

**CARDIO
RUN
2025**

**17^{ème} CONGRÈS DE PATHOLOGIE
CARDIO-VASCULAIRE**

17-18-19 SEPTEMBRE 2025

Hôtel Saint Alexis **ILE DE LA RÉUNION** France



FA détectée par les prothèses implantées

Anticoagulation ou non ?

Philippe Mabo
Université de Rennes
17 septembre 2025

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Mes relations avec l'industrie

Consultant:

Biosency, Implicity, Medinthepocket, Oktoscience

Détecter la FA – ESC guidelines 2000

It is recommended to interrogate pacemakers and implantable cardioverter defibrillators on a regular basis for AHRE.^{c224,226}

I

B

**Arythmies atriales infracliniques
détectées par les prothèses implantables
Feu vert pour l'anticoagulation ?**

2 essais randomisés

NOAH-AFNET 6 and ARTESIA trials

ORIGINAL ARTICLE

August 25 2023

Anticoagulation with Edoxaban in Patients with Atrial High-Rate Episodes

P. Kirchhof, T. Toennis, A. Goette, A.J. Camm, H.C. Diener, N. Becher, E. Bertaglia, C. Blomstrom Lundqvist, M. Borlich, A. Brandes, N. Cabanelas, M. Calvert, G. Chlouverakis, G.-A. Dan, J.R. de Groot, W. Dichtl, B. Kravchuk, A. Lubiński, E. Marijon, B. Merkely, L. Mont, A.-K. Ozga, K. Rajappan, A. Sarkozy, D. Scherr, R. Sznajder, V. Velchev, D. Wichterle, S. Sehner, E. Simantirakis, G.Y.H. Lip, P. Vardas, U. Schotten, and A. Zapf, for the NOAH-AFNET 6 Investigators*

Device-detected atrial high-rate episodes (AHREs)

Age $\geq$ 65 years

1 additional stroke risk factor

AHREs lasting at least 6 mn

1:1 Randomization Edoxaban or placebo

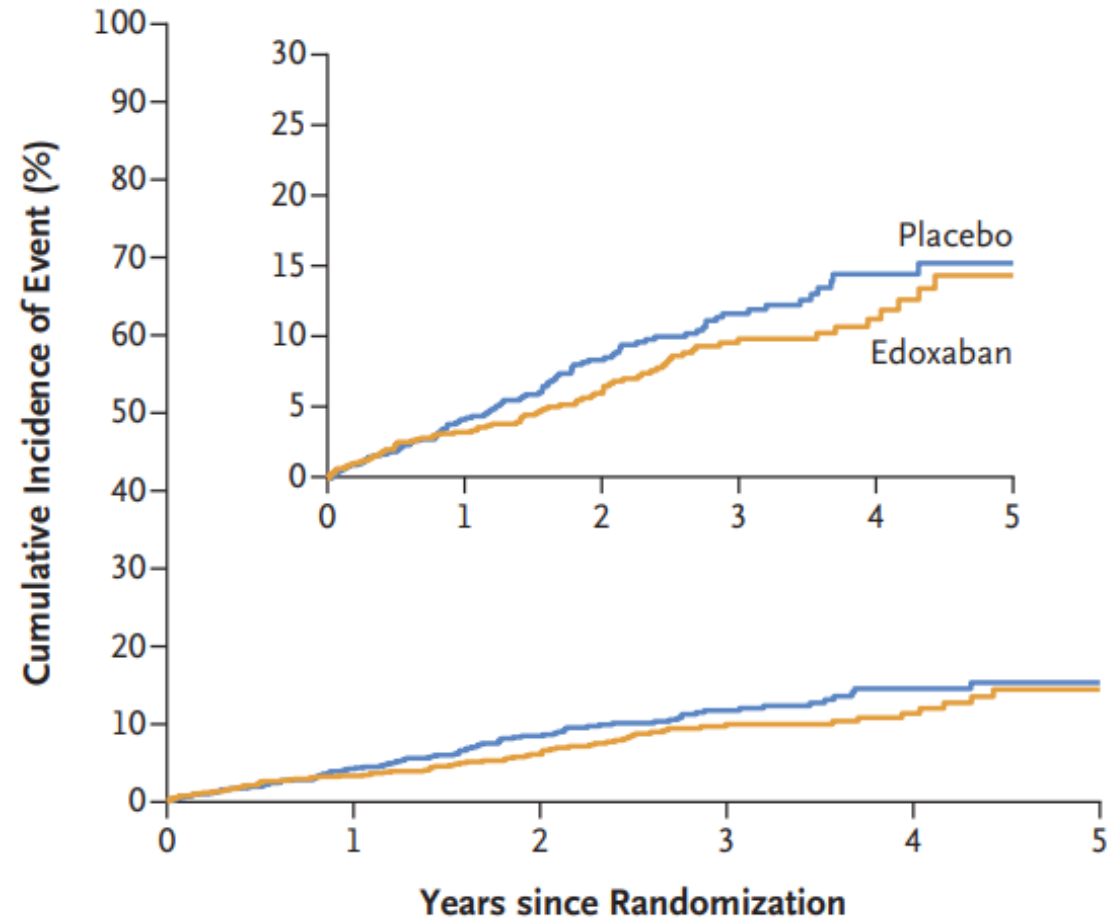
Primary efficacy outcome: composite of CV death, stroke, systemic embolism

Safety outcome: death from any cause or major bleeding

Patient characteristics

Characteristic	Edoxaban (N = 1270)	Placebo (N = 1266)	Total (N = 2536)
→ Age — yr	77.4±6.5	77.5±6.8	77.5±6.7
Age ≥75 yr — no./total no. (%)	845/1270 (66.5)	855/1266 (67.5)	1700/2536 (67.0)
Female sex — no./total no. (%)	469/1270 (36.9)	480/1266 (37.9)	949/2536 (37.4)
Device used to record AHREs — no./total no. (%)			
→ Pacemaker	1017/1270 (80.1)	1055/1266 (83.3)	2072/2536 (81.7)
Defibrillator	100/1270 (7.9)	88/1266 (7.0)	188/2536 (7.4)
Cardiac resynchronization device	138/1270 (10.9)	113/1266 (8.9)	251/2536 (9.9)
Implanted loop recorder	15/1270 (1.2)	10/1266 (0.8)	25/2536 (1.0)
Median duration of AHREs (IQR) — hr†	2.8 (0.8–9.2)	2.8 (0.7–9.5)	2.8 (0.8–9.4)
AHREs with atrial rates >200 beats/ min — no./total no. (%)	918/944 (97.2)	896/925 (96.9)	1814/1869 (97.1)
→ Median CHA ₂ DS ₂ -VASc score (IQR)‡	4 (3–5)	4 (3–5)	4 (3–5)
Median CHA ₂ DS ₂ -VA score (IQR)‡	3 (3–4)	3 (3–4)	3 (3–4)
Heart failure — no./total no. (%)§	361/1270 (28.4)	335/1266 (26.5)	696/2536 (27.4)
Hypertension — no./total no. (%)¶	1096/1270 (86.3)	1109/1266 (87.6)	2205/2536 (86.9)
Diabetes mellitus — no./total no. (%)	350/1270 (27.6)	331/1266 (26.1)	681/2536 (26.9)
→ Previous stroke or transient ischemic attack — no./total no. (%)	122/1270 (9.6)	131/1266 (10.3)	253/2536 (10.0)
Indication for acetylsalicylic acid at randomization — no./total no. (%)	684/1270 (53.9)	683/1266 (53.9)	1367/2536 (53.9)

