Long-term results of endocardial pacing with Autocapture™ threshold tracking pacemakers in children

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Abstract
Aim We aimed to evaluate the long-term results of endocardial pacing with Autocapture™ threshold tracking pacemakers in children.

Methods and results Implantation and follow-up data of 20 children with these pacemakers were retrospectively evaluated. The pacemakers were implanted subpectorally in five and subcutaneously in 15 patients. The indication for pacing was high-grade atrioventricular block in 18 cases. The mean age at implantation was $7 \pm 4.8$ years. Four patients were pacemaker dependant (heart rate $< 30$ bpm). At implantation, the mean pacing threshold was $0.5$ V at $0.5$ ms. The mean evoked response (ER) signal was $8.5 \pm 3.6$ mV, and the polarisation signal (PS) was $< 1$ mV in 15 patients and $1-2$ mV in five patients. During the mean follow-up period of 60 months, mean ER signal decreased significantly to $7.7 \pm 6.3$ mV at 24 months and $6.5 \pm 2.5$ mV at 60 months ($P < 0.05$). In four of 15 patients (26.6%), with a predischarge PS value of $< 1$ mV, it increased between 1 and 2 mV over time. During follow-up, autocapture function was deactivated in six (30%) patients; due to inappropriate ER/PS values in four and due to severe muscle twitching in two with subpectorally implants. These problems occurred during a median period of 21 months after implantation. Generators were replaced in three patients with Microny pacemakers because of battery depletion at 54, 66 and 78 months. In two of them autocapture function had been working since implantation. In seven of 10 patients, who completed $\geq 60$ months of follow-up, battery impedances were still at the predischarge level.

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Conclusions

Autocapture function works well in most children at implantation. Mean ER signal significantly decreases over time despite stable pacing parameters. Autocapture function may become nonoperational due to decreased ER signal in some patients. Muscle twitching may be an important problem that may result in discontinuation of autocapture function in children with subpectoral implants.

Introduction

The "Autocapture™" (AC) (St. Jude Medical-Pacesetter AB, Veddesta, Sweden) feature is a programmable function that provides automatic capture verification and adjustment of the pacemaker output settings by a constant output safety margin of only 0.3 V instead of the traditional 100% [1,2]. There are many reports of short and medium term results and efficacy of these devices in adults [3–7], but there are only few clinical studies concerning their use with epicardial leads in children [8–12]. Theoretical calculations, based on chronic stimulation thresholds, suggest that AC may markedly prolong battery longevity [1,2,10,13,14]. These studies indicate that in most of the patients AC can be activated before discharge and it functions well in short term follow-up [11]. But, there is no study concerning transvenous leads with these pacemakers in children, and changes in AC function in the long term. The purpose of this study was to evaluate the long term results of endocardial pacing with AC pacemakers in children.

Methods

Patients

From December 1995 to November 2002, 29 children received AC pacemakers. Nine of them were excluded from the study because of loss of follow-up in four, pacemaker system explantation in four (due to restoration of sinus rhythm, generator change due to infection and lead dislodgement) and a follow-up period <12 months in one.

Pacing system and AC algorithm

The implanted devices (Microny™ SR+, Regency™ SR+ and Entity™ DR, St. Jude Medical-Pacesetter AB, Veddesta, Sweden) were pacemakers with AC function. The AC algorithm has been previously described in detail. It works with unipolar pacing and bipolar sensing [1,6]. In all patients a low polarization, low threshold bipolar lead (Membrane E 1400T, 1450T or Membrane EX 1470T, St. Jude Medical-Pacesetter AB, Veddesta, Sweden) was used, as recommended [15,16]. All devices and leads were first implants.

Measurements at implantation

Leads were implanted in ventricular sites from where satisfactory intrinsic R wave amplitude, lead impedance and pacing threshold, at 0.5 ms pulse duration, values could be measured. Autocapture parameters were not measured, and AC was programmed "Off”.

