Was ist neu bei Vorhofflimmern? Neue Konzepte, Energieformen, Antikoagulation

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Disclosures

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- Speaking/proctoring honoraria from
  - Medtronic
  - Biosense Webster
  - Boston Scientific

New concepts: the new AF guidelines

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ESC European Society of Cardiology
European Heart Journal (2024) 45, 3314–3414
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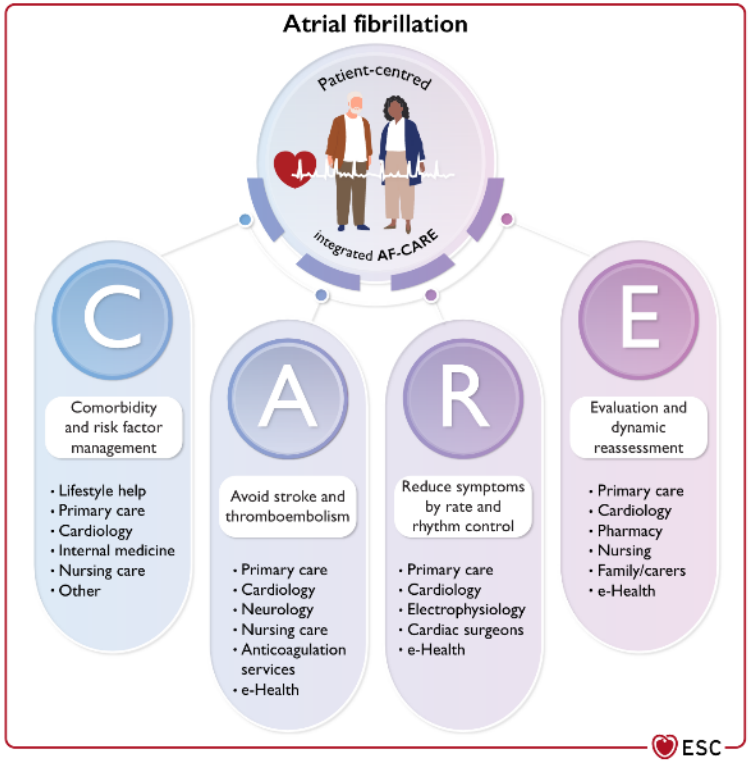
ESC GUIDELINES

2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)

Developed by the task force for the management of atrial fibrillation of the European Society of Cardiology (ESC), with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC.
Endorsed by the European Stroke Organisation (ESO)

Authors/Task Force Members: Isabelle C. Van Gelder *†, (Chairperson) (Netherlands), Michiel Rienstra ±, (Task Force Co-ordinator) (Netherlands), Karina V. Bunting ±, (Task Force Co-ordinator) (United Kingdom), Ruben Casado-Arroyo (Belgium), Valeria Caso [1] (Italy), Harry J.G.M. Crijns (Netherlands), Tom J.R. De Potter (Belgium), Jeremy Dwight (United Kingdom), Luigina Guasti (Italy), Thorsten Hanke [2] (Germany), Tiny Jaarsma (Sweden), Maddalena Lettino (Italy), Maja-Lisa Løchen (Norway), R. Thomas Lumbers (United Kingdom), Bart Maesen [2] (Netherlands), Inge Mølgaard (Denmark), Giuseppe M.C. Rosano (United Kingdom), Prashanthan Sanders (Australia), Renate B. Schnabel (Germany), Piotr Suwalski [2] (Poland), Emma Svennberg (Sweden), Juan Tamargo (Spain), Otilia Tica (Romania), Vassil Traykov (Bulgaria), Stylianos Tzeis (Greece), Dipak Kotecha *†, (Chairperson) (United Kingdom), and ESC Scientific Document Group



Van Gelder et al. EHJ 2024

New concepts in the AF guidelines

Rhythm control

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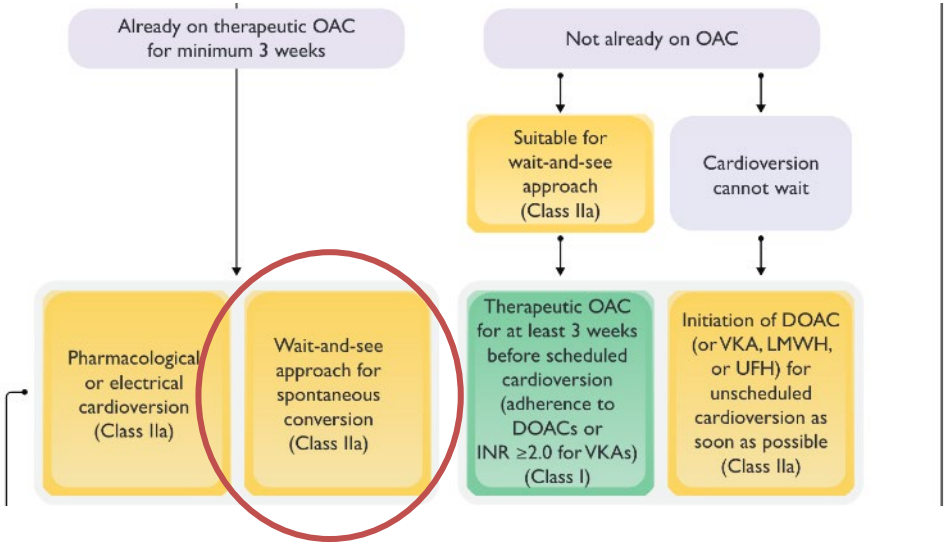
- 1st : Rate Control
  - Betablockers
  - Calcium antagonists
  - Digoxin

