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An observational study on detection of atrial and ventricular arrhythmias with smartphone-based ECG

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***Abstract*---**The Interpretation provided by the smartphone-based Portable ECG devices is still questioned for its reliability and are a subject of study for the detection of arrhythmia and abnormal cases. The heart abnormality is the marker of the uncertain change in the electrical activity of the heart. Hence, its early and true detection can prevent sudden cardiac death and, in some cases even Myocardial Infarction. This study provides insights into such kind of smartphone-based ECG device in comparison to the 12-lead gold standard ECG. Arrhythmia Detection for both atrial and ventricular abnormalities is done by 12- lead ECG machines. Here, we have compared and observed the performance of one such kind of portable device with clinical interpretation and 12 lead gold standard generated computer interpretations. Among the 153 number of enrolled participants 110 subjects were taken into the consideration as per the study protocols.

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The trials were validated according to the specificity and sensitivity of the smartphone-based ECG which was evaluated at 97.2% specific and 98.63% sensitive in detecting the ventricular and atrial abnormalities in the subjects. Whereas, NPV and PPV were evaluated at 97.2 % and 98.6% respectively.

***Keywords*---**12 lead gold standard, American heart association, smartphone ECG, portable medical device, spandan ECG.

Introduction

According to World Health Organization (WHO) the cardiovascular disease (CVD) is the number one cause of life loss globally. With over 17.9 million annual fatalities, four out of five CVDs associated deaths are accelerated due to heart attacks and strokes [1]. Cardiac arrhythmias origins due to the irregular heartbeats and abnormalities in heart's electrical conduction. Electrocardiography (ECG) is considered as a safe and non-invasive way to detect the abnormal heart rhythms and signs of potential heart disease. An arrhythmia occurs when the electrical impulses are too slow (Bradycardia), too fast (Tachycardia), too early (premature contraction), or too erratically (fibrillation) [3]. Most of the smartphone-based ECG available in the markets are handheld and provides 30 seconds test to check for the heart abnormality [6]. As cardiologists and physicians prefer a 12 lead ECG as the gold standard tool to detect cardiovascular abnormalities [7]. Portable ECG recording devices such as the Apple Watch [3], AliveCor [7,8] provides Lead I test to check for the Rhythm abnormality like Atrial Fibrillation (AF) [10]. The Arrhythmias are classified broadly into two parts i.e., Ventricular arrhythmias and Atrial arrhythmias respectively [11]. These arrhythmias need to be detected with the high specificity and sensitivity to remove any possibilities of false positives detection using a 12-lead gold standard ECG [12]. According to the American Heart Association (AHA), rhythm strip or Lead II is sufficient to diagnose any cardiac arrhythmia [13]. Hence, the most

commonly available Smartphone-based portable ECG devices that are sufficient to provide the Lead II test are present in the global markets but their accuracy and clinical validity are still questioned as given in table 1 [14]. As Atrial Fibrillation is the most life-threatening kind of atrial abnormality, many smartwatches and the handheld ECG devices have claimed to detect AF with higher specificity and sensitivity [10,15,16]. But the pilot study has shown that Apple watch is unable to detect AF if the patient has no symptoms or the AF is paroxysmal in nature [17]. Apple Watch, that is readily available smartwatch is capable of taking the Lead II which provides the risk estimation of AF and other arrhythmias in terms of apple score and are based on the voltage analysis and electrophysiological endpoint [18]. A study suggested that the highest sensitivity reached by the Kardia Monitor was 99.6% (97.9– 100%) and specificity of 97.8% (95.3–99.2%) in the clinical trial of the 124 subjects as shown in table I.

