Long-Term Follow-up of Transvenous Defibrillation Leads
—— High Incidence of Fracture in Coaxial Polyurethane Lead ——

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Background  As a result of longer follow-up after implantation of cardioverter defibrillators (ICD), fatigue of the leads has become a concern. The aim of this study was to determine the incidence and clinical presentation of ICD lead failures.

Methods and Results  The study population consisted of 241 patients with 249 ICD leads who underwent implantation of an ICD with a transvenous lead system. After device implantation, the patients were routinely followed up every 4 months. Five lead failures (2.0%) occurred as an oversensing of artifact during the follow-up period (2.6±2.1 years); 4 of those 5 patients received inappropriate shocks and 1 case of lead failure was identified in a patient with frequent episodes of non-sustained ventricular fibrillation. In particular, the right ventricular polyurethane transvenous lead in the Medtronic model 6936 failed in 4 (13%) of 31 cases. Percutaneous lead extraction was not available in all cases, so an additional ICD lead was inserted through the same site of the subclavian vein.

Conclusions  Lead failures may occur 5 years after ICD implantation and polyurethane leads have an especially high incidence of failure. However, there were no follow-up parameters observed that predicted lead failures.

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Key Words:  Follow-up; Implantable cardioverter-defibrillator; Lead failure; Polyurethane

The implantable cardioverter-defibrillator (ICD) is an established treatment for the prevention of sudden cardiac death in patients with a history of life-threatening ventricular tachyarrhythmias, and recent studies have reported their efficacy in the primary prevention of sudden cardiac death in patients with structural heart disease and decreased left ventricular (LV) function. Therefore, the number of prophylactic use of ICDs has increased worldwide, and as both the number of patients with an ICD and the follow-up period have increased, several issues concerning ICD management, including lead fractures, have arisen. ICD lead failures associated with long-term fatigue is a serious complication because it results in oversensing of noise and subsequent inappropriate shocks or failure of the ICD to deliver a shock. In particular, ICD leads with a coaxial polyurethane insulated design have frequently been the cause of lead failures and inappropriate shocks. However, the long-term consequences of ICD lead malfunctions in the Japanese patient population have not been analyzed and that was the goal of the present study.

Methods

Patients  The study population comprised 241 patients with 249 ICD leads who underwent implantation of an ICD with a transvenous lead system at the National Cardiovascular Center from December 1991 to August 2003 (Table 1).

Lead and Device Implantation Procedure  The implanted leads included the Sprint models 6932, 6936, 6943, 6944 and 6945, manufactured by Medtronic (Minneapolis, USA). The ICD devices implanted were the PCD 7217B, GEM 7227, 7229, 7271 and 7273, Jewel plus 7220C, Micro Jewel 7221CX, Micro Jewel II 7223Cx and Ventak Mini IV 1790.

All implant procedures were performed under general anesthesia using propofol or thiopental sodium in the oper-

| Table 1 Clinical Characteristics of the Patients With an ICD |
|------------------|------------------|
| N                | 249              |
| Sex, male        | 196 (79%)        |
| Age, years       | 58±14            |
| Cardiac diagnosis|                  |
| CAD              | 69 (28%)         |
| NonCAD           | 109 (44%)        |
| Other            | 71 (29%)         |
| Arrhythmia       |                  |
| VF               | 130 (56%)        |
| Sustained VT     | 97 (39%)         |
| Non-sustained VT | 13 (5%)          |
| Other            | 9 (4%)           |
| LVEF, %          | 43±31            |
| Dual chamber ICD | 82 (33%)         |

ICD, implantable cardioverter defibrillator; CAD, coronary artery disease; VF, ventricular fibrillation; VT, ventricular tachycardia; LVEF, left ventricular ejection fraction.
The transvenous leads were inserted first by a cutdown of the left cephalic vein. Subclavian vein punctures were performed if the cutdown procedure was not successful for introducing the leads. An amplitude of more than 5 mV measured from the intracardiac recordings and a pacing threshold of less than 2.0 V with a 0.5 ms pulse width were considered acceptable, and the ranges of lead impedance and high voltage impedance were within normal. A defibrillation threshold of more than 10 J as a safety margin at implantation was required.