- 2nd: Rhythm Control
  - ECV if unstable
  - “wait and see” if stable
  - TOE if AF duration > 24 hours



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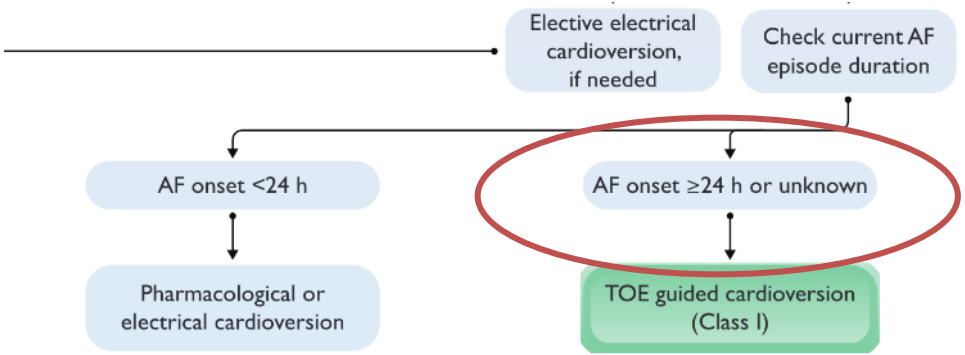
New!



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New concepts in the AF guidelines

First line AF Ablation treatment

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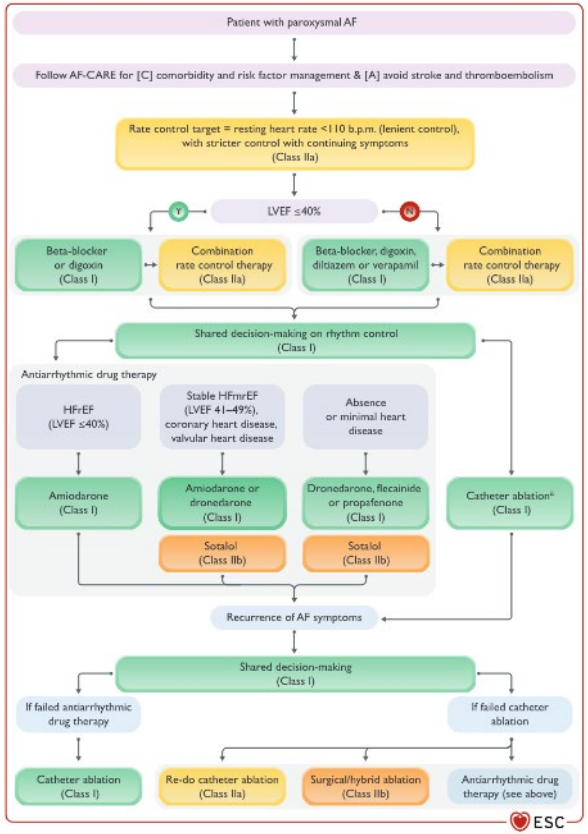
1. Rate Control

2. Rhythm control
   1. AAD (I)
   2. Ablation (I)



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New concepts in the AF guidelines

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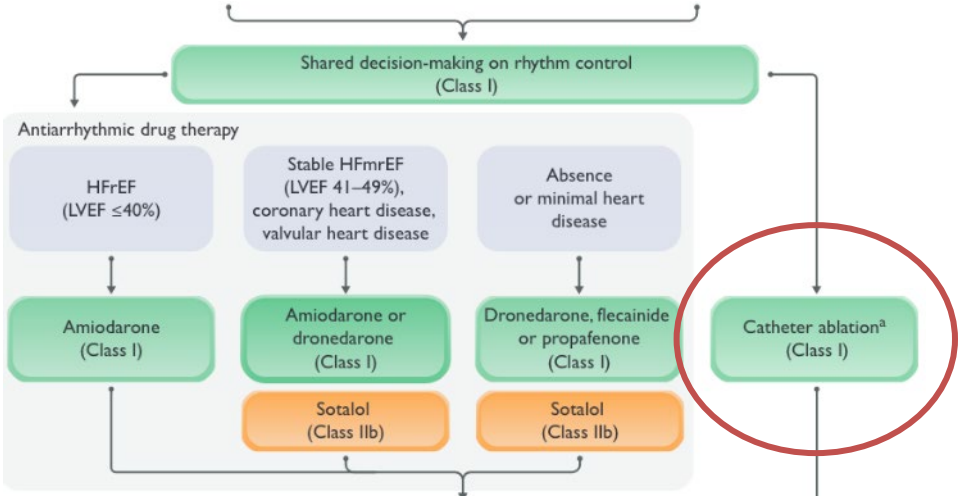

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New concepts in the AF guidelines

First line AF Ablation treatment

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1. Rate Control

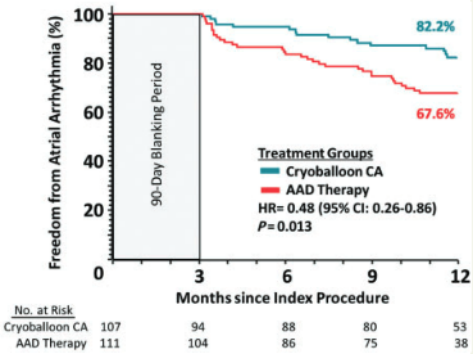
2. Rhythm control
   1. AAD (I)
   2. Ablation (I)

