Failure rate and conductor externalization in the Biotronik Linox/Sorin Vigila implantable cardioverter-defibrillator lead

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BACKGROUND We observed a case of conductor externalization in a Biotronik Linox lead.

OBJECTIVE The purpose of this study was to investigate lead performance of the Linox lead and the identical Sorin Vigila lead and prevalence of conductor externalization.

METHODS We compared lead performance of all Linox and Vigila leads implanted at our center (BL group; n = 93) with that of all Boston Scientific Endotak Reliance leads (ER group; n = 190) and Medtronic Sprint Quattro leads (SQ group; n = 202) implanted during the same period. We screened all patients in the BL group for conductor externalization.

RESULTS We identified 8 cases of lead failures in the BL group (index case of conductor externalization, 6 cases of nonphysiological high-rate sensing, and 1 case of high-voltage conductor fracture). Prospective fluoroscopic screening of 98% of all active BL group cases revealed 1 additional case of conductor externalization. The median follow-up was 41, 27, and 29 months for the BL group, ER group, and SQ group, respectively; lead survival was 94.9%, 99.2%, and 100% at 3 years and 88%, 97.5%, and 100% at 5 years ($P = .038$ for BL group vs ER group and $P = .007$ for BL group vs SQ group using the log-rank test). Younger age at implant was an independent predictor of lead failure in the BL group (adjusted hazard ratio 0.85; 95% confidence interval 0.77–0.94; $P = .001$).

CONCLUSION At our center, survival of the Linox lead is 88% at 5 years and significantly worse than that of other leads. Conductor externalization is present in a minority of failed Linox leads. Younger age at implant is an independent predictor of Linox lead failure.

KEYWORDS Defibrillator lead; Lead failure; Conductor externalization; Linox; Sprint Quattro; Endotak Reliance

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Introduction

Implantable cardioverter-defibrillators (ICDs) reliably prevent sudden cardiac death in patients at high risk of ventricular arrhythmias.[1] The defibrillator lead is a critical component of the ICD system because of its susceptibility to mechanical defects. In recent years, Sprint Fidelis (Medtronic, Minneapolis, MN) and Riata/Riata ST (St. Jude Medical, Sylmar, CA) defibrillator leads were withdrawn from the market because of an unacceptably high rate of lead failures.[2,3] The Riata lead recall also brought a new failure mechanism to the attention of the electrophysiology community: conductor externalization.[3]

In August 2014, on the occasion of an ICD replacement for battery depletion, we discovered an externalized conductor in a Linox (Biotronik, Berlin, Germany) defibrillator lead (index case). This lead had been implanted 71 months ago and did not show any electrical abnormalities. Case reports of externalized conductors in Linox leads as well as in the older lead model Kentrox had already been published at that time.[4–6] We also knew about several cases of lead failures in our patient population implanted with a Linox lead. For safety reasons, and in view of our experience with the Riata lead,[7] we decided to prospectively investigate lead status of our patient population implanted with a Linox lead and to screen all active cases for the presence of conductor externalization. Linox S/SD leads are also marketed by Sorin Group (Milan, Italy) as Vigila 1CR/2CR leads, and we therefore included these leads in our analysis.

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Methods

Since January 2008, we have maintained an electronic registry on all ICD interventions performed at our center. Before 2008, all ICD implants were listed in an electronic log book. From these sources, all patients implanted with a Biotronik Linox S/SD lead or a Sorin Vigila 1CR/2CR lead were identified. The first lead was implanted in December 2006 and the last lead in May 2014. From the same sources, we identified all Sprint Quattro leads (models 6935 and 6947, Medtronic) and all Endotak Reliance leads (Boston Scientific, Marlborough, MA) implanted from July 2006 to June 2014. Patients without at least 1 follow-up visit after lead implant were excluded from the analysis. The clinical records of all patients were reviewed, including patient characteristics at lead implant and number and type of reinterventions performed during follow-up. Current lead status of all leads was assessed at the end of the year 2014, and all lead failures were analyzed in detail. *Lead failure* was defined by the presence of any of the following criteria:

- Nonphysiological high-rate sensing, not attributable to electromagnetic interferences, myopotential or T-wave oversensing, with or without inappropriate shocks
- Sudden change in long-term pace/sense or high-voltage impedance ($>100\%$ increase or $>50\%$ decrease) or values outside the interval of 200–2000 Ω or 20–200 Ω, respectively, and loose set screw excluded at revision
- Fluoroscopic observation of an externalized conductor
- Visual observation of an exposed or externalized conductor
- Sudden increase in right ventricular threshold and/or decrease in R-wave sensing, without alternative explanation

Lead dislodgments or perforations and lead revisions because of electrical abnormalities that normalized with reuse of the lead were not considered lead failures.

All patients alive implanted with a Linox or Vigila lead and followed up by our clinic were invited once to prospective fluoroscopic screening from October to December 2014, combined with a routine or extraordinary device interrogation, as appropriate. In patients in whom prospective fluoroscopic screening was not possible, we evaluated fluoroscopic movies recorded during coronary angiography or device replacement, if applicable (retrospective fluoroscopy).

The circumstances of death of all patients who died with a functional Linox or Vigila lead were investigated. The most probable cause of death was determined after review of hospital records or, when appropriate, after contacting the physician who had lastly treated the patient.

Patients were included in our electronic registry only after written informed consent was obtained. The study was conducted in accordance with the local institutional committee on human research and national regulatory authorities.

Statistical analysis

Categorical variables are expressed as numbers and percentages and continuous variables as mean ± SD or median and range. Differences between groups were determined using the χ^2 test, the Fisher exact test, or an analysis of variance, as appropriate. Lead abandonment or explantation not related to lead failure as well as deceased cases were treated as censored observations. Patients followed up externally were censored at the time of the last follow-up visit at our clinic. The cumulative lead failure rate was estimated using the Kaplan-Meier method and lead survival compared with the log-rank test. Predictors of lead failure in the Linox/Vigila group were assessed using a Cox proportional hazards model. Variables with a P value of $\leq .1$ in the univariate analysis were included in the multivariate Cox proportional hazards model. A 2-sided P value of $<.05$ was considered statistically significant. All analyses were performed using SPSS 21.0 (SPSS Inc., Chicago, IL).

Results

A total of 93 Linox/Vigila leads (74 Linox and 19 Vigila leads), 190 Endotak Reliance leads, and 202 Sprint Quattro leads were included in this study. Patient characteristics at implant, type and number of ICD reinterventions during follow-up, and lead status at the end of follow-up are listed in Table 1. The median time from implant to follow-up was 41, 27, and 29 months for the Linox/Vigila group, Endotak Reliance group, and Sprint Quattro group, respectively ($P < .001$). The median follow-up was 53 months for Linox leads and 20 months for Vigila leads. The flowchart shown in Figure 1 gives an overview of the lead status of all Linox/Vigila leads, as well as the number of leads with completed prospective fluoroscopic screening or retrospective fluoroscopy. Figure 2A shows the externalized conductor of the index case. The median time from implant to prospective fluoroscopic screening and retrospective fluoroscopy was 54 and 34 months, respectively. Prospective fluoroscopic screening revealed 1 additional case of conductor externalization proximal to the right ventricular coil (Figure 2B; Table 2, case 2). Retrospective fluoroscopy did not reveal any lead abnormalities.

Including the index case and the case revealed by prospective fluoroscopic screening, 9 Linox/Vigila leads failed during follow-up, compared with 2 Endotak Reliance leads and 2 Sprint Quattro leads. Lead failures are described in detail in Table 2. All lead failures in the Linox/Vigila group concerned Linox leads. Linox lead failures mainly presented as inappropriate shocks (5 of 9 cases), and these 5 patients experienced a median of 21 inappropriate shocks. The median time from implant to lead failure in the Linox/Vigila group was 46 months (range 31–94 months). In the Endotak Reliance group, 1 lead with insulation abrasion and exposure of the high-voltage conductor within the ICD pocket met our lead failure definition (Table 2, case B2). However, this lead was repaired with silicone adhesive and a silicone sleeve and remained functional. Both lead failures in