

FERMETURE AG, une alternative aux AOD?



CARDIO
RUN
2023



G. Montalescot

Dr. Montalescot reports research Grants to the Institution or Consulting/Lecture Fees from Abbott, Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, Boston Scientific, Bristol-Myers-Squibb, Cell-Prothera, CSL-Behring, Europa, Idorsia, Servier, Medtronic, MSD, Novartis, Pfizer, Quantum Genomics, Sanofi-Aventis.

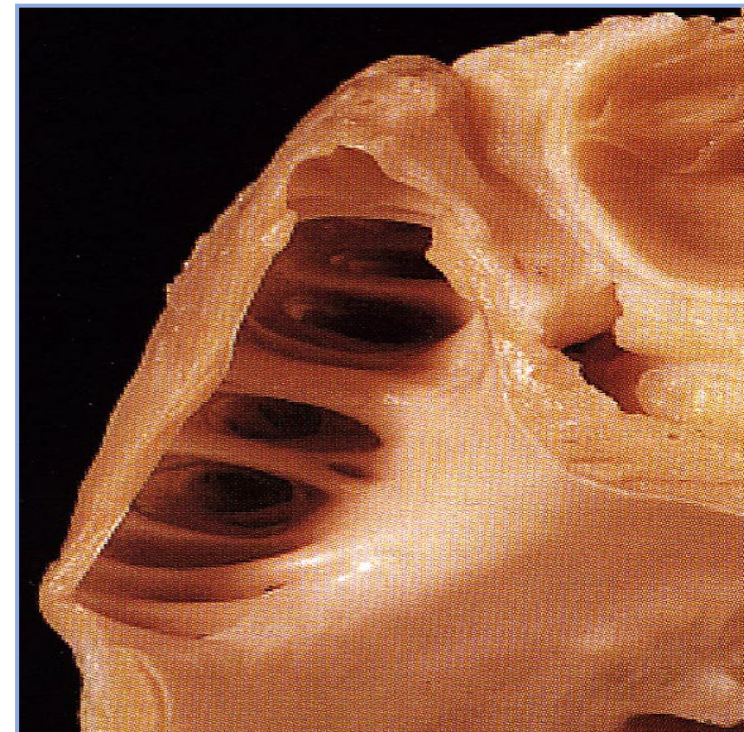
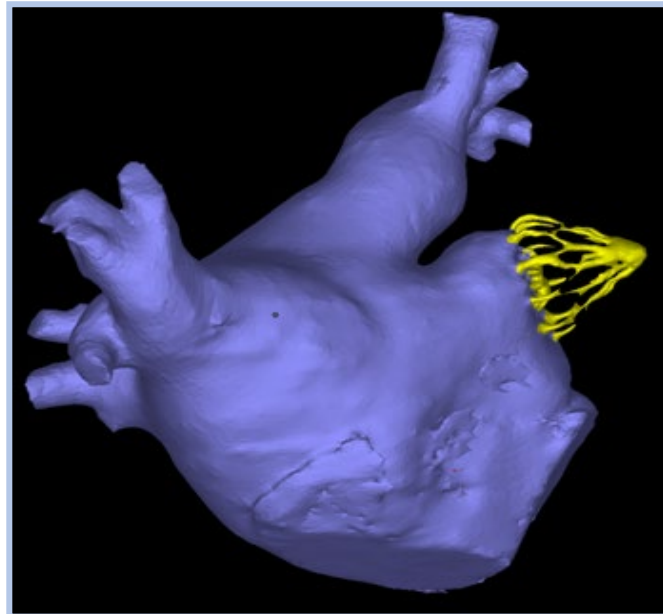
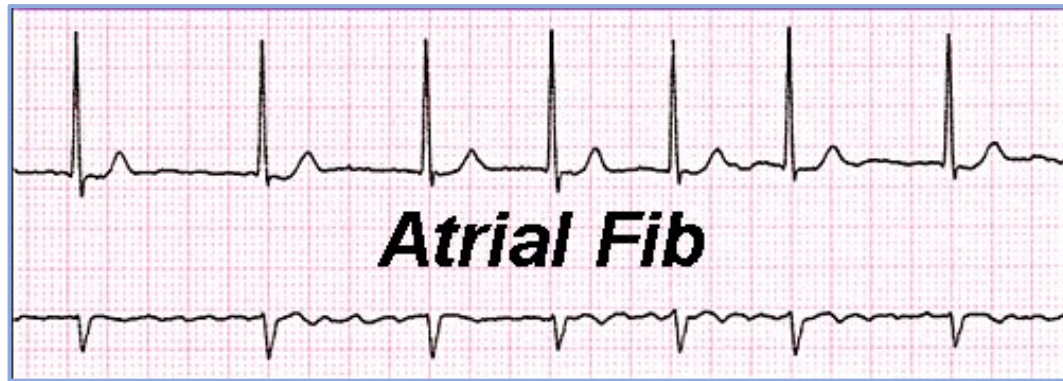


Paris, France

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Expérience initiale



PLAATO®

P: 189.5 (coil)

Sep 27 2004

DFOV 16.9cm

CA

R
P

L
A

26.1 / Vol. Render.

