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Fluoroscopic investigation of Riata® transvenous defibrillator leads

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Abstract

Background: *Implantable cardioverter-defibrillator leads from Riata® family (St. Jude Medical Inc., Sylmar, CA, USA) have been recently recalled by Food and Drug Administration for concerns of a unique type of "inside-out" insulation failure leading to conductor externalization. The objective of this study was to evaluate the prevalence and predictors of conductor externalization in patients implanted with Riata 8 French (Fr) and 7 Fr leads.*

Methods: *Patients implanted with Riata® and Riata ST® who were actively followed up in our institution were scheduled for high resolution 3 view fluoroscopy and device interrogation including high voltage (HV) lead impedance testing. Fluoroscopic images were graded as presence of externalization or no externalization.*

Results: *Of the 90 patients who underwent screening fluoroscopy, majority had dual coil leads (62.5%) and median duration from the implant time to screening was 79.5 months. Twenty four (26.7%) patients exhibited evidence of lead externalization with 10 (41.6%) of these showing electrical abnormalities at the time of screening. No externalization was seen in the 7 Fr leads. Pacing thresholds were significantly elevated in the externalized cohort compared to non-externalized group (1.42 ± 1.23 vs. 0.93 ± 0.53; p = 0.01). Time since lead implant and lead diameter emerged as significant predictors of lead externalization on univariate analysis with only lead diameter being significant on multivariate analysis (odds ratio 30.68; 4.95–∞,* p = 0.001).

Conclusions: *Prevalence of insulation failure exhibiting as conductor externalization is high (26.7%) among the large diameter 8 Fr Riata® leads with a significant proportion of patients manifesting electrical failure. High resolution 3 view fluoroscopy is a reasonable approach to screen for this unique type of insulation failure.* (Cardiol J 2015; 22, 1: 57–67)

Key words: implantable cardioverter-defibrillators, Riata leads, fluoroscopy screening, externalization, electrical failure, lead recall

Introduction

Since the introduction of implantable cardioverter-defibrillator (ICD) for sudden cardiac death prevention, there have been a number of reported malfunctions related to lead durability or performance [1]. Lead material and design play a crucial role in optimal performance of an ICD system and over the years, there have been several attempts to make thinner leads offering easier and better implantation profiles. Recently, leads from Riata® family (St. Jude Medical Inc., Sylmar, CA) have come under Food and Drug Administration (FDA) class I recall after cases of lead insulation failure

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surfaced in various publications [2–4]. Specifically, the silicone insulation on the multi-lumen Riata® and Riata® ST leads has been noted to break in a unique "inside-out" fashion causing externalization of the various internal conductors from the main lead body. Prior studies have reported various electrical abnormalities associated with lead externalization such as pacing impedance rise, increased capture threshold or inappropriate ICD shocks due to noise [2, 5]. Earlier studies have shown a low rate of lead insulation failure (< 1%) but these studies were limited due to the way insulation failure were analyzed (no consistent fluoroscopy) or shorter period of follow up [6, 7]. A recent large study by Hauser et al. [8] reported an alarming number of deaths in patients implanted with Riata® and Riata® ST leads primarily associated with failed defibrillation. A number of other reports have indicated that the actual prevalence of this unique "inside-out" abrasion defect is higher than that of previous reports, citing rates of insulation breach of around 20–33% when examined by a systematic fluoroscopic approach [9–11]. So far no clear answers have been discovered as to what causes the lead insulation to break in this unique fashion thereby causing conductor externalization and only the duration of lead implant (dwell time) and lead size have emerged as the significant predictors of lead externalization in various studies.

This study was initiated to further define the prevalence of lead failures at our center and to investigate the predictors of lead externalization by performing systematic fluoroscopic screening.

Methods

Study population

All patients who received a single chamber, dual chamber, or biventricular ICD at our institution from January 2002 to December 2010 were screened from our central database software (Medtronic Paceart®) to identify individuals in whom a 7 and 8 French (Fr) transvenous Riata® family leads (models 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7040, 7041 and 7042) were implanted. Of the total 271 patients who were implanted at our institution, 87 were found to be deceased, 3 had heart transplantation and 57 patients were followed at other institutions. We contacted 124 patients via telephone for study participation and informed them about the FDA recall. Ninety patients agreed to participate and were scheduled for voluntary screening fluoroscopy and simultaneous device interrogation. Data pertaining to baseline demographics, medical history and device/lead specifics were collected by chart review through the electronic medical record database. This protocol was approved by our institution review board. The following clinical variables were analyzed: age, sex, device indication (primary vs. secondary prevention as well as underlying etiology of cardiomyopathy), lead access technique (subclavian vs. axillary puncture), number of high voltage coils (single or dual), device type (single chamber, dual chamber or biventricular), lead size (7 Fr or 8 Fr), as well as the presence and severity of any detected tricuspid regurgitation after implant.

