Long-Term Follow Up of Ventricular Endocardial Pacing Leads
Complications, Electrical Performance, and Longevity of 561 Right Ventricular Leads

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Summary
Five hundred and sixty-one endocardial pacing leads implanted in the right ventricle of 502 patients between 1971 and 1990 were followed for up to 17 years regarding their complications, stimulation threshold behavior, and overall longevity.

Lead tip dislodgement occurred in 16 leads (2.9%), in 14 of which dislodgement occurred within 2 months after implantation. The incidence of dislodgement was significantly smaller in tined leads than in nontined leads. Lead conductor fracture occurred in 19 leads (3.4%), in 15 of which fracture occurred within 5 years after implantation. Two particular sites of lead fracture were identified; i.e., one within the pacemaker pocket and the other at a particular point in the subclavian vein between the clavicle and the first rib. Fixation ligature in the former site and the venopuncture point for lead insertion in the latter site are thought to be related to lead fracture.

Other complications included insulator break in 3 leads (0.5%), exit block in 7 leads (1.2%), and poor sensing in 2 leads (0.4%).

The cumulative survival of leads was 94.1±2.7% (mean±95% confidence interval) at 5 years, 86.3±6.3% at 10 years, and 74.2±14.0% at 15 years after implantation.

The minimal stimulation threshold, lead impedance and R wave amplitude were all found to be stable for up to 10 years, and there were no tendencies toward higher stimulation threshold during the observation period of this study. (Jpn Heart J 34: 193–200, 1993.)

Key Words:
Pacemaker Lead fracture

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N recent years there has been remarkable progress in clinical pacing technology. The latest pulse generators offer multiple pacing modes and their longevity has been much prolonged by introducing lithium power sources. A number of studies have contributed to establishing suitable guidelines for optimum clinical pacing. On the other hand, there is a dearth of information on the structural and functional behavior of pacing leads, without which the integrity of effective and uncomplicated pacing cannot be assured. Hence there is a need to evaluate the behavior of pacing leads, particularly their long-term behavior. This study presents a follow-up of endocardial pacing leads implanted at our institution over a recent 19-year period. The findings are thought to increase our understanding of the behavior of pacing leads.

**MATERIALS AND METHODS**

Five hundred and sixty-one right ventricular endocardial pacing leads implanted in 502 patients between September, 1971 and August, 1990 were the subject of this study. They were evaluated with respect to their complications, threshold behavior, and overall longevity. A total of 55 models from 11 manufacturers were identified among these leads (Table I).

There were two screw-in leads (Medtronic, model 6957), but all other leads were ring-tip, flanged ring-tip, and target-tip leads. There were 259 unipolar and 296 bipolar leads (in 6 leads the lead type was not recorded), and 191 nontined and 351 tined leads (for 17 leads no records were available as to tines on the lead tip). These leads were inserted into the right or left subclavian (axillary) vein by

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Models</th>
<th>Number of Leads</th>
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<tbody>
<tr>
<td>Cardiac Pacemakers</td>
<td>4109</td>
<td>11</td>
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<tr>
<td>Devices</td>
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<td>6907, 6957, 6971, 8423</td>
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<tr>
<td>Pacesetter</td>
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<tr>
<td></td>
<td>411S, 423S</td>
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<td>Telectronics</td>
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<tr>
<td>Others</td>
<td></td>
<td>41</td>
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the cephalic vein cut down technique (265 leads) or by the subclavian vein puncture technique (264 leads). The lead insertion method was not identified in 32 leads.

The follow-up periods were 1,911 patient-years (mean 3.8 years per patient, the longest being 19 years) and 1,915 lead-years (mean 3.4 years per lead, the longest being 17 years). A total of 175 patients (34.9%) were not seen at the outpatient clinic for over 1 year at the time of data collection (December, 1990). For these patients the follow up period was determined according to the date of their last visit to the outpatient clinic. Sixty-four patients (12.7%) died a few days to 11 years after pacemaker implantation, in many of whom integrity of pulse generators and leads were not precisely evaluated at the time of their death. The unpaired Student's t-test was used for statistical analysis.