1st line paroxysmal AF ablation

ESC

CLINICAL RESEARCH

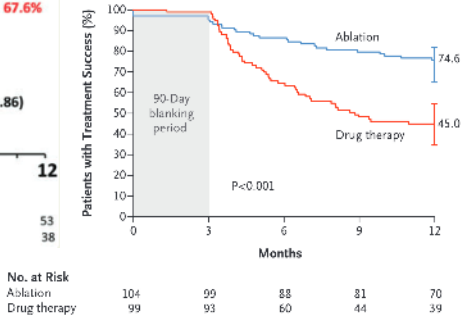
Cryoballoon ablation vs. antiarrhythmic drugs: first-line therapy for patients with paroxysmal atrial fibrillation



THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

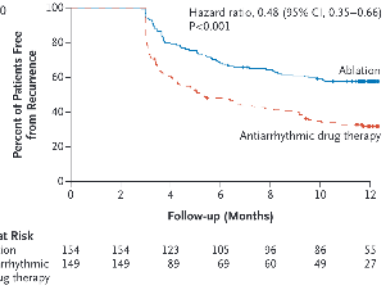
Cryoballoon Ablation as Initial Therapy for Atrial Fibrillation



THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation



Cryo First- Kuniss et al Europace 2021

Stop AF First - Wazni et al NEJM 2020

Early AF- Andrade et al NEJM 2020

What are the ablation targets for AF ablation?

Current AF Ablation targets

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ESC European Society of Cardiology
Europace (2024) 26, 1–107
https://doi.org/10.1093/europace/euae043
EHRA DOCUMENT
EHRA European Heart Rhythm Association

2024 European Heart Rhythm Association/ Heart Rhythm Society/Asia Pacific Heart Rhythm Society/Latin American Heart Rhythm Society expert consensus statement on catheter and surgical ablation of atrial fibrillation

Stylianos Tzeis [1]* (EHRA Chair), Edward P. Gerstenfeld[2] (HRS Co-Chair), Jonathan Kalman [3,4] (APHRS Co-Chair), Eduardo B. Saad [5,6] (LAHRS Co-Chair), Alireza Sepehri Shamloo [7] (Writing Group Coordinator), Jason G. Andrade [8], Chirag R. Barbhaiya [9], Tina Baykaner[10], Serge Boveda [11,12], Hugh Calkins [13], Ngai-Yin Chan [14], Minglong Chen [15], Shih-Ann Chen[16], Nikolaos Dagres [17], Ralph J. Damiano[18], Tom De Potter [19], Isabel Deisenhofer [20], Nicolas Derval [21], Luigi Di Biase [22], Mattias Duytschaever [23], Katia Dyrda [24], Gerhard Hindricks [17], Meleze Hocini [21], Young-Hoon Kim[25], Mark la Meir [26], Jose Luis Merino [27,28], Gregory F. Michaud[29], Andrea Natale [30,31,32,33], Isabelle Nault [34], Santiago Nava [35], Takashi Nitta [36], Mark O'Neill [37], Hui-Nam Pak [38], Jonathan P. Piccini [39], Helmut Pürerfellner [40], Tobias Reichlin [41], Luis Carlos Saenz [42], Prashanthan Sanders [43], Richard Schilling [44], Boris Schmidt [45], Gregory E. Supple [46], Kevin L. Thomas [39], Claudio Tondo [47,48], Atul Verma [49], and Elaine Y. Wan [50]

Ablation strategies	Category of advice
Pulmonary vein isolation	
Electrical isolation of the PVs is required during all AF ablation procedures	Advice TO DO
Achievement of electrical isolation requires, at a minimum, assessment and demonstration of entrance block into the PVs	Advice TO DO
A waiting period (e.g. 20 min) following initial PVI may be reasonable to monitor for PV reconnection	Area of uncertainty
Administration of adenosine 20 min following initial PVI, with reablation if PV reconnection occurs, may be reasonable to improve PVI durability	Area of uncertainty
Pace capture–guided approach following PVI using RF energy may be reasonable to improve PVI durability	Area of uncertainty
Adjunctive ablation targets beyond pulmonary vein isolation	
If linear ablation lesions are deployed, mapping and pacing maneuvers are required to document conduction block	Advice TO DO
If a reproducible focal trigger that initiates AF is identified outside the PV ostia at the time of an AF ablation procedure, ablation of the focal trigger is beneficial	Advice TO DO
Vein of Marshal ethanol infusion is reasonable to facilitate achieving block in the lateral mitral isthmus in patients with mitral annular flutter	May be appropriate TO DO
Ablation of areas of abnormal myocardial tissue identified with voltage mapping during sinus rhythm may be reasonable during persistent AF ablation	Area of uncertainty
Vein of Marshal ethanol infusion may be reasonable during persistent AF ablation	Area of uncertainty
Mapping and ablation of non-PV triggers may be reasonable during persistent AF ablation	Area of uncertainty
Isolation of the left atrial posterior wall may be reasonable during repeat ablation of persistent AF	Area of uncertainty
Ablation of MRI-detected atrial delayed enhancement areas is not beneficial during persistent AF ablation[a]	Advice NOT TO DO

