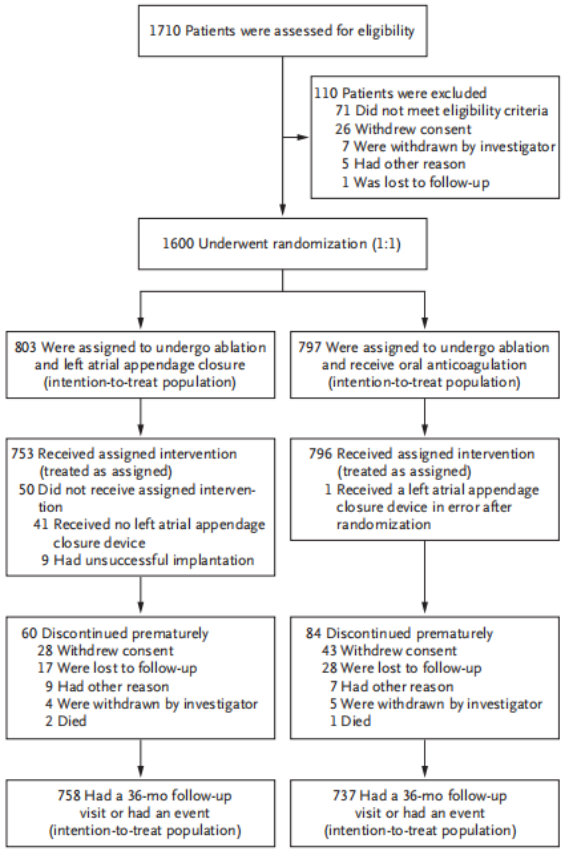
Nouvelles techniques et nouvelles stratégies. Est-ce l'avenir ?

Ablation de FA et fermeture auricule percutanée dans la foulée

D Klug: Lille

ORIGINAL ARTICLE

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation



OPTION Trial

OAC

36 months

AF Ablation

CHADS-Vasc: 3.5±1.3

HAS-BLED: 1.2±0.8

90 Days

120 Days

LAA closure | OAC + aspirin | **aspirin**

N Engl J Med. 2025 Apr 3;392(13):1277-1287

OPTION Trial

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

Table 2. Primary and Secondary End Points at 36 Months (Kaplan–Meier Estimates).*

End Point	Analysis	Device Group (N = 803)	Anticoagulation Group (N = 797)	Difference (one-sided 97.5% upper confidence limit)	P Value
		no. of patients (%)		*percentage points*	
Primary end points					
Safety: non–procedure-related bleeding†	Superiority	65 (8.5)	137 (18.1)	—	<0.001
Efficacy: death from any cause, stroke, or systemic embolism‡	Noninferiority, with 5.0-percentage-point margin	41 (5.3)	44 (5.8)	−0.5 (1.8)	<0.001
Secondary end point					
Major bleeding event§	Noninferiority, with 5.25-percentage-point margin	30 (3.9)	38 (5.0)	−1.1 (1.0)	<0.001

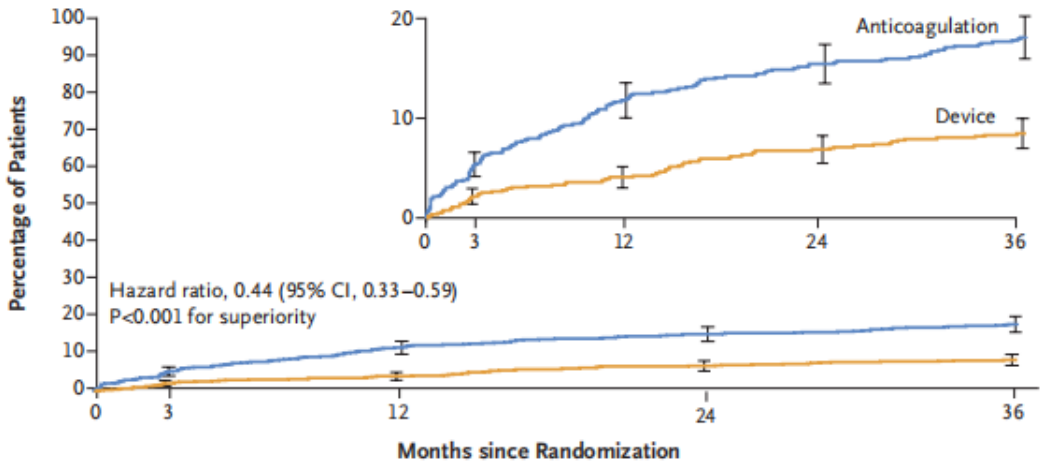
N Engl J Med. 2025 Apr 3;392(13):1277-1287

OPTION Trial

ORIGINAL ARTICLE

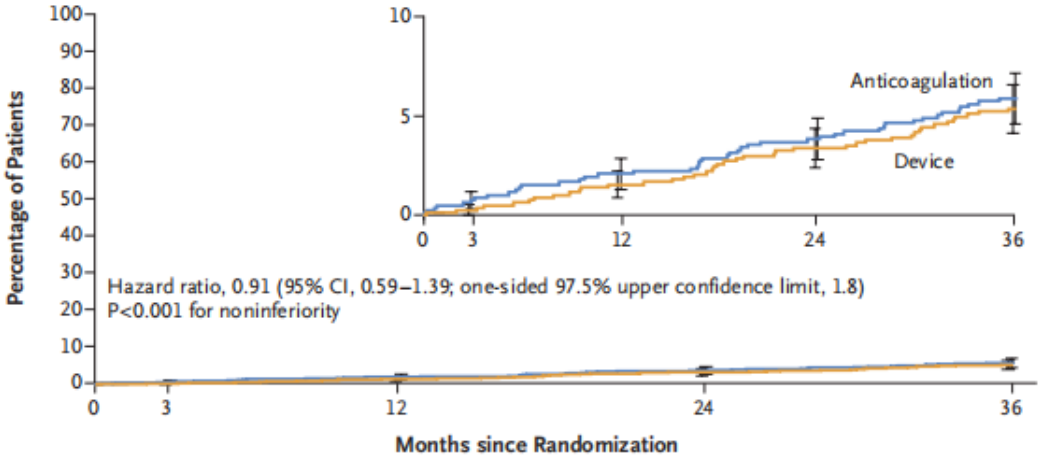
Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

A Non–Procedure-Related Major Bleeding or Clinically Relevant Nonmajor Bleeding (primary safety end point)