kv 120

mA 286

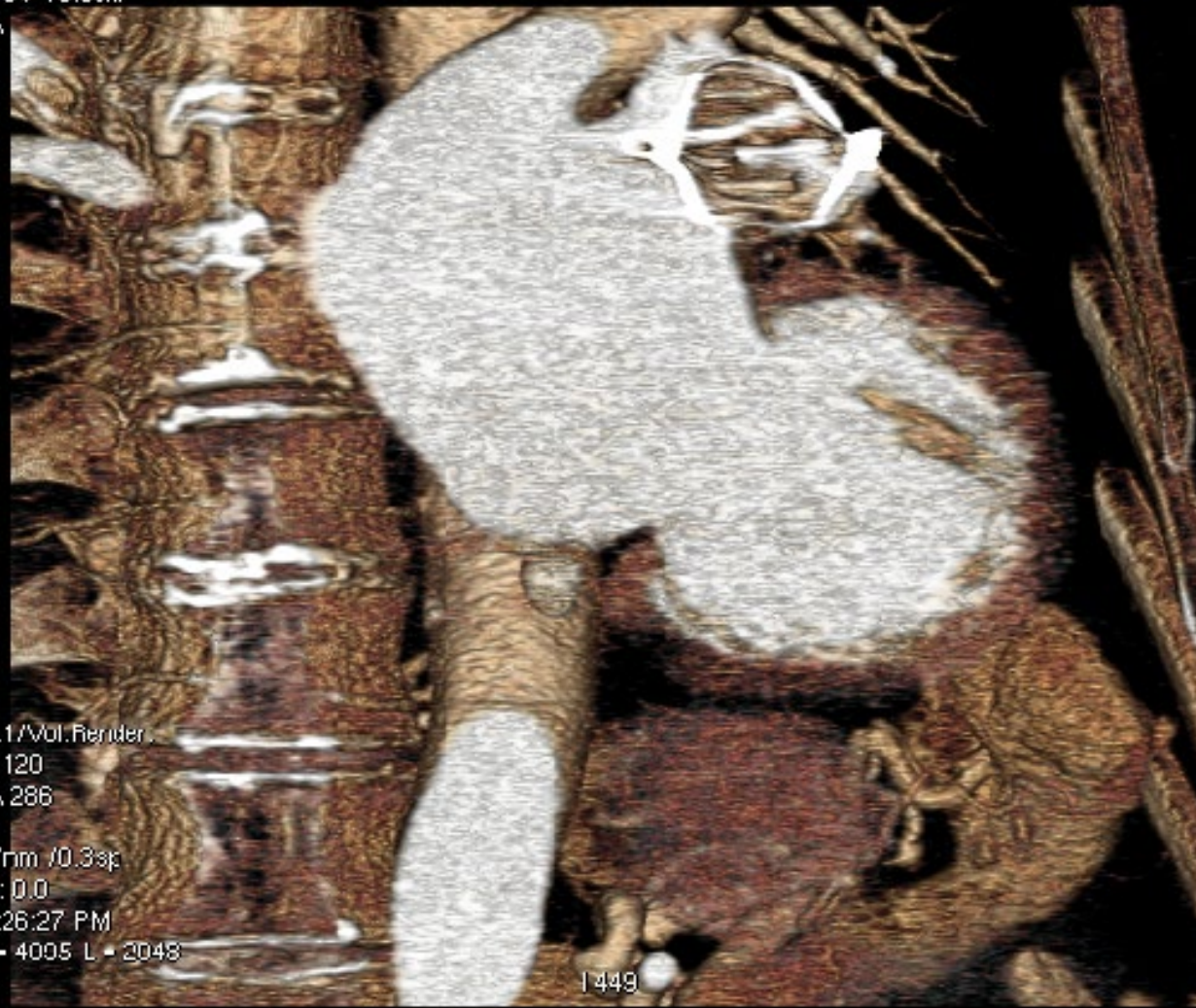
0.7mm / 0.3sp

Tilt: 0.0

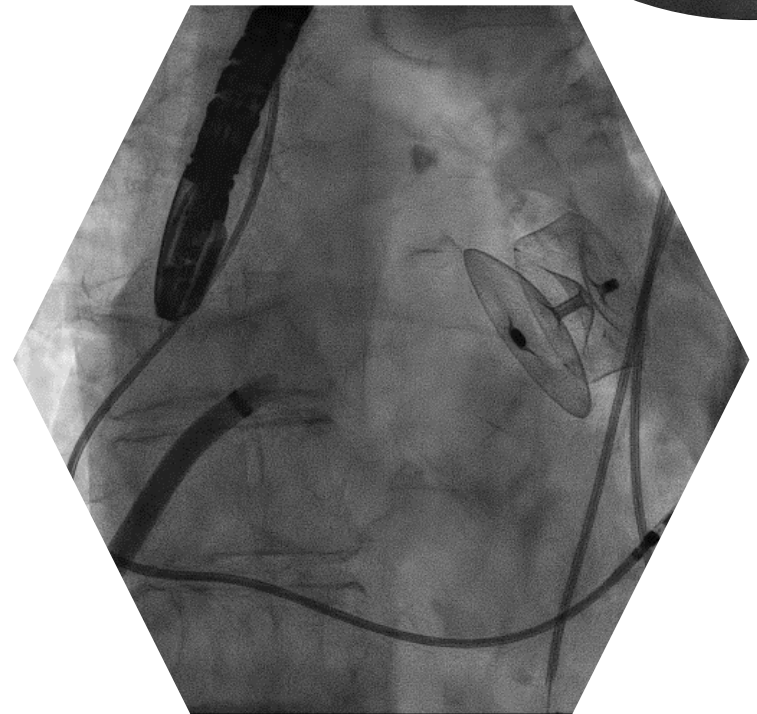
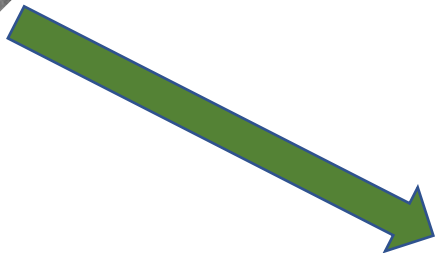
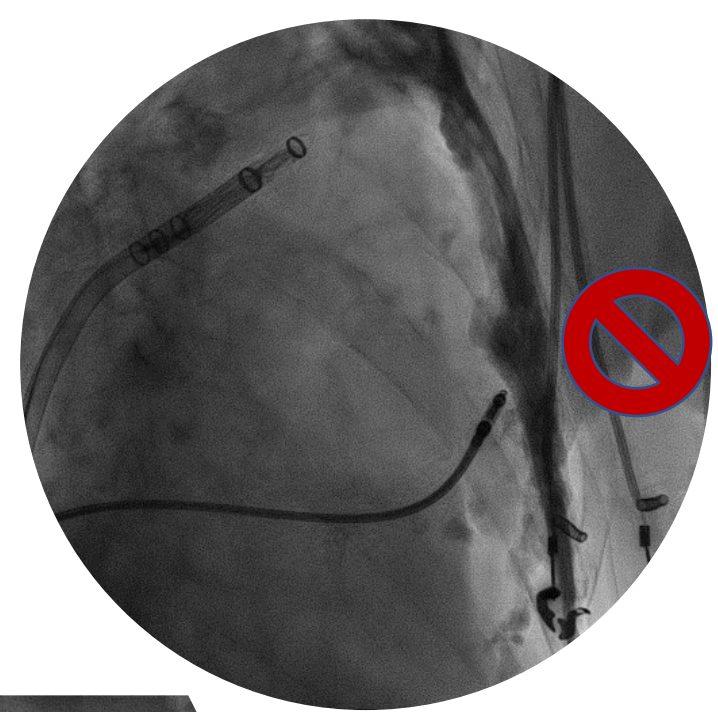
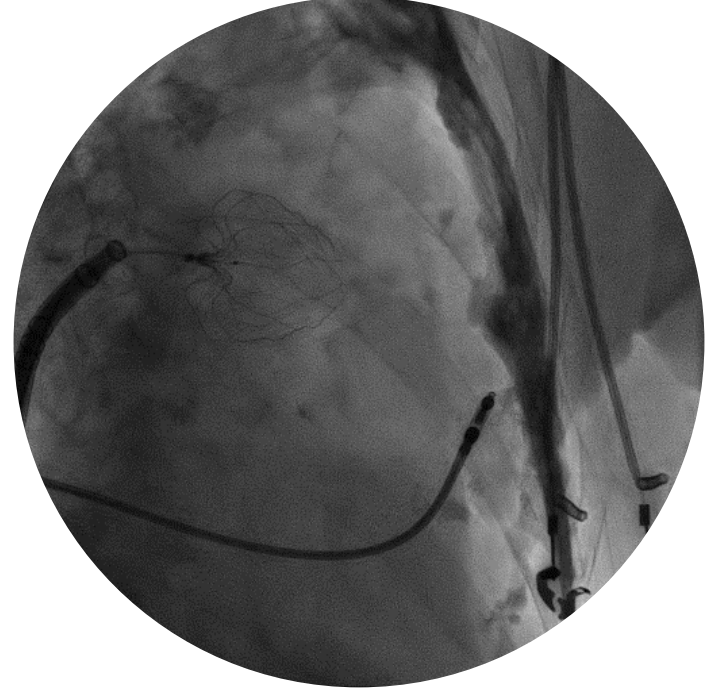
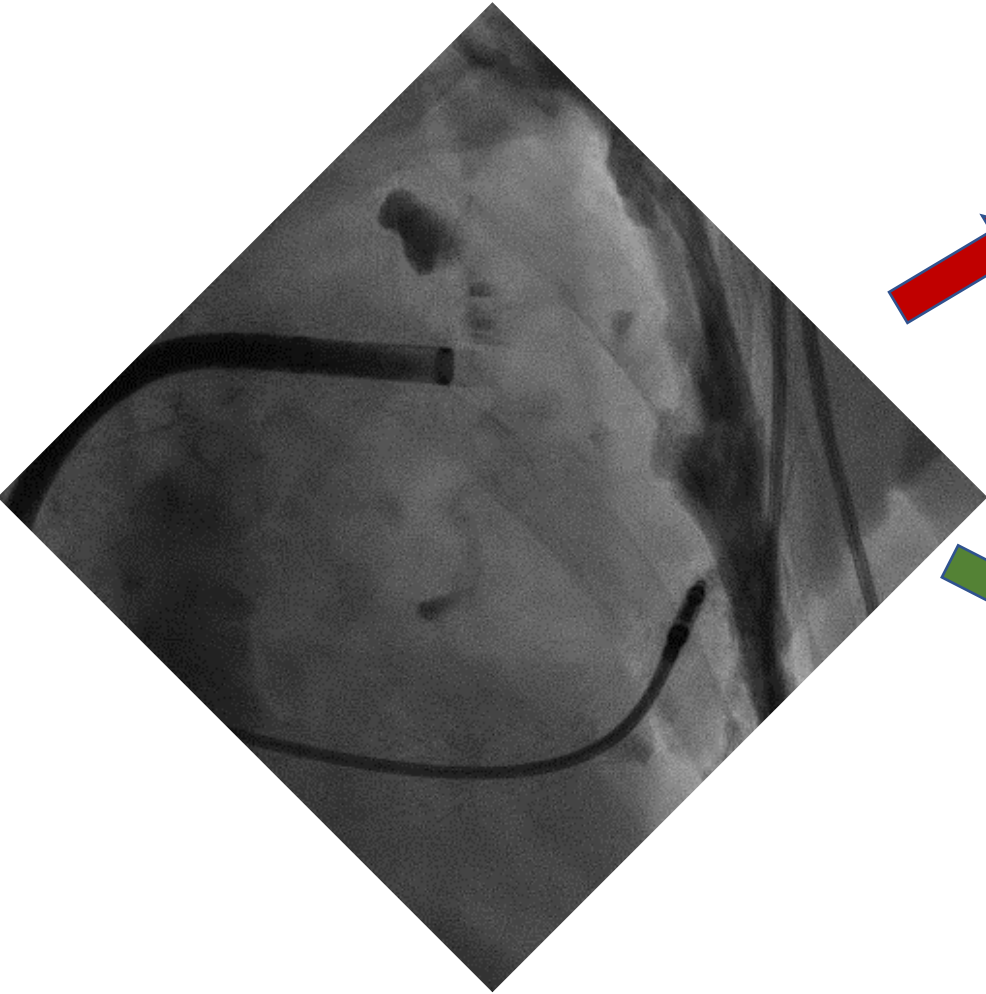
03:26:27 PM

