

ORIGINAL ARTICLE

Silent Atrial Fibrillation in Elderly Pacemaker Users: A Randomized Trial Using Home Monitoring

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Background: Pacemaker with remote monitoring (PRM) may be useful for silent atrial fibrillation (AF) detection. The aims of this study were to evaluate the incidence of silent AF, the role of PRM, and to determine predictors of silent AF occurrence.

Methods: Three hundred elderly patients with permanent pacemaker (PPM) were randomly assigned to the remote group (RG) or control group (CG). All patients received PPM with remote monitoring capabilities. Primary end point was AF occurrence rate and the secondary end points were time to AF detection and number of days with AF.

Results: During the average follow-up of 15.7±7.7 months, AF episodes were detected in 21.6% (RG = 24% vs CG = 19.3%, $P = 0.36$). There was no difference in the time to detect the first AF episode. However, the median time to detect AF recurrence in the RG was lower than that in the CG (54 days vs 100 days, $P = 0.004$). The average number of days with AF was 16.0 and 51.2 in the RG and CG, respectively ($P = 0.028$). Predictors of silent AF were left atrial diameter (odds ratio [OR] 1.2; 95% CI = 1.1–1.3; $P < 0.001$) and diastolic dysfunction (OR 4.8; 95% CI = 1.6–14.0; $P = 0.005$).

Conclusions: The incidence of silent AF is high in elderly patients with pacemaker; left atrial diameter and diastolic dysfunction were predictors of its occurrence. AF monitoring by means of pacemaker is a valuable tool for silent AF detection and continuous remote monitoring allows early AF recurrence detection and reduces the number of days with AF.

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atrial fibrillation; pacemaker; home monitoring; elderly

Atrial fibrillation (AF) is the most common sustained arrhythmia in clinical practice. Prevalence and incidence of AF are increasing, especially in the elderly population.^{1,2}

AF may appear benign, but it may reveal its detrimental effects many years after. AF has been associated with a twofold increase in the risk of death, irrespective of other known predictors of mortality.³ Ischemic stroke is the most important cause of morbidity and mortality in patients with

AF,^{4,5} and about 15% of strokes can be ascribed to a documented AF.⁶ In about 25% of patients who have ischemic strokes, no etiologic factor was identified,^{7,8} and asymptomatic or subclinical AF may be related to those episodes.⁹ The CRYSTAL-AF trial¹⁰ studied 441 patients who had had an unexplained stroke. All received at least 24 hours of standard cardiac monitoring within 90 days of the stroke, and half were then submitted to an insertable cardiac monitor implantation. By

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12 months, AF was detected in 12.4% of patients in the continuous monitoring group versus 2.0% of the patients in the control group (hazard ratio, 7.3; $P < 0.001$).

In patients with cardiac implantable electronic devices the detection of atrial high rate episodes (AHRE) has increased the understanding of the true incidence of atrial tachyarrhythmias. Systems that allow for pacemaker remote monitoring (PRM) keep detailed information about AHRE. These episodes are thought to represent asymptomatic or silent AF, and they may be indicators of sustained AF. Remote monitoring provides continuous access to stored data, and alerts may be programmed for specific events.

The prevalence and prognostic value of silent AF have been difficult to assess.^{8,9} How strict the monitoring should be remains unknown, furthermore, there is currently no consensus regarding the screening and management of silent AF. The objectives of this study were to assess the incidence of silent AF, the role of PRM and to determine predictors of silent AF occurrence, in elderly pacemaker users from a tertiary hospital.

MATERIALS AND METHODS

Study Design

This was a single center randomized study comparing the time to detect AHRE with PRM versus conventional follow-up (as described below) in elderly patients (≥ 60 years old) with standard indications for permanent pacemaker (PPM) implantation or generator replacement.¹¹

The exclusion criteria were a history of AF, terminal illnesses limiting survival, and the use of antithrombotic therapy or antiarrhythmic drug (AAD) class I or III.¹² All patients provided written informed consent before randomization. The study protocol was approved by the Local Ethic Committee and conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

All patients received dual-chamber PPMs (Philos II DR-T or Cylos DR-T models; Biotronik, Berlin, Germany) with remote monitoring capability (Home Monitoring). The Home Monitoring technology is described in detail elsewhere.¹³

Immediately after PPM implantation, patients were randomly assigned in a 1:1 ratio to one of the two monitoring strategies—PRM group (RG) and

