XVI Symposium on Progress in Clinical Pacing, Rome, Italy - Dec 2 to 7, 2014

ICD leads survival and troubles in the last 10 years

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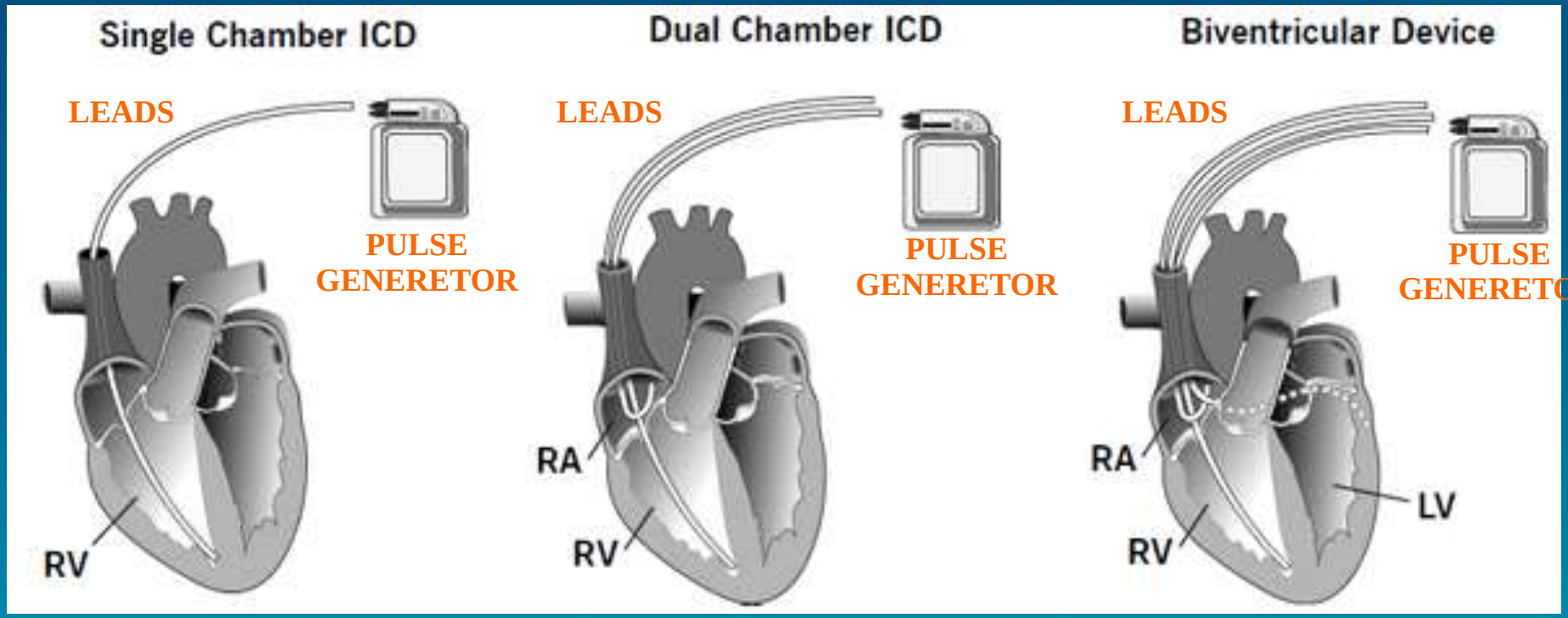
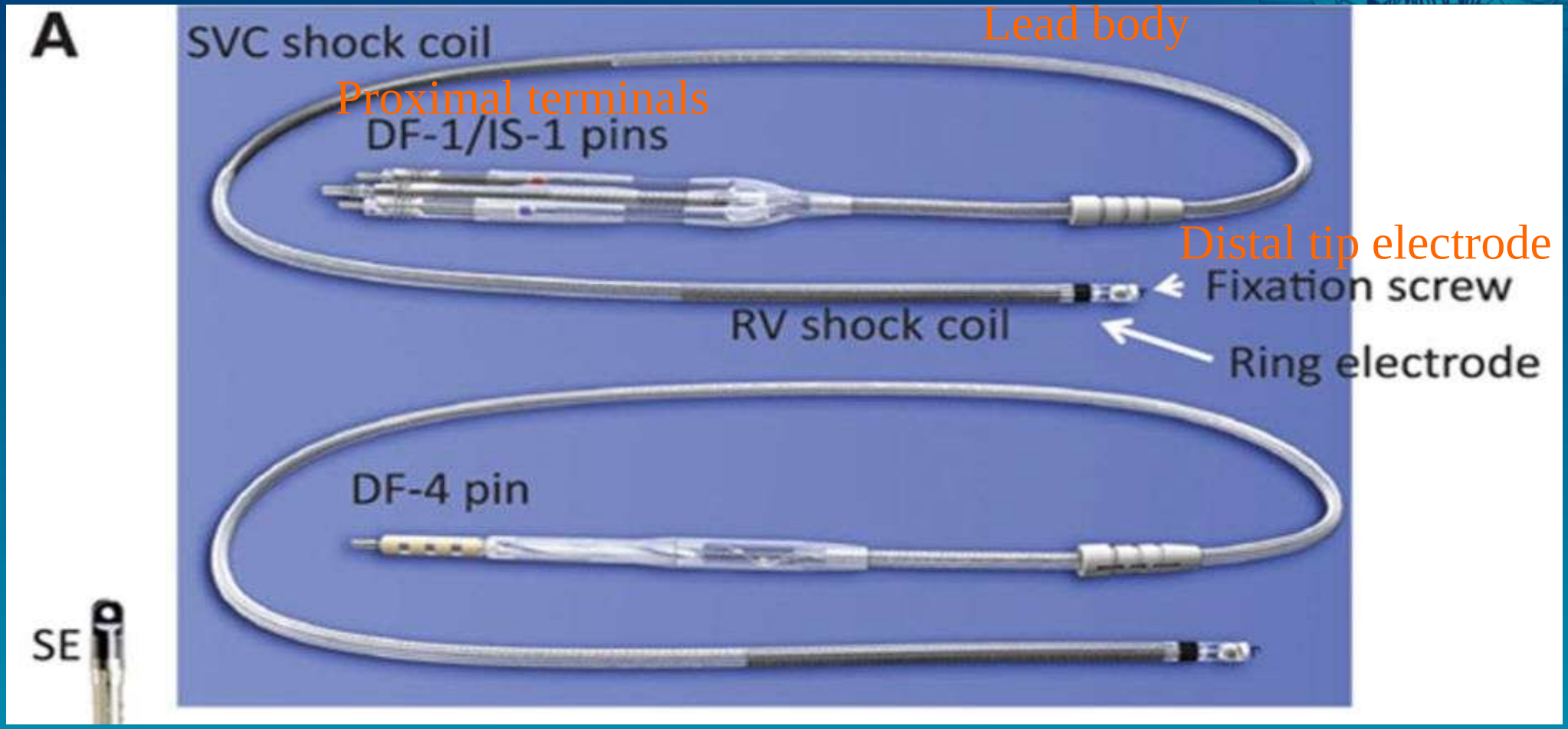
ICD & SCD

