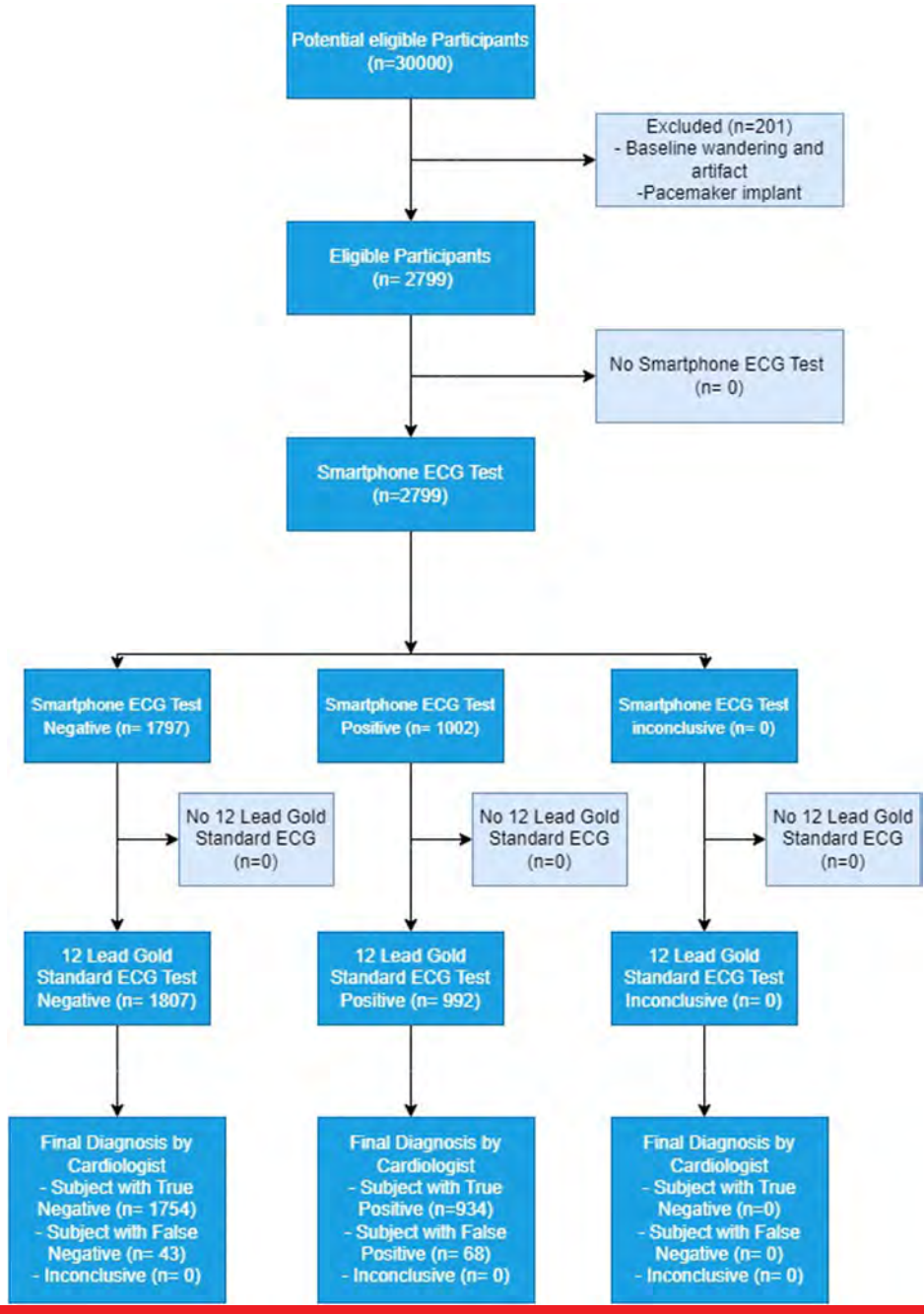

Figure 5. Standards for Reporting Diagnostic Accuracy Studies Flowchart of the Study: Flow diagram for the inclusion of patients in this study's subjects from August 2, 2022 to June 2, 2023, according to the Standards for Reporting of Diagnostic Accuracy studies.

