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Validation of a novel single lead ambulatory ECG monitor – Cardiostat™ – Compared to a standard ECG Holter monitoring

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ABSTRACT

Background: Cardiostat™ is a single lead ambulatory ECG monitor. Recording is made through 2 electrodes positioned in a lead 1-like configuration. We first validated its accuracy for atrial fibrillation detection compared to a 12-lead ECG. In the second phase of the study, arrhythmia detection accuracy was compared between Cardiostat™ ambulatory ECG and a standard 24 h Holter ECG monitoring.

Method/results: Phase one of the study included patients undergoing cardioversion for atrial fibrillation (AF) or atrial flutter. Cardiostat™ tracings were compared with standard 12-lead ECG.

In the second phase, patients undergoing 24 h ambulatory Holter ECG monitoring for control or suspicion of atrial fibrillation (AF) were included. Simultaneous Holter monitoring and Cardiostat™ ECG recordings were performed. Tracings were analysed and compared.

Two hundred twelve monitoring were compared. AF was diagnosed in 73 patients. Agreement between Cardiostat™ ECG and standard Holter monitoring was 99% for AF detection with kappa = 0.99. Kappa correlation for atrial flutter detection was only moderate at 0.51. AF burden was similar in both recordings. Noise hindered analysis in a greater proportion with Cardiostat™ compared to Holter ambulatory ECG (8.5 vs 3.8%).

Conclusion: Cardiostat™ ambulatory ECG device showed excellent correlation with the standard Holter ECG monitoring for AF detection. Holter monitoring was however superior to discriminate premature atrial and ventricular beats and to qualify the morphology of PVCs since it has more vectors for analysis. Added value of Cardiostat™ includes longer monitoring duration, less cumbersome installation and water resistance.

Brief summary

We investigated the performance of Cardiostat™ ambulatory ECG patch compared to a standard 24 h ECG Holter monitoring for arrhythmia detection. Cardiostat™ device continuously records a single ECG lead for 48 h to 14 days. Excellent correlation was seen between both devices for detection of atrial fibrillation. The Holter ECG monitoring was however superior to discriminate premature atrial from ventricular beats and was more accurate to assess PVC morphology. Added value of the Cardiostat™ patch includes longer monitoring duration, less cumbersome installation and water resistance.

Introduction

Ambulatory ECG monitoring is indicated to detect asymptomatic arrhythmias or to establish a diagnosis in the presence of symptoms suggestive of arrhythmia such as palpitations, dyspnea and dizziness [1,2]. Many arrhythmias are intermittent, and some are infrequent, therefore longer sampling time increases the diagnostic yield of monitoring.

It is of utmost importance to make a timely diagnosis for many arrhythmias since treatment significantly alters the risk of associated morbidity, for example in atrial fibrillation (AF). AF is the most frequent cardiac arrhythmia affecting 1–2% of the general population [3] and it is associated with an increased risk of stroke, which can be reduced by adequate treatment [3–5]. Clinical symptoms attributable to AF include dyspnea, reduced exercise tolerance, thrombo-embolic events, palpitations, and sometimes dizziness [6]. AF can also be silent [7], nonetheless, asymptomatic patients carry the same stroke risk as symptomatic patients [8]. Approximately 23% of ischemic strokes are related to AF [9].

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Recent studies have shown that silent AF is often diagnosed in patients with stroke, and longer recording periods, beyond 24 h, lead to increased AF detection [10–12]. However, 24 h Holter ECG monitoring, despite its short duration, is still the most widely used technology for arrhythmia detection in patients with symptoms or in search for asymptomatic AF in patients with cryptogenic stroke.

We investigated the performance of a novel device, Cardiostat™ (Icentia, Quebec, Canada), to detect arrhythmia (Fig. 1). Cardiostat™ is an ambulatory ECG monitor with continuous recording of a single lead tracing. It is less cumbersome than a regular 3 lead Holter monitoring, it is waterproof and it has a longer recording capacity (up to 14 days). Electrodes can be replaced by the patient during prolonged monitoring periods.

Since AF is the most frequent clinically significant arrhythmia encountered, we included patients at risk of AF and compared AF detection and global arrhythmia detection with 24 h Holter versus 24 h Cardiostat™ ambulatory ECG monitoring.

The aim of this study was to validate the diagnostic accuracy of Cardiostat™. The aim of phase 1 was to compare Cardiostat™ ECG recording to a standard 12 lead ECG in patients with atrial fibrillation or flutter undergoing cardioversion, in order to test the diagnostic accuracy of Cardiostat™ for atrial arrhythmia. The aim of phase 2 was to compare diagnostic accuracy of Cardiostat ™ to that of a standard 24 h Holter monitoring for arrhythmia detection in an ambulatory setting.

Methods

This is a single-center study conducted at a tertiary care cardiology center.

The protocol was reviewed and approved by the institutional Ethical review board. All subjects provided written informed consent.

The study was divided in 2 phases.