ICD interrogation

Device interrogation was performed to measure sensing and capture threshold along with pace-sense impedance testing. High voltage (HV) integrity testing to determine HV lead impedance was also done at the time of interrogation. We did not perform HV impedance testing by delivering maximal output shock. These electrical parameters were compared to the baseline values at the time of lead implant as ascertained by reviewing the operative notes in our hospital electronic record system. Both remote and in-clinic interrogation reports were also reviewed for any events suggestive of abnormal electrical parameters or delivered therapies prior to the screening period. Similar data up to 6 months post screening was also collected.

Fluoroscopy

Cine fluoroscopy at 15 frames per second was performed in our electrophysiology laboratory in 3 views: anteroposterior, left anterior oblique (LAO) and right anterior oblique (RAO) around 30° each. Additional views were also obtained to bring out the maximal lead separation in cases where lead defects were noted. Frame by frame analysis was done and leads were followed from the lead tip in the ventricle to the can pocket. Prior available chest X-rays were also viewed at high magnification for cases where evidence of lead externalization was seen on fluoroscopy to retrospectively determine the earliest time when externalization was visualized. We also evaluated the presence of the lead curve in the right atrium before it enters the right ventricle (called RA/RV heel in this study) to assess if the curvature acts as the point of maximum stress causing insulation damage.

Definition of lead failure

Lead externalization was defined as any visible defect where the inside conductor was clearly separated from the main body of the lead. Cases were grouped as having evidence of lead externalization or no externalization. Patients with evidence of abnormal conductor spacing without overt separation from main lead body (early externalization) were analyzed in the externalization cohort. Abnormal electrical parameters were defined as (a) Change in HV lead impedance to < 25 Ω or > 200 Ω; (b) RV pace-sense lead impedance decrease to < 200 Ω or > 2000 Ω; (c) Presence of non-physiological signals on the intracardiac ventricular electrogram tracings; (d) Rise in capture threshold to > 2 V at 0.5 ms from baseline of < 1 V or rise to > 5 V; (e) Undersensing of the ventricular signal < 3.0 mV; (f) Inappropriate shocks were defined as those due to noise (in the absence of external interference or oversensing) detected on the leads. Inappropriate shocks due to supraventricular tachycardia and due to oversensing were excluded from our definition of inappropriate shocks. Episodes due to short RR intervals as a result of sensing of non-physiologic potentials leading to shocks were considered as inappropriate shocks.

Statistical techniques

Continuous variables are expressed as mean ± ± standard deviation as assessed by the χ^2 test. Categorical parameters are presented as percentages using Wilcoxon 2-sample test. Primary end point of our study was to determine the prevalence of lead externalization behavior among all Riata leads with secondary focus on electrical abnormalities. A multivariate analysis was performed in a forward stepwise fashion to determine predictors of lead externalization. A two sided p-value of < 0.05 was considered statistically significant for the purpose of this study. All analyses were performed using SAS® version 9.1 (SAS Institute Inc., Cary, NC, USA).

Results

Patient characteristics and ICD leads

Baseline characteristics and device/lead data is presented in Table 1. Ninety patients underwent concomitant fluoroscopy and device interrogation with mean age of the cohort being 68.8 ± ± 12.2 years at the time of interrogation. Mean left ventricular ejection fraction at the time of lead implantation was 25.6 ± 11.4%. Almost half of the patients in each group had underlying ischemic cardiomyopathy with most devices implanted for primary prevention of sudden cardiac death (84.4% of the total cohort). A majority of the leads belonged to the larger diameter 8 Fr series (60%). There were no significant differences in baseline characteristics between the two groups except for lead diameter with lead externalization seen only in the larger 8 Fr diameters leads (100% vs. 45%, p = 0.001).

Results of cine-fluoroscopic lead evaluation

Twenty four (26.7%) out of the total cohort of 90 study patients showed evidence of lead externalization on high-resolution fluoroscopy as exemplified in Figure 1. Only 1 (1.1%) case of early externalization was noted. Early externalization was defined as abnormal separation of internal conductors without overt separation from the main lead body. Of the patients with conductor externalization, 10 (41.6%) had a single chamber ICD, 9 (37.5%) had a dual chamber ICD with remaining 5 (20.8%) being biventricular ICD. Twenty one leads in the externalized groups were positioned in the right ventricle apex and 3 in the septal position. A significant proportion of the leads (62.5%) were dual coil leads. The distribution of patients with lead externalization in relation to time since implant is depicted in Figure 2. The rate of externalization was 0/36 (0%) for leads with dwell time < 5.5 years as compared to 24/54 (44.4%) with dwell time > 5.5 years (p = 0.001). The majority of lead externalizations (75%) were seen in the RA where the lead bends to cross the tricuspid valve followed by the region proximal to the distal coil. Most of the leads showed externalization in both LAO and RAO views without requiring additional views. A significant proportion of the externalizations were noted among the 8 Fr single and dual coil Riata® leads corresponding to series no: 1582 (6/24; 25%) and 1581 (10/24;42%), respectively as depicted in Figure 3. RA/RV heel was present almost equally amongst the two groups (83.3% vs. 86.4%, p = 0.718).

