

PFO Closure for Stroke Prevention

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Interventional Cardiology and Structural Heart Disease

**Community
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DISCLOSURES:

NONE

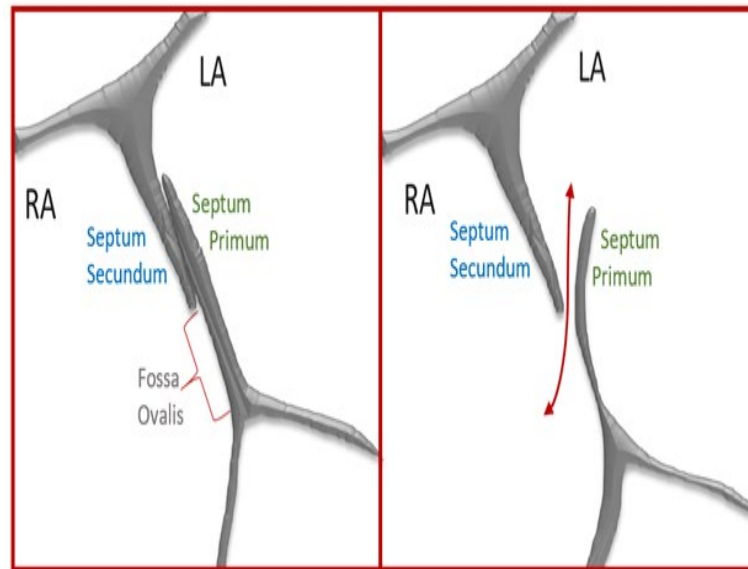
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Understanding PFO: Anatomy & Prevalence

What Is a PFO?

- Remnant of the fetal foramen ovale — normally fuses within 1 year of birth
- Persists in ~25–27% of the general adult population
- Creates a flap valve between septum primum and septum secundum
- Opened transiently by any maneuver that raises right atrial pressure (Valsalva, cough, straining)
- Larger PFOs (>4 mm), associated ASA, or prominent Eustachian valve increase embolic risk

