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Feasibility of using chest strap and dry electrode system for longer term cardiac arrhythmia monitoring: Results from a pilot observational study

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ABSTRACT

Background and aim: Cardiac arrhythmia diagnostic yield improves with increased duration of monitoring. We investigated patient comfort, diagnostic quality of ECG, and arrhythmia diagnostic yield using a single lead longer term external cardiac monitor (ECM).

Methods: The observational ECM feasibility study enrolled patients with increased risk of cardiac arrhythmia. The ECM investigational prototype was designed using a chest strap with dry electrodes connected to module capable of triggered loop recording of ECG, and automatic detection of arrhythmia. In group-A of study (24-h inpatient), patients wore ECM and Holter that recorded ECG from the ECM and adhesive electrodes. In group-B of study (12-weeks ambulatory), at monthly follow-ups patients filled out a comfort survey and device stored arrhythmia episodes were reviewed.

Results: The study enrolled 34 patients (38 % females, average age 57.5 years, 65 % had palpitations, 12 % had syncope). Diagnostic quality ECG was recorded on 76.5 % of the monitoring duration in 12 of 20 patients with reviewable data in group-A, with motion artifacts causing loss in ECG signal for 18.7 % of the time. In 14 patients in group-B, 94.9 % of the survey responses indicated that ECM was comfortable to wear. Cardiac arrhythmia was observed in 4 of 17 patients (24 %) in group-A and 9 of 14 patients (64 %) in group-B in device recorded episodes. All ECM detected pause and tachycardia were inappropriate detections due to motion artifacts and temporary device removal.

Conclusion: The chest strap-based ECM device was mostly comfortable to wear and recorded diagnostic quality ECG in three-fourth of monitoring period. Cardiac arrhythmia was observed in 64 % of patients over 3-month monitoring along with large number of motion artifact induced inappropriate detections.

What's New

- The study shows that it is feasible to perform ambulatory 3-month cardiac arrhythmia monitoring using a chest strap and dry electrode based external cardiac monitoring system
- The external cardiac monitor is mostly comfortable to wear continuously for 3 months with minimal irritation to the skin
- Diagnostic quality ECG was observed over 75 % of the time during a 24-h period of monitoring

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- Cardiac arrhythmia diagnostic yield was 24 % over a 24-h period and increases to 64 % over a 3-month monitoring period
- Motion artifacts caused a lot of inappropriate pause and tachycardia detection by the device, which can be reduced significantly using simple algorithm modifications

1. Introduction

Cardiac arrhythmia is primarily diagnosed with point of care electrocardiogram (ECG) recordings in the in-clinic or in-hospital setting on symptomatic presentation. If a diagnosis is not reached, then Holter monitors are prescribed for 24–48 h. Adhesive patches are also being used for ambulatory cardiac arrhythmia monitoring for 7–14 days and has shown to improve diagnostic yield. [1] Discomfort associated with adhesive electrodes, requirements for patient compliance, extensive overhead of a monitoring center for episode review limit such monitoring systems for a period of 7–10 days for single use. Many external devices [2] and wearable smartwatches [3,4], [5] are currently being used for longer term ambulatory monitoring to screen for cardiac arrhythmia, particularly atrial fibrillation (AF), worldwide 6–10.

Subcutaneous insertable cardiac monitors (ICM) have been used for continuous longer term automatic detection of cardiac arrhythmias and patient symptom triggered storage of loop recorded recent ECG. [11], [12] ICMs are minimally invasive and are implanted in the subcutaneous space. ICMs have been used for diagnosing the cause of unexplained syncope, [13], [14] monitoring of recurrent atrial fibrillation (AF) after ablation of AF, [15] and in patients with history of cryptogenic stroke. [16] In most of these cases the main objective is to deliver therapeutic interventions to patients in a timely manner to reduce clinical morbidity associated with these clinical conditions in a safe and cost efficient manner. [14], [17] While ICMs are considered the gold standard for cardiac arrhythmia monitoring it is often not considered an affordable option in multiple countries around the world due to device cost. The diagnostic yield for ICM based monitoring is highest due to the continuous long duration of monitoring requiring no patient compliance. [18], [19]

Chest strap employing dry electrodes have been used as ECG and heart rate monitors in the setting of fitness, athletic training, and military operations to monitor heart rate and respiratory rates during physically and mentally strenuous activity [20–24]. The objective of this study was to design an investigational external cardiac monitor (ECM) using chest strap with single lead dry electrodes and ICM electronics and evaluate the feasibility of using such a system for longer term (3–6 months) cardiac monitoring in an affordable manner. The overarching goal of such a system would be to bridge the gap in diagnostic yield, for intermittent and asymptomatic cardiac arrhythmia, between short-term monitoring using patches and long-term monitoring using ICMs in a manner that is comfortable to the patients. This study investigated (1) whether the diagnostic quality of the ECG is similar to ECG obtained using adhesive electrodes, (2) whether it is comfortable for patients to wear the designed ECM continuously for 3 months, and (3) the diagnostic yield of cardiac arrhythmia during short term and longer-term monitoring and the cardiac arrhythmia review burden for such a system.