Comparison with the Existing Literature

In this study, there were 52 patients with 1st Degree AV Block diagnosed, with a predominance of males (85%) and the most afflic ed age group being individuals aged 60 and above. This study showed a high correlation between aging, diabetes, and 1st AV Block. In diabetic individuals, a signifi antly higher ratio of developing 1st AV Block was observed in males than in females. Previously, studies have shown an increased diabetes and an elevated risk for 3rd Degree AV Block,[34-36] This study demonstrates that diabetes also elevates the risk of 1st Degree AV Block. However, further research on larger populations is needed to validate these finding . The presence of 1st Degree AV Block in high-risk groups highlights the importance of closer monitoring to prevent progression to severe arrhythmias.

Premature ventricular complexes were the most common arrhythmia identified, observed in 114 patients, with a higher prevalence among males and individuals aged 60 and above. Premature ventricular complexes were particularly frequent in patients with diabetes mellitus, with males again exhibiting a signifi antly higher risk than females. These findings align with the previous study by De Sensi et al (2022)[37], which

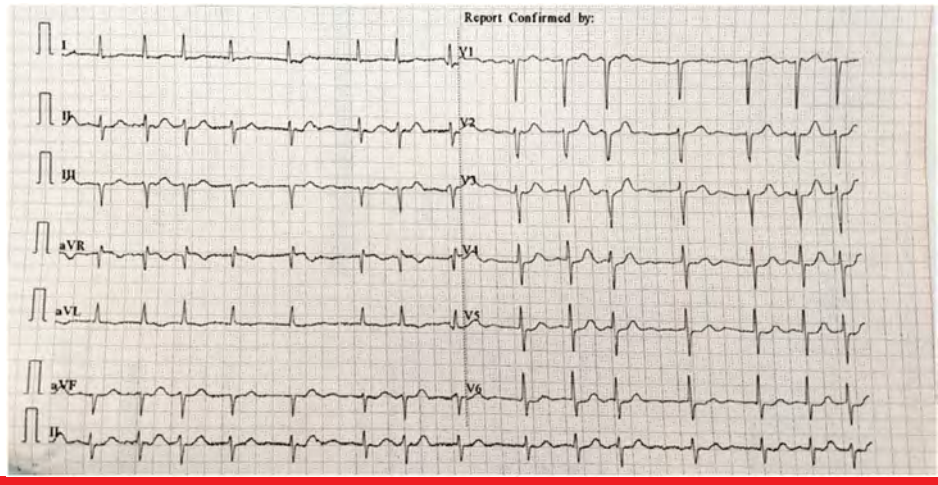

Figure 6. Gold Standard ECG: Patient showing atrial fibrillation as interpreted by computerized analysis of only lead II ECG strip from the gold standard ECG machine.

reported that diabetes mellitus patients are more likely to experience PVCs.

Atrial fibrillation was observed in 68 patients in this study, with the condition primarily affecting older individuals, particularly those aged 60 and above, highlighting age as a signifi ant risk factor. Additionally, males were slightly more affected than females. The study also identifie hypertension as a key contributor to the risk of developing AF. These findings suggest that targeted screening for AF in hypertensive patients, especially in elderly males, could be beneficial for early diagnosis and effective management. Consistent with previous research, this study reinforces the association between hypertension and an increased risk of AF.[38,39]

Although the gold standard 12-lead ECG has to be taken in clinical settings only and with considerable care towards electrode placement and requires medical assistance, the present device is helpful in remote locations by facilitating easy usability and portability, which aids in providing good monitoring irrespective of healthcare setup. Several prior studies agree with these conclusions by establishing that real-time arrhythmia detection is feasible in any type of healthcare environment, either in rural or in the urban setup.[40-42]

Moreover, in a review by Bhavnani SP et al (2018)[43], the authors discussed the broader implications of mobile health technologies, underscoring the transformative potential of these tools in modern healthcare. These studies collectively support the notion that smartphone-based ECG devices, such as Spandan, are not only clinically viable but also highly beneficial in enhancing patient care through improved diagnostic accuracy and timely intervention.

