Sensing Failure Associated with the Medtronic Sprint Fidelis Defibrillator Lead

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Sensing Failure of the Medtronic Fidelis ICD Lead. ***Introduction:*** **The diameter of implantable cardioverter-defibrillator (ICD) leads has become progressively smaller over time. However, the long-term performance characteristics of these smaller ICD leads are unknown.**

Methods: **We retrospectively evaluated 357 patients who underwent implantation of a Medtronic Sprint Fidelis™ defibrillating lead at two separate centers between September 2004 and October 2006. Lead characteristics were measured at implant, at early follow-up (1–4 days post implant), and every 3–6 months thereafter.**

Results: **During the study period, 357 patients underwent implantation of the Medtronic Sprint Fidelis™ lead. The mean R-wave measured at implant through the device was not different (P = NS) when compared with that measured at first follow-up (10.5 ± 5.0 mV vs 10.7 ± 5.1 mV). Forty-one patients (13%) had an R-wave amplitude ≤ 5 mV measured through the device at implant. Of those patients with an R-wave amplitude ≤ 5 mV at implant measured through the device, 63% (n = 26) remained ≤ 5 mV for the duration of follow-up. The mean time to R-wave amplitude ≤ 5 mV was 96.2 ± 123 days. During follow-up, 65 (18%) patients developed R-wave ≤ 5 mV. Overall 10 lead revisions (2.8%) were performed during the first year of follow-up.**

Conclusion: **Abnormal R-wave sensing is frequently observed during follow-up with the Medtronic Fidelis ICD lead. Lead revision was necessary in 2.8% of the patients, most often (8 of 10) due to abnormal R-wave sensing along with elevated pacing threshold. Whether this issue is limited to this lead or reflects a potential problem with all downsized ICD leads merits further investigation.** *(J Cardiovasc Electrophysiol, Vol. 19, pp. 270-274, March 2008)*

implantable devices, implantable cardioverter defibrillator, pacing threshold, sensing threshold, lead implantation, lead revision

Introduction

Implantable cardioverter defibrillator (ICD) therapy has become the standard of care for patients at high risk for sudden death. Over the past decade, the diameter of ICD leads have become progressively smaller. Potential advantages of smaller leads include easier passage into the right ventricle, increased compatibility with multiple lead systems, superior extractability, and reduced potential for crush injury. However, the long-term performance characteristics of smaller ICD leads are unknown.

With the substantial rise in ICD implants, long-term reliability of ICD leads is a primary concern. Lead dysfunction may result in failure to deliver therapy or delivery of inappropriate shocks. Lead dysfunction may also be clinically silent. In either case, the need for operative revision or removal of the lead system results in additional hospitalizations and health care costs.

When released, the Medtronic Sprint Fidelis™ was the first ICD lead capable of passing through a 7 Fr introducer. The lead, which has a 6.6 Fr body, offers true bipolar sensing and an extendable-retractable active fixation mechanism. Based on our clinical impression that a low chronic R-wave amplitude was observed in a high number of patients implanted with these leads we sought to systematically evaluate their long-term performance.

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TABLE 1
Baseline Patient Demographics of the 357 Patients with the Fidelis™ Lead Studied

	Medtronic Fidelis™ n = 357
Age (years)	64 ± 14
Women, n (%)	177 (49%)
Follow-up (days)	267 ± 137
Ischemic cardiomyopathy	182(51%)
Ejection fraction (%)	29 ± 13
QRS duration (ms)	126 ± 31
Body surface area (m^2)	1.82 ± 0.28
New implant	303 (85%)
Biventricular system	107 (30%)
Single chamber	43 (12%)
Dual chamber	207 (58%)
Right ventricular apical lead position	343 (96%)

