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CLINICAL RESEARCH
Pacing and cardiac resynchronization therapy

Active periodic electrograms in remote monitoring of pacemaker recipients: the PREMS study

Arnaud Lazarus[1]*, Benoit Guy-Moyat[2], Pierre Mondoly[3], Frédéric Pons[4], Carlo Quaglia[5], Jean-Philippe Elkaim[6], Sandrine Bayle[7], and Frédéric Victor[8]; for the PREMS trial Investigators

[1]Rhythmology Unit, Clinique Ambroise Paré, 25-27 boulevard Victor Hugo, 92200 Neuilly-Sur-Seine, France; [2]Cardiology Unit, Centre Hospitalier Universitaire de Limoges, 2 avenue Martin Luther King, 87000 Limoges, France; [3]Cardiology Unit, Centre Hospitalier Rangueil, 1 avenue du Pr Jean Poulhès, 31000 Toulouse, France; [4]Cardiology Unit, Hôpital d'Instruction des Armées Saint-Anne, 2 boulevard Sainte-Anne, 83000 Toulon, France; [5]Cardiology Unit, Centre Hospitalier de Roanne, 28 rue de Charlieu, 42300 Roanne, France; [6]Cardiology Unit, Centre Hospitalier de Douarnenez, 85 rue Laennec, 29100 Douarnenez, France; [7]Cardiology Unit, Centre Hospitalier Louis Pasteur, 4 rue Claude Bernard, 28630 Le Coudray, France; and [8]Cardiology Unit, Polyclinique Saint-Laurent, 320 avenue Général George S. Patton, 35700 Rennes, France

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Aims Remote monitoring (RM) is considered as a standard of care for pacemaker recipients. Remote monitoring systems provide calendar-based intracardiac electrogram recordings (IEGM) only with the current pacemaker settings (passive IEGM). PREMS (Pacemaker Remote Electrogram Monitoring Study), an observational, multicentre trial, prospectively evaluated the clinical value of an active IEGM (aIEGM), including three 10-s sections (passive IEGM, encouraged sensing, and encouraged pacing), compared to other RM data and to its passive IEGM section. Secondary objectives included the added value of the aIEGM to fully assess the sensing and pacing functions of each lead.

Methods and results Patients were enrolled within 3 months after pacemaker implantation and followed until the first transmitted aIEGM, which was analysed together with all other RM data. In total, 567 patients were enrolled (79 ± 9 years, 62% men, 19% single-chamber, and 81% dual-chamber pacemakers). Of 547 aIEGMs transmitted in 547 patients, 161 [29.4%; 95% confidence interval (95% CI) 25.6–33.3%] indicated at least one anomaly non-detectable with certainty—or at all—on other RM data, including atrial arrhythmia, extrasystoles, undersensing, oversensing, and loss of capture. In 21.7% of cases the detected events deserved a corrective action. The sensing and pacing function of each lead could be fully assessed in 77.3% of aIEGM (95% CI 72.6–82.0%) vs. 15.5% (95% CI 11.4–19.6%) when considering only the passive IEGM section ($P < 0.001$).

Conclusion An active IEGM improves the clinical value of remote pacemaker follow-up. Furthermore, compared to a passive IEGM, the aIEGM increases the capability to fully assess remotely the sensing and pacing functions.

Keywords Telemedicine • Remote monitoring • Remote follow-up • Pacemaker • Electrograms

Introduction

Remote monitoring (RM) of patients equipped with cardiac implantable electronic devices associates the analysis of event reports and calendar-based remote follow-ups (FU).[1] A benefit of RM has been reported in clinical studies and daily-life registries on total mortality and in pacemaker FU.[2–9]

Practice guidelines recommend pacemaker recipients to be followed every 3 to 12 months, either in-person or remotely, and

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* Corresponding author. Tel: +33 1 46415023; fax: +33 1 46415025. *E-mail address*: lazarus@inparys.com

What's new?

