

Device Implant Complications

How to deal with them

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Latest UK complication data

Br Heart J. 1995 Jun;73(96):571-5

Early complications DDD vs VVI

- Apr 1992 – Jan 1994
- 1088 implants (DDD 54%)
- Complications
 - Pneumothorax 1.8%
 - Arterial puncture 2.7%
 - Lead displacement 1.4%
 - Haematoma 0.5%
 - Explant (1yr) 1.5%

Review of RCT ICD/CRT (JACC;58:10:995-1000)

- Pneumothorax 0.9% ICD and CRT
- Lead displacement
 - LV 6.8%
 - RA 1%
 - RV 0.5%
- LV lead complication 2%
- Haematoma 2.2% ICD 2.4% CRT

16 yr trends in infection PPM/ICD (JACC;58:10:1001-6)

- Review of hospital coding/procedures 1993-2008
- 4.2M implants, annual increase 4.7%
- Overall infection rate 1.61%
- 1.54% 1993-2004 increasing to 2.4% 2008
- Increase in infection related to increase in co-morbidity

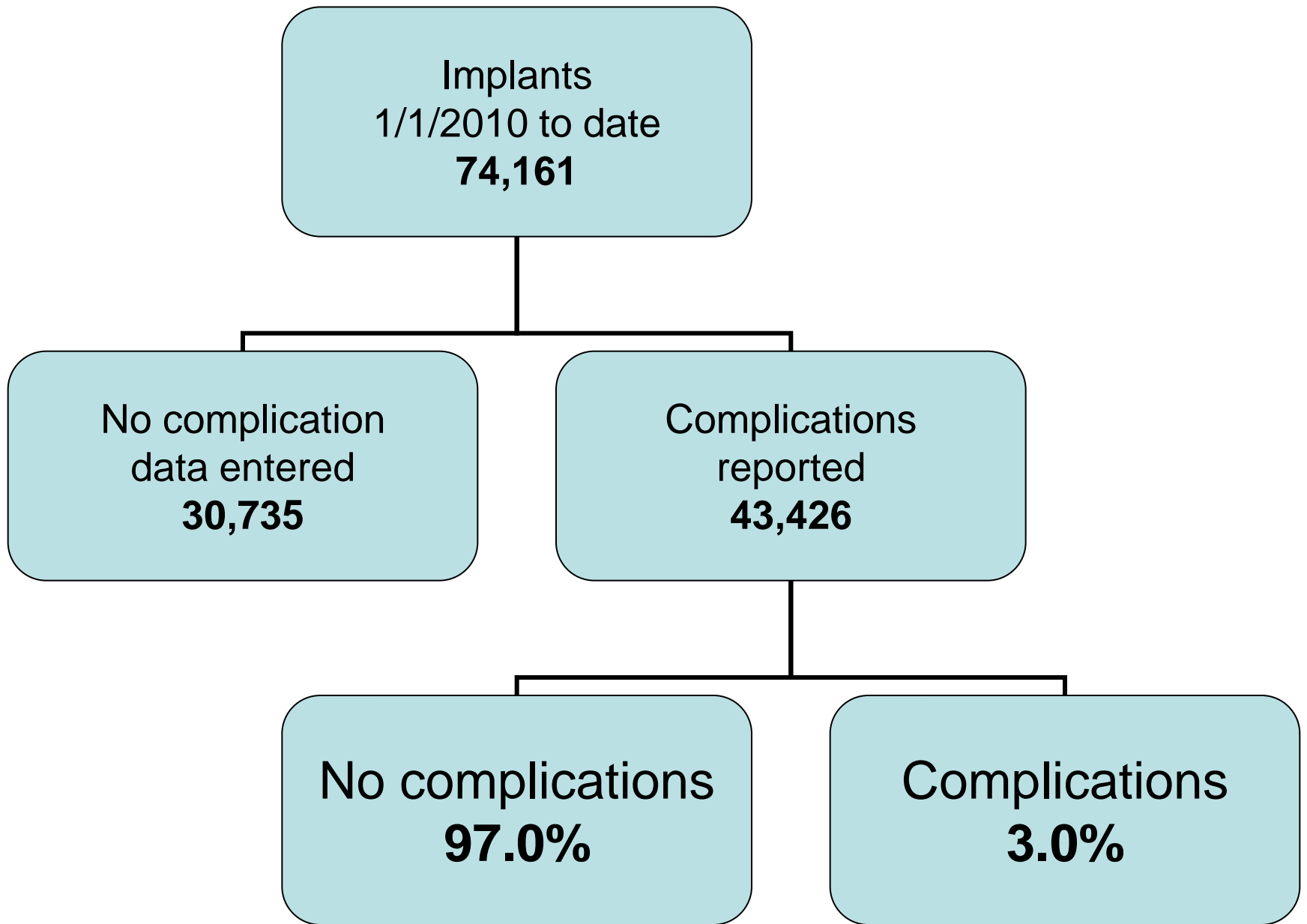
Danish experience (Eur Heart J 2011;32:991-8)

