Conductor externalization of the Biotronik Kentrox internal cardioverter-defibrillator lead: The tip of another iceberg?

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Introduction

As the indications for implantation of an implantable cardioverter-defibrillator (ICD) are expanding and the number of patients with longer follow-up is growing, the incidence of complications is increasing. Insulation abrasion is the most common cause of ICD lead failure.[1] Recently, several reports of a unique failure mechanism in the 8Fr Riata and 7Fr Riata ST family of ICD leads (St. Jude Medical) have been published.[2] Riata and Riata ST leads were insulated with silicone rubber (the high-voltage conductors have an additional layer of ethylene tetrafluoroethylene insulation). In 2006, an additional silicone–polyurethane copolymer (Optim™) covering was added to Riata ST models, and this new lead model was renamed the Riata ST Optim. Here we report insulation abrasion of a new lead, the Biotronik Kentrox SL, which presented with inappropriate shocks, high pacing impedance, and an externalized conductor. The Kentrox SL is a 9.3Fr lead insulated with silicone rubber similar to the insulation of the Riata leads, but it does not have an outer Optim or stiff abrasion-resistant coating. This unique finding prompted a discussion of the mechanisms for this failure, the risk factors for such an occurrence with emphasis on design issues and patient-specific factors, and the implications of such failures and their appropriate management.

KEYWORDS Implantable cardioverter-defibrillator lead; Externalized conductor; Kentrox; Implantable cardioverter-defibrillator shock; Insulation defect; Advisory

ABBREVIATIONS ICD = implantable cardioverter-defibrillator (Heart Rhythm 2014;11:1648–1650)

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Case report

A 38-year-old man with Brugada syndrome who had undergone implantation of a Biotronik Kentrox SL single-lead/dual-coil Biotronik ICD in 2007 after sustaining a cardiac arrest had a device change-out with a Medtronic Virtuoso device in January 2013, complicated by a moderate size hematoma. Four weeks later, he presented with several inappropriate shocks due to lead fracture confirmed by noise on the intracardiac electrogram, high impedance on device check, and evidence of an externalized conductor on fluoroscopy. A new Medtronic Quattro dual-coil ICD lead was implanted, and the old Biotronik lead was abandoned.

Less than 5 months later the patient presented to his local physician with erosion of the lead through the pocket and redness over the incision site. He was referred to the electrophysiology laboratory for device and lead extraction.

An incision was made over the left prepectoral pocket, and the device was delivered through the incision. There was no pus in the pocket, and the capsule was not grossly infected or necrotic. The capsule was dissected out entirely. The fixation screw of the Medtronic Quattro lead was retracted, and the lead was removed with gentle traction. The old passive fixation Biotronik lead demonstrated externalized conductor by fluoroscopy (Figure 1). Gentle traction was ineffective, and the lead was prepped with a locking stylet and suture. A 13Fr Cook Evolution sheath was advanced over the lead using the outer Teflon sheath, with removal of the lead. Moderate-to-heavy fibrosis was noted in the subclavian vein, over the superior vena cava coil, and at the tricuspid valve annulus. After the lead was removed, the patient remained hemodynamically stable without complications through discharge from the hospital. The pocket was copiously irrigated with antibiotic solution, and the incision was closed. Visual inspection of the lead showed a clear externalization of