Methods

The study population comprised consecutive patients who underwent implantation of an active fixation right ventricular ICD lead with single or dual coils (Sprint Fidelis™ and Medtronic Minneapolis, MN, USA) at either Cornell University Medical Center or Virginia Commonwealth University Medical Center between September 2004 and October 2006 during ICD implantation. Routine recording of sensing thresholds (mV), pacing thresholds (V), and impedance (Ω) was performed both through the pacing system analyzer (PSA, Medtronic Model 2290), as well as through the implanted device. A majority of patients had these parameters reassessed at ICD testing performed on postimplant days 1–4. Patients were subsequently followed in the ICD clinic every 3–6 months thereafter. In order to standardize pacing thresholds for all patients, threshold data are reported as energy [amplitude (V) squared multiplied by the pulse width (ms)].[1] Lead revisions were performed at the discretion of the electrophysiologist for abnormal R-wave sensing and/or an elevated pacing threshold.

Statistical Analysis

Continuous variables were expressed as a mean ± standard deviation (SD) and were compared using an unpaired two-tailed Student's *t*-test. Categorical variables were compared using the chi-square test. A Kaplan–Meier curve was created to demonstrate time to R-wave ≤ 5 mV and time to lead revision. Relative risk (RR) with 95% confidence intervals (CI) was computed where appropriate. A P value < 0.05 was considered to be statistically significant. A Cox proportional hazards regression model was used to evaluate the independent contribution of baseline clinical characteristics to the development of the end point in a forward stepwise manner. At each step, a significance of 0.10 was required to enter into the model, while those with probabilities less than 0.05 were considered statistically significant. All analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA).

Results

During the study period, 357 patients underwent implantation of the Medtronic Sprint Fidelis™ lead and followed for a mean of 242 ± 150 days. The demographics of the study population are summarized in Table 1. Of note, 95.5% of patients had a Medtronic ICD generator implanted in conjunction with the Sprint Fidelis™ lead; the other 4.5% had a Guidant (Boston Scientific, Natick, MA, USA) generator implanted.

At implant, through the Medtronic PSA, the mean R-wave for the Sprint Fidelis lead was 15.0 ± 7.2 mV. Seventeen (4.7%) patients were pacemaker-dependent at implant; therefore, sensing measurements could not be obtained.

Figure 1 shows the comparison of mean R-wave amplitude at each time interval. The mean R-wave measured by the

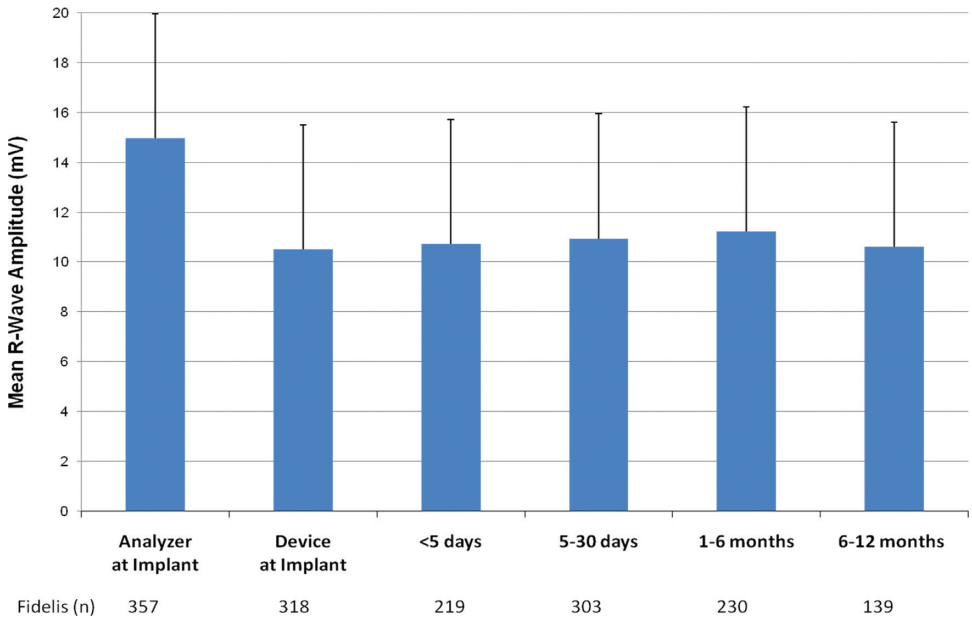

Figure 1. *Fidelis™ lead mean R-wave amplitude over time. The numbers beneath the time interval on the X axis represent the number of patients followed at that time point.*

