Riata type implantable cardiac defibrillator leads: increasingly small, progressively troublesome

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Already in 1970, Mirowski and colleagues worked on the development of the first implantable cardiac defibrillator (ICD). Since then, important progression has been made by increasingly complex pacing and defibrillation functions, higher battery durability, and reduction of both device and shock lead size. A large amount of evidence has shown that ICDs are life-saving and cost-effective, both for primary and secondary prevention of sudden arrhythmic cardiac death. In the last decade, a quest for smaller shock lead design was initiated, but unfortunately increasing dysfunction rates of ICD generators and leads were to be unmasked only a few years later.[1, 2] Medtronic's 6.7 Fr Sprint Fidelis lead was recalled by the FDA in 2007 and St. Jude's 7.6 Fr Riata and 6.3 Riata ST leads were recalled by the manufacturer, FDA and the Dutch authorities in 2011. By then, the vast amount of approximately 227,000 Riata leads, and 268,000 Sprint Fidelis leads had been distributed worldwide.

Smaller leads, greater problems

An analysis comparing the 'standard' >8 Fr leads (Medtronic Sprint, Sprint Quattro, Sprint Quattro Secure; Boston Scientific Endotak Reliance; St Jude SPL Ventitrex), with the smaller leads (Riata and Sprint Fidelis), depicted a multivariately corrected hazard ratio of 5.0 for failure of the smaller diameter leads.[3] Rates of lead failure per device year are typically <1 % for 'standard' leads, 2–3.5 % for Riata leads and 2–6.3 % for Sprint Fidelis leads. Although the smaller leads show higher failure rates, the modes of failure are different. Thus, the problem seems to originate

from both design issues and size, with lead fracture in Sprint Fidelis, and externalisation and unusually high electrical dysfunction rates in Riata leads.

In the present edition of the Journal, Valk and colleagues assessed the externalisation and electrical dysfunction rates of Riata leads, implanted in the Erasmus Medical Centre Rotterdam between 2003 and 2007.[4] In their retrospective study that consisted of 257 patients, they concluded that with a median follow-up of 3 years, externalisation was present in 9.7 % of the leads. Electrical dysfunction, mostly noise/oversensing, occurred in 7.8 % of patients and externalisation was present in 85 % of these. In electrically functional leads, the externalisation rate was 3.4 %, suggesting that externalisation is associated with electrical dysfunction. Unfortunately, the precise relation between electrical dysfunction and externalisation was not investigated in depth. Other reports show similar or higher Riata externalisation and electrical dysfunction rates, and clearly a linear time-dependent rise of dysfunction. Valk and colleagues concluded that no variables were associated with lead dysfunction, except for low left ventricular ejection fraction in multivariate analysis. Unlike their conclusions, other groups have indicated predictors for externalisation, such as 8 versus 7 Fr Riata leads, non-ischæmic cardiomyopathy and the presence of multiple leads. There is no clear information regarding predictors of electrical dysfunction of Riata leads, and Valk and colleagues do not report on this topic.

Pathophysiology of Riata lead failure

When we examine the design of the Riata lead, we can conclude that different mechanisms contribute to its unusually high dysfunction rate. Firstly, the lead seems to have a weak silicone insulation through which internal conductors can externalise. The multilumen design, where two or three

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hollow lumina each contain two internal conductors, contributes to internal movement of conductors and increased risk of externalisation or fracture. As the internal conductors themselves have an ethylene-tetrafluoroethylene insulation, externalisation of conductors is not per se accompanied by electrical dysfunction. That mechanical forces are an important predictor of externalisation is illustrated by the fact that most externalisations occur near the tricuspid valve.

Externalisation and electrical dysfunction

What is the true meaning of externalisation? Until recently, the manufacturer has reported very low electrical dysfunction rates. Their opinion was that externalisation could not be regarded as lead dysfunction. The exact relation of mechanical dysfunction (externalisation) and electrical dysfunction is pivotal for its management and remains to be elucidated. Hauser reported 22 possible deaths by Riata lead dysfunction.[5] Valk and colleagues describe a case (only in their abstract), where external defibrillation was needed because of Riata lead dysfunction. Thus, Riata lead failure is a potentially life-threatening issue in some patients. A shortcoming of the present literature is that all data are cross-sectional. There is a need for longitudinal follow-up. Only in this way can we reliably assess the precise nature and extent of Riata lead dysfunction. The Netherlands Heart Rhythm Association (NHRA) device committee, supported by all ICD implanting centres in the Netherlands, will provide these data by serial examinations with both device interrogation and fluoroscopy. When examining the time-dependent rise of lead dysfunction, it could well be that the present reports only show the tip of the iceberg.

From Riata to Durata

How should we deal with the problem, in order to prevent this tip of the iceberg from turning into a Titanic-like story? Firstly, the lead is no longer distributed. Secondly, as both the Riata and Riata ST type of leads had high rates of electrical dysfunction and externalisation, an extra silicone-polyurethane amalgam coating layer was applied on the surface of the lead, resulting in the Riata ST Optim lead. The manufacturer claims a 50 % wall thickness increase and a 50× more abrasion resistance. Probably because of increased lead perforations due to the more solid lead, the manufacturer designed a soft silicone tip with a more curved RV coil (the Durata lead), reducing tip pressure by 51 % to prevent excess lead perforations. Only one report showed that Riata ST Optim and Durata leads could be prone to outside-in insulation abrasion, which may be similar to the inside-out abrasions found in Riata and Riata ST

leads. These kinds of outside-in abrasions, however, although uncommon, occur in all lead models. Until present, the Durata lead seems to have withstood the test of time, with the test still ongoing however. Serial device interrogation and fluoroscopy seems mandatory in order to assess mechanical and electrical dysfunction of Riata leads. After the NHRA in 2011, the FDA indicated the same advice in 2012. Whether the fluoroscopic follow-up should include patients with non-functional Riata, for example after another shock lead is implanted, remains a question.

Lead failure

If lead failure is present by electrical dysfunction, it is clear that a new shock lead should be implanted. If externalisation is present, close follow-up is warranted with device interrogation per 6 months or shorter periods and fluoroscopy once a year. In selected cases, a new shock lead could be implanted when the patient undergoes a generator change. As to whether the Riata lead has to be extracted, much is unknown. In all cases, the high risks of extraction should be weighed against its possible benefits. We advise to follow the general guidelines and to extract only when infection is present or suspected and in case of mechanical complications. When the patient is young or when the Riata lead was implanted <1 year ago, it could also be considered to try to extract the lead. In all cases of extraction of leads, it is advised to perform the procedure in specialised centres by cardiologists with large experience in lead extractions, with on-site backup of cardiothoracic surgery.

In conclusion, Valk and colleagues contribute to gaining insight into the vast problem of mechanical and electrical Riata lead failure at present. The upcoming years will show the community which part of the iceberg we had in sight.

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