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Original Research Article

Validation of interpretation of ST-elevation myocardial infarction using the smartphone based 12 lead electrocardiograms in comparison to the cardiologist-a cross sectional study, validation study, single-center study

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ABSTRACT

Background: In patients experiencing an ST-elevation myocardial infarction (STEMI), rapid diagnosis leads to optimal clinical outcomes. Recent technology has provided access to a reliable means of obtaining an ECG reading through a smartphone application (app) that works with an attachment providing all 12-leads of a standard ECG system. We developed a 12-lead smartphone-based electrocardiogram (ECG) called "Spandan", and an application to accurately assess the presence of STEMI in patients presenting with chest pain. Objectives of study was to perform clinical observation studies on the patients screened for STEMIs and evaluate the variation in the diagnosis of STEMIs detected in both 12-lead gold standard and Spandan 12 lead ECG.
Methods: This single-center study was carried out at Shri Mahant Indresh hospital (SMIH), Dehradun, Uttarakhand, India from April-2022 to November-2022. All patients (n=278) visiting the ECG room with symptoms of chest pain, shortness of breath and past history of cardiovascular disease at the department of cardiology of the SMIH, Dehradun were included in the study.
Results: Mean age (SD) was 53.96±15.31 years. The male gender participants was 75.17%. 14.3% were STEMI patients as per the standard 12 lead interpretation, smartphone ECG interpreted 7.1% of the participants as STEMI and cardiologist interpreted nearly 15.4% of the participants of STEMI.
Conclusions: This study confirmed the potential of a smartphone ECG for evaluation of STEMI and the feasibility of studying this technology further to define the diagnostic accuracy, limitations, and appropriate use of this new technology.

Keywords: ECG, STEMI/ STEMI, Smartphone, Validation

INTRODUCTION

ST-elevation myocardial infarction (STEMI) is related to the occlusion of coronary artery due to thrombus or other medicating factors.[1] Subjects suffering from STEMI either need to go through an immediate catheter-based reperfusion therapy or the primary PCI.[2] The cases with undiagnosed STEMI or non-reperfused STEMI dies within 24 hours of the event.[3-5] Most deaths due to STEMI occur in the prehospital settings in 1 to 2 hours if treated undiagnosed and most of the deaths are usually due to ventricular fibrillation. Patients usually do not appear to seek the medical care for STEMI up to 2 hours after symptom onset.[6]

An ECG is the instrument that is used to detect the arrhythmias in form of electrical rhythms and is being frequently used to access the fatal electrical rhythms like ventricular fibrillation and atrial fibrillation. Whereas, an ECG also used to detect coronary artery disease (CAD) and the acute coronary syndrome (ACS).[7] ECG has the capability to verify the presence of ST elevation myocardial Infarction, the localization of a STEMI leads to declaration of an emergency status in the need of the reperfusion therapy. These-condition usually requires a rapid transport to a hospital with the capability of performing primary PCI. Detection of STEMI using ECG is usually followed by further testing of serum cardiac markers and serial ECGs in the hospitals for diagnosis and therapy. 12-lead ECG not only assists the medical practitioner during decision making for diagnosis but also plays an important role in patient management during critical situations. Earliest treatment of STEMI reduces possibilities of mortality and morbidity, it is thus very crucial for the medical practitioner to timely recognize STEMI related episode and events.[8]

Spread of the smartphone technologies have become readily available in both developed and developing nations around the world.[9]

To improve point of care contact, several smartphone-based healthcare technologies have been developed in form of applications and hardware devices in recent years that has increased patient access to timely care and diagnosis, these technologies include ECG hardware and smartphone application for easy acquisition of 12 lead ECGs to detect arrhythmia and CAD.[10-12]

A prototype named Spandan 12 L ECG, a single channel ECG has been developed as a smartphone ECG system. It has the potential of 12–lead recordings acquisition based on the Goldberg ECG system or standard 12-lead ECG system. Such smartphone-based ECG device, once proven to provide reliable and accurate parameters and ECG traces, can be used by non-medical personnel around the world. In India, metropolitan cities are prosperous and facing the cardiac problem due to lifestyle disorders. Whereas, a vast region is remote, under-developed and lack the basic facilities of healthcare infrastructure, standard ECG machines are not generally expected to be available, hence the availability of such smartphone based portable technology can be an inexpensive access to a reliable 12–lead ECG tracing by even trained medical personnel.

In view of the above, the objectives of this study were to a) perform clinical observation studies on the patients screened for STEMIs and other heart abnormalities in trials, b) evaluate the variation in the diagnosis of STEMIs detected in both 12-lead gold standard and Spandan 12 lead ECG and c) assess the impact of using the Spandan 12 lead ECG instead of the traditional ECG machine in the ECG room.

METHOD

Individuals visiting the ECG room at the department of cardiology of Shri Mahant Indresh hospital (SMIH), Dehradun, Uttarakhand, India between April-2022 to November-2022 were invited to participate and were included in this non-randomized, single blinded, cross-sectional, single-center study after obtaining their written informed consent. The final selected study population was composed of 278 participants of either gender.

