RESEARCH ARTICLE

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Diagnostic Accuracy of a Smartphone-based 12-lead ECG for Detection of Common Bradycardias, Tachycardias, and Ectopic Arrhythmias

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Abstract

Background and Aim: Electrocardiography (ECG) remains the cornerstone for diagnosing cardiac arrhythmias. The purpose of this study was to assess the diagnostic performance of a smartphone-based ECG device (Spandan Ultra 12-lead) compared with a standard 12-lead ECG device for detecting common cardiac arrhythmias (bradycardias, tachycardias, and ectopic arrhythmias), with a cardiologist as the reference standard.

Materials and Methods: The study was a prospective, cross-sectional, single-blind, observational, comparative diagnostic accuracy study conducted in 321 patients aged ≥20 years who exhibited signs of arrhythmias. For analysis of diagnostic performance, sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), accuracy, F-score, positive and negative likelihood ratios [(positive likelihood ratio (PLR) and negative likelihood ratio (NLR)], Matthews correlation coefficient (MCC), and the Farrington-Manning score were used to provide a comprehensive evaluation.

Results: The mean age was 51.95±14.51 years; 50.47% were male. The smartphone-based ECG demonstrated higher sensitivity (86.54% vs. 77.80%), specificity (93.68% vs. 91.38%), PPV (72.58% vs. 64.61%), NPV (97.29% vs. 95.31%), accuracy (92.52% vs. 89.09%), F1 score (0.79 vs. 0.70), PLR (13.7 vs. 9.05), MCC (0.75 vs. 0.64), area under the curve (0.851 vs. 0.846), and lower NLR (0.14 vs. 0.24) compared with the standard 12-lead ECG. The Farrington-Manning non-inferiority test demonstrates that the smartphone-based ECG was non-inferior to the standard 12-lead ECG on all validation parameters.

Conclusion: The Spandan Ultra 12-lead smartphone-based ECG is a reliable diagnostic tool for detecting common bradycardias, tachycardias, and ectopic arrhythmias. Its simultaneous multichannel recording enables rapid and accurate rhythm assessment, demonstrating comparable diagnostic performance to that of the standard 12-lead ECG and serving as a complementary diagnostic tool for detecting common arrhythmias.

Keywords: Cardiac arrhythmias, 12-lead ECG, portable ECG, medical device

INTRODUCTION

The World Health Organization states that cardiovascular diseases, particularly cardiac arrhythmias, are the leading cause of death worldwide because they are often asymptomatic and go undetected. Early and accurate diagnosis is essential to address this worldwide burden.[1] An arrhythmia is any abnormality in the rhythm or rate of a person's heartbeat. An irregular heartbeat (arrhythmia) can result from electrical

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impulses that are too slow (less than 60 beats per minute), too fast (more than 100 beats per minute), or erratic. An increased, decreased, or irregular heartbeat results from a defect in the electrical impulses that control the heart's rhythm.[2]

The sinoatrial node generates electrical impulses that control the rhythm of the heart. When electrical impulses do not function properly, an arrhythmia can develop. This malfunction can result in several life-threatening conditions, including stroke, heart failure, and death.[3] The most commonly seen types are bradycardia, atrial fibrillation (AF), ventricular tachycardia (VT), ventricular fibrillation (VF), supraventricular tachycardia (SVT), premature atrial contractions (PAC), and premature ventricular contractions (PVC). AF affected more than 33 million individuals globally in 2019,[4,5] while AF/atrial flutter remained the most common arrhythmia globally in 2021, with an estimated prevalence of 52.55 million.[6]

Electrocardiogram (ECG) signals are typically used to identify cardiac arrhythmias. Early diagnosis and treatment of cardiovascular problems depend mainly on ECG-detected cardiac arrhythmias. ECG is a non-invasive diagnostic technique that records the electrical activity of the heart using electrodes placed on the chest, upper, and lower limbs.[2] The gold standard for clinical cardiac examination remains the 12-lead ECG, which is recorded with 10 electrodes and is used in nearly all clinical settings.[7] Due to their large size and limited portability, standard 12-lead ECG devices are practically limited in their use in both local and remote settings.

However, in recent years, smartphone ECG devices have become more accessible, transforming the sector by providing portable, affordable, and convenient means for real-time arrhythmia detection. A smartphone-enabled ECG device helps identify different cardiac rhythm disturbances.[8] Many researchers have focused on the use of portable ECG devices in various scenarios for early diagnosis and effective treatment of cardiac issues.[9,10] Older equipment consisted of single-lead or limited-lead systems, which compromised diagnostic performance for detecting complex arrhythmias and ischemic changes, despite these improvements. Although some 12-lead ECG smartphone devices have been developed, data directly comparing their diagnostic performance with conventional 12-lead ECGs are limited.

