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Research Article

Comprehensive Cardiovascular Assessment in Critical Patients: The Predictive Role of a Smartphone-based 12-Lead ECG Device

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Abstract

Background: With the increasing prevalence of cardiovascular diseases, there is a growing need for innovative and easily accessible cardiac monitoring tools. This study evaluates the predictive capability of Spandan, a smartphone-based 12-lead electrocardiogram (ECG) device, for assessing cardiovascular abnormalities in critically ill ICU patients at a tertiary care hospital in Uttarakhand.

Methods: A cohort of 203 critically ill patients was actively enrolled in the study. Utilizing the Spandan smartphone-based ECG device, comprehensive 12-lead ECG recordings were obtained from each participant. These recordings underwent comparative analysis against the Gold Standard ECG, with diagnoses provided by cardiologists. The study aimed to assess the operational feasibility and accuracy of Spandan in identifying cardiovascular abnormalities within this high-risk population.

Result: Initial findings reveal a significant alignment between the ECG recordings obtained via Spandan and the gold standard ECG, corroborating the diagnoses provided by cardiologists. The smartphone-based ECG device demonstrates promising outcomes in detecting various cardiovascular abnormalities in critical patients, including arrhythmias, ischemic changes, and conduction abnormalities. Notably, Spandan exhibits a specificity of 70%, surpassing the Gold Standard's 42%. This suggests Spandan's advantageous capability in accurately identifying true negative cases, thereby offering a higher specificity.

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Conclusion: The Spandan 12-lead ECG device shows promise as a valuable tool for comprehensive cardiovascular assessment in critically ill patients. Its operational feasibility and precision in identifying cardiovascular abnormalities highlight its potential to facilitate prompt diagnosis and management in this vulnerable demographic. Further extensive research and larger-scale trials are warranted to validate these initial findings and confirm the broad applicability of smartphone-based ECG devices in critical care settings.

Keywords: Smartphone-based ECG; Critical patients; Cardiovascular assessment; Spandan device; Operational feasibility; Cardiovascular abnormalities.

Introduction

Cardiovascular diseases (CVDs) remain a significant global health challenge, contributing substantially to morbidity and mortality worldwide. This underscores the pressing need for innovative technologies that enable timely diagnosis and effective management. Within cardiac monitoring, advancements in mobile health technologies have led to the development of smartphone-based electrocardiogram (ECG) devices, offering a convenient and accessible means of assessing cardiac function. These devices incorporate improved computerized algorithms for arrhythmia detection, ST-segment/ischemia monitoring software, efficient noise-reduction methods, enhanced multi-lead monitoring capabilities, and the utilization of reduced lead sets for generating 12-lead ECGs with minimal electrodes.

In the Intensive Care Unit (ICU) setting, studies report a prevalence of approximately 30% for QT prolongation, a condition associated with an increased risk of Torsade de pointes (TdP) ventricular tachycardia, which can progress to ventricular fibrillation (VF) and carry a high fatality risk. Factors such as electrolyte imbalances and certain medications predispose patients to QT interval prolongation, emphasizing the significance of timely detection and management.

Recent advancements in cardiac monitoring technologies allow for the prediction of proarrhythmic effects of antiarrhythmic drugs, enabling clinicians to tailor therapy and avoid potentially hazardous treatments. Smartphone-based portable ECG devices offer a practical solution for frequent electrophysiological monitoring, facilitating prompt arrhythmia diagnosis and selection of appropriate therapy.

This research examines the predictive capabilities of the Spandan smartphone-based 12-lead ECG device in systematically assessing cardiovascular abnormalities in critically ill ICU patients. These patients, due to their compromised health status, are particularly vulnerable to cardiovascular abnormalities that may evade detection in conventional monitoring environments. The portability and user-friendly design of the Spandan device holds promise for transforming cardiac monitoring in high-acuity settings.

