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Comparison of ECG Morphological Parameters between a Mobile 12 Lead ECG Compared To the Gold Standard 12 Lead ECG in Cardiology Patients

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Abstract: Background: Interval duration measurements (IDMs) were compared between standard 12-lead electrocardiograms (ECGs) and 12 lead mobile ECG recorded with Spadnan ECG based ECG device, a single channel, hand-held mobile device designed for use by patients at home. Objective: Objective of this prospective, cross-sectional, within patient diagnostic validation study was to compare the interval durations between standard 12 lead ECG and 12 lead mobile ECG recorded with Spadnan ECG based single channel ECG device. Materials and Methods: This single-center study was carried out at Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India from January 2019 to August 2022. All patients (n=2308) visiting the electrocardiogram (ECG) room at the Department of Cardiology of the SMIH, Dehradun during the study period were enrolled in the study by taking their written consent and explaining the purpose of the study. Results: Smartphone-operated 12 lead ECGs showed good diagnostic accuracy for QT, PR, QRS, QTc and Heart rate measurement in comparison to the standard 12 lead ECG machine. The PR interval, QRS duration and Heart rate were under the clinical agreement levels. Whereas, the QT and QTc showed the variability of more than 20 ms. hence, the detection of the Arrhythmias associated with shorten PR intervals, prolonged PR intervals can be detected by the Smartphone ECG with accuracy, the conduction blockages like LBBB involving the QRS duration can be precisely be detected by the smartphone ECG. Conclusion: Our research evidence proved the equivalency of device in measuring the morphological parameters like PR intervals and QRS duration. Our study observed variation in detection of the QT and QTc intervals at above 25 ms, which might make it difficult to be used in diagnosis but for general purpose where no medical facility is available, our device can be used for primary care. Hence, the Smartphone ECGs can be used in the primary care and for general use.

Keywords: Bland–Altman, electrocardiogram, interval duration measurements, QTc.

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INTRODUCTION

12-lead electrocardiograms (ECGs) are a standard evaluation and are used for evaluation of cardiac rhythm, conduction, chamber size, myocardial infarction, potential ischemia, pericarditis, and many other cardiac findings.[1] The interval duration measurements (IDMs), typically including heart rate (HR), PR interval, QRS duration, QT interval, and the heart rate corrected QTc value, are an important part of the evaluation of any ECG.[2] Measurements may be determined by automated ECG machine algorithms, manually measured by the physician/site investigator, or measured by a centralized ECG core laboratory.[3]

A major limitation of the standard 12-lead ECG is related to the placement of the four limb electrodes and the six precordial electrodes.[4] In order to allow reliable measurements and interpretation, as well as to permit comparison between serial ECGs, the electrodes must be placed correctly, with little tolerance for incorrect lead positioning (especially for the precordial leads).[5] The requirements for accurate electrode placement and supine position make it extremely difficult for a patient to record a 12-lead ECG outside of an investigational site or other medical facilities.[6] It would therefore be very useful to have a method for collecting patient-recorded ECGs from home that would not require a medical professional with a standard 12-lead ECG device to visit the patient's home.[7]
A new device, the Spandan Portable ECG device 12L, a portable ECG designed for quick access of 12 Lead ECG at homes and clinics has become available.[8]

This study was designed to compare the interval durations from the Spandan Portable ECG device 12L to ECGs collected with standard 12-lead ECG devices.

METHOD

This hospital-based, single center, retrospective and prospective cross-sectional, within patient diagnostic validation study was carried out at Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India from January 2019 to August 2022. The study population was composed of 2308 patients of either gender. Patients were enrolled in the study by taking their written consent and explaining the purpose of the study. Cases of acute MI, Electrical disturbance in ECG were excluded from the study.

ECG sources

Patients referred to the Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India between January 2019 to August 2022 were enrolled in our retrospective and prospective study in which a standard 12-lead ECG and a 12-lead mobile 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 sit up and, after instructions by study nurses. Utilizing a smartphone-based application, the digital files containing the 12-lead recording were uploaded to a cloud-based server for subsequent analysis.

12-lead ECG recordings

The 12-lead ECGs were recorded with the Spandan 12L The 12 lead ECG from both the devices were recorded 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 port to an application loaded into the patient's smartphone, which allows the ECG recordings to be uploaded to Spandan's Internet cloud-based servers.

Statistical methods

The data was collected on an excel sheet and descriptive statistical analysis was performed. The Bland–Altman method[9] was used as the primary comparison method. Mean IDMs from each subject's 12-lead ECG were subtracted from the values obtained from the 12-lead ECG, and differences were displayed as a function of the mean of the two measurements. Limits of agreement (LoA) and 2-sided 95% confidence intervals (CI) for the mean difference and LoA were calculated.

