Manual QT interval measurement with a smartphone-operated single-lead ECG versus 12-lead ECG: a within-patient diagnostic validation study in primary care

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ABSTRACT

Objective To determine the accuracy of QT measurement in a smartphone-operated, single-lead ECG (1L-ECG) device (AliveCor KardiaMobile 1L).

Design Cross-sectional, within-patient diagnostic validation study.

Setting/participants Patients underwent a 12-lead ECG (12L-ECG) for any non-acute indication in primary care, April 2017–July 2018.

Intervention Simultaneous recording of 1L-ECGs and 12L-ECGs with blinded manual QT assessment.

Outcomes of interest (1) Difference in QT interval in milliseconds (ms) between the devices; (2) measurement agreement between the devices (excellent agreement <20 ms and clinically acceptable agreement <40 ms absolute difference); (3) sensitivity and specificity for detection of extreme QTc (short (<340 ms) or long (≥480 ms)), on 1L-ECGs versus 12L-ECGs as reference standard. In case of significant discrepancy between lead I/II of 12L-ECGs and 1L-ECGs, we developed a correction tool by adding the difference between QT measurements of 12L-ECGs and 1L-ECGs.

Results 250 ECGs of 125 patients were included. The mean QTc interval, using Bazett’s formula (QTcB), was 393±25 ms (mean±SD) in 1L-ECGs and 392±27 ms in lead I of 12L-ECGs, a mean difference of 1±21 ms, which was not statistically different (paired t-test (p=0.51) and Bland Altman method (p=0.23)). In terms of agreement between 1L-ECGs and lead I, QTcB had excellent agreement in 66.9% and clinically acceptable agreement in 93.4% of observations. The sensitivity and specificity of detecting extreme QTc were 94.3% and 99.2%, respectively. The comparison of 1L-ECG QTcB with lead II of 12L-ECGs showed a significant difference (p<0.01), but when using a correction factor (+9 ms) this difference was cancelled (paired t-test (p=0.43) or Bland Altman test (p=0.57)). Moreover, it led to improved rates of excellent (71.3%) and clinically acceptable (94.3%) agreement.

Conclusion Smartphone-operated 1L-ECGs can be used to accurately measure the QTc interval compared with simultaneously obtained 12L-ECGs in a primary care population. This may provide an opportunity for monitoring the effects of potential QTc-prolonging medications.

INTRODUCTION

Frequently, physicians who carry out consultations will have to prescribe medications that may prolong the QT interval (QTi).1-3 QT prolongation increases the likelihood of the malignant ventricular arrhythmia ‘Torsade de Pointes’ and sudden cardiac death, particularly in the presence of risk factors, such as hypokalaemia, use of diuretics, anti-arrhythmic drugs or congenital long QT syndromes.4 5 Obtaining an ECG to measure and monitor QTIs is therefore clinically relevant. Although automated ECG interpretation including QT measurements are available on most ECG machines, these may not be accurate and specialists prefer manual interpretation.6 Importantly, practical guidelines on QT measures and interpretation are available.7
Preferably, general practitioners (GPs) who make ECGs should be able to sufficiently measure and interpret these QTIs. However, the compliance of GPs to recommendations for ECG monitoring in patients on QT prolonging drugs is very low. Logistical challenges may present one hurdle, as not every general practice has the possibility to make a standard 12-lead ECG (12L-ECG) and obtaining 12L-ECGs during home visits can be challenging. As such, the recent introduction of handheld single-lead ECG (1L-ECG) devices may present a welcome solution. They allow immediate ECG recording and require minimal effort by holding a device with two hands for up to 1 min, without the need to undress and attach patches. More recently issued 1L-ECGs provide a smartphone-based technique for rhythm and interval registration. Of all CE certified and FDA approved devices, the AliveCor heart monitor is among those most extensively validated against 12L-ECGs as reference standard. Generally, the device has been studied for accurate detection of atrial fibrillation (AF). Validation studies in which the usability of QT times was assessed are, however, lacking. Only a handful of studies discussed QTI variations. Of those, only one assessed 1L-ECGs and 12L-ECGs simultaneously, which may have accounted for interval variations in the studies who did not record simultaneously. Moreover, all of these studies reviewed selected patient populations (paediatric/cardiology/athletes), which made them less suitable for community-based populations.