ICD interrogation

When overall lead failure rate was considered, 30% (27/90) of the leads showed evidence of lead externalization or electrical malfunction. Three of the 27 leads showed no externalization but rise in capture threshold to > 2 V at 0.5 ms. Ten (41.6%) of the 24 leads with evidence of fluoroscopic externalization showed electrical abnormalities compared to 3/66 (4.5%) non-externalized leads (p = 0.001).

Table 1. Baseline characteristics of patients implanted with Riata® and Riata® ST leads.

	Variable	Total cohort (n = 90)	Externalized lead cohort (n = 24)	Non externalized cohort (n = 66)	P
Demographics	Age [years]	68.8 ± 12.2	69.2 ± 9.5	68.6 ± 13.0	0.999
	Female	32.2 (29)	29.2 (7)	33.3 (22)	0.708
	Black	43.3 (39)	41.7 (10)	44.0 (29)	0.714
Clinical parameters	Hypertension	95.6 (86)	91.7 (22)	97.0 (64)	0.280
	Diabetes	32.2 (29)	20.8 (5)	36.4 (24)	0.163
	CKD	37.8 (34)	29.2 (7)	40.9 (27)	0.310
	Atrial fibrillation	25.6 (23)	12.5 (3)	30.3 (20)	0.087
	ICM	53.3 (48)	58.3 (14)	51.5 (34)	0.438
	Moderate/severe TR	25.8 (23)	16.6 (4)	28.9 (19)	0.282
	LVEF at implant	25.6 ± 11.4	25.4 ± 11.9	25.7 ± 11.3	0.923
	Recent LVEF	35.0 ±13.7	34.9 ± 13.9	35.6 ± 14.1	0.828
	LVEF change	9.6 ± 14.8	8.8 ± 12.3	9.9 ± 15.6	0.828
Device parameters	Primary prevention	84.4 (76)	79.2 (19)	86.4 (57)	0.405
	Single chamber	51.1 (46)	41.7 (10)	54.5 (36)	0.491
	Dual chamber	28.9 (26)	37.5 (9)	25.8 (17)	
	Biventricular	20.0 (18)	20.8 (5)	19.7 (13)	
Lead parameters	RV-apex	66.6 (60)	87.5 (21)	91.0 (60)	0.634
	≥ 2 RV leads	5.5 (5)	8.3 (2)	4.6 (3)	0.488
	Left sided access	95.6 (86)	87.5 (21)	98.5 (65)	0.166
	Active fixation	80.0 (72)	79.2 (19)	80.3 (53)	0.905
	Dual coil	71.1 (64)	62.5 (15)	74.2 (49)	0.277
	8 Fr leads	60.0 (54)	100.0 (24)	45.5 (30)	**0.001**
	RA TV heel	85.6 (77)	83.3 (20)	86.4 (57)	0.718
	Duration of lead implant [months]	70.1 ± 18.9	84.3 ± 13.3	65.0 ± 18.1	**0.001**

Categorical variables presented as percentage; CKD — chronic kidney disease, ICM — ischemic cardiomyopathy; TR — tricuspid regurgitation; LVEF — left ventricular ejection faction; Recent LVEF — LVEF within 1 year of screening; RV — right ventricular; Fr — French; RA TV — right atrium tricuspid valve;

Table 2 shows the device electrical parameters at baseline (at the time of lead implantation) and at the time of screening fluoroscopy. Table 3 depicts the type of electrical abnormalities detected in externalized leads. Four out of 24 (16.6%) patients with externalized lead had pacing threshold > 2.0 V at the time of screening compared to 4/66 (6.0%) in the non-externalized cohort. Externalized leads showed higher ventricular pacing thresholds at the time of screening (1.42 ± 1.23 vs. 0.93 ± 0.53, p = 0.011) as compared to non-externalized leads with no statistically significant difference at the time of implantation. Also the mean threshold change between the two groups was significantly higher for the externalized leads (0.93 ± 1.36 vs. 0.37 ± 0.58, p = 0.009). No significant difference was noted for pace-sense lead impedance or HV lead impendence between the two groups. When more than 30% decrease in R wave amplitude was looked at, we found no major differences.