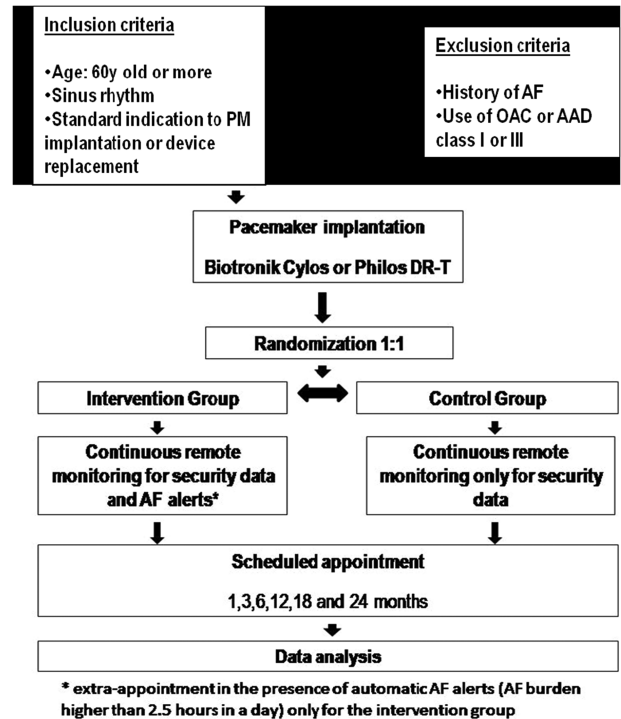


Figure 1. Fluxogram of the study.

AAD = antiarrhythmic drugs; AF = atrial fibrillation; OAC = oral anticoagulation; PM = pacemaker.

the control group (CG). Patients were then followed for 24 months.

The primary end points were AF occurrence rate and the time to AF detection (occurrence and recurrence). The secondary end point was the number of daily AF burden $\geq 10\%$.

Details of trial enrollment and follow-up are shown in Figure 1.

STUDY PROCEDURES

Baseline Assessment

The patient's medical history, physical-examination findings, use of medications and 12-lead ECG were recorded. The patients underwent two-dimensional Doppler flow echocardiography. Diastolic dysfunction was defined as functional abnormalities during left ventricular relaxation/filling and was assessed integrating several techniques: analysis of mitral flow, pulmonary venous flow, tissue Doppler, color M-mode flow propagation velocity, and left atrial volume.¹⁴ The ratio of early mitral flow velocity to early mitral annulus

velocity ≥ 8 defined the presence of diastolic dysfunction. The reference values followed the American guidelines recommendations.¹⁵

Device Programming

All devices were programmed to DDD mode with lower rate of 60 pulses per minute (ppm). The automatic mode switching (AMS) detection was programmed to an atrial rate of ≥ 160 beats per minute; cross-channel and far-field blanking were programmed to 72 and 175 ms, respectively. Stored intracardiac electrograms (IEGMs) were analyzed for each episode, and true device-detected AF was the designation for AHREs lasting two minutes or more and episodes in atrial tachycardia (AT) histogram higher than 250 ppm. A sensitivity and specificity analysis was performed in order to evaluate this programming for AHREs detection. The AHREs were excluded if artifacts were identified or if they lasted less than 2 minutes.

Using a device with wireless capability of transmission, the PRM system was able to receive daily information from PPM of all patients included in this study. The Home Monitoring system sends AF alerts of 10%, 25%, 75%, or 100% daily AF burden according with the programming. Specific automatic alerts were programmed in both groups to detect device dysfunctions as high (≥ 3000 Ohms) or low (< 200 Ohms) lead impedance and abnormalities in the sensitivity parameters. For RG, automatic AF alerts were programmed for episodes lasting at least 2.5 hours in a day (daily AF burden $\geq 10\%$), which is the minimum parameter to AF reports. We obtained the number of daily AF burden $\geq 10\%$ by means of a retrospective analysis of stored data in the PRM systems of both groups.

Follow-Up

For both groups, follow-up appointments were scheduled at 30, 90, and 180 days and then every 6 months. Patients in the RG had additional appointments if automatic AF alerts were sent by PRM. The device data regarding AF occurrence were analyzed during the entire follow-up. The physician-investigator had exclusive access to the PRM data from the RG, and the committee members had access to all PRM data in both groups for safety.

The time to AF detection was defined as the time between the date of AF diagnosis and the last in-office appointment. The AF diagnosis in RG was documented during additional appointment motivated by AF alerts and in the CG during routine follow-up visit.

