Improvements in implantable cardioverter defibrillator patient stratification

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Chapter 8

Update on Medtronic Sprint Fidelis and St. Jude Medical Riata Implantable Cardioverter-Defibrillator Leads Performance

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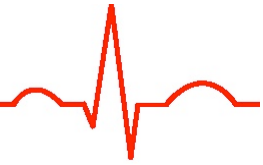
Submitted

Abstract

Background: The performance of small diameter implantable cardioverter defibrillator (ICD) leads has been questioned. The current study provides an update on the lead failure and cardiac perforation rate of Medtronic's Sprint Fidelis ICD lead and St. Jude Medical's Riata ICD lead in comparison to a large benchmark cohort.

Methods and Results: Since 1996, all ICD system implantations at the Leiden University Medical Center, the Netherlands, are registered. For the current study, data on 396 Sprint Fidelis leads (follow-up 3.4±1.5 years), 165 8-French (F) Riata leads (follow-up 4.6±2.6 years) and 30 7-F Riata leads (follow-up 2.9±1.3 years) were compared with a benchmark cohort of 1602 transvenously implanted ICD leads (follow-up 3.4±2.7 years) and assessed for the occurrence of lead failure and cardiac perforation. During follow-up, the yearly lead failure rate of the Sprint Fidelis lead, 7-F Riata lead, 8-F Riata lead and the benchmark cohort was 3.54%, 2.28% 0.78% and 1.14%, respectively. In comparison to the benchmark cohort, the adjusted hazard ratio of lead failure was 3.7 (95%CI 2.4-5.7, $p<0.001$) for the Sprint Fidelis lead and 4.2 (95%CI 1.0-18.0, $p<0.05$) for the 7-F Riata lead. Only one cardiac perforation was observed (0.05%) in the Riata group versus none in the Sprint Fidelis lead population.

Conclusion: The risk of lead failure was significantly increased for both the Sprint Fidelis and the 7-F Riata lead in comparison the benchmark cohort. The occurrence of cardiac perforations was rare.



Background

Manufacturers of implantable cardioverter defibrillator (ICD) leads constantly aim to improve design to allow easier implantation of additional leads, maintain venous blood flow and reduce subclavian crush syndrome.[1] However, recently became clear that these developments go together with some serious drawbacks. In particular, studies have reported on higher-than-expected lead failure rates for Medtronic's Sprint Fidelis lead (Medtronic Inc, MN, USA) as well as for St. Jude's 7-F Riata lead (St. Jude Medical Inc, MN, USA).[2-6] Moreover, studies have observed relatively high cardiac perforation rates associated with the Riata 1580/1581 lead (8-F) and the Riata 7000 series (7-F).[5, 7] As a consequence, Medtronic ceased production of the Sprint Fidelis lead and announced several safety advisories to improve early detection and reduce the number of inappropriate shocks due to lead failure. [4, 8, 9]

Given the high number of leads implanted worldwide (268 000 Sprint Fidelis leads and 227 000 Riata leads) it is important to monitor these patients carefully and provide up-to-date data on lead performance. Our center reported earlier on preliminary results of the performance of the Sprint Fidelis and 7-F Riata lead.[7, 10] This study provides an update on the performance of both leads with an extended follow-up duration and compares lead failure and cardiac perforation rates of the Sprint Fidelis lead, the Riata 7-F and the Riata 8-F lead with complication rates of a large benchmark cohort. Furthermore, the effects of Medtronic's safety advisories are evaluated.

Methods

Patient population

Since 1996, all patients who received an ICD system at the Leiden University Medical Center, Leiden, the Netherlands, are registered in the departmental Cardiology Information System (EPD-vision®, Leiden University Medical Center). Data of the implant procedure and all follow-up

visits were recorded. For the current analysis, only patients with a Sprint Fidelis lead (Medtronic Inc, MN, USA; model type 6949, 6948, 6931, 6930) and patients with a Riata lead (St. Jude Medical Inc, MN, USA; model type 1570, 1580, 1582, 7000, 7001, 7002, 7020) were included. For comparison of follow-up data, a large benchmark cohort of patients with transvenously implanted defibrillation leads, other than Sprint Fidelis leads or Riata leads was used. These leads were manufactured by Boston Scientific (MA, USA [formerly CPI Guidant, MN, USA]), Biotronik (Germany), Medtronic (MN, USA) and St. Jude Medical/Ventritex (MN, USA).

