



Abbott

Abbott
15900 Valley View Court
Sylmar, CA 91342 USA
Main 818 362 6822
Fax 818 364 5814

PUBLICATION SUMMARY PERTAINING TO ABBOTT™ RIATA™ LEADS (WITH >100 PATIENTS OR RIATA LEADS UNLESS NOTED)

2016–2017 Publications

| Citation | Sample Size | Study Note | Conclusions |
|--|--------------------|------------------------------|--|
| “Long-term Performance of the Riata/ST Implantable Cardioverter-Defibrillator Lead” <i>American Journal of Cardiology</i> , 2016; 117:807-812 Ströker et al. | 154 | Single Center Belgium | A retrospective review of Riata lead 8 F (n = 72), Riata™ ST lead 7 F (n = 52), and Riata™ ST Optim™ lead (n = 30) lead performance using three management approaches: monitoring, capping, or extracting. Electrical failure (EF) was identified in 14 Riata/ST leads (13%) and none (0) of the ST Optim leads. |
| “Canadian Registry of Implantable Electronic Device Outcomes Surveillance of the Riata lead Under Advisory” <i>Heart Rhythm</i> , 2017; 10.1016/j.hrthm.2017.11.033 Parkash et al. | 1352 | Nationwide (Canada) | The 12-year rate of electrical failure for the 8F lead was 9.45% while the 10-year failure rate for the 7F lead was 7.25%. No significant differences were observed between the 2 lead models with respect to electrical failure. 76% of the leads revised were abandoned and 24% were extracted with power tools. The rate of major complications in each group was 5.6% and 5.9% respectively. After a dwell time of 10 years the risk of failure exceeds the risk of peri-procedural major complications, indicating that risk-benefit is favorable to revise the lead in appropriate clinical scenarios. |
| “The incidence of Riata Defibrillator Lead Failure: a Single-Center Experience” <i>J Korean Med Sci</i> , 2017;32:1610-1615 Gwag H.B. et al. | 44 | Single Site (South Korea) | All patients implanted with Riata defibrillator leads between January 2003 and December 2010 were investigated for externalized conductor (EC) and electrical dysfunction (ED). There was no difference in ED-free survival rate between patients with and without EC (P=0.628). |
| “Nationwide Longitudinal Follow-up of Riata Leads Under Advisory at 3 Annual Screening” <i>JACC: Clinical Electrophysiology</i> , 2017; 3:8 (887-893) Theuns et al. | 882 | Nationwide (Netherlands) | The development of conductor externalization (CE) is progressive with an incidence rate of 4.9 per 100 patient-years (7.0 for 8F riata and 3.2 for 7F Riata ST). There no association observed between CE and electrical failure. |
| “Canadian Registry of Implantable Electronic Device Outcomes Surveillance of the Riata lead Under Advisory” <i>Circ Arrhythm Electrophysiol</i> , 2016;9(10):1-9 Parkash et al. | 3763 | Nationwide (Canada) | The overall electrical failure rate was 5.2% at 8 years with no difference between 7-French and 8-French models. Cable externalization was found to be more common in the 8-French model (12.3% vs 5.2%, P<0.0001). Predictors of electrical lead failure include cable externalization, higher left ventricular ejection fraction, younger age, higher body mass index and a passive fixation lead. These predictors can assist with clinical decisions as to whether lead revision should be performed prophylactically. |

