



What's the Best Anti-thrombotic Regimen after LAAO: Factors We Should Consider



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COI Disclosure

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The authors have no financial conflicts of interest to disclose concerning the presentation



Case

- M/83
- HT, ESRD on HD
- AF on apixaban → D/C d/t ongoing anemia
- Severe AS, s/p TAVI (2022.12)
- Thrombocytopenia developed after TAVI: probably d/t consumption

- 2023.4 multiple thromboembolic infarction
- 2023.5 LAA occlusion with Amulet

- What's the best anti-thrombotic regimen for this patient?



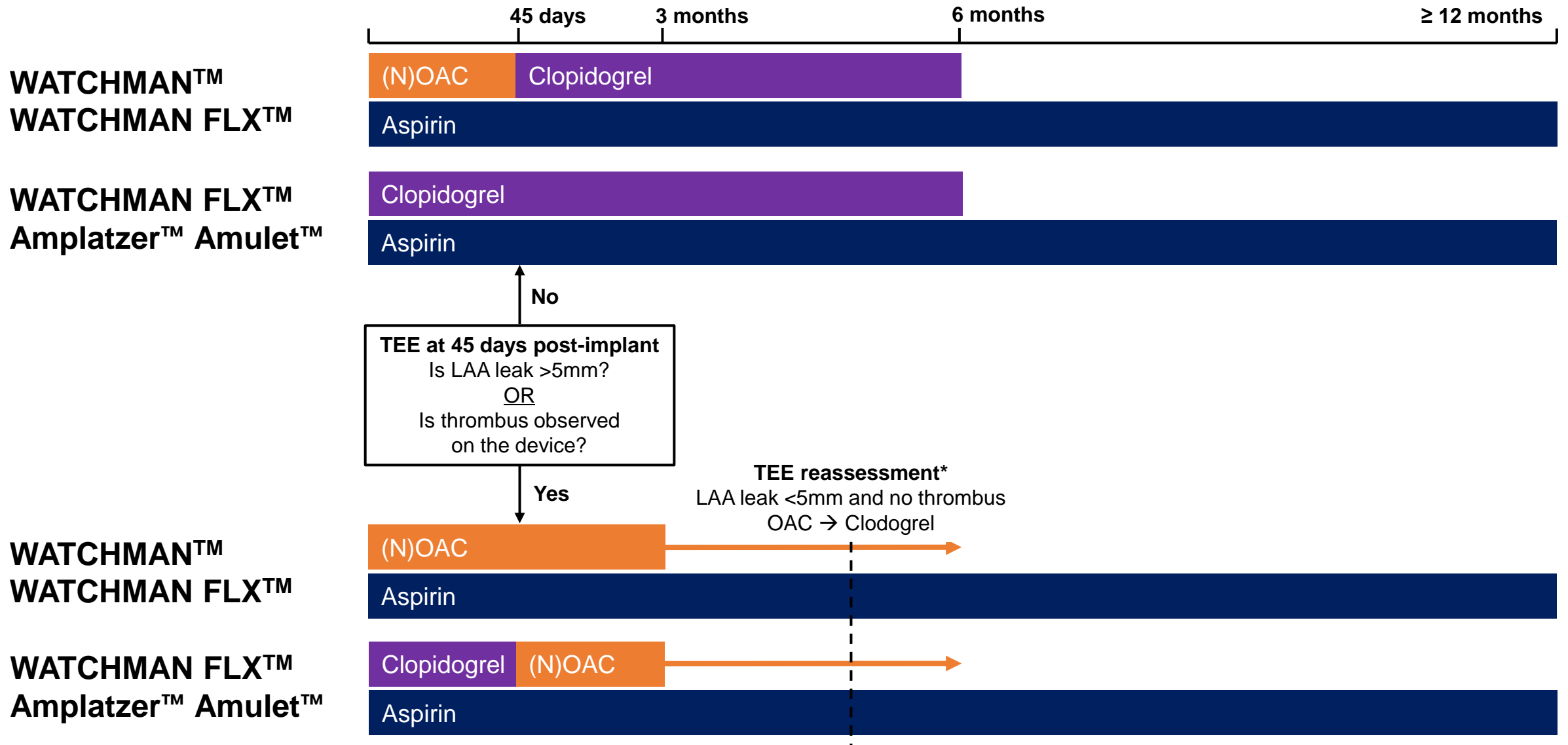
Things to consider for best antithrombotic therapy

- Patient-related factor
 - Stroke risk
 - Bleeding risk
 - Eligibility for anticoagulation therapy (especially for short-term OAC)
- Device-related factor
 - Single occlusive mechanism vs. Dual occlusive mechanism
- Post-procedural TEE findings
 - Peri-device leak
 - Device-related thrombosis

Pivotal studies and antithrombotic regimen protocols

- WATCHMAN™
 - RCTs (Watchman vs. OAC): PROTECT AF, PREVAIL
 - Protocol: Warfarin + aspirin for 45d → DAPT for 6mo → aspirin
- WATCHMAN FLX™
 - Prospective study for FDA approval: PINNACLE FLX
 - Protocol: Warfarin/NOAC + aspirin for 45d → DAPT for 6mo → aspirin
- Amplatzer™ Amulet™
 - No pivotal trials defining anti-thrombotic regimen
 - Approved protocol: DAPT for 6mo → aspirin
- Not enough data regarding the patients contraindicative to OACs

