ORIGINAL ARTICLE

Is the diagnostic function of pacemakers a reliable source of information about ventricular arrhythmias?

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Abstract

Background: *The aim of this study was to evaluate the reliability of pacemaker diagnostic function in diagnosing ventricular arrhythmias.*

Methods: *We compared the occurrence of ventricular ectopic beats in 51 simultaneous 24-hour electrocardiogram (ECG) recordings and pacemaker event counters printouts. The diagnostic function of a pacemaker allowed also for a qualitative assessment in 38 patients. In these cases, the occurrence of complex forms of ventricular arrhythmias was cross-checked for accelerated ventricular rhythms together with ventricular tachycardia, and triplets and couplets. The detection of at least one type of complex ventricular form of arrhythmia, diagnosed by both methods, was considered as an agreement between the methods.*

Results: *The results of ventricular ectopic beat counts differed significantly between the methods. In three (6%) patients, the results were consistent; in 20 (39%) the pacemaker underestimated results; in 28 (55%) they were overestimated. When more liberal criteria of agreement were applied, clinically significant differences were observed in 24 (47%) patients; in seven (29%) patients the count made by the pacemaker was lowered; and in 17 (71%) it was overestimated. Ventricular tachycardias were recorded in 24-hour ECG in eight patients. In three, they were identified by the pacemaker diagnostic function. In five, the pacemaker did not recognize tachycardia (because of its frequency being below 120/min). In nine, tachycardia was recognized falsely. The sensitivity in ventricular tachycardia diagnosis by pacemaker diagnostic function was 38%, specificity — 70%, the value of a positive result — 25%, negative — 81%.*

Conclusions: *The evaluation of ventricular arrhythmias by pacemaker cannot serve as the only reliable diagnostic method of arrhythmias. The presence of a large number of sequences that may correspond to ventricular arrhythmia or failure to sense, should result in verification via 24-hour ECG monitoring.* (Cardiol J 2010; 17, 5: 495–502)

Key words: pacemaker diagnostic functions, ventricular arrhythmias, 24-hour Holter ECG monitoring

Introduction

Pacemakers were introduced into clinical practice several decades ago, and are used in growing numbers of patients. Simple diagnostic functions have been available in pacemakers for about 20 years. So far, there have been few studies looking at the possibility of their use in clinical practice [1]. Almost all implanted pacemakers have Holter functions [2]. As they are an easy way to obtain interesting information such as statistics on the occurrence of ventricular ectopic beats, in the longer than one day time intervals, we are encouraged to use this option [3]. A longer observation time should increase the effectiveness of arrhythmia diagnosis. However, longer-term monitoring using pacemakers does not allow us to correlate symptoms with arrhythmia [3]. A correct interpretation of the data derived from classic pacemaker event counters requires thorough knowledge about the algorithm and function of the device. It is also important to determine the degree of data reliability compared to the 'gold standard' diagnostic 24-hour electrocardiogram (ECG) Holter monitoring [3].

Dual chamber pacemakers allow for assessing the diagnosis of arrhythmia. In different pacemaker models, we can estimate the number of ventricular ectopy (VE) events based on the information about the sequence of impulses. Some types of pacemaker have programs to assess ventricular arrhythmias including complex forms: couplets, triplets and tachycardia. In Biotronik pacemakers, this option is interchangeable with the function that evaluates the rhythm frequency trend. ELA Medical's and Medtronic's pacemakers can be a source of information about supraventricular arrhythmia. The groups of patients, described previously, have not been large (up to 60 patients). Most authors have emphasized the necessity of further studies [1, 4, 5] and simplification, along with improvement of the reliability of these functions [6].

The aim of our study was to evaluate the reliability of Biotronik pacemaker diagnostic functions in analyzing ventricular arrhythmias.

Methods

The study group consisted of 51 patients: 18 women and 33 men. The average age was 60.4 ± ± 13.6 years.

24-hour Holter ECG recordings were compared with printouts from the pacemaker, obtained at the same time. The pacemakers implanted in the patients of study group were Biotronik: Actros D — 31, Actros DR — 2, Actros SLR — 9, Kairos D — 2, Kairos DR — 3, Kairos SL — 1, Dromos DR — 2, Dromos SL — 1. They worked in the stimulation modes: DDD — 39 (including 6 DDDR), DDI — 2, VDD — 10 (including 1 VDDR).

