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OCEANIC-AF: Asundexian vs. Apixaban in Patients with Atrial Fibrillation

OCEANIC AF

ESC Late-Breaking Trial Presentation
September 1st, 2024

Manesh R. Patel, MD on behalf of the OCEANIC-AF Executive Committee, Steering Committee, and Investigators

Duke Clinical Research Institute

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Asundexian versus Apixaban in Patients with Atrial Fibrillation

J.P. Piccini, M.R. Patel, J. Steffel, K. Ferdinand, I.C. Van Gelder, A.M. Russo, C.-S. Ma, S.G. Goodman, J. Oldgren, C. Hammett, R.D. Lopes, M. Akao, R. De Caterina, P. Kirchhof, D.A. Gorog, M. Hemels, M. Rienstra, W.S. Jones, J. Harrington, G.Y.H. Lip, S.J. Ellis, F.W. Rockhold, C. Neumann, J.H. Alexander, T. Viethen, J. Hung, R. Coppolecchia, H. Mundl, and V. Caso, for the OCEANIC-AF Steering Committee and Investigators*

NEJM, September 2024

Background: The Need for a Better Antithrombotic Therapy for Atrial Fibrillation

OCEANIC AF

- DOACs now accepted as first-line therapy over warfarin, with lower rates of stroke, mortality, and ICH
- Patients on DOACs still face a bleeding risk of 2.7–3.5%/year
- Bleeding and fear of bleeding remain a major challenge for DOAC therapy and adherence to treatment, resulting in:

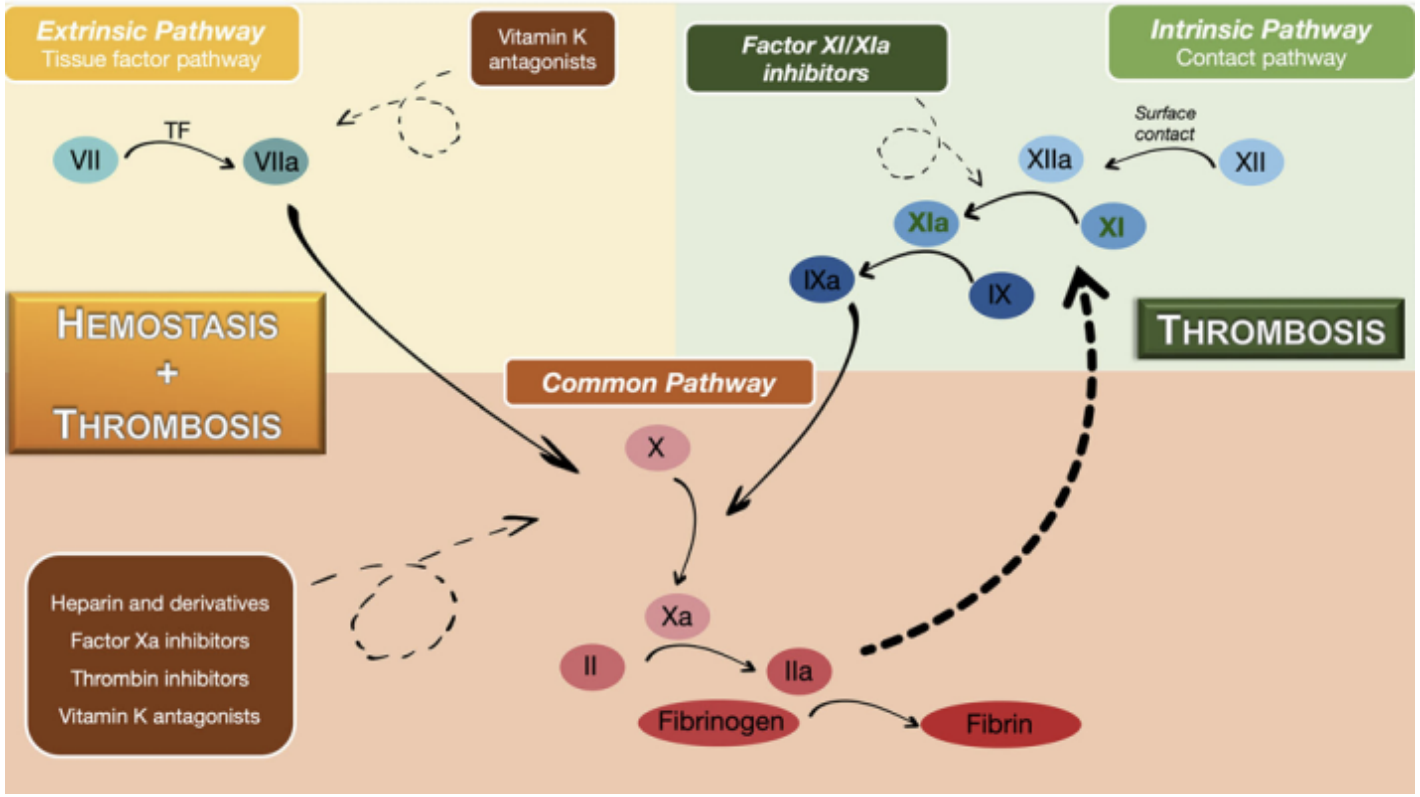
Undertreatment
< 66% of patients with atrial fibrillation and CHA_2DS_2-VASc ≥ 2 are prescribed an OAC at all

Underdosing
Up to 25% of patients on DOACs are underdosed, which might result in higher rates of thromboembolic events

Poor treatment compliance
1 in 3 patients adhere to their DOAC < 80% of the time and the nonadherence is associated with poor clinical outcomes

January et al. JACC 2019;74:104–132.
Carnicelli et al. Circulation 2022;145:242–255.
Oldgren et al. Circulation 2014;129:1568–1576.
Camm et al. JACC 2020; 76:1425–1436.
Kakkar et al. PLoS One 2013;8:e63479.

BACKGROUND

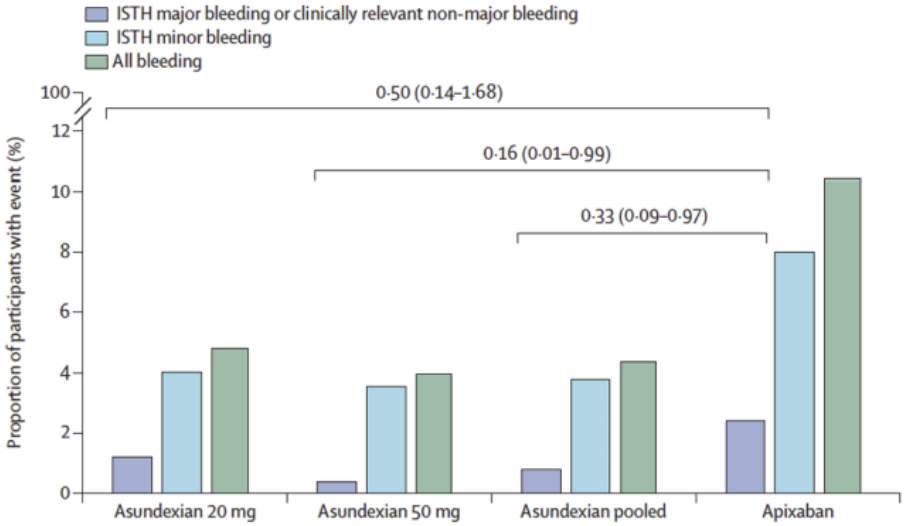


PACIFIC-AF

Safety of the oral factor XIa inhibitor asundexian compared with apixaban in patients with atrial fibrillation (PACIFIC-AF): a multicentre, randomised, double-blind, double-dummy, dose-finding phase 2 study