Table I
Comparison of accuracy parameters in different available smartwatch ECG[19,20]

ECG device name	Studies	Sensitivity/Specificity/PPV/NPV
Cardio Rhythm app	Chan et al., 2016	Sensitivity: 92.9%; specificity: 97.7%; PPV: 53.1%; NPV: 99.8%
Apple watch (FDA approved)	Turakhia et al., 2019	PPV of tachogram: 71%; PPV of notification: 84%
Kardia Band (FDA approved)	Bumgarner et al., 2018	Sensitivity: 93%; specificity: 84%
Alive Cor single lead EKG (FDA approved)	Chan et al., 2016	Sensitivity: 71.4%; specificity: 99.4%; PPV: 76.9%; NPV: 99.2%
My Diagnostic	Koshy et al., 2018	Cardiology ward: sensitivity: 54.5 %; specificity: 97.5%

In this study, we have considered a Smartphone-based portable ECG device that is capable to take lead II and also 12 lead ECG by using derived ECG methods. Spandan portable ECG (Sunfox Technologies Pvt. Ltd.) is a sequential 12 lead ECG machine that works with the smartphone using an application interface as shown in fig 1. The test ECG device claimed to evaluate the ventricular and atrial defects in the rhythms. Hence, validation was done by evaluating sensitivity of arrhythmia detection results produced by the Spandan ECG with respect to 12 lead gold standard Phillips's page writer tc 20 ECG machine as shown in fig 2. According to Food and Drug Administration and American Heart Association standards, the specificity and sensitivity is the correct method to evaluate the accuracy of the results provided by any smartphone-based ECG machine [16,17]. Besides this, this study evaluates the Negative Predicted Values (NPV) and Positive Predicted Values (PPV) too. So that the relation between detecting an abnormal and positive case and normal and negative case can be established in comparison to the clinical interpretation.

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

Fig.2. Phillips page writer tc 20 used in conducting the clinical trials

The observational study was conducted in the Fortis Escort Hospital, Dehradun under the supervision of cardiologists. Table II shows the characteristics of the trial participants with normal and abnormal heart abnormalities. Our objective was to evaluate the false positive and false negative during the trial. Clinical investigations section was developed independently by a Principal investigator for reporting study protocols , safety standards, effective data collection, adverse events and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analysis, The test subject considered for the observational study were either suffered from chest pain or discharged with post-surgery condition or with the arrhythmic cardiac conditions. There was no restriction to the age group. Out of 153 enrolled participants only 110 cases were included for considerations. The test cases were classified under the two categories i.e., ventricular abnormality and atrial abnormality otherwise taken as normal. The defects that were taken into the study were either Normal with no heart defects or abnormal with a ventricular abnormality or Atrial abnormality. The subjects with ventricular abnormality were classified if the reports are diagnosed as - Ventricular Rhythm (VR), Ventricular Fibrillation (VF), Ventricular Flutter (VFL), Ventricular Tachycardia (VT), AV block (AVB). The Atrial abnormality consists of the participants with Atrial Rhythm (AR), Atrial Fibrillation (AF), Atrial Flutter (AFL),

Atrial Tachycardia (AT), and Multifocal Atrial Tachycardia (MAT). The objective of the study was not limited to validate the outcome of smartphone-based ECG interpretation to clinical interpretation. But also, to compare Lead II significance in comparison to 12 lead gold standard ECG trace. The consent of the subjects was also taken as per the Helsinki declaration prior to taking their test via smartphone based portable ECG.

Methodology

The evaluation study was performed under the protocol set by the principal investigator and, a cardiologist was intervened to interpret the study and was blinded from the investigator which made study unbiased in decision making. The study protocol required an informed consent from all patients; labelling stating that the device is for study purpose only. Hence, this protocol was strictly followed in the whole procedure of observational trials. The Interpretation of heart defects by Smartphone based ECG device was taken as the characteristic attribute for the validation study. There was difference of not more than five minutes between the test taken by Spandan ECG and 12 lead gold standard Phillips's machine. The case with time difference of more than five minutes were excluded. When the case was with baseline wander and motion artefacts or with wrinkled skin the cases were excluded as per the cardiologist discretion. Firstly, the test was taken from 12 lead gold standard ECG and after that the smartphone-based ECG was tested. The combinations for True and false cases of abnormal and normal cases respectively and positive and negative in the classification of Atrial and ventricular abnormality were used to classify the test cases as True Positives and False Positives, True Negatives and False Positives as given in table II and table III.