Patients were enrolled in the study by taking their written consent and explaining the purpose of the study. Patients with chest pain, shortness of breath, syncope, dizziness, light headedness and past medical history of cardiovascular diseases were screened in the study were included in study whereas patients with only arrhythmia and Normal cases, emergency cases, electrical disturbance in ECG excluded/ who could not provide informed consent were excluded from study. Institutional ethics committee of SMIH approved this study.

STEMI analysis

A diagnosis of STEMI will be made when there is ST elevation at the J point in two contiguous leads with the cut points of ≥ 0.1 mV (i.e., ≥1 mm) in all leads other than V2-V3, where the cut points of ≥ 0.2 mV (≥ 2 mm) were used.[13]

In addition to the above STEMI criteria, the term ‘STEMI equivalent’ is used for ≥1 mm ST segment depression in ≥ 8 ECG leads plus ≥1 mm ST segment elevation in lead aVR (or V1). Isolated ST segment depression of ≥1mm in contiguous leads V1-3 also is considered a STEMI equivalent for posterior myocardial infarction (i.e., generally due to isolated left circumflex occlusion).[13]

ECG sources

Patients referred to the Shri Mahant Indresh hospital (SMIH), Dehradun, Uttarakhand, India in which a standard 12-lead ECG and Spandan portable 12-lead ECG were recorded sequentially at the same patient visit. The 12-lead ECGs were collected with the patients in the resting position. The patients were then allowed to be in supine position and, followed the instructions by study nurses. Utilizing a Spandan smartphone ECG-based application, the digital files containing the 12-lead recording were uploaded to a Google cloud-based server for subsequent analysis.

12-lead ECG recordings

The 12-lead ECGs were recorded with both the Spandan 12L and 12 lead ECG devices at 500Hz sampling frequency. The patients were at resting positions and the nurse collected 10 second ECG for participants using Standard 12 lead ECG and Spandan 12 lead ECG. The device is connected via Micro USB cable to an

application loaded into the patient's Spandan smartphone ECG, which allows the ECG recordings to be uploaded 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.

Statistical methods

The data was collected on an excel sheet and descriptive statistical analysis was performed. Evaluation of the accuracy was done by evaluation of specificity, sensitivity, positive predictive value and negative predictive value (NPV and PPV) of the detection of STEMIs using Smartphone ECG was evaluated in comparison to the cardiologist diagnosis.

RESULTS

In total, 300 patients were enrolled for the study and a few (n=22) subjects later withdrew consent or patients were fitting within the exclusion criteria. Hence, 278 subjects agreed to participate and underwent both an mECG and 12-lead ECG recording. Mean age was 53.96 years (range in years: 25 and above) and 209 subjects (75.17%) were males. Below Table 1 summarizes the baseline characteristics of ECG morphology within the study population for Spandan smartphone ECG and standard ECG.

A summary of the baseline characteristics of ECG morphology within study population is shown in above Table 1. The male gender (n=209, 75.17%) shows the maximum frequency than female gender.

The classification of the STEMIs and normal interpretation done by standard 12 lead ECG, smartphone 12 lead ECG and cardiologist is given in Table 2. Out of 278 participants 14.3% were STEMI patients as per the standard 12 lead interpretation, smartphone ECG interpreted 7.1% of the participants as STEMI and cardiologist interpreted nearly 15.4% of the participants of STEMI. Interpretation of the ECGs by cardiologist evaluated that there were 1.4% cases of left branch bundle block, 15.8% cases were observed to have ST-T abnormality, 3.2% of the participants had right branch bundle block.

The number of similar and different diagnoses between the 12-lead smartphone and 12-lead ECG is shown in above Table 3. This table 3 shows the total STEMI/ STEMI equivalent cases interpreted by the standard 12 lead ECG, Smartphone ECG and the cardiologist diagnosis.

A summary of the confusion matrix of 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis for overall evaluation is shown in above Table 4. True negative score between 12 lead gold standard and 12 lead Spandan smartphone ECG were identical. The 12 lead Spandan smartphone ECG recorded higher false positive cases (20 versus 10) and lower true positive cases (88 versus 90).

The validation parameters are evaluated for interpretation of STEMIs by smartphone ECG and Standard 12 lead ECG in comparison to the cardiologist's diagnosis as given in Table 5. As compared to Standard 12 lead ECG, smartphone ECG scored better sensitivity (100%) and NPV (100%).

Table 1: Baseline characteristics of ECG morphology within study population.