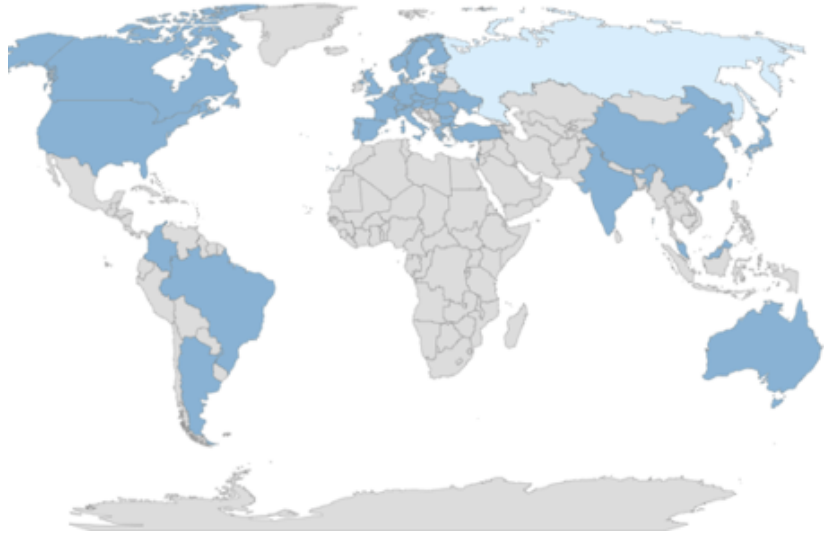
Jonathan P Piccini, Valeria Caso, Stuart J Connolly, Keith A A Fox, Jonas Oldgren, W Schuyler Jones, Diana A Gorog, Václav Durdil, Thomas Viethen, Christoph Neumann, Hardi Mundl, Manesh R Patel, on behalf of the PACIFIC-AF Investigators*

Primary Safety Outcome (ISTH bleeding classification)



OCEANIC-AF Study Design

Etude randomisée
Non infériorité



Atrial Fibrillation

Asundexian
50 mg QD

Apixaban
5 mg or 2.5 mg BID

Randomize
Double-Blind /
Double-Dummy
(n ~ 18,000)

Sample size of 18,000 (24 months randomization) allows for reaching **340 primary efficacy (90% power) events** within 33 months for incidence rate 1.5.

Monthly Monitoring
Adherence to standard-of-care guidelines

Primary Efficacy Endpoint: Stroke or Systemic Embolism

Primary Safety Endpoint: ISTH Major Bleeding

Primary Net Clinical Benefit Endpoint: Stroke or Systemic Embolism and ISTH Major Bleeding

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Inclusion Criteria

OCEANIC AF

Patients will be eligible for the study if they have:

- Atrial fibrillation* with indication for indefinite treatment with an anticoagulant
- A CHA_2DS_2-VASc score ≥ 3 if male or ≥ 4 if female

OR

- A CHA_2DS_2-VASc score of 2 if male or 3 if female **AND at least 1 of the following:**
  - age ≥ 70 years
  - previous stroke, transient ischemic attack, or systemic embolism
  - renal dysfunction with CKD-EPI eGFR < 50 mL/min/1.73m^2 within 14 days prior to randomization
  - prior episode of non-traumatic major bleeding
  - current single agent antiplatelet therapy planned for at least the next 6 months
  - ≤ 6 consecutive weeks of treatment with oral anticoagulant prior to randomization (OAC Naïve)

** Documented on 6 (or more) lead EKG or as ≥ 30 seconds on continuous rhythm strip in last 12 months*

Key Exclusion Criteria

Patients will be not eligible for the study:

- Mechanical heart valve prosthesis (not including transcatheter aortic valve replacement)
- Moderate-to-severe mitral stenosis at the time of inclusion into the study
- Atrial fibrillation only due to reversible cause (e.g., thyrotoxicosis, endocarditis, pneumonia, pulmonary embolism)
- Participants after successful ablation therapy without documented recurrent atrial fibrillation or participants after left atrial appendage (LAA) occlusion / exclusion or plan for ablation or LAA occlusion / exclusion within the next 6 months starting from randomization
- Recent ischemic stroke (within 7 days prior to randomization)
- eGFR < 25 mL/min/1.73m^2 within 14 days prior to randomization or on dialysis or expected to be started on dialysis within the next 12 months starting from randomization
- Requirement for chronic anticoagulation for a different indication than atrial fibrillation, e.g., mechanical heart valve or left ventricular cardiac thrombus (atrial thrombus is allowed), or dual antiplatelet therapy (single agent therapy is allowed)

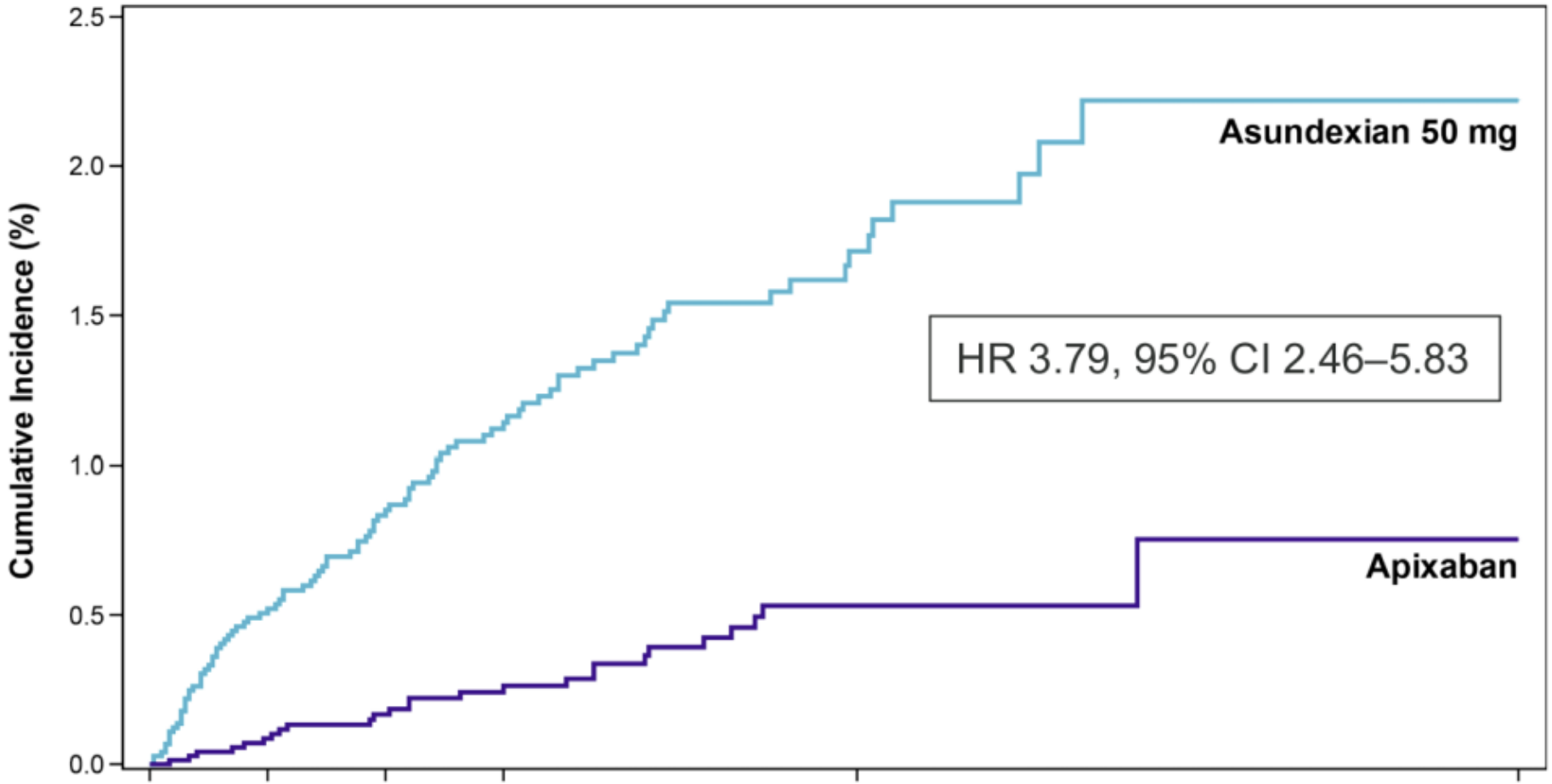
Patient Demographics

	Asundexian 50 mg (N=7415)	Apixaban (N=7395)	Total (N=14,810)
Age, mean (SD), yrs	73.9 (7.7)	73.9 (7.7)	73.9 (7.7)
Female	2656 (35.8%)	2558 (34.6%)	5214 (35.2%)
Race, White	5216 (70%)	5211 (70%)	10,427 (70%)
Region			
Eastern Europe	1520 (20.5%)	1515 (20.5%)	3035 (20.5%)
North America	1405 (18.9%)	1406 (19.0%)	2811 (19.0%)
South America	400 (5.4%)	401 (5.4%)	801 (5.4%)
Asia	2114 (28.5%)	2108 (28.5%)	4222 (28.5%)
Western EU, Australia, Israel	1976 (26.6%)	1965 (26.6%)	3941 (26.6%)
≤6 weeks of prior OAC use (DOAC or warfarin)	1238 (16.7%)	1255 (17.0%)	2493 (16.8%)
SAPT for >6 months	742 (10.0%)	743 (10.0%)	1485 (10.0%)
CHA_2DS_2-VASc score mean (SD)	4.3 (1.3)	4.3 (1.3)	4.3 (1.3)
Type of AF			
First detected	118 (1.6%)	134 (1.8%)	252 (1.7%)
Paroxysmal	2760 (37%)	2641 (36%)	5401 (36%)
Persistent	1773 (24%)	1805 (24%)	3578 (24%)
Long-standing persistent	436 (5.9%)	428 (5.8%)	864 (5.8%)
Permanent	2327 (31%)	2384 (32%)	4711 (32%)

