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Robert G. Hauser, David L. Hayes

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The Increasing Hazard of Sprint Fidelis Implantable Cardioverter-Defibrillator Lead Failure

Robert G. Hauser MD and David L. Hayes MD

Minneapolis Heart Institute Foundation, Minneapolis, Minnesota

Mayo Clinic, Rochester, Minnesota

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Correspondence to:

Robert G. Hauser MD

920 East 28th Street, Suite 300

Minneapolis, MN 55407

Email: rhauser747@aol.com

Tel: 612-863-3900

Fax: 952-476-1795

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Dr. Hauser:

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ICD = implantable cardioverter-defibrillator

Abstract

Background The Medtronic Sprint Fidelis defibrillator lead is prone to fracture and was recalled in 2007 after 665 failures and 5 reported deaths. Approximately 150,000 patients at risk for sudden death in the United States have Sprint Fidelis leads. The rate of Sprint Fidelis lead failure may be increasing, and physicians are confronted with the decision to replace it prophylactically.

Objective To determine if the hazard of Sprint Fidelis lead failure is changing and compare its performance to other contemporary ICD leads.

Methods Transvenous implantable cardioverter-defibrillator leads implanted and followed at our two tertiary care referral centers between January 2004 and December 2008 were included. Lead failure data were entered prospectively by both centers via the Multicenter Registry. Clinical data were collected prospectively by each center and merged for the purpose of this study

Results During 5,700 years of follow-up (average: 1.9 ± 1.3 years), 94 of 3,037 defibrillator leads failed (1.65%/year), including 72 of 848 (8.5%) Sprint Fidelis leads. The cumulative hazard of Sprint Fidelis failure was significantly greater compared to 2,189 other defibrillator leads ($p < 0.0001$), and the hazard of Sprint Fidelis failure accelerated after the first year and continued to increase during the study. In contrast to other defibrillator leads, the Sprint Fidelis failure rate was significantly higher (3.75%/year vs 0.58%/year) and the 3-year estimated survival significantly lower (87.9%, 95% CI 84.8,90.9 vs

98.5%, 95% CI 97.8, 99.3) ($p < 0.0001$). The chance that a Sprint Fidelis lead would survive another year decreased progressively during the study. Most Sprint Fidelis failures were caused by pace-sense conductor fracture ($n=63$; 87.5%), which caused inappropriate shocks in 36 of 72 patients.

Conclusion The hazard of Sprint Fidelis lead failure is increasing, while the failure rates of other defibrillator leads are low and stable. Physicians should consider these data when managing patients who have Sprint Fidelis leads.

Introduction

The Medtronic Sprint Fidelis implantable cardioverter-defibrillator high-voltage lead is prone to fracture.^{1,2} The manufacturer voluntarily removed it from the market in October 2007 after 665 confirmed fractures and 5 reported deaths.³ Medtronic currently estimates that 150,000 patients at high-risk for sudden cardiac death in the United States have Fidelis leads.⁴ While initial reports suggested failure rates <2%,^{1,2} recent evidence suggests that the risk of Fidelis lead fracture is increasing with time.⁵ Moreover, the manufacturer's clinical studies show a downward trend in Fidelis survival.⁶

At issue is whether the manufacturer's current recommendations regarding patient management are appropriate for the majority of patients, namely to monitor the Fidelis for signs of fracture and not replace it unless a defect is identified.⁷ However, prophylactic replacement of Fidelis leads in selected patients may be reasonable if the benefits clearly outweigh the risks. Patients who have received an implantable cardioverter-defibrillator (ICD) for secondary prevention of sudden cardiac death, who have been rescued by the ICD, or who are pacemaker dependent (asystolic) may benefit from prophylactic Fidelis replacement. Nevertheless, lead replacement with or without extraction of a chronic lead is associated with known complications, including infection, pericardial tamponade, and death. However, these major adverse events may be mitigated if Fidelis lead replacement is performed at the time of pulse generator change by experienced operators in high-volume centers. While the procedural risks are specific to individual patients, operators, and hospitals,⁸ the

device risks depend on the chance of a Fidelis failing over time, the potential clinical consequences of Fidelis failure for an individual patient, and the reliability of the replacement lead. We therefore sought to examine the performance of Fidelis leads at our 2 centers to determine if the hazard of Fidelis failure is changing and to compare the Fidelis failure rate and survival to other ICD lead models that were implanted at our hospitals during the same period.