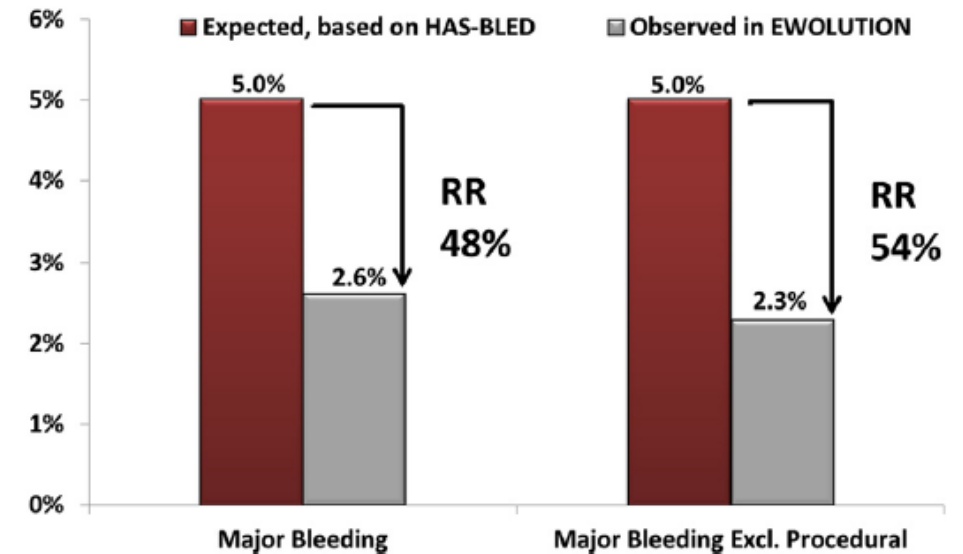
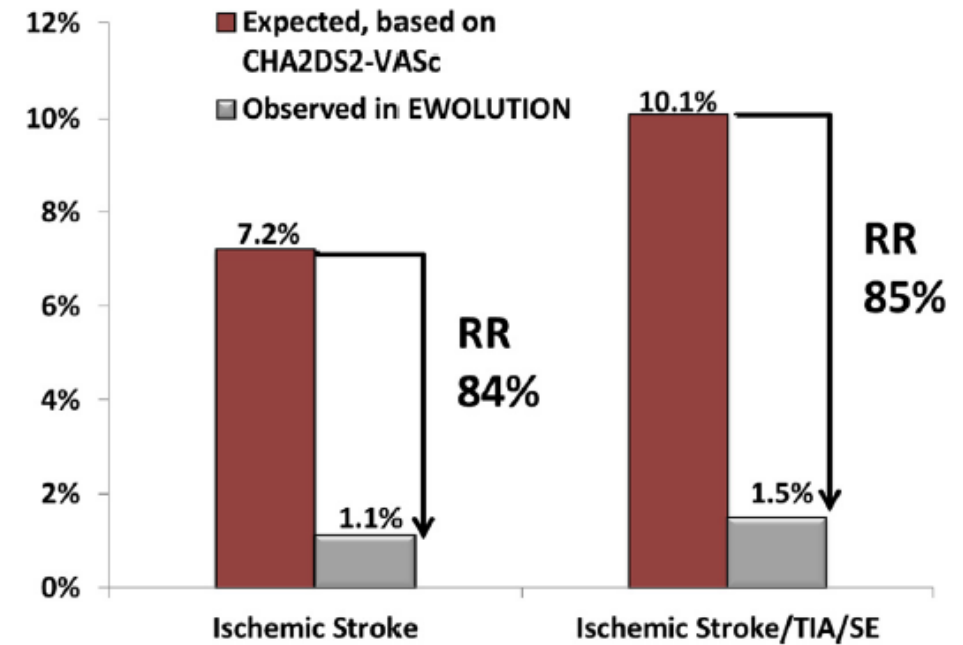
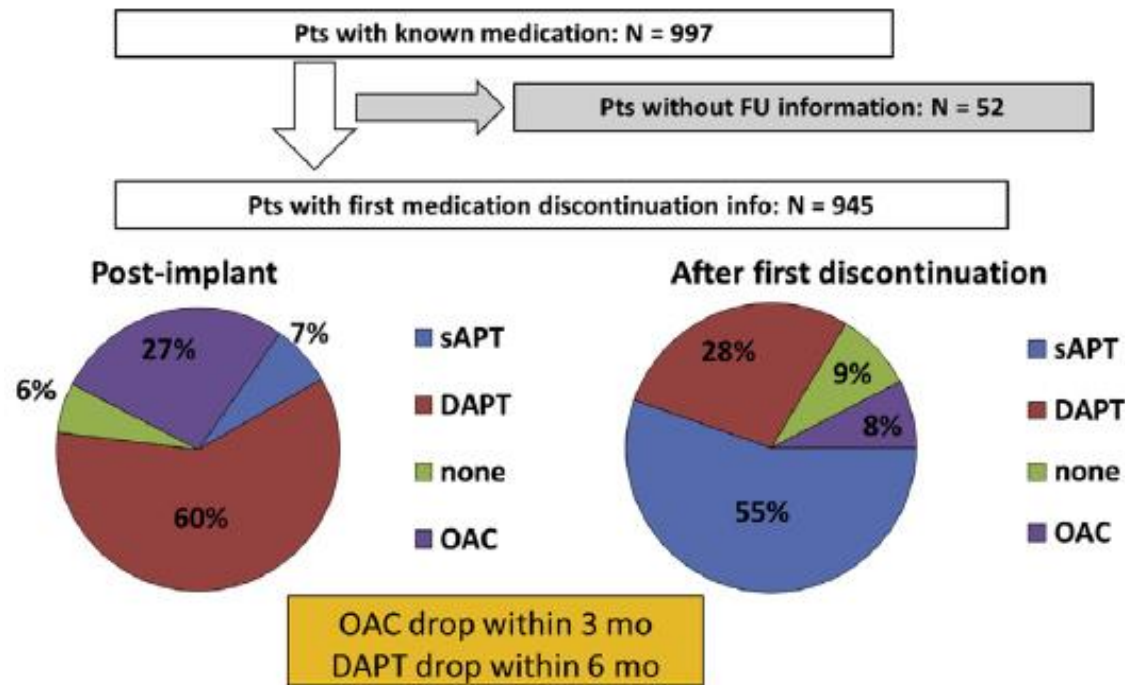
Post-procedural antithrombotic therapy protocol



