One Device, Many Anatomies: The Versatility of WATCHMAN FLX in LAAC treatment

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The Connection Between Stroke and Atrial Fibrillation Has Been Recognized For Greater Than 350 Years

"To this variety of apoplexy those are most liable who lead an idle life, who are obese, whose face and hands are constantly livid and *whose pulse constantly unequal*."

Historiae Apoplecticorum
Johann Jakob Wepfer, 1658

Three Hundred Years Later, Warfarin (Rat Poison) is Introduced!

https://www.wisconsinacademy.org

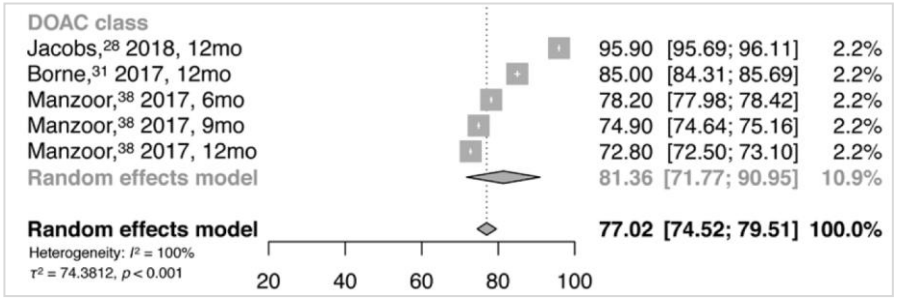
NOACs vs. Warfarin: Comparative Yearly Bleeding Rates

Study	Treatment	Total Bleeding	Major Bleeding	GI Bleeding	Intracranial Bleeding
RE-LY	Dabigatran (150mg)	16.4%	3.11%	1.51%	0.30%
	Warfarin	18.2%	3.4%	1.02%	0.74%
ROCKET-AF	Rivaroxaban	14.91%	3.60%	3.2%	0.5%
	Warfarin	14.52%	3.45%	2.2%	0.7%
ARISTOTLE	Apixaban	18.1%	2.13%	0.76%	0.33%
	Warfarin	25.8%	3.09%	0.86%	0.80%

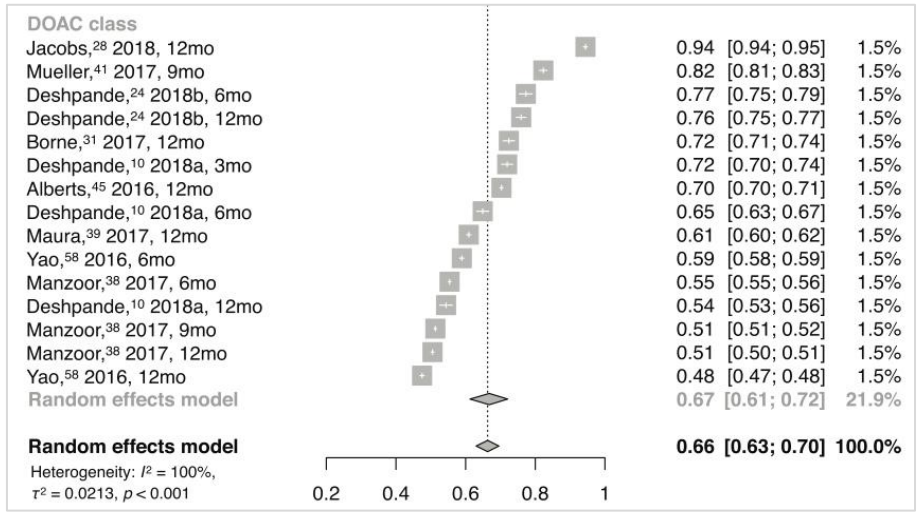
Patel, M. NEJM 2011; 365(10):883-891. Granger, C NEJM 2011; 365(11):981-992. Connolly, S. NEJM 2009; 361(12): 1139-1151, Giugliano, R. NEJM 2013; 369(22): 2093-2104.

Real-World Adherence And Persistence To Doacs In Patients With Atrial Fibrillation

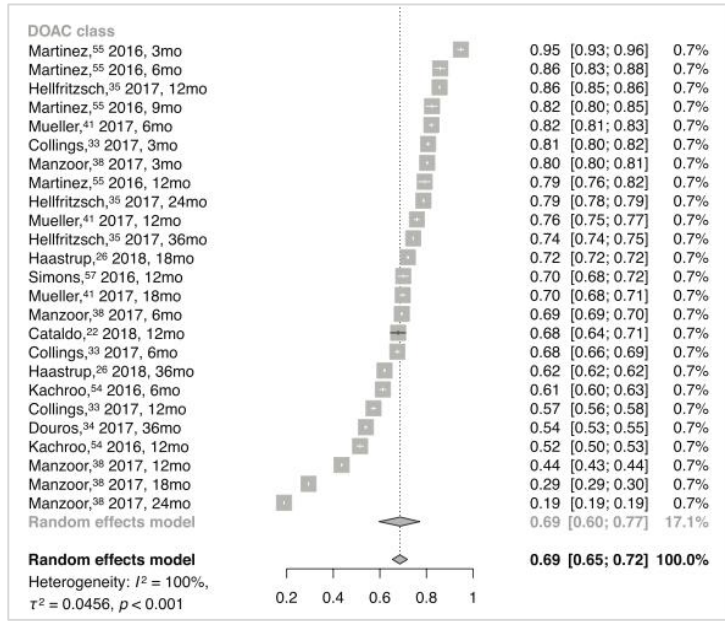
Mean proportion of days covered: 77%



Good adherence (>80%): 66%



Persistence: 69%



Meta-analysis of 48 studies comprising 594,784 patients

- **Patients do not take their DOAC 1 out of 4 days**
- **1/3 of patients show poor adherence**
- **Persistence with therapy at 12-months: 62% (apixaban + rivoraxaban> warfarin, dabigatran = warfarin)**

THE BAD ACTOR: THE LEFT ATRIAL APPENDAGE

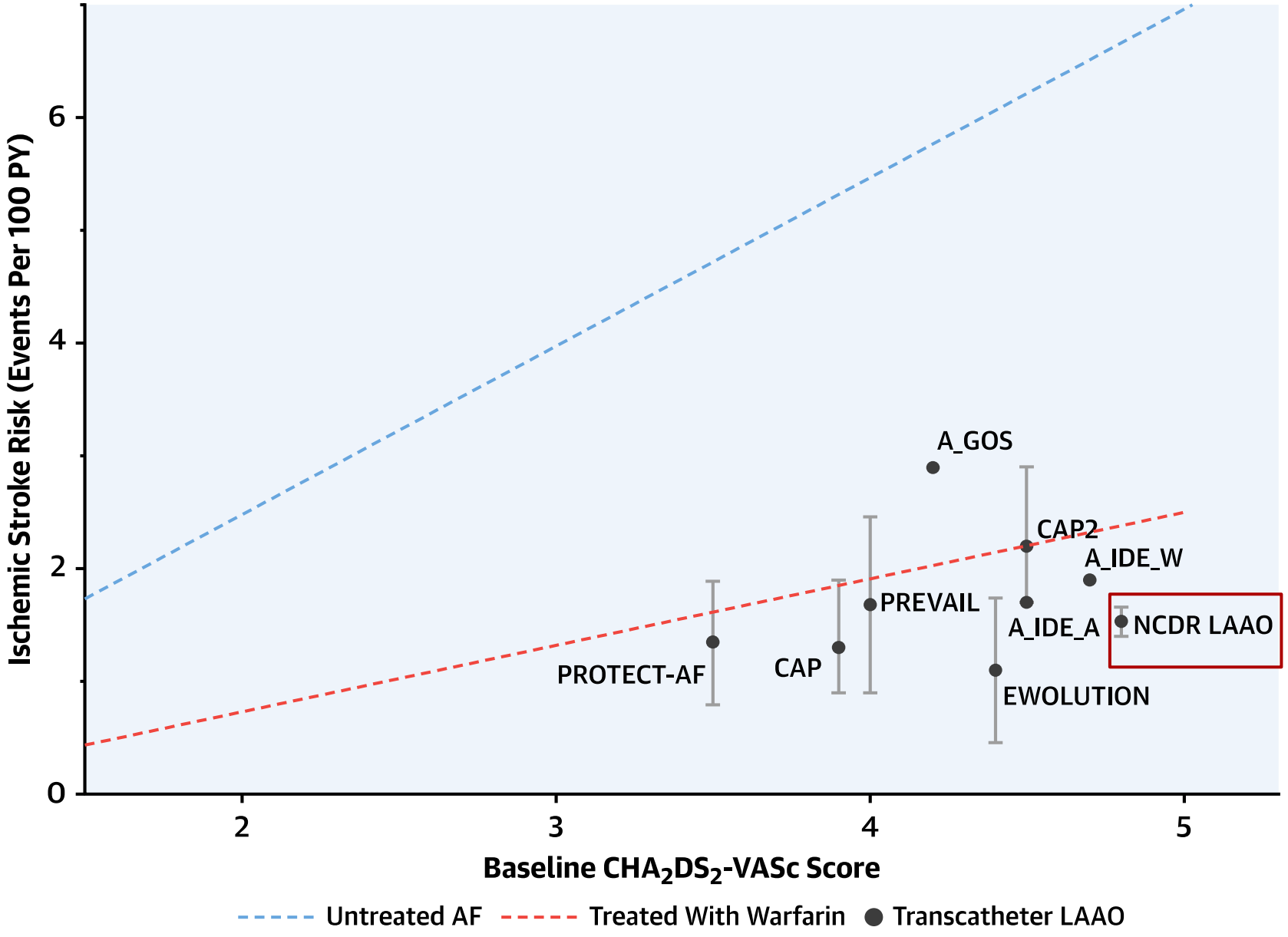
Why not a local therapy for a local problem?

