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Performance of an implantable cardioverter-defibrillator lead family

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Abstract

Background: Lead failure is the major limitation in implantable cardioverter-defibrillator (ICD) therapy. Long-term follow-up data for Biotronik Linox ICD leads are limited. Therefore, we analyzed the performance of all these leads implanted at our institution.

Materials and Methods: All Linox and Linox Smart ICD leads implanted between 2006 and 2015 were identified. Lead failure was defined as electrical dysfunction (oversensing, abnormal impedance, exit block). Lead survival was described, according to Kaplan–Meier. Associations between lead failure and specific variables were examined. $p < .05$ was considered significant.

Results: We included 417 ICD leads. The median follow-up time for Linox ($n = 205$) was 81 months and for Linox Smart ($n = 212$) 75 months. During that follow-up time, 30 Linox (14.6%) and 16 Linox Smart leads (7.6%) showed a malfunction. The 5-year lead survival probability was 97.4% for Linox and 95.2% for Linox Smart (log-rank test, $p = .19$). The 6- and 8-year lead survival probability for Linox was 93.6% and 84.6%, and for Linox Smart 93% and 91.9%. The only factor significantly associated with lead failure was younger patient age at implantation (hazard ratio/year: 0.97, 95% CI: 0.94–0.99, $p = .002$).

Conclusion: This relatively large study with a long follow-up period highlights a relevant failure rate of Biotronik Linox leads. The performance of Linox versus Linox Smart ICD leads was comparable. Although we show an acceptable 5-year lead survival probability, we observed a marked drop after just 1 more year of follow-up. In an era of improving heart failure survival probability, a prolonged follow-up of ICD leads is increasingly clinically relevant.

KEYWORDS

implantable cardioverter-defibrillator, lead, lead failure, lead performance, Linox, Linox Smart

1 | INTRODUCTION

Implantable cardioverter-defibrillator (ICD) therapy is a well-established method to prevent sudden cardiac arrest in patients at risk.[1] Over the years, different ICD leads have been manufactured which differ regarding the probability of lead failure. For example, the Riata (St. Jude Medical) and Sprint Fidelis (Medtronic) ICD leads have already been withdrawn from the market due to a high failure rate.[2] Linox leads are produced by the German manufacturer Biotronik and were initially introduced in 2006.[2] A derivative, the Linox Smart lead, was released in 2010. Since that time up to December 31, 2019, a total of 104 660 Linox (Linox S/SD/T/TD) and 146,420 Linox Smart (Linox Smart S/S DX/SD/TD) leads were implanted worldwide.[3] They are 7.8 French in diameter, silicon-insulated ICD leads with a symmetric body. Linox Smart leads are provided with a special outer silicon insulation called Silglide® (Applied Membrane Technology Inc.) that is expected to reduce the risk of abrasion according to the lead manufacturer.[4] Long-term follow-up data for Linox ICD leads are limited. Therefore, we analyzed the performance of all Linox leads implanted during 10 years at our institution.

2 | MATERIALS AND METHODS

2.1 | Study inclusion

We retrospectively analyzed all patients with a Linox (Linox S/SD/T/TD) or Linox Smart (Linox Smart S/S DX/SD/TD) ICD lead that was implanted at our hospital between January 1, 2006 and December 31, 2015. We collected the data from the patient files at the hospital in Traunstein. The study was categorized as a measure of quality assurance by the responsible ethics committee.

2.2 | Follow-up

Follow-up was defined from 3 months after implantation to February 28, 2022. During this time patients were seen in our outpatient clinic, by cardiologists nearby, or in other hospitals at 6-month intervals. In the case of an active remote monitoring system, follow-up intervals were prolonged to 12 months.

2.3 | Lead failure

Lead failure was defined as an electrical dysfunction, resulting in oversensing or undersensing, sudden change of pacing (≤200 or >2000 Ω) or high-voltage impedance (≤20 or >150 Ω). Oversensing due to physiological/external signals, chronic change of R-wave amplitude, or lead dislodgement was not considered as lead failure. Lead-related oversensing was defined as high-frequency electrograms which occur intermittently, with a high amplitude and variation detected only on the right ventricular (RV) channel. We did not consider pectoral myopotentials to indicate a conductor fracture as those findings would suggest an insulation breach.