The cardiologist was bound to conclude positive and negative cases in comparison to the 12-lead gold standard ECG and clinical interpret the ECGs that were not interpreted correctly by the gold standard ECG machines. Following were the assumptions made for the diagnosis of arrhythmic cardiac conditions in the observational study: -

Table II.
Classification of true and false detection of the test in comparison to 12 lead gold standard ECG

Spandan/12 lead gold standard	Abnormal/Sinus Rhythm	Abnormal /Defect	Normal/Sinus Rhythm	Normal/ Defect
Abnormal/ Sinus Rhythm	true	true	true	False
Abnormal/Defect	true	true	false	True
Normal/ Sinus Rhythm	true	false	true	True
Normal/Defect	false	true	true	true

Table III.
Classification of positive and negative detection of the test in comparison to 12 lead gold standard ECG

The Spandan/12 lead gold standard	Atrial Abnormality	Ventricular Abnormality	No Abnormality
Atrial Abnormality	Positive	Negative	Negative
Ventricular Abnormality	Negative	Positive	Negative
No Abnormality	Positive	Positive	Positive

1. Atrial fibrillation and Atrial flutter with left bundle branch block aberration referred as ventricular tachycardia (VT) or ventricular abnormality.
2. Left ventricular hypertrophy (LVH) is a maladaptive response to chronic pressure overload and an important risk factor for AF, diastolic heart failure, systolic heart failure, and sudden death in patients with hypertension. Hence LVH and AF could lead to a positive result which can be a ventricular abnormality.
3. Aberrant conduction is not a mechanism of arrhythmia; it is a ventricular conduction disturbance; hence it is described under Ventricular Abnormality.
4. VT is a well-known complication of myocardial ischemia and may be provoked by exercise; many patients may appreciate only angina and be unaware of the unduly rapid heart rate that precipitates it. Hence Normal sinus rhythm with Ischemia is taken into the Ventricular Abnormality.
5. The ECG showing AF and left branch bundle block (LBBB) with intermittent left axis deviation or atrial fibrillation and LBBB with intermittent right axis deviation are taken as Atrial Abnormality. Hence AF with Bundle Branch Block will stand positive to left axis deviation and right axis deviation as a ventricular abnormality.
6. Myocardial infarction (MI) is associated with the development of AF. We aimed to characterize the atrial abnormalities because of MI and determine the role of ischemia to the AF substrate.

The results were visualized under certain parametric assumptions as overall specificity and sensitivity in detecting the defects, Specificity and sensitivity in detecting Atrial abnormalities as well as Specificity and sensitivity in detecting Ventricular abnormalities. The data with the following combinations of results were re-classified as true results and false results: -

1) Borderline ECG in Spandan portable ECG and Borderline ECG in 12 lead gold standards is a true result.
2) Borderline ECG in Spandan portable ECG and Abnormal ECG in 12 lead gold standard is a true result.
3) Borderline ECG in Spandan portable ECG and Normal ECG in 12 lead gold standard is the true result.
4) Abnormal ECG in Spandan portable ECG and Borderline ECG in 12 lead gold standard is a true result.

5) Normal ECG in Spandan portable ECG and Borderline ECG in 12 lead gold standard is the true result.

The condition in exception to above conditions were considered false.