- The implantable cardioverter-defibrillator (ICD) has become the standard therapy for patients with aborted SCD and those at high risk of developing potentially letal ventricular tachyarrhythmias

ICD components



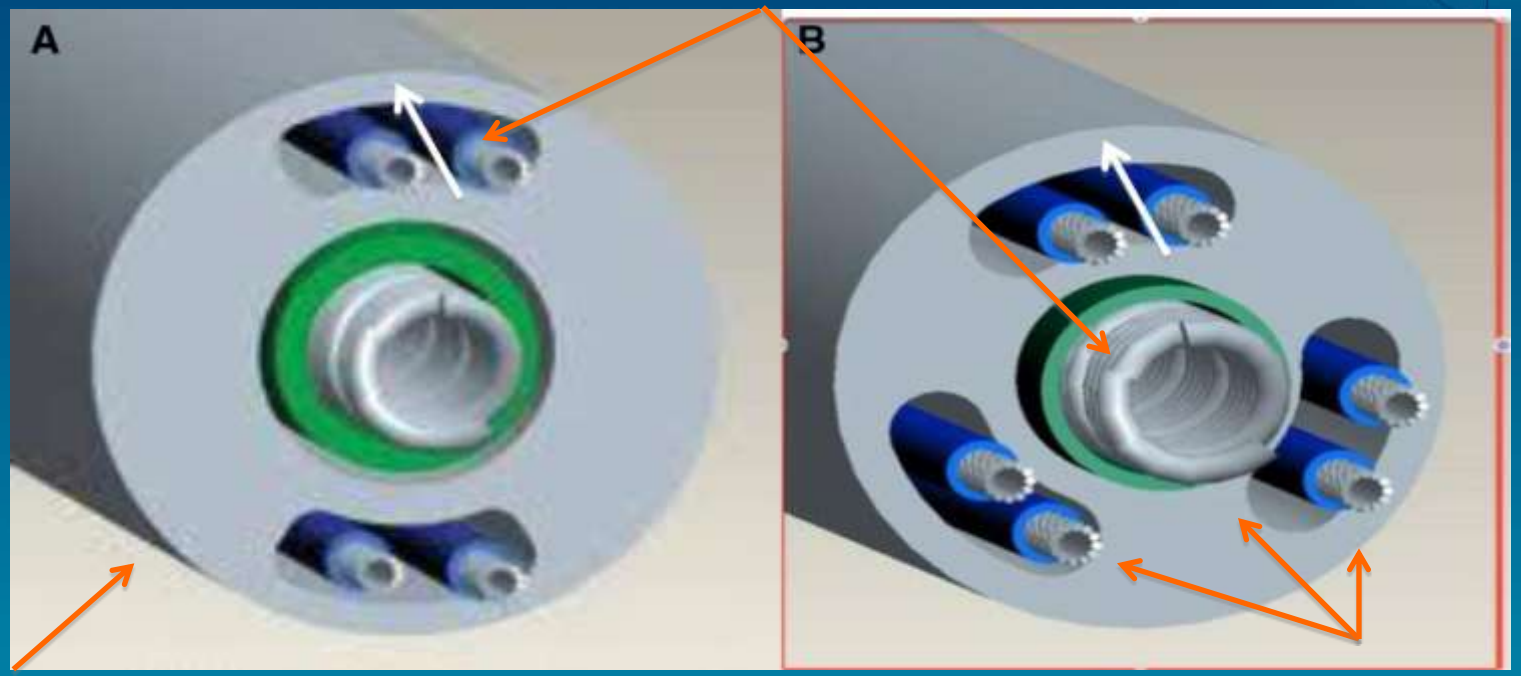
Modern RV defibrillation lead



Swerdlow C D , and Ellenbogen K A Circulation. 2013;128:2062-2071

ICD lead body

Conductors

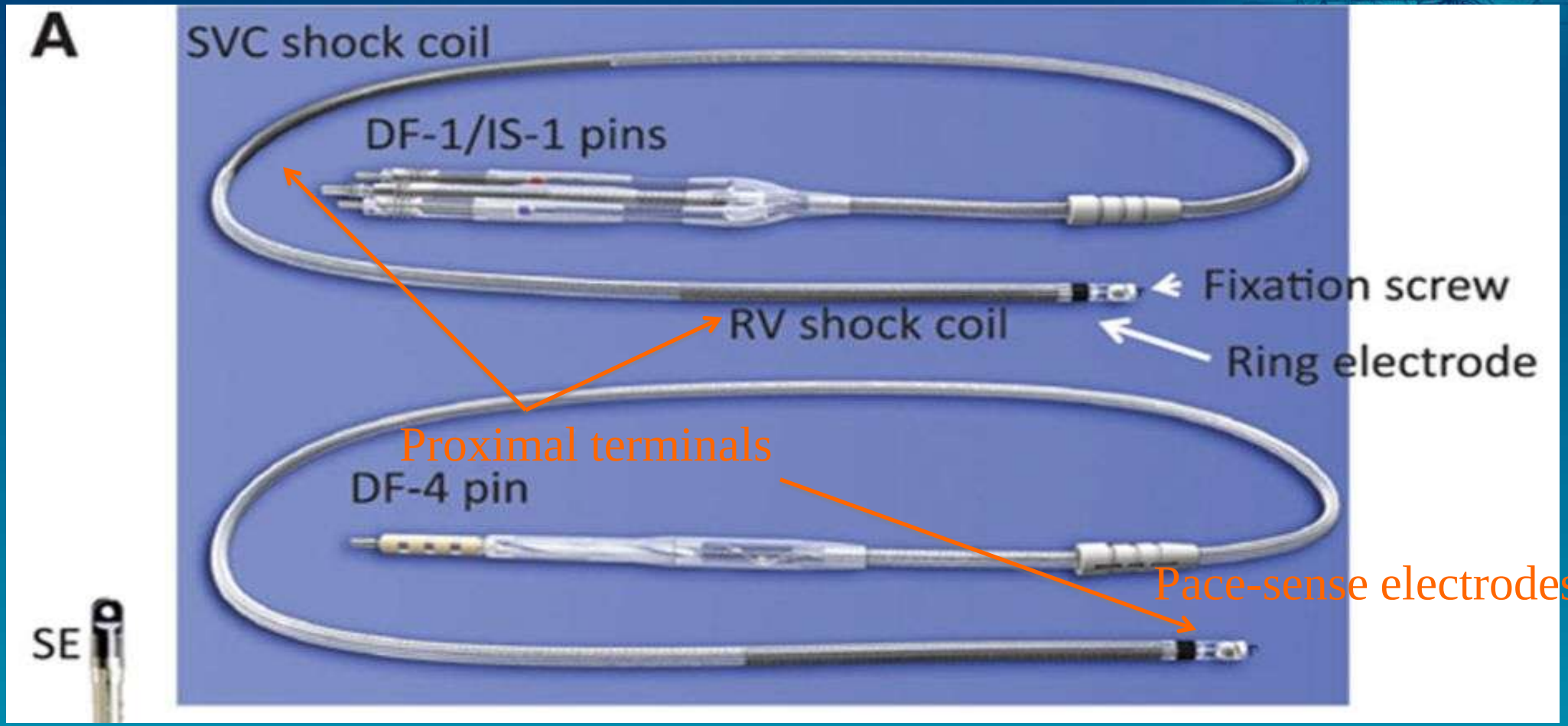


Flexible insulating cylinder (silicone – polyurethane)

Parallel logitudinal lumens

Hauser RG et al. Heart Rhythm 2012; 9: 742-749

Modern RV defibrillation lead



Swerdlow C D , and Ellenbogen K A Circulation. 2013;128:2062-2071

ICD leads

- ICD leads are the most vulnerable component of the ICD systems, especially the RV defibrillation lead. It must remain chemically inert in an hostile biological enviroment, withstand flexible for hundreds of millions of cardiac cycles, and retain electricl integrity during high voltage shocks.

ICD lead failure / Incidence

Table 4 Lead failure rates

Reference	Study design	Lead types	Failure rate	Observation period	Yearly failure rate	Long term failure rates	Accelerating failure rate?
Farwell[124]	Retrospective, single centre	Medtronic fidelis	17/471 (3.5%)	19.8 months	2.12%	Not reported	Yes