- 46 299 patients 1982-2007
- Infection at 1 yr 0.5% after initial implant
 1.2% after replacement
- Associated risk factors
number of procedures, male sex, young age,
absence of antibiotics

Issues with device complications

- Variable definitions over differing timescales
- Variable data collection and reporting
- No National dataset
- Difficult to perform appraisal
- Revalidation looming

CCAD Devices Survey



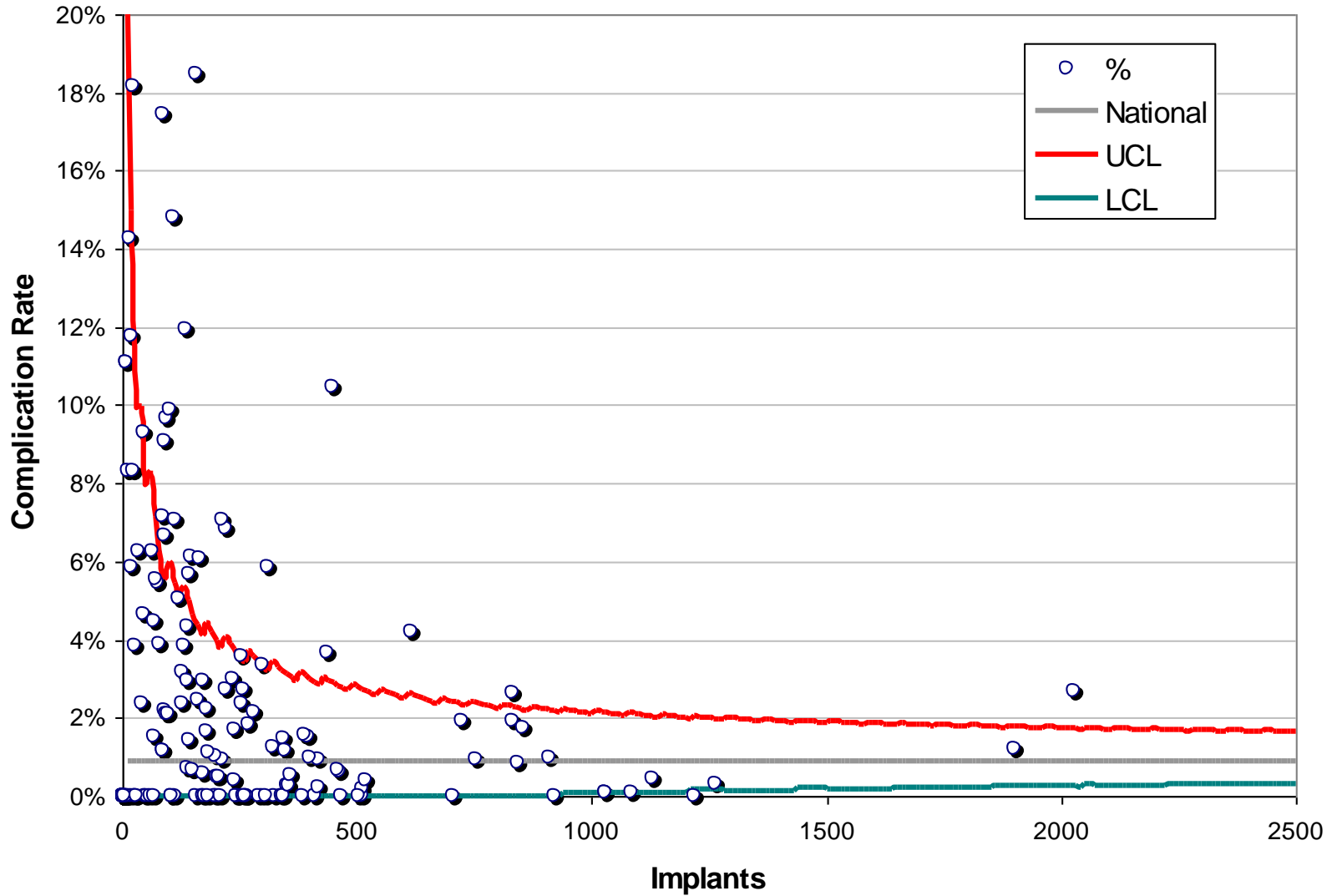
Hospital reporting

- 186 hospitals reporting to survey
- 101 hospitals reported some complications (range 5-100%)
- Complication rates 0.09-100%
- 36 hospitals reported no complications at all
- 49 hospitals no complication data at all

