



Rate and predictors of electrical failure in non-recalled defibrillator leads

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ABSTRACT

Background: Implantable cardioverter defibrillator (ICD) leads are considered as the 'weakest link' in defibrillator systems due to FDA recalls and advisories involving popular lead models from major manufacturers. The rate of electrical failure of ICD leads not implicated in a recall is however not well determined.

Methods: Medical records of patients implanted with ICDs at hospitals of the University of Pittsburgh Medical Center between 2002 and 2014 were analyzed. Leads were classified as having electrically failed if removed or replaced for reasons other than infection or heart transplantation. Patients were followed to endpoint of death or electrical lead failure.

Results: 2410 consecutive ICD recipients (mean age 66 ± 13 years, women 22%, single/dual/biventricular-ICD 20%/44%/36%) were included. During a mean follow-up of 3.9 ± 3.3 years, 1272 patients (53%) died, 55 patients (2.3%) had ICD lead electrical failure, and 1052 (44%) patients were alive with functional leads at the time of last follow-up. Patients with failed leads had higher BMI ($p = 0.07$), better functional status ($p = 0.04$), higher serum creatinine ($p = 0.004$), wider QRS complex ($p = 0.01$), higher number of implanted leads ($p = 0.06$) and were more likely to have ischemic cardiomyopathy ($p = 0.03$). After adjusting for these variables in a binary logistic regression model, only a lower BMI, presence of non-ischemic cardiomyopathy, and a better functional status remained independently predictive of electrical failure.

Conclusions: Only 2.3% of non-recalled ICD leads experience electrical failure (annual failure rate of 0.6%). A higher patient functional status, lower BMI, and non-ischemic etiology of cardiomyopathy are independently associated with higher rates of ICD lead failure.

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1. Introduction

Implantable cardioverter defibrillator (ICD) devices are indicated for primary and secondary prevention of sudden cardiac death [1]. ICD leads are considered the 'weakest link' in defibrillator systems [2] because of their high rates of failure and recall, such as with the previously popular Sprint Fidelis (Medtronic, Minneapolis, MN) and Riata (St. Jude Medical, Sylmar CA) ICD leads, recalled in 2007 and 2011, respectively [3]. These recalled ICD leads are prone to electrical failure by conductor fractures and/or insulation breaches [4]. Their annual rates of lead failure are 2.8% and 1.8%,

respectively which has led to their FDA recall [5].

It remains unclear, however, what the rate of ICD lead failure is after excluding recalled leads. Our study was therefore designed to investigate the rate of electrical failure of non-recalled defibrillator leads and analyze the clinical predictors of their electrical failure.

2. Methods

This study was approved by the Institutional Review Board at the University of Pittsburgh. All patients who underwent ICD implantation with non-recalled ICD leads at the University of Pittsburgh Medical Center between 2002 and 2014 were included in the study. Demographic and clinical characteristics were collected on all patients using the electronic medical record. Patients were followed in the outpatient device clinic with no less than 1 clinic visit and 3 remote checks per year, or 2 clinic visits per year in patients

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with no remote home monitoring. As the cohort spans the years 2002–2014, the overwhelming majority of patients in our cohort were not on home monitoring but rather followed in device clinic and electrical failure signals were noted either during scheduled clinic visits, or visits triggered by device auditory alarms.

As previously described [5–7], leads were classified in follow-up as (1) functional lead, patient deceased (from any cause); (2) functional lead replaced for any reason other than electrical lead failure (e.g., infection, heart transplantation); (3) electrically failed lead, replaced; or (4) functional lead, active. Lead failure was defined as electrical malfunction resulting in lead extraction or replacement with a new ICD lead. Criteria for lead failure were similar to previously defined standards [5,6,8]. Patients were followed to the endpoint of death (last date of record checking was August 2015), or electrical lead failure.

