Clinical Evaluation of a New Automatic Ventricular Capture Control Algorithm Based on Evoked Response

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Summary

The fractal electrode coating provides a safe and efficient low energy pacing. Fractal technology, combined with a pacing system capable of ensuring capture through automatic output adjustment, can further improve patient safety and the physician's confidence in low voltage pulses extending pacemaker battery life. The aim of this study was to evaluate a new pacemaker algorithm for automatic ventricular capture control based on the evoked response. The algorithm was embedded in a laptop computer attached to an external pacemaker system, and tested during pacemaker implantation in 25 patients. Bipolar passive fixation leads from three manufacturers were used in the evaluations. The first step in the algorithm was signal quality check, evaluating polarization artifacts in the unipolar and bipolar lead configurations for a range of output pulse amplitudes. Whenever the signal quality check showed satisfactory results, an automatic threshold search was performed in both lead configurations. Threshold results were then compared to the manually obtained values using a pacing system analyzer. The collected data were processed beat-to-beat (offline). Low polarization leads passed the signal quality check in both lead configurations and high polarization leads only in the unipolar configuration. A total of 17,188 ventricular pacing pulses were delivered and analyzed for capture detection accuracy. The sensitivity of the automatic capture control algorithm was 99.6 % (i.e., probability that capture was detected given that the event was a capture) and the specificity was 99.5 % (i.e., probability that non-capture was detected given that the event was a non-capture). There was a close agreement between manually and automatically determined pacing thresholds.

Key Words

Automatic output regulation, ventricular evoked response, fractal coated electrode

Introduction

The introduction of fractal electrode coating has significantly improved pacing and sensing performance of pacemaker leads [1-8]. Low and stable pacing thresholds in fractal electrodes encouraged clinical use of low output settings without compromising patient safety. Typically, at pacemaker implant and at subsequent follow-up visits, the clinician measures the pacing threshold and programs the pacing output to twice the pulse amplitude while maintaining a constant pulse duration, or, alternatively, tripling the pulse duration while maintaining a constant pulse amplitude. The difference between the pacing threshold and the programmed output is referred to as the safety margin. The purpose of the safety margin is to compensate for an increase in the threshold between follow-up visits. Variations in threshold may be caused by lead maturation, changes in medication, lead micro-dislodgment, pathology evolution, or physiologic changes such as exercise.

The unique sensing characteristics of fractal electrodes, owing to the 1000x increase in the electrochemically active area at the cauliflower-like fractal surface, allows sensing of undistorted intracardiac signals such as ventricular evoked response (VER) and

