Clinical Predictors of Fidelis Lead Failure
Report From the Canadian Heart Rhythm Society Device Committee

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Background—Approximately 268 000 Fidelis leads were implanted worldwide until distribution was suspended because of a high rate of early failure. Careful analyses of predictors of increased lead failure hazard are required to help direct future lead design and also to inform decision making on lead replacement. We sought to perform a comprehensive analysis of all potential predictors in a multicenter study.

Methods and Results—A total of 3169 Sprint Fidelis leads were implanted in 11 centers with a total of 251 failures. Lead failure rates at 3, 4, and 5 years were 5.3%, 10.6%, and 16.8%, respectively. The rate of lead failure continues to accelerate (P<0.001). There were 4 independent predictors of failure: center, sex, access vein, and previous lead failure. Women had a higher hazard of failure (hazard ratio 1.51; 95% confidence interval, 1.14–2.04; P=0.005). Both axillary and subclavian access increased the hazard of failure (P=0.007); hazard ratio for axillary was 1.94, (95% confidence interval, 1.23–3.04) and for subclavian 1.63 (95% confidence interval, 1.08–2.46). Previous lead failure increased the hazard of a subsequent Fidelis failure with a hazard ratio of 3.12 (95% confidence interval, 1.80–5.41; P<0.001).

Conclusions—The rate of Fidelis failure continues to increase over time, with failures approaching 17% at 5 years. Women, patients with leads inserted via the subclavian or axillary vein, and those with a previous lead fracture were at greatest risk of Fidelis failure. Our data suggest that Fidelis replacement should be strongly considered at the time of generator replacement. (Circulation. 2012;125:1217-1225.)

Key Words: implantable cardioverter-defibrillator ■ lead failure ■ advisory ■ predictors ■ failure rate

Sprint Fidelis is a 6.6 French bipolar high-voltage implantable cardioverter-defibrillator (ICD) lead (Medtronic Inc, Minneapolis, MN). The lead was approved by Health Canada in 2004 and ~268 000 leads were implanted worldwide.1 Concerns about the early failure rate of the lead were first reported in April 2007.2 On October 15, 2007, the manufacturer suspended distribution of Sprint Fidelis leads.3 Subsequent single-center studies have demonstrated accelerating failure rates,3–5 but there is clear intercenter variation in failure rates.6–7 Also, the independent, single, and limited multicenter reported failure rates are generally higher3–5,8 than the manufacturer’s self-reported data.6 It is possible that this discrepancy relates, in part or entirely, to reporting bias (ie, higher–failure rate centers more likely to publish). Remote monitoring provides an unprecedented opportunity to track the outcome of a large number of leads but lacks information on patients and implant factors that influence lead performance. Hence, there is a need for large-scale multicenter independent lead failure data.

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Careful analyses of predictors of increased lead failure hazard are required to help direct future lead design and also to inform decision making on lead replacement. This is particularly important because the Fidelis cohort is reaching elective generator replacement. Previous studies have suggested that younger age,8–9 female sex,8 and higher4,10 or preserved8 left ventricular ejection fraction predispose to failure. However, previous studies had small sample sizes, incomplete data on potential predictors, or both. We sought to perform a comprehensive analysis of all potential predictors in a multicenter study.

Methods

Center Selection Process

All 23 adult Canadian ICD-implantation centers participate in the Canadian Heart Rhythm Society Device Committee. The nature and mandate of the Canadian Heart Rhythm Society Device Committee
has been previously described. All centers reported their center-specific failure rates. The centers were then stratified into high and low failure rate centers (above and below median). The median center and 5 centers from each strata were selected using a random methods selection process. The aim was to follow up 50% of all Fidelis leads implanted in Canada.

Data Retrieval
The study was coordinated by the University of Ottawa Heart Institute Cardiovascular Methods Centre. The central study coordinator trained data abstractors at each site. All sites had device clinic databases that were interrogated to obtain a complete list of Fidelis implants. Only Fidelis leads implanted at the 11 sites were eligible for inclusion. However, if a patient subsequently was transferred to another ICD follow-up center, then that center (regardless of whether it was one of the 11 selected sites) was contacted for full follow-up details.

