Risk of Failure of Transvenous Implantable Cardioverter-Defibrillator Leads

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Background—Despite the positive effect on mortality in selected patients, implantable cardioverter-defibrillator therapy is also associated with potential malfunction of the implanted system. The present study provides the long-term lead failure rate in a large single-center cohort.

Methods and Results—Since 1992, a total of 2068 implantable cardioverter-defibrillator patients with 2161 defibrillation leads were prospectively collected. Data of the implant procedure and all follow-up visits were recorded. All cases of lead removal or capping or placing of an additional pace or sense lead were noted and analyzed. Lead models were grouped by manufacturer and approximate lead diameter in French. During a mean follow-up of 36 months, 82 (3.8%) cases of lead failure were identified. Cumulative incidence of lead failure at 1 year was 0.6%; at 5 years, 6.5%; and at 10 years, 16.4%. The highest risk of lead failure was found in small-diameter leads. Adjusted hazard ratio was 6.4 (95% CI, 3.2 to 12.8) for Medtronic 7F leads, when compared with all other leads.

Conclusions—In this large single-center experience, the overall incidence of lead failure was 1.3 (95% CI, 1.0 to 1.6) per 100 lead-years. Comparison of different groups of leads shows major differences in event rates. Specific manufacturer’s small-diameter defibrillation leads may have a higher risk of early lead failure. (Circ Arrhythmia Electrophysiol. 2009; 2:411-416.)

Key Words: implantable cardioverter-defibrillator | lead | failure | defibrillation

Large randomized trials have shown a beneficial effect on mortality of an implantable cardioverter-defibrillator (ICD) in the secondary and primary prevention of sudden cardiac death in selected groups of patients.1–7 With the rapid expansion of indications, the worldwide annual implant rate has increased to more than 100 000 units in 2007. Despite the positive effect on mortality in selected patients, ICD therapy is also associated with some serious drawbacks that potentially may harm patients and increase the costs of ICD therapy. One of the most important is the limited lifespan of the ICD necessitating the replacement of the ICD every 4 to 5 years. Furthermore, in the survival of an implanted system, the right ventricular defibrillation lead, as shown by several studies, is the weakest link, and a recent study has revealed that lead failure can reach 20% in 10-year-old leads.8,9 When in need of information about specific leads, practitioners must rely on data reported by the manufacturers on lead survival. These data are usually based on the leads returned to the manufacturer after removal. However, in daily practice, lead failure is often not reported to the manufacturer either because the lead is simply not returned or, instead of removing, the lead is capped and an additional pace or sense (P/S) lead is inserted. Initiatives such as nationwide data registries in the United States and some European countries may help to improve surveillance of ICD and lead performance.

Clinical Perspective on p 416

We determined the survival and failure rate in a large number (n=2161) of defibrillation leads, implanted over a 16-year period in a large university hospital in The Netherlands.

Methods

Patient and Lead Characteristics

Since 1992, all patients who received an ICD system in the Leiden University Medical Center were registered in the departmental Cardiology Information System (EPD-Vision, Leiden University Medical Center). Data of the implant procedure and all follow-up visits were recorded (Table 1). At the first of February 2008, this registry contained information about 2249 defibrillation leads. Leads connected to an abdominal system and leads with a coaxial construction or polyurethane coating were excluded from this analysis because these are known to be prone to failure and are no longer in use.10–16 Eligibility for ICD implantation was based on international guidelines and included secondary prevention (survival of a life-threatening
ventricular arrhythmia and primary prevention (poor left ventricular ejection fraction).17,18 Because of evolving guidelines, the indications have changed over time. All patients were screened before implantation according to a standardized protocol adapted from the international guidelines as described previously.19,20 All leads in this analysis were implanted transvenously and without thoracotomy. During the implant procedure, testing of sensing and pacing thresholds and defibrillation threshold testing were performed.

Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>All Leads (n=2161)</th>
<th>All Removal or Capping (n=146)</th>
<th>Lead Failure (n=82)</th>
<th>Lead Failure or Dislodgement (n=93)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>61±13</td>
<td>57±16</td>
<td>56±16</td>
<td>56±16</td>
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<tr>
<td>Male sex, %</td>
<td>80</td>
<td>84</td>
<td>83</td>
<td>83</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>34±15</td>
<td>35±16</td>
<td>35±16</td>
<td>37±17</td>
</tr>
<tr>
<td>Ischemic etiology, %</td>
<td>65</td>
<td>72</td>
<td>73</td>
<td>71</td>
</tr>
<tr>
<td>Primary indication, %</td>
<td>55</td>
<td>41</td>
<td>37</td>
<td>42</td>
</tr>
<tr>
<td>Implanted ICD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single chamber, %</td>
<td>15</td>
<td>32</td>
<td>37</td>
<td>34</td>
</tr>
<tr>
<td>Dual chamber, %</td>
<td>49</td>
<td>48</td>
<td>44</td>
<td>48</td>
</tr>
<tr>
<td>Biventricular, %</td>
<td>36</td>
<td>21</td>
<td>20</td>
<td>17</td>
</tr>
</tbody>
</table>

Continuous variables are expressed as mean±SD.

End Points and Follow-Up

The follow-up was from lead implantation occurring between 1992 and 2007 to February 1, 2008. In the Dutch health care system, all patients are followed by the implanting center. Because periodic follow-up was performed every 3 to 6 months, patients without data after the first of August 2007 were considered as lost to follow-up. During these examinations, all leads were systematically screened for adequate function and integrity. Any case of lead removal or capping, placing of an additional P/S lead, or lead repositioning because of dislodgement was recorded. All cases were individually analyzed by the technician and supervisor and classified as “lead failure” or “non lead failure.” The current analysis used 3 end points: (1) all-cause lead removal or capping; (2) lead failure; or (3) lead failure or dislodgement within 6 months.

Definition of Lead Failure

Defibrillation lead removal or capping was classified as lead failure according to the report of the North American Society of Pacing and Electrophysiology.21 At least 1 of the following criteria had to be met to define suspected lead failure (1 and 2) or verified lead failure (3 to 6): (1) loss of capture or markedly elevated thresholds; (2) loss of sensing, oversensing, or skeletal muscular stimulation; (3) a visible conductor fracture or insulation defect seen at surgery; (4) a change in lead impedance, judged to be caused by conductor or insulation failure; (5) an evident fracture seen on chest roentgenogram; or (6) manufacturer’s returned product report confirming the failure.

Statistical Analysis

For analysis purposes, leads were grouped per manufacturer and per recommended introducer diameter. This classification divides the different generations of leads. Manufacturers of implanted leads were Biotronik (Berlin, Germany), Medtronic (Minneapolis, Minn), Boston Scientific (Natick, Mass) (formerly CPI, Guidant [St Paul, Minn]), and St Jude Medical/Ventrixi (St Paul, Minn). Classification on lead diameter (French) resulted in 9 groups, as shown in Table 2: (1) Biotronik, 8F; (2) Boston Scientific, 11F; (3) Boston Scientific, 9F; (4) Medtronic, 10.5F; (5) Medtronic, 9F; (6) Medtronic, 7F; (7) St Jude Medical, 11F; (8) St Jude Medical, 8F; and (9) St Jude Medical, 7F. The leads with a recommended introducer diameter of 7F were described as small-diameter leads.

Continuous data are expressed as mean and standard deviation or range, median, and first and third quartiles where appropriate; nominal data are presented as numbers and percentages. Cumulative incidences were analyzed by the method of Kaplan-Meier. Cox regression analysis was performed as multivariable modeling to obtain age-adjusted hazard ratios as an estimate of the incidence ratio. Event rates were corrected for age, sex, and left ventricular ejection fraction. Death or heart transplantation was counted as a censoring event.

Results

Patient and Lead Characteristics

A total of 2249 defibrillation leads were implanted in 2145 patients between 1992 and 2007. For the current analysis, all leads connected to an abdominal system, with coaxial construction or polyurethane coating (n=39, 1.7%) were excluded. Forty-nine (2.2%) patients were lost to follow-up. The remaining 2161 defibrillation (2068 patients) leads were included in the analysis. Three hundred eight patients died (n=300) or underwent heart transplantation (n=8) with their lead still intact at last follow-up. Median time between last follow-up and death was 62 days (interquartile range, 29 to 109 days).