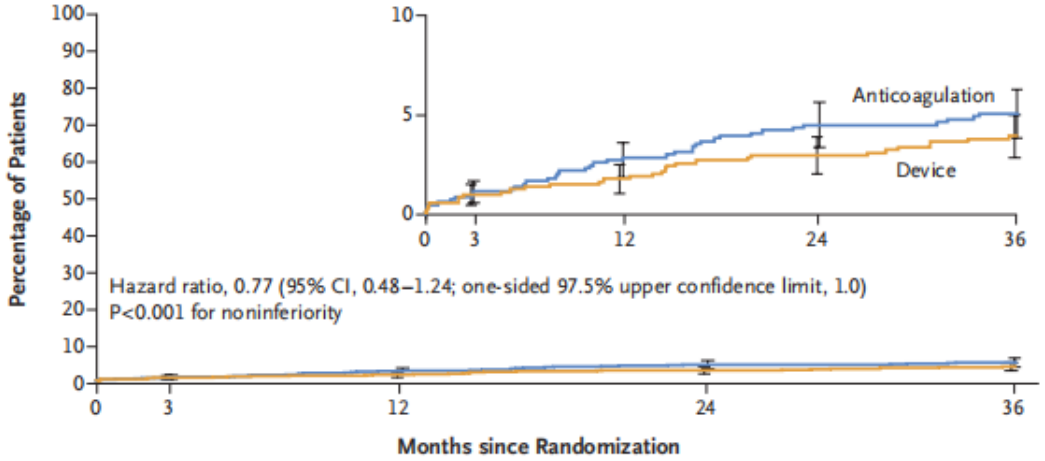
No. at Risk					
Anticoagulation	797	753	701	657	598
Device	803	776	749	728	681

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



No. at Risk					
Anticoagulation	797	775	754	740	701
Device	803	782	772	757	722

C Major Bleeding (secondary end point)



No. at Risk					
Anticoagulation	797	772	749	726	678
Device	803	778	763	746	708

N Engl J Med. 2025 Apr 3;392(13):1277-1287

OUI MAIS

- Pas de différence pour les AVC ischémiques
- Bénéfice essentiellement sur les hémorragies cliniquement significatives
- Nombre d'accidents hémorragiques très élevés pour un HAS-BLED à 1,2±08

- Si ablation efficace le patient est en rythme sinusal…. plus de FA !!!

Est-ce logique de fermer l’auricule à un patient en rythme sinusal ?

Patterns of Anticoagulation Use and Cardioembolic Risk After Catheter Ablation for Atrial Fibrillation

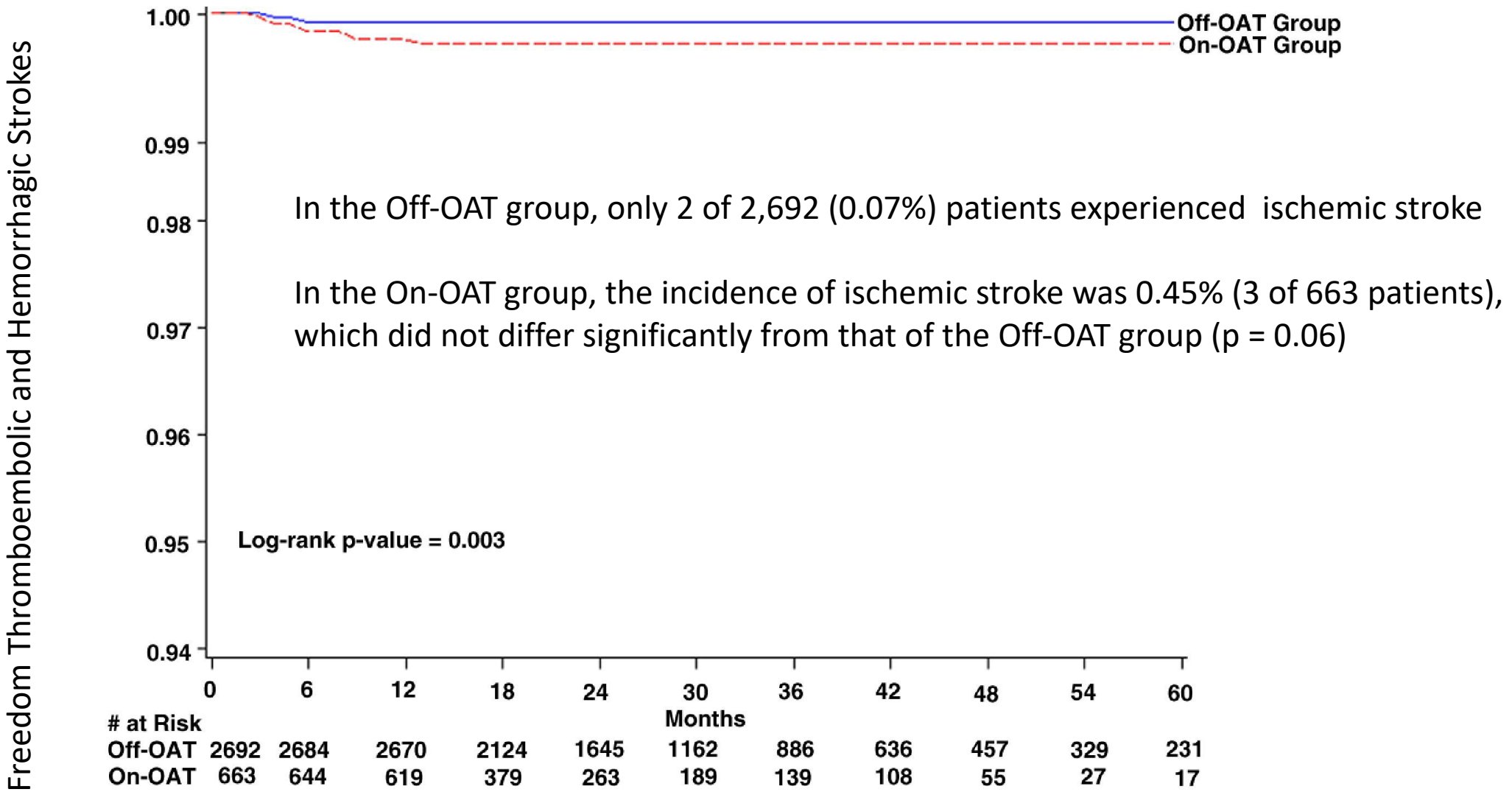
- 6886 patients within a large national administrative claims database
- OAC discontinuation was high, with only 60.5% and 31.3% of patients remaining on OAC at 3 and 12 months

- **The risk of cardioembolism beyond 3 months**
  - **was increased with OAC discontinuation among high-risk patients (hazard ratio 2.48 [95% CI 1.11–5.52], *P*<0.05)**
  - **but not low-risk patients**

- SR or AF ??????

