

Percutaneous occlusion of the LA appendage A real alternative to warfarin?

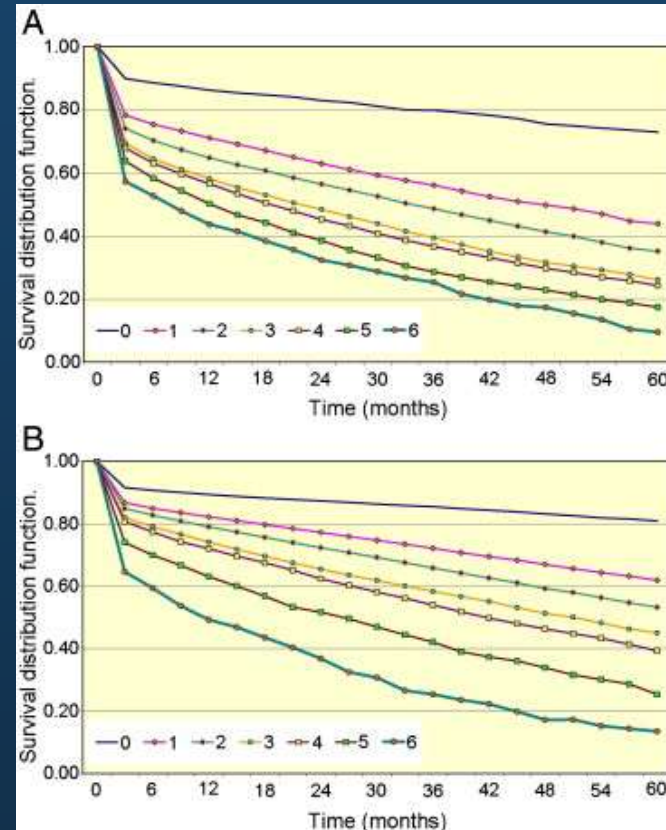


Mark Earley
St Bartholomew's Hospital



Stroke in AF

- ↑ mortality
- ↑ hospital stay
- ↑ disability



AF

No AF

Pathology of stroke in AF

Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients With Atrial Fibrillation

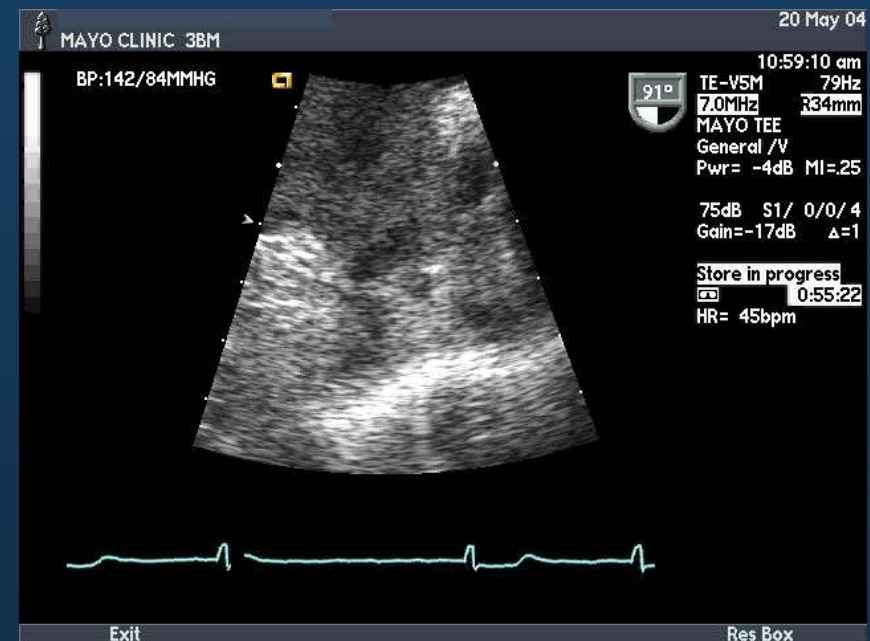
Joseph L. Blackshear, MD, and John A. Odell, FRCS(Ed)

Division of Cardiovascular Diseases, Mayo Clinic Jacksonville, Jacksonville, Florida and Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota

(Ann Thorac Surg 1996;61:755-9)

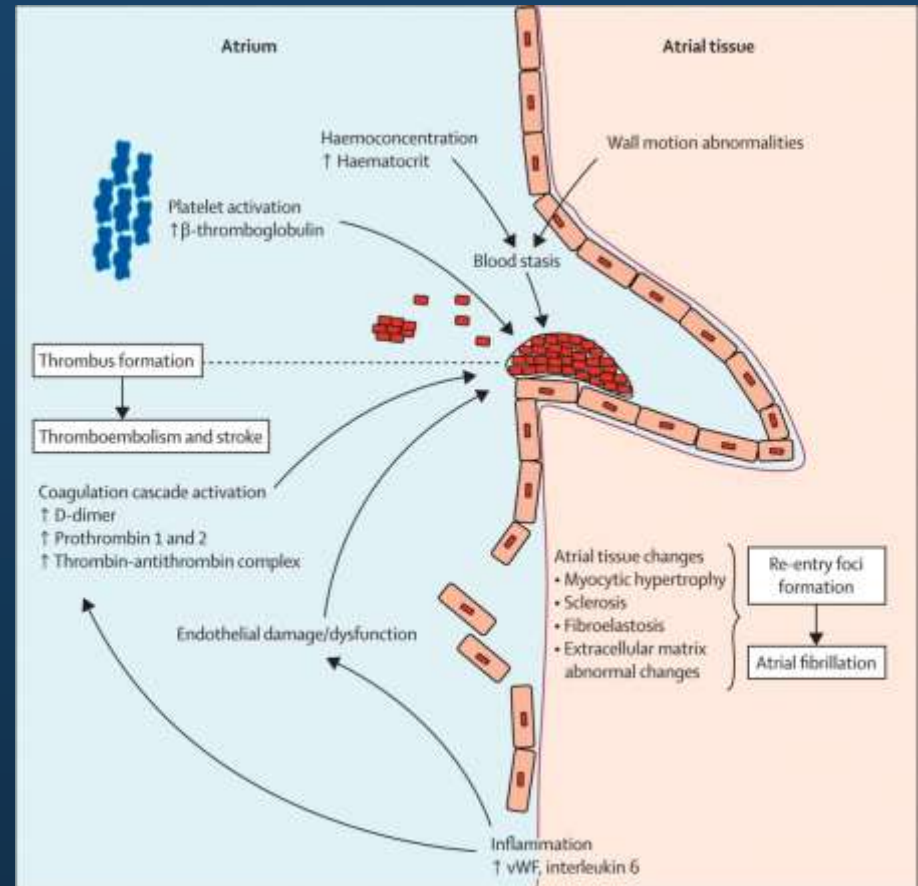
- 90% of LA thrombus is confined to LA appendage
- Low stroke rates in AF ablation surgery
- LAA thrombus predicts stroke

Is the LA appendage the predominant source thrombus causing stroke in AF?



