Patient Safety: the optimal lead body design

E. Soldati

U.O. Malattie Cardiovascolari II
Azienda Ospedaliero Universitaria Pisana

Advances in Cardiac Arrhythmias
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In several decades of experience with implanted devices, leads have shown to be the weakest point in the system.

ICD leads in particular are showing worrying failure rates and their reliability has become one of the major 'hot topic' of the moment among CRM community.
Lead Malfunction

Incidences:

- **Pacing leads**: up to 28% after 10 years\(^1\)
- **ICD leads**: up to 40% after 10 years\(^2\)
- **CS leads**: about 10% after 5 years\(^3\)

Depending on:

- Definition of lead malfunction
- Performance of different lead models
- Patient characteristic
- Physician implantation techniques

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1 Fortesque, et al, Heart Rhythm 2004 1:150-159;
3 Lau PACE 2009; 32:1466-1477

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Lead Malfunction

Pacing vs ICD

Pacing leads → Malfunction up to 28% after 10 years

Definition of malfunction

Different lead models
- SJM 1010T
- MDT 4004
- Telectronics Accufix

Patient characteristic
- Age
- Activity

Implant techniques

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Implant Technique

- Cefalic vein (use introducer)
- Extratoracic subclavian vein puncture


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Fractured lead

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Technique Failure

Courtesy of Prof. B. Wilkoff
Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

Study Limitations
As all implants originated from a single implanting center, our observations and conclusions may not necessarily be generalizable. However, ICD implantation procedures were performed by surgeons who had >10 years of experience with pacemaker and defibrillator implants and performed >95% of all implantations and generator replacements.

About 95% of the leads were implanted with the subclavian technique. As subclavian puncture is known to have a higher lead complication rate, these results may not be extended to leads that are implanted via more desirable access routes such as the cephalic vein.

Because of the long implant duration, lead extraction was not performed routinely. Therefore, the precise cause of lead failure could not be clarified in detail. The reliability of the estimated lead survival rates is decreased because of inconsistent follow-up, loss of patients over time to death from heart failure, and other causes. The number of lead failures has presumably been underestimated.

Figure 1. Common lead introduction sites.

Thomas Kleemann. (Circulation. 2007;115:2474-2480.)

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Lead Malfunction

Inappropriate implantable cardioverter-defibrillator discharges unrelated to supraventricular tachyarrhythmias

Eraldo Occhetta*, Miriam Bortnik, Andrea Magnani, Gabriella Francalacci, and Paolo Marino

REVIEW

Ventricular oversensing: a frequent implanted cardiac defibrillator malfunction, and solutions

Europace (2007) 9, 1041-1047

T. Rauwolf*, M. Guenther†, N. Hass, A. Schnabel, M. Bock, M.U. Braun, and R.H. Strasser

Complications of Implantable Cardioverter Defibrillator Therapy in 440 Consecutive Patients

PETER ALTER,* STEFAN WALDHANS,† EVELINE PLACHTA,* RAINER MOOSDORF,† and WOLFRAM GRIMM*

From the *Department of Internal Medicine-Cardiology, and †Department of Cardiovascular Surgery, Philipps University of Marburg/Lahn, Marburg, Germany

PACE 2005; 28:926-932
Need for lead reliability

As patients live longer and younger and more active patients get devices, there is an increasing need for leads with long-term reliability.

Hauser study - Survival of patients and high voltage implantable cardioverter-defibrillator leads.²

Need for lead reliability

- Literature reports values for inappropriate therapies due to lead failure up to 14% in pediatric patients \(^1\)\(^-\)\(^2\)

- Up to 76% of failing ICD leads are reported to result in inappropriate therapies \(^3\)

1- Berul CI et al, JACC Vol. 51, No. 17, 2008
2- Korte T. et al, PACE 2004; 27:924-932
3- Eckstein et al, Circulation 2008; 117:2727-2733
Noise, Artifact, and Oversensing Related Inappropriate ICD Shock Evaluation: ALTITUDE NOISE Study

**Background:** Approximately 12–21% of implantable cardioverter defibrillator (ICD) patients receive inappropriate shocks. We sought to determine the incidence and causes of noise/artifact and oversensing (NAO) resulting in ICD shocks.

