Journal of Cardiovascular Diseases & Diagnosis

Barr, J Cardiovasc Dis Diagn 2019, 7:5

Research Article Open Access

Comparison of Accuracy and Diagnostic Validity of a Novel Non-Invasive Electrocardiographic Monitoring Device with a Standard 3 Lead Holter Monitor and an ECG Patch over a 24 hours Period

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Received: October 04, 2019; **Accepted:** October 14, 2019; **Published:** October 21, 2019

Abstract

Conventional 24-hour Holter monitoring is the most widely used ambulatory electrocardiographic (ECG) monitoring method to detect cardiac arrhythmias. However, such devices are cumbersome to wear, with multiple wires and patches which limit patients during daily activities.

In a study of 31 participants, we evaluated the effectiveness of QardioCore, a novel electro-cardiographic monitoring device with a convenient design without leads and patches, in generating rhythm strip data that fulfill the requirements of clinical quality and accuracy when evaluated against two comparison devices: A standard three lead Holter monitor (sub-group 1) and an ECG patch (sub-group 2), over 24-hour period.

Contrasting the ECG recordings taken with the QardioCore ECG Monitor and the comparison devices has not highlighted any differences considered clinically relevant or statistically significant. The regression analysis of the RR intervals between QardioCore and the Holter monitor and ECG patch reported a correlation of 0.95 ($p<0.05$) with a R-squared of 0.90. Patient gender and age did not affect the relative performance of the QardioCore ECG monitor with the two comparison devices. Within sub-group 1, the R-squared of the RR intervals between QardioCore and the Holter monitor was 0.87, while within sub-group 2, the R-squared of the RR intervals between QardioCore and the ECG patch was 0.96.

This study demonstrated that the QardioCore ECG monitor, a small, comfortable and easy to use ECG recording system, is a clinically valid tool that can be used to accurately identify rhythm disorders compared to a standard Holter monitor and ECG patch.

Keywords: QardioCore; Cardiac rhythm; Electrocardiograph; ECG patch

Introduction

Cardiac arrhythmias, such as atrial fibrillation is relatively common and routinely go undiagnosed because they are often asymptomatic and yet are often associated with adverse outcomes such as embolic stroke [1,2]. Moreover, asymptomatic arrhythmia event management is expensive, costing upwards of $26 billion annually for atrial fibrillation in the United States alone [3]. Ambulatory electrocardiographic (ECG) monitoring with a Holter monitor is the mostly widely used method to detect cardiac arrhythmias for a variety of symptoms and conditions since its introduction in the 1960s [4,5]. However, Holter monitoring solutions are limited by the patient convenience they offer, as many are bulky in size, require leads, and generally present an obstacle to a variety of daily activities [6,7].

The QardioCore ECG Monitor (manufactured by Qardio, Inc., San Francisco, CA, USA), by virtue of its small size, low-profile and design without external leads or wires and without adhesive patches, offers patients a "wearing" experience, with minimal disruption in most daily activities. This allows patients to overcome the recurrent difficulties with traditional electrocardiographs related to patient compliance, electrode disconnections caused by perspiration and movement, and skin irritation caused by adhesives patches [8].

In this study we evaluated the effectiveness of the QardioCore ECG Monitor in generating rhythm strip data in an ambulatory setting that fulfill the requirements of clinical quality and accuracy, with the purpose of clinically validating the QardioCore ECG Monitor's effectiveness for reliable cardiac rhythm diagnosis. This investigation is based on a study group of 31 participating patients, subdivided in two sub-groups: sub-group 1 simultaneously recorded ECG data with the QardioCore ECG Monitor and with the Novacor Vista Plus Holter Monitor (Novacor Vista Plus, Cedex, France), while sub-group 2 simultaneously recorded ECG data with the QardioCore ECG Monitor and with the iRhythm ZIO patch (iRhythm Technologies, Inc, San Francisco, CA, USA). All patients were requested to wear their set of ECG monitors for 24 hours [9].

Both the The iRhythm ZIO patch and the Novacor Vista Plus are FDA-cleared and CE-marked continuous ECG monitors and the latter has been, for many years, a commonly used Holter monitor.

