Long-Term Performance of Active-Fixation Pacing Leads: A Prospective Study

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Background: Despite the increasingly widespread use of active-fixation leads, long-term clinical follow-up of pacing lead outcomes is lacking. The aim was to analyze pacing parameters over a 2-year follow-up. We performed a prospective observational study of consecutive new pacemaker implants using the 1488T St. Jude (100) and the Medtronic 5076 (100) active-fixation leads. Detailed analysis of pacing parameters was collected at implant, day 1, and 1, 3, 6, 12, 18, and 24 months.

Methods and Results: One hundred patients underwent implantation of 100 dual-chamber pacemakers. Initial pacing parameters in the ventricle were threshold 0.7 ± 0.2 V, R wave 12.0 ± 6.5 mV, and impedance 879 ± 224 Ω. Threshold increased significantly from day 1 (0.7 ± 0.2 V) to month 1 (0.9 ± 0.6 V, P < 0.01) and remained stable over the long term. Four of the 100 patients had a threshold > 2 V (mean 3.3 ± 0.9 V) all between day 1 and month 3. For all patients, R wave remained stable, but impedance declined significantly from day 1 (879 ± 184 Ω) to month 1 (677 ± 122 Ω, P < 0.01). There were no ventricular lead complications. Initial pacing parameters in the atrium were threshold 0.9 ± 0.3 V, P wave 3.3 ± 2.4 mV, and impedance 606 ± 144 Ω. Threshold remained stable over the long-term follow-up. One of 100 patients had a rise in threshold > 2 V (2.2 V) between day 1 and month 1. No patients underwent lead repositioning. Sensing and impedance remained stable over the long term. Patient follow-up was completed in 94% (6 unrelated deaths). There was an 8% incidence of atrial fibrillation.

Conclusion: Active-fixation leads are generally associated with stable long-term pacing parameters. (PACE 2006; 29:226–230)

pacemakers, pacemaker leads

Introduction

With a broadening of the indications for pacing and an aging population, the number of pacemaker implants is increasing.1,2 There is also a global shift toward the use of active-fixation leads, which offers the potential advantages of reduced lead dislodgement, rapid implantation, and easier lead extraction compared with passive-fixation leads.1,3–5 There has also been an interest in “selective” site pacing in the ventricle, fueled by concerns regarding the adverse outcomes of right ventricular apical pacing on left ventricular function.6,7 In the atrium, pacing from selective sites such as Bachmann’s bundle or the ostium of the coronary sinus may reduce the occurrence of atrial fibrillation.8–10 In both atrial and ventricular selective sites, active-fixation leads are required for secure attachment.

Despite the advantages of active-fixation leads, there has been a general reluctance toward their routine use, particularly in the ventricle due to concerns regarding higher stimulation thresholds. Although the stimulation thresholds at implant are generally higher than with tined leads, there is, however, a fall within the first 24 hours and the recorded levels remain stable in the short term.11 However, detailed information regarding long-term parameters with active-fixation pacing leads is limited. The aim of the present study was to perform a prospective study of the pacing parameters for active-fixation leads over a 2-year period.

Methods and Materials

Patients were recruited from a single institution (The Royal Melbourne Hospital). Patients who presented with conventional dual-chamber indications were eligible for inclusion in the study. Exclusion criteria included a history of previous device implantation, complex congenital heart disease, or patients were unable to attend locally for routine follow-up. The study population consisted of 100 patients undergoing implantation of 100 dual-chamber pacemakers between November 1999 and December 2002. The indications for permanent pacing are presented in Table I. The procedures were performed under local anesthesia including sedation using a combination of intravenous midazolam and fentanyl. All patients received preoperative antibiotics. For each patient,
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Table I.

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>St. Jude 1488T (n = 50 patients)</th>
<th>Medtronic 5076 (n = 50 patients)</th>
<th>P-Value</th>
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<tbody>
<tr>
<td>Patient</td>
<td></td>
<td></td>
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<td>75 years</td>
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</tr>
<tr>
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<td>Pacing indications</td>
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<tr>
<td>High AV block</td>
<td>28</td>
<td>30</td>
<td>NS</td>
</tr>
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<td>14</td>
<td>14</td>
<td>NS</td>
</tr>
<tr>
<td>AF with pauses</td>
<td>3</td>
<td>4</td>
<td>NS</td>
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<tr>
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<td>5</td>
<td>2</td>
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<td>Pacing lead</td>
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<td>Acetate collar</td>
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<td>silicone</td>
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<td>Threshold &gt;2 V</td>
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<td>1</td>
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</tr>
</tbody>
</table>

58-cm bipolar active-fixation leads from the same company were used in both atrium and ventricle. The first 50 patients received the St. Jude 1488T (St. Jude Medical, St Paul, MN, USA). The next 50 patients received the Medtronic 5076 (Medtronic Inc., Minneapolis, MN, USA). The characteristics of the pacing leads are described in Table I. All ventricular leads were positioned at the right ventricular apex and atrial leads placed within or as close as possible to the right atrial appendage. Leads intraoperative testing was performed at a pulse width of 0.5 ms using a pacing system analyzer (Medtronic model 2090). All patients received a Telescronics dual-chamber, minute-ventilation sensor pulse generator with identical atrial and ventricular stimulation threshold measuring algorithms and calibrated electrograms for measuring the P and R waves (Telescronics, St. Jude Medical). The lead impedance was automatically measured at interrogation.

