




НОВИ ПЕРКУТАННИ ТЕХНИКИ ЗА ПРЕВЕНЦИЯ НА ИНСУЛТ ПРИ ПРЕДСЪРДНО МЪЖДЕНЕ

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Предсърдно мъждене и инсулт

- ПМ е най-честата сърдечна аритмия- около 0,5 % от общата популация
- 5 пъти по-висок риск от инсулт при ПМ

Инсултът е най-честата причина за инвадизиране и третата по-честота причина за смърт

87% от инсултите са емболични

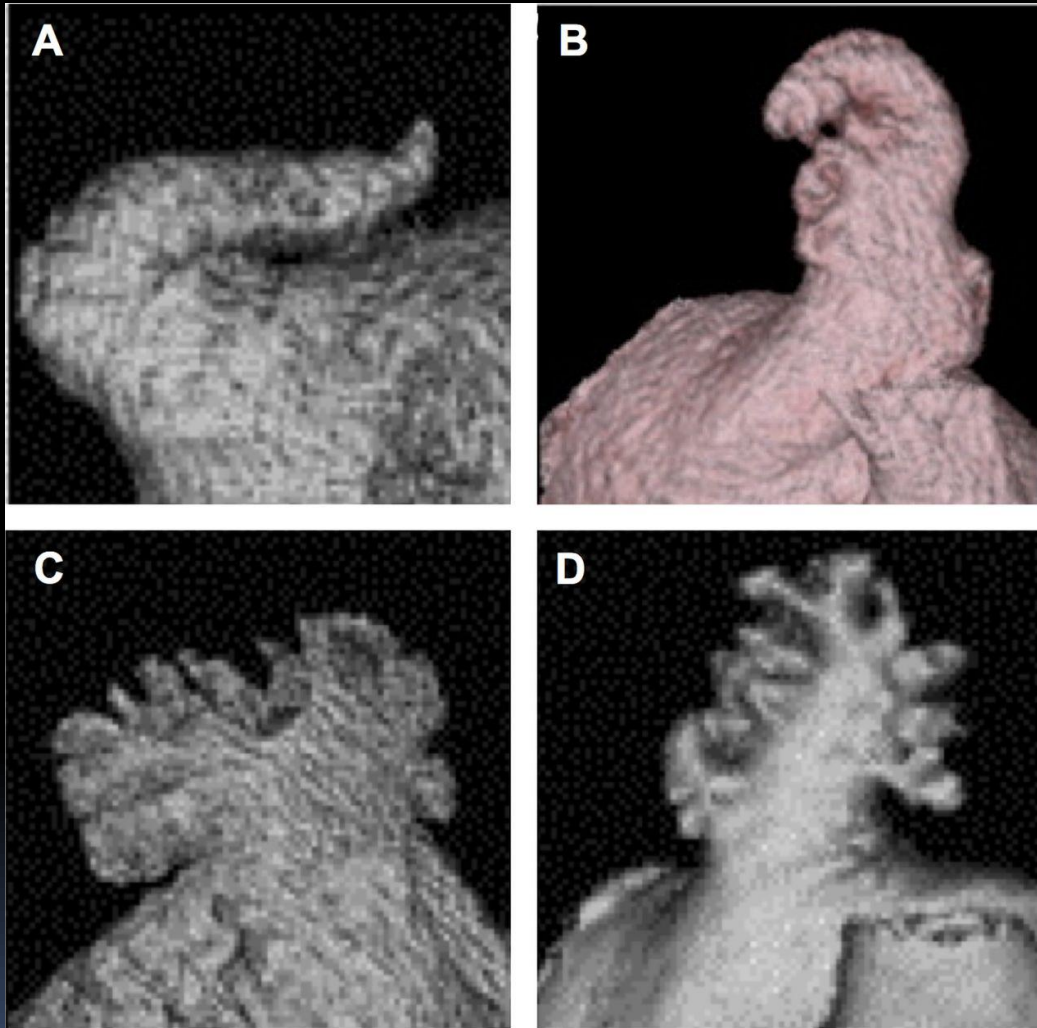
Патология на инсулта при ПМ без клапна патология

- Липса на контракция води стаза на кръв в ухото на ЛП
- Най вероятна причина за инсулт – емболия от АЛП
- 90% тромба е в АЛП
- Риска зависи и от морфологията на ухото, CHADS₂, възраст, обем на ЛП, фиброза на предсърдието определена с ЯМР

Blackshear: Ann Thoracic Surg 61, 1996

Johnson: Eur J Cardiothoracic Surg 17, 2000

Fagan: Echocardiography 17, 2000

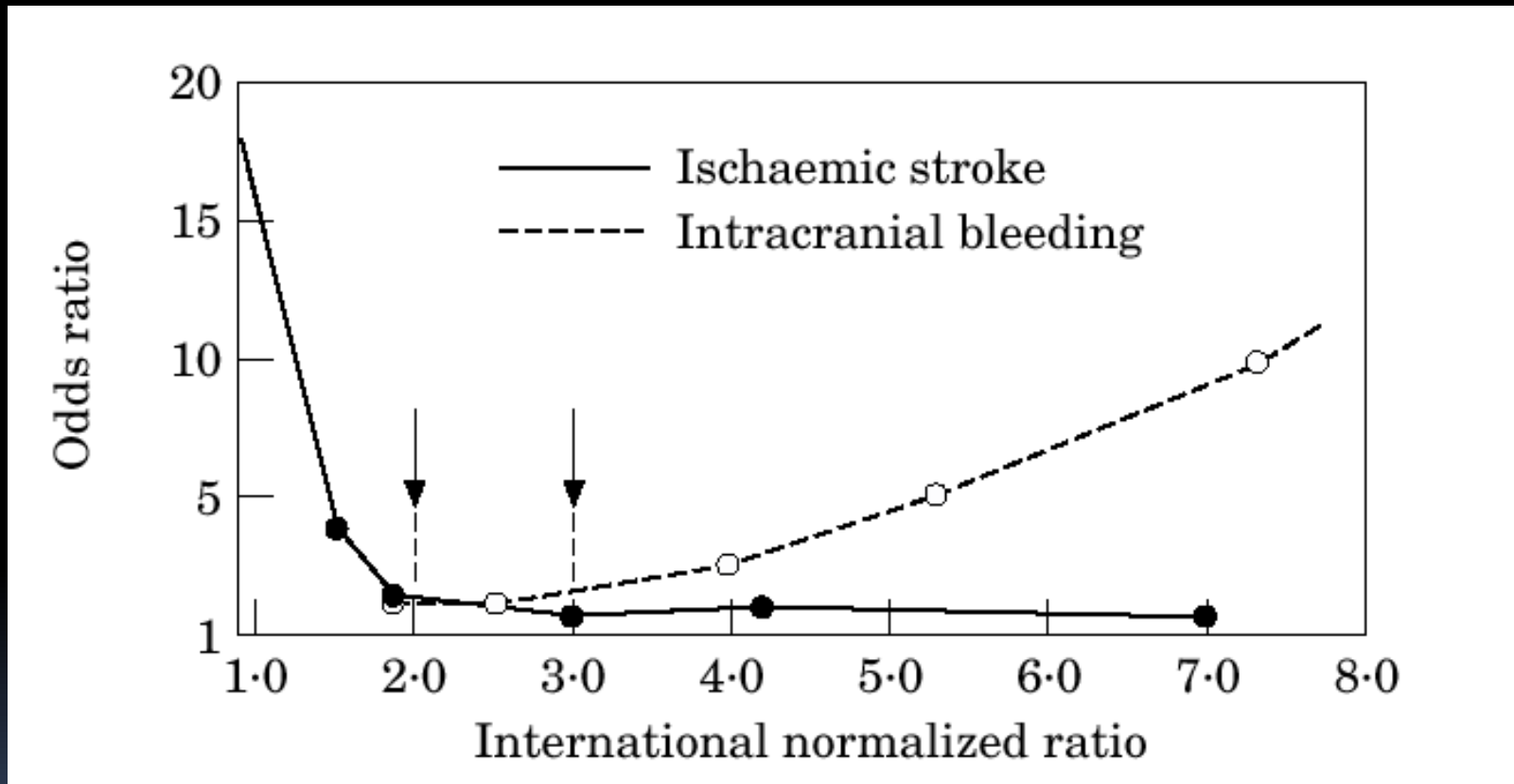


De Backer O et al. Open Heart 2014;1:e000020

Лечение

- Златен стандарт- антикоагуланти (Синтром)
 - тесен терапевтичен прозорец (INR 2-3)
 - необходимост за често мониториране
 - 60% в терапевтичен прозорец; 29 % под 2 INR; 15% над 3,0 INR (SPORTIF trial)
 - около 1/3 не получават Warfarin, поради непоносимост или нисък комплаянс на пациентите (Stafford and Singer, Arch Int Med, 1996)

