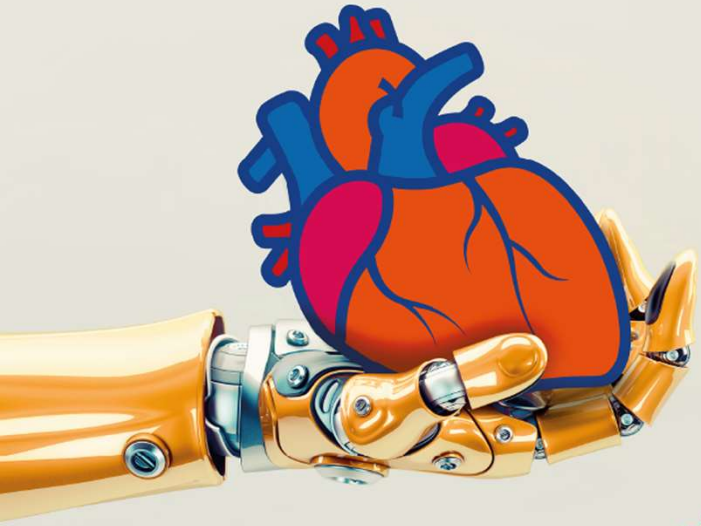


17° Meeting

CardioLucca

Heart Brings Heart 2023

Lucca, 22-24 Giugno 2023

Centro Congressi Auditorium San Francesco

Fondazione Monasterio

la ricerca che cura

Sergio Berti

Quando escludere l'auricola nella fibrillazione atriale

Ospedale del Cuore
Fondazione C.N.R. Reg. Toscana , Massa/Pisa
berti@ftgm.it

Consiglio Nazionale delle Ricerche

17° Meeting
CardioLucca
Heart Brings Heart 2023

Lucca,
22-24 Giugno
2023
Centro Congressi
Auditorium San Francesco

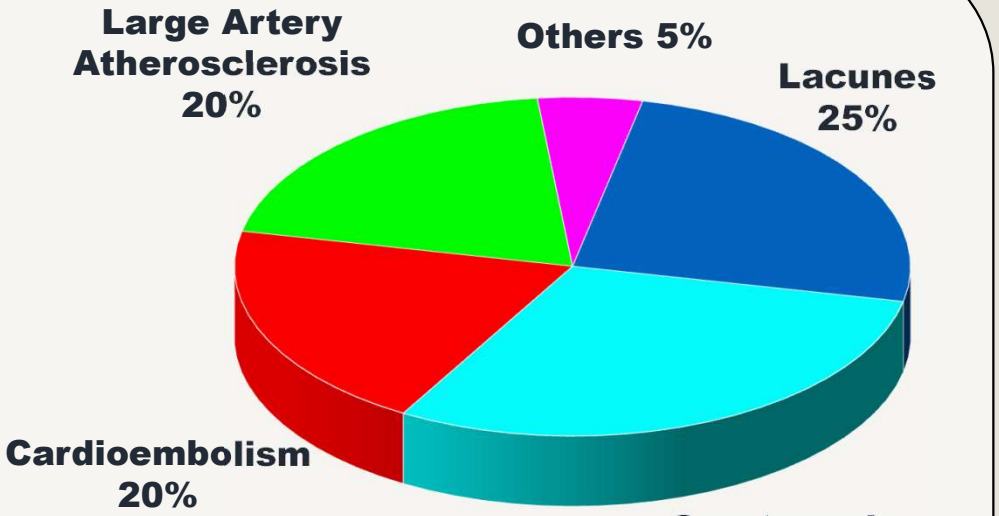
Il sottoscritto Sergio Berti
in qualità di *relatore*

ai sensi dell'art. 76 sul Conflitto di Interessi, comma 4 dell'Accordo Stato-Regioni del 2 febbraio 2017 e del paragrafo 4.5. del Manuale nazionale di accreditamento per l'erogazione di eventi ECM

dichiara
che negli ultimi due anni ha avuto i seguenti rapporti anche di finanziamento con soggetti portatori di interessi commerciali in campo sanitario:

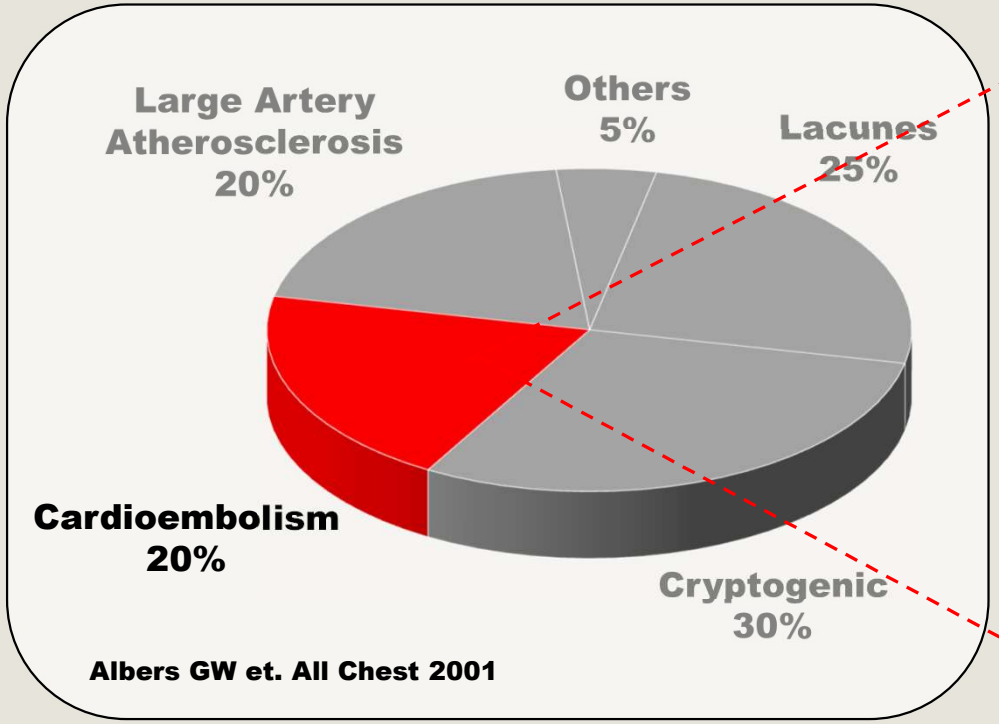
Proctor: Edwards, Boston, Abbott, J&J

Stroke etiology



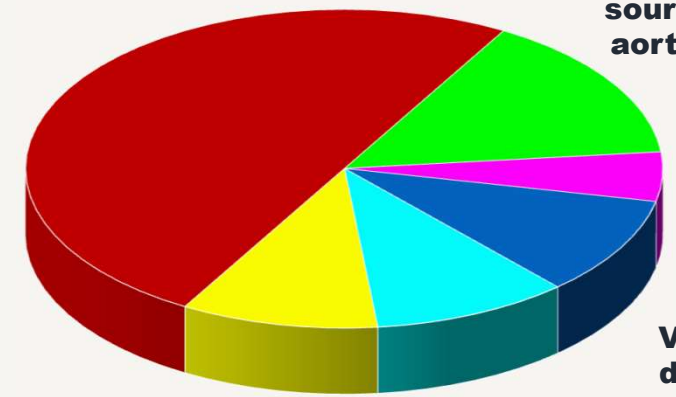
Albers GW et. All Chest 2001

Stroke etiology

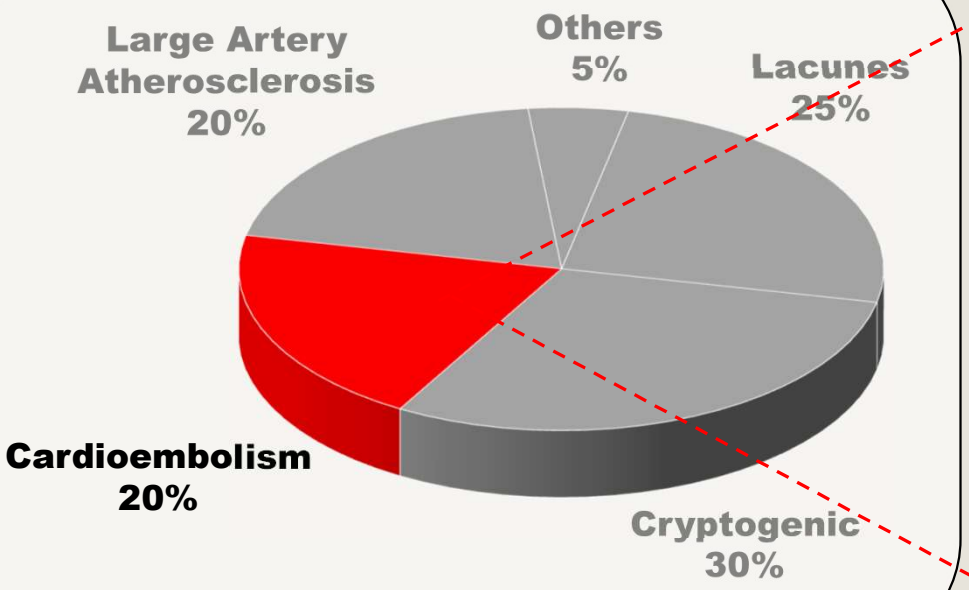


Albers GW et. All Chest 2001

Cardio-embolic strokes



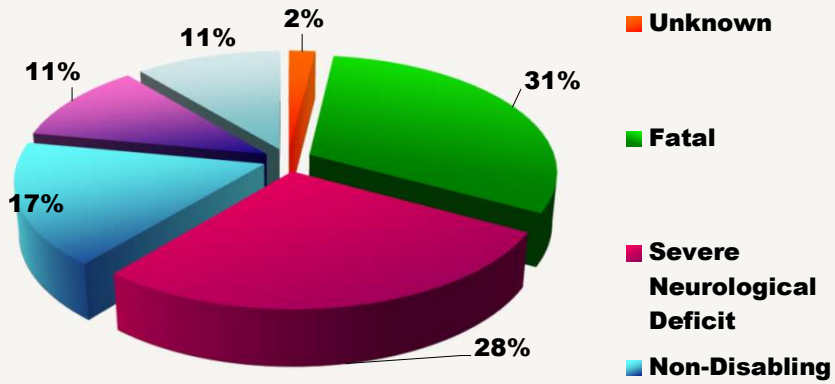
Stroke etiology



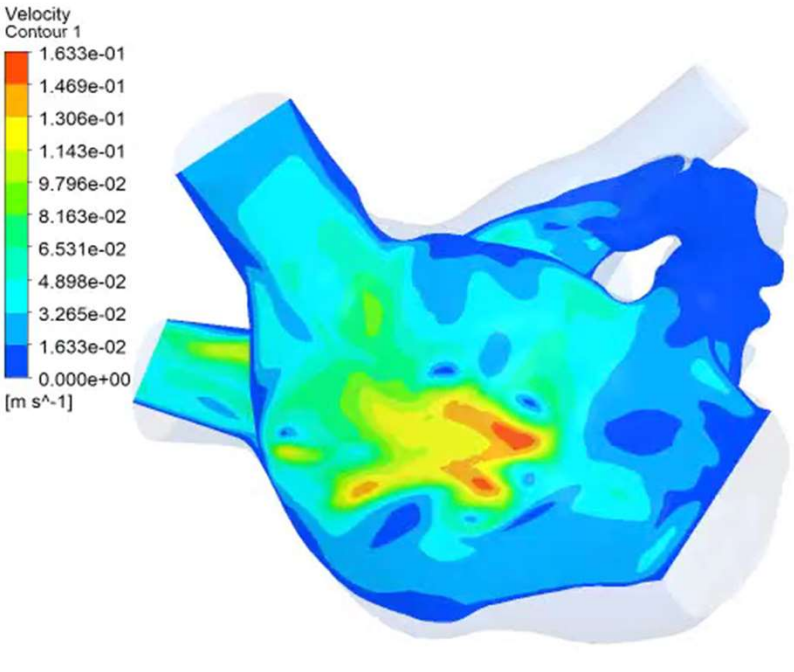
Albers GW et. All Chest 2001

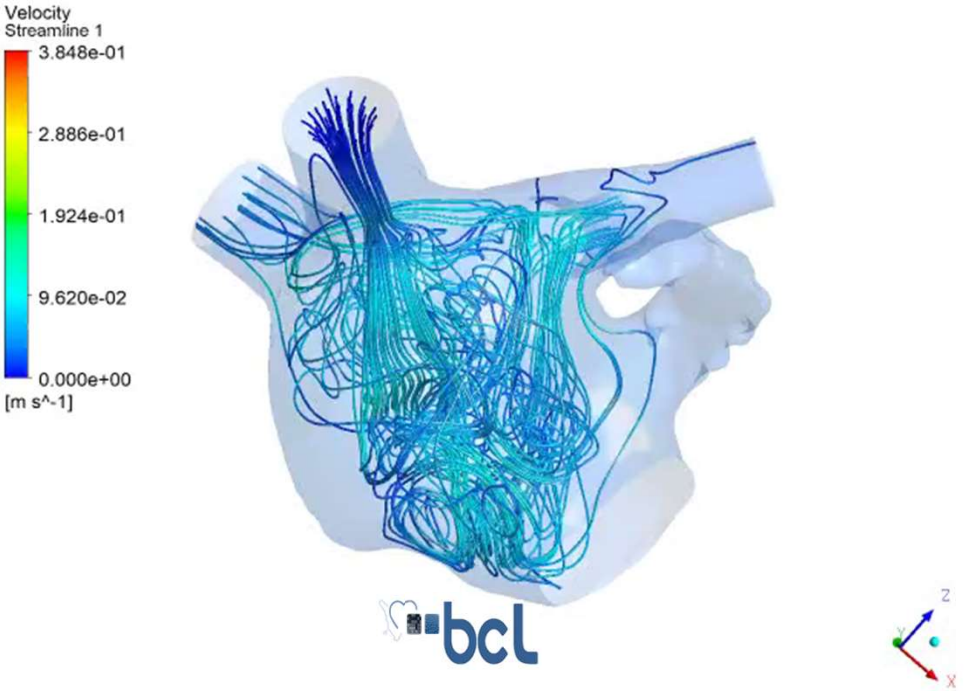
Cardio-embolic strokes

Stroke Severity

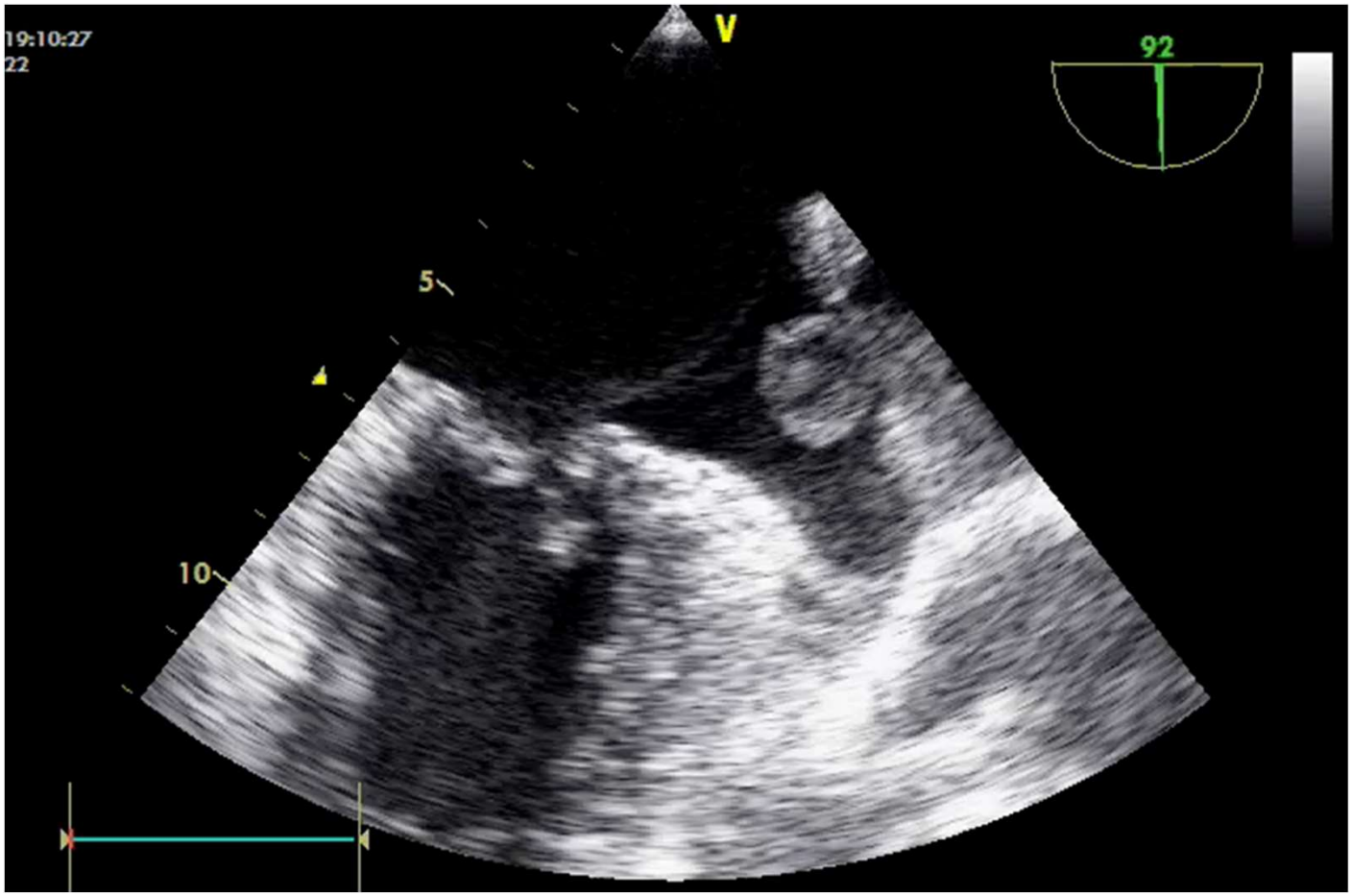


LA and LAA Flow

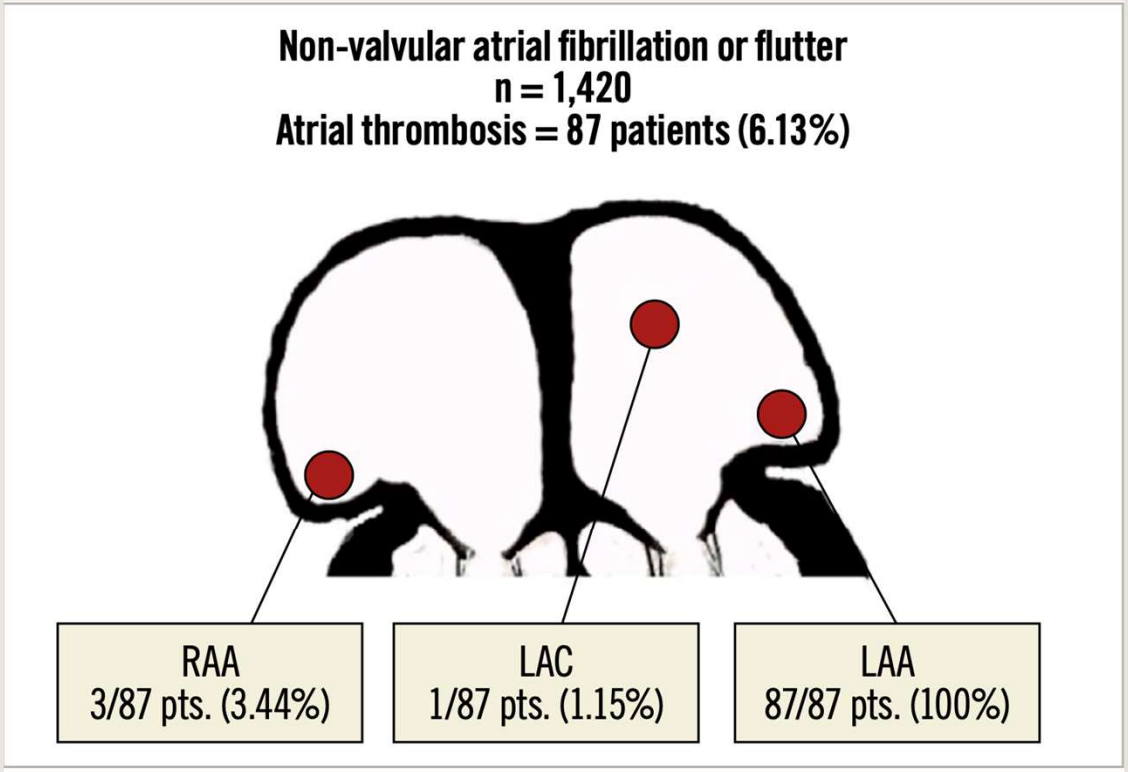




Mechanism of Stroke in Patients with AF



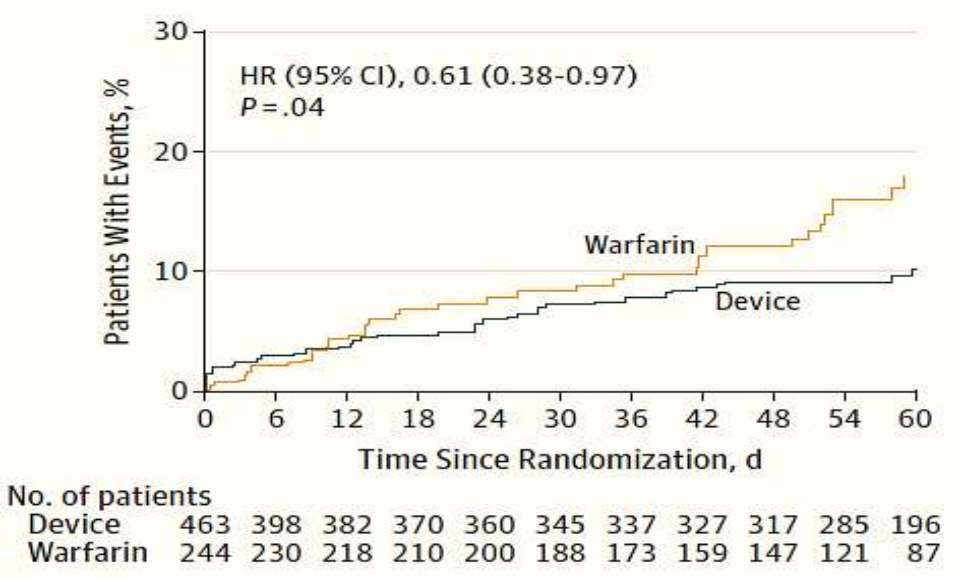
The localisation of atrial thrombi



A. Cresti EuroIntervention 2019;15:

PROTECT-AF 4 Years:
Primary Efficacy endpoint

Event	Device Group (n = 463)		Warfarin Group (n = 244)		Device/Warfarin Rate Ratio (95% Credible Interval)	Posterior Probabilities, %	
	Events/Patient-Years	Observed Rate[a]	Events/Patient-Years	Observed Rate[a]		Noninferiority	Superiority
Primary efficacy end point[b]	39/1720.2	2.3 (1.7-3.2)	34/900.8	3.8 (2.5-4.9)	0.60 (0.41-1.05)	>99	96

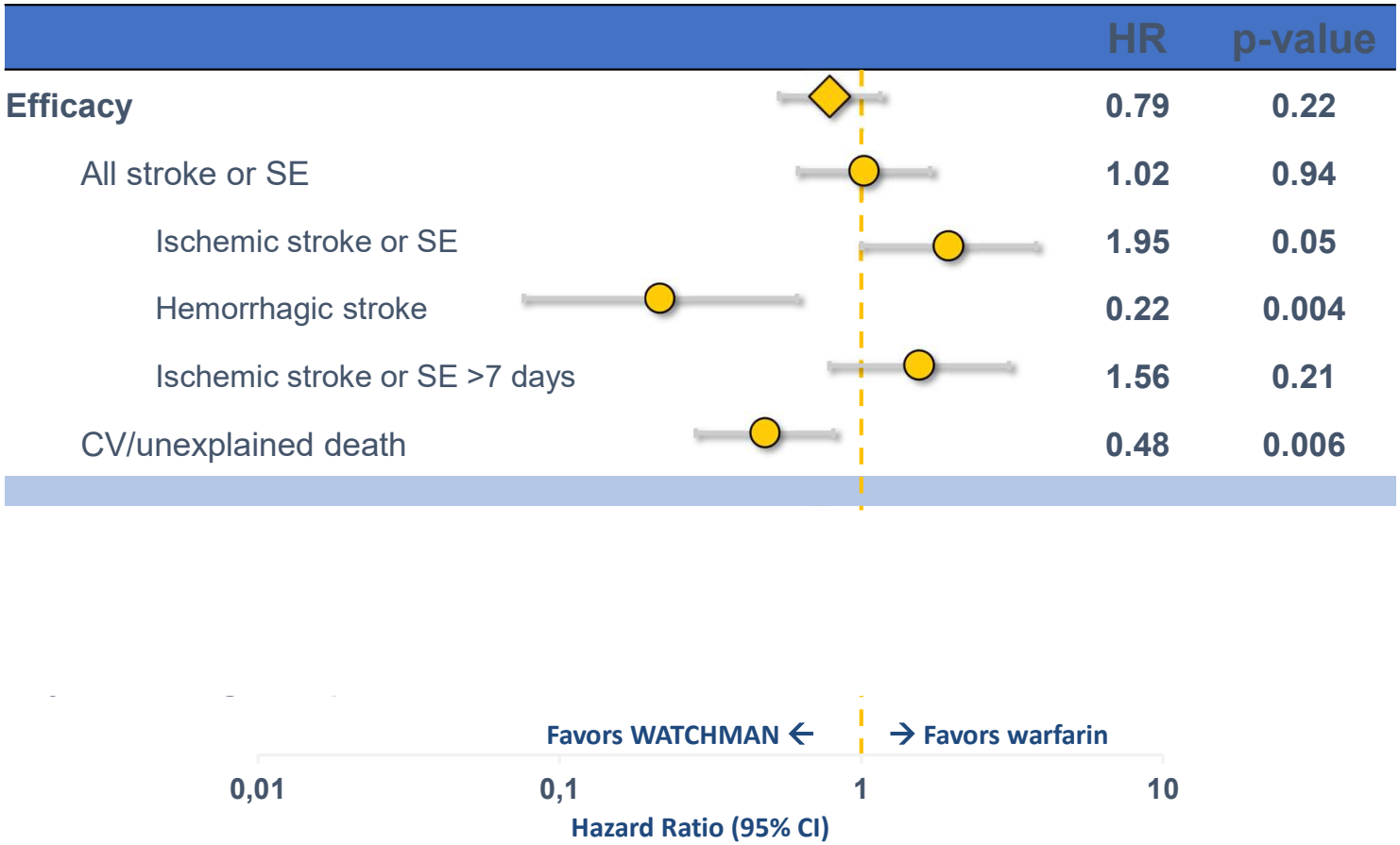


a. **Events per 100 patient-years (95% credible interval);**
b. **Composite of stroke, systemic embolization, or cardiovascular/unexplained death**

For Bayesian analysis, a posterior probability of 97.5% represents non-inferiority; ≥95% represents superiority.

Reddy, VY et al. JAMA. 2014; 312(19)

PROTECT-AF/PREVAIL Meta Analysis:
WATCHMAN™ Comparable to Warfarin



Holmes, DR et al. JACC 2015.

