ELECTROPHYSIOLOGY
Original Paper

https://doi.org/10.24207/jca.v37il.3507

Comparison of one-patch and standard 12-lead electrocardiogram

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ABSTRACT

Pre-connected and positioned patch devices have attempted to simplify the electrocardiogram (ECG) testing process. However, these devices have not been extensively tested and compared with standard ECG systems. The purpose of this study was to compare a novel patch-based ECG device with a standard 12-lead ECG system in order to determine clinical equivalence. Study participants underwent two consecutive ECG tests in a randomized fashion. ECG measurements (heart rate, PR, RR, QRS, QT intervals) were compared between the standard 12-lead ECG and the one-patch ECG. Paired t-test analysis was used for the comparisons conducted using GraphPad Prism. A total of 30 participants underwent the ECG testing (80% female; mean age 35 ± 16 years). One participant presented with first degree AV Block. All other participants were in normal sinus rhythm/sinus arrhythmia. There were no statistically significant differences identified in heart rate, PR interval, RR interval, QRS interval, and QT interval ($p > 0.05$) between the one-patch ECG and standard 12-lead ECG. These findings suggest that one-patch devices may provide equivalent ECG measurements compared with conventional 12-lead systems. Given the advantages of a one-patch, pre-positioned ECG system, this technology shows promising potential for cardiovascular screening.

KEYWORDS: Electrocardiogram; Medical Devices; Technology.

INTRODUCTION

The 12-lead electrocardiogram (ECG) is one of the most widely used non-invasive tests for diagnosing cardiac arrhythmias and cardiovascular screening. However, a standard 12-lead ECG requires the placement of electrodes in specific anatomical locations for accurate interpretation. There is evidence of electrode misplacement among clinicians, particularly in the chest leads[1,2]. Incorrect electrode cable connection is another common error experienced in clinical settings[3]. Electrode misplacement and cable connection errors may lead to abnormal changes in wave morphology, simulating arrhythmias and infarction[4]. Therefore, accurate ECG interpretation has significant clinical implications.

Technological advancements have attempted to simplify the ECG testing process and reduce procedural errors. The latest technological developments include glove-based ECG systems[5], wireless mobile-compatible devices[6], and pre-positioned patch devices[7,8]. The one-patch design allows clinicians to capture a full 12-lead ECG without having to connect 10 separate electrodes. Pre-connected and pre-positioned patch devices may reduce electrode placement error

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Received: Jan. 25, 2024 | **Accepted:** Aug. 07, 2024

rates and ECG acquisition time[7,9]. Furthermore, patients lacking ECG training may be able to record their own ECGs at home and transmit those results to their cardiologist for interpretation. Nevertheless, these one-patch devices have not been extensively tested and compared with standard ECG systems.

The objective of this study was to compare a novel patch-based ECG device (QT Medical PCA 500®) with a standard 12-lead ECG system (Quinton Q-Stress®) in order to determine clinical equivalency. Specifically, heart rate, PR, RR, QRS, and QT intervals were compared between the two ECG devices.

METHODS

One-patch ECG device

The PCA 500® is an ECG patch device manufactured by QT Medical, a company based in Diamond Bar, California, USA (Fig. 1). The device has been granted approval by the United States Food and Drug Administration (FDA) for use in adult and pediatric populations. The single patch consists of pre-positioned chest and right-leg electrodes. The main patch is pre-connected to the right arm, left arm, and left leg electrodes. A compact recorder is connected to the main electrode patch and transmits ECG results wirelessly (via Bluetooth) to iOS and Android devices. A built-in rechargeable battery provides up to 16 hours of continuous use. ECG data is stored in a HIPAA-compliant cloud, where clinicians can view and download reports.

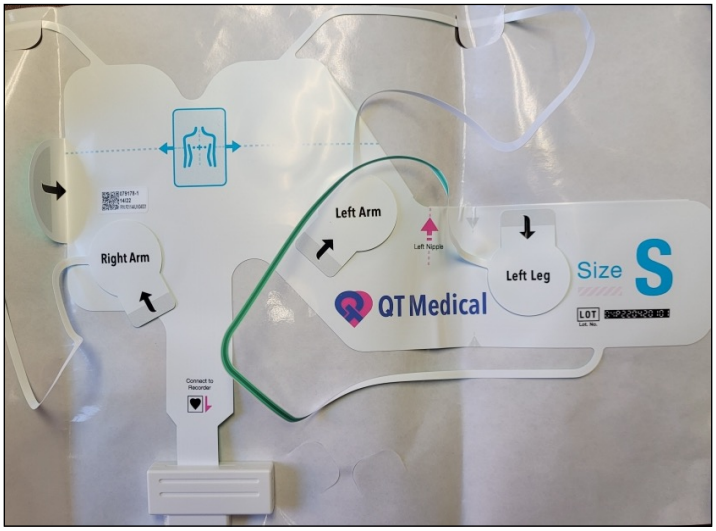

Figure 1. One-patch ECG device
Source: Elaborated by the authors.

