ORIGINAL RESEARCH

Transvenous Implantable Cardioverter-Defibrillator Lead Reliability: Implications for Postmarket Surveillance

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***Background*—**As implantable cardioverter-defibrillator technology evolves, clinicians and patients need reliable performance data on current transvenous implantable cardioverter-defibrillator systems. In addition, real-world reliability data could inform postmarket surveillance strategies directed by regulators and manufacturers.

***Methods and Results*—**We evaluated Medtronic Sprint Quattro, Boston Scientific Endotak, and St Jude Medical Durata and Riata ST Optim leads implanted by participating center physicians between January 1, 2006 and September 1, 2012. Our analytic sample of 2653 patients (median age 65, male 73%) included 445 St Jude, 1819 Medtronic, and 389 Boston Scientific leads. After a median of 3.2 years, lead failure was 0.28% per year (95% CI, 0.19 to 0.43), with no statistically significant difference among manufacturers. Simulations based on these results suggest that detecting performance differences among generally safe leads would require nearly 10 000 patients or very long follow-up.

***Conclusions*—**Currently marketed implantable cardioverter-defibrillator leads rarely fail, which may be reassuring to clinicians advising patients about risks and benefits of transvenous implantable cardioverter-defibrillator systems. Regulators should consider the sample size implications when designing comparative effectiveness studies and evaluating new technology for preventing sudden cardiac death. **(*J Am Heart Assoc*. 2015;4:e001672 doi: 10.1161/JAHA.114.001672)**

Key Words: ICD leads • implantable cardioverter-defibrillators • postmarket surveillance

Implantable cardioverter-defibrillator (ICD) lead performance continues to capture the attention of clinicians, patients, and public health advocates. In recent years, analysis and debate have focused on recalled models, whose prior widespread use continues to pose vexing management questions and cast a shadow over ICD technology.[1,2] New connector systems and insulation materials and completely new designs such as subcutaneous ICD systems further heighten attention on the performance of transvenous ICD systems.[3,4]

Questions around lead performance parallel efforts in the European Union and United States to improve postmarket surveillance for medical devices, particularly life-sustaining technology such as ICDs.[5,6] For example, the unique device identifier system promises to integrate device data with medical records and streamline adverse event analysis, which is particularly useful for monitoring ICDs.[7] However, several technical and policy hurdles plague unique device identifier implantation,[8] not least creation of a global unique device identifier website and integration across electronic medical records, insurance claims, and device registries. Thus large, well-powered studies for ICD lead performance will remain an elusive public health goal.

The need for reliable tracking of ICD lead performance gains further momentum as investigators and regulators have focused additional scrutiny on ICD leads with Optim™ insulation. The United States Food and Drug Administration approved Optim™ for the St Jude Medical Riata ST Optim™ leads in 2006 and then Durata leads in 2007.[9] Both were approved as "supplements" to a premarket approval application originally approved in 1996.[9] Despite favorable early data,[10,11] subsequent reports suggest that late insulation abrasions cause Riata ST Optim™ and Durata ICD leads to fail.[12–14] Fatal lead failures not attributed to device malfunction pose a particular challenge when comparing marketed leads.[15,16] Thus, our primary aim was to compare longevity of

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Riata ST Optim™ and Durata leads with established models from Medtronic (Sprint Quattro Secure™) and Boston Scientific (Endotak Endurance/Reliance™). Our secondary aim was to use these data to inform power simulations of postmarket ICD lead surveillance studies.

Methods

Study Design

We identified patients 18 years and older implanted with Riata ST Optim™, Durata, Quattro, and Reliance leads between January 1, 2006 and September 1, 2012 at each study center and followed there. Local data managers and clinicians reviewed medical records for lead failures and patient vital status through February 1, 2014. Data were submitted electronically to the coordinating center at the Minneapolis Heart Institute Foundation. Institutional Review Boards at all participating centers approved this study.

Variables

Study staff at each center abstracted data on device implantation and follow-up for patients implanted there. Lead failures were centrally adjudicated according to prespecified definitions (see Definitions section below). Demographic variables at implant included date of birth, gender, and race/ethnicity (white, African American, Hispanic, Asian, or other/unknown). Cardiac disease features included coronary artery disease, idiopathic/dilated cardiomyopathy, hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, long QT syndrome, and other/unknown. We characterized indication for the ICD as primary or secondary prevention according to history of ventricular fibrillation or sustained ventricular tachycardia, with or without cardiac arrest. We also recorded atrial fibrillation and type (paroxysmal or persistent).