Most comparison tests were performed in 75% (38 persons) of the patients more than 30 days after implantation.

24-hour ECG registrations were performed in patients with various clinical indications, such as control of antiarrhythmic therapy, evaluation of pacemaker function, and signs suggesting the presence of arrhythmias.

24-hour ECG recordings were carried out with Del-Mar analog and digital recorders with pacemaker option and were analyzed on computers adapted to the acquisition and analysis of pacemaker recordings. The ECG signal was recorded with a sample rate of 128 Hz, and resolution of 8 bits. After the introduction of recording to the central processing unit (analog-digital conversion), the option to evaluate the pacemaker was chosen. This option enables an assessment of two ECG channels and the channel with pacemaker pulse registration to be done. At the beginning of analysis, the mode of stimulation, basic rate cycle, hysteresis, atrio-ventricular delay (in the case of mode VDD and DDD), and upper rate are defined. More advanced pacemakers require individual manual assessment and cannot be analyzed fully automatically. The study recordings were analyzed prospectively using the superimposition function and assessment of the current RR interval trend (arrhythmiagraph). The analysis of the current RR interval trend checks the reliability of arrhythmia and stimulation evaluation. A prospective analysis of the superimposition function allows the specification of pseudofusion and fusion beats.

Part of stimulation disorders cannot be assessed automatically, because the system does not take into account the periods of atrial or ventricular lead refraction. For this reason, in some cases a precise quantitative assessment of stimulation abnormalities based on the automatic analysis is impossible. Then, in our department, pacing failures are defined as intermittent (up to 100 episodes per day) or frequent (more than 100 episodes per day).

The memory of the pacemaker diagnostic function was reset and the event counter was switched on simultaneously with the start of ECG registration.

Dual-chamber pacemakers distinguish the following impulse sequences:
— atrial sensed–ventricular sensed (As–Vs);
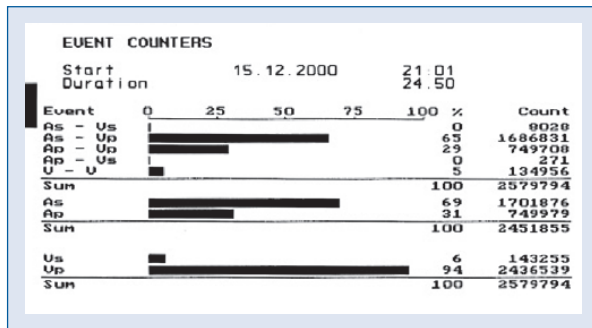— atrial sensed–ventricular paced (As–Vp);

Figure 1. Pacemaker printout of impulse sequences: 1 — atrial sensed–ventricular sensed (As–Vs); 2 — atrial paced–ventricular sensed (Ap–Vs); 3 — atrial paced––ventricular sensed (Ap–Vs); 4 — atrial paced–ventricular paced (Ap–Vp); 5 — ventricular sensed/paced–ventricular sensed (V–V) sequence represents two consecutive ventricular beats, not separated by atrial paced or sensed beats.

— atrial paced–ventricular sensed (Ap–Vs);
— atrial paced–ventricular paced (Ap–Vp).

A ventricular sensed/paced–ventricular sensed (V–V) sequence represents two consecutive ventricular beats, not separated by atrial paced or sensed beats (Fig. 1).

The sequences of two consecutive ventricular sensed impulses, not separated by paced or sensed atrial beats (V-V sequences) may reflect ectopic ventricular beats (VE), but they can also be due to sensing failure of atrial lead or supraventricular arrhythmia.

The diagnostic function of counting ventricular arrhythmias is available in Actros pacemakers [7]. It must be switched on with the programmer, and it is interchangeable with the rhythm trend and percentage of paced beats. This option provides information about the quantitative evaluation of ventricular arrhythmia assessment, and qualitative assessment within a specified period of time. The qualitative assessment includes the number of couplets, triplets, sequences from four to eight ventricular beats, and the sequence of more than eight beats. It also gives information about the shortest interval between two successive ventricular beats. However, this function has its limitations. The distance between successive ventricular beats to be counted as a couplet, triplet or sequence must be shorter than 500 ms, the pacemaker will not recognize the frequency of ventricular tachycardia of less than 120 bpm, or accelerated ventricular rhythms. It can also ignore irregular complex ventricular arrhythmias, such as a sequence of intervals 550, 520,

450, 520, 440 ms. If a consecutive ventricular beat occurs after a period of more than 500 ms, it will be ignored. The correctness of this function is also based on perfect atrial electrode sensing. Atrial undersensing results in counting sinus tachycardia or atrial fibrillation as false ventricular tachycardia.

