Complications Associated With Revision of Sprint Fidelis Leads
Report From the Canadian Heart Rhythm Society Device Advisory Committee

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Background—It has been observed that replacement of an implantable cardioverter-defibrillator generator in response to a device advisory may be associated with a substantial rate of complications, including death. The risk of lead revision in response to a lead advisory has not been determined previously.

Methods and Results—Twenty-five implantable cardioverter-defibrillator implantation and follow-up centers from the Canadian Heart Rhythm Society Device Advisory Committee were surveyed to assess complication rates as a result of lead revisions due to the Sprint Fidelis advisory issued in October 2007. As of June 1, 2009, there had been 310 lead failures found in 6237 Sprint Fidelis leads in Canada (4.97%) over a follow-up of 40 months. There were 469 leads to be revised, 66% for confirmed fracture. Of the patients who underwent revision, 95% had a new lead inserted, whereas 4% had a pace/sense lead added. The lead was removed in 248 cases (53%), by simple traction in 61% and by laser lead extraction in 33%. Complications were encountered in 14.5% of the lead revisions; 7.25% of these were major, whereas 7.25% were minor. There were 2 deaths (0.43%). The overall risk of complications (19.8%) was greater in those who underwent lead removal at the time of revision than in those whose leads were abandoned (8.6%; \( P=0.0008 \)).

Conclusions—The overall rate of major complications that arose from lead revision due to the Sprint Fidelis advisory was significant. This must be taken into account when lead revision is planned in those patients who have not yet demonstrated an abnormality in lead performance. (Circulation. 2010;121:2384-2387.)

Key Words: complications • follow-up studies • implantable defibrillators

The Canadian Heart Rhythm Society Device Advisory Committee has reported previously on the increased risk of generator replacement associated with device advisories.1,2 The Sprint Fidelis lead advisory was issued in October 20073 and affected 6415 leads in Canada and 245,000 worldwide.4 The rate of fracture was initially thought to be approximately 1% to 1.5% per year, accelerating to approximately 3% at 30 months.3 Recent data suggest the risk increases by 2.74-fold per year after implantation and that the risk is higher than originally projected.5 Up to 50% of patients with lead fractures may present with inappropriate shocks, some with severe psychological impairment due to the number of shocks received.5 Lead Integrity Alert software (Medtronic, Minneapolis, Minn) only recently became available in Canada and has reduced the incidence of this kind of presentation.6 Routine prophylactic replacement of the Sprint Fidelis lead has not been practiced widely owing to the known risks associated with lead revision, which include infection, hematoma, and, in the case of laser lead extraction, a 0.5% to
2.0% mortality risk. Lead replacement at the time of pulse generator replacement is often considered and has been practiced widely. Given the increasing risk of lead failure, prophylactic replacement of all Sprint Fidelis leads has also been considered. The decision to replace a lead routinely or at generator replacement must include a weighing of the risks of lead revision against the risks of lead failure. Using an established cross-country network, the Canadian Heart Rhythm Society Device Advisory Committee sought to determine the complications associated with lead revision in the Canadian cohort of Sprint Fidelis lead recipients to provide guidance in this matter.

Clinical Perspective on p 2387

Methods

All 25 Canadian implantable cardioverter-defibrillator implantation centers were approached to participate in a survey of outcomes of the Fidelis lead advisory. The Queen Elizabeth II Health Sciences Ethics Review Board approved the study. All centers agreed to participate in the survey process and obtained ethics approval if necessary in each respective center. Only leads that were followed up in Canada were included (n=6237).

Survey

The survey questionnaire was circulated to a working group identified to review it for clarity, content, and ease of use. The working group arrived at the final survey through consensus. The data collected in the survey were divided into 4 areas: (1) Frequency of lead failure, including inappropriate shocks; (2) success and failure of lead removal, including laser lead extraction versus simple traction; (3) the reason for revision (lead fracture, at the time of pulse generator change, preventively for pacemaker dependence, secondary prevention, or other reasons); and (4) follow-up data related to complications.

Definitions

Lead failure was defined as nonphysiological high-rate sensing with a high pacing impedance that suggested fracture, a sudden change in sensing or pacing impedance, or a rise in high-voltage impedance that suggested coil fracture that led to a decision to perform lead replacement, as described previously. The local investigator at each center identified whether or not a lead was fractured.