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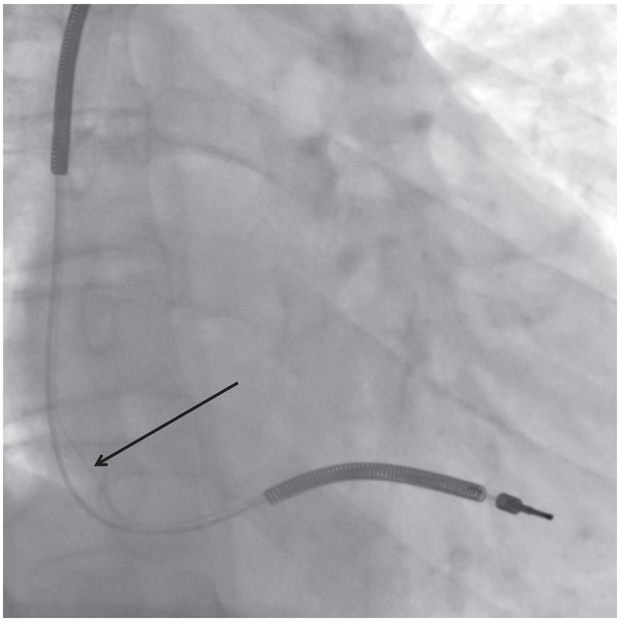

Figure 1 Fluoroscopic image of conductor externalization of the Biotronik Kentrox silicone ICD lead.

the conductor through the insulation at the level of the tricuspid valve between the coils (Figure 2). The lead was sent to the microbiology laboratory per the infectious disease consultant team request and could not be returned to the manufacturer for analysis.

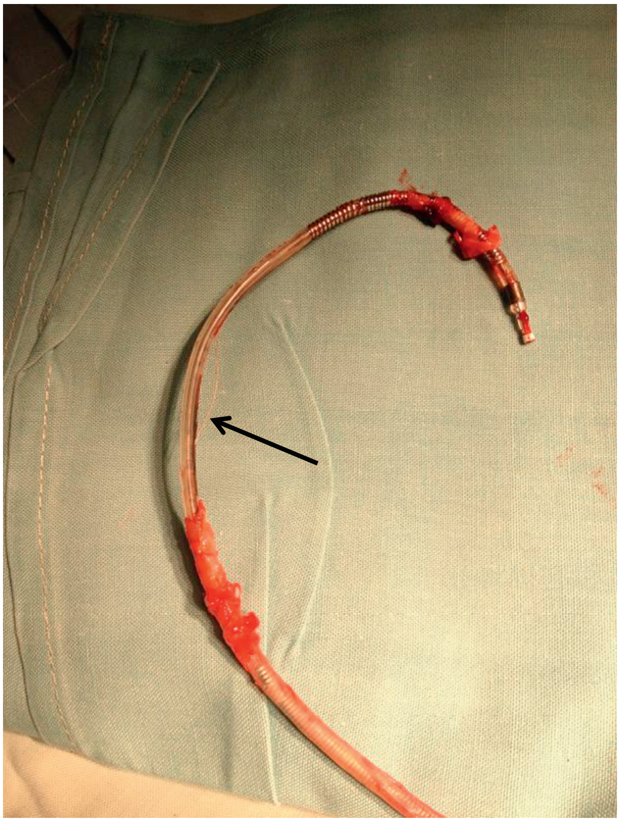

Figure 2 The extracted lead. A segment of the lead showing an externalized conductor (*arrow*), which had abrased the outer insulation.

Discussion

We present the case of a patient with a Biotronik ICD lead with externalized conductors and electrical failure. To our knowledge, this is the first report of externalized conductors in the Biotronik Kentrox lead. The Kentrox SL is a 9.3Fr lead insulated with silicone rubber only, similar to the Riata lead insulation; however, it does not have an outer Optim or stiff abrasion-resistant coating (Figure 3). In contrast to the Riata lead, the Kentrox does not have a grossly redundant cable design that might result in movement of the twin cables within the lumen.

Lead externalization was discovered because the patient presented with inappropriate shocks and a change in impedance on electrophysiologic testing. Gross inspection after lead removal revealed a site of complete conductor externalization.

