Multicenter Experience With Extraction of the Sprint Fidelis Implantable Cardioverter-Defibrillator Lead

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Objectives
This study was undertaken to determine the safety and feasibility of extraction of the Sprint Fidelis (Medtronic, Minneapolis, Minnesota) lead.

Background
The reported failure rate of the Sprint Fidelis defibrillator lead has increased to a range greater than initially appreciated with emerging evidence of an accelerating rate of fracture. At present, consensus guidelines continue to recommend against prophylactic extraction of the lead, citing major complication rates between 1.4% and 7.3%. However, data regarding the safety and feasibility of extraction of small-diameter, backfilled implantable cardioverter-defibrillator leads such as the Sprint Fidelis are limited.

Methods
We performed a retrospective cohort study of consecutive patients undergoing extraction of Sprint Fidelis (models 6930, 6931, 6948, 6949) leads at 5 high-volume centers. Patient characteristics, indications for extraction, and use of countertraction sheath (CTS) assistance are reported. The risk of major and minor complications was determined. A multivariable logistic regression model was developed to predict factors associated with the use of CTS assistance.

Results
Between May 2005 and August 2009, 349 Sprint Fidelis leads were extracted from 348 patients. All leads were removed completely. The average duration of the implanted lead was 27.5 months (range 0.03 to 58.8 months). Approximately one-half of the extracted leads were fractured (49.4%), and 26.5% were extracted prophylactically. The other major indication for extraction was infection (22.8%). Extraction was achieved with simple traction in 49.4% leads; CTS assistance was required in 174 cases (50.6%). In multivariable models, length of time since implantation was directly related to the need for CTS assistance (odds ratio per month since implantation: 1.035; 95% confidence interval: 1.010 to 1.061; p = 0.006). There were no major procedural complications or deaths.

Conclusions
Extraction of the Sprint Fidelis lead can be performed safely by experienced operators at high-volume centers with a complication rate lower than that reported for older generation leads. However, leads with longer implant durations are associated with the use of CTS assistance. Recommendations regarding prophylactic Sprint Fidelis lead extraction may warrant reconsideration. (J Am Coll Cardiol 2010;56:646–50) © 2010 by the American College of Cardiology Foundation

The reported failure rate of the Sprint Fidelis defibrillator lead (Medtronic, Minneapolis, Minnesota) has increased to a range greater than initially appreciated with emerging evidence of an accelerating rate of fracture (1–3). With observed failure rates as high as 3.75% per year (3), the limitations of available programmable alerts and alarms...
(4–6), and the potential for significant morbidity and mortality (6,7), clinicians remain uncertain as to the best management of patients with active and failed Sprint Fidelis defibrillator leads. Available management options include observation (for functioning leads), adding a new implantable cardioverter-defibrillator (ICD) or pace sense lead to the system while abandoning the Fidelis lead, and extracting the Fidelis lead and reimplanting a new ICD lead.

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At present, consensus guidelines recommend against prophylactic extraction of the lead, citing major complication rates between 1.4% and 7.3% (8). These data cited by Medtronic regarding the risks of extraction are incomplete and not current (8). More recent registries at high-volume centers have reported high success rates with exceedingly low complication rates (0.4% to 0.9%) (9,10). Moreover, data regarding the safety and feasibility of extraction of a small-diameter, back-filled ICD leads such as the Sprint Fidelis, with a relatively short implant duration, are limited. This study examined the experience at 5 extraction referral centers with regard to extraction of the Sprint Fidelis lead and assessment of the morbidity and mortality of this procedure when performed by experienced, high-volume operators.

Methods

We identified a cohort of consecutive patients undergoing extraction of Medtronic Sprint Fidelis (models 6930, 6931, 6948, 6949) leads at 5 high-volume centers and retrospectively analyzed patient characteristics, procedural outcomes, and complications. The lead extraction technique used was the decision of the operator. All operators are highly skilled and well versed in all extraction modalities with a large volume of experience (>100 lead extractions/year). Patient characteristics and the indications, outcomes, and need for countertraction sheath (CTS) assistance were examined. Logistic regression analysis was performed to identify predictors of the use of CTS and to correct for possible confounders.

