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Left Atrial Appendage Closure (LAAC) What Every Provider Should Know

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Disclosures

- I have no financial relationships to disclose

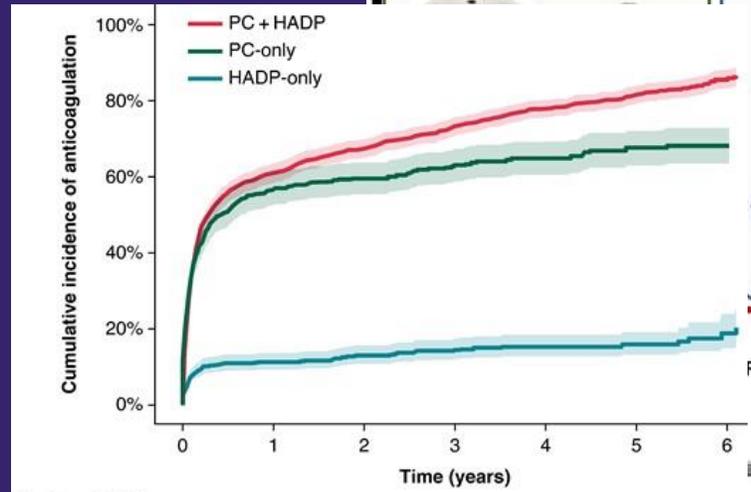
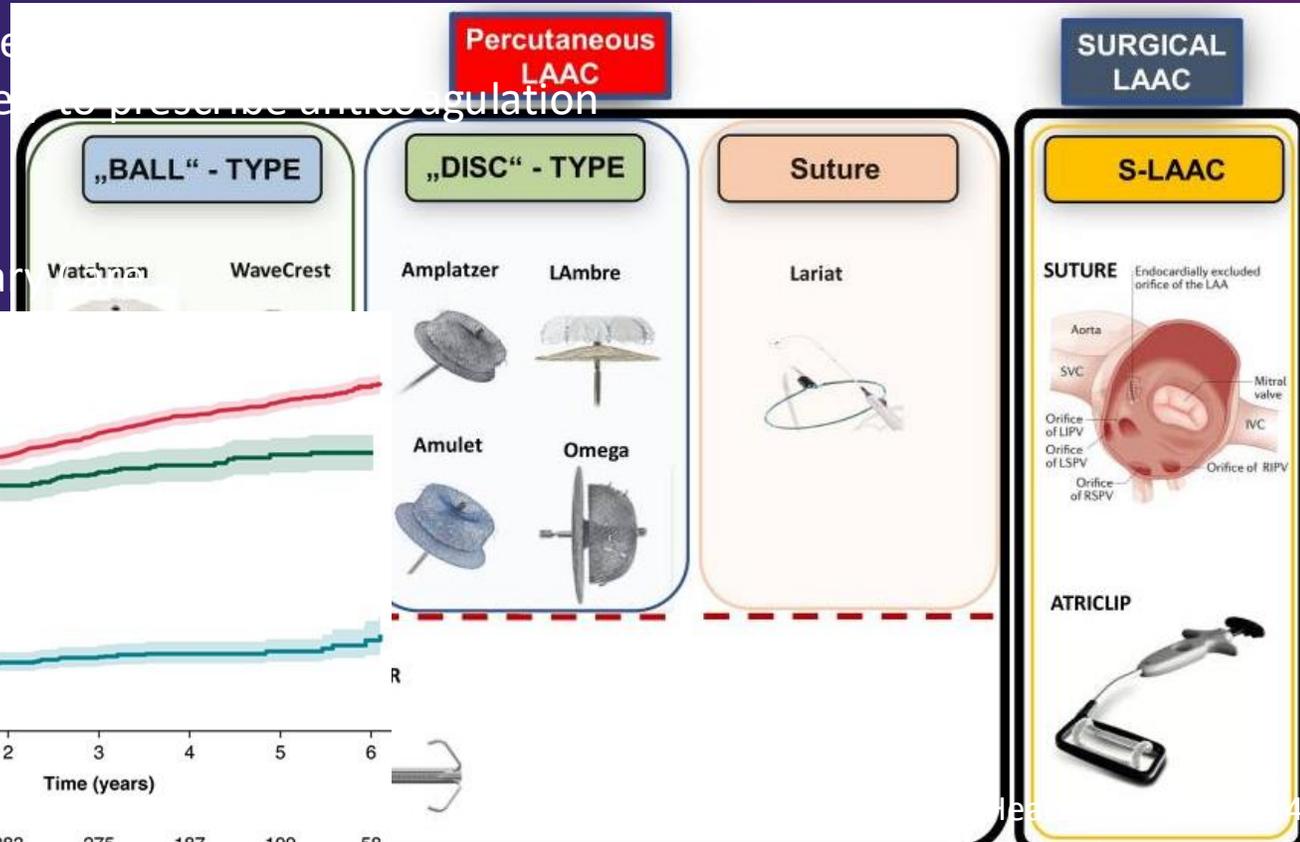
Left Atrial Appendage Closure: Isn't this just a cardiology thing?

UK Biobank

4374 patients with afib
Majority 46.2% Diagnosed in
Primary Care—more likely to prescribe anticoagulation

Dutch Cohort

55% Diagnosed in Primary Care

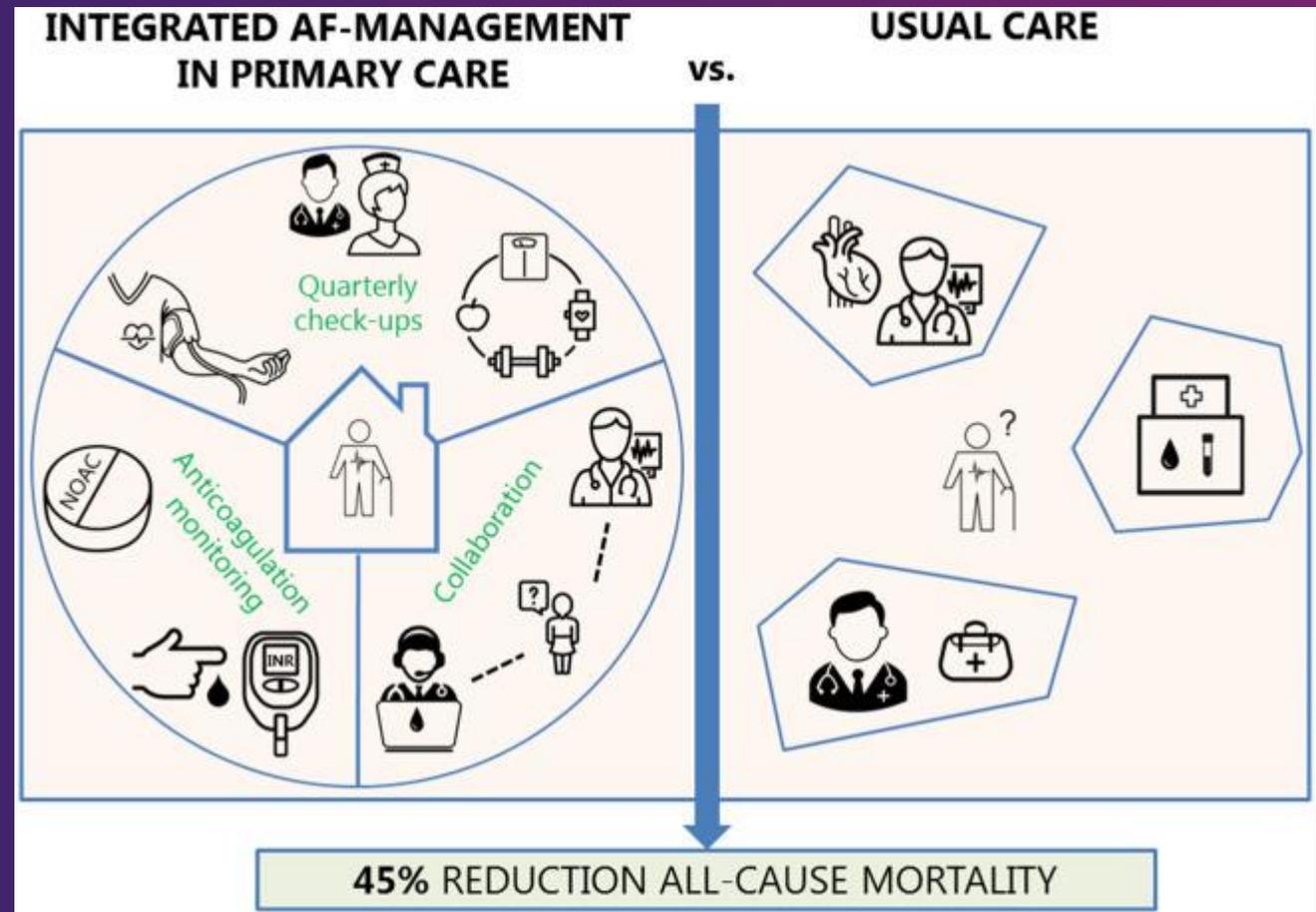
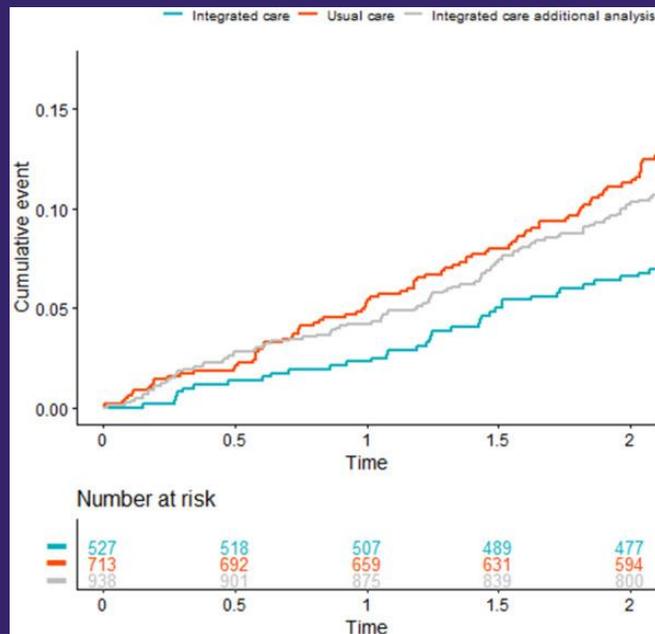


Number at risk	0	1	2	3	4	5	6
PC + HADP	1437	503	383	275	187	109	58
PC-only	574	202	154	113	75	52	16
HADP-only	918	540	413	307	219	140	60

Lee et al. Heart. 2023;109(12):1511-1518.
 Camm CF. EP Europace, Volume 27, Issue 2, February 2025.
 Verbiest-van Gorp N. et al. Heart J. 2022 Sep 1;31(2):76-82.

Integrated Primary Care Management of Afib

- ALL-IN Clustered Randomized Trial
- Quarterly AF checkups RN/PCP
- Anticoagulation Clinic Monitoring
- Cardiology referral if necessary

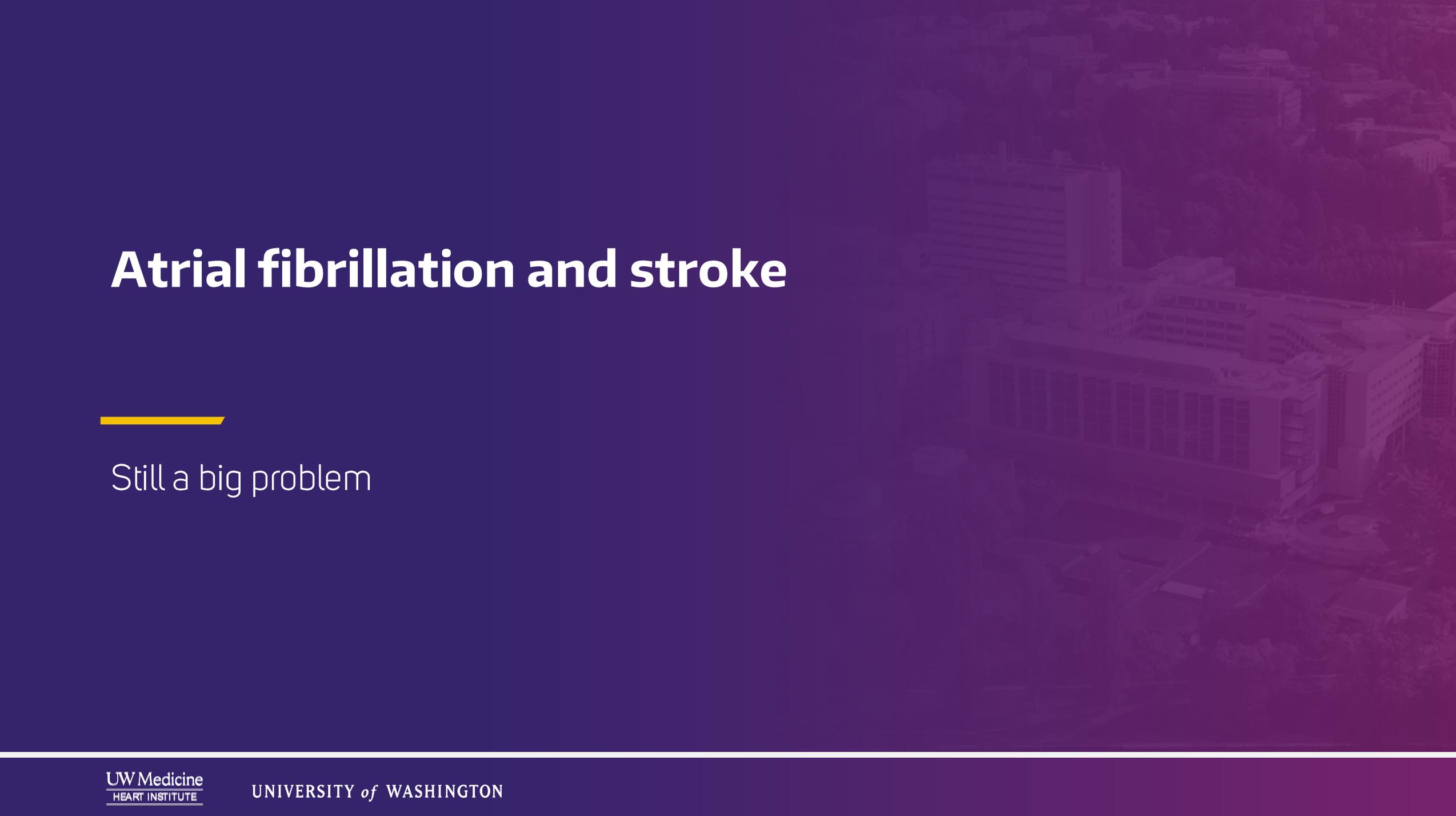


Big questions

- How well does this really work? Isn't there a high rate of complications?
- Ok, warfarin sucks, but has LAAC been compared to DOACs?
- Don't patients need to take anticoagulation for several months?
- Isn't it bad for high bleeding risk patients?
 - What about CLOSURE AF?
- What about patients with stroke on anticoagulation?
- Do patients need anticoagulation for DCCV?



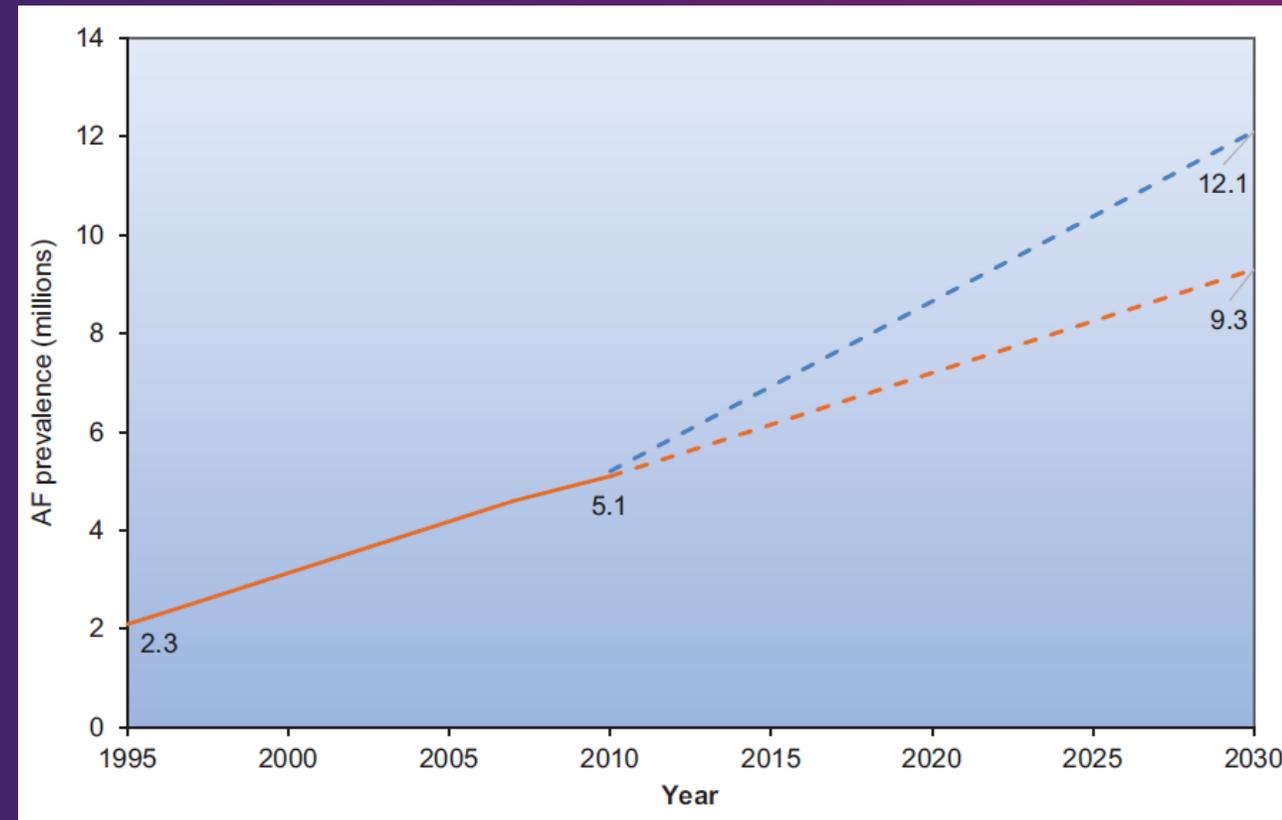
Atrial fibrillation and stroke



Still a big problem

Atrial Fibrillation Prevalence in US

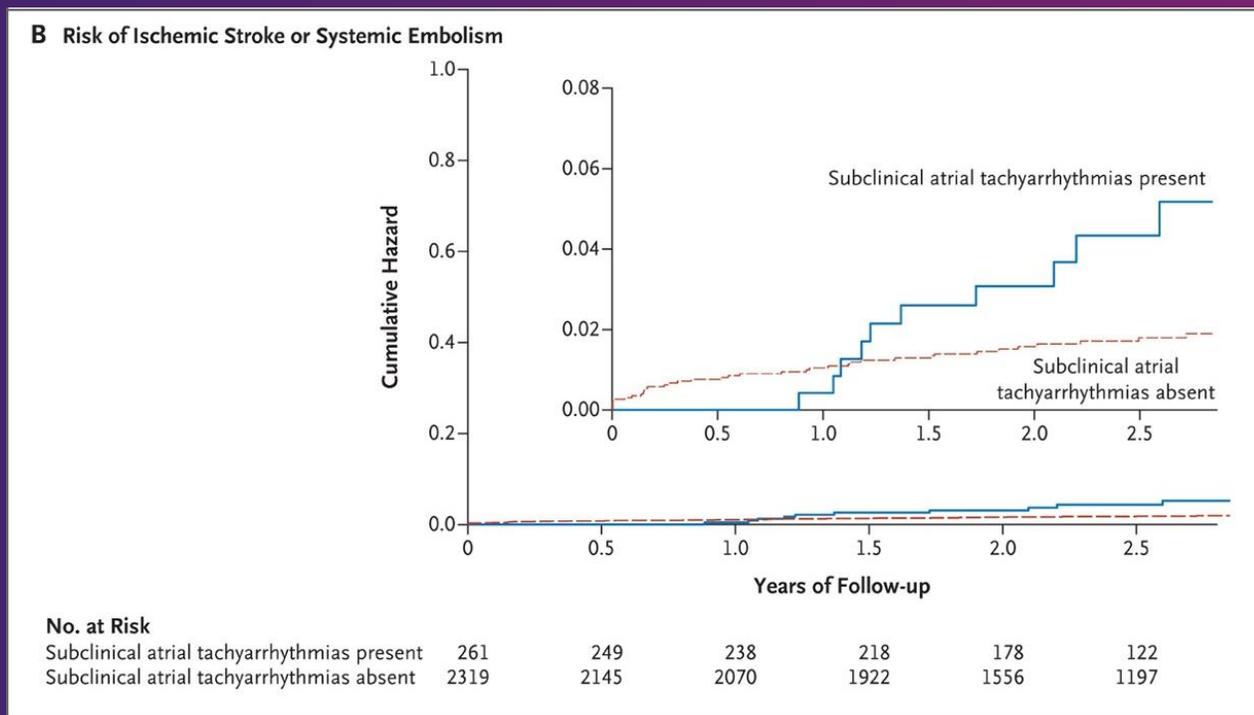
- 2-4% of the population
- Prevalence 2.7 to 6.1 million in US
- Underestimated
 - Subclinical afib 5-30% patients ≥ 65 yrs
 - Ischemic stroke HR 2.50
 - ~20% for patients ≥ 80 years



Subclinical Atrial Fibrillation: ASSERT

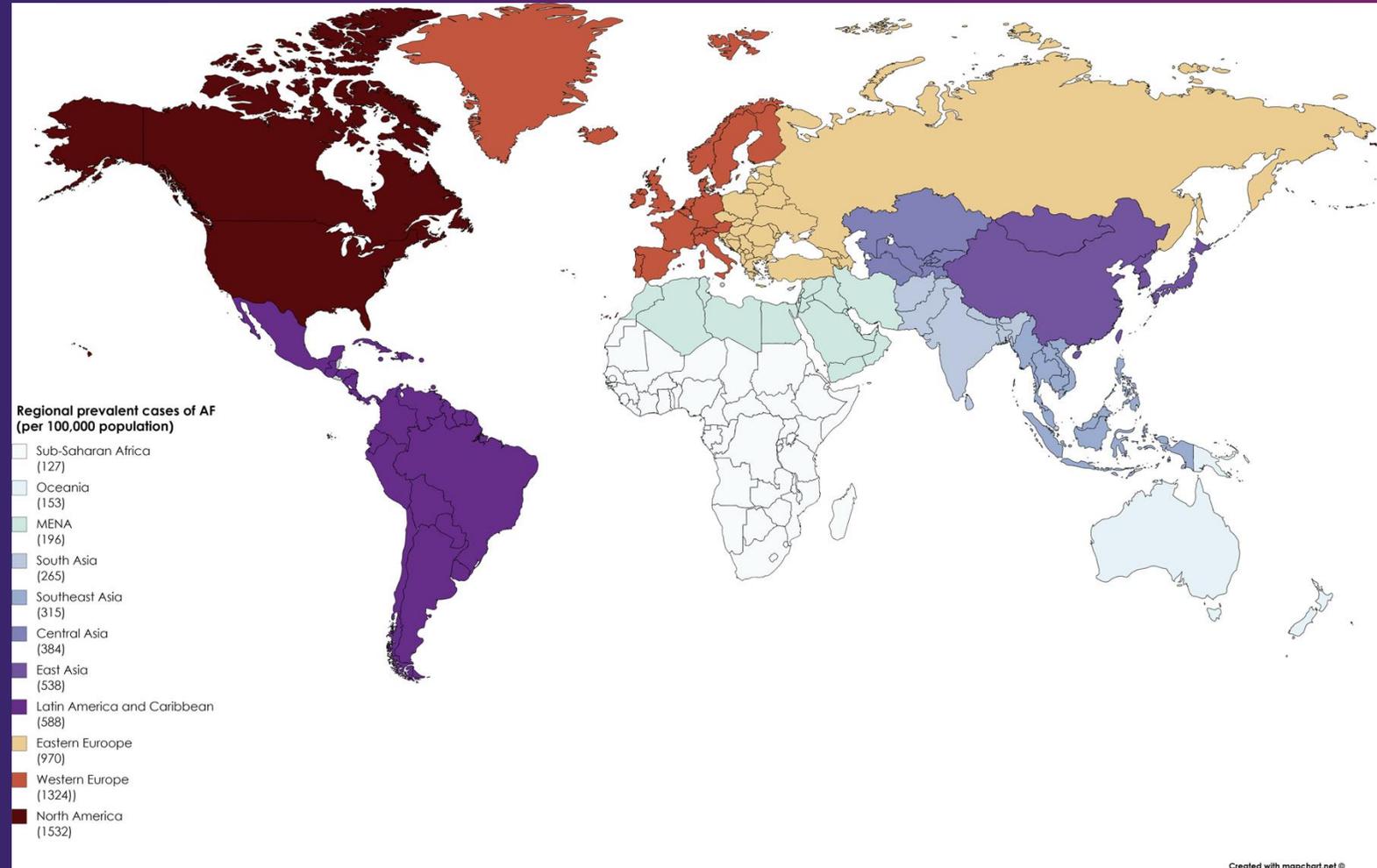
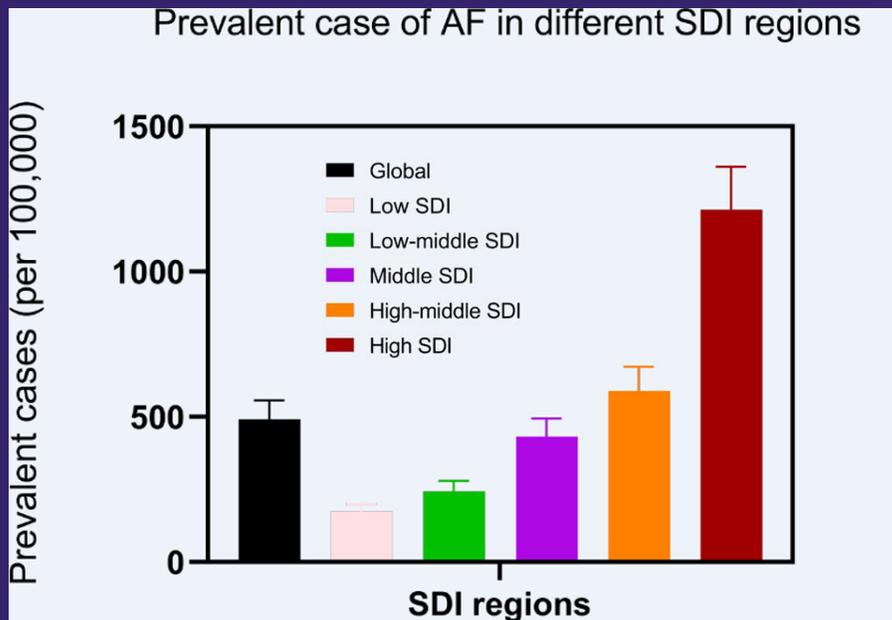
- 2580 patients ≥ 65 without AFIB undergoing pacemaker implant
- 10% of patients with subclinical afib at 3 months
- 34.7% of patients with subclinical afib at 2.5 y follow-up
- Ischemic stroke HR 2.50; 95% CI, 1.28–4.89; $P < 0.008$
- Annual ischemic stroke or systemic embolism rate of 1.69% (versus 0.69%)
- Primarily if afib duration > 24 hrs

