Performance of a New Leadless Implantable Cardiac Monitor in Detecting and Quantifying Atrial Fibrillation
Results of the XPECT Trial

Gerhard Hindricks, MD, PhD; Evgyenii Pokushalov, MD; Lubos Urban, MD; Milos Taborsky, MD, PhD; Karl-Heinz Kuck, MD, PhD; Dmitry Lebedev, MD, PhD; Guido Rieger, MD; Helmut Pürerfellner, MD; on behalf of the XPECT Trial Investigators

Background—Current methods for detecting atrial fibrillation (AF) have limited diagnostic yield. Continuous monitoring with automatic arrhythmia detection and classification may improve detection of symptomatic and asymptomatic AF and subsequent patient treatment. The study purpose was to quantify the performance of the first implantable leadless cardiac monitor (ICM) with dedicated AF detection capabilities.

Methods and Results—Patients (n=247) with an implanted ICM (Reveal XT, Medtronic Inc, Minneapolis, Minn) who were likely to present with paroxysmal AF were selected. A special Holter device stored 46 hours of subcutaneously recorded ECG, ICM markers, and 2 surface ECG leads. The ICM automatic arrhythmia classification was compared with the core laboratory classification of the surface ECG. Of the 206 analyzable Holter recordings collected, 76 (37%) contained at least 1 episode of core laboratory classified AF. The sensitivity, specificity, positive predictive value, and negative predictive value for identifying patients with any AF were 96.1%, 85.4%, 79.3%, and 97.4%, respectively. The AF burden measured with the ICM was very well correlated with the reference value derived from the Holter (Pearson coefficient 0.97). The overall accuracy of the ICM for detecting AF was 98.5%.

Conclusions—In this ICM validation study, the dedicated AF detection algorithm reliably detected the presence or absence of AF and the AF burden was accurately quantified. The ICM is a promising new diagnostic and monitoring tool for the clinician to treat AF patients independently of symptoms. Long-term studies are needed to evaluate the clinical benefits of the technology.

Clinical Trial Registration—clinicaltrials.gov Identifier NCT00680927. (Circ Arrhythm Electrophysiol. 2010;3:141-147.)

Key Words: arrhythmia ■ atrial fibrillation ■ implantable cardiac monitor ■ monitoring ■ loop recorder

Atrial fibrillation (AF) is the most common arrhythmia, increasing in prevalence with age. An estimated 2.2 million people in the United States and 4.5 million in the European Union have AF.1,2 AF is associated with heart failure, hemodynamic impairment, and symptoms affecting quality of life. Patients have an increased risk of thromboembolic events, including stroke, resulting in significant morbidity, mortality, and costs.1,3–5 Treatment of AF consists of restoring and maintaining normal sinus rhythm, and/or control of the ventricular rate, and/or antithrombotic therapy, based on the severity of patient symptoms and on current stroke risk stratification schemes, such as the CHADS2 score.1 The adverse effects of paroxysmal AF have been correlated to the duration of the episodes and to the AF burden (defined as the percentage of time during which the heart is in AF).4–6

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Diagnosis of AF is made by routine ECG recordings and ambulatory Holter monitoring. Recently, new extended monitoring methods have been introduced, including transtelephonic ECG transmissions, 7-day Holter recording, and 30-day event recording. The diagnostic yield of these methods is limited, but there is a clear relationship between the duration of monitoring and the diagnostic yield. Depending on the specific external monitoring method, the sensitivity lies between 31.3% and 71.0%, whereas the negative predictive value (NPV) ranges between 21.5% and 64.6%.6–8
Patients with symptoms have an increased likelihood that AF is diagnosed. However, there is a well-known poor correlation between symptoms and AF episodes: AF episodes may be asymptomatic, and symptoms may not relate to AF episodes. Recent studies showed that only 13% to 21% of episodes with symptoms suggestive of AF reported by patients with implanted pacemakers were AF episodes according to the pacemaker log. Thus, technologies for the reliable detection of AF irrespective of symptoms are warranted, both for clinical and scientific reasons. Continuous rhythm monitoring over long periods of time is superior to intermittent recording using external monitors. A recent expert consensus statement and a position paper by the European Heart Rhythm Association recommend the use of continuous rhythm monitoring technologies such as implantable cardiac monitors for AF detection.

