

The Medtronic Sprint Fidelis® lead history revisited-Extended follow-up of passive leads

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BACKGROUND

Due to high failure rates, Medtronic withdrew the Sprint Fidelis lead (SFL) from the market. Passive fixation lead models exhibited better survival than active models, but most studies have limited follow-up. Aim of this study was to give insights into passive lead survival with a follow-up of 10 years.

METHODS

In two large Swiss centers, patients with passive SFLs were identified and data from routine implantable cardioverter defibrillator (ICD) follow-ups were collected. Patients were censored at time of death, last device interrogation (if lost to follow-up), time of lead revision (in non-SFL-related problems), or at database closure (31st December 2017). We defined lead failure as any of the following: lead fracture with inappropriate discharge; sudden increase in low-voltage impedance to >1500 or high-voltage impedance to $>100 \Omega$; >300 nonphysiological short VV-intervals.

RESULTS

We identified 145 patients. Age at implant was 60 ± 12 years with a median follow-up of 10.2 (interquartile range [IQR]: 5.0-11.2) years. Thirty-five percent of patients died after 5.4 ± 2.7 years. A total of 19 leads (13%) failed after 6.7 ± 3.2 years (range: 1.2-12.0). Overt malfunction with shocks existed in four patients (3%). Cumulative lead survival was 93.1% at 6, 88.2% at 8, 83.8% at 10, and 77.6% at 11 years, respectively, with 35% of implanted leads under monitoring at 10 years. Lead survival fits best a Weibull distribution with accelerating failure rates ($k = 1.95$, 95% CI 1.32-2.87, $P < 0.001$).

CONCLUSIONS

During very long-term follow-up, failure rate of the passive SFL shows an increase resulting in an impaired lead survival of 84% at 10 years.

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