**Methods:** A random sample of 2,000 patients who received ICD and cardiac resynchronization therapy defibrillator shocks and were followed by a remote monitoring system was included. Seven electrophysiologists analyzed stored electrograms from the 5,279 shock episodes. Episodes were adjudicated as appropriate or inappropriate shocks.

**Results:** Of the 5,248 shock episodes with complete adjudication, 1,570 (30%) were judged to be inappropriate shocks. Of these, 1,570, 134 (8.5%) were a result of NAO. The 134 NAO episodes were determined to be due to external noise in 76 (57%), lead connector-related in 37 (28%), muscle noise in 11 (8%), oversensing of atrium in seven (5%), T-wave oversensing in two (2%), and other noise in one (1%). The ICD shock itself resulted in a marked decrease in the level of noise in 60 of 134 (45%) NAO episodes, and the magnitude of this effect varied with the type of NAO (58% for external noise, 35% for 3). There was no significant difference in 32 vs dedicated bipolar 9/140, P = 0.67). The primary causes, while T-wave

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**Table II.**

Mechanism for Noise, Artifact, and Oversensing that Resulted in ICD Shocks

<table>
<thead>
<tr>
<th>Classification</th>
<th>Percent of NAO Episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>External noise</td>
<td>56.7%</td>
</tr>
<tr>
<td>Lead/Connector</td>
<td>27.6%</td>
</tr>
<tr>
<td>Muscle noise</td>
<td>8.2%</td>
</tr>
<tr>
<td>Ventricular lead oversensing of</td>
<td>5.2%</td>
</tr>
<tr>
<td>T-wave oversensing</td>
<td>1.5%</td>
</tr>
<tr>
<td>Other noise, oversensing</td>
<td>0.7%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
Cost implications of defibrillator lead failures

John D. Groarke¹,², Una Buckley², Damien Collison¹, James O’Neill², Niall G. Mahon², and Brendan Foley¹

¹Department of Cardiology, St James’s Hospital, James’s Street, Dublin 8, Ireland; and ²Department of Cardiology, Mater Misericordiae University Hospital, Eccles Street, Dublin 7, Ireland

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Aims

The prevalence of lead failures is increasing with a growing population of implantable cardioverter defibrillator (ICD) recipients. The cost of managing defibrillator lead failures requires investigation.

Methods and results

A retrospective cohort study of patients requiring lead replacement for defibrillator lead failure was performed. Details pertaining to admissions were recorded. The cost per lead replacement was determined. Twenty-three patients [mean age [standard deviation (SD); range] = 56 (17; 18–83) years; 87% male] underwent lead replacement at a mean (SD; range) interval from implant of 3.0 (1.8; 0.9–9.0) years. The median (SD; range) length of hospital stay was 4.5 (8.6; 1–43) days. Procedure-related complications were recorded for three (13%) patients. Thirty days and 1-year mortality were 0 and 4% (1 of 23). The median (SD; range) cost per lead replacement was €7660 (€10 964; €1472–39 663). Bed day costs accounted for 54% of overall costs. Extraction of the failed lead by manual traction at time of lead replacement did not significantly increase costs. The median (SD; range) cost of lead replacement was higher in patients receiving a new ICD generator (n = 6), compared with patients retaining existing generators (n = 17): €23 394 (€5026; €17 266–31 245) vs. €4470 (€9080; €1472–39 663); P = 0.005. The median (SD; range) cost of lead replacement among patients who remained in hospital pending lead replacement (n = 16) was higher than for patients who underwent replacement on an emergent outpatient basis (n = 7): €8508 (€11 920; €1472–39 663) vs. €4372 (€7256; €1555–20 478); however, this observation was not statistically significant, P = 0.21.

Conclusions

Defibrillator lead failures incur significant cost and are likely to undermine overall cost effectiveness of ICDs. Cost-effectiveness analyses of device therapy should include costs related to such complications.

