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Analysis of the variation in computer interpretation of Myocardial Infarction by using smartphone-based ECG devices

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ABSTRACT

ECGs are crucial for monitoring heart health, especially in detecting arrhythmias and conduction issues. They play a vital role in diagnosing ST-elevated myocardial infarctions (STEMI). However, the accuracy of computer-generated ECG interpretations is often questioned. In this study, we compared two such ECG interpretation platforms with cardiologist diagnoses on 12-lead ECGs. Out of 309 participants, only one case was falsely diagnosed as negative, and one case falsely as positive by the Spandan ECG platform compared to the cardiologist's diagnosis. The overall trial demonstrated remarkable sensitivity (99.5%), specificity (98.7%), negative predictive value (98.7%), and positive predictive value (99.5%).

KEYWORDS

Cardiovascular disease(CVD), Electrocardiography(ECG), Ischemic Heart Disease(IHD), Myocardial Infarction(MI), Portable ECG, Smart health platforms

1. INTRODUCTION

Ischemic heart disease and Myocardial Infarction are leading in causing fatalities every year [1]. At the worldwide level, cardiovascular diseases (CVDs) are the leading cause of death; more people die from CVDs each year than from any other cause [2]. According to a WHO study finding, 17.3 million people died from CVDs in 2008, which represents 30% of all fatalities worldwide; by 2030, it is expected that there will be roughly 23.6 million CVD deaths, primarily due to heart disease and stroke [3]. People with undetected Myocardial infarction (MI) and ischemic heart disease (IHD) are more prone to suffer from cardiovascular disease which mainly arises as a result of lifestyle, stress, and insufficient sleep [2]. Many studies have suggested that social issues like relationship-related stress are major contributing factors to IHD and STEMI [4]. In 2016, cardiovascular heart disease was recorded as the leading cause of death [5]. According to data, nearly US \$863 billion has been spent in 2010 to treat cardiovascular disease [6]. An ECG is a primary tool that is used to classify normal and abnormal cases based on cardiovascular diseases [7]. The ECG morphological changes suggest whether the case is ischemic, or Myocardial infarction. Acute Myocardial Ischemia leads to the alteration of the QRS complex in a stepwise process which can be easily monitored in the 12 lead ECG reports [8]. The presence of pathological Q waves or ST-segment elevation or depression is a sign of Myocardial Infarction. The diagnosis of MI needs the detection of high troponin levels in a blood sample [9].

The ECG is the most cost-effective test available in comparison to an enzyme test as the troponin levels elevate after certain time of onset of Myocardial Infarction [10]. Hence, many Emergency Medical Services (EMS) that contains physician and cardiologist use 12 lead ECG as a primary tool for interpreting the abnormalities [11].

ECG was discovered more than 125 years ago but the attempts to alternate it go back to the late 1950s. The computerized interpreted ECG came into trend in 1980 and till 2015 it was noted that about 300 million ECG tests are conducted annually in the United States of America (USA), capturing a market of \$200 million yearly [12]. The underlying problem with computerized ECG interpretation is categorized under the following points [13].

- Lack of standardized methods to find the defects.
- Unperformed test of commercially available CIE programs due to resistance of manufacturers.

In a study in 1991, the computerized ECG programs were compared by a diagnosis of 8 cardiologists for 1220 clinical datasets for various diseases like Left ventricular hypertrophy (LVH), and Old Myocardial infarction. The computerized ECGs were found 6.6% less accurate than cardiologists [14]. Some computerized programs worked as cardiologist diagnoses whereas some were inferior, and some programs were superior for the cardiologist [15]. A study by Abedin Z. Gaugh, and Abedin M. Siddique found that false positives in detecting Old Myocardial infarction cases were higher [16]. Hence, the physician's dependency on computerized detection has decreased and they have been suggested to practice regularly, systematically, and faithfully the art of interpretation. Computerized ECG interpretation can