The data from the pacemaker was printed out, at the end of ECG registration.

The ECG analysis was performed prospectively and interactively using the superimposition function and current trend of RR intervals. In the study we used 24-hour ECG registrations, which had less than one hour of artifacts. The person responsible for ECG analysis (M.K.) was blind to the assessment of arrhythmias made by the pacemaker diagnostic function. The data from the pacemakers was analyzed by a person expert in the field (E.K.).

The data was archived. ECG recordings were reanalyzed if the results of arrhythmia evaluation obtained by both methods differed significantly.

The number of ventricular ectopic beats was compared in 51 patients with dual-chamber pacemakers. In 38 subjects, when the function of counting complex forms of ventricular arrhythmias was on, the accordance of their occurrence was assessed. That is, the occurrence of triplets and couplets, and accelerated ventricular rhythms combined with ventricular tachycardias (VT) was evaluated. In 13 individuals, the number of ventricular beats was estimated on the basis of V-V sequences (ventricular sensed or paced-ventricular sense) because the counting algorithm was not turned on or there was no such option in the pacemaker (only quantitative assessment was possible) (Dromos type).

Since the quantitative differences in ventricular ectopic beats assessed by both methods were significant (Table 1), we adopted the quantitative analysis of compliance using more liberal criteria (Fig. 2). We assumed lack of agreement if the number of beats exceeded specified intervals depending on the number of impulses found during the analysis in 24-hour ECG. For example, if in 24-hour ECG 50 ventricular beats were present, lack of agreement was found when the diagnostic function recognized more than 500 impulses, or fewer than five. We used these criteria to see if the diagnostic function had any clinical value in estimating the number of ventricular beats.

The agreement was assumed in qualitative analyses of ventricular ectopic beats when at least one type of arrhythmia (couplet, triplet or VT) was recognized by both methods (e.g. one couplet recognized by ambulatory ECG and one by pacemaker

Table 1. Mean ventricular arrhythmia events in 24-hour Holter electrocardiogram (ECG) and printouts from pacemaker (PM) and mean differences between both methods, including standard deviation in whole group (51 subjects) and subgroup (38 subjects) with special option to count ventricular arrhythmia turned on.

Group studied	Mean ECG ± SD	Mean PM ± SD	Mean difference PM–ECG
N = 51	1382 ± 3436	2454 ± 9017	1072 ± 9058
N = 38	1495 ± 3749	1126 ± 2341	–368 ± 1997

Number of beats	Significant diferrences
10–50	> X 10 more or > X 10 less
51–100	> X 5 more or > X 5 less
101–300	> X 4 more or > X 4 less
> 300	> X 3 more or > X 3 less

Figure 2. Liberal criteria adopted to a quantitative analysis of compliance.

counter). The quality indices of diagnostic function were counted: sensitivity, specificity, positive predictive value, negative predictive value and total predictive value (accuracy) of the method.

The study was approved by the local bioethical committee and all patients gave their informed consent.

Results

A quantitative comparison of the presence of ventricular arrhythmias was performed in 51 patients with dual chamber pacemakers. In 13, the number of ventricular beats was estimated based on the V-V sequence.

Ventricular beats from one to 19,294 were recorded in 44 patients in 24-hour ECG monitoring. In 24-hour simultaneous printouts derived from the pacemakers there were between three and 63,214 ventricular beats in 47 patients.

The results were fully consistent in three (6%) patients; in 20 (39%) the pacemaker underestimated results; in 28 (55%) it overestimated. In accordance with the liberal criteria, clinically significant differences were observed in 24 (47%) patients, including seven (29%) where pacemaker counts were underestimated, and 17 (71%) where they were overestimated. In clinically significant differences, the number of ventricular beats tended to be overestimated by the pacemaker counter.

In the evaluation of complex forms, ventricular couplets were recorded in 24-hour ECG in 18 patients. In 15, they were identified by the pacemaker diagnostic function (agreement in the couplets count occurred in one patient). In three, the pacemaker did not recognize couplets; in seven, it recognized their presence falsely.