Keywords

Defibrillator lead fractures • Defibrillator lead failures • Cost implications of lead replacements • Lead revisions

Europace (2012) 14, 1156–1160
Definitions

**Lead Malfunction:** Failure of a lead to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the lead. The intended performance of a lead refers to the intended use for which the lead is labeled or marketed (FDA Regulations 803.3(n)). Whenever possible, lead malfunction should be confirmed by laboratory analysis. Malfunctions do not include physician induced damage during the course of implanting, revising, or removing the lead. *Extrinsic malfunctions* are those caused by external factors (e.g., therapeutic radiation, excessive physical damage including subclavian crush and direct trauma to the device pocket, etc.) including, but not limited to, hazards that are listed in product labeling.

**Lead Performance:** A comprehensive assessment of lead quality, usability, freedom from failure (malfunction), and conformance to applicable labeling.

**Lead Reliability:** A measure of a lead to be free of specific structural and electrical failures, typically expressed at a given point in time or a failure rate per unit of time (e.g., failure rate per month).

**Lead Removed from Service Unrelated to Malfunction:** A lead that is removed from service (surgical abandonment, extraction, or programmed off) for reasons not related to failure: infection, device upgrade (pacemaker to ICD, for example), pacer/lead incompatibility, cardiac transplantation, mode change not due to lead failure, patient death unrelated to lead failure, etc.
ICD lead performance

ICD Lead survival varies from
- 91 to 99% at 2 years
- 85 to 98% at 5 years
- 60 to 72% at 8 years


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**ICD lead performance**

**Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years**

*Thomas Kleemann, MD; Torsten Becker, MD; Klaus Doenges, MD;*

*Brief summary:*

**Background—** The increasing reliability of implantable cardioverter-defibrillator (ICD) technology over the past 20 years has led to an increase in the number of ICD implantations. However, lead-related complications remain an important issue. The present study aimed to assess the long-term performance of transvenous ICD leads over a period of >10 years.

**Methods and Results—** The study included a cohort of patients with ICDs implanted between 1986 and 2006. The primary outcome was the occurrence of lead-related complications requiring interventions or lead replacement. The Kaplan-Meier curve shows the event-free lead function over time. The cumulative event rate for lead-related complications was 10% at 10 years, with a steady decrease in the rate of new complications as time since implantation increased.

**Discussion—** The long-term data suggest that the reliability of ICD leads has improved significantly, with a reduction in lead-related complications over the years. However, newer leads may still present challenges, and regular monitoring is recommended to detect early signs of deterioration.

*Figure 1. Kaplan-Meier curves of event-free lead function of all lead models (n=990).*

*Conference presentation:*

- Patients with lead defects are younger and more often female. (Circulation, 2007, 15:2474-2480.)
Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years

Figure 3. Incidence of different causes of lead defects versus time after lead implantation.

Thomas Kleemann. (Circulation, 2007;115:2474-2480.)
Industry data on lead survival

Lead survival rate including all leads

*All data from 2011 PPR report from BSC, MDT and SJM

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Performance of different technologies

Leiden University in the Netherlands conducted a long term study* to determine the ICD lead survivability over multiple manufacturers:

- Large number of ICD leads (n=2161)
- Implanted over a 16 year period
- 4 Manufacturers

![Figure 2. Average Failure Rate Across all Manufacturers](image)

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*Borleffs et al., Risk of Failure of Transvenous Implantable Cardioverter-Defibrillator Leads. Circ Arrhythm Electrophysiol 2009;2:411-416

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Lead body design comparison

St. Jude
Riata®
6.8 F (2.3mm)

BSC
RELIANCE®
8.1 F (2.7mm)

Medtronic
Sprint Quattro® Secure
8.4 F (2.8mm)

Wall size: Indicates the insulation thickness between conductors and outer lead body

Images taken from "Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy",

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Letter to the Editor

Sprint Fidelis defibrillator leads—Should we keep the faith?