Patient Demographics

Comorbidities	Asundexian 50 mg (N=7415)	Apixaban (N=7395)	Total (N=14,810)
Hypertension	6558 (88.4%)	6565 (88.8%)	13123 (88.6%)
Hyperlipidemia	4747 (64.0%)	4719 (63.8%)	9466 (63.9%)
Heart failure	3456 (46.6%)	3473 (47.0%)	6929 (46.8%)
Coronary artery disease	2496 (33.7%)	2452 (33.2%)	4948 (33.4%)
Diabetes mellitus	2722 (36.7%)	2748 (37.2%)	5470 (36.9%)
Chronic kidney disease	1399 (18.9%)	1357 (18.4%)	2756 (18.6%)
Obstructive sleep apnea	786 (10.6%)	744 (10.1%)	1530 (10.3%)
Peripheral artery disease	442 (6.0%)	485 (6.6%)	927 (6.3%)
Deep venous thrombosis	170 (2.3%)	162 (2.2%)	332 (2.2%)
Gastrointestinal bleed	276 (3.7%)	214 (2.9%)	490 (3.3%)
Hyperuricemia	841 (11.3%)	763 (10.3%)	1604 (10.8%)
Osteoarthritis	951 (12.8%)	984 (13.3%)	1935 (13.1%)
Gastroesophageal reflux disease	775 (10.5%)	766 (10.4%)	1541 (10.4%)
Anemia	1432 (19.3%)	1346 (18.2%)	2778 (18.8%)
Stroke or TIA	1389 (18.7%)	1305 (17.6%)	2694 (18.2%)

Cumulative Event Rate for the Primary Efficacy Endpoint



Median follow-up: 160 days

Number of participants at risk						
Asundexian 50 mg	7415	6564	5574	4622	1958	1
Apixaban	7395	6596	5624	4657	1979	0

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Efficacy Events

Efficacy Events According to ITT	Asundexian (N=7415)	Apixaban (N=7395)	Total (N=14,810)	csHR (95% CI)*
Stroke or SE	98 (1.3%)	26 (0.4%)	124 (0.8%)	3.79 (2.46–5.83)
Ischemic stroke or SE	96 (1.3%)	22 (0.3%)	118 (0.8%)	4.38 (2.76–6.96)
All-cause mortality	60 (0.8%)	71 (1.0%)	131 (0.9%)	0.84 (0.60–1.19)
Ischemic stroke	85 (1.1%)	21 (0.3%)	106 (0.7%)	4.06 (2.52–6.54)
CV death	48 (0.6%)	44 (0.6%)	92 (0.6%)	1.09 (0.72–1.64)
CV death, MI, or stroke	155 (2.1%)	77 (1.0%)	232 (1.6%)	2.02 (1.54–2.66)

*Derived from a stratified cause-specific Cox proportional hazards regression model. Cumulative Incidence Rates provided
CI indicates confidence interval; csHR, cause-specific hazard ratio; CV, cardiovascular; ITT, intention to treat; MI, myocardial infarction; SE, systemic embolism.

Safety Events

	Asundexian 50 mg (N=7373)	Apixaban (N=7364)	Total (N=14,737)	csHR (95% CI)†
ISTH major bleeding	17 (0.2%)	53 (0.7%)	70 (0.5%)	0.32 (0.18–0.55)
ISTH major and CRNM bleeding	83 (1.1%)	188 (2.6%)	271 (1.8%)	0.44 (0.34–0.57)
ISTH CRNM bleeding	67 (0.9%)	140 (1.9%)	207 (1.4%)	0.48 (0.36–0.64)
Hemorrhagic stroke	1 (<0.1%)	6 (0.1%)	7 (<0.1%)	0.17 (0.02–1.42)
Symptomatic intracranial hemorrhage	3 (<0.1%)	18 (0.2%)	21 (0.1%)	0.16 (0.05–0.55)
Fatal bleeding	0 (0%)	4 (0.1%)	4 (<0.1%)	Not calculated
ISTH minor bleeding	187 (2.5%)	317 (4.3%)	504 (3.4%)	0.59 (0.49–0.70)
Stroke, SE, or ISTH major bleeding (net clinical benefit endpoint)	120 (1.6%)	75 (1.0%)	195 (1.3%)	1.61 (1.21–2.15)

*The primary safety estimand is the cause-specific hazard ratio of ISTH major bleeding when treatment with Asundexian is compared with treatment with Apixaban in adult patients with atrial fibrillation at risk for stroke who have taken at least one dose of Asundexian or Apixaban while alive and while exposed to Asundexian or Apixaban.
†Cause-specific hazard ratios and their associated 95% confidence intervals were derived from a stratified cause-specific Cox proportional hazards regression model.
CI indicates confidence interval; CRNM, clinically relevant non-major; csHR, cause-specific hazard ratio; ISTH, International Society on Thrombosis and Haemostasis; SE, systemic embolism.

Conclusions

- Over 14,810 patients with atrial fibrillation at risk for stroke were enrolled over 11 months worldwide.
- Asundexian 50 mg once daily was inferior for prevention of stroke and systemic embolism compared with Apixaban in patients with atrial fibrillation at high risk for stroke.
- More research is needed to determine the correct amount of FXIa inhibition for atrial fibrillation stroke prevention.
- Multiple ongoing studies with Factor XI inhibition in different indications are ongoing with IDMC oversight.

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Predictors and Outcomes of AF Progression in Patients with Device-Detected Subclinical AF: Insights from the ARTESiA Trial

Giuseppe Boriani, Marco Proietti, William F. McIntyre, Shun Fu Lee, Taya V. Glotzer, Vidal Essebag, Cristopher B. Granger, Stuart J. Connolly, Jens Cosedis Nielsen, Juan Benezet Mazuecos, Philippe Mabo, Benoit Coutu, Michael R. Gold, Renato D. Lopes, Jeff S. Healey.
for the ARTESiA Investigators

ESC Congress 2024
London & Online

August 31st, 2024

BACKGROUND

- **Subclinical AF (SCAF):**
  - short-lasting, asymptomatic AF detected with long-term continuous monitoring with an implantable cardiac device
  - associated with an increased risk of stroke

