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MULTIMEDIA REPORT

Comparison of lead failure manifestation of Biotronik Linox with St. Jude Medical Riata and Medtronic Sprint Fidelis lead

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Abstract

Purpose To compare lead failure manifestation and lead performance of the Biotronik Linox/Sorin Vigila defibrillator lead (Linox group) with the St. Jude Medical Riata/Riata ST (Riata group) and Medtronic Sprint Fidelis defibrillator leads (Fidelis group).

Methods We assessed the performance of all aforementioned leads implanted at our center and investigated the manifestation of lead failures.

Results Of 93 Linox, 86 Riata, and 81 Fidelis leads implanted at our center, 11 (12%), 22 (26%), and 25 (31%) leads failed during a median follow-up of 46, 61, and 84 months, respectively. Inappropriate shocks were delivered in 64% (Linox), 5% (Riata), and 32% (Fidelis) of lead failures; a device alert was noted in none (Linox), 5% (Riata), and 52% (Fidelis); and lead failure was a coincidental finding in 36% (Linox), 91% (Riata), and 16% (Fidelis) of cases ($p < 0.001$). Non-physiological high rate signals were observed in 73% (Linox), 27% (Riata), and 80% (Fidelis) of lead failures ($p = 0.001$) and damaged lead integrity was found in 36% (Linox), 73% (Riata), and 24% (Fidelis) of cases ($p = 0.064$). Lead survival at 5 years was 88%, 92%, and 71% for Linox, Riata, and Fidelis group, respectively.

Conclusions The most frequent clinical manifestation of lead failure was inappropriate shocks for Linox, coincidental finding for Riata and device alert for Fidelis leads. Non-physiological high rate signals were frequently observed in Linox and Fidelis lead failures whereas in Riata lead failures, a damaged lead integrity was the predominant finding.

Keywords Defibrillator lead · Lead failure · Linox · Riata · Sprint fidelis

Abbreviations

CRT	Cardiac resynchronization therapy
Fi	Sprint Fidelis
ICD	Implantable cardioverter defibrillator
Li	Linox/Vigila
Ri	Riata/Riata ST
SJM	St. Jude Medical

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1 Introduction

Implantable cardioverter defibrillator (ICD) lead failures continue to be among the most dreaded complications of ICD therapy. They may lead to inappropriate ICD shocks, ineffective ICD therapy, and they mostly necessitate re-interventions on the ICD system including defibrillator lead extraction. In recent years, many thousands of patients have been affected by advisories of the St. Jude Medical Riata/Riata ST (St. Jude Medical, St. Paul, MN, USA) and Medtronic Sprint Fidelis (Medtronic, Minneapolis, MN, USA) defibrillator leads [1, 2]. As a consequence, research in this area has increased substantially and the electrophysiology community has learned how to deal with

Riata/Riata ST and Sprint Fidelis defibrillator lead issues [3, 4]. Specific recommendations about management of recalled but functioning defibrillator leads as well as procedures in case of defibrillator lead failure have been issued [5, 6]. Insights into the failure manifestation of recalled leads have resulted in the development of different algorithms to prevent inappropriate shocks like the Medtronic lead integrity alert and lead noise algorithms or the St. Jude Medical SecureSense algorithm [7, 8]. Finally, the lead failure mechanisms of the above-mentioned defibrillator leads have been clarified and resulted in adaptations of lead design.

The Biotronik Linox (Biotronik, Berlin, Germany) defibrillator lead was introduced in 2006 and well over 80,000 Linox leads were implanted worldwide. Lead survival rates according to a product performance report were 97.7% and 97.1% at 5 years for Linox SD and S leads, respectively (published by Biotronik in 2017: https://www.biotronik.com/en-us/healthcare-professionals/product-performance-report). Similarly, multicenter, prospective, non-randomized registries estimated a cumulative survival probability of 96.3% at 5 years after Linox lead implant [9]. However, several groups, including ours, have described a worse survival rate of the Linox defibrillator lead, ranging from 88 to 93.6% at 5 years [10–12]. A more recent study described a similar low lead survival rate of 81% at 7 years in an Asian population [13]. Conductor externalization—a unique lead failure mechanism mainly observed in Riata leads—was also found in some of the failed Linox leads in these studies.