Subcutaneous implantable monitors are largely accepted in clinical practice for diagnosing patients with unexplained syncope. The same technology, enhanced with a dedicated AF detection algorithm, can now be used in patients at risk of new-onset AF or recurrence of symptomatic or asymptomatic AF episodes.

The Reveal XT Performance Trial (XPLECT) evaluated the detection performance of a new subcutaneous, leadless implantable cardiac monitor (ICM) with a dedicated AF detection algorithm.

Methods

Study Design

Between September 2007 and July 2008, 247 patients from 24 medical centers mainly in Europe and Canada were enrolled in this prospective study. Patients with an implanted ICM (Reveal XT, Model 9529, Medtronic Inc, Minneapolis, Minn) and who (1) were scheduled for pulmonary vein ablation or surgical rhythm control intervention, (2) had documented frequent AF or frequent symptoms attributable to AF, or (3) had undergone pulmonary vein ablation within the last 6 months and still had symptoms attributable to AF were eligible for enrollment. Patients presenting with persistent or permanent AF were excluded. The study was compliant with the Declaration of Helsinki and the international standard for clinical investigation of medical devices in human subjects, ISO 14155, and all patients gave written informed consent. The study protocol was approved by the medical ethics committee of the participating medical centers. After a stabilization phase of 4 to 6 weeks after ICM implantation, patients underwent 46 hours of continuous recording with a special Holter device, capable of storing the subcutaneous ECGs from the ICM, as well as recordings from 2 surface ECG leads.

Device Characteristics and Implant Procedure

The ICM (Reveal XT, Medtronic Inc) is equipped with a new AF detection algorithm that is designed to detect the presence of AF episodes and to quantify the AF burden. In addition, the ICM features detection algorithms for bradyarrhythmias and ventricular tachyarrhythmias.

Physiological sinus rhythm and AF each have a unique R-R interval pattern. The dedicated AF detection algorithm uses irregularity and incoherence of R-R intervals to identify and classify patterns in the ventricular conduction. The R-R intervals are analyzed within each 2-minute period of time, and the difference in duration between consecutive R-R intervals (ΔR-R) is calculated. Subsequently, the variability of these ΔR-R intervals is calculated, similar to constructing a Lorenz plot. When the R-R intervals within the 2-minute interval show a certain pattern of uncorrelated irregularity, the heart rhythm in this interval is classified as AF. If R-R intervals are regular with some sinus node modulations, the interval is defined as normal sinus rhythm.

The ICM can store up to 49.5 minutes of recorded ECG, which is allocated to 27 minutes of automatically activated events and 22.5 minutes of patient-activated events. In addition, the ICM has an episode log that can catalogue 30 automatically detected AF episodes and up to 10 patient-activated episodes. When the memory is full, an additional episode will overwrite the oldest stored episode.

All ICMs were inserted subcutaneously under local anesthesia and the atrial episode detection parameters remained in the nominal settings. All data in this report are based on the current detection algorithm.

Holter Recordings

Holter recorders (DR220, NorthEast Monitoring Inc, Maynard, Mass) were used to store simultaneous and continuous 46-hour recordings of the subcutaneous ECG, sensing and arrhythmia classification markers, and timestamps uploaded from the ICM, as well as a 2-channel surface ECG recording (leads II and III). Patients were asked to perform their usual daily activities.

Episode Annotation

In this study, the ICM performance was assessed against the established method of Holter recording. The surface ECGs from the Holter recording were annotated on a beat-to-beat basis with respect to the occurrence of arrhythmia by qualified independent cardiologists at a core laboratory (CardiaBase, Nancy, France). This method of annotating surface ECGs is much more stringent than routine Holter analysis, which is considered the gold standard in clinical practice. The core laboratory was blinded to all ICM data and patient-related information. Segments of the Holter recording (1) annotated as atrial flutter, (2) with missing telemetry signals from the ICM, or (3) with noninterpretable surface ECG due to noise or artifacts were excluded. Holter recordings with less than 18 hours of remaining valid data were excluded from the analysis, as predefined in the protocol.