Research Methodology

Between December 11, 2017 and January 12, 2018, 31 patients referred to the Cardiology Department of Russells Hall NHS Hospital were enrolled prospectively in a consecutive fashion.

All patients were 18 years or older, capable of providing informed consent, and referred for rhythm monitoring for routine indications including palpitations and known rhythm problems. There were no patient exclusion criteria applied. The study personnel recording the patient ECG orally presented each participant with the study aims and methods. If the patient affirmed interest in participating in the study, then they were provided with Informed Consent and Authorization for Release of Protected Health Information (PHI) for Research forms to participate for written recording of participant informed consent.

Each participant was then assigned a de-identified ID consisting of two numbers. This ID was written at the top of the consent form and used to label all copies of the participant's ECG data and utilized in any subsequent referencing of that patient's data. The numbers were assigned in ascending sequential order.

Study participants were fitted for continuous and simultaneous ECG recording with a QardioCore ECG Monitor and either a 3 lead Holter Monitor (sub-group 1) or an ECG patch (sub-group 2), and the ECG recording was activated simultaneously on both devices. 22 patients were assigned to sub-group 1 and 9 patients were assigned to sub-group 2.

Patients descriptive statistics were used to summarize the composition of the group of patients participating in the study. The reviewer performed rhythm categorization and measured and correlated the ECG RR duration across the two systems. A standard chi-squared test was used to confirm statistical significance. QardioCore ECG monitors were provided free of charge by Qardio, Inc.

Group						
Gender	**Participants**			**%**		
Male	19			61%		
Female	12			39%		
Total	31			100%		
Age (years)	**Group**		**Male only**		**Female only**	
Median age	62		63		51	
Average age	59		62		54	
Min age	23		31		23	
Max age	85		80		85	
Age distribution (years)	**Group**		**Male only**		**Female only**	
	Participants	**%**	**Participants**	**%**	**Participants**	**%**
30 or less	2	6%	0	0%	2	17%
Between 30 and 45	6	19%	3	16%	3	25%
Between 45 and 60	5	16%	3	16%	2	17%
More than 60	18	58%	13	68%	5	42%
Total	31	100%	19	100%	12	103%
Sub-group 1 (simultaneous CardioCore and 3-lead bolter)						
Gender	**Participants**			**%**		
Mate	11			50%		
Female	11			50%		
Total	22			100%		
Age (years)	**Sub-group**		**Male only**		**Female only**	
Median age	63		63		53	
Average age	61		67		54	

Min age	23		53		23	
Max age	85		80		85	
Age distribution (years)	**Sub-group**		**Male only**		**Female only**	
	Participants	**%**	**Participants**	**%**	**Participants**	**%**
30 or less	2	9%	0	0%	2	18%
Between 30 and 45	3	14%	0	0%	3	27%
Between 45 and 60	3	14%	2	18%	1	9%
More than 60	14	64%	9	82%	5	45%
Total	22	100%	11	100%	11	100%
Sub-group 2 (simultaneous Qardiocore and ECG patch)						
Gender	**Participants**			**%**		
Male	8			89%		
Female	1			11%		
Total	9			103%		
Age (years)	**Sub-group**		**Male only**		**Female only**	
Median age	58		64		49	
Average age	56		57		49	
Min age	31		31		49	
Max age	78		78		49	
Age distribution (years)	**Sub-group**		**Male only**		**Female only**	
	Participants	**%**	**Participants**	**%**	**Participants**	**%**
30 or less	0	0%	0	0%	0	0%
Between 30 and 45	3	33%	3	38%	0	0%
Between 45 and 60	2	22%	1	13%	1	100%
More than 60	4	44%	4	50%	0	0%
Total	9	100%	8	100%	1	100%

Table 1: Descriptive statistics of the group, sub-group 1, sub-group 2.

Results

Of the 31 study participants, 61% were male and 39% were female. Median participant age was 62 years. The study group age ranged between 23 and 85 years of age, with 58% participants more than 60 years old. The median age was 63 years for male participants, and 51 years for female participants.