Tzeis et al Europace/Heart Rhythm 2022

Paroxysmal AF Ablation

The central role of PVI

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Ablation strategies	Category of advice
Pulmonary vein isolation	
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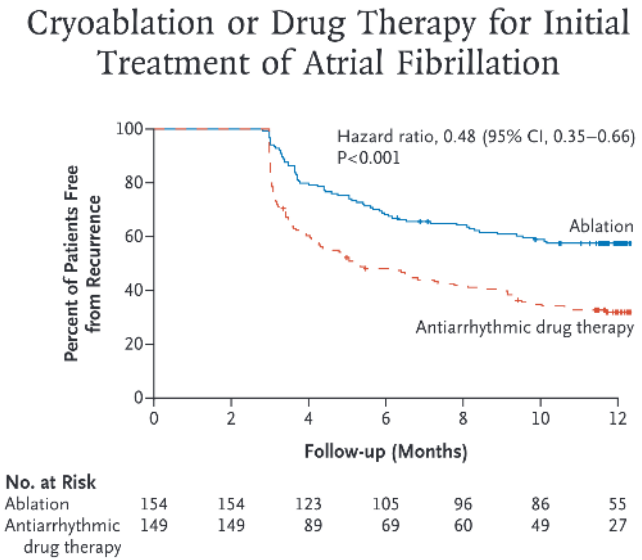
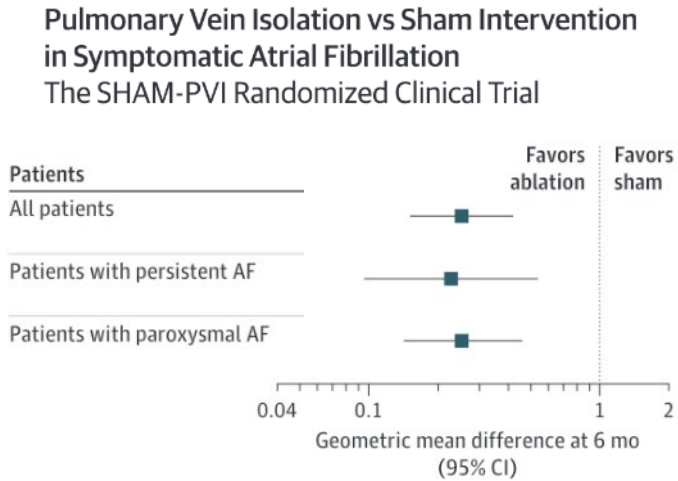
Tzeis et al Europace/Heart Rhythm 2022



Early AF- Andrade et al NEJM 2020



Dulai et al JAMA 2024

Additional ablation targets

… in persistent AF

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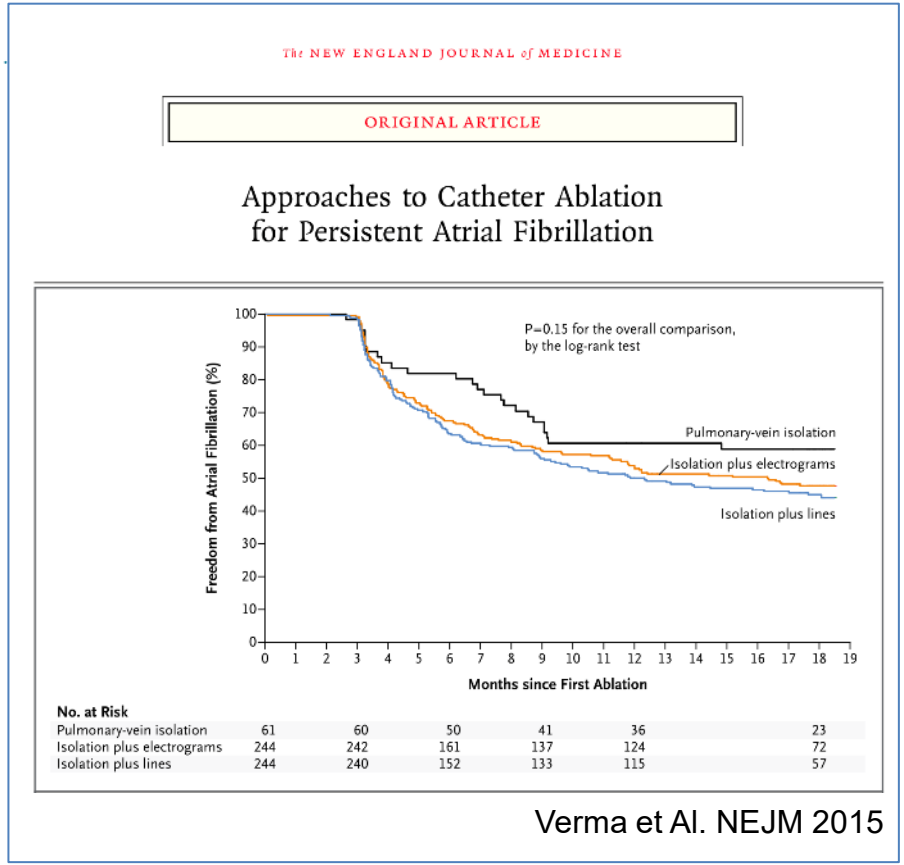
Tzeis et al Europace/Heart Rhythm 2022



