McGill University Health Centre

UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

Scientific Sessions

Anti-thrombotic therapy after successful catheter ablation of atrial fibrillation: The OCEAN Trial

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American Heart Association.

#AHA25

DISCLOSURES

Grants: Abbott, Cardiofocus, JNJ MedTech, Medtronic

Advisory: Abbott, Adagio Medical, Cardiofocus, Kardium, JNJ MedTech, Medtronic, Volta Medical

BACKGROUND

Catheter ablation for atrial fibrillation (AF) burden is known to reduce recurrence and AF burden.

Whether AF burden is reduced sufficiently to obviate the need for ongoing oral anticoagulation is unknown.

Guidelines[1] recommend continuing oral anticoagulation for life after AF ablation based on CHA_2DS_2-VASc score and not on apparent success of procedure.

1 Tzeis et al, 2024 Expert consensus statement on catheter and surgical ablation of atrial fibrillation, Europace 2025

HYPOTHESIS

A strategy of continued oral anticoagulation will be superior to antiplatelet therapy for reducing the risk of stroke, systemic embolism, or covert embolic stroke (MRI infarct ≥ 15 mm) after successful ablation of AF.

Covert embolic stroke has been used as an endpoint for other stroke trials[1].

Covert embolic stroke associated with clinical stroke, cognitive decline, and mortality[2,3].

1 Lansberg et al, JAMA Neurol 2025; 2 Kim et al, Stroke Stroke 2023;
3 Neurovision investigators, Lancet 2019

METHODS

Multicenter, international, prospective, randomized, open-label, blinded endpoint trial at 56 sites in 6 countries.

Clinical outcomes adjudicated by independent, blinded committee.

METHODS

Inclusion Criteria:

At least one year after successful AF ablation(s) – at least one 24-hour Holter 2-6 months post; 24-hour Holter >6 months; 48-hour Holter prior to enrollment – absence of atrial arrhythmia >30 seconds

CHA_2DS_2-VASc score of 1 or more; 2 or more if female sex or vascular disease

METHODS

Exclusion Criteria:

Valvular AF (mechanical valve, rheumatic mitral disease)

Creatinine clearance <30 ml/min

Contraindication to anticoagulation or antiplatelet therapy

Contraindication to MRI

Disabling stroke within 1 year, any stroke within 14 days

Hypercoagulability disorders, known intracranial vascular anomalies

Age >85

METHODS

1:1 randomization:

Rivaroxaban (15 mg) or aspirin (70-120 mg)

Rivaroxaban 15 mg has 80-90% pharmacokinetic overlap to 20 mg, no increased risk of stroke with this dose with normal renal function[1], less bleeding risk

Aspirin of no benefit in lower risk patients, but may have benefit in higher risk[2]

1 Santos et al, Br J Clin Phamacol 2020;86:533–547;
2 Hart et al, Ann Int Med 2007

METHODS

All patients underwent brain MRI at baseline, 1 year, and 3 years by original protocol.

Because of COVID-19 pandemic, requirement for 1 year MRI was lifted after first 658 patients.

Magnetic resonance imaging (MRI) outcomes adjudicated by blinded core lab (University of Calgary).

METHODS

For cardioversions, acute coronary interventions, or interventional or surgical procedures, temporary addition, switching, or interruption of anticoagulation or antiplatelet was protocol-defined (not crossover).

Patients undergoing repeat AF ablation were exited from study at time of ablation per protocol.

Follow-up of three years.

OUTCOMES

Primary Efficacy Outcome

Composite of stroke, systemic embolism, and covert embolic stroke defined as one or more infarcts ≥ 15 mm detected between baseline and 3-year MRI

Primary Safety Outcome

Fatal and major bleeding as defined by ISTH

Secondary outcomes

Components of primary outcome, safety outcome, minor bleeding, and clinically relevant non-major bleeding, new covert strokes <15 mm

RESULTS

We planned sample size of 1572 patients based on annual event rate of primary outcome of 3.5% per year.