2. Methods

2.1. Design of the investigational ECM prototype

The considerations for the design of the investigation ECM prototype were that it needs to be comfortable and affordable for longer term use. Washable chest straps using dry electrodes (FDA-approved Zephyr™ BioHarness – Medtronic Inc., Minneapolis, USA) is used in the design to make the ECM comfortable for longer term and multiple use. The electronics used was what is available in the FDA-approved Reveal LINQ™ ICM (Medtronic Inc., Minneapolis, USA) to make it compatible with existing systems and infrastructure for wireless remote monitoring. The ICM is capable of loop recording patient triggered symptomatic events with up to 20 min of ECG recordable prior to the patient using a patient activator to trigger ECG storage after a symptomatic event. Further, the ICM has algorithms which are capable of automatically detecting pause, bradycardia, tachycardia, atrial fibrillation and atrial tachycardia from a single lead ECG. Replaceable off the shelf coin cell battery was used to power the electronics to make it compatible for multiple re-use of electronic components in multiple patients to make it affordable. Fig. 1 shows the various components of the designed investigational ECM.

2.2. Feasibility study design

The ECM feasibility study was a multi-center prospective observational study using the investigational prototype. The purpose of study was to demonstrate feasibility of using the ECM prototype as a longer-term external loop recorder by characterizing the diagnostic quality of the acquired ECG signal in an acute 24-h Holter study and the feasibility (patient comfort and diagnostic yield) of doing continuous longer-term monitoring (up to 3 months) using the prototype. Patients with history of cardiovascular disease and suspected cardiac arrhythmia were enrolled in 2 sites in India.

Group An underwent short-term inpatient cardiac monitoring with prototype and DR220 Holter for up to 24 h while admitted in the hospital (Fig. 2). Clinical history, demographics, clinical events before enrollment, save to disk from prototype, Holter flash card, and patient survey at exit was collected. Group B followed a longer-term cardiac ambulatory monitoring of 3 Months with ECM (Fig. 2). At baseline clinical history, demographics, and symptoms were collected. At 1-,2-,3-month follow-up and unscheduled visits, clinical actions taken, clinical events, device save to disk file, symptoms, patient survey, and patient diary were collected. The device is capable of remote monitoring but was not used as part of the study.

2.3. Data analysis

The diagnostic quality of the ECG recorded by the investigational device was evaluated in group-A (short-term) of the study, where patients were continuously monitored for 24 h in an inpatient setting. Enrolled patients wore the ECM prototype in parallel with the DR220 Holter monitoring device to acquire raw ECG signal from the ECM device and surface ECG electrodes using adhesive electrodes. Segments in the Holter recording was marked for periods of diagnostic quality ECG, periods of baseline wandering, periods of motion artifacts, and periods of loss of Holter telemetry. Proportion of duration of diagnostic quality ECG was quantified for periods when there was no loss of telemetry from device to the Holter system.

Patient comfort level of wearing a chest strap based dry electrode system for continuous monitoring for a period of 3 months was investigated in group-B of the study, where patients were continuously monitored for 3-months in an ambulatory setting. Enrolled patients wore the investigational ECM prototype at home continuously except when they were having a bath or having discomfort. Patient filled out a survey, designed for this study, at 2-, 4-, 8-, and 12-week follow-ups which answered five questions related to their comfort level in using the device continuously (Fig. 3). Patients also maintained a diary noting down the number of times they temporarily removed the device and the reason for the removal (Fig. 3). The responses in the survey and diary were summarized.

Diagnostic yield evaluation was performed both in group-A (short-term) of the study, where patients were continuously monitored for 24 h in an inpatient setting, and in Group-B (longer-term) of the study, where patients were continuously monitored for 3-months in an ambulatory setting. The prototype electronics was capable of loop recording ECG initiated by patient, and automatic detection of pause, bradycardia,