By comparing diagnostic outcomes between the Spandan system and the established Gold Standard of 12 Lead ECG, this study aims to evaluate the sensitivity, specificity, and predictive values of the Spandan system in

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identifying myocardial infarction and ischemic events. The methodological rigor of this single-blinded, cross-sectional study ensures the reliability and validity of the findings, contributing valuable insights to advancing cardiac care for critically ill patients.

Methodology

Study Design

This investigation adopts a meticulously crafted study design characterized as a single-blinded, cross-sectional, and non-randomized prospective approach. Its primary objective is the thorough evaluation of the predictive capacity of the smartphone ECG system in diagnosing cardiac issues among a cohort of critically ill individuals.

Participants

The study encompasses a population of 203 individuals aged 20 years or older, selected based on specific symptoms such as chest pain, palpitations, shortness of breath, and a documented history of coronary artery disease (CAD). Exclusion criteria were applied, excluding individuals with pacemakers and those exhibiting baseline wandering or artifacts in the ECG data. Subsequent to the application of these criteria, 182 individuals were considered eligible for inclusion, ensuring the representativeness of the cohort relative to the target population.

Setting

The clinical trial was conducted within the controlled environment of the Intensive Care Unit (ICU) at Shri Mahant Indresh Hospital (SMIH) in Dehradun, a tertiary care hospital. This setting leverages specialized infrastructure and expertise conducive to rigorous scientific inquiry.

Supervision and Oversight

All tests were conducted under the vigilant supervision of a Cardiologist, ensuring precision and strict adherence to standardized procedures. This meticulous oversight is paramount in enhancing the reliability and accuracy of the collected data.

Reference Standard

The diagnostic accuracy of the smartphone ECG system is evaluated by juxtaposing its outcomes with the well-established Gold Standard, the 12 Lead ECG. This comparative analysis serves as a benchmark for assessing the sensitivity and specificity of the Spandan system in detecting cardiac abnormalities.

Data Collection

A comprehensive approach to data collection involves securing written consent and obtaining detailed medical histories from each participant. This valuable information is systematically recorded in a Case Report Form (CRF), facilitating a holistic understanding of the patient's background.

Timing Considerations

To mitigate potential biases, a minimum interval of 2 hours is observed between the issuance of the Spandan system report and the Gold Standard 12 Lead ECG report. This temporal demarcation ensures an impartial

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and stringent assessment of diagnostic accuracy.

Statistical Analysis

The statistical analysis aims to ascertain key metrics, including Specificity, Sensitivity, Negative Predictive Value (NPV), and Positive Predictive Value (PPV). Calculations extend to validation parameters, providing a comprehensive insight into the performance of the Spandan system.

Data Storage

The pivotal ECG reports, integral to the study, are systematically uploaded to a centralized server. Redundant storage on both Google Drive and Excel sheets is implemented to safeguard data integrity and facilitate accessibility for subsequent analysis.

Archival

Demonstrating a commitment to transparency and future reference, scanned case report formats will be accessible on Google Drive. This archival approach facilitates meticulous scrutiny and verification of the study findings.

Results

The study initially involved the participation of 203 individuals, yet after a meticulous assessment, only 182 of them met the criteria for inclusion. Among the 182 participants, 29 were female and 153 were male, reflecting the gender distribution within the population. Consistent with hospital protocols, every patient admitted to the Intensive Care Unit (ICU) had their electrocardiogram (ECG) documented. In the specific context of this research, an additional ECG was recorded using a smartphone-based ECG device. This supplementary recording aimed to assess both the accuracy and feasibility of employing such technology in the monitoring of critically ill patients.

Variables	Number	Percentage
Anteroseptal MI	24	15.48%
Ischemia	102	65.81%
RBBB	19	12.26%
LBBB	14	9.03%
ST-T Changes	24	15.48%
Anterior wall MI	23	14.83%
Inferolateral MI	8	5.16%
Inferior wall MI	5	7.75%
Antero-apical MI	1	1.55%
Anterolateral MI	1	1.55%
Lateral wall MI	2	3.10%
J-point Elevation	14	21.70%

Table 1: Participants with Abnormal Cases (n=155).

