RIATA ICD LEAD FAILURE: RESULTS OF THE MANUFACTURERS ANALYSIS OF RETURNED LEADS

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Background: About 100,000 U.S. patients have Riata and Riata ST defibrillator leads (St. Jude Medical, Inc., Sylmar). Reports suggest that Riata and Riata ST leads are prone to a unique failure mechanism whereby the conductor cables wear through the silicone insulation from inside-out and appear outside the lead body (externalized cables) on fluoroscopy or x-ray. Little is known of this defect, its clinical signs, adverse events, or implications for patient management. Accordingly, we assessed the manufacturer’s analyses of explanted leads that had inside-out insulation defects.

Methods: The FDA MAUDE database was searched for the manufacturer’s reports describing Riata inside-out insulation defects. Data were extracted for failure signs, documented lead defects, and complications.

Results: The search identified 105 returned Riata and Riata ST leads that were found by the manufacturer to have inside-out insulation defects; average implant time was 62.1±18.6 mos (range: 15-108 months). A total of 222 insulation defects (2.11/lead) were found, including 143 inside-out insulation defects (1.36/lead), 34 outside-in defects (0.32/lead), 36 defects caused by the ICD can (0.34/lead), and 9 unspecified defects. Of the 143 inside-out insulation defects, 93 (65.0%) were distal to the proximal shocking coil and 33 (31%) had exposed conductor cables. The ETFE high voltage cable insulation was abraded in 22 of 43 (51.2%) leads reported. Clinical signs of failure included: noise/oversensing (45/105; 42.8%); impedance changes (23/105; 21.9%); high threshold or loss of capture (11/105; 10.4%); and other (26/105; 24.7%) including 7 externalized cables (6.6%). Inappropriate shocks affected 29 patients (27.6%), and one death was associated with a can abrasion and truncated high voltage shock.

Conclusions: 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.