MARSHALL JOURNAL OF MEDICINE
Serving the Mountain State, Appalachia and Beyond

Volume 4 | Issue 2 Article 7

2018

ECG measurement parameters of athletes are reliable when made with a smartphone based ECG device

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DOI: http://dx.doi.org/10.18590/mjm.2018.vol4.iss2.7

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ECG measurement parameters of athletes are reliable when made with a smartphone based ECG device

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The authors have no financial disclosures to declare and no conflicts of interest to report.

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Abstract

Athletic pre-participation cardiac screening including electrocardiogram (ECG) is a subject of controversy among sports medicine practitioners. Opponents of pre-participation ECG screening cite concerns regarding the cost and accuracy of the testing. Recently, a single lead ECG accessory has become available for use with smartphones. The purpose of this study was to evaluate the between and within rater validity and reliability of the Kardia device in recording the ECG parameters rate, rhythm, and PR, QRS, QT intervals. The ECG parameters recorded with the smartphone were also compared to same measures made using a 12 lead electrocardiograph.

This investigation used a repeated measures cross-sectional design. The investigation was conducted in two separate phases using separate participant samples. Phase 1 (N=10) was used to determine the within rater reliability with the Kardia device. Phase 2 (N=12) was used to determine the reliability between the Kardia device and the 12 lead electrocardiograph.

The between rater and between device reliability for the rate, QT interval and QRS duration parameters ranged good to very good (ICC = 0.667 – 0.981). The current investigation showed that the reliability of the ECG parameters measured using the smartphone technology ranged from good to very good. This paper serves as support for a technological advancement that will help advance the debate on the utility of ECG testing as part of the athletic pre-participation physical.

Keywords

athletic pre-participation screening, smartphone application, Seattle Criteria, sudden cardiac death, electrocardiogram

Introduction

Sudden cardiac death (SCD) is an uncommon yet tragic problem that exists in competitive athletics. In the United States, the incidence of SCD amongst high school and collegiate athletes is estimated to be 1 in 200,000, with hypertrophic cardiomyopathy (HCM) the most common killer (36%).[1] Approximately 5% of SCD are attributed to arrhythmias such as long QT syndrome (LQT), Wolff-Parkinson-White syndrome (WPW), and Brugada syndrome.[1] Identification of these electrical disorders in an athletic patient has been the topic of discussion amongst sports medicine physicians.

The pre-participation cardiac screen including electrocardiogram (ECG) is a subject of controversy among sports medicine practitioners.[2] Some sports medicine practitioners advocate that the benefits of pre-participation screening including ECG do not justify the risks of false positive test results leading to unnecessary additional workup and lost sport time.[2] Opponents of mass ECG screening have their argument buttressed by studies that demonstrate the difficulty in consistent and correct interpretation of an athlete's ECG, across interpreters of varying medical specialty and education.[3] This can lead to a relatively high rate of false-positive interpretations and unnecessary secondary evaluations.[3,4]

DOI: http://dx.doi.org/10.18590/mjm.2018.vol4.iss2.7

A compelling contrary viewpoint based on evolving knowledge of ECG interpretation and its implementation in the athletic setting has been identified. A recent systematic review and meta-analysis of fifteen papers (over 47,000 athletes) found ECG screening has a significantly higher sensitivity and a lower false positive rate than history or physical exam alone.[5] To further strengthen the argument for the use of ECG in pre-participation screening there is opinion across many levels of sport internationally that the mass implementation of ECG has benefit for the athletic population.[6] The increasing use of ECG in the pre-participation cardiac screening calls for improved agreement in the criteria used to interpret the ECG of the athlete.

To improve ECG interpretation, the European Society of Cardiology (ESC) developed recommendations for physicians to use when analyzing the ECG of athletes.[7] The ESC's recommendations decreased the errors seen between physicians when interpreting the ECG of athletes.