J Am Heart Assoc. 2015;4(11)

3,355 patients, 2,692 discontinued OAT 3 to 6 months after ablation (Off-OAT group) and 663 remained on OAT after this period (On-OAT group)



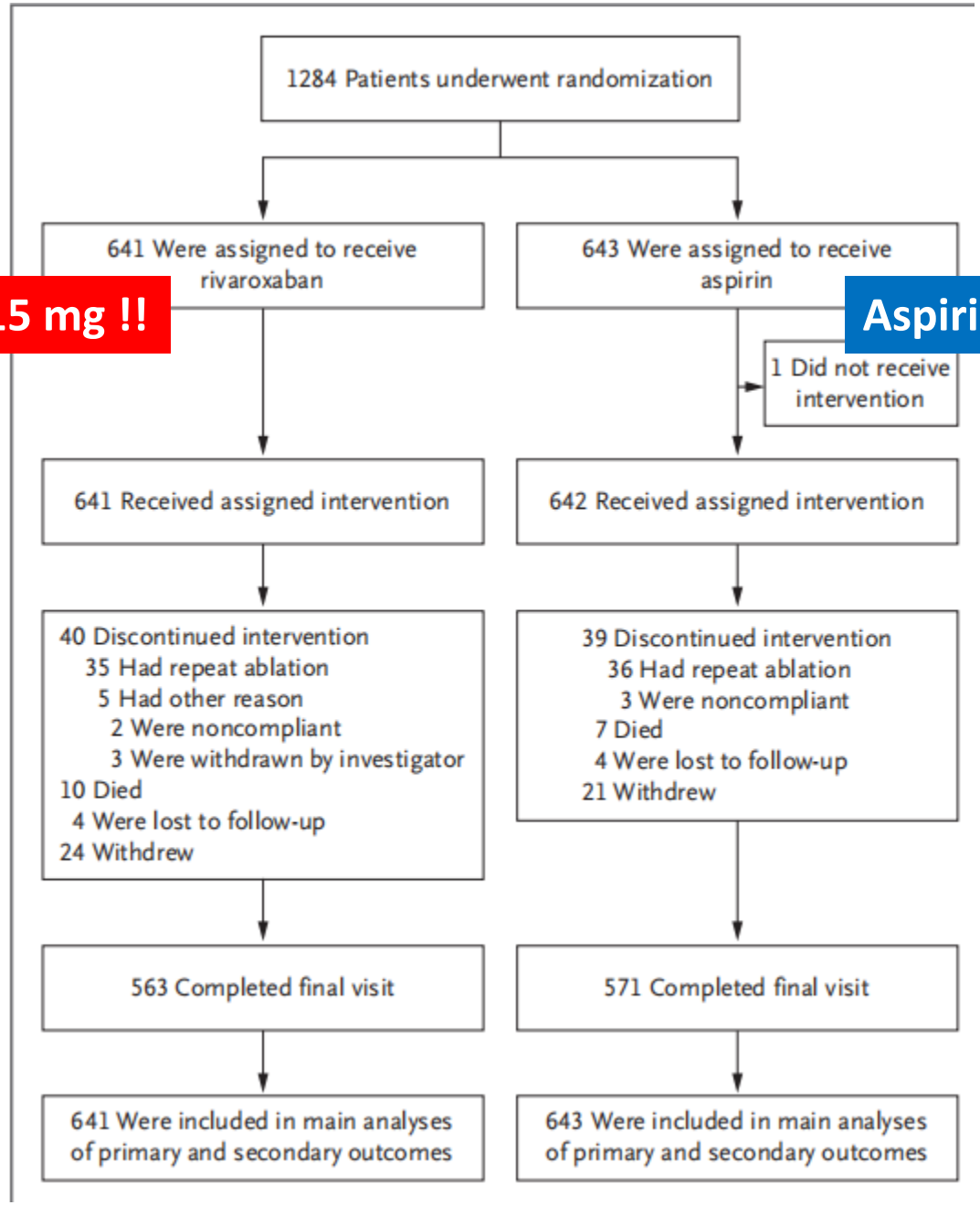
In the Off-OAT group, only 2 of 2,692 (0.07%) patients experienced ischemic stroke

In the On-OAT group, the incidence of ischemic stroke was 0.45% (3 of 663 patients), which did not differ significantly from that of the Off-OAT group (p = 0.06)

J Am Coll Cardiol. 2010 Feb 23;55(8):735-43

ORIGINAL ARTICLE

Antithrombotic Therapy after Successful Catheter Ablation for Atrial Fibrillation



Rivaroxaban 15 mg !!

Aspirin 70 to 120 mg

OCEAN study

Table 2. Primary and Secondary Efficacy Outcomes.*

Outcome	Rivaroxaban (N=641)	Aspirin (N=643)	Relative Risk (95% CI)	Absolute Risk Difference (95% CI)†
Primary composite outcome: stroke, systemic embolism, or new covert embolic stroke				
No. of patients (%)	5 (0.8)	9 (1.4)	0.56 (0.19 to 1.65)	−0.6 (−1.8 to 0.5)‡
Annualized rate — events per 100 patient-yr	0.31	0.66	—	—
Components of primary outcome				
All stroke				
No. of patients (%)	5 (0.8)	7 (1.1)	0.72 (0.23 to 2.25)	−0.3 (−1.4 to 0.7)
Annualized rate — events per 100 patient-yr	0.31	0.58	—	—
Systemic embolism				
No. of patients (%)	0	0	—	—
Annualized rate — events per 100 patient-yr	0	0	—	—
New covert embolic stroke				
No. of patients (%)	0	2 (0.3)	0	−0.3 (−0.7 to 0.1)
Annualized rate — events per 100 patient-yr	0	0.08	—	—
Other secondary outcomes				
All stroke or systemic embolism				
No. of patients (%)	5 (0.8)	7 (1.1)	0.72 (0.23 to 2.25)	−0.3 (−1.4 to 0.7)
Annualized rate — events per 100 patient-yr	0.29	0.58	—	—
Transient ischemic attack				
No. of patients (%)	1 (0.2)	5 (0.8)	0.20 (0.02 to 1.71)	−0.6 (−1.4 to 0.1)
Annualized rate — events per 100 patient-yr	0.05	0.26	—	—

CHA2DS2VASc score:2,2±1,1

HASBLED:1.4±0.9

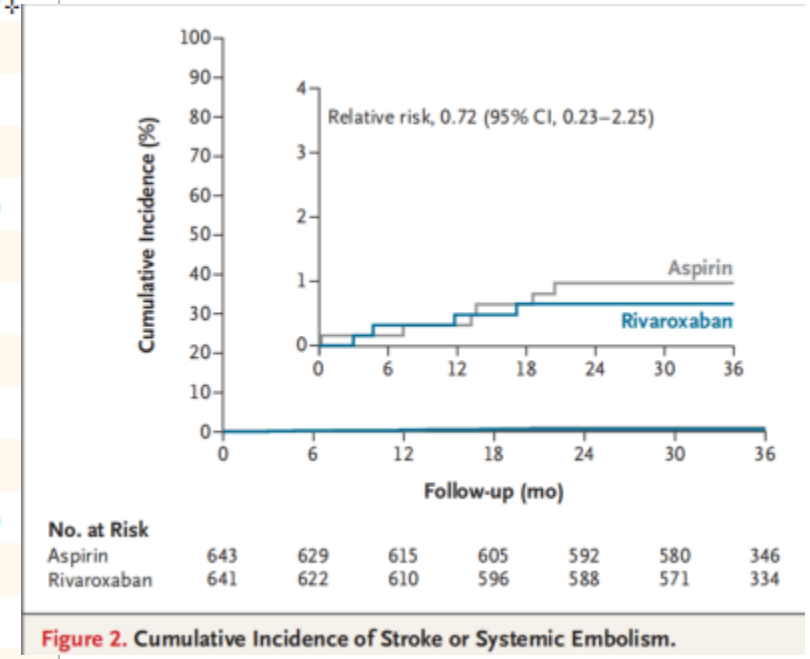


Figure 2. Cumulative Incidence of Stroke or Systemic Embolism.