One of these inventions is the Spandan Ultra 12-lead ECG (Sunfox Technologies, Dehradun) (Figure 1). Sunfox Technologies has designed a series of ECG devices, primarily point-of-care, which have proven effective in identifying various arrhythmias.[11-14] Previous models functioned as sequential ECG devices, recording one lead after another. Conversely, the Spandan Ultra 12-lead ECG is designed for diagnostic use, offering portability without compromising diagnostic quality. It is a multichannel instrument that can record and display all 12 leads simultaneously, enabling the capture of the entire electrical activity of the heart in 10 seconds. The present study was conducted to assess the diagnostic accuracy of the Spandan Ultra 12-lead ECG compared with the standard 12-lead ECG in diagnosing cardiac arrhythmias.

METHODS

Study Design and Setting

This prospective, cross-sectional, single-blinded observational comparative diagnostic accuracy study assessed the accuracy of smartphone-based ECGs in diagnosing various cardiac arrhythmias by comparing blinded interpretations of smartphone ECG tracings with diagnoses from standard ECGs. In this study, we describe the overall accuracy, sensitivity, and specificity of interpretations of cardiac rhythms recorded using the smartphone-based ECG. The research was conducted between June 6 and July 31, 2024, in the ECG room of a local hospital in Dehradun, Uttarakhand, India.

Participants and Ethical Considerations

The study included 405 participants referred by a cardiologist for an ECG due to symptoms of arrhythmias. After applying inclusion and exclusion criteria, ECG test reports from 321 participants, obtained from both ECG devices, were deemed eligible for analysis. The sample size was determined using the Yamane formula. The formula is expressed as $n=N/(1+Ne^2)$.

Figure 1. Integration of Spandan Ultra 12-lead ECG device with smartphone for data acquisition

ECG: Electrocardiogram

Participants aged ≥20 years who presented with complaints suggestive of arrhythmias and who were able to provide informed consent were included in the study. Reports with poor ECG tracings (because of artifacts or baseline wandering), participants with loose skin or dense chest hair, interference from deep breathing, individuals in critical condition, patients experiencing hemodynamic instability, pregnant women, and participants who refused were not included in the study.

The study was approved by the Institutional Ethics Committee of Swami Rama Himalayan University (approval number: SRHU/HIMS/E-1/2024/06, date: 06.02.2024) and registered with ClinicalTrials Registry-India (CTRI no: CTRI/2024/07/070766) prior to initiation; it was conducted in accordance with the Declaration of Helsinki. Consent was given by the study participants both verbally and in writing after they received detailed information regarding the methods and procedures, possible risks, and benefits of participating in the study prior to their enrollment. The consent form stated that participants could withdraw from the study at any time without penalty.

Data Collection and Procedure

Firstly, informed consent was obtained from the participants, and then trained clinical trial assistants completed the case report form (CRF) for the participants, which included detailed information about the participants' demographic details and their clinical history. The CRF assisted the cardiologist in making the diagnosis. The participants underwent ECG recordings with both ECG devices. Initially, a standard 12-lead ECG device was used, followed by a smartphone-based ECG device; both devices had automated interpretation capabilities. Arrhythmias were diagnosed by an experienced cardiologist by interpreting ECG reports, and the findings of the two ECG devices were compared. The reference standard used in this investigation to interpret cardiac arrhythmias from both devices was an experienced cardiologist. To minimize bias and enhance the reliability and accuracy of the study, the cardiologist was fully blinded to the computerized interpretations from both devices and conducted the assessments at least one week apart to ensure independence between readings.

To mitigate potential bias, the time interval between the standard 12-lead ECG and the smartphone-based ECG recordings was 2-3 minutes for most participants, and the maximum interval was less than 15 minutes. This time difference is due to the time required to remove the electrodes of a standard 12-lead ECG and to place the electrodes of the smartphone-based ECG.

Statistical Analysis

Clinical and demographic features were summarized using descriptive statistics; categorical variables were presented as frequencies and percentages. To assess the diagnostic performance of the smartphone-based ECG device, confusion matrix elements such as true negatives (TN), false negatives (FN), false positives (FP), and true positives (TP) were determined. Overall accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were used as key performance indicators. In addition, higher-level diagnostic statistics such as the F-score, positive and negative likelihood ratios (PLR and NLR), the Matthews correlation coefficient (MCC), and the Farrington-Manning score were applied to provide a comprehensive evaluation. For receiver operating characteristic (ROC) curve analysis, the DeLong test was used to compare smartphone-based and standard ECGs. Interpretation by a cardiologist based on the standard 12-lead ECG report was used as the reference standard. All analyses were performed with Microsoft Excel.