Strengths and Limitations

Strengths

- Large Sample Size: 2799 participants enhance the statistical power and generalizability of these finding .
- Real-world Setting: The conduct of the study in a hospital setup in which a diversity of patient population can be seen improves the external validity of the results.
- Comprehensive Comparison: Comparison directly with the Gold Standard ECG and diagnosis by cardiologists provide a robust validation of the device Spandan.

Limitations

- Exclusion Criteria: Excluding patients with pacemakers and those with signifi ant baseline ECG artifacts might limit the applicability of the findings o these subgroups.

Addressing Selection Bias

Exclusion of Patients with Pacemakers

Excluding pacemaker patients limits the study's applicability, as pacing signals alter the natural ECG waveforms, complicating arrhythmia detection. Future studies should develop algorithms to differentiate natural activity from pacing artifacts and validate arrhythmia detection in this group. Subgroup analyses with modified Spandan devices could enhance its relevance for pacemaker populations.

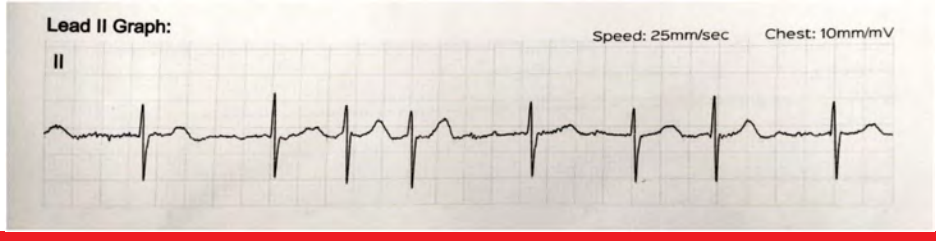

Figure 7. Spandan ECG: Patient depicting atrial fibrillation as i terpreted by computerized analysis of Spandan.

Table 1. Participants with Abnormal Cases (n = 979)

Types of Arrhythmias Detected	Number of Cases	Percentage (%)
Atrial flut er	7	0.7
Atrial fibrillatio	68	6.9
Accelerated junctional rhythm	4	0.4
Atrial tachycardia	2	0.2
Junctional rhythm	9	0.9
Premature ventricular complexes	114	11.6
Sinus bradycardia	329	33.6
Sinus tachycardia	404	41.2
Supraventricular tachycardia	1	0.1
Ventricular tachycardia	4	0.4
Supraventricular ectopic	64	6.5
First-degree atrio-ventricular block	52	5.3
Second-degree atrio-ventricular block	4	0.4
Complete atrio-ventricular block	1	0.1

Table 2. Baseline Characteristics of the Participants

Variables	Number	Percentage (%)
Hypertension	692	24.7
Diabetes	491	17.5
CAD	1018	36.37
Stent	871	31.1
Smoking	172	6.1

Exclusion of Patients with Baseline Artifacts

Excluding patients with baseline artifacts ensures that data is clean for the validation of algorithms but limits the real-world applicability where tremors, respiration, or electrode placement are a common source of common noise. Future studies should integrate advanced noise fil ering techniques and test performance in artifact-prone settings, challenging the robustness, usability, and accuracy of the device under everyday clinical and home conditions.

Table 3. Confusion Matrix of ECG Interpretation of Gold Standard and Spandan Lead II ECG

Parameter	Spandan ECG	Gold Standard ECG
True positive	934	896
True negative	1754	1764
False positive	68	96
False negative	43	43

Table 4. The specificit , Sensitivity, Nnegative Predictive Value, and Positive Predictive Value of Gold standard and Spandan Lead II ECG

Validation Parameter	Spandan ECG (%)	Gold Standard ECG (%)
Specificit	96.3	94.8
Sensitivity	95.5	95.4
NPV	97.6	97.6
PPV	93.2	90.3

Addressing Selection Bias in General

To broaden applicability, future research should aim to recruit diverse samples, including patients with complex ECG morphologies or cardiac devices such as pacemakers. Technological enhancements like real-time artifact detection and correction algorithms in the device and specialized protocols for pacemaker patients, can improve diagnostics and inclusivity, addressing current technical limitations effectively.

