Pacemaker Memory Data Compared to Twenty-Four-Hour Holter Monitoring in Patients with VVI Pacemakers and Chronic Atrial Fibrillation

Michał Chudzik, M.D., Ph.D.,* Jerzy Krzysztof Wranicz, M.D., Ph.D.,*
Iwona Cygankiewicz, M.D., Ph.D.,* Jan Henryk Goch, M.D., Ph.D.,*
and Włodzimierz Kargul, M.D., Ph.D.†

*Department of Cardiology, Medical University of Łódź, Poland and †Department of Electrophysiology, Silesian School of Medicine, Katowice, Poland

Background: In light of the results from the AFFIRM trial, the “rate control” strategy has become an accepted treatment modality for patients with atrial fibrillation (AF). Establishing effective rate control requires long-term monitoring of the heart rate. The aim of the study was to compare the heart rate and rhythm monitoring capabilities of the pacemaker memory data (PMD) algorithm and traditional twenty-four-hour Holter monitoring.

Methods: The study included 55 patients with chronic AF and a permanent VVI pacemaker. The mean and maximum heart rate as well as the percentage of sensed and paced events obtained from the twenty-four-hour Holter were compared with the results retrieved from PMD, started simultaneously. The study was performed over two consecutive days with pacemakers programmed in VVI 40 and 80 bpm mode.

Results: Data retrieved from PMD regarding percentage of sensed and paced episodes as well as mean heart rate strongly correlated with data obtained from twenty-four-hour Holter monitoring. The maximum heart rate reported by PMD was significantly higher than that found in the Holter.

Conclusions: PMD provides accurate information regarding long-term monitoring of heart rate in patients with AF who have an implanted permanent pacemaker and thus may facilitate optimized drug therapy to achieve rate control of AF.

A.N.E. 2005;10(3):348–355

Holter monitoring; VVI pacemaker; atrial fibrillation; pacemaker memory data

Atrial fibrillation (AF) is the most common arrhythmia seen in everyday clinical practice, and its incidence increases with age.^{1–2} Although the therapeutic choice of “rhythm versus rate control” remains open in light of the recent trials, the rate control strategy is considered the preferred method.³ Nevertheless, pharmacological treatment aimed at rate control does not always give us satisfactory results regarding reduction of rapid ventricular response episodes. Furthermore, pharmacotherapy is associated with adverse effects, including drug-induced bradycardia and/or pauses in the ventricle rate. Bradycardia-tachycardia syndrome is often an indication for permanent pacemaker implantation. In order to optimize drug therapy in AF, it is necessary to evaluate the heart rate, pay-

ing attention not only to the temporary heart rate recorded during a resting electrocardiogram (ECG) but also to the circadian pattern of heart rate during normal daily activity of patients. For years, twenty-four-hour ambulatory Holter monitoring (24 HM) has been considered the best method of assessing the efficacy of rate control in patients with chronic AF.⁴ However, the relatively short duration of this method is a disadvantage. Modern technology has introduced special heart rate monitoring algorithms into pacemaker devices, including some of the functions of traditional ambulatory Holter devices (pacemaker memory data [PMD]).^{5–15} Data regarding the mean and maximum heart rate as well as the number of episodes of rapid rate and the percentage of paced complexes may be stored in PMD and

include a period of up to several months. The longer recording time compared to traditional ambulatory monitoring is the major advantage of internal pacemaker Holter monitoring. There are limited data evaluating the accuracy of PMD as compared to ambulatory twenty-four-hour ECG monitoring.^{13,16–17} Therefore, the aim of this study was to compare mean and maximum heart rate as well as the percentage of sensed and paced events retrieved from PMD with the results obtained from traditional twenty-four-hour Holter monitoring in patients with chronic AF and permanent VVI pacemakers.

METHODS

Studied Population

The study population included 55 patients (28 males and 27 females) aged 52–86 years (mean 72 ± 7) with chronic AF (over a 6-month duration) who were implanted with an Actros S VVI pacemaker (BIOTRONIK, Germany) between 1998 and 2000. Detailed characteristics of the studied patients are shown in Table 1. In the majority of patients (64%), coexisting heart disease was present, with atrial hypertension and ischemic heart disease being the most frequent underlying condition (51% and 27%, respectively). Left ventricular ejection fraction assessed by echocardiography varied from 22% to 81% with a mean of 61%. Thirty-seven patients (42%) reported heart failure symptoms according to NYHA class I–IV, the majority of them in class II (18 pts or 33%).