Despite these contradictory performance reports, we consider further in-depth investigation of Linox lead failures necessary and valuable for the future management of patients implanted with these leads. This study aims to compare lead failure manifestation of the Linox with lead failure manifestation of the Riata and Sprint Fidelis defibrillator leads.

2 Methods

Since January 2008, we maintain an electronic registry of all ICD interventions performed at our center. Before 2008, all ICD implants were listed in an electronic logbook. All Biotronik Linox S/SD leads, all Riata/Riata ST leads (Model 1570, 1580, 7000, and 7002; St. Jude Medical, St. Paul, MN, USA) and all Sprint Fidelis leads (Model 6931 and 6949; Medtronic, Minneapolis, MN, USA) implanted at our center were identified from these sources. Sorin Vigila 1CR/2CR leads, which correspond to Biotronik Linox S/SD leads marketed by former Sorin group, were also included in the Linox group. Patients without at least one follow-up visit at our center after lead implant were excluded from the analysis.

The clinical records of all patients were reviewed, including patient characteristics at lead implantation and number and type of re-interventions performed during follow-up. Current lead status of all leads was assessed in January 2016, and all lead failures were analyzed in detail. Lead failure was defined by the presence of any of the following criteria:

- Non-physiological high rate signals, not attributable to electromagnetic interferences, myopotential or T wave oversensing, with or without inappropriate shocks
- Sudden change of long-term pace/sense or high voltage impedance (> 100% increase or > 50% decrease) or values outside the interval of 200–2000 Ω or 20–200 Ω, respectively, and loose set screw excluded at revision
- Fluoroscopic observation of an externalized conductor
- Visual observation of an exposed or externalized conductor
- Sudden increase in right ventricular threshold and/or decrease of R wave sensing, without alternative explanation

Lead dislodgements or perforations and lead revisions because of electrical abnormalities that normalized with reuse of the lead were not considered lead failures.

We have previously reported the performance of all Linox and Vigila leads implanted at our center including prospective fluoroscopy to assess lead integrity [12]. We have also previously performed prospective fluoroscopy in patients implanted with a Riata/Riata ST lead followed-up at our institution [14]. For the present study, lead status of these populations was updated and completed on January 2016 but without additional prospective fluoroscopy.

Clinical manifestation of each lead failure was classified into one of the following events: (i) device alert, (ii) coincidental finding during ICD control or during device intervention, or (iii) inappropriate shock(s). Lead-related manifestations were grouped into (i) abnormal electrical parameters, (ii) non-physiological high rate signals, and (iii) damaged lead integrity according to visual inspection or fluoroscopy.

The study was conducted in accordance with the local institutional committee on human research and national regulatory authorities.

2.1 Statistical analysis

Categorical variables are expressed as numbers and percentages and continuous variables as mean ± standard deviation or median and range. Differences between groups were determined using the Chi-square test, Fisher's exact test, or an analysis of variance, as appropriate. Lead abandonment or explantation not related to lead failure as well as deceased cases were treated as censored observations. Patients followed up externally were censored at the time of the last follow-up visit at our clinic. The cumulative lead failure rate was estimated using the Kaplan-Meier method and lead survival compared with the log-rank test. All analyses were performed using SPSS 21.0 (SPSS Inc., Chicago, IL, USA).

