

Examining the Specificity of Smartphone Based ECG Devices in Decision–Making for ST–Elevation Myocardial Infarction and Non–ST–Elevation Myocardial Infarction

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Abstract

Background & Objectives: Electrocardiography (ECG) stands as a cornerstone diagnostic tool for assessing cardiac health, particularly in ruling out abnormalities. The integration of smartphone devices presents a promising avenue for expedited detection of cardiac irregularities. This study aims to evaluate the diagnostic efficacy of smartphone ECG devices in subjects admitted to Cardiac Care Units (CCUs) and Cardiac Intensive Care Units (CICUs).

Methods: A retrospective analysis was conducted on a cohort comprising 62 patients presenting with cardiac symptoms. Utilizing smartphone ECG devices as the index, 12-lead ECG tests were administered alongside the Gold Standard ECG machine for comparison among patients in CCUs and CICUs. Diagnostic decisions concerning the presence of ST-Elevation Myocardial Infarction (STEMI) or Non-ST-Elevation Myocardial Infarction (NSTEMI) were made by a team of cardiologists following a meticulous review of both sets of ECG reports.

Results: Data analysis was conducted on 56 patients. The smartphone-based ECG device exhibited 100% specificity, 93% sensitivity, 80% Negative Predictive Value, and 100% Positive Predictive Value, yielding an F-score of 0.96 and a Mathew Correlation Coefficient value of 0.86.

Discussions: This study unequivocally underscores the significant potential of the Spandan ECG device in accurately identifying a range of cardiac abnormalities, including critical conditions such as STEMI and ischemia. Despite its portable nature, smartphone ECG technology demonstrates utility within Critical Care Units for timely monitoring and diagnosis.

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Keywords: Digital health, Electrocardiography, mHealth, Ischemia, Smartphone ECG, ST-elevation myocardial infarction.

Introduction

India currently grapples with the highest prevalence of acute coronary syndrome (ACS) and ST-segment elevation myocardial infarction (STEMI) globally. Alarming statistics from 2013 highlight 261,694 deaths, marking a disturbing surge of 138% since 1990, indicating a significant and concerning dimension within India's healthcare landscape. Compared to other ethnic groups, Indians exhibit a higher likelihood of hospitalization for coronary artery disease (CAD) complications, with admission rates 5–10 times higher for individuals under 40.¹ STEMI represents a critical and often fatal form of myocardial infarction characterized by the occlusion of one or more coronary arteries, resulting in severe reduction or cessation of blood flow to the heart muscle. Typically, this acute event is precipitated by the rupture, erosion, fissuring, or dissection of coronary artery plaques, culminating in the formation of an obstructive thrombus. Primary factors contributing to ST-elevation myocardial infarction include dyslipidemia, diabetes mellitus, hypertension, tobacco use, and familial history of coronary artery disease.²⁻³ The timely diagnosis of STEMI is imperative, directly impacting mortality and morbidity rates. Swift recognition and intervention significantly enhance the anticipation of positive outcomes for patients. As the electrocardiogram (ECG) remains the most widely employed and accessible diagnostic tool for STEMI, there is an intriguing postulation that making reliable ECGs readily available to high-risk outpatient populations could profoundly impact outcomes. Such an approach holds the potential to substantially mitigate delays in early diagnosis and subsequent treatment, facilitating the expeditious implementation of life-saving revascularization procedures.⁴

ST-segment elevation serves as a crucial diagnostic marker discerned in the 12-lead ECG. When ST elevation is observed, the ECG becomes pivotal in ascertaining the occurrence of STEMI. This diagnostic tool records the intricate electrical patterns of the heart, offering invaluable insights into cardiac health.⁵⁻⁷

The 12-lead ECG plays a pivotal role in patient care, particularly in emergencies, aiding in diagnosis and guiding medical interventions. Therefore, it is of utmost importance for healthcare professionals to promptly identify STEMI-related episodes and incidents.⁸

Table 1. Baseline demographics and clinical characteristics of the participants.

