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Adapting detection sensitivity based on evidence of irregular sinus arrhythmia to improve atrial fibrillation detection in insertable cardiac monitors

Helmut Pürerfellner[1]*, Prashanthan Sanders[2], Shantanu Sarkar[3], Erin Reisfeld[3], Jerry Reiland[3], Jodi Koehler[3], Evgeny Pokushalov[4], Ľuboš Urban[5], and Lukas R.C. Dekker[6]

[1]Department of Cardiology, Public Hospital Elisabethinen, Academic Teaching Hospital, Ordensklinikum A-4020 Linz, Fadingerstraße 1, Austria; [2]Department of Cardiology, Centre for Heart Rhythm Disorders, South Australian Health and Medical Research Institute, University of Adelaide and Royal Adelaide Hospital, Adelaide, South Australia 5005, Australia; [3]Research and Development, Cardiac Rhythm and Heart Failure, Medtronic Plc., Moundsview, MN, 55112, USA; Moundsview, MN, USA; [4]Arrhythmia Department and Electrophysiology Laboratory, State Research Institute of Circulation Pathology, Rechkunovskaya 15, Novosibirsk, 630055, Russia Research Institute of Circulation Pathology, Novosibirsk, Russia; [5]Department of Arrhythmias and Cardiac Pacing, The National Institute of Cardiovascular Diseases, Pod Krśnou hôrkou 1, 833 48 Bratislava 37, Slovakia; and [6]Department of Cardiology, Catharina Hospital, Michelangelolaan 2, 5623 EJ Eindhoven, The Netherlands

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Aims Intermittent change in p-wave discernibility during periods of ectopy and sinus arrhythmia is a cause of inappropriate atrial fibrillation (AF) detection in insertable cardiac monitors (ICM). To address this, we developed and validated an enhanced AF detection algorithm.

Methods and results Atrial fibrillation detection in Reveal LINQ ICM uses patterns of incoherence in RR intervals and absence of P-wave evidence over a 2-min period. The enhanced algorithm includes P-wave evidence during RR irregularity as evidence of sinus arrhythmia or ectopy to adaptively optimize sensitivity for AF detection. The algorithm was developed and validated using Holter data from the XPECT and LINQ Usability studies which collected surface electrocardiogram (ECG) and continuous ICM ECG over a 24–48 h period. The algorithm detections were compared with Holter annotations, performed by multiple reviewers, to compute episode and duration detection performance. The validation dataset comprised of 3187 h of valid Holter and LINQ recordings from 138 patients, with true AF in 37 patients yielding 108 true AF episodes ≥2-min and 449 h of AF. The enhanced algorithm reduced inappropriately detected episodes by 49% and duration by 66% with <1% loss in true episodes or duration. The algorithm correctly identified 98.9% of total AF duration and 99.8% of total sinus or non-AF rhythm duration. The algorithm detected 97.2% (99.7% per-patient average) of all AF episodes ≥2-min, and 84.9% (95.3% per-patient average) of detected episodes involved AF.

Conclusion An enhancement that adapts sensitivity for AF detection reduced inappropriately detected episodes and duration with minimal reduction in sensitivity.

Keywords Atrial fibrillation • Insertable cardiac monitors • Diagnosis and monitoring

* Corresponding author. Tel: +43 732 7676 4917; fax: +43 732 7676 2106. *E-mail address*: helmut.puererfellner@ordensklinikum.at

What's new?

- Identified that intermittent ineffectiveness of p-wave sensing as a cause of inappropriate AF detection in insertable cardiac monitor (ICM) employing p-wave sensing to reject inappropriate detections during periods of RR irregularity.
- Developed a new method to identify presence of runs of ectopy or sinus arrhythmia in patients based on patterns in RR interval irregularity and presence of single p-wave between two r-waves.
- Developed a new method of adapting atrial fibrillation (AF) detection sensitivity with time based on what the device learns about the presence of runs of ectopy or sinus arrhythmia in patients on an ongoing basis.
- Validated improved performance of AF detection in insertable cardiac monitors using the enhanced algorithm.
- Provided perspectives on how to interpret AF detection performance results in ICM devices.

Introduction

Subcutaneous insertable cardiac monitors (ICM) have been shown to be clinically useful for continuous long-term diagnosis and monitoring of atrial fibrillation (AF) after surgical[1] or catheter AF ablation,[2–4] atrial flutter ablation,[5] and to investigate cryptogenic stroke.[6–8] The clinical goal of AF detection in an ICM is to determine if a patient has AF and quantify the amount or burden of AF. Several studies have shown that knowing the relevant amount of AF may be clinically important.[9–11] While ICMs have been shown to have high accuracy in quantifying AF burden,[12–15] one hindrance for using ICMs has been the inappropriate AF detection caused by runs of atrial ectopy with irregular coupling intervals and sinus arrhythmia.[3,4,13] Most of these inappropriate detections are short in duration and do not significantly affect the accuracy of AF burden[3,13]; however, they do increase the clinical workload required to review these episodes.[4]