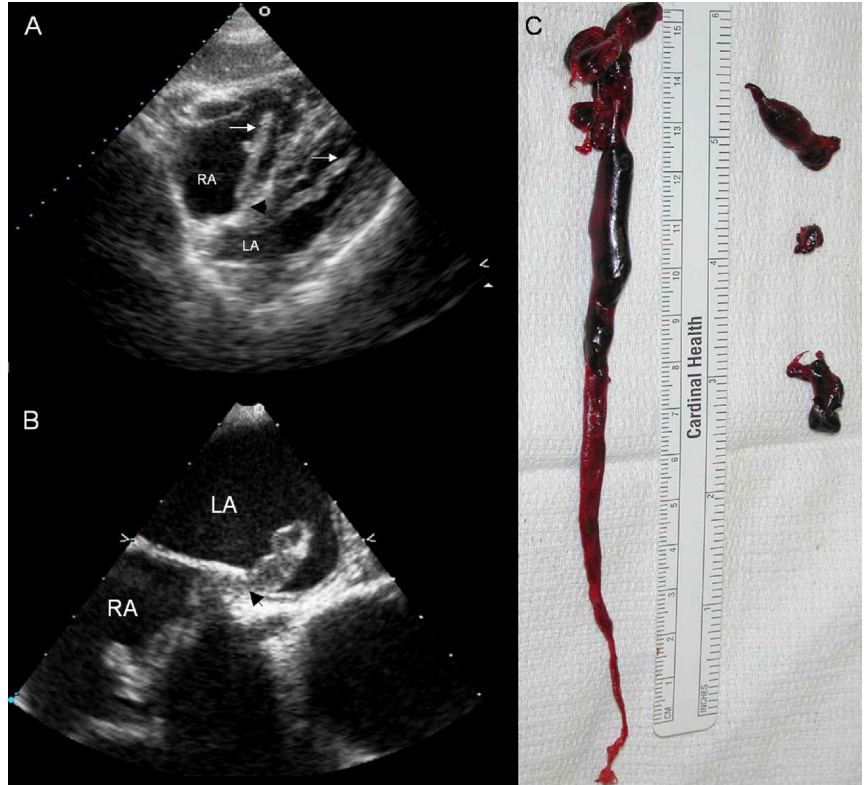


Prevalence: ~25% of adults | Higher in cryptogenic stroke: 40–56%

Understanding PFO: Anatomy & Prevalence

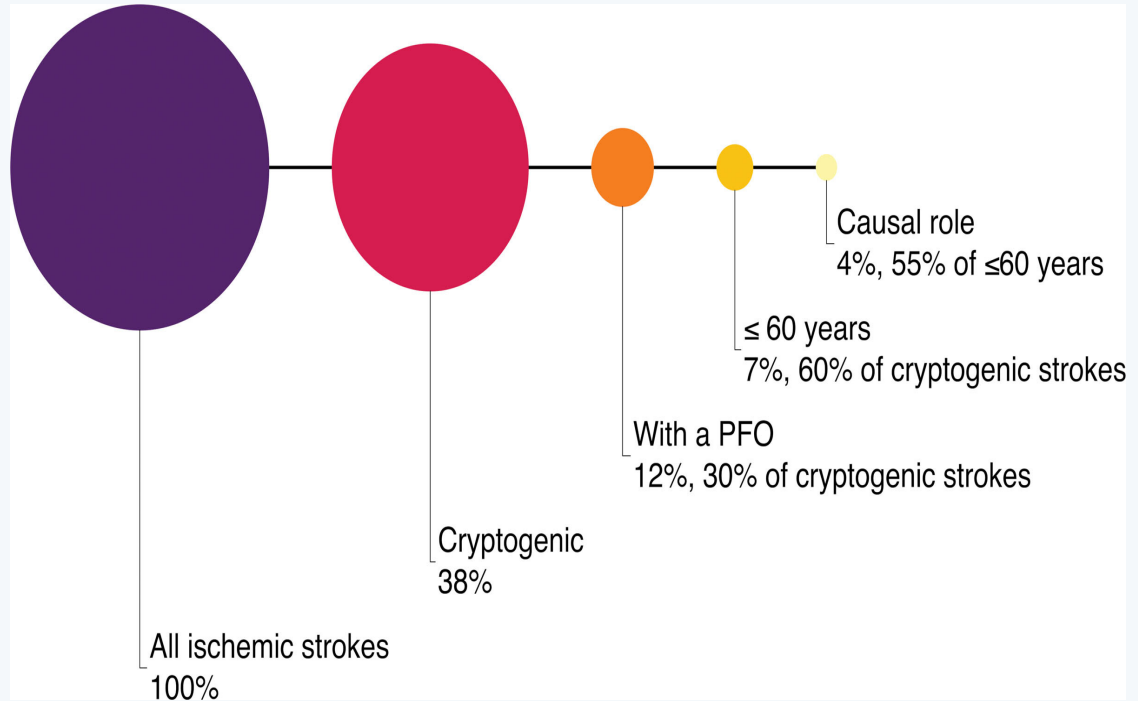
Proposed Mechanisms of Paradoxical Embolism

- Paradoxical embolism: DVT or pelvic thrombus traverses PFO into systemic circulation
- In situ thrombus formation within the PFO tunnel itself
- Mean diameter of PFO is 9.9 mm, thrombi traversing PFO are large enough to occlude middle cerebral artery (3 mm) or cortical branches (1 mm)
- Coexistent hypercoagulable states (antiphospholipid Ab, Factor V Leiden) amplify risk



Cryptogenic Stroke & the PFO Connection

- Stroke Prevalence is increasing in US and worldwide (7.5 million; 2019).
- 10% occur in 18-50 year olds
- Since 1990 >20% increase in prevalence with incidence rates rising by 15% in this age group.



Patient Selection: The RoPE Score

Risk of Paradoxical Embolism (RoPE) Score

Feature	Points
No hypertension	+1
No diabetes	+1
No prior stroke/TIA	+1
Non-smoker	+1
Cortical infarct on imaging	+1
Age 18–29	+5
Age 30–39	+4
Age 40–49	+3
Age 50–59	+2
Age 60–69	+1
Age ≥70	0