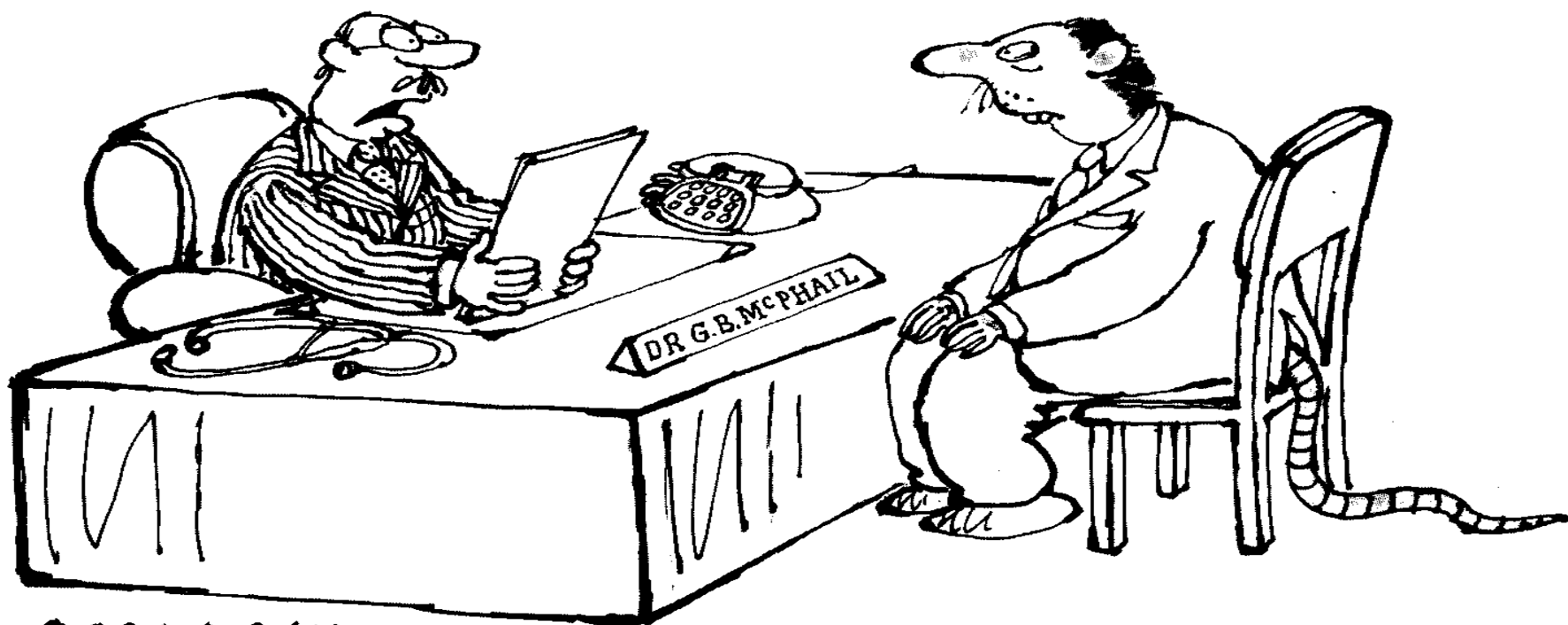
Pathology of stroke in AF

- Virchow's triad ...
- Complex atherosclerotic plaques present
- Not all strokes embolic



Watson et al Lancet 2009;373:155–196

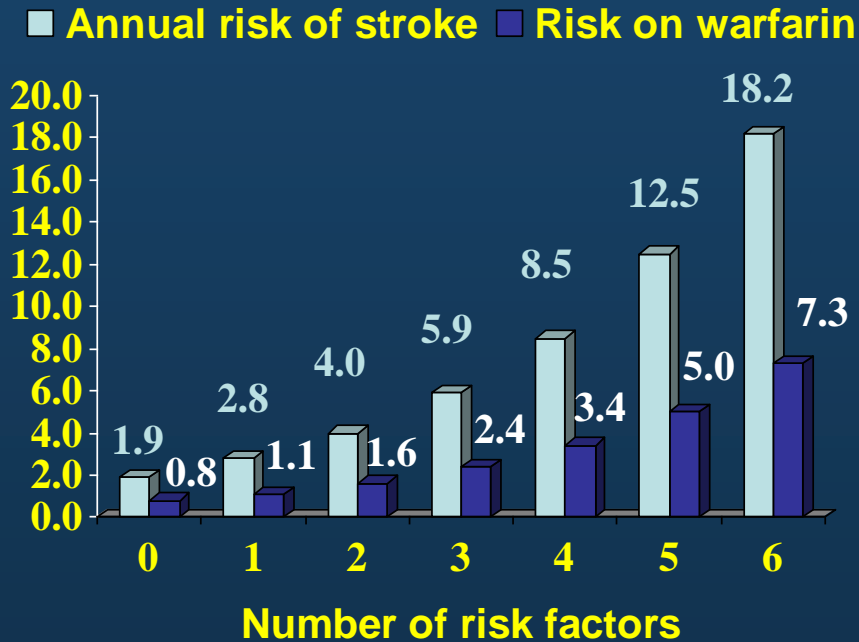
CARDIAC
&
VASCULAR
UNIT



MCLACHLAN

'I did warn you that there might be some side effects with the Warfarin treatment, Mr Gadwall.'

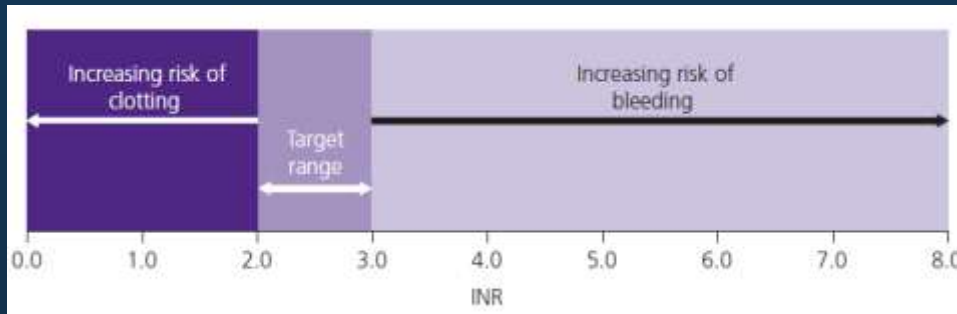
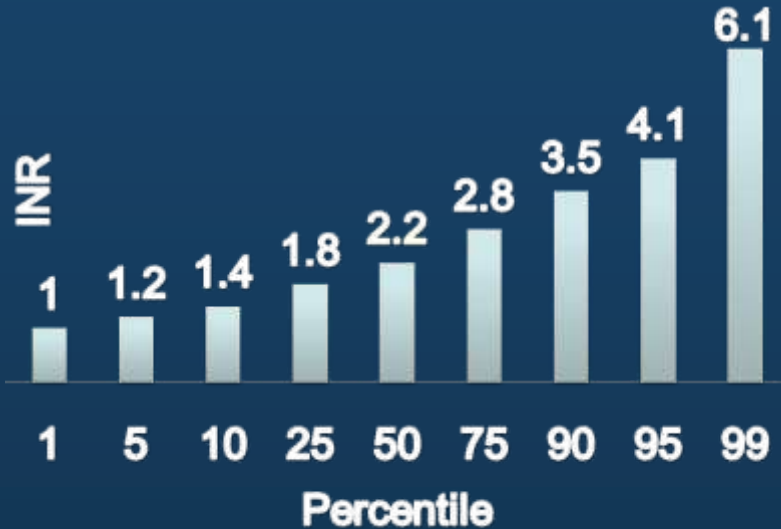
Stroke prevention - warfarin



CHADS₂ risk factors

- Congestive Heart Failure
- Hypertension
- Age > 75
- Diabetes
- Previous stroke (score 2)

Problems with warfarin – therapeutic index



- n=13000
- Median INR = 2.2
- 1/5 INR 2-3 100% of time
- 1/3 INR 2-3 <20% of time
- INR <2 RR stroke = 2.4
- INR >3 RR IC haemorrhage = 2.1

