Generator exchange is associated with an increased rate of Sprint Fidelis lead failure

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BACKGROUND The Medtronic Sprint Fidelis defibrillator lead is at an increased risk for failure and was recalled in October 2007. Approximately 268,000 leads were implanted, and more than 100,000 patients still have active Fidelis leads. A number of studies have examined the rate and clinical predictors of lead failure, but none has addressed the effect of an implantable cardioverter-defibrillator generator exchange on subsequent lead failure. Although the manufacturer asserts that "Sprint Fidelis performance after device change-out is similar to lead performance without device change-out," published data are lacking.

OBJECTIVE To assess the effect of implantable cardioverter-defibrillator generator exchange on the rate of Fidelis lead failure.

METHODS A chart review was conducted in patients who underwent implantation of a Fidelis lead. Patients with a functioning Fidelis lead at generator exchange were compared with controls with leads implanted for a comparable amount of time not undergoing ICD replacement.

RESULTS A total of 1366 patients received a Fidelis lead prior to the recall, of which 479 were still actively followed. Seventy-two patients with a functioning lead underwent generator exchange without lead replacement. Following generator replacement, 15 leads failed. Sixty percent of the Fidelis leads failed within 3 months. Generator exchange increased the rate of lead failure compared with matched controls (20.8% vs 2.54%; $P < .001$).

CONCLUSIONS Generator exchange is associated with a higher than expected rate of Fidelis lead failure, often within 3 months. The risk-benefit ratio of Fidelis lead replacement at the time of generator exchange may be greater than appreciated.

KEYWORDS Fidelis Lead; Generator exchange; Lead failure; Sprint Fidelis

ABBREVIATION ICD = implantable cardioverter-defibrillator

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Introduction

The Sprint Fidelis lead developed by Medtronic was smaller in diameter than previous models and was implanted in large numbers after it was introduced in the United States in September 2004. The lead was withdrawn from the market in October 2007 because of a higher than expected rate of failure during follow-up monitoring.[1] During these 3 years, more than 268,000 Sprint Fidelis leads were implanted, and even today, more than 100,000 patients still have an active Sprint Fidelis lead.[2] Failure of the Sprint Fidelis lead often manifests as oversensing from conductor fracture. Even with the enhanced monitoring recommended by the manufacturer, lead failure can lead to inappropriate shocks, and in rare instances, death.[3–6] Implantable cardioverter-defibrillator (lCD) lead replacement is also associated with significant risk. Even in experienced hands, ICD lead extraction has a major adverse event rate approaching 1%–1.5%.[7–9] Thus, there is considerable controversy regarding the management of patients with these leads. The difficult decision to reuse or replace a functioning Sprint Fidelis lead is often made at the time of ICD replacement. The manufacturer has asserted that the process of ICD generator replacement does not affect the performance of the Sprint Fidelis lead.[10] However, we noted several instances in which lead failure occurred shortly after a generator exchange. Therefore, the purpose of this study was to review our entire experience with this lead and assess the effect of ICD generator exchange on the rate of subsequent Sprint Fidelis lead failure.

Methods

All patients with Medtronic Sprint Fidelis (model number 6949) ICD leads followed at Emory University Hospital (Atlanta, GA) and Emory University Hospital Midtown (Atlanta, GA) that were implanted from September 2004 through October 2007 were included in the study. Data regarding ICD lead implantation and follow-up were collected prospectively at each center as part of our institutional ICD database. Within the study cohort, we identified a subset of patients undergoing generator exchange with a normally functioning Sprint Fidelis lead at the time of the ICD replacement procedure. Data regarding age, sex, ICD lead length, and the duration of the Fidelis implant in this

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Table 1 Cohort of Sprint Fidelis patients

Implanted	1366
Inactive	667
Deceased	220
Active	479
Age (y)	63.6 ± 9.7
Sex (male)	68.0%
Lead length (65 cm)	62.0%
Fidelis implant duration (mo)	60.2 ± 10.5

subgroup were extracted from the database. Additional information regarding height, weight, left ventricular ejection fraction, indication for ICD implantation, and ICD lead vascular introduction site were gathered from chart review. A control group was created with patients matched for Fidelis lead implant duration who did not undergo ICD replacement during follow-up.

A lead was categorized as a failure if rate-sensing impedance >1500 Ω, high-voltage impedance >100 Ω, or nonphysiologically short R-R intervals (<200 ms) triggered an alert. Patients with electrical noise on more than 1 stored electrogram were also considered to have lead failure, as were any patients who developed intermittent failure to capture.