The therapeutic management included electrical cardioversion procedure, AAD and antithrombotic therapy, alone or associated, according to the physician discretion.

Statistical Analysis

The sample size was based on an estimated AF incidence of 15%. To detect a reduction of 5% on the AF occurrence of RG, with 80% power and type I error (two-sided α) of 0.05, it was estimated 276 patients. Including 8% of loss to follow-up, the same size resulted in 300 patients.

Comparison of groups was performed using *t*-test or Mann-Whitney *U* test and categorical data were analyzed by chi-square test according to Pearson or Fisher's exact test as appropriate. Logistic regression model was performed to determine predictors of silent AF occurrence. All tests were two-tailed and significance level was set at 0.05. The statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, version 18.0 for Windows).

RESULTS

Patients were selected between March 2007 and January 2010, and the mean follow-up time was 15.7 ± 7.7 months (RG = 15.8 ± 7.8 vs CG = 15.5 ± 7.8 , $P = 0.56$). The overall average age was 75.2 years old, and female gender was more prevalent (56%). Patients received first PPM implantation in 54%, mostly due to advanced AV block (88.3%). Hypertension was common (95%), 83.3% had no cardiomyopathy, and the average left ventricular ejection fraction was 58.5%. The overall mean CHADS₂ score was 1.8 ± 0.9 and 61.3% of the patients had CHADS₂ scores ≥ 2 (Table 1).

The occurrence rate of AF was 21.6% (RG = 24% [36 episodes] vs CG = 19.3% [29 episodes], $P = 0.360$) during the entire follow-up, yielding an annual AF incidence of 16.5%. Forty-four (58.6%) of the 65 episodes of AF occurred in the first six months after the inclusion, being 26 (72.3%) in the RG, and 18 (62.0%) in the CG, $P = 0.408$.

Table 1. Baseline Characteristics

	Total Population	Remote Group	Control Group	P Value*
Patients (n)	300	150	150	
Gender, n (%)				
Male	132 (44)	68 (45.3)	64 (42.6)	0.46
Female	168 (56)	82 (54.7)	86 (57.4)	
Age (years)	75.2 ± 7.9	75.6 ± 7.9	74.8 ± 7.8	0.44
BMI (kg/m ²)	26.0 ± 4.2	26.2 ± 4.2	25.7 ± 4.3	0.91
Type of procedure, n (%)				
First PPM implant	162 (54)	78 (52)	84 (56)	0.48
Device replacement	138 (46)	72 (48)	66 (44)	
PPM indication, n (%)				
SND	35 (11.7)	18 (10.3)	17 (11.3)	0.84
AV block	265 (88.3)	132 (89.7)	133 (88.7)	
Functional class (NYHA), n (%)				1.0
FC I	222 (74)	111 (74)	111 (74)	
FC II	78 (26)	39 (26)	39 (26)	
Cardiomyopathy, n (%)				
No heart disease	250 (83.3)	127 (84.6)	123 (82.0)	0.55
Ischemic	5 (1.6)	2 (1.3)	3 (2.0)	
Chagasic	24 (8.0)	10 (6.6)	14 (9.3)	
Congenital	1 (0.3)	0 (0)	1 (0.6)	
Hypertensive	18 (6.0)	10 (6.6)	8 (5.3)	
Valvular	2 (0.6)	1 (0.6)	1 (0.6)	
Echocardiogram	n = 258	n = 127	n = 131	
LA (mm)	39.7 ± 5.8	40.5 ± 6.0	38.9 ± 5.4	0.03
LVDd (mm)	50.8 ± 7.0	51.6 ± 7.1	50.1 ± 6.8	0.09
LVSd (mm)	35.3 ± 8.8	36.2 ± 8.9	34.3 ± 8.7	0.14
Diastolic dysfunction, n (%)	86 (33.3)	45 (35.4)	41 (31.3)	0.64
LVEF (%)	58.0 ± 13.6	57.8 ± 12.4	58.3 ± 12.9	0.77
LVEF ≤ 0.35	24 (9.3)	13 (10.2)	11 (8.4)	0.84
Comorbidity, n (%)				
Hypertension	285 (95)	139 (92.6)	146 (97.3)	0.11
Diabetes	88 (29.3)	36 (24)	52 (34.6)	0.06
Dyslipidemia	115 (38.3)	62 (40)	53 (37.1)	0.34
Hypothyroidism	29 (9.6)	13 (8.6)	16 (10.6)	0.55
History of stroke	07 (2.3)	06 (4.0)	01 (0.6)	0.12
CHADS ₂ score	1.8 (0.9)	1.8 (0.9)	1.8 (0.8)	1.0
CHADS ₂ score ≥ 2	184 (61.3)	89 (59.3)	95 (63.3)	0.09
Pharmacological therapy, n (%)				
ACE inhibitor or ARA2	203 (76.0)	119 (79.3)	121 (80.6)	0.19
β-Blocker	95 (35.5)	67 (44.6)	56 (37.3)	0.15
Diuretic	148 (55.4)	91 (60.6)	80 (53.3)	0.52
Statin	102 (38.2)	67 (40)	56 (36.3)	0.61
ASA	116 (43.4)	75 (50)	61 (40.6)	0.02

