Validation Study of a Derived 12 Lead Reconstructed ECG Interpretation in a Smartphone-Based ECG Device

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Abstract For the detection of focal Ischemia and transient intermittent episode of arrhythmia, 12 lead ST-segment monitoring is widely used. The 12 lead ECG consists of 3 Limb leads, 3 Augmented leads, and 6 Precordial Leads. The Increase of Portable ECG machines in the Indian and International markets has led to uncertainty for the Accuracy related queries and confusion regarding the reliability and age of accessibility of these medical devices. In this study, we have clinically validated the Interpretation capabilities of a portable smartphone-based ECG device. A total of 202 subjects were tested with sequential 12 lead ECG machine. The trials were conducted for 112 days in an observational setup. Each 12 lead ECG test took an average time of 1 min and 30 s. The Clinical Interpretation of the ST-Elevation and Arrhythmias via. the gold standard ECG machines present in the hospital are compared with Smartphone-based 12 lead Data for computer Interpretation of the reconstructed ECG reports. This study aims to evaluate the sensitivity, specificity, Negative Predictive Value, and Positive Predictive Value of the tests taken in various subjects.

Keywords Cardiac abnormalities · Derived 12 lead ECG · Ischemia · Myocardial infarction

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1 Introduction

Twelve lead ECG is a widely used non-invasive method for detection and quantification of Ischemia and Arrhythmic episodes [1]. ST-Elevation and Depression are the key biomarkers for diagnosing Myocardial Infarction and Ischemia. According to the American Heart Association (AHA), the 12 lead Ambulatory ECG machines should be evaluated clinically for their Specificity and Sensitivity. Electrocardiography provides greater convenience and lower cost of use in clinical practice and clinical trials. Besides, some ECG abnormalities have been shown to have independent clinical prognostic value [2].

Here, the validation study is done on the derived 12 lead ECG methods by using the derived 12 lead ECG method by using derived 12 lead strategy which requires fewer the electrode, as a result, there may be a decrease in inpatient management, cost per test and also provide better access to the user. For the detection and diagnosing of heart disease, recording the resting ECG is the most commonly used procedure. This procedure is simple, safe as well as reproducible [3]. Just like other laboratory procedures, for accurate and appropriate use of ECG requires its specificity and sensitivity, so that it can be better understood and also considered in the interpretation of the recording [4]. ECGs are somewhat more complex and difficult to understand as it contains several waveforms and each waveform has its specificity and sensitivity which can be influenced or get affected by physiologic and pathophysiologic factors [5]. In the diagnosis of arrhythmia structural and/or metabolic activities, the specificity and sensitivity of ECGs are far higher than in the diagnosis of arrhythmia and conduction disturbances [6].

There are several studies that examined the computer ECG interpretation program and they have suggested that the interpretation of ECG provided by the computer analysis cannot substitute the analysis of physician interpretation. In 1991 a study was performed where ECG programs are 6.6% less accurate than cardiologists at identifying ventricular hypertrophy and MI. The most accurate interpretation is given by a cardiologist in comparison to a computerized 12 lead ECG machine [7].

In some cases, the computerized ECG machine provides correct interpretation rather than some incorrectly read cases by physicians. AHA recommends the ECG interpretation under the supervision of a physician or a cardiologist for studying the competence of the 12 lead ECG traces [8]. ECG abnormalities are subjected to be interpreted differently many times, mostly it is observed during interpreting early repolarization or pericarditis or presence of both left ventricular hypertrophy with left bundle branch block or left ventricular hypertrophy The computer interpretation of the ECG on which some physicians rely may be incorrect [9] But, the Computerized interpretation of MI and IHD cases depends on the electrocardiogram in daily cardiovascular healthcare [10]. Smartphone-based healthcare devices like ECGs are playing an important role during sudden palpitations and symptoms to find the critical information related to MI and IHD [11]. Some of the studies are also done on detecting Acute Coronary Disease using Machine learning algorithms. The results

suggest that the model was calculated for Specificity of 76%, Sensitivity was calculated as 77%, and PPV and NPV were found to be 43% and 94%, respectively, in detecting and predicting any Acute Coronary Syndrome [12]. Hence, the comparison of our study is made with the existing models too.