2.1. Statistical analysis

Continuous variables are presented as mean \pm SD. Categorical variables are presented as absolute numbers or percentages. Univariate predictors of electrical lead failure were assessed using the student *t*-test and chi square test, as appropriate. All variables with *p* value $<$ 0.10 on univariate analysis were included in a multivariate binary logistic regression model to assess the independent predictors of electrical failure. A *p* value $<$ 0.05 was considered statistically significant. All statistical analyses were performed on SPSS, version 24.0 (IBM Inc., Armonk, New York).

3. Results

During the study period, 2410 consecutive recipients of non-recalled ICD leads were identified (mean age 66 ± 13 years, women 22%, single/dual/biventricular-ICD 20%/44%/36%, Single-coil 9%) and followed for a mean duration of 3.9 ± 3.3 years. The baseline characteristics of the overall cohort stratified by the absence or presence of ICD electrical lead failure is shown in Table 1.

Table 1
Baseline characteristics of patients with and without electrical ICD lead failure.

	Overall Cohort (N = 2410)	No Electrical Failure (N = 2355)	Electrical Failure (N = 55)	P- value
Age at implantation	66.18 \pm 12.9	66.2 \pm 12.9	65.4 \pm 13.5	0.51
Women	22%	21%	29%	0.18
BMI	29.42 \pm 6.3	29.4 \pm 6.3	30.5 \pm 7.6	0.07
Smoker	14%	14%	11%	0.49
Hypertension	58%	58%	54%	0.23
Diabetes	33%	33%	35%	0.84
Chronic Kidney Disease	18%	18%	26%	0.17
Chronic obstructive pulmonary disease	13%	13%	18%	0.29
Atrial Fibrillation	29%	29%	27%	0.74
Cerebrovascular event	11%	11%	7%	0.39
Peripheral Vascular Disease	8%	8%	2%	0.80
Total CHA ₂ DS ₂ -VASc Score	2.46 \pm 1.1	2.46 \pm 1.1	2.28 \pm 0.9	0.25
NYHA Functional class	2.33 \pm 0.9	2.33 \pm 0.94	2.07 \pm 0.79	0.042
Hemoglobin	12.94 \pm 1.9	12.94 \pm 1.9	13.0 \pm 1.5	0.67
Creatinine	1.33 \pm 0.9	1.32 \pm 0.9	1.39 \pm 2.1	0.004
QRS duration	131.11 \pm 34	130.8 \pm 34.1	142.2 \pm 35.3	0.01
LVEF	28.05 \pm 11.5	28.0 \pm 11.5	27.7 \pm 11.5	0.84
LA diameter	45.82 \pm 8.0	45.8 \pm 7.9	46.0 \pm 9.9	0.89
LV septal thickness	11.80 \pm 3.0	11.7 \pm 3.1	12.7 \pm 2.5	0.12
Number of leads	2.16 \pm 0.7	2.15 \pm 0.7	2.34 \pm 0.7	0.06
Ischemic cardiomyopathy	68%	32%	46%	0.03
Left shoulder device	95%	95%	93%	0.54
Lead Models				0.27
Boston Scientific 0158	62%	62%	65%	
Boston Scientific 0185	19%	18%	27%	
Medtronic 6947	10%	10%	4%	
Medtronic 6935	9%	10%	4%	

BMI = body mass index; LA = left atrium; LV = left ventricle; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

During follow-up, 1272 patients (53%) died, 84 patients (3.5%) had ICD system explanted, for infection (*n* = 45) or for heart transplantation (*n* = 39), 55 patients (2.3%) had electrical failure of ICD lead, and 1052 (44%) patients were still alive with functional leads at the time of last follow-up. Of the 55 patients with electrical ICD lead failure, 19 (35%) were confirmed to be pacemaker-dependent. The overall lead survival rate free from electrical failure was 97.5%, which translates into an annual electrical failure rate of approximately 0.6%.

Univariate predictors of electrical lead failure included higher BMI (*p* = 0.07), better patient functional status (*p* = 0.04), higher creatinine (*p* = 0.004), a wider QRS complex (*p* = 0.01), higher number of implanted leads (*p* = 0.06) and presence of ischemic cardiomyopathy (*p* = 0.03). After including all these variables into a binary logistic regression multivariate model, only lower BMI, the presence of non-ischemic cardiomyopathy, and a better functional status remained independently predictive of electrical failure in non-recalled ICD leads (Table 2).

