Annals of Cardiology and Cardiovascular Medicine

Research Article
Published: 26 Apr, 2021

Clinically Indicated Lead Revision Rates for Four Different Internal Cardioverter-Defibrillator Lead Models

Roman Brenner, Joelle Hüppi, David Altmann, Micha T. Maeder, Hans Rickli and Peter Ammann*

Department of Cardiology, Kantonsspital St. Gallen, Switzerland

Abstract

Purpose: Revisions of Internal Cardioverter Defibrillator (ICD) leads are associated with increased morbidity and mortality. Data regarding lead performances in different studies depend on lead failure definition. The aim of this study was to assess the lead revision rate of four contemporary ICD leads.

Methods: Data on ICD lead revisions at a single centre was retrospectively assessed between 2004 and 2016. The incidence rate of lead revision of four ICD leads (Medtronic Sprint Quattro [SQ], Medtronic Sprint Fidelis [SF], Biotronik Linox [BL] and Boston Scientific Endotak Reliance [ER]) was compared. The primary endpoint was clinically indicated lead revisions (inacceptable electric parameters, non-physiological oversensing).

Results: Overall, 529 leads in 497 patients were observed (53.1% SQ, 10.8% SF, 14.4% BL and 21.7% ER). Sixteen leads had a primary endpoint during a median (interquartile range) follow-up of 3.5 (1.0, 6.4) years. The cumulative incidence of lead revisions was significantly higher in passive *vs.* active leads (10.2 *vs.* 1.1%, HR: 4.9 [95% CI 2.0, 11.7], p<0.001) and was 0.7%, 10.5%, 0% and 7.0% for SQ, SF, BL and ER (p=0.007) with a significantly higher Hazard Ratio (HR) for SF (HR: 8.9 [95% CI 1.8, 44.5], p=0.008) and ER (HR: 6.3 [95% CI 1.3, 29.8], p=0.021) compared to SQ leads (referent).

Conclusion: A strategy of early, clinically indicated ICD lead revisions might be associated with a higher rate of lead revisions in passive compared to active and in ER compared to SQ ICD leads.

Keywords: ICD leads; ICD lead failure; ICD lead revision; ICD lead performance; Endotak Reliance; ICD lead survival

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Correspondence:
Roman Brenner, Department of Cardiology, Kantonsspital St. Gallen, Rorschacherstrasse 95, CH-9007 St. Gallen, Switzerland, Tel: 0041-71-494-11-11;
E-mail: Roman.brenner@kssg.ch

Received Date: *25 Mar 2021*
Accepted Date: *21 Apr 2021*
Published Date: *26 Apr 2021*

Citation:
Brenner R, Hüppi J, Altmann D, Maeder MT, Rickli H, Ammann P. Clinically Indicated Lead Revision Rates for Four Different Internal Cardioverter-Defibrillator Lead Models. Ann Cardiol Cardiovasc Med. 2021; 5(1): 1043.

Introduction

Cardiac Implantable Electronic Device (CIED) reoperations are associated with significant complication risks, particularly if lead revisions are involved [1]. Of special interest because of the potentially serious consequences are Internal Cardioverter Defibrillator (ICD) leads requiring lead revisions. Several ICD leads have been shown to be associated with a higher risk of lead malfunction such as the Medtronic Sprint Fidelis (SF) and SJM Riata ICD leads with FDA recalls and the Biotronik Linox lead (BL) [2]. In contrast, the Medtronic Sprint Quattro (SQ) and Boston Scientific Endotak Reliance (ER) leads are generally reported to have an excellent lead performance [3]. However, Lead Related Problems (LRP) might differ in various observational studies due to different populations, different definitions of LRP, or different surgical implantation techniques [4-6]. Of note, product performance reports of ICD leads reporting on these LRP rates and published periodically by the device manufacturers are prone to a reporting bias. In addition, monitoring of lead performance relies primarily on industry-based, post-market surveillance and voluntary reporting to the Food and Drug Administration (FDA). Therefore, these reports are prone to overestimating lead survival when compared to a real-world setting [2].