In 2013 the Seattle Criteria were developed with the hope to further decrease the variability of the ECG interpretations of athletes.[8] The Seattle Criteria utilizes a checklist of findings to guide physicians in ECG interpretations.[8] This checklist includes the same criteria as of the European Cardiology Society, as well as expands the guidelines for diagnosis of several electrical disorders of the heart. In 2014 the Refined Criteria created guidelines using a combination of the guidelines of European Cardiology Society and Seattle Criteria, and added some new boundaries. The frequency of abnormal ECG readings have decreased with the use of each criteria: European Cardiology Society 22%, Seattle Criteria 11.6%, Refined Criteria 5.3%.[9] This demonstrates that Refined Criteria has had the most success in decreasing false positives in ECG interpretation by combining the most effective aspects of each criteria system and by standardizing interpretation techniques.

More recently, a newer evaluation protocol has evolved. The International Criteria published in March 2017 is an amalgam of the best evidence to date.[10] It has been endorsed by many governing bodies, including the American Medical Society for Sports Medicine, International Olympic Committee, European Society of Cardiology, and the American College of Cardiology. The International Criteria provides a consensus protocol from which those practicing within the field of cardiologic sports medicine should take direction. Among other items, it provides an algorithm for interpretation of ECG within the athletic subset defining findings as either "normal," "abnormal," or "borderline".

In light of the development of the International Criteria, reducing the burden associated with ECG collection and interpretation may be an effective strategy to make ECG screening more practical for application in athletic screening. This is especially important in the current sports medicine climate. Due to unfortunate tragedy associated with undiagnosed arrhythmias and a perceived lack in resource utilization, it is the authors' belief that it is incumbent upon physicians practicing within the athletic population to strongly consider the implementation of ECG screening during pre-participation physical examination.

Smartphone based technology for ECG screening might further reduce the burden of mass ECG screening. Recently, a single lead ECG accessory (Kardia, AlivCore, San Francisco, CA) has become available for use with smartphones. This device is capable of recording a single lead ECG corresponding to leads I, II, or an anterior precordial lead depending on its placement upon the body. The application of this device in various populations and cardiac conditions has been investigated.[11-18] The Kardia device could represent a cost-effective alternative to the standard 12

lead ECG in detecting life-threatening arrythmogenic pathology where a rhythm strip may be sufficient to detect pathology, such as WPW, LQT, Brugada, etc. The reduced cost and the increased ease of use of these devices will likely lead to an increase in the use of smartphone integrated ECG recording devices by sports medicine providers, in turn leading to greater variability in the level of medical training of the medical practitioner that are interpreting and applying the results of the ECG screening.

The purpose of this investigation was to evaluate the validity and reliability of the Kardia device in measuring rate, rhythm, and the PR, QRS, and QT intervals on ECG strips collected using the Kardia device. We explored the consistency of the interpretation of the ECG amongst clinicians with varied training. The authors hypothesize that the Kardia device will perform comparably to a standard 12 lead ECG and that there will not be a statistically significant difference in the interpretation amongst clinicians beyond the accepted differences already acknowledged.

Methods

Three physicians participated in this investigation: a fellowship trained primary care sports medicine physician, a pediatric cardiologist, and a family medicine physician. Of these three physicians, two were well practiced and aware of the controversy and varying methods of ECG interpretation for the athletic subset. The project was conducted in two phases. The goal of phase 1 was to determine the consistencies of the ECG measures within and between raters. Phase 2 determined the consistency of the ECG measures made between a smartphone ECG base device and a traditional 12 lead ECG in athletes. For phase 1 the ECG was collected from ten volunteers (8 male, 2 female); all were healthy and did not have a history of cardiac disease or injury. For phase 2 ECG data was collected from 12 healthy intercollegiate male basketball athletes of a similar age range to that of phase 1 group. All participants provided written informed consent prior to data collection procedures. The current study was approved by the Marshall University Internal Review Board (IRBNet ID# 826364-1).

Phase 1

The ECG signals were collected using the smartphone based Kardia (AliveCor Inc., San Francisco, CA, USA). One ECG strip was recorded from each participant, 2 copies of each strip were provided to each rater for interpretation.