PRAGUE-17 4-years: Study design

• *PRAGUE-17 (*NCT02426944): an investigator-initiated, multicenter, prospective, open-label, randomized non-inferiority trial

• Goal: to compare LAAC with NOAC in high risk AF patients

• Enrollment period: October 2015 to January 2019, extended follow- up up to June 2021

Composite Primary Endpoint:

1 Stroke or transient ischemic attack (TIA)

2 Systemic embolism

3 Clinically-relevant bleeding

4 Cardiovascular death, or

5 Significant peri-procedural or device-related complication

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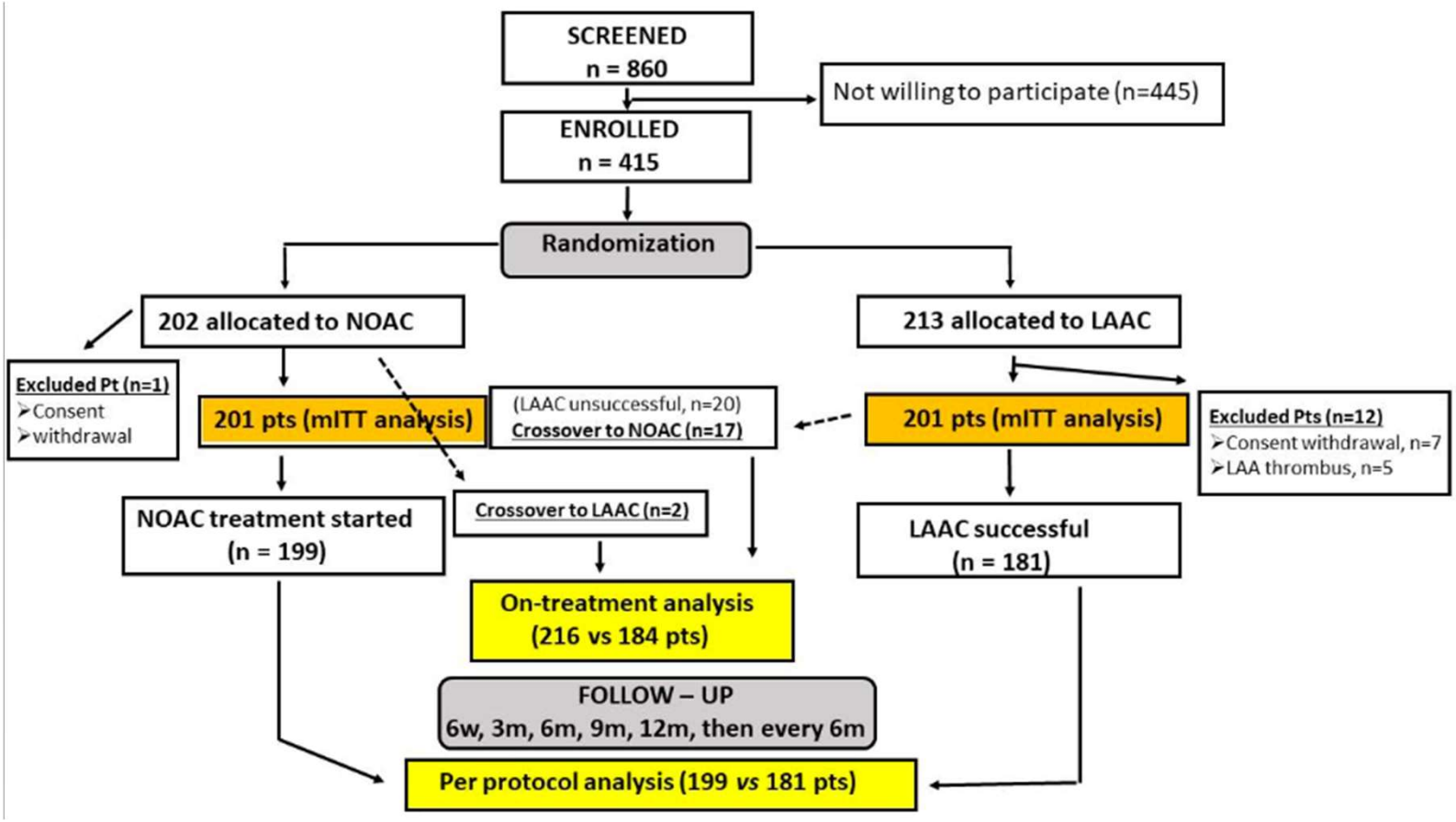
Study diagram



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Baseline characteristics

	NOAC (n=201)	LAAC (n=201)
Age (years)	73.2 ± 7.2	73.4 ± 6.7
Male gender (%)	130 (64.7%)	134 (66.7%)
Paroxysmal AF (%)	67 (33.3%)	53 (26.4%)
CHA_2DS_2-VASc score	**4.7 ± 1.5**	**4.7 ± 1.5**
CHA_2DS_2-VASc ≥ 6 (%)	54 (26.9%)	56 (27.9%)
History of cardioembolic event (%)	69 (34.3%)	73 (36.3%)
HAS-BLED score	**3.0 ± 0.9**	**3.1 ± 0.9**
History of bleeding/bleeding predisposition	95 (47.3%)	109 (54.2%)
Heart failure (%)	90 (44.8%)	88 (43.8%)
Hypertension (%)	186 (92.5%)	186 (92.5%)
Diabetes mellitus (%)	90 (44.8%)	73 (36.3%)

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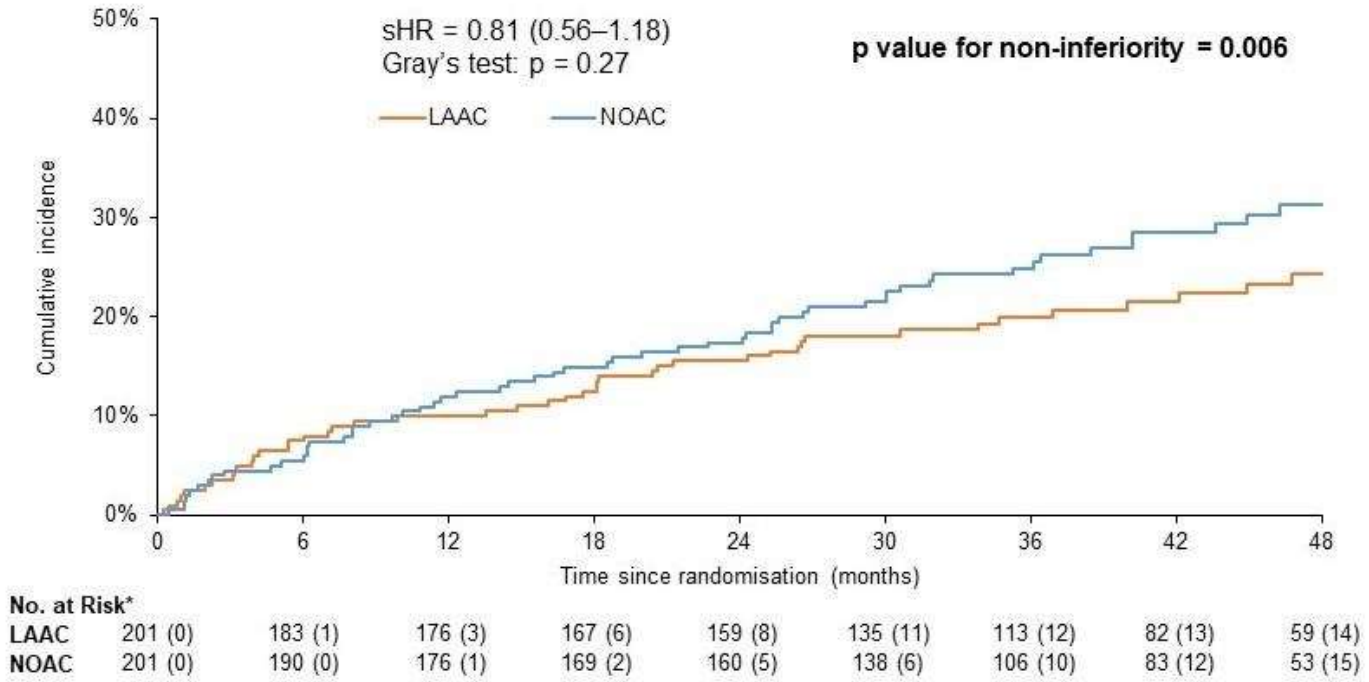
Cumulative incidence function for primary study endpoint in intention-to-treat populations



LAAC: 8.6 events per 100 pt-years **NOAC:** 11.9 events per 100 pt-years

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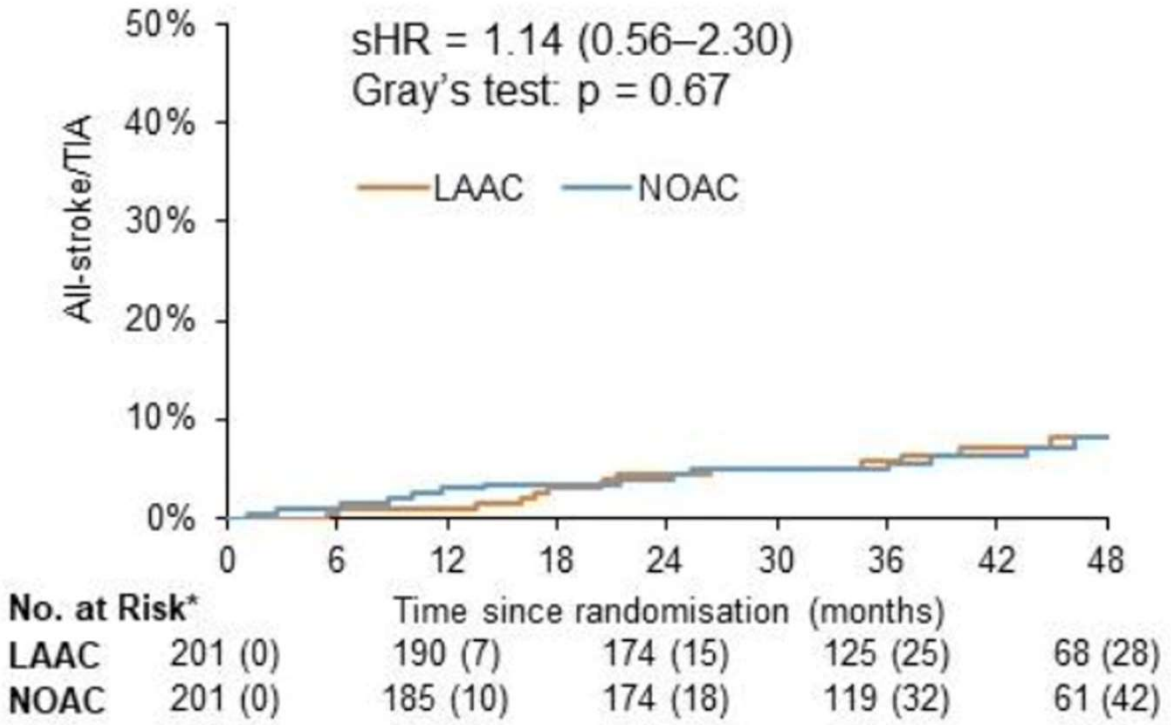
Cumulative incidence function for all-stroke/TIA in ITT populations



LAAC: 2.4 events per 100 pt-years
NOAC: 2.7 events per 100 pt-years

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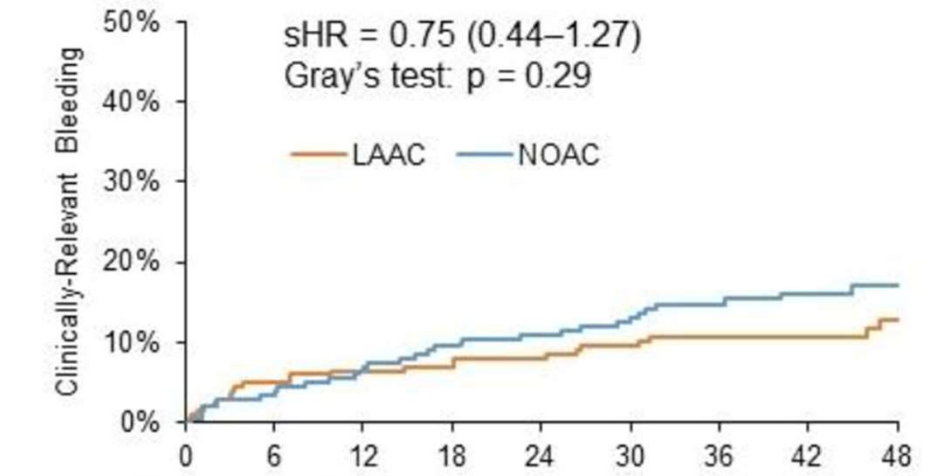
Cumulative incidence function for clinically-relevant, and non- procedural clinically-relevant bleeding in ITT populations



No. at Risk*					
LAAC	201 (0)	180 (6)	168 (14)	121 (22)	64 (26)
NOAC	201 (0)	181 (7)	165 (13)	110 (26)	56 (33)

*Number of patients who are free of any event is supplemented (in brackets) by number of patients with competing risk up to given time.

LAAC: 4.3 events per 100 pt-years
NOAC: 5.9 events per 100 pt-years

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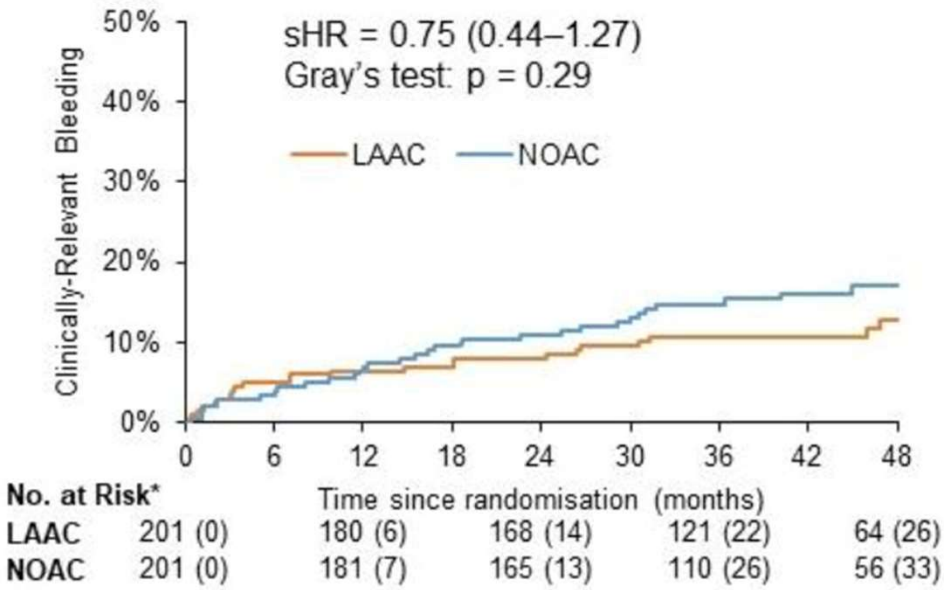
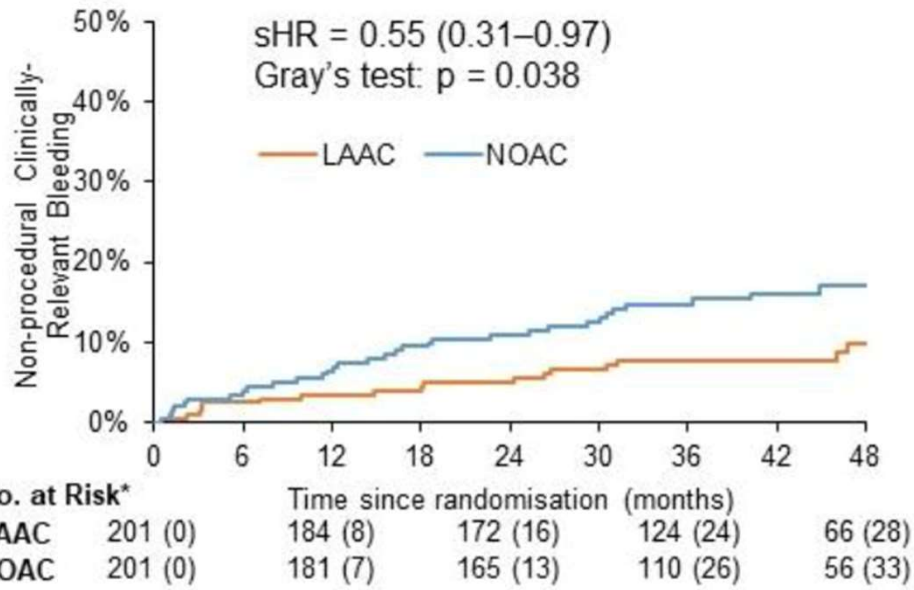
Cumulative incidence function for clinically-relevant, and non- procedural clinically-relevant bleeding in ITT populations



No. at Risk*					
LAAC	201 (0)	180 (6)	168 (14)	121 (22)	64 (26)
NOAC	201 (0)	181 (7)	165 (13)	110 (26)	56 (33)



No. at Risk*					
LAAC	201 (0)	184 (8)	172 (16)	124 (24)	66 (28)
NOAC	201 (0)	181 (7)	165 (13)	110 (26)	56 (33)

*Number of patients who are free of any event is supplemented (in brackets) by number of patients with competing risk up to given time.