Predictors of lead externalization

On univariate analysis, time since lead implant and lead diameter emerged as the significant predictors of lead externalization. Duration of lead implant had an odds ratio of 1.07 for a 1-month period with a 95% confidence interval of 1.03–1.10. When multivariate analysis was performed in a forward stepwise fashion, only the lead diameter came out as a significant predictor of lead externalization with an odds ratio of 30.68 (4.95–∞, p = 0.001). All other variable when adjusted for lead size became insignificant. Presence of dual coil, lead tip position, presence of RA/RV heel, tricuspid regurgitation severity did not predicted the outcome of interest.

Electrical behavior of externalized leads

Of the 24 externalized leads, 10 (41.6%) leads were found to have functional electrical abnormalities of lead performance as outlined in Table 3.

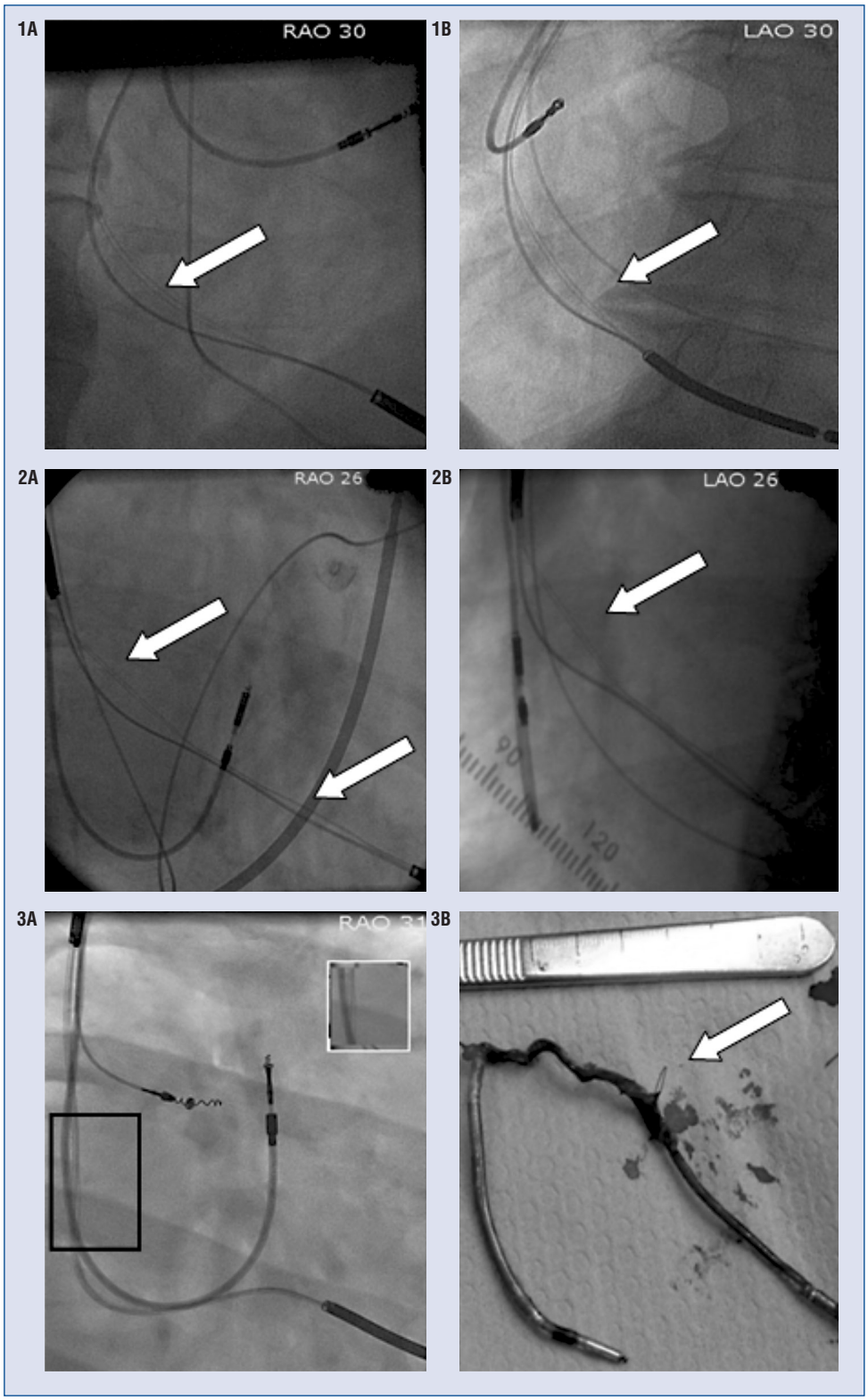

Figure 1. Cable externalization in three different cases as visualized by high resolution fluroscopy in right anterior oblique (RAO) and left anterior oblique (LAO) projections. Externalization noted at multiple levels in case 2. An example of grossly visible conductor externalization (arrow) (3B) seen on explantation along with its fluroscopy counterpart (3A).

