Simplifying Pacemaker Follow-Up Using Automatic Threshold Determination in Ventricle

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Summary

In this study, the reliability and the usefulness of an automatic threshold testing feature in the DDD pacemaker is evaluated. The test algorithm recognizes capture by means of the morphology of the ventricular evoked response (VER). For detecting this intracardial signal reliably and free of disturbances, fractal coated electrodes were used. Pacing thresholds in 28 patients were determined automatically at different pulse widths and compared with the values received manually. It could be shown that in 73.8% the two values were equal, in 21.8% a difference of ± 0.1 V and in 4.4% a difference of ± 0.2 V was detected. With these results, the functionality of this test is confirmed and guarantees appropriate ventricular pacing threshold measurement with very good accuracy.

Key Words

Automatic ventricular threshold test, ventricular evoked response (VER)

Introduction

One of the most important PM programmable parameters is ventricle pulse amplitude. For its appropriate programming, a telemetrical measurement of ventricular pacing threshold is necessary. Most of the currently manufactured PMs have the possibility of measuring the ventricle pacing threshold by manually decreasing the pulse amplitude and/or width. The other PMs dispose by semiautomatic threshold tests, but surface ECG monitoring is necessary. The following study evaluates the automatic ventricle pacing threshold test performed during patient follow-up procedures. Its accuracy is compared intraindividually with standard manual ventricle pacing threshold test by the same DDD pacemaker.

Methods

The Logos pacemaker and bipolar fractal coated electrodes, atrial SX-JBP (26 times) and TIJ-BP (2 times) and ventricular SX-BP (26 times) and TIR-BP (2 times) (all Biotronik, Germany) were implanted to 28 patients (17 female, 11 male), between January 1997 and December 1998. Standard follow-up procedures like P/R amplitude and lead impedance measurements were performed. The stimulation threshold tests with a pulse width of 0.3, 0.4 and 0.5 ms for manual and automatic configuration were performed during every follow-up. The first standard follow-up was carried out six weeks after implantation and the second six weeks after the initial follow-up. The data pool was not fully completed due to various reasons. One patient only passed the first follow-up. Another patient died after the first follow-up. His death was not in connection with pacing. There were quite often technical problems with starting the autothreshold test at 0.5 ms (six times the test was not performed).

It was not possible to determine the pacing threshold in six patients, presumably due to frequent ventricular premature beats. In all pacemakers unipolar pacing and bipolar sensing were programmed in atrium and ventricle.

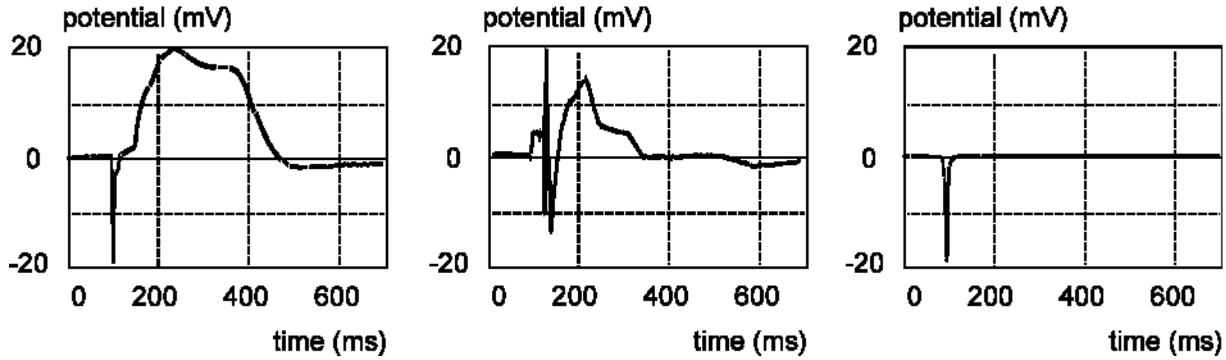

Figure 1. Reaction to a pacing pulse: a) effective stimulation, ventricular evoked response (left); b) fusion beat (middle); c) ineffective stimulation (right).

