An Increase In Complications Due To Surgical Revision Of Defective Sprint Fidelis Leads

Lead Wire Extraction Surgery Might Be More Hazardous Than Once Thought, Including Serious Cardiovascular Injuries And Deaths

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 30, 2010; see http://bit.ly/9N7UhU)

The Sprint Fidelis lead wire, a heart defibrillator cable made by Medtronic, was removed from the market in October 2007 due to a defect that caused it to malfunction, which may have resulted in at least five patient deaths.

An April 7, 2009 *New York Times* news report by Barry Meier, "Removing Medtronic Heart Cables Is Hard Choice", describes what was the then-current thinking about the consequences for patients who had one of these defective Sprint Fidelis leads -- and things have seemingly gotten worse for them since then:

> But only now is the full scope of the public health problem becoming clear for the Sprint Fidelis, which is still used by 150,000 people in this country.
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> In the next few years, thousands of those patients may face risky surgical procedures to remove and replace the electrical cable, which connects a defibrillator to a chamber of the heart.
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> Medtronic estimates that the cable has failed in a little more than 5 percent of patients after 45 months of being implanted. But as a preventive measure, some patients with working cables are having them removed.
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> Already, four patients have died during extractions. Experts fear that the toll could quickly rise if such procedures are not performed by skilled doctors at medical centers that have performed many of the operations.
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> "I think we are just seeing the tip of the iceberg," said Dr. Charles J. Love, a cardiologist at Ohio State University Medical Center in Columbus, who specializes in cable extractions.

As regards how things may be worse now, to begin, I will quickly touch upon the failure rate aspect by referring back to a couple of articles which I posted here in the past:

From December 2009: "Sprint Fidelis Lead Wire Failure Rate Could Rise To 30 Percent By Four Years" -- About 260,000 Medtronic Sprint Fidelis Leads Were Implanted In US, With Approximately 143,000 Still Active

From February 2010: "There Is Disagreement Over The Three-Year Failure Rate For Sprint Fidelis Lead Wires"-- Medtronic Says 4.6 Percent Of Leads Failed, While Reports From Some Hospitals Indicate 9.2 Percent Of Sprint Fidelis Wires Failed

We turn next to the surgical complications aspect. We will start with an April 2010 *Medscape* article, "Deaths and Cardiovascular Injuries Due to Device-assisted Implantable Cardioverter–Defibrillator and Pacemaker Lead Extraction" (free registration required) by Robert G. Hauser, M.D. -- who has been an active participant in the debate about the consequences of the Sprint Fidelis recall -- and colleagues. From this Dr. Hauser article, we get these points:

- The controversy surrounding the management of patients who have Sprint Fidelis ICD leads and the report of deaths associated with Sprint Fidelis lead extraction prompted us to examine the worldwide adverse events that have been reported by manufacturers, hospitals, and health providers to the US Food and Drug Administration (FDA). The aim of this study was to determine whether complications due to device-assisted lead extraction might be more hazardous than available data suggest, and whether procedural safety precautions, including standby cardiothoracic surgery, are effective. [footnotes omitted]
- This study shows that device-assisted lead extraction has resulted in fatal cardiovascular injuries often despite emergency surgical intervention. Moreover, the majority of the reported deaths have occurred in the last 2 years, and most of them were caused by lacerations of major veins during

laser or mechanical dilator sheath extractions. This finding is timely and important because more than 100 000 patients have underperforming Sprint Fidelis ICD leads that may require replacement. Medtronic has announced that 4 of the 13 deaths due to fractures of Sprint Fidelis leads were associated with the extraction of the failed lead.

- **Conclusion** These findings suggest that device-assisted lead extraction is a high-risk procedure and that serious complications including death may not be mitigated by emergency surgery. However, skilled standby cardiothoracic surgery is essential when performing pacemaker and ICD lead extractions. Although the incidence of these complications is unknown,...

And the last part of that Conclusion, above, makes especially significant this June 2010 article, "Complications Associated With Revision of Sprint Fidelis Leads", published by the medical journal *Circulation*. From the Abstract for this article:

> ***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.
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> ***Methods and Results***— .... 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).
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> ***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.

So the patient who still has a defective Sprint Fidelis lead wire implanted is probably being advised to keep it in place until a break or fracture occurs -- which potentially causes a massive unnecessary shock to the patient's heart, or causes the defibrillator battery to go dead and the implantable heart device fails to deliver a necessary life-saving shock.

If and when the Sprint Fidelis lead wire breaks or fractures, then the patient is faced with a revision surgery which appears to be associated with a significant rate of hazardous, and possibly fatal, complications.

In the end, it seems relatively clear that this is quite an unfortunate situation to be in for any such patient.

P.S. "Psychological Adjustment in ICD Patients Living With Advisory Fidelis Leads", published early -- August 19, 2010 -- online by *The Journal of Cardiovascular Electrophysiology*.

From the Abstract:

- This study focused on the Sprint Fidelis advisory.
- The study had 2 objectives: (1) to examine whether there is adverse psychological adjustment when an ICD is under advisory, and (2) to assess the psychological sequel of advisory ICD component malfunction.
- On one side, the risk of device malfunction and the likely severity of clinical sequelae have to be estimated. This estimate has to be weighed against the risks of surgery to replace the advisory component.