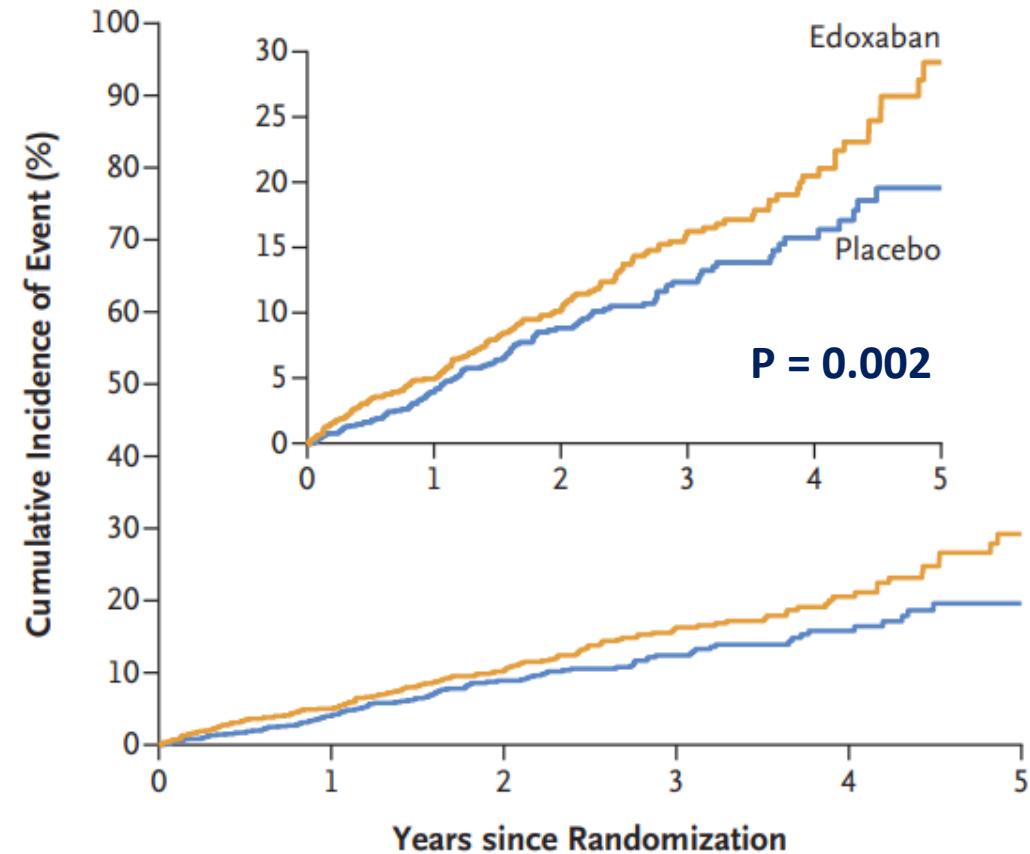
Stroke, systemic embolism, CV death



No. at Risk (no. of events)

Edoxaban	1270 (37)	873 (20)	559 (19)	327 (3)	148 (4)	42
Placebo	1266 (44)	822 (30)	534 (16)	329 (7)	137 (1)	50

Major bleeding or death from any cause



No. at Risk (no. of events)

Edoxaban	1270 (57)	866 (41)	551 (30)	324 (11)	145 (10)	44
Placebo	1266 (42)	829 (36)	538 (17)	332 (9)	138 (5)	49

Safety outcome

Outcome	Edoxaban (N=1270)	Placebo (N=1266)	Adjusted Hazard Ratio (95% CI)	P Value
	no. of patients with event/patient-yr (% per patient-yr)			
→ Composite safety outcome†	149/2534 (5.9)	114/2508 (4.5)	1.31 (1.02 to 1.67)	0.03
→ Death from any cause	111/2595 (4.3)	94/2540 (3.7)	1.16 (0.88 to 1.53)	0.28
Cardiovascular death	52/2595 (2.0)	57/2540 (2.2)	—	—
Cancer-related death	22/2595 (0.8)	9/2540 (0.4)	—	—
Covid-19–associated death	15/2595 (0.6)	12/2540 (0.5)	—	—
Death due to acute infection or sepsis	12/2595 (0.5)	9/2540 (0.4)	—	—
Death due to frailty or old age	3/2595 (0.1)	2/2540 (0.1)	—	—
Death due to accident or poly- trauma	3/2595 (0.1)	1/2540 (<0.1)	—	—
Death due to lung disease	2/2595 (0.1)	1/2540 (<0.1)	—	—
Death due to acute abdomen	0	2/2540 (0.1)	—	—
Kidney-related death	1/2595 (<0.1)	0	—	—
Dementia-related death	0	1/2540 (<0.1)	—	—
Suicide	1/2595 (<0.1)	0	—	—
→ Major bleeding	53/2534 (2.1)	25/2508 (1.0)	2.10 (1.30 to 3.38)	0.002
Mean no. of major bleeding events per patient	0.06±0.35	0.02±0.16	3.06 (1.74 to 5.36)‡	<0.001

ORIGINAL ARTICLE

Apixaban for Stroke Prevention in Subclinical Atrial Fibrillation

J.S. Healey, R.D. Lopes, C.B. Granger, M. Alings, L. Rivard, W.F. McIntyre,
D. Atar, D.H. Birnie, G. Boriani, A.J. Camm, D. Conen, J.W. Erath, M.R. Gold,
S.H. Hohnloser, J. Ip, J. Kautzner, V. Kutyifa, C. Linde, P. Mabo, G. Mairesse,
J. Benezet Mazuecos, J. Cosedis Nielsen, F. Philippon, M. Proietti, C. Sticherling,
J.A. Wong, D.J. Wright, I.G. Zarraga, S.B. Coutts, A. Kaplan, M. Pombo,
F. Ayala-Paredes, L. Xu, K. Simek, S. Nevills, R. Mian, and S.J. Connolly,
for the ARTESIA Investigators*

