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Necessity for Surgical Revision of Defibrillator Leads Implanted Long-Term

Causes and Management

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Background—Defibrillator lead malfunction is a potential long-term complication in patients with an implantable cardioverter-defibrillator (ICD). The aim of this study was to determine the incidence and causes of lead malfunction necessitating surgical revision and to evaluate 2 approaches to treat lead malfunction.

Methods and Results—We included 1317 consecutive patients with an ICD implanted at 3 European centers between 1993 and 2004. The types and causes of lead malfunction were recorded. If the integrity of the high-voltage part of the lead could be ascertained, an additional pace/sense lead was implanted. Otherwise, the patients received a new ICD lead. Of the 1317 patients, 38 experienced lead malfunction requiring surgical revision and 315 died during a median follow-up of 6.4 years. At 5 years, the cumulative incidence was 2.5% (95% confidence interval, 1.5 to 3.6). Lead malfunction resulted in inappropriate ICD therapies in 76% of the cases. Implantation of a pace/sense lead was feasible in 63%. Both lead revision strategies were similar with regard to lead malfunction recurrence ($P=0.8$). However, the cumulative incidence of recurrence was high (20% at 5 years; 95% confidence interval, 1.7 to 37.7).

Conclusions—ICD lead malfunction necessitating surgical revision becomes a clinically relevant problem in 2.5% of ICD recipients within 5 years. In selected cases, simple implantation of an additional pace/sense lead is feasible. Regardless of the chosen approach, the incidence of recurrent ICD lead-related problems after lead revision is 8-fold higher in this population. **(*Circulation*. 2008;117:2727-2733.)**

Key Words: defibrillation ■ defibrillators, implantable ■ electrical stimulation ■ heart arrest ■ pacing

An implantable cardioverter-defibrillator (ICD) has become the standard therapy for patients with aborted sudden cardiac death and those at high risk for sudden cardiac death. Numerous primary and secondary prevention trials resulted in the expansion of the ICD indications.[1–3] Consequently, the number of implanted ICD systems is continuously growing. ICD leads are the weakest part of the ICD systems because they have a complex design and need to withstand mechanical strain. In recent studies, estimated lead survival rates ranged from 85% at 5 years to 60% at 8 years.[4–7]

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Possible strategies to resolve ICD lead problems depend on the causes of lead failure. If the high-voltage part of the lead is not functioning, a new defibrillation lead has to be implanted.[8] On the other hand, other causes of lead failures can be managed by simply implanting an additional pace/sense (P/S) lead. Examples are wire fractures and insulation defects restricted to the P/S part of the lead or inappropriate sensing with potential deleterious effects for the patient.[9,10] If lead failure is due to a sensing problem and cannot be corrected by reprogramming, implantation of an additional P/S lead usually is required. Compared with new defibrillation leads, these leads are smaller in diameter, are easier to implant, are less costly, and have a less complex design.

The aim of this study was to assess the incidence and causes of ICD lead problems requiring surgical revision in a large cohort of consecutive ICD patients. Furthermore, the 2 strategies of implanting an additional P/S lead or a new ICD lead to manage lead malfunction were studied, and the cumulative incidence of recurrent lead problems was compared with the cumulative incidence of first lead malfunction.

Methods

Study Design and Participants

We conducted a retrospective study of all patients who attended any of 3 European high-volume tertiary care centers for ICD implanta-

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tion. The study population consisted of 1317 patients treated between March 1993 and January 2004 at the University Hospital in Basel, Switzerland (n=369), the Charité University Hospital Benjamin Franklin in Berlin, Germany (n=420), and the Herz-Zentrum Bad Krozingen, Bad Krozingen, Germany (n=528).

We reviewed the charts of all patients to determine the time from ICD implantation until the patients either died of any cause or suffered lead failure. We defined and counted a lead failure as a study end point if a case required surgical revision to correct the lead-related problem. For all patients with lead malfunction requiring surgical revision, we assessed the type of lead initially implanted and the strategy used to resolve lead failure. Causes of lead malfunction were classified as follows: structural problems, including insulation defects and lead fractures, and functional problems, including noise or far-field sensing, T-wave oversensing, and others (noise resulting from contact with another lead, unstable impedance measurements, R-wave reduction, and loss of capture).