contribute to diagnostic inaccuracies which can increase detrimental delays in the diagnosis of STEMI [17]. Some of the reference studies suggest that they found the computerized ECG interpretation 95% sensitive and 73% specific to the detection of ischemic heart disease and Myocardial infarction [8]. Whereas in another study ischemic heart disease and Myocardial infarction were detected with 85% sensitivity, and 83% specificity [9]. Baxt et al. studied sensitivity and specificity at 97.2% and 96.2% [10]. Nowadays many companies have launched portable ECG machines that can capture 12 lead ECG and interpret them on the smartphone only. However, the underlying problem with its use is the accuracy of its interpretation according to the cardiologist's diagnosis. One of the factors that influence the cardiologist to improvise the clinical interpretation is the amount of clinical history provided during the diagnosis. [18]. Hence, our purpose of the study is to conduct an observational study to compare the computerized interpretation of ischemic heart disease and Myocardial infarction patients with two different ECG machines for the same subject and evaluate the performance while taking a cardiologist's diagnosis as a reference standard. The ECG report interpretation platform Tricog Insta as shown in Figure 1 was taken as the first ECG machine, whereas the Spandan ECG machine developed by Sunfox Technologies Pvt. Ltd. as shown in Figure 2 was taken as the second machine. Both of the ECG machines were capable of Computational Interpretation of ECG reports. Computer interpretations of both the machines were then compared with the diagnosis given by the experienced cardiologists to evaluate the diagnostic capabilities of these ECG devices.

2. METHODOLOGY

2.1 Objective

The main objective of this study is to find the relevance of the computerized interpreted ECGs in comparison to the cardiologist diagnosis and to quantize the error of interpretation by the different ECG interpretation platforms.

2.2 Ethical consideration

This study was approved by the Institutional Review Board (IRB) and the data was collected after obtaining informed consent from the study participants.

2.3 Baseline characteristics

This study was a virtual, observational study. The patients who enrolled in our online Medical Healthy Heart Programme in Dehradun in collaboration with SMIH and Fortis Escort Dehradun were screened for eligibility. The data of the patients were collected after taking written and verbal content along with a briefing on the purpose of the data collection and its associated objectives. The exclusion of patients was done among the enrolled patients if the ECG acquisition was done with baseline wandering, motion artifacts, or baseline interference. The inclusion criteria of subjects were the subjects of age above 20 years. The cases with human error like misplacement of the ECG electrodes while conducting 12 lead ECG were taken into

the exclusion criteria [19]. The data of 12 lead ECGs were collected from the Spandan ECG device for enrolled patients and the reports were interpreted by computer algorithms of both Spandan ECG and Tricog Insta ECG interpretation portals. Spandan ECG (developed by Sunfox Technologies, Dehradun, Uttarakhand, India) is a smartphone-based 12-lead single-channel ECG device that provides computer-interpreted data. Spandan records a 10-second ECG for 12 leads and interprets it as a normal, abnormal, and critical ECG. Further, the ECG reports evaluated as critical and abnormal are interpreted for myocardial infarction and ischemia using computer algorithms. Another ECG device considered for the study was Tricog Insta ECG (developed by Tricog Health India Bangalore, India), a platform for the interpretation of ECG based on artificial intelligence which was evaluated by its Tricog Insta ECG portal where users share their ECG image data and receive an interpretation.

2.4 ECG recording protocol

Sequential 12 lead ECGs were recorded using a Spandan device on the Spandan ECG android application. To minimize the baseline artifact, the operator had been told to place all of the chest leads in the correct places and ensure that the electrodes made good contact with the skin. In the cases where precordial leads were positioned incorrectly had to be retaken to be correct. The total duration of the 12 lead ECG tests recorded is for ten seconds.

2.4.1 ECG annotation process

Spandan is used to record the 12-lead sequential ECG. Spandan interprets ECG reports for Myocardial Infarction and Myocardial Ischemia based on biomarkers like ST elevation, ST Depression, Biphasic T-wave, etc. The reports were then uploaded to the Tricog Insta platform, which analyzed the reports and interpreted them for the underlying abnormality. A cardiologist was assigned to review the ECG reports after the computer interpretations. The cardiologist interpreted the reports only based on the specific biomarkers of Myocardial Infarction and Myocardial Ischemia. Some of these biomarkers were T wave abnormalities, Bi-phasic T wave, ST-segment elevation, ST depression, etc. The parameters like PR interval, QRS complex, QTc intervals, and heart rate were also secondary biomarkers of interpretation of ECG by the cardiologist. The pathological Q wave was taken as the biomarker of an Old Myocardial infarction [20]. The cases of MI like an anterolateral, anteroseptal, inferior wall, infer lateral, and anteroseptal were taken into consideration in the study. Cardiologists made the interpretation only under the following criteria:

If the interpretation from Tricog Insta ECG and Spandan ECG are contradictory for the detection of normal and abnormal cases, the cardiologist's opinion was taken for correct interpretation.