W - 4005 L - 2048

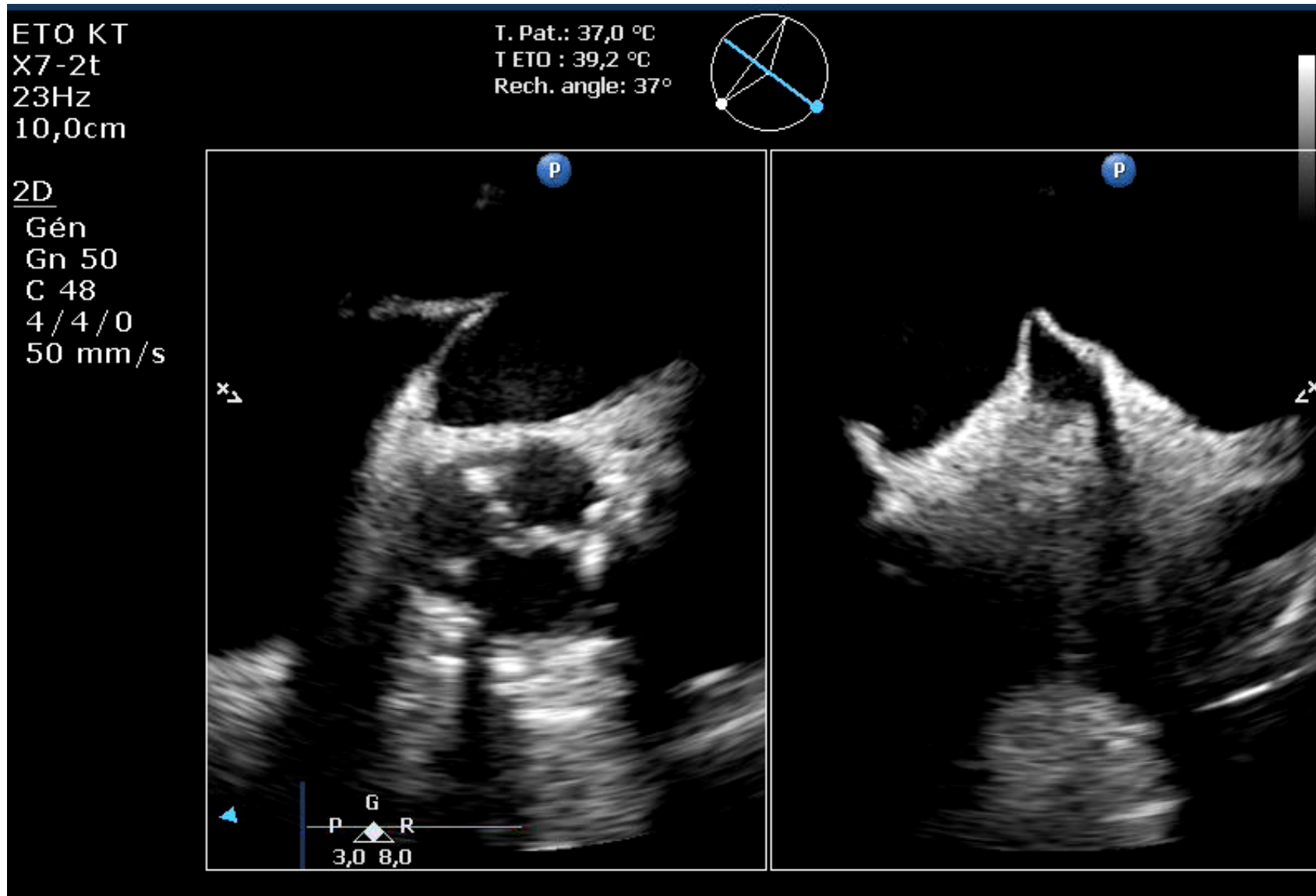
1449



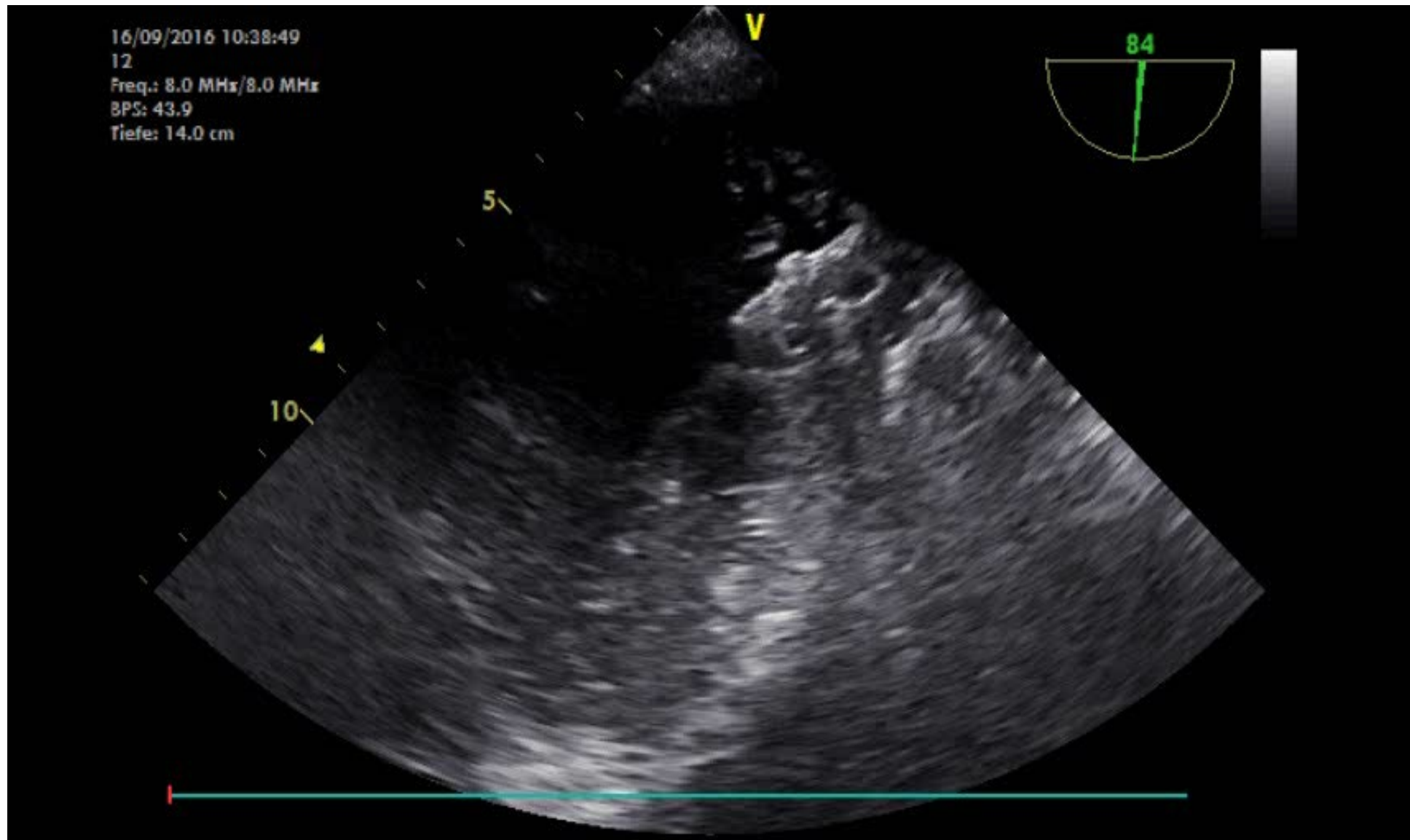
Fermer tout auricule