Verma et Al. NEJM 2015

Additional ablation targets

… in persistent AF

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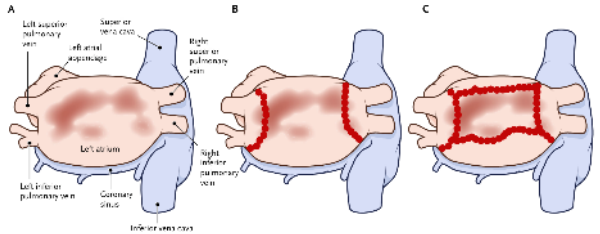
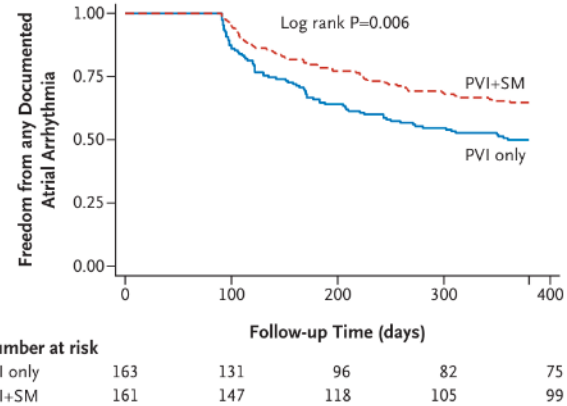
Tzeis et al Europace/Heart Rhythm 2022

ORIGINAL ARTICLE

Low-Voltage Myocardium-Guided Ablation Trial of Persistent Atrial Fibrillation





Huo et al. NEJM Evidence 2022

The Prompt AF Trial

Brand new data on substrate modification

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JAMA | Original Investigation

Pulmonary Vein Isolation With Optimized Linear Ablation vs Pulmonary Vein Isolation Alone for Persistent AF
The PROMPT-AF Randomized Clinical Trial

Caihua Sang, MD; Qiang Liu, MD; Yiwei Lai, MD; Shijun Xia, MD; Ruhong Jiang, MD; Songnan Li, MD; Qi Guo, MD; Qifan Li, MD; Mingyang Gao, MD; Xueyuan Guo, MD; Lihong Huang, MD; Nian Liu, MD; Chenxi Jiang, MD; Song Zuo, MD; Xiaoxia Liu, MD; Mengmeng Li, MD; Weili Ge, MD; Shangming Song, MD; Lianghua Chen, MD; Shuanglun Xie, MD; Jiangang Zou, MD; Ke Chen, MD; Xiangfei Liu, MD; Hesheng Hu, MD; Xinhua Wang, MD; Jinlin Zhang, MD; Zhaojun Wang, MD; Chi Wang, MPH; Liu He, PhD; Chao Jiang, MD; Ribo Tang, MD; Ning Zhou, MD; Yunlong Wang, MD; Deyong Long, MD; Xin Du, MD; Chenyang Jiang, MD; Laurent Macle, MD; Jianzeng Dong, MD; Changsheng Ma, MD; for the PROMPT-AF investigators

IMPORTANCE Success rates of pulmonary vein isolation (PVI) are modest for persistent atrial fibrillation (AF). Additional linear ablation beyond PVI has not been proved superior to PVI alone in randomized trials. Ethanol infusion of the vein of Marshall (EIVOM) facilitates ablation at the mitral isthmus and may lead to improved effectiveness of a linear ablation strategy.

OBJECTIVE To determine whether linear ablation with radiofrequency energy combined with EIVOM added to PVI improves sinus rhythm maintenance compared with PVI alone in patients with persistent AF.

DESIGN, SETTING, AND PARTICIPANTS The PROMPT-AF trial is an investigator-initiated, multicenter, open-label, randomized trial involving 12 tertiary hospitals in China. A total of 498 patients aged 18 to 80 years, with AF persisting for more than 3 months, undergoing first-time AF ablation, were enrolled and randomized from August 27, 2021, to July 16, 2023.

INTERVENTIONS Patients were randomized to undergo PVI alone or PVI plus EIVOM and linear ablation (intervention). The latter group first underwent EIVOM, followed by PVI and linear ablation of the left atrial roof, mitral isthmus, and cavotricuspid isthmus.

MAIN OUTCOMES AND MEASURES The primary end point was freedom from any documented atrial arrhythmias lasting more than 30 seconds, without the use of antiarrhythmic drugs within 12 months. Secondary outcomes included freedom from atrial arrhythmia recurrence, AF, atrial arrhythmia recurrence after multiple procedures, and documented atrial tachycardia or atrial flutter with or without antiarrhythmic drugs; AF burden; and improvement in quality of life. Patients were monitored with wearable single-lead electrocardiographic (ECG) patches, worn for 24 hours a week, supplemented by symptom-triggered ECGs and Holter monitoring.

RESULTS Among 498 randomized patients, 495 (99.4%) were included in the primary analysis (mean age, 61.1 years [SD, 9.7] years, 361 male [72.9%]). After 12 months, 174 of 246 patients (70.7%) assigned to undergo PVI plus EIVOM and linear ablation and 153 of 249 patients (61.5%) assigned to undergo PVI alone remained free from atrial arrhythmias without taking antiarrhythmic drugs (hazard ratio, 0.73; 95% CI, 0.54-0.99, $P = .045$). The intervention effect was consistent across all prespecified subgroups. The comparison of secondary outcomes did not demonstrate significant results.