Complications by Device Type

Complication	PM	ICD	CRTP	CRTD	All
Pneumothorax	0.67%	0.41%	1.16%	1.07%	0.68%
Haematoma	0.18%	0.20%	0.26%	0.33%	0.20%
Tamponade	0.01%	0.00%	0.00%	0.05%	0.01%
Lead displacement	0.71%	0.10%	0.53%	0.51%	0.62%
Pericardial effusion	0.01%	0.00%	0.05%	0.00%	0.01%
Infection	0.08%	0.06%	0.05%	0.19%	0.08%
Death	0.04%	0.00%	0.05%	0.00%	0.03%
Other	1.29%	1.58%	2.05%	1.82%	1.38%
Total	2.99%	2.35%	4.16%	3.97%	3.02%

All Centres



What to do next?

- We cannot rely on the current accuracy of reporting
- Solutions:
 - Formally enrol enthusiastic centres?
 - Commission one year of accurate reporting?
 - Publish in 2011 national device report?
 - Mandate reporting for future revalidation

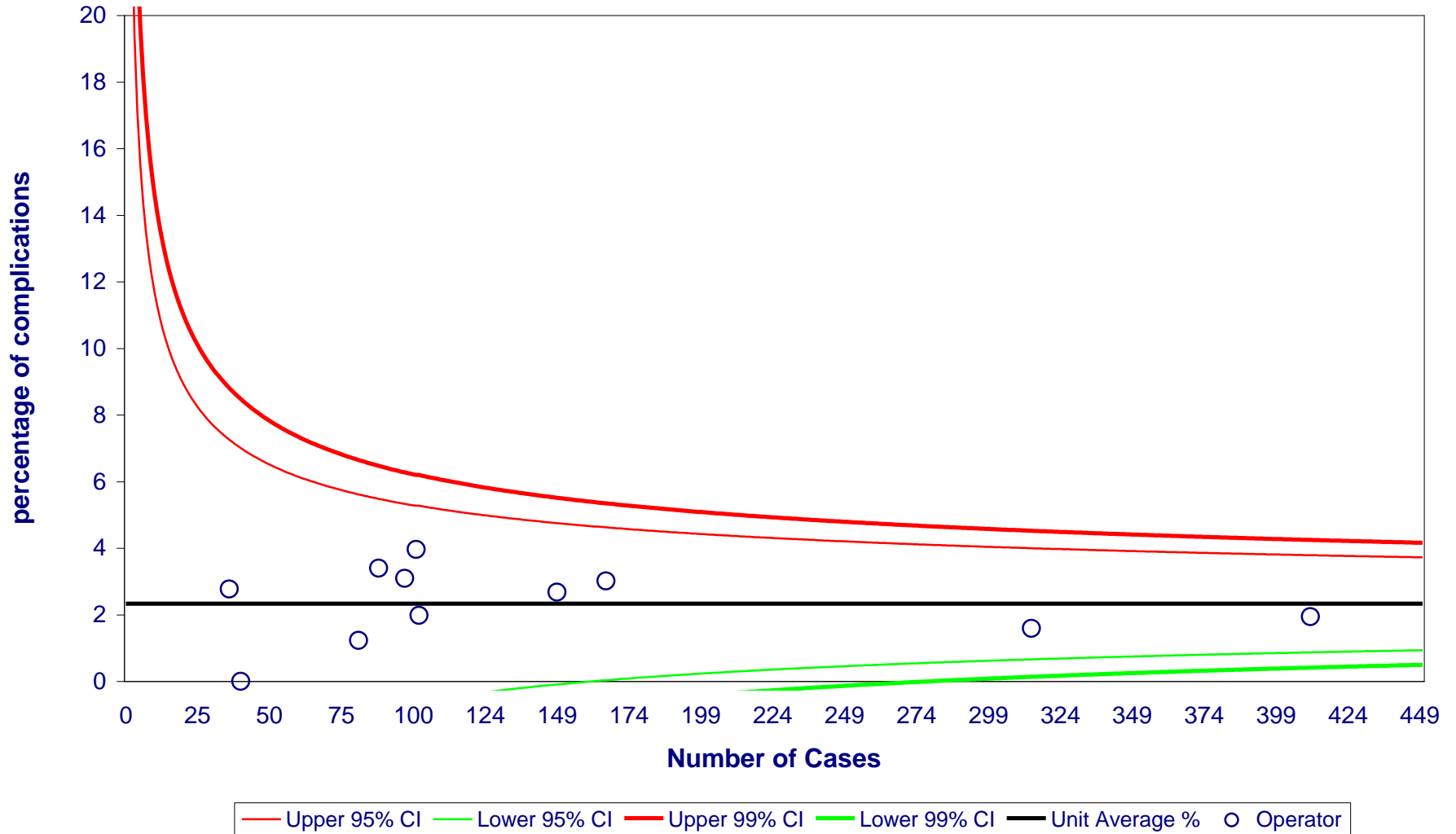
