Filtering of remote monitoring alerts transmitted by cardiac implantable electronic devices and reclassification of atrial fibrillation events by a new algorithm

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BACKGROUND Cardiac implantable electronic devices (CIEDs) are an important means of atrial fibrillation (AF) detection. However, the AF burden measurements and notifications transmitted by CIEDs are not directly related to the clinical classification of paroxysmal, persistent, or permanent AF. Moreover, AF alerts are the most frequent form of notification, imposing a time-consuming review on caregivers.

OBJECTIVE The purpose of this study was to compare the incidence of standard AF burden-related notifications in remotely monitored (RM) patients with the incidence of events detected after filtering by a new proprietary algorithm implementing the standard European Society of Cardiology classification of AF.

METHODS Between 2017 and 2022, all RM patients with daily AF burden measurements available for $\geq$30 days and $\geq$1 AF burden-related alerts were enrolled at 68 medical centers. The incidence of CIED-transmitted alerts was compared to that of AF episodes detected by a new proprietary algorithm and classified as "first recorded episode of AF", "paroxysmal AF", "increased paroxysmal AF", "persistent AF", or "end of persistent AF back to paroxysmal AF or back to sinus rhythm."

RESULTS Between January 2017 and September 2022, this retrospective study analyzed data from 4162 recipients of an Abbott, Biotronik, Boston Scientific, or Medtronic CIED, RM over mean follow-up of 605 $\pm$ 386 days. The algorithm broke down 67,883 AF burden-related alerts into 9728 (14.3%) clinically relevant AF events.

CONCLUSION A new AF alert algorithm successfully identified clinically significant AF events in RM CIED recipients and would markedly limit the total number of transmitted alerts that require review by caregivers.

KEYWORDS Cardiac implantable electronic device; Atrial fibrillation; Atrial fibrillation burden; Remote monitoring; Alert burden

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Introduction

Atrial fibrillation (AF), a highly prevalent cardiac arrhythmia associated with an increased risk of systemic embolism and stroke, imposes a heavy burden on the health care system.[1] Its incidence per 1000 men reported recently over 2.7 years of observation was 1.7 in those between 20 and 24 years of age and 234.3 in those between 75 and 79 years of age. Over the same observation period, the incidence was 0.7 and 219.2 per 1000 women in the younger and older age groups, respectively.[2] The same study observed a higher death rate, which increased with age, among patients who presented with AF than in a matched control population.

The relationship of cardiac implantable electronic devices (CIEDs) with AF has been widely studied.[3–5] The detection of AF by CIED has implications on the programming of atrial sensing and the optimization of low-voltage signal detection.[6] AF is detected in 75% of dual-chamber pacemaker recipients, and in 69% of these patients AF is detected by the device in the absence of symptoms.[7] The abnormal events are remotely transmitted by the CIED to the manufacturer, before being transferred to the caregiver, who may be overwhelmed by the amount of data that requires analysis.

Remote monitoring (RM) is recommended to limit the number of in-office follow-up visits of recipients of implanted devices.[8,9] It also can be used to follow the evolution

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KEY FINDINGS

- Using a new algorithm that detects clinically relevant events leads to a >85% decrease in atrial fibrillation (AF) burden–related alerts compared to alerts transmitted by a cardiac implantable electronic device (CIED).
- The algorithm processing daily data to detect the development of AF presentations allows the detection AF improvements such as "return to sinus rhythm," which is not possible with AF burden–related alerts emitted by CIEDs.
- Creating a new set of clinically relevant alerts, based on the detection of AF presentations by the algorithm, should save time for caregivers and thus promote the adoption of remote monitoring, increasing the efficiency and quality of care of patients with AF.

to clinical AF and monitor the incidence of atrial high-rate and asymptomatic AF episodes.[10] AF burden is defined as the amount or percentage of time spent daily in AF.[11,12] An increase in AF burden increases health care costs[13,14] and is more negatively correlated with quality of life than the duration or number of AF episodes.[15] Furthermore, in a study of patients with heart failure and AF, the AF burden was correlated with an increased risk of adverse clinical events and death from all causes.[1]

This study compared the rate of AF burden–related notifications transmitted by CIED recipients undergoing RM with the rate of clinically significant events detected by a new proprietary algorithm.