In all cases, chronic AF with symptomatic pauses over 3 seconds during the daytime and/or 4 seconds at nighttime constituted indications for permanent pacing. All patients were implanted with

an Actros S ventricular pacemaker and with passive fixation Synox SX 60-BP endocardial bipolar leads (all BIOTRONIK).

Study Algorithm

Ambulatory twenty-four-hour Holter monitoring was performed 2–24 days after pacemaker implantation (mean: 8 days). All recordings were repeated over two consecutive days. During the first day of the study, the patients' pacemakers were set to 40 bpm in VVI mode with the aim of achieving intrinsic rhythm (AF) for a high percentage of patients with a small percentage of pacing. On the second day, the pacemakers were reprogrammed to VVI mode and 80 bpm. Collection of PMD was begun simultaneously with the start of ambulatory Holter monitoring.

Holter Recordings

Ambulatory ECG Holter recordings were taken by means of analog Oxford MR 45-4 recorders with pacemaker option using typical CS2, CM5, and IS leads; the recordings were analyzed using the Oxford Medilog Excel 2 system. Both automatic and manual analyses were performed. After editing and visual verification of recordings, the following parameters were assessed: percentage of native rhythm beats (Vs), percentage of paced beats (Vp), mean heart rate (av.HR), and maximum heart rate (max.HR). Manual verification of ECG data also included the analysis of fusion and pseudofusion beats. Fusion beats were determined when spikes did not change the T wave morphology in QRS complexes. Additionally, failure to sense and failure to pace episodes were assessed.

Diagnostic memory data collection of the BIOTRONIK pacemakers was begun simultaneously with the start of traditional Holter monitoring. Ventricular sense events (Vs) and ventricular paced events (Vp) were evaluated by means of an event counter. The event counter classifies fusion beats as paced beats. The mean and maximum heart rates were taken from printed activity reports. All results were retrieved from memory data during telemetry using the BIOTRONIK PMS 1000 programmer.

Statistics

Continuous variables are presented as mean $\pm$ SD. Data obtained from PMD were compared with

Table 1. Clinical Characteristics of Studied Patients

Clinical Characteristics	n = 55
Age (years)	52–86, mean 72 ± 7
Men	28 (51%)
Women	27 (49%)
Arterial hypertension	28 (51%)
Ischemic heart disease	15 (27%)
Prior myocardial infarction	9 (16%)
Valvular heart disease	6 (11%)
Dilated cardiomyopathy	5 (9%)
Heart failure symptoms	37 (42%)
Left ventricular ejection fraction (%)	22–81%, mean 61%

Table 2. Mean Values of the Percentage of Sensed and Paced Events, Mean Heart Rate, and Maximum Heart Rate Obtained by Means of Ambulatory Holter Monitoring and Pacemaker Memory Data

	24 HM	PMD	P Value
Day 1 (VVI 40 bpm)			
%Vs	89.8 ± 18	90.2 ± 17	NS
%Vp	10.2 ± 17	9.8 ± 17	NS
AvHR (bpm)	68.2 ± 12	67.8 ± 11	NS
Max. HR (bpm)	141 ± 28	181 ± 29	<0.05
Day 2 (VVI 80 bpm)			
%Vs	16.6 ± 19	16.3 ± 18	NS
%Vp	83.4 ± 19	83.7 ± 20	NS
AvHR (bpm)	83.3 ± 3	81.9 ± 3	NS
Max HR (bpm)	136 ± 27	186 ± 33	<0.05

%Vs = percentage of sensed beats; %Vp = percentage of paced beats; avHR = mean heart rate; MaxHR = maximum heart rate; 24 HM = ambulatory Holter monitoring; PMD = pacemaker memory data; NS = not significant.

data from ambulatory monitoring separately for day 1 (VVI 40 bpm) and day 2 (VVI 80 bpm). Comparison of mean heart rate, maximum heart rate, and Vs and Vp assessed by PMD and 24 HM was done using the Wilcoxon paired test. The correlation between results obtained from PMD and 24 HM was analyzed by means of the Spearman test. A P value < 0.05 was considered statistically significant.