*The performance and timing of the LAA seal reassessment is left to physician discretion

EWOLUTION Registry

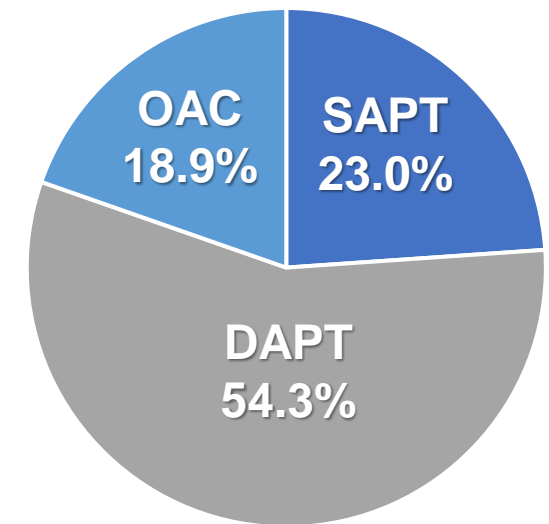
- Prospective multicenter cohort study
- LAAO with WATCHMAN
- 61.8% of 1021 patients were ineligible for OAC
 - 38.7% prior major bleed or predisposition to bleed



AMPLATZER Amulet Post-Marketing Registry

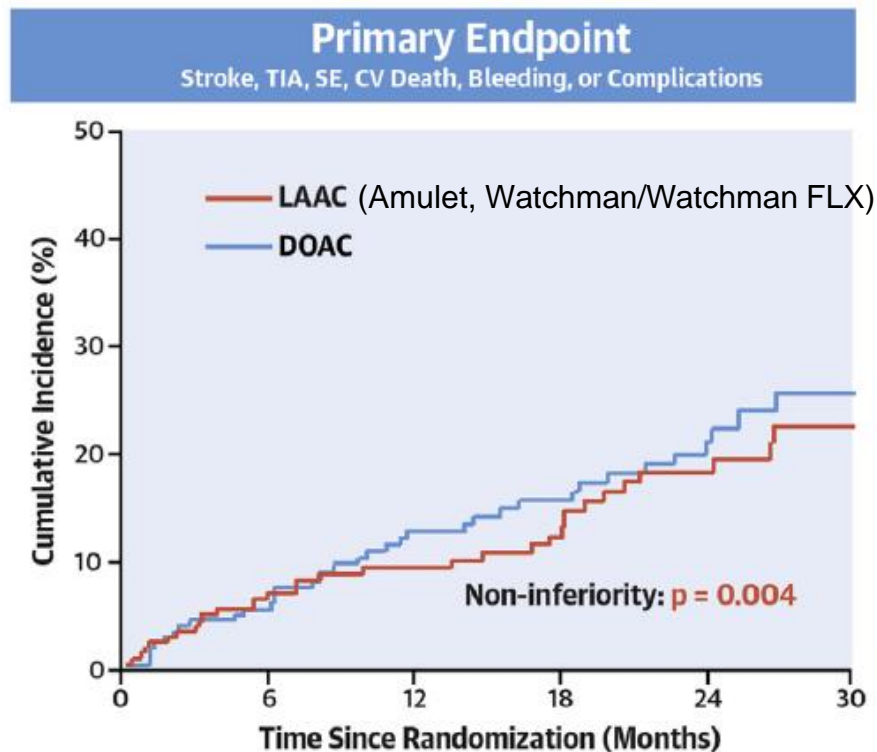
- Prospective multicenter cohort study
- LAAO with AMPLATZER Amulet
- 82.8% of 1088 patients were contraindicated to OAC
 - 72.4% previous major bleeding
- TEE follow-up 67 ± 23 days-post procedure in 673 patients
 - Adequate (<3 mm jet) occlusion of the appendage in 98.2%
 - Device thrombus in 10 patients (1.5%)

Discharge anti-thrombotics



LAAC vs. NOAC in high-risk AF pts: PLAGUE-17

- 402 high-risk AF pts (CHA2DS2-VASc 4.7, HAS-BLED 3.1)
- Non-inferiority trial: LAAC (n=201) vs. NOAC (n=201)
- Recommended antithrombotics: DAPT for 3mo → aspirin (if no leak or DRT)
 - High risk of bleeding: DAPT for 6wks
 - Very high risk of stroke: NOAC for 3mo or NOAC 6wks/DAPT 6wks