Methods

Study Design

Transvenous ICD lead failure data were entered prospectively into the Multicenter Registry database.⁹ Implant and follow-up data were collected prospectively by each center and merged for the purposes of the study.

Study Population

All transvenous leads that were implanted and followed at the Minneapolis Heart Institute in Minneapolis and the Mayo Clinic in Rochester for a minimum of one month between January 2004 and December 2008 were included.

Implant Techniques and Follow-up

Leads were inserted via left- or right-sided venous access by cephalic cut-down, or by axillary or subclavian vein access using standard techniques. Leads were positioned in the right ventricular apex or ventricular septum. Defibrillation safety margins and pacing and sensing thresholds were determined according to each center's

customary practice to ensure adequate detection and termination of ventricular tachyarrhythmias and to provide rate support in the event of bradycardia. Atrial and left ventricular leads were added in those patients requiring multichamber pacing and sensing. Patients were followed every 3-4 months and their devices were evaluated either in the clinic or via telephone using monitoring services when appropriate.

Definitions

A lead was considered implanted once it had been tested, connected to the ICD pulse generator, and the incision closed. A lead failed if it undersensed or oversensed normal cardiac electrical activity or could not provide effective electrical therapy including sensing, pacing, or defibrillation. The cause of failure was determined by the center based on stored diagnostic data and findings at the time of lead revision. Failure data were validated by the center investigator who was required to specify how the failure was confirmed, including measurements at revision. The submitted information was independently reviewed and adjudicated by the Multicenter Registry. A lead that displaced after the incision was closed was considered a failure if it was removed from service and was found to have a defective fixation mechanism, e.g. an unstable or fractured helix or screw. A lead that displaced after the incision was closed and was not removed from service (e.g., repositioned) or did not have a fixation mechanism defect was not a failure. Functional abnormalities (physiologic oversensing, undersensing, and exit block in the presence of an electrically intact lead), and elective lead revisions

(including replacement of recalled leads) were not classified as failures unless a lead defect was identified

Statistics

Survival probabilities were estimated by the Kaplan-Meier method with 95% confidence bounds computed via the effective sample size approach of Dorey and Korn.¹⁰ Survival curves were compared using the logrank test (2-sides). Probabilities of lead survival conditioned on having not failed at T years (e.g., probability of a lead failing in the next year given that the lead has not yet failed at T years) were calculated by first excluding all observations with less than T years of follow-up, subtracting T from the remaining follow-up times so that T becomes the new origin, and then using the aforementioned Kaplan-Meier survival estimation techniques.

Results

During the study, 3,037 leads were implanted and followed by the two centers. Of these, 2,318 (75.8%) were active as of December 2008, 94 had failed (3.0%), 272 (9.3%) had been removed from service due to patient death, 176 (6.3%) were abandoned or explanted for reasons unrelated to lead performance, and 177 patients (5.7%) were lost to follow-up >90 days after implant. The average lead was implanted 22.5 ± 15.3 months (median 19.8 months) (range: 31 days to 57.9 months).

Lead Failure Rates

Average lead failure rates are shown in Table 1. The overall failure rate was 1.65%/year. The failure rate for Fidelis leads was 3.75%/year, which was significantly higher than the failure rates for other lead models. The combined failure rate for all leads excluding Fidelis was 0.582%/year. The cumulative hazard of Fidelis failure is depicted in Figure 1. The risk of failure increased with time and appeared to accelerate after the first implant year. The cumulative hazard of Fidelis failure compared to the Sprint Quattro Secure (Medtronic Inc, Minneapolis) and the Endotak Reliance G/SG (Boston Scientific Inc, St. Paul) and to all other study leads are shown in Figure 2. The differences in cumulative hazard between Fidelis and other lead models are highly significant ($p < 0.001$).