RESULTS

Ambulatory Holter monitoring did not reveal any sensing and/or pacing disturbances in the studied group. Table 2 shows the percentage of Vs, Vp, mean and maximum heart rate obtained from PMD and 24 HM during day 1 (40 bpm) and day 2 (80 bpm). Not surprisingly, during 80 bpm pacing, a higher mean heart rate as well as a higher percentage of paced complexes were observed when compared to pacing at 40 bpm (Figs. 1A and B). No significant differences were observed among the percentage of Vs, percentage of Vp, and mean heart rate assessed by PMD and 24 HM (Figs. 1A and B). Regarding the percentage of Vs and Vp events, the data obtained from PMD highly correlated (r from 0.94 to 0.97, P value < 0.01) with the values retrieved from 24 HM both during day 1 and day 2 (Figs. 2A and B, Figs. 3A and B). The values of maximum heart rate assessed by PMD were significantly higher than those obtained by 24 HM both during day 1 (181 bpm vs 141 bpm) and day 2 (186 bpm vs 136 bpm) (P value < 0.01 in both cases) (Figs. 1A and B).

DISCUSSION

Since the early beginning, ambulatory Holter monitoring has been considered as a valuable tool for diagnosing arrhythmias and monitoring the efficacy and side effects of antiarrhythmic treatment.⁴ Its value in assessing the diagnosis of pacemaker function is also well established.¹⁸ Antiarrhythmic treatment in patients with AF who failed successful sinus rhythm restoration aims mainly to control fast heart rate episodes. However, there is also a group of patients who are refractory to antiarrhythmic therapy or those who suffer from side effects such as bradyarrhythmia. Therefore, sometimes permanent pacemakers need to be implanted due to bradycardia or as a part of an "ablate and pace" strategy.¹⁹ Careful estimation of heart rate in patients with AF should include long-term ECG recording. Ambulatory Holter recording generally allows us to estimate for 24- to 48-hours periods. Recently, Holter devices with a prolonged recording time (up to 7 days) were introduced. Nevertheless, these devices are not yet widely available in everyday clinical practice. Very often, to optimize antiarrhythmic therapy in patients with AF, Holter recordings need to be repeated, which is not only inconvenient for patients but also increases the costs of diagnosis and treatment. The relatively short recording time seems to be the main disadvantage of ambulatory Holter monitoring.

The first attempts to implement Holter-derived algorithms in pacemaker devices date back to the 1970s.⁵ The possibility of classifying complexes as intrinsic (sensed events) or stimulated (paced

VVI 40 bpm = ventricular pacing with 40 bpm; VVI 80 bpm = ventricular pacing with 80 bpm; %Vs = percentage of ventricular sensing event; %Vp = percentage of ventricular pacing event; HM = 24-hour Holter monitoring; PMD = pacemaker memory data

VVI 40 bpm = ventricular pacing with 40 bpm; VVI 80 bpm = ventricular pacing with 80 bpm; avHR = average heart rate; max HR = maximum heart rate; HM = 24-hour Holter monitoring; PMD = pacemaker memory data

Figure 1. Percentage of sensed and paced events (A), mean and maximum heart rate (B) obtained through pacemaker memory data (PMD) and ambulatory Holter monitoring (HM) during day 1 (VVI 40 bpm mode pacing) and day 2 (VVI 80 bpm pacing). VVI 40 bpm = ventricular pacing with 40 bpm; VVI 80 bpm = ventricular pacing with 80 bpm; %Vs = percentage of ventricular sensing event; %Vp = percentage of ventricular pacing event; HM = twenty-four-hour Holter monitoring; PMD = pacemaker memory data; avHR = average heart rate; max. HR = maximum heart rate; HM = twenty-four-hour Holter monitoring; PMD = pacemaker memory data.

events) was the first function introduced into pacemakers. Subsequent years of experience and the development of a pacemaker memory function resulted in more and more frequent and common utilization of internal Holter algorithms in pacemaker devices. The contemporary pacemaker is not only a pacing device but also a sophisticated diagnostic tool. The capacity of RAM memories in pacemakers is the main reason for limited Holter functions

in implanted devices. As a result of this limitation, ECG data are stored as events and not as full ECG strips. This method of data storage is much easier to achieve. A standard pacemaker is capable of storing all R-R cycles of the heart rate counted over a period of many years.⁶⁻¹⁵

Our study revealed a strong correlation between sensed and paced events assessed by automatic PMD and data from manually verified ECG strips

Figure 2. Correlation between the percentage of ventricular sensed events assessed by pacemaker memory data (PMD) and ambulatory Holter monitoring (HM) during day 1 (VVI 40 bpm mode pacing) (A) and day 2 (VVI 80 bpm mode pacing) (B). %Vs PMD = percentage of ventricular sense events in pacemaker memory data; %Vs HM = percentage of ventricular sense events in twenty-four-hour Holter monitoring.