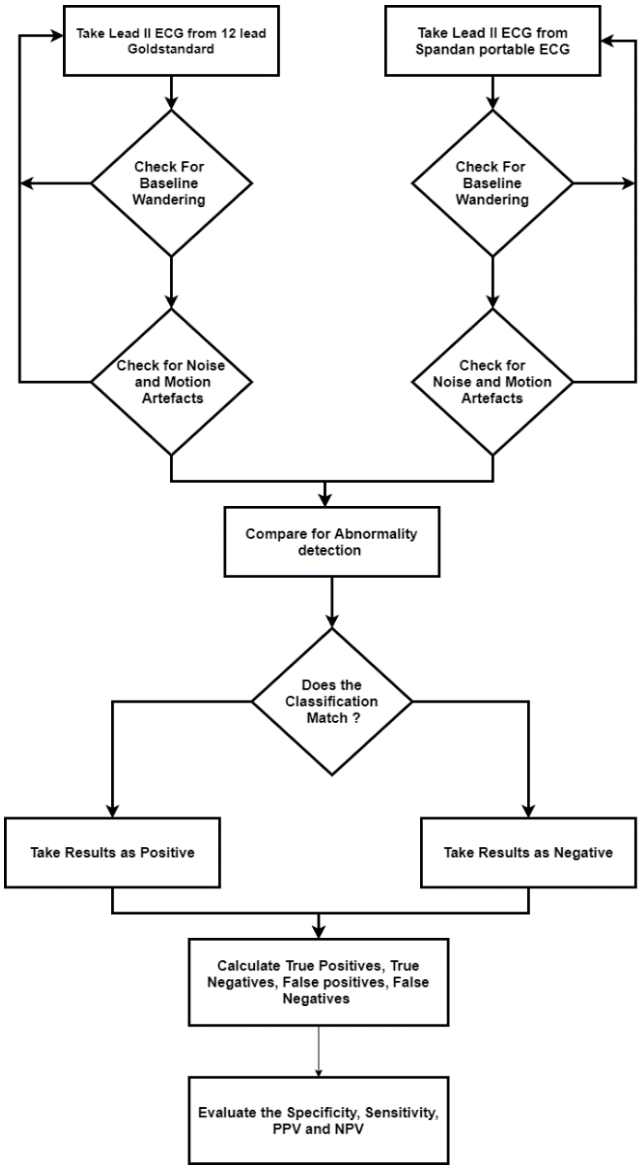

Fig. 3.
Methodology of the observational study procedure

Results and Discussions

The study was performed on 110 subjects which were evaluated with a consideration of 5 % human error. Table IV shows the characteristics of participants enrolled in the study. 108 cases were found to be true and 2 false

cases detected using the smartphone based portable ECG device in comparison to the gold standard 12 lead ECG. The accuracy calculated was 98.1% in interpreting the Abnormal and normal cases in comparison to clinical interpretation conducted by a cardiologist. There was total positive detection of 48 cases whereas 62 cases were detected as negative. As per the AHA, there is no computer program that can provide the correct interpretation as a skillful physician, hence the challenge was to bring the accuracy as near to the clinical interpretation done on 12-lead gold standard ECG. There were 72 true positive, 36 true negative, 1 false positive, 1 false negative case, that were further validated for accuracy in comparison to the clinical interpretation. Hence, Overall specificity and sensitivity in detecting defects were evaluated by using confusion matrix in table V.

Table IV.
Characteristics of participants

Parameter	Males	Females	Total (n = 110)
No. of cases	93	17	110
Age (mean ± SD)	49(±5)	45(±3)	NA
Ventricular abnormalities in Gold standard machine	20	3	23
Atrial Abnormalities in Gold standard machine	27	5	32
Normal cases in Gold standard machine	46	9	55
Ventricular abnormalities in Smartphone ECG	13	1	14
Atrial abnormalities in Smartphone ECG	28	4	32
Normal cases in Smartphone ECG	52	12	62

The Specificity is calculated by using the formula

$$Specificity = \frac{True\ Negative}{True\ Negative + False\ Positive}$$

Hence, Spandan is 98.63% specific in nature which defines the probability of detecting a negative test when the defect is absent. The Sensitivity is evaluated by using

$$Sensitivity = \frac{True\ positive}{True\ Positive + False\ Negative}$$

The calculated sensitivity of Spandan in the detection of Cardiac defects is 97.8%. Hence, the probability of detection of disease when a cardiac defect is present is 97.8%. The Positive predictive value (PPV) by Spandan portable ECG is given by

$$PPV = \frac{True\ positive}{True\ Positive + False\ Positive}$$

The obtained PPV for 153 clinical trial cases is 100 %. Hence, the probability of the patient having the disease while the test is positive is 100%. The Negative Predictive Value by Spandan ECG is given by

$$NPV = \frac{True\ Negative}{True\ Negative + False\ Negative}$$

The obtained NPV is 81.25 %, which can be interpreted as the probability of not having a disease to the patient when the test is negative 3.