Phase 2

The ECG signals were collected using 2 devices, the smartphone based Kardia and a traditional 12 lead ECG device (Marquette Case 2, GE Medical Systems, Milwaukee, WI, USA). Raters were presented with 1 copy of the ECG strip from each device

The ECG collection protocol was the same for both devices. The ECG signal was collected for 60 seconds and analysis was performed on the middle 30 seconds of each ECG strip. Participants sat quietly for five minutes prior to the data collection. Data from each device was collected following the manufacturer's instructions by a clinician experienced and trained with the use of each device. All data was collected by the same investigator to ensure consistency. Following collection each ECG strip was identified by a coded identifier number. Lead 1 from the 12 lead and Kardia was used for analysis; lead 1 was chosen due to the ease of collection of lead 1 from the Kardia device. The identification of each ECG strip was removed and replaced by a random identifier prior to ECG analysis. Each rater analyzed all ECG strips. The ECG strips were presented to each rater in predetermined random order; random order was different for each

DOI: http://dx.doi.org/10.18590/mjm.2018.vol4.iss2.7

rater. All rater were blinded to any output other than the ECG tracing and the measurements made by the other raters. Each rater measured rate, rhythm and the PR, QRS, and QT intervals of all ECG strips. The ECG parameters were measured to the nearest millisecond using guidelines based on the rater's specific training in ECG analysis. Raters recorded their measurements on paper data collection forms. Data was collated and entered into the database by the investigator that assigned the random identifier. Data analysis was performed by an investigator that was not active in the assessment in the ECG strips.

Statistical Analysis

The reliability of measures was determined using the Interclass Correlation coefficient (Model 2) for the continuous measures (rate, QT interval and QRS duration) and the Kappa statistic for the nominal data. Bland-Altman plots were produced in order to assess for systematic error.[19] The difference between the first and second measurement for all continuous variables was calculated, a single sample t test was used to test if the differences were different than zero. All statistical calculations were performed using SPSS 22 (SPSS, Chicago, IL), and statistical significance was determined at $p<0.05$. Intraclass correlation coefficients [ICC (2-way fixed)] was used to determine the inter-rater reliability of the continuous variables (rate, QT interval and QRS duration). The ICC value is considered very good for values 0.81–1.00, good for 0.61–0.80, moderate for 0.41–0.60, fair for 0.21 – 0.40, and poor for values below 0.20.[20] The kappa statistic greater than 0.80 is considered as representing excellent agreement, 0.60–0.79 substantial agreement, 0.40–0.59 moderate agreement.[20] Measurement error was calculated with the standard error of measure (SEM) = standard deviation x [$\sqrt{}$(1 - ICC)], which estimates the error about a single measure of a variable. The minimal detectable change (MDC) represents the error when a measure is taken twice (change over time), and was calculated by multiplying the SEM by the square root of 2.[21,22]

Results

Phase 1

The between rater ICC for the heart rate showed excellent reliability (ICC = 0.981, 95%CI 0.955 – 0.995) across the three raters. (Table 1)

Table 1. Between rater measurement parameters, Phase 1

	Mean	STD	SEM	MDC
Rate	71.6	11.7	1.6	2.3
PR interval	138	20.2	9.1	12.8
QRS interval	83	11.9	6.9	9.7
QT interval	352	25.8	11.8	16.7

The between rater ICC for the PR (ICC = 0.798, 95%CI = 0.533 – 0.940), QRS (ICC = 0.667, 95%CI = 0.287 – 0.897), and QT (ICC = 0.790, 95%CI = 0.509 – 0.938) intervals showed good reliability. The within rater ICC, SEM, and MDC values are presented in table 2.