If afib detected in first 3 months

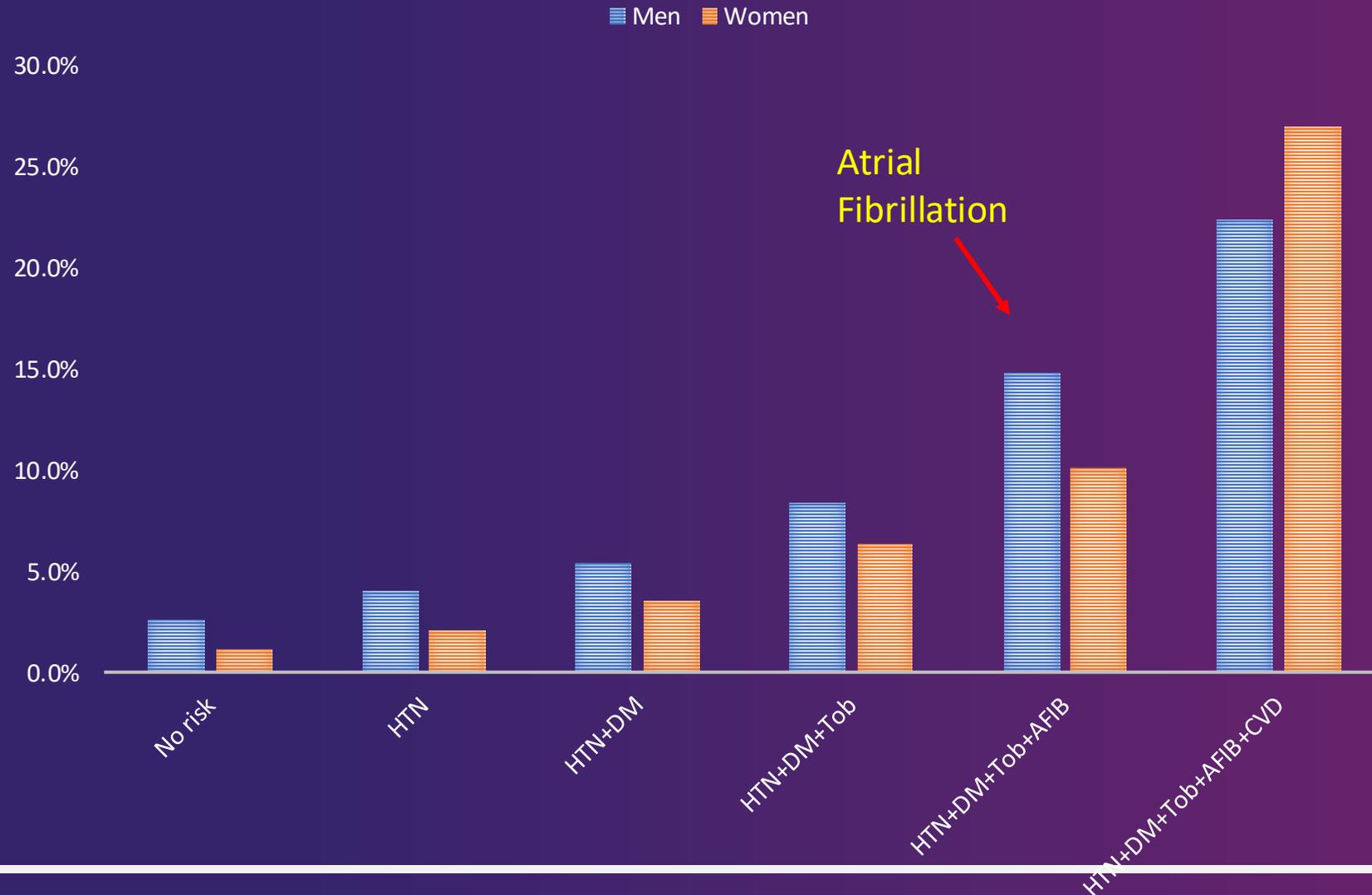


Global Burden of Atrial Fibrillation

- Worldwide 37.6 million
- Increase 60% by 2050

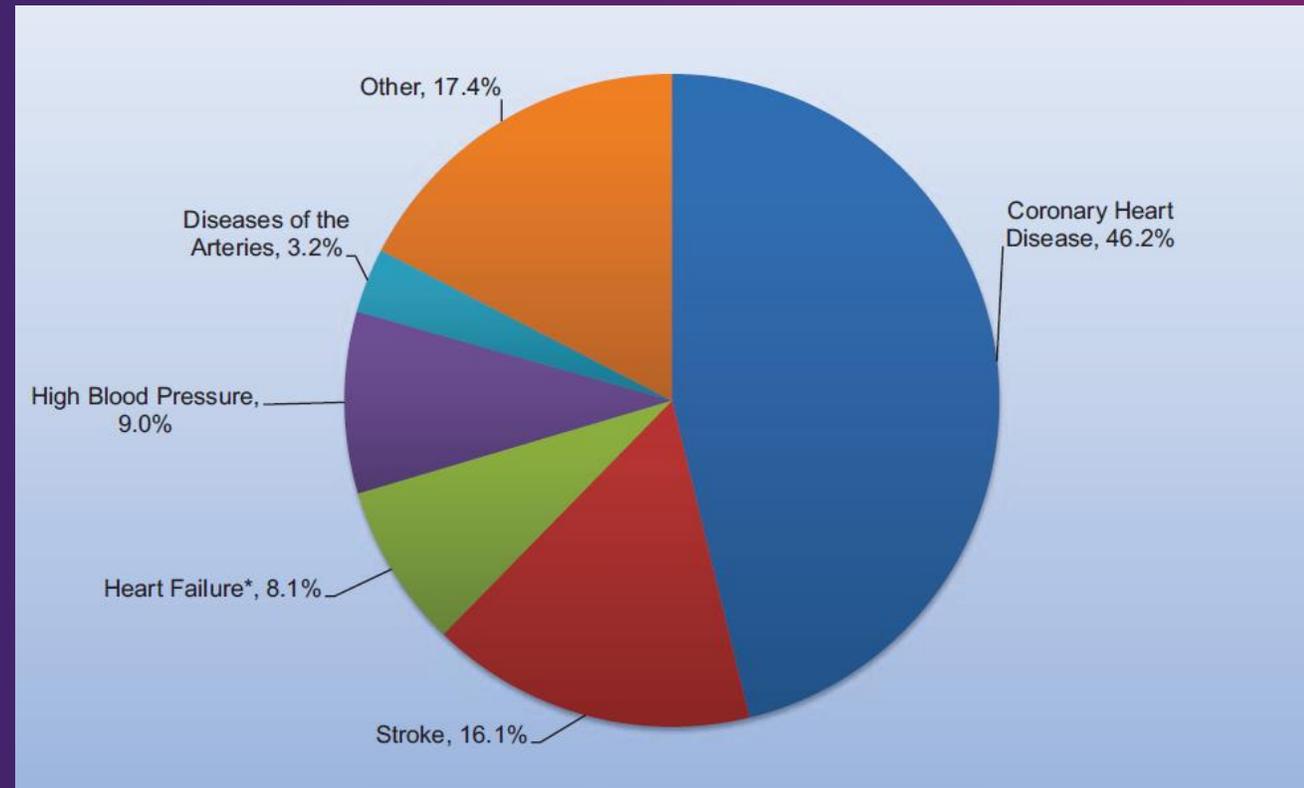
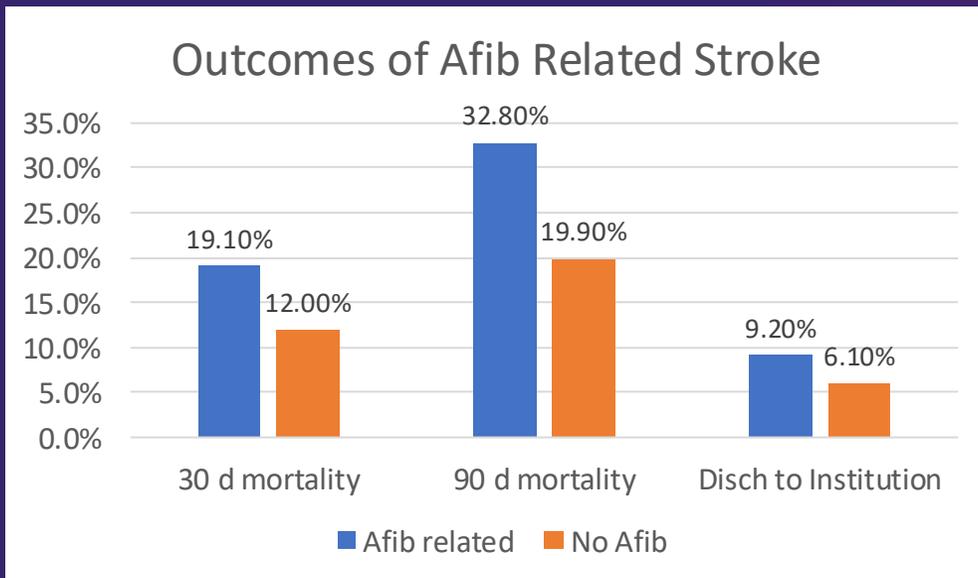


Proportional attributable risk: AFIB



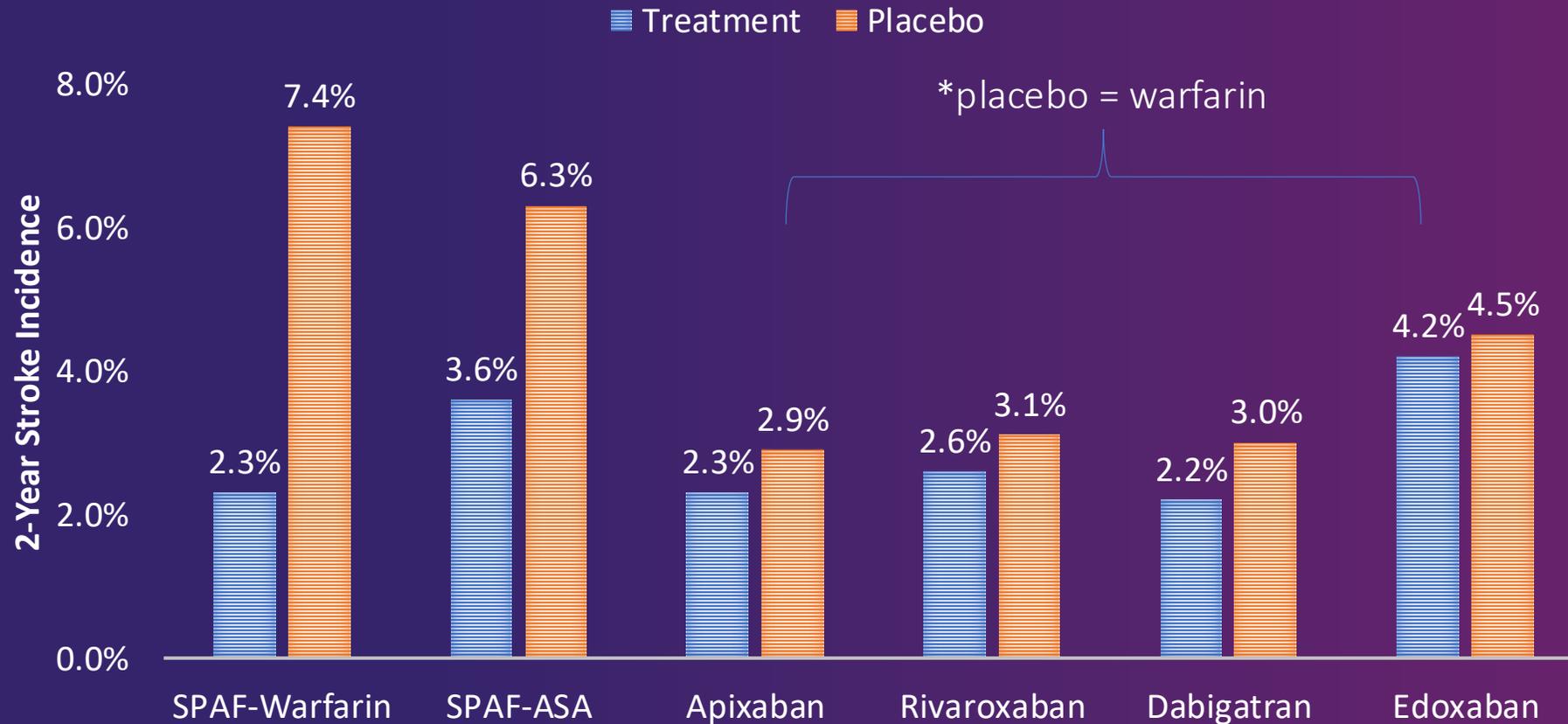
Stroke Impact

- Stroke: US 5th leading cause of death
 - World-wide 2nd leading cause of death
- Afib Strokes
 - 3-month disability OR 1.43 (95% CI 1.13-1.80)



Centers for Disease Control and Prevention (CDC). Prevalence of stroke: United States, 2006–2010. *MMWR Morb Mortal WklyRep*.2012;61:379–382.
Lamassa M. Stroke. 2001 Feb;32(2):392-8.

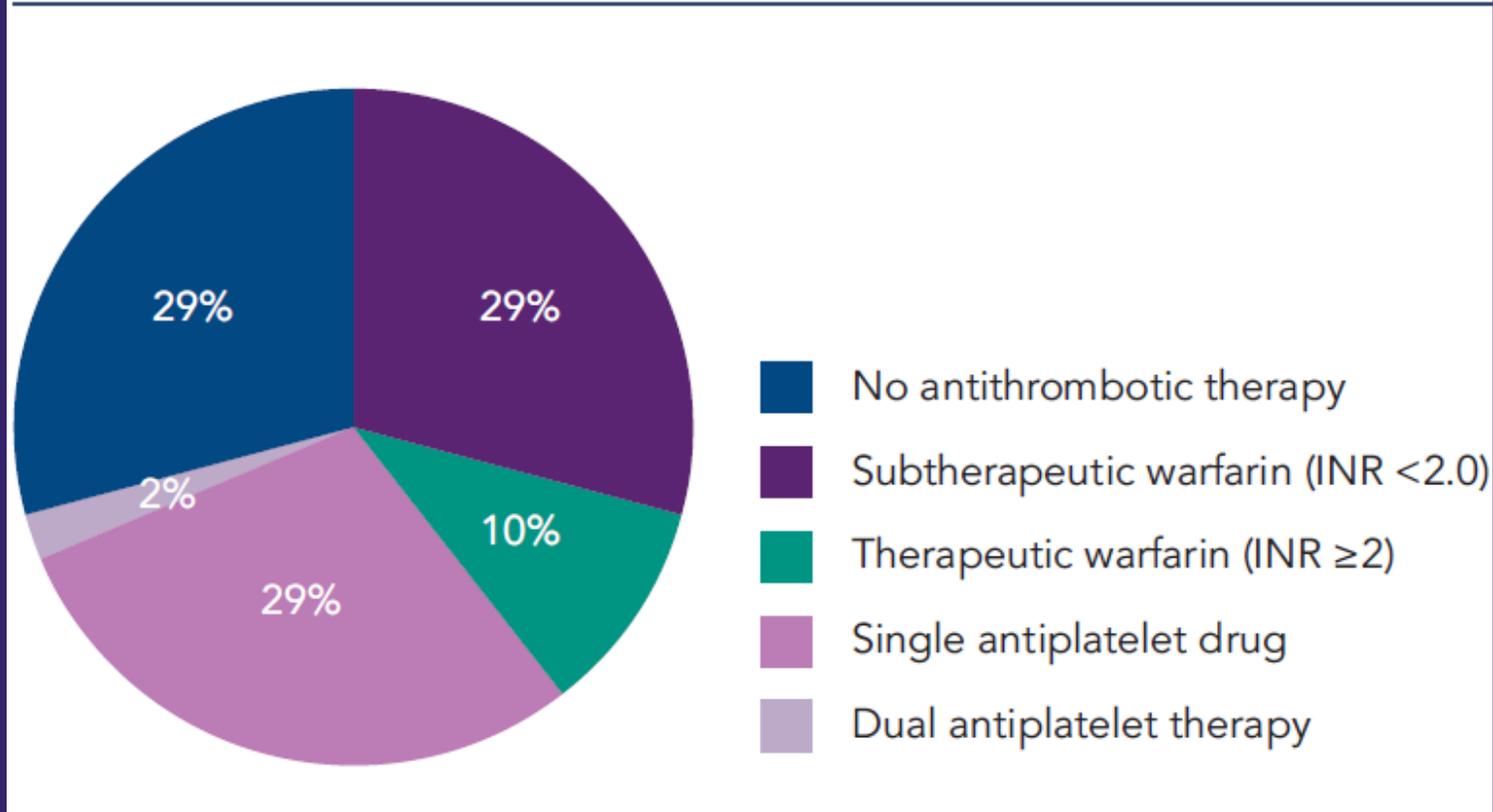
Anticoagulation and stroke reduction



SPAF Investigators. Circulation. 1996; Patel MR. NEJM. 2011; Granger CB. NEJM. 2011; Giugliano RP. NEJM. 2013.
Don C et al. Catheter Interventions for Structural Heart Disease. 2013. Adapted from Go AS et al. JAMA 2003.

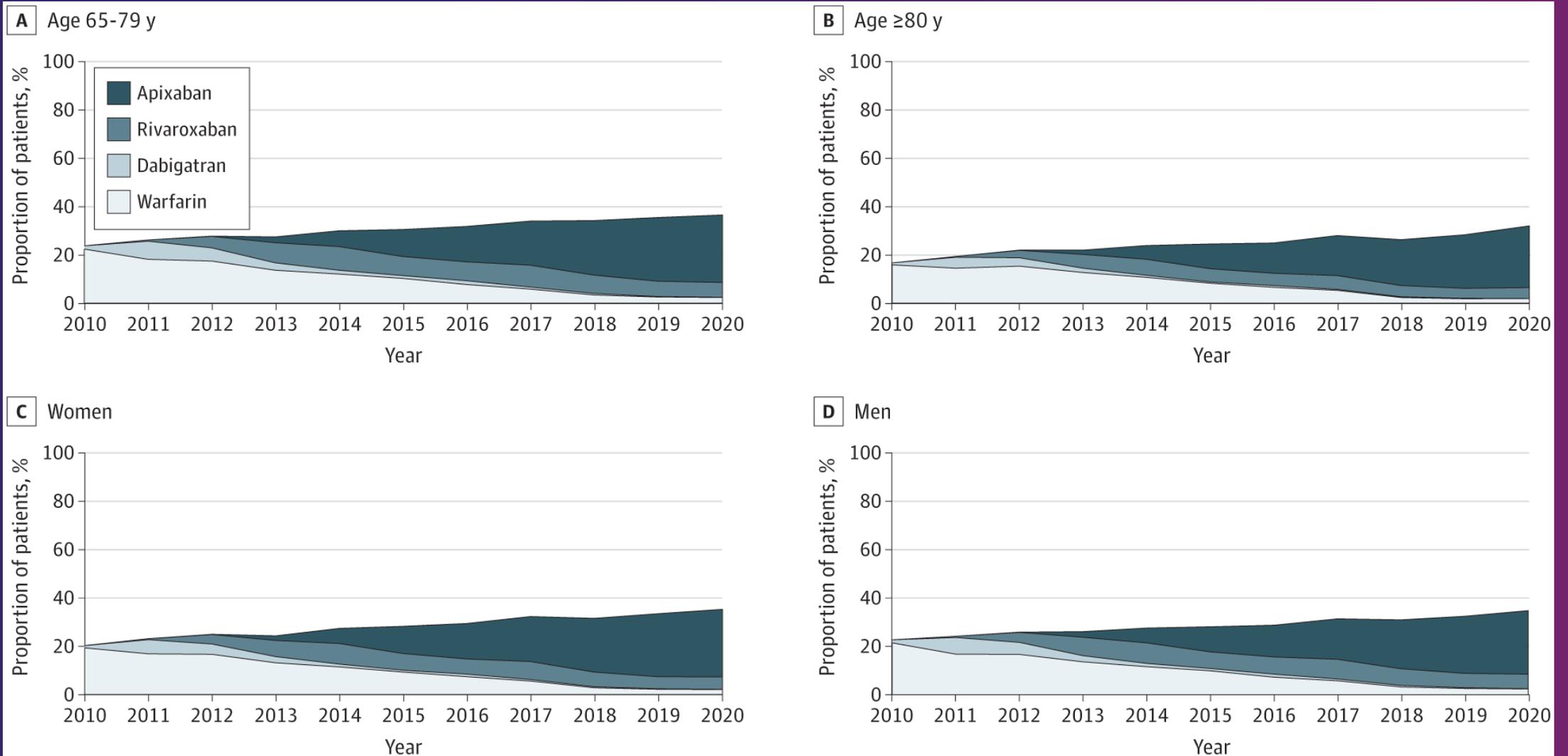
Under treatment causes strokes

Figure 5: Preadmission Medications in Patients with Known Atrial Fibrillation Who Were Admitted with Acute Ischaemic Stroke (High-Risk Cohort, n=597)



Source: Gladstone et al, 2009.³¹

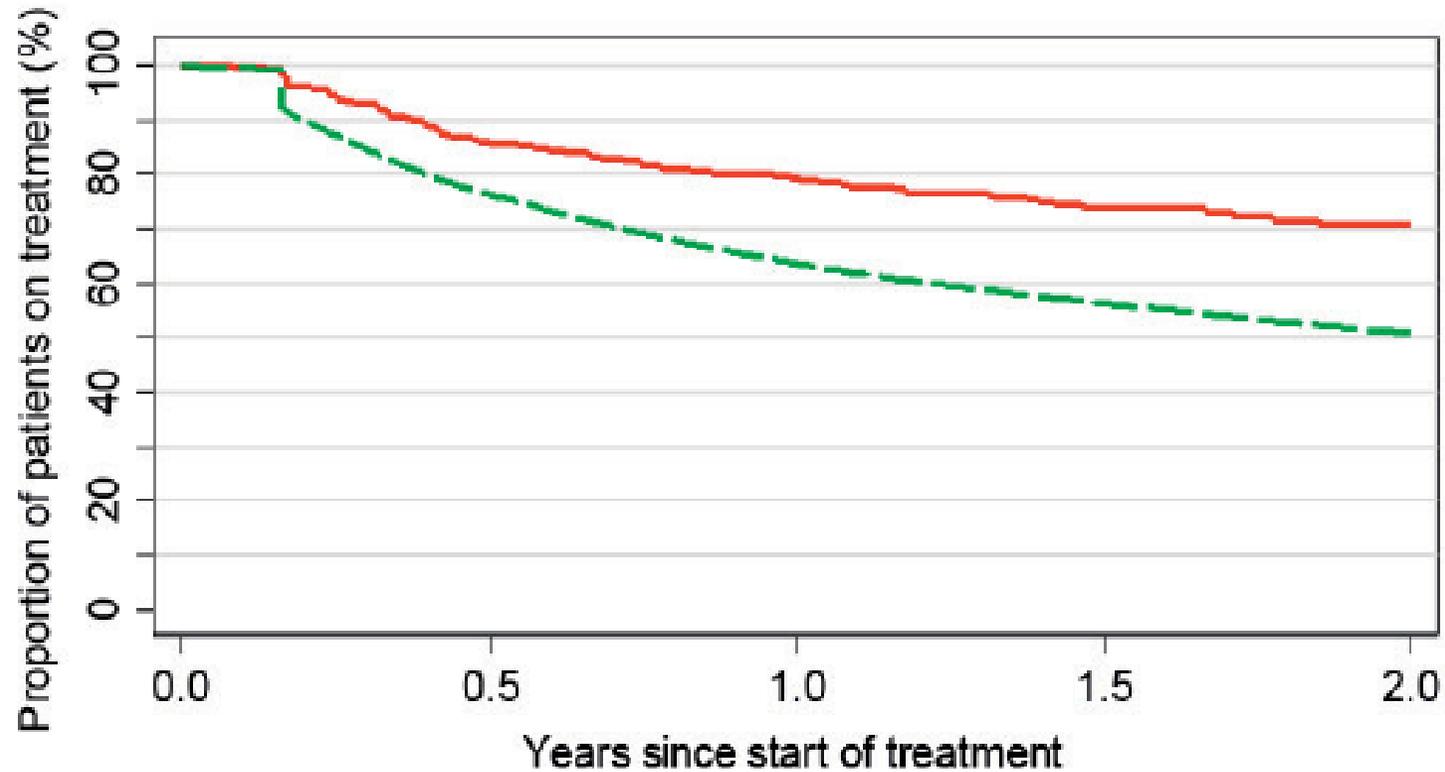
Anticoagulation—initiation w/in 12 mo of AF diagnosis



