Clinical Insights

A PUBLICATION DELIVERING CONCISE CLINICAL DATA

AMPLATZER™ AMULET™ OCCLUDER

OBSERVATIONAL STUDY DATA CONFIRMS SOLID SAFETY PROFILE OF AMPLATZER™ AMULET™ OCCLUDER IN DAILY CLINICAL PRACTICE

KEY MESSAGE

The main objective of this study is to document procedural and long-term clinical outcome data on catheter-based LAA occlusion using the AMPLATZER Amulet device for the prevention of ischemic stroke.

This multicentre prospective real-world registry included 1,088 patients with non-valvular atrial fibrillation; 82.8% of patients were considered to have an absolute or relative contraindication to long-term anticoagulation and 72.4% had had a previous major bleeding episode. The aim of this report is to describe the periprocedural and early clinical/TEE results from this study.

Implant success rate (99.0%) and early safety profile (MAE, Major Adverse Event: 3.2% during index hospitalization) confirm that the AMPLATZER Amulet LAA Occluder is a safe alternative for prevention of stroke in patients with non-valvular AF. It is the largest, prospective evaluation of the AMPLATZER Amulet device in a clinical (CEC adjudicated) and echocardiographic (Core Lab evaluated) study.

STUDY DESIGN & PATIENT CHARACTERISTICS

In this prospective observational study, a total of 1,088 patients were enrolled in 61 centers in Europe, Australia, Israel, Chile and Hong Kong. All patients suffered from non-valvular atrial fibrillation; 82.8% of patients were considered to have an absolute or relative contraindication to long-term anticoagulation and 72.4% had had a previous major bleeding. With 64.9% of the patients having a CHA2DS2-VASc score ≥4 and 77.1% having a HAS-BLED score ≥3, the study cohort represented a population at high risk for stroke as well as for bleeding (fig. 1).

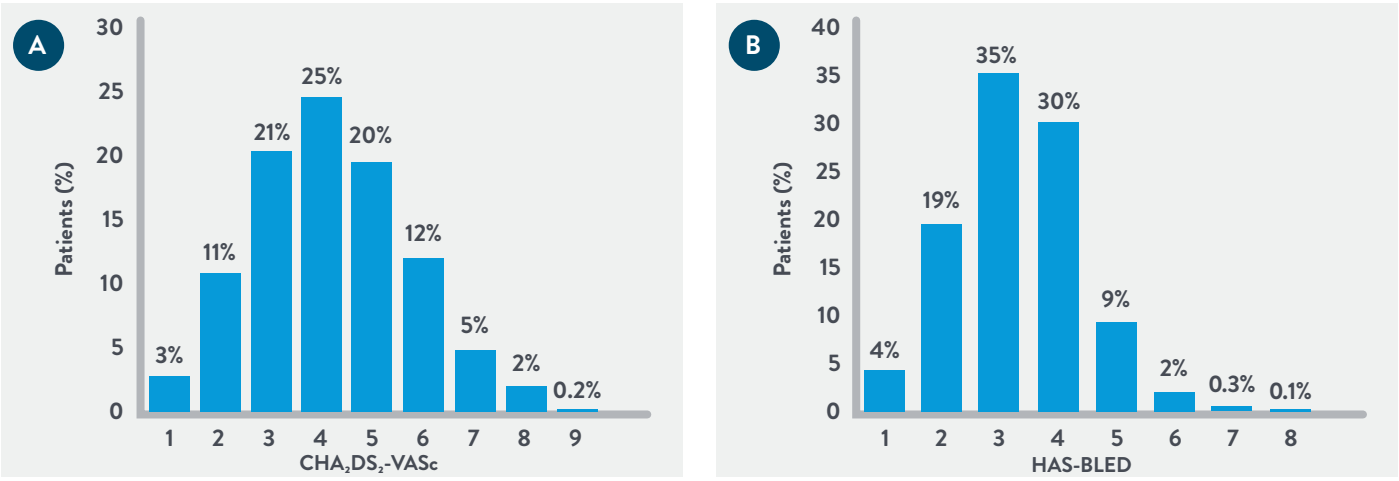

FIGURE 1: DISTRIBUTION OF STROKE RISK (CHA_2DS_2-VASC SCORE) AND BLEEDING RISK (HAS-BLED SCORE) IN THE STUDY POPULATION (MODIFIED ACCORDING TO LANDMESSER ET AL., 2017).