The defibrillator lead is the most fragile component of the ICD system.[1] An understanding of the implications of ICD lead failure is the most important missing link toward ensuring appropriate management of patients. Published case reports demonstrate a peculiar set of complications for lead externalization, including inappropriate shock,[3,4] oversensing,[5,6] changes in baseline electrophysiologic interrogation, and an episode of diaphragmatic pacing.[7] Specifically, changes in impedance such as those reported in our patient seem to be some of the more commonly observed electrical abnormalities, composing up to 37% of electrical presentations of externalized leads. The Kentrox SL lead is a passive fixation lead coated with fractal iridium for use in lead placement. Two possible mechanisms of externalization of conductors are (1) an inside–out abrasion and (2) an outside–in abrasion. Although superficially the Kentrox SL lead abrasion looked like an inside–out abrasion (as was seen in the Riata leads) and not an outside–in mechanism of failure, it was not possible to determine definitively whether the pace/sense electrode cable or the shocking coil cable externalized because the lead was sent to the bacteriology laboratory for culture and thus could not be examined closely under magnification.

Insulation failure is the most frequent cause of lead failure, but lead fracture, loss of capture, abnormal impedance, and sensing failure also can occur.[1] Insulation defects are complex complications that are related to patient-specific factors such as

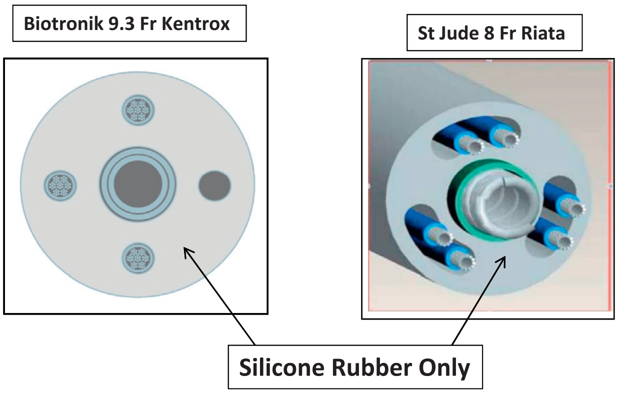

Figure 3 Schematic diagram showing the Kentrox SL in cross-section compared to the Riata (both covered with silicone rubber only).

anatomy and heart function, lead design issues, and implantation technique and approach. Early on, it was shown that both insulation material and venous approach were significantly associated with increases in insulation defects, with studies showing a silicon coating to be highly reliable.[8] The leads may function electrically in a normal manner if the insulation covering the pace/sense and high-voltage cables is intact.[9] The most common location of the insulation defect is proximal to the distal shock coil at the level of the tricuspid valve and lower right atrium.[3,10] However, Hauser et al[11] reported that leads with inside–out abrasion frequently also display multiple insulation defects distributed along the length of the lead. Local abrasive forces from neighboring myocardial structures (i.e., movement of the tricuspid valve) may play a role in causing insulation breach in this type of lead.[7,12] Another explanation may be inside–out abrasion caused by movement of the conductors within the insulation leading to conductor externalization through the outer insulation.

The diagnosis of lead externalization in our patient was easy because the defect was noted on a recent chest X-ray film ordered for alternative purposes. However, the utility of plane X-ray film specifically for identification of lead externalization has been questioned.[13] Instead, studies utilizing cine fluoroscopy consistently report higher incidences of lead externalization, and fluoroscopy with 3 views is the most accurate screening method, with sensitivity and specificity of 86% and 100%, respectively.[14]

In contrast to the case of our patient with documented electrical compromise, the long-term significance of asymptomatic cable extrusion is unknown, making management of such cases a particularly difficult issue. As highlighted by Liu et al,[15] the ultimate decision about management will depend on patient-specific factors such as dependence on ICD as well as physician and institutional factors.

Our case report sheds the light on the potential clinical problems of both electrical failure and externalization of conductors in Kentrox leads. Externalized conductors in Kentrox leads is of uncertain significance and in this case was also associated with electrical dysfunction. This may or may not be similar in mechanism to the Riata lead issues. All patients with ICD leads need to have both device and clinical follow-up to detect conditions that are potentially clinically impactful.

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