CONCLUSION Among patients with persistent AF, linear ablation combined with EIVOM in addition to PVI significantly improved freedom from atrial arrhythmias within 12 months compared with PVI alone.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT04497376

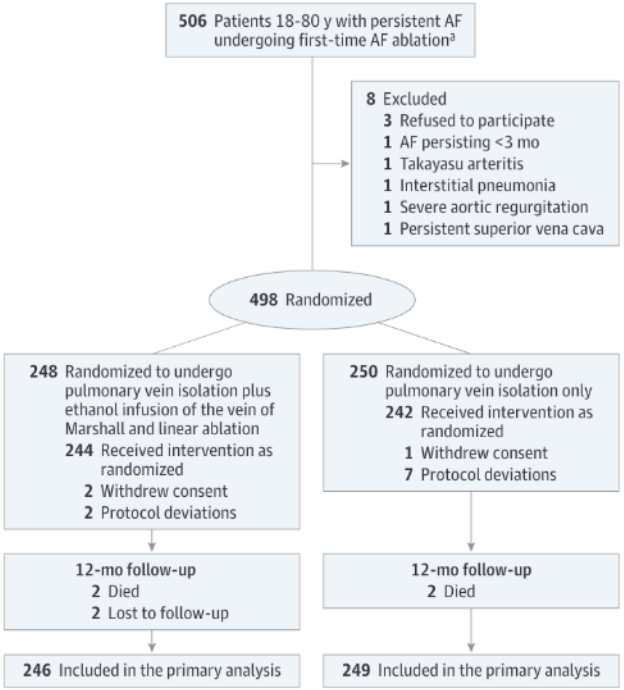
Visual Abstract
Editorial
Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: The PROMPT-AF investigators are listed in Supplement 3.

Corresponding Authors: Changsheng Ma, MD, Department of Cardiology, Beijing Anzhen Hospital,

Figure 2. Patient Recruitment and Study Flow of the PROMPT-AF Trial



Sang et al. JAMA Nov 2024

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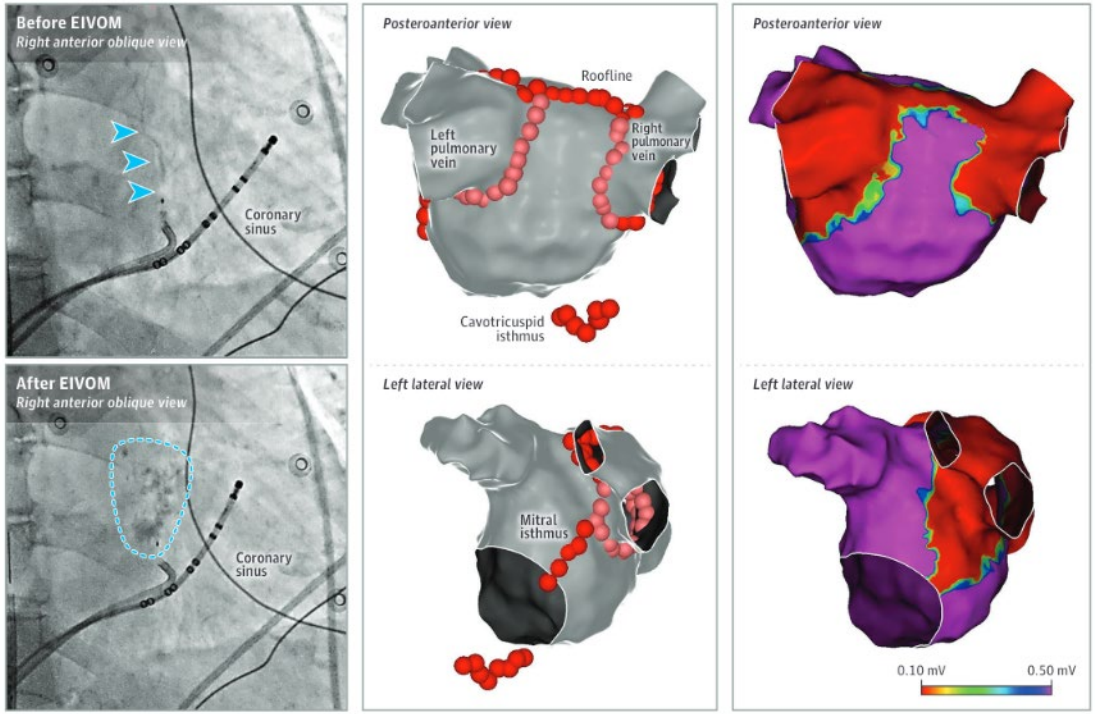
Visual Abstr
Editorial
Supplement

Author Affiliatio
affiliations are lis
article.
Group Informati
investigators are l
Supplement 3.
Corresponding Authors:
Changsheng Ma, MD, Department of Cardiology, Beijing Anzhen Hospital,

Figure 1. Linear Ablation Combined With Ethanol Infusion via the Vein of Marshall in Addition to Pulmonary Vein Isolation



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The Prompt AF Trial

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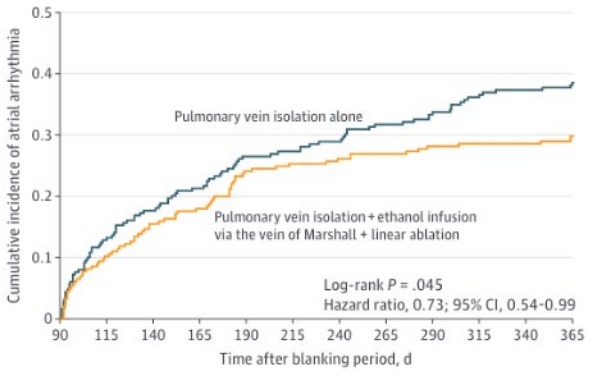
Figure 3. Freedom From Recurrence of Atrial Arrhythmias Without Antiarrhythmic Drugs



