Implantable cardioverter defibrillator treatment : benefits and pitfalls in the currently indicated population

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Chapter 14

Risk of Failure of Transvenous Implantable Cardioverter Defibrillator Leads.

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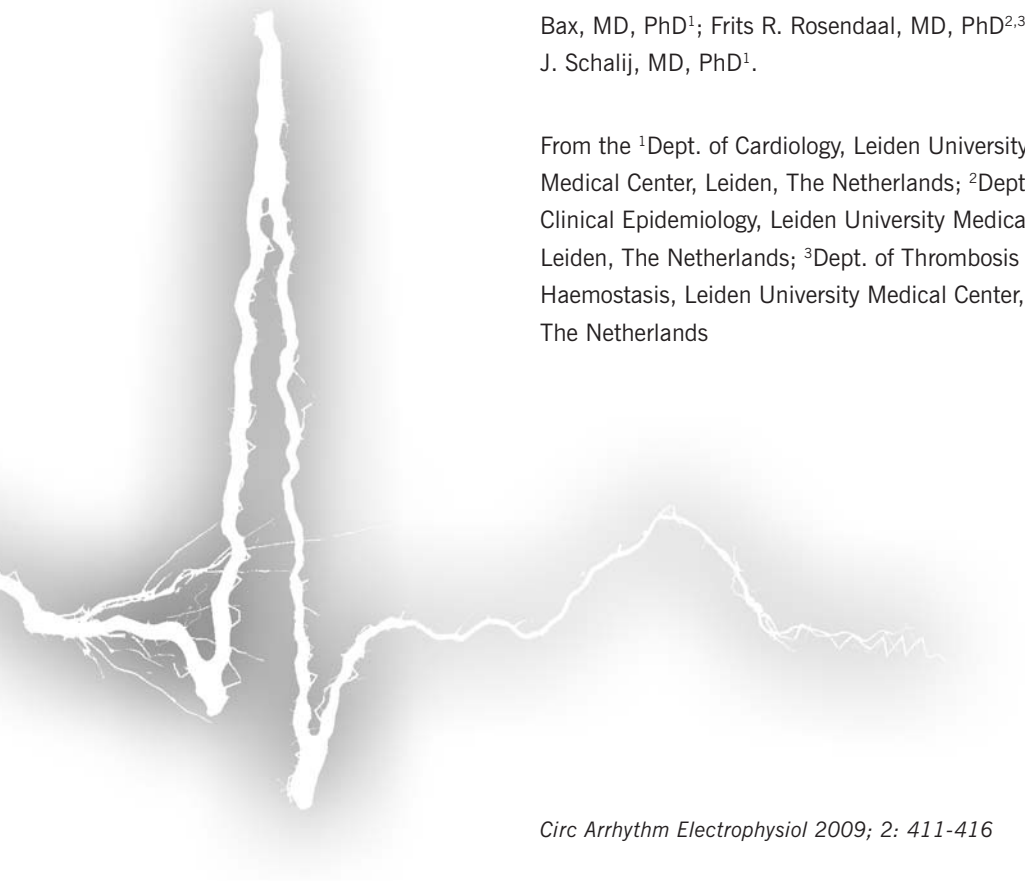

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Abstract

Background: Despite the positive effect on mortality in selected patients, implantable cardioverter defibrillator (ICD) 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 ICD 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 (Fr). During a mean follow-up of 36 months, 82 (3.8%) cases of lead failure were identified. Cumulative incidence of lead failure at one year was 0.6%, at five years 6.5% and 16.4% at ten years. The highest risk of lead failure was found in small-diameter leads. Adjusted hazard ratio was 6.4 (95% CI 3.2-12.8) for Medtronic 7 Fr leads, when compared to all other leads.

Conclusions: In this large single-center experience, the overall incidence of lead failure was 1.3 (95% CI 1.0-1.6) 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.

Introduction

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 over 100 000 units in 2007. Despite the positive effect on mortality in selected patients, ICD therapy is also associated with some serious drawbacks which 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 have to 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 USA and some European countries may help to improve surveillance of ICD and lead performance.

We have 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 since 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 [LVEF]).[17, 18] Due to 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,

Table 1: Patient characteristics.

	All leads	All removal or capping	lead failure	lead failure or dislodgement
Variable	(n=2161)	(n=146)	(n=82)	(n=93)
Base-line characteristics				
Age, years	61±13	57±16	56±16	56±16
Male sex, %	80	84	83	83
Ejection fraction, %	34±15	35±16	35±16	37±17
Ischemic etiology, %	65	72	73	71
Primary indication, %	55	41	37	42
Implanted ICD				
Single chamber, %	15	32	37	34
Dual chamber, %	49	48	44	48
Biventricular, %	36	21	20	17

Continuous variables are expressed as mean ± SD.
ICD indicates implantable cardioverter defibrillator.