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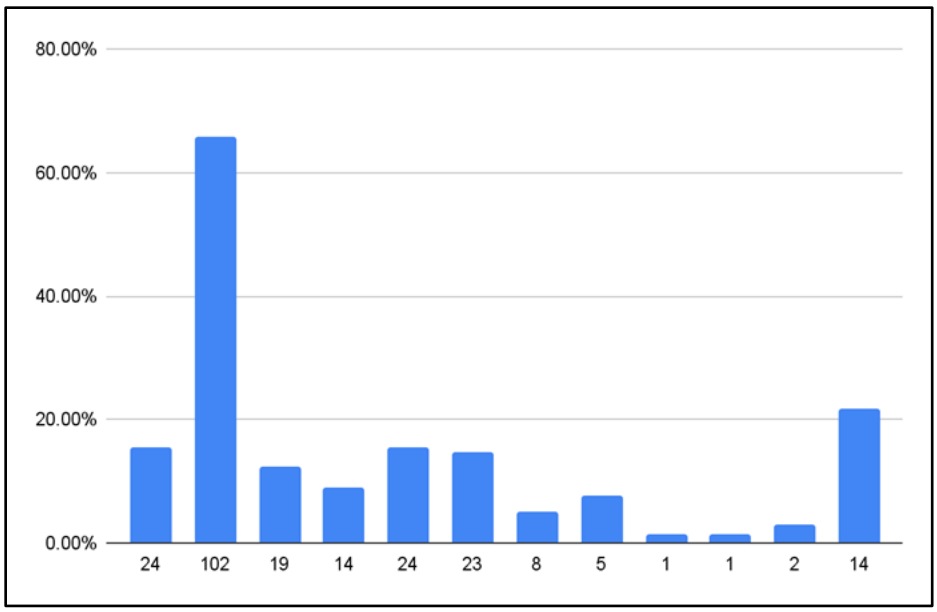

Figure 1: Graphical Representation of Abnormal Cases with reference to Table 1.

Among the 182 subjects deemed eligible, 29 were identified as female, while 153 were male. Further details and baseline characteristics of the participants are presented in Figure 1. The additional collection of ECG data using a smartphone-based device is noteworthy as it investigates the potential integration of modern technology into the routine monitoring procedures of critically ill patients. This approach offers a more comprehensive understanding of their cardiac status, contributing to enhanced patient care and management strategies.

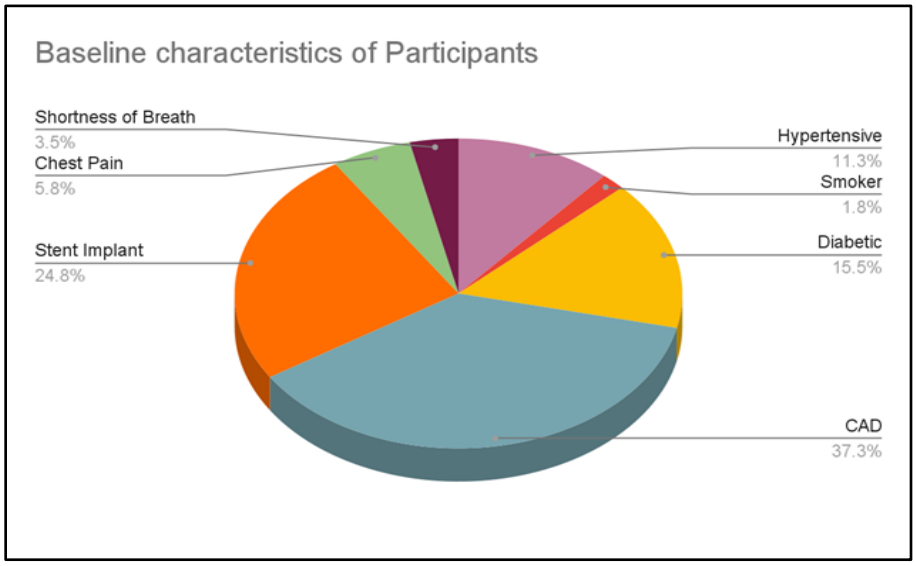

Figure 2: Graphical Representation of Baseline Characteristics of Participants.

