Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

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Background—The number of patients with longer follow-up after implantation of an implantable cardioverter-defibrillator is increasing continuously. Defibrillation lead failure is a typical long-term complication. Therefore, the long-term reliability of implantable cardioverter-defibrillator leads has become an increasing concern. The aim of the present study was to assess the annual rate of transvenous defibrillation lead defects related to follow-up time after lead implantation.

Methods and Results—A total of 990 consecutive patients who underwent first implantation of an implantable cardioverter-defibrillator between 1992 and May 2005 were analyzed. Median follow-up time was 934 days (interquartile range, 368 to 1870). Overall, 148 defibrillation leads (15%) failed during the follow-up. The estimated lead survival rates at 5 and 8 years after implantation were 85% and 60%, respectively. The annual failure rate increased progressively with time after implantation and reached 20% in 10-year-old leads (P<0.001). Lead defects affected newer as well as older models. Patients with lead defects were 3 years younger at implantation and more often female. Multiple lead implantation was associated with a trend to a higher rate of defibrillation lead defects (P=0.06). The major lead complications were insulation defects (56%), lead fractures (12%), loss of ventricular capture (11%), abnormal lead impedance (10%), and sensing failure (10%).

Conclusions—An increasing annual lead failure rate is noted primarily during long-term follow-up and reached 20% in 10-year-old leads. Patients with lead defects are younger and more often female. (Circulation. 2007;115:2474-2480.)

Key Words: defibrillation ■ cardioverter-defibrillators, implantable ■ tachyarrhythmia

With the expansion of indication for the implantation of the implantable cardioverter-defibrillator (ICD), the use of ICDs has increased sharply over the past decade.1-5 At the same time, the number of patients with longer follow-up after implantation of an ICD is continuously increasing. Complications associated with the pectoral defibrillator and its transvenous leads have been recognized more frequently than before. Furthermore, the long-term performance of defibrillator leads has raised concern as a result of an increased incidence of lead failure that was observed at follow-up time of >5 years.6-10 In particular, ICD leads with a coaxial single lumen polyurethane insulated design like in the 6936 or 6966 models from Medtronic have frequently been the cause of lead failures and inappropriate shocks.11,12 It is unclear if newer models with a multilumen design or silicone insulation materials have a better long-term reliability.13-15 ICD lead failure may result in failure of the ICD to deliver therapy for ventricular tachycardia and result in syncope or sudden death. Lead dysfunction may also result in inappropriate shocks and subsequent psychological distress, need for operative revision, or removal, which results in additional morbidity and mortality, as well as increased healthcare costs. Therefore, a systematic and prospective evaluation of long-term complications of defibrillator leads is mandatory. The present study analyzes the annual rate of transvenous defibrillation lead defects of 990 right ventricular defibrillation leads, which were implanted between 1992 and May 2005. Furthermore, the complications of older models are compared with those of newer models.

Methods

Patient Characteristics and Implantation Data
Patients who underwent an ICD-implantation from 1992 to May 2005 were consecutively enrolled in the prospective, single-center ICD registry of Ludwigshafen. Overall, 1048 patients were included...
into the registry. For the present study, only patients who underwent first implantation of an ICD with a transvenous system were enrolled (n=990). Patients with lead dislodgment during follow-up and those patients who required explantation of the device and lead system as a result of an infection were excluded. The median follow-up time was 934 days (interquartile range, 368 to 1870). Cardiac catheterization, which included coronary angiography and, if necessary, revascularization, was performed before ICD implantation on all patients with coronary artery disease. The implanted leads are listed in Table 1. The models 6936 and 6966 from Medtronic and the Endotak models 072, 074, and 075 from CPI were implanted between 1991 and 1998. All other models represented newer models that were implanted from 1997 onwards. The Transvene 6936/6966 coaxial polyurethane ICD leads differ only in the type of connector and are known to be prone to long-term structural failure.\(^{11,16}\) Therefore, these models were combined and compared with the newer models implanted from 1997 onwards. Lead implantation was performed successfully via a transvenous approach with the use of nonthoracotomy lead systems. Most of the transvenous leads (95%) were implanted by puncture of the subclavian vein. A total of 939 leads were connected to pectoral pulse generators, and 51 leads were tunneled to an abdominal pocket. These leads consisted only of Medtronic 6936 and 6966 models and were implanted between 1991 and 1994. Routine ICD testing of pacing and sensing thresholds and defibrillation thresholds (DFT) was performed at the time of implantation.