- >90% of stroke-causing thrombus originates in the LAA
- Thromboembolic stroke from AF more debilitating – due to size of clots

Blackshear J.L. Odell J.A., Annals of Thoracic Surgery, 1996;61:755-759

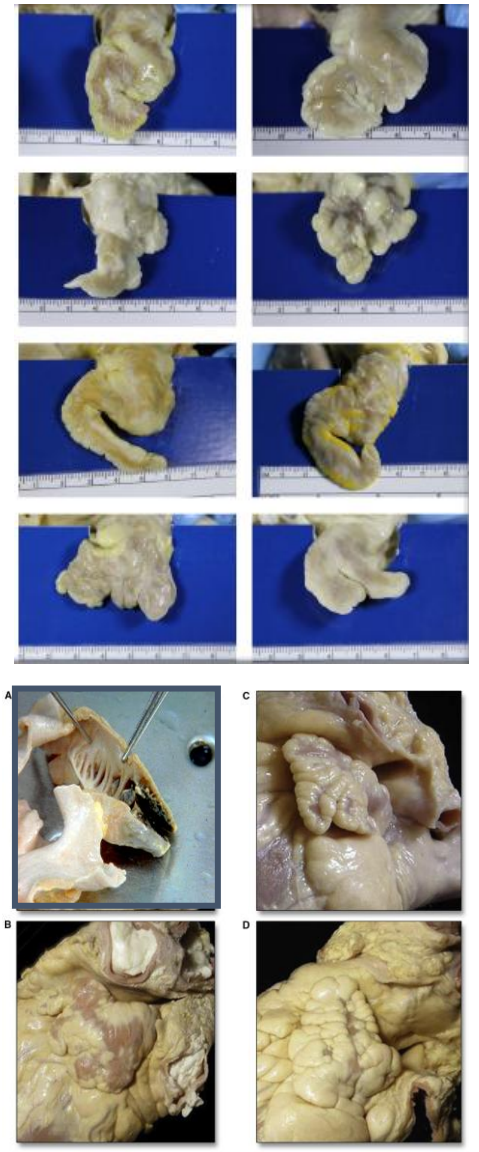
Ischemic Stroke Rates in Randomized Trials and Observational Registries of LAAO as a Function of Baseline CHA_2DS_2-VASc Score

NCDR LAAO Registry: 1.53 strokes/100 PY



Unmet Needs For LAA Closure

- Enhance implant success
- Maximize procedural safety
- Minimize peri-device leaks
- Improve long-term outcomes
- Reduce/eliminate the need for post-procedural anticoagulation/antiplatelets
- Establish LAAO as front-line therapy for stroke reduction in AF



Evolution of the Watchman Device

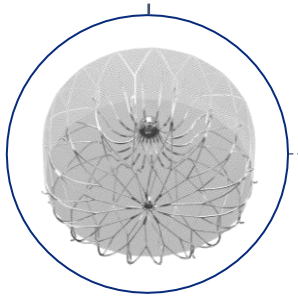
Watchman “2.5”

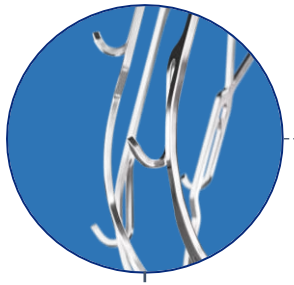
Watchman FLX

Watchman FLX Pro

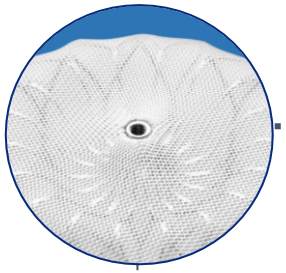
WATCHMAN FLX™ Device Overview

Full recapture, reposition & redeploy
For precise device placement

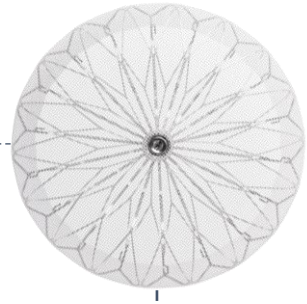




Dual Row Precision Anchors:
designed to provide optimal device engagement with LAA tissue for long-term stability



Reduced metal exposure



18 Strut Frame:
Designed for conformability to appendage and **improved sealing**

Closed end
Fully-Rounded
WATCHMAN FLX Ball
Designed to safely advance & maneuver within the LAA

Treatment range 14.0 – 31.5 mm appendages

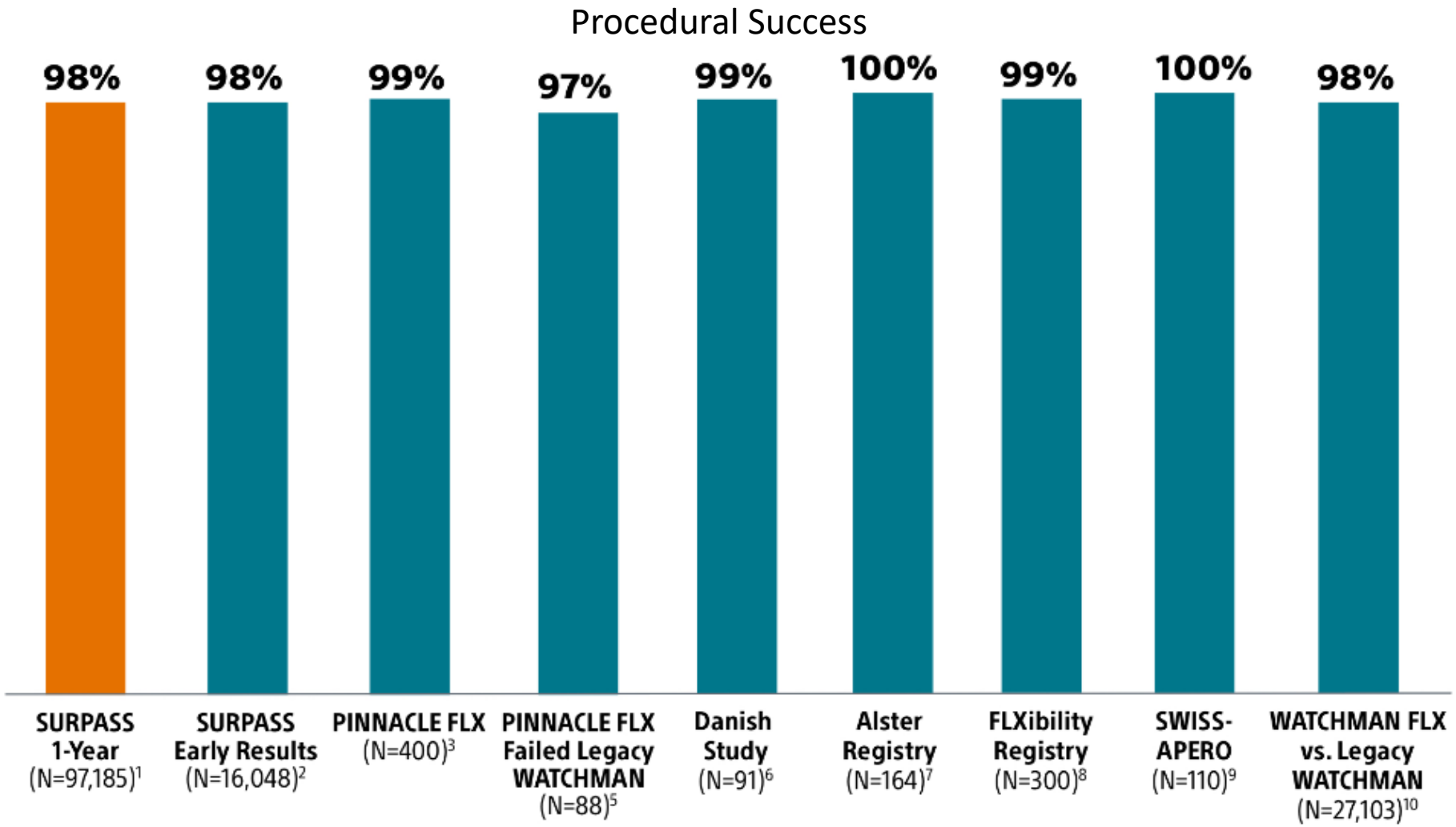
What Type of Patients Are Getting Treated With Watchman FLX In The United States?

Very high stroke and bleeding risk!

Characteristic	Watchman FLX (N=27,013)
Age (mean+/-SD), yrs	76.1±7.9
Male sex (n, %)	15987 (59.2%)
CHA_2DS_2-VASc score (mean+SD)	4.8±1.5
Congestive heart failure (n, %)	10467 (38.8%)
Hypertension (n, %)	24740 (91.7%)
Diabetes (n, %)	9639 (35.8%)
Stroke (n, %)	5929 (22.0%)
Transient ischemic attack (n, %)	3290 (12.2%)
Vascular disease (n, %)	14601 (54.2%)
Prior myocardial infarction (n, %)	4228 (15.7%)
Peripheral arterial disease (n, %)	2912 (10.8%)
HAS-BLED score (mean+SD)	2.8±1.1
Prior clinical bleeding	68.0%

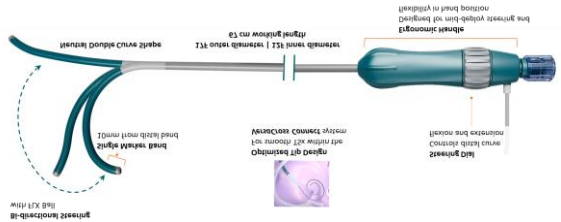
Price MJ et al. JACC Cardiovasc Interv. 2022;15:2115-212

98% Implant Success With Watchman FLXin SURPASS Analysis Consistent Across Trials and Registries



1. Kapadia, Circ CI 2024. 2. Kapadia, CRT 2022. 3. Kar, Circulation 2021. 4. Ellis, Heart Rhythm, 2021. 5. Korsholm, WM FLX First Experience, JACC, 2020. 6. Bergmann, Alster Registry, Presented ePCR 2021. 7. Betts, EHRA 2022. 8. Galea, SWISS APERO Trial, Cirulation, 2021. 9. Freeman, HRS 2022. 10. Price MJ, JACC CVI 2022