Cumulative No.												
Pulmonary vein isolation + ethanol infusion via the vein of Marshall + linear ablation												
Event	0	25	38	44	59	62	64	66	69	70	70	72
Death	0	0	0	0	0	0	0	0	0	0	0	2
Atrial fibrillation	0	23	36	41	47	50	51	53	56	56	57	58
Redo procedure	0	1	5	6	7	8	9	10	10	10	11	11
Pulmonary vein isolation alone												
Event	0	33	44	53	66	68	72	79	84	91	93	96
Death	0	0	0	0	0	1	2	2	2	2	2	2
Atrial fibrillation	0	27	34	42	48	49	54	62	64	70	74	75
Redo procedure	0	7	7	9	9	9	10	16	17	17	18	20

Table 3. Procedure-Related Adverse Events

	No. of adverse events	
	PVI + EIVOM and linear ablation	PVI
Cardiac		
Tamponade		
Requiring pericardiocentesis	1	1
Requiring surgery	1	0
Pericarditis or pericardial effusion not requiring drainage[a,b]	7	0
Coronary event[c]	1	1
Third-degree atrioventricular block	0	1
Vascular		
Pseudoaneurysm of femoral artery	1	1
Deep venous thrombosis	1	0
Other		
Postprocedural fever	1	1
Antiarrhythmic drugs related complication	0	1

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Can we do better?

Maybe we should seek some help…

Of arificial intelligence (?)

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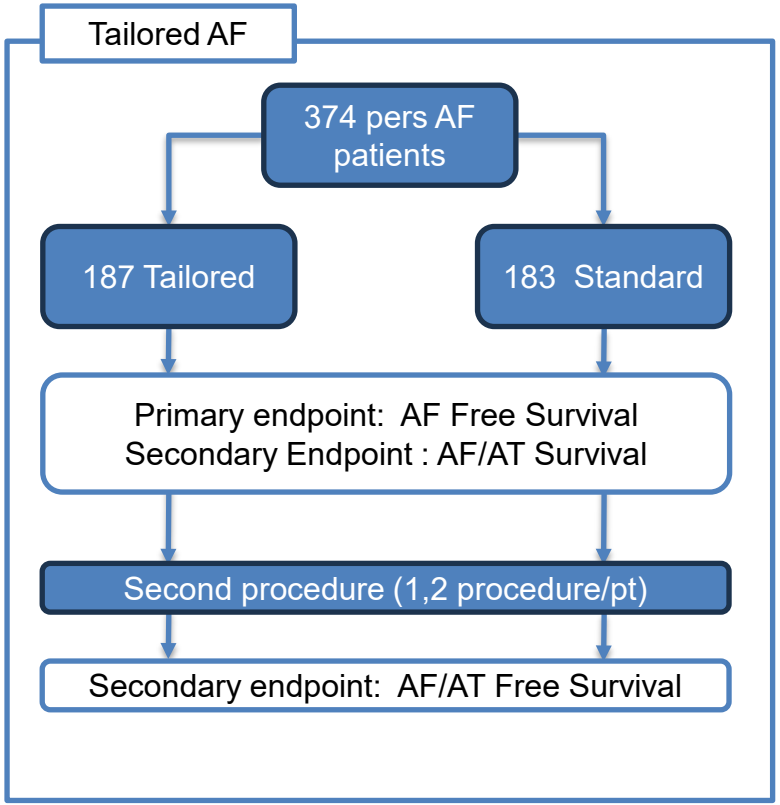

