Clinical Outcome of Implantable Cardioverter Defibrillators With Recalled and Non-Recalled Leads in Japanese Patients

– Increased Failure Rate of The Sprint Fidelis Lead –

Satoshi Yanagisawa, MD; Yasuya Inden, MD, PhD; Masayuki Shimano, MD, PhD; Naoki Yoshida, MD, PhD; Hiroshi Ichiyanagi; Masaya Fujita, MD; Shiou Ohguchi, MD; Shinji Ishikawa, MD; Hiroyuki Kato, MD; Satoshi Okumura, MD; Aya Miyoshi, MD; Tomoyuki Nagao, MD; Toshihiko Yamamoto, MD; Makoto Hirai, MD, PhD; Toyoaki Murohara, MD, PhD

Background: In recent years, there has been a series of recalls of popular implantable cardioverter defibrillators leads, and several reports have demonstrated an increasing rate of failure of such leads over time in Caucasian patients. However, little is known about the performance of these leads in Asian patients. The aim of this study was to investigate the rate of failure of the recalled leads and the characteristics as compared with non-recalled leads in Japanese patients.

Methods and Results: A retrospective chart review was conducted in 214 patients (75 Sprint Fidelis, 8 Riata, and 131 Sprint Quattro leads) who underwent implantation and follow-up at Nagoya University Hospital. During the follow-up period, 14 Sprint Fidelis leads (19%) and 1 Riata lead (13%) failed, but no abnormality was found in the Sprint Quattro, non-recalled leads. Five patients (4 Sprint Fidelis and 1 Riata, 33% of lead failure patients) received inappropriate shocks. The 3-, 4-, and 5-year lead survival rates in Sprint Fidelis leads were 95.1% (95% confidence interval [CI]: 89.6%–100%), 89.8% (95% CI: 82.1%–97.6%), and 88.0% (95% CI: 79.6%–96.4%), respectively. A previous device implantation before Sprint Fidelis lead was the only significant predictor for lead fracture (hazard ratio, 5.33; 95% CI: 1.55–18.4; P=0.008).

Conclusions: The rate of Sprint Fidelis lead failure continues to increase over time in Japanese patients. (Circ J 2014; 78: 353–359)

Key Words: Implantable cardioverter defibrillator; Japanese; Risk factor; Survival

Implantable cardioverter defibrillator (ICD) is a reliable and established treatment for the prevention of sudden cardiac death in patients with a history of life-threatening ventricular arrhythmia and in patients with a high risk of malignant arrhythmia.1,2 Many ICD devices have been implanted worldwide, and numerous patients have benefited from them thus far.3 Although ICD implantation is less invasive, complications such as infection, lead dislodgement, and erosion may occur during device implantation.4 These complications are mainly associated with external factors such as patient immunosuppression and physician procedure. The lead itself, however, may cause complications. In recent years, there have been recalls for the Medtronic Sprint Fidelis and the St. Jude Medical Riata ICD lead families.

The Sprint Fidelis lead, a 6.6-Fr bipolar high-voltage ICD lead developed by Medtronic, was introduced to the market in 2004. These leads have a more compact design compared to other previously developed leads, and it was expected that these leads would be easily inserted or removed. However, soon after the first concerns were raised regarding device failure, and early failure rates were reported in April 2007,5 the manufacturer voluntarily suspended the worldwide distribution of Sprint Fi-
October 2005 to July 2011, and who were followed up at the Nagoya University Hospital. Patients were identified retrospectively by reviewing the Nagoya University Hospital records and device database. Data regarding age, sex, indication for implantation, and other baseline patient characteristics were obtained from hospital records, and implantation details such as lead length, venous site access, number of implanted leads, and so on, were obtained from the institutional device database. The follow-up was completed until June 2013. Informed consent was obtained from all patients prior to implantation and subsequent invasive therapy.

**Implantation Techniques**

Leads were inserted preferably via a left- or a right-sided venous access via the subclavian vein using standard extrathoracic puncture and introducer sheath techniques. Leads were positioned in the right ventricular apex or ventricular septum. Defibrillation safety margins, pace threshold, and sense measurements were obtained based on individual physician protocols in order to provide rate support and to ensure adequate detection and termination of ventricular fibrillation and ventricular tachycardia.

**Definition of Lead Failure**

Lead fracture was defined as non-physiologic high-rate sensing. Sudden change of sense and pace, coil impedance out of normal limits or inappropriate shock due to sensing of electrical noise artifacts were suggestive of lead failure. All the lead dysfunctions were confirmed on electrocardiogram tracings.