Follow-up protocol

The patients were discharged from hospital between the second and fifth days after implantation and follow-ups were performed at first, third and sixth month and then every six months. Each evaluation included routine physical examination, 12-lead electrocardiogram, chest X-ray, and the assessment of measured data including threshold with VARIO and autocapture tests at 0.49 ms, lead impedance, R wave amplitude, evoked response (ER) signal and polarisation signal (PS) measurements. Autocapture was programmed “on” at the first visit in which ER/PS test results were suitable. At the time of AC activation, pacing and sensing configurations were adjusted to be unipolar and bipolar, respectively. In patients in whom AC was not recommended, pulse amplitude was programmed with a 100% safety margin above the pacing threshold. At each visit, the ER sensitivity was adjusted to the value that was proposed by the analyser depending on the ER/PS test. Pacemaker checks were made using two different programmers (Pacesetter System Inc; APS-II Model 3004, Software version 3204c, APS-III Model 3500, Software versions 1.2, 3.1.1, 4.0).

Statistical analysis

Simple regression was used for statistical analysis. When needed, the t-test (Wilcoxon test) was used to compare means. A P value < 0.05 was considered.
significant. The mean values are given with standard deviation (mean ± SD).

Results

Twenty patients formed the study group. The mean age at implantation was 7.0 ± 4.8 years (range 1–16 years, median 6.5 years), and 18 patients were male. Eighteen of the patients required permanent pacemaker implantation due to high-grade atrioventricular block. Three types of pacemaker with AC were implanted (Table 1).

Implantation data

At the time of implantation, the pacing threshold was <1 V at 0.5 ms in all patients (mean 0.5 ± 0.2 V, range 0.3–0.9 V, median 0.5 V), the mean lead impedance was 608 ± 169 Ω (range 460–980 Ω, median 535 Ω) and the mean intrinsic ventricular R wave was 8.3 ± 2.5 mV (range 3.8–13.1 mV, median 8.1 mV). Measurements were made during unipolar pacing. Four patients (20%) were pacemaker dependent with an intrinsic heart rate < 30 beats per minute.

At predischarge evaluation, the mean ER signal was measured as 8.5 ± 3.6 mV (range 1.9–14.6 mV, median 8.5 mV). The PS was <1 mV in 15 and between 1 and 2 mV in five patients (20%). Because of a low ER signal, AC could not be activated in only one (5%) patient.

Follow-up data

The mean follow-up period was 60 ± 23 months (range 12–90 m, median 66 m). In 12 patients, follow-up period was ≥60 months. Mean pacing threshold increased significantly at the first month (1.1 ± 0.7 V at 0.49 ms, range 0.3–2.7 V, median 1 V) compared with predischarge (P < 0.01). It did not change significantly after the first month (f = 0.014, P > 0.05). A significant increase was observed in lead impedance at the first compared with predischarge. Thereafter, it did not change significantly (f = 3.896, P = 0.05) (Fig. 1).

Changes in ER signal, PS and AC function

A slow, but statistically significant decrease in mean ER signal was observed during follow-up. During the mean follow-up period of 60 months, mean ER signal decreased significantly from 8.5 ± 3.6 mV to 7.7 ± 6.3 mV at 24 months and 6.5 ± 2.5 mV at 60 months (f = 5.839, P < 0.05) (Figs. 1 and 2). In four of 15 patients (26.6%), with a predischarge value of <1 mV, PS increased to between 1 and 2 mV during follow-up. The patient, in whom AC function was not activated immediately after implant, never became suitable for AC. In three additional patients (Table 2, patients 18–20) the analyzer system did not recommend AC at 18th, 24th and 48th months due to inadequate ER/PS values.

Two patients with subpectoral implants developed severe muscle twitching, causing arm movements, at sixth and 54th months, and despite suitable ER/PS values AC could not be maintained. In these patients muscle twitching was not related to backup pulses but to unipolar pacing with subpectoral implants. Bipolar pacing after deactivation of AC solved the problem. A total of six patients (30%) were not suitable for AC at the last follow-up (Table 2).

Battery status

During the long-term, generators were replaced in three patients due to battery depletion (Table 3). In two of them AC was working. In one battery depletion occurred at 54 months in spite of low (<1 V) threshold values and functioning AC.

Ten patients reached ≥60 months with their pacemakers showing no battery depletion. In seven of them AC was working from implant (median follow-up period was 78 months). Two of them, with Microny units, showed battery impedance rises.