Kron[60]	Retrospective analysis of prospective multicentre study	All manufacturers	15/539 (2.8%)	27.0±13.4	1.2%	5% at 5 years	No
Alter[61]	Prospective, single centre	All manufacturers	27/440 (6.1%)	46±37 months	1.6%	Not reported	Not reported
Faulknier[66]	Retrospective, single centre	Medtronic fidelis	38/426 8.92%	2.3 years	3.6%	9% at 3 years	Yes
Hauser[125]	Retrospective, 3 centre	Medtronic fidelis	80/1023 (7.8%)	2.78 y	2.8%	13% at 4 years	Yes
Hauser[125]	Retrospective, single centre	Medtronic quatro	23/1668 (1.4%)	3.18 y	0.43%	1.3% at 4 years	No
Kleemann[63]	Prospective, single centre	All manufacturers	148/990 (15%)	934 days	5.8%	15% at 5 years; 40% at 8 years;	Yes
Eckstein[65]	Retrospective, 3 centre	All manufacturers	38/1317 (2.9%)	6.4 years	0.45%	2.5% at 5 years	No
Luria[30]	Retrospective, single centre	All manufacturers	18/391 (4.6%)	19 months	2.9%	18% failure at 4 years	Yes
Kitamura[126]	Retrospective, single centre	Medtronic models	5/241 (2%)	2.6±2.1 years	Not reported	Not reported	No
Hauser[127]	Retrospective, 3 centre	Transvene 6936/6966	44/521 (8.4%)	4.8±2.1 years	2.2%	16% at 84 months	Yes
Dorwarth[128]	Retrospective, single centre	Transvene 6884, 6966, 6936	31/261 (12%)	4.0±2.6 years	4.75%	38% at 8 years	Yes

