

Atrial Fibrillation Detection by a Subcutaneous Monitoring Device

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Abstract

The Reveal XT subcutaneous insertable cardiac monitor detects Atrial Fibrillation (AF) from the irregularity of the ventricular rhythm. This study is a first assessment of the AF detection performance using subcutaneous signals from implanted devices. Patients implanted with a Reveal XT device were monitored by a dedicated Holter system, recording the surface ECG and uplinked device data. Device detections of AF were reconstructed from the uplinked data and classified as either true positive, false positive and false negative using the surface ECG for reference. In a total of 82 Holter recordings from 60 patients, the mean AF episode detection sensitivity was 90.6% and 98.1% for AF episodes ≥ 2 minutes and ≥ 4 minutes, respectively. The mean episode PPV was 55.1%. False positive detections were clustered within a few patients with irregular rhythms that were not annotated as AF.

1. Introduction

Reliable characterization of AF is essential in the treatment of this cardiac arrhythmia. However, AF is often asymptomatic and infrequent, and therefore difficult to capture with short term monitoring systems. Long term monitoring alternatives are often burdensome for the patient and depending on patient compliance. Continuous monitoring of AF by means of an insertable subcutaneous monitoring device offers a new opportunity to reveal the full picture of AF.

The Medtronic Reveal XT device was developed as a subcutaneous, insertable device for continuous cardiac rhythm monitoring and arrhythmia detection. Initial validation of the AF detection performance was done by using standard surface ECG databases [1]. These standard databases mainly contain well defined sinus rhythm and AF and almost no noise or other sensing artifacts. With this data an episode sensitivity of 99% and a positive predictive value (PPV) of 76% were observed. The present study was the first in vivo validation of the AF

detection performance, using subcutaneous signals from implanted devices. This evaluation will provide an assessment of the AF detection performance of the implanted device in a real-life setting.

2. Methods

The Reveal XT device is a subcutaneous insertable cardiac monitor, aimed at detection of cardiac arrhythmias, including bradycardia, asystole, ventricular tachycardia and atrial tachycardia and atrial fibrillation. The subcutaneous ECG is sensed by means of two electrodes with a 40 mm electrode distance, incorporated in the 61 x 19 x 8 mm can. The device is optimized for sensing the subcutaneous R-wave [2], and all cardiac rhythm classification is based on the sensed RR-intervals. Hence, the detection of AF is based on the ventricular response to an atrial arrhythmia.

The irregularity of the ventricular rhythm is evaluated over a 2 minutes period by means of a Lorenz plot of the differences in RR-intervals [3]. Typical examples of plots representing normal sinus rhythm and AF are shown in Figure 1. Based on the distribution of datapoints within this plot the rhythm is classified as sinus rhythm or AF. Additional analysis is done to detect a high degree of irregularity typical for atrial flutter.

Subcutaneous sensing is susceptible to sensing of myopotentials, which may cause false positive AF detections. To prevent this, the device determines the amount of noisy RR-intervals and postpones the decision as to a change in the atrial rhythm if the noise level exceeds a pre-programmed threshold.

Upon detection of an AF episode the subcutaneous ECG of the 2 minutes leading to the detection are stored in the memory of the device. In this way, the physician is able to confirm appropriate detection of AF. A maximum of 13 episodes can be stored in the memory. Although the design of the detection algorithm was focused on achieving a high AF detection sensitivity, it should also yield a sufficiently high specificity, to ensure that the majority of the stored episodes are representing true AF.