The cardiologist's decision was considered when the ECG interpretation platforms differed in interpreting normal and abnormal ECG reports.

In this study, the term "normal ECG" denotes an electrocardiogram characterized by regular heartbeats, with all PQRST waves manifesting within the established parameters of standard electrocardiography. Specifically, the R-R interval, QRS duration, QTc, QT, and PR intervals are observed to fall within the clinically accepted ranges, indicating a typical and

healthy cardiac electrical activity profile. Moreover, to ascertain the accuracy of ECG interpretations, cases were categorized based on the agreement between the automated ECG machine diagnosis and the expert evaluation by a cardiologist. Instances where the ECG machine's interpretation aligns with the cardiologist's diagnosis for identifying normal or abnormal cases are deemed true-positive or true-negative, respectively. Conversely, cases exhibiting disparities between the machine interpretation and the cardiologist's diagnosis are classified as false-positive or false-negative, depending on whether the machine incorrectly identifies a normal case as abnormal or vice versa. This methodology facilitates a comprehensive evaluation of the reliability and concordance between automated ECG analyses and expert cardiologist assessments.



Fig. 1 Tricog Insta ECG device developed by Tricog Health India Pvt. Ltd.

The statistical analysis was performed by the detection of parameters of the confusion matrix. The diagnostic value of ECG was evaluated by calculating the sensitivity, specificity, Negative Predictive Value (NPV), and Positive Predictive Value (PPV).

3. RESULTS AND DISCUSSION

A total of 309 subjects were enrolled for the observational study. Among these, only 278 subjects were able to make it into the inclusion criteria as shown in Figure 3. The 12 lead ECG data was collected for one month from August 2021 to September 2021. The subjects were of age ranging from 18 to 70 years. The subjects were asked to sign the digital consent for sharing 12 lead ECG data with age and gender-based only. Table 1 shows the characteristics of the participants who participated in the observational trials.

Table 2 describes the baseline characteristics of the Insta contains 17 female and 106 male participants. Among a total of 278 subjects, 129 cases were normal of which 29 were females and 100 were males. The cases diagnosed by Spandan ECG for ischemic heart disease (IHD) had 24 females and 46 cases of males. Out of 139 cases interpreted by Spandan for myocardial infarction, 11 were females and 128 were males. The baseline characteristics for the subjects diagnosed with Spandan ECG are given in Table 3.



Fig 2 Spandan portable ECG device developed by Sunfox Technologies Pvt. Ltd

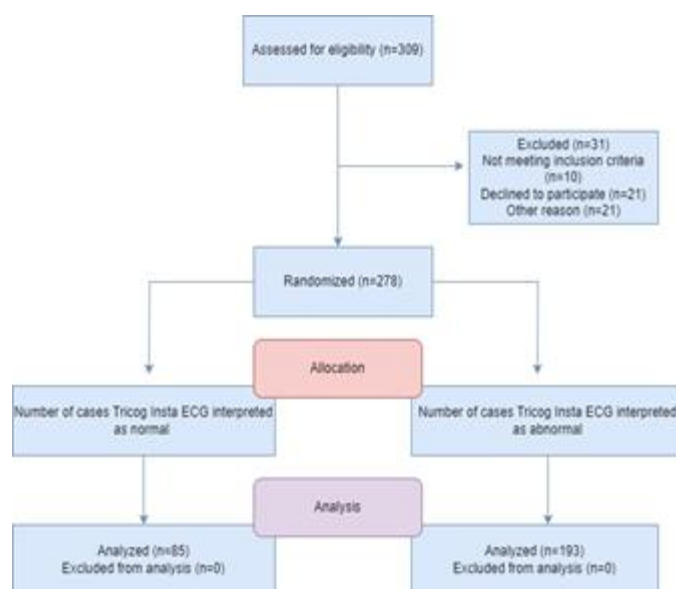


Fig 3 Flow diagram of observational study for IHD and MI patients

Table 1. The flow of the participants in each stage of the observational study

Stage	Number of people included	Number of people excluded
Enrolment	309	31*
Analysis	278**	0

