Clinical Evaluation of a New DDD Pacemaker with Automatic Capture Control Using the Ventricular Evoked Response

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Summary

Continuous capture control in implantable pacemakers with consecutive amplitude adjustment of the stimulation pulse enables threshold adapted cardiac pacing, thus saving battery energy and extending pacemaker lifetime. This paper describes, the technical realization of continuous capture control, as well as the clinical application of an algorithm for capture confirmation which was integrated into the Logos™ DDD pacemaker (BIOTRONIK, Inc.). As a prerequisite for the detection of ineffective stimuli, the ventricular evoked response (VER) of the heart is monitored. 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. To evaluate capture control and automatic output adjustment 12 patients implanted with a Logos™ DDD pacemaker (BIOTRONIK, Inc.) were studied. VER measurements were performed during exercise and resting conditions 6 weeks, 3 months and 6 months after implantation. The study gives evidence for the implementation of automatic capture control in an implantable DDD device.

Key Words

ventricular evoked response, capture control, automatic output adjustment, implantable pacemaker, fractally coated leads

Introduction

The use of cardiac pacemakers has changed within the last 20 years. Whereas in the first two decades of cardiac pacing, pacemakers only had to prevent bradycardia or asystolic events, the incorporation of different sensors enabled for a more physiological therapy. The introduction of fractally coated pacemaker leads, which exhibit low pacing thresholds and excellent sensing properties for the artifact-free measurement of intracardiac signals, improved signal detection; thus additional information from the heart can be acquired and processed by the pacemaker [1].

The ventricular evoked response (VER) is an intracardiac signal resulting from the heart's electrical reaction to every effective ventricular pacing pulse and is derived in a unipolar fashion 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. The VER can be analyzed automatically by the pacemaker, because it can be reliably detected and has a characteristic morphology and a good long-term stability [1].

Since the VER is exclusively formed as a result of an effective pacing pulse and differs morphologically from intrinsic events, it 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 even if the pacing threshold exceeds the initial pacemaker output setting caused by microdislodgment of the electrode or the influences of drugs, especially antiarrhythmic drug therapy. Ineffective pacing pulses which are life-threatening 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, two areas require particular attention - artifact-free signal detection and the consideration of fusion beats. Fusion beats occur when a stimulus and an intrinsic event coincide, and due to their varying morphology, event-identification is made more difficult. While artifact-free detection of the VER has been accomplished with fractally coated leads [2], fusion beats still represent an acute challenge to the algorithm.

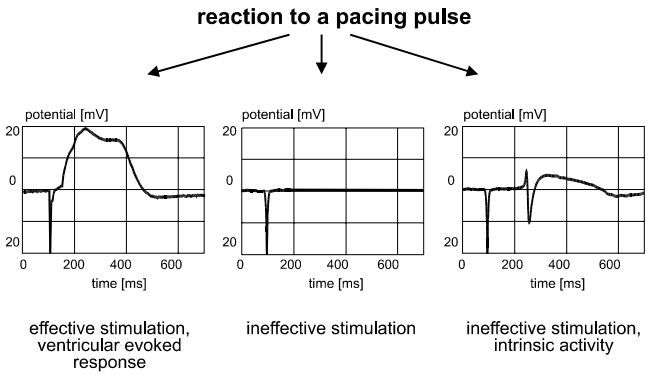

Figure 1. *Different reactions of the myocardium to a pacemaker stimulus.*

With the Logos™ pacemaker (BIOTRONIK, Inc.), the first implantable DDD pacemaker with automatic capture control has recently become available. The aim of this clinical study was to evaluate the efficacy and reliability of the long-term capture detection of the Logos™ pacemaker using measurements of the VER.

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, and their maximum amplitudes are within the high-frequency Q- and R-peaks at the first part of the signal. In contrast, the VER shows especially high amplitudes in the low-frequency portion of the signal. To exploit 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 counteracts 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.

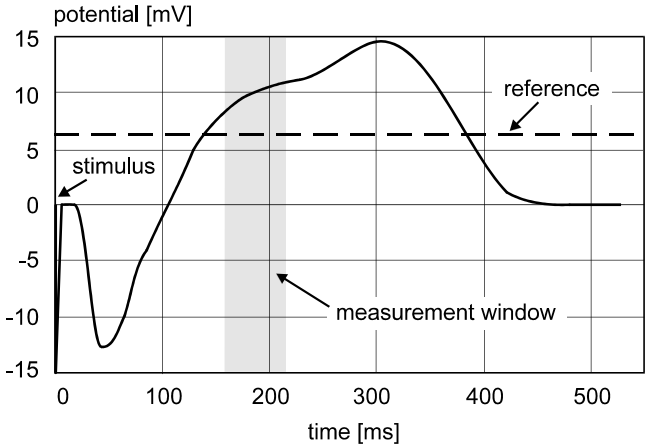

Figure 2. *Capture detection of a stimulus: if all measured values inside a measurement window are above a pre-defined reference voltage, the stimulus is defined as effective.*

While intrinsic events and VER can be easily differentiated, fusion beats represent a problem in capture detection.