Episode Detection and Duration Definitions

The core laboratory defined AF was any episode longer than 9 R-R intervals, with no visible P waves and increased heart rate with ≥75% R-R prematurity. All episodes were classified by a cardiologist to exclude other arrhythmias. Because the ICM algorithm classifies the rhythm for each subsequent time interval of 2 minutes, only episodes with a duration of at least 2 minutes were included in the analysis.

To identify true-positive and false-positive (TP, FP) and true-negative and false-negative (TN, FN) detections, the AF detections derived from the ICM were compared with the annotated Holter recording. Figure 1 shows how ICM detections were classified. For AF episode detection sensitivity, a TP detection (TPH) was defined as any true AF episode that overlapped with a device detected episode. For positive predictive value (PPV) of episode detection, TP detection was defined as any device detected AF episode overlapping with a true AF episode (TPH). Consequently, a single true AF episode could result in 1 or more TPH classified detections, and multiple true AF episodes could result in a single TP, classified detection. A true AF episode without any overlap with device detection was classified as FN detection. Device detections that did not overlap with true AF were classified as FP detections. Device-detected AF episodes during atrial tachycardia or triggered by other arrhythmias were also considered FP.

Statistical Analysis

Descriptive statistics are reported as count and percentage for categorical variables and mean and standard deviation for continuous variables. The overall accuracy of the ICM for AF detection was calculated.

The following parameters were used to quantify the performance of the ICM AF detection algorithm: the sensitivity, specificity, NPV, and PPV of detecting presence or confirming absence of AF per patient; the sensitivity, specificity, NPV, and PPV of identifying the
total accumulated AF duration across all patients; and the sensitivity and PPV of AF episode detection for episodes lasting at least 2, 6, 10, and 20 minutes.

Episode detection sensitivity and PPV were calculated per Holter recording. A logistic regression model was used to estimate episode detection sensitivity and PPV across all Holter recordings. Generalized estimating equations methodology, with an exchangeable correlation structure, was used to adjust for the variation in the number of episodes across Holter recordings and the possible correlation of AF detection performance on episodes from the same Holter recording. In addition, covariate-adjusted analyses of the sensitivity and PPV for the detection of AF episodes lasting at least 2 minutes were completed.

The absolute difference between the AF burden derived from the ICM and the Holter was described using the median, percentiles, and range. The AF burden determined by the ICM was compared with the reference AF burden by calculating the Pearson correlation coefficient between the paired measurements, the intraclass correlation coefficient, and by a Bland-Altman plot. All statistical analyses were performed by a senior Medtronic statistician using validated SAS 9.1 software.

Results

Study Population
The characteristics of the study population are listed in the Table. Baseline data of 1 patient (0.4%) were missing. Patients were 57±10 years old, the majority were male (66.8%), and 10.2% had a history of stroke or transient ischemic attack. The indications for the ICM were (1) increased risk of atrial arrhythmias (n=141, 57.1%), (2) symptoms suggesting atrial arrhythmias (n=85, 34.4%), and (3) other, including syncope and assessment of oral anticoagulation requirement (n=20, 8.1%).

Detection of Presence and Absence of AF
Of the 247 enrolled patients, 12 patients withdrew from the study because of the perceived burden of long-term Holter monitoring. In 235 patients, a Holter recording was performed, of which 206 recordings were suitable for analysis. Of the 29 recordings not suitable for analysis, 11 were excluded because the analyzable recording time was less than the minimum 18 hours prespecified in the study protocol. Other reasons for exclusion of recordings were as follows: Holter file conversion errors (n=8), inconclusive Holter results from the core laboratory (n=5), telemetry errors (n=4), and lost Holter file (n=1). From the 235 Holter recordings, a total of 9683 hours of Holter recordings were available, of which 8853 hours were annotated and included in the analysis and 830 hours (8.6%) were excluded from the analysis. The included recordings contained a total of 1309.8 hours (14.8%) of core laboratory classified AF, 1285.4 TP hours (14.5%), 7430.5 TN hours (83.4%), 112.7 FP hours (1.3%), and 24.4 FN hours (0.3%). The overall accuracy of the ICM for detecting AF was 98.5%.