In this study, the GEMAC 2000, a 12 lead Simultaneous ECG machine by GE Healthcare, and Philips Pagewriter TC20 12 lead Simultaneous ECG machine by Philips Healthcare are taken as the referential machine for clinical diagnosis under the supervision of the Principal Investigator. The comparative study is done for the Smartphone-based 12 lead Sequential ECG which works on the derived ECG methods as shown in Fig. 1. Spandan ECG is developed by Sunfox Technologies Pvt. Ltd. This ECG requires the Precordial Leads (V1 to V6) and two Limb leads (Lead I and Lead II) to derive the Augmented Leads and Lead III. The study was conducted in Fortis Hospitals, Dehradun, and Shri Mahant Indresh Hospital, Dehradun under the designed procedure. The Data is collected from all participants after collecting the written consent for the test and then classified using the inclusion and exclusion criteria set by the Investigator. A total of 230 participants were enrolled in this study with prior consent from the Hospital's Authority and the Patient too, out of which a total of 202 cases made it to the final phase of the study [13]. The Outcomes were later compared to existing models.

Fig. 1 Spandan portable ECG device developed by Sunfox Technologies Pvt. Ltd.

2 Methodology

The observation study and collection of data were taken with the consent of the Consultant Cardiologist, Department of Cardiology, Shri Mahant Indresh Hospital (SMIH), Dehradun, and Consultant Cardiologist, Department of Cardiology, Fortis Hospital, Dehradun. The procedure of the study was divided into three parts to ease the process of Interpretation. The patients at Shri Mahant Indresh Hospital and Fortis Hospital who had been scheduled to undergo the routine heart checkup were the part of the study, also the enrolled subjects at two hospitals were taken to ECG rooms for conducting the standard 12 lead ECG test using the both machines. The Inclusion criteria of the patients were males and females of age more than 6 years. The patients with prior cardiac abnormalities and Healthy ones were included in this study. The cases of Abnormalities include the cases with ST-Elevation, ST-Depression, and arrhythmias. Subjects with the history of Pacemaker implants, Hypertension, Chest pain, Diabetes, Open Heart Surgeries, Double Stenting, Single Stenting, Cardiac Arrest (post CAG), Cataract, Valve Replacement were included in the study to remark the information for the vulnerable events as shown in Table 1. Patients with loose skin and higher motion artifacts were excluded from the study. Followed by the exclusion of the reports with baseline wandering. Hence out of 230 subjects a total of 28 cases were found to be excluded from the study. After sorting the subjects suitable for the trials, a trial operator was hired to conduct the protocol in an unbiased manner. Filling the patient consent forms for conducting non-invasive ECG trials study were also collected. The Case Report Format (CRF) is also generated to store the health history of the participant. In the first strategy, all limb leads and precordial leads, augmented leads, and Limb leads were recorded in the GEMAC 2000 and Philips Pagewriter TC 20 simultaneous ECG machine. Followed by the recording of precordial lead and Lead I and Lead II from Spandan 12 lead single-channel sequential ECG machine. The Derived 12 ECG reports were saved in the Smartphone and were then sent to the Principal Investigator. The Principal Investigator compared the clinical diagnosis to the interpretation of the Derived 12 lead ECG report. The Data was then saved to the centralized database and was evaluated for further validation and analysis by a statistician. The Male's and female's range more than 6 years were included in the study. The cases with any Heart abnormality and Normal/Healthy controls were taken into consideration. The cases with loosening skin, motion artifacts, and Baseline wandering were excluded from the study.