2.4 | Statistical analysis

For statistical analysis, SPSS version 25.0 (IBM SPSS Statistics) was used. Categorial variables were compared using the χ^2 test. We employed the mean, standard deviation, median with quartiles, and the *t*-test to analyze continuous numeric variables. We used the Kaplan–Meier survival method to describe and compare Linox and Linox Smart ICD leads. Both survival functions were compared using the log-rank test. The association between lead failure and specific variables was examined with the Cox proportional analysis. A $p < .05$ was considered to be statistically significant.

3 | RESULTS

3.1 | Patient characteristics

A total of 421 patients received a Linox or a Linox Smart ICD lead in our hospital. We were not able to obtain a follow-up from 14 patients; four leads showed early infection or lead dislodgement less than 3 months after implantation. We included a total of 407 patients (and 417 ICD leads) for the analysis. As some patients experienced lead failure, a new lead (Linox or Linox Smart $n = 10$) was implanted which led to a slightly higher total number of total ICD leads (see Table 1). Linox leads were implanted from August 23, 2006 to June 16, 2011 and Linox Smart leads were implanted from February 26, 2010 to December 25, 2015 (see Table 1, for a summary of the patient characteristics). Most patients were male (78.1%), and ischemic cardiomyopathy was the most common underlying heart disease (69.2% of all cases). The mean patient age at implantation of a Linox lead was significantly higher compared to Linox Smart (mean ± SD : 71.2 ± 10.4 vs. 68 ± 10.7 years, $p = .002$). A remote monitoring system was used in a quarter of patients with a Linox ICD lead compared to half of the patients with Linox Smart leads (25.4% vs. 50.5%, $p < .001$) All our patients received an ICD generator of Biotronik, the Lumax model was implanted in most cases (72.7%).

3.2 | Lead characteristics

Most of the leads were single-coil leads (91.4%) which in most cases were implanted in the subclavian vein with the Seldinger technique (87.1%) and on the left side (80.6%). During a median follow-up of 76 months, the total failure rate was 11%. The median follow-up was 81 months for Linox and 75 months for Linox Smart leads. During this follow-up time, 14.6% of all Linox leads and 7.6% of all Linox Smart leads showed a lead failure. The most frequently seen electronic dysfunction was oversensing in 84.8% of all cases. All patients with lead failure were referred to and devices were interrogated at our

TABLE 1 Patient characteristics

	All patients (*n* = 407)	Patients with Linox (*n* = 205)	Patients with Linox Smart (*n* = 212)	*p*
Patient's age (years, mean ± SD)	69.7 ± 10.6	71.18 ± 10.4	68.03 ± 10.7	.002
Male gender, *n* (%)	318 (78.1)	167 (81.5)	159 (75)	.11
BMI (kg/m^2)	27.92 ± 4.96	28.17 ± 4.78	27.68 ± 5.17	.22
CVRF, *n* (%)				
Hypertension	326 (80.1)	170 (82.9)	165 (77.8)	.19
Dyslipidaemia	287 (70.5)	155 (75.6)	140 (66)	.03
Smoking	155 (38.1)	71 (34.6)	88 (41.5)	.15
Diabetes	133 (32.7)	57 (27.8)	80 (37.7)	.03
Family history of CVD	91 (22.4)	40 (19.5)	53 (25)	.18
ICM, *n* (%)	256 (62.9)	138 (67.3)	124 (58.5)	.06
LVEF (%, mean ± SD)	31.50 ± 13.92	31.75 ± 13.80	31.42 ± 14.17	.8
NYHA, *n* (%)				
I	97 (23.8)	50 (24.4)	48 (22.6)	.76
II	103 (25.3)	40 (19.5)	63 (29.7)	.02
III	139 (34.2)	80 (39)	67 (31.6)	.09
IV	37 (9.1)	24 (11.7)	13 (6.1)	.05
Not reported	31 (7.6)	11 (5.4)	21 (9.9)	.08
Primary prevention indication, *n* (%)	275 (67.7)	132 (64.4)	148 (69.8)	.24
Comorbidities, *n* (%)				
COPD	45 (11.1)	24 (11.7)	22 (10.4)	.57
CKD	155 (38.1)	95 (46.3)	66 (31.1)	.001
Medication, *n* (%)				
ACE/ARB	389 (95.6)	196 (95.6)	203 (95.8)	.96
Aldosterone antagonist	215 (52.8)	92 (44.9)	127 (59.9)	.002
Amiodarone	74 (18.2)	36 (17.6)	39 (18.4)	.83
Beta-blockers	385 (94.6)	192 (93.7)	203 (95.8)	.45
Calcium channel blockers	36 (8.8)	16 (7.8)	21 (9.9)	.45
Digitalis	19 (4.7)	11 (5.4)	8 (3.8)	.44
Diuretics	328 (80.6)	168 (82)	168 (79.3)	.42
Ivabradine	10 (2.5)	1 (0.5)	9 (4.3)	.01
Statines	288 (70.8)	158 (77.1)	139 (65.6)	.01
Device, *n* (%)				
VVI	223 (54.8)	117 (57.1)	112 (52.8)	.33
DDD	35 (8.6)	17 (8.3)	18 (8.5)	.94
CRT-D	149 (36.6)	71 (34.6)	82 (38.7)	.39
ICD-generator, *n* (%)				
Lumax	296 (72.7)	137 (66.8)	166 (78.3)	.01
Lexos	61 (15)	64 (31.2)	0	<.001
Iforia	40 (9.8)	0	40 (18.9)	<.001