- PREMS (Pacemaker Remote Electrogram Monitoring Study) is the first study to prospectively evaluate the added clinical value of an active periodic intracardiac electrogram (aIEGM) during remote pacemaker follow-up (FU).
- The aIEGM allows to detect arrhythmias or sensing/pacing problems, not formally identifiable when looking at other remote monitoring data and deserving a clinical action once in five.
- Compared to a passive IEGM, the aIEGM reveals a higher number of anomalies.
- Compared to a passive IEGM, the aIEGM increases the capability to assess both the sensing and pacing function of each lead during a remote pacemaker FU, as recommended by practice guidelines.

experts now recommend RM as the preferred method for cardiac implantable electronic devices FU.[1,10,11]

In order to support remote FU, manufacturers' systems provide an extended RM data set and calendar-based intracardiac electrograms (IEGM),[12,13] comparable to recordings obtained during in-office visits. These electrograms display current rhythm and may reveal arrhythmias or sensing/pacing anomalies.[14] While most RM systems only provide IEGM registered at the programmed device settings (passive IEGM), some recent pacemaker models record an active IEGM, made of three 10-s sections: passive IEGM, encouraged sensing, and encouraged pacing.

The purpose of the PREMS (Pacemaker Remote Electrogram Monitoring Study) is to evaluate the added clinical value of an active IEGM, with respect to other RM data and to the passive IEGM.

Methods

Remote monitoring system

Home Monitoring® (Biotronik SE and Co. KG, Berlin, Germany) is a system that automatically transmits the data stored in implantable devices to the Biotronik Service Center, over a wireless global system for mobile communications network. After an automatic analysis, messages are posted daily on a secure website accessible to the physician responsible for the patient's care. In case of clinical or technical anomaly, the device emits warning messages, immediately forwarded by the Service Center to the physician.

Active intracardiac electrogram

The aIEGM is automatically recorded at night, 30 min before data transmission to the Biotronik Service Center, set by default between 1:00 and 2:00 AM. It comprises three 10-s sections. Section 1 is a passive IEGM recorded at the current pacemaker settings. Section 2 is an encouraged sensing phase, with the hysteresis rate and atrioventricular hysteresis changed temporarily to promote intrinsic cardiac activity. Section 3 is an encouraged pacing phase, with the atrial pacing rate temporarily set to be 12.5% faster than the average intrinsic rate for the last eight events (applied also in case of single-chamber programming) and 100 ms atrioventricular delay, in order to favour pacing.

Study objectives

The main objective of PREMS was to evaluate the added clinical value of the periodic aIEGM, with respect to other global RM data. The primary endpoint was based on the rate of patients with at least one rhythm or sensing/pacing anomaly detected on the periodic aIEGM but non-detectable with certainty—or at all—by the sole analysis of the other RM data set. Only the first aIEGM transmitted after implant was analysed.

Other clinical objectives included the assessment of (i) the rate of patients with anomalies identified on the periodic IEGM and/or on other RM data, and their types; (ii) the rate of anomalies which led to a corrective action; and (iii) the added value of each aIEGM section, based on the sections where the anomaly is detected.

Finally, the capability of the periodic aIEGM to fulfil the required assessment of the sensing and pacing functions during pacemaker FU was evaluated by measuring the rate of patients in whom both sensing and pacing performance of each lead could be assessed on the aIEGM, excluding cases when sensing or pacing was not analysable due to ongoing atrial arrhythmia precluding atrial capture evaluation or due to pacemaker dependency. The performance of the full aIEGM was compared to that of the passive aIEGM section.

Trial participants

To participate in the study, patients had to be implanted with a single- or dual-chamber Evia or Eluna Biotronik pacemaker (within last 3 months), with the Home Monitoring® option activated and functional, and the periodic IEGM feature programmed to 30-day intervals. Patients also had to be willing and able to comply with the protocol and to be in stable medical situation. All patients provided written informed consent.

