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The quality of ECG data acquisition, and diagnostic performance of a novel adhesive patch for ambulatory cardiac rhythm monitoring in arrhythmia detection☆

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ABSTRACT

Background: Short and long ambulatory electrocardiographic monitoring with different systems is a widely used method to detect cardiac arrhythmias. In this study, we aimed to evaluate the effectiveness of a novel monitoring device on cardiac arrhythmia detection.
Methods: We used two different protocols to evaluate device performance. For the first one, 36 healthy subjects were enrolled. The standard 12-lead, 24-h Holter monitoring and the novel single lead electrocardiogram (ECG) Patch Monitor (EPM) device (BeyondCare®, Rooti Labs Ltd., Taipei, Taiwan) were simultaneously applied to all subjects for 24 h. The quality of ECG data acquisition of novel system was compared to that of standard Holter. The second phase included 73 patients that were referred from our outpatient arrhythmia clinic for evaluation of their symptoms relevant to the cardiac arrhythmias. Advanced algorithms, statistical methods (cross-correlation method, Pearson's correlation coefficient, Bland-Altman plots) were used to process and verify the acquired data.
Results: The overall average beat per minute correlation between BeyondCare® and standard 12-lead Holter was found 98% in 33 healthy subjects. The mean percentage of invalid measurements in BeyondCare® was 1.6% while the Holter's was 1.7%. In the second protocol of the study, prospective data from 67 patients who were referred for evaluation of their symptoms relevant to cardiac arrhythmias, showed that the mean BeyondCare® wear time was 4.7 ± 0.5 days out of five total days per protocol. The mean analyzable wear time was 93.6%. The water-resistant design enabled 73.5% of the participants to take a shower. 7.3% of participants had minor skin irritations related to the electrodes. Among the patients with detected arrhythmia (40.2% of all patients), 29.6% had their first arrhythmia after the initial two days period. A clinically significant pause was detected in one patient, ventricular tachycardia was detected in four patients, and supraventricular tachycardia was detected in 15 patients. Paroxysmal atrial fibrillation was identified in seven patients. Three of them had their first episodes after the second day of monitoring.
Conclusion: BeyondCare® Patch was well-tolerated and allowed prolonged time periods for continuous ECG monitoring, may result in an improvement in clinical accuracy and detection of arrhythmias by cloud-based artificial intelligence operating system.

Introduction

Cardiac arrhythmias are associated with critical adverse outcomes, such as syncope, embolic stroke and heart failure [1,2]. To prevent these complications, comprehensive evaluation and treatments are recommended for patients presenting with symptoms relevant to the cardiac arrhythmias [3].

Standard 24–48 h Holter monitoring has been a cornerstone for diagnosing symptomatic and asymptomatic events in clinical practice

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for a long time [4,5]. The limitations of Holter monitoring are a relatively brief monitoring duration resulting with a low diagnostic yield, the impossibility of transmitting real-time data to attending cardiac unit and an inconvenient design for the user [6]. In some Holter devices, it is time-consuming for physicians to review raw and processed electrocardiogram (ECG) data and edit the final report.

External loop recorders (ELRs), which extend the period of ambulatory monitoring by saving only the ECG recordings when the patient activates loop recorder properly during the clinical event, may have a higher diagnostic yield [7,8]. When ELR findings are inconclusive, or palpitations are severe and infrequent, with an inter symptom interval >30 days, implantable loop recorders (ILR) may be useful. ILRs are also indicated to the evaluation of patients with recurrent syncope of uncertain origin [9,10]. However, the use of ILRs generally has been limited because of higher costs and the need for a minimal surgical procedure.

The studies for more convenient and prolonged continuous ambulatory ECG monitoring have resulted in development ECG patch monitoring devices (EPM) which are capable of continuously recording ECG signals up to seven or 14 days [11–13]. Their low-profile wireless design and mostly water-resistant properties allow patients to participate in almost all activities of daily living. The first studies have been demonstrated that EPMs can enable clinicians to diagnose arrhythmic events better and can be worn for a prolonged duration with minimal side effects [14–16]. Cloud-based operating systems can also provide dynamic, timely, central solutions to improve EPM operating system via feedbacks from end-user physicians.

In the present study, we aimed to verify the performance of a novel, rechargeable and reusable EPM device (Fig. 1; BeyondCare®, Rooti Labs Ltd., Taipei, Taiwan) for ambulatory ECG monitoring compared with standard 24-h Holter monitoring in healthy people. We also aimed to analyze the diagnostic yield of BeyondCare®, to detect cardiac arrhythmias in a prolonged ambulatory cardiac rhythm monitoring up to five days in the patients referred for evaluation of their symptoms relevant to the cardiac arrhythmias.