Managing complications

Prevention better than treatment

Basic Rules

- No substitute for experience
- Learn from different teachers
- Learn from others mistakes and your own
- Rigorous audit
- Be open to change when indicated

Complication following Pacing & ICD Procedures April 2009- March 2010



Complication percentage against procedures

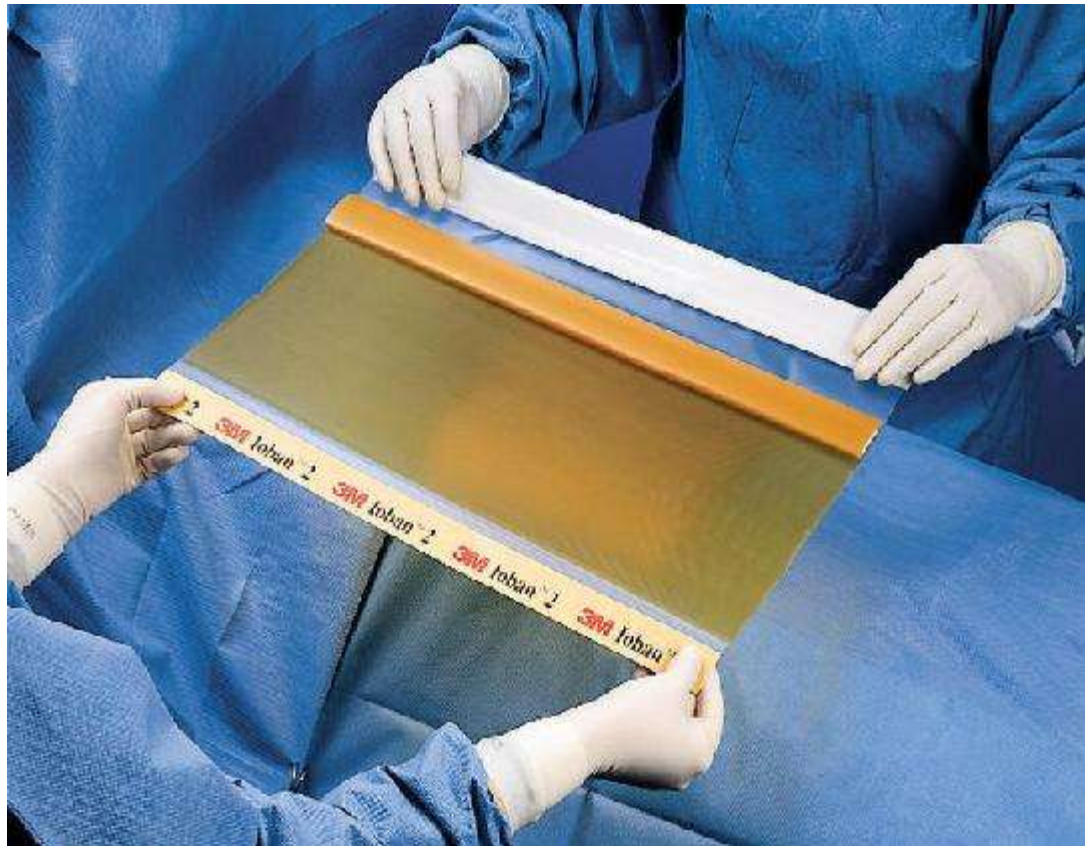
	Total							
Consultant	Procedures	Reveals	Pacemakers	ICD's	BiV'S	Complications	%	
DG	101	5	66	20	10	4	3.96	
MH	166	28	91	20	27	5	3.01	
JH	81	3	33	22	23	1	1.23	
WLM	36	6	29	1	0	1	2.77	
JP	149	3	68	21	57	4	2.68	
DRR	40	9	30	1	0	0	0	
AR	411	35	191	54	131	8	1.94	
RS	101	14	59	17	11	2	1.98	
DT	88	15	38	12	23	3	3.4	
JEW	97	11	53	19	14	3	3.09	
DJW	314	16	155	83	60	5	1.59	