The AF detection algorithm in the Reveal LINQ™ ICM looks for incoherence in an RR interval time series[12,13] and absence of evidence of a single p-wave between two r-waves to detect AF.[14,15] The addition of p-wave evidence was shown to significantly improve performance of the original RR interval based algorithm.[14,15] Intermittent ineffectiveness of ascertaining p-wave evidence under certain circumstances may lead to detection of short duration inappropriate episodes, particularly in patients with sinus arrhythmia or long runs of atrial ectopy with irregular coupling. The main goal of this study is to develop and validate an enhanced algorithm designed to improve AF detection in ICMs based on adapting the sensitivity for AF detection over time based on detecting the presence of irregular sinus rhythm.

Methods

Algorithm design

Figure 1 shows the basic schematic of AF detection in the predicate Reveal LINQ ICM along with the components of the algorithm enhancement described in this study. The enhanced AF detection algorithm is implemented in three steps. In the first step, the algorithm looks for patterns of incoherence in a Lorenz plot of difference in RR intervals to compute an AF evidence score every 2 min.[12,13] This is the original AF detection algorithm utilized in the predicate Reveal XT ICM. As has been discussed in earlier studies,[12,14] the 2-min detection period was a deliberate choice based on significant improvement of algorithm performance for a detection period of 2 min compared with 30 s. *Figure 2* shows a patient record of 10 h with sinus arrhythmia and runs of ectopy, a challenging case for the AF detection algorithm. *Figure 2A* illustrates how this AF evidence score obtained from the Lorenz plot can be compared with a threshold to detect AF. In this example, AF evidence score derived from

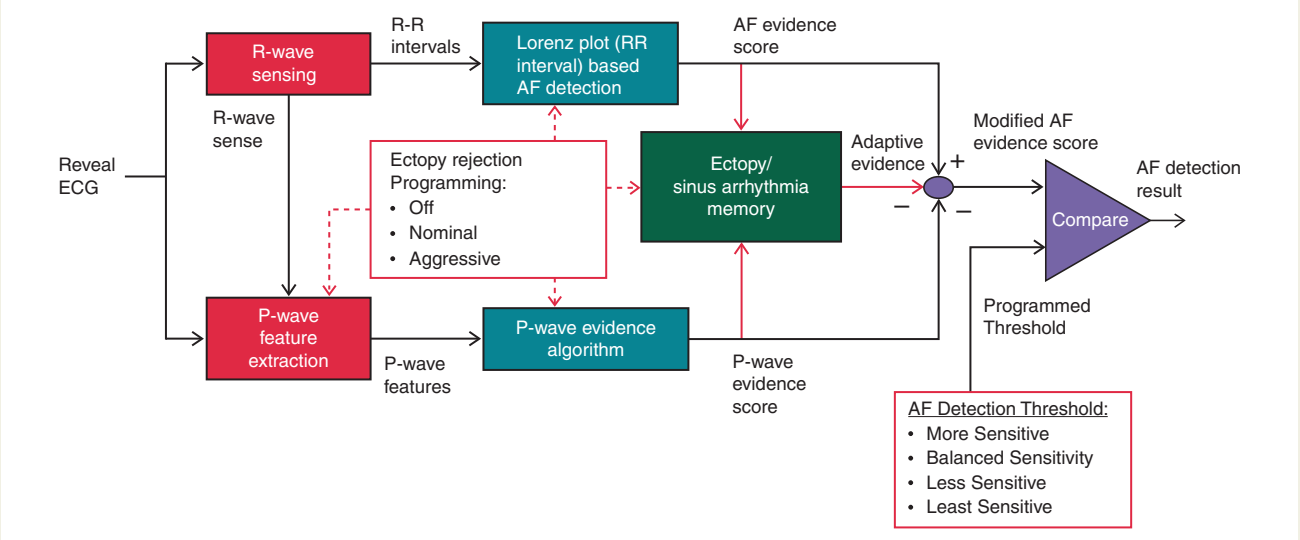

Figure 1 The schematic for the combination of the adaptive evidence with P-wave evidence and the Lorenz plot based AF detection algorithm. The three components of the algorithm, the Lorenz plot based AF evidence score, the P-wave evidence score, and the adaptive evidence score, is combined to generate a modified AF evidence score which is compared with threshold to detect AF. AF, atrial fibrillation.

