# Exclusion percutanée de l'auricule gauche: une alternative au traitement anticoagulant?

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INSERM U1148 LVTS,

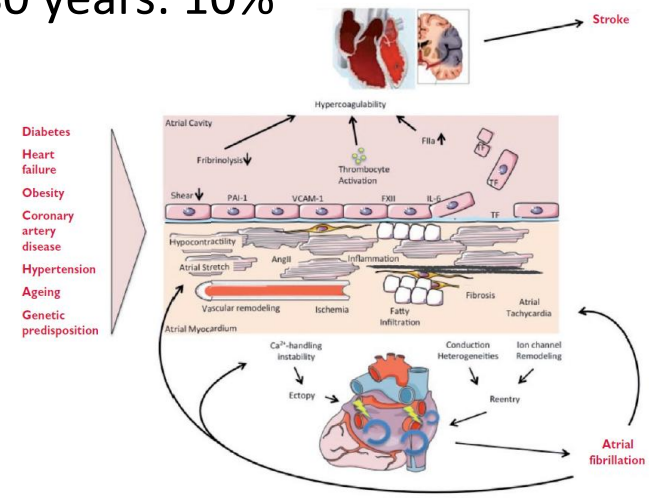
French Alliance for Cardiovascular Clinical Trials

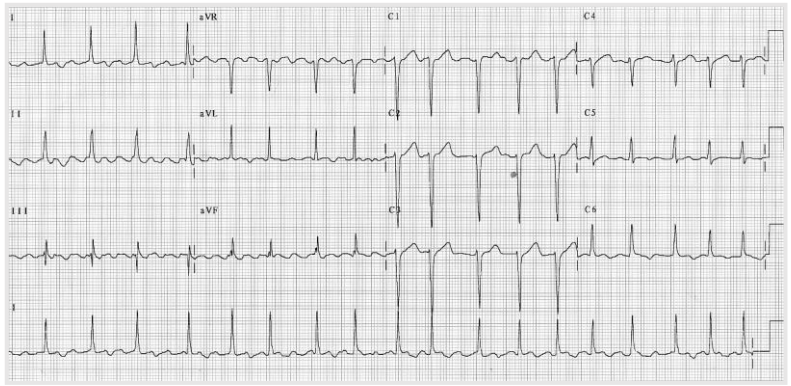
# Exclusion percutanée de l’auricule gauche: une alternative au traitement anticoagulant?

- Problématique

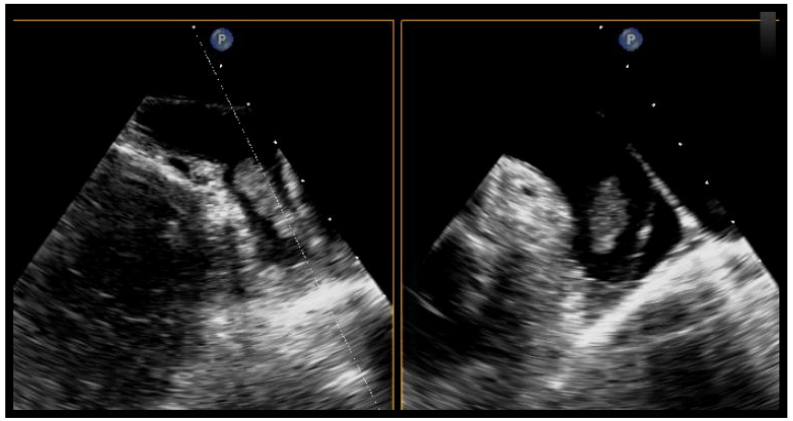
# Fibrillation auriculaire

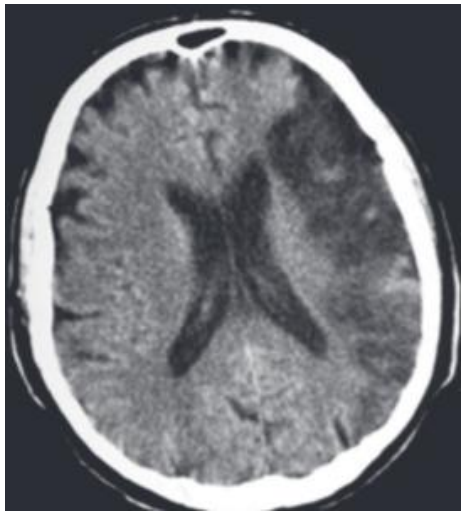
Prévalence : 0.4% of de la population générale
> 80 years: 10%



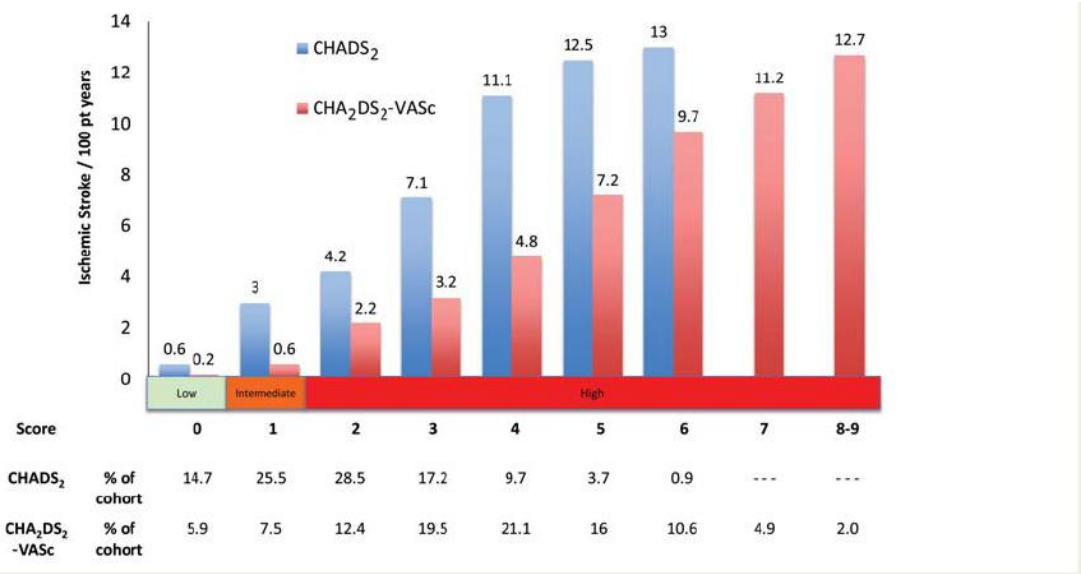
15% des AVC





# Comment évaluer le risque d'AVC dans la fibrillation auriculaire?

| $CHA_2DS_2$-VA component | | Definition and comments | Points awarded[a] |
|---|---|---|---|
| C | Chronic heart failure | Symptoms and signs of heart failure (irrespective of LVEF, thus including HFpEF, HFmrEF, and HFrEF), or the presence of asymptomatic LVEF ≤40%.[261–263] | 1 |
| H | Hypertension | Resting blood pressure >140/90 mmHg on at least two occasions, or current antihypertensive treatment. The optimal BP target associated with lowest risk of major cardiovascular events is 120–129/70–79 mmHg (or keep as low as reasonably achievable).[162,264] | 1 |
| A | Age 75 years or above | Age is an independent determinant of ischaemic stroke risk.[265] Age-related risk is a continuum, but for reasons of practicality, two points are given for age ≥75 years. | 2 |
| D | Diabetes mellitus | Diabetes mellitus (type 1 or type 2), as defined by currently accepted criteria,[266] or treatment with glucose lowering therapy. | 1 |
| S | Prior stroke, TIA, or arterial thromboembolism | Previous thromboembolism is associated with highly elevated risk of recurrence and therefore weighted 2 points. | 2 |
| V | Vascular disease | Coronary artery disease, including prior myocardial infarction, angina, history of coronary revascularization (surgical or percutaneous), and significant CAD on angiography or cardiac imaging.[267]<br>OR<br>Peripheral vascular disease, including: intermittent claudication, previous revascularization for PVD, percutaneous or surgical intervention on the abdominal aorta, and complex aortic plaque on imaging (defined as features of mobility, ulceration, pedunculation, or thickness ≥4 mm).[268,269] | 1 |
| A | Age 65–74 years | 1 point is given for age between 65 and 74 years. | 1 |




Guidelines ESC FA 2024

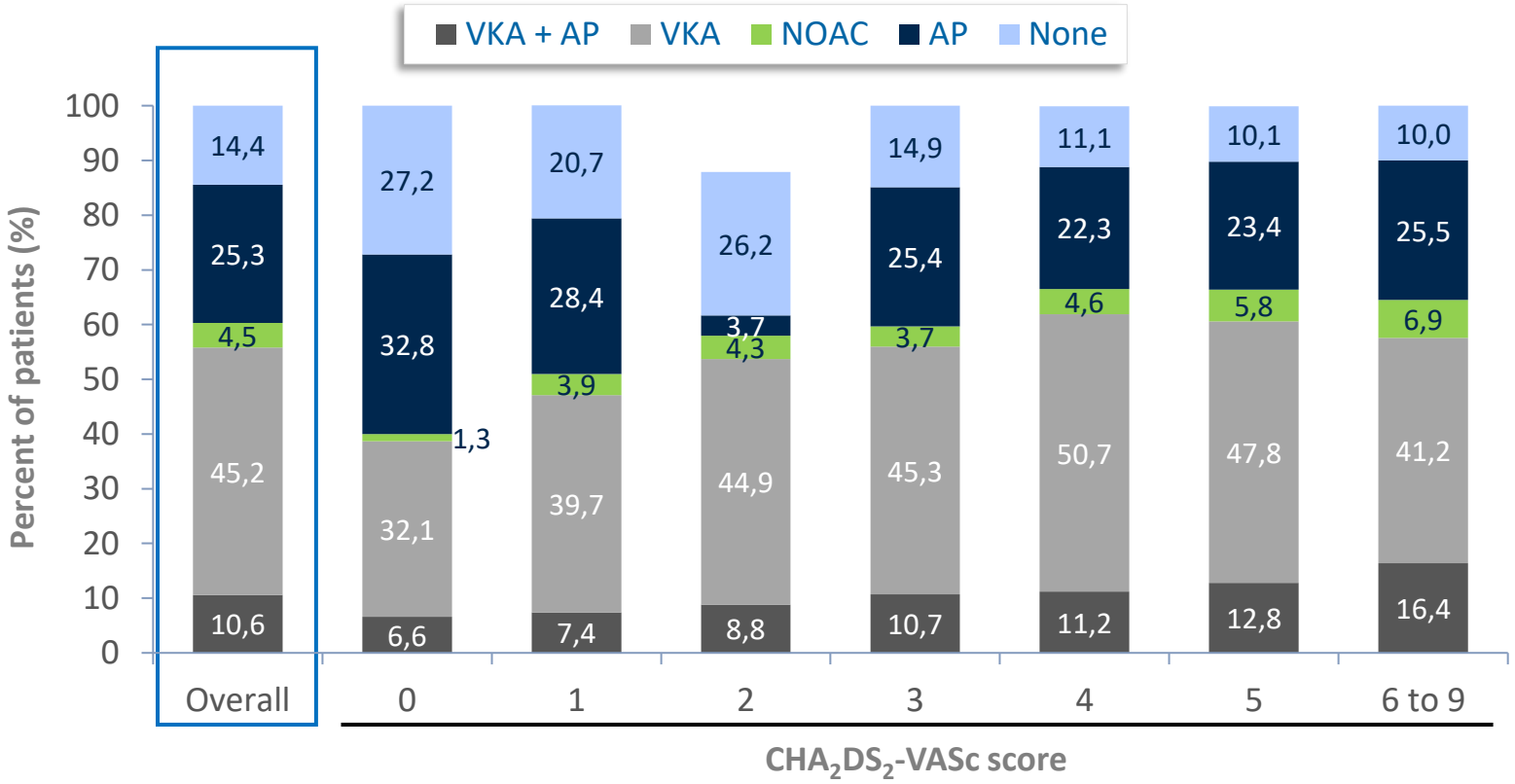
Piccini et al Eur Heart J 2012;33:1431-33

| Recommendations | Class[a] | Level[b] |
|---|---|---|
| Oral anticoagulation is recommended in patients with clinical AF at elevated thromboembolic risk to prevent ischaemic stroke and thromboembolism.[239,240] | I | A |
| A $CHA_2DS_2$-VA score of 2 or more is recommended as an indicator of elevated thromboembolic risk for decisions on initiating oral anticoagulation. | I | C |
| Oral anticoagulation is recommended in all patients with AF and hypertrophic cardiomyopathy or cardiac amyloidosis, regardless of $CHA_2DS_2$-VA score, to prevent ischaemic stroke and thromboembolism.[270–276] | I | B |
| Individualized reassessment of thromboembolic risk is recommended at periodic intervals in patients with AF to ensure anticoagulation is started in appropriate patients.[277–280] | I | B |

Guidelines ESC FA 2024

# Un tiers des patients en fibrillation auriculaire ne reçoivent pas de traitement ou un traitement inaproprié

Type of antithrombotic therapy according to $CHA_2DS_2$-VASc scores in patients newly diagnosed with AF from the GARFIELD registry (19 countries, N=10 607)



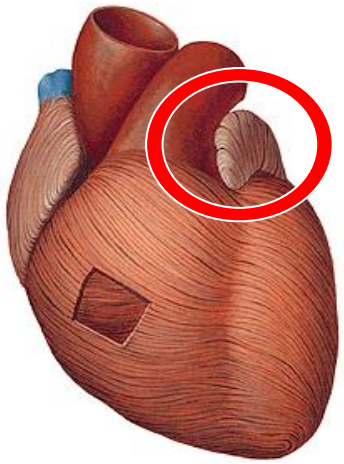

AP, antiplatelet (74% of patients received aspirin); VKA, vitamin K antagonist; NOAC, novel oral anticoagulant (factor Xa inhibitors and direct thrombin inhibitor)

Kakkar et al PLoS ONE 2013; 8(5): e63479. doi:10.1371/journal/pone.0063479

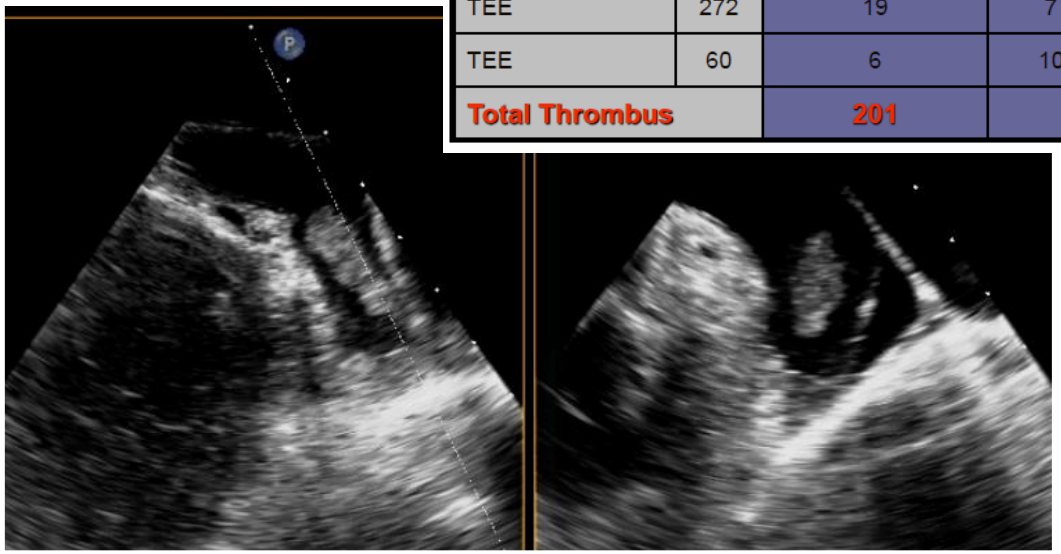
# Exclusion percutanée de l’auricule gauche: une alternative au traitement anticoagulant?

