Reliability of Determining Ventricular Pacing Threshold by a Purely Automatic Method Using the Ventricular Evoked Response Signal

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Summary

Continuous monitoring of the ventricular evoked response (VER) signal has been used to determine the effectiveness of the ventricular pacing output. Non detection of the VER is considered to be capture failure and results in increase of the pacing output. A further application of this concept has been used recently in a multiprogrammable dual chamber pacemaker LOGOS DDDC in conjunction with the Programmer PMS1000 (all Biotronik, Germany) to determine the ventricular pacing threshold (VPT) by a purely automatic method during follow-up. The algorithm has been tested in 10 patients (4 male, 6 female, 67-84 years) 6 months after implantation and compared to manual threshold test. In all patients a bipolar low polarization lead (SYNOX SX 60BP, Biotronik) was implanted. Statistical analysis of the 2 methods shows a strong correlation between both methods (0.9971 Pearson Correlation Coefficient). Although the number of patients is small, the automatic method seems to be very reliable.

Key Words

Ventricular evoked response, fractally coated low polarization bipolar lead, automatic threshold test

Introduction

Pacing threshold can be determined either manually or by a semi automatic method e.g. using an appropriate pacemaker programmer like the PMS1000 (Biotronik, Germany). In either case the ECG or endocavitary signals (intracardiac electrocardiogram, IEGM) has to be particularly analyzed to determine whether the pacing spike still depolarizes the myocardium or not. Recently two different pacing devices use the ventricular evoked response (VER) to assess the loss of capture in ventricle [1,2]. In case of a non captured beat assessed by non detection of the VER the output is automatically increased. An extension of this algorithm is used in the LOGOS DDDC pacemaker in conjunction with the pacemaker programmer PMS1000 (all Biotronik) to evaluate the pacing threshold in the ventricle during follow-up on a fully automatic basis.

Beginning from a safety output voltage the pacemaker automatically reduces the output until loss of VER detection. The last output value with detection of VER is assumed to be the ventricular pacing threshold (VPT). This method is supposed to be faster than the manual or semi-manual VPT test and therefore, minimizing follow-up time and enhancing comfort of the patient.

In the present study, the VPT obtained by this fully automatic method has been compared to the classical manual method.

Patients and Method

The study group consisted of 10 patients (4 male, 6 female) aged 67-84 years. In all patients a multiprogrammable dual chamber pacemakers LOGOS with bipolar low polarization leads SYNOX BP (all Biotronik) were implanted. Indications for implantation were complete heart block in 2 pts, hypersensitive carotid sinus syndrome in 2 pts, sinus node dysfunction with symptomatic bradycardia in 2 pts, syncopal trifascicular block in 2 pts and type II second degree AV block in 2 pts. Concomitant heart disease was present in 4 patients: congestive heart disease was present in 1 pt, ischemic heart disease in 2 pts, and high BP in 1 pt. The patients with concomitant heart disease were on drug therapy which included oral nitrates, amiodarone,