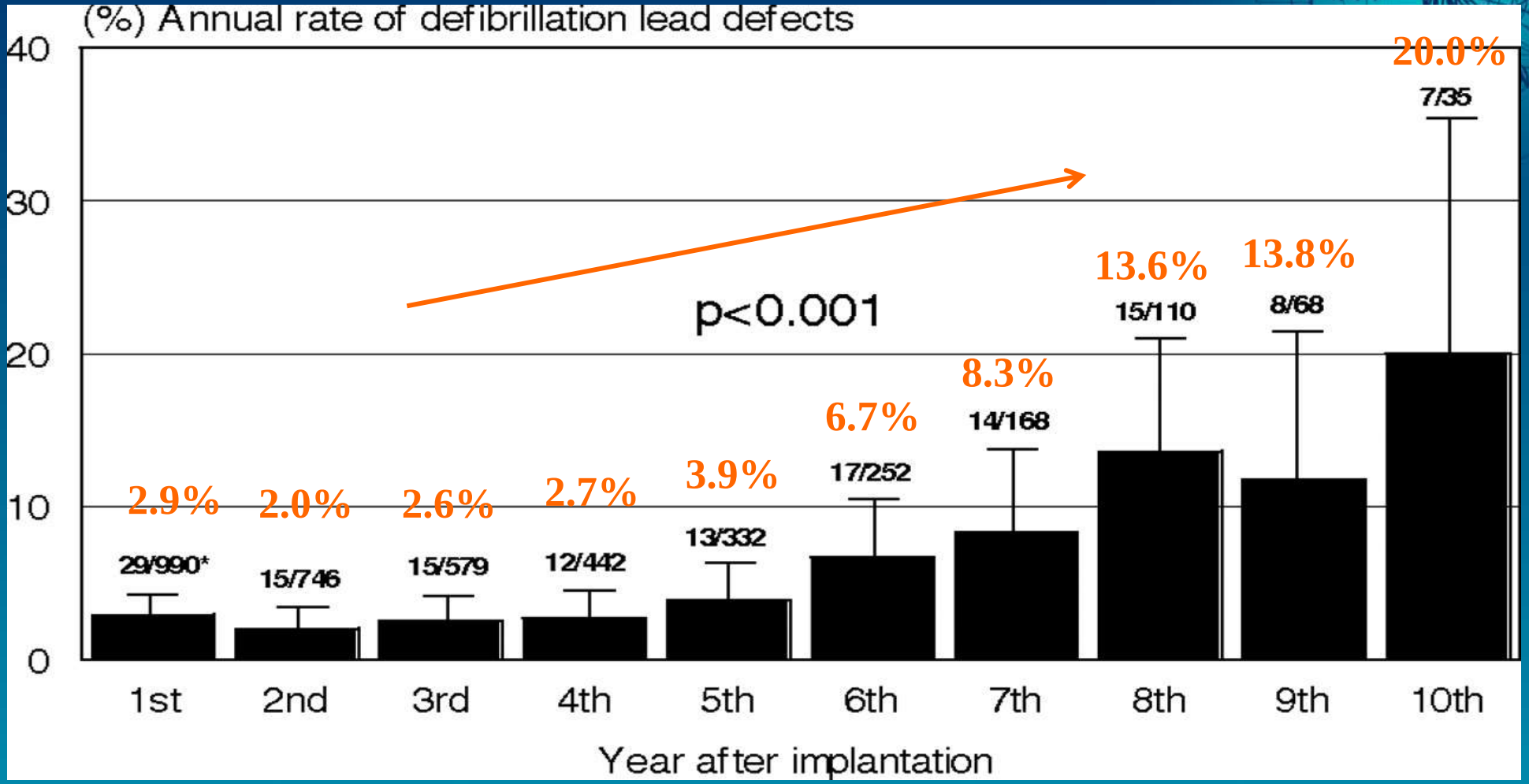
Atwater BD et al. Heart 2012; 98: 764-772

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

Thomas Kleemann, Torsten Becker, Klaus Doenges, Margit Vater, Jochen Senges, Steffen Schneider, Werner Saggau, Udo Weisse, and Karlheinz Seidl

