

Watchman Device For LAA Closure:

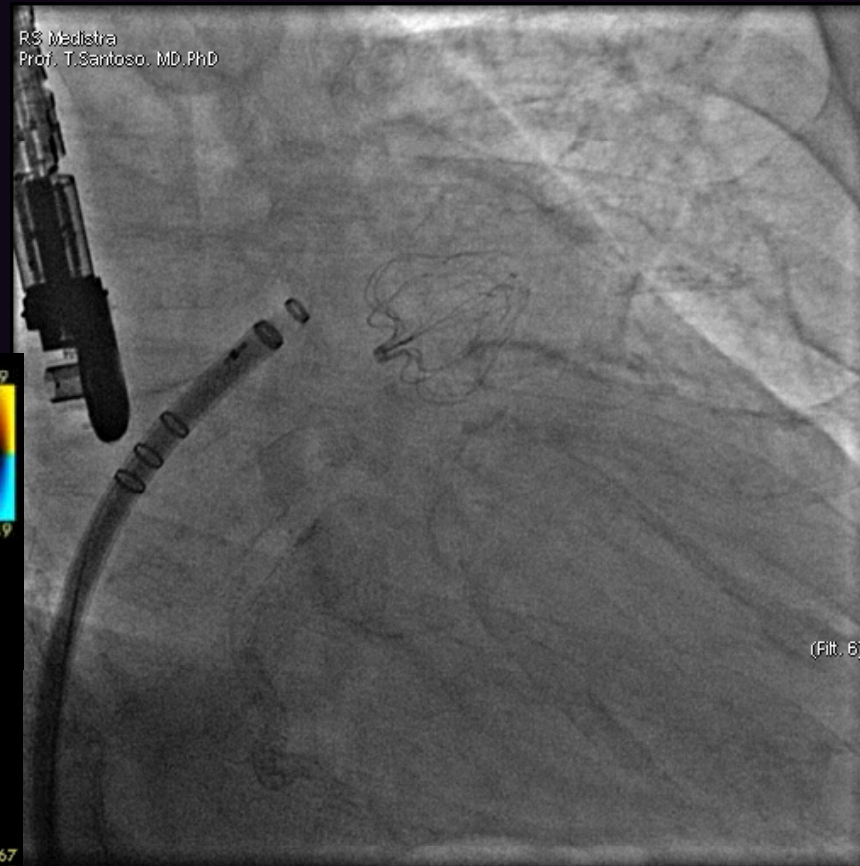
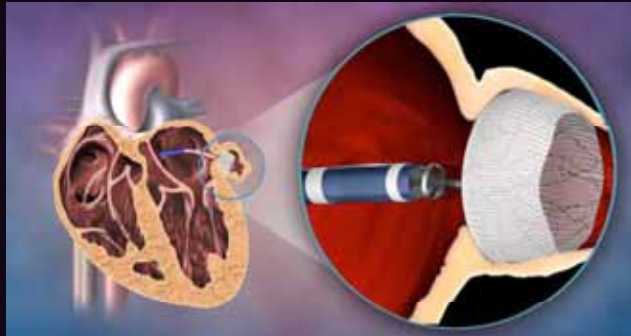
1. A Good Transseptal Puncture Is The Prerequisite For Success
2. Single center experience



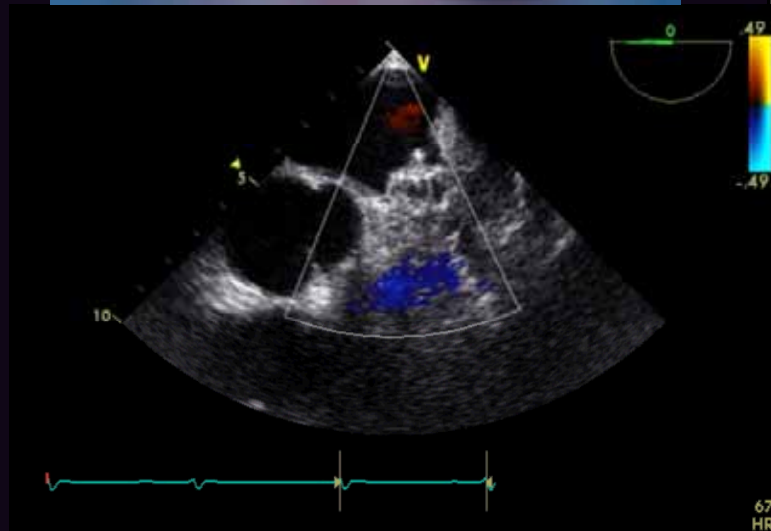
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Left Atrial Appendage (LAA) Closure



TEE



Fluoro

LAA Closure Involves Transseptal Puncture (TSP)

Why should it be correctly performed ?:

- A poorly positioned TSP will result in difficulty maneuvering the device in the LA
- Inappropriate TSP may lead to complications

Appropriate Location During Transseptal Puncture Will Ease The Procedure & Prevent Tamponade

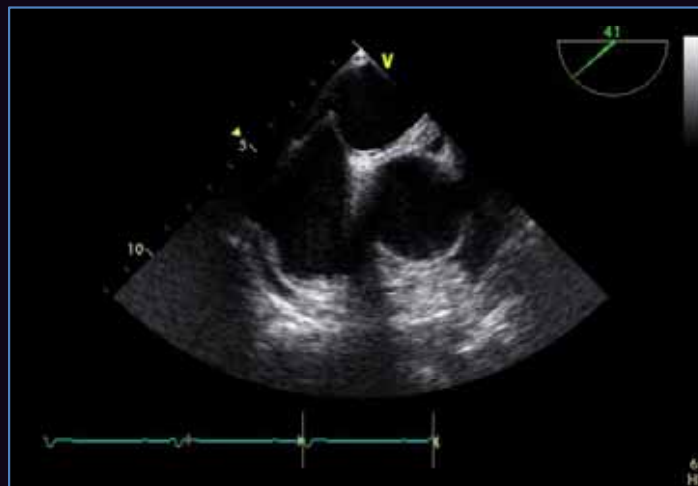
Fluoroscopy : AP or RAO 20° & LAO 90°

TEE : **essential !!** (*midfossa & posterior*)