May 19, 2022, DSMB recommended stopping the trial because of high likelihood that trial would not demonstrate a benefit for rivaroxaban.

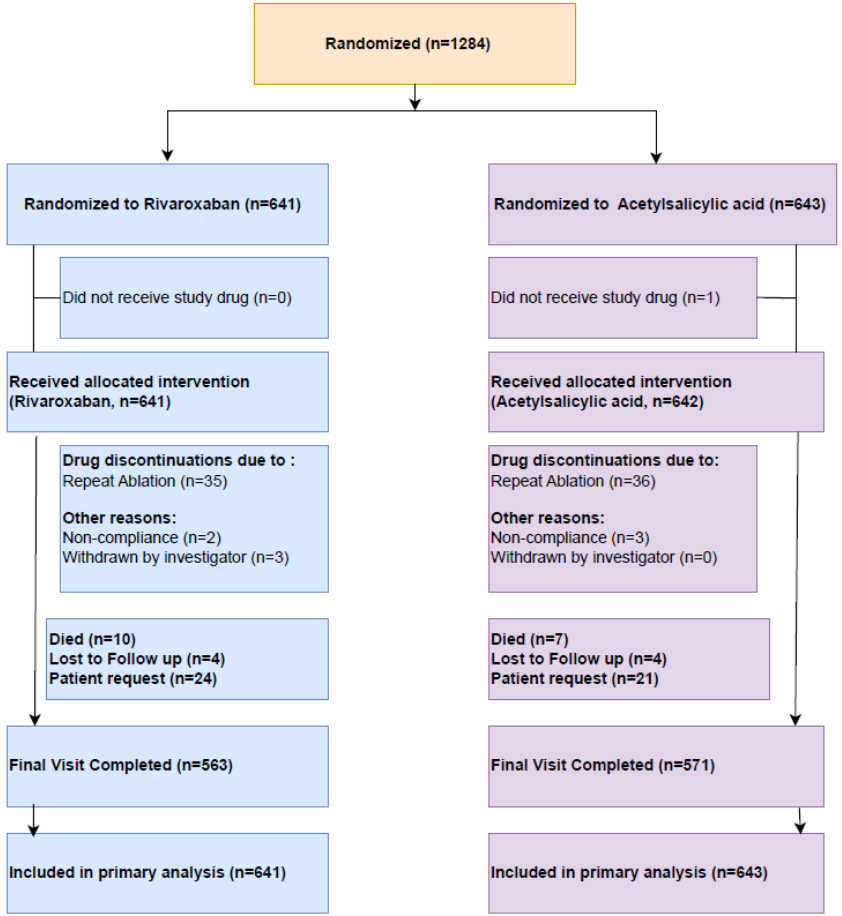
Investigators were not made aware of interim results; all randomized patients (n=1284) were permitted to complete follow-up in randomized group.

RESULTS

Only 4 patients lost to follow-up in each arm.

71 (5.5%) patients exited because of repeat AF ablation.

97.4% of surviving patients received their 3-year brain MRI.



