

Original Research Article

Validation of the detection of ischemia using 12 lead smartphone based electrocardiography - a non-randomized, single blinded, cross-sectional, multicenter study

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ABSTRACT

Background: Reliable and early detection of myocardial ischemia using computer-aided analysis of electrocardiograms (ECG) provides an important reference for early diagnosis of CVD. We developed a 12-lead smartphone-based electrocardiogram (ECG) acquisition and monitoring system (called “Spandan”), and an application to assess underlying ischemia from analysis of electrocardiographic (ECG) signals only. Objectives of this study were to validate the Spandan 12 lead ECG interpretation for accuracy in the detection of Ischemia in comparison to cardiologists’ diagnosis and to evaluate the accuracy of ischemia in comparison to the interpretation of standard 12 lead ECG.

Methods: In this multi-center study all patients (n=597) visiting the ECG room at the department of cardiology were enrolled in the study by taking their written consent and explaining the purpose of the study.

Results: Mean age was 52.85 years. The male gender (n=344, 57.62%) shows the maximum frequency than female gender. 12 lead Spandan smartphone ECG recorded fewer false positive cases (8 versus 230) and identified greater true negative cases (310 versus 115). Spandan smartphone ECG recorded better specificity (97.4% versus 33.3%) and positive predictive value (87.4% versus 51.4%) as compared to gold standard ECG. The accuracy of interpretation of Ischemia by cardiologists diagnosis through 12 lead Spandan smartphone ECG was better (100%) as compared gold standard (95.3%).

Conclusions: Our study highlights the potential of Spandan smartphone ECG in the detection of myocardial ischemia. This may improve patient satisfaction and reduce healthcare costs.

Keywords: Electrocardiogram, Myocardial ischemia, Smartphone, Validation

INTRODUCTION

Coronary heart disease is one of the most common and chronic cardiovascular condition among Indian population.¹ It has been recognized that when managing patients with coronary heart disease, relying on symptoms of angina leads to a significant underestimation of the true frequency of myocardial ischemia, as ischemia is often silent. Therefore, ambulatory monitoring of

electrocardiographic ST-segment changes has the potential to detect ischemia earlier and, in turn, prompt appropriate interventions sooner, then would be otherwise be possible.² Moreover, silent ambulatory ST-segment depression is associated with an increased incidence of coronary events in asymptomatic men, so routine assessment of such ST-segment depression could be used to better stratify populations at risk.³

The 12-lead electrocardiogram is the primary screening tool for myocardial ischemia.⁴ ECG signs suggestive of ischemia, and include ST-depression, T wave abnormalities, the development of pathological Q waves and at times new conduction disturbances.⁵ The specific ECG leads showing these changes correspond to the area and size of myocardium affected by ischemia, which in turn is dependent on the localization of the coronary artery occlusion.⁶ The ECG changes also reflect the duration of the ischemic event.⁷ An ECG is the first diagnostic test performed in suspected ACS as given in class 1 practice guidelines.⁸ The utility of ECG in localizing the coronary culprit territory is not finalized in the setting of the NSTEMI. ST-depression, ST elevation, T wave inversion and biphasic T waves are the signs of earliest manifestation of Myocardial Ischemia.⁹

Currently, only a few studies have documented the accuracy of determining myocardial ischemia through a 12-lead smart phone based ECG.¹⁰⁻¹⁵ A new device, the Spandan portable ECG device 12L is a portable ECG designed for quick access of 12 Lead ECG at homes and clinics has become available in the diagnostics market.

In view of the above, the objectives of this study were to evaluate and validate the Spandan 12 lead ECG interpretation for accuracy in detection of ischemia in comparison to cardiologists diagnosis and to evaluate the accuracy of ischemia in comparison to interpretation of standard 12 lead ECG.

METHODS

Individuals visiting the outpatient and emergency clinics of the cardiology department of Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India and Shri Mahant Indresh Hospital, Dehradun and Fortis Hospital, Dehradun between 12 February 2021 to 09 September 2022 were invited to participate and were included in this non-randomized, single blinded, cross-sectional, multicenter study after obtaining their written informed consent. The final selected study population was composed of 597 participants (108 patients with ischemia included) 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 at emergency departments and who were part of the STEMI protocols were screened in the study were included in the study whereas patients with loose skin or within whom the ECGs recordings experienced with electrical disturbances or who could not provide informed consent were excluded from the study. The Institutional Ethics Committee of SMIH approved this study.