The classification was based on the information recorded in the patient's chart. If the electrode condition was documented (fracture or insulation defect), this information was used primarily for classification. If a sensing failure was documented, the classification was done accordingly. Furthermore, we determined whether the problem became apparent during routine ICD interrogation, as inappropriate therapy, or as loss of capture.

Early postoperative lead dislodgements within the first 2 weeks were considered perioperative surgical problems and therefore were not included in the analysis.

Follow-Up

Patient follow-up started at the time of first implantation and lasted until death of any cause or the end of follow-up, which consisted of administrative censoring in January 2004 or of the date of the latest documented device interrogation for patients lost to follow-up. At implantation, all ICD systems were tested according to standard clinical practice, including determination of sensing, lead and shock impedances, pacing thresholds, and defibrillation thresholds after repetitive induction of ventricular fibrillation.[11] Follow-up was performed at the ICD outpatient clinic of each center every 3 to 6 months or earlier as needed. Follow-up consisted of interrogation and retrieval of all stored data since the last visit, as well as determination of sensing, impedance measurements, and pacing thresholds. Follow-up visits were performed according to standard fashion in the ICD clinic. No patients were lost to follow-up after lead revision.

Determination and Management of Lead Malfunction

Lead malfunction was suspected and identified after activation of the alert function of the device, if intracardiac electrograms showed artifacts, after delivery of inappropriate therapies, or after device interrogation at regular visits. Subsequently, a chest x-ray was taken to search for radiological abnormalities of the lead such as visible discontinuities or sharp bends. If lead failure was confirmed by any of the above approaches, leads and connectors were examined, and threshold and impedance measurements were repeated during surgery. The P/S part of the lead was tested in a bipolar fashion.[11] The high-voltage part was tested in both a unipolar and a bipolar fashion. If any result indicated a defect of the high-voltage part of the ICD lead, a new ICD lead was implanted. If no sign of failure of the high-voltage part of the ICD lead was detected, an additional P/S lead was implanted and connected to the ICD instead of the P/S part of the ICD lead. Subsequently, ventricular fibrillation was induced, and appropriate function of the system was tested with a standard approach. The policy on removal of the dysfunctional ICD leads varied between the participating centers, but the majority of leads (35 of 38, 92%) were left in place.

Statistical Analysis

We calculated the cumulative incidence function for the end point of time to lead malfunction using competing risk methodology. Death without prior lead malfunction constitutes a competing event that makes lead malfunction impossible. Although frequently used, cumulative incidence estimates based on Kaplan–Meier analyses for the event of interest (lead malfunction) would require the censoring of patients who died without having experienced lead malfunction. The Kaplan–Meier approach leads to inflated malfunction probabilities because dead (and thus censored) subjects are treated as if they could experience lead malfunction in the future.[12,13] The cumulative incidence function, however, is an easy-to-interpret and therefore appealing method to analyze the probability of distinct malfunction causes (eg, lead malfunction) that occur as time progresses. We thus analyzed time to first lead malfunction using the ICD implantation date as time 0 and analyzed lead malfunction recurrences in patients with lead malfunction using the revision date as time 0. Furthermore, in patients who experienced lead malfunction, we displayed the proportion of lead malfunction recurrences according to the 2 revision strategies of P/S lead versus new ICD lead.

We used R version 2.3.1,[14] especially the library cmprsk for cumulative incidence function analyses. All reported confidence intervals (CIs) are 2-sided 95% CIs, and tests with a value of $P<0.05$ were regarded as significant.

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.