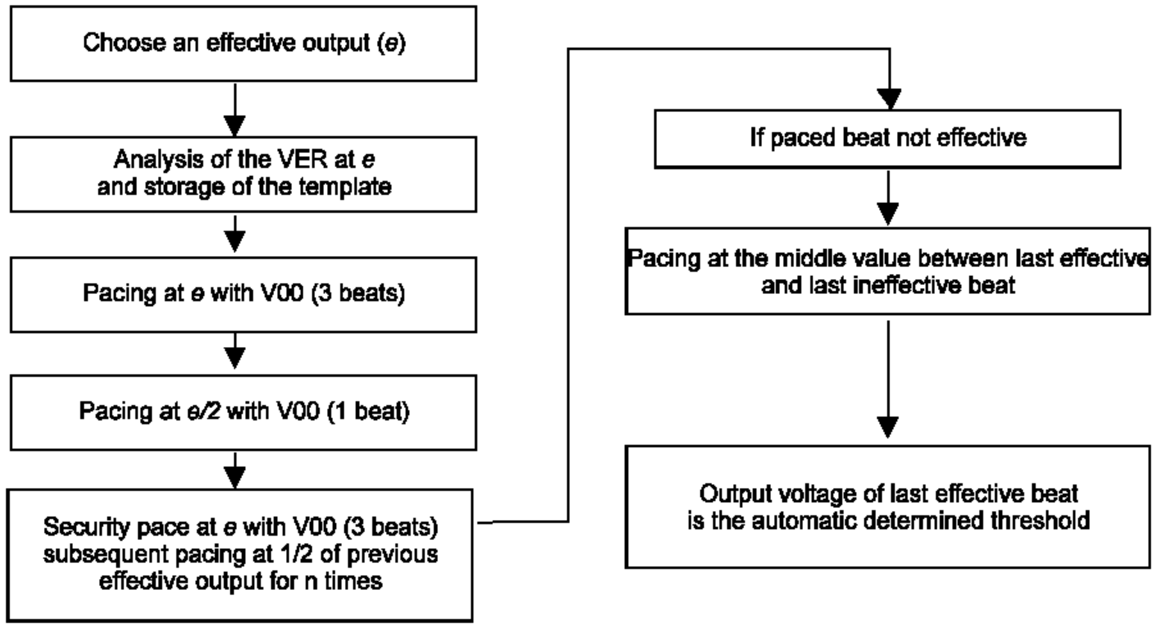

Figure 1. Algorithm showing the method used to determine the VPT by the automatic method. See text for explanation.

diuretics, and calcium antagonists. The study protocol was performed at the 6 month follow-up.

Measurements

In the first part of the study protocol, VPT was measured using a fully manual method. Three ECG leads in which the ventricular spike was most easily observable and one endocavitary signal from ventricle (IEGM) were recorded and analyzed. Pacing was performed in the VVI mode at 100 ppm to ensure ventricular pacing. The ventricular output was reduced gradually at a fixed pulse width of 0.4 ms until no capture occurred. The least value producing a permanent ventricular depolarization was taken as the VPT at the given pulse width.

In the second part of the protocol, the ventricular pacing threshold was determined by the fully automatic method. During the whole test the programmer head of the programmer (PMS1000) is placed appropriately to ensure permanent telemetric link between programmer and pacemaker. During the automatic threshold test, the IEGM is permanently displayed allowing the physician to control the automatic test. The automatic threshold test is automatically controlled by the programmer and needs no intervention by the physician. Nevertheless the test can be stopped at any time e.g. by lifting the programmer head. The algorithm is shown in Figure 1 and consisted of 2 phases. During the first phase ventricular evoked signals were analyzed at a fixed pacing rate with a sufficient output to achieve a reference signal. Pacing was done in the VOO mode at a stimulation rate of 100 bpm or at a chosen value higher than the intrinsic heart rate of the patient. From 10 beats a template of the VER was determined. The pacing output of the template (e) was termed the security output. The VER at e was used as the reference signal. Every beat during phase 2 of the test was compared with the reference VER. If the test signals deviate from the reference VER the beat was classified as a non-captured beat. During the second phase the determination of the pacing threshold was performed. The pacing rate was automatically set to 100 ppm or to the chosen value during phase 1. To ensure appropriate ventricular rate every test beat was followed by three security beats at security output. The test starts by delivering a test beat at an amplitude of e/2 V. Afterwards the VER was analyzed and compared to the reference value. If the tested amplitude of e/2 V was considered effective, then the next test beat was at ½*e/2 V again followed by the security pacing. This procedure was repeated until the test beat at a value of 1/n*e/2 V failed to depolarize the ventricle. Then the next test beat was delivered at the middle value