- Problématique
- Fermeture d’auricule gauche: principes

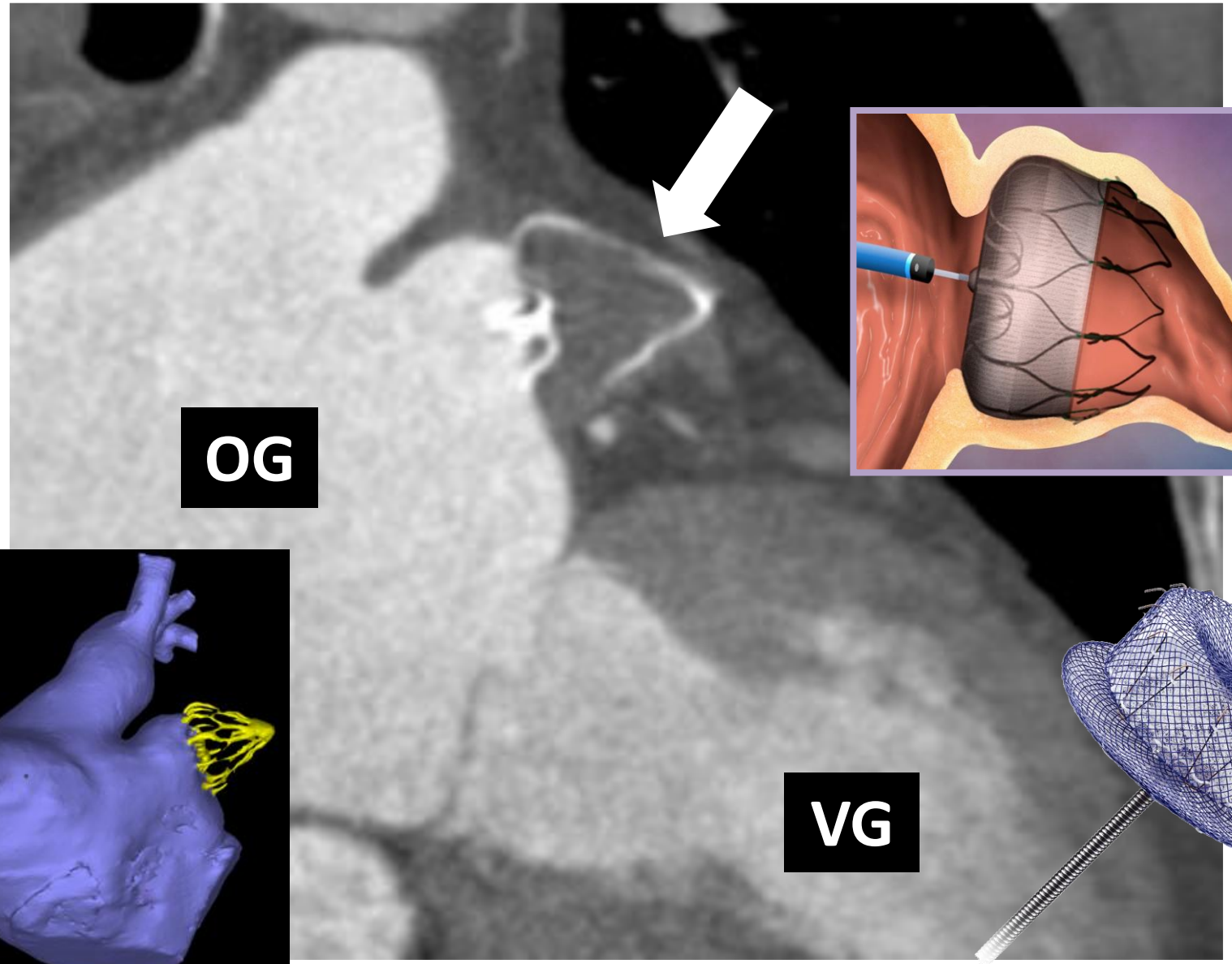
# > 90 % de thrombi sont localisés dans l'auricule

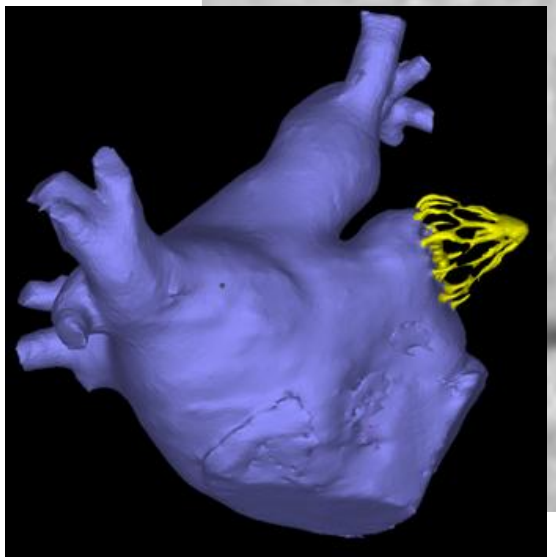


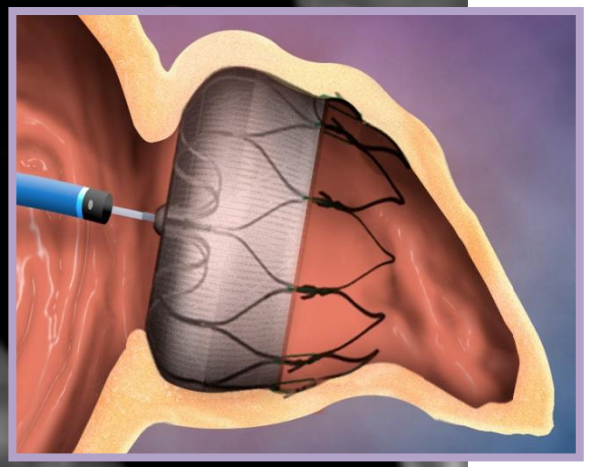
| Setting | N | Appendage | Percent | LA Body | Percent | Reference |
|---|---|---|---|---|---|---|
| TEE | 317 | 66 | 21 | 1 | 0.3 | Stoddard; JACC, 1995 |
| TEE | 233 | 34 | 15 | 1 | 0.4 | Manning; Circ, 1994 |
| Autopsy | 506 | 35 | 7 | 12 | 2.4 | Aberg; Acta Med Scan, 1969 |
| TEE | 52 | 2 | 4 | 2 | 3.8 | Tsai; JFMA, 1990 |
| TEE | 48 | 12 | 25 | 1 | 2.1 | Klein; Int J Card Image, 1993 |
| TEE & Operation | 171 | 8 | 5 | 3 | 1.8 | Manning; Circ, 1994 |
| SPAF III TEE | 359 | 19 | 5 | 1 | 0.3 | Klein; Circ, 1994 |
| TEE | 272 | 19 | 7 | 0 | 0.0 | Leung; JACC, 1994 |
| TEE | 60 | 6 | 10 | 0 | 0.0 | Hart; Stroke, 1994 |
| Total Thrombus | | 201 | | 21 | | |

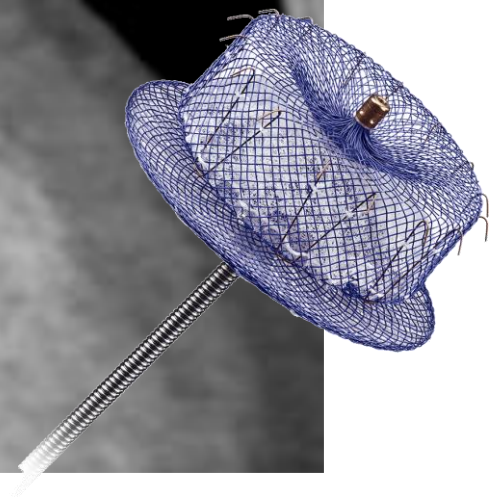


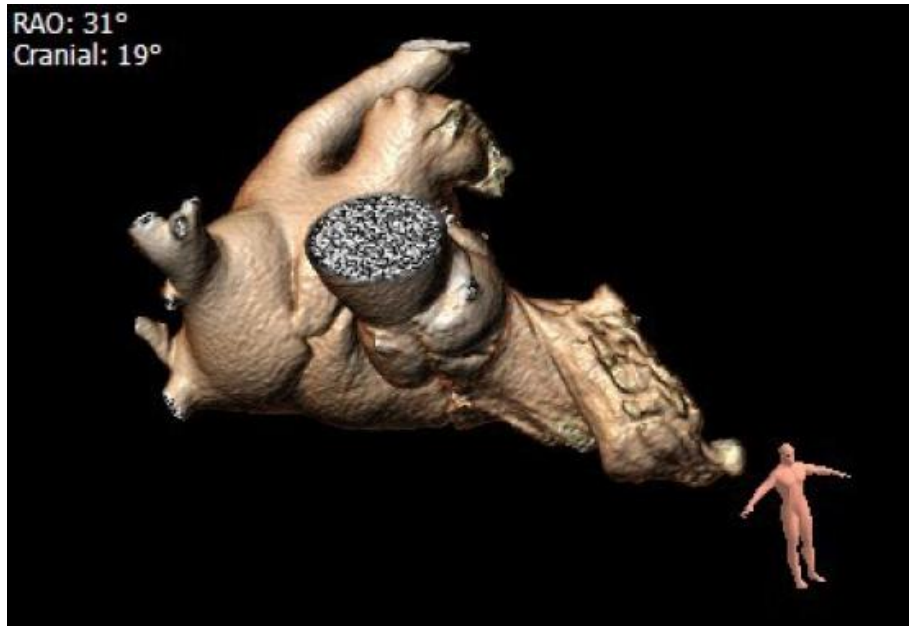
# Fermeture d’auricule

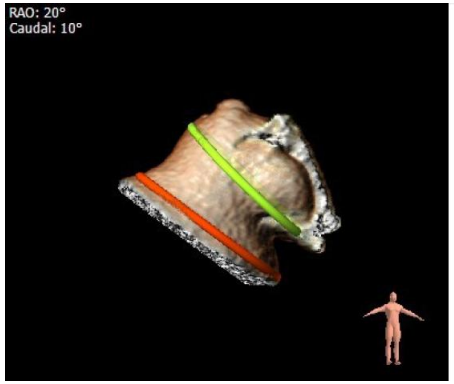


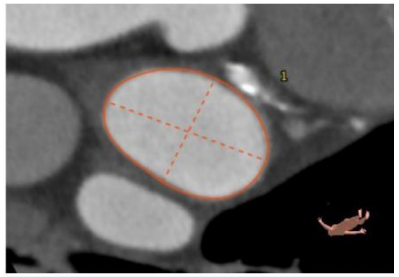




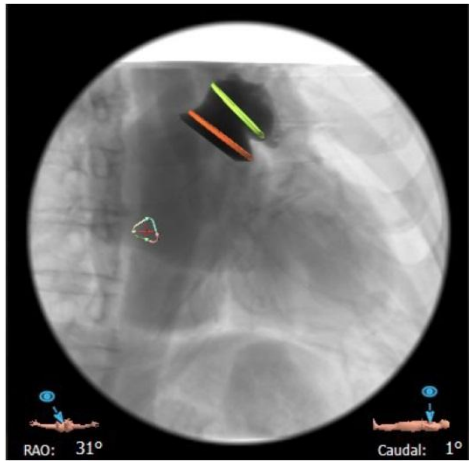


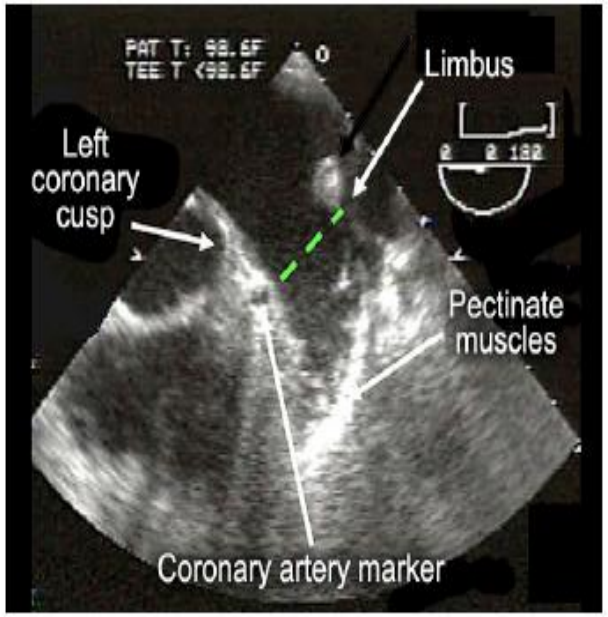


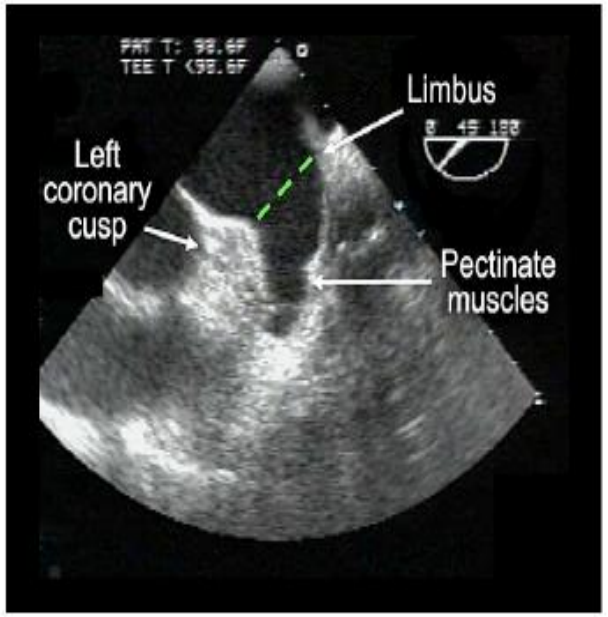


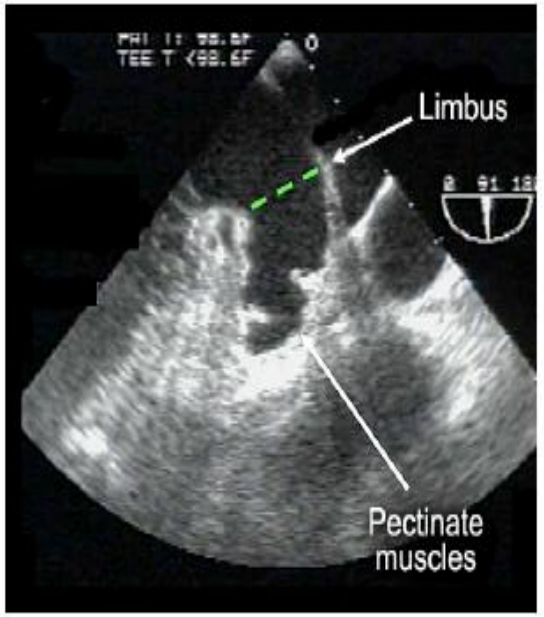

| ID | Type | Label | Value |
|---|---|---|---|
| 1 | Orifice Measurement | Min Diameter | 25,8 mm |
| | | Max Diameter | 37,8 mm |
| | | Avg Diameter | 31,8 mm |
| | | Area derived Ø | 31,5 mm |
| | | Perimeter derived Ø | 32,4 mm |
| | | Area | 778,3 mm² |
| | | Perimeter | 101,9 mm |