Antithrombotic Therapy after Successful Catheter Ablation for Atrial Fibrillation

ça saigne plus !!!

Table 3. Safety Outcomes.*

Outcome	Rivaroxaban (N=641)	Aspirin (N=643)	Hazard Ratio (95% CI)
	no. of patients (%)		
Primary composite safety outcome: fatal bleeding or major bleeding	10 (1.6)	4 (0.6)	2.51 (0.79–7.95)
Secondary safety outcomes			
Fatal bleeding	0	0	—
Major bleeding	10 (1.6)	4 (0.6)	2.51 (0.79–7.95)
Intracranial bleeding	5 (0.8)	1 (0.2)	5.02 (0.59–42.81)
Gastrointestinal bleeding	3 (0.5)	2 (0.3)	1.50 (0.25–8.97)
Other major bleeding	2 (0.3)	1 (0.2)	2.01 (0.18–22.07)
Minor bleeding	74 (11.5)	20 (3.1)	3.71 (2.29–6.01)
Clinically relevant nonmajor bleeding	35 (5.5)	10 (1.6)	3.51 (1.75–7.03)
Composite of major bleeding or minor bleeding	83 (12.9)	23 (3.6)	3.62 (2.31–5.67)
Death from any cause	10 (1.6)	7 (1.1)	1.43 (0.55–3.74)

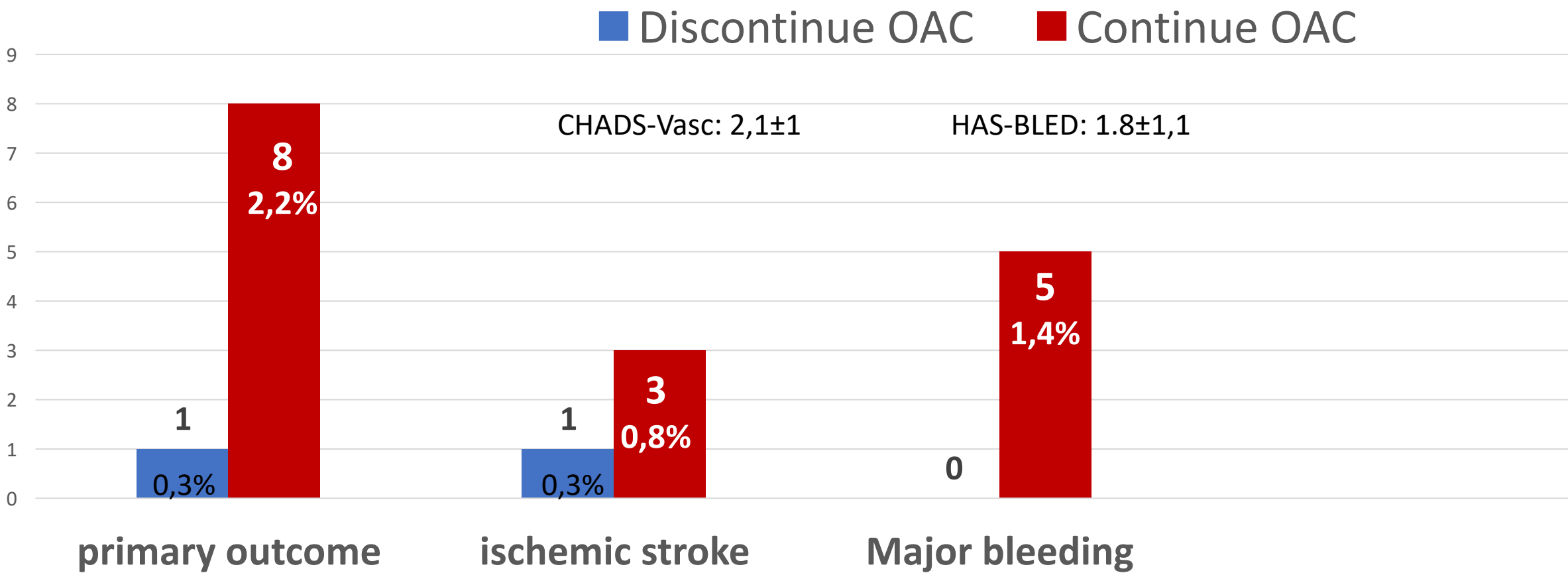
OCEAN study

Long-Term Anticoagulation Discontinuation After Catheter Ablation for Atrial Fibrillation The ALONE-AF Randomized Clinical Trial

- **840 adult patients with no documented recurrence of atrial arrhythmia for at least 1 year after catheter ablation for AF**
  - mean age:64 (SD, 8) years, 24.9% were women, mean CHA_2DS_2-VASc score was 2.1 (SD, 1.0), and 67.6% had paroxysmal AF
- **Patients were randomly assigned in a 1:1 ratio to discontinue OAC therapy (n = 417) or continue direct OAC therapy (n = 423)**
- The primary outcome was the first occurrence of a composite of stroke, systemic embolism, and major bleeding at 2 years.
- Individual components of the primary outcome (such as ischemic stroke and major bleeding) were assessed as secondary outcomes.

JAMA. 2025 Oct 14;334(14):1246-1254

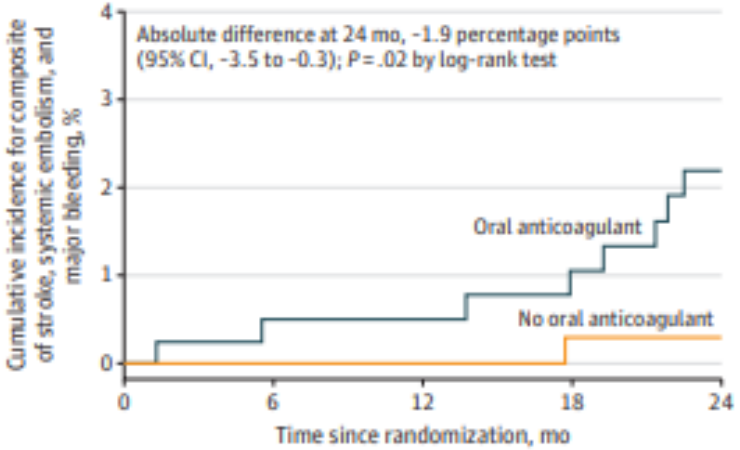
Ablation for Atrial Fibrillation The ALONE-AF Randomized Clinical Trial