Materials and methods

In this study, we used two different protocols having a prospective design. The first protocol aims to verify the performance of BeyondCare® compared with a standard 24-h Holter monitoring (Schiller Medilog FD 12 Plus, Schiller AG, Baar, Switzerland). In the second protocol, we investigated the arrhythmia detection rate, analyzable wear time and patient compliance of BeyondCare® for cardiac monitoring up to five days. Koç University Ethics Committee approved the protocols, and all the enrolled participants gave informed consent to participate in the study.

Device characteristics

BeyondCare® is a small device (Fig. 1A) consisting of an integrated sensor system, a microelectronic board with memory storage and an internal rechargeable battery inside. The rechargeable battery gives the advantage of multiple usages for the same or another patient.

BeyondCare® can be used both in the recording or real-time monitoring mode. BeyondCare® can make continuous ECG monitoring for up to three days in 500 Hz and up to seven days in 250 Hz frequencies with 24-bit high resolution. It has a trigger button to create a tag that enables the patient to give feedback about what he/she feels. Proprietary algorithms analyze recorded data, and it can generate a patient's ECG monitoring final reports based on analyzed data. Final reports are created after the physician's review and editing. Then, the reports are sent to referring physicians. BeyondCare® is the same as RootiRx®; a specific trademark uses in Turkey.

BeyondCare® has a Conformité Européenne (CE) mark and Food and Drug Administration (FDA) clearance.

First protocol of the study

Thirty-six healthy willing subjects were enrolled in the first protocol of the study from October 2016 to January 2017 in the Cardiology Department of Koç University Hospital, Istanbul, Turkey. Baseline characteristics of the subjects were recorded. Exclusion criteria were age 18 years or below, any known skin allergy, the presence of any known heart disease and cardiac risk factors such as hypertension and diabetes mellitus, a pacemaker or implantable defibrillator or pregnancy.

After preparation of the skin, BeyondCare® device was applied horizontally over the left upper pectoral region of the subject's chest using two ECG electrodes that it is appropriate for long-term monitoring (Fig. 1B). The subjects classically wore the 12-lead Holter device simultaneously. Both devices were activated. All subjects were instructed about the device usage and their daily activities.

After completion of 24 h of ambulatory monitoring, both devices were removed, and participants were asked to tell about their device preference for their daily routine activities and if they had any skin irritations by completing a short questionnaire.

The standard 24-h Holter's ECG records were downloaded from the device memory to the PC based local Holter system, and after that, the records were processed and analyzed by the software. Similarly, BeyondCare® devices were returned at the end of each monitoring period. The recorded data of BeyondCare® were transmitted to the cloud-based operating system. All endpoints in the cloud were protected by secure access and login (Secure Socket Layers (SSL)/Transport Layer Security (TLS) endpoint security + user authentication). The data were processed according to the BeyondCare® algorithms in the

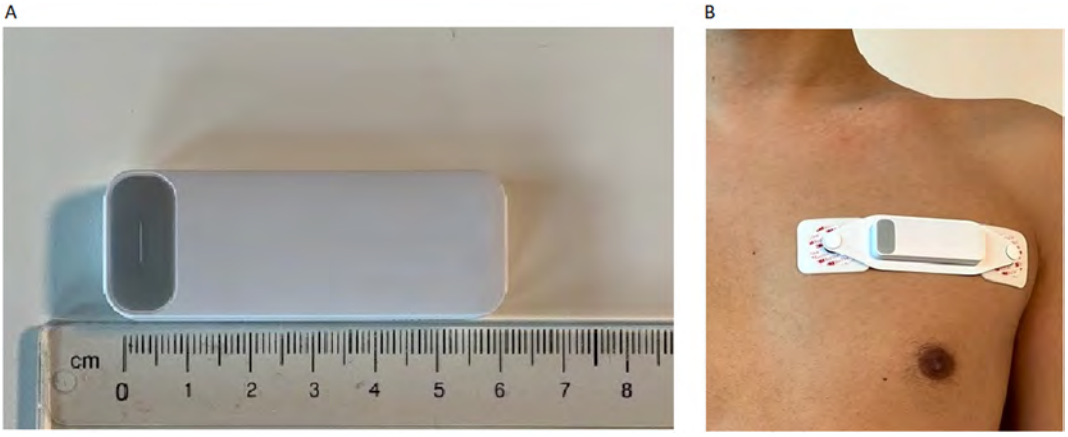

Fig. 1. A: Size of BeyondCare® EPM device in centimeters. 1.B: Body location of the BeyondCare® EPM Device applied with BeyondCare® patch (Rooti Labs Ltd., Taipei, Taiwan) and wet electrodes (Red Dot 2570®, 3M Health Care, St. Paul, Canada).