	All patients (*n* = 407)	Patients with Linox (*n* = 205)	Patients with Linox Smart (*n* = 212)	*p*
Itrevia	5 (1.2)	0	5 (2.6)	.03
Lumos	4 (1)	3 (1.5)	1 (0.5)	.3
Xelos	1 (0.3)	1 (0.5)	0	.32
Home Monitoring	156 (38.3)	52 (25.4)	107 (50.5)	<.001

Abbreviations: ACE, angiotensin-converting-enzyme-inhibitor; ARB, angiotensin-receptor blocker; BMI, body mass index; CKD, chronic kidney disease; COPD, chronic obstructive lung disease; CRT-D, cardiac resynchronization therapy-defibrillator; CVD, cardiovascular disease; CVRF, cardiovascular risk factor; ICD, implantable cardioverter defibrillator; ICM, ischemic cardiomyopathy; LVEF, left ventricular ejection fraction; SD, standard deviation.

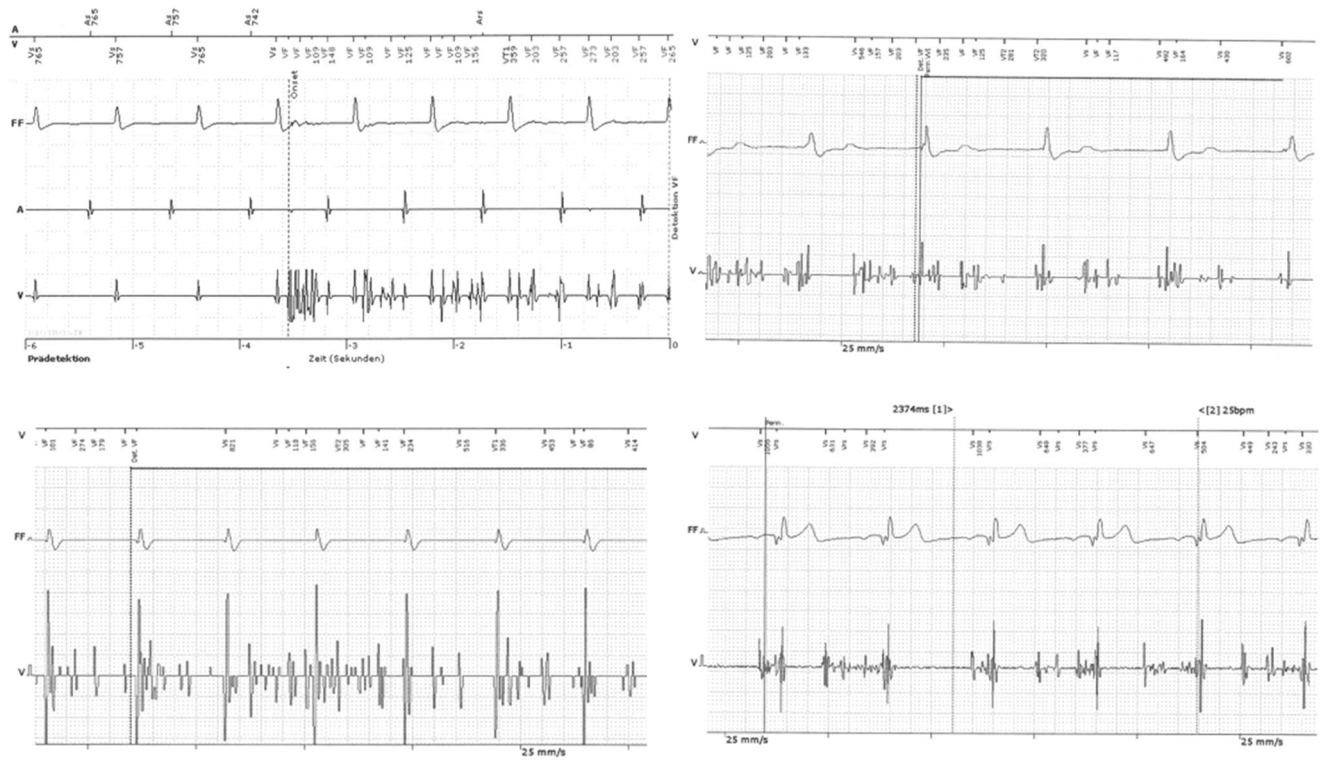


FIGURE 1 Examples for oversensing electrograms on the right ventricular channel

institution, even if they were admitted by external physicians. The diagnosis of lead failure was exclusively based on the device interrogation or electrogram adjudication at our institution by the authors and one retired experienced colleague. Lead-related oversensing was characterized by high-frequency electrograms which occur intermittently with a rather high amplitude and variation detected on the true bipolar RV pace/sense channel only. However, we did not find unequivocal signs of saturation of the sensing amplifier. Examples of these electrograms are shown in Figure 1. In 15.2% we observed sudden increases in the pacing impedance (to >2000 Ω) and in 10.9% of the high-voltage component (to >150 Ω). These findings prompted us to suspect a conductor fracture in 45 of 46 cases. Decreases in the pacing impedance suggested an insulation breach and were seen in 3 of 46 cases. A total