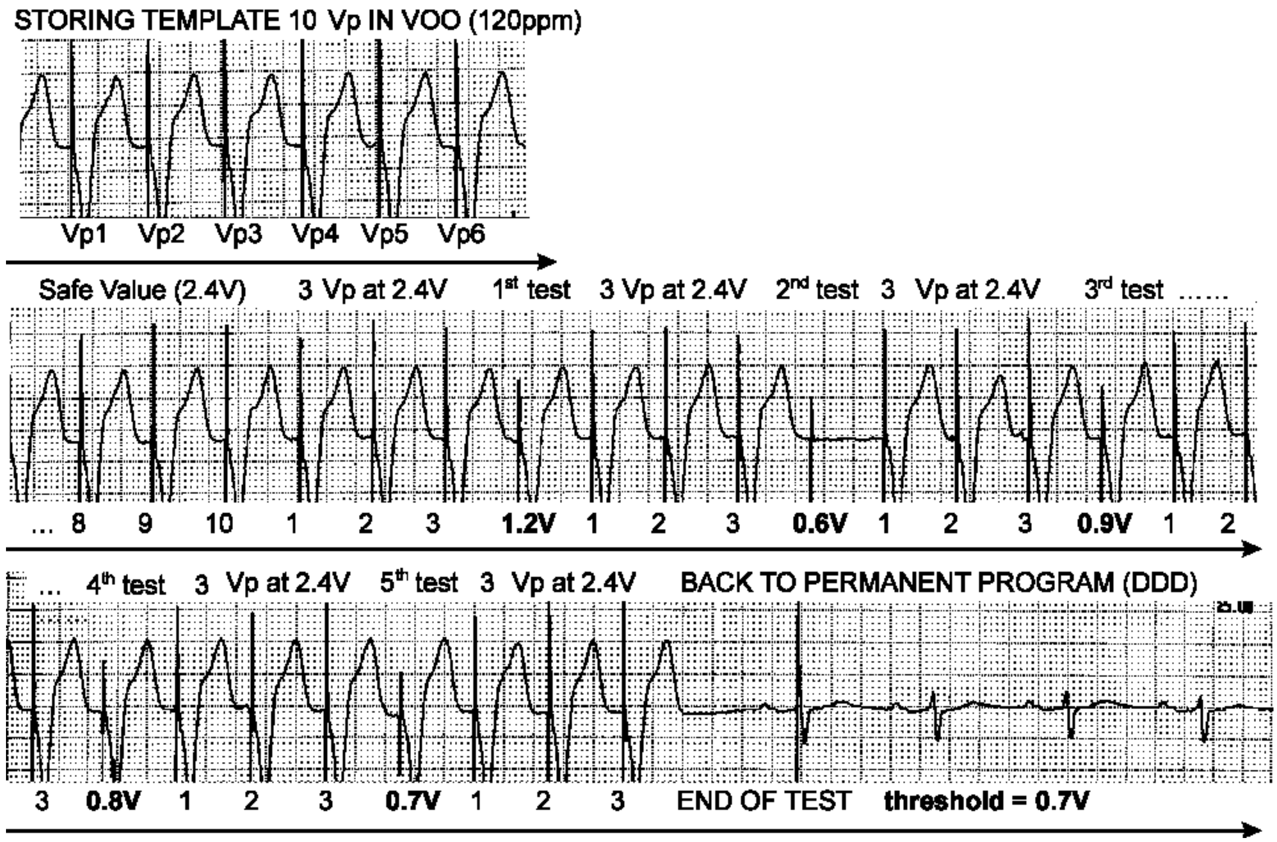

Figure 2. ECG monitoring showing the actual function of the algorithm.

between the last effective and the last ineffective value (example: security output = 3.6 V and threshold = 0.6 V. Test beats delivered at 3.6 to 1.8 to 0.9 to 0.5 (non capture) to 0.7 to 0.6 V (capture). In this example the test needs 6 test beats and 18 security beats which takes 15 s at 100 bpm). The test stops when the difference between the last effective and ineffective value was equal 0.1 V. After phase 2 of the test the pacemaker is automatically reprogrammed to the last permanent program. Figure 2 depicts an ECG tracing showing phase 1 and 2 of the algorithm.

Statistical analysis

The results of the manual and automatic test at the 6 month follow-up was analyzed using a scatterplot. The method of Bland and Altman was used to calculate the 95% limits of coincidence. A Wilcoxon signed rank test was performed to check the reliability between both methods.