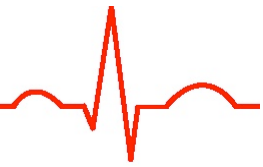
Eligibility for ICD implantation was based on international guidelines and included both secondary prevention and primary prevention of sudden cardiac death.[11, 12] Testing of sensing and pacing thresholds and defibrillation threshold testing were performed during the implant procedure.

Follow-up

The follow-up was from lead implantation to February 1, 2011. Periodic device interrogation was performed every 3–6 months or earlier if patient had symptomatic events. During these examinations, all leads were systematically evaluated for adequate function and integrity. As reported previously, all patients with a Sprint Fidelis lead and a Medtronic device were invited for implementation of Medtronic's safety advisories.[10] In brief, advisories consisted of adjustment of device settings, uploading of the Lead Integrity Algorithm and remote monitoring with CareLink®.[10] The benchmark cohort was followed and assessed for the occurrence of lead failure up to February 2008.[7]

Definition of lead failure and cardiac perforation

Defibrillation lead removal or capping was classified as lead failure if one of the following criteria was met: (1) undersensing or oversensing of normal electrical cardiac activity; (2)



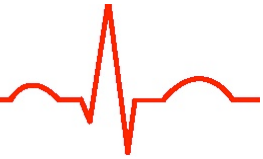
incapability of sensing, pacing, or defibrillation; (3) inappropriate shocks secondary to electrical noise artifacts; (4) abnormal lead impedance; (5) Lead Integrity Algorithm triggering an ICD alert.[3, 4] Cardiac perforation was diagnosed when a pericardial effusion was detected by transthoracic echocardiography in combination with abnormal lead impedance and/or pacing thresholds during follow-up.[5]

Statistical analysis

Continuous variables were analyzed as mean±SD. Categorical variables were analyzed as percentages as numbers and percentages. The cumulative incidence of lead failure was calculated using the Kaplan-Meier methodology. Chi-square tests were used to compare categorical variables and student t-tests were used for continuous variables. The occurrence of lead failure was compared with the benchmark cohort using three groups based on manufacturer and lead diameter: 1) Sprint Fidelis leads, 2) 7-F Riata leads (comprising lead model types 7000, 7001, 7002, 7020) and 3) 8-F Riata leads (comprising lead model types 1570, 1580, 1582). Cumulative incidences were analyzed by method of Kaplan-Meier and compared using the log-rank test. The 95% confidence intervals (CI) were calculated as 1.96 times the standard error in each direction. Multivariate Cox regression analysis, adjusted for known confounders (left ventricular ejection fraction, age, gender, and cardiomyopathy), was used to assess the risk of lead failure, described as hazard ratios (HR) with 95% CI.[13, 14] The statistical tests were performed using SPSS 18.0 for Windows. For all tests, a p-value <0.05 was considered significant.

Results

Since 1996, a total of 396 Sprint Fidelis defibrillation leads were implanted in 390 patients and 195 Riata defibrillation leads were implanted in 188 patients. The benchmark cohort consisted of



1602 leads, implanted in 1553 patients. As can be seen in Table 1, the majority of patients was male and had ischemic cardiomyopathy. During an average follow-up of 3.5±2.5 years, 372 patients died. To our knowledge, no patient died as a direct or indirect result of lead failure or cardiac perforation.

Table 1. Baseline clinical characteristics.