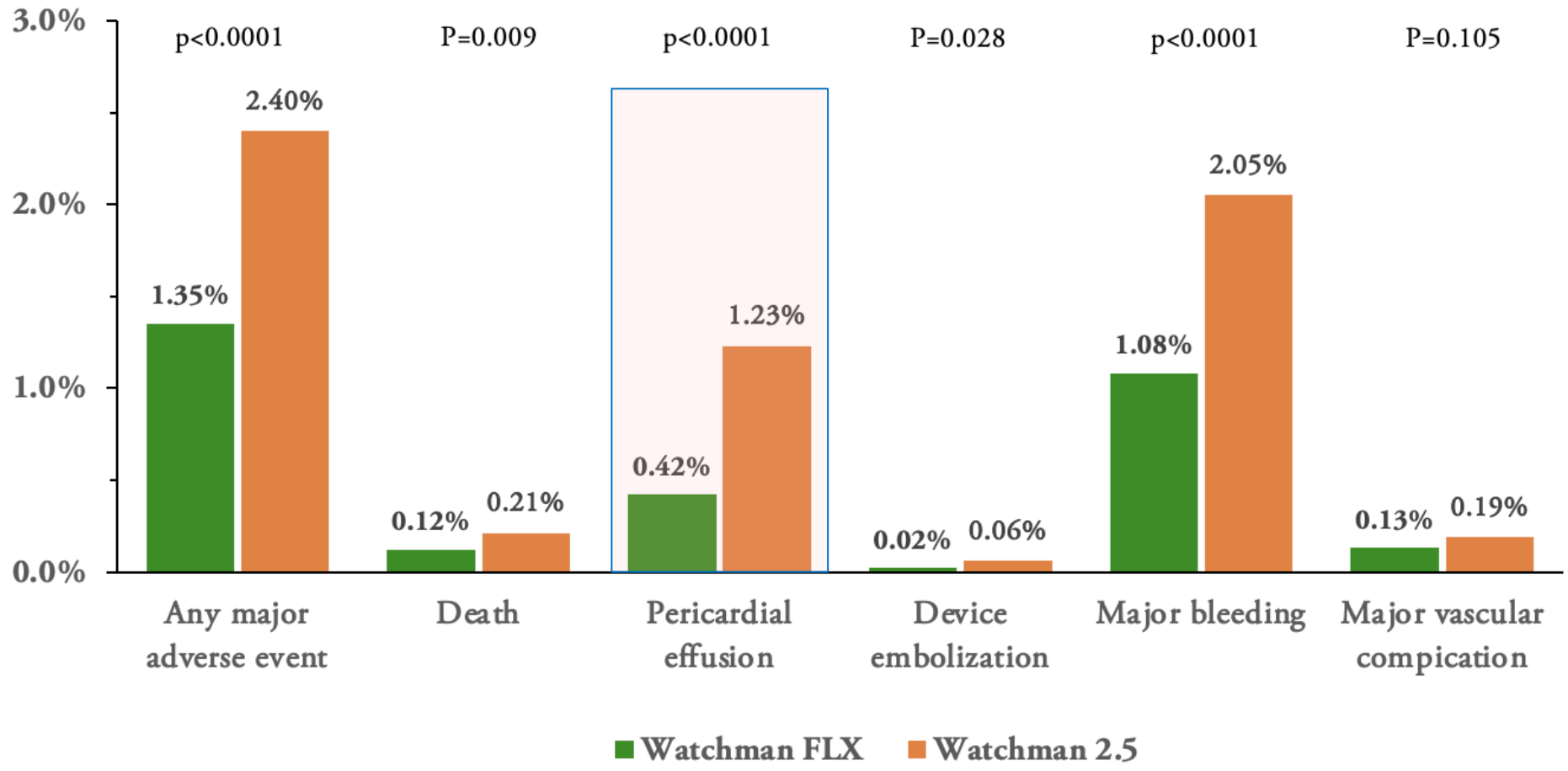
Improved procedural efficiency and greater implant success with Steerable Delivery Sheath compared to Standard Delivery Sheaths



	TruSteer n = 200	Other Access Systems n = 500	P-value
Imaging modality			
TEE	72.5% (145/200)	76.6% (383/500)	.28
ICE	27.5% (55/200)	23.4% (117/500)	.26
Total procedure time (min)	33.0±18.3	35.9±23.4	.12
Total fluoroscopy time (min)	7.1±5.5	8.2±8.3	.08
Left atrium dwell time (min)	21.4±13.0	23.6±17.8	.12
Total transseptal time (min)	9.3±6.3	11.8±13.7	.01
Device Successfully Implanted	99.5% (199/200)	96.4% (482/500)	.02
If no, reason	n=1	n=18	
Release criteria not met	0	9	
Unsuitable LAA anatomy	0	9	
Other	1*	0	
Devices Unsuccessfully Attempted	11.2% (25/224 devices)	14.8% (84/566 devices)	

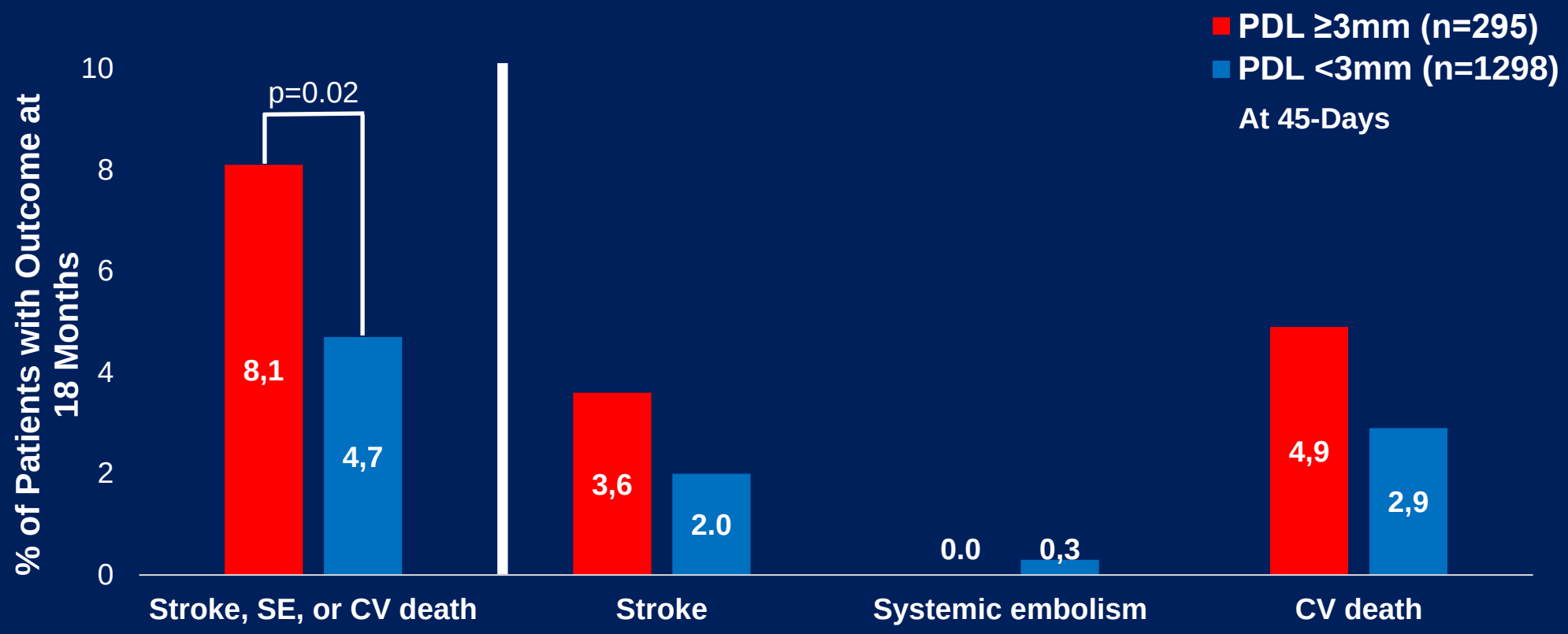
Kanj, et al. TCT, 2024

Very Low Rates of Procedural Complications with Watchman FLX:
Natural Experiment Analysis (N=54,206)



Price MJ et al. JACC Cardiovasc Interv. 2022;15:2115-212

Peri-Device Leak >3mm After LAAO Associated with Worse Clinical Outcomes Through 18 Months



A landmark analysis set at 45 days was performed and Kaplan-Meier event rates are provided (p-values calculated from Cox model)
CV = cardiovascular, SE = systemic embolism.

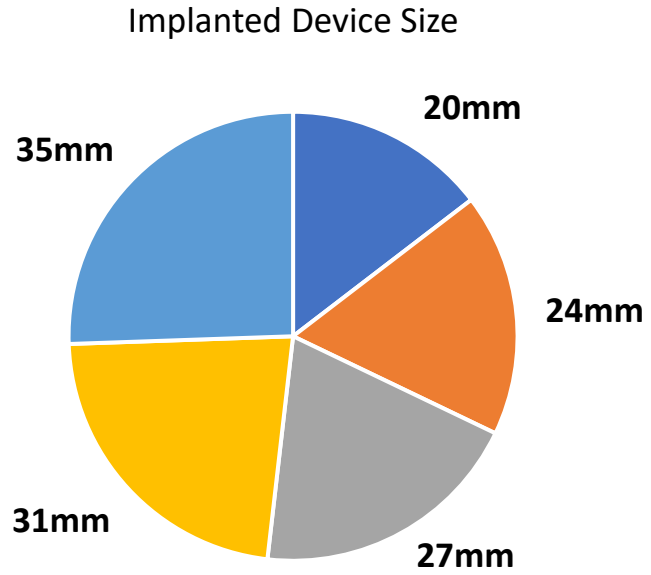
Price MJ et al. *JACC Cardiovasc Interv*. 2022;15:2127-2138.

