Fermeture de l'Auricule Gauche et Fibrillation Atriale Paroxystique

XVIe congrès CARDIORUN
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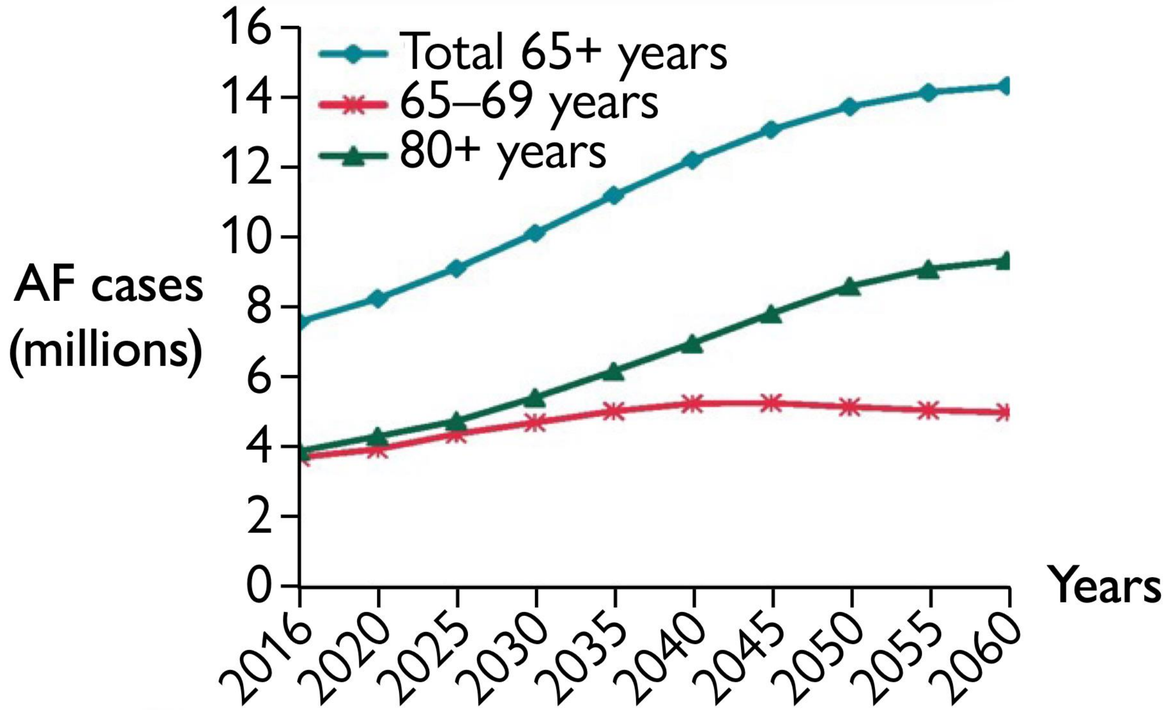
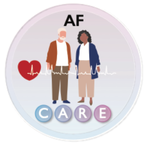
CarMeN LYON

AF = most common cardiac arrhytmia, and growing



~8 M People 65+ with AF in Europe, expected to double by 2060

Landmesser, Eur Heart J 2024



Equality in healthcare provision (gender, ethnicity, socioeconomic) (Class I)

Education for patients, families and healthcare professionals (Class I)

Patient-centred AF management with a multidisciplinary approach (Class IIa)

C — Comorbidity and risk factor management

Hypertension	Heart failure	Overweight or obese	Obstructive sleep apnoea	Alcohol
Blood pressure lowering treatment (Class I)	Diuretics for congestion (Class I)	Weight loss (target 10%)[a] (Class I)	Management of OSA[a] (Class IIb)	Reduce to ≤3 drinks per week (Class I)

A — Avoid stroke and thromboembolism

Risk of thrombo-embolism	Use locally-validated risk score or CHA_2DS_2-VA	Choice of anticoagulant	Assess bleeding risk	Prevent bleeding
Start oral anticoagulation (Class I)	OAC if CHA_2DS_2-VA score = 2 or more (Class I)	Use DOAC, except mechanical valve or mitral stenosis (Class I)	Assess and manage all modifiable risk factors for bleeding (Class I)	Do not combine antiplatelets and OAC for stroke prevention (Class III)
Temporal pattern of AF not relevant (Class III)	OAC if CHA_2DS_2-VA score = 1 (Class IIa)	If VKA: Target INR 2.0–3.0; (Class I) >70% INR range; (Class IIa) or switch to DOAC (Class I)	Do not use risk scores to withhold anticoagulation (Class III)	Avoid antiplatelets beyond 12 months in OAC treated CCS/PVD (Class III)
Antiplatelet therapy not an alternative (Class III)				

