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Accuracy of Mobile 12 Lead ECG Device for Assessment of Qtc Interval in Arrhythmia Patients: A Prospective and Retrospective Validation Study

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Abstract: Background: Ambulatory assessment of the heart rate–corrected QT interval (QTc) within arrhythmia patients can be of diagnostic value where these patients are on QTc-prolonging medication. Repeating sequential 12-lead electrocardiograms (ECGs) to monitor the QTc is cumbersome, but Spandan Smartphone ECG devices can potentially solve this problem. Objective: Objective of this prospective and retrospective, cross-sectional, within patient diagnostic validation study was to validate the measurement of QTc interval in Spandan 12 lead ECG and to assess the accuracy of the 12 lead Spandan Smartphone ECG device in measuring the QTc intervals in the general cardiology outpatient population with normal ECG and arrhythmias. Materials and Methods: This single-center study was carried out at Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India from August 2022 to October 2022. All patients (n=1168) 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: Mean (SD) age was 54.36±4.9 years. The male gender (n=783,67.03%) shows the maximum frequency than female gender. Primary Coronary Intervention was noted in 426 (36.4%) of the study population. All the four parameters showed positive Pearson correlation between 12 Lead Standard ECG and Spandan Smartphone ECG. The maximum mean difference between 12 Lead Standard ECG and Spandan Smartphone ECG was noted for QTc parameter in overall participants. Conclusion: 12-lead Spandan Smartphone ECG allows for QTc assessment with good accuracy and can be used safely in ambulatory QTc monitoring. This may improve patient satisfaction and reduce healthcare costs.

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

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INTRODUCTION

An abnormally shortened or prolonged QTc intervals may cause potentially fatal cardiac arrhythmias, such as torsades de pointes (TdP) and sudden cardiac death particularly in the presence of risk factors such as congenital QTc prolongation[1], female sex, age greater than 65 years, ischemic cardiomyopathy, severe bradycardia, electrolyte imbalance, and liver/kidney insufficiency.[2] Also, more than 170 drugs may prolong QTc interval, including antiarrhythmics, antipsychotics, and antifungal agents.[3]

In patients with risk factors, QTc interval monitoring with 12-lead derivation electrocardiogram (ECG) is recommended to prevent fatal arrhythmia due to QTc prolongation. Assessment of the QTc is traditionally performed using a 12-lead ECG, but this type of recording requires a visit to a cardiology outpatient clinic or other medical facility.[4,5]

The novel coronavirus disease 2019 (COVID-19) pandemic has revolutionized the diagnostics sector, including cardiology subsector. Out of the several developments, the introduction of direct-to-consumer mobile devices for obtaining electrocardiogram (ECG) recordings has profound applications.[6] Mobile ECG (mECG) devices can potentially simplify QTc monitoring and be more cost-effective than utilising 12-lead ECG recorders. The infrastructure of existing remote arrhythmia monitoring programmes could facilitate the introduction of QTc monitoring if measurements are sufficiently reliable.[7,8]

Currently, only a few studies have documented the accuracy of determining the QTc on a 12-lead mECG.[9-15] 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 validate the measurement of QTc interval in Spandan 12 lead ECG and to assess the accuracy of Spandan Portable ECG device 12L for assessment of QTc interval in arrhythmia patients admitted to the cardiology department.

METHOD

Individuals visiting the outpatient clinics of the Cardiology department of Shri Mahant Indresh Hospital (SMIH), Dehradun, Uttarakhand, India between August 2022 to October 022 were invited to participate and were included in this hospital-based, single center, prospective and retrospective, cross-sectional, within patient diagnostic validation study after obtaining their written informed consent. The final selected study population was composed of 1168 patients of either gender.

Patients were enrolled in the study by taking their written consent and explaining the purpose of the study. Cases that underwent 12 lead ECG for any kind of arrhythmia were included in the study whereas cases who were physically unable to use the Spandan Smartphone ECG device or 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 between August 2022 to October 2022 were enrolled in a prospective and retrospective 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 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.

