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INTRODUCTION

- **WATCHMAN FLX (WMF)**: left atrial appendage closure device for the prevention of intracardiac thrombosis in non-valvular atrial fibrillation patients. FDA-approved in July 2020.
- Studies on the previous model (WATCHMAN) suggest a potential association between device size and device-related thrombosis.[1]

OBJECTIVE

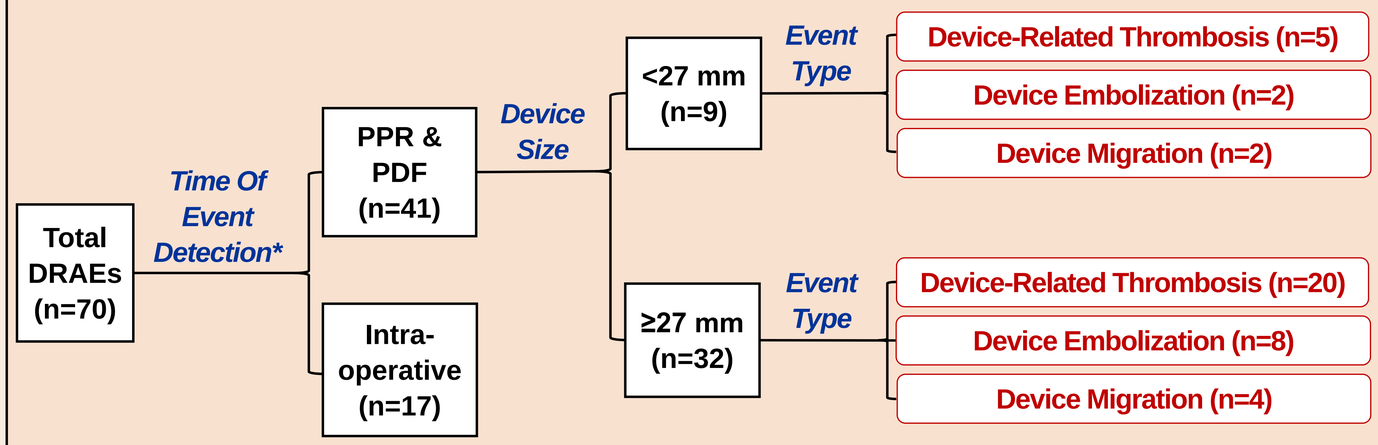
To characterize common device-related complications based on varying WMF sizes.

METHODS

- **Manufacturer And User Device Experience (MAUDE)**: FDA database containing self-reported adverse events for FDA-approved medical devices. Database queried for WMF-related events (Jan. 2020 – Jan. 2021).
- Case narratives analyzed for:
  - Time Of Event Detection
  - Device Size
  - Device-Related Adverse Events (DRAE)
- Time of event detection:
  - Intraoperative
  - Post-Procedure Recovery
  - Post-Discharge Follow-Up
- DRAEs grouped by size (<27 mm vs. ≥27 mm) for analysis using Fisher's Exact; p-value <0.05 was considered statistically significant.

RESULTS I

Figure 1. Total number of DRAEs counted from reports that included device size and time of event detection

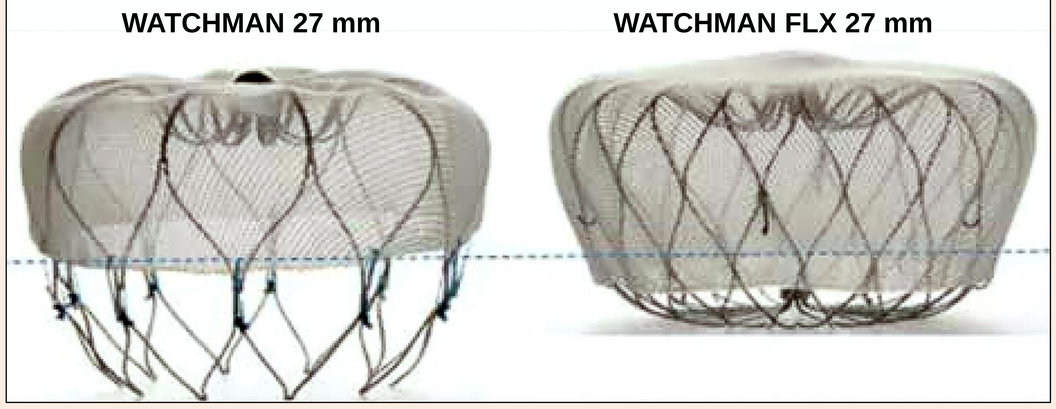


Post-Procedure Recovery (PPR), Post-Discharge Follow-Up (PDF)

Table 1. Comparison of DRAE rates based on WMF device size (<27 mm & ≥27 mm)

DRAE	<27 mm (N=24)	≥27 mm (N=50)	p-value (Fisher's Exact)
Device-Related Thrombosis	5 (20.8%)	20 (40%)	0.122
Device Embolization	2 (8.3%)	8 (16%)	1.000
Device Migration	2 (8.3%)	4 (8%)	0.484

Image 1. WATCHMAN & WATCHMAN FLX [2]



RESULTS II

- Three most common DRAEs:
  - Device-Related Thrombosis (n=25)
  - Device Embolization (n=10)
  - Device Migration (n=6)
- No significant difference in rates of DRAEs between both groups (<27 mm & ≥27 mm).

CONCLUSION

- **No significant difference in rates of device-related thrombosis, device migration, and device embolization between the two groups of WMF sizes (< 27mm vs ≥27).**
- These findings should provide additional qualitative insight for management of WMF patients.

LIMITATIONS

MAUDE database does not account for all WMF placements performed in the U.S.

1. Kubo S, Mizutani Y, Meemook K, Nakajima Y, Hussaini A, Kar S. Incidence, Characteristics, and Clinical Course of Device-Related Thrombus After Watchman Left Atrial Appendage Occlusion Device Implantation in Atrial Fibrillation Patients. JACC Clin Electrophysiol. 2017 Dec 11;3(12):1380-1386

2. Department of Cardiology, Poznan University of Medical Sciences, Poznan, Poland. (2017). The Watchman FLX – a new device for left atrial appendage occlusion – design, potential benefits and first clinical experience. Advances In Interventional Cardiology, 1(47), 63.