n = number; BMI = body mass index; PPM = permanent pacemaker; SND = sinus node disease; AV = atrioventricular; FC = functional class; NYHA = New York Heart Association; LA = left atrium; LVDd = left ventricle end-diastolic diameter; LVSd = left ventricle end-systolic diameter; LVEF = left ventricular ejection fraction; ACE = angiotensin converting enzyme; ARA2 = angiotensin two receptor antagonist; ASA = acetylsalicylic acid. The data are expressed as the means ± standard deviations or numbers (%).

* P value for chi-square or two-sample *t*-test when applicable.

The rate of AF recurrence was also similar between groups; 16% for the first (RG = 16.0% [24 episodes] vs CG = 16.0% [24 episodes], *P* = NS) and 8.3% for the second recurrence (RG = 8.0% [12 episodes] vs CG = 8.6% [13 episodes], *P* = 0.910).

The median time to detection the first AF episode was not different between RG and CG, 59, and 63 days, respectively, *P* = 0.200. However, it was significantly shorter in the RG to detection the first AF recurrence, 54 days for RG versus 100 days for CG, *P* = 0.004 (Fig. 2). Considering the median

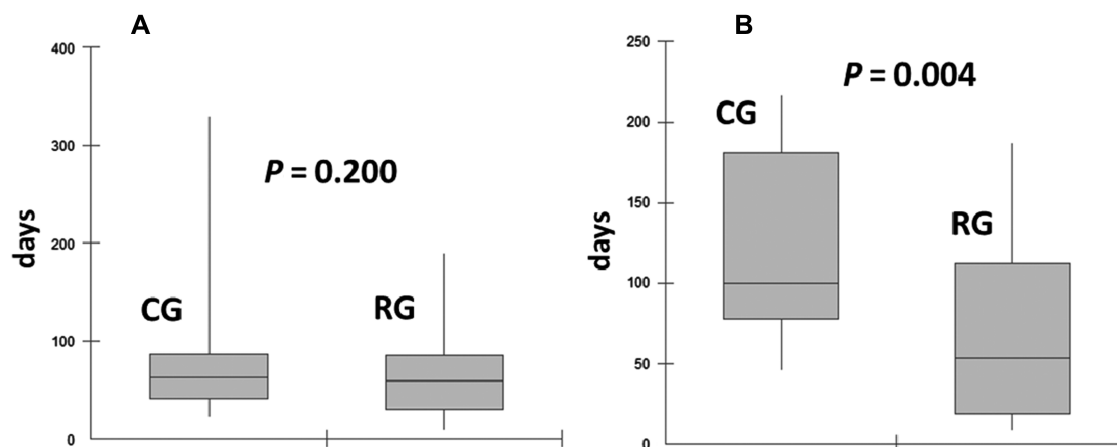


Figure 2. Comparison of the time to detect atrial fibrillation occurrence (A) and recurrences (B) between the two groups studied.

CG = control group; RG = remote group.

time to AF detection after the inclusion, it was 111 and 196 days for occurrence and recurrence, respectively ($P < 0.001$).

The average number of daily AF burden $\geq 10\%$ was 16.0 (95% confidence interval [CI]: 8.9 to 23.2) in the RG and 51.2 (95% CI: 21.9–81.9) in the CG, $P = 0.028$ (Fig. 3). The overall AF documentation by ECG was 7%, being 10% in the RG, and 4% in the CG ($P = 0.042$).