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

In total, 1200 patients were enrolled for the study and a few (n=32) subjects later withdrew consent or patients were fitting within the exclusion criteria. Hence, 1168 subjects agreed to participate and underwent both an mECG and 12-lead ECG recording. Mean (SD) age was 54.36±4.9 years (range in years: 20-94), 783 subjects (67.03%) were male, and 360 participants (30.8%) had a history of coronary heart disease. Below **Table 1** summarizes the baseline characteristics of ECG morphology within the study population for test and standard ECG.

Table 1. Baseline characteristics of ECG morphology within study population

ECG machine used	Spandan Smartphone ECG	Standard 12 lead ECG
Age±SD (in years)	1168 (54.36±4.9)	

Variable	**Number**		**Percentage (%)**	
Gender				
Male	783		67.03	
Female	385		32.9	
Obesity (BMI>30 kg/m^2	89		7.6	
Previous medical history				
Smoking (Current)	132		11.3	
Hypertension	104		8.9	
Primary Coronary Intervention	426		36.4	
Diabetes	182		15.5	
Coronary heart Disease	360		30.8	
Chest Pain	83		7.1	
ECG parameters	**N**	**%**	**N**	**%**
Atrial Fibrillation	49	4.1	23	1.9
Bradycardia	69	5.9	89	7.6
Sinus Tachycardia	94	8.04	100	8.5
Ventricular Ectopics	37	3.1	44	3.7
Ventricular Tachycardia	24	2.05	19	1.6
Other Arrhythmias	45	3.8	79	6.7
Medications				
Anti-Arrhythmic Drug	9		0.7	
Anti-Coagulant Drug	321		27.4	
Diuretic Drug	198		16.9	
Antacid	243		20.8	
Anti-hyperlipidemic Drug	294		25.1	
Hypoglycemic Drugs	152		13.0	
Anti-Hypertensive Drugs	407		34.8	
Antibiotics	59		5	
Anti-Anginal	74		6.33	

Abbreviations: 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=783,67.03%) shows the maximum frequency than female gender. Primary Coronary Intervention was noted in 426 (36.4%) of the study population.

Table 2. Average QT and QTc with standard deviation, pearson corelation and p-value using Spandan Smartphone ECG electrocardiography and 12-lead electrocardiography

Kind of Electrocardiography	12 Lead Standard ECG	Spandan Smartphone ECG	Pearson's Correlations (r)
Mean QT interval in non- arrhythmic participant (ms±SD)	319.6±19.8	277.01±17.82	0.71
Mean QTc interval in non-arrhythmic participant (ms±SD)	316.17±19.05	316.27±20.35	0.87
Mean QT interval in Arrhythmic participant (ms±SD)	382±19.4	316.46±17.7	0.94
Mean QTc interval in Arrhythmic participant (ms±SD)	443.8±20.9	370.83±19.19	0.96

A summary of the Average QT and QTc with standard deviation, Pearson correlation and p-value using Spandan Smartphone ECG and 12-lead electrocardiography is presented in Table 2. All the four parameters show positive Pearson correlation between 12 Lead Standard ECG and Spandan Smartphone ECG.

Table 3: Comparing parameter of Spandan 12 lead ECG with standard 12-lead ECGs samples using Bland-Altman Analysis

Parameters	Mean difference (ms)	Upper line of Agreement (ms)	Lower line of Agreement (ms)	Percentage of agreement limits (%) at (CI =95%)
QT in overall participants (ms)	-51.25	119.07	-221.54	70% to -81%
QTc in overall participants (ms)	-55	115	-266	67.6% to -82.8%
QT in normal participants (ms)	-42.64	114.53	-144.53	73% to -77.15%
QTc in normal participants (ms)	-44.89	115.86	-205.64	72.07% to -72.2%
QT in arrhytmic participants (ms)	79	116.64	-42.16	59.6% to -34.6%
QTc in arrhytmic participants (ms)	-9.50	72.036	-91.036	88.3% to -90.5%

A summary of the Comparing parameter of Spandan 12 lead ECG with standard 12-lead ECGs samples using Bland-Altman Analysis is shown in above Table 3. The maximum mean difference between 12 Lead Standard ECG and Spandan Smartphone ECG was noted for QTc parameter in overall participants.