Instructions for Operating the Spandan Ultra 12-lead ECG Device Recording System

To record an ECG using the Spandan Ultra 12-lead ECG device, an internet connection is not required. Ensure that the device is connected to the smartphone with a micro-USB cable. The electrodes had to be placed carefully to acquire accurate signals. The Goldberg lead placement procedure was followed, with right arm and left arm electrodes positioned on the right and left wrists or forearms, and right leg/neutral and left leg/foot electrodes positioned on the right and left legs, respectively. The chest electrodes were placed as follows: C1 (red) at the fourth intercostal space at the right sternal border, C2 (yellow) at the same level at the left sternal border, C3 (green) midway between C2 and C4, C4 (brown) at the fifth intercostal space at the midclavicular line, C5 (black) at the fifth intercostal space midway between C4 and C6, and C6 (purple) at the fifth intercostal space at the midaxillary line.

A description of the algorithm utilized by the smartphone-based ECG device for detecting arrhythmias is presented in Figure 2.

RESULTS

The study initially enrolled 405 participants who presented with symptoms of arrhythmia. After applying the inclusion and exclusion criteria, ECGs from 321 participants were evaluated. All participants underwent testing with both ECG devices, and the reports from both ECGs were interpreted by a cardiologist. The Standards for Reporting Diagnostic Accuracy Studies checklist was followed in conducting the study (Figure 3). The mean age was 51.95±14.51 years; 162 patients (50.47%) were male and 159 patients (49.53%) were female. Of all participants, 50 presented with abnormal ECGs according to the cardiologist's interpretation of the smartphone-based 12-lead ECG; of these, first-degree atrioventricular (AV) block was present in 5 (10%)

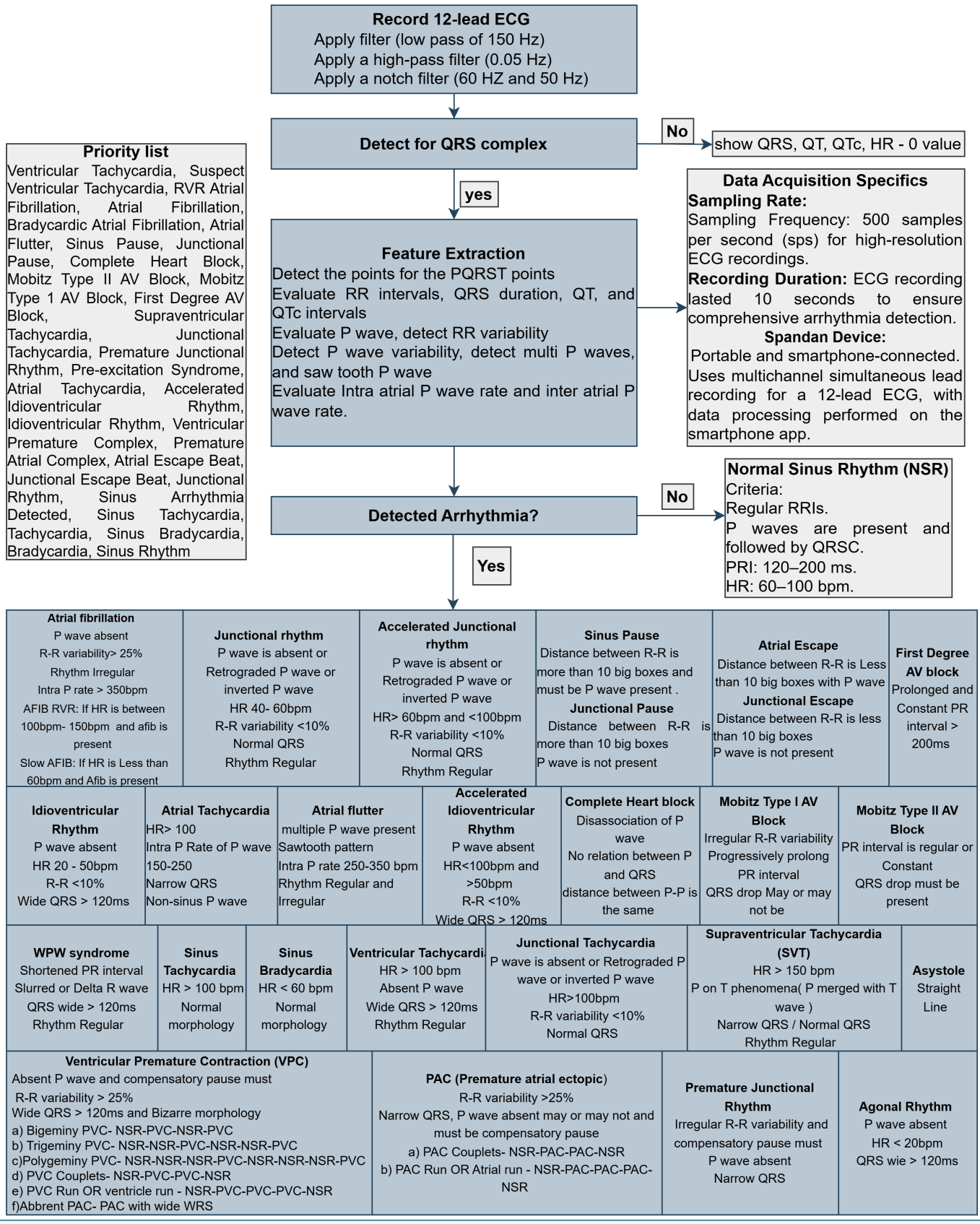

Figure 2. Spandan Ultra-12-lead ECG device algorithm for arrhythmia identification