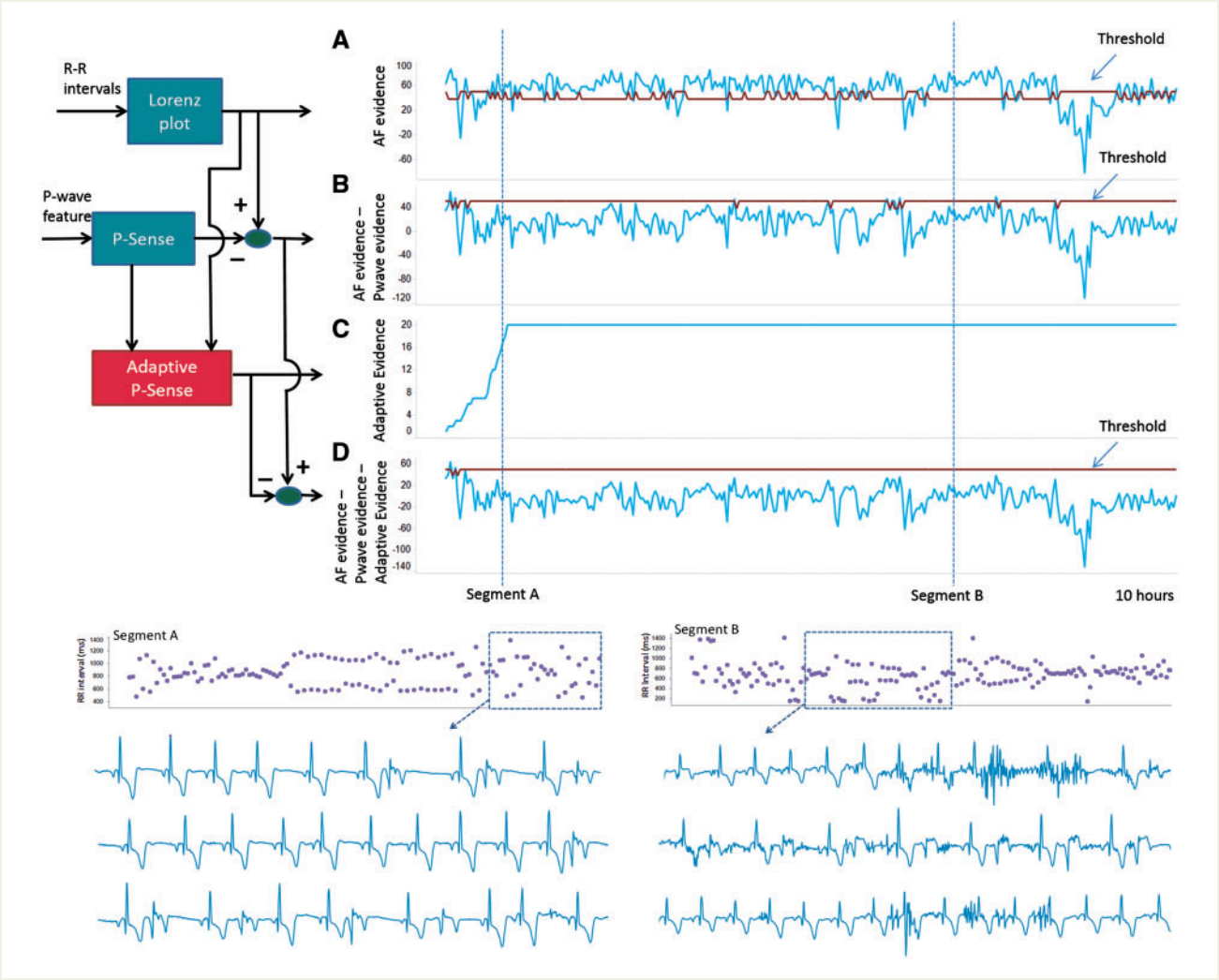

Figure 2 An example to show how different steps of the Adaptive P-Sense algorithm reduces inappropriate AF episode detection in a patient with runs of ectopy and sinus arrhythmia. (*A*) The Lorenz plot based AF evidence score computed using only RR intervals. The score is greater than threshold for large proportion of time to generate false detections. (*B*) AF evidence score from Lorenz plot reduced by P-wave evidence score (P-Sense) show significant reduction of false detections. Segment A shows an example 2-min period inappropriately detected by Lorenz plot algorithm, but rejected by the P-Sense algorithm. (*C*) Periods of effective P-Sense algorithm leads to accumulation of adaptive evidence. The period shown in segment A increments the adaptive evidence score. (*D*) AF evidence score from Lorenz plot reduced by P-wave evidence and adaptive evidence illustrates how adaptive P-Sense further reduces false detection with the modified AF evidence score below threshold for entire 10-h duration. Segment-B shows a 2-min period where P-Sense is ineffective in rejecting false detection due to presence of baseline noise and faster rates, but Adaptive P-Sense is successful in rejecting the inappropriate detection. AF, atrial fibrillation.

Lorenz plot is above threshold for significant amount of time, thus detecting AF inappropriately. Electrocardiogram (ECG) and RR interval record from segment A in *Figure 2* shows an example of inappropriate AF detection using the Lorenz plot algorithm by itself.