2015 Publications

| Citation | Sample Size | Study Note | Conclusions |
|--|-------------|-------------------------------|--|
| <p>“A Comparative Study of Defibrillator Leads at a Large-Volume Implanting Hospital: Results from the Pacemaker and Implantable Defibrillator Leads Survival Study (“PAIDLESS”)”</p> <p><i>Journal of Invasive Cardiology</i>, 2015; 27(6): 292-300</p> <p>Cohen et al.</p> | 703 | Single Center (Winthrop U.) | Recalled St. Jude Medical™ leads performed better than recalled Medtronic™ leads in our study. Recalled St. Jude Medical leads had no significant difference in lead failure when compared with the other manufacturer’s non-recalled leads. |
| <p>“Insight into the mechanism of failure of the Riata lead under advisory”</p> <p><i>Heart Rhythm</i>, 2015; 12:574-579</p> <p>Parkash et al.</p> | 263 | Nationwide Canada | Lead-can abrasion is the most common form of insulation defect in the Riata™ group of leads under advisory. Management of this group of leads under advisory should not neglect the issue of lead-can abrasion, in addition to detection of cable externalization. |
| <p>“Pulse Generator Exchange does not accelerate the rate of electrical failure in a recalled small caliber lead”</p> <p><i>American Journal of Cardiology</i>, 2016; 117:807-812</p> <p>Ströker et al.</p> | 153 | Single Center (Emory) | Conductor externalization was seen frequently in our cohort of patients. ICD generator exchange did not accelerate the rate of Riata™ lead failure at 1 year. Although both the control and the change-out cohorts failed at a rate much greater than non-recalled leads, generator exchange did not appear to add to the problem. |
| <p>“Assessment of implantable cardioverter defibrillator leads with evidence of conductor externalization: An observational study”</p> <p><i>European Heart Journal</i>, 2015; 36 Suppl.1 (47)</p> <p>McKeag et al.</p> | 202 | Single Center (N. Ireland) | Between 2010 and 2014, 47 of 202 (23%) Riata leads had evidence of conductor externalization. During four years of follow-up, 10.6% of patients with a Riata™ ICD lead and evidence of conductor externalization developed an electrical abnormality of the lead (5 of 47). |
| <p>“Incidence of new externalized conductors and electrical dysfunction in Riata leads: Results from a Multicenter Study”</p> <p><i>Europace</i>, 2015; 17 SUPPL. 3 (iii147)</p> <p>Hayes et al.</p> | 776 | Multi-center (RLES & CLAS) | Through two years of follow-up, there has been development of new EC post enrollment in 8 F Riata and 7 F Riata™ ST silicone leads. However, the presence of externalized conductors is not associated with an increased risk for electrical dysfunction. |
| <p>“Fluoroscopic investigation of Riata transvenous defibrillator leads”</p> <p><i>Cardiology Journal</i>, 2015; 22:1 (57-67)</p> <p>Singh et al.</p> | 90 | Single Center (Michigan) | Prevalence of insulation failure exhibiting as conductor externalization is high (26.7%) among large diameter 8 F Riata leads with a significant proportion of patients manifesting electrical failure. High resolution 3 view fluoroscopy is a reasonable approach to screen for this unique type of insulation failure. |
| <p>“Optimal Management of Riata Leads with no known electrical abnormalities or externalization: a decision analysis”</p> <p><i>Journal of Cardio Electrophysiology</i>, 2015; 26:2 (184-191)</p> <p>Pokorney et al.</p> | n/a | n/a | Overall there were minimal differences in survival with monitoring versus active lead management approaches. There is no evidence to support fluoroscopic screening for externalization of Riata or Riata ST leads. |
| <p>“PA/Lateral Chest X-Ray is Equivalent to Cine-Fluoroscopy for the Detection of Conductor Externalization in Defibrillation Leads”</p> <p><i>PACE</i>, 2015; 38:77-83</p> <p>Steinberg et al.</p> | 78 | Single Center (Quebec) | PA/lateral CXR with zooming is equivalent to cine-fluoroscopy for the detection of Riata lead insulation defects and should be considered as the preferred screening method. |
| <p>“Outcomes of Sprint Fidelis and Riata lead extraction: Data from 2 high-volume centers”</p> <p><i>Heart Rhythm</i>, 2015; 12:6 (1216-1220)</p> <p>Cohen et al.</p> | 102 | Multi-center (Emory and UPMC) | Our data from two high-volume centers suggest that extraction of Sprint Fidelis™ and Riata leads is associated with excellent clinical success and a similar rate of major procedural complications. |
| <p>“Transvenous extraction profile of Riata leads: Procedural outcomes and technical complexity of mechanical removal”</p> <p><i>Heart Rhythm</i>, 2015; 12:3 (580-587)</p> <p>Bongiorni et al.</p> | n/a | n/a | In clinical practice, rates of conductor externalization (CE) in Riata leads are substantial. CE is associated with significant increase in the risk of electrical failure (EF), the incidence of EF without externalization is not trivial. |
| <p>“Cable externalization and electrical failure of the Riata family of implantable cardioverter-defibrillator leads: A systematic review and meta-analysis”</p> <p><i>Heart Rhythm</i>, 2015; 12:6 (1233-1240)</p> <p>Zeitler et al.</p> | n/a | n/a | In clinical practice, rates of conductor externalization (CE) in Riata leads are substantial. While CE is associated with significant increase in the risk of electrical failure (EF), the incidence of EF without externalization is not trivial. |