Score Interpretation

0–3

PFO-Attributable Fraction: ~15%

PFO prevalence in stroke at this score: ~30% • Low yield from closure

4–5

PFO-Attributable Fraction: ~40%

PFO prevalence in stroke at this score: ~50% • Intermediate yield from closure

6–7

PFO-Attributable Fraction: ~65%

PFO prevalence in stroke at this score: ~60% • High yield from closure

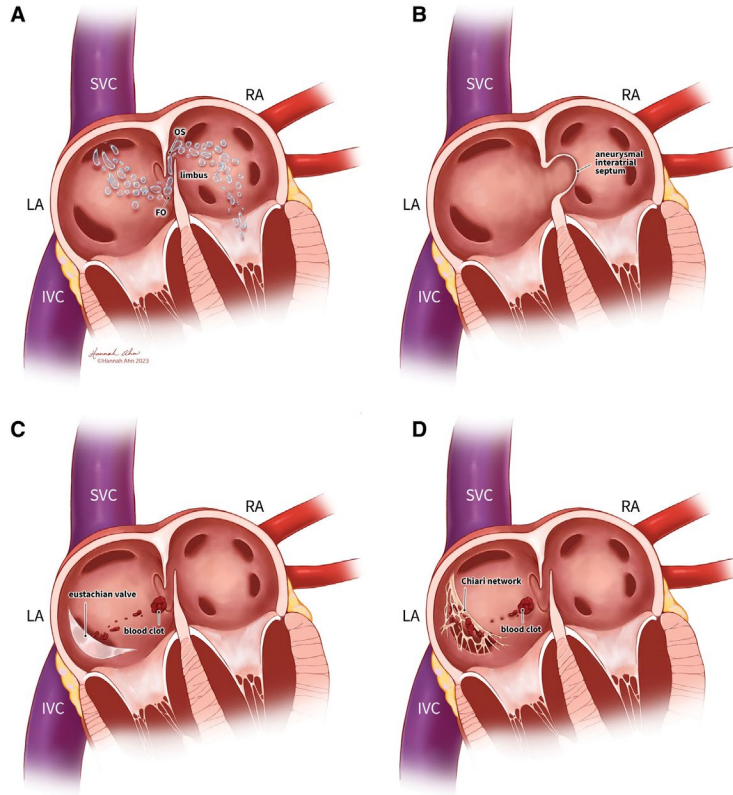
8–10

PFO-Attributable Fraction: ~88%

PFO prevalence in stroke at this score: ~75% • Very High yield from closure

Target for closure: RoPE ≥ 7, age < 60, cryptogenic after monitoring

High risk features of a PFO



A

High-risk PFO
Large shunt or ASA

No ————— Yes

RoPE
Score
 <7
 ≥ 7

Unlikely (15%)	Possible (37%)
Possible (37%)	Probable (48%)

Risk of Paradoxical Embolism Combined Scoring

RoPE score calculator	
Patient characteristics	Points
No history of hypertension	+1
No history of diabetes	+1
No history of stroke or TIA	+1
Nonsmoker	+1
Cortical infarct on imaging	+1
Age, years	
18–29	+5
30–39	+4
40–49	+3
50–59	+2
60–69	+1
≥70	+0
Total RoPE score	0–10