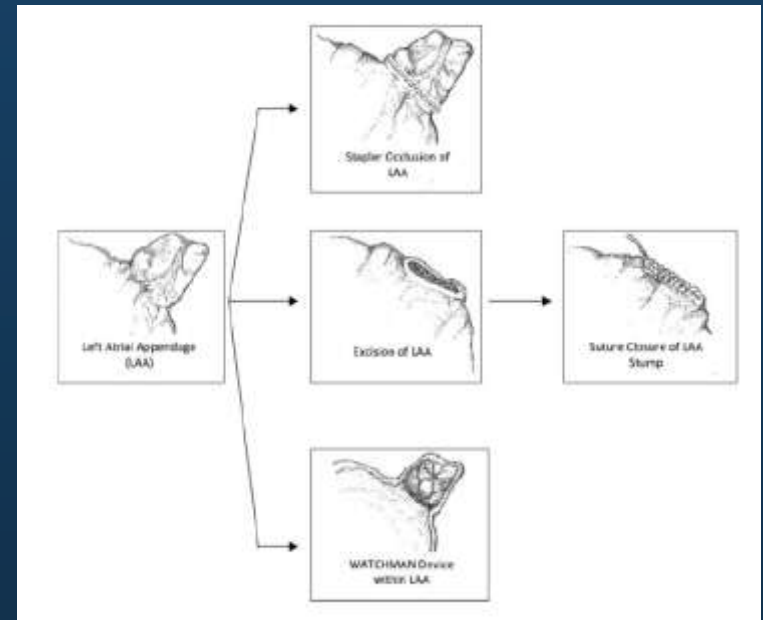
Walker et al Heart Rhythm 2008;5:1365–1372

Systemic v local approach

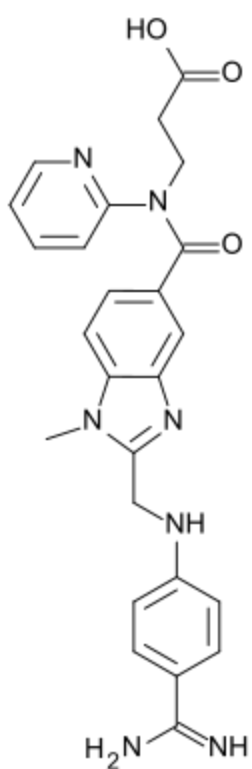
Systemic

- Aspirin ± clopidogrel
- Warfarin
- Direct Thrombin Inhibitors
 - Dabigatran

Local



Dabigatran



RE-LY	Warfarin	Dabigatran 110mg bd	Dabigatran 150mg bd
Stroke or embolism	1.69	1.31	1.11
Major bleed	3.36	2.71	3.11
Event rate - % pa			

Connolly et al N Engl J Med. 2009 Sep 17;361(12):1139-51

Percutaneous closure devices



PLAATO



Watchman



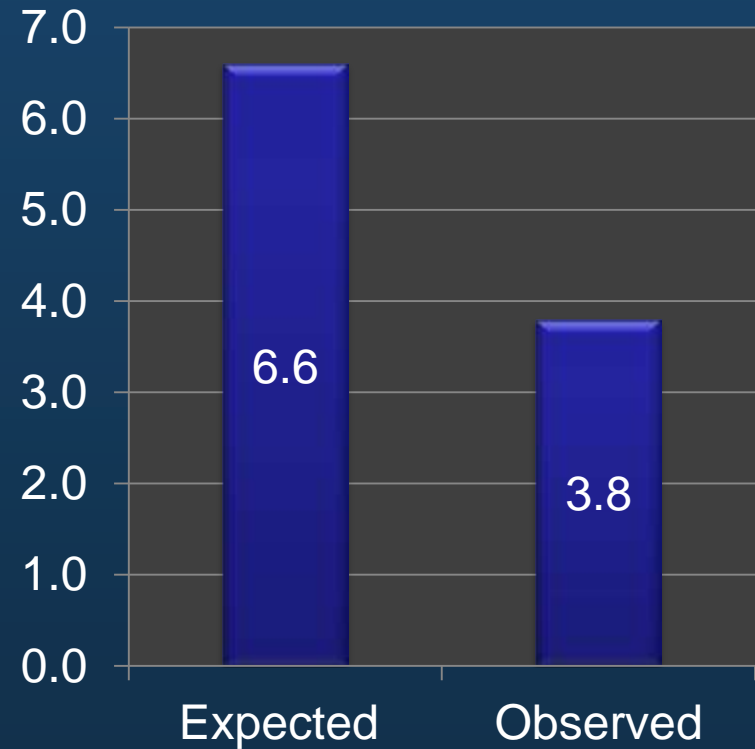
Amplatzer

PLAATO

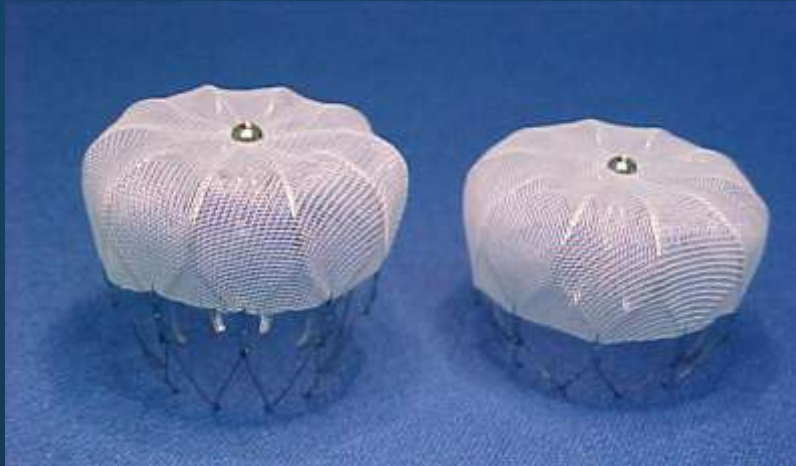
- n=64 AF, CHADS₂>2, CI to warfarin
- Age 73
- CHADS₂ = 2.6
- 1/64 CV surgery + death
- 249 pt years follow up

