Clinical Surveillance of a Thin Bipolar Pacing Lead

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A total number of 415 co-radial, bipolar pacing leads (189 atrial leads; 226 ventricular leads) were implanted in 228 patients between November 1994 and July 1999. Mean pacing thresholds at the implantation were normal at 0.6 V in the atrium and at 0.4 V in the ventricle with a pulse duration of 0.4-0.5 ms. Lead impedance was relatively low (337-447 ohms for atrial leads; 369-459 ohms for ventricular leads) at the implantation and during the follow-up periods. No definite failure in lead materials was observed in either atrial or ventricular leads (mean follow-up of 19.7 and 19.2 months, respectively; up to 52.9 months for both leads). Predicted clinical surveillance up to 10 years calculated statistically showed that the upper 95% confidence limit was a constant of 100%. The lower 95% confidence limits at 5, 7, and 10 years were estimated to be 98.0%, 97.2%, and 96.0%, respectively. From the present study, the ThinLine™ lead is reliable for both sensing and pacing thresholds, and has excellent predicted lead longevity. Nevertheless, further observation is required regarding cost performance, such as early replacement of the pacemaker generator, because of the lower pacing lead impedance. (Jpn Circ J 2000; 64: 933-936)

Key Words: Bipolar; Lead performance; Lead survival; Longevity; Pacing lead

Surveillance in relation to patient safety and cost-performance conducted on permanent pacing leads is an important factor in the selection of pacing leads. The main disadvantage of the bipolar pacing leads compared with unipolar pacing leads is the thick diameter and stiffness of the lead, resulting in relatively higher incidence of complication and lead troubles.1-6 The ThinLine™ bipolar pacing leads (Intermedics, Angleton, TX, USA) have a revolutionary design consisting of 2 separately isolated, helically wound (co-radial), parallel coils, resulting in a lead body diameter of 4.7 French. Initial clinical experience of these leads has demonstrated significant clinical advantages, including superior electrical and handling characteristics.7-9 However, there are no available data describing the long-term follow-up of this lead, so the present study investigated the clinical outcome of long-term follow-up and calculated statistically its 10 years predicted clinical surveillance.

Methods

A total number of 415 ThinLine™ leads (189 atrial leads, model 432-04; 226 ventricular leads, model 430-10) were implanted in 228 patients (113 males, 115 females; mean age at implantation, 74±9.5 years (mean ± SD)) between November 1994 and July 1999 at University Hospital, University of Occupational and Environmental Health, Japan. The baseline heart diseases requiring pacemaker implantation are listed in Table 1.

Pacing and sensing thresholds, lead impedance, and battery status of generators (Dash, Relay, Marathon SR, or Marathon DR; Intermedics) were measured annually using the RX5000 programmer (Intermedics). Threshold rise for pacing was defined as more than 0.5 ms of pulse duration with constant pulse amplitude of 2.5 V, or more than 0.16 ms of pulse duration with constant pulse amplitude of 5.0 V, as previously described by Gilksin et al.10 Clinical events were either observation corrected by reprogramming the pulse generator, or complications requiring surgical intervention. Lead lifetime was defined as the time from implant to the first lead-event, which was any electrical or mechanical failure of the lead. Lead failure was determined either by either a pacing or sensing failure, or both, accompanied by an abrupt impedance change, and/or by X-ray examination.

For the lead survival analysis, no distinction was made between atrial and ventricular leads, because any electrical failure would be attributed to a compromise of the lead body, which is essentially the same for both lead models. Each lead lifetime was censored at the earliest of (1) the date of the last follow-up, (2) patient death (32 patients, all of which were not lead-related), (3) electrical abandonment because of reprogramming for a non-lead-related event (13 leads), or (4) the date that the patient was lost to follow-up (3 patients). The lower bound on the 95% confidence interval for the cumulative survival was calculated using the following