Lead Survival

Lead survival estimates with 95% confidence bounds for all leads and for individual models are shown in Table 2. The 3-year survival for Fidelis was 87.9% (84.8, 90.9) compared to 98.7% (97.7, 99.6) for the Sprint Quattro Secure and 99.1% (97.7, 100) for the Endotak Reliance G/SG ($p < 0.0001$). The overall survival of leads in the study was significantly impacted by Fidelis failures. Excluding Fidelis leads the combined 3-year survival of all other leads was 98.5% (97.4, 99.3).

Conditional survival probabilities for Fidelis leads functioning normally after 1, 2 and 3 years are shown in Figure 3. If a Fidelis was functioning normally at 1 year, the chance it would survive another year was 96.0% (97.5, 94.5); if functioning at 2 years, the chance of

surviving another year was 92.6% (95.4,89.8); and, if functioning at 3 years the chance of surviving one more year was 77.5% (95.8,61.7).

Causes of Lead Failure

The causes of lead failure were determined from pulse generator diagnostic data and verified by observations during lead revision. Pace-sense conductor fracture caused 72 of the 94 lead failures (77%) and most of these involved Fidelis leads (n=63). Fracture of the high-voltage conductor affected 5 leads, including 4 Fidelis leads and one Sprint Quattro Secure model. Other causes of failure were fixation mechanism malfunction (n=5), insulation (n=6) and terminal pin (n=1) defects, and both insulation and conductor defects (n=5).

Clinical Observations Associated with Lead Failure

Oversensing of non-physiologic lead signals resulted in inappropriate shocks in 41 patients (44%) whose leads failed (Table 3). The majority of these inappropriate shocks were caused by Fidelis lead fractures (n=36;88%). Inhibition of pacing due to oversensing and failure to capture was observed in 19 patients; 13 of these were caused by Fidelis fractures, and one resulted in syncope.

Thirty-four lead failures were not associated with a clinical event and were signified by changes in lead impedance (n=22), oversensing based on pulse generator diagnostic data (n=6), and visual observations (n=6). There were no deaths or serious injuries due to lead failure, and no major surgical complications occurred as the result of lead replacement or revision, including 57 patients whose failed leads (including 47 Fidelis leads) and were extracted.

Discussion

The results of this prospective two-center study show that the hazard of Sprint Fidelis failure is increasing significantly when compared to other contemporary defibrillator leads. Furthermore, the rate of Fidelis failure appeared to accelerate after the first implant year and showed no sign of abating. The chance that a Fidelis lead would survive another year decreased progressively during the study. These findings are timely and important because physicians are increasingly confronted with the decision to prophylactically replace normally functioning Fidelis leads during pulse generator change or to continue to monitor them according to the manufacturer's recommendations. The data further indicate that the failure rates of other major lead models we studied, including the Sprint Quattro Secure and Endotak Reliance G/SG, are low (<1%/year) and appear stable.

The Fidelis failure rate in this study was 3.75%/year during an average follow-up of 27 months. A multicenter study² of 6,181 patients reported a Fidelis failure rate of 1.29% at 21 months. In their single center study of 502 Fidelis leads Farwell et al⁵ found the hazard of Fidelis fracture increased with time by a power of 2.74 (95% CI: 2.57 to 2.91, $p < 0.0001$). In its May 2008 letter to physicians,⁷ Medtronic stated there was no evidence that the Fidelis survival curve was "flattening at the leading edge". Since the cumulative hazard function is the negative logarithm of the survival

curve, Medtronic's observation suggests that its data also show an increasing rate of Fidelis failure.

Medtronic regularly updates Fidelis survival information from its System Longevity Study and CareLink data.⁶ The number of Fidelis and Sprint Quattro Secure leads in our study is similar to the sample sizes for these leads in the System Longevity Study. As of December 2008 when our study closed, Medtronic reported Fidelis 3-year survival to be 95.0% (97.0, 91.8) for the SLS and 97.0% (97.4, 96.5) for the CareLink data.⁶ Medtronic's reported Fidelis survival estimates are notably higher than we found in this study (Fig 4). However, our survival estimates for the Sprint Quattro Secure lead are comparable to those found in the SLS,⁴ and our survival estimates for the Endotak Reliance G/SG and Riata leads are similar to those reported by their respective manufacturers.^{11,12}

