

Debate: Lead extraction in the 21st century - should it be done in a cardiothoracic centre?

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Liverpool Heart and Chest Hospital
HRC 2010**



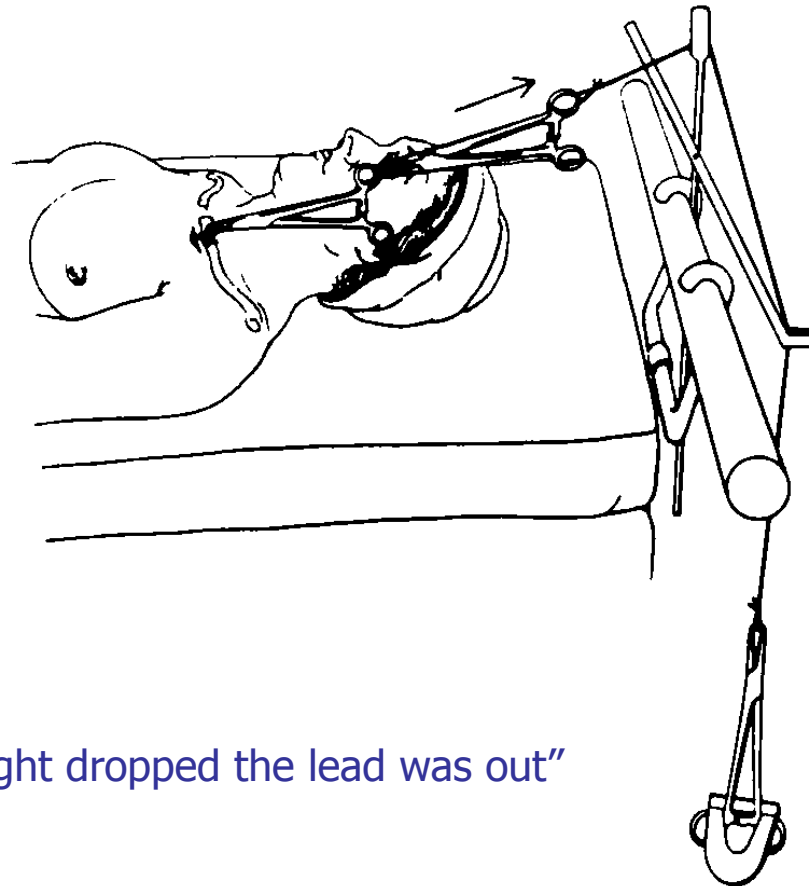
Definition of extraction

- **Lead Removal:** removal of a pacing or a defibrillator lead using any technique
- **Lead Explant:** a lead removal using simple traction only
- **Lead Extraction:** removal of a lead that has been implanted for more than a year, or a lead regardless of duration of implant requiring the assistance of specialised equipment that is not included as part of the typical implant package