Scalability and Cost-Effectiveness

1. **Affordability:** Traditional 12-lead ECG systems involve high costs for equipment, maintenance, and consumables

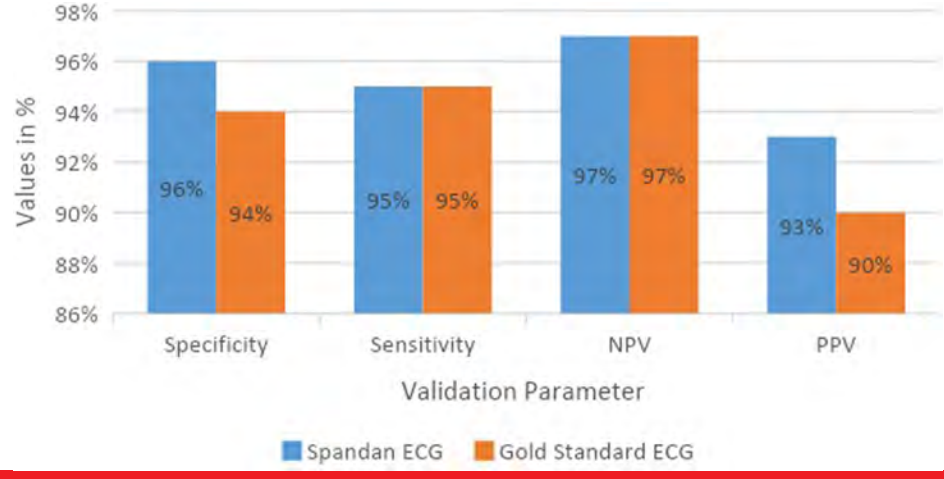

Figure 8. Validation parameters: Specificit , senstivity, negative predictive value, and positive predictive value of Spandan lead II ECG and gold standard.

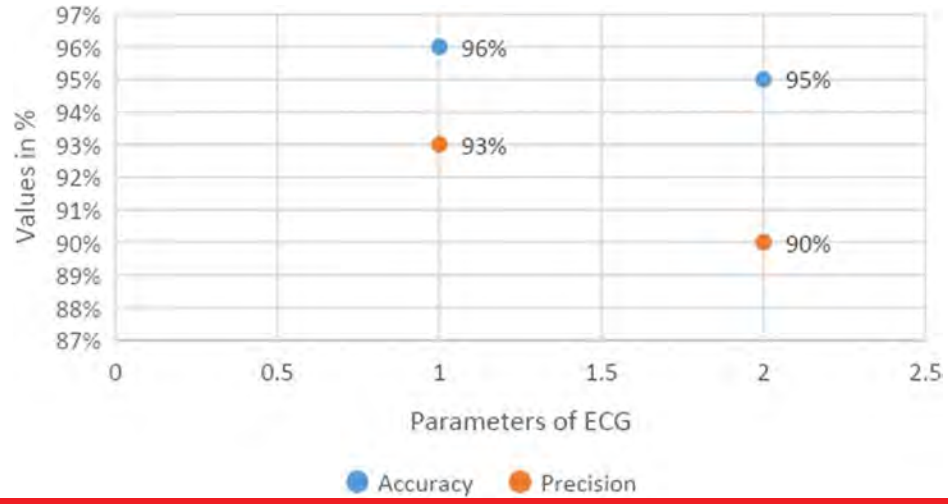

Figure 9. Parameters: Accuracy and precision of Spandan lead II ECG and gold standard ECG.

Table 5. The Accuracy and Precision of Spandan Lead II ECG and Gold standard ECG

Parameters	Spandan ECG (%)	Gold Standard ECG (%)
Accuracy	96.0	95.0
Precision	93.2	90.3

Table 6. The *F*-score and the Matthew Correlation Coefficie t for Spandan Lead II ECG and Gold Standard ECG

Parameters	Spandan ECG	Gold Standard ECG
F-Score	0.94	0.93
Matthew Correlation Coefficie t	0.913	0.891

(e.g., paper rolls), while the Spandan device, with smartphone integration, offers low upfront costs and minimal operating expenses, making it economically feasible for clinics, low-resource settings, community health workers, and individual users.