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HIGH IMPLANT SUCCESS RATE AND EFFECTIVE LAA CLOSURE

The AMPLATZER Amulet LAA occluder was successfully implanted in 1,077 of 1,088 patients (fig. 2); this corresponds to a technical success rate of 99.0%. The evaluation of the intraprocedurally obtained transesophageal echocardiographic (TEE) images by a core laboratory showed effective closure of the left atrial appendage, defined as no or only small peri-device leak (jet < 3 mm), in 99.6% of the patients. At the first follow-up after 1–3 months (mean value 67 ± 23 days), the closure rate was still high at 98.2%.[1]

HIGH INTRAPROCEDURAL LAA CLOSURE RATE: >99%

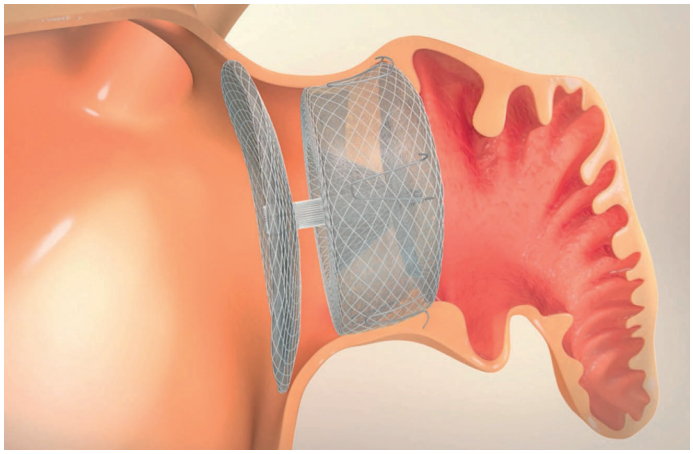

FIGURE 2: AMPLATZER AMULET LAA OCCUDER IN THE LEFT ATRIAL APPENDAGE.

LOW COMPLICATION RATES

To minimize bias and subjective interpretation, all adverse events were adjudicated by an independent expert committee. During the procedure and index hospitalization, 35 patients (3.2%) had a major adverse event, (MAE), an additional 4 patients experienced an MAE within 7 days after occlude implantation (tab. 1). Among MAE, serious bleedings were the most common event, while major vascular complications occurred in 10 patients and 4 patients suffered ischemic stroke. 61 patients experienced serious adverse device effects (SADE) within 7 days after the procedure or during the hospitalization; the SADE rate was therefore 5.6%. During the 7 day post-implant time, 2 patients showed thrombus formation on the LAA occluder and 1 patient experienced device embolization.[1]

LOW MAE RATE DURING HOSPITALIZATION >3.2%

	Number of Patients with Event(s), n (%)	
EVENT	Early (within ≤ 7 days after implantation or prior to discharge)	Late (> 7 days after implantation, within 3 months of procedure)
ISCHEMIC STROKES, SYSTEMIC EMBOLISMS AND CARDIOVASCULAR DEATHS	7 (0.6%)	15 (1.4%)
MAJOR ADVERSE EVENTS	39 (3.6%)	Not documented
EMBOLIZATIONS	1 (0.1%)	1 (0.1%)
ALL SERIOUS ADVERSE DEVICE EFFECTS	61 (5.6%)	26 (2.4%)

TABLE 1: SAFETY-RELATED EVENTS DURING THE FOLLOW-UP PERIOD (ADAPTED FROM LANDMESSER ET AL., 2017)

During the follow-up period, the rate for serious device-related complications decreased to 2.4% (26 patients). During the TEE performed 1–3 months after implantation a device-related thrombus was found in 8 patients. This means that in total, 10 patients showed device-related thrombi (1.5%) within the follow up period. 23 patients died prior to the first follow-up visit; of these, 13 cases were cardiovascular.[1]

CONCLUSION

This registry study is associated with the usual limitations of an observational study. However, the standard-surpassing measures such as the evaluation of TEE images by a core laboratory and the adjudication of adverse events by an independent expert committee show that it was of great importance to ensure as high a degree of objectivity as possible and to prevent bias. For this reason the obtained data provides valid evidence that the AMPLATZER Amulet LAA occluder can be safely implanted in an everyday patient collective and that it enables long-lasting LAA closure.

References:

1. Landmesser U, Schmidt B, Nielsen-Kudsk JE et al. Left atrial appendage occlusion with the AMPLATZER Amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study. EuroIntervention. 2017; 13(7):867-876.

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