Device implant = surgical procedure

- Theatre superior to cath lab
- Immaculate surgical technique
- Monofilament sutures which dissolve slowly
- Basic surgical skills course
- Limit personnel movement
- Identify those at greatest risk – preadmission
- Use all facilities available to you!

Facilitators

- Antibiotics better than none
- Little evidence for comparison of different antibiotics or route of administration
- Iban better for general procedures
- Iodine vs chlorhexidine
- Little evidence for Collatamp and Rifampicin mesh for device procedures

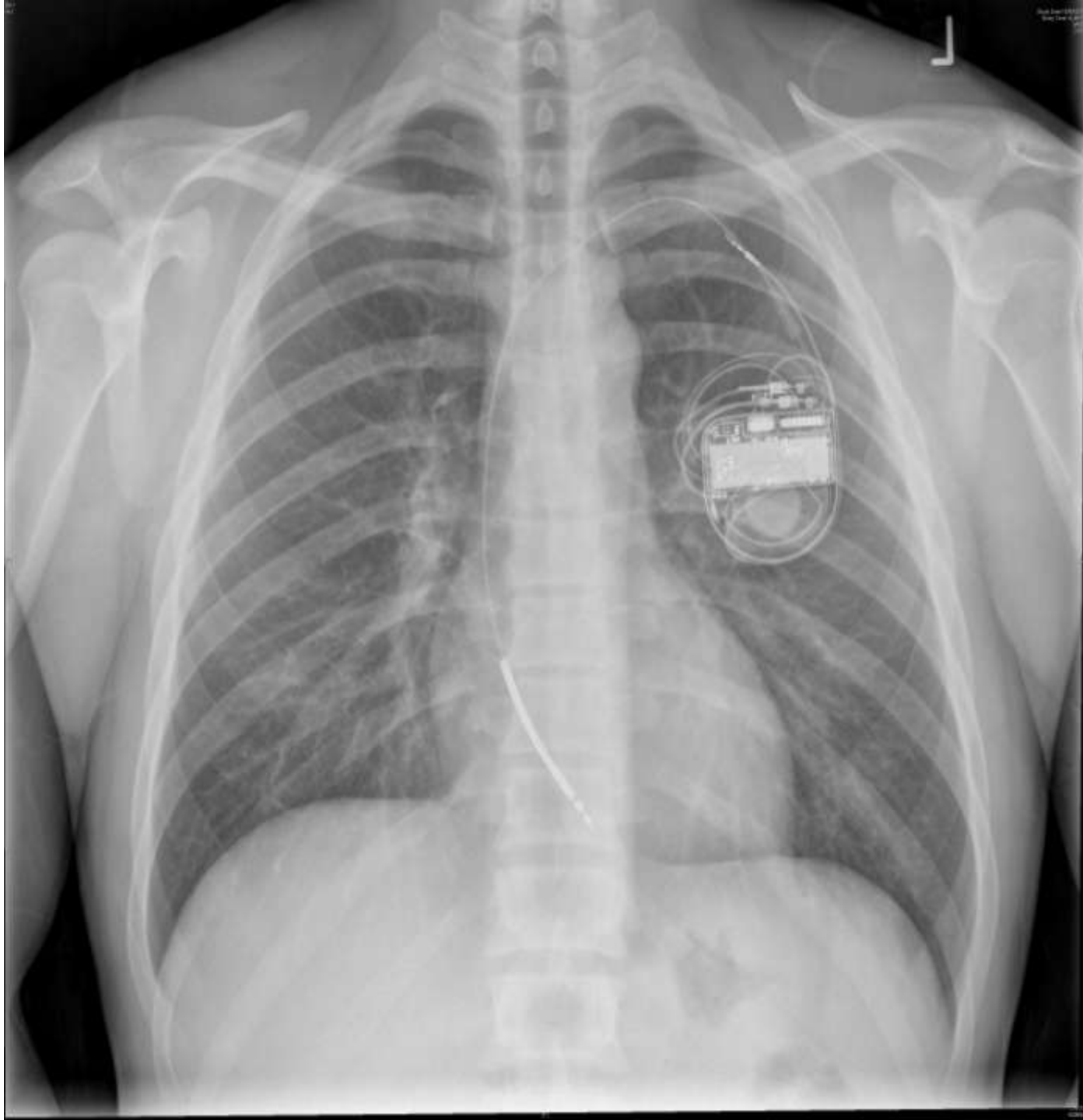




Consideration of specific complications

Lead Displacement

- Commonest complication in reliable series
- Usually early complication
- $LV > RA > RV$ (?RVA vs RVOT)
- More likely with anatomical abnormality
- Less likely with active fixation lead
- Less likely with high experience
- Consider referring on difficult cases