HEART RHYTHM

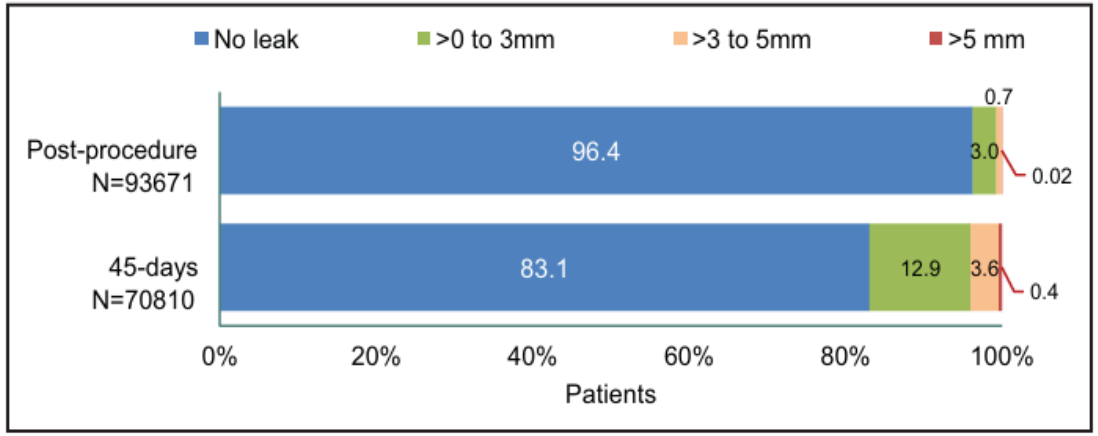
SURPASS Registry: Rate of Any PDL

	SURPASS (N=97185)
Implant success	94,784 (97.5%)
Procedure Time* (min)	78.7±80.5
Number of devices used per case	1.2±0.5
General Anesthesia	94.8%

*Defined as from when patient entered the procedure location until the time when the operator breaks scrub at the end of the procedure.



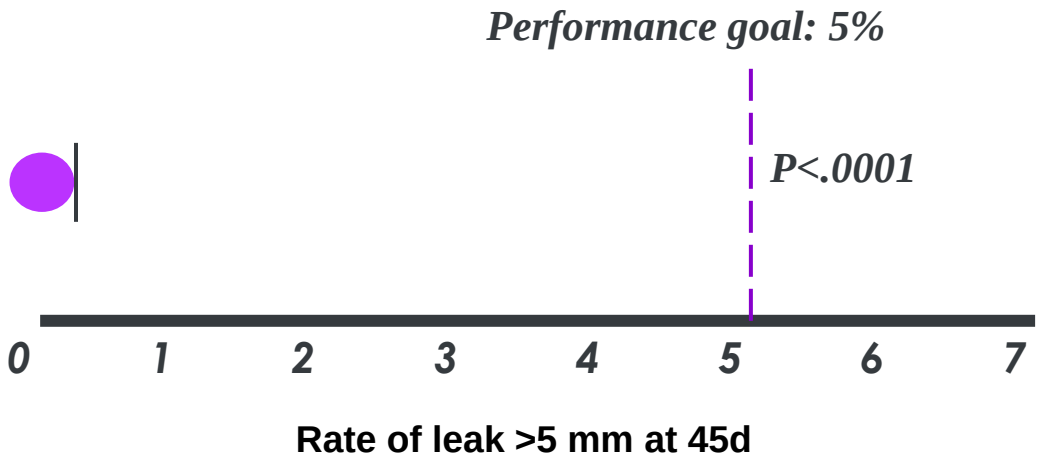
- More than 83% of patients had no leak at 45 days
- 99.6% had effective device closure (leak <5mm)



Kapadia SR, Yeh RW, Price MJ et al, *Circ Cardiovasc Interv*. 2024

HEAL LAA: Post Implant Sealing with Watchman FLX PRO

Endpoint is **achieved** as rate of leak >5 mm is **0%,** significantly less than 5% performance goal (p < 0.0001).



N=500

LAA Seal	Post Implant	45 Days
Complete seal	92.5% (331/358)	82.7% (334/404)
>0-3 mm leak	7.5% (27/358)	17.1% (69/404)
>3-5 mm leak	0.0% (0/358)	0.2% (1/404)
>5 mm leak	0.0% (0/358)	0.0% (0/404)

P-value calculated from Z-test. Confidence intervals calculated from Z-test are not applicable as there were 0 cases of leak > 5mm and upper and lower bounds would both be 0.

Even Lower 1-Year Stroke Rates After LAAC With Watchman FLX Compared With Earlier Generation Watchman

TABLE 3 Clinical Outcomes at 1 Year

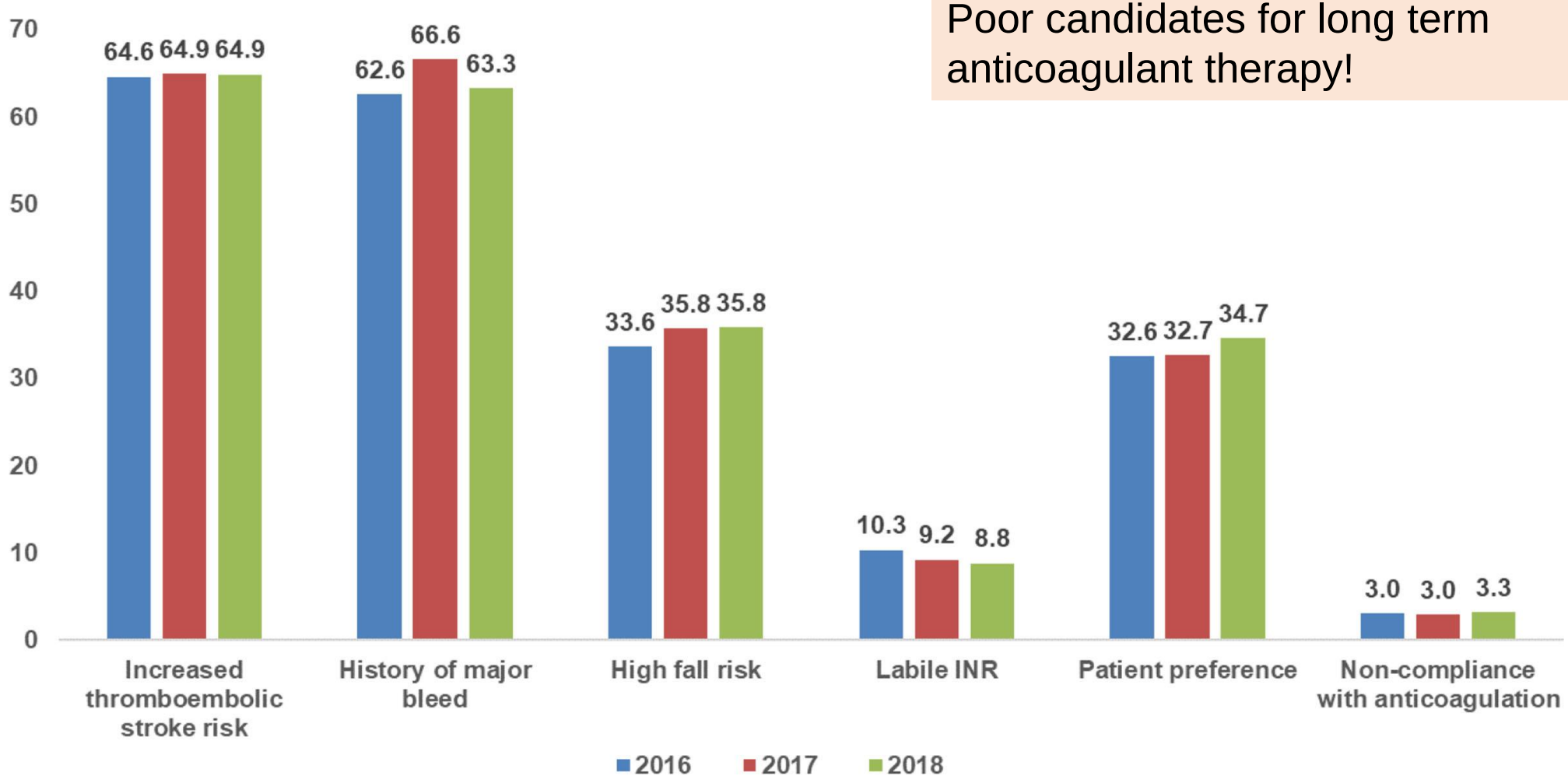
	Watchman 2.5 (n = 26,061)	Watchman FLX (n = 26,057)	*P* Value	Unadjusted HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value
Major adverse events	4,184 (16.1)	3,488 (13.4)	<0.0001	0.820 (0.782-0.859)	<0.0001	0.839 (0.801-0.880)	<0.0001
Ischemic stroke	273 (1.0)	219 (0.8)	0.0145	0.792 (0.663-0.946)	0.0102	0.816 (0.683-0.975)	0.0253
Systemic embolism	59 (0.2)	22 (0.1)	<0.0001	0.37 (0.23-0.60)	<0.0001	0.383 (0.235-0.626)	0.0001
Ischemic stroke or systemic embolism	330 (1.3)	238 (0.9)	0.0001	0.71 (0.60-0.84)	<0.0001	0.735 (0.622-0.868)	0.0003
Any stroke	371 (1.4)	279 (1.1)	0.0003	0.742 (0.636-0.867)	0.0002	0.760 (0.651-0.888)	0.00006
Major bleeding	1,835 (7.0)	1,288 (4.9)	<0.0001	0.690 (0.642-0.740)	<0.0001	0.705 (0.657-0.757)	<0.0001
Death	2,006 (7.7)	1,911 (7.3)	0.1156	0.938 (0.881-0.999)	0.0448	0.965 (0.906-1.028)	0.2656

Observed rates; HRs according to the Kaplan-Meier method.