2014 Publications

| Citation | Sample Size | Study Note | Conclusions |
|---|-------------|-------------------------|--|
| Larsen et al. Prospective nationwide fluoroscopic and electrical longitudinal follow-up of recalled Riata defibrillator leads in Denmark. <i>Heart Rhythm</i> . Dec 2014. | 239 | Nationwide | The development of externalized conductors (EC) is a dynamic process despite long lead dwell time. ECs are associated with a higher risk of electrical abnormalities. Therefore, lead replacement should be considered, especially in patients with a long life expectancy. |
| Larsen et al. The patient perspective on the Riata defibrillator lead advisory: A Danish nationwide study. <i>Heart Rhythm</i> . Dec 2014. | 256 | Nationwide | The Riata lead advisory is associated with a persistent small reduction in device acceptance and a small increase in device-related concerns with minimal improvement over time. Female sex is a predictor of a high negative advisory impact on general well-being. A need for counseling may arise in vulnerable subsets of patients. |
| Parkash et al. Insight into the Mechanism of Failure in the Riata Lead Under Advisory. <i>Heart Rhythm</i> . Dec 2014. | 263 | Nationwide | Lead-can abrasion is the most common form of insulation defect in the Riata group of leads under advisory. Management of this group of leads under advisory should not neglect the issue of lead-can abrasion, in addition to detection of cable externalization. |
| Steinberg et al. Longitudinal follow-up of Riata leads reveals high annual incidence of new conductor externalization and electrical failure. <i>J Interv Card Electrophysiol</i> . Dec 2014. | 147 | Single Center | The annual incidence of new insulation defects in Riata™ leads is much higher than previously reported. Lead models 1580, 1582, and 1590 are at highest risk for new conductor externalization. Electrical dysfunction in Riata™ leads is also much higher than reported and is associated with conductor externalization. |
| Mckeag et al. Fluoroscopic and Electrical Assessment of Implantable Cardioverter Defibrillator Leads: A Prospective Observational Study. <i>Pacing Clin Electrophysiol</i> . Nov 2014. | 147 | Single Center | Conductor externalization (CE) was observed at a rate of 3.6 per 100 patient-years of follow-up, in 140 individuals with a Riata ICD lead and no definite evidence of CE at baseline. |
| Maytin et al. Multicenter experience with extraction of the Riata/Riata ST ICD lead. <i>Heart Rhythm</i> . Sept 2014. | 577 | Multi-center Extraction | Extraction of the Riata/Riata ST leads can be challenging, and leads with externalized cables may require specific extraction techniques. Extraction of the Riata/Riata ST leads can be performed safely by experienced operators at high-volume centers with a complication rate comparable to published data. |
| Cutts et al. Value of Active Surveillance in Collecting Lead Adverse event Data. Heart Rhythm Society's Annual Scientific Sessions, San Francisco, CA, May 8, 2014. PO05-202. | n/a | Other | Externalized conductor (EC) rates from Lead Evaluation Study (LES) and Product Performance Reports (PPR) are vastly disparate. Actively collected LES data are likely to be more representative of actual EC rate. PPRs are helpful tools in evaluating clinical performance of leads, but reliance on passive reporting limits their utility. Underreporting is not limited to one manufacturer of another, but rather an industrywide challenge that deserves discussion. These observations reinforce the need for industrywide effort to perform active surveillance and to improve voluntary reporting. |
| Cunnane et al. Single Chest X-Ray Versus Multi-Angled fluoroscopy in Identifying Structural Abnormalities in Riata Leads. Heart Rhythm Society's Annual Scientific Sessions, San Francisco, CA, May 8, 2014. PO06-27. | 128 | Single Center | Chest x-ray, though helpful, appears not to be as sensitive as multi-angle fluoroscopy for identifying structural dysfunction of the Riata lead. Serial examination of Riata leads annually by fluoroscopy is supported by these findings. Examining zones within the heart has the highest yield. |
| Hayes et al. Incidence of New Externalized Conductors and Electrical Dysfunction in Riata and Riata ST Silicone ICD Leads: 1 year Results from a Prospective, Multicenter Study. Heart Rhythm Society's Annual Scientific Sessions, San Francisco, CA, May 8, 2014. AB05-02. | 776 | Multi-center | Through 1 year of follow-up, the incidence of new externalized conductors in 8F Riata and 7F Riata ST silicone leads is low. The presence of externalized conductors is not associated with an increased risk for electrical dysfunction. |
| Larsen et al. Conductor Externalization is strongly Associated with Electrical Abnormality in Recalled Riata Defibrillator Leads—A Danish Nationwide Perspective Follow-up Study. Heart Rhythm Society's Annual Scientific Sessions, San Francisco, CA, May 8, 2014. AB05-04. | 298 | Nationwide | Riata lead conductor externalization is strongly associated with electrical abnormalities. The rates of new electrical abnormalities and externalizations are relatively high. This emphasizes the need to consider lead replacement in case of externalization especially in patients with long life expectancy. |

2014 Publications (continued)

| Citation | Sample Size | Study Note | Conclusions |
|--|-------------|---------------|---|
| Zhao et al. Riata Silicone Defibrillator Leads Failure: Increase in Prevalence After 5 years of Follow-up. Heart Rhythm Society's Annual Scientific Sessions, San Francisco, CA, May 8, 2014. PO06-26. | 198 | Single Center | Riata leads had a high rate of malfunction in different period after implantation. Insulation defects of leads are especially higher after 5 years that implies a very careful and strict follow-up on the long run. |
| Demirel et al. Mechanical and electrical dysfunction of Riata implantable cardioverter-defibrillator leads. <i>Europace</i> . Jan 2014. | 273 | Single Center | Riata leads show progressive and high externalization rates without correlation between externalization and electrical lead failure. Non-ischaemic cardiomyopathy and impaired LVEF are independent predictors of structural lead failure in cross-sectional analysis, whereas 7 Fr lead is a predictor of electrical lead failure. |
| Liu et al. Longitudinal Follow-Up of Implantable Cardioverter Defibrillator Leads. <i>Am J Cardiol</i> . Jan 2014. | 5,288 | Single Center | This study represents a comprehensive retrospective review of ICD lead survival rate from major US lead manufacturers. Our data demonstrate that failure-free survival curves of recalled ICD leads diverge from those of non-recalled leads 2 years after implantation. Furthermore, an overall ICD lead survival rate on the order of 90% is seen at 5 years. |
| Richardson et al. Comparative outcomes of transvenous extraction of sprint fidelis and Riata defibrillator leads: a single center experience. <i>J Cardiovasc Electrophysiol</i> . Jan 2014. | 192 | Single Center | Despite differences in baseline characteristics, this study indicates that Medtronic Sprint Fidelis™ and St. Jude Medical Riata™ ICD leads have similar procedural outcomes with transvenous lead extraction. |