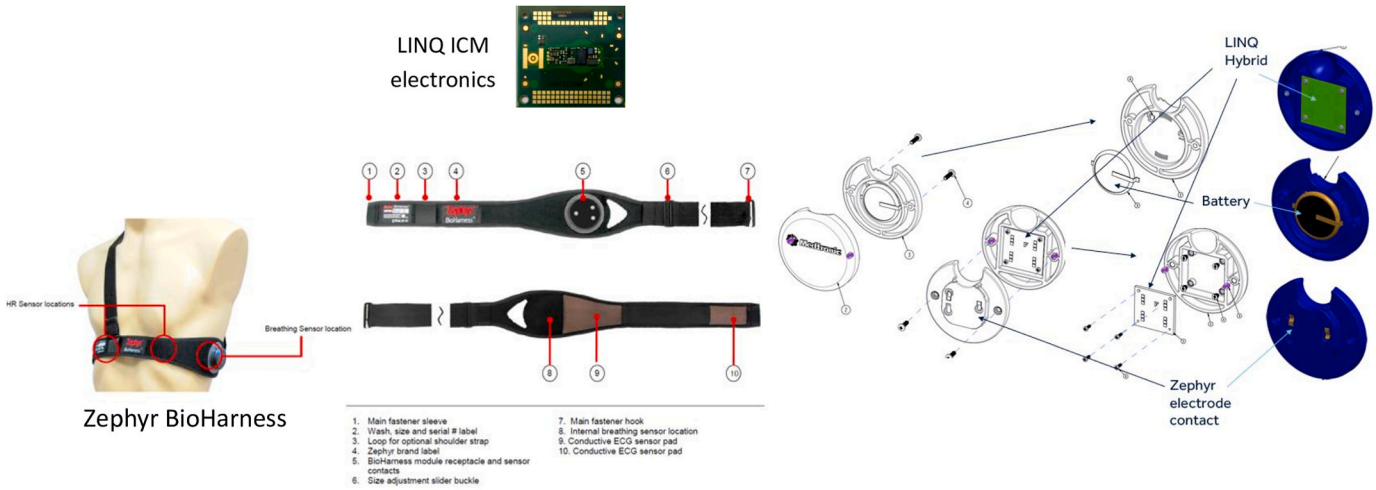

Fig. 1. Components of the external cardiac monitor investigational prototype.

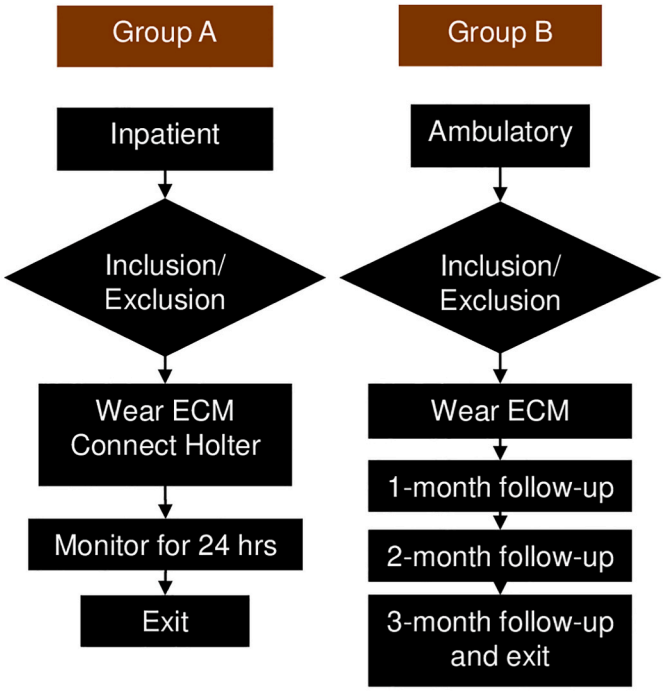

Fig. 2. The external cardiac monitor feasibility study workflow.

tachycardia, and atrial tachycardia/fibrillation (AT/AF). Patient completed 4-, 8-, and 12-week clinic follow-ups during which device stored episodes were downloaded using a programmer. The ECM device recorded cardiac arrhythmia episode data was reviewed for presence of true arrhythmia.

3. Results

The study enrolled a total of 34 patients (average age 57.5 years, 38 % females, 65 % had history of palpitations, 12 % had history of syncope) of which 20 patients enrolled in Group-A for 24-h inpatient monitoring (average age 63.4 years, 53 % females, average BMI 24.8 kg/m^2) and the other 14 patients enrolled in Group-B for 12 week ambulatory monitoring (average age 49.7 years, 21 % females, average BMI 26.1 kg/m^2).

3.1. Signal quality

Of the 20 patients enrolled in group-A of the study, reviewable data for evaluating signal quality was successfully telemetered to DR220 Holter in 12 patients. Two patients exited the study prior to start of Holter recording and the other 6 patients had telemetry error in the uplink of the raw device measured ECG to the DR220 Holter. This telemetry uplink functionality of the device is specially designed for use in clinical studies and is not intended for routine clinical use. The ECM signal looks comparable (Fig. 4A) to surface ECG with adhesive ECG electrodes, with respect to visibility of p-waves, QRS complex, and T-waves, when prototype dry electrodes are in contact with the skin. The ICM polarity is dependent on the electrode position relative to the two inputs to the ICM electronics and the QRS polarity may be reversed based on the electrode configuration in specific devices. The diagnostic quality ECG was recorded on an average 76.5 % of the monitoring duration with successful ECG recording uplink to the Holter device (Fig. 4B). Motion artifacts, which included durations with complete displacement of the chest strap, caused loss in ECG signal for 18.7 % of the time leading to false pause or tachycardia detection by the device. Cardiac arrhythmia in 3 of 12 patients with Holter recordings (two patients with 3 episodes of AF and one patient with junctional arrhythmia). All episodes were detected by ECM - the device automatically detected true AT/AF in 2 patients, junctional rhythm in 1 patient; however, duration was underestimated due to motion artifacts.

3.2. Patient comfort

In the group-B patients, 43 patient comfort survey responses were completed with 14, 10, 10, and 9 patients filling out the survey at 2-, 4-, 8-, and 12- week follow-ups respectively. Overall, only 5.1 % of the responses indicated that patients disagreed that the ECM system was comfortable to wear, 2.8 % indicating ECM device was uncomfortable during sleep and 1.4 % indicating that it was uncomfortable for the skin (Fig. 5).