Results

Cumulative Incidence of ICD Lead Malfunction Necessitating Surgical Revision

The baseline characteristics of the implanted ICD leads are depicted in Table 1. During a median follow-up of 6.4 years (95% CI, 6.0 to 6.6), 38 lead malfunctions requiring surgery and 315 deaths without prior lead malfunction occurred in 1317 patients. The cumulative incidence function of lead malfunction and prior death is shown in the Figure. Cumulative lead malfunction incidences were 1.8% (95% CI, 1.1 to 2.6), 2.5% (95% CI, 1.5 to 3.3), and 4.6% (95% CI, 3.0 to 6.2%) at years 3, 5, and 10 after implantation, respectively. At the same time, mortality without lead malfunction was much higher, with cumulative incidences of 14.5% (95% CI, 12.5 to 16.6), 22.8% (95% CI, 20.3 to 25.3), and 33.6% (95% CI, 30.2 to 37.1) at years 3, 5, and 10, respectively (the Figure).

Lead Characteristics

Lead characteristics and the corresponding number of lead malfunctions are shown in Table 2 for the study population. No statistically significant differences were found on the number of lead malfunctions between single- and dual-shock coils, single-lumen and multilumen designs, true bipolar or integrated bipolar leads, or pectoral and abdominal ICD implantation sites.

Characteristics of Patients Requiring Surgery for Lead Malfunction

The 38 patients requiring lead revision showed the characteristics of a contemporary ICD population. The group included 32 men (84%), the mean age was 64±13 years, and the mean ejection fraction 0.42±0.13. The underlying cardiac disease was coronary artery disease in 20 patients (53%), dilated cardiomyopathy in 10 patients (26%), and other heart diseases (long-QT syndrome, hypertrophic cardiomyopathy, postinflammatory arrhythmias) in 8 patients (21%). The

Table 1. ICD Lead Characteristics

ICD Lead	n	Failures, n	Polarity	Coils	Lumen
Biotronik KAINOX RV	33	3*	True bipolar	Single	Multilumen
Biotronik KAINOX RV-S	5	1*	True bipolar	Single	Multilumen
Biotronik KAINOX SL	54	3*	True bipolar	Dual	Multilumen
Biotronik KAINOX VDD	20	0	True bipolar	Single	Multilumen
Biotronik KENTROX RV-S	15	0	True bipolar	Single	Multilumen
Biotronik KENTROX SL	1	0	True bipolar	Dual	Multilumen
Biotronik SPS UP/BP	14	0	True bipolar	Single	Multilumen
Biotronik TEROX RV	3	0	True bipolar	Single	Multilumen
CPI Endotak 0062	10	1*	Integrated bipolar	Dual	Multilumen
CPI Endotak 0072	79	5*	Integrated bipolar	Dual	Multilumen
CPI Endotak 0095	19	3*	Integrated bipolar	Dual	Multilumen
CPI Endotak 0125	90	6*	Integrated bipolar	Dual	Multilumen
CPI Endotak 0145	38	1*	Integrated bipolar	Dual	Multilumen
CPI Endotak 0148	159	1*	Integrated bipolar	Dual	Multilumen
CPI 0040 A67 Epicard	4	0	Unipolar	NA	Multilumen
CPI 0041 L67 Epicard	10	0	Unipolar	NA	Multilumen
CPI 4312 Epicard	4	0	Unipolar	NA	Multilumen
CPI Endotak xxxx family	152	0	Integrated bipolar	Dual	Multilumen
Intermedics 497-19	13	1*	Integrated bipolar	Single	Coaxial
Intermedics 497-xx family	12	0	Integrated bipolar	Single	Coaxial
Intermedics 497-10 SQ	1	0	Unipolar	NA	Coaxial
Medtronic 141081	4	1*	Integrated bipolar	Single	Coaxial
Medtronic 6932	32	1*	True bipolar	Single	Multilumen
Medtronic 6936	81	6*	True bipolar	Single	Coaxial
Medtronic 6943	40	1*	True bipolar	Single	Multilumen
Medtronic 6944	90	2*	True bipolar	Single	Multilumen
Medtronic 6947	13	1*	True bipolar	Dual	Multilumen
Medtronic 6884	4	0	True bipolar	Single	Coaxial
Medtronic 6897 Epicard	1	0	NA	Single	NA
Medtronic 6933 SVC	1	0	NA	Single	NA
Medtronic 6934	3	0	True bipolar	Single	Coaxial
Medtronic 6939 SQ	2	0	NA	Single	NA
Medtronic 6963	3	0	NA	Single	NA
Medtronic 6966	14	0	True bipolar	Single	Coaxial
Medtronic 694x family	154	0	Integrated bipolar	Dual	Multilumen
St Jude 15xx RIATA family	42	0	True bipolar	Dual	Multilumen
St Jude SP xx family	68	0	Unipolar	Dual	Coaxial
St Jude RV xx famliy	25	0	Integrated bipolar	Single	Coaxial
Total	1317	38			