Narrow anticoagulant therapeutic window

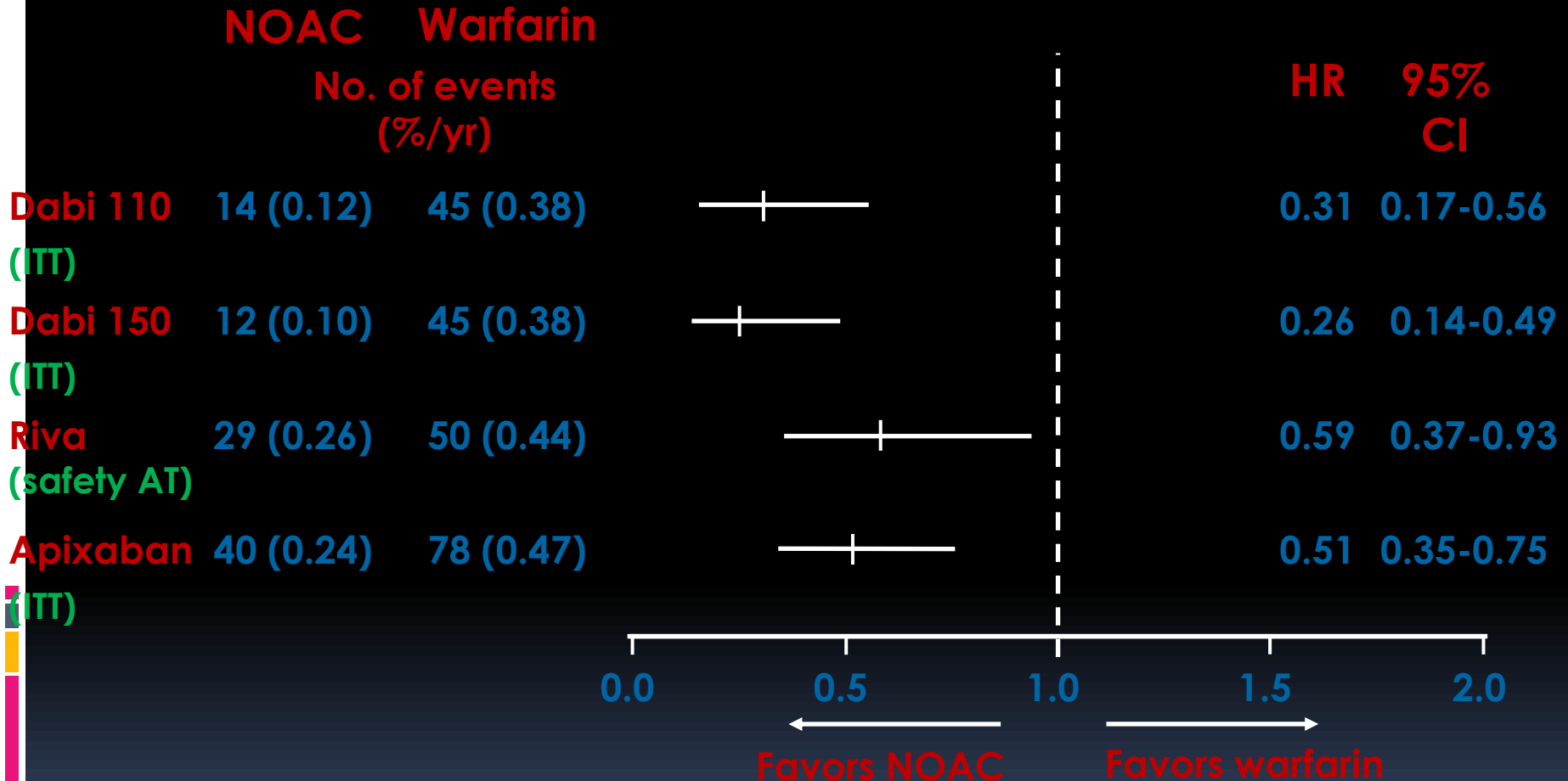


Stroke risk increases at $\text{INR} < 2$
Bleeding risk increases at $\text{INR} > 3$

Ефикасност и безопасност на НОАС в проведените проучвания

	RELY ¹	ROCKET ²	ARISTOTLE ³
Sample size	18,113	14,266	18,201
Stroke + systemic embolism (primary)	519 (1.44 %/yr)	575 (2.25 %/yr)	477 (1.44 %/yr)
Major ISTH bleeding (primary safety)	1163 (3.25%/yr)	781 (3.5%/yr)	789 (2.61%/yr)
Intracranial bleeding	150 (0.42%/yr)	139 (0.60%/yr)	174 (0.57%/yr)
All-cause death	1371 (3.84%/yr)	1214 (4.70%/yr)	1272 (3.73%/yr)
Cardiovascular death	880 (2.47%/yr)	Not reported	652 (1.91%/yr)
Myocardial infarction	270 (0.76%/yr)	227 (1.00%/yr)	192 (0.57%/yr)
Rate of discontinuation	NOAC: 21% W: 16.6%	NOAC: 23.9% W: 22.4%	NOAC: 25.3% W: 27.5%

Хеморагичен инсулт



ITT: Intention to Treat – AT: as treated.

Not head to head comparison – For illustrative purpose only – adapted from references 1-4

1. Connolly et al. NEJM 2009; 361: 1139-51.
2. Connolly et al. NEJM 2010; 363: 1875-6.
3. Patel et al. NEJM 2011; 365: 883-91.
4. Granger et al. NEJM 2011; 365: 981-92.

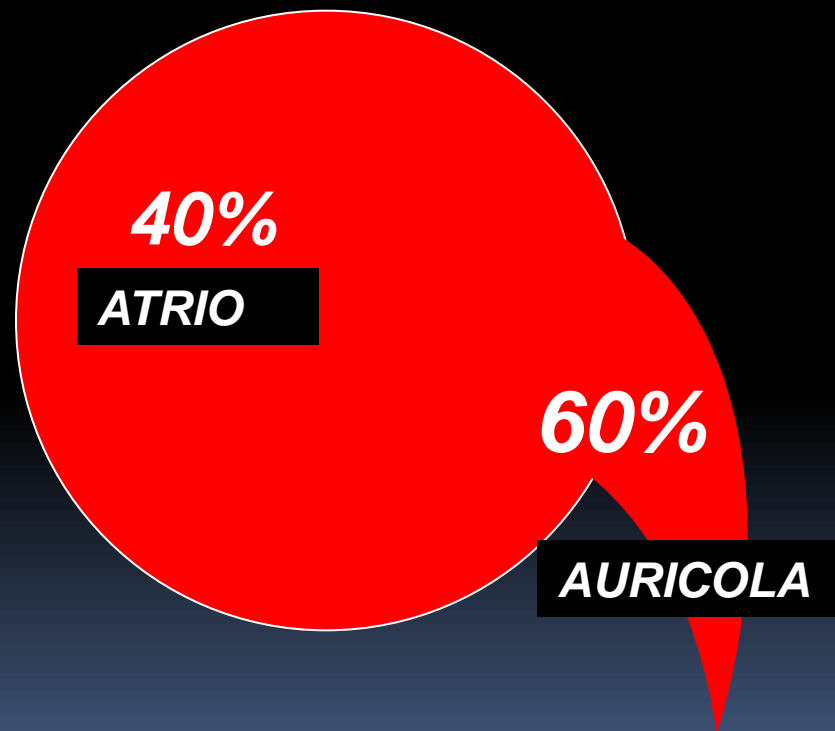
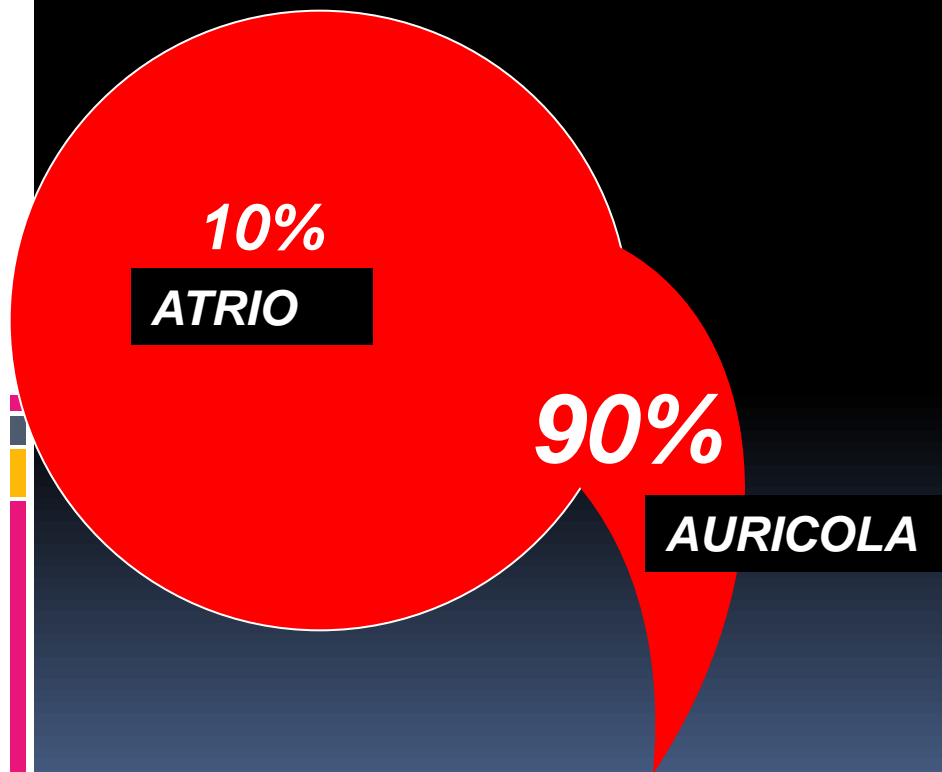
За всички антикоагуланти