Variables	Number	Percentage (%)
Gender-	61	98.3%
Male		
Hypertensive	7	11.2%
Smoker	4	6.45%
Diabetic	13	20.9%
CAD	52	83.8%
Pacemaker implant	1	1.61%
Stent implant	36	58%
Chest Pain	8	12.9%
Shortness of Breath	5	8.06%

To date, smartphone-based ECG machines have been extensively studied for screening arrhythmias and myocardial infarctions in clinical settings. However, their presence in intensive care units for diagnostic usage remains limited. A smartphone-based portable ECG device (SPANDAN PRO) that is capable of taking lead 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 Spandan device, a smartphone-based 12-lead, single-channel device, was utilized in this study for the detection of myocardial infarctions and arrhythmias.⁹ The objective of this research was to evaluate the specificity in guiding clinical decisions regarding STEMI and NSTEMI in CCUs and CICUs setups by comparing algorithmic interpretation of Spandan smartphone-based 12 lead ECG, developed by Sunfox Technologies Private Limited, Dehradun, Uttarakhand, India with diagnoses made by cardiologists using the 12-lead gold standard machine. The study also included a comprehensive comparative analysis of key diagnostic metrics, including Specificity, Sensitivity, Negative Predictive Value, Positive Predictive Value, Accuracy, Precision, F-score, MCC value, and likelihood ratios for both Spandan ECG and Gold Standard ECG reports.

Methods

Study Design

This cross-sectional, single-blinded, retrospective study was conducted from November 7, 2022, to



Figure 1. Spandan Pro ECG Device.

Table 2. Distribution of the severity of disease in the subjects with target conditions.

Variables	Number	Percentage (%)
Anteroseptal MI	6	10.71%
Anterior wall MI	10	17.85%
Inferolateral MI	2	3.57%
Inferior wall MI	1	1.78%
Antero apical MI	1	1.78%
Ischemia	37	66.07%
LBBB	4	7.14%
RBBB	1	1.78%
ST-T Changes	15	26.78%
J-point Elevation	1	1.78%

December 15, 2022. Reference data from the 12-lead gold standard machine were previously recorded from subjects during their admission to the Cardiac Care Unit (CCU) and Cardiac Intensive Care Unit (CICU), while ECG data from the smartphone device were obtained subsequently. Cardiologist diagnosis were recorded only for ECG reports generated by the 12-lead gold standard ECG machine.

Participants

A cohort of 62 patients, aged over 20 years, presenting with symptoms of chest pain, palpitations, shortness of breath, and pre-existing coronary artery disease (CAD), were included in this study. Patients were recruited from the CCU and CICU of Shri Mahant Indiresk Hospital at Dehradun, Uttarakhand, India, based on convenience and after obtaining written informed consent from each participant. Patients with loose skin were excluded from the study, as were ECG reports exhibiting baseline wandering or indications of only arrhythmia. Additionally, individuals who declined to participate were excluded.

Test Methods

Comprehensive demographic information and detailed medical histories of study participants were recorded in Case Report Forms (CRFs) according to rigorous research protocols. ECGs were obtained for each participant, initially using the 12-lead Gold Standard ECG machine, followed by the Spandan smartphone ECG device. The Mason-Likar placement system was employed for recording ECGs from the smartphone ECG device, while the Goldberger ECG system was used for ECGs from the gold standard machine.

Both sets of 12-lead ECG reports were forwarded to cardiologists for diagnostic evaluation. Cardiologists assessed the reports according to specific criteria for diagnosing ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI). The physician's diagnosis was considered the standard evaluation of the specificity of the smartphone ECG device, as its algorithmic outcomes should correlate with clinical diagnosis. Cardiologists were blinded to computer-generated interpretations of both reports to mitigate any bias in diagnosis. ECGs with abnormal outcomes of STEMI and NSTEMI were considered positive, while normal reports were considered negative, with a similar rationale applied to the 12-lead gold standard ECG reports.

Analysis

To analyze the accuracy of the smartphone ECG device, algorithmically generated interpretations were systematically compared with interpretations provided by cardiologists for the 12-lead gold standard ECG reports. Data were compiled and organized within a cloud-based server, while scanned CRFs were securely archived for comprehensive data management. Fixed effect models were employed for the analysis, which involved a comprehensive examination and comparison of ECG reports and their key diagnostic parameters for STEMI and NSTEMI. The parameters analyzed included ST elevations, ST depression, and T wave inversion, categorized by anatomical regions such as the anterior, lateral wall, septal wall, and inferior wall. Data was meticulously evaluated using spreadsheets to calculate diagnostic metrics including true positive, true negative, false positive, false negative, sensitivity,