Inappropriate high-voltage shocks were common adverse clinical events and they occurred in 50% of patients whose Fidelis lead failed. Such shocks are usually multiple, painful, psychologically disturbing, and they have been reported to be arrhythmogenic and possibly lethal.^{13,14} A lead impedance monitoring technique designed to forewarn patients of impending Fidelis lead fracture failed to prevent inappropriate shocks in most of our patients.¹⁵ A recent downloadable software enhancement, which monitors pace-sense conductors for signs of noise and abnormal impedance, may reduce the proportion of patients who are inappropriately shocked when a Fidelis lead fractures.¹⁶ However, this lead-integrity algorithm is only available for Medtronic ICD pulse generators.

Reported ICD lead survivals vary widely and depend on the definition of lead failure, inclusion of lead models with known performance issues, characteristics of the patient population studied, and the tools available to follow and evaluate lead function. In a single-center study of 990 leads implanted between 1992 and 2005 Kleeman et al¹⁷ found a 85% survival rate at 5 years during a median follow-up of 2.6 years. In their study, 24% of the leads implanted were failure-prone Transvene models (Medtronic, Inc),¹⁸ which accounted for 64 of the 148 failures. In contrast, Ekstein and colleagues¹⁹ reported lead survivals of 98.2% and 97.5% at 3 and 5 years respectively. Their multicenter study of 1317 patients implanted between 1993 and 2004 identified 38 lead failures during a median follow-up of 6.4 years, which implies a failure rate of about 0.45%/year. Unlike the study by Kleeman and co-workers,¹⁷ the overall lead survival in the Ekstein et al¹⁹ study was not substantially impacted by underperforming models like Transvene. When Fidelis leads are excluded from our study, the 3-year survival and overall failure rate are similar to those reported by Ekstein et al.¹⁹ The results of our study and the observations by Ekstein et al¹⁹ suggest that 5-year lead failures rates <0.6%/year are achievable, and further that an annual failure rate >1% for a defibrillator lead model during the first 5 years after market release is probably excessive.

The results of this study do not support and we do not advocate routine prophylactic replacement of normally functioning Fidelis leads. However, our data do show that the risk of Fidelis failure is increasing, and that the performances of other currently available

leads appear satisfactory. Physicians should consider these findings as well as clinical factors and procedural risks when making management decisions in individual patients with a Fidelis lead. Selected patients may warrant prophylactic Fidelis replacement during pulse generator change because they have a history of resuscitated SCD, are at risk of asystole or syncope in the absence of pacing, or belong to a subset of patients at high-risk for Fidelis fracture such as young, active adults who have normal left ventricular function.^{5,16} The later group includes patients with inherited diseases, such as hypertrophic cardiomyopathy and long QT syndromes, who generally have an excellent prognosis provided SCD can be prevented.

This study has certain limitations. Leads are subject to a variety of failure mechanisms during years of wear and tear. Given the implant times in this study, no conclusion can be drawn regarding their long-term performance. We could not verify the causes of most lead failures with returned product analyses. We did not assess the potential impact of clinical variables, such as patient age or left ventricular function on the risk of lead failure.

Conclusion

The hazard of Sprint Fidelis defibrillator lead fracture appears to be accelerating. In contrast, the failure rates of other contemporary leads are low and stable. These data should be considered when physicians decide whether a normally functioning Fidelis lead should be replaced at the time of pulse generator change. However, the

results of this study do not justify routine prophylactic replacement of normally functioning Fidelis leads. Such a decision should be based on the indication for ICD implantation, therapy history, patient characteristics, and the physician's individualized assessment of surgical risk based on his or her qualifications and experience.

