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Device-Related Adverse Events From WATCHMAN FLX Implants As Reported By The Food And Drug Administration



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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

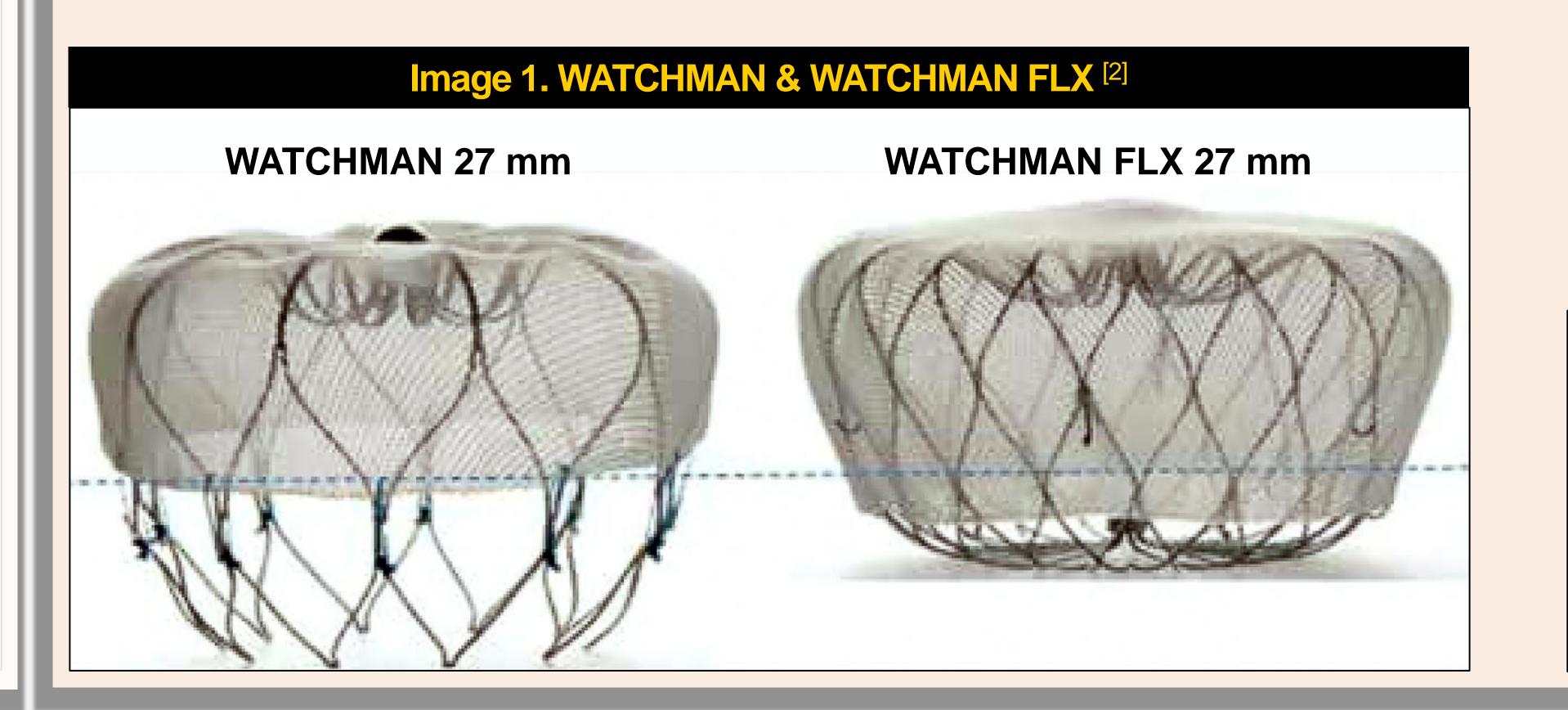
To characterize common device-related complications based on varying WMF sizes.

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 **Device-Related Thrombosis (n=5) Event Type** <27 mm Device Embolization (n=2) **Device** (n=9)PPR & Size Device Migration (n=2) **PDF** Time Of (n=41)**Event Total** Detection* **DRAEs Device-Related Thrombosis (n=20) Event** (n=70)≥27 mm Type Intra-**Device Embolization (n=8)** (n=32)operative Device Migration (n=4) (n=17)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





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.