E — Evaluation and dynamic reassessment

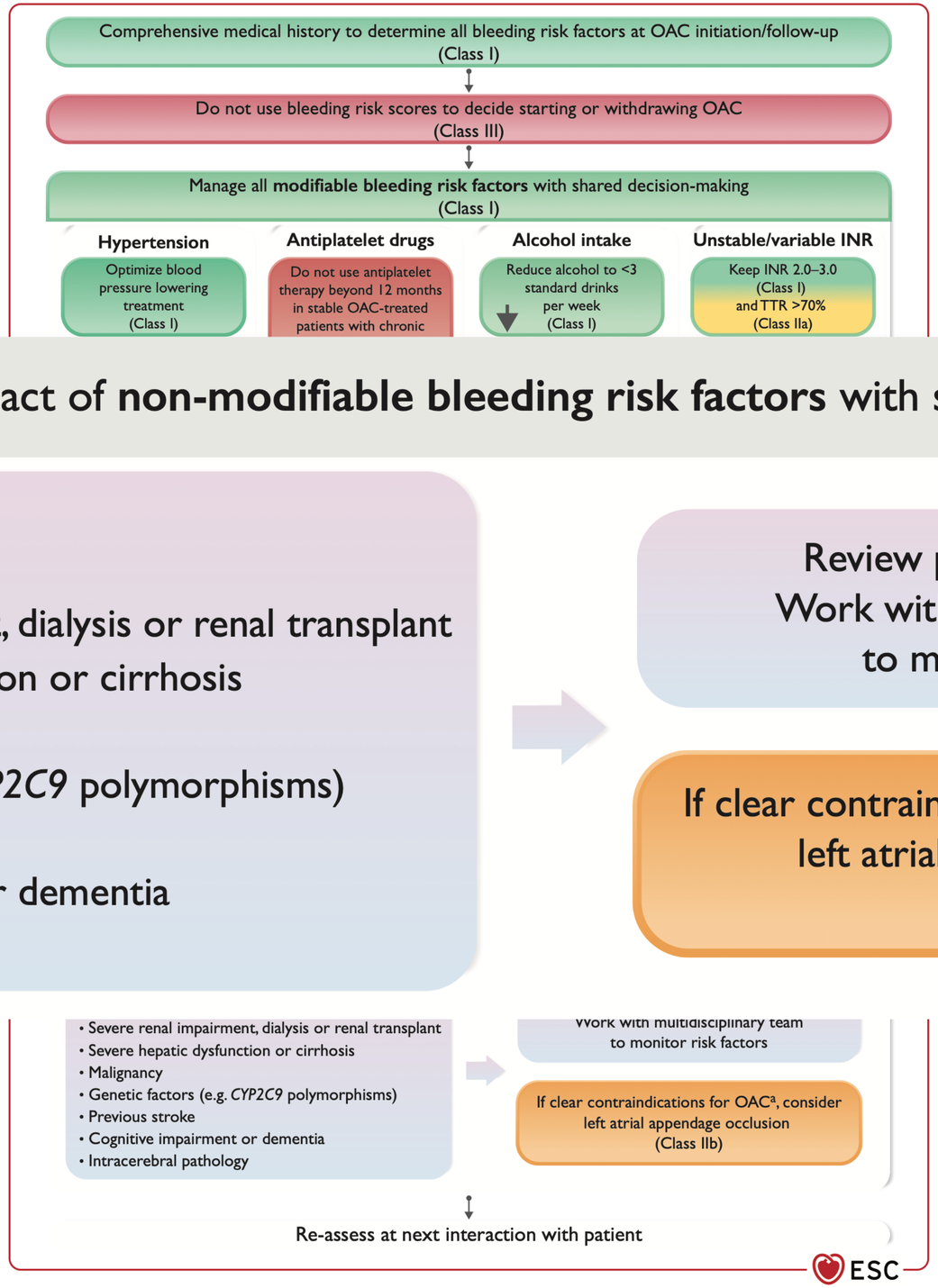
Re-evaluate when AF episodes or non-AF admissions

Regular re-evaluation: 6 months after presentation, and then at least annually or based on clinical need

ECG, blood tests, cardiac imaging, ambulatory ECG, other imaging as needed	Assess new and existing risk factors and comorbidities (Class I)	Stratify risk for stroke and thromboembolism (Class I)	Check impact of AF symptoms before and after treatment (Class I)	Assess and manage modifiable bleeding risk factors (Class I)	Continue OAC despite rhythm control if risk of thromboembolism (Class I)

ESC

ESC 2024



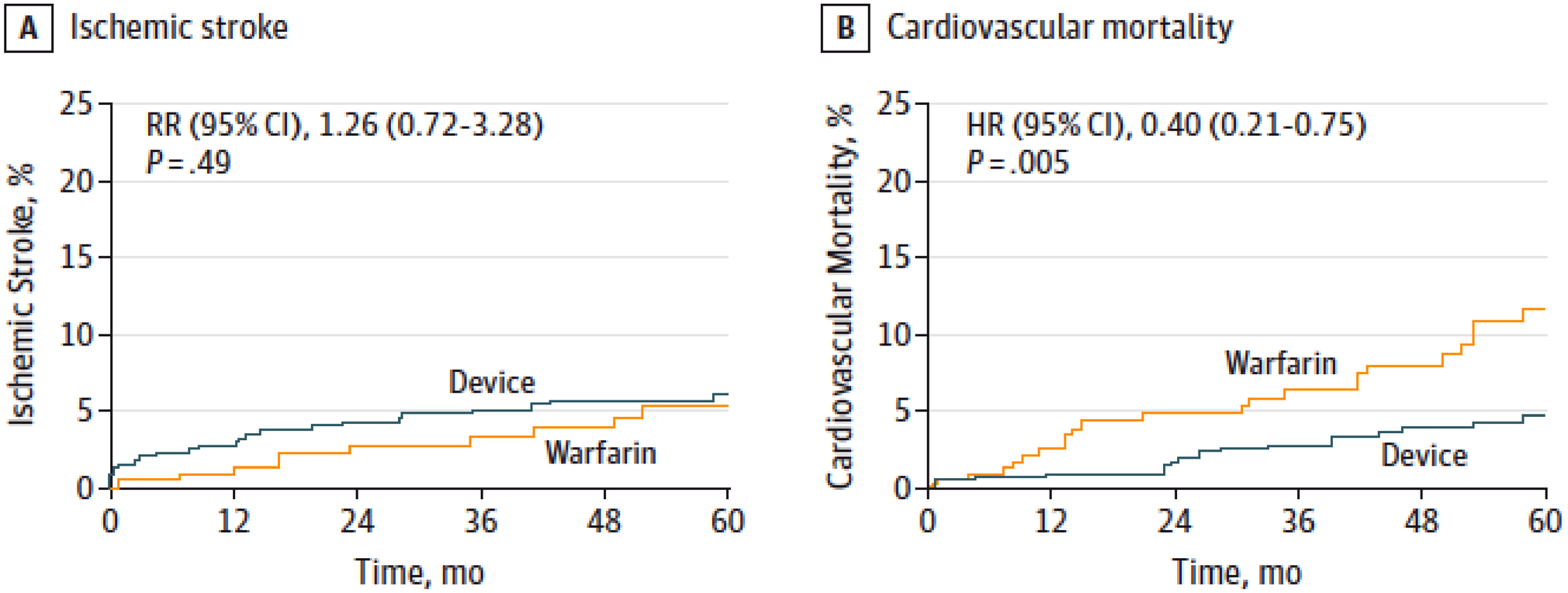
Consider the impact of **non-modifiable bleeding risk factors** with shared decision-making

- Age
- Previous major bleeding
- Severe renal impairment, dialysis or renal transplant
- Severe hepatic dysfunction or cirrhosis
- Malignancy
- Genetic factors (e.g. *CYP2C9* polymorphisms)
- Previous stroke
- Cognitive impairment or dementia
- Intracerebral pathology

Review patient more regularly
Work with multidisciplinary team
to monitor risk factors