Table 1 Patient characteristics

	Linox/Vigila, $n = 93$	Riata/Riata ST, $n = 86$	Sprint Fidelis, $n = 81$	P value
Age at implant, years	59.9 ± 10.4	60.9 ± 10.4	55.3 ± 15.6	0.008
Male	72 (77%)	78 (91%)	64 (79%)	0.043
Body mass index, kg/m^2	26.8 ± 4.6	27.6 ± 4.0	27.3 ± 4.7	0.462
LVEF, %	35.5 ± 15.1	35.4 ± 14.2	35.8 ± 18.2	0.986
Heart disease				0.008
IHD	54 (58%)	65 (76%)	40 (51%)	
DCM	22 (24%)	9 (11%)	14 (18%)	
HCM	5 (5%)	1 (1%)	5 (6%)	
Other	12 (13%)	11 (13%)	20 (25%)	
Secondary prevention ICD	53 (57%)	56 (65%)	56 (69%)	0.234
Device				< 0.001
Single chamber	59 (63%)	73 (85%)	56 (69%)	
Dual chamber	22 (24%)	12 (14%)	9 (11%)	
CRT	12 (13%)	1 (1%)	16 (20%)	
Venous access				< 0.001
Cephalic	67 (72%)	63 (73%)	38 (47%)	
Subclavian	26 (28%)	23 (27%)	43 (53%)	
Right-sided implantation	3 (3%)	–	2 (3%)	0.125
Dual coil	22 (24%)	74 (86%)	37 (46%)	< 0.001
Prior ICD implantation	4 (4%)	8 (9%)	20 (25%)	< 0.001
Prior lead failure	3 (3%)	3 (3%)	12 (15%)	
Prior ICD infection	–	1 (1%)	2 (2%)	
Other reason	1 (1%)	2 (2%)	5 (6%)	
Additional leads*	5 (5%)	2 (2%)	10 (12%)	0.028
Number of ICD re-interventions during FU†				0.011
0	64 (69%)	54 (63%)	66 (82%)	
1	27 (29%)	29 (34%)	10 (12%)	
2	2 (2%)	3 (4%)	3 (4%)	
3	–	–	2 (3%)	
Type of ICD re-interventions during FU				
RV lead revision	2 (2%)	1 (1%)	2 (3%)	0.799
Generator replacement	18 (19%)	28 (33%)	6 (7%)	< 0.001
Upgrade to CRT	9 (10%)	2 (2%)	7 (9%)	0.117
Other intervention	5 (5%)	3 (4%)	5 (6%)	0.702
Lead status at last FU				< 0.001
Active	44 (47%)	11 (13%)	10 (12%)	
Deceased	23 (25%)	16 (19%)	10 (12%)	
External FU	9 (10%)	19 (22%)	17 (21%)	
Abandoned/explanted lead not because of lead failure	6 (7%)	6 (8%)	3 (4%)	
Abandoned/explanted functional lead (preventively)	–	12 (14%)	16 (20%)	
Lead failure	11 (12%)	22 (26%)	25 (31%)	

Shown are mean ± standard deviation, or numbers with percentages in parentheses

*Abandoned leads or additional SVC coil

† Several interventions were sometimes performed simultaneously

IHD ischemic heart disease, *DCM* dilated cardiomyopathy, *HCM* hypertrophic cardiomyopathy, *LVEF* left ventricular ejection fraction, *ICD* implantable cardioverter defibrillator, *CRT* cardiac resynchronization therapy, *FU* follow-up