BeyondCare® cloud system. A physician involved in the study reviewed and edited Holter and BeyondCare® data to create the final reports. Only allowed physicians could reach the final reports.

The duration of monitoring was calculated as the total wear time, which was from the point of activation to the point of the last recorded analyzable signal. Analyzable signal time was defined as the proportions of the total wear time to the time that the ECG signal is interpretable.

Second protocol of the study

Between July 2017 and February 2018, we prospectively included 73 ambulatory patients who were referred to outpatient arrhythmia clinic for evaluation of their symptoms relevant to the cardiac arrhythmias. Inclusion criteria included capable of providing informed consent and able to comply with continuous ECG monitoring for up to five days. Exclusion criteria were age 18 or below, any known skin allergy, a pacemaker or implantable defibrillator. 6 patients were also excluded from the final statistical analysis because they had >20% artifact in total analyzable signal time.

BeyondCare® was applied for monitoring time of five days. Patients' baseline characteristics and clinical information were recorded. After completion of the monitoring period, the ECG data were subsequently extracted from the device. Final reports were created as mentioned in protocol one. The duration of wear time, analyzable signal time, the number and type of arrhythmias were documented. Clinically significant arrhythmias were defined as detection of any one of five arrhythmias, including supraventricular tachycardia (≥ 3 consecutive supraventricular beats, not including atrial fibrillation or flutter), ventricular tachycardia (≥3 consecutive ventricular beats), atrial fibrillation/flutter (any duration), pause ≥3 s, and atrioventricular block (second or third-degree atrioventricular block).

For patients with paroxysmal atrial fibrillation (PAF), the atrial fibrillation (AF) burden was calculated as the proportion of the analyzable signal time that consisted of AF. Symptomatic events were evaluated according to the patients' diary or recorded tagging.

Data analysis and statistics

In the first protocol, the sampling rate of the 12-lead Holter was 250 Hz, while the sampling rate of BeyondCare® EPM device was 500 Hz. Since the data sampling rates and the initial start-up moments