Bias analysis was also performed to assess the potential bias of measurements between recording devices.

RESULTS

Interpretable 12-lead recordings were available for 2308 out of 2308 (100%) eligible patients enrolled prospectively between January 2019 to August 2022. The average patient age was 54±14.8 years, with 67.2% males and 32.8% females. The most common diagnosis was obesity, hypertension, Diabetes and Chest Pain at 22.5%, 4.15%, 3.98% and 6.4%, respectively. Smaller numbers of patients had Primary Coronary Intervention (116 [5.02%]), Coronary heart Disease (298 [12.9%]), and Atrial Fibrillation (3 [0.0012%]).

Table 1. Observed values for smartphone electrocardiography and 12-lead electrocardiography measurements and differences with descriptive statistics and Pearson's correlation

Kind of Electrocardiography	12 Lead Standard ECG	Spandan Smartphone ECG	Confidence Intervals (CI) under 95% in spandan Smartphone ECG	Pearson's Correlations (r)
Mean HR (BPM±SD)	78.37±15.8	79.7±25.4	79.7±1.036	0.6
Mean QT interval (ms±SD)	368.6±49.6	345±80	340.50±3.618	0.42
Mean QTc interval (ms±SD)	416.38±49.5	385.5±84.6	384.55±3.496	0.37
Mean PR interval (ms±SD)	149.67±34.4	139±34.5	138.47±1.503	0.97
Mean QRS intervals (ms±SD)	90.3±19.89	91.6±26.46	91.60±1.149	0.34

Abbreviations: bpm, beats per minute; HR, heart rate; ms, milliseconds; SD, standard deviation

A summary of the mean values for the IDMs with the smartphone electrocardiography and 12-lead electrocardiography recordings is shown in above Table 1. The least value of Pearson's Correlations (*r*=0.6) was recorded for the mean QRS intervals recording between 12 Lead Standard ECG and Spandan Smartphone ECG. The largest value of Pearson's Correlations (*r*=0.97) was recorded for the mean PR interval recording between 12 Lead Standard ECG and Spandan Smartphone ECG.

Table 2. Summary of differences between interval duration measurements from smartphone electrocardiography and 12-lead electrocardiography with upper and lower limits of agreement

Parameters	Mean difference (ms)	Upper line of Agreement (ms)	Lower line of Agreement (ms)	Percentage of agreement limits (%) at (CI =95%)
QRS(ms)	-1.95	54.89	-58.81	96% to -96%
PR(ms)	10.69	31.65	-10.26	74% to -50%
QT(ms)	28.10	83.17	-28.1	74% to -50%
QTc(ms)	-2.4	94.23	-30.56	97.5% to -92%
HR(bpm)	2.04	1.96	-6.05	50% to -74%

Abbreviations: bpm, beats per min; CI, confidence intervals

A summary of the differences between interval duration measurements from smartphone electrocardiography and 12-lead electrocardiography with upper and lower limits of agreement is presented in Table 2. The least mean difference (ms=-1.95) was recorded for the mean QRS intervals recording between 12 Lead Standard ECG and Spandan Smartphone ECG. The highest mean difference (ms=28.10) was recorded for the mean QT intervals recording between 12 Lead Standard ECG and Spandan Smartphone ECG.

Heart rate

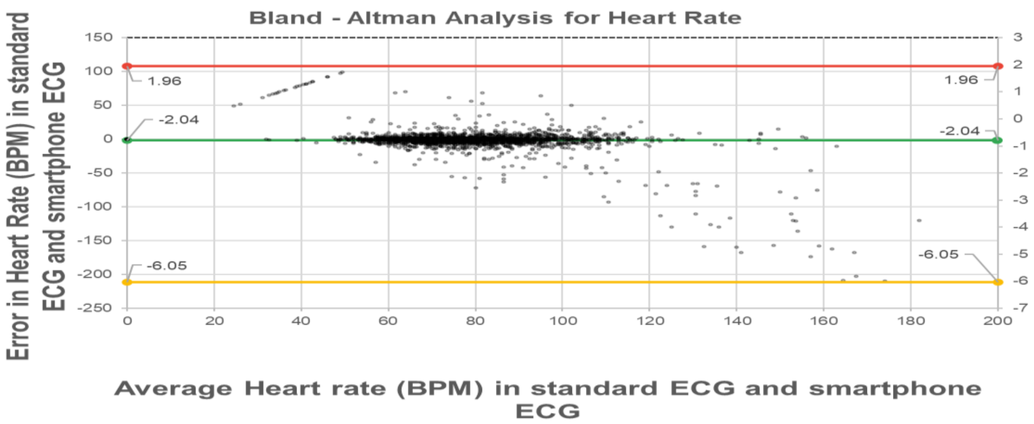

Figure 1. Bland–Altman assessment plots for heart rate (HR)

