Comparison of AliveCor KardiaMobile Six-Lead ECG with Standard ECG in Pediatric Patients

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Abstract

Background: The AliveCor KardiaMobile (ACKM) is a remote electrocardiogram (ECG) monitoring device. Little research has been conducted on its accuracy with pediatric patients. This prospective study aims to compare the ACKM six-lead device with a standard fifteen-lead ECG in measuring the QTc, QRS, and axis in pediatric patients.

Methods: Pediatric patients ages 5 to 21 years were enrolled prospectively to have their ECG recorded using an ACKM six-lead device following a recording with the standard fifteen-lead ECG. A pediatric electrophysiologist measured the QTc, QRS interval, and QRS axis for both ECGs. Bland-Altman analysis was performed to assess agreement among measurements.

Results: The study included 141 patients. The mean age was 12.3 ± 4.4 years. Average heart rate was 79 ± 16 bpm. The mean difference in the QTc measurements for a paired standard ECG and ACKM was -0.6 ms [95% confidence interval -48 to 47 ms]. Of the ACKM QTc measurements, 117 (83%) were within 30 ms of the standard ECG. The mean difference in paired QRS measurements was -1.3 ms [95% confidence interval -23 to 21 ms]. Of the ACKM QRS measurements, 134 (95%) were within 20 ms of the standard ECG. The measured axis was the same for 84% of ACKM and standard ECGs.

Conclusions: Over 80% of the ACKM six-lead ECGs produced QTc, QRS, and axis deviation measurements within a clinically useful range of the standard ECG. However, it is not accurate enough to be used consistently in place of a standard ECG for QTc and QRS measurement for pediatric patients.

Introduction

Remote electrocardiogram (ECG) monitoring devices have become increasingly available in recent years [1]. The AliveCor KardiaMobile (ACKM) is one of these devices, which records an ECG on a smartphone-based app. A single-lead form of the device has been on the market for several years.

Much of the early research with this single-lead device focused on adult patients with atrial fibrillation [2,3]. ACKM was shown to have excellent sensitivity and specificity for atrial fibrillation when the tracings were read by electrophysiologists [2]. This single-lead device has been studied less in adults with congenital heart disease and in the pediatric population [4-6]. The SPEAR trial showed that 96% of readings generated by the single-lead ACKM device were of diagnostic quality across sinus rhythm, sinus tachycardia, and supraventricular tachycardia in pediatric patients [5].

Studies with the single-lead ACKM device have explored the utility of the device in measuring QTc intervals in various populations. These studies in adults have been small but endorsed accuracy of QTc measurement with the ACKM device with a standard deviation of error as low as 11 milliseconds (ms) [7,8]. Studies with pediatric populations have reported accuracy of QTc measurement with ACKM, though with a Pearson's correlation coefficient of 0.57 and standard deviation of 20 ms [9,10].

A six-lead version of the ACKM received Food and Drug Administration approval in 2019. Relatively few studies have investigated the six-lead device version. One small study showed the six-lead ACKM device underestimated QTc in twelve of thirteen patients with multidrug-resistant tuberculosis by a mean difference of 3% [11]. Pilot data has also shown good agreement of QTc, PR, and QRS intervals between the six-lead device and a standard twelve-lead ECG in young healthy athletes [12], however, there is no information on the accuracy of the device in a pediatric population

The goal of this prospective study is to compare the diagnostic yield of the ACKM six-lead device compared to a standard fifteen-lead ECG in measuring the QTc, QRS width and axis in pediatric patients. The study also aims to determine if age, weight, birth sex, presence of heart disease, and prior cardiac surgery have an effect of the diagnostic yield of ACKM six-lead QT and QTc intervals.

Material And Methods

Patient Recruitment

A total of 144 pediatric and adolescent patients ages 5 to 21 years who were referred to pediatric cardiology clinic were enrolled prospectively between June 2021 and November 2021. Informed consent was obtained from patients or their families. IRB approval was granted by Columbia University Irving Medical Center. Patients with an implanted cardiac device or an ECG not compatible with QTc measurement were excluded (such as flat T waves or very frequent ectopy). Demographic data was collected, including age, birth sex, body surface area, heart disease, prior cardiac surgery, and prior heart transplant.