	Patients with Sprint Fidelis lead (n=390)	Patients with 7-F Riata lead (n=28)	Patients with 8-F Riata lead (n=160)	Benchmark cohort (n=1553)
Baseline characteristics				
Age, year	63±12	63±13	63±12	61±14
Male sex, %	81	89	82	80
Ejection fraction, %	32±14	39±11	38±15	34±14
Ischemic etiology, %	67	74	72	64
Primary indication, %	73	67	58	58

ICD = Implantable cardioverter defibrillator; F = French

Sprint Fidelis lead performance

The average follow-up of all 396 Sprint Fidelis lead was 3.4±1.5 years. As demonstrated in Table 2, the majority of patients received a Sprint Fidelis lead of Model Type 6931 (62%). During follow-up, 47 leads (12%) failed. These were implanted in 47 patients, of whom, 17 (36%) received 117 inappropriate shocks in total. Average time from implant to lead failure was 2.6±1.0 years. As can be seen in Figure 1, cumulative incidence of lead failure increased exponentially after 1 year of follow-up. After 2 years of follow-up, cumulative incidence was 4.1% (95%CI 1.9-6.3%), after 4 years 15.0% (95%CI 10.7-19.3%) and after 6 years 17.8% (95%CI 12.9-22.7%). In addition, yearly lead failure rates in first, second, third and fourth year of follow-up were 0.4%, 3.8%, 5.2% and 7.3%, respectively.

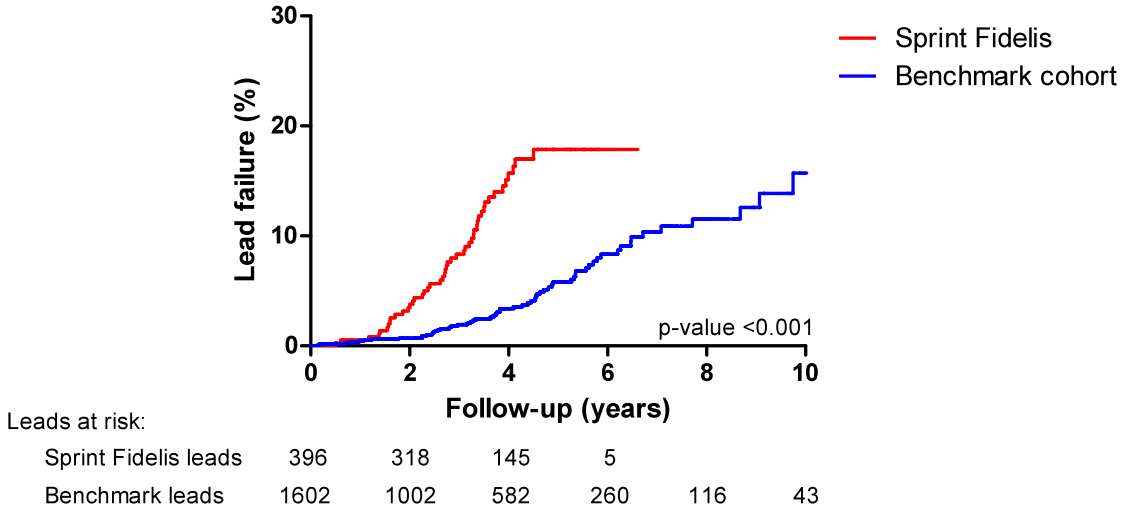


Figure 1. Failure of Sprint Fidelis leads. Kaplan Meier curve for cumulative incidences of lead failure.

Of the 47 failed leads, 8 failures (17%) were observed during routine evaluation, 21 patients (45%) were warned by a device alert without experiencing inappropriate shocks, 18 patients (38%) received inappropriate shocks of whom 2 patients were alerted by the device minutes before the shocks. Prior to implementation of the Lead Integrity Algorithm (only available for Medtronic ICDs), 10 out of 15 (67%) patients with a Medtronic ICD received an inappropriate shock related to lead failure. After implementation, 6 out of 24 (25%) patients received an inappropriate shocks related to lead failure ($p<0.05$). In addition, average number of repetitive inappropriate shocks decreased from 5.6±7.7 to 1.0±2.9 inappropriate shocks per case of lead failure ($p<0.05$) after implementation of the advisories. No cardiac perforations were observed in patients with a Sprint Fidelis lead.

Table 2. Model type of all implanted ICD leads.