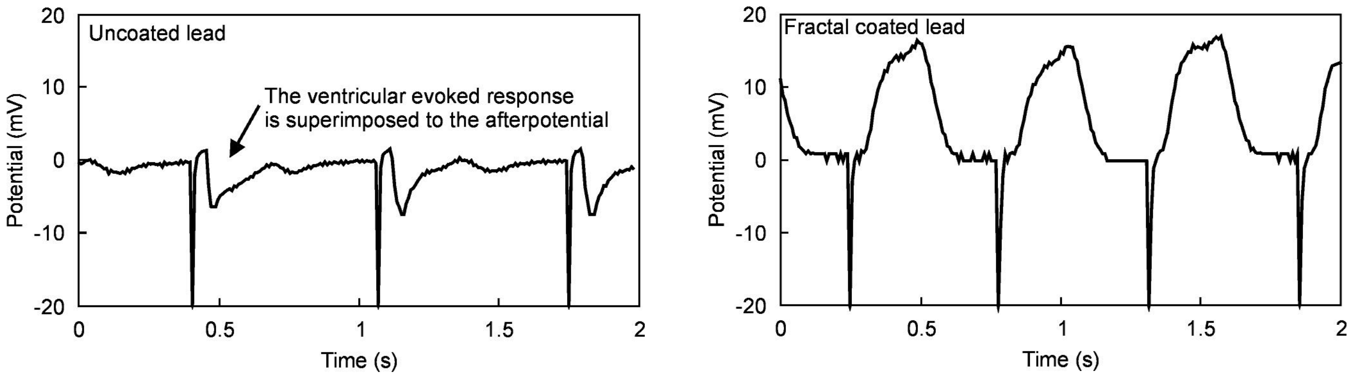

Figure 1. Intracardiac electrograms recorded at supraliminal pacing. Uncoated Elgiloy electrode: the afterpotential overlaps the barely-recognizable response of the heart. Fractal coated electrode: the ventricular evoked response signal has a large amplitude and is undistorted by the afterpotential.

for diminished electrode polarization even for very small, high-impedance electrodes (Figure 1) [1-6]. The VER is an intracardiac signal resulting from the heart's electrical reaction to every effective pacing pulse. This signal can be reliably detected by a pacemaker and has good long-term stability. For these reasons, it is the most commonly used signal for determination of the effectiveness of automatic pacing amplitude control [9-11].

This study evaluated a new feature-based morphological Automatic Capture Control (ACC) algorithm (Biotronik, Germany), intended for the use in sophisticated implantable pacing systems. The algorithm continuously monitors amplitude of the VER signal to verify whether a pacing pulse triggered ventricular depolarization (is captured). In case of capture, the output level is considered appropriate. If the capture fails, a "back-up" pacing pulse at a higher energy level is delivered within 130 ms of the previous ineffective pulse. If two out of three ventricular pacing pulses at a certain output level result in non-capture (followed by back-up pulses), the Automatic Threshold Search (ATS) function is initiated to determine actual pacing threshold. The ATS occurs over a series of cardiac cycles and begins at a relatively high output amplitude that is gradually decreased until capture is lost. The lowest voltage that induces myocardial depolarization is the pacing threshold. The pacing amplitude is then set to the pacing threshold, plus a programmable voltage safety margin. In addition to performing the ATS at failed capture, the search is conducted periodically to provide an accurate safety margin in the event of a decreasing or gradually increasing threshold.

Critical to the function of an ACC algorithm is its ability to distinguish capture from non-capture. Advances in pacemaker lead technology facilitate ACC performance. Leads whose electrodes have a low polarization potential may be used to discriminate between capture and non-capture using standard pacing pulses [9-11]. Conversely, leads with high-polarization electrodes cannot reliably separate capture from non-capture using standard pacing pulses, because the polarization voltage generated by the lead is too large with respect to the evoked signal generated by the myocardium [12-13]. A major task of a sophisticated ACC algorithm is to distinguish high from low polarization leads so that the remainder of the algorithm operates only in pacing systems with appropriate leads. Previous ACC algorithms have assumed that an appropriate lead is attached. These algorithms could cause inaccurate classification, resulting in sub-threshold pacing in systems with leads of inadequate quality. The current algorithm represents the first attempt to automatically distinguish low from high polarization leads.

Materials and Methods

Twenty-five patients were included in the study (18 male and 7 female, mean age 77 ± 7 years, range 55 – 85). At implant, an external pacemaker with a typical front-end pacing and sensing hardware was used to test the ACC algorithm in the ventricle. The test was conducted in both unipolar and bipolar lead configurations at pulse amplitudes of 3.6 V, 4.8 V and 6.4 V, using 0.42 ms pulse duration. The external pacemaker was controlled, and its parameters were reprogrammed, by a

	Biotronik Polyrox	Medtronic 4092	Pacesetter 1472T
No. of leads tested	20	3	2
Polarization	Low	High	Low
Tip surface area (mm^2)	3.5	5.8	2.3
Tip surface material	Iridium	Platinum	Titanium-nitride
Tip coating	Fractal	Platinized microporous	Co-polymer membrane
Ring surface area (mm^2)	45	36	30
Ring surface material	Platinum-Iridium	Platinum	Titanium-nitride
Ring coating	Fractal	None	None