There was a total of 726 days with temporary removal of device as reported by the patients in the patient diary. There was a total of 613, 102, and 11 days with 1, 2, or 3 removals per day respectively. Most of the removals (675 removals, 93 %) was for $\leq$2 h in duration in a day of which a fair share (591 removals, 81 %) was $\leq$2 h in duration. The main reason for removal was for bathing (677 instances, 93 %) as instructed per protocol of the study. The other reasons for removal included sleep disturbance (31 instances in 1 patient), discomfort (7 instances, 2 patients) and skin irritation or rashes or itching on 11 instances in 2 patients.

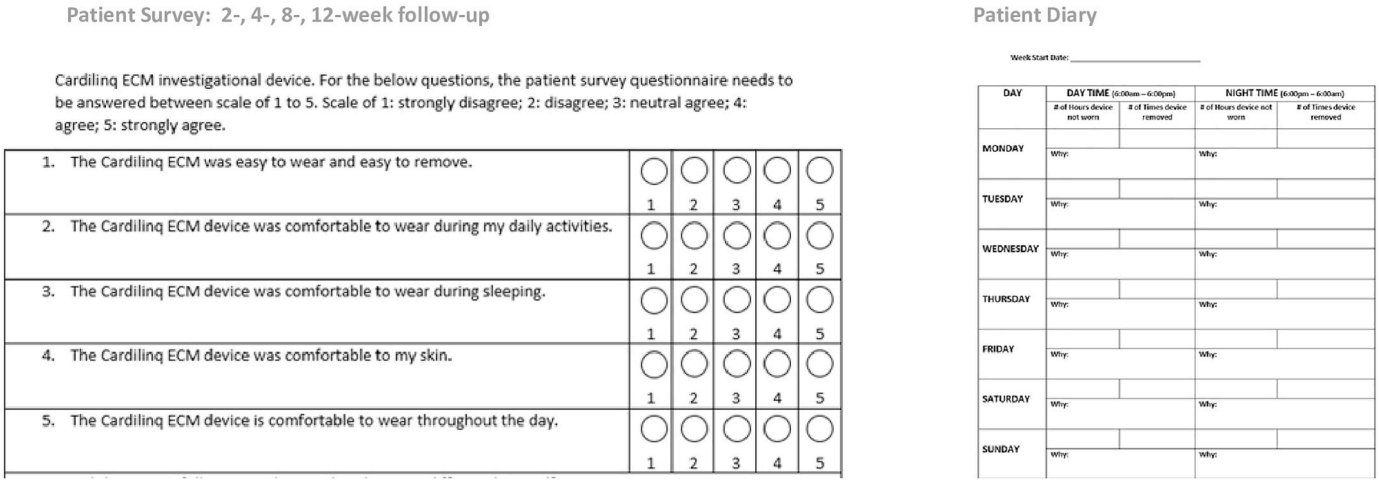

Fig. 3. Patient survey questionnaire and the patient diary used during the study to collect information on patient comfort in using the investigational prototype for longer term cardiac arrhythmia monitoring in an ambulatory setting.