Outcomes were based on the most recent Heart Rhythm Society lead management consensus (11) and defined as follows: 1) complete procedural success if all targeted leads and lead material were removed from the vascular space; 2) clinical success if all targeted leads and lead material were removed but with retention of a small portion of the lead that does not negatively affect outcome goals; and 3) failure if neither complete procedural nor clinical success could be achieved. Major complications were defined as death; cardiac or vascular avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair; pulmonary embolism requiring surgical intervention; respiratory arrest or anesthesia complication leading to prolongation of hospitalization; stroke; and pacing system–related infection of a previously noninfected site; minor complications were defined as pericardial effusion not requiring pericardiocentesis or surgical intervention; hemothorax not requiring a chest tube; hematoma at the surgical site requiring reoperation for drainage; arm swelling or thrombosis of implant veins resulting in medical intervention; vascular repair near the implant site or venous entry site; hemodynamically significant air embolism; migrated lead fragment without sequelae; blood transfusion related to blood loss during surgery; pneumothorax requiring a chest tube; and pulmonary embolism not requiring surgical intervention. Patients were followed in-hospital, and 30-day procedure-related outcomes are reported.

Means, medians, and proportions for baseline clinical variables were calculated for the entire cohort. Continuous variables were expressed as mean ± SD or median and interquartile range (IQR). Chi-square tests were used to compare categorical variables. Student t tests were used to compare normally distributed continuous variables, and Wilcoxon rank sum tests were used for continuous variables that were not normally distributed. Logistic regression analysis was used to identify clinical variables associated with CTS assistance. Variables in the multivariable logistic regression model included age at extraction, sex, presence of infection, left ventricular ejection fraction, number of leads implanted, implant duration, and clinical site. Age at extraction and implant duration were modeled as continuous variables after the linearity assumption was tested. Missing value indicators were created for variables with missing covariate data (left ventricular ejection fraction and number of leads). All tests of significance were 2 sided, and a p value of <0.05 was considered significant. Statistical data analysis was performed using SAS version 9.1.3 (SAS Institute, Cary, North Carolina).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Baseline Patient Characteristics</th>
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<tbody>
<tr>
<td>Age (yrs)</td>
<td>60 ± 16</td>
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<tr>
<td>Male sex</td>
<td>73.3</td>
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<tr>
<td>Etiology of cardiomyopathy</td>
<td></td>
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<tr>
<td>Ischemic</td>
<td>47.6</td>
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<tr>
<td>Nonischemic</td>
<td>25.6</td>
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<tr>
<td>Other</td>
<td>26.2</td>
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<tr>
<td>Ejection fraction (%)</td>
<td>34 ± 15</td>
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<tr>
<td>New York Heart Association functional class (n)</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>28</td>
</tr>
<tr>
<td>II</td>
<td>30</td>
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<tr>
<td>III</td>
<td>36</td>
</tr>
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<td>IV</td>
<td>6</td>
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<td>ICD indication (primary prevention)</td>
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<tr>
<td>Number of implanted leads</td>
<td>2.2 ± 0.9</td>
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<tr>
<td>Previous cardiac surgery</td>
<td>34.6</td>
</tr>
<tr>
<td>Pacemaker dependence</td>
<td>22.9</td>
</tr>
</tbody>
</table>

Values are mean ± SD or % unless otherwise indicated. ICD = implantable cardioverter-defibrillator.
Results

Between May 2005 and August 2009, a total of 349 Sprint Fidelis leads were removed from 348 patients. Baseline characteristics are presented in Table 1. The mean patient age at the time of the procedure was 59.9 ± 16 years (median 63 years, IQR 50 to 72 years), and 74% were men. The majority (48%) of patients had underlying ischemic cardiomyopathy. Twenty-six percent had nonischemic cardiomyopathy, and the remainder had other cardiac conditions such as hypertrophic cardiomyopathy, cardiac sarcoid, and arrhythmogenic right ventricular cardiomyopathy. The mean ejection fraction was 34.1 ± 15.1% (median 31%, IQR 21% to 45%). The indication for device implantation was primary prevention in 75% of patients. Pacemaker dependence was present in 22% of patients, and 34% had previous cardiac surgery.

The predominant Sprint Fidelis lead model extracted was the dual-coil, active-fixation lead (model 6949, 80.4%), followed by the single-coil, active-fixation lead (model 6931, 10.0%), the dual-coil, passive-fixation lead (model 6948, 9.2%), and the single-coil, passive-fixation lead (model 6930, 0.4%). The average number of intravascular procedures was 2.2 ± 0.9 (range 1 to 5). The mean implant duration was 27.5 ± 14.2 months (median 27.6 months, IQR 17.4 to 37.4 months); the oldest lead was in place for 58.8 months. Indications for lead extraction are listed in Table 2. The most common indication was lead fracture (49.4%), followed by prophylactic reasons (26.5%) and infection (22.8%).