In this study we therefore set out to validate a smartphone-operated 1L-ECG device for accuracy of QT measurement with a simultaneously recorded 12L-ECG as reference standard in primary care.

METHODS

We followed the standards for reporting diagnostic accuracy (STARD 2015) for uniform methodological reporting of our methods and findings. All participants provided written informed consent.

Study design

We conducted a cross-sectional, diagnostic validation study using ECG data from the ‘Validation of a mobile bedside ECG Screening and diagnostic Tool for Arrhythmias in general practice’ (VESTA) study, which included 222 patients from 10 participating general practices who underwent a standard 12L-ECG for any indication between April 2017 and July 2018. This was a diagnostic validation study that assessed the validity of 1L-ECGs for the detection of AF and rhythm and conduction abnormalities compared with simultaneously performed 12L-ECGs, assessed by blinded cardiologists, as a reference standard.

In short, patients consulting their GP underwent a 12L-ECG based on routine medical care, simultaneously a 1L-ECG was obtained. A small capturing device containing two electrodes was held for 30 s between the fingers of both hands, corresponding with lead I of Einthoven’s triangle. The recordings of 1L-ECGs and 12L-ECGs were deidentified and stored in an electronic data capturing system (CastorEDC). Patients were at least 18 years old and provided informed consent. Haemodynamically unstable patients, patients with clinical suspicion of acute coronary syndrome, or with a pacemaker were excluded. Baseline variables included demographics and cardiovascular history and medication. Two independent cardiologists screened the 1L-ECGs and 12L-ECG recordings in random order for arrhythmias or conduction abnormalities. A detailed description of the study design is published elsewhere.

Patient involvement

No patients were asked for input in the creation of this article.

AliveCor single-lead ECG

KardiaMobile (AliveCor, Mountain View, CA, USA) is a smartphone-connected, 1L-ECG device that displays ECG-recordings in real time (30 s) using a smartphone application. The recording of 1L-ECGs coincides with a 10 s recording of lead I of 12L-ECGs. The AliveCor device has a sampling rate of 300 /s resulting in a temporal resolution of 3.3 ms. We used the online PDF version of the 1L-ECGs with 200% magnification and a paper speed of 25 mm/s to measure the QT (figure 1).

ECG selection

We excluded patients with incomplete or non-overlapping ECG pairs. Since the QTI can only be measured under optimal conditions, we excluded ECGs with poor technical quality as assessed visually. Patients with no measurable interval of five consecutive RR-complexes were excluded, as this would impede a valid heart rate assessment. ECGs with AF, bundle branch-blocks (BBB) or other arrhythmias were also excluded because unforeseen changes in the repolarisation may occur if the depolarisation changes, which makes interpretation difficult. Furthermore, most QTc formulas are not suitable to calculate the QT time in other rhythms than a stable sinus rhythm.

Reading single-lead ECG, as index test

Two independent readers (LB and LPva) manually measured heart rate, QRS interval and QT interval of the 1L-ECGs without any knowledge of clinical data. All measurements required a motion artefact and ectopic beat-free section of five consecutive RR-complexes, as recommended. We measured the heart rate by taking the average of this free section of the R wave and the next P-wave of the five RR-complexes, in case of high variability the PQ segments were used. We measured the first five QRS and QT complexes to calculate the mean QRS interval and QT interval. The QRS interval was computed from QRS onset to the J-point, the point where the sharp deflections of the QRS complex merge into the ST-segment. Finally, we determined the QT interval using the tangent method. We drew a tangent to the steepest slope of the last limb of the T-wave until it crosses the baseline,
(see figure 1). When the T-wave consisted of two positive segments or was biphasic, the readers chose the end of the highest wave. U-waves that occurred after the T-wave were not incorporated in QT measurement. In cases where disagreement about the end of the T-wave could not be solved through consensus, a third ECG reader (REH) was consulted.

