Long-Term Follow-Up of Endocardial Pacing Leads Implanted with Extrathoracic Subclavian Venous Approach

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The extrathoracic subclavian venous approach is a new approach with the aim to exclude the disadvantages of the conventional subclavian venous approach that carries a risk of pneumothorax and may result in lead damage. We investigated long-term survival of the leads implanted by this new approach between May 1995 and June 2005. A total of 482 leads implanted in 309 patients were analyzed. In cases of patient death, meeting criteria for lead failure or difficulty of continuing follow-up for other reasons, the follow-up was terminated at that time. Therefore, the follow-up was complete for 358 leads (74.3%) and the mean follow-up time was 55.0 ± 32.1 months (range 1–122 months). The overall lead survival rate was 100% at 5 years and 98.3% at 7 years. This finding suggested that this approach might reduce the incidence of lead failure.

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Key words: Pacemaker, Endocardial lead, Lead failure, Lead survival

Introduction

The conventional subclavian venous approach (CSA) is still the most commonly performed method for implantation of pacemaker (PM) leads.1,2) It has been widely accepted for its speed, simplicity and ease for multiple leads insertion. Despite its popularity, the CSA has a well-known complication during the procedure and has the potential of damaging the lead.3–7) To avoid these peculiar troubles with the CSA, the extrathoracic subclavian venous approach (ESA) has gradually become popular in recent years.8–14) The aim of this study was to assess the long-term survival of leads implanted with the ESA.

Method

A total of 482 leads implanted in 309 patients...
using ESA were included in this analysis. Indications for pacing are showed in Table 1. When the lead placement failed using the ESA, the axillary venous approach (AA) was applied as an alternative to the ESA. All lead implants occurred between May 1995 and June 2005 and had at least 1 month of follow-up.

**Implant Technique**

The subclavian vein extends from the take-off of the internal jugular vein to the inferior margin of the first rib. It goes under the subclavius muscle and the costoclavicular ligament when it emerges from the thoracic cavity, and then becomes extrathoracic as it crosses the first rib. The subclavian vein becomes the axillary vein that continues to the brachial vein at the outer margin of the pectoralis major muscle. The placement of the lead via the extrathoracic subclavian vein and the axillary vein avoids possible entrapment in the soft tissues associated with the clavicle. Moreover since the extrathoracic subclavian vein is punctured on the first rib that blocks the needle to advance into the lung, the ESA minimizes the risk of pneumothorax and lung injury.\(^{6–17}\)

Infrequently puncturing of the extrathoracic subclavian vein was difficult because it was hidden just beneath the clavicle or constricted by the needle puncture. In such cases, the AA was applied as a second choice.\(^{15–17}\) (Figure 1).

With the ESA, after preparation and draping of the sterile field, 1% lidocaine is used for local anesthesia. An incision long enough to accommodate the pulse generator to be used is made approximately 2 cm below and parallel to the left or right clavicle. The incision is made from the junction of the medial and middle thirds of the clavicle to the outside. Dissection is carried out to the prepectoralis fascia, and a pocket is then developed in the prepectoralis fascia, using blunt dissection. The needle is inserted into the extrathoracic subclavian vein following venography with 10–15 ml of a 1:1 contrast medium: normal saline solution. After entry, a guide wire is placed and the dilator sheath set follows. The dilator and sheath are advanced over the guide wire into the subclavian vein and superior vena cava. After removal of the guide wire and dilator, the lead is advanced through the sheath. The lead is then placed within the chamber in the usual fashion.

**Follow-up**

Telemetric ECG monitoring was started immediately after the procedure, and biplane chest X rays were obtained the following day to rule out evidence of pneumothorax and lead dislodgement. Each patient was followed at 1 week, 1 month, 3 months, 6 months, 1 year and yearly after PM implantation to monitor lead dislodgement and infection and to

<table>
<thead>
<tr>
<th>Indication</th>
<th>No.</th>
<th>%</th>
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<tbody>
<tr>
<td>SSS</td>
<td>149</td>
<td>48.2</td>
</tr>
<tr>
<td>AVB</td>
<td>102</td>
<td>33.0</td>
</tr>
<tr>
<td>AF bradycardia</td>
<td>58</td>
<td>18.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>309</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 1 Indications for pacing in 309 patients.
reprogram to the appropriate pacing/sensing parameters.

