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

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Abstract

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 centres, patients with passive SFLs were identified and data from routine 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 (31th December 2017). We defined lead failure as any of the following: lead fracture with inappropriate discharge; sudden increase in low-voltage impedance to >1'500 or high-voltage impedance to >100 Ohm; >300 non-physiological short VV-intervals.

Results

We identified 145 patients. Age at implant was 60±12 years, median follow-up 10.2 (IQR 5.0-11.2) years. Thirty-five percent of patients died after 5.4±2.7 years. 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 six, 88.2% at eight, 83.8% at ten and 77.6% at eleven years, respectively, with 35% of implanted leads under monitoring at ten 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 ten years.

Keywords: Medtronic™ Sprint Fidelis ® lead, Implantable Cardioverter Defibrillator (ICD), passive lead configuration, long-term performance, failure rate, lead failure

Introduction

Medtronic withdrew their Sprint Fidelis ® ICD lead (SFL) from the market in 2007 after reports on elevated failure rates(1). Several studies on the performance of this small diameter defibrillator lead, prone to fracture, were published since, almost entirely on the active fixation lead model.(2,3,12,13,4–11) The reported annual failure rate varied considerably (1.3%(3) - 4.8%/year(4)) depending on lead model, definition of lead failure, and population studied. A recent meta-analysis demonstrated an average yearly failure rate of 2.2% for the SFL (n = 11’709) versus 0.3% for the Medtronic Sprint Quattro ® lead (n = 16’119)(12). Many of these earlier publications had a rather short follow-up and data on long-term follow-up is scarce (except the Medtronic product performance report(14)). In 2012, our group published that the passive SFL model had a better survival than the active fixation model(10) and that also the five year survival rate was better than assumed(15).

Aim of this study was to update the outcome of all our patients with a passive SFL model and to extend their follow-up to more than ten years.

Methods

At the beginning of 2018, we reassessed all patients who received a passive SFL model at the University Hospital Basel and at the Kantonsspital St.Gallen, both in Switzerland. All patients had the Sprint Fidelis (SF) dual-coil 6948 lead implanted. Implantation period was between December 2004 and time of lead withdrawal in October 2007 (n = 145). To give a more realistic performance report for this analysis, we included all patients with a passive lead implanted, whereas in the prior publications, we excluded patients with a follow-up shorter than 6 months (n = 8). We pooled data from both centres and analyzed them retrospectively. Patients were censored at the time of death (n=51), downgrade to a pacemaker (n=6), explantation of a functioning lead (n=8 [infections 4, twiddler syndrome 1, heart transplantation 1, tricuspid valve reconstruction 1, elective lead replacement due to low sensing values 1]), implantation of a new pacing/sensing lead due to low sensing or high pacing threshold values, clearly not related to fracture (n=5), implantation of a new ICD lead due to high pacing threshold (n=1), last device check in patients lost to follow-up (n=11), or at the time the database was last accessed (31th of December 2017, n=40). As recommended by Medtronic, devices were interrogated every three months, and the "lead integrity alert" safety tool was activated in all patients.

Due to lack of a universal definition of lead failure, we used two different definitions of lead failure, as previously described(15):

A strict definition, i.e. failure due to any of these reasons:

- lead fracture with inappropriate discharge due to noise sensing
- *sudden* increase in lead impedance to > 1'500 Ohm
- *sudden* increase in the high-voltage circuit impedance to > 100 Ohm
- > 300 occurrences of non-physiological short VV-intervals

Lenient definition, i.e. failure due to any of the above-mentioned criteria but also due to

- linear increase in lead impedance to > 1’500 Ohm up to a level that the treating cardiologist considered inappropriate
- linear, but not sudden, decrease in sensing value up to a level that the treating cardiologist considered inappropriate

Statistical Analysis

Continuous data are expressed as mean values (± one standard deviation). Calculation of the cumulative lead survival was performed with the survival function (Kaplan-Meier) of SPSS™, version 22. The Fisher’s exact test was used for categorical variables. To analyse whether failure rates accelerate during follow-up, we fitted common parametric survival models (exponential, Weibull, Gompertz, log-normal and log-logistic) to our data. We chose the model with the best fit according to Akaike’s information criterion (AIC, lower values fit better). In an analysis of a Weibull distribution, a shape parameter k smaller than 1 1 indicates decreasing, of 1 constant and of bigger than 1 increasing failure rates.