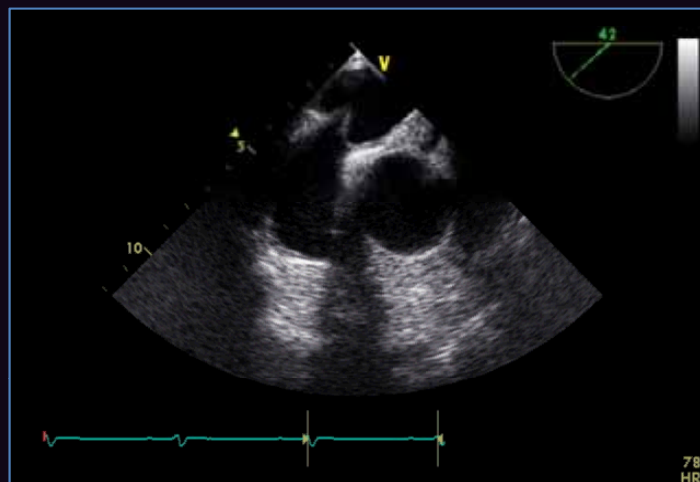
Bicaval view, 90-100°



Short axis view, 35-50°



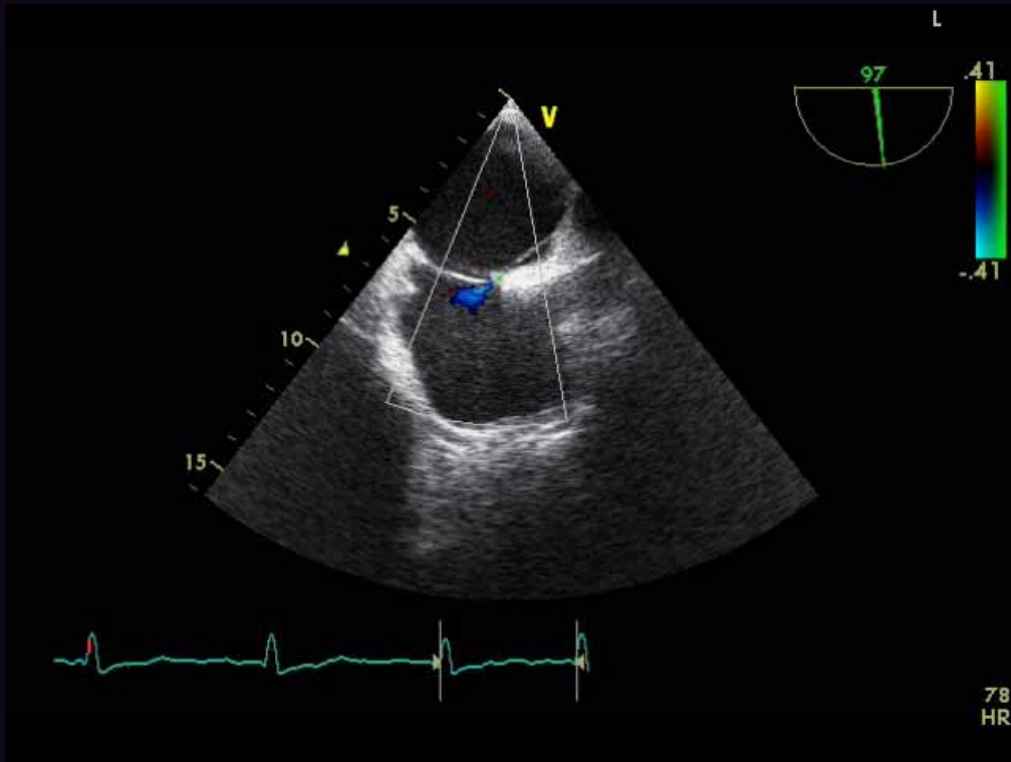
The sheath/needle tip is indicated by **IAS tenting**.



Avoid excessive tenting.

Use of **stylet** or **back end of a coronary guide wire** may help penetration. If the IAS is very thick & resistant, **electrocoagulation** may also help

Special Situations Of Transseptal Puncture (1): Patent Foramen Ovale



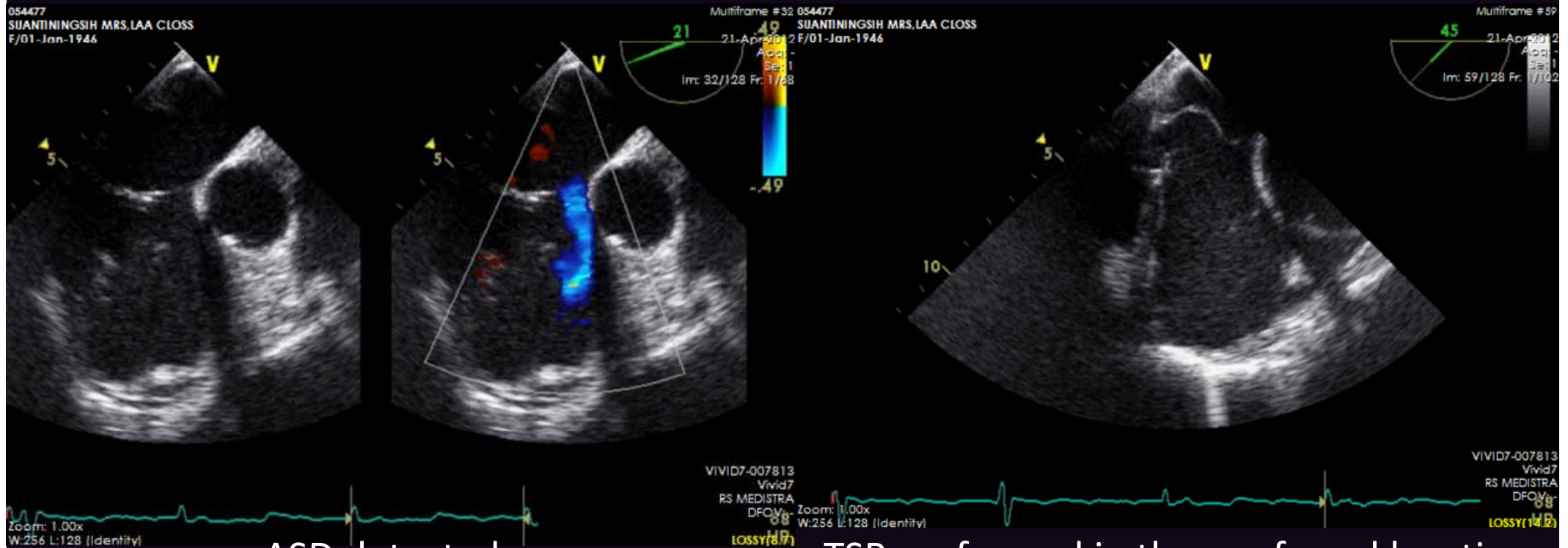
Stretched PFO with L-R shunting

- May **bias the needle** superiorly & may limit steering of catheter/access system.
- Also, with PFO or floppy IAS, the **needle may slide out** of position (difficult to create tenting).

- Tiny wire dilator or back end of coronary GW may help.
- Use greater curve at the TS needle.

Special Situations Of Transseptal Puncture (2):