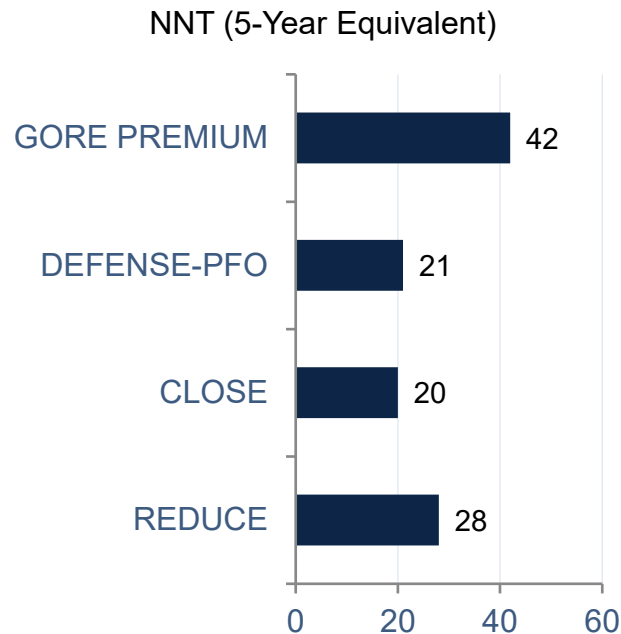
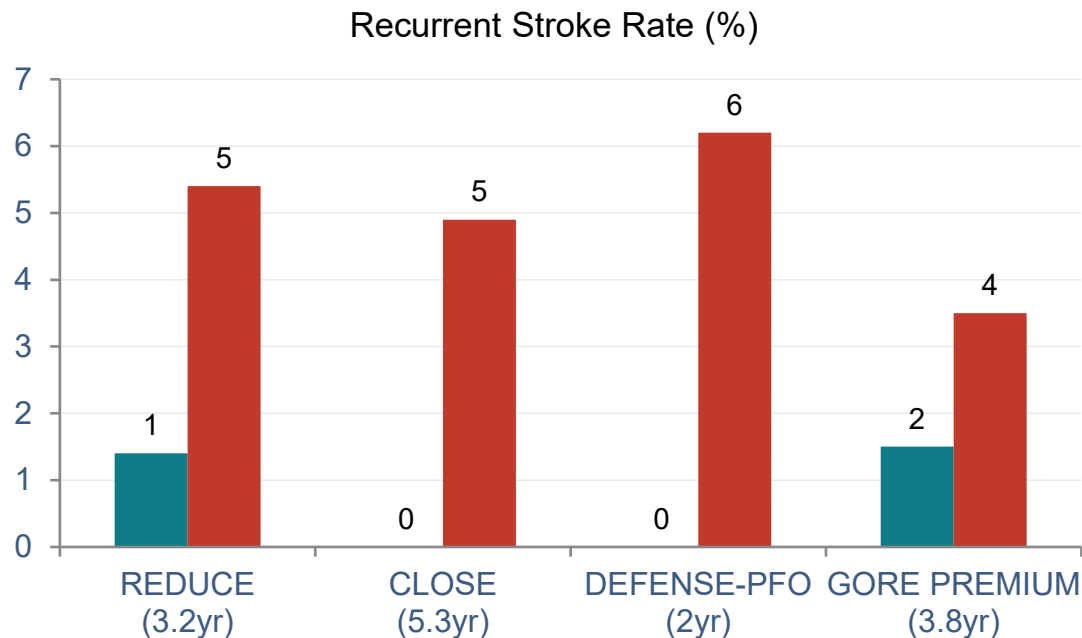
PASCAL classification system		
High RoPE score (≥7)	High-risk PFO feature (LS and/or ASA)	PFO-related stroke
Absent	Absent	Unlikely
Absent	Present	Possible
Present	Absent	
Present	Present	Probable

Landmark RCT Evidence: The Three Trials That Changed Practice

Trial	Year	N	Device	Follow-up	Primary Endpoint RRR	NNT (5 yr)	Afib Risk
CLOSURE I	2012	909	STARFlex	2 yr	NS (p=0.37)	—	~5%
REDUCE	2017	664	Helex/Cardioform	3.2 yr	77% (p=0.002)	~28	6.6%
CLOSE	2017	663	Various	5.3 yr	97% (p<0.001)	~20	4.6%
DEFENSE-PFO	2018	120	Amplatzer PFO	2 yr	100% (p=0.013)	~21	0%
GORE PREMIUM	2020	1390	Cardioform	3.8 yr	59% (p=0.04)	~42	4.2%