ECG Acquisition

Enrolled patients consented to have their ECG recorded using an ACKM six-lead device (AliveCor, San Francisco, California, United States) following a recording with the standard fifteen-lead ECG in a supine position. The ACKM recording was taken directly after the standard ECG when possible. Patients were instructed to place the second digit of each hand on the top leads of the device. Meanwhile, they held the bottom lead of the device against their left thigh just proximal to the knee or medial left ankle, depending on which position was more comfortable. Patients were sitting up to avoid shaking while holding the device against the leg. The ACKM recording was taken for 30 seconds. The ACKM ECG recordings were printed from the app for future analysis. A copy of the standard fifteen-lead ECG was also printed.

ECG Analysis

Two experienced pediatric electrophysiologists read the initial ten paired ECGs in a blinded manner. The intraclass correlations coefficient of 0.91 between their readings indicated strong agreement. The remainder of the ECGs were read in a blinded fashion by one of the two pediatric electrophysiologists. Measurements of QT, RR, and QRS interval using manual calipers and QRS axis for the standard ECG and ACKM ECG were obtained. QTc was calculated using Bazett’s formula.

Statistical Analysis

Descriptive statistics were calculated for patient background data. Bland-Altman analyses were performed to assess agreement among the ECG measurements. Paired T tests were used to determine if binary categorical variables affected ECG measurements and linear regressions were used to determine if continuous variables affected ECG measurements. A two-sample variance comparison test was used to compare margins of error. All analysis was performed in Stata 17.0 BE. Data visualization was performed in Microsoft Excel 16.16.27. P values < 0.05 were considered significant.

Results

Of the 144 patients in the study, three were excluded (two for atrial bigeminy and one for flat T waves on the ACKM readings). Of the 141 patients whose data was analyzed, the average age was 12.3 ± 4.4 years. Forty-two (30%) were age 5 to 9, 62 (44%) were age 10 to 15, and 37 (26%) were age 16 to 21. Fifty-two (37%) were female. Average body surface area (BSA) was 1.44 ± 0.46 m^2. Eighty (57%) patients had heart disease. The most common forms of heart disease were valvular stenosis (10 patients), Tetralogy of Fallot (9), transposition of the great arteries (8), and dilated cardiomyopathy (8). Among the patients in the study, 53 (38%) had a prior cardiac surgery and 14 (10%) had a heart transplant.

ECG Measurement Accuracy

The average heart rate for the ECGs was 79 ± 16 beats per minute (bpm) for the standard ECGs and 86 ± 15 bpm for ACKM ECGs (p<0.01). The average measured QTc interval was 419 ± 28 milliseconds (ms) by the standard ECG and 418 ± 30 ms for the ACKM ECG (p=0.78). The mean difference in the QTc measurements for a paired standard ECG and ACKM was -0.6 ms [95% confidence interval -48 to 47 ms] (Figure 1). Of the ACKM QTc measurements, 117 (83%) were within 30 ms of the QTc from the standard ECG and 90 (64%) were in within 20 ms. The average measured QRS interval was 94 ± 18 ms by the standard ECG and 93 ± 19 ms for the ACKM ECG (p=0.18). The mean difference in the QRS measurements for a paired standard ECG and ACKM was -1.3 ms [95% confidence interval -23 to 21 ms]. Of the ACKM QRS measurements, 134 (95%) were within 20 ms of the QRS from the standard ECG. The measured axis was the same for 119 (84%) of paired ACKM and standard ECG readings.

Modifying Factors

Age and BSA were found to have no association with agreement of standard ECG and ACKM ECG QTc measurements. Birth sex did have an effect (p=0.04) with females having a mean QTc 4.7 ms longer on ACKM than the standard ECG and males having a mean QTc 3.7 ms shorter. Age (p=0.01) and BSA (p=0.02) were found to have a significant association with QRS agreement. Birth sex was not found to have an association with QRS measurement agreement. The 95% confidence range of the Bland Altman analysis for QTc improved slightly when patients with a heart rate difference >20 bpm between standard and ACKM ECGs were excluded (-46 to 40 ms) and remained the same when patients with significant sinus arrhythmia (RR interval difference >20% on a single ECG) were excluded (-49 to 45 ms) (Table 1).