Benchmark cohort (n=1602)	
Biotronik 8-F, n (%)	98 (6)
Boston Scientific 11-F, n (%)	163 (10)
Boston Scientific 9-F, n (%)	911 (57)
Medtronic 10.5-F, n (%)	76 (5)
Medtronic 9-F, n (%)	322 (20)
St Jude Medical 11-F, n (%)	32 (2)
Medtronic's 7-F Sprint Fidelis leads (n=396)	
6930, n (%)	1 (<1)
6931, n (%)	247 (62)
6948, n (%)	48 (12)
6949, n (%)	100 (25)
St Jude Medical's 7-F and 8-F Riata leads (n=195)	
1570, n (%)	114 (59)
1580, n (%)	44 (22)
1582, n (%)	7 (4)
7000, n (%)	5 (3)
7001, n (%)	1 (<1)
7002, n (%)	23 (12)
7020, n (%)	1 (<1)

ICD = Implantable cardioverter defibrillator; F = French

Removal of the leads was performed in 25 (53%) of the cases, sealing of the lead occurred in 22 patients (47%; Table 3). Two minor complications (4.2%) associated with Sprint Fidelis lead revision were observed: 1) right atrial lead dislodgement and 2) detachment of the distal part of the Sprint Fidelis lead (model type 6949) during manual traction, which required an extra intervention.

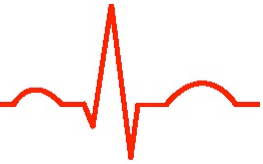


Table 3. Performance of the implanted ICD leads

	Sprint Fidelis (n=396)	Riata 8-F (n=165)	Riata 7-F (n=30)	Benchmark cohort (n=1602)
Active, n (%)	198 (50.0)	90 (54.5)	19 (63.3)	1063 (66.4)
Failed, n (%)	47 (11.9)	6 (3.6)	2 (6.7)	62 (3.9)
Non-active, n (%)	110 (27.8)	51 (30.9)	5 (16.7)	314 (19.6)
Died, n (%)	81 (20.4)	32 (19.4)	3 (10.0)	256 (16.0)
Prophylactically replaced or sealed, n (%)	12 (3.0)	0 (0.0)	0 (0.0)	0 (0.0
Replaced/sealed for other reasons, n (%)	7 (1.8)	2 (1.2)	1 (3.3)	15 (0.9)
Infection, n (%)	10 (2.5)	17 (10.3)	0 (0.0)	43 (2.7)
Followed up elsewhere, n (%)	41 (10.4)	18 (10.9)	4 (13.3)	163 (10.1)
Average follow-up, y	3.4±1.5	4.6±2.6	2.9±1.3	3.4±2.7
Total follow-up, y	1327.1	767.0	87.6	5449.3
Failure rate %/y	3.54	0.78	2.28	1.14

ICD = Implantable cardioverter defibrillator; F = French

Riata lead performance

Of the 195 implanted Riata leads, 165 leads had a diameter of 8-F and 30 leads a diameter of 7-F. During an average follow-up of 4.4±2.5 years, 8 (4.1%) leads implanted in 7 different patients failed. Due to the failure, 2 patients experienced a total of 11 inappropriate shocks. For 7-F leads, cumulative incidence of lead failure was 3.8% (95%CI 0-11.2) after 2 years and 8.0% (95%CI 0-18.8) after 4 years. For 8-F leads, cumulative incidence was 1.5% (95%CI 0-3.5%) after 2 years and 3.2% (95%CI 0.1-6.3%) after 4 years of follow-up (Figure 2). Average time from implant to lead failure was 1.9±0.5 years for 7-F leads and 3.8±2.3 years for 8-F leads.

Revision of the 8 failed leads resulted in removal of 3 leads and sealing of 5 leads. One complication occurred during these revisions, which consisted of right atrial lead dislodgement. One cardiac perforation (0.5%), caused by a 7-F Riata lead, model type 7002, was observed within 1 day following ICD implantation and confirmed by echocardiography.

Lead performance in benchmark cohort

In 1602 leads in the benchmark cohort, 62 cases (3.9%) of lead failure occurred during 3.4±2.7 years follow-up. Cumulative incidence of lead failure was 0.7% (95%CI 0.3-1.1%) after 2 years of follow-up, 3.4% (95%CI 2.2-4.6%) after 4 years, 8.3 % (95%CI 5.9-10.7%) after 6 years and 11.5% (95%CI 8.2-14.8%) after 8 years (Figure 1&2). Average time from implant to lead failure was 4.2±2.3 years.