2013 Publications

| Citation | Sample Size | Study Note | Conclusions |
|---|-------------|-----------------------------------|---|
| Greenslade et al. Single centre experience with Riata defibrillator leads. <i>Heart, Lung and Circulation</i> . 2013. DOI: http://dx.doi.org/10.1016/j.hlc.2013.04.031 . | 100 | Single Center | 9% electrical failure rate with Riata leads which is higher than published data. |
| Jayam et al. Does the Riata™ Lead Deliver Adequate Defibrillation Shocks? A Single Center Experience in 289 Patients. <i>Heart Rhythm</i> . 2013. The Riata Conundrum AB11-02. | 289 | Single Center | Externalized conductors was observed in 13.1% of 8F leads and 4.8% in 7F; failure of defibrillation efficacy only occurred in one patient; in 99% of this cohort, sensing and HV function remained intact. |
| Lindemann et al. The Role of Lead Integrity Alerts and Remote Monitoring in Reducing Morbidity Associated With the St Jude Medical Riata ICD Lead. <i>Heart, Lung and Circulation</i> . 2013. DOI: http://dx.doi.org/10.1016/j.hlc.2013.05.295 . | 103 | Single Center Medtronic Sponsored | Despite a normally functioning Riata lead at generator change, 8% of leads failed at a median of 17 months post generator change. The Lead Integrity alert and Remote Monitoring appear to be helpful in preventing inappropriate shocks. |
| Lorvidhaya et al. Prospective evaluation of cinefluoroscopy and chest radiography for Riata lead defects: Implications for future lead screening. <i>J Interv Card Electrophysiol</i> . 2013. | 102 | Single Center | Cinefluoroscopy appears to be more sensitive than CXR for the detection of Riata cable extrusion. Interpretation of CXR by a radiologist with education in lead defects correlates highly with cinefluoroscopy with very high specificity. Depending on available resources for screening, CXR may be a reasonable alternative to cinefluoroscopy. Multidisciplinary collaboration across specialties (radiology and electrophysiology) can lead to improved diagnostic capability and thus the potential for enhanced quality of care. |
| Rordorf et al. Failure of Implantable Cardioverter Defibrillator Leads: Is It a Matter of Lead Size? <i>Heart Rhythm</i> . 2013;10(2): 184-190. Rordorf et al. Failure of Implantable Cardioverter Defibrillator Leads: Is It a Matter of Lead Size? <i>Heart Rhythm</i> . 2012;9(5): S60. AB27-04. Rordorf R et al. Incidence of ICD lead fracture: comparison of small vs standard-diameter leads implanted in a single center. <i>European Heart Journal</i> . 2012 33 SUPPL. 1 (539) Abstract 3255. | 890 | Single Center | During a median follow-up of 33 months, the overall failure rate was 6.3%. The failure rate was significantly higher in Sprint Fidelis leads than in both standard-diameter (4.8%/year vs 0.8%/year; P<.001) and Riata/Riata ST (4.8%/year vs 2.6%/year; P = .03) leads. Compared with standard-diameter leads, both Sprint Fidelis and Riata/Riata ST small-diameter ICD leads are at an increased risk of failure, although the incidence of events is significantly lower in the Riata than in the Sprint Fidelis group. |
| Ellenbogen et al. Performance of lead integrity alert to assist in the clinical diagnosis of implantable cardioverter defibrillator lead failures: analysis of different implantable cardioverter defibrillator leads. <i>Circ Arrhythm Electrophysiol</i> . Dec 2013. | 12,793 | CareLink™ data | Analyzed data 6123 St. Jude Riata or Durata™, 5114 Boston Scientific Endotak™, and 1556 Fidelis™ combinations followed in the Medtronic CareLink™ remote monitoring network for Lead system events and lead failures. The Lead Integrity Alert (Medtronic) markedly increased the detection rate of Lead system events compared with conventional impedance monitoring. |
| Hayes et al. Prevalence of Externalized Conductors in Riata and Riata ST Silicone Leads: Results from the Prospective, Multicenter, Riata Lead Evaluation Study. <i>Heart Rhythm</i> . Dec 2013. | 776 | Multi-center | Larger-diameter Riata leads were more prone to EC than smaller-diameter Riata ST leads. The prevalence of electrical dysfunction was not associated with EC. |
| Marcus et al. The year in review of clinical cardiac electrophysiology. <i>J Am Coll Cardiol</i> . Dec 2013. | n/a | Review paper | Summarizes results from the VA, Abdelhadi, and Canadian HRS studies. |
| Liu et al. Longitudinal Follow-Up of Externalized Riata Leads. <i>Am J Cardiol</i> . Nov 2013. | 329 | Single Center | Prospective follow-up data on externalized Riata leads suggest an electrical failure rate in excess of 6% per year. This high failure rate warrants consideration of prophylactic replacement of externalized Riata leads. Further studies examining the natural history of Riata leads are warranted. |
| Cheung et al. Mechanisms, Predictors and Trends of Electrical Failure of Riata Leads. <i>Heart Rhythm</i> . Oct 2013. | 314 | Single Center | Younger age and female gender are independent predictors of Riata lead failure. Loss of integrity of conductor cables with ethylene tetrafluoroethylene coating is an important mode of electrical failure of the Riata lead. Further study of Riata lead failure trends is warranted to guide lead management. |