LAAC: 4.3 events per 100 pt-years
NOAC: 5.9 events per 100 pt-years

LAAC: 3.4 events per 100 pt-years
NOAC: 5.9 events per 100 pt-years

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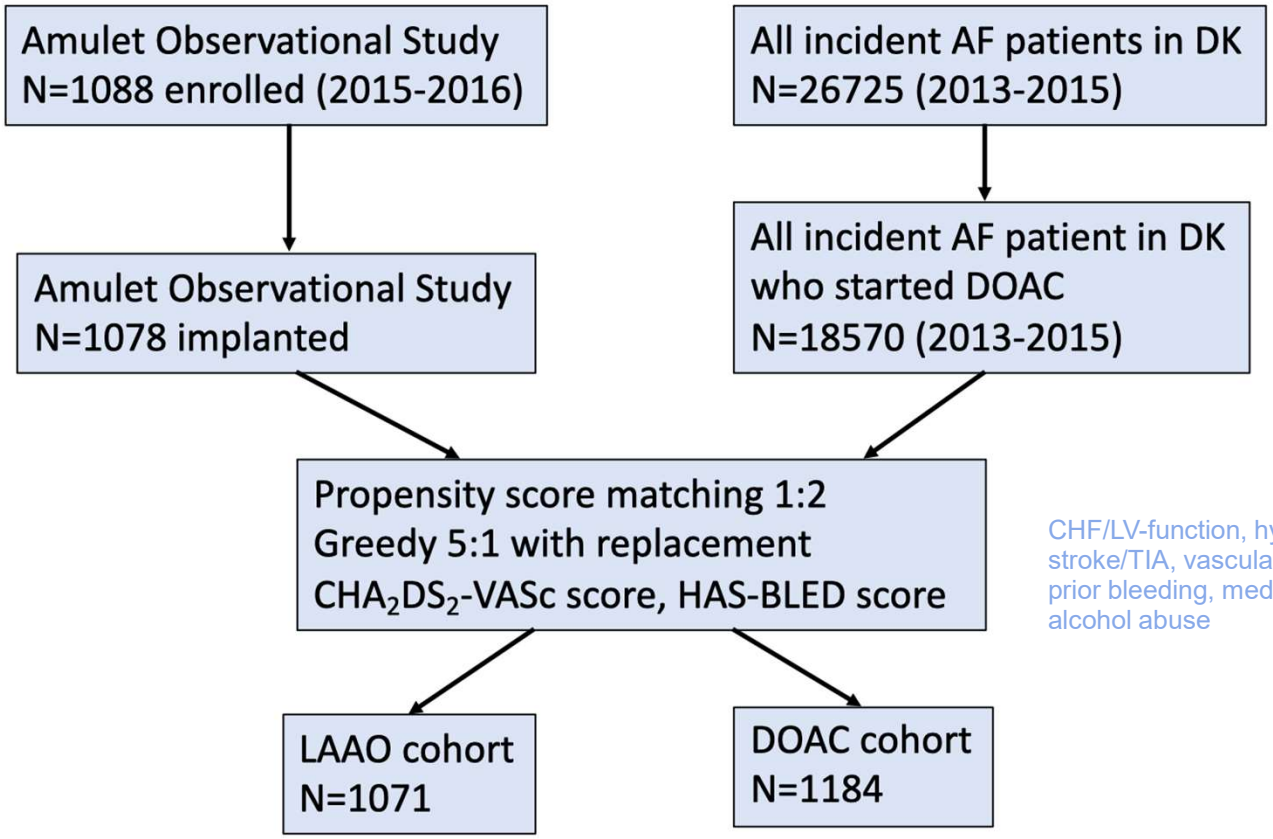
LAAO vs DOAC: A PS-matched study



CHF/LV-function, hypertension, age, diabetes, prior stroke/TIA, vascular disease, sex, renal/liver disease, prior bleeding, medication predisposing to bleeding, alcohol abuse

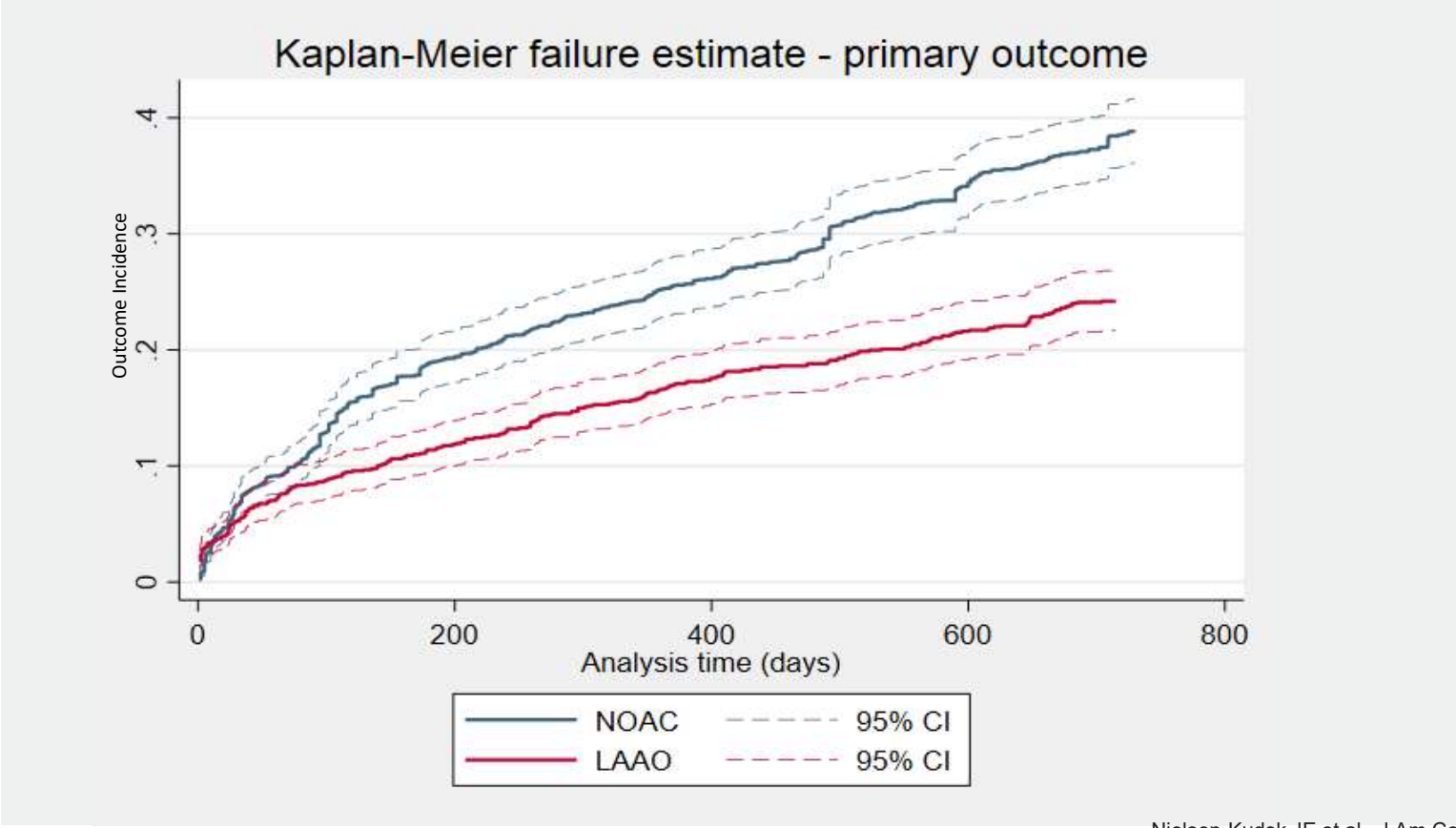
Nielsen-Kudsk JE et al., J Am Coll Cardiol Int. 2021;14:69-78

Patient characteristics

Patient characteristics	LAAO (n=1071)	NOAC (n=1184)
Age, mean (SD)	**75.1** (8.5)	**75.1** (10.5)
Gender (male) n (%)	64.2	61.4
Congestive heart failure (%)	16.6	18.9
Hypertension (%)	83.7	86.5
Diabetes mellitus (%)	31.1	35.8
Stroke (%)	31.1	31.8
Vascular disease (%)	37.2	37.6
Abnormal renal function (%)	13.9	14.3
Abnormal liver function (%)	4.8	6.5
Bleeding (%)	74.1	75.0
Drugs (%)	30.0	37.1
Alcohol (%)	4.7	5.1
CHA_2DS_2-VASc mean (SD)	**4.2** (1.6)	**4.3** (1.7)
HAS-BLED mean (SD)	**3.3** (1.0)	**3.4** (1.2)

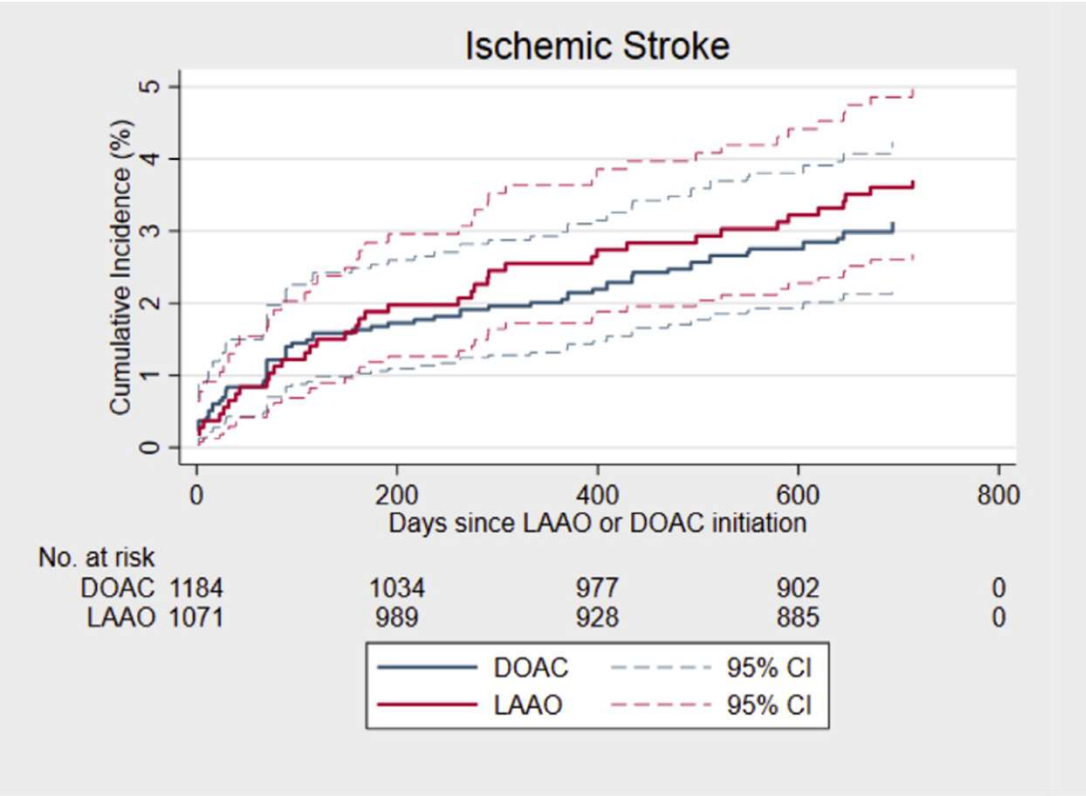
Nielsen-Kudsk JE et al., J Am Coll Cardiol Int. 2021;14:69-78

Results: primary outcome (ISCHEMIC STROKE, MAJOR BLEEDING, MORTALITY)



