EMERGE LAA POST-APPROVAL STUDY: **REAL-WORLD EXPERIENCE WITH THE AMPLATZER™ AMULET™ LAA OCCLUDER IN THE UNITED STATES**

HRS 2024: Feasibility of Amulet Occluder Implantation after failed LAA Occlusion attempt with Single Lobe Device

Makkar A et al. HRS Conference 2024

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BACKGROUND

Left atrial appendage closure often fails with single lobe LAAO devices[1] in appendages that have shallow depth, multiple lobes, many trabeculations, wide orifice, shallow vertical take-off, or chicken wing anatomy.

CONCLUSION

Analysis of real-world Amulet occluder data in the US demonstrated:

- A **high degree of implant success** and a **low rate of adverse events** can be achieved using the Amulet LAA occluder.
- Amulet LAAO is **safe and effective in a broad range of anatomies**.
- In patients with a prior failed LAAO attempt with a single lobe device, the Amulet occluder (with dual-seal mechanism) **facilitates successful closure**.

ANALYSIS DESIGN

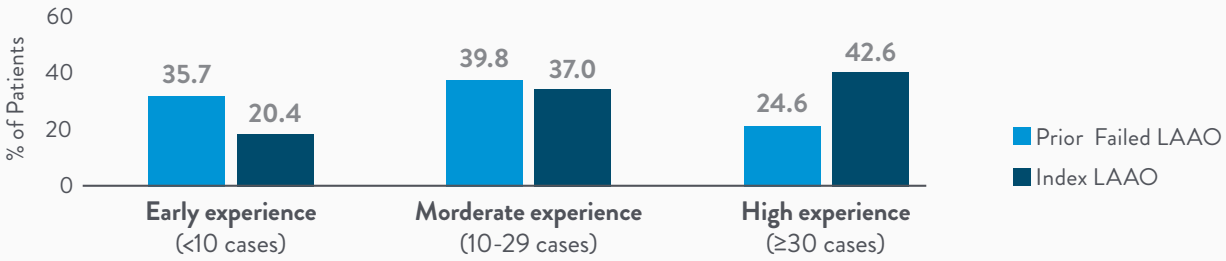
Purpose	This analysis characterizes outcomes of patients who had experienced prior failed percutaneous LAAO procedures utilizing Watchman 2.5™ or Watchman FLX™ device who underwent subsequent attempt with an Amulet occluder in EMERGE LAA.
Population	Includes patients who underwent an Amulet occluder implant attempt between August 14, 2021 and June 30, 2023 and enrolled in the National Cardiovascular Data Registry (NCDR) LAAO Registry™
Follow-up	Procedural, discharge, and 45 days
Outcomes and Patient Population	• Procedure details, closure assessment, and outcomes through 45 days • Comparison analysis from patients with: - Documentation of previous attempt of non-Amulet percutaneous LAAO with subsequent Amulet occluder attempt (Prior Failed LAAO) - **244 patients** - First LAAO Attempt with Amulet (Index LAAO) - **8347 patients**

KEY STUDY CONSIDERATIONS

IMPLANTER AMULET LAAO CASE EXPERIENCE LEVEL

- Majority of implanters in both cohorts had limited experience (<30 cases) implanting Amulet LAAO
- >1/3 of the implants in the Prior Failed LAAO cohort were done within the operators' first nine Amulet LAAO procedures

IMPLANTER AMULET LAAO CASE EXPERIENCE LEVEL



BASELINE CHARACTERISTICS WERE MORE CHALLENGING IN PRIOR FAILED LAAO COHORT THAN IN INDEX LAAO COHORT

- Increased history of congestive heart failure (42.6% vs. 33.8%; p=0.004)
- More prior bleeding events (73.4% vs. 65.9%; p=0.015)
- Larger LAA orifice width (23.6±6.2 mm vs. 22.2±5.9 mm; p<0.001)