- По дефиниция :
 - Трябва да се дават цял живот
 - имат риск от кървене!!!
- Кървенето се повишава с възрастта
- В някои случаи антикоагулантите трябва да бъдат спирани (хирургични интервенции)
- Добре е антикоагулантите да не се предписват при възрастни пациенти
- Добре е антикоагулантите да не се предписват при млади пациенти, поради дългия период на приемане- катетърна аблация

Предилекционни места за образуване на тромб при пациенти с предсърдно мъждене

Неревматично

Ревматично



Нефармакологични подходи за превенция на тромбообразуване в АЛП

- Аблация на ПМ – успеха е лимитиран от тежестта на фиброзата в ПЛ
- Хирургично изолиране/ексцизия на АЛП

Успеха е зависим от използваната техниката

Изисква стернотомия

- Перкутанна оклузия на АЛП

LAA SURGICAL OBLITERATION

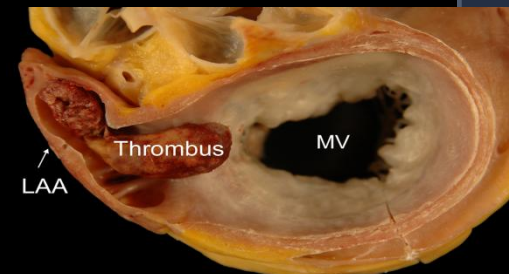
During surgery for mitral stenosis “amputation of the left atrial appendage is recommended to reduce the likelihood of postoperative thromboembolic events”

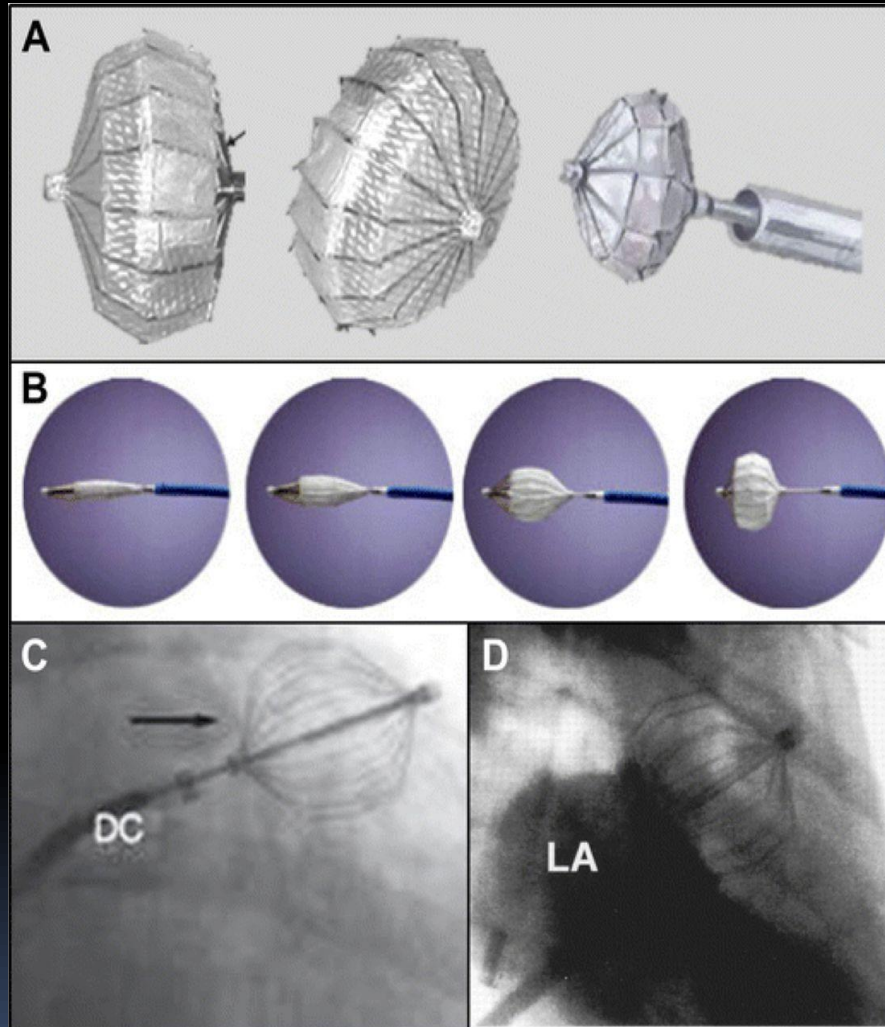
ACC/AHA 2006 Guidelines for valvular heart disease

Role of left atrial appendage obliteration in stroke reduction in patients with mitral valve prosthesis: a transesophageal echocardiographic study

“An incomplete LAA ligation during surgery of mitral valve replacement considered together with the absence of LAA ligation, increased risk of embolism at follow-up (up to 11.9 x)”

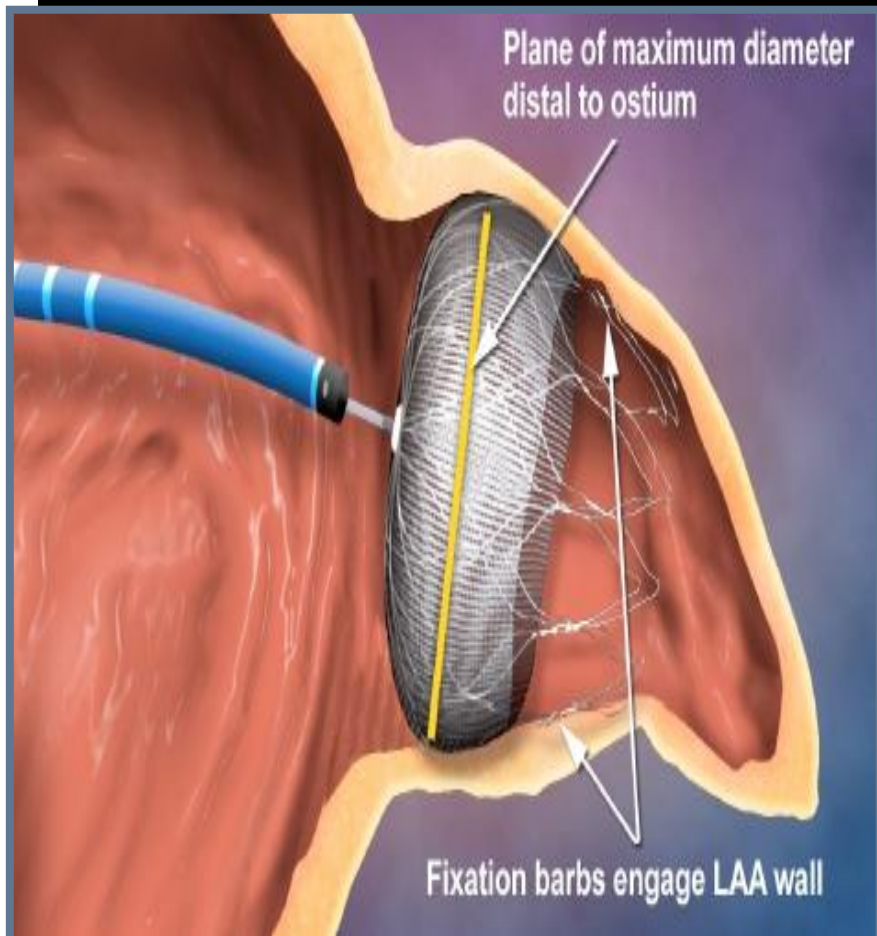
Garcia-Fernandez MA et al, *J Am Coll Cardiol* 2003;42:1253-8