Figure 2 shows the breakdown of enrolled patients with and without AF episodes ≥2 minutes. Seventy-six patients had at least 1 episode of core laboratory–classified AF. In 73 patients (96.1%) at least 1 AF episode was also detected by the ICM, whereas 3 (3.9%) were classified as not having AF. The durations of the AF episodes in the 3 patients that the ICM did not detect were 2.2, 3.4, and 12.6 minutes. The sensitivity for identifying patients with any AF is therefore 96.1%. One hundred thirty patients were classified as not having AF by the core laboratory. In 111 of 130 patients, the ICM confirmed the absence of AF, resulting in a specificity for identifying patients with no AF of 85.4%. The PPV and NPV of detecting any or no AF in a patient, respectively, are 79.3% (73 of 92 patients) and 97.4% (111 of 114 patients).

Of the 130 patients without AF, 19 (14.6%) had FP AF episodes stored by the ICM. These episodes were falsely classified as AF due to frequent premature atrial or ventricular complexes with varying coupling intervals (8 of 19 patients), myopotentials (6 of 19 patients), irregular sinus rhythm (5 of 19 patients), bigeminy (1 of 19 patients), undersensing of R-waves (3 of 19 patients), and other atrial arrhythmia (3 of 19 patients). Some patients had more than 1 type of FP episode.
AF Burden
The AF burden is defined as the percentage of time that the patient is in AF. The mean absolute difference between the AF burden measured by the ICM and the reference value derived from the Holter recording was 1.4 ± 6.4% (range, 0% to 66.3%) and the median was 0% (interquartile range, 0% to 6.2%). The Pearson correlation coefficient and the intraclass correlation coefficient between the 2 measurements were both 0.976 (Figure 3). Outliers are caused by FP classification of AF, leading to an overestimation of the AF burden. The sensitivity, specificity, PPV, and NPV for identifying how much AF patients had were, respectively, 98.1% (CI, 96.6% to 99.7%), 98.5% (CI, 97.5% to 99.5%), 91.9% (CI, 86.6% to 97.3%), and 99.7% (CI, 99.4% to 99.9%). The Bland-Altman plot showed a good correspondence of the 2 measurements.

AF Episode Detection Performance
The recordings included in the analysis contained a total number of 500 episodes classified as AF by the core laboratory. The studied ICM offers the possibility to program the minimum duration of AF for which the subcutaneous ECG is stored to be 2, 6, 10, and 20 minutes. Therefore, AF episode detection performance was assessed for episodes ≥2, ≥6, ≥10, and ≥20 minutes, in accordance with the ICM programmable episode storage options. The results are shown in Figure 4 and indicate particularly high sensitivity and PPV increase with the duration of the AF episodes.

The covariate-adjusted analyses showed that the AF episode sensitivity depended on the duration of the Holter recording. Holter recording times varied from 18 to 46.3 hours. Forty-five hours of recording time was used as a cutoff for ease of interpretation, and 58% of the recordings had at least 45 hours of recording time. The generalized estimating equation–adjusted sensitivity for AF episode detection was significantly higher in recordings with a recording time of at least 45 hours, compared with recordings with a recording time of less than 45 hours (94.2% vs 82.6%, P = 0.02). This difference in sensitivity was also significant when analyzed on a per-hour of recording continuous scale. The AF episode sensitivity was not dependent on age, sex, body mass index, or time since ICM implantation.