Table 1 Indications for Pacing in 228 Patients

<table>
<thead>
<tr>
<th>Indication</th>
<th>Patients</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSS</td>
<td>109</td>
<td>47.8</td>
</tr>
<tr>
<td>High-degree AV block</td>
<td>75</td>
<td>32.9</td>
</tr>
<tr>
<td>AF bradycardia</td>
<td>37</td>
<td>16.2</td>
</tr>
<tr>
<td>Other*</td>
<td>7</td>
<td>3.1</td>
</tr>
</tbody>
</table>

*HOCM: 1; Long QT syndrome: 2; AF = AV block: 3; SSS = AV block: 1. SSS, sick sinus syndrome; AV, atrioventricular; AF, atrial fibrillation; HOCM, hypertrophic obstructive cardiomyopathy.
formula:

Lower Bound = exp (m × ln 0.05/f)

where m is the number of months for the predicted survival, and f is the number of follow-up months.

Summarized data are expressed as mean ± standard deviation (SD) with N representing the number of patients or leads except otherwise noted.

### Results

**Implantation Data**

Acute sensing threshold values at implantation were 3.7±1.7 mV (range, 0.6–11.4 mV) for P wave sensing and at 12.1±4.7 mV (range, 3.4–39.0 mV) for R wave sensing. Pacing thresholds with a pulse duration of 0.45–0.50 ms were 0.6±0.2 V (range, 0.3–2.2 V) in the atrium and 0.4±0.2 V (range, 0.2–2.5 V) in the ventricle. Lead impedance measurements were 337±59 ohms (range, 220–532 ohms) for atrial leads and at 446±85 ohms (range, 250–720 ohms) for ventricular leads. There were no major acute complications such as lead dislodgement or myocardial perforation, which have been reported as infrequent complications, in any of the 228 patients.

**Late Complications**

There were 12 patient-related observations and 1 patient-or generator-related observation during the follow-up periods: (1) 7 patients were reprogrammed to VVI or VVIR mode from DDD mode because of atrial fibrillation (AF), (2) 2 patients were reprogrammed to VVI mode from DDD mode because of atrial lead dislodgement, (3) 2 patients were reprogrammed to VDD or VVIR mode from DDD mode because of an increase in atrial pacing threshold, (4) 1 patient was reprogrammed to AAI mode from DDD mode because of intact V-A conduction confirmed during the first follow-up session, and (5) 1 patient was reprogrammed to VVI mode from DDD mode because of muscle twitching.

**Long-Term Follow-up of Pacing Thresholds**

Mean bipolar pacing thresholds, measured by decrementing pulse duration at a pulse amplitude of 2.5 V, are shown in Table 2. Mean atrial pacing thresholds shows constant 0.09±0.04 ms, 0.08±0.03 ms, 0.08±0.02 ms, 0.08±0.02 ms, and 0.11 ms at 1 year, 2 years, 3 years, 4 years, and 5 years follow-up, respectively. Atrial pacing threshold rise to the point of non-capture with constant pulse amplitude of 2.5 V occurred in 26 of 170 patients (15.3%). In 2 of those 26 patients, the atrial leads were electrically abandoned because of thresholds exceeding the safety margin (8.1 V and 0.37 ms in 1 patient, 8.1 V and 1.1 ms in another patient). Ventricular pacing thresholds were constant 0.09±0.03 ms, 0.08±0.03 ms, 0.08±0.03 ms, 0.08±0.02 ms, and 0.10±0.02 ms at 1 year, 2 years, 3 years, 4 years, and 5 years follow-up, respectively. Ventricular pacing threshold rise to the point of non-capture with constant pacing amplitude of 2.5 V occurred in 12 of...
220 patients (5.5%). However, ventricular lead threshold rises were within the safety margin and no ventricular leads were abandoned. No patients experienced rising pacing thresholds after the 1-year follow-up period.

**Long-Term Follow-up of Sensing Thresholds**

Sensing thresholds during the follow-up periods are summarized and listed in Table 3. Because of the limitation of an automatic sensing test, sensing amplitude are displayed as median values. Median atrial sensing thresholds were more than 3.5 mV during the 1-4-year follow-up period. Sensing failure was observed in 2 leads accompanied by lead dislodgement as described earlier. Mean ventricular sensing thresholds were more than 7 mV during the 1-5-year follow-up period.