Since CIED lead revisions are associated with a substantial complication risk, reoperations should be done only with good indications. On the other hand, avoidance of inappropriate ICD discharges due to a LRP and ensuring life-saving therapies when necessary are equally important. In this context, decisions to replace a lead before overt lead failure is present must often be taken in clinical practice, and this decision is mostly guided by electrical parameters. In our clinic, we noticed a substantial proportion of lead revisions of ER leads not reported in literature so far. The aim of our study was to systematically assess the frequency of clinically indicated lead revisions in four

contemporary ICD leads.

Methods

Study design, subjects and data collection

Clinical and device data from all patients referred for ICD implantation at the Kantonsspital St. Gallen, Switzerland are prospectively collected. We conducted a retrospective study of all patients undergoing ICD lead implantation between 2004 and 2016. For all patients, we assessed the date of lead placement, date and reason of lead revision, manufacturer, model and characteristics of the implanted lead and the venous access for lead placement (cephalic *vs.* non-cephalic). Patients with SQ (reference group), SF, BL and ER leads were included in the analysis.

ICD lead implantation and lead revisions

All implantations were performed by three experienced electrophysiologists at the Kantonsspital St. Gallen (Switzerland) between 2004 and 2016. ICD leads were implanted via a cephalic vein or via puncture of the axillary or subclavian vein. The device implantation was performed under local anesthesia and conscious sedation if required. ICD leads were positioned in the right ventricular apex. After ICD lead implantation, pacing threshold, R-wave amplitude, and lead impedance were measured in all patients. Defibrillation threshold testing was not performed routinely.

Decisions on which lead to implant was driven by the cardiologist mandated with the follow-up examinations of the patient. If the choice of the company was no issue, the devices were selected randomly with a partition of 60% Medtronic, 25% Boston Scientific and 15% Biotronik.

According to our clinical practice, we did not extract leads with a LRP implanted for more than six months and instead implanted a new lead and abandoned the replaced lead.

Follow up

We reviewed the charts of all patients to determine the interval between ICD lead implantation until and surgical lead revision or last clinical follow-up with device interrogation. All patients were evaluated in the outpatient clinic one month after implantation and then every six months with in-clinic device interrogation or by remote monitoring when informed consent was obtained from the subject. Earlier in-clinic interrogations were performed if clinically indicated e.g. based on abnormalities detected by remote monitoring or alert sounds. Follow-up consisted of interrogation and retrieval of all stored data since the last visit, as well as determination of sensing, impedance measurements, and pacing thresholds.

Outcomes

The primary endpoint was defined as a LRP indicative for surgical lead revision. Similar to previous studies [7,8], LRP was defined on the following criteria:

(1) Inappropriate discharge due to noise sensing

(2) Increase in lead impedance to >1500 Ω

(3) Sudden increase in the high-voltage circuit impedance to >100 Ω or increase to >125 Ω

(4) Occurrence of >300 non-physiological short VV-intervals or high-rate signals within the VT detection window

(5) Linear, but not sudden, decrease in sensing value up to a level that the treating cardiologist considered inappropriate

In patients with LRP, a chest X-ray was performed in order to assess the lead for a structural, radiographically visible defect. This examination was reviewed by two independent examiners.

In addition, we defined a secondary endpoint for LRP (primary endpoint) occurring later than six months after lead implantation. This secondary endpoint was introduced because the healing phase at the lead-myocardium interface was considered completed by this time point with (micro)-dislocations becoming less probable [9,10].

Statistics

Categorical data are reported as numbers and percentages. Continuous data are presented as median (interquartile range). Chi-square test was used to compare categorical data. Mann-Whitney tests and Kruksal-Wallis tests were used to compare continuous variables between two and more groups, respectively. For ANOVA post-hoc test, a Conover post-hoc analysis was calculated. Kaplan-Meier plots were constructed, and groups were compared using log rank tests. Kaplan-Meier survival probabilities were given as percentage (± standard error). Leads replaced for other reasons than the defined endpoints were censored at the time of replacement. A Cox proportional hazard model was used to calculate hazard ratios. Because of the low number of endpoints, a meaningful multivariable analysis was not performed. Medcalc statistical software version 19.1.5 (MedCalc Software bv, Ostend, Belgium) was used for the statistical calculations.

The study complied with the declaration of Helsinki. The research protocol was approved by the local Institutional Review Board. Because of the retrospective nature of the study, an individual informed consent of every patient was not deemed necessary according our ethics committee.