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**Table 1 Clinical and pacemaker data of patients**

<table>
<thead>
<tr>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)²  7.0 ± 4.8 (1–16)</td>
</tr>
<tr>
<td>Weight (kg)²  22.3 ± 13.7 (8.6–53)</td>
</tr>
<tr>
<td>Gender (male/female)  18/2</td>
</tr>
<tr>
<td>Indication for pacemaker</td>
</tr>
<tr>
<td>High grade atrioventricular block 18</td>
</tr>
<tr>
<td>Sinus node dysfunction 1</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy 1</td>
</tr>
<tr>
<td>Pacemaker model</td>
</tr>
<tr>
<td>Microny SR+ (2425T/2525T) 9 (7/2)</td>
</tr>
<tr>
<td>Regency SR+ 10</td>
</tr>
<tr>
<td>Entity DR+ 1</td>
</tr>
<tr>
<td>Implantation site</td>
</tr>
<tr>
<td>Subcutaneous 15</td>
</tr>
<tr>
<td>Subpectoral 5</td>
</tr>
</tbody>
</table>

² Values are given as mean ± SD (range).
(>1 kΩ at 54th and 72th months) or low battery voltage was found.

**Discussion**

Prolongation of pacemaker longevity is a worthy goal in reduction of the cost of cardiac pacing. Programming the stimulation output to a value that will provide a 2:1 voltage safety margin, results in excessive battery drain thereby reducing battery life. On the other hand, this safety margin does not always guarantee safe pacing, since such patients may face various adverse influences on capture threshold [13]. So, pacemakers with the capability of beat-to-beat capture verification represent an important development in pacing technology. Although several techniques have been described in an effort to identify ventricular capture [17–22], the first clinically successful implementation of threshold tracking pacing was AC. In short and medium term studies and using theoretical longevity calculations, available data suggest that AC works well, and may provide a significant improvement in pacemaker longevity [1–3,10,13,14]. Although there have been some reports of use of epicardial leads in children [8–12], most of the studies with AC have been performed in adults. There is no study concerning endocardial use and the long-term results of these pacemakers in children. The present study is the first to give important clues about changes in ER, PS signal, AC function and device longevity in children.

Threshold tracking pacing is based on an accurate detection of the ER signal to determine whether or not a pacemaker stimulus has captured the myocardium. Following a pacemaker stimulus, PS always occurs. Accurate detection of the ER signals while precluding detection of PS after the pacemaker stimulus is a prerequisite for appropriate function of AC pacing systems. Autocapture can only be activated in the presence of a suitable ER/PS ratio [1]. AC can be activated at predischarge in as many as 94.5% of patients [4]. Some
studies have found stable mean ERs and PS in medium term follow-up [3,11]. Lau et al. [4] reported a significant increase in mean ER signals, with stable PS. However, Schuchert et al. [23] reported three different patterns in ER signals; stable, significantly increased and significantly decreased. The most important is the third group with decreased ER signals, because, this may result in loss of AC function. ER and PS monitoring must be performed to detect the changes over time. In our study, the mean ER signal showed a significant decrease in follow-up, and some patients lost AC function due to significantly decreased ER signals. It is an important finding that AC may become nonoperational, as long as 48 months after implantation, because of significantly decreased ER signals, or marginal PS values.

The use of a bipolar lead with low polarization properties is mandatory in order to obtain reliable PS. Sensing is programmed bipolar in order to avoid interference from muscle activity, whereas, pacing has to be unipolar to increase the signal-to-noise ratio and to avoid generation of afterpotentials on the ring electrode. Because of the requirement for

Figure 2  The evoked response signals at first and last visits of all patients.

| Pt. 15 | 7 | CHB | 16 | 2.8 mV | PreD | 0.5 | 4 | 1.95 | 1.1 |
| Pt. 16 | 4.5 | 15.5 | CHB | 6th m | 0.5 | 1.2 | 6.4 | 10.9 | 1.7 |
| Pt. 17 | 2 | 9.6 | SHB | 54th m | 0.5 | 1.2 | 6.9 | 11.2 | 1.6 |
| Pt. 18 | 7.5 | 24 | CHB | LPSM < 2.8 mV | 0.5 | 0.9 | 4.9 | 11.5 | 1.1 |
| Pt. 19 | 2 | 11.8 | SHB | 24th m | 0.9 | 1.34 | 4.2 | 8.4 | 1.2 |
| Pt. 20 | 10 | 32 | CHB | or LPSM < 2.8 mV | 0.5 | 1 | 4.2 | 8.4 | 1.2 |

