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Debate

Lead Extraction in the 20th century –
does not necessarily
have to be done
in a Cardio-Thoracic Centre.....

Declarations of Interest

Member of the European Society of Cardiology (ESC) /
European Heart Rhythm Association (EHRA)

Task Force on ..

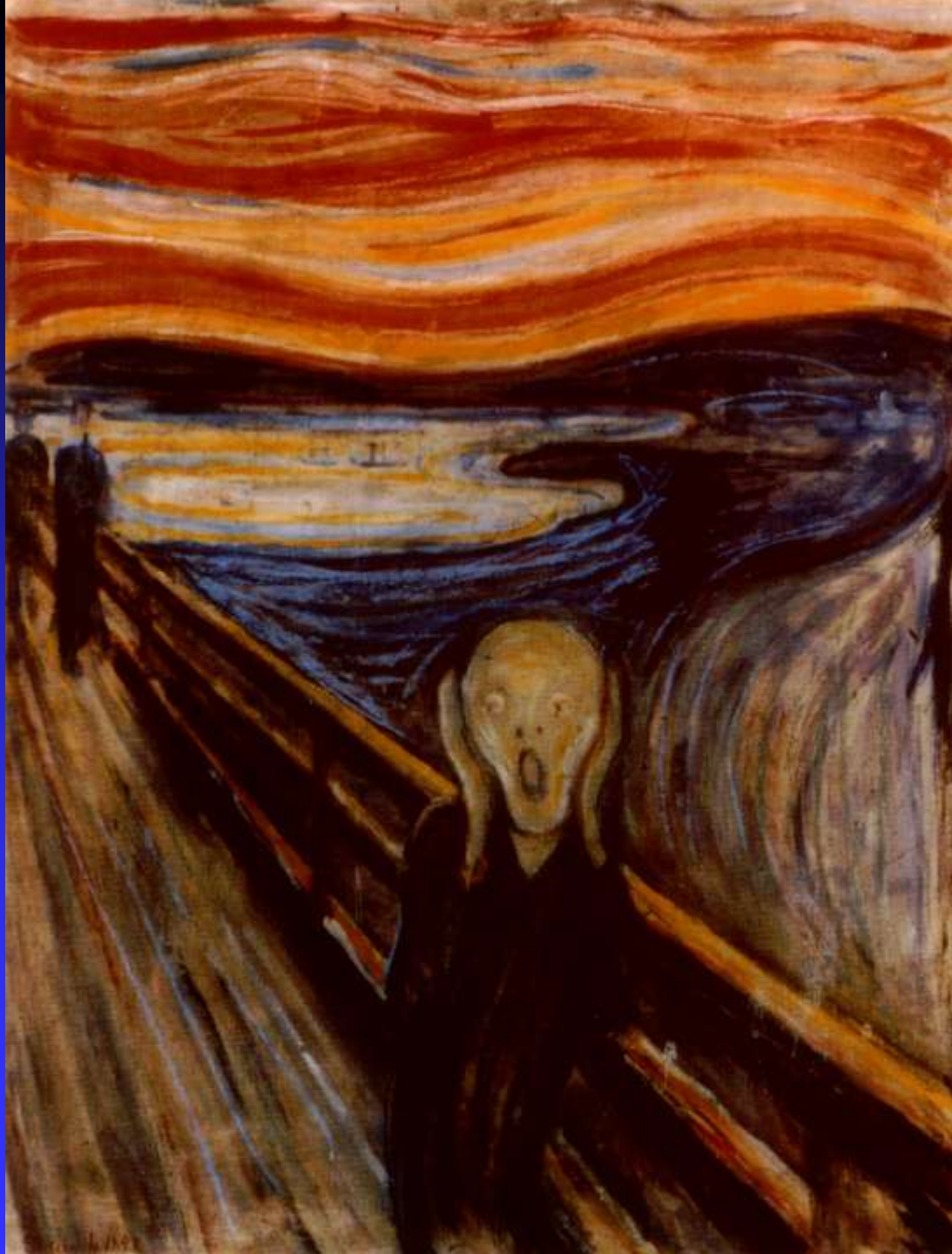
Pathways for Training and Accreditation for Lead
Extraction

What is Lead Extraction ?

Removal of a lead ...