Results for overall cases

The QT and QTc interval are compared for overall population of the study using Bland Altman analysis for Spandan Smartphone ECG and standard ECG. the limit of agreement was 70% to -81% and 67.6% to -82.8% respectively. QT interval deviated by -51.25 ms from the standard ECG, QTc interval deviated by -55 ms as shown in figure 1 below.

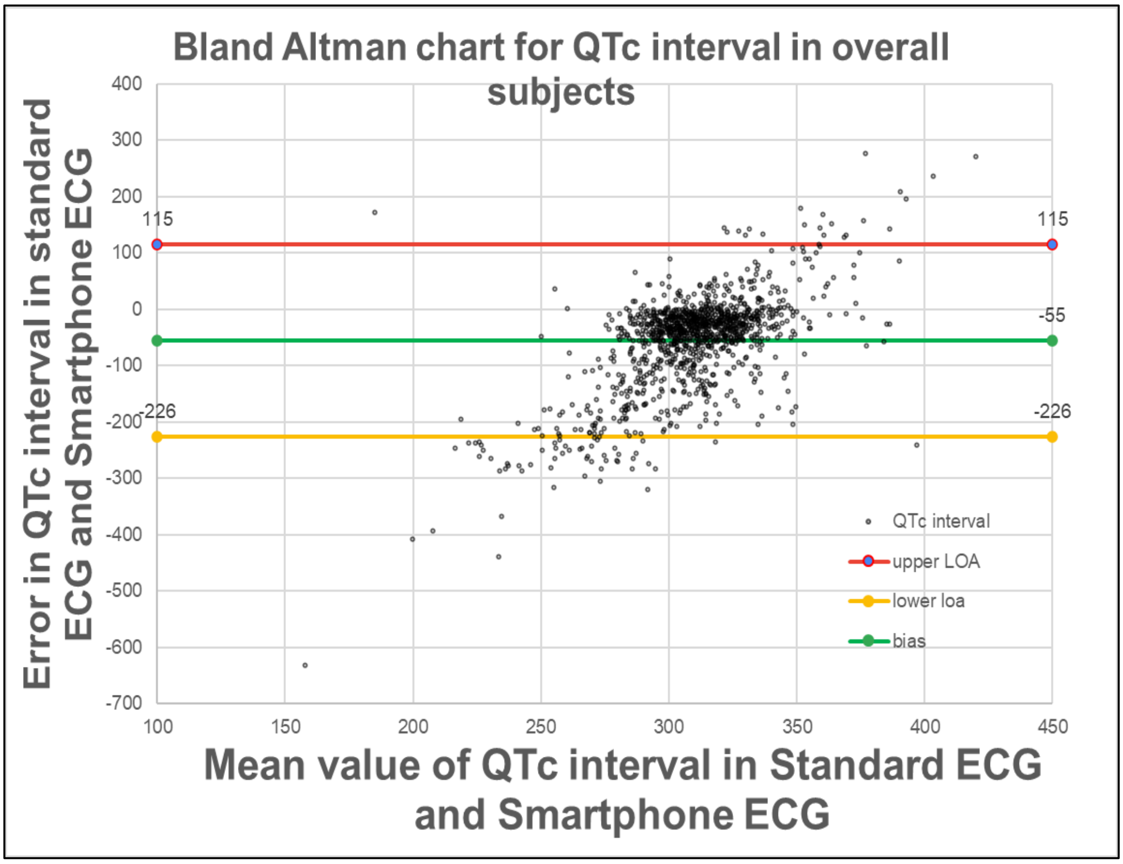

Figure 1: Bland-Altman plot for QTc intervals in Overall patients