**Follow-up**

After implantation of the device, the patients were routinely followed up every 4 months and at ICD shock deliveries. The evaluation included a patient history and interrogation of the device for any arrhythmic events and the stored intracardiac electrograms were reviewed. More than 50% change in a parameter was defined as significant.

**Table 2** Symptoms and Lead Data in Patients With ICD Lead Failure

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Diagnosis</th>
<th>Age (years)</th>
<th>Sex</th>
<th>Lead-type</th>
<th>Follow up (years)</th>
<th>Clinical presentation</th>
<th>Inappropriate shock</th>
<th>Abnormal parameter</th>
<th>Lead fracture on X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DCM</td>
<td>69</td>
<td>F</td>
<td>6936</td>
<td>6.8</td>
<td>Oversensing of VF</td>
<td>+</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>Idiopathic VF</td>
<td>70</td>
<td>M</td>
<td>6936</td>
<td>6.5</td>
<td>Oversensing</td>
<td>+</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>3</td>
<td>Idiopathic VF</td>
<td>69</td>
<td>M</td>
<td>6936</td>
<td>6.1</td>
<td>Oversensing of NSVT</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>4</td>
<td>Idiopathic VF</td>
<td>42</td>
<td>M</td>
<td>6936</td>
<td>5.1</td>
<td>Oversensing of VF</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>5</td>
<td>DCM</td>
<td>49</td>
<td>M</td>
<td>6936</td>
<td>4.2</td>
<td>Oversensing of VF</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

ICD, implantable cardioverter defibrillator; DCM, dilated cardiomyopathy; VF, ventricular fibrillation; NSVT, nonsustained ventricular tachycardia; NA, not available.

**Fig 1.** Kaplan-Meier survival curves for all leads types: Medtronic model 6936 lead, and others.

**Fig 2.** Follow-up data from the 4 months before detection of lead failure. Zero (0) is the time at which the lead failure was detected. (A) Sensed R wave, (B) Lead impedance, (C) Pacing threshold with measurement of implantable cardioverter defibrillator. The sensed R wave, lead impedance, and pacing threshold did not change significantly between the time the lead failure was detected and the most recent follow-up within 20 months in 4 patients.
Long-Term Follow-up of ICD Lead

Lead function was determined by measuring impedance, pacing threshold and sensed electrogram amplitude.

Classification of Events
Each event was classified on the basis of the intracardiac recordings obtained during arrhythmic events. The following criteria were defined as a lead failure: (1) there was documented oversensing unrelated to the cardiac cycle; (2) there was evidence of a lead failure during electrical testing; and (3) a fracture was observed on X-ray.

Statistical Analysis
Data are expressed as mean±SD. Each parameter was compared by a non-paired t-test. The cumulative lead survival rate was assessed using a Kaplan-Meier analysis.

Results

Patients and Follow-up
The mean age of the 241 patients was 60 years. Of the 249 leads, 31 were A Medtronic right ventricular polyurethane transvenous lead, model 6936. The site of lead introduction was the cephalic vein for 219 leads (88%); the subclavian vein for 25 leads (10%); 2 leads (1%) were placed using an epicardial patch, and the site of remaining 3 lead placements (1%) was unknown. The mean follow-up period was 2.6±2.1 years (range 0.1–8.4 years). The average sensed R wave was 11.7 mV and the average pacing threshold was 0.96 mV/0.5 ms at implantation. Thirteen patients died during the follow-up: 3 died from an electrical storm for which the ICD therapy for ventricular fibrillation (VF) or tachycardia was unsuccessful, but which were defined as appropriate shocks with normal coil impedances; 2 from sudden death, but no events were recorded by the ICD; 5 died of heart failure, and 3 died of non-cardiac causes. Postmortem device interrogation in those patients showed that the therapies were appropriate and had normal coil impedances.