The second step of the algorithm comprises of reducing the AF evidence score derived from Lorenz plot by a P-wave evidence score (P-Sense) before comparison to a threshold to detect AF[14,15] as illustrated in *Figure 2B*. The P-Sense component of the algorithm is implemented in the predicate Reveal LINQ ICM device. The P-wave evidence score is computed based on the presence of a single P-wave and absence of atrial flutter waves or noise between two r-waves.[14] Electrocardiogram and RR interval record from segment A in *Figure 2* shows an example of inappropriate AF detection using the Lorenz plot alone being successfully rejected by the P-Sense algorithm. While the P-Sense algorithm is able to reduce a significant number of inappropriate detections, intermittent ineffectiveness of P-Sense during prolonged duration of sinus arrhythmia or runs of ectopy may still lead to detection of inappropriate episodes (*Figure 2B*). This intermittent ineffectiveness of the P-Sense algorithm can be caused by p-wave amplitude fluctuation, baseline noise, rapid rates, or long P-R intervals. Segment B in *Figure 2* shows an example of ECG and RR interval record of an inappropriately detected episode that could not be rejected by P-Sense algorithm due to baseline noise and faster ventricular rates.

The third and final step of the algorithm is an enhancement of the P-Sense algorithm (adaptive P-Sense) that is evaluated in this study. The adaptive P-Sense enhancement is a self-learning algorithm that learns

if a patient has presence of p-wave evidence during periods of RR irregularity, i.e. when the P-Sense algorithm is effective in reducing inappropriate detection, as evidence of the presence of sinus arrhythmia or runs of ectopy (*Figure 1*). The algorithm accumulates evidence of presence of sinus arrhythmia or runs of ectopy in an adaptive evidence score (*Figure 2C*) which is used to adaptively reduce the AF evidence score over a period of time (*Figures 1* and *2D*). The adaptive evidence score is reset to zero on detecting a longer duration AF episode or prolonged absence of RR irregularity or p-wave evidence. Segment B in *Figure 2* shows an example of an episode which was inappropriately detected after application of P-Sense, but was rejected after application of adaptive P-Sense. The adaptive P-Sense algorithm will only be effective in patients where the P-Sense algorithm has been effective in rejecting RR interval based irregularity for periods of time (*Figure 2B*).

The adaptive P-Sense algorithm can work in a 'nominal' or 'aggressive' mode in which the adaptive evidence is accumulated faster and has a higher maximum limit. This is in addition to the difference in the P-Sense algorithm 'nominal' and 'aggressive' mode of operation as programmed by the ectopy rejection parameter.[14] The programmable AF threshold can be set to four different values consisting of 'more sensitive', 'balanced sensitivity', 'less sensitive', and 'least sensitive' with increased specificity for AF detection from the first setting to the last setting. The AF detection parameters are assigned nominally to different thresholds at implant depending on the indication for ICM. For AF monitoring in patients with known AF the device is programmed to AF-only detection mode with the AF threshold set at 'balanced sensitivity' and ectopy rejection set to 'nominal'. For example, for AF diagnosis in patients after cryptogenic stroke, the device is programmed to AF-only with a 'balanced sensitivity' threshold and 'aggressive' ectopy rejection setting.

Dataset

The adaptive P-Sense algorithm was developed using a subset of patients from the XPECT Holter study (NCT00680927). The first validation dataset comprised of the remaining patients from XPECT study and second Holters where available from development set patients. The second validation dataset comprised of patient Holters from the Reveal LINQ usability study (NCT01965899). Patients were enrolled in the XPECT study if they were ablation candidates or had documented history or symptoms of AF. The Reveal LINQ Usability study had two phases, the first 30 enrolled patients with any indication for an ICM; the subsequent 121 patients with a documented history of AF and ablation candidates. In both studies, North-East Monitoring DR220 Holter recorders were used to record two leads of the patient's surface ECG as well as the ICM ECG that was uplinked by continuous telemetry to the Holter. The XPECT patients were implanted with a Reveal XT ICM and underwent Holter monitoring for 46-h, whereas in the Usability study patients were implanted with a Reveal LINQ ICM device and Holter recording was done for 24 h. Patients from both studies were provided written informed consent, and the study protocols were reviewed and approved by the Human Research Ethics Committee of each participating institution.

The surface ECG in the Holter recording in the XPECT study was annotated by an independent core-lab cardiologist for the occurrence of AF. Two reviewers annotated the two channels of surface ECG and Reveal LINQ ECG collected in Usability study for presence of AF and atrial tachycardia (AT). All annotated AF episodes were reviewed a third time to ascertain the accuracy of the AF annotation and the onset and termination times of the episode. The reviewers were blinded to the device episode detection information during the annotation process. Holter recording segments with non-interpretable surface ECG or ICM uplink telemetry errors were excluded from the analysis. Periods of telemetry dropouts leading to periods of no uplink and storage of ICM ECG in the XPECT study and AF detection parameters in the Reveal LINQ usability study were also excluded. Segments annotated as atrial flutter were also excluded from the analysis.