Outcomes

The main outcome of this survey was complication rate as a result of lead revision associated with the Sprint Fidelis lead. Early (<30 days) and late (>30 days) complications were recorded, along with details of the nature of complications observed. Determination of whether or not the lead was removed successfully was taken into account for each complication. Major complications after or during lead revision included death, cardiac arrest, nonfatal myocardial infarction, cardiogenic shock, and any other complications that required reoperation. Minor complications included pneumothorax, deep venous thrombosis, incisional infection, and wound hematoma that did not require reoperation, as well as any other complication not already classified as a major complication.

Statistical Analysis

Continuous variables were analyzed as mean±SD. Categorical variables were analyzed as percentages unless otherwise specified. Differences among groups were determined with the \( \chi^2 \) test; \( P<0.05 \) was considered statistically significant.

Results

Data were obtained from 25 implantable cardioverter-defibrillator implantation and follow-up centers, which represented all 6237 Sprint Fidelis leads implanted from market release (July 2004) until product withdrawal (October 2007) and followed up in Canada. As of June 1, 2009, there were 310 leads with lead failures (4.97%) over an estimated 40 months of follow-up, 145 of which resulted in inappropriate shocks (3.1% overall, 43.0% of all fractures).

A further 159 leads were revised for other reasons (Table 1), which resulted in 469 leads (7.52%) that were deemed to be revised. Of these, a new defibrillation lead was inserted in 443 cases (94.5%), whereas in 25 cases (5.3%), only a pace/sense lead was added. In 1 case of confirmed fracture, the patient refused to have a revision, which left 468 leads that underwent revision. The lead was explanted in 248 cases (53%); this was done by simple traction in 163 cases (66%), by laser lead extraction in 82 cases (33%), and with nonpowered extraction tools in 3 cases (1%). Failed traction without formal lead extraction led to lead abandonment in an additional 51 patients (11%). No attempt at removal was made in the remainder of the patients (n=169).

Complications

Complications are summarized in Table 2. The total number of complications was 68, which resulted in a rate of 14.5% of total leads revised. There were 34 major complications (7.25%) and 34 minor complications (7.25%).

Major Complications

The major complications included death in 2 cases (0.43%), cardiac arrest in 2 cases (0.43%, both successfully resuscitated), superior vena cava tear requiring urgent surgery in 1 case (0.21%), and a complication that required reoperation in 29 cases (6.23%). The 2 deaths occurred early postoperatively. One was due to pneumonia in a patient whose lead was abandoned, and this death was not directly related to the procedure; the second was due to postoperative sepsis after reoperation for a wound hematoma in a patient whose lead had been removed.

Minor Complications

The minor complications included incisional infection in 19 patients who did not require intervention and were treated with antibiotics (3.84%), wound hematoma in 7 patients (1.49%), and other causes in 9 patients (1.92%). There was a greater rate of overall complications observed in procedures in which a lead was removed than in those in which the lead was abandoned (19.8% versus 8.6%, \( P=0.0008 \); Figure). The

Table 1. Reasons for Sprint Fidelis Lead Revision (in a Total of 468 Revised Leads)

<table>
<thead>
<tr>
<th>Reason for Revision</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead failure</td>
<td>310 (66.2)</td>
</tr>
<tr>
<td>Pacemaker dependence</td>
<td>12 (2.6)</td>
</tr>
<tr>
<td>At time of PG change or upgrade to CRT</td>
<td>41 (8.7)</td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>15 (3.2)</td>
</tr>
<tr>
<td>Patient choice</td>
<td>11 (2.3)</td>
</tr>
<tr>
<td>Infection</td>
<td>29 (6.2)</td>
</tr>
<tr>
<td>Lead dislodgement</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>Transplant</td>
<td>8 (1.7)</td>
</tr>
<tr>
<td>Other lead problem*</td>
<td>37 (7.7)</td>
</tr>
</tbody>
</table>

PG indicates pulse generator; CRT, cardiac resynchronization therapy.

