PFO Closure: Insights and Updates

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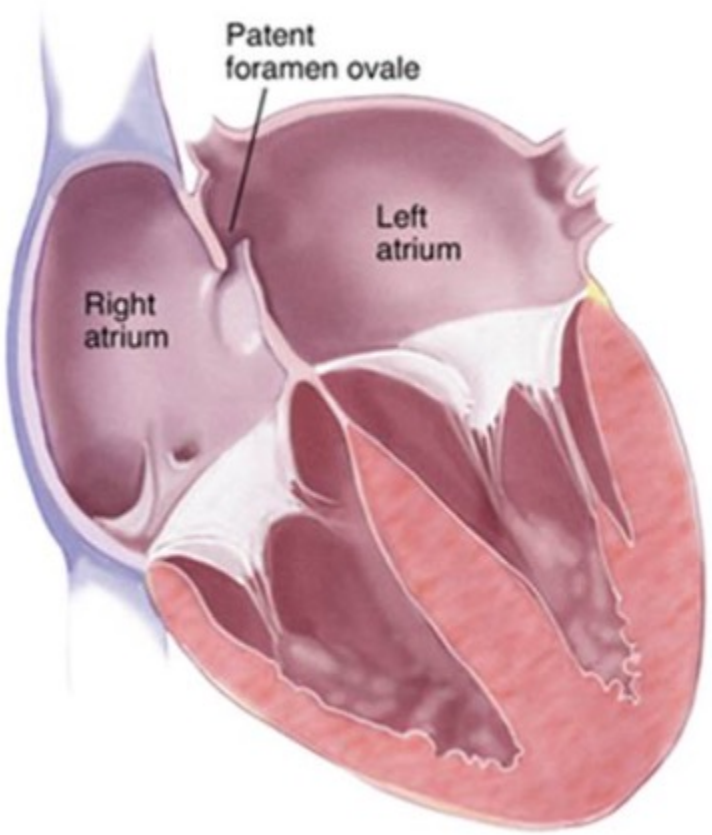
Learning Objectives

- Understand PFO anatomy
- Identify indications for closure
- Clinical trial data
- Guidelines from AAN and SCAI
- Complications

PATENT FORAMEN OVALE



- Foramen Ovale is a normal component of fetal circulation.
- Allows blood to flow from the venous to systemic circulation.
- Increased pulmonary flow at birth leads to closure of the foramen ovale with anatomic closure by 12 months.
- Persistently patent foramen ovale (PFO) is seen in upto 25% of the population.
- May be associated with paradoxical emboli from venous to arterial circulation.

PFO and Stroke

- PFO incidence 20-25%.
- Atrial Septal Aneurysm incidence 2.2%.
- 83% of people with ASA have a PFO.

- In 18-60years with stroke, PFO's are found in 50-60% of patients.
- Cryptogenic stroke: 2.3 fold risk of PFO present.
- Probability theory: PFO is causative in 73% of these patients with cryptogenic stroke.

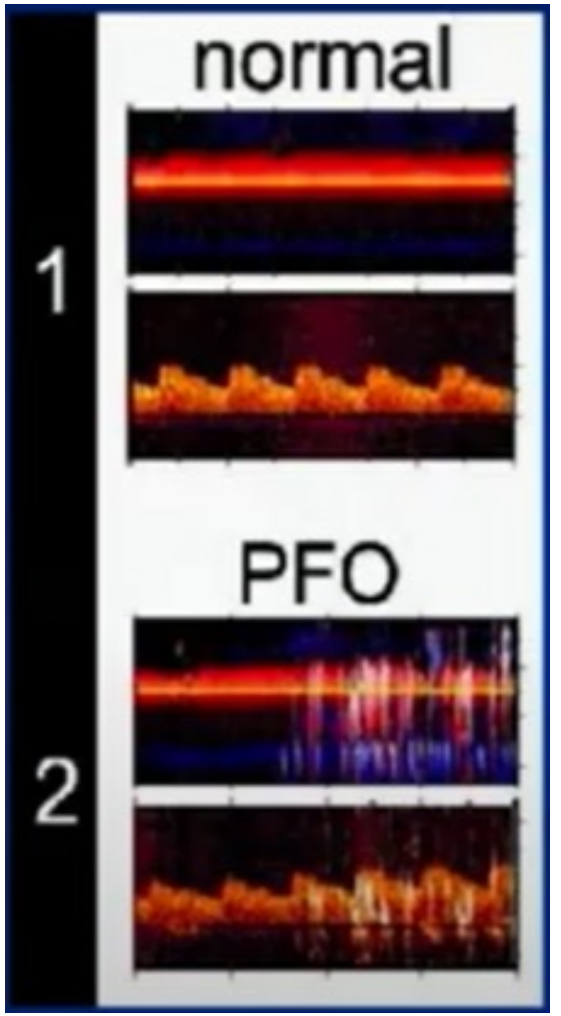
Saver et al. Stroke, 2018:49

Clinical Clues of Paradoxical Embolism

- History of DVT or pulmonary embolism
- Migraine
- Recent prolonged travel
- Sleep apnea
- Waking up with TIA or stroke
- Valsalva maneuver preceding the event