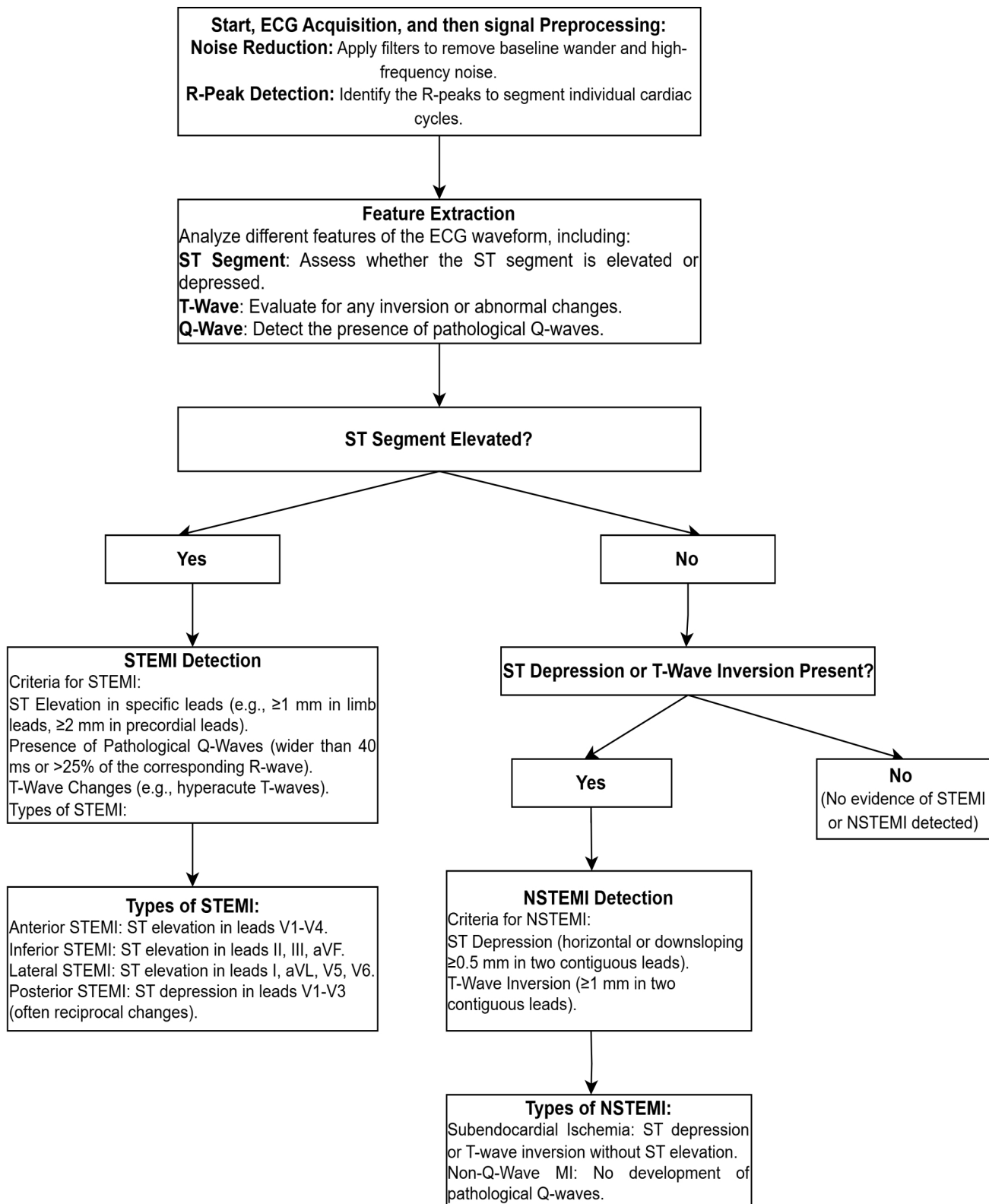


Figure 2. Algorithm of the Device

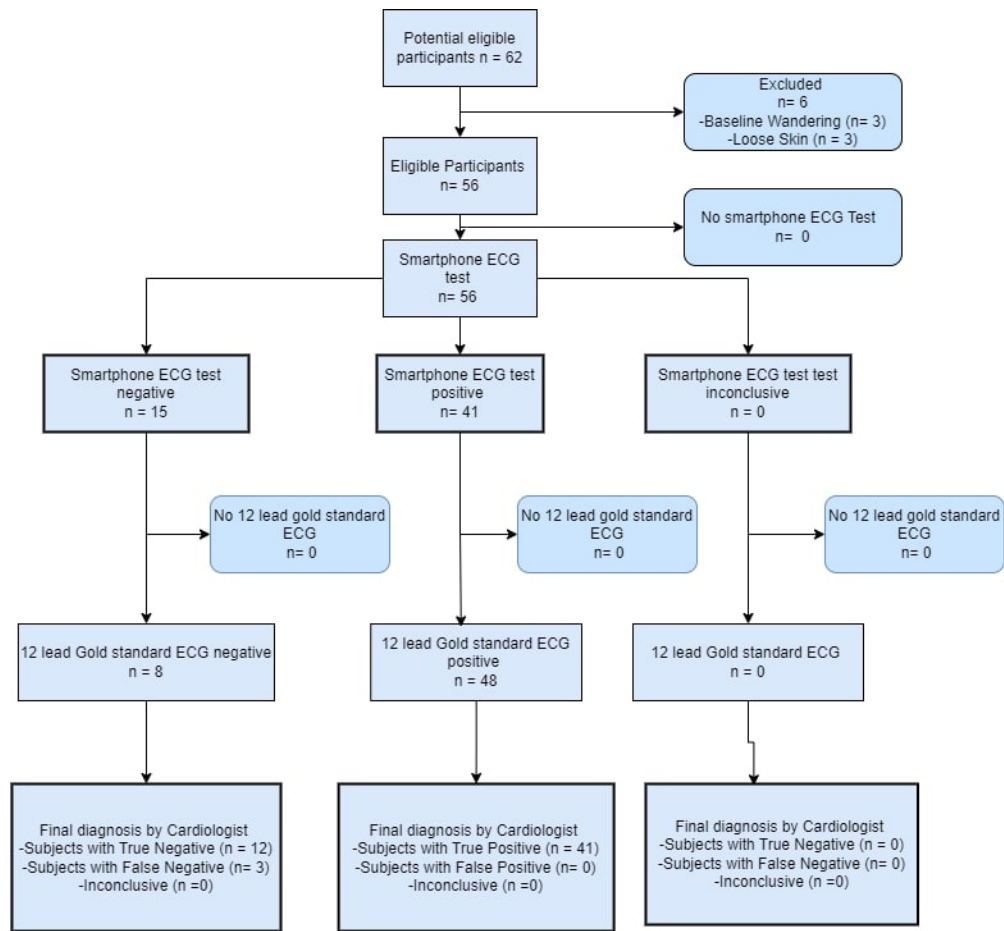


Figure 3. STARD Flow Diagram of the Study: Illustrates participant enrollment, .

specificity, negative predictive value (NPV), positive predictive value (PPV), precision, accuracy, F-score, and Matthew's correlation coefficient (MCC). Statistical evaluations also included a t-test and heterogeneity analysis. Furthermore, likelihood ratios (positive and negative) and 95% confidence intervals for sensitivity, specificity, PPV, and NPV were calculated to assess diagnostic accuracy comprehensively.

Guide for Using the Spandan Pro ECG Device

To perform the ECG recording, the Spandan Pro ECG device was connected to a smartphone to ensure a secure and stable connection. Proper electrode placement was critical for accurate signal acquisition. Following the Goldberg lead placement system, the RA and LA electrodes were positioned on the right and left

forearms or wrists, while LL/F and RL/N electrodes were placed on the left and right legs, respectively. Chest electrodes were positioned as follows: C1 (red) at the 4th intercostal space along the right sternum margin, C2 (yellow) at the same level on the left sternum margin, C3 (green) midway between C2 and C4, C4 (brown) at the 5th intercostal space along the mid-clavicular line, C5 (black) at the 5th intercostal space midway between C4 and C6, and C6 (purple) at the 5th intercostal space at the mid-axillary line.

Once the electrodes were securely placed, the test was initiated using the smartphone application, ensuring the patient remained still during the procedure. The generated ECG report was subsequently reviewed for clinical interpretation. In this clinical trial, the Goldberg

Table 3. The decision-making for the accuracy matrix of Spandan ECG and Gold Standard 12 Lead ECG.