Block et al JACC CVI 2009

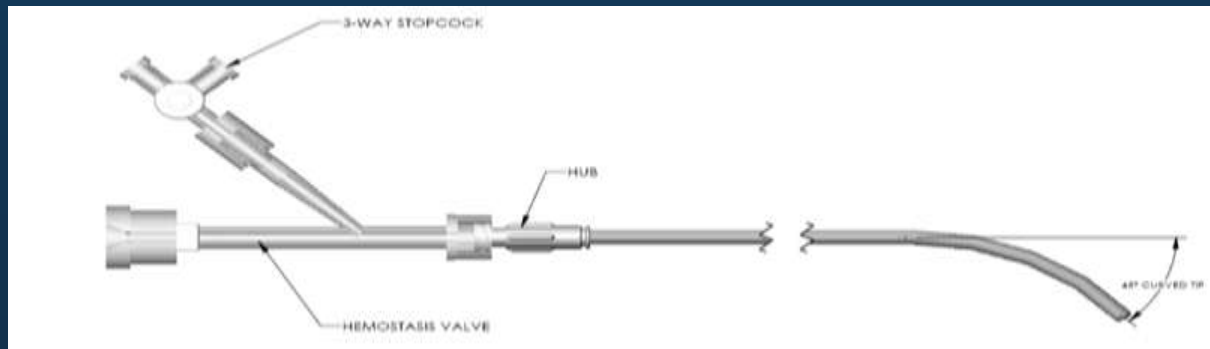
Annual stroke risk %

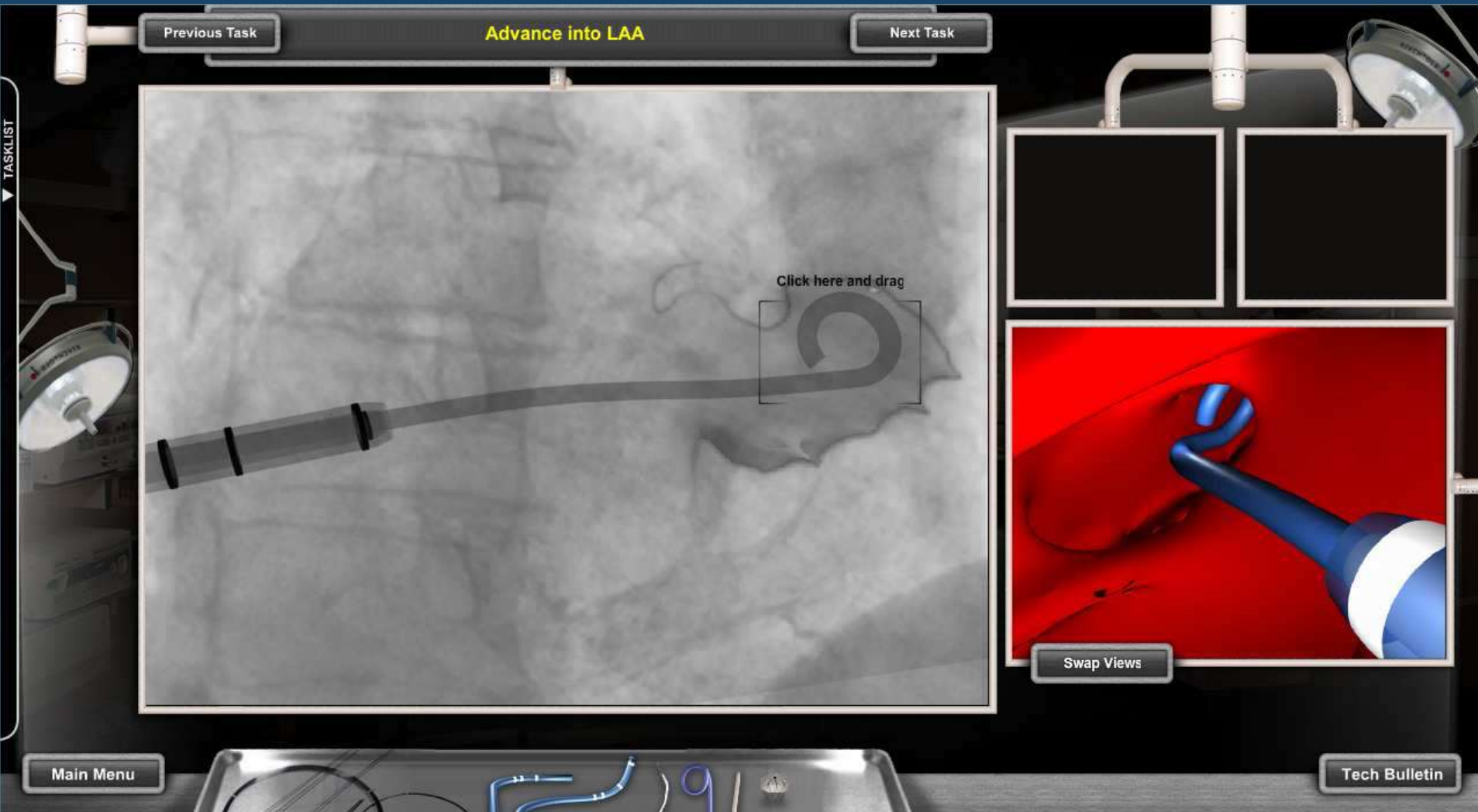


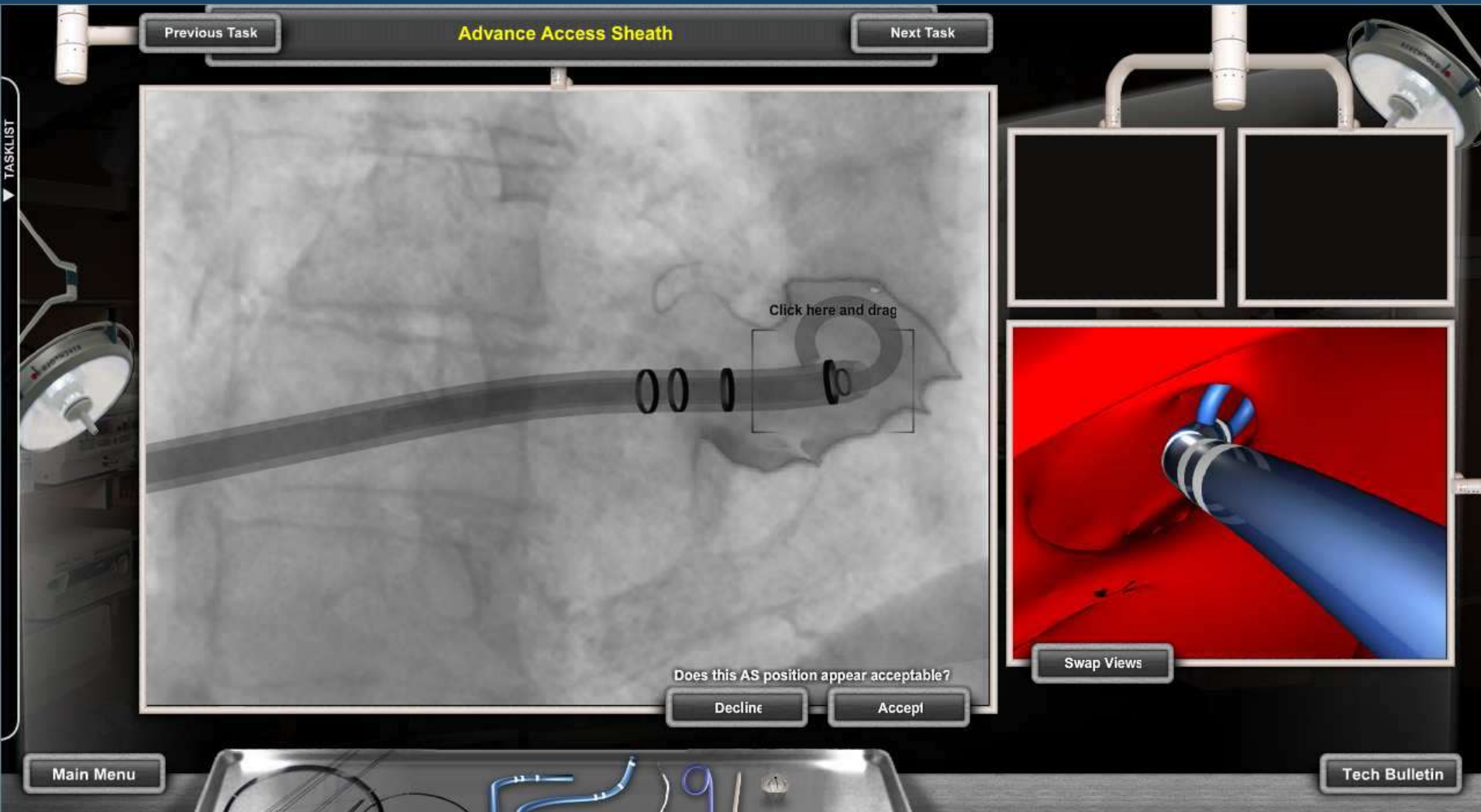
Watchman™