Statistical analysis

The Holter annotations for true AF episodes were compared with the AF detections by the ICM device. The same definitions of true positive, false positive, false negative, and true negative duration were used for computation of episode and duration detection performance metrics as reported in earlier studies.[13–15] Only true AF episodes that were annotated to be ≥2 min in duration were used for data analysis. Diagnostic sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of detecting the presence or absence of AF by the ICM were evaluated for the duration of the Holter recording period for each patient. Duration detection sensitivity, specificity, PPV, and NPV which measure accuracy of AF burden (cumulative AF duration per unit time), were computed for the entire Holter duration from all patients (gross average) and for each patient and then averaged across patients (patient average). Gross and patient average episode detection sensitivity and PPV were computed. Generalized estimation equation (GEE) estimates, which adjust for multiple episodes in a patient, were also computed for episode detection sensitivity and PPV.

Results

Performance analysis from XPECT study population

The XPECT study enrolled a total of 247 patients. The baseline characteristics of the enrolled patients were reported earlier.[13] Patients had a mean age of 57 ± 10 years with 67% being male with history of paroxysmal AF in 92% and atrial flutter in 24% of patients. A total number of 208 Holter recordings were included in this analysis after exclusion of Holters with <10 h of analysable ECG due to missing telemetry and/or uninterpretable surface ECG. The development set consisted of the first 56 patients with valid Holter recordings with a total of 2162 h of valid recording time (39 h/patient). In 16 patients true AF was observed, yielding a total of 89 true AF episodes of ≥2-min and 200 h of AF. The validation set comprised of 176 patients, Holters from the remaining 152 patients and second Holters in 24 patients in the development set. The validation set had a total follow-up duration of 7271 h (41 h/patient) with true AF observed in 60 patients, yielding 393 true AF episodes ≥2 min and 990 h of AF.

The episode and duration detection performance comparison between the P-Sense and adaptive P-Sense enhancement for the development and validation datasets from the XPECT study is shown in *Table 1*. In the validation set, the adaptive P-Sense enhancement was able to reduce inappropriate episodes by 28% in AF monitoring and by 37% in the AF diagnosis programmable settings (with an average reduction of 32% assuming equal instances of the two programmable settings) compared with the P-Sense algorithm with <1% loss in true episodes (*Figure 3*). Further, the enhanced algorithm reduced inappropriately detected AF duration by 22 and 21% in the respective programming modes with minimal loss in detected true positive duration.

Table 2 shows how duration sensitivity reduces and duration specificity increases with increasing AF detection threshold from 'More Sensitive' to 'Least Sensitive' and ectopy rejection programmed to

Table 1 Performance comparison for XPECT study development and validation set between predicate AF detection algorithm (P-Sense) and adaptive P-Sense (aP-Sense) algorithm enhancement for two programmable setting most often used for AF diagnosis and monitoring

Performance metrics	Development dataset (*N* = 56)				Validation dataset (*N* = 176)			
	AF monitoring		AF diagnosis		AF monitoring		AF diagnosis	
	P-sense	aP-sense	P-sense	aP-sense	P-sense	aP-sense	P-sense	aP-sense
True positive episodes (Pts)	79 (16)	79 (16)	76 (16)	76 (16)	332 (56)	330 (56)	331 (56)	328 (56)
False positives episodes (Pts)	112 (7)	57 (7)	68 (7)	36 (7)	253 (23)	183 (22)	196 (20)	124 (17)
True positive duration in hours	196	196	195	195	969	969	967	967
False positive duration in hours	17	11	11	8	41	32	33	26
Episode sensitivity								
Gross	88.8%	88.8%	85.4%	85.4%	84.5%	84.0%	84.2%	83.5%
Patient average	97.2%	97.2%	96.3%	96.3%	88.1%	88.0%	88.1%	87.8%
GEE (95% CI)	96.8% (81.2–99.5)	96.8% (81.2–99.5)	96.3% (78.4–99.5)	96.3% (78.4–99.5)	87.9% (79.6–93.1)	87.7% (79.4–93.0)	87.8% (79.5–93.0)	87.3% (79.1–92.6)
Episode PPV								
Gross	39.8%	56.5%	55.3%	70.0%	54.4%	62.1%	61.7%	71.7%
Patient average	76.2%	76.2%	76.3%	76.3%	76.5%	77.7%	79.8%	83.8%
GEE (95% CI)	76.2% (55.4–89.2)	76.2% (55.4–89.2)	76.3% (55.5–89.3)	76.4% (55.7–89.3)	76.5% (66.1–84.5)	77.6% (67.2–85.4)	79.8% (69.5–87.3)	83.7% (73.8–90.3)
Duration sensitivity								
Gross	98.0%	98.0%	97.0%	97.0%	97.8%	97.8%	97.7%	97.7%
Patient average	93.6%	93.5%	92.0%	92.0%	86.6%	86.5%	86.4%	86.3%
Duration specificity								
Gross	99.1%	99.4%	99.4%	99.6%	99.3%	99.5%	99.5%	99.6%
Patient average	95.4%	95.8%	95.8%	96.0%	92.5%	92.6%	92.1%	92.2%
Duration PPV								
Gross	92.0%	94.7%	94.7%	96.1%	95.9%	96.8%	96.7%	97.4%
Patient average	74.2%	74.2%	75.2%	75.2%	78.9%	80.1%	81.4%	85.3%
Duration NPV								
Gross	99.8%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%
Patient average	96.1%	96.1%	96.0%	96.0%	91.9%	91.9%	91.9%	91.9%