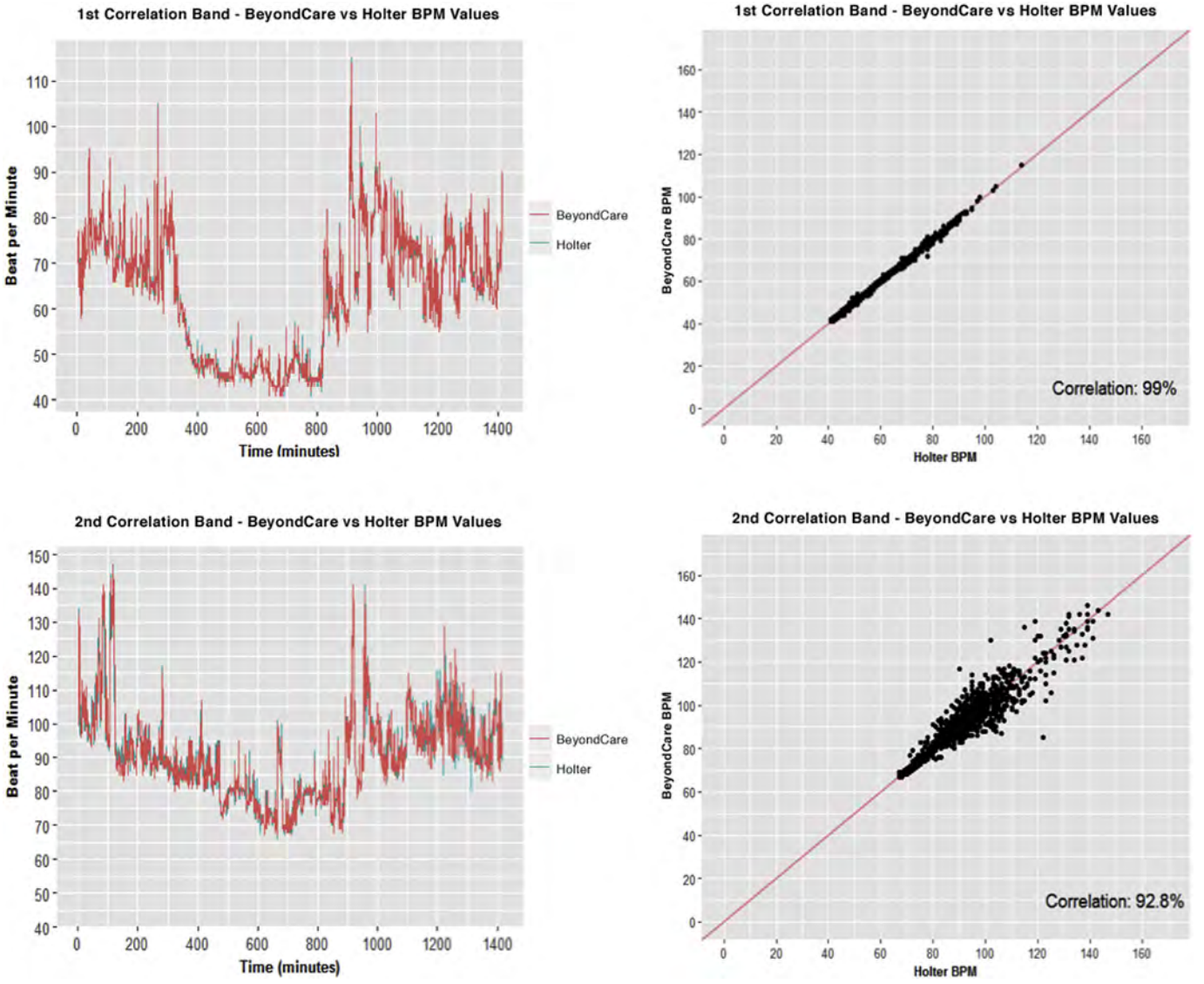

Fig. 2. On per beat-to-beat correlation study, the two-correlation band graph examples are given above for the I- 95%-100% and II- 90%-95% of correlations. In the first correlation band group, the average beat per minute (bpm) correlation of 27 patients was 99%. In the second correlation band group, the average bpm correlation of six patients was 92.8%. The average of 12-lead Holter invalid measure were 2% and 0.3%; the average BeyondCare® invalid measure were 1% and 4.5% in the first and second correlation band groups consequently.

differ from each other, the data gathered from devices had to be aligned for each patient's measurements.

At the beginning of the alignment process, the signal positions where the RR beats occurred were determined for both devices. By using the RR positions, a beat (RR) per second measures was calculated for each patient's measurement. Next, the calculated beat per seconds of data was aligned by using the cross-correlation method.

Cross-correlation method helped us to identify the time offset value between the beat per second measurements of both devices; it was performed for each patient separately to align the beat per seconds. The time offset value was chosen as where the cross-correlation has the highest peak. After the alignment step for each patient, the beat per minute values were calculated as the next step. To perform a more accurate comparison, the accurate R-R interval artifact correction and their editing were needed.

In experimental field, it is prevalent to find poor quality ECG signals, related to unstandardized moves, poorly attached electrodes, source power noise, and other internal – external influences, resulting in heart rate variability (HRV) signals with a significant amount of missing or redundant beats which will lead to misinterpreted results. To solve the problems related to the presence of mentioned artifacts in HRV signals, different correction methods have been proposed. Some of the most common correction methods used in RR time series are deletion, linear and non-linear interpolation, moving an average window and non-linear predictive interpolation of the problematic segments. These methods usually have been implemented to deal with problems like ectopic beats, noise, non-uniform sampling the R-R intervals.

In this study, the noise filter was defined as; standard deviation of RR intervals was >300 ms and total beats (RR) value was <30 in a one-minute segment. As most researchers edit or exclude the artifact and require at least 80% of normal R-R intervals, the participants who had equal or >80% of analyzable signal time rate was included in the statistical analysis [17]. After applying the filter to RR intervals and total beats in a one-minute segment, at least 80.3% of the measured data for each subject were included and analyzed during the study. Finally, after excluding the invalid data by using the filter defined above, the beat per minute comparison was performed by using Pearson's correlation coefficient to analyze the relationship between the total beats for both devices' measurements. The mentioned alignment and calculations algorithms were developed in R software version 3.3.3 (Copyright (C) 2017 The R Foundation for Statistical Computing).

The standard deviation of RR intervals (SDRR) is the measure of the variability or dispersion of a data set. SDRR is calculated as;

Eq. (1) – The standard deviation of RR intervals (SDRR)

$$SDRR = \sqrt{\frac{1}{N-1}\sum_{i=1}^{N}\left(RR_i - \bar{RR}\right)^2} \tag{1}$$

Eq. (2) – Pearson correlation coefficient

$$r = \frac{\sum_{i=1}^{N}\left(BC_i - \bar{BC}\right)\left(HO_i - \bar{HO}\right)}{\sqrt{\sum_{i=1}^{N}\left(BC_i - \bar{BC}\right)^2}\sqrt{\sum_{i=1}^{N}\left(HO_i - \bar{HO}\right)^2}} \tag{2}$$

where N is the number of observations, RR_i; RR values, BC_i; BeyondCare® beats per minute (BPM) values, HO_i; Holter BPM values and $\bar{RR}$, $\bar{BC}$, $\bar{HO}$ are the mean values.