ACCEPTED MANUSCRIPT

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Figure 1. Cumulative hazard of Sprint Fidelis defibrillator lead failure (solid line) \pm 95 confidence bounds (dashed lines)

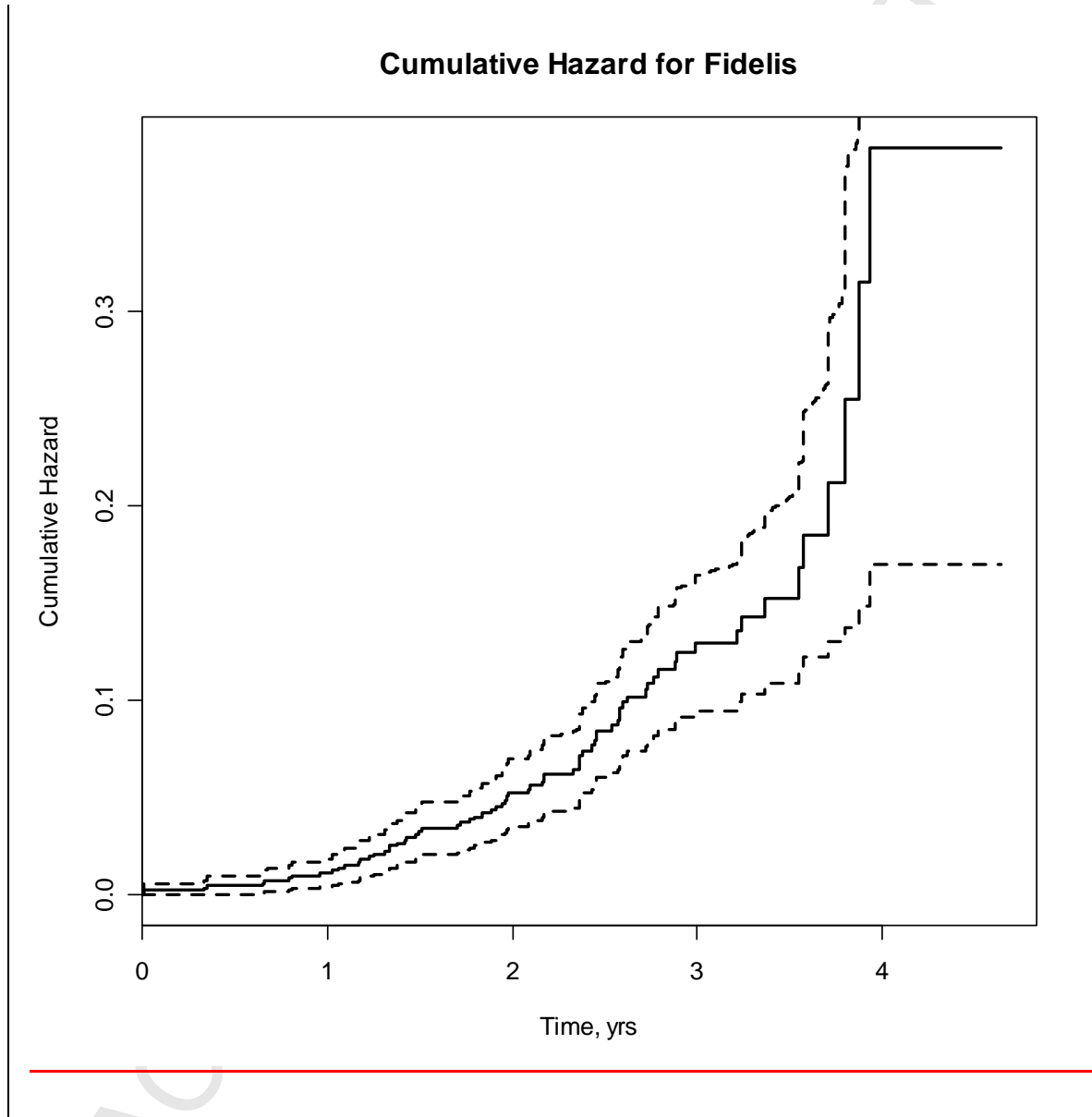


Figure 2. Cumulative Hazard of Sprint Fidelis lead failure compared to the Endotak Reliance G/SG and Sprint Quattro Secure (Panel A) and to all other study leads (Panel B). Logrank tests of Fidelis vs Secure, Fidelis vs Reliance G/SG, and Fidelis vs all other study leads yield $p < 0.0001$.