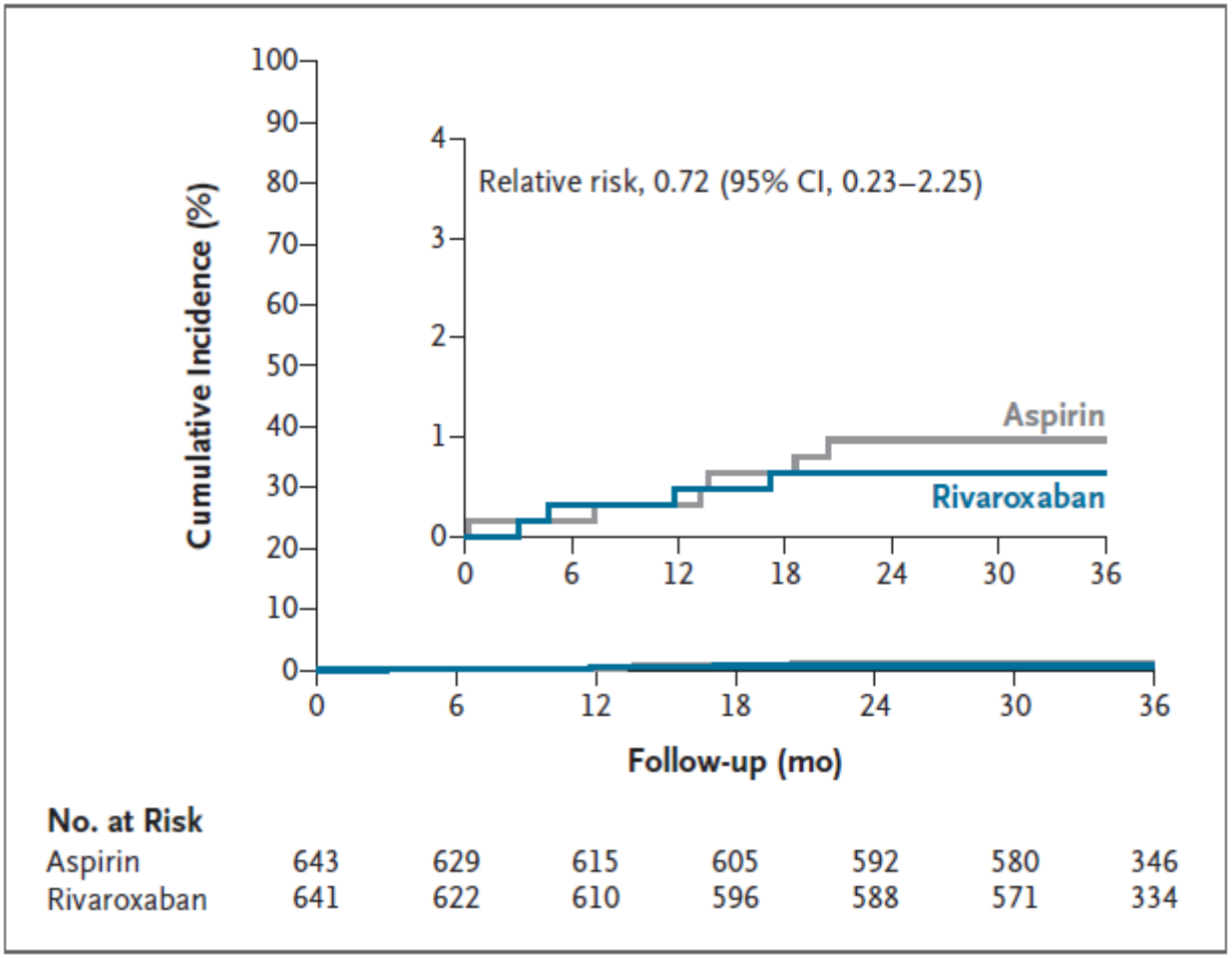
RESULTS

	Rivaroxaban (n=641)	Aspirin (n=643)
Age (years)	66.3±7.1	66.3±7.6
Male sex	458 (71.5)	459 (71.4)
Months since ablation (IQR)	16.4 (13.4-25.2)	16.5 (13.6-25.2)
Paroxysmal AF	431 (67.2)	421 (65.5)
CHA_2DS_2-VASc score 1 2 3 4 or more	2.2 ± 1.1 194 (30.3) 241 (37.6) 138 (21.5) 68 (10.6)	2.2 ± 1.1 196 (30.5) 243 (37.8) 127 (19.8) 77 (12.0)
HASBLED score	1.4 ± 0.9	1.3 ± 0.8
Prior stroke or TIA	28 (4.4)	50 (7.7)
LA diameter (mm)	40.7 ± 16.0	40.4 ± 19.2