ARTESIA

Inclusion Criteria:

- **Permanent pacemaker or defibrillator (with or without resynchronization) or insertable cardiac monitor capable of detecting Sub Clinical AF**
- **At least one episode of SCAF $\geq$ 6 minutes but no single episode $>$ 24 hours**
- **CHA2 DS2 -VASc score $\geq$ 3**
- **Age $\geq$ 55 years**
- **Risk Factor(s) for Stroke:**
 - Previous stroke, TIA or systemic arterial embolism**
 - or Age at least 75**
 - or Age 65-74 with at least 2 other risk factors**
 - or Age 55-64 with at least 3 other risk factors**
- **Randomization: Apixaban vs aspirin 81 mg**
- **Efficacy endpoint: ischemic stroke and ischemic embolism**
- **Safety outcome: major bleeding**

Population

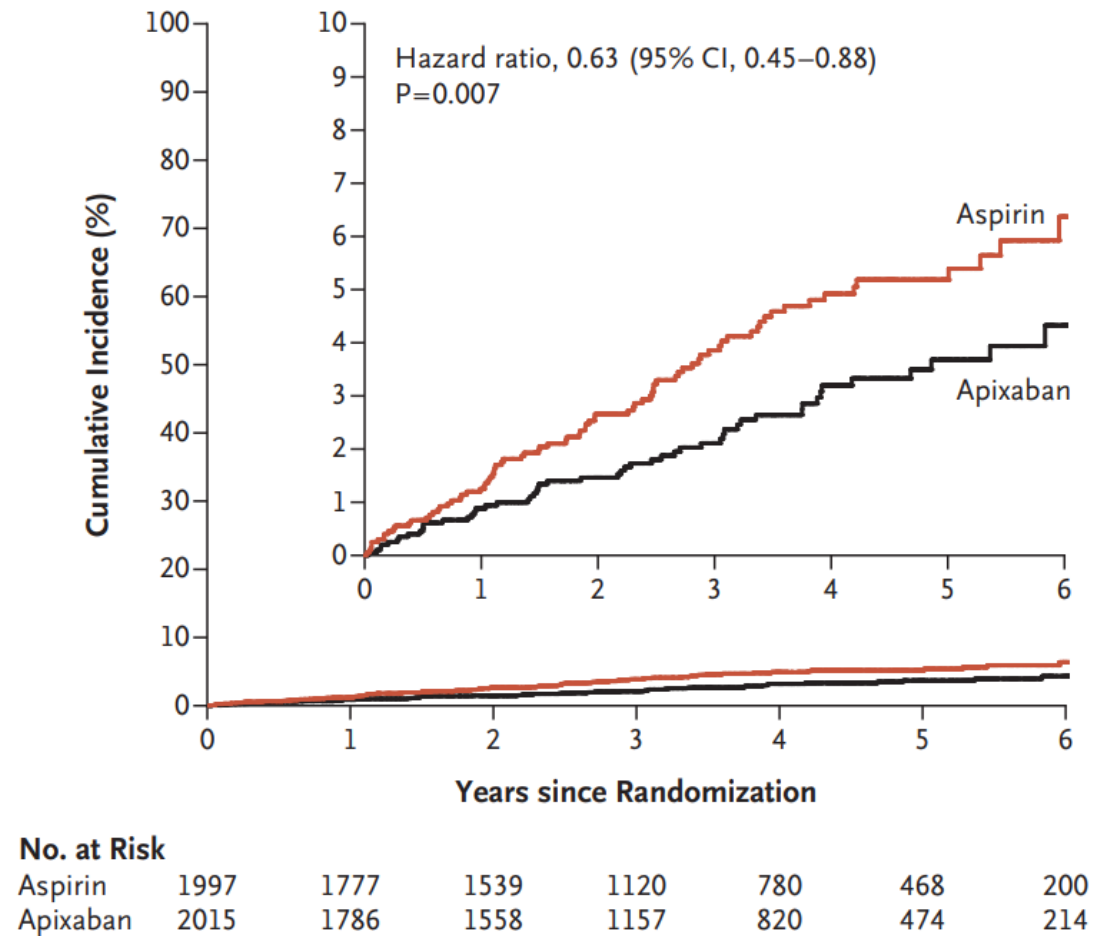
Characteristic	Apixaban (N = 2015)	Aspirin (N = 1997)	Total (N = 4012)
→ Age — yr	76.9±7.6	76.7±7.7	76.8±7.6
Female sex — no. (%)	719 (35.7)	728 (36.5)	1447 (36.1)
CHA ₂ DS ₂ -VASc score†			
→ Mean	3.9±1.1	3.9±1.1	3.9±1.1
Score ≥4 — no. (%)	1220 (60.5)	1214 (60.8)	2434 (60.7)
History of hypertension — no. (%)	1643 (81.5)	1626 (81.4)	3269 (81.5)
History of coronary artery disease — no. (%)	731 (36.3)	754 (37.8)	1485 (37.0)
Peripheral arterial disease — no. (%)	168 (8.3)	166 (8.3)	334 (8.3)
Diabetes mellitus — no. (%)	583 (28.9)	584 (29.2)	1167 (29.1)
History of heart failure — no. (%)	550 (27.3)	587 (29.4)	1137 (28.3)
→ History of stroke, systemic embolism, or TIA — no. (%)	180 (8.9)	181 (9.1)	361 (9.0)

Population

Characteristic	Apixaban (N = 2015)	Aspirin (N = 1997)	Total (N = 4012)
Baseline antiplatelet use — no. (%)			
Aspirin	1165 (57.8)	1137 (56.9)	2302 (57.4)
Other single antiplatelet agent	77 (3.8)	81 (4.1)	158 (3.9)
Dual antiplatelet therapy	67 (3.3)	70 (3.5)	137 (3.4)
Creatinine clearance — ml/min	70.8±26.7	72.1±30.6	71.4±28.7
Weight — kg	82.5±18.3	82.9±18.1	82.7±18.2
History of major bleeding >6 mo before enrollment — no. (%)	50 (2.5)	47 (2.4)	97 (2.4)
Blood pressure — mm Hg			
Systolic	135.0±18.9	135.0±18.7	135.0±18.8
Diastolic	75.4±10.4	75.5±10.4	75.5±10.4
Device type — no. (%)			
Pacemaker	1414 (70.2)	1370 (68.6)	2784 (69.4)
ICD	270 (13.4)	284 (14.2)	554 (13.8)
CRT-ICD or CRT pacemaker	228 (11.3)	237 (11.9)	465 (11.6)
ICM	103 (5.1)	106 (5.3)	209 (5.2)