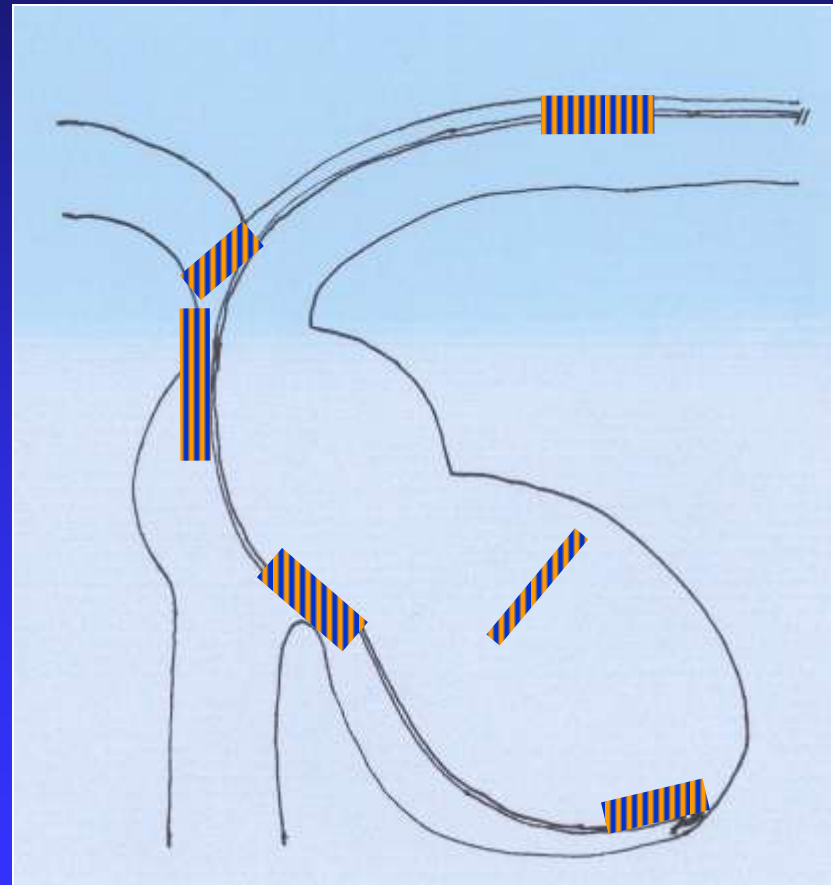
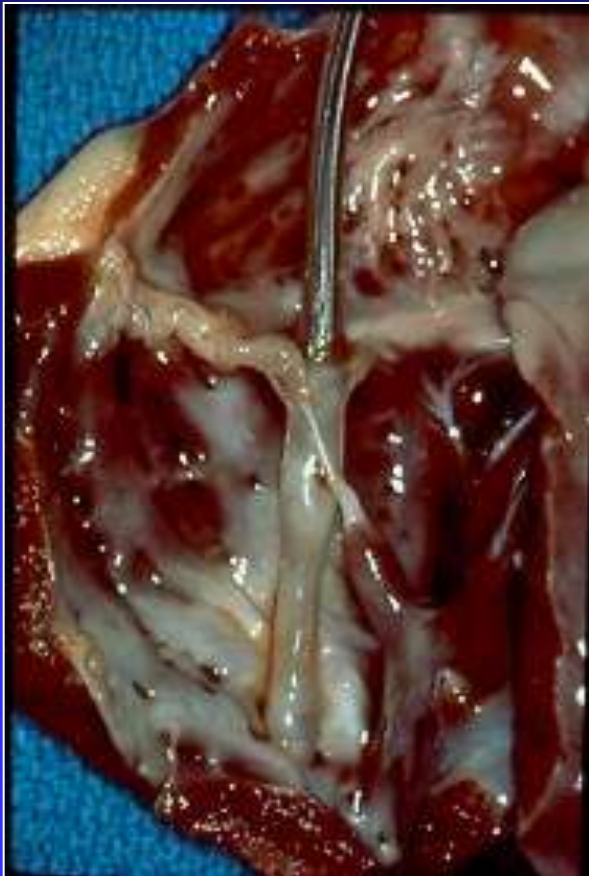
1. that has been implanted for more than one year
2. requiring the assistance of specialized equipment
3. from a route other than via the implant vein

Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management 2009



Main Risk Fibrous Adhesions

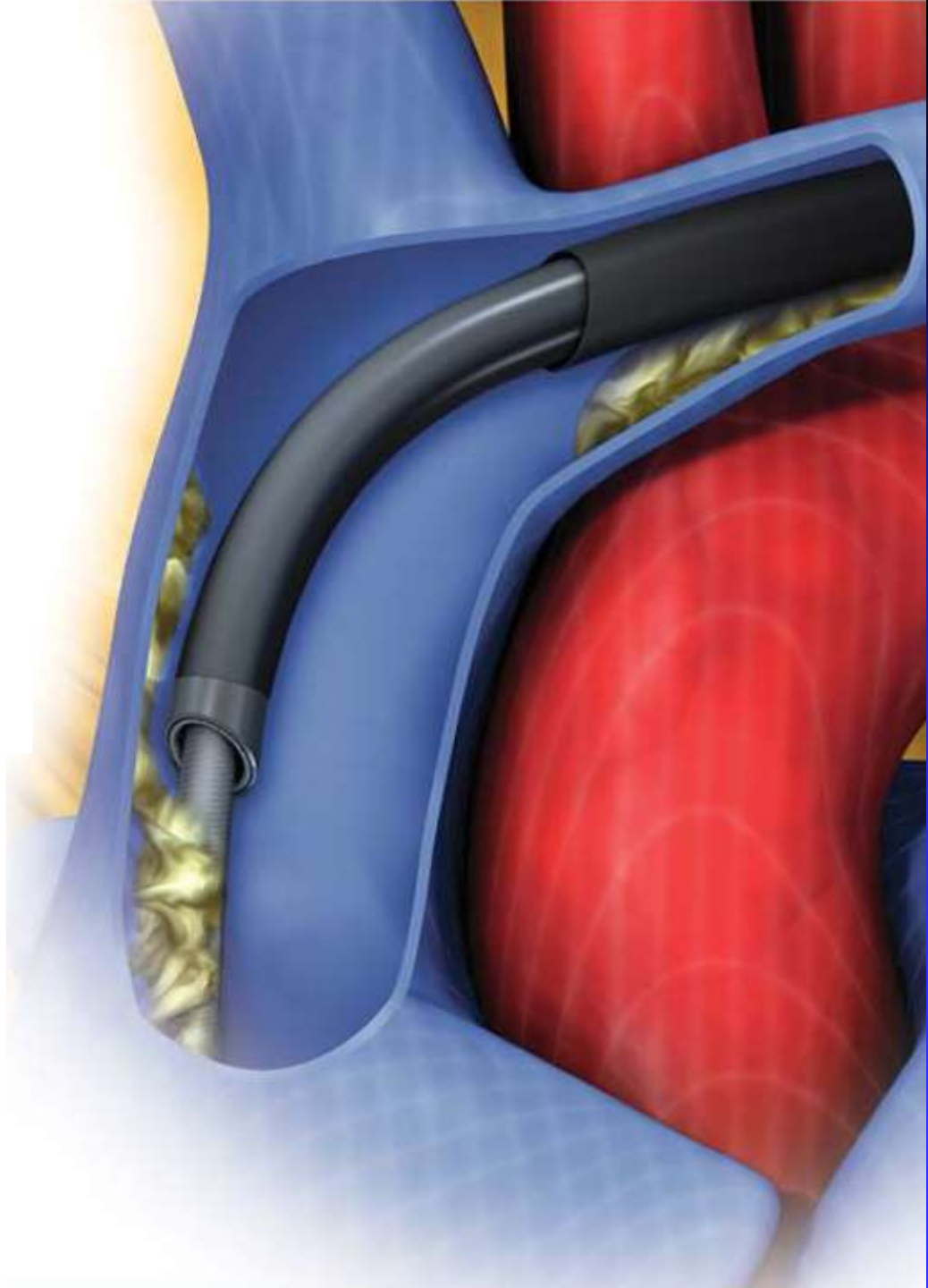
- causing cardiovascular rupture during extraction