ASD

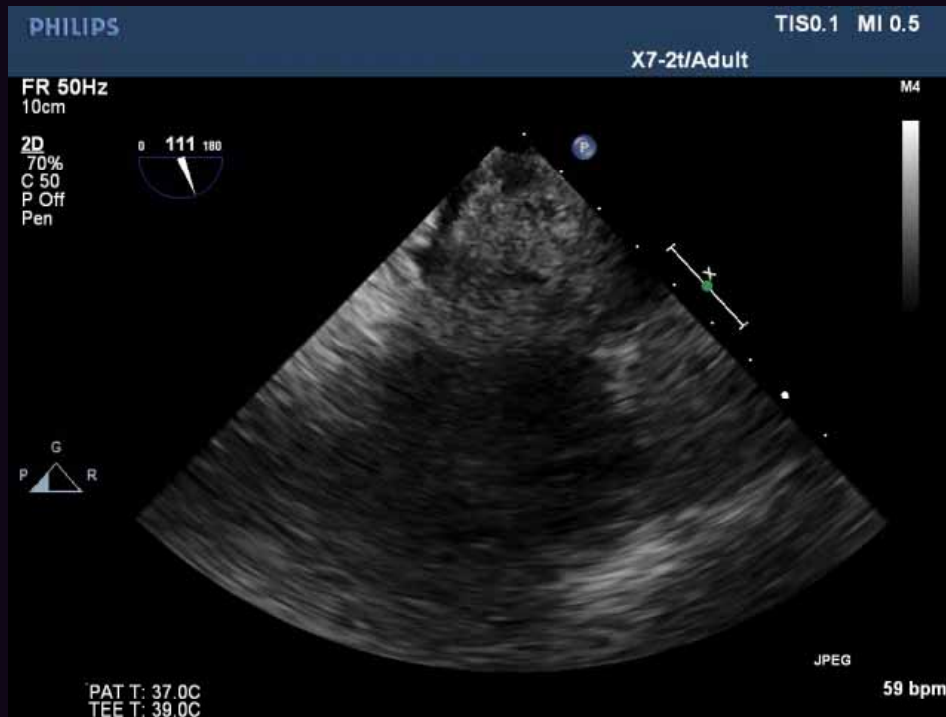


ASD detected

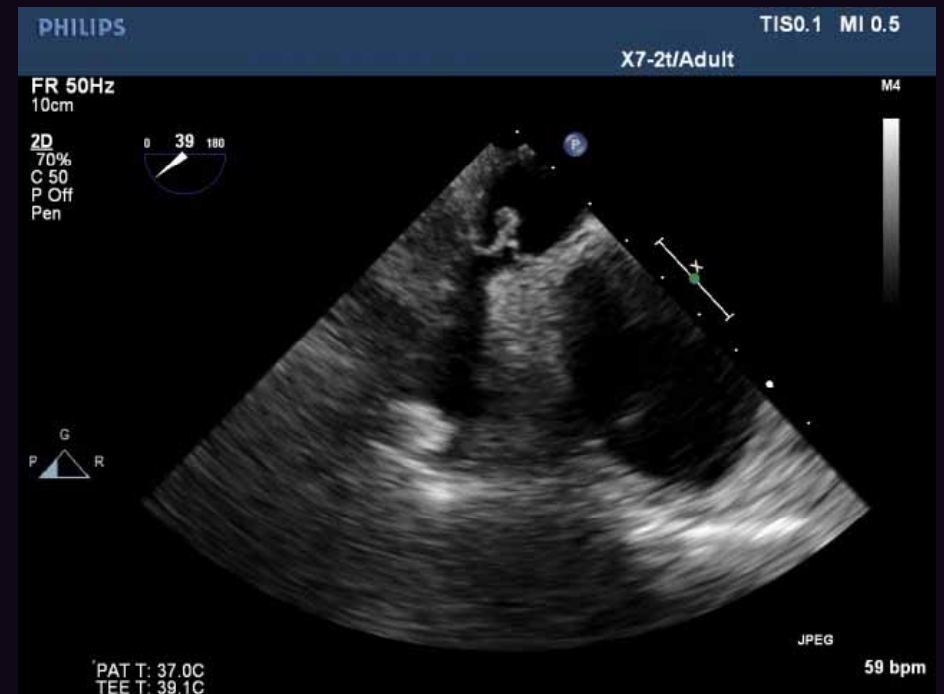
TSP performed in the preferred location

- The constraint depends on its size, location, & whether it is single or fenestrated ASD.
- Always choose optimal location rather than crossing the ASD.
- Very rarely TSP in the ideal location may result in a tear of the IAS causing big L-R shunting

Special Situations Of Transseptal Puncture (3): Interatrial Septal Aneurysm



Interatrial septal aneurysm



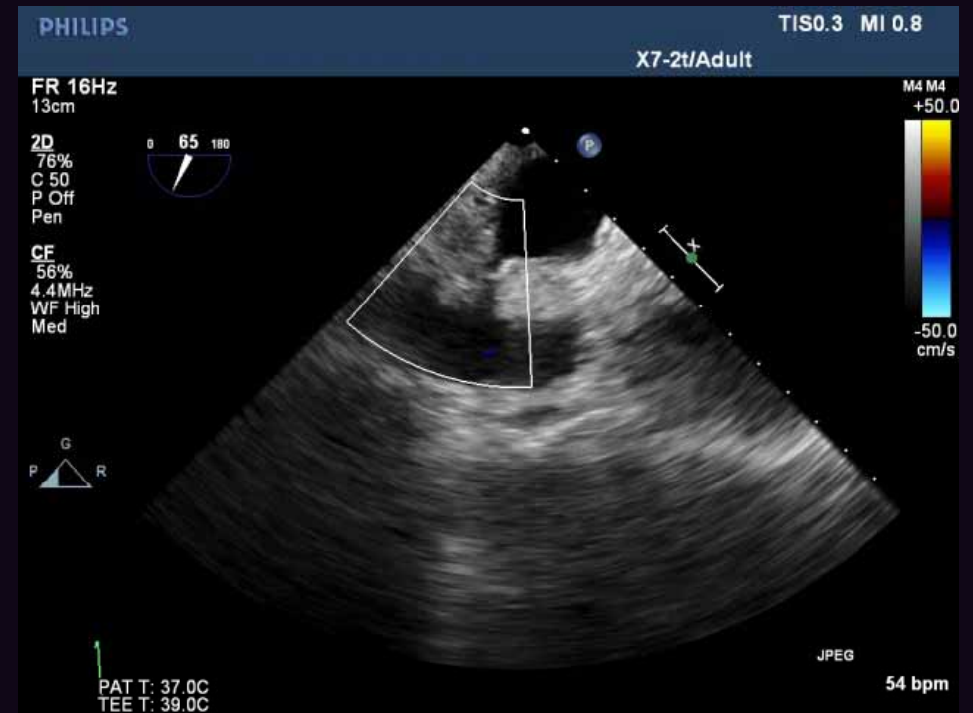
TSP creates a very deep tenting

- May or may not be associated with PFO.
- As it is usually very floppy, crossing the IAS is more difficult as the **TS needle tends to create a very deep tent.**

Special Situations Of Transseptal Puncture (3): Interatrial Septal Aneurysm



Tear of IAS



Tear of IAS with L-R shunting

- Be patient & apply very gentle pressure too **avoid perforation or tearing of IAS.**

Special Situations Of Transseptal Puncture (4): Resistant, Thick Interatrial Septum



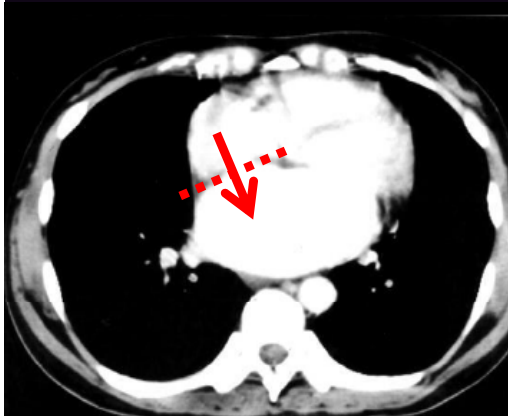
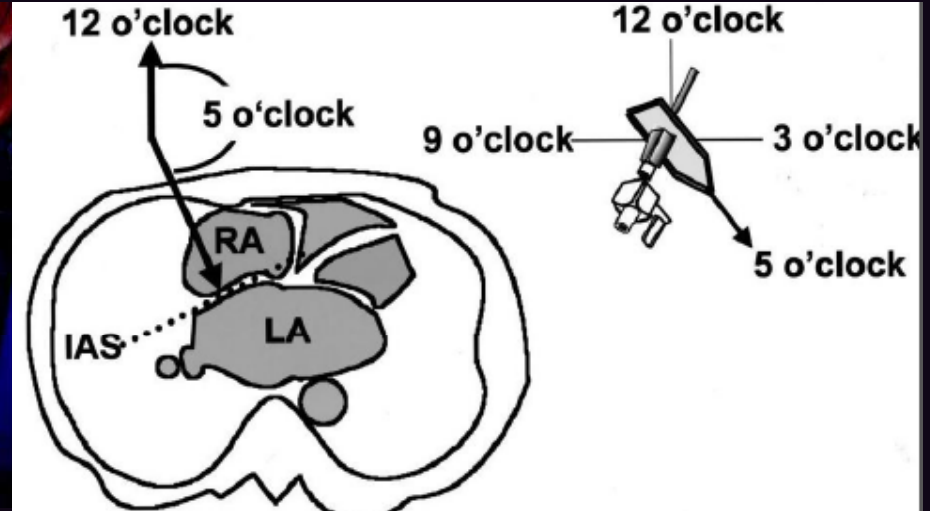
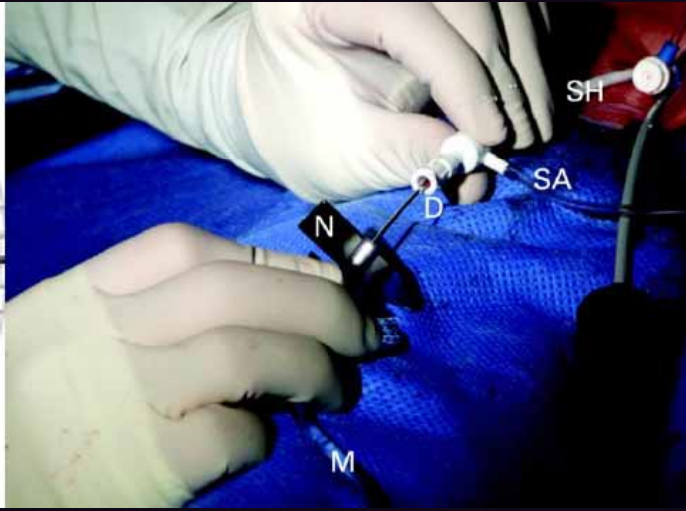
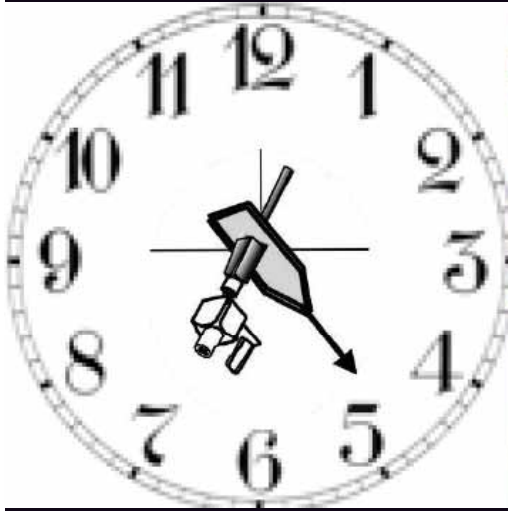
Thick IAS (note: TS sheath/needle)



