

Monitoring cardiac adaptation in elite, adolescent athletes using a novel, smartphone-based 22-lead ECG

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Abstract

Introduction The 12-lead electrocardiogram (ECG) is the primary cardiac screening and diagnostic tool for athletes; however, it lacks portability where it would be useful in making fast and accurate diagnoses at the pitch side. Recently, smartphone applications (apps) have become available that can record 12-/22-lead ECGs with only four electrodes, which could improve accessibility of ECGs in the athletic setting. In this study, a novel ECG app, CardioSecur, will be compared against the gold standard 12-lead ECG (herein referred to as normal ECG [nECG]) in 31 elite, adolescent footballers to establish if there are any clinically significant differences between the devices.

Methods A full range of amplitudes, durations, intervals and waveforms were manually measured in 93 ECGs (31 nECGs, 31 12-lead CardioSecur ECGs and 31 22-lead CardioSecur ECGs) and agreement was assessed using the Bland–Altman method.

Results Our data showed clinically acceptable agreement for heart rate, PR interval, QRS duration, Bazett's corrected QT (QTc) interval, T-wave axis, P-wave duration, Q-wave amplitude, Q-wave duration, rhythm, T-wave character and ST-segment position. Unsatisfactory agreement was observed in the QRS axis, P-wave axis, P-wave amplitude and QRS amplitude.

Conclusion CardioSecur sufficiently agrees with the gold standard for 'on-field' use in athletic training facilities but, at present, should not replace the gold standard for cardiac screening.

Introduction

To manage the increased cardiovascular demand of a high-level athlete, the heart undergoes an array of adaptations known as electrical and structural remodelling.^{1,2} These changes can be identified using an electrocardiogram (ECG). It is now understood that, in some athletes, these changes, which include early repolarisation and left ventricular hypertrophy (LVH), may overlap with pathological findings.³ Specialist guidelines exist for ECG interpretation in athletes.⁴ However, data are lacking in adolescents. This is important, as competitive athletes are three times more at risk of sudden cardiac death (SCD) than the general population.^{5,6}

The 12-lead ECG is an invaluable cardiac screening tool; however, it lacks portability and the attachment of ten electrodes is often subject to misplacement. CardioSecur (Personal Medsystems GmbH, Frankfurt, Germany) is a smartphone application (app) that can generate a 12- and 22-lead ECG from just four electrodes

that are directly connected to a phone or tablet device. Based on the established EASI system (a vector-based, 5-electrode, 12-lead ECG),⁷⁻¹¹ CardioSecur has the potential to reduce electrode misplacement (**Figure 1**) and improve the accessibility of ECG recording in training or competition settings. Little, if any, data exists on 22-lead ECG interpretation in athletes. Therefore, in this study, CardioSecur ECG will be compared against the gold standard 12-lead ECG (herein referred to as normal ECG [nECG]) in adolescent athletes to assess its use in cardiac screening.

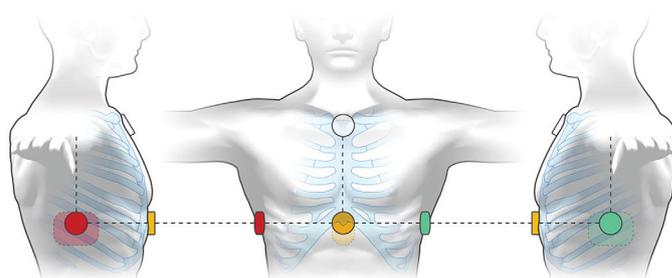


Figure 1. CardioSecur ECG electrode placement. Red, right mid axillary line (MAL) parallel with the xiphoid process; green, MAL parallel with xiphoid process; white, superior sternum (midline); yellow, xiphoid process (midline). Image provided by and used with permission from Personal Medsystems GmbH, Germany.