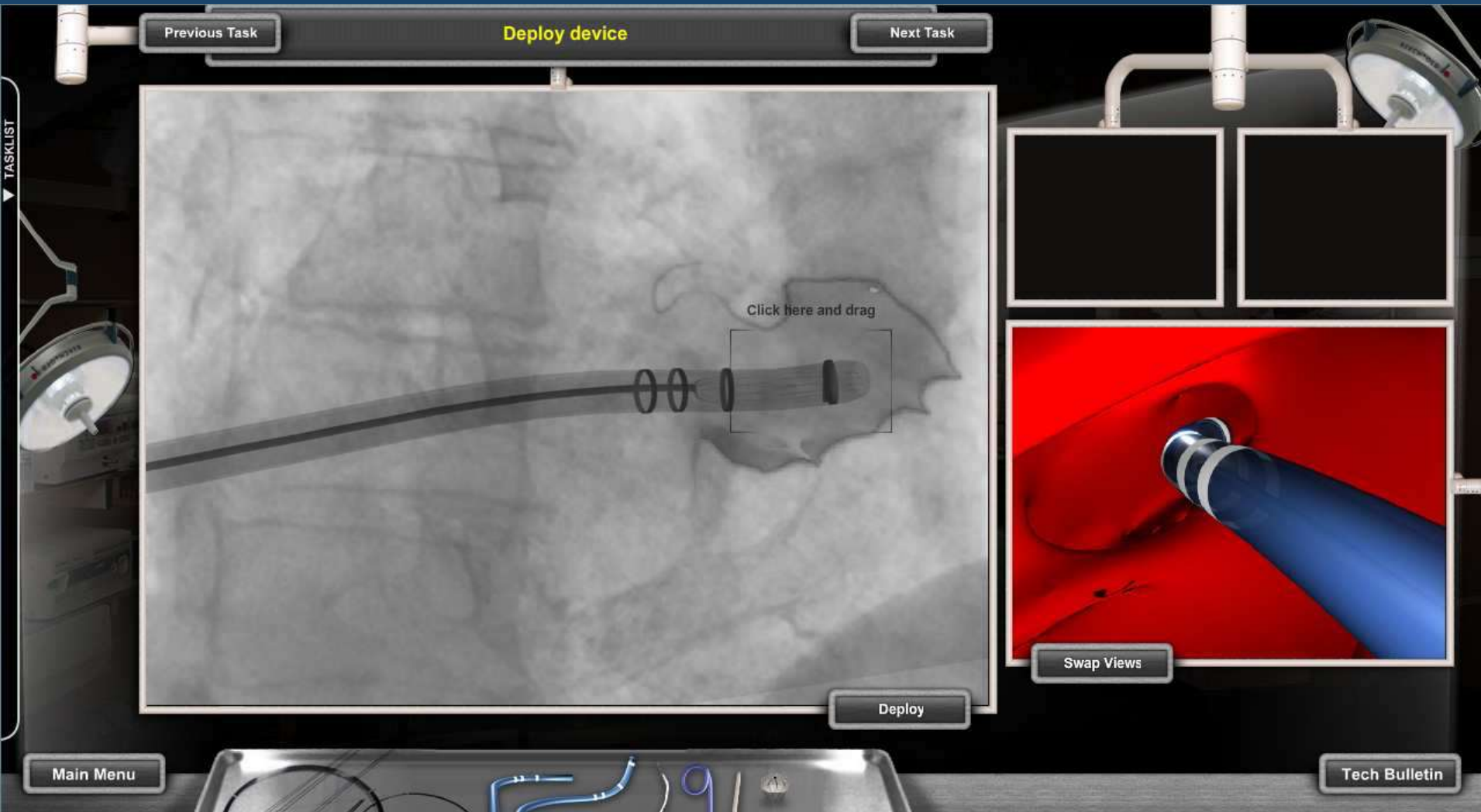


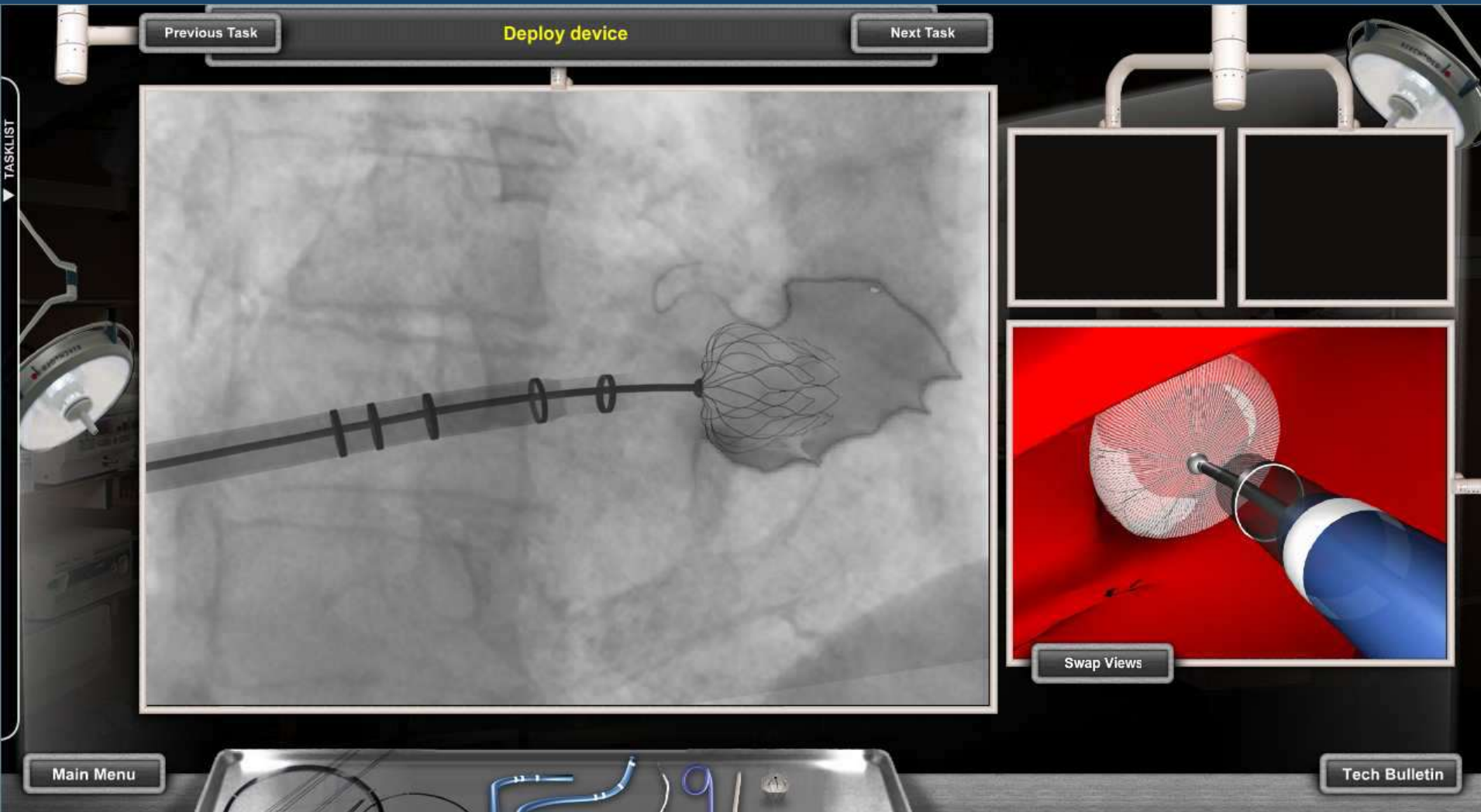
- Nitinol frame + fixation barbs
- 21-33mm diameter
- Catheter delivery via transeptal approach
- GA
- TOE + fluoroscopic guidance

