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ORIGINAL ARTICLE

Long-term performance of the St Jude Riata 1580–1582 ICD lead family

S. D. A. Valk · D. A. M. J. Theuns · L. Jordaens

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Abstract
Objective Safety concerns about the Riata ICD shock lead were recently raised, with insulation failure due to conductor externalisation. Its incidence and presentation were assessed, and predictors of insulation failure and lead survival of the Riata 1580–1582 were studied, retrospectively, before the official recall.
Methods All 374 patients at the Erasmus Medical Center between July 2003 and December 2007 with a 1580, 1581 or 1582 shock lead.
Results The majority of the patients were male (78 %), with a median age of 60 years (IQR 52–70); primary prevention in 61 %. Median follow-up was 60.3 months (IQR 35.5–73.2), with 117 (31 %) patients dying. Electrical abnormalities (mainly noise, 65 %) were observed in 20/257 patients (7.8 %). Definite conductor externalisation was confirmed with fluoroscopy or chest X-ray in 16 patients, and in one after extraction. One patient presented with a drop in the high-voltage impedance trend with a short circuit of the ICD system during defibrillation testing, and needed to be shocked externally. In 8 more patients, conductor externalisation was found during an elective procedure. No predictors of externalisation could be found, except for the use of single coil (p=0.02). Median time to conductor externalisation was 5 years (IQR 3.1–6.2). Lead externalisation was observed in 5.4 % (95 % CI 3.1–9.3) at 5 years and 22.7 % (95 % CI 13.6–36.6) at 8 years.
Conclusion A high incidence of insulation defects associated with conductor externalisation in the Riata ICD lead family is observed. The mode of presentation is diverse. This type of insulation failure can lead to failure of therapy delivery.

S. D. A. Valk · D. A. M. J. Theuns · L. Jordaens (✉)
Department of Clinical Electrophysiology, Thorax Center,
Erasmus Medical Center,
Room Ba 591, Thorax Center, ‘s Gravendijkwal 230,
3015 CE Rotterdam, the Netherlands
e-mail: l.jordaens@gmail.com

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Introduction

Implantable cardioverter defibrillators (ICDs) are implanted for primary and secondary prevention of sudden cardiac death in patients at high risk for life-threatening ventricular arrhythmias [1]. The ICD has evolved from a large device which needed abdominal implantation to a much smaller device that can be implanted subcutaneously. Although ICDs have become smaller, the device therapy possibilities have become more sophisticated, from shock only to tiered therapy. The defibrillator leads have also evolved from epicardial patches to transvenous leads with even smaller lead diameters due to changes in lead design [2]. However, while the number of ICDs implanted still increases, this is not paralleled with real technological advancement: ICD longevity has decreased, and attention becomes more focused on other ICD and ICD lead-related problems [3, 4]. Malfunction of ICD components may lead to inappropriate therapy or can even be involved in withholding appropriate therapy, which may lead to life-threatening situations. The defibrillator lead is the most fragile component of the ICD system [5]. The number of complications increases with the time that the lead is in place [5, 6]. Insulation failure is the most frequent cause of lead failure, but lead fracture, loss of capture, abnormal impedance and sensing failure can also occur [5]. Recently, in the Medtronic Sprint Fidelis ICD lead, failure was caused by a pace-sense conductor fracture which led to lead failure in up to 8.5 % [7, 8].

We previously encountered changes in electrical parameters in a patient implanted with a Riata 1580–1582 series ICD lead (St Jude Medical, Sylmar, CA, USA), which were caused by an insulation defect of the ICD lead with conductor

externalisation [9]. This has led us to pay attention to all ICD patients who have undergone an elective device-related procedure for such failure and as we increasingly saw similar failures, in this study we aimed to assess the incidence and mode of presentation of insulation failure of the St Jude Riata 1580, 1581 and 1582. We wanted to find predictors of conductor externalisation and determine lead survival of the defibrillator leads implanted at the Erasmus Medical Center. The study describes our population before an official recall was issued.

Methods

Study population

For the present study, all 374 consecutive patients implanted with Riata ICD leads between July 2003 and December 2007 at the Erasmus Medical Center were included.

