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Pacing Technology: Advances in Threshold Management

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SIU AND LAU: Pacing Technology: Advances in Threshold Management. Over the last 5 decades, pacemaker therapy has undergone remarkable technological advances with increasing sophistication of pacemaker features. However, device longevity has remained one of the major issues in pacemaker design ever since the first endocardial pacing lead implantation in 1958. In addition to various hardware design to enhance device longevity, software-based solutions to minimize pacing energy and yet with good safety margin have also been developed. Together with desire and need of fully automatic pacing system in increasingly busy pacemaker clinic, several manufacturers have introduced different automatic threshold management algorithm. This article summarizes the current state of art in pacing threshold management in the modern pacemakers. (J HK Coll Cardiol 2010;18:11-16)

Capture management, pacemaker

Introduction

With the aging population, there have been an increasing trend in cardiac pacemaker implantation worldwide. In the United States, up to 2.25 million electronic pacemakers were implanted in the period from 1990 to 2002, and the annual implantation rate increased almost 3-fold. Similar trend has also been observed in Hong Kong with over 1,000 electronic pacemaker implanted in 2002. Despite pacemaker therapy has undergone remarkable technological advances as reflected by the increase in number of circuitry components from a mere two to three transistors in early pacemakers to nearly 1 million components with RAM size up to 124,000 bytes,1 the need and desire to lengthen device longevity have remained one of the major issues in pacemaker design ever since the first endocardial pacing lead implantation in 1958. Hardware improvements to improve device longevity including high-energy density battery and high impedance, low threshold leads have been developed. Likewise, software-based solutions to pace the cardiac chamber of interest with the lowest feasible energy with good safety margin have also been developed. This article summarizes the current state of art in pacing threshold management in the modern pacemakers.

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Capture Management

The primary function of a pacemaker is to pace effectively at an efficient energy output, which in turn depends on the pacing threshold that varies significantly between individuals, and within an individual over time. The intra-individual variation of pacing threshold may occur due to spontaneous threshold rise after implantation, gross or microdislodgment of pacemaker lead, diurnal changes, and changes secondary to drugs and/or myocardial ischemia. From a clinical standpoint, variation in threshold may lead to an inadequate safety margin of stimulation, thus raising potential safety issues. Thereby, the ability to track threshold automatically will maximize patient safety, minimize battery drain for pacing, and, importantly, simplify programming. Furthermore, threshold measurement remains time consuming, and if an alternative and safe method is available, the burden of programming can be reduced. Table 1 lists the reasons necessitating automatic capture management.

Several manufacturers have introduced algorithms for detecting ventricular, atrial, and left ventricular (in cardiac resynchronization therapy (CRT)) thresholds. The detection of an evoked response is based on either evoked response or impedance. The threshold data are used either on a beat-by-beat basis to ensure a paced response or intermittently to adjust output parameters.

St. Jude/Pacesetter Autocapture™

St. Jude Medical first introduced the Autocapture™ pacing system in a single chamber Microny™ pacemaker in 1995. It is designed to verify a response which represents capture or myocardial depolarization, to each pacemaker stimulation, and to automatically adjust the pacing output accordingly in a beat-to-beat basis. Specifically, after a ventricular pacing stimulus, the algorithm opens an evoked response (ER) detection window for 46 ms after a 14 ms blanking period, and the detection of an ER is used to diagnose capture (Figure 1). In the event that an ER is not detected (loss of capture), a high energy back-up pulse of 4.5 V is discharged at 100 ms after the ventricular pacing stimulus, to avoid long pauses. If two consecutive back-up pulses have been delivered, the algorithm starts a stimulation threshold search by increasing the output to effect two consecutive captures. In single chamber devices (Microny and Regency SR), a margin of 0.3 V is added. In addition, to avoid pacing at high output due to diurnal fluctuation in threshold, the device automatically performs a threshold search once every 8 hours. A safety margin of 0.3 V is added to the detected threshold. In dual chamber devices, the A-V interval is shortened to 50 ms (Ap) or 25 ms (As) to ensure overdrive of intrinsic ventricular rhythm. In the Affinity DR, automatic decrements and increments of output during threshold search are 0.25 and 0.125V, respectively. In addition, beat-to-beat capture verification has recently been extended to atrial stimulation in Zephyr pacemaker by St. Jude Medical (ACP™ confirm), as the small atrial electrical signal represents a major challenge in discrimination between ER signal and pace-induced after polarization.

Table 1. Potential benefits of capture management

<table>
<thead>
<tr>
<th>Benefits</th>
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<tr>
<td>Increase in battery drain (e.g., sensors, electrogram monitoring, and multisite pacing)</td>
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<td>Increase in battery longevity</td>
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<td>Two-third of patients will be alive at the time of battery replacement</td>
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<td>Pacing for populations such as those with AF and after atrioventricular nodal ablation</td>
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<tr>
<td>Reduction in battery size</td>
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<tr>
<td>Physiologic/medical variation in threshold</td>
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<tr>
<td>Reduction in time for pacemaker programming</td>
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The efficacy as well as the safety of the capture management algorithm depends very much on accuracy of detection of ER. Table 2 lists factors that affect Autocapture detection of ER. One major challenge is the difficulty to discriminate between the ER signal and the pace-induced after potential; for instance, a large electrode polarization artifact relative to size of ER can affect ER detection. This can be reduced either with the use of low polarization electrodes (made possible by increasing the microscopic electrode-tissue interface area), or with a biphasic waveform that comprises a fast precharge followed by a negative postcharge to minimize polarization effect. The effect of a modified fast prepulse on Autocapture™ algorithm was tested in 45 patients with leads from two manufacturers (Medtronic 4024 Cap Sure, and Pacesetter 1450 K/T and 1470 T leads). Whereas the ER was independent of the type of pacing pulse, the polarization artifact was significantly less during the modified pulse compared with the conventional pacing pulse, leading to an improved efficacy of the Autocapture algorithm (94% versus 71% successful ER detection). An adequate ER amplitude of greater than 2.5 mV is recommended before activation of the autocapture algorithm, and this was present in 93% of 60 patients in one study. Neither the clinical data nor the conventional electrical parameters were effective in predicting the size of the ER signal. Body posture and exercise had relatively little effect on the ER. Recently, a new ER algorithm measuring the depolarization integral (area) instead of ER signal amplitudes (voltage) to determine ER has enhanced the accuracy of capture verification; in fact, the algorithm allows ER determination even with old high polarization bipolar leads (Figure 2). Because of the enhanced sensitivity, discrimination of small atrial ER from pace-induced after potential has become possible.