Results

Patient population and ICD leads

Overall, 529 leads in 497 patients were observed. 465 patients had one lead during the observation period and 32 patients' two leads. The median age at first ICD lead implantation was 62.9 (53.6, 70.4) years.

The number of observed leads were 281 (53.1%), 57 (10.8%), 76 (14.4%) and 115 (21.7%) for SQ, SF, BL, and ER, respectively. The median age at lead implantation was 63.6 (55.2, 71.3), 63.3 (54.8, 69.2), 65.3 (56.7, 72.0) and 58.5 (49.0, 67.1) years for SQ, SF, BL and ER respectively ($p<0.01$). Compared to the SQ and BL group, patients in the ER group were significantly younger (ANOVA $p=0.002$).

Lead characteristics and venous access

The lead and venous access characteristics are presented in Table 1. Overall, 31.6% were passive leads. The median age in patients with passive leads was similar to patients with active leads (61.8 [53.9, 69.0] *vs.* 63.3 [53.1, 71.4] years, $p=0.27$). ER was the only lead with integrated bipolar sensing configuration, all other implanted lead models had dedicated bipolar sensing configuration.

Outcomes

After a median follow-up of 3.5 (1.0, 6.4) years, 16 leads (3.0%) reached the primary endpoint (Table 2). The overall lead survival was 96.1 (± 0.01) % at five years and 92.8 (± 0.02) % at ten years. The cumulative incidence of LRP was 0.7%, 10.5%, 0% and 7.0% in SQ, SF, BL and ER leads, respectively (log rank $p=0.007$, Figure 1) with a significantly higher HR for LRP in SF (HR: 8.9 [95% CI 1.8, 44.5],

Table 1: Lead characteristics of all ICD leads grouped according the lead model.

	SQ (n=281)	SF (n=57)	BL (n=76)	ER (n=115)	p-value[1]
Number of defibrillator coils					<0.01
- Single coil, n (%)	50 (17.8)	0 (0)	24 (31.6)	10 (8.7)	
- Dual coil, n (%)	231 (82.2)	57 (100)	52 (68.4)	105 (91.3)	
Fixation mechanism					<0.01
- Active, n (%)	234 (83.3)	9 (15.8)	68 (89.5)	51 (44.3)	
- Passive, n (%)	47 (16.7)	48 (84.2)	8 (10.5)	64 (55.7)	
Venous access					<0.01
- Cephalic vein, n (%)	94 (34.2)	25 (46.3)	56 (76.7)	48 (43.2)	
- Non-cephalic access, n (%)	181 (65.8)	29 (53.7)	17 (23.3)	63 (56.8)	
Connector pin					<0.01
- DF-1, n (%)	211 (75.1)	57 (100)	76 (100)	107 (93.0)	
- DF-4, n (%)	70 (24.9)	0 (0)	0 (0)	8 (7.0)	

BL: Biotronik Linox; ER: Boston Scientific Endotak Reliance; SF: Medtronic Sprint Fidelis; SQ: Medtronic Sprint Quattro; [1]: p-value for differences between the four lead groups

Table 2: Number of leads with respective components of the primary endpoint and grouped according to the lead model. Percentages are given as proportion of leads in the respective lead model group.

N (%)	Sprint Quattro (n=281)	Sprint Fidelis (n=57)	Linox (n=76)	Endotak (n=115)	Total (n=529)
Number of lead revisions	2 (0.7%)	6 (10.5%)	0 (0%)	8 (7.0%)	16
Inappropriate discharge due to noise sensing [1]	0	0	0	1	1
Increase in lead impedance to >1500 Ω	1	2	0	2	5
Increase in the high-voltage circuit [2]	0	1	0	1	2
Non-physiological high-rate signals [3]	0	1	0	2	3
Decrease in sensing value [4]	2	2	0	3	7

