Clinical Investigation of an Automatic Capture Control Using the Ventricular Evoked Response

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Summary

Saving battery energy and extending pacemaker lifetime is a very important aspect in pacemaker technology. Continuous capture control in implantable pacemakers with consecutive amplitude adjustment of the stimulation pulse takes into account this aspect. This paper describes the technical realization of continuous capture control, which has been integrated into the Logos DDD pacemaker (BIOTRONIK, Inc.). The second part of the paper presents the clinical results of this study. The ventricular evoked response (VER) of the heart is monitored to detect effective and ineffective stimuli. The VER is based upon action potentials of myocardial cells and therefore reflects their electrophysiological status, as well as the course of excitation in the myocardium. In order to evaluate capture control and automatic output adjustment, 14 patients were implanted with a Logos DDD pacemaker (BIOTRONIK, Inc.) were examined. VER measurements were performed 6 weeks, 3 months and 6 months after implantation. The study shows that automatic capture control in implantable DDD devices is possible.

Keywords

Ventricular evoked response (VER) capture control, automatic output adjustment, implantable pacemaker, fractally coated leads

Introduction

In the first two decades of cardiac pacing, pacemakers only had to prevent bradycardia or asystolic events. The development of different sensors and features made a more physiological therapy possible. The introduction of fractal coated pacemaker leads improved the measuring of intracardiac signals. These leads show low pacing thresholds and excellent sensing properties for an artifact-free measurement of intracardiac signals. So, additional information from the heart can be acquired and processed by the pacemaker [1].

Some of this information can be used to control the consequences of the pacemaker stimuli. The threshold of pacemaker leads increases mostly during the postoperative phase after implantation. Inflammatory processes at the tip of the lead and microdislodgment can affect this reaction. Also, during the chronic phase drugs, changes of the myocardium, cardiac insufficiency and myocardial infarctions can cause an increase of the threshold. Therefore, a security feature, which controls the effectiveness of the pacemaker stimuli is very useful. Further, it is possible to program the output of the pacemaker only 0.5 V above the measured threshold. The saved energy can be used for more diagnostic options or it is stored within the pacemaker.

The ventricular evoked response (VER) is an intracardiac signal, which is suitable for detecting the effectiveness of the pacemaker stimulation. The VER results from the heart's electrical reaction to every effective ventricular pacing pulse. The VER is a unipolar signal, which is measured between the lead tip and the pacemaker housing. The VER 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. This signal can be ana-

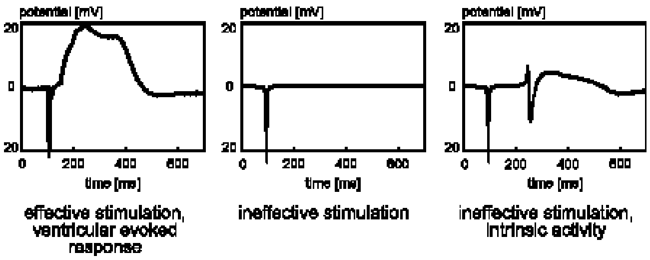

Figure 1. Different reactions of the myocardium to a pacemaker stimulus.

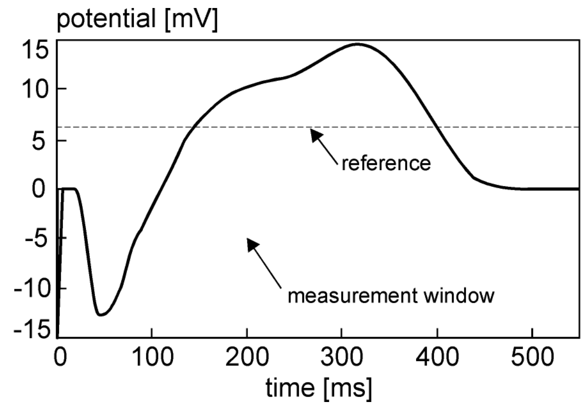

Figure 2. Capture detection of a stimulus and the measurement window.

lyzed automatically by the pacemaker, because it can be reliably detected and has got a characteristic morphology and a good long-term stability [1].

The VER is exclusively formed as a result of an effective pacing pulse and differs morphologically from intrinsic events. So this signal can be used for the automatic control of the effectiveness of pacemaker stimulation (Figure 1). Combined with automatic amplitude adjustment, continuous capture control guarantees safe stimulation. Ineffective pacing pulses which could be perilous for the patient, are automatically recognized by the pacemaker using capture control and are followed by an increase in the stimulation voltage.