from ambulatory Holter monitoring. The results were independently comparable to the predominant rhythm: intrinsic AF or pacemaker pacing (days 1 and 2). Similarly, no difference between the mean heart rate derived from PMD or 24 HM was observed. The maximum heart rate was the only parameter that differed between the results of PMD and 24 HM. Independent of the type of pacing (VVI 40 or VVI 80 bpm), the maximum heart rate obtained by internal Holter was higher than that assessed by ambulatory ECG monitoring. This

discrepancy results from the different algorithms used for calculating the maximum heart rate. The internal pacemaker Holter converts the minimum RR interval found in maximum heart rate, given in beats per minute, while the Oxford Holter averages three consecutive RR intervals to give a final maximum HR result. Therefore, not surprisingly, higher maximum heart rates will always be observed in PMD recordings.

There are limited data concerning the comparison of data retrieved from the internal pacemaker

%Vp PMD = percentage of ventricular pace events in pacemaker memory data;
%Vp HM = percentage of ventricular pace events in 24-hour Holter monitoring

%Vp PMD = percentage of ventricular pace events in pacemaker memory data;
%Vp HM = percentage of ventricular pace events in 24-hour Holter monitoring.

Figure 3. Correlation between the percentage of ventricular paced events assessed by pacemaker memory data (PMD) and ambulatory Holter monitoring (HM) during day 1 (VVI 40 bpm mode pacing) (A) and day 2 (VVI 80 bpm pacing) (B). %Vp PMD = percentage of ventricular pace events in pacemaker memory data; %Vp HM = percentage of ventricular pace events in twenty-four-hour Holter monitoring.

Holter and data obtained from ambulatory Holter monitoring. Our observations support the previously reported high correlation between results from PMD and ambulatory ECG monitor-

ing.^{13,16-17} Similar to the results published in these studies, we also observed that the percentage of paced and sensed episodes and mean heart rates obtained from PMD highly correlated (r between

0.94 and 0.97: P value < 0.001) with the results obtained after visual inspection of ECG strips. Nevertheless, Nowak²⁰ advise to remain critical regarding the capability of pacemaker algorithms to distinguish paced and sensed complexes.

The pacemaker event counter is not capable of distinguishing whether a beat recorded as a sense event is a real sense event or is it a consequence of oversensing episodes. These situations may occur during myopotential inhibition, far-field sensing, crosstalk, and/or the electromagnetic interference. Similarly, pace events recorded by the event counter may represent only a spike with no effective heart pacing.^{21–22} In our study, all patients were implanted with bipolar leads, with sensing set to bipolar configuration, which should decrease the possibility of oversensing events. This was confirmed by the results of ambulatory Holter monitoring, which did not reveal any episodes of oversensing or failure to capture after careful visual inspection of ECG strips.

A high correlation between the results obtained from PMD as compared to ambulatory Holter monitoring lead to the conclusion that we may rely on the internal pacemaker Holter for evaluating paced and sensed episodes and mean heart rate. Therefore, this method may serve the long-term monitoring of heart rate in patients with AF. This may facilitate the control of antiarrhythmic therapy in patients with AF and VVI pacemakers in everyday clinical practice. A long duration of heart rate control increases the sensitivity and specificity of rate control assessment. The most significant disadvantage of the internal Holter compared to a traditional Holter is the impossibility of storing and analyzing ECG strips. Nevertheless, continued technological development may result in a new generation of pacemakers with increased RAM memories that will be able to store ECG data as is the case with implantable cardioverter-defibrillator (ICD) devices.

Therefore, an internal Holter may not only provide us with information regarding device function but may also be essential for long-term monitoring of heart rate in patients with AF, thus possibly facilitating optimized drug therapy.