Threshold testing algorithm

Every automatic testing algorithm must take special care of patient safety as immediate physician intervention is not always guaranteed. This requirement is fulfilled in the algorithm under investigation. When the test is started, the pacemaker switches to the V00-mode with a standard rate of 100 bpm (programming is possible). The amplitude is reduced by a half in every fourth pulse. This procedure is continued until capture is recognized in the morphology of the VER. If the VER signal is missing - non capture (see Figure 1 b, c) the algorithm increases the amplitude to half the value between capture and non-capture. If capture is detected now, the amplitude is decreased again, and so on. In case of ineffective pacing the next three stimuli of save value are emitted for patient's safety. The behavior of the algorithm is illustrated in Figure 2.

The manual threshold test is carried out in 0.1 V steps during a temporary programming. After removing the programming head, the pacemaker returns to the permanent program. The physician decides by means of surface ECG monitoring about the pacing threshold.

Results

Effective and safe threshold measurement with the automatic test could be demonstrated in all 28 patients during two follow-up procedures. Each measurement took about 12 s. P/R waves and lead impedances have been in appropriate values in all patients.

The threshold values for pulse widths of 0.3, 0.4 and 0.5 ms for the automatic and manual threshold tests were evaluated. Subjective difficulties during automatic test have not been felt by any patient.

The results are shown in Figure 3, where the chronaxie-rheobase-function (CRF) is recognizable both in manual and in automatic test configuration. This means that the pacing threshold decreases with longer pacing pulses.

To show equality between both tests, the differences between the manual and the automatic threshold values of the corresponding pulse width and the same follow-up were compared. Thus, the differences of the 156 paired values were calculated (manual vs. automatic threshold tests). In 115 cases (73.8%) the two values were equal, in 34 (21.8%) cases a difference of ± 0.1 V and in seven (4.4%) cases a difference of ± 0.2 V was detected. These calculations show that 149 (95.5%) differences are within one programming step (± 0.1 V).

To be able to apply an appropriate statistical test, which confirms the hypothesis that manual and automatic threshold testing come from equal distributions (error probability α = 5%) we must know, whether or not the data belongs to a standard distribution. The Kolmogorov-Smirnov-Test shows that the measure-

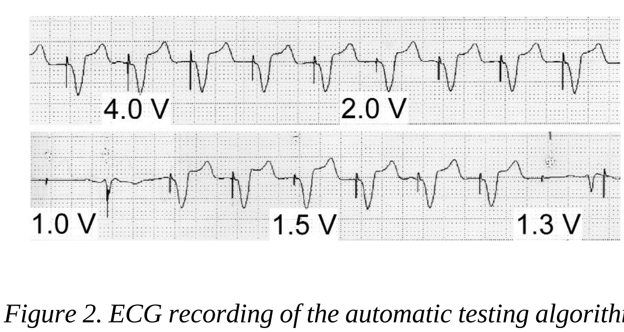

Figure 2. ECG recording of the automatic testing algorithm. The pulse ampltude is decreased every fourth beat by the half, if capture is detected. The three beats in between are at save value (4 V).

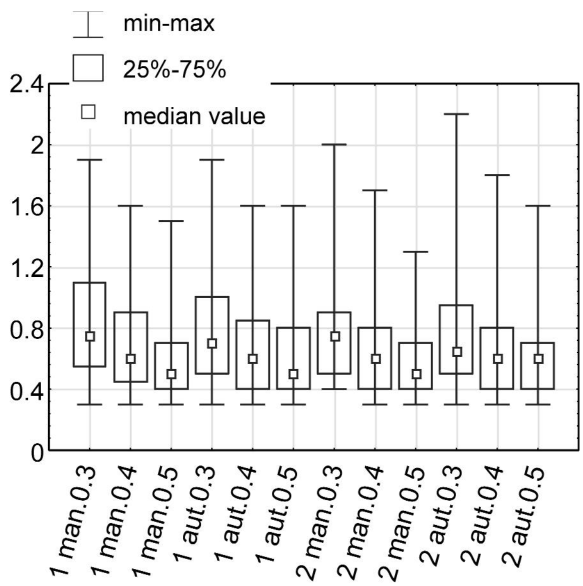

Figure 3. Boxplot of the threshold values, displayed are all available results. First figure means the number of follow-up procedure, then manual or automatic testing configuration, last pulse length.

ments of each pulse length (manual and automatic) does not fulfil the requirements of the distribution (error probability α = 5%) [1][2].