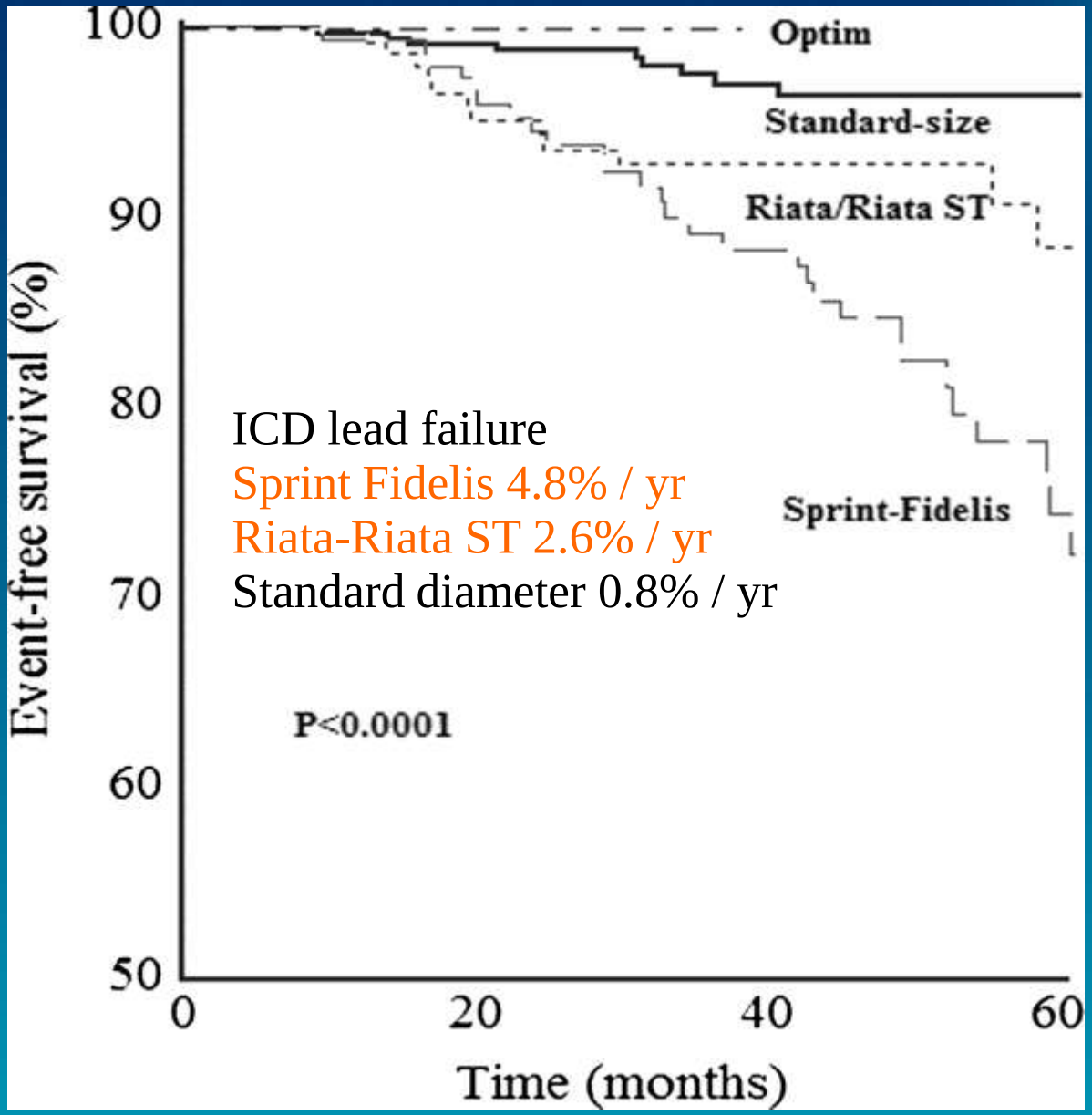
Circulation 2007; 115: 2474-2480

Annual rate of defibrillation lead defects versus time after lead implantation

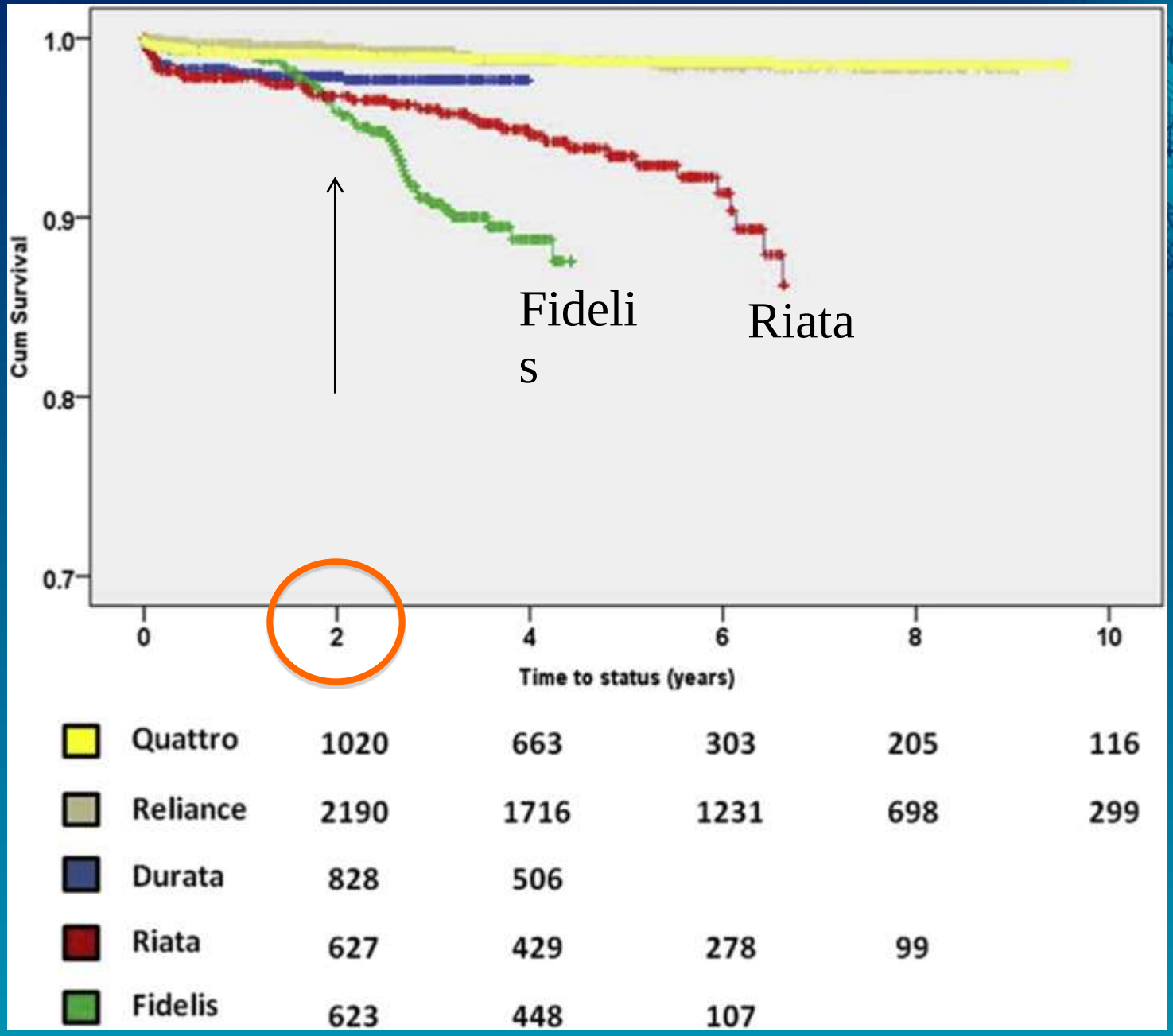


Kleemann T et al. Circulation. 2007;115:2474-2480

Lead failure event-free survival in the 4 ICD lead groups



Rordorf R et al. Heart Rhythm 2013 10, 184-190



Liu J. et al. Am J Cardiol 2014; 113: 103-106

ICD leads / FDA recall &

- These surprisingly high rates of premature lead failure have obliged in 2007 and 2011 the FDA to a recall and the manifacturing Industries, Medtronic and St Jude, to a withdrawal of these leads from the market