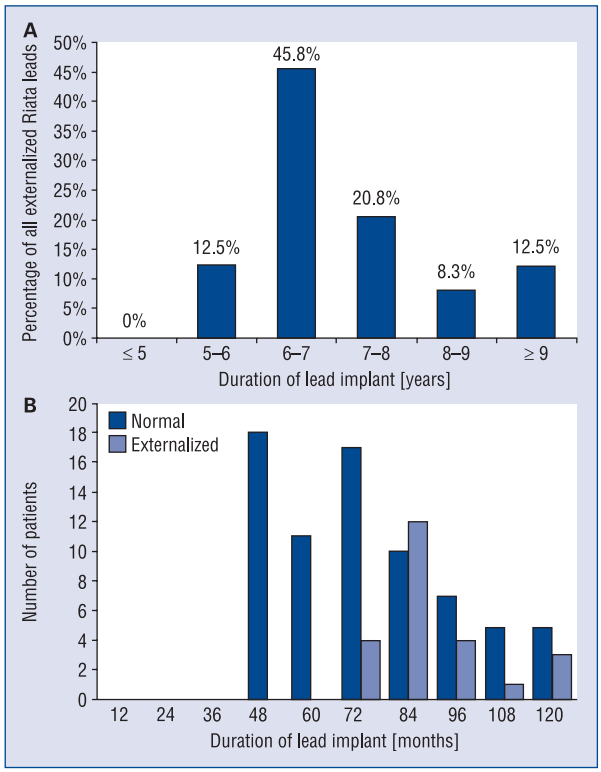

Figure 2. A. Distribution of externalized Riata leads by implant duration time; **B.** Distribution of externalized and non-externalized cohort in relation to implant duration.

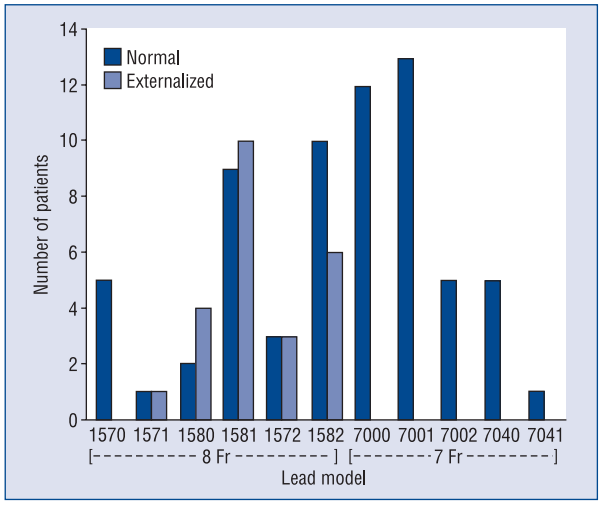

Figure 3. Distribution of conductor externalization according to lead model type (8 Fr single coil models: 1572, 1582; 7 Fr single coil models: 7002).

Most common presentation was rise in capture threshold followed by non-physiological noise on the leads. One patient in the non-externalized group with a Riata® 7040 dual coil 7 Fr lead was found to have sudden battery drain to < 2.2 V compared to a 3 month prior value of 2.67 V who underwent successful generator replacement with stable lead parameters.

Discussion

Our findings contribute to a growing pool of evidence regarding the high failure rates in Riata® family of leads. Our relatively high rate of lead externalization (26.7%) is comparable to that found in other recent studies involving similar strategy of fluoroscopy of patients with Riata® and Riata® ST ICD leads. Study by Shen et al. [10] involving systematic fluoroscopy of 84 patients with 8 Fr and 7 Fr leads showed a prevalence of 27.4% of lead externalization. A similar strategy used by Liu et al. [9] in 245 asymptomatic patients implanted with Riata® and Riata® ST leads revealed a prevalence of 21.6%. Earlier studies reported a very low incidence of lead insulation damage at 0.16% in 6,405 patients with a median follow-up of 24 months [7]. Another large series involving 15,378 patients with a median follow-up period of 13.5 months reported insulation defects of the order of 0.21% [6]. These studies were limited by the way insulation defects were ascertained and no systematic fluoroscopy was used. Cine fluoroscopy with higher resolution capabilities is certainly more sensitive in detecting insulation breach compared to two view chest X-ray where the prevalence of lead externalization has been reported of the order of 11.5% to 24.3% [12, 13].