Primary efficacy outcome – Stroke or systemic embolism



Other outcomes - Major bleeding

Outcome	Apixaban (N = 2015)		Aspirin (N = 1997)		Hazard Ratio (95% CI)	P Value
	<i>no. of patients with event</i>	<i>%/patient-yr</i>	<i>no. of patients with event</i>	<i>%/patient-yr</i>		
Stroke, systemic embolism, or death from cardiovascular causes	148	2.10	171	2.47	0.85 (0.68–1.06)	
Stroke, myocardial infarction, systemic embolism, or death	419	6.01	418	6.10	0.98 (0.86–1.12)	
Myocardial infarction	37	0.52	41	0.59	0.89 (0.57–1.40)	
Death	362	5.06	341	4.82	1.04 (0.90–1.21)	
Death from cardiovascular causes	105	1.47	108	1.53	0.96 (0.73–1.25)	
→ Major bleeding¶	106	1.53	78	1.12	1.36 (1.01–1.82)	0.04
Fatal bleeding	10	0.14	14	0.20	0.70 (0.31–1.57)	
Symptomatic intracranial hemorrhage	17	0.24	23	0.33	0.73 (0.39–1.36)	
Gastrointestinal bleeding	55	0.78	31	0.44	1.76 (1.13–2.74)	
Transfusion performed	35	0.49	31	0.44	1.11 (0.68–1.80)	

Other outcomes

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NOAH-AFNET 6 TRIAL vs ARTESIA

- Baseline characteristics were similar
- NOAHAFNET 6 trial was stopped early, had relatively few stroke events, and was thus underpowered.
- The primary efficacy outcome of the NOAH-AFNET 6 trial included death from cardiovascular causes. Because deaths in this population of patients are rarely due to stroke and are commonly due to underlying cardiovascular disease and old age, adding death from cardiovascular causes to the primary outcome dilutes any potential signal related to stroke reduction.
- The control group in the ARTESIA trial were assigned to receive aspirin. Aspirin is effective for stroke prevention in patients with previous stroke, but whether it reduces the risk of stroke among patients with atrial fibrillation is controversial. The use of aspirin in the control group in the ARTESIA trial probably had little effect on the signal for reduction in stroke but almost certainly mitigated the signal for harm, because aspirin is known to increase bleeding.

NOAH-AFNET 6 + ARTESIA trials

Circulation

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<https://doi.org/10.1161/CIRCULATIONAHA.123.067512>



ORIGINAL RESEARCH ARTICLE

Direct Oral Anticoagulants for Stroke Prevention in Patients With Device-Detected Atrial Fibrillation: A Study-Level Meta-Analysis of the NOAH-AFNET 6 and ARTESiA Trials

Editorial, see p 989

William F. McIntyre, MD, PhD , Alexander P. Benz, MD, MSc , Nina Becher, MD , Jeffrey S. Healey, MD, MSc , Christopher B. Granger, MD , Lena Rivard, MD, MSc , A. John Camm, MD , Andreas Goette, MD , Antonia Zapf, PhD , Marco Alings, MD, PhD , Stuart J. Connolly, MD, MSc , Paulus Kirchhof, MD , and Renato D. Lopes, MD, MHS, PhD 

NOAH-AFNET 6 + ARTESIA trials

Ischemic Stroke



Composite of All-cause Stroke, Peripheral Arterial Embolism, Myocardial Infarction, Pulmonary Embolism or Cardiovascular Death