* Cases excluded were either due to human error during taking ECG or due to baseline artefacts

** All of the ECG reports were then part of the analysis with the Tricog Insta ECG portal.

Table 2. Baseline characteristics of the participants in trials diagnosed by the Tricog Insta ECG platform

Characteristics	Overall patients	For IHD	For MI
Total number of patients	278	26	123
Age (mean SD) (in years)	45.01	50.5	45.5
Females, n (%)	53 (20.8%)	7(26.9%)	17 (13.8%)
Males, n (%)	225 (79.2%)	19(73.1%)	106 (86.2%)

Table 3. Baseline characteristics of the participants in trials diagnosed by the Spandan ECG platform

Characteristics	Overall patients	For IHD	For MI
Total number of patients	278	70	139
Age (mean SD)	45.0 10	48.6	46.8
Females, n (%)	53 (20.8%)	24(34.2%)	11(7.9%)
Males, n (%)	225 (79.2%)	46(65.8%)	128 (92.2%)

The division of the True and False Cases was done based on the similarity and dissimilarity of ECG interpretations with Tricog Insta and Spandan respective to cardiologist diagnosis. The cases interpreted as normal by cardiologist outcomes are taken as negative, whereas the interpretation of 12 lead ECG is found to have any abnormality, the outcome is taken as positive. Hence, Tricog Insta reported 276 True cases and 2 false cases. Whereas a total of 200 cases were found to be positive and 78 cases were negative in the Spandan ECG for abnormality detection as given in Table 4.

Table 4. Confusion matrix of detection of normal and abnormal cases

Confusion Matrix	Value
True Negative cases	77
True Positive cases	199
False Negative cases	1
False Positive cases	1

The cases were later put on confusion matrix. The normal cases are those that were detected as normal by both the ECG machines were 79, and the abnormal cases detected correctly by both the machines were 194. One case was found to be false

negative and 4 cases were false positive as shown in Table 4. Hence, Spandan-generated reports were found to have 99.48% sensitivity and 98.7% specificity in the detection of cases with existing ischemic heart disease and Myocardial Infarction as shown in Table 5. According to the diagnosis provided by a cardiologist for 12 lead tests taken by the Spandan 12 lead ECG, the confusion matrix was derived where 77 cases were true negative, 199 cases were true positive, 1 case was false positive and 1 case was a false negative.

Table 5. Validation parameters of Spandan ECG device compared to clinical interpretation of normal and abnormal cases

Validation Parameters	Values (in %)
Sensitivity	99.48
Specificity	98.7
NPV	98.7
PPV	99.5

Validation Parameters of Spandan & Tricog ECG Normal /Abnormal interpretations to clinical Diagnosis

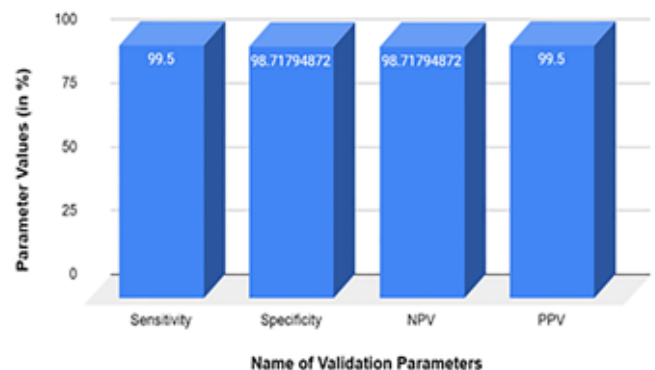


Fig 4 Validation parameters for comparative study of the Spandan ECG platform concerning the clinical diagnosis

The ability to detect normal cases correctly with Spandan ECG interpretation was found to have an NPV of 98.7% whereas Spandan was found to have 99.5% of the positive predictive value (PPV) as shown in Table 5.