Results

One hundred forty-five patients were included with an age at implantation of 60±12 years. Median follow-up was 10.2 (interquartile range 5.0–11.2) years. The SFL was used for cardiac resynchronization therapy in 45 patients (31%). During follow-up 51 (35%) patients died after 5.4±2.7 years (range 0.1-10.9).

Applying the strict lead failure definition, 19 leads (13%) failed after 6.7±3.2 years (range 1.2-12.0). Applying the lenient definition, 23 leads (16%) failed after 6.7±3.1 years (range 1.2-12.0). Table 1 shows the reasons for lead failure, the most frequent ones being sudden increase in impedance to >1’500 Ohm (n=7), overt malfunction with shocks, increase in short VV-intervals, and increase in high-voltage circuit impedance (all n=4, respectively). No patient had more than one reason for lead failure and no lead was replaced solely on patient’s

preference. The Kaplan-Meier curve of lead survival (strict definition) is shown in figure 1. The survival curve of the lenient lead failure definition is depicted in the Appendix Figure 1. In the goodness of fit analysis for parametric survival models, a constant hazard model, namely an exponential model, showed poor fit compared to models with changing hazard rates, of which the Weibull showed the best fit (AIC values Weibull: 279.9, Gompertz: 280.1, log-logistic: 280.2, log-normal: 281.3, exponential 286.7). More details are displayed in the Appendix Figure 2 and Appendix Table 1. With a shape parameter "k" of $k > 1$ in the Weibull analysis, increasing failure rates over time are present (scale 275.2, 95% CI 182.8 – 414.5, $p < 0.001$; $k = 1.995$, 95% CI 1.32 – 2.87, $p < 0.001$). This increase in failure rate is illustrated in figure 2. Table 2 depicts the cumulative lead survival rates in yearly intervals between five and eleven years of follow-up. At the time points five and ten years after implant, 70% (n = 101) and 35% (n = 50) of all initially implanted leads were still part of the study population. Sixty-nine (48%) patients underwent generator replacement after 6.6±2.2 years. There was no difference regarding strict lead failure in patients with replacement or in those without (12% (8/69) versus 14% (11/76), $p = 0.78$). Clinical events and time point of failure are displayed in table 3.

Six patients underwent lead revision for issues most probably not related to the SFL. Three patients had permanent low sensing values, and the treating cardiologist considered the value as being too low for safe arrhythmia detection. During upgrade to CRT, two patients with a chronic stable impedance of 1'300 Ohm and 45 short VV intervals had lead revision performed. Finally, one patient received a new lead during generator exchange due to a high pacing threshold. Five pace/sense leads and one Medtronic Quattro ® lead were implanted in these patients. These are not considered as "cases" and thus were censored at the time of surgery.

Discussion

The main finding of this study is that the cumulative survival of passive model of the SFL is not only impaired after five years, but that the failure rate accelerates during further follow-up. Numerically, lead survival was 94% at five years, 91% at seven years and 84% at ten years. Fortunately, only four patients (3%) presented with inappropriate shocks due to lead fracture.