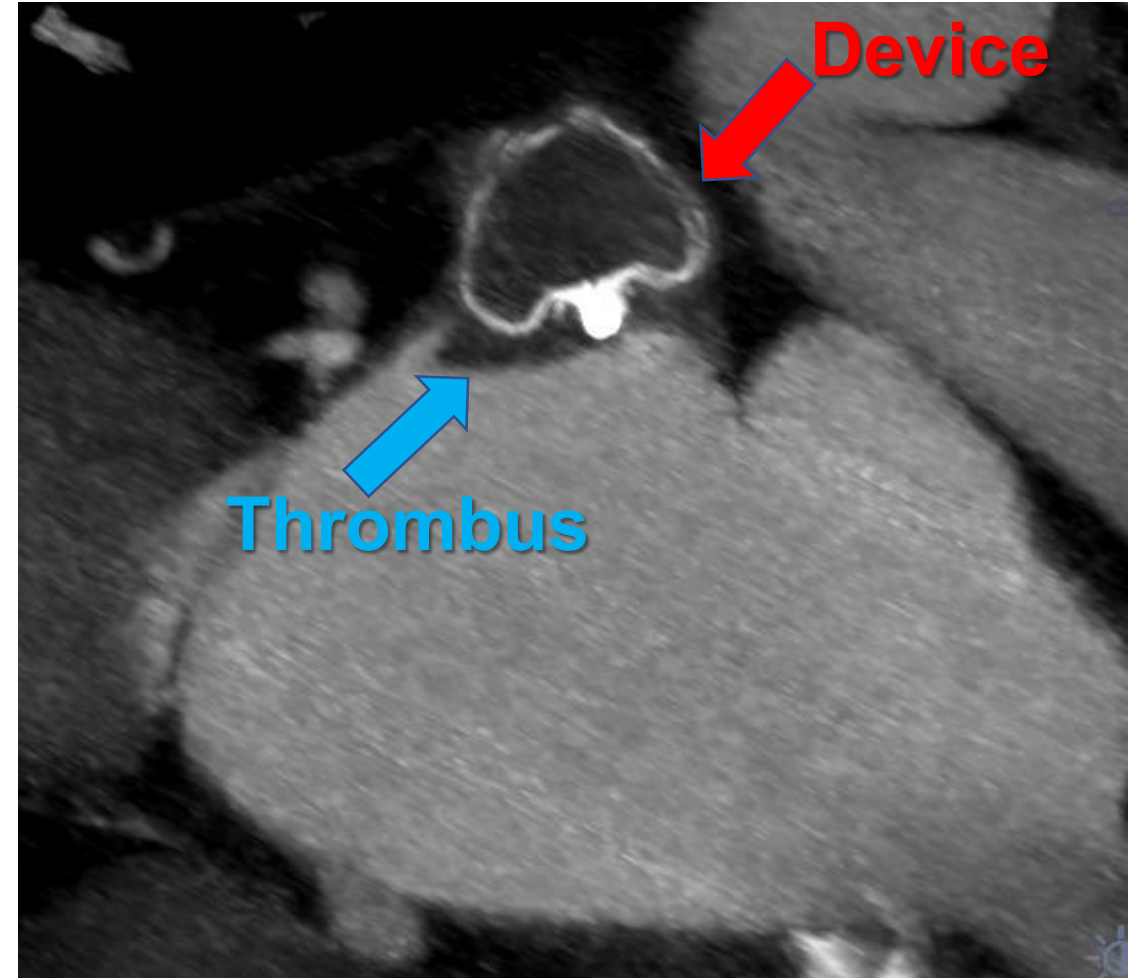
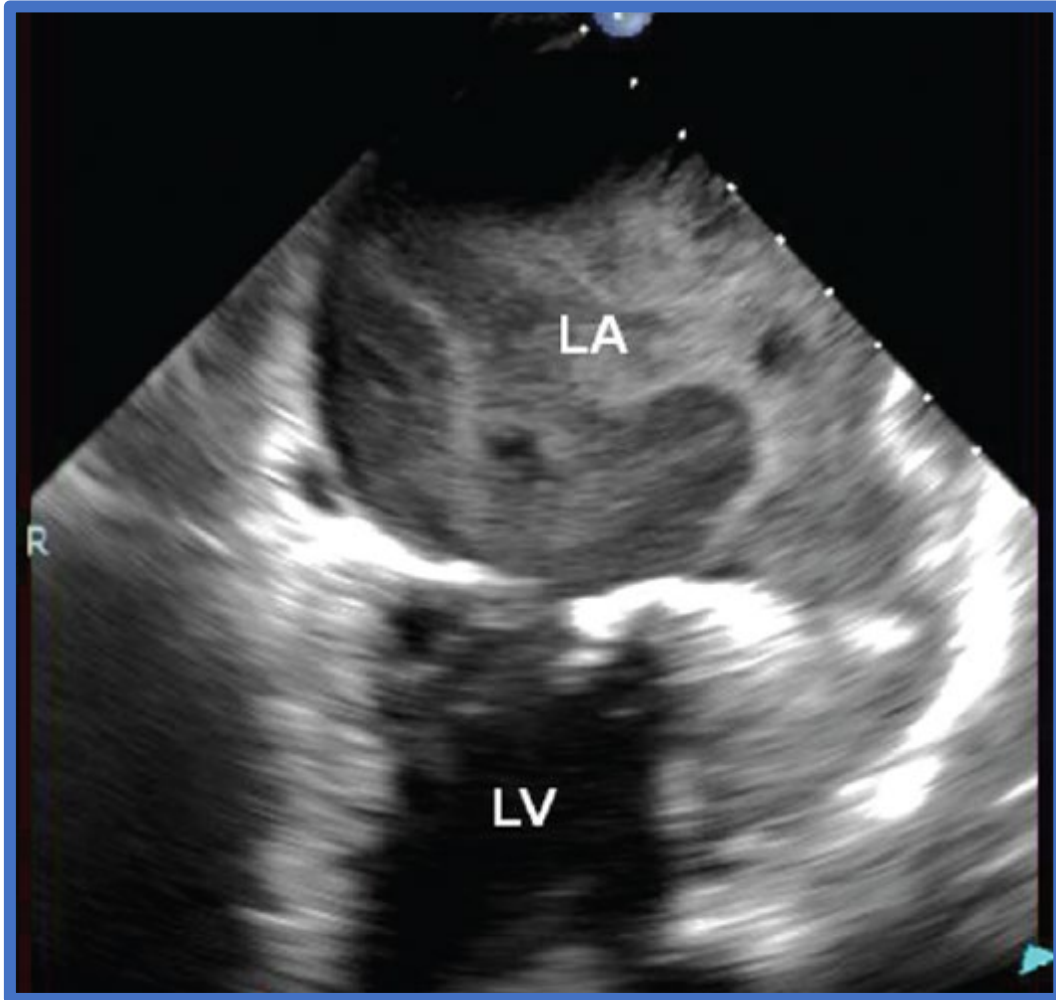
Eviter les complications