Lead externalization has been deemed as a time dependent process with multiple studies showing lead dwell time to be an independent predictor of the unique "inside-out" insulation failure. In our study, patients with evidence of lead externalization had longer duration of lead implant time (84.3 ± 13.3 months vs. 65.0 ± 18.1 months, $p = 0.01$). Median time from implantation to detection of lead externalization was 79.5 months. In the study by Liu et al. [9], 79.6% of the leads with definite externalization had > 5 years dwell time and 18.8% had dwell time between 3 and 5 years at the time of screening. All leads in our externalized cohort had a dwell time > 5 years. When adjusted for lead diameter in multivariate analysis, lead dwell time was not an independent predictor of lead externalization in our study. This result might suggest that the actual lead type rather than lead dwell time by itself is responsible for the externalization behavior. This observation is further strengthened by

Table 2. Summary of various electrical parameters at the time of initial lead implant and at screening. Data expressed as mean ± standard deviation.

Variable	Total cohort (n = 90)	Externalized lead cohort (n = 24)	Non externalized cohort (n = 66)	P
R wave amplitude [mV]				
Baseline	13.5 ± 6.4	14.8 ± 5.0	13.1 ± 6.8	0.062
Screening	10.6 ± 3.5	10.8 ± 3.9	10.5 ± 3.3	0.590
Change	–2.9 ± 6.2	–4.00 ± 5.1	–2.5 ± 6.5	0.114
> 30% R amplitude decrease	26.6 (24)	33.3 (8)	24.2 (16)	0.414
Pacing threshold [V at 0.5 ms]				
Baseline	0.54 ± 0.22	0.50 ± 0.14	0.55± 0.24	0.652
Screening	1.06 ± 0.83	1.42 ± 1.23	0.93 ± 0.53	**0.011**
Change	0.52 ± 0.88	0.93 ± 1.36	0.37 ± 0.58	**0.009**
High voltage impedance [Ω]				
Baseline	45.8 ± 12.6	47.0 ± 11.3	45.3 ± 13.0	0.379
Screening	52.9 ± 14.3	54.5 ± 15.0	52.5 ± 14.1	0.348
Change	7.3 ± 13.8	9.1 ± 13.7	6.7 ± 13.9	0.649
Right ventricular impedance [Ω]				
Baseline	657.1 ± 176.5	666.2 ± 189.5	654.0 ± 173.1	0.704
Screening	472.6 ± 208.0	488.3 ± 332.9	466.7 ± 140.0	0.168
Change	–187.2 ± 260.5	–172.5 ± 388.0	–192.4 ± 201.0	0.534

Table 3. Summary of clinical/electrical presentation of patients with externalized conductors.

No.	Age	Time since implant [months]	Impedance at screening [Ω]	High voltage impedance [Ω]	Capture threshold [V at 0.5 ms]	R wave amplitude [mV]	Noise Y/N	Unde--sensing	Increase capture threshold	IS Y/N
1	82	76	353	31	1.2	8.3	N	N	N	N
2	84	79	350	52	0.25	8.8	N	N	N	N
3	73	96	300	37	0.625	11.9	N	N	N	N
4	80	72	360	44	1	12	N	N	N	N
5	74	69	420	47	0.5	12	N	N	N	N
6	76	68	335	42	1	11.5	N	N	N	N
7	70	113	589	75	0.75	20	**Y**	N	N	N
8	67	84	405	33	1.25	11	N	N	N	N
9	65	76	475	57	0.75	12	N	N	N	N
10	59	83	540	60	0.5	9.8	**Y**	N	N	N
11	71	73	720	47	6	12	N	N	**Y**	N
12	75	85	430	53	2	7.7	N	N	N	N
13	51	76	380	77	0.75	12.1	N	N	N	N
14	75	111	290	46	1	11.7	N	N	N	N
15	54	78	425	54	1.25	9.7	N	N	N	N
16	49	84	380	51	1	1.8	N	**Y**	N	N
17	66	70	365	49	1.5	10.4	N	N	N	N
18	61	109	374	63	0.7	21	**Y**	N	N	N
19	71	94	390	57	0.75	11.9	N	N	N	N
20	74	78	1950	57	2.75	11.6	N	N	**Y**	N
21	82	80	760	67	2.0	4.9	**Y**	N	N	N
22	65	100	380	45	4	9	N	N	**Y**	N
23	64	77	350	90	2.25	5.4	N	N	**Y**	N
24	72	91	400	72	0.5	11.1	N	N	N	N

Y — yes; N — no; IS — inappropriate shock

description of Krebsbach et al. [2] case where they reported cable externalization as early as 4 months post implant in a lead extracted for concerns of microperforation. Schmutz et al. [12] reported 4 cases with externalization visualized on prior coronary angiograms as early as 19 months post implant. When we looked at the available chest X-rays for patients in our externalized cohort, we found evidence of insulation defects as early as 22 months in one of the patients.

Most of the leads in our study (75%) showed insulation break in the RA/tricuspid valve region as described previously in the study by Erkapic et al. [3]. This observation likely points to the fact that the tricuspid valve/low RA level where the lead takes a curve before entering the RV, represents the area of maximum stress which together with repetitive motion and contact with the valve during the cardiac cycle creates the right milieu for insulation failure.

