HEALTHTRUST®
Education & Clinical Resources

Physician Insight

Left Atrial Appendage Closure Devices

A request was placed to the Physician Advisor Network to provide insight and information on the definition, use, and considerations around left atrial appendage closure devices.

Overview

The left atrial appendage (LAA) is typically an angled extension, of varied morphology (cactus, windsock, cauliflower, or chicken wing shape) and size, occurring off of the left atrium of the heart.[1] It has significant importance with regard to atrial fibrillation (AF) and thrombus formation, as the LAA is the primary location where thrombi in AF is formed.[1,2] Atrial fibrillation is the most common cardiac arrhythmia, which is estimated to affect more than 12 million people in the United States by the year 2030.[3] Thromboembolic stroke is a potential complication of AF, which often necessitates chronic oral anticoagulation as a preventative strategy. There is literature dedicated to understanding the role and management of LAA in order to provide alternatives to this treatment methodology.[4] Such devices providing potential alternatives include the Watchman® Left Atrial Appendage Closure Device and Watchman FLX by Boston Scientific and the Amplatzer Amulet by Abbott. These devices work by permanently closing off the LAA in order to prevent the formation of blood clots in the space. They have no impact on the continued presence of atrial fibrillation.

Indications for Use

The Watchman®, Watchman FLX, and the Amulet devices are approved by the FDA (in 2015, 2020, and 2021 respectively) and are indicated for use to reduce the risk of thromboembolism from the LAA in patients with nonvalvular atrial fibrillation. Both are permanent, percutaneous, transcatheter devices formulated out of a Nitinol mesh with similar and specific contraindications listed in their approval orders (found here: Watchman and Amulet). The Watchman FLX offers more size options than the previous generation Watchman.

Clinical Evidence

There is substantial evidence to support the use of closure devices in the treatment of LAA. A few key studies are shown below, but are not representative of the total scope of research available.

- An IDE trial by Lakireddy et al. (2021) randomly assigned 1878 patients to receive the Watchman or Amulet device, with safety and effectiveness (all-cause death, major bleeding, procedural complications, LAA occlusion at 45 days) as the primary outcomes. The authors concluded that the Amulet device was noninferior and LAA occlusion was higher when compared with the Watchman (98.9% v. 96.8%; [95% CI, 0.41–3.66]; *P*<0.001 for noninferiority; *P*=0.003 for superiority).[5]
- A meta-analysis by Ray et al. (2020) reviewing six studies (n = 614 total patients), indicated that insignificant peridevice leakages were higher in the Watchman group, but generally, both devices had low complication rates.
- A paper by Reddy et al. (2017) described the 5-year outcomes of patients included in the PROTECT and PREVAIL AF trials.[6-8] In both studies, the Watchman device was compared to long term warfarin therapy.

After review of five-year outcomes, the authors concluded that closure of the LAA with Watchman provided stroke prevention comparable to warfarin for patients with nonvalvular atrial fibrillation.[6]

- The PREVAIL trial by Holmes et al. (2014) was a randomized design to further assess the safety and efficacy of the Watchman for LAA occlusion as compared with long-term warfarin therapy.[8] The authors concluded noninferiority to warfarin for stroke prevention > 7 days post-procedure.[8]

Society Guidelines

The *2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation* states:

> "Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation."[9]

They indicate that this recommendation is due to new data from clinical trials and the additional approval of the Watchman device by the FDA.

Physician Advisor Insight

A panel of Interventional Cardiologist and Electrophysiologists within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of closure devices for LAA, specifically related to the use of the Watchman and Amulet devices. The Physician Advisors reported the following:

- Primary utilization is with the Watchman device, citing the completeness and availability of data, given the device's almost 10-year presence on the market.
- The Amulet device may have more versatility dependent on LAA morphology and depth.
- Provider expertise in deployment is essential for both devices, although time to mastery may be shorter with the Amulet.
- LAA procedures were potentially able to be completed with the Watchman in 80-100% of cases.
- The need for anti-coagulation may be different between devices.
- More Watchman versus Amulet trials are needed.

References

1. Di Biase L, Natale A, Romero J. Thrombogenic and Arrhythmogenic Roles of the Left Atrial Appendage in Atrial Fibrillation. *Circulation.* 2018;138(18):2036-2050.
2. Beigel R, Wunderlich NC, Ho SY, Arsanjani R, Siegel RJ. The left atrial appendage: anatomy, function, and noninvasive evaluation. *JACC Cardiovasc Imaging.* 2014;7(12):1251-1265.
3. Centers for Disease Control and Prevention. Atrial Fibrillation https://www.cdc.gov/heartdisease/atrial_fibrillation.htm. Accessed 5/31/2022.
4. Whitlock RP, Belley-Cote EP, Paparella D, et al. Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke. *N Engl J Med.* 2021;384(22):2081-2091.
5. Lakkireddy D, Thaler D, Ellis CR, et al. Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial. *Circulation.* 2021;144(19):1543-1552.
6. Reddy VY, Doshi SK, Kar S, et al. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. *J Am Coll Cardiol.* 2017;70(24):2964-2975.
7. Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. *Lancet.* 2009;374(9689):534-542.
8. Holmes DR, Jr., Kar S, Price MJ, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. *J Am Coll Cardiol.* 2014;64(1):1-12.
9. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* 2019;74(1):104-132.

Initial or Update	Date	Completed by	Changes Made
Initial	06.01.2022	JW	Created