There were 12,738 AMS activations detected during the entire follow-up. Of 5681 stored IEGM, we excluded artifacts and high ventricular rate episodes and identified 1124 with specific AF characteristics, being 261 during at least two minutes. Criteria for true AF, including IEGM lasting two minutes or more and episodes higher than 250 beats per minute documented in AT histogram, were observed in 19 of 21 patients with AF documented by ECG (one underdiagnosed in each group), and in 44 of 179 patients without AF documented by ECG, yielding a sensibility and specificity of 90% and 84%, respectively (Fig. 4).

There was no difference in the average cumulative atrial pacing (AP) or ventricular pacing (VP) percentages between the groups (RG: AP = 31%; VP = 82%, and CG: AP = 33%; VP = 82%). It was possible to determine the right ventricle pacing site in 167 patients and there was no difference between the groups. Right ventricular apical pacing was performed in 55 patients in the RG and in 63 patients in the CG. Right ventricular outflow tract pacing was performed in 27 patients in the RG and in 22 patients in the CG.

The overall mean CHADS₂ score was 1.8 ± 0.9 and 61.3% of the patients had CHADS₂ scores ≥ 2 . There were eight patients with a history of prior stroke (RG = 7 and CG = 1) and stroke occurred in only one patient in the RG. Regarding antithrombotic therapy, acetylsalicylic acid (300 mg per day) was prescribed in 20 patients (RG = 14 vs CG = 6; $P = 0.027$), including eight patients with CHADS₂ scores < 2 and 12 patients with CHADS₂ score ≥ 2 , because warfarin was contraindicated. Warfarin was initiated in 28 patients (RG = 17 vs CG = 11; $P = \text{NS}$), but only 16 were still on warfarin therapy at the end of the study. The remaining 17 patients with AF did not receive antithrombotic therapy due to CHADS₂ scores < 2 or patient refusal. The occurrence rates of AF and drug therapy management (antiarrhythmic and antithrombotic) are shown in Table 2. Considering AF-related symptoms, only one patient in each group presented symptomatic AF.

On multivariate analysis, predictors of silent AF occurrence (Table 3) were left atrial diameter (Odds ratio, 1.20; 95% CI 1.10–1.30; $P < 0.001$) and presence of diastolic dysfunction (Odds ratio, 4.8; 95% CI 1.6–14.0; $P = 0.005$). Left atrial diameter above 39.5mm has sensitivity of 81.8% and specificity of 100% for silent AF occurrence.

DISCUSSION

Major findings of this randomized trial were that in elderly patients with a dual-chamber PPM, the

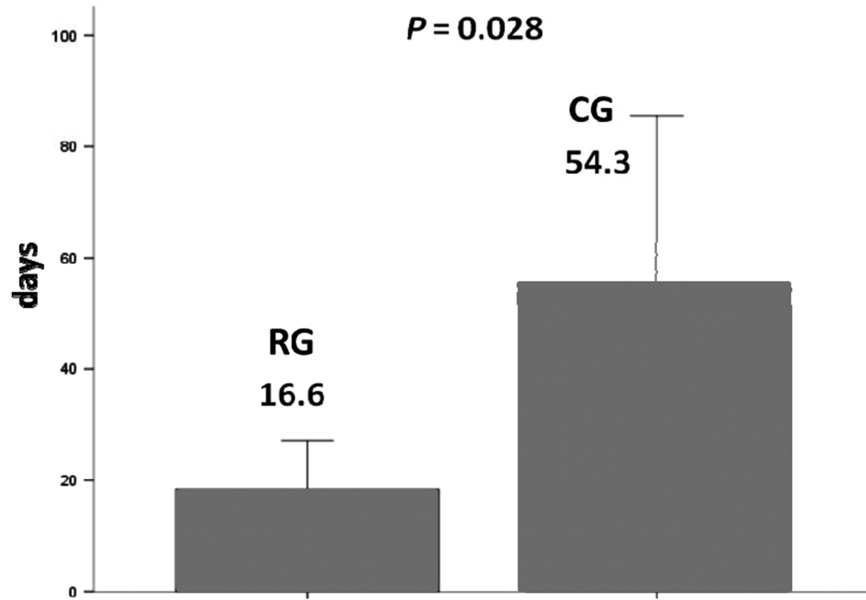


Figure 3. Comparison of the number of atrial fibrillation days between the two groups. There was an approximately three-fold reduction in the remote group (RG) compared to the control group (CG).