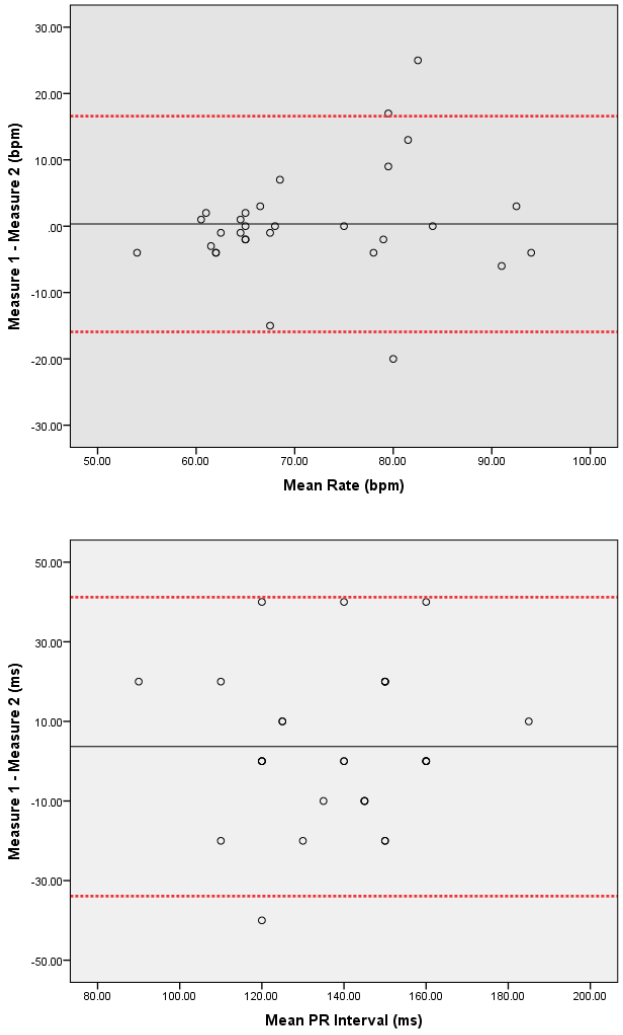
Table 2. Within rater measurement parameters, Phase 1.

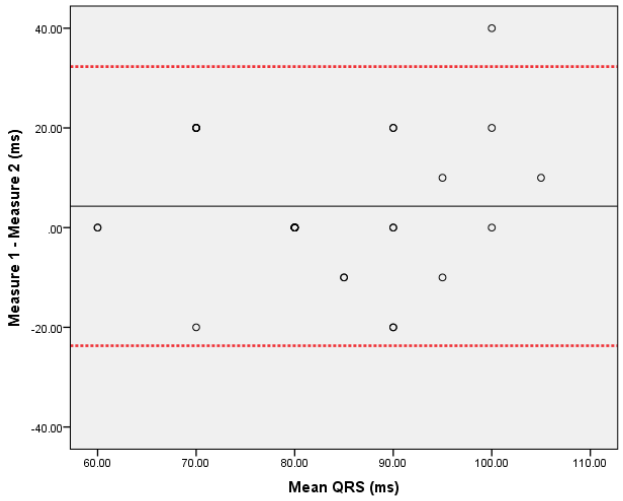
	ICC			SEM			MDC		
	1	2	3	1	2	3	1	2	3
Rate	0.916	0.983	0.948	3.0	1.4	3.1	4.2	2.0	4.4
PR interval	0.776	0.733	0.819	7.8	12.0	8.9	11.0	17.0	12.6
QRS interval	0.087	0.640	0.640	11.8	8.6	5.4	16.7	12.2	7.6
QT interval	0.653	0.344	0.946	14.3	24.4	5.4	20.2	34.5	7.6

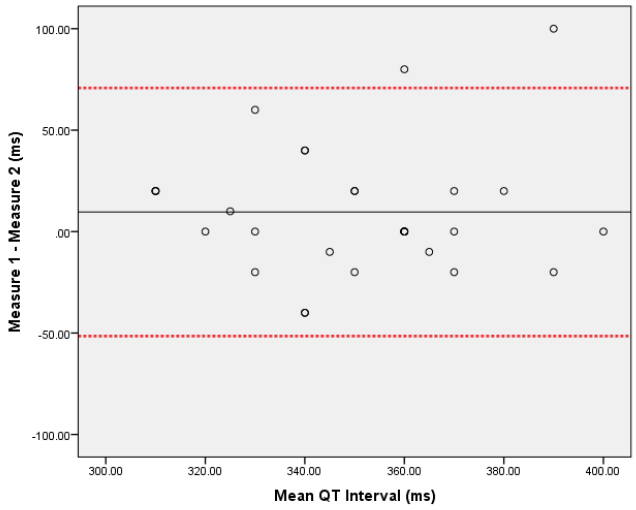
Collapsed across all raters, the agreement of the cardiac rhythm between the 2 strips showed substantial agreement (kappa = 0.692, $p < 0.01$). Individually the raters showed moderate to excellent agreement: rater 1 showed excellent agreement (kappa = 1.00, $p = 0.01$), rater 2 (kappa = 0.615, $p = 0.03$) and rater 3 (kappa = 0.583, $p = 0.01$) showed moderate agreement. Bland-Altman plots (Figure 1) do not show a systematic bias with any of the parameter measures. The differences between the first and second measurements were not statistically different ($p > 0.05$) from zero for any of the parameters measured.