RESULTS

Complications of Implanted Leads

(1) Dislodgement
Dislodgement of the lead tip occurred in 16 leads (2.9%), in 14 of which dislodgement occurred within 2 months after implantation. Thirteen leads were nontined and 3 leads were tined (p<0.001), indicating that tines on the lead tip contribute to better lead lodging.

(2) Fracture (conductor failure)
Fracture of the lead conductor was confirmed on x-ray examination or after retrieval in 19 leads (3.4%). Thirteen of the fractured leads were bipolar and the others were unipolar (NS). Fifteen of 19 fractures occurred within 5 years after implantation, and 4 of them between 8 and 15 years. The site of fracture was identified in the portion of the lead within the pacemaker pocket in 11 leads, and in most of these leads fracture was seen at the site of fixation ligatures (Fig. 1). In 5 leads fracture occurred at a particular segment between the clavicle and the first rib within the subclavian vein (Fig. 2). It is interesting that these 5 leads had all been inserted by the puncture technique. In one lead a fracture occurred within the superior vena cava, and in one other lead severe corrosion was found in the joint segment 15 years after implantation. The site of fracture was not identified in one lead.

(3) Insulator break
Insulator break with reduced lead impedance occurred in 3 leads (0.5%) between 2 and 7 years after implantation. In none of these leads was the precise point of insulator break confirmed.

(4) Other complications
Seven leads were replaced because of exit block after 1 to 12 years follow-
up, and 2 other leads were replaced because of poor sensing after 1 and 8 years.

**Cumulative Survival of Leads**

The cumulative survival of leads calculated by the actuarial method was 94.1±2.7% (mean±95% confidence interval) at 5 years, 86.3±6.3% at 10 years, and 74.2±14.0% at 15 years after implantation. There was a relatively sharp decline in the cumulative survival after 10 years in service (Fig. 3).

**Electrical Performance of Leads**

There were 70 leads in which pacing threshold measurements were made at the initial implantation and at least once at the time of replacement of pulse generator. Voltage threshold (at a pulse width of 0.5 ms), current amplitude and impedance therein, and R wave amplitude were measured intraoperatively. No noninvasive methods were employed.

(1) **Voltage threshold**

Voltage threshold was 0.54±0.11 volts (mean±SD) at the time of initial
implantation, and it rose steadily to 1.56±0.55 volts (p<0.001) by the third year after implantation. It remained well within the 2.5 volts range thereafter for over a period of up to 10 years (Fig. 4a).

(2) Current amplitude

Current amplitude at the voltage threshold was 1.05±0.60 mAs at the initial implantation. It rose to 2.72±1.2 mAs (p<0.001) at the second year after implantation and remained at approximately the 3 mA level thereafter (Fig. 4b).
(3) Lead impedance
Reflecting increases in current amplitude, the lead impedance decreased somewhat after initial implantation, but it remained between 400 to 600 ohms throughout the observation period (Fig. 4c).

(4) R wave amplitude
The R-wave amplitude of the endocardial electrocardiogram decreased from the initial level of 8.1±4.1 mvolts to 5.9±3.3 mvolts after one year (p<0.05), but it rose to the 8 to 13 mvolt range thereafter and remained in this range for up to 10 years (Fig. 4d).

All of the above parameters of pacing threshold remained stable throughout the observation period.

DISCUSSION

This study has demonstrated that ventricular pacing leads are susceptible to failure due to several causes after implantation. The cause of pacing failure in the early period after implantation is usually dislodgement. In our present series 14 leads (2.5%) had to be repositioned because of dislodgement within 2 months after initial implantation. However, the incidence of dislodgement was significantly reduced after introduction of tined leads. It can be concluded that tines contribute to better fixation of the lead tip in the trabeculum and lead dislodgement will not be a frequent occurrence in the future. Screw-in leads are also noted for lead stability.1)

Lead fracture has been reported to accumulate in the first 5 years after implantation,2)-4) and a local point of stress rather than general fatigue is suggested as its cause. It was noted in our study as well that 15 of 19 fractures occurred within 5 years after implantation, and two particular fracture sites were identified. One was in the segment of the lead within the pacemaker pocket, and the other was within the subclavian vein at a point where the subclavian vein runs between the clavicle and the first rib. In the former segment, fracture was invariably associated with overlying fixation ligatures. It is very likely that the fixation point of the lead serves as a point of stress and causes accelerated mechanical fatigue of lead materials.2) Ligatures must be fixed with caution so as not to induce mechanical fatigue of the lead material.