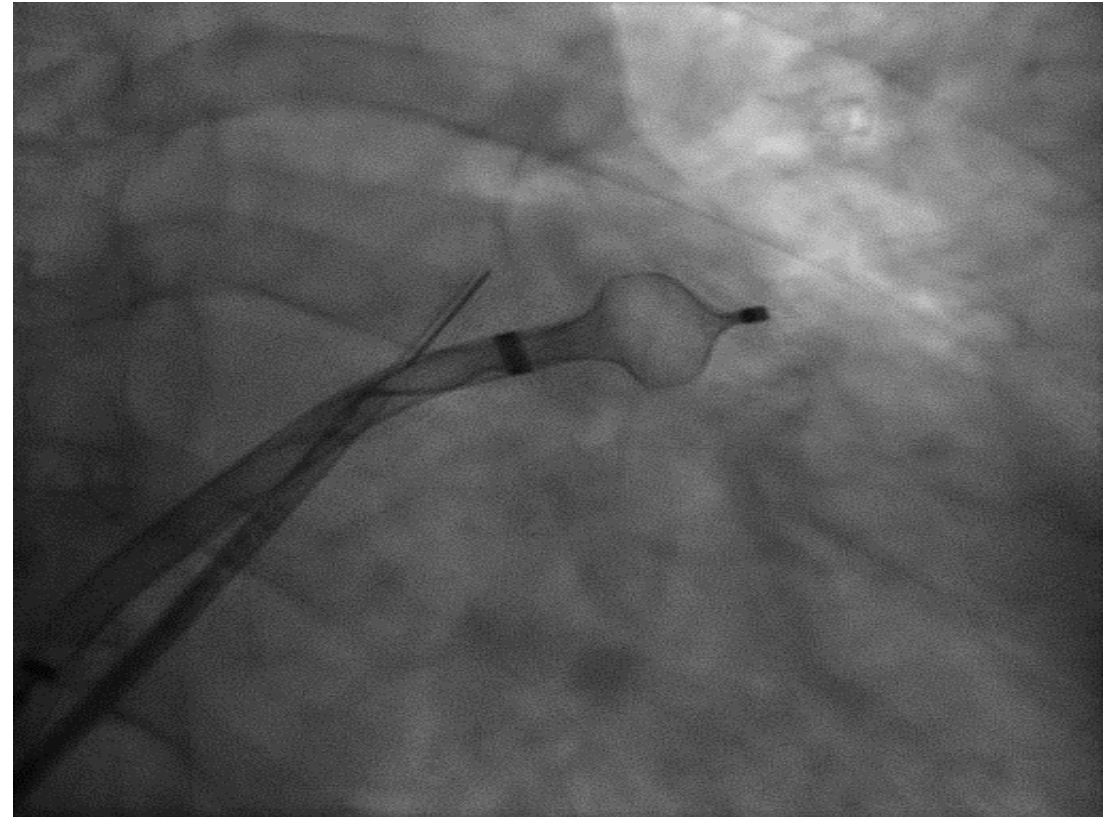
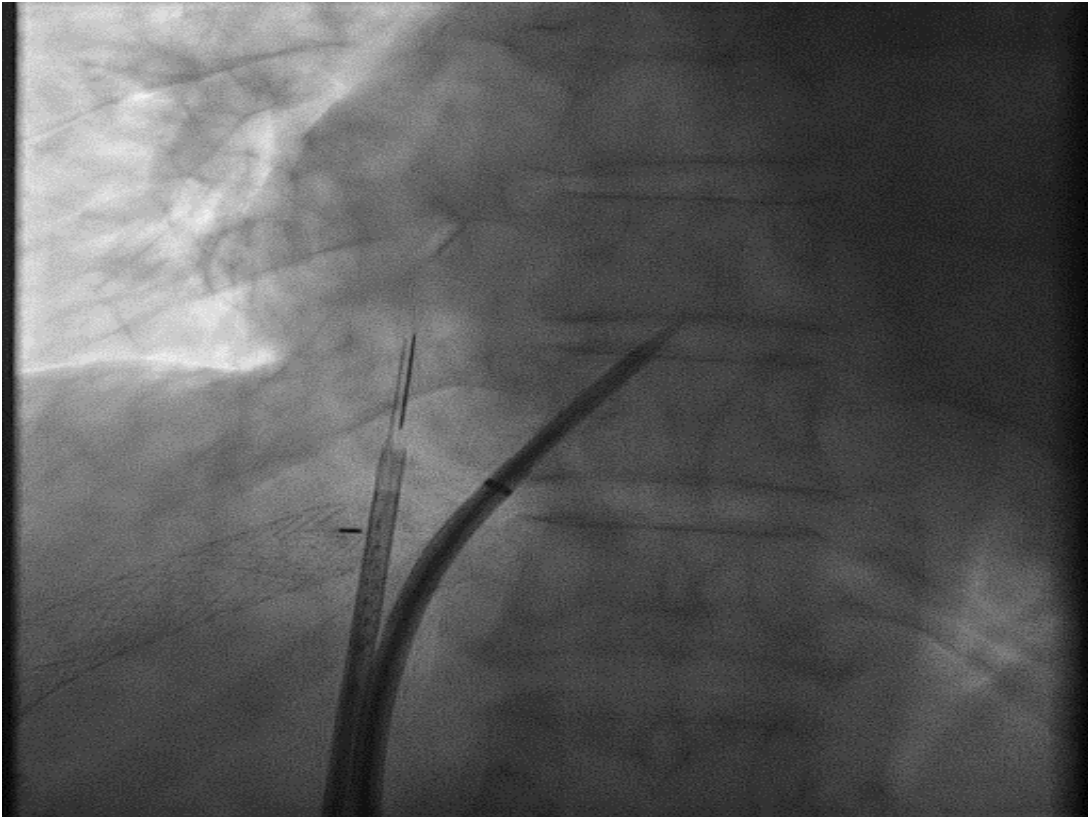
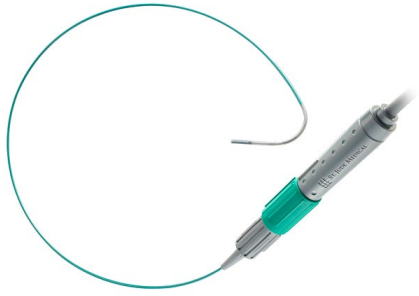
Eviter les complications



Eviter les complications



Adapter les techniques aux patients



SCAI and HR societies recommendations (2023)

1. Transcatheter LAAC is appropriate for patients with nonvalvular atrial fibrillation with high thromboembolic risk but for whom long-term **oral anticoagulation may be contraindicated** and who have at least 1 year's life expectancy.
2. **Operators** should have performed at least 50 prior left-sided ablations or structural procedures and at least 25 transseptal punctures (TSPs). Interventional-imaging physicians should have experience in guiding 25 or more TSPs before supporting LAAC procedures independently.
3. To maintain skills, operators should do 25 or more TSPs and at least **12 LAACs over each 2-year period**.
4. **On-site cardiovascular surgery backup** should be available for new programs and for operators early in their learning curve.
5. **Baseline imaging** with transesophageal echocardiography (TEE) or cardiac computed tomography should be performed before LAAC.
6. **Intraprocedural imaging guidance** with TEE or intracardiac echocardiography.
7. **Follow labeling** of each specific LAAC device for technical aspects of the procedure.
8. Familiarity with avoiding, recognizing, and **managing LAAC complications**.
9. **Predischarge 2-dimensional TTE** to rule out pericardial effusion and device embolization.
10. **Anticoagulation** for device-related thrombus.
11. Make all efforts to **minimize peridevice leaks** during implantation because their clinical impact and management isn't well understood.
12. **Antithrombotic therapy with warfarin, DOAC, or dual-antiplatelet therapy** after LAAC based on the studied regimen and instructions for each specific device, tailored to the bleeding risks for each patient.
13. **TEE or cardiac computed tomography at 45-90 days** after LAAC for device surveillance to assess for peridevice leak and device-related thrombus.

FAG vs. AOD (RCT)

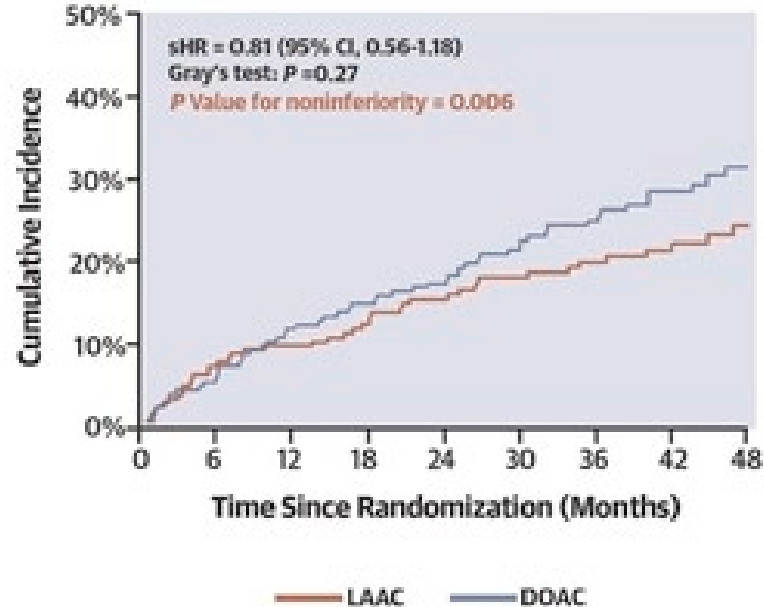
PRAGUE-17 Trial: Long-Term (4-Year) Follow-Up



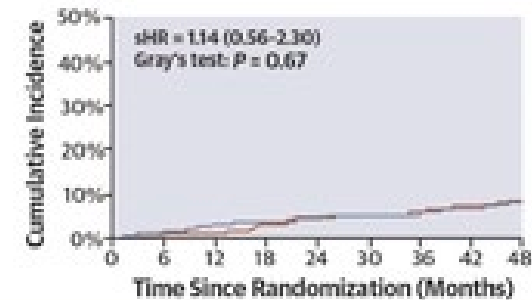
- 402 High-risk AF pts → Randomized
- CHA₂DS₂-VASc = 4.7 ± 1.5
- HAS-BLED = 3.1 ± 0.9
- Median Follow-up: 3.5 years (IQR 2.6-4.3), 1,354 pt-year



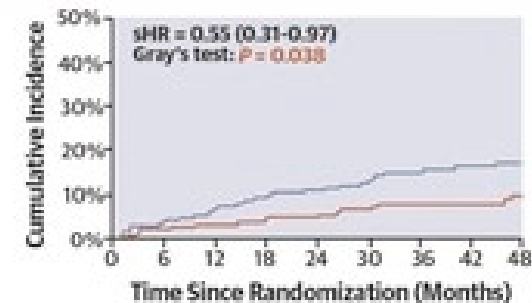
Primary Endpoint Stroke, TIA, SE, CV Death, Bleeding or Complications