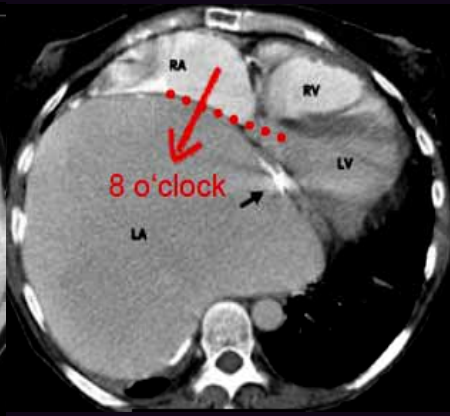
Tenting

- Forceful forward pressure on needle may not be enough to overcome the resistance & may not be safe in normal sized LA. Use of **back end of a coronary GW** or **electrocauterization** may help.
- In rare situation **where the needle does cross but SLO sheath/dilator cannot cross**, use a **long exchange-length coronary GW**. The GW is threaded through the TS needle & looped into the LA. Passage of SLO sheath/dilator will then be over the GW. Alternatively, use **coronary balloon to dilate IAS** before advancing the SLO sheath/dilator.

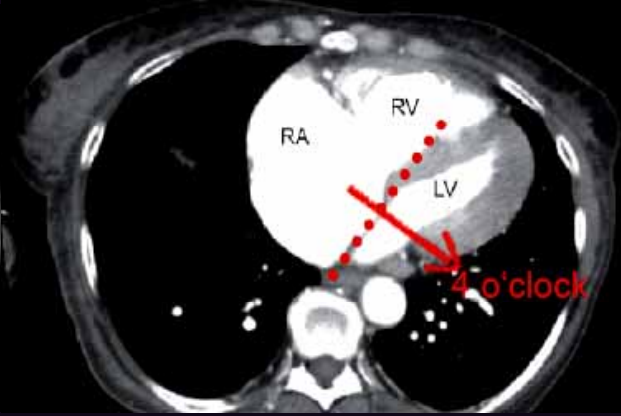
Special Situations Of Transseptal Puncture (5): Large RA, Large LA, Biatrial Enlargement



Normal

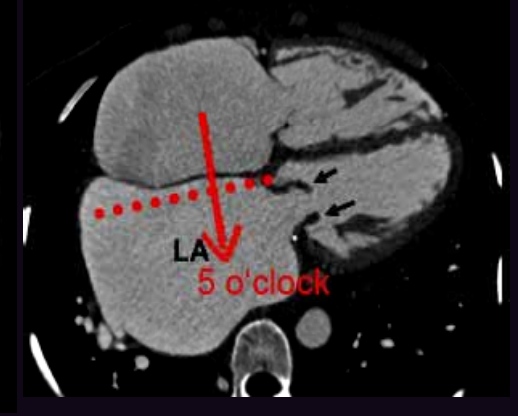


Giant LA



RA enlargement

Use larger needle
curve to reach IAS



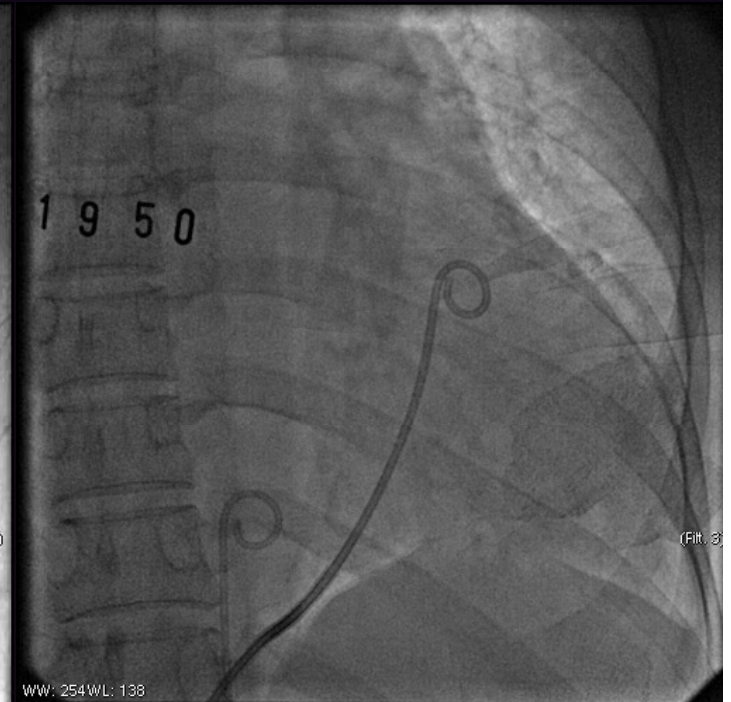
Bi-atrial enlargement

Potential Complications Of Transseptal Puncture (1)

Complication	Prevention	Treatment
Atrial arrhythmia	Avoid trigger irritation (guidewire, catheter/needle)	Usually benign , self terminating, rarely requires IV anti-arrhythmics
Vasovagal reaction	Unpredictable	SA, fluid
Inadvertent puncture of cardiac structures besides the IAS (aorta, SVC, IVC, RA/RAA, LA/LAA, PV)	TEE guidance. Anticoagulation given only after successful TSP	Needle retraction & reversal of anticoagulation usually sufficient. For larger perforation , echo-guided pericardiocentesis , volume replacement, auto-transfusion , rarely requires surgery

LA Perforation With Tamponade Caused By Transseptal Puncture

Case undergoing successful balloon mitral valvuloplasty



Perforation of the
LA roof

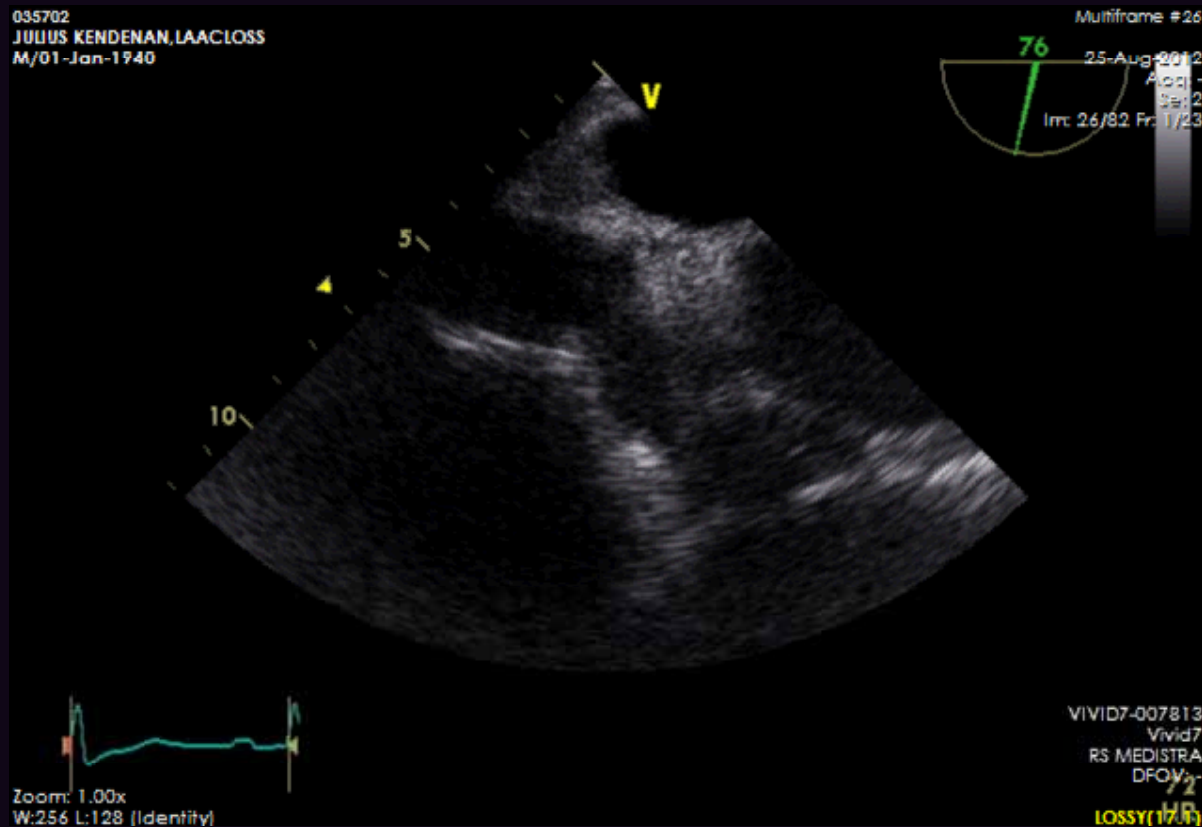
Ballon mitral
valvuloplasty.
Note: pericardial effusion