'aggressive' compared with 'nominal.' Similarly episode detection sensitivity reduces and episode detection PPV increases with increasing AF detection threshold and more aggressive ectopy rejection programming (*Table 2*). In the overall dataset of 208 patients in the AF monitoring setting, the adaptive P-Sense algorithm detected AF in 73 of 76 patients with AF and 14 of 132 patients with no AF on Holter monitor. Further, in 87 patients with device detected AF, 73 also had AF in Holter and in the remaining 132 patients with no device detected AF, 3 had AF in Holter.

Performance analysis from the Reveal LINQ usability study population

The Reveal LINQ usability study enrolled a total of 151 patients. The baseline characteristics of the enrolled patients were reported earlier.[15] Patients had a mean age of 57 ± 12 years with 67% being male with a history of paroxysmal AF in 67%, and atrial flutter in 16% of patients. The indication for ICM implant was unexplained syncope 13%, cryptogenic stroke in 1%, palpitations or suspected AF in 5%, and AF ablation or AF management in 81%. After exclusion of recorded segments with missing telemetry or uninterpretable surface ECG and periods of AT, this second validation dataset comprised of valid Holter recordings from 138 patients with a total follow-up duration of 3187 h (23 h/patient) with true AF observed in 37 patients, yielding 108 true AF episodes ≥2 min and 449 h of AF.

The episode and duration detection performance comparison between the P-Sense and adaptive P-Sense enhancement for the second validation dataset from the Reveal LINQ usability study is shown in *Table 3*. The adaptive P-Sense enhancement was able to reduce inappropriately detected episodes by 49% compared with the P-Sense algorithm with <1% loss in true positives (*Figure 3*). Further the enhanced algorithm reduced inappropriately detected AF duration by 66% with minimal loss in detected true positive duration. The gross duration sensitivity and specificity performance means that if there are 100 h of true AF the algorithm detected 98.9 h as AF, and if there are 100 h of normal sinus or other non-AF rhythms the algorithm inappropriately detected only 0.2 h as AF. The overall duration (or AF burden) accuracy, defined as total correctly identified duration, was 99.7%.

The gross episode detection performance implies that the enhanced algorithm detected 97 of every 100 episodes of true AF