Continuous variables are presented as a mean ± SD, and discrete variables are summarized by using group percentages. Comparisons between the subset of patients who underwent ICD generator replacement and matched controls were tested by using the Pearson χ^2 test or the Fisher exact test for continuous variables and the Student *t*-test for discrete variables. The relationship between patient demographics and device characteristics was subjected to univariate analysis by using Cox proportional hazards models. Unadjusted lead survival was estimated by utilizing the Kaplan-Meier method.

Results

Fidelis lead failure rate

The Emory healthcare ICD clinic database was analyzed, and we identified a total of 1366 patients who had received a Sprint Fidelis ICD lead. Of these, 667 were no longer followed by our center and 220 were deceased. The remaining 479 patients who continued to be actively followed at our center formed the study cohort (Table 1). Their mean age was 63.6 years, and 68% were men. The majority of Sprint Fidelis leads, 62%, were the 65 cm model, and the average time from Sprint Fidelis implant until data analysis was 60.2 months (Table 1). There were 67 Sprint Fidelis ICD lead fractures in the group of 479 patients actively followed at our institution. The estimated 5-year survival rate for Fidelis leads was 85.7% (95% confidence interval, 82.6–88.8) (Table 2). There were no significant differences in age, sex, or type of Fidelis lead in the group of patients with lead failure compared with those with normal lead function.

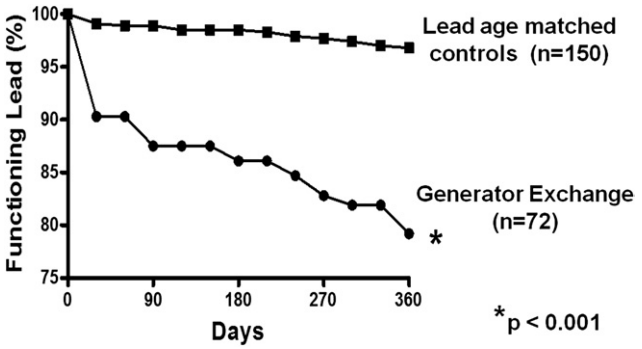

Figure 1 Sprint Fidelis lead failure after ICD replacement compared with age-matched controls. Seventy-two of the 479 cohort patients underwent elective replacement of their ICD. The performance of the Fidelis lead after replacement is shown in the circles compared with a group of 150 patients (squares) matched for Fidelis lead implant duration. The failure rate was 20.8% in the year following ICD generator replacement, compared with 2.5% in the controls ($P < .001$). ICD = implantable cardioverter-defibrillator.

Fidelis lead failure rate after generator exchange

During the study period, 72 of the 479 cohort patients underwent elective replacement of their ICD generator. The performance of the Fidelis lead after replacement in these 72 patients is shown in Figure 1. It was compared with that of a group of 150 patients who were matched for Fidelis implant duration with the patients in the generator exchange group. Even though the Fidelis leads were the same age, there was a failure rate of 20.8% in the year following ICD generator replacement, compared with 2.5% in the controls, a difference that was highly significant.

The 72 patients with Fidelis leads who had ICD generator replacement were compared with the controls matched for Fidelis implant duration (Table 3). There were no differences in age, sex, or length of lead used. This suggests that the replacement procedure, rather than demographic differences, was responsible for the dramatically higher failure rate in the ICD exchange group.

The distribution of Fidelis failure as a function of time after ICD replacement is shown in Figure 2. More than half of the lead failures occurred in the first 3 months after

Table 2 Comparison of Sprint Fidelis lead failure in 4 cohorts

	n	1 y	2 y	3 y	4 y	5 y
Current study failure rate (%)	479	1.3 (0.6–2.7)	3.3 (2.1–5.4)	6.9 (5.0–9.5)	11.9 (9.3–15.1)	14.0 (11.2–17.4)
Birnie et al failure rate (%)	2584	0.1 (0.04–0.4)	1.8 (1.3–2.5)	4.7 (3.8–5.7)	10.0 (8.5–11.7)	16.4 (13.8–19.5)
Hauser et al failure rate (%)	1023	0.2 (0–0.5)	2.6 (1.6–3.7)	7.4 (5.4–9.2)	13.0 (9.9–16.4)	
Carelink failure rate (%)	21500	0.3 (0.1–0.3)	1.3 (1.0–1.2)	3.5 (3.3–3.8)	6.4 (5.8–6.7)	9.1 (8.7–9.5)