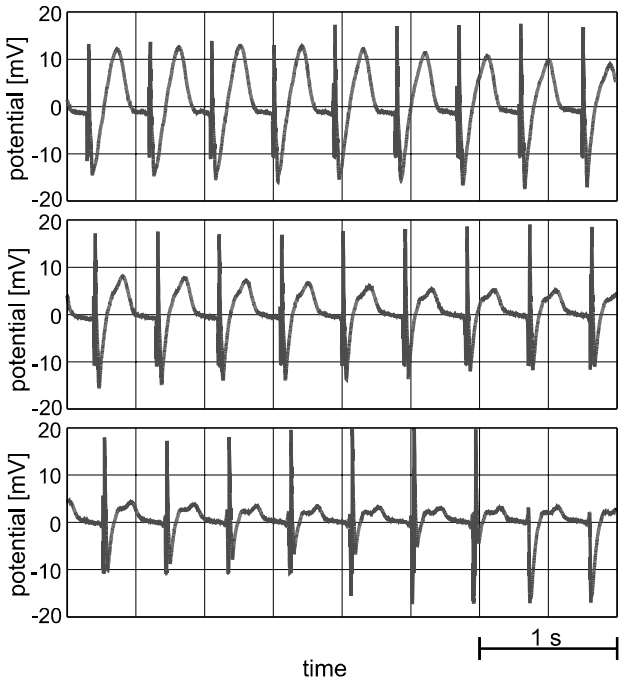

Figure 3. *Intracardiac recording of fusion beats during the transition from stimulated to intrinsic events. The signal morphology changes smoothly from that of the VER to the intrinsic event.*

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.

In the DDD-mode, this may be achieved by programming a very short AV-delay, which is shorter than the intrinsic conduction time. As programming of the AV-delay to such low values is in general contraindicated therapeutically, the AV-delay is reduced to 50 ms in the algorithm only 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 re-set to its original value. The clinical response of the algorithm is demonstrated in Figure 5.