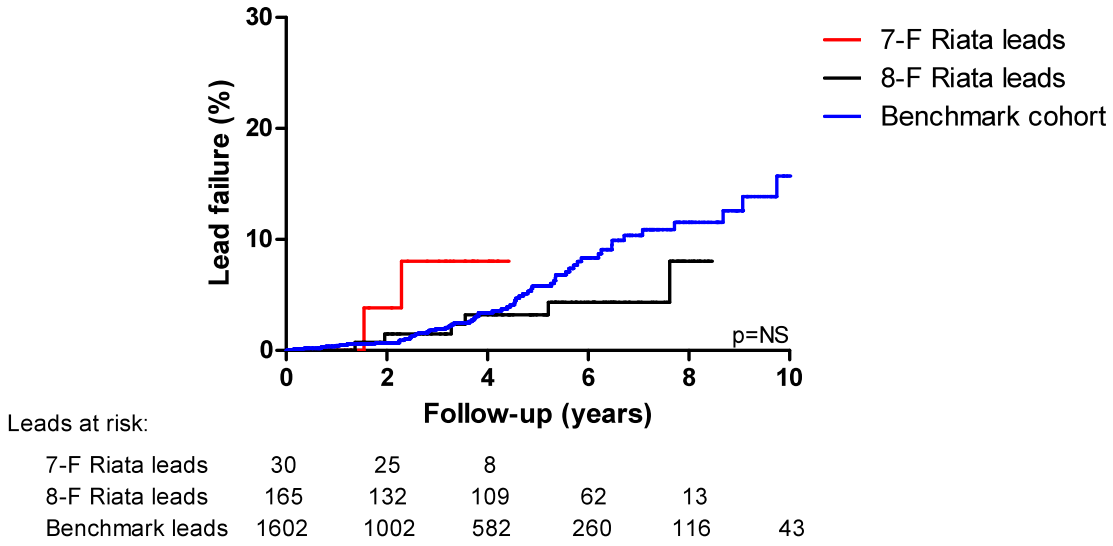


Figure 2. Failure of Riata leads. Kaplan Meier curve for cumulative incidences of lead failure, grouped by lead diameter (French).

Differences in failure rate

As can be seen in Table 2, major differences in failure rates were observed between the groups. Whereas the benchmark cohort and the 8-F Riata leads demonstrated yearly lead failure rates of 1.14% and 0.78%, respectively, the Sprint Fidelis showed a yearly lead of 3.54% and the 7-F Riata lead of 2.28%. The adjusted risk of failure was 3.7 times higher for Sprint Fidelis leads in comparison to the benchmark cohort (HR 3.7 95%CI 2.4-5.7, p<0.001) and 4.2 times higher for the Riata 7-F leads in comparison to benchmark cohort (HR 4.2 95%CI 1.0-18.0, p<0.05).

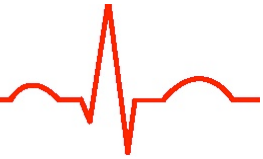
Discussion

The principal findings of this update study can be summarized as follows: 1) the risk for lead failure was significantly increased for both the Sprint Fidelis and the 7-F Riata lead as compared to a benchmark cohort, 2) implementation of Medtronic's safety advisories significantly reduced the number of inappropriate shocks, 3) cardiac perforations occurred rarely.

Sprint Fidelis lead performance

Three years after its introduction in 2004, Hauser et al. were first to report the higher-than-expected failure rate of Sprint Fidelis leads.[2] Within three months following this preliminary report, Medtronic suspended distribution and announced recommendations for impedance alert programming, followed one year later, by recommending the usage of remote monitoring and Lead Integrity Algorithm. Since then several studies have reported high yearly failure rates varying from 2.8% to 3.6%.[2, 14-16] The current study observed an overall yearly lead failure rate of 3.5% as compared to 1.1% in the benchmark cohort. Additionally, this failure rate accelerated over time: if a lead survived its first 3 years of follow-up, the failure rate for the following year increased up to 7.3%. This accelerating phenomenon was first described by Farwell et al. during a mean follow-up of 1.7 year and in the current study with an extended follow-up of 3.5 years, this was confirmed.[3] This sheds important light on the still ongoing discussion whether or not to replace the leads prophylactically, especially since an estimated 166000 Sprint Fidelis leads are still active worldwide.[17]