4. Discussion

ICD lead failure requires prompt diagnosis due to serious consequences associated with delayed recognition. Lead failure may initially be clinically silent, and early detection before clinical

Table 2
Multivariate analysis for predictors of electrical ICD lead failure.

	Hazard Ratio (95% CI)	P- value
BMI	0.94 (0.89–0.99)	0.012
NYHA Functional class	0.46 (0.27–0.75)	0.004
Creatinine	0.80 (0.38–1.65)	0.54
QRS duration	1.00 (0.99–1.01)	0.97
Number of leads	1.10 (0.60–2.02)	0.75
Ischemic cardiomyopathy	0.43 (0.20–0.93)	0.031

BMI = body mass index; NYHA = New York Heart Association.
Bold is used for statistical significance (*p* $<$ 0.05).

presentation with inappropriate shocks or sudden death is thus important. This study represents a single-center experience providing follow-up data on 2410 non-recalled ICD leads. The main findings of our study are: (i) Electrical lead failure rate among non-recalled defibrillator leads is approximately 0.6% per year during an average follow-up period of 3.9 years, which argues against the ICD lead being the “weakest link” when recalls and advisories are excluded. (ii) In multivariate models, better functional status, non-ischemic etiology of cardiomyopathy and lower BMI are independent predictors of electrical failure.

There is a significant amount of reporting bias in determining the incidence of lead failure, particularly that most failed leads are not extracted or returned to the manufacturer for analysis. The true incidence of failed leads is therefore likely higher than estimates from industry-maintained product performance reports. Monitoring of lead performance relies primarily on industry-based, post-market surveillance and voluntary reporting to the Food and Drug Administration. The Sprint Fidelis (Medtronic, Minneapolis, Minnesota) and Riata family of leads (St. Jude Medical, St. Paul, Minnesota) are small caliber defibrillator lead that were implanted in approximately 150,000 and 79,000 patients in the United States respectively, at the time of their recall, which was in 2007 for the Fidelis and 2011 for the Riata. The estimated annual incidence of conductor fracture for the Fidelis lead was between 2.6% and 4.8% [9–11] whereas the insulation failure and conductor externalization of the Riata lead occurred in 1% to 2.8% of leads per year [10–13]. Our study shows that the rate of electrical lead failure among non-recalled defibrillator leads is approximately 0.6% per year during an average follow-up period of 3.9 years which is substantially lower than the failure rates of recalled leads discussed above.

Previous studies observed that leads in younger more active patients with less impairment of left ventricular function are more prone to failure [9,14,15]. Younger patients exhibit a higher level of physical activity which can result in higher incidence of movement and wear and tear affecting the leads. Less impairment of LVEF could also lead to ICD lead failure by similar mechanisms [15]. In our study, better NYHA functional class was associated with increased risk of lead failure likely related to greater physical activity.

On the contrary, Demirel et al. [16] reported that non-ischemic cardiomyopathy and impaired LVEF are also independent predictors of structural lead failure in cross-sectional analysis. The finding in our study is consistent with this observation. The association between non-ischemic cardiomyopathy and lead failure is likely a manifestation of survival bias. Patients with ischemic cardiomyopathy have a worse prognosis compared to non-ischemic cardiomyopathy [17] and therefore these patients may have shorter duration of follow-up. As the chances of lead failure increase with the dwell-time of the lead, the lower incidence of lead failure among patients with ischemic cardiomyopathy may be partially explained by the higher mortality rate in this group of ICD recipients.

Contemporary literature search does not yield any reported association between lower BMI and higher rates of electrical failure of ICD leads. Although not proven, we speculate that leads in patients with a lower BMI may be more crowded both intravascularly and in the device pocket, due to the smaller space. This may lead to higher radii of curvature of leads which could possibly result in mechanical failure and subsequent electrical failure. Paradoxically, the BMI was borderline higher in patients with lead failure, but in multivariate analysis, higher BMI was protective against electrical failure. This can potentially be explained by the fact that BMI may have partially tracked with functional status whereby higher BMI is likely associated with lower functional status, which was protective

against lead failure.