**Methods**

**Subjects**

We conducted a retrospective review of patients with Sprint Fidelis leads (model 6949), Riata leads (model 1580), and Sprint Quattro leads (model 6947) that were implanted between October 2005 to July 2011, and who were followed up at the Nagoya University Hospital. Patients were identified retrospectively by reviewing the Nagoya University Hospital records and device database. Data regarding age, sex, indication for implantation, and other baseline patient characteristics were obtained from hospital records, and implantation details such as lead length, venous site access, number of implanted leads, and so on, were obtained from the institutional device database. The follow-up was completed until June 2013. Informed consent was obtained from all patients prior to implantation and subsequent invasive therapy.

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**Table 1. Baseline Characteristics and Implantation Details**

|                        | Sprint Fidelis | Riata | Sprint Quattro |
|------------------------|---------------|-------|---------------|
| No. patients           | 75            | 8     | 131           |
| Age at implantation (years) | 58.5±16.3    | 60.1±15.1 | 61.1±14.5    |
| Male                   | 56 (75)       | 6 (75)  | 95 (73)       |
| Height (cm)            | 162.8±8.9     | 160.1±8.5 | 163.1±10.0   |
| Weight (kg)            | 60.6±15.5     | 57.1±10.1 | 60.8±13.3    |
| BMI (kg/m²)            | 22.6±4.3      | 22.2±2.2  | 22.7±4.1     |
| Primary prevention indication | 34 (45)    | 3 (38)  | 46 (35)       |
| Pathogenesis of cardiac disease |             |       |               |
| Coronary artery disease | 20 (27)      | 2 (25)  | 47 (36)       |
| DCM                    | 18 (24)       | 2 (25)  | 25 (19)       |
| HCM                    | 11 (15)       | 2 (25)  | 10 (8)        |
| Brugada syndrome       | 7 (9)         | 2 (25)  | 10 (8)        |
| Congenital disease     | 3 (4)         | 0 (0)   | 34 (3)        |
| Others                 | 16 (21)       | 0 (0)   | 5 (27)        |
| LVEF (%)               | 45.2±20.7     | 45.0±19.6 | 44.0±18.6    |

Data given as mean±SD or n (%). *P<0.05 for comparison of Sprint Fidelis to Sprint Quattro. Previous device implantation is applicable to patients who had a history of device implantation before implantable cardioverter-defibrillators lead implantation.

BMI, body mass index; DCM, dilated cardiomyopathy; HCM, hypertrophic cardiomyopathy; LVEF, left ventricular ejection fraction.
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stored in the device. If the patients were suspected of lead fracture, even though there were no abnormalities in the usual pace-sense check test, we performed additional stress tests, such as change in the patient’s body position, putting external pressure on the device generator, high-voltage pace, and induction of electrical noise artifacts, all of which could result in the diagnosis of lead failure. Although reduced sense R waves are suggestive of possible lead trouble, functional abnormalities including physiological oversensing in the presence of an electrically intact lead were not considered failure. Lead extraction caused by infection or lead dislodgement was not considered lead failure. The remote monitoring system and lead integrity alert (LIA) algorithm were also used to detect early lead fractures as described in previous reports.17–19 For lead survival analysis, the date of lead dysfunction was identified on device interrogation as the first occurrence of any lead abnormality fulfilling the definition of lead fracture, as aforementioned. Once the patient was diagnosed with lead failure, the patient was admitted to hospital immediately and was scheduled for extraction of the failed lead and replacement with a new intact lead as soon as possible.

### Statistical Analysis

Continuous variables are expressed as mean±SD, and categorical variables as numbers and proportions. Continuous variables were compared between groups using Student’s t-test. Categorical variables were compared using the chi-squared test or Fisher’s exact test. Two-sided 95% confidence intervals (CI) were calculated as the difference between groups ±1.96 SEM. The prognostic value of each factor was evaluated on univariate Cox proportional hazard regression analysis. The proportional hazard assumption was confirmed by inspection of the log–log (survival function) curves. The Kaplan-Meier method was used for the estimation of event-free survival during follow-up and differences between the curves were compared using log-rank analysis. P<0.05 was considered statistically significant.