Phase 1

Phase 1 evaluated the accuracy of Cardiostat™ compared to a 12-lead ECG in patients with AF or atrial flutter referred for an electrical cardioversion. The study included patients 18 years or older with a diagnosis of AF or atrial flutter presenting for an elective electrical cardioversion. Before and after the cardioversion, each patient had a 10-second rhythm strip with Cardiostat™ and had a standard 12-lead ECG (MAC 5500, GE). The four tracings obtained for each patient were then reviewed by 2 blinded electrophysiologists. Rhythm identification and signal amplitude were assessed.

Phase 2

Phase 2 of the study aimed to validate the accuracy of Cardiostat™ ECG montoring in an ambulatory setting, compared to a 24 h-Holter ECG monitoring (SEER Light, GE Healthcare). Cardiostat™ was installed simultaneously with a 24 h Holter monitor in patients undergoing monitoring for the following indications: suspicion of AF, recent stroke, assessment of rate/rhythm control in patients with documented AF or monitoring after AF ablation. Cardiostat™ can monitor continuously for up to two weeks, however for the purpose of this study, only 24 h recordings were performed.

Inclusion criteria were age ≥18 years old and ability to give informed consent.

Exclusion criteria were: refusal to consent, allergy to a device component, failure to obtain interpretable tracings (improper activation of the recording device) and for phase 1, left appendage thrombus precluding cardioversion or spontaneous return in sinus rhythm.

The standard 24 h Holter ECG monitor (SEER Light, GE Healthcare) had 7 electrodes linked to the monitor by cables (Fig. 1A). Electrodes were positioned as recommended by the manufacturer (Fig. 1A). This configuration recorded a modified V5 lead on channel 1, a modified V1 on channel 2 and a modified aVF on channel 3.

The Cardiostat™ (Icentia, Quebec Canada) had 2 electrodes attached to a microprocessor inside a rubber band. The 2 electrodes were installed each side of the sternum at the second intercostal space (Fig. 1B). This configuration recorded a modified lead 1.

Patients were instructed on how to use the notification button located on the Cardiostat™ if symptoms were felt during the monitoring. They were asked how easy it was to find the event marker button and how confident they were of having used it properly.

When performing analysis and interpretation of the tracings, technicians and electrophysiologists were blinded to the results of the corresponding test for the same patient using the other device.

An electrophysiology technician screened the 24 h tracings for arrhythmic events (Holter: Mars 7.2, GE Healthcare; Cardiostat™: EART™, Icentia). The EART™ analysis software is based on a 2D color coded ECG representation scheme allowing the user to visualize a large number of QRS complexes in the tens of thousands representing several hours of ECG recording in one static view. The number of QRS and the ECG duration which can be displayed in a single screen view vary depending on the heart rate of the recording and the screen resolution. All tracings with arrhythmia were submitted for validation. The preliminary report contained all rhythm strips with arrhythmia, the percentage of tracing with noise that prohibited interpretation, the mean, minimal, maximal heart rate, and longest RR interval. AF was

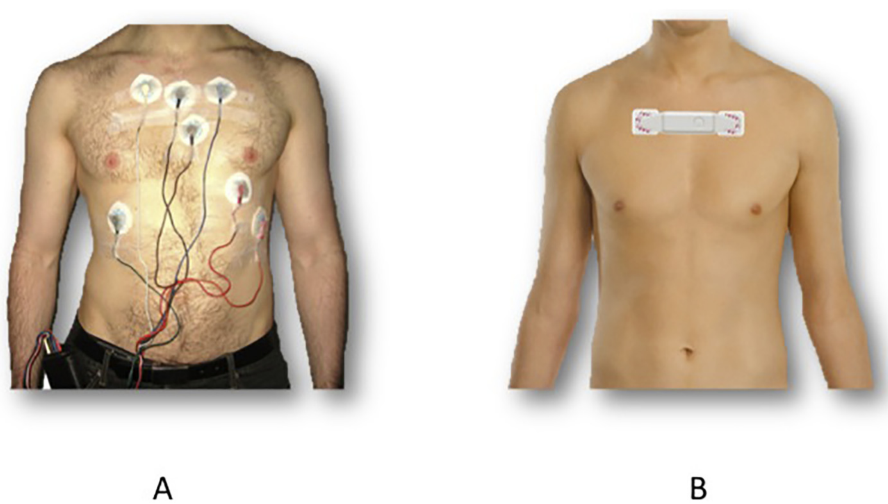

Fig. 1. A: Installation of a conventional Holter. B: Installation of a Cardiostat™.