Clinical and device interrogation data were retrieved from the site ICD databases. Additional data were obtained from local clinical records. The following data were abstracted on all Fidelis patients from all selected centers; demographics, lead model, patient and lead status, details of diagnosis of failure, clinical action taken when lead failed, and potential predictors of failure (including age, number of additional leads/procedures, implantation vein, left ventricular ejection fraction [LVEF], and underlying heart disease). All data entry was performed locally with Web-based electronic case report forms.

Definitions and Classification
Lead failure was defined as a sudden rise in long-term pacing or defibrillation impedance and/or inappropriate shocks (IS) secondary to sensing of electric noise artifacts from nonphysiological make-break potentials, and a clinical decision to remove the Fidelis lead from service and lose set screw replaced at replacement.

For analysis, patients were classified into 3 groups of cardiac disease: patients with cardiomyopathy with left ventricular dysfunction, patients with hypertrophic cardiomyopathy (HOCM), and patients with normal left ventricular function. The third group included patients with arrhythmogenic right ventricular cardiomyopathy (ARVC), primary electrical disease (PED), idiopathic ventricular fibrillation (IVF), and congenital heart disease (CongHD).

Statistical Analysis
The study database was developed, maintained, and analyzed at the University of Ottawa Heart Institute Cardiovascular Methods Center. Kaplan-Meier analysis was performed to plot failure rates. Failure hazards for Sprint Fidelis stratified by access vein, lead type, and gender were compared using the log-rank test. The estimate of the hazards for Sprint Fidelis stratified by access vein, lead type, and gender were compared using the log-rank test. The median follow-up was 3.4 (interquartile range 2.1, 4.2) years. Baseline demographics are shown in Table 1. During follow-up, 524 patients (16.5%) died, 202 leads (6.4%) were electively replaced, and 69 (2.2%) were removed from service for other reasons (41 because of cardiac transplantation and 26 because of system infection).

There were a total of 251 failures. Lead failure rates at 1, 2, 3, 4, and 5 years were 0.2%, 2.1%, 5.3%, 10.6%, and 16.8%, respectively (see Figure 1). Figure 2 shows failure rates for the entire cohort stratified by lead model. Data for 6930 is not shown because of the small number of leads (n=7). Table 2 compares model 6949 lead failure with 3 published cohorts. Lead failure rates at 1, 2, 3, 4, and 5 years for model 6949 were 0.2%, 1.8%, 4.7%, 9.9%, and 16.6%.

Hazard of Fidelis Failure With Time
The rate of failure increased significantly with time. The equation is $\log(h(t)) = -4.61 + 1.28\log(t)$. Because the slope parameter $b$ is 1.28 (ie, $>1$), it indicates that the risk of fracture is increasing over time. (95% confidence interval [CI] for $b$: 1.17–1.38; $P<0.001$; $R^2=0.87$).

Presentation of Sprint Fidelis Failure
The failure was in the pace/sense circuit in 229 (92.0%) patients and in the high voltage circuit in 20 (8.0%) and unknown in 2 cases. The majority of patients (130, 52.0%) presented with alert tones and no IS, 103 (41.0%) patients presented with IS, and 11 (4.4%) presented with symptomatic inhibition of pacing. In 121 patients, the lead integrity alert (LIA) had been uploaded before the patients presented with failure. In 127 patients, the LIA had not been uploaded; the status of the other 3 patients was unknown. The 2 groups were not different in terms of all other baseline and demographic details (data not shown). In the latter group, 65/127 (51.2%) presented with inappropriate shock(s), in contrast to the former group where 37/121 patients (30.6%, $P<0.001$) presented with inappropriate shock(s). However, the median number of shocks was the same in the patients presenting with IS, with or without LIA (median of 6 in both groups, $P=0.605$).

Predictors of Lead Failure in Whole Cohort
Table 3 shows univariate analysis of baseline characteristics with failure. The failure rate for model 6931 (single coil, active fixation) was 47/391 (12.02%), for model 6949 (dual coil, active fixation), 189/2584 (7.31%), and for model 6948...
Women had a higher hazard of failure (hazard ratio 1.51, 95% CI 1.14–2.04, \(P=0.005\)). Figure 3 shows failure by sex (log rank \(P<0.001\)).