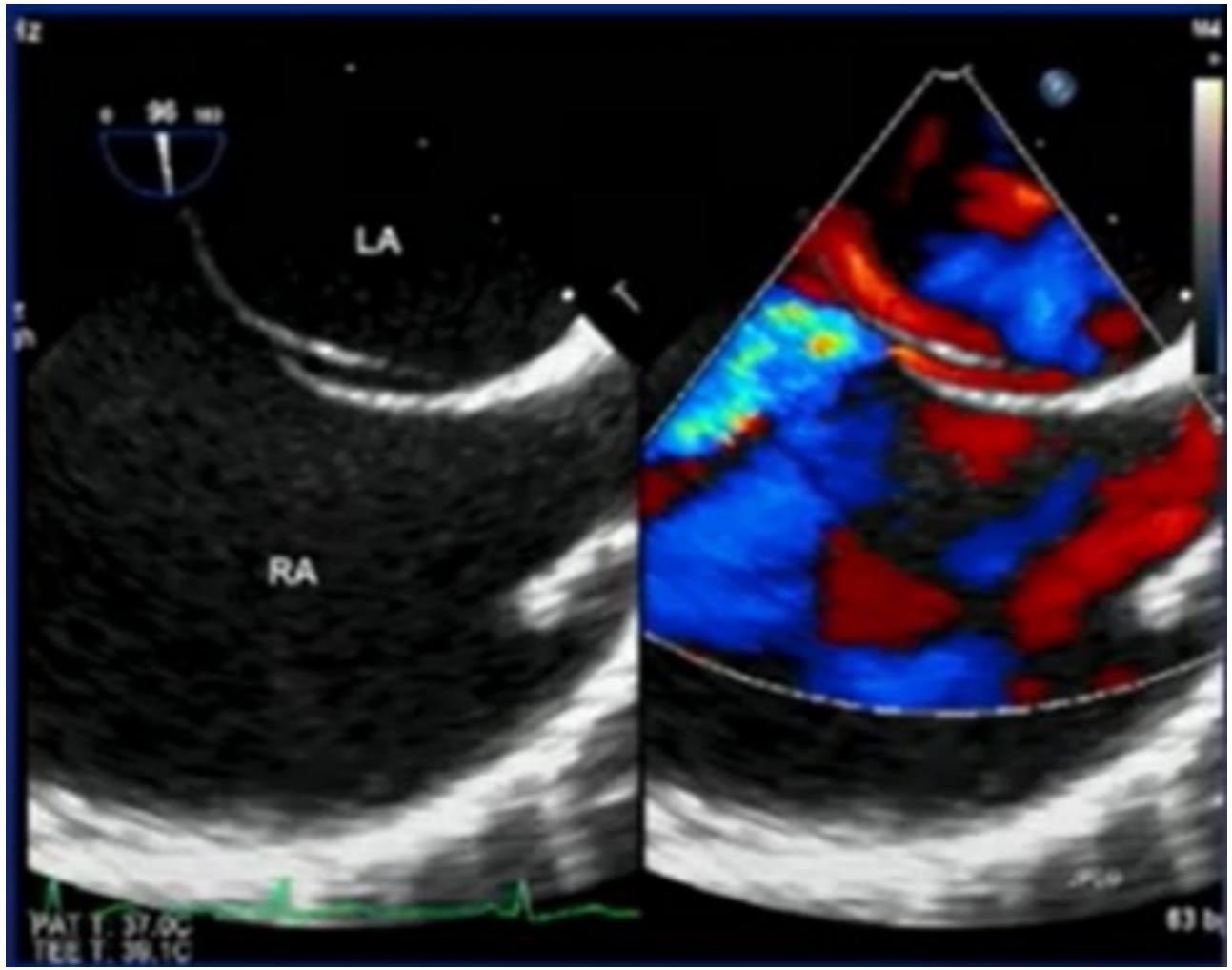
Diagnosis: Transcranial Doppler

- TCD sensitivity is similar to TEE in some studies.
- Anatomy of the PFO cannot be evaluated.
- Shunting microbubbles appear as spikes superimposed to the normal blood flow pattern in the middle cerebral artery when PFO is present.