**Reading 12-lead ECGs, as reference standard**

The same two independent readers manually measured heart rate, QRS and QT of randomly ordered 12L-ECGs with a paper speed of 25 mm/s. Blinded for clinical data, they followed the same procedure as described with the 1L-ECGs for setting the baseline, QRS and QT measurements (lead I and II) and frequency (lead II). We chose lead I and II, although QTIs are preferably measured in lead II, a 1L-ECG most closely resembles lead I of the 12L-ECG, and lead I has been proposed as an alternative to lead II in case lead II is uninterpretable.\(^7\) Prior work showed that when manually assessing QTc intervals, 1L-ECG measurements more closely resemble the 12L-ECG’s lead I than lead II.\(^17\)

The QRS and QT measurements were performed in the first five P-QRS-T complexes of lead II and in the number of P-QRS-T complexes present in lead I.\(^7\) If one of the leads I or II was not measurable due to poor baseline, poor T-top quality or premature ventricular or atrial contraction (PVC/PAC), the remaining leads were used for further analysis. A third reader was consulted when disagreement between the two readers about the end of the T-wave could not be solved through consensus.

**QT correction**

We corrected the QTc for heart rate.\(^7\)\(^25\) The primary correction method for heart rate was Bazett’s formula (QTcB: QT/RR\(^{1/2}\)). We also presented Framingham’s formula (QTcFra: QT+0.154 (1−RR)) as secondary correction method.\(^28\)\(^29\)

**Outcomes of interest**

The primary outcome of interest was the absolute mean difference in QTc in milliseconds (ms) between pooled 1L-ECG and 12L-ECG measurements. The secondary outcome was the within-patient interdevice agreement, defined as excellent agreement (<20 ms difference) and clinically acceptable agreement (<40 ms difference) between 1L- and 12L-ECG QTc measurements. Cut-offs for this outcome were based on prior work which showed a 20 ms median QTc difference between 1L- and 12L-ECG, with 20% of all measurements resulting in 40 ms QTc dispersion.\(^30\) The same cut-off for excellent agreement was also used in a prior comparison of manual QTc measurements between AliveCor 1L-ECGs and 12L-ECGs.\(^17\) The tertiary outcome of interest was agreement in detecting a clinically relevant short and long QTc interval (‘extreme QTc’), defined as ≤340 ms or ≥480 ms, respectively, in both men and women.\(^31\)

**Statistical analysis**

We reported continuous data as mean±SD and categorical variables as numbers and percentages. Statistical significance in all analyses was assessed at the 0.05 level. The statistical analysis was performed using IBM SPSS software.
We used three different methods to assess the diagnostic accuracy of QT measurements of 1L-ECGs compared with 12L-ECGs:

1. Primary outcome: we assessed statistical difference using the paired t-test and Bland Altman methods. We calculated the absolute mean difference, SD and 95% CI for heart frequency, QRS, QT and QTc intervals. We plotted the difference with 95% CI of the two measurement techniques against the mean. All of these tests were conducted for QTcB and QTcFra. We expected that a minimum of 63 patients would have to be included to be sufficiently (80%) powered with 5% chance of type I errors, assuming that QTIs (as continuous variable, in ms) on 1L-ECGs would deviate up to 20 ms from 12L-ECGs with a SD of 40 ms. We based these assumptions conservatively on a prior study on manually assessed QTc difference between AliveCor 1L-ECG and 12L-ECG.17

2. Secondary outcome: we presented the percentage of QTc comparisons resulting in excellent and clinically acceptable agreement between 1L-ECG and 12L-ECG leads I and II.

3. Tertiary outcome: We presented 2×2 contingency tables for the presence or absence of extreme QTc intervals on 1L- versus 12L-ECG leads I and II, and determined the sensitivity and specificity of detecting an extreme QTc value on 1L-ECGs with 12L-ECGs as reference standard.

Finally, in case of a significant discrepancy between 12L-ECG measurements (lead I or II) and 1L-ECGs, we explored whether such a difference may have been due to systematic differences in assessment between lead I and II. We developed a correction tool by adding the difference between the QT measurements of 12L-ECGs to the 1L-ECGs, and then reassessed agreement between 1L-ECG and 12L-ECG using the newly acquired correction factor.