The Bland–Altman bias analysis plot for heart rate are shown in above Figure 1. The solid horizontal red line represents the mean difference, and the yellow line represents the 95% confidence bounds for the measurement pairs. The horizontal green line represents the limits of agreement. The mean difference between the HR as measured on the 12 Lead Standard ECG and Spandan Smartphone ECG was 1.33 beats per minute. The bias analysis demonstrated a percentage of agreement of the Heart rate in spandan 12 lead ECG was 50% to -74%.

QT interval

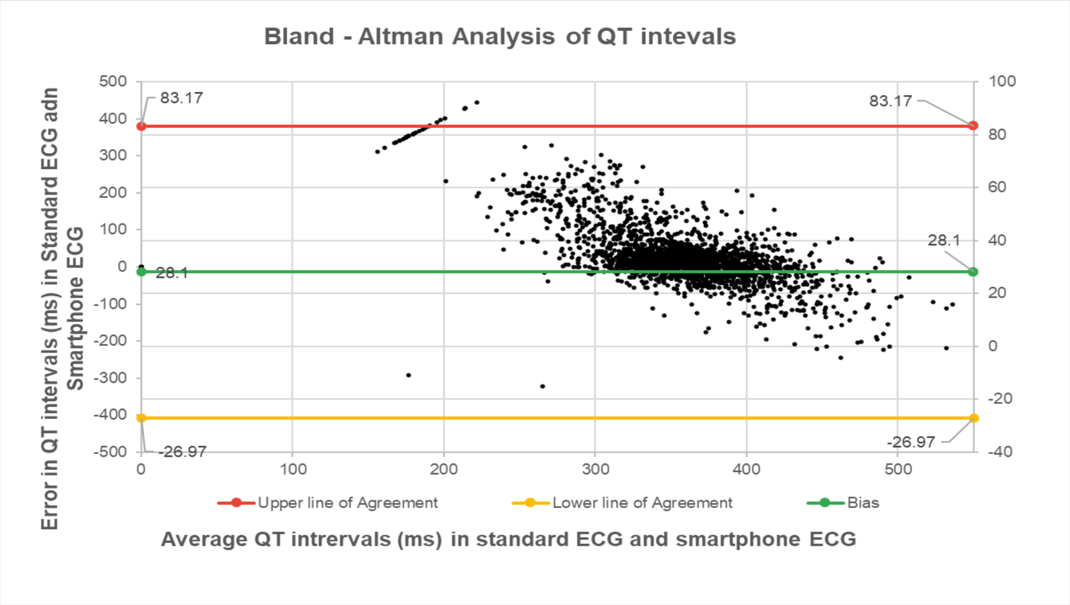

Figure 2. Bland–Altman assessment plots for QT intervals

The Bland–Altman plot for QT interval are shown in above Figure 2. The solid horizontal red line represents the mean difference, and the yellow line represents the 95% confidence bounds for the measurement pairs. The horizontal green line represents the limits of agreement. The mean difference between the QT as measured on the 12 Lead Standard ECG and Spandan Smartphone ECG was 23.6 ms. The bias analysis demonstrated a percentage of agreement of the QT interval in spandan 12 lead ECG was 74% to -50%.