We noted lead manufacturer, model name, and number, and characterized additional pacing leads, as well as subsequent (postimplant) lead revisions and whether the patient received shocks or antitachycardia pacing. Each center reviewed medical records to determine whether device therapies were appropriate. Vital status was determined by record review at each center.

Definitions

We considered a lead implanted after the clinician tested it, connected it to the ICD pulse generator, and closed the incision. Co-investigators at each clinical center reviewed lead failures, and coordinating center investigators adjudicated. Our failure definition included (1) abnormal impedance (eg, impedance outside the labeled normal range for that model); (2) electrical noise manifest as nonphysiologic signals on the electrogram or as pulse generator diagnostic data suggesting rapid oversensing (eg, nonphysiologic short intervals and/or recurrent nonsustained ventricular tachycardia with intervals usually <220 ms); (3) increase in pacing threshold or decline in R-wave amplitude necessitating lead replacement; (4) inability to provide effective therapy due to a lead defect; (5) externalized conductor that breached the outer insulation and appeared outside the lead body on fluoroscopy or radiography; and (6) lead dislodgment, except simple dislodgments without an identified fixation mechanism defect. We did not consider functional abnormalities, including exit block and physiologic oversensing in an electrically intact lead, as failures.

Statistical Analysis

We compared the 3 manufacturers' lead failure times using Kaplan–Meier curves and log-rank (Mantel–Haenszel) tests. In secondary analyses, we adjusted for clinical center, which was the best predictor of lead type. We examined clinical variables for evidence of confounding, but found no clinical or procedural factors that substantially changed our survival model effect estimates. We also studied the sensitivity of our conclusions to treating death as a semicompeting event with lead failure. Finally, we simulated failure, censoring, and death times designed to match our observed data and computed the sample size necessary to detect differences among manufacturers' failure rates in hypothetical postmarket studies.

Results

Baseline Characteristics

Four clinical centers enrolled 2653 eligible patients; Table 1 displays their demographic, clinical, and device-related characteristics. The cohort's median age was 65 (25% to 75% interquartile range, 55 to 74) and patients were predominantly male (73%) and white (88%). Nearly half (49%) had coronary artery disease, and a quarter (27%) had idiopathic/dilated cardiomyopathy. Most patients (80%) received ICDs for primary prevention. Implanted leads included 445 from St Jude, 1819 from Medtronic, and 389 from Boston Scientific (Table 2).

Patient and ICD Lead Survival

Table 3 describes the total person-years of follow-up for each manufacturer's leads. Lead failures were rare, with only 2 failures in St Jude leads, 17 in Medtronic, and 6 in Boston Scientific (Table 3 and Figure 1), for an overall failure rate of

Table 1. Demographic and Clinical Characteristics of the Study Population

Characteristics	N (%)
Study site	
Beth Israel Deaconess Medical Center	290 (11)
Minneapolis Heart Institute Foundation	1332 (50)
Summa Cardiovascular Institute	575 (21)
Vanderbilt Heart and Vascular Institute	456 (17)
Demographics	
Age at implant, median (IQR)	65 (55 to 74)
Male	1943 (73)
Race	
White	2345 (88)
African American	154 (6)
Hispanic	17 (<1)
Asian	16 (<1)
Other/unknown	118 (4)
Alive at last follow-up	2462 (93)
Cardiac history	
Ischemic cardiomyopathy	1304 (49)
Dilated cardiomyopathy	707 (27)
Hypertrophic cardiomyopathy	136 (5)
Channelopathy	46 (2)
Arrhythmogenic right ventricular dysplasia (ARVD)	44 (2)
Long QT	1 (<1)
Other/unknown/mixed	415 (16)
Indication	
Primary prevention	2117 (80)
Secondary prevention	440 (17)
VT/VF with arrest	52 (2)
VT/VF without arrest	31 (1)
Atrial fibrillation	
Yes (unspecified)	446 (17)
Yes (persistent)	127 (5)
Yes (paroxysmal)	198 (7)
No	1853 (70)
Unknown	29 (1)
LVEF	
<20	286 (11)
20 to 34	1131 (42)
35 to 49	550 (21)
≥50	507 (19)
Unknown	179 (7)

LVEF indicates left ventricular ejection fraction; VT/VF, ventricular tachycardia/fibrillation.