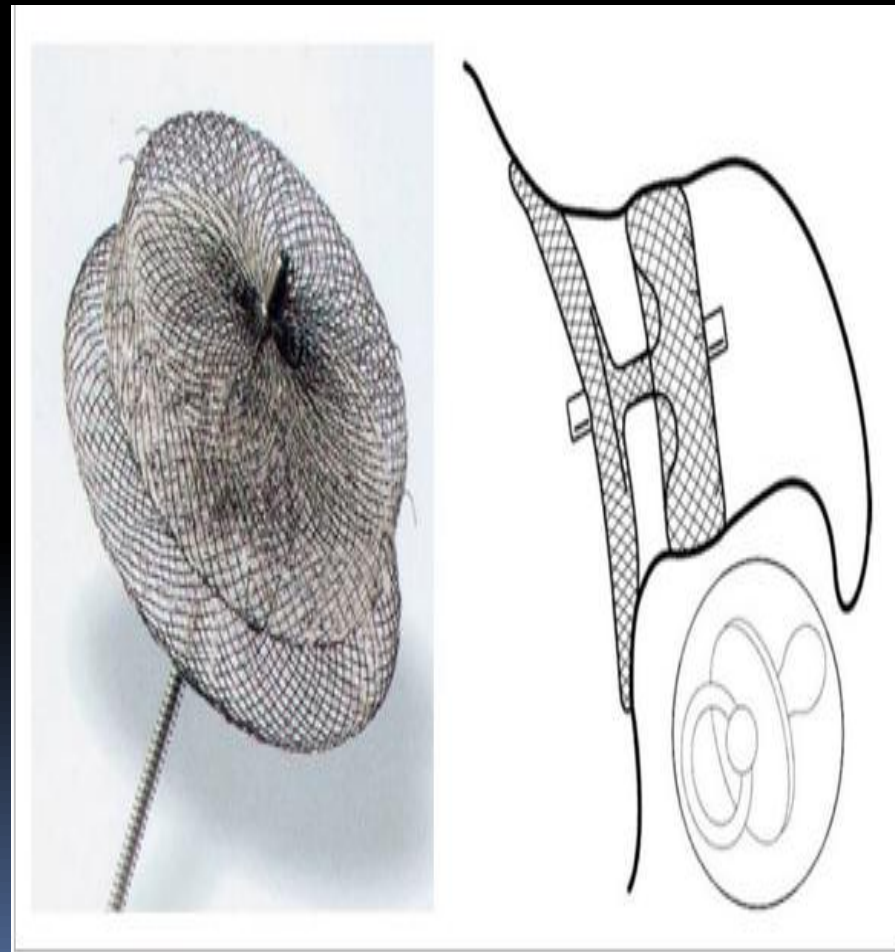


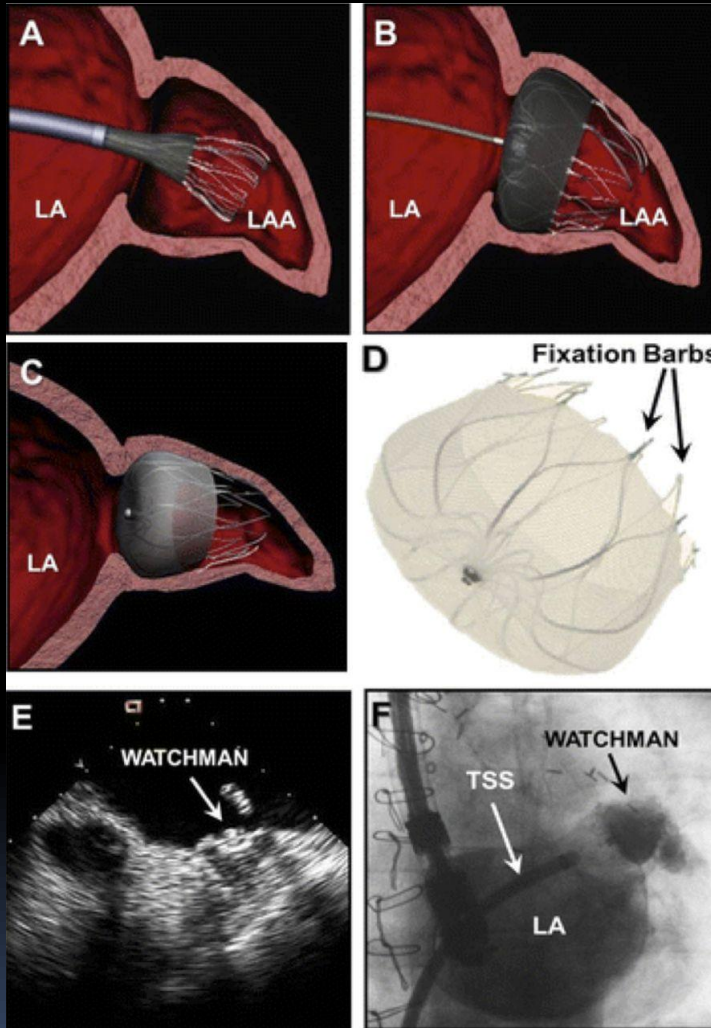
De Backer O et al. Open Heart 2014;1:e000020

Watchman



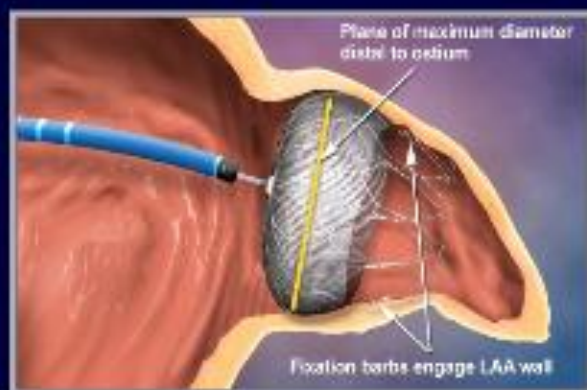
Amplatzer





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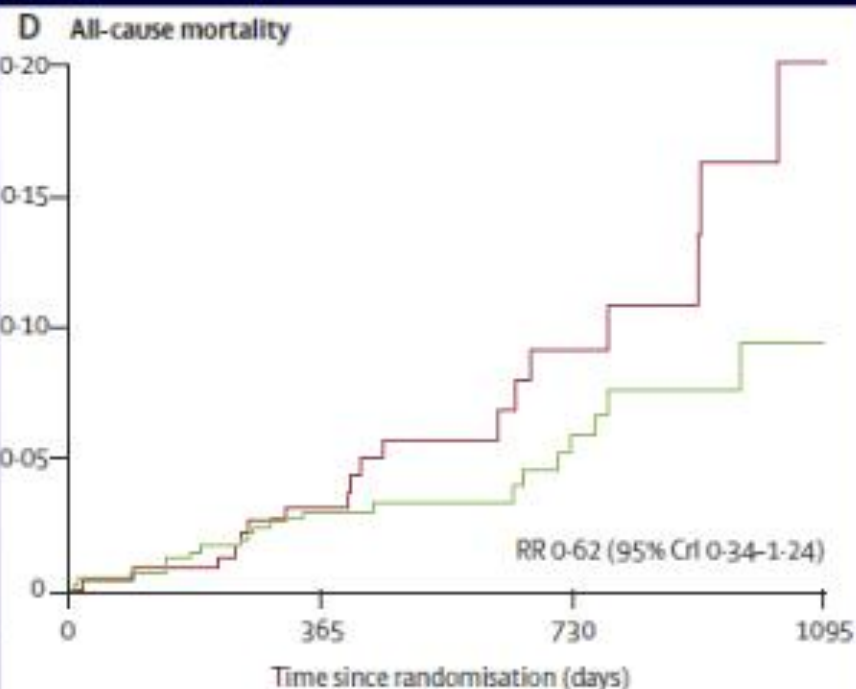
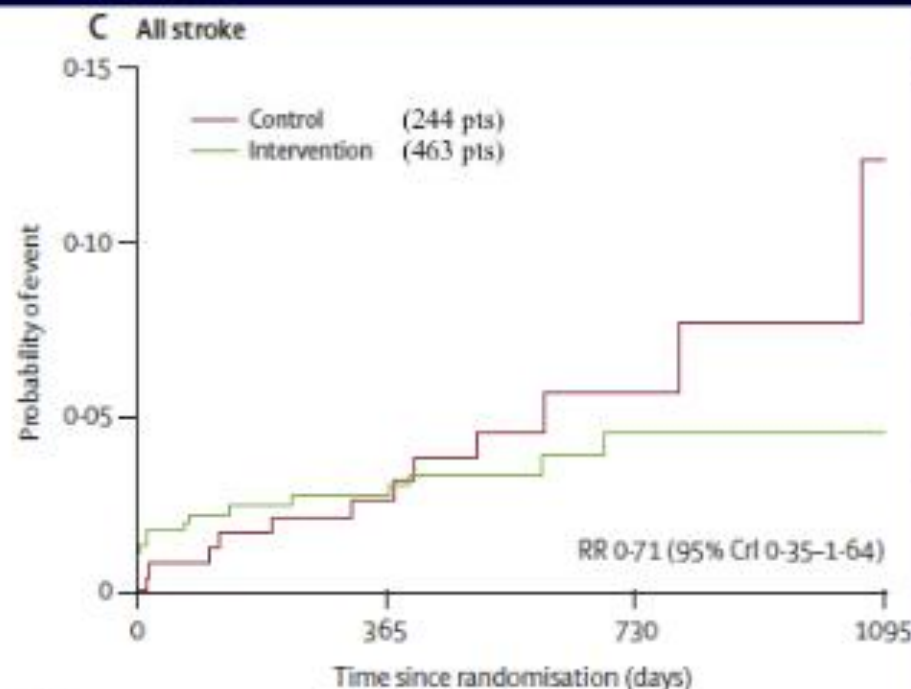
PROTECT AF Randomized Trial with WATCHMAN LAA Closure Device



