

## References

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1. InterQual® Level of Care Criteria 2019, Acute Care Adult, McKesson Health Solutions, LLC.
2. Sutton MG. Devices for percutaneous closure of a secundum atrial septal defect. *UpToDate*. Updated Dec 09, 2015.
3. Doyle T, Kavanaugh-McHugh A, Soslow J, Hill K. Management of patent ductus arteriosus. *UpToDate*. Reviewed Oct 19, 2015.
4. Messe SR, Ammash NM. Treatment of atrial septal abnormalities (PFO, ASD, and ASA) for prevention of stroke in adults. *UpToDate*. Reviewed Dec 10, 2015.
5. Messé, S, Gronseth, G, Kent, D, Kizer, G, et al. Practice advisory: Recurrent stroke with patent foramen ovale (update of practice parameter): *Neurology*. 2016;87(8): 815-821.
6. Saver JL, Carroll JD, Thaler DE, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med*. 2017;377:1022-1032.
7. Søndergaard L, Kasner SE, Rhodes JF, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med*. 2017;377(11):1033-1042.
8. Mas JL, Derumeaux G, Guillon B, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med*. 2017;377:1011-1021.
9. Kent DM, Dahabreh IJ, Ruthazer R, et al. Device closure of patent foramen ovale after stroke: pooled analysis of completed randomized trials. *Am J Cardio*. 2016;67(8):907-917.
10. U.S. Food and Drug Administration. Summary of safety and effectiveness data. Gore cardioform septal occluder. March 30, 2018. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf5/P050006s060b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050006s060b.pdf). Accessed April 10, 2019.
11. Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Patent foramen ovale (PFO) occluder (PMA P120021). 2016; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf12/P120021B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120021B.pdf). Accessed April 9, 2019.
12. Rogers T, Slack M, Waksman R. Overview of the 2016 US Food and Drug Administration circulatory system devices panel meeting on the amplatzer patent foramen ovale occluder. *Am J Cardiol*. 2017; 119(1):153-155.
13. Li J, Liu J, Liu M, et al. Closure versus medical therapy for preventing recurrent stroke in patients with patent foramen ovale and a history of

cryptogenic stroke or transient ischemic attack. *Cochrane Database of Syst Rev.* 2015 ;(9).

14. Shah R, Nayyar M, Jovin IS, et al. Device closure versus medical therapy alone for patent foramen ovale in patients with cryptogenic stroke: a systematic review and meta-analysis. *Ann Intern Med.* 2018;168(5):335-342.
15. De Rosa S, Sievert H, Sabatino J, et al. Percutaneous closure versus medical treatment in stroke patients with patent foramen ovale: a systematic review and meta-analysis. *Ann Intern Med.* 2018; 168(5):343-350.
16. Alushi, BB, Lauten, AA, Cassese, SS, et al. Patent foramen ovale closure versus medical therapy for prevention of recurrent cryptogenic embolism: updated meta-analysis of randomized clinical trials. *Clin Res Cardiol,* 2018; 107(9).
17. Rigatelli G, Pedon L, Zecchel R, et al. Long-term outcomes and complications of intracardiac echocardiography- assisted patent foramen ovale closure in 1,000 consecutive patients. *J Interv Cardiol.* 2016;29(5):530-538.
18. Mattle HP, Evers S, Hildick-Smith D, et al. Percutaneous closure of patent foramen ovale in migraine with aura, a randomized controlled trial. *Eur Heart J.* 2016;37(26):2029-2036.
19. Tobis JM, Charles A, Silberstein SD, et al. Percutaneous closure of patent foramen ovale in patients with migraine: the PREMIUM trial. *J Am Coll Cardiol.* 2017;70(22):2766-2774.
20. Snijder RJ, Luermans JG, de Heij AH, et al. Patent foramen ovale with atrial septal aneurysm is strongly associated with migraine with aura: a large observational study. *J Am Heart Assoc.* 2016; 5(12).
21. Mojadidi MK, Gevorgyan R, Nouredin N, Tobis, J. The effect of patent foramen ovale closure in patients with platypnea-orthodeoxia syndrome. *Catheter Cardiovasc Interv.* 2015; 86(4):701-707.
22. Chen TH, Hsiao YC, Cheng CC, et al. In-hospital and 4-year clinical outcomes following transcatheter versus surgical closure for secundum atrial septal defect in adults: a national cohort propensity score analysis. *Medicine (Baltimore).* 2015; 94(38).
23. Jalal ZZ, Hascoët SS, Gronier CC, et al. Long-term outcomes after percutaneous closure of ostium secundum atrial septal defect in the young: A nationwide cohort study. *JACC Cardiovasc Interv.* 2018;11(8).
24. Hayes Inc. Health Medical Technology Direct Report. *Transcatheter Closure of Patent Foramen Ovale for Prevention of Recurrent Cryptogenic Stroke* . Lansdale, Pa. Hayes, Inc; Published May 31, 2018. Accessed June 27, 2019.

25. Fang GH, Chen Q, Hong ZN, et al. The comparison of periventricular device closure with transcatheter device closure and the surgical repair via median sternotomy for perimembranous ventricular septal Defect. *Ann Thorac Cardiovasc Surg.* 2018; 24:308-314.
26. Hayes Inc. Health Medical Technology Direct Report. *Gore Cardioform Septal Occluder (W.L. Gore & Associates Inc.) for Closure of Atrial Septal Defects* Lansdale, Pa: Hayes, Inc; December 12, 2019
27. Tashiro H, Suda K, Iemura M, Teramachi Y. Intergenerational differences in the effects of transcatheter closure of atrial septal defects on cardiac function. *J Cardiol.* 2017; 70(6):620-6.
28. Hayes, Inc. Evidence Analysis Research Brief. *Amplatzer Piccolo (Abbott) For Closure of Patent Ductus Arteriosus.* Lansdale, Pa: Hayes, Inc.; January 24, 2020.
29. Kernan WN, Ovbiagele B, Black HR, et al. Guidelines for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. 2014;45(7):2160-236.
30. Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC Guideline for the management of adults with congenital heart disease: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *J Am Coll Cardiol.* 2019;73(12): e81-e192.
31. de Hemptinne Q, Horlick EM, Osten MD, et al. Initial clinical experience with the GORE® CARDIOFORM ASD occluder for transcatheter atrial septal defect closure. *Catheter Cardiovasc Interv.* 2017;90(3):495-503.
32. Lee PH, Song JK, Kim JS, et al. Cryptogenic stroke and high-risk patent foramen ovale: the DEFENSE-PFO trial. *J Am Coll Cardiol.* 2018;71(20):2335-42.
33. Merkler AE, Gialdini G, Yaghi S, et al. Safety outcomes after percutaneous transcatheter closure of patent foramen ovale. 2017;48(11):3073-7.