Table 2. Characteristics of Implantable Cardioverter-Defibrillator Leads

Characteristic	N (%)
Lead manufacturer	
Boston Scientific (Endotak Reliance)	389 (15)
Medtronic (Quattro Secure)	1819 (69)
St Jude (Durata, Riata ST Optim)	445 (17)
DF4 connector	251 (9)
Additional intracardiac leads	
None	624 (24)
1	986 (37)
2	868 (33)
3 or more	175 (7)
Subsequently revised	46 (2)
Inappropriate shock/anti-tachycardia pacing	117 (4)
Lead status at last follow-up	
Active and functioning	2289 (86)
Patient died	236 (9)
Failed	25 (<1)
Elective removal/abandonment	36 (1)
Infected	22 (<1)
Other/unknown	44 (2)

0.28% per year (95% CI, 0.19 to 0.43). Our data did not support any difference between the failure rate of the newer St Jude leads (Durata and Riata ST Optim, 0.15% per year with 95% CI 0.03 to 0.61) and the pooled failure rate of established leads from Metronic and Boston Scientific (0.31% per year with 95% CI 0.20 to 0.47; χ^2=0.94 on 1 df, P=0.33). Neither could we detect a difference among the 3 manufacturers' failure rates based on a global test (χ^2=1.8 on 2 df, P=0.40; Figure 2). Sensing problems were common in failed leads (17/25), mostly oversensing (15). Pacing problems were rare (2/25), and only 1 lead failed to defibrillate. Four failed leads displayed conductor fractures.

Sensitivity Analyses

The test for differences among manufacturers' failure rates stratified by clinical center remained nonsignificant (χ^2=1.1 on 2 df, P=0.59). Similarly, semi- and fully parametric models adjusted for clinical center and potential confounders failed to change this result. Finally, to study the potential for deaths to obscure differences in lead failures, we re-analyzed the data with failure defined as lead failure or death from any cause. This analysis posits a worst-case scenario of a same-day lead failure in every patient who died with an intact lead. Again, we

Table 3. Characteristics of Implantable Cardioverter-Defibrillator Lead Follow-up and Survival Time

	Boston Scientific (Endotak)	Medtronic (Quattro)	St Jude (Durata)
Follow-up time per person, years	Median 3.4 (IQR 2.0 to 5.2)	Median 3.3 (IQR 2.0 to 4.6)	Median 2.9 (IQR 1.8 to 4.0)
Total person-years of follow-up*	1407	6079	1311
Raw failure rate (per person-year)	0.43% CI: 0.17% to 0.98%	0.28% CI: 0.17% to 0.46%	0.15% CI: 0.03% to 0.61%
Failures	6 (2%)	17 (1%)	2 (<1%)
Censored by death	44 (11%)	166 (9%)	26 (6%)
Censored by end of follow-up	325 (84%)	1567 (86%)	397 (89%)
Censored by other†	14 (4%)	68 (4%)	20 (4%)
Total leads	389 (100%)	1818 (100%)	445 (100%)

*Taking last follow-up date as censoring/failure time regardless of ordering (person vs lead follow-up).
†Infection, elective removal, etc.

found insufficient evidence to describe a difference among manufacturers (χ^2=3.7 on 2 df, P=0.15).

Power Simulations for Postmarket Surveillance

We compared the sample size requirements for postmarket safety surveillance and comparative-effectiveness studies of lead failure. In all scenarios, we reproduced 2 features of our observed data: unbalanced manufacturer shares (0.15, 0.25, and 0.60) and a censoring distribution similar to our observed data. We considered follow-up times of 3 years, as in our study, and 5 years, similar to the requirements for new leads in the United States. We described the results in terms of the failure rate ratio between the manufacturer with the smallest share of leads (0.15) versus the largest (0.60). We fixed the failure rate in the remaining manufacturer (share=0.25) at 0.3% per year. Rate ratios <1 indicate the dominant manufacturer has the highest failure rate, and >1 that the smallest manufacturer has the highest failure rate. In our comparative effectiveness scenarios, we used rate ratios of 0.5 and 2, corresponding to the 0.4% and 0.2% failure rates in our real data. In our safety surveillance scenarios, we used rate ratios between 0.07 and 13, corresponding to elevated failure rates from 0.8% to 2.6%.

We found that comparative effectiveness studies designed to detect differences among low failure rates as in currently marketed leads would require very large sample sizes or long follow-up. One would need to follow ≈14 000 leads for 3 years or 8000 leads for 5 years to detect differences among failure rates like those in our real data.