*Other lead problem includes high pacing threshold, T-wave oversensing, damage during procedure, set screw problem, and poor sensing of R wave.
Table 2. Complications Associated With Sprint Fidelis Revision

<table>
<thead>
<tr>
<th>Complications</th>
<th>Lead Removed (n=248)</th>
<th>Lead Abandoned (n=220)</th>
<th>All (n=468)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>49 (19.8)</td>
<td>19 (8.6)</td>
<td>68 (14.5)</td>
</tr>
<tr>
<td>Major complications</td>
<td>20 (8.1)</td>
<td>13 (5.9)</td>
<td>33 (7.0)</td>
</tr>
<tr>
<td>Death</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>2 (0.43)</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>2 (0.43)</td>
</tr>
<tr>
<td>Need for reoperation</td>
<td>18 (7.3)</td>
<td>11 (5.0)</td>
<td>29 (6.2)</td>
</tr>
<tr>
<td>SVC tear during laser lead extraction</td>
<td>1 (0.4)</td>
<td>0</td>
<td>1 (0.21)</td>
</tr>
<tr>
<td>Infection that required system removal</td>
<td>7 (2.8)</td>
<td>2 (0.9)</td>
<td>9 (1.9)</td>
</tr>
<tr>
<td>Hematoma that required intervention</td>
<td>4 (1.6)</td>
<td>0</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>Lead dislodgement/set screw</td>
<td>6 (2.4)</td>
<td>9 (4.1)</td>
<td>15 (3.2)</td>
</tr>
<tr>
<td>Minor complications</td>
<td>29 (11.7)</td>
<td>6 (2.8)</td>
<td>35 (7.5)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>3 (1.2)</td>
<td>0</td>
<td>3 (0.64)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>0</td>
<td>1 (0.5)</td>
<td>2 (0.43)</td>
</tr>
<tr>
<td>DVT of left arm</td>
<td>2 (0.8)</td>
<td>0</td>
<td>2 (0.43)</td>
</tr>
<tr>
<td>Infection that did not require system removal</td>
<td>16 (6.5)</td>
<td>3 (1.4)</td>
<td>19 (4.1)</td>
</tr>
<tr>
<td>Hematoma that did not require intervention</td>
<td>6 (2.4)</td>
<td>1 (0.5)</td>
<td>7 (1.5)</td>
</tr>
<tr>
<td>Other (anemia, desaturation)</td>
<td>1 (0.4)</td>
<td>1 (0.5)</td>
<td>2 (0.43)</td>
</tr>
</tbody>
</table>

SVC indicates superior vena cava; DVT, deep venous thrombosis. Values are n (%).

The rate of major complications, however, was similar in those patients whose leads were not removed (5.9% versus 8.1% in patients whose lead was removed, \( P=0.1826 \)). Minor complications were more common in the group in whom the lead was removed (11.7% versus 2.8%, \( P=0.0003 \)). There was no difference in mortality between the 2 groups (0.45% for lead removed versus 0.40% for lead not removed, \( P=0.8314 \)).

Discussion

In this national survey, we report the complications associated with revisions that have occurred in response to the Sprint Fidelis advisory issued in October 2007. Since that time, there have been a substantial number of failures of this lead, now amounting to 4.97% over 40 months. At this point in time, the overall complication rate (among patients undergoing lead revision) of 14.5% is higher than the Sprint Fidelis failure rate, as is the 7.25% major complication rate, which in the present series included death, cardiac arrest, and complications that resulted in reoperation. The overall mortality rate among patients whose leads were removed was not significantly different from that of those whose leads were left in place.

This is the first study to systematically report on the complication rate that results from lead revision due to an advisory. The overall complication rate was marginally higher than what has been reported in the most recent REPLACE registry results. The total percentage of complications after generator change was 10.9% in that study, with major complications accounting for 4.2%. The higher rate of complications seen in the present study cohort is not unexpected, because the nature of the procedures was considerably more complex than simple generator replacement. Nearly 100% of patients underwent a lead revision with a new lead inserted, and in 17% of cases, a laser lead extraction was performed. The mortality rate in those who underwent lead extraction was similar to what has been reported in the literature.

There are several issues that must be highlighted in interpretation of the observed complication rate. Some of the centers that performed laser lead extraction were low-volume extraction centers; hence, some of the observed complications may not have occurred had the procedures been performed at high-volume extraction centers. Hauser and Hayes reported 1 complication of pocket infection in 90 patients who underwent lead extraction as a result of the Sprint Fidelis advisory at 2 high-volume centers. Patient-specific data on lead age before extraction were not available in the present study. Presumably, those leads that were extracted earlier after implantation may have been easier to remove, whereas older leads would be more likely to require formal extraction, with an associated increase in complications. It is difficult to interpret whether this was the case because of the overall small number of complications in patients who underwent laser lead extraction. Finally, the indication for lead extraction may have been responsible for the observed complications, rather than the extraction itself.