DOAC discontinuation—clinical trials

Treatment	Study Drug Discontinuation Rate	Major Bleeding (rate/year)
Rivaroxaban¹	24%	3.6%
Apixaban²	25%	2.1%
Dabigatran³ (150 mg)	21%	3.1%
Edoxaban⁴ (60 mg / 30 mg)	33 % / 34%	2.8% / 1.6%
Warfarin¹⁻⁴	17 – 28%	3.1 – 3.6%

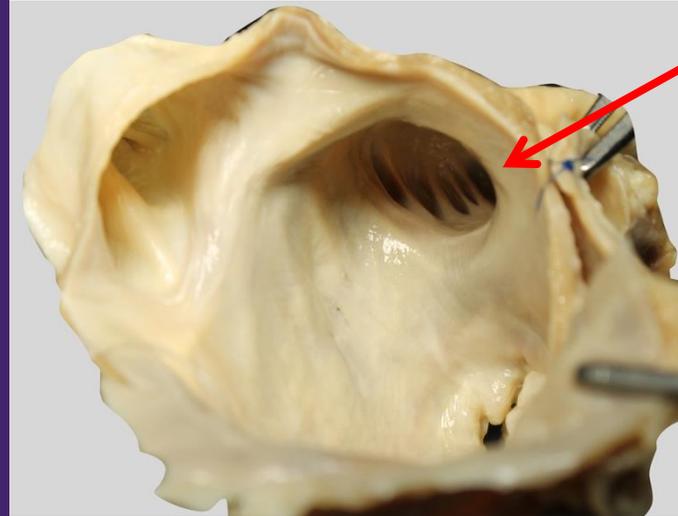
DOAC discontinuation—real world



NOAC	914	651	342	139	41
VKA	12307	8453	5762	3915	2506

Strokes and the Left Atrial Appendage

Benefits of LAA closure



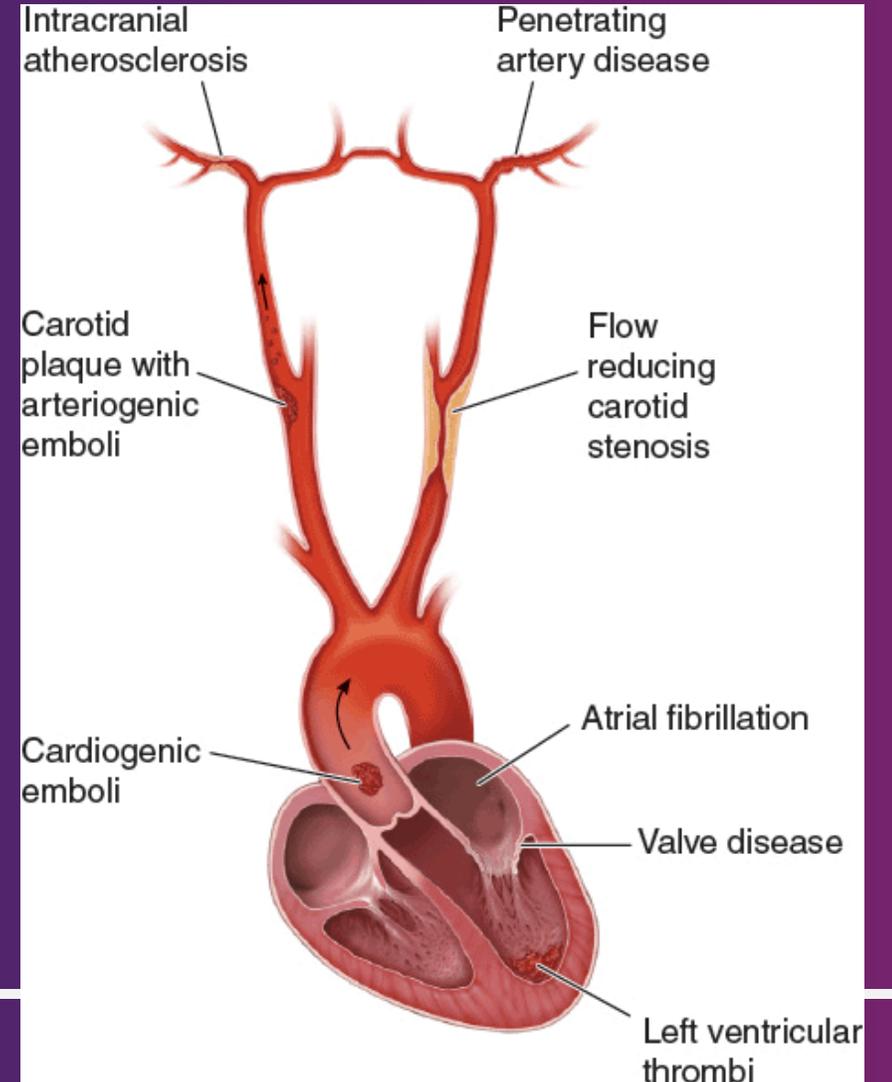
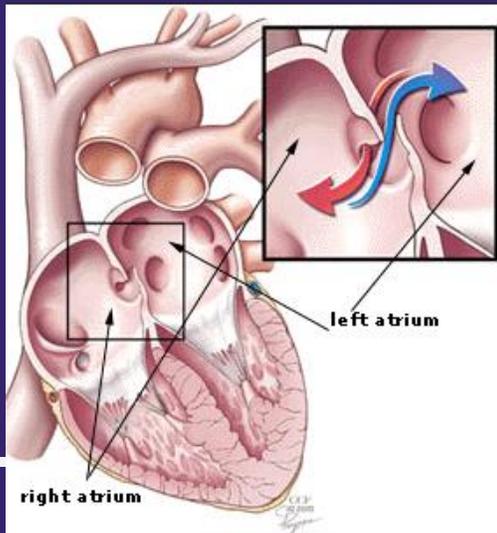
Where do strokes come from?

Cardioembolic strokes—20% of all stroke

- Atrial fibrillation—atrial clots
- LV dysfunction—LV clots
- Valvular disease
- PFO (Patent foramen ovale)



80% from vascular source:
Aorta, Carotids, Cerebral arteries



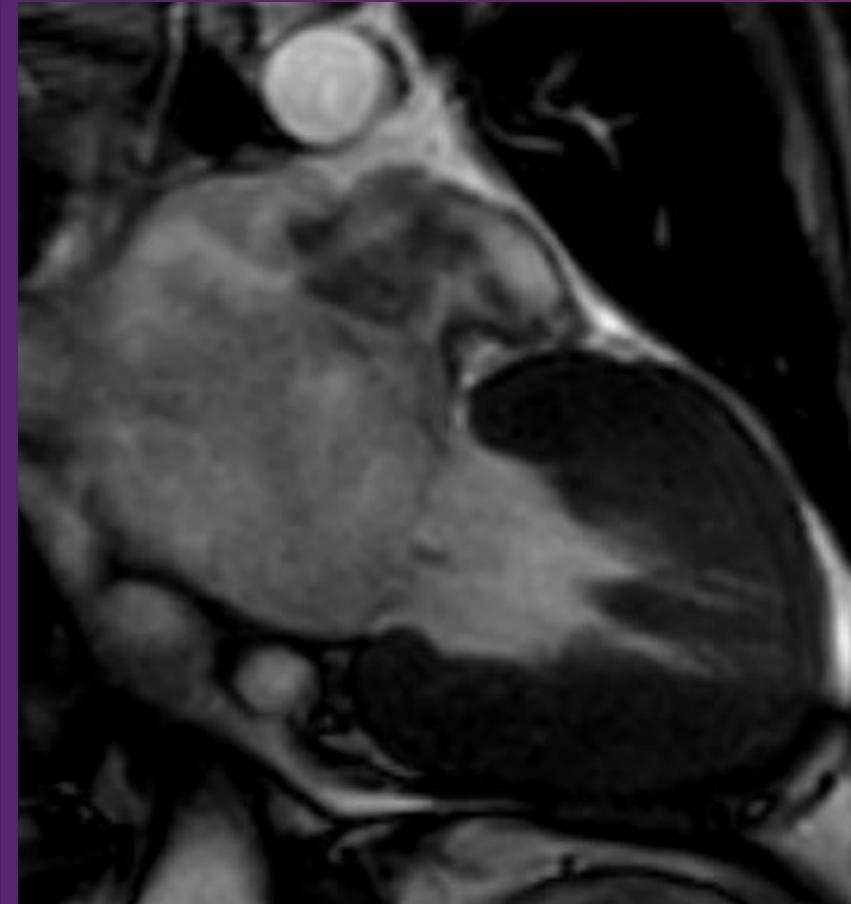
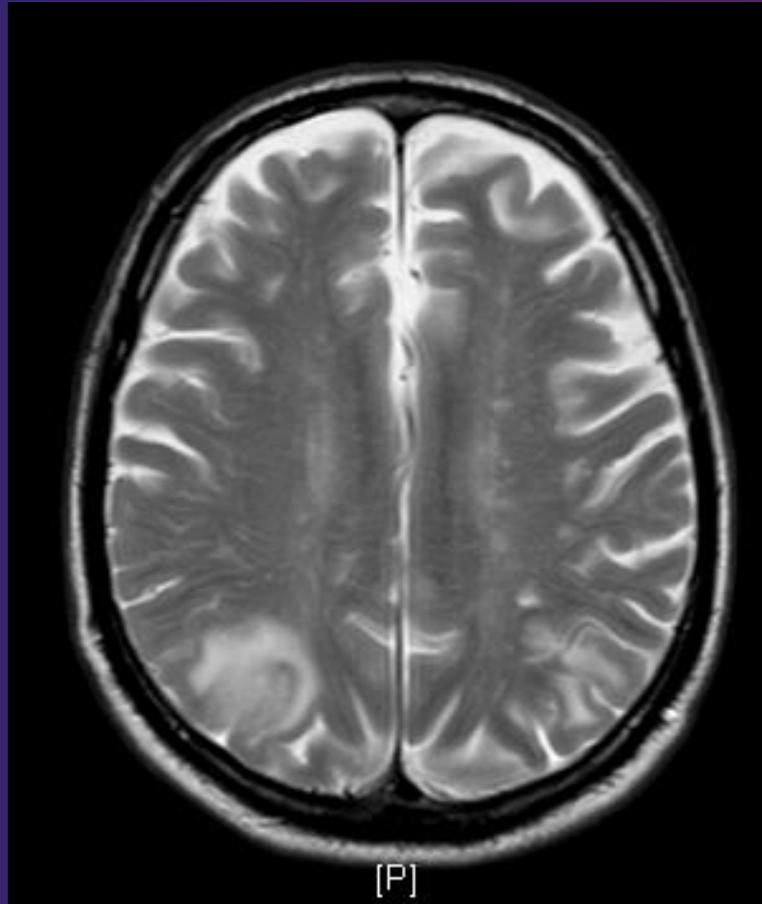
Thrombus location

- Approximately 25% of embolic events in afib are associated with atrial thrombi
- Rheumatic atrial fibrillation
 - Thrombus in LA appendage: 57%
- Non-rheumatic atrial fibrillation
 - Thrombus in LA appendage: 91%

Study	N	LA Appendage	LA chamber
TEE	317	66	1
TEE	233	34	1
Autopsy	506	35	12
TEE	52	2	2
TEE	48	12	1
TEE + surgery	171	8	3
TEE (SPAF 3)	359	19	1
TEE	272	19	0
TEE	60	6	0
Total	1288	201	21

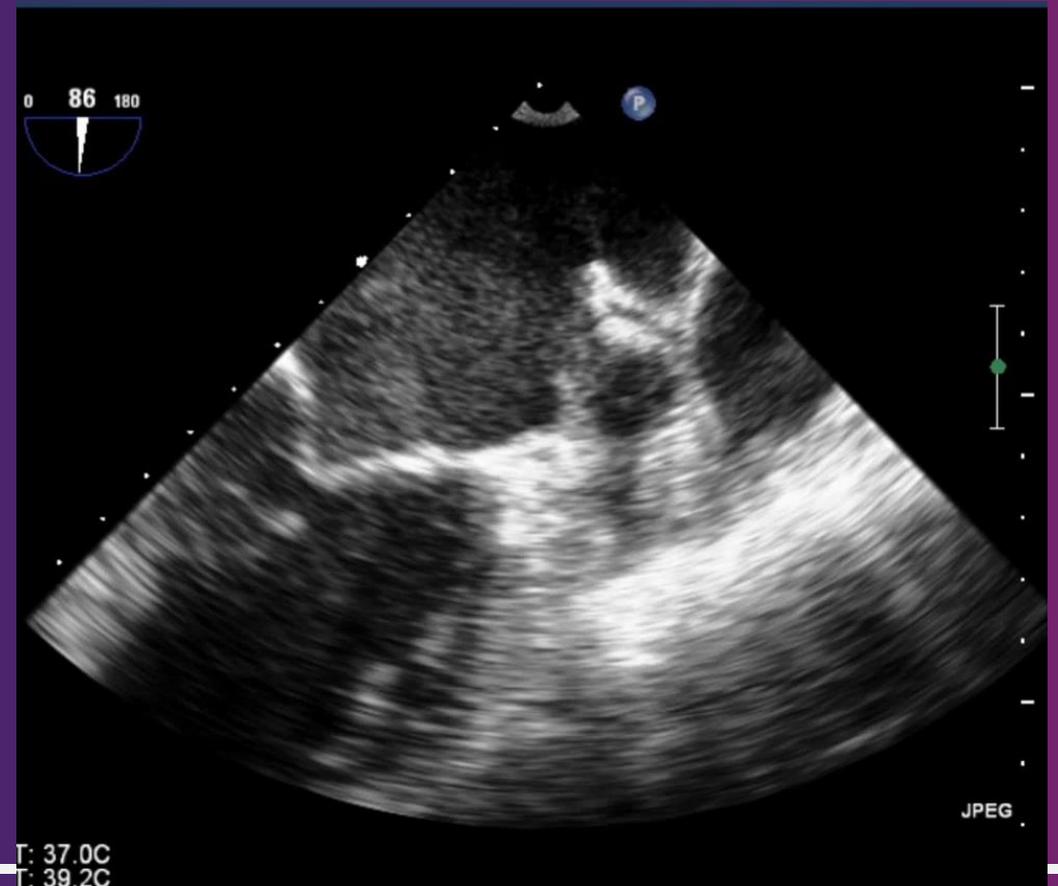
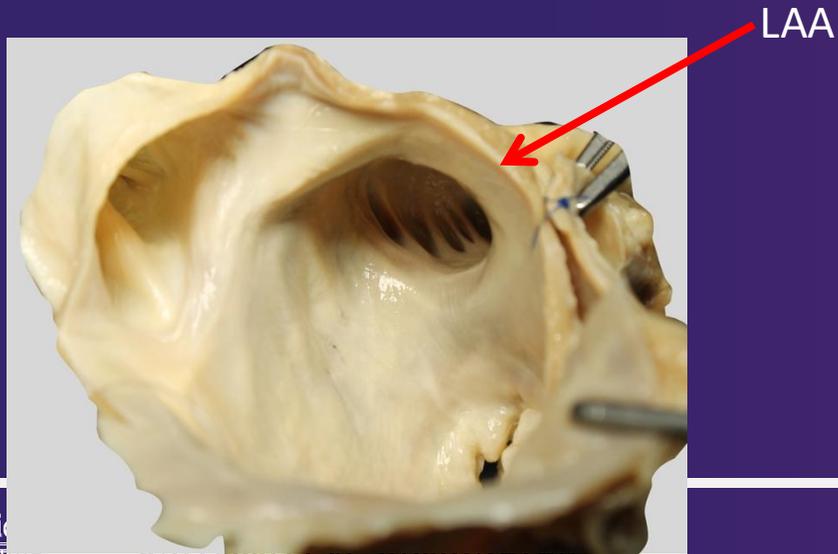
70 year old with stroke

- HTN
- CAD/PVD
- Amyloidosis
- Renal Insufficiency
- Myocardial Infarction
 - LV dysfunction EF 45%
- Atrial fibrillation



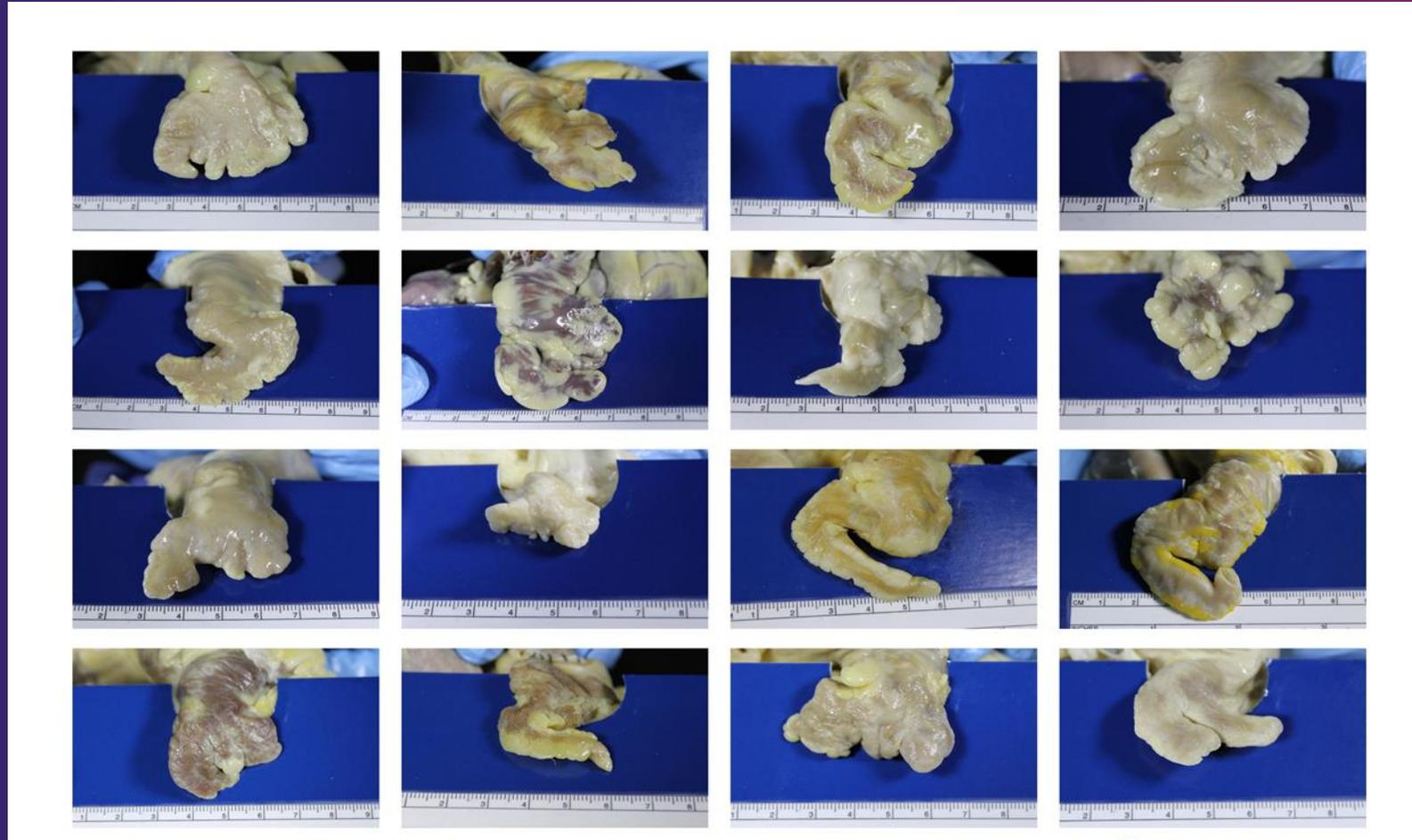
Mechanisms of Stroke with Atrial Fibrillation

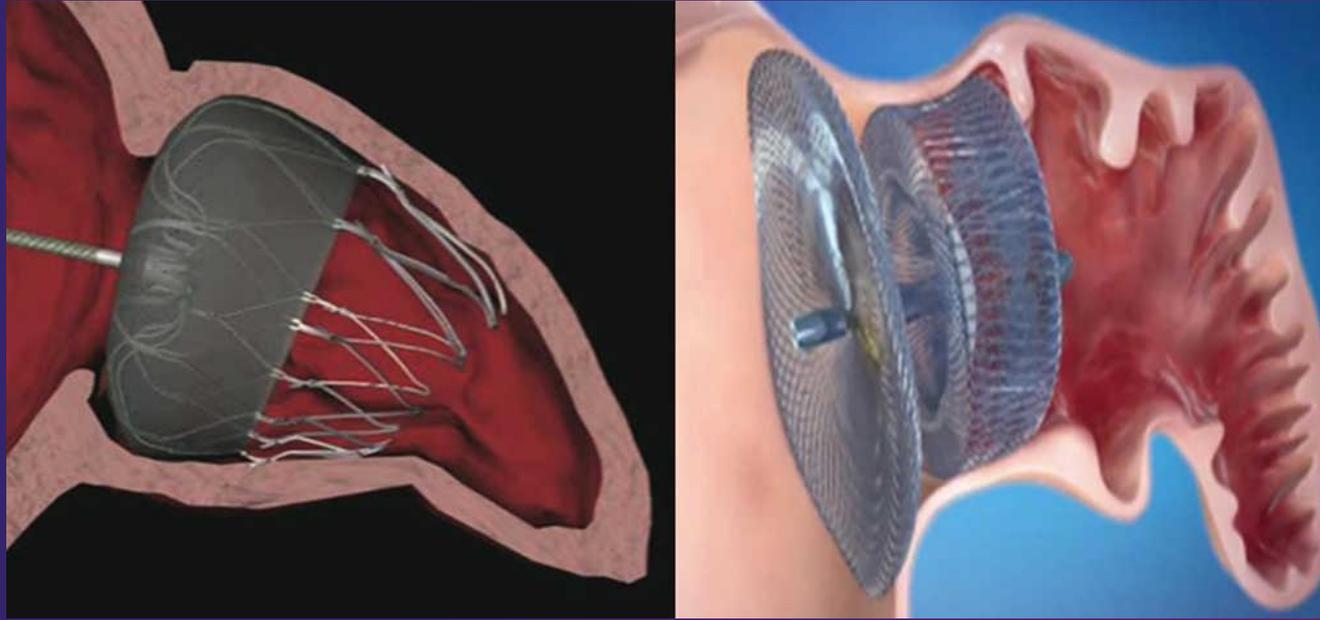
- Stasis of blood
 - Spontaneous echo contrast
 - Increased thrombus with larger left atria
- Left atrial appendage anatomy



Left atrial appendage anatomy and risk for embolism

- Morphology
 - Number of lobes
 - Shape of lobes
- Volume
- Tribeculation
- Flow velocity