Defibrillator leads

The Riata 1580 and 1581 are dual-coil shock leads. The Riata 1582 is a single-coil shock lead. All are active fixation, true bipolar, 8 French leads. The leads have a multi-lumen design with symmetrically aligned cables in the lead body. Outer insulation material is Dow Corning Q7-4780 silicone. Inner insulation material surrounding the conductors is made of ethylene tetrafluoroethylene (ETFE). The dual-coil leads (1580 and 1581) have three lumina for the conductors that are spaced equally around the inner coil. The single-coil lead (1582) has two lumina opposite to one another.

Data collection and follow-up

Clinical data were obtained from patient records, procedural records and our local ICD database. Follow-up for vital status was 100 % complete at the administrative censoring date of 30 November 2011. All patients underwent routine device check-ups every 3 to 6 months except for patients with home monitoring (every 6 to 12 months). Capture thresholds, sensing amplitudes and pacing and shock impedance were routinely measured and checked for abnormal changes.

Statistical analysis

Normality of distribution was assessed using the Kolmogorov-Smirnov test. Continuous variables were expressed as mean ± SD, if normally distributed, otherwise by median and interquartile ranges (IQR). Continuous data were analysed with Student's *t* test or Mann–Whitney *U* test, when appropriate. Categorical data are expressed as number and percentage and compared with the Chi-square test or Fisher's exact test when appropriate. Rates of externalised conductors were estimated by life-table analysis with 95 % confidence intervals (CIs). Univariate Cox proportional hazards analysis was performed to identify those variables that significantly predicted lead failure. The following covariates were predefined to enter the model: age, gender, left ventricular ejection fraction, coronary artery disease (CAD), type of device (i.e. single-chamber, dual-chamber, or resynchronisation), and venous access site. Statistical analysis was performed using Stata version 12 SE for Windows (StataCorp, College Station, TX). A two-sided *P* value of <0.05 was considered statistically significant.

Results

Clinical and technical characteristics

The study cohort consisted of 374 patients. The population was predominantly male (78 %), with a median age of 60 years (IQR 52 to 70 years). The majority of patients had New York Heart Association (NYHA) functional class II (53 %), with a median left ventricular ejection fraction (LVEF) of 27 % (IQR 21 to 33 %), and a median QRS duration of 130 ms (IQR 106 to 166 ms). Further baseline characteristics of the study patients are presented in Table 1. During a median follow-up of 3.0 years (IQR 3.0 to 6.1), 117 patients (31 %) died and 15 patients (4 %) underwent heart transplantation. Information on the leads of the transplantation patients was available, so they were included for lead survival analysis.

Table 1 Baseline characteristics of the study patients

	n=374
Age (years)	60 (52–70)
Male gender	293 (78 %)
Follow-up (years)	5.0 (3.0–6.1)
Underlying heart disease	
- Coronary artery disease	222 (59 %)
- Prior myocardial infarction	181 (49 %)
- Dilated cardiomyopathy	96 (26 %)
- Hypertrophic cardiomyopathy	13 (3 %)
NYHA class	
- I	55 (15 %)
- II	199 (53 %)
- III-IV	117 (31 %)
Ejection fraction (%)	27 (21–33)
QRS duration (ms)	130 (106–166)
Indication type	
- Primary prevention	227 (61 %)
- Secondary prevention	147 (39 %)

Table 2 shows the technical aspects of ICD implantation. A single-chamber ICD was implanted in 39 % of the patients. The majority of implantations (95 %) were performed on the left side. The venous access site was the left cephalic vein in 59 %. Eighty percent of the patients received a St Jude Riata 1580 shock lead.

Lead failure and mode of presentation

Seven patients developed device infection during follow-up for which the ICD system was extracted (2 %). There were no ventricular lead perforations or ICD malfunctions. Electrical abnormalities were found during follow-up in 20 of 257 surviving patients (7.8 %) (Table 3). This was noise in 13 patients (65 %), sometimes accompanied by other electrical defects. Inappropriate shocks occurred in 9 patients. The other patients presented with a decrease in pacing or high-voltage (HV) impedance, non-capture, or a decreased sensing. One patient presented with a decrease in long-term HV impedance trend. A defibrillation test was performed to ascertain the integrity of the ICD system. During testing there was a short circuit in the ICD which led to failure of therapy delivery for which the patient needed external defibrillation.