**Definition of Lead Defects and Follow-Up**

Lead defect was defined as a severe lead failure that required surgical correction. A lead failure was diagnosed if one or more of the following criteria were fulfilled: (1) oversensing unrelated to the cardiac cycle was documented; (2) the lead impedance was out of normal range, and a surgical revision was suggested by the experts of the manufacturer; (3) a fracture was observed on x-ray; (4) evidence existed of a lead failure during electrical testing. A sensing failure was assumed if T-wave oversensing was present that could not be overcome by reprogramming of the device or the ventricular sensing was assumed if no visual abnormality was found by x-ray, and the manufacturer suggested a surgical revision. After discharge, all patients visited the defibrillator outpatient clinic every 3 months as well as in case of any adverse event. Evaluation in the ICD clinic consisted of interrogation of the ICD with retrieval of all stored events and intracardiac electrograms, measurement of pacing and sensing thresholds, measurement of lead impedance, recordings of real-time electrograms, and evaluation of nonsustained ventricular tachycardia counters assessment of nonphysiological events. Routine annual ICD testing of DFTs was not performed. The time to follow-up was the period up to the most recent follow-up visit, the time to death, or time to first lead failure. The follow-up ended in September 2005. Death was a censoring mechanism with respect to lead failure.

### Statistical Analysis

Absolute numbers, percentages, means and standard deviation, medians, and upper/lower quartile were computed as appropriate. Categorical variables were compared with the \(\chi^2\) or Fisher exact test, as appropriate. For trend analysis the Cochran-Armitage test was used. Cumulative lead survival rates were assessed by Kaplan-Meier analysis. Log-rank tests were used for statistical comparison among groups. Cox regression analysis was performed to find predictors for lead failure. Results were adjusted for age, gender, ejection fraction, number of leads per ICD, and implantation year. All \(P\) values were 2-tailed. \(P<0.05\) was considered to be statistically significant. The tests were performed with the SAS statistical package, version 8.02 (Cary, North Carolina).

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

#### TABLE 1. Implanted Transvenous Right Ventricular Lead Models and Number of Defective Leads

<table>
<thead>
<tr>
<th>RV Lead Model</th>
<th>Total No. of Implanted Leads</th>
<th>No. of Defective Leads</th>
<th>Follow-Up Time, d*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik Kainox SL</td>
<td>2</td>
<td>2</td>
<td>1024 (966/1081)</td>
</tr>
<tr>
<td>CPI 072</td>
<td>5</td>
<td>3</td>
<td>3085 (1799/4354)</td>
</tr>
<tr>
<td>CPI 074</td>
<td>1</td>
<td>1</td>
<td>3402</td>
</tr>
<tr>
<td>CPI 0125</td>
<td>17</td>
<td>4</td>
<td>1748 (875/2636)</td>
</tr>
<tr>
<td>CPI 075/0135/0145/0148</td>
<td>4</td>
<td>0</td>
<td>2394 (1951/2683)</td>
</tr>
<tr>
<td>ELA 4041</td>
<td>11</td>
<td>3</td>
<td>1589 (1060/1767)</td>
</tr>
<tr>
<td>ELA 4042/4071</td>
<td>2</td>
<td>0</td>
<td>1089 (657/1521)</td>
</tr>
<tr>
<td>St. Jude 1559</td>
<td>95</td>
<td>18</td>
<td>988 (764/1321)</td>
</tr>
<tr>
<td>St. Jude 1580</td>
<td>134</td>
<td>5</td>
<td>195 (98/392)</td>
</tr>
<tr>
<td>St. Jude 1581</td>
<td>38</td>
<td>5</td>
<td>536 (319/944)</td>
</tr>
<tr>
<td>St. Jude 1582</td>
<td>27</td>
<td>3</td>
<td>547 (448/585)</td>
</tr>
<tr>
<td>Medtronic 6932/6934/6940</td>
<td>3</td>
<td>0</td>
<td>2781 (2578/2984)</td>
</tr>
<tr>
<td>Medtronic 6936</td>
<td>194</td>
<td>52</td>
<td>2015 (1123/2790)</td>
</tr>
<tr>
<td>Medtronic 6942</td>
<td>12</td>
<td>2</td>
<td>1888 (1333/2533)</td>
</tr>
<tr>
<td>Medtronic 6943</td>
<td>208</td>
<td>27</td>
<td>1302 (813/2060)</td>
</tr>
<tr>
<td>Medtronic 6945</td>
<td>57</td>
<td>11</td>
<td>1584 (842/2102)</td>
</tr>
<tr>
<td>Medtronic 6947</td>
<td>139</td>
<td>0</td>
<td>407 (251/632)</td>
</tr>
<tr>
<td>Medtronic 6949</td>
<td>1</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Medtronic 6966</td>
<td>40</td>
<td>12</td>
<td>2311 (1162/3194)</td>
</tr>
</tbody>
</table>