Update ACC 2010 (23 months mean FU)

- Relative risk for stroke - 31%
- Relative risk for other complications + 1.6

Boston Scientific – Atritech
Plymouth, MN



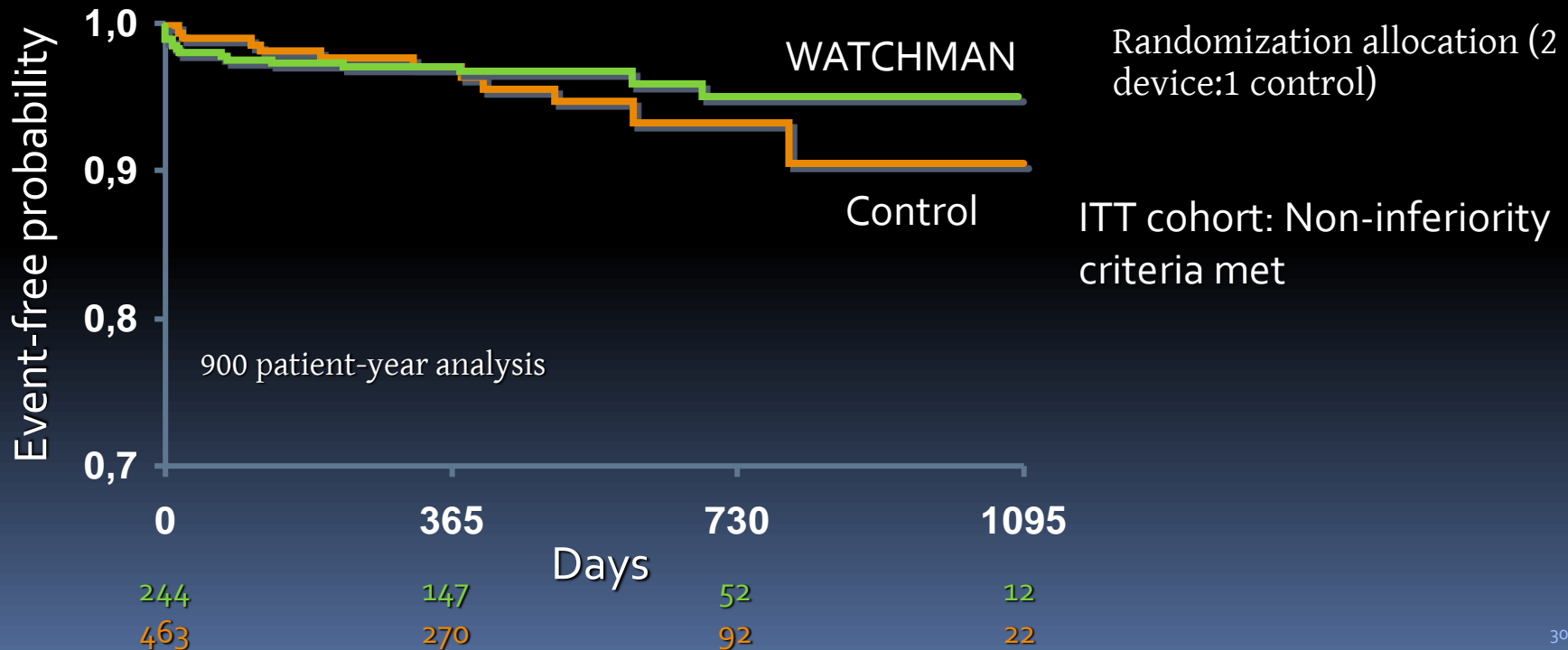
Number at risk

	0	365	730	1095
Control	244	174	67	17
Intervention	463	332	132	34

	0	365	730	1095
Control	244	176	68	17
Intervention	463	337	136	35

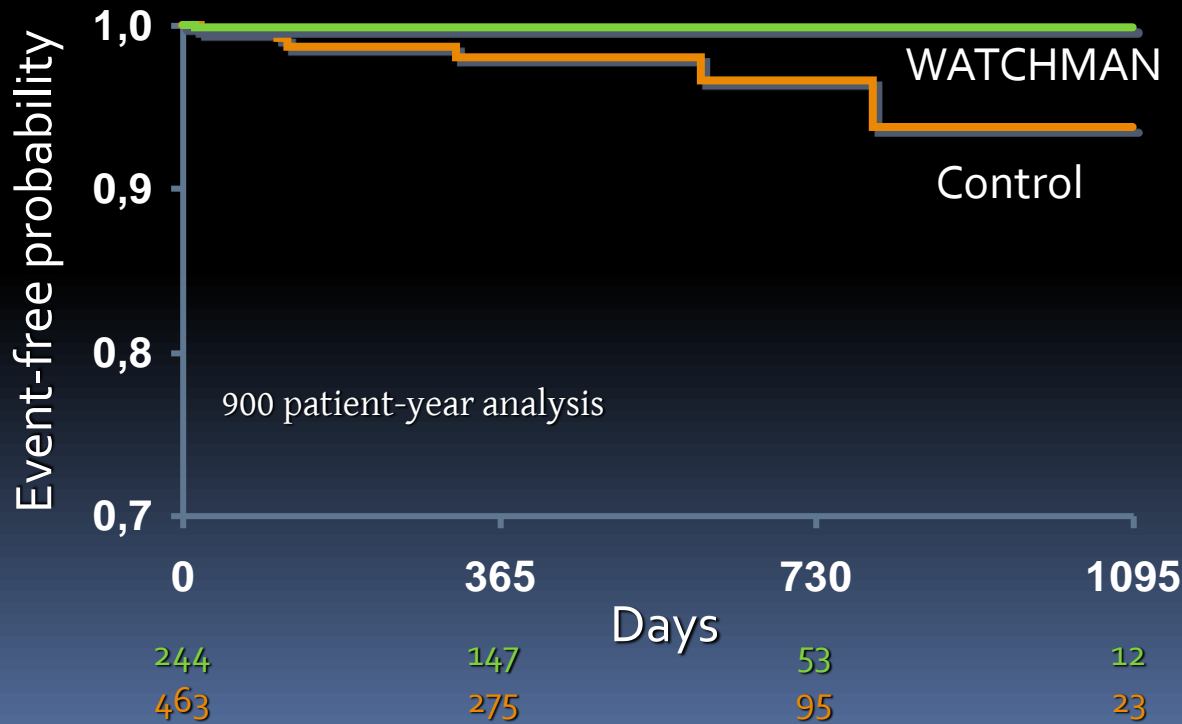
Intent-to-Treat All Stroke

Cohort	Device			Control			Posterior probabilities		
	Events eve	Total pt-yr	Rate (95% CI)	Events (no.)	Total pt-yr	Rate (95% CI)	RR (95% CI)	Non- inferiority	Superiority
600 pt-yr	14	409.3	3.4 (1.9, 5.5)	8	223.6	3.6 (1.5, 6.3)	0.96 (0.43, 2.57)	0.927	0.488
900 pt-yr	15	582.9	2.6 (1.5, 4.1)	11	318.1	3.5 (1.7, 5.7)	0.74 (0.36, 1.76)	0.998	0.731



Intent-to-Treat Hemorrhagic Stroke

Cohort	Device			Control			Posterior probabilities		
	Events (no.)	Total pt-yr	Rate (95% CI)	Events (no.)	Total pt-yr	Rate (95% CI)	RR (95% CI)	Non-inferiority	Superiority
600 pt-yr	1	416.7	0.2 (0.0, 0.9)	4	224.7	1.8 (0.5, 3.9)	0.13 (0.00, 0.80)	0.998	0.986
900 pt-yr	1	593.6	0.2 (0.0, 0.6)	6	319.4	1.9 (0.7, 3.7)	0.09 (0.00, 0.45)	>0.999	0.998



Randomization allocation (2 device:1 control)