Discussion
The major finding of this short-term verification study is that a subcutaneous, leadless ICM equipped with a dedicated AF detection algorithm is sensitive in detecting the presence of AF with a high specificity and PPV. It is also reliable in confirming freedom from AF, as shown by the high NPV. These performance metrics have much higher values compared with conventional monitoring methods such as repeated 24-hour Holter recordings, 7-day monitoring, or 30-day monitoring.6–8 In addition, the ICM precisely measured AF burden. Thus, the technology appears to be promising to improve both the precise detection of AF and the confirmation of absence of AF during long-term follow-up, as well as accurately assessing the AF burden.

The use of traditional methods to diagnose AF such as standard surface ECG, 24-hour Holter recordings, and even 7- or 30-day external monitor recordings are limited by the short documentation period covered, poor patient compliance, and by the well-known high incidence of asymptomatic AF episodes even in patients presenting with highly symptomatic AF. Recent studies clearly showed that extending the monitoring duration from 24 hours to 7 days significantly increased the AF detection rate.6–8,22 However, it is currently not known what percentage of true AF episodes or AF burden is not recognized and documented even when repetitive 7-day Holter recordings are performed.19 Moreover, it is not known how many hours or days of continuous or intermittent recording are necessary to reliably prove the absence of AF in an individual patient.22 An implantable leadless cardiac monitor with a reliable AF detection algorithm and a longevity of 3 years is expected to overcome these limitations of traditional methods of AF detection.

Table. Patient Characteristics (n=246)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>165 (66.8%)</td>
</tr>
<tr>
<td>Age, y</td>
<td>57 ± 10 (range, 26 to 82)</td>
</tr>
<tr>
<td>Time from device implant to recording visit, wk</td>
<td>9.2 ± 5.8 (range, 1.6 to 56.7)</td>
</tr>
<tr>
<td>Structural cardiovascular disease, nonexclusive</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>41 (16.7%)</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>16 (6.5%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>14 (5.7%)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>7 (2.8%)</td>
</tr>
<tr>
<td>Cardiomyopathy, nonischemic</td>
<td>4 (1.6%)</td>
</tr>
<tr>
<td>Other cardiovascular disease</td>
<td>11 (4.5%)</td>
</tr>
<tr>
<td>Medical history, nonexclusive</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>136 (55.3%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>19 (7.7%)</td>
</tr>
<tr>
<td>Cerebrovascular accident/stroke</td>
<td>13 (5.3%)</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>12 (4.9%)</td>
</tr>
<tr>
<td>Atrial arrhythmia history, nonexclusive</td>
<td></td>
</tr>
<tr>
<td>Paroxysmal AF</td>
<td>227 (92.3%)</td>
</tr>
<tr>
<td>Persistent AF with successful cardioversion</td>
<td>28 (11.4%)</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>58 (23.6%)</td>
</tr>
<tr>
<td>Brady-tachy syndrome</td>
<td>10 (4.1%)</td>
</tr>
<tr>
<td>Other atrial tachyarrhythmias</td>
<td>7 (2.8%)</td>
</tr>
<tr>
<td>Cardiovascular medication, nonexclusive</td>
<td></td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>71 (30.1%)</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>56 (23.7%)</td>
</tr>
<tr>
<td>Anti-platelets</td>
<td>70 (29.7%)</td>
</tr>
<tr>
<td>β-blocker</td>
<td>131 (55.5%)</td>
</tr>
<tr>
<td>Calcium antagonists</td>
<td>35 (14.8%)</td>
</tr>
<tr>
<td>Class I antiarrhythmics</td>
<td>74 (31.4%)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>28 (11.9%)</td>
</tr>
<tr>
<td>Heparin</td>
<td>13 (5.5%)</td>
</tr>
<tr>
<td>Oral anticoagulants</td>
<td>146 (61.9%)</td>
</tr>
<tr>
<td>Sotalol</td>
<td>23 (9.7%)</td>
</tr>
<tr>
<td>Statins</td>
<td>66 (26.8%)</td>
</tr>
<tr>
<td>Other cardiovascular medications</td>
<td>53 (22.5%)</td>
</tr>
</tbody>
</table>
Considering the potential complications of AF, a high sensitivity for AF detection should be the primary requisite of an AF detection algorithm. In the present study, the ICM correctly identified the presence of AF in 96.1% of all patients with AF, thereby proving a high sensitivity. In 3 patients (3.9%), the ICM did not diagnose the arrhythmia. These results show that even with an ICM, the presence of AF may not be detected in patients with a low AF burden when the recording time is short. The clinical consequence of this observation is currently unknown.