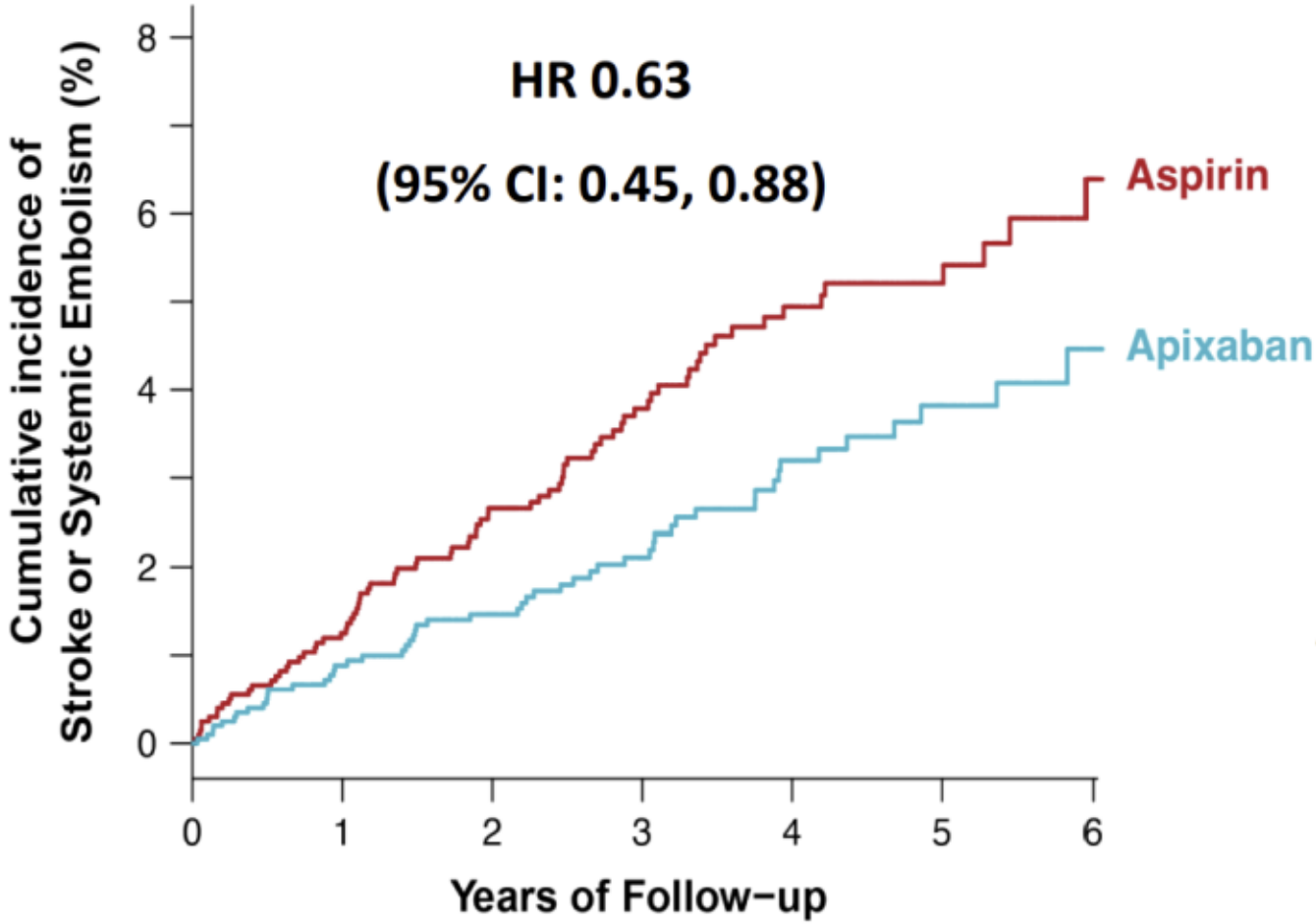
- **Patients with SCAF can progress:**
  - to clinical AF
  - or SCAF of long duration (> 24 hours) – shown in ASSERT to be high risk

- **The clinical factors associated with SCAF progression and the effect of oral anticoagulation in this group are unclear.**

METHODS

- **ARTESiA trial:**
  - Patients with at least one episode of SCAF ≥ 6 minutes (but none > 24 hours)
  - Randomised to apixaban or aspirin
  - For pts developing clinical AF documented by surface ECG, discontinuation of blinded study drug and start of open-label oral anticoagulant (OAC) *was recommended*
  - In case of SCAF > 24 hrs the decision to discontinue blinded study drug and start an open-label OAC *was left to the discretion of the investigator*
  - In the main ARTESiA analysis, participants were censored after clinical AF or SCAF > 24 hours
- **AIM of this pre-specified secondary analysis:**
  - Describe patients with SCAF Progression in ARTESiA patients in terms of:
    - Predictors of progression
    - Clinical outcomes with and without oral anticoagulation

Apixaban reduces stroke due to device-detected AF



No. at Risk

Aspirin	1997	1777	1539	1121	779	468	200
Apixaban	2015	1786	1556	1157	822	474	214

Patients with:

- Subclinical AF ≥ 6 mins but < 24 hours

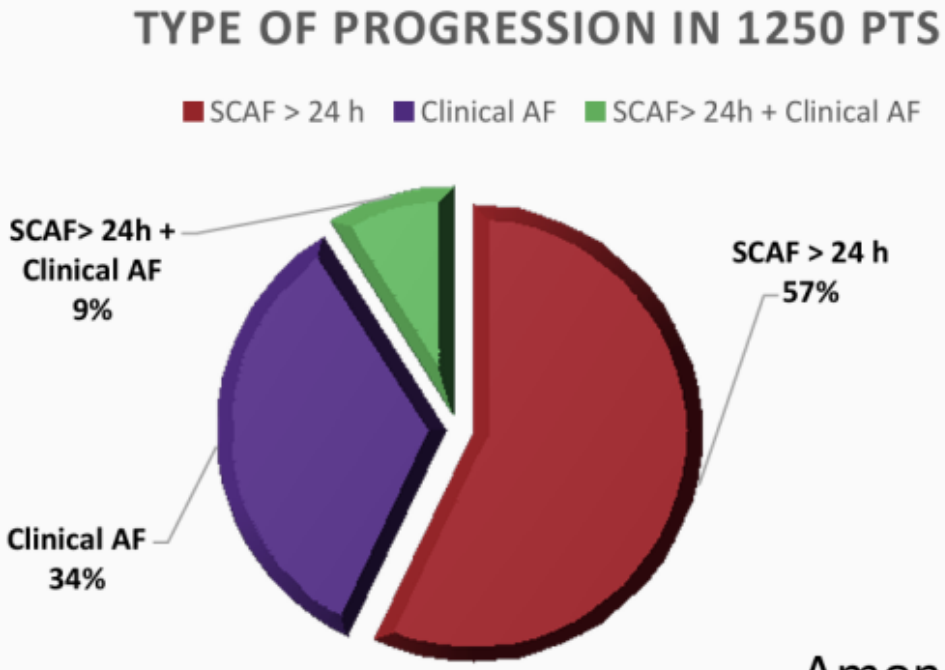
AND one of:

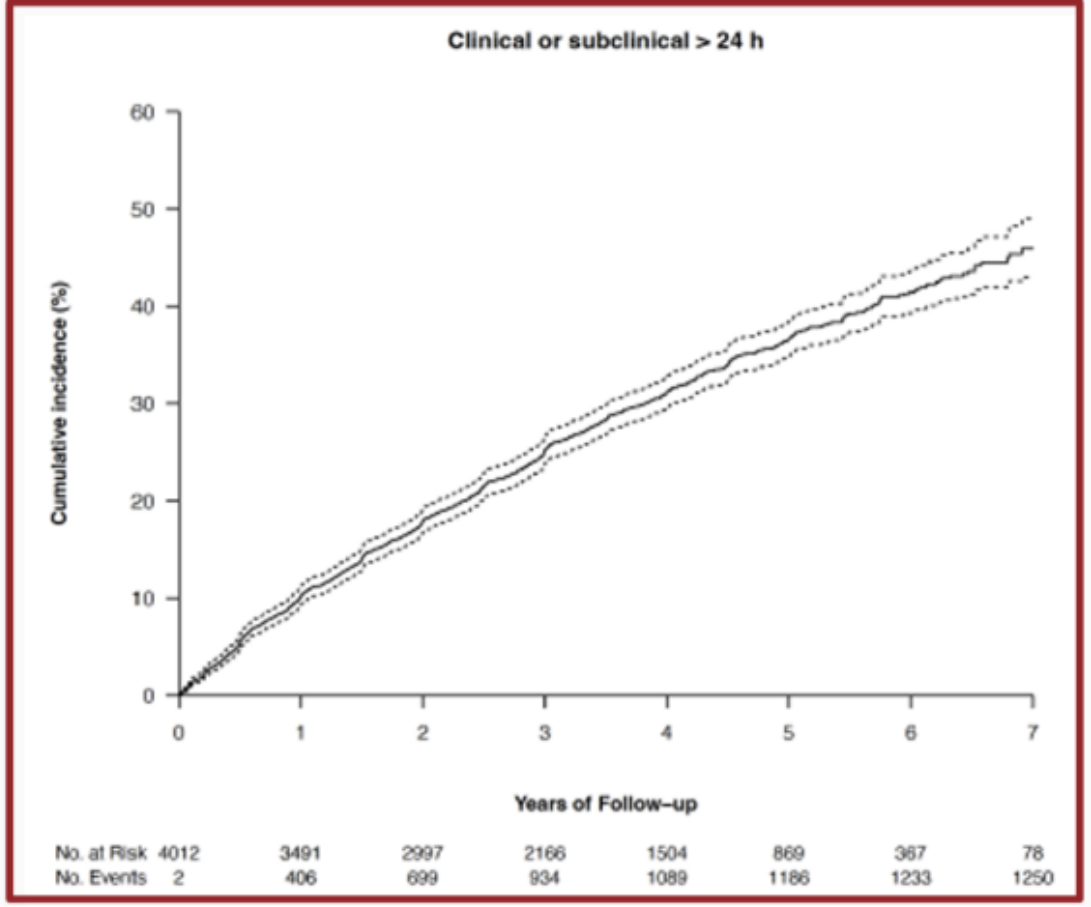
- ≥55 years with CHA_2DS_2-VASc ≥3
- ≥ 75 years
- Prior stroke