Pneumothorax

- Potentially serious if missed
- Intercostal drain may add further complication
- Less likely with cephalic or axillary access
- Less likely with experience
- More likely with low BMI and COPD

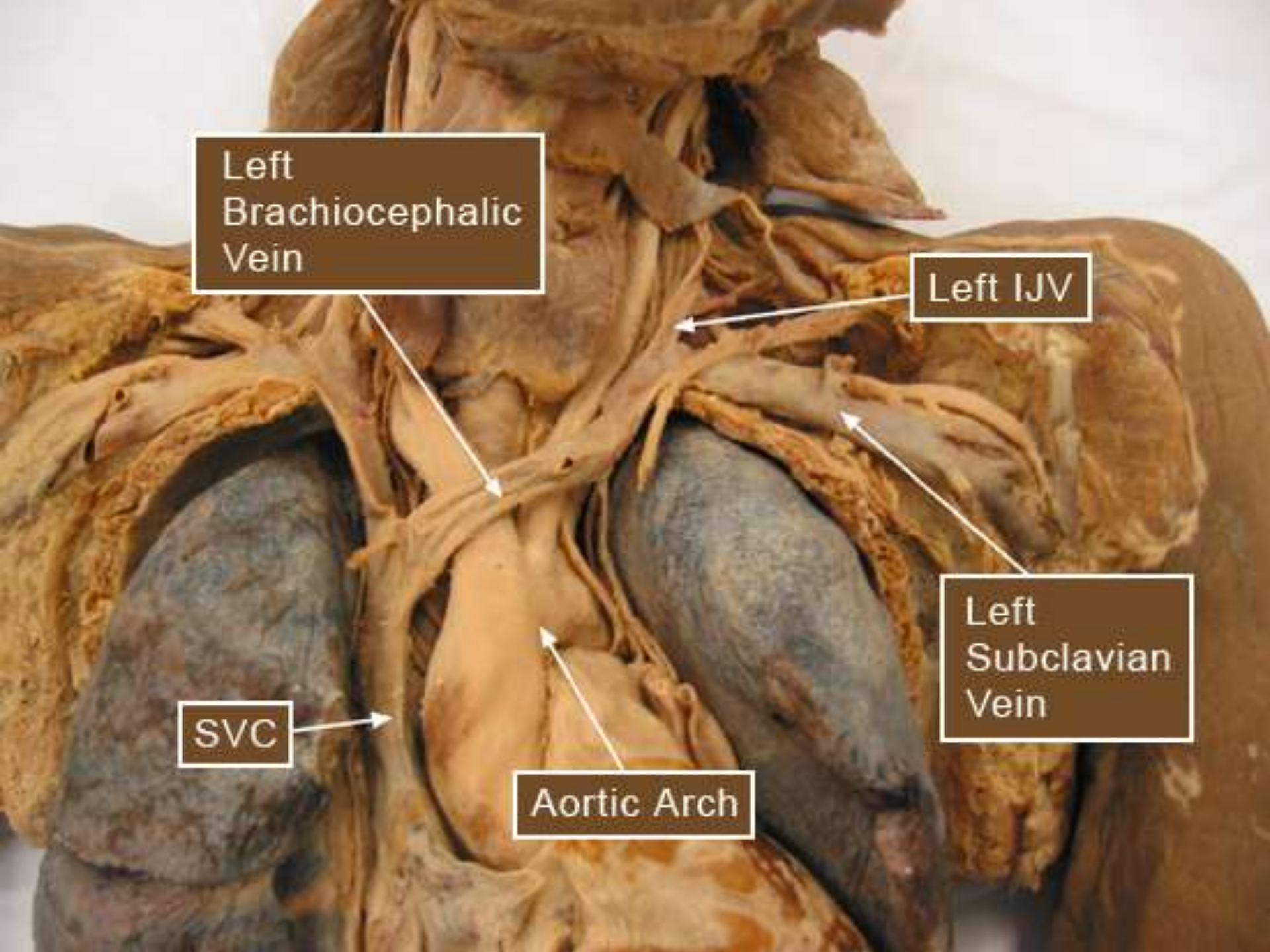
Left
Brachiocephalic