Polarity: 0=integrated bipolar, 1=unipolar, 2=true bipolar; coils: 1=single coil, 2=dual coil; tubing: 1=multilumen, 0=coaxial. CPI Endotak xxxx family includes Endotak 0060 (n=1), 0074 (n=6), 0075 (n=6), 0094 (n=4), 0127 (n=2), 0128 (n=4), 0134 (n=10), 0135 (n=5), 0144 (n=29), 0146 (n=1), 0147 (n=41), 0149 (n=3), 0154 (n=2), 0155 (n=12), 0156 (n=1), 0157 (n=2), 0158 (n=9), 0174 (n=3), and 0175 (n=11); Intermedics 497-xx family includes Intermedics 497-07 (n=2), 497-20 (n=3), and 497-23 (n=7); Medtronic 694x family includes Medtronic 6940 (n=1), 6942 (n=124), and 6945 (n=29); St Jude 15xx RIATA family includes St Jude 1570 (n=31), 1572 (n=4), 1580 (n=5), and 1581 (n=2); St Jude SP xx family includes St Jude SP 01 (n=51) and SP 02 (n=17); and St Jude RV xx family includes St Jude RV 02 (n=20) and 06 (n=5).

*ICD leads with problems requiring intervention.

indications for ICD implantation were survived resuscitation or defibrillation for ventricular tachycardia or ventricular fibrillation in 18 patients (47%), spontaneous sustained ventricular tachycardia in 13 patients (34%), syncope with suspected ventricular tachyarrhythmia in 3 patients (8%), and primary prevention in 4 patients. Thirty-two of the devices (84%) in the lead malfunction group were single-chamber and 6 (16%) were dual-chamber ICDs.

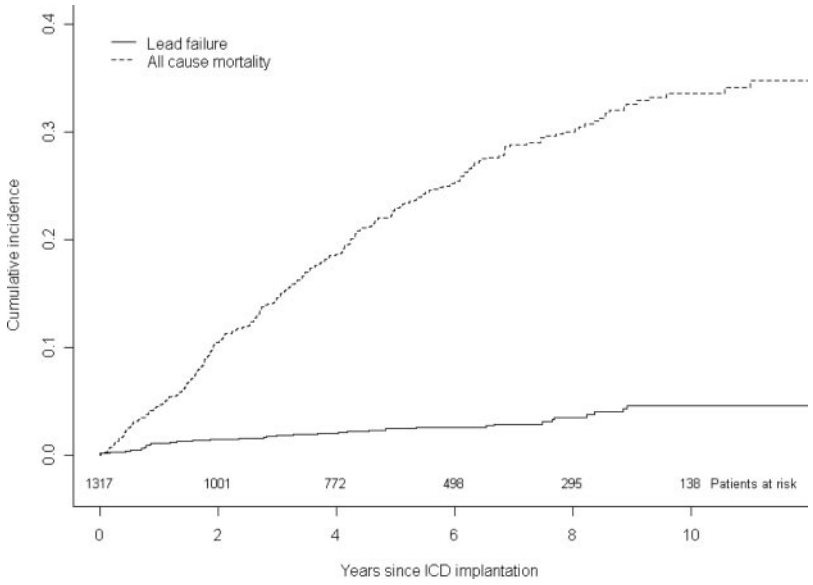

Figure. Cumulative incidence of ICD lead malfunction requiring surgical revision or death in 1317 patients with an ICD implanted at 3 European tertiary care centers.