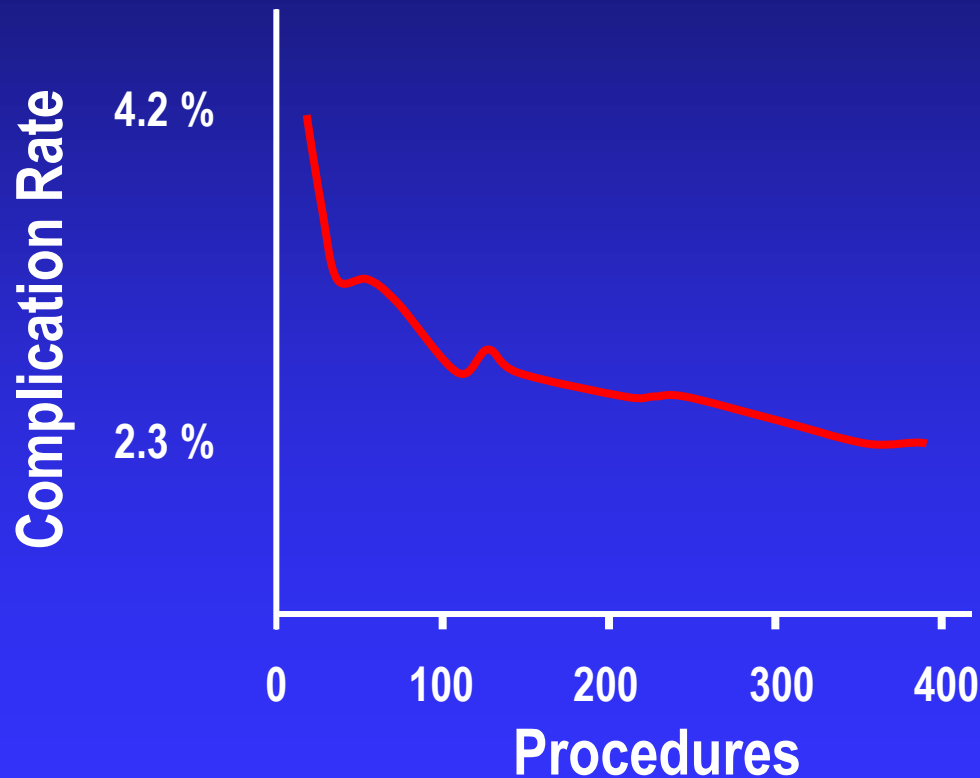


The SVC - RA -
Innominate
Territory

Haemothorax
Tamponade



Key to Reducing Major Complications is Training Laser Sheath: 1995 - 1999



Catheter Ablation for Atrial Fibrillation: Medicare 2001 – 2006, excluding AV node therapy

Centre Volume N = Cases	Number	In Hospital Death %	All Vascular Complications %
> 104	1,565	0.1	6.0
50 -103	1,466	0.3	5.5
25 -49	1,521	0.7 *	5.1
12 -24	1,513	0.6 *	6.2
< 12	2,223	?	?

Relationship	RISK / COMPLEXITY			Notes, References
	Low	Medium	High	
PATIENT				
BMI kg/m	> 25	< 25		Probably accounts for risk > in females
Age: years	40 - 80	20 - 40 or > 80	< 20	Age related lead fibrosis and co-morbidities
Heart Failure: LVEF %	> 40	20 - 40	< 20	
Previous heart surgery	x			Closed pericardial space
Vein occluded /severely stenosed		x		Lead route restricted
Lead access side	left	right		
Septicaemia	none	mild	severe	
Vegetations: cm	none	≤ 2	> 2	Risk and consequences of embolisation
Bleeding disorder	none	mild	> mild	
Number of leads	1	2 - 3	> 3	
LEAD				
Implantation time: years	< 1	1 – 6	> 6	>15 the risk is very high
Fixation mechanism	Active	Passive	Starfix, unretractable screws	
Isodiametric	Yes	No		
ICD coil	Single coated	Single uncoated Dual coated	Dual uncoated	SVC risk partly because of location.
Location	CS	RA, RV		Limited experience for CS leads > 5 years
Subclavian entry route	no	Lateral access	Medial access	Tight costo-clavicular space

How to Minimise Risks

- Plan each case – individual risks
- Be an expert extractor
- Be fully set up
- Highest risk cases in cardio-thoracic theatre

Dorset Heart Centre

- Consultant surgical support on standby (6)
- EP Lab / General Catheter Lab
- Full range of mechanical and powered extraction equipment
- Echocardiography – TTE + / TOE
- Percardiocentesis, thoracotomy and chest drain sets
- Temporary pacing support, Defibrillator – external pacer
- Full monitoring – continuous arterial pressure, O2, ECG
- Central vein access, Temperature and fluid balance control
- GA, Fully draped for surgery, Diathermy
- X-matched blood

Dorset Heart Centre

- Over 500 lead extraction procedures
- Over 20 years
- No peri-operative deaths
- 1 tamponade
- Procedural protocols in place
- 3 transfers having intervened (2 pre-laser, 1 SVC obstruction)
- Pool of extractors - 5 cardiologists, 3 interventional radiologists

What is Acceptable Risk ?