# Planification de l’intervention

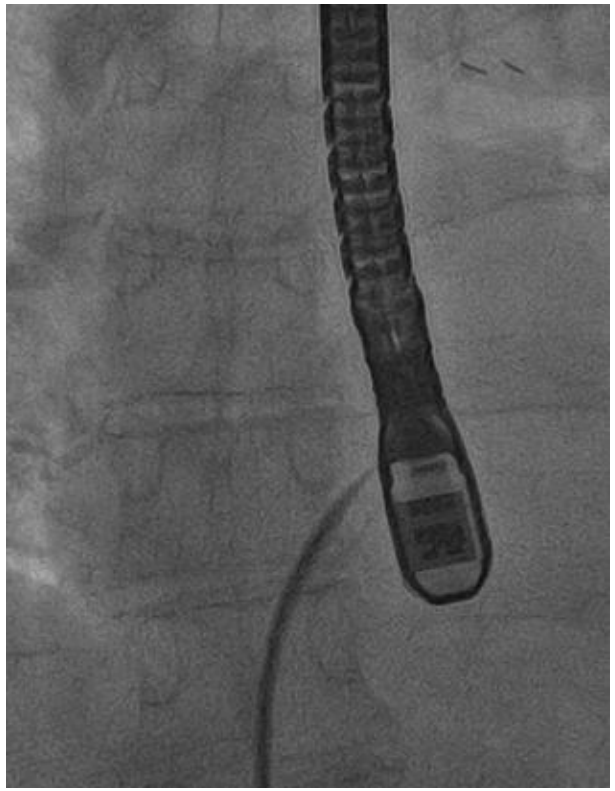


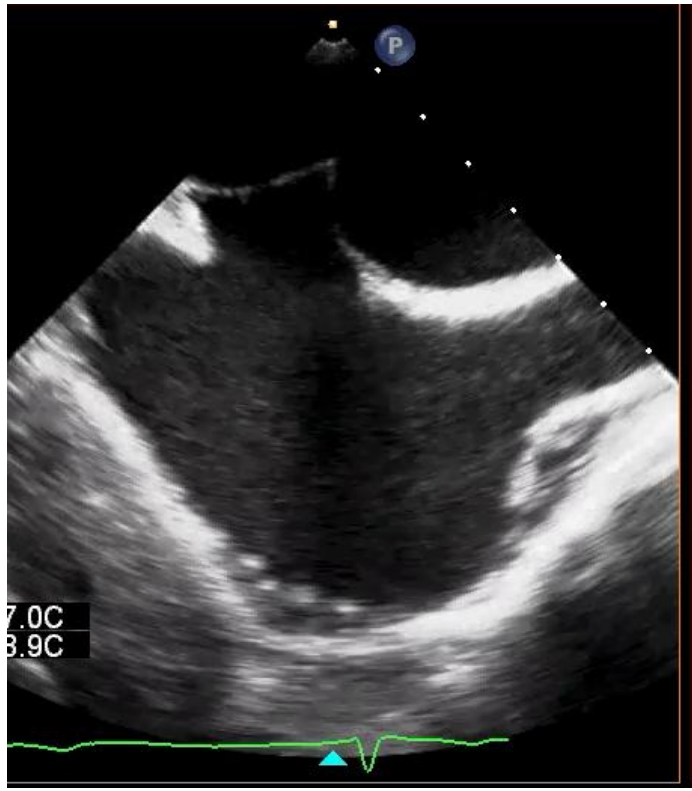




LAA measurements at 0°, 45°, and 90° on TEE

# Ponction transseptale échoguidée

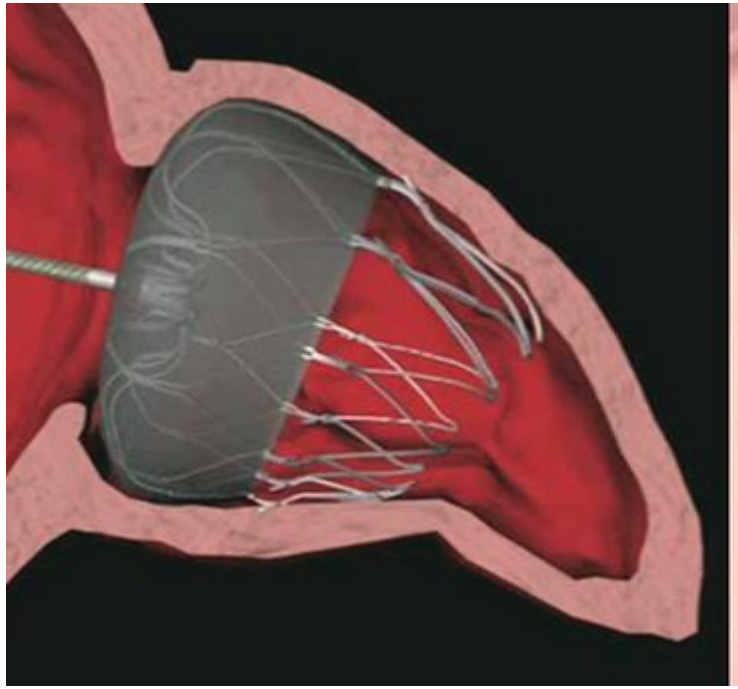




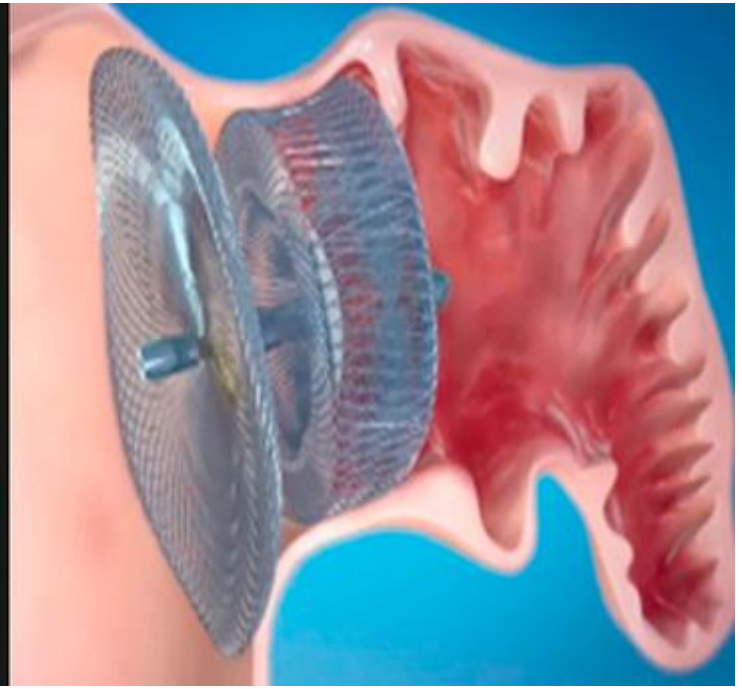

Bicavale


Petit axe

# Choix du device



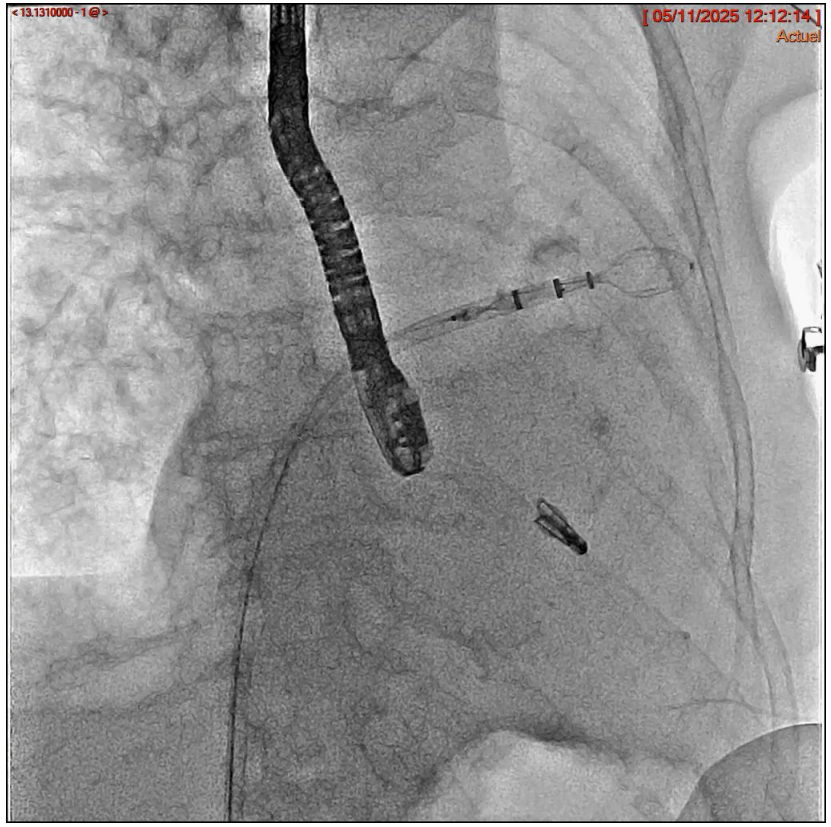
Watchman

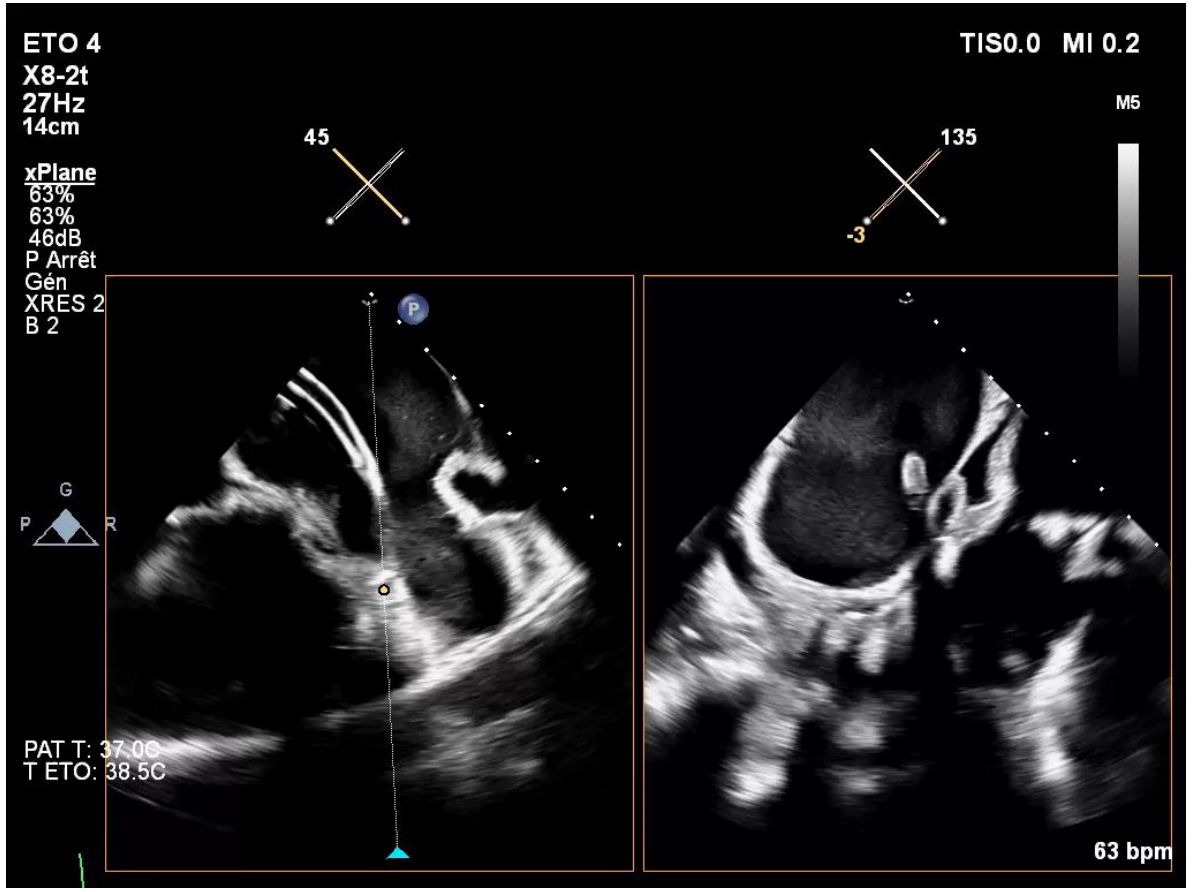


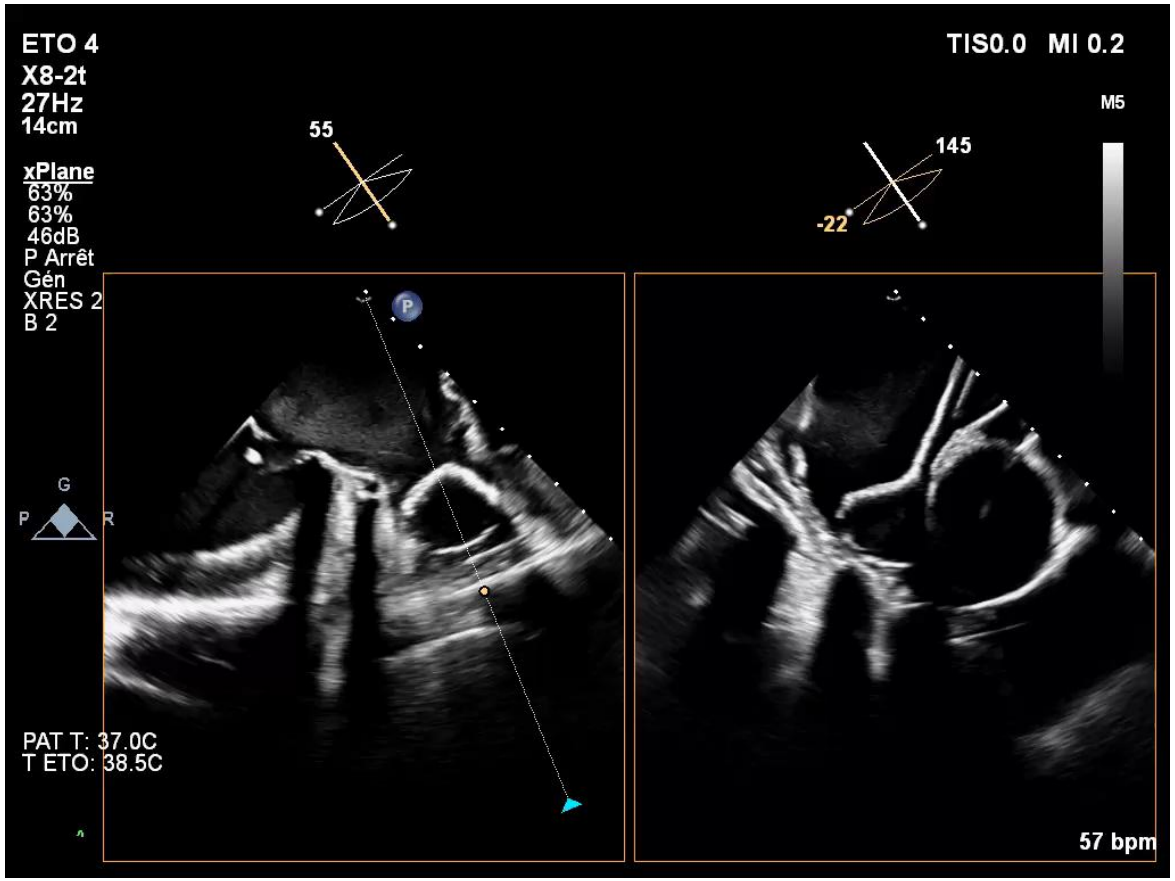
Amulet

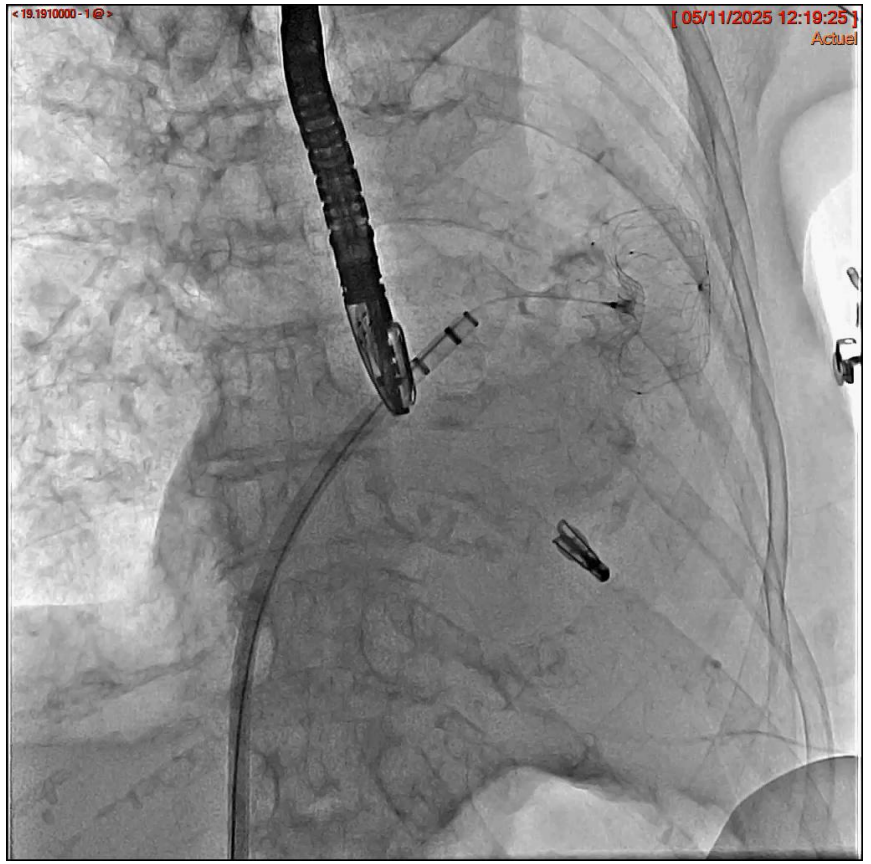
Lambre

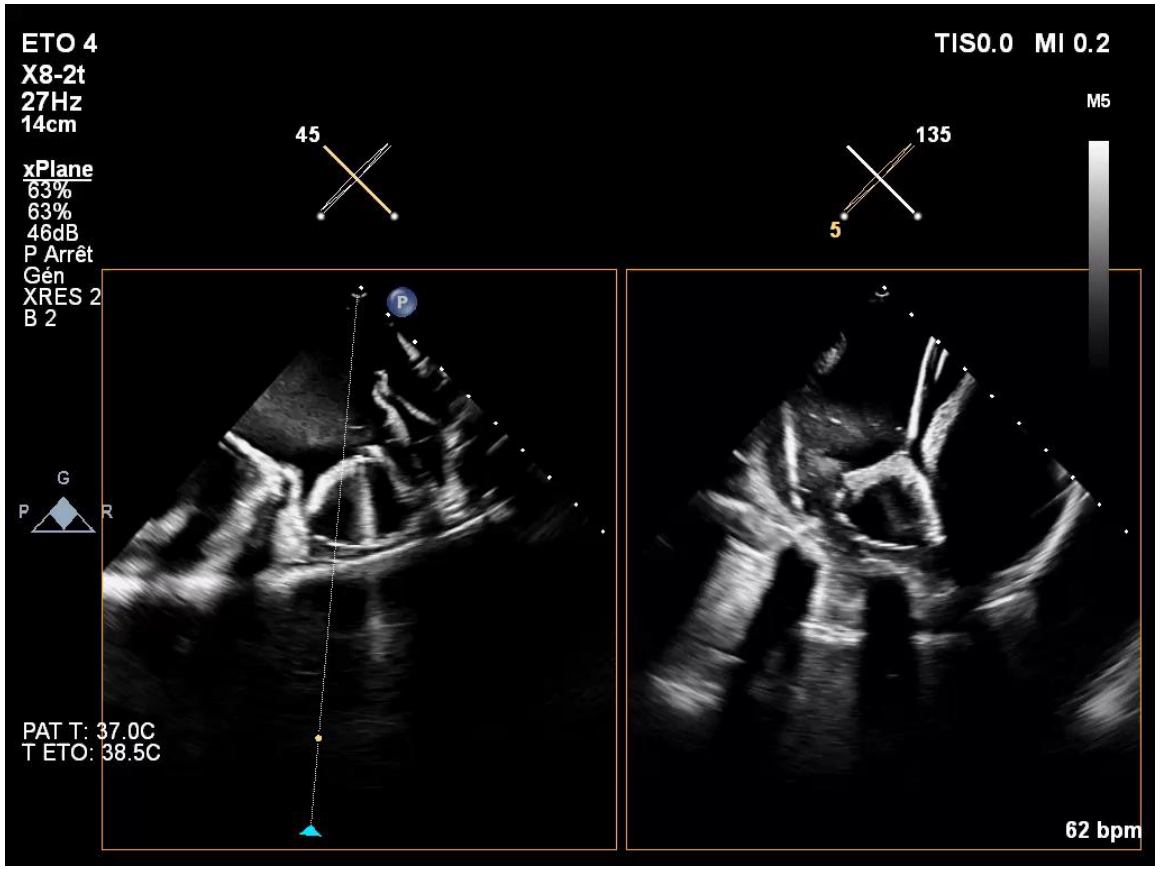
# Déploiement

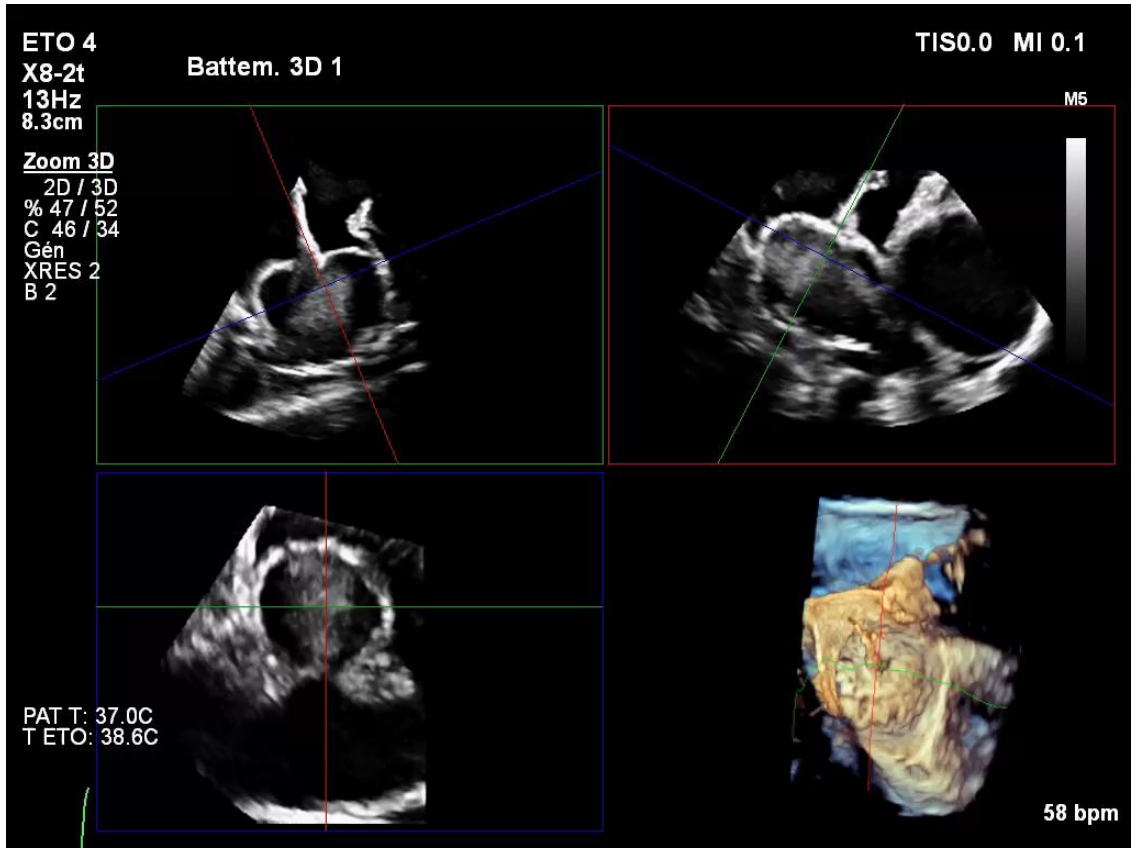


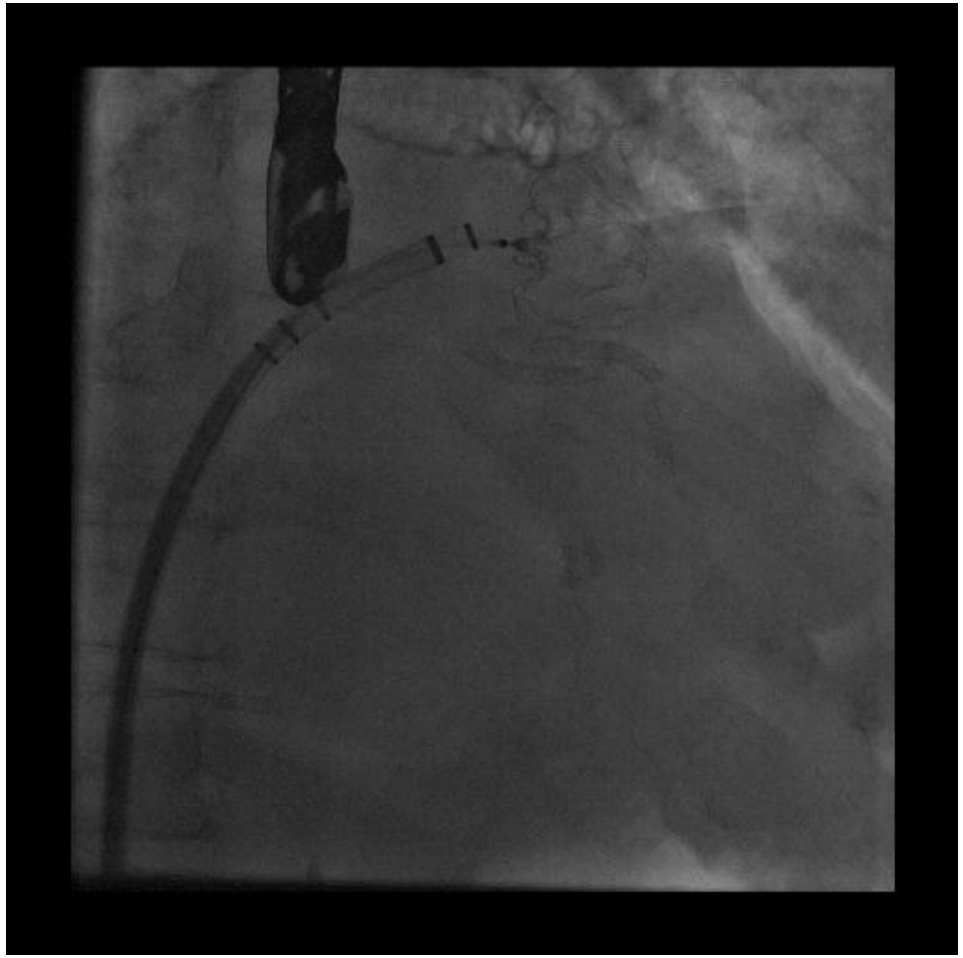

ETO 4
X8-2t
27Hz
14cm
xPlane
63%
63%
46dB
P Arrêt
Gén
XRES 2
B 2
TIS0.0 MI 0.2
M5
55
145
-22
G
P
R
PAT T: 37.0C
T ETO: 38.5C
57 bpm


[ 05/11/2025 12:19:25 ]
Actuel


ETO 4
X8-2t
27Hz
14cm
xPlane
63%
63%
46dB
P Arrêt
Gén
XRES 2
B 2
TIS0.0 MI 0.2
M5
45
135
5
G
P
R
PAT T: 37.0C
T ETO: 38.5C
62 bpm


ETO 4
X8-2t
13Hz
8.3cm
Battem. 3D 1
TIS0.0 MI 0.1
M5
Zoom 3D
2D / 3D
% 47 / 52
C 46 / 34
Gén
XRES 2
B 2