Nielsen-Kudsk JE et al., J Am Coll Cardiol Int. 2021;14:69-78

Results: secondary outcome

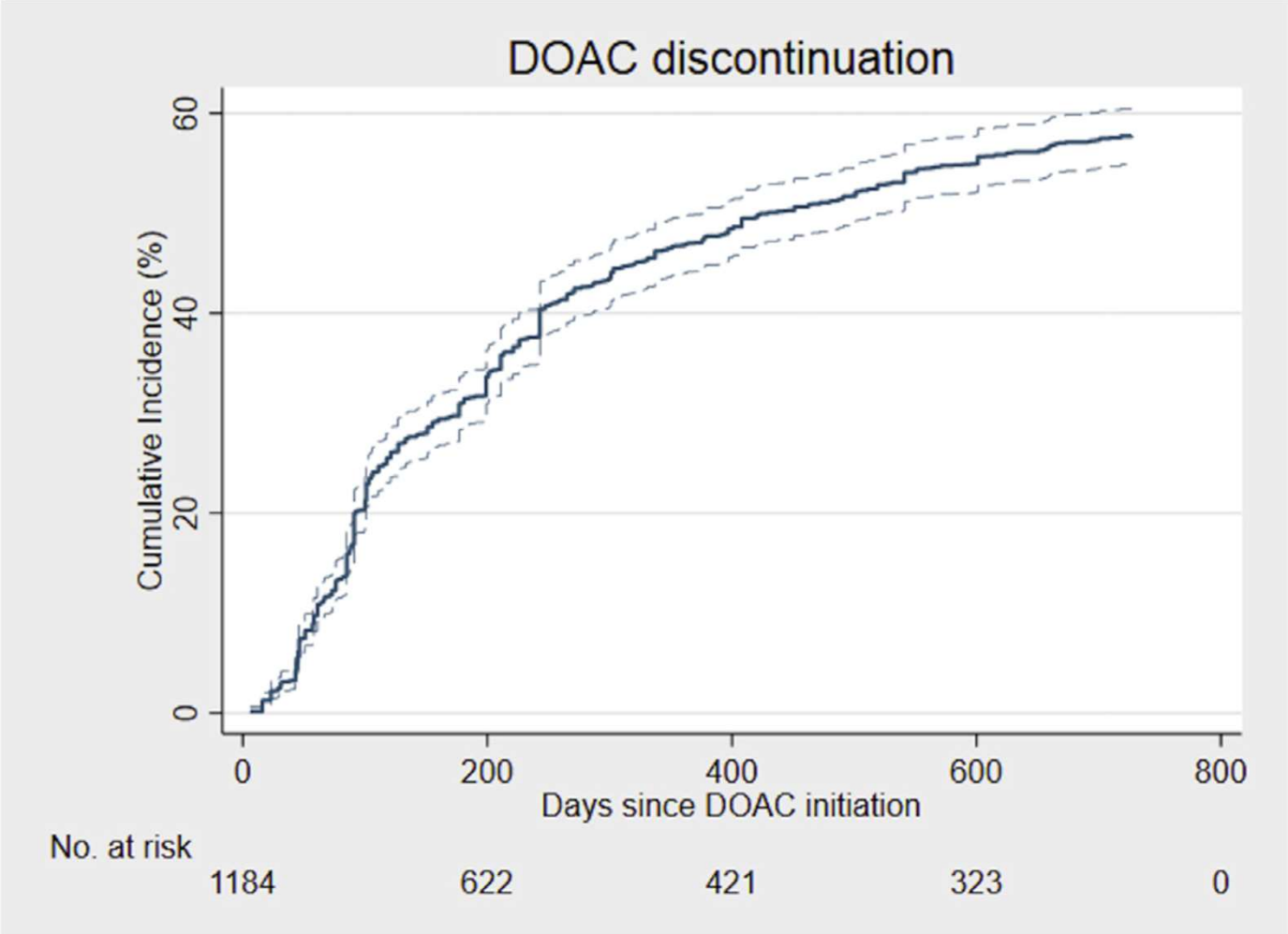


Nielsen-Kudsk JE et al., J Am Coll Cardiol Int. 2021;14:69-78

Results

	LAAO (n=1071)	NOAC (n=1184)
Isch. stroke/major bleeding/mortality		
Events, Event rate (pr. 100 pts yrs)(95% CI)	**256; 14.5** (12.8-16.5)	**461; 25.7** (22.1-30.0)
Hazard ratio (LAAO vs NOAC)(95% CI)	**0.57** (0.49-0.67)	
Ischemic stroke		
Events, Event rate (pr. 100 pts yrs)(95% CI)	**39; 2.1** (1.5-2.9)	**37; 1.9** (1.3-2.7)
Hazard ratio (LAAO vs NOAC)(95% CI)	**1.11** (0.71-1.75)	
Major bleeding		
Events, Event rate (pr. 100 pts yrs)(95% CI)	**108; 6.0** (4.9-7.3)	**183; 10.0** (8.0-12.6)
Hazard ratio (LAAO vs NOAC) (95% CI)	**0.62** (0.49-0.79)	
Mortality		
Events, Event rate (pr. 100 pts yrs)(95% CI)	**155; 8.0** (6.9-9.4)	**308; 15.3** (12.6-18.6)
Hazard ratio (LAAO vs NOAC) (95% CI)	**0.53** (0.43-0.64)	

Nielsen-Kudsk JE et al., J Am Coll Cardiol Int. 2021;14:69-78



DOAC discontinuation

3 months	20%
1 year	50%
2 years	58%

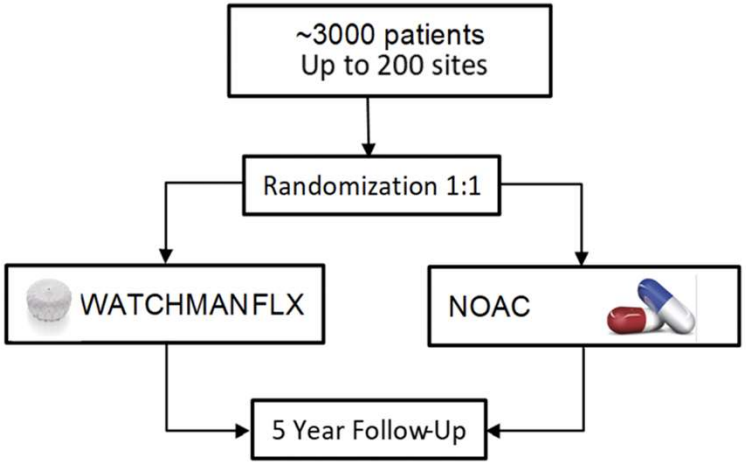
Nielsen-Kudsk JE et al., J Am Coll Cardiol Int. 2021;14:69-78

Trial: CHAMPION

PROMOTOR: BOSTON

DEVICE: WATCHMAN FLX

enrollement closed



Transthoracic Echo Exclusion Criteria	1. The subject has LVEF < 30% 2. The subject has an existing pericardial effusion with a circumferential echo-free space > 5mm 3. The subject has a high-risk patent foramen ovale (PFO) with an atrial septal aneurysm excursion > 15mm or length > 15mm 4. The subject has significant mitral valve stenosis (i.e., MV area <1.5 cm^2) Note: TEE, TTE, Cardiac CT or MRI performed within 180 days prior to randomization may be used if all the exclusion criteria can be evaluated.

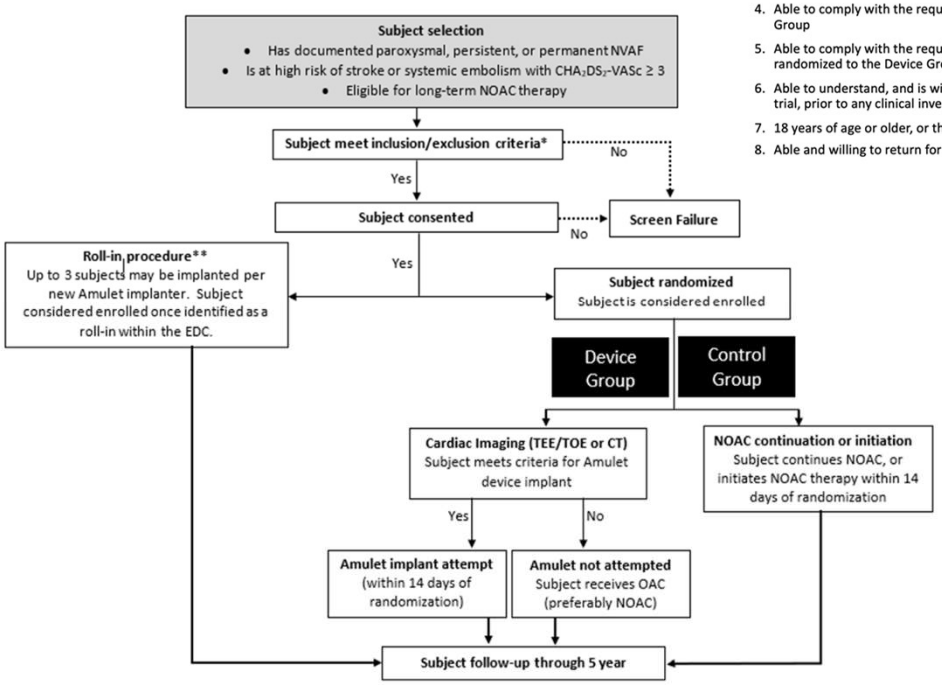
Inclusion Criteria	1. The subject is of legal age to participate in the study per the laws of their respective geography 2. The subject has documented non-valvular atrial fibrillation (i.e., atrial fibrillation in the absence of moderate or greater mitral stenosis or a mechanical heart valve) 3. The subject has a calculated CHA_2DS_2-VASc score of 2 or greater for men and 3 or greater for women 4. The subject is deemed to be suitable for the protocol defined pharmacologic regimens in both the test and control arms 5. The subject or legal representative is able to understand and willing to provide written informed consent to participate in the trial 6. The subject is able and willing to return for required follow-up visits and examinations

Exclusion Criteria	1. Subjects who are currently enrolled in another investigational study, except when the subject is participating in a mandatory governmental registry, or a purely observational registry with no associated treatments 2. The subject requires long-term anticoagulation therapy for reasons other than AF-related stroke risk reduction, for example due to an underlying hypercoagulable state (i.e., even if the device is implanted, the subjects would not be eligible to discontinue OAC due to other medical conditions requiring chronic OAC therapy) 3. The subject is contraindicated or allergic to oral anticoagulation medication and/or aspirin 4. The subject is indicated for chronic P2Y12 platelet inhibitor therapy 5. The subject had or is planning to have any cardiac or non-cardiac intervention or surgical procedure within 30 days prior to or 60 days after implant (including, but not limited to: cardioversion, percutaneous coronary intervention (PCI), cardiac ablation, cataract surgery, etc.) 6. The subject had a prior stroke (of any cause, whether ischemic or hemorrhagic) or transient ischemic attack (TIA) within the 30 days prior to enrollment 7. The subject had a prior major bleeding event per ISTH definition within the 30 days prior to randomization. Lack of resolution of related clinical sequelae or planned and pending interventions to resolve bleeding/bleeding source, are a further exclusion regardless of timing of the bleeding event 8. The subject has an active bleed 9. The subject has a reversible cause of AF or transient AF 10. The subject is absent of a LAA or the LAA is surgically ligated 11. The subject has had a myocardial infarction (MI) documented in the clinical record as either a non-ST elevation MI (NSTEMI) or as an ST-elevation MI (STEMI), with or without intervention, within 30 days prior to enrollment 12. The subject has a history of atrial septal repair or has an ASD/PFO device 13. The subject has an implanted mechanical valve prosthesis in any position 14. The subject has a known contraindication to percutaneous catheterization procedure 15. The subject has a known contraindication to TEE 16. The subject has a cardiac tumor 17. The subject has signs/symptoms of acute or chronic pericarditis. 18. The subject has an active infection 19. There is evidence of tamponade physiology 20. The subject has New York Heart Association Class IV Congestive Heart Failure at the time of enrollment 21. The subject is of childbearing potential and is, or plans to become, pregnant during the time of the study (method of assessment upon study physician's discretion) 22. The subject has a documented life expectancy of less than 3 years

Trial: CATALYST

PROMOTOR: ABBOTT
DEVICE: AMULET

enrollment on going



THE CATALYST TRIAL

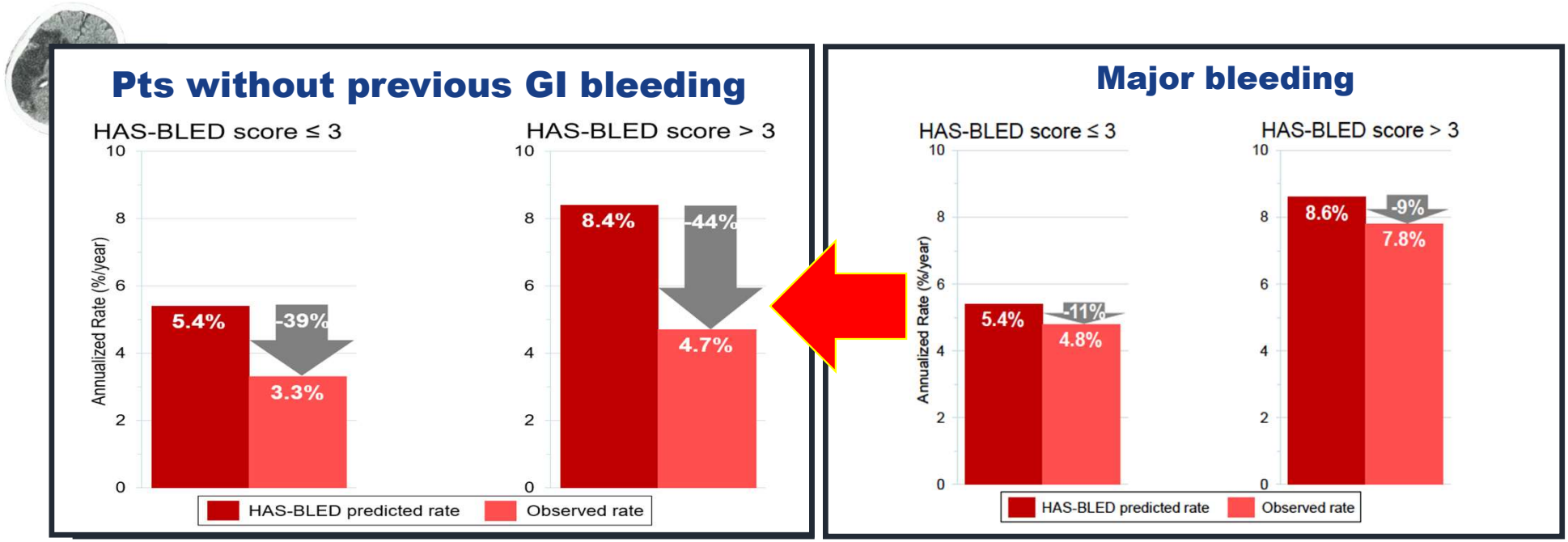
Inclusion Criteria

1. Documented paroxysmal, persistent, or permanent non-valvular AF (documentation must include an electrocardiogram, Holter, or event recorder)
2. At high risk of stroke or systemic embolism, defined as a CHA_2DS_2-VASc score of ≥ 3
3. Eligible for long-term NOAC therapy
4. Able to comply with the required NOAC medication regimen if randomized to the Control Group
5. Able to comply with the required medication regimen post-device implant if subject is randomized to the Device Group or subject is a Roll-in
6. Able to understand, and is willing to provide, written informed consent to participate in the trial, prior to any clinical investigation related procedure or assessment
7. 18 years of age or older, or the age of legal consent
8. Able and willing to return for required follow-up visits and assessments

Exclusion Criteria

1. Requires long-term OAC therapy for a condition other than AF
2. Planned cardiac intervention or surgery, which is invasive or requires sedation or anesthesia, within 3 months following randomization, other than study-related procedures such as LAAO and cardiac imaging (if applicable)
3. Known contraindication to, or allergic to, aspirin, clopidogrel, or OAC medication use
4. Indicated for P_2Y_{12} platelet inhibitor for > 1 year post-randomization
5. In the opinion of the investigator, is considered at high risk for general anesthesia and general anesthesia is planned for the study procedure
6. Has undergone atrial septal defect (ASD) repair or has an ASD closure device present
7. Has undergone patent foramen ovale (PFO) repair or has a PFO closure device implanted
8. Is implanted with a mechanical valve prosthesis
9. Is implanted with an inferior vena cava filter
10. History of rheumatic or congenital mitral valve heart disease
11. Has any of the customary contraindications for a percutaneous catheterization procedure (e.g. subject is too small to accommodate the ICE probe (if planned) or required catheters, or subject has active infection or bleeding disorder)
12. Customary contraindications for TEE/TOE (e.g., presence of esophageal varices, esophageal stricture, or history of esophageal cancer)
13. Experienced stroke or transient ischemic attack (TIA) within 90 days prior to randomization or implant procedure (as applicable)
14. Underwent any cardiac or non-cardiac intervention or surgery within 30 days prior to randomization
15. Underwent catheter ablation for AF or atrial flutter within 60 days prior to randomization
16. Experienced myocardial infarction within 90 days prior to randomization
17. New York Heart Association Class IV Congestive Heart Failure
18. Left ventricular ejection fraction ≤ 30% (per most recent assessment)
19. Symptomatic carotid disease (defined as > 50% lumen diameter narrowing on CTA, MRA, or TCD with symptoms of ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral stroke); if subject has a history of carotid stent or endarterectomy the subject is eligible if there is < 50% lumen diameter narrowing
20. Has known intracranial atherosclerosis and/or intracranial small vessel disease (defined as 6 points on the Fazekas Scale)
21. Reversible cause of AF (i.e., secondary to thyroid disorders, acute alcohol intoxication, trauma, recent major surgical procedures)
22. History of idiopathic or recurrent venous thromboembolism
23. LAA is obliterated or surgically ligated
24. Thrombocytopenia (defined as < 50,000 platelets per microliter (<50 x 109 /L)) or anemia (defined as hemoglobin < 10 g/dL) requiring transfusions
25. Hypersensitivity to any portion of the device material or individual components of the Amulet LAA occluder device (e.g., nickel allergy)
26. Actively enrolled in, or plans to enroll in, a concurrent clinical study in which the active treatment arm may confound the results of this trial
27. Is pregnant or breastfeeding, or pregnancy is planned during the course of the investigation
28. Active endocarditis or other infection producing bacteremia
29. Transient case of AF (i.e., never previously detected, provoked/induced by surgical or catheter manipulations, etc.)
30. Severe renal failure (estimated glomerular filtration rate <30 ml/min/1.73m2), but not on dialysis
31. Life expectancy is less than 2 years in the opinion of the Investigator
32. Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the Investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow up requirements, or impact the scientific soundness of the clinical investigation results.