2. **Ease of Use:** The Spandan device's user-friendly design enables non-clinical personnel to record ECGs with minimal training. Its smartphone app offers automated analysis and diagnostic suggestions, reducing reliance on expert interpretation and ensuring rapid deployment in rural areas.
3. **Portability:** Unlike bulky traditional ECG machines, the Spandan device is lightweight and easily transportable, making it ideal for field ork and emergency care.
4. **Minimal Infrastructure Requirements:** The Spandan device eliminates the need for dedicated facilities such as specialized ECG rooms or stationary equipment, enabling its use in homes, rural clinics, and ambulances, while leveraging existing smartphone technology for accessibility in low-resource settings.

Table 7. Distribution of Diabetic Patients by Gender in Normal and Abnormal Groups

	Normal	Percentage (%)	Abnormal	Percentage (%)
Diabetes				
Male	226	12.40	110	11.20
Female	95	5.20	60	6.10
Hypertension				
Male	326	17.90	166	16.90
Female	115	6.30	85	8.60
Smoking				
Male	131	7.10	32	3.20
Female	8	0.40	1	0.10

Table 8. Confounding Factor – Variability in Patient Demographics

Cardiac Arrhythmia		1st Degree AV Block	Ventricular Premature Complexes (VPC)	Atrial Fibrillation
Total patients		52	114	68
Gender	Male	44	70	41
	Female	08	44	27
Age group (more prevalent)		60 Above	60 Above	60 Above
Patients with Diabetes	Total Patients	19	29	09
	Male	17	16	03
	Female	02	13	06
	Age Group (More Prevalent)	60 Above	60 Above	60 Above
Patients with Hypertension	Total Patients	10	28	20
	Male	08	18	13
	Female	02	10	07
	Age Group (More Prevalent)	60 Above	60 Above	60 Above

Table 9. Comparative Analysis of Spandan Smartphone ECG Outcomes with Previous Studies on Cardiac Arrhythmia Detection

Study Name	Turnbull et al (2024)[26] Study for Arrhythmia (AliveCor KardiaMobile)	Alnasser et al (2023)[27] Study for Arrhythmia (Apple Watch)	Spandan ECG for Arrhythmia
Sensitivity (%)	89.7	88.19	95
Specificity (%	94.23	92.98	96

5. **Potential for Telemedicine:** The Spandan device enables remote ECG sharing for specialist consultations, improving early diagnosis in isolated areas where access to specialists is limited. Integration with electronic medical records or cloud-based platforms supports continuity of care and facilitates large-scale health data analytics.
6. **Deployment in Remote Healthcare Programs**: The device supports outreach programs for screening at-risk individuals for conditions like arrhythmias, ischemic heart disease, or heart failure, aids emergency responders in pre-hospital ECG tests, and enables routine monitoring in chronic disease management, reducing hospital visits and associated costs.

Clinical Signifi ance

Our study demonstrates the clinical validity and usability of lead II-based arrhythmia testing using the Spandan smartphone-based ECG device. Achieving high accuracy, sensitivity, and specificity for the Spandan smartphone-based ECG device suggests that it is a very useful device for the early detection and diagnosis of cardiac arrhythmias in both hospital and non-hospital settings. Comprehensive smartphone-based ECGs from a non-hospital setup could perhaps facilitate timely diagnosis and management of patients with paroxysmal or asymptomatic arrhythmias. This could potentially reduce the burden on healthcare facilities and improve patient outcomes by providing continuous monitoring and early intervention.

CONCLUSION

The research thus showed that the Spandan, a smartphone-based ECG device, was effective, with high reliability in diagnosing cardiac arrhythmias. The device seems to be very sensitive and specific in detecting cardiac arrhythmias compared to the only Lead II ECG strip from the Gold standard ECG machine. With high sensitivity at 95.5% and specificity at 96.3%, Spandan ECG proved very effective in accurately determining rhythm abnormalities in a large cohort of 2799 participants. This arrhythmia study was conducted using a Lead II rhythm strip (Spandan ECG) rather than a 12-lead ECG (Spandan ECG). To reduce noise when analyzing with the Spandan ECG device, fil ers are used. In the case of single-lead analysis (Lead II), these fil ers may sometimes result in the absence of a P wave. When this occurs, a 12-lead Spandan ECG can be utilized for confirmation by comparing the results of 12 leads with Lead II, thereby improving diagnostic accuracy. Despite this, for point-of-care use, the Spandan Lead II test demonstrates a strong correlation in detecting arrhythmias, making it effective for quick assessments. Therefore, these findings underline the clinical validity of the arrhythmia test based on Lead II and establish Spandan ECG as a dependable tool for detecting arrhythmia. Portability, ease of use, and cost-effectiveness in the scenarios of hospitals, ambulances, and remote areas make smartphone-based ECG devices like Spandan enhance their utility. This enables continuous monitoring and real-time detection of arrhythmias, which can enhance patient outcomes with timely diagnosis and intervention. Routine clinical use of Spandan ECG integration may reduce the burden on traditional ECG facilities with efforts toward making arrhythmia detection more accessible and efficie t.