PAT T: 37.0C
T ETO: 38.6C
58 bpm

# Libération du device



# Sécurité de la procédure?

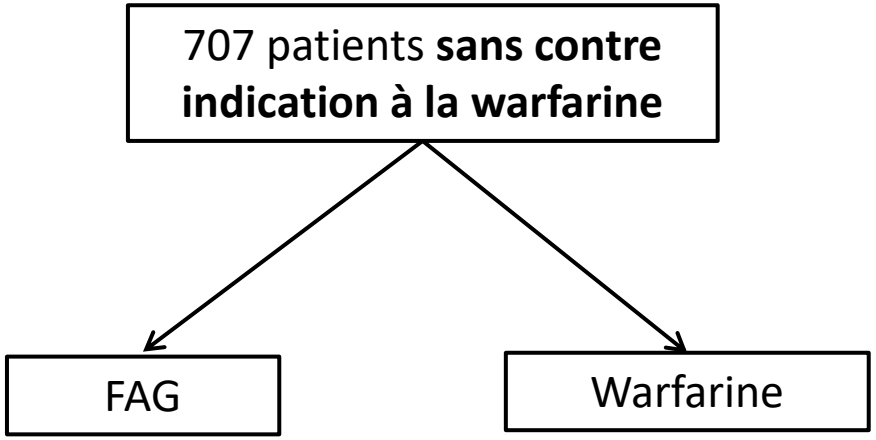
Registre français 1053 patients dans 53 centres 2018-2021

| | All patients (n=1053) | |
|---|---|---|
| | Periprocedural period* | Follow-up |
| Pericardial effusion requiring pericardiocentesis | 21 (2.0) | 2 (0.2) |
| Surgical pericardiocentesis | 8 (0.8) | 1 (0.1) |
| Subxyphoid pericardiocentesis | 13 (1.2) | 1 (0.1) |
| Recurrence of pericardial effusion | 0 (0.0) | 2 (0.2) |
| Device embolisation | 5 (0.5) | 0 (0.0) |
| Requiring surgery | 2 (0.2) | 0 (0.0) |
| Snared | 3 (0.3) | 0 (0.0) |
| Ischaemic stroke or systemic embolism | 5 (0.5) | 6 (0.6)† |
| Transient ischaemic attack | 1 (0.1) | 0 (0.0) |
| Vascular or haemorrhagic complications | 17 (1.6) | 0 (0.0) |
| Life-threatening | 4 (0.4) | 0 (0.0) |
| Major | 13 (1.2) | 0 (0.0) |
| Air embolism | 3 (0.3) | 0 (0.0) |
| Death | 7 (0.7) | 2 (0.2)‡ |

Teiger et al Heart 2023

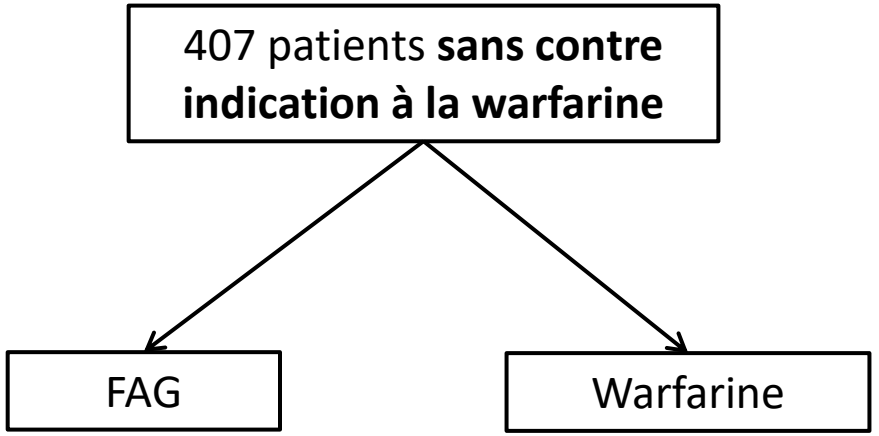
# Fermeture d'auricule gauche: sur quelles études se base-t-on?