*Median values are given with interquartile ranges (the 25th and 75th percentiles).
Results

Patient Characteristics
A total of 990 ICD leads were implanted between 1992 and May 2005 in 990 patients. During the median follow-up of 934 days (interquartile range, 368 to 1870), 148 defibrillation leads (15%) failed. A total of 214 leads were removed from service as a result of patient death (n=207) or heart transplantation (n=7); 34 patients (3%) were lost during follow-up. Among failed leads, the median time to failure was 1704 days (interquartile range, 578 to 2414). The affected lead models are listed in Table 1. Baseline clinical data of the enrolled patients are summarized in Table 2. The follow-up time of patients who suffered from lead failure was about 2 years longer than in patients without lead defects. Patients with lead failure were 3 years younger, more often female, and had better-preserved left ventricular dysfunction (Table 2). The indication for ICD-implantation did not differ between both groups. About 75% of the ICDs were implanted as a result of secondary prevention, and 25% of the patients received a prophylactic ICD.

Lead Survival Outcome and Cause of Lead Failure
The estimated lead survival rates at 5 and 8 years after implantation were 85% and 60%, respectively (Figure 1). The annual failure rate increased with progressive time after implantation and reached 20% in 10-year-old leads (Figure 2). This was confirmed by a trend analysis (P<0.001). The major lead complications were insulation defects (56%), lead fractures (12%), loss of ventricular capture (11%), abnormal lead impedance (10%), and sensing failure (10%). The incidence of insulation failure increased with time after implantation. Insulation failure accounted for 70% of lead failures in leads older than 6 years (Figure 3). Lead defects occurred in newer as well as older models. Kaplan-Meier lead survival curves showed a trend to a better lead survival of the lead models 6936 and 6966 compared with the pooled group of models implanted from 1997 onwards (Figure 4). A better lead survival of 6936 and 6966 leads was particularly observed during the first 5 years after implantation. The estimated survival rate of the models 6936 and 6966 after 5 years was 93% compared with 80% in the pooled model group (P<0.05) (Figure 4). The major cause of lead failure in both groups was insulation defects (56% in 6936/6966 leads versus 46% in the pooled model group; P=0.2). Younger age and female gender were associated with a higher incidence of lead defects, whereas single-chamber ICD and implantation before 1998 tended to be associated with a better lead survival (Figure 5).

Diagnosis of Lead Defect
Diagnosis of lead defect was made by clinical presentation (inappropriate shocks) in 33% of patients and in 65% by electrical parameters during routine device evaluation. Intraoperative ICD-testing performed during elective generator replacement detected 2% of lead defects. One lead failure was detected after the patient was resuscitated by external defibrillation as a result of ventricular fibrillation. This lead had a fracture; therefore, defibrillation shock could not be delivered. The number of inappropriate shocks in patients ranged from 1 to 17 shocks (median 2, 95% confidence interval 1 to 5 shocks). Inappropriate shocks were caused by artifact sensing in 77%, T-wave oversensing in 18%, and fracture in 5% of leads.

Clinical Outcome
During the median follow-up of 934 days (interquartile range, 368 to 1870), 207 patients (21%) died: 115 patients (55%) died from congestive heart failure, 4 (2%) from sudden death, 18 (9%) from other cardiovascular death, and 27 (13%) from noncardiac causes. In 45 patients (21%), the cause of death remained unknown. Seven patients underwent heart transplantation.

Discussion
Major Findings
The annual rate of ICD lead defects that require intervention increases with time and reaches 20% in 10-year-old leads. Lead defect is an overall problem encountered in all lead models; older models as well as newer models are affected. Patients with lead defects are younger, more often female, and have better preserved left ventricular dysfunction at ICD
implantation. In addition, implantation of multiple transvenous leads for dual-chamber or biventricular devices is associated with a trend to a higher rate of defibrillation lead defects. These data emphasize that lead failure may become a prominent concern, independently of the lead model used, in ICD patients with a relatively long life span.