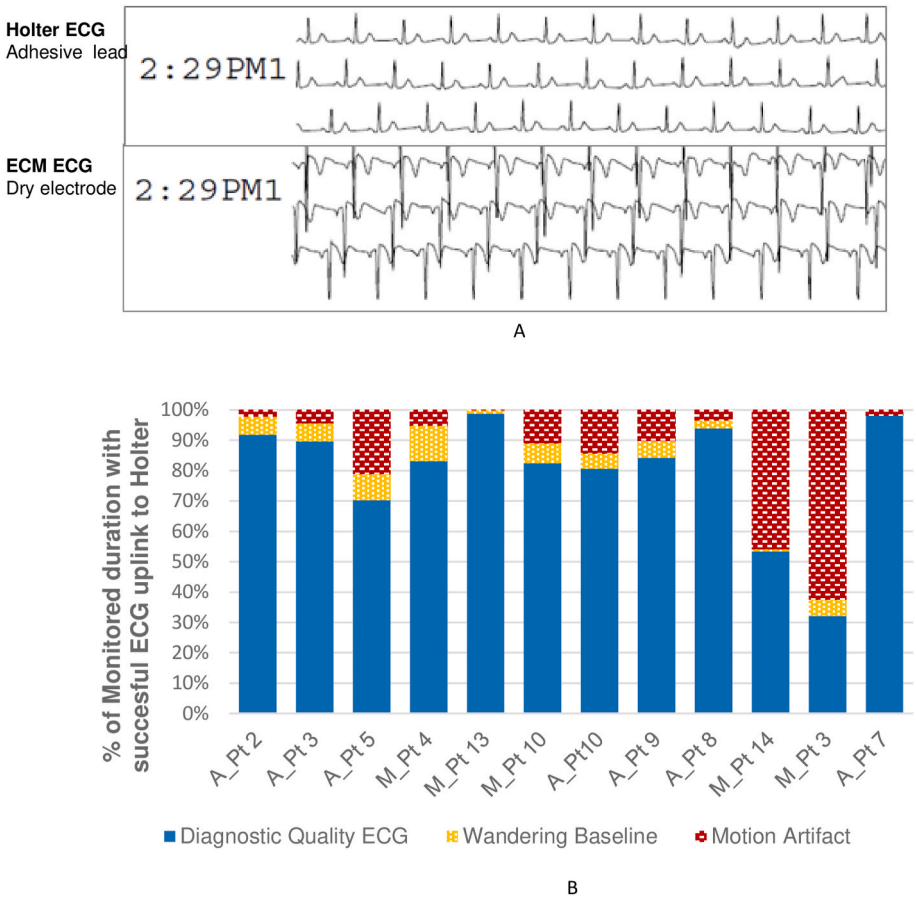

Fig. 4. (A) ECG quality comparison between adhesive lead based Holter recording and ECG recorded simultaneously using dry electrode based investigational ECM system. (B) Proportion of diagnostic quality ECG recorded in each group A patient.

3.3. Diagnostic yield

Device stored episodes available for review in 31 of the 34 patients enrolled in the study. Table 1 shows the total number episodes stored by the device and was available for review. The table also shows the total number of patients where cardiac arrhythmia was observed in the patients. Cardiac arrhythmia was observed in 4 of 17 patients (24 %) in group-A (24-hr inpatient); 9 of 14 patients (64 %) in Group-B (12-week ambulatory). Fig. 6 shows examples of device stored true cardiac arrhythmia episodes. Highest diagnostic yield was observed in device detected AT/AF episodes followed by patient activated and device detected bradycardia episodes. All device detected pause and tachycardia were false detections due to motion artifacts and temporary device removal. An example of falsely detected pause episode is shown in Fig. 7. It was observed that most false episodes had <20 RR intervals in last 30 s prior to detection or had more than two RR intervals <220 ms

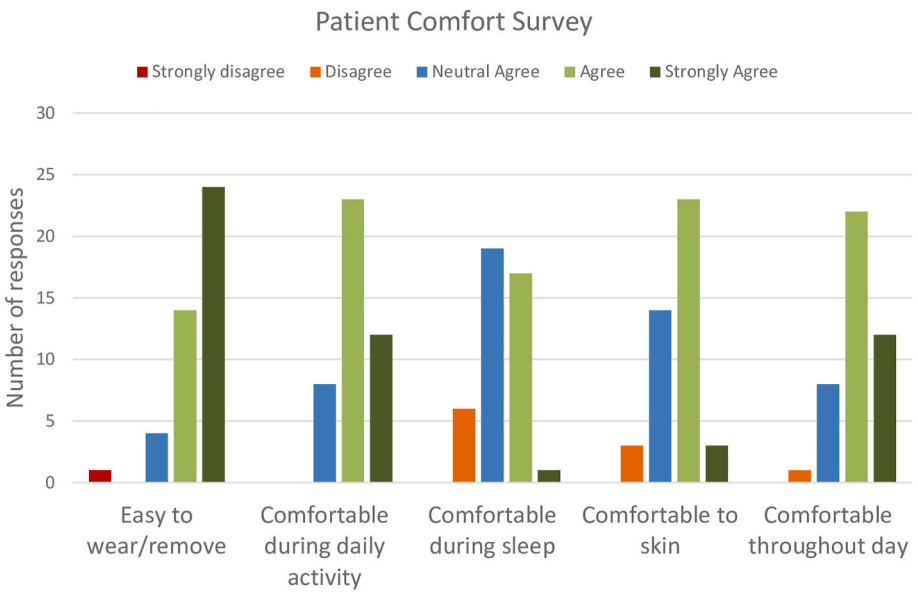

Fig. 5. Summary of results from the patient survey related to the evaluation of patient comfort in wearing the investigational prototype daily for a period of up to 12 weeks.

Table 1
Total number of investigational device recorded episodes that were reviewable. The total number of patients with true arrhythmia observed in any of those reviewable episodes.

		Group-A	Group-B
	Patients	17	14
	Monitoring Duration	24 h	12 weeks
Number of device recorded episodes with ECG (patients)	AT/AF	33 (7)	33 (7)
	Bradycardia	7 (3)	37 (7)
	Pause	198 (16)	537 (13)
	Tachycardia	24 (9)	103 (13)
	Patient Activated	0 (0)	52 (11)
Number of patients with true cardiac arrhythmia	AT/AF	3	2
	Bradycardia/pause	0	2
	PVC	0	3
	Sinus Arrhythmia	0	1
	Sinus Tachycardia	0	4
	Junctional Rhythm	1	0

Device detected episode type	Group A – 24-h monitoring (N = 17 patients)			Group B – 12-week monitoring (N = 14 patients)		
	Number of detected episodes	Patients with detected episodes	Patients with true episodes	Number of detected episodes	Patients with detected episodes	Patients with true episodes
AT/AF	33	7	3 AF, 1 junctional rhythm	33	7	2 AF
Bradycardia	7	3	0	37	7	1 Bradycardia 1 pause
Pause	198	16	0	537	13	0
Tachycardia	24	9	0	103	13	0
Patient Activated	0	0	0	52	12	3 PVC 4 sinus tachycardia 1 sinus arrhythmia

(180 ms for tachycardia episodes) or had more than two RR intervals >1200 ms or had more than two beat to beat RR interval difference was >1000 ms. Simple post-hoc algorithm modifications, that employs counting short intervals, long intervals and change in intervals above the thresholds mentioned above, was able to reduce the number of false detections reported in Table 1 by 97 %.