**PROTECT**




*Holmes et al Lancet 2009*

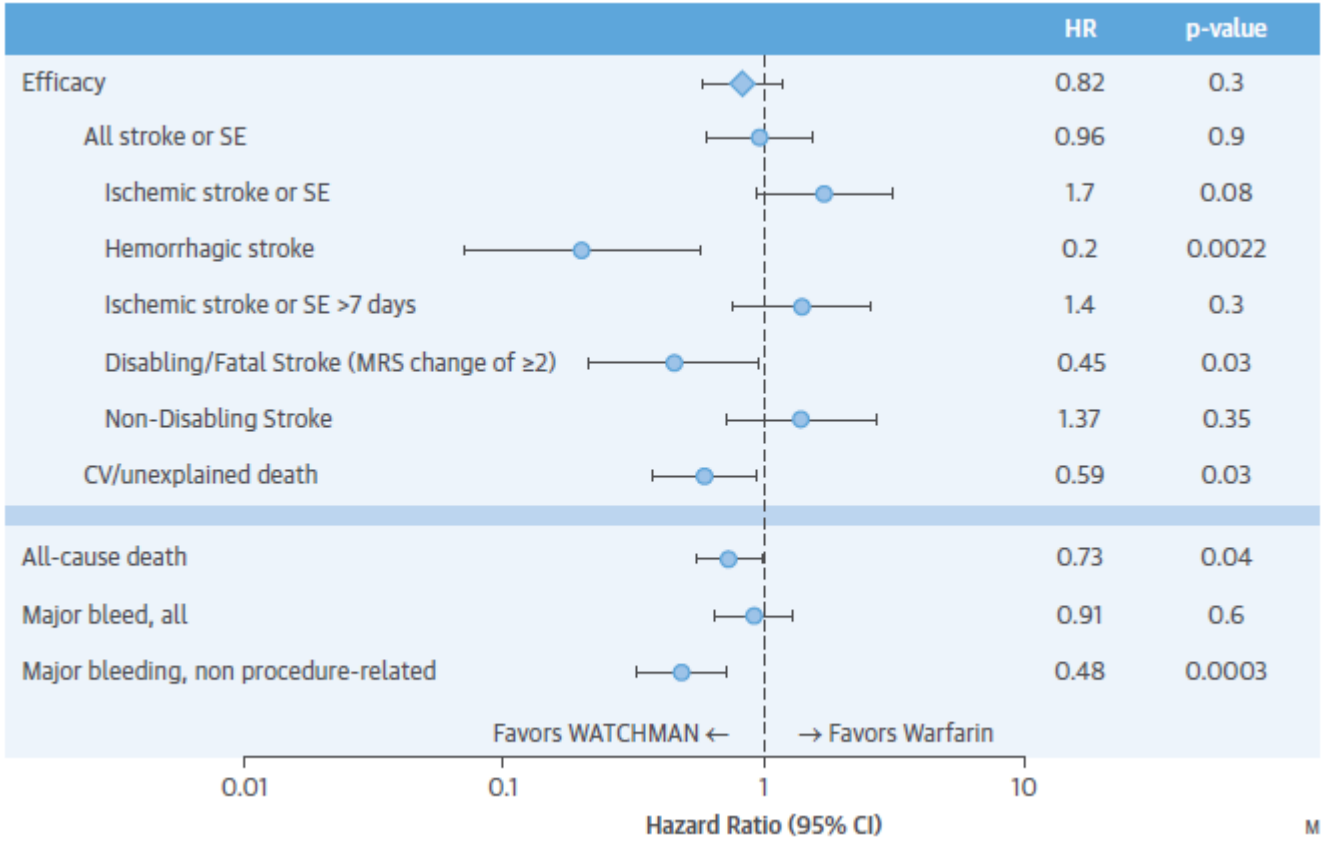
**PREVAIL**




*Holmes et al JACC 2014*

# Analyse poolée PROTECT + PREVAIL à 5 ans

1114 patients




**Reddy et al JACC 2017**

# Exclusion percutanée de l’auricule gauche: une alternative au traitement anticoagulant?

- Problématique
- Fermeture d’auricule gauche: principes
- Fermeture d’auricule gauche chez la patients ayant une contre indication au traitement anticoagulant

# Patients avec contre-indication au traitement anticoagulant?

## ASAP-TOO

Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation

### ASAP-TOO Study Design

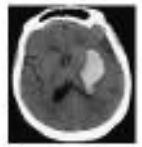
- Prospective, randomized, multi-center, global
- Patients with non-valvular atrial fibrillation deemed not suitable for oral anti-coagulation therapy to reduce the risk of stroke.
- Randomized 2:1 (Watchman vs Control)
- Considering Group Sequential Design
  - Allows early looks; potential to stop early for benefit
- 888 subjects at up to 100 global sites
- Follow-Up*
  - 45 Day with TEE
  - 6,18 month phone visit
  - 12 month with TEE
  - Years 2-5 bi-annually

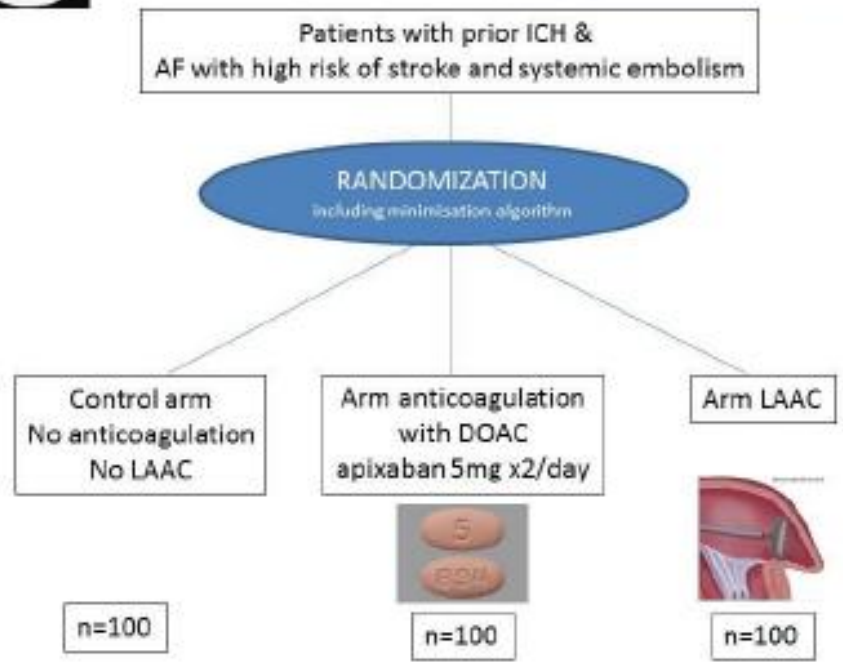
* Brain imaging required at baseline if prior stroke or TIA

# Post hémorragie intracrânienne

**Avoid Anticoagulation After IntraCerebral Haemorrhage**

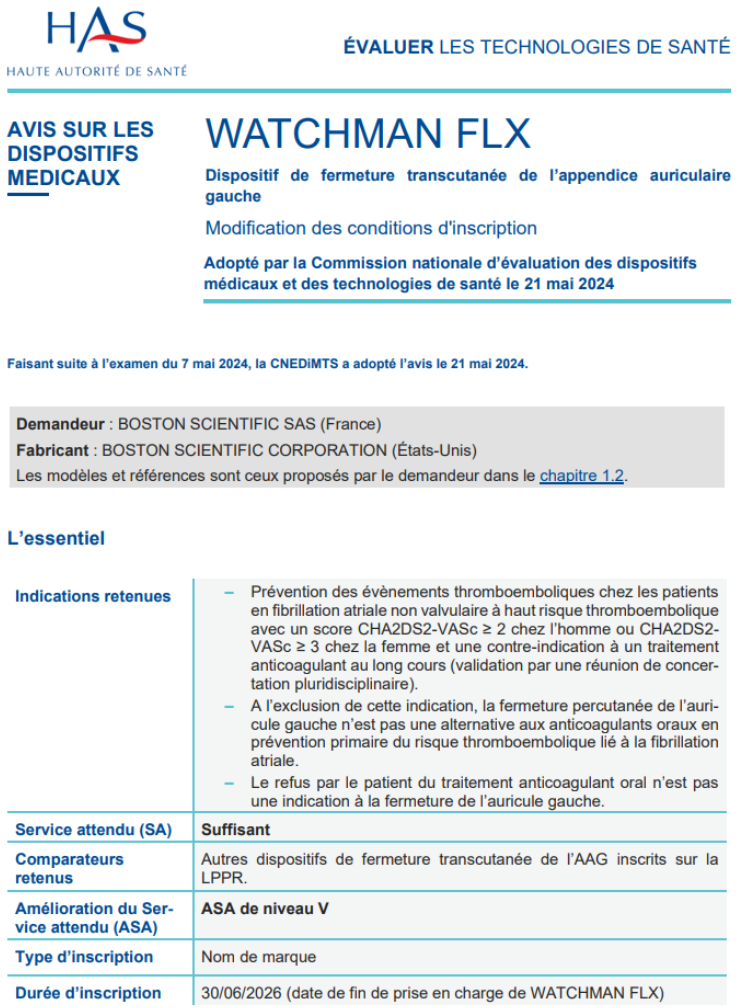
**$A_3$ I C H**





# Indication de fermeture d'auricule actuellement remboursée en France

- Contre indication à un traitement anticoagulant au long cours
- Pas une alternative au traitement anticoagulant
- Validée par une équipe multidisciplinaire



HAS
HAUTE AUTORITÉ DE SANTÉ

**ÉVALUER** LES TECHNOLOGIES DE SANTÉ

**AVIS SUR LES DISPOSITIFS MEDICAUX**

## WATCHMAN FLX

**Dispositif de fermeture transcutanée de l'appendice auriculaire gauche**

Modification des conditions d'inscription

**Adopté par la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé le 21 mai 2024**

**Faisant suite à l'examen du 7 mai 2024, la CNEDiMTS a adopté l'avis le 21 mai 2024.**

**Demandeur** : BOSTON SCIENTIFIC SAS (France)
**Fabricant** : BOSTON SCIENTIFIC CORPORATION (États-Unis)
Les modèles et références sont ceux proposés par le demandeur dans le chapitre 1.2.

**L'essentiel**

| | |
|---|---|
| **Indications retenues** | – Prévention des évènements thromboemboliques chez les patients en fibrillation atriale non valvulaire à haut risque thromboembolique avec un score CHA2DS2-VASc ≥ 2 chez l'homme ou CHA2DS2-VASc ≥ 3 chez la femme et une contre-indication à un traitement anticoagulant au long cours (validation par une réunion de concertation pluridisciplinaire).<br>– A l'exclusion de cette indication, la fermeture percutanée de l'auricule gauche n'est pas une alternative aux anticoagulants oraux en prévention primaire du risque thromboembolique lié à la fibrillation atriale.<br>– Le refus par le patient du traitement anticoagulant oral n'est pas une indication à la fermeture de l'auricule gauche. |
| **Service attendu (SA)** | **Suffisant** |
| **Comparateurs retenus** | Autres dispositifs de fermeture transcutanée de l'AAG inscrits sur la LPPR. |
| **Amélioration du Service attendu (ASA)** | **ASA de niveau V** |
| **Type d'inscription** | Nom de marque |
| **Durée d'inscription** | 30/06/2026 (date de fin de prise en charge de WATCHMAN FLX) |

# Guidelines ESC

| Recommendation | Class[a] | Level[b] |
| --- | --- | --- |
| Percutaneous LAA occlusion may be considered in patients with AF and contraindications for long-term anticoagulant treatment to prevent ischaemic stroke and thromboembolism.[372,376,386,387] | IIb | C |

Guidelines FA 2024

# Guidelines ACC AHA

| 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 ($CHA_2DS_2$-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] |

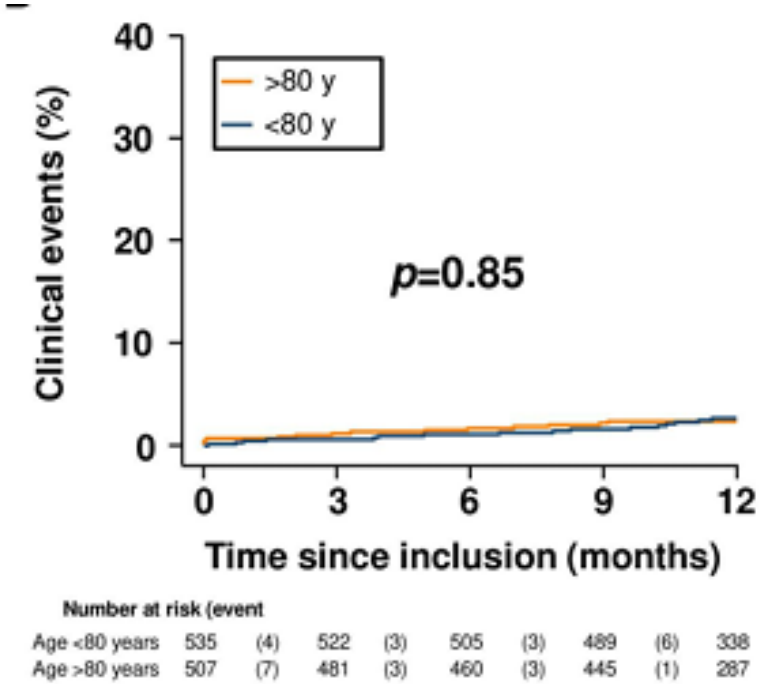
ACC AHA guidelines 2023

# Principales indications en pratique clinique en France

- Neurologie
  - Hémorragies intra-craniennes
- Gastro-enterologie
  - Angiodysplasies
  - Cirrhose?
- Gériatrie
  - Saignements spontanés
  - +/- chutes itératives

# Registre français FLAAC 2

## 1053 patients, 53 centres



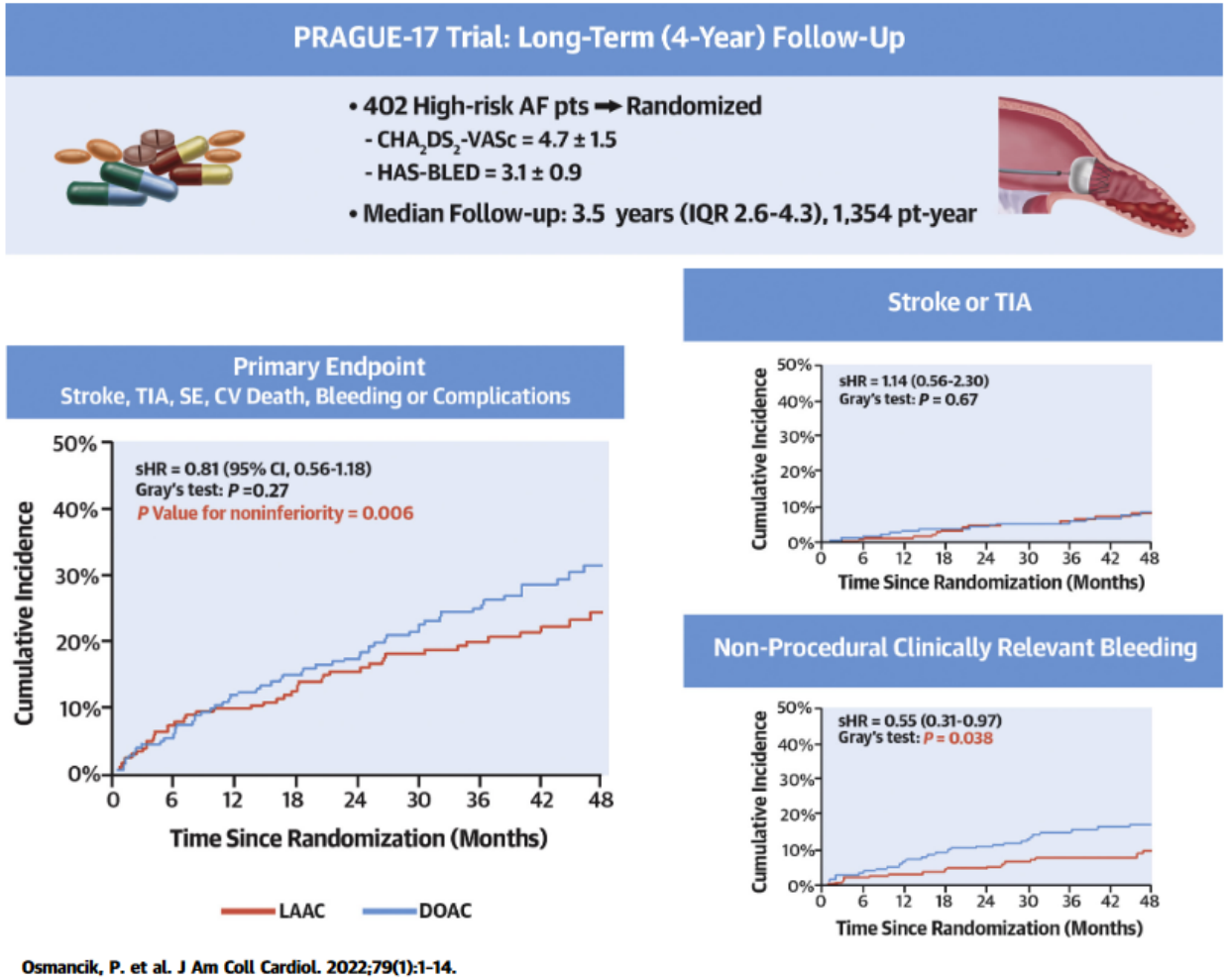

AVC / embolie systémique

Teiger et al Heart 2024

# Exclusion percutanée de l'auricule gauche: une alternative au traitement anticoagulant?

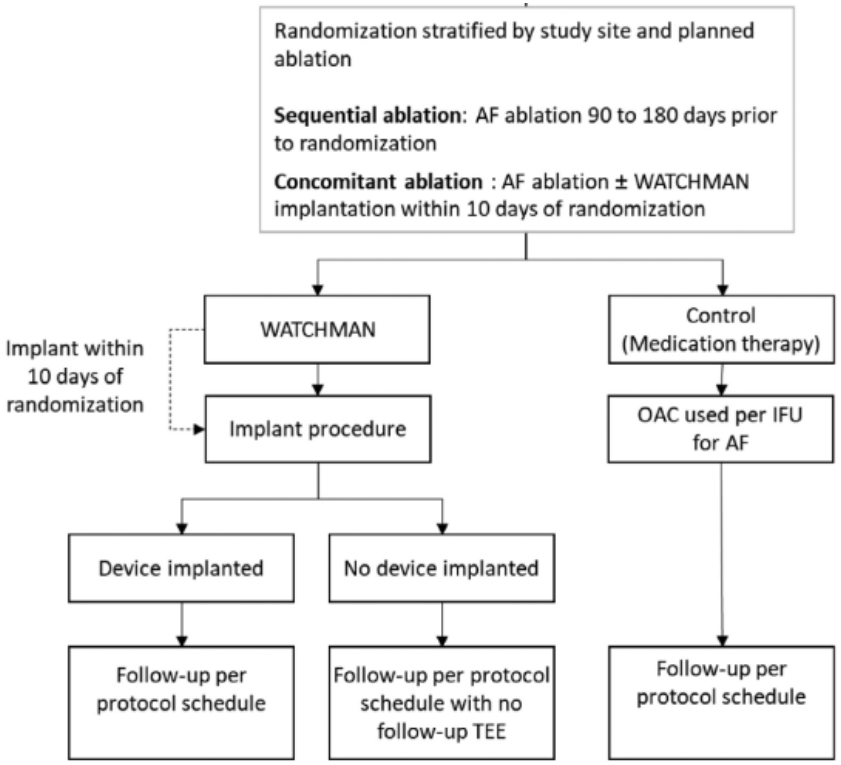
- Problématique
- Fermeture d'auricule gauche: principes
- Fermeture d'auricule gauche chez la patients ayant une contre indication au traitement anticoagulant
- Fermeture d'auricule en alternative chez les patients n'ayant pas de contre indication au traitement anticoagulant