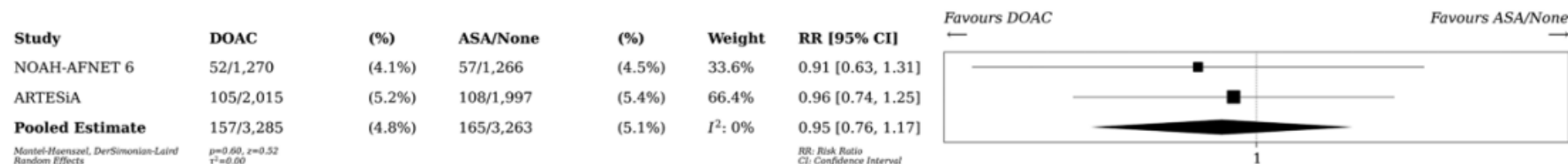
All-cause Stroke



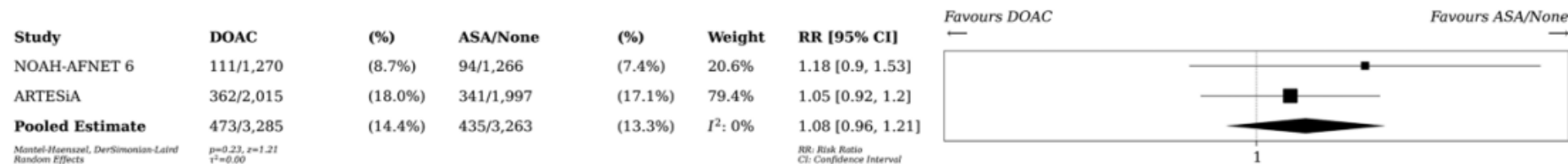
All-cause Stroke or Systemic Embolism



Cardiovascular Death



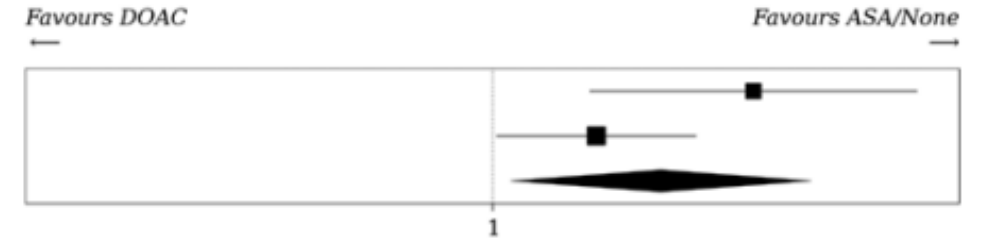
All-cause Mortality



NOAH-AFNET 6 + ARTESiA trials

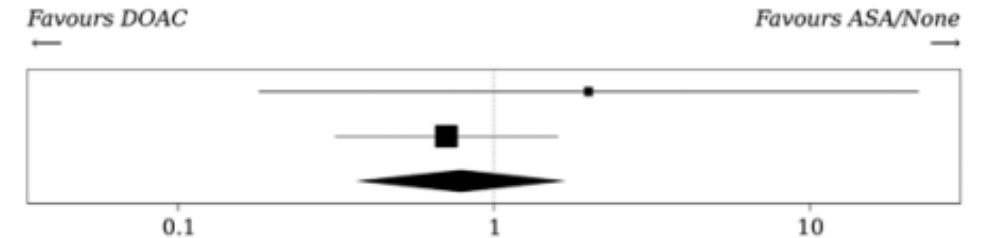
Major Bleeding

Study	DOAC	(%)	ASA/None	(%)	Weight	RR [95% CI]
NOAH-AFNET 6	53/1,270	(4.2%)	25/1,266	(2.0%)	41.1%	2.11 [1.32, 3.38]
ARTESiA	106/2,015	(5.3%)	78/1,997	(3.9%)	58.9%	1.35 [1.01, 1.79]
Pooled Estimate	159/3,285	(4.8%)	103/3,263	(3.2%)	I^2: 61%	1.62 [1.05, 2.5]
<i>Mantel-Haenszel, DerSimonian-Laird</i>		<i>Random Effects</i>		<i>RR: Risk Ratio CI: Confidence Interval</i>		
		<i>p=0.03, z=2.18</i>				
		<i>$\tau^2=0.06$</i>				



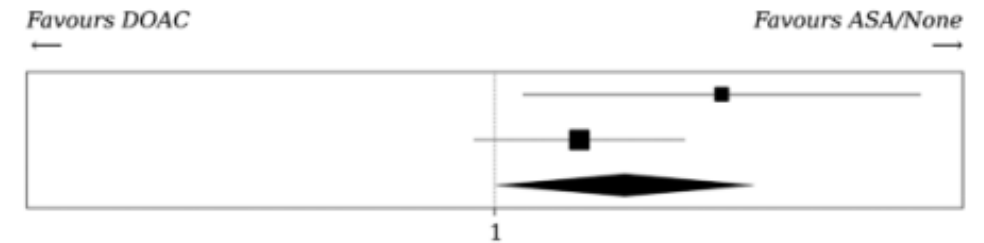
Fatal Bleeding

Study	DOAC	(%)	ASA/None	(%)	Weight	RR [95% CI]
NOAH-AFNET 6	2/1,270	(0.2%)	1/1,266	(0.1%)	10.2%	1.99 [0.18, 21.96]
ARTESiA	10/2,015	(0.5%)	14/1,997	(0.7%)	89.8%	0.71 [0.32, 1.59]
Pooled Estimate	12/3,285	(0.4%)	15/3,263	(0.5%)	I^2: 0%	0.79 [0.37, 1.69]
<i>Mantel-Haenszel, DerSimonian-Laird</i>		<i>Random Effects</i>		<i>RR: Risk Ratio CI: Confidence Interval</i>		
		<i>p=0.54, z=0.61</i>				
		<i>$\tau^2=0.00$</i>				



All-cause Mortality or Major Bleeding

Study	DOAC	(%)	ASA/None	(%)	Weight	RR [95% CI]
NOAH-AFNET 6	149/1,270	(11.7%)	114/1,266	(9.0%)	31.9%	1.3 [1.03, 1.64]
ARTESiA	431/2,015	(21.4%)	387/1,997	(19.4%)	68.1%	1.1 [0.98, 1.25]
Pooled Estimate	580/3,285	(17.7%)	501/3,263	(15.4%)	I^2: 35%	1.16 [1.0, 1.35]
<i>Mantel-Haenszel, DerSimonian-Laird</i>		<i>Random Effects</i>		<i>RR: Risk Ratio CI: Confidence Interval</i>		
		<i>p=0.05, z=1.96</i>				
		<i>$\tau^2=0.00$</i>				



CONCLUSIONS

The results of the NOAH-AFNET 6 and ARTESiA trials are consistent with each other. Meta-analysis of these 2 large randomized trials provides high-quality evidence that oral anticoagulation with edoxaban or apixaban reduces the risk of stroke in patients with device-detected AF and increases the risk of major bleeding.

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Que faire en pratique?

