MedicalXpress

Recalled ICD leads fail in women, youths most often

January 31 2011

The recalled Sprint Fidelis implantable cardioverter-defibrillator (ICD) leads (Medtronic) failed more often in younger patients, women, and individuals with hereditary heart disease, according to a multicenter study published online Jan. 17 in *Circulation*. The researchers found that lead failure was not associated with death or serious injuries.

However, about half of the patients whose leads fractured experienced painful inappropriate shocks, according to lead author Robert G. Hauser, MD, of the Minneapolis Heart Institute® at Abbott Northwestern Hospital. In a previous study, published in HeartRhythm in 2010, Hauser and colleagues found these inappropriate shocks could be mitigated by a software program available in Medtronic ICDs.

The manufacturer voluntarily removed Sprint Fidelis leads from the market in 2007 after 268,000 were implanted globally. Currently, more than 100,000 patients have Fidelis leads.

In this observational study, 1,023 Fidelis and 1,668 Quattro leads were implanted and followed at three centers (Minneapolis Heart Institute® in Minneapolis, Mayo Clinic in Rochester, Minn., and Beth Israel Deaconess Medical Center in Boston) from November 2001 to January 2009

"We were particularly interested in whether Fidelis leads were continuing to fail, in whom they were failing and what the implications might be for those patients," Hauser says. "We found that patients who

were young and active with relatively normal pump function were at highest risk, as well as women compared with men."

The researchers found the failure rate for Fidelis leads was 2.81 percent per year, compared with 0.43 percent per year for Quattro Secure leads, also manufactured by Medtronic.. The authors described the Quattro failure rate as being "well below the suggested benchmark of 0.6 percent per year. The survival of Fidelis leads at four years was 87 percent, compared with 98.7 percent for Quattro leads

These findings could have significant implications for the management of patients who have Fidelis leads. While Fidelis continue to fail, Hauser and his colleagues conclude that there is currently no indication for arbitrarily replacing leads in patients who were indicated for ICDs, particularly due to the potential risk with the replacement procedures.

"Only in the hands of experienced operators should Fidelis lead replacement even be considered in these younger patients or women, who are expected to live with an ICD for a number of years," Hauser stresses.

Provided by Minneapolis Heart Institute Foundation