JAMA. 2025 Oct 14;334(14):1246-1254

The ALONE-AF

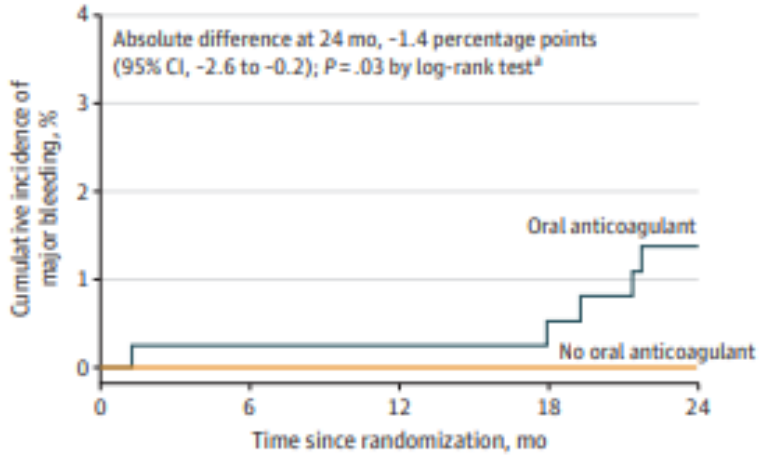
A Cumulative incidence for composite of stroke, systemic embolism, and major bleeding (primary outcome)



No. at risk

No oral anticoagulant	417	378	353	334	321
Oral anticoagulant	423	392	376		

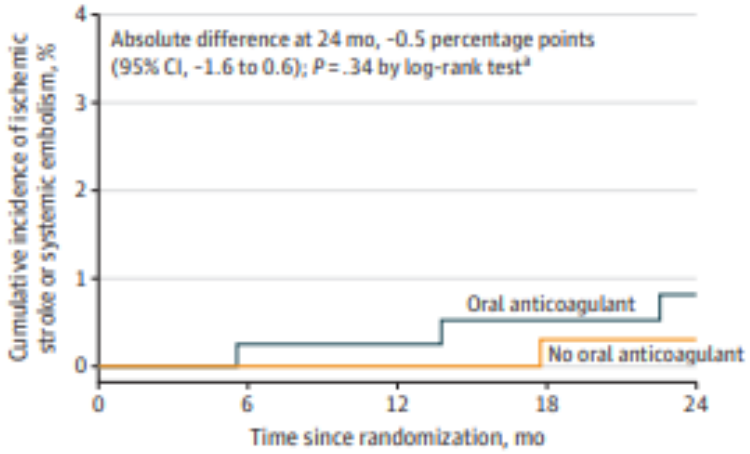
C Cumulative incidence of major bleeding



No. at risk

No oral anticoagulant	417	378	353	335	322
Oral anticoagulant	423	393	377	359	341

B Cumulative incidence of ischemic stroke or systemic embolism

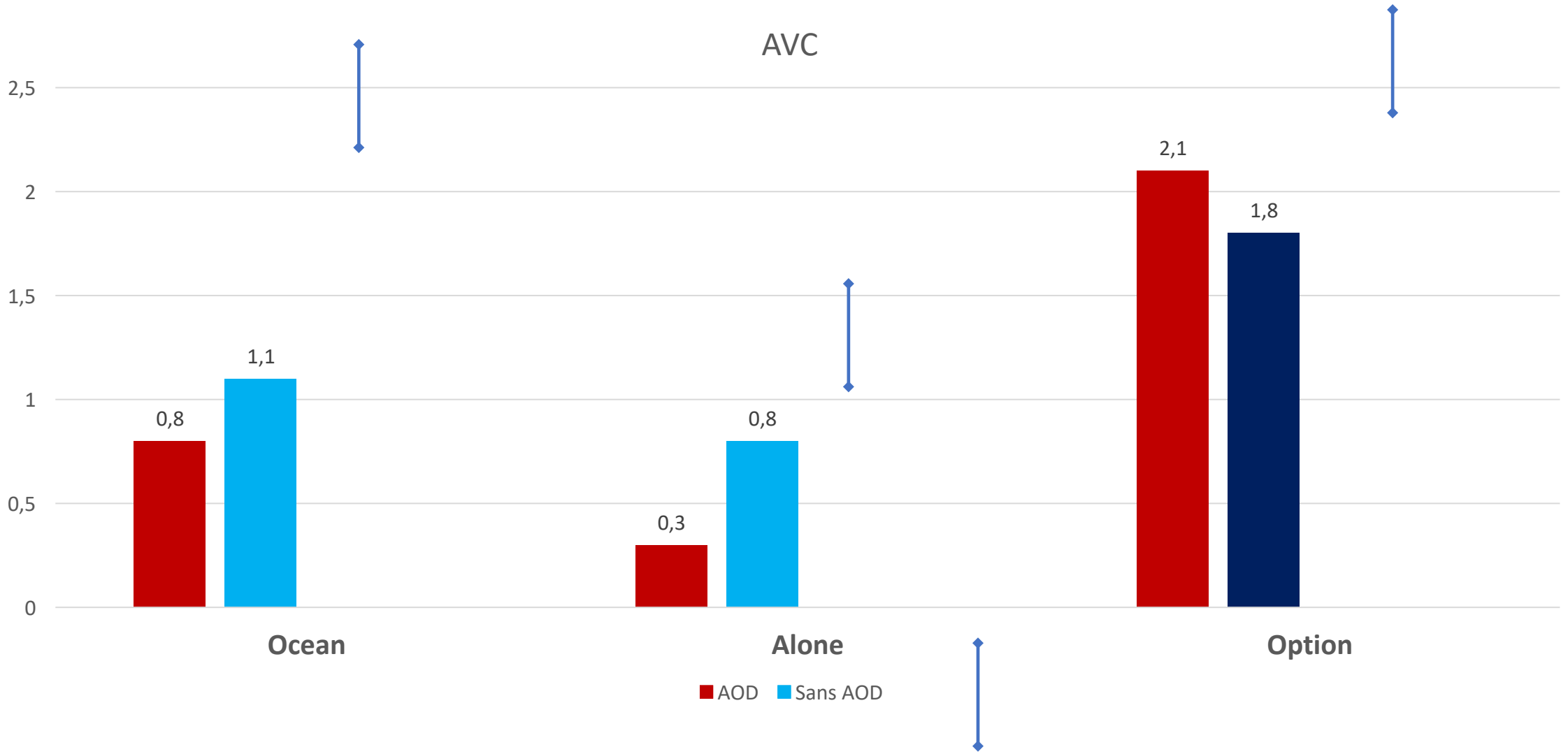


No. at risk

No oral anticoagulant	417	378	353	334	321
Oral anticoagulant	423	393	377	359	343

JAMA. 2025 Oct 14;334(14):1246-1254

- **Risque d'AVC sous AOD CHA2DS2-VASc=2**
  - 0,6-0,8%/an 1,8-2,4% à 3 ans
- **Risque d'AVC sous AOD CHA2DS2-VASc= 3**
  - 0,8-1,5%/an 2,4-4,5% à 3 ans
- **Risque d'AVC sous AOD CHA2DS2-VASc=4**
  - 1,2-1,6%/an 3,6-4,8% à 3 ans
- **Ocean après ablation CHA2DS2-VASc=2,2**
  - AOD: 0,8% a 3ans ; aspirine 1,1% à 3 ans
- **ALONE CHA2DS2-VASc=2,1**
  - AOD: 0,3% a 3ans ; sans AOD 0,8% à 2 ans
- **Option CHA2DS2-VASc= 3.5±1.3**
  - Occlusion: 1,8% à 3 ans; AOD:2,1% à 3 ans