Incidence and Cause of Lead Failure

Lead-related complications are reported in 1% to 14% of ICD patients.6–10 This widespread range derives from different data acquisition modalities: retrospective data analysis, short-term follow-up periods, and nonstandardized inclusion criteria. The present study shows that lead defect depends mainly on the follow-up time after the lead was implanted. The estimated lead survival rates at 5 and 8 years are 85% and 60%, respectively. The annual defect rate increases with time and reaches 20% in 10-year-old leads. This is important because many of these leads remain in service. Lead-related problems can occur at any time during long-term follow-up. In addition, in accordance with other studies, a growing number of insulation defects have to be expected with increasing time after implantation.11,12 In the present study, more than half of the lead defects resulted from insulation defects. Insulation defect is a typical cause of lead failure in coaxial polyurethane-insulated leads like the Medtronic models 6936 and 6966. Polyurethane breakdown, in most cases caused by metal ion oxidation, was shown to be the mode of failure of most coaxial polyurethane pacing leads.17–19 The observed failure rate of the Medtronic 6936 and 6966 ICD leads is similar to that reported by others, as well as by the manufacturer.12,13,16,20 Both Hauser et al and Luria et al reported failure rates of close to 20% at 4 years for the 6936 and other similar coaxial polyurethane ICD leads.16,20 Dorwarth et al reported a lead survival rate of 62% at 8-year follow-up.12 The incidence of insulation defects caused by polyurethane breakdown increases during the late follow-up. In the present study, the decline in lead survival of the 6936/6966 models appears to accelerate after 5 years, which might be caused by polyurethane degradation of the 6936/6966 leads caused by metal ion oxidation.

Comparison Between Newer and Older Models

When the polyurethane ICD leads 6936 and 6966 are compared with the newer models implanted from 1997 onwards, the survival curves of the leads 6936 and 6966 show a trend to better lead survival. The newer lead models have a multilumen design: each conductor is individually insulated by silicone rubber, which should prevent the lead from degradation and injury by mechanical stress. The rate of insulation defects observed is less than in the Transvene 6936/6966 leads but still represents the main cause of lead failure.
leads is partly a result of the larger diameter. Survival during the first years of the 6936 or 6966 ICD versus 12 F). One could speculate that the better lead Transvene 6936/6966 lead models (smaller than 10 F itself. Newer models have a smaller diameter than the damage might also depend on the stability of the lead function who have a longer life expectancy. Insulation becomes more common a problem in younger ICD patients and patients with better preserved left ventricular mechanical stress is time dependent. Therefore, lead failure. Silicone leads therefore also seem to be prone to insulation failure. Mewis et al reported a high incidence of insulation defects (12%) in silicone lead systems (CPI Endotak C models 0064 and 0072) that required operative revisions during a mean follow-up of 23.8±10.9 months. Abrasion of ICD lead insulation material was a frequent finding in silicone leads during generator replacement in a study by de Lurgio et al. After an average lead implant duration of 53±18 months, 79% of silicone leads showed abrasions, whereas only 1 of 11 polyurethane leads was affected.

Mechanisms of Lead Failure
Mechanisms of insulation defect that apply to all models should also be considered. These are chronic excessive pressure on the body of the lead from the ligature used for lead fixation or mechanical injury such as subclavian crush syndrome,18,23 In the present study, about 95% of the leads were implanted with the subclavian technique. Subclavian puncture is known to have a higher lead complication rate and might have led to an increased incidence of insulation failure caused by subclavian crush syndromes. Additional causes for chronic mechanical stress on the lead could be higher activity as in younger patients, restricted anatomic circumstances as in female patients, or multiple leads in the vein. Insulation damage caused by mechanical stress is time dependent. Therefore, lead failure becomes more common a problem in younger ICD patients and patients with better preserved left ventricular function who have a longer life expectancy. Insulation damage might also depend on the stability of the lead itself. Newer models have a smaller diameter than the Transvene 6936/6966 lead models (smaller than 10 F versus 12 F). One could speculate that the better lead survival during the first years of the 6936 or 6966 ICD leads is partly a result of the larger diameter.

Diagnosis of Lead Failure
Diagnosis of lead failure was made by clinical presentation with inappropriate shocks in 33% patients. The number of inappropriate shocks in patients ranged from 1 to 17 shocks (median 2, 95% confidence interval 1 to 5 shocks). Because routine ICD follow-up did not routinely include high voltage coil impedance measurements or DFT testing, it is possible that isolated high-voltage coil failures had been missed. Routine DFT testing might have led to an earlier diagnosis of lead failure and might decrease the rate of inappropriate shocks. The main causes of inappropriate shocks were artifact detection or T-wave oversensing. Routine DFT testing might have provoked postshock oversensing, which is reported to be a specific sign of coaxial polyurethane ICD lead failure. Routine 3-month ICD evaluation led to the diagnosis of 65% of lead defects. This result emphasizes the need for increased surveillence of patients with older leads. In addition to routine device interrogation, the evaluation should include testing for oversensing during provocative maneuvers and measurement of high voltage coil and pace/sense impedances if possible. Only intraoperative ICD testing performed during elective generator replacement detected 2% of lead defects. Preoperatively measured electrical parameters during routine ICD interrogation did not indicate lead failure.