Methods

ECG recording

Written consent was obtained retrospectively from our study population of elite adolescent athletes and ethical approval was granted. Participants were between the ages of 13 and 16 years old and played for a premier league football academy ($n=31$). Data collection was conducted as part of a Football Association (FA)-approved cardiac screening programme and all nECGs were analysed by the team's cardiologist who was present at the time of data collection. Each participant received an nECG followed by a 12- and 22-lead CardioSecur ECG (see **Figure 1** for CardioSecur electrode placement). All ECGs were recorded at an amplitude of 10mm/mV and a paper speed of 25mm/s.

Data analysis

The parameters chosen for comparative analysis were heart rate, PR interval, QRS duration, Bazett's corrected QT (QTc) interval, QRS axis, P-wave axis, T-wave axis, QRS voltage, P-wave duration, P-wave amplitude, T-wave amplitude, Q-wave amplitude and Q-wave duration. Non-numerical parameters, including rhythm, ST-segment

and T-waves, were recorded as numerical codes. The 12- and 22-lead CardioSecur ECGs were compared with the nECGs in separate paired analyses. The additional leads (V7–V9, VR3–VR9) were omitted in the comparative analysis due to the lack of an equivalent comparator in the 12-lead nECG. Statistical agreement was assessed with a Bland–Altman¹² (mean-difference) plot performed with GraphPad Prism 8.0.2 (San Diego, CA, USA).

Statistical agreement To achieve statistical agreement, differences in parameter measurement must be minor enough to be of clinical insignificance and, thus, unlikely to result in misdiagnosis. Graphically, this corresponds with low bias (mean difference), narrow 95% limits of agreement (an estimated interval where 95% of differences will lie) and the absence of positive or negative trends that would indicate intrinsic bias.

Results

Comparison of the 12-lead CardioSecur ECG with nECG

Satisfactory agreement was observed in heart rate (bias = -2.00 bpm), PR interval (bias = -8.00 ms), QRS duration (bias=1.67 ms), QTc interval (bias=0.931 ms) (**Figure 2**), P-wave duration (bias=2.67 ms), P-wave amplitude (bias=0.00167 mV), T-wave axis (bias=8.04°), T-wave amplitude (bias=0.0232 mV) and Q-wave duration (bias=5.36 ms). Unsatisfactory agreement was observed in QRS axis (bias=23.4°), QRS amplitude (bias=0.333 mV), P-wave axis (bias=6.33°) and Q-wave amplitude (bias=0.207 mV).

Comparison of the 22-lead CardioSecur with nECG

Satisfactory agreement was observed in heart rate (bias=0.613 bpm), PR interval (bias = -1.73 ms), QRS duration (bias=7.05 ms), QTc interval (bias=2.03 ms), T-wave axis (bias=6.55°), P-wave duration (bias = -0.941 ms), Q-wave amplitude (bias=0.0195 mV), Q-wave duration (bias=1.69 ms), rhythm (bias=0.0667), T-wave character (bias = -0.0460) and ST-segment position (bias = -0.0629). Unsatisfactory agreement was observed in QRS axis (bias = -19.4°), P-wave axis (bias = -0.670°), QRS amplitude (bias = -0.660 mV), P-wave amplitude (bias=0.0400 mV) and T-wave amplitude (bias = -0.0675 mV). Refer to **Table 1** for the 95% limits of agreement.

Comparing QTc measurements using the 12-Lead cardiosecur ECG and the gold standard nECG