### Table 2. Clinical Outcome

|                  | Sprint Fidelis | Riata  | Sprint Quattro |
|------------------|----------------|--------|----------------|
| Follow-up period (years) | 4.8±2.2*       | 4.9±1.1 | 2.9±1.3        |
| All-cause death  | 17 (23)*       | 3 (38) | 9 (7)          |
| Lead failure     | 14 (19)*       | 1 (13) | 0 (0)          |
| Time to lead failure (years) | 4.6±1.7       | 4.7    | –             |
| Device generator replacement | 27 (36)*       | 2 (25) | 18 (14)        |
| Lead failure after generator replacement | 5 (7)         | 0 (0)  | –             |
| Time to lead failure after replacement (years) | 1.7±0.6       | –      | –             |

Data given as mean±SD or n (%). *P<0.05 for comparison of Sprint Fidelis to Sprint Quattro.

### Table 3. Demographics and Fracture Signs in Lead Failure Patients

| Patients | Type of lead | Sex | Implant to failure (years) | Lead impedance >1,000 ohms | Inappropriate shock (times) | Previous device implantation | Alert sign | Other abnormal sign | Electrical noise artifacts (induction method) |
|----------|--------------|-----|---------------------------|-----------------------------|-----------------------------|-----------------------------|------------|---------------------|---------------------------------------------|
| 1        | Fidelis      | F   | 2.5                       | +                           | –                           | –                           | Lead impedance | Pacing failure and reduced sense R wave | –                                           |
| 2        | Fidelis      | M   | 3.3                       | +                           | –                           | –                           | Lead impedance | –                   | –                                           |
| 3        | Fidelis      | M   | 2.2                       | +                           | –                           | +                           | Lead impedance | –                   | + (High-voltage pace)                      |
| 4        | Fidelis      | M   | 2.9                       | +                           | –                           | –                           | Lead impedance | –                   | –                                           |
| 5        | Fidelis      | F   | 3.0                       | +                           | 1                           | +                           | Lead impedance and LIA | Pacing failure | –                                           |
| 6        | Fidelis      | F   | 3.9                       | –                           | –                           | –                           | –                       | LIA                  | +                                           |
| 7        | Fidelis      | M   | 5.3                       | +                           | 19                          | –                           | Lead impedance and LIA | Reduced sense R wave | + (Putting generator)                     |
| 8        | Fidelis      | M   | 5.1                       | –                           | 1                           | –                           | LIA                     | –                   | + (Shoulder rotation)                      |
| 9        | Fidelis      | M   | 4.6                       | +                           | 4                           | +                           | Lead impedance and LIA | Pacing failure | –                                           |
| 10       | Fidelis      | F   | 5.7                       | –                           | –                           | –                           | LIA                     | Pacing failure and reduced sense R wave | + (Putting generator)                     |
| 11       | Fidelis      | M   | 6.1                       | –                           | –                           | +                           | LIA                     | Reduced sense R wave | + (Putting generator)                     |
| 12       | Fidelis      | M   | 6.6                       | –                           | –                           | –                           | LIA                     | Reduced sense R wave | –                                           |
| 13       | Fidelis      | M   | 7.1                       | –                           | –                           | –                           | LIA                     | –                   | + (High-voltage pace)                      |
| 14       | Fidelis      | M   | 6.6                       | +                           | –                           | –                           | Lead impedance and LIA | –                   | + (Shoulder rotation)                      |
| 15       | Riata        | M   | 4.7                       | –                           | 8                           | –                           | –                       | –                   | +                                           |

LIA, lead integrity alert.
Results

A total of 214 patients (75 Sprint Fidelis, 8 Riata, and 131 Sprint Quattro) were included in this cohort. The Sprint Fidelis leads were implanted between October 2005 and October 2007. The Riata leads were implanted in November and December 2007. The Sprint Quattro leads were implanted from January 2008 to July 2011. The demographic data and implantation details of the Sprint Fidelis, Riata, and Sprint Quattro patients are listed in Table 1. All the leads were inserted by performing extrathoracic vein puncture. The screw-in leads were attached to the myocardium in all the patients in this cohort. The average number of implanted leads and prevalence of cardiac resynchronization therapy for the Sprint Quattro patients were significantly greater than that for the Sprint Fidelis patients.

During each follow-up period, all-cause death occurred in 17 Sprint Fidelis patients (23%), 3 Riata patients (38%), and 9 Sprint Quattro patients (7%), in whom there was no association with lead fracture. We identified lead failure in 14 Sprint Fidelis leads (19%) and 1 Riata lead (13%). No lead fracture was found in the Sprint Quattro cohort. The average time to lead failure for the Sprint Fidelis and Riata leads after implantation was 4.6±1.7 years, and 4.7 years, respectively. Device generator replacement after ICD lead implantation was performed in 27 Sprint Fidelis patients (36%), 2 Riata patients (25%), and 18 Sprint Quattro patients (14%). The follow-up period was significantly longer and the prevalence of all-cause death, lead fracture, and generator replacement were higher in the Sprint Fidelis group than in the Sprint Quattro group. The status of each lead and the performance are summarized in Table 2. There were three patients with abandoned leads because of device infection, not because of lead fracture.

