

## Mandatory Diagnostic Screening Tests to Individualize Therapy

### A Curious Paradox

St Jude Medical released the Riata 1500 series defibrillator lead to the US market in 2002, and the Riata ST 7000 series lead in 2005. By 2010, it was evident that these leads were subject to a unique form of structural failure and they were voluntarily removed from distribution by the manufacturer. The Food and Drug Administration issued a class I recall of these leads in 2011. Since then, guidance regarding management of patients with these leads has been limited to consensus expert opinion. Only recently have the manufacturer and the Food and Drug Administration provided recommendations to physicians regarding patient surveillance.<sup>1,2</sup>

The Food and Drug Administration recommends that patients with recalled Riata leads should undergo screening radiographs or other imaging alternatives in an effort to identify structural failure and to individualize patient treatment plans. However, this rationale suffers from 2 key limitations. First, uniform recommendations do not facilitate individualized evaluation or management. Second, and more importantly, the available data do not support the use of radiographic screening.

Screening studies using fluoroscopy (rather than chest x-rays) have yielded sensitivities of 60% to 67% and specificities of 63% to 87% for the detection of leads with electrical failure; further, there is no standard or uniform definition of a positive radiographic screening test.<sup>3,4</sup> Thus, if the frequency of externalized leads is 15% to 33%,<sup>3-5</sup> then for every 1000 patients screened there will be 87 to 315 false-positive results and 49 to 221 false-negative results. False-positive studies have tremendous potential to cause harm, particularly when further therapeutic options (such as lead extraction or device testing) may entail significant risks. Moreover, electrical abnormalities or failure are best identified by thorough device interrogation and potentially defibrillation testing in select patients at high risk. In a published screening study, 30.1% of leads with component externalization demonstrated electrical abnormalities, whereas 29.7% of leads with no electrical abnormalities demonstrated cable externalization.<sup>3</sup> Therefore, it is not entirely clear that there is a direct correlation between structural and electrical failure. Unfortunately, we do not have a validated method by which to identify those at risk for catastrophic electrical failure.

Why did the Food and Drug Administration issue a recommendation for radiographic screening of recalled Riata leads? Based

on the available data, the answer to this question remains unclear. Radiographic screening suffers from lack of standardization, poor sensitivity, and an unacceptably high false-positive rate. Most importantly, the test does not produce clear and uniformly actionable results. On the contrary, there is a significant chance that overdiagnosis and treatment could lead to harm. Although recalled Riata leads do represent a significant and dangerous clinical problem, these leads require individualized, case-by-case, patient-centered care. Despite the Food and Drug Administration recommendations, there are no data to support mandatory radiographic screening as a means to improve patient outcomes.

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