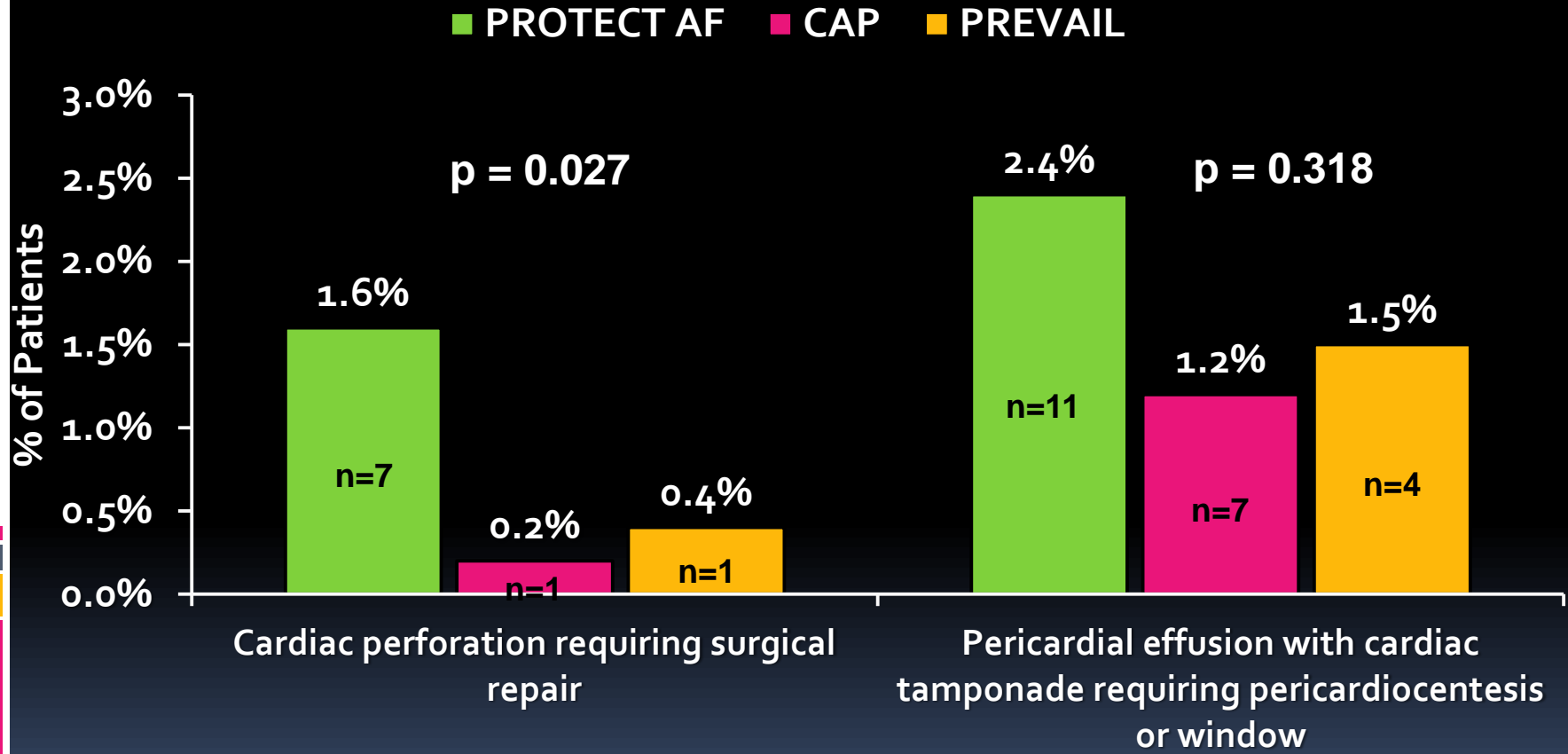
ITT cohort: Superiority criteria met

PROTECT AF TRIAL

- In PROTECT AF:
 - **Noninferiority** for all strokes – 26% lower in device group
 - **Superiority** for hemorrhagic stroke – 91% lower in device group
 - **Noninferiority** for mortality rate – 39% lower rate in device group

In PROTECT AF, there are **early safety adverse events**, specifically pericardial effusion; these events have **decreased over time**

Pericardial Effusions Requiring Intervention



PROTECT AF and CAP data from Reddy, VY et al. *Circulation*. 2011;123:417-424.

LAA Closure with Amplatzer Cardiac Plug in AF: Initial European Experience

Results

In 137 of 143 pts, LAA occlusion was attempted, and successfully performed in 132 (96%).

Major complications in 10 (7.0%) pts: 3 ischemic stroke; 2 device embolization, both percutaneously recaptured; 5 clinically significant pericardial effusions.

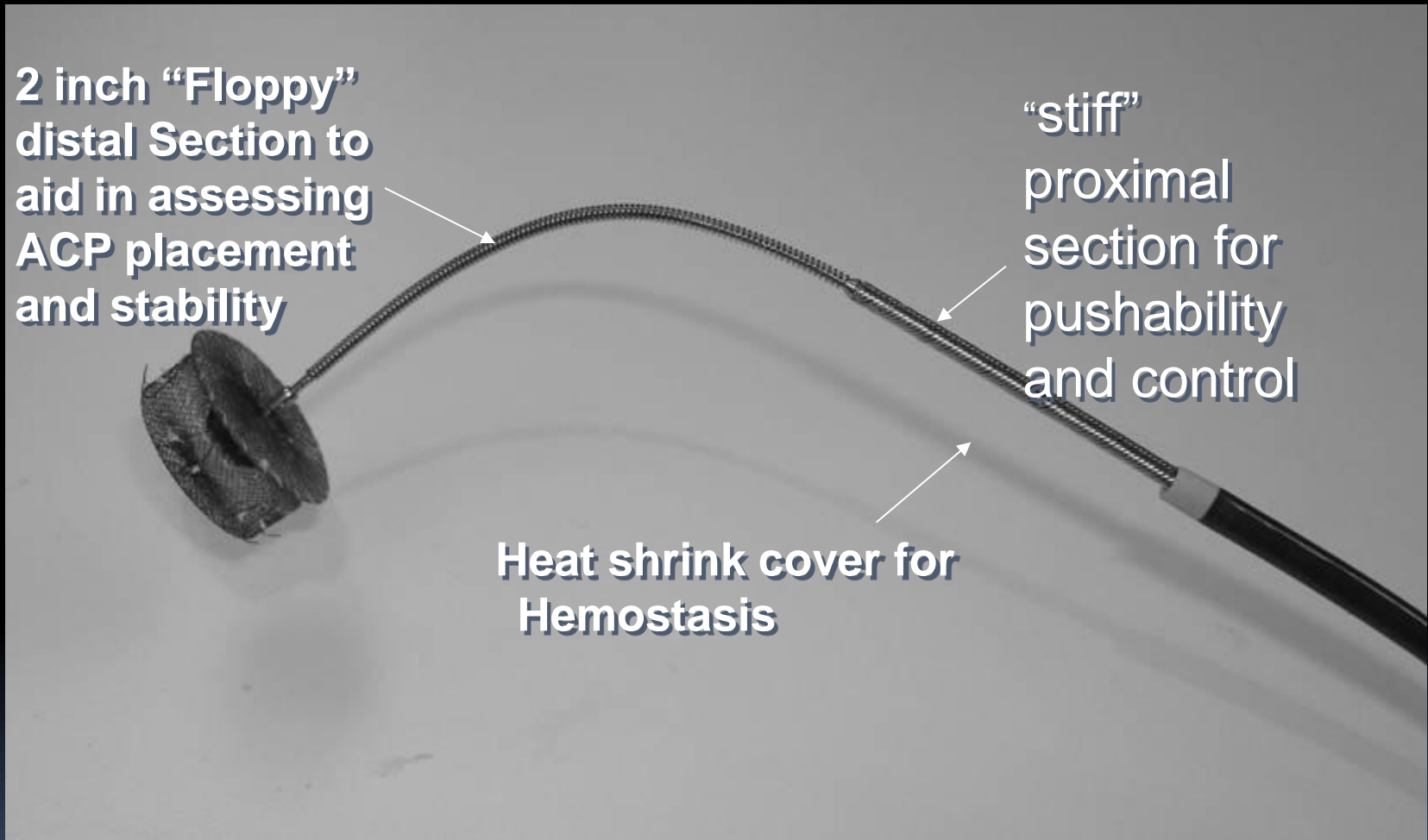
Minor complications: 4 pericardial effusions, 2 transient myocardial ischemia, 1 loss of the device in the venous system.