Chitra R. (2013) presented a classification system designed for early-stage heart attack prediction utilizing 270 patients' medical records.[21] However, the accuracy of predictions heavily relies upon the quality and completeness of the input medical records. Recording ECG with hand-held ECG devices while also considering the medical history of the patient can enhance the correctness of the early diagnosis of heart pathologies.

While certain studies propose that an AI-ECG algorithm surpasses the performance of an established standard automated computer program on 500 randomly selected ECGs [22] and more accurately approximates expert over-read for a thorough 12-lead ECG interpretation, contrasting viewpoints suggest that cardiologists demonstrate superior proficiency in ECG interpretation.[22, 26,27]

In contrast to the earlier study by Milliken et al. involving nine experienced electrocardiographers and the Veterans Administration (VA) program which was evaluated against ECG-independent evidence of 180 patients, our research endeavor has reported notably improved performance metrics for computer interpretations of ECG.[28] According to the findings of our study, the computer interpretations achieved an impressive sensitivity of 99.54% and specificity of 98.7%.

This stark contrast in results underscores the advancements made in ECG technology and computational algorithms over time. The Spandan ECG device, boasting a sensitivity exceeding 99% and a specificity of 98.7%, reflects a substantial leap forward in accuracy compared to the earlier study's collective accuracy of 62%, even with the assistance of a computer report.[28]

In a previous investigation conducted by Jensen et al., the assessment of General Practitioners' (GPs) ECG interpretation skills and the utility of automatic ECG recorder interpretations in general practice were explored. This study involved the examination of 902 ECGs obtained from a random sample of individuals aged 31-51 years in Denmark. The findings revealed that the sensitivity of abnormal diagnoses by GPs (69.8%) was significantly lower ($P < 0.001$) than that achieved by interpretive ECG recorders (84.4%). Conversely, the overall specificity of abnormal diagnoses made by GPs (85.7%) was significantly higher ($P < 0.001$) than that of the interpretive ECG recorder (75.6%). Notably, GPs demonstrated proficiency in rectifying false-positive diagnoses generated by the interpretive ECG recorder. [29]

In the year 2022, Ford et al. conducted a comprehensive investigation aimed at evaluating the diagnostic efficacy of the Apple Watch Series 4 (AW4) and KardiaBand (KB) among a cohort of 225 patients. The study specifically focused on the detection of atrial fibrillation. The results demonstrated that the KardiaBand exhibited a sensitivity of 89% and a negative predictive value of 97%, whereas the Apple Watch Series 4 showed a sensitivity of 19% and a negative predictive value of 82%. Despite the satisfactory quality of the tracings obtained from these devices, the study's findings emphasize a critical aspect—relying solely on automated diagnosis may not be adequate for informing clinical decisions pertaining to the diagnosis and management of atrial fibrillation. This underscores the importance of a comprehensive and nuanced approach to the interpretation of data generated by wearable devices in a clinical context. [30]

It is worth highlighting that our current study contributes a novel dimension by comparing computer-generated interpretations of 12-lead ECG from two distinct smartphone-ECG recording

devices. This comparison adds depth to the understanding of the interpretive capabilities of different technologies in ECG analysis within the context of our investigation.

These advancements could have profound implications for clinical practice, suggesting higher reliability and precision in ECG interpretations through automated algorithms. The enhanced sensitivity and specificity figures imply a reduced likelihood of both false positives and false negatives, enhancing the diagnostic utility of ECG technology in contemporary healthcare settings. The comparison highlights the evolving landscape of medical technology and the substantial strides made in leveraging computational tools for accurate and efficient ECG interpretation.

4. CONCLUSION

The computer interpretation-based ECG machines can be contradicting each other as in the case of our present study where the detection of normal and abnormal ECGs with Ischemia and Myocardial Infarction is based on large differences compared to cardiologist diagnosis. The 12-lead ECG-based computerized interpretation may not be a good option to perform diagnosis but can be a helpful tool for physicians and cardiologists who practice regularly and skillfully. The ECGs with different algorithms can perform better depending on the manufacturer's algorithms. In this study, Spandan 12 lead provided interpretations that can be a suggestive outcome for physicians and consultant doctors.

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