# AOD vs. fermeture d'auricule

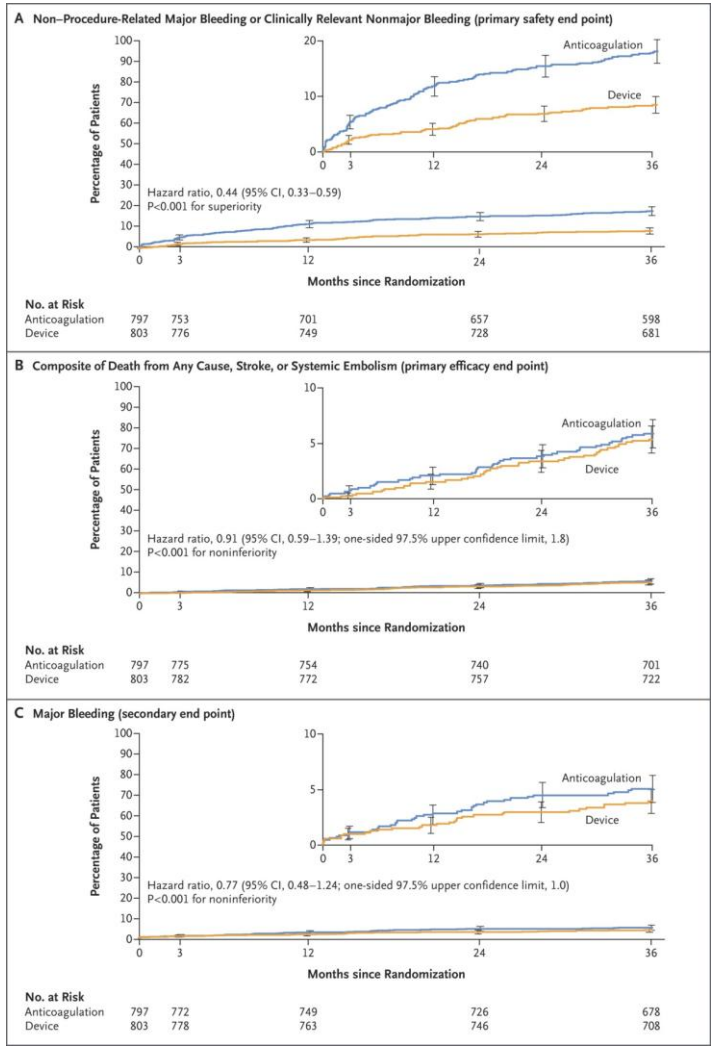



Osmancik, P. et al. J Am Coll Cardiol. 2022;79(1):1-14.

# FAG après ablation de FA: OPTION trial




Wazni et al Am Heart J 2022




Etude OPTION
Wazni et al NEJM 2025

# STUDY DESIGN: CLOSURE-AF

CLOSURE-AF
DZHK TRIAL 16

**Atrial fibrillation with**
- **CHA2DS2Vasc-Score ≥2**
- **Increased Bleeding Risk**
  - **HASBLED-Score ≥3 or**
  - **History of Bleeding# or**
  - **CKD: eGFR 15-29 ml/min/1.73m²**

# History of bleeding:
- BARC-3 A-C or
- History of intracranial/intraspinal bleeding, intraocular bleeding imparing vision , or
- GI, GU or Respiratory Tract bleeding with persistently increased bleeding risk

**Randomisation 1:1**

**Catheter-based Left atrial appendage closure**

**Physician-directed Best medical care**

*

*

**Primary endpoint:***
**Composite of stroke, systemic embolism, cardiovascular/unexplained death or major bleeding (BARC≥3)**

Landmesser U et al.; *Am Heart J* 2025

*At least 18 months and 6 months follow up after 1th and 2nd interim analysis, respectively.

# PRIMARY OUTCOME: CLOSURE-AF

**STROKE, SYSTEMIC EMBOLISM, CARDIOVASCULAR/UNEXPLAINED DEATH, OR MAJOR BLEEDING (BARC≥3)**

CLOSURE-AF
DZHK TRIAL 16

| | **Left atrial appendage closure (N=446)**<br><br>**Events/patient-years**<br>(Incidence per 100 patient-years) | **Physician-directed Best medical care (N=442)**<br><br>**Events/patient-years**<br>(Incidence per 100 patient-years) | |
|---|---|---|---|
| **Outcome** | | | **Adjusted hazard ratio** **(95% CI)** |
| **Primary Outcome (ITT)** | **155**/920.8 (16.83) | **127**/957.0 (13.27) | 1.28 (1.01, 1.62) |
| No. of patients evaluated (PP) | N = 411 | N = 392 | |
| **Primary Outcome (PP)** | **144**/870.0 (16.55) | **108**/864.5 (12.50) | 1.34 (1.04, 1.72) |

# SECONDARY OUTCOMES: CLOSURE-AF

CLOSURE-AF
DZHK TRIAL 16

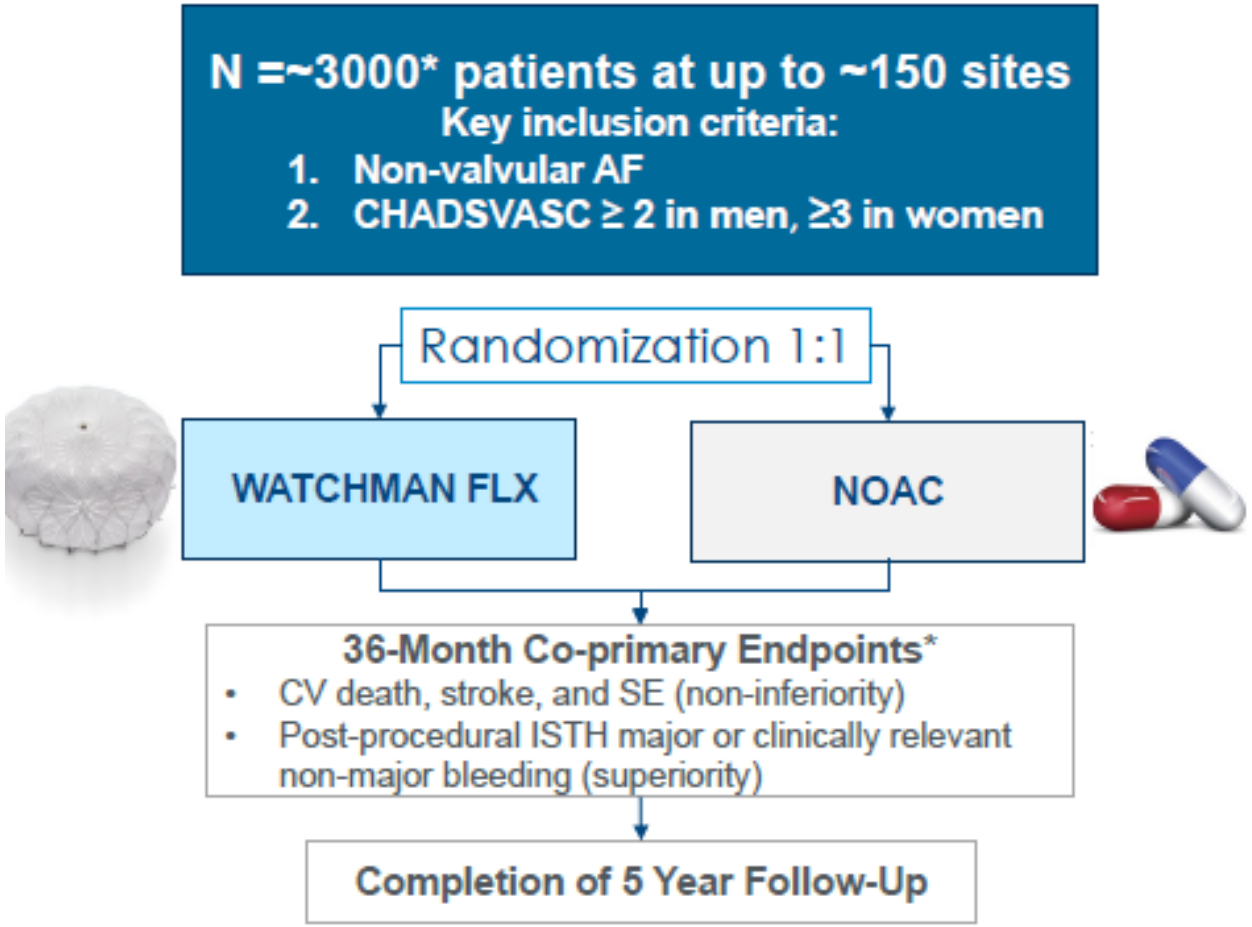
| Outcome | Left Atrial Appendage Closure (N=446)<br>Events/patient-years<br>(Incidence per 100 patient-years) | Physician-directed Best Medical Care (N=442)<br>Events/patient-years<br>(Incidence per 100 patient-years) | Adjusted hazard ratio<br>( 95% CI) |
|---|---|---|---|
| **Systemic embolism** | **3**/1042.7 (0.29) | **1**/1045.4 (0.10) | 2.99 (0.31, 28.79) |
| **Stroke including ischemic or hemorrhagic stroke** | **27**/1019.0 (2.65) | **27**/1015.1 (2.66) | 1.02 (0.59, 1.74) |
| **Major bleeding** | **70**/941.5 (7.43) | **61**/978.7 (6.23) | 1.21 (0.86, 1.71) |
| **Cardiovascular or unexplained death** | **99**/1045.2 (9.47) | **81**/1045.4 (7.75) | 1.25 (0.93, 1.68) |
| **All-cause death** | **155**/1045.2 (14.83) | **141**/1045.4 (13.49) | 1.12 (0.89, 1.40) |

# PERIPROCEDURAL COMPLICATIONS: CLOSURE-AF

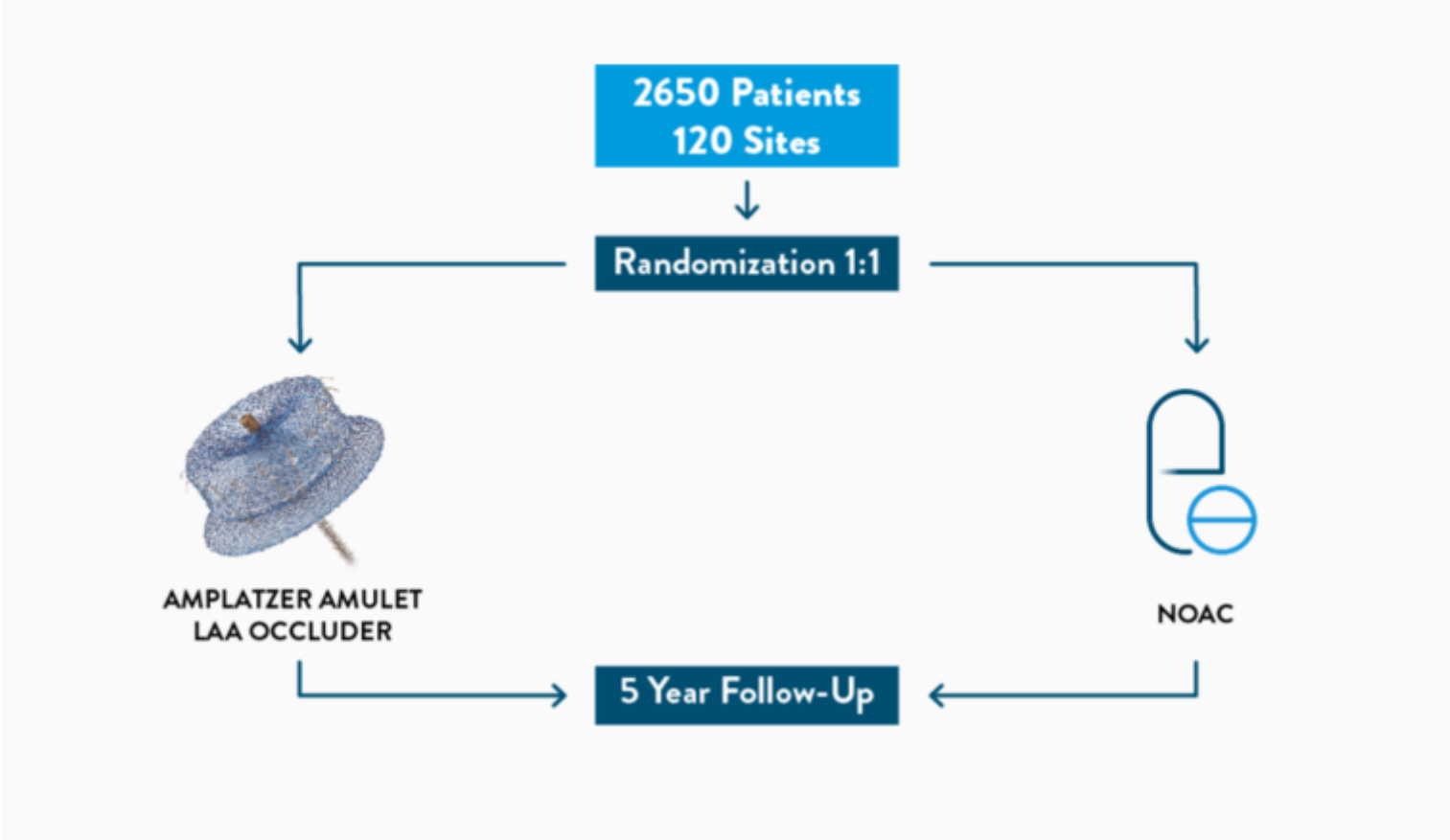
CLOSURE-AF
DZHK TRIAL 16

| Peri-procedural complications at 7 days or discharge | |
|---|---|
| **Pericardial tamponade** | 5 |
| **Major bleeding requiring transfusion** (BARC 3-5) | 18 |
| **Device embolization** (removed surgically) | 1 |
| **Procedure-related TIA** | 1 |
| **Peripheral embolism** | 1 |
| **Death within 7 days after implantation** | 2 |