AVC
2,5
2
1,5
1
0,5
0
0,8
1,1
0,3
0,8
2,1
1,8
Ocean
Alone
Option
AOD
Sans AOD

Peut-être une bonne idée si risque élevé !?

Patterns of Anticoagulation Use and Cardioembolic Risk After Catheter Ablation for Atrial Fibrillation

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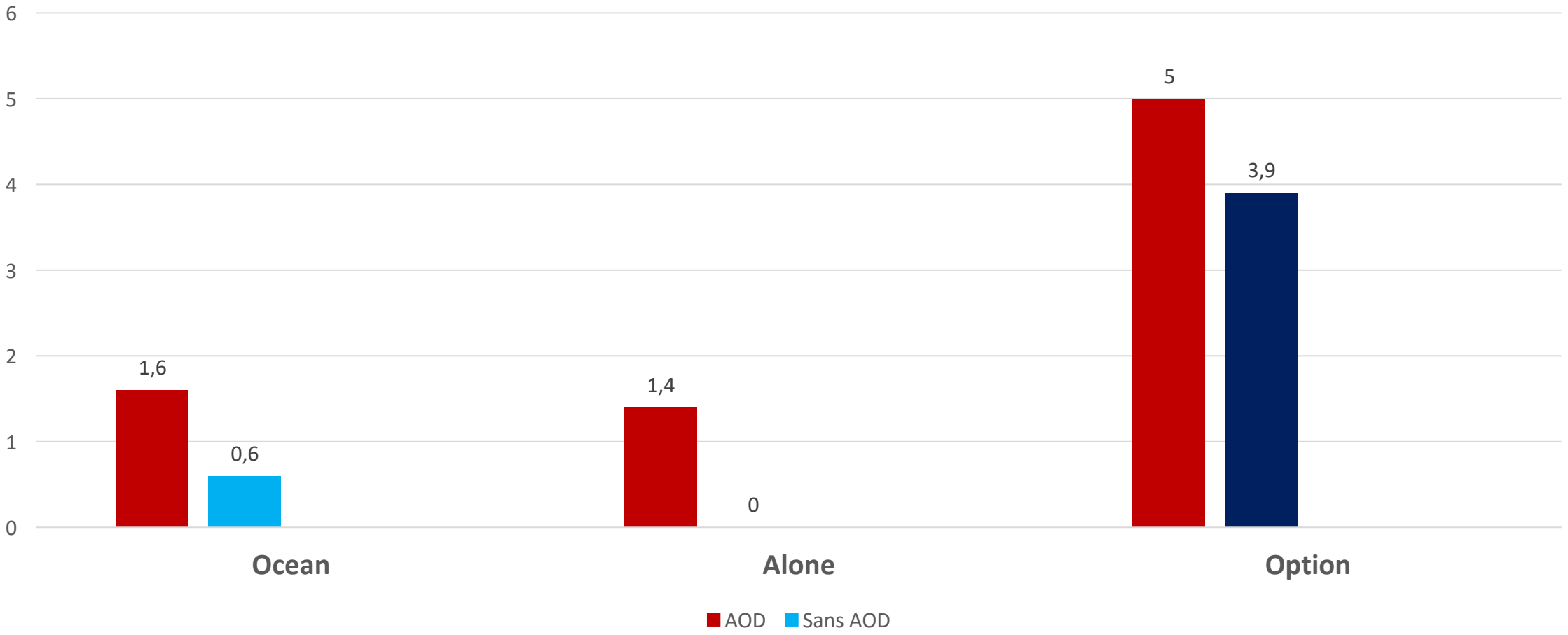
  - **but not low-risk patients**

- SR or AF ??????

J Am Heart Assoc. 2015;4(11)

- **Risque de saignement majeur HASBLED =1**
  - 1,0-1,6%/an sous AOD (0,3-0,6% sans AOD)
- **Risque de saignement majeur HASBLED =2**
  - 1,9-2,5%/an sous AOD (0,7-1,2% sans AOD)
- **Ocean après ablation HASBLED = 1.4±0.9**
  - AOD: 1,6% à 3ans ; aspirine 0,6% à 3 ans
- **ALONE après ablation HASBLED = 1.8±1,1**
  - AOD: 1,4% à 2ans ; sans AOD 0 à 2 ans
- **Option HASBLED= 1.2±0.8**
  - AOD:5% à 3 ans ; Occlusion: 3,9% à 3 ans


6
5
4
3
2
1
0
1,6
0,6
1,4
0
5
3,9
Ocean
Alone
Option
AOD
Sans AOD

CLOSURE-AF
DZHK TRIAL 16

DZHK
Deutsches Zentrum für
Herz-Kreislauf-Forschung

Scientific Sessions

CLOSURE-AF:

LEFT ATRIAL APPENDAGE CLOSURE IN PATIENTS WITH ATRIAL FIBRILLATION AT HIGH RISK OF STROKE AND BLEEDING COMPARED TO MEDICAL THERAPY

Ulf Landmesser, MD | On Behalf of the CLOSURE AF Steering Committee

Chairman, Department of Cardiology, Angiology and Intensive Care Medicine,

Deutsches Herzzentrum Charité, Campus Benjamin Franklin, Charité University Medicine Berlin, Germany

American Heart Association.