Table 2 Lead failures

Case #	Age, sex	Lead model	Device	Access	Lead age (months)	Type of failure	Electrical abnormalities	Presentation
Linox/Vigila								
1	52, m	S	VVI	Cephalic	71	Conductor externalization	None	Device replacement
2	53, m	SD	DDD	Cephalic	94	Conductor externalization	None	Fluoroscopic screening
3	37, m	S	VVI	Subclavian	33	Non-physiological high rate signals	None	Routine ICD control
4	60, f	S	DDD	Subclavian	46	Insulation abrasion (pocket and distal) with non-physiological high rate signals	Unknown	Inappropriate shocks ($n = 36$)
5	37, m	S	VVI	Cephalic	31	Non-physiological high rate signals	Increase of P/S impedance, increase of pacing threshold, rate histogram shows high frequency peak	Inappropriate shock ($n = 1$)
6	45, f	SD	DDD	Subclavian	35	Non-physiological high rate signals after appropriate shock	None	Inappropriate shocks ($n = 19$)
7	64, f	SD	DDD	Subclavian	55	Sudden rise of high voltage impedance	High voltage impedance > 150 Ω; Non-physiological high rate artifacts on far-field electrogram	Routine ICD control
8	50, m	SD	VVI	Cephalic	44	Non-physiological high rate signals	Decrease of P/S impedance, decrease of R wave amplitude	Inappropriate shocks ($n = 36$)
9	43, f	SD	VVI	Subclavian	63	Non-physiological high rate signals	Intermittent increase of P/S impedance (> 3000 Ω) during manipulation of ICD pocket	Inappropriate shocks ($n = 21$)
10	51, m	S	VVI	Cephalic	93	Conductor externalization	Unknown	Inappropriate shock ($n = 1$)
11	55, m	S	CRT	Subclavian	44	Non-physiological high rate signals	none	Inappropriate shocks ($n = 4$)
Riata/Riata ST								
1	73, m	1580	VVI	Subclavian	80	Conductor externalization	None	Fluoroscopic screening
2	44, m	1580	VVI	Cephalic	88	Electrical abnormalities	Increase of pacing threshold and impedance	Device alert
3	49, m	1570	VVI	Cephalic	79	Insulation abrasion in pocket	None	Device replacement
4	70, m	1580	VVI	Cephalic	61	Electrical abnormalities	Decrease of R wave amplitude	Routine ICD control
5	39, m	1570	VVI	Cephalic	18	Insulation abrasion in pocket	Decrease of HV impedance	Routine ICD control
6	63, m	1570	DDD	Subclavian	99	Conductor externalization	None	Fluoroscopic screening
7	59, m	1570	VVI	Cephalic	76	Insulation abrasion in pocket	None	CRT-D-Upgrade
8	68, m	1580	VVI	Subclavian	92	Conductor externalization	None	Fluoroscopic screening
9	44, m	1582	VVI	Subclavian	86	Non-physiological high rate signals	Increase of pacing threshold	Routine ICD control
10	62, m	1580	VVI	Cephalic	72	Conductor externalization	None	CRT-D-Upgrade
11	42, m	1580	VVI	Cephalic	87	Conductor externalization and insulation abrasion in pocket	None	Device replacement
12	63, m	1580	DDD	Cephalic	95	Conductor externalization	None	Routine ICD control
13		1580	VVI	Cephalic	74	Insulation abrasion in pocket	None	

Table 2 (continued)