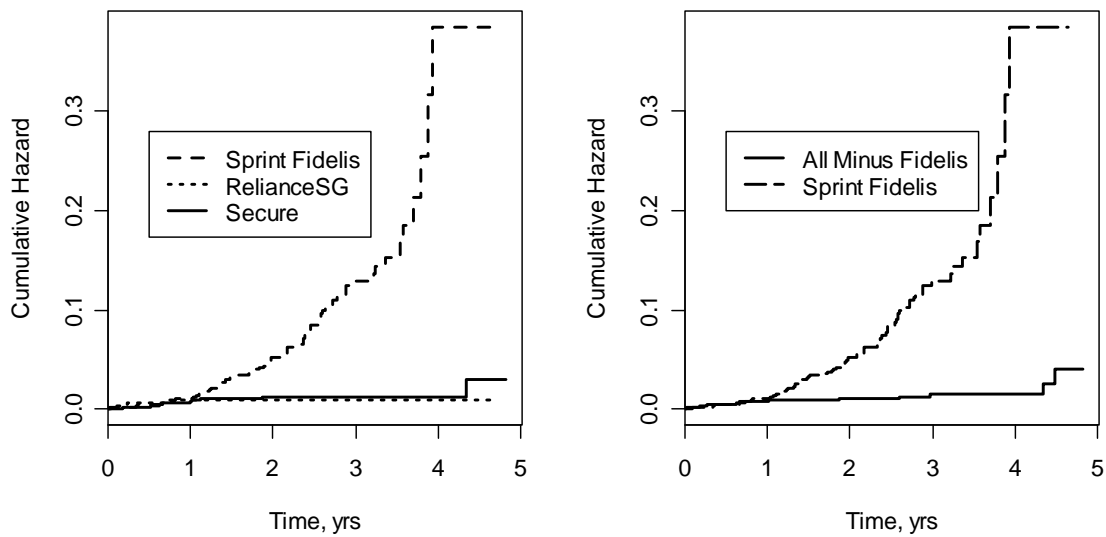
**A****B**

Figure 3. Conditional survival probabilities for Sprint Fidelis leads that are functioning normally at 1, 2 and 3 years after implant.