Cardiologist Diagnosis	Spandan /Gold standard ECG Interpretation	Accuracy Matrix
Abnormal	Abnormal	True
Normal	Normal	True
Normal	Abnormal	False
Abnormal	Normal	False
Non cases	STEMI/ NSTEMI	Positive
STEMI/ NSTEMI	STEMI/ NSTEMI	Positive
STEMI/ NSTEMI	Non cases	Negative
Non cases	Non cases	Negative
ST-T Changes	15	26.78%
J-point Elevation	1	1.78%

system was employed for electrode placement, and the algorithm utilized by the device, as outlined in Figure 2, was applied for analysis.

Results

This study utilized data from a cohort of 62 patients presenting with both ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI) to evaluate the diagnostic efficacy of the Spandan smartphone-based 12-lead ECG device. Table 1 presents an overview of the baseline characteristics considered during the ECG assessments of the 62 study participants, with no adverse events recorded. Among these participants, Spandan successfully detected 56 cases exhibiting a spectrum of cardiac abnormalities, including STEMI, ischemia, left bundle branch block/right bundle branch block (LBBB/RBBB), ST-T changes, and J-point elevation, as outlined in Table 2.

The average time difference between capturing the ECG recording with the 12-lead gold standard machine and the Smartphone-based ECG device was 3 hours, primarily due to ECGs being obtained in the Cardiac Care Unit (CCU) and Cardiac Intensive Care Unit (CICU) during patient triage. Meanwhile, recordings with the smartphone ECG machine were acquired

Table 4. Confusion Matrix of ECG Interpretation of Gold standard and Spandan 12 lead ECG.

Parameter	Spandan 12 Lead ECG Interpretation compared to Cardiologist interpretation	Gold Standard ECG Interpretation compared to Cardiologist interpretation
True Positive	41	39
True Negative	12	3
False Positive	0	9
False Negative	3	5

while the patient was admitted to the CCU and CICU. Consequently, a comparative analysis of ECG outcomes related to interpretations by cardiologists is illustrated in Figure 3. Interpretations by cardiologists for gold standard ECG reports that did not align with these findings, particularly those interpreted as normal or exhibiting baseline wandering, or presenting with arrhythmias without any ST-segment elevation myocardial infarction (STEMI) or non-ST-segment elevation myocardial infarction (NSTEMI), were excluded from the study. The cardiologist's clinical interpretation confirmed the presence of inferolateral myocardial infarction (MI) and ischemia in the patient, thereby highlighting the potential diagnostic utility of the Spandan ECG device, as depicted in Figure 4 for the 12-lead gold standard ECG and Figure 5 for the Smartphone ECG device.

The evaluation process involved a meticulous comparison between computer-generated interpretations of both the Spandan-derived 12-lead ECG report and the Gold Standard 12-lead ECG report, juxtaposed against the clinical interpretation provided by the investigator.

This comparison was conducted within predefined boundary standards, resulting in the classification of cases into four distinct categories. True positive cases were instances where both computer-generated interpretations and the clinical investigator's interpretation aligned, confirming the presence of detected STEMI/NSTEMI. Cases were considered true negative if both interpretations concurred by correctly indicating the absence of STEMI/NSTEMI under scrutiny. False positive cases comprised computer-generated interpretations suggesting the presence of