Complete procedural success was achieved in all procedures. Extraction was achieved with simple traction in 170 of 344 leads (49.4%). Powered CTS assistance was used with the Excimer Laser System (Spectranetics, Colorado Springs, Colorado) in 142 cases (41.9%) and the Evolution device (Cook Medical, Bloomington, Indiana) in 3 cases (0.9%). Mechanical CTS assistance with a telescoping sheath was used in 27 cases (7.9%).

In univariate analysis, CTS assistance was associated with a longer mean implant duration compared with leads extracted with simple traction (25.4 ± 14.7 months vs. 29.6 ± 13.7 months; p = 0.006) and younger age (odds ratio: 0.972; p = 0.0004). In multivariable analysis (Table 3), CTS assistance was significantly associated with longer lead implant duration, noninfected versus infected leads, and younger age. For each additional month’s duration of lead implant, the odds of requiring CTS assistance increased significantly by 3.5% (95% confidence interval: 1.01% to 1.06%). The presence of infection had the most dramatic impact on the need for CTS assistance. Patients with either local or systemic infection had markedly reduced odds of requiring CTS assistance (odds ratio: 0.15; 95% confidence interval: 0.041 to 0.572).

There were no major in-hospital complications associated with lead extraction. The mean estimated blood loss per procedure was 103 ± 65 ml (median 50 ml, IQR 20 to 100 ml). There were 2 minor procedural complications (0.57%). No procedure-related deaths occurred (Table 4). There were 3 in-hospital deaths due to overwhelming sepsis in patients who presented with sepsis/endocarditis.

Discussion

On October 15, 2007, Medtronic voluntarily suspended distribution of the Sprint Fidelis lead due to growing concerns regarding an abnormally high fracture rate with 665 lead failures and 5 potential resultant deaths (12). Initial performance reports from Medtronic did not identify a statistically significant difference in lead survival compared with other lead models such as the Sprint Quattro, although the difference was projected to reach statistical significance if the failure rate remained constant. Recommendations regarding management included routine monitoring with adjustment of impedance alarm thresholds. Medtronic and its Independent Physician Quality Panel deemed the current failure rate of 2.3% at 30 months inadequate to justify prophylactic lead replacement, citing major complication rates of extraction between 1.4% and 7.3% (8,13–15).

Since this initial report, several groups have reported observations of higher failure rates (2,3,16). Krahn et al. (16) described a 3.91% failure rate at 32 months in a cohort of 6,215 leads implanted in multiple centers across Canada. Subsequently, Hauser and Hayes (3) reported a significantly higher
observed fracture rate of 3.75% per year with an estimated 3-year survival rate of 87.9% in a series of 848 leads implanted at 2 centers. Despite these reports and evidence of an exponentially increasing rate of failure (2), Medtronic has continued to recommend against extraction, stating that the “risk of prophylactic intervention appears to be greater than the risk of serious injury resulting from lead fracture” (7).

We provide the first data regarding the safety and feasibility of transvenous extraction of the Sprint Fidelis lead. In our experience with 349 Sprint Fidelis leads, we observed complete procedural success in all cases with no major complications or procedure-related deaths regardless of the method of extraction. The minor in-hospital complication rate was 0.57% and well within reported complication rates for device implantation (17). The minor complications seen in this cohort were not associated with the lead extraction itself; rather, they are risks associated with any cardiac rhythm device implant. As is the case with extraction of other leads (14,18,19), we found that lead implant duration, younger patient age, and the absence of infection were associated with a significant increase in the need for CTS assistance, thereby increasing the complexity of the extraction procedure.