Data Collection

The patient’s characteristics were retrospectively obtained from the medical records and follow up data from the PM clinic in our hospital. The mean age of the patients at the time of the implant was 75.6 ± 9.6 years (range 41–98). From a total of 309 patients, 149 (48.2%) were males and 160 (51.8%) were females and 27 (8.7%) were under 65 years. One hundred ninety-four leads (40.2%) were implanted in the atrium and 288 leads (59.8%) were implanted in the ventricle. The distribution of venous access was 92.3% extrathoracic subclavian (n = 445 leads) and 7.7% axillary (n = 37 leads). The implantations were performed mainly using the left-side approach (n = 294 patients (95.1%)).

Lead Models

In our patients, 46 pacing lead models, from 8 manufacturers were used. The lead mix relative to chamber and polarity was 34 (7.1%) ventricular unipolar, 221 (45.9%) ventricular bipolar, 18 (3.7%) atrial unipolar, 176 (36.5%) atrial bipolar, 3 (0.6%) single pass VDD unipolar and 30 (6.2%) single pass VDD bipolar leads. The distribution of lead polarity was unipolar in 55 leads (11.4%), and bipolar in 427 leads (88.6%). The fixation mechanism was active in 6 leads (1.2%), and passive in 476 leads (98.8%). The lead insulation materials were 477 (99.0%) silicone and 5 (1.0%) polyurethane (Table 2).

Lead Performance

Lead failure was defined as follows: (1) visible conductor fracture or insulation break seen radio graphically or observed in the operating room, (2) the lead impedance measured by telemetry indicating $\leq 200$ ohm, $\geq 2000$ ohm in conventional lead or $\geq 3000$ ohm in high-impedance lead and a drop of more than 50% from the initially measured value at follow-up visit 3–4 months after lead implantation, or (3) use of the lead being discontinued because of loss of capture, loss of sensing failure, oversensing, muscular stimulation and elevated thresholds.

Statistical Analysis

Cumulative survival rate, as an object of the atrial and ventricular leads implanted by the extrathoracic subclavian venous approach and/or the axillary venous approach, was calculated with Kaplan–Meyer method.

Result

The follow-up ended at the time of patient death, fulfilled criteria for lead failure, or impossibility of follow-up for reasons unrelated to lead failure (e.g., infection, transfer to other hospitals). All the follow-ups ended on June 31, 2005. Therefore, the follow-up was complete in 358 leads (74.3%). The mean follow-up duration was 55.0 ± 32.1 months (range 1–122 months). The overall lead survival for the lead population is shown in Table 3. Two cases of ventricular lead failure were discovered in this study. One case was a 56-year-old male who had a DDD-PM with an atrial bipolar lead and a ventricular unipolar lead. The impedance of his ventricular lead abruptly indicated $>9999$ ohm with no ventricular output 6 years after implantation. But the insulation break as well as the lead fracture could not be found in spite of careful examination on

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**Table 2** All implanted leads by polarity, insulation and fixation.

<table>
<thead>
<tr>
<th>Position</th>
<th>Polarity</th>
<th>Insulation</th>
<th>Fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unipolar</td>
<td>Bipolar</td>
<td>Silicone</td>
</tr>
<tr>
<td>Atrial</td>
<td>18</td>
<td>176</td>
<td>193</td>
</tr>
<tr>
<td>Ventricular</td>
<td>34</td>
<td>221</td>
<td>251</td>
</tr>
<tr>
<td>Single pass VDD</td>
<td>3</td>
<td>30</td>
<td>33</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
<td>427</td>
<td>477</td>
</tr>
</tbody>
</table>