The clinical features and device data for patients with lead failure are given in Table 3. Five patients (4, Sprint Fidelis; 1, Riata; 33% of lead failure patients) had oversensing and received inappropriate shock caused by lead fracture. Although almost all of the patients had experienced a rise in impedance or its alert, some patients presented normal data during the device program check-up. Those patients subsequently underwent stress tests or high-voltage pace, which induced electrical noise artifacts, and a diagnosis of lead failure was finally established.

Upon the diagnosis of lead failure and replacement with a new
lead, we attempted to extract the leads by performing manual traction, but only 1 lead was successfully extracted from the patient’s body. Two patients were found to have a complete obstruction of the ipsilateral subclavian vein; thus, the new lead was inserted via the opposite vein site. The Riata lead failure patient underwent cinefluoroscopy to detect conductor externalization at revision procedure, but there was no obvious sign of conductor externalization. Chest radiography did not detect conductor externalization in patients with normally functioning Riata leads either.

Kaplan-Meier curves of cumulative lead survival rates for Sprint Fidelis, Riata and Sprint Quattro leads are shown in Figure 1, and confirmed that patients with Sprint Fidelis leads had significantly decreased event-free survival than patients with Sprint Quattro leads (P=0.009). The failure rate for Sprint Fidelis leads was 3.9% per year. The survival rate of Sprint Fidelis leads at 3, 4, and 5 years was 95.1% (95% CI: 89.6%–96.4%), 89.8% (95% CI: 82.1%–97.6%), and 88.0% (95% CI: 79.6%–96.4%), respectively. The cumulative hazard of Sprint Fidelis lead failure is shown in Figure 2. The risk of lead fracture increased and appeared to rise with time. Consequently, we sought to examine a possible factor of Sprint Fidelis lead fracture, and univariate Cox proportional hazard regression analysis identified previous device implantation before implantation of Sprint Fidelis lead (hazard ratio, 5.33; 95% CI: 1.55–18.4; P=0.008) as the only predictor significantly associated with lead failure (Table 4). Four patients with history of previous device implantation presented with Sprint Fidelis lead failure. Among them, 3 patients underwent implantation of Sprint Fidelis lead as an upgrade procedure, and 1 patient underwent re-implantation because of a previous infection complication. Ipsilateral access vein site and device pocket were used in all but 1 patient.

### Discussion

The present study investigated ICD lead performance, including that of recently recalled leads, at a single center. In particular, we found that the rate of Sprint Fidelis lead failure increased over time and showed no signs of abating. This is the first description of the outcome of Sprint Fidelis leads and the lead survival rate having a consistent downward trend for long-term implants in Japanese patients. Furthermore, previous device implantation before the Sprint Fidelis lead was the only significant predictor for lead fracture.

Although initial reports suggested that Sprint Fidelis lead failure rates per year were <2%, recent evidence evaluating long-term lead survival rates suggests that the rate of lead failure is increasing. A 2-center study reported a fracture rate of 3.75% per year in 848 patients with Sprint Fidelis leads during a 27-month follow-up. Moreover, a single-center study of 604 patients reported that the fracture rates stabilized at 4.5% per year during an average follow-up of 3.3 years. Those outcomes were mostly reported for Caucasian patients. To date, however, no data are available with regard to the performance of Sprint Fidelis leads in Asian patients, who have small physiques. We found a Japanese Sprint Fidelis lead failure rate of 3.9% per year during an average follow-up of 4.8 years, which is in agreement with the failure rate reported in the aforementioned studies. We also calculated the cumulative hazard of lead fracture, and found that the risk of fracture increased as time elapsed after the initial phase. As for the long term outcome of Sprint Fidelis leads, the present 3-, 4-, and 5-year lead survival rates were 95.1%, 89.8%, and 88.0%, respectively, which are similar to those found in other recent studies (Table 5). Even though Japanese patients are likely to have smaller physiques (mean body mass index [BMI], 22.6) compared to Caucasian patients (mean BMI, 28.1), there were no obvious differences in the performance of Sprint Fidelis leads among the 2 ethnic groups.