Implanted leads consisted mostly of models manufactured by Boston Scientific (n=1074) or Medtronic (n=774). Median follow-up time was 885 days (interquartile range, 375 to 1618). The majority of patients (80% men; mean age, 61

Table 2. Classification of Defibrillation Leads by Manufacturer and Lead Diameter

<table>
<thead>
<tr>
<th>Lead Group</th>
<th>Linox</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik, 8F</td>
<td>Linox</td>
</tr>
<tr>
<td>Boston Scientific, 11F</td>
<td>Endotak</td>
</tr>
<tr>
<td></td>
<td>0125, 0144, 0145, and 0155</td>
</tr>
<tr>
<td>Boston Scientific, 9F</td>
<td>Endotak</td>
</tr>
<tr>
<td></td>
<td>0138, 0147, 0148, 0161, 0164, 0165, 0175, 0181, and 0185</td>
</tr>
<tr>
<td>Medtronic, 10.5F</td>
<td>Sprint</td>
</tr>
<tr>
<td></td>
<td>6932, 6942, and 6945</td>
</tr>
<tr>
<td>Medtronic, 9F</td>
<td>Sprint</td>
</tr>
<tr>
<td></td>
<td>Quattro 6944 and 6947</td>
</tr>
<tr>
<td>Medtronic, 7F</td>
<td>Sprint</td>
</tr>
<tr>
<td></td>
<td>Fidelis 6930, 6931, 6948, and 6949</td>
</tr>
<tr>
<td>St Jude Medical, 11F</td>
<td>SPL</td>
</tr>
<tr>
<td></td>
<td>SP01 and SP02</td>
</tr>
<tr>
<td>St Jude Medical, 8F</td>
<td>Riata</td>
</tr>
<tr>
<td></td>
<td>1570, 1580, and 1582</td>
</tr>
<tr>
<td>St Jude Medical, 7F</td>
<td>Riata</td>
</tr>
<tr>
<td></td>
<td>7000 and 7002</td>
</tr>
</tbody>
</table>
years; range, 5 to 86 years) had ischemic heart disease (65%) and a poor left ventricular ejection fraction (34±15%; Table 1). Leads were connected to a single-chamber device in 15% (n=332), dual-chamber device in 49% (n=1052), or resynchronization ICD in 36% (n=777).

**Lead Survival**

One hundred forty-six leads (6.8%) were removed or capped during follow-up (in 139 patients). The cause of removal or capping was found to be other than lead failure in 64 patients, consisting mostly of pocket infections (n=36) or decubitus ulcers (n=14). Median time to all-cause lead removal or capping was 892 days (interquartile range, 352 to 1710 days). The overall incidence rate of all-cause removal or capping was 2.2 per 100 lead-years (95% CI, 1.9 to 2.6 per 100 lead-years). Cumulative (Figure 1) lead failure at 1 year was 1.9%; at 2 years, 3.5%; at 5 years, 10.4%; and at 10 years, 26.9%, meaning that after 10 years, 73.1% of all implanted leads were still functioning.

**Lead Failure**

During follow-up, 82 (3.8%) cases of lead failure were identified, with a median time to lead failure of 1187 days (interquartile range, 597 to 1783 days). In 40 instances, an additional P/S lead was implanted and the failing lead was capped. Forty-two leads were completely removed and replaced with a new defibrillation lead. Diagnosis was made at a routine device follow-up (61%), after the occurrence of inappropriate shocks (27%) or during elective ICD replacement (12%). Inappropriate shocks were caused by malsensing in 64%, fracture of the sense lead in 18%, T-wave oversensing in 14%, and P-wave oversensing in 5%.

Cumulative incidence of lead failure–free follow-up at 1 year was 99.4%; at 2 years, 98.6%; at 5 years, 93.5%; and at 10 years, 83.6%. Kaplan-Meier curves for the different groups of leads are shown in Figure 2, where the bold line represents all 2161 leads together and the dashed lines the specific group. No lead failure occurred in the leads manufactured by Biotronik. Median follow-up for leads by Biotronik was 155 days (interquartile range, 88 to 296 days).