HV: High Voltage; [1]: the rows represent the components of the primary endpoint as described in the methods section; [2]: sudden increase in the high-voltage circuit impedance to >100 Ω or increase to >125 Ω; [3]: occurrence of >300 non-physiological short VV-intervals or high-rate signals within the VT detection window; [4]: linear, but not sudden, decrease in sensing value up to a level that the treating cardiologist considered inappropriate

p=0.008) and ER (HR: 6.3 [95% CI 1.3, 29.8], p=0.021) compared to SQ leads (referent). Correspondingly, the five-year survival rates were 98.6% (± 0.01), 89.4% (± 0.05), 100% and 94.2% (± 0.03) for the SQ, SF, BL and ER leads, respectively. The details related to the LRP are given in Table 2. Only three ER leads (2.4%) and one SF leads (1.8%) showed signs of non-physiological oversensing, one patient (with ER lead) experienced an inappropriate ICD shock due to non-physiological oversensing. A structural defect visible on the chest X-ray was not found in any replaced lead. Three leads were explanted and replaced by another ICD lead. None of the explanted leads had a macroscopically visible structural defect. In the 13 other reoperations, the lead was abandoned and a new additional ICD lead was implanted.

The detailed reasons for lead revisions in ER leads are given in Table 3. All eight ER leads with a LRP were dual coil leads, six had a passive fixation mechanism and five were implanted *via* a non-cephalic vein. In seven patients, the lead was abandoned and a new ICD lead was implanted.

The cumulative incidence of the primary endpoint was similar for leads with DF-1 and DF-4 connector pins (4.7 *vs.* 0%, log rank p=0.20), and no significant difference was seen between single coil *vs.* dual coil leads (cumulative incidence of lead revision: 1.2 *vs.* 4.5%, log rank p=0.51). Age was not a significant predictor of lead revision (HR 0.98 [95% CI 0.95, 1.01], p=0.14 per increased year of age). In addition, no significant difference was observed between leads

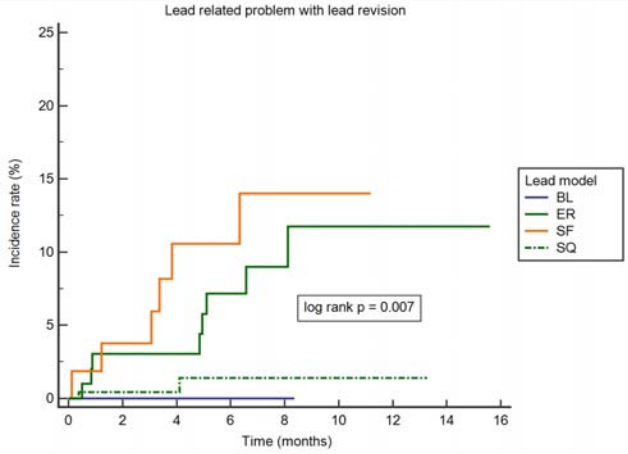

Figure 1: Kaplan-Meier curve of the primary endpoint in four different ICD leads.

implanted *via* vena cephalic compared to a non-cephalic access (4.3 *vs.* 3.0%, log rank p=0.54). However, the cumulative incidence of lead revisions was significantly higher in passive *vs.* active leads (10.2 *vs.* 1.1%, HR: 4.9 [95% CI 2.0, 11.7], log rank p<0.001). Only four lead revisions were performed in leads with active fixation mechanism, two (0.7%) in SQ and two (1.7%) in ER leads.

The cumulative incidence of lead revisions later than six months

Table 3: Characteristics of replaced Endotak Reliance leads.

