Performance and survival of transvenous defibrillation leads: need for a European data registry

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Although the use of implantable cardioverter defibrillator (ICD) therapy has increased over the last decades, the reporting of ICD lead performance is inadequate. So far, there is neither a European nor worldwide registry on ICD leads. The published long-term results from national or multicentre registries encompass relatively small patient cohorts. Nevertheless, the failure of ICD leads may have substantial clinical consequences, including failure to sense, failure to pace, failure to defibrillate, inappropriate shocks, and even death of the patient. The reported ICD lead survival varies significantly between studies: 91–99% at 2 years, 85–95% at 5 years, and 60–72% at 8 years. Thus, the true incidence of lead malfunction cannot be defined as outlined in the present review. One current initiative of the European Heart Rhythm Association is to initiate and develop a Europe-wide registry to monitor, over a prolonged follow-up period, the performance of ICDs and ICD leads.

Introduction

The use of the implantable cardioverter defibrillator (ICD) to prevent sudden cardiac death (SCD) has become the standard of care for patients at risk or who have suffered from life-threatening cardiac arrhythmia.¹–⁴ In recent years, greatest uptake of ICD therapy has been in the SCD at risk patients—primary prevention—and thus an ICD recipient population has developed among whom multiple device replacement will be indicated over a long time horizon.⁵–⁷ The attention of the clinical community has tended to focus on ICD generator reliability and longevity rather than defibrillation/pace–sense lead reliability. The latter can also be responsible for delivery of inappropriate shock therapies or even patient death, and now there is growing concern about long-term reliability of chronically implanted leads.⁸–¹¹ There have been several recent reports of catastrophic lead malfunction, in excess of manufacturing norms and expectations, which have resulted in manufacturers either withdrawing or increasing scrutiny for their products.¹²–⁰ Attempts to gauge lead ‘real-life’ performance in European clinical practice have highlighted the lack of systematically registered lead performance data for all manufacturers, despite the large number of ICD leads implanted annually in Europe.

Implantable cardioverter defibrillator leads

Modern ICD leads consist of electrodes, conductors, insulation, a distal fixation mechanism, and a connector.²¹–²³ Implantable cardioverter defibrillator leads have a multi-lumen design that incorporates straight wires and coiled conductors into an electrode body (Table 1). The current lead design has a bulky (ICD) connector part, comprising a separate pace–sense connector and one or

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two separate shock coil connectors (depending on single or dual coil lead design). To decrease the complexity and bulkiness of this arrangement, industry has collaborated on the development of the IS-4 connector that is quadripolar in construction, accommodating pace–sense and shocking coil connectors in a single structure. There may be some reluctance on industry’s part to introduce this design to the market as long-term reliability remains unclear.

Conductors and insulation are sheathed with insulation layers. Silicone and polyurethane are most frequently used insulation materials. In contrast to multi-lumen lead body design, coaxial leads have three concentric conductors of progressively smaller diameter, separated by insulating material (single lumen polyurethane and silicone tubing). The outer conductor is connected to the defibrillation coil, the middle conductor to the sensing ring, and the inner conductor to the pacing tip. Nevertheless, no two ICD lead models of different manufactures are alike.

Multiple factors influence ICD performance in the longer term include biophysical stress and changes at the electrode–tissue interface. Implantable cardioverter defibrillator leads must withstand hundreds of millions of cardiac cycles. As well as this mechanical distress, the electrode body is also affected by biological processes (ion oxidation) occurring at the endocardial surface and in the blood stream. Pathological examinations have revealed that the electrode–myocardial interfaces of ICD leads are characterized by scarring at the lead tip and around the lead body.24 Furthermore, the leads are encased by sheaths of fibroelastic tissue. Fibrotic tissue is also found adjacent to the lead in the current path of ICD shocks. Thus, these tissue responses influence lead performance and lead survival in long term.

In the past decade, dual and multisite pacing in combination with defibrillation capabilities have been introduced.25,26 This has increased the need for ICD leads with small diameters, because small ICD leads might facilitate multiple lead implantation procedures.23,27–29 However, latest performance data on ICD leads with diameters smaller than 7 Fr indicate increased risk of long-term failure, suggesting that the trade-off between diameter and durability is not completely predictable. Medtronic (Minneapolis, MN, USA) released a family of small-diameter leads, named Sprint Fidelis, in 2004 with a 6.6 Fr lead body—a 23% reduction in lead diameter compared with older 8 Fr leads. The Sprint Fidelis lead (Model 6949 and 6948) has a silicone multi-lumen design and is a true bipolar lead where sensing is between the lead tip and the ring electrode. Medtronic Inc. voluntarily decided in October 2007 to withdraw the Sprint Fidelis lead from the market as a consequence of lead performance below the company standard.16 In particular, two ‘hot spots’ for lead failure were identified: under the suture sleeve when used for tightening the lead to the muscle and in proximity of the lead anode. Similarly, other leads have mechanical properties that have also been implicated in patient complications.18,30,31 Thus changed mechanical properties, representing technological response to physician demands, may have compromised long-term lead survival, but we have a paucity of data for these leads to confirm or refute clinical suspicions of compromised lead performance.