of 34 lead defects resulted in the implantation of an additional new lead. In 8 of these 34 cases, an insulation breach was detected macroscopically in or near the generator pocket during this procedure. This insulation breach was probably the result of mechanical generator-lead interaction. In all these eight cases, typical oversensing electrogram patterns had been recorded before the procedure suggesting conductor fracture. In 12 patients with lead failure, the ICD function was deactivated without any operation due to a meanwhile improved left ventricular ejection fraction or the patients' wish, for example. Inappropriate shocks occurred in 39.1% of all cases with

TABLE 2 Lead characteristics

	Total leads (*n* = 417)	Linox (*n* = 205)	Linox Smart (*n* = 212)	*p*
Venous access, *n* (%)				
Left side	336 (80.6)	156 (76.1)	180 (84.9)	.02
Subclavian	363 (87.1)	171 (83.4)	192 (90.6)	.02
Cephalic	41 (9.8)	31 (15.1)	10 (4.7)	<.001
Axillary	13 (3.1)	3 (1.5)	10 (4.7)	.1
Single-coil lead, *n* (%)	381 (91.4)	202 (98.5)	179 (84.4)	<.001
Acute complications				
Pneumothorax, *n* (%)				
Total	10 (2.4)	3 (1.5)	7 (3.3)	.22
With intervention	9 (2.2)	3 (1.5)	6 (2.8)	.34
Subcutaneous hematoma, *n* (%)				
Total	19 (4,6)	10 (5)	9 (4,2)	.76
With intervention	1 (0.2)	1 (0.5)	0	.31
Lead dislodgement, *n* (%)	7 (1.7)	1 (0.5)	6 (2.8)	
Infection with device explantation during FU, *n* (%)	6 (1.4)	2 (1)	4 (1.9)	.44
Deaths, *n*		168 (40.3)	100 (48.8)	68 (32.1)
Median FU, *months* (quartiles)		76 (39, 103.5)	81 (38, 123)	75 (41, 96.8)

Abbreviation: FU, follow-up.

lead failure (Tables 2 and 3). None of the failed leads were explanted. Therefore, an exact analysis of the defect mechanism is not available.