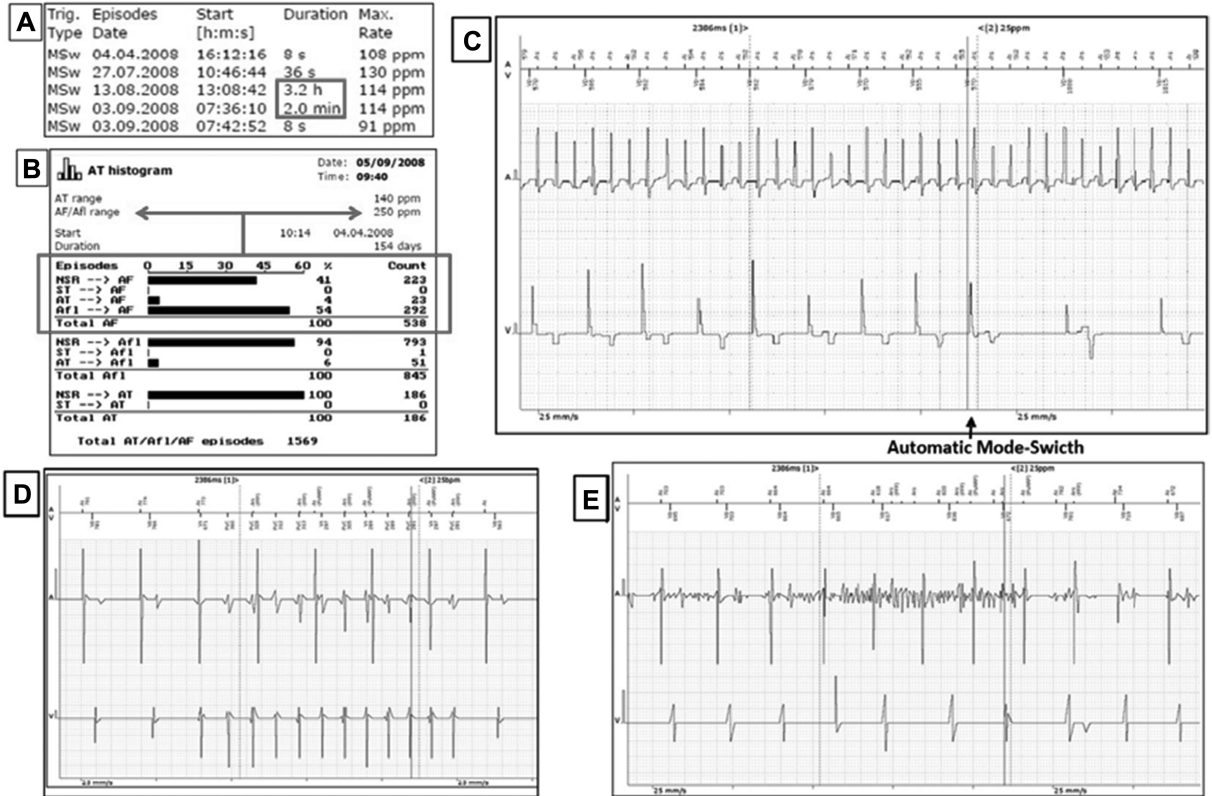


Figure 4. True AF criteria of stored data in pacemaker memory and reasons for inappropriate AHRE detections. (A) Stored IEGM during at least two minutes; (B) Atrial tachycardia histogram with AHRE higher than 250 ppm documented; (C) IEGM with AF characteristics; (D) High rate episode; and (E) Artifact.

Table 2. Occurrence of AF Documented by ECG and Atrial High-Rate Episodes Device-Detected, Including Antiarrhythmic and Antithrombotic Therapy

Type of Detection of AF	Total Population (n = 300)		Remote Group (n = 150)		Control Group (n = 150)		Odds Ratio for AF Occurrence	95% CI	P Value
	Number of Events (%)	Number of Events (%)	Number of Events (%)	Number of Events (%)					
AF documented by ECG	21 (7)	15 (10)	6 (4)	2.67	1.01-7.07	0.042			
AHREs device-detected	63 (21.0)	35 (23.3)	28 (18.7)	1.33	0.76-2.32	0.321			
AF management	Therapeutics options applied at least once during follow-up								
	N total (n = 65)	Remote group (36)	Control group (29)	Odds Ratio for AF management		95% CI		P Value	
Patients with AF		Number of patients (%)							
No therapy	17 (26.2)	5 (13.8)	12 (41.3)						
Amiodarone	14 (21.5)	8 (22.2)	6 (20.6)	1.34	0.45-3.97	0.593			
Antithrombotic therapy (ASA or warfarin)	48 (73.8)	31 (86.1)	17 (58.6)	2.53	1.26-5.08	0.008			
Electrical cardioversion	13 (20.0)	8 (22.2)	5 (17.2)	1.63	0.52-5.11	0.400			

Abbreviations: ASA = acetylsalicylic acid; ECG = electrocardiogram; AF = atrial fibrillation; AHREs = atrial high-rate episodes; CI = confidence interval.