2013 Publications (continued)

| Citation | Sample Size | Study Note | Conclusions |
|--|-------------|----------------------------------|--|
| Hauser et al. Early fatigue fractures in the IS-1 connector leg of a small diameter ICD lead: Value of returned product analysis for improving device safety. <i>Heart Rhythm</i> . Oct 2013 | n/a | MAUDE database (April 11, 2013) | Search found 59 leads with fractures in the IS-1 leg. Most fractures were in leads implanted in 2008–2009; no fractures were found in leads implanted after 2010. SJM's small diameter leads that were manufactured before 2011 are prone to early outer coil fatigue fractures in the IS-1 leg. The failure mechanism appears to have been mitigated by a design change. Returned Product Analysis is important for improving device safety. |
| Swerdlow et al. Implantable cardioverter-defibrillator leads: Design, diagnostics, and management. <i>Circulation</i> . Oct 2013. | n/a | Review paper about device design | Addresses design issues with both Sprint Fidelis and Riata leads, as well as potential signs of lead failure and management. |
| Fazal et al. Comparison of Sprint Fidelis and Riata defibrillator lead failure rates. <i>Int J Cardiol</i> . Sep 2013. | 219 | Single Center | Sprint Fidelis and Riata leads have a significant but comparable failure rate at 2.60% per year and 2.71% per year of follow-up respectively. The number of deaths in both groups is similar and no deaths have been identified as being related to lead failure in either cohort. |
| Badenco et al. Riata and Riata ST defibrillator leads failure: cable externalization is one problem, but other electrical failures seem more preoccupant. <i>Eur Heart J</i> . Aug 2013 DOI: http://dx.doi.org/10.1093/eurheartj/eh308.P1396 | 181 | Two Centers | Riata lead failure mostly concerns 8-French leads. Attention is especially paid to conductor externalization risk, but global failure rate with electrical complications seems more preoccupant and needs to be emphasized. |
| Kouraki et al. Incidence of Riata lead failure in clinical practice: a single center experience. <i>Eur Heart J</i> . Aug 2013 DOI: http://dx.doi.org/10.1093/eurheartj/eh308.P1405 | 680 | Single Center | Ten percent of implanted Riata leads had to be replaced due to lead failure after a median time of 1056 days after first implantation. One fourth of these patients presented Riata lead groups with an inadequate shock. Rate of lead failure did not differ between the various Riata lead groups. |
| Mahajan et al. Different manifestations of right ventricular ICD advisory leads using impedance and noise. <i>Eur Heart J</i> . Aug 2013 DOI: http://dx.doi.org/10.1093/eurheartj/eh308.P1393 | 995 | Boston Scientific sponsored | Fidelis patients had more noise episodes and RV Z $\geq 2000 \Omega$ consistent with early Pace/Sense conductor malfunctions. Riata leads had more abrupt changes in RV impedance and Shock-impedance $\leq 20 \Omega$ consistent with the insulation and HV conductor malfunctions. Riata lead noise episodes tend to be more variable in rate than Fidelis noise episodes. |
| Segreti et al. Transvenous removal of recalled ICD leads: Riata vs. Sprint Fidelis. <i>Eur Heart J</i> . Aug 2013 DOI: http://dx.doi.org/10.1093/eurheartj/eh309.P3654 | 513 | Single Center Extraction | Experience shows that the extraction of recalled Sprint Fidelis and Riata ICD leads is feasible and effective. However, extraction of Riata leads is more complex than Sprint Fidelis leads. Lack of coil backfilling and cable externalization in Riata lead group may account for these differences. The decision to extract or not to extract Riata leads should be individualized. |
| Liu et al. Failure-free survival of the Durata defibrillator lead. <i>Europace</i> . Jul 2013. | 2,175 | Single Center | The Durata lead failure-free survival is significantly better than the 8 Fr. Riata lead, albeit at a shorter follow-up time. Riata lead and comparable with that of the 7 Fr. Riata ST and the Sprint Quattro ICD leads. These data provide an insight into the mechanism of electrical failure of Riata leads and have implications for patient management. |
| Brunner et al. Transvenous extraction of implantable cardioverter defibrillator leads under advisory – a comparison of Riata, Sprint Fidelis, and non-recalled implantable cardioverter defibrillator leads. <i>Heart Rhythm</i> . Jun 2013. | 1,079 | Single Center Extraction | ICD lead extraction procedures were performed in 1079 patients, including 430 patients with recalled leads (121 Riata, 308 Sprint Fidelis, and 1 Riata and Sprint Fidelis) and 649 patients with non-recalled ICD leads. Recalled ICD leads were extracted with safety and efficacy comparable to that of non-recalled ICD leads. |
| Larsen et al. Nationwide fluoroscopic screening of recalled Riata defibrillator leads in Denmark. <i>Heart Rhythm</i> . Jun 2013. | 299 | Nationwide | The prevalence of externalization in a nationwide screening is at the same level as reported in previous studies with similar lead dwell times. The degree of externalization is time dependent, and location seems to differ between single and dual coil leads. Long-term lead performance and association with electrical failure need further clarification. Fluoroscopy has a good diagnostic performance in clinical practice. |

2013 Publications (continued)

| Citation | Sample Size | Study Note | Conclusions |
|---|-------------|--------------------------|--|
| <p>Parkash et al. Failure rate of the Riata lead under advisory: A report from the CHRS Device Committee. <i>Heart Rhythm</i>. May 2013.</p> <p>Parkash et al. Riata Leads Failure: Report from the CHRS Device Committee. <i>Heart Rhythm</i>. 2012;9(5):S13. AB06-04.</p> | 5,043 | Nationwide | The overall rate of lead failure in the Riata (8-F) and Riata ST (7-F) leads is higher than previously reported by using passive surveillance data. The impact of recent advisories related to these leads is not yet apparent. |
| <p>Kremers et al. The National ICD Registry Report: Version 2.1 including leads and pediatrics for years 2010 and 2011. <i>Heart Rhythm</i>. Apr 2013.</p> | n/a | National ICD Registry | <p>There were 23,234 Medtronic Sprint Fidelis leads tracked in the registry. Of the assessed Fidelis leads, about 1 in 5 (19.6%) were found to be functioning abnormally. The lead was removed or abandoned in 7910 (34.1%), and reused in 15,072 (64.9%).</p> <p>There were 8755 St Jude Medical Riata 8-F leads and 3213 Riata ST 7-F leads identified. Of those functionally assessed, 715 (8.2%) 8-F leads and 236 (7.4%) 7-F leads functioned abnormally. These leads were extracted or abandoned in 929 (10.6%) and 345 (10.7%), respectively.</p> |
| <p>Patel et al. Extraction of defibrillator leads recalled for cable externalization and failure. <i>J Interv Card Electrophysiol</i>. Apr. 2013.</p> | 627 | Single Center Extraction | <p>From a total of 627 patients implanted with the Riata lead, 20 patients underwent lead extraction.</p> <p>Extraction of the Riata lead seems to be successful and safe and frequently requires the use of powered sheaths.</p> |
| <p>Abdelhadi et al. Independent multicenter study of Riata and Riata ST implantable cardioverter-defibrillator leads. <i>Heart Rhythm</i>. Mar 2013.</p> <p>Abdelhadi et al. Independent Multicenter Study of Riata and Riata ST ICD Leads. <i>Heart Rhythm</i>. 2012. LBCT Abstract SP09</p> | 2,749 | Multi-center | The survival of Riata (but not Riata ST) leads was lower than Quattro leads; however, Riata ST leads had significantly shorter follow-up than Riata leads. ECs were common in Riata leads, and more than a quarter of Riata leads that had ECs were malfunctioning. |
| <p>Steinberg et al. Detection of high incidence of Riata lead breaches by systematic postero-anterior and lateral chest X-ray in a large cohort. <i>Europace</i>. Mar 2013.</p> | 284 | Single Center | The incidence of insulation breach in Riata leads is much higher than quoted by the manufacturer or reported by most of the literature. A PA and lateral CXR with zooming appears adequate to identify lead breaches when reviewed by an electrophysiologist. Riata lead breaches without electrical abnormalities present a management dilemma and will require further studies. |
| <p>Valk et al. Long-term performance of the St Jude Riata 1580-1582 ICD lead family. <i>Neth Heart J</i>. Mar 2013.</p> <p>Jordaens et al. Analysis of the Riata 1580, 1581 and 1582 Leads. <i>Europace</i>. 2012; 14(1). Abstract 96P.59.</p> | 374 | Single Center | A high incidence of insulation defects associated with conductor externalisation in the Riata ICD lead family is observed. The mode of presentation is diverse. This type of insulation failure can lead to failure of therapy delivery. |