History of Lead Extraction

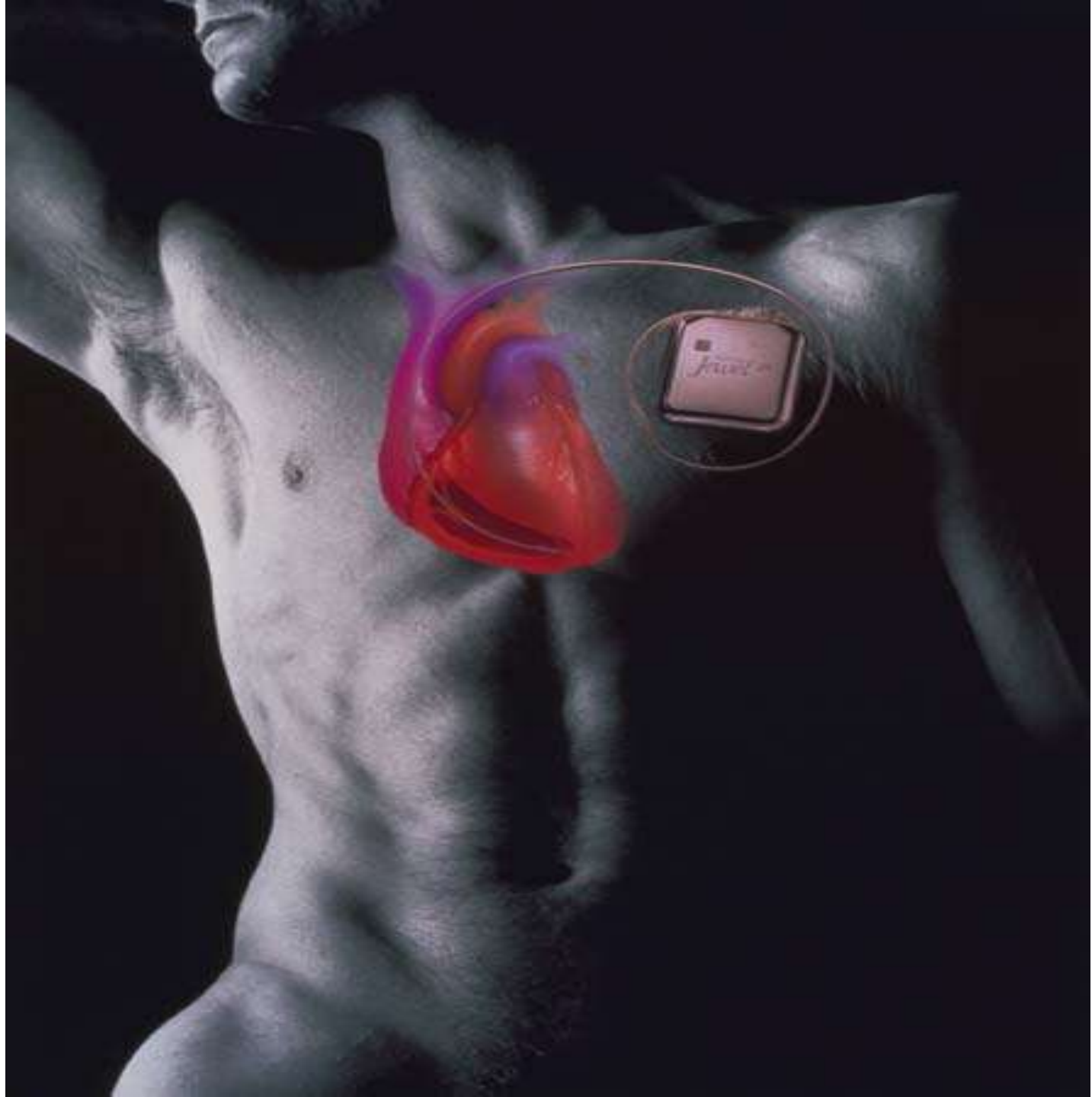
- Abandon (cap and leave) -1950's to date
- Surgical removal - 1950's to date
- Traction - 1950's to date
- Shortening over Forceps

Traction with Weights



“When the weight dropped the lead was out”