The large sample size and robust study methodology increase the weight of evidence from this study, making the results more reliable for clinical applications of Spandan ECG. Spandan Lead II ECG has been compared with others concerning its superior diagnostic accuracy; it has been one of the best-proven aids in better arrhythmia management.

In summary, the Spandan smartphone ECG-based lead II device provides practical and valuable solutions for diagnosing arrhythmias—highly accurate diagnostically with broad applicability. Its application in clinical and emergency settings helps improve the management of cardiac arrhythmias and, therefore, leads to better patient care and outcomes.

Ethics Committee Approval: Ethical considerations for this study were conducted under the guidance of the head of the Cardiology Department due to the non-interventional nature of the research and no clinical decisions or medications were administered based on the smartphone ECG device results. All clinical decisions were made by cardiologists using the gold standard 12-lead ECG. As a result, local institutional ethics committee approval was not sought. The study was carried out in accordance with the principles of the Declaration of Helsinki.

Informed Consent: Before being included in the study, each participant provided their informed consent. Both verbally and in written form.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - S.M., S.G., Y.S.; Design - S.M., S.G., Y.S.; Supervision - S.G., S.M., T.B.; Resource - N.C., D.A., R.S.; Materials - S.M., N.C., D.A.; Data Collection and/or Processing - N.C., D.A., R.S.; Analysis and/or Interpretation - S.M., N.C., D.A.; Literature Search - N.C., D.A., T.B.; Writing - N.C., D.A., T.B.; Critical Reviews- S.M., N.C., Y.S.