**Table 3** Long-term survival of 482 endocardial pacing leads.

<table>
<thead>
<tr>
<th>Years from implant</th>
<th>Survival (No.)</th>
<th>Failure (No.)</th>
<th>Cumulative Survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>151</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>4</td>
<td>123</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>84</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>6</td>
<td>63</td>
<td>1</td>
<td>98.8</td>
</tr>
<tr>
<td>7</td>
<td>44</td>
<td>0</td>
<td>98.3</td>
</tr>
</tbody>
</table>
biplane chest X-rays, under fluoroscopy and in the operating room. Another case was an 89-year-old female whose ventricular bipolar lead showed a complete fracture just on the connector block in the generator pocket 6.5 years after implantation. Her back was severely bowed from working in her field, and it could be deduced that her repetitive arm motions had forced the generator head to bend the fractured part of the ventricular lead. In the former it was not quite clear why the lead was damaged and in the latter it was considered that the lead fracture was unrelated to the method for lead implantation. Therefore by excluding the latter case from this study, the overall lead survival rate was 100.0% at 5 years and 98.3% at 7 years. Since the number of patients with follow-up > 7 years is too small to allow reliable statistical analysis of probability of lead failure, their results are excluded (Table 3). No major complications related to this procedure such as pneumothorax, hemothorax, brachial plexus injury and vascular damage were observed.

Discussion

Lead survival may be linked to the implanted lead model, insulation material, polarity, route of venous access, age and gender registered.18–22) Further, differences of definitions and criteria make the comparison difficult in the literatures on lead survival. It is known that the unipolar leads survive significantly longer than the bipolar leads and that polyurethane leads might induce inner insulation failure due to metal ion oxidation.21,23–25) The leads used in this study were mostly bipolar (88.6%) with silicone rubber insulation (99.0%) and included no specific lead models that were reported to have a poor performance. Helguera et al. found no differences in lead failure for patient sex, lead polarity, fixation mechanism, implantation route, insulation material or types of polyurethane, and reported the overall survival rates of endocardial pacing leads implanted 5 and 10 years were 96.4% and 93.6%, respectively, using CSA and had 51 lead failures (2.2%) out of 2298 leads when applying their soft analysis for suspected structural lead failure similar to ours.20) Our lead survival was 100.0% at 5 years and 98.3% at 7 years with one lead failure (0.2%) out of 482 leads.

The cephalic vein cut-down approach (CCA) has longer lead survival than the CSA.3,5,7,18,22,25,26) The high rate of lead survival is based on the fact that the leads inserted by the CCA pass into the thorax through the subclavian vein cavity and thus are able to avoid being entrapped in the subclavian soft tissues. The literature suggests that lead fractures mostly occur as they pass just beneath the clavicle.3–18,22,25,27) Lead fracture might not only cause life-threatening events in PM dependent patients but also require invasive corrective procedures that are troublesome and possibly hazards in PM independent patients. Previously we examined on chest X-ray films with the upper extremity exercise of PM implant side in 116 patients and suggested that the CSA has a high incidence of two types of stress (i.e. subclavian traction of 84.6% and compression of 11.5%), while the ESA apparently has a lower stress rate with the traction of 3.1% and none of compression.27) There were no major complications including pneumothorax in the present study. Aggarwal et al. and Lloyd et al. reported the incidence of pneumothorax with CSA was low rate of 1.9% and 1.0% respectively,28,29) while Gardini et al. experienced no pneumothorax with the ESA.12)

Limitation

A limitation of the present study is the small sample size and that the implanted leads were mostly silicone rubber and bipolar leads. Abandonment by reprogramming for reasons other than lead failure (e.g., atrial fibrillation) was not covered.

Conclusion

The ESA recently has been accepted to a degree and much has been reported about its safety and effectiveness as a technique for lead insertion; however its acceptance seems to be insufficient. To the best of our knowledge, literature related to the long-term follow-up of the leads implanted with this approach has not yet been published. The present study showed that the ESA has a high lead survival rate in a 7-year period. Our data also suggested that the placement of endocardial leads using the ESA should be accepted as the standard method and the CSA should be discontinued as soon as possible because of poor lead survival and procedure-related risk. To establish whether the ESA boosts the lead survival, further investigations with a long-term follow-up are needed.

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