ECG sources

Patients referred to the Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India and Shri Mahant Indresh Hospital, Dehradun and Fortis Hospital, Dehradun

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. ECGs were classified for ischemia-related abnormality (pathological Q-waves, abnormal ST-segment elevation and ST-segment depression, and inverted or biphasic T waves), normal and unclassified cases.

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, NPV and PPV of the overall screening and then accuracy of ischemia detection was detected for the abnormal ECG reports.

RESULTS

In total, 700 patients were enrolled for the study and a few (n=103) subjects later withdrew consent or patients were fitting within the exclusion criteria. Hence, 597 subjects agreed to participate and underwent both an mECG and 12-lead ECG recording. Mean age was 52.85 years (range in years: 25-90) and 344 subjects (57.62%) 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 confusion matrix of 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis for overall evaluation is shown in above Table 2. True positive score between 12 lead Gold standard and 12 lead Spandan smartphone ECG were identical. 12 lead Spandan smartphone ECG recorded fewer false positive cases (8 versus 230) and identified greater true negative cases (310 versus 115).

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

Parameters	Overall (n=597)	Standard 12 lead ECG	12 lead smartphone ECG	Cardiologist's diagnosis
Age (years), mean±SD	52.80±15.38			
Gender - male	344			
Gender - female	253			
Body mass index (kg/m ²)	23.48			
Normal ECG		130	322	344
Non-ischemic patients detected		492	489	489

BMI: body mass index, SD, standard deviation

A summary of the baseline characteristics of ECG morphology within study population is shown in above Table 1. The male gender (n=344, 57.62%) shows the maximum frequency than female gender.

Table 2. The confusion matrix of 12 lead standard ECG and smartphone ECG in comparison to cardiologist diagnosis for overall evaluation.

Parameters	12 lead gold standard	Smartphone ECG
True positive	244	244
False positive	230	8
True negative	115	310
False negative	8	35

A summary of the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the standard ECG and 12 lead Spandan smartphone ECG for a computerized Interpretation in comparison to cardiologist diagnosis is shown in above Table 3. 12 lead Spandan smartphone ECG recorded better specificity (97.4% versus 33.3%) and positive predictive value (87.4% versus 51.4%) as compared to 12 lead standard ECG. A summary of the accuracy of interpretation of ischemia detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists diagnosis is shown in above Table 4. As evident from the above table, the accuracy of interpretation of ischemia by cardiologists diagnosis through 12 lead Spandan smartphone ECG was better (100%) as compared to 12 lead gold standard (95.3%).

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

Parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Gold standard 12 lead ECG	96.8	33.3	51.4	93.4
Smartphone Spandan ECG	87.4	97.4	87.4	89.85

Table 4: Accuracy of interpretation of ischemia detected by the standard 12 lead ECG and smartphone ECG in comparison to cardiologists diagnosis (n=108).

Parameters	12 lead gold standard	Smartphone ECG
Ischemia detected correctly	103	108
Accuracy of detection (%)	95.3	100

DISCUSSION

This prospective and retrospective study in a representative population of cardiology outpatients showed a good degree of accuracy for MI 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 myocardial infarction (MI). To our knowledge, this is the first study to validate the Spandan smartphone ECG for MI against simultaneously performed 12L ECG in a primary care population.

Patients who present to their primary care physician with palpitations often no longer have symptoms at the time of consultation or when ECG is performed.¹⁴ When ECG is performed during palpitations, an abnormal heart rhythm is found in approximately one-half of patients, whereas this drops to approximately one-fifth when symptoms are no longer present at the time of ECG.¹⁴ The findings from the present study are therefore highly relevant for primary care physicians because the smartphone-operated ECG device operates as a point-of-care test and allows for immediate rhythm assessment during a symptomatic episode.

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. Second, the study design ensured simultaneous rather than consecutive 1L- and

12L-ECG recordings, as done in prior studies.¹⁶⁻¹⁸ This allowed for a comparison on the detection of ectopic beats, which may be a frequent cause for palpitations in primary care.^{19,20}

Regarding the limitations of our study, we must emphasize that it was carried out in a fewer center's (two centers in the current study) and with a single device. Another potential limitation of this study was that the average age of study population was around 52 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

The detection of the abnormal and normal reports according to the cardiologist diagnosis for smartphone ECG satisfies the clinical requirements and performs at par as compared to the reference standard 12 lead ECG. Even in interpretation of ischemic changes, the smartphone ECG's interpretation performs well in comparison to the standard 12 lead ECG machine. Hence, the smartphone ECGs in markets can be relied upon for initial detection of myocardial ischemia. 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 Myocardial Ischemia can be established.

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Conflict of interest: None declared

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

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