### Implantable cardioverter defibrillator lead failure

Failure of ICD leads may have substantial clinical consequences, including failure to sense, failure to pace, failure to defibrillate, inappropriate shocks, and even death of the patient.32–34 In contrast to ICD generators, which can easily be explanted in the case of malfunction, ICD leads cannot be easily removed due to fibroelastic scarring at the lead tip and around the lead body.24 Reported ICD lead survival varies significantly between studies: 91–99% at 2 years, 85–95% at 5 years, and 60–72% at 8 years.19,20 One reason for this variability in lead performance is that definition of lead malfunction is open to interpretation. Indeed, it requires careful technical examination of returned product to define whether an ICD lead complication relates to a manufacturing/design fault, physician/implanter use of the device, ICD programming parameters, disease process, or external/unrelated factors and sometimes a definitive conclusion may not be reached. Thus, the clinical indication for lead replacement varies from institution to institution. Most commonly ICD lead malfunction is defined as abnormality of the electrical lead properties including oversensing or a visible lead fracture on chest X rays (Table 2).35,36

Insulation defects are the most common abnormalities in ICD leads.10 Polyurethane leads especially can degenerate due to metal ion oxidation causing insulation defects and lead failure.21,32,37,38 Polyurethane polymers and the production of complex coaxial leads seem to be the combination with the highest incidence of lead malfunction. Of note, ~66% of ICD lead malfunctions are recognized at routine follow-up.11,12 Lead malfunction causes inappropriate ICD shocks in ~75% of cases. Interestingly, fracture within the pace–sense circuit of Sprint Fidelis leads can induce inappropriate shocks triggered by electromagnetic interference by the device programmer during interrogation of the device.32 Of note, patients who had a lead revision due to ICD lead failure appear to have an eight-fold increased risk for...
Another lead failure. This underscores the presence of individual patient factors, which influence lead survival. Cox regression analysis in a total of 990 consecutive patients further showed that younger age and female gender are associated with a higher survival rate. Within the 990 patients, 20% had a better lead survival. 20 This finding might be explained by increased mechanical stress on the leads in younger active patients, restricted anatomic space in female patients, and by the presence of multiple, especially small diameter, leads.

In recent years, several studies have tried to define algorithms to predict lead failure. 21,29,39 Daily lead-impedance measurements, which might be incorporated in a remote disease management program, promise accurate detection of lead failures. 29 In addition, the quantification of very short RR intervals (<140 ms) may also allow the detection of electrical noise over-sensing. In the event of lead malfunction, the lead extraction is often required. This procedure carries with it significant risk of mortality or morbidity, and is an important undertaking which likely reduces the clinical and cost efficacy of ICD therapy as a whole. It does not offer a simple solution to lead failure. 40

### Reporting of implantable cardioverter defibrillator and lead failure in Europe

Although the use of ICD therapy has increased over the last decades, the reporting of ICD lead performance is inadequate. So far, there is neither a European nor worldwide registry on ICD leads. The published long-term results from national or multi-centre registries encompass a maximum of 1317 patients. 11,19 Thus, the true incidence of lead malfunction cannot be defined at present. Due to under-reporting of lead problems, it appears to be possible that lead reliability is substantially overestimated. Manufacturers have argued that 'in-house' surveillance (facilitated by remote management technologies) or specific local registries offer adequate data. However, these mechanisms are not independent of industry and selective in nature. They leave open the possibility that device failure goes unrecognized when early corrective or patient surveillance actions could reduce ICD therapy-related morbidity or mortality. Thus, a large international registry will help determine more precisely the lead performance in the long term. In addition, the impact of various additional factors such as operator experience, size of implanting hospitals, different pacing sites, cost-effectiveness, etc., could be analysed. Of note, the Heart Rhythm society announced in March 2008 the formation of a Task Force on Lead Performance Policies and Guidelines. This Task Force is designated to make recommendation to the US Food and Drug Administration, manufacturers, physicians, and patients on lead performance and malfunction.

### Conclusions

In our capacity as the Scientific Initiatives Committee of the European Heart Rhythm Association, European Society of Cardiology, we recommend that a partnership of industry, physicians, and regulatory bodies in Europe and European Union Commission representatives urgently collaborate to develop a Europe-wide registry to monitor, over a prolonged follow-up period, the performance of ICDs and ICD leads. Importantly, the registry must be embedded into other initiatives regarding monitoring of cardiovascular implantable electronic devices. Without this we risk compromising trust in the value of ICD therapy resulting in lessened uptake of ICD therapy in patients with the potential to benefit, and the possibility of exposing patients to device-related complications through ignorance of device failures.

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