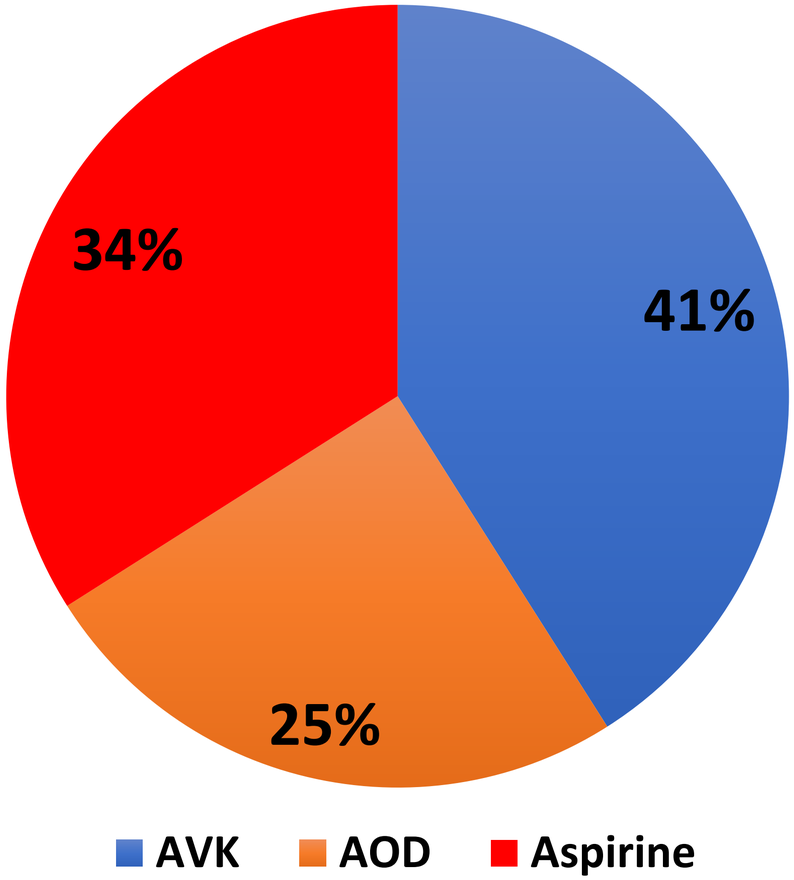
If clear contraindications for OAC[a], consider
left atrial appendage occlusion
(Class IIb)

PROTECT-AF 4y FU



Reddy et al. JAMA 2014;312:1988

PROBLEME N°1: Fibrillation Atriale: Prescription des anticoagulants en France



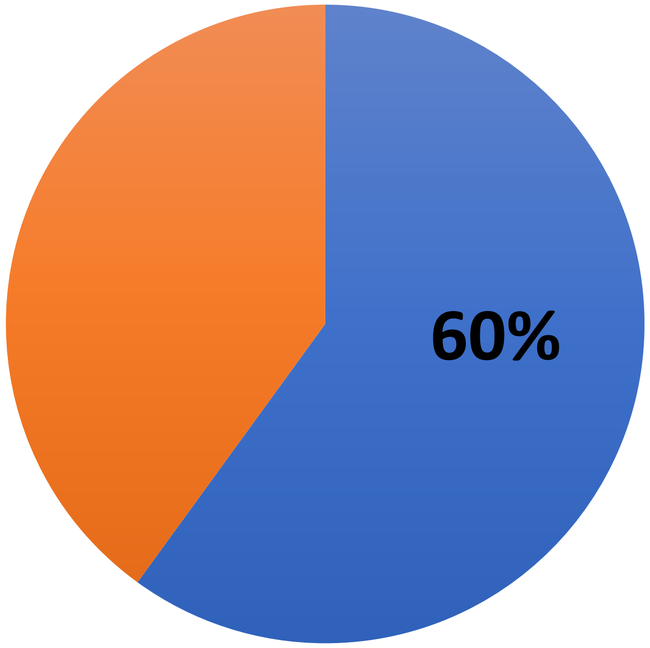
En 2015, 10% des résidents en EPAD sont en Fibrillation Atriale
seulement 50% ont un traitement anti-coagulant

Bahri J Am Geriatr Soc 2015

Maura BMJ Open 2018

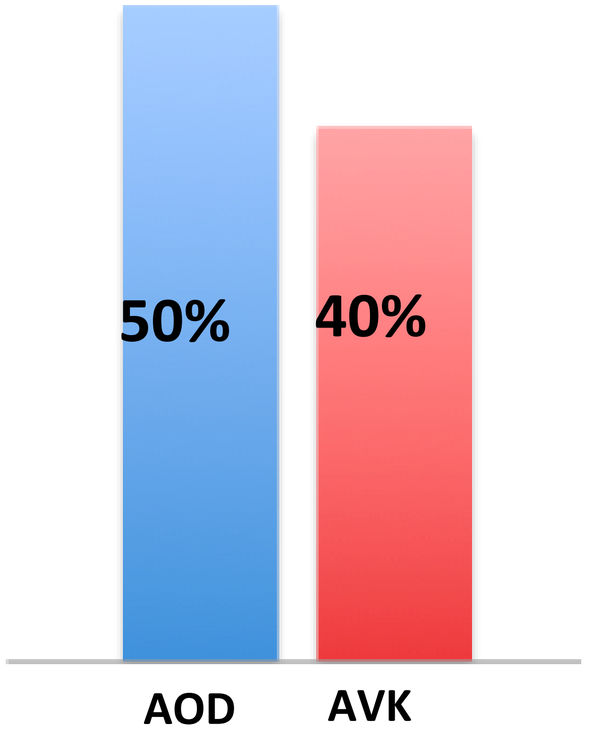
PROBLEME N°2: Anticoagulants, efficacité et compliance

AVK: fenêtre thérapeutique



Wallentin Lancet 2010
Wallentin Circulation 2013

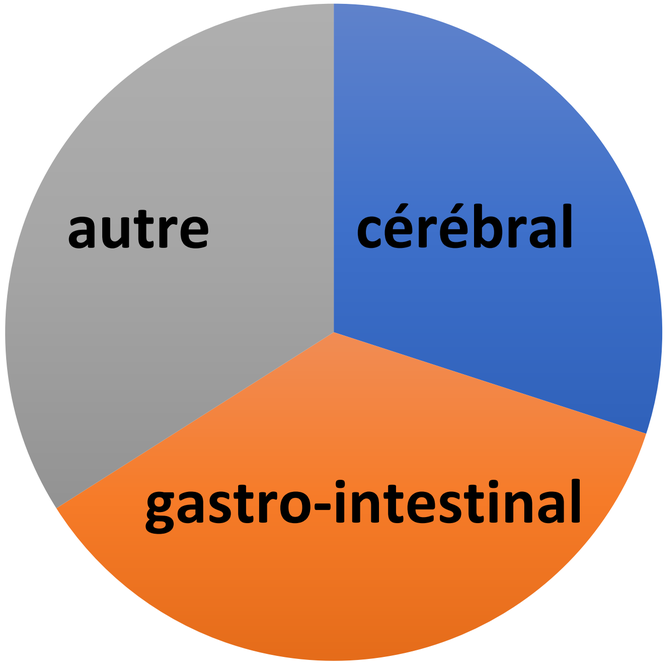
compliance



Yao JAHA 2016

PROBLEME N°3: Les accidents des anticoagulants en France (ANSM 2014)