Price MJ et al, JACC Cardiovasc Interv. 2025;18:1318–1326

Indications for LAAO In the US: Data from the NCDR LAAO Registry

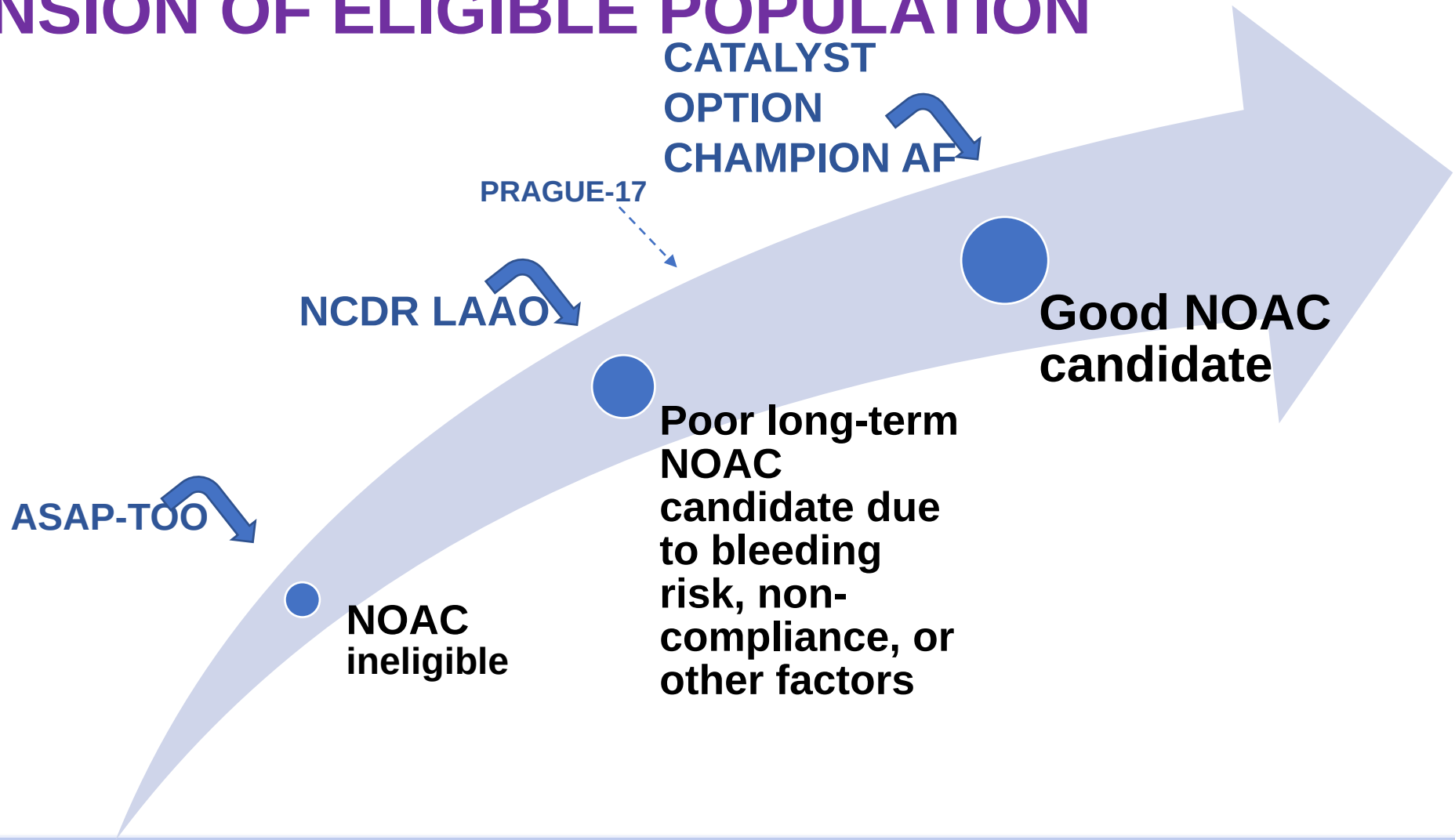
Poor candidates for long term anticoagulant therapy!



Daimee UA, Wang Y, Masoudi FA, Varosy PD, Friedman DJ, Du C, Koutras C, Reddy VY, Saw J, Price MJ, Kusumoto FM, Curtis JP and Freeman JV, Circ Cardiovasc Qual Outcomes. 2022 Aug;15(8):e008418.

ONGOING OR PLANNED CLINICAL TRIALS AND REGISTRIES OF TRANSCATHETER LAA CLOSURE:

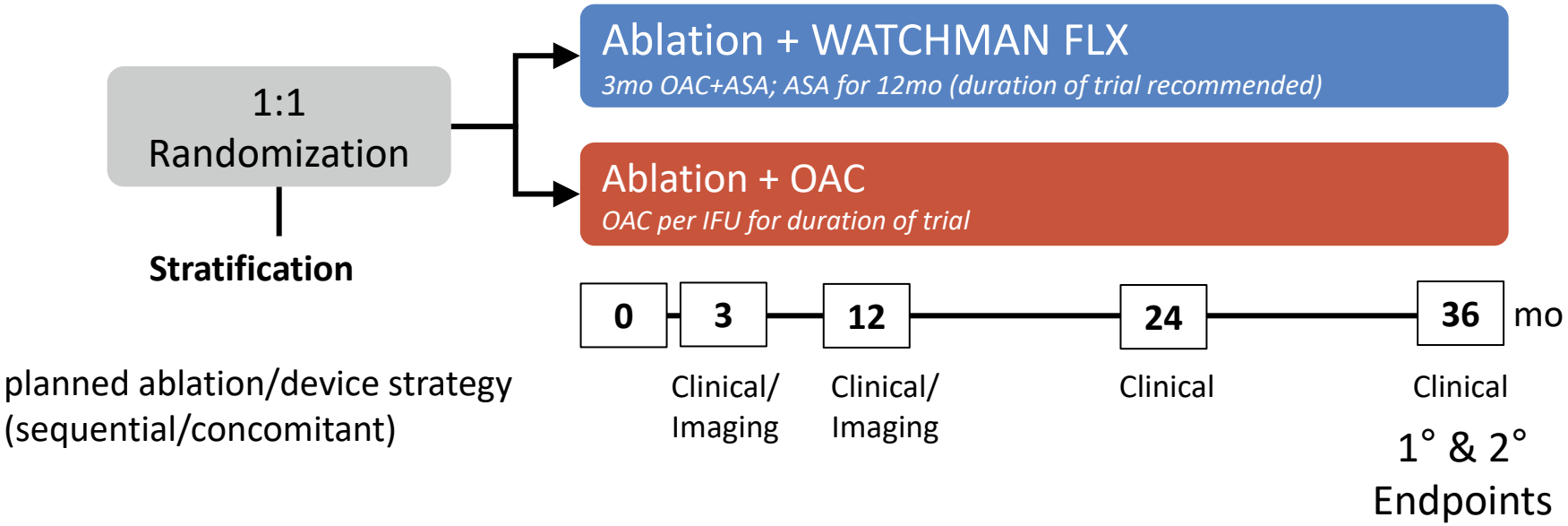
EXPANSION OF ELIGIBLE POPULATION



OPTION Study Design

Patient Population

- AF patients indicated for ablation
- CHA_2DS_2-VASc score of ≥2 for males or ≥3 for females & ***suitable for OAC***

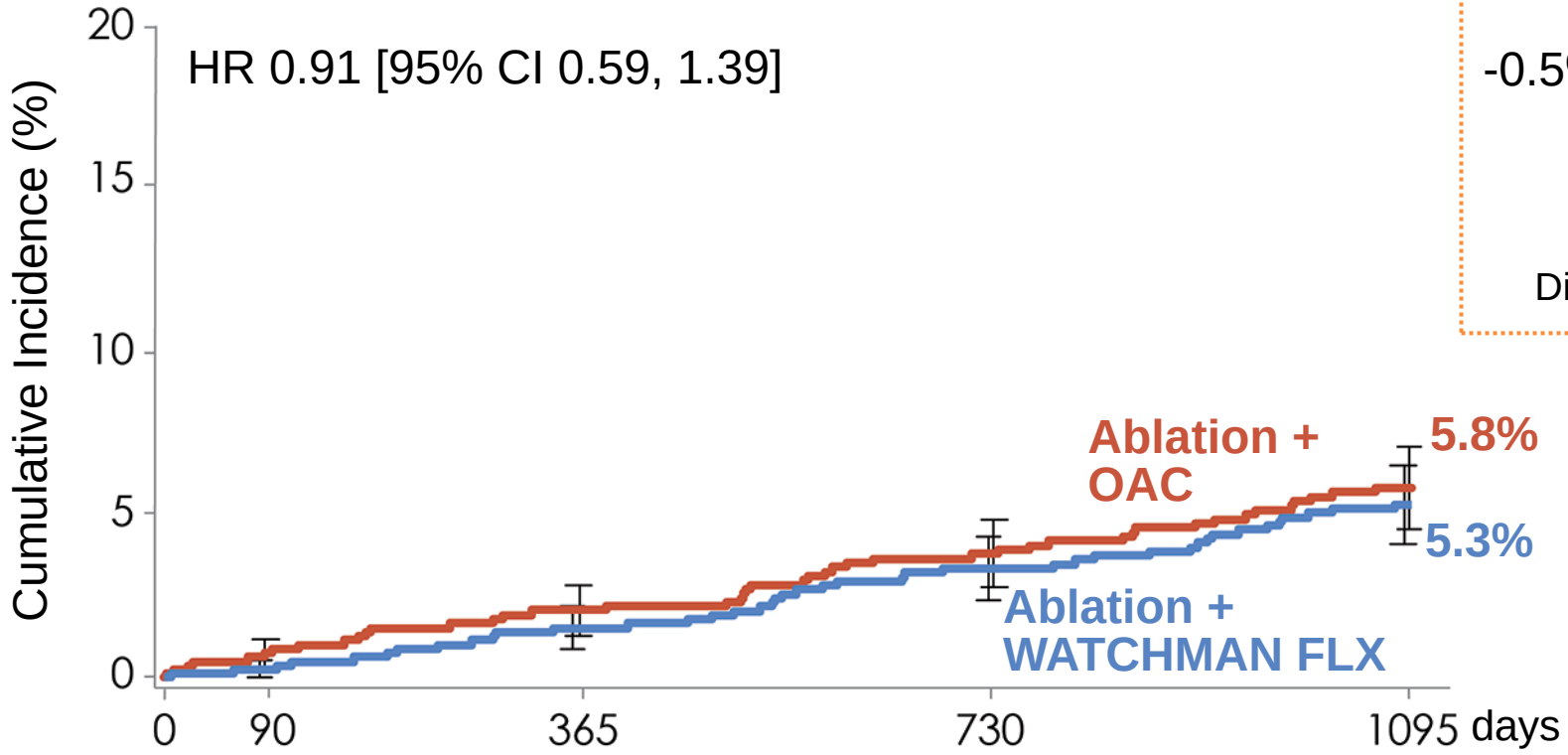


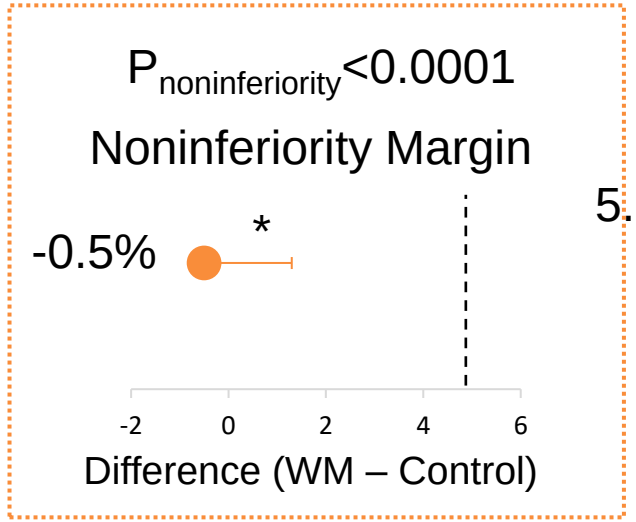
Sequential: AF ablation 90 to 180 days prior to randomization
Concomitant : AF ablation ± WATCHMAN implantation within 10 days of randomization

Wazni O, et al. Randomized Comparison of Left Atrial Appendage Closure with Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation, LBCT AHA 2024.