Baseline characteristics of ARTESiA patients according to AF progression in follow-up

	Overall	Pts with Clinical AF or SCAF > 24 hours during the follow-up	Pts without Clinical AF or SCAF > 24 hours during the follow up	P value [ab]
Patients randomized	4012	1250 31%	2762	
Age (years)- mean±SD[a]	76.8±7.6	77.2±7.3	76.6±7.8	0.034
Male Sex	2565 (63.9)	862 (69.0)	1703 (61.7)	<0.001
Hypertension	3269 (81.5)	1033 (82.6)	2236 (81.0)	0.203
Heart failure	1137 (28.3)	394 (31.5)	743 (26.9)	0.003
Diabetes mellitus	1167 (29.1)	385 (30.8)	782 (28.3)	0.108
Prior Stroke/TIA/Systemic embolism	361 (9.0)	123 (9.8)	238 (8.6)	0.210
CAD	1485 (37.0)	505 (40.4)	980 (35.5)	0.003
PAD	334 (8.3)	99 (7.9)	235 (8.5)	0.532
Aortic plaque	106 (2.6)	33 (2.6)	73 (2.6)	0.996
CHA2DS2VaSC score - mean±SD[a]	3.9±1.1	4.0±1.1	3.9±1.1	0.003
CHA2DS2VaSC >= 4	2434 (60.7)	790 (63.2)	1644 (59.5)	0.027
History of bleeding	97 (2.4)	34 (2.7)	63 (2.3)	0.402
Creatinine clearance < 60 ml/min	1531 (38.2)	478 (38.2)	1053 (38.1)	0.944
LA diameter > 41 mm	407 (10.1)	156 (12.5)	251 (9.1)	<0.001
Estimated LVEF - mean±SD[a]	51.8±13.4	51.0±13.5	52.2±13.3	0.082
Number of episodes of SCAF > 6 min duration detected in past 6 months				<0.001
0	710 (17.7)	180 (14.4)	530 (19.2)	
1 to 5	2557 (63.7)	766 (61.3)	1791 (64.9)	
6 or more	744 (18.5)	304 (24.3)	440 (15.9)	
SCAF duration >1hr in the last 6 months with at least one episode	2243 (55.9)	815 (65.2)	1428 (51.7)	<0.001
Legend: a Two-sample independent t test; b Wilcoxon rank-sum test				

Pattern of Progression and Prescription of OAC





Among 4012 patients followed for a mean of 3.5 years:

- 1250 (31.2%) experienced SCAF progression (9.28%/pt-yr)
- Mean time to progression: 1226 ± 678 days **3,5 ans**
- Mean post-progression follow-up: 846 ± 599 days
- 54.2% (n=678) prescribed an open-label OAC
- OAC use after progression to Clinical AF = 64.6%
- OAC use after after SCAF > 24 hrs = 50.6% (p<0.001)

Factors associated with progression to Clinical AF or SCAF>24hr

Variable	HR(95%CI)	P-Value
Age (years)	**1.01(1.01- 1.02)**	**0.001**
Sex (Male)	**1.22(1.08- 1.39)**	**0.002**
Heart failure	**1.17(1.02- 1.33)**	**0.020**
Diabetes mellitus	1.12(0.99- 1.26)	0.080
Prior Stroke/TIA/Systemic embo	1.12(0.93- 1.36)	0.221
CAD	1.08(0.96- 1.23)	0.192
PAD	0.90(0.73- 1.11)	0.326
Aortic plaque	1.00(0.70- 1.42)	0.995
Creatinine clearance < 60 ml/m	0.97(0.85- 1.10)	0.599
LA diameter > 4.1 cm	**1.22(1.03- 1.45)**	**0.021**
SCAF episode duration >1hr with at least 1 episode in the prior 6 months	**1.50(1.34- 1.69)**	**<0.001**

Cox Model, C-Statistic = 0.60

Stroke and Bleeding in ARTESiA patients who had SCAF Progression (observational)

	Oral Anticoagulation		Aspirin	Relative difference on Aspirin
	Open-label *Transitioned following progression*	**Blinded** *Continued on Blinded Apixaban following progression*	*Continued on Blinded Aspirin following progression*	
Stroke/ Systemic Embolism	14/678 0.84% /pt-year	5/281 0.81%/pt-year	8/252 1.42% /pt-year	+ 71.1%
	Overall 19/959 0.83 %/pt-year			
Major Bleeding	20/678 1.21% /pt-year	11/281 1.82% /pt-year	8/252 1.44% /pt-year	+4.3%
	Overall 31/959 1.38 % /pt-year			

Comparison of outcomes in patients with and without SCAF Progression (Observational)

	Progression to Clinical AF or SCAF > 24h		No Progression to Clinical AF or SCAF > 24h	
	OAC ***Open-label or Apixaban Blinded study drug***	**Aspirin** ***Continued Blinded study drug***	**Apixaban** ***Blinded study drug***	**Aspirin** ***Blinded study drug***
Stroke/ Systemic Embolism	19 /959 0.83 %/pt-year	8/252 1.42 %/pt-year	45/1384 0.83 %/pt-year	67/1378 1.27%/pt-year
	Relative % difference with OAC = -41.5%		**Relative % difference with OAC = -34.6%**	
	Relative % difference in risk with progression = +11.8% In Aspirin-treated patients			
Major bleeding	31/959 1.38 %/pt-year	8/252 1.44 %/pt-year	76/1384 1.42 %/pt-year	64/1378 1.21 %/pt-year
	Relative % difference with OAC = -4.2%		**Relative % difference with OAC = +14.8%**	
	Relative % difference in risk with progression = +19.0% In Aspirin-treated patients			

Conclusions

In this pre-specified observational analysis from the ARTESiA Trial:

- In patients with SCAF 6 min- 24 hours, Progression to clinical AF or SCAF > 24 hrs:
  - occurred in 31% of patients over 3.5 years
  - was predicted by older age, male sex, heart failure, left atrial dilatation and SCAF duration >1 hour.
- Among Aspirin-assigned patients, failure to prescribe open-label OAC following progression to Clinical AF or SCAF > 24 hrs was associated with:
  - a higher occurrence of stroke/SE, as compared with OAC-treated patients
  - a similar occurrence of major bleeding as compared with OAC-treated patients.
- In Aspirin-treated patients who experienced SCAF progression:
  - the rate of stroke/systemic embolism was 1.42 %/pt-year
  - this rate of stroke/systemic embolism reflected a slightly higher relative risk (+11.8%) compared with Aspirin-treated patients without progression.