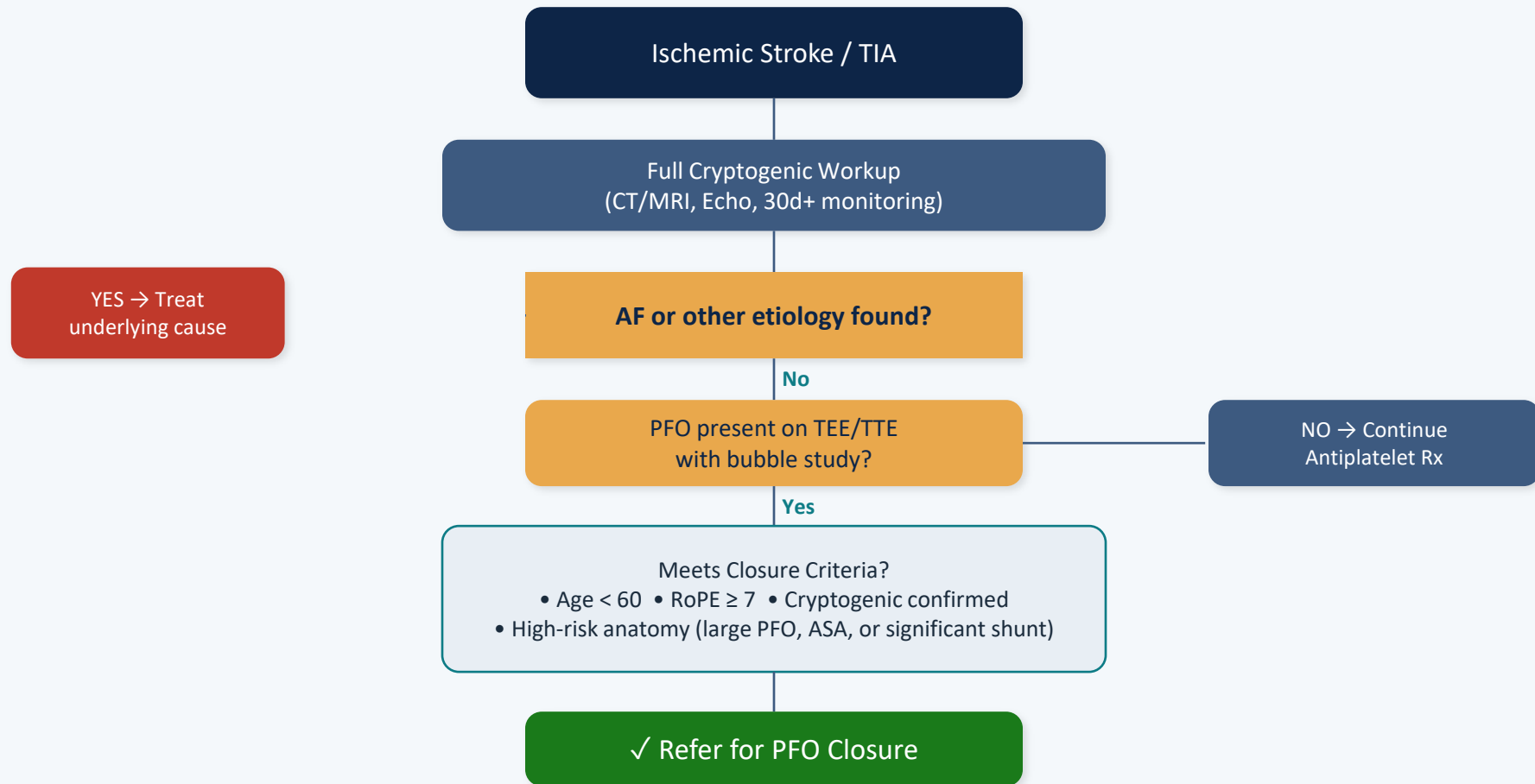
Key Insight: CLOSURE I failed because of device design (STARFlex → high incomplete closure rates) and suboptimal patient selection. The three 2017–2020 trials used rigorous prolonged cardiac monitoring to exclude occult AF, enrolled younger patients (<60 yo) with high-risk PFO anatomy, and showed consistent benefit with NNT of 20–42 over 3–5 years.

Outcome Data: Closure vs. Medical Therapy



Clinical Context: An NNT of 20–28 over 3–5 years is highly favorable compared to most cardiovascular interventions. For reference: statins for primary prevention NNT $\approx$ 100–200 over 5 years; carotid endarterectomy for symptomatic high-grade stenosis NNT $\approx$ 17 over 2 years. Closure appears cost-effective at standard willingness-to-pay thresholds.

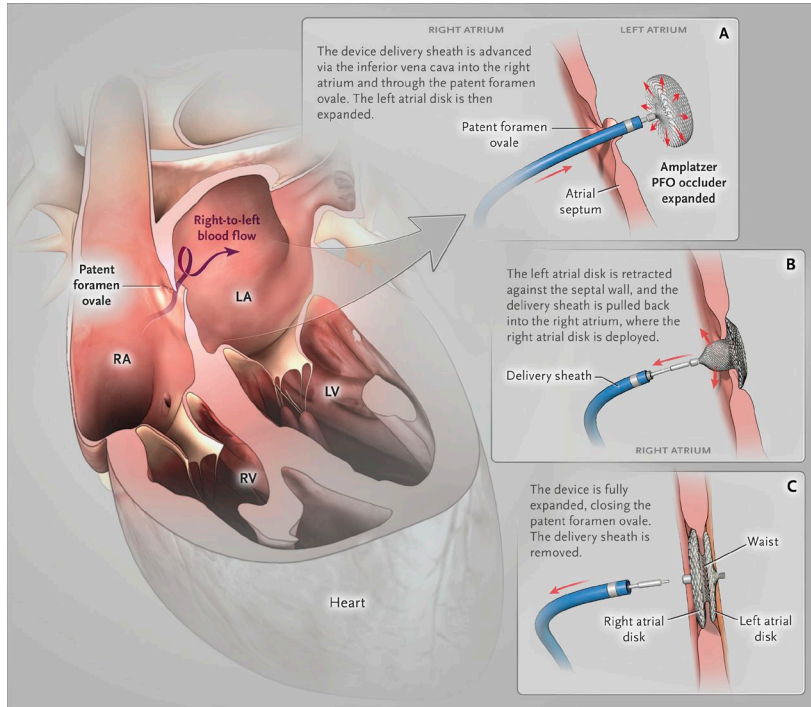
Patient Selection Algorithm: Who Gets Referred for Closure?