Case #	Age, sex	Lead model	Device	Access	Lead age (months)	Type of failure	Electrical abnormalities	Presentation
	58, m							Device replacement
14	67, m	1580	VVI	Cephalic	26	Insulation abrasion in pocket and non-physiological high rate signals	None	Routine ICD control
15	67, m	1580	CRT	Cephalic	22	Insulation abrasion in pocket	Decrease of HV impedance	Routine ICD control
16	49, m	1580	VVI	Cephalic	73	Conductor externalization	None	Fluoroscopic screening
17	72, m	1580	VVI	Subclavian	24	Non-physiological high rate signals	None	Inappropriate shocks ($n = 48$)
18	67, m	1580	VVI	Subclavian	58	Conductor externalization	None	Fluoroscopic screening
19	54, m	1580	VVI	Subclavian	49	Non-physiological high rate signals	None	Routine ICD control
20	53, m	7000	VVI	Cephalic	84	Electrical abnormalities	Increase of pacing threshold	Routine ICD control
21	75, m	7002	VVI	Cephalic	81	Conductor externalization	None	Device replacement
22	46, m	7002	VVI	Cephalic	100	Insulation abrasion in pocket and non-physiological high rate signals	None	Routine ICD control
Sprint Fidelis								
1	59, f	6949	VVI	Cephalic	36	Insulation abrasion in pocket	Decrease of R wave amplitude	Device replacement
2	16, m	6931	VVI	Cephalic, right	44	Lead fracture and non-physiological high rate signals	None	Device alert and lead fracture in X-Ray
3	46, m	6931	VVI	Subclavian	39	Fatigue fracture of tip conductor at 28.7 cm from conductor pin and non-physiological high rate signals	Increase of P/S impedance	Inappropriate shocks ($n = 12$)
4	80, m	6949	VVI	Cephalic	79	Non-physiological high rate signals	Increase of pacing threshold and impedance	Device alert
5	63, m	6949	DDD	Cephalic	59	Electrical abnormalities	Increase of pacing threshold	Routine ICD control
6	69, m	6931	VVI	Cephalic	24	Non-physiological high rate signals	Instable high voltage and P/S impedance, increase of R wave amplitude and pacing threshold	Inappropriate shocks ($n = 7$)
7	34, f	6931	VVI	Cephalic	63	Electrical abnormalities	Increase of P/S impedance, stepwise increase of pacing threshold, slow decrease of R wave amplitude	Routine ICD control
8	67, m	6949	VVI	Subclavian	25	Non-physiological high rate signals	Decrease of R wave amplitude and increase of pacing threshold	Inappropriate shock ($n = 1$)
9	42, m	6949	VVI	Cephalic	117	Non-physiological high rate signals	None	Device alert
10	59, m	6949	VVI	Subclavian	56	Non-physiological high rate signals	Increase of P/S impedance	Device alert
11	71, m	6949	VVI	Subclavian	47	Non-physiological high rate signals	Increase of P/S impedance	Inappropriate shocks ($n = 7$)
12	44, f	6931	VVI	Subclavian	16	Non-physiological high rate signals	None	Inappropriate shocks ($n = 3$)
13	18, f	6931	VVI	Cephalic	79	Non-physiological high rate signals	Increase of P/S impedance	Device alert
14	14, f	6931	VVI	Subclavian	27	Fracture of ring conductor at 62.5 cm from connector pin and non-physiological high rate signals	Increase of P/S impedance	Device alert
15	35, m	6931	VVI	Subclavian	52	Non-physiological high rate signals	None	Inappropriate shocks ($n = 4$)

Table 2 (continued)

Case #	Age, sex	Lead model	Device	Access	Lead age (months)	Type of failure	Electrical abnormalities	Presentation
16	35, m	6931	VVI	Subclavian	39	Electrical abnormalities	Instable P/S impedance (680–2700 Ω)	Device alert
17	45, m	6931	VVI	Subclavian	55	Lead fracture and non-physiological high rate signals	Instable P/S impedance (500–3000 Ω)	Device alert and fluoroscopy
18	65, f	6931	CRT	Subclavian	80	Non-physiological high rate signals	Increase of P/S impedance	Device alert
19	60, m	6931	VVI	Cephalic	42	Ring conductor fracture at 62.3 cm and non-physiological high rate signals	None	Inappropriate shocks ($n = 2$)
20	72, m	6931	DDD	Subclavian	47	Electrical abnormalities	Increase of P/S impedance	Device alert
21	67, m	6931	VVI	Cephalic	8	Non-physiological high rate signals	Decrease of R wave amplitude	Inappropriate shocks ($n = 2$)
22	68, m	6931	CRT	Cephalic	51	Non-physiological high rate signals	None	Device alert
23	38, m	6931	VVI	Subclavian	60	Non-physiological high rate signals	Increase of P/S impedance	Device alert
24	70, m	6931	VVI	Subclavian	56	Non-physiological high rate signals	Increase of P/S impedance	Device alert
25	44, f	6931	VVI	Cephalic, right	62	Non-physiological high rate signals	Instable impedance and increase of pacing threshold	Routine ICD control

CRT cardiac resynchronization therapy, *DDD* dual-chamber, *f* female, *ICD* implantable cardioverter defibrillator, *m* male, *P/S* pace/sense, *VVI* single-chamber

3 Results

A total of 93 Linox/Vigila leads (74 Linox and 19 Vigila leads), 86 Riata/Riata ST leads, and 81 Sprint Fidelis leads were included in this study. Patient characteristics at implant, type, and number of ICD re-interventions during follow-up, and lead status at the end of follow-up are listed in Table 1.

