Managing recalled and superfluous leads

Luca Segreti, MD

University Hospital of Pisa, Italy

Director M. G. Bongiorni

11.00-13.00

Core Curriculum

Lead extraction and device infection

Program Chairmen: Maria G. Bongiorni – Charles Kennergren

CIED LEAD RELIABILITY

Chairmen: **R.G. Carrillo** / Miami, USA – **A. Proclemer** / Udine, Italy

Development, testing, trialing and approval of new leads
E. Trip / Berlin, Germany

A systematic approach to trouble-shooting leads
A. Curnis / Brescia, Italy

Managing recalled and superfluous leads
M.G. Bongiorni / Pisa, Italy

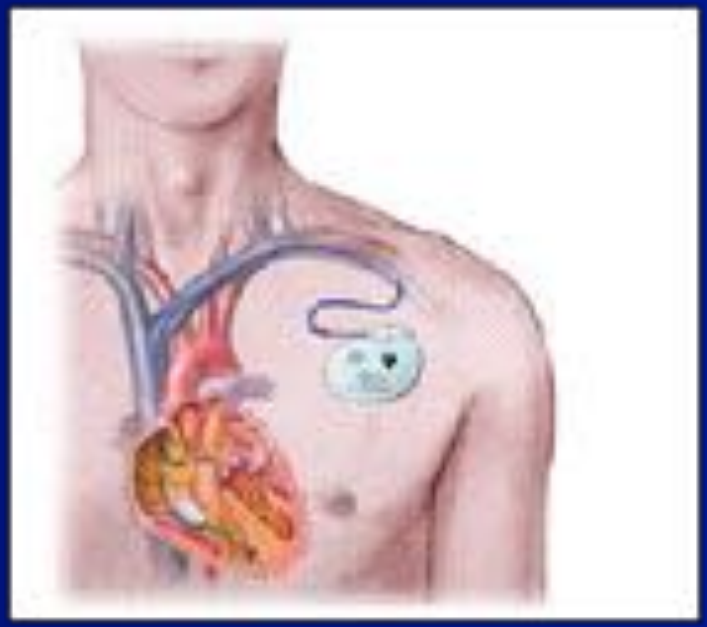
Can all leads be made redundant in the future?
N. Linker / Middlesbrough, UK

Sunday 18 morning - Cenacolo Room

DISCLOSURE

- No disclosure

Growing number of CRM Systems & Leads



DEVICES

7 million devices worldwide

700.000 new devices annually

LEADS

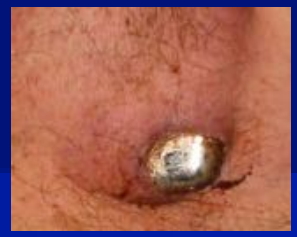
14 million leads worldwide

1.4 million new lead annually

1. Medtronic CRDM Product Performance Report, Mar 2013. Eucomed (2012)
2. Boston Scientific CRM Product Performance Report, Q1 2013. Eucomed (2012)
3. St. Jude Medical CRM Product Performance Report, Apr 2013. Eucomed (2012)
4. Biotronik Product performance Report, JAN 2013

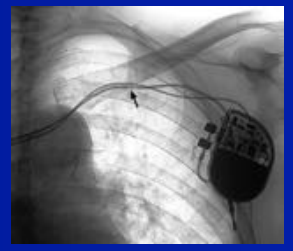
Patients:→ Estimated annual complication rate ≈ 5%

- Infection ≈ 1 %
  - 2-7% infection rate for replacement/upgrades[1]
  - ≤ 0.5% infection rate for new implants[1]



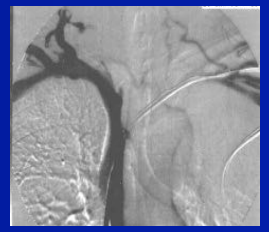
1. Wilkoff, Bruce L. , et al. How to treat and identify device infections. *Heart Rhythm*, Vol 4, No 11, 2007, 1467-1470.

- Malfunction ≈ 2.5 %
  - 1.65-20% annual ICD lead failure based on age[2,3]



2. Hauser, Robert, et. al., The Increasing Hazard of Sprint Fidelis Implantable Cardioverter-Defibrillator Lead Failuree, *Heart Rhythm*, Vol. 6, No 5, May 2009.
3. Kleeman Thomas, et al. Annual Rate of Transvenous Defibrillation Lead Defect in Implantable Cardioverter-Defibrillators over a Period of >10 Years. *Circulation* 2007; 115:2474-2490.

- Occlusion ≈ 0.5 %
  - 9-12% of device replacement or upgrade[4]
- Redundant leads[4] ≈ 1 %



4. Field M.E., Jones S.O., Epstien L.M. How to select patients for lead extraction. Heart Rhythm 2007; 4:978-985

HRS 2009 Lead Extraction indications:

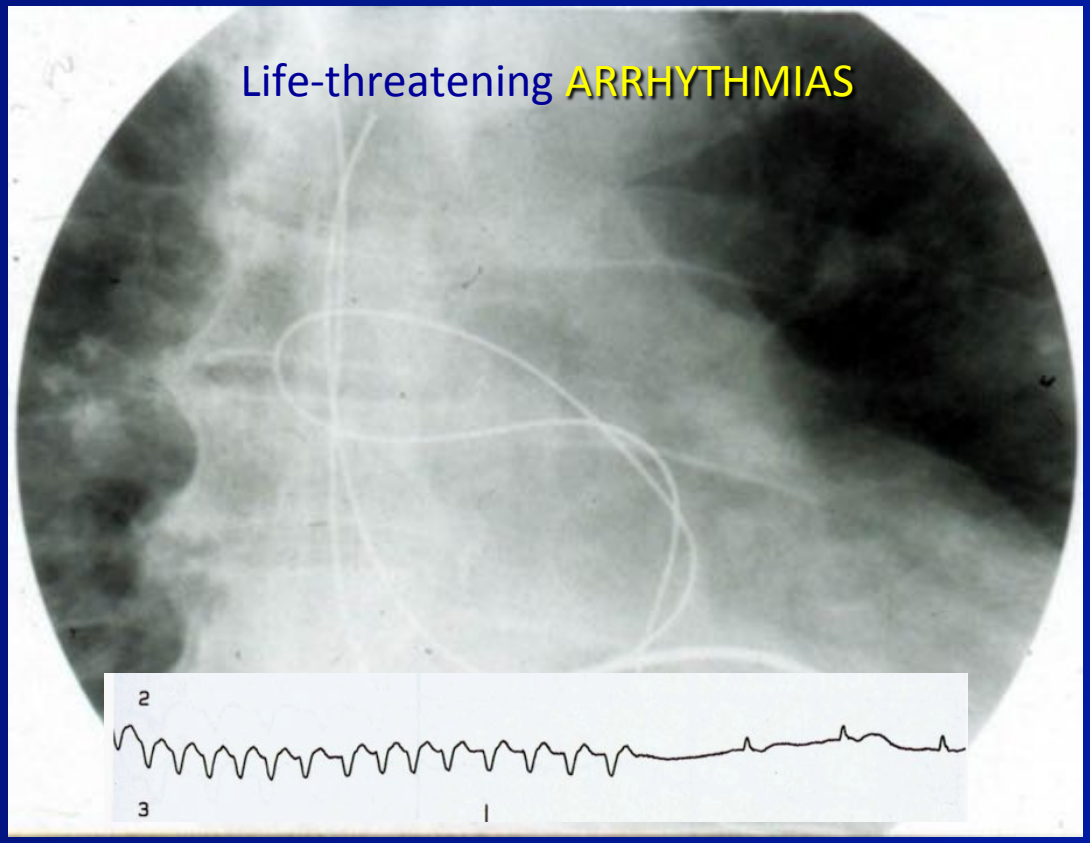
- INFECTION
- CHRONIC PAIN
- THROMBOSIS OR VENOUS STENOSIS
- FUNCTIONAL LEADS
- NON-FUNCTIONAL LEADS

Heart Rhythm : July 2009

FUNCTIONAL and NON FUNCTIONAL LEADS:

Class I

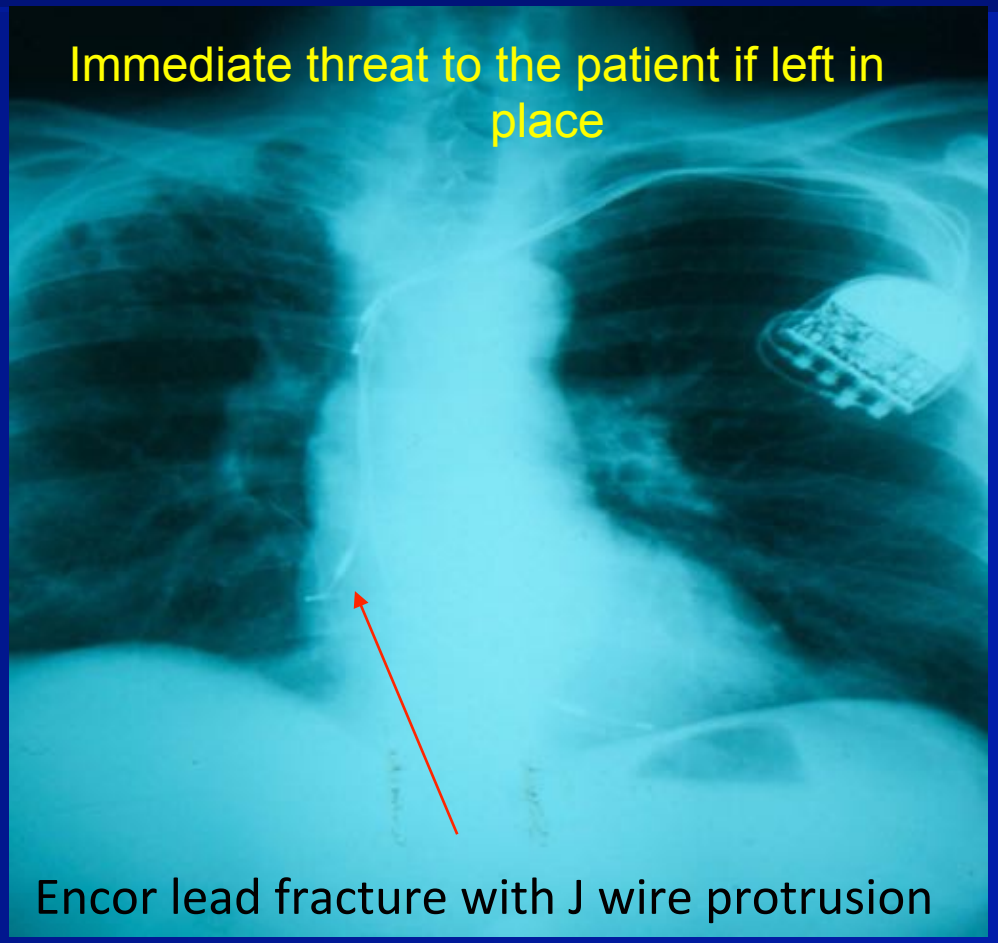
1. Lead removal is recommended in patients with life threatening arrhythmias secondary to retained leads. (Level of evidence: B)



FUNCTIONAL and NON FUNCTIONAL LEADS:

Class I

2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place (e.g. Telectronics ACCUFIX J wire fracture with protrusion). (Level of evidence: B)

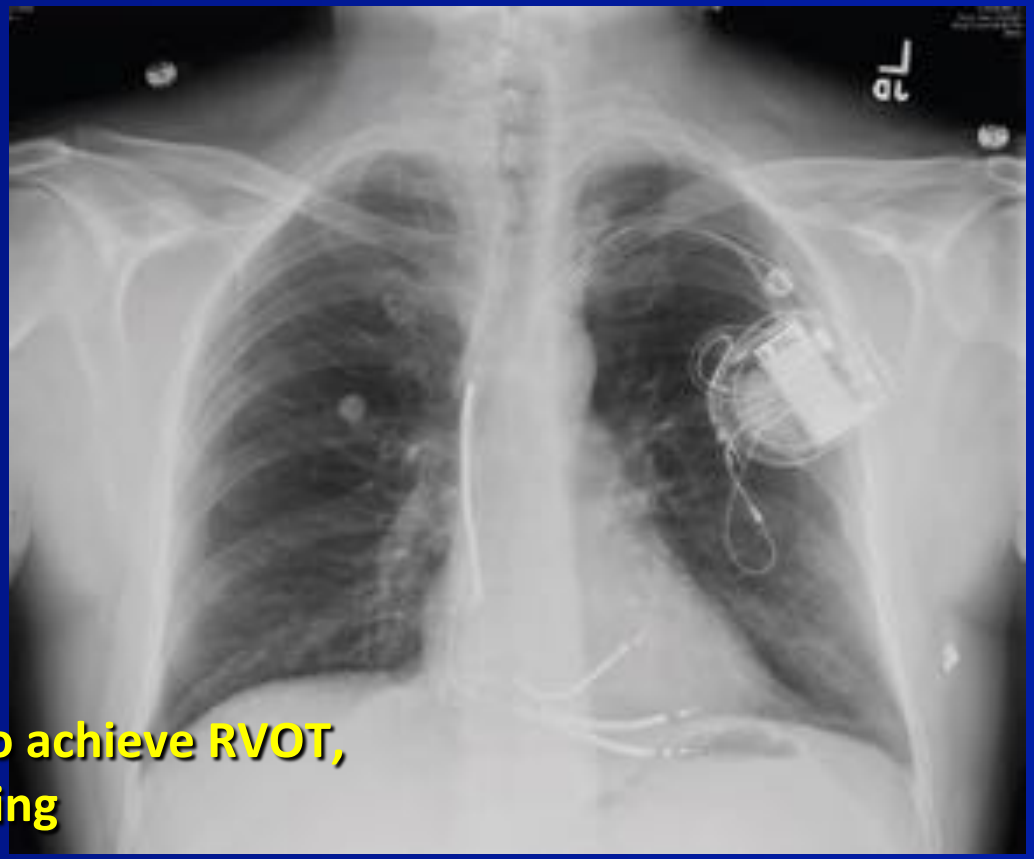


Encor lead fracture with J wire protrusion

FUNCTIONAL and NON FUNCTIONAL LEADS:

Class I

3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (Level of evidence: B)



I think they were trying to achieve RVOT, as opposed to, apical pacing

Indications to transvenous lead extraction

Wilkoff BL, Love CJ, Byrd CL, Bongiorni MG, et al HRS Lead Extraction Consensus - 2009

CLASS I

- Device system revision or upgrade in the setting of bilateral subclavian vein thrombosis,
- SVC occlusion,
- Ipsilateral venous occlusion preventing ipsilateral implantation with contraindications to contralateral implant (eg, arteriovenous fistula, vascular access port, mastectomy, etc)

CLASS IIa

- The need for lead implantation with ipsilateral venous occlusion preventing ipsilateral implantation without contraindications to contralateral implant or
- lead implantation that would result in 4 leads in the implant vein or 5 leads through the SVC.

CLASS IIb

- Superfluous leads with the potential for CIED interference and
- Abandoned or redundant leads

Lead Replacement vs Abandonment in Non-infected Leads

Study	Study Type	Groups Studied	N° of Patients	N° of Leads	Follow-up	Composite Results: Abandon vs Remove
Wollman	Retro	Add HV vs replace HV	33avs 53r	2.6vs1.4	9.3vs6.7y	↔ (Add HV decision due to failed TLE attempt in 70%)
Wollman	Retro	Add P/S	151	2.3	3.6 y	N/A (Conclude removal best given 28.5% failure rate of new P/S requiring repeat procedure
Suga	Retro	Pz with ≥1 aband leads	433	2.8	3.1 y	N/A (N. Abandoned leads higher in those with complications
Glikson	Retro	Aband. HV or P/S	78	1.5 (ab)	3.1 y	N/A (No sensing malfunction, venous trombosis or DFTchange
deCock	PRO	Pz with ≥3 leads vs control	48	3.2vs2.0	7.4 y	N/A
Bohm	Retro	Pz with ≥1 aband leads	60	1.0 (ab)	NA	N/A (20% event rate driven by migration of cut leads)
Sweeney	PRO	Device upgrades add vs replace	58	NA	1.1 Y	↔
Parry	Retro	Pz with ≥1 aband leads	119	NA	NA	N/A (42% vs 3% rate of major compl infectius vs non)
Amelot	Retro	Abb. vs Extr. HV or PS	26a vs 32r	3.4vs1.7	3.2 y	No Difference

Rigorous evidence from large-scale, randomized trials is lacking, and the available reported studies are often underpowered, generating more confusion than ansvers

End Points: Event-free Survival

Concerns about abandoning leads

Abandoned Leads are not harmless

- Increased risk/difficulty of extraction in the future
- Infection
  - ICD (as opposed to PPM)
  - > 2 leads

Sohail et al: CiD, 2007; Uslan et al: Archives IM, 2007

- Venous Obstruction
- Lead-lead interaction
- MRI compatibility

Advisory Leads

Implanted Leads may be dangerous

- Over time leads have shown to be the weakest point in the PM/ICD systems
- Particularly ICD leads are showing poor reliability (malfunction up to 40% after 10 years).

- Telectronic Accufix/Encor 1994
- MDT Sprint Fidelis 2007
- SJM Riata 2011

Advisory lead

- Leads that can cause harm
- Leads that can fail
- Leads that have failed

Management Options

- Observation
- Abandonment
- Replacement

Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines

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.