Over a total of 6540 lead-years in the current analysis, the incidence rate for lead failure per 100 lead-years was 1.3 (95% CI, 1.0 to 1.6). Incidence rates for lead failure were found to be higher in the small-diameter defibrillation leads, with 2.7 (95% CI, 1.6 to 4.4) per 100 lead-years for the Medtronic 7F leads. Data for all groups are shown in Table 3. The hazard ratio (adjusted for age, sex, and left ventricular ejection fraction) for small-diameter leads compared with the other leads was 10.9 (95% CI, 1.4 to 85.5) for St Jude Medical and 6.4 (95% CI, 3.2 to 12.8) for Medtronic. Implantation with either group of Boston Scientific defibrillation leads decreased the risk of lead failure: For the group with 11F and 9F diameter, adjusted hazard ratios were 0.3 (95% CI, 0.2 to 0.8) and 0.5 (95% CI, 0.3 to 0.9), respectively, relative to all other leads.

After categorization by manufacturer and generation, other previously reported risk factors for lead failure (subclavian versus cephalic venous [hazard ratio (HR), 1.0; 95% CI, 0.6 to 1.5; P=0.9], active versus passive lead fixation [HR, 1.2; 95% CI, 0.6 to 2.4; P=0.6], dual-coil versus single-coil leads [HR, 0.8; 95% CI, 0.4 to 1.9; P=0.6], and dedicated versus integrated bipolar leads [HR, 0.8; 95% CI, 0.1 to 6.2; P=0.8]) did not influence the risk on lead survival in our series.

**Lead Failure and Lead Dislodgement**

Twelve cases of defibrillation lead dislodgement occurred within the 6 months after implantation, with a median time to event of 34 days (interquartile range, 4 to 68 days). After relocation, 1 of the leads (Medtronic 7F) failed during follow-up, which brings the number of leads reaching the combined end point of lead failure and lead dislodgement to 93. Overall incidence rate was 1.4 (95% CI, 1.2 to 1.7) per 100 lead-years.
Discussion

In this large single-center experience, the findings can be summarized as follows: (1) overall incidence of all-cause lead removal or capping is 2.2 (95% CI, 1.9 to 2.6) per 100 lead-years, with a 10-year event-free lead survival of 73.1%; (2) the incidence of lead failure is 1.3 (95% CI, 1.0 to 1.6) per 100 lead-years; (3) grouping by manufacturer and lead diameter revealed major differences in event rates; and (4) specific manufacturer’s small-diameter defibrillation leads exhibit a higher failure rate.

Lead Failure

Results of previous studies on the frequency of lead failure vary widely, mostly depending on the lead types and the duration of follow-up. Lead survival in nonabdominal leads varies from 91% to 99% at 2 years,8,12,23–25 85% to 98% at 5 years,8,12,23–25 and 60% to 72% at 8 years.8,10,24 In comparison to these figures, our rates of lead failure tend to be average during the first 5 years (93.5% failure-free). However, in long-term follow-up, our cohort (83.6% failure-free at 10 years) demonstrates far fewer lead failures than the 40% failure at 8 years found by Kleemann and coworkers.8 A plausible explanation for this lower rate of failure is the exclusion of leads connected to an abdominal system, leads with a coaxial construction, and leads with a polyurethane coating. Characteristically, polyurethane-insulated leads show a rapid increase in failure rate after 5 years of follow-up.12 Therefore, exclusion of these leads from the current analysis could explain that our event rates are similar to other studies in the first 5 years of follow-up and significantly lower during follow-up longer than 5 years. Furthermore, the dissimilarity between our long-term findings and those of others may be caused by the difference in what each study cited as a threshold to replace a lead or place an additional P/S lead. Gradual increasing or chronic high impedances without further signs of lead malfunction should not necessarily demand acute replacement. In daily practice, clinicians often choose to monitor further changes in electric parameters before surgically intervening. The possibility that an important number of failing leads have been missed is small because all periodic 3- to 6-month device interrogations were performed by the recommended protocol as described by Kleemann et al.8

Previous studies have identified risk factors for lead failure, such as subclavian approach, hypothesized to increase the chance for subclavian crush syndrome.26 Interestingly, neither the approach (subclavian versus cephalic) nor other potential risk factors (passive versus active lead fixation, dual coil versus single coil, dedicated versus integrated bipolar) demonstrated an additive value over the stratification by lead generation in the prediction of lead failure.