Causes of Lead Malfunction and Inappropriate Therapies

Lead malfunction resulted in inappropriate ICD therapies in 29 of 38 patients (76%). The remaining lead malfunctions were detected during routine follow-up. The causes for malfunction were insulation defect in 10 patients (26%), artifact oversensing in 9 patients (24%), lead fracture in 9 patients (24%), T-wave oversensing that could not be treated by reprogramming the ICD in 5 patients (13%), and other problems in 6 patients (13%; noise caused by contact with another lead [n=1], unstable impedance measurements [n=1], R-wave reduction [n=3], loss of capture [n=1]). In 1 case, a combination of insulation defect and lead fracture was detected.

Surgical Lead Revision

The ICD lead problem was treated by placement of an additional P/S lead in 24 cases (63%) and replacement of the ICD lead in 13 cases (34%). In 1 case, the newly implanted ICD lead (15 days) had to be repositioned after diagnosis of an increasing pacing threshold. In total, 3 of the 38 affected leads (8%) were removed. Three patients with a visible fracture of the P/S part of the ICD lead and 4 patients with a proximal insulation defect received an additional P/S lead after successful testing of the integrity of the high-voltage part of the ICD lead. In all other cases, functional sensing problems without a visible defect were the indications for implantation of an additional P/S lead.

Table 2. Lead Characteristics and Malfunctions

Lead Characteristic	n	Malfunctions, n (%)
Dual coil	892	22 (2.5)
Single coil	425	16 (3.8)
True bipolar	510	19 (3.7)
Integrated bipolar	807	19 (2.4)
Pectoral	1151	30 (2.3)
Abdominal	166	8 (4.8)
Single lumen	230	10 (4.3)
Multilumen	1087	28 (2.6)

Long-Term Outcome After Lead Revision

The median follow-up of the 38 patients with lead malfunction was 3.1 years (95% CI, 1.5 to 4.8). Five patients (13%) within the lead malfunction group died during follow-up, 3 patients (12%) in the P/S lead group and 2 patients (15%) in the new lead group. Six patients (16%) experienced lead failure recurrence: 3 patients in the P/S lead group (12%) and 3 in the new lead group (23%). The cumulative incidences of lead failure recurrence were 4.4%, 14.1%, and 19.8% at years 2, 3, and 4, respectively, and nearly 10-fold the cumulative incidence of first failure. Table 3 depicts the causes and the actions taken to solve these problems.

Discussion

Main Findings

The data presented demonstrate that ICD lead malfunction with the subsequent need for surgical revision is a clinically relevant problem with a cumulative incidence of 1.1% at 1 year and 2.5% at 5 years after ICD implantation. Lead malfunction became apparent by the delivery of an inappropriate ICD therapy in 76% of the affected patients. In 63% of the patients, lead malfunction could be resolved by implantation of an additional P/S electrode. As ascertained during subsequent follow-up, these patients did not experience any more problems compared with a full replacement of the ICD lead. Because removal of the nonfunctioning ICD lead is the exception, addition of a smaller P/S lead instead of a second ICD lead maybe generally adopted on the basis of these data. Nonetheless, and regardless of the approach, 20% of the patients with a revised lead will experience recurrent lead-related problems during the next 5 years.

Comparison With Other Studies

Recently, Kleemann and coworkers[7] published their long-term experience with ICD leads in 990 patients. They

Table 3. Characteristics of the 6 Patients Who Experienced Recurrent Lead Malfunction

Initial Lead	Cause of First Malfunction	Inappropriate Shocks	Treatment Type of Lead	Cause and Time of Second Malfunction	Inappropriate Shocks	Treatment Type of Lead
Medtronic 6944	Noise sensing	Yes	New HV lead, Medtronic 6942	Noise sensing, 21 mo	No	P/S lead, Medtronic 6940
Intermedics 497-19	Insulation defect	No	New HV lead, CPI Endotak 148	Noise sensing, 24 mo	Yes	P/S lead, Guidant 4471
CPI Endotak 072	Lead fracture	Yes	New HV lead, CPI Endotak 072	T-wave oversensing, 94 mo	No	New HV lead, CPI Endotak 158+
Medtronic 6936	Insulation defect	Yes	P/S lead, Medtronic 4068	Lead fracture, 21 mo	Yes	New HV lead, Medtronic 6943
Medtronic 6947	T-wave oversensing	Yes	P/S lead, Medtronic 5076	Threshold elevation, 43 mo	No	New HV lead, Medtronic 6947
Biotronik Kainox SL	Noise sensing	Yes	P/S lead, Biotronik Elox 60	Noise sensing, 11 mo	Yes	P/S lead, Medtronic 5075