1.5 million de patients
1/3 des accidents iatrogènes médicamenteux
5000 décès / an

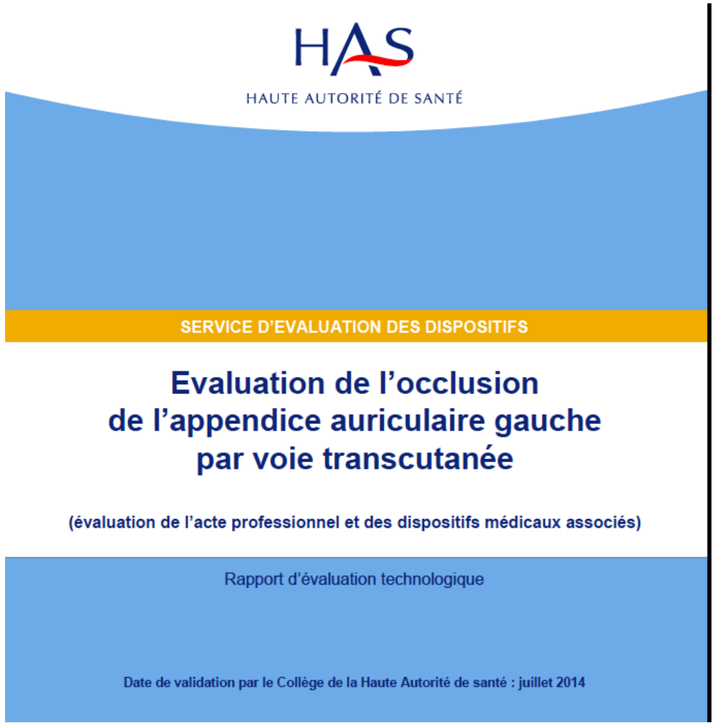


	Sur-risque
ATCD saignement	**X 5.5**
ATCD de chutes	**X 3.1**
Cancer	**X 2.4**
Homme	+ 40%
Polymédications	+ 30%
HTA	+ 30%

saignement grave: 2% par patient/an

Poli Circulation 2011

2014


HAS
HAUTE AUTORITÉ DE SANTÉ

SERVICE D'EVALUATION DES DISPOSITIFS

Evaluation de l'occlusion
de l'appendice auriculaire gauche
par voie transcutanée

(évaluation de l'acte professionnel et des dispositifs médicaux associés)

Rapport d'évaluation technologique

Date de validation par le Collège de la Haute Autorité de santé : juillet 2014

CHA_2DS_2-VASc ≥4
ET
contre-indication aux anticoagulants

2024


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

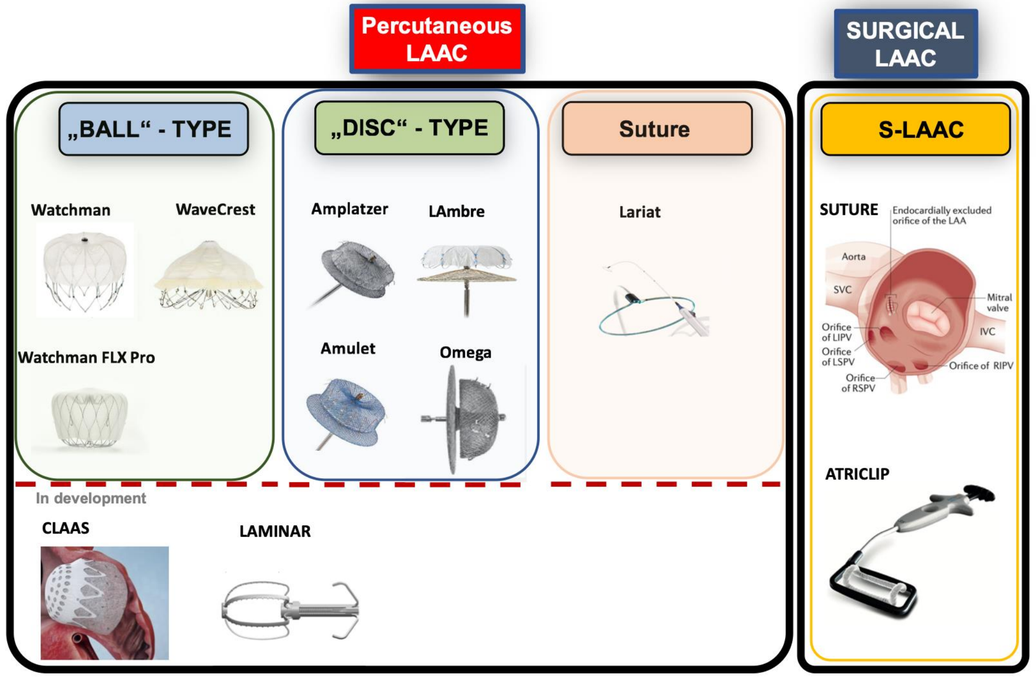
Adopté par la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé le 21 mai 2024

CHA_2DS_2-VASc  **≥2**  **≥3**
ET
contre-indication aux anticoagulants

La Commission recommande l'inscription sous nom de marque et retient les indications suivantes :

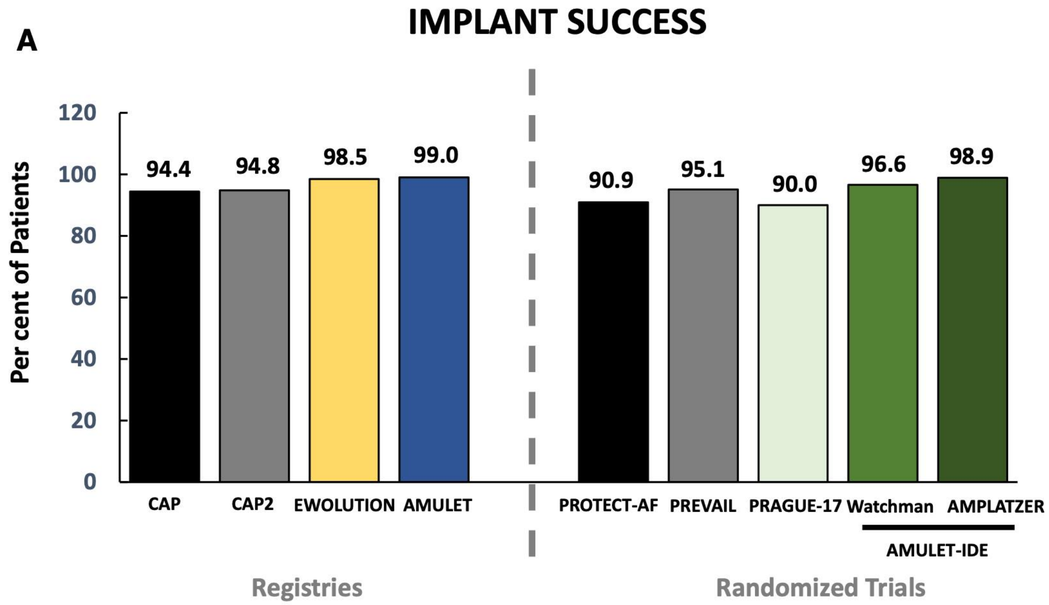
- **Prévention des évènements thromboemboliques chez les patients en fibrillation atriale non valvulaire à haut risque thromboembolique avec un score CHA2DS2-VASc ≥ 2 chez l'homme ou CHA2DS2-VASc ≥ 3 chez la femme et une contre-indication à un traitement anticoagulant au long cours (validation par une réunion de concertation pluridisciplinaire).**
- **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.**
- **Le refus par le patient du traitement anticoagulant oral n'est pas une indication à la fermeture de l'auricule gauche.**