Participants

After obtaining Institutional Review Board approval, faculty, staff, and students at a Mid-Atlantic University were invited to participate in the study via email announcements. All participants completed an Informed Consent Form and Health History Questionnaire before the study procedures. Adults aged between 18 and 65 years were eligible to participate in the study. The exclusion criteria consisted of the following: 1) Known electrolyte abnormalities or ingestion of medication which has the potential to cause electrolyte imbalance (e.g. diuretics, potassium supplements); 2) Congestive heart failure; 3) History of renal and hepatic impairment; 4) Acute illness on the day that the ECGs were to be acquired; 5) Ingestion of medication which could affect the heart rate and rhythm; 6) Presence of dermatological disease which may affect the skin sites for electrode application; and 7) Implanted pacemaker or automated implanted cardiac defibrillator (AICD). A total of 30 participants completed the study.

Study procedures

Each participant was required to attend the laboratory on one occasion for testing, which consisted of height and weight measurements, as well as two sequential ECG measurements: 1) Standard 12-lead ECG; 2) One-patch ECG. All ECG testing was conducted with the participant in a supine position on an examination table. The participants underwent ECG testing in a randomized order, with some participants receiving the one-patch ECG first and others receiving the standard ECG first. ECG preparation consisted of cleaning the skin with alcohol wipes at the site for electrode placement. The participants were instructed to assume a supine position on the examination table, breathe normally, and refrain from movement or talking during the ECG test. The standard 12-lead ECG was recorded using a Quinton® Q-Stress system manufactured by Welch Allyn. Standard ECG electrodes were positioned following Mason-Likar placement, with leg electrodes in the lower abdominal quadrant and arm electrodes in the infraclavicular fossa. The one-patch ECG was recorded using a PCA 500® device manufactured by QT Medical (Fig. 2). The one-patch device uses a pre-positioned chest electrode patch that consists of individual hydrogel sensors. The electrodes on the right arm, left arm, and left leg were connected to the main patch, which was in turn connected to an ECG recording device.

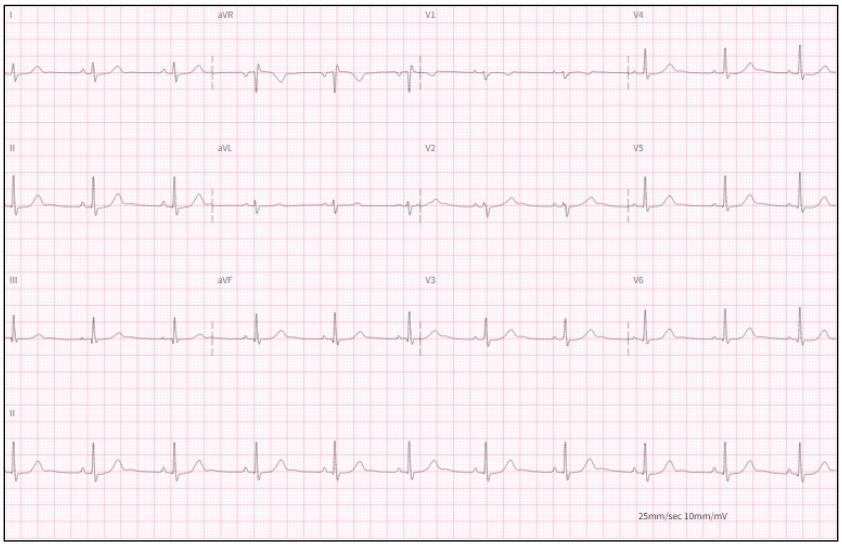

Figure 2. Sample ECG from one-patch ECG device
Source: Elaborated by the authors.