defined as 30 consecutive seconds or more of an irregular heart rhythm without discrete atrial activity [13]. Noise was defined as uninterpretable signal, either because of artifact, interference or lead disconnection. If the signal was partly interpretable (for example one lead with clean signal and one disconnected lead in a Holter monitor) it was not classified as noise since some ECG was interpretable. Noise was calculated as a percentage of the total recording time. Premature atrial beats and premature ventricular beats counts, as well as AF burden were calculated automatically and confirmed by the EP technician after visual analysis. Atrial fibrillation burden was defined as the percentage of time in atrial fibrillation. Only episodes of atrial fibrillation lasting 30 s or more were accounted, and the cumulative time in atrial fibrillation was calculated. Noise was excluded from the burden calculation (the time denominator excluded noise) Atrial and ventricular premature beats couplets were defined as 2 consecutive premature beats and runs of atrial or ventricular tachycardia were defined as 3 or more consecutive beats [1]. The different morphologies of premature ventricular beats were quantified by visual assessment. Cardiostat™ tracings were interpreted by two electrophysiologists. If the interpretations were discordant, a third electrophysiologist was asked to review.

Statistical analysis

Sample size for phase 1 was calculated at 30 patients, assuming that 99% of patients would have AF identified by the 12-lead ECG at the time of recording, and that the accuracy of Cardiostat™ would be at least 90%.

Sample-size calculation for phase 2 was based on the results from phase 1 study. The observed concordance with the standard 12 derivation-ECG as the reference method was 98.3%. It was assumed that 99% of tracings would have concordant results, and the device would identify accurately atrial rhythm in no <93.3% of the tracings (equivalence limit of 5%). To test whether Cardiostat™ was equivalent compared to the Holter, we determined that 212 patients would be needed for the study to have a power of 90% at an alpha level of 2.5%.

Continuous data are reported as mean ± standard deviation (SD) or median (interquartile range [IQR]) depending on variable distribution. Normally distributed data were compared using paired-*t*-test. Continuous data not normally distributed were compared using Mann-Whitney *U* test. Categorical data are reported as percentage and compared using Chi-Square test. Interobserver agreement was calculated using Kappa correlation.

Results

Phase 1

Fifty-four consecutive individuals presented for an elective electrical cardioversion and were screened for the study. Of those, 21 patients did not participate: 11 had an exclusion criteria, 4 refused to participate, 5 did not undergo cardioversion because of spontaneous return to sinus rhythm (n = 4) or the presence of a left atrial appendage clot (n = 1), and one had a potential allergy to one of the device's components. Accordingly, 33 patients agreed to participate in the study but 3 patients were not included in the analysis because of improper activation of the recording device (n = 3). After the attempted cardioversion, 26 returned to normal sinus rhythm and 4 remained in either atrial flutter or AF. With the standard ECG as the reference method, the observers correctly identified the presence of atrial arrhythmia on the device in all but one patient (97%) with a very good agreement between ECG and Cardiostat™ (kappa = 0.92; 95% CI [0.85–0.99]) The inter-observer agreement in identifying normal sinus rhythm versus atrial arrhythmia was very good (kappa = 0.93; 95% CI [0.87–1.00]). For each physician, intra-observer agreement for arrhythmia detection with Cardiostat™ and ECG was also very good (kappa $_{MD1}$ = 0.97; 95% CI [0.90–1.00]; kappa $_{MD2}$ = 0.87; 95% CI [0,75–0,99]). The discrimination between atrial flutter, AF or atrial tachycardia was lower with an inter-observer agreement between the device and the ECG (kappa = 0.38; 95% CI [0.15–0.63] and kappa = 0.63; 95% CI [0.38–0.87] respectively). When compared to the standard ECG, physicians identified the rhythm accurately (AF vs atrial flutter vs sinus rhythm) in 85% of tracings with Cardiostat™, which reflects a good overall agreement (kappa = 0.77; 95% CI [0.68–0.86]).

Phase 2

Two-hundred and thirteen patients were included in the second phase comparing simultaneous ambulatory 24 h monitoring with Holter and Cardiostat™. One patient had no Holter recording due to a technical problem and therefore was excluded. A total of 212 recordings were completed and analysed. The mean age was 67 ± 11 years with 61 females and 151 males. The mean weight was 82 ± 17 kg, with a mean height 172 ± 10 cm and mean Body Mass Index 28 ± 5 kg/m^2.

Atrial arrhythmia (AF or atrial flutter) was detected in 73 patients (34%) according to the Holter and 74 patients (35%) according to Cardiostat™. Agreement between Holter and Cardiostat™ was excellent at 99.5% (Kappa = 0.99, SE 0.01, 95% CI 0.97–1.0). The AF/atrial flutter burden recorded by both devices was similar (25% ± 42% in both groups, p = ns). Disagreement was seen in only one patient in whom the interpretation of Cardiostat™ concluded to AF whereas Holter monitoring did not. However, agreement between the devices for the discrimination between atrial flutter and AF was only moderate ((kappa 0.51) DE 0.109, 95% CI 0.3–0.7).

In 28 recordings, AF was present during the whole monitoring period. In the remaining patients with atrial fibrillation, episodes lasted >30 s but were not continuous during the whole recording.