In clinical method comparison studies, it has been suggested that the Bland-Altman plots should also be performed [18]. Thus, in addition to correlation plots given in Fig. 2, Bland-Altman plots are also presented for the BPM values of BeyondCare® and Holter (Fig. 3). Bland-Altman method states that if differences are normally distributed (Gaussian), 95% of differences will lie within the range defined by mean differences ±1.96 multiplied by the standard deviation (SD) of the differences [18]. Bland-Altman plots are given in Fig. 3.

In the second protocol, the patients who had equal or >80% of analyzable signal time rate were included in statistical analysis. The prevalence of detected arrhythmias was calculated daily to understand the efficacy of the prolonged monitoring time in means of the number of the detected events in daily percentage.

Results

In the first protocol, 36 healthy subjects underwent simultaneous ambulatory monitoring with standard 12-lead Holter and BeyondCare®. One of the subject's data in BeyondCare® device was very noisy due to

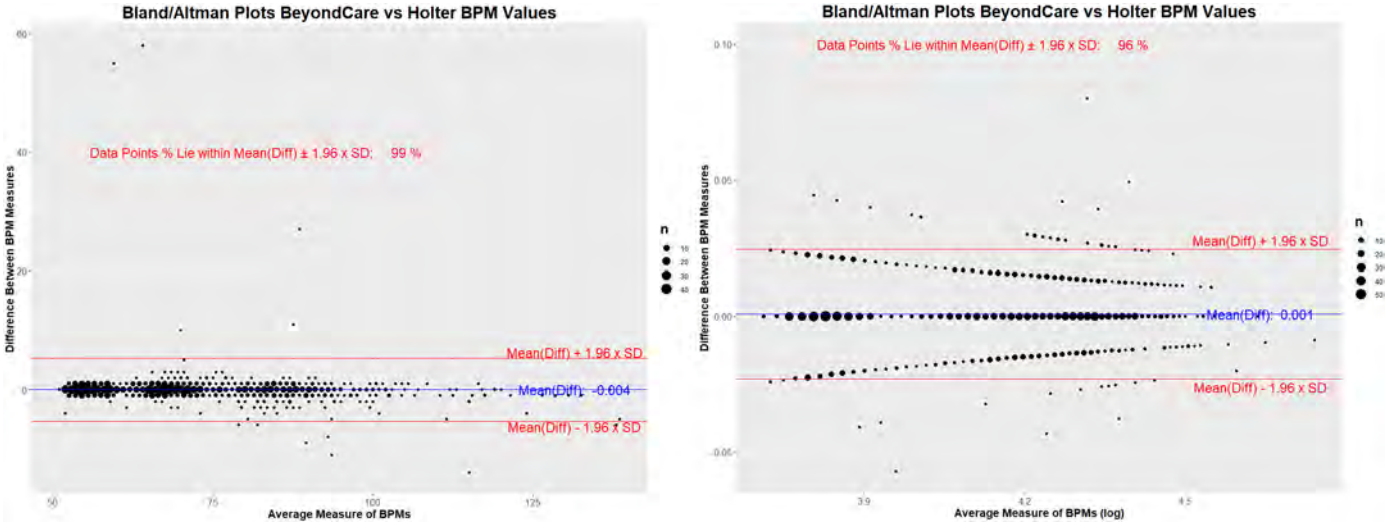

Fig. 3. Bland-Altman plots were given above for the BeyondCare® and Holter BPM values. The first graph is performed without any transformation on the BPM data. On the other hand, while performing the second graph, logarithmic values of the BPM values were used.

Table 1
Baseline characteristics and indication for monitoring of the patients enrolled in the second protocol of the study.

Patients enrolled (n)	73
Excluded patients from the final analysis[a]	6
Patients evaluated for final analysis	67
Gender (female)	43 (64.1%)
Age (mean, SD)	56.4 (16.4)
Medical history	
HTN (n, %)	34 (50.7%)
CAD (n, %)	10 (14.9%)
Diabetes (n, %)	8 (11.9%)
CHF (n, %)	3 (4.4%)
AF	4 (5.9%)
Medications[b]	42 (62.6%)
Beta-blocker (n, %)	32 (64%)
Calcium channel blocker (n, %)	7 (14%)
AAD (n, %)	11 (22%)
Reported clinical indication for monitoring[c]	
Palpitations (n, %)	57 (85.2%)
Syncope or presyncope (n, %)	9 (13.2%)
Dizziness (n, %)	15 (22%)
Dyspnea (n, %)	17 (25%)
Chest pain (n, %)	10 (14.7%)
AF (n, %)	4 (5.9%)
Day of BeyondCare® recording (mean, SD)	4.7 (0.5)
Analyzable signal time (mean, SD)	93.6% (5.5)
Skin irritation	5 (7.3%)

HTN: history of hypertension, CAD: history of coronary artery disease, CHF: history of congestive heart failure, AAD: current use of antiarrhythmic medication, AF: atrial fibrillation, SD: standard deviation.