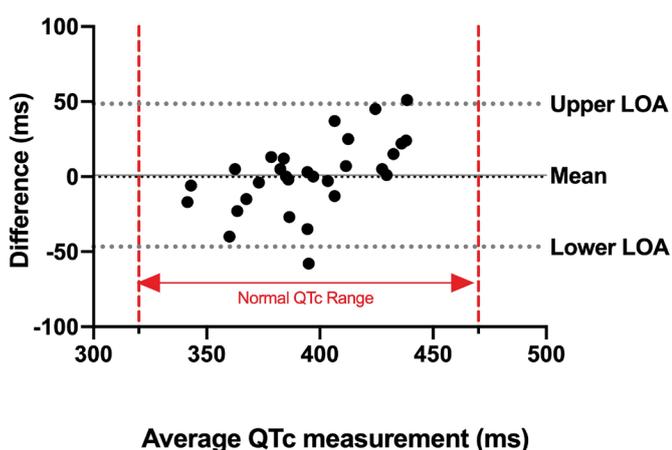


Figure 2. Bland–Altman plot comparing QTc intervals in the CardioSecur ECG (cECG) and nECG (n=31). Variability is consistent and the mean difference (bias) is close to zero. One criticism would be that the 95% limits of agreement (LOAs) are marginally wide for QTc measurements.

Table 1. Assessing agreement: comparing the 22-lead CardioSecur ECG with the nECG.

Parameter	Bias	95% upper LOA	95% lower LOA	Interpretation of agreement
Heart rate (bpm)	0.6	11.2	-12.4	Low bias, narrow limits
PR interval (ms)	-1.7	30.4	-33.9	Low bias, narrow limits
QRS duration (ms)	7.1	29.2	-15.1	Low bias, narrow limits
QTc interval (ms)	2.0	53.2	-49.1	Low bias, moderate limits
QRS axis (°)	-19.4	28.4	-67.1	cECG underestimates and positive trend
QRS amplitude (mV)	-0.66	1.18	-2.50	cECG underestimates and wide limits
P-wave axis (°)	-0.7	83.4	-84.8	Low bias, wide limits
P-wave duration (ms)	-0.9	24.9	-26.8	Low bias, narrow limits
P-wave amplitude (mV)	0.040	0.158	-0.078	Low bias, wide limits
T-wave axis (°)	6.6	28.3	-15.2	Low bias, narrow limits
T-wave amplitude (mV)	-0.068	0.378	-0.513	Low bias, wide limits
Q-wave amplitude (mV)	0.020	0.155	-0.116	Low bias, narrow limits
Q-wave duration (ms)	1.7	19.3	-15.9	Low bias, narrow limits
Rhythm	0.067	0.782	-0.649	Low bias, narrow limits
ST-segment analysis	-0.06	1.62	-1.75	Low bias, narrow limits
T-wave morphology	-0.05	2.27	-2.36	Low bias, narrow limits

Satisfactory agreement, green; unsatisfactory agreement, red
cECG, CardioSecur ECG; LOA, limit of agreement

Discussion

Early studies on CardioSecur ECGs have shown excellent agreement with approved ECG devices in diagnostic accuracy; however, higher absolute wave peaks have been found^{13,14} and our study confirmed these results. In this study, the Bland–Altman analysis, a statistical method for identifying bias and assessing agreement between devices,¹² was used to show that the CardioSecur device was reliable for T-wave, ST-segment and duration measurements, which are core parameters when distinguishing training-related physiological changes from cardiac pathology in athletes.⁴ In our study, differences in parameter measurements were often negligible and clinically insignificant.

The QRS and P-wave axes recorded by CardioSecur ECG would potentially increase the misdiagnoses of axis deviation. Our data showed that, while CardioSecur ECG was accurate (low bias) in axis measurement, it lacked precision (statistically illustrated by wide 95% LOAs; **Table 1**). Similarly, the wide LOA for QRS amplitude could lead to false suspicion of an LVH, leading to unnecessary concerns.

Limitations of this study include the lack of adjustment for intra-observer variation, a transversal study design, the absence of comparative echocardiographic input (to correlate with ECG findings) and the low participant number. Adjustment for observer

variation and a larger study population would improve the strength of this study.

In conclusion, the statistical agreement between CardioSecur ECG and the gold standard nECG observed in this study means that CardioSecur ECG would be suitable for 'on-field' use by medical staff. However, cardiac screening programmes should, at present, still use the gold standard nECG. Importantly, the CardioSecur device was reliable for T-wave, ST-segment and duration measurements. With minor adjustments to axis and amplitude recording, this technology has great potential to streamline the ECG process.

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