HV indicates high voltage.

reported a surprisingly high defect rate of 15% after 5 years and 40% after 8 years. This is in sharp contrast to only a 2.5% cumulative ICD lead malfunction probability 5 years after ICD implantation in our study. There may be several reasons for this discrepancy. First, most patients with lead defects in the study by Kleemann et al were detected during routine follow-up, and only 33% presented with inappropriate shocks. In contrast, in 76% of our patients, the lead malfunction came to clinical attention because of inappropriate ICD therapies. It is unlikely that we missed a relevant number of patients with lead malfunction during follow-up because the participating centers carried out the same recommended follow-up routine reported by Kleemann et al. It is possible that Kleemann et al were more aggressive in changing leads than we were. Continuous increases in lead impedances, for instance, may be monitored for prolonged periods of time and do not always mandate immediate replacement. Likewise, many sensing issues like decreases in R-wave and T-wave oversensing can be dealt with by changing the sensing characteristics and repeating ventricular fibrillation induction. It is unlikely that we missed pertinent lead malfunctions because the mortality of patients without prior lead defects in our group (315 of 1317 patients, 24%) is comparable to the mortality in their group (207 of 990 patients, 21%).

Finally, Kleemann et al[7] chose a Kaplan–Meier approach to calculate the event-free lead performance. A Kaplan–Meier approach always overestimates the cumulative incidence of lead malfunction because of censoring deaths that occurred before lead malfunction. The Kaplan–Meier method attempts to predict what the malfunction rate would be in an imaginary world in which no patient ever died. The Kaplan–Meier method relies on the assumption of noninformative censoring not only for the patients who are alive but also for the patients who have died. This assumption might not be true in this situation.[15] Because subjects who will never have lead malfunction are treated as if they could do so in the future (they are censored), the naïve Kaplan–Meier approach overestimates the probability of lead malfunction. If the patients who died before lead malfunction were revived and allowed to continue on to lead malfunction, they would lower the estimate given by the Kaplan–Meier method. The bias is greater when the competition is heavier (ie, with a high mortality before lead malfunction), which is the case in our population (the Figure). Instead, we used the interpretation-friendly cumulative incidence function approach, which estimates the actual probability that a patient will experience lead malfunction as time accrues.[12,15]

Alter et al[16] studied 440 ICD patients with a median follow-up of 46 months and found a lead-related dysfunction in 52 patients (12%). When perioperative lead dislodgement and connector problems were excluded, the percentage of lead-related problems was in the realm of 6%, which is comparable to our data. Mehta et al[17] analyzed 3 different combinations of leads and pectorally implanted ICD for reasons of lead failure. They concluded that weight and volume of the ICD device were independent risk factors for insulation defects of the leads, possibly because of pressure in the pectoral pocket. Although smaller devices and advances in lead design will probably decrease the incidence of lead-related ICD complications further, many patients will still experience lead-related problems.

Management of Lead Malfunction

Ellenbogen et al[8] reported on long-term failure and management of a polyurethane lead and recommended laser extraction for most patients in case of documented lead failure. One has to bear in mind that extraction of leads that have been implanted long-term carries an increased perioperative risk. According to the current Heart Rhythm Society recommendations, only an ICD or pacemaker infection is a class I indication for extraction.[18] With these criteria, the majority (92%) of failing leads in our study population were left in place. An intervention after lead revision was necessary in only 1 case because of contact of the lead in situ with the new lead. Only one of the patients receiving an additional P/S lead needed a third intervention owing to subsequent confirmed problems with the high-voltage part of the old lead. In general, we could show that the incidence of recurrence is substantially increased compared with first lead malfunction (20% cumulative incidence compared with 2.5% cumulative incidence at 5 years), regardless of the revision approach taken (additional P/S versus new ICD lead). This translated to

a cumulative freedom of lead-related problems after lead revision of 84% after 4 years in our population. This is higher than in the study by Wollmann et al,[19] which demonstrated a cumulative freedom of lead-related complications after implantation of an additional P/S lead of 82% after 2 years and 60% after 5 years. The reason may be that more abdominal and older-generation leads were used in their study.

