Impact of generator replacement on the risk of Fidelis lead fracture

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BACKGROUND A dilemma arises about the merits of conservative management vs lead replacement and/or extraction when patients with a Medtronic Sprint Fidelis lead undergo generator replacement. Conflicting reports suggest that the fracture rate may increase after generator change.

OBJECTIVE The purpose of this study was to investigate the effect of generator replacement on Fidelis lead performance.

METHODS The Carelink PLUS cohort is composed of 21,500 Fidelis leads (model 6949) implanted in 1,006 centers. The survival rate for leads that remained active after the first generator replacement was compared with that for a control group with matched lead implant duration, patient age, patient sex, and generator type using the Kaplan-Meier method. The control group's starting point was adjusted to match the implant duration of each lead in the replacement group to allow for the comparison of similarly aged leads.

RESULTS Of the 2,988 implanted leads in each group, there was no statistical difference in the number of lead fractures between cases and controls (replacement, n = 227; no replacement, n = 257; Fisher exact, $P = .169$). Lead survival analysis demonstrated that lead performance since the first replacement procedure did not differ from that of the matched control group.

CONCLUSION The Fidelis lead survival rate after generator replacement does not differ from that of the Fidelis leads that have not had replacement. In the event of generator replacement with no manifestation of lead fracture, the lead model, patient age and life expectancy, ejection fraction, comorbidities, ease of extraction, local extraction expertise, and patient preference should be considered to determine the best course of action.

KEYWORDS Implantable defibrillator; Generator replacement; Lead fracture; Lead extraction

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Introduction

The Medtronic Sprint Fidelis lead family (Minneapolis, MN) is composed of small diameter ventricular leads used to deliver defibrillation therapies to patients at risk for sudden cardiac death. The Fidelis leads were withdrawn from the market in October 2007 because of higher-than-expected fracture rates. As lead extraction carries a certain level of risk, a dilemma arises about the merits of conservative management of remaining Fidelis leads in the field vs implanting a new lead, extracting a functioning lead, or both when patients undergo generator replacement. The risk of a single procedure that combines generator replacement with a lead intervention is typically discussed when a system that includes an advisory lead comes for generator replacement, weighed against the risk of a second potential procedure in the event of a lead performance issue if simple generator replacement is preferred.

Conflicting reports[1,2] suggest that the fracture rate may increase after generator change. Small sample size, case series studies from a limited number of implant centers prompted the hypothesis that generator change may induce strain on the lead that triggers an increase in fracture rate. We tested this hypothesis in a large data set of patients undergoing remote monitoring, comparing potentially affected patients to concurrent controls. The purpose of this study was to investigate the effect of generator replacement on fracture-free survival of the Fidelis lead in a large cohort, with the potential to inform prophylactic lead replacement strategy at the time of generator replacement.

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Methods

A retrospective analysis was performed on existing data pulled from Medtronic's Device and Registrant Tracking and Global Complaint Handling databases. Data were also reviewed from CareLink transmissions. A retrospective cohort study was performed using the CareLink PLUS population,[3] comprising 21,500 model 6949 Fidelis leads implanted in 1006 centers between August 2004 and January 2006. The CareLink PLUS cohort is an existing data set composed of a subset of registered patients in the United States that were transmitting on the CareLink network when the cohort was defined in 2008. The purpose of the cohort was to identify a group of patients to inform leading edge performance and patient management recommendations. Lead model 6949 is a dual coil, active fixation defibrillation lead and was chosen for this study because of its high volume relative to other Fidelis lead models. Every 6949 lead model that was implanted in the United States before January 31, 2006, and had an available CareLink file transmission between April 20, 2007, and April 15, 2008, was included in the cohort. CareLink PLUS is a performance analysis that includes data from CareLink transmissions plus returned product and save-to-disk analysis. The median follow-up time in the CareLink PLUS study population is 90.7 months.

Given the data sources used (existing data sets rather than newly created sets through a traditional clinical trial setting), no consent was necessary, as this activity did not result in altered protocols or treatment for any patient. Patients provided consent to undergo remote monitoring as part of routine clinical care. Although serial numbers were included in the data set for the purpose of determining patient parameters for the analysis (ie, age, sex, and associated devices), all patient identification information was removed from the aggregated data shown in the article.

Fractures were determined using several data sources. CareLink transmissions from devices attached to cohort leads were analyzed by trained Medtronic personnel for indications of fractures. Fractures in the pacing circuit were determined if 2 or more of the following criteria were met: doubling of pacing impedance, a daily average of greater than 8 short RR intervals ($<$200 ms), nonsustained tachycardias under 220 ms, and noise on the electrogram. Fractures in the high-voltage circuit were defined by doubling of high-voltage impedance and impedance greater than 100 Ω. Set screw issues and impedance spikes due to disconnecting the lead from the device at change out were excluded from the fracture criteria. In addition, the Medtronic complaint-handling database was used for information on returned leads with confirmed fractures, save-to-disk files from returned implantable cardioverter-defibrillators/cardiac resynchronization therapy with defibrillators (ICDs/CRT-Ds), and other evidence of fracture such as x-ray films. Together, these data sources comprise the numerator of fractured leads. The denominator or total population was determined using Medtronic registry data for implant intervals for each patient in the CareLink PLUS cohort. Deceased patients and non–fracture-related lead removals/replacements were censored.

The CareLink PLUS cohort was broken into 2 smaller groups on the basis of whether the lead had experienced generator replacement during the follow-up period. There were 8,900 Fidelis leads that remained active after generator replacement. These leads were matched with a control Fidelis lead with matched patient age, patient sex, and generator type that had not undergone generator replacement (n = 2,988 per group). Lead implant time was adjusted for by shifting the starting point for the control leads to match the duration between implant and first generator replacement of the corresponding lead in the replacement group. The breakdown of the Carelink PLUS cohort into 2 subgroups is displayed in Figure 1. The demographic characteristics of the Carelink PLUS cohort and its 2 subgroups are summarized in Table 1.

The fracture-free survival rates of the replacement and control groups were compared using a Fisher exact test and a Kaplan-Meier survival curve. The Kaplan-Meier curve was generated on the basis of survival after the first generator replacement for the replacement group and survival after the adjusted starting point for the control group to allow for the comparison of similarly aged leads.

Burri and Combescure[1] developed a decision model to assess the long-term effect of different Fidelis lead management strategies at generator replacement. The authors of the decision model[1] shared their R statistical software analysis code to allow us to input the current large-scale fracture rate estimate into the identical model. In brief, the model was updated on the basis of the present analysis estimate of fracture rates using 2 approaches. In the first approach, the fracture rate in years 1 and 6 from the present study was used instead of the 20.8% value reported by Lovelock et al,[2] and the model's baseline fracture rate of 7.2% in other years was left unchanged.[4] The second approach updated this baseline fracture rate to a value of 3.0% on the basis of the CareLink PLUS cohort. We compared the results of these 2 approaches with those of the previously published model's main analysis as well as the sensitivity analysis at both 5 and 10 years.

Results

The study involved a total of 5,976 replacement patients and matched controls from a cohort of 21,500 CareLink Plus patients (Table 1). The replacement group had 227 fracture events (7.6%) after generator replacement, while the control group had 257 fracture events (8.6%). There was no difference in survival probability between the replacement group and the control group after matching patient age, patient sex, device type, and implant time (Fisher exact, $P = .17$).

Figure 2 compares the lead survival curve since the first change-out procedure with that for the matched control group. As previously described, the control group's starting point is adjusted to match the implant duration of each lead in the replacement group. The replacement and control groups perform similarly. The Fidelis lead survival rate after