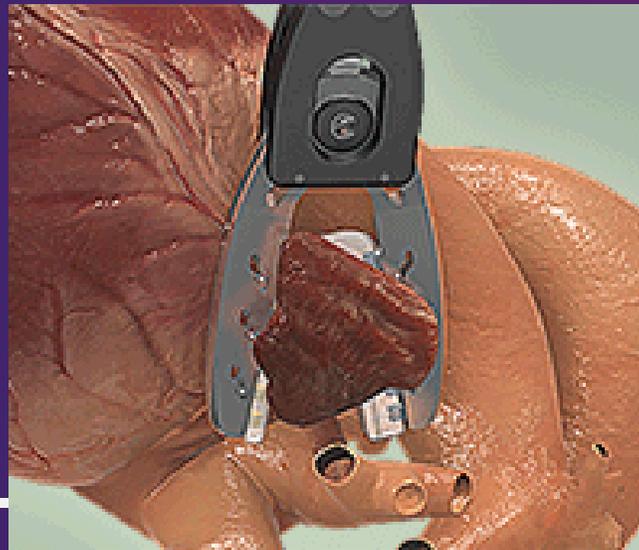




Left Atrial Appendage Closure

Left atrial appendage closure

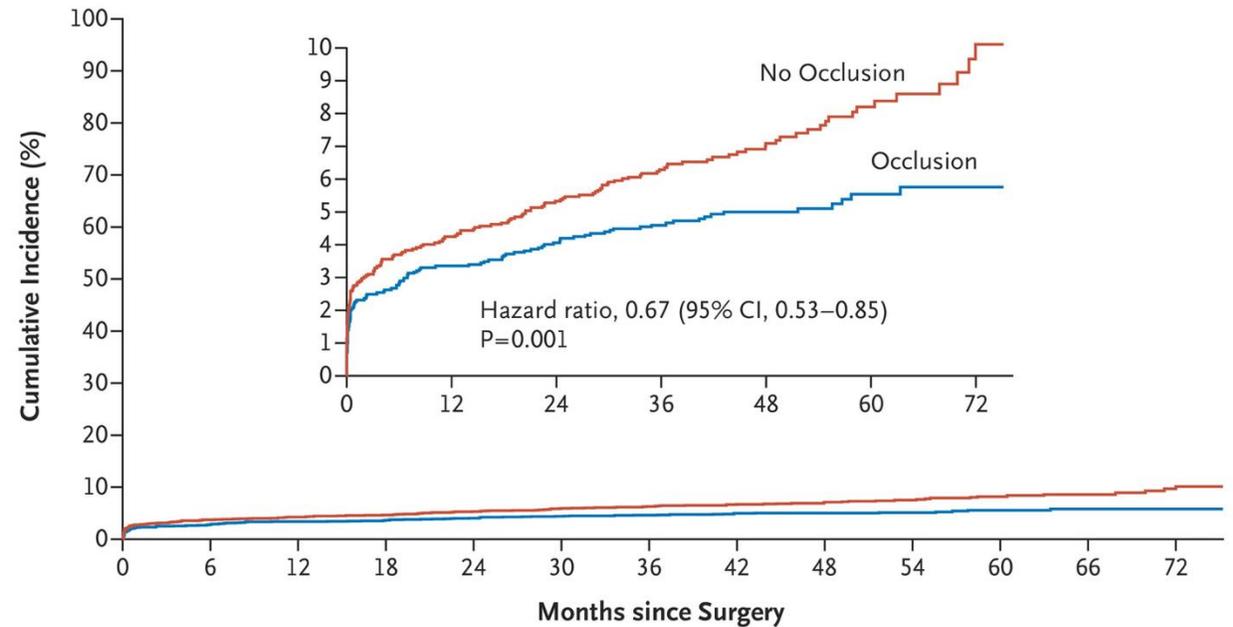
- Atricure, Tiger Paw



Cardiac Surgery and LAAO

- LAAOS III Study
- 4,811 patients with afib undergoing unrelated cardiac surgery randomized to LAAO or control
- Increase in bypass time 5 min
- Closure devices, cut and sew, or staples
- Anticoagulation at provider discretion (75-83% at 3 yrs)

Stroke or Arterial Embolism



No. at Risk

No Occlusion	2391	2134	2081	2030	1981	1897	1607	1291	1016	751	540	348	205
Occlusion	2379	2163	2105	2059	2020	1948	1642	1322	1046	781	550	349	199

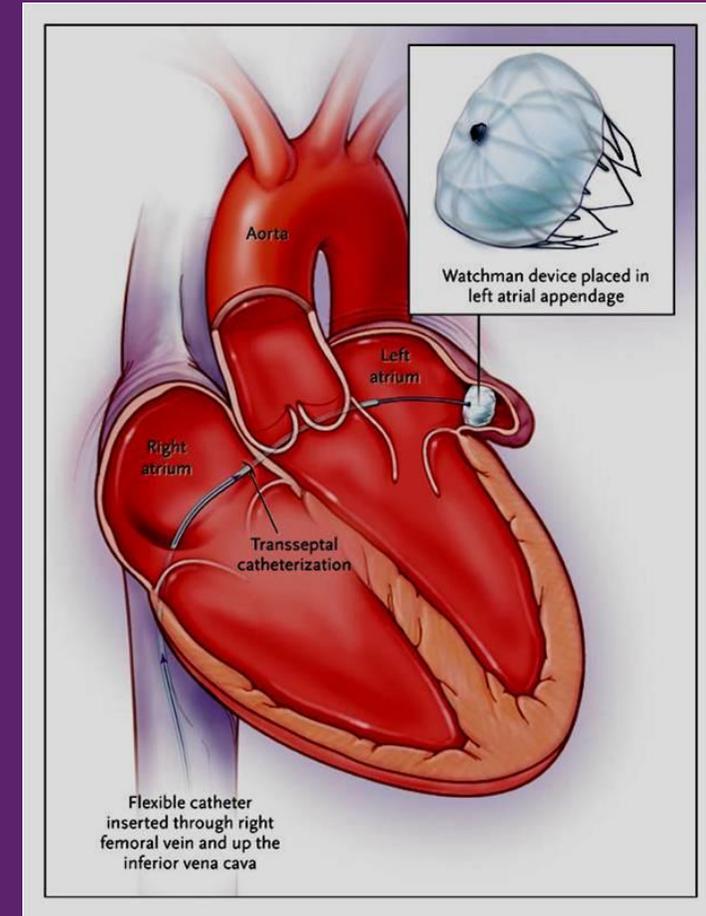
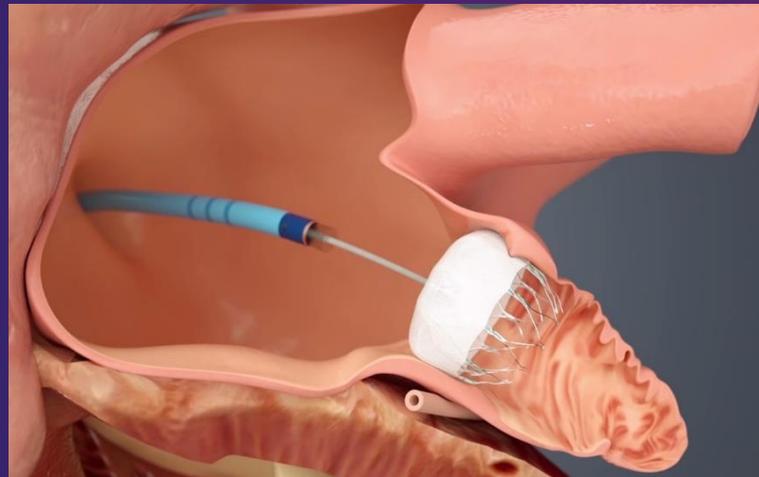
Watchman LAA closure device

160 Micron Membrane

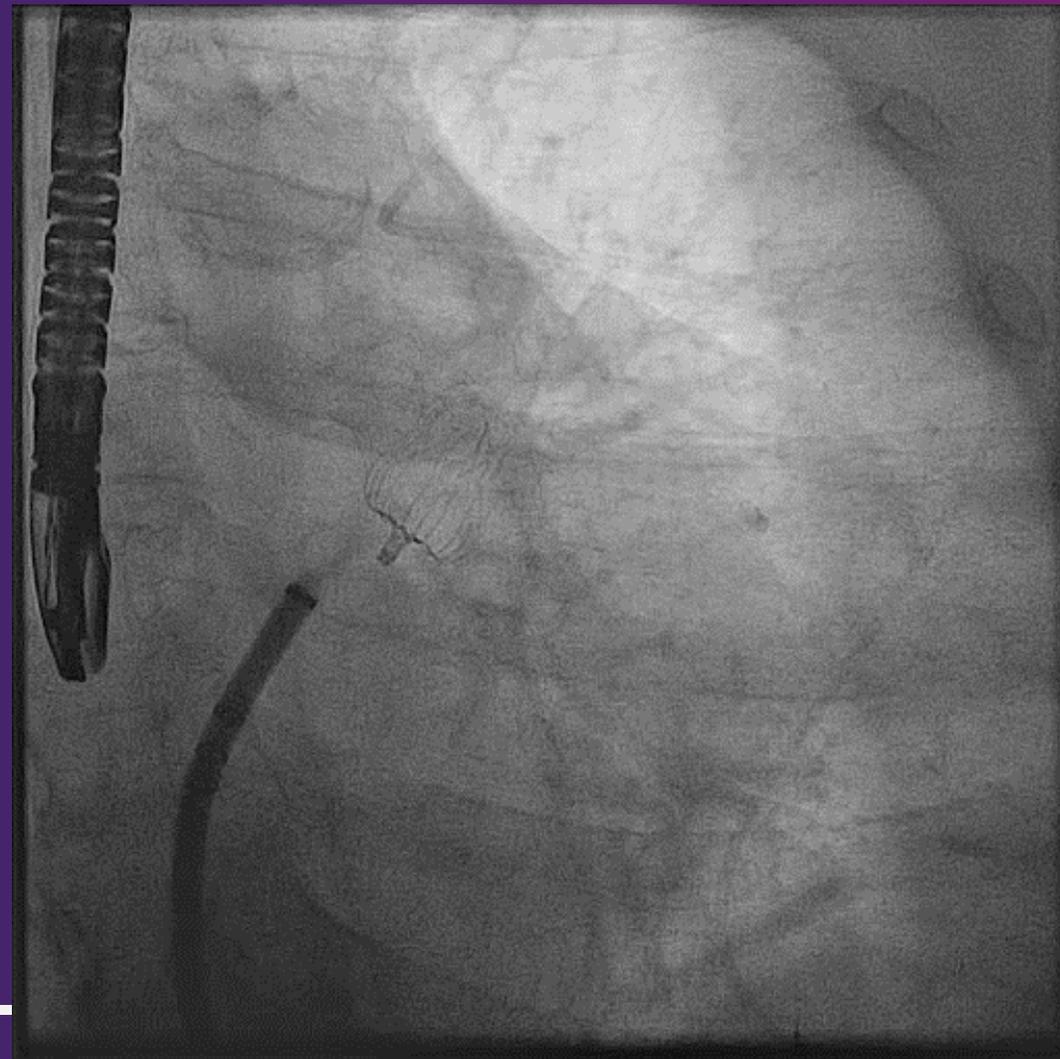
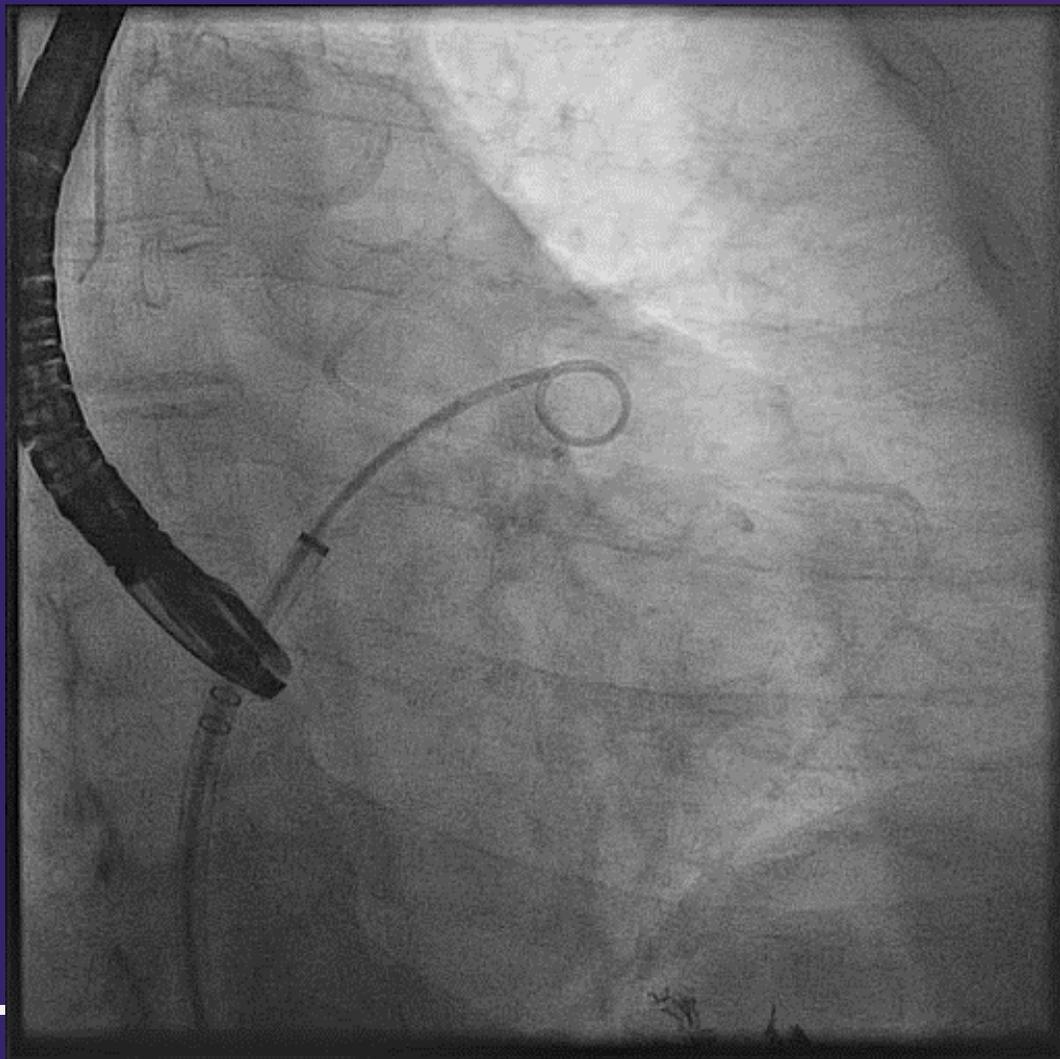


Nitinol frame with Anchors

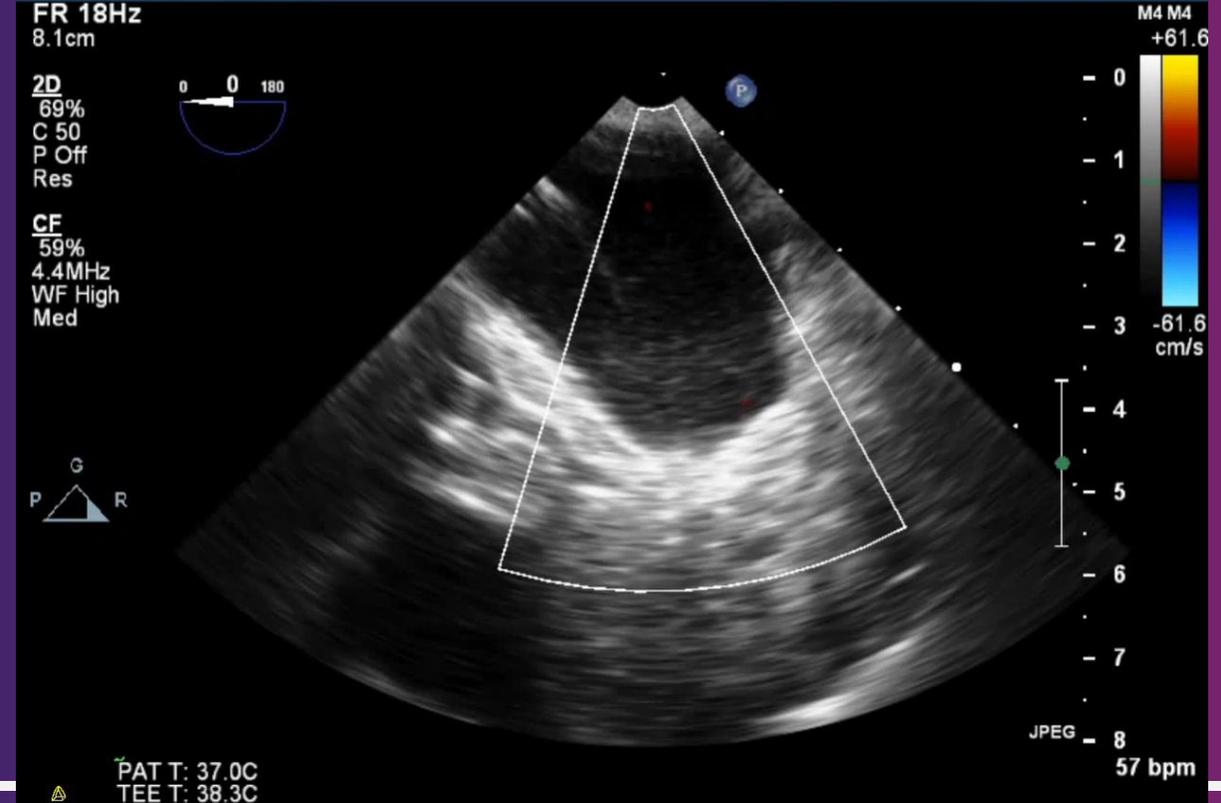
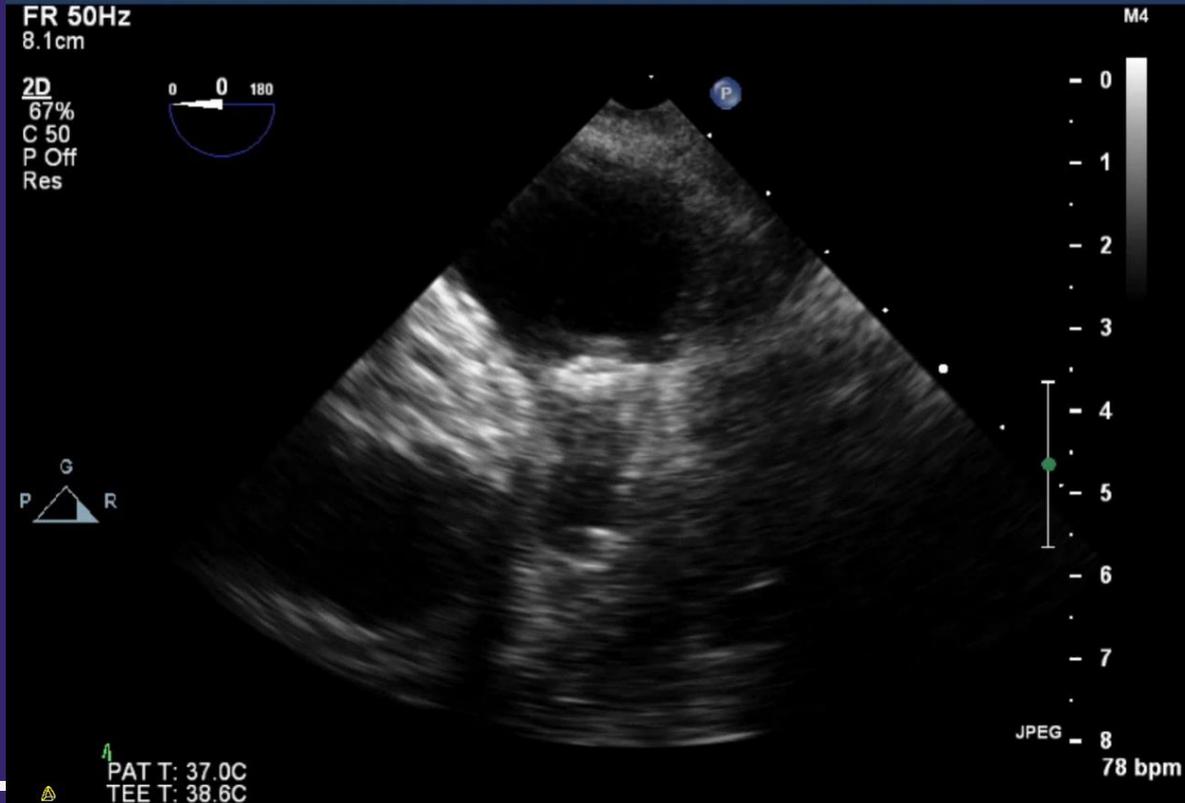
- 60 min procedure
- Moderate Sedation
- Overnight hospitalization?



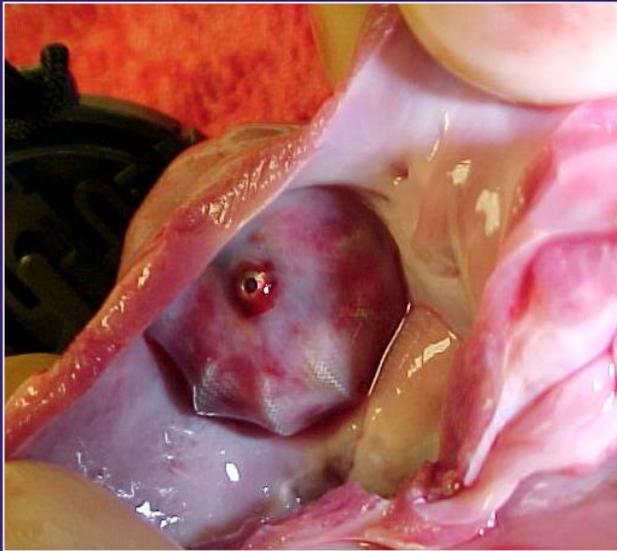
Left Atrial Appendage Closure



Left Atrial Appendage Closure



Left Atrial Appendage Closure



Canine model
30 day



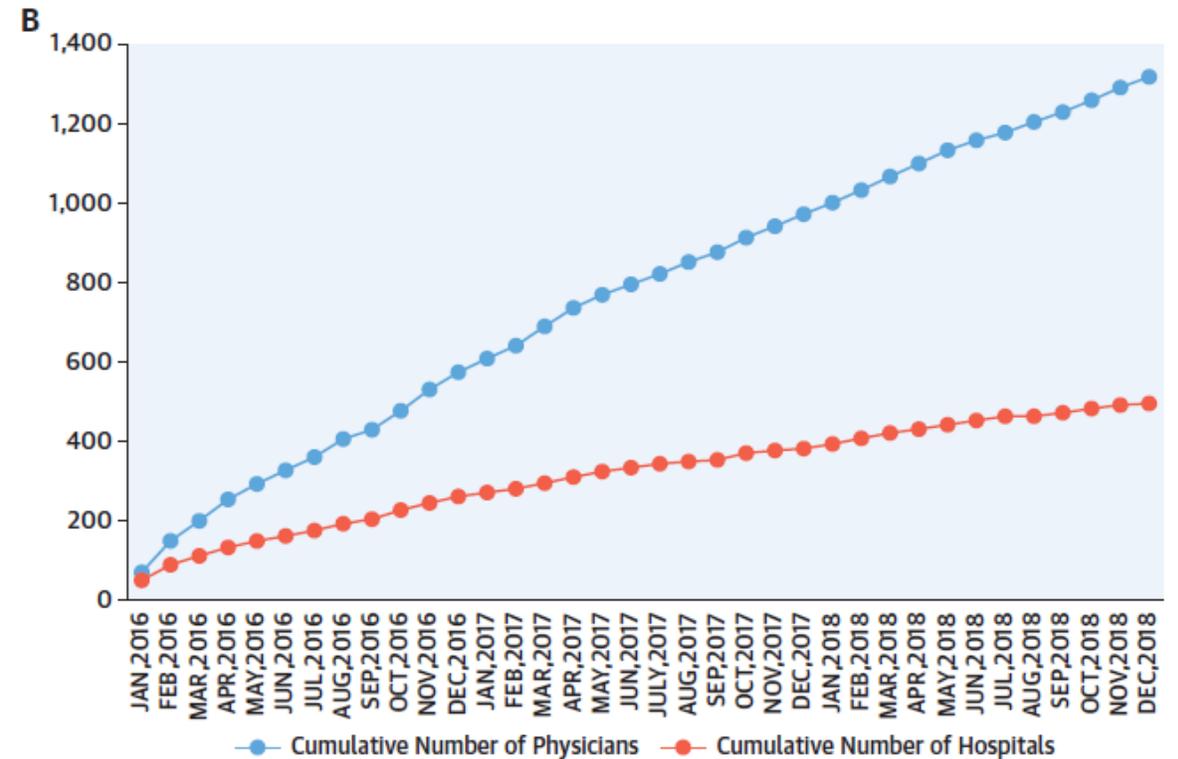
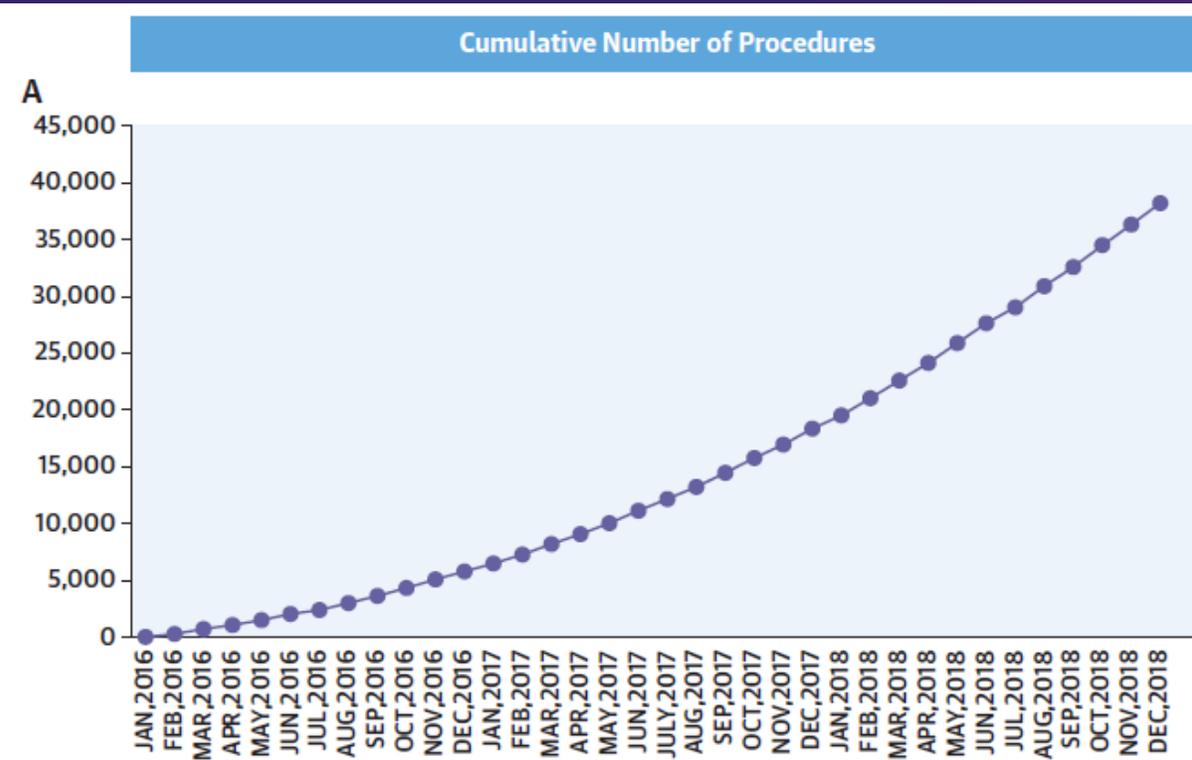
Canine model
45 day