Triplets were recorded in 24-hour ECG in seven patients. In four, they were identified by the diagnostic function. In three cases, the pacemaker did not recognize triplets; in nine patients, their presence was recognized falsely.

Ventricular tachycardias were recorded in 24-hour ECG in eight patients. In three, they were identified by the pacemaker diagnostic function. In five, the pacemaker did not recognize tachycardia; in nine patients, their presence was recognized falsely (Table 2).

The table presents the evaluation of sensitivity, specificity, positive predictive value, negative predictive value and total predictive value (accuracy) of the method. We note the low value of a positive predictive value of ventricular tachycardia diagnosis at only 25%.

In 19 (37%) study group patients, pacing disorders were diagnosed. In five (10%) patients, they were numerous or clinically significant. However,

Table 2. Sensitivity, specificity and diagnostic value of complex arrhythmia diagnosed by pacemaker.

Results	Tp	Fn	Fp	Tn	TPV	PPV	NPV	SE	SP
Couplets	15	3	7	13	74%	68%	81%	83%	65%
Triplets	4	3	9	22	68%	31%	88%	57%	71%
VT	3	5	9	21	63%	25%	81%	38%	70%

VT — ventricular tachycardia; Tp — true positive (consistent); Fn — false negative; Fp — false positive; Tn — true negative; TPV — total predictive value (accuracy); PPV — positive predictive value; NPV — negative predictive value; SE — sensitivity of pacemaker diagnosis; SP — specificity

Table 3. Patient with false positive ventricular tachycardia diagnosed by pacemaker diagnostic function.

Initials	Days (D)/months (M) from implantation	Pacing disturbances found in Holter ECG	Other arrythmia	Percentage of paced beats	Max HR Holter ECG
W.M.	4 M	None	None	2%	147/min
G.M.	1 M	None	None	75%	115/min
S.A.	8 M	None	AF/T	8%	157/min
J.R.	4 D	None	None	98%	122/min
R.K.	3 M	Intermittent failure to sense	SVT	87%	109/min
J.M.	2 M	None	None	16%	122/min
J.K.	1 M	Intermittent failure to sense	None	92%	130/min
D.J.	10 D	Frequent failure to sense	AF	100%	100/min
J.M.	4 M	None	SVT	56%	85/min

D — days; M — months; AF/T — atrial flutter; AF — atrial fibrillation; SVT — supraventricular tachycardia; max HR — maximum heart rate

the diagnosis of complex ventricular arrhythmias was not more accurate in patients with accurate pacing in ECG monitoring. Paradoxically, the group without pacing failures presented with more clinically significant quantitative differences. Numerous sensing failures occurred in three patients with VDD pacemakers and in two of the DDD. Fairly short time after pacemaker implantation till ECG monitoring (from three to 16 days) drawn our attention in four out five patients with numerous stimulation disorders.

Pacemaker diagnosis of complex ventricular arrhythmias was not associated with the presence of pacing failures. In the group with VT false positive detection, in four out of nine we found episodes of atrial fibrillation, flutter or supraventricular tachycardia in 24-hour ambulatory ECG; in six out of nine, the paced rhythm was less than 90% of the recording, (so pacing failures could not be detected while a patient was in sinus rhythm). Failure to sense and supraventricular tachycardias could be potential causes of false VT detection (Table 3).

In the group of undetected VTs, their frequency was less than 120 bpm, which means they were not detected because of the pacemaker algorithm that could detect only sequences faster than 120 bpm.

Discussion

The clinical value of the pacemaker diagnostic function evaluating the occurrence of ventricular arrhythmias has not been the subject of many studies.