Multicentre, prospective, real-world registry (N=1,088 patients) 82.8% of pts contraindicated to long-term anticoagulation 72.4% with previous major bleeding



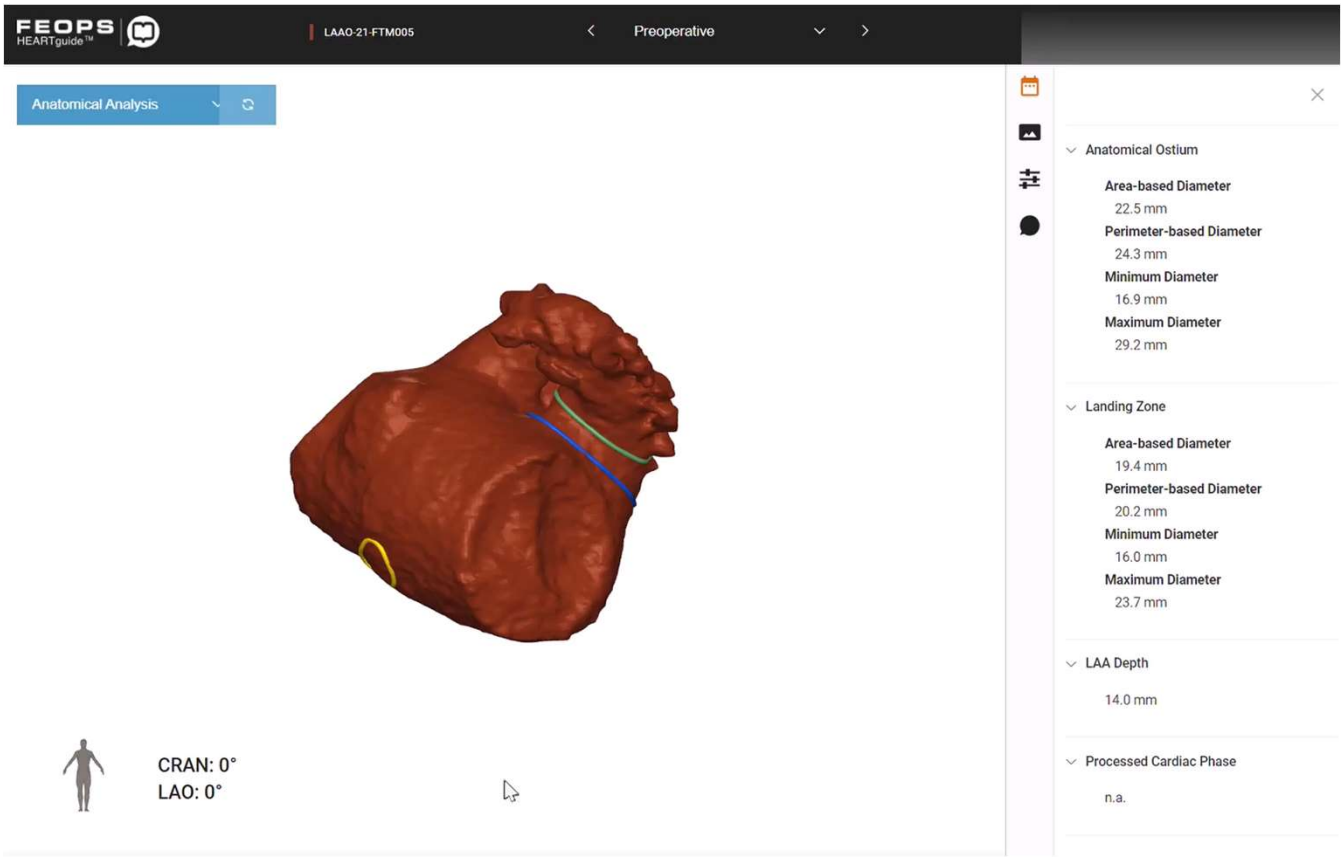
JACC Intv. 2020

Comparison of Clinical Features Between Ischemic & Hemorrhagic Strokes *(4764 pts)*

	Hemorrhagic Strokes	Ischemic Strokes	P value
Age	74.5 ± 13.2	75.8 ± 14.7	0.009
Male Sex	55%	49.3%	0.001
Hypertension	77%	79%	0.17
Diabetes	31.8%	32%	0.88
Hyperlipidemia	49.2%	49.6%	0.84
Pre-stroke Disability	6.6%	9.3%	0.02
CHA_2DS_2-VASc	3.96	4.17	0.001
NIHSS	12 ± 10	10.4 ± 9	<0.001
Length of Stay (days)	9.3 ± 9	7.4 ± 7	<0.001
Death/Disability at DC	76%	57%	<0.001
In Hospital Case Fatality	38%	11.7%	<0.001

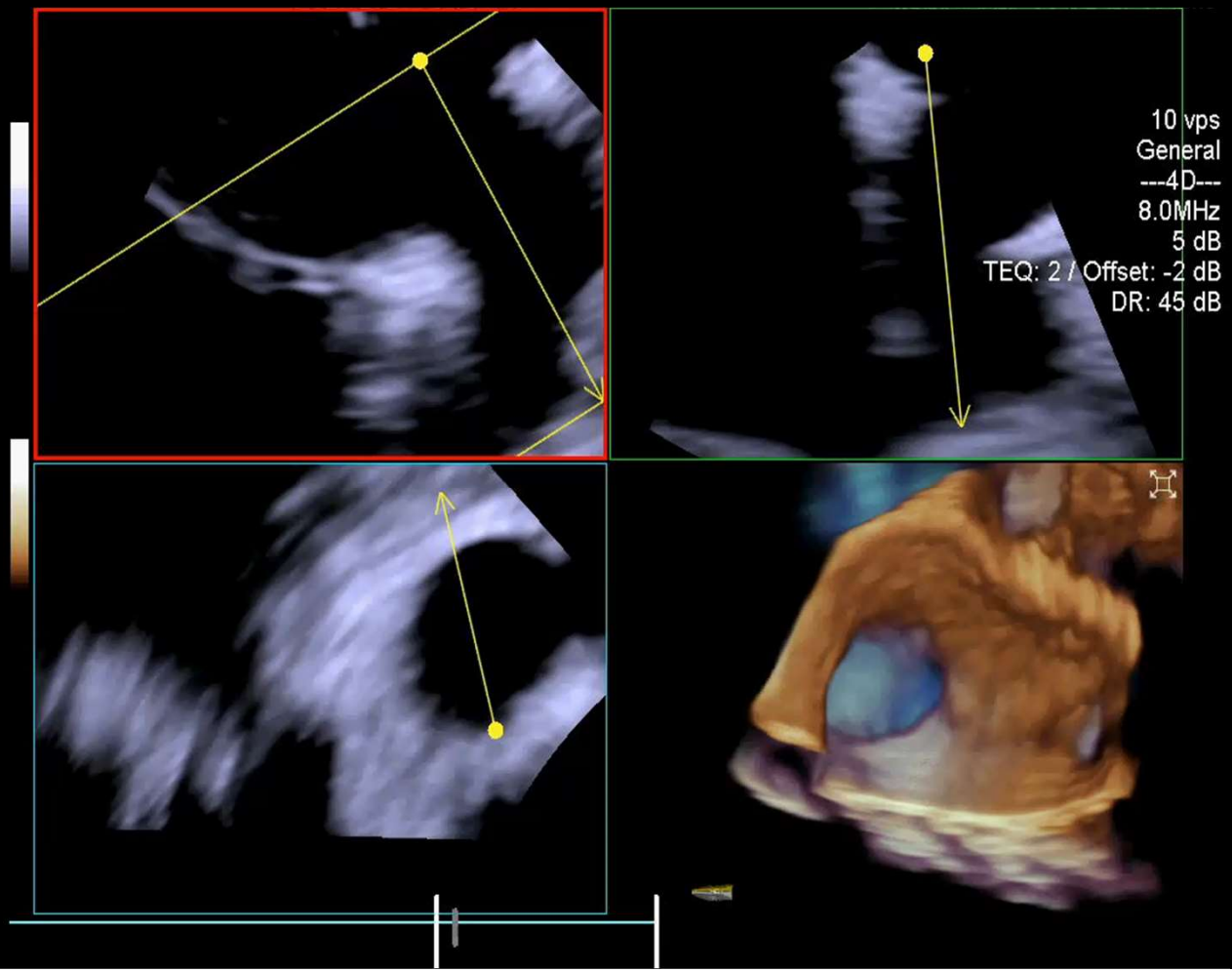
Gurol E, Neuro AF 2021

FEops HEARTguide™ - Case report at Fondazione Toscana Gabriele Monasterio, Massa, Italy

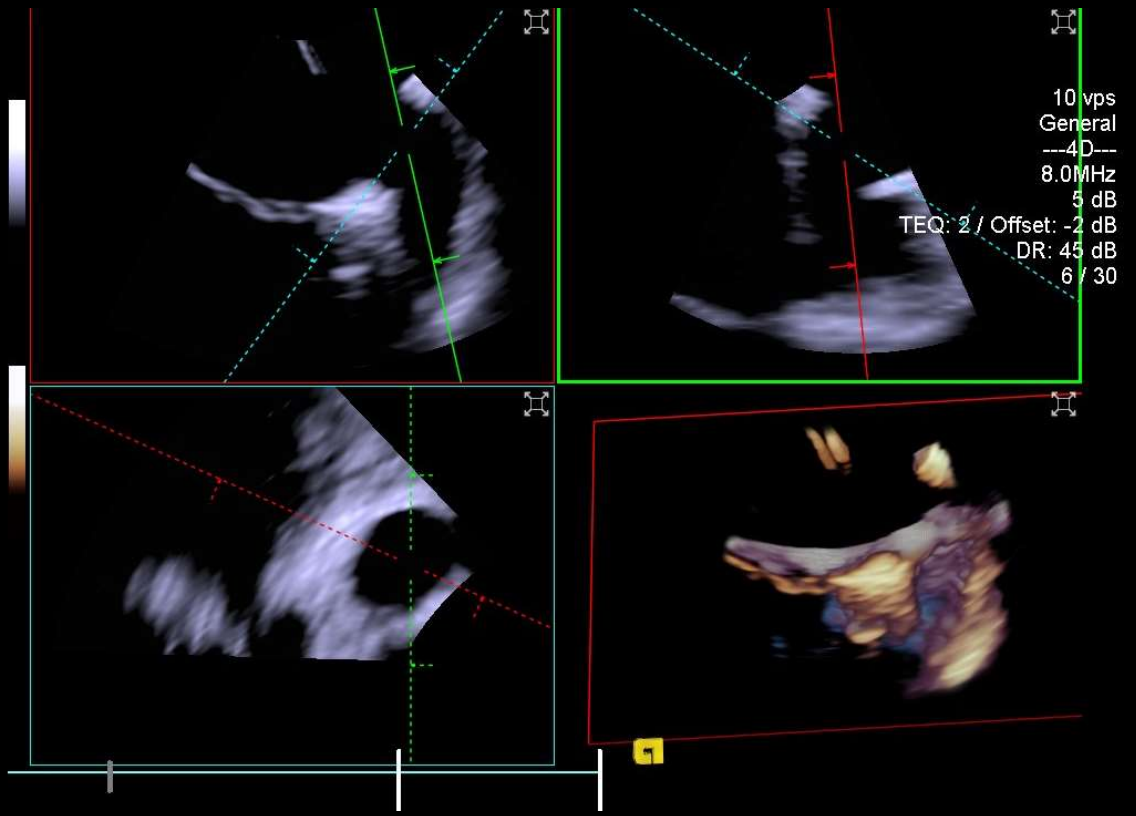


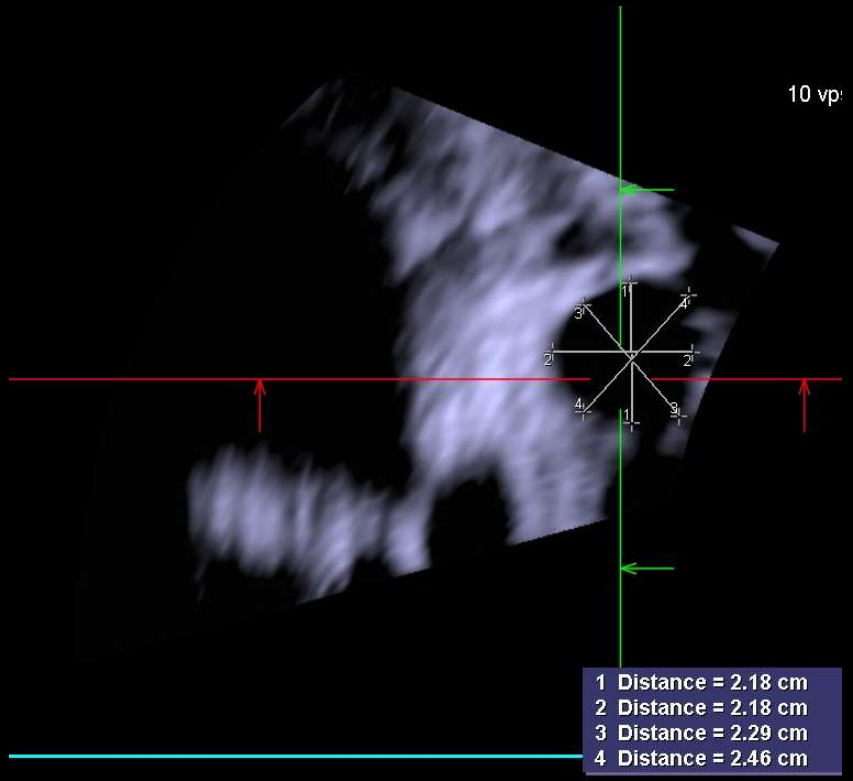
Case LAAO-21-FTM005, Fondazione Toscana Gabriele Monasterio, Massa, Italy