Human pathology - 9 months
(non-device related death)

NCDR LAAO Registry

- 38,158 procedures performed (2016-2018)



Patient Characteristics (NCDR)

38,158 Patients Undergoing LAAO 2016-2018

Characteristic	
HAS-BLED	3.0 (SD 1.1)
Hemorrhagic Stroke	7.3%
Other Prior Bleeding	69.4%
• Intracranial	11.9%
• Epistaxis	6.4%
• Gastrointestinal	41.8%
• Other	14.9%
Fall risk	39.5%
Coagulopathy	0.9%

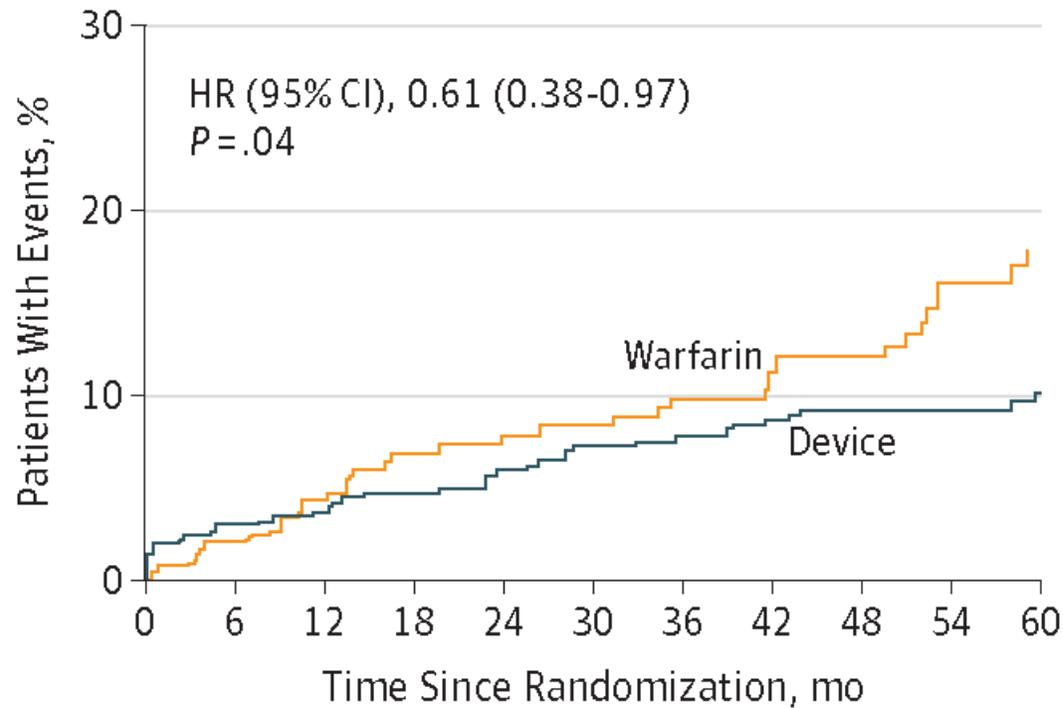
Clinical Studies

- Randomized (LAAC v. Medical Therapy)
 - PROTECT-AF/PREVAIL
 - PRAGUE 17
 - OPTION
 - CLOSURE AF
 - LAAOS III
- Ongoing
 - CHAMPION AF (LAAC v. DOACs)
 - CATALYST (LAAC v. DOACs in lower risk stroke patients)
 - LAAOS IV (Surgical LAAC v. DOACs)
 - ELAPSE (LAAC in patients with breakthrough strokes on DOACs)

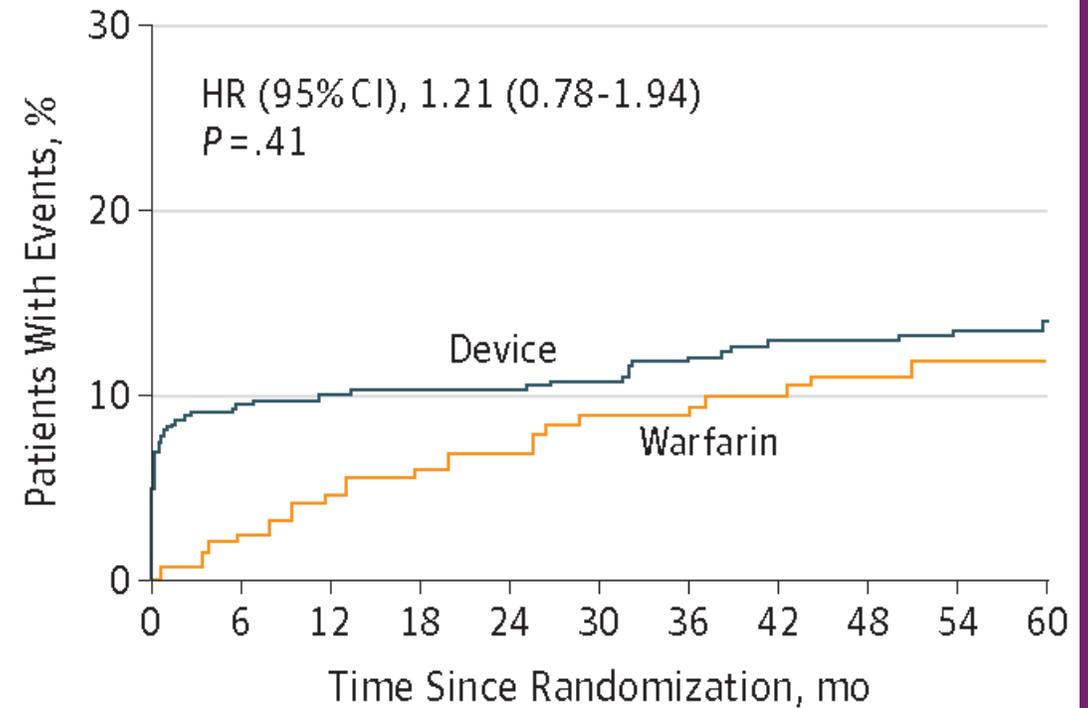
Left atrial appendage closure PROTECT AF: 4-year results

- 707 patients randomized 2:1 LAAC (Watchman) vs. Warfarin 2:1
- Endpoint: Stroke, embolism, death

A Primary efficacy end point



B Primary safety end point

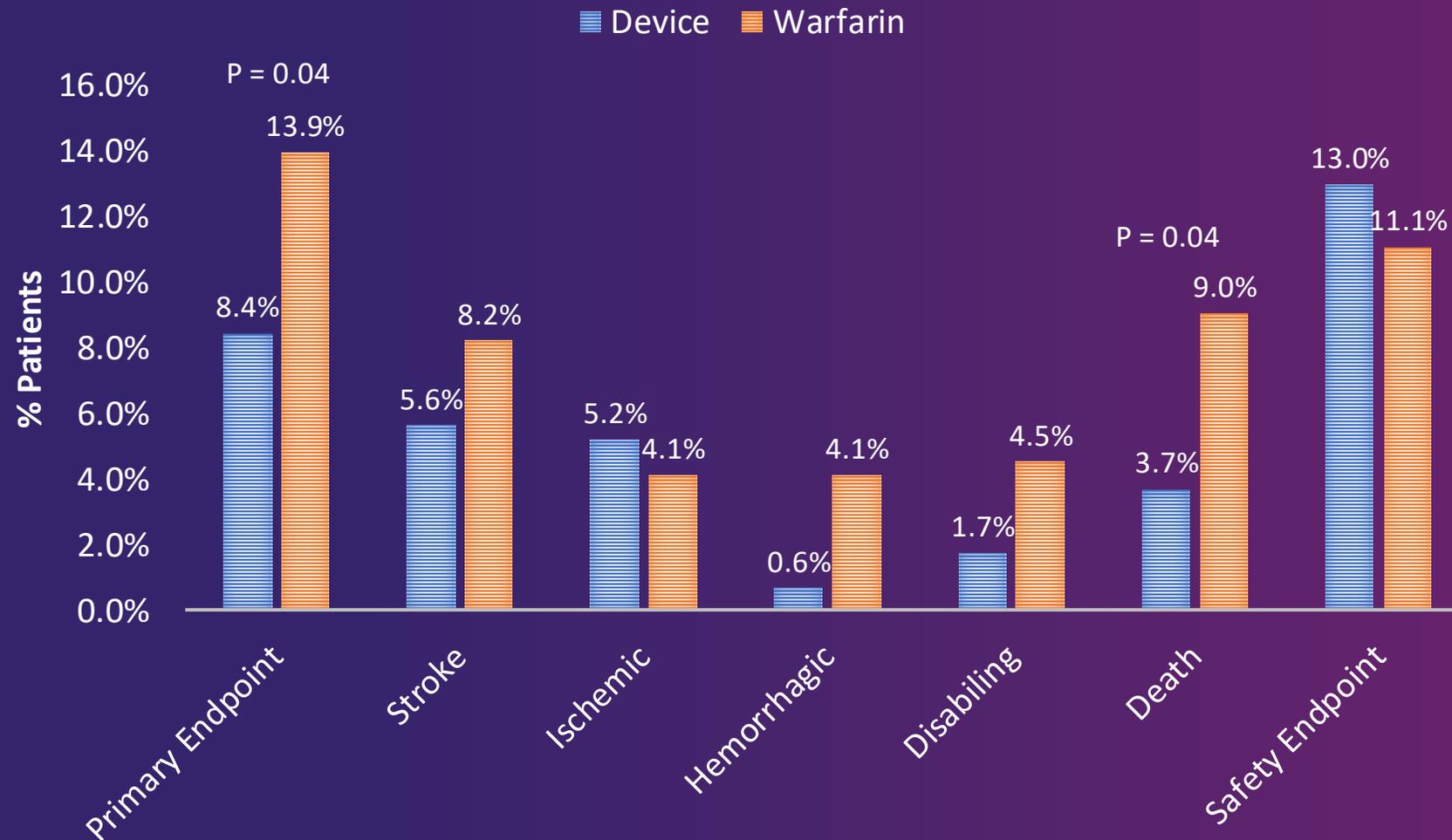


No. of patients

Device	463	398	382	370	360	345	337	327	317	285	196
Warfarin	244	230	218	210	200	188	173	159	147	121	87

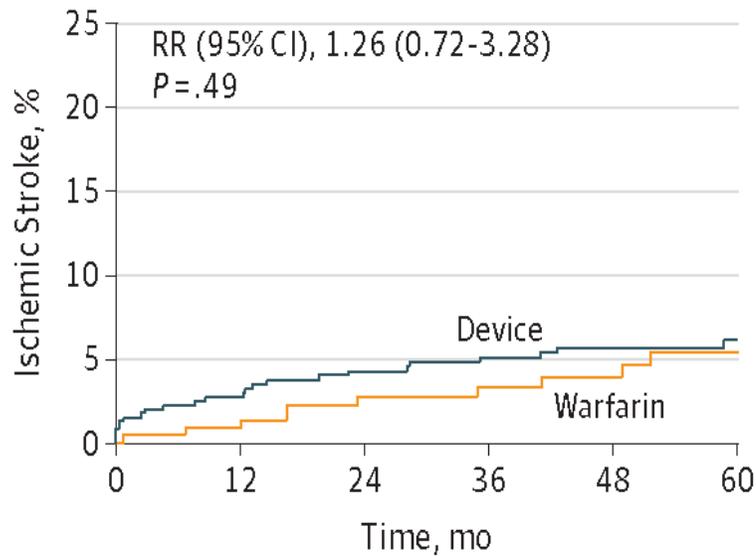
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Warfarin	244	228	214	207	195	183	169	153	139	117	86

Left atrial appendage closure PROTECT AF: 4-year results

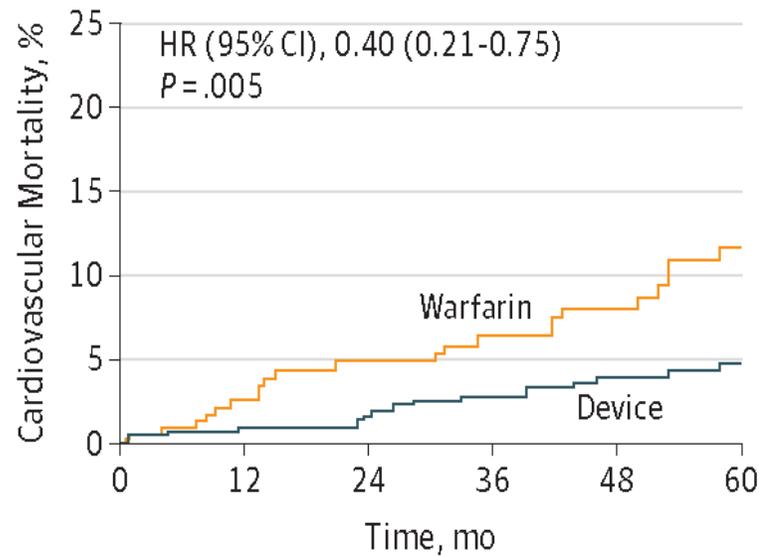


Left atrial appendage closure PROTECT AF: 4-year results

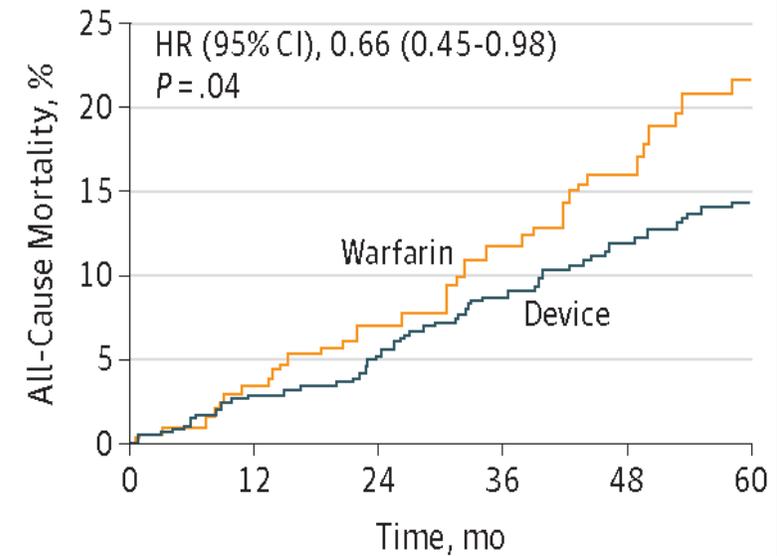
A Ischemic stroke



B Cardiovascular mortality



C All-cause mortality



No. of patients

Device	463	382	360	336	314	156
Warfarin	244	220	200	172	144	64

463	389	372	351	328	165
244	222	204	176	147	69

463	389	373	352	330	202
244	222	204	177	150	92

PROTECT-AF Trial: Mortality

Table 3. Causes of Mortality by Treatment Group

	Device Group, No. (%) (n = 463)	Warfarin Group, No. (%) (n = 244)	P Value
Cardiovascular	17 (3.7)	22 (9.0)	.005
Heart failure	3 (0.6)	2 (0.8)	>.99
Hemorrhagic stroke	2 (0.4)	8 (3.3)	.004
Ischemic stroke	1 (0.2)	1 (0.4)	>.99
Myocardial infarction	2 (0.4)	2 (0.8)	.61
Sudden cardiac death	4 (0.9)	4 (1.6)	.46
Unexplained/other	5 (1.0)	5 (2.0)	.23
Cancer	2 (0.4)	2 (0.8)	.66
Pulmonary	1 (0.2)	1 (0.4)	.11
Neurologic	1 (0.2)	1 (0.4)	.99
Multisystem organ failure	6 (1.3)	1 (0.4)	.43
Other	9 (1.9)	5 (2.0)	>.99
Renal failure	3 (0.6)	3 (1.2)	.42
Sepsis	2 (0.4)	1 (0.4)	>.99
Unexplained/other	4 (0.9)	1 (0.4)	.66

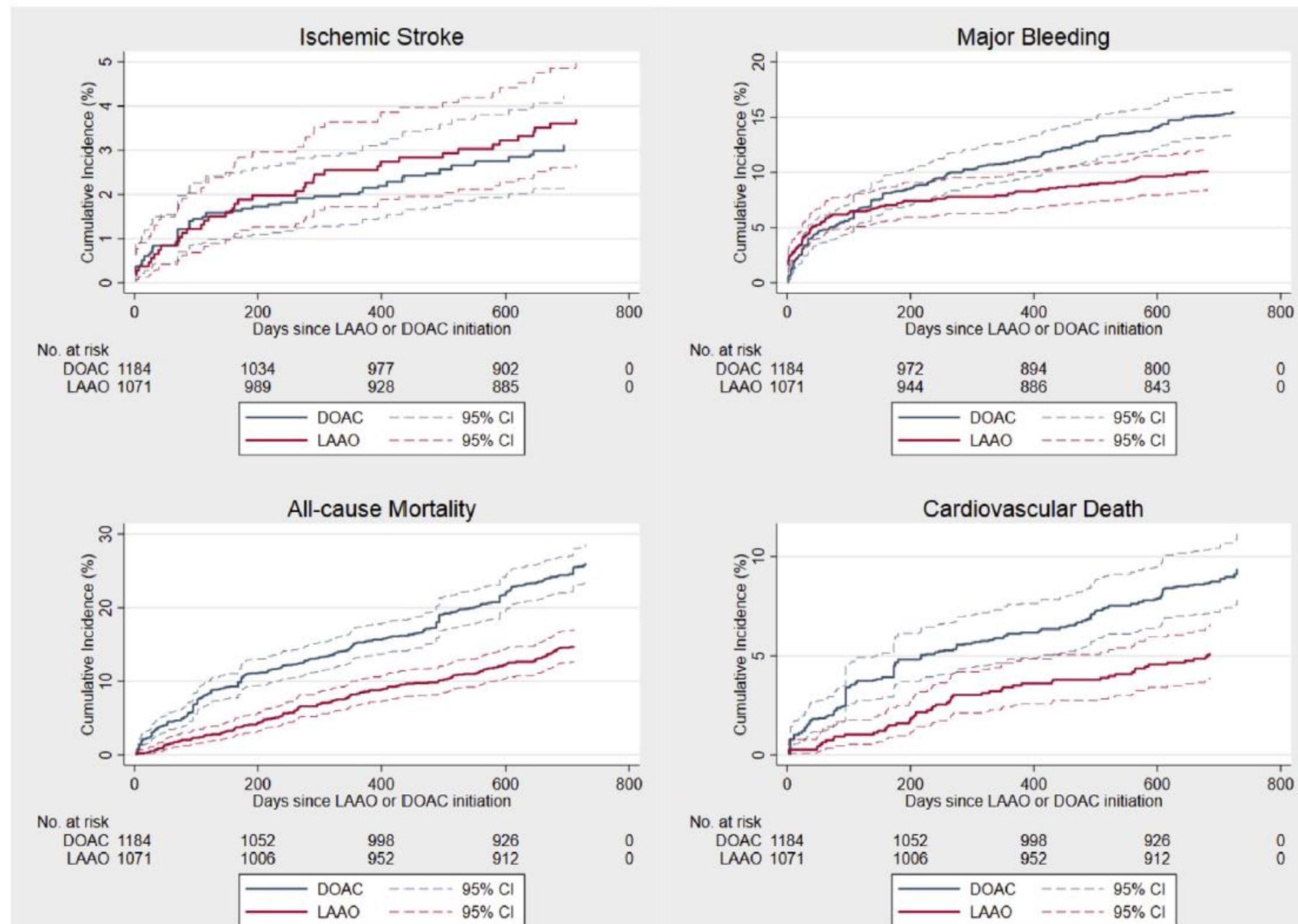
Warfarin is terrible, right?

LAAO v. DOACs

- 1,078 patients with Amulet LAAO
- Propensity matched to 1,184 patients on DOACs
- 60% DOACs discontinued at 2.5 years

Nielsen-Kudsk JACC CI. 2021

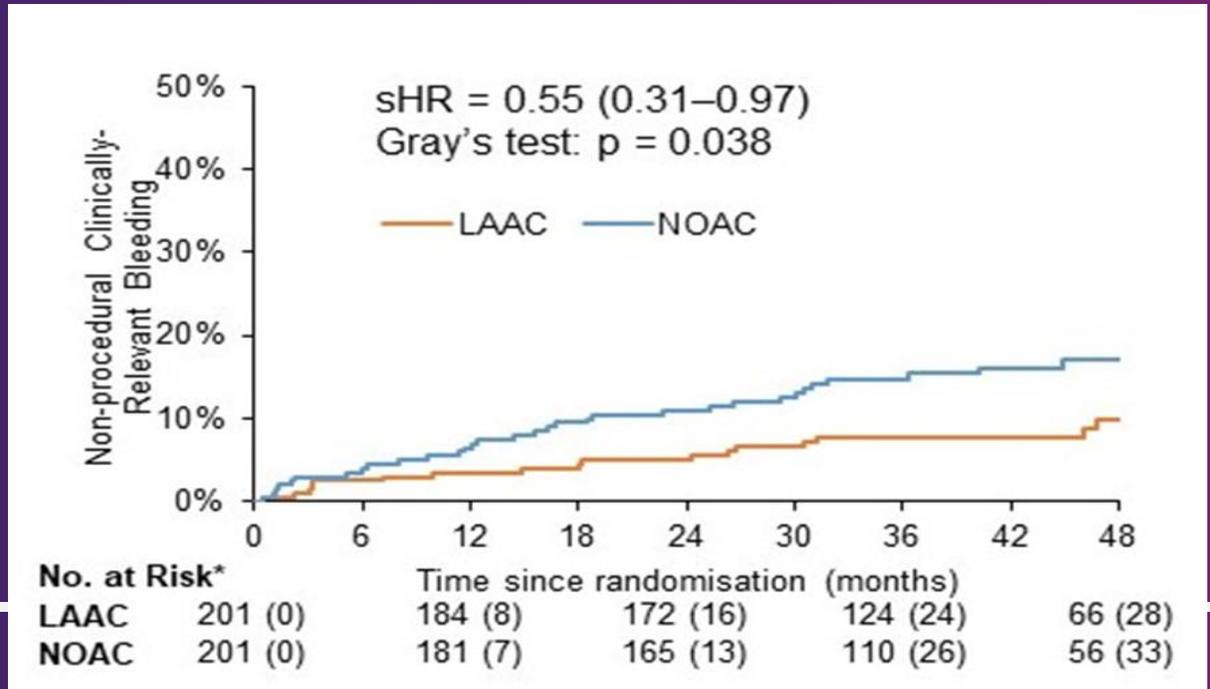
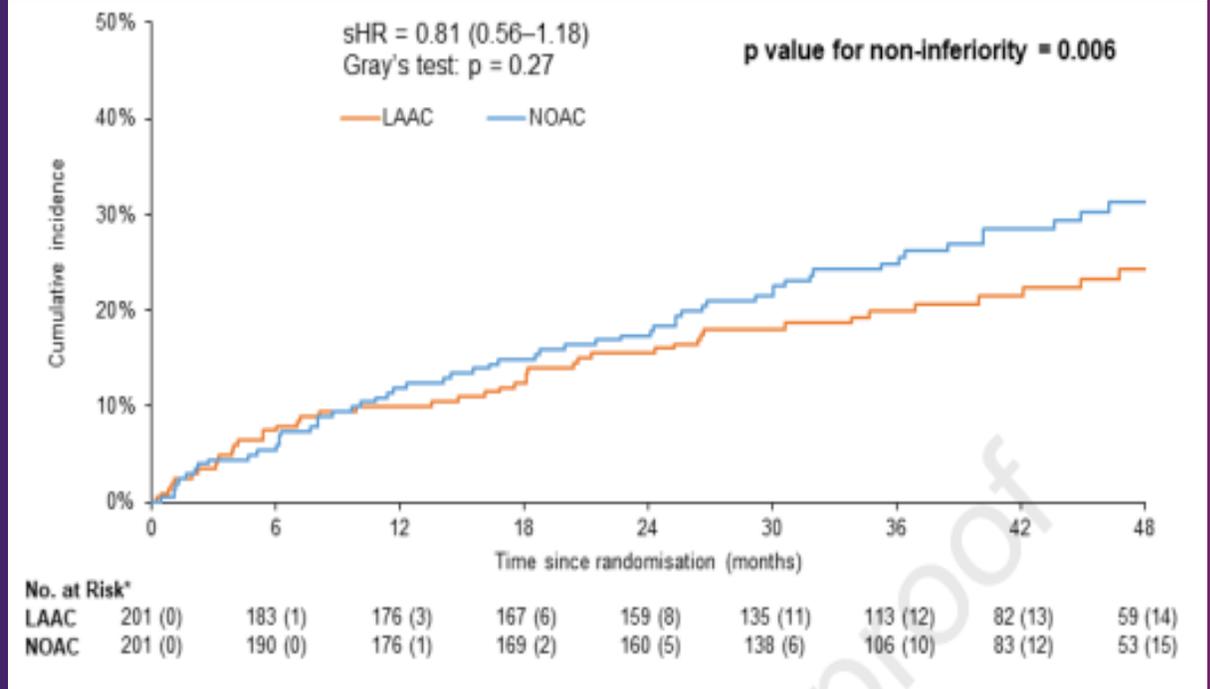
FIGURE 1 Secondary Clinical Outcomes