Incidence of Lead Malfunction
Among the 249 leads, 5 leads (2%) in 5 patients failed (Table 2). In particular, 4 (13%) of the 31 Medtronic model 6936 failed during the follow-up period (mean 5.2±2.2 years; Fig 1). The incidence of failure of the Medtronic model 6936 lead increased after 5 years of follow-up and had occurred in approximately 30% of the patients at 8 years of follow-up.
Mode of Lead Failure

Table 2 shows the mode of the lead failure in the 5 patients and Fig 2 shows the temporal changes of the sensed R wave, pacing threshold and pacing impedance.

Patient 1 had an inappropriate shock because of sensing of a noise signal during sinus rhythm at rest and there were 120 episodes of non-sustained ventricular tachycardia (NSVT) in the stored episode data of the ICD during the month after the latest follow-up.

Patient 3 had 278 episodes of NSVT without an inappropriate shock during the 4 months before the lead failure was detected at the ICD clinic.

Patient 5 had inappropriate shock as VF therapy because of oversensing of noise during sinus rhythm at preening (Fig 3). All follow-up parameters were normal even after inappropriate shocks, but the episodes of NSVT suddenly increased 2 weeks before the inappropriate shock (Fig 4).

Patient 4 had an increase in the number of episodes of NSVT just 1 month after a generator exchange and finally received inappropriate VF therapy. In this patient, the sensed R wave and lead impedance had decreased transiently, but not significantly, 8 months before the inappropriate shock (Fig 2).

In summary, in the analysis of the stored arrhythmic events 4 patients who comprised 1 patient with a multilumen silicon lead (Medtronic model 6932 lead) and 3 with model 6936 leads, showed frequent episodes of NSVT with a non-physiological short cycle length (120–200 ms) on average 2.3 months before inappropriate ICD shocks (Fig 4). Further, in Patient 3, lead failure was identified by oversensing of artifact, which resulted in NSVT without an inappropriate shock.

In Patient 4, the sensed R wave and lead impedance had decreased transiently, but not significantly, 8 months before the inappropriate shock (Fig 2).

Management of ICD Lead-Related Problems

None of the 5 patients with lead failure could undergo lead extraction and all underwent re-implantation with a new ICD lead introduced on the same side as the prior implantation after venography confirmed antegrade flow in the subclavian vein.

Discussion

This report showed that (1) lead failures may occur 5 years after ICD implantation; (2) inappropriate shocks because of sensing noise is the mode of lead failure, although the R wave sensing, pacing threshold and lead impedance do not significantly change before or after lead failure; (3) frequent episodes of NSVT with short cycle lengths may predict lead failure before the inappropriate ICD shock; and (4) coaxial polyurethane ICD leads have a high incidence of failures.

Failure of the Medtronic model 6936 ICD lead has been frequently reported;6–8 in 1 study the incidence of lead failure was approximately 20% at 4 years. In our study, 4 of 5 (80%) patients with lead failures had the Medtronic model 6936 lead and lead failure occurred in only 1 of 210 patients (0.5%) with the multilumen lead. In the Kaplan-Meier analysis, the overall lead survival rate at 5 years was 98% and at 8 years was 71.9%. An increased incidence of lead failures (63.2% at 8 years) was observed after the 5-year follow-up period in patients with the Medtronic model 6936 lead. Lead failure was significantly more frequent in the Medtronic model 6936 lead than in other types of leads.

In a previous report of pacing lead failure,9 13 of 290 (4.4%) leads failed and all were of polyurethane design (7.5%). In a multicenter study of polyurethane insulated ventricular pacing leads (the Medtronic 4004/4004M), lead failure occurred in 14.1% at 4-year follow-up.