[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 was performed.

End-points and follow-up

The follow-up was from lead implantation, occurring between 1992 and 2007, to February 1st 2008. In the Dutch health care system, all patients are followed by the implanting center. Since periodic follow-up was performed every three to six 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 three end-points: (1) all-cause lead removal or capping; (2) lead failure; (3) lead failure or dislodgement within six 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 one 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; (6) manufacturer’s returned product report confirming the failure.

Table 2: Classification of defibrillation leads by manufacturer and lead diameter.

Lead group	Lead models
Biotronik 8 Fr	Linox
Boston Scientific 11 Fr	Endotak 0125, 0144, 0145 and 0155
Boston Scientific 9 Fr	Endotak 0138, 0147, 0148, 0161, 0164, 0165, 0175, 0181 and 0185
Medtronic 10.5 Fr	Sprint 6932, 6942 and 6945
Medtronic 9 Fr	Sprint Quattro 6944 and 6947
Medtronic 7 Fr	Sprint Fidelis 6930, 6931, 6948 and 6949
St. Jude Medical 11Fr	SPL SP01 and SP02
St. Jude Medical 8 Fr	Riata 1570, 1580 and 1582
St. Jude Medical 7 Fr	Riata 7000 and 7002

Fr indicates French

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, MN, United States), Boston Scientific (Natick, MA, United States) (formerly CPI, Guidant [St. Paul, MN, United States]) and St. Jude Medical/Ventritex (St. Paul, MN, United States). Classification on lead diameter in French (Fr) resulted in nine groups, as shown in Table 2: (1) Biotronik 8 Fr; (2) Boston Scientific 11 Fr; (3) Boston Scientific 9 Fr; (4) Medtronic 10.5 Fr; (5) Medtronic 9 Fr; (6) Medtronic 7 Fr; (7) St Jude Medical 11 Fr; (8) St Jude Medical 8 Fr; (9) St Jude Medical 7 Fr. The leads with a recommended introducer diameter of 7 Fr were described as small diameter leads.

Continuous data are expressed as mean and standard deviation or range, median and first and third quartile where appropriate; nominal data are presented as numbers and percentages. Cumulative incidences were analyzed by 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 LVEF. Death or heart transplantation was counted as censoring events.

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

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-and-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 years, range 5 to 86 years) had ischemic heart disease (65%) and a poor LVEF (34±15% Table 1: patient characteristics). 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 found to be 2.2 per 100 lead-years (95% CI 1.9-2.6 per 100 lead-years). Cumulative (Figure 1) lead failure at one year was 1.9%, at two years 3.5%, at five years 10.4% and at ten 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

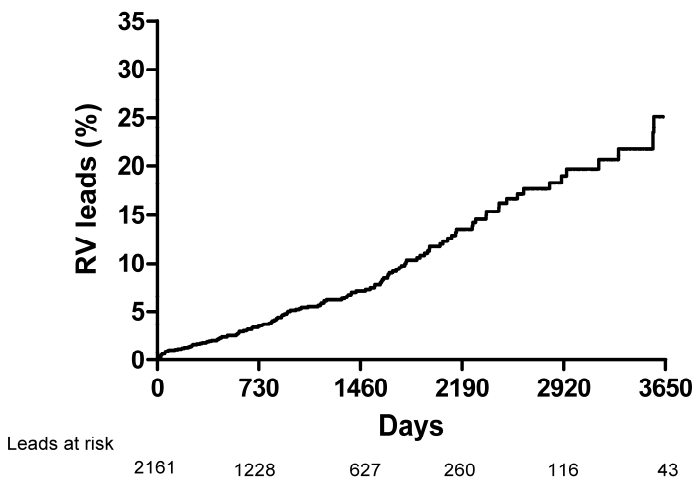

Figure 1. Kaplan-Meier curve for all-cause lead removal or capping.

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 mal-sensing 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 one year was 99.4%, at two years 98.6%, at five years 93.5% and 83.6% at ten years. 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 1.0-1.6). Incidence rates for lead failure were found to be higher in the small diameter defibrillation leads with 2.7 (95% CI 1.6-4.4) per 100 lead-years for the Medtronic 7 Fr leads. Data for all groups are shown in Table 3. The hazard ratio (adjusted for age, sex, and LVEF) for small diameter leads, compared to the other leads was 10.9 (95% CI 1.4-85.5) for St Jude Medical and 6.4 (95% CI 3.2-12.8) for Medtronic. Implantation with either group of Boston Scientific defibrillation leads decreased the risk of lead failure: For the group with 11 Fr and 9 Fr diameter, adjusted hazard ratios were 0.3 (95% CI 0.2-0.8) and 0.5 (95% CI 0.3-0.9) respectively, relative to all other leads.