REFERENCES

1. Feinberg WM, Blackshear JL, Laupacis A, et al. Prevalence, age and gender of patients with atrial fibrillation: Analysis and implications. *Arch Intern Med* 1995;155:469–473.
2. Go AS, Hylek EM, Phillips KA, et al. Prevalence of diagnosed atrial fibrillation in adults. National implications for rhythm management and stroke prevention: The anticoagulation and risk factors in atrial fibrillation (ATRIA) study. *JAMA* 2001;285:2370–2375.
3. Wyse DG, Waldo AL, Di Marco JP, et al. The atrial fibrillation follow up investigation of rhythm management (AFFIRM) investigators. A comparison of rate control and rhythm control in patients with atrial fibrillation. *N Engl J Med* 2002;374:1825–1833.
4. Wijffels MC, Crijns HJ. Non-invasive characteristics of atrial fibrillation: The value of Holter recordings for the treatment of AF. *Card Electrophysiol Rev* 2002;6:233–238.
5. Attuel P, Mugica J, Buffet J. The diagnostic pacemaker. First European Symposium on Cardiac Pacing, London, 1978.
6. Pollak WM, Simmons JD, Interian A Jr, et al. Pacemaker diagnostics: A critical appraisal of current technology. *Pacing Clin Electrophysiol* 2003;26(pt1):76–98.
7. Hayes DL, Higano ST. Utility of rate histograms in programming and follow up of a DDDR pacemaker. *Mayo Clin Proc* 1989;64:495–502.
8. Levine PA. Holter and pacemaker diagnostics. In: Aubert AE, Ector H, Stroobandt R (eds.): *Cardiac Pacing and Electrophysiology: A Bridge to the 21st Century*. The Netherlands, Kluwer Academic Publisher, 1994, pp. 325–331.
9. Ripart A, Jacobson P. Memory technology and implantable Holter systems. In: Barold S, Mugica J (eds.): *The Third Decade of Cardiac Pacing*. Mount Kisco, NY, Futura Publishing Inc., 1982, pp. 353–364.
10. Cazeau S, Ritter P, Garrigue S, et al. Contemporary pacemaker memory systems. In: Barold S, Mugica J (eds.): *Recent Advances in Cardiac Pacing: Goals for the 21st Century*. Armonk, NY, Futura Publishing Inc., 1998, pp. 395–407.
11. Cazeau S, Ritter P, Nitzsche R, et al. Diagnosis of atrial arrhythmias using the Holter Function of a new DDD pacemaker. *Pacing Clin Electrophysiol* 2000;17:2106–2113.
12. Limousin M, Geroux L, Nitzsche R, et al. Value of automatic processing and reliability of stored data in an implanted pacemaker: Initial results in 59 patients. *Pacing Clin Electrophysiol* 1997;20:2893–2898.
13. Israel CW, Bockenforde JB. Pacemaker event counters: Possible sources of error in calculation of AV synchrony in VDD single lead systems as an example for present limitations. *Pacing Clin Electrophysiol* 1998;21:489–493.
14. Nowak B, Middeldorf T, Housworth CM, et al. Holter recordings with continuous marker annotation: A new tool in pacemaker diagnosis. *Pacing Clin Electrophysiol* 1996;19:1791–1795.
15. Begeman MSJ, Boute W. Heart rate monitoring in implanted pacemakers. *Pacing Clin Electrophysiol* 1988;11:1687–1692.
16. Ritter P, Cazeau S, Lazarus A. What can pacemakers tell us about atrial fibrillation? In: Murgatroyd F, Camm AJ (eds.): *Nonpharmacological Management of Atrial Fibrillation*. Armonk, NY, Futura Publishing Inc., 1997, pp. 319–337.
17. Wranicz JK, Chudzik M, Cygankiewicz I, et al. Comparison of pacemaker Biotronik Actros S memory data and 24 hour Holter monitoring. *Ann Noninvasive Electrocardiol* 2000;5:28 (abstract).
18. Kadish AH, Buxton AE, Kennedy HL, et al. ACC/AHA clinical competence statement on electrocardiography and ambulatory electrocardiography: A report of the ACC/AHA/ACP-ASIM task force on clinical competence (ACC/AHA Committee to develop a clinical competence statement on electrocardiography and ambulatory electrocardiography) endorsed by the International Society for Holter and Noninvasive electrocardiology. *Circulation* 2001;104:3169–3178.

19. Queiroga A, Marshall HJ, Clune M, et al. Ablate and pace revisited: Long term survival and predictors of permanent atrial fibrillation. *Heart* 2003;89:1035-1038.
20. Nowak B. Taking advantage of sophisticated pacemaker diagnostics. *Am J Cardiol* 1999;83:172D-179D.
21. Igdbashian D, Scalise T, Igdbashian S. Unipolar leads: Advantages and limits. *Mediterranean J Pacing Electrophysiol* 1999;1:215-254.
22. Wranicz JK, Chudzik M, Cygankiewicz I. Is Holter monitoring useful in patients with VVI pacemakers with bipolar leads? *Mediterranean J Pacing Electrophysiol* 2000;2:127.