[a] Analyzable signal time was found under 80% because of the inconsistent signal quality.
[b] Some patients used ≥2 drugs.
[c] Some patients had >1 clinical indication for cardiac monitoring.

lack of preparation. In the other two subjects, adhesive electrode stickers were found lead-off after sleeping period and could not able to record afterward. Therefore, a total of 33 patients having data on both the 24-h Holter monitor and the adhesive patch monitor were included in final analysis. The mean age was 33 ± 7.8 years, and 30.3% of subjects were male. The mean wear time was 23.7 ± 0.4 h. Thirty of 32 patients that answered the questionnaire stated that they would prefer to wear BeyondCare® in their daily routine thanks to the lightweight and wireless design. Two patients reported that they had skin irritations with both Holter and BeyondCare® electrodes.

The beat (RR) per minute comparison of BeyondCare® and standard 12-lead Holter were evaluated in the total amount of valid measurement time after the alignment. The overall measurement time of 33 subjects was 93.603 min, and after applying the filter, the comparable total valid measurement time was 89.270 min with 97% of the overall measurement time after disregarding the invalid measurements. Poor or noisy signal, loosening of the electrodes or motion artifacts caused the invalid measurements. Artifacts were determined by applying the filter to RR intervals' standard deviations and total beats (RR) in the one-minute segment. The mean percentage of invalid measurements in BeyondCare® recordings was 1.6% while the Holter's was 1.7%. The main problem that was encountered with six patients was the hair on the chest area and removal of the electrodes.

In the given correlation plots (Fig. 2), it was shown that the overall average beat per minute correlation was 98%. Thirty-three subjects were divided into two categories according to their beat per minute correlation percentage. In 27 subjects, 82% of the total group, average beat per minute correlation was perfect with 99% (range 99.84%–96.93%) in the 95%–100% correlation band. Six subjects in the 90%- 95% correlation band have an average beat per minute correlation of 92.8%. The leading causes of the higher percentage of invalid measurement of the six patients are probably due to varying body types, hairy chest, and loosening of the electrodes. In beat (RR) per minute correlation study, BeyondCare® and 12-lead Holter values were plotted in two separate graphs for each two-correlation band (Fig. 2).

Table 2
Prevalence of detected arrhythmias.

Variable	All patients with arrhythmias n (%)	Patients with first arrhythmia occurred within the first day n (%)	Patients with first arrhythmia occurred within the second day n (%)	Patients with first arrhythmia occurred after two days n (%)	All arrhythmic events occurred within the first day n (%)	All arrhythmic events occurred within the second day n (%)	All arrhythmic events occurred after two days n (%)
Any arrhythmia (excluding chronic AF)	27 (100%)	13(48,2%)	6 (22.2%)	8 (29,6%)	22 (28.2%)	16 (20.5%)	40 (51.3%)
Paroxysmal AF	7 (25.9%)	4 (57,1%)	0	3 (42,9%)	5 (20.8%)	4 (16.7%)	15 (62.5%)
Pause	1 (3.7%)	1(100%)	0	0	1 (14.3%)	1 (14.3%)	5 (71.4%)
VT	4 (14.8%)	0	3 (75%)	1(25%)	0	3 (60%)	2 (40%)
SVT	15 (55.5%)	8 (53.3%)	3 (20%)	4 (26.7%)	16 (38.1%)	8 (19.1%)	18 (42.8%)

AF: atrial fibrillation, VT: ventricular tachycardia, SVT: supraventricular tachycardia. Among the patients with detected arrhythmia (40.2% of all patients), 29.6% had their first arrhythmia after the initial 2 day period.

In the given Bland-Altman plots (Fig. 3), the condition mentioned above, differences should lie within the range defined by mean differences ±1.96 multiplied by the standard deviation (SD) of the differences, was satisfied. Furthermore, the average discrepancy between methods (shown as the mean blue line in the plots, and called bias) was significantly close to 0, the variability is mostly consistent across the graph, and the scatter around the bias line does not get larger as the average gets higher.

In the second protocol, a total of 73 patients were enrolled. The results of six patients were not included in the statistical evaluation. In their recordings, analyzable signal time was found under 80% because of the inconsistent signal quality. The mean age of the remaining 67 patients was 56.4 ± 16.4 years, and 64.1% of patients were female. The baseline characteristics of patients were shown in Table 1.