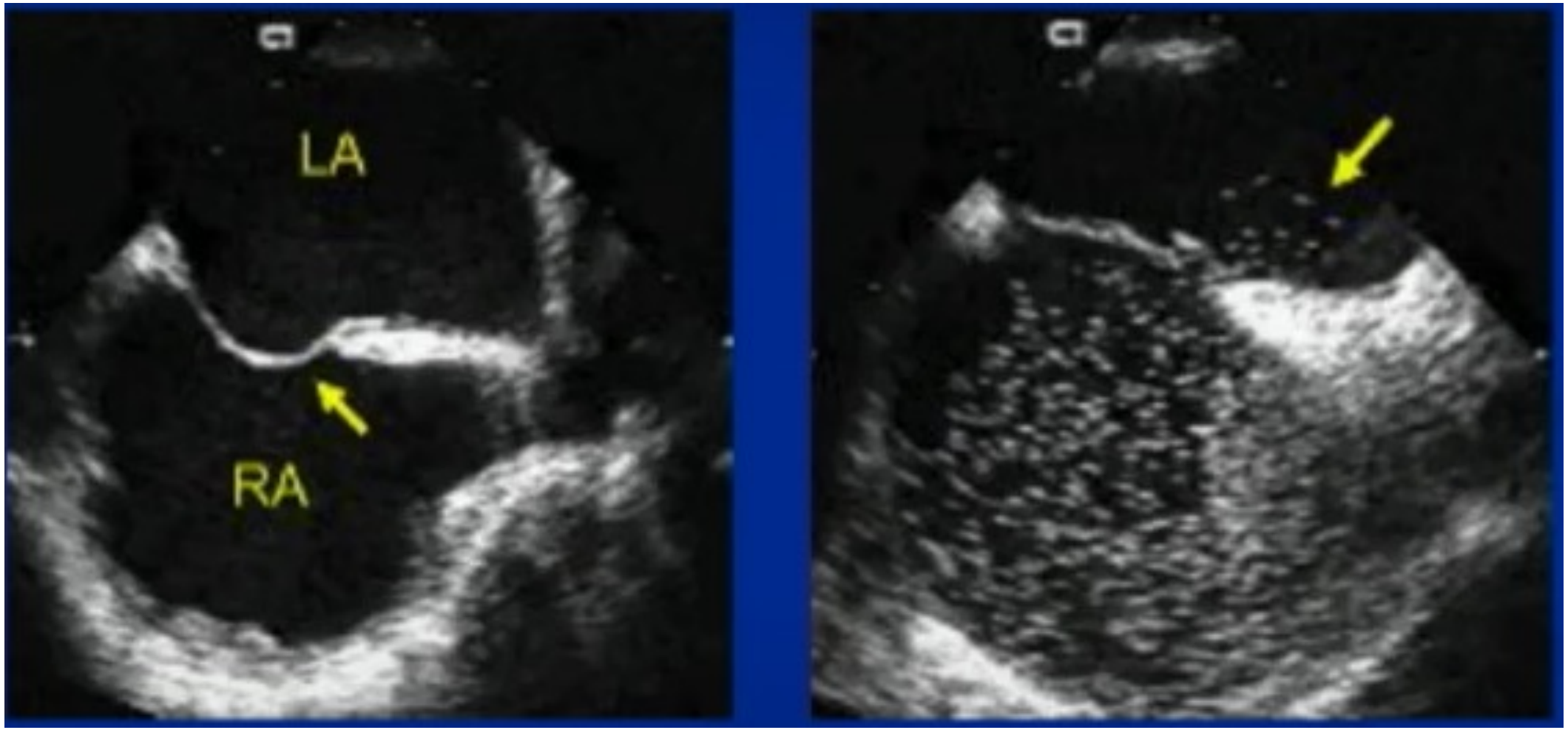


Diagnosis: Transesophageal Echocardiogram

- Gold standard.
- Up to 100% sensitivity and specificity when both color Doppler and contrast are used.
- Evaluate anatomy.



Diagnostics: Transesophageal Echocardiogram



Amplatzer Talisman PFO Occluder

Gore Cardioform Septal Occluder

Risk of Paradoxical Embolism (RoPE) Score

Identifies stroke-related PFO in patients with cryptogenic stroke.

INSTRUCTIONS

Use in patients with cryptogenic stroke found to have PFO and no other compelling cause for stroke.

When to Use | Pearls/Pitfalls | Why Use

History of hypertension	**No +1**	Yes 0
History of diabetes	**No +1**	Yes 0
History of stroke or TIA	**No +1**	Yes 0
Smoker	**No +1**	Yes 0
Cortical infarct on imaging	No 0	**Yes +1**
Age		years