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REFERENCES

1. Desai DS, Hajouli S. Arrhythmias. [Updated 2023 June 5]. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. Available at: https://www.ncbi.nlm.nih.gov/books/NBK558923/.
2. Lakshminarayan K, Anderson DC, Herzog CA, Qureshi AI. Clinical epidemiology of atrial fibrillation and related cerebrovascular events in the United States. *Neurologist*. 2008;14(3):143-150. [CrossRef]
3. Martis RJ, Acharya UR, Adeli H. Current methods in electrocardiogram characterization. *Comput Biol Med*. 2014;48:133-149. [CrossRef]
4. Sattar Y, Chhabra L. Electrocardiogram. [Updated 2023 Jun 5]. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. Available at: https://www.ncbi.nlm.nih.gov/books/NBK549803/.
5. Goldberger AL, Goldberger ZD, Shvilkin A. *Clinical Electrocardiography: A Simplified Approach: Clinical Electrocardiography: A Simplified Approach E-book*. Elsevier Health Sciences; Amsterdam; 2017 March 19.
6. Baman JR, Mathew DT, Jiang M, Passman RS. Mobile health for arrhythmia diagnosis and management. *J Gen Intern Med*. 2022;37(1):188-197. [CrossRef]
7. Mahajan S, Garg S, Singh Y, et al. Comparison of ECG morphological parameters between a mobile 12 lead ECG compared to the gold standard 12 lead ECG in cardiology patients. *Eur J Cardiovasc Med*. 2023;13(1).
8. Jewson JL, Orchard JW, Semsarian C, Fitzpatrick J, La Gerche A, Orchard JJ. Use of a smartphone electrocardiogram to diagnose arrhythmias during exercise in athletes: a case series. *Eur Heart J Case Rep*. 2022;6(4):ytac126. [CrossRef]
9. Issa MF, Yousry A, Tuboly G, Juhasz Z, AbuEl-Atta AH, Selim MM. Heartbeat classifi ation based on single lead-II ECG using deep learning. *Heliyon*. 2023;9(7):e17974. [CrossRef]
10. Haseeb S, Hussain MM, Alam SMK, Hossain MA. Artificial intelligence integration with smartphone ECG devices for enhanced arrhythmia detection. *J Med Devices*. 2021;15(4):041004. [CrossRef]
11. Hossain M, Islam MS, Arafat Y, Haseeb S. Benefits of real-time monitoring with smartphone ECG devices in chronic cardiac conditions. *Int J Cardiol*. 2020;299:296-300. [CrossRef]
12. Zimetbaum PJ, Nguyen E. The role of mobile health technologies in chronic disease management. *Am J Med*. 2018;131(11):1296-1301. [CrossRef]
13. Gadaleta M, Harrington P, Barnhill E, et al. Prediction of atrial fibrillation from at-home single-lead ECG signals without arrhythmias. *NPJ Digit Med*. 2023;6(1):229. [CrossRef]
14. Hothersall J, Sweeting M, Guitian J, et al. Evaluation of accuracy and utility of a smartphone-based ECG device compared to a standard base-apex lead ECG in horses. *Res Vet Sci*. 2019;125:141-147. [CrossRef]
15. Gruwez H, Verbrugge FH, Proesmans T, et al. Smartphone-based atrial fibrillation screening in the general population: feasibility and impact on medical treatment. *Eur Heart J Digit Health*. 2023;4(6):464-472. [CrossRef]
16. Rajakariar K, Koshy AN, Sajeev JK, Nair S, Roberts L, Teh AW. Accuracy of a smartwatch based single-lead electrocardiogram device in detection of atrial fibrillation. *Heart*. 2020;106(9):665-670. [CrossRef]
17. Chandola N, Singh Y, Mahajan S, Garg S, Bansal B. Observational study on detection of atrial and ventricular arrhythmias with smartphone-based ECG. *Int J Health Sci*. 2022;6(4):5373-5384. [CrossRef]
18. Chandola N, Singh Y, Mahajan S, Garg S, Bansal B. Validation study of a derived 12 lead reconstructed ECG interpretation in a smartphone-based ECG device. In: Tuba M, Akashe S, Joshi A, eds. *InICT Systems and Sustainability*. Singapore: Springer; 2023:43-51. [CrossRef]
19. Mahajan S, Garg S, Sharma R, 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(4):1165-1169. [CrossRef]
20. Chandola N, Mahajan S, Garg S, et al. A single-blinded, cross-sectional, single-center study for the validation of atrial fibri - lation detection using Spandan Smartphone ECG. *J Integr Cardiol Open Access*. 2023:1-5. [CrossRef]
21. Singh Y, Pandey CB, Chandola N, Agarwal D. Utilizing smartphone ECG for early detection and management of ischemic heart disease: a case report. *J Cardiol CardioVasc Med*. 2024;9:093-097.
22. Singh Y, Pandey CB, Chandola N, Agarwal D. Smartphone-based 12-lead electrocardiogram monitoring in an elderly patient with multimorbidity: A case report of comprehensive cardiac assessment using the Spandan device. *Heart India*. 2024;12(2):124-130. [CrossRef]
23. Singh Y, Pandey CB, Pandey S, Chandola N, Agarwal D. Case report on the utilization of mHealth-based smartphone ECG for early detection and management of atrial septal defect. *Cardiol Cardiovasc Med*. 2024;8(4):303-306. [CrossRef]
24. Chandola N. An ingenious application of 12 lead smartphone ECG for automatic implantable cardioverter-defibrilla or implantation. 2023;8(5):001-003. [CrossRef]
25. Singh Y, Pandey CB, Pandey S, Chandola N, Agarwal D. Smartphone ECG based successful diagnosis of WPW syndrome under both resting and stress test conditions: a case report. *J Cardiol CardioVasc Res*. 2024;5(1):117-124. [CrossRef]
26. Turnbull S, Garikapati K, Bennett RG, et al. Accuracy of a single-lead ECG device for diagnosis of cardiac arrhythmias compared against cardiac electrophysiology study. *Heart Lung Circ*. 2024;33(10):1465-1474. [CrossRef]
27. Alnasser S, Alkalthem D, Alenazi S, Alsowinea M, Alanazi N, Al Fagih A. The reliability of the Apple Watch's electrocardiogram. *Cureus*. 2023;15(12):e49786. [CrossRef]
28. Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. *Circulation*. 2014;129(8):837-847. [CrossRef]
29. Tegene E, Tadesse I, Markos Y, Gobena T. Prevalence and risk factors for atrial fibrillation and its anticoagulant requirement in adults aged≥ 40 in Jimma Town, Southwest Ethiopia: a community based cross-sectional study. *Int J Cardiol Heart Vasc*. 2019;22:199-204. [CrossRef]
30. Lindberg T, Wimo A, Elmståhl S, Qiu C, Bohman DM, Sanmartin Berglund J. Prevalence and incidence of atrial fibrillation and other arrhythmias in the general older population: findings from the Swedish National Study on aging and care. *Gerontol Geriatr Med*. 2019;5:2333721419859687. [CrossRef]
31. Heeringa J, van der Kuip DA, Hofman A, et al. Prevalence, incidence and lifetime risk of atrial fibrillation: the Rotterdam study. *Eur Heart J*. 2006;27(8):949-953. [CrossRef]
32. Saggu DK, Sundar G, Nair SG, et al. Prevalence of atrial fibrill - tion in an urban population in India: the Nagpur pilot study. *Heart Asia*. 2016;8(1):56-59. [CrossRef]
33. Soni A, Karna S, Fahey N, et al. Age-and-sex stratified prevalence of atrial fibrillation in rural Western India: results of