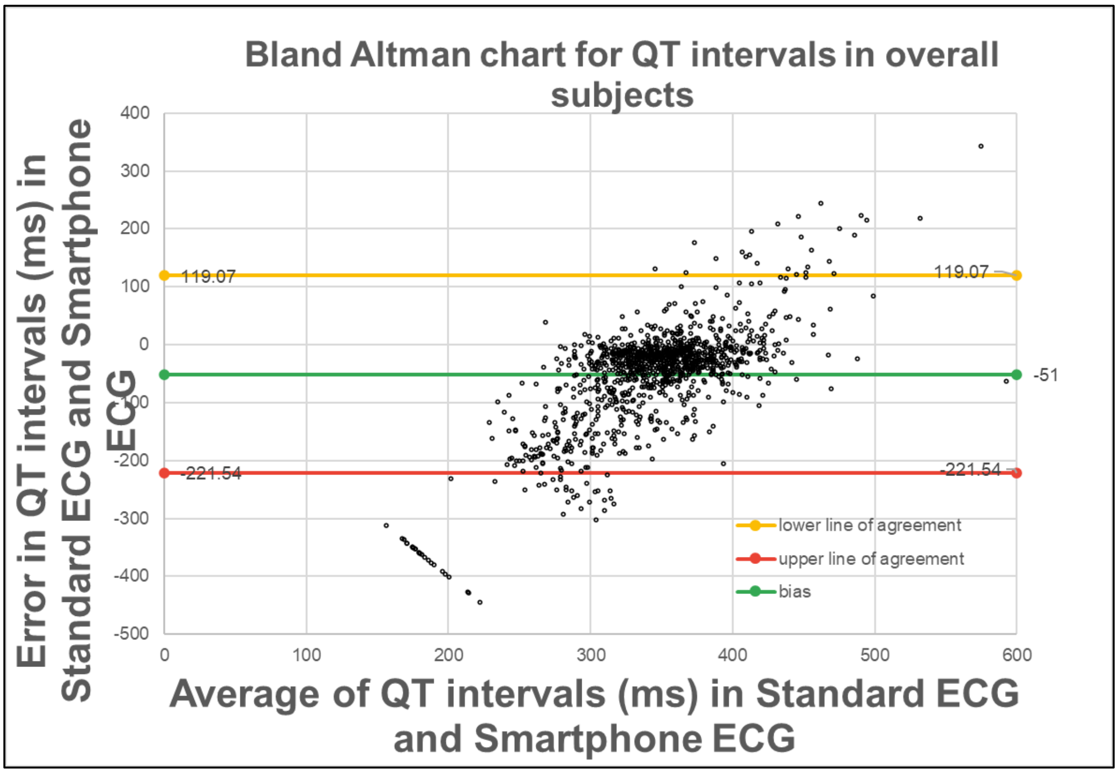

Figure 2: Bland-Altman plot for QT intervals in Overall patients

Results for Normal cases

The QT and QTc interval are compared for Normal population of the study using Bland Altman analysis for Spandan Smartphone ECG and standard ECG. The limit of agreement was 73% to -77.15% and 72.07% to -72.2%. QT interval deviated by -42.64 ms from the standard ECG, QTc interval deviated by -44.89 ms as shown in figure below.