Trial design

PREMS was a French-based observational, multicentre, and prospective trial. Remote monitoring was activated between pacemaker implantation and the first in-office FU. Patients were prospectively followed until the first periodic aIEGM was transmitted remotely.

The investigator had to analyse this periodic aIEGM and other RM data in order to identify a possible rhythm or sensing/pacing anomaly.

Scheduled visits were not determined by the protocol or by the use of the RM system. Except for periodic aIEGM recordings, remote patient management was made according to routine practice of each centre, including extra FU visits if considered relevant by the physician.

The protocol complied with the declaration of Helsinki, was reviewed and approved by the pertinent ethics committees. Patient information was treated confidentially. All aIEGMs transmitted by RM, and all other RM data were also reviewed by an adjudication committee composed of two cardiologists who did not participate in the trial and one technical engineer, in order to have a medical and technical perspective (Supplementary material online, *Appendix*).

Device programming

The RM system had to be activated and the periodic IEGM feature programmed to 30 days. Other parameters were left to the physician's discretion but bipolar atrial sensing was recommended.

Statistical analysis

A descriptive analysis of baseline patient characteristics and study findings was performed. Normally distributed variables were compared using Student's two-tailed *t*-test, after confirmation of the equality of variances by the Levene's test. For categorical variables, the groups were compared by the χ^2 test. A *P*-value <0.05 was considered statistically significant. The

Table 1 Baseline patient characteristics

	All patients ($n = 567$)	Type of pacemaker	
		Single chamber ($n = 108$)	Dual chamber ($n = 459$)
Age (years)	78.6 ± 9.4	83.4 ± 6.6	77.4 ± 9.6
Men	353 (62.3)	68 (63)	285 (62.1)
Indication for pacemaker implantation			
Atrioventricular block (any degree)	341 (60.1)	44 (40.7)	297 (64.7)
Brady-tachy syndrome—sinus node disease	257 (44.8)	69 (63.9)	188 (41)
Other	12 (2.1)	1 (0.9)	11 (2.4)
Device implantation			
First implantation	476 (84)	84 (77.8)	392 (85.4)
Replacement	91 (16)	24 (22.2)	67 (14.6)
Underlying heart disease			
Ischaemic heart disease	109 (19.2)	20 (18.5)	89 (19.4)
Valvular heart disease	61 (10.8)	19 (17.6)	42 (9.2)
Dilated cardiomyopathy	5 (0.9)	2 (1.9)	3 (0.7)
Hypertrophic cardiomyopathy	20 (3.5)	3 (2.8)	17 (3.7)
Other	13 (2.1)	1 (0.9)	5 (1.1)
None	384 (67.8)	69 (63.9)	315 (68.6)
History of atrial arrhythmias	248 (43.7)	95 (88)	153 (33.3)

Data are *n* (%), or mean ± SD.
SD, standard deviation.

SPSS version 18.0 (SPSS Institute Inc., Chicago, IL, USA) statistical software was used for the analyses.

Results

Study population

Between July 2014 and September 2015, 47 French medical centres (see Supplementary material online, *Appendix*) enrolled 567 patients (mean age 79 ± 9 years; 62% men), who received a single-chamber (19%) or a dual-chamber pacemaker (81%). Baseline patient characteristics are summarized in *Table* 1.

Twenty patients terminated the study early because of consent withdrawal ($n = 8$), death ($n = 7$), pacemaker explantation ($n = 2$), or other reasons ($n = 3$). The remaining 547 patients (96.5%) had a regular study termination with a periodic aIEGM transmitted and analysed.

Added clinical value of active intracardiac electrogram analysis for remote pacemaker follow-up

In 92.7% of the cases, the investigators evaluated the quality of aIEGM tracings as good or very good. The number of patients with at least one rhythm or sensing/pacing anomaly (*Figure* 1) detected on the periodic aIEGM, but non-detectable with certainty—or at all—when analysing the other RM data, was 161 [29.4%, 95% confidence interval (95% CI) 25.6–33.3%] (*Table* 2). Of the detected events, 21.7% required a corrective action and 7.5% necessitated an additional in-office FU (*Table* 3).