# LAA O vs. AOD: CHAMPION trial



# LAA O vs. AOD: CATALYST trial



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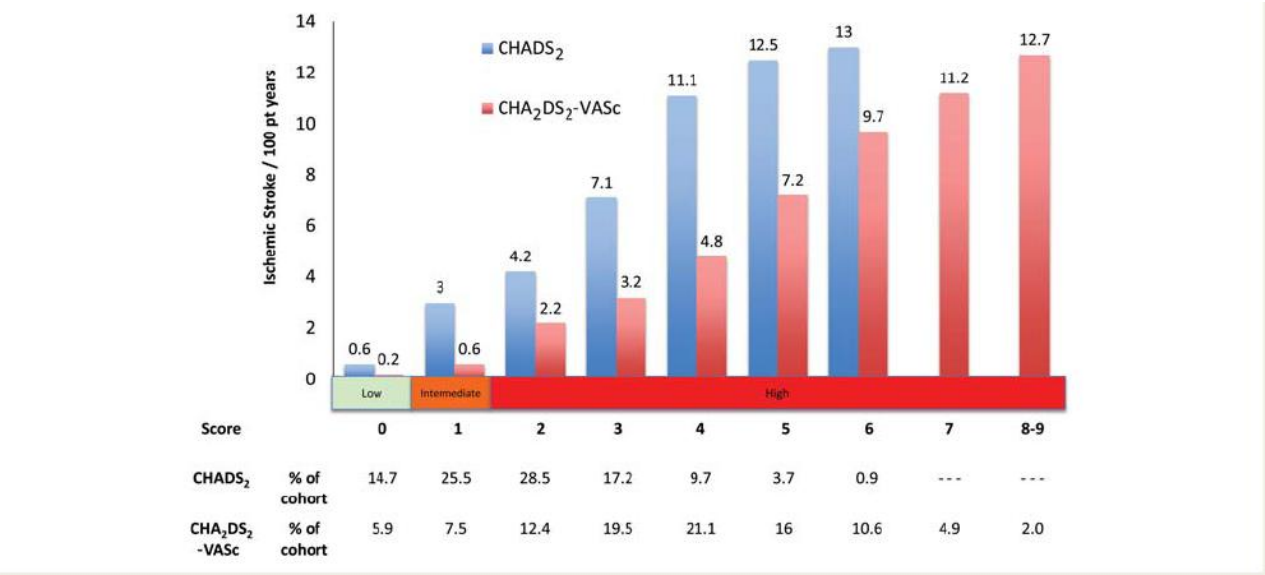
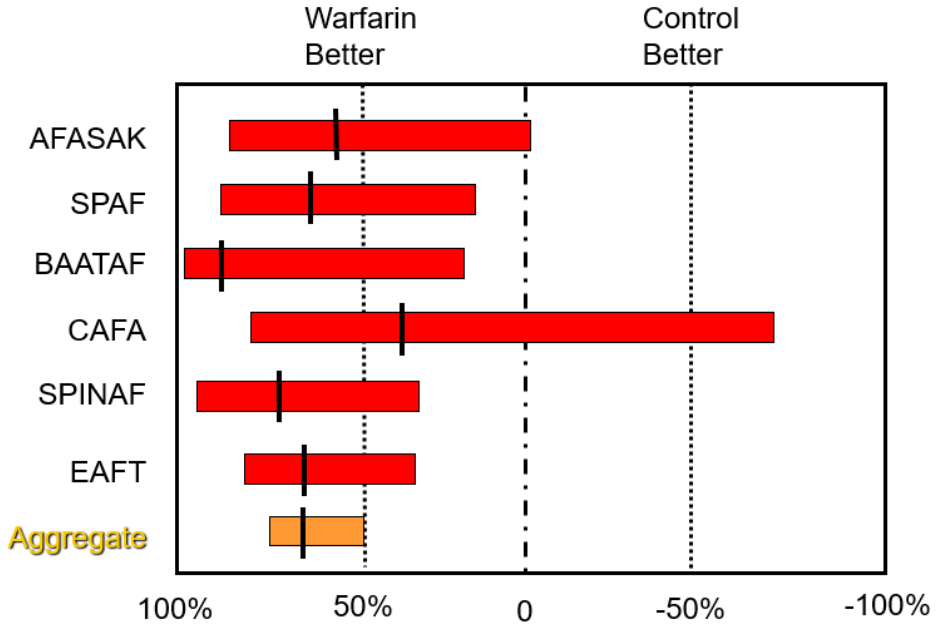
- Fermeture d'auricule en plus du traitement anticoagulant

# Risque résiduel dans la FA




Piccini et al Eur Heart J 2012;33:1431-33




Hart R, et al. ***Ann Intern Med*** 1999;131:492

# Bénéfice additif de LAAO / anticoagulants
# LAAOS III

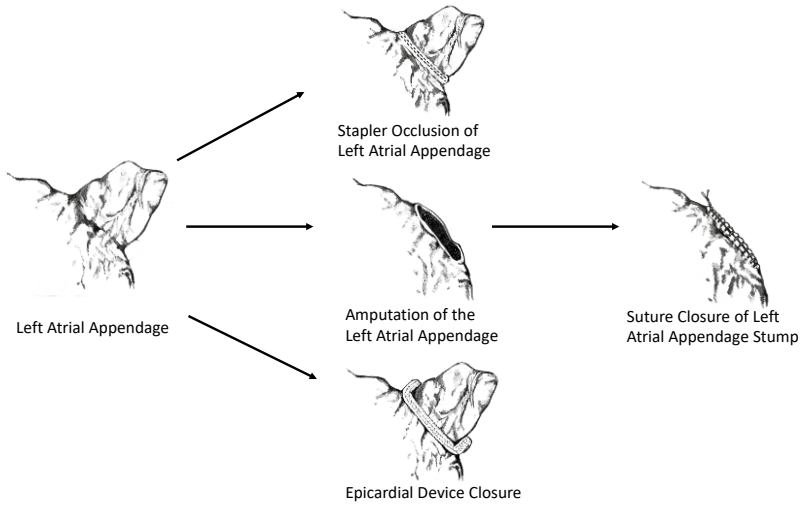
Occlusion chirurgicale d'auricule chez les patients ayant une chirugie cardique pour une autre indication. Maintien du traitement anticoagulant

$CHA_2DS_2$-VASc $\geq 2$

- LAA occlusion

vs.

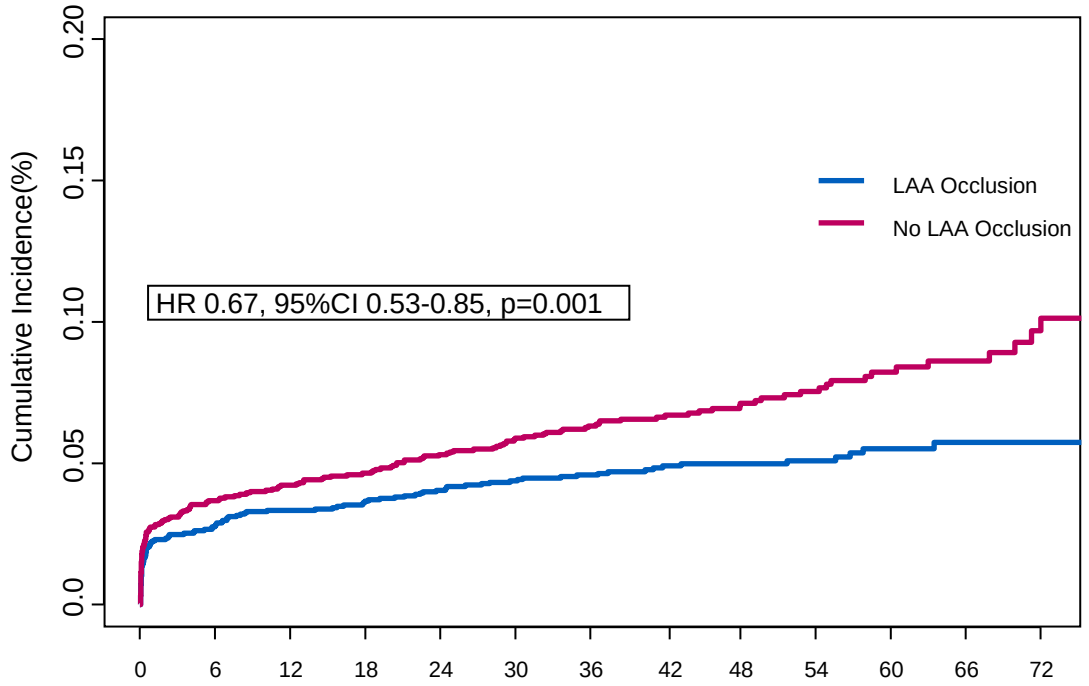
- No occlusion




Whitlock et al NEJM 2021

# Stroke or Systemic Embolism

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 |

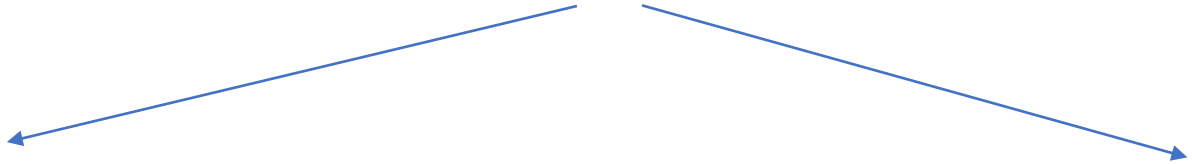
Whitlock et al NEJM 2021

# Bénéfice additif de LAAO / anticoagulants
# LAAOS IV

4000 patients

FA

CHADS-VASc >= 4



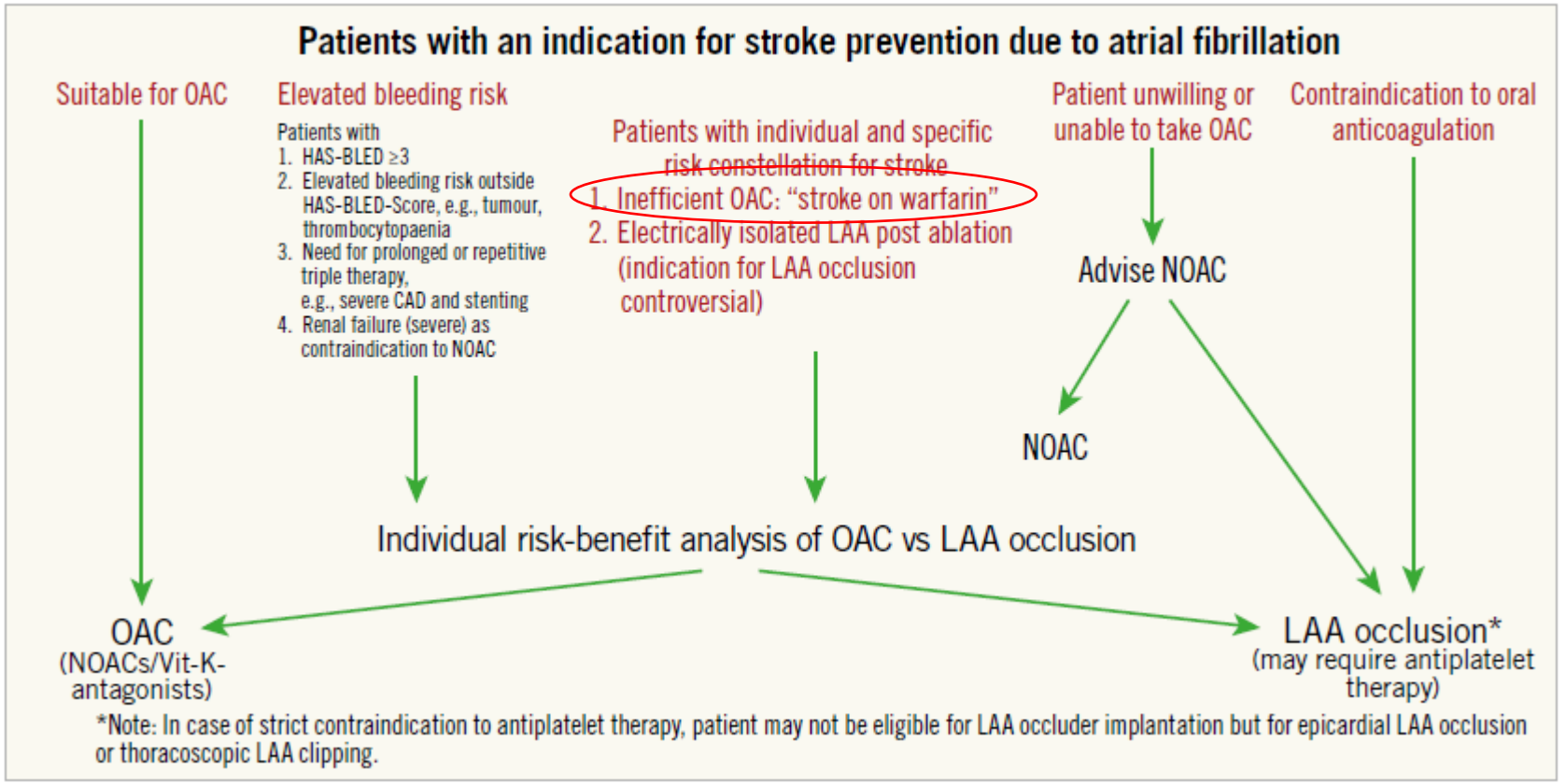
Anticoagulants seuls

FAG + anticoagulants

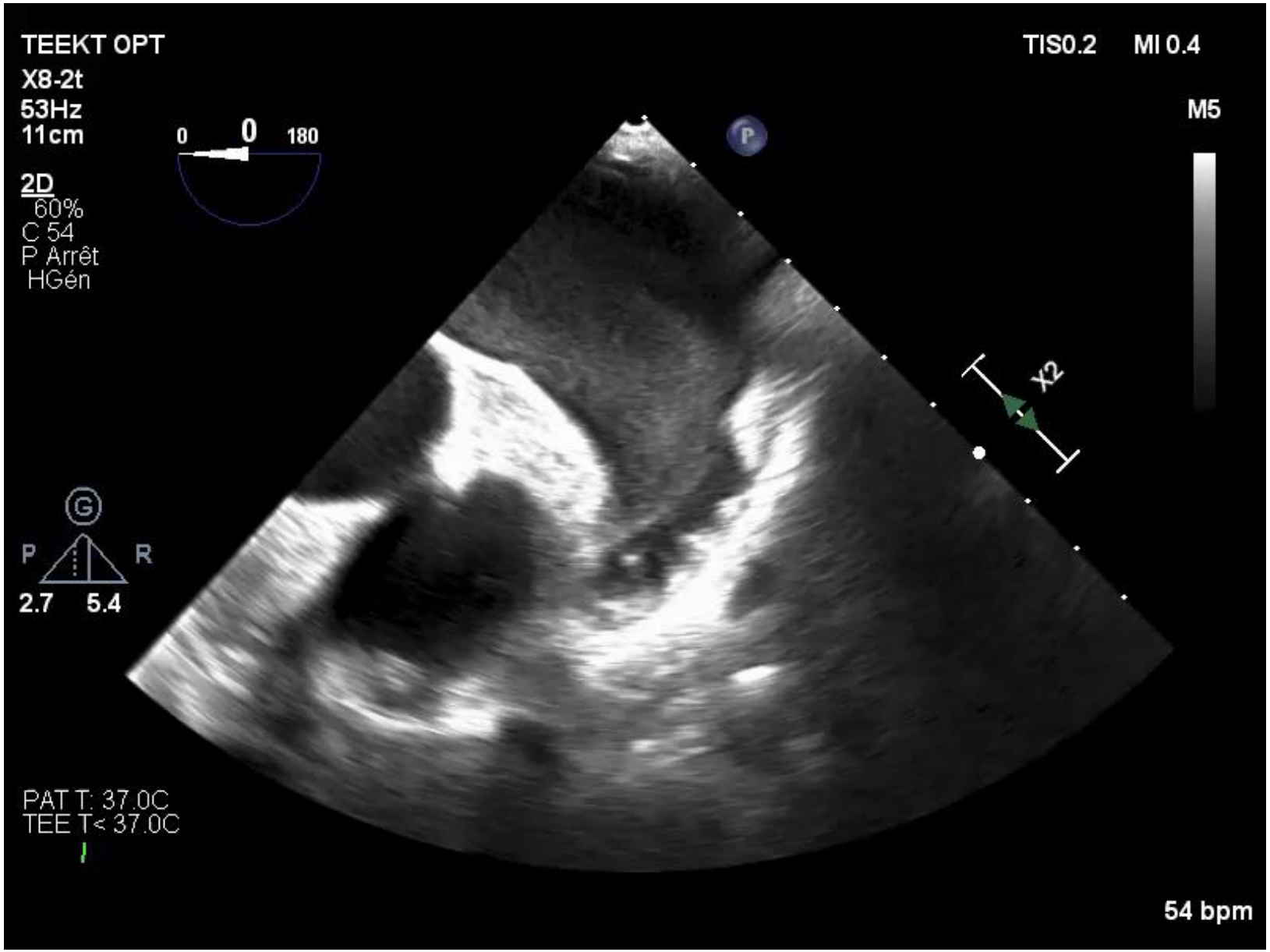
# Conclusions

- La fermeture d'auricule est déjà une alternative au traitement anticoagulant chez les patients contre-indiqués.
- Cette indication est amenée à évoluer avec les résultats d'essais cliniques en cours
  - Alternative chez le patients sans contre indication?
  - Adjonction au traitement anticoagulant chez les patients à haut risque?