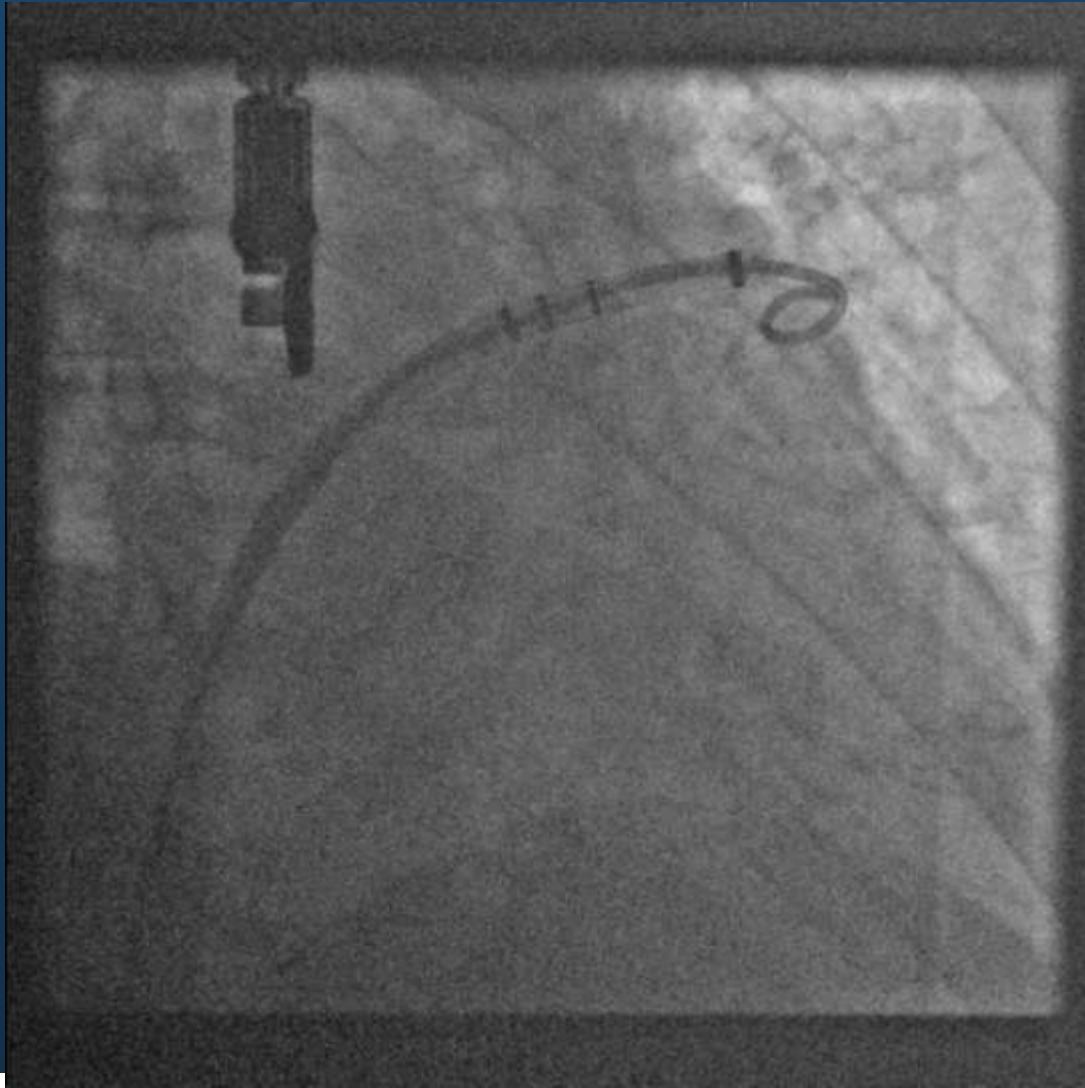


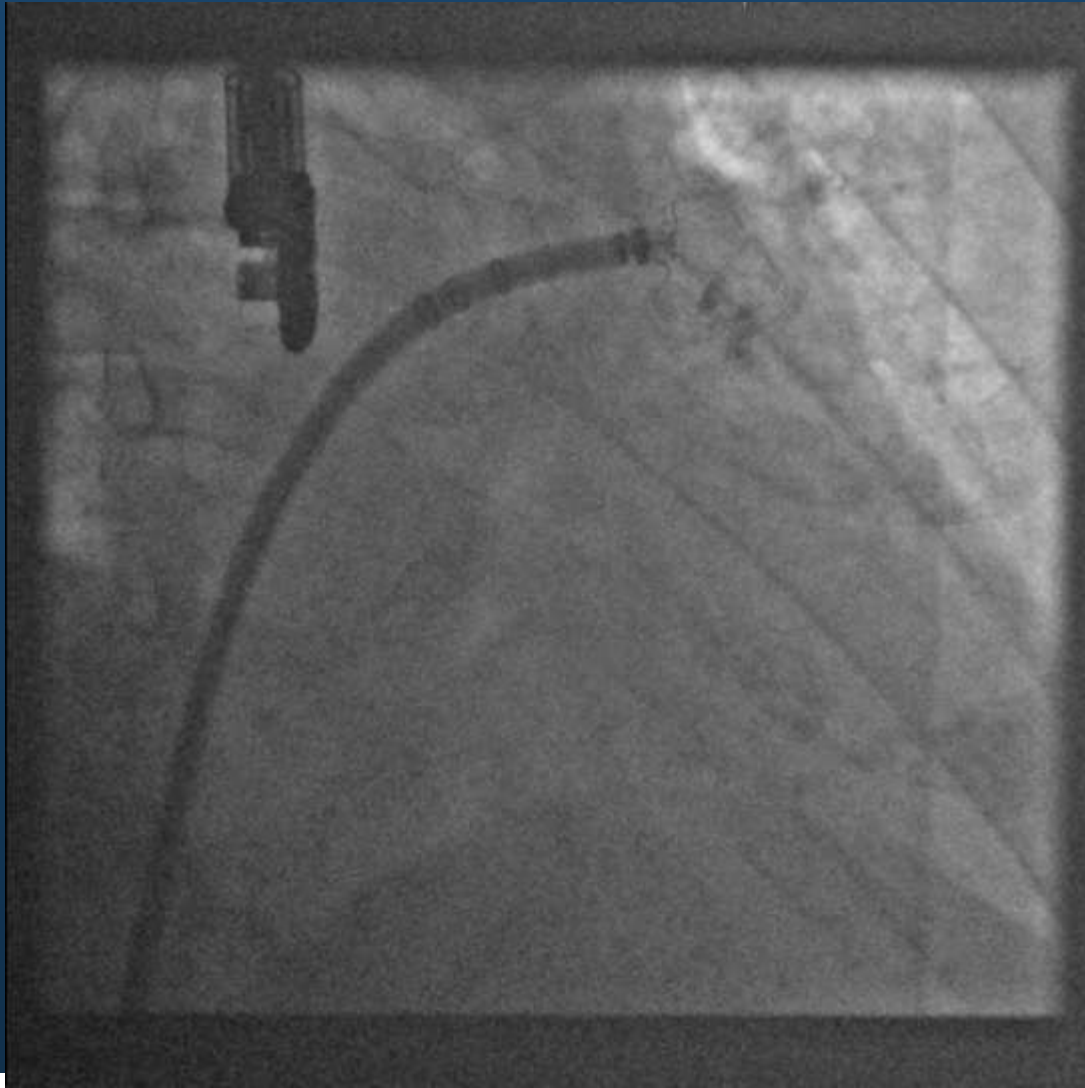


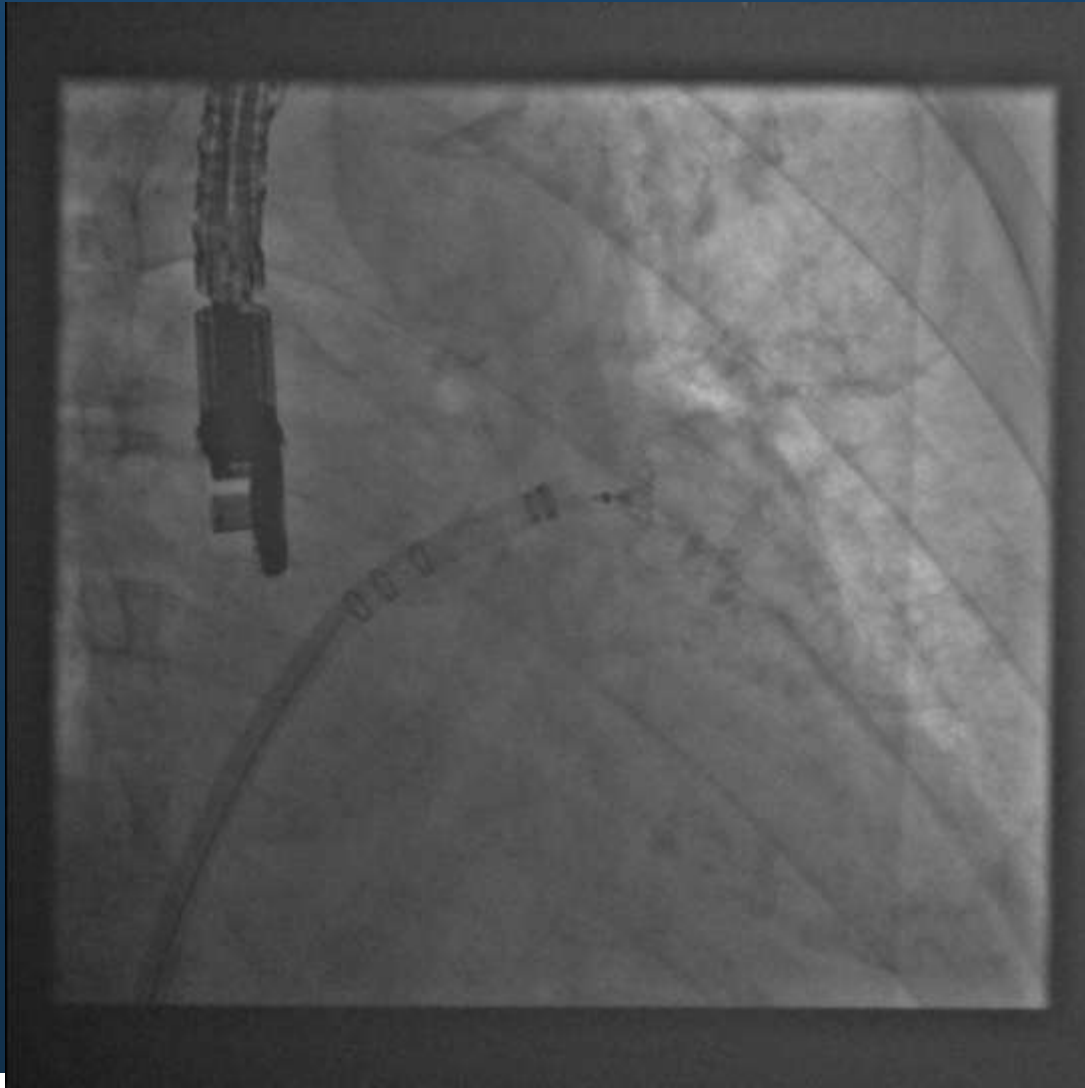


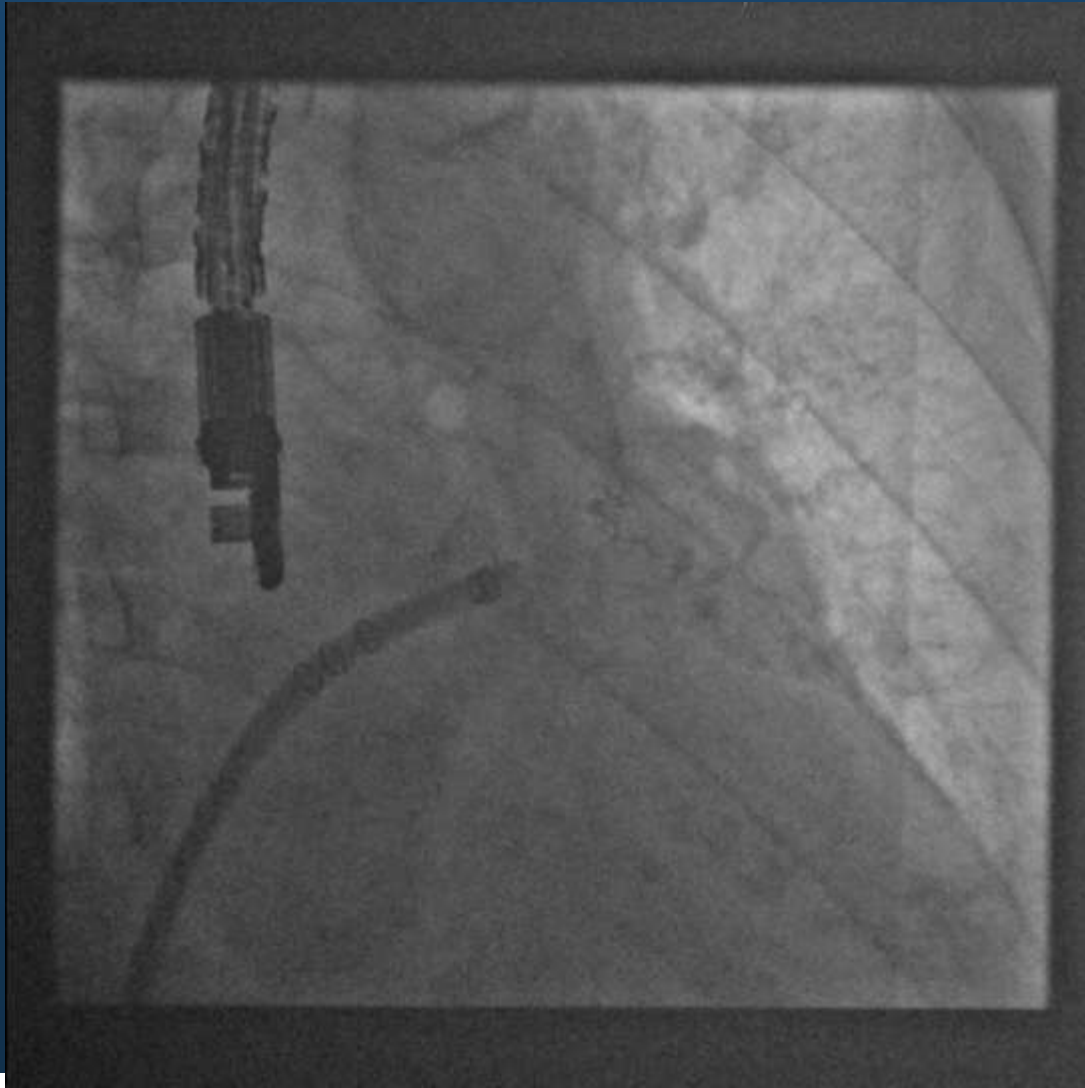




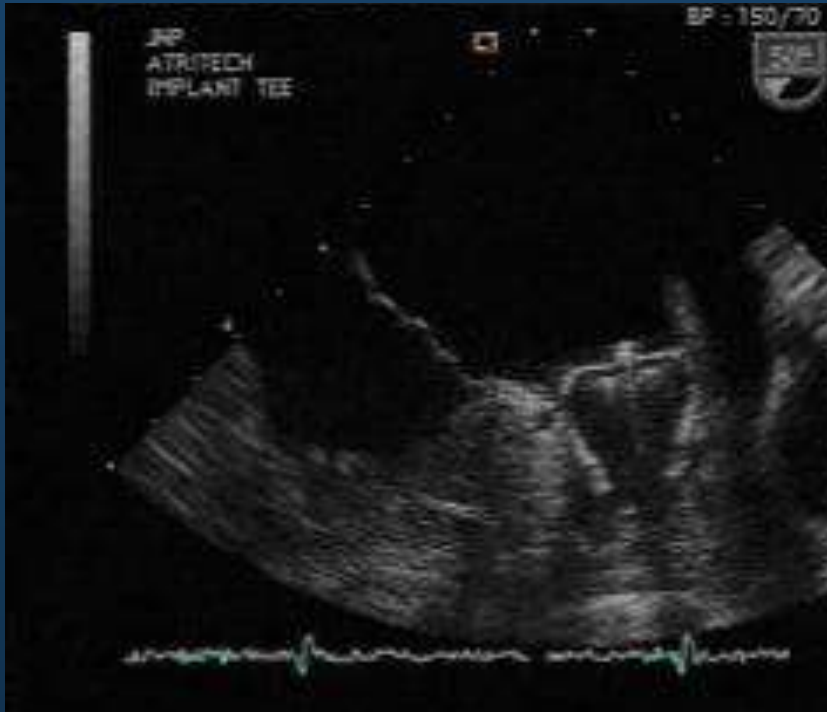






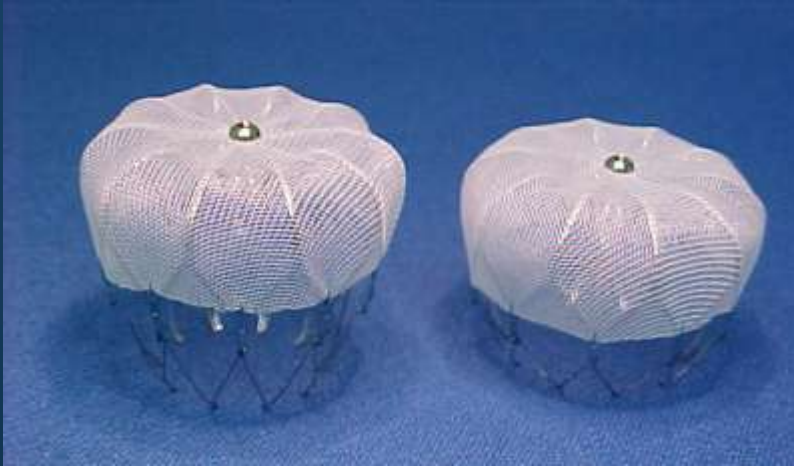


LA appendage – ensure occlusion



- TOE at 0 + 45 days
 - Size
 - Position
 - Seal
- Anticoagulants stopped at 6 weeks

Watchman – Protect AF

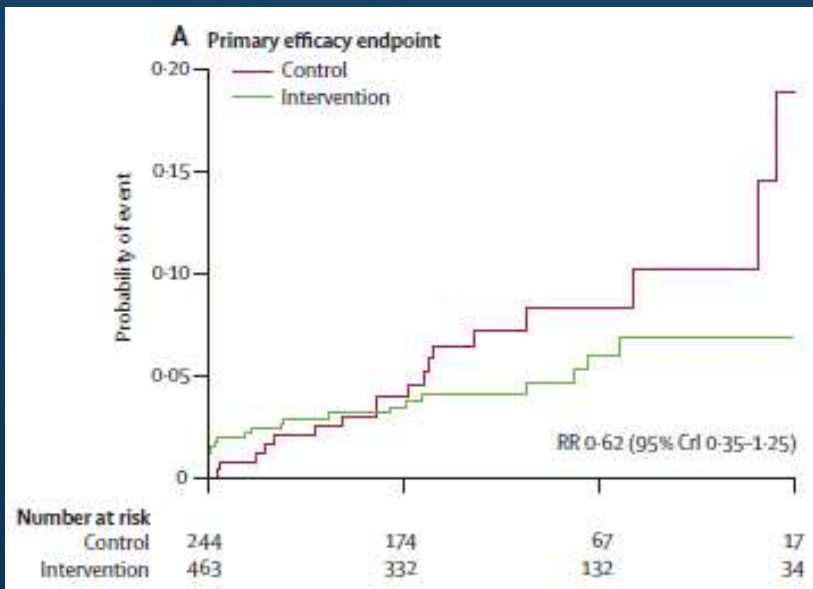


RANDOMISED CONTROLLED TRIAL

- n=707 (463 intervention, 244 warfarin)
- CHADS \geq 1
- Warfarin 45 days,
- aspirin/clopidogrel 6/12
- Endpoint:stroke/death/embolism
- Safety endpoint: IC haemorrhage/GI bleed/procedure complication

Holmes et al Lancet 2009; 374: 534–42

Protect AF - efficacy



	Watchman	Warfarin