2.1 ECG Recording Protocol

The operators were asked to check that all the chest leads are placed in a defined position and the electrodes are in good contact with the skin, in order to minimize the motion artifacts. Tests with incorrect placement of the precordial leads were made to retake the test for correct and undistorted ECG traces. The test duration for the

Table 1 Baseline characteristics of the participants in Fortis and SMIH

Variable	Total	Males	Females
Age (yr)	52 (14.6)	65.24 (10.6)	47.4 (12.6)
Non-specific ST-abnormality	52 (14.6)	65.24 (10.6)	47.4 (12.6)
STEMI	64	19	45
Normal	43	15	28
Healthy	79	47	32
Critical severity level cases	60	33	27
Minor severity level cases	8	5	3
Moderate severity level cases	104	31	73
Hypertensive	90	15	75
Diabetic	102	52	50
Stenting	38	18	20
Chest pain	54	30	24
Pacemaker placed	31	27	4
Medication prescribed	5	4	1

derived 12 lead tests was made to be recorded. AHA recommended standard settings of 25 mm per second and 10 mm per mV were used for the recording of the ECG traces. The ultimate responsibility for making a correct interpretation of an ECG was done by the principal investigator as shown in Fig. 2.

3 Results and Discussion

A total of 202 cases were part of the study conducted in Shri Mahant Indresh Hospital (SMIH), Dehradun, and Fortis Hospital, Dehradun. Of these cases, 128 were classified as abnormal cases and 74 were diagnosed as normal cases. There were 29 cases of Arrhythmia and 99 cases of abnormal ST-elevation and Depression whereas, normal cases were composed of 67 Healthy cases with no symptoms of cardiac abnormalities and 7 cases of Normal/Chest pain. The clinical Interpretation by the Investigator was compared with the computer-generated Interpretation of the Spandan Derived 12 lead ECG report. The cases were divided into True and false cases under the following boundary conditions.

- The clinically interpreted Normal cases are considered true interpreted if, the derived 12 lead ECG interpretation is, Sinus Rhythm with some no ST-Elevation abnormalities.

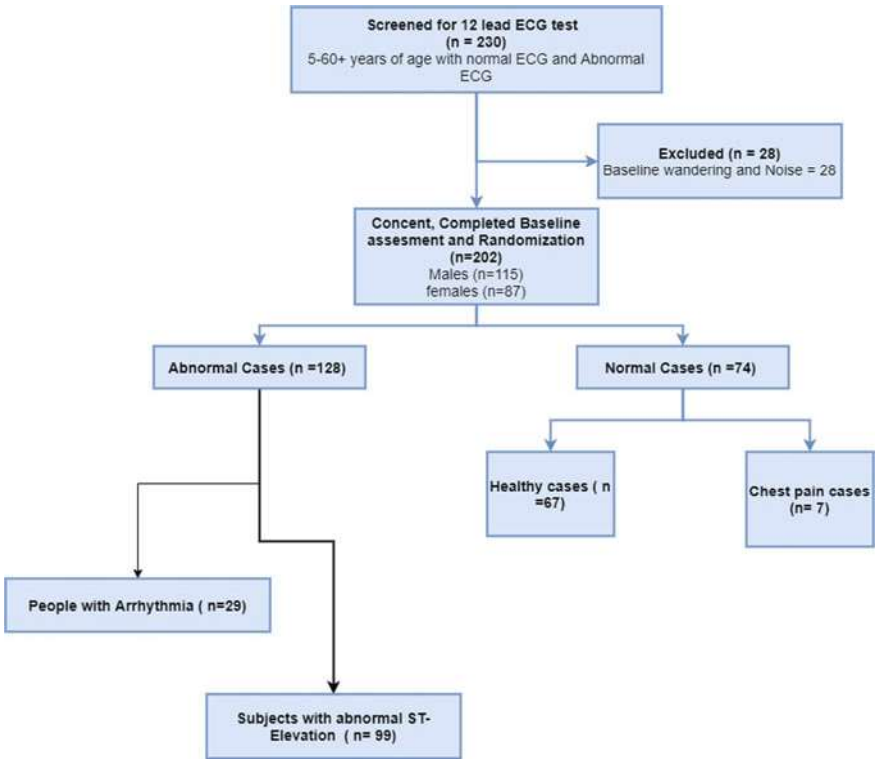

Fig. 2 Patient flow of 12 lead observational study

- The clinically interpreted Abnormal cases are considered true is, the derived 12 lead ECG interpretation is Sinus Rhythm with ST-Elevated abnormalities.
- The clinically interpreted Abnormal cases are considered true is, the derived 12 lead ECG interpretation is Arrhythmia with ST-Elevated abnormalities.
- The clinically interpreted Abnormal cases with arrhythmia are considered true if, the derived 12 lead ECG is Arrhythmia with ST-Elevation abnormalities.
- The clinically interpreted Abnormal cases with arrhythmia are considered true if, the derived 12 lead ECG is Arrhythmia with no ST-elevation abnormalities (Table 1).