Confidence ranges of agreement were similar for patients with a QTc <460 ms on standard ECG (-48 to 48 ms) to those with a QTc >460 ms (-46 to 35 ms) with no significant differences in the confidence ranges ($p=0.52$). Significant artifact was noted in 49 (35%) of the ACKM ECGs. The confidence ranges of agreement had a larger width on ECGs with artifact (-55 to 56 ms) than those without artifact (-44 to 42 ms), and there was a significant difference in the confidence ranges ($p=0.03$).

Table 1: QTc Agreement – Bland-Altman Analysis

QTc Agreement – Bland-Altman Analysis

Inclusion Criteria		Count	Mean Difference	Min of 95% Range	Max of 95% Range	Range +/- from Mean
All		141	-0.6	-48.0	46.9	47.5
HR Difference >20						
	Yes	18	15.5	-47.8	78.7	63.3
	No	123	-2.9	-46.0	40.0	43.0
QTc >460						
	Yes	13	-5.4	-45.9	35.1	40.5
	No	128	-0.1	-48.2	48.1	48.2
Sinus Arrhythmia						
	Yes	51	2.5	-45.7	50.8	48.3
	No	90	-2.3	-49.2	44.5	46.9
Artifact						
	Yes	49	0.3	-55.3	56.0	55.7
	No	92	-1.0	-43.8	41.6	42.7
Age						
	5-9	42	0.7	-50.9	52.3	51.6
	10-15	62	-2.3	-44.9	40.3	42.6
	16-21	37	0.9	-50.2	52.0	51.1
BSA >2*						
	Yes	13	-6.3	-53.7	41.0	47.4
	No	127	0.2	-47.4	47.7	47.6
Heart Disease						
	Yes	80	-0.6	-46.4	45.2	45.8
	No	61	-0.5	-50.5	49.4	50.0
Surgery						

	Yes	53	0.2	-50.3	50.6	50.5
	No	88	-1.0	-46.8	44.8	45.8
Transplant						
	Yes	14	-3.2	-36.5	30.1	33.3
	No	127	-0.3	-49.1	48.5	48.8

*One patient's BSA was not obtained.

Table 1: Shows QTc interval 95% limits of agreement from Bland-Altman analysis for subgroups within the patient population.

Accuracy of Screening for Prolonged QTc and QRS Intervals

Of the 13 patients with a prolonged QTc >460 ms on standard ECG, 7 patients were correctly identified with a prolonged QTc on ACKM ECG (sensitivity 54%). Of the 128 patients with a QTc <460 ms on standard ECG, 121 patients were correctly identified with a normal QTc (specificity 95%). Of the 15 patients with a prolonged QRS 120 ms on standard ECG, 12 patients were correctly identified with a prolonged QRS on ACKM ECG (sensitivity 80%). Of the 126 patients with a QRS <120 ms on standard ECG, 122 patients were correctly identified with a normal QRS (specificity 97%). Of the 6 patients with a bundle branch block on the standard ECG, 4 (67%) were found to have a bundle branch block on ACKM.

Heart Disease and Post-Surgical Patients

A history of heart disease, cardiac surgery, or transplant were not associated with the changes in the agreement of standard and ACKM ECG measurements for QTc or QRS intervals. Bland Altman 95% confidence ranges for QTc agreement were similar between standard ECG and ACKM measurements for patients with and without heart disease, cardiac surgery, and cardiac transplant. Confidence ranges of agreement were -51 to 49 ms for patients without heart disease and -46 to 45 ms for patients with heart disease. They were -47 to 45 ms for patients without a cardiac surgical history and -50 to 51 ms for patients with a cardiac surgical history. The range for a small group of 14 patients with a transplant were -37 to 30 ms, as compared to -49 to 49 ms for patients without a transplant.

