UPMC Heart and Vascular Institute

Early Experience with the Amulet: A Real-World Comparison with Watchman FLX for Left Atrial Appendage Occlusion

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Background:

- Watchman and Amplatzer devices are the most used LAAO systems
- Real-world comparisons of the newer generation devices, Watchman FLX and Amulet, are scarce

Objective:

- Assess the early implementation of the Amulet in a real-world setting and compare it to Watchman FLX

Methods:

- Retrospective analysis of the early adoption of the Amulet at a multi hospital healthcare system from September 2021 – December 2022
- Comparison to similar number of unselected Watchman FLX recipients
- Analysis of procedural success rates, peri-device leaks (PDLs) and device related thrombosis (DRTs) at 45-day follow-up imaging (TEE or CCTA), in-hospital complications and clinical outcomes at 6 months

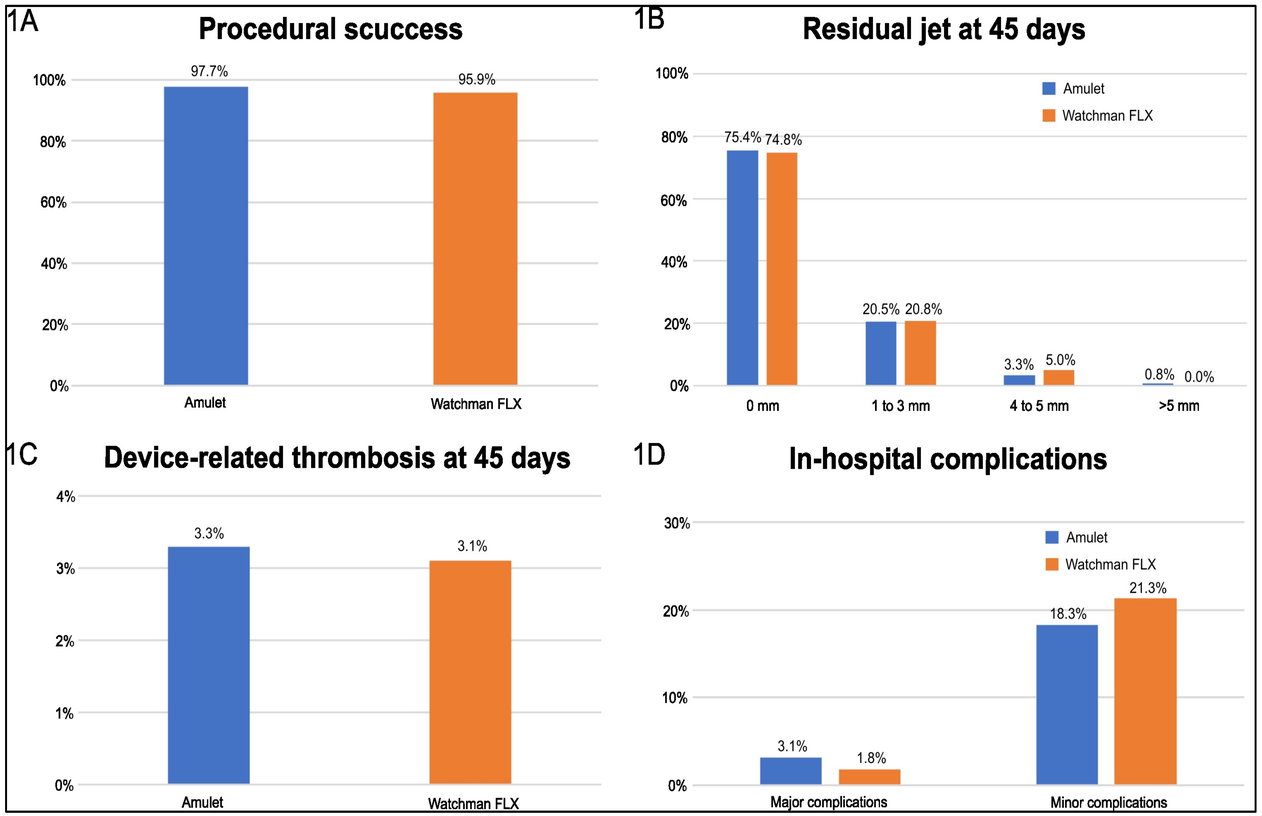

Figure 1. Procedural success rates (A), residual jets (B) and rates of DRT (C) at 45 days and in-hospital complications (D).