1990 ...”the mortality associated with **(diagnostic) cardiac catheterisation** ...may be reduced by having surgical facilities immediately available....**it may be more desirable to expand the existing facilities at the regional centres** and to encourage their use by appropriately trained cardiologists from district hospitals.”

St Georges and Southampton

BHJ

1996 ...”Surgical cover for **PTCA** procedures should be mandatory and **on site cover** remains the strongly preferred option.”

British Cardiac Society (BCS) and British Cardiovascular Intervention Society (BCIS) working group on interventional cardiology

Heart

Major Extraction Series: 975 or more Leads

Number of Leads	Extraction Period	Procedural Deaths %	Major Complications %	Emergency Surgery %
2405	2004-2007	0.28	1.4	?
975	2000-2007	0	0.4	0.2
2062	1997-2007	0.3	0.7	0.4
1032	1990-2007	0	0.9	0.9
2561	1995-1999	?	1.9	?
1285	1996-1998	0.8	3.5	?
3540	1994-1996	0.1	1.4	0.6
2195	1988-1994	0.6	1.9	?

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Standards of Good Practice for Cardiac Implantable Devices: Lead Extraction HRUK Council 2005

“The ideal facility ... is an operating theatre with emergency availability for general anaesthesia and support from a cardiothoracic surgical team...

urgent cardiac surgical support (within 30 minutes) ...

extraction will usually be undertaken in tertiary cardiac centres, but there may be historical and geographical reasons for a service to be established in a secondary centre with adequate/appropriate facilities, staffing, experience and surgical support ...(cardiac/ thoracic/ vascular surgeons)”

Have things changed ?

Lead Extraction in 38 European EP Centres: Survey of EHRA Members

Primary operator – 63% Cardiologists, 34% Surgeons

Location – 43% Lab, 54% in theatre

Views of the need for a cardio-thoracic surgeon –

- Desired at the actual procedure 9%
- Standby in the hospital sufficient 83%
- Presence not required 9%

Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management 2009

“Required Personnel ... Cardiothoracic surgeon well versed in the potential complications of lead extraction and techniques for their treatment, on site and immediately available.....

We therefore strongly recommend that the surgeon is aware of the procedure, especially in smaller hospitals that may not have operating rooms and support staff available at all times.....”

US Site Survey of Endovascular Lead Extraction

Data from the 88% of **252** HRS Physicians who performed endovascular lead extraction or had admitting privileges....

Speciality performing extraction at hospital site –

83% - Electrophysiologists

20% - Cardiac Surgeons

Site and preparation for extraction –

36% - OR with surgeon present or immediately available

39% - EP Lab with surgeon and OR identified and available

25% - EP Lab without surgeon or OR identified

Lead Extraction is on the Rise....

- Infection accounts for 2/3 of extractions..
- Risk of device infection has increased..
 - older population
 - more device interventions during lifespan
 - more complex systems
- Increase in implant rate for a given indication
- Wider indications

Cardiovascular Implantable Electronic Devices US National Hospital Discharge Survey

Year	Total	Infected	% Infected
2004	199,516	8,273	4.1
2005	208,966	10,004	4.8
2006	222,940	12,979	5.8
2010 ?			

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2010 ?	600,000 ?	40,000 ?	6.6 ?

Lead extraction associated with deaths and serious injuries
FDA MAUDE database 1995–2008
Powered sheaths only

	Death	Life threatening
SVC-RA-Innominate	24	17
Tamponade	5	4
Other / Unspecified	2	1
TOTAL	31	22

What does this mean?