Materials and methods

The Implicity™ (Implicity, Paris, France) RM platform records, stores, and displays all manufacturers' teletransmissions via a single interface. The present study is based on a retrospective analysis of data collected using this platform between January 2017 and September 2022. It complies with the regulations regarding the protection of personal health data and follows ISO 27001 for data security. Because this study was a retrospective analysis of clinical data, it was exempt from reviews and approvals by the institutional review boards of the participating institutions, in accordance with the European "General Data Protection Regulation" (UE 2016/679). Data were not collected for all patients who had refused to contribute their data to research. All data were de-identified to ensure the protection of personal health data, according to the regulations and French reference methodology (MR-004).

Patient population

Patients eligible for the study underwent implantation of a CIED after 2015 and were followed by the Implicity RM platform at 68 medical centers in France, the United Kingdom, Germany, and Finland.

Inclusion criteria

Recipients of a CIED with ≥1 atrial endocardial leads were eligible for inclusion in this study. Therefore, subcutaneous implantable cardioverter-defibrillators and insertable cardiac monitors were excluded because they record surface electrocardiograms instead of electrograms. AF burden–related alerts are emitted by CIEDs to inform caregivers that the AF burden has crossed a predefined limit. Patients who had ≥1 AF burden–related alert and daily AF burden measurements for ≥30 days were retained for this analysis.

Exclusion criteria

From this initial sample, all patients whose data were inconsistent, such as AF burden >100% or incoherent device implantation dates, were excluded from the analysis. Figure 1 summarizes the composition of the final study sample.

Algorithm development and implementation

A group of expert cardiologists developed a new atrial management algorithm (AMA), based on a white box model and the standard European Society of Cardiology classification of AF,[10] to describe clinically relevant trends in AF burden recorded daily and detailed in Table 2A. The input consists of daily AF burdens recorded over the study period and a set of parameters. The algorithm uses the first 7 datapoints available in a range of 14 days to determine whether the patient is in "Sinus rhythm," "Paroxysmal AF," or "Persistent AF" status. If a sufficient number of points is not available within the first 30 days of history, the patient's status is set by default to "Sinus rhythm." After this period of initialization, the AMA processed the data daily to identify short-term variations, examined the trend against previous AF burden measurements, and detected the development of predefined AF presentations. Thus, the AMA converted multiple alerts caused by the same AF event into a single, clinically relevant alert, and we hypothesized that this would allow a reduction in the number of alerts to be reviewed by caregivers.

Statistical analysis

Data are given as mean ± SD, median (interquartile range [Q1; Q3]), or count (percentage), as appropriate. Data were stratified by gender, median age, and type of implanted device. A test of normality was applied to the distributions of data. The Wilcoxon rank-sum test was used to compare non-normally distributed variables, such as the number of alerts. Proportions were compared using the χ^2 test. Medians were compared with the Mood median test. The population was divided into 2 age groups, with a cutoff at the median age (50% of the population). $P < .05$ was considered significant. Data were processed using Python Version 3.8 (Python Software Foundation, Wilmington, DE), and the statistical analyses performed using XLSTAT Version 2022 (Addinsoft, Paris, France).

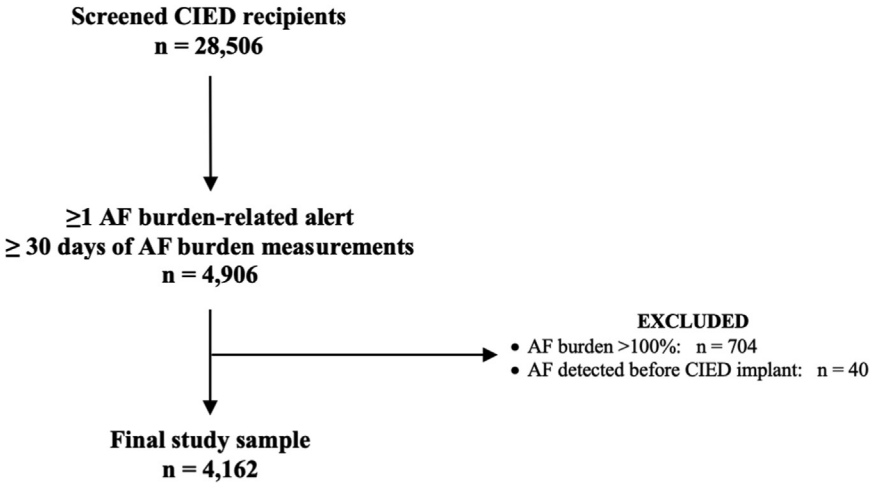

Figure 1 Study flowchart. AF = atrial fibrillation; CIED = cardiac implantable electronic device.