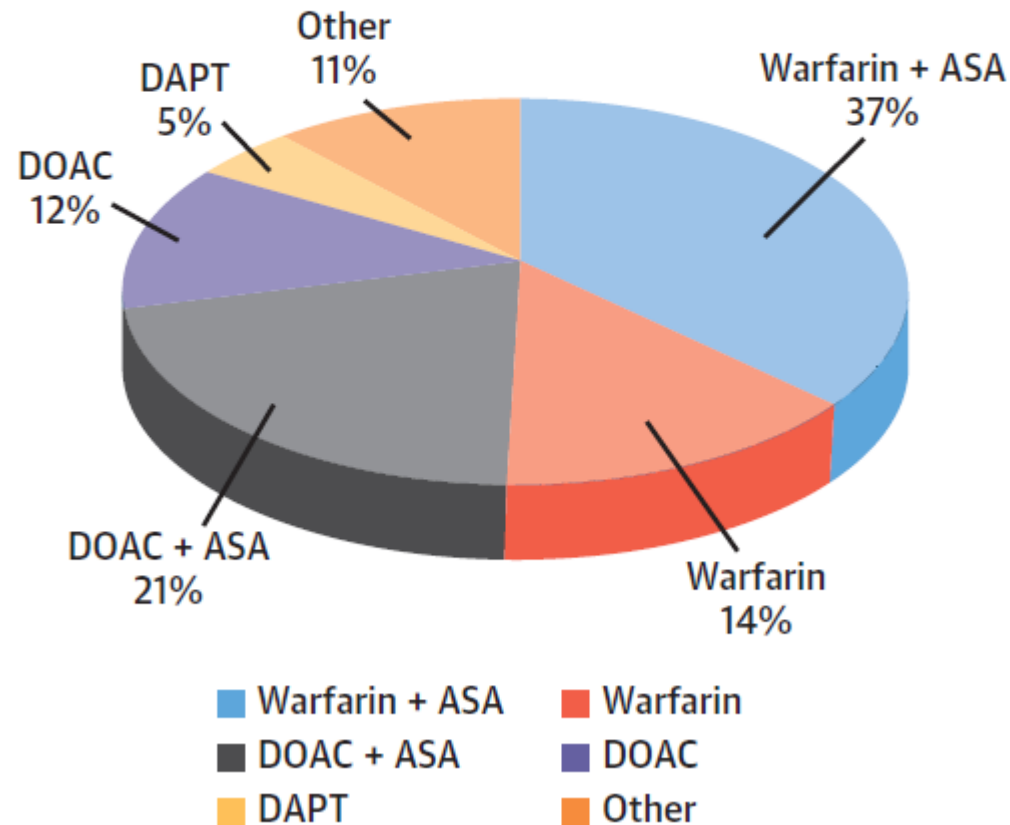
	sHR (95% CI)	p value
Primary Endpoint		
mITT	0.84 (0.53-1.31)	0.44
Per Protocol	0.82 (0.52-1.30)	0.40
On-Treatment	0.79 (0.49-1.25)	0.31
All-Stroke/TIA	1.00 (0.40-2.51)	0.99
CV Death	0.75 (0.34-1.62)	0.46
Major + NMCR Bleeding		
All	0.81 (0.44-1.52)	0.51
Nonprocedural	0.53 (0.26-1.06)	0.07

Contemporary anti-thrombotic use after LAAO in US

- NCDR LAAO Registry: 31,994 patients with Watchman implants (2016-2018)

Most Common Discharge Antithrombotic Strategies

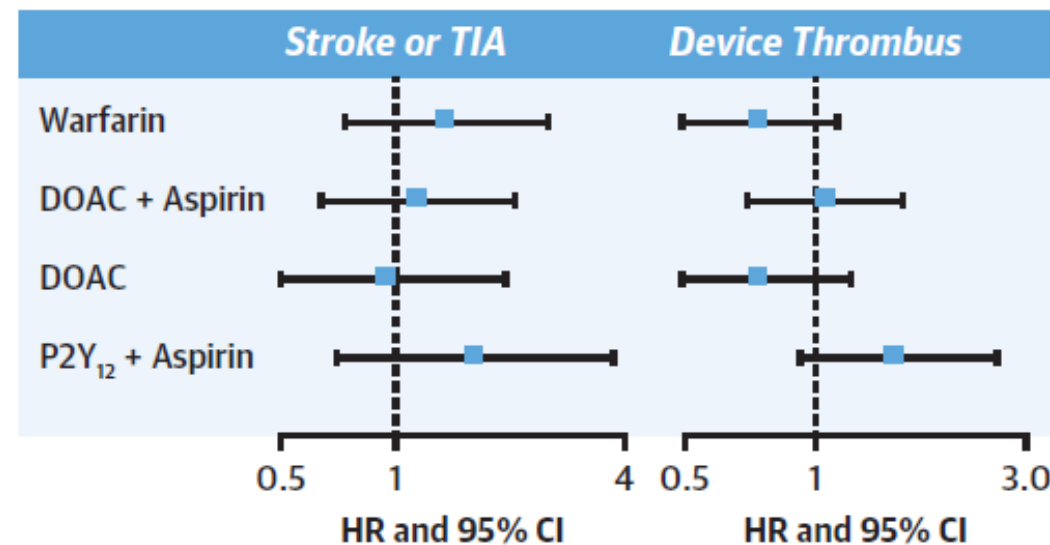
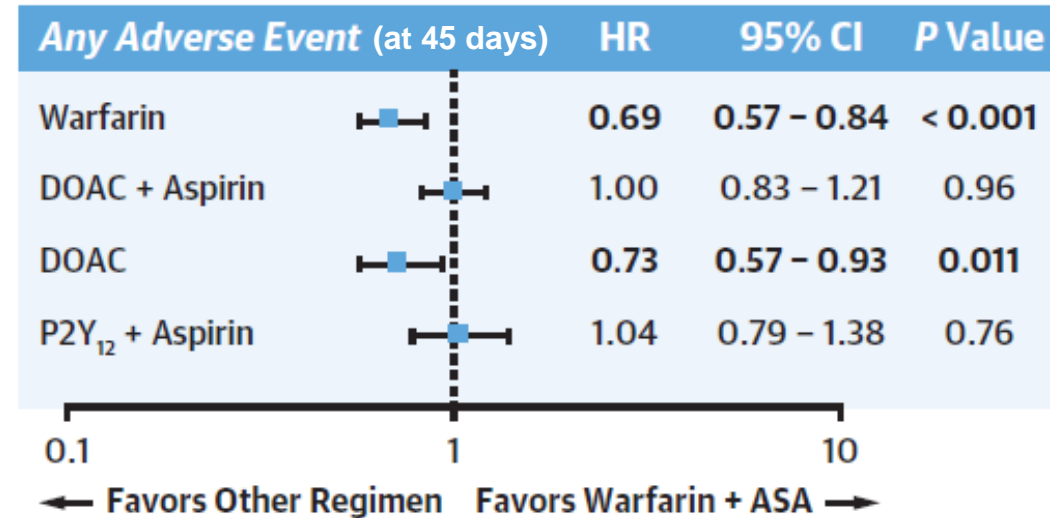
- Only 12.2% received FDA-approved postimplant regimen