4. Discussion

The ECM feasibility study was a pilot study designed to evaluate the feasibility of an investigational external monitoring device intended for continuous longer-term monitoring of cardiac arrhythmia in an ambulatory setting. During the 24-h inpatient monitoring, diagnostic quality ECG was observed in over 75 % of the monitoring duration during the short term study with ECG characteristics comparable to simultaneous Holter recordings using adhesive electrodes. During the 12 week ambulatory monitoring, around 5 % of patient responses indicated that the device was uncomfortable to wear with only 1.4 % responses indicating skin irritation. Cardiac arrhythmia, that might explain patient symptoms, was observed in 24 % of patients during 24-h inpatient monitoring and 64 % of patients during 12 week ambulatory monitoring.

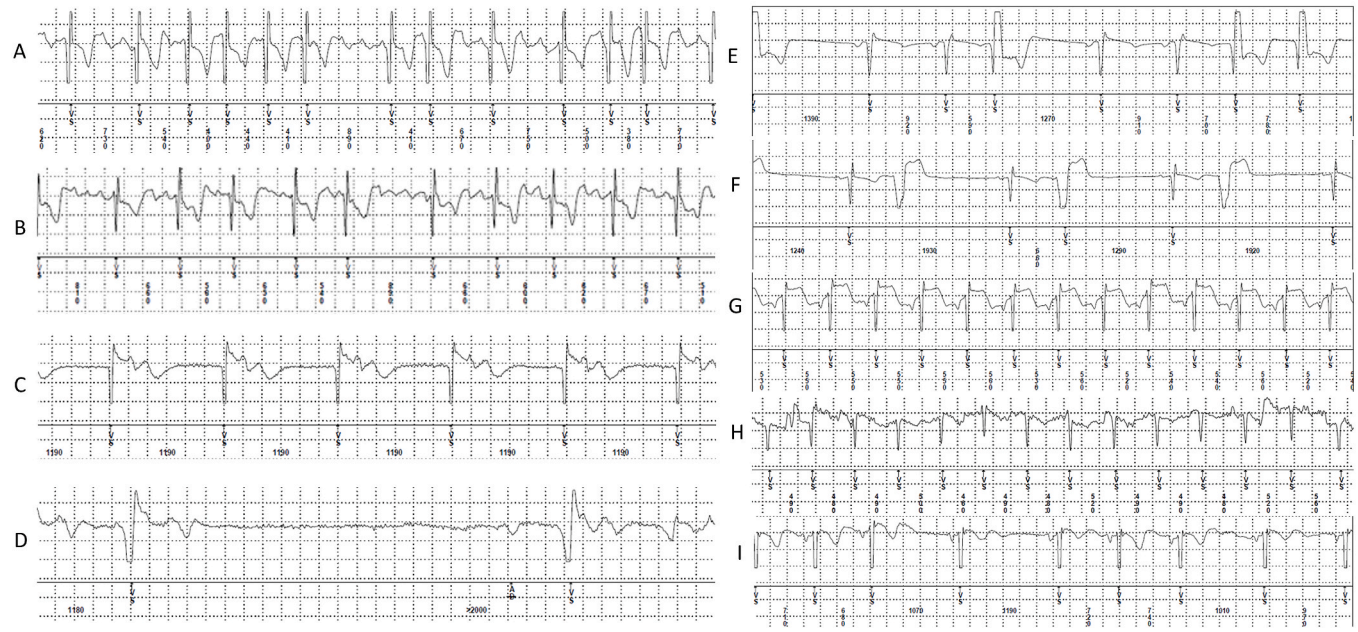

Fig. 6. Examples of different kind of true arrhythmia detected and stored by investigational ECM device. A–B: atrial arrhythmia; C: Junctional rhythm; D: sinus pause; E–F: premature ventricular contractions; G–H: sinus tachycardia; I: sinus arrhythmia.

Holter based 24-h monitoring systems with conventional adhesive electrodes has reported less than 2 % unanalyzable recording due to noise or motion artifact. [25] Adhesive patch based monitoring systems report noisy or low diagnostic quality signals anywhere between 2 % and 12 % of the monitoring time when the patch is staying on the patient depending on the setting for monitoring use [25–29]. In contrast, results from this study show that diagnostic quality ECG could not be recorded around 24 % of time using the investigational ECM prototype using dry non-adhesive electrodes in a chest strap designed for longer than 12-week monitoring. Thus, the device is functional in detecting cardia arrhythmias for around three-fourth of the time which includes time when the device is not worn or worn incorrectly. A non-adhesive dry electrode system will not have the same measurement coverage as an adhesive Holter or patch system daily, but it also enables prolonged monitoring which will increase the total duration of monitoring. The designed capability of extended monitoring duration of more than 12-weeks, enables recovery of diagnostic yield for intermittent and asymptomatic cardiac arrhythmia such as AF as has been reported elsewhere [1,18,19]. Further, it has been reported for smart watch based systems the measurement coverage is in the range from 25 % to 58 % over a 24 h monitoring period in an ambulatory setting [30–32]. Most of these devices uses signal quality assessment to reject segments of data due to motion artifacts to improve detection performance. Stricter the rules for signal quality, lower was the measurement coverage.