In 19 of 130 patients (15%) without AF documented on the Holter recording, the ICM falsely classified episodes as AF. In this setting, the manual analysis of the electrogram stored in the device memory is useful to identify episodes as being FP. However, considering the limited electrogram storage capacity of the device, the diagnostic accuracy of the ICM may be lower in patients with a high number of FP episodes. Thus, whenever the electrogram memory is filled up with FP episodes only but additional AF episodes are listed in the episode log of the ICM (without corresponding electrograms available), the results provided by the device may be of limited diagnostic value. Further improvement of the individual device programming and/or development of the detection algorithm to improve specificity may be helpful to overcome this potential problem.

The clinical and scientific implications of reliable continuous rhythm monitoring of AF patients are significant. The studied ICM offers this option for the first time. Continuous and precise rhythm follow-up may help uncover the true incidence and duration of both symptomatic and asymptomatic AF episodes and establish a new standard to compare the efficacy of different AF treatment strategies. The ICM will potentially help guide individual patient treatment. The CRYSTAL AF study will assess the benefit of continuous monitoring using an ICM compared with optimal standard of care in patients with cryptogenic stroke. Further studies are needed to demonstrate the potential impact of ICMs on clinical care and patient treatment in other patient subgroups.

**Study Limitations**

The ICM used in this study classifies the heart rhythm for each subsequent time interval of 2 minutes, and only AF episodes with at least 2 minutes duration were included in the analysis. Therefore, the study results are not valid for episodes shorter than 2 minutes. However, it is a subject of ongoing debate of when AF, in terms of pattern, episode duration, and AF burden, becomes clinically relevant with respect to comorbidity, in particular stroke. Recent publications appear to support the hypothesis that the AF episode duration should be at least 5 minutes to consider the episode clinically relevant.

**Figure 2.** Results for all enrolled patients.

**Figure 3.** AF burden measured by the ICM compared with AF burden calculated from the core laboratory–annotated Holter recording for all patients (r indicates Pearson correlation coefficient).

**Figure 4.** AF episode detection sensitivity (left) and PPV (right), depending on episode duration. Episodes longer than the minimum duration are included in the analysis for each result. Bars denote confidence intervals.
Sensitivity and specificity for determining whether a patient has AF are a function of the monitoring duration. The comparison between ICM detected episodes and the core laboratory annotated surface ECG was limited to a 46-hour period. Consequently, it is difficult to extrapolate the study results to a longer follow-up period. Sensitivity is expected to increase, whereas specificity may decrease with a longer monitoring period, whereas PPV and NPV depend more on the incidence rate of true AF in the patients. The study was performed in a specific patient population selected for a high risk of AF, and the results may not be generalized to other patient populations.

The study focused on AF detection, and in case the ICM stored episodes of atrial tachycardia or other arrhythmias with irregular ventricular response, these were considered FP. In addition, 29 patients (11%) enrolled into the study could not be analyzed, mainly because of technical problems with the Holter recording. This may have affected study results. However, no patient was excluded from the analysis because of performance issues with the ICM.

Finally, the study results cannot be generalized to ICM devices other than the studied device.

Conclusion

Continuous monitoring using an ICM with dedicated AF detection capabilities reliably detected the presence or absence of AF, with a high sensitivity and NPV, while showing a good specificity and PPV. The AF burden, the percentage of time patients were in AF, was accurately measured in the large majority of patients. The ICM is a promising new diagnostic and monitoring tool for the clinician to treat AF patients independently of symptoms. Long-term studies are needed to evaluate the clinical benefits of the technology.

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Disclosures

Dr Hindricks is a member of the AF Advisory Boards for St Jude Medical, Biotronik, and Biosense Webster. Dr Pürerfellner is a member of the AF Advisory Boards for St Jude Medical, Biotronik, and Biosense Webster. Dr Pokushalov has done minor consulting for Medtronic. Bakken Research Center. Dr Rieger is an employee of Medtronic, Bakken Research Center. and holds Medtronic stock options.