3.3 | Clinical outcomes

The cumulative 5-year lead survival probability for Linox was 97.4% and 95.2% for Linox Smart. Our data show no significant difference in ICD lead survival between the Linox and Linox Smart series ($p = .19$). The 6- and 8-year lead survival probability for Linox was 93.6% and 84.6%, and for Linox Smart 93% and 91.9%. These results are shown in Figure 2.

3.4 | Predictors of lead failure

To identify potential causes of lead failure we employed the Cox proportional hazards model. Younger patient age was significantly associated with lead failure (hazard ratio [HR]/year: 0.97, 95% CI: 0.94–0.99, $p = .002$). Other parameters such as the site of venous access, gender, or single-coil lead showed no significant association with lead failure. Evaluated parameters are presented in Table 4.

4 | DISCUSSION

4.1 | Comparison to other studies

Our results show a failure rate of 11% of both Linox and Linox Smart ICD leads during a median follow-up of 76 months. There was no statistically significant difference between Linox and Linox Smart ICD leads regarding the failure rate. This result may be distorted as patients with a Linox Smart lead were significantly younger than patients with a Linox lead. Furthermore, we showed that younger patient age is related to a higher lead failure probability. These findings could indicate a better performance of the Linox Smart lead because, for a younger patient population, a higher failure rate would be expected. However, the number of cases was too low to test this hypothesis reliably. Based on a median follow-up of 81 months, the Linox lead showed a failure rate of 14.6% in our study.

One of the earliest studies concerning failure rates of the Linox ICD leads is a multicenter study from Padfield et al.[2] They detected a failure rate of 3.4% over a median follow-up of 38.4 months and showed a statistically significant lower 5-year lead survival compared to Durata leads from the manufacturer St. Jude Medical (Linox vs. Durata: 91.6% vs. 99.4%, $p = .001$). In contrast to these findings, our data show a better 5-year lead survival of the Linox series of 97.4%. However, the 6-year lead survival presented above (93.6%) seems

TABLE 3 Lead failures

	Total (*n* = 417)	Linox (*n* = 205)	Linox Smart (*n* = 212)
Median FU, *months (quartiles)*	76 (39, 103.5)	81 (38, 123)	75 (41, 96.8)
Total lead failures, *n* (%)	46 (11)	30 (14.6)	16 (7.6)
P/S	40 (87)	25 (83.3)	15 (93.8)
Shock-coil	3 (6.5)	3 (10)	0
P/S and shock-coil	3 (6.5)	2 (6.7)	1 (6.3)
Clinical presentation, *n* (%)			
Oversensing	39 (84.8)	24 (80)	15 (93.8)
Increase of P/S impedance	7 (15.2)	6 (0.2)	1 (6.3)
Decrease of P/S impedance	3 (6.5)	1 (3.3)	2 (12.5)
Increase in high-voltage impedance	5 (10.9)	4 (13.3)	1 (6.3)
Decrease of high-voltage impedance	0	0	0
Exitblock	5 (10.9)	2 (6.7)	3 (18.8)
Undersensing	0	0	0
Inappropriate ATP	1 (2.2)	1 (3.3)	0
Inappropriate shock	18 (39.1)	13 (43.3)	5 (31.3)
Procedure, *n* (%)			
Device deactivation	12 (26)	7 (23.3)	5 (31.3)
Implantation of a new lead	34 (73.9)	23 (76.7)	11 (68.8)