**Predictors of Lead Failure in Patients in Whom Fidelis Was Not Inserted at First Device Surgery**

Table 5 shows the multivariable analysis in the 406 patients in whom Fidelis was not inserted at first device surgery. In this subgroup, there were 38 Fidelis failures. Of these 38 patients, 17/38 (44.7%) had a previous lead failure compared with 56/368 patients (15.2%) who had not had a Fidelis failure (\(P<0.001\)). In multivariable analysis, a history of a previous (non-Fidelis) lead failure increased the hazard of a subsequent Fidelis failure, with a hazard ratio of 3.12 (95% CI 1.80–5.41, \(P<0.001\)).

Table 6 shows forecasted failure rates. If the failure rate plateaus at the year 5 failure rate (ie, 6.2%/y), then it can be estimated that over the subsequent 5 years 386/1631 leads (23.7%) will fail.

**Discussion**

This large, independent, multicenter study of 3169 Fidelis leads shows that the rate of failure continues to accelerate, with 3-, 4-, and 5-year lead-failure rates of 5.3%, 10.6%, and 16.8%, respectively. Multivariable predictors of increased hazard of lead failure included patient and implant variables: female sex, center, and noncephalic access. In addition, in the subgroup of patients in whom Fidelis was not inserted at first surgery, a history of any previous lead failure was a very important predictor of subsequent Fidelis failure. Finally, we found that use of the LIA reduced the proportion of lead failures that presented with IS.

The failure rate of Fidelis leads in this study and other reports is higher than Medtronic has reported from its own data. This is possibly explained, at least in part, by variable center failure rates and perhaps bias toward reporting of data from centers with higher rates. In the current study, we controlled for this by selecting centers from high and low strata of failure rate. Another explanation for the discrepancy between the result of this study and Medtronic data may relate to the country of origin of the respective data. This study was performed in Canada whereas the largest of the Medtronic postmarket studies is from the United States. There are some important differences in the demographics of patients receiving ICDs in the 2 countries. For example, 27% of ICD recipients were female in the US NCDR (226,764 implants). By comparison in this study 18.2% of patients were female which is consistent with other Canadian data.

We and others have shown that gender is a predictor of lead failure, and hence to some extent, the higher failure rate in our study might be explained by population demographics.

It is unclear why there is intercenter variation in failure rates. In our study, this variation was independent of multiple patient and implant factors. It is possible that other unmeasured implant factors (eg, pocket wrap or lead slack) or patient factors are important in this regard.
This is the first independent publication to examine whether Fidelis lead submodels have different failure rates. Previous publications have largely focused on model 6949, which reflects the overwhelming market share. We found that the failure rate for 6931 (single coil, active fixation) was 12.02%, for model 6949 (dual coil, active fixation), 7.31%, and for model 6948 (dual coil, passive fixation), 4.84%. These relative data are similar to the results of Medtronic.6 It

![Figure 1. Survival curve for failure in total cohort (95% CI in broken lines). CI indicates confidence interval.](image1)

![Figure 2. Survival curve for failure by model of Fidelis. CI indicates confidence interval.](image2)
is unclear why the 6931 failure rate is significantly higher. Many physicians prefer single-coil leads in younger patients without significant structural heart disease because these patients are more likely to need lead extraction in the future. The passive-fixation lead had the lowest failure rate. Olgun et al recently showed similar results in non-Fidelis ICD leads (ie, that active ICD leads have higher failure rates) in 264 children receiving a wide range of leads.

Female sex increased the hazard of failure. This finding is consistent with data from other Fidelis studies.\(^6\)\(^-\)\(^8\) This lead-specific observation and its magnitude are consistent with the report by Kleemann et al in 990 patients receiving a variety of ICD leads (none were Fidelis).\(^13\) In that study, the hazard ratio for failure was 1.61 for female sex. It has been suggested that differences in vascular anatomy may be the explanation for sex findings; further research is necessary. Together these data suggest that similar stresses may contribute to failure in Fidelis (in an accelerated fashion) and non-Fidelis ICD leads. This highlights that lessons learned from the Fidelis experience should be integrated into future ICD lead design.