Patients mostly agreed that device in this study was comfortable to wear for prolonged duration. In around 5 % of responses over prolonged monitoring – 10 of 14 patients wore the device for more than 8 weeks - patients mentioned discomfort. Skin irritation, one of the main concerns with such a system, was negligible. Due to the non-adhesive nature of the electrodes, patients could remove the device for periods of time and wear it again without having to replace the device. In contrast, for adhesive patch based system, close to 6–7% of patients report discomfort in 10–11 days of monitoring. [1] More than 80 % of patients preferred patch monitoring compared to Holter monitoring showing that Holter monitoring systems are more uncomfortable to wear. [1] Further, adhesive based patch monitoring systems require a new patch in case the patch is removed, which is not the case for the system investigated in this study - a key advantage of non-adhesive dry electrode systems.

Holter based monitoring systems report diagnostic yield for cardiac arrhythmias in the range from 10 to 15 % and 10–14 day adhesive patch based monitoring systems report cardiac arrhythmia diagnostic yield around 40–50 % [1,25–29]. with a fair share of arrhythmia being non-clinically actionable supraventricular tachycardia. The investigational device in this study was able to diagnose cardiac arrhythmia, which may explain their symptoms, in a fair share of patients – 24 % in the 24-h monitoring and 64 % in 12-week monitoring. However, higher diagnostic yield also came at the cost of having to review large number of false detections due to motion artifacts. While remote monitoring transmissions was not utilized in this study, but with capabilities of remote monitoring that is present in these devices, further improvement in diagnostic yield is expected.

Automatic cardiac arrhythmia detection has improved in ICMs over the last decade [33–36]. The current state of the art devices are able to maintain high sensitivity for detection of atrial fibrillation, pause, bradycardia, and tachycardia while also maintaining a reasonable episode review burden for clinicians using artificial intelligence algorithms to reduce inappropriate detections. [37–39] Artificial Intelligence algorithms (AccuRhythm™ AI) is currently being used for ICM devices, deployed in the CareLink remote monitoring cloud platform, which has reduced 88 % and 97 % of inappropriate AF and pause detections in ICM [37,38]. One of the goal of this study was to evaluate whether these algorithms when applied to non-implantable setting will also perform similarly. The main observed difference was a significant increase in false detections of pause and tachycardia due to motion artifacts. ICMs are not susceptible to motion artifacts, and thus the algorithms in those devices were not designed to reject motion artifact related false detection. Minor algorithm modifications were evaluated which would reduce false detections by over 97 %. Further artificial intelligence derived algorithms when trained to incorporate motion artifact signals can further reduce the false detections in the future. Alternatively, one can use a third-party service to curate the information presented to physicians as is done by Holter and patch based devices. Finally, the device algorithms can be programmed differently for different patient populations as has been practiced for ICM devices (e.g. only looking for pauses >4.5 s instead of 3 s for patients who do not have syncope, or requiring larger number of consecutive intervals of shorter