Parameters	Overall (n=278)	Standard 12 lead ECG	12 lead smartphone ECG	Cardiologist's diagnosis
Age (Years) mean ± SD	53.96±15.31	53.96±15.31	53.96±15.31	53.96±15.31
Gender				
Male	209	209	209	209
Female	88	88	88	88
BMI (kg/m^2)	23.48	23.48	23.48	23.48
Diabetes	67	67	67	67
Smoking	52	52	52	52
Prev. coronary interventions	80	80	80	80
Normal ECG		91	113	121
Abnormal ECG		187	165	157
Anterior wall MI		28	16	28
Inferior wall MI		8	4	15
Lateral wall MI		4	0	0
LBBB		2	7	4
RBBB		9	16	9
ST-T abnormal		50	68	44
Arrhythmia		64	54	26
Other abnormality		22	0	31

Abbreviations: BMI: body mass index, SD, standard deviation, MI: Myocardial Infarction, LBBB: Left branch bundle block RBBB: Right branch bundle block.

Table 2: Distribution of the diagnosis under STEMI/ STEMI equivalent criteria among the 12 lead ECG, 12 lead smartphone ECG and cardiologist interpretation.

Parameters	12 lead gold standard	Smartphone ECG	Cardiologist's diagnosis
STEMI (n=278 patients)	40	20	43
LBBB	2	7	4
ST-T abnormality	50	68	44
RBBB	9	16	9
Other abnormality	64	32	35
Normal	91	113	121
Not interpretable	22	22	22

Table 3: The number of similar and different diagnoses between the 12-lead smartphone and 12-lead ECG.

Parameters	STEMI and STEMI equivalent detected in standard 12 lead ECG	STEMI and STEMI equivalent detected in smartphone 12 lead ECG	STEMI and STEMI equivalent detected in cardiologist's diagnosis
Number of participants	101	111	100

Table 4: The confusion matrix of 12 lead standard ECG in comparison to cardiologist diagnosis.

Parameters	12 lead gold standard	Smartphone ECG
True positive	90	88
False positive	10	20
True negative	170	170
False negative	8	0

Table 5: The sensitivity, specificity, NPV and PPV of the 12 lead smartphone ECG for a STEMI/LBBB and not-STEMI diagnosis.

Parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Gold standard 12 lead ECG	91.8	94.4	90	95.5
Smartphone Spandan ECG	100	81.4	81.14	100

DISCUSSION

This cross-sectional study, validation study, single-center study importantly demonstrates that the smartphone ECG is capable of identifying an ST-segment myocardial infarction using a technology platform that is now readily available. The significance of this lies in its ability to extend electrocardiographic evaluation into new use case scenarios, including personalized use by the owner or point-of-care, out-of-hospital first medical contact. These and other important scenarios include settings where a standard 12-lead ECG is not immediately available.

Settings of particular need includes rural areas with no nearby medical facilities, developing nations and regions, and travel scenarios such as cruise ships and tour buses.[14] It would be unfeasible to provide standard 12-lead ECG devices in such settings, but smartphone penetration has already become commonplace and has potential to provide foundation for greater spread of ECG.[15-17]

Our study showed a good degree of accuracy for STEMI between Spandan smartphone ECG and standard ECG recordings. The diagnostic properties of the 12 lead Spandan smartphone ECG as assessed by blinded cardiologists against simultaneously performed standard 12L ECG in a primary care population were excellent for STEMI. To our knowledge, this is the first study to validate the interpretation of STEMI using Smartphone based 12 Lead ECG in comparison to cardiologist.

The combined marked improvements in smart device technology, its miniaturization (now hand-held), ready connectivity and ubiquitous nature provide a platform to extend care and diagnostic capabilities for clinical decision and patient facing treatment support. The ability to obtain point-of-care 12-lead ECGs on smart devices owned by the general population that shall be uploaded almost immediately to an accessible shared cloud-based server, provides an opportunity to change the way healthcare is delivered and provided.[15]

Local hospitals or healthcare systems as well as EMS services and communities may elect to create and subscribe to services that provide monitoring, alerts, and two-way communication to facilitate both access and speed of care.[18] Technology is outpacing our current

healthcare system approach, and this study will help to assess whether a smartphone obtained 12-Lead ECG is an acceptable alternative to identify STEMI, which, if true, future study should assess the "sharing capabilities" of the smart device ECG and whether it can be used outside of the hospital setting by non-clinicians.[19]

A previous study with a related product found that receptionists were uncomfortable performing a single lead recording, whereas nursing staff were much more comfortable.[20]

Our study had a number of strengths. First, we included consecutive patients who underwent 12L ECG as part of routine medical practice, resulting in a cohort generalizable to general practice.

Regarding the limitations of our study, we must emphasize that it was carried out in a single center and with a single device. Another potential limitation of this study was that the average age of study population was around 54 years, which is higher than the average age of the Indian population. Therefore, the results may not adequately represent the results that would be observed in the general population.

CONCLUSION

This technology holds substantial promise for the diagnosis and management of patients experiencing STEMI by enabling more rapid diagnosis and treatment, leading to improved outcomes in primary care and in general use. Further refinement of system software and hardware should further improve on these results and broaden clinical application to many common real-world scenarios through increased ease-of-use and reliability. More research into factors influencing the deviation of Spandan smartphone ECG from standard 12 lead ECG is needed before the added value of the Spandan smartphone ECG in the early detection of STEMI can be established.

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