Data analysis

A comparison was conducted between the standard 12-lead ECG and one-patch ECG with regard to the measurement of various cardiac parameters, including heart rate, PR, RR, QRS, and QT intervals. Paired t-test analysis was used for the comparisons. Using paired t-tests at $\alpha = 0.05$ & $\beta = 0.80$ to detect an effect size of 0.45, G*Power (Kiel University, Germany) software 3.1.9.7 estimated sample size of 30 for this study. A p-value of less than 0.05 was considered statistically significant. All data analysis was conducted using Prism (GraphPad Software, Massachusetts, USA).

RESULTS

Participant characteristics

Participant characteristics are listed in Table 1. A total of 30 participants (24 females and 6 males, age range 18 – 64 years) completed this study. Only one participant presented with first degree AV Block. All other participants were in normal sinus rhythm/sinus arrhythmia during the assessment. No injuries or adverse events were reported during testing.

Table 1. Participant characteristics (n = 30)

Variable	Mean ± SD
Age, yr	35.4 ± 16.8
Height, cm	165.9 ± 8.9
Weight, kg	69.9 ± 19.0
BMI, kg/m^2	25.3 ± 6.2

Source: Elaborated by the authors.

ECG Measurements

Descriptive and inferential outcomes for ECG measurements are reported in Table 2. There were no statistically significant differences identified in heart rate, PR interval, RR interval, QRS interval, and QT interval between the one-patch ECG and standard Q-Stress ECG (Fig. 3) (all $p > 0.05$).

Table 2. ECG measurements obtained via one-patch and standard q-stress system

Variable	One Patch (Mean ± SD)	Q-Stress (Mean ± SD)	Mean Difference (Mean ± SD)	*p* value	η^2	95% CI
HR[a], bpm	72.86 ± 13.22	72.76 ±1 2.38	0.10 ± 2.83	0.424	0.001	-1.16 - 0.96
PR interval, ms	151.20 ± 23.95	150.3 3± 25.93	0.87 ± 7.29	0.519	0.014	-3.59 - 1.85
RR interval, ms	849.10 ± 151.44	853.00 ± 137.57	3.90 ± 39.54	0.593	0.009	-10.87 - 18.67
QRS interval, ms	90.47 ± 12.35	90.00 ± 11.74	0.47 ± 4.93	0.304	0.009	-2.31 - 1.37
QT interval, ms	378.93 ± 28.95	379.00 ± 30.10	0.07 ± 4.03	0.464	0.000	-1.44 - 1.57

[a]HR, heart rate, [b]PR, P wave to R wave; RR, R wave to R wave; QRS, Q wave to S wave; QT, Q wave to T wave.
Source: Elaborated by the authors.