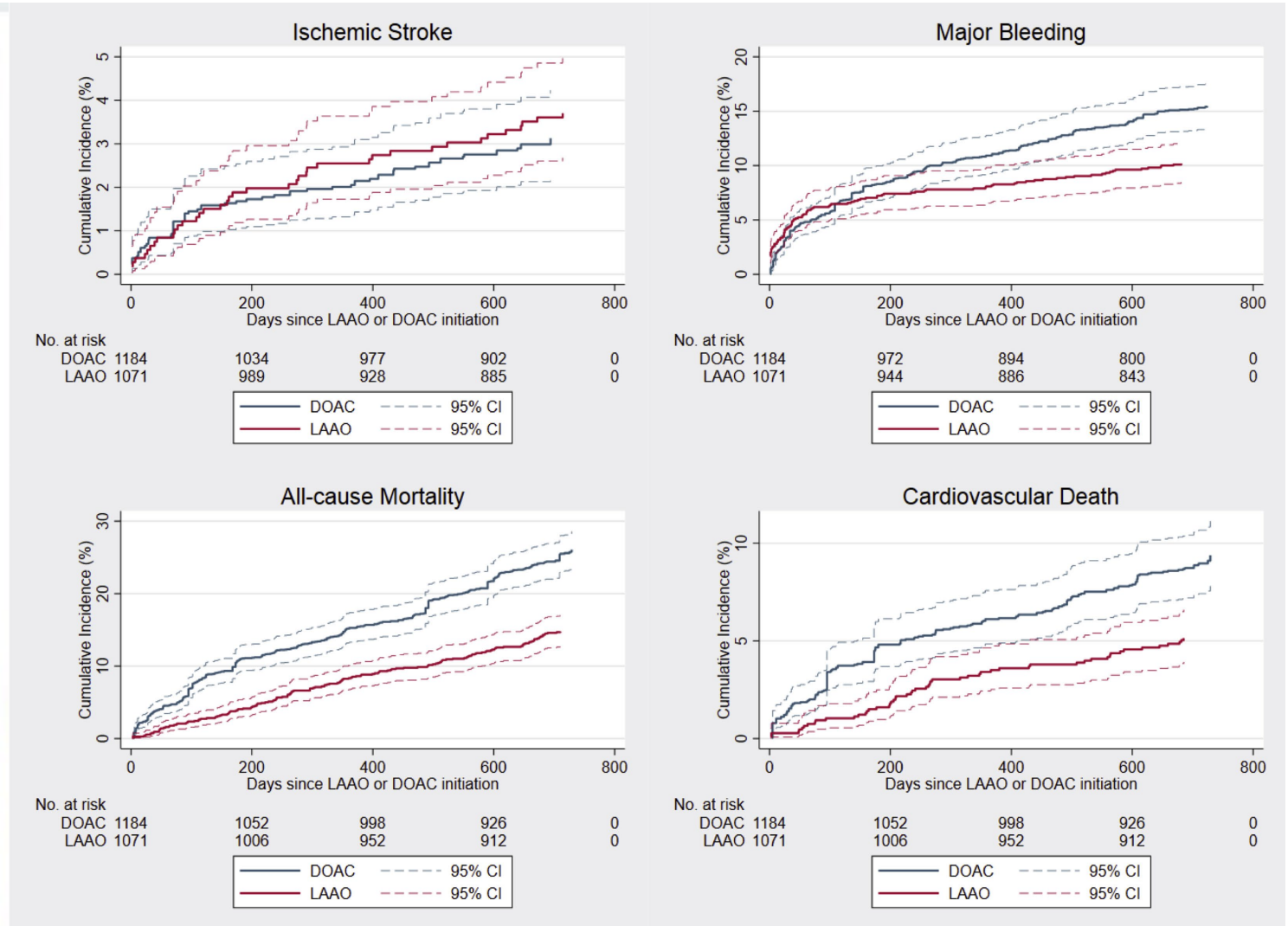
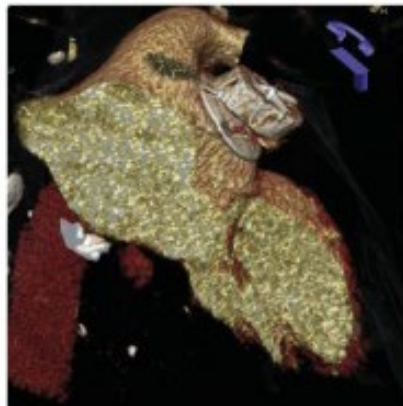
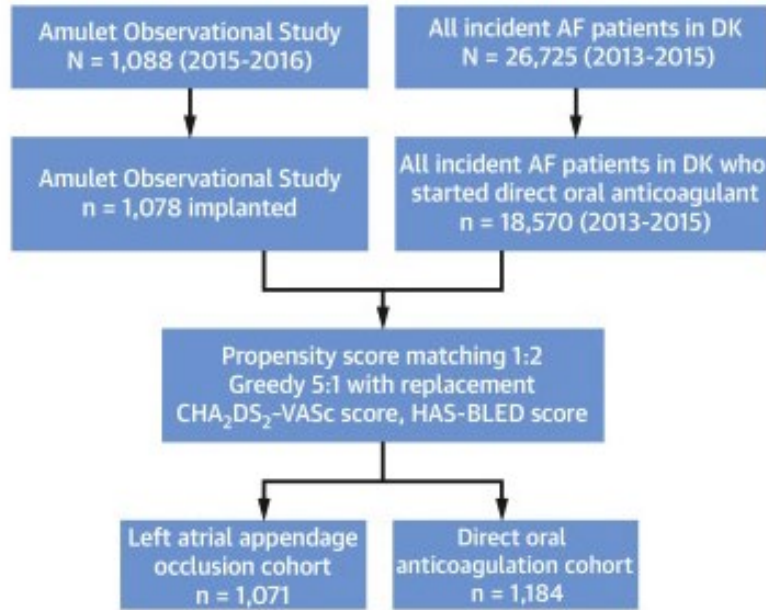
Stroke or TIA



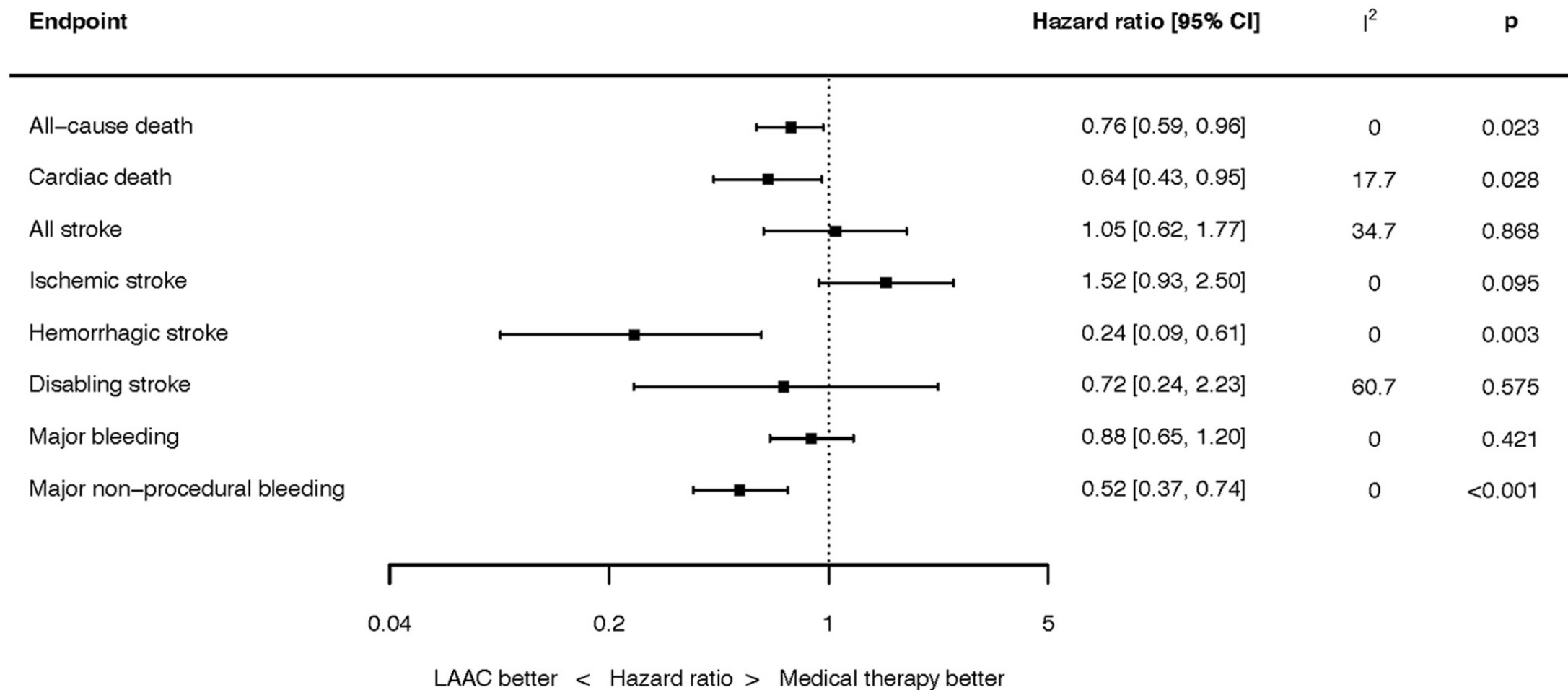
Non-Procedural Clinically Relevant Bleeding