FDA-Approved Devices for PFO Closure

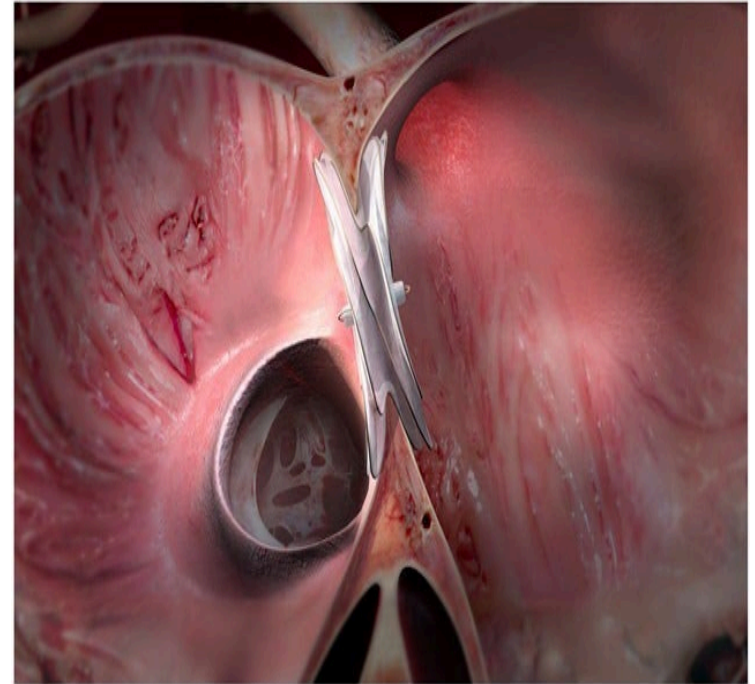
Amplatzer™ PFO Occluder

Abbott (FDA approved 2016)



GORE® Cardioform Septal Occluder

W.L. Gore (FDA approved 2018)



Procedural Steps: PFO Closure Walkthrough

01 Vascular Access & Anticoagulation

Right femoral vein access (6–9 Fr sheath). UFH bolus: ACT $\geq$ 250 sec. Optional TEE or ICE catheter guidance.

02 Transseptal Crossing

Cross PFO with J-wire or standard 0.035" wire. Confirm position in left atrium with fluoroscopy. No transseptal puncture needed — PFO is a natural channel.

03 Sizing & Imaging

TEE measurement of tunnel length, PFO diameter, septum secundum thickness. Bubble contrast to characterize shunt grade (I–IV). ICE alternative for conscious sedation cases.

04 Device Deployment

Advance delivery sheath to LA. Deploy LA disc. Pull back until LA disc contacts septum primum. Deploy RA disc. 'Minnesota Wiggle' to confirm secure seating. Release under imaging confirmation.

05 Post-Deployment Assessment

Repeat bubble study (should show no/minimal residual shunt). Assess device position, pericardial effusion, mitral valve function. Remove sheath with manual compression.

06 Post-Procedure Care & Antiplatelet Therapy

Aspirin 81–325 mg x 6 months + clopidogrel 75 mg x 1–3 months. Resume antiplatelet monotherapy at 6 months. Follow-up echo at 1 month and 6 months.

Complications: Recognizing & Managing Risk

Moderate

4–6%

New-Onset Atrial Fibrillation

Usually transient, often device-related mechanical irritation or unmasking occult paroxysmal AF. Monitor 24h post-procedure. Rate-control; anticoagulate if persistent >24h.

High

<0.5%

Device Embolization

Rare but catastrophic. Requires percutaneous or surgical retrieval. Prevented by rigorous deployment QC and Minnesota Wiggle test.

Low

5–10%

Residual Shunt

Grade I–II residual common at 1 month; majority close by 6–12 months with endothelialization. Persistent grade III–IV shunt: consider repeat closure.

Low–Moderate

1–2%

Vascular Access Complications

Hematoma, AV fistula, retroperitoneal bleed. Use ultrasound-guided access and proper hemostasis.