Both axillary and subclavian access increased the hazard of failure compared with cephalic access. The relative merits of cephalic vein cut-down compared with subclavian puncture lead implantation have been debated for many years.\(^18\) Also, in the last 15 years alternative techniques to avoid subclavian crush have been suggested, including more lateral subclavian vein puncture\(^19\) and axillary vein access.\(^20\) There are few contemporary data comparing these newer approaches with cephalic vein access. The 3 largest studies of ICD failure, Kleemann et al (990 patients),\(^13\) Hauser et al (1023 patients),\(^7\) and Ecksten et al (1317 patients)\(^21\) did not report data on access vein. Two of the small single-center Fidelis publications did have data on access vein, and both studies did not find that vein was predictive. However, both were likely underpowered to detect differences, with only 18 and 26 failures.\(^8\)\(^-\)\(^9\) Bonney\(^22\) examined ICD lead failure in 70 pediatric patients with access obtained via cephalic cut-down in 66/70. They found lead failure to be similar to adult rates of ICD lead failure. Recently, Erkapic\(^23\) reported on 357 patients who received 7 French ICD leads with a total of 30 lead failures (8%). Lead access via the subclavian vein (compared with cephalic access) was 1 of 2 independent predictors of lead failure, with an odds ratio of 3.47. These data and the data from our study suggest that the debate about the relative merits of cephalic versus noncephalic access should be revisited. Certainly it is likely that newer techniques avoid classic subclavian crush, but additional mechanisms of lead failure may be important. Possibilities include the lead traversing through the pectoral muscles and in particular the angle of passage through the pectoral muscle, which can approach 90° in some techniques of axillary vein access.\(^20\)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Hazard Ratio (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at implantation, mean±SD*</td>
<td>0.99 (0.98–1.00)</td>
<td>0.016</td>
</tr>
<tr>
<td>Women</td>
<td>1.56 (1.18–2.08)</td>
<td>0.002</td>
</tr>
<tr>
<td>BMI, mean±SD*</td>
<td>0.99 (0.97–1.02)</td>
<td>0.529</td>
</tr>
<tr>
<td>Primary prevention indication for ICD</td>
<td>0.96 (0.73–1.25)</td>
<td>0.740</td>
</tr>
<tr>
<td>Pathogenesis of cardiac disease</td>
<td>0.036</td>
<td></td>
</tr>
<tr>
<td>Cardiomyopathy with LV dysfunction</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>HOCM</td>
<td>2.19 (1.03–4.64)</td>
<td></td>
</tr>
<tr>
<td>ARVC, PED, IVF, CongHD</td>
<td>1.52 (0.93–2.49)</td>
<td></td>
</tr>
<tr>
<td>Previous lead failure(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>≥1</td>
<td>3.30 (2.14–5.08)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fidelis lead inserted at first device surgery</td>
<td>0.77 (0.54–1.08)</td>
<td>0.133</td>
</tr>
<tr>
<td>No. of ipsilateral leads after Fidelis implantation</td>
<td>0.98 (0.84–1.15)</td>
<td>0.795</td>
</tr>
<tr>
<td>Access vein for Fidelis</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>Cephalic</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Axillary</td>
<td>2.18 (1.45–3.27)</td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td>1.53 (1.08–2.18)</td>
<td></td>
</tr>
<tr>
<td>LVEF %, mean±SD**</td>
<td>1.01 (1.00–1.02)</td>
<td>0.026</td>
</tr>
<tr>
<td>Center</td>
<td>0.002</td>
<td></td>
</tr>
</tbody>
</table>

*For each 10 years.
**For each 10% absolute change.

ICD indicates implantable cardioverter-defibrillator; LV, left ventricle; HOCM, hypertrophic cardiomyopathy; ARVC, arrhythmogenic right ventricular cardiomyopathy; PED, primary electrical disease; IVF, idiopathic ventricular fibrillation; CongHD, congenital heart disease; and LVEF, left ventricular ejection fraction.

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**Table 4. Multivariable Cox Model for Failure**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Hazard Ratio (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>1.51 (1.14–2.04)</td>
<td>0.005</td>
</tr>
<tr>
<td>Access vein for Fidelis</td>
<td>0.007</td>
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<tr>
<td>Cephalic</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Axillary</td>
<td>1.94 (1.23–3.04)</td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td>1.63 (1.08–2.46)</td>
<td></td>
</tr>
<tr>
<td>Center</td>
<td>0.016</td>
<td></td>
</tr>
</tbody>
</table>

Model prediction ability: Harrel C-index: 0.84 (0.74–0.91).

