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

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Received 26 September 2008; accepted 8 October 2008; online publish-ahead-of-print 11 November 2008

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.12–20 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...
Table 1 Implantable cardioverter defibrillator lead characteristics

<table>
<thead>
<tr>
<th>Implantable cardioverter defibrillator lead</th>
<th>Polarity</th>
<th>Coils</th>
<th>Lumen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik KAINOX family</td>
<td>True bipolar</td>
<td>Single/dual</td>
<td>Multi-lumen</td>
</tr>
<tr>
<td>CPI Endotak xxx family</td>
<td>Integrated bipolar</td>
<td>Dual</td>
<td>Multi-lumen</td>
</tr>
<tr>
<td>Intermedics 497-xx Family</td>
<td>Integrated bipolar</td>
<td>Single</td>
<td>Coaxial</td>
</tr>
<tr>
<td>Medtronic 694x family</td>
<td>Integrated bipolar</td>
<td>Dual</td>
<td>Multi-lumen</td>
</tr>
<tr>
<td>St Jude 15xx RIATA family</td>
<td>True bipolar</td>
<td>Dual</td>
<td>Multi-lumen</td>
</tr>
<tr>
<td>St Jude SPxx family</td>
<td>Unipolar</td>
<td>Dual</td>
<td>Coaxial</td>
</tr>
<tr>
<td>St Jude RV XX family</td>
<td>Integrated bipolar</td>
<td>Single</td>
<td>Coaxial</td>
</tr>
<tr>
<td>Sorin Group Isoline 2CXX family</td>
<td>Integrated bipolar</td>
<td>Dual</td>
<td>Multi-lumen</td>
</tr>
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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.10–14 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.16 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.15 Of note, patients who had a lead revision due to ICD lead failure appear to have an eight-fold increased risk for...
Failure rate, whereas single-chamber ICD and ICD implantation in younger age and female gender are associated with a higher risk in a total of 990 consecutive patients further showed that patient factors, which influence lead survival. Cox regression analysis predicted lead failure. Daily lead-impedance measurements, active patients, restricted anatomic space in female patients, and explained by increased mechanical stress on the leads in younger program, promise accurate detection of lead failures. In addition, which might be incorporated in a remote disease management, allow the detection of electrical noise over-sensing. In the quantification of very short RR intervals (abnormally low in those cases with insulation breakdown and ‘infinite’ in those cases with conductor fracture) An evident fracture seen on chest roentgenogram Manufacturer’s returned product report confirming the failure.

Table 2 Definition of lead failure

<table>
<thead>
<tr>
<th>Lead failure category</th>
<th>Definition</th>
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<tbody>
<tr>
<td>No structural failure</td>
<td>Lead functions normally, or has been discontinued for reasons unrelated to lead failure (e.g. patient death or infection)</td>
</tr>
<tr>
<td>Suspected structural failure</td>
<td>One of the following clinical findings of malfunction without verified lead structural failure: Loss of capture or markedly elevated thresholds Loss of sensing, over-sensing, or skeletal muscular stimulation</td>
</tr>
<tr>
<td>Verified structural failure</td>
<td>One of the following findings of malfunction A visible conductor fracture or insulation defect seen at surgery A change in the lead impedance, judged to be caused by conductor or insulation failure (abnormally low in those cases with insulation breakdown and ‘infinite’ in those cases with conductor fracture) An evident fracture seen on chest roentgenogram Manufacturer’s returned product report confirming the failure</td>
</tr>
</tbody>
</table>

*Abnormality led to discontinued use (either surgically or non-invasively).*

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 failure rate, whereas single-chamber ICD and ICD implantation before 1998 have a better lead survival. 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. Daily lead-impedance measurements, which might be incorporated in a remote disease management program, promise accurate detection of lead failures. 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.

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 multicentre 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 have reduced 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, manufactures, 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.

Acknowledgements

The European Heart Rhythm Association Board has reviewed and agreed the publication of this manuscript. The authors thank all the Board members for their input and particularly Professor Brugada, Professor Vardas, and Professor Priori.

Conflict of interest: A.G. has received speaker fees from Boston Scientific. J.M.M. receives consultancy fees from Medtronic and Sorin and unrestricted grants for the support of research staff.

Funding

This work was supported by the European Heart Rhythm Association and the European Society of Cardiology.

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