Primary End Point	3.0	4.9
Ischaemic stroke	2.2	1.6
Haemorrhagic stroke	0.1	1.6
Death	0.7	2.7
Systemic embolism	0.3	0
PEP successfully treated	1.9	4.6
Event Rate per 100 patient years follow up		

Protect AF - safety

	Watchman	Wafarin
Primary safety event rate (Per 100 year follow up)	7.4	4.4
If successfully treated (Per 100 year follow up)	1.4	4.4
Tamponade	22 (4.8)	0
Major bleed	16 (3.5)	10 (4.1)
Procedural ischaemic stroke	5 (1.1)	0
Device embolisation	3 (0.6)	0
Haemorrhagic stroke	1 (0.2)	6 (2.5)
Other	2 (0.4)	0
N (%)		

Protect AF - limitations

- Short follow up
- Warfarin needed for 45 days
- Low risk group – 1/3 CHADS=1, 1/3 =2
- High procedure complication rate
- Assignment of treatment groups:
 - 10% intervention – warfarin
 - Intervention group 1/3 follow up either warfarin or aspirin/clopidogrel
 - Only 66% INR therapeutic
- Cost

NICE guidance

2006 IPG 181

- Safety and efficacy uncertain
- Only performed when medical therapy unsuitable
- Cardiac surgery on site
- Make outcomes available to CCAD

2010 IPG 349

- Efficacy established and low risk
- Multidisciplinary team to review and consider all options
- Cardiac surgery on site
- Technically challenging – need appropriate training
- Report problems to MHRA

Conclusions

- LAA occlusion is a viable alternative to warfarin but unanswered questions:
 - Is it alone sufficient to prevent stroke in AF?
 - How will it compare to warfarin in long term studies?
 - How will it compare to new anticoagulants?
 - Is it cost efficient?

New options