Sprint Fidelis / Primary mechanism of lead failure

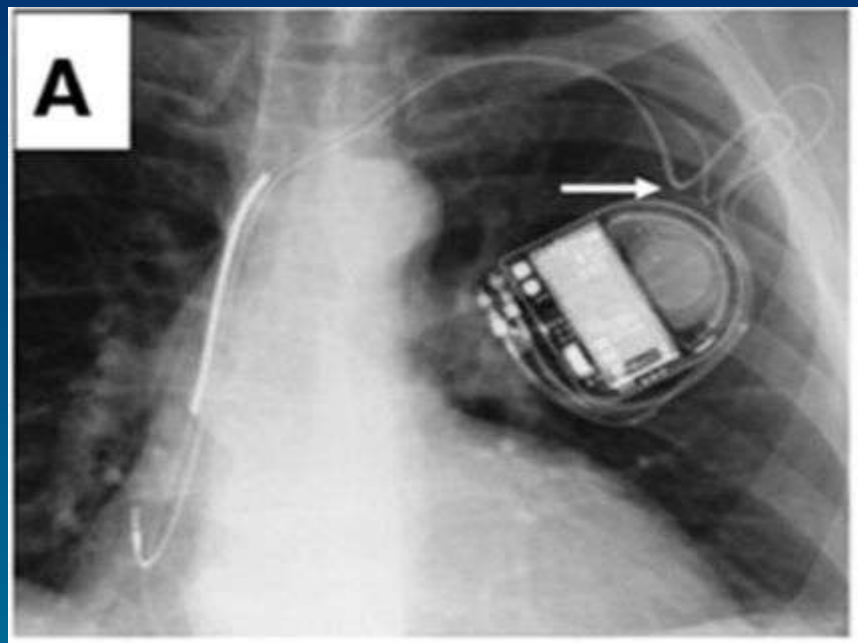
- Conductor fracture

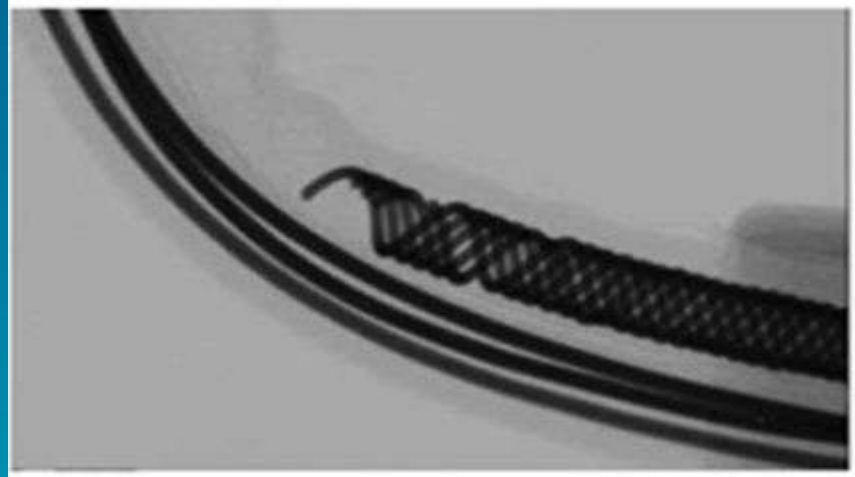
  Sprint Fidelis is a highly flexible lead that permits bending with a short radius, which increases the force applied to the coil and cable, thus favoring fracture of these elements