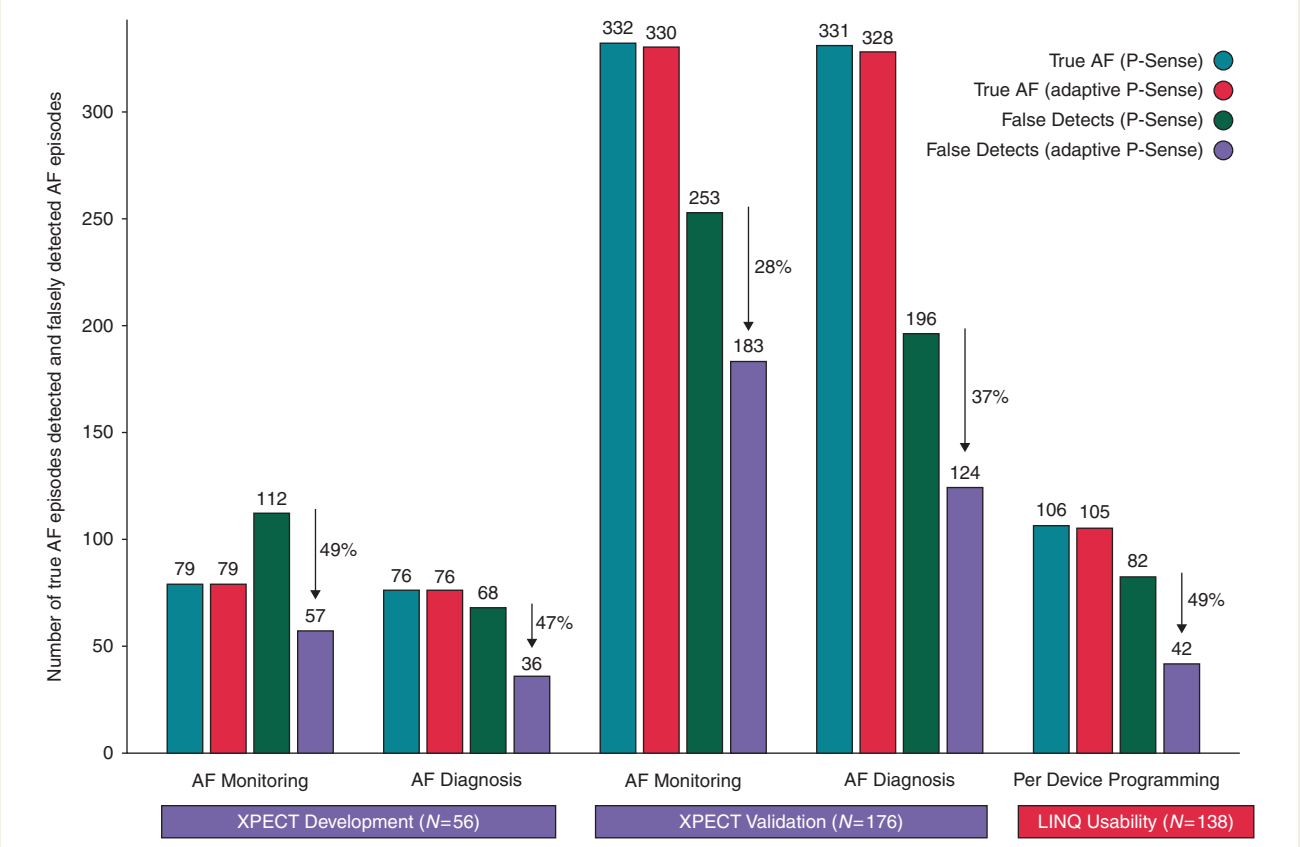

Figure 3 Number of true AF episodes that are detected and number of falsely detected AF episodes before and after application of adaptive P-Sense algorithm. Significant reduction of false detections was achieved in development and both validation sets with minimal reduction in true detections. AF, atrial fibrillation.

Table 2 Gross duration detection sensitivity and specificity and episode detection sensitivity and PPV as a function of the AF detection threshold and mode of operation (nominal/aggressive) of the adaptive P-Sense algorithm in XPECT study validation set

Ectopy rejection programming	Nominal				Aggressive			
AF detection threshold programming	More sensitive (%)	Balanced sensitivity (%)	Less sensitive (%)	Least sensitive (%)	More sensitive (%)	Balanced sensitivity (%)	Less sensitive (%)	Least sensitive (%)
Gross duration sensitivity	98.0	97.8	97.6	96.3	97.9	97.7	97.3	94.9
Gross duration specificity	99.3	99.5	99.6	99.7	99.5	99.6	99.6	99.7
gross episode sensitivity	84.7	84.0	82.7	76.6	84.2	83.5	81.4	74.3
Gross episode PPV	53.8	62.1	74.0	84.1	62.5	71.7	80.2	86.7

≥2-min in duration, and of every 100 episodes detected across patients, 85 of them had true AF. The patient average and the GEE estimation numbers imply that <0.3% of patients with true episodes will be missed and <5% of patients with detected episodes will have only false episodes. For all detected episodes (≥2-min) the 'gross' episode PPV was 85% and it improved to 93, 96, 97, 99, and 100% for detected episodes ≥ 6, 10, 20, 30, and 60 min respectively. Thus, if the algorithm detects an AF episode which is >1-h, it is close to 100%

Table 3 Performance comparison for Reveal LINQ usability study validation set (*N* = 138 pts; 37 pts with true AF: 108 episodes and 449 h of AF) between predicate AF detection algorithm (P-Sense) and enhanced AF detection algorithm (Adaptive P-Sense) using algorithm settings as programmed in device during Holter study

Performance metrics	P-sense	Adaptive P-sense
True episodes detected (patients)	106 (37)	105 (37)
Falsely detected episodes (patients)	82 (5)	42 (3)
True detected duration in hours	444.4	444.3
Falsely detected duration in hours	13.1	4.4
Episode sensitivity (%)		
Gross	98.1%	97.2%
Patient average	99.8%	99.7%
GEE (95% CI)	97.1% (97.0–97.1)	94.2% (94.1–94.2)
Episode PPV (%)		
Gross	74.4%	84.9%
Patient Average	90.4%	95.3%
GEE (95% CI)	90.4% (77.6–96.2)	95.1% (83.2–98.7)
Duration sensitivity (%)		
Gross	98.9%	98.9%
Patient average	96.7%	96.7%
Duration specificity (%)		
Gross	99.5%	99.8%
Patient average	99.6%	99.8%
Duration PPV (%)		
Gross	97.1%	99.0%
Patient average	90.6%	95.4%
Duration NPV (%)		
Gross	99.8%	99.8%
Patient average	98.8%	98.8%

likely that episode is a true AF episode. The longest inappropriate detection was 48 min in duration in this study.