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Pulsed Field vs Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

Recurrent Atrial Arrhythmia Burden

ADVENT: Postablation Atrial Arrhythmia Burden

HEART RHYTHM 24
BRINGING THE WORLD OF EP TOGETHER
MAY 16 - 19, 2024 • BOSTON, MA

ADVENT

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Pulsed Field vs Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

Recurrent Atrial Arrhythmia Burden

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ADVENT Trial

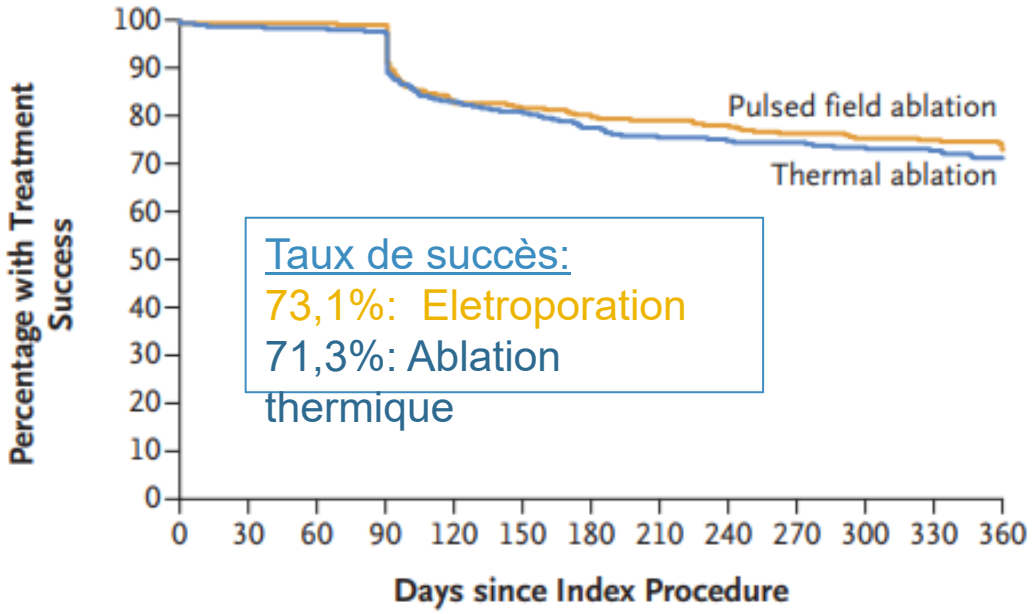
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

Vivek Y. Reddy, M.D., Edward P. Gerstenfeld, M.D., Andrea Natale, M.D.,

- Etude randomisée multicentrique, 30 centres USA
- de non infériorité
- 687 patients, âgés de 62 ans en moyenne
- PFA vs énergies thermiques
- FA parox résistante au traitement AAR



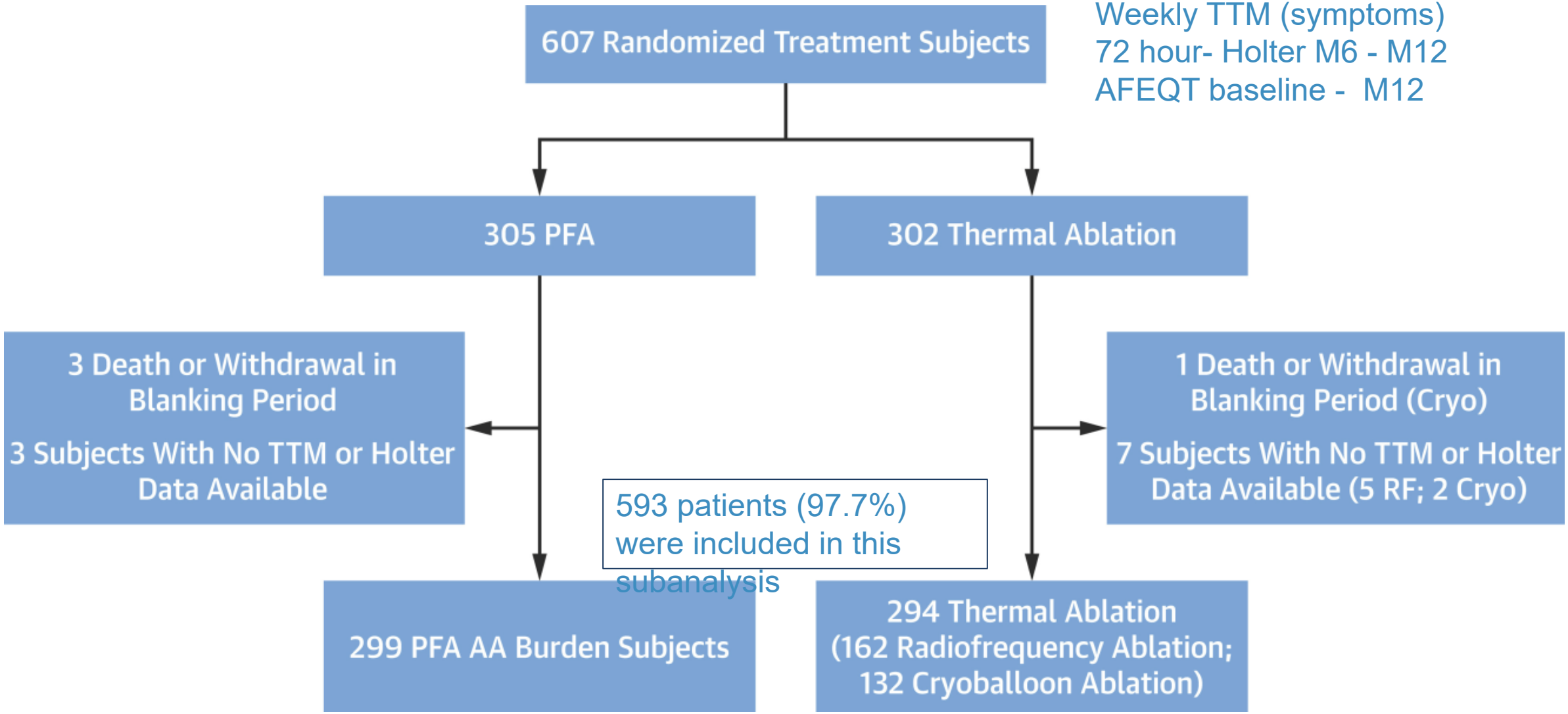
Taux de succès:
73,1%: Eletroporation
71,3%: Ablation thermique

No. at Risk					
Pulsed field ablation	301	298	238	228	176
Thermal ablation	296	292	228	219	150

Treatment Success (%)					
Pulsed field ablation	99.3	99.0	79.7	76.4	73.1
Thermal ablation	98.7	97.3	77.5	74.5	71.3

Vivek Y. Reddy et al. N Engl J Med 2023;389:1660-1671

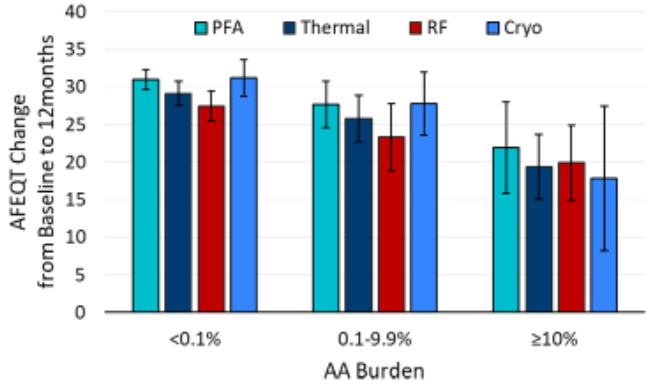
During 1 year:
Weekly TTM (symptoms)
72 hour- Holter M6 - M12
AFEQT baseline - M12



- the overall compliance for weekly TTMs and 72-hour Holter monitoring was 67.5% and 81.3%, respectively.

- The AA burden analysis included
  - an average of 27 weeks of TTM from 589 patients, and
  - 61,841 hours of Holter recordings (an average of 114.7 hours per patient) from 539 patients

A



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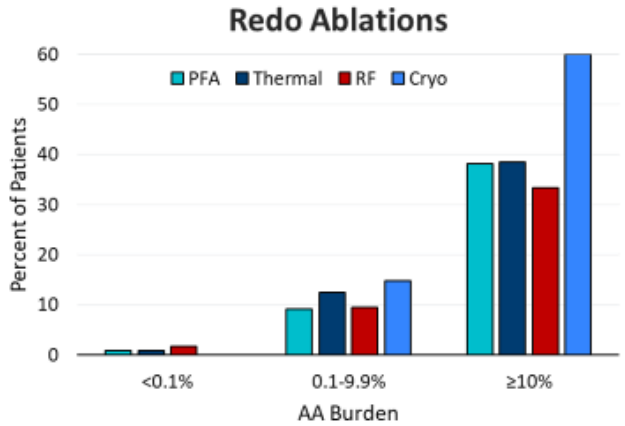

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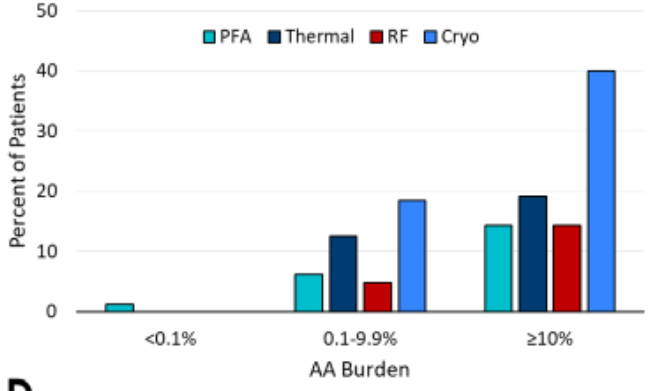