ECG: Electrocardiogram, HR: Heart rate, AV: Atrioventricular, PAC: Premature atrial contraction, NSR: Normal sinus rhythm

cases, sinus bradycardia in 20 (40%) cases, sinus tachycardia in 14 (28%) cases, PAC in 6 (12%) cases, and PVC in 5 (10%) cases (Table 1). Among all participants, 38 patients (11.52%) were diabetic and were referred for an ECG test, of whom 19 were male and 19 were female.

The confusion matrix of ECG interpretation for both smartphone-based and standard 12-lead ECGs is summarized in Table 2. A smartphone-based ECG performed better than a standard 12-lead ECG in detecting TP cases (45 vs. 42) and true negative cases (252 vs. 244). The smartphone-based device also exhibited fewer false-negative cases (7 vs. 12) and false-positive cases (17 vs. 23) compared with the standard 12-lead ECG. For instance, a case of first-degree AV block was initially detected using both a standard 12-lead ECG and a smartphone-based ECG. Both interpretations were confirmed by the cardiologist, and it was therefore regarded as a true-positive case (Figure 4).

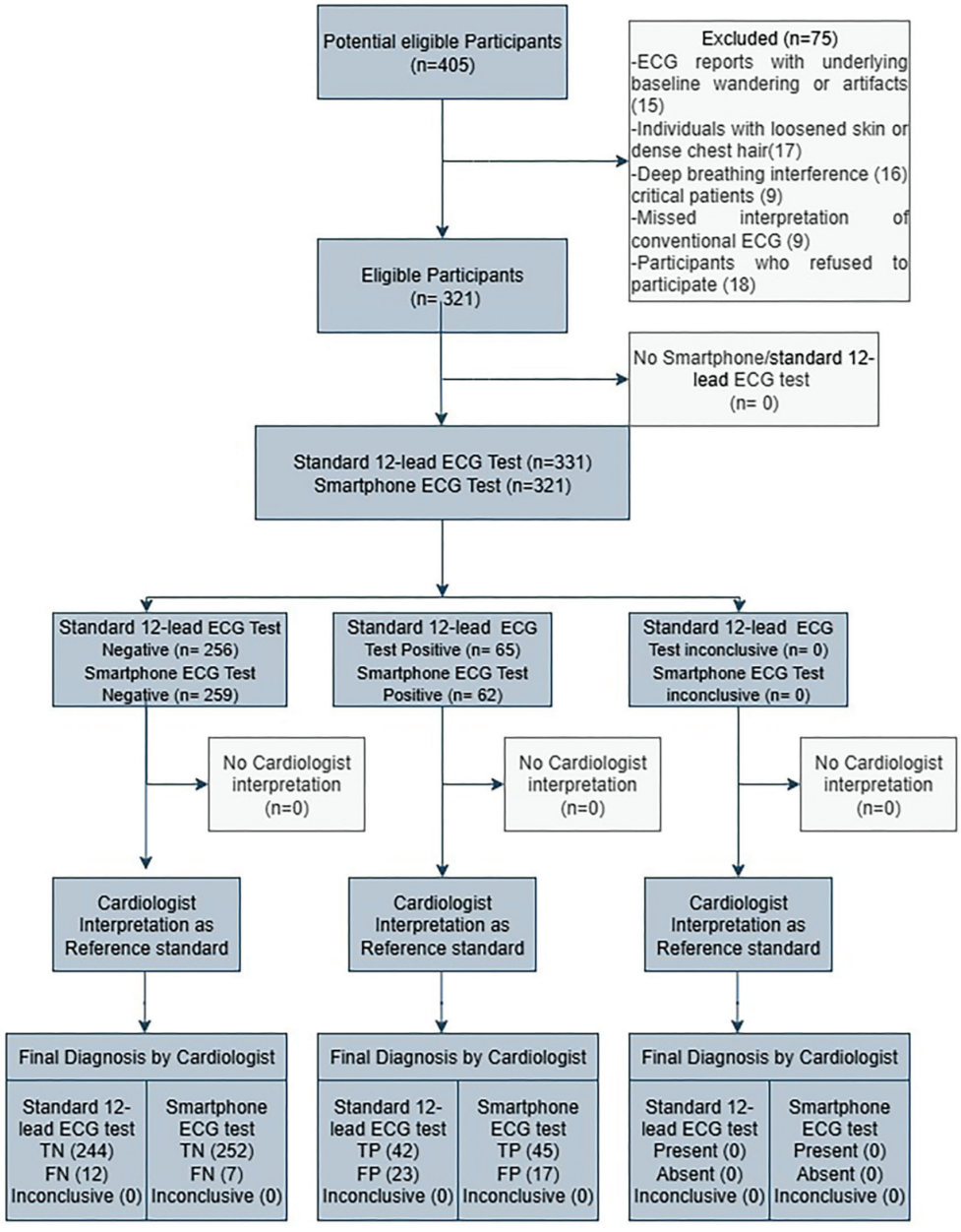

Figure 3. Standards for Reporting Diagnostic Accuracy Studies compliant flow diagram showing the number of patients assessed, excluded, and included in the validation of smartphone-based ECG compared with standard 12-lead ECG, using cardiologist interpretation as the reference standard

ECG: Electrocardiography, TN: True negatives, FN: False negatives, FP: False positives

The sensitivity, specificity, PPV, NPV, accuracy, precision, F1 score, MCC, PLR, and NLR of the smartphone-based ECG and the standard 12-lead ECG, along with their ECG interpretations compared with cardiologist diagnoses, are presented in Table 3. Compared to the standard 12-lead ECG, the smartphone-based ECG demonstrated higher specificity (93.68% vs. 91.38%), sensitivity (86.54% vs. 77.80%), PPV (72.58% vs. 64.61%), NPV (97.29% vs. 95.31%), and overall accuracy (92.52% vs. 89.09%). The smartphone-based ECG also demonstrated a higher F-score (0.79 vs. 0.70), a higher PLR (13.7 vs. 9.05), and a higher MCC (0.75 vs. 0.64), as well as a lower NLR (0.14 vs. 0.24). A comparison of the two ECGs reveals that the smartphone-based ECG has comparable diagnostic performance and may be a suitable alternative to the standard 12-lead ECG. These results underscore the smartphone-based ECG's strong predictive capability and reliability in distinguishing cases with and without disease.

The validation parameters for the smartphone-based ECG and the standard 12-lead ECG are shown in Table 4. The confidence intervals for a smartphone-based ECG indicated higher ranges of sensitivity (0.747-0.933 vs. 0.65-0.88), specificity (0.902-0.962 vs. 0.87-0.95), and accuracy (0.891-0.949 vs. 0.85-0.93) compared with the standard 12-lead ECG.

Table 5 summarizes the Farrington-Manning score non-inferiority test for sensitivity, specificity, and accuracy. The smartphone-based ECG has approximately 8.8% higher sensitivity and is statistically significant (P = 0.007). It has approximately 2.3% higher specificity and is statistically

Table 1. Participants with abnormal cases (50)

Abnormality	Number of abnormal cases	Percentage
1st degree AV block	5	10
Sinus bradycardia	20	40
Sinus tachycardia	14	28
PAC	6	12
PVC	5	10

AV: Atrioventricular, PAC: Premature atrial contractions, PVC: Premature ventricular contractions

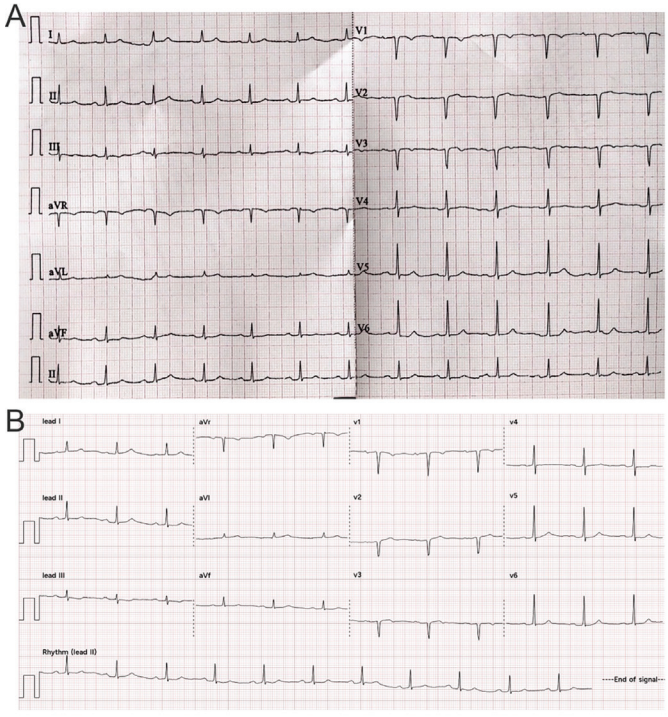

Figure 4. Example of a true positive case. (A) 1st degree AV block detected by the standard 12-lead ECG. (B) 1st degree AV block detected by the smartphone-based 12-lead ECG and confirmed by the cardiologist