LAAC v. DOAC: PRAGUE 17

- Randomized open label trial (Watchman or Amulet) v. DOACs
- Post-LAAC (DAPT ~3 months)
- 402 patients
- Composite Endpoint:
 - Stroke/TIA
 - Systemic Embolism
 - Bleeding
 - CV Death
 - Procedural/Device Complications

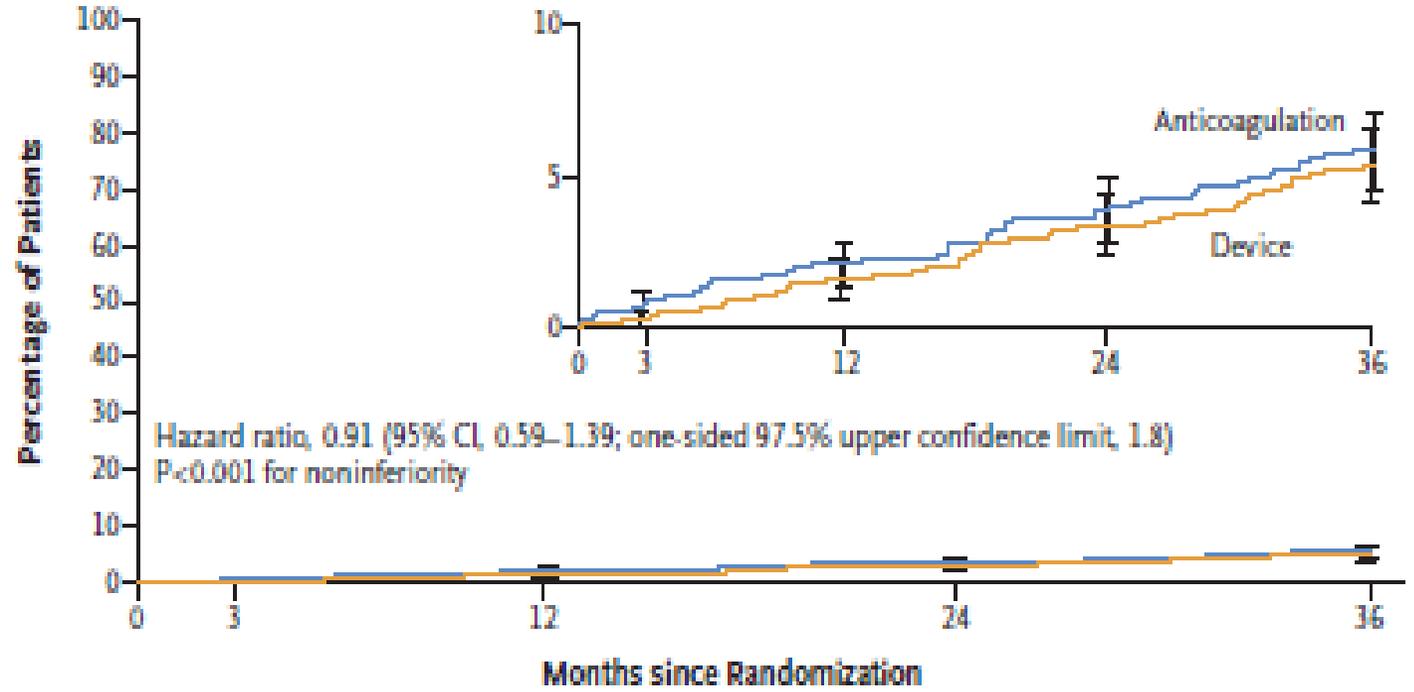
Osmancik P et al. JACC. 2021



OPTION Trial

- 1600 patients undergoing EP catheter ablation for afib
- CHA2DS2VASC ≥ 2 (men) ≥ 3 (women)
- Randomized to LAAC or anticoagulation
 - LAAC—12 mo antiocoag
- Average Age 69
- HAS-BLED 1.2 ± 0.8
- Concomitant 40.8%

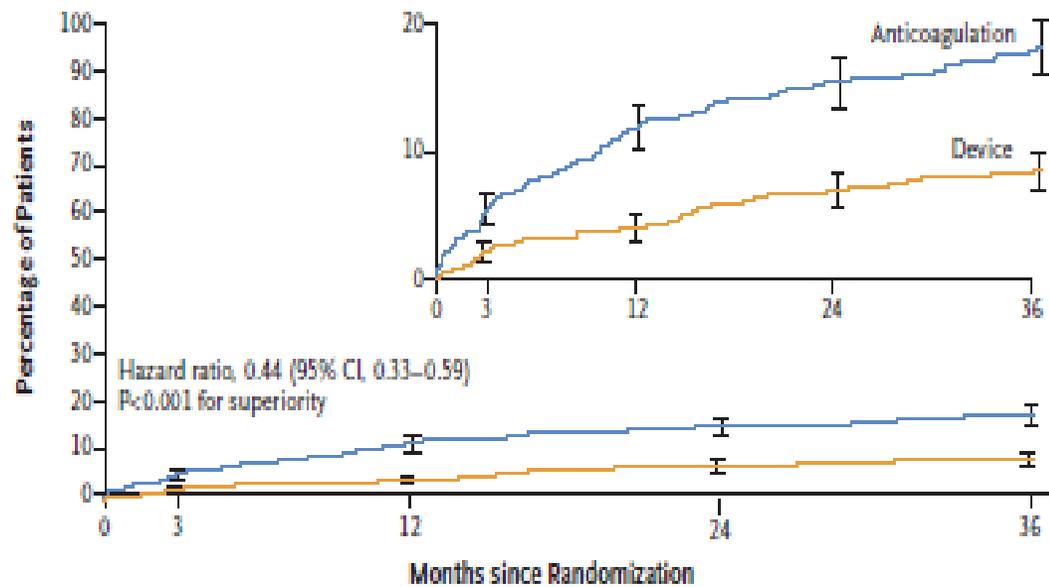
B Composite of Death from Any Cause, Stroke, or Systemic Embolism (primary efficacy end point)



No. at Risk	0	3	12	24	36
Anticoagulation	797	775	754	740	701
Device	803	782	772	757	722

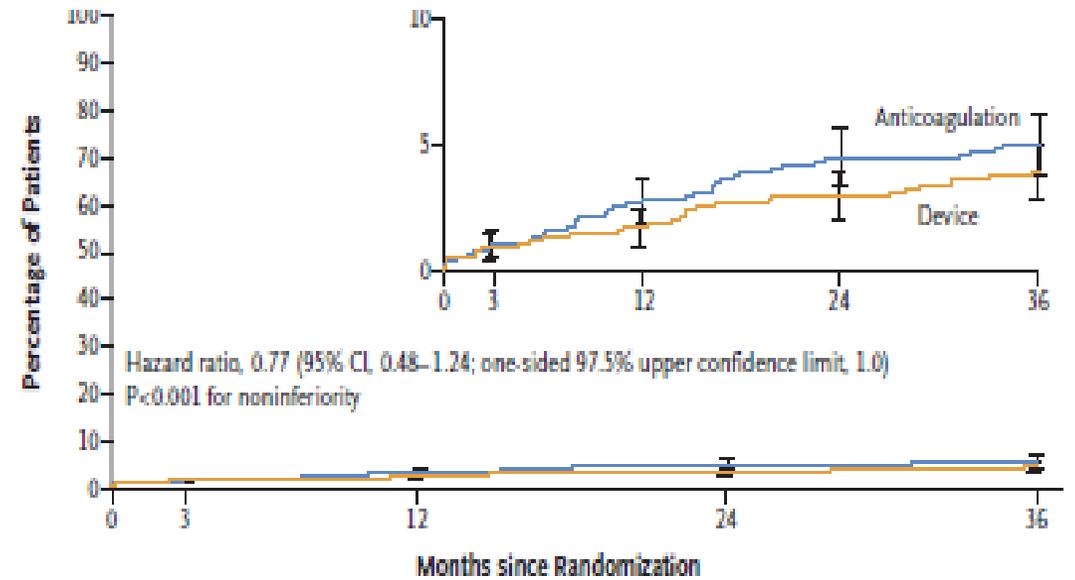
OPTION Trial

Non-Procedure-Related Major Bleeding or Clinically Relevant Nonmajor Bleeding (primary safety endpoint)



No. at Risk	0	3	12	24	36
Anticoagulation	797	753	701	657	598
Device	803	776	749	728	681

Major bleeding (including perioperative)



No. at Risk	0	3	12	24	36
Anticoagulation	797	772	749	726	678
Device	803	778	763	746	708

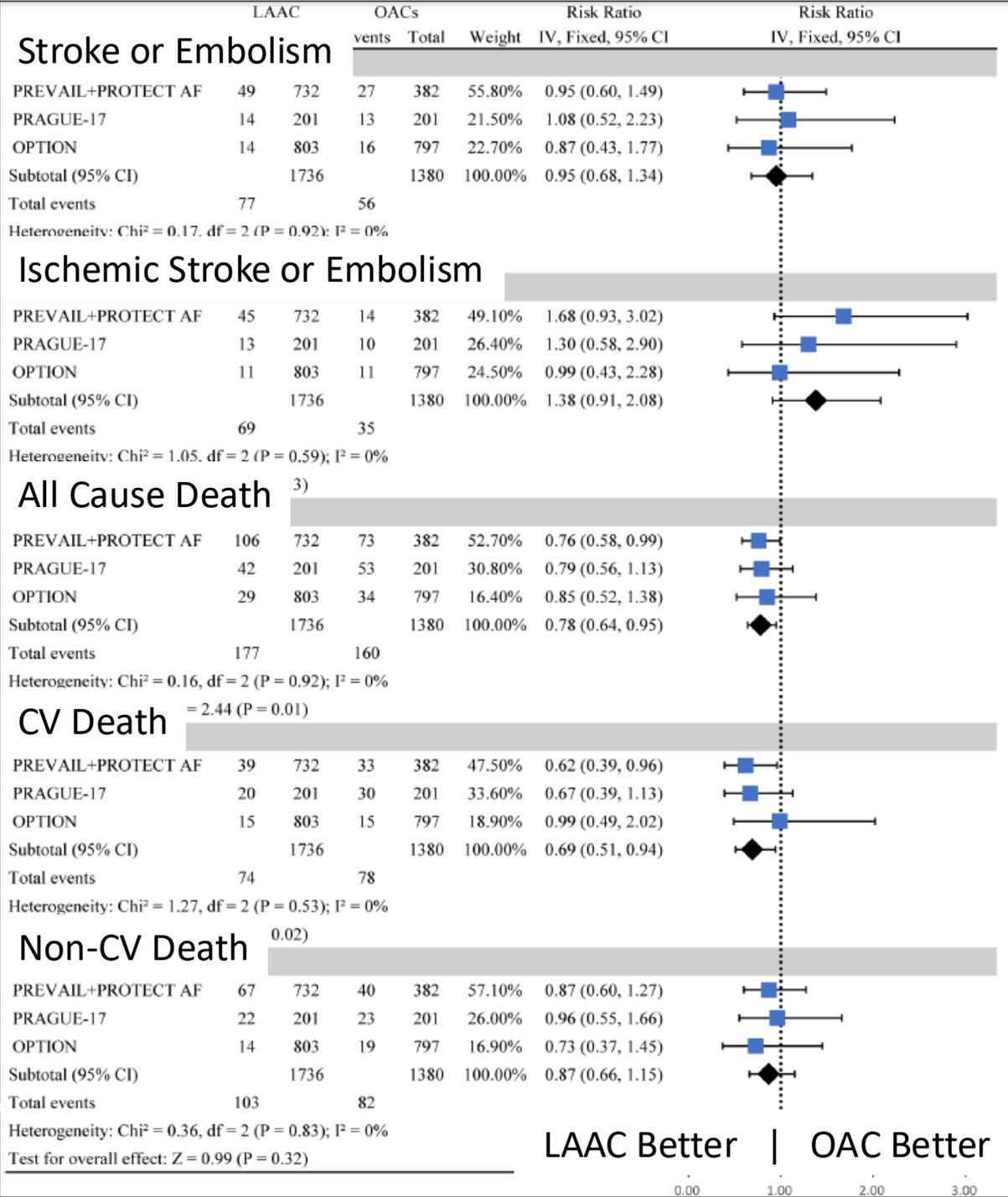
OPTION Trial: LAAC v. DOAC

- Anticoagulation in Control Arm

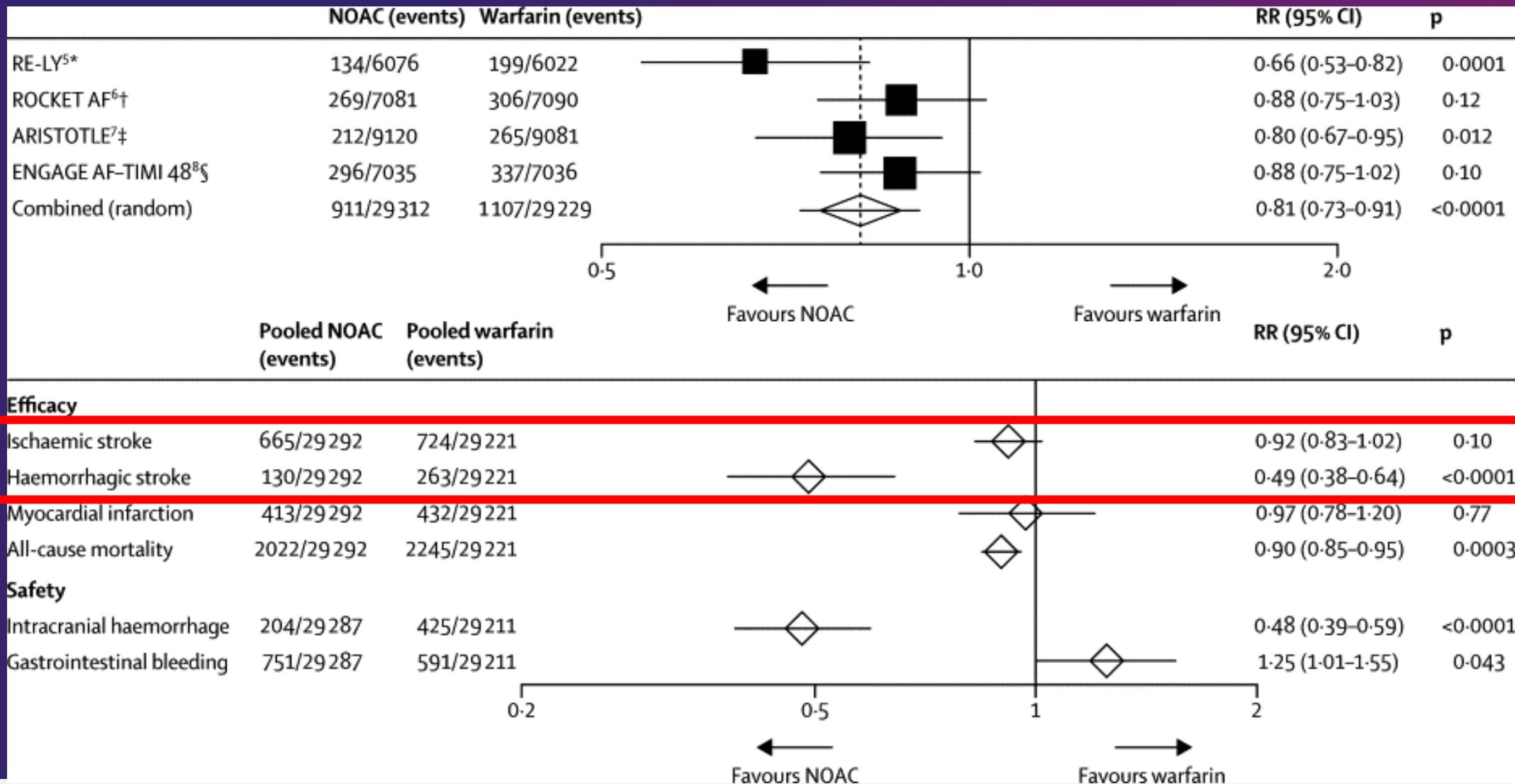
Medication	Percent
Apixaban	59.3%
Rivaroxaban	27.2%
Edoxaban	4.3%
Dabigatran	3.9%
Other DOAC	0.3%
Warfarin	5%

Meta-analysis

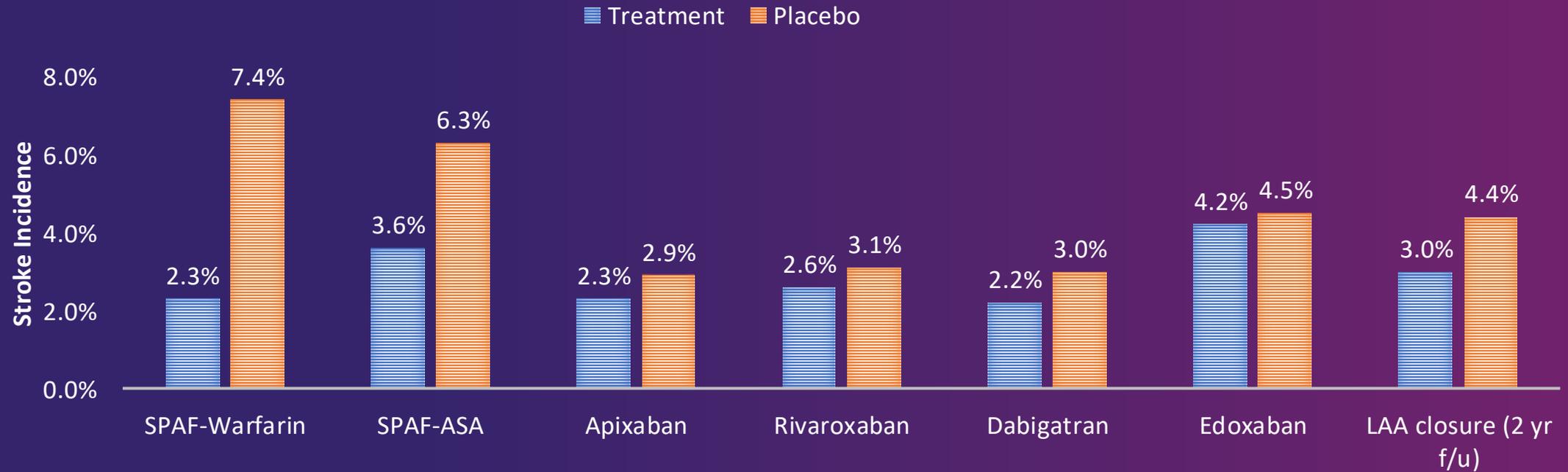
- PROTECT AF-PREVAIL
- PRAGUE 17
- OPTION



DOACs and Warfarin



Anticoagulation and stroke reduction



SPAF Investigators. Circulation. 1996; Patel MR. NEJM. 2011; Granger CB. NEJM. 2011; Giugliano RP. NEJM. 2013.

ACC/AHA/ACCP/HRS 2023 guidelines

- Gastrointestinal, pulmonary, or genitourinary bleeding
- Intracranial hemorrhage
- Recurrent falls with serious bleeding

6.5.1. Percutaneous Approaches to Occlude the LAA

Recommendations for Percutaneous Approaches to Occlude the LAA
Referenced studies that support the recommendations are summarized in the [Online Data Supplement](#).

COR	LOE	Recommendations
2a	B-NR	1. In patients with AF, a moderate to high risk of stroke (CHA ₂ DS ₂ -VASc score ≥ 2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable. ¹⁻⁴
2b	B-R	2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive. ^{1-3,5,6}

Other IIB Recommendations

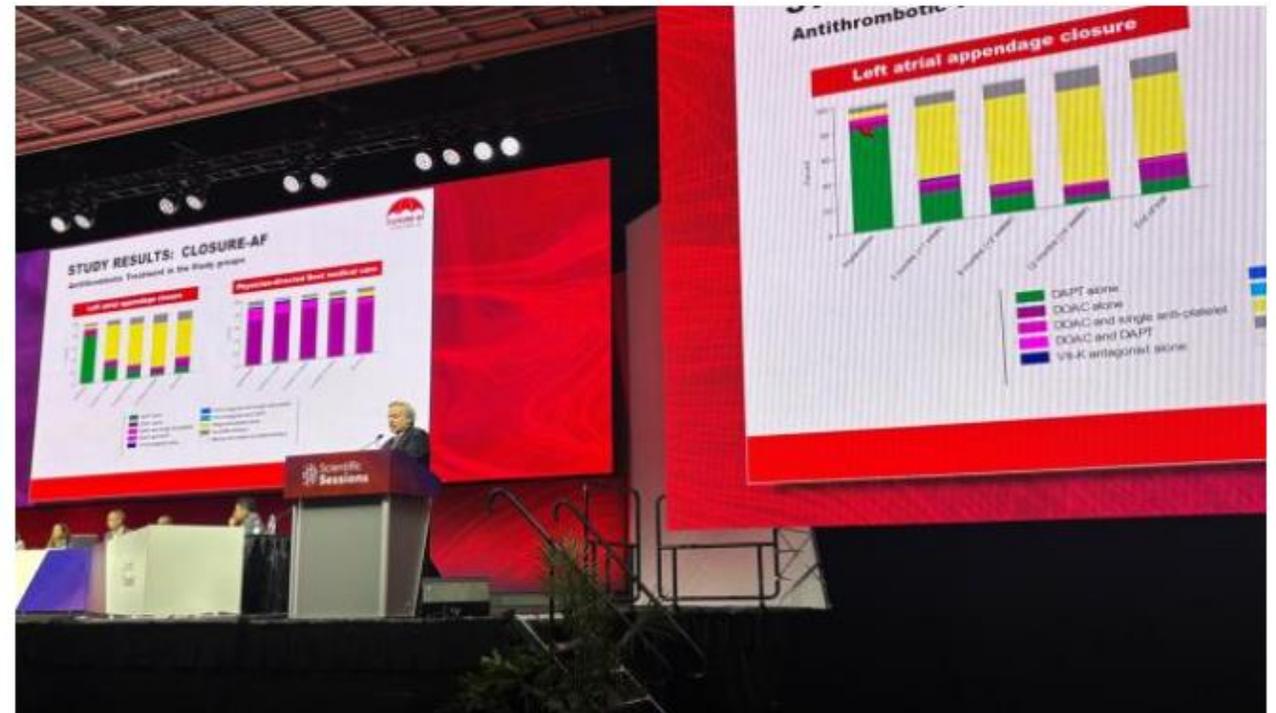
- Beta-blockers or calcium channel blockers for HTN in patients with angina
- Anticoagulation for afib in patients with ESRD
- PCI or CABG for stable coronary artery disease
- Valve Replacement for Asymptomatic Severe Aortic Valve Stenosis

But I just heard
appendage
closure doesn't
work!

LAAO Doesn't Match Medical Therapy for High-risk AF Patients: CLOSURE-AF

The noninferiority trial of patients at risk for both bleeding and stroke, in a surprise turn, found standard care to be superior.

by [Caitlin E. Cox](#) | NOVEMBER 09, 2025



CLOSURE AF: LAAC in high bleeding risk patients

- 912 patients randomized to anticoagulation (DOAC) v. LAAC
- Median Age 79 years
- Watchman/Amulet + 3 mo DAPT
- 3-year median follow-up
- Many events in the peri-procedural period (bleeding and deaths)
- Higher cardiovascular death
- More bleeding events in the LAAC group

**Non-valvular atrial fibrillation
+ CHA₂DS₂Vasc-Score ≥2
+ Increased bleeding risk defined as**

- HASBLED-Score ≥3 or
- Hemorrhagic/bleeding complication fulfilling BARC type 3A-C or History of intracranial bleeding/intraspinal bleed/intraocular bleed compromising vision and/or gastrointestinal tract/genitourinary tract or respiratory tract bleeding, with persistently increased risk of bleeding, e.g. the cause of bleeding cannot be successfully eliminated.
- Chronic kidney disease with eGFR 15-29 ml/min/1.73 m²

	Events/patient-years (Incidence per 100 patient-years)		Adjusted HR (95% CI)	P value Non-inferiority
	LAA closure	Best Medical Care		
Primary outcome				
Composite of stroke, systemic embolism, cardiovascular/unexplained death or major bleeding (BARC≥3)	16.83%	13.27%	1.28 (1.01, 1.62)	0.44

RESULTS: Over a median follow-up of 3 years, LAA closure was associated with a higher risk of the combined primary outcome compared to physician-directed best medical care.