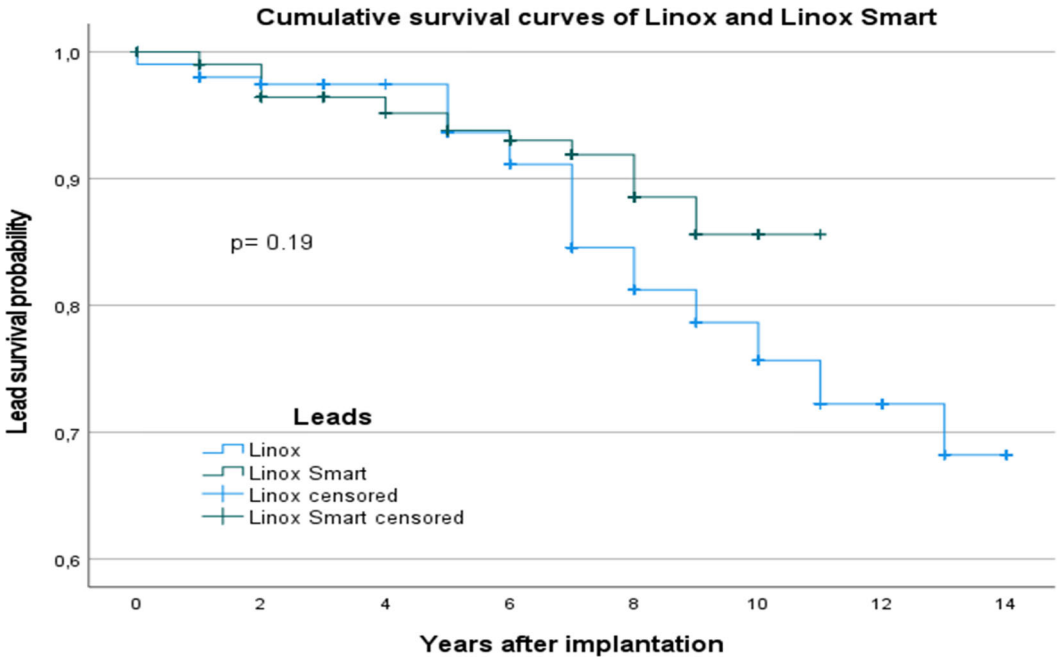
Abbreviations: ATP, antitachycardia pacing; FU, follow-up; P/S, pace/sense channel.

comparable to the data of Padfield et al.[2] A possible explanation for the higher failure rate reported by Padfield et al. is the combination of a Linox ICD lead with a Medtronic device. This device has a specific "lead integrity alert" that could be more sensitive to lead fracture signals resulting in an earlier diagnosis of lead failure. However, the remote monitoring system used in 38.3% of our patients also allowed an early diagnosis of lead failure. There are further single-center studies describing a comparably high failure rate of the Linox ICD lead as shown in Table 2. van Malderen et al.[5] analyzed a total of 408 Linox S/SD leads and compared them to 340 Durata leads (St. Jude Medical) and 343 Endotak Reliance leads (Boston Scientific). They showed a cumulative failure rate of 6.4% during a follow-up of 5 years for Linox leads being significantly higher than that of the two other leads (Durata: 2%, $p = .003$, Endotak Reliance: 0.4%, $p \leq 0.001$).[5]

A study from Japan by Kawada et al.[6] shows a 7-year survival rate of only 81% of 90 Linox ICD leads which is significantly lower than that of the compared 90 Endotak Reliance leads (95.8%, $p = .049$). For comparison, in our study, 91.1% of all Linox leads were still functioning after a follow-up of 7 years. All these reported Linox lead survival probabilities are remarkably lower compared to the manufacturer's annual performance report (7-year lead survival probability: 95.9%).[3]

Until now, only limited data regarding the lead failure rate of the Linox Smart lead have been published. In our study, we analyzed 212 Linox Smart leads over a median follow-up of 75 months and show a failure rate of 7.6% and a 5-year lead survival of 95.2%. In comparison to leads of other manufacturers, a retrospective single-center study by Weberndörfer et al.[7] described a significantly higher 5-year failure rate of 113 Linox Smart ICD leads (14%, $p = .028$). Another retrospective single-center study by Díez et al.[8] compared 120 Linox Smart leads from Biotronik to 145 Sprint Quattro leads from Medtronic and 173 Endotak Reliance leads from Boston Scientific. This study indicates that Linox Smart ICD leads had a significantly worse performance than the other leads ($p = .001$) over a median follow-up of 4.6 years. All studies concerning the Linox Smart family are summarized in Tables 5 and 6.