Thoracic outlet syndrome was documented as the cause of lead fracture occurring in the lead segment between the clavicle and the first ribs.5) However, thoracic outlet syndrome was not present in any of our 5 cases in which lead fracture occurred at this particular site. We suspect that the method of lead insertion is related to this complication, since, in our series, all of these 5 leads had been inserted into the subclavian vein by the puncture method, while in
none of the leads inserted by the cephalic vein cut down technique was this complication seen. When the puncture technique is employed for inserting a lead, the periostial fibromuscular tissue of the clavicle and the first rib, through which the lead is inserted into the vein, possibly fixes the lead more or less firmly therein. Subsequent shoulder movement causes stress in the lead segment fixed in these structures. On the other hand, a lead will not be fixed firmly between the clavicle and the first rib when it is introduced into the axillary vein via the cephalic vein. Thus when one employs the subclavian puncture technique, it is advisable not to let the lead pass through the periostial fibromuscular tissue of the clavicle and the first rib; i.e., the subclavian vein puncture point must be chosen distal to the first rib.

It is likely that the exit block seen in 7 leads of our series was not due to malfunction of the leads themselves but to a tissue condition at the electrode-endocardial interface, since all of these leads were of normal appearance on x-ray examination and their impedance was within normal range. It is known that certain leads with their tip in good contact with the endocardium develop pacing failure within months or years after implantation. The precise mechanism of pacing failure of this type has not been fully elucidated, but it is proposed that the endocardial tissue becomes electrically inactive because of inflammatory reaction and formation of fibrous connective tissue.\(^6\) The recently introduced steroid-eluting electrode prevents excess fibrous tissue formation, and maintains a low stimulation threshold in the acute and chronic situations after implantation.\(^6\),\(^7\)

The longevity of pacing leads so far reported varies considerably according to investigators. Furman et al\(^3\) reported an overall longevity of 98% at 15 years after implantation, but Oseroff et al\(^8\) observed a survival rate of 70% at 15 years with a particular lead model, and Levander-Lindgren\(^9\) reported an even lower survival rate of 58% at 15 years after implantation. In our present investigation there was a slow but steady decline in the lead failure-free rate in the first 10 year follow-up and there was an acceleration of the failure rate after 10 years in service, resulting in an overall survival of 74% at 15 years. We feel that pacing leads should be carefully observed for their integrity, particularly after 10 years in service, and lead replacement should be considered when substantial likelihood of lead failure exists.

It is well known that pacing thresholds are elevated for a few weeks or months after implantation and they stabilize to a level 2 or 3 times that of the initial value.\(^10\),\(^11\) However, the long-term threshold behavior is not well known. Lagergren et al\(^12\) reported that pacing voltage thresholds were constant at 5 and 10 years after implantation. Angello et al\(^13\) found no tendency for pacing thresholds to rise during the first 6 years after implantation, and neither did Levander-
Lindgren\(^9\) in his observation of 120 patients for up to 7 years. However, Luceri et al\(^{14}\) found that in about 20% of their cases, pacing thresholds continued to rise at an annual rate of 14%. We found in our present investigation that parameters of pacing threshold were stable for at least 10 years and there were no tendencies toward higher pacing thresholds. Chronic fibrous tissue formation around the electrode tip interfering with stimulation is not a common phenomenon and stable pacing thresholds can be expected to last for at least 10 years in the majority of ventricular pacing leads.

In conclusion, the cumulative survival of ventricular pacing leads was 74±14% at 15 years after implantation. Lead material failure accounted for the major cause of lead failure. Careful handling of leads at the time of implantation may help to decrease the incidence of lead material failure. On the other hand, the chronic pacing threshold was found to be very stable in the majority of leads investigated.

**REFERENCES**

7. Kruse M, Terpstra B: Acute and long-term atrial and ventricular stimulation thresholds with a steroid-eluting electrode. PACE 8: 45, 1985