Conductor externalisation was confirmed with fluoroscopy in 16 of the surviving patients (80 %). In 12 patients the defect was also visible on chest X-ray. This was predominantly on the left lateral X-ray (Fig. 1). In 4 patients there was no documented fluoroscopy or chest X-ray available. The lead was extracted in 1 patient and conductor externalisation was visible (Fig. 2), so that a total number of 17 patients had confirmed externalisation. In 1 patient there was 'bulging' of the lead on the lateral chest X-ray, suggesting a possible insulation defect. In the remaining 2 patients data were insufficient.

Table 2 Technical characteristics

	n=374
Device	
- Single chamber	145 (39 %)
- Dual chamber	103 (28 %)
- CRT	126 (34 %)
Side of implantation	
- Right	17 (5 %)
- Left	357 (95 %)
Venous access	
- Left cephalic vein	222 (59 %)
- Right cephalic vein	5 (1,5 %)
- Left subclavian vein	134 (36 %)
- Right subclavian vein	12 (3 %)
- Left axillary vein	1 (0.5 %)
Lead	
- Single coil	
- 1582	30 (8 %)
- Dual coil	
- 1580	301 (80 %)
- 1581	43 (12 %)

CRT cardiac resynchronisation therapy

These findings led to a meticulous search for conductor externalisation in patients without electrical abnormalities who underwent an elective device procedure, (i.e. elective replacement or device upgrade). In 8 patients conductor externalisation was found in this way during fluoroscopy as performed during or before implantation (Table 4). This was detectable on chest X-ray in only 3 out of 7 patients (no chest X-ray available in 1 patient). In all patients the insulation defect with conductor externalisation was proximal to the distal RV shock coil at the level of the tricuspid valve or lower right atrium. This means that we had in total 25 patients (9.7 %) with a conductor externalisation.

Outcome

In the 20 patients who presented with electrical abnormalities, the lead was successfully extracted and replaced in 12 patients. It was returned to the manufacturer in 6 patients. In 5 patients an additional pace/sense lead was added. One patient had an additional shock lead implanted. Extraction was unsuccessful in one patient and a subcutaneous ICD was implanted. The ICD was switched off at the explicit wish of one patient.

In the 8 patients in whom the defect was discovered during an elective procedure, 3 patients underwent extraction and replacement of the ICD lead. Four patients received an additional ICD lead and the old lead was abandoned. In one patient, the ICD was replaced with a home-monitoring device as all electrical parameters were completely normal.

Time to conductor externalisation

Life-table analysis was performed to estimate the rate of externalised conductors in Riata leads as function of service time after implantation. The estimated rates of externalised conductors are shown in Fig. 3. The rates of externalised conductors were 5.4 % (95 % CI, 3.1 % to 9.3 %) and 22.7 % (95 % CI, 13.6 % to 36.6 %), at 5 and 8 years after implantation, respectively. The median time to insulation failure was 5.0 years (IQR 3.1 to 6.2 years).

Predictors of conductor externalisation

Univariate Cox proportional hazards analysis could not identify any covariate significantly associated with conductor externalisation, except for a low LVEF (p=0.04). The