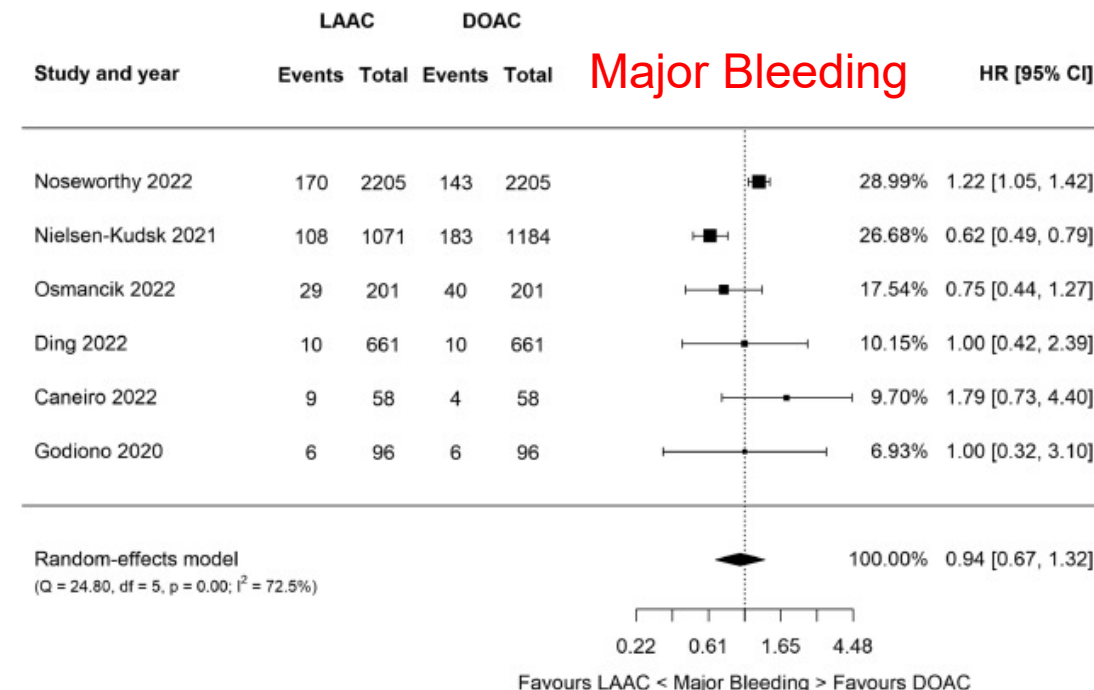
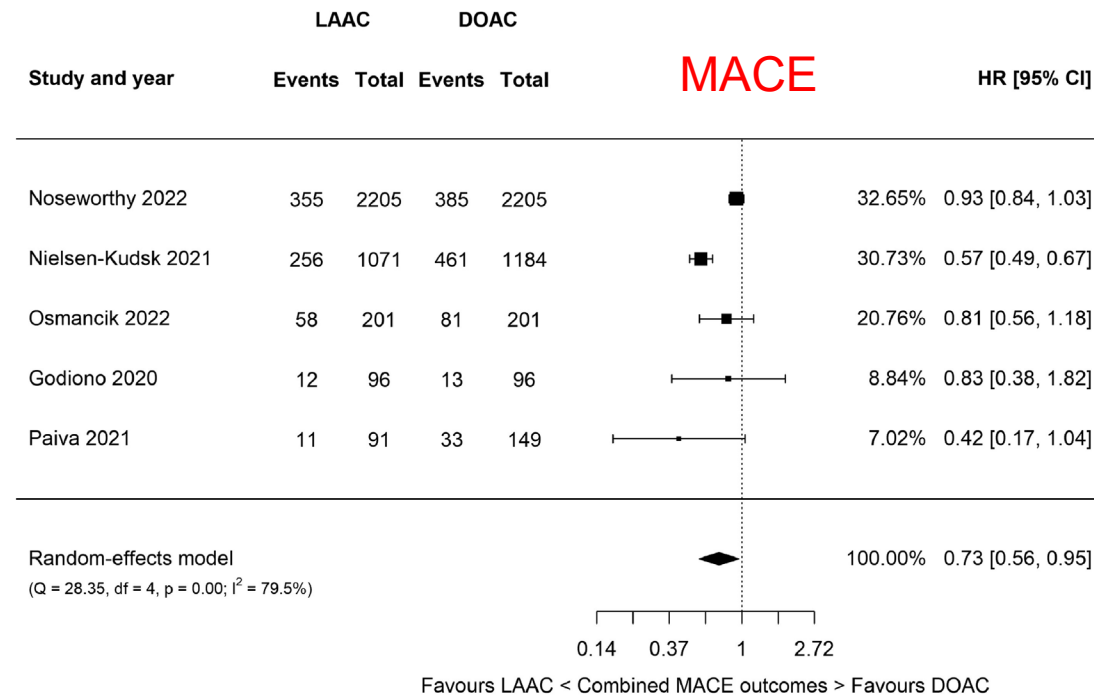
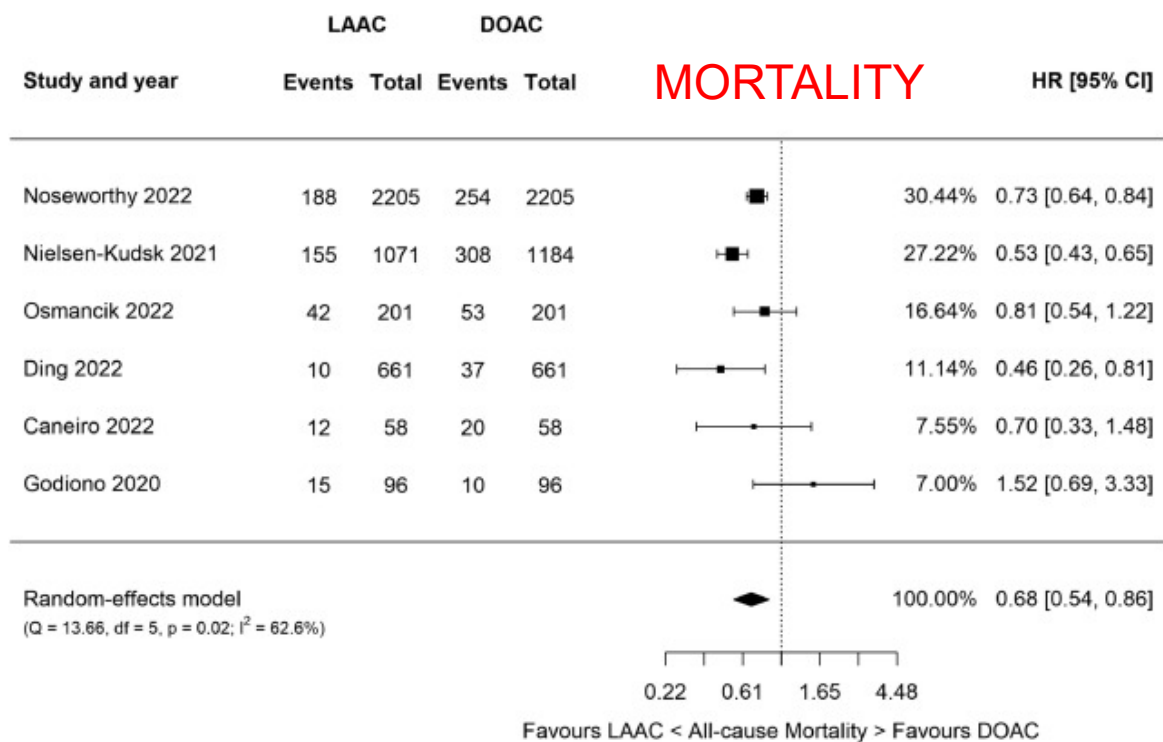
FAG vs. AOD (propensity score matching)



FAG vs AOD (metaanalysis of 3 RCTs)



FAG vs AOD (metaanalysis of 7 comparative studies)



FAG vs. AOD (ongoing RCTs)

OPTION

N = 1600
130 Global Sites
Key Inclusion: Non-Valvular AF
CHA₂DS₂-VASc ≥2 (men) ≥3 (women)

AF Ablation** + WATCHMAN™ FLX™
+ Short Term OAC + ASA
N = 800
**ablation 3-6 months
prior or concomitant

AF Ablation + OAC
N = 800

3-YEAR
FOLLOW-UP

3-YEAR
FOLLOW-UP

CO-PRIMARY ENDPOINTS
Death, stroke, and systemic embolism (NON-INFERIORITY)
Non-procedural bleeding (SUPERIORITY)