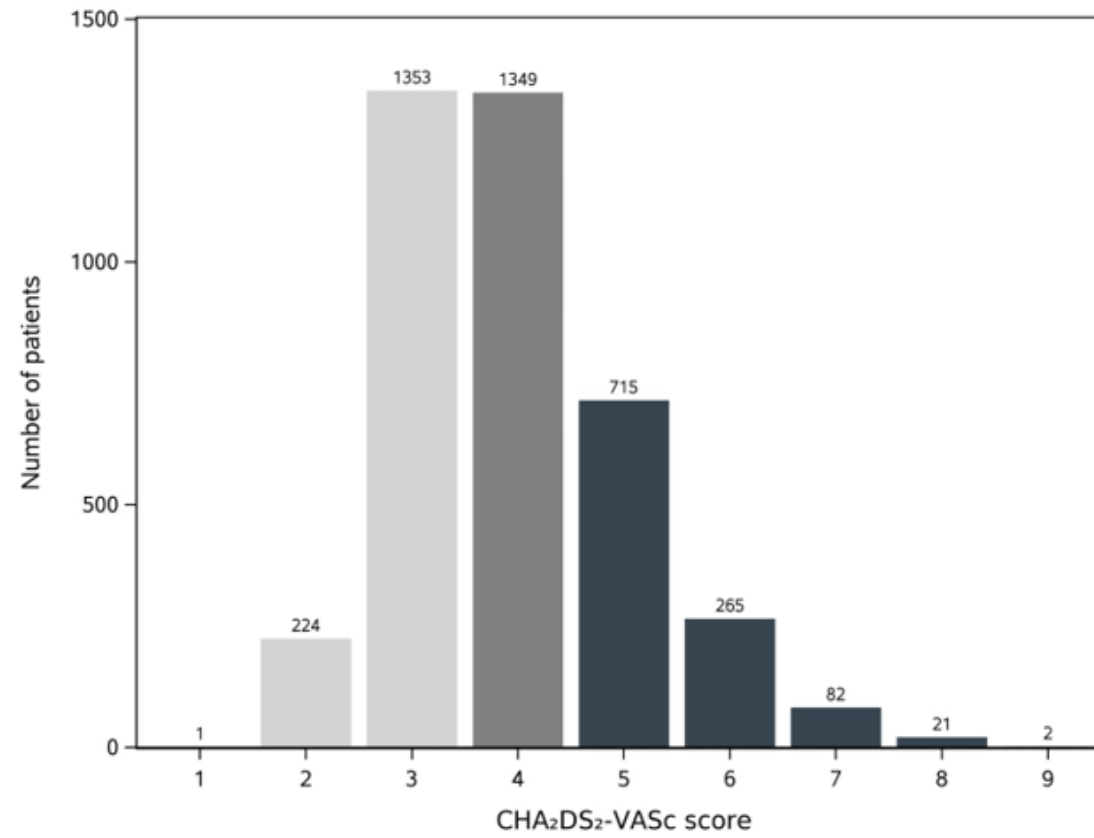
CONCLUSIONS

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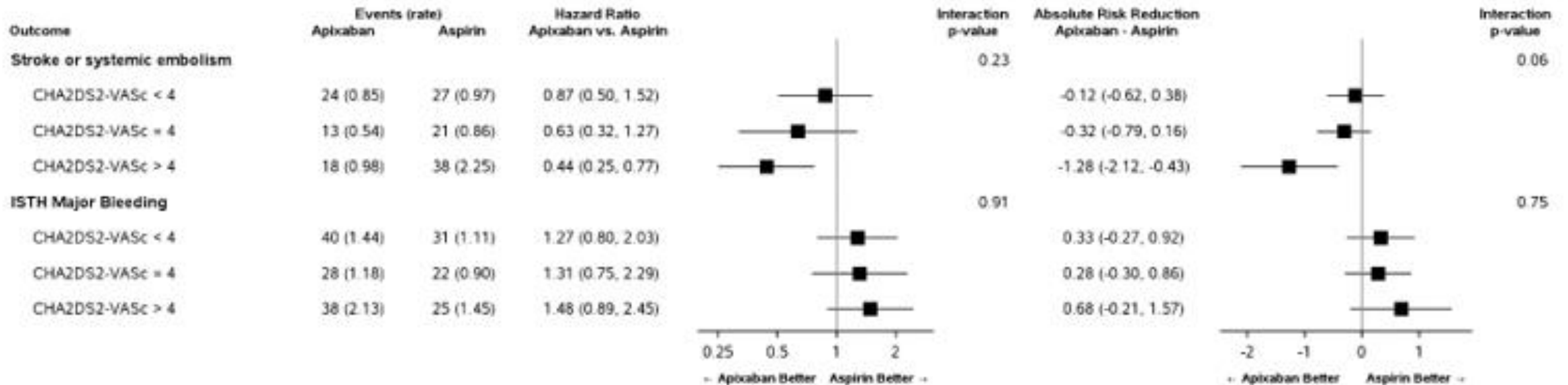
Que faire en pratique?

Prendre en compte le score CHADSVA ?

ARTESIA – CHADSVASc score



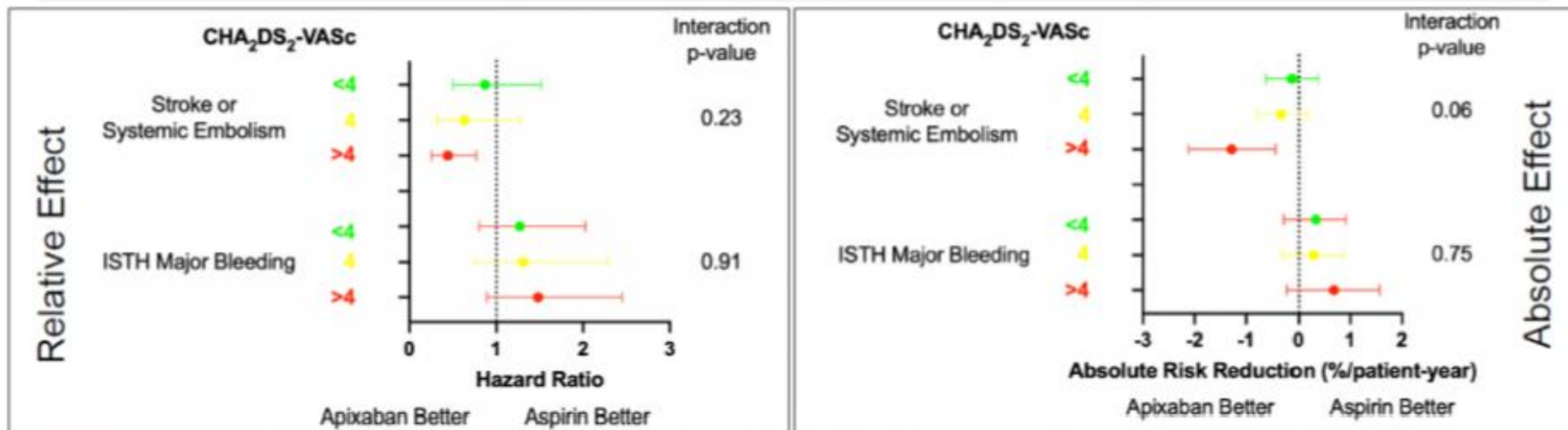
ARTESIA – CHADSVASc score



Footnote: rates per 100 patient-years of follow-up, absolute risk reduction per 100 patient-years of follow-up

ARTESiA: Apixaban versus aspirin in patients with subclinical atrial fibrillation