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When compared to the cardiologist's assessment, among the 182 cases, Spandan ECG confirmed 124 cases as true positives, while the gold standard confirmed 136 cases. Additionally, 24 cases were identified as true negatives by Spandan ECG and 15 by the gold standard. Spandan ECG detected 10 false positives, whereas the gold standard identified 20 false positives. Furthermore, Spandan ECG identified 24 false negatives, while the gold standard detected 11 false negatives.

Parameter	Spandan 12 Lead ECG	Gold Standard ECG
True Positive	124	136
True Negative	24	15
False Positive	10	20
False Negative	24	11

Table 2: Confusion Matrix of ECG Interpretation of Gold standard and Spandan 12 lead ECG.

According to recent data, Spandan has a specificity of 70%, sensitivity of 83%, negative predictive value of 50%, and positive predictive value of 92%. On the other hand, the gold standard ECG machine has a specificity of 42%, sensitivity of 92%, negative predictive value of 57%, and positive predictive value of 87%.

Validation Parameter	Spandan 12 Lead ECG	Gold Standard ECG
Specificity	70%	42%
Sensitivity	83%	92%
NPV	50%	57%
PPV	92%	87%

Table 3: The specificity, Sensitivity, NPV, and PPV of Gold standard and Spandan 12 lead ECG.

It was found that the Spandan 12 Lead ECG had an accuracy of %, 100% precision, 95.8% F-score, and a P-value of 0.75. Meanwhile, the Gold Standard 12 Lead ECG had an accuracy of 87.75%, 87.23% precision, 93.18% F-score, and a P-value of 0.46.

Parameters	Spandan 12 Lead ECG	Gold Standard ECG
Accuracy	81%	82%
Precision	92%	87%

Table 4: The accuracy and Precision of Spandan 12 Lead ECG and Gold standard ECG.

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It was found that the Spandan 12 Lead ECG had 93% accuracy, 100% precision, 95.8% F-score, and a P-value of 0.75, while the Gold Standard 12 Lead ECG had 87.75% accuracy, 87.23% precision, 93.18% F-score, and a P-value of 0.46.

Parameters	Spandan 12 Lead ECG	Gold Standard ECG
F-Score	0.87	0.89
PLR	2.7	1.58
NLR	0.24	0.19

Table 5: The F-score, Positive Likelihood ratio, and Negative Likelihood ratio of Spandan 12 Lead ECG and Gold standard ECG.

The Matthew Correlation Coefficient was utilized to determine the P-values. Spandan 12 Lead has a P-value of 0.48, and the Gold Standard has a P-value of 0.39.

Matthew Correlation Coefficient	Value
Spandan 12 Lead ECG vs Cardiologist	0.48
Gold Standard ECG vs Cardiologist	0.39

Table 6: The Matthew Correlation Coefficient for Spandan 12 Lead ECG and Gold Standard 12 Lead ECG.

The 95% Confidence Interval (CI) for Sensitivity ranges from 0.77 to 0.88 for the Spandan system and from 0.88 to 0.95 for the Gold Standard. For Specificity, the 95% CI varies from 0.68 to 0.97 for Spandan and from 0.19 to 0.65 for the Gold Standard. Regarding Positive Predictive Value (PPV), the 95% CI fluctuates from 0.87 to 0.96 for Spandan and from 0.81 to 0.92 for the Gold Standard. Additionally, the 95% CI for Negative Predictive Value (NPV) spans from 0.35 to 0.64 for Spandan and from 0.38 to 0.75 for the Gold Standard.