We found that previous device implantation before a Sprint Fidelis lead was the only significant predictor of lead failure. Recent studies with large sample sizes reported female sex to be an independent predictor of Fidelis lead fracture. Several studies have also identified younger age, higher ejection fraction, and non-cephalic access as significant predictors of Sprint Fidelis lead fracture. We observed similar trends with each of these risk factors, but none of these differences was statistically significant. This inability to detect a significant difference may have been due to the lack of a larger sample size. The present significant predictor for lead failure, previous device implantation, was not discussed in previous studies. In the REPLACE Registry, pacemaker and ICD generator upgrade replacements were reported to have many complications. In addition, a recent report stated that in patients who had a different device implanted during the first surgery, a history of previous lead failure was a very important predictor of subsequent Sprint Fidelis lead fractures. It might be possible that after a new Sprint Fidelis lead insertion, interaction with the old lead, stress from venous stenosis, or tissue adhesions after previous device insertion may be responsible for clinically silent damage of the Sprint Fidelis lead. Accumulation of further data on risk factors for lead failure will be helpful in the decision-making process regarding whether to prophylactically replace Sprint Fidelis leads in selective high-risk patients possibly at the time of generator replacement or not.

In contrast, there was 1 Riata lead failure in a patient who received inappropriate shock caused by electrical noise artifacts without conductor externalization, as determined on cinefluoroscopy. Although recent focus has primarily been on the association between insulation defects and externalized conductors, not all insulation defect are related to Riata lead abnormality. In a study of Japanese patients, only Sato et al reported insulation defects in 2 of 10 Riata patients seen on chest X-ray. One patient received inappropriate ICD therapies, but another...
had an insulation defect without any clinically manifested electrical troubles. Because the number of implanted Riata leads was low in the present study, we could not derive sufficient data regarding survival outcome and statistical comparison with the other leads. A systematic large-scale study on Riata leads in the Japanese population is required, as was performed in European and North American reports.\textsuperscript{15}

The mechanism underlying the Sprint Fidelis lead and the Riata lead failures are unknown. The Sprint Fidelis lead abnormality is mainly due to mechanical stress.\textsuperscript{5} Excess stress might be applied to the distal tip of the lead during implantation, or an acute angle between the vein and the device pocket through the extrathoracic puncture might be associated with proximal lead dysfunction. In contrast, the Riata lead failure could occur due to the insulation defect, which resulted in conductor externalization and, consequently, electronic abnormalities. Insulation defect is caused by mechanical “inside-out” abrasion due to continuous movement of the conductor cable in the lead insulation lumen.\textsuperscript{15,27} We could not provide data regarding the injured site of the failed lead because only 1 lead was completely extracted from the body. Further studies are needed on the mechanisms of lead failure.

Amazingly, there was no lead failure in the Sprint Quattro leads. Previous reports have described the acceptable performance of Sprint Quattro leads, their low failure rate (<1%/year), and stable appearance.\textsuperscript{9,21,27} Perhaps, the small cohort and short follow-up period were the reasons for this excellent data. In the comparison of Sprint Fidelis lead survival, we noted significantly different survival rates for recalled and non-recalled leads, similar to the reports on Caucasian patients.\textsuperscript{9,21,27} Considering that there were no major changes in implantation method during the study period, we can be certain of the safety of our implantation method based on the acceptable performance of the Sprint Quattro leads, and emphasize the problems regarding the Sprint Fidelis lead itself. The reason that Sprint Quattro patients had better outcome in all-cause death than Sprint Fidelis patients might be that the follow-up duration for the Sprint Quattro leads was shorter than that for the Sprint Fidelis leads.

There are several limitations to the present study. First, the study was retrospective, and conducted on a small single-center cohort. Although we conducted follow-up for as long as possible, some patients were lost soon after lead implantation. Second, although all leads were implanted continuously during each period and there was no device selection bias, the Riata lead cohort was too small to assess statistical outcome. Moreover, the average follow-up period for the Sprint Quattro leads was shorter than that for the other leads. Third, with respect to the lead extraction method, we performed only simple manual extraction in patients with lead failure, and we did not perform other invasive extraction techniques. One of the possible reasons for this is that the approval for the Excimer laser sheath was delayed in Japan compared to Europe and North America.\textsuperscript{28} Thus, the removal rate of failed leads was lower compared to that in other published reports.

### Conclusions

The present study describes the clinical outcome of recently recalled and non-recalled ICD leads and the increased failure rate of Sprint Fidelis leads in Japanese patients. The fracture rate of the Sprint Fidelis lead was 3.9% per year during an average follow-up of 4.8 years, which is similar to data reported for
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Caucasian patients. Previous device implantation before the Sprint Fidelis lead was the only significant predictor for lead failure. The present results may provide support for risk stratification in lead revision.

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