device was significantly lower than that measured by the PSA (15.0 ± 7.2 mV vs 10.5 ± 5.0 mV, P < 0.001), and then remained relatively stable. The difference in R-wave amplitude when measured by PSA and analyzed by the device is likely due to the difference in the two methods of measurement.

The mean R-wave measured at implant through the device was not different (P = NS) when compared with that measured at first follow-up (10.5 ± 5.0 mV vs 10.7 ± 5.1 mV). There was no difference in number of patients with R-wave ≤ 5 mV measured through the device at implant (n = 41, 13%), compared with measurements at first follow-up (n = 28, 13%). However, 16 (4.5%) patients with R-waves ≤ 5 mV measured through the device at implant remained ≤ 5 mV at first follow-up. Of those patients with R-waves ≤ 5 mV at implant through the device, 63% (n = 26) remained ≤ 5 mV for the duration of the entire follow-up. Twelve patients had R-waves greater than 5 mV at implant by the device that dropped to ≤ 5 mV by first follow-up. The average decrease in R-wave amplitude in these 12 patients was 4.8 ± 3.5 mV.

At first follow-up, generally at 1–4 days post-implant (median one day), the mean R-wave in the Fidelis group measured through the device (10.7 ± 5.1 mV) was lower when compared with the value obtained at implant through the PSA (15.0 ± 7.2 mV). Although only 7 (2.0%) patients had R-waves ≤ 5 mV through the PSA at implant, 28 (12.7%) patients had R-waves ≤ 5 mV at first follow-up.

Impedance (Ω) measured at implant with the PSA was 847.8 ± 197.4 ohms and decreased to 508.5 ± 146 ohms by the final follow up measurements (P < 0.001). Figure 2 demonstrates lead impedance at each time interval. Pacing thresholds expressed as work (J-s) are shown in Figure 3. There was a significant increase in threshold from 0.26 ± 0.2 J-s measured by PSA to 0.37 ± 0.4 J-s at last follow-up (P = 0.005).

During follow-up, 65 (18%) patients developed R-wave ≤ 5 mV. Figure 4 is a Kaplan–Meier curve showing the time to R-wave ≤5 mV. To our knowledge, no failure to sense events of ventricular tachycardia or ventricular fibrillation were observed in the group of patients with R-waves ≤ 5 mV.

Overall 10 (2.8%) lead revisions (Table 2) were performed during the first year of follow-up. Eight were performed less than 2 months after implant. Two were performed late after implant; both due to documented lead fractures. Of the 8 lead revisions, 5 were performed because of low R-wave amplitude and elevated pacing thresholds, one for low R-wave amplitude and complete loss of capture and two for complete lead dislodgment with both failure to capture and failure to sense. None of the leads with R-waves measured less ≤ 5 mV at implant were revised during the follow-up.

Multivariate regression analysis was performed to determine overall predictors of R-wave diminution ≤ 5 mV during follow-up. Multivariate analysis revealed that mean R-wave amplitude measured during the first 4 days after implant was the only independent predictor of R-wave ≤ 5 mV with hazard ratio of 0.61 (95% CI: 0.52, 0.71, P < 0.001). The risk of R-wave ≤ 5 mV declined by 39% for every 1 mV increment in R-wave at first follow-up. When adjusted for age, gender, body surface area, and implant center, mean R-wave amplitude during the first 4 days after implant was associated with R-wave ≤ 5 mV at follow-up (HR = 0.65, 95% CI: 0.57, 0.75, P < 0.001).