Discussion

The ACKM has been reported to be of great utility for detection of arrhythmias in symptomatic pediatric patients [5,6]; however, the overall accuracy of the ACKM device for QTc measurement did not meet cutoffs for clinical utility. The mean differences between ACKM and standard ECG measurements were very small at -0.6 ms for QTc and -1.3 ms for QRS. However, the ranges of confidence were large. The margin of error of the QTc range of 47.5 ms was too large to be considered clinically useful. In fact, only 64% of the patients had a QTc within 20 ms difference and the ACKM missed 6 of the 13 patients (46%) with QT prolongation. Garabelli et al. were able to show better accuracy of the single-lead ACKM in healthy adult patients with an average difference of 4 ms and a standard deviation of 11 ms (margin of error of 22 ms) [8]. Chung et al. also found that all single-lead ACKM QTc measurements were within 20 ms of a standard ECG, though this was with an adult population of only 5 patients [7]. Studies with pediatric and young adult patients have demonstrated less accurate ACKM results, more similar to our study. In a larger study on pediatric patients with the single-lead ACKM, Karacan et al. reported a slightly larger mean difference in QTc (4 ms) measurements than our study (0.6 ms), with a Pearson's correlation of only 0.57 [9]. Meanwhile a smaller study of 30 elite athletes with a mean age of 18.9 years by Orchard et al. using a six-lead ACKM showed an average difference of QTc of -10 ms with a standard deviation of 18 ms (margin of error 35 ms). The QRS results were slightly better than in our study, with a mean difference of -3 ms and a standard deviation of 7 ms (margin of error 14 ms) [12]. Our study's agreement rate of ACKM QTc measurements with 20 ms of the standard ECG was only slightly lower (64%) than those reported by Garabelli et al. and Beers et al (72% each) [9,13].

We postulated that sinus arrhythmia, variations in patient heart rate between the paired ECG readings, and artifact in the ACKM may have made significant contributions to the inaccuracy of the ACKM. The margin of error of the QTc difference improved slightly when excluding ECGs with significant heart rate differences between the ACKM and standard ECG (margin of error 43.0 ms) and artifact in the ACKM (margin of error 42.7 ms) but not when excluding sinus arrhythmia (margin of error 46.9 ms). However, none of the narrowed populations approached the cutoff for clinical usefulness.

A significant portion of the study population had a history of heart disease, cardiac surgery, or cardiac transplant. The rates are much higher than in similar studies such as the one performed by Karacan et al., in which 7% of patients had congenital heart disease [7]. We hypothesized that these conditions may affect the accuracy of the ECG readings, given that Garabelli et al. found standard deviation of differences in QTc measurements to be much higher in hospitalized patients than healthy volunteers [8]. However, confidence ranges for QTc and QRS measurement were not different in patient populations with and without heart disease, cardiac surgery, and cardiac transplant. This indicates that the device retains its level of accuracy in patients with heart disease and cardiac surgery. The transplant population of 14 patients was too small to draw conclusions.

Of the 144 ACKM ECG readings, only one (0.7%) was excluded for an ECG for which intervals could not be measured. This was for one with flattened T waves, when the corresponding standard ECG did not have flattened T waves. This is better than the 7% rate reported by Karacan et al., which they attributed to artifacts and unclear T wave termination [9]. While accuracy of the ACKM device remained stable with later uses, we encountered some durability issues with the device. Subjectively, it appeared that the device had more difficulty detecting good bare-skin contact with all three electrodes for patients enrolled later in the study. This was particularly true for the left ankle/knee electrode, which lead to the last patients recruited often having to reposition the electrode on their leg multiple times. Signal noise also appeared to be increased in later patient readings, though the filter applied by the device software removed most of the noise. There were no battery issues with the device.

Limitations:

One limitation to this study is that it does not reflect the general pediatric population. Given that it was performed in a pediatric cardiology clinic at a tertiary academic pediatric hospital, large proportions of the study participants had a history of heart disease, cardiac surgery, and cardiac transplant. While the accuracy of the device appeared to be similar between patients with these conditions and those without, the population is still one that has more ECG abnormalities than the general pediatric population. Additionally, there were two limitations in how the ECGs were measured. First, the ACKM ECG was measured after the standard ECG as opposed to concurrently. This was done because it was deemed too difficult for many participants to do both at the same time and we did not want to compromise the standard ECG for the patient’s clinic visit. Additionally, all patients were supine for the standard ECG, while the vast majority of patients were sitting upright for the ACKM ECG. This occurred because most patients had difficulty remaining still and comfortable while trying to record the ACKM ECG supine. This could account for some of the difference in heart rates between corresponding ECGs.

Conclusion

While over 80% of the ACKM six-lead device ECGs produced QTc, QRS, and axis deviation measurements within a clinically useful range of the standard ECG, overall too many ECGs displayed significant variation from the standard ECG for the ACKM device to be clinically accurate in the pediatric population. While the device is reported to be of clinical utility for the detection of arrhythmias in symptomatic patients, it is not accurate enough to be used consistently in place of a standard ECG for QTc and QRS measurement in pediatric and adolescent patients.