The clinical indications for electrocardiographic monitoring of the patients were given in Table 1. The most common indication was

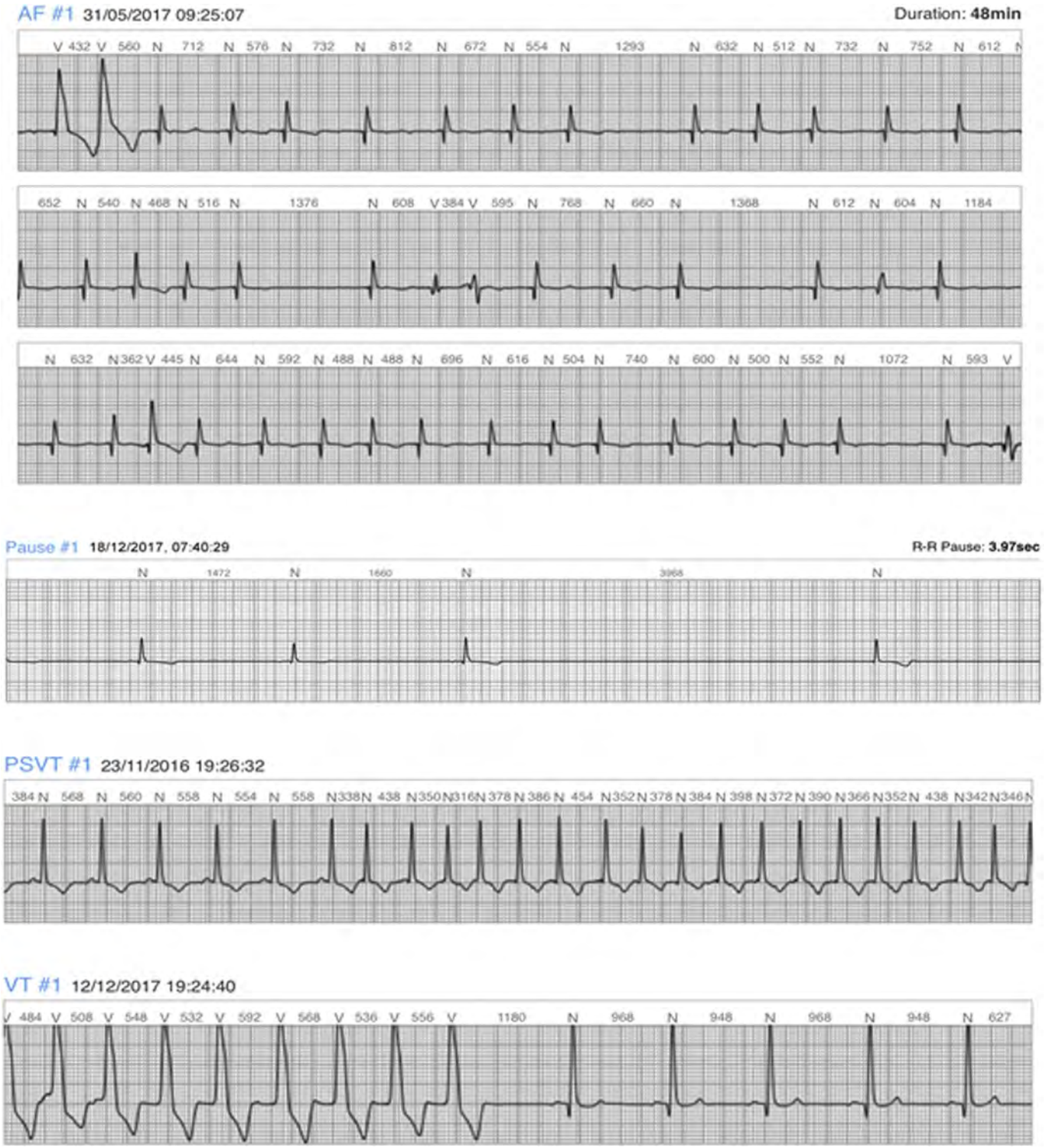

Fig. 4. The ECG strip samples from detected arrhythmia events. AF; paroxysmal atrial fibrillation, pause, PSVT; paroxysmal supraventricular tachycardia, and VT; ventricular tachycardia.

palpitation (85.2%). The other indications were dizziness (22%), dyspnea (25%), chest pain (14.7%), syncope or presyncope (13.2%), and AF (5.9%). Some patients had more than one clinical indication for cardiac monitoring.

The mean analyzable wear time was 93.6%. The water-resistant design enabled 73.5% of the participants to take a shower. 7.3% of participants had minor skin irritations related to the electrodes.

Among 67 patients, 27 (40.2%) had arrhythmic events. The prevalence and the daily distribution of the detected arrhythmias were given in Table 2. Among the patients with detected arrhythmia, 29.6% had their first.

arrhythmia, after the initial two day period. The most common arrhythmia type was supraventricular tachycardia (SVT). In only one patient, seven ventricular pause events greater than 3 s were detected. The most extended pause was detected in the third day as 3.9 s (Fig. 4).