One lead failure was detected after the patient was resuscitated by external defibrillation as a result of ventricular fibrillation. This lead had a fracture, and consecutive defibrillation shocks could not be delivered. If the patient had not been successfully resuscitated, he would have died from sudden death. Sudden death in patients with ICD is not uncommon. In the present study, 4 patients died from sudden death. Pooled data of randomized clinical trials that involve >3500 patients indicate an ICD-unresponsive sudden-death rate of nearly 5%. Few data are available on the mode of death in these patients. About one third is attributed to sudden cardiac death, whereas the mode of up to 25% of sudden death remains unclear. Future ICD studies should focus on mode of death in ICD patients and lead failure as a mode of death should be considered.

Conclusions
The annual rate of ICD lead defects that require intervention increases with time and reaches 20% in 10-year-old leads. Lead defect is an overall problem encountered in all lead models. Lead defects occur in newer as well as older models. Patients with lead defects are younger and more often female. Multiple lead implantations are associated with a trend to a higher rate of defibrillation lead defects. Nearly two thirds of lead defects can be detected by electrical parameters during routine ICD control, whereas in one third of patients lead defect is recognized only after the occurrence of inappropriate shocks.

These findings raise important issues for patients with expected longer life span at time of ICD implantation, such as younger patients, patients with preserved left ventricular function, or patients who have a prophylactic ICD. The high incidence of lead complications in these patients should be considered at time of implantation in the selection of device or mode of surgical approach for lead implantation. Furthermore, patients with longer follow-up after lead implantation should have increased surveillence. When the increasing rate of lead failure with time is considered, leads should be carefully evaluated at the time of pulse generator replace-
ment. DFT testing, measurement of high-voltage coil and pace/sense impedances, and electrogram recordings should be performed before a decision is made to retain or replace the lead. The data that form the present study do not support routine replacement of intact, normally functioning, transvenous defibrillation leads. However, additional studies are needed to identify predictors of lead failure and safe management strategies to minimize inappropriate shocks and number of additional lead revisions. Consideration of novel approaches to these patients such as “leadless” ICDs deserves further attention.28

Study Limitations

As all implants originated from a single implanting center, our observations and conclusions may not necessarily be generalizable. However, ICD implantation procedures were performed by surgeons who had >10 years of experience with pacemaker and defibrillator implants and performed >95% of all implantations and generator replacements.

About 95% of the leads were implanted with the subclavian technique. As subclavian puncture is known to have a higher lead complication rate, these results may not be extended to leads that are implanted via more desirable access routes such as the cephalic vein.

Because of the long implant duration, lead extraction was not performed routinely. Therefore, the precise cause of lead failure could not be clarified in detail. The reliability of the estimated lead survival rates is decreased because of inconsistent follow-up, loss of patients over time to death from heart failure, and other causes. The number of lead failures has presumably been underestimated.

Disclosures

None.

References

CLINICAL PERSPECTIVE

The long-term reliability of implantable cardioverter-defibrillator leads becomes increasingly important as implantable cardioverter-defibrillators are implanted in more patients with long life expectancies. In the present article, we analyze the rate of significant lead problems after implantation of 990 transvenous defibrillation leads implanted between 1992 and 2005. The lead failure rate increased with time and was encountered in all lead models from all manufacturers. Lead defects occurred more often in younger patients and in women. The presence of multiple implanted leads was associated with a trend to a higher rate of defibrillation lead problems. The findings have important implications for patients with expected longer life span at time of implantable cardioverter-defibrillator implantation. Lead problems occurred with a substantially greater frequency than the reported implantable cardioverter-defibrillator pulse generator failures that have received substantial attention in the lay press in recent years. The authors conclude that the high incidence of lead complications should be taken into consideration at the time of implantation as some surgical approaches may be associated with less risk of lead problems. In addition, leads should always be carefully evaluated at the time of pulse generator replacement.
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Circulation. 2007;115:2474-2480; originally published online April 30, 2007; doi: 10.1161/CIRCULATIONAHA.106.663807
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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