Although several risk factors are associated with lead failure, predicting its occurrence is difficult in the clinical setting. In light of our findings, a subset of population may benefit from increased surveillance before clinical manifestations of lead failure occur, which is now possible through home monitoring systems, without the inconvenience of frequent clinic visits to the patient. As the use of totally subcutaneous ICDs without intravenous leads continues to expand, driven by data supporting their efficacy and safety, these devices may provide a solution for patients at high risk of ICD lead failure [18,19].

Our study has limitations. First, it is a single-center, retrospective analysis, and as such may be subject to bias and its results may not be readily applicable to patients in other settings. However, this study included all consecutive patients with leads implanted by multiple operators at a high-volume center thus minimizing referral and selection bias. In addition, our follow-up was limited to a mean of about 4 years. Over this relatively short period of time, few patients experienced lead failure. It is possible, albeit not proven, that with longer follow-up, a higher percentage of leads would exhibit electrical failure which is a time-dependent complication. Still, most of the recalled leads (Fidelis and Riata) had demonstrated significantly higher failure rates at follow-up durations comparable to ours [5].

In conclusion, we demonstrate that the rate of electrical failure of non-recalled ICD leads is significantly lower than that of recalled leads. Independent predictors of electrical failure of ICD leads include a higher patient functional status, lower BMI and a non-ischemic etiology of cardiomyopathy. Our results have direct implications to the counselling of ICD recipients and potentially to the recommended intensity of their device follow-up.

Author contributions

Furqan Khattak, MD – Concept/Design, Data collection, Data interpretation, Drafting tables, Critical revision.

Aman Gupta, MD – Drafting article, Critical revision.

Krishna Alluri, MD – Data collection, Data analysis.

Nasir Shariff, MD – Data collection and analysis.

Samir Saba, MD – Concept/design, Statistics, Critical review and approval.

Declarations of interests

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References

- [1] Epstein AE, DiMarco JP, Ellenbogen KA, Estes NAM, Freedman RA, Gettes LS, et al. ACC/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American college of cardiology/American heart association task force on practice guidelines (writing committee to revise the ACC/AHA/NASPE 2002 guideline. *Circulation* 2008;117:e350–408. <https://doi.org/10.1161/CIRCULATIONAHA.108.189742>.
- [2] Maisel WH. Transvenous implantable cardioverter-defibrillator leads: the weakest link. *Circulation* 2007;115:2461–3. <https://doi.org/10.1161/CIRCULATIONAHA.107.698597>.
- [3] Birnie DH, Parkash R, Exner DV, Essebag V, Healey JS, Verma A, et al. Clinical predictors of Fidelis lead failure: report from the Canadian heart rhythm society device committee. *Circulation* 2012;125:1217–25. <https://doi.org/10.1161/CIRCULATIONAHA.111.053744>.
- [4] Swerdlow CD, Kalahasty G, Ellenbogen KA. Implantable cardiac defibrillator lead failure and management. *J Am Coll Cardiol* 2016;67:1358–68. <https://doi.org/10.1016/j.jacc.2016.05.044>.