AV: Atrioventricular, ECG: Electrocardiography

Table 2. ECG interpretation confusion matrix of both ECG devices

Parameter	Smartphone-based ECG	Standard 12-lead ECG
True positive	45	42
True negative	252	244
False positive	17	23
False negative	7	12

ECG: Electrocardiogram

Table 3. Diagnostic performance of both the ECG devices

Validation parameter	Smartphone-based ECG	Standard 12-lead ECG
Specificity	93.68%	91.38%
Sensitivity	86.54%	77.80%
PPV	72.58%	64.61%
NPV	97.29%	95.31%
Accuracy	92.52%	89.09%
Precision	72.58%	64.61%
F1 score	0.79	0.706
MCC	0.75	0.642
PLR	13.7	9.05
NLR	0.14	0.24

ECG: Electrocardiogram, PPV: Positive predictive value, NPV: Negative predictive value, MCC: Matthew's correlation coefficient, PLR: Positive likelihood ratio, NLR: Negative likelihood ratio

Table 4. Validation parameters for both the ECG devices

Validation parameter	Smartphone-based ECG	Standard 12-lead ECG
95% CI of sensitivity (L-U)	0.747-0.933	0.65-0.88
95% CI of specificity (L-U)	0.902-0.962	0.87-0.95
95% CI of accuracy (L-U)	0.891-0.949	0.85-0.93

ECG: Electrocardiogram, CI: Confidence interval, L: Lower bound, U: Upper bound

Table 5. Farrington-Manning (score) non-inferiority test			
Metric	**Sensitivity**	**Specificity**	**Accuracy**
Difference	0.088	0.023	0.034
Variance under H0	0.006	0.001	0.001
T-tests	2.434	4.772	5.351
One-sided *P*-value = 1-Φ(z)	0.007	<0.001	<0.001

significant ($P < 0.001$). Similarly, it has approximately 3.4% higher accuracy and is highly statistically significant ($P < 0.001$).

The ROC curves for the comparisons between standard 12-lead ECG and cardiologist interpretation, and between smartphone-based ECG and cardiologist interpretation are shown in Figure 5. Cardiologist interpretation of the standard 12-lead ECG report was considered the reference standard for ROC analysis; the area under the curve (AUC) was 0.846 for the gold-standard ECG and 0.851 for the smartphone-based ECG. No statistically significant difference was observed between the two AUCs ($P = 0.937$), indicating comparable diagnostic performance.

DISCUSSION

The present study evaluated the diagnostic performance of a smartphone-based ECG compared with the standard 12-lead ECG for detecting cardiac arrhythmias (common bradycardias, tachycardias, and ectopic arrhythmias). The study detected different types of arrhythmias, such as first-degree AV block, sinus tachycardia and sinus bradycardia, PAC, and PVC. The

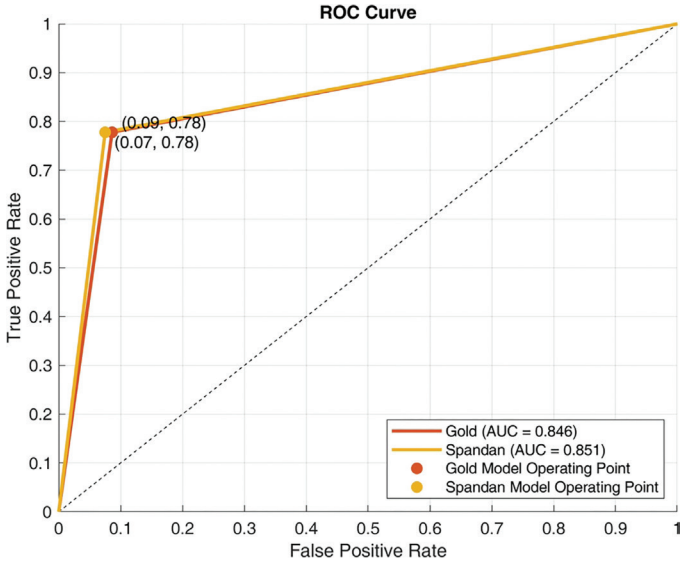

Figure 5. ROC curve comparison for both the ECG devices

ECG: Electrocardiography, ROC: Receiver operating characteristic, AUC: Area under the curve

mean age of participants in this study was 51.95±14.51 years, and the proportion of males was 50.47%, whereas the mean age of patients diagnosed with general arrhythmia in the study by Kwon et al.[15] was 55.1±12.8 years, and the proportion of males was 48.3%. In the study by Niu et al.[16] the mean age of participants was 63.77±13.90 years; in the study by Turnbull et al.[17] patients with arrhythmias had a mean age of 58±19 years.