Table 3 Lead defects presenting with electrical abnormalities

	Gender	Age (years)	Lead	Presentation	Inappropriate shock	Interval	Externalisation on fluoroscopy	Externalisation on chest X-ray	AP	LL	Action	Remarks
1	M	71	1580	Noise	No	2489	Yes	Yes	No	Yes	Extraction	
2	M	52	1580	Noise	Yes	705	Yes	Yes	No	Yes	P/S lead added	
3	M	70	1580	Noise	Yes	2542	Yes	Yes	No	Yes	ICD switched off	
4	F	61	1580	Noise	Yes	2380	Yes	Yes	Yes	Yes	Extraction	
5	M	61	1582	Noise	Yes	1405	Yes	Yes	Yes	Yes	Extraction	
6	F	34	1582	Noise, no pacing	Yes	1560	NA	No			P/S lead added	Near bulging
7	M	66	1580	Noise	Yes	1541	NA	No			P/S lead added	
8	M	62	1580	Noise	No	1076	NA	No			Extraction	Externalised
9	M	50	1580	HV impedance ↓	No	1362	Yes	Yes	No	Yes	Extraction	ICD fails during DFT
10	M	56	1582	Noise/TW oversensing	Yes	1015	Yes	Yes	No	Yes	Extraction	Stylet blocks
11	F	69	1581	Noise	Yes	1214	Yes	NA			Extraction	
12	M	55	1580	Pacing impedance ↓	No	2624	Yes	No			Shock lead added	
13	F	52	1582	Sensing ↓	No	1616	Yes	No			extraction	
14	F	56	1580	Noise	Yes	1599	Yes	Yes	No	Yes	Extraction	
15	M	56	1580	Pacing impedance ↓	No	2814	Yes	Yes	No	Yes	Extraction	
16	F	48	1580	HV impedance ↓	No	3056	Yes	Yes	No	Yes	Extraction	
17	F	55	1581	Non-capture	No	1957	NA	No			P/S lead added	Insufficient data
18	M	69	1581	Non-capture	No	1264	Yes	Yes	No	Yes	Failed extraction	S-ICD
19	M	46	1580	Noise/TW oversensing	No	2854	Yes	Yes	No	Yes	P/S lead added	
20	M	21	1582	Noise	No	813	Yes	No			Extraction	

AP antero-posterior, *DFT* defibrillation threshold testing, *F* female, *HV* high voltage, *LL* latero-lateral, *M* male, *NA* not available, *TW* T wave, *P/S* pace-sense, *S-ICD* subcutaneous ICD

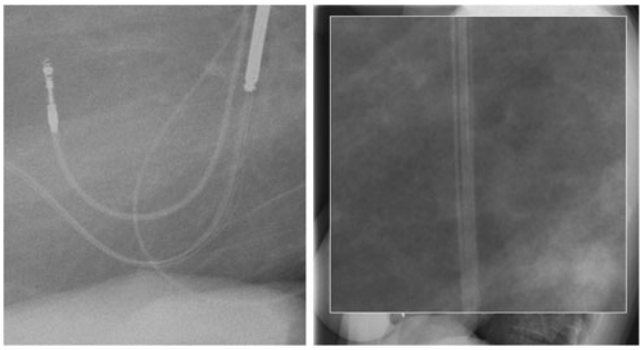

Fig. 1 At the left: lateral view; fluoroscopic image of an externalised conductor in patient 9 (which led to a defect ICD after a high-voltage shock). At the right a lateral view with enlargement of a lead segment which is near normal. This patient had an electrical defect with noise, and could no longer be paced

use of single-coil leads was borderline significant (p=0.06). It was the only remaining significant variable in multivariate analysis with a HR of 4.4 (95 % CI 1.2–15.8; p=0.02).

Discussion

The aim of this study was to describe the incidence and mode of presentation of insulation failure, to assess predictors of lead failure and determine lead survival of the St Jude Riata 1580, 1581 and 1582 leads implanted at the Erasmus Medical Center. The main findings of this study are that insulation failure with conductor externalisation is more frequent than previously described and that the mode of presentation is not uniform and can even be without electrical abnormalities. No predictors of insulation damage with externalised conductors could be found, except for the use of a single-coil Riata.

Incidence of conductor externalisation

A large retrospective study in more than 15 thousand patients implanted with Riata 1580 and 7000 series combined showed insulation damage in 0.21 % of the patients [10]. A report by St Jude from December 2010 mentions an insulation abrasion rate of 0.47 % over 9 years of use [11]. This number was revised in the product information update in November 2011 to 0.63 % all-cause abrasion rate, with externalised conductors in 15 % of these cases [12]. Single-centre studies reported insulation defects in 0.13 % up to 2 % of the patients [13, 14]. We found conductor externalisation in more than 9 % of the patients.