For capture detection using VER an artifact-free signal detection and the consideration of fusion beats has to be observed. While artifact-free detection of the VER has been accomplished with fractal coated leads [2], fusion beats still represent an important challenge to the algorithm of the pacemaker.

Principle of the Capture Control Algorithm

As demonstrated in Figure 1, stimulated and spontaneous events as well as ineffective stimuli, can be clearly discriminated due to their different signal morphology. Intrinsic events show lower amplitude values than the VER. The maximum amplitude is reached during the first part of the signal, which is within the high-frequency Q- and R-peaks. In contrast, the VER shows especially high amplitudes in the low-frequency portion of the signal. To use the difference between the frequency content of both signals, the signal amplitude is measured for 60 ms. The measuring window is started 150 to 200 ms after the stimulus (Figure 2). A stimulus is deemed effective, if all measured values of the sensing window are above a pre-determined threshold value. This evaluation avoids the false interpretation of the high-frequency portions of the intrinsic activity as effective stimulation. Threshold values and starting times of the measuring window are adjusted individually, due to the signal variability of different patients [4].

While intrinsic events and VER can be optimally differentiated, fusion beats represent a problem in capture detection. When intrinsic and paced events concur, two different excitation fronts spread throughout the heart. Their overlap produces different morphologies as compared to paced or intrinsic events. Due to electromechanical coupling in the heart, a different signal results. It shows any intermediary shape depending on the time between the two events (Figure 3). Fusion beats must be excluded from processing to avoid false interpretation [4].

In the DDD-mode, this problem can be solved by programming a very short AV-delay, This AV-delay has to be shorter than the intrinsic conduction time. As programming of such a short AV-delay is, in general, therapeutically contraindicated, the AV-delay is only reduced to 50 ms in the algorithm when a stimulus is verified ineffective. The following stimulus is evaluated without any risk of a fusion beat, as shown in Figure 4. In the following cycle, the AV-delay is then reset to its original value [4].

Methods

In this study, 14 patients (9 male, 5 female) were included. The mean age aggregated 68 ± 11 years

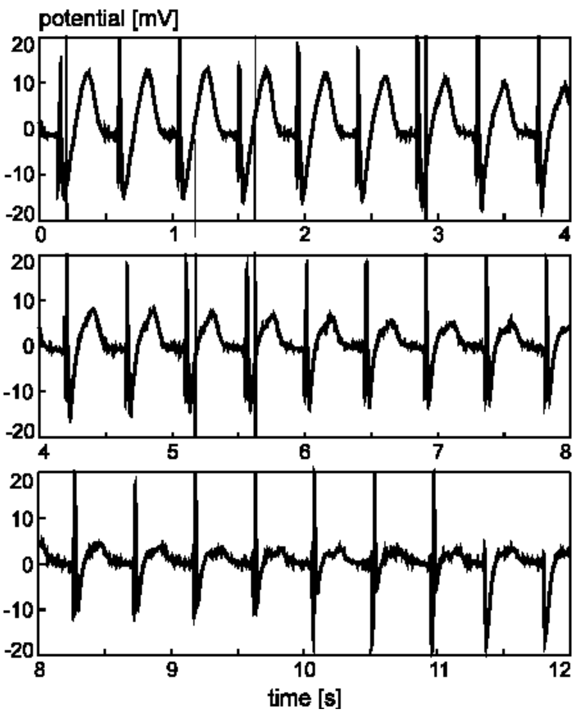

Figure 3. Intracardiac recording of fusion beats during the transition from stimulated to intrinsic events.

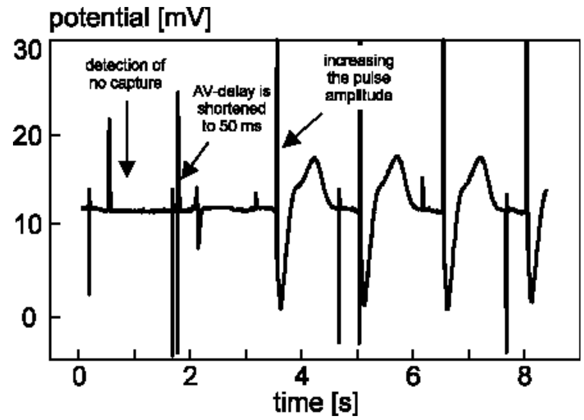

Figure 4. Capture control and output adjustment algorithm in the case of loss of ventricular capture during DDD stimulation.