Arrhythmia device management has become increasingly complex in the face of the recent increase in the number of advisories. Decision making surrounding these advisories can be extraordinarily difficult, because the data to judge the risk-benefit association for the affected patients often are not available. The Canadian Heart Rhythm Society Device Advisory Committee has reported previously that the risk of complications outweighed the benefit in response to a device generator advisory. In the present case, the answer may not be as straightforward. Although the risk of major complications is substantial, the risk of lead failure is approaching the same rate. Presumably, the complication rate remains static or may even decrease as we become more aware of the risks associated with such procedures and take further precautions to avoid hematomas, infections, and other issues that result in reoperation. It remains unclear how to treat a confirmed fracture or how to treat those patients undergoing a generator change or other lead revision.

There are 2 questions that remain difficult to answer: How should patients who have no sign of fracture be handled? Should
pacemaker-dependent patients or patients at high risk of recurrent implantable cardioverter-defibrillator therapy undergo prophylactic lead revision? The data from this report suggest that careful observation might be prudent in the group of patients who have had no sign of fracture. In the situation in which patients are pacemaker dependent or at high risk of recurrent therapy, current data suggest that the risk of serious complication from failure of the lead, such as syncope or death due to lack of pacing output or death due to untreated ventricular tachycardia/ventricular fibrillation, is low. In a study examining lead fractures at 2 US centers, Hauser and Hayes noted 1 episode of syncope and no deaths attributable to lead malfunction in examination of 3037 leads (0.03%). These observations must be weighed against the apparent progressive failure rate of this lead and the serious outcomes that might occur in pacemaker-dependent patients, which warrants a more aggressive approach. Individualized decisions based on risk versus benefit are imperative in such a scenario.

The main limitation of the present study is that only summary data were collected. Patient factors such as age and left ventricular function and lead factors such as implantation considerations or age of the lead that may have contributed to complications were not explored. The balance of time-dependent lead failure and progressive lead fibrosis suggests that the challenge of lead removal will increase over time, necessitating formal lead extraction with its attendant risks. This balance must be considered in patients with high use of their lead, including pacemaker-dependent patients. Future studies are required to inform this challenging decision-making process. Lead abandonment was associated with fewer complications in the present report. Follow-up was limited to 40 months, and therefore, data on late complications that might occur from lead abandonment, such as venous thrombosis, stenosis, or a higher risk of late lead extraction, were not captured.

Conclusions
The risk of complications associated with lead revision due to an advisory is significant. Given the increasing prevalence of lead fracture associated with this advisory, however, revision at the time of pulse generator change or other intervention resulting in opening of the pocket may be warranted. Further data on risk factors for lead fracture will be helpful in advising patients of the risk and benefit associated with replacing leads affected by an advisory.

Disclosures
Dr Parkash has received research grants from Medtronic Inc and St Jude Medical. Drs Crystal, Exner, and Thibault have received grant support from Medtronic, St Jude Medical, Boston Scientific, and Sorin/ELA. Dr Birnie has received grant support from Medtronic. Dr Verma has received honoraria and research grants from St Jude Medical, Biosense Webster, Medtronic Inc, Sanofi Aventis, and Boehringer-Ingelheim. Dr Essebag has received honoraria and minor speaker fees from Medtronic Inc. Dr Sanatani has received honoraria from Medtronic. The remaining authors report no conflicts.

References

CLINICAL PERSPECTIVE
It has been observed that implantable cardioverter-defibrillator generator replacement in response to a device advisory may be associated with a substantial rate of complications, including death. We sought to determine the risk of lead revision in response to a lead advisory, which has not been determined previously. Twenty-five implantable cardioverter-defibrillator implantation and follow-up centers from the Canadian Heart Rhythm Society Device Advisory Committee were surveyed to assess complications rates as a result of lead revision due to the Sprint Fidelis advisory issued in October 2007. Complications were encountered in 14.5% of the lead revisions. There were 2 deaths (0.43%). The overall risk of complications (19.8%) was greater among those who underwent lead removal at the time of revision than among those whose leads were abandoned (8.6%; P=0.0008). The risk of complications associated with lead revision due to an advisory is significant. Given the increasing prevalence of lead fracture associated with this advisory (4.97%), however, revision at the time of pulse generator change or other intervention that results in opening of the pocket may be warranted. The present data suggest that lead abandonment at the time of revision may be associated with a lower complication rate. Further data on risk factors for lead fracture will be helpful in advising patients of the risk and benefit in replacing leads affected by an advisory.
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