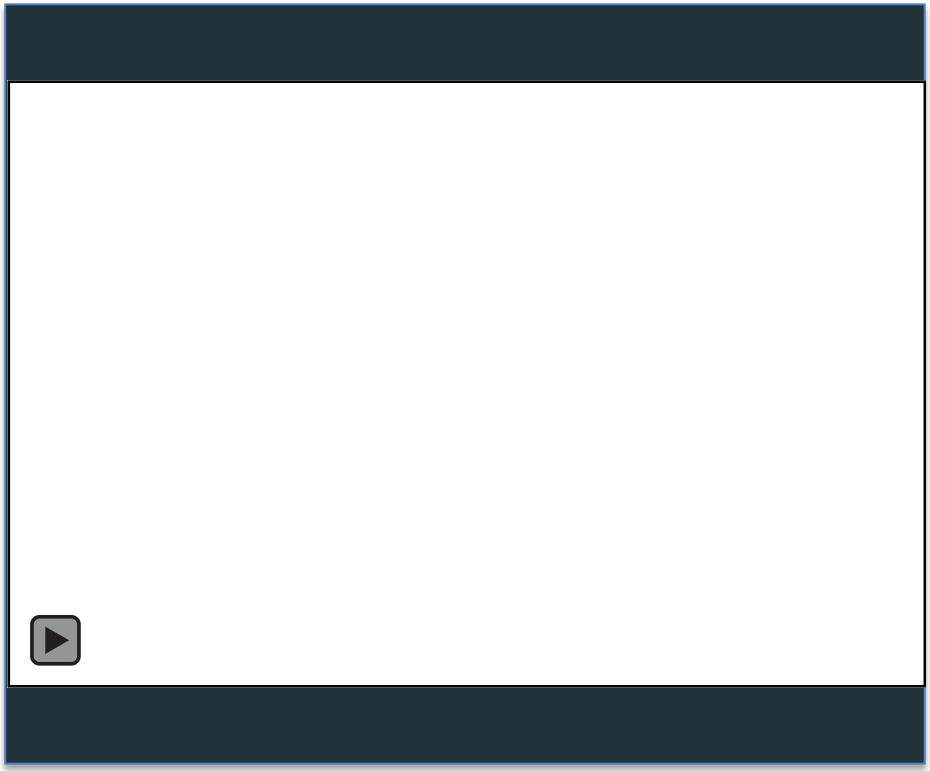

Maybe we should seek some help…

Of arificial intelligence (?)

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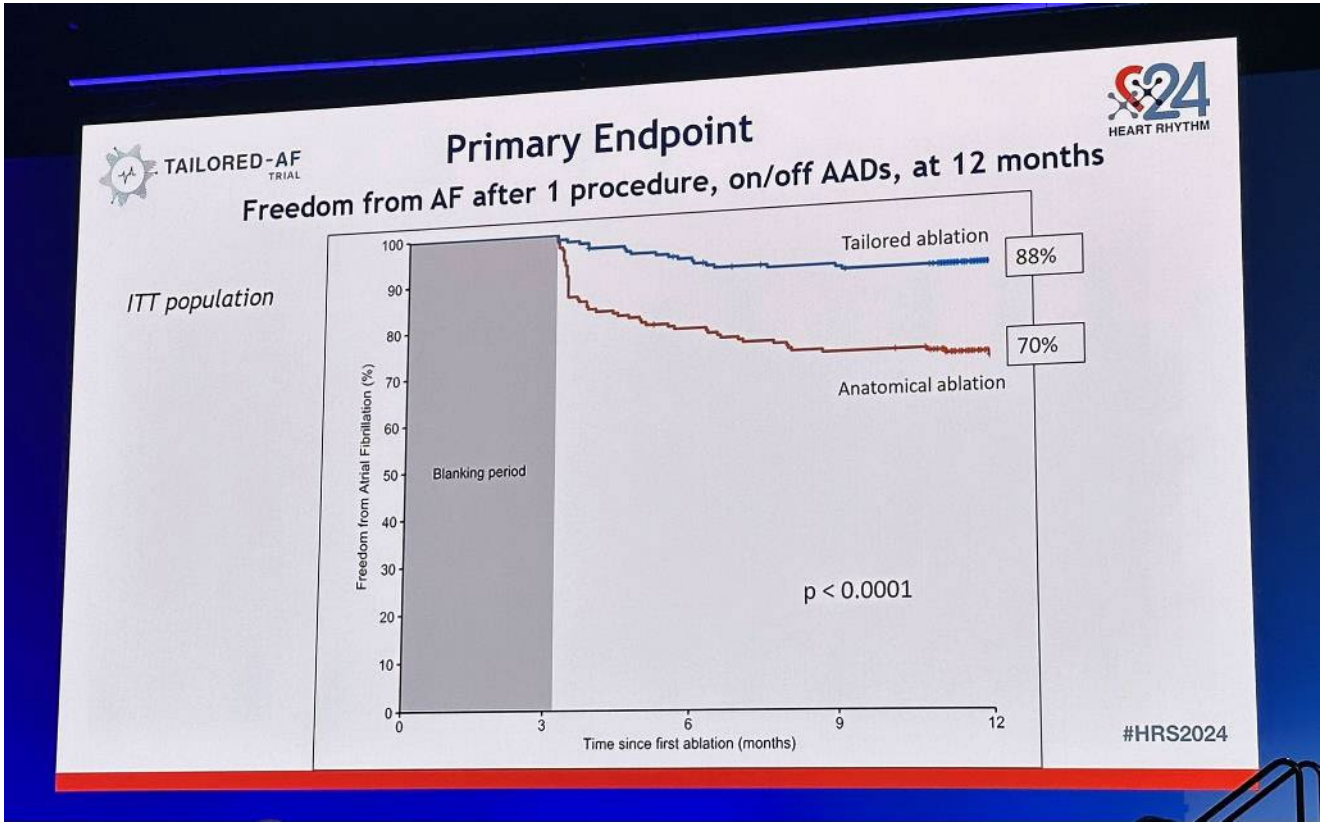

Deisenhofer LBCT Heart Rhythm 2024

Was ist neu bei Vorhofflimmern? Neue Konzepte, Energieformen, antikoagulation

How can we perform PVI?

Pulmonary vein isolation

How can we perform it?

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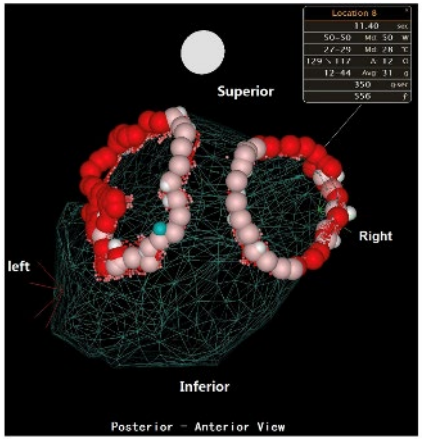