With this result, we know that it would be inappropriate to state a mean value and a standard deviation for each pulse width and testing configuration. More meaningful statistical information is included in the boxplots of the measured data (see Figure 3). Therefore, a non-parametrical statistical test like the Wilcoxon signed rank test for ordered categorical data is applied. The results of the statistical test are shown in Table 1.

Discussion

One aspect in the evolution of PMs is the development and the improvement of programmability and automatic functions. The idea behind this is to increase user-friendliness and reliability. This should go together with a reduction of time-consuming follow-up procedures and, with technical simplification bringing benefits for patient and physician.

One prominent example in the field of electrotherapy of the heart was the on-going development of the initialization in rate responsive pacemaker systems [3][4]. Another, perhaps even more impressive example which

compared data	N	Z	p
1 man.0.3 & 1 aut.0.3	28	2.31	0.02
1 man.0.4 & 1 aut.0.4	28	0.13	0.89
1 man.0.5 & 1 aut.0.5	27	1.26	0.21
2 man.0.3 & 2 aut.0.3	26	0.07	0.94
2 man.0.4 & 2 aut.0.4	26	1.48	0.14
2 man.0.5 & 2 aut.0.5	21	0.94	0.35

Table 1. Results of the Wilcoxon signed rank test, comparison of the values derived with manual and automatic testing configuration. N: number of valid outcomes for manual and automatic test. z: standardized value, computed from the observed number of cases where threshold manual > automatic. See Figure 3 for more legends.

is realized in DDD(R) mode in case of atrial tachyarrhythmias, is the automatic mode switching or mode conversion function [5][6][7]. However, the development of automation of the main pacing parameters like automatic adjustment of the pulse amplitude, the A-V period, protection algorithms against endless loop tachycardia, should not go ahead with a loss of serviceability, as easy handling is an important point for many physicians [8][9][10]. The programming of advanced PMs must be easy for non-experiened or infrequent users. Nevertheless, it is reported that about 80% of the implanted PMs remain at default settings for the whole service life, presumably because many clinicians are not familiar with the technology or do not have time to perform the PM follow-up properly [11].

Threshold tests have been considered to be important in the variety of programmable possibilities since stimulation energy can be saved and the PM life service prolonged [12]. The main principle of the ventricular pacing threshold tests is the patient's safety. Patients could live with an sub-optimal rate response, although under restricted conditions. But they could even die with sub-threshold pacing in ventricles.

In this study, a simple automatic stimulation threshold test in a specially configured PM is reported on. This feature was evaluated in this article and furthermore, the results are compared intra-individually with values of the corresponding manual test. It is evaluated in this investigation, whether the manual and the automatic threshold tests show equal threshold values.

Unlike many other test of this kind, this one is fully automatic and does not depend on surface electrocardiogram (ECG) monitoring. The VER results from the heart's electrical reaction to every effective ventricular pacing pulse. It is based upon the action potentials of the myocardial cells and reflects the electrophysiological state, as well as the course of excitation in the myocardium. The use of the VER to detect capture requires artifact-free signals and the exclusion of fusion beats as the morphology of paced events differs in comparison to other events (see Figure 1). Fractal coated PM electrodes which exhibit low pacing threshold values and excellent sensing properties are required. With these sophisticated electrodes, the signal is derived in a unipolar fashion between the lead tip and the pacemaker case. Long term stability of signal morphology was evidenced in previous studies [13][14].

In general, the two compared methods of manual and automatic threshold tests show a quite good relation. This was possible due to the use of fractal coated electrodes, with which even at a high impedance VER monitoring is feasible. With this feature, a further function is available which makes pacemaker programming easier for the physician and safer for the patient. A further step could be the implementation of an automatic CRF-test, which would determine the optimal pulse amplitude and width.

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