Table 3. Multivariate Logistic Regression Model for Predictors of AF Occurrence

	Odds Ratio with 95%CI	P Value
Left atrium	1.20 (1.10 - 1.30)	<0.001
Diastolic dysfunction	4.80 (1.60 - 14.0)	0.005

AF = atrial fibrillation; CI = confidence interval.

time to AF occurrence did not differ between PRM versus a standard follow-up visits, while there was a difference for the recurrence time.

The lack of difference for the time to AF occurrence between RG and CG is likely related to the moment of the AF occurrence and the scheduled follow-up visits. Most of the first AF episodes (72.3% for the RG and 62.0% for the CG) occurred in the first six months of the inclusion, a period when the visits were more frequent in the CG (at least three visits). This is corroborated by the median time between the study inclusion and the first AF detection (111 days).

The median time to first AF recurrence was significantly shorter in the RG and the median time between the study inclusion and the first AF recurrence was 196 days, a period which reflects the biannual follow-up and the benefit of PRM system.

Another important finding of this study was the significant reduction in the number of days with AF burden $\geq 10\%$ in RG, probably due to standard therapy (AAD and electrical cardioversion procedure) anticipation. The number of AF days in patients with conventional follow-up was almost three times higher than the number of AF days in the RG. AF episodes with longer duration could represent an increased risk for thromboembolic events.¹⁶ Botto et al. showed that the higher the score CHADS₂ is, and the longer the AF duration, the greater the thromboembolic risk.¹⁷

Boriani et al.¹⁸ showed that AF burden was an independent predictor of ischemic stroke; moreover, among the thresholds of AF burden evaluated, one hour time was associated with the highest hazard ratio (2.11) for ischemic stroke.

The incidence of silent AF and the cutoff values of atrial rate and the episode duration varies widely among different studies. The reported annual incidence is 10-79% and the episode duration of AHREs varies from 20 seconds to 6 minutes.¹⁹ Furthermore, these episodes have

already been correlated to cardiovascular events in the studies ASSERT,²⁰ TRENDS,²¹ and MOST.²² PRM also allowed significantly higher proportion of patients who needed antithrombotic therapy for stroke prevention, based on CHADS₂ scores. The likelihood of using an antithrombotic therapy in the RG was 2.5 times higher than in the CG.

The incidence of AF in this population was high (21.6%), considering diagnoses based on PRM, AHREs device-detected, and episodes of AF documented by ECG. Considering only documented AF by ECG, which currently is the gold standard exam for AF diagnosis, AF incidence was 7.0%. The diagnostic capability of AF was significantly increased, due to continuous remote monitoring and stored data in PPM memory. Furthermore, the RG patients had an approximately threefold greater likelihood of having AF documentation by ECG. The earlier additional appointments motivated by AF alerts would facilitate the ECG documentation of paroxysmal AF episodes and IEGM correlation.

Ricci et al.²³ reported in the first clinical experience on AF detection by Home Monitoring system that 80% of the patients had relatively few (< 30) AF days which they defined as a mode-switch burden > 20% within 24 hours. Longer follow-up would miss AF episodes of spontaneous reversal to sinus rhythm due to priorities criteria of PPM memory and replacement of stored IEGM AF-related.

Orlov et al.²⁴ showed in the A-HIRATE study high AF incidence based on AHREs stored in the PPM of 427 elderly subjects. Patients without a history of AF showed an AF incidence of 46.2% over a follow-up of an average of two years. In our study, 80% of patients had AV block and patients with prior AF were excluded. These patients' characteristics explain the lower AF incidence in our study in comparison to A-HIRATE results, which had higher number of patients with sick sinus syndrome (45%). Considering this, we believe that the AF incidence found in our study is compatible with the real occurrence of this type of arrhythmia for the profile of the studied population.