The median time from implant to follow-up were 46 months (IQR 33;74), 84 months (49;104), and 61 months (30;86) for Linox/Vigila leads, Riata/Riata ST leads, and Sprint Fidelis leads, respectively. As mentioned above, we have previously reported the performance of our Linox/Vigila population including prospective fluoroscopy [12]. Supplemental Figure 1 gives an updated overview of current lead status of our Linox/

Table 3 Overview of lead failure manifestation

	Linox/Vigila, $n = 11$	Riata/Riata ST, $n = 22$	Sprint Fidelis, $n = 25$	P value
Clinical manifestation				
Device alert	0 (0%)	1 (5%)	13 (52%)	< 0.001
Coincidental findings*	4 (36%)	20 (91%)	4 (16%)	< 0.001
Inappropriate shocks	7 (64%)	1 (5%)	8 (32%)	0.001
Median number of shocks (range)	19 (1;36)	48	4 (1;12)	0.005
Lead-related manifestation†				
Abnormal electrical parameters	4 (36%)	6 (27%)	20 (80%)	0.001
Non-physiological high rate signals	8 (73%)	6 (27%)	20 (80%)	0.001
Normal electrical parameters	3 (38%)	2 (33%)	4 (20%)	0.395
Damaged lead integrity	4 (36%)	16 (73%)	6 (24%)	0.001
Normal electrical parameters	2 (50%)	14 (88%)	1 (17%)	< 0.001
Fluoroscopic finding	1 (25%)	5 (31%)	2 (33%)	0.249
Visual finding upon pocket inspection	3 (75%)	11 (69%)	4 (67%)	0.026

*Lead failures detected by chance during ICD control, fluoroscopic screening or device intervention without any clinical manifestation or electrical abnormalities

† Several lead-related manifestations may have occurred simultaneously in a given patient

IQR interquartile range

Table 4 Overview of abandoned, explanted, and revised leads, not meeting lead failure definition

	Linox/Vigila, $n = 93$	Riata/Riata ST, $n = 86$	Sprint Fidelis, $n = 81$
Abandoned or explanted leads			
Functional lead	–	12	16
Infection	1	–	3
Heart transplantation	2	2	–
Recovered heart function	1	–	–
Myopotential or T wave oversensing	1	2	–
Insulation abrasion	1	–	–
Lead dislodgement	–	1	–
Patient choice	–	1	–
Revised leads			
Lead dislodgement	2	–	–

Vigila population. Since our original publication, two additional lead failures have occurred (Table 1, cases no. 10 and no. 11). In both cases, inappropriate shocks were delivered. Fluoroscopy revealed an externalized conductor in case no. 10. This case was not screened prospectively in our original publication because of external follow-up, but was transferred to our center for lead revision after lead failure and delivery of an inappropriate shock. In the other additional case (case no. 11), no obvious lead failure mechanism was detected upon lead revision and fluoroscopy. However, the failed lead was not explanted.

In total 11 (12%) Linox/Vigila leads, 22 (26%) Riata/Riata ST leads and 25 (31%) Sprint Fidelis leads failed during follow-up. Lead failures are described in detail in Table 2. The clinical manifestations as well as the lead-related manifestations of lead failures are summarized in Table 3. Of all failed leads, 15 leads were extracted during lead revision (two in the Linox group; one in the Riata group; and 12 in the Sprint Fidelis group) and only six were sent for analysis (two in the Linox group; none in the Riata group; and four in the Sprint Fidelis group). Both Linox leads (cases no. 3 and no. 4) demonstrated an external insulation abrasion, probably because of a mechanical interaction with another implanted lead or with the ICD can. All returned Sprint Fidelis leads showed a lead fracture (fracture of tip in cases no. 3 and no. 6 and fracture of ring conductor in cases no. 14 and no. 19).