To come to a well-considered decision, one should realize that the risk of complications with lead revision is substantial. In literature, complication rates associated with revision/extraction of Sprint Fidelis leads vary. Whereas Maytin et al observed no major and only



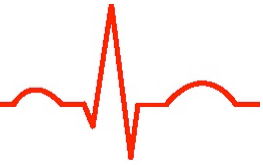
two minor complications in 348 patients who underwent Sprint Fidelis lead revision, Parkash et al reported on major complications in 7.0% and minor complications in 7.5% of 468 Sprint Fidelis lead revisions.[18, 19] Noteworthy, all revisions reported in the study by Maytin et al were performed by highly skilled operators with a large volume of experience.[18] In the current study, no major complications occurred and the minor complication rate was 4.2%. Overall, the complication rate is still too high to justify prophylactic lead replacement, although, taken in mind the accelerating risk of lead failure, over time the benefits of prophylactic lead replacement might outweigh the lead failure-related risks.

Riata lead and cardiac perforation

Around 2007, several studies and case reports observed higher-than-expected cardiac perforation rates in patients with a Riata lead. When taken these reports as a whole, the cardiac perforation rate was 2.5% which far exceeds registry data (<0.5%).[20] Hereafter, Danik et al demonstrated a comparable rate (2.8%) in a larger population with longer follow-up duration. However, they observed perforations only in patients with a specific Riata lead model type including 1580/1581 (8-F) and 7000 (7-F) and stated that similarities in design of the lead, rather than the size of the lead alone, might contributed to this relatively high complication rate.[5] In addition, Ellis and Rottman found comparable high risks of cardiac perforation for these specific lead types.[6]

In sharp contrast to the previous reports is an industry-sponsored study of the Riata lead, comprising more than 15 000 patients. They observed a perforation rate of 0.38% and owed the differences with the previous results to a statistical phenomenon.[21, 22] In the current study, only one perforation was observed in a patient with a Riata lead (0.5%) versus none in patients with a Sprint Fidelis lead, which is in accordance with the large registry studies.[21, 22]

Failure of the Riata lead



Interestingly, this study also demonstrated that the adjusted risk of failure for the 7-F Riata leads was more than four times higher than the benchmark cohort. This was earlier observed in a study by Ellis et al. who demonstrated in 62 patients with a 7-F Riata lead an even higher failure rate of 8.1% during a follow-up of less than 1 year.[6] And although this is preliminary data of a small cohort of 30 (this study) and 62 leads, the high lead failure rate is worrying. Again data of the multiple registry studies did not support this and reported a lead failure rate of <1%.[21, 22] However, it should be noted that data of industry driven studies are sometimes better than clinical practice studies – as was the case with data of Medtronic on the performance of the Sprint Fidelis lead.[14] For proper analysis, it is therefore essential to have a non-industry driven European or worldwide data registry.[23]

Limitations

The presented results are subjected to the usual limitations of a retrospective analysis. Furthermore, cases of lead failure and cardiac perforation might occur without symptoms or changes in electric parameters, causing them to go unnoticed.

Conclusion

From this study becomes clear that the risk of Sprint Fidelis lead failure continues to accelerate over time. Adverse events related to Sprint Fidelis lead failure were significantly reduced as a result of the safety advisories. A comparable failure rate was observed for the smallest 7-F Riata lead. In contrast, no higher-than-expected cardiac perforation rates were observed for the Sprint Fidelis and the Riata leads.