Table 2 Clinical and pacemaker data of patients in whom Autocapture was deactivated

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Weight (kg)</th>
<th>Arrhythmia</th>
<th>Implantation site</th>
<th>Reason for deactivation</th>
<th>Time of deactivation</th>
<th>Pacing Threshold (PreD-ToD) (V)</th>
<th>R wave (PreD-ToD) (mV)</th>
<th>ER signal (PreD-ToD) (mV)</th>
<th>PS (PreD-ToD) (mV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt. 15</td>
<td>16</td>
<td>CHB</td>
<td>16</td>
<td>MT</td>
<td>4th m</td>
<td>0.3-1.2</td>
<td>13.6-16.2</td>
<td>6.4-5.2</td>
<td>1.1-1.03</td>
</tr>
<tr>
<td>Pt. 16</td>
<td>15.5</td>
<td>CHB</td>
<td>6th m</td>
<td>ER ≤ 2.8 mV</td>
<td>0.6-1.2</td>
<td>10-9.7-7.6</td>
<td>1.9-1.5</td>
<td>1.5-1.2</td>
<td>1-1.2</td>
</tr>
<tr>
<td>Pt. 17</td>
<td>9.6</td>
<td>SHB</td>
<td>LPSM &lt; 1.7:1</td>
<td>ER ≤ 2.8 mV</td>
<td>0.5-1.2</td>
<td>11.2-4.2</td>
<td>8.4-4.1</td>
<td>11.5-2.5</td>
<td>1-1.2</td>
</tr>
<tr>
<td>Pt. 18</td>
<td>24</td>
<td>CHB</td>
<td>48th m</td>
<td>ER ≤ 2.8 mV</td>
<td>0.5-1.2</td>
<td>11.5-2.5</td>
<td>8.4-4.1</td>
<td>11.5-2.5</td>
<td>1-1.2</td>
</tr>
<tr>
<td>Pt. 19</td>
<td>11.8</td>
<td>SHB</td>
<td>18th m</td>
<td>ER ≤ 2.8 mV</td>
<td>0.5-1.2</td>
<td>11.5-2.5</td>
<td>8.4-4.1</td>
<td>11.5-2.5</td>
<td>1-1.2</td>
</tr>
<tr>
<td>Pt. 20</td>
<td>32</td>
<td>CHB</td>
<td>24th m</td>
<td>ER ≤ 2.8 mV</td>
<td>0.5-1.2</td>
<td>11.5-2.5</td>
<td>8.4-4.1</td>
<td>11.5-2.5</td>
<td>1-1.2</td>
</tr>
</tbody>
</table>

CHB: congenital heart block; ER: evoked response; LPSM: lead polarization safety margin; m: month; MT: muscle twitching; PreD: predischarge; PS: polarization signal; R wave: threshold tracking pacemakers.
unipolar pacing, pocket stimulation may occur during high output back-up pulses [1]. This feature has not been reported as a problem in current studies. However, in two of our patients AC function was deactivated because of severe muscle twitching, despite relatively low pacing thresholds, stable lead impedance values and in the absence of high output back-up pulses.

The projected longevity for the first pacemaker with AC (Microny™ SR+) is 7.1 years with default pacing parameters. It is longer for other pacemakers (Regency™, Entity™) with more battery capacity [1]. Pacemaker life spans may be considerably different from those estimated for some individuals. In one of our patients, in whom AC was active from discharge, the battery became depleted relatively early. In this patient, there were frequent high output periods, possibly due to micromovements of the lead tip, and is the reason for early battery depletion. In spite of this, five of seven pacemakers with AC on, had reached a median of 78 months without any sign of battery ageing.

In conclusion, AC works well in most children at implantation. Mean ER signal significantly decreases over time despite stable pacing parameters, and small but important increases in PS may occur. In some patients, AC may become nonoperational due to decreased ER signal or increased PS. In children with subpectoral implants, muscle twitching with troublesome arm movements may be an important problem causing discontinuation of AC.

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References