The results of this study are consistent with previous reports on portable and mobile ECG devices, which have also shown improved accuracy compared with standard 12-lead, hospital-based ECG systems. Access to point-of-care healthcare devices is improved by handheld technologies, which are particularly advantageous when prompt clinical decision-making and time efficiency are required.[18] In the current study, the smartphone-based ECG device demonstrated increased sensitivity, which means it has performed better in detecting true abnormal cases and in minimizing missed arrhythmia cases compared with the standard 12-lead ECG. Likewise, the increased TN rate and the decreased FP rate indicate greater specificity. As in our research, Shahid et al.[19] had reported the Apple Watch's pooled sensitivity of 94.8% and specificity of 95% for detecting AF. In a trial by Himmelreich et al.[20] the 1L-ECG (AliveCor Kardia Mobile), determined by cardiologists, was 90.9% sensitive and 93.5% specific for any rhythm abnormality, figures very close to those found in our trial. In the study by Desteghe et al.[21] the sensitivity and specificity of MyDiagnostick in the cardiology ward were 81.8% and 94.2%, respectively, and those of AliveCor were 54.5% and 97.5%, respectively. In the geriatrics ward, MyDiagnostick's sensitivity and specificity were 89.5% and 95.7%, respectively, whereas AliveCor's were 78.9% and 97.9%.[21] The sensitivity of both devices was lower than that observed in our study, indicating they can detect fewer TP cases. Comparable to our study's accuracy of 92.52%, Turnbull et al.[17] in their study of 49 patients, recorded 843 cardiac rhythms; single-lead ECG produced a mean overall accuracy of 92%. Notably, Turnbull et al.[17] achieved greater accuracy for overall various arrhythmia types, e.g., AF accuracy was 91%, SVT 89%, VT 91%, VF 98%, asystole 100%, and PVC 91%.

In the present study, MCC was 0.75 and the F-score was 0.79, indicating an improved balance between recall and precision and greater overall classification reliability when utilizing a smartphone-based ECG device for arrhythmia detection. They were consistent with the findings reported in a recent AI-powered ECG model published by Tian et al.[22] For example, the knowledge-augmented ECG diagnosis foundation model leveraged large language models to incorporate domain-specific ECG signal knowledge and achieved an MCC of 0.72 and an F1 score of 0.776, which is slightly lower than in our research.[22] Importantly, the Farrington-Manning non-inferiority analysis confirmed that the smartphone-based ECG was non-inferior to standard 12-lead ECG across all validation

parameters, underscoring the reliability of the smartphone-based ECG for arrhythmia detection. Furthermore, the area under the ROC curve for the smartphone-based ECG was 0.851, indicating excellent diagnostic performance.

The clinical significance of this study lies in demonstrating that smartphone-based ECGs can achieve diagnostic accuracy comparable to standard 12-lead ECGs for diagnosing common cardiac arrhythmias, including bradycardias, tachycardias, and ectopic arrhythmias, with high sensitivity, specificity, accuracy, and overall diagnostic agreement. Compared with other single-lead or sequential multi-lead smartphone technologies, "Spandan Ultra 12-lead ECG" is a true 12-lead multichannel system capable of simultaneous recording within 10 seconds. This simultaneous multichannel recording preserves the spatial and temporal fidelity of electrical activity across all vectors with no beat-to-beat differences, meaning that each lead records identical cardiac cycles. This feature is absent in sequential 12-lead ECG recordings, which can be affected by cardiac rhythm and conduction changes. This simultaneous recording facilitates precise analysis of rhythm regularity, AV and intraventricular conduction, axis deviation, and ectopic activity. These technical advantages and performance are probably reflected in their high ROC curves, higher predictive values, and lower probability of missed cases, thus preventing diagnostic delays and assisting in clinical decisions, especially in cases of subtle and intermittent arrhythmias. In addition to its diagnostic and clinical benefits, this diagnostic aid has several technical advantages that increase its clinical utility. Its portable, water-resistant, and dust-resistant design with an IP55-rated construction enhances durability and enables use in any setting. Users no longer require conventional ECG paper to obtain multiple leads; recordings can be stored digitally without producing paper. If required, they can be printed on A4 paper, and the device is tolerant of variations in humidity and temperature. The addition of a unique hospital identification enables the direct linkage of recordings to patient records and the secure sharing of reports. While these findings establish diagnostic accuracy as a critical first step, the true clinical value lies in rapid point-of-care rhythm assessment. High-quality, diagnostic-grade tracings can be obtained within seconds, making the device suitable for time-sensitive settings such as emergency departments, outpatient clinics, and resource-limited or rural facilities. The device can help streamline care pathways, such as the acute coronary syndrome (ACS) pathway, by enabling immediate ECG acquisition and interpretation. This is because early detection of arrhythmias or ischemic changes expedites triage, guides urgent management, and reduces time to reperfusion therapy. Being lightweight, easy to operate, and not requiring internet connectivity, the Spandan Ultra is a promising device to increase access to accurate and immediate cardiac evaluation and to optimize the evaluation and management of arrhythmias.