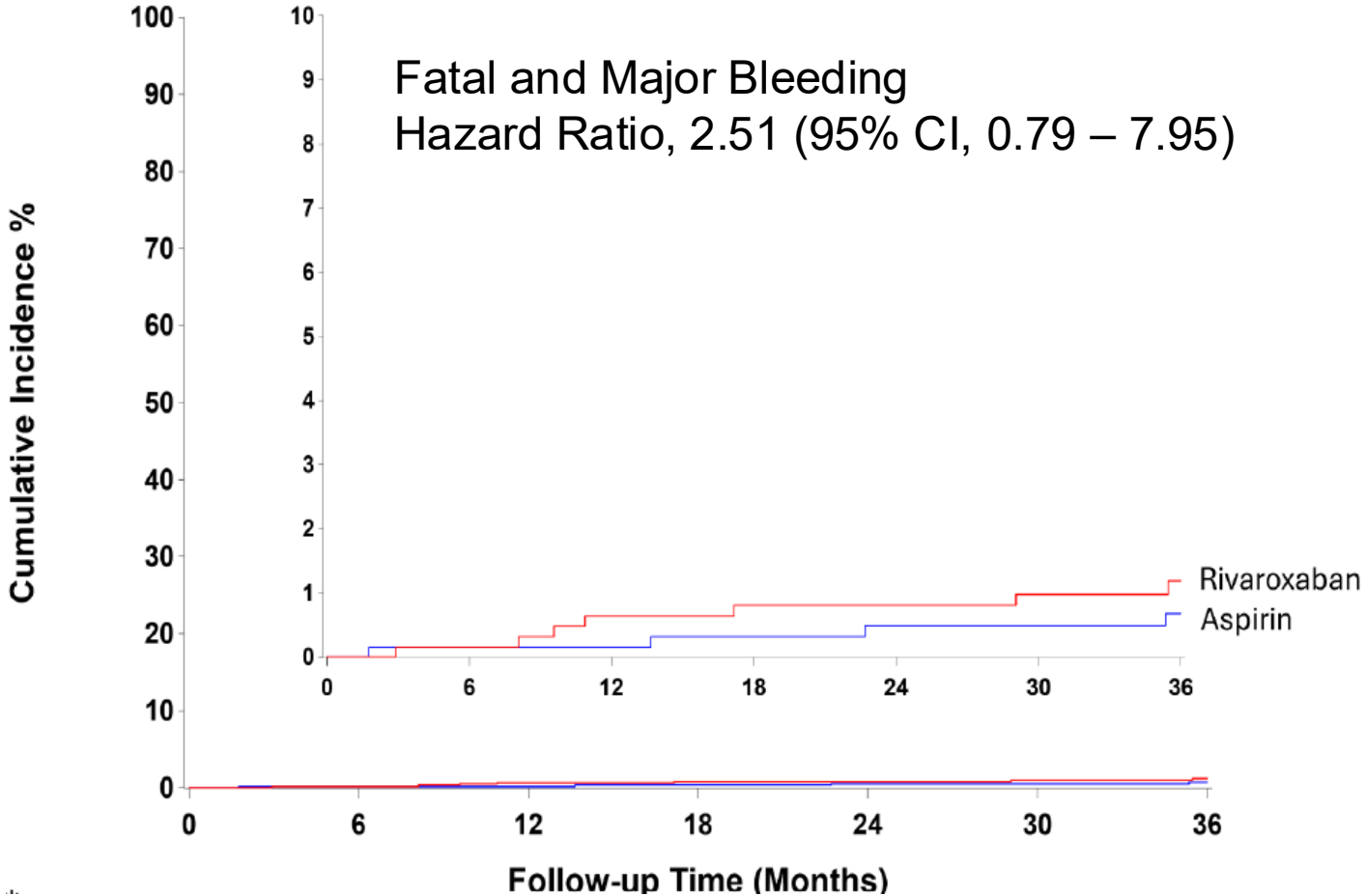
	Rivaroxaban n=641	Aspirin n=643	Relative Risk (95% CI)	Annualized Risk Rivaroxaban	Annualized Risk Aspirin	P value
Primary composite outcome	5	9	0.56 (0.19 to 1.65)	0.31%	0.66%	0.28
All Stroke	5	7	0.72 (0.23 to 2.25)	0.31%	0.58%	
Systemic embolism	0	0	-	0%	0	
Covert embolic stroke	0	2	0	0%	0.08%	
All Stroke or systemic embolism	5	7	0.72 (0.2 to 2.25)	0.29%	0.58%	
Any MRI infarct <15 mm	22	26	0.89 (0.51 to 1.55)			