RESULTS

Between April 2017 and July 2018, 222 eligible patients were included. We excluded 13 patients (5.9%) for incomplete or non-overlapping ECG-pairs. After visual inspection of the 1L-ECGs and 12L-ECGs, 84 patients (37.8%) were excluded due to poor technical quality (n=25), no measurable heart rate (n=23), no sinus rhythm (n=25) or BBB (n=11). The ECG related exclusion criteria separated for 1L- and 12L-ECGs are listed in online supplemental table 1. The final study population consisted of 125 patients, with 250 simultaneously obtained ECGs, as shown in figure 2. In 7 of the 125 included ECG pairs, one of the leads I or II was excluded due to poor baseline or T-top quality, or due to PVCs/PACs causing arrhythmia. The remaining leads were used for further analysis (see figure 2 for participant flowchart).

Mean age of included patients was 61±14 years, half of patients (n=62, 49.6%) were female. One ECG was obtained because new medication (verapamil) was started, the other ECGs were made because of symptoms (n=61) or were protocol driven (n=63). Regarding cardiovascular medication, 12.0% of the patients used calcium channel blockers (n=15) and 15.2% used beta-blockers (n=19). Baseline characteristics of the study population are shown in table 1.

QTc differences in milliseconds

As shown in table 2, the mean QTcB interval was 393±25 ms in 1L-ECGs and 392±27 ms in lead I of the 12L-ECGs, with a mean difference of 1±21 ms. Comparing QTcB of 1L-ECGs with those of lead II of 12L-ECGs showed a mean difference of 8±22 ms. Table 2 additionally lists the mean and SD of heart rate, QRS and QT of all leads. Comparisons using Framingham’s formula resulted in similar differences between 1L-ECG and lead I and II of 12L-ECGs (online supplemental tables 2 and 3).

Mean QT and QTcB comparison showed no significant difference (p=0.94 and p=0.51, respectively) between 1L-ECG and lead I. However, QT and QTcB measurements in 1L-ECGs differed significantly compared with lead II (p<0.01). There were no statistically significant differences in the comparisons of mean heart rate and
QRS difference between the three analysed leads (see table 3). The Bland Altman analysis detected no significant proportional bias (p=0.23) of QTcB on 1L-ECG versus lead I (see online supplemental figure 1).

There were no significant differences between 1L-ECGs when looking at genders separately. The males and females within our population showed similar outcome measurements between 1L-ECGs (385±26 ms and 401±20 ms, respectively) and lead I (383±28 ms and 400±24 ms, respectively). In online supplemental table 4, heart rate, mean QT, QRS and QTc are listed for males and females.

**Within-patient agreement between 1L-ECG and 12L-ECG**

There was excellent agreement of QTcB in 66.9% of 1L-ECGs compared with lead I, as illustrated by cases within the green lines in figure 3. Of the measurements, 93.4% were within the limits of clinically acceptable agreement, as illustrated by cases within the red lines in figure 3. Comparing uncorrected QT resulted in a higher degree of excellent agreement (71.9%) as well as acceptable agreement (95.9%) than with QTcB.

**Agreement in detecting clinically relevant extreme QTc values**

In comparing 1L-ECG with 12L-ECGs as reference for detecting extreme QTcB values, the sensitivity and specificity for extreme QTcB in 1L-ECGs with lead I as reference were 0% and 99.2%, respectively (see online supplemental table 5 for 2×2 contingency tables for QTcB as well as QTcFra analyses). As shown in figure 3, the majority of cases where 1L-ECG and lead I measurements disagreed on assessing a case as extreme (indicated as blue dots outside of the limits for short and long QTcB, in orange) was within the clinically acceptable agreement between the two devices. Assessing QTcB for 1L-ECGs compared with lead II gave similar specificity (99.2%), with inability to calculate the sensitivity due to the absence of extreme cases on lead II.