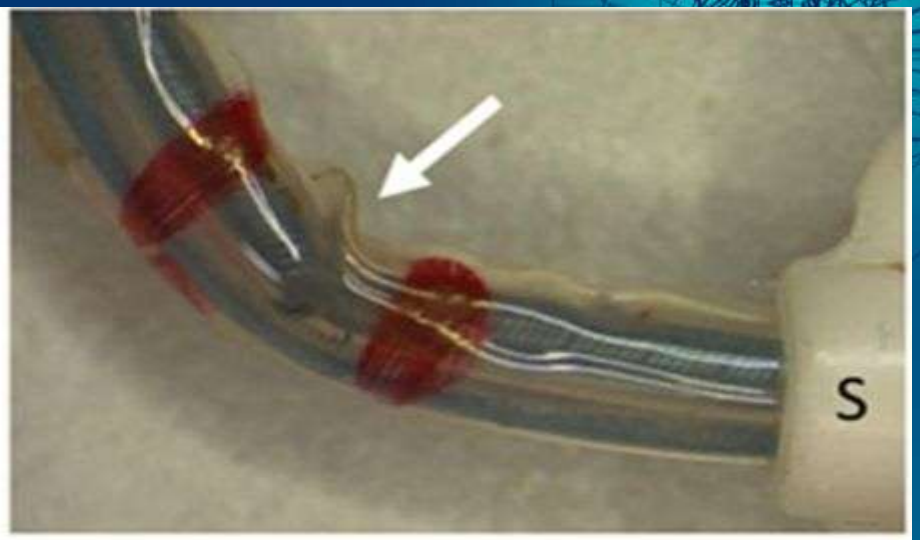
Sprint Fidelis / Conductor fracture

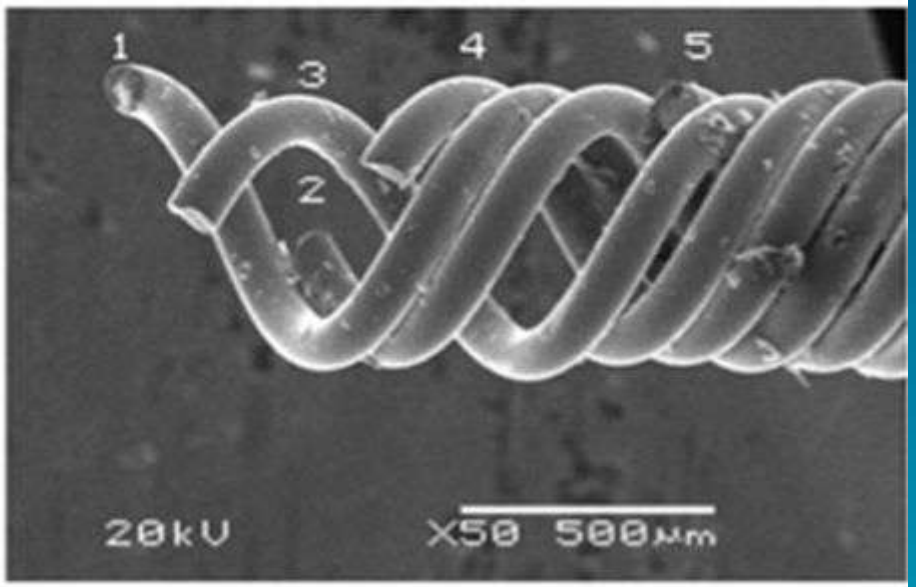
- pace-sense conductor: 94%
  - central helical coil to the tip catheter : 43%
  - the cable to the ring electrode: 57%
- high-voltage conductor: 6%
  - the cable to the distal coil: 56%
  - the cable to the proximal coil: 36%
  - both: 8%

Conductor fracture at tie-down sleeve (Medtronic Sprint Fidelis)









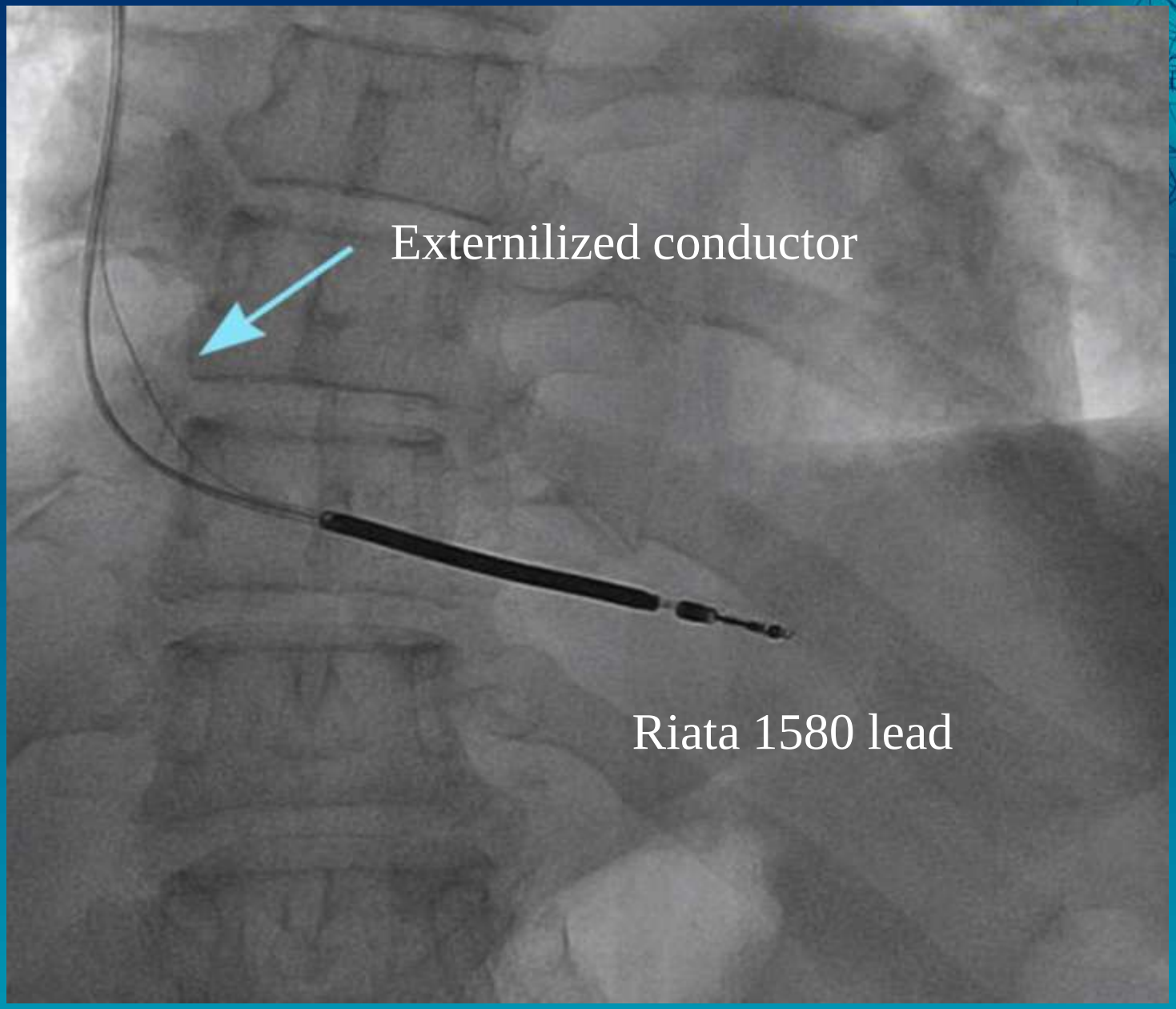
Swerdlow C D , and Ellenbogen K A Circulation. 2013;128:2062-2071