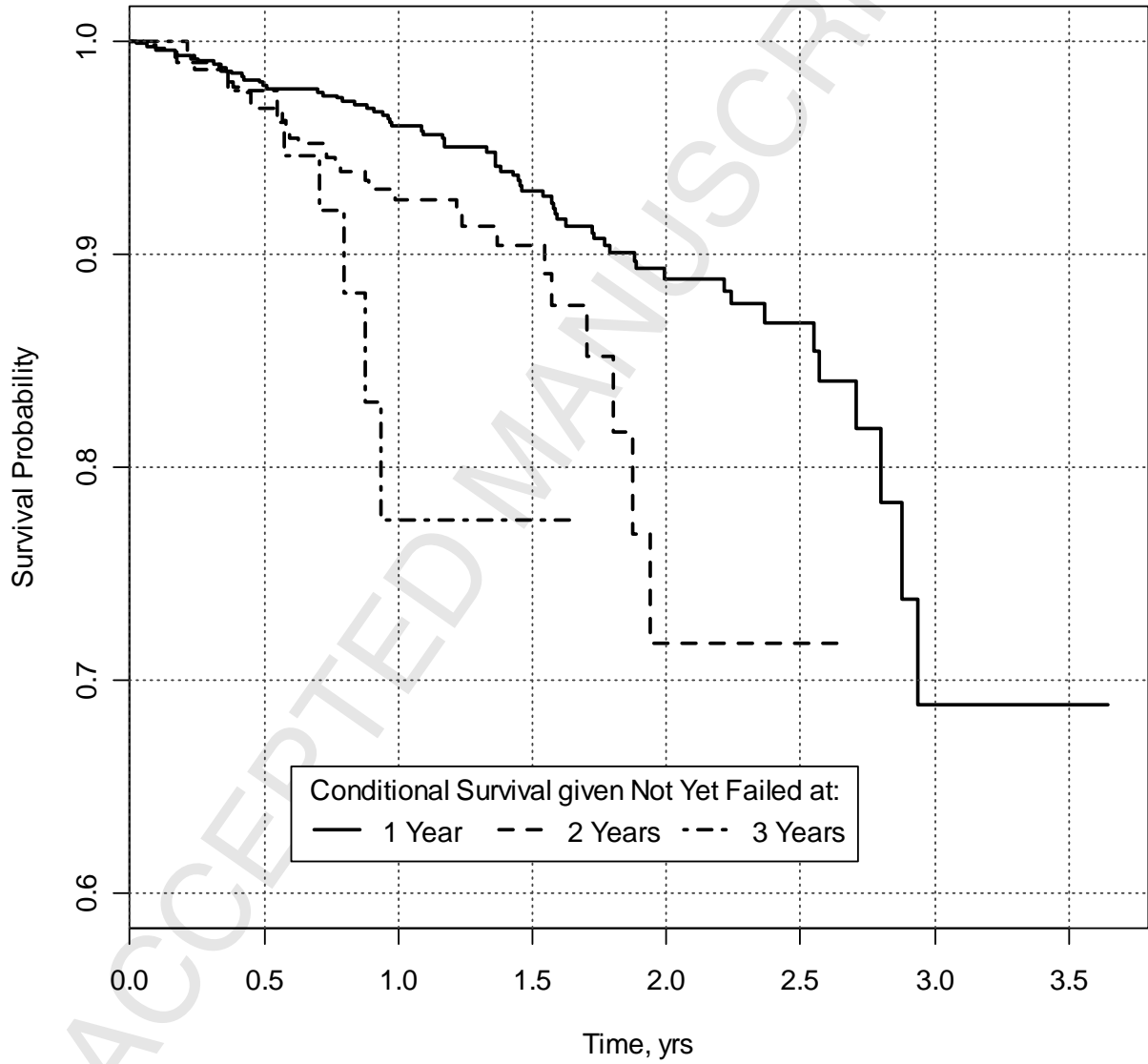
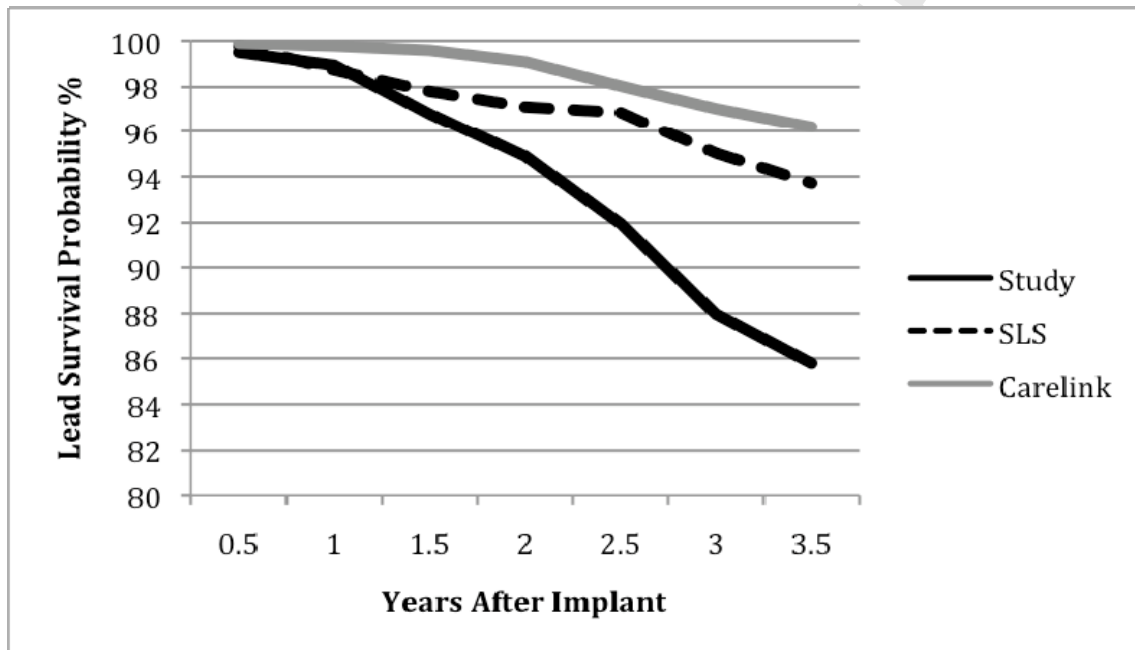


Figure 4. Sprint Fidelis lead survival probabilities for leads in this study and those reported by Medtronic for its System Longevity Study (SLS) and CareLink data.