The management of patients with an implanted Sprint Fidelis ICD lead is challenging. Pocket or systemic infection is a class 1 indication for complete device and lead removal. Therefore, in the setting of a device-related infection, management of a patient with a Sprint Fidelis lead is a straightforward decision. The management of noninfected patients with a fractured or functional Sprint Fidelis ICD lead is more difficult. The options include adding a new pace-sense lead, adding a new ICD lead, and extracting and replacing the fractured lead. The risks of each of these options need to be carefully considered on a case-by-case basis as stated in the 2009 Heart Rhythm Society Expert Consensus document on transvenous lead extraction (11). The first option of adding a pace-sense lead is suboptimal given the 10% failure rate of the high-voltage portion of the lead (10), particularly among patients with fractured leads that have already demonstrated failure of 1 component. The first and second options require consideration of the risks associated with abandoned leads, data for which are both contradictory and limited. The reported complication rates of abandoned leads vary widely from insignificant to 20%, with the majority of available data from abandoned pacemaker and not defibrillator leads (20–25). Most authorities would agree that the incontrovertible risks of defibrillator lead abandonment are related to the potential need for future extraction, with 1 report of the risk of extraction doubling every 3 years (15) and the higher number of leads present at the time of extraction increasing the rate of potential complications (26). In the present study, we demonstrate that the risks associated with the third option, lead extraction, when performed in experienced centers, are low enough to consider extraction of fractured Sprint Fidelis leads as a primary approach, especially among younger patients. In our cohort of 348 patients and 349 Sprint Fidelis leads, there were no deaths or major complications.

In the present study, we also demonstrated that for each month since the initial implantation of the Sprint Fidelis lead, the odds of requiring CTS assistance increase significantly by 3.5%. Given the exponential failure rate for the Sprint Fidelis ICD lead (1–3), these data raise the concern that a strategy of surveillance followed by removal only when the lead fails may not be the best strategy. Although leaving the lead intact with implementation of the Lead Integrity Alert software patch (Medtronic, Minneapolis, Minnesota) is “expected to provide three days advance notice prior to inappropriate therapy to 76% of the patients with lead fractures” (7), its utility remains to be tested (4–6). ICD lead fracture is associated with significant morbidity and even mortality. The fracture can result in nondelivery of pacing or defibrillator therapy, which can be particularly dangerous in patients who are pacemaker dependent, have a history of appropriate therapy, or received their device for a secondary prevention indication (2,6). Inappropriate shocks have significant negative psychological effects (27), and, although rare, inappropriate therapy can induce a life-threatening arrhythmia, which may not be treated due to lead failure (6). In addition, recent studies suggest that inappropriate shocks themselves can have a negative impact on mortality (28–30). Therefore, in patients in whom lead failure could be particularly dangerous and who may be at higher risk of failure (young age, normal ejection fraction, noncatheter access, right-sided implants, subpectoral position) (2,31), consideration of prophylactic extraction, especially at the time of generator change, when the risk of pocket infection is already present, may also be warranted.

Decisions regarding extraction of the Sprint Fidelis lead must be made on a case-by-case basis considering multiple patient- and physician-related variables. An invasive approach, with the potential for significant morbidity and mortality, may not be warranted in patients with a poor prognosis or in whom the risks of intervention clearly outweigh the benefits. In addition, lead extractions should not be performed by those inexperienced in the procedure, by those without the necessary tools available to attain complete success, or in a setting not prepared and committed to the complete and safe performance of the procedure.

**Study limitations.** The major limitation of this study is that it represents a retrospective analysis of the experience of 5 high-volume centers. As such, these data and outcomes may not be replicated in the general community. We are, therefore, not advocating the widespread extraction of Sprint Fidelis leads. Deaths have been reported in patients undergoing Sprint Fidelis extraction (7). In addition, this study was not designed to compare different approaches to the management of patients with a Sprint Fidelis lead. Therefore, no definitive conclusions regarding optimal management can be drawn from this study. Finally, follow-up was limited to the index hospitalization and the immediate post-procedure period. Given the referral nature
of the population and the lack of long-term follow-up, late complications could be unrecognized.

**Conclusions**

In this multicenter experience, transvenous extraction of the Sprint Fidelis lead was performed with a 100% success rate and a low rate of minor complications, with no associated major complications or mortality. Independent predictors of the need for CTS assistance included longer lead implant duration, younger patient age, and the absence of a device-related infection. We are not advocating that all Sprint Fidelis leads be extracted. The present study demonstrates that, in selected patients and in experienced hands, the current recommendations regarding Sprint Fidelis lead extraction warrant reconsideration.

**Addendum**

Since manuscript submission, the authors have performed an additional 208 Fidelis lead extractions for a total of 557 leads removed with 100% complete procedural success. There were no major complications and no procedural deaths. The authors believe that this additional data emphasizes that transvenous extraction of the Sprint Fidelis lead can be a safe procedure in experienced hands.

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**REFERENCES**


**Key Words**: implantable cardioverter-defibrillator • lead extraction • lead management.