Mechanisms of Lead Failure

A previous report suggested that failure of pacing or defibrillation leads insulated with polyurethane is caused by the material and its design.6,9–11 The Medtronic model 6936 lead has a coaxial body design with polyurethane insulation (Fig 5). There are 3 concentric conductors, with the high-voltage conductor in the outer layer, the sensing conductor in the middle layer and the pacing conductor in the inner layer. Each conductor has a polyurethane insulating sheath, which deteriorates progressively from metal ion oxidation (MIO), resulting in unsheathing and breakdown of the conductors6,9 In an analysis of returned leads, there was polyurethane breakdown caused by MIO in 6 of 7 cases, and in the other lead, the breakdown was caused by
mechanical stress (subclavian crush).

The multilumen design leads consist of 3 separate channels for each conductor, each of which is individually insulated by silicone rubber, which prevents the lead from degradation and injury by mechanical stress. In the present study, the 1 case of failure in a multilumen lead did not show the specific clinical presentation seen with the coaxial polyurethane leads. Dorwarth et al suggest that damage to the insulation of the leads occurs when there is chronic excessive pressure on the body of lead from the ligature used for lead fixation? In addition, mechanical injury such as subclavian crush syndrome may have a role. These mechanisms of lead failure apply to all leads and may have had an effect in the failure of Medtronic model 6932 lead in the present study (Patient 5). Lead analysis was not possible because none of the patients underwent extraction and so the precise cause of lead failure could not be clarified in our study.

Indicators and Predictors of Lead Failure

Even after inappropriate shocks caused by sensing noise from failed leads, the ICD testing results for the pacing and sensing thresholds, the analysis of the lead impedance and recordings of real time intracardiac electrograms were normal in all of our patients. Further, routine analyses every 4–6 months at the ICD clinic could not identify a lead failure or prevent the inappropriate ICD shocks caused by sensing lead noise.

Ellenbogen et al8 analyzed the intracardiac electrograms just after the termination of VF during the DFT test in 37 ICD patients with a Medtronic model 6936 lead that had not failed. They reported that the ICD shocks for terminating VF raised the noise on the intracardiac electrogram in 5 of 37 patients and 4 of them had a variable ring-to-coil impedance. According to that report, changes in the pacing or sensing thresholds or lead impedance are not helpful in predicting or detecting lead problems, but performing DFT testing may unmask lead failures before inappropriate shocks. However, the DFT test has a high risk of inducing heart failure in patients with low LV function. Many of the present patients had decreased LV function, so we did not routinely perform induction of VF.

There were frequent episodes of NSVT with very short cycle lengths before the inappropriate shocks were delivered by the ICD, mostly occurring 2 months before the inappropriate therapy, which suggests that lead failure occurs rapidly. Therefore, it may be difficult to predict lead failure during routine follow-up performed only every 4–6 months. Our study strongly suggests that more frequent follow-up is required to avoid inappropriate therapy for patients with the Medtronic model 6936 lead.

Management of ICD Lead Failure

In Japan, we do not have any lead extraction systems and open heart surgery is required, but most patients with an ICD have a decreased LV function and a thoracotomy is a high risk procedure for them. We usually insert a new ICD lead through the same side of the subclavian vein using a puncture method without extracting the broken lead. Implantation of an ICD from the right side may cause the risk of increasing the DFT of the ICD therapy, and occlusion of the SVC by multiple lead implantations from both sides. Occlusion of the vein can create serious problems, such as superior vena cava syndrome, and make it difficult to introduce an additional atrial lead or LV lead for cardiac resynchronization therapy. The percutaneous lead extraction systems are strongly needed in Japan.

Conclusions

Failures of ICD leads may occur 5 years after the implantation and coaxial polyurethane leads have a particularly high incidence of failure. However, there are no parameters that can be used to predict lead failure during follow-up.

References


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