2012 Publications

| Citation | Sample Size | Study Note | Conclusions |
|--|-------------|----------------|---|
| Cohen et al. The Pacemaker and Defibrillator Lead Survival and Malfunctions Study: Which Core Lead Design Elements Influence Leads Failure? <i>Heart Rhythm</i> . 2012;9(5): S13. AB06-05. | 2,967 | Single Center | Improved survival with BSX compared to MDT or SJM: BSX vs MDT [Hazard ratio (HR) = 0.36 (95% CI: 0.21-0.60)]; SJM vs MDT [HR = 0.47 (0.29-0.76)]; BSX vs SJM [HR = 0.54 (0.26-1.13)]. |
| Corbisiero et al. Incidence of Externalized Conductors in ICD Leads Using PA and Lateral Chest X-Ray Imaging. <i>Heart Rhythm</i> . 2012;9(5): S236. PO3-44. | 389 | Single Center | After review of the most recent PA/LAT CXR, externalized conductors were observed in 6 leads (5 Riata, 1 Riata ST, 0 Durata). The mean time to externalized conductors was 3.86 years, up to 5.4 years. One lead with an EC had decreased shock impedance 1.5 years after externalized conductors noted. All other leads are functioning normally 1.61 years post observation of externalized conductors. |
| Fazal et al. Incidence of Riata Defibrillator Lead Failure Higher than Previously Reported. <i>Europace</i> . 2012; 14(1). Abstract 96P.63. | — | Single Center | The Riata lead failure rate was 10.4% (2.4% per year). |
| Hauser et al. Performance of Riata ICD leads: results from an independent multicenter study. <i>European Heart Journal</i> . 2012 33 SUPPL. 1 (539) Abstract 3254. | 1,060 | Multi-center | All groups < 9F had lower survival compared to 9+F. 7F and 8F leads had lower survival than 9+F leads. |
| Johansen et al. Defibrillator Lead Diameter as a Predictor of Lead Survival Time. <i>Heart Rhythm</i> . 2012;9(5): S60. AB27-03. Johansen J et al. Poor Survival of Defibrillator Leads with Small Diameter. <i>Europace</i> .2012; 14(1). Abstract 96P.58. | 4,251 | Nationwide | Our local experience with the Riata HV leads suggests a much higher incidence of lead related adverse events requiring invasive intervention. This is in contrast to recently published data as well as the performance report from SJM. |
| Ng et al. St Jude Medical Riata High Voltage ICD Lead Long Term Performance Report a Single Centre Experience. <i>Heart, Lung and Circulation</i> . 2012;21(1): S138-S139. DOI: http://dx.doi.org/10.1016/j.hlc.2012.05.350 . | 171 | Single Center | A high incidence of insulation defects associated with conductor externalisation in the Riata ICD lead family is observed. The mode of presentation is diverse. This type of insulation failure can lead to failure of therapy delivery. |
| See et al. Variable Pattern of Lead Defects in Riata Family ICD Leads. <i>Heart Rhythm</i> . 2012;9(5): S454. PO06-44. | 105 | Single Center | 4 leads (3.7%) had evidence of compromise requiring invasive management (extraction or lead implant). Insulation breach resulting in inappropriate therapy was observed in 2 leads. Externalized conductors were observed in one lead on fluoro without any electrical issues. |
| Steinberg et al. High Incidence of Riata Lead Breaches – A Single Center Experience. <i>Heart Rhythm</i> . 2012;9(5): S60. AB27-01. | 106 | Single Center | PA and lateral chest x-ray showed 21.7% leads with externalized conductors. Abnormal CXR was more frequent with 8F leads compared to 7F leads (28% vs. 7%). |
| Steinberg et al. High Prevalence of Riata Insulation Defects Detected by Systematic PA/Lateral Chest-X Ray - A Single Center Experience. <i>Canadian Journal of Cardiology</i> . 2012. | 269 | Single Center | There is a high frequency of cable externalization in Riata leads, which can be detected in up to 24.1% in a larger cohort. The prevalence of insulation breaches in Riata leads is much higher than quoted by the manufacturer or reported in the literature. Careful analysis of a PA/lateral CXR with zooming has a high diagnostic yield to detect lead extrusion making fluoroscopy probably unnecessary. Cable externalizations are associated with subtle, but significant electrical abnormalities over time and there is a strong association between cable externalization and clinical lead failure. |
| Swerdlow et al. Performance of ICD Lead Integrity Alert for Diagnosis of Riata Lead Failures. <i>Circulation</i> . 2012. http://circ.ahajournals.org/cgi/content/meeting_abstract/126/21_MeetingAbstracts/A11384 | 1,944 | CareLink™ data | Lead Integrity Alert (LIA) follow-up resulted in 30 alerts, 21 lead events (70%) and 9 false positives (30%). Lead events included 20 lead failures (LF) and 1 dislodgment. The 9 false-positive alerts were caused by T-wave oversensing, electromagnetic interference, and ventricular fibrillation. Riata LFs identified by LIA are detected primarily by transient oversensing, often of distinctive spikey signals. Impedance is usually stable. The rate of inappropriate shocks is low for LIA-enabled ICDs. Rare false-positive LIA alerts identify clinically-significant events. |