Riata-Riata ST / Primary mechanism of lead failure

- Insulation breach

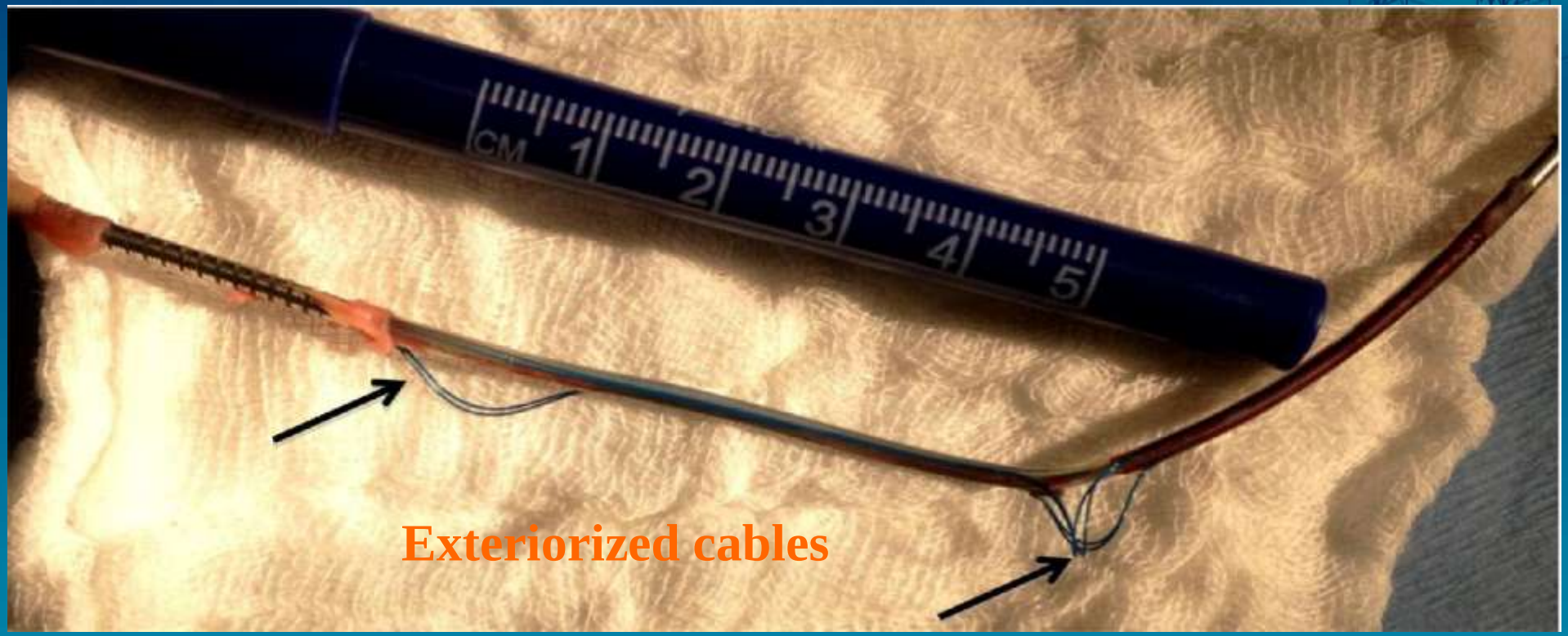
Riata are multilumen silicone-body leads without an outer protective coating that have large-diameter lumens that permit the cables to move more freely and abrade against and through silicone insulation which results in a unique failure mode of inside-out insulation breach and exteriorization of the cables

Fluoroscopic anterior posterior projection



Heart Rhythm 2013 10, 1444-1450

Extracted dual-coil RIATA lead



Hauser RG et al. Heart Rhythm 2012; 9: 742-749

Riata-Riata ST/ Cable exteriorization

- **Riata 8F lead: 17.9%***
- **Riata ST 7F lead: 9.4%***

* for leads implanted < 6 years

ICD lead failure / Risk factors

- Younger age (< 60 years)
- Female sex
- Underlying cardiac disease
- Multiple lead implantation
- Small-diameter leads

ICD lead failure

- Functional consequences

  may be multiple and can result in significant clinical events, including death.

  Pace-sense mulfunctions are more frequent than shock component failure

ICD lead failure/ Pace-sense mulfunctions

- Oversensing of rapid non-physiologic signals
  - Inappropriate shocks
  - Pacing inhibition
- Loss of capture
- Elevated pacing threshold
- Undersensing of low amplitude electrograms
  - Pacing failure
  - Lack of delivery of appropriate shocks

ICD lead failure/ Shock component failure

- Failed defibrillation in case of sustained VT/VF
- Catastrophic failure of the pulse generator as consequence of short-circuit of high-voltage outputs

ICD lead failure/ Diagnosis

- **Documenting oversensing on the internal ECG channels**

  (events that occur on the sensing channel but not on the shock channel indicate oversensing)

- **Documenting a change in the lead impedance**

  (usually a rapid increase - >75% in a week - is indicative of conductor fracture and a low impedance - < 200 Ω - of insulation breach)

- **Identifying exteriorized cables at cinefluoroscopy or a visible conductor fracture or insulation defect at surgery**

ICD lead failure/ Early identification

- It is obviously important to develop methods to detect ICD lead failure in an early stage before clinical presentation, both to reduce the risk of inappropriate shocks and to prevent fatal events.

ICD lead failure/ Early identification

- Novel algorithms, such as those that recognize numerous extremely short R-R intervals, those that compare sensing and shocks electrograms, and those that monitor abnormal pace-sense impedance and transient rapid oversensing and trigger an audible alert tone if these creteria are fulfilled, as well as
- Remote internet-based monitoring

  may facilitate early diagnosis of lead failure and start prompt decision making and/or therapeutic intervention

ICD lead failure/ Therapeutic options

- Implantation of an additional pace/sense lead
- Implantation of a new ICD lead with capping of the in-situ lead
- Extraction of the failed lead and implantation of a new ICD lead

ICD lead failure/ Decision making

- The decision depends on the risk of extraction, which in turn depends on the patient, operator/institution, and specific lead model considerations

Conclusions

- Despite the remarkable progress of ICD technology in the last years, we need further significant advances especially in leads reliability and durability, in order to substantially reduce the rate of mid- and long-term complications of ICD therapy.

Conclusions

- We are confident that in the near future improvements in the lead design and materials and more stringent premarket testing, and postmarket surveillance will increase patients' safety and improve, in this way, the credibility of ICD therapy among both general cardiologists and practitioners