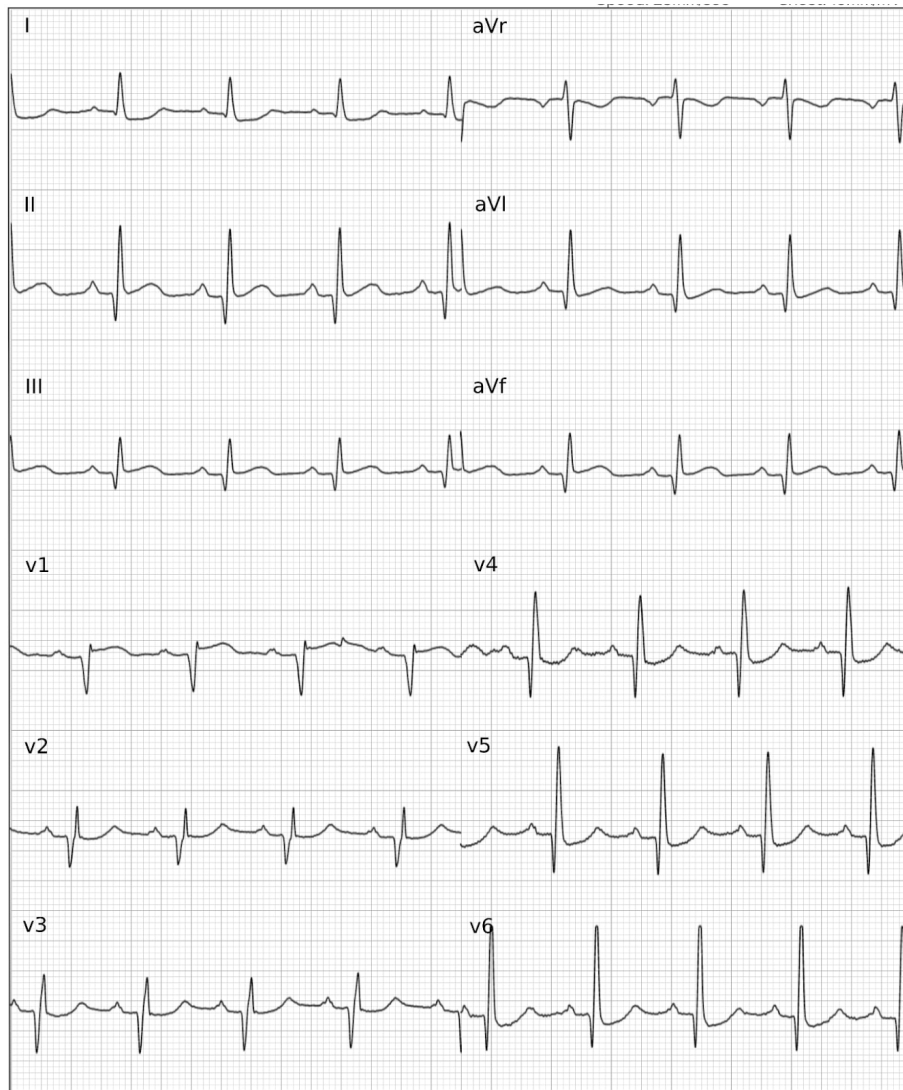


Figure 4. Spandan ECG report of a patient.

STEMI/NSTEMI, but contradicted by the clinical investigator's assessment, resulting in an erroneous positive classification. Conversely, false negative cases occurred when computer-generated interpretations failed to identify STEMI/NSTEMI clinically confirmed by the investigator, leading to misclassification as negative, as outlined in Table 3.

In this analysis of 56 cases, the smartphone-based 12-lead ECG and the gold standard ECG demonstrated comparable diagnostic performance. Both methods correctly identified true positives, true negatives, false positives, and false negatives, as detailed in Table 4.

The validation parameters of the Spandan

smartphone ECG device and the gold standard ECG machine are presented in Table 5.

The study demonstrates an F-score of 0.96 for the smartphone-based ECG machine, with a positive likelihood ratio (PLR) of 0.93 and a negative likelihood ratio (NLR) of 0.07. Similarly, the Gold Standard ECG machine demonstrated an F-score of 0.84, indicating a balanced performance in terms of precision and recall. The positive likelihood ratio (PLR) of 1.17 suggests a modest increase in the probability of correctly identifying STEMI/NSTEMI cases when the test is positive. Conversely, the negative likelihood ratio (NLR) of 0.48 reflects a moderate decrease in the probability of ruling

Table 5. Validation parameters of Spandan smartphone ECG and Gold Standard ECG.

Validation Parameter	Spandan 12 Lead ECG	Gold Standard ECG
Specificity	100%	25%
Sensitivity	93%	88%
NPV	80%	37%
PPV	100%	81%
Accuracy	94%	75%
Precision	100%	81%

out STEMI/NSTEMI when the test result is negative. These metrics underscore the diagnostic capabilities of the Gold Standard ECG machine while providing a basis for comparison with alternative methods, such as the Spandan Smartphone ECG. A 95% confidence interval (CI), the true sensitivity of the Smartphone ECG falls within the range of 0.88 to 0.98. Similarly, for the Gold Standard ECG machine, the sensitivity range of 0.83 to 0.93 implies that the equivalent interval lies within the range with the same level of confidence.