Zia Zuberi *, Paresh Mehta, Senthil Kirubakaran, C. Aldo Rinaldi

Department of Cardiology, 6th Floor East Wing, St Thomas’ Hospital, Westminster Bridge Road, London, United Kingdom


Conductor externalization of the Riata internal cardioverter defibrillator lead: tip of the iceberg? Report of three cases and review of literature

H.G. Reinhart Dorman*, Jurren M. van Opstal, Jeroen Stevenhagen, and Marcoen F. Scholten

Europace (2012) 14, 1161–1164

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Fidelis Lead Advisory

- Voluntary recall October 2007
- Initial 2.3% 30 month failure rate
- 3 year failure rate: 5%
- Increasing failure rate: 3.75%/year

Medtronic Sprint Fidelis Performance reports; Hauser, Heart Rhythm 2009

Fidelis® Lead

Risk of not extracting  Risk of extracting

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ICD Lead Failure Sprint Fidelis

Swerdlow CD et al, Circulation 2008; 118: 2122-2129

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These findings have significant implications for the management of patients who have Fidelis leads, and they demonstrate the importance of weighing clinical variables in assessments of ICD lead performance.
RIATA Lead Advisory (278,000 worldwide)

Externalized Conductors up to 15% (25 out of 165 patients), including 5 leads (3%) that were associated with an electrical abnormality. (Belfast Experience)

Riata (8Fr) single shock coil models exhibit a significantly higher incidence rate of externalized conductors than all other Riata (8Fr) and Riata ST (7Fr) models.

Externalized Conductors: 85% inside-out and 15% outside-in

Lead movement associated with a patient’s heart beat → location of the externalization within 8 centimeters proximal to the RV shock coil

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RIATA Lead Advisory

- Externalized Conductors
- Electrical Anomalies

HRS Riata Webinar & SJM Returned Product Analysis

- Noise without Rx 18%
- Inappropriate Rx 36%
- Δ pace/shock Ω 37%
- Pacing threshold 9%
High prevalence of insulation failure with externalized cables in St Jude Medical Riata family ICD leads: Fluoroscopic grading scale and correlation to extracted leads
Division of Cardiovascular Diseases - University Hospital of Pisa (Italy)

Class I recall of defibrillator leads: A comparison of the Sprint Fidelis and Riata families

Jeffrey Liu, MD, Genevieve Brumberg, MD, Rohit Rattan, MD, Sandeep Jain, MD, FHRS, Samir Saba, MD, FHRS

From the Cardiac Electrophysiology Section, Heart and Vascular Institute, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania.

Heart Rhythm, Vol 9, No 8, August 2012

Table 2 Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Riata (n = 627)</th>
<th>Fidelis (n = 623)</th>
<th>Quattro (n = 1020)</th>
<th>P (SQ vs SF)</th>
<th>P (SQ vs R)</th>
<th>P (R vs SF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>31.6%</td>
<td>12.4%</td>
<td>25.9%</td>
<td>&lt;.0001</td>
<td>.993</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Failed leads</td>
<td>6.1%</td>
<td>7.5%</td>
<td>1.1%</td>
<td>&lt;.0001</td>
<td>&lt;.0001</td>
<td>.298</td>
</tr>
<tr>
<td>Functional leads removed</td>
<td>3.7%</td>
<td>15.7%</td>
<td>3.0%</td>
<td>&lt;.0001</td>
<td>.823</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Active leads</td>
<td>58.6%</td>
<td>64.4%</td>
<td>69.3%</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Failed leads before recall</td>
<td>5.9%</td>
<td>1.3%</td>
<td>1.1%</td>
<td>.743</td>
<td>&lt;.0001</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

R = Riata; SF = Sprint Fidelis; SQ = Sprint Quattro.
Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines

Developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA)

TABLE 4 Recommendations for Clinicians Managing Lead Advisory Notices

1. Conservative non-invasive management with periodic device monitoring (remote or in-person, as appropriate) should be strongly considered particularly for:
   - Patients who are not pacemaker dependent*
   - Patients with an ICD for primary prevention of sudden cardiac death who have not required device therapy for a ventricular arrhythmia
   - Patients whose operative risk is high or patients who have other significant competing morbidities even when the risk of lead malfunction or patient harm is substantial.
2. Lead revision or replacement should be considered if in the clinician’s judgment:
   - The risk of malfunction is likely to lead to patient death or serious harm, and
   - The risk of revision or replacement is believed to be less than the risk of patient harm from the lead malfunction.
3. Reprogramming of the pacemaker or ICD should be performed when this can mitigate the risk of an adverse event from a lead malfunction.

