Reliability of cardiac implantable electronic device leads

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This editorial refers to ‘Failure of a novel silicone–polyurethane copolymer (OptimTM) to prevent implantable cardioverter-defibrillator lead insulation abrasions’ by R.G. Hauser et al., on page 278–283

Leads are unquestionably the weak link in cardiac implantable electronic device (CIED) treatment, the insulation material in particular. Since the first fully implantable pacemaker employing epicardial leads in 1958, there has been an ongoing struggle to find the perfect insulation material. Various forms of silicone and polyurethane have been the main alternatives in addition to ethylene-tetrafluoroethylene and polytetrafluoroethylene for internal electrical insulation. Silicone and polyurethane have their advantages and disadvantages and have been associated with considerable problems over the years; many will remember the shortcomings of the promising, at the time, 80 Da polyurethane.

The development of lead insulation material is associated with several intrinsic problems; in vivo failures often show after considerable dwelling time. Even the best bench and animal tests have a problem imitating the challenging mechanical, chemical, and thermal environment of leads, especially reproducing long-term use in vivo. In addition to resisting these challenges, lead insulation materials need to provide sound electrical insulation. The fact that both manufacturers and physicians encourage the speedy development of thinner leads presents an additional challenge to lead reliability. Finally, the previous lack of strict regulatory rules when introducing new leads has been a shortcoming.

It should be acknowledged that manufacturers have tried hard to provide better products and have improved their lead development processes in many ways, not least by better bench testing, extended clinical trials and remote monitoring. Despite these efforts, lead recalls due to insulation and conductor failures remain a problem causing major adverse events (MAE) and mortality. However, it must also be realized that the perfect lead is a utopia, and that random dysfunction is a reality; few lives are lost due to lead dysfunction compared with the number of lives saved by modern CIED treatment.

A significant step towards a better and more abrasion-resistant insulation material seemed to be the introduction of the proprietary silicone/polyurethane copolymer OptimTM by St Jude Medical (SJM) in 2006. According to the manufacturer, Optim is 50 times more abrasion-resistant than silicone while providing all other necessary lead insulation characteristics. According to recent SJM data on >278,000 leads and >5 years experience, 99.9% of all leads were free from any type of abrasion. Consequently, the report by Hauser et al.1 on Optim/Durata ICD lead abrasion published in this issue of the journal is very important and calls for further urgent studies. Of special interest is that the abrasion damages were noted to occur relatively early.

Hauser et al.2 have previously reported on fatal abrasion failures of non-Optim Riata and Riata ST ICD leads, now under recall. Following this recall, SJM stated that, unlike the Riata and Riata ST leads, Optim-covered leads (Riata Optim and Durata) were not affected due to more durable insulation and improved design. Challenging this statement, Hauser et al. have now found a number of abrasion-caused events involving Riata Optim (introduced in 2006) and Durata (introduced in 2007) leads when searching the US Federal Drug Administration (FDA) Manufacturers and Users Facility Device Experience (MAUDE) database. The MAUDE database contains information on adverse events involving medical devices that have been reported to US manufacturers by users worldwide. Manufacturers regulated by FDA are mandated to report to MAUDE all events that are communicated to them, including the results of investigations of the causes of device malfunction. Most manufacturers require all employees to report all known serious adverse events, at risk of loosing their employment by not doing so. The vast majority of lead events reported to MAUDE seem to originate from manufacturers and <5% from user facilities, doctors, and other observers2. The number of Optim/Durata events reported to MAUDE is small compared with the number of these lead models implanted and fits approximately with the level of reliability reported by SJM. However, underreporting to SJM (and MAUDE) from the medical community can be expected to be significant3. The current, real failure rate is unknown, as are future failure rates.
Earlier this year, FDA order SJM to collect clinical data related to the potential premature insulation failure in Riata and Riata ST leads, including Riata Optim/Durata leads. This seems very appropriate in light of the present report by Hauser et al. In a very recent communication, FDA recommended imaging Riata and Riata ST leads and close monitoring of patients with these leads. Assuming this report had been available to FDA, Riata Optim/Durata leads might have been included in the imaging recommendation as well.

Generally, lead failure rates based on data reported in a non-compulsory way, or not derived from large prospective clinical studies in consecutive patients are unlikely to be accurate and will not provide data necessary for drafting appropriate recommendations. Consequently, to improve lead reliability and patient safety, ‘compulsory reporting by individual doctors’ to independent, well-organized databases are now needed. The Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), Association of Medical Instrumentation (AAMI), and other professional associations must without delay take the lead and work with regulatory agencies worldwide to achieve this goal. Some recommendations have been issued, e.g. by HRS, but do not seem to have sufficient following. Reporting compliance and financing of independent registries are major obstacles necessary to overcome.

Large clinical, long-term studies are necessary to prove safety and should be mandatory when manufacturers introduce new leads. The present regulatory clinical study requirements are stricter than several years ago; however, extended data, especially regarding long-term function, are needed. US Federal Drug Administration is now requiring more acute and long-term data on new leads before approval. Further considerations in this field should be made by FDA and especially by regulatory agencies in other geographies. Remote monitoring offers a unique opportunity to follow large series of leads in the long-term and may become the best method to assure lead reliability in the future.

Long-term lead reliability is a first priority in CIED treatment and much more important than the hasty introduction of slightly improved or thinner new leads. The cost of developing, trialing, and approving new leads can be expected to be higher and the approval process much slower, when adhering to stricter standards, as can be learnt from the pharmaceutical world. This is a price necessary to pay for improved reliability and lower morbidity.

In summary, lead function [especially implantable cardioverter defibrillator (ICD) leads] remains the weak link in CIED therapy despite improvements in development and clinical evaluation. Lead failures have the potential to be fatal, and consequently lead reliability is much more important than further improvements in function and size. More accurate, acute, and especially long-term data are now necessary to assess the quality of new leads. This can be obtained by mandatory MAE reporting from all involved parties (particularly doctors), product returns, independent databases, extended clinical trials, and remote follow-up. Regarding Riata Optim and Durata leads, it is essential that individual doctors and company representatives without exception report insulation abrasion, lead dysfunction, and MAEs to SJM and appropriate existing databases and regulatory bodies. Extracted leads must be returned to SJM for analysis. Time for these actions is now of the essence as lead extraction risk and difficulty will increase over time, should lead removal due to intrinsic dysfunction be indicated in any type of Optim-covered leads.

Conflicts of interest: none declared.

References