Contemporary anti-thrombotic use after LAAO in US

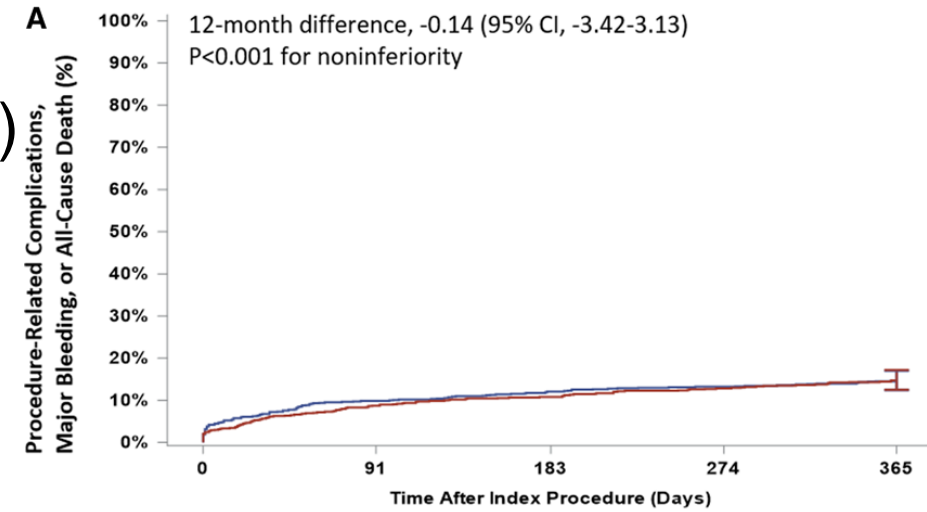
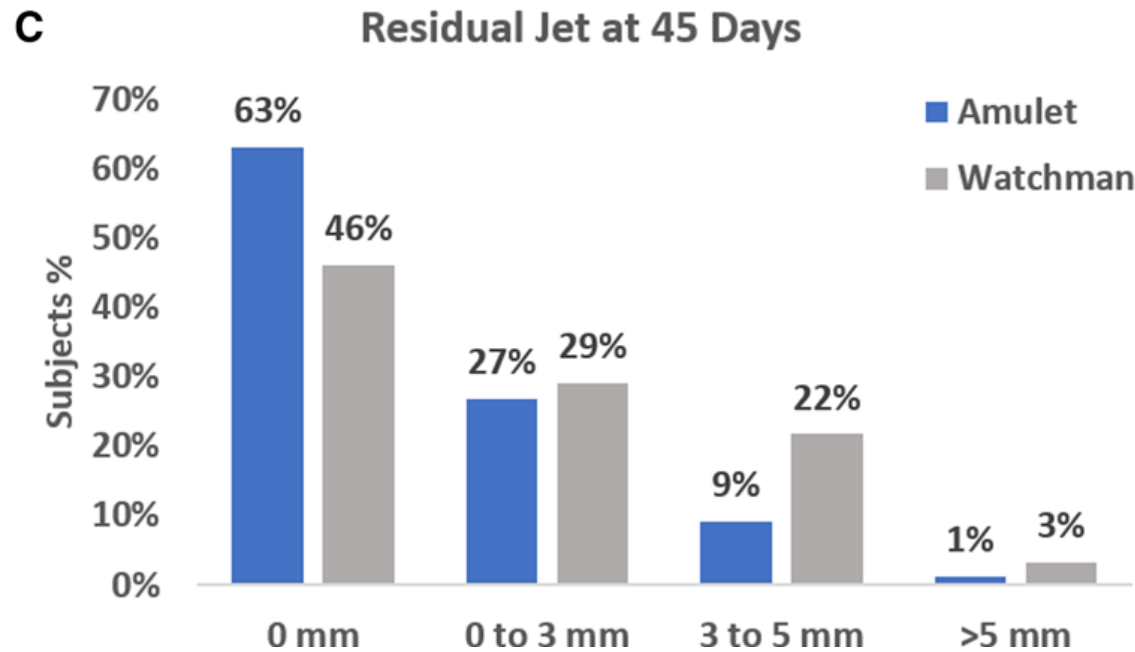
	Warfarin and Aspirin	Warfarin Only	DOAC and Aspirin	DOAC Only	DAPT	P Value ^a
Any adverse event	626 (5.72)	157 (4.01)	321 (5.27)	134 (3.83)	78 (5.56)	<0.0001
Any major adverse event ^b	483 (4.41)	130 (3.32)	262 (4.30)	111 (3.17)	60 (4.28)	0.0017
Death	88 (0.80)	32 (0.82)	52 (0.85)	27 (0.77)	14 (1.00)	0.0205
Ischemic stroke	16 (0.15)	9 (0.23)	20 (0.33)	7 (0.20)	6 (0.43)	<0.0001
Hemorrhagic stroke	15 (0.14)	1 (0.03)	10 (0.16)	2 (0.06)	2 (0.14)	<0.0001
Undetermined stroke	2 (0.02)	0 (0.00)	0 (0.00)	2 (0.06)	1 (0.07)	<0.0001
TIA	11 (0.10)	8 (0.20)	6 (0.10)	4 (0.11)	0 (0.00)	<0.0001
Intracranial hemorrhage	9 (0.08)	2 (0.05)	5 (0.08)	2 (0.06)	1 (0.07)	0.0001
Systemic arterial embolism	4 (0.04)	1 (0.03)	0 (0.00)	3 (0.09)	2 (0.14)	<0.0001
Major bleeding	336 (3.07)	72 (1.84)	172 (2.83)	60 (1.71)	31 (2.21)	<0.0001
Major vascular complication	17 (0.16)	9 (0.23)	12 (0.20)	3 (0.09)	1 (0.07)	<0.0001
Myocardial infarction	18 (0.16)	6 (0.15)	7 (0.11)	2 (0.06)	4 (0.29)	0.0022
Pericardial effusion requiring intervention	24 (0.22)	1 (0.03)	12 (0.20)	6 (0.17)	5 (0.36)	0.0006
Device embolization	3 (0.03)	3 (0.08)	0 (0.00)	2 (0.06)	0 (0.00)	0.0006
Readmission	616 (5.62)	209 (5.33)	355 (5.83)	176 (5.03)	77 (5.49)	0.5183
Any stroke or TIA	43 (0.39)	18 (0.46)	36 (0.59)	15 (0.43)	9 (0.64)	0.3589
Atrial or device-related thrombus among those with TEE	187 (1.85)	53 (1.48)	96 (1.73)	58 (1.82)	37 (3.31)	<0.0001
Peridevice leak >5 mm among those with TEE	86 (0.85)	20 (0.56)	34 (0.61)	26 (0.82)	5 (0.45)	0.1940