Eighteen asymptomatic and six symptomatic paroxysmal AF events were identified in seven patients. 62.5% of these events occurred after the initial two days period.

Discussion

In the first protocol of the study, we found that BeyondCare® has comparable performance to the standard 24-h Holter regarding the signal quality of ECG data acquisition. Highly fitted beat (RR) per minute correlation graphs showed 98% correlation (Fig. 2), and Bland-Altman plots results proved that BeyondCare® EPM device provides valid results for ambulatory ECG monitoring (Fig. 3) when compared to the standard 12-lead Holter monitoring device measurements.

According to the results of the second protocol of the study, BeyondCare® patch was well-tolerated and allowed prolonged ECG monitoring period, which may result in an improvement in clinical accuracy and detection of arrhythmias.

In the second protocol, we found that BeyondCare® has high patient compliance regarding wearing time. Among the patients with detected arrhythmia (40.2% of all patients), 29.6% had their first arrhythmia after the initial two day period. Similar results have also been reported in previous studies using another patch-based ambulatory ECG monitoring device named the Zio Patch®. Barrett et al. compared the 24-h Holter monitor with a Zio Patch® in 146 patients referred for the evaluation of cardiac arrhythmia [14]. The primary outcome of the study was to compare the detection of arrhythmia events over total wearing time for both devices. Arrhythmia events were defined as detection of any one of the following arrhythmias as supraventricular tachycardia, atrial fibrillation/flutter, and pause greater than 3 s, atrioventricular block, ventricular tachycardia, or polymorphic ventricular tachycardia/fibrillation. The median wearing time for the adhesive patch monitor was 11 days. Of the patients, 93.7% found the adhesive monitoring patch comfortable to wear. The authors demonstrated that the adhesive patch monitor could detect significantly more arrhythmic events (96 vs. 61 events; $p < 0.001$) in their study. When the outcome was narrowed to five clinically significant arrhythmias, excluding supraventricular tachycardia, the adhesive patch monitor continued to detect more events (41 vs. 27 events; $p < 0.001$).

In another study, Turakhia et al., evaluated compliance, analyzable signal time, interval to the arrhythmia detection, and diagnostic yield of the Zio Patch®, in 26.751 consecutive patients [15]. The mean wear time was 7.6 ± 3.6 days, and the median analyzable time was 99% of the total wear time. Among the patients with detected arrhythmias (60.3% of all patients), 29.9% have had their first arrhythmia, and 51.1% have had their first symptom triggered arrhythmia after the initial 48-h period. Compared with the first 48 h of monitoring, the overall diagnostic yield was higher when data from the entire Zio Patch® wearing duration were included for any arrhythmia (62.2% vs. 43.9%, $p < 0.001$). Although in this study, the mean wear time is longer than our study, the rate of patients who had their first arrhythmia after the first two days was similar in both studies. Turakhia et al., also reported that 90% of all patients with arrhythmias were identified within five days of monitoring. In one retrospective study, analysis of a sample of 951 NUVANT (mobile cardiac telemetry system) patients has revealed that in all cases with arrhythmias including AF the mean patient time to arrhythmia ECG presentation was more than the two day Holter period [19].

In our study, among the patients with detected AF (25.9% of all patients with arrhythmia), 42.8% had their first AF episodes after the initial 2-day period. Consistent with our findings, two previous studies reported that extending ECG monitoring beyond 24–48 h increases the diagnostic yield of paroxysmal atrial fibrillation [15,16]. In one of this studies, Turakhia and colleagues pointed out that among the patients with AF, 23.4% had their first episodes, and 47.2% had their first symptomatic episodes after the initial two days period.

Our study had several limitations. Despite the favorable outcome of our studies, more extensive studies will be necessary to determine the long-term impact of the use of the BeyondCare® device in arrhythmia diagnosis and management. In this study, no direct head-to-head comparison was conducted between BeyondCare® and the Holter device. Although there have been published studies made of this comparison with different patch devices, differences in duration of monitoring, signal processing and detection algorithms of BeyondCare® could have led to variation in the diagnosis of arrhythmias when compared to other recorder devices.

It is also worth to note that the lack of different ECG patterns which may facilitate the localization of some arrhythmias may appear as a limitation of the ECG patch monitor using only one channel.

To conclude, BeyondCare® was well tolerated and allowed prolonged ECG monitoring period, resulting in an improvement in clinical accuracy and detection of arrhythmias. Furthermore, although the situation will be clarified in new studies evaluating the cost-effectiveness of this new device, it's reusability feature may make it affordable and cost-efficient.

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