Table 1. Bipolar, passive fixation ventricular leads used in the evaluation of the Automatic Capture Control and Automatic Threshold Search algorithms.

specifically designed software loaded in a laptop personal computer (PC). The PC simulated the function of the pacemaker microprocessor running under the actual embedded software code. The same software was also utilized for recording electrograms and pacemaker events for later offline analysis. Ten patients were tested in the DDD mode and 15 in the VVI mode. Bipolar passive fixation ventricular leads from three manufacturers were used in the ACC and ATS evaluation (Table 1). ATS-measured thresholds were compared to the values measured by a pacing system analyzer (ERA 300, Biotronik, Germany); the data were processed using specific software for beat-to-beat analysis.

Results

A total of 17,188 ventricular pacing events, from which 16,993 (98.8 %) captured and 195 (1.2 %) did not capture were evaluated by a visual analysis of the recorded electrograms and pacemaker events. Table 2 summarizes the results. The sensitivity (i.e., the probability that capture was detected by ACC given that the event was a capture) was 99.6 % and the specificity (i.e., the probability that non-capture was detected by ACC given that the event was a non-capture) was 99.5 %. Of the 72 captured beats misclassified as non-captures (Table 2), 64 (88.8 %) occurred in a single patient.

	Detected by ACC as non-capture	Detected by ACC as capture
True non-capture	194	1
True capture	72	16921

Table 2. Capture detection accuracy of the Automatic Capture Control (ACC) algorithm.

All low polarization leads (Table 1) passed the signal quality check (SQC) acceptability criteria for artifact discrimination in both unipolar and bipolar configurations and at pulse amplitudes up to 6.4 V. The high polarization lead CapSure 4092 (Medtronic, USA) passed SQC only in the unipolar configuration. In general, there was a close agreement between manually and automatically determined threshold values. A paired t-test was used to evaluate similarity of the threshold values. The ATS-measured threshold was 0.51 ± 0.21 V (mean ± standard deviation), while the threshold determined by the pacing system analyzer was 0.39 ± 0.16 V. The mean difference was 0.12 V (P = 0.046).

Discussion

The results of this acute clinical study on the ACC event classifier algorithm demonstrated very satisfactory sensitivity and specificity of the algorithm in the differentiation between capture and non-capture in ventricular leads that passed SQC. The algorithm was effective in all leads (with either low or high polarization) in at least one lead configuration. An interesting finding was that the CapSure 4092 lead performed well in the unipolar, but not in the bipolar configuration. This lead has a large surface area tip electrode and a polished ring electrode (anode). The smoothness of the indifferent ring electrode decreased inter-electrode capacitance, and consequently increases the amplitude of the polarization artifact in the bipolar configuration. The lead thus passed SQC and was accepted by ACC only in the unipolar configuration.

Conclusions

A safe and effective ACC discrimination between capture and non-capture was technically feasible with the tested leads. SQC is a safe method for the evaluation of polarization artifacts. No relevant difference in safety and efficacy was observed between unipolar and bipolar lead configurations.

This ACC system may operate with a small threshold safety margin. A smaller safety margin reduces power consumption by the pacemaker hardware, resulting in extended longevity of the device, significant cost savings, and fewer surgical procedures. The automatic adjustment also allows the pulse output to increase beyond the safety margin typically programmed by the clinician. In addition, a back-up safety pulse is always available in the event of non-capture. These two features increase patient safety by ensuring continued capture even in the event of large increases in pacing threshold. ACC could also reduce follow-up costs by decreasing the time required to evaluate pacemaker function. At follow-up, the physician may simply choose to verify correct pacemaker output by observing statistical data gathered in the pacemaker memory during daily life, rather than performing a pacing threshold test.

The greatest limitation of the present study was its acute nature. The ACC algorithm remains to be verified in chronic conditions, as the evoked response waveforms and polarization artifacts may vary with time, especially in high polarization leads.

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