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

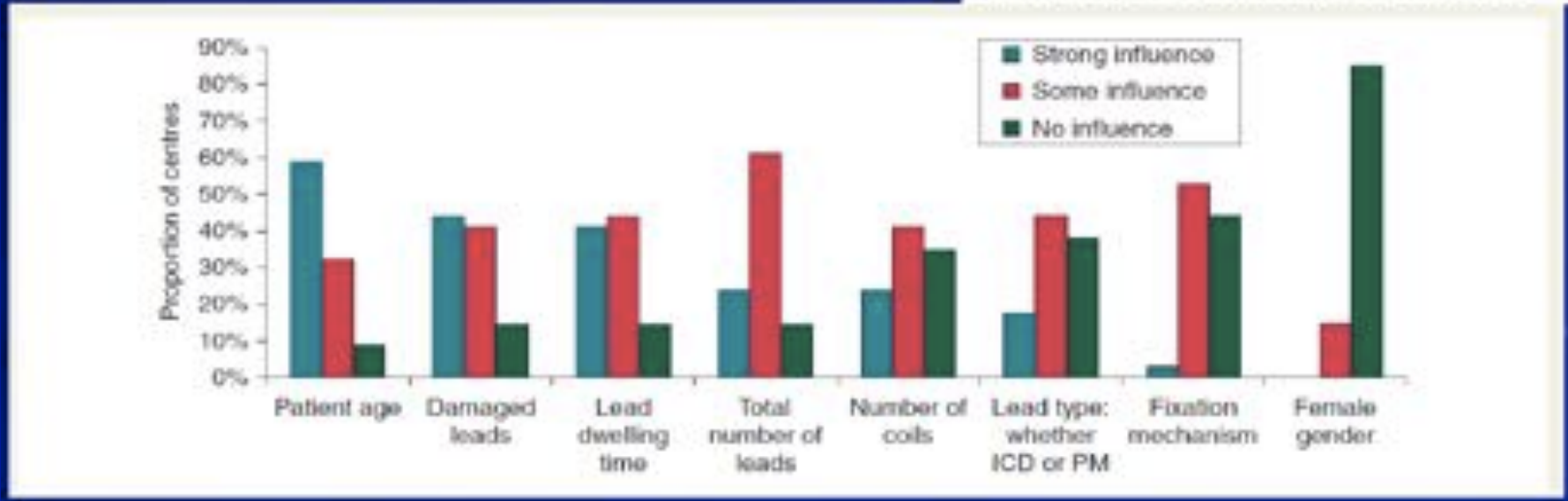
HOME MONITORING

Heart Rhythm, Vol 6, No 6, June 2009

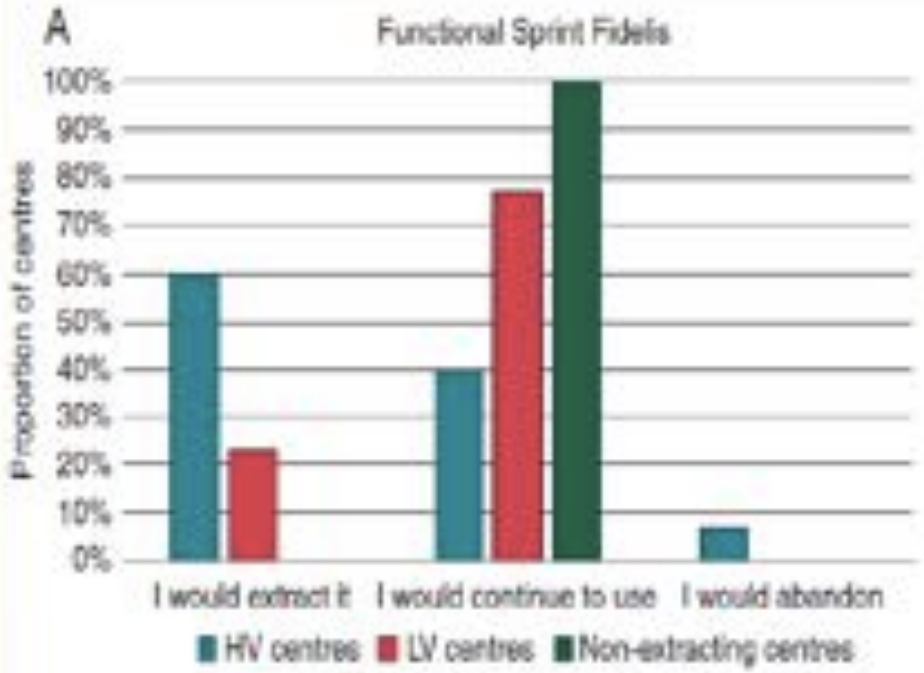
Management of malfunctioning and recalled pacemaker and defibrillator leads: results of the European Heart Rhythm Association survey

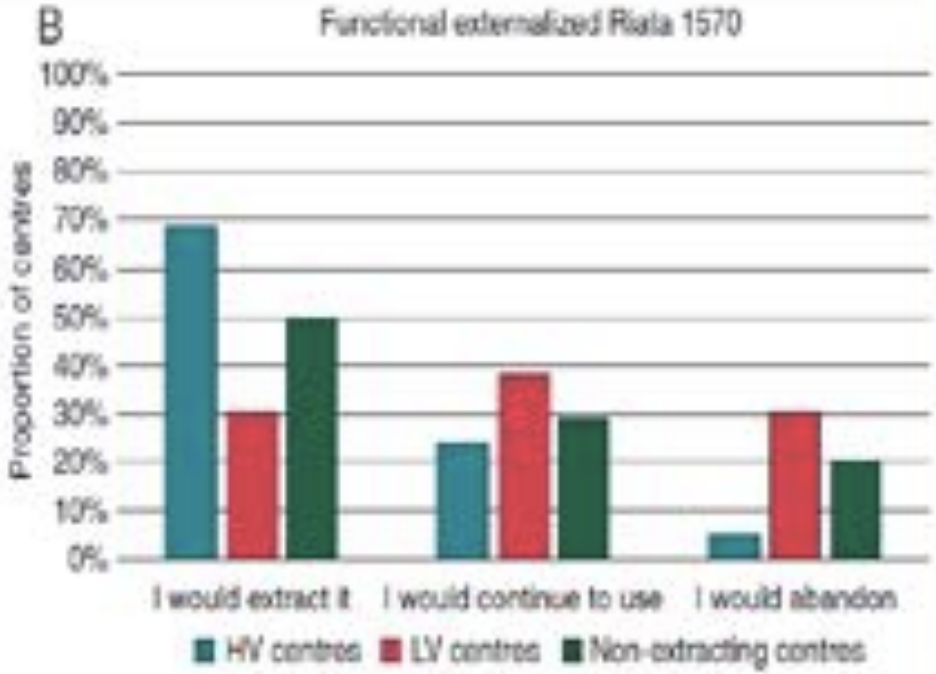
Maria Grazia Bongiorni[1*], Nikolaos Dagres[2], Heidi Estner[3], Laurent Pison[4], Derick Todd[5], and Carina Blomstrom-Lundqvist[6], conducted by the Scientific Initiative Committee, European Heart Rhythm Association

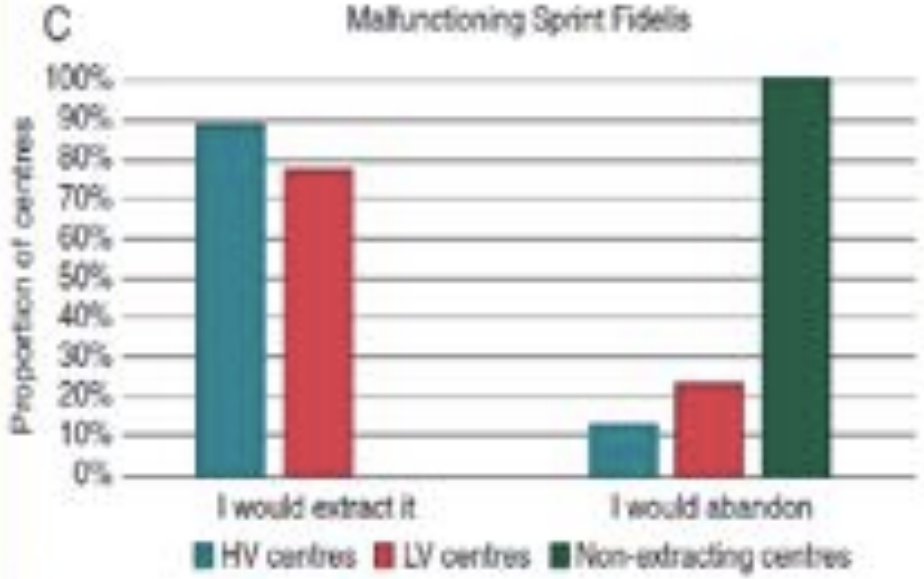
Europace (2014) **16**, 1674–1678
doi:10.1093/europace/euu302

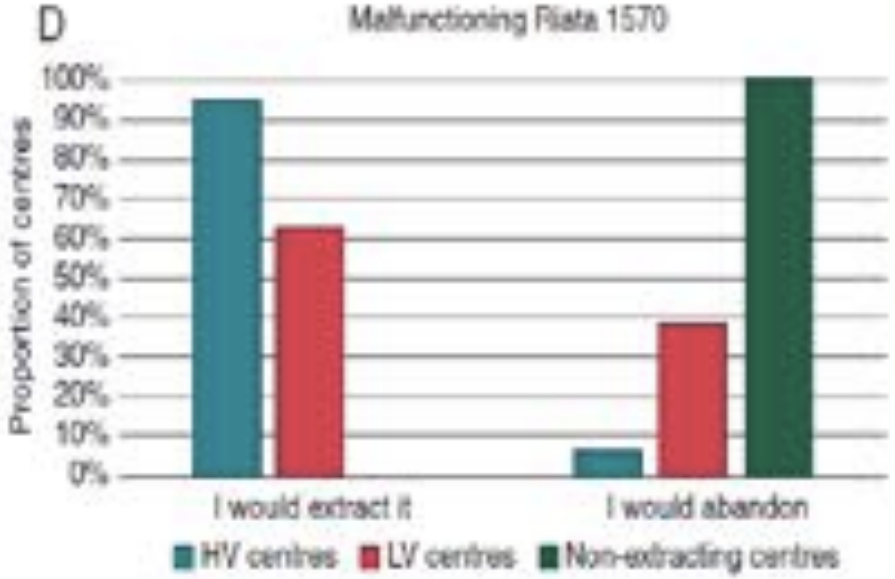


The main factors strong influencing the decision making were patient's age (59%), the presence of damaged leads (44%) and the lead dwelling time (44%)


A
Functional Sprint Fidelis
Proportion of centres
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
I would extract it
I would continue to use
I would abandon
HV centres
LV centres
Non-extracting centres


B
Functional externalized Riata 1570
Proportion of centres
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
I would extract it
I would continue to use
I would abandon
HV centres
LV centres
Non-extracting centres


C
Malfunctioning Sprint Fidelis
Proportion of centres
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
I would extract it
I would abandon
HV centres
LV centres
Non-extracting centres


D
Malfunctioning Riata 1570
Proportion of centres
100%
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70%
60%
50%
40%
30%
20%
10%
0%
I would extract it
I would abandon
HV centres
LV centres
Non-extracting centres

At what age is a patient considered “young” in lead management?