Comparable to our results, a prospective multicenter study published by Good et al.[16] which collected their data from two multicenter prospective non-randomized registries called GALAXY and CELESTIAL, showed no significant difference between the Linox and Linox Smart family leads ($p = .215$). They analyzed a total of 3.933 Linox and Linox Smart leads from 146 different centers in the USA during a follow-up of 5 years after implantation. The Linox leads showed a cumulative 5-year survival of 96.3% and the Linox Smart leads a cumulative 4-year survival of 96.6%. These results are comparable to the results of our study, but as we can see from our data and from other single-center studies, Linox leads seem to show a pronounced failure rate if the follow-up exceeds 5 years. Our results for example show a 5-year lead survival of 97.4% for Linox



Linox

Years after implant	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Survival (%)	99	97.4	97.4	97.4	97.4	93.6	91.1	84.6	81.2	78.6	75.7	72.2	68.2	68.2
± 95% Confidence	±	±	±	±	±	±	±	±	±	±	±	±	±	±
interval	0.007	0.011	0.011	0.011	0.011	0.02	0.024	0.033	0.037	0.04	0.043	0.048	0.06	0.06
Cumulative events	3	5	5	5	6	11	14	21	24	26	28	29	30	30
Units at risk	192	176	159	138	127	111	96	75	62	52	43	27	17	8

Linox Smart

Years after implant	1	2	3	4	5	6	7	8	9	10	11
Survival (%)	100	99	96.4	96.4	95.2	93	91.9	91.9	85.6	85.6	85.6
± 95% Confidence	±	±	±	±	±	±	±	±	±	±	±
interval	0	0.007	0.013	0.013	0.016	0.02	0.023	0.023	0.042	0.042	0.042
Cumulative events	1	3	7	8	10	12	13	14	16	16	16
Units at risk	202	190	167	152	139	119	81	54	29	13	1

FIGURE 2 Lead survival probability by the Kaplan–Meier method

leads whereas the 6-year lead survival was 93.6% only. As a consequence of these facts, ICD leads may not be regarded as safe based only on an acceptable 4- to 5-year lead survival probability. The product performance report of Biotronik[3] from 2020 shows a 4-year survival probability of Linox Smart of 98.2%. That is substantially higher compared to Good et al. and to our data (Good et al: 96.6%, our study: 96.4%). Concerning the 8-year survival probability of Linox ICD leads, the product performance report shows a result of 94.8% for Linox S leads. In comparison, our data indicates an 8-year lead survival probability of 84.6% only. Good et al. reported no results beyond 5 years of follow-up. A likely reason for the higher lead survival probabilities reported by the manufacturer is underreporting by clinicians compared to registries with close follow-up of all implanted leads. As most ICD recipients today survive more than 5 years, lead failure after this time is clinically highly important.

4.2 | Predictors of lead failure

Several studies indicate that a younger patient age is significantly associated with a higher risk of lead failure.[2,6,10,11] Accordingly, we found a significant association between younger patient age and risk of lead failure by the proportional hazard model (HR/year: 0.97, 95% CI: 0.94–0.99, $p = .002$). A reason for these results may be the higher physical activity of younger patients resulting in a higher tear stress affecting the lead material. In the study of Padfield et al.[2] female gender was significantly associated with a higher failure rate

TABLE 4 Predictors of lead failure

	Hazard ratio (95% confidence interval)	*p*
Linox Smart	0.542 (0.289-1.017)	.057
Patients age (years)	0.965 (0.943-0.987)	.002
Male gender	1.356 (0.711-2.586)	.356
Venous access		
Subclavian vein	0.445 (0.102-1.194)	.282
Left side implantation	1.019 (0.491-2.118)	.959
Single-coil	1.652 (0.399-6.847)	.489
Primary prevention indication	0.895 (0.407-1.965)	.782
ICM	0.83 (0.446-1.544)	.556
CRT-D	1.679 (0.821-3.431)	.156
LVEF (%)	1.017 (0.996-1.039)	.112

Abbreviations: CRT-D, cardiac resynchronization therapy-defibrillator; ICM, ischemic cardiomyopathy; LVEF, left ventricular ejection fraction.