Only the larger diameter 8 Fr leads exclusively demonstrated lead insulation failure of this unique type in our study. Our results differ markedly from other studies in that we did not find any case of lead externalization in smaller 7 Fr leads which comprised 40% of the total patient cohort. In a large study from Netherlands [14] involving 1,029 patients, 29.8% (44/147) leads with externalization belonged to the 7 Fr group. In the manufacturer driven phase I study, 259 leads out of 718 were of 7 Fr diameter and the overall prevalence of externalization was lower (9.3% vs. 24.0%, $p < 0.001$) compared to 8 Fr diameter leads [15]. Given that the 70XX series leads were introduced later than the 15XX series contributing to lesser implant duration times, an analysis accounting for lead implant time in the same study still showed lower prevalence of externalization in the 7 Fr series (9.4% vs. 17.9%, $p = 0.02$). St. Jude Medical attributes these differences in externalization behavior among the smaller diameter leads to better lead design whereby the conductors are situated closer to the smaller central coil with similar thickness of silicone insulation [15]. The fact that we did not find any evidence of externalization in the 7 Fr series could be due to small number of patients screened in our study.

Leads with extruded cable conductors had a significantly higher capture threshold at the time of screening in our study compared to non-externalized leads (1.42 ± 1.23 vs. 0.93 ± 0.53, $p = 0.01$). Even the change in capture threshold compared to implant values was significant ($p = 0.009$). Similar finding was observed in the study by Steinberg et al. [13] where abnormal leads had higher pacing threshold (1.1 ± 0.8 vs. 0.9 ± 0.4 V, $p = 0.02$). We did not find any significant differences with other electrical parameters among the two groups. In the nationwide fluoroscopy screening series from Denmark involving 298 patients, only the pacing lead impedance was different among the normal and externalized group at the time of implant with no significant differences in any of the other electrical parameters at screening [15]. Data from a large cross sectional study from Canada surveying 4,358 leads revealed an overall 4.6% rate of electrical abnormalities, most common being elevated pacing thresholds and pacing lead impedance [16]. A multicenter study by Abdelhadi et al. [17] also found higher electrical failure in 27% of the externalized lead cohort, suggesting leads with externalization are more likely to have electrical malfunction. These findings likely suggest that leads with externalization will likely manifest some form of electrical malfunction over time and as such require very close monitoring of electrical parameters and should prompt appropriate action, if significant electrical defects are detected. We did not observe significant differences in R wave amplitude decrease as has been seen in the study by Liu et al. [9] and Kubala et al. [18].

High voltage impedance values remained stable in both groups in our study which has been seen in almost all other published studies. We have reported a case of failed defibrillation in a patient who came to our attention when his device recorded low ($< 10\ \Omega$) HV impedance during therapy delivery for a supraventricular tachycardia detected as ventricular tachycardia [19]. Hauser et al. [20] found 13 out of 22 cases of deaths related to Riata® and Riata ST® where HV impedance issues were detected. In their analysis of explanted leads from the Manufacturer and User Facility Device Defined Experience (MAUDE) database of 105 patients, almost a quarter (26.7%) leads had evidence of inside-out insulation defect under one or more of the HV shocking coils [20]. These observations are worrisome as the integrity and functionality of the HV system may not come into attention until delivery of therapy as no significant deviations are noted on routine surveillance. What is even more worrisome is the possibility of potential insulation failure under the shocking coil without externalization anywhere else which is not visible with any imaging techniques. These findings highlight an important and complex issue regarding patient management, especially in those who have a device

for secondary prevention of sudden cardiac death as failure to deliver therapy could be catastrophic at the time of need.

To make the matter more complex, extraction of Riata® and Riata ST® leads poses unique challenges with resultant higher procedural risks. Even though the extraction procedure was reported to be safe in a study by Patel et al. [21] where they extracted 20 dual coil leads with a mean dwell time of 48 ± 27 months, almost 90% of them required laser-powered tools and larger sheaths for extraction. This complexity arises from the lead design in Riata® and Riata® ST leads where the externalized conductors (attached to the distal edge of the proximal HV coil) when pulled during the extraction maneuver start to "bunch-up" in front of the sheath. This "snowplowing" effect as described by Patel et al. [21] then requires larger sheaths to accommodate the conductors thus raising the complications rates. Moreover, the HV coil has a round profile in the 8 Fr 15XX series leads compared to 7 Fr leads where the profile is flat and backfilled with silicone material. This lack of backfill in the larger 8 Fr leads invites more tissue in-growth in the lead leading to difficulty during extraction.