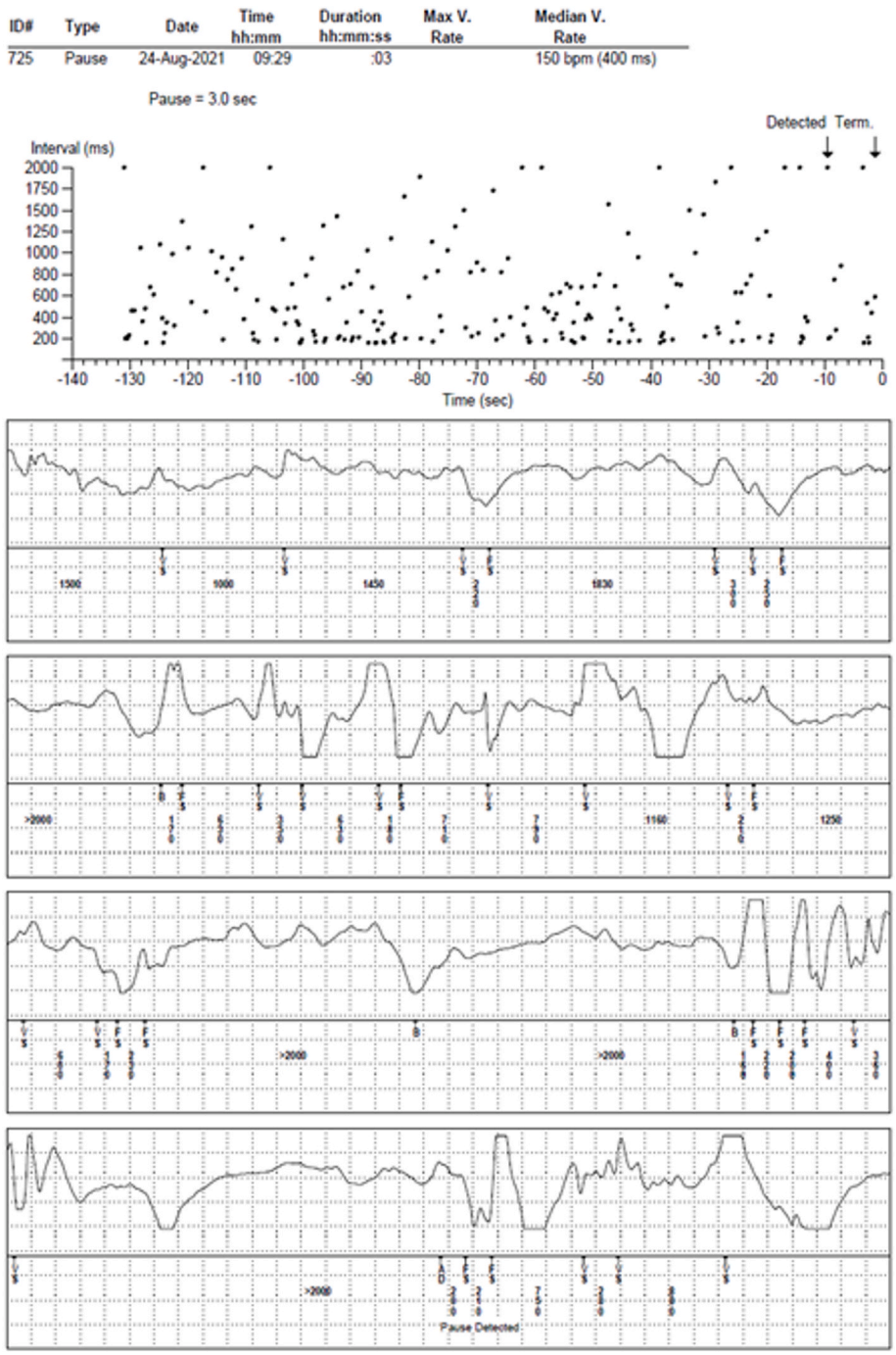

Fig. 7. Examples of false arrhythmia detected and stored by investigational ECM device.

or longer cycle lengths to detect tachycardia and bradycardia, respectively, in patient who are being monitored for AF) will also reduce false detections.

The main advantage of the investigational ECM system is the non-adhesive dry electrodes which enables multiple use in the same or additional patients without having to replace the strap or the electronics. The strap is washable and hence can be used multiple times. The electronics have batteries which will last for more than 5 years without needing to change it, thus enabling multiple use. Patients can remove the device and put it back on, which enables prolonged monitoring in patients if required. The device was not designed to replace adhesive patch based monitoring, but may be useful for patients who have intermittent and asymptomatic cardiac arrhythmia which may require longer term monitoring beyond 10–14 days. Based on the results of this feasibility study, the current investigational device is feasible for automatic detection of AT/AF and recording of preceding ECG when patients are having symptoms as not a lot of artifact induced false detections or ECG corruption was observed in these type of episodes. Pause and tachycardia detection needs algorithm modifications before it can be feasible for routine clinical use. Additionally, tighter chest straps and vests and strain gauge based automatic detection of chest strap tightness may be useful in the future. Additional data is going to be collected in an amended study with the second generation of the investigational prototype. Future enhancements being considered include multi-lead

systems with additional sensors which can potentially measure other parameters to monitor for additional disease states.

The primary limitation of the study is the limited number of patients included for analysis. Additional data will be collected in the future in an expanded study with a second generation of the investigational prototype. Further, the study did not utilize wireless transmission and remote monitoring capability due to some logistical limitation during the study. Thus, device recorded ECG were only reviewed at the monthly follow-ups hence limiting the number of episodes reviewed. Despite this limitation the diagnostic yield for cardiac arrhythmia was above 50 % for longer term monitoring. Finally, the quality of the signal as well as the patient comfort level is very dependent on the size of the strap utilized and the tightness of the fit of the device for various patients. Only two sizes were available and hence the variance in diagnostic quality across different patients. Data on the tightness of the strap worn was not collected and hence could not be analyzed.

5. Conclusion

A chest strap based investigational external cardiac monitoring system using non-adhesive dry electrodes for prolonged cardiac monitoring was feasible. Recorded ECG was of similar diagnostic quality as Holter systems with adhesive electrodes with recordings devoid of noise or motion artifacts more than 75 % of time. It was mostly comfortable for patients to wear the system for a long periods daily and continuously for 4–12 weeks. Cardiac arrhythmia was diagnosed in more than 60 % of the patients during longer term monitoring along with large number of inappropriate detections.

Funding sources

Funding for this project was received from Medtronic Inc.

Patient consent

All patients provided consent at the time of enrollment to the ECM feasibility study.

Ethics statement

The clinical study was approved by Institutional ethics committees where the study was conducted.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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