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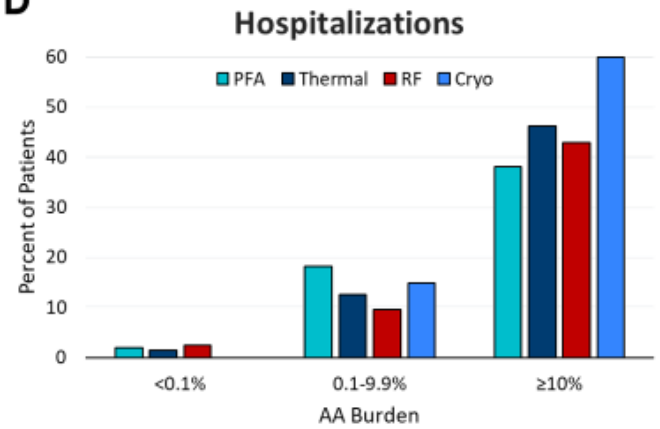
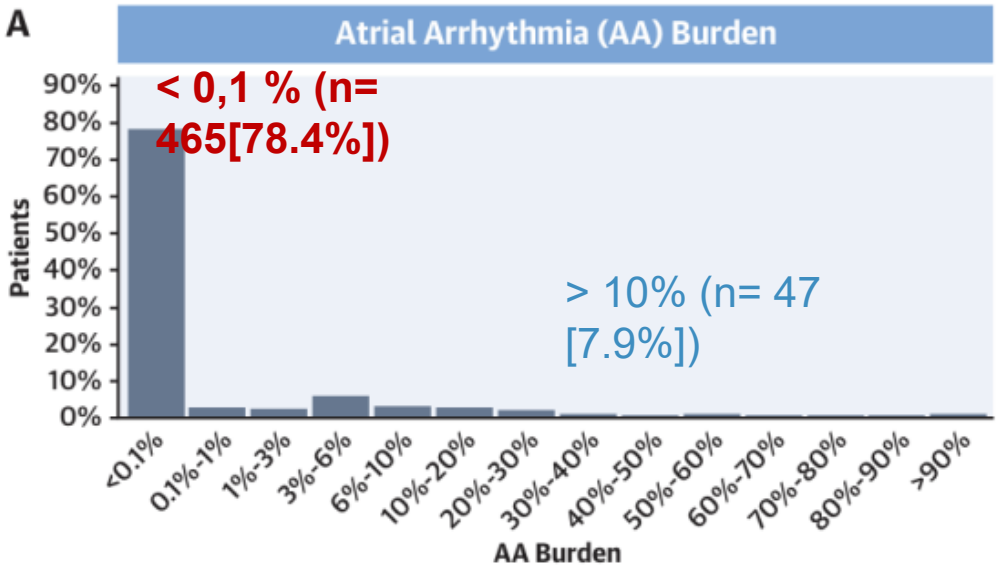
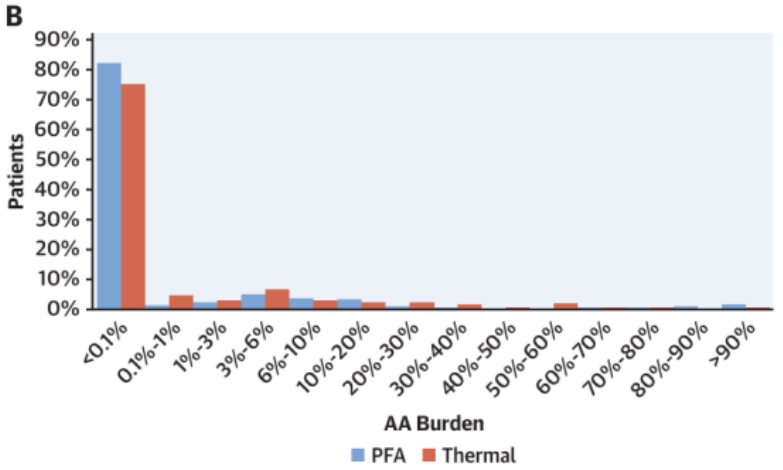


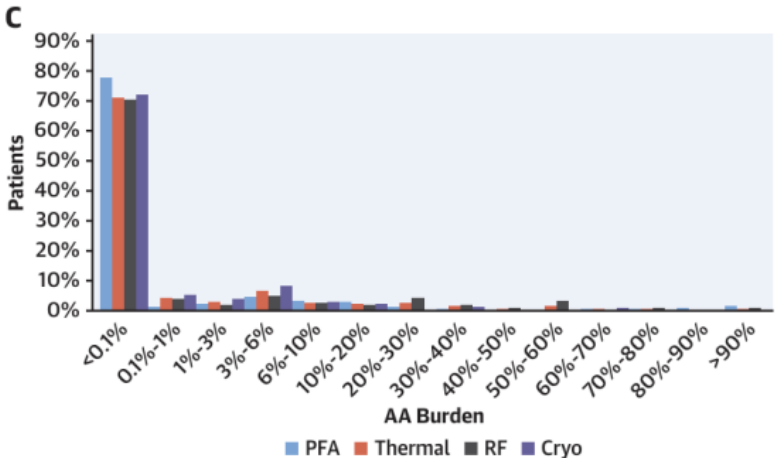
>0 to <0.01% (<1 min/week)
>0.01 to <0.1% (<10 min/week)
No or subclinical AF burden

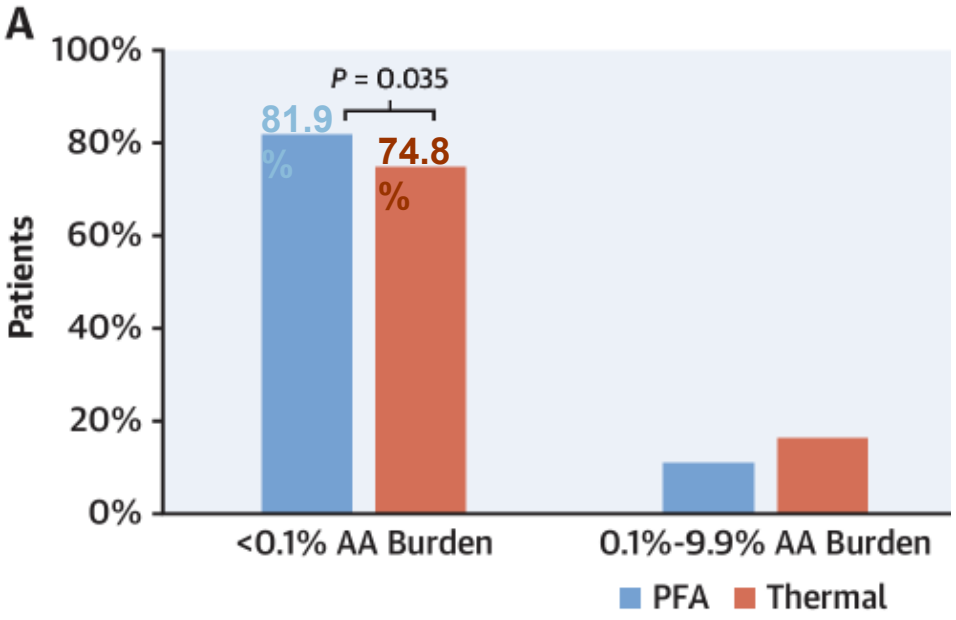
Table 1	AA Burden		
	<0.1%	0.1-9.9%	≥10%
Redo Ablations	0.86%	11.1%	38.3%
Cardioversions	0.65%	9.9%	17.0%
Hospitalizations	1.72%	14.8%	42.6%