Discussion

The general design of the Medtronic Sprint™ leads has relied on silicone multilumen tubing combined with parallel coil and cable conductors. The original coaxial Sprint™ leads passed through a 12 Fr introducer. Later generation smaller multilumen Sprint™ leads pass through a 10.5 Fr introducer. The next model, Sprint Quattro™, has an 8.2 Fr diameter and passes through a 9 Fr introducer. The latest iteration design is the Sprint Fidelis,™ which is a 6.6 Fr lead passing through a 7 Fr introducer. The Sprint Fidelis™ family consists of the single coil extendable-retractable helix model 6931 and

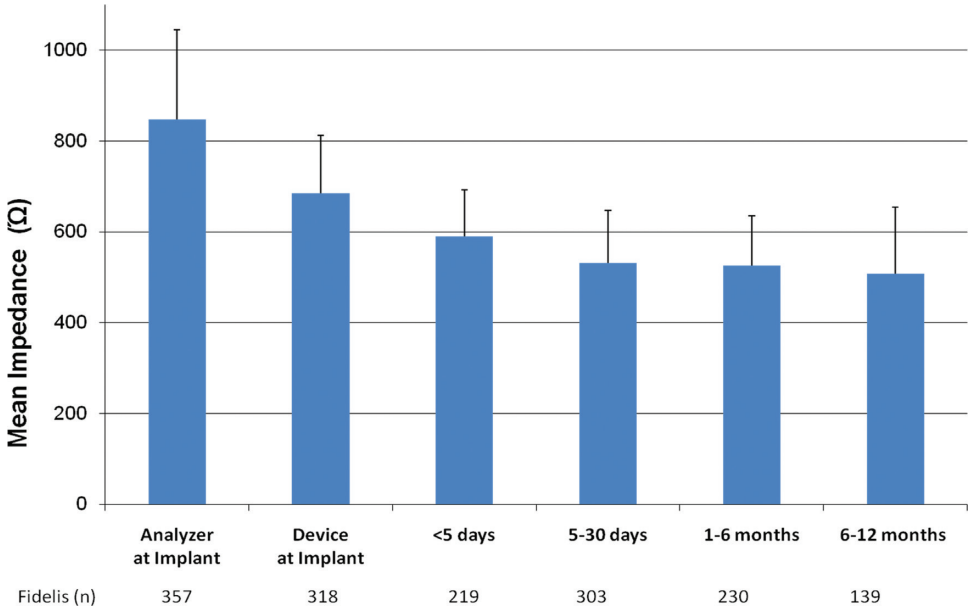

Figure 2. *Fidelis™ lead impedance over time. The numbers beneath the time interval on the X axis represent the number of patients followed at that time point.*