Hence, it was found that there are 191 true cases and 11 false cases that were detected during the clinical evaluation of the study as given in Table 2. The clinical interpreted data is also divided into true and false cases under the following conditions:

The clinically interpreted cases were considered Positive if, the 12 lead Simultaneous ECG is diagnosed as ST-Elevation Abnormal or ST-elevation Abnormal, Arrhythmia.

Table 2 Detection of normal and abnormal cases in comparison to clinical interpretation

Accuracy parameters	Value
True cases	191
False cases	11
Positive cases	128
Negative cases	74

Table 3 Confusion matrix of detection of normal and abnormal cases

Confusion matrix	Value
True positive	120
False positive	8
True negative	71
False positive	3

- The clinically interpreted cases were considered Negative if the 12 lead Simultaneous ECG is diagnosed as Normal with Chest pain and Healthy (not affected by any disease).
- 128 cases were clinically interpreted as Positive, hence 128 cases were abnormal in comparison to 74 negative cases that were normal or having Normal with Chest pain conditions as shown in Table 3.

The evaluated accuracy parameters suggest that 120 cases were detected as true positive, 8 cases were false positive, 71 cases were True negative and 3 cases were false negative. Hence, there were a total of 11 cases that were inaccurate to its relative clinical interpretation in the derived 12 lead ECG report as given Table 3. Which sets the interpretation accuracy of Spandan 12 lead ECG at 94.5%. The information obtained according to the AHA standard of evaluation of Specificity was 90%, i.e., Spandan derived 12 lead ECG algorithm is 90% specific in detection of True Negative cases of Heart abnormalities. Whereas the Sensitivity of the ECG Interpretation was found to be 97.56%, i.e., the Derived ECG is sensitive to the 97.56% of the tests recorded in the trials as given in Table 4.

The probability to predict positive cases when the clinical diagnosis was positive was 93.75%. Whereas, the probability of detecting a negative case when the clinical diagnosis is 96% (Fig. 3).

Table 4 Validation parameters of Spandan ECG platform in comparison to clinical interpretation of abnormal and normal cases

Validation parameters	Value (in %)
Specificity	90
Sensitivity	97.56
PPV	93.75
NPV	964

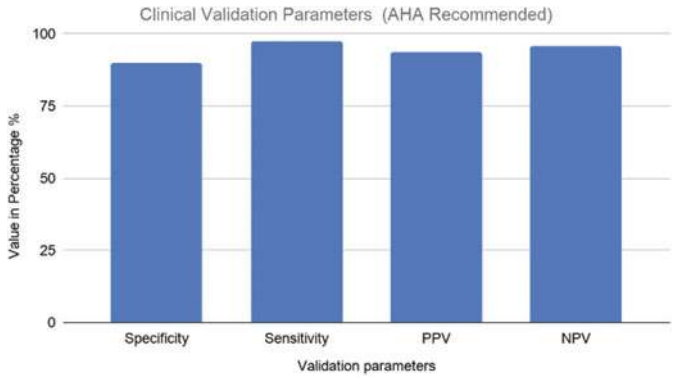

Fig. 3 Validation parameters for 12 lead reconstructed ECG detection for MI and Ischemia

4 Conclusion

In the following observational study, it was found that the derived 12 lead ECG can be interpreted under the range of higher sensitivity and specificity. As compared to the 12 lead simultaneous ECG, the 12 lead sequential ECG machines are 95% accurate in interpreting normal and abnormal cases.

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