PROTECT AF: Safety Endpoints

- 74% of safety events were periprocedural (within 7 days)

Table 4. Individual Components of the Primary Safety End Point by Treatment Group

	Device Group, No. (%) (n = 463)			Warfarin Group, No. (%) (n = 244)
	Total Events	Early Events ^a	Late Events	Events
Serious pericardial effusion	22 (4.8)	22 (4.8)	0	
Major bleeding	22 (4.8)	3 (0.6)	19 (4.1)	18 (7.4)
Procedure-related ischemic stroke	6 (1.3)	5 (1.1)	1 (0.2)	
Device embolization	3 (0.6)	3 (0.6)	0	
Hemorrhagic stroke	3 (0.6)	0	3 (0.6)	9 (3.7)
Other	4 (0.9)	4 (0.9)	0	

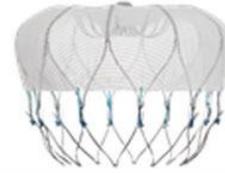
244 228 214 207 195 183 169 153 139 117 86

PINNACLE FLX Trial

- Single arm study 400 patients
- Implant Success 98.8%
- Procedural safety endpoint: 0.5% stroke
 - No Tamponade, death, embolization
- Peri-device flow 0-5 mm
 - Implant 7.4%
 - 45 days 17.2%
 - 12 mo 10.5%
 - None were > 5 mm
- DRT at 12-months
 - 7 patients (1.8%)
 - 2 died (carotid dissection, limb ischemia)

Kar S. Circulation. 2021

First generation
percutaneous left
atrial appendage
closure device



Large size range
and shorter device



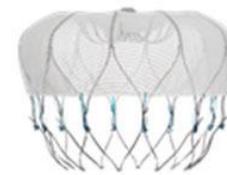
Next generation
percutaneous left
atrial appendage
closure device



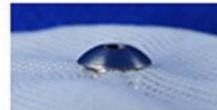
Distal tines folded back



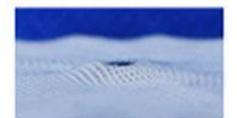
Greater number of struts



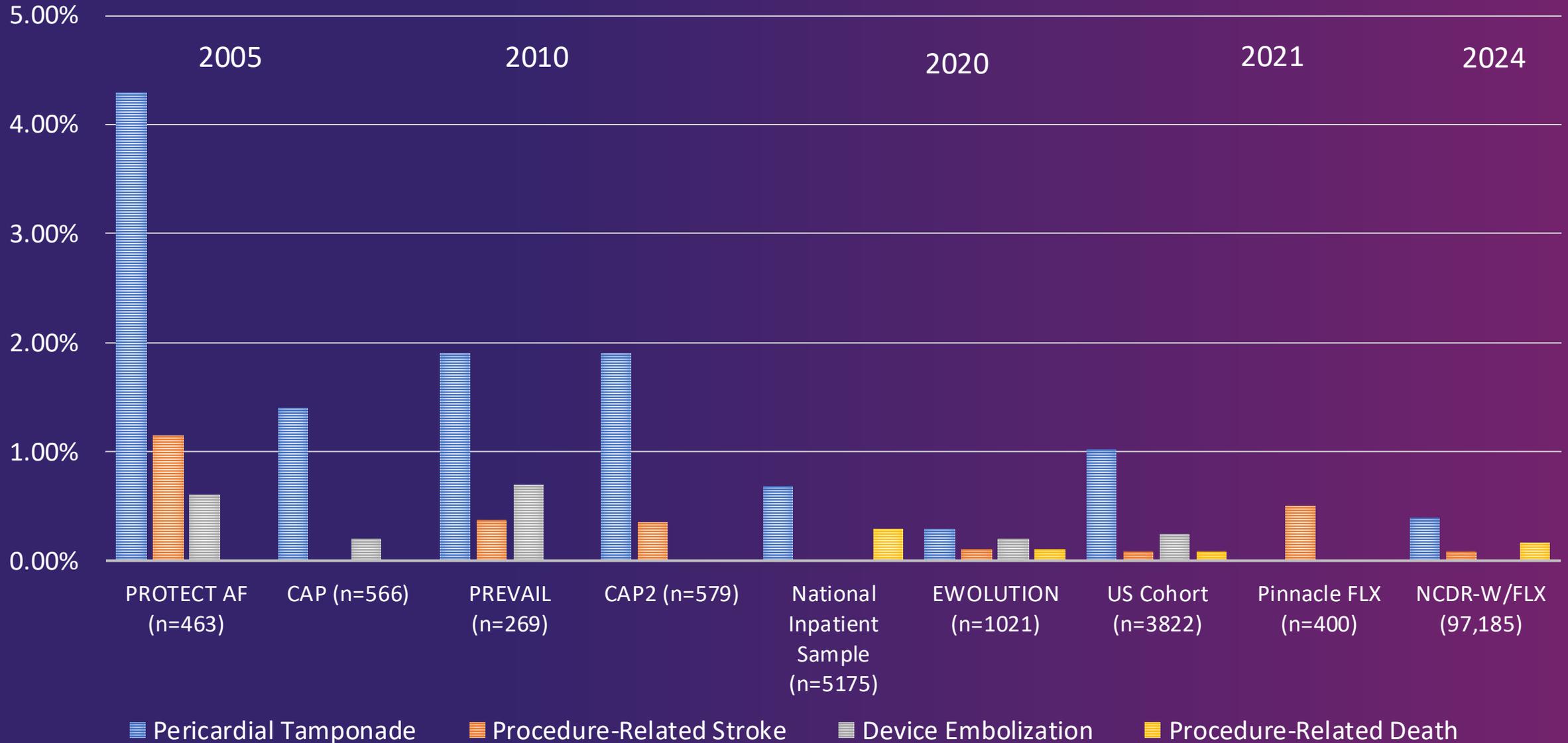
Dual-row
anchors



Reduced metal
exposure

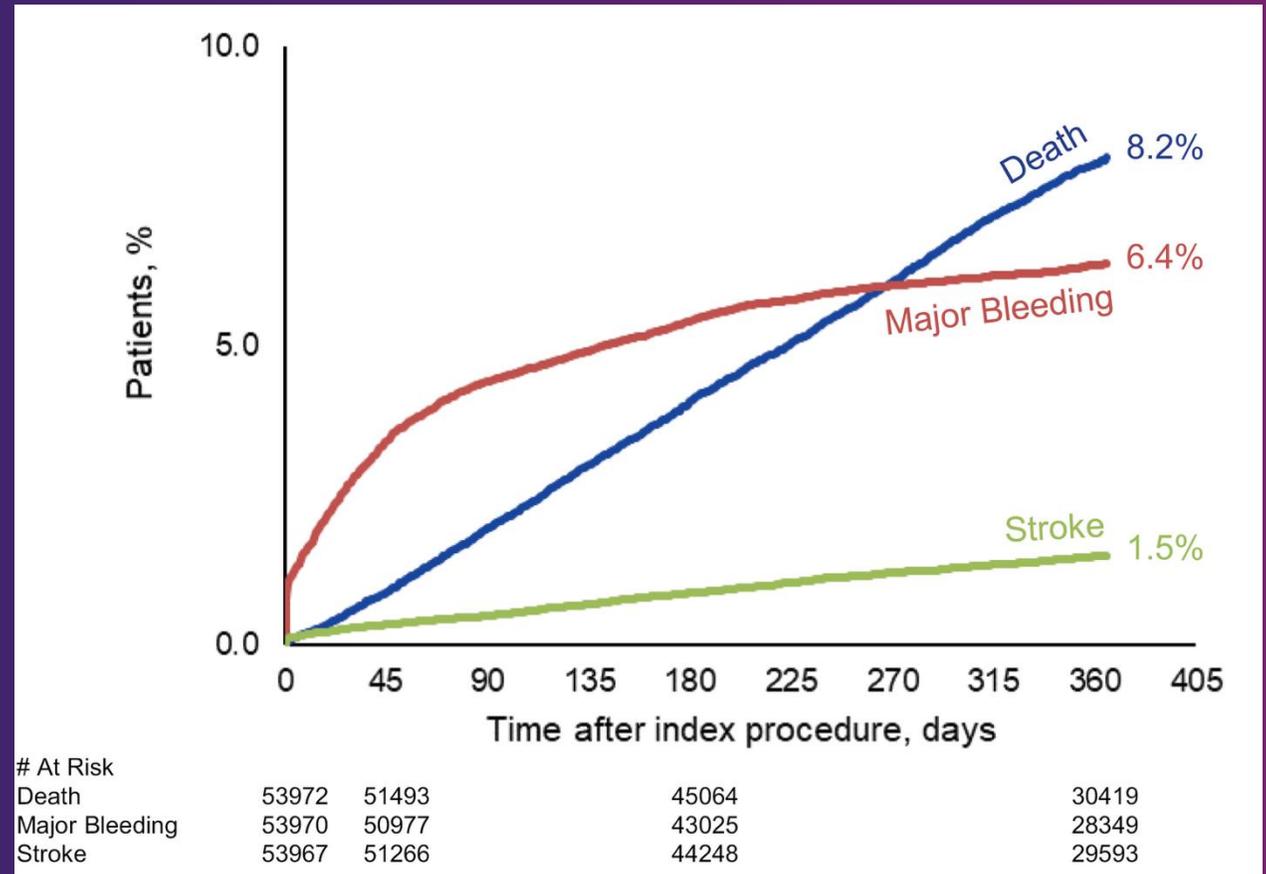


Procedural Complications



NCDR LAAO Registry

- 97,185 patients (2020 to 2022)
- WATCHMAN FLX device
- Age 76.4 (± 7.9)
- CHA2DS2-VASC 4.8 ± 1.50
- HAS-BLED 2.8 ± 1.1
- Creatinine 1.3 ± 1.0
- Hospital Complications
 - Pericardial effusion 0.39%
 - Stroke 0.08%
 - Major bleeding 1.0%



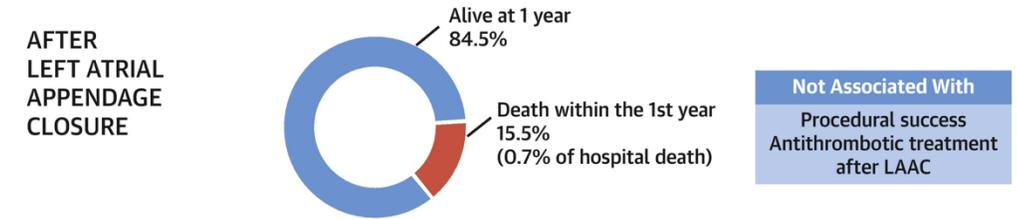
Different Populations (OPTION v. CLOSURE AF)

	OPTION	CLOSURE AF
Age (yrs)	68	79
CHA2DS2-VASc	≥2	≥2
Bleeding History	Exclude: Patients unsuitable for chronic anticoagulation and/or aspirin therapy due to bleeding risk	Include: Hx Bleeding that could not be eliminated
HAS-BLED	1.2	≥3
Post-implant regimen	DOAC x 12 mo → ASA	DAPT x 3 mo → SAPT

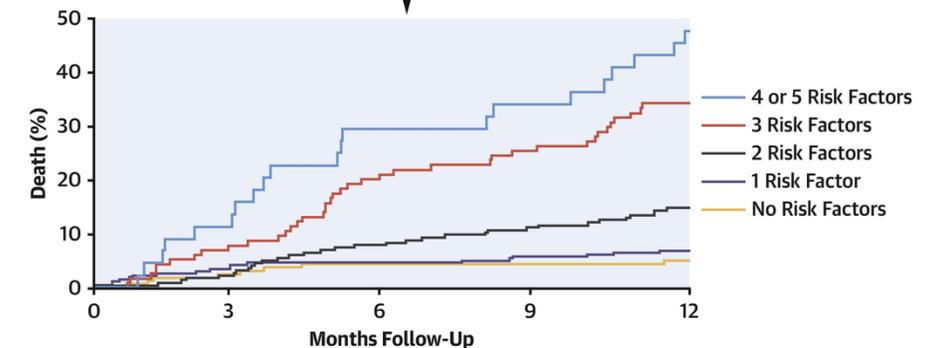
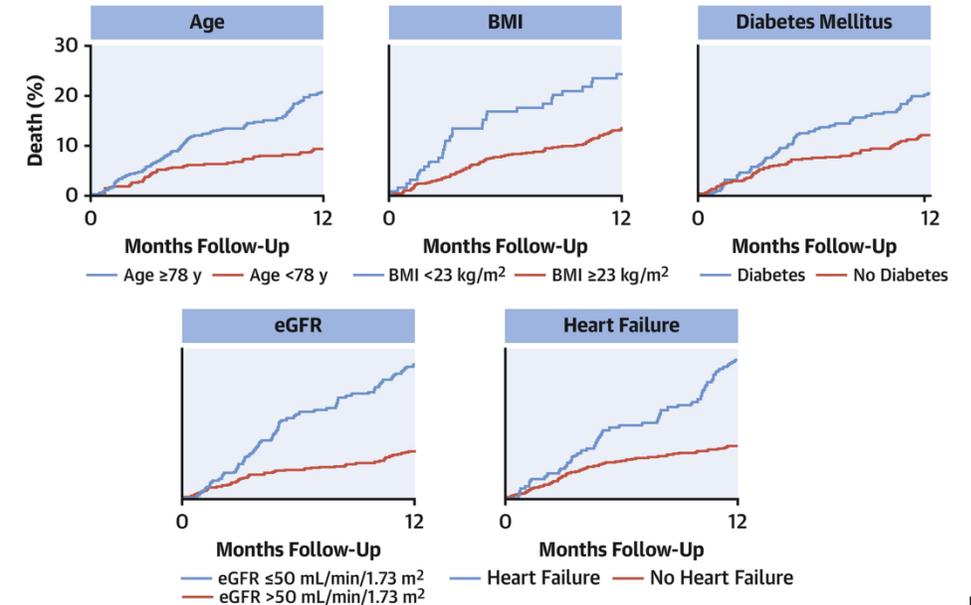
Real world outcomes?

- 10-year registry 807 patients
- 1-year mortality 15.5% → No benefit?
 - Elderly (>78 years)
 - Lower BMI
 - DM
 - CHF
 - Renal Failure
 - 4-5 risk factors → nearly 50% mortality

CENTRAL ILLUSTRATION: Independent Predictors and Their Cumulative Effects on Early Death After Percutaneous Left Atrial Appendage Closure

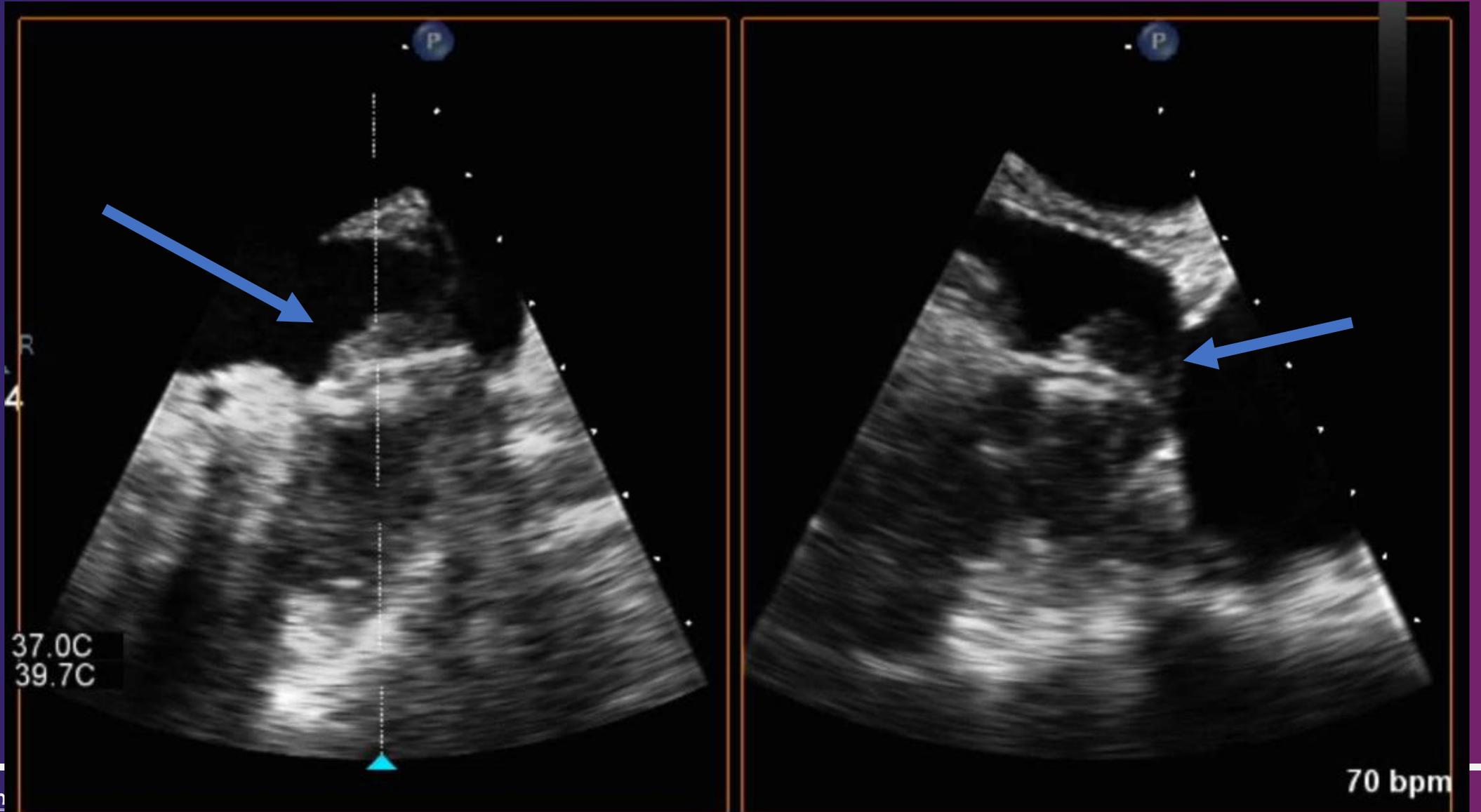


Independent Predictors of Early Death After LAAC



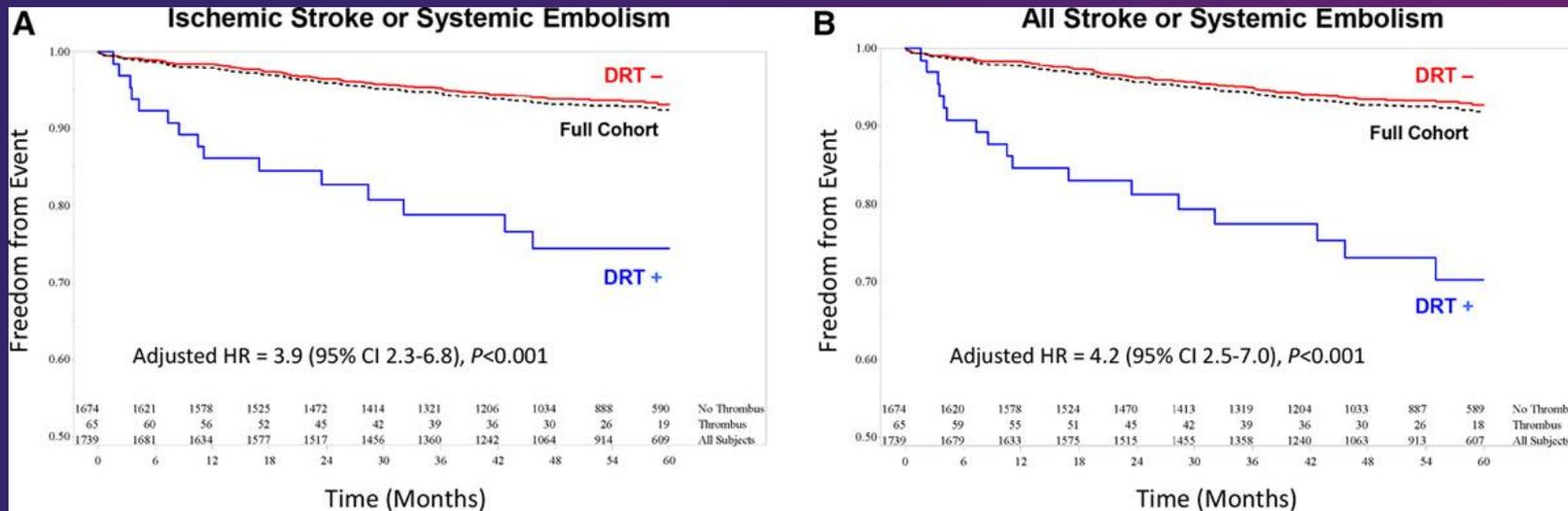
**Why not just minimize post-LAAC
anticoagulation?**

Device Related Thrombus



Device related thrombus (DRT)

- DRT in 1-3% of all patients
- Systemic embolization with DRT Adj rate ratio 3.22 (1.90-5.45, $p < 0.001$)
- Risk Factors
 - ▶ History of CVA/TIA
 - ▶ Hypercoagulability
 - ▶ Renal Insufficiency
 - ▶ Permanent/Non-paroxysmal afib
 - ▶ Pericardial effusion
 - ▶ Lower LVEF
 - ▶ Larger LAAO
 - ▶ Implant depth > 10 mm



DAPT and LAAO

- Watchman new labeling for DAPT
- Retrospective analysis of 4256 patients with FLX device

Events* (Between Date of Discharge and 45-days Post Procedure)	DAPT (N=1407)	Control (N=1407)
All-Cause Death	0.50% (7/1407)	0.78% (11/1407)
All Stroke	0.28% (4/1407)	0.28% (4/1407)
Ischemic Stroke	0.21% (3/1407)	0.14% (2/1407)
Hemorrhagic Stroke	0.07% (1/1407)	0.14% (2/1407)
Undetermined Stroke	0.00% (0/1407)	0.00% (0/1407)
Device-Related Thrombus (DRT)	0.14% (2/1407)	0.00% (0/1407)
Systemic Embolism	0.00% (0/1407)	0.00% (0/1407)
Major Bleed	2.27% (32/1407)	2.20% (31/1407)

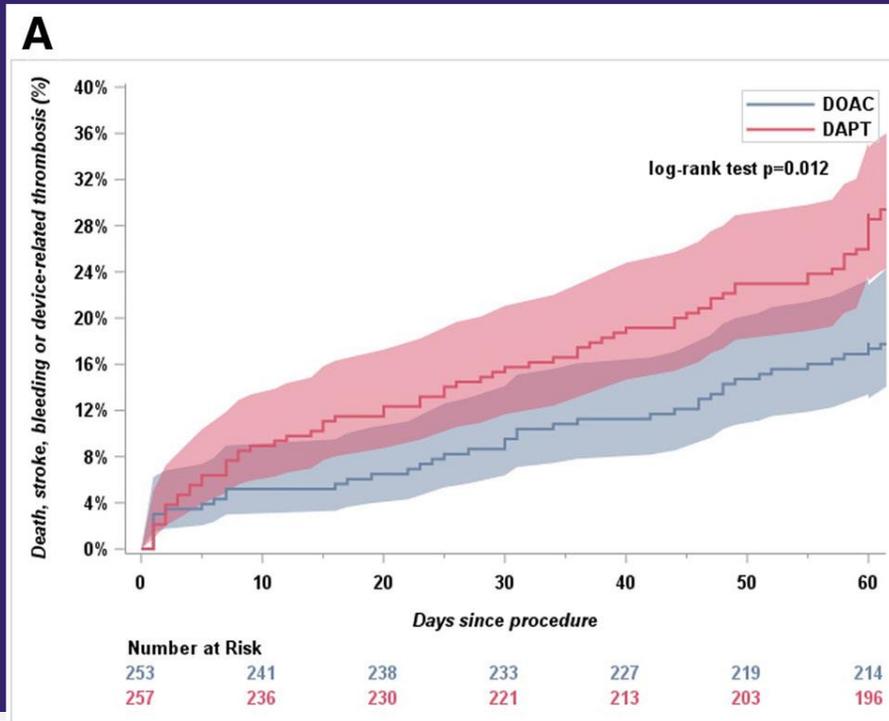
DOACs v. DAPT v. SAPT

- EMERGE LAAC – post-market analysis Amulet LAAO (2021-2023)
- 11,445 patients—compare patients by discharge regimen

	DAPT	SAPT	OAC	P-value
Prior bleeding*	65.4%	74.3%	58.8%	<0.01
45d major bleed	2.1%	2.2%	1.4%	0.13
6mo major bleed	4.8%	3.9%	3.4%	0.07
All Stroke	0.8%	0.4%	0.5%	0.36
Safety Composite	8.8%	7.0%	7.0%	0.04

DOAC v. DAPT after LAAC (ANDES Study)

- Randomized trial 510 patients following LAAC
- DOAC v. DAPT (ASA/Clopid) for 60 days
- CHA2DS2-VASc 4.2 ± 1.4
- HAS-BLED 3.4 ± 1.1



	DOAC n=205	DAPT N=194	Difference (95% CI)	p value
Device-related thrombosis (Primary Outcome)	3 (1.5%)	8 (4.1%)	-2.7 (-6.0 to 0.6)	0.110
Combined safety outcome	52 (22.5%)	82 (34.9%)	-12.4 (-20.6 to -4.2)	0.003
Death	6 (2.4%)	11 (4.3%)	-1.9 (-5.0 to 1.2)	0.230
Stroke	0 (0%)	2 (0.8%)	-0.8 (-1.9 to 0.3)	0.158
Bleeding	44 (17.4%)	64 (24.9%)	-7.5 (-14.6 to -0.4)	0.038
Minor	29 (11.5%)	41 (15.9%)	-4.5 (-10.5 to 1.5)	0.141
Major/life-threatening bleeding	16 (6.3%)	26 (10.1%)	-3.8 (-8.6 to 0.9)	0.119

Low Dose DOAC v. DAPT (ADALA Trial)

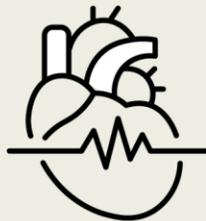
- Open-label randomized trial

JAMA Cardiology

RCT: Low-Dose Direct Oral Anticoagulation vs Dual Antiplatelet Therapy After Left Atrial Appendage Occlusion

POPULATION

60 Men, 30 Women



Adults with atrial fibrillation who underwent successful left atrial appendage occlusion (LAAO)
Mean age, 77 y

SETTINGS / LOCATIONS



3 University hospitals
in Spain

INTERVENTION

90 Participants analyzed



44 Low-dose apixaban
Apixaban 2.5 mg twice daily for the first 3 mo after LAAO, followed by aspirin 100 mg daily



46 Dual antiplatelet therapy (DAPT)
Aspirin 100 mg daily + clopidogrel 75 mg daily for first 3 mo after LAAO, then aspirin 100 mg daily