Results

Selection of the study sample is summarized in Figure 1. Among 28,506 patients who had undergone implantation of an Abbott (Chicago, IL), Biotronik (Berlin, Germany), Boston Scientific (Marlborough, MA), or Medtronic (Dublin, Ireland) CIED and were remotely followed between January 2017 and September 2022, 4906 had ≥1 AF burden–related alerts and ≥30 days of AF burden measurements. We excluded 704 patients whose AF burden measurements were >100% and 40 for whom the dates of measurements preceded the CIED implantation. A detailed history of the daily AF burden measurements and AF burden-related alerts was collected in the remaining 4162 patients over mean follow-up of 605 ± 386 days (median 561.5 [298; 839] days) with median connectivity rate of 99.3% [91.7%; 100%]. Mean age was 76.7 ± 11.3 years (median 78.0 [71; 84] years), and 73.3% were men. Other important characteristics are given in Table 1. A total of 67,883 AF burden–related alerts were transmitted by the various CIEDs and 9728 AF presentations were detected by the algorithm, representing an 85.7% decrease (95% confidence interval 85.4% to 85.9%) in the number of alerts to be examined. Table 2B lists the number of AF presentations given in Table 2A. Median number of AF presentations was significantly different when considering all classes of AF (P <.0001). The number of "First recorded episode of AF" per patient-year was the lowest because it was detected only once per patient (0.60 [0.41; 1.06] detections per patient-year). The highest median number of detections was "Persistent AF" (0.98 [0.55; 1.84] detections per patient-year). Overall, the median number of alerts per patient-year transmitted by the CIED decreased from 3.1 [1.1; 9.1] to 1.3 [0.6; 2.7] after treatment by the AMA, corresponding to a 57.9% decrease in the median value (P <.0001).

Mean [median] numbers of alerts per patient-year transmitted by the CIED vs treated by the AMA, classified according to gender, age groups, and implanted devices, are compared in Table 3. In each comparison, the overall number of alerts transmitted by the CIED was significantly greater than the number of alerts treated by the AMA (P <.0001). When considering only the AMA, a significant difference is obtained among devices (P <.0001). The highest median numbers of alerts per patient-year were transmitted by cardiac resynchronization therapy–pacemakers (CRT-Ps) (1.6 [0.8; 3.0]) and pacemakers (PMs) (1.5 [0.7; 2.9]), and the lowest by implantable cardioverter-defibrillators (ICDs) (1.0 [0.5; 2.1]) and cardiac resynchronization therapy–defibrillators (CRT-Ds) (1.2 [0.6; 2.5]). When devices were grouped by type, the median number of alerts per patient-year with PM/CRT-P was 1.45 [0.7; 2.9], 24.5% higher than with ICD/CRT-D (1.17 [0.6; 2.4] (P <.0001). Mean rates of alerts treated by the algorithm in

Table 1 Characteristics of the study sample

No. of study participants	4162
Age (y)	76.7 ± 11.3
Men	3050 (73.3)
Participating medical centers	68
Patients per center	59.5 ± 61.8 (36.0 [11; 86])
Atrial fibrillation burden–related alerts	67,883
Days of follow-up	605 ± 386 (561.5 [297.5; 838.5])
Device manufacturer	
Biotronik	1444 (34.7)
Medtronic	1194 (28.7)
Abbott	1070 (25.7)
Boston Scientific	454 (10.9)
Implanted device	
Pacemaker	1926 (46.3)
Cardiac resynchronization therapy–defibrillator	1220 (29.3)
Implantable cardioverter-defibrillator	758 (18.2)
Cardiac resynchronization therapy–pacemaker	258 (6.2)

Values are number (%) of observations or mean ± SD (median [interquartile range Q1; Q3]) unless otherwise indicated.