96% of pts had no new infarct of any size on MRI at 3 years

RESULTS

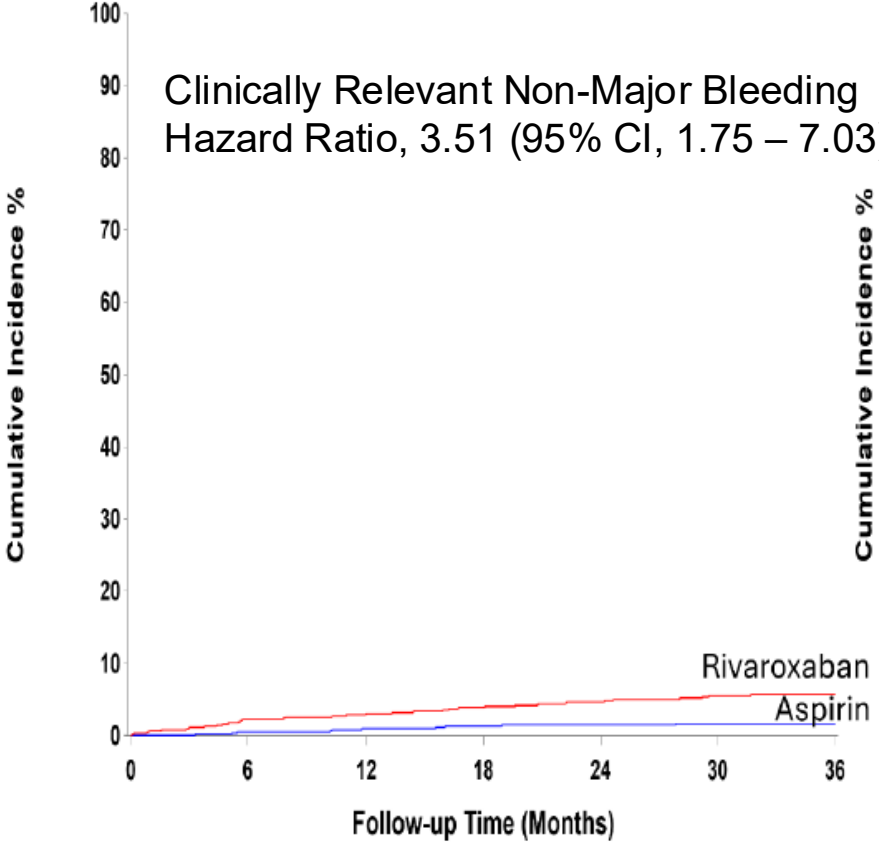

Cumulative Incidence (%)
100
90
80
70
60
50
40
30
20
10
0
Relative risk, 0.72 (95% CI, 0.23–2.25)
4
3
2
1
0
Aspirin
Rivaroxaban
0
6
12
18
24
30
36
Follow-up (mo)
No. at Risk
Aspirin 643 629 615 605 592 580 346
Rivaroxaban 641 622 610 596 588 571 334