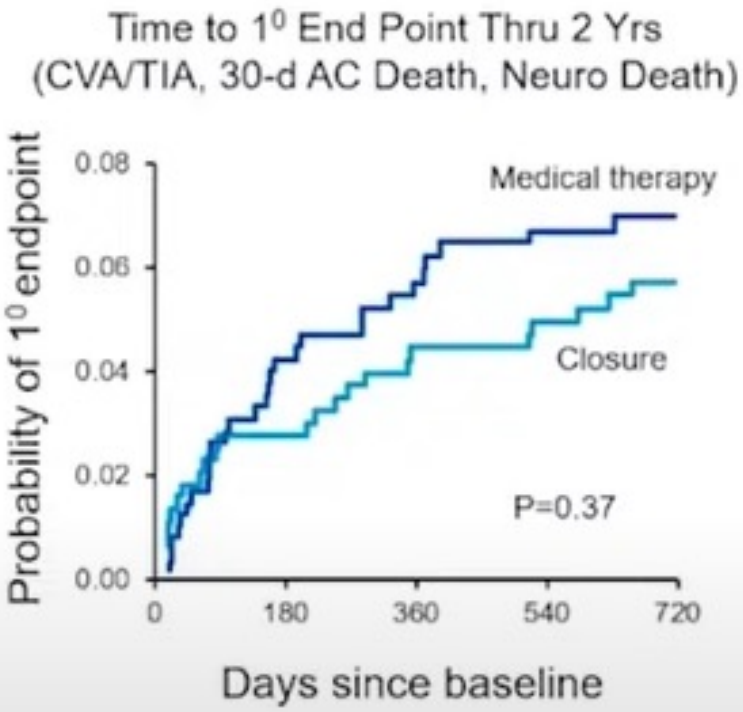
Kent et al. Neurology, 2013; 81:619

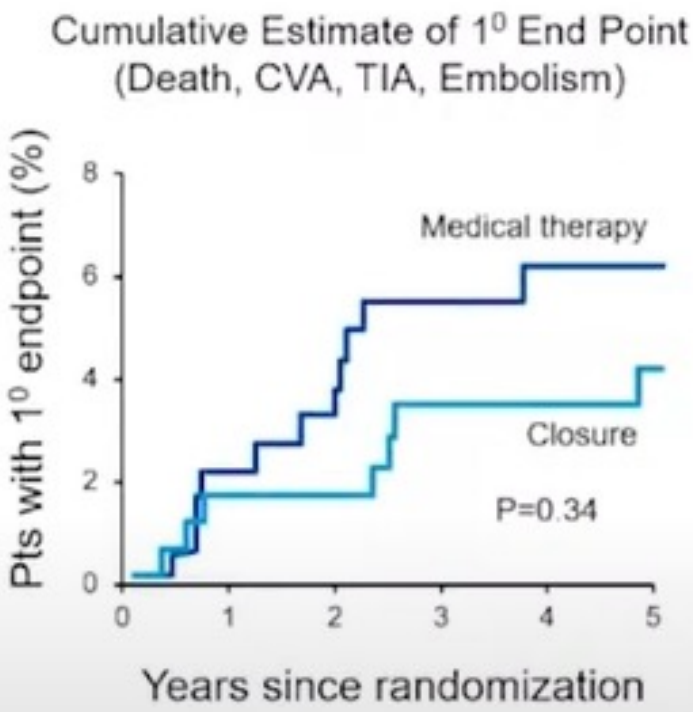
PASCAL Classification

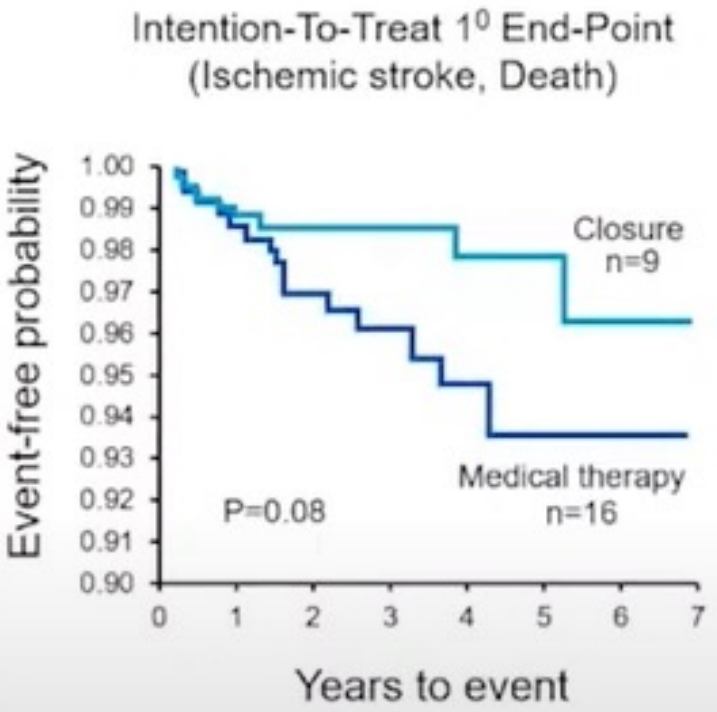
Risk source	Features	RoPE score	
		Low¶	High¶
Very high	A PFO and a straddling thrombus	Definite	Definite
High	(1) Concomitant pulmonary embolism or deep venous thrombosis preceding an index infarct combined with either (2a) a PFO and an atrial septal aneurysm or (2b) a large-shunt PFO	Probable	Highly probable
Medium	Either (1) a PFO and an atrial septal aneurysm or (2) a large-shunt PFO	Possible	Probable
Low	A small-shunt PFO without an atrial septal aneurysm	Unlikely	Possible