The 95% confidence interval for specificity and positive predictive value (PPV) was 1 for the smartphone-based ECG, while for the Gold Standard Machine, these values were between -0.22 to 0.72 and 0.71 to 0.90, respectively. The confidence interval of negative predictive value (NPV) for Smartphone ECG was between 0.2 to 1.4, whereas for the Gold Standard machine, it lies between 0.1 to 0.64.

Additionally, the results indicate that the Smartphone 12-lead ECG yielded Matthew's correlation coefficient (MCC) value of 0.86, while the Gold Standard 12-lead ECG produced an MCC value of 0.16. This substantial discrepancy in MCC values suggests that the diagnostic performance of Spandan significantly outperformed the Gold Standard ECG, reinforcing the robustness of Smartphone ECG's diagnostic capabilities.

The p-value of 0.002 observed in the comparison of the gold standard versus cardiologist interpretation and Spandan versus cardiologist interpretation for detecting STEMI/NSTEMI indicates a statistically significant difference between these diagnostic approaches. Additionally, the high heterogeneity reflected in the I² statistic (99.68% for specificity and 95.4% for sensitivity) highlights substantial variability across the studies included in the analysis. This suggests that the differences in sensitivity and specificity outcomes

Table 6. Comparison of the Spandan Smartphone ECG outcomes to the previous studies.

Study Name	Muller et al. Study for Smartphone ECG	Towhari et al study for Arrhythmia	Spandan ECG
Sensitivity (%)	88	97.3	100%
Specificity (%)	69	99.6	93%
PPV (%)	83	NA	80%
NPV (%)	NA	NA	100%

may be influenced by diverse study methodologies, population characteristics, or diagnostic protocols, emphasizing the need for standardized evaluation across varied clinical settings. A detailed comparison of the Spandan Smartphone ECG's diagnostic performance with outcomes from prior research is presented in Table 6.

Discussion

The primary aim of this study was to validate the effectiveness of the Spandan smartphone-based ECG device in making crucial decisions related to ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI). Compared to the Gold Standard ECG, the Smartphone ECG device demonstrated a notably higher level of accuracy and precision. This finding suggests that Smartphone-based 12-lead ECG could play a crucial role in setups like Intensive Care Units (ICUs) and Cardiac Intensive Care Units (CICUs) where the gold standard ECG has limitations in providing digitized ECG reports during the physical absence of the cardiologist. Previous studies have shown that handheld ECG and portable ECG devices are good alternatives for cardiac care monitoring in home settings, primary healthcare facilities, and rural areas. In addition to early detection of cardiac abnormalities like arrhythmias, Smartphone-based 12-lead ECG machines can also facilitate early discharge of patients and provide timely diagnosis even when the cardiologist is unavailable in the CCU and CICU.

Muhlestein et al. in 2019 assessed the accuracy of diagnosing STEMI by combining consecutive single-lead smartphone ECGs to create a simulated 12-lead

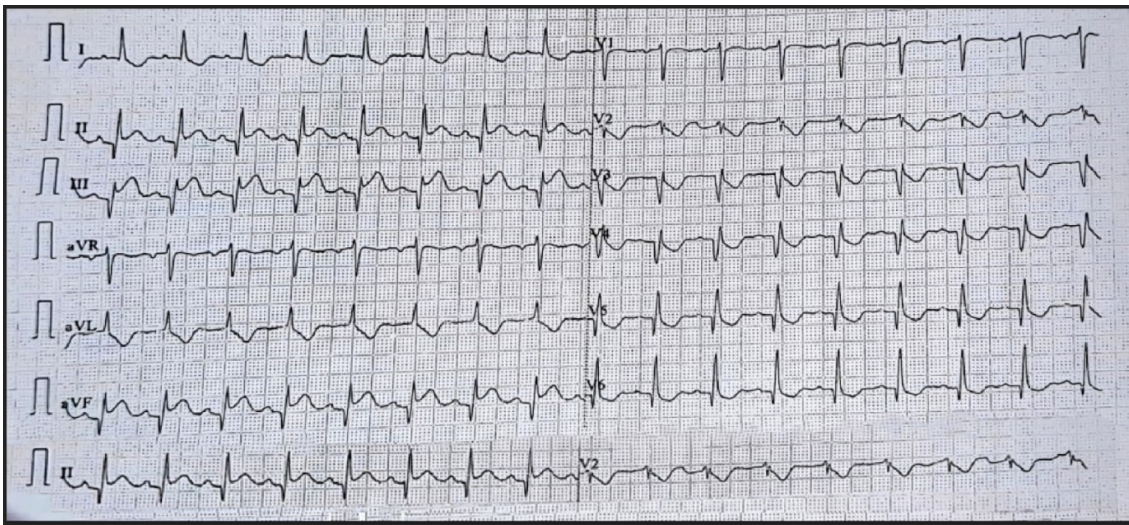


Figure 5. Gold Standard ECG report of a patient.