- Over half of these severe ruptures lead to death despite surgery
- “...when the SVC was torn or perforated, delays from injury to having open access to the heart of more than 5 -10 minutes were often associated with a fatal outcome” HRS Expert Consensus 2009
- Do these considerations determine the UK Extraction reality ?....
- **Answer ... NO**
the cardiologist is usually the primary operator and no surgeon present
the procedure is usually done in a lab rather than a theatre
not all patients are done under GA
in CT centres a surgeon is there but not usually on immediate standby



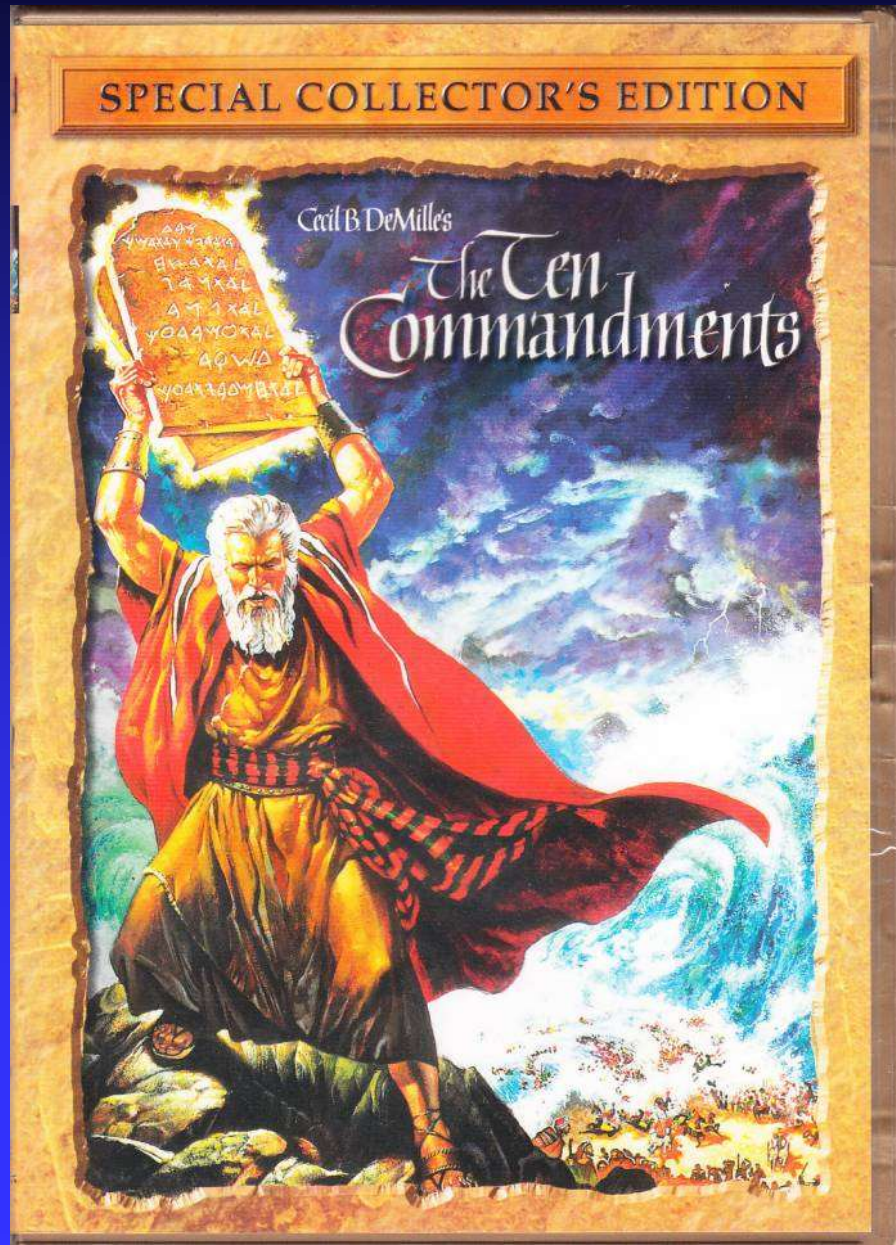
Summary

- Numbers of lead extractions are increasing
- Extraction Centres are justified if there is sufficient demand
- Such Centres must be properly equipped and staffed
- Surgical support is essential
- Lead Extraction Services do not necessarily need to be housed in a Cardio-thoracic Centre

Rebuttal

- Absolute Risk is low in experienced hands
- High Risk cases are to a fair degree predictable
- High risk cases should be done in a CT theatre
- Regular review of procedures
- Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management 2009
.....85% Consensus
- NICE Consultation period and Appeal mechanism

A Guideline Provides Guidance ...