**Correction of single-lead QTc**

As shown above, the QTc-interval of 1L-ECGs differed significantly from the QTc-interval of lead II of 12L-ECGs. The mean QTcB of lead I of the 12L-ECGs was 9±17 ms (median=9 ms) shorter than in lead II. We performed a new analysis comparing 1L-ECGs with lead II while adding

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**Table 1 Baseline characteristics of the VESTA QTc study population (n=125)**

| Variable                                      | Subcategory     | Mean, SD | Number (n=) | Percentage (%) |
|-----------------------------------------------|-----------------|----------|-------------|----------------|
| Age (years)                                   |                 |          |             |                |
| Gender (female)                               |                 |          |             |                |
| Obesity (BMI >30 kg/m²)                       |                 |          |             |                |
| Smoking (current)                             |                 |          |             |                |
| Alcohol abuse                                 |                 |          |             |                |
| Hypertension                                  |                 |          |             |                |
| Diabetes                                      |                 |          |             |                |
| Hypercholesterolaemia                         |                 |          |             |                |
| Atrial fibrillation                           |                 |          |             |                |
| Other arrhythmias                             |                 |          |             |                |
| Bradycardia                                   |                 |          |             |                |
| Coronary heart disease                        |                 |          |             |                |
| TIA or ischaemic stroke                       |                 |          |             |                |
| Valvular heart disease                        |                 |          |             |                |
| Heart failure                                 |                 |          |             |                |
| Chronic obstructive pulmonary disease         |                 |          |             |                |
| Peripheral vascular disease                   |                 |          |             |                |
| Chronic renal failure                         |                 |          |             |                |
| eGFR of patients with chronic renal failure   |                 |          |             |                |
| Medication                                    | Sodium channel blocker |          |             |                |
|                                               | Beta blockers    |          |             |                |
|                                               | Potassium channel blocker |          |             |                |
|                                               | Calcium channel blocker |          |             |                |
|                                               | Digoxin          |          |             |                |

BMI, body mass index; eGFR, estimated glomerular filtration rate; TIA, transient ischaemic attack; VESTA, Validation of a mobile bedside ECG Screening and diagnostic Tool for Arrhythmias in general practice.
9 ms to the QTc of 1L-ECGs. Comparing the QTc +9 ms of 1L-ECGs with lead II showed a non-significant difference of both the t-test (p=0.43) and Bland Altman (p=0.57). There were now 71.3% of cases with excellent agreement, and 94.3% with clinically acceptable agreement between 1L-ECG and lead II. The specificity using the cut-off values for detection of short or long QTc was now 100%, with inability to calculate the sensitivity due to absence of extreme cases on lead II.

DISCUSSION
Smartphone-operated 1L-ECGs showed good diagnostic accuracy for QT measurement versus concomitantly obtained 12L-ECGs in a primary care population, as assessed by a low absolute mean QTc difference and high rate of cases with excellent and clinically acceptable interdevice agreement. In detecting clinically significant extreme QTc intervals, however, 1L-ECG showed poor sensitivity in this low-prevalent population. The degree of agreement between the QTc of 1L-ECGs was higher when compared with lead I than compared with lead II of 12L-ECGs, with QTc intervals of 1L-ECGs being significantly shorter compared with lead II. The use of a correction factor obtained by adding the QTc difference between leads I and II of the 12L-ECG to 1L-ECG QTc values led to improvement of the comparison between 1L-ECG and lead II. Overall, these results suggest that smartphone-obtained ECGs can be used for QT assessment in primary care, however caution is warranted in cases where an extreme QT is suspected.

Strengths and limitations
This study represented primary care patients who underwent ECG for any clinical indication as assessed by local

Table 2  Comparison of the mean heart rate, QTcB, QT and QRS in single-lead ECGs versus leads I and II of 12-lead ECGs

|                      | 12-lead ECG | Lead I | Lead II |
|----------------------|-------------|--------|---------|
| Heart rate (/min)    |             |        |         |
| n                    | 125         | 125    |         |
| Mean                 | 73          | 72     |         |
| SD                   | 13          |        | 13      |
| QRS (ms)             |             |        |         |
| n                    | 125         | 121    | 122     |
| Mean                 | 85          | 83     | 84      |
| SD                   | 8           | 10     | 10      |
| QT (ms)              |             |        |         |
| Mean                 | 360         | 360    | 369     |
| SD                   | 29          | 33     | 32      |
| QTcB (ms)            |             |        |         |
| Mean                 | 393         | 392    | 401     |
| SD                   | 25          | 27     | 26      |

QTcB, corrected QT interval by Bazett’s formula.