Table 2 Presentations of atrial fibrillation

A. Qualitative descriptions

Presentation	Description
First recorded episode of AF	First AF burden >0%
Paroxysmal AF	AF burden between 5% and 90% for 7 days
Increasing paroxysmal AF	AF burden increasing by 30% for 7 days
Persistent AF	AF burden >90% for 7 days
Change from persistent to paroxysmal AF	Decrease in AF burden <90% for 7 days
Conversion of persistent AF to sinus rhythm	Decrease in AF burden <5% for 7 days

B. Quantitative analysis

	Episodes per patient-year	
Presentation	N (%)	Median [interquartile range]
First recorded episode of AF	3170 (40.6)	0.60 [0.41; 1.06]
Paroxysmal AF	981 (12.6)	0.81 [0.50; 1.51]
Increasing paroxysmal AF	470 (6.0)	0.71 [0.45; 1.29]
Persistent AF	1863 (23.9)	0.98 [0.55; 1.84]
Change from persistent to paroxysmal AF	432 (5.5)	0.81 [0.49; 1.59]
Conversion of persistent AF to sinus rhythm	895 (11.5)	0.70 [0.45; 1.22]
P value	<.0001	<.0001

AF = atrial fibrillation.

men vs women and in patients <78 years vs ≥78 years of age were similar (Table 3).

Discussion

The main observation made in this study was a >85% decrease in AF burden–related alerts transmitted by CIEDs using a new algorithm that detects clinically relevant events. The median number of alerts per patient-year decreased by 57.9%. The incidence of AF burden–related alerts transmitted by PM/CRT-P was higher than that transmitted by ICD/CRT-D. Because the indications for ICD/CRT-D vs those for PM/CRT-P are dissimilar, the percentage of ventricular pacing associated with both types of CIED is different. PM/CRT-P are mostly indicated for the management of bradyarrhythmias and are associated with higher ventricular pacing rates and thus a higher risk of AF.[16]

The median number of transmitted alerts per patient-year was not gender- or old age-dependent. It has been reported

Table 3 Comparison of alerts transmitted by CIED vs treated by the AMA, per patient-year, according to gender, age group, and implanted device

	Alerts		
	Transmitted by CIED	Treated by AMA	*P* value
A. Gender			
Women	8.3 ± 20.1 (2.6 [1.1; 7.2])	2.2 ± 2.7 (1.3 [0.6; 2.7])	<.0001
Men	13.7 ± 43.5 (3.3 [1.1; 10.2])	2.3 ± 3.0 (1.3 [0.6; 2.7])	<.0001
P value	<.0001	NS	
B. Age group			
<78 y	12.3 ± 40.0 (3.0 [1.0; 9.1])	2.1 ± 2.6 (1.2 [0.6; 2.5])	<.0001
≥78 y	12.2 ± 37.6 (3.2 [1.2; 9.2])	2.4 ± 3.2 (1.4 [0.7; 2.8])	<.0001
P value	NS	NS	
C. Implanted device	9.7 ± 15.7 (3.8 [1.1; 9.6])	2.7 ± 3.4 (1.6 [0.8; 3.0])	<.0001
Cardiac resynchronization therapy–pacemaker Pacemaker	8.5 ± 27.9 (2.9 [1.1; 7.5])	2.5 ± 3.0 (1.5 [0.7; 2.9])	<.0001
Cardiac resynchronization therapy–defibrillator	18.8 ± 50.3 (3.9 [1.2; 14.3])	2.1 ± 2.6 (1.2 [0.6; 2.5])	<.0001
Implantable cardioverter-defibrillator	12.2 ± 45.0 (2.4 [0.9; 7.9]-	1.9 ± 2.9 (1.0 [0.5; 2.1])	<.0001
P value	<.0001	<.0001	

Data are given as mean ± SD (median [interquartile range Q1; Q3]). *P* values were calculated by comparing medians using the Mood test (paired test when comparing cardiac implantable electronic device (CIED) vs atrial management algorithm (AMA).

that 23% of RM transmissions require a follow-up phone conversation with the patient.[17] Although in the TRUST (Lumos-T Safely Reduces Routine Office Device Follow-Up) study, actionable events in ICD recipients were reliably detected by RM, follow-up clinical interventions were limited to <10% of the scheduled transmissions.[18]