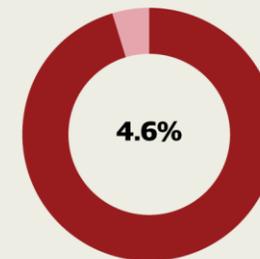
PRIMARY OUTCOME

Composite of safety (major bleeding defined as Bleeding Academic Research Consortium type 3 or higher) and efficacy (thromboembolic events) within the first 3 mo after successful LAAO

FINDINGS

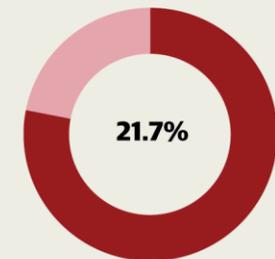
At 3 mo, incidence of the composite end point was significantly reduced in the low-dose apixaban group compared with the DAPT group

Low-dose apixaban



2 of 44 Participants

DAPT

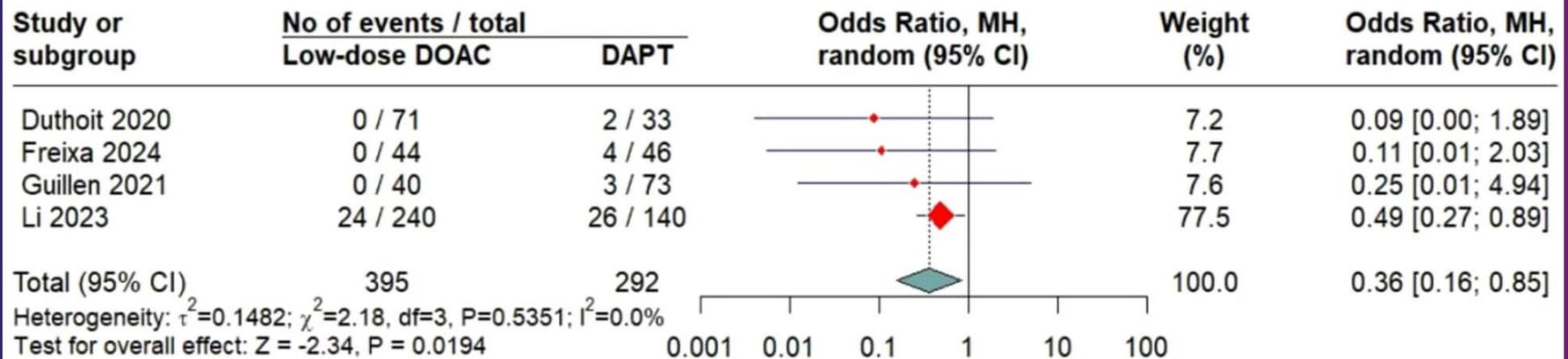


10 of 46 Participants

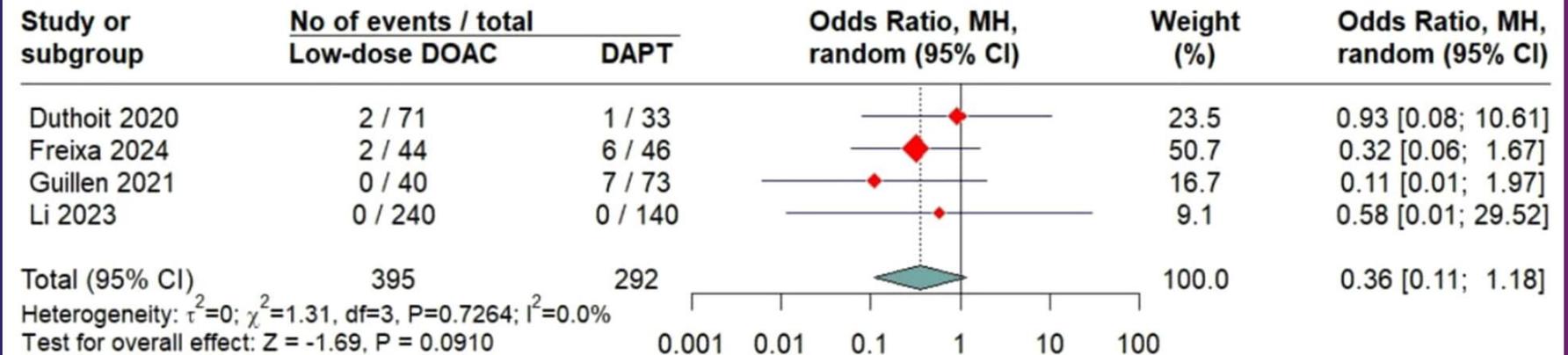
Hazard ratio, 0.19 (95% CI, 0.04-0.88); $P = .02$

Low Dose DOAC v. DAPT

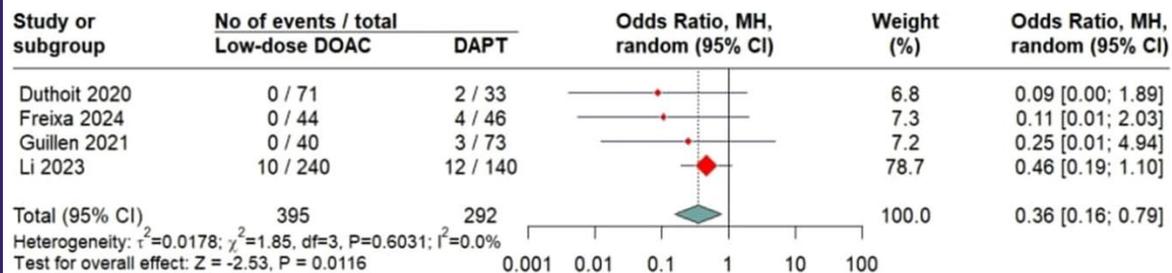
A: Forest plot for Efficacy Endpoint [Stroke + SE + DRT]



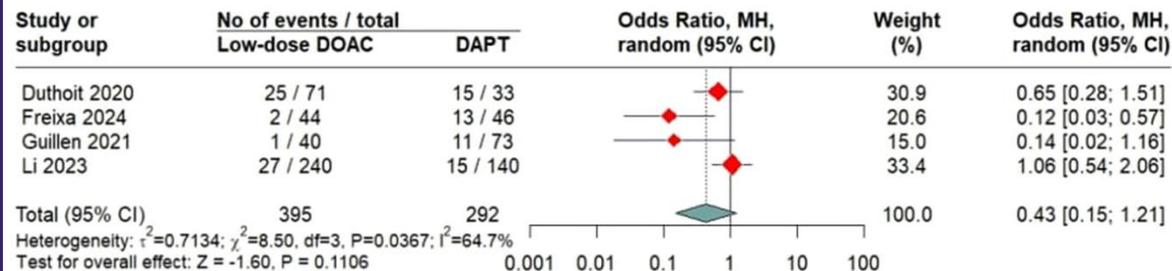
B: Forest plot for Safety Endpoint [Major bleeding]



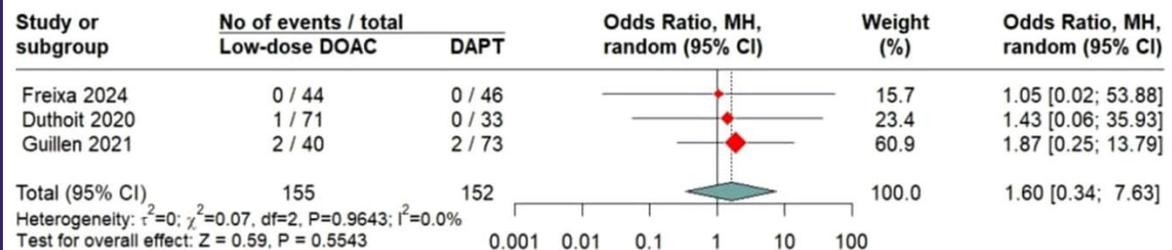
A: Forest plot for device-related thrombosis



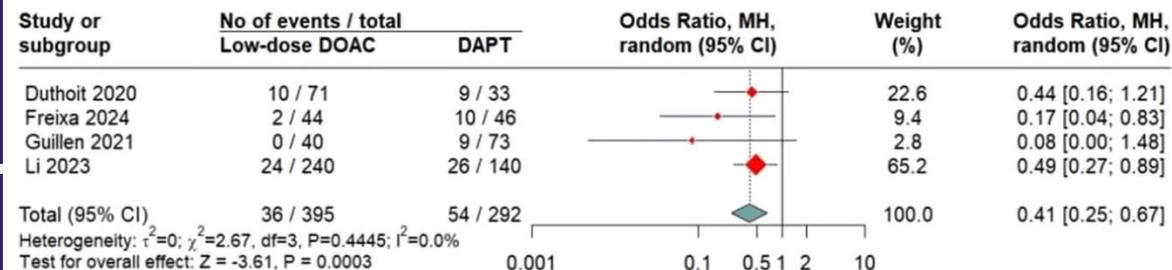
B: Forest plot for all bleeding (major & minor)



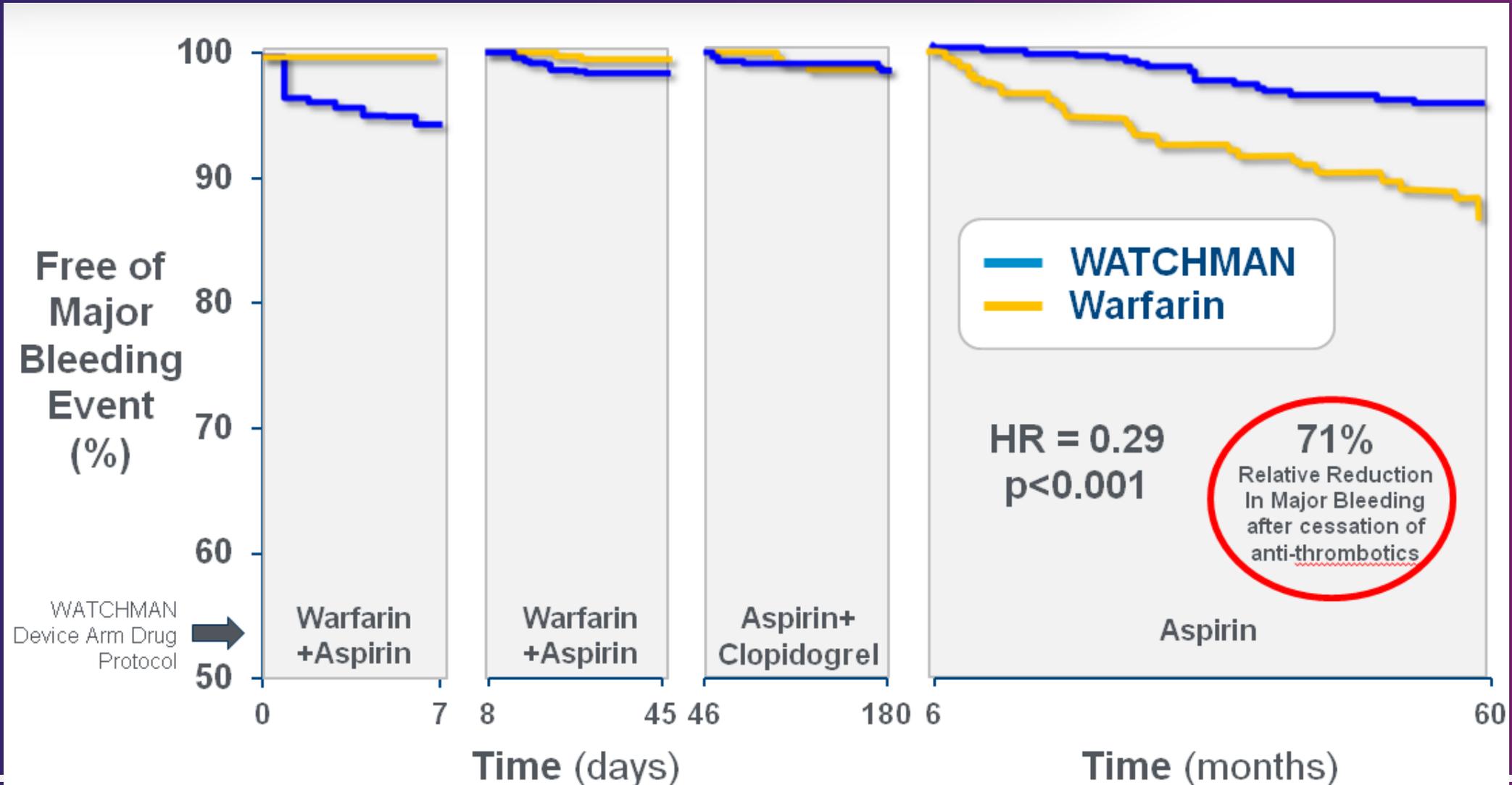
C: Forest plot for All-cause Mortality

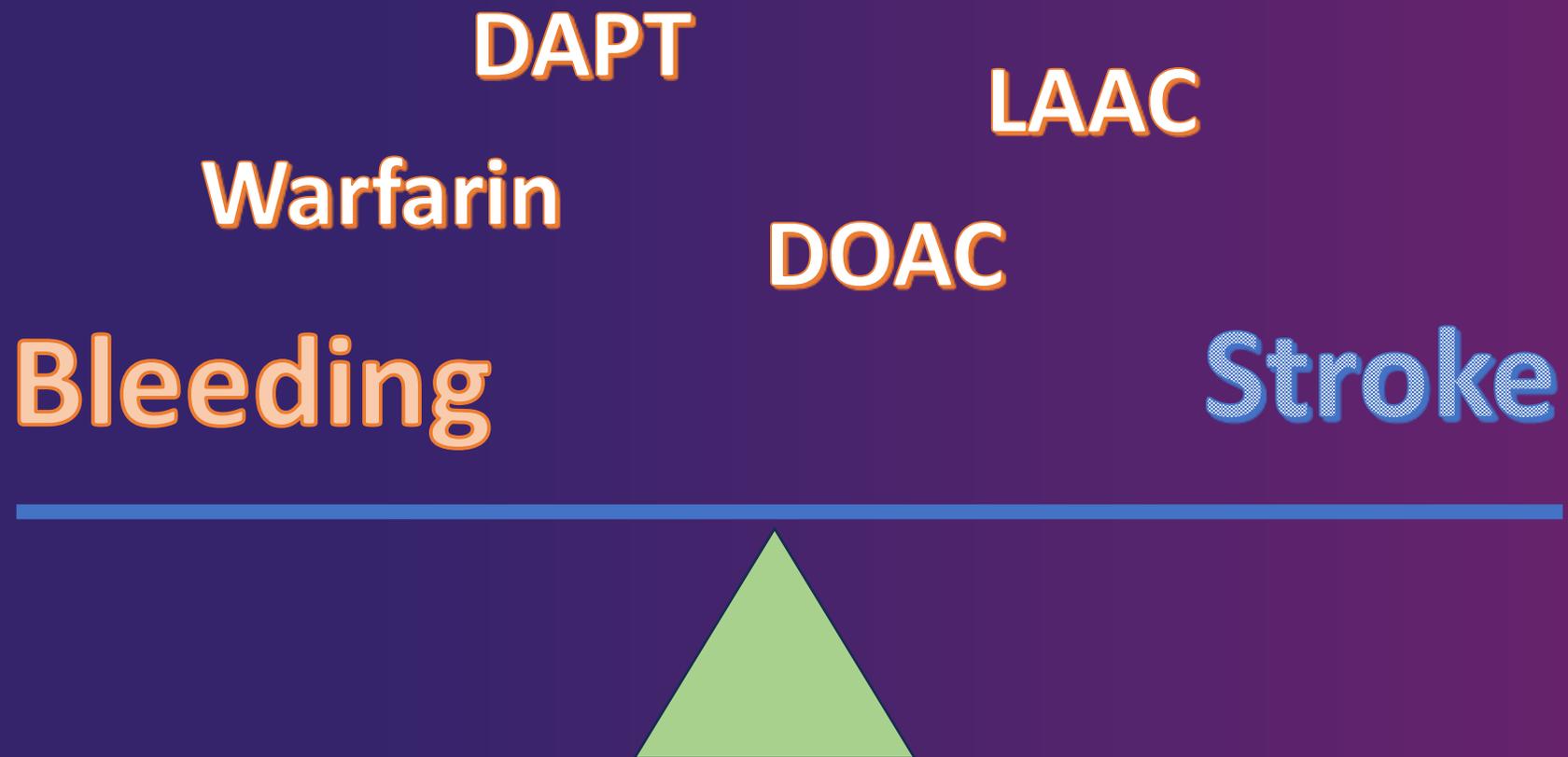


D: Forest plot for Composite Endpoint [Efficacy + Safety Endpoints]



Long-term reduction in bleeding

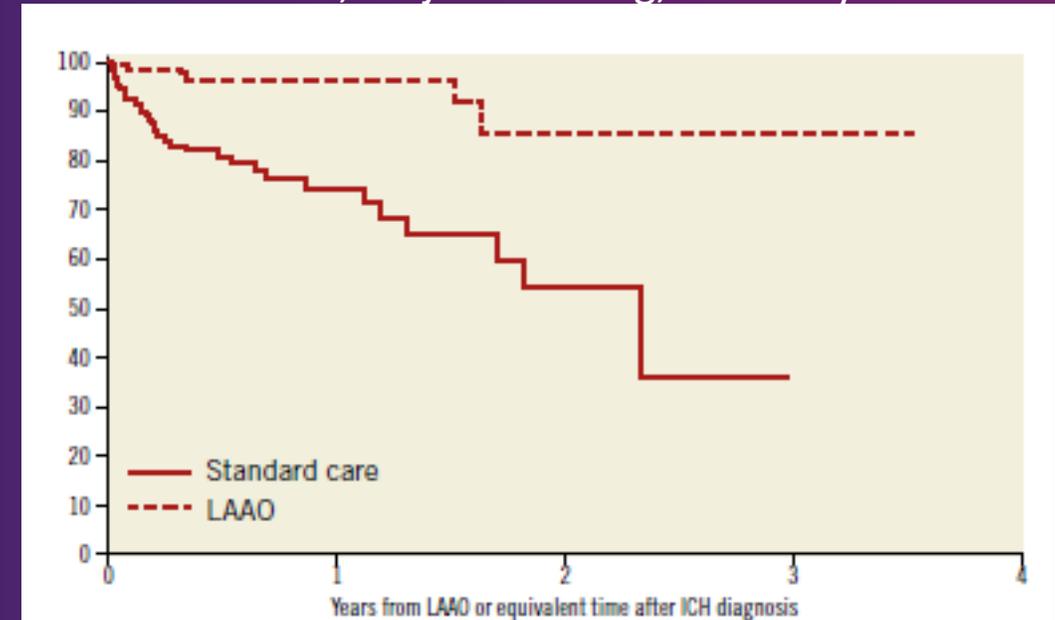




Intracranial Hemorrhage

- Patients with afib and ICH
- 151 with LAAO
- 151 on medical tx
 - Anticoag 20%
 - Antiplatelet 51%
 - No tx 31%
- Matched for stroke and bleeding risk

Stroke, major bleeding, mortality



Outcome	Hazard ratio (95% CI)
Ischaemic stroke/major bleeding/ all-cause mortality	0.16 (0.07-0.37)
Ischaemic stroke	0.21 (0.05-1.00)
Major bleeding	0.28 (0.09-0.85)
recurrent ICH	0.10 (0.01-0.81)
All-cause mortality	0.11 (0.03-0.51)

ICH: intracerebral haemorrhage; LAAO: left atrial appendage occlusion

Nielsen-Kudsk. Eurointervention. 2017

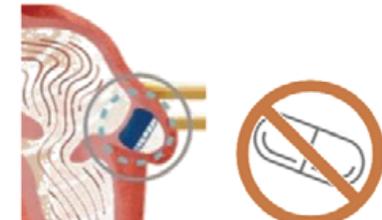
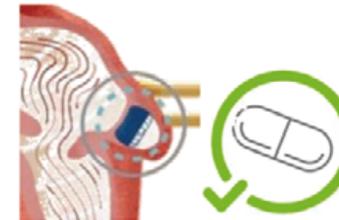
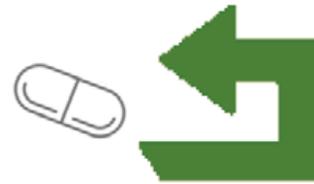
Ischemic stroke despite anticoagulation

- Retrospective study of patients with stroke while on anticoagulation
- 141 continued on anticoagulation, 95 treated with additional LAAC

The cumulative 3-year incidence of outcomes compared among the four subgroups



Strategy after AFIDA

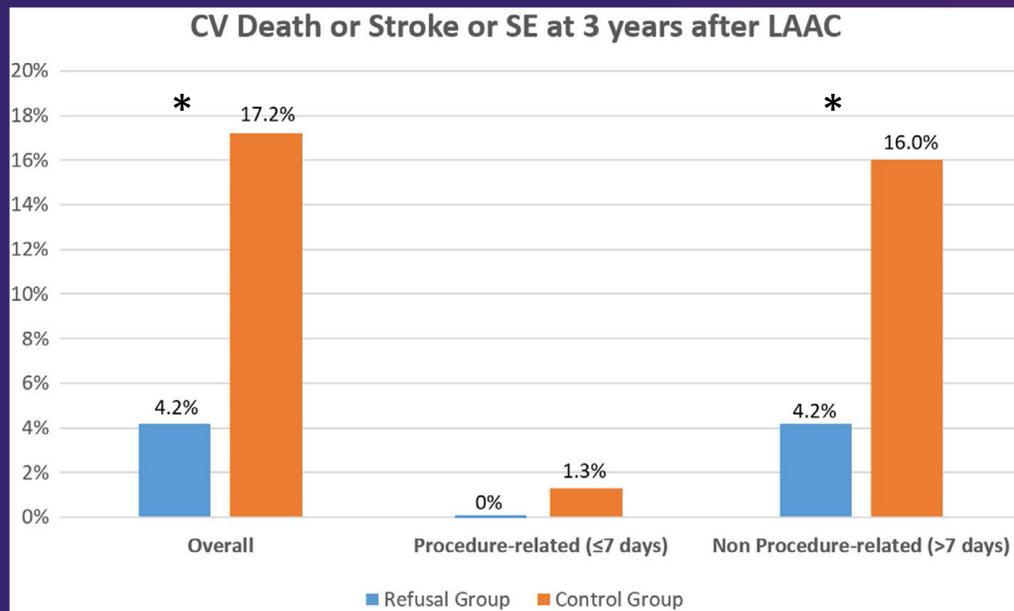


Cumulative 3-year incidence	Aggressive OAC	Conventional OAC	LAAC with OAC	LAAC without OAC
Ischemic stroke	15.6%	15.2%	7.2%	16.4%
Fatal/disabling stroke	14.1%	16.0%	0%	5.3%
Major bleeding	33.1%	12.6%	4.5%	5.9%
Fatal bleeding	10.6%	0%	0%	0%

LAAC may potentially prevent fatal or disabling stroke and fatal bleeding in AFIDA.

Patients who refuse to take anticoagulation

- Retrospective evaluation of 2649 patients undergoing LAAC
- 119 Patients who refused to take anticoagulation compared to controls



	Observed events*	Expected events*	Standardized event ratio (95% CI)
Thromboembolic events	2.3	5.9 [†]	0.38 (0.10–1.40)
Major bleedings	1.9	3.6 [‡]	0.53 (0.13–2.18)
Nonprocedural major bleedings	1.2	3.6 [‡]	0.35 (0.06–1.99)

Cardioversion without anticoagulation

- Retrospective study of 1398 patients undergoing cardioversion

3-Month and 1-Year outcomes before and after propensity score matched of patients with atrial fibrillation who had left atrial appendage closure and underwent cardioversion with and without oral anticoagulation.

Outcomes	Before propensity score matching			After propensity score matching		
	AC group <i>n</i> = 543	Non-AC group <i>n</i> = 855	Odd ratios (95 % CI)	AC group <i>n</i> = 517	Non-AC group <i>n</i> = 517	Odd ratios (95 % CI)
3-month outcomes						
Primary outcome						
• Stroke or systemic thromboembolism	29 (5.34 %)	49 (5.73 %)	0.93 (0.58–1.49)	26 (5.03 %)	29 (5.61 %)	0.89 (0.52–1.54)
• Significant bleeding ^a	46 (8.47 %)	64 (7.49 %)	1.14 (0.78–1.70)	47 (9.09 %)	43 (8.32 %)	1.10 (0.71–1.70)
Secondary outcome						
• Ischemic stroke or transient ischemic attack	29 (5.34 %)	47 (5.50 %)	0.97 (0.60–1.56)	25 (4.84 %)	27 (5.22 %)	0.92 (0.53–1.61)
• Blood transfusion	20 (3.43 %)	14 (1.64 %)	2.30 (1.15–4.59)	20 (3.87 %)	11 (2.13 %)	1.85 (0.88–3.90)
• Gastrointestinal bleeding	20 (3.68 %)	31 (3.63 %)	1.02 (0.57–1.80)	19 (3.68 %)	19 (3.68 %)	1.00 (0.52–1.91)

Putting it together

- Atrial fibrillation is a leading cause for strokes
- Anticoagulation can reduce the risk for cardiac and other atherosclerotic strokes
- Left atrial appendage closure (LAAC) can help reduce afib related strokes and bleeding
 - Lower bleeding/stroke risk patients
 - Balanced against upfront bleeding risks
- This takes coordination between primary care, pharmacy, and cardiology

Upcoming studies

- CHAMPION AF
 - LAAC v. DOACs
- CATALYST
 - LAAC v. DOACs in low-risk patients
- LAAOS IV
 - Surgical LAAC v. DOACs
- ELAPSE
 - LAAC in patients with breakthrough strokes on DOACs

Thank You

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- UW Structural heart

206-598-VALV (8258)