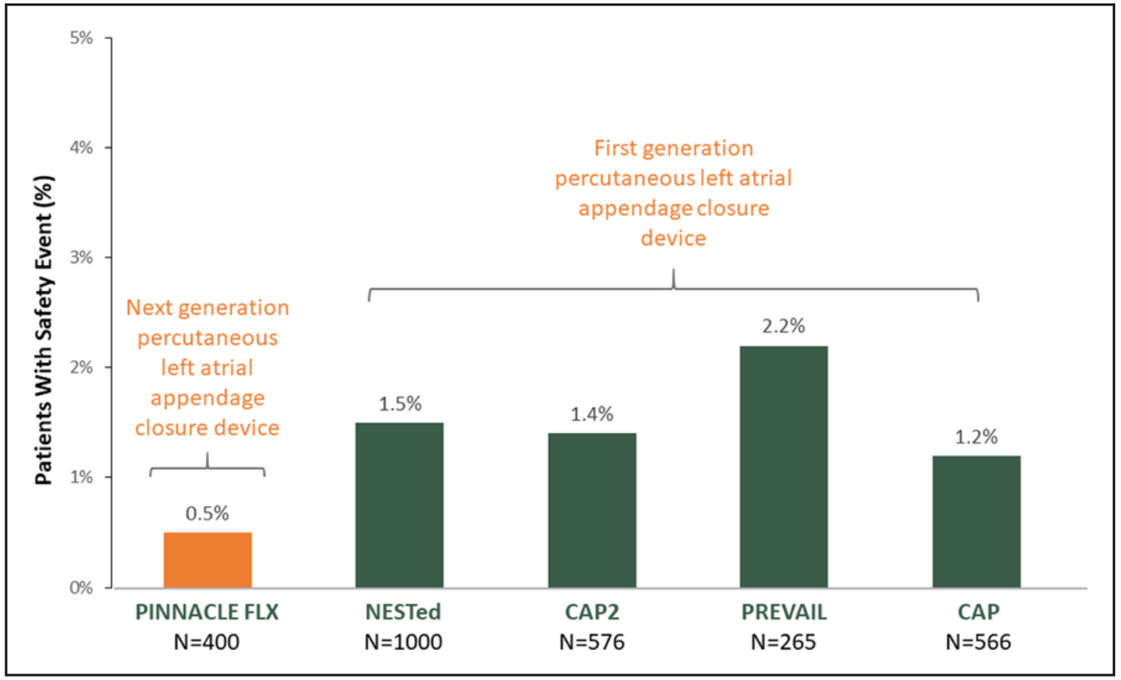
La population cible du dispositif de fermeture transcutanée de l'AAG WATCHMAN FLX est estimée, au maximum, à 50 000 patients par an.



Code CCAM	Intitulé de l'acte	2018	2019	2020	2021	2022
DASF074	Fermeture de l'appendice atrial gauche par dispositif par voie veineuse transcutanée et voie transseptale avec guidage échographie-doppler par voie transoesophagienne	1479	1544	1583	1881	**2116**

LAAC= 4% of expected !!!!





Landmesser, Eur Heart J 2024

Kar Circulation 2021

Consent for colonoscopy: risks

1. Risks of sedation.
2. Cardiopulmonary events.
3. Perforation (<1:2000 without polypectomy, <1:1000 with polypectomy).
4. Bleeding (1:400 without polypectomy, 1:100 with polypectomy).
5. Missed lesion.
6. Repeat procedure.

The risks of perforation and bleeding doubled after 75 years (10.3/10,000) compared to 70–74 years (5.6/10,000) [273334]. Adverse events from colonoscopy increase by 10% after age 65, and the risk of perforation by 30% [2631]. Cardiovascular and pulmonary complications related to anaesthesia increased from 26/1000 after 65 years to 35/1000 after 80 years [2631].