RM of CIED recipients has enabled a 56% decrease in the number of ambulatory visits.[8] It is substantively cost-effective by decreasing the time spent by health care professionals in outpatient care, decreasing the need for hospitalizations, and markedly decreasing the consumption of health care resources.[19,20] However, some caregivers remain unwilling to use RM because of the excess of unnecessary, false-positive, or irrelevant alerts received. Consequently, most alerts are simply archived without prompting a medical intervention.[21] In a preliminary study of an artificial intelligence–based prototype that classifies the alerts automatically, the burden represented by RM notifications was alleviated by >80%.[22] The creation of a new set of relevant alerts, based on the detection of distinct presentations of AF, should increase the efficiency and quality of care of patients with AF, save time for the medical staff and thereby promote the adoption of RM, and decrease the number of patient visits and hospitalizations.

Clinical classification of AF events by reducing the number of RM alerts is innovative support of ambulatory patient care. The "return to sinus rhythm" events detected by the AMA reflect the spontaneous termination of AF or the effectiveness of a prescribed antiarrhythmic treatment, which might help in the choice and adjustment of antiarrhythmic therapy. A reclassification of the AF alerts transmitted by CIEDs according to professional practice guidelines should help in the clinical management of patients.

The data used for this retrospective study are real-life data and the AMA is based on a white-box model that always returns the same output for a given input, which explains why a prospective study should perform as well as this retrospective study.

Study limitations

The AMA cannot be used for patients who do not have daily measurements of AF burden. For the patients having daily measurements of AF burden, the only case in which the algorithm would not be able to raise an alert would be if the data are missing for more than 1 week. In that specific case, a warning indicating that "AF data are not available" is provided instead of alerts.

After the detection of the "first recorded episode of AF," there cannot be any AF presentations detected in less than 1 week because a 7-day period of observation is required to meet one of the defined criteria. The period of observation was set to 7 days because that is the limit over which the AF turns to persistent AF according to the European Society of Cardiology classification of AF. Because the risk of stroke should be assessed after the "first recorded episode of AF" presentation and so as not to overwhelm physicians with too many alerts, the algorithm is not programmed to detect all episodes of paroxysmal AF but only those that last for 1 week as well as the increase of the 7-day average of AF burden compared to the 7-day average of the previous detection through the "increasing paroxysmal AF" presentation. The clinical use of AMA could be safer for patients receiving continuous anticoagulation because it may introduce a delay between some AF episodes and the detection of one of the AF presentations listed in Table 2A.

The alerts produced by the AMA are meant to be more clinically relevant than the RM alerts. Therefore, the algorithm is not supposed to reclassify the RM alerts as true-positive or false-positive but to replace the RM alerts, thus explaining why this study presents results as alert reduction rate and not as sensitivity, positive predictive value, or false-positive rate.

This study is based on data collected retrospectively. A prospective study using the AMA and including patient outcomes is needed to validate the retrospective results and to ascertain the clinical and organizational impacts of the algorithm.

In the future, the classification of atrial arrhythmias will be available based on analysis of electrograms using an artificial intelligence algorithm.

Conclusion

The AMA successfully identified clinically significant AF events in RM CIED recipients and would markedly limit the total number of transmitted alerts that require review by caregivers.

Funding Sources

Because this study is a retrospective analysis of a database, it is not funded.

Disclosures

Marika Gentils, Dr Stefan Klaes, Dr Issam Ibnouhsein, and Dr Jean-Luc Bonnet are employees of Implicity. Dr Arnaud Rosier is CEO and major shareholder of Implicity. Dr Jagmeet P. Singh is a consultant for Implicity. Dr Arnaud Lazarus is a minor shareholder of Implicity. Marika Gentils, Dr Stefan Klaes, and Dr Arnaud Rosier filed a patent, not yet delivered. All other authors have no conflicts to disclose.

Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

All patients had granted their written approval to contribute the data at the time of RM activation. All data were de-identified to ensure the protection of personal health data, according to the European regulation and French reference methodology (MR-004).

Ethics Statement

Because this was a retrospective analysis of prospectively collected clinical data in real-life practice, this study was exempt from reviews and approvals by the institutional review boards of the participating institutions. Postprocessing was conducted in accordance with the European "General Data Protection Regulation" (UE 2016/679).

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