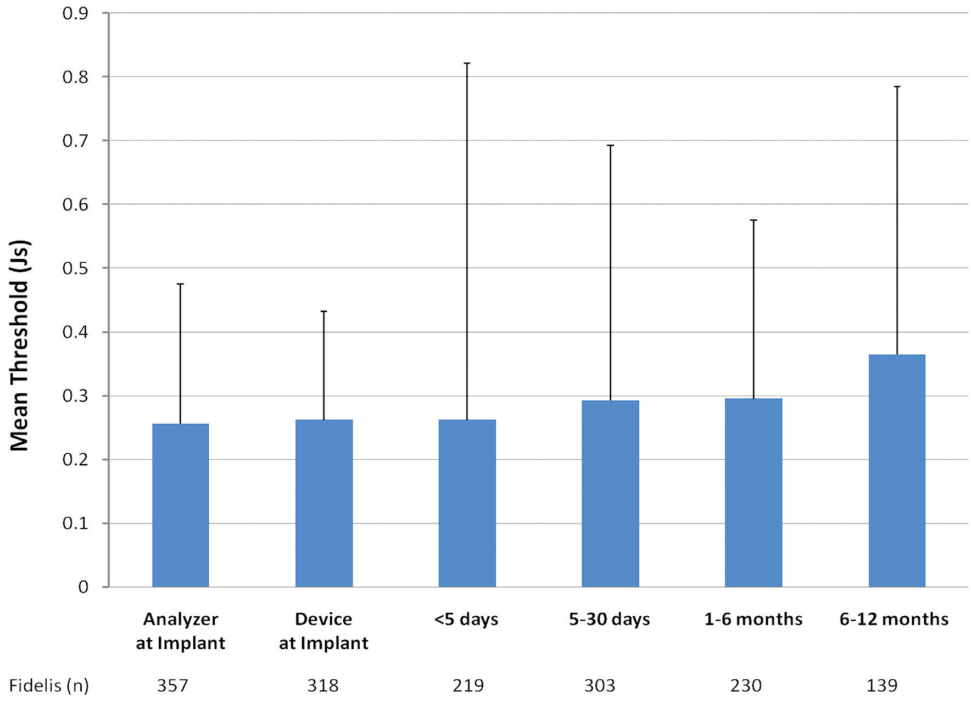

Figure 3. *Fidelis™ lead pacing threshold expressed as J-s over time. The numbers beneath the time interval on the X axis represent the number of patients followed at that time point.*

the dual coil extendable-retractable helix model 6949. St. Jude currently offers similar versions of reduced-caliber ICD leads, which have recently been reported to result in a significant number of lead revisions and cardiac perforations.[2]

With the substantial rise in ICD implants, long-term reliability of ICD leads is a primary concern. Lead dysfunction may result in failure to deliver therapy or inappropriate shocks. Lead dysfunction may also be clinically silent. In either case, the need for operative revision or removal of the lead system results in additional hospitalizations and health care costs. Recent increased concern has focused on ICD pulse generator reliability, but ICD lead failure is probably 100 to 1,000 times more common.[3]

Diminishing R-wave amplitudes post implant is not an uncommon clinical dilemma. Our data suggest that down-sized leads may perform poorly over time, compared with traditional sized leads, because of abnormal sensing. Twelve (4.3%) patients implanted with the Fidelis™ had diminution of R-wave amplitude to less that 5 mV before discharge from the hospital after having normal R-wave sensing at implant with both PSA and implanted device measurement. It is currently unknown what absolute R-wave amplitude is acceptable to ensure adequate VT/VF sensing. However, R-wave amplitude in sinus rhythm tends to reflect R-wave amplitude during ventricular tachycardia and ventricular fibrillation.[4–7]

The Sprint Fidelis™ lead is a true bipolar lead where sensing is between the lead tip and the ring.[8] There was a significant difference between the R-wave measured from the Medtronic PSA compared with that measured through the implanted device. R-wave amplitude is processed through the Medtronic PSA by using a signal filtered twice, rectified, and measured via a peak detector. This is a wider band signal that provides for more diagnostic capability at the time

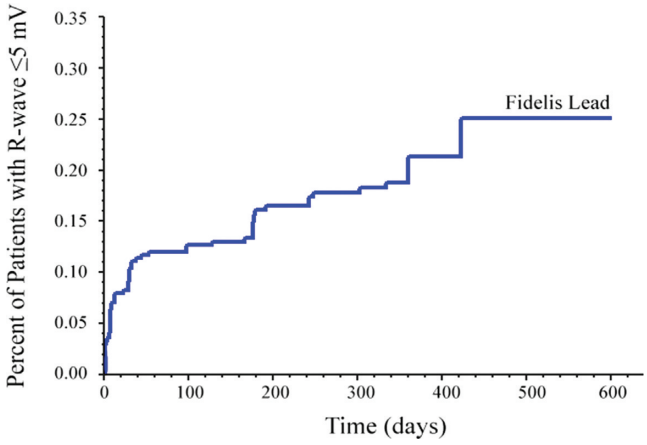

Figure 4. *A Kaplan–Meier curve demonstrating the time to R-wave ≤ 5 mV in patients with the Fidelis™ lead.*