Looking at the RM data except aIEGMs, the uncertainty about diagnosis of atrial arrhythmia correlated with the number of episodes and atrial arrhythmia burden: 0.8/day and 1.6% (burden) in 61 patients with suspected but uncertain atrial arrhythmia vs. 6.6/day and 25.8% in 68 patients with certain diagnosis of atrial arrhythmia.

After analysis of all RM data, including aIEGMs, the number of patients with at least one anomaly was 201 (36.7%, 95% CI 32.6–40.8%). In 67.9% of these cases, the anomaly was not previously noted or reported by RM notifications. In 15.2% of all cases, the investigators considered that the decision would not have been the same without the analysis of the aIEGM.

Added diagnostic value of the active intracardiac electrogram compared to passive intracardiac electrogram

An anomaly was identified on the aIEGM in 173 patients (31.6%) (*Table* 2), compared to 95 patients (17.4%) when only section 1 of the IEGM was taken into account ($P < 0.001$). The main anomalies that were not visible on the aIEGM section 1 were atrial ($n = 30$) or ventricular ($n = 30$) extrasystoles or salvos, atrial oversensing ($n = 26$), and loss of ventricular sensing ($n = 6$).

Assessment of sensing and pacing functions with the active intracardiac electrogram

Based on our definition of >95% pacing since previous FU, 4.9% and 37.7% of the study cohort was classified as pacemaker-dependent in the atrium or in the ventricle, respectively. After exclusion of cases not allowing to evaluate sensing and/or pacing (ongoing atrial arrhythmia, atrial/ventricular dependency), the