LAAo: ICE 4D Intraprocedural Views

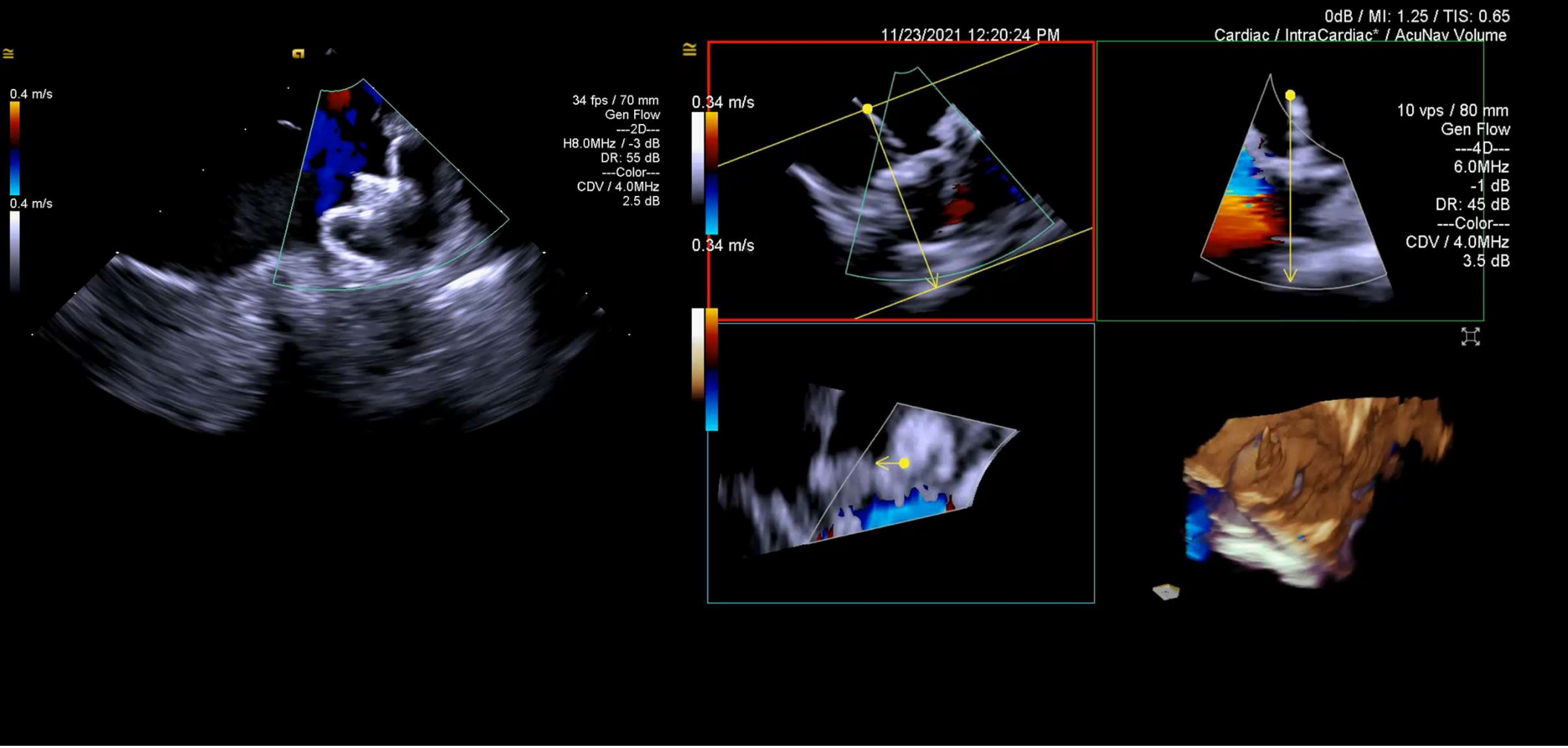


LAAo: ICE 4D Intraprocedural Views, MPR evaluation



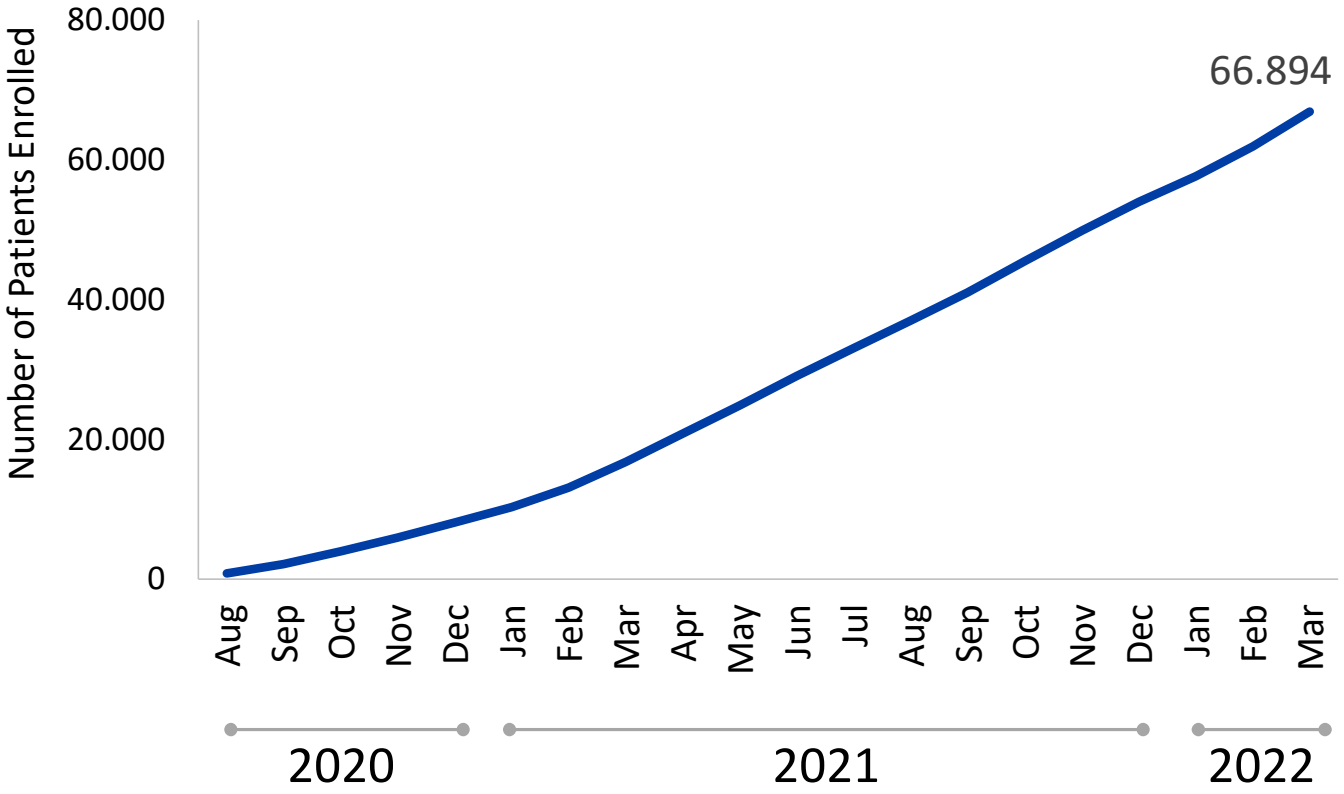


LAAo: ICE 4D Intraprocedural Views



SURPASS: FLX data from the US LAAO registry

Patient Flow & Enrolment Cadence



Patient Flow

Discharge* N=66,894

N=4931 no follow-up or event

45-day Follow-up N=61,963**

N=43,730 not yet in 1-year follow-up window or lost-to-follow-up

1-year Follow-up N=18,233**

*Enrolled between 5Aug20 to 31Mar22 at 743 sites

**Patients with follow-up or an event 31 days or 305 days after the procedure

Kapadia et al. Real-world Experience with WATCHMAN FLX: Outcomes at One-year from SURPASS, LBCT, CRT, 2023

SH-1537410-AA

Key Safety Endpoint

Defined as the occurrence of all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention between device implantation and seven days or hospital discharge (whichever is later)

Event	SURPASS N=66,894
Key Safety Endpoint	0.49% (328/66,894)
All-cause death	0.18% (123/66,894)
Ischemic stroke	0.13% (84/66,894)
Systemic embolism	0.00% (3/66,894)
Device or procedure related events requiring intervention	0.22% (150/66,894)

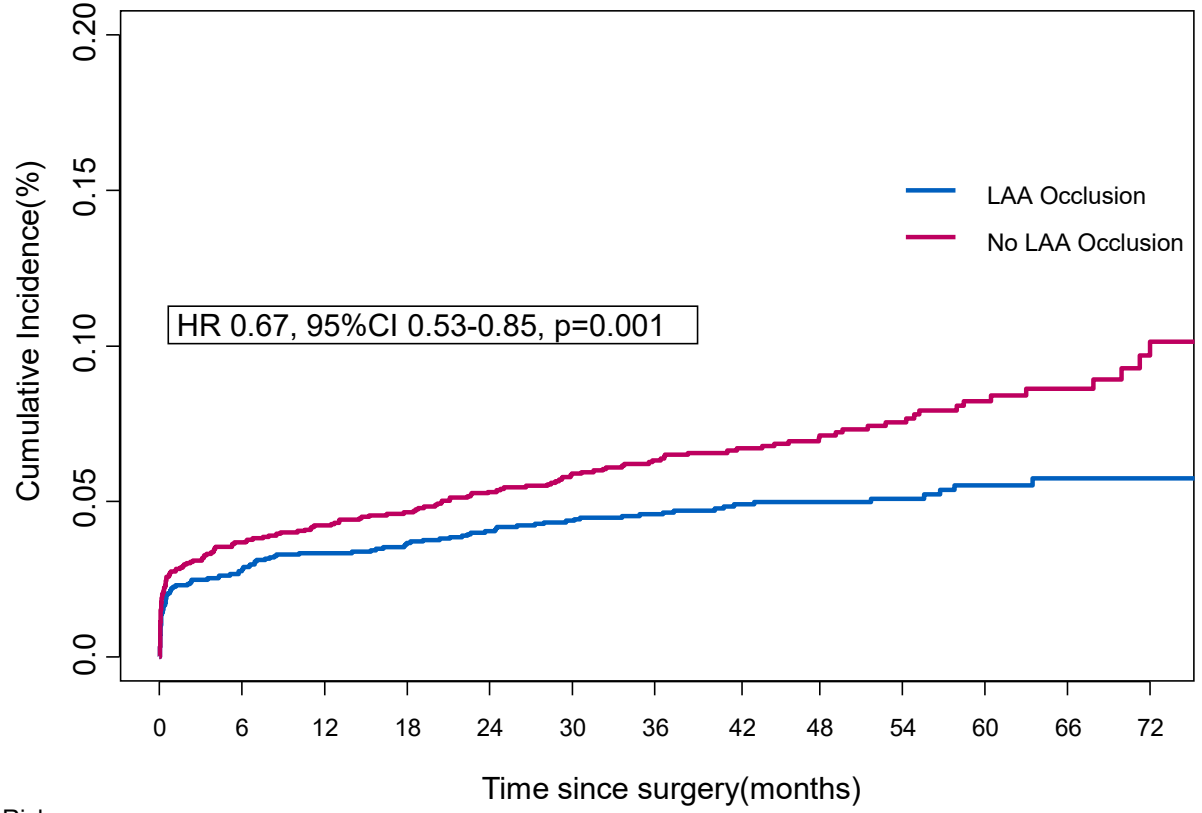
Binary rate; patients may have had more than one safety event.