Compared to most of the published studies that focused mainly on active lead models with survival rates of around 83% at five years(5), the passive SFL performed considerably better. The Medtronic CareLink ® network (14) reports a failure rate of 11% at ten years for the passive SFL (cave: data not peer-reviewed), which is lower than those in independent studies. Even though the overall number of passive leads is impressive in the network, the percentage of patients at risk at ten years is extremely low (3%, 147/4664), as compared to our population (34.5%, 50/145). That said, even though our investigator-initiated data depict a smaller population, they reflect more likely “real life” with still 35% of patients at risk at the time point ten years. Early after withdrawal of the SFL from the market, Hauser et al(7), observed an accelerated failure rate in active leads after the first year of follow-up. Cheung and colleagues(6) subsequently perceived a transition from an initially exponential to a linear pattern at three years. In our cohort with only passive leads, we observed the same increase. The question remains why the passive lead model performed better than the active model. From the CRHF Product Performance publication by Medtronic(16,17), most failure reasons of returned leads were a conductor fracture in both models (6948: 205/211, 97%; 6949: 7769/7899, 98%). One can speculate that this small-calibre lead was overengineered and too small. Therefore, the stability of the lead was reduced. One less moving part (no active fixation mechanism) makes the passive model probably simpler and thus more durable.

As the survival rate of passive SFL declines considerably over time, the question of optimal management of patients with a functioning lead is legitimate. Bashir et al(18) estimated that an elective lead replacement might trigger only half of the costs compared to a lead revision in an emergency setting. Still, patients with a functioning SFL have a survival similar to patients with the non-advisory Medtronic Quattro lead.(19) In addition, Salgado(20) et al. demonstrated that the rate of failure after generator replacement was similar between functioning SF and other defibrillator leads (3.5% versus 3.6% after one year, $p = 0.97$), and insofar did not recommend preemptive lead replacement or removal.

As many risk factors for lead failures are established, decision on elective replacement of a functioning SFL should be based on the number of risk factors for subsequent failure in an individual (ejection fraction >45%(3), female gender(5,6,8), inherited cardiomyopathy(8), non-cephalic access(5), previous lead failure(5), number of leads(9), passive lead configuration(10), cardiac resynchronization therapy(21), generator exchange(22)). In our centres, we do not routinely replace a functioning SFL at the time of generator replacement. Based on the data presented, this seems a reasonable approach.

Limitations of this study are the lack of a control group with a non-recalled lead and the restricted number of patients compared to some of the series with active leads. As implantation technique affects SFL survival (e.g. non-cephalic access is associated with higher risk(5)), differences in implantation technique could be a confounding factor leading to a better survival of leads in our cohort. Unfortunately, data on implantation access was not systematically collected for this analysis. The main advantage, however, is our impeccably monitored cohort with a low proportion of patients lost to follow-up (7.5%) and a high percentage of patients at risk (34.5% at 10 years).

Conclusions

In patients with passive SFL, long-term lead failure rate accelerates during follow-up leading to an impaired ten year survival of 84%. This performance is still considerably better compared to published data on active models.

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Author contributions

Simon Frey: data collection, analysis and interpretation; drafting of article, statistics

Christian Sticherling: critical revision of article, approval of article

David Altmann: data collection, critical revision of article, approval of article

Roman Brenner: data collection, critical revision of article, approval of article

Michael Kühne: critical revision of article, approval of article

Peter Ammann: data collection, critical revision of article, approval of article

Michael Coslovsky: statistical analysis, critical revision of article, approval of article

Stefan Osswald: critical revision of article, approval of article

Beat Schaer: concept/design, analysis/interpretation of data, drafting and critical revision of article, approval of article

Conflicts of interest

Simon Frey: none declared

Christian Sticherling: has served on the speakers' bureau for Medtronic, Biotronik, Boston Scientific and Microport CRM and had scientific support from Medtronic, Biotronik, Boston Scientific and Microport CRM.

David Altmann: none declared

Roman Brenner: none declared

Michael Kühne: has served on the speakers' bureau for Boston Scientific, Abbott and Biotronik. He has received lecture/consulting fees from Microport CRM and Medtronic

Peter Ammann: has served on the advisory board of Medtronic

Michael Coslovsky: none declared

Stefan Osswald: Dr Osswald has served on the speakers' bureau for Medtronic, Boston Scientific, Biotronik, Abbott and has received unrestricted grants from Medtronic, Boston Scientific, Biotronik, and Abbott

Beat Schaer: has served on the speakers' bureau for Medtronic and Microport CRM.

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Legend of figures and tables

Content of Supplementary File