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Original Research Article

Smartphone based 12 lead ECG as decision support in STEMI: a prospective, cross sectional study, non-randomised, single blinded and single-center study

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ABSTRACT

Background: When a severe heart attack called a ST segment elevation myocardial infarction (STEMI) is not treated, heart muscle is killed per minute. Hence, early detection and treatment are essential for patient survival. The objectives of this study were to evaluate the accuracy for detection of (a) the ST elevation myocardial infarction of smartphone 12 lead ECG system in comparison to 12 lead gold standard hospital ECG machine; and (b) classification of STEMI in smartphone ECG and hospital ECG.
Methods: This prospective, cross sectional study, non-randomised, single blinded and single-center study was carried out at Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India from 30 May 2022 to 17 January 2023. All patients (n=154) with chest pain, shortness of breath, palpitation under the observations before and after the Percutaneous coronary intervention (PCI) like Coronary angioplasty, bypass surgery were enrolled from Critical care unit (CCU) and intensive critical care unit (ICCU).
Results: Mean age (SD) was 53.90±11.7 years. The male gender (83.12%) shows the maximum frequency than female gender. True positive cases derived from confusion matrix for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis was 113 as compared to 129 from 12 lead Gold standard. Sensitivity of smartphone Spandan ECG (87.5%) was comparable to gold standard 12 lead ECG (98.4%). And, specificity and PPV of smartphone Spandan ECG was recorded to be better than gold standard 12 Lead ECG. STEMI was detected correctly in 132 (86.3%) cases and 141 (80.85%) cases by smartphone ECG and 12 lead Gold standard, respectively.
Conclusions: Spandan ECG device scored a high accuracy and sensitivity. The overall accuracy of smartphone ECG in detecting the STEMI increased by 5.45%, i.e. the significance rise in accuracy of computer interpretation when compared to the cardiologists' diagnosis.

Keywords: STEMI, Smartphone, Specificity, Sensitivity, Accuracy, Validation

INTRODUCTION

The pathogenesis of ST-elevation myocardial infarction (STEMI), which can result from thrombus or other mediating factors, is connected to sudden complete blockage of the coronary artery lumen in acute coronary syndrome.[1-4] For the best clinical outcome in STEMI patients, quick catheter-based or pharmacologic reperfusion therapy is required. According to reports, non-reperfused STEMI victims lose one-third of their lives during the first 24 hours following the event. Most STEMI fatalities take place in the prehospital environment within

the first 1 to 2 hours and are typically caused by the accompanying heart arrhythmia ventricular fibrillation. It seems that many STEMI patients frequently delay seeking medical attention for up to two hours following the beginning of symptoms.[5-7]

Before patients are transported to nearby hospitals for treatment, emergency medical staff on the scene commonly employ ECG to check for deadly electrical arrhythmias and/or ACS. Because to the likely requirement for urgent reperfusion treatment in the presence of ST elevation, an emergent status is often proclaimed and prompt transportation to a hospital equipped to conduct primary PCI is offered. The presence or absence of a myocardial infarction will obviously require further in-hospital testing using blood cardiac markers and more ECGs.[8] The initial 12-lead ECG is critical, nevertheless, to correctly guide the patient's early therapy.

Accelerating the recognition of STEMI incidents is essential since earlier STEMI therapy reduces mortality and morbidity. Smartphone technologies are now pervasive and easily accessible in both affluent and developing countries, making them almost universal in their existence and penetration globally. Non-medical people may be able to use this technology anywhere in the world after it has been scientifically shown to offer reliable and accurate diagnoses.[9-12] This technology may make it possible for even skilled medical staff in resource-constrained nations like India, where standard ECG equipment are not often accessible, to obtain a solid 12-lead ECG trace at a low cost.[13-16]

In view of the above, the objectives of this study were to evaluate the accuracy (a) for detection of the ST elevation myocardial infarction of smartphone 12 lead ECG system in comparison to 12 lead Gold standard hospital ECG machine; and (b) of classification of STEMI in smartphone ECG and hospital ECG.