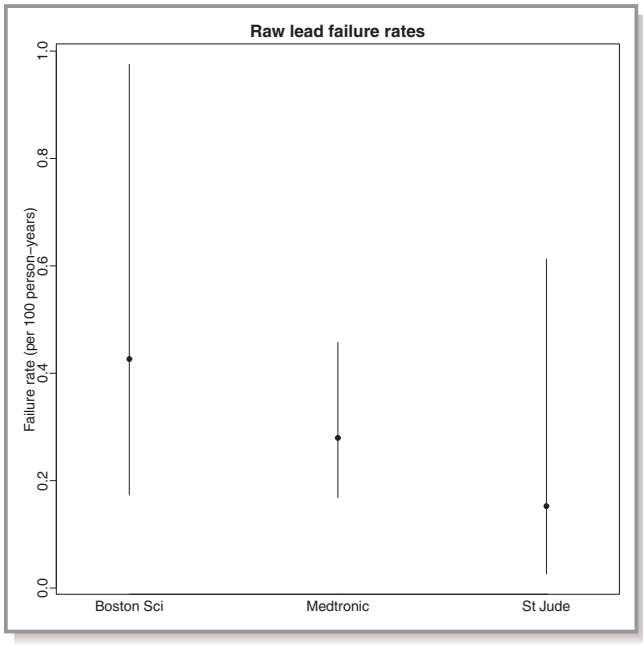

Figure 1. Raw failure rate of leads per 100 person-years of follow-up.

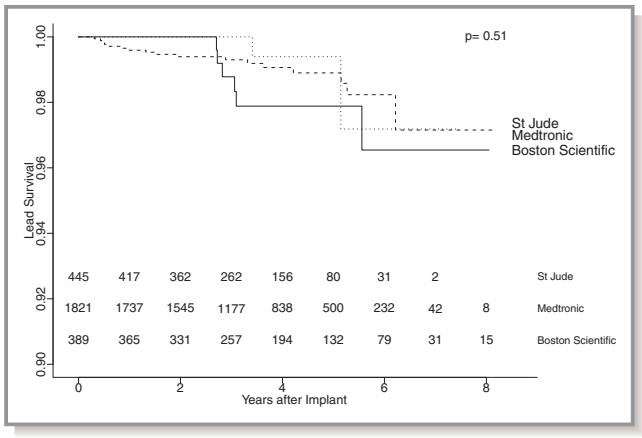

Figure 2. Unadjusted Kaplan–Meier survival curves of implantable cardioverter-defibrillator leads by manufacturer. Number of leads at risk each year is shown along the *x* axis.

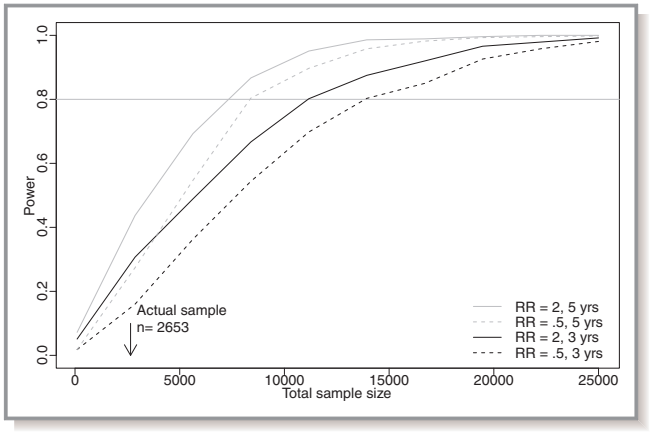

Figure 3. Minimum sample size for 80% power to detect differences among failure rates in 3 manufacturers. Rate ratio (RR) <1 (solid lines) indicates that the dominant manufacturer has the highest failure rate, and RR >1 (dashed lines) indicates that the smallest manufacturer has the highest failure rate. Black vs gray lines describe sample sizes with study follow-up similar to the current study (3 years, black) or with 2 additional years (5 years, gray).

However, Figure 3 illustrates that for postmarket safety surveillance designed to detect high failure rates in a faulty product, sample sizes are less daunting. This is true even when the defective leads comprise a small portion of the studied leads. With our study's sample size, we would have power to detect failure rates of 0.80%. This is twice the highest failure rate we observed, but still much lower than Sprint Fidelis and thus a reasonable magnitude to signal a potentially faulty lead.

Discussion

This analysis of transvenous lead reliability evaluated commonly utilized ICD leads exclusive of recalled models known to fail prematurely. With those problematic leads excluded, we identified a low annual rate of lead failure —0.28%—and identified no differences among the 3 represented manufacturers with 8797 patient-years of follow-up. In addition, modeling failure rates derived from our observational findings indicated that traditional approaches to ICD lead surveillance —even if bolstered by unique device identifiers—will need robust sample sizes with long follow-up to demonstrate meaningful deviations in performance within the normal range. However, our simulation results also support efforts to identify seriously flawed leads, such as Sprint Fidelis, in near real time using multicenter implant and follow-up databases.[17] In sum, these data should buttress confidence in current standards for transvenous lead design, while also providing essential clinical and statistical context for ongoing discussions regarding postmarket surveillance and comparative effectiveness research in this area.