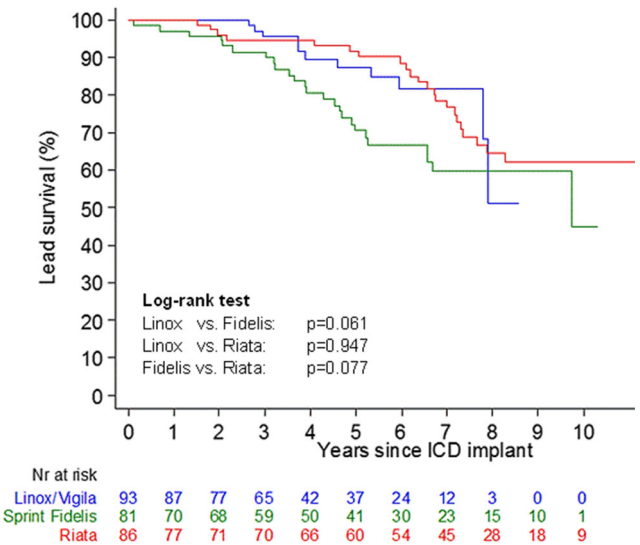

Fig. 1 Kaplan-Meier survival curves of the Linox/Vigila, Riata/Riata ST, and Sprint Fidelis defibrillator leads

Inappropriate shocks were the most frequent clinical manifestation of Linox/Vigila lead failures (64%), whereas Riata/Riata ST lead failures mostly were coincidental findings (91%) and Sprint Fidelis lead failures mainly manifested through device alerts (52%). Non-physiological high rate signals were frequently observed during Linox/Vigila and Sprint Fidelis lead failures but were rare during Riata/Riata/ST lead failures (73%, 80%, and 27%, respectively; $p = 0.001$). The latter more frequently manifested through damaged lead integrity.

Table 4 lists all abandoned, explanted and revised leads not meeting lead failure definition. In the Linox/Vigila group, one lead was replaced during generator replacement because of significant insulation abrasion within the ICD pocket, but without conductor exposure and therefore did not meet the lead failure definition.

After publication of the safety advisories regarding the Sprint Fidelis and Riata/Riata ST defibrillator leads a total of 16 functional Sprint Fidelis leads (20%) and 12 functional Riata/Riata ST leads (14%) were abandoned or explanted for preventive reasons, mostly during elective ICD generator replacement. Kaplan-Meier lead survival curves are shown in Fig. 1. Lead survival for the Linox/Vigila, Riata/

Table 5 Incident cases of lead failure

Lead group	No. of Leads	Risk time (y)	Incident lead failures	Incidence rate per 100 lead years (95% CI)
Linox/Vigila	93	392.8	11	2.8 (1.6–5.1)
Riata/Riata ST	86	543.0	22	4.1 (2.7–6.2)
Sprint Fidelis	81	402.2	25	6.2 (4.2–9.2)

Risk time is presented as total lead years under observation

CI confidence interval

Riata ST, and Sprint Fidelis leads were 96%, 95%, and 90% at 3 years and 88%, 92%, and 71% at 5 years, respectively. The incidence rate of lead failure for each lead group is presented in Table 5.

4 Discussion

This study shows that the manifestation of defibrillator lead failures differs, depending on affected lead type. In Linox and Fidelis lead failures, non-physiological high rate signals are frequent, whereas in Riata leads, a damaged lead integrity is the main finding. Correspondingly, inappropriate shocks are the predominant clinical manifestation of Linox lead failures and are also found in one third of Fidelis lead failures. Because of the lead integrity alert of Medtronic, a device alert was the main clinical manifestation of Fidelis lead failures, when combined with a Medtronic ICD. Riata lead failures however were mostly found coincidentally during device replacement or during another procedure involving thoracic fluoroscopy.

Other studies on lead failures have described very similar rates of non-physiological high rate signals in Linox lead failures [10, 11] and in Fidelis lead failures [15, 16], as in our study. In Riata lead failures, reported rates of non-physiological high rate signals vary from 15 to 53% [2, 4, 16, 17]. However, these rates may be influenced by lead failure definitions and lead management, including prospective fluoroscopic screening and abandonment of leads with conductor externalization, as it was the case at our center [12, 18].