RESULTS

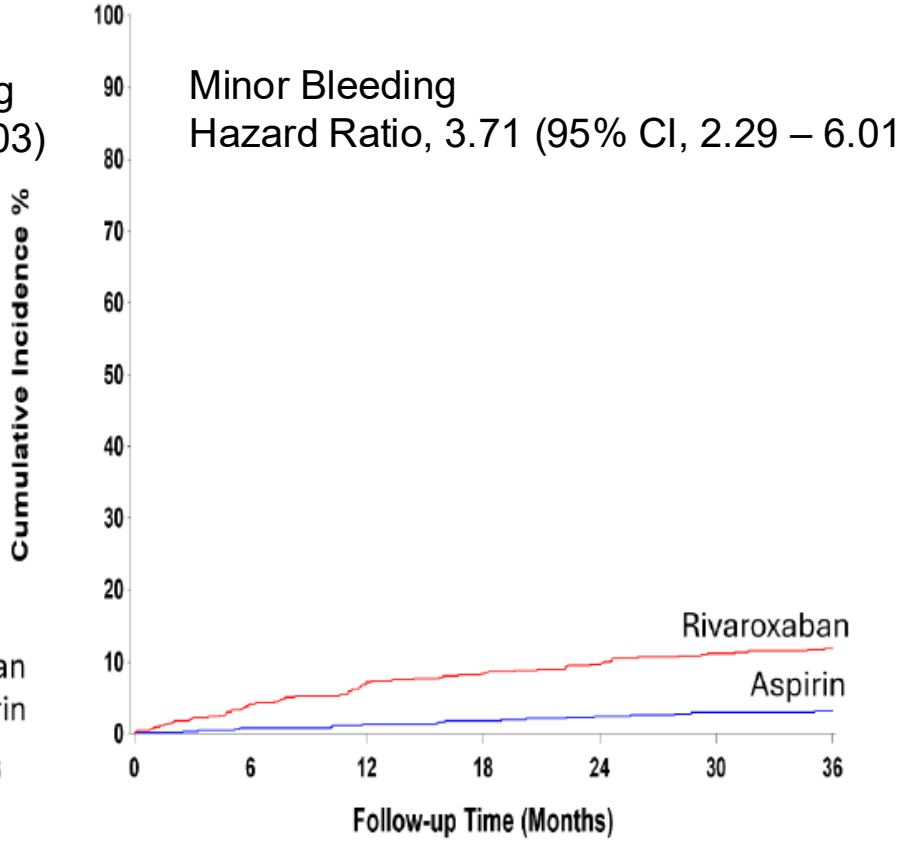

Fatal and Major Bleeding
Hazard Ratio, 2.51 (95% CI, 0.79 – 7.95)
Cumulative Incidence %
100
90
80
70
60
50
40
30
20
10
0
10
9
8
7
6
5
4
3
2
1
0
0
6
12
18
24
30
36
Rivaroxaban
Aspirin
Follow-up Time (Months)

RESULTS

Clinically Relevant Non-Major Bleeding
Hazard Ratio, 3.51 (95% CI, 1.75 – 7.03)



Minor Bleeding
Hazard Ratio, 3.71 (95% CI, 2.29 – 6.01)



LIMITATIONS

Placebo instead of aspirin – if aspirin has no benefit on stroke, then placebo would not have changed results

20 mg dose would not have changed results over 15 mg dose

No extended monitoring during enrollment or follow-up – practical trial

Low-moderate risk patients – for very high-risk patients, findings are not relevant

CONCLUSIONS

Rivaroxaban did not decrease the rate of a composite of stroke, systemic embolism, and covert embolic stroke compared to aspirin.

Major bleeding appeared similar in both groups.

Clinically relevant non-major and minor bleeding were increased by rivaroxaban.

Annualized rate of stroke, systemic embolism, and covert stroke is very low after successful AF ablation – falls below traditional threshold for anticoagulation.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Antithrombotic Therapy after Successful Catheter Ablation for Atrial Fibrillation

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