Transvenous ICD lead performance has long been identified as the "weakest link" in a system broadly recognizable over 30 years of clinical development.[18] Advancement beyond initial coaxial lead designs have been associated with improvements in lead durability, but prior reports still suggested lead survival rates as low as 85% at 5 years.[19] However, other data suggest much lower rates of failure,[20,21] muddying the picture of ICD lead performance even before the widely reported recalls of popular lead models.[22] These recalled models, with failure rates as high as 16.8% at 5 years for the Medtronic Sprint Fidelis lead,[23] generated more urgency for evaluating the engineering, regulation, and clinical evaluation of ICD leads.[24] Recalls also created understandable skepticism regarding ongoing advances such as novel connector systems[3] and lead coating materials.[12]

Viewed against this backdrop of concern, our findings may provide further reassurance regarding current lead performance. In particular, the low rate of failure in our study for the St Jude Durata and Riata ST Optim leads accords with a prior report from Canada describing annual failure rates of 0.24% and 0.27%, respectively,[25] and both our study and the Canadian report had lower rates than the annual Riata ST failure rate noted in a Veteran's Affairs database (0.82%).[21] These differences may reflect differences in the study population, particular in contrasting our study to the Veteran's Affairs database, in which remote monitoring of a much larger sample (>24 000 in total) coordinated through a national surveillance center may have identified more failures than our passive methodology. Our rates for the Boston Scientific Endotak and Medtronic Sprint Quattro models are lower than that described in a single-center European study (1.14%), but comparable to data gleaned from the Veteran's Affairs Database[21] and a prior comparison of Fidelis to Quattro leads identifying a 0.43%/year failure rate in the latter.[2]

Nevertheless, premarket evaluation of ICD leads, particularly via the premarket approval supplement pathway, relies heavily on engineering and bench testing to identify problematic lead design, and is unlikely to identify clinical lead failures. Incorporating our findings into a parametric model demonstrates that current approaches to postmarket surveillance for ICD leads may be markedly underpowered. Manufacturers in the United States may be required to collect information on up to 1000 recipients of a new ICD lead as a condition of approval.[26] However, even with relatively long follow-up and careful adjudication of possible failures, our results suggest that this approach is unlikely to detect anything more subtle than a marked deviation in lead performance.

Indeed, while the National Cardiovascular Data Registry—ICD Registry adds in excess of 10 000 cases each month, clinical follow-up and in particular adjudication of deaths or lead-related complications is not currently incorporated into its analytic framework, despite recommendations from the Heart Rhythm Society in 2004 to do so.[27] For example, few prior studies have described the performance of ICD leads

with DF-4 connectors. Though our overall failure rate was too low to identify significant differences between DF-1 and DF-4 leads, this will remain an open question with important implications for device design and patient management, and not clearly answerable by any current approach. Our findings also have implications for evaluating subcutaneous ICD systems, whose long-term reliability is largely unknown, and now must be compared with an increasingly solid long-term performance for modern transvenous systems. Thus, we argue for further support for the ICD Registry to take a leadership role in lead surveillance, particularly given the Registry's demonstrated ability to link individual records to Medicare claims[28] and, potentially, remote monitoring.[29] Integrating unique device identifiers into this registry would potentially leverage these existing linkages to great effect.

This study has several limitations. Selection of leads utilized in each case was at the discretion of the operator, and thus unmeasured confounders may have influenced both lead choice as well as lead failure and patient survival. However, we accounted for clinical variables and study center and did not identify important predictors of lead choice that would be expected to confound our findings. Our multicenter consortium consists of academic referral centers, and thus the results may not necessarily extend to community practice. Though we adjudicated suspected lead failures both locally and centrally, both levels of review depended heavily on medical records for content and context of lead revisions, and we relied on passive reporting without mandated fluoroscopy or radiographs. Some underreporting of patient deaths may have occurred, and whether deaths were related to catastrophic lead failure remains unknown. In addition, though longitudinal follow-up at 1 of the study centers was a criterion for inclusion, it is possible that patients hospitalized elsewhere for lead-related complications may not have been subsequently reported as such to their original study center. Last, while we have characterized our identified lead failure rate as reassuringly low, in concert with findings of other investigators, little consensus exists around what actually constitutes an acceptable performance standard for ICD leads or generators.[30]

In sum, 3 models of transvenous ICD leads currently in clinical practice experience very low failure rates. The clinical community, regulators, and manufacturers should take this into account in evaluating new and competing technology as well as in the design of postmarket surveillance systems.

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Disclosures

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