Flexible Delivery Cable

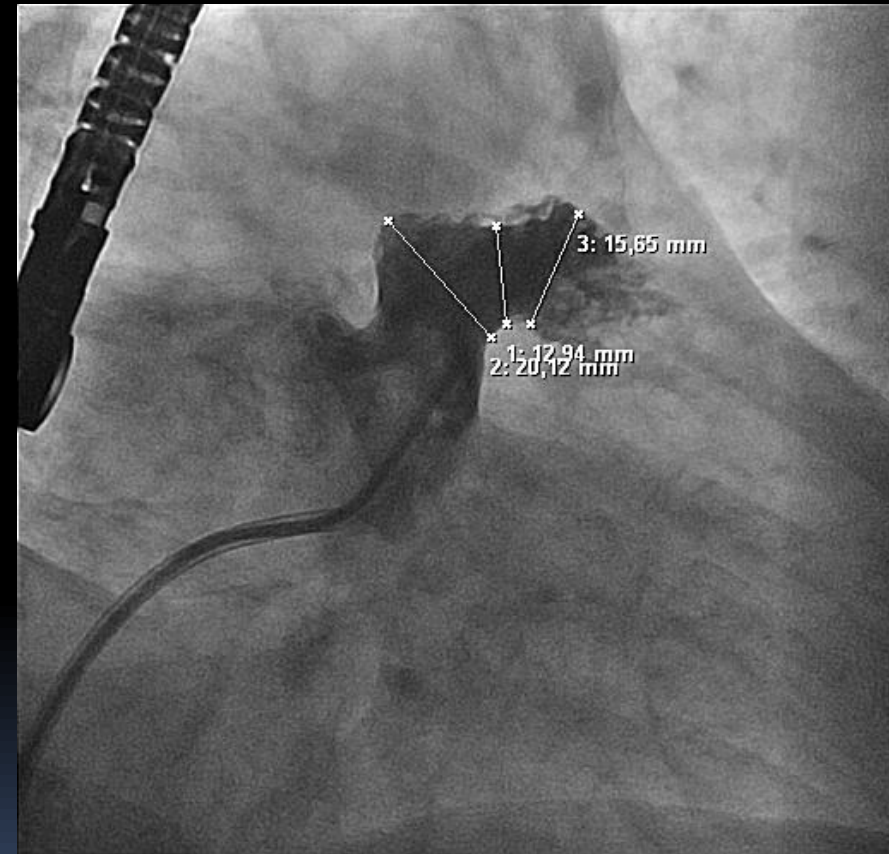
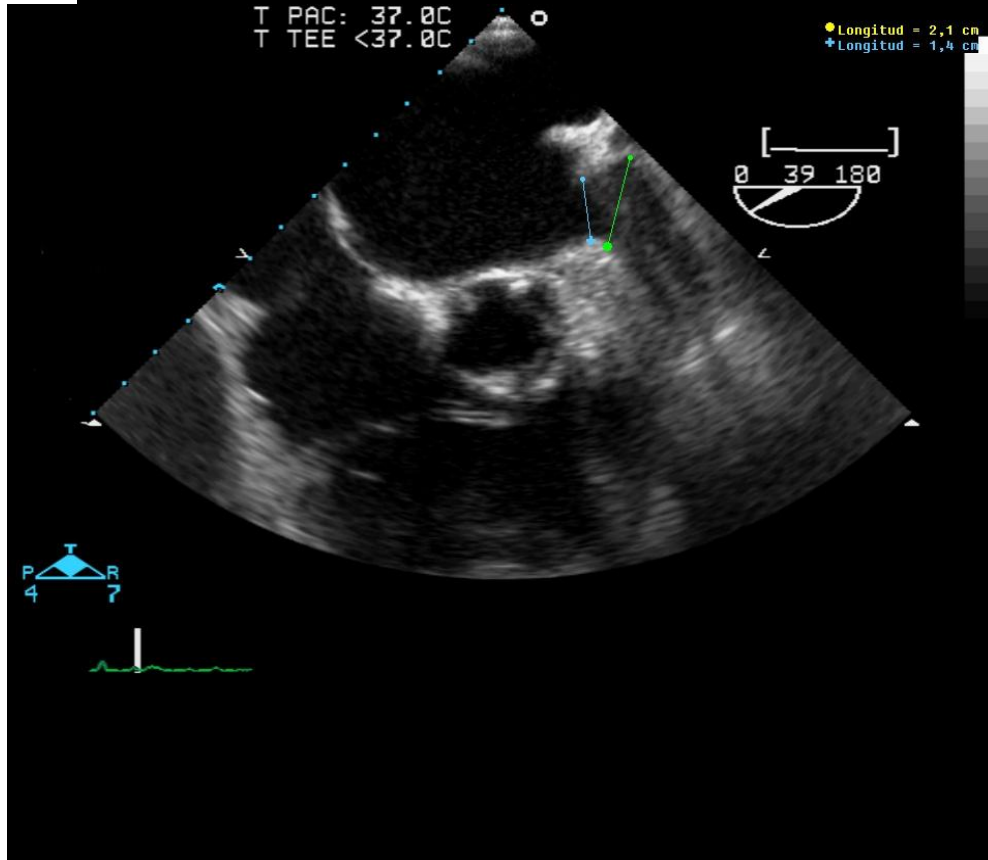
2 inch "Floppy" distal Section to aid in assessing ACP placement and stability

"stiff" proximal section for pushability and control

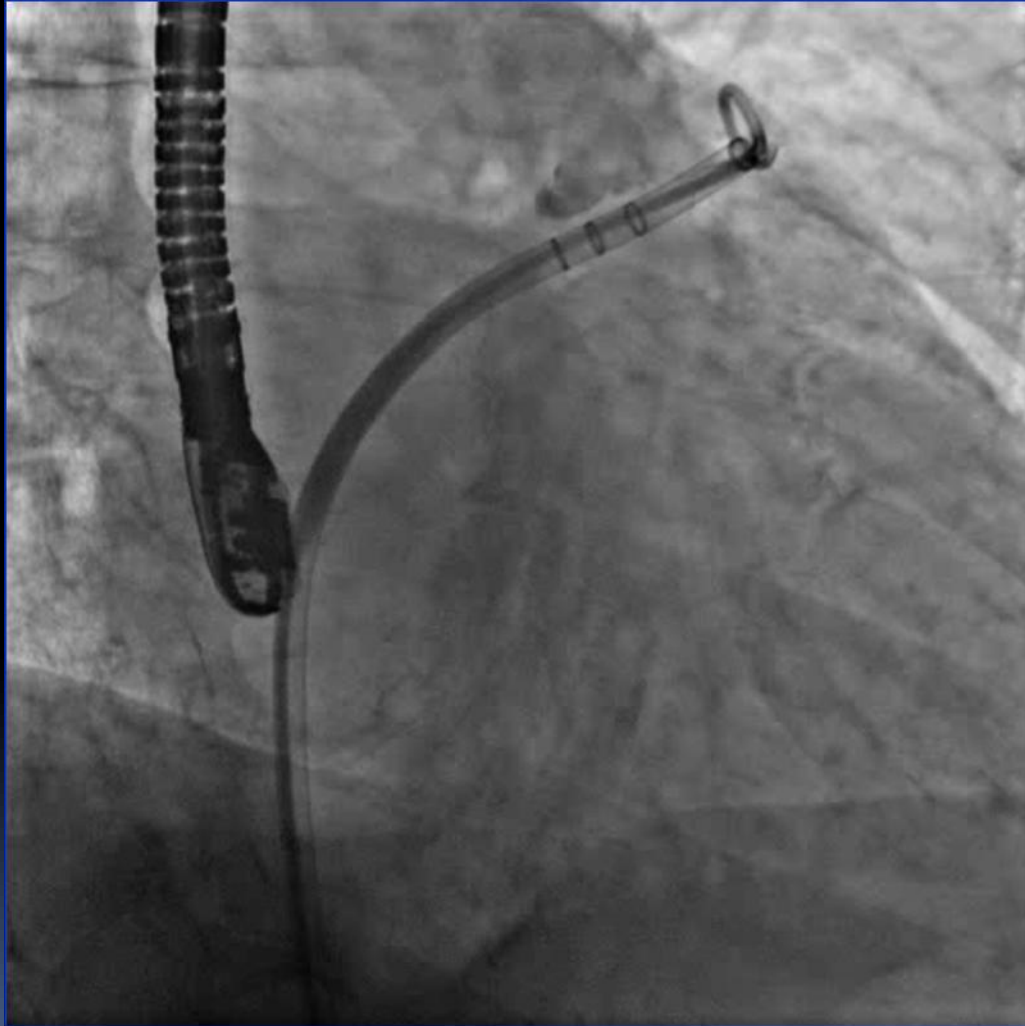
Heat shrink cover for Hemostasis



Pre-Implant Echo and Angio Measurement



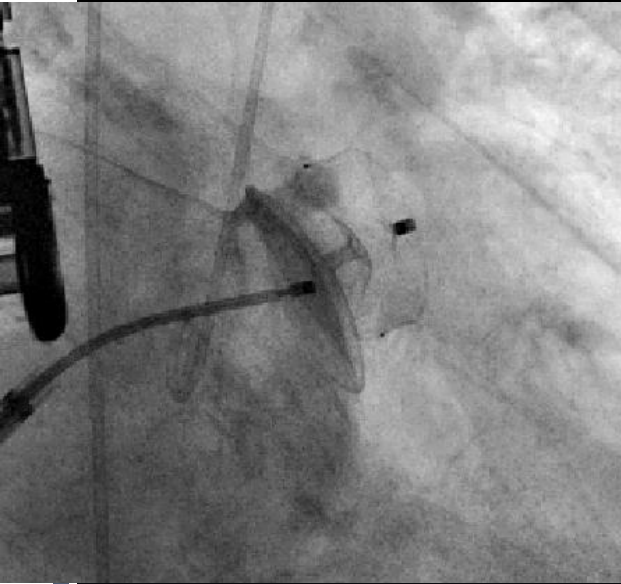
Access into LAA and angiogram RAO caudal (Echo 135°)