Warfarin and DOAC alone without aspirin were associated with lower risks of any adverse event compared with **warfarin and aspirin**, largely driven by **lower risk of bleeding**

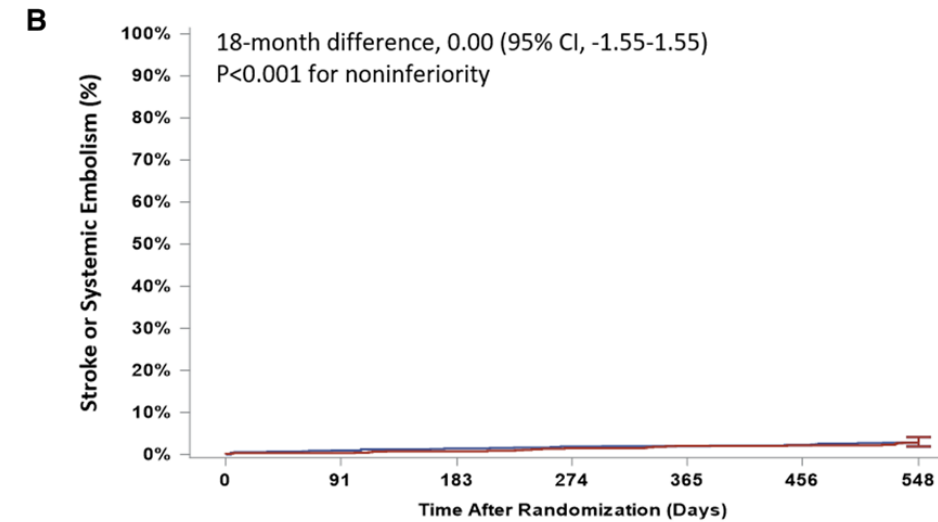


Amulet IDE Trial

- Noninferiority trial: Amulet vs. Watchman (control)
- Primary endpoints: safety, effectiveness, and LAA occlusion at 45 days