Elgendy et al. JAMA Neurology, 2020; 77:878

Initial Randomized Trials of PFO Closure Versus Medical Therapy

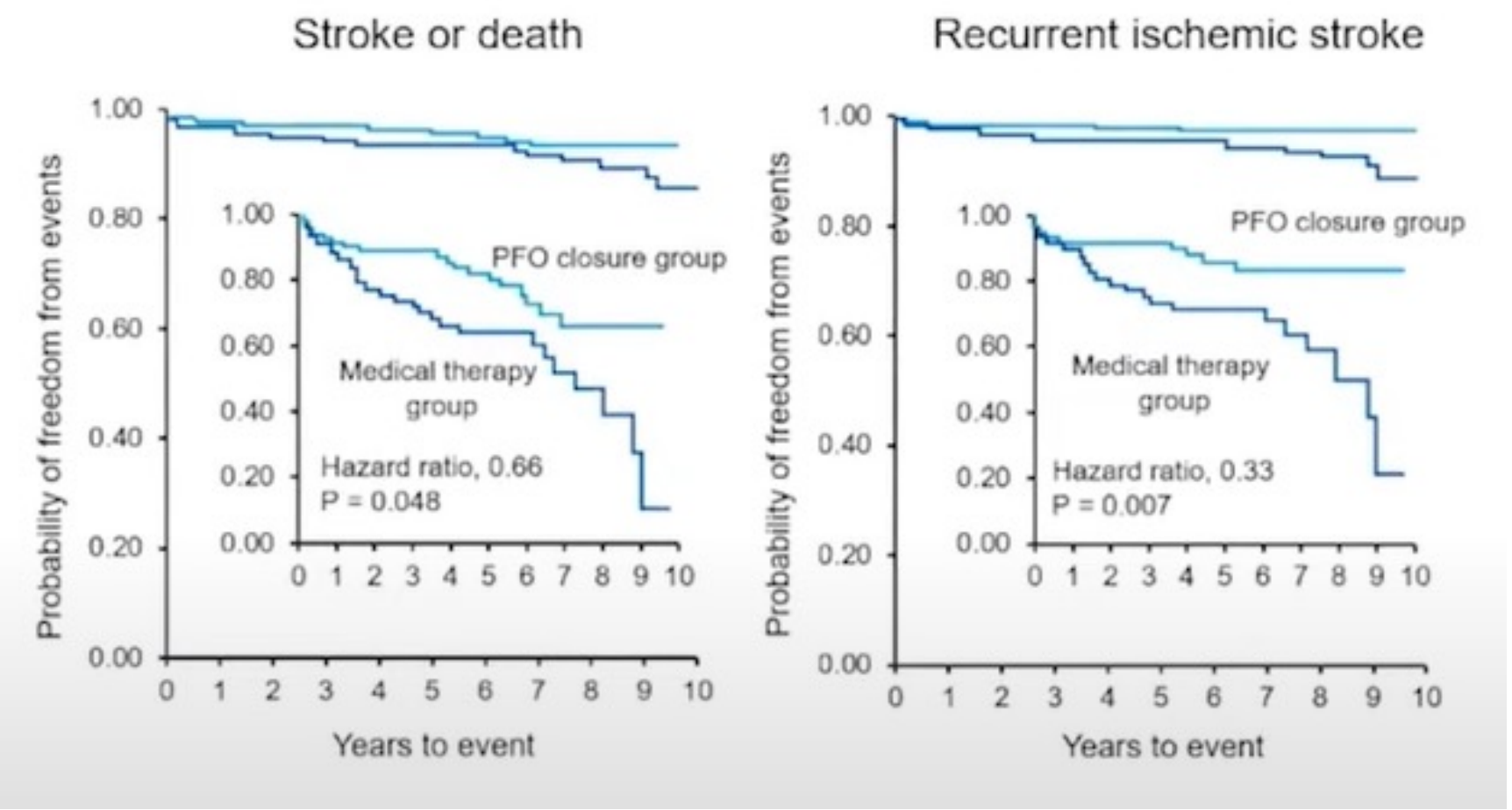






Furlan et al. NEJM, 2012 366(11):991; Meier et al. NEJM, 2013 368(12):1083; Carroll et al. NEJM, 2013 368:12