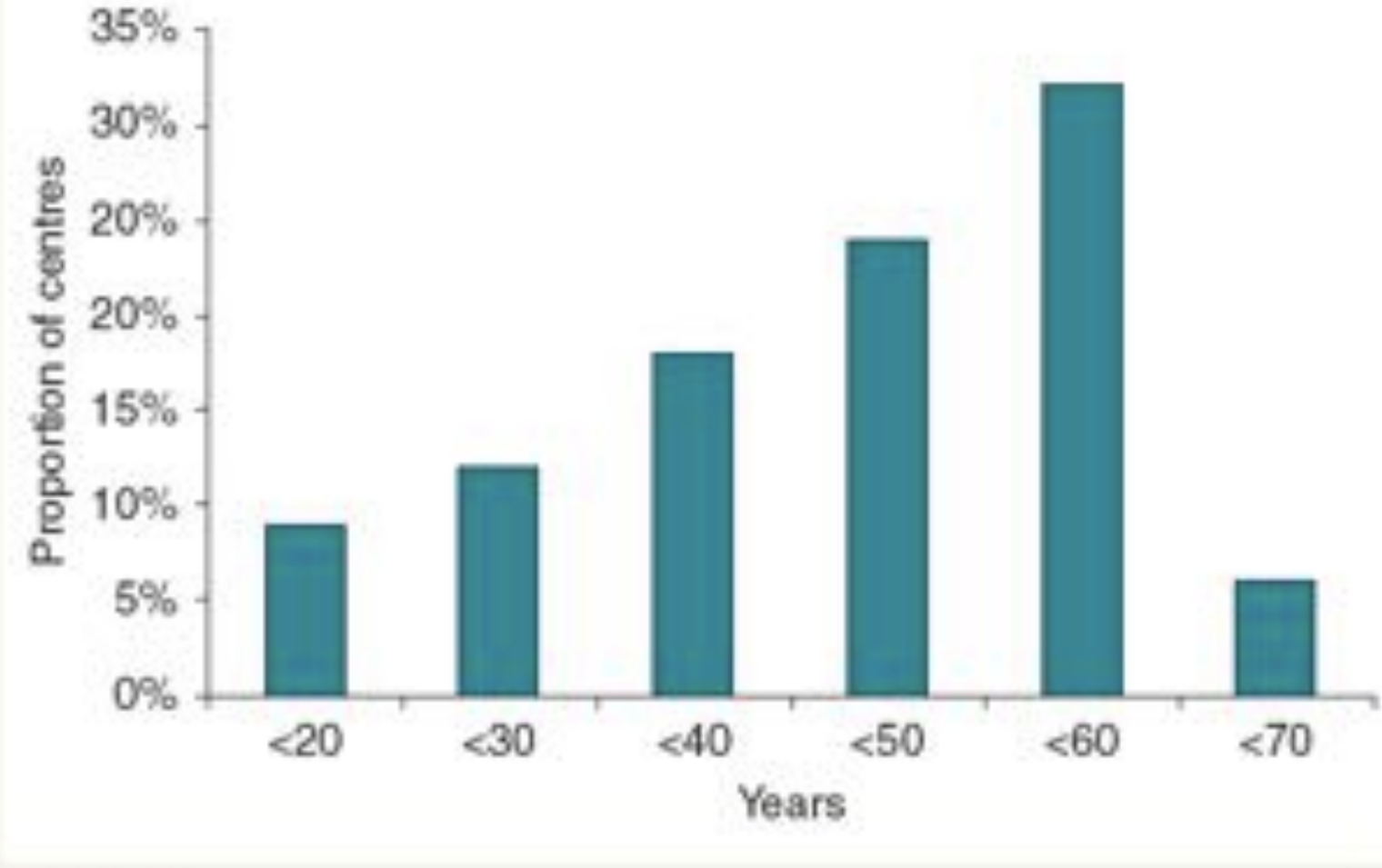
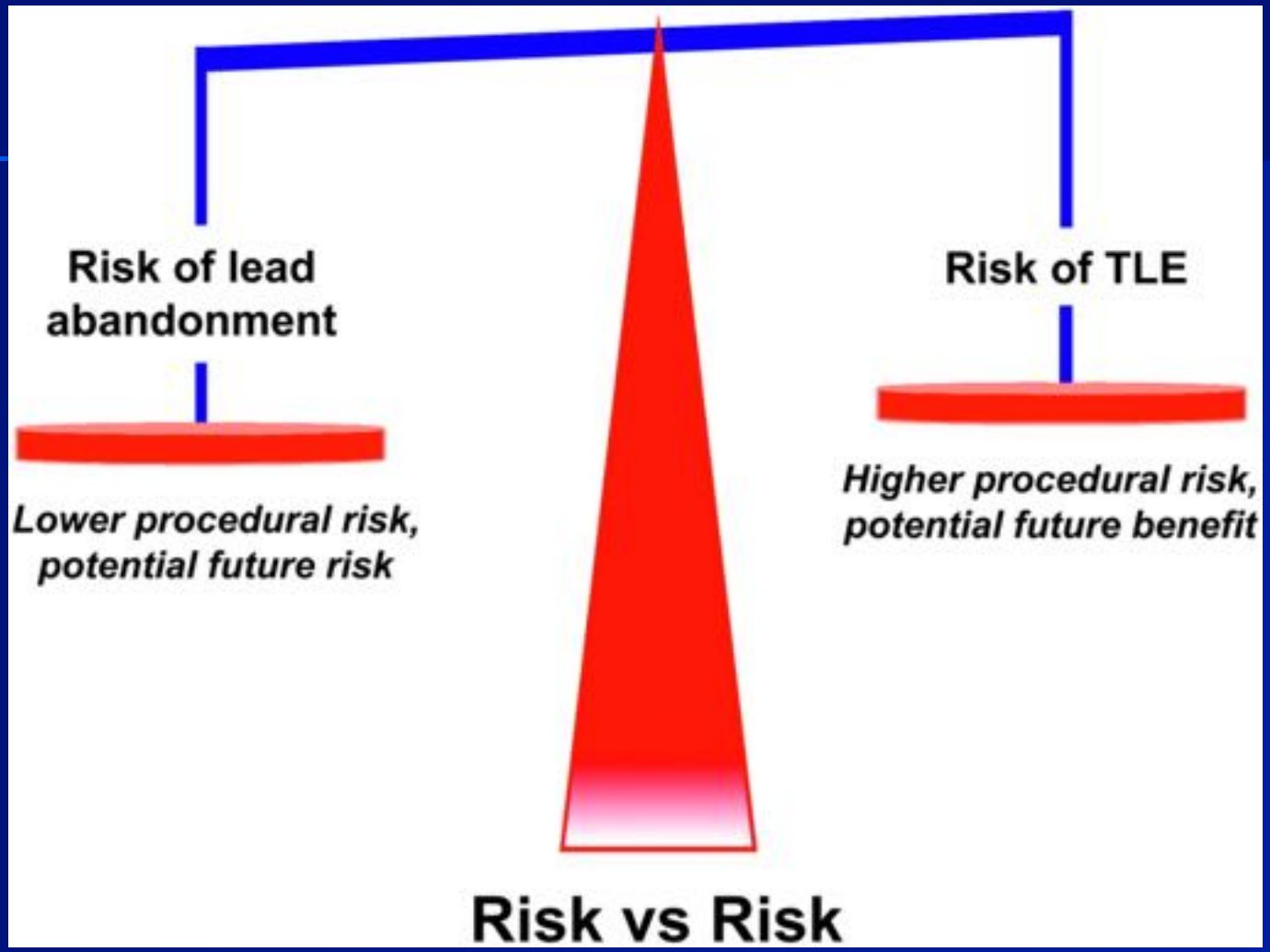


Table I List of concerns related to lead abandonment

	Strong concerns (%)	Some concerns (%)	No concerns (%)
Difficulty for future extraction	61	30	9
Future infections	32	50	18
CIED interferences	24	68	8
Venous thrombosis	15	56	29
MRI preclusion	12	50	38
Bulk in the pocket	9	62	29
Tricuspid regurgitation	15	59	26