QTc interval

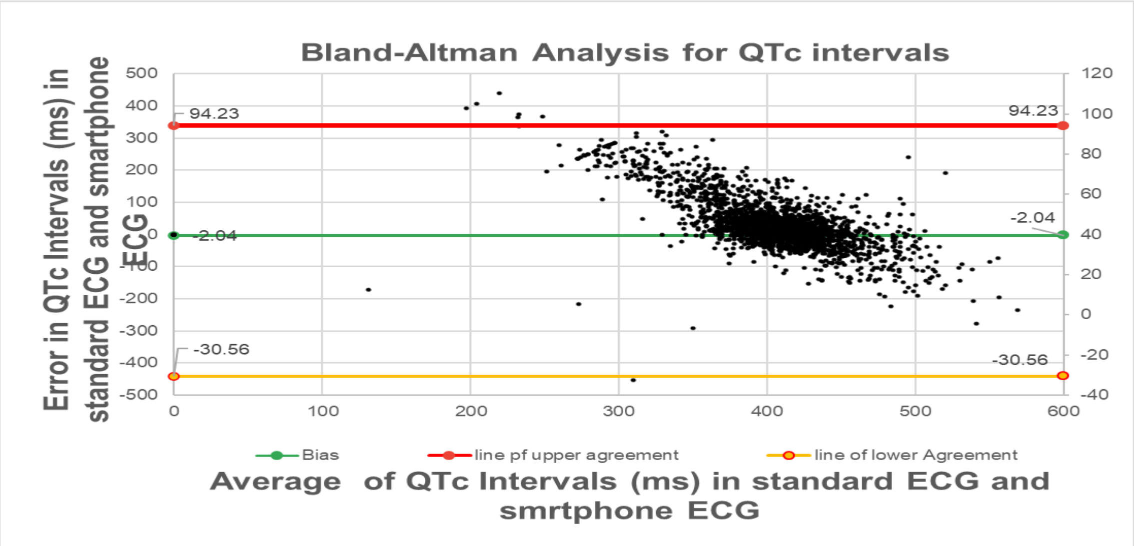

Figure 3. Bland–Altman assessment plots for QTc intervals

The Bland–Altman plot for QT interval are shown in above Figure 3. The solid horizontal red line represents the mean difference, and the yellow line represents the 95% confidence bounds for the measurement pairs. The horizontal green line represents the limits of agreement. The mean difference between the QTc as measured on the 12 Lead Standard ECG and Spandan Smartphone ECG was 30 ms. The bias analysis demonstrated a percentage of agreement of the QTc interval in Spandan 12 lead ECG was 97.5% to -92%.

PR interval

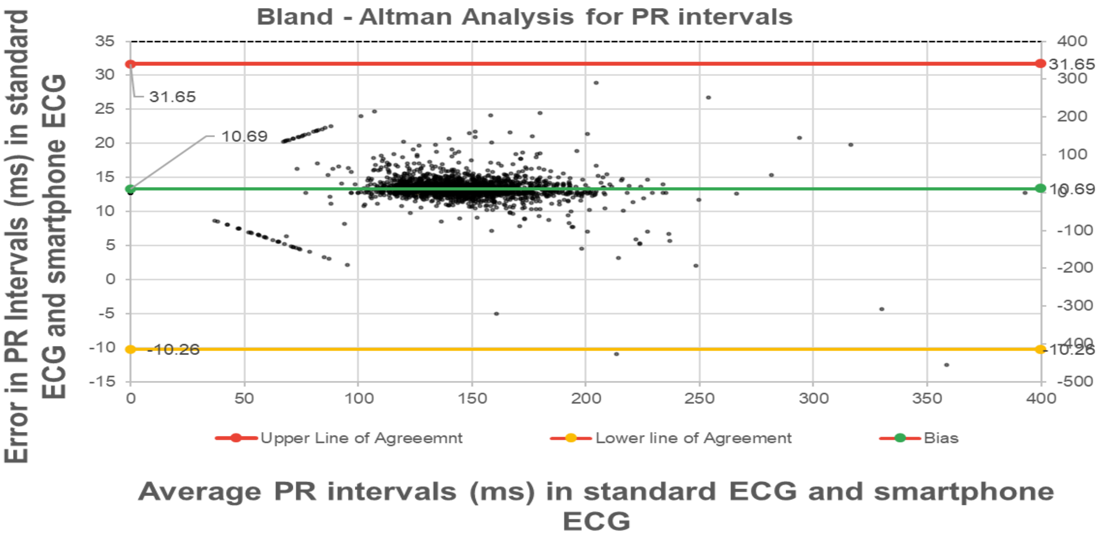

Figure 4. Bland–Altman assessment plots for PR intervals

The Bland–Altman and bias assessment plots for PR are shown in above Figure 4. The mean difference between the PR interval measured on the Spandan 12 Lead ECG and standard 12-lead ECGs was 10 ms. The percentage of agreement of the PR interval in spandan 12 lead ECG was 74% to -50%.

