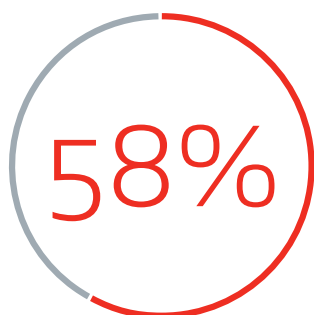


PFO CLOSURE META-ANALYSIS

"Meta-analysis comparing patent foramen ovale (PFO) closure versus medical therapy to prevent recurrent cryptogenic stroke" as published in the *American Journal of Cardiology*

Meta-analysis of five randomized controlled trials (RCTs) found PFO closure plus medical management significantly reduces the risk of recurrent stroke compared to medical management alone.¹



Relative recurrent stroke risk reduction with PFO closure plus medical therapy versus medical therapy alone¹

Stroke events

(p = .03)

Closure	Medical
(N = 1829)	(N = 1611)
37 (2%)	72 (4.5%)

Major bleeding

(p = .93)

No increased risk of major bleeding with PFO closure¹

Closure	Medical
(N = 1760)	(N = 1523)
24 (1.4%)	19 (1.2%)

Atrial fibrillation (AF)

(p = .0001)

Increased risk of AF with PFO closure¹

Closure	Medical
(N = 1784)	(N = 1607)
76 (4.3%)*	12 (.7%)*

71% (54 / 76) of AF events were considered transient¹

* Newly detected AF.

3,440 Patients

- Cryptogenic stroke† and PFO‡
- Mean age range: 43–50
- Mean follow-up: 4.1 years

1,829 PFO closure group

- Devices varied
- Medical therapy regimen: Varied per study — Antiplatelet, anticoagulation or both

1,611 Medical therapy group

- Medical therapy regimen: Varied per study — Antiplatelet, anticoagulation or both

RCTs: Closure 1-2012²,
PC Trial-2013³,
REDUCE-2017⁴,
RESPECT-2017⁵
and CLOSE-2017⁶

† Variable rates of cardiovascular risk factors.

‡ Variable rates of high-risk PFO features.

1. Ando T, Holmes AA, Pahuja M, et al. Meta-analysis comparing patent foramen ovale closure versus medical therapy to prevent recurrent cryptogenic stroke. *American Journal of Cardiology* 2018;121(5):649-655.
2. Furlan AJ, Reisman M, Massaro J, Mauri L, Adams H, Albers GW, Felberg R, Herrmann H, Kar S, Landzberg M, Raizner A, Wechsler L, CLOSURE I Investigators. Closure or medical therapy for cryptogenic stroke with patent foramen ovale. *N Engl J Med* 2012;366:991-999.
3. Meier B, Kalesan B, Mattle HP, Khattab AA, Hildick-Smith D, Dudek D, Andersen G, Ibrahim R, Schuler G, Walton AS, Wahl A, Windecker S, Juni P, PC Trial Investigators. Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N Engl J Med* 2013;368:1083-1091.
4. Sondergaard L, Kasner SE, Rhodes JF, Andersen G, Iversen HK, Nielsen-Kudsk JE, Settergren M, Sjostrand C, Roine RO, Hildick-Smith D, Spence JD, Thomassen L, Gore REDUCE Clinical Study Investigators. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med* 2017;377:1033-1042.
5. Saver JL, Carroll JD, Thaler DE, Smalling RW, MacDonald LA, Marks DS, Tirschwell DL, RESPECT Investigators. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med* 2017;377:1022-1032.
6. Mas JL, Derumeaux G, Guillon B, Massardier E, Hosseini H, Mechtouff L, Arquizan C, Bejot Y, Vuillier F, Detante O, Guidoux C, Canaple S, Vaduva C, Dequatre-Ponchelle N, Sibon I, Garnier P, Ferrier A, Timsit S, Robinet-Borgomano E, Sablot D, Lacour JC, Zuber M, Favrole P, Pinel JF, Apoil M, Reiner P, Lefebvre C, Guerin P, Piot C, Rossi R, Dubois-Rande JL, Eicher JC, Meneveau N, Lussan JR, Bertrand B, Schleich JM, Godart F, Thambo JB, Leborgne L, Michel P, Pierard L, Turc G, Barthelet M, Charles-Nelson A, Weimar C, Moulin T, Juliard JM, Chatellier G, CLOSE Investigators. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med* 2017;377:1011-1021.

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