RESPECT: Long term outcome



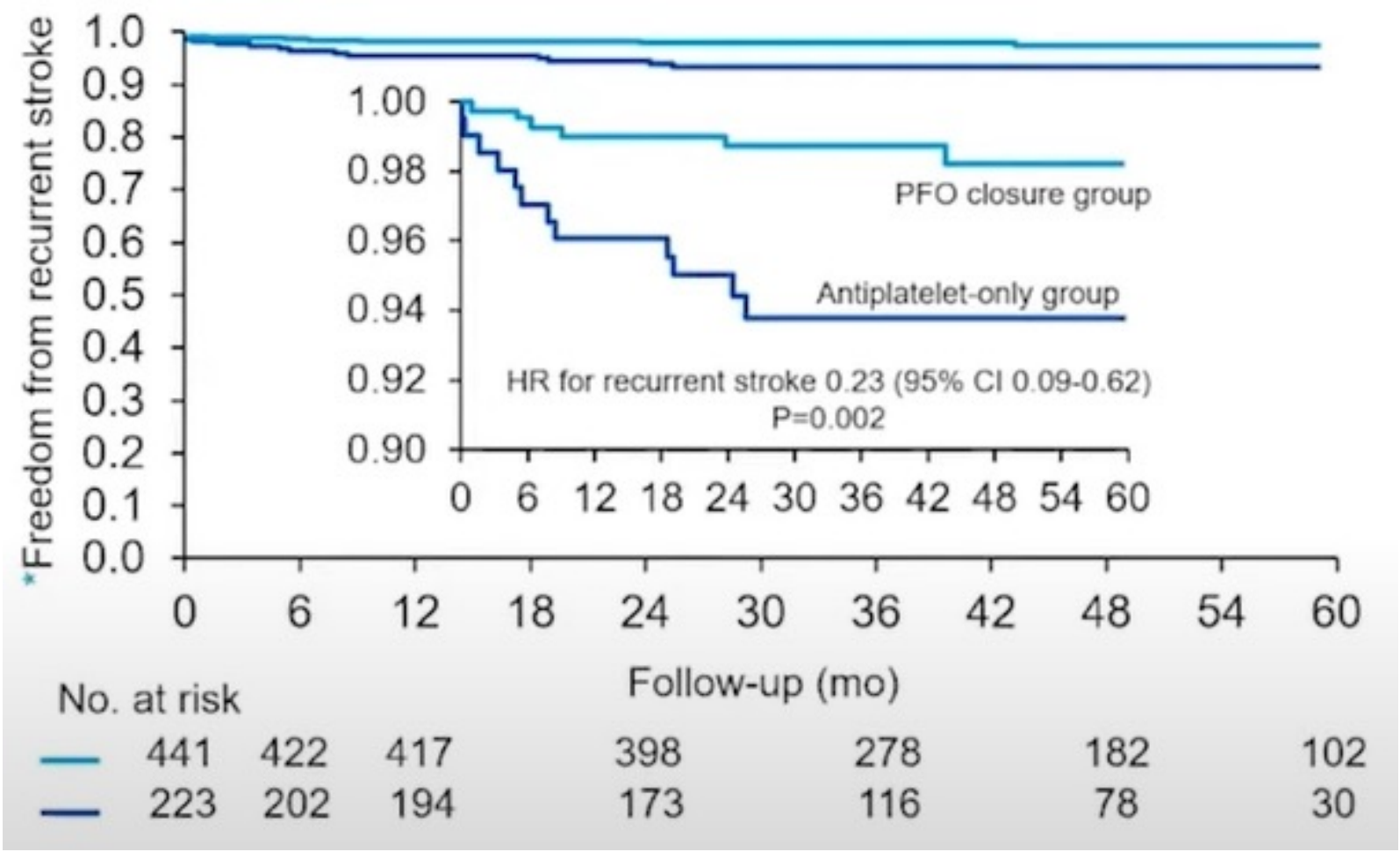
980 patients

Mean Age 46 years

Median follow up 5.9 years

Saver et al. NEJM, 2017;377:1022-32

GORE REDUCE



664 patients

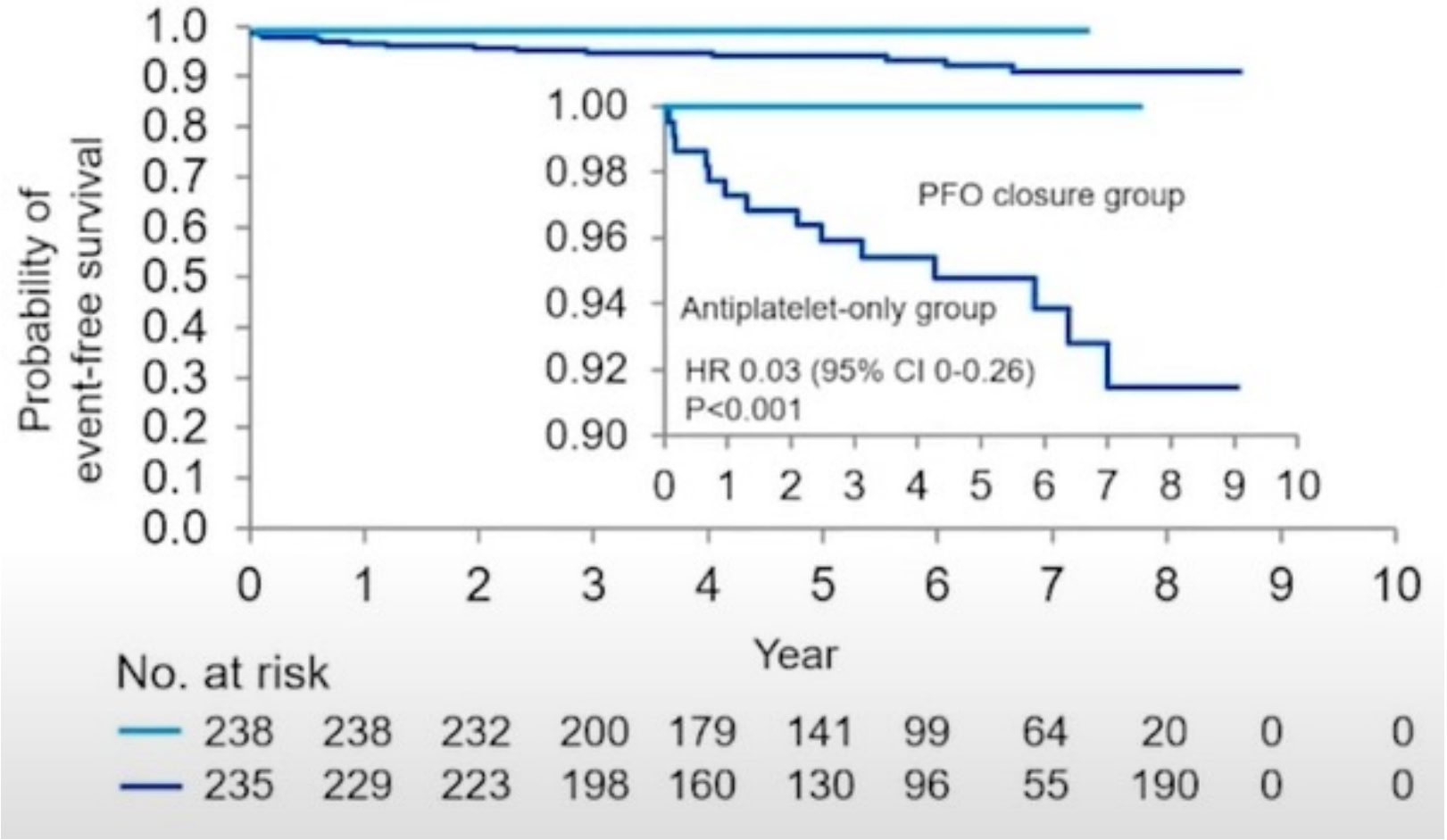
18-59 years

Median follow up 3.2 years

Atrial Fibrillation: 6.6% vs. 0.4%

Sondergaard et al. NEJM, 2017

CLOSE



Mas et al. NEJM, 2017

Atrial septal aneurysm or large shunt

524 patients

16-60 years, mean 43 years

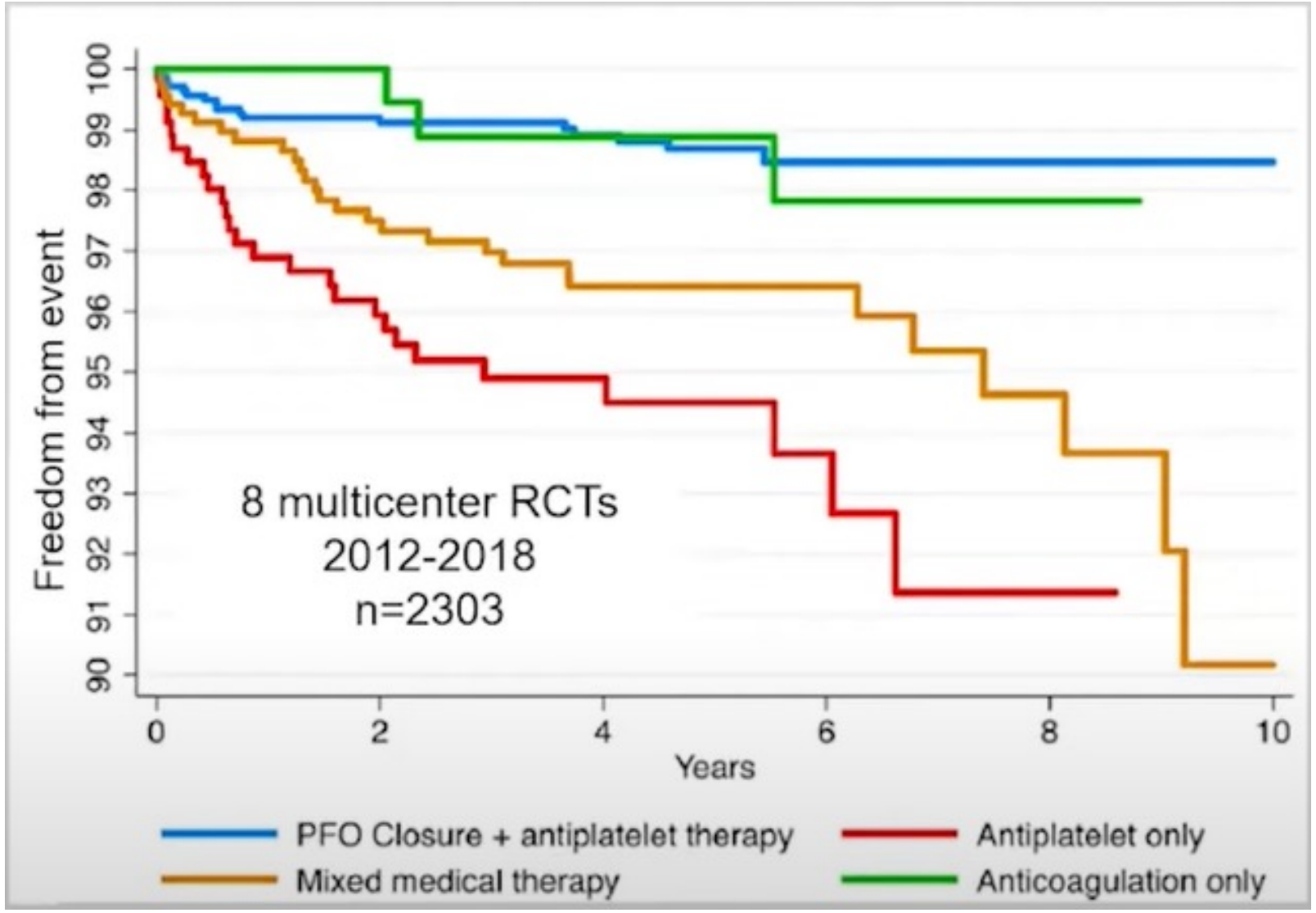
Mean follow up 5.3 years

0/238 strokes in PFO group
14/233 strokes in antiplatelet-only group

Atrial fibrillation: 4.6% vs. 0.9%

Cryptogenic Stroke Network Metaanalysis

PFO closure vs Antiplatelet vs Anticoagulation



5-year ARR 8.7% from 10% to 1.3% compared with antiplatelet therapy

Less absolute stroke reduction when compared with anticoagulation but lesser bleeding.

1.8% increase in atrial fibrillation

No difference in death, bleeding, PE, TIA, embolism

Mir et al. BMJ Open, 2018:18

Practice advisory update summary: Patent foramen ovale and secondary stroke prevention

Report of the Guideline Subcommittee of the American Academy of Neurology

Steven R. Messé, MD, Gary S. Gronseth, MD, David M. Kent, MD, MSc, Jorge R. Kizer, MD, MSc, Shunichi Homma, MD, Lee Rosterman, DO, John D. Carroll, MD, Koto Ishida, MD, Navdeep Sangha, MD, and Scott E. Kasner, MD, MSCE