After categorization by manufacturer and generation, other, previously reported, risk factors for lead failure (subclavian vs cephalic venous (HR 1.0 (95% CI 0.6-1.5), p=0.9), active vs. passive lead fixation (HR 1.2 (95% CI 0.6-2.4), p=0.6), dual vs. single coil leads (HR 0.8 (95% CI 0.4-1.9), p=0.6) and dedicated vs. integrated bipolar leads (HR 0.8 (95% CI 0.1-6.2), 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 six months following implantation with a median time to event of 34 days (interquartile range, 4 to 68 days). After relocation, one of the leads (Medtronic 7 Fr) 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 1.2-1.7) per 100 lead-years.

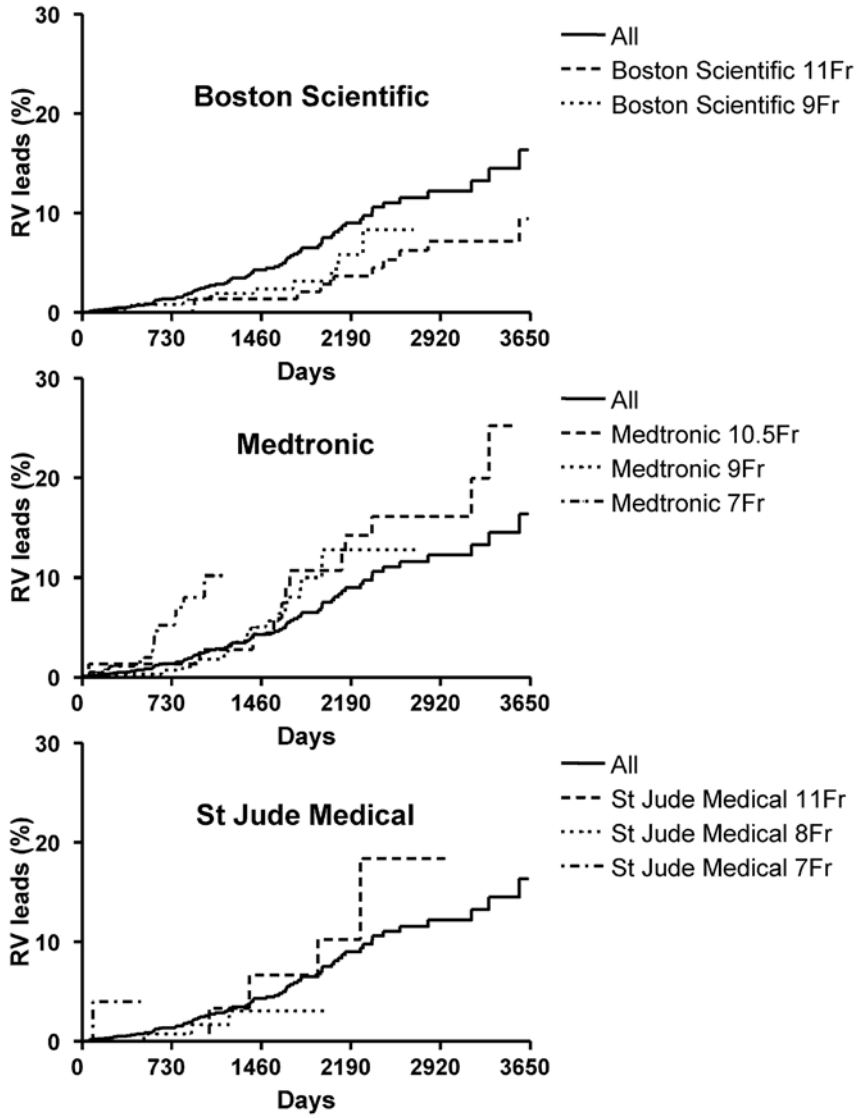

Figure 2. Kaplan-Meier curve for lead failure comparing all leads to the leads from Boston Scientific, Medtronic and St Jude Medical, grouped by lead diameter in French (Fr).

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 1.9-2.6) 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 1.0-1.6) per 100 lead-years; 3) Grouping by manufacturer and lead diameter

Table 3: Defibrillation leads, grouped by manufacturer and groups of implanted transvenous defibrillation leads models with events and incidence rates (IR).