Comparison of premature beats counts, heart rate, and automated counts are shown in Table 1. Noise was seen more frequent with Cardiostat™ compared to Holter monitoring. Examples of tracings are seen in Figs. 2 and 3.

One patient had one sequence of second degree type 2 AV block and 2 patients had second degree type one AV block sequences (Figs. 4 and 5), documented accurately by both devices. In 2 patients, blocked premature atrial beats were documented by the 2 devices and one patient alternated between junctional rhythm and sinus rhythm, documented by both devices. Pauses longer than 3 s were recorded in 11 patients, and one patient had a 5 s pause, all identified by the 2 devices.

Most patient did not use the event marker button (161). In the 37 patients who used it, 4 said the button was hard to find, 20 said it was moderately easy and 10 said it was very easy to find. Three were uncertain, 7 were moderately certain and 24 were absolutely certain they manipulated it properly. In 2 patients, the button was hit by mistake and in one, no scoring was given. Fifteen patients did not provide feedback.

Table 1
Comparative results of Holter and Cardiostat TM ECG monitoring.

	Holter n = 212	CardioStat n = 212	p value
Total number of beats	96,624 ± 27,951	86,651 ± 19,455	<0.0001
% time in bradycardia HR < 60 bpm (%)	30 ± 27	30 ± 26	ns
% time in tachycardia HR > 100 (%)	4 ± 9	7 ± 11	0.017
Atrial fibrillation burden (%)	25 ± 42	25 ± 42	ns
Noise (%)	3.8 ± 4.3	8.5 ± 11.7	0.001
Mean HR (BPM)	68 ± 12	67 ± 11	ns
Max HR (BPM)	116 ± 30	117 ± 60	ns
Min HR (BPM)	47 ± 13	48 ± 12	ns
Longest RR interval (s)	1.88 ± 0.57	1.86 ± 0.55	ns
PAC count (#)	665 ± 1858	897 ± 2629	ns
Atrial runs (#)	13 ± 51	11 ± 38	ns
PAC couplet (#)	44 ± 241	53 ± 275	ns
PVC count (#)	1093 ± 3763	747 ± 3060	ns
PVC couplet (#)	20 ± 94	15 ± 71	ns
VT runs (#)	5 ± 45	1 ± 8	ns
PVC morphology (#)	2.4 ± 1.3	1.9 ± 1.3	0.0001