Waddingham, BMJ Open Gastroenterol 2023

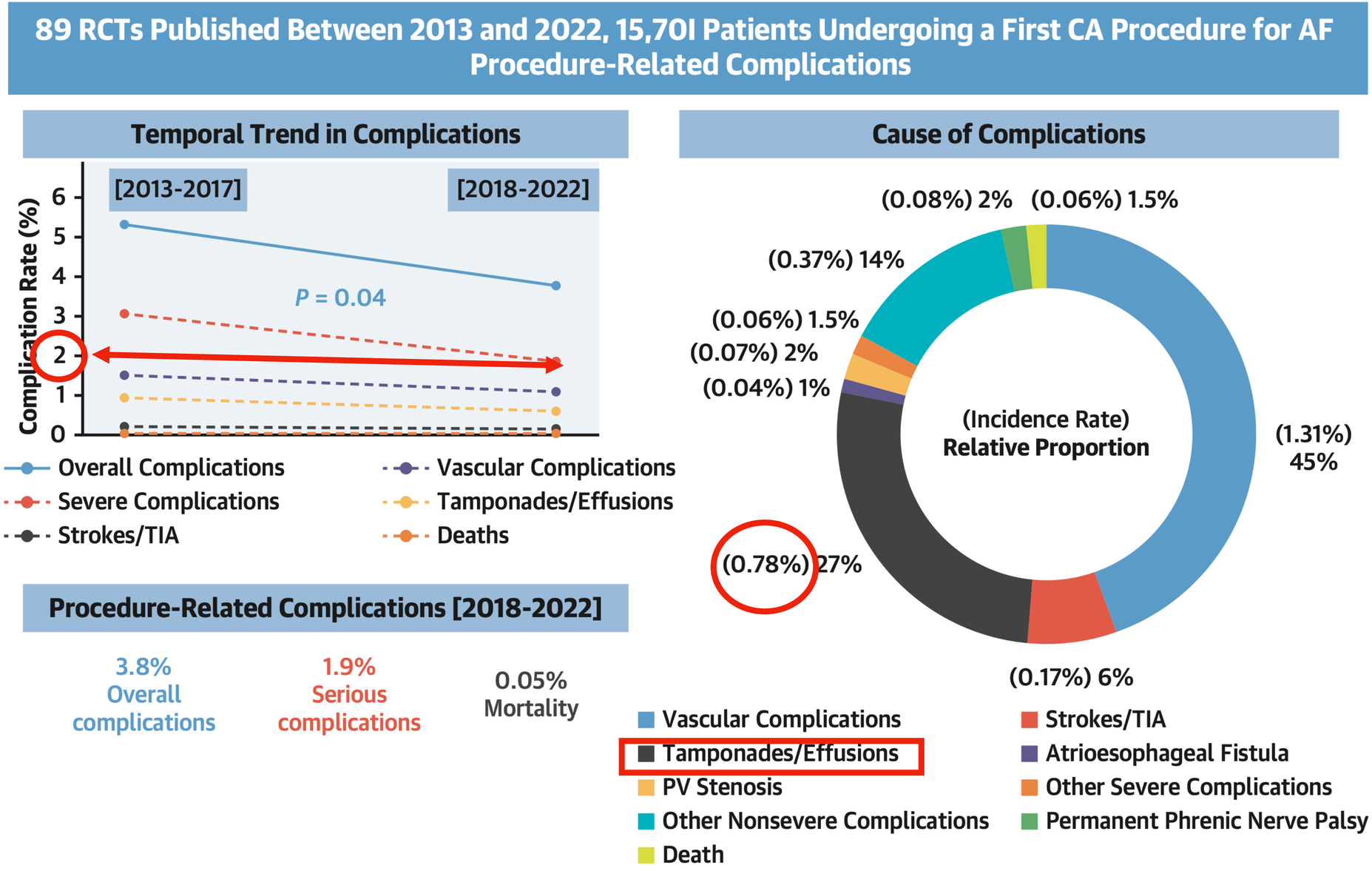
Guittet, BMC Cancer 2023

Table 8 Procedure-Related Complications in Patients Without STEMI

	PCI Patients Without STEMI (n = 787,980)	Diagnostic Catheterization Only Patients Without STEMI (n = 1,091,557)
Complications (%)		
Any adverse event	4.53	1.35
Cardiogenic shock	0.47	0.24
Heart failure	0.59	0.38
Pericardial tamponade	0.07	0.03
CVA/stroke	0.17	0.17
% of total strokes that were hemorrhagic	15.6	9.16
New requirement for dialysis	0.19	0.14
In-hospital mortality		
Non–risk-adjusted	0.65	0.72
Non–risk-adjusted excluding CABG patients	0.62	0.60
CABG performed during admission	0.81	7.47
CABG status		
Salvage/emergency	0.01/0.17	0.01/0.27
Urgent/elective	0.47/0.16	5.27/1.92
CABG indication		
PCI failure without clinical deterioration	0.26	
PCI complication	0.14	
Bleeding complications (%)		
Any bleeding event within 72 h of procedure	1.40	0.49
Any other vascular complication requiring treatment	0.44	0.15
RBC/whole-blood transfusion	2.07	N/R

Dehmer, JACC 2012

CENTRAL ILLUSTRATION **Temporal Trend in Procedure-Related Complications of Catheter Ablation for Atrial Fibrillation**



Benali K, et al. J Am Coll Cardiol. 2023;81(21):2089-2099.

Biais neuro-cognitif?

Impact of adverse events on prescribing warfarin in patients with atrial fibrillation: matched pair analysis

Niteesh K Choudhry, Geoffrey M Anderson, Andreas Laupacis, Dennis Ross-Degnan, Sharon-Lise T Normand, Stephen B Soumerai

Table 2 Association between adverse events associated with warfarin and prescriptions for warfarin and ACE inhibitors in different comparison periods

Comparison period (days after exposure)	No of physicians evaluated	Odds ratio (95% CI)	
		Warfarin use*	ACE inhibitor use*
Bleeding analysis			
0-90	530	0.79 (0.62 to 1.00)	1.13 (0.87 to 1.47)
91-180	521	0.60 (0.46 to 0.79)	1.16 (0.90 to 1.51)
181-270	488	0.61 (0.46 to 0.81)	1.11 (0.84 to 1.46)
271-360	469	0.72 (0.54 to 0.97)	1.06 (0.79 to 1.41)
Stroke analysis			
0-90	704	0.95 (0.75 to 1.19)	0.88 (0.70 to 1.11)
91-180	664	1.05 (0.82 to 1.34)	0.99 (0.78 to 1.26)
181-270	656	1.22 (0.96 to 1.55)	1.17 (0.92 to 1.50)
271-360	621	1.23 (0.96 to 1.58)	1.08 (0.84 to 1.40)

*Analyses adjusted for risk factors for stroke and bleeding as well as cardiology involvement in patient's care.