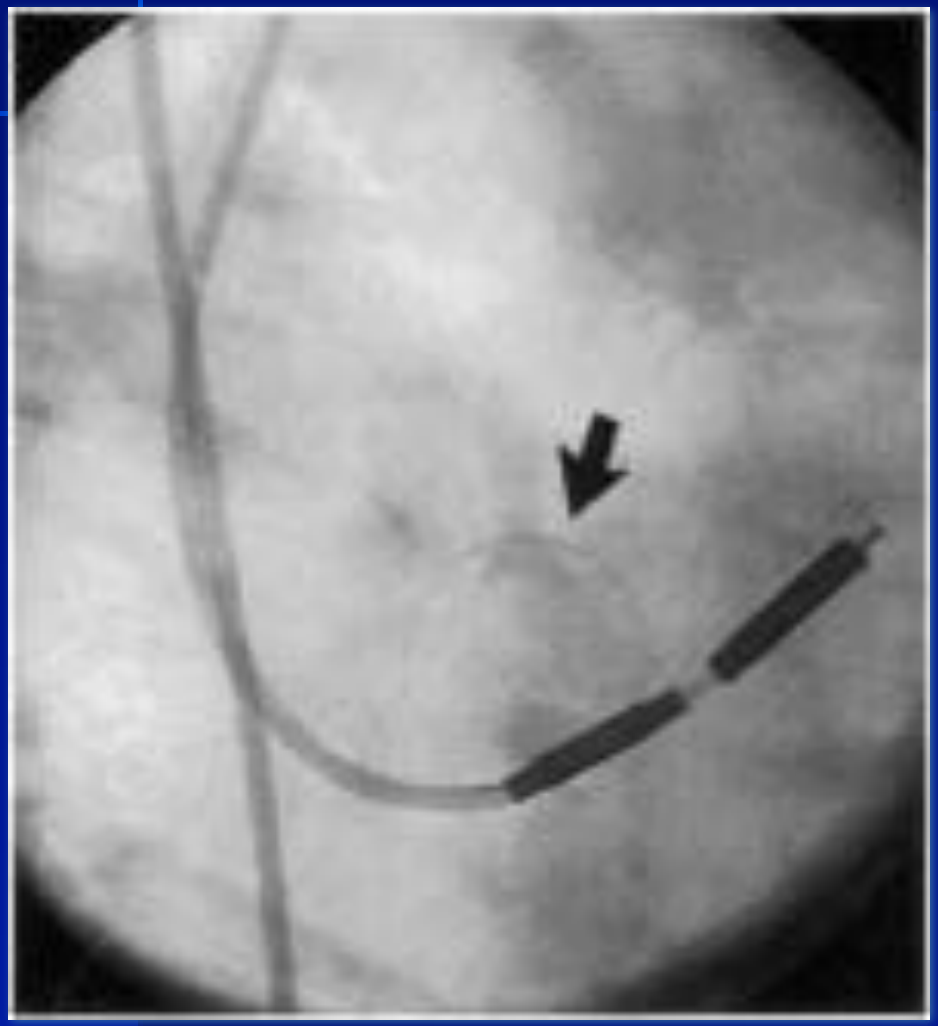
CIED, cardiac implantable electronic devices; MRI, magnetic resonance imaging.

Recalled and Superfluous leads Management



Melanie Maytin, Laurence M Epstein
Heart 2011;97:425-434

Learning from History: Telectronics Accufix/Encor – 1994 Recall



Lead in place

40 injuries, including 6 deaths

Injury from lead: 0.1%

Mortality from lead: 0.017%

Lead Extraction

5299 leads extracted (13%)

Serious complications (1.3%)

16 deaths (0.4%)

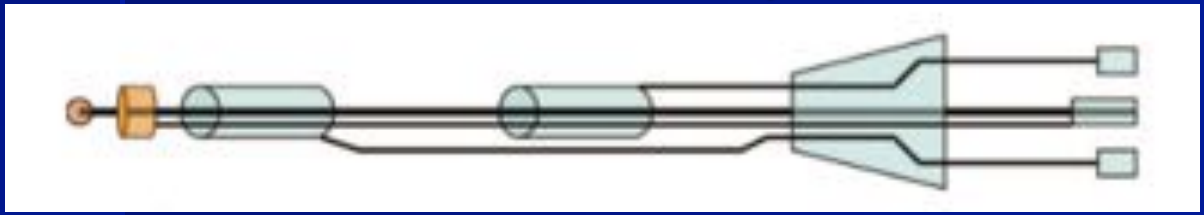
Mortality= 24x greater !!

Advisory Leads Management

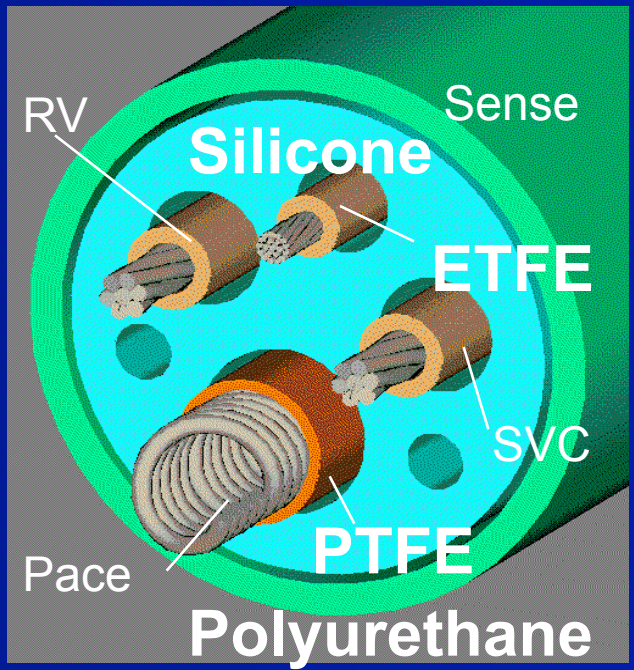
- There is no one right answer:
  - an individual decision
- What is the advisory?
- What are the consequences of lead failure?
  - Loss of lead function: pacing, defibrillation
  - Lead malfunction: inappropriate/ineffective shocks
- What is the patient's prognosis?

ICD Leads Construction: Components and Materials

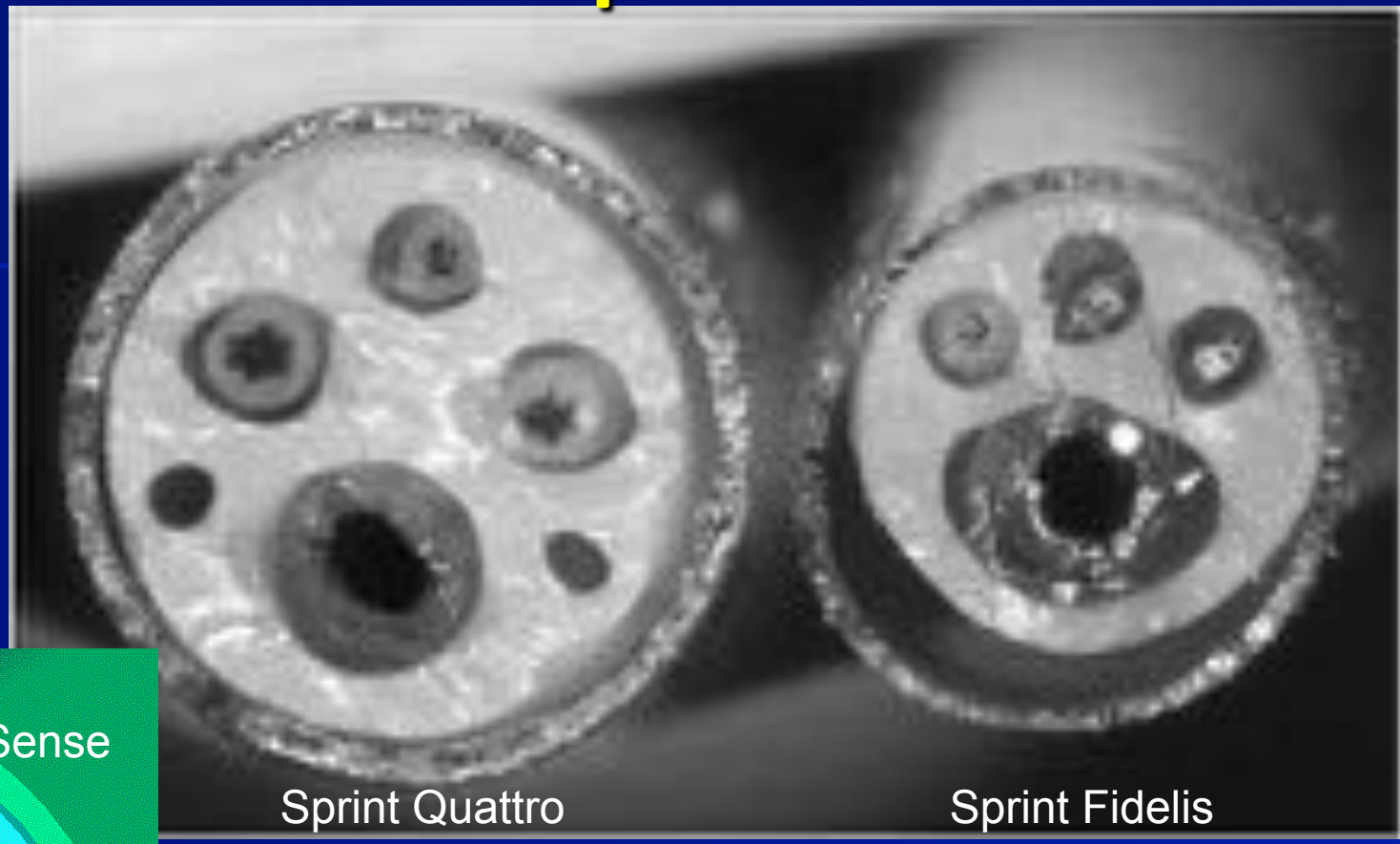
- Conductors, with 3 desiderable properties
  - Resistance to fatigue with repetitive stress
  - Resistance to corrosion
  - Low electrical resistivity