2012 Publications (continued)

| Citation | Sample Size | Study Note | Conclusions |
|---|-------------|---------------------------|---|
| Wright et al. Long Term Outcomes of ICD Leads: A Difference in Failure Mechanisms. <i>Heart Rhythm</i> . 2012;9(5): S297. PO04-16. | 758 | Single Center | 6.2% leads failed during 57 +/- 28 months. |
| Wright et al. Varying Modes of Presentation of Lead Failure in the 8F Silicone Riata ICD Lead. <i>Heart, Lung and Circulation</i> . 2012. DOI: http://dx.doi.org/10.1016/j.hlc.2012.05.359 . | 432 | Single Center | Lead failure resulted in 10% of Riata leads undergoing revision during long term followup. Noise and changes in impedance related to insulation failures being the most common abnormality. Inappropriate shocks occurred in 23%. DFT testing should be routinely performed at generator change to ensure normal function. Remote monitoring may be of value to allow earlier detection of potential lead problems. |
| Kodoth VN, Hodkinson EC, Noad RL, et al. Fluoroscopic and Electrical Assessment of a Series of Defibrillation Leads: Prevalence of Externalized Conductors. <i>Pacing and Clin Electrophysiol</i> . Dec 2012. Kodoth V, et al. Riata lead failure; A report from Northern Ireland Riata lead screening programme. <i>European Heart Journal</i> . (2011) 32 (Abstract Supplement), 310. Abstract #1838. | 212 | Single Center | A significant proportion (15%) of patients with a Riata lead had an insulation breach 4 years after implantation. High-resolution fluoroscopic imaging in at least two orthogonal views is required to identify this abnormality. |
| Sung et al. Long-term electrical survival analysis of Riata and Riata ST silicone leads: National Veterans Affairs experience. <i>Heart Rhythm</i> . Dec 2012. Sung et al. Survival Analysis of St. Jude Medical Riata and Riata ST High-Voltage Leads in Comparison to Medtronic Sprint Quattro, Fidelis and Boston Scientific Endotak Leads. <i>Heart Rhythm</i> . 2012;9(5):S13. Abstract AB06-01 | 14,968 | Nationwide | There is decreased survival probability of Riata/ST leads compared to other contemporary high-voltage leads, with decreased survival of Riata ST silicone compared to Riata lead series. |
| Theuns et al. Prevalence and presentation of externalized conductors and electrical abnormalities in Riata defibrillator leads after fluoroscopic screening: Report from the Netherlands Heart Rhythm Association device advisory committee. <i>Circ Arrhythm Electrophysiol</i> . Dec 2012. | 1,029 | Nationwide | The prevalence of externalized conductors in Riata leads is significantly high (14.3%) using fluoroscopic screening. The majority of externalized conductors are not detectable with standard ICD interrogation. Screening with fluoroscopy is reasonable. |
| Hauser et al. Deaths Caused By the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads. <i>Heart Rhythm</i> . Aug 2012. Hauser et al. Deaths caused by Riata ICD Lead failure: Analysis of the U.S. FDA Device Database. <i>European Heart Journal</i> . 2012 33 SUPPL. 1 (540) Abstract 3257. | n/a | MAUDE Database (Feb 2012) | Over 8 years, 133 deaths associated with these leads were identified in the MAUDE database: 71 involving Riata silicone and Riata ST silicone leads and 62 involving Quattro Secure leads. Riata and Riata ST ICD leads are prone to failures that have resulted in death. These failures appeared to have been caused by insulation defects that resulted in short circuiting between high-voltage components. Externalized conductors were not a factor in these deaths. |
| Liu et al. Class I recall of defibrillator leads: a comparison of the Sprint Fidelis and Riata families. <i>Heart Rhythm</i> . Aug 2012. | 2,270 | Single Center | In this study, a comparative analysis of the failure-free survival of 2 recalled leads (Medtronic Sprint Fidelis and St. Jude Medical Riata) demonstrates discrepancies in the timing of the recall despite comparable failure-free survival patterns leading to the recall. The causes of these discrepancies are unclear and raise questions regarding the consistency of postmarketing surveillance and manufacturers' reporting of malfunctions of medical devices. |
| Liu et al. Fluoroscopic screening of asymptomatic patients implanted with the recalled Riata lead family. <i>Circ Arrhythm Electrophysiol</i> . Aug 2012. | 245 | Single Center | The Riata lead exhibits time-dependent high rates of cable externalization exceeding 20% at >5 years of dwell time. Externalized leads are associated with a more pronounced decrease in R-wave amplitude, which may be an early marker of future electric failure. The use of fluoroscopic and electric screening of asymptomatic patients with the Riata lead remains controversial in the management of patients affected by the recent Food and Drug Administration recall. |