Follow-Up

Stimulation threshold, sensing, and impedance were performed at day 1, and 1, 3, 6, 12, 18, and 24 months.

Statistical Analysis

Data are expressed as mean ± SD. Statistical analysis was performed utilizing GB-Stat software (Version 6.5, Dynamic Microsystems Inc., Silver Spring, MD, USA). Comparisons between groups were performed using either a Student’s t-test or Mann-Whitney U-test. Comparisons over time were performed by ANOVA, with post hoc analysis using the Tukey Kramer procedure. Statistical significance was assumed at P < 0.05.

Results

Ventricle

The initial pacing parameters at the time of implantation were stimulation threshold 0.7 ± 0.2 V, R wave 12.0 ± 6.5 mV, and impedance 879 ± 224 Ω. The stimulation threshold increased significantly from day 1 (0.7 ± 0.2 V) to month 1 (0.9 ± 0.6 V, P < 0.01) and remained stable over long-term follow-up (Fig. 1A).

The R wave at day 1 (6.9 ± 2.5 mV, P < 0.01) was stable over long-term follow-up (Fig. 2). Impedance declined significantly from day 1 (879 ± 184 Ω) to month 1 (677 ± 122 Ω, P < 0.01) and then remained stable (Fig. 3).

High Stimulation Thresholds

Four of the 100 patients had a significant rise in threshold beyond 2 V during the study period. The indications for pacing were: paroxysmal atrial fibrillation and symptomatic pauses in 2, high-degree AV block in 1, and sick sinus syndrome in 1. There were 3 SJM 1488T and 1 Medtronic 5076 ventricular leads positioned at the RVA. In all 4 patients the stimulation threshold increased between implantation (0.7 ± 0.2 V) and month 1.
Figure 1. (A) Long-term results for stimulation threshold in the atrium and ventricle over time (D = day, M = month). A significant fall in stimulation threshold occurred in the atrium from day 0 to day 1. A significant rise in stimulation threshold occurred in the ventricle from day 1 to month 1. (B) A comparison of long term stimulation thresholds between the St. Jude Medical and Medtronic pacing leads (D = day, M = month).

(3.0 ± 1.4 V, P = 0.15). The stimulation threshold remained stable between months 3 and 24 (2.9 ± 0.1 V). No patients underwent lead repositioning because an adequate pacing safety margin could be programmed and minimal ventricular pacing was achieved by prolonging the AV delay. There were no ventricular lead dislodgements.

Pacing Lead Type

At day 1 there was no significant difference in stimulation thresholds between the Medtronic 5076 (0.8 ± 0.4 V) and St. Jude Medical 1488T (0.7 ± 0.2 V) pacing leads. At 3 months the stimulation threshold of the Medtronic 5076 (0.8 ± 0.4 V) was significantly lower than the St. Jude 1488T (1.0 ± 0.4 V, P < 0.05). This difference remained statistically significant at 6, 12, and 24 months (P < 0.01, Fig. 1B).

The stimulation threshold for the St. Jude 1488T ventricular pacing lead increased significantly from month 1 to 12 (P = 0.01), 18 (P < 0.01), and 24 (P < 0.01) months. There was no significant increase in stimulation threshold over time for the Medtronic 5076 (Fig. 1B).

Atrium

The initial pacing parameters at the time of implantation were: stimulation threshold 0.9 ± 0.3 V, P wave 3.3 ± 2.4 mV, and impedance 606 ± 144 Ω. The stimulation threshold at day 1 was 0.8 ± 0.2 V, P < 0.01 and remained stable over long-term follow-up (Fig. 1A). Atrial lead assessment was limited in 8% of patients due to the occurrence of paroxysmal or permanent atrial fibrillation.

Atrial sensing remained stable over long-term follow-up (Fig. 2).

Atrial impedance remained stable over long-term follow-up (Fig. 3).

High Stimulation Thresholds

One of 92 patients with a St. Jude 1488T pacing lead had a significant rise in stimulation threshold beyond 2 V between implantation (0.9 V) and month 1 (2.2 V). The indication for pacing was high-degree AV block. Stimulation threshold remained stable between 3 and 24 (1.8 V) months. The atrial lead was not repositioned as an adequate pacing safety margin could be programmed and the patient developed atrial fibrillation after 1 year.
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Figure 3. Pacing lead impedance in atrium remained stable over long-term follow-up. Pacing lead impedance in the ventricle declined significantly from day 0 to day 1.