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- Recommend PFO closure for ESUS when age<60 years.
- Age>60 if no other high-risk mechanism identified.
- Long-term monitoring cardiac monitoring for atrial fibrillation.
- Neurological imaging.
- TTE/TEE/TCD with bubble study.
- Heart Brain team.
- Shared decision making.
- If patient defers closure, consider antiplatelet or anticoagulation.

SCAI Guidelines for the Management of Patent Foramen Ovale

Clifford J. Kavinsky, MD, PhD, MSCAI (Chair) [a,*], Molly Szerlip, MD, FSCAI (Vice-Chair) [b], Andrew M. Goldsweig, MD, MS, FSCAI [c], Zahid Amin, MD, MSCAI [d], Konstantinos Dean Boudoulas, MD, FSCAI [e], John D. Carroll, MD, MSCAI [f], Megan Coylewright, MD, MPH, FSCAI [g], Sammy Elmariah, MD, MPH, FSCAI [h], Lee A. MacDonald, MD, FSCAI [i], Atman P. Shah, MD, FSCAI [j], Christian Spies, MD, FSCAI [k], Jonathan M. Tobis, MD, MSCAI [l], Steven R. Messé, MD [m,†], Emily Senerth, MS [n], Yngve Falck-Ytter, MD [o], Ifeoluwa Babatunde, PharmD, MS [p], Rebecca L. Morgan, PhD, MPH [q]

1. PFO closure vs medical therapy/no therapy in adults without a prior PFO-associated stroke.
2. PFO closure vs antiplatelet therapy in adults with a prior PFO-associated stroke.
3. PFO closure vs anticoagulation therapy in adults with a prior PFO-associated stroke.
4. PFO closure plus lifelong anticoagulation vs anticoagulation alone in adults with a prior PFO-associated stroke.
5. Post-procedure management of antiplatelet regimen or anticoagulation