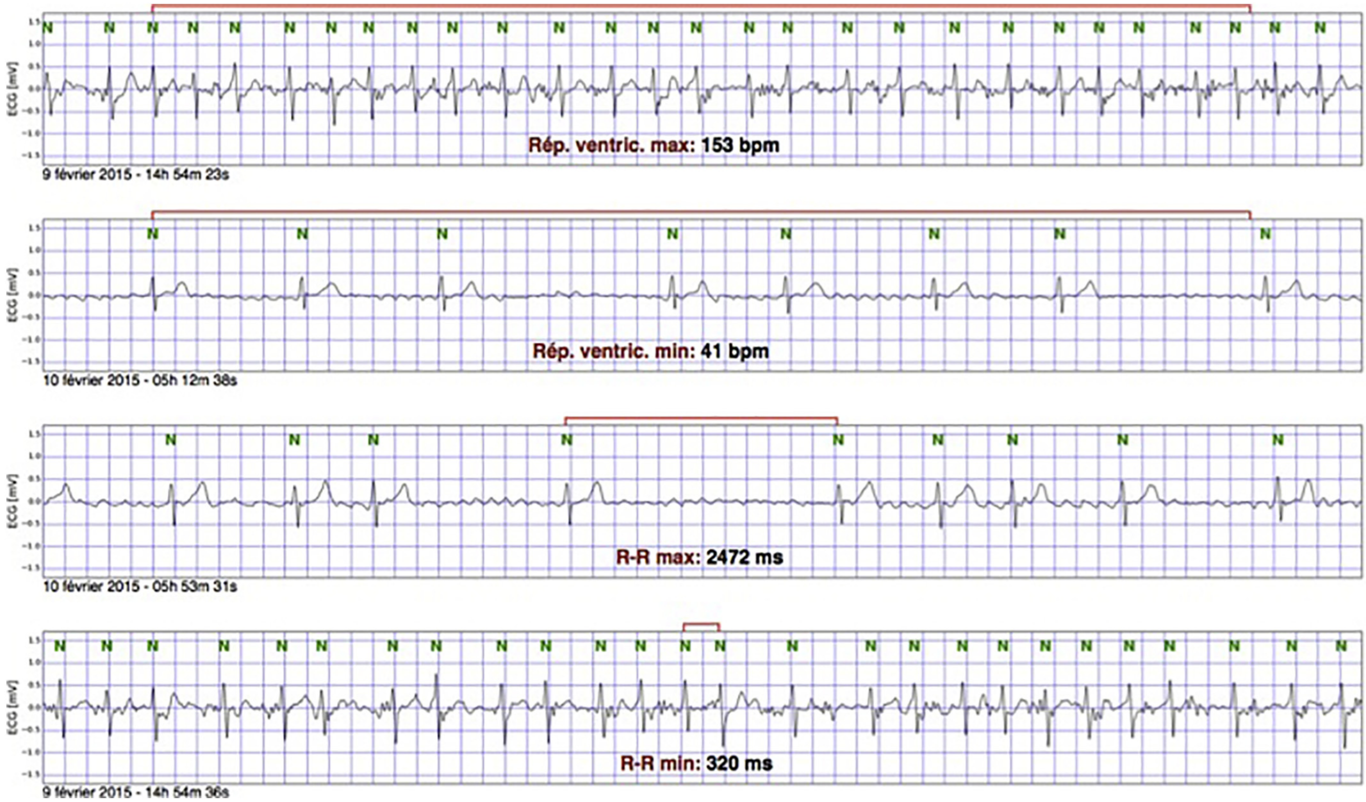

Fig. 2. Cardiostat™ tracings of atrial fibrillation.

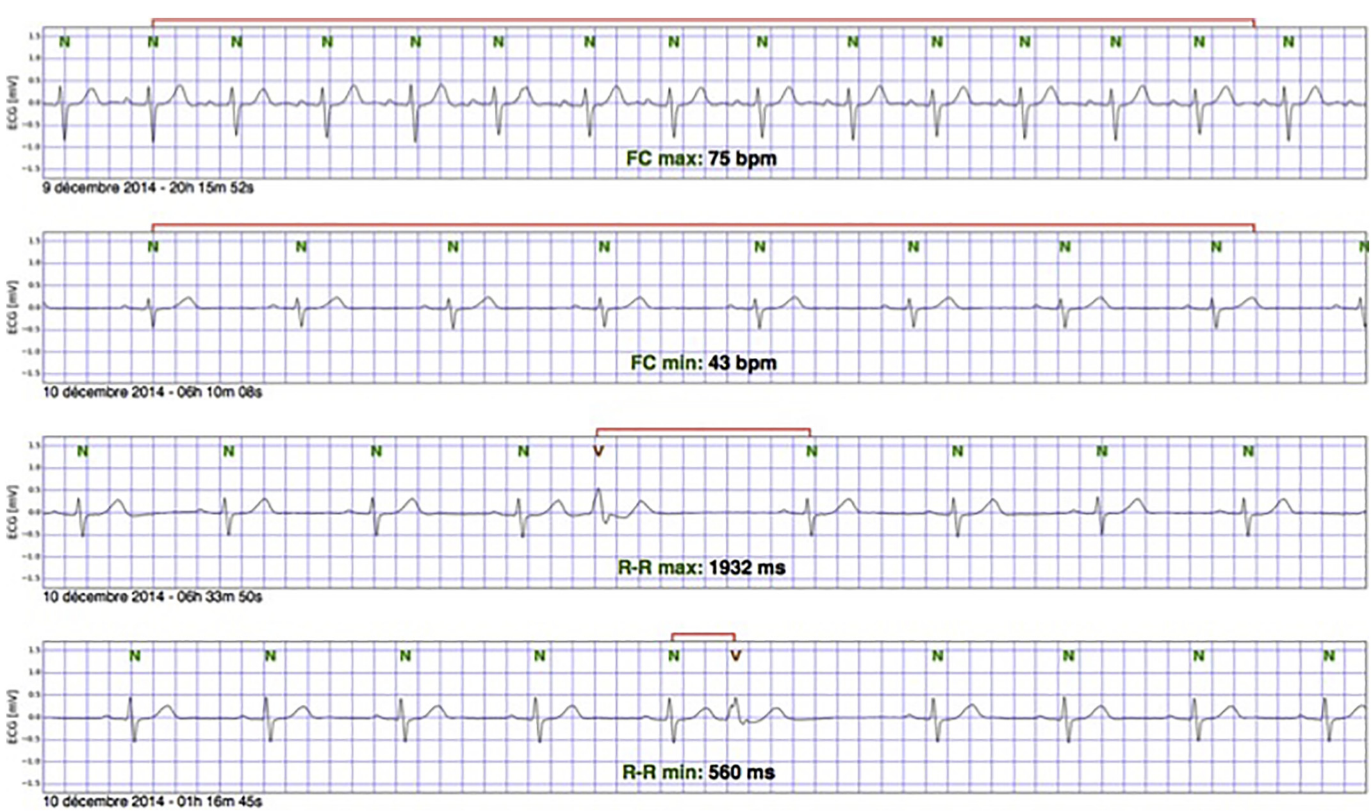

Fig. 3. Cardiostat™ tracings of sinus rhythm and isolated premature ventricular beats.