	0 yr	1 yr	2 yr	3 yr	At 42 mo
Study	848	736 98.9% (99.6,98.1)	545 94.9% (96.5,93.3)	199 87.9% (91.0,84.9)	73 85.8% (89.7,81.5)
SLS	759	609 98.9% (99.5,97.7)	286 97.1% (98.2,95.3)	114 95.0% (97.0,91.8)	40 93.7% (96.4,89.2)
Carelink	21,500	19,287 99.8% (99.9,99.8)	10,440 99.1% (99.2,98.9)	1,069 97.0% (97.4,96.5)	857 96.2% (96.8,95.5)

Lead	# Implanted	Average Follow-up months ± SD	Implant Years	# Failures	Failure Rate %/year
All Leads	3037	22.5±15.3	5700	94	1.65
Sprint Fidelis	848	27.1±11.4	1923	72	3.75
Sprint Quattro Secure	1273	18.9±15.7	2013	11	0.55
Endotak Reliance G/SG	498	23.1±16.1	960	4	0.42
Endotak Reliance	109	29.8±19.8	281	3	1.07
Riata	90	28.3±15.7	213	1	0.47
All Leads Except Fidelis	2189	20.7±16.2	3777	22	0.58

Table 1. Average failure rates for all leads, all leads except Sprint Fidelis, and for major study models with >1 year average implant time.

% Surviving (95% CI) and N at risk					
Lead	#	1 year	2 years	3 years	4 years
All Leads	3037	99.1 (98.7,99.5) 2053	97.3 (96.5,98.0) 1308	94.3 (93.1,95.6) 676	91.9 (89.8,94.0) 211
Sprint Fidelis	848	98.9 (98.1,99.6) 736	94.9 (93.3,96.5) 545	87.9 (84.8,90.9) 199	68.1 (54.0,84.4) 11
Sprint Quattro Secure	1273	99.3 (98.8,99.8) 699	98.7 (97.9,99.6) 374	98.7 (97.7,99.6) 236	98.7 (97.2,99.6) 108
Endotak Reliance G/SG	498	99.1 (98.2,100) 320	99.1 (98.0,100) 233	99.1 (97.7,100) 138	99.1 (95.8,100) 24
Endotak Reliance	109	100 (100,100) 80	100 (100,100) 63	96.2 (91.1,100) 47	96.2 (90.5,100) 37
Riata	90	98.9 (96.5,100) 77	98.9 (96.0,100) 51	98.9 (95.3,100) 32	98.9 (93.6,100) 14
All Leads Except Fidelis	2189	99.2 (98.8,99.6) 1317	98.9 (98.4,99.4) 763	98.5 (97.8,99.3) 477	98.65 (97.4,99.3) 200

Table 2. Survival estimates for all leads, all leads except Fidelis and for major models with > 1-year average implant time.

p-values for pairwise logrank tests for a difference in lead survival:

Fidelis vs Sprint Quattro Secure $p < 0.0001$; Fidelis vs Endotak Reliance G/SG $p < 0.0001$; Fidelis vs Endotak Reliance $p = 0.001$; Fidelis vs Riata $p < 0.004$. Other comparisons not significant ($p > 0.05$).

	#	Oversensing		Failure to Capture
		Inappropriate Shocks	Pacing Inhibition	
All Leads	94	41 (44%)	10 (11%)	9 (10%)
Sprint Fidelis	72	36	8	5
Sprint Quattro Secure	11	2	1	3
Endotak Reliance G/SG	4	1	1	0
Endotak Reliance	3	1	0	0
Riata	1	1	0	0

Table 3. Clinical observations associated with lead failure. Oversensing and failure to capture were associated with identified lead defects. Thirty-four of the 94 lead failures (36%) were not associated with a clinical event.