TABLE 2

Lead Model, Lead Abnormality, and Day of Revision in 10 Patients with the Fidelis™ Lead That Underwent Lead Revisions

Patient No.	Lead Model	Lead Abnormality	Day
1	6949	Low R-wave amplitude; Elevated pacing threshold	7
2	6931	Failure to capture/sense (Lead dislodgement)	9
3	6931	Low R-wave amplitude; Elevated pacing threshold	13
4	6949	Low R-wave amplitude; Elevated pacing threshold	16
5	6949	Low R-wave amplitude: Elevated pacing threshold	22
6	6949	Low R-wave amplitude; Elevated pacing threshold	38
7	6931	Low R-wave amplitude; Failure to capture	55
8	6949	Failure to capture/sense (Lead dislodgement)	4
9	6949	Lead fracture	639
10	6949	Lead fracture	663

of implant. The device automatic R-wave measurement on the other hand uses the signal filtered three times, rectified and measured with an automatic peak detector within a 50 ms window after exceeding the sensitivity threshold at that point in time. Therefore, it is not unexpected for the R-wave amplitude to be lower when measured through the device.

The only characteristic that predicted low R-wave during follow-up as well as ultimate lead revisions in our cohort was low R-wave amplitude at the first interrogation after implant. This was usually prior to discharge from the hospital. Often, the implanting physician is confronted with the reality of discharging a patient with a low R-wave amplitude after having appropriate measurements at implant. Although a "watchful waiting" period is sometimes employed, perhaps early revision may be more appropriate.

A plausible explanation of the mechanism of diminished R-waves might be related to the flawed deployment of the helix at implant. Because of its size, the Fidelis lead is less stiff, making it more susceptible to bending and torsional stress. Therefore, during active fixation of the lead, the lead body may back away from the ventricular myocardium. The current recommendation for the Sprint Fidelis™ lead is at least two lead body turns during implantation to ensure good endocardial contact and combat this "backing away" phenomenon.

Two of the 10 lead revisions were late lead fractures, a different process than the sensing abnormalities associated with early lead revision. Industry data, based on return product analysis, represented that chronic fracture-free survival at 2 years was 98.9%.[9] A recent report by Hauser and colleagues suggests a higher rate of lead fracture. In this report, the authors note that the Sprint Fidelis™ lead appears to be prone to a higher rate of early lead failure.[10] Their data suggest that survival of Sprint Fidelis™ leads was significantly less than Sprint Quattro Secure™ model 6947 leads ($P = 0.005$). Six patients presented with Sprint Fidelis lead failure 4–23 months after implant.

Despite the evolution of leads to smaller diameter, lead failure remains the "dark side" of device therapy in this day and age.[11-15] Lead issues are more common than the often highlighted generator failure. Due to an increased focus by regulating bodies on improvements to generator quality and performance, device functions continue to improve. The same scrutiny and long-term follow-up is needed for leads, especially high-voltage ICD leads. Advances in technology, including remote monitoring and follow-up, should help. Models to predict lead failure are needed. Most importantly, better quality leads rather than smaller leads should be developed by industry.

The limitations of our analysis relates to the fact that it is a retrospective, nonrandomized review of the lead data with incomplete follow-up for each patient. This is a preliminary analysis of a downsized Medtronic lead, and further prospective, randomized-controlled studies need to be performed.

Early lead revision continues to be an important problem post-ICD-implantation with smaller defibrillator leads. Early lead revisions occur primarily because of abnormal R-wave sensing (≤ 5.0 mV). Mechanisms that account for this compromised sensing still need to be elucidated.

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