Results

The values of VPT obtained for each patient is shown in Table 1. Statistical analysis of these values results a very high correlation between the 2 methods (0.99710; Pearson correlation coefficient). Also the reliability is very high showing an intraclass correlation coefficient of 0.9953. The mean difference between the 2 methods is -0.02 with 95% limits of confidence ranging from -0.15 to 0.11 at a p value of 0.37 (Wilcoxon signed rank test). A scatterplot illustrates the results (Figure 3). As can be noted, the agreement is perfect in the interval from 0.3 to 0.6 V of threshold. There is, however, a difference of 0.1 V between the two methods between 0.9 to 2.4 V. The number of patients is too small to check whether the automatic method is less reliable at higher pacing thresholds. 8 patients had pacing threshold values of less or equal 1 volt by either method. The two remaining patients had higher pacing thresholds. None of these 2 patients had additional heart disease or was on drug therapy.

Patient	Manual test	Automatic test
1	0.5	0.5
2	1.5	1.6
3	0.6	0.6
4	2.4	2.5
5	0.9	1.0
6	0.3	0.3
7	0.5	0.5
8	0.4	0.4
9	0.9	0.9
10	0.9	0.8

Table 1. Pacing threshold values obtained by manual and automatic method. Values are expressed in volts.

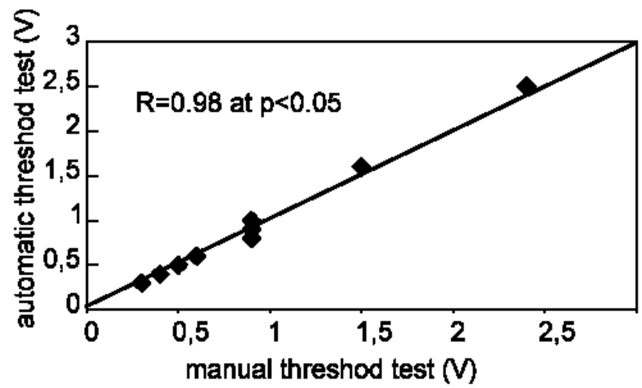

Figure 3. Reliability between the 2 test methods. Linear correlation R = 0.98 at $p < 0.05$.

Discussion

The ventricular evoked response, the summed signal of cardiac cells responding to effective depolarization, has been used as a sensor signal in rate response pacemakers [3] and to monitor ventricular stimulation to automatically adjust the output amplitude (CaptureControl). The CaptureControl can also be used to evaluate the VPT during follow up. In this study we have compared a automatic method for determining VPT with the classical manual method as the reference. The statistical analysis of the data shows that there is a very high correlation and a perfect reliability between the two methods. The used high-impedance leads did not affect the function of the automatic threshold test. No adverse effect was documented.

One major handicap in detecting the VER is the polarization artifact of the stimulus. Polarization occurs at the tip of the electrode following the stimulus. During the stimulus charges are accumulated at the electrodes thus creating a electric field in the surrounding fluid. The polarization effect decays slowly and interferes with VER. To minimize the polarization artifacts two methods can be used. First a fast recharge pulse having a polarity opposite to the stimulating impulse is given shortly after the pacing spike [4]. This reversal of polarity neutralizes the charges present at the electrode-electrolyte interface. Another method to reduce polarization is to use an electrode with a large electrochemical surface area. This can be achieved by fractally coating of the electrode tip [5]. Such electrodes have a large active surface area, a very low interface impedance to detect IEGM signals and thus a very low polarization artifact. Nevertheless fractal coated electrodes can be used with high-impedance leads like Synox to combine the advantages of high pacing-impedance and low polarization artifact. The latter method for preventing polarization was used in our study. It permits the accurate analysis of the VER. This allows to determine precisely any loss of capture and therefore, quantifying the pacing threshold with good reliability.

Conclusion

This is the first study comparing the automatic method of determining VPT with its manual counterpart. VPT values were obtained by analysing the VER. Even with high impedance leads accurate VER detection could be performed by using fractal coated electrodes. Although the number of patients is small, the automatic method is seems to be very reliable and faster than manual or semi-automatic threshold tests. The algorithm by including the 3 safety pacing output after every tested amplitude ensures the safety of the patient effectively.

References

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