Kapadia et al. Real-world Experience with WATCHMAN FLX: Outcomes at One-year from SURPASS, LBCT, CRT, 2023

LAAOS III Methods

- Primary outcome is ischemic stroke or systemic embolism
- Intention-to-treat analysis of all patients who had surgery
- Secondary landmark analysis, starting 30 days post-op
- Primary safety outcome was hospitalization for heart failure

Stroke or Systemic Embolism



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

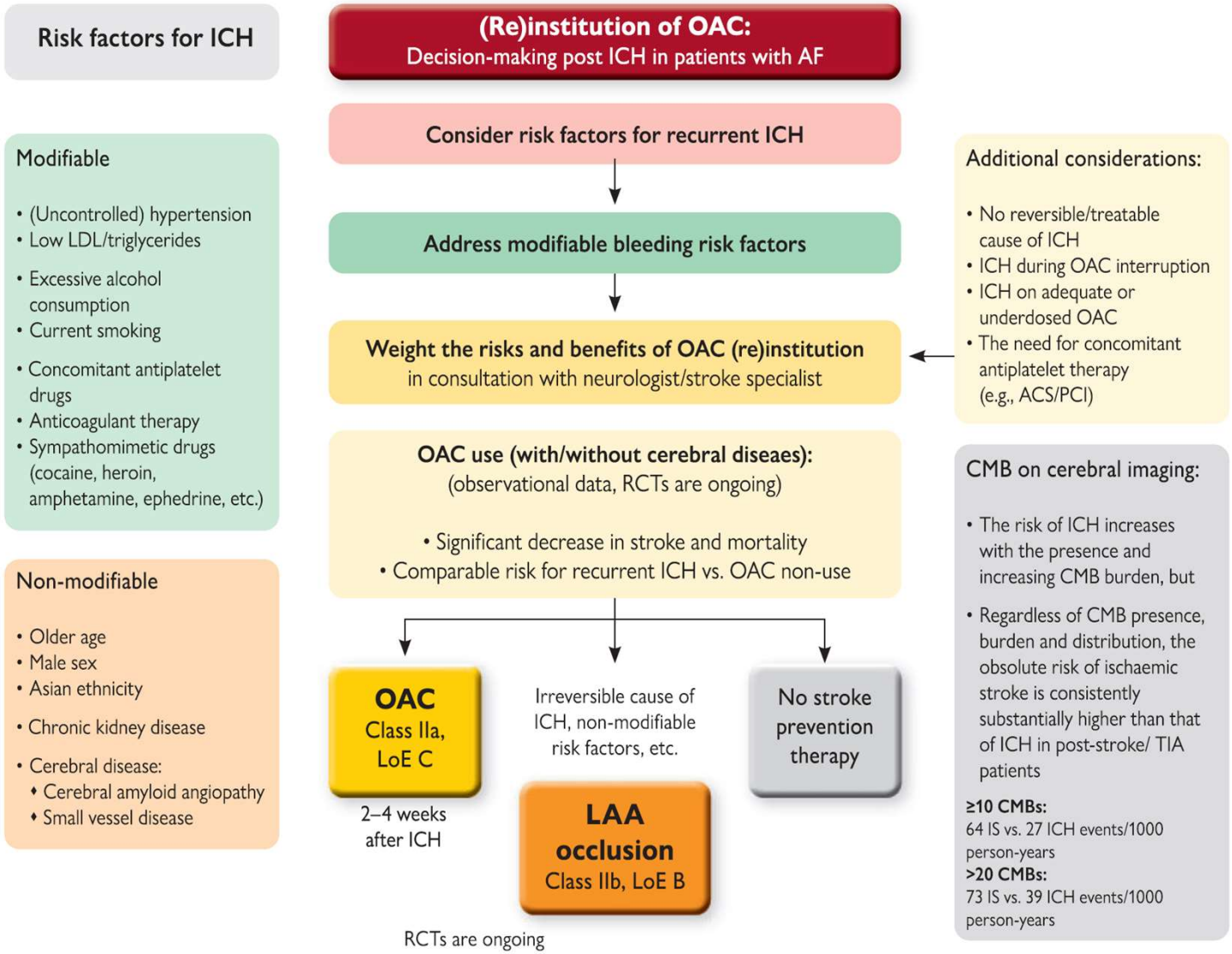
ESC European Society of Cardiology

European Heart Journal (2020) **42**, 373–498
doi:10.1093/eurheartj/ehaa612

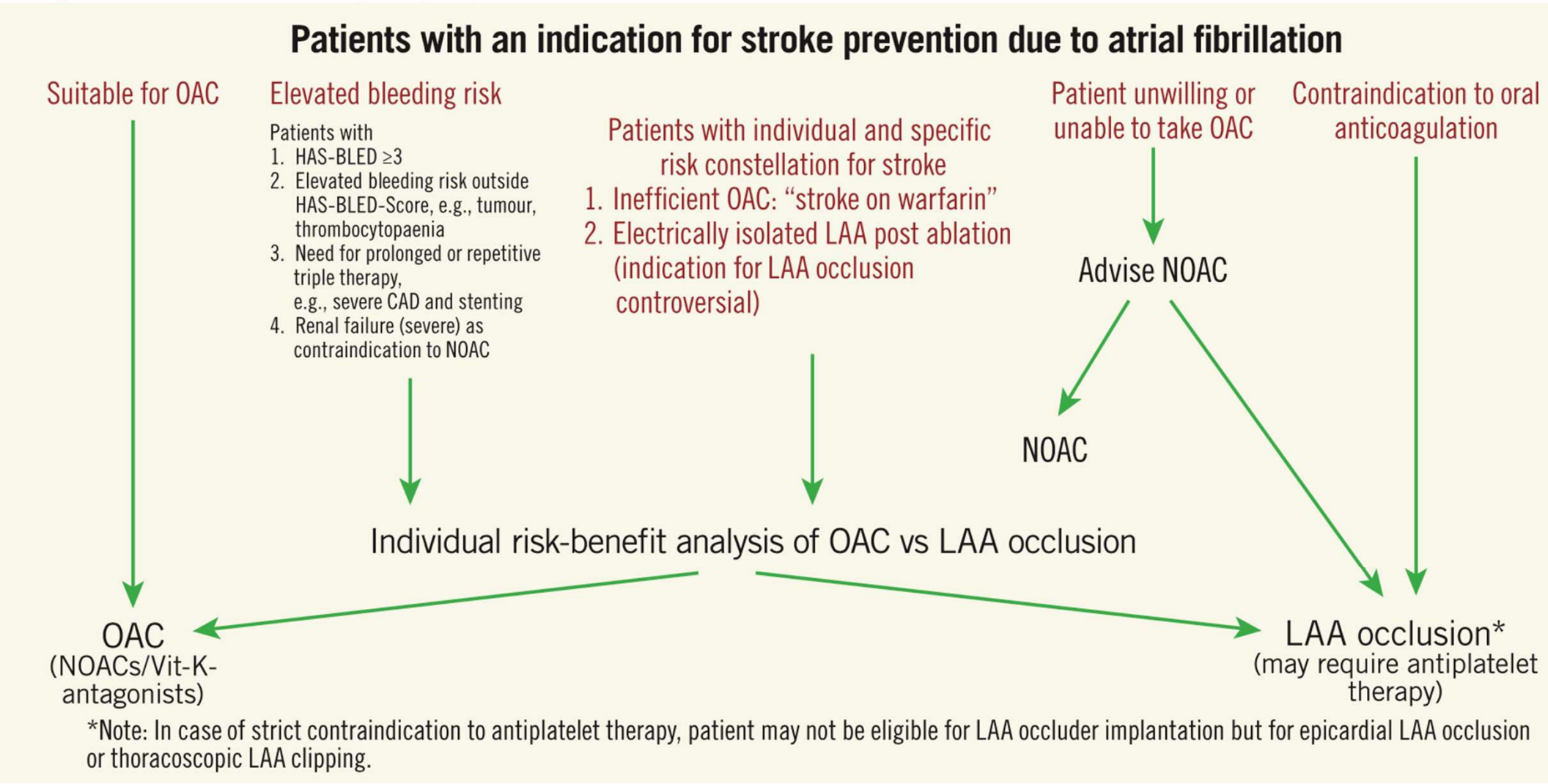
ESC GUIDELINES

2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)

Recommendations for occlusion or exclusion of the LAA		
LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (e.g. intracranial bleeding without a reversible cause).[448,449,481,482]	IIb	B
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery.[459,483]	IIb	C

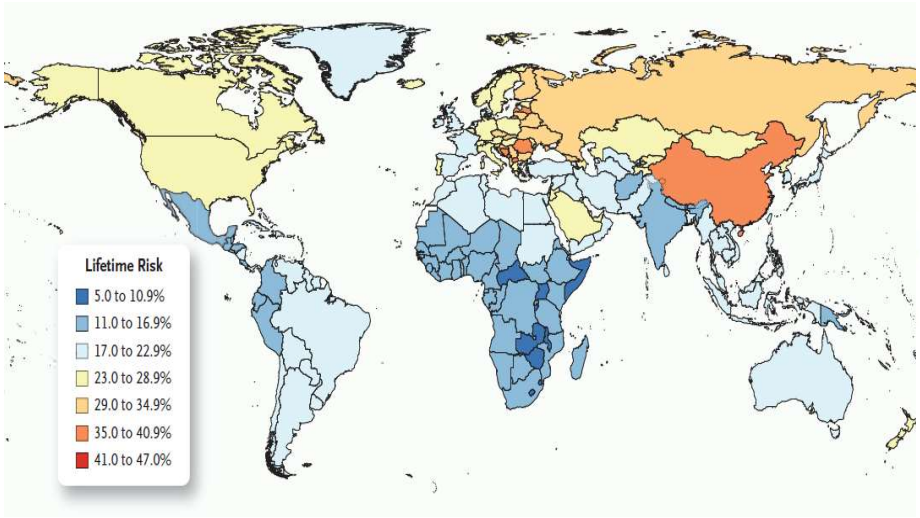

Risk factors for ICH
Modifiable
• (Uncontrolled) hypertension
• Low LDL/triglycerides
• Excessive alcohol consumption
• Current smoking
• Concomitant antiplatelet drugs
• Anticoagulant therapy
• Sympathomimetic drugs (cocaine, heroin, amphetamine, ephedrine, etc.)
Non-modifiable
• Older age
• Male sex
• Asian ethnicity
• Chronic kidney disease
• Cerebral disease:
♦ Cerebral amyloid angiopathy
♦ Small vessel disease
(Re)institution of OAC:
Decision-making post ICH in patients with AF
Consider risk factors for recurrent ICH
Address modifiable bleeding risk factors
Weight the risks and benefits of OAC (re)institution
in consultation with neurologist/stroke specialist
OAC use (with/without cerebral diseaes):
(observational data, RCTs are ongoing)
• Significant decrease in stroke and mortality
• Comparable risk for recurrent ICH vs. OAC non-use
OAC
Class IIa, LoE C
2–4 weeks after ICH
Irreversible cause of ICH, non-modifiable risk factors, etc.
LAA occlusion
Class IIb, LoE B
RCTs are ongoing
No stroke prevention therapy
Additional considerations:
• No reversible/treatable cause of ICH
• ICH during OAC interruption
• ICH on adequate or underdosed OAC
• The need for concomitant antiplatelet therapy (e.g., ACS/PCI)
CMB on cerebral imaging:
• The risk of ICH increases with the presence and increasing CMB burden, but
• Regardless of CMB presence, burden and distribution, the obsolute risk of ischaemic stroke is consistently substantially higher than that of ICH in post-stroke/ TIA patients
≥10 CMBs:
64 IS vs. 27 ICH events/1000 person-years
>20 CMBs:
73 IS vs. 39 ICH events/1000 person-years

ESC Europace (2019) **0**, 1–50

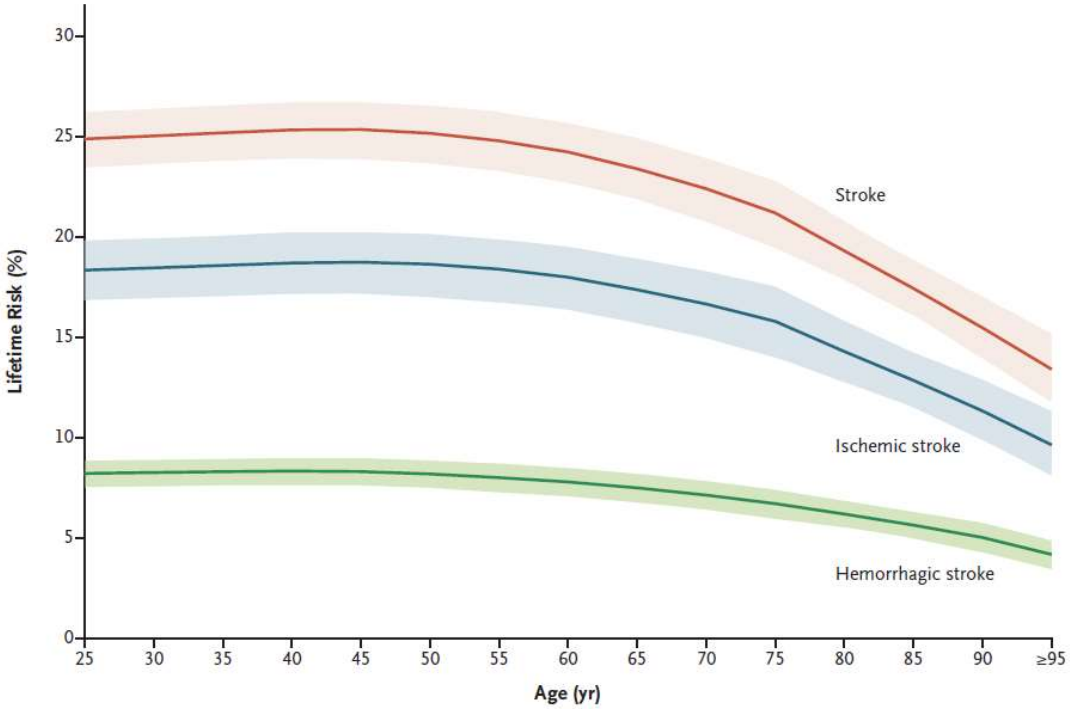


GLOBAL STROKE RISK OVER THE COURSE OF LIFE

(PCS ≥ 25 YEARS)



Rischio globale di stroke nel mondo, 2016



probabilità lifetime di essere colpiti da stroke

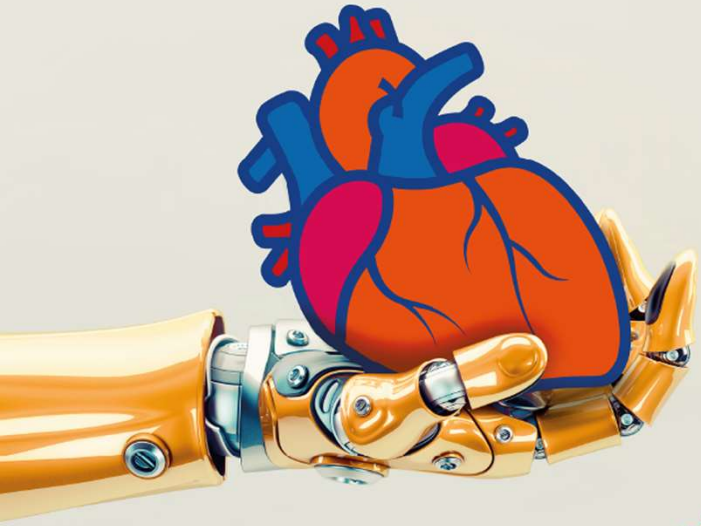
Feigin V.L. et N Engl J Med 2018;379:2429-37.al;

Documento di posizione della Società Italiana di Cardiologia Interventistica (SICI-GISE): Chiusura percutanea dell'auricola sinistra in pazienti affetti da fibrillazione atriale non valvolare

Sergio Berti[1], Claudio Tondo[2], Cristina Basso[3], Achille Gaspardone[4], Paolo Golino[5], Francesco Meucci[6], Matteo Montorfano[7], Guido Parodi[8], Filippo Russo[7], Francesco Saia[9], Francesco Cardaioli[10], Gennaro Santoro[11], Antonio Rapacciuc osito[14], Giuseppe Tarantini[10]

GISE
Società Italiana di Cardiologia Interventistica

G Ital Cardiol 2022;23(2):136-154



17° Meeting

CardioLucca

Heart Brings Heart 2023

Lucca, 22-24 Giugno 2023

Centro Congressi Auditorium San Francesco

Fondazione Monasterio

la ricerca che cura

Sergio Berti

Quando escludere l'auricola nella fibrillazione atriale

Ospedale del Cuore
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Consiglio Nazionale delle Ricerche