The first sub-group, consisting of 22 patients equally distributed between male and female participants, with males and female having a median age of 63 and 53 years, respectively, wore simultaneously a standard 3 lead Holter monitor and a QardioCore wireless ECG monitor. The second sub-group, consisting of 9 patients, included only one female participant, with males having a median age of 64 and the female being aged 49, wore simultaneously an ECG patch and a QardioCore ECG monitor. A review of the descriptive statistics of the study group and of sub-groups 1 and 2 is shown in Table 1.

All patients in sub-group 1 and in sub-group 2 were asked to simultaneously wear both devices assigned to them for 24 hours. Of the 31 participants, 5 failed to record sufficient ECG time with one or both devices and were excluded from the analysis: 4 of these participants were in sub-group 1 with the Holter monitor, and 1 of these participants was in sub-group 2 with the ECG patch. Of the 26 participants with sufficient ECG recording time, 18 were part of sub-group 1, and 8 were part of sub-group 2. Each participant served as their own control as they wore QardioCore and another system simultaneously. QardioCore rhythm data and data from Holter

monitor and the ECG patch reports were read in a blinded fashion by experienced electrophysiologists unaware of the findings in the other corresponding ECG recordings.

The objective of the study was to compare the rhythm findings from each device. In addition to rhythm categorization, the ECG RR intervals were correlated between QardioCore and the reference system in each of the two sub-groups. The correlation analysis of the RR intervals between QardioCore and the Holter monitor and ECG patch is shown in Figure 1.

The RR intervals were measured at the average heart rate seen for each respective patient in the first 24 hours of measurement of the study and reported a correlation of 0.95 ($p<0.05$) with a R-squared of 0.90. Patient gender and age did not affect the relative performance of the QardioCore ECG monitor with the two comparison devices. Within sub-group 1, the R-squared of the RR intervals between QardioCore and the Holter monitor was 0.87, while within sub-group 2, the R-squared of the RR intervals between QardioCore and the ECG patch was 0.96.

Discussion

In this study of 31 participants, we compared the continuous ECG monitoring performance of a novel non-invasive electrocardiographic monitoring device with simultaneous wearing over a period of 24 hours with a 3 lead Holter monitor and an ECG patch.

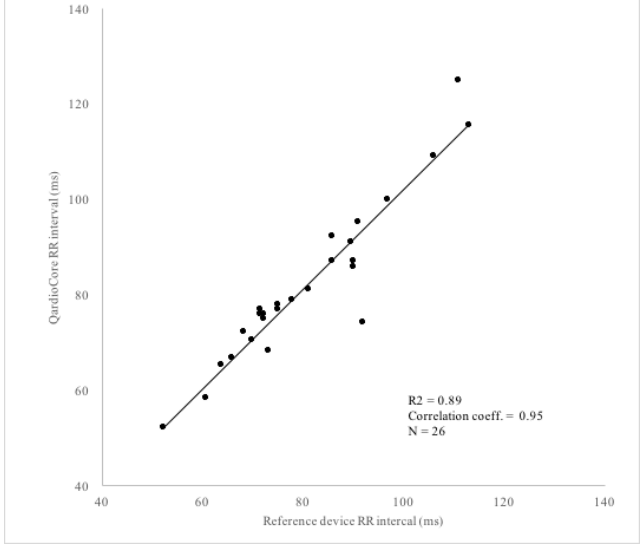

Figure 1: Correlation of RR intervals for the Qardiocore ECG monitor with 3 lead Holter monitor and ECG patch.

Contrasting the ECG recordings taken with the QardioCore ECG Monitor and the comparison devices has not highlighted any differences considered clinically relevant or statistically significant.

The QardioCore ECG Monitor, by virtue of its design without external leads and adhesive patches promises to offer an enhanced experience to patient, with greater comfort and compliance, and this study has shown its diagnostic effectiveness for ECG recording in ambulatory settings when compared to Holter monitors and ECG patches.

Conclusion

This study demonstrated that the QardioCore ECG monitor, a small, comfortable and easy to use ECG recording system, is a clinically valid tool that can be used to accurately identify rhythm disorders compared to a standard Holter monitor and ECG patch.

Future Investigation

Benefits of QardioCore ECG remote real-time analysis and reporting for extending Holter monitoring.

Conflicts of Interest

There are no conflicts of interest for the present study.

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