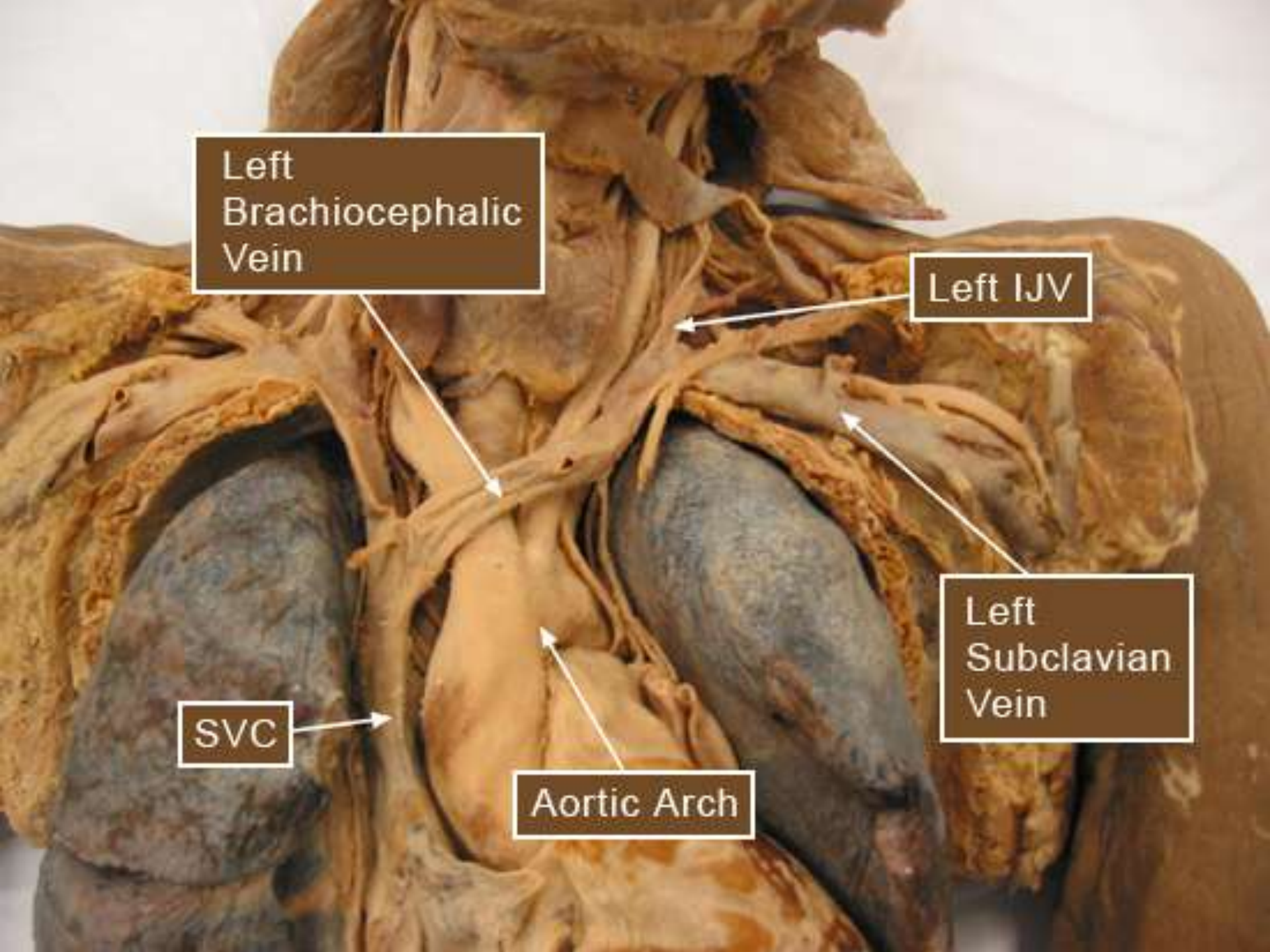
Left
Brachiocephalic
Vein

Left IJV

Left
Subclavian
Vein

SVC

Aortic Arch



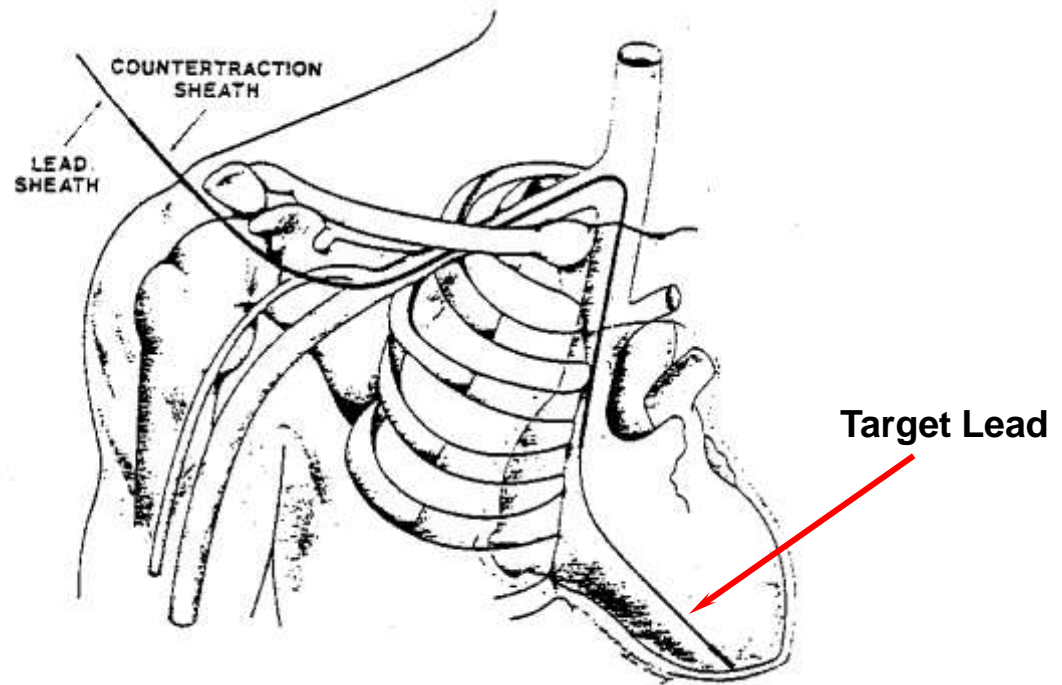
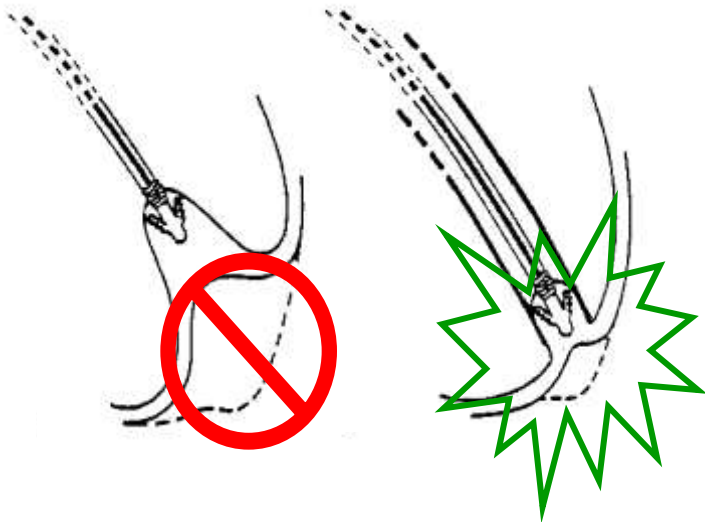
History of Lead Extraction

- Counter-traction, (Cook[®]) Locking Stylets[™] & Telescoping Sheaths - 1990 to date
- Femoral snares / work station
- Laser Assisted Lead Removal (Spectranetics[®]) - SLS[™] 1997 & LLD[™] 1999 to date
- Electrosurgical Dissection Sheath – May 2001
- SLS II – Newest Generation May 2002