Case No	Patient age at implantation (years)	Sex	Number of coils	Fixation mechanism	Venous access	Lead age (years)	Type of failure	Electrical abnormalities	Clinical presentation	Management
1	56.8	M	Dual	passive	Cephalic	5	Non-physiological high rate signals	Increasing pacing impedance Increasing pacing threshold	Device alert	Abandonment of lead, implantation of new ICD lead
2	42.2	M	Dual	Active	Cephalic	8.1	Electrical abnormalities	Increasing HV impedance	Device alert	Abandonment of lead, implantation of new ICD lead
3	51	M	Dual	Passive	Non-cephalic	4.9	Electrical abnormalities	Increasing pacing impedance Increasing pacing threshold	Routine ICD control	Abandonment of lead, implantation of new ICD lead
4	54.1	M	Dual	Passive	Non-cephalic	6.6	Non-physiological high rate signals	Increasing pacing impedance, but <1500 Ohms	Routine ICD control	Abandonment of lead, implantation of new ICD lead
5	65.9	M	Dual	Passive	Non-cephalic	5.1	Electrical abnormalities	Decreasing of R-wave with gradual increase of pacing impedance (but <1500 Ohms)	Routine ICD control	Abandonment of lead, implantation of new ICD lead
6	57.7	M	Dual	Passive	Non-cephalic	0.8	Non-physiological high rate signals	Decreasing R-wave (4 mV) Increasing pacing impedance, but <1500 Ohms	inappropriate shock	Abandonment of lead, implantation of new ICD lead
7	73.4	F	Dual	Active	Cephalic	0.5	Electrical abnormalities	Decreasing R-wave Decreasing of pacing impedance	Routine ICD control	Lead explantation, implantation of new ICD lead
8	52.8	M	Dual	Passive	Non-cephalic	0.9	Electrical abnormalities	Decreasing R wave	Routine ICD control	Abandonment of lead, implantation of new ICD lead

F: Female; HV: High Voltage; M: Male; ms: milliseconds; mV: millivolt; V: Volt

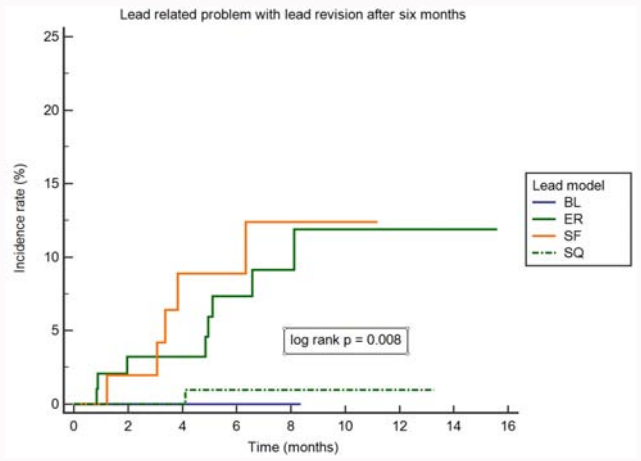

Figure 2: Kaplan-Meier curve of the secondary endpoint in four different ICD leads.

after implantation (secondary endpoint) was 0.4%, 8.8%, 0% and 7.0% in SQ, SF, BL and ER leads, respectively (log rank p=0.008; Figure 2). SF (HR: 13.7 (95% CI 1.6, 118.3, p=0.017) and ER (HR: 11.8 [95% CI 1.5, 94.9], p=0.021) were significantly more frequently associated with the second secondary endpoint than the SQ lead model. In addition, leads with passive fixation had a significantly higher risk for the secondary endpoint than active leads (log rank p<0.001). There was no significant difference between different venous accesses (log rank p=0.74) or age (HR per year of age 1.0 [95% CI 0.9, 1.0]).

Discussion

In our study, we found significant differences in LRP between the four ICD lead models routinely implanted in our hospital over a period of more than a decade. Most interestingly, we found a significantly higher rate of lead revisions in ER leads compared to SQ leads. The observed five-year survival of the ER lead in our study was 94.2%, which is significantly lower than reported in the product performance report (98.4% to 99.1%) [11] and other registries [8], in which the lead performance of the ER lead was comparable to the SQ lead [3]. Our observed lead performance rate was similar between ER and SF leads and was inferior than in BL leads.

Different definitions of lead failure make the comparisons between the different studies comparing lead survival rates difficult but are a central point in the evaluation of lead performance. Malderen et al. [8] reported in a Dutch ICD registry a five year failure rate of 0.4% for the ER lead. The authors of this study applied a strict definition of lead failure of structural lead failure, relevant non-physiological oversensing or electrical parameters out of a measurable range [8]. In this study, only five lead failures in 343 ER leads were observed, one due to failure to capture and four due to non-physiological signal sensing. In the study by Liu et al. the authors adopted a more liberal definition of lead failure [12]. However, only 1% of the ER leads (n=26) were replaced due to electrical failure during a median follow-up time of 3.7 years with a lead survival of 98.5% at eight years [12]. Half of the failed ER leads showed sensing problems including noise sensing, six had a high threshold and four had perforation/dislodgement.