DOI: http://dx.doi.org/10.18590/mjm.2018.vol4.iss2.7

Figure 1. Bland-Altman plots for the repeated Alivcore measures, rate (top left), PR interval (top right), QRS interval (bottom left), QT (interval bottom right).




Measure 1 - Measure 2 (ms)
40.00
20.00
.00
-20.00
-40.00
60.00
70.00
80.00
90.00
100.00
110.00
Mean QRS (ms)


Measure 1 - Measure 2 (ms)
100.00
50.00
.00
-50.00
-100.00
300.00
320.00
340.00
360.00
380.00
400.00
Mean QT Interval (ms)

Phase 2

The reliability of the measures between devices ranged from good to excellent (ICC = 0.678 – 0.980). The between device ICC values ranged from poor to excellent; ICC, SEM, and MCD are presented in table 3.

Table 3. Between device measurements parameters, collapsed across raters Phase 2.

	Mean		STD		ICC		SEM		MDC	
	12 Lead	Alivecore	12 Lead	Alivecore	12 Lead	Alivecore	12 Lead	Alivecore	12 Lead	Alivecore
rate	62.7	61.8	11.2	12.5	0.944	0.979	2.7	1.8	3.7	2.6
PR interval	157	156	21	25	0.673	0.632	12.0	15.2	17.0	21.4
QRS interval	91.1	82.4	13.6	14	0.494	0.678	9.7	7.9	13.7	11.2
QT interval	392	387	41.5	30.1	0.777	0.583	19.6	19.4	27.7	27.5

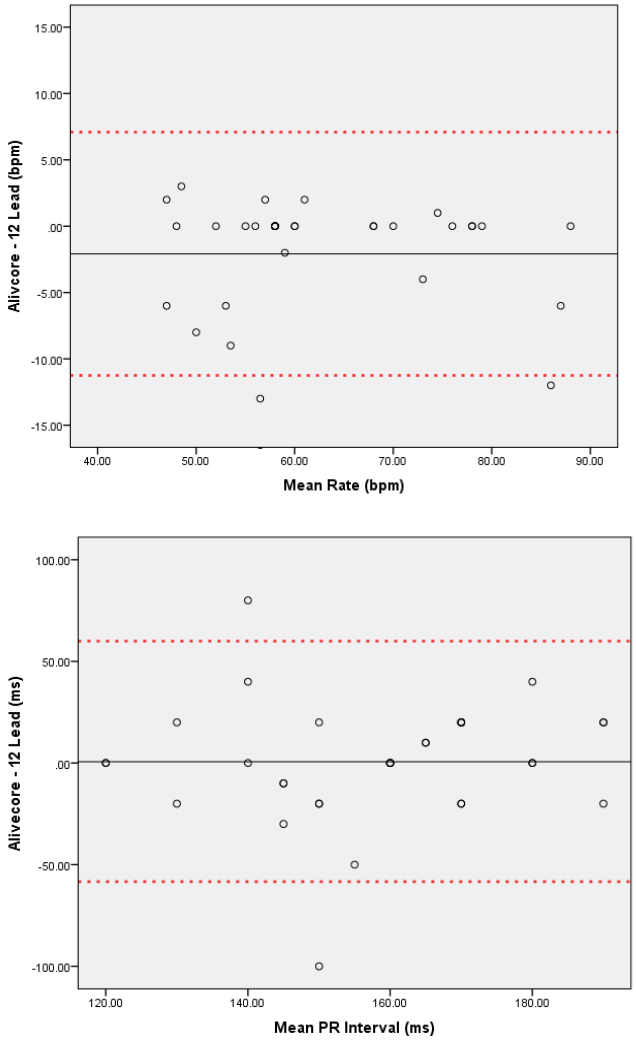
The within rater ICC, SEM, and MDC values are presented in table 4.