Lascault et al. [8] were among the first to describe a case where the pacemaker diagnostic function made it possible to make a diagnosis of recurrent slow VTs as the cause of tachyarrythmic cardiomyopathy. This function was used, however, complementary to the traditional 24-hour ECG monitoring. Yet, diagnosing ventricular arrhythmias with the use of the pacemaker diagnostic functions has not been of great interest since then. The reliability of these functions was assessed in papers devoted to the diagnosis of supraventricular arrhythmias by pacemakers [9, 10]. In his work, Mabo et al. [10] analyzed the recognition of supraventricular and ventricular arrhythmias in 28 patients with Pulsar Max (Guidant) pacemakers, not only with the automatic diagnostic function, but also with the use of intracardiac electrogram (IECG). The total respective sensitivity and specificity of diagnosis of (both ventricular and supraventricular) arrhythmias by pacemaker was 75.5% and 87.5%. The sensitivity increased with the use of IECG, reaching 80%. The pacemaker reader gave two false positive results in VT assessment and two false negative; only one result was consistent. False positive results were due to the reading of sinus tachycardia as ventricular tachycardia — P wave was not detected because it occurred in the refraction time of the atrial electrode (PVARP, post ventricular atrial refractory period). This fact was confirmed by IECG.

The study sponsored by Medtronic stated that the use of the pacemaker diagnostic function enhanced the ability to detect arrhythmias. The study was conducted on 315 patients [9].

Also 57.8% of ventricular ectopic beats were incorrectly diagnosed in 20 patients examined in a trial investigating the usefulness of a new device with continuous maker annotations of pacemaker discharge directly from the device to conventional ECG monitoring. They were classified as conducted or fusion beats [11].

There have been no publications evaluating the reliability of assessing ventricular arrhythmias in the diagnostic functions of the Biotronik pacemakers. Our study showed large discrepancies between

the results of evaluation of ventricular arrhythmias between the two methods. Despite fairly liberal compatibility criteria, clinically significant differences in the quantitative assessment were found in almost 50% of patients. Also, qualitative assessment has proved fraught, with a high percentage of both false positive and false negative diagnoses. For example, the positive predictive value of at least one triplet or VT did not exceed 30%. It is important to say that such a result was not affected by the occurrence of stimulation disorders in 24-hour ECG Holter monitoring. Together, these results may raise serious questions about the desirability of using the pacemaker diagnostic function in clinical practice.

The discrepancies mentioned above may have multiple causes.

Firstly, the mechanism of recognizing complex ventricular arrhythmias in the pacemakers studied is imperfect. The pacemaker treats as multiple beats only those forms the interval between which is less than 500 ms. Otherwise, beats are ignored [7]. Therefore it ignores accelerated ventricular rhythms and VT of 100–120 bpm frequency. The fact was probably the cause of false negative diagnosis. Unfortunately, it is impossible to change parameter settings of ventricular arrhythmia identification.

Secondly, atrial sensing disorders or lack of P-wave detection in PVARP in a properly functioning pacemaker can lead to counting sinus tachycardia as false VTs. We cannot prove the existence of such disorders in 24-hour ECG monitoring, if the pacemaker pacing rate is relatively low and patient is in sinus rhythm throughout the monitoring. This phenomenon can be excluded by comparing the maximum frequency registered in 24-hour ECG. This was one of the possible causes of the false positives results.

Thirdly, the pacemaker can count, in the manner described above, fast atrial fibrillation episodes.

Stimulation disturbances are not uncommon and include those in unselected groups of patients [12–14]. They are reported to occur in as many as 60% of asymptomatic patients. Patients who had false positive results in the assessment of VT had also a fairly large percentage of sinus rhythm. Sensing disturbances during episodes of own rhythm faster than the pacemaker settings (pacemaker does not have to pace), may remain undetected in 24-hour ECG monitoring.

There are attempts to use printouts from pacemaker and event counters to assess atrio-ventricular synchronization. Israel and Boeckenfoerde [15]

described the inaccuracy which this method of control can cause. You cannot distinguish whether the lack of atrio-ventricular synchronization is due to sensing disorders of atrial electrode stand, whether it is caused by sinus bradycardia, or 'sensor override' in pacemakers with R function. The pacemaker does not distinguish between impulses originating from ventricle from atrial failure to sense and sinus beat. Regardless of the method of quantification, when the patient's own rhythm is above upper tracking limit, even with perfect sensing, the results of the event counter will not be correct, because the patient's own atrial agitations are found in PVARP and 'functional'" undersensing will be observed. Episodes of sinus rhythm above the upper tracking rate are counted as VT. Data obtained directly from the pacemaker is only part of the information necessary for full control of the pacemaker [15]. These considerations indirectly explain failures in the diagnosis of ventricular arrhythmias.

Rare, clinically insignificant, often difficult to repair, failure to sense can potentially change the outcome of the pacemaker evaluation of ventricular arrhythmia [14].