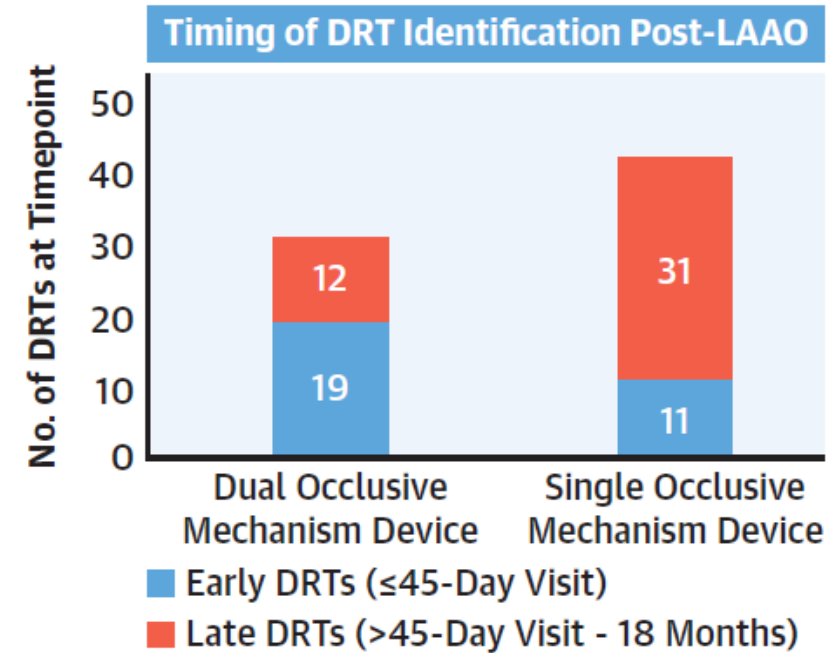
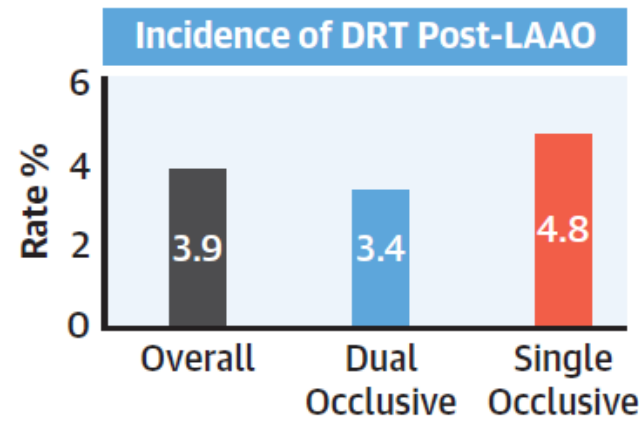
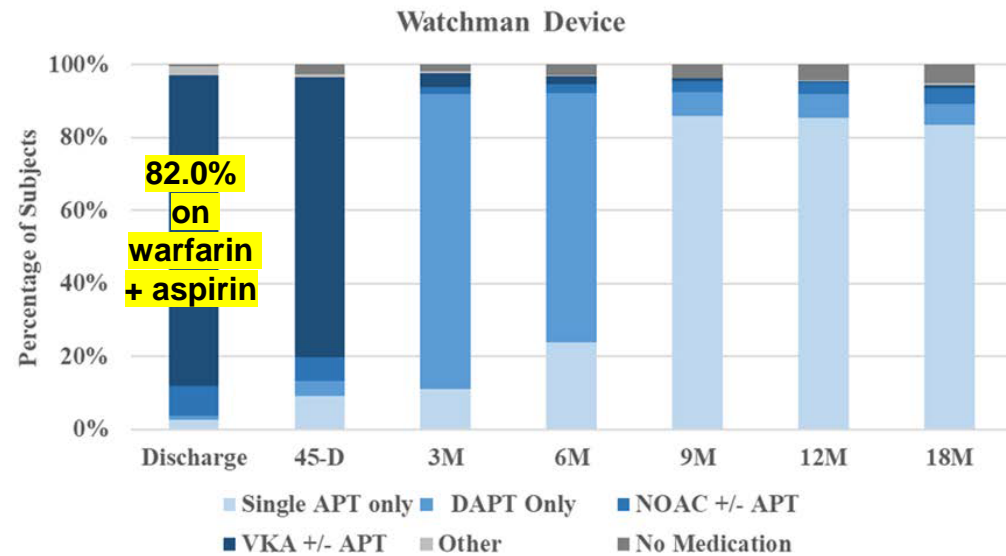
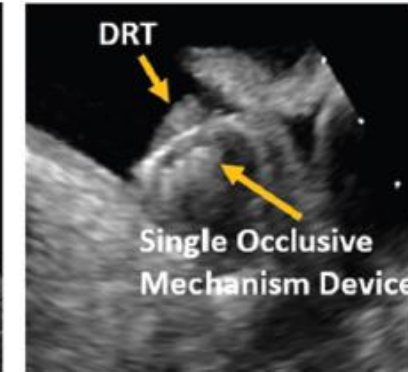
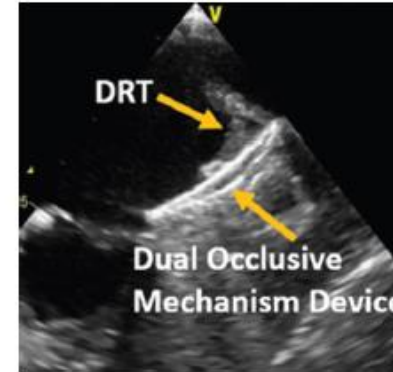
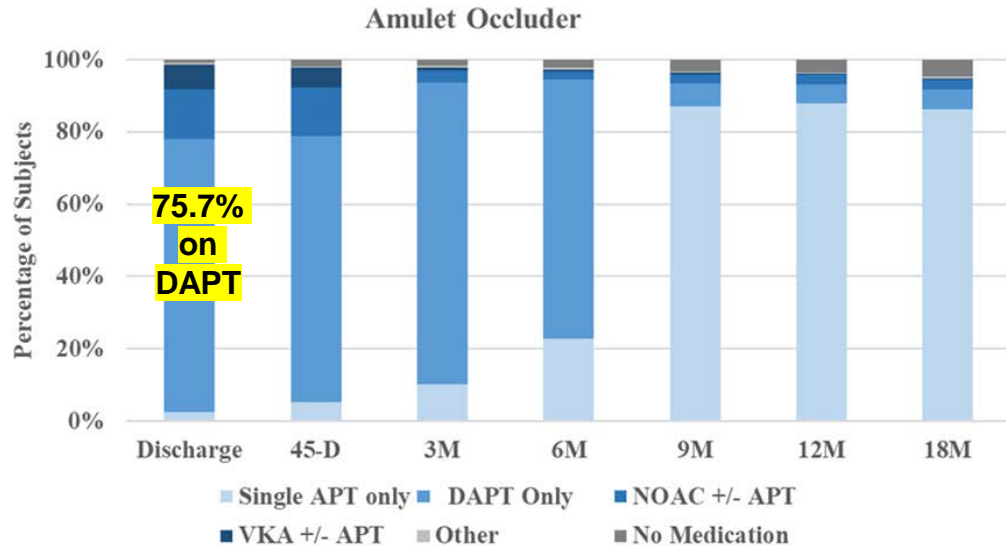