Successful BMV.
No effusion after
pericardial drainage.

Potential Complications Of Transseptal Puncture (2)

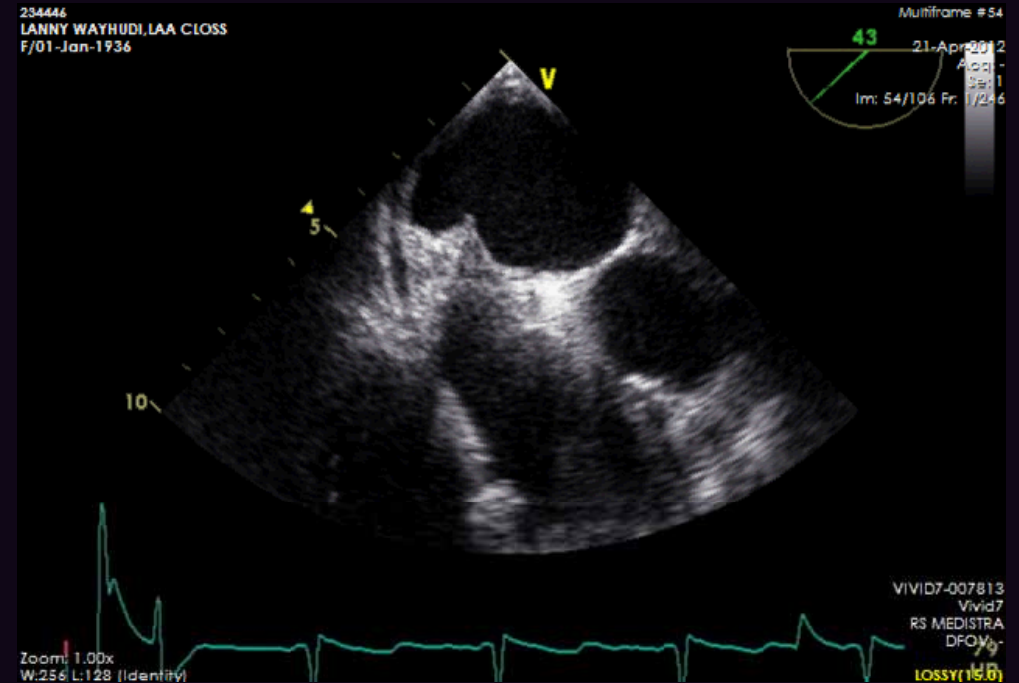
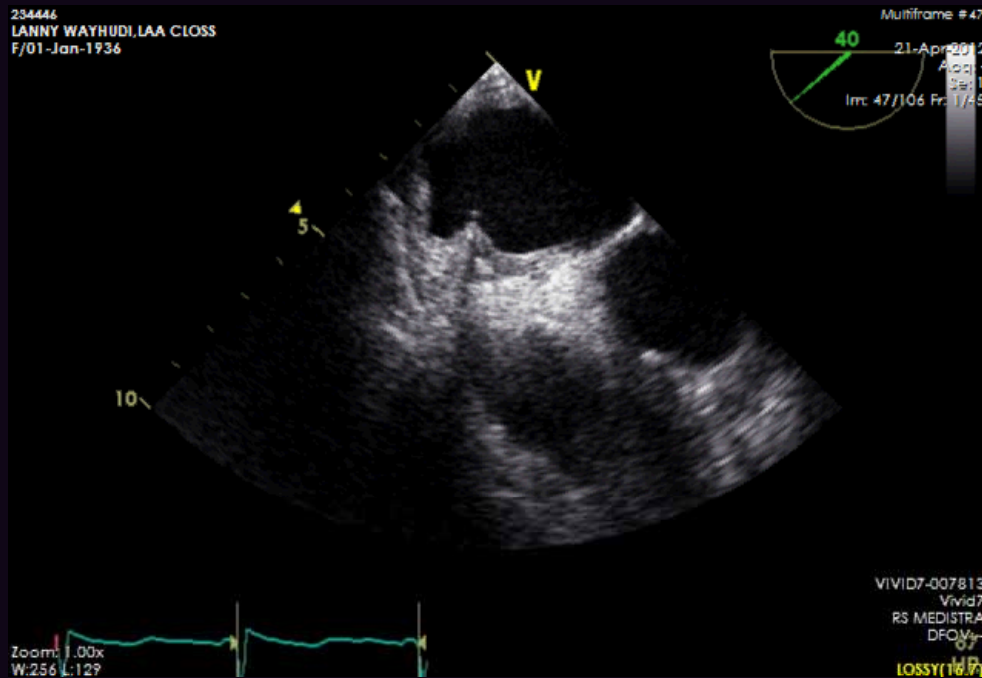
Complication	Prevention	Treatment
Air embolism (cerebral, coronary [RCA more common])	Careful system de-airing	Usual organ resuscitation
Thrombus formation (sheath, & more commonly in the wire)	Avoid prolonged procedure in the right heart. Heparin immediately after successful TSP (ACT > 250 s)	Thrombus aspiration or electrocauterization. If necessary abort the procedure
Iatrogenic ASD	TEE guidance	Usually closes over time. Transcatheter closure very rarely needed