	Total	Follow-up	All removal or capping		lead failure		lead failure or dislodgement	
Lead model	N	Days (1st – 3rd quartile)	N	IR (95% CI)	N	IR (95% CI)	N	IR (95% CI)
Biotronik 8 Fr	98	155 (88-296)	2	3.9 (0.5-14.2)	0	0.0 (0.0-7.2)	2	4.1 (0.5-14.7)
Boston Scientific 11 Fr	163	2937 (2055-3553)	21	1.7 (1.1-2.6)	11	0.9 (0.5-1.6)	11	0.9 (0.5-1.6)
Boston Scientific 9 Fr	911	783 (331-1338)	41	1.8 (1.3-2.5)	15	0.7 (0.4-1.1)	18	0.8 (0.5-1.3)
Medtronic 10.5 Fr	76	2676 (1689-3264)	15	3.0 (1.7-4.9)	12	2.4 (1.2-4.2)	12	2.4 (1.2-4.2)
Medtronic 9 Fr	322	1456 (1154-1864)	27	2.2 (1.4-3.2)	20	1.6 (1.0-2.5)	23	1.9 (1.2-2.8)
Medtronic 7 Fr	376	567 (316-804)	19	3.2 (1.9-5.0)	16	2.7 (1.6-4.4)	18	3.1 (1.8-4.9)
St. Jude Medical 11Fr	32	2151 (2049-2291)	5	2.8 (0.9-6.5)	4	2.2 (0.6-5.7)	5	2.9 (0.9-6.8)
St. Jude Medical 8 Fr	158	1120 (698-1516)	15	3.1 (1.7-5.1)	3	0.6 (0.1-1.8)	3	0.6 (0.1-1.8)
St. Jude Medical 7 Fr	25	276 (252-408)	1	4.6 (0.1-25.7)	1	4.6 (0.1-25.7)	1	4.6 (0.1-25.7)
Total	2161	885 (375-1618)	146	2.2 (1.9-2.6)	82	1.3 (1.0-1.6)	93	1.4 (1.2-1.7)

revealed major differences in event rates; 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 non-abdominal leads varies from 91% to 99% at two years,[22] 85% to 98% at five years,[8, 12, 23-25] and 60% to 72% at eight years.[8, 10, 24] In comparison to these figures, our rates of lead failure tend to be average during the first five years (93.5% failure-free). However, in long-term follow-up our cohort (83.6% failure-free at ten years) demonstrates far less lead failures than the 40% failure at eight 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 five years 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 five years of follow-up and significantly lower during follow-up longer than five 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 electrical parameters before surgically intervening. The possibility that an important number of failing leads have been missed is small since all periodic three-six months device interrogations have been 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 vs. cephalic), nor other potential risk factors (passive vs. active lead fixation, dual vs. single coil, dedicated vs. 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 has to 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 1.0-1.6) 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. Firstly, 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. Secondly, the compliance of clinicians to return extracted leads will, even in the most willing, never reach hundred percent.[12]

Lead insulation

Different studies on the reason 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] Mid 1990's, several studies showed a higher then average failure rate caused by metal oxidation after inner insulation environmental 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 returned product analysis.[12, 32] These findings caused a recall of more than 400,000 leads through 1995 and marked the end of polyurethane usage in newly implanted leads.[33] Nowadays, since the vast 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.[34]

Small-diameter leads

Defibrillation leads characterized by a small-diameter body and coil exhibit several advantages. Their smaller thickness might makes it easier to implant additional leads, maintain venous blood flow, and reduce subclavian crush syndrome.[26] Among the nine groups of leads formed in the present study were two containing small-diameter leads: Medtronic 7 Fr, better known as the Sprint Fidelis family, and the St. Jude 7 Fr, 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 7 Fr, these figures varied from no increase in failure rate[35] to 1 per 100 patient-years when compared to the Medtronic 9 Fr.[36] Lower rates than our findings (2.7 [95% CI 1.6-4.4] per 100 lead-years) can be explained by the fact that data was acquired from the Manufacturer and User Facility Device Experience (MAUDE) database. Since the MAUDE database obtains 95% of cases from manufacturer reports, the database will show similar figures as manufacturer reports.

Studies reporting failures in St. Jude 7 Fr 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.[37] However, the one case of St. Jude Medical 7 Fr 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 (0.1-25.7).

Limitations

Cases of lead failure might occur without clinical symptoms or changes in electrical measurements, causing them to go unnoticed. Furthermore, in case of slight changes, or chronic elevated or depressed electrical measurements a clinician not always immediately chooses to replace the lead. Lastly, we assumed that patient death within six months after a follow-up visit without signs of lead failure was not lead-related. All three 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 has shown major differences in failure rates between 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 ten years, every effort should be addressed to improve lead performance.

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