Treatment benefit according to CHA₂DS₂-VASc Score



CHA₂DS₂-VASc < 4

Low risk

Likely no benefit with apixaban

Exception: Treat if prior Stroke

CHA₂DS₂-VASc = 4

Intermediate risk

Consider apixaban based on
bleeding risk and patient values

CHA₂DS₂-VASc > 4

High risk

Treat with apixaban
Unless prohibitive bleeding risk

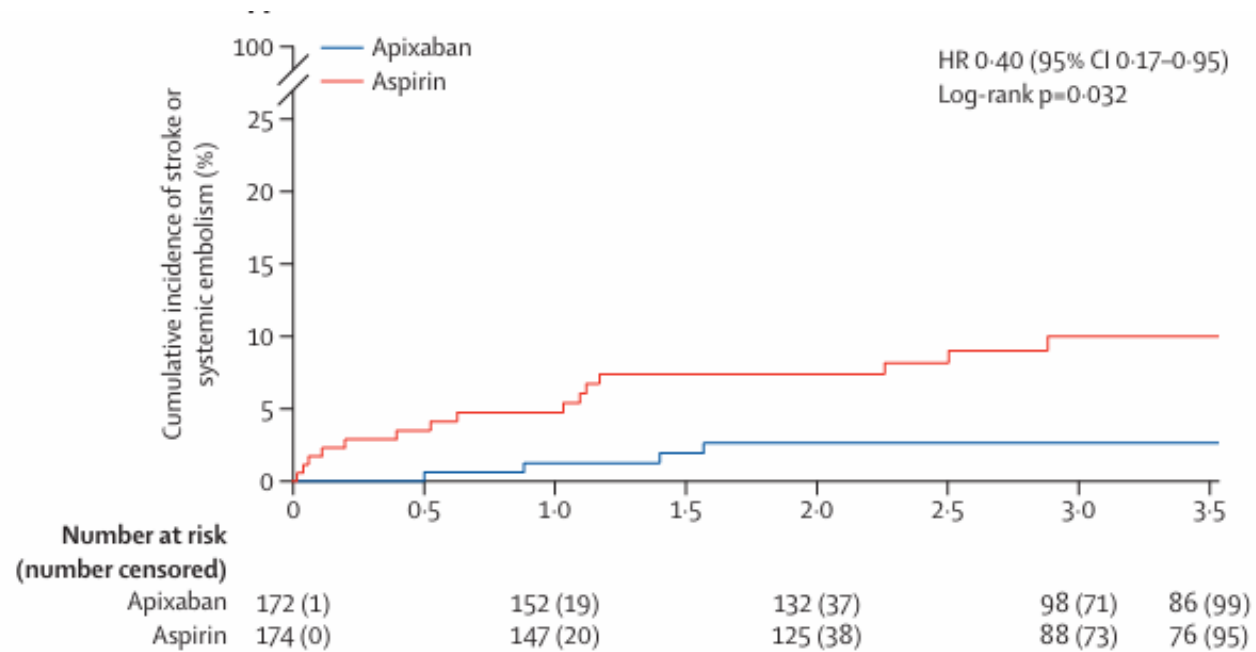
Que faire en pratique?

**Prendre en compte les antécédents
d'accidents emboliques ?**

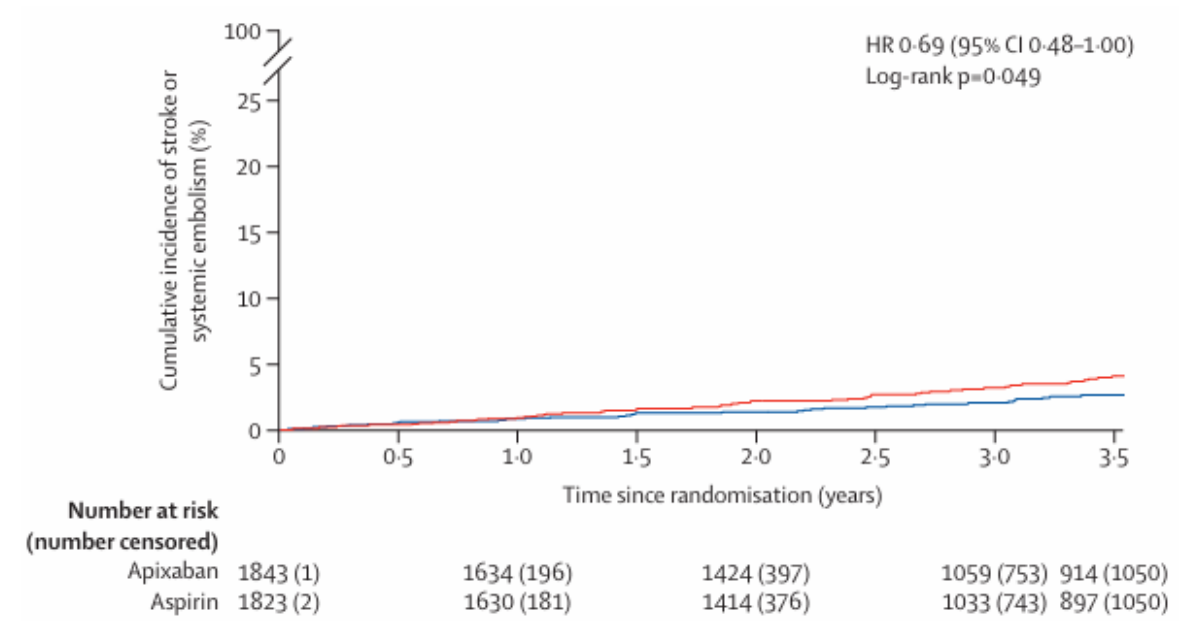
Apixaban versus aspirin for stroke prevention in people with subclinical atrial fibrillation and a history of stroke or transient ischaemic attack: subgroup analysis of the ARTESiA randomised controlled trial

*Ashkan Shoamanesh, Thalia S Field, Shelagh B Coutts, Mukul Sharma, David Gladstone, Robert G Hart, Giuseppe Boriani, David J Wright, Christian Sticherling, David H Birnie, Michael R Gold, Julia W Erath, Valentina Kutyifa, Rajibul Mian, Alexander P Benz, Christopher B Granger, William F McIntyre, Stuart J Connolly, Jens Cosedis Nielsen, Marco Alings, Lena Rivard, Renato D Lopes, Jeff S Healey, on behalf of the ARTESiA study investigators**

Lancet Neurol 2025; 24: 140–51



History of stroke or transient ischemic attack



No history of stroke or transient ischemic attack

Que faire en pratique?

**Prendre en compte les caractéristiques
des épisodes documentés ?**

Circulation

ORIGINAL RESEARCH ARTICLE

Risk of Stroke or Systemic Embolism According to Baseline Frequency and Duration of Subclinical Atrial Fibrillation: Insights From the ARTESiA Trial

William F. McIntyre, MD, PhD; Alexander P. Benz, MD, MSc; Jeff S. Healey^{id}, MD, MSc; Stuart J. Connolly^{id}, MD, MSc; Mu Yang^{id}, MSc; Shun Fu Lee^{id}, PhD; Thalia S. Field^{id}, MD, MHSc; Marco Alings^{id}, MD, PhD; J. Benezet-Mazuecos^{id}, MD; Giuseppe Boriani^{id}, MD, PhD; J. Cosedis Nielsen^{id}, MD, DMSc, PhD; Michael R. Gold, MD, PhD; Francesco Pergolini^{id}, MD; Taya V. Glotzer^{id}, MD; Christopher B. Granger^{id}, MD; Renato D. Lopes^{id}, MD, MHS, PhD

Circulation. 2024;150:1747–1755.