QRS intervals

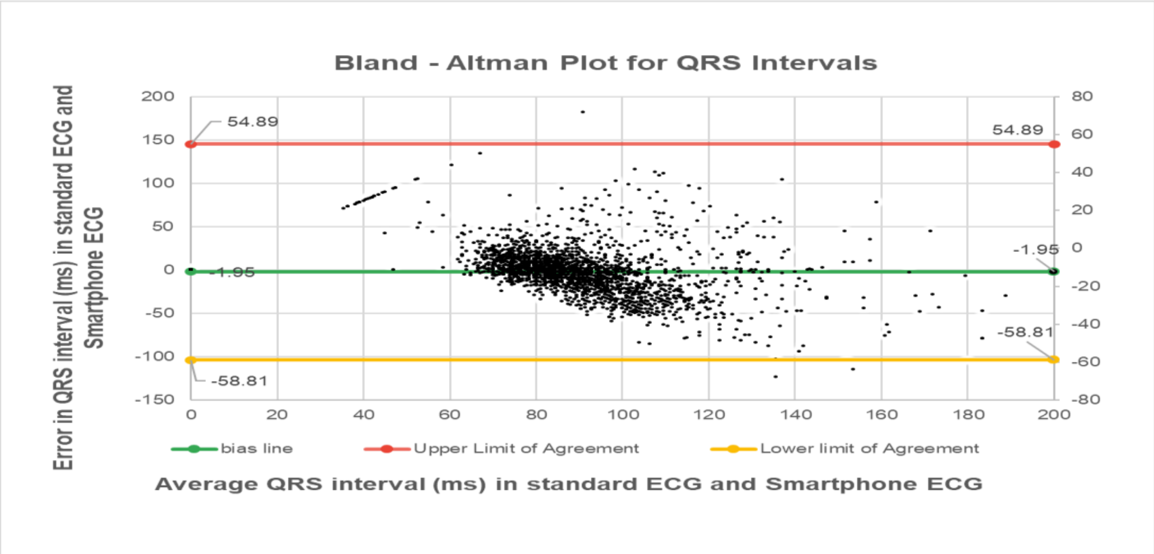

Figure 5. Bland–Altman assessment plots for QRS intervals

The Bland–Altman and bias assessment plots for QRS duration are shown in above Figure 5. The mean difference between the QRS duration measured on the Spandan 12 Lead ECG and standard 12-lead ECGs was 1 ms. The bias analysis demonstrated a percentage of agreement of the QRS interval in spandan 12 lead ECG was 96% to -96%.

DISCUSSION

The 12-lead ECG is an important tool that is used regularly in clinical practice.[10] The complexity of placing the limb has traditionally limited the collection of 12-lead ECGs to physician offices, hospitals, and diagnostic laboratories. It would be extremely helpful to be able to collect high-quality self-administered ECGs at home, with the patient capable of recording and transmitting the ECG to the patient's physician.[11]

The Spandan Smartphone ECG 12L is a simple, mobile device that allows almost any patient to collect a 12-lead ECG, and then transmit the ECG for evaluation.[8] Since the ECGs in this study were not collected simultaneously (often with

10–20 min between recordings) or with the patient in the same position, the two QTc measurements for a single patient would not be expected to be identical.

In a large enough population, one would expect that in the absence of any significant physiologic events, repeat ECG measurements recorded 5–30min apart would demonstrate very small mean changes, whether the recordings were performed with the same or different ECG devices.[12]

Smartphone-operated 12 lead ECGs showed good diagnostic accuracy for QT, PR, QRS, QTc and Heart rate measurement in comparison to the standard 12 lead ECG machine.[13] The PR interval, QRS duration and Heart rate were under the clinical agreement levels.[14] Whereas, the QT and QTc showed the variability of more than 20 ms. hence, the detection of the Arrhythmias associated with shorten PR intervals, prolonged PR intervals can be detected by the Smartphone ECG with accuracy, the conduction blockages like LBBB involving the QRS duration can be precisely be detected by the smartphone ECG.[15] Whereas, there is variation in detection of the QT and QTc intervals were above 25 ms, which makes it difficult to be used in diagnosis but for general purpose where no medical facility is available, the device can be used for primary care.[16]

The results of this study confirm that ECG measurements remain, on average, relatively stable over short intervals. A few instances of large differences in intervals were observed, and in reach, instances were related to significant changes in ECG rhythm or T-wave morphology.[17]

The results of this study suggest that the use of this smartphone-enabled, mobile technology would be appropriate for many uses in clinical medicine.[18] This is not the device that one would want to use for patients with unstable angina, but would be ideal to allow following the rhythm of a patient who has had paroxysmal atrial fibrillation or an atrial fibrillation ablation, or for following the QTc value of a patient receiving one or more QT-prolonging medications.[19] This would enhance our ability to assess patient safety between scheduled visits (rapid assessment of new symptoms or period checks to detect large increases in QTc, PR, or QRS).[20]

One potential limitation of this study is that the average age was 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

Our research evidence proved the equivalency of device in measuring the morphological parameters like PR intervals and QRS duration. The error in the QT and QTc were not up to the level of clinical agreement of 25 ms. Hence, the Smartphone ECGs can be used in the primary care and for general use. This technology should not be viewed as a replacement for 12-lead ECGs, for it is not. Instead, it may represent a valuable method for expanding our reach for collecting high-quality ECG data.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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