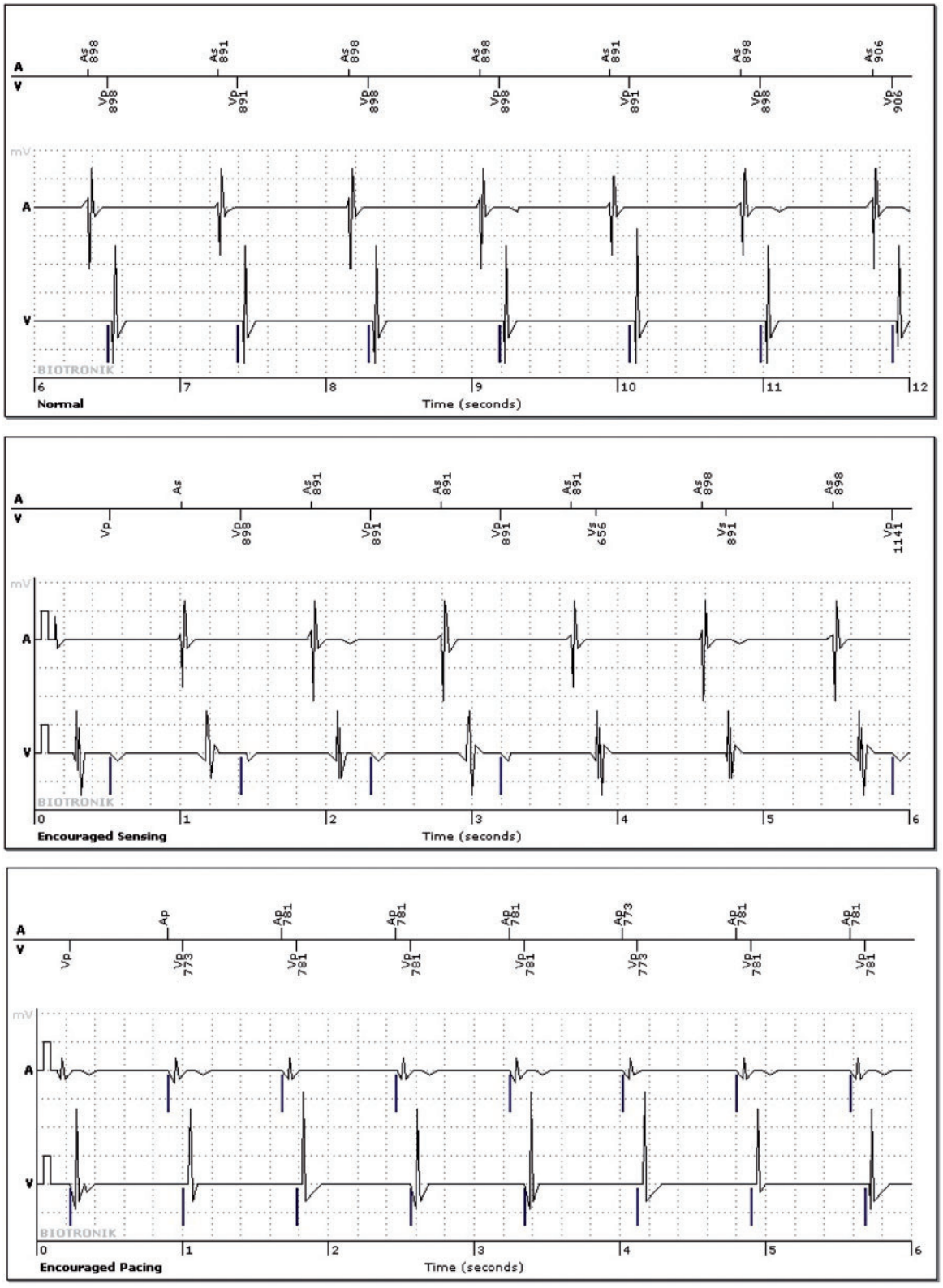

Figure 1 Added value of an active intracardiac electrogram (aIEGM): The passive section (*normal*) of this periodic aIEGM only displays effective atrial sensing and ventricular capture, which does not allow atrial capture and ventricular sensing assessment. Section 2 (*encouraged sensing*) reveals an undiagnosed intermittent loss of ventricular sensing on the first four and on the last ventricular beat, followed by a useless ventricular pacing, whereas Section 3 (*encouraged pacing*) allows to check effective atrial capture. Atrial and ventricular sensing and pacing functions are thus fully analysable thanks to all aIEGM sections. The loss of ventricular sensing triggered an additional follow-up to adapt the ventricular sensitivity. Top line in each section: markers (Ap, atrial pacing; As, atrial sensing; Vp, ventricular pacing; Vs, ventricular sensing); A line, atrial electrogram; V line, ventricular electrogram. N.B.: For editorial reasons, only the first 5 s (instead of 10 s) of each aIEGM section are displayed.

Table 2 Anomalies identified on the periodic aIEGM and on other remote monitoring data

Source of identified anomalies	RM data	aIEGM	aIEGM and non-detectable with certainty by other RM data	RM data and not visible on the aIEGM
***n* (%) of patients with anomalies**	74 (13.5)	173 (31.6)	161 (29.4)	48 (8.8)
Type of anomaly[a]				
Atrial arrhythmia	68	25	1	44
Ventricular arrhythmia	1	0	0	1
PAC	0	56	56	0
PVC	3	54	52	1
Loss of atrial sensing	4	15[b]	13[c]	2
Loss of ventricular sensing	0	6	6	0
Atrial oversensing	3	49[d]	47	1
Ventricular oversensing	0	1	1	0
Loss of atrial capture	0	1	1	0
Loss of ventricular capture	0	2	2	0
Retrograde P wave	0	2	2	0
Possible lead dysfunction	2	0	0	2

Data are *n* (%) or *n* of patients.
aIEGM, active intracardiac electrogram; PAC, premature atrial complexes; PVC, premature ventricular complexes; RM, remote monitoring.
[a]A patient can have several anomalies detected.
[b]Intermittent, related to variable signal amplitude during ongoing atrial arrhythmia ($n = 13$), possible lead dislodgement ($n = 2$).
[c]Including one possible lead dislodgement.
[d]Including possible lead dislodgement or misplacement ($n = 1$) and far field R-wave sensing ($n = 48$).