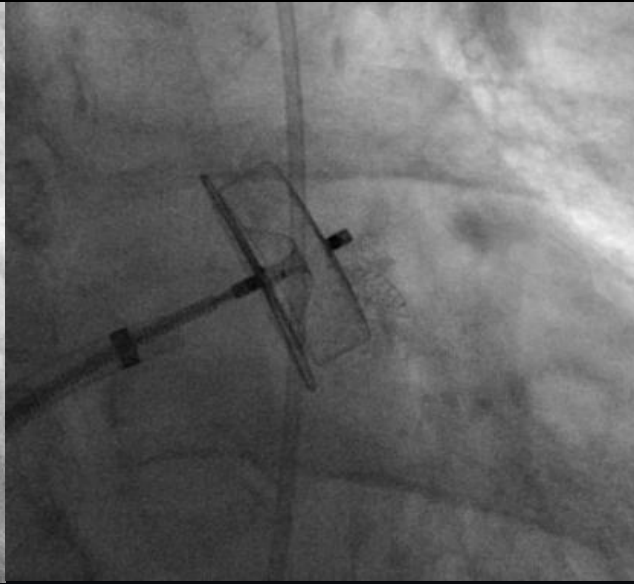
- Pig tail advanced into LAA
- Advance sheath over pig tail
- LAA angio (Right Cranial view)
- Sizing of Device
- 20% larger than max diameter

Configuration of Proper Device Size

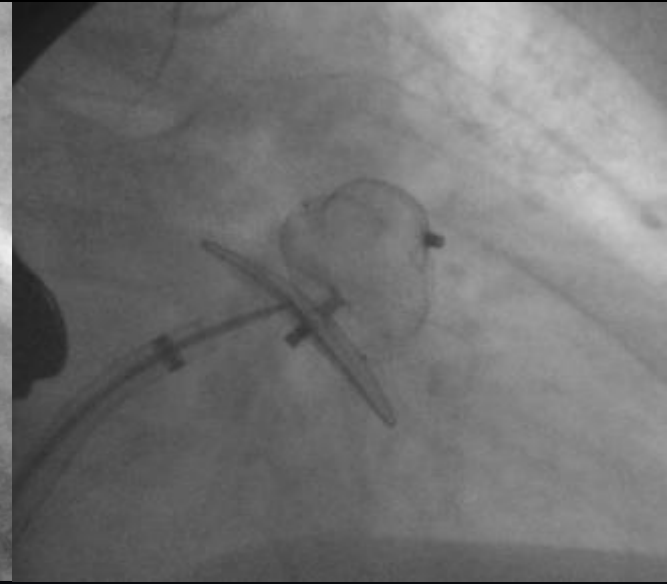
Proper Size



Under Size



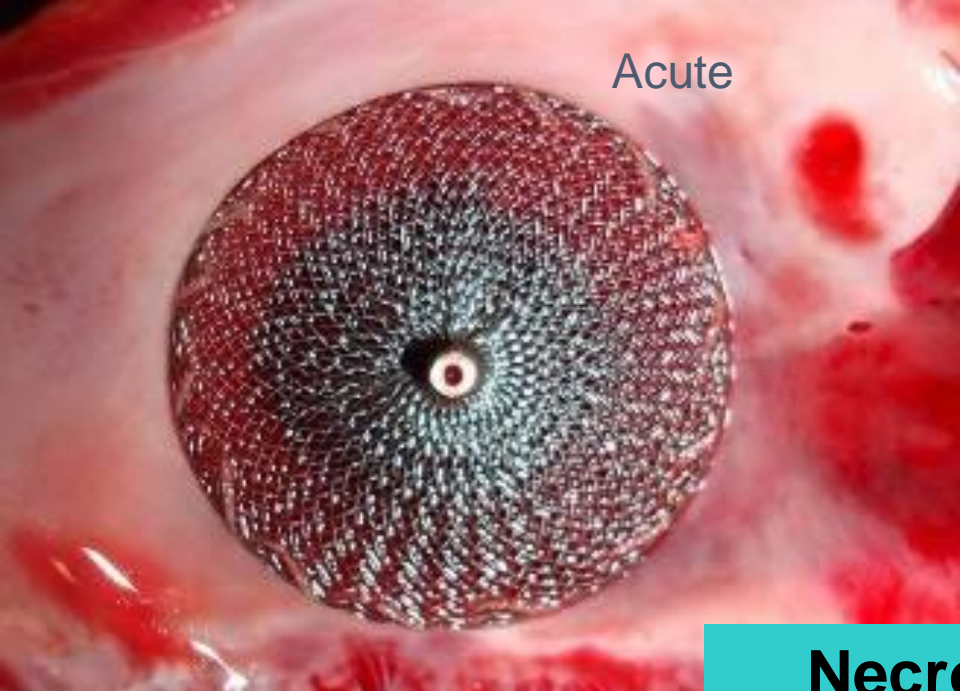
Over Size



“Tire” shaped-- Proper tension on the device by the LAA

“Square” shaped – No tension on the device from the LAA wall

“Strawberry” shaped – the device is being squeezed

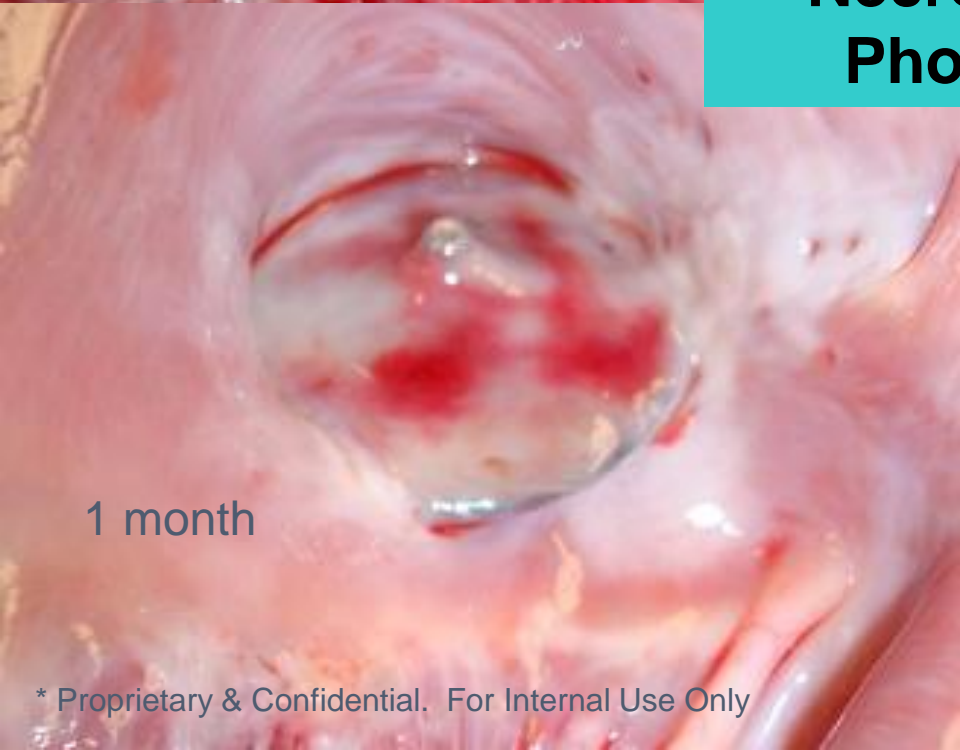


Acute



2 days

**Necropsy
Photos**



1 month



3 months

Заключение

- Лечението с антикоагуланти е ефективно, но в някои случаи може да бъде неоптимално или рисково
- В PROTECT AF и Prevail trials (RCTs) се установи, че WATCHMAN device е сравним с warfarin
- В PROTECT AF Prevail trials хеморагични инсулт е сигнификантно по-малко в групата с имплантирано устройство.
 - При наличие на хеморагичен инсулт, риска от смъртен изход се повишава

Кога да затворим АЛП?

ПМ без клапен порок, висок риск от емболичен инцидент

- Контраиндикации за ОАКТ
- Висок риск от кървене ОАКТ
- Лош комплајнс към медикаменти?

Усложнения на оклузия АЛП

1. Тампонада < 1%
2. Инсулт
3. Остатъчен шънт

Могат да бъдат сведени до минимум с прокторска програма и натрупване на опит