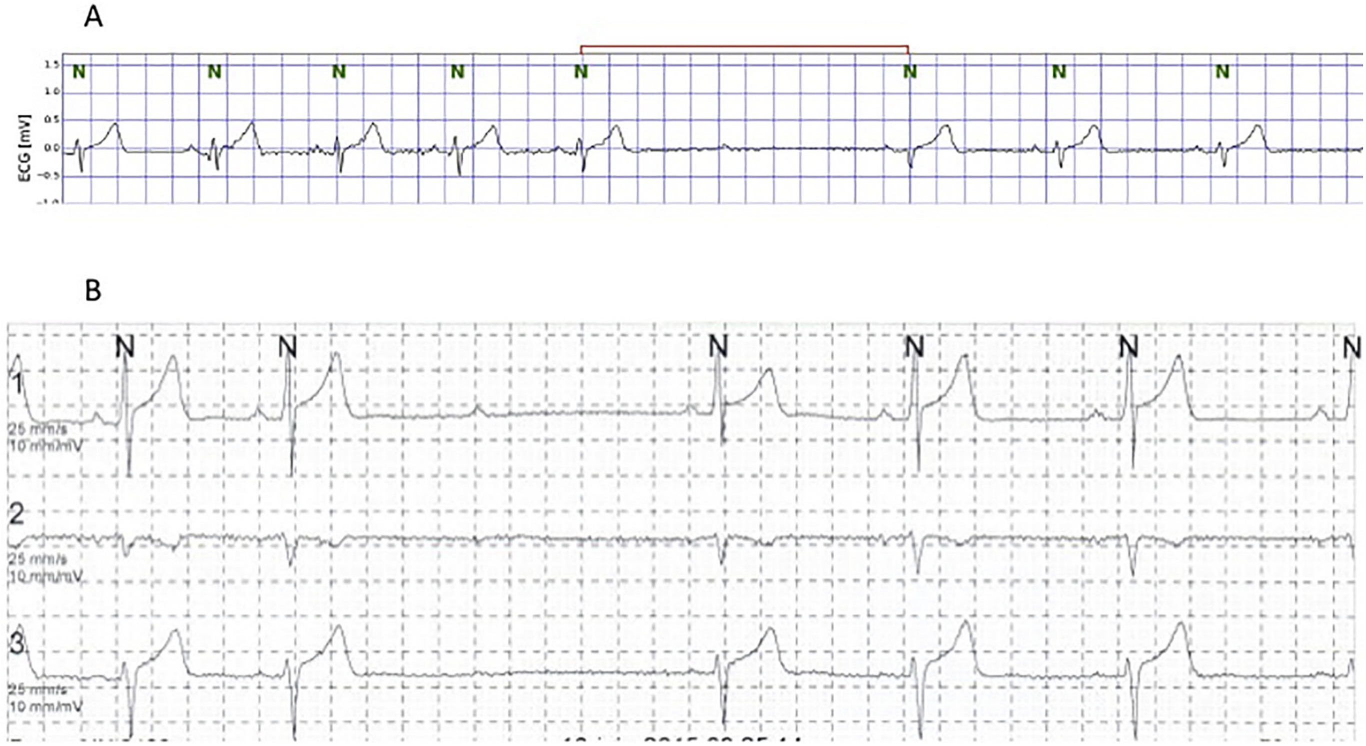

Fig. 4. Simultaneous ECG recorded with Cardiostat™ (A) and with Holter monitor (B) showing second degree type2 AV block (Mobitz 2).

Discussion

In this validation study, accuracy of Cardiostat™ ambulatory ECG monitoring for the diagnosis of AF was excellent when compared to a 24 h Holter ECG monitor. Only one case yielded discordant interpretation. The tracings were reanalysed and compared post hoc: on the Holter ECG the sequences were considered atrial tachycardia runs since at some point there was a rapid but regular atrial activity preceding the QRS although it did become disorganized into AF at one point for a duration exceeding 30 s. Although for all analyses the Holter ECG was considered the gold standard, in this particular case it appeared that the Cardiostat™ yielded the right diagnosis. Despite the only lead with Cardiostat™ ambulatory ECG, the high resolution and signal quality allows accurate p wave and atrial rhythm assessment (Figs. 2 and 3).

The accuracy of Cardiostat™ ambulatory ECG monitoring to diagnose atrial flutter was only moderate (93%, kappa 0.51). The discrimination