Vein

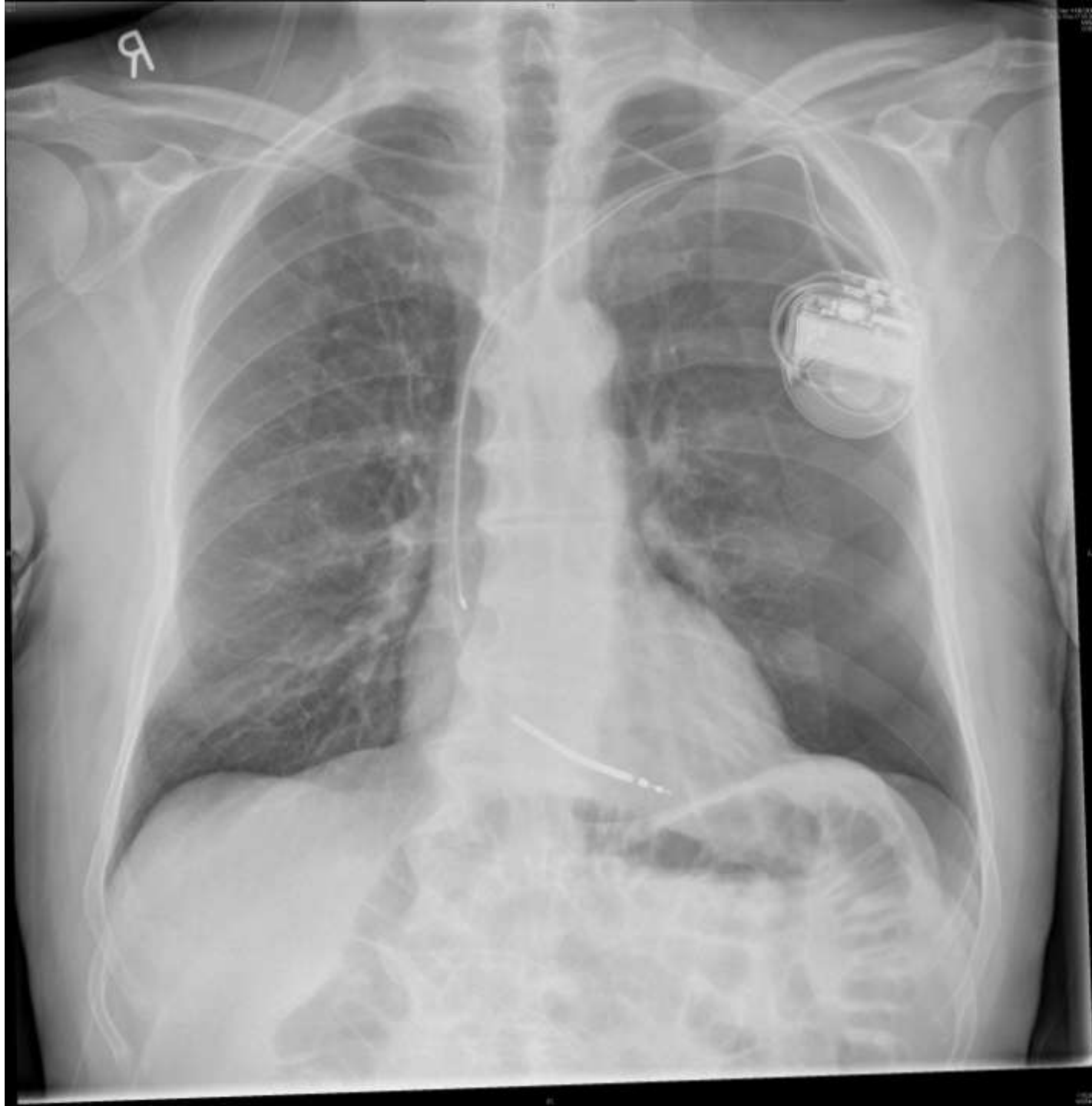
Left IJV

Left
Subclavian
Vein

SVC

Aortic Arch







Haemothorax

- Medical emergency
- Inform thoracic surgical team
- Frequent observations
- FBC, CXR, ABG, X-match
- More frequent with active fixation, low BMI