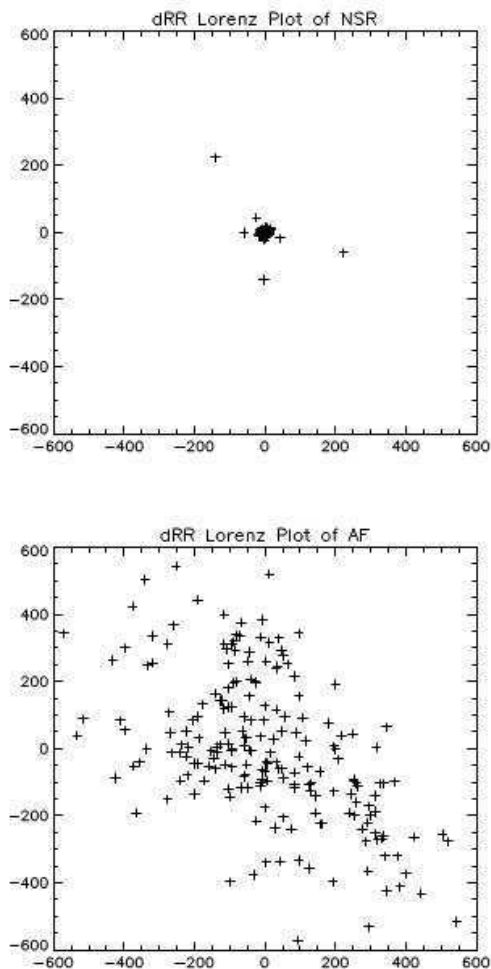


Figure 1: Typical Lorenz plots for normal sinus rhythm (upper panel) and Atrial Fibrillation (lower panel). Units for all axis are ms.

To be enrolled for this study, patients should have an implanted Reveal XT device and have a high likelihood of AF recurrences, based on a scheduled or recently performed pulmonary vein ablation and/or frequent AF recurrences or symptoms attributable to AF. Patients were monitored with a dedicated Holter monitoring system (DR220, NorthEast Monitoring), able to record two surface ECG channels and the uplinked data of the implanted device for a maximum of 46 hours. The uplinked device data included the digitalized subcutaneous ECG and information on the classification of each sensed R-wave, the amount of irregularity in the ventricular rhythm and markers indicating the detection of arrhythmias.

If the device indicated AF burden during the Holter monitoring period was less than 2%, a second Holter recording was obtained from the same patient and both recordings were combined to determine the detection performance metrics for that individual patient.

Analysis was done on the recorded segments for which the quality of the surface ECG allowed unambiguous interpretation of the atrial rhythm and for which the uplinked device data was available. Rhythm annotation of the surface ECG recordings was performed by an independent core-lab. Device detections of AF were reconstructed from the uplinked data. Device detected AF episodes were classified as either true positive (TP), false positive (FP) and false negative (FN) detections. Based on the overlap between true AF episodes and device detected AF episodes the device detected duration of AF was classified similarly.

Sensitivity and PPV for episode detection and duration detection were calculated for each individual patient, and mean detection metrics, averaged over the overall population were calculated.

Because the detection algorithm classifies the rhythm on a 2 minutes grid, the likelihood of detecting AF episodes, shorter than 2 minutes is relatively small. Therefore, episode and duration performance metrics were determined for all true AF episodes and for true AF episodes ≥ 2 minutes separately.

3. Results

In this study, a total of 82 valid Holter recordings from 60 patients were collected. After exclusion of recording segments with missing uplinked device data and/or insufficient recording quality, 2982 hours of valid recording was included in the analysis.

True AF was observed in 17 Holter recordings from 17 patients, including 83 AF episodes ≥ 2 minutes with a total duration of 198.7 hours. In 17 recordings from 14 patients FP AF detections were observed, the remaining 46 patients had no FP detections. A summary of the classification of all device detections identified in this study is provided in Table 1.

Episodes	TP	FN	FP
All	145	82	433
≥ 2 min	69	14	

False negative as well as false positive detections showed to be clustered in specific patients. Of the 14 FN detections of episodes ≥ 2 minutes, 13 were from a single patient, presenting with a highly regular ventricular rhythm resulting from 3:1 conduction of a

supraventricular arrhythmia. Another patient had a single 3.4 minutes AF episode that was not detected. In 5 Holter recordings from 4 patients a total of 380 FP detections were identified, accounting for 88% of all FP device detections observed in this population. These patients showed frequent sinus arrhythmia and/or ventricular bigeminy, causing sufficient irregularity in the ventricular rhythm to trigger AF detection. Myopotential sensing was a common observation in this population, but in only 13 occasions FP detections were attributed to excessive myopotential sensing. In addition, as shown in Figure 2, the majority of FP detections were short in duration; 260 FP detections (60%) were 6 minutes or shorter.

