Sprint Fidelis leads can be safely extracted in high-volume facilities

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Extraction of the Sprint Fidelis lead (Medtronic) can be safely performed in an experienced large volume center, according to research presented at the 2011 Heart Rhythm Society (HRS) conference in San Francisco last week.

The Sprint Fidelis lead has been associated with increased failure rate which resulted in the lead being removed from the market in 2007. However, even if the lead does not fail, physicians are tasked with the decision as to whether or not to prophylactically remove the Sprint Fidelis leads, explained the study's lead author Raed H. Abdelhadi, MD, a cardiac electrophysiologist at the Minneapolis Heart Institute® at Abbott Northwestern Hospital in Minneapolis.

While recent studies have shown a discrepancy in complication rates with Sprint Fidelis lead extraction, research has also demonstrated "unacceptable" failure rates, said Abdelhadi. However, there are a large number of these leads still implanted, as it was a popular lead when it was first approved by the FDA. At Minneapolis Heart Institute® alone, physicians implanted approximately 570 Sprint Fidelis leads.

"Traditionally, providers are hesitant to extract leads due to the reportedly high complication rates with the procedure," Abdelhadi explained.

Therefore, to better understand the complication rates and help guide management of patients with such leads, the researchers examined 148

patients with Medtronic Sprint Fidelis leads who underwent lead extraction at the Minneapolis Heart Institute® of Abbott Northwestern Hospital between April 2006 and July 2009.

According to the researchers, all procedures were performed by experienced electrophysiologists who met all of the training requirements set forth by the HRS.

Of the 148 Sprint Fidelis leads that were extracted, 46 percent were removed due to lead failure, 46 percent were removed prophylactically and 7 percent were removed due to infection. The average duration of the implanted leads was 36.2 months.

Of the extracted leads, 55 percent were removed by manual traction, 42 percent required the use Excimer laser sheath (SLS II, Spectranetics) and 3 percent were removed using mechanical sheaths.

All extractions were completed successfully, with no deaths or major complications associated with the extraction procedure, Abdelhadi reported.

Overall, there were three minor complications (two patients had thrombosis of the implant vein and one patient had pulmonary embolism, all were treated with anticoagulation) resulting in a 2 percent minor complication rate.

"Our results are consistent with a recent U.S. multi-center study, evaluating lead extraction among high-volume institutions," said Abdelhadi. "Understanding the actual complication rates is important because it can help providers to make decisions in properly managing this distinct patient population."

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