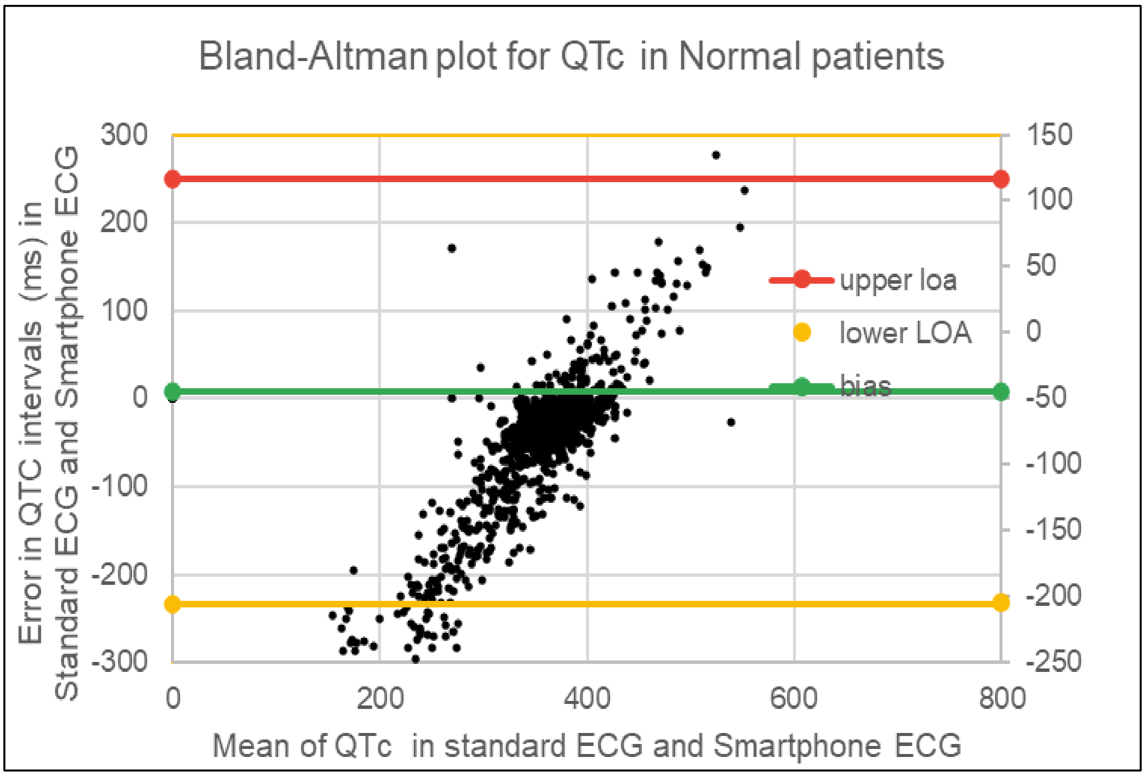

Figure 3: Bland-Altman plot for QTc interval in Arrhythmic patients

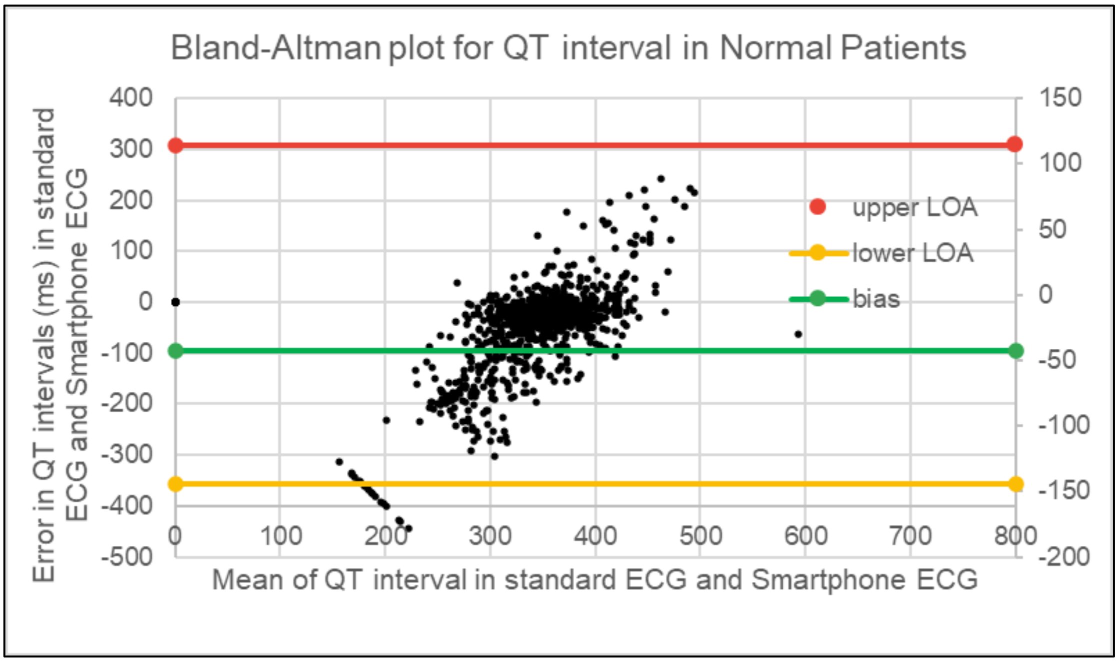

Figure 4: Bland-Altman plot for QT interval in Normal patients

Results for Arrhythmia patients

The QT and QTc interval are compared for Arrhythmia population of the study using Bland Altman analysis for Spandan Smartphone ECG and standard ECG. The limit of agreement was 59.6% to -34.6% and 88.3% to -90.5%. QT interval deviated by -79 ms from the standard ECG, QTc interval deviated by -9.5 ms as shown in figure below.