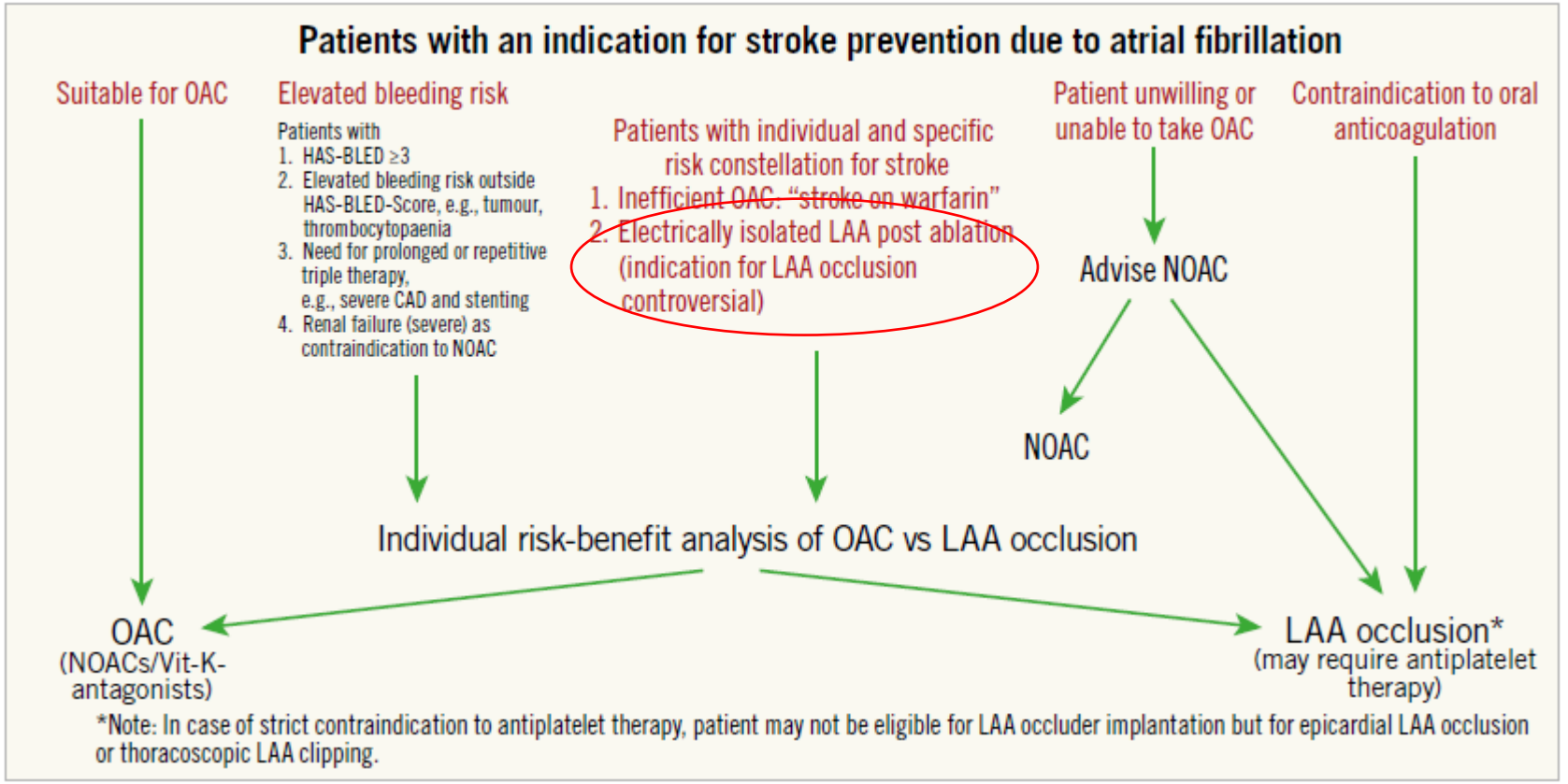
# Occasional indications



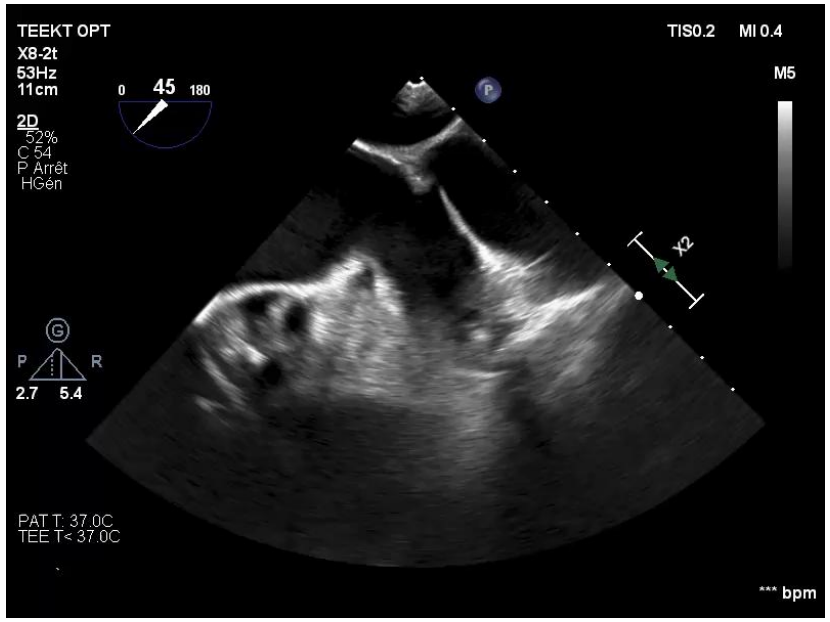

EHRA / EAPCI consensus statement on LAA occlusion 2019

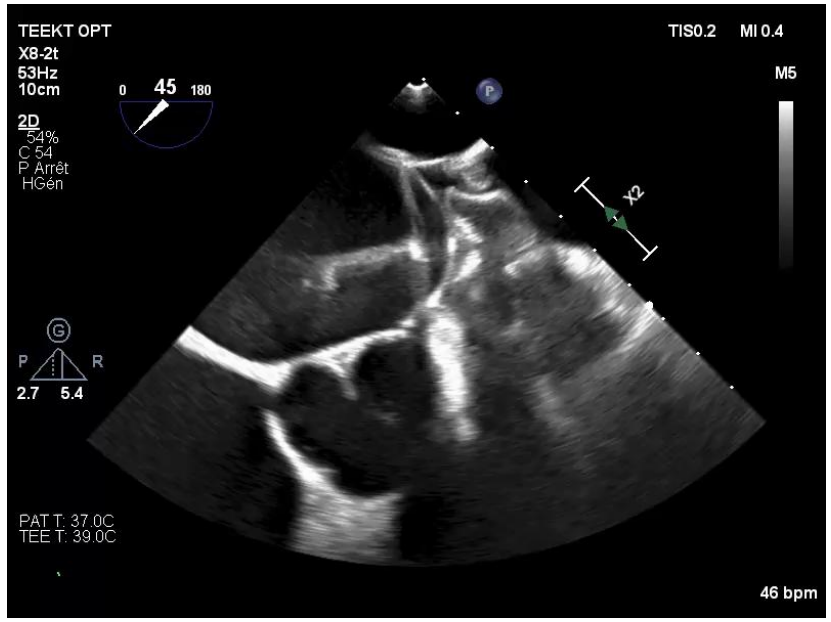

TEEKT OPT
X8-2t
53Hz
11cm
2D
60%
C 54
P Arrêt
HGén
0
0
180
TIS0.2
MI 0.4
M5
X2
G
P
R
2.7
5.4
PAT T: 37.0C
TEE T< 37.0C
54 bpm

# Indications occasionnelles

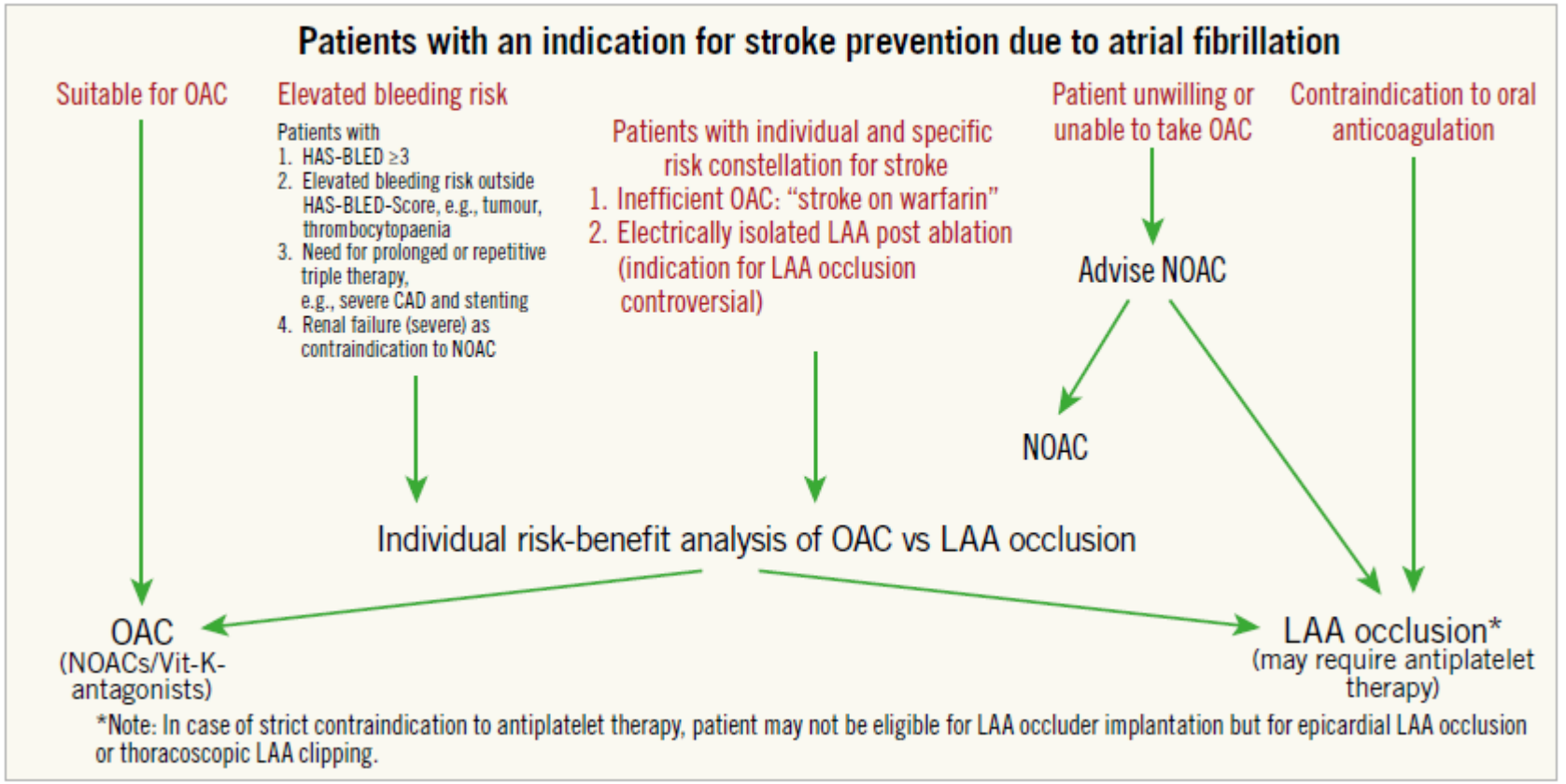



EHRA / EAPCI consensus statement on LAA occlusion 2019


TEEKT OPT
X8-2t
53Hz
11cm
2D
52%
C 54
P Arrêt
HGén
0
45
180
TIS0.2
MI 0.4
M5
X2
P
R
2.7
5.4
PAT T: 37.0C
TEE T< 37.0C
*** bpm


TEEKT OPT
X8-2t
53Hz
10cm
2D
54%
C 54
P Arrêt
HGén
0
45
180
TIS0.2
MI 0.4
M5
X2
P
R
2.7
5.4
PAT T: 37.0C
TEE T: 39.0C
46 bpm

# La position française n'est pas la seule!




EHRA / EAPCI consensus statement on LAA occlusion 2019

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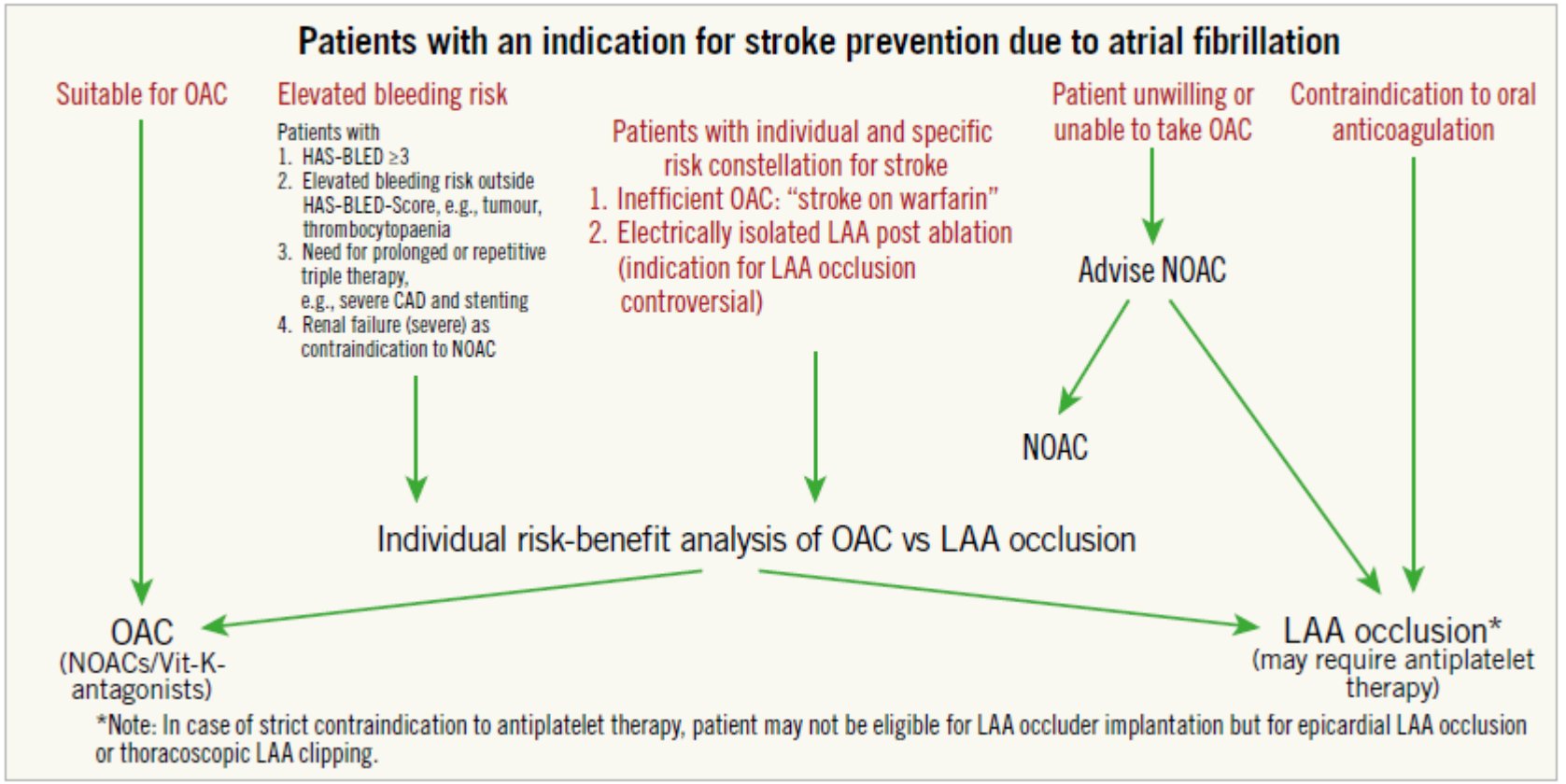


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