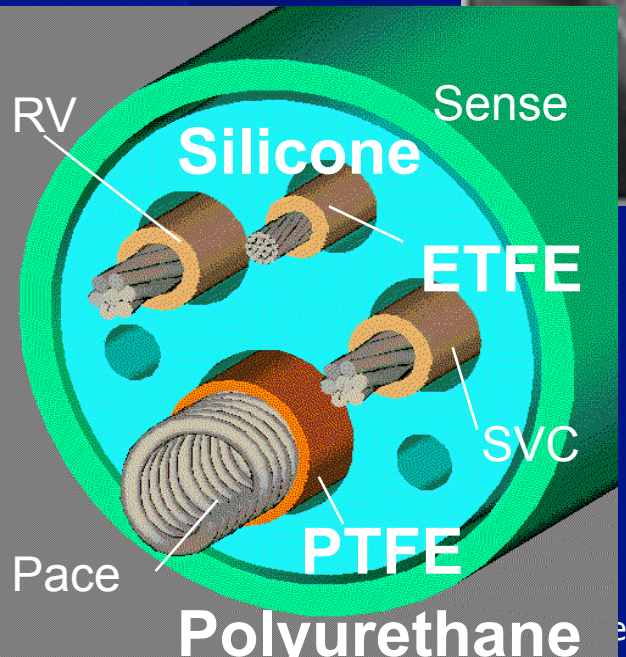


- Insulation, prevents current from escaping from the conductors into tissue
  - Silicone
  - Polyurethane
  - Optim
  - Fluoropolumers (PTFE, ETFE, ePTFE)



Conductors Failure → Sprint Fidelis





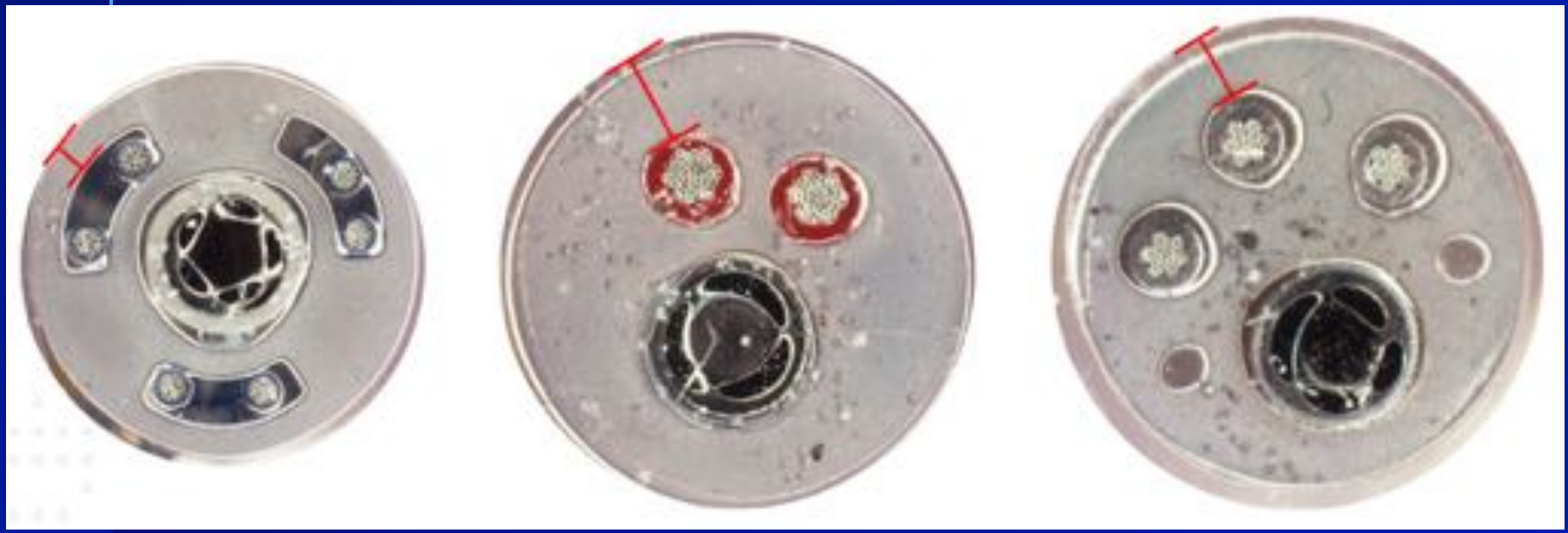
Sprint Fidelis:
- Smaller diameter
- No separate Compression Lumens
- Less insulation between the conductors
- Less insulation between conductors and outer tube

Haqqani & Mond, PACE 2009

Insulation Failure → Riata

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

reduction in wall size → inside-out abrasion → cable externalization

Images taken from “Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy", 3rd edition. Ellenbogen, Kay, Lau and Wilkoff.

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

J Am Coll Cardiol 2010;56:646–50

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.

Multicenter experience with extraction of the Riata/Riata ST ICD lead

Maytin M, Wilkoff BL, Brunner M, Cronin E, Love CJ, Bongiorni MG, Segreti L, et al
Heart Rhythm 2014

Conclusion

Extraction of the Riata/Riata ST leads can be challenging, and leads with externalized cables may require specific extraction techniques. Extraction of the Riata/Riata ST leads can be performed safely by experienced operators at high-volume centers with a complication rate comparable to published data, but clinical management decisions should remain individualized on a case-by-case basis.

577 Riata leads were extracted from 577 patients.
Total Removal 99.1%.
Major complications 0.87%
(1 death, 1 tamponade, 1 SVC laceration)
In leads with cable externalization, laser sheaths were used more frequently

Transvenous extraction profile of Riata leads: Procedural outcomes and technical complexity of mechanical removal

BACKGROUND Riata (RT) and Sprint Fidelis (SF) leads were recalled by the United States Food and Drug Administration because of an increased rate of failure mainly due to conductor fracture or insulation abrasion. According to lead design and type of failure, extraction complexity may be different, potentially affecting procedural outcomes and indications.

OBJECTIVE The purpose of this study was to assess the extraction profile of RT leads with and without cable externalization in comparison to SF leads.

METHODS From January 1997 to April 2014, all consecutive RT and SF leads extracted transvenously were analyzed. Among 661 consecutive patients with 705 ventricular implantable cardioverter-defibrillator (ICD) leads extracted, 194 patients with 134 RT leads (RT group) and 61 SF leads (SF group) were identified. Removal indications often were infective (64%), and extracted leads had a prevalence of dual-coil design (89%). Baseline patients and lead characteristics were comparable between groups.

RESULTS Success rate was high in both groups (97.8% RT vs 100% SF) without major complications. Mechanical dilation was comparable between groups, but RT leads often required larger sheaths (11.7 ± 1.4 vs 11.3 ± 1.4), a more frequent crossover to the internal transjugular approach (14% vs 3%), and a longer procedural time (23 ± 33 minutes vs 12 ± 16 minutes). Implantation time (odds ratio 4.84, 95% confidence interval 1.05–22.2, $P = .042$) and RT leads (odds ratio 1.04, 95% confidence interval 1.02–1.06, $P < .001$) were independent predictors of the internal transjugular approach.

CONCLUSION Extraction of RT leads is feasible and effective. However, extraction of RT leads is more complex than that of SF leads. Lack of coil backfilling and cable externalization in RT group may account for these differences.