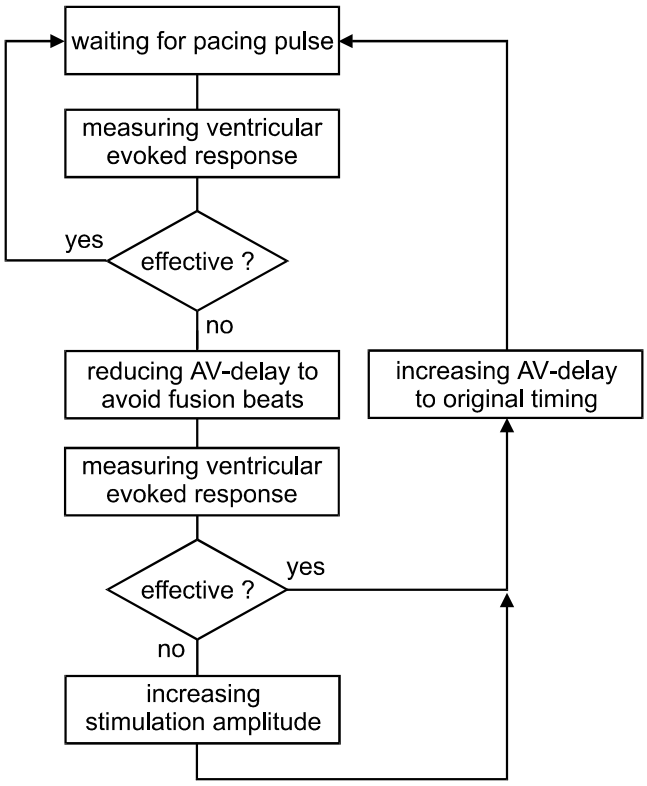

Figure 4. *Flow chart of suppression of fusion beats in the DDD-mode.*

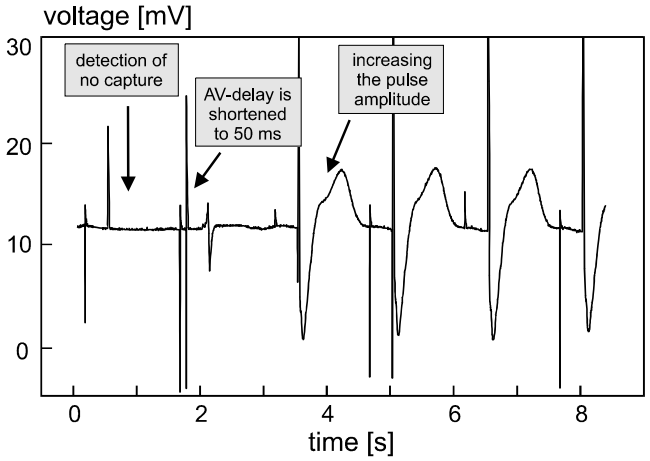

Figure 5. *Capture control and output adjustment algorithm in the case of loss of ventricular capture during DDD stimulation.*

Methods

The study population consisted of 12 patients (7 male, 5 female) with a mean age of 66 ± 15 years (range 48 to 84 years). Indications for pacing were third-degree AV-block (8), second-degree AV-block (3) and sinus arrest (1). All patients were implanted with the Logos™ dual-chamber pacemaker and the ventricular fractally coated unipolar lead PX 60-UP (BIOTRONIK, Inc.) with a 3.5 mm² surface. Follow-up examinations were performed 6 weeks, 3 months and 6 months after implantation.

At the start of each test the capture control was initialized automatically. 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 pre-determined pacing threshold and the capture control algorithm was activated. Ineffective stimulation was automatically recognized and the stimulation amplitude was increased by 2 V. After a predetermined testing interval of 8 minutes, the stimulation amplitude was automatically reset to the ineffective value. Efficacy of the capture control algorithm was documented with a 6-channel ECG.

Results

Effective capture control could be demonstrated in all but one of the 12 patients. In this female patient only during the first follow-up initialization was automatically terminated due to an unstable signal morphol-

ogy. During the 3 and 6 month follow-up the correct function of the algorithm could be demonstrated in this patient.

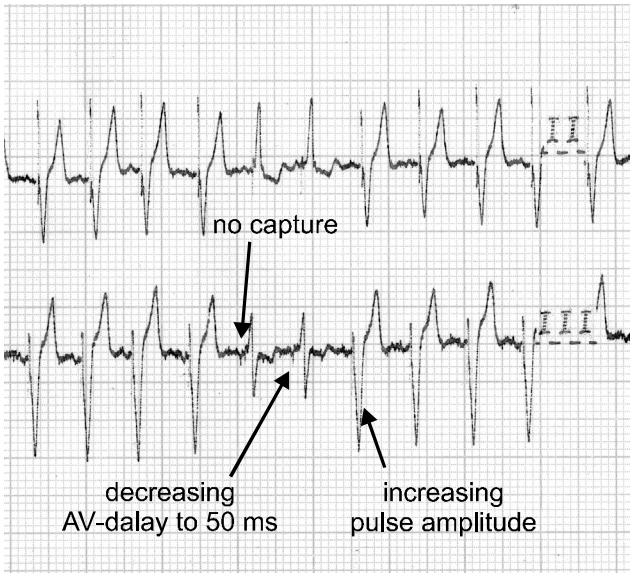

Figure 6. *Pacemaker response with ineffective stimulation after the test interval. An ineffective stimulus leads to a decrease of the AV-delay (exclusion of fusion beats, second ineffective stimulus). The subsequent increase of the stimulation amplitude reestablished effective stimulation.*

In the remaining patients loss of capture was detected at every follow-up after activation of capture control. This response always led to an automatic increase of the stimulation amplitude by 2 V, which also resulted in effective stimulation in every instance. After the 8-minute test interval, ineffective stimulation was again present due to the automatic resetting of the stimulation amplitude to the originally programmed value. 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 6).

Discussion

The present study gives evidence for the reliable functioning of automatic capture control in the Logos™ DDD pacemaker. The concept of VER sensing using fractal electrodes, combined with AV-delay shortening to avoid fusion beats, is suitable for fast and appropriate identification of ineffective ventricular stimulation in implantable DDD pacemakers.

Automatic capture control with consecutive adaptation to the output amplitude offers optimal patient safety. Additionally, this function enables the usual safety margins to be reduced when programming the stimulation amplitude. This contributes to an extended pacemaker service life. Successful application of the VER suggests additional uses of this physiological signal in electrotherapy of the heart for the future, bringing ever closer to reality the vision of the automatic pacemaker [3].

References

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