ARTESIA - Nombre et durée des épisodes

Model type	Overall events/n (% per person-year)	Apixaban events/n (% per person-year)	Aspirin events/n (% per person-year)	Apixaban vs aspirin		<i>P</i> _{interaction}	<i>P</i> _{trend}
				HR (95% CI)	<i>P</i> value		
Duration of longest SCAF episode, h							
<1	39/1030 (1.0)	11/534 (0.6)	28/496 (1.5)	0.37 (0.18– 0.74)	0.005	0.2	
1–6	61/1421 (1.2)	23/679 (1.0)	38/742 (1.5)	0.62 (0.37– 1.05)	0.075		0.1
>6	27/832 (1.0)	13/437 (0.9)	14/395 (1.1)	0.90 (0.42– 1.92)	0.786		

Apixaban for stroke prevention in subclinical atrial fibrillation detected by an implantable cardiac monitor: A subgroup analysis of ARTESiA

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ARTESIA – Implantable Cardiac Monitor

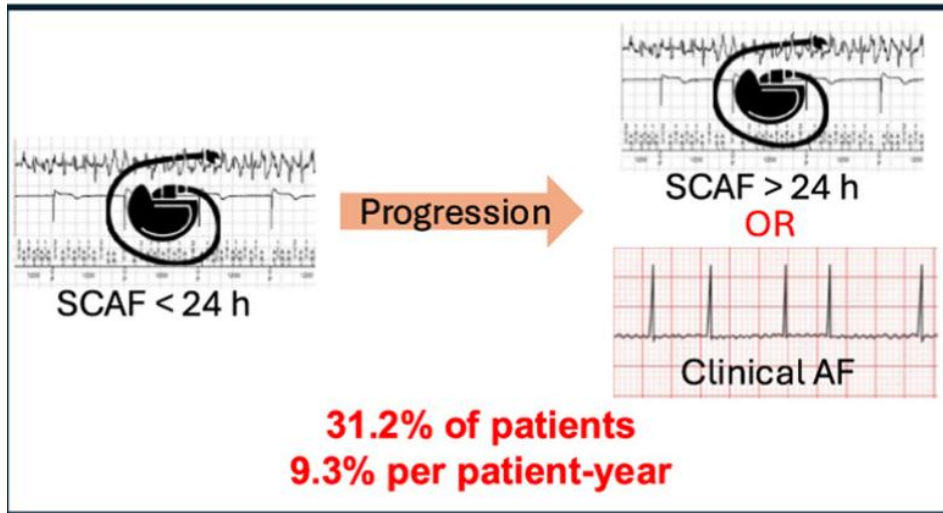
	ICM	PM/ICD
N	209 (5.2%)	3803 (94.8%)
Man age (years)	74.9 ± 7.4	76.9 ± 7.6
Female	50.2%	35.3%
Previous stroke	24.9%	7.7%

	Apixaban	Aspirin
Stroke/systemic embolism	1 / 103 (0.3%/year)	9 / 106 (2.6%/year)
HR 0.11 ; 95% CI 0.01–0.88]		
Absolute risk reduction 2.31%/year [95% CI, 0.55–4.07]		

ARTESIA

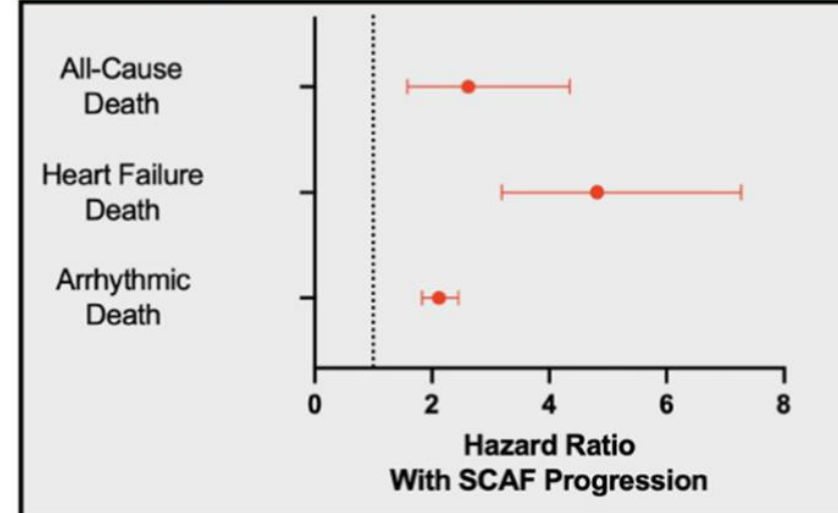
Progression from subclinical atrial fibrillation (SCAF) < 24 hours to clinical AF or SCAF > 24 hours in the ARTESIA trial

Total follow-up: 4.1 ± 1.7 years



SCAF progression modestly predicted by:
age, male sex, heart failure,
diabetes, left atrial diameter > 4.1 cm,
baseline duration of longest
SCAF episode >1hr

Post-progression follow-up: 2.3 ± 1.6 years



Rate of stroke/systemic embolism in aspirin-treated patients following progression to SCAF > 24 hours:

CHA₂DS₂VASc ≤4:
2.21% per patient-year
CHA₂DS₂VASc >4:
1.51% per patient-year

Prévention du risque embolique

FA infraclinique détectée par les prothèses

Après ARTESIA et NOAH

Patients had a low burden of device-detected subclinical AF in both trials (median duration 1.5 h and 2.8 h, respectively), with lower rates of thromboembolism (around 1% per patient-year) than would be expected for an equivalent cohort of patients with clinical AF and a CHA₂DS₂-VASc score of 4.

Prévention du risque embolique

FA infraclinique détectée par les prothèses

Après ARTESIA et NOAH

Considering the trade-off between potential benefit and the risk of major bleeding, this task force concludes that DOAC therapy may be considered in subgroups of patients with asymptomatic device-detected subclinical AF who have high estimated stroke risk and an absence of major bleeding risk factors (see Section 6.7).

Prévention du risque embolique

FA infraclinique détectée par les prothèses

Après ARTESIA et NOAH

The duration and burden of subclinical AF that could indicate potential benefit from OAC remains uncertain.³⁴⁴ Regardless of the initial decision on OAC, patients with subclinical AF should receive management and follow-up for all aspects of AF-CARE as the risk of developing clinical AF is high (6%–9% per year).

Prévention du risque embolique

FA infraclinique détectée par les prothèses

Après ARTESIA et NOAH

Direct oral anticoagulant therapy may be considered in patients with asymptomatic device-detected subclinical AF and elevated thromboembolic risk to prevent ischaemic stroke and thromboembolism, excluding patients at high risk of bleeding.^{281,282}

IIb

B

Conclusions

- **Un concept de prévention qui a du mal à trouver sa population**
- **Les « croyances » même fortes nécessitent toujours une évaluation**
- **Des recommandations désormais « timides »**
- **Comment avancer au-delà des essais randomisés ?**
- **L'IA, un outil pour redistribuer les cartes**