Conductor externalization of the Riata internal cardioverter defibrillator lead: tip of the iceberg? Report of three cases and review of literature

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Aims
Recently, concerns about St Jude’s Riata lead family have come to light. We present three cases of patients with Riata internal cardioverter defibrillator (ICD) leads with externalized conductors.

Methods and results
All patients had the same insulation defect, with externalized conductors, but differed in presentation and symptoms. These cases, which form 3 of 179 (1.68%) of our total Riata lead population, presented four or more years after implantation. This may be an indication that the problem with the Riata lead may well be greater than reported in the recent St Jude Medical device advisory letter.

Conclusion
The management of the Riata lead problem is discussed as, up until now, management of patients with an implanted Riata lead has been based on detecting electric abnormalities on regular ICD interrogation only.

Keywords
ICD † Riata † Insulation defect † Externalized conductors † Advisory

Introduction
As the indication for implantation of an internal cardioverter defibrillator (ICD) is expanding and the number of patients with longer follow-up is growing, the incidence of complications is increasing. In particular, the long-term reliability of ICD leads is worrisome.1,2 This may be due to the fact that ICD leads are of high complexity, with pace-sense and defibrillator capabilities combined in a single lead.3 Recently, concerns about St Jude’s Riata lead family have come to light. The 8-French (F) Riata ICD lead was market released in the USA in 2002 and was removed from distribution in 2010 after ~227 000 leads were sold worldwide. The Riata ST models were introduced in 2005 and were 7 F diameter leads. Riata and Riata ST leads were insulated with silicone rubber [the high-voltage conductors have an additional layer of ethylenetetrafluoroethylene (ETFE) insulation]. In 2006 an additional silicone–polyurethane co-polymer (Optim™) covering was added to Riata ST models.4 This new lead model was renamed Riata ST Optium.

The Riata and Riata ST leads appear to be prone to a unique failure mechanism whereby the conductor cables wear through the silicone insulation and appear outside the lead body (externalized conductors).

Since 2005 we implanted 179 Riata ICD leads in our centre and only recently three patients with externalized conductors Riata ICD leads came to our attention.

Case 1
A 71-year-old woman received a biventricular ICD (Atlas, St Jude Medical, Sylmar, CA, USA) in 2005. The right ventricular lead was a dual-coil St Jude Medical Riata 1580. She encountered several appropriate ICD therapies, because of ventricular tachycardia. Routine device check-ups showed no signs of malfunction of the device, or the leads.

Because the system was reaching end-of-life, replacement of the device was scheduled. During the procedure, which took place in November 2011, fluoroscopy revealed an extensive insulation defect and externalization of the conductors (Figure 1A). Because...
there were no signs of electrical lead failure and extensive thrombotic occlusion of the subclavian vein was present on angiography, the lead was not replaced. A new device with lead integrity alert and lead noise algorithm (Protecta, Medtronic, Inc., Minneapolis, MN, USA) was implanted. The patient was put on remote monitoring as well as close monitoring with every 3 months follow-up.

Case 2
In 2006, a 71-year-old woman underwent implantation of a single-chamber ICD (Atlas, St Jude Medical) and a single active coil St Jude Medical Riata 1582-65 lead. This for secondary prevention of sudden cardiac death after an out-of-hospital cardiac arrest due to ventricular fibrillation. On routine device check-ups, a decreasing trend was seen for lead impedance and R-wave sensing. Fluoroscopy showed the same pattern of insulation defect as in the previous case (Figure 1B). The Riata lead could be easily extracted using a locking stylet. A new lead and ICD were implanted. The extracted lead with externalized conductors is shown in Figure 2.

Case 3
A 61-year-old man, with a history of coronary artery bypass grafting, received a single-chamber ICD (Virtuoso, Medtronic, Inc.) with a St Jude Medical Riata single active coil 1582-65 lead in 2007 for primary prevention of sudden cardiac death. In 2008 ventricular tachycardia was appropriately treated by the ICD. In December 2011 the patient was seen at the outpatient clinic, for a scheduled device check-up. Interrogation of the device revealed noise on the intracardiac electrogram (Figure 3), which was interpreted by the device as short V–V intervals. All other parameters were normal. The ICD was switched off and the patient scheduled for lead replacement. During the procedure, fluoroscopy showed an extensive insulation defect (Figure 1C). The Riata lead was disconnected, but not removed, and a new ICD lead was implanted. Post-procedural testing was normal and the patient was discharged from the hospital the day after the procedure.

Discussion
The evolution of transvenous ICD leads has been of great importance to the treatment of ventricular arrhythmia and the prevention of sudden cardiac death. However, the ICD lead remains the weakest link in the complete ICD system. The majority of lead defects can only be detected by routine ICD interrogation, but in a considerable number of the cases, inappropriate ICD therapy is the first sign of a defective lead. Insulation defect is the most common cause of lead malfunction.

On 28 November 2011 St Jude Medical issued a medical device advisory on insulation failure of the Riata and Riata ST defibrillator leads, which was classified by the United States Food and Drug Administration as a Class I recall. In this advisory, prophylactic explant, or replacement of a defected lead is not recommended. In addition, routine fluoroscopic evaluation is not recommended. The three cases in this report describe an insulation defect of the Riata ICD leads. All three have the same type of defect, but have different presentations. The first patient was asymptomatic and all parameters were normal, whereas the third case had short V–V intervals which could in the worst case lead to inappropriate ICD shocks.