The one-year stability of the algorithm has been tested in a multicenter study involving 113 patients.

Table 2. Factors affecting capture detection

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<thead>
<tr>
<th>Factor</th>
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<tr>
<td>Electrode polarization</td>
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<tr>
<td>Fusion beats (false negative)</td>
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<tr>
<td>Ventricular capture, intrinsic beat</td>
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<tr>
<td>Pseudofusion beats (false positive)</td>
</tr>
<tr>
<td>Pacing spike (and failure of capture), intrinsic beat</td>
</tr>
<tr>
<td>Algorithm related: Unipolar pacing, bipolar sensing</td>
</tr>
<tr>
<td>Adequate ER</td>
</tr>
<tr>
<td>Other applications: atrial, epicardial, and left ventricle</td>
</tr>
</tbody>
</table>

Figure 1. Evoked response detection. After a ventricular pacing stimulus, the algorithm opens an evoked response (ER) detection window for 46 ms after a 14 ms blanking period, and the detection of an ER (voltage) is used to diagnose capture.
implanted with Pacesetter Microny SR+. Evoked response was satisfactory for Autocapture in 102 of 113 patients, and the evoked response was stable over time. Furthermore, both the acute and chronic pacing thresholds measured at the clinic using VARIO significantly correlated with that derived from Autocapture, despite that the Autocapture threshold was higher (0.11±0.22 V) owing to the way in which threshold was derived. During Holter recordings, there was no failure of ventricular capture, and back-up pulses were used in 1.1% of all paced beats. Most were due to fusion or pseudofusion beats (87%), undersensing of either R wave or ER (4.6%), and truly due to loss of capture in only 7%. Although these did not affect pacing performance, the need for back-up pulses may negate the energy saving by the Autocapture itself. Consistently, similar positive results from the Autocapture algorithm in medium term for safety and efficacy have also been published. Compared with the factory-set pacemaker setting of 5 V, Autocapture™ algorithm reduced the energy drain in the Microny SR+ (with 0.35 Ah), which translated into an increased device longevity by 53%. For the Regency SR+ with a larger battery (0.79 Ah), the increase in device longevity was more remarkable (245%). However, when the conventional output was reduced to 2.5 V, the benefit of Autocapture on battery life was much less impressive.

**Boston Scientific Automatic Capture**

Likewise, the automatic capture algorithm from Boston Scientific provides also a beat-to-beat verification of myocardial capture based on the ventricular ER. The ventricular voltage output was automatically adjusted to 0.5 V above the measured threshold. Upon the occurrence of loss of capture, a backup pacing pulse 1.5 V higher than the measured threshold is delivered 100 ms after the primary stimulus. When loss of capture is confirmed for two cycles out of four beats, an automatic threshold test will check for the new threshold.

**Biotronik Capture Control**

The Logos pacemakers from Biotronik measure the ER signals from several successful capture beats, in order to generate a reference curve, against which failure of capture is compared. There are no back-up pacing pulses, but persistent loss of capture results in increase of pulse output in 2 V steps. After a programmable period of time, the output is reduced to the programmed value. This algorithm ensures patient safety through beat-by-beat capture verification.

**Medtronic Ventricular Capture Management**

The Kappa 700 pacemakers from Medtronic incorporate a threshold assessment based on ER: the Pacing Threshold Search (ambulatory) and Capture
Management Threshold Test (bedside). During the procedure, the threshold at the Rheobase is determined at 1 ms by amplitude decrement until loss of capture followed by amplitude increment until capture confirmed. The Chronaxie is then determined by doubling the programmed amplitude, and decreasing the pulse width (followed by increasing amplitude to capture). A recommended pacing setting is then determined. The physician can use the ambulatory threshold data to automatically adjust the threshold (adaptive), or to use for monitoring only, or the algorithm can be turned off. A minimal adapted output needs to be programmed. The ventricular capture management can be activated once every 15 minutes for 42 days, and is not a beat-by-beat threshold tracking algorithm. In a predictive analysis, the device longevity of Medtronic Kappa 700 serues pacemakers featuring three automatic algorithm including Capture management, Sinus Preference, and Search AV was tested in 22 patients. The overall longevity with all three features programmed was estimated to be 106.3±8.4 months with 8.1±5.8 months more compared with that without Capture management and Search AV.

Summary

The increased sophistication in pacemaker technology has led to pacemaker features that average pacemaker implanters may not have the time either to understand or to program appropriately, as well as prolonged pacemaker interrogation time during regular follow-up. The automaticity of the optimization of many pacing parameters has significantly facilitated daily clinical management. In fact, programming of threshold can be simplified as the algorithm-determined threshold was significantly correlated with conventional threshold assessment. The main benefit of automatic pacing threshold algorithm is to maintain effective capture during threshold changes, to prolong device longevity and to ensure patient safety. These algorithms have been demonstrated to be safe and useful for prolonging device longevity.

References