References


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Detection of paroxysmal atrial fibrillation (AF) can be difficult. Asymptomatic episodes are recognized to occur, even in patients who also have symptomatic AF. Intermittent ambulatory monitoring has significant limitations. The XPECT study assessed the ability of a leadless implantable cardiac monitor (ICM) with a dedicated AF detection algorithm to detect AF during continuous long-term monitoring. The device is implanted subcutaneously and has longevity of up to 3 years. In 247 patients with a high risk of AF, 46-hour ECG recordings were compared with AF detection capabilities of the ICM. The ICM algorithm identified AF episodes exceeding 2 minutes in duration with a high degree of sensitivity. False-positive AF detections caused by frequent atrial extrasystoles or oversensing of myopotentials were observed in some patients. The ICM may be a useful tool for AF detection and quantification of AF. Further studies are warranted to assess potential clinical utility.
Performance of a New Leadless Implantable Cardiac Monitor in Detecting and Quantifying Atrial Fibrillation Results of the XPECT Trial
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SUPPLEMENTAL MATERIAL

Appendix 1. Participating Investigators

The following investigators and centers participated in the study: Dr. T. Blum, Herzzentrum Bad Krozingen, Bad Krozingen, Germany; Dr. J. Champagne, Hôpital Laval, Quebec, Canada; Prof, Dr. H. Crijns, Academisch Ziekenhuis Maastricht, Maastricht, The Netherlands; Prof. Dr. R. Hatala, The National Institute of Cardiovascular Diseases, Bratislava, Slovakia; Prof. Dr. H. Heidbüchel, University Hospital Gasthuisberg, Leuven, Belgium; Prof. Dr. G. Hindricks, Universitätsklinikum Leipzig, Leipzig, Germany; Dr. F. Hintringer, Universitätskliniken Innsbruck, Innsbruck, Austria; Dr. G. Kaliska, Middle-Slovak Institute of Cardiovascular Diseases, Banská Bystrica, Slovakia; Prof. J. Kautzner, Institute for Clinical and Experimental Medicine, Prague, Czech Republic; Dr. C. Kirchhof, Rijnland Ziekenhuis, Leiderdorp, the Netherlands; Prof. Dr. K. Kuck, Asklepios Klinik St. Georg, Hamburg, Germany; Dr. D. Lebedev, Almazov Federal Center of the Heart, Blood and Endocrinology, St. Petersburg, Russia; Prof. Dr. L. Lickfett, Universitätsklinikum Bonn, Bonn, Germany; Dr. P. Novak, Victoria Royal Jubilee Hospital, Victoria, Canada; Dr. E. Pokushalov, State Research Institute of Circulation Pathology, Novosibirsk, Russia; Ass. Prof. Dr. H. Pürerfellner, Krankenhaus der Elisabethinen Linz, Linz, Austria; Dr. J. Ruiter, Medisch Centrum Alkmaar, Alkmaar, the Netherlands; Dr. J. Schreieck, Universitätsklinikum Tübingen, Tübingen, Germany; Dr. J. Sperzel, Kerckhoff Klinik, Bad Nauheim, Germany; Dr. B. Strohmer, Salzburger Landeskliniken, Salzburg, Austria; Dr. M. Taborsky, Na Homolce Hospital, Prague, Czech Republic; Prof. Dr. H. Theres, Charité Campus Mitte, Berlin, Germany; Dr. S. Tung, St. Paul’s
Hospital, Vancouver, Canada; Dr. J. Vlašínová, Fakultní Nemocnice Brno, Brno, Czech Republic.

**Supplemental Figure Legend**

Bland-Altman plot of differences against averages of the two measurement methods for all patients. The dashed lines show the limits of agreement (AF, atrial fibrillation; ICM, implantable cardiac monitor; SD, standard deviation).

**Supplemental Figure**

![Bland-Altman Plot](image)