KEYWORDS Riata; Sprint Fidelis; Lead extraction; Jugular vein; Mechanical dilation

ABBREVIATIONS **ICD** = implantable cardioverter-defibrillator; **ITA** = internal transjugular approach; **RT** = Riata; **SF** = Sprint Fidelis

(Heart Rhythm 2015;12:580–587)

Bongiorni MG, Di Cori A, Segreti L, et al. Heart Rhythm 2015;12:580–587

Division of Cardiovascular Diseases - University Hospital of Pisa (Italy)

Riata leads Characteristics

- Fragility of insulation
- Damage of inner conductor
- Tissue ingrove into the coils (1500)
- Conductors externalization

Riata leads Characteristics

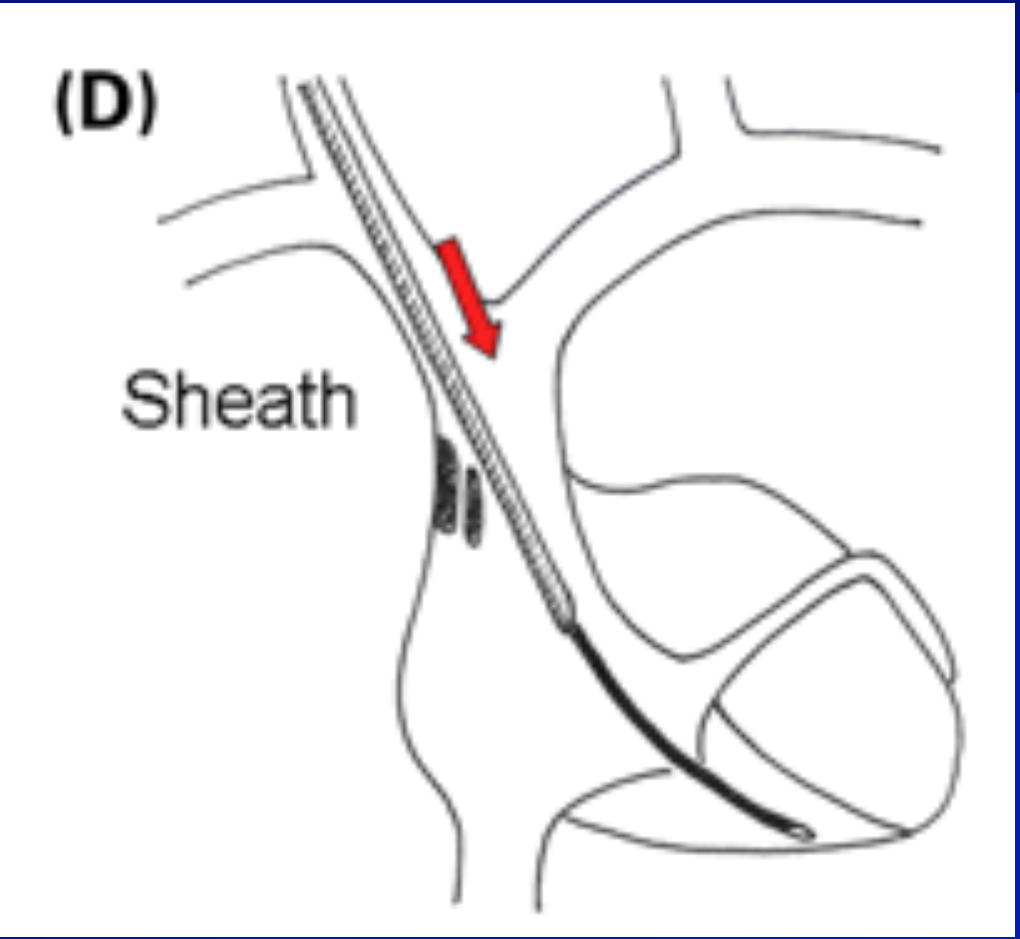
- Damage of inner conductor
  - Stylet stops early
- Tissue ingrove into the coils (1500)
  - Need for dilatation
- Fragility of insulation
  - Easy breakage

Difficult to use the rail effect

Riata leads Extraction

Internal Jugular Approach

- Straight course of the lead
- Free from binding sites
- Easier use of upsized dilators



Bongiorni, M. G. et al.
Eur Heart J 2008

European Heart Journal

17 years Experience on Lead Extraction (01/1997-07/2015)

Not-infected vs Infected Leads

Not-infected Leads		Infected Leads
598 (418)	Patients (M)	1733 (1364)
57.5	Mean age (y)	68.1
756 (529-227) (30)	Leads (Pacing – ICD)	3505 (2904/601) (17)
58.6	Mean Implant time (m)	74.3
732 (96.8)	Complete Removal(%)	3429 (97.8)
66 (8.7)	Jugular Approach (%)	306 (8.7)
2 (0.33) 0 (0)	Major Complications(%) Deaths (%)	13 (0.75) 4 (0.23)

Recalled and Superfluous leads Management

Extraction

Higher risk of procedure

Elimination of future issues

Lead addition

Lower risk of procedure

Creation of future issues

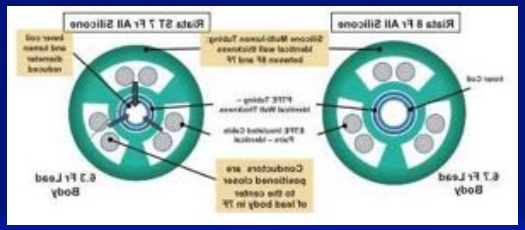
Concerns about abandoning leads

Venous Obtruction – Lead-lead interaction – MRI compatibility – Infection – Increased risk/difficulty of extraction in the future

Take account of

Number of Leads – Implant Duration – Defibrillator vs Pacing electrodes – Patient Age, Comorbidities and Wishes

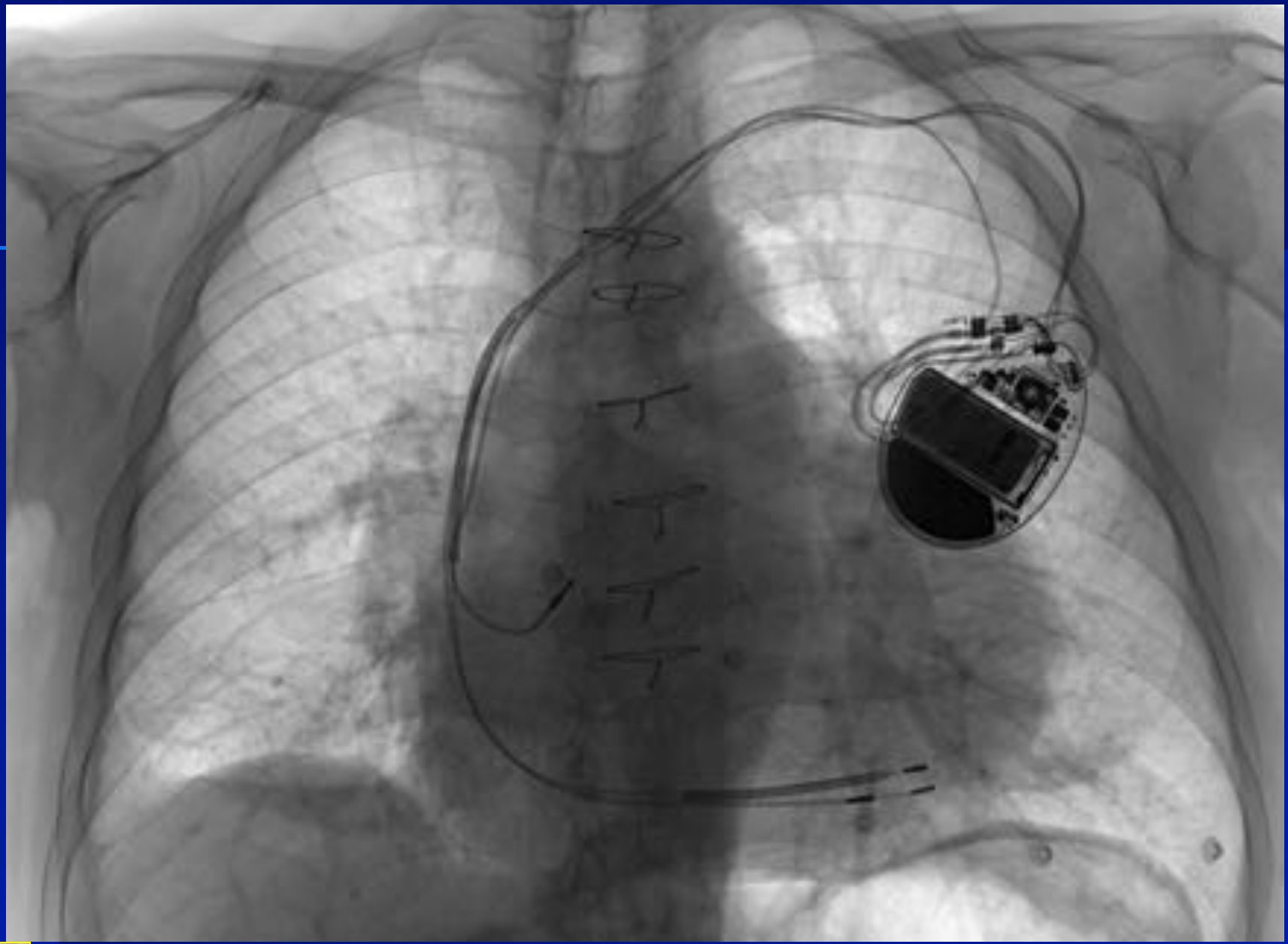
Recalled and Superfluous leads Management