Seven variables (age at implantation, gender, pathogenesis of cardiac disease, model No., previous device, access vein for Fidelis, and center) with P<0.2 in the univariable analysis were included in the model, and only 3 variables remained (P<0.05). History of previous failure was not included in the model (see text for explanation). CI indicates confidence interval.
We found that a previous lead failure was an important predictor of Fidelis failure in the subgroup of 406 patients in whom Fidelis was not inserted at first device surgery. In this subgroup, there were 38 Fidelis failures. Of these 38 patients, 17/38 (44.7%) had had a previous lead failure compared with 56/368 of patients (15.2%) who had not had a Fidelis failure ($P<0.001$). These data are similar to those of a recent study from Eckstein et al.\textsuperscript{21} They followed 38 patients who had had ICD lead malfunction for an average of a further 3.1 years and found that 6 of these 38 patients experienced recurrent lead failure. The cumulative incidence of lead failure recurrence was nearly 10 times the incidence of first failure.\textsuperscript{21} These data support the widespread anecdote that there are a group of patients who for unknown reasons have recurrent ICD lead failures. The explanation is unclear but needs further investigation; however, it should be noted that in this high-risk subgroup cephalic vein access still significantly reduced the hazard of recurrent failure. This suggests that after an initial noncephalic lead failure, replacement leads ideally should be inserted via the cephalic vein.

The LIA algorithm was designed to improve early detection of transient pace sense conductor failures and to decrease the incidence and number of IS.\textsuperscript{24} Reducing IS is critically important because nearly half of these patients are left with clinical levels of anxiety and/or depression after shocks.\textsuperscript{25} In our study, before LIA upload 51.2% of patients presented with IS. After LIA upload, 30.6% of patients presented with IS ($P<0.001$). These data point in a similar direction, although with less magnitude, as 2 previous single-center experiences.\textsuperscript{26,27} Inappropriate shocks were a first sign of lead failure in 69%\textsuperscript{26} and 52%\textsuperscript{27} of patients preceding LIA and in only 17%\textsuperscript{26} and 21%\textsuperscript{27} of patients after LIA was uploaded. Both studies also reported that, in patients presenting with IS, the mean number of shocks was reduced; however, we did not observe this in our study. One potential explanation for the discrepancy in results may be the different rates of remote monitoring in the studies. CareLink was introduced later in Canada than in the United States, and the incremental benefit of remote monitoring with LIA has been clearly shown. In patients with LIA and wireless CareLink, only 2 of 14 patients (14%) received IS; among patients with LIA and no wireless CareLink, 26% received IS.\textsuperscript{27}

Our study has a number of limitations. We had no data on the site of lead failure in our individual cases. Returned product analysis has show that the lead usually fails near the anchor sleeve or close to the tip of the lead.\textsuperscript{24} It is likely that a different balance of factors predisposes to failure at the 2 sites. Also, we had no data on other aspects of implant technique. (examples include extent of lead manipulation before final positioning and role of operator experience and use of fellows in training).

**Clinical Implications**

The physician panel of Medtronic advises a conservative management approach in most patients (ie, replacement after failure).\textsuperscript{28} However, many of these patients are approaching elective pulse generator replacement, and the risks/benefit ratio is therefore considerably different. Many factors should
be considered when discussing whether to replace (with or without extraction) Fidelis at the time of generator change. The risks of Fidelis extraction are somewhat controversial, with one study suggesting significant morbidity. However, a recent study found no major complications or deaths at 5 high-volume extraction centers. These replacement risks have to be weighed against the risks of not replacing Fidelis (ie, the estimated risk of failure and the potential clinical sequelae of a failure). The potential clinical sequelae of a failure include a risk of IS of perhaps 14% to 30%, with half of patients presenting with IS subsequently suffering clinically important levels of anxiety, depression, or both. In addition, many other factors have to be considered in decision making, including the number of ipsilateral leads, the remaining vascular access, patient age, comorbidities, and life expectancy. If the ipsilateral vein is patent, then the addition of a new lead without extraction is reasonable. If extraction is indicated, then this should be performed at experienced centers.