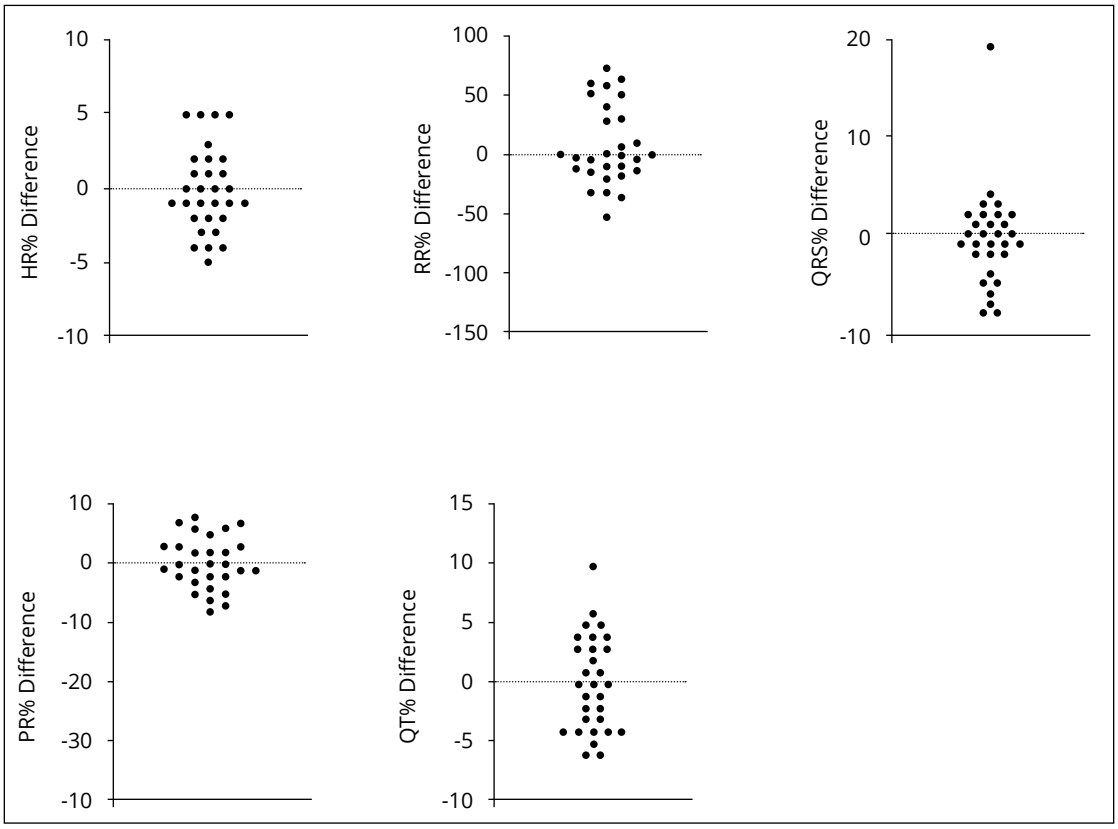

Figure 3. HR, RR, QRS, PR, and QT percent differences between one-patch device and standard system
Source: Elaborated by the authors.

DISCUSSION

The results of this study provide evidence a one-patch, pre-positioned, ECG device may provide equivalent ECG measurements compared with a standard 12-lead ECG. These findings have several implications for clinical practice. Accurate ECG interpretation requires precise electrode placement. Despite adequate training and experience, ECG placement mistakes in clinical practice still occur[1-3]. A one-patch, pre-positioned electrode may help reduce these placement mistakes, while providing equivalent measurements of key ECG intervals. Moreover, prompt diagnosis via ECG is essential in emergency interventions[10]. Previous research has identified a significant advantage to a pre-positioned ECG device was improved efficiency, with reductions in electrode placement and total overall duration of the ECG procedure[7]. Furthermore, the use of pre-positioned electrodes may also improve ECG procedure consistency and allow individuals to obtain accurate ECG recordings with minimal training. In fact, one study found parents were able to capture medical-diagnostic quality ECGs on their newborn infants using a similar one-patch device[8].

Another study of 1000 patients found 92.9% completed their own clinical quality ECGs at home using a one-patch device[12]. This current study builds on previous literature by providing additional evidence a one-patch ECG device may provide equivalent ECG measurements compared with a standard 12-lead ECG in adult populations. These findings support additional ECG accessibility and availability as medical technology continues to evolve.

Limitations

One potential limitation is the impact of physiological variability on ECG interpretation. In order to minimise this potential impact, timing between both ECG measurements was kept as short as possible. Another limitation is evident in the composition of the study sample. Although a power analysis was conducted in order to ensure an adequate sample size for statistical analysis, the overall sample size of 30 is still considered relatively small. Participants were predominately female (80%) and free of cardiovascular disease. Sex differences in ECG measurements have been reported in the literature[11]; therefore, future research should investigate these differences using new ECG technology. Furthermore, it remains unclear whether differences in ECG measurements would have been detectable in populations with cardiovascular disease. There was no ST analysis conducted in this study and only normal electrocardiograms were analyzed. However, a similar study involving 100 subjects referred from the Emergency Department and Cardiac Lab for ECG testing found comparable results between testing methods[7].

CONCLUSIONS

A 12-lead ECG obtained via a one-patch device was found to be equivalent to a conventional ECG system in terms of measuring heart rate and various intervals in healthy adults. These results are consistent with those of previous studies, which found clinical equivalency between the two systems in various age groups and populations[7,8]. Given the advantages of a one-patch, pre-positioned ECG system, this technology shows promising potential for cardiovascular screening.

CONFLICT OF INTEREST

Nothing to declare.

AUTHOR CONTRIBUTIONS

Substantive scientific and intellectual contributions to the study: Townsend Z. and Werner T.; **Conception and design:** Townsend Z.; **Data analysis and interpretation:** Townsend Z. and Werner T.; **Article writing:** Townsend Z. and Werner T.; **Critical revision:** Townsend Z.; **Final approval:** Townsend Z. and Werner T.

DATA AVAILABILITY STATEMENT

All data sets were generated or analyzed in the current study.

FUNDING

Not applicable.

ACKNOWLEDGMENTS

Not applicable.

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