Amulet	903	813	790	778	763
Watchman	896	810	787	757	728



Amulet	934	900	882	867	854	837	804
Watchman	944	903	881	850	818	797	743

DRT after LAAO: Amulet IDE Trial

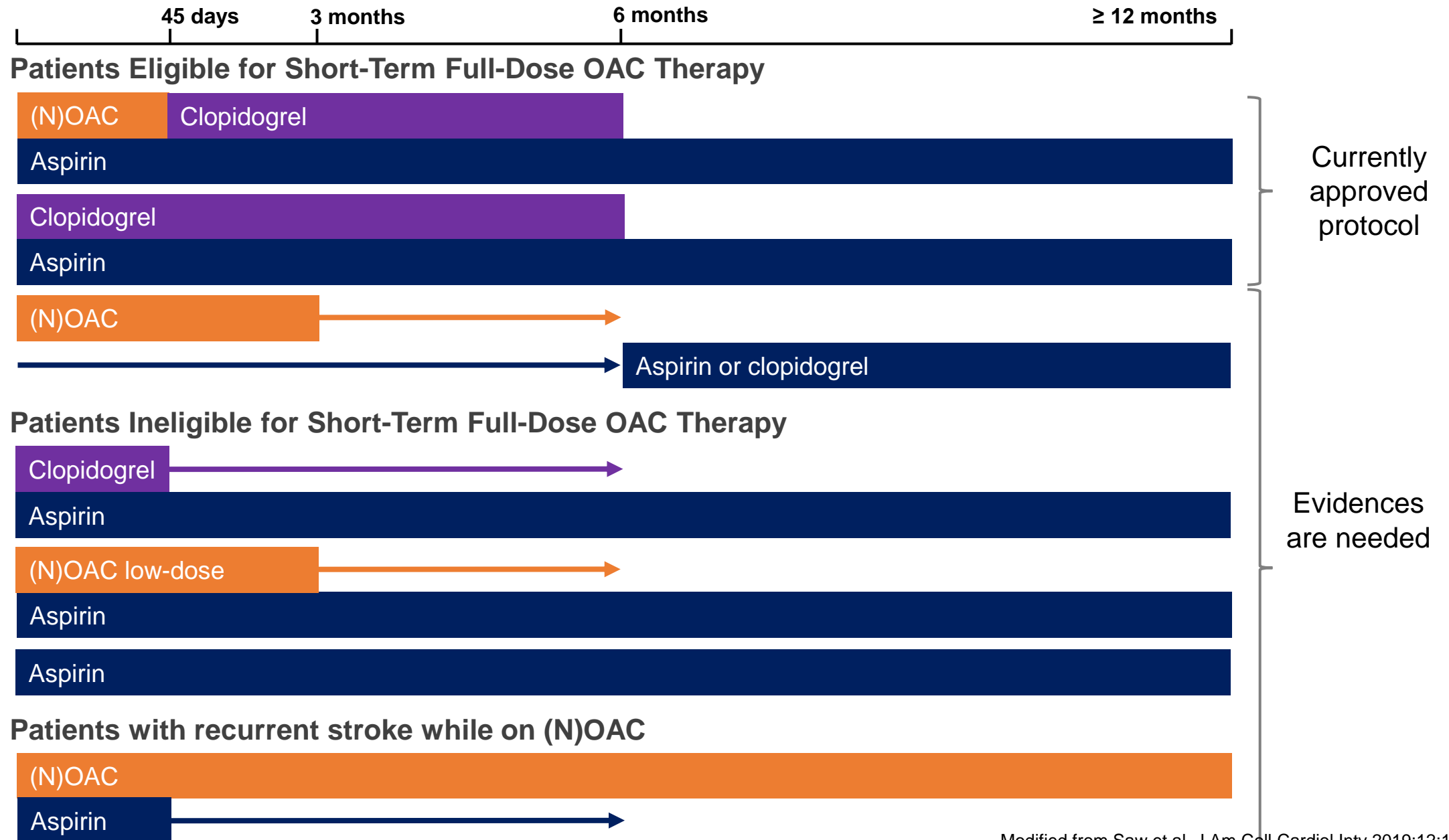


Ongoing endovascular LAAC randomized controlled trials and postprocedural antithrombotic strategies

	OAC-eligible patients			OAC-contraindicated patients		
Trial	OPTION trial: WATCHMAN FLX vs OAC after PV ablation	CHAMPION-AF trial: WATCHMAN FLX vs DOAC	CATALYST trial: Amulet vs DOAC	ASAP-T00 trial: WATCHMAN vs control	STROKE-CLOSE trial: Amulet vs control	CLOSURE-AF trial: LAAC vs OAC
N	1600	3000	2650	888 ^a	750	1512
Postprocedural antithrombotic strategies	DOAC or warfarin and aspirin for 3 mo after LAAC	DOAC and aspirin or DAPT for 3 mo after LAAC	DAPT for 3 mo after LAAC	DAPT for 3 mo after LAAC	Aspirin ± clopidogrel for 45 d after LAAC	DAPT after LAAC
Control	OAC	DOAC	DOAC	Aspirin or none	OAC, antiplatelet, or none	DOAC or warfarin

DAPT = dual antiplatelet therapy; DOAC = direct oral anticoagulation; LAAC = left atrial appendage closure; OAC = oral anticoagulation; PV = pulmonary vein.
^aStudy stopped prematurely (~500 patients enrolled).

Feasible antithrombotic regimens (If TEE reveals no DRT)



Case

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- HT, ESRD on HD
- AF on apixaban → D/C d/t ongoing anemia
- Severe AS, s/p TAVI (2022.12)
- Thrombocytopenia developed after TAVI: probably d/t consumption

- 2023.4 multiple thromboembolic infarction
- 2023.5 LAA occlusion with Amulet

- DAPT for 3 months followed by aspirin monotherapy after 3 months



Thank You For Your Attention!

Contemporary anti-thrombotic use in US

NCDR LAAO Registry: 31,994 Patients With Watchman Implants

Most Common Discharge Antithrombotic Strategies

• Only 12.2% received FDA-approved postimplant regimen