Pacing Lead Type

At day 1 there was no significant difference in stimulation thresholds between the Medtronic 5076 (0.8 ± 0.2 V) and St. Jude Medical 1488T (0.7 ± 0.2 V) pacing leads. At 3 months the stimulation threshold of the Medtronic 5076 (0.7 ± 0.1 V) was significantly lower than the St. Jude 1488T (0.9 ± 0.3 V, P < 0.05). A difference in stimulation threshold remained over follow-up (Fig. 1B). There was no significant increase in the stimulation threshold over time for the St. Jude 1488T or the Medtronic 5076 pacing lead positioned in the atrium.

Follow-up was completed in 94% of the patients with 6 unrelated deaths during the 2-year observation period.

Discussion

In a large patient population active-fixation leads were associated with stable pacing parameters over a 2-year follow-up. A rise in stimulation threshold occurred in 3% of patients typically in the first 3 months following implantation. No patients required lead reposition as a result of a persistent high threshold. In this study cohort, there were no atrial or ventricular lead dislodgements.

Stimulation Threshold

The long-term safety of passive-fixation leads is well established, yet there is limited follow-up on active-fixation leads. Kistler et al. demonstrated an acute fall in stimulation threshold using steroid-eluting active-fixation leads, which was most evident in the 4 minutes following deployment of the fixation device. A gradual decline continued over the next 24 hours. The stimulation threshold remained stable at short-term follow-up. The immediate rise (hours) in stimulation threshold is likely to represent acute myocardial injury. The later rise (days) in stimulation threshold is a direct result of inflammation at the electrode-tissue interface. The acute response includes edema, fibrin deposition, capillary dilatation, leukocyte migration, and phagocytosis resulting in lysosomal release of numerous inflammatory mediators that can kill nearby monocytes that produce microscopic levels of necrosis.

The mechanical design of a pacing lead is clearly important in the development of the inflammatory response. Whereas an electrode supported by a passive-fixation device lying gently against the endocardium causes minimal local irritation, a screw-in active-fixation design will exacerbate injury to the endomycardium and provoke or accelerate inflammation. It was not surprising therefore that glucocorticoids and, in particular dexamethasone, resulted in a significant reduction in both acute and chronic stimulation thresholds following implantation of both active- and passive-fixation leads.

In the present study a significant difference was observed in the long-term stimulation thresholds of the two pacing leads. However, although a statistical difference was apparent the absolute difference in stimulation thresholds between the two lead types was 0.2 V and did not affect the programming of adequate safety margins. The observation may be explained by a smaller electrode, Medtronic 5076 (4.2 mm²) compared to the St. Jude 1488T (8 mm²). The difference in the steroid compound between the two leads is unlikely to be a factor as an earlier short-term study demonstrated no difference in lead performance. The steroid delivery systems are very similar although one is called a plug and the other a collar.

Advantages of a Wider Acceptance of Active-Fixation Leads

Active-fixation leads have the potential advantages of reduced lead dislodgement, rapid implantation, implantation at selective sites, and easier lead extraction. In the present study involving the implantation of 200 active-fixation leads, there was a zero dislodgement rate. Hidden-Lucet et al. reported no dislodgements in 38 patients who received Guidant 4244/4245 active-fixation leads and were followed up for 14 months. This compares favorably with our previously reported dislodgement rate for passive-fixation leads of 0% in the ventricle and 1–2% in the atrium.

Active-fixation leads are particularly useful when aiming to implant leads away from the traditional sites of the right atrial appendage and right ventricular apex. The right ventricular apex has been a convenient target for the implanter offering
stability in the absence of fixation mechanisms and ready accessibility. The quest for selective site pacing in the ventricle has been fueled by the adverse outcomes of right ventricular apical pacing on left ventricular function although there are conflicting results regarding the perceived benefits of outflow tract pacing over apical pacing. In a randomized prospective study Tse et al. demonstrated less myocardial perfusion defects and a higher ejection fraction in patients paced from the RVOT compared to the RVA followed for 18 months. In patients with sinus bradycardia and paroxysmal atrial fibrillation, implantation of an active-fixation lead at the interatrial septum has demonstrated a reduction in atrial fibrillation recurrences. In addition, pacing at Bachmann’s bundle has also demonstrated a reduction in atrial fibrillation. Currently, atrial septal pacing is not widely performed due to limitations in technology and delivery systems.

The possibility of lead extraction is also an important consideration given the increasing numbers of implantable cardioverter defibrillators (ICD) and associated interactions with old pacing leads. Extraction of chronically implanted leads is more successful with active-fixation leads than passive-fixation.

The present study provides long-term data supporting the safety and reliability of active-fixation pacing leads important in the context of their potential advantages and increasing use.

**Conclusion**

Active-fixation leads are generally associated with stable long-term pacing parameters. A rise in lead threshold occurred in 3% of patients and was typically observed in the first 3 months following implant.

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References