Thrombus In RA



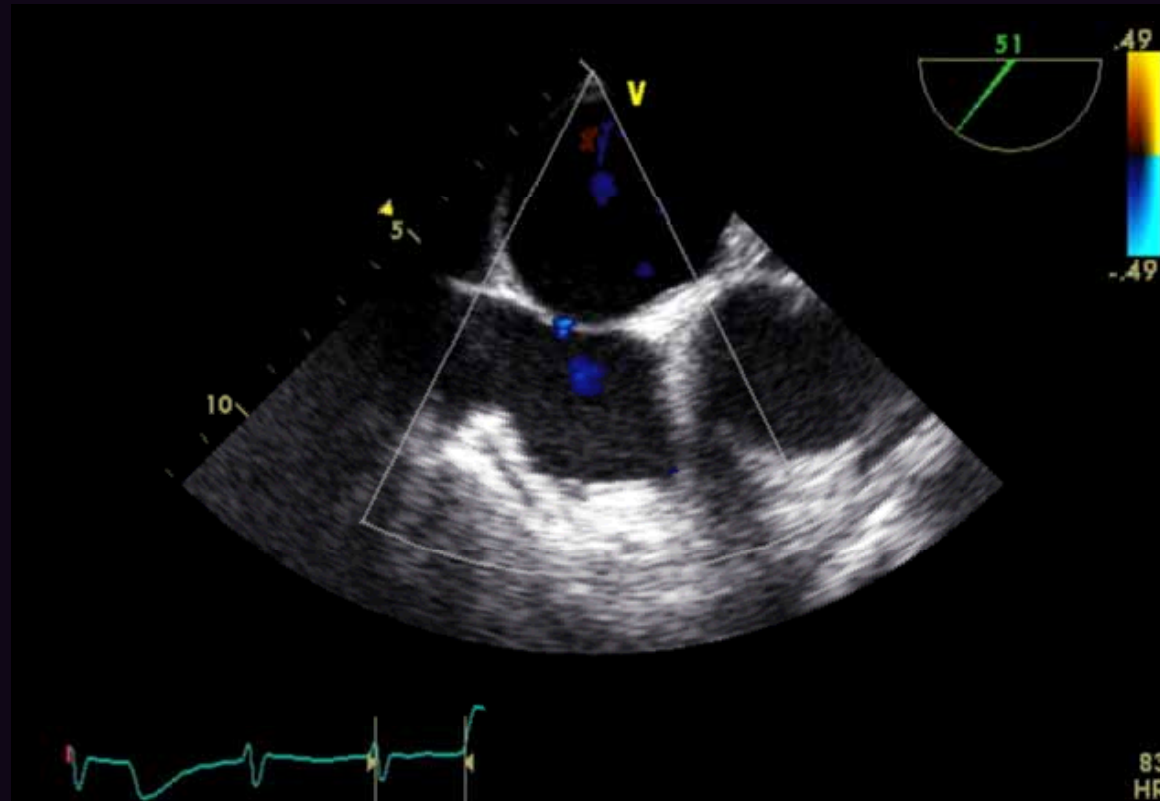
RA thrombus noted & was aspirated.
Subsequent procedure went well & uncomplicated.

Thrombus In Interatrial Septum



Thrombus noted in the IAS & was electrocauterized.
Subsequent procedure went well & uncomplicated.

After LAA Closure: L-R Shunting



Small residual R-L shunting at follow up
(of no clinical significance)



Indonesia Single Center Experience

Watchman LAA Closure : *Inclusion Criteria*

- Non valvular AF with CHA2DS2-VASc score ≥ 1
- No co-morbidities mandating chronic warfarin use other than AF



Indonesia Single Center Experience

Watchman LAA Closure : *Exclusion Criteria*

Key Echo Exclusion Criteria:

- *Intracardiac thrombus or spontaneous echo-contrast (SPEC) on TEE*
- LVEF < 30%
- Existing pericardial effusion > 2mm
- High risk PFO
- Significant mitral valve stenosis (MVA < 1.5 mm²)
- Complex atheroma with mobile plaque of the descending aorta and/or aortic arch (thickness \geq 4 mm)
- Cardiac tumor
- Endocarditis
- Maximum *LAA ostium width* > 32 mm or < 17 mm in at least 3 consecutive views
- Maximum *LAA length insufficient* to accommodate the device



Indonesia Single Center Experience

Demography

Characteristics (n=27)	
Age (yrs)	65 ± 11
- Age > 75 yrs	5 (18.5%)
- Age 65-75 yrs	11 (40.7%)
Male:female	19:8
CHADS2VASc2 Score (M ± SD)	4 ± 1.5
HASBLED Score (M ± SD)	3 ± 1.2
Congestive heart failure (n, %)	5 (18.5%)
History of hypertension (n, %)	24 (88.9%)
Diabetes (n, %)	12 (44.4%)
Previous TIA/ischemic stroke (n, %)	6 (22.2%)
Vascular disease (n, %)	24 (88.9%)
LV ejection fraction (%)(M ± SD)	64 ± 10



Indonesia Single Center Experience

Characteristics (n=27)	N (%)
Previous oral anticoagulant use:	
- Warfarin	5 (18.5%)
- Dabigatran	7 (25.9%)
- Rivaroxaban	11 (40.7%)
- None	4 (14.9%)
Pattern of AF:	
- Paroxysmal AF	1 (3.7%)
- Persistent AF	7 (25.9%)
- Permanent AF	19 (70.4%)
Onset of AF (yrs) (M \pm SD)	2 \pm 1.8



Indonesia Single Center Experience: Complications

Complications (n=27)	N (%)
Pericardial effusion requiring percutaneous or surgical drainage	0
Major bleeding	0
Device embolization	0
Procedure-related stroke	0
Hemorrhagic stroke	0
Vascular access complication (significant groin hematoma, AV fistula, etc.)	0



Indonesia Single Center Experience: Follow Up At 45 Days

Results at 45 days (n=24) ^Π	
Clinical	
- Ischemic stroke	0
- Hemorrhagic stroke	0
- Systemic embolism	0
- Cardiovascular death	1 [#]
TEE (n=22)*	
- Residual jet < 5 mm (<i>insignificant</i>)	12 (54.4%)
- Residual jet ≥ 5 mm	0
- Thrombus	1 (9.1%)
- Significant shoulder (depending on device size)	4 (18.1%)
- L-R interatrial shunting: trivial / mild (<i>insignificant</i>)	3 (13.6%)

^Π3 are waiting for f up; [#] sudden death, unknown cause, 80 yr old man with CICM; * Two pts underwent contrast CT exam only instead of TEE. This showed excellent result in one & significant gap (7 mm) in another