ECG, indicating equivalence to the 12-lead gold standard ECG in detecting STEMI effectively. This innovative approach not only broadens the possibilities for quicker and more comprehensive diagnosis but also has the potential to enhance STEMI treatment outcomes by facilitating early intervention.

Similarly, Muller et al. in 2008 showed that out-of-hospital ECG had an 88% sensitivity, 69% specificity, 77% positive predictive value, and 83% negative predictive value. Towhari et al. in 2019 compared the diagnostic accuracy of smartphone ECG recorders with that of standard 12-lead ECG in hospital settings. Analysis revealed diagnostic metrics of smartphone ECG recorders similar to standard 12-lead ECG rhythm, including sensitivity (97.3% vs. 98%) and specificity (99.6% vs. 99.6%). However, their study was limited to arrhythmias, whereas the current study included STEMI and NSTEMI to further evaluate the diagnostic accuracy of smartphone electrocardiogram devices in critical patients. On comparing these findings with the Spandan smartphone ECG, accuracy parameters showed higher values for the Spandan ECG.

Although these findings were analyzed for a small sample size, this research opens the door for a large-scale study. The smartphone ECG machine used in this study shows extreme sensitivity in the ECG traces, signifying that these devices can be used in the screening of vulnerable STEMIs and NSTEMIs. The algorithms of computer interpretation are 24% more specific compared to the study conducted by Muller

et al. Additionally, the Smartphone ECG in this study predicted no false positive values.

With the limitation that the research was conducted on a small number of participants within a single healthcare facility, the majority of whom were males, the generalizability of the findings to a broader and more diverse population may be restricted. Additionally, a single device was employed to carry out all tests. While this was done under the guidance of well-trained trial assistants, it's crucial to recognize that the accuracy of recorded ECG tracings may vary when utilized by individuals without specialized training, especially if they do not follow proper usage instructions.

The use of mobile devices by healthcare professionals is transforming clinical practice. Numerous medical software applications can now assist with tasks ranging from information and time management to clinical decision-making at the point of care. Mobile devices and applications offer a wide array of advantages to healthcare professionals, including heightened accessibility to point-of-care tools. This increased accessibility has been shown to play a pivotal role in enhancing clinical decision-making processes, ultimately resulting in improved patient outcomes. In essence, mobile technology empowers healthcare professionals by equipping them with an arsenal of tools and information that can significantly impact the quality of care they provide and, by extension, the well-being of their patients.

Nonetheless, further research is warranted to

explore smartphone-based ECG potential in detecting a broader spectrum of its capability to make percutaneous coronary intervention (PCI) related decisions and its correlation to 2D and 3D imaging techniques like echocardiography and angiography.

Conclusion

The Spandan ECG, a smartphone-based device, demonstrates remarkable efficacy in the detection of ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI), making it a promising solution for Cardiac Care Units (CCUs) and Cardiac Intensive Care Units (CICUs) settings for monitoring purposes. The findings of this observational study emphasize smartphone-based ECG's diagnostic capabilities for specifically detecting STEMI and NSTEMI in critical patients, particularly in terms of specificity (100%) and accuracy (93%). These results highlight that the digital health device has the potential to aid cardiologists in making timely diagnoses and initiating treatment, ultimately contributing to the reduction of mortality rates associated with cardiovascular conditions.

List of Abbreviations

CCU	Cardiac Care Unit
CICU	Cardiac Intensive Care Unit
ECG	Electrocardiogram
ICU	Intensive Care Unit
MCC	Matthew's correlation coefficient
MI	Myocardial Infarction
NLR	Negative Likelihood Ratio
NPV	Negative Predictive Value
	Non-ST-segment elevation
NSTEMI	myocardial infarction
PCI	Percutaneous Coronary Intervention
PLR	Positive Likelihood Ratio
PPV	Positive Predictive Value
SST	T-segment elevation myocardial infarction

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