1° Efficacy Endpoint: Met noninferiority

All-cause death, stroke, or systemic embolism at 36 months





No. at risk				
	0	90	365	730	1095 days after randomization
Ablation + WATCHMAN FLX	803		772	757	722
Ablation + OAC	797		754	740	701

ITT; KM Event Rate ± 1.5 SE; log-rank *P* value

*1-sided 97.5% Z upper confidence Interval = 1.8%

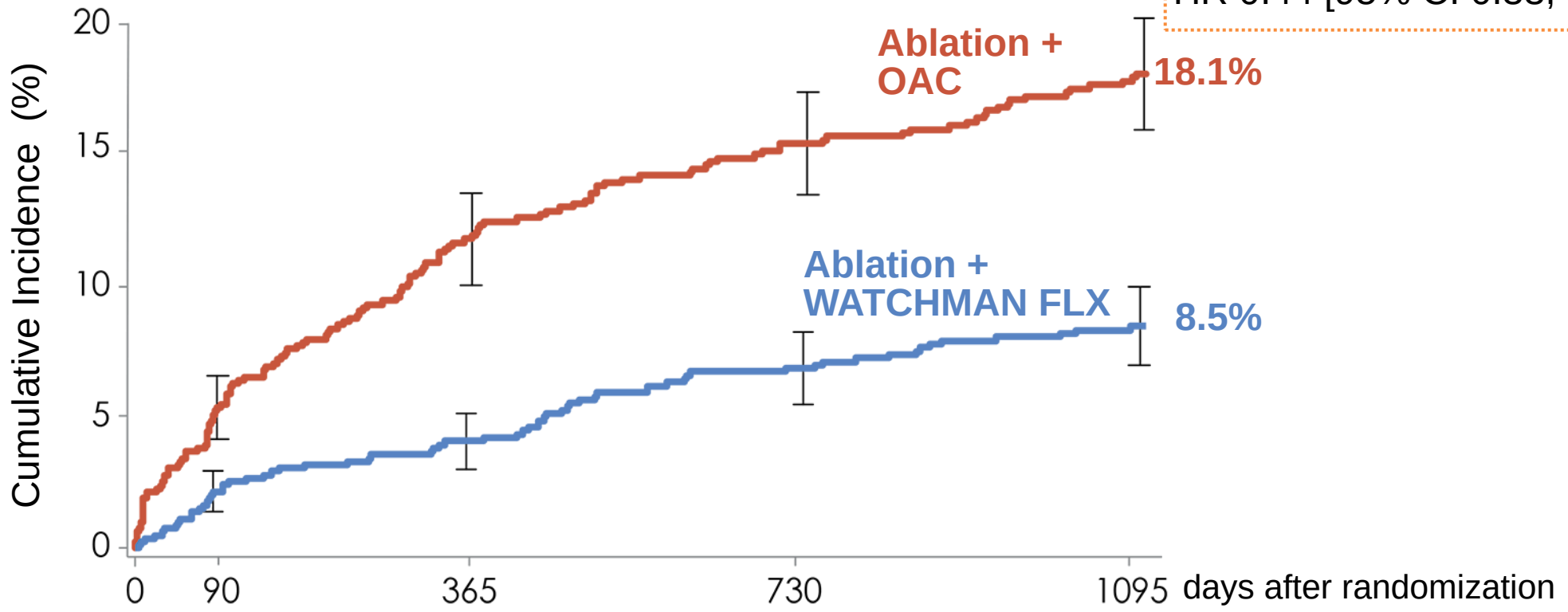
Wazni O, et al. Randomized Comparison of Left Atrial Appendage Closure with Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation, LBCT AHA 2024.

1° Safety Endpoint: met superiority

Non-procedural ISTH major bleeding/clinically relevant non-major bleeding at 36 months

$P_{superiority}$<0.0001

HR 0.44 [95% CI 0.33, 0.59]



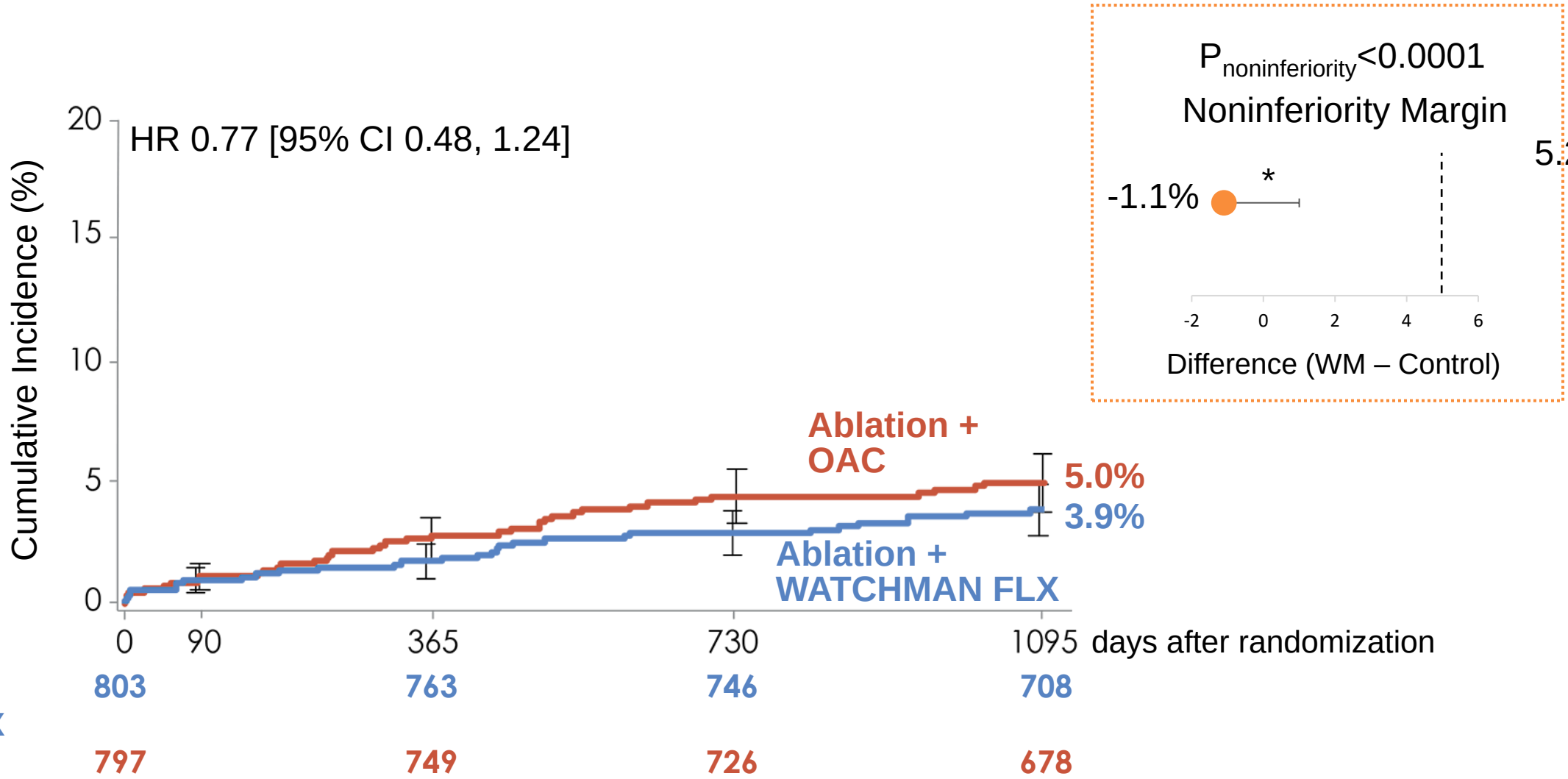
No. at risk				
Ablation + WATCHMAN FLX	803	749	728	681
Ablation + OAC	797	701	657	598

ITT; KM Event Rate ± 1.5 SE; log-rank *P* value

Wazni O, et al. Randomized Comparison of Left Atrial Appendage Closure with Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation, LBCT AHA 2024.