2012 Publications (continued)

| Citation | Sample Size | Study Note | Conclusions |
|---|-------------|---|---|
| Theuns et al. Impact of fluoroscopic screening on failure rates of the Riata high-voltage implantable defibrillator lead. <i>European Heart Journal</i> . Aug 2012. 33 SUPPL. 1 (540) Abstract 3256. | 452 | Leads: Riata (N = 374), Riata ST (N = 78) | The failure rate of the Riata high-voltage lead is low when physicians rely solely on electrical abnormalities. The extent of externalized conductors is much higher when we screen Riata high-voltage leads using fluoroscopy, with a failure rate up to 39.7% at 8 years. The definitive management of patients with Riata high-voltage leads and externalized conductors needs to be clarified soon as the failure rate of this specific lead will increase. |
| Van Rees et al. Update on small-diameter implantable cardioverter-defibrillator leads performance. <i>Pacing Clin Electrophysiol</i> . Jun 2012. | 591 | Single Center | The current update demonstrates that the risk of lead failure during long-term follow-up is significantly increased for both the Sprint Fidelis and the 7-F Riata lead in comparison to the benchmark cohort. |
| Hauser et al. Riata implantable cardioverter-defibrillator lead failure: analysis of explanted leads with a unique insulation defect. <i>Heart Rhythm</i> . May 2012. | n/a | MAUDE Database (Sep 2011) | A total of 226 insulation defects were found in 105 Riata and Riata ST leads. 32 leads were reported to show exposed cables or externalized conductors. 43 out of 105 leads which were reported to have been assessed for integrity of ETFE cable coating of which 51.2% were found to be abraded, exposing the conductor. |
| Hauser et al. Riata ICD Lead Failure: Results of the Manufacturers Analysis of Returned leads. <i>JACC</i> . Mar 2012 DOI: http://dx.doi.org/10.1016/S0735-1097(12)60585-3 . Hauser RG, et al. Riata ICD lead failure: results of the manufacturer's analysis of returned leads. <i>JACC</i> . (2012) vol. 59 issue 13 (Abstract Supplement). | n/a | MAUDE Database | Explanted Riata and Riata ST leads were found to have multiple inside-out insulation defects which often involved the low voltage conductors. Thus lead noise and inappropriate shocks were common. High voltage cable insulation abrasion also occurred. These observations suggest that Riata leads may have more widespread damage than can be detected by fluoroscopic examination. |
| Hodkinson et al. Follow-up Riata Screening in Northern Ireland. <i>JACC</i> . Mar 2012. DOI: http://dx.doi.org/10.1016/S0735-1097(12)60586-5 . Hodkinson et al. Follow-Up Riata Screening in Northern Ireland. <i>JACC</i> . (2012) vol. 59 issue 13 (Abstract Supplement). | 165 | Nationwide | Riata lead population found to have a lead failure incidence of 2.6%/year and a prevalence of 19%. This exceeds the manufacturer quoted 0.47%. Our data suggests that insulation failure is progressive over time. Therefore interval lead screening by fluoroscopy, in addition to the advised lead parameter checks is justified. Lead screening programmes & strategies for dealing with lead failure should be developed & agreed. |

2011 Publications

| Citation | Sample Size | Study Note | Conclusions |
|--|-------------|--------------|--|
| Wilkoff et al. Decreased Incidence of Lead Abrasion with Optim Insulation. <i>Europace Journal</i> . (2011) 13 (3), Abstract P381. | 616,000 | Multi-center | 138,000 Silicone HV leads and 96,000 Optim™ HV leads. The abrasion failure probability of Optim defibrillation leads was lower than that for silicone defibrillation leads (0.045% vs. 0.27%, p < 0.0001). |

Bench Testing

| Citation | Sample Size | Study Note | Conclusions |
|--|-------------|---------------|---|
| <p>Lau EW. Differential Lead Component Pulling as a Possible Mechanism of Inside-Out Abrasion and Conductor Cable Externalization. <i>Pacing Clin Electrophysiol</i>. Sep 2013.</p> <p>Lau EW. Compression-bending of multi-component semi-rigid columns in response to axial loads and conjugate reciprocal extension-prediction of mechanical behaviours and implications for structural design. <i>J Mech Behav Biomed Mater</i>. Jan 2013.</p> | n/a | Bench testing | The Durata, Riata ST Optim, QuickFlex™ μ, and Quartet™ leads should be relatively immune to conductor cable externalization with protrusion (CCE*). The Durata leads are extremely resistant to longitudinal deformation and probably cause mediastinal displacement rather than differential pulling in response to pectoral movements in vivo. Implantation techniques and lead designs can be used to minimize the risk of CCE*. A bench test for CCE* can be constructed. |
| Fischer et al. Contribution of ethylenetetrafluoroethylene (ETFE) insulation to the electrical performance of Riata silicone leads having externalized conductors. <i>J Interv Card Electrophysiol</i> . Aug 2013. | n/a | Bench testing | Testing of ETFE-coated conductors following multiple preconditioning steps showed that ETFE serves as a redundant layer of insulation. In the event that the ETFE coating is breached, the potential gradient seen resulting from a high-voltage defibrillation shock was similar to a lead with no breach to the ETFE, even after 100 shocks. |