EMERGING TECHNIQUES

Extraction of Recalled Riata Leads

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Introduction

In December 2011, the Food and Drug Administrations (FDA) issued a class-one recall for the Riata (St Jude Medical, Sylmar, CA) defibrillator lead (models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, and 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042). There are two types of recalled leads in the Riata family: the 8-French Riata model (released in 2002), and the 7-French Riata ST model (2005). Approximately 227,000 leads were sold worldwide. Currently, approximately 79,000 Riata leads remain active in the United States.1

Current recommended management for patients with normally functioning leads is fluoroscopy to check for externalized cables, and close follow-up.2 The relationship between mechanical malfunction and electrical failure, however, remains to be understood; some leads function normally with externalized cables, and others present with electrical failure in the absence of fluoroscopic evidence of externalization.

The management of patients with externalized cables and normally functioning leads is evolving. While these patients are likely to be at risk for lead failure, the time course and our ability to predict it is poorly understood. If there is electrical lead failure, however, one must make a decision to remove or abandon the lead. Extraction of Riata leads is uniquely challenging in the presence of externalized conductors. Few reports exist on the challenges and safety of extracting Riata leads.3,4 In this study, we describe our techniques and experiences in the transvenous extraction of Riata leads with the use of either manual traction or Excimer laser (Spectranetics, Colorado Springs, CO) in order to assess the safety and success rate.

Methods

Data collection

The University of Miami Hospital has a large extraction registry of over 1,997 leads. We identified all patients with Riata lead extraction (n=82) from January 2004 through December 2012 (Figure 1). Clinical demographics, medical comorbidities, lead types, extraction methods, complications, and success rates were analyzed.

Extraction method

General anesthesia and intraoperative transesophageal echocardiogram were used in all extraction procedures in the operating room. An incision was made in the infraclavicular space. The Cardiovascular implantable electronic device was then removed, and the leads dissected to the subclavian ligament. Capsulectomy was performed in all cases. Laser sheaths were used in all cases when traction could not be unexploded by simple manual traction. Patients underwent laser lead extraction (LLE) using the CVX-300 (Spectranetics) laser system with the SLS II (Spectranetics) laser sheath between January 1, 2004, and May 31, 2012, and GlideLight (Spectranetics) laser sheath between June 1, 2012, and December 24, 2012. Under fluoroscopic guidance, a laser
sheath was used to clear the scar tissue and fibrotic adhesions where they existed around the lead. As the sheath moved closer to the myocardium, countertraction technique was used to free the tip of the lead. Multilayer closure was used in patients with malfunction. In patients with infection, the wounds were closed primarily with 2-0 nylon, and subcutaneous drains were left in the pocket. All procedures were performed by a single operator.

**Outcomes**

We used definitions of procedural success and complications outlined in the HRS 2009 Lead Extraction Expert Consensus.\(^5\)

**Statistics**

Continuous variables are analyzed as mean ± standard deviation. Categorical variables are analyzed as numbers or percentages. Statistical analysis was performed using the SAS version 9.1 (SAS Institute Inc., Cary, NC) \(p\)-values <0.05 were considered statistically significant.

**Procedural characteristics**

LLE was performed on 79 (96.3%) leads and manual traction was used in three (3.7%) extractions. The 14-French sheath was used most commonly (72.2%), and mean laser time was 50.3±49.6 s. Average time from implant to extraction for the Riata leads was 3.1±2.3 years (Riata model 3.7±2.3 years, Riata ST model 2.1±1.7 years).

**Results**

**Patient population**

There were a total of 82 Riata leads extracted from 80 patients; two patients had two Riata leads extracted in the same procedure (one active, one abandoned). Baseline characteristics are presented in **Table 1**. There were 62 males (77.5%), with an average age of 62±14 years, average New York Heart Association class of 2.3±1.1, and mean ejection fraction of 33.4±14.4%. Implanted device types were implantable cardioverter-defibrillator (ICD) in 67.5% and cardiac resynchronization therapy defibrillator (CRTD) in 23.5%. The most common indication for extraction was infection (72.5%), followed by malfunction (27.5%).

**Figure 1**: Flow char of the patient enrollment. TVR: tricuspid valve replacement.
A total of 181 leads were extracted in the 80 procedures (Table 2). Of the 82 extracted Riata leads, 32 were Riata ST, and 50 were Riata. Riata lead model numbers in the population are presented in Table 3. There were 74 dual coil leads (90.2%) and 54 active fixation leads (65.9%).