Counter-traction

Traction

Counter-traction





Laser Assisted Lead Removal

- First Performed by Dr. Charles Byrd on November 29, 1994



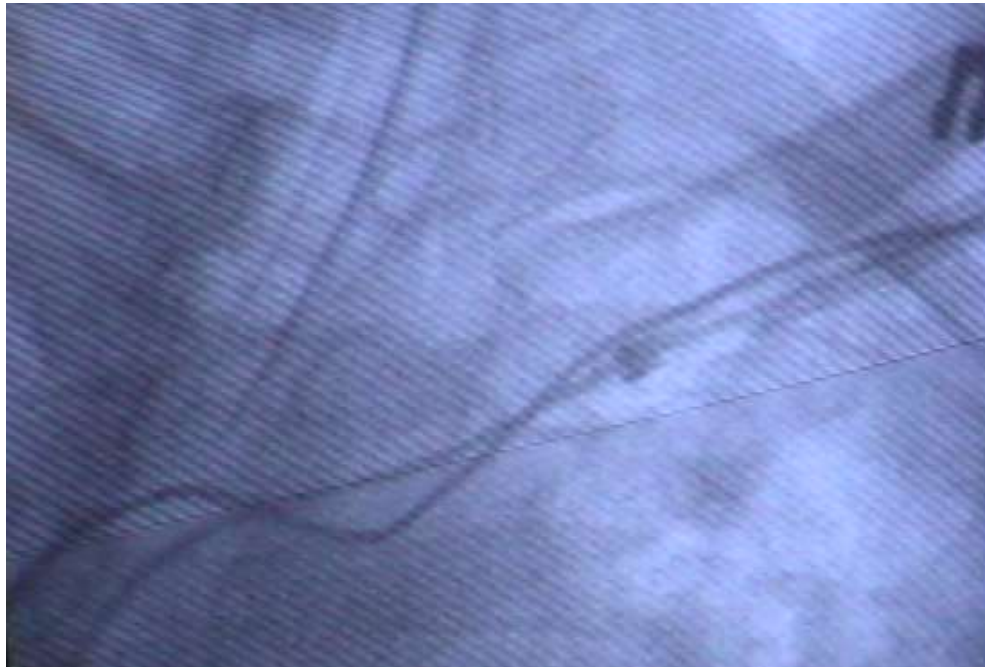
The Procedure Set-up



Proceed to activate Laser train using only steady forward finger pressure on SLS assembly