Comparative Demographics

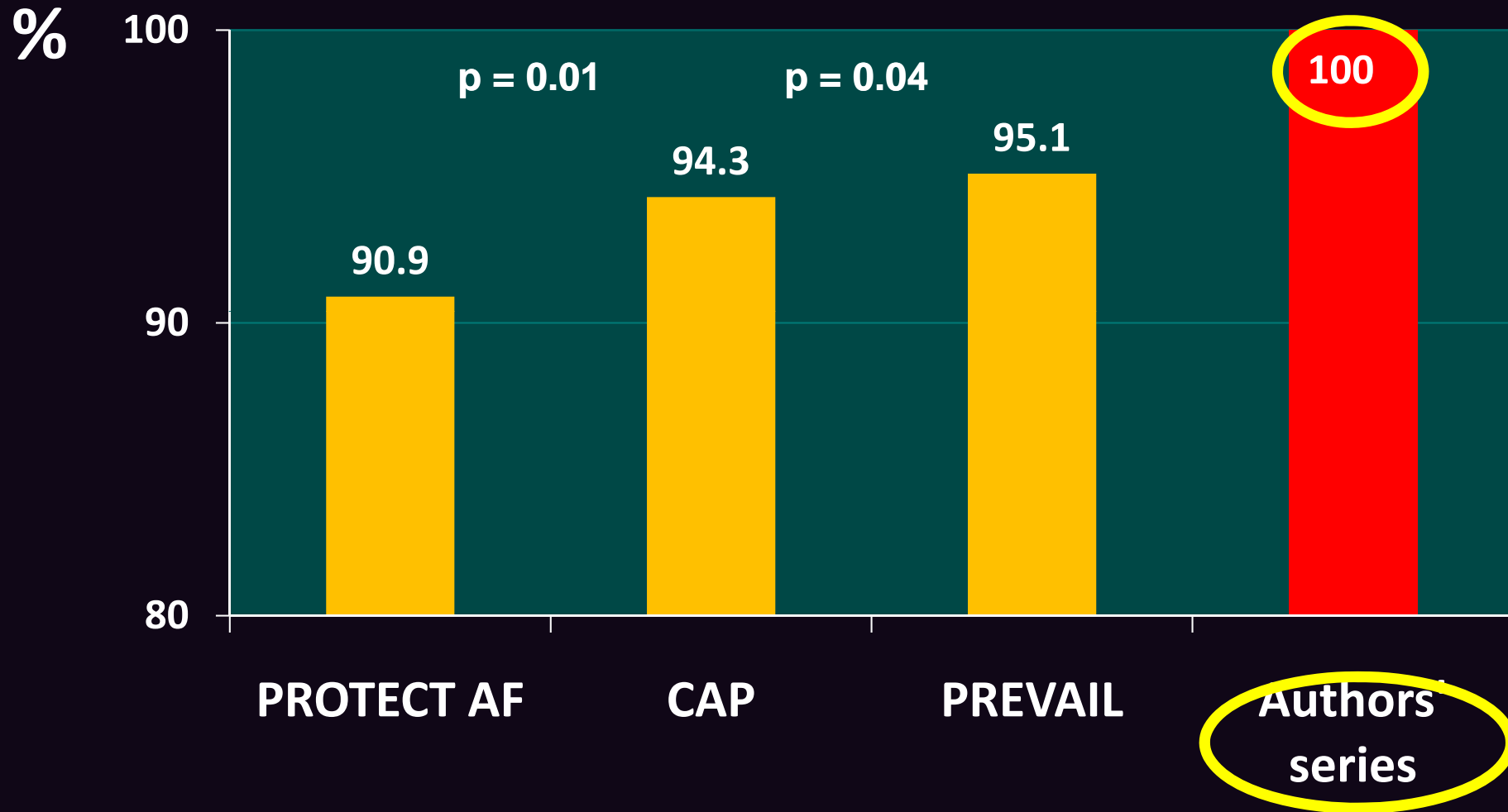
PROTECT AF, CAP, ASAP*, Authors' Series

Characteristic	PROTECT AF N=463	CAP N=566	PREVAIL N=269	Authors' series N=27
Age, years	71.7 ± 8.8 (46.0, 95.0)	74.0 ± 8.3 (44.0, 94.0)	74.0 ± 7.4 (50.0, 94.0)	65 ± 11 (36.0, 83.0)
Gender (Male)	326 (70.4%)	371 (65.5%)	182 (67.7%)	19 (70.3%)
CHADS ₂ Score (Continuous)	2.2 ± 1.2 (1.0, 6.0)	2.5 ± 1.2 (1.0, 6.0)	2.6 ± 1.0 (1.0, 6.0)	2.0 ± 1.4 (1.0, 5.0)
CHADS ₂ Risk Factors				
CHF	124 (26.8%)	108 (19.1%)	63 (23.4%)	5 (18.5%)
Hypertension	415 (89.6%)	503 (88.9%)	238 (88.5%)	24 (88.9%)
Age ≥ 75	190 (41.0%)	293 (51.8%)	140 (52.0%)	5 (18.5%)
Diabetes	113 (24.4%)	141 (24.9%)	91 (33.8%)	12 (44.4%)
Stroke/TIA	82 (17.7%)	172 (30.4%)	74 (27.5%)	6 (22.2%)

*Reddy, VY et al. *Circulation*. 2011;123:417-424; Holmes D, et al. ACC 2013.

Procedure Implant Success

PROTECT AF, CAP, ASAP, Authors' Series

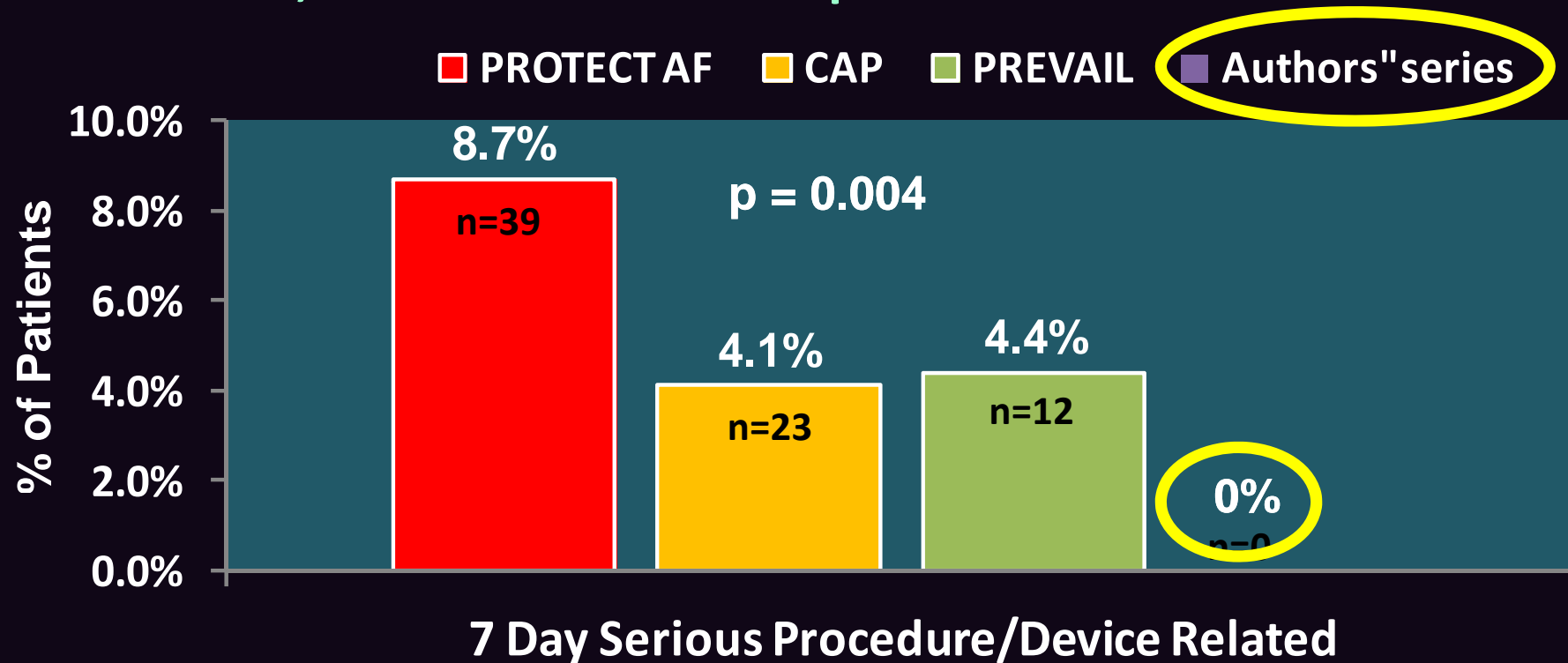


Implant success defined as deployment & release of the device into the left atrial appendage

Vascular Complications

PROTECT AF, CAP, ASAP, Authors' Series

Composite of vascular complications includes cardiac perforation, pericardial effusion with tamponade, ischemic stroke, device embolization, & other vascular complications¹