When Managing Normally Functioning Leads Subject to Advisory

*All factors should be considered when formulating a clinical plan for individual patients. No single factor should determine the clinical management plan.

PATIENT
- Pacemaker dependence†
- Prior history of ventricular arrhythmia
- Patient prognosis
- Risk of future arrhythmia
- Surgical risk of revision/replacement procedure
- Patient anxiety about lead failure
- Impending battery depletion

LEAD
- Rate of abnormal performance (observed or projected) in Advisory Lead
- Lead failure rates
- Malfunction characteristics (gradual vs. sudden, predictable vs. unpredictable, etc.)
- Identified lead subset with higher failure rate (Serial numbers, vascular access, etc.)
- Malfunction mechanism known/understood
- Adverse clinical consequences of lead failure
- Availability of reprogramming to Mitigate Clinical Risk
- Availability of algorithms for early detection of lead abnormality

*Pacemaker dependence refers to patients who have no hemodynamically stable underlying heart rhythm in the absence of pacing.

†Pacemaker dependence refers to patients who have no hemodynamically stable underlying heart rhythm in the absence of pacing.
ENDOTAK Lead Technology

Trilumen lead

- Design that maximizes insulation thickness
- Designed to be durable and crush resistant

ENDOTAK Reliance™

High-voltage DBS wire
Pace/sense conductor coil

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Reliance vs 4-Front

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**Lead**

<table>
<thead>
<tr>
<th>RELIANCE 4-FRONT</th>
<th>RELIANCE</th>
</tr>
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<tbody>
<tr>
<td>Silicone</td>
<td>Silicone</td>
</tr>
<tr>
<td>Wall Thick &gt; 0.178 mm</td>
<td>Wall Thick &gt; 0.178 mm</td>
</tr>
<tr>
<td>Web Thick &gt; 0.127 mm</td>
<td>Web Thick &gt; 0.127 mm</td>
</tr>
</tbody>
</table>

**Trilumen Silicone (wall thickness)**

- RELIANCE 4-FRONT: 0.229 mm
- RELIANCE: 0.229 mm

**Abrasion Silicone (wall thickness)**

- RELIANCE 4-FRONT: 0.051 mm
- RELIANCE: 0.051 mm

**Abrasion PU (wall thickness)**

- RELIANCE 4-FRONT: 0.051 mm
- RELIANCE: 0.051 mm

**PTFE (wall thickness)**

- RELIANCE 4-FRONT: 0.051 mm
- RELIANCE: 0.051 mm

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Built on the RELIANCE platform, 4-FRONT is smaller without compromising insulation thickness.

- Reduced high voltage cables thickness.

**RELIANCE 4-SITE™**
8.1F (2.7mm)

**RELIANCE 4-FRONT™**
7.3F (2.4mm)

Same insulation thickness

Smaller cables

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**Incorporation of GORE™**


Group A = RELIANCE™ G   n = 17  
Group B = Sprint Quattro™ 6944   n = 20  
Group C = Riata™ 1570   n = 36

* Group A vs Group B  p<0.05  
** Group A vs Group C  p<0.05

**Easier extraction due to ePTFE**

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Multicenter Experience With Extraction of the Sprint Fidelis Implantable Cardioverter-Defibrillator Lead

Melanie Maytin, MD,* Charles J. Love, MD,† Avi Fischer, MD,‡ Roger G. Carrillo, MD,§ Juan D. Garisto, MD,§ Maria Grazia Bongiorni, MD,|| Luca Segreti, MD,|| Roy M. John, MD, PhD,* Gregory F. Michaud, MD,* Christine M. Albert, MD, MPH,* Laurence M. Epstein, MD*

349 Sprint Fidelis leads were extracted from 348 patients. All leads were removed completely. There were no major procedural complications or deaths.

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Optimal lead body design

- Average body thickness
- Maximized insulation thickness
- Single coil
- Isodiametric
- Fibrosis ingrowth prevention