**Long-Term Follow-up of Lead Impedance**

Lead impedance during the follow-up periods is summarized and listed in Table 4. Mean atrial lead impedance was 417±114 ohms, 450±130 ohms, 433±99 ohms, 446±124 ohms, and 431±130 ohms at 1 year, 2 years, 3 years, 4 years, and 5 years, respectively. Mean ventricular lead impedance was 458±108 ohms, 442±96 ohms, 420±85 ohms, 413±65 ohms, and 369±68 ohms at the same times, respectively. Although there were some variations in the measured lead impedances, mean values of lead impedance were considerably low at implantation and throughout the follow-up periods. No abrupt impedance change was observed in any patient.

**Lead Survival (Fig 1)**

Mean follow-up was 19.7±14.8 months for atrial leads and 19.2±14.6 months for ventricular leads (range, 0.2–52.9 months for both). Because no lead-related events were observed in the present study, the combined lead survival provability up to 10 years was estimated at a constant 100%, where the upper 95% confidence limit was 100%. On the other hand, the lower 95% confidence limit at 5, 7, and 10 years was estimated to be 98.0%, 97.2%, and 96.0%, respectively.

**Discussion**

The Intermedics Irox ThinLine™ bipolar leads (models 432-04 and 430-10) consist of 2 separately insulated, helically wound (co-radial), parallel coils. One of the proposed advantages of these leads is the double protection of the coil, namely, the electrode coil is made of iridium oxide-coated titanium covered with an insulator, ethylene-tetra-fluoro-ethylene (ETFE), and the helically wound anode and cathode coils are covered with 55D polyurethane. It has been reported that the fatigue limit of the coil is higher than conventional coils and that the dielectric strength of the inner insulator (ETFE) is about 3 times stronger than silicone. Another advantage of this lead technology is that the design results in a thinner lead-body diameter (4.7F) compared with conventional bipolar leads.

The data obtained during implantation of the pacemaker was favorable and were consistent with previous reports for intrinsic wave amplitude, pacing threshold and lead impedance. In addition, there were no lead material failures, including insulation or conductor breakage, in the present study. Longer surveillance extrapolated up to 10 years showed encouraging results with this lead.

Several beneficial effects arise with the use of this lead. First, the thinness of the bipolar lead, the diameter of which is compatible with unipolar leads, may reduce friction between the clavicle and the first rib. In the present study, we implanted pacing leads using the subclavian vein puncture method in all patients, with subclavian venography performed prior to the implantation of the pacing lead(s) for easier insertion in all patients. Nevertheless, the subclavian crush syndrome has been reported, even when ThinLine™ leads were used. Using the cephalic vein may reduce lead material failure and an approach from the outer side of the subclavian vein to avoid narrow thoracic inlet is also recommended. In addition, the incidence of tricuspid valve regurgitation induced by the ventricular pacing lead would be decreased with the use of this thin lead. In fact, there were no episodes of clinical right heart failure or massive tricuspid valve regurgitation throughout the follow-up period in the present study.

During the follow up period of this study, lead impedance as a whole was found to be within an acceptable range without any significant deviations. However, thin bipolar leads showed a lower stimulation impedance (337–459 ohms in this report) compared with standards bipolar leads. Lower impedance of the lead may be the main disadvantage in relation to the cost-performance of the product! In fact, 2 of the patients in this study showed battery depletion within 5 years despite no evidence of sensing or pacing failure, increased pacing thresholds or a significant change in lead impedance. Because lead impedance, as well as pacing threshold, plays a major role in battery consumption and longevity, further follow-up is required to assess the cost-performance of this lead.

In conclusion, the present study indicates that the ThinLine™ bipolar lead is more reliable when compared with conventional bipolar leads and illustrates the effectiveness of this lead in clinical practice, including the minimization of lead fracture and right heart failure induced by tricuspid regurgitation. However, long term follow-up is required to assess its cost-performance resulting from its lower stimulation impedance.

**References**