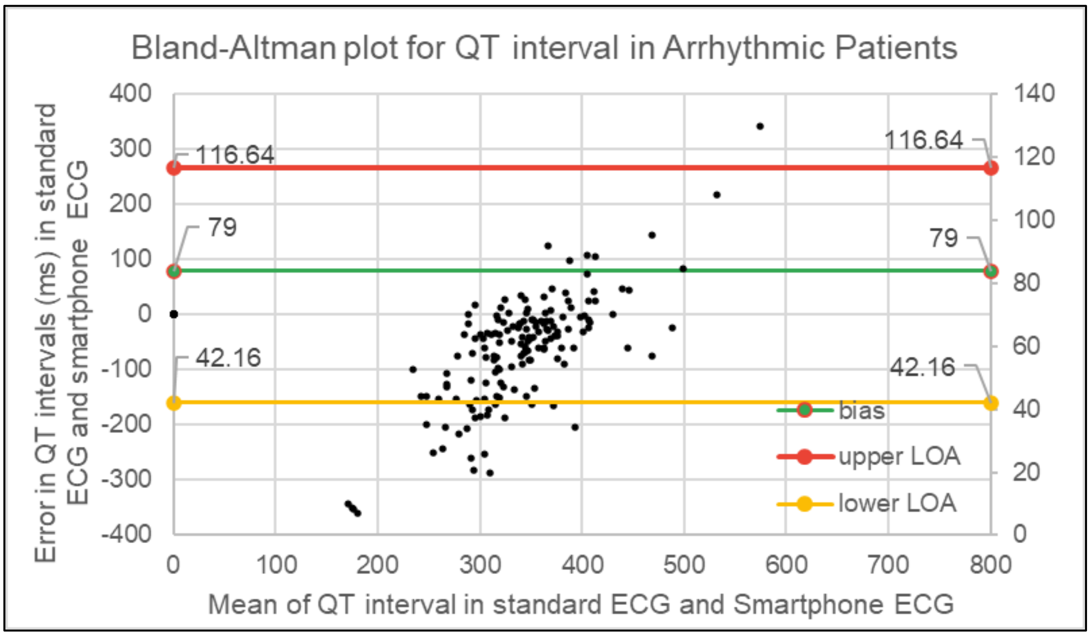

Figure 5: Bland-Altman plot for QT interval in Arrhythmic patients

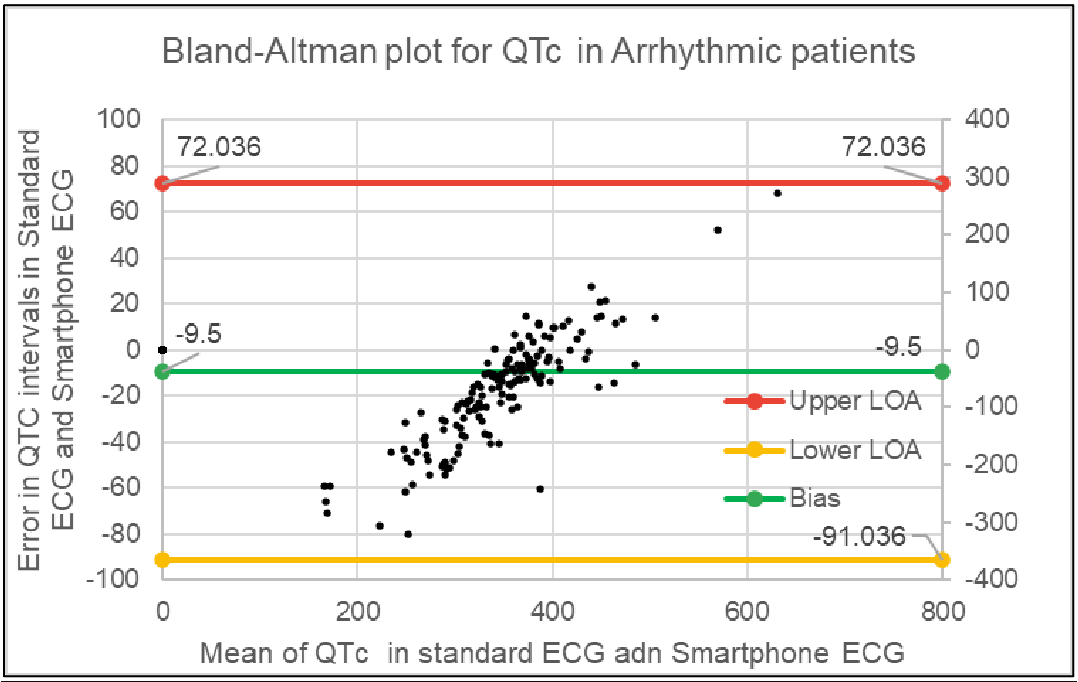

Figure 6: Bland-Altman plot for QTc interval in Arrhythmic patients

DISCUSSION

This prospective and retrospective study in a representative population of cardiology outpatients showed a good degree of accuracy of QTc measurements between Spandan Smartphone ECG and standard ECG recordings.

The present study is among the first to assess the accuracy of a 12-lead mECG of measuring the QTc. Kleiman et al. conducted a study with a similar design in a large cohort of patients (n= 705) presenting at a genetic arrhythmia clinic.[16]

The principal distinction with our study is the patient population: our study included a sample of a general cardiology outpatient population who were older and had more comorbidities.

Smartphone ECG devices offer unique advantages over traditional 12-lead ECG recorders.[17] Firstly, an ECG can be recorded with a smartphone ECG device at any location. The simplicity of use also allows operators without experience to record an ECG nearly instantaneously. Secondly, the smartphone ECG device does not utilize any disposables, thereby limiting waste and reducing the carbon footprint.[18] Lastly, its low cost of use renders the device usable in a wide range of settings and could make QTc monitoring more cost-effective. Multi-lead smartphone ECG devices may be used to remotely monitor the QTc by having patients at risk of QTc prolongation sending smartphone ECGs to their cardiologist at predetermined moments, thereby potentially mitigating a visit to the outpatient clinic or hospital.[19] Another advantage is the ability to perform repeated QTc measurements on multiple days.[20]

Regarding the limitations of our study, we must emphasize that it was carried out in a single center and with a single device. Another potential limitation of this study was that the average age of study population was around 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

The use of a 12-lead mECG enabled QTc measurement with a good degree of accuracy compared with 12-lead standard ECG in common populations. The Spandan Smartphone ECG can be helpful in the remote areas where patients are not in reach of the physicians or for general use when medical facility is not available. The overall evaluation shows that the Spandan Smartphone ECG is capable of assessment of patients in primary care. Also, remote QTc assessment may improve patient satisfaction and safety and contribute to cost-effectiveness in cardiology care.

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

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