- doi.org/10.1016/j.jacc.2015.12.067.
- [5] Liu J, Brumberg G, Rattan R, Jain S, Saba S. Class I recall of defibrillator leads: a comparison of the Sprint Fidelis and Riata families. *Heart Rhythm* 2012;9:1251–5. <https://doi.org/10.1016/j.hrthm.2012.04.003>.
- [6] Liu J, Brumberg G, Rattan R, Patel D, Adelstein E, Jain S, et al. Longitudinal follow-up of implantable cardioverter defibrillator leads. *Am J Cardiol* 2014;113:103–6. <https://doi.org/10.1016/j.amjcard.2013.08.046>.
- [7] Shariff N, Alluri K, Saba S. Failure rates of single- versus dual-coil nonrecalled sprint quattro defibrillator leads. *Am J Cardiol* 2015;115:202–5. <https://doi.org/10.1016/j.amjcard.2014.10.025>.
- [8] Liu J, Patel D, Rattan R, Brumberg G, Saini A, Vaghassia N, et al. Failure-free survival of the Durata defibrillator lead. *Europace* 2013;15:1002–6. <https://doi.org/10.1093/europace/eut010>.
- [9] Hauser RG, Maisel WH, Friedman PA, Kallinen LM, Mugglin AS, Kumar K, et al. Longevity of Sprint Fidelis implantable cardioverter-defibrillator leads and risk factors for failure: implications for patient management. *Circulation* 2011;123:358–63. <https://doi.org/10.1161/CIRCULATIONAHA.110.975219>.
- [10] Fazal IA, Shepherd EJ, Tynan M, Plummer CJ, McComb JM. Comparison of Sprint Fidelis and Riata defibrillator lead failure rates. *Int J Cardiol* 2013;168:848–52. <https://doi.org/10.1016/j.ijcard.2012.10.015>.
- [11] Rordorf R, Poggio L, Savastano S, Vicentini A, Petracci B, Chieffo E, et al. Failure of implantable cardioverter-defibrillator leads: a matter of lead size? *Heart Rhythm* 2013;10:184–90. <https://doi.org/10.1016/j.hrthm.2012.10.017>.
- [12] Parkash R, Exner D, Champagne J, Mangat I, Thibault B, Healey JS, et al. Failure rate of the Riata lead under advisory: a report from the CHRS Device Committee. *Heart Rhythm* 2013;10:692–5. <https://doi.org/10.1016/j.hrthm.2013.01.018>.
- [13] Abdelhadi RH, Saba SF, Ellis CR, Mason PK, Kramer DB, Friedman PA, et al. Independent multicenter study of Riata and Riata ST implantable cardioverter-defibrillator leads. *Heart Rhythm* 2013;10:361–5. <https://doi.org/10.1016/j.hrthm.2012.10.045>.
- [14] Morrison T Ben, Rea RF, Hodge DO, Crusan D, Koestler C, Asirvatham SJ, et al. Risk factors for implantable defibrillator lead fracture in a recalled and a nonrecalled lead. *J Cardiovasc Electrophysiol* 2010;21:671–7. <https://doi.org/10.1111/j.1540-8167.2009.01683.x>.
- [15] Farwell D, Green MS, Lemery R, Gollob MH, Birnie DH. Accelerating risk of Fidelis lead fracture. *Heart Rhythm* 2008;5:1375–9. <https://doi.org/10.1016/j.hrthm.2008.06.024>.
- [16] Demirel F, Adiyaman A, Delnoy PPHM, Smit JJJ, Ramdat Misier AR, Elvan A. Mechanical and electrical dysfunction of Riata implantable cardioverter-defibrillator leads. *Europace* 2014;16:1787–94. <https://doi.org/10.1093/europace/euu079>.
- [17] Kolodziejczak M, Andreotti F, Kowalewski M, Buffon A, Ciccone MM, Parati G, et al. Implantable cardioverter-defibrillators for primary prevention in patients with ischemic or nonischemic cardiomyopathy. *Ann Intern Med* 2017;167:103. <https://doi.org/10.7326/M17-0120>.
- [18] Rutzen-Lopez H, Silva J, Helm RH. Leadless cardiac devices-pacemakers and implantable cardioverter-defibrillators. *Curr Treat Options Cardiovasc Med* 2016;18:49. <https://doi.org/10.1007/s11936-016-0472-8>.
- [19] Olde Nordkamp LRA, Dabiri Abkenari L, Boersma LVA, Maass AH, de Groot JR, van Oostrom AJHHM, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. *J Am Coll Cardiol* 2012;60. <https://doi.org/10.1016/j.jacc.2012.06.053>. 1933–9.