CHAMPION

3000 Patients
150 Sites

Randomization 1:1

WATCHMAN FLX

NOAC

5 Year Follow-Up

CATALYST

2650 Patients
120 Sites

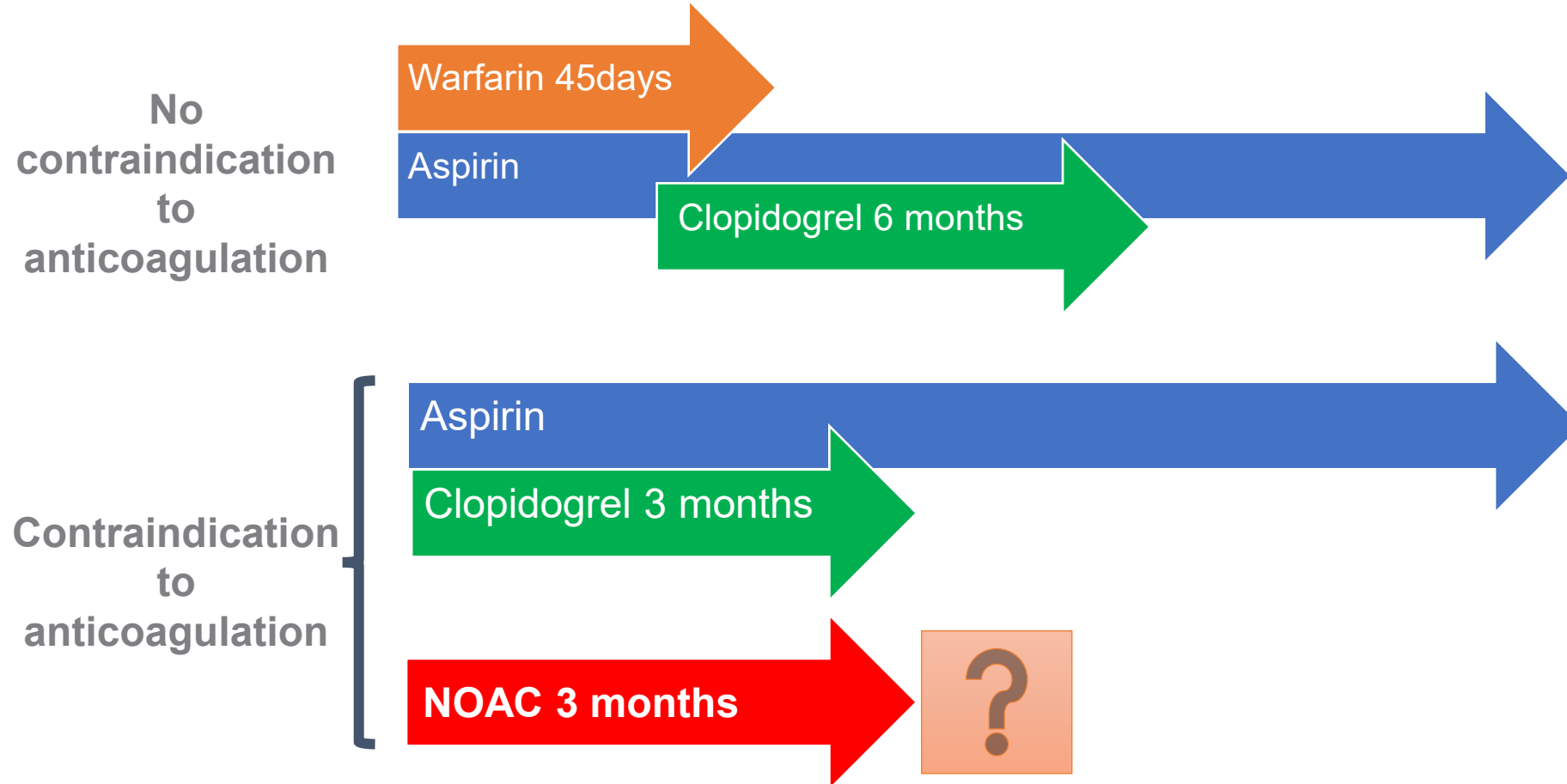
Randomization 1:1

AMPLATZER AMULET
LAA OCCLUDER

NOAC

5 Year Follow-Up

Post-LAAC antithrombotic treatment



ADRIFT

105 patients with successful LAAC

Randomisation 1:1:1

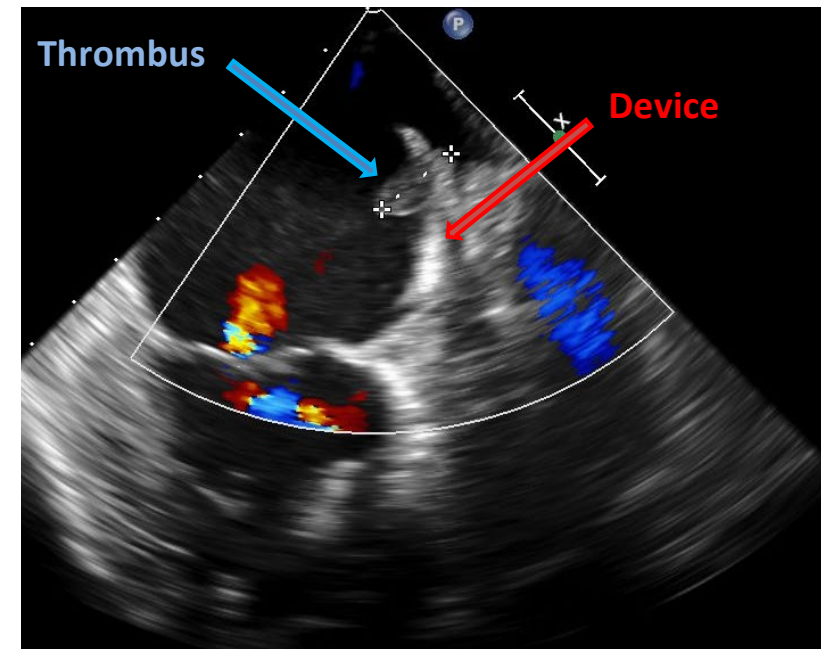
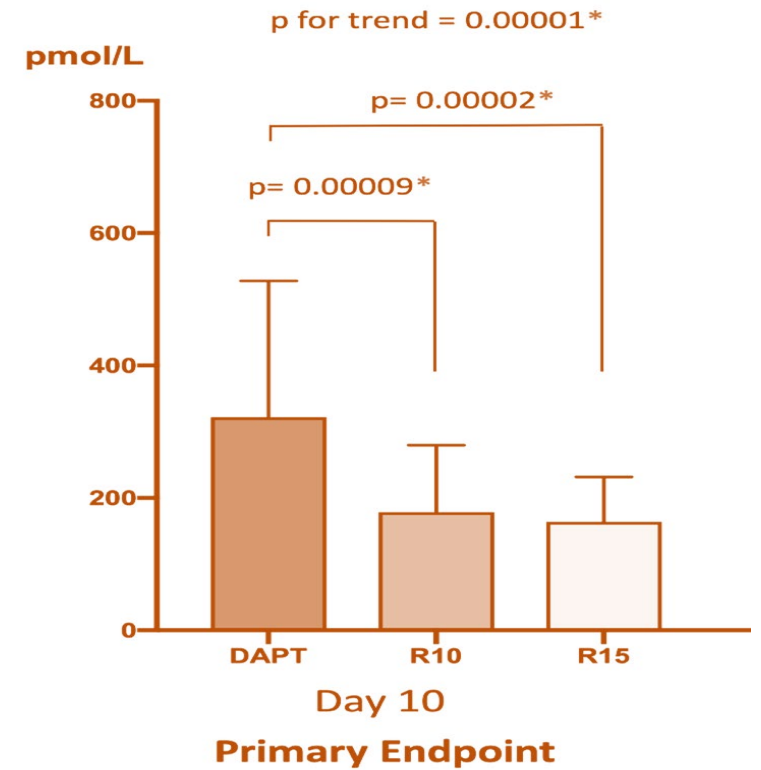
Rivaroxaban
10 mg OD

Rivaroxaban
15 mg OD

DAPT

1° endpoint, D10: Thrombin generation (F1+2)

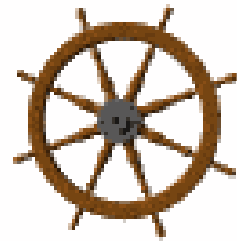
2° endpoint, D90: F1+2, TAT, D-Dimers and clinical events



Indications

- **Intra-cranial bleeding** on anticoagulation
 - 1/3 of ischemic stroke develop hemorrhagic transformation on anticoagulation (Mudd P et al. 2010)
- **Extra-cranial bleeding** on anticoagulation
 - GI bleeding (e.g. angiodysplasia)
- **Contra-indication** to anticoagulation
 - Cerebral microbleeds or amyloid angiopathy
 - Low platelet count
- **Intolerance to NOAC**
 - Renal insufficiency; Liver dysfunction
 - GI intolerance
- **Stroke on anticoagulation**
- **No compliance** to anticoagulation
- **No prescription** of anticoagulation (alternative?)

Merci!



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Pitié-Salpêtrière