Study Limitations

This study has a few limitations. Because the sample was small and drawn from a single center, these findings may not generalize to larger populations. Secondly, only a few arrhythmias were studied; these included first-degree AV block (10%), sinus bradycardia (40%), sinus tachycardia (28%), PACs (12%), and PVCs (10%). Although these are common rhythm disturbances in day-to-day practice, rarer, more complex rhythms such as atrial flutter, SVT, VT, and higher-degree AV blocks were not included, thereby limiting the applicability of the findings across the full spectrum of cardiac arrhythmias. The limited intensity of the arrhythmia pattern may be associated with the pilot nature of the current study, because it was intended to test its feasibility and initial diagnostic capability. The study is monitored by an experienced cardiologist; thus, the quality of the ECGs recorded may differ when the device is operated by untrained users, depending on patient compliance, lead placement accuracy, and comorbidities. A significant limitation of this study is that the reference standard depended on a single experienced cardiologist for ECG interpretation. Although the cardiologist was entirely blinded throughout the investigation, and assessments were conducted at least one week apart to avoid any influence, the use of a single observer does not account for inter-observer variability, especially given the complexity of ECG signals. Consequently, this may limit the generalizability of the findings, particularly in cases of subtle or complex arrhythmias where interpretations may vary between experts.

Future studies with larger sample sizes and multicenter designs are required to further validate its diagnostic accuracy across different patient groups and a broader range of arrhythmias. Validation using well-established public ECG databases such as the Massachusetts Institute of Technology-Beth Israel Hospital (MIT-BIH) arrhythmia database, Physikalisch-Technische Bundesanstalt diagnostic ECG database, St. Petersburg Institute of Cardiological Technics database, and MIT-BIH ST-segment and T wave changes database will also be conducted to enable comprehensive testing of more complex or less common rhythm disorders. Such studies will help determine whether speed, portability, and accessibility translate into improved clinical outcomes, such as earlier diagnosis, reduced time to treatment, optimized management of arrhythmias, and improved patient-centered outcomes. More importantly, triage within ACS pathways may be faster using a 12-lead ECG acquired from a portable device at initial presentation, thereby enabling early detection of arrhythmias, ischemic changes, or occlusive myocardial infarction, prompt guideline-initiated treatment, and improved patient management. Moreover, the inclusion of multiple independent cardiologists in future analyses may further strengthen diagnostic validation, reduce inter-observer variability, and enhance the robustness of study findings.

CONCLUSION

This study demonstrates that the Spandan Ultra 12-lead smartphone-based ECG has comparable diagnostic accuracy to the standard 12-lead ECG for the specific arrhythmias evaluated. The device reliably detected common, benign, non-life-threatening arrhythmias, including bradycardias, tachycardias, and ectopic rhythms. These findings support its potential role as a complementary tool for common arrhythmia screening and diagnostic assessment, rather than as a universal replacement for standard 12-lead ECG systems. Its capability to record all 12 leads at once through a multichannel system within seconds offers rapid, high-quality recordings, minimizing the risk of missed or delayed diagnoses and thereby enabling timely, precise clinical evaluation. The device also demonstrated high predictive reliability, low false-negative and false-positive rates, and strong ROC performance, supporting its use in clinical applications for precise arrhythmia detection. Unlike most smartphone-based ECG devices, which are limited to single-lead or sequential multi-lead recordings, Spandan Ultra provides diagnostic-grade data comparable to a standard 12-lead ECG, and hence it is particularly beneficial for comprehensive cardiac assessment. These results highlight its utility as a reliable and effective tool for physicians and cardiologists and a viable alternative to routine ECG for diagnosis when accuracy, speed, and reliability are essential to optimal patient care.

Ethics

Ethics Committee Approval: The study was approved by the Institutional Ethics Committee of Swami Rama Himalayan University (approval number: SRHU/HIMS/E-1/2024/06, date: 06.02.2024) and registered with Clinical Trials Registry-India (CTRI no: CTRI/2024/07/070766).

Informed Consent: Both written and verbal informed consent were obtained from all the participants.

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Footnotes

Authorship Contributions

Concept: C.M., K.G., A.R., Y.S., Design: C.M., K.G., A.R., Y.S., Data Collection or Processing: K.G., N.C., D.A., Analysis or Interpretation: A.R., N.C., D.A., Literature Search: N.C., S.Y.P.S., M.P., Writing: S.Y.P.S., M.P.

Conflict of Interest: N.C., D.A., S.Y.P.S. and M.P. are currently employed by Sunfox Technologies. None of the other authors has any conflict of interest.

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