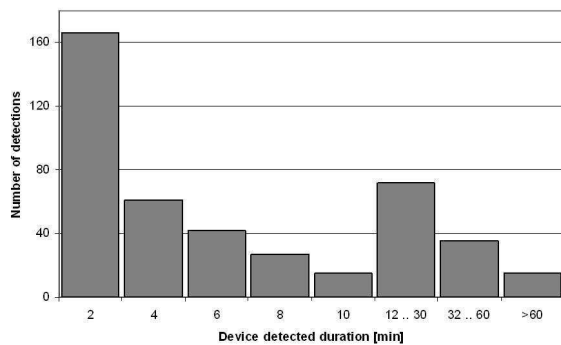


Figure 2: Duration histogram of false positive AF detections

The metrics for episode detection and duration detection, averaged over all patients, are presented in Tables 2 and 3, respectively. Furthermore, the mean AF detection sensitivity for episodes ≥ 4 minutes was 98.1%.

Episodes	Sensitivity	PPV
All	65.2 \pm 40.7 %	55.1 \pm 48.4 %
≥ 2 min	90.6 \pm 27.4 %	55.1 \pm 48.4 %

Episodes	Sensitivity	PPV
All	76.9 \pm 37.3 %	52.7 \pm 46.0 %
≥ 2 min	86.8 \pm 26.9 %	55.0 \pm 47.4 %

Due to the relatively small number of episodes and detections in each patient, a wide range in individual detection metrics was observed. From the 17 patients with true AF recurrences ≥ 2 minutes, an episode

detection sensitivity of 100% was found in 15 patients, the two remaining patients had a sensitivity of 40.1% and 0%, respectively. Similarly, individual PPV values ranged from 0% (11 patients) to 100% (13 patients).

4. Discussion and conclusions

Decisions in the treatment of AF require a reliable characterization of AF. In the absence of a full disclosure of the patient’s AF status, physicians are driven to conservative therapeutic decisions and/or may be left with symptoms alone to base their decisions on. In particular, AF may remain unnoticed in asymptomatic patients and pose the patient at risk of stroke [4].

The results of this study show that the AF detection algorithm of the Reveal XT device is highly sensitive in the detection of AF recurrences. Given the design of the algorithm, episodes shorter than 2 minutes are unlikely to be detected, as is reflected by the results from this study. On the other hand, the algorithm detects almost all true AF episodes ≥ 4 minutes. Moreover, among the 17 patients with AF recurrences, 16 were identified by the device and the remaining patient had only a single, short AF episode.

Nearly half of the AF detections showed to be false positive. The device stores the detected episodes and thereby allows the physician to verify the detected AF recurrences. However, in case of many FP detections within one patient, true AF detections may be overwritten and the verification of appropriate AF detection remains inconclusive. Based upon the observation that many FP detections are relatively short in duration, more advanced ECG storage based on the detected duration may increase the likelihood of storing true and relatively long AF episodes. Although commonly observed in the Holter recordings, myopotential sensing showed to be a rare cause of FP detections. In a few patients, frequent sinus arrhythmias and irregular ventricular rhythms such as extrasystoles and bigeminy caused an excessive number of FP detections. Further advancements in the algorithm may be incorporated to detect these specific rhythms and prevent the device from classifying them as AF.

In conclusion, this study shows that the Reveal XT device has a high sensitivity for AF episodes ≥ 2 minutes. In some patients, irregular ventricular rhythms, not caused by AF, may result in frequent FP detections of AF.

References

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