PFO closure vs medical therapy/no therapy in adults without a prior PFO-associated stroke.

Suggest against routine closure

- Migraines.
- SCUBA divers to prevent decompression illness.
- Thrombophilia
- Atrial septal aneurysm
- DVT
- TIA- if recurrent and high probability patient may choose PFO closure

Suggest closure

- Systemic embolism
- Platypnea-orthodeoxia syndrome- may choose no PFO closure

PFO closure vs antiplatelet therapy in adults with a prior PFO-associated stroke.

Recommend closure	• Patients between 18 and 60 years • High-risk anatomy like ASA • Elevated RoPE score≥7 • >60 years.
Suggest closure	• Thrombophilia on antiplatelet therapy but not on anticoagulation therapy.
Suggest against closure	• History of atrial fibrillation.

PFO closure vs anticoagulation therapy in adults with a prior PFO-associated stroke.

Suggest closure	• Patients between 18 and 60 years and no other indication for anticoagulation. • High-risk anatomy like ASA • Elevated RoPE score≥7 • >60 years.

Post-procedure management of antiplatelet regimen or anticoagulation

- No recommendation beyond 1 month of dual antiplatelet therapy after PFO closure.

Complications of PFO Closure

- Periprocedural atrial fibrillation ~3%.
  - Occurs early and not associated with stroke risk.
- Air embolus <1%
- Device embolization 1-2%
- Tamponade <1%
- Erosion 0.1-0.3% with Amplatzer device

Thank you