METHODS

Individuals visiting the critical care unit (CCU) and intensive critical care unit (ICCU) of Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India between 30 May 2022 to 17 January 2023 were invited to participate in this prospective, cross sectional study, non-randomised, single blinded and single-center study after obtaining their written informed consent. The final selected study population was composed of 154 participants of either gender.

Patients were enrolled in the study by taking their written consent and explaining the purpose of the study. Patients chest pain, shortness of breath, palpitation under the observations before and after the percutaneous coronary intervention (PCI) like Coronary angioplasty, bypass surgery was included in the study whereas patients with loose skin, ECGs recorded with electrical disturbances and at emergency state or who could not provide informed consent were excluded from the study. The Institutional Ethics Committee of SMIH approved this study.

Analysis of STEMIs

The STEMIs that were considered under this study were anterior wall MI, antero septal MI, antero lateral MI, lateral MI, inferior Wall MI, infero-lateral MI, infero-septal MI, right branch bundle block and left branch bundle block. ECGs were generated and viewed according to instructions provided by Sunfox Technologies Private Limited. The patients were in a resting position when the ECGs were taken. The patients were subsequently given permission to lie down and followed the research nurses' instructions. The digital data including the 12-lead recording were transferred to a Google cloud-based server for further analysis using a Spandan Smartphone ECG-based application.

12-lead ECG recordings

Under the direction of a cardiologist, the BPL cardiart 9108 devices were used to capture the 12-lead ECGs for 10 seconds utilising both the Spandan 12L and Goldberg 12 lead ECG. The participants' ECGs were taken over a 10-second period while the patients were in resting positions by the nurse using a 12-lead standard and Spandan ECG.

The patient's Spandan smartphone ECG was used to link the device through micro USB to an application that allowed the patient to submit the ECG recordings to Google cloud-based servers.

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

Statistical analysis

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

RESULTS

In total, 154 patients with chest pain, shortness of breath, palpitation under the observations before and after the PCI like coronary angioplasty, bypass surgery were enrolled from CCU and ICCU.

Below Table 1 summarizes the baseline characteristics of the study population. Mean age was 53.90±11.7 years (range in years: 40 years and above) and 128 subjects (83.12%) were males while remaining 26 subjects (16.88%) were females. Below Table 2 summarizes the

confusion matrix of ECG interpretation for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis for overall evaluation. True positive cases derived from confusion matrix for 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis was 113 as compared to 129 from 12 lead gold standard.

Below Table 3 summarizes the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the standard ECG and 12 lead smartphone ECG for interpretation in comparison to cardiologist diagnosis.

Sensitivity of smartphone Spandan ECG (87.5%) was comparable to gold standard 12 lead ECG (98.4%). And, specificity and PPV of smartphone Spandan ECG was recorded to be better than gold standard 12 Lead ECG.

Below Table 4 depicts the accuracy of interpretation of ischemia detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists diagnosis.

STEMI was detected correctly in 132 (86.3%) cases and 141 (80.85%) cases by smartphone ECG and 12 lead gold standard, respectively.

Table 1: Baseline characteristics of study population.

Parameters	Overall patients (n=154)	Standard 12 lead ECG	12 lead smartphone ECG	Cardiologist's diagnosis
Age in years (mean±SD) years	53.90±11.7			
Female, n (%)				
Male, n (%)	26 (16.88)			
BMI (mean) (kg/m^2)	128 (83.12)			
Chest pain	22.9			
Shortness of breath	37			
CAD	10			
Stent implantation	50			
Pacemaker implantation	129			
Smoker	5			
Diabetic	7			
Normal ECG	NA	13	22	40
Anterior wall MI	NA	0	1	0
Anteroseptal MI	NA	28	20	11
Inferior wall MI	NA	26	12	4
Infero-lateral MI	NA	2	15	4
Lateral wall MI	NA	7	1	2
Infero-septal MI	NA	14	10	3
RBBB	NA	8	6	7
LBBB	NA	2	9	7
NSTEMI with ST elevations	NA	54	58	76

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

Parameters	12 lead gold standard	Smartphone ECG
True positive	129	113
True negative	19	9
False positive	4	16
False negative	2	16

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

Parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Gold standard 12 Lead ECG	98.4	17.3	87.1	66.6
Smartphone Spandan ECG	87.5	64.0	92.6	50.0

Table 4: Accuracy of interpretation of STEMIs detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists diagnosis (n=114).