Table 3 Corrective actions following identification of anomalies on the aIEGM in 161 patients, not detectable with certainty—or at all—on other RM data

	All (161 patients) *n* (%)	Single-chamber PM (14 patients) *n* (%)	Dual-chamber PM (147 patients) *n* (%)
Action needed?			
Yes	35 (21.7)	1 (7.1)	34 (23.1)
Closer RM surveillance	13 (8.1)	2 (14.3)	11 (7.5)
Type of action			
Changes in drug treatment	11 (6.8)	0 (0)	11 (7.5)
Device reprogramming	25 (15.5)	1 (7.1)	24 (16.3)
Lead repositioning	3 (1.9)	0 (0)	3 (2)
Timing for action			
Next scheduled follow-up	21 (13)	1 (7.1)	20 (13.6)
Additional follow-up	12 (7.5)	0 (0)	12 (8.2)
Other[a]	2 (1.2)	0 (0)	2 (1.4)

χ^2 test (action taken needed/device model): $P = 0.005$.
aIEGM, active intracardiac electrogram; PM, pacemaker; RM, remote monitoring.
[a]Right ventricular lead repositioning ($n = 1$); phone call to the cardiologist in order to adapt drug treatment, during an anticipated post-implant follow-up due to the atrial burden ($n = 1$).

proportion of patients with all sensing and pacing functions analysable on the periodic IEGM was 77.3% (95% CI 72.6–82.0%) for aIEGM, vs. 15.5% (95% CI 11.4–19.6%) for aIEGM section 1 ($P < 0.001$) (*Figure* 1).

Table 4 shows the ability to evaluate sensing and capture according to each aIEGM section. Active aIEGM sections (sections 2 and 3) performed better than the passive aIEGM section (Section 1) that often did not display sensed and paced events at the same time: for the assessment of atrial and ventricular sensing, the performance of section 2 is significantly superior to section 1 ($P < 0.001$ and $P = 0.01$, respectively); for the assessment of atrial and ventricular capture, the performance of section 3 is significantly superior to section 1 ($P < 0.001$).

Table 4 Ability to evaluate sensing and capture according to each aIEGM section

	Percent of patients with function analysable on the IEGM section (95% CI)
Atrial sensing ($n = 414$)[a]	
Section 1	69.3 (64.8–73.7)
Section 2	88.4 (85.3–91.5) ($P < 0.001$ vs. Section 1)
Section 3	19.1 (15.3–22.9)
Atrial capture ($n = 415$)[a]	
Section 1	54.7 (49.9–59.5)
Section 2	37.1 (32.5–41.8)
Section 3	97.8 (96.4–99.2) ($P < 0.001$ vs. Section 1)
Ventricular sensing ($n = 341$)[a]	
Section 1	75.6 (71–80.2)
Section 2	83.6 (79.7–87.5) ($P = 0.01$ vs. Section 1)
Section 3	14.7 (10.9–18.5)
Ventricular capture ($n = 547$)	
Section 1	63.8 (59.7–67.8)
Section 2	60.9 (56.8–65)
Section 3	97.8 (96.5–99) ($P < 0.001$ vs. Section 1)

Section 1 denotes passive intracardiac electrogram; Section 2 denotes aIEGM with encouraged sensing; Section 3 denotes aIEGM with encouraged pacing.
aIEGM, active intracardiac electrogram; CI, confidence interval.
[a]Atrial and ventricular sensing were not assessed in pacemaker-dependent patients, defined as >95% pacing since the last follow-up. Atrial capture was evaluated in patients without ongoing atrial arrhythmia.

Safety

No serious adverse events or deaths were considered to be related to the investigational device. Notably, no adverse side effect was reported related to aIEGM recordings.