Differences in Performance

In daily practice, a clinician still must rely on product performance reports constructed by manufacturers. In the 2007 reports, lead failure rates in the leads used in the current study with a follow-up longer than 24 months vary from 0.2 to 0.9 per 100 lead-years.27–30 In contrast with our mean lead failure rate of 1.3 (95% CI, 1.0 to 1.6) per 100 lead-years, it seems clear that these reports, often based on the return of failed products, suffer from a gross underestimation of clinical practice. Two main reasons for this underestimation can be sought in the return of failed leads. First, once a lead fails, a clinician can extract the lead or, in case of malfunction in pacing or sensing without signs of insulation defects or fracture, place an additional P/S lead and cap the pace and sense port of the original lead. Although clearly having failed, these leads are not extracted and therefore will not be returned to the manufacturer. Second, the compliance of clinicians to return extracted leads will, even in the most willing, never reach 100%.12

Lead Insulation

Different studies on the reasons for lead failure have proven lead insulation defects to be the most frequent cause, accounting for 48% to 56% of all lead failures.8,31 In the mid-1990s, several studies showed a higher then average failure rate caused by metal oxidation after inner insulation environmen-
talar stress cracking in polyurethane-insulated leads. Hauser et al. demonstrated a higher failure rate up to an estimated 84% in 7-year-old leads, confirmed by the manufacturer-retained product analysis. These findings caused a recall of more than 400,000 leads through 1995 and marked the end of polyurethane usage in newly implanted leads. Nowadays, because the majority of current leads use silicone rubber as insulation, insulation should not be a ground for differences in event rates. Even though at elective abdominal device replacement Lurgio et al. describe 79% abrasion lesions in silicone-coated leads, this sporadically resulted in lead malfunction.

Small-Diameter Leads
Defibrillation leads characterized by a small-diameter body and coil exhibit several advantages. Their smaller thickness might make it easier to implant additional leads, maintain venous blood flow, and reduce subclavian crush syndrome. Among the 9 groups of leads formed in the present study were 2 containing small-diameter leads: Medtronic 7F, better known as the Sprint Fidelis family, and the St Jude 7F, consisting of the Riata ST 7000 and 7002 series. Previous studies assessing their long-term functioning have shown a higher than expected failure rate in both groups of leads. For the Medtronic 7F, these figures varied from no increase in failure rate to 1 per 100 patient-years when compared with the Medtronic 9F. Lower rates than our findings (2.7 [95% CI, 1.6 to 4.4] per 100 lead-years) can be explained by the fact that data were acquired from the Manufacturer and User Facility Device Experience (MAUDE) database. Because the MAUDE database obtains 95% of cases from manufacturer reports, the database will show figures similar to those of the manufacturer reports.

Studies reporting failures in St Jude 7F leads focused on the potential risk of perforation of the right ventricle, hypothesized to be caused by an increased pressure and stiffness at the tip of the lead. However, the 1 case of St Jude Medical 7F failure in our cohort was caused by severely elevated thresholds and not by perforation. Note that the relatively small number of implanted leads from this group causes the 95% confidence interval to be wide (0.1 to 25.7).

Limitations
Cases of lead failure might occur without clinical symptoms or changes in electric measurements, causing them to go unnoticed. Furthermore, in case of slight changes or chronic elevated or depressed electric measurements, a clinician does not always immediately choose to replace the lead. Last, we assumed that patient death within 6 months after a follow-up visit without signs of lead failure was not lead-related. All 3 examples could lead to an underestimation of the actual rate of lead failure, although we believe these effects would have been small.

Conclusions
This study shows major differences in failure rates among different groups of leads. Small-diameter leads of a specific manufacturer may have a higher risk of early lead failure. Furthermore, with the current lead survival rate of 73% after 10 years, every effort should be addressed to improve lead performance.

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Disclosures
None.

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**CLINICAL PERSPECTIVE**

Implanted cardioverter-defibrillators differ significantly in high-risk populations, but malfunctions, which are most commonly related to lead failure, are important concerns. The present study provides the long-term lead failure rate for 2161 defibrillation leads implanted in 2068 consecutive patients at a single center. The cumulative incidence of lead failure was 0.6% at 1 year, 6.5% at 5 years, and 16.4% at 10 years, respectively. Lead failures varied among different leads. Certain small-diameter defibrillation leads may have a higher risk of early lead failure. Recognition of the lead failure rates is important for assessment of risk of implantable cardioverter-defibrillator adverse events during follow-up.
Risk of Failure of Transvenous Implantable Cardioverter-Defibrillator Leads
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