(range 53 to 83 years). Indications for pacemaker implantation were third-degree AV-block (3), second-degree AV-block (7), sinus arrest (1), brady-tachycardia syndrome plus paroxysmal atrial fibrillation (1) and brady-tachycardia syndrome plus sinus bradycardia (2). All patients were implanted with the Logos dual-chamber pacemaker and a ventricular fractal coated unipolar lead (SX 60UP (4) or TIR 60BP (10), BIOTRONIK, Berlin). Follow-up examinations were performed 6 weeks, 3 months and 6 months after implantation.

At the beginning of each test, the AV-delay was reduced to 100 ms and capture control was automatically initialized. During effective stimulation, the individual typical morphology of the VER was established to determine the beginning of the measuring window and the reference voltage.

After the automatic initialization of the capture control algorithm, the ventricular pacing voltage was programmed to an output level below the predetermined pacing threshold. The capture control algorithm was activated after the coil was removed. Ineffective stimulation was automatically recognized and the stimulation amplitude was increased by 2 V. After a predetermined testing interval of 8.5 minutes, the stimulation amplitude was automatically reset to the ineffective value. Efficacy of the capture control algorithm was documented with a 6-channel ECG. The clinical response of the algorithm is demonstrated in Figure 4.

Results

Effective capture control could be demonstrated in all but one of the 14 patients. In this male patient, the initialization was automatically terminated during the first follow-up. The reason for this was an unstable VER morphology. During the 3 and 6 month follow-up, the correct function of the algorithm could be demonstrated in this patient.

In the remaining patients, loss of capture was detected at every follow-up after activation of capture control. After the coil was removed, the algorithms took 6 ± 1 ineffective stimuli before the amplitude was automatically increased by 2 V. That increase resulted in effective stimulation in every instance. After the test interval, ineffective stimulation was again present due to the automatic resetting of the stimulation amplitude to the originally programmed value. The first test happened 7.1 ± 3.1 minutes after the coil was removed. Following an additional ineffective stimulus to avoid fusion beats, the stimulation voltage was increased automatically and reliably, resulting in effective stimulation (as demonstrated in Figure 5). The reduction of

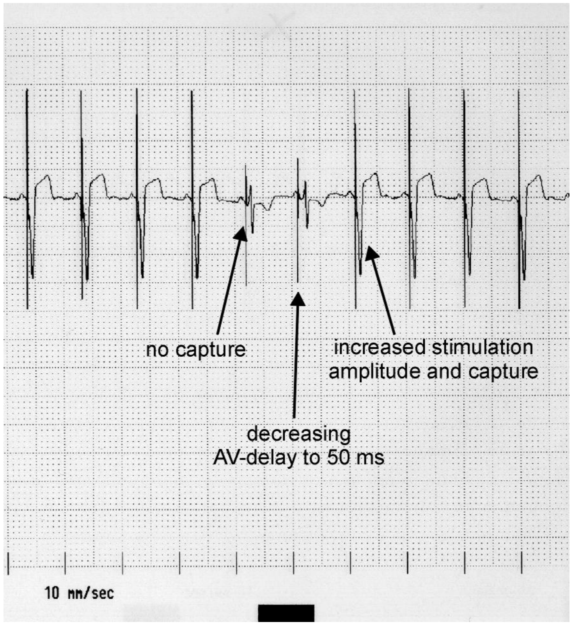

Figure 5. Pacemaker response with ineffective stimulation after the test interval. An ineffective stimulus leads to a decrease of the AV-delay The subsequent increase of the stimulation amplitude reestablished effective stimulation.

the AV-delay to 50 ms was carried out by the algorithms during all follow-up examinations. During 8 follow-up sessions, it was waited up to the second automatic resetting of the stimulation amplitude. The second test happened 8.5 ± 0 minutes after the first test and the algorithms worked without any problems.

Discussion

the excitation of the heart by using the automatic cap-

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cept of VER sensing using fractal electrodes, com bined with AV-delay shortening to avoid fusion beats, is suitable for fast and appropriate identification of

pacemakers. The pacemaker needed only 2 ineffective stimuli to recognize the need of the higher output dur ing the test interval.

Automatic capture control with consecutive adaptation

patient safety. Additionally, this function enables the usual safety margins of 100% to be reduced when pro gramming the stimulation amplitude. This contributes to an extended pacemaker lifetime or results more

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