Strict definitions of lead failure are more specific for technical lead problems such as conductor fracture or insulation breach. Leads known to be prone to these failure mechanisms are the SF and SJM Riata leads (recalled leads by the FDA). The most frequent observation of lead failure in these leads is oversensing of non-physiologic signals, which was reported in 78% of failed Riata and 89% of failed SF leads [13]. In addition, Lam et al. observed inappropriate shocks in 64%

(BL), 5% (Riata), and 32% (SF) and non-physiological high rate signals in 73% (BL), 27% (Riata), and 80% (SF) of lead failures [2]. In contrast, we observed only four leads (25% of the revised leads) with non-physiologic signal oversensing. Nevertheless, we adopted similar lead failure criteria than other studies [7,8] and found similar lead 5-year failure rates in passive SF leads compared to these studies [7].

The reasons for our findings are speculative, because we did not extract the ICD leads and the chest X-ray did not reveal any abnormalities in the replaced leads. Recently, concerns about calcifications in ER leads appeared in the scientific literature [14]. Hauser et al. [14] reported calcifications in 109 ER leads compared to only one SQ and three Durata & Riata leads. The calcifications were found on the high voltage coil (especially in Gore ePTFE covered shocking coils) and/or the distal pacing electrode. The hallmark of these changes was a gradual increase of the pacing or high voltage impedance. A significant proportion of patients had also an increase in pacing threshold. Interestingly, the calcification of the pacing electrode manifested significantly earlier (after a median time of about five years after implantation) than that of the high voltage coil (about seven years after implantation). In the light of these novel findings, we can speculate that our data are related to possible lead calcifications, although this was not proven by extracting the leads in our study.

Although speculative, the integrated bipolar lead design, which was only present in ER leads in our study, might have played a role for the increased lead revision rate in ER compared to the SQ leads, because integrated bipolar leads might be more prone to sensing abnormalities [15]. Other studies, in contrast, report similar pacing and sensing behavior of integrated and dedicated bipolar ICD leads, although these studies refer mostly to measurements at implantation [16,17]. In line with this hypothesis, Hauser et al. postulated that the integrated bipolar design of ER leads is associated with the observed calcifications at the pacing electrode [14].

Because conductor fracture or insulation defects are typically heralded by non-physiological signal oversensing and/or abrupt pacing impedance abnormalities, our endpoints could possibly include issues at the electrode-tissue interface such as lead maturation, lead calcification or even microdislocation. A passive lead fixation was associated with a higher incidence of the primary and secondary in our study, which theoretically could be associated with more microdislocations compared to active leads which are screwed in the myocardium, although this hypothesis is not supported by enough evidence and by the fact that we observed a persistently higher risk for lead revisions in ER compared to SQ leads even beyond six months after lead implantation (secondary endpoint) when dislocations are rare [9] and the healing phase of myocardium after lead implantation should be completed. Furthermore, in a big Danish pacing registry, active fixation leads had a similar complication rate compared to passive fixation leads within the first three months after implantation [18]. Nevertheless, in clinical practice, passive ICD leads are implanted infrequently nowadays.

Interestingly, the BL lead performance in our series was excellent with no LRP in 76 leads. Similarly good survival rates were found in the product performance report of the BL lead (>97%) [19] and the manufacturer-sponsored CELESTAL and GALAXY trials (five year survival of the BL lead 96.3%, four year survival of the BL Smart lead of 96.6%) [20]. However, there are several studies reporting a far lower five-year survival [8,21]. A study from Switzerland reported a BL five year survival rate of 88% [21], although the authors invited patients with BL leads for a radiologic follow-up examination in addition to the routine ICD control. These inferior performance rates of BL leads are not reported consistently, and lead survival rates similar to that observed in our study were reported in other series [20]. However, the relatively low number of BL leads implanted in our study might be associated with a wide confidence interval.

Limitations

The relatively low number of patients/ICD leads included in this single centre study and the low number of endpoints is clearly a limitation. For this reason, a meaningful multivariable analysis was not possible.

Conclusion

In conclusion, a strategy of early, clinically indicated ICD lead revisions might be associated with a higher rate of lead revisions in passive compared to active and in ER compared to SQ ICD leads.

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