Discussion

The PREMS study evaluated a new kind of calendar-based IEGM, namely the active IEGM, designed not only to display the current rhythm and eventually reveal ongoing arrhythmias but also to analyse basic pacemaker functions: cardiac sensing and capture for all pacing leads, as recommended by guidelines.[10,11] This is achieved by an active behaviour comparable to the temporary programming used commonly during in-office FU to favour spontaneous cardiac activity or cardiac pacing.

The aIEGM illustrates the differences that may exist between various RM systems.[15] In our standard pacemaker population, the *focal* aIEGM data appeared as a useful complement to the *global* RM data and performing better than a conventional passive IEGM.

Indeed, in 29.4% of the PREMS patients, the aIEGM revealed or confirmed an anomaly not identified with certainty based on the other RM data. This percentage is superior to the 13.5% of anomalies found on the other RM data, including 8.8% that were not visible on the aIEGM, for example paroxysmal atrial arrhythmias that had stopped at the time of aIEGM recording. Of note, anomalies were far most frequent in dual-chamber than in single-chamber devices.

Although some of these anomalies, such as isolated extrasystoles, are benign, the value of the aIEGM appears obvious since a clinical action was considered mandatory in one out of five cases. Clinical action was either deferred to the next planned FU or taken during an additional in-office FU. It mainly included changes in drug treatment or modification of pacemaker settings, but also a lead revision in some cases. It should be emphasized that based on investigators judgement, the clinical decision in 15.2% of patients was clearly influenced by the aIEGM analysis.

As shown in the case reports published by Ploux *et al.*,[14] a periodic passive IEGM can sometimes reveal undiagnosed technical troubles or arrhythmias not triggering alerts. PREMS demonstrated that the dynamic behaviour of the aIEGM increased the rate of detected anomalies significantly (31.6% vs. 17.4%) with respect to passive IEGM, represented by the first section of the aIEGM.

Guidelines require to determine during FU appropriate sensing and capture of each lead.[10,11] In PREMS, the aIEGM strongly increased the capability to remotely assess appropriate sensing and effective capture in each lead location (77.3% vs. 15.5% for passive IEGM). One can notice that the pacing function was more often analysable (>98%) than was sensing (87–91%). This difference may be attributed to the aIEGM recording during night, when the parasympathetic tone, which is responsible for a lower sinus rate and a slowdown of the atrioventricular conduction, is higher. This precluded in some patients the occurrence of spontaneous rhythm despite the fact that the settings applied during the aIEGM section 2 encouraged sensing. The decision to focus on patient safety probably prevailed in the choice of the parameters applied for this aIEGM section, instead of allowing, for instance, a temporary ventricular pacing with atrial and ventricular sensing pacing mode at 30 b.p.m. As expected, sensing was most often assessable in the aIEGM section 2 'encouraged sensing', and capture in the aIEGM section 3 'encouraged pacing'.

Study limitations

The study has several limitations. First, only the first transmitted aIEGM was assessed, in patients recently (<3 months) implanted with a pacemaker. The rate and kind of events on aIEGM may vary over time as a result of changes in drug therapy and the increasing number of recordings. Second, clinical actions decided by the investigators were not monitored since it was routine care. Third, cardiac resynchronization devices were not included. A different incidence and distribution of anomalies can be expected in this specific population with altered cardiac function. Fourth, the successors of Evia pacemakers (90.7% of our study population), such as Eluna, transmit additionally event-triggered IEGM related to atrial and ventricular arrhythmias, allowing direct arrhythmias diagnosis as opposed to our study population.

Conclusion

To conclude, PREMS demonstrates that during remote pacemaker FU the focal data of a periodic active IEGM are a useful complement to the global RM data, revealing a wider range of rhythm and technical anomalies and being more performant than a classical passive IEGM. Its added clinical value is illustrated by the significant percentage of

actionable events and could be even higher in cardiac resynchronization recipients considering their higher risk of lead-related complications.[16]

Supplementary material

Supplementary material is available at *Europace* online.

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