Another study addressing the management of lead failure in leads with insulation defects limited to the sensing part of the ICD lead was performed by Mahapatra et al.[20] Their study showed that in case of an insulation defect limited to the sensing part of the ICD lead, it is feasible to repair the insulation with commercially available kits and achieve results comparable to those of complete lead replacement during a 4-year follow-up. This technique was not applied in our patients but provides another option to manage lead failure limited to the proximal P/S part of the ICD lead.

Clinical Implications

It is feasible and safe to solve sensing-related problems and rises in pacing thresholds by implanting an additional P/S lead. In the case of insulation defects, lead fractures, and noise, we strongly favor the implantation of a new ICD lead for security reasons. However, patients with an ICD lead problem have an 8-fold-increased risk for recurrent ICD lead problems.

Study Limitations

It cannot be ruled out that the true incidence of lead failure is higher because some lead malfunctions may be clinically silent and cause no clinical problem. It also is possible that some deaths in our ICD population were due to lead-related problems because only a minority of devices were interrogated postmortem. We were not able to provide data on the impact of the subclavian vein as opposed to the cephalic vein approach to implant the lead. Finally, we have no data on the cause of death in the 5 patients who died with a revised lead. However, a death rate of 13% over 36 months is comparable to the mortality of the general ICD population.[3] Moreover, the comparison of the lead revision strategies (P/S lead versus new lead) should be regarded as preliminary because of the small sample and therefore the limited power to show any difference. In addition, allocation to strategy was not randomized.

Conclusions

This study demonstrates that malfunction of modern ICD leads requiring surgical revision is clinically relevant. If the integrity of the high-voltage part of the ICD lead can be ascertained, simply implanting an additional P/S lead might evolve as a safe option. However, the high incidence of lead malfunction recurrence requires a closer follow-up after a first lead revision.

Disclosures

Dr Sticherling is a consultant for Medtronic and Boston Scientific; Dr Zabel, for Biotronik, Medtronic and Boston Scientific; and Dr Osswald, for Medtronic, Boston Scientific, Biotronik, and St Jude Medical. Dr Schaer has received honoraria from Boston Scientific. The other authors report no conflicts.

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CLINICAL PERSPECTIVE

An implantable cardioverter-defibrillator has become standard care for secondary prevention of sudden cardiac death and for primary prevention in patients at high risk for sudden cardiac death. Malfunction of the defibrillator lead is a potential long-term complication in this population. The aim of this study was to determine the incidence and causes of lead malfunction necessitating surgical revision and to evaluate 2 surgical approaches to treat lead malfunction. For this purpose, we analyzed 1317 patients who received an implantable cardioverter-defibrillator between 1994 and 2004. During a mean follow-up of 6.5 years, 38 patients required surgery to solve a lead-related problem. Cumulative lead malfunction incidences were 1.8%, 2.5%, and 4.6% at years 3, 5, and 10 years after implantation. At the same time, mortality without lead malfunction was much higher, with cumulative incidences of 14.5%, 22.8%, and 33.6%. The main reasons for lead malfunction were insulation defects (26%), artifact oversensing (24%), and lead fractures (24%). Lead malfunction resulted in inappropriate implantable cardioverter-defibrillator therapy in 76% of the cases. If the integrity of the high-voltage part of the defibrillator lead could be ascertained, only an additional pace/sense lead could be implanted. Otherwise, a new defibrillator lead was used. However, once a malfunction has occurred, the cumulative incidence of recurrent lead malfunction was 8-fold higher and therefore warrants a closer follow-up.