Procedural and short-term follow-up outcomes of Amplatzer Amulet occluder versus Watchman FLX device: A meta-analysis

Domenico G. Della Rocca, MD, PhD,* Michele Magnocavallo, MD, *†
Carola Gianni, MD, PhD,* Sanghamitra Mohanty, MD, * Veronica N. Natale, MPH, ‡
Amin Al-Ahmad, MD, * Carlo Lavalle, MD, † Rodney P. Horton, MD, *
Luigi Di Biase, MD, PhD, †∥ Andrea Natale, MD, FHRSh

From the *Texas Cardiac Arrhythmia Institute, St. David’s Medical Center, Austin, Texas. † Department of Cardiovascular/Respiratory Diseases, Nephrology, Anesthesiology, and Geriatric Sciences, Policlinico Umberto I, Sapienza University of Rome, Rome, Italy. ‡ Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland. Department of Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, New York. § Department of Cardiology, MetroHealth Medical Center, Case Western Reserve University School of Medicine, Cleveland, Ohio, and || Interventional Electrophysiology, Scripps Clinic, La Jolla, California.

Left atrial appendage (LAA) occlusion (LAAO) provides effective protection against thromboembolic events in high-risk, atrial fibrillation patients. Two percutaneous devices currently are available in the United States for stroke prophylaxis: the Watchman™ device (Boston Scientific Corporation, Marlborough, MA) and the Amplatzer™ Amulet™ LAA occluder (Abbott, Minneapolis, MN). The latter recently received US Food and Drug Administration approval as a result of the findings of the Amulet IDE randomized trial,1 which showed superiority for LAAO (lower rates of leaks >5 mm) based on a comparison between the second-generation Amplatzer™ plug, namely, the Amulet™ occluder, and the old-generation Watchman™ 2.5. However, this comparison does not reflect current clinical practice, as the old Watchman 2.5 has been replaced by the new-generation Watchman FLX. The FLX implements some important architectural changes that aim to reduce the risk of complications and improve sealing features. We sought to compare for the first time the periprocedural success and short-term outcomes with the Amulet vs the new-generation Watchman FLX.

Electronic databases were searched from inception until December 31, 2021, for eligible English literature. Procedural success was defined as successful deployment of the device within the appendage. Safety endpoint was the occurrence of death, stroke, major bleeding, myocardial infarction, major vascular complications, device embolization, or pericardial effusion within 7 days postprocedure. Data from a first imaging study performed within 3 months were used to assess the incidence of peridevice leaks >5 mm and device-related thrombosis. Statistical analysis was performed using meta-package for R Version 5 and RStudio Version 1.2. Freeman-Tukey double arcsine transformation was used to establish variance of raw proportions. We used the Hartung-Knapp-Sidik-Jonkman method with the random effect model to combine the transformed proportions.

We included 21 studies for a total of 4186 LAAO patients (mean age 75 ± 8 years; 61.9% male; CHA2DS2-VASc score 4.3 ± 1.5; HAS-BLED score 3.1 ± 1.1). Among these patients, 3187 received an Amulet and 999 a Watchman FLX. Thromboembolic risk was not different between groups (CHA2DS2-VASc score 4.3 ± 1.5 for Amulet and 4.2 ± 1.5 for Watchman FLX; P = .63). Procedural success was achieved in 99.4% for Amulet (95% confidence interval [CI] 98.9–99.8) and 99.9% for FLX (95% CI 99.2–100) (P = .08). The primary safety endpoint was significantly higher in the Amulet group (4.7%; 95% CI 2.9–6.7) than the FLX group (0.6%; 95% CI 0–2.3) (P < .01) (Figure 1A). Overall pericardial effusion/tamponade occurred in 2.5% of the Amulet

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group (95% CI 1.1–4.2) and 0.1% of the FLX group (95% CI 0–1.3) (P < .01). Similarly, clinically relevant pericardial effusion/tamponade was statistically significant (Amulet: 0.7%; 95% CI 0.3–1.4; vs FLX: 0.01%; 95% CI 0–0.4; P = .01). Periprocedural major/intracranial bleeding was 2.3% (95% CI 1.1–3.7) in the Amulet group and 0.1% (95% CI 0–1.2) in the FLX group (P = .01). No differences were observed for other periprocedural complications, such as death and stroke. Device dislodgments were 15 (0.1%; 95% CI 0–0.3) with Amulet vs none with FLX. Device-related thrombosis occurred in 1.6% (95% CI 0.6–3.1) of patients in the Amulet group and 1% (95% CI 0.1–2.6) of patients in the FLX group (P = .49).

Among 2363 follow-up transesophageal echocardiographic studies, Amulet was associated with a trend toward a higher incidence of peridevice leaks >5 mm [0.34%; 95% CI 0.04–0.86] vs FLX (0.01%; 95% CI 0–0.24) (P = .06) (Figure 1B).

In this meta-analysis, LAAO with the Amulet occluder showed a significantly higher incidence of periprocedural complications (P < .01) as well as a trend toward lower procedural success (P = .08) and more frequent incomplete appendage occlusion (leaks >5 mm; P = .06) compared to the new-generation Watchman FLX.

The Amulet occluder is a self-expanding nitinol device with a lobe and disk architecture that provides a double-sealing mechanism. These features may explain the findings of the recently published Amulet IDE randomized trial,1 which reported a lower rate of incomplete LAO with the Amulet compared to the parachute-shaped, old-generation Watchman 2.5. However, the latter device was recently replaced by the new Watchman FLX, which introduces some key features designed to improve periprocedural safety, device stability, and appendage occlusion (eg,atraumatic distal end, ability for full recapture, 2 rows of anchors). Additionally, the open architecture with an 18-strout design should better conform to irregular ostia, thereby reducing the risk of significant peridevice leaks.2 The revised design of the FLX may explain the results of this meta-analysis, which, to our knowledge, is the first study comparing periprocedural and short-term outcomes of the Amulet vs the new-generation Watchman.

In conclusion, LAAO with the new Watchman FLX may be associated with a lower incidence of periprocedural adverse events and peridevice leaks compared to the Amulet occluder.

References

Figure 1  Forest plots comparing periprocedural complications (A) and peridevice leaks (B). PMID/Abstract number reported in parenthesis. CI = confidence interval.