Use of Computed Tomography as a Screening Modality Before Lead Extraction for Patients Affected by Failure of the Recalled Riata Leads: A Case Report

1IBRAHIM SIDIQI, MD, 1,2WAEL GHALAYINI, MD, 3TAREK ZUGHAIB and 1,2CHRISTIAN MACHADO, MD

1St. John Providence Health System, Department of Cardiology, Southfield, MI
2Providence Hospital Heart Institute, Southfield, MI
3American University of Beirut, Beirut, Lebanon

ABSTRACT. In the past 5 years, the Riata lead family of implantable cardioverter-defibrillator (ICD) electrodes have generated significant concerns because of their poor performance records. Reports of perforation associated with these leads have been mounting. Currently, different screening strategies are used by physicians prior to extraction of the failed Riata lead and implantation of a new lead system. Despite the fact that fluoroscopy and X-ray imaging are not optimal to show wall perforation, there is no consensus yet as to which screening method is to be used. We present a case of Riata lead with electrical and structural component failure. The patient was referred to our center for lead extraction and replacement of an undiagnosed, subclinical ventricular wall perforation.


Introduction

The Riata lead family of implantable cardioverter-defibrillators (ICDs) consisting of 7- and 8-French leads with silicone external insulation was released worldwide by St. Jude Medical in 2002. In the past 5 years, these leads have generated significant concerns regarding their design because of a less than desirable performance record. Another alarming factor associated with this family of leads is the reported possible increased risk of ventricular wall perforation.1–3

In 2010, the Riata family leads were removed from distribution after 227,000 were sold worldwide, and they were placed under a Class I Food and Drug Administration recall in December 2011. It is estimated that approximately 79,000 Riata leads remain actively used in the United States.4

The failures described can be classified as structural, electrical, or both. The high-voltage leads with smaller diameter (Riata and Riata ST) are associated with greater failure rates than standard-diameter leads. Several studies have demonstrated a clinically significant failure rate of the high-voltage component for defibrillation, with potentially fatal consequences.5,6 Different centers have developed different screening strategies because of the potentially fatal outcomes of lead failure. The difficulty in predicting electrical failure on the basis of fluoroscopic findings of presence or absence of structural components has made it challenging to obtain a consensus on a screening protocol. Meanwhile, clear recommendations from the Heart Rhythm Society, industry, and government agencies are required to assist clinicians with this clinical problem. What is clear is that when patients have structural lead and electrical failure,
implantation of a new lead system is required, preferably with extraction of the failed Riata lead.

Here, we present the case of a patient whose Riata lead showed electrical and structural component failure and was referred to our center for lead extraction and replacement; the patient also had undiagnosed subclinical ventricular wall perforation.

Case report

The patient was a 71-year-old African American man (Institutional Review Board approval 371963-1) who had a history of ischemic cardiomyopathy and had previously undergone implantation of a dual-chamber Riata 8-French high-voltage lead for the primary prevention of sudden cardiac death. The patient presented with inappropriate ICD shocks due to oversensing in the ventricular channel. The results of physical examination were unremarkable. An echocardiogram done at a different institution prior to presentation showed no evidence of lead perforation. Electrical abnormalities were noticed using non-invasive program stimulation, which showed oversensing and undersensing with impedance changes in his high-voltage Riata lead. Pre-extraction parameters of the right ventricular (RV) lead were the following: R wave amplitude of 12 mV, impedance of 405 Ω, and threshold of 4.25 V. Fluoroscopic examination showed that the inner conductor of the high-voltage lead was completely externalized from the right atrial superior vena cava junction to beyond the tricuspid valve. Lead removal using a Spectranetics (Colorado Springs, CO) laser sheath removal kit was planned. The atrial lead was extracted without difficulty. The ventricular lead was dissected down to 1 cm proximal from the distal rate-sensing bipolar electrode. However, every attempt to go beyond this point by using the laser sheath resulted in non-sustained ventricular tachycardia with hemodynamic compromise. A femoral approach with a Cook (Bloomington, IN) extractor system consisting of a 13-French snare was used to retract the RV high-voltage lead by using an inferior approach, but repeat episodes of transient hypotension and non-sustained ventricular tachycardia were also triggered by this approach. During fluoroscopic examination, the RV lead appeared embedded with atypical pendular movement independent of the cardiac cycle. The extraction procedure was aborted because it seemed very likely that the lead was located in an epicardial area. A new lead (Integrated Bipolar Lead, Boston Scientific Corp., Boston, MA) was inserted. It was set in the RV outflow tract to avoid any chatter effect or interaction between the two high-voltage leads. After the new system was implanted and the chronic Riata lead was capped, the patient was discharged in stable condition. A radiograph (Figure 1) and a computed tomography (CT) scan (Figure 2) of the chest were obtained to investigate the possibility that the Riata high-voltage lead had an epicardial trajectory. The RV lead was found to have perforated the RV and traveled to a pericardial location with self-containment; pericardial effusion was not observed. The patient was referred back to his primary cardiologist. In addition, regular follow-up at the pacemaker clinic, and periodic communication with his primary cardiologist has been carried out. The standard...
follow-up protocol is being followed. Thus far the patient has had a follow-up echocardiogram, threshold measurements, and repeat fluoroscopy without evidence of potential lead perforation.