Procedural outcomes

Complete procedural success and clinical success was seen in all patients. There was one partial laser lead extraction of a Riata lead (model 1580), with remainder of the lead successfully removed through a femoral access. There were four hematomas at the surgical site and one pericardial effusion (did not require pericardiocentesis). No death resulted from the procedure, but one death occurred from sepsis because of device endocarditis during the index hospitalization.

Table 2: Riata leads baseline characteristics

<table>
<thead>
<tr>
<th>All extracted leads</th>
<th>Total 181 (2.3 ± 1.0/pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM</td>
<td>83</td>
</tr>
<tr>
<td>ICD</td>
<td>98</td>
</tr>
<tr>
<td>Riata</td>
<td>50</td>
</tr>
<tr>
<td>Riata ST</td>
<td>32</td>
</tr>
<tr>
<td>Manual traction</td>
<td>3.7% (n=3)</td>
</tr>
<tr>
<td>Laser lead extraction</td>
<td>96.3% (n=79)</td>
</tr>
<tr>
<td>Laser sheath size (Fr)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>10 (12.7%)</td>
</tr>
<tr>
<td>14</td>
<td>10 (12.7%)</td>
</tr>
<tr>
<td>16</td>
<td>12 (15.2%)</td>
</tr>
<tr>
<td>Mean laser time (s)</td>
<td>50.3 ± 49.6</td>
</tr>
<tr>
<td>Mean implanted time (years)</td>
<td>3.1 ± 2.3</td>
</tr>
<tr>
<td>Riata implanted time</td>
<td>3.7 ± 2.3</td>
</tr>
<tr>
<td>Riata ST implanted time</td>
<td>2.1 ± 1.7</td>
</tr>
</tbody>
</table>

PM: pacemaker; ICD: Implantable cardioverter-defibrillator.

Discussion

In this study, we demonstrate that extraction of Riata leads can be done successfully and with low complication rates. Complication rate for laser lead extraction in general is 1–4%.6–9 We achieved procedural success for all of our Riata lead extractions (82/82) with a similar complication rate (1.3%). Patel et al3 recently published similar results from their experience with Riata lead extractions; however, their population was much smaller (20 Riata leads) and use of laser sheath lower (90%) than our study. Moreover, they described 18 patients with Riata leads capped by an operator who was not trained for extracting leads.

The decision to abandon a Riata lead may place patients at increased risk for complications. In our experience, we saw 20 patients with capped Riata leads who presented with infection of the new leads. Other unique challenges that we have seen include externalized cable fragments that have migrated to the pulmonary artery, and leads with extracardiac location. Herein we describe our technique for conquering the Riata lead, and strategies for approaching its unique challenges.

Procedure planning

Prior to the procedure, all patients had posteroanterior and lateral chest radiographs, and most of them had non-contrast electrocardiogram-gated computed tomography scans. These images reveal the path of the lead, the extent of angulation, and intra- or extracardiac location. The presence of angulation or extracardiac location should be identified prior to starting procedure.

Table 4: Procedural complication

<table>
<thead>
<tr>
<th>Complication</th>
<th>Riata (n = 50)</th>
<th>Riata ST (n = 32)</th>
</tr>
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<tbody>
<tr>
<td>Major</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Minor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma at the surgical site</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Pericardial effusion with spontaneous resolution</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

We used definitions outlined in the HRS 2009 Lead Extraction Expert Consensus.
1. Extracardiac lead location: The tip of the Riata lead is known to be stiffer than other leads\textsuperscript{10} and there have been previous reports of cardiac perforations.\textsuperscript{11} We had three patients (3.8\%) with extracardiac leads (Figure 2). Extracardiac location increases procedural risk. For extracardiac leads, lasering should be stopped at a greater distance from the lead tip than for intracardiac leads.