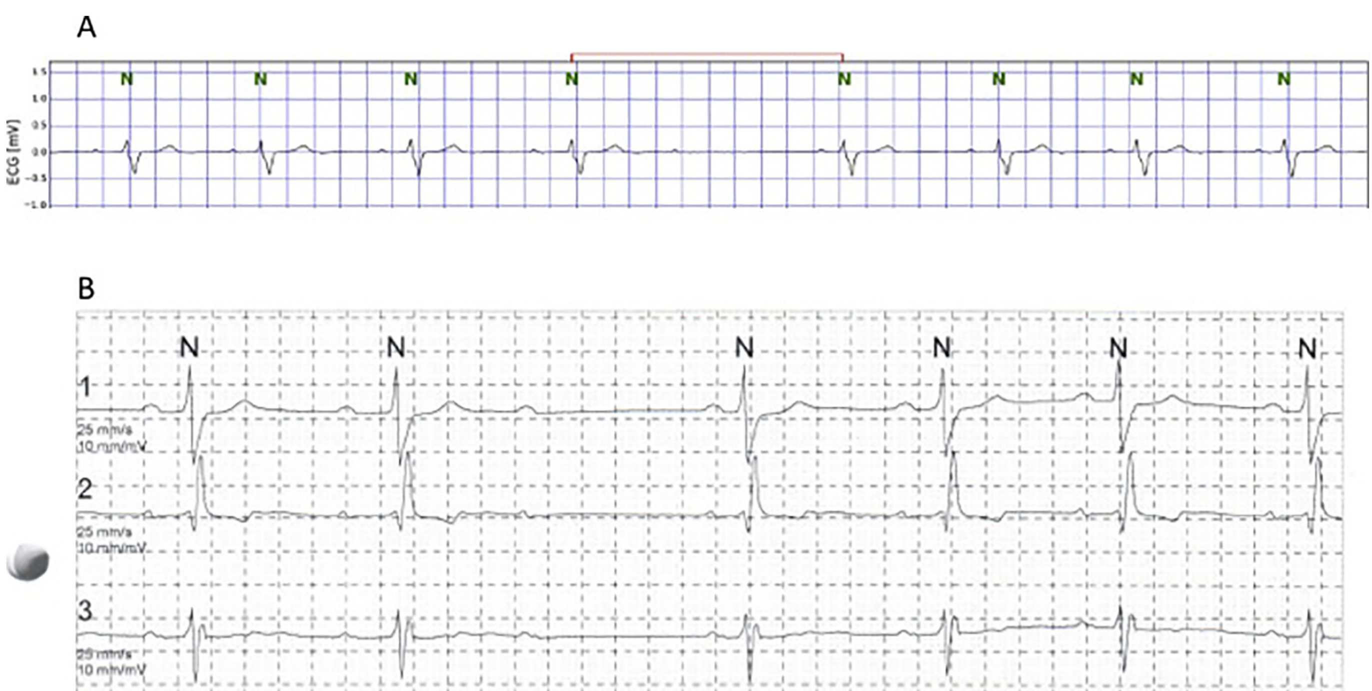

Fig. 5. Simultaneous ECG recorded with Cardiostat™ (A) and with Holter monitor (B) showing second degree type 1 AV block (Wenckebach).

between AF and atrial flutter can be difficult, even with a Holter ECG monitor, and the gold standard is a 12-lead ECG for this diagnosis. Therefore, it may be possible that some cases classified as flutter by the Holter ECG monitor might have been misclassified. The clinical implication is however limited, since diagnosis confirmation of atrial flutter by a 12-lead ECG is required and since medical management of atrial flutter and fibrillation is similar.

Atrio-ventricular block was documented in a few patients and was recognized by both devices Figs. 4 and 5. Significant pauses were also recorded in a few patients and recognized by the 2 devices.

The Cardiostat™ device recorded more noise than the Holter monitor. By having only 2 electrodes and 1 lead, it is more vulnerable since if one electrode detaches or interference in seen in the only lead, the whole tracing is compromised whereas with a Holter having 3 leads, the signal may be seen in other leads. The difference in the total number of beats seen in this study was due to the higher percentage of tracing hindered by noise with Cardiostat™, therefore those beats were “lost”. Why this did not lead to a difference in mean heart rate may be the distribution of the time sample lost to noise and the limited time lost. Noise tended to happen during sleep (electrode detachment) or exercise, representing heart rate extremes.

The accuracy for premature atrial and ventricular beats detection and the discrimination between different PVC morphology with Cardiostat™ was not as good as for AF detection although there was no statistically significant difference in counts between Holter and Cardiostat™ (Table 1). This was likely due to the higher available number of leads recorded by the Holter monitor to analyse the QRS morphology. Also, the proportion of tracing hindered by noise was higher in the Cardiostat™ group, therefore not all premature beats were accounted for, neither not all heart beats. Moreover, the unique lead with Cardiostat™ could have lead to an erroneous diagnosis of a PAC instead of a PVC since the morphology could not be assessed in 3 leads like in a standard Holter. Therefore the Holter seemed better at discriminating PVC morphology. A 12-lead Holter monitor would provide an even better accuracy of the number of PVC morphologies. There were 5 patients with high PVC burden that were detected only by the Holter. In some rare cases, ectopy was also noted on the Cardiostat™, albeit was classified as PAC. For example, one patient had an ectopy burden on the Holter as follow: PAC 1%/PVC 15% whereas the Cardiostat™ reported PAC 18%/PVC < 1%. When reviewed, PVCs on Cardiostat™ were misclassified as PACs. Longer ECG monitoring extending beyond 24 h may however be justified since the occurrence of nonsustained ventricular arrhythmias such as PVCs and nonsustained VT was shown to be variable in time in a previous study, without short term reproducibility [14].