2° Endpoint: met noninferiority

ISTH major bleeding at 36 months (including procedural bleeding)



ITT; KM Event Rate ± 1.5 SE; log-rank *P* value

*1-sided 97.5% Z upper confidence Interval = 1.0%

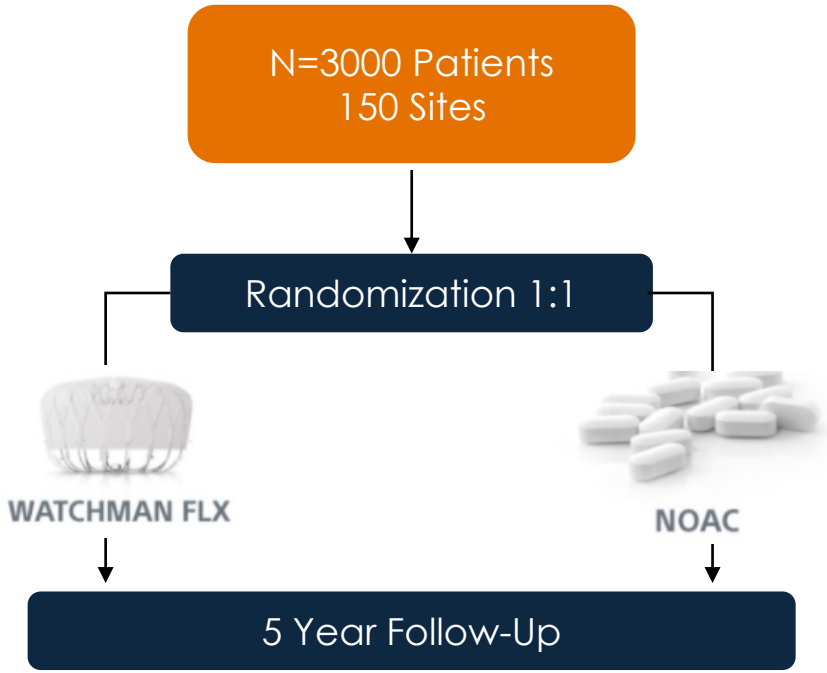
Wazni O, et al. Randomized Comparison of Left Atrial Appendage Closure with Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation, LBCT AHA 2024.

CHAMPION-AF trial overview

Objective: To determine if LAAC with WATCHMAN FLX is a reasonable alternative compared with NOACs in patients with non-valvular AF

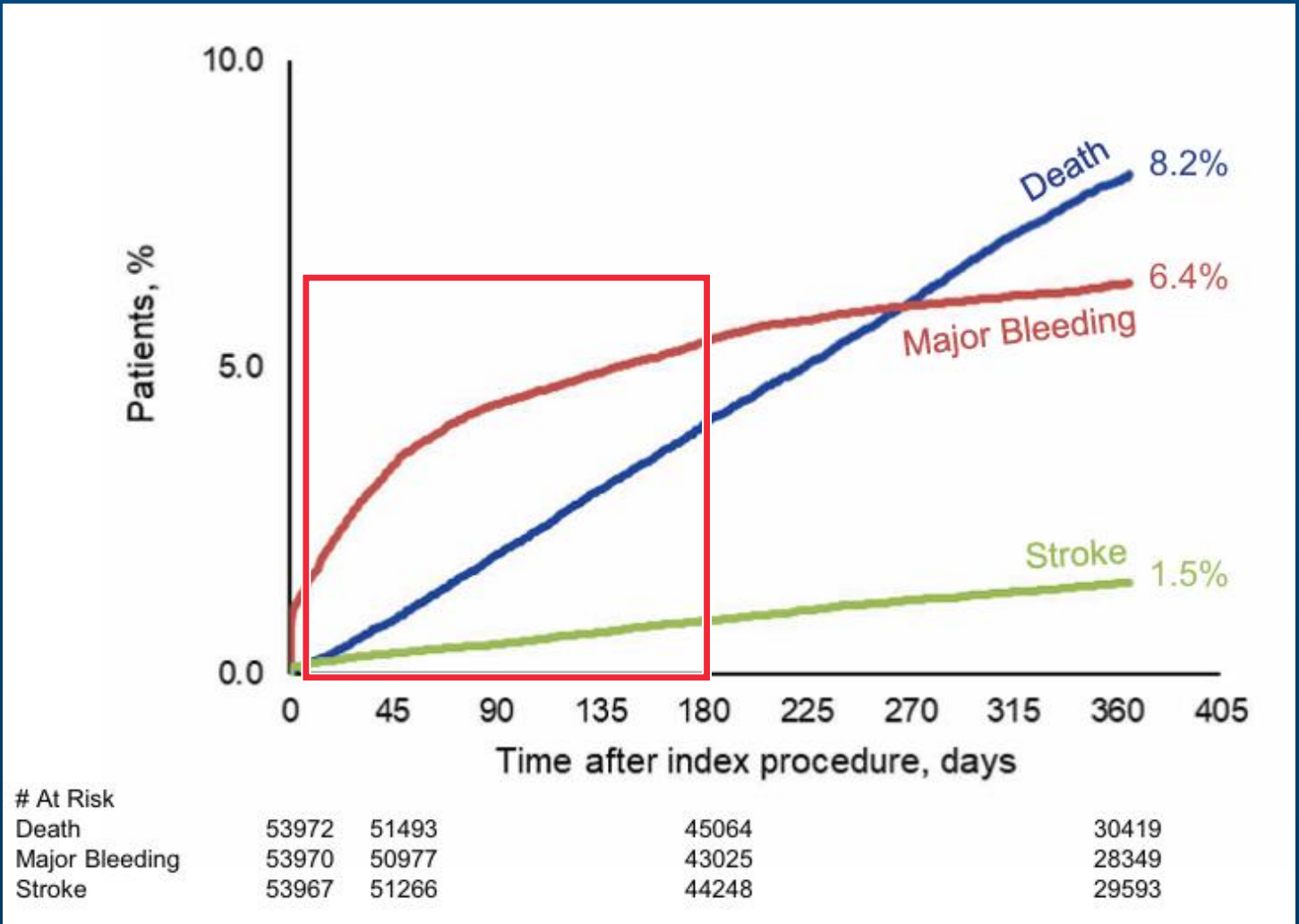
Study Design & Primary Endpoints

- WATCHMAN FLX is **non-inferior for the occurrence of stroke, cardiovascular (CV) death and systemic embolism** at 36 months.
- WATCHMAN FLX is **superior for non-procedural bleeding** (ISTH major bleeding and clinically relevant non-major bleeding) at 36 months.
- WATCHMAN FLX is **non-inferior for the occurrence of ischemic stroke and systemic embolism** at 60 months.



Enrollment Completed
3-year primary endpoint data expected 1H 2026

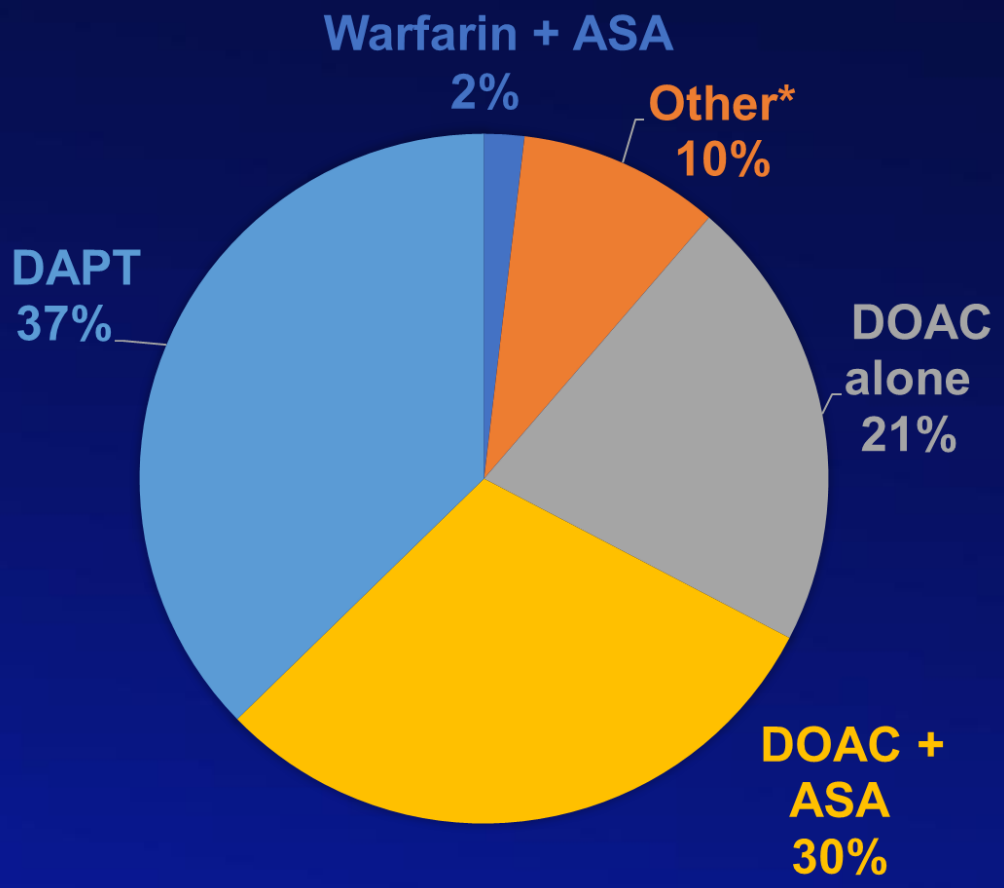
Real World WATCHMAN FLX: Can We Improve Early Post-Procedural Care?



- The greatest risk after Watchman FLX LAAC is bleeding during the period of mandated post-procedural pharmacotherapy
- Do we need such intensive anticoagulant/antiplatelet therapy post-procedure?

Kapadia SR, Yeh RW, Price MJ et al, *Circ Cardiovasc Interv*. 2024;17:e013750.

SURPASS PRO: Current Discharge Medication Practice



At discharge, most patients were prescribed DAPT (37%) followed by DOAC + aspirin (30%) and DOAC alone (21%).