Abbreviations

ACKM: AliveCor KardiaMobile

bpm: beats per minute

BSA: body surface area

ECG: electrocardiogram

ms: milliseconds

QTc: corrected QT interval

Statements And Declarations

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Data Availability: If requested, all authors will provide the data or will cooperate fully in obtaining and providing the data on which the manuscript is based.

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Figures

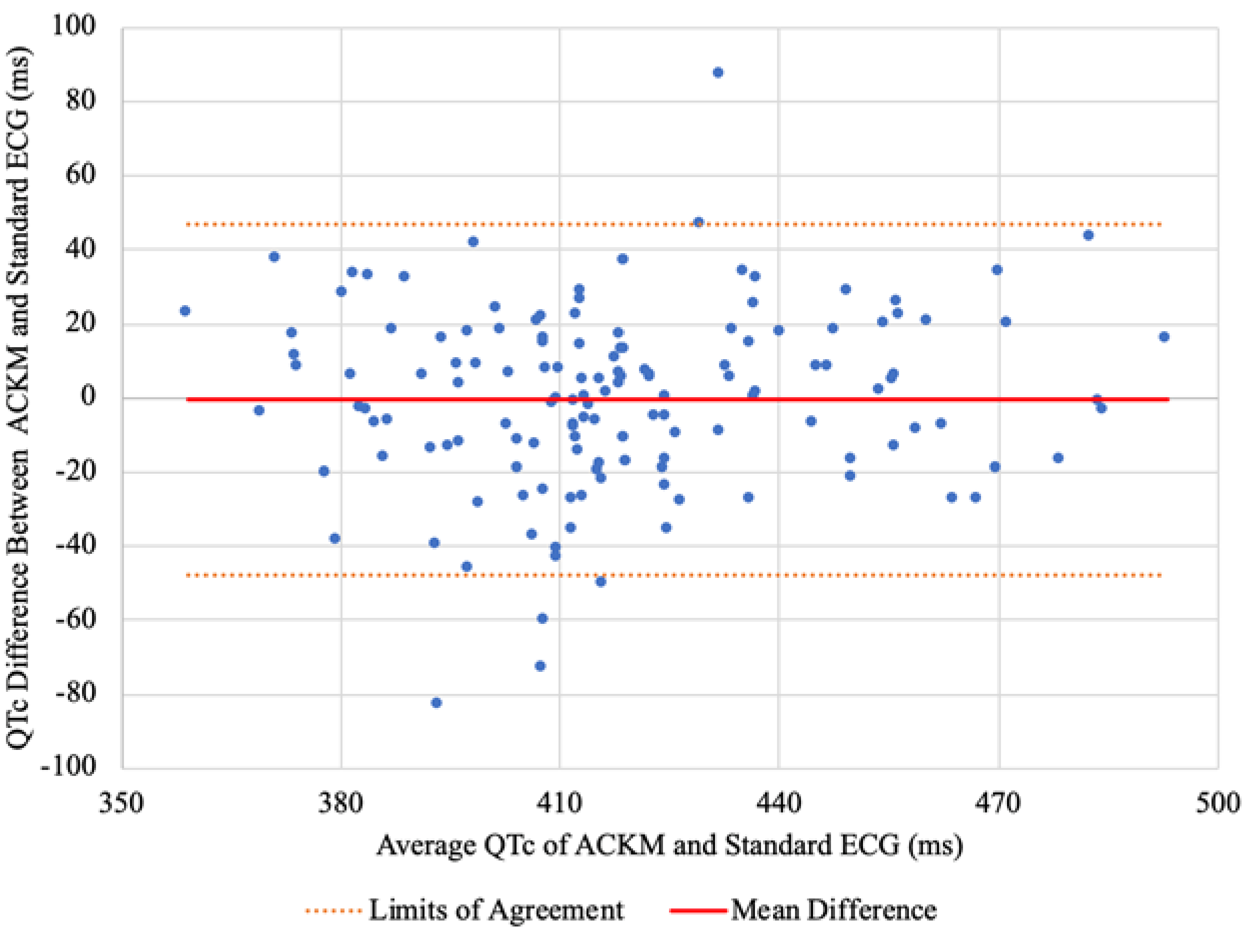

Figure 1

Bland-Altman QTc Intervals

Bland-Altman scatter plot showing the difference in QTc values measured on standard ECG and ACKM for individual patients.