DZC
DEUTSCHES HERZZENTRUM
DER CHARITÉ

#AHA25

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**

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)

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

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

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

PATIENT CHARACTERISTICS: CLOSURE-AF

CLOSURE-AF
DZHK TRIAL 16

Characteristic	Left atrial appendage closure (N=446)	Physician-directed Best medical care (N=442)	Total (N=888)
Age (IQR)–yr	**79.5** (74.6, 83.0)	**78.4** (72.8, 82.6)	**79.1** (73.9, 82.8)
Female – no./total no. (%)	**172**/446 (38.6)	**171**/442 (38.7)	**343**/888 (38.6)
Race/ethnic group – no./total no. (%)			
Caucasian	415/446 (93.0)	416/442 (94.1)	831/888 (93.6)
Black	2/446 (0.4)	1/442 (0.2)	3/888 (0.3)
Not disclosed	29/446 (6.5)	25/442 (5.7)	54/888 (6.1)
CHA2DS2-VASc-Score	**5.2 ± 1.5**	**5.1 ± 1.6**	**5.2 ± 1.5**
HAS-BLED score	**3.1 ± 0.9**	**3.0 ± 0.9**	**3.0 ± 0.9**
Diabetes – no./total no. (%)	**175**/446 (39.2)	**186**/442 (42.1)	**361**/888 (40.7)
Hypertension – no./total no. (%)	**417**/446 (93.5)	**417**/442 (94.3)	**834**/888 (93.9)
Dyslipidemia – no./total no. (%)	**269**/433 (62.1)	**241**/422 (57.1)	**510**/855 (59.6)
Smoking – no./total no. (%)	**30**/415 (7.2)	**50**/411 (12.2)	**80**/826 (9.7)

PERIPROCEDURAL COMPLICATIONS: CLOSURE-AF

CLOSURE-A
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

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) **Events/patient-years** (Incidence per 100 patient-years)	**Physician-directed Best medical care (N=442)** **Events/patient-years** (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

Outcome	Left Atrial Appendage Closure (N=446) Events/patient-years (Incidence per 100 patient-years)	Physician-directed Best Medical Care (N=442) Events/patient-years (Incidence per 100 patient-years)	Adjusted hazard ratio (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)

- la FA parox est associée au risque thromboembolique
- la durée de la FA responsable de la formation d'AVC peut être très courte
- la FA est le témoin d'une atriopathie
- la FA fait partie d'un risque thromboembolique global
- **Il y a des FA asymptomatiques**
- **l'arrêt de l'anticoagulation après retour en RS est associé à un risque d'AVC**

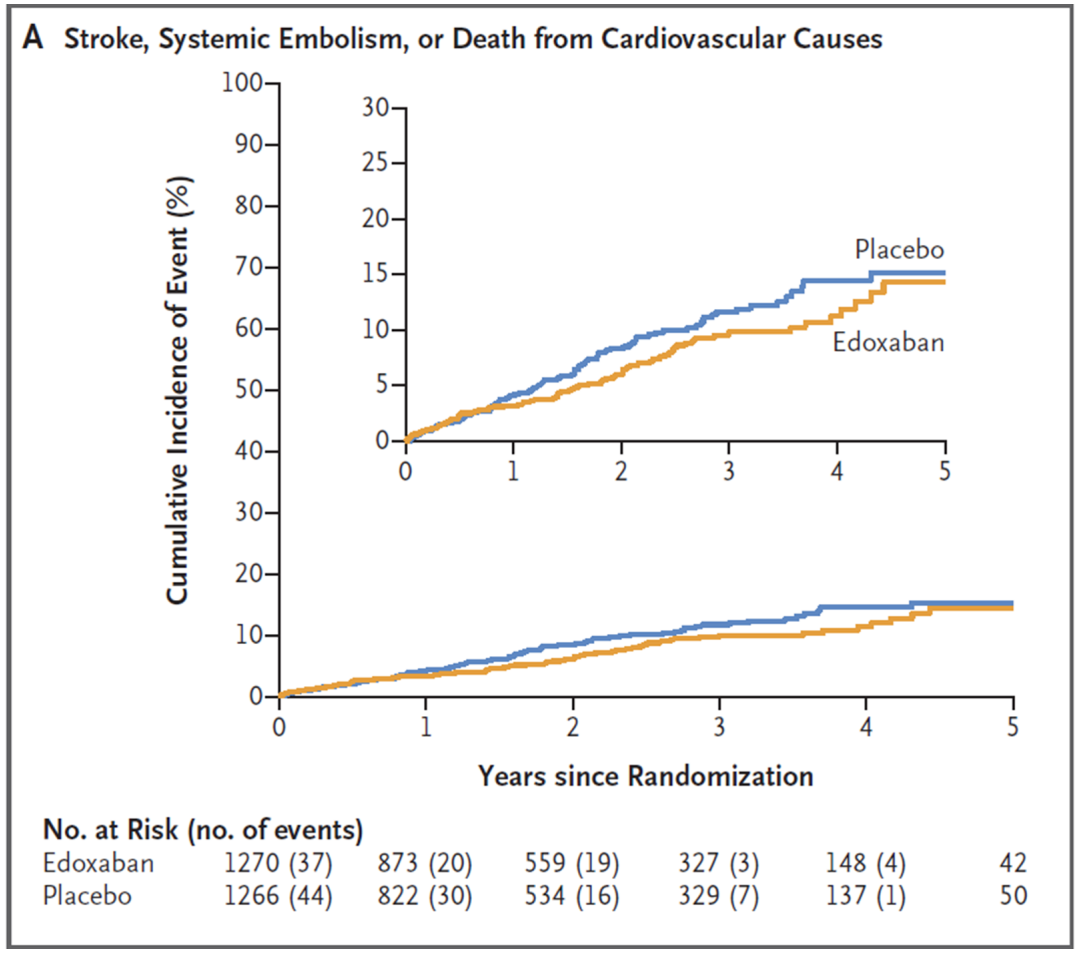
Courte FA un jours - longue FA demain ?