High

<0.5%

Pericardial Effusion / Tamponade

Rare with PFO (more common with ASD closure due to disc-wall friction). Echo QC on table; maintain pericardiocentesis capability.

Moderate

<1%

Thrombus on Device

Risk window: first 1–6 months before endothelialization complete. Dual antiplatelet during this period. TEE/TTE at 1 month if symptoms.

Current Guideline Recommendations

AHA/ASA 2021 Stroke Prevention

Class IIa, LOE B-R

PFO closure is reasonable in patients aged 18–60 with cryptogenic ischemic stroke and high-risk PFO features (large PFO, ASA, or significant right-to-left shunt) after exclusion of other stroke etiologies.

ESC 2020 Cardiology Guidance

Class IIa, LOE B

PFO closure should be considered for secondary prevention in patients aged ≤60 years with PFO-attributable cryptogenic stroke or TIA, who meet high-risk anatomical criteria.

ACC/AHA 2023 Valvular Heart Disease

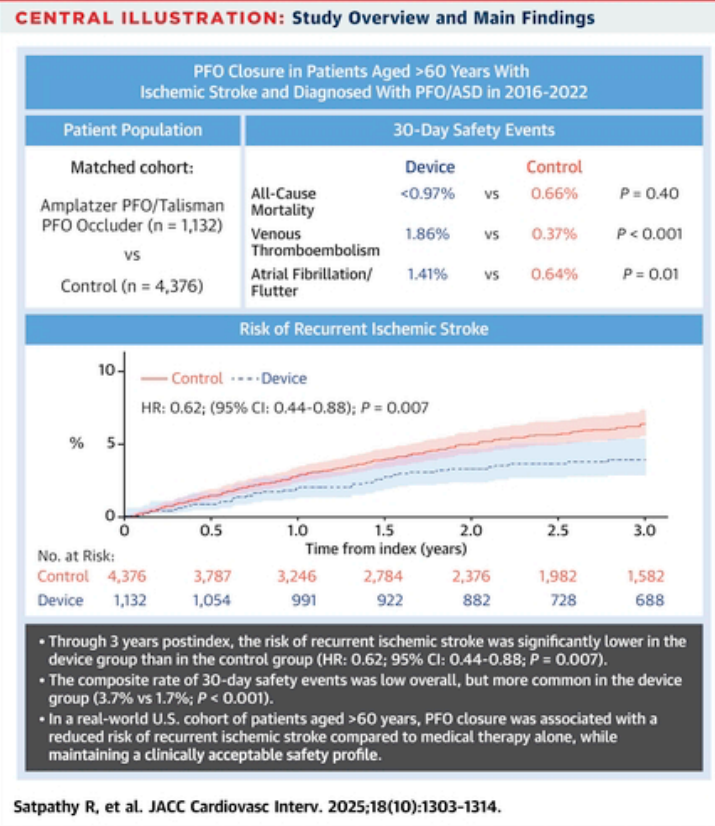
Class IIb

In patients >60 years with cryptogenic stroke and PFO, the benefit of closure over medical therapy alone is uncertain; shared decision-making is recommended.

Bottom line: Strong Class IIa support for ages 18–60, cryptogenic stroke, high-risk anatomy, AF excluded. Uncertainty remains for age

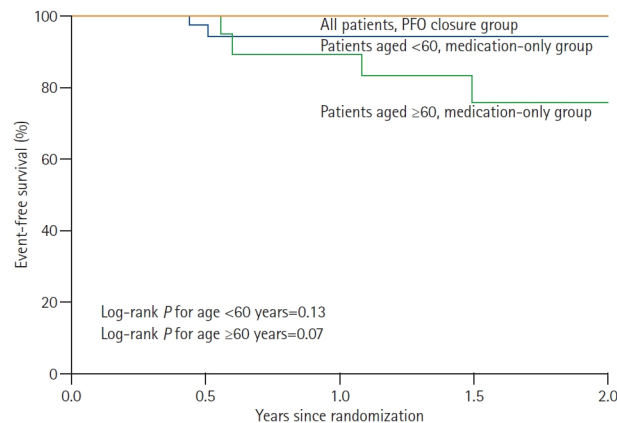
PFO Closure in patients > 60

- PFO attributable strokes considered lower in patients > 60.
- Competing mechanisms (AF, carotid disease, valvular heart disease) more prevalent in this population.
- Recurrent cryptogenic events higher in PFO attributable patients > 60 in observational studies.
- PFO seem to be larger in elderly with high risk of comorbidities like venous thromboembolism and increased right heart pressures.