Inappropriate shocks were the most frequent clinical manifestation of lead failure (64%) in our Linox lead failure group. Others reported lower rates of inappropriate shocks with these leads when connected to a Medtronic ICD with the lead integrity alert enabled [11, 19]. This lead integrity alert has proven to reduce inappropriate shocks in Fidelis lead failures and was also enabled in our Fidelis lead group, one available [15]. In our study, inappropriate shocks were exceedingly rare in the Riata group (5%), comparable to other reports [2, 17].

The most frequent mechanism of Riata lead failure is insulation abrasion in 70% of cases (lead to can or lead to other device) and inside out abrasion in 30% [20]. Lead fracture is exceedingly rare in Riata lead failures whereas fracture of the pace-sense conductor is the predominant failure mechanism in Fidelis lead failures [1]. Lead fracture of the pace-sense conductor may instantaneously lead to the appearance of non-physiological high rate signals and consecutive inappropriate shocks, whereas insulation abrasion will take longer to affect the pace-sense conductor up to the appearance of electrical abnormalities and non-physiological high rate signals. These differences in lead failure mechanism may explain the different clinical manifestations of lead failures among Fidelis and Riata leads. The mechanism of Linox lead failures is less well clarified. Insulation abrasion including inside out abrasion is also a rather frequent finding in Linox lead failures and is probably a consequence of a similar lead design as the Riata lead family. However, non-physiological high rate signals with or without abrupt increases in conductor impedances (both pace-sense and high voltage conductors may be affected) are also frequently observed in Linox lead failures and point to an additional, different failure mechanism of Linox leads compared to Riata lead failures. To date, no study has been published that analyzed the failure mechanisms of failed and explanted Linox leads.

Figure 1 illustrates the survival curves of the three leads under investigation. However, with less than 100 leads included in each group, we cannot draw any definite conclusions when comparing lead survival among these leads. Survival rates of Fidelis and Riata leads have been investigated by other groups [17]. To date, the performance of the Linox lead is still under investigation and a matter of debate.

In the meantime, what can we learn from this study that is important for clinical practice? First, as with Riata leads, lead integrity of Linox leads should be checked meticulously upon device replacement by visual inspection and fluoroscopy, and any opportunity for fluoroscopy, e.g., during coronary angiography, should be seized. Second, remote monitoring may be offered to patients implanted with a Linox lead, especially when combined with a Biotronik ICD, as these devices do

not offer the possibility of auditory or vibratory alerts. Third, if remote monitoring is not feasible, Linox leads may be combined with an ICD offering the possibility of an auditory or vibratory alert. Fourth, Biotronik should come up with an equivalent of the Medtronic lead integrity alert, so that these patients could potentially be identified prior to receiving an inappropriate shock.

4.1 Study limitations

This is a single-center study with rather small number of leads in each group. No uniform defibrillator lead failure definition exists and findings may differ according to this definition. As mentioned, we performed prospective fluoroscopy of our populations implanted with a Linox or Riata lead and included asymptomatic conductor externalization in our lead failure definition, thereby increasing lead failure rate in these two groups. All Linox leads are combined with a Biotronik ICD at our center and we do not routinely activate remote monitoring as would be recommended in the HRS expert consensus paper [21]. Inappropriate shocks might have been prevented by early identification of electrical abnormalities through remote monitoring in this group. Additionally, there are important differences among lead groups regarding, e.g., implant route, prior ICD implantation and number of additional leads, which may have influenced lead failure rates irrespective of lead model.

5 Conclusions

Lead failure manifestations differ among lead types. Linox lead failures mainly manifest as inappropriate shocks, Fidelis lead failures through a device alert and Riata lead failures mostly are a coincidental finding. Non-physiological high rate signals are a frequent finding in Linox and Fidelis lead failures whereas in Riata lead failures, a damaged lead integrity is the predominant finding. These particularities may be taken into account for the optimal management of patients implanted with one of these leads.

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Compliance with ethical standards The study was conducted in accordance with the local institutional committee on human research and national regulatory authorities.

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