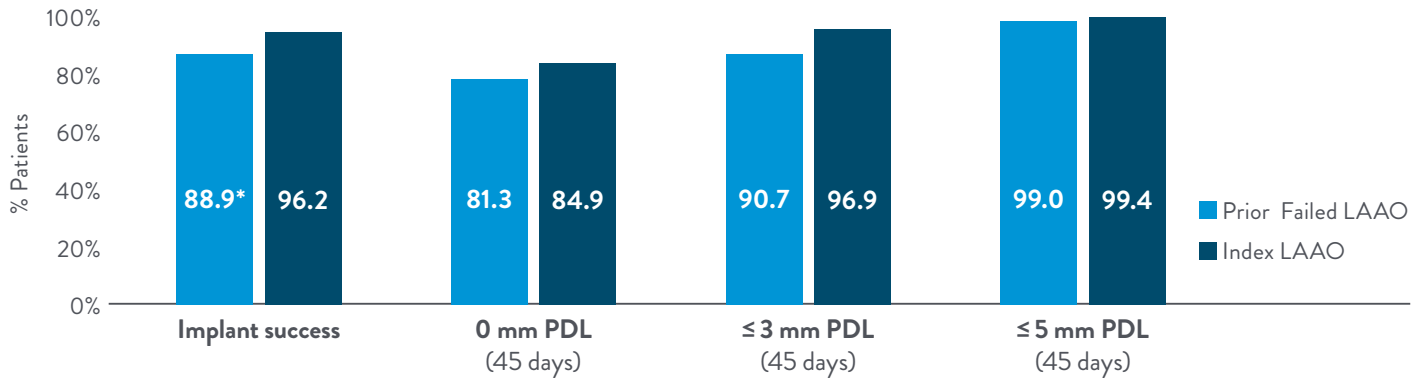
PATIENTS WERE AT HIGH RISK REGARDLESS OF PRIOR LAAO HISTORY

- Average CHA_2DS_2-VASc score of 4.7
- Average HAS-BLED score of 2.7

IMPLANT SUCCESS AND CLOSURE

HIGH DEGREE OF ACUTE IMPLANT SUCCESS AND CLOSURE THROUGH 45 DAYS

- When implantation of Watchman 2.5 or Watchman FLX LAAC device failed, subsequent Amulet LAAO attempt yielded 88.9% implant success rate
- > 90% clinically relevant closure (≤3mm PDL) with Amulet LAAO in Prior Failed LAAO cohort (45 days)
- 99% closure rate (≤5mm PDL) with Amulet LAAO in Prior Failed LAAO cohort (45 days)



*Most common reason for unsuccessful attempt in Prior Failed LAAO group was from anatomy not being conducive for implant (n=23 of 27 failed procedures) which may indicate these patients are not suitable for either dual or single occlusive device designs.

See Important Safety Information referenced within.

SAFETY

LOW RATE OF SAFETY EVENTS PERI-PROCEDURALLY AND THROUGH 45 DAYS

Even in high risk patient group with more challenging baseline characteristics and a prior failed Watchman LAAC device attempt, low adverse event rates were achieved.

	Prior Failed LAAO Cohort	Index LAAO Cohort
Safety endpoint composite*	1.6%	0.8%
All-stroke rate (45 days)	0.4%	0.3%
PE requiring intervention rate (45 days)	2.5% (1.7% for highly-experienced implanters**)	2.0% (1.7% for highly-experienced implanters**)

* Composite of all-cause death, ischemic stroke, systemic embolism, or device/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later).[2, 3]

** Highly-experienced implanters have implanted >30 Amulet LAAO devices.

RX ONLY

IMPORTANT SAFETY INFORMATION
AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

INDICATION FOR USE
The Amplatzer™ Amulet™ Left Atrial Appendage Occluder is a percutaneous transcatheter device intended to reduce the risk of thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation and who are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2D_2-VASc scores, are suitable for short term anticoagulation therapy, and have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.

CONTRAINDICATIONS
The Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder is contraindicated for patients:
- With the presence of intracardiac thrombus.
- With active endocarditis or other infections producing bacteremia.
- Where placement of the device would interfere with any intracardiac or intravascular structures.

POTENTIAL ADVERSE EVENTS
Potential adverse events associated with the device or implant procedure include, but are not limited to, the following: Air embolism; Airway trauma; Allergic reaction; Anemia; Anesthesia reaction (nausea, vasovagal reaction, confusion/altered mental status or other); Arrhythmia; Atrial septal defect; Bleeding; Cardiac arrest; Cardiac tamponade; Chest pain/discomfort; Congestive heart failure; Death; Device embolization; Device erosion; Device malfunction; Device malposition; Device migration; Device-related thrombus; Fever; Hematuria; Hypertension/hypotension; Infection; Multi-organ failure; Myocardial infarction; Perforation; Pericardial effusion; Pleural effusion; Renal failure/dysfunction; Respiratory failure; Seizure; Significant residual flow; Stroke; Thrombocytopenia; Thromboembolism: peripheral and pulmonary; Thrombus formation; Transient ischemic attack; Valvular regurgitation/insufficiency; Vascular access site injury (hematoma, pseudoaneurysm, arteriovenous fistula, groin pain or other); Vessel trauma/injury.

1. Makkar et al. Heart Rhythm 2023;20.
2. 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;64:1-12.
3. Kar S, Doshi SK, Sadhu A et al. Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial Circulation 2021;143:1754-1762.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference to the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

See Important Safety Information referenced within.

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