SITTING BULL • LAST STAND HILL • THE CROWS NEST • MEDICINETAIL COULEE

Custer's Last Stand

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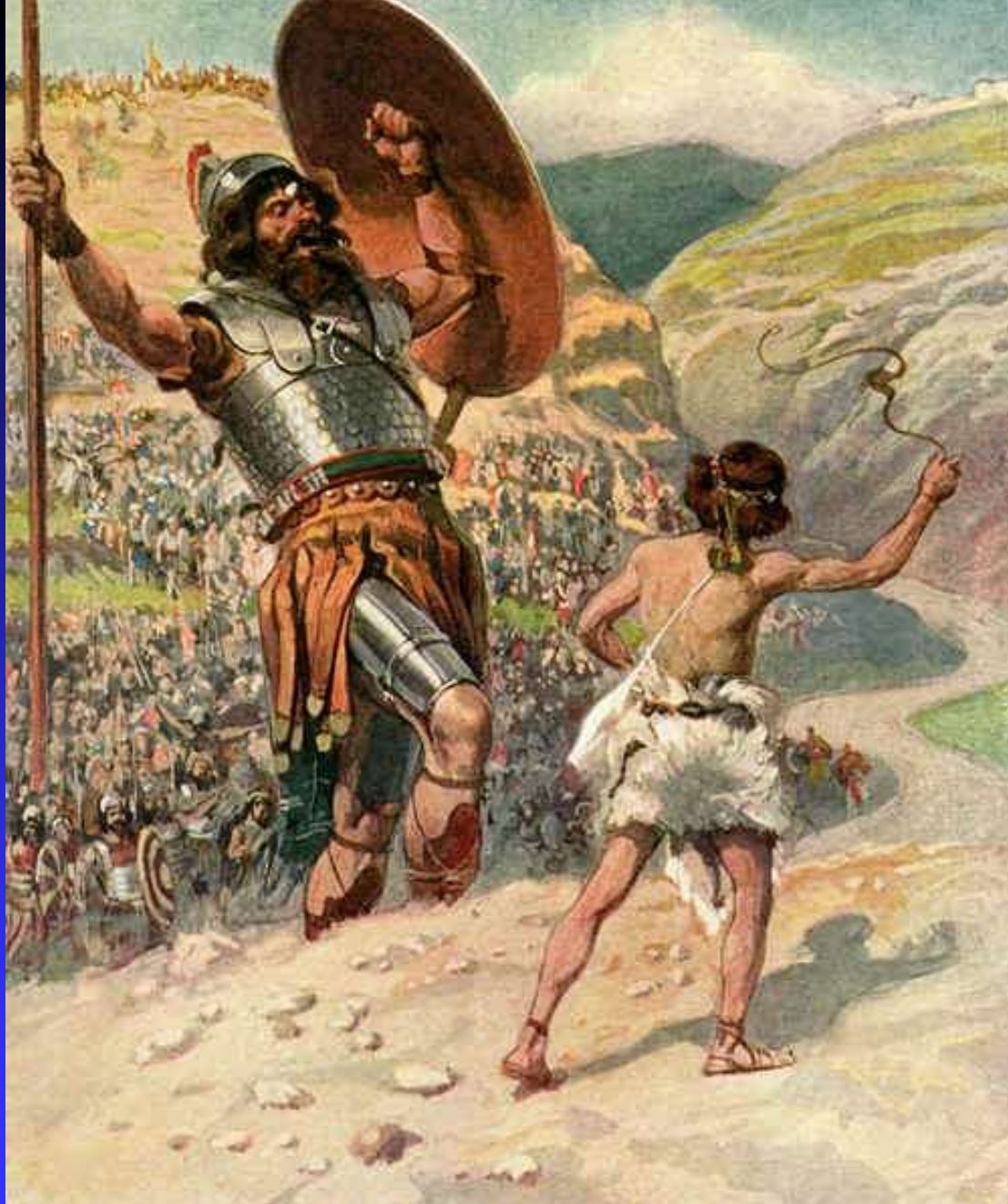


WARNING:
CHOKING HAZARD • Small Parts.
Not for Children under 14 years.

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Bad guys deserve to loose ...



Odds are overwhelming ...



The opposition can be mean ...



But you can't keep a good man down ...