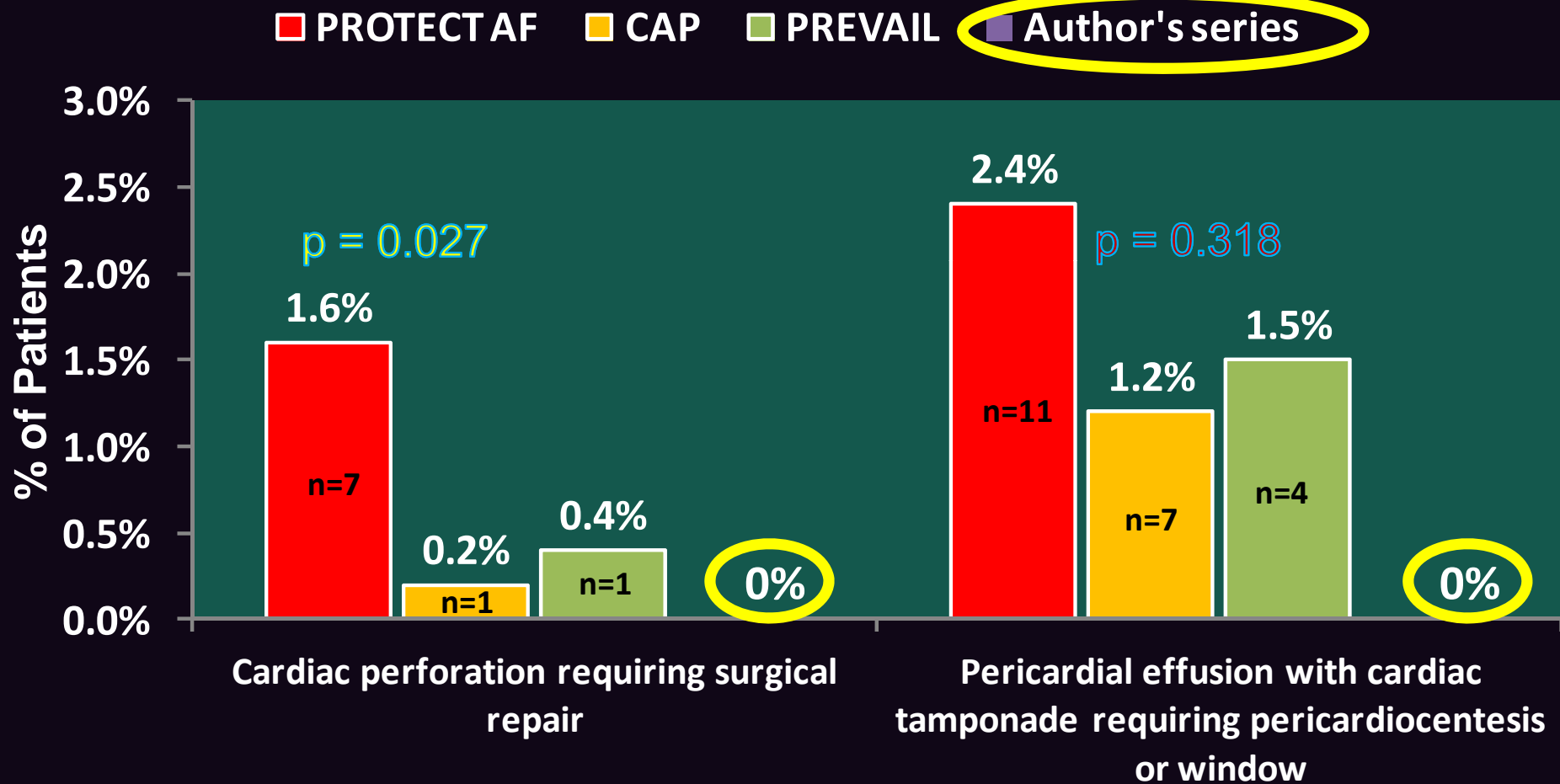


No procedure-related deaths reported in any of the trials

¹Includes observed PE not necessitating intervention, AV fistula, major bleeding requiring transfusion, pseudoaneurysm, hematoma & groin bleeding

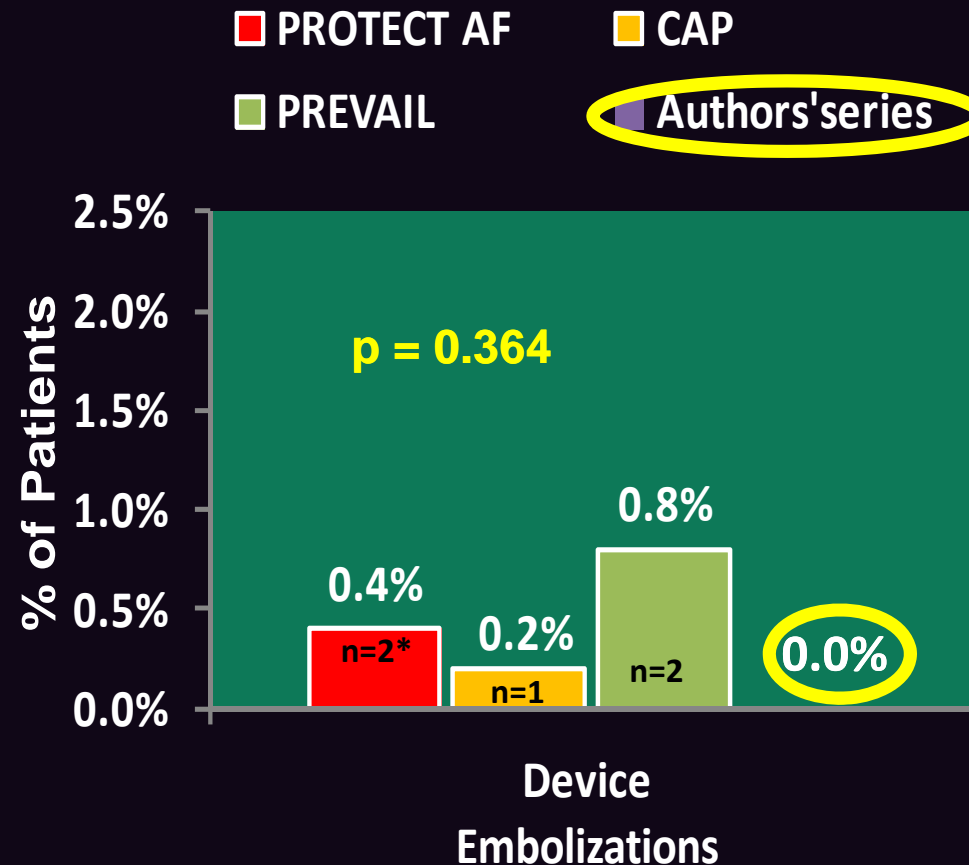
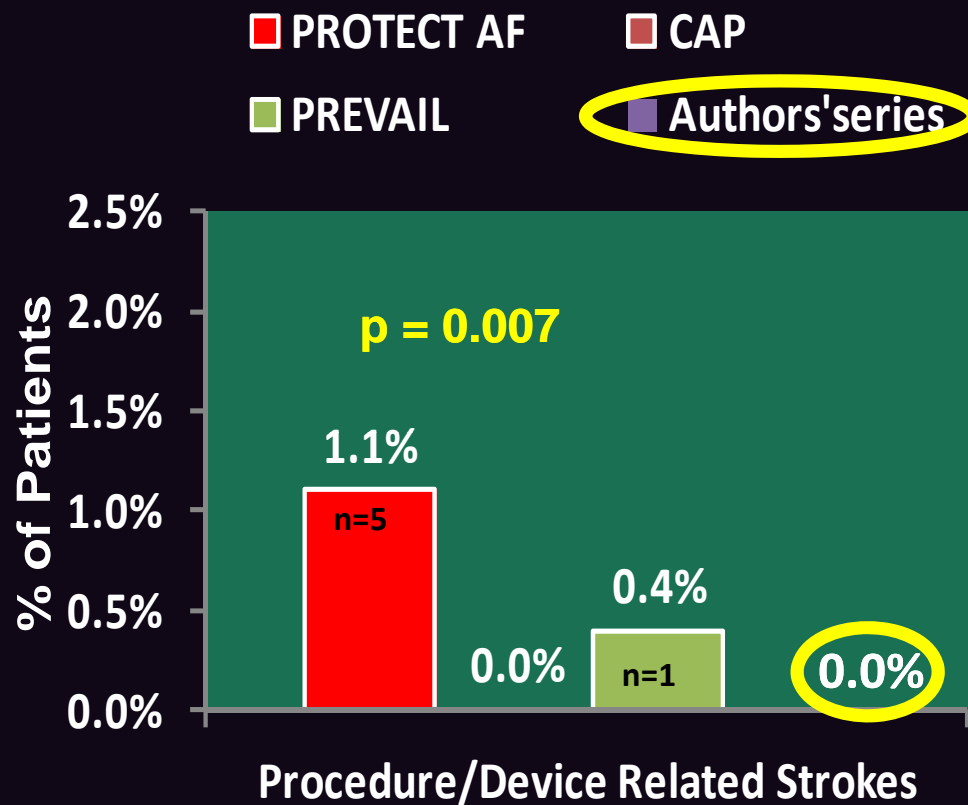
Serious Trans-septal Puncture Complication In Watchman LAA Occluder Studies

Pericardial Effusions Requiring Intervention



No procedure-related deaths reported in any of the trials

Stroke & Device Embolization



**Procedure related strokes were reduced
Device embolizations remained low**

*1 additional device embolization was reported at 45 days

Summary

- LAA closure device is a **safe & effective** treatment of all types of non-valvular AF^{1,2}.
- The clinical **benefit is greater** in patients with a **higher risk for stroke** (high CHADS₂ or CHA₂DS₂VASc score) and also in patients with a **higher risk of bleeding** (high HASBLED score) or have **contraindications for chronic anticoagulation therapy**^{1,2}. Probably also more so in **Asian patients**
- LAA closure provides **life-long stroke prophylaxis** without the need for daily OAC.
- The results of our own **experience in Indonesia** are very **encouraging**