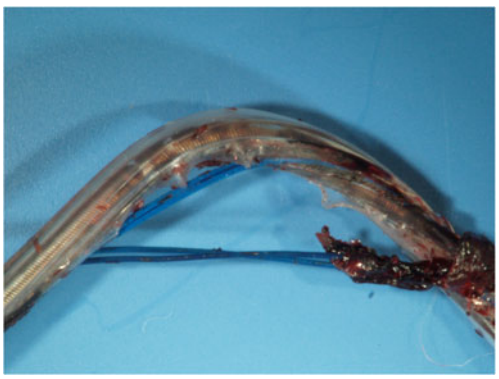

Fig. 2 Segment of the lead showing 4 externalised conductors which had abrased the outer isolation

The reported company numbers are based on data reported to St Jude and on leads returned for analysis. Not all leads are extracted and returned to the manufacturer. This may lead to an underestimation of the actual number of this type of insulation defect. Recent abstracts are more in line with our data, and suggest Riata failure rates of 8–15 % including leads that are electrically intact but exhibit externalised conductors. The leads may function electrically normally if the insulation that covers the pace-sense and high voltage cables is intact [15].

Location of insulation defect

Usually, insulation defects occur in the pocket due to abrasion of the lead by the ICD, at the level of lead fixation, in the vasculature or heart due to lead to lead abrasion, or at the level of the clavicle [16]. The location of the insulation defect in this study was proximal to the distal shock coil at the level of the tricuspid valve and lower right atrium in all patients. This was also reported by others [9, 14, 17]. Hauser et al. describe that leads with inside-out abrasion frequently also display multiple insulation defects distributed along the length of the lead [18]. Local abrasive forces from neighbouring myocardial structures (i.e. movement of the tricuspid valve) may play a role in causing insulation breach in this type of lead [14, 19]. Another explanation may be inside-out abrasion caused by movement of the conductors within the insulation leading to conductor externalisation through the outer insulation material as was shown by analysis of the returned leads by St Jude in 85 %. The remaining 15 % were due to external sources of abrasion [12]. Further, it is tempting to believe that leads implanted with more ‘slack’ leading to excessive movement develop more insulation defects at this particular site.

Mode of presentation

Insulation defects in general may present with oversensing and undersensing, loss of capture, and changes in pacing or high-voltage (HV) lead impedance. Previous studies on the Riata lead have reported noise and inappropriate shocks as mode of presentation [9]. Also, a rise in pacing impedance and threshold has been described [17, 20–22].

Table 4 Lead defects discovered at the time of elective device procedure

	Gender	Age	Lead	Presentation	Inappropriate shock	Interval	Externalisation on fluoroscopy	Externalisation on chest X-ray	AP	LL	Action	Remarks
1	M	56	1580	ERI	No	2062	Yes	No			Extraction	
2	M	44	1581	ERI	No	1962	Yes	NA			Extraction failed, ICD lead added	Stylet blocks
3	M	54	1580	ERI	No	1848	Yes	No			ICD lead added	
4	M	58	1580	TW oversening	Yes	942	Yes	No			Extraction	
5	F	63	1580	upgrade	No	2057	Yes	Yes	Yes	Yes	ICD lead added	
6	M	23	1582	ERI	No	1882	Yes	Yes	No	Yes	Extraction	
7	M	68	1580	ERI	No	2215	Yes	Yes	Yes	No	ICD lead added	
8	M	68	1580	ERI	No	1813	Yes	No	No	No	Home monitoring	Normal electrical parameters

AP antero-posterior, *ERI* elective replacement indication, *F* female, *LL* latero-lateral, *M* male, *NA* not available, *TW* T wave

Based on review of returned leads, St Jude reports pacing or HV impedance changes in 37 %, inappropriate therapy in 36 %, noise and oversensing in 18 % and a rise in threshold in 9 % as mode of presentation [12]. The mode of presentation of this type of insulation defect is also not uniform in this study. It ranges from a change in pacing or HV impedance, to noise with inappropriate therapy, to non-capture and even decreased sensing.

