Long-term performance of the Medtronic Sprint Fidelis lead: a matter of lead type?

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AIMS
In 2007, the Medtronic™ Sprint Fidelis(®) lead was withdrawn from the market due to elevated failure rates. Since then, several studies were published with failure rates between 1.3 and 3.75%/year. However, they included a very high percentage of active fixation leads. Data in a population with passive leads are missing.

METHODS AND RESULTS
All 166 patients who received a Fidelis lead between December 2004 and October 2007 in two teaching hospitals were identified. We excluded nine patients with incomplete data and 18 with active fixation leads. The study population thus consists of 139 patients with passive leads. Pacing and high-voltage impedance values were systematically collected at implant and in intervals of 6 months. Follow-up was 49 ± 15 months. All leads were 6948 models. During a follow-up of 41 ± 15 months, nine leads (6.5%) failed. Annual failure rate was 1.9%/year (95% CI 0.4-4.2), cumulative 5-year survival 95.8%. There were no differences between leads used in resynchronization and non-resynchronization devices (8.9 and 5.3%, P value 0.47).

CONCLUSION
In a population with only passive leads, the Fidelis lead exhibited an impaired long-term survival, but performance was better than in previous studies in which >90% of leads were active models.