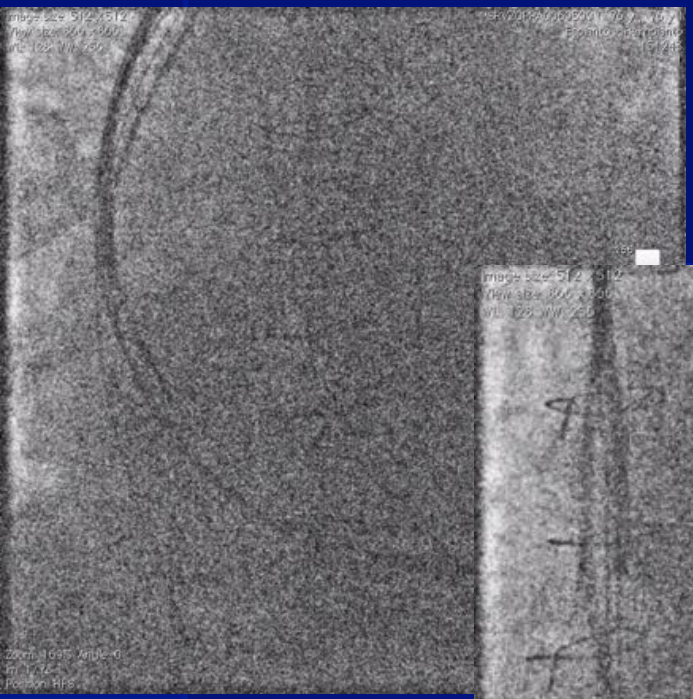
- Management is sometimes challenging
- The decision about the best management has to be taken on individual basis, integrating various patient and lead characteristics and operator-related variables
- Transvenous lead extraction must be considered in many cases
- In experienced centers success rate and safety of transvenous extraction may suggest a more aggressive approach

U.A. male, 76 years old

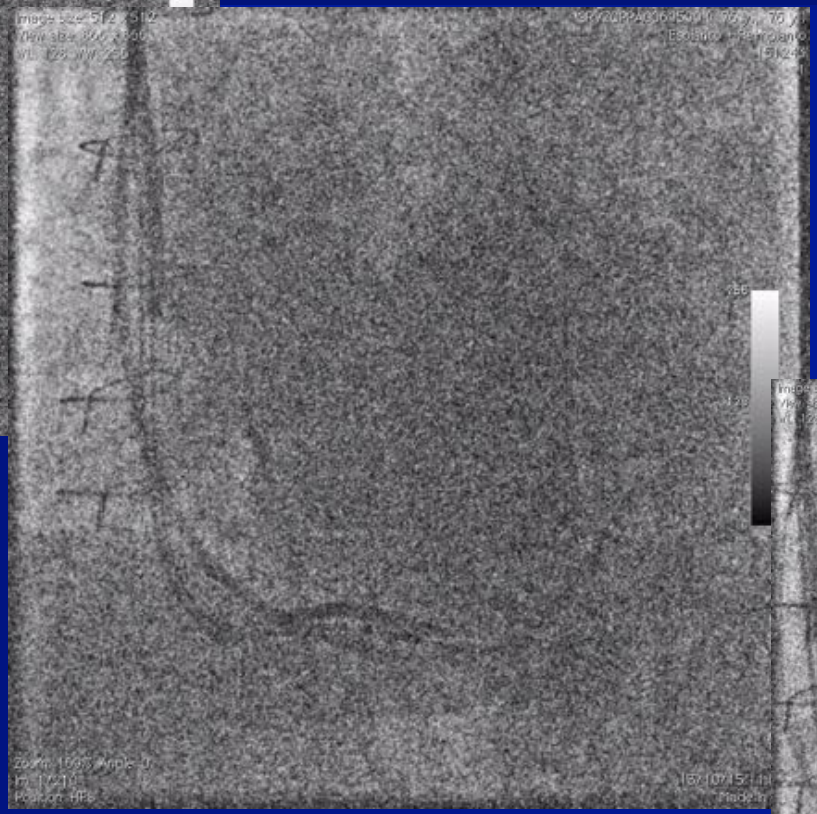
- Hyschemic cardiomiopaty with previous MI (1987), CABG (1990) and PCI (2005)
- 2009 sinus bradycardia → dual chamber PM implantation
- 2010 reduced EF → upgrating to dual chamber ICD (DF-1) (normal functioning RV lead was abandoned)
- 2014 Permanent Atrial Fibrillation
- 2015 Congestive Heart Failure and indication to CRT-D



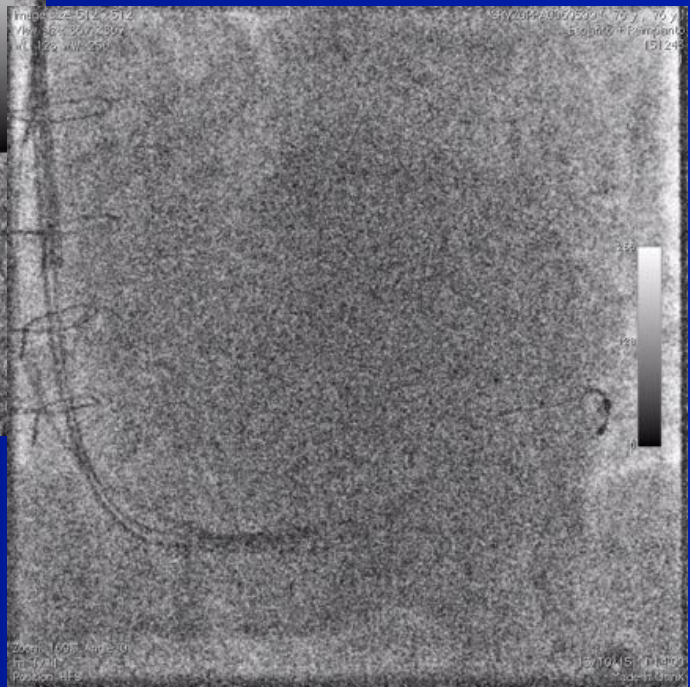
ATRIAL LEAD REMOVAL

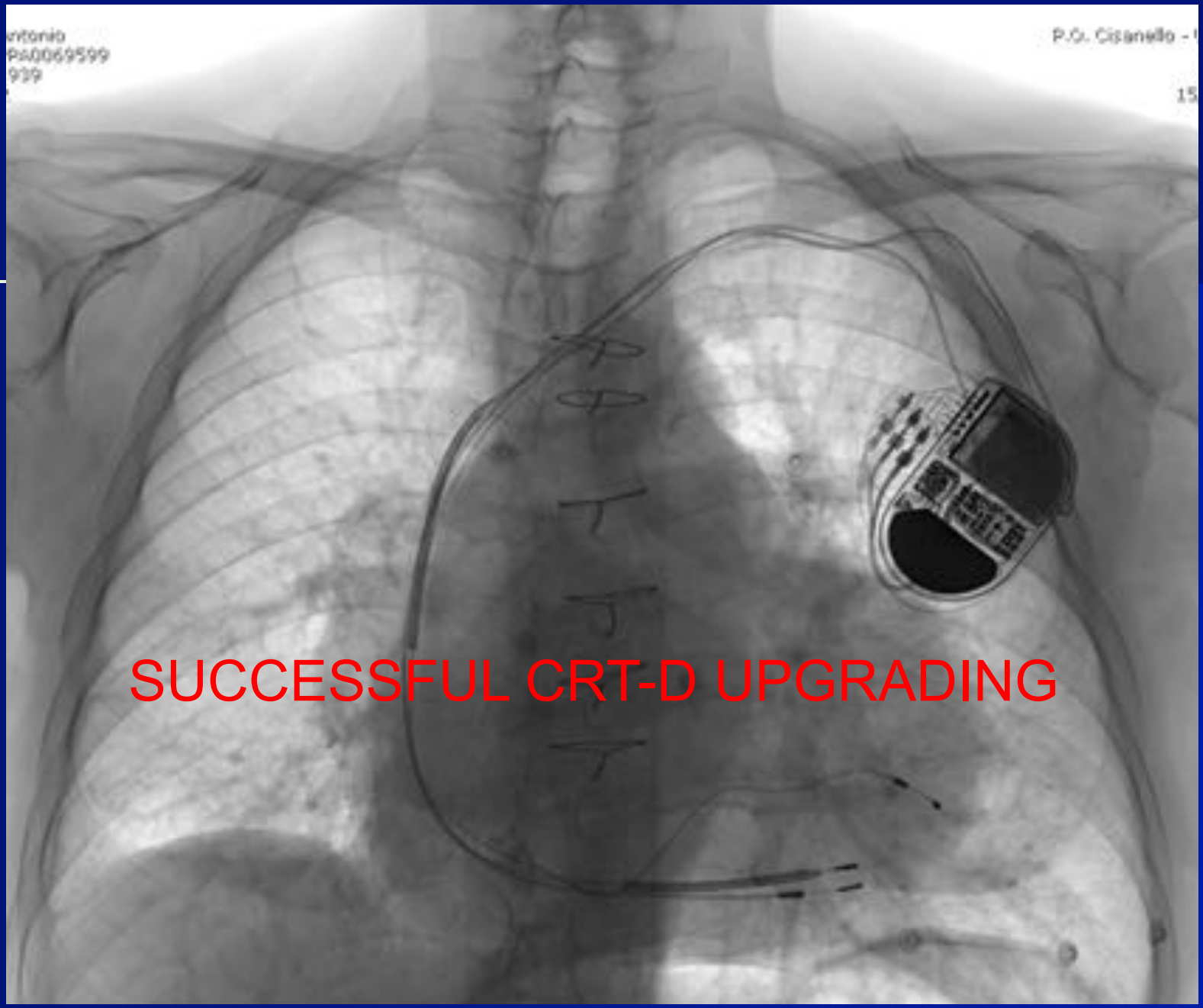


CS CANNULATION



LV INSERTION




SUCCESSFUL CRT-D UPGRADING