Discussion

This study reveals notable patterns in the performance of the Gold Standard and the Spandan system, particularly concerning False Positives and False Negatives. The Gold Standard exhibits a higher tendency for False Positives, indicating an inclination to incorrectly identify positive conditions in the absence of their presence. Conversely, Spandan displays a greater inclination toward False Negatives, implying a higher likelihood of missing or failing to detect positive conditions when present. These observations

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underscore the nuanced trade-offs between sensitivity and specificity in diagnostic accuracy. Despite the occurrence of False Negatives, the smartphone-based ECG device demonstrates higher specificity compared to the Gold Standard, as evidenced by the fewer false negative cases.

The Gold Standard demonstrates higher sensitivity at 92%, surpassing Spandan, which achieved a sensitivity of 83%. Sensitivity is crucial for detecting true positive cases, suggesting the Gold Standard's superior ability to identify patients with cardiac abnormalities. However, the implications of this discrepancy warrant careful consideration, especially concerning the Spandan system's potential for timely, real-time monitoring.

The Matthews Correlation Coefficient (MCC) value for Spandan was calculated at 0.48, indicating a positive correlation considered good but not perfect. This finding suggests room for improvement in Spandan's algorithmic precision. Future enhancements to the Spandan system could address this limitation, aiming for a more precise and perfect correlation to bolster its diagnostic reliability.

Both Spandan and the Gold Standard demonstrate effective performance for sensitivity and Positive Predictive Value (PPV), with F1 scores of 0.87 and 0.89, respectively. This underscores the utility of both devices in accurately identifying true positive cases, reinforcing their efficacy in critical patient care.

Significantly, Spandan demonstrates a specificity of 70%, outperforming the Gold Standard's 42%. This indicates that Spandan possesses an advantageous capability in accurately identifying true negative cases, thereby providing a higher degree of specificity. This observation holds implications for the device's efficacy in excluding the presence of cardiac abnormalities. Additionally, previous research corroborates Spandan's higher specificity compared to the gold standard device in detecting ST-elevation myocardial infarction [15].

The Positive Likelihood Ratio (PLR) for Spandan is 2.7, indicating that a positive result in an individual with a suspected condition is 2.7 times more likely to be accurate. This highlights Spandan's ability to provide valuable support for diagnosis when the condition is present. Conversely, the Negative Likelihood Ratio (NLR) for Spandan is 0.24, signifying a strong correlation between a negative test result and the absence of the condition. Future trials may consider a value lower than 0.24 to further scrutinize and refine the efficacy of the Spandan device.

Given the higher incidence of false positive cases with the Gold Standard, individuals undergoing the Gold Standard ECG are advised to seek consultation with a cardiologist. This precautionary measure ensures a thorough evaluation of results, minimizing the impact of false positives and promoting accurate and reliable diagnostic outcomes.

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Conclusion

The nuanced analysis of False Positives, False Negatives, sensitivity, specificity, and likelihood ratios provides a comprehensive understanding of the diagnostic performance of both the Gold Standard and the Spandan system. These insights contribute significantly to the ongoing discourse on optimizing cardiac diagnostics in critical care settings. It underscores the need for continuous refinement and innovation in ECG technologies to enhance diagnostic accuracy and patient care outcomes.

In conclusion, while the Gold Standard exhibits higher sensitivity, the Spandan system demonstrates superior specificity. These findings highlight the complementary nature of these diagnostic tools and underscore the importance of considering multiple factors, including sensitivity, specificity, and likelihood ratios, when evaluating diagnostic performance. As technology continues to evolve, further research and development are essential to refine and optimize ECG technologies for improved cardiac diagnostics in critical care settings.

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Conflicts of interest

The authors of this study declare that they have no conflicts of interest that could affect the objectivity, integrity, or impartiality of the research.

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