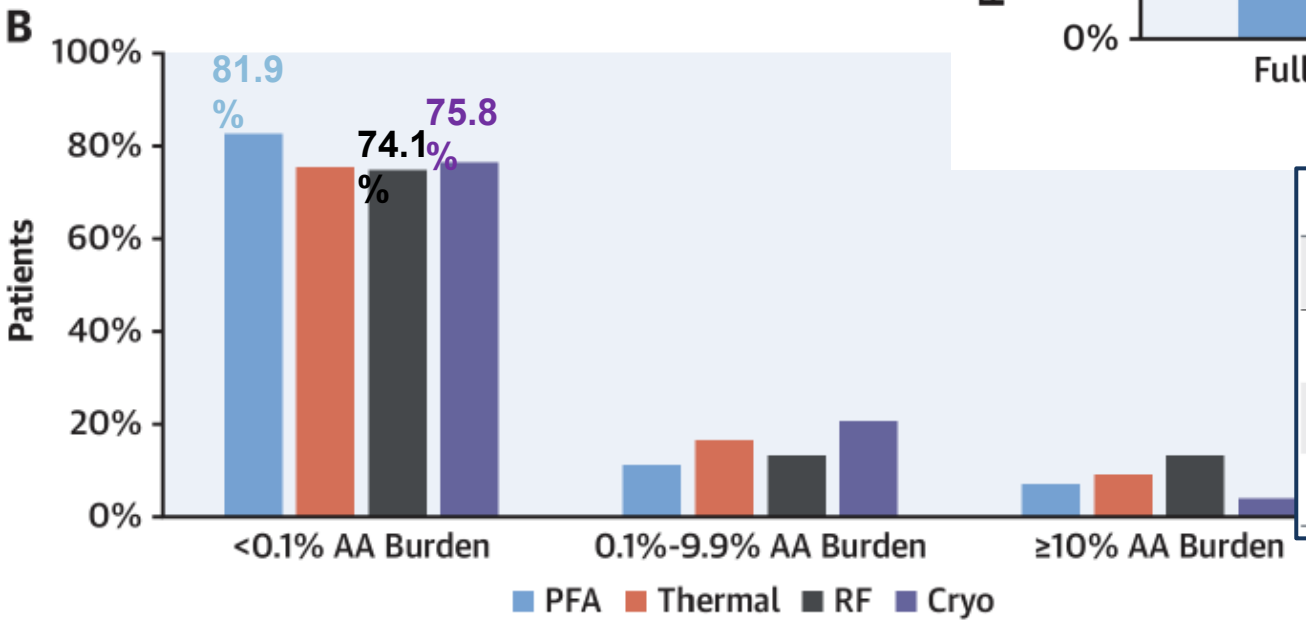
The vast majority of patients (465 [78.4%]) had a residual AA burden of < 0,1%): < 1.4 min AA per day

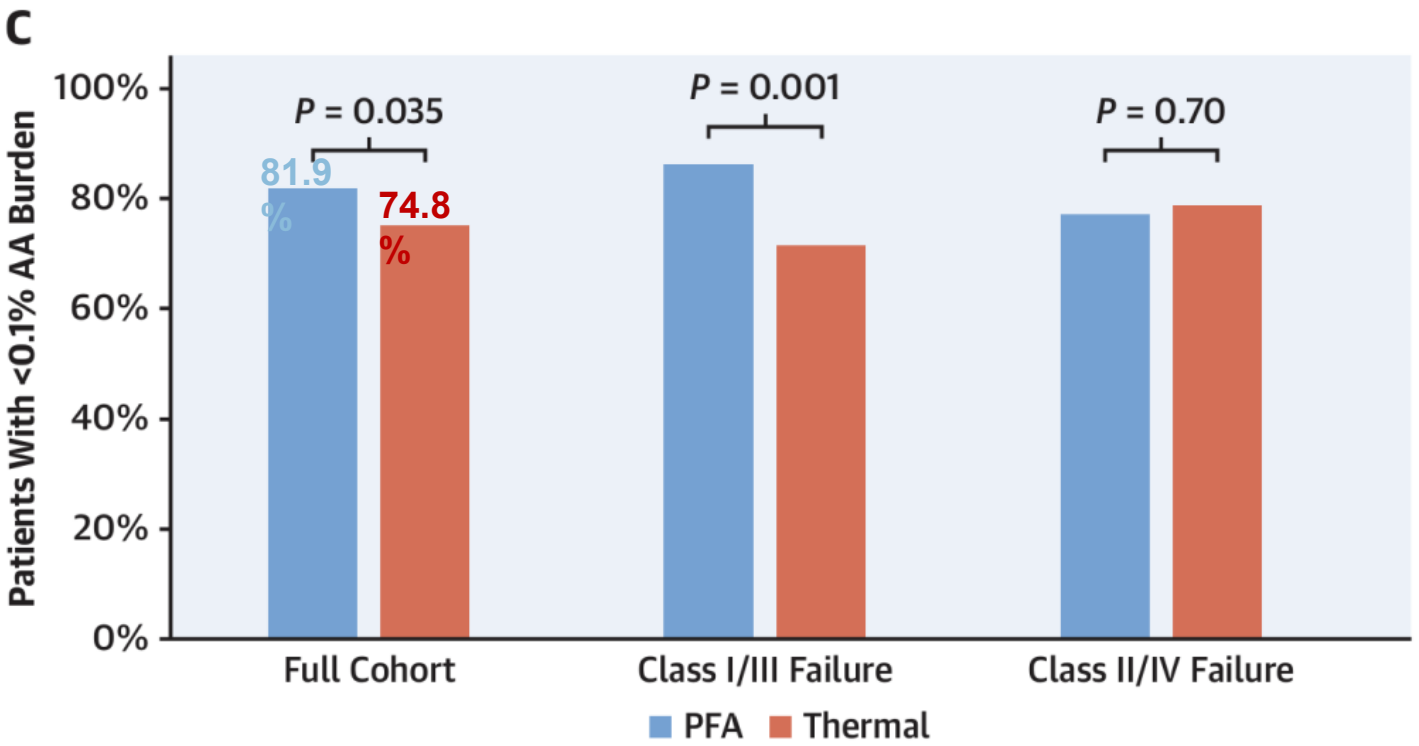












Odds Ratio (Probability of <0.1% AA Burden)

Comparison	Odds Ratio	95% CI	P value
PFA vs Thermal	1.5	1.0, 2.3	0.036
PFA vs Thermal in Class I/III fails	2.5	1.4, 4.3	0.002
PFA vs Thermal in Class II/IV fails	0.9	0.5, 1.6	0.70

Variable	N PFA	N Thermal	Interaction *P* Value	OR for Zero AA Burden (Log Scale)	OR (95% CI)
Treatment Group	299	294	0.04*		1.5 (1.0-2.3)
Age <60 y	99	97	0.39		2.0 (1.0-4.1)
Age ≥60 y	200	197			1.4 (0.8-2.2)
Female	100	104	0.57		1.3 (0.7-2.5)
Male	199	190			1.7 (1.0-2.8)
BMI <30 kg/m^2	200	181	0.35		1.8 (1.0-2.9)
BMI ≥30 kg/m^2	99	113			1.2 (0.6-2.2)
No Sleep Apnea	220	208	0.34		1.3 (0.8-2.1)
Sleep Apnea	79	86			2.1 (1.0-4.4)
Heart Failure	57	58	0.65		1.2 (0.5-3.3)
No Heart Failure	242	236			1.6 (1.0-2.5)
Hypertension	170	152	0.10		1.2 (0.7-1.9)
No Hypertension	129	142			2.3 (1.2-4.4)
AF Diagnosis <3 y Before Ablation	196	191	0.28		1.8 (1.1-3.1)
AF Diagnosis ≥3 y Before Ablation	103	103			1.2 (0.6-2.2)
Class I/III AAD Failure	165	157	0.01		2.5 (1.4-4.3)
Class II/IV AAD Failure	134	137			0.9 (0.5-1.6)
1 Failed AAD at Baseline	182	175	0.16		1.2 (0.7-2.0)
≥2 Failed AADs at Baseline	117	119			2.1 (1.1-4.0)

Conclusions

- A post ablation residual AA burden of < 0.1% over 1-year follow-up is associated with the greatest improvement in quality of life;
- this residual AA burden of < 0.1% is also associated with the fewest clinical interventions:
  - redoablation, electrical cardioversion, or hospitalization
  - and a > 10% residual AA burden is associated with the largest increase in such interventions
- patients in both randomized arms of the trial, PFA and thermal ablation, did quite well, with 78.4% expressing a 1-year post ablation AA burden < 0.1%
- the1-yearpost ablation AA burden is less for PFA than thermal ablation
- In subgroup analyses, patients in whom classI/III AADs failed pre ablation demonstrated the greatest differential in residual AA burden between PFA and thermal ablation

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