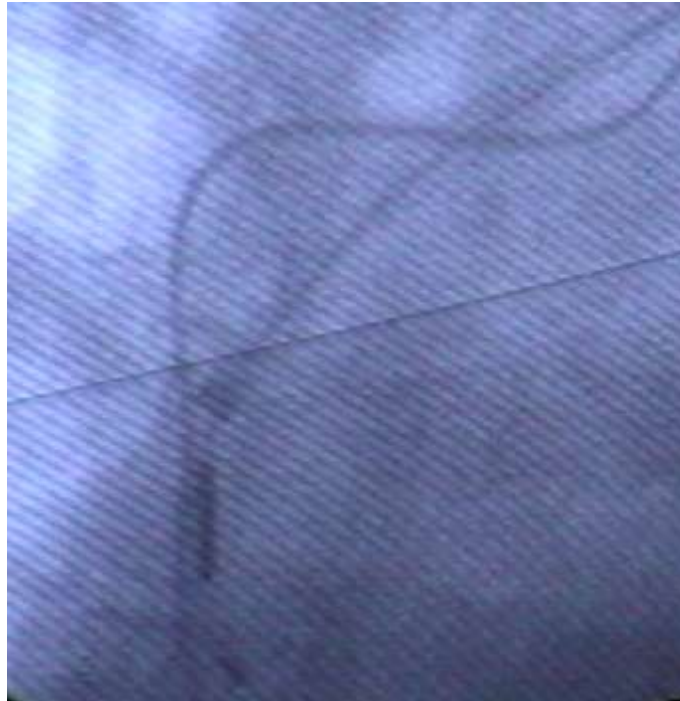


The Procedure



SLS over Target Lead

The Procedure

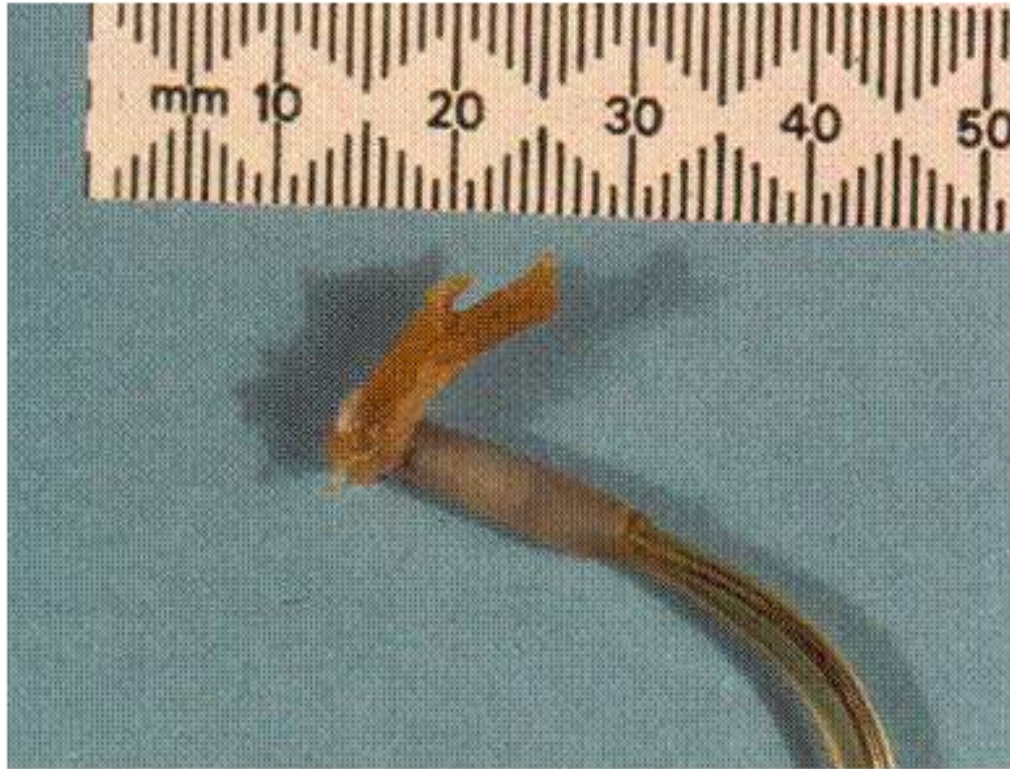


SLS at Ring Electrode of Target Lead

The End Result ...



Lead removed



Patient Data

	US	EU	Σ
n =	1620	260	1880
Male %	64	68	
Mean Age yrs.	64	61	
Age Range yrs.	1-102	13-95	

Registry Acute Results

	US %	EUR%
Clinical success	91.5	96
Complete success	86.8	92
Partial success	4.7	4
Failure	8.5	4

Acute Complications Summary

	US	EUR
Hemoperricardium/Tamponade	24	5
Hemothorax	10	3
Embolism	2	3
Migrating lead fragments	1	1
Bacteremia	0	1
VT	1	0
Perforation	9	0
Myocardial avulsion	2	0
Venous avulsion	2	0
Other	<u>23</u>	<u>2</u>
	74 (4.5%)	15 (6%)

(Pts. With multiple complications were score as worse complication)

LHCH Experience

- 2005-2010 456 extractions (2 principal operators)
- 1 death
- 2 sternotomies

- Same time period 2 sternotomies for TPW



JACC 2010 Aug 17;56(8):646-50

- 349 Sprint Fidelis extractions in 5 centres
- Implant duration mean 27/12 (0.03-59)
- 349 completely removed
- Simple traction 49.4%
- CTS 50.6%
- NO complications or deaths

Circulation 2010 Jun 8;121(22):2384-7

- 469 Sprint Fidelis lead revisions in Canadian registry
- 248 (53%) removed
- Traction 61% and CTS 39%
- Complications with removal 14.5 %
- Major 7.25%, 2 deaths (0.43%)
- Complication with abandonment 8.6%

Indications for Extraction

- Infection
- Pain
- Thrombosis or venous stenosis
- Functional lead
- Non-functional lead