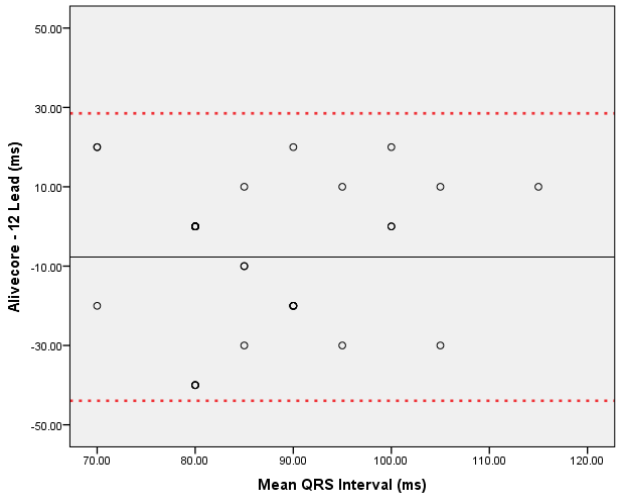
Table 4. Within rater measurement parameters, phase 2

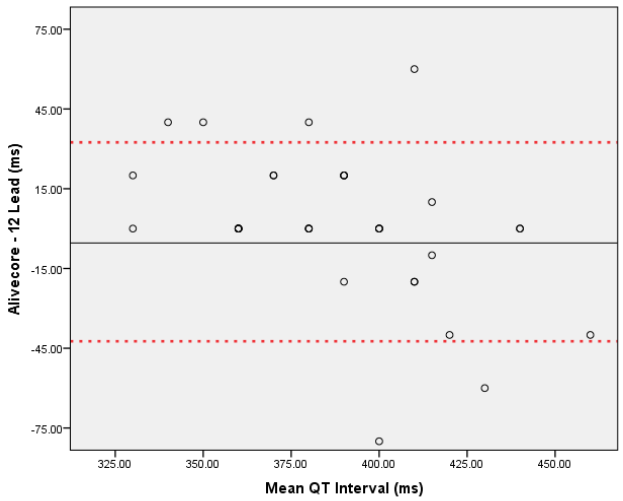
	ICC			SEM			MDC		
	1	2	3	1	2	3	1	2	3
rate	0.952	0.951	0.882	2.8	3.0	3.2	3.9	4.2	4.5
PR internval	0.66	0.631	0.015	11.7	10.9	30.3	16.5	15.5	42.8
QRS interval	0.181	0.327	0.263	12.2	15.3	14.0	17.2	21.7	19.9
QT interval	0.868	0.919	0.182	13.1	8.2	38.7	18.5	11.6	54.7

Collapsed across all raters there was moderate agreement (kappa = 0.467, $p < 0.01$) for rhythm between the devices. The agreement for individual raters was varied; rater one showed poor agreement (kappa = 0.153, p = 0.40), rater two moderate agreement (kappa = 0.455, p = 0.02) while rater three rated all subjects as have a normal sinus rhythm based on the ECG strips collected from both devices. Visual evaluation of the Bland-Altman plots shows an apparent systematic bias for the rate and the PR interval. The difference in the rate measures (mean difference 2.1±4.7 bpm, t=-2.636, p = 0.01) and QRS interval (mean difference = 7.71±18.5ms, t = -469, p = 0.02) between the Kardia and 12 lead were statistically different from zero. The Kardia measurement was higher than the measurement made using the 12 lead, suggesting that the values were consistently overestimated when using the Kardia. The Bland-Altman plots (Figure 2) for the PR and QRS intervals showed a random distribution of the difference between the devices.

Figure 2. Bland-Altman plots for the between device comparisons, rate (top left), PR interval (top right), QRS interval (bottom left), QT (interval bottom right).