Parameters	12 lead gold standard	Smartphone ECG
STEMI detected correctly	141	132
Accuracy of detection (%)	80.85	86.3

DISCUSSION

This prospective, cross-sectional, validation research, single-center study made a significant contribution by showing that the smartphone ECG can recognise an ST-segment myocardial infarction utilising a technological platform that is already accessible. This is significant because it allows electrocardiographic assessment to be expanded into new use case scenarios, such as personalised usage by the owner or point-of-care, out-of-hospital first medical contact. Situations where a typical 12-lead ECG is not readily accessible are among the crucial ones. Rural locations without access to healthcare, developing nations and regions, and travel settings like cruise ships and tour buses are among the settings with the greatest demand.[17]

Standard 12-lead ECG equipment could not be made available in such circumstances, but the widespread use of smartphones might provide the groundwork for a wider use of electrocardiography.[18-20] Our research revealed a high degree of STEMI accuracy across Spandan smartphone ECG records and traditional ECG readings. The 12 lead Spandan smartphone ECG has superior diagnostic capabilities for STEMI when compared to simultaneously conducted traditional 12L ECG in a primary care population, according to blinded cardiologists. To our knowledge, this is the first study to compare the smartphone-based 12-lead ECG with a cardiologist to validate the diagnosis of STEMI.
The extended care and diagnostic capabilities for clinical decision-making and patient-facing treatment assistance are made possible by the remarkable developments in smart device technology, their downsizing (now hand-held), easy connection, and ubiquitous nature. the availability of point-of-care 12-lead ECGs taken on smart devices owned by the general public and uploaded practically instantly to a common cloud-based server present a chance to alter how healthcare is given and delivered. In order to improve access and timeliness of care, local hospitals or healthcare systems, EMS services, and communities may decide to develop and sign up for services that include monitoring, alarms, and two-way communication.

Our current healthcare system's approach is being outpaced by technology, so this study will determine whether a smartphone-obtained 12-lead ECG is a reliable substitute for diagnosing STEMI. If this is the case, a follow-up study should evaluate the "sharing capabilities" of the smart device ECG and determine whether it can be used by non-clinicians outside of the hospital setting. In a prior study using a comparable device, it was discovered that nurses were far better at ease making single lead recordings than receptionists. There were several advantages to our investigation. Initially, we created a cohort generalizable to general practise by include consecutive patients who received a 12L ECG as part of standard medical practise.

The confirmation of rhythmic abnormalities detection using Spandan, in contrast to other methods, enables the user's smartphone to display ECG data in real-time. The application must be installed on the user's smartphone and connected to Spandan through Bluetooth in order for real-time monitoring to be possible. Because of this, it has advantages for real-time ECG monitoring but also poses a potential data loss risk due to bluetooth disconnecting. The advantage of Spandan is that it is light (15 g).

The device is simple to reuse since it uses swappable electrodes and a coin cell battery. The real-time ECG monitoring in Spandan, according to this study's theory, makes it likely to be useful in figuring out whether a patient's condition is caused by intermittent arrhythmia. Furthermore, because of the Spandan's light weight and small size, increased patient compliance with utilising the device is anticipated.

Limitations

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

CONCLUSION

The STEMI reaction is a time-sensitive activity requiring quick and decisive action. Making the diagnosis faster can possibly save lives. The diagnostic and treatment procedure can be accelerated with the help of a mobile application. Spandan is a user-friendly, stand-alone smartphone app that has shown good results for detecting rhythm irregularities. Spandan ECG device received great marks for accuracy, sensitivity, and specificity. The overall accuracy of smartphone ECG in detecting the rhythm abnormalities increase by 9%, i.e. the significance rises in accuracy of computer interpretation when compared to the cardiologists diagnosis. Hence, we can conclude that of the

smartphone based ECG will not only bring the convenience to the primary healthcare provider but also enhance the patient experience. These results make the app a potential candidate for inclusion in next rhythm abnormality screening or case-finding programmes. Before acting on electrocardiographic diagnosis produced by this smartphone-based 12-lead ECG equipment, doctors should use care.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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