However, it is difficult to explain that good agreement in the assessment of ventricular arrhythmias in one patient with VDD pacemaker with total loss of atrial sensing. Such compliance should be regarded as accidental.

Paradoxically, more clinically relevant differences were observed in patients without stimulation disturbances registered in 24-hour ECG.

There is a warning in the pacemaker instruction manuals about the influence of pacing disorders on the outcome of arrhythmia analysis [7]. There is also a description of the algorithm counting complex ventricular arrhythmia and its limitations. However, lack of such warnings in pacemaker printouts can lead to printouts being treated as 24-hour ECG monitoring results. This may cause important diagnostic errors. Most stimulation disorders, like sensing disturbances, do not usually cause symptoms. They are often also few or clinically insignificant and there is no need to reprogram the pacemaker. Therefore, we cannot expect the sensing and pacing to be always perfect. This in turn means that algorithm evaluating ventricular arrhythmias will not be a reliable tool without the possibility to review IECG. Their reading requires confirmation of a 24-hour Holter ECG.

The trial sponsored by Medtronic studied the usefulness of the diagnostic features of: Kappa and Thera pacemakers, in detecting supraventricular and ventricular arrhythmias. The authors demon-

strated that the use of diagnostic features in the study group (166 patients) significantly increased the detection of new supraventricular arrhythmias, yet did not increase the detection of ventricular arrhythmias. The reliability was not verified, and comparison with 24-hour ECG monitoring was not performed. The aim of the study was only a general problem:how the use of diagnostic function may be clinically helpful [9]. British authors, Waktare et al. [2], in their review paper of various diagnostic programs, also emphasized that the pacemaker Holter function cannot distinguish whether counted beats are properly paced beats and the patient's own beats, or if there is 'crosstalk', counting of muscle potentials, or the electrode is damaged. Such technical problems are partly reduced by the optimal blanking period and bipolar electrode settings. The authors emphasize that the use of the pacemaker diagnostic function must always take into account the clinical context [2].

Some pacemakers such as Kappa (Medtronic) have the option of being activated by the patient, allowing for the registration of IECG. The pacemaker saves three minutes before and two minutes of event annotations, and 11 s of ECG, after being activated by a small external device. This option may improve the sensitivity of arrhythmia recognition [10].

It should be noted that IECG does not always allow a clear distinction between supraventricular and ventricular arrhythmias. Such problems occur in 5–10% of records [2]. The opportunity to review IECG recordings can improve the reliability of the diagnostic features [16]. Especially, the addition of annotations of paced beats to the IECG facilitates the identification and stimulation disturbances or arrhythmia [17]. In one study, 69% of incorrect pacemaker Holter function diagnoses were verified by IECG [18].

Limitations of the study

There are a few limitations of the study.

Only a few patients presented with complex ventricular arrhythmias, but the great divergence of results obtained by both methods cannot be accidental.

On the one hand, a random selection of patients without prior examination of the pacemaker parameters can be considered as limiting the work. On the other hand, it allows the assessment of unselected, average population of paced patients.

The study evaluated only the diagnostic functions in the older generation of pacemakers produced by one company. The results should not be simply extrapolated to pacemakers manufactured by other companies, nor to new generations of Biotronik pacemakers.

Conclusions

The results obtained using the diagnostic pacemaker Holter function should be treated with caution. Their interpretation must take into account the clinical data, and the person using the printout should be well familiar with the algorithm of the equipment and its limitations.

The Holter function evaluating ventricular arrhythmias in Biotronik pacemakers cannot serve as the only reliable diagnostic method. The presence of a large number of sequences that may correspond to ventricular rhythm disturbance or sensing disturbance should be verified by 24-hour ECG monitoring.

At present, the diagnostic pacemaker functions cannot replace 24-hour Holter ECG monitoring in the accurate assessment of ventricular arrhythmias. They can though be used as a complementary method.

Large discrepancies in the assessment of ventricular arrhythmias are probably due to pacemaker algorithm limitations, atrial sensing failures, and counting supraventricular tachycardia and sinus arrhythmia as ventricular tachycardia.

As far as we are concerned, the evaluation of ventricular arrhythmia by the pacemaker diagnostic function needs a further multicenter study, which should include patients with new, more sophisticated pacemakers, where the diagnosis can be checked with intracardiac ECG.

Acknowledgements

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