Pericardial effusion

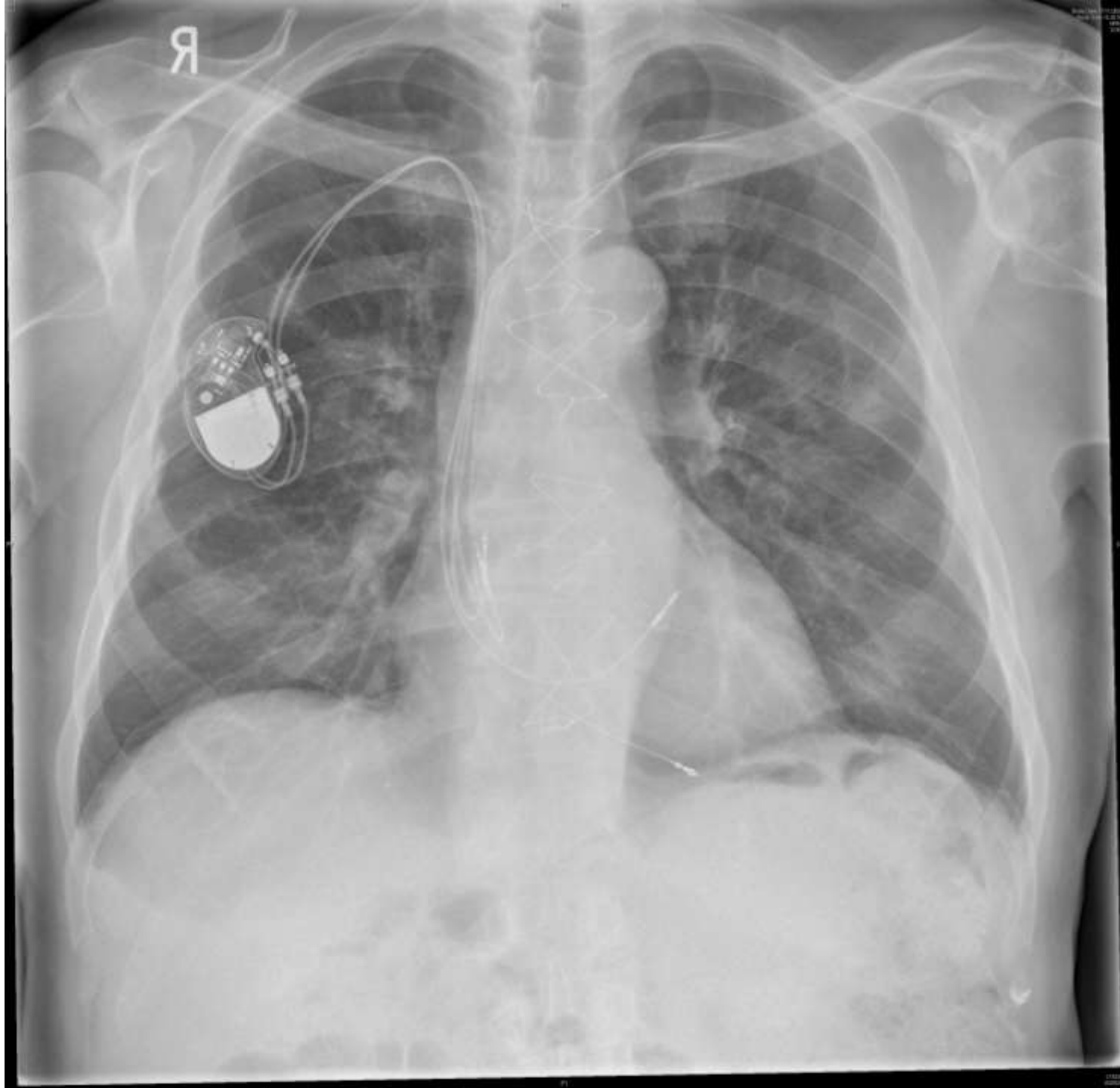
- May present with non specific chest pain
- Avoid use of anticoagulants/antiplatelet agents
- More likely with active leads
- More likely in slender older patients
- More likely in prolonged procedure with multiple lead repositions
- Less likely post sternotomy

Infection

- Most difficult to audit
- May occur late or be indolent
- Beware endocarditis
- Remove all hardware with surgical cover
- Don't underestimate risk to patient







Summary

- More experience = less complications
- Prevention, prevention, prevention
- MDT helpful, discuss with surgical colleagues
- Refer difficult cases on
- Audit your performance you will be exposed to revalidation at some point