The relevance of having exact count of premature beats when performing a long duration monitoring can be debated. The indications for which long duration monitoring (7 days or more) is prescribed include symptoms of palpitations, dizziness, and searching for asymptomatic arrhythmia, most often AF. In these cases, the most important goal is to correlate accurately arrhythmias to symptoms. It could even be debated if a continuous recording is necessary or if a loop monitoring type of recording could be sufficient (recording only pre-specified arrhythmias, or during symptoms as marked by the patient). However we do believe that continuous recording is superior as it allows for human confirmation of arrhythmias and access to all the data is preserved.

Cardiostat™ technology is innovative and has several advantages over a conventional Holter ambulatory ECG monitoring. It is smaller, easier to wear and less cumbersome. Once the monitoring is completed, the device can be returned by mail for analysis and the patient does not have to bring the device back to the clinic. Compared to other similar technologies, electrodes can be replaced if it fall off and the recording can continue for the desired duration. It also is water resistant, which allows patients to take a shower with the device, a condition that is important for long duration monitoring. Finally, it is versatile and several duration of monitoring from 48 h up to 2 weeks are available. Other ECG monitoring patches have been clinically validated, and showed similar excellent performance and high acceptability by the patient [15,16]. However it is not a real time monitoring, and data is analysed off line after the end of the monitoring period. Some ambulatory ECG monitoring patches have transmission capability and allow for real time telemetry [17]. Whereas real time telemetry leads to timely arrhythmia recognition and potential treatment, it is more costly and alerts need to be carefully selected in order to avoid and unnecessary call burden to the prescribing physician. Both real time and off line analysis of monitoring have a role. Patient selection, physician's expectation and the severity of the suspected condition should guide the choice of device.

In the objective of assessing silent atrial fibrillation, several other non-invasive tools have been evaluated. Hand-held single-lead ECG with dry electrodes has excellent sensitivity and specificity [18]. However, it is ineffective compared to a continuous recording to detect short asymptomatic runs of AF. Automated BP machine with AF detection algorithm [19] have the same drawbacks given the paroxysmal nature of the arrhythmia and the short duration of the monitoring.

One other wearable waterproof patch device has been evaluated with an excellent correlation with the Holter [20]. However, unlike with CardioStat™, the electrodes cannot be replaced, leading to an early discontinuation of the recording in their study. In one study comparing a 24 h Holter with a 14 days adhesive patch ECG monitoring, the 14 days monitoring detected significantly more events than the Holter monitor [21]. Ambulatory ECG monitoring using new technology such as patches has advantages, such as patient's acceptance and tolerability for longer period. It is reliable to assess atrial arrhythmia burden, and it improves the diagnostic yield for infrequent symptoms suggestive of arrhythmia [2].

Limitations

This is a single center study. Heart beat counts, proportion of bradycardia and tachycardia, AF burden, and heart rates were determined by the analysis software and not manually. The diagnosis of AF was however made by the cardiologist and was not an automated function. A qualitative assessment of PAC, PVC and runs of atrial tachycardia and ventricular tachycardia was made upon the rhythm strips presented. No manual count of PAC or PVC was performed.

Wearing the Holter and Cardiostat™ monitors simultaneously could have interfered with individual recordings, however care was taken in order to tape and fix correctly all wires. Subsequent clinical use of the Cardiostat™ revealed similar proportion of noise as seen in the study, therefore noise induced by interference between the Holter and the Cardiostat™ does not seem to be likely.

Although Cardiostat™ has a 48 h to 14 days recording duration, recording only lasted 24 h in this study. The performance of the device for longer duration has not been evaluated.

The 2 types of ambulatory ECG monitoring used in this study, namely the Cardiostat™ and the Holter monitoring did not record the same ECG lead: Cardiostat recorded a modified lead 1, whereas standard Holter monitoring recorded leads avF, V1 and V5, therefore the 2 devices did not record the same vector and amplitude of the signal may have differed significantly between the 2 modalities. This limitation could explain the discordance in PAC/PVC counts seen in some tracings. It could also lead to underdetection of p wave.

With one lead, information on QT interval, or ST-segment may not be reliably assessed.

Conclusion

Cardiostat™ ambulatory ECG monitoring device showed an excellent correlation with the standard Holter ECG monitoring for detection of AF, of AV block and of pauses, despite a higher noise recording level. When present, AF was detected in all patients when compared to a conventional Holter. The Holter ECG monitoring is however superior at discriminating premature atrial and ventricular beats and at qualifying the morphology of PVCs since it has more leads for analysis. Added value of Cardiostat™ include the possibility of longer monitoring duration (up to 14 days), less cumbersome installation (2 electrodes and no wires, patient self-positioning) and water resistance (patient can shower with the device).

Disclosures

The authors have no conflict of interest to declare with regard to the content of this manuscript. Icentia provided the cardiostat free of charge for the study however did not provide any additional funding.

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