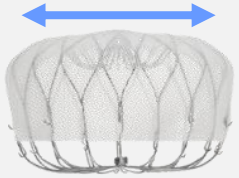
*Other includes SAPT, warfarin alone, triple therapy, DOAC + P2Y12 inhibitor, Warfarin + P2Y12 inhibitor, No OAC or APT, other
ASA=aspirin; DAPT=dual anti-platelet therapy; DOAC=direct oral anticoagulant

Addressing Healing Post-Procedure: Watchman FLX Pro

Design Goals

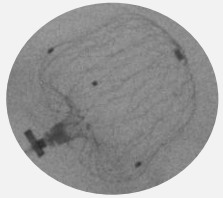
Surface Coating

Improve hemocompatibility to reduce the severity of acute foreign body response, encouraging controlled healing



40mm Size

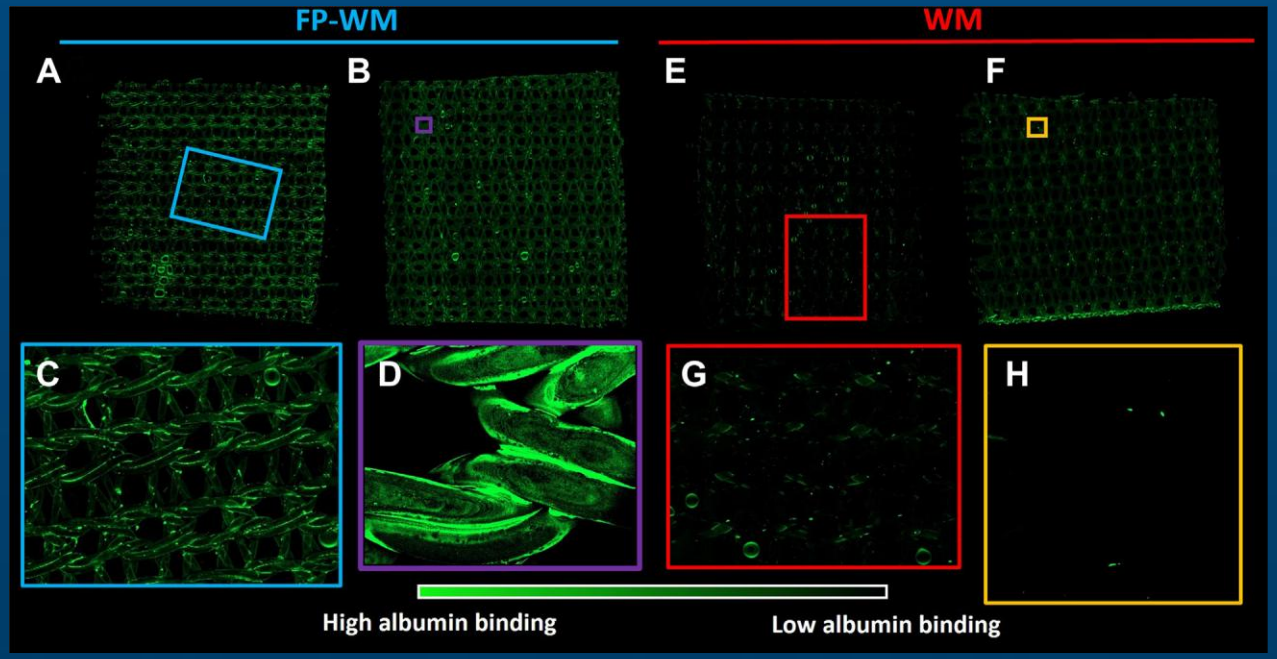
Expand matrix to treat the largest range of patient anatomies

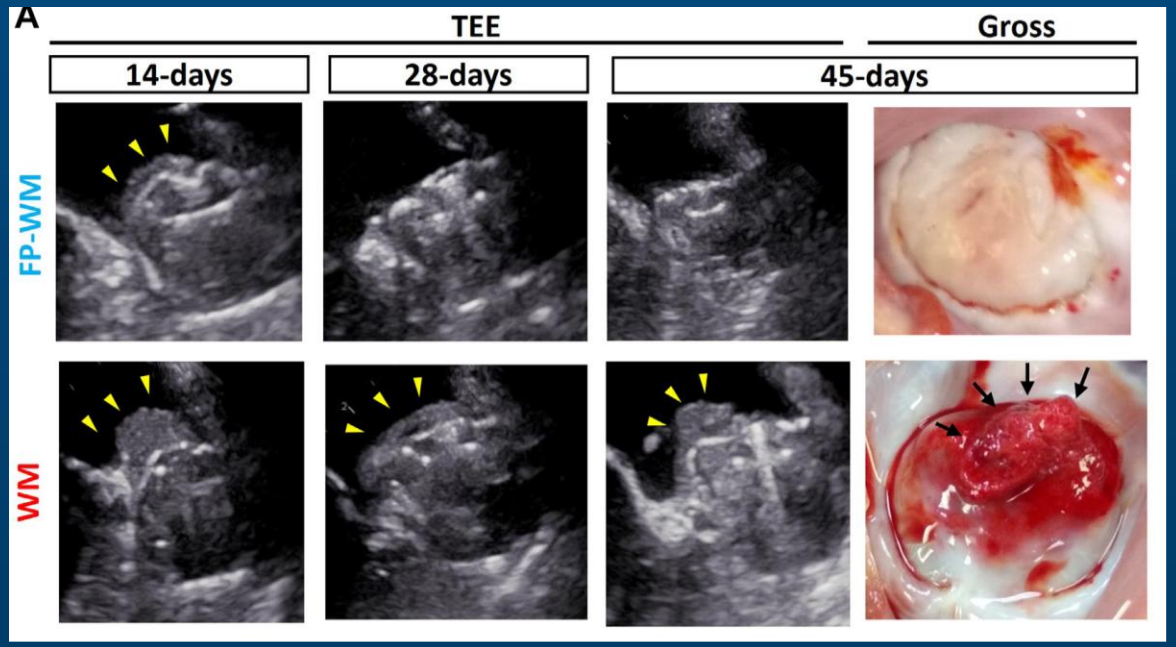


Radiopaque Markers

Increase fluoroscopic visibility for positioning & deployment

Watchman FLX PRO: Hemo-Compatible Polyvinyldenefluouride-Hexfluoropropylene (PVDF-HFP) Coating

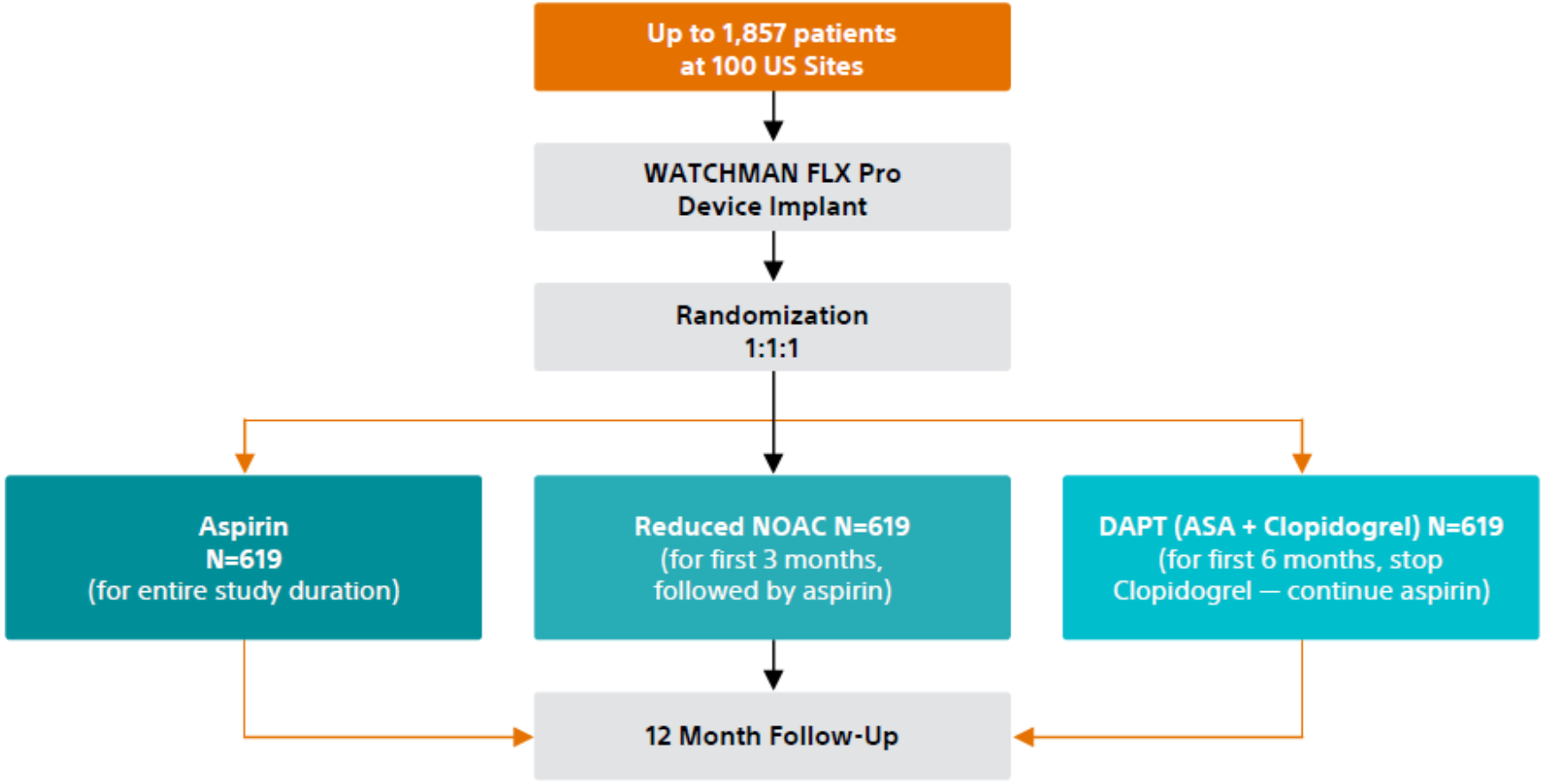




- Increased albumin binding, reduced platelet binding, less inflammation, and greater endothelial coverage
- Canine model: less thrombus and reduced inflammation than non-coated devices

Saliba WI et al JACC Clin Electrophysiol. 2023;9:1555-1567

SIMPLAAFY Trial Design



Primary Endpoint: Composite rate of all death, all stroke, systemic embolism and major bleeding at 6 months after randomization

Secondary Endpoint: Ischemic stroke or systemic embolism rate at 12 months after randomization

Contemporary LAA Closure with Watchman FLX

- Implant success rates of 98%
- Safe procedure: tamponade rate<0.4% (new standard of care)
- Low rates of significant PDL
- Low rates of ischemic stroke over follow-up
- *Expanding Indications?*
  - *OPTION:* WM FLX PRO non-inferior to NOAC after AF ablation
  - *CHAMPION AF:* Frontline option for stroke prevention in AF?
- Therapeutic advantage of polymer coating?
  - *SIMPLAAFY*: Will less intensive post-procedure therapy safely reduce major bleeding?

Thank You!