Seidl et al.²⁵ demonstrated that appropriate device programming for atrial high-rate episodes allows for sensitivity and specificity of 98% and 100%, respectively, in the diagnosis of arrhythmia. In our study, we observed good sensitivity and specificity, being 90% and 84%, respectively, to make diagnosis of true AF using stored data in

a dual-chamber PPM memory with a cutoff of AHRE ≥ 2 minutes and ≥ 250 beats per minute documented in AT histogram and IEGM.

It is important to notice that not every AHREs documented by pacemaker is necessarily true AF. The false-positive detections can be found due to noise, R wave oversensing and repetitive non-reentrant V-A synchrony. Kaufman et al.,²⁶ in a recently published study, by using a cutoff of > 6 minutes and > 190 beats per minute, showed that the rate of false-positive AHREs is 17.3%, making physician review of IEGMs essential. For AHREs lasting >6 hours the rate of false positives is 3.3%, making physician review less crucial.

Another important finding of this study was that most patients with AF diagnoses were fully asymptomatic (99%). Stroke risk is not related to whether AF presentation is paroxysmal or permanent and most patients with paroxysmal AF had never reported typical clinical symptoms.²⁷⁻³¹

The ASSERT study,²⁰ which was designed to evaluate the occurrence of ischemic stroke in a large cohort of elderly patients with PPM or implantable cardioverter-defibrillators, showed an annual event rate of 3.78%. It was associated to the AF occurrence, detected only for three months after patients' inclusion and in CHADS₂ scores ≥ 2 .

Our study did not confirm data of ASSERT study,²⁰ but we demonstrated that the incidence of silent AF detected by the device was high in elderly patients with dual chamber PPM submitted to continuous heart rhythm monitoring, i.e., during day by day activities. Otherwise, most of patients included in this study presented CHADS₂ scores ≥ 2 , characterizing a population of moderate to high risk of stroke and emphasizing the relevance of PRM.

Ricci et al.³² using Monte Carlo methods, a special class of computer simulations, demonstrated that remote monitoring systems may reduce stroke risk by 9-18% if compared with standard in-person visits scheduled every 6-12 months, with an absolute reduction of 0.2-0.6%. In this study, the rate of stroke occurrence was very low and precluded a statistical analysis of this clinical event. Similarly, the benefit of PRM in total mortality might have been underestimated.

The role of antithrombotic therapy on silent AF is an unresolved question and studies addressing this subject are mandatory. Unfortunately we did not intent to address this topic in this study, mainly because the limited follow-up period and

because the low rate of thromboembolic events expected. In order to answer this question we are next to start the SILENT trial—Subclinical Atrial Fibrillation and Stroke Prevention Trial (<https://clinicaltrials.gov/ct2/show/NCT02004509>). This randomized study aims to assess the impact of antithrombotic therapy on silent AF, driven by findings of cardiac implantable electronic device (CIED) intensive monitoring, on the incidence of stroke and systemic embolism and correlate the AF episodes detected by CIED with thromboembolic events.

STUDY LIMITATIONS

The decision to analyze AF episodes of two minutes or higher may be a stringent criterion. This cutoff was chosen because in the first cases we observed a high rate of false positive findings in episodes lasting less than two minutes, mainly associated to the occurrence of noise, resulting in reduced sensibility. In addition, it was not possible to identify the right ventricular lead location in patients submitted to generator replacement, as the x-ray is not a routine exam for patients undergoing this procedure, in our institution. Our inability to ascertain stroke risk and mortality was due to the limited follow-up period and we are also unable to extrapolate our findings to elderly patients without PPM or to patients with left ventricular systolic dysfunction.

CONCLUSIONS

In the elderly population with a pacemaker of a tertiary hospital, the incidence of silent AF is high (16.5% per year). Higher left atrial diameter and presence of diastolic dysfunction were independent predictors of silent AF occurrence. Stored data in pacemaker memory is a valuable tool for prolonged ambulatory monitoring of AF detection in a conventional follow-up, and continuous remote monitoring of these data might ameliorate the management of AF therapy since it allowed for early AF recurrence detection and reduction in the number of days of AF.

Clinical Implications

The use of implantable devices with remote monitoring system would definitely help establish

the AF burden predictor of a higher risk of stroke. It would be especially useful for asymptomatic patients, in whom prognoses are unclear today. However, routine use of these devices in all patients has some difficulties, regarding economic and organizational issues, as well as of the patient's compliance matter. Analysis of PRM transmissions, in fact, has significant implications for the device clinic workflow, especially when the patient's compliance is poor as it may happen in elderly population.³³

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