(HR: 2.1, 95% CI: 1.3–3.4, $p = .004$). In contrast, according to our data male gender tended to be associated with a higher risk of lead failure, although this was not statistically significant (HR: 1.36, 95% CI: 0.71–2.59, $p = .36$). There are studies that indicate a higher survival probability of Durata and Endotak Reliance leads in comparison to Linox ICD leads.[5,6,11] Rordorf et al.[17] suggest that different lead constructions could be responsible for the different failure rates. In their study, a diameter ≤8 French was associated with a higher failure rate. Comparable results are presented by van Malderen et al.[5] and Hauser et al.[18] One reason for the better performance of Durata leads could be the outer insulation surface with polyurethan–silicon copopolymer, a material that seems to be more resilient than silicon.[19] Linox Smart ICD leads are provided with a special outer silicon coating called Silglide®.[4] However, as our data, and also the study of Good et al.[16] show, there is no significant difference in lead survival between Linox and Linox Smart ICD leads.

4.3 | Limitations of this study

This study is a nonrandomized retrospective single-center study, which makes it susceptible to institutional-specific failures. However, since almost all patients at our institution received a Biotronik lead during the study period, a relevant bias with respect to lead selection is unlikely. Furthermore, the 5-year lead survival probability in our cohort was not lower than in other publications (Tables 5 and 6). Additionally, a sample size of 407 patients and 417 leads is relatively large and follow-up was longer than in comparable studies. The exact mechanism of lead failure could not be defined. Standard chest X-rays did not show clear structural failure (insulation breach,

TABLE 5 Studies of Linox Leads

Author	Study	Year/country	Number of Linox Leads	Median follow-up in months	Lead failures in %	5-year survival probability in %
Padfield et al.[2]	Multicenter retrospective	2014/Canada	477	39	3.4	91.6
Howe et al.[9]	Single-center retrospective	2015/UK	86	83	3.5	Not available
Noti et al.[10]	Single-center retrospective	2016/Switzerland	93	41	8.6	88
van Malderen et al.[5]	Single-center retrospective	2016/The Netherlands	408	60	6.4	Not available
Kawada et al.[6]	Single-center retrospective	2017/Japan	90	43	11.1	Not available
O'Connor et al.[11]	Single-center retrospective	2018/New Zealand	151	66.7	12.6	Not available
Lam et al.[12]	Single-center retrospective	2019/Switzerland	93	46	12	88
Marai et al.[13]	Single-center retrospective	2019/Israel	340	66.5	3.5	97.3
Alasti et al.[14]	Single-center retrospective	2020/Australia	149	75	4.8	97.1
This study	Single-center retrospective	2022/Germany	205	81	14.6	97.4

TABLE 6 Studies of Linox Smart leads

Author	Study	Year/country	Number of Linox Smart leads	Median follow-up in months	Lead failures in %	5-year survival probability in %
McKeag et al.[15]	Single-center prospective	2018/UK	183	30.2	2.7	97.3
Weberndörfer et al.[7]	Single-center retrospective	2018/Switzerland	113	45.6	12.4	Not available
Diez et al.[8]	Single-center retrospective	2018/Spain	120	55.2	7.5	Not available
This study	Single-center retrospective	2022/Germany	212	75	7.6	95.2

externalization of conductors, or fracture), and systematic fluoroscopic evaluation had not been performed.

5 | CONCLUSION

This relatively large study with a long follow-up period highlights a rather high failure rate of Biotronik Linox leads. We did not find a significant difference between Linox and Linox Smart ICD leads. Although we show an acceptable 5-year lead survival probability that is comparable to the only prospective registry concerning Linox and Linox Smart ICD leads,[16] we observed a marked drop in the lead survival probability after just one more year of follow-up time. Thus, a follow-up longer than 5 years after lead implantation seems to be essential to assess ICD lead performance. Today, heart failure survival has increased due to better pharmacological therapies compared to the time, when ICD studies for primary prevention of sudden cardiac death had been conducted. Therefore, such a prolonged follow-up of ICD leads has become even more meaningful.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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