SMART-India, a population-based screening study. *Int J Cardiol*. 2019;280:84-88. [CrossRef]
34. Movahed MR, Hashemzadeh M, Jamal MM. Increased prevalence of third-degree atrioventricular block in patients with type II diabetes mellitus. *Chest*. 2005;128(4):2611-2614. [CrossRef]
35. Haxha S, Halili A, Malmborg M, et al. Type 2 diabetes mellitus and higher rate of complete atrioventricular block: a Danish Nationwide Registry. *Eur Heart J*. 2023;44(9):752-761. [CrossRef]
36. Movahed MR, Bahrami A, Manrique C, Hashemzadeh M. Strong independent association between third-degree AV-block and diabetes mellitus using a large database. *Diabetes Res Clin Pract*. 2023;205:110948. [CrossRef]
37. DE Sensi F, Penela D, Soto-Iglesias D, et al. Premature ventricular complex site of origin and ablation outcomes in patients with diabetes mellitus. *Minerva Cardiol Angiol*. 2022;70(3):403-411. [CrossRef]
38. Georgiopoulos G, Ntritsos G, Stamatelopoulos K, et al. The relationship between blood pressure and risk of atrial fibrillation: a Mendelian randomization study. [published correction appears in *Eur J Prev Cardiol*. 2021;28(14):1617. [CrossRef]] *Eur J Prev Cardiol*. Published online February 9, 2021. (https://doi.org/10.1093/eurjpc/zwab005)
39. Aune D, Mahamat-Saleh Y, Kobeissi E, Feng T, Heath AK, Janszky I. Blood pressure, hypertension and the risk of atrial fibrillation: a systematic review and meta-analysis of cohort studies. *Eur J Epidemiol*. 2023;38(2):145-178. [CrossRef]
40. Evans GF, Shirk A, Muturi P, Soliman EZ. Feasibility of using mobile ECG recording technology to detect atrial fibrillation in low-resource settings. *Glob Heart*. 2017;12(4):285-289. [CrossRef]
41. Mittal A, Elkaldi Y, Shih S, Nathu R, Segal M. Mobile electrocardiograms in the detection of subclinical atrial fibrillation in high-risk outpatient populations: protocol for an observational study. *JMIR Res Protoc*. 2024;13:e52647. [CrossRef]
42. Huhn S, Matzke I, Koch M, et al. Using wearable devices to generate real-world, individual-level data in rural, low-resource contexts in Burkina Faso, Africa: a case study. *Front Public Health*. 2022;10:972177. [CrossRef]
43. Bhavnani SP, Narula J, Sengupta PP. Mobile technology and the digitization of healthcare. *Eur Heart J*. 2016;37(18):1428-1438. [CrossRef]