Choudhry et al. BMJ 2006

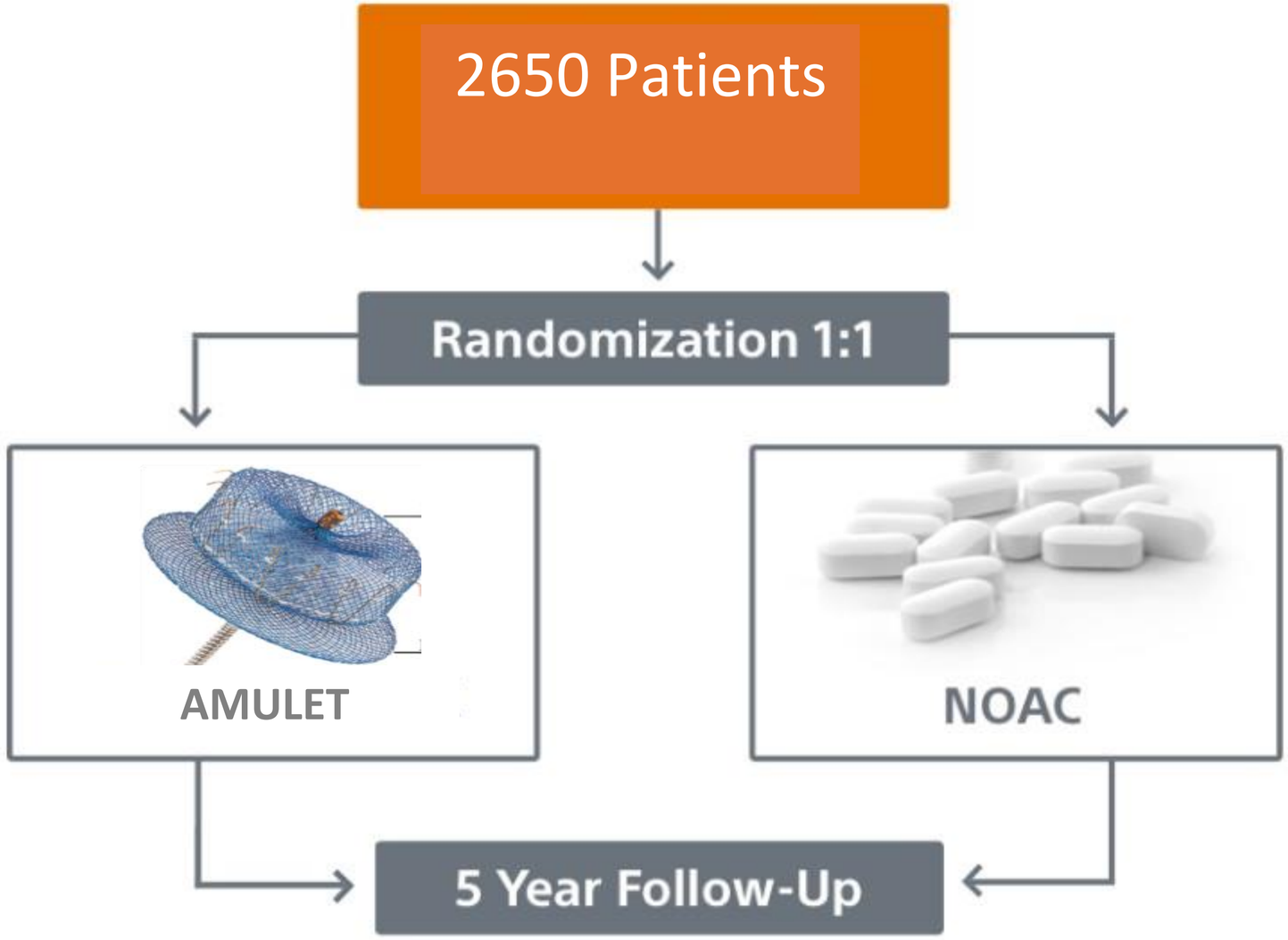
OCEANIC-AF

Table 3. Safety End Points (Safety Population).*

End Point	Asundexian, 50 mg (N=7373)	Apixaban (N=7364)	Total (N=14,737)	Cause-Specific Hazard Ratio (95% CI)†
Primary safety end point: ISTH major bleeding				
No. of patients (%)	17 (0.2)	53 (0.7)	70 (0.5)	0.32 (0.18–0.55)
Events/100 patient-yr (95% CI)	0.62 (0.36–0.95)	1.93 (1.45–2.48)	1.28 (1.00–1.60)	
ISTH major or clinically relevant nonmajor bleeding				
No. of patients (%)	83 (1.1)	188 (2.6)	271 (1.8)	0.44 (0.34–0.57)
Events/100 patient-yr (95% CI)	3.07 (2.44–3.76)	6.92 (5.97–7.94)	5.00 (4.42–5.61)	

Piccini, NEJM 2024

CHAMPION AF/ CATALYST



La fermeture d'auricule gauche protège contre les AVC de la Fibrillation Atriale

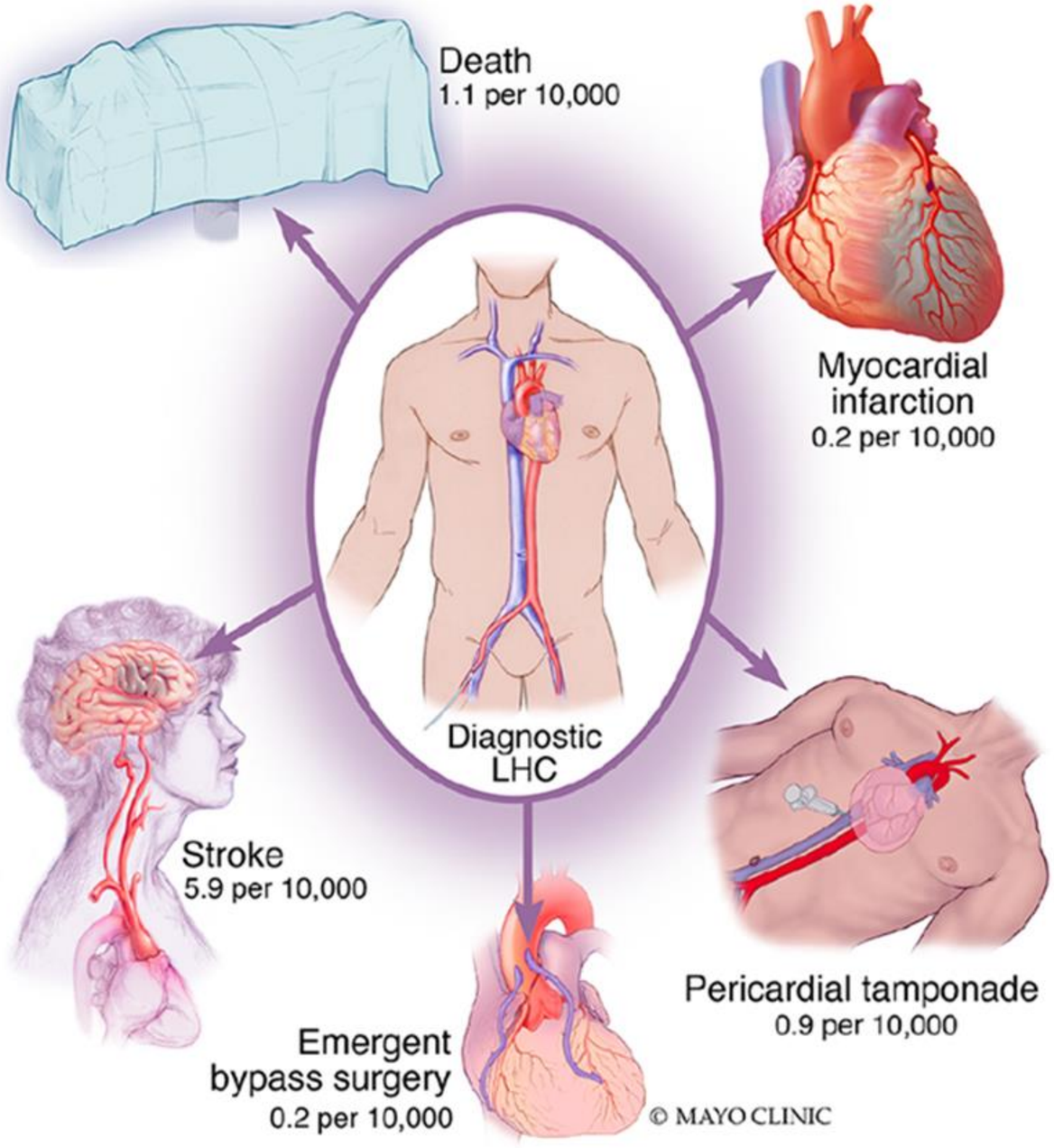
en pratique:

- **Traitement antithrombotique qui ne fait pas saigner**
- **Compliance au traitement de 100%**
- **Fait jeu égal avec un traitement AVK**
- **Fait jeu égal avec un traitement AOD ?**
- **Alternative aux anti-coagulants en cas**
  - **de contre-indication Hémorragique**
  - **de Non Prescription**

- **>40 000 patients/an en défaut possible de traitement**
- **Absence de raison rationnelle évidente**
- **Soyons attentifs au non agir**

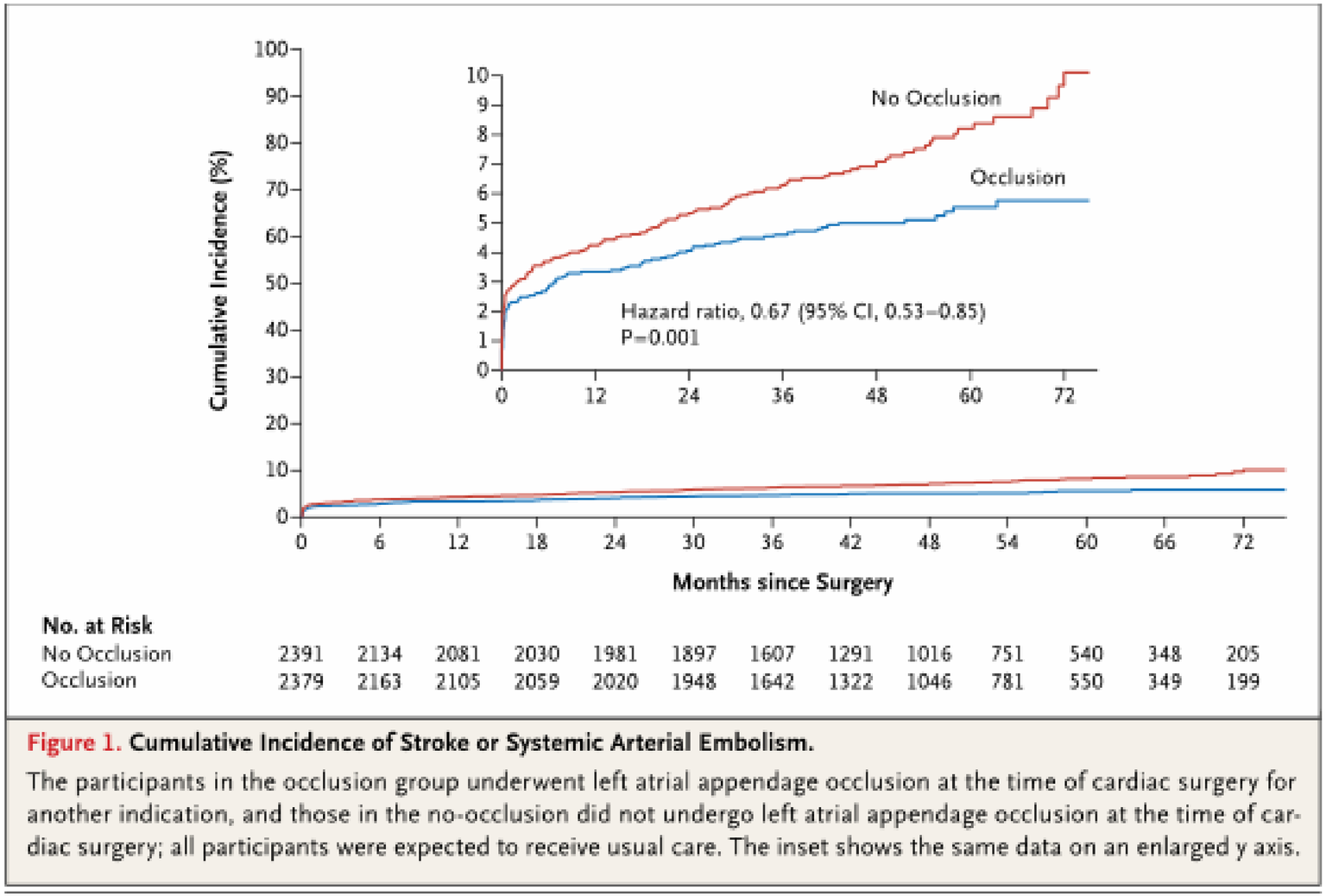
Mayo clinic

43700 diagnostic angiogram



Al-Hijji, Circ Cardiovasc Interv 2019

LAAOS III



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

Figure 1. Cumulative Incidence of Stroke or Systemic Arterial Embolism.

The participants in the occlusion group underwent left atrial appendage occlusion at the time of cardiac surgery for another indication, and those in the no-occlusion did not undergo left atrial appendage occlusion at the time of cardiac surgery; all participants were expected to receive usual care. The inset shows the same data on an enlarged y axis.

Whitlock NEJM 2021

Table 4 Procedural and late postprocedural complications of left atrial appendage occlusion.

Periprocedural complications	Postprocedural complications
Death (<0.2%)	Late pericardial effusion & tamponade (~1%)
Stroke (<0.2%): Ischemic: air or thromboembolism; Hemorrhagic	Peridevice leak: >5 mm on TEE: 1%-3%; >3 mm on TEE: 10%-25%
Systemic embolism (rare)	Device-related thrombus (3%-5%)
Pericardial tamponade (~1%)	Late device migration/ embolization (infrequent)
Device embolization (~0.2%)	Device erosion (rare)
Vascular complications: retroperitoneal bleed, arteriovenous fistula, pseudoaneurysm	Iatrogenic atrial septal defects (rare to require intervention)
Other: major bleeding, renal failure, respiratory failure, sepsis, MI, endotracheal/ esophageal damage, interfering surrounding structures, device/contrast allergy, pericarditis	

MI = myocardial infarction; TEE = transesophageal echocardiography.

Saw, Heart Rhythm 2023