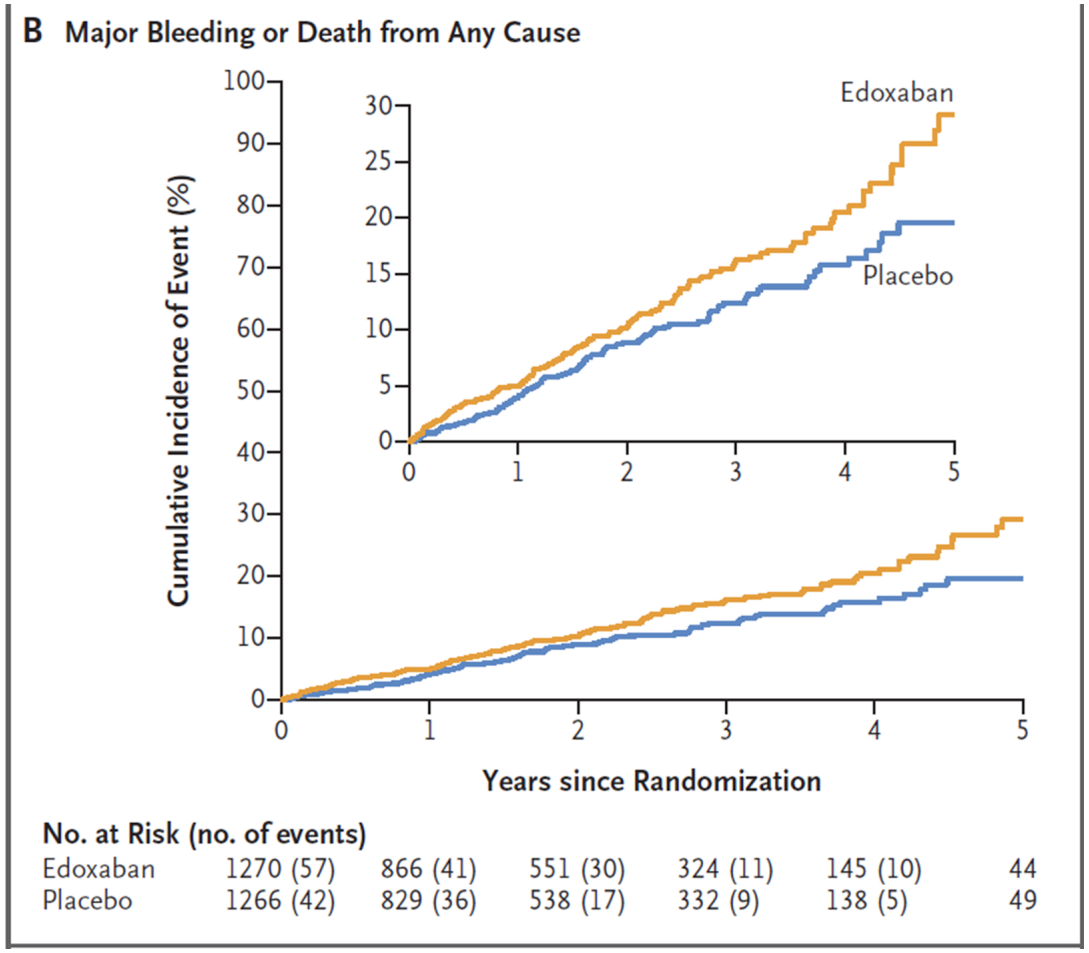
Anticoagulation with Edoxaban in Patients with Atrial High-Rate Episodes

NOAH-AFNET 6

event-driven, double-blind, double-dummy, randomized trial

patients 65 years of age or older who had AHREs lasting for at least **6 minutes** and who had at least one additional risk factor for stroke.





P. Kirchhof et al. NEJM 2023

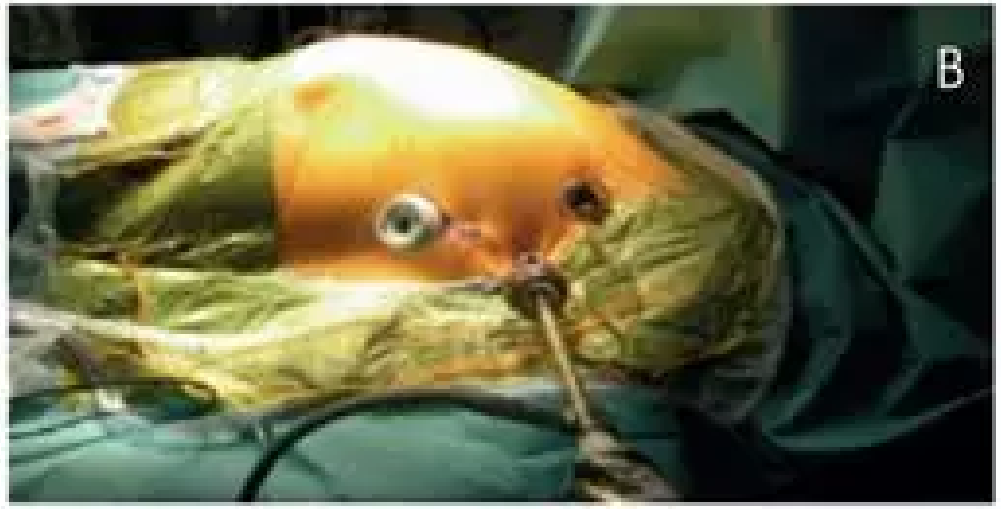
- la FA parox est associée au risque thromboembolique
- la durée de la FA responsable de la formation d'AVC peut être très courte

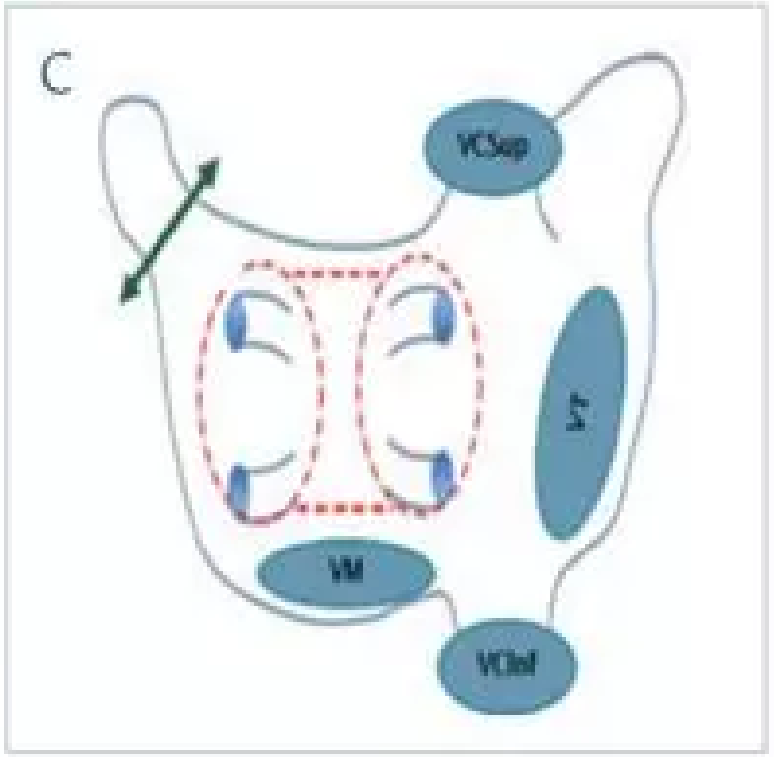
- **la FA est le témoin d'une atriopathie**
- **En post-ablation zones cicatricielles**
  - **Probable situation proembolique**

- la FA fait partie d'un risque thromboembolique global
- Il y a des FA asymptomatiques
- l'arrêt de l'anticoagulation après retour en RS est associé à un risque d'AVC

Conclusions

- Niveau de preuve faible: 1 étude critiquable et pas de supériorité
- Pourquoi ne pas attendre de savoir si l'ablation est efficace
- 2 procédures emboligènes associées: on augmente les risques per-procédures
- Peut-être dans une population particulière ??????
  - Très à risque de récidive avec atriopathie ++++
  - Si auricule atone
  - Auricules polylobés: cactus, brocoli…
- Prix procédure……..un problème





A : (système atrium®) clamp d'ablation bipolaire ventrale épicardique des veines pulmonaires, clip d'occlusion de l'auricule gauche, stylet d'ablation bipolaire pour la réalisation de ligne épicardique.
B : approche thoracoscopique unilatérale.
C : synthèse des lésions (en rouge) réalisée.