Table 3  Comparing single-lead ECGs with leads I and II of 12-lead ECGs in paired samples

|                      | Mean diff. | SD mean | SE mean | 95% CI of diff. | Lower | Upper | T     | Sig. (2-tailed) |
|----------------------|------------|---------|---------|-----------------|-------|-------|-------|----------------|
| Heart rate (/min)    | Single-lead vs Lead I | 0.79    | 5.36    | 0.48            | -0.16 | 1.74 | 1.65 | 0.10           |
|                      | Lead II    |         |         |                 |       |       |       |                |
| QRS (ms)             | Single-lead vs Lead I | 1.55    | 11.35   | 1.03            | -0.50 | 3.59 | 1.50 | 0.14           |
|                      | Lead II    | 1.13    | 11.36   | 1.03            | -0.91 | 3.17 | 1.10 | 0.27           |
| QT (ms)              | Single-lead vs Lead I | 0.13    | 19.13   | 1.74            | -3.57 | 3.31 | 0.07 | 0.94           |
|                      | Lead II    | 9.39    | 20.99   | 1.90            | -13.16 | -5.63 | 4.94 | <0.001         |
| QTcB (ms)            | Single-lead vs Lead I | 1.29    | 21.32   | 1.94            | -2.55 | 5.12 | 0.66 | 0.51           |
|                      | Lead II    | 7.78    | 21.89   | 1.98            | -11.70 | -3.85 | 3.92 | <0.001         |

diff., difference; QTcB, corrected QT time by Bazett’s formula; Sig. (2-tailed), two-tailed significance of t-value; T, t-value.
QT measurement has been recommended over autocorrelation rather than the left hand.16 Such measurements showed no indication for more severe disagreement between relevant. We have tried to cope with this limitation by providing the Bland Altman plot and p-value where we saw no indication for more severe disagreement between 1L-ECG and 12L-ECG towards the clinical extremes of QTc range. Further research is however needed to assess the validity of 1L-ECG for diagnosing extreme QTIs in primary care patients at higher risk of clinically relevant extreme QTc values.

Comparison with prior studies
Only a limited number of studies have previously evaluated the accuracy of QTc interval assessment using 1L-ECGs with 12L-ECGs as reference standard. Earlier validation studies used different smartphone-operated 1L-ECG devices, Alivecor10 17 20 and ECG Check.19 In line with prior studies, our work showed that the QT and QTc intervals in 1L-ECGs more closely resembled those in lead I of the 12L-ECGs. The mean QTcB of our population (393±25 ms) was comparable to the healthy volunteers (398±3 ms) of Garabelli et al.17 The difference in QTcB measurements between lead I of 12L-ECGs and 1L-ECGs (1±21 ms) in our work also corroborates with Garabelli et al. (4±11 ms),17 but had been much higher in another previous study on the AliveCor versus 12-lead ECG.10

Our comparison of lead II with 1L-ECGs showed a significant difference. Haverkamp et al19 also demonstrated a significant difference in QTc, although it was not clear whether this involved lead I or II. In contrast, Garabelli et al.17 observed no significant differences between 1L-ECGs and any of the leads of a 12L-ECG. Only the QT and corresponding QTcB in lead II showed a significant difference from 1L-ECGs. This implies that heart rate and QRS interval had no significant influence. Similar to Haberman et al.16 our study revealed smaller differences between 1L-ECGs and 12L-ECGs in heart rate and QRS, than in QT and QTc.

Garabelli et al reported 72% of their QTc times to be in excellent agreement.17 Our percentages were similar for QT (71.9%). After QTc correction, our percentages were slightly lower for QTcB (66.9%). We chose to add the category of clinically acceptable agreement as well based on previous work where QTc difference between devices remained <40 ms in 80% of cases.39 We were aware that a difference of 40 ms between 1L-ECG and 12L-ECG may have a consequence for clinical assessment when occurring near the limits of long or short QT, for example, on whether or not dofetilide can be started. We therefore reported on the cases where interdevice disagreement resulted in different clinical conclusions, and what proportion of such cases had <40 or even <20 ms difference between the devices.

Consistent with Viskin et al.,35 our results on detecting clinically relevant extreme QTc values (≤340 or ≥480 ms) showed longer QTc intervals measured in women than in men. However, the number of cases with abnormal QT in our sample was limited, and this has likely limited the ability to validly compare these results to previous work.