Leads from the Riata family have been subject of debate in the last years. From the year 2007, several reports mentioned an increase in perforations of Riata leads. These observations led to retrospective studies, which came to the conclusion that there were no significant differences in complication rate between Riata and other leads. However, in 2009, Ellis and Rottman reported in their retrospective study more lead-related
complications in small-diameter ICD leads (Riata 1580, Riata ST 7000, and Medtronic Sprint Fidelis 6949 and 6948).

Recently, there have been reports of another type of lead failure. In 2008, Duray et al.\textsuperscript{11} and in 2010, Richards et al.\textsuperscript{12} described cases with an insulation defect with protruding of the inner wiring. These defects were brought to light because of abnormal pacing parameters. These observations led to a retrospective single-centre analysis of all implanted Riata leads at that centre. In 30 of 357 (8%) there was lead failure necessitating lead replacement. In six cases (20% of the failed leads) insulation defects at the level of the tricuspid valve were the cause of the failure.\textsuperscript{13}

Insulation defects as described in this and in other case reports are not always accompanied by aberrant parameters such as impedance, or sensing. Krebsbach et al.\textsuperscript{14} reported a case of a Riata insulation defect, which went without abnormal measurements.\textsuperscript{15}

The design of Riata leads is based on a multilumen construction, with silicon, or since 2006 Optim\textsuperscript{TM} insulation. The latter insulation has not been described to have inside–out abrasion problems; however, the follow-up of these leads is still limited.\textsuperscript{4,16} Pairs of conductors are located in the outer part of the insulation connecting to the proximal ring pacing electrode and the defibrillation coil electrode. The conductors have an additional layer of ETFE insulation. This may be the explanation why an outer insulation defect does not necessarily result in electric abnormalities.\textsuperscript{13} Moreover 8 F single-coil Riata models may be more prone to externalization than dual-coil Riata and Riata ST models. This may be explained by the different design of the dual-coil Riata and Riata ST models. Riata 8 F single-coil leads have two lumens directly opposed to one another, whereas the dual-coil Riata and Riata ST models have three lumens that are equally spaced around the inner coil, which could reduce tension on the outer insulation.

\textbf{Figure 3} Intracardiac electrogram revealing noise, which was interpreted by the internal cardioverter defibrillator as short V–V intervals.

\textbf{Figure 4} Schematic view of an 8 F Riata single-coil lead and a 7 F Riata ST single-coil lead. (Courtesy of St Jude Medical.)
conductors. In single-coil Riata ST leads, the third cable pair provides no electrical function (Figure 4).4,16

The first case in this report also had normal parameters and the lead defect was not discovered until a scheduled device change was performed, because of low battery status. Although it is not clear what the exact meaning of an asymptomatic insulation defect as previously described is, one could state that this bears a potential threat of adverse events such as inappropriate shocks. Therefore, regarding these and other published cases of insulation defects of Riata leads, systematic fluoroscopic evaluation could be considered. It is noteworthy that the defect is not always visible on standard chest X-ray and therefore in case of any suspicion of lead defect (e.g. impedance change, sensing problems) or at the time of generator replacement, a thorough fluoroscopic evaluation in at least three axes is in our view mandatory.

In the afore mentioned advisory, St Jude adjusted the all cause abrasion rate for leads from the Riata family from 0.47 to 0.63%. In our centre we perform follow-up on 179 patients with an ICD lead of the Riata family (1580, 1581, 1582-65, 7001-65, and 7002-65). In 167 of those patients, the lead was implanted at our centre. Consequently, the incidence of (discovered) externalized conductors at our centre is currently 3 of 179 (1.68%). Based on this and other case reports, the Riata problem may well be greater than the rate mentioned in the St Jude advisory. Typical timing of lead defects is after 5 years, as in our case report, and could mean that we only see ‘the tip of the iceberg’ at this moment. Besides, as described in this and other reports, externalized conductors do not necessarily lead to abnormal electric measurements.4,16

Currently, there are no data to support neither that externalized conductor leads will eventually fail nor that externalized conductors pose a mechanical or anatomic threat to the patient. Very recently, in the Netherlands the National Society of Cardiology issued a class I recall to all Riata leads with mandatory screening for lead integrity by electrical measurements as well as fluoroscopy in three directions for all patients.17 Follow-up is dependent on findings: (i) no externalized conductors and no electrical abnormalities: remote monitoring and if this is not possible every 3 months follow-up. Minimal once a year fluoroscopic evaluation; (ii) externalized conductors and normal electrical measurements: consider replacement or abandon the RIATA electrode and implant a new electrode, depending on the risk–benefit ratio for the individual patient. If no new lead is implanted same advice as in (i).

(3) Externalized conductors and abnormal electrical measurements: replace or abandon the Riata electrode and implant a new defibrillation electrode. Time will tell if this is the right management, as prospective data from follow-up of externalized Riata ICD leads will emerge.

Conclusion

Externalized conductors are becoming a more than incidental finding of leads from the Riata and Riata ST family. The presentation of this phenomenon ranges from normal electrical measurements to malfunctioning leads which can result in serious clinical sequelae. Management of patients with an implanted Riata lead is still unclear but should be based on early detection of electrical abnormalities and thorough fluoroscopic evaluation.

Conflict of interest: none declared.

References