Discussion

Cardiac perforation is a well-known complication of lead implantation, and several reports of perforation associated with the Riata leads have been recently published. The incidence of perforation for the Riata family of leads in the Advancements in ICD Therapy (ACT) and OptimTM Lead Insulation Material (OPTIMUM) registries (industry-sponsored registries) is 0.34–0.50%. Other studies have reported a 5.5% incidence of cardiac perforation with ICD leads. However, this may underrepresent the true incidence of lead perforations due to subclinical and asymptomatic presentation of delayed lead perforation. In fact, subclinical lead perforation may occur more frequently. Incidental identification of lead perforation on CT scans obtained for other reasons has been reported in up to 15% of such cases. A plausible explanation for the disparity in the numbers may be due to underreporting by physicians, which may occur either because they lack awareness of the registry or assume that such a complication is rare and fail to report the event.

Lead perforations have been attributed to multiple factors. Pacemaker and ICD lead sizes have been reduced in an effort to improve leads to minimize subclavian crush syndrome and vessel occlusion and provide space for additional catheters and devices. Consequently, these modifications have led to structural changes in the lead with reduced insulation thickness and increased tip pressure and stiffness. Rordorf et al reported that smaller diameter ICD leads are associated with a higher risk of delayed cardiac perforation. The technical aspects during implantation such as loop size, active versus passive fixation, and lead tension contribute to the overall risk of cardiac perforation. In another study, the non-apical lead position was found to be associated with fewer perforations, suggesting that the lead position affects perforation risk. Patient anatomy and operator experience are relevant factors that should be considered in the effort to minimize complications.

Cardiac perforation is a serious complication associated with the use of Riata leads. Delayed complications often present asymptotically. However, symptoms may include shortness of breath, chest pain, tamponade symptoms, or other non-specific symptoms. Risk factors for cardiac perforation include female gender, body mass index <20 kg/m², anticoagulation therapy, and steroid use. Echocardiographs and chest radiographs may not adequately identify small perforations or accurately identify lead positions. Failure to recognize cardiac lead perforation can lead to significant complications and even death. The use of chest CT is essential when patients are asymptomatic or at risk of perforation.

The patient in the present case was asymptomatic and the chest radiograph was normal despite lead perforation. In such cases, obtaining a CT scan of the thorax is critical for confirming the diagnosis since any attempt to retrieve the protruding lead can result in serious clinical and hemodynamic consequences due to hemorrhage into the pericardial space. Similar cases reported in the literature demonstrate the essential role of CT scanning prior to lead extraction.

Conclusion

Pericardial perforation is a significant complication associated with Riata leads. Most patients are asymptomatic, and there is no standardized modality to diagnose perforation or threatened perforation. We propose that patients undergoing Riata lead extraction should routinely undergo chest CT prior to the procedure.

References


1327 The Journal of Innovations in Cardiac Rhythm Management, July 2013