Table V.
Evaluated accuracy parameters for the Spandan portable ECG

Parameters	OVERALL DEFECTS
Specificity (%)	97.29
Sensitivity (%)	98.6
NPV (%)	97.29
PPV (%)	98.6

The ventricular and atrial abnormalities detected by the gold standard and the smartphone-based ECG machine is shown in the fig.4. There was a difference of 9 cases in detection of normal subjects, 9 cases were detected more by gold standard for ventricular abnormalities and atrial abnormality detection were same in numbers for both the machines.

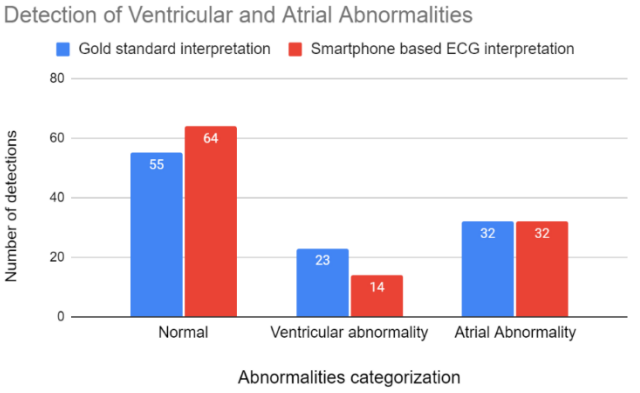

Fig. 4. Comparison of interpretation by Gold standard and smartphone-based ECG devices

According to the comparison done for the existing smartwatches and portable ECG device as shown in table VI. The smartphone-based ECG device taken for the reference in the present study performs well in detecting the various kind of arrhythmic events in the subjects. The fig 5. Shows the comparative chart of the three prime devices based on detection of arrhythmia using the lead II.

Table VI
Comparison of accuracies for market available ECG machines with Spandan ECG

ECG Devices	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Cardio Rhythm	92.9	97.7	53.1	99.8
Apple Watch	NA	NA	71	NA
Kardia Band	93%	84	NA	NA
Alive Cor	71.4	99.4	76.9	99.2
My Diagnostic	54.5	97.5	NA	NA
Spandan ECG	98.6	97.29	98.6	97.29

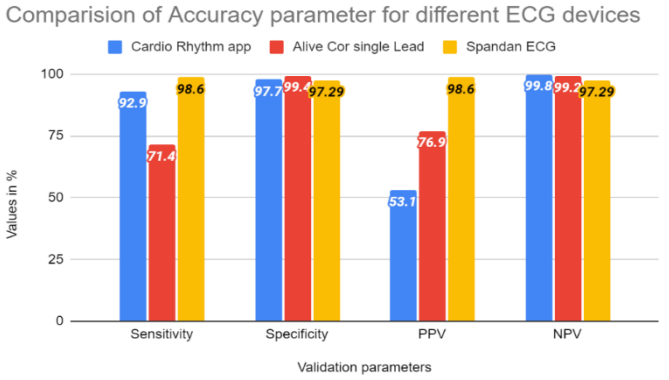

Fig. 5. Comparison of Accuracy parameter for different ECG devices available in market

Conclusion

In this study, we found that smartphone based portable ECG is 98.5% accurate as compared to the 12-lead gold standard ECG machine. Smartphone-based ECGs are capable in interpreting similar results under permissible limits of ±5 % error by medical standards. This study also provided a perspective that the medical devices taken in the study are suitable for detection of heart abnormalities like arrhythmia and STEMI. Cardiac patients and elderly people for event monitoring can use smartphone-based portable ECG devices. The sensitivity and specificity of these devices remain a pain point regarding validating the interpretation. However, this study shows the clarity that Smartphone-based portable ECG machines are reliable in interpreting abnormal and normal cases. As a limitation the specifying of the interpretation can be checked for large number of samples based on the geographic location.

The statistical method of measuring the Sensitivity, Specificity, PPV, and NPV is the right method to validate the real-life use of the medical device. Hence, these

values are in the standard range to provide an accurate measure of cardiac disease. The Spandan portable ECG settles for good practice in the clinical trial of predicting the high positive values, hence it could withstand the OPD's and pre and post-surgery monitoring. As there is less to none False positives, hence this device can be helpful to large number of physicians and Health-conscious individuals.

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