# Cameron Health touts positive study results of lead-less ICD

Mass Device

Cameron Health Inc. is touting a clinical trial of its subcutaneous implantable cardiac defibrillator, which eliminates the need for threading electrical leads through blood vessels to the heart.

Results from the study of the San Clemente, Calif.-based -based company's S-ICD System were published in the *New England Journal of Medicine* this week.

In conventional ICDs, the transvenous wiring eventually becomes enveloped by tissue, leading to the bulk of the complications stemming from ICD implantations. They're also difficult to repair or replace should something go awry, as occurred with Medtronic Inc.'s (NYSE:MDT) Sprint Fidelis leads. The leads were wont to fracture after implantation, leading to a massive recall, and were implicated in 100 deaths. A class action lawsuit covering 600 cases was eventually dismissed on preemption grounds, because the leads were FDA-approved [1].

Cameron Health Inc. developed its new defibrillator and sponsored the study [2], which was presented May 12 at the Heart Rhythm Society's 31st Annual Scientific Sessions in Denver, Colo. The study indicated [3] that the device was as effective as traditional ICDs but needed to supply about three times as much electricity. In a six-patient pilot study in which 18 episodes of ventricular fibrillation were induced, all were detected and all sustained episodes were successfully converted. A 55-patient single-arm trial, all sustained ventricular fibrillation episodes were detected and 98 percent of patients satisfied implant testing criteria, according to a press release. A 330-patient Food & Drug Administration trial of the device began last month.

Despite the early success of Cameron Health's device, transvenous leads aren't going away anytime soon: Boston Scientific Corp. (NYSE:BSX) won FDA clearance for a new device for implanting CRT leads [4] designed make the procedure safer.

SOURCE [5]

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