QT interval correction
We used Bazett’s formula for QTc calculation since it is the most commonly used formula. In addition, we
presented the results of Framingham’s formula in the supplemental material since this method was reported to be superior for rate correction. QTcB showed lower rates of excellent and clinically acceptable agreement than QTcFra in our analyses, which could indicate that the correction of heart rate by Bazett had a negative effect on the agreement. VanderBerk et al also concluded that Framingham’s linear formula showed better results in QT-correction. A second difference between the QTc formulas concerned the Bland Altman method. Despite corresponding paired t-tests, this method presented a significant difference using QTcFra and no significant difference using QTcB. This should indicate correct measurement of the QTcB of 1L-ECGs compared with lead I and minor measurement differences between the two when using QTcFra. We were not able to identify any other explanation for this difference than the formula itself.

Implications for clinical practice and future directions

QT measurement is an essential part of medicine, given the risk of ventricular arrhythmias in short or prolonged QTc time. Unfortunately, QT measurements are challenging as automatic measurements can overestimate the QTc interval and manual measurements are difficult to perform and to interpret for physicians. Considering that conventional QT measurements are cumbersome, the use of a 1L-ECG could lower the threshold to perform QT measurements in daily practice. This simplicity is supported by Garabelli et al who stated that using the two-handed technique in 1L-ECGs is perhaps the easiest method to obtain an ECG. Likewise, young subjects preferred 1L-ECGs over 12L-ECGs, with an increasing need for assistance in elderly. Therefore, similarity between the QTc of 1L-ECGs and 12L-ECGs shown by our results is relevant for the potential use of easy-to-perform measurement equipment in clinical practice. Here, the use of an automatic algorithm for QTc measurements in 1L-ECGs would make the use even more practical. Further research could focus on the validity and use of automatic interval assessment in 1L-ECGs. An important point to mention here is that the 1L-ECG can be considered an easy method to use, but the ECG must be of a good quality to measure the QT time. The user will have to look at this critically, because it is not possible to resort to another lead, as is the case with a 12L-ECG.

The use of QT time influencing medication poses a risk, just as patients with underlying congenital long QT syndrome are exposed to this risk as well. QT measurements with 1L-ECGs could contribute to the implementation of a standard baseline measurement and a second measurement after the start of medication. This could improve timely notification of a potentially fatal condition. In addition, the 1L-ECG could potentially assist in the initiation of various antiarrhythmic drugs, such as dofetilide or sotalol, which currently requires extensive clinical monitoring. Prior work has already showed the potential of using AliveCor for this purpose in newly treated dofetilide patients.

Future work could focus on examining cost-effectiveness and the best way to implement 1L-ECGs in primary care. Such studies may concentrate on the measurement and interpretation of QTc times in 1L-ECGs by GPs. Based on Postema et al, we expect that even inexperienced ECG readers will be able to accurately distinguish normal and extended QTc times when using the tangent technique. However, this will require further research on the best formulas for QT correction and suitable cut-off values for QTc time in 1L-ECGs.

CONCLUSION

Rhythm strips obtained from AliveCor’s 1L-ECGs can be used to accurately measure the QTI compared with simultaneously obtained 12L-ECGs in a cohort of primary care patients. However, before 1L-ECGs can be implemented for QT measurement in primary care, further work is needed on the measurement and interpretation of the QT(c) interval by GPs, and to extend validation to primary care populations at higher risk of clinically relevant QTc extremes.

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Contributors JCLH, EPMK and REH designed the initial study protocol model and collected the data. LB, WAML and REH developed the theoretical framework of the current study. LB and LPvA performed the measurements, REH supervised the measurements. JRdG interpreted the ECGs. LB processed the data, performed the analysis and designed the figures. WAML, REH supervised the process and act as guarantors for the overall content. PGP, JSSGJ, EPMK, JCLH, WAML and REH contributed to the interpretation of the results. LB and LPvA wrote the final manuscript with input from all authors.

Funding This work was supported by the Department of General Practice of the Amsterdam UMC, University of Amsterdam.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study protocol was approved by our institution’s Medical Ethical Review Committee (VESTA study, 2017_023).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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