After application of the adaptive P-Sense algorithm the device identified patients having AF in 37 of 37 patients with AF (diagnostic sensitivity of 100%), and in 1 out of 101 patients with absence of AF in their 24 h Holter recordings (diagnostic specificity of 99%). The algorithm identified 38 patients with AF of which 37 had AF in Holter recordings (diagnostic PPV of 97%), and 100 patients to not have any AF of which 100 patients also had no AF in their Holter recordings (diagnostic NPV of 100%).

Discussion

The results of the adaptive P-Sense algorithm enhancement for AF detection in Reveal LINQ ICM as shown by the Reveal LINQ usability study data can be summarized as follows: It is expected to reduce false episodes by 49% and false duration by 66% without significantly reducing true episodes and true duration. In addition, the enhanced algorithm appropriately detected close to 99% of total AF duration and over 99.8% of total sinus or non-AF rhythm duration. Taking only AF episodes ≥2 min in length, 97% (99.7% patient average) were correctly classified. Finally, 85% of all detected episodes (95% patient average) and 100% of detected episodes ≥1 h had AF.

There are certain perspectives to consider while interpreting the results presented in this study as well as other similar studies.[13–17] The performance of AF detection in ICM devices, particularly the diagnostic metrics and episode and duration detection metrics such as PPV and NPV, depend significantly on the patient population, incidence rate of AF, the duration of monitoring and the type of AF. For example, diagnostic sensitivity will get closer to 100% for longer monitoring duration for the study[17] or in studies that are more likely to have higher proportion of patients with persistent AF.[15–17] The overall AF detection algorithm performance improves for longer duration of AF hence it would perform better in patients with persistent AF compared with paroxysmal AF. In the XPECT study, done in the earlier days of AF ablation, more than 92% of patients had a history of paroxysmal AF compared with 67% in the LINQ Usability study. The XPECT study had more shorter duration episodes that are more likely to be missed due to the asynchronous nature of the 2-min detection periods. Further, episode detection PPV will be highly dependent on incidence rate of AF in the patient cohort[18] and number of incidences of inappropriate termination and re-detection of the same true episode. The performance metrics which may be most applicable across patient cohorts and monitoring durations are duration sensitivity and specificity and episode sensitivity. For example, high duration sensitivity in a known-AF patient cohort improves the odds of detecting AF with high sensitivity in cryptogenic stroke patients with intermittent paroxysmal AF. Maximizing duration specificity is a design consideration to reduce inappropriate detections; however that should not be achieved by compromising significantly on duration sensitivity.

The two primary patient populations where the LINQ ICM device is being used for AF diagnosis and monitoring are in cryptogenic stroke patients and in AF ablation/AF management patients, respectively. The performance results presented in this study is primarily from patients with known history of AF, i.e. in ablation/AF management patient cohort. Both the XPECT[13] and the Reveal LINQ usability[15] Holter study were performed in this patient cohort as they provided for the best chance of having patients with AF during the day of Holter recording and evaluating the sensitivity of AF detection. The AF incidence is very low in cryptogenic stroke patient population and a very large study will be needed to have sufficient Holters with AF in this patient cohort. Some performance metrics in other patient cohorts was recently reported from a real-world study.[18] A similar study could be performed to evaluate the prospective effectiveness of the adaptive P-Sense algorithm in patients with cryptogenic stroke.

Besides the higher incidence of paroxysmal AF in XPECT study, there are some other technical differences between these two studies which affect performance results. The XPECT study was performed with Reveal XT devices with no standard implant procedure. Many false detections and missed detections are attributed to a loose implant pocket where the device can move in the pocket leading to electrodes losing contact. For example, a large proportion of missed AF episodes in the XPECT are attributed to loss of contact and no measured ECG during the AF episodes. The smaller size of the

device, standardized implant technique to form a tight pocket, and improved electrode coating all improved signal quality in the LINQ device which was used in the Usability study reducing the loss of contact related performance issues significantly. Thus the performance of the adaptive P-Sense algorithm in the Usability study is more applicable. The XPECT study had fewer telemetry errors in the uplinked ECG and hence it was useful in the development and validation of the algorithm across all programmable settings.

Limitations

The primary limitation of this study is that the Holter studies were done only for the duration of 24 or 48 h and hence some of the performance results, particularly the diagnostic metrics, may not apply for a longer duration of monitoring. The longer the monitoring duration the more likely the device will detect AF in a patient either appropriately or inappropriately. Another limitation of this study is that it does not address the ability of the algorithm to detect atrial flutter or AT, and AF episodes that are <2 min in duration. The reasons for these exclusions include low incidence of atrial flutter in the studies, AF-only mode being the nominal mode of operation of the device and a 2-min detection period used by the algorithm.

Conclusion

An enhanced algorithm that adapts the sensitivity for AF detection over time based on evidence of irregular sinus is developed and validated using data from multiple Holter study data. This algorithm substantially reduces inappropriately detected episodes and duration with minimal reduction in sensitivity for detecting AF.

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