Our study can be used to estimate the projected risk of failure in patient subgroups. Obviously, these risk estimates have a number of caveats. Most importantly, it is unclear whether the rate of failure will plateau or continue to accelerate. If the failure rate plateaus at the year-5 rate of 6.2%, then it can be estimated that over the subsequent 5 years (potential lifetime of a new generator) the risk of failure can be estimated to be 23.7%. However, if the failure rate continues to accelerate then the 5-year risk of failure is likely much higher. We also identified a number of high-risk subgroups (women, patients with noncephalic access, and patients with previous non-Fidelis lead failures). In conclusion, our data suggest that Fidelis replacement should be strongly considered in most patients at the time of generator replacement.

Two final clinical implications are firstly our findings of higher failure rates related to noncephalic access. Physicians should consider cephalic access as the primary access for all ICD lead implantation. Finally, reducing IS is critically important levels of anxiety, depression, or both. In addition, many other factors have to be considered in decision making, including the number of ipsilateral leads, the remaining vascular access, patient age, comorbidities, and life expectancy. If the ipsilateral vein is patent, then the addition of a new lead without extraction is reasonable. If extraction is indicated, then this should be performed at experienced centers.

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Table 5. Multivariable Analysis of Baseline Characteristics With Failure in Patients in Whom Fidelis Was Not Implanted at First Device Surgery

<table>
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<tr>
<th>Variables</th>
<th>Hazard Ratio (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous lead failure(s)</td>
<td>3.12 (1.80–5.41)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Access vein for Fidelis</td>
<td>0.048</td>
<td></td>
</tr>
<tr>
<td>Cephalic</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Axillary</td>
<td>3.53 (0.81–15.4)</td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td>1.69 (0.39–7.27)</td>
<td></td>
</tr>
</tbody>
</table>

Model prediction ability: Harrel C-index: 0.72 (0.39, 0.97).

Four variables (age at implantation, previous lead failure[s], model No., and access vein for Fidelis) with P<0.2 in the univariable analysis were included in the multivariable Cox model and only 2 variables remained (P<0.05 in the final model). CI indicates confidence interval.
important for patients’ psychological well-being. In our study, before LIA upload 51.2% of patients presented with IS; in contrast, after LIA upload 30.6% of patients presented with IS (P < 0.001). Hence, although the use of LIA has been somewhat helpful, significant numbers of patients still receive IS and therefore further work is required to improve LIA and other similar software.

Conclusions

This large, independent, multicenter study of 3169 Fidelis leads shows that the hazard of failure continues to accelerate, with 3-, 4-, and 5-year lead failure rates of 5.3%, 10.6%, and 16.8%, respectively. Multivariable predictors of increased hazard of lead failure were female sex, center, and non-cathodic access. In addition, in the subgroup of patients in whom Fidelis was not inserted at first surgery a history of any previous lead failure was a very important predictor of subsequent Fidelis failure. Our data suggest that Fidelis replacement should be strongly considered in most patients at the time of generator change.

Acknowledgments

We thank Karen MacDonald for coordinating the project, My Linh Tran for database support, and Lily Chen for statistical analysis. We also thank research staff at the 11 centers.

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Disclosures

Dr Birnie and F. Ayala-Paredes have received speaker honoraria and research grants from Medtronic of Canada. Dr Essebag has received speaker honoraria from Medtronic of Canada. The other authors report no conflicts.

References


Approximately 268,000 Fidelis leads were implanted until distribution was suspended because of a high rate of early failure. Careful analyses of predictors of increased lead-failure hazard are required to help direct future lead design and also to inform decision making on lead replacement. We sought to perform a comprehensive analysis of all potential predictors in a multicenter study. Lead failure rates at 3, 4, and 5 years lead were 5.3%, 10.6%, and 16.8%, respectively. We found that the rate of lead failure continues to accelerate with time. There were 4 independent predictors of higher hazard of failure: center, female gender, noncephalic access vein, and previous lead failure. The major clinical implication of our study relates to management of nonfailed leads at the time of elective pulse generator change. If the failure rate plateaus, then the addition of a new lead without extraction is reasonable. If extraction is indicated, then this should be performed at experienced centers.

**CLINICAL PERSPECTIVE**

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