Decision regarding abandoning the externalized lead instead of extracting is very complex which involves careful consideration of each individual patient factor such as age, presence of co--morbidities, pacemaker dependence, overall frailty and indication for the ICD. Addition of another ICD lead to an existing lead with extruded conductors can possibly interfere with the ICD lead function such as during delivery of HV shock due to possibility of short circuiting thereby leading to failed defibrillation. In a large Veterans Affairs study by Sung et al. [22], defibrillation testing demonstrated a 10-J safety margin in 18 patients who had abandoned Riata® family leads and underwent addition on a new ICD lead. Also no electrical malfunctions due to lead-lead interaction were observed for an average follow-up of 18.2 months in the same study. It is to be noted that data regarding lead externalization was not available in this particular study.

It is well known that medical grade silicone has high tensile strength, flexibility and bio-stability but low resistance to abrasion. A recent study from Kołodzińska et al. [23] has challenged the bio--stability of silicone by observing extensive macrophage accumulation at the site of already abraded silicone using electron microscopic techniques. They also observed accelerated silicone degradation in the presence of microorganisms such as Staphylococcus aureus species. These results raise an important issue with externalized Riata® family leads where the already abraded silicone insulation might serve an easy nidus for infective endocarditis, should these patients develop blood stream infections. Externalized conductors have also been associated with thrombus formation as described in a recent case report by Ricciardi et al. [24] where they found a 3.5 cm × 1.5 cm thrombus attached to the externalized segment of the lead with extensive fibrotic attachment to the tricuspid valve.

Limitations of the study

This is a single center study involving a modest number of patients. Exclusion of expired patients at the time of study possibly introduces a selection bias. We did not collect data on expired patients or those who refused the screening. Also due to the retrospective analytic design of the study, the actual time from lead implantation to insulation failure cannot be determined which remains the biggest limitation in all other published studies as well. None of the patients included had Riata ST Optim® leads, thereby limiting our analysis to non-optim® coated Riata leads.

Clinical implications

Insulation failure especially the inside-out variety, in patients implanted with Riata® and Riata ST® ICD leads is emerging as a growing problem. Clearly the prevalence of lead externalization is high in the range of > 20% as shown by ours and recent other studies. Most of the visual lead defects are electrically silent on a routine interrogation but stakes are high as demonstrated by failed device therapy delivery for arrhythmias and by the deaths reported in the study from Hauser et al. [8]. Our study showed that over time, electrical parameters do show a trend towards higher pacing thresholds in leads with extruded conductors, however the timing and ultimate outcome of these changes remain unknown and at the present can't be used to dictate clinical practice. Currently published literature on Riata® family of leads has led to more questions than answers. There are no clear guidelines as to when to perform fluoroscopy and how often, whether to perform noninvasive programmed stimulation testing and when to extract leads with externalized conductors. We recommend close monitoring of patients with 3-monthly office or remote monitoring and paying special attention to small changes in electrical parameters. We agree with the manufacturer recommended lead monitoring to use an unused electrogram channel to monitor for HV lead noise, program upper and

lower limits for pacing lead impedance to 1000 Ω and 200 Ω, respectively, use Secure Sense™ RV noise discriminator algorithm in devices where available. Also it has been proposed to change the detection criteria for ventricular fibrillation to increase the detection intervals to 30 to avoid brief episodes of noise being detected as tachycardia episode. Direct alert notifications via Merlin.net® patient care network should be set to "Urgent" or "Standard" modes whenever lead impedance, noise or noise reversion issues are detected. As of present, the FDA has mandated routine imaging either with fluoroscopy or 2-view chest X-ray to assess lead externalization in all patients with Riata® family leads [25]. Decision regarding abandoning vs. extracting a Riata lead needs to be individualized based on patient factors, indication for ICD, need for pacing and operator experience. Given the complexities associated with extracting leads with extruded cables, it seems reasonable to extract only those leads with electrical malfunction and closely following the ones with externalization and normal electrical parameters, or normal fluoroscopic appearance. There is no consensus as of yet to determine the frequency of imaging patients who have no evidence of conductor externalization on initial fluoroscopy. We think it is reasonable to continue with systematic imaging at reasonable intervals in patients showing marked externalization and normal electrical testing. Large-scale prospective studies such as one being conducted by St. Jude Medical might help to further define this growing problem and to determine optimal management strategy for these high-risk patients [26].

Conclusions

Insulation failure among the Riata® large diameter ICD leads as determined by high resolution 3 view fluoroscopy is significant (~27%) with rise in pacing threshold over time. Patients may present with loss of HV lead integrity/function at the time of need during life threatening ventricular arrhythmias with potential fatal consequences. Systematic lead fluoroscopy as recommend by FDA and regular device interrogation with close attention to small changes in electrical parameters seems to be most prudent approach at this juncture in time for this high risk patient population.

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