Alivecore - 12 Lead (ms)
50.00
30.00
10.00
-10.00
-30.00
-50.00
70.00
80.00
90.00
100.00
110.00
120.00
Mean QRS Interval (ms)


Alivecore - 12 Lead (ms)
75.00
45.00
15.00
-15.00
-45.00
-75.00
325.00
350.00
375.00
400.00
425.00
450.00
Mean QT Interval (ms)

Discussion

The current investigation showed that the reliability of the ECG parameters measured using the smartphone technology ranged from good to very good. When reliability within each clinician was explored the reliability decreased particularly for the QRS and QT interval measures. None of the data analysis included QTc. With respect to QRS, it is reasonable to assert that this difference is due to the narrow measurement window. A difference of 0.05 milliseconds could skew data points widely. It is important to note that none of the interpreters measured QT or QRS to be "abnormal".

The reliability of the ECG parameters between the devices ranged from fair to very good when calculated collapsed across the clinicians. The reliability decreased when calculated between the clinicians. The greatest decreases were found for the interval measures. The difference in the reliability amongst the clinicians may suggest that the clinician's level of training and experience with interpreting ECG strips affects the consistency of these measurements. The systematic errors revealed in the rate and QRS interval measures between the two devices might also suggest that there are differences in the responsiveness of the devices.

At the time of testing all participants were healthy with no known cardiac conditions. No abnormal findings were found during testing for the current study. The 95% confidence interval for all of the smartphone measured ECG parameters fell within the 95% confidence intervals for the published age based norms (Table 5).[23]

Table 5. The 95% confedence intervals for age related normal values and values measured uisng the Kardia wirerless device.

	95% CI *Norm*	Alivecor measure 95%CI SEM
rate	46 - 96 bpm	59 -65 bpm
PR interval	114 -193ms	138 - 174 ms
QRS interval	78 -118 ms	69 -96 ms
QT interval	341 - 455 ms	364 -410 ms

No parameter measures exceeded the limits of European or Seattle Criteria. The results from the twelve basketball players would not produce false positive tests with respect to this single lead.

This paper had many limitations. Given the small sample size of this investigation, readers must apply the results with caution. Stronger conclusions could be made if the investigation was duplicated utilizing larger sample sizes. Utilization of a single lead as a screening device during pre-participation examination is not an accepted practice nor one that is being advocated for by any medical body at the time of this writing. Even the most basic ECG screening requires multiple anatomical leads for analysis, not solely a rhythm strip. It is the opinion of the authors that the use of the Kardia device is not to be advocated for in the pre-participation setting unless solely looking for the aforementioned arrythmogenic pathologies. The authors believe there is a definite role for its use in the on-field/athletic training clinic setting to rule out acute events such as arrhythmia. It is impossible to assert from the current investigation its efficacy in such a setting nor was it the intention of this study to do so.

DOI: http://dx.doi.org/10.18590/mjm.2018.vol4.iss2.7

Another limitation that was seen in this study echoes the known patterns of error associated with ECG interpretation.[24] Discrepancies in interpretation were seen across the three subspecialties represented within the study. Whether this is from the narrow measurement difference resulting in broad statistical difference, interpreter error, or variability within the smartphone device is unknown. The latter argument is made less likely by the fact that these problems are pervasive in the traditional ECG environment already.[3] It is the opinion of the authors that the current study helps to validate the limited data this smartphone device is able to relay to the interpreter.

The implementation of ECG screening within the athletic setting remains controversial. The current investigation showed that the reliability of the ECG parameters measured using the smartphone technology ranged from good to very good. This paper serves as support for a technological advancement that will help advance the debate on the utility of ECG testing as part of the athletic pre-participation physical. Evolution in technology will continue to allow for arguments for and against the utility of pre-participation ECG screening. This evolution of ECG technology may introduce new variables and create new quandaries. The same trends seen in generally accepted means of pre-participation ECG screening can be seen within this study.[23] Further advancements in improvement in consistent interpreter quality, availability of measuring devices, and the reduction of burden associated with further work up following a positive ECG screen have been and remain necessary.

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DOI: http://dx.doi.org/10.18590/mjm.2018.vol4.iss2.7