

Validation of a Handheld 6-Lead Device for QT Interval Monitoring in Resource-Limited Settings

Metcalfe JZ, et al. *JAMA Netw Open*. 2024;7(6):e2415576.

Background

Patients with multidrug or rifampin-resistant (RR) tuberculosis (TB) have worse treatment outcomes and higher risks of adverse events from TB medications. One of such adverse events is torsade de pointes, a form of polymorphic ventricular tachycardia.

To reduce this risk, electrocardiographic monitoring of the QT interval is recommended at baseline and during treatment. Patients with a prolonged QT interval above 500 milliseconds have an increased risk of torsade de pointes.

The 12-lead ECG remains the standard tool for monitoring cardiac events. However, it consumes power, time, and human personnel; resources not readily available in resource-limited settings like routine RR-TB treatment settings.

The AliveCor KardiaMobile 6L ECG monitor is a highly portable handheld ECG device *which can accurately represent the 6 limb lead*. It can assess cardiac rate and rhythm, including atrioventricular conduction. It can potentially overcome the barrier to scaling up RR-TB treatment in resource constraint settings.

Objectives

Serial ECG measurements were done with AliveCor KardiaMobile 6L on participants on a six-month regimen of bedaquiline, delamanid, linezolid, levofloxacin, and clofazimin for RR-TB. These measurements were done within 15 minutes after 12-lead ECG recordings, to assess AliveCor KardiaMobile 6L:

1. Diagnostic accuracy
2. Repeatability
3. Feasibility

Methods

This prospective cohort study included 191 patients (age range, 13 to 69 years; mean age, 36 years). It was nested within the BEAT Tuberculosis Trial, a multicenter open-label phase 3 trial that assessed the efficacy and safety of RR-TB drug regimen in South Africa.* Eligible patients had ECG measurements with the 12-lead ECG and AliveCor KardiaMobile 6L at each clinic visit for 6 months.

- Participating hospitals included Jose Person TB Hospital South Africa, and King DinuZulu Hospital Complex South Africa.

Results

OBJECTIVE 1: Diagnostic accuracy

1. At a 480-millisecond QTc threshold, the 6-lead device had 4 false negatives and 9 false positives for a negative predictive value NPV of 99.2% (95% CI, 97.9%–99.8%) and a positive predictive value PPV of 18.2% (95% CI, 2.3%–51.8%)
2. At a 500 milliseconds QTc threshold, the 6-lead ECG device had a NPV of 99.8% (95% CI, 98.8%–99.9%) and a PPV of 16.7% (95% CI, 0.4%–64.1%).

Repeatability

1. The range of variability* of the 6-Lead ECG Device was ± 50.2 milliseconds (coefficient of variation, 6.0%)
2. The range of variability of the standard 12-lead ECG was ± 22.0 milliseconds (coefficient of variation, 2.7%).

Feasibility

1. 75% of nurses reported better ease of use with the 6-lead ECG than the 12-lead ECG.
2. 75% of nurses reported better patient satisfaction with the 6-lead ECG than the 12-lead ECG.
3. 100% of nurses felt the 6-lead ECG would improve clinical workflow.
4. 75% of nurses recommended the 6-lead ECG over the standard 12-lead ECG.

Cost Analysis

A standard 12-lead ECG device (\$3000 - \$7500) costs 20 to 50 times that of a 6-lead device.

- Variability was defined as how much repeated measurements under identical conditions would vary.

Importance to AliveCor

This study demonstrates that the AliveCor KardiaMobile 6L monitor can overcome the barrier to scaling RR-TB interventions in resource-constraint settings by improving clinical workflow in triage settings and increasing reach to more patient groups.

Conclusion

The high negative predictive value of AliveCor KardiaMobile 6L makes it useful as a triage tool in settings with resource constraints.


By reducing the need to perform 12-lead ECG in these settings, AliveCor KardiaMobile 6L can extend QTc assessment to more patients and consequently increase patient-centered care.

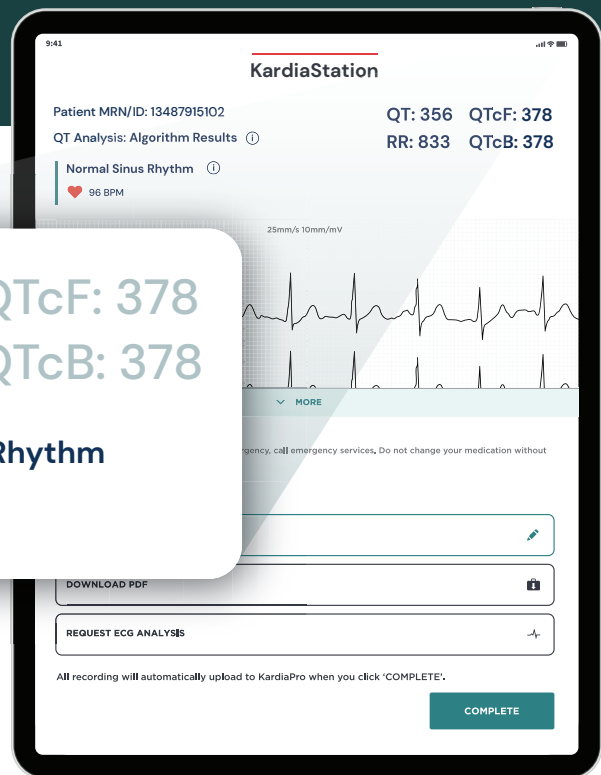
Furthermore, in phase 2 and 3 clinical trials where QTc assessment is a secondary endpoint, AliveCor KardiaMobile 6L can increase reach while minimizing costs.

Nurses were confident that AliveCor KardiaMobile 6L can improve clinical workflow due to its ease of use.



QT: 356 **QTcF: 378**
RR: 833 **QTcB: 378**

Normal Sinus Rhythm
 **96 BPM**



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