A large study in the FDA medical device database reports impedance changes and sensing problems as most frequent modes of presentation, followed by pacing problems [23]. Conductor externalisation can also be present without changes in electrical parameters. The latter is particularly worrisome as this leaves the patient unknown to the physician and potentially unprotected. Normal electrical findings may be present if the inner ETFE insulation layer of the conductors is still intact. A study, however, reports breached ETFE insulation in 21 % of the returned leads with normal electrical findings in 6 %. This shows the magnitude of the problem. In patients with normal electrical findings, there may be

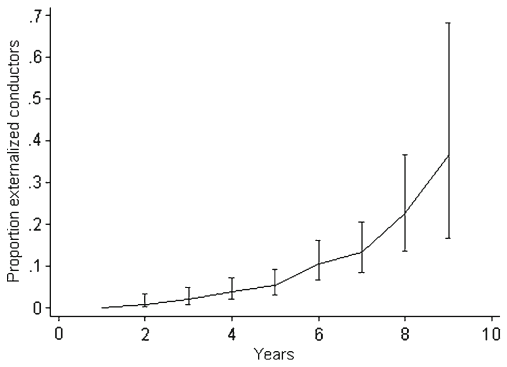

Fig. 3 Proportion of externalised conductors as appearing over time with 95 % confidence intervals

externalisation of the conductors with still intact or even with breached ETFE insulation [24].

It remains unknown when or if this layer of insulation will eventually break and what will happen when the conductors are exposed to blood and excessive movement without the protective silicone layer. St. Jude reports there are no data to support that externalised conductors will fail or pose a mechanical or anatomical threat [25]. The latter is confirmed by Hauser et al., but the former is in contrast with the patient in our study with the short circuit. This was also detected by other investigators [20]. Another study conducted by Hauser and coworkers shows that Riata and Riata ST leads are prone to high voltage failure that has resulted in death. None of these failures could be attributed to externalised conductors [18]. It requires further investigation in our study population to ascertain the cause of death in the patients who died during follow-up. To our opinion, the integrity of the system can therefore not be counted on. As the mode and time of presentation is so diverse, and even sometimes without a change in electrical parameters, the system should be checked extensively when there is only the slightest suspicion of a lead problem and maybe even on a routine basis

Fluoroscopy and chest X-ray

This study shows that the findings of insulation defect and conductor externalisation can be so subtle that they cannot always be detected on a chest X-ray. An explanation may be lack of resolution or the phase of the cardiac cycle in which the image is made. The images are still and made in full inspiration, which leads to a non-physiological situation. Fluoroscopy images are moving and made during normal respiration. Therefore, fluoroscopy should always be performed and especially from different angles and magnification to check the

integrity of the insulation [20]. Using only standard fluoroscopy projections may lead to underdetection of the insulation defect.

Time to insulation failure

Kleemann and co-workers showed that estimated ICD lead survival was 85 % and 60 %, 5 and 8 years, respectively, after implantation. They also showed that the annual failure rate increased progressively over time after implantation and was associated with multiple implanted leads.5 The time to insulation failure of the Riata lead in our study was 5.0 years (IQR 3.1 to 6.2 years). However, a patient with a Riata 1570 lead with an insulation defect was reported only 4 months after implantation [20].

Predictors of lead failure

Predictors of insulation failure could not be found in this study. This may be due to the small number of patients. A recent report by Erkapic et al. found that non-ischaemic cardiomyopathy was an independent univariate predictor of this type of insulation failure [14]. We can confirm the observation that single-coil leads are more susceptible to inside–out abrasion.

Limitations

Fluoroscopy was only performed in patients who were scheduled for an elective device procedure or in patients who had electrical abnormalities or noise. The incidence of insulation defect may be underestimated or overestimated. Selection and observer bias may have played a role since we are now focused on this problem with this type of lead.

Conclusion

This observational retrospective study shows that the incidence of insulation damage in Riata 1580–1582 ICD leads is higher than previously described. The mode of presentation of the insulation defect is not uniform, although in the majority of cases it presented with noise. However, insulation defects were also seen at routine fluoroscopy screening at the time of elective box change without noise or changes in electrical parameters. Therefore a more structured approach to patients with this type of lead is needed. Routine chest X-ray cannot exclude an insulation defect. In patients with Riata 1580, 1581 or 1582 leads, careful fluoroscopic evaluation of the RV defibrillation lead from multiple angulations should be considered, especially at the time of ICD generator exchanges or when there is an unexpected change in interrogation data.

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