Reference List

1. Roelke M, O'Nunain SS, Osswald S, Garan H, Harthorne JW, Ruskin JN. Subclavian crush syndrome complicating transvenous cardioverter defibrillator systems. Pacing Clin Electrophysiol 1995;18:973-9.
2. Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. Heart Rhythm 2007;4:892-6.
3. Farwell D, Green MS, Lemery R, Gollob MH, Birnie DH. Accelerating risk of Fidelis lead fracture. Heart Rhythm 2008;5:1375-9.
4. Hauser RG, Hayes DL. Increasing hazard of Sprint Fidelis implantable cardioverter-defibrillator lead failure. Heart Rhythm 2009;6:605-10.
5. Danik SB, Mansour M, Heist EK, Ellinor P, Milan D, Singh J et al. Timing of delayed perforation with the St. Jude Riata lead: a single-center experience and a review of the literature. Heart Rhythm 2008;5:1667-72.
6. Ellis CR, Rottman JN. Increased rate of subacute lead complications with small-caliber implantable cardioverter-defibrillator leads. Heart Rhythm 2009;6:619-24.
7. Borleffs CJ, van EL, van Bommel RJ, van der Velde ET, van der Wall EE, Bax JJ et al. Risk of failure of transvenous implantable cardioverter-defibrillator leads. Circ Arrhythm Electrophysiol 2009;2:411-6.
8. Groves R; Sprint Fidelis Lead Performance Update (Models 6949, 6948, 6931, 6930). Minneapolis: Medtronic, May 7, 2008. (Accessed November 25, 2008, at http://www.medtronic.com/product-advisories/physician/sprint-fidelis/index.htm.). 2008 May.
9. Groves R; Urgent medical device information: Sprint Fidelis lead patient management recommendations. Minneapolis: Medtronic,October 15, 2007. (Accessed November 25, 2008, at http://www.medtronic.com/product-advisories/physician/sprint-fidelis/PROD-ADVISORY-OCT.htm). 2007 Oct.
10. van Rees JB, Borleffs CJ, Bax JJ, Nagtegaal EM, van der Velde ET, van EL et al. Implementation of lead safety recommendations. Pacing Clin Electrophysiol 2010;33:431-6.
11. Zipes DP, Camm AJ, Borggrefe M, Buxton AE, Chaitman B, Fromer M et al. ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (writing committee to develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Circulation 2006;114:e385-e484.
12. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA, III, 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 Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Circulation 2008;117:e350-e408.
13. Ha AC, Vezi BZ, Keren A, Alanazi H, Gollob MH, Green MS et al. Predictors of fracture risk of a small caliber implantable cardioverter defibrillator lead. Pacing Clin Electrophysiol 2010;33:437-43.

14. 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.
15. Kallinen LM, Hauser RG, Tang C, Melby DP, Almquist AK, Katsiyiannis WT et al. Lead integrity alert algorithm decreases inappropriate shocks in patients who have Sprint Fidelis pace-sense conductor fractures. Heart Rhythm 2010;7:1048-55.
16. Faulknier BA, Traub DM, Aktas MK, Aguila A, Rosero S, Daubert JP et al. Time-dependent risk of Fidelis lead failure. Am J Cardiol 2010;105:95-9.
17. Fischer A. How much scrutiny and stress can the Fidelis lead withstand? Circulation 2011;123:353-4.
18. Maytin M, Love CJ, Fischer A, Carrillo RG, Garisto JD, Bongiorni MG et al. Multicenter experience with extraction of the Sprint Fidelis implantable cardioverter-defibrillator lead. J Am Coll Cardiol 2010;56:646-50.
19. Parkash R, Crystal E, Bashir J, Simpson C, Birnie D, Sterns L et al. Complications associated with revision of Sprint Fidelis leads: report from the Canadian Heart Rhythm Society Device Advisory Committee. Circulation 2010;121:2384-7.
20. Lloyd MS, Shaik MN, Riley M, Langberg JJ. More late perforations with the Riata defibrillator lead from a high-volume center: an update on the numbers. Pacing Clin Electrophysiol 2008;31:784-5.
21. Epstein AE, Baker JH, Beau SL, Deering TF, Greenberg SM, Goldman DS. Performance of the St. Jude Medical Riata leads. Heart Rhythm 2009;6:204-9.
22. Porterfield JG, Porterfield LM, Kuck KH, Corbisiero R, Greenberg SM, Hindricks G et al. Clinical performance of the St. Jude Medical Riata defibrillation lead in a large patient population. J Cardiovasc Electrophysiol 2010;21:551-6.
23. Goette A, Cantu F, van EL, Geelen P, Halimi F, Merino JL et al. Performance and survival of transvenous defibrillation leads: need for a European data registry. Europace 2009;11:31-4.