2. Scarring of high voltage coils with severe angulations: When scarring around the non-backfilled, high-voltage coils is produced (dual coiled leads), a severe angulation may be formed in the superior vena cava and innominate vein. Angulations of this type tend to deflect in a posterior direction (or bend) increasing the risk of a perforation when using laser sheathes (Figures 3 and 4) (visit Video 1 at innovationsincrm.com).
Procedure technique

Lead preparation
1. Cut the proximal end of the Riata lead and expose the central lumen coil and cable conductors (Figure 5). Insert an LLD EZ lead locking stylet (Spectranetics) into the lumen (Figure 6). Then, roll the lead over the sharp edge of an 11 blade at about 5–8 cm from the proximal end to remove the outer insulation in order to expose the conductor cables (Figure 7).
2. Place the conductor cables through the loop of a Bulldog Lead Extender (Cook Medical, Grandegrift, PA) (Figure 8) and advance the locking tube until the cables are locked (Figure 9). Tie the conductor cables to the distal tip of the Bulldog (Figure 10). One of the advantages of using the conductor cables is that they allow pulling of the lead with greater force.

Figure 4: Cutting the insulation and exposure of the conductor cables.

Figure 5: Placing of the conductor cables through the loop of the Bulldog® (Cook Medical, Grandegrift, PA, USA).
Figure 6: Advancement of the actuator tube to lock the cables. Tie the conductor cables to the distal tip of the bulldog (image 6).

Figure 7: Tying of the conductor cables.
Techniques and Strategies

Figure 8: Left: The Bulldog® (Cook Medical, Grandegrift, PA, USA), the conductor cables and the lead (X40) Right: The 16 French laser sheath passing over the Bulldog, the conductor cables and the lead (X40).

Figure 9: Non contrast EKG gated CT scan showing extracardiac lead.
3. Prepare a 16-French laser sheath with a mounted, VisiSheath (Spectranetics) outer sheath. Although we first started to extract Riata leads with a 14-French laser sheath, we learned that a 16-French laser sheath makes the extraction easier.

4. Insert the prepared lead into the 16-French laser sheath (Figure 11) (Entire procedure, visit Video 2 on innovationsincrm.com).

Procedure challenges
1. Difficulty passing a lead locking device: The lead locking device may not be positioned past the ring electrode. The most common location is at the right atrial level, and angulations may play a role. Leads without a locking stylet at the tip are also more prone to stretch during the procedure.

2. Snow plowing effect of externalized cables: Riata leads with externalization of conductors may bunch together with dense tissue and cause snowplowing (Figure 12). The use of an outer sheath is helpful to engulf the cables and tissue, without the use of laser energy (visit Video 3 on innovationsincrm.com).

3. Stretching of the high-voltage coils: In most non-Riata leads, the conductor cable is welded at the proximal end of the coil, resulting in a decrease in coil diameter when traction is applied. In Riata leads, however, the conductor cables are welded to the distal end of the high-voltage coil. When traction is applied, the coils bunch up, the diameter of the coil’s distal section widens, and the distance between each turn in the coil decreases (Figure 13). Use of the 16-French sheath is particularly helpful for this challenge.

Clinical implications
The management of Riata leads remains a puzzle. Electrical malfunction is not as high as Fidelis (Medtronic Corporation, Minneapolis, MN) leads and, therefore, prophylactic extraction is not currently advised. The failure rate is higher, however, than other ICD leads (failure rate of 0.67% per device year). Screening with fluoroscopy may help to identify externalized conductors. Studies show that most externalized cables are electrically intact, and many patients with electrical abnormalities have normal leads on fluoroscopic examination. This phenomenon is
Figure 11: Scarring of high voltage coils with severe angulations (right) and normal angulations (left).

Figure 12: Bundling and snowplowing.
supported by recent data that suggest the rate of electrical failure is distinct from structural failure.\textsuperscript{4} We believe that all Riata leads with electrical failure should be extracted. Decisions should be taken uniquely for each patient, and operator experience must be considered.

**Study limitations**

This was a single-center study of lead extractions performed by a single experienced operator at a tertiary referral center. Our outcomes, therefore, may not be generalizable. We did not compare outcomes after transvenous lead removal or lead abandonment, and as such we do not know which is optimal. A comparison between extractions of single or dual coil leads could not be analyzed, because of the small number of single coil leads in the population. Despite these limitations, this study to date is the largest Riata lead extraction experience with the highest procedural success rate.

**Conclusion**

Although specific techniques are required, Riata lead extraction can be safely performed with a high success rate and low complication rate. If the extraction procedure is done properly, one can expect a success rate comparable to any other lead.

**References**

2. U.S. Food and Drug Administration. FDA recommends X-ray or other imaging on implanted heart defibrillators with St. Jude Medical Riata leads to help guide treatment. FDA news release August 16 2012;888-INFO-FDA.