Increasing Incidence

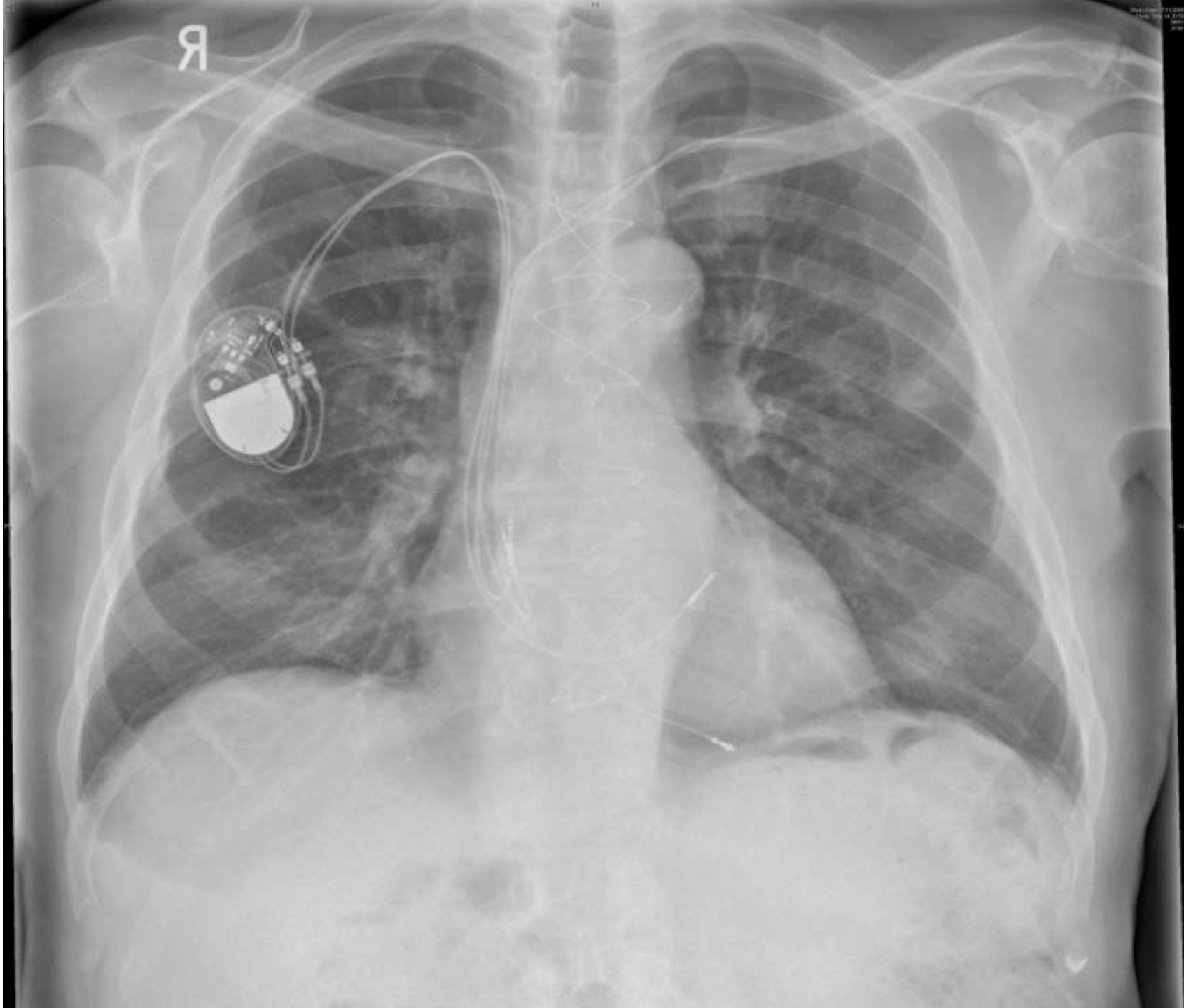
- USA last 5 yrs
- 125% increase in implants
- 600% increase in explants/revisions

- Aging population
- More device replacements/revisions
- More complex devices in sick population

Can we avoid the need for a
cardiothoracic centre by
avoiding the extraction
altogether ?

Extract or Abandon

- Infected systems
- Abandoned leads almost always re-present
- Endocarditis may ensue
- Surgical recommendations for complete extraction and debridement
- Appropriate antibiotic therapy (microbiology directed)
- Remote site reimplant



Extract or Abandon

- Painful system
- Option to rebury/revise
- Pain often due to low grade infection
- More procedures = more risk
- Risk/benefit ratio timing of intervention to consider
- Some superficial systems due to poor technique



Extract or Abandon

- Venous thrombosis/stenosis
- Depends on need for access/ symptoms
- Consider contralateral implant ? Bilat thrombosis

Extract or Abandon

- Functional lead
- By definition needs removing
- Abandoning leaves risk in place

Extract or Abandon

- Non functional lead
- Consider simply implanting new lead
- risk from lead itself
- Risk from total number of leads in situ
- Patient longevity – outlasting leads
- Lead recalls

Complications Due to Abandoned Noninfected Pacemaker Leads

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BÖHM, Á., ET AL.: *Complications Due to Abandoned Noninfected Pacemaker Leads.* Noninfected unwanted pacemaker leads are usually abandoned since the reported complication rate related to them is low. We followed 60 patients with noninfected retained leads, and complication was observed in 12 (20%) of them. Lead migration occurred in 5 patients, skin erosion in 3 patients, venous thrombosis in 2 patients, and muscle stimulation in 2 patients. Management of the complications was a surgical procedure in seven patients, including two cases of open heart surgery, while chronic medical treatment was necessary in the other five patients. The results of this study suggest that complications due to noninfected abandoned leads may not be as rare as it was previously thought and may present a significant morbidity and cost burden. With the lead extraction technique available, the issue of the removal of all unwanted pacemaker leads should be addressed. (PACE 2001; 24:1721-1724)

retained pacemaker lead, complication, noninfected, lead migration, skin erosion, muscle stimulation