PFO Closure in patients > 60

- Subanalysis of DEFENCE PFO trial comparing younger (<60 years) versus older (≥ 60 years) patients, the 2-year event rate difference between medical treatment versus PFO closure was 24.6% (HR, 7.36; 95% CI, 0.28-195.81; log-rank $P=0.07$) in patients >60 years after a median follow-up of 3 years
- Even higher (80%) in patients ≥ 70 years (HR, 11.64; 95% CI, 0.43-318.81; log-rank $P=0.03$)



Number at risk

Age <60 years

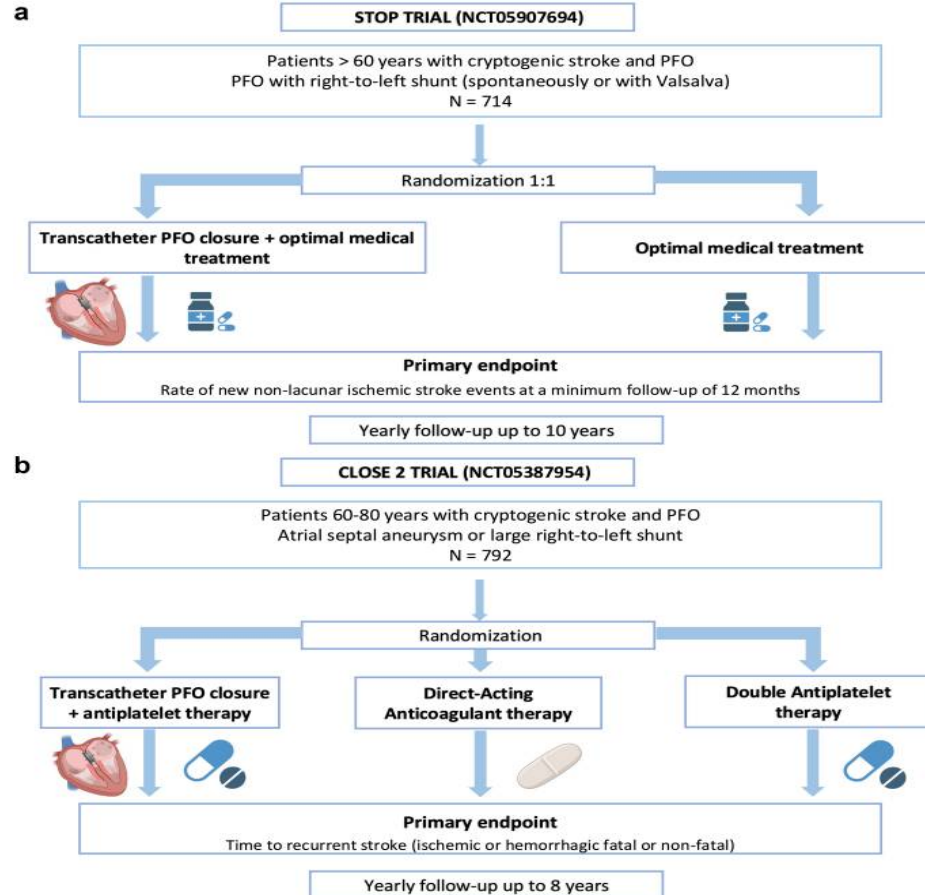
PFO closure	47	39	35	31	29
Medication-only	39	32	28	26	25

Age ≥ 60 years

PFO closure	13	13	12	12	12
Medication-only	21	19	15	10	10

Patent Foramen Ovale Closure in Old Stroke Patients: A Subgroup Analysis of the DEFENSE-PFO Trial
J Stroke. 2021;23(2):289-292.

Ongoing PFO Closure trials in patients > 60



Clinical Takeaways & Referral Guide



Refer if:

Age <60 • Cryptogenic stroke confirmed • PFO on bubble study • RoPE ≥ 7 • AF excluded after ≥ 30 day monitoring



Do NOT close if:

Occult AF found • No PFO on adequate bubble study • Alternative stroke etiology identified • Patient declines after counseling



Timing:

Ideally 3–6 months post-stroke (allow neurological stability). Avoid closure during acute thrombotic phase.



Bridge antithrombotic:

Aspirin 81–325 mg from diagnosis until closure. Continue dual antiplatelet (ASA + clopidogrel) for 3–6 months post-closure.



Older individuals on a case by case basis if no alternative diagnosis may benefit.

Thank you !

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