Results:

- 300 patients studied (n=300, mean age 76.5 ±7.1 years, 40% women, LVEF 52±9%, means CHA_2DS_2-Vasc Score 4.5±1.3), with 131 Amulet and 169 Watchman FLX recipients (Table 1)
- Procedural success rates were similar between device types (97.7% vs. 95.9%, p=0.37, Figure 1A) for Amulet vs. Watchman FLX
- Rates of PDL (24.6% vs. 25.2%, p=0.91; Figure 1B) and DRTs (3.3% vs. 3.1%, p=0.91; Figure 1C) at 45 days were similar in Amulet vs. Watchman FLX
- Major (3.8% vs. 1.8%, p=0.3) and minor (18.3% vs. 21.3%, p=0.52) complications were comparable between Amulet vs. Watchman FLX (Figure 1D)
- All-cause mortality (7.6% vs. 4.3%, p=0.27), cardioembolic (2.3% vs. 1.3%, p=0.54) and major bleeding (17.2% vs. 11.5%, p=0.2) events at 6 months were not different between Amulet and Watchman FLX (Table 1)

Conclusions:

- Despite early experience, the Amulet device exhibited comparable safety and efficiency results to the Watchman FLX for LAAO in a real-world setting
- Both devices represent reasonable options for LAAO

Clinical characteristics	Amulet (n=131)	Watchman FLX (n=169)	P value
Age (years)	76.9±7.3	76.1±7.0	0.31
Female	53 (40.5%)	67 (39.6%)	0.88
BMI (kg/m²)	29.2±6.4	30.2±6.5	0.09
HTN	119 (90.8%)	163 (96.4%)	0.042
Diabetes	51 (38.9%)	49 (29%)	0.07
Prior MI	39 (29.8%)	77 (45.6%)	0.005
Prior CVA	38 (29%)	38 (22.5%)	0.19
LVEF (%)	53.2±8.1	51.8±9.5	0.08
CHA_2DS_2-Vasc	4.6±1.4	4.5±1.3	0.15
HAS-BLED	2.7±0.9	2.4±0.8	<0.001
Paroxysmal AF	83 (63.4%)	97 (57.4%)	0.29
Major bleeding history	101 (77.7%)	122 (72.2%)	0.28
Recurrent falls	39 (29.8%)	52 (30.8%)	0.85
Procedural characteristics	**Amulet (n=131)**	**Watchman FLX (n=169)**	**P value**
Sinus at beginning	63 (48.1%)	88 (52.1%)	0.49
Successful implantation	128 (97.7%)	162 (95.9%)	0.37
PDL on procedural TEE	4 (3.1%)	11 (6.7%)	0.17
Procedure time (min)	70.3±30.1	62.6±42.9	0.038
Fluoroscopy time (min)	11.4±7.6	12.1±10.0	0.53
Major hospital complications	4 (3.1%)	3 (1.8%)	0.7
Minor hospital complications	24 (18.3%)	36 (21.3%)	0.52
45-day follow up	**Amulet (n=124)**	**Watchman FLX (n=158)**	**P value**
Any PDL (TTE or CCTA)	30 (24.6%)	40 (25.2%)	0.91
PDL size (mm)	2.4±1.4	2.6±1.1	0.51
DRT	4 (3.3%)	5 (3.1%)	0.91
6-month follow up	**Amulet (n=85)**	**Watchman FLX (n=155)**	**P value**
Death	7 (7.6%)	7 (4.3%)	0.27
Cardioembolic events	2 (2.3%)	2 (1.3%)	0.54
Major bleeding events	16 (17.2%)	18 (11.5%)	0.2

Table 1. Baseline, procedural and follow-up characteristics.

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