Introduction

A permanent pacemaker lead may be abandoned due to infection or lead failure. Infected retained leads may produce potentially life-threatening complications, therefore, removal of the infected system is generally recommended.^{1,2} Data in the literature suggest that complications due to noninfected retained leads are rare.³⁻⁵ Since pacemaker electrodes firmly stick to the myocardium within a few weeks after implantation, removal of them usually requires lead extraction or open heart surgery. Therefore, the practice generally was to abandon noninfected leads. In the authors' experience, however, serious complications due to noninfected abandoned pacemaker leads are not rare. The aim of this retrospective study was to assess the complication rate in the patients with retained noninfected leads followed at the authors' Pacemaker Clinic.

Patients and Methods

Lead replacement was required for noninfection related reasons in 89 (2.5%) of the 3,445 patients who underwent permanent pacemaker implantation between January 1, 1969 and December 31, 1999. Before 1997, an attempt was made to remove the lead by pulling it, resulting in an exposure

of the proximal part of the lead. Therefore, the lead that could not be extracted was cut short. When feasible, the lead was capped and secured to the underlying fascia by a suture, in the other cases it was let to retract. Since 1997, every effort was made to cap the abandoned leads and anchor them to prevent lead migration. There was no sign of infection at the time of lead replacement or thereafter. Data for follow-up were available for 60 patients (30 men, 30 women, age at the time of implantation 23-89 years, average 57.4 years), whereas 21 patients died and 8 were lost to follow-up for other reasons. Follow-up of the patients consisted of regular pacemaker checkup twice a year, posteroanterior and lateral chest X rays once a year, and inspection of the venous circulation of the upper extremities.

Among the 60 patients regularly followed, 51 patients had abandoned transvenous lead(s), 8 had an abandoned epicardial lead, and 1 patient had an auxiliary electrode retained. Forty-six patients had a single abandoned transvenous lead (43 ventricular, 3 atrial), 4 patients had 2 abandoned transvenous leads (3 patients with a ventricular and an atrial lead, 1 patient with 2 ventricular leads), and 1 patient had 3 abandoned transvenous leads (2 ventricular and 1 atrial). Altogether, 60 patients had 66 abandoned leads, 50 of them being transvenous ventricular, 7 of them being transvenous atrial, 8 of them being epicardial, and 1 of them being an auxiliary electrode. All transvenous ventricular electrodes were unipolar with a passive-fixation lead, while the transvenous atrial electrodes were unipolar [wires.

The reasons for electrode abandonment are summarized in Table I. Electrical failure included

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- Paper highlights:
 - 1st article that takes a hard look at complication rates of abandoned leads.
 - Not authored by a lead removal "expert."
 - Reported a 20% complication rate.
 - "... the removal of all unwanted pacemaker leads should be addressed."

What do the Guidelines say ?

Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management

This document was endorsed by the American Heart Association (AHA).

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Institutional support

- Torrential bleeding rare but requires ability to immediately open chest
- Delay > 5 mins associated with increased mortality

Facilities

- High quality fluoroscopy
- Spectrum of extraction tools
- Extraction snares
- Echo inc TOE
- Bypass facilities

Personnel – team approach

- Primary operator
- Cardiothoracic surgeon
- Anaesthetist
- Radiographer
- physiologist
- Non-scrub personnel



Experience

- Complete success increases with > 20 procedures ¹
- Experienced operators have less complications ²
- Significant reduction in complications with > 30 cases ³

¹ Bracke FA, PACE 1998;21:2309-13

² Wazni O, HRS 2009 Boston MA

³ Ghosh N, PACE 2005;28:180-4

**Heart Rhythm UK
Standards for Implantation
and Follow-up of
Cardiac Rhythm Management
Devices
HRUK Council, June 2010**

Conclusions

- Lead extraction is safe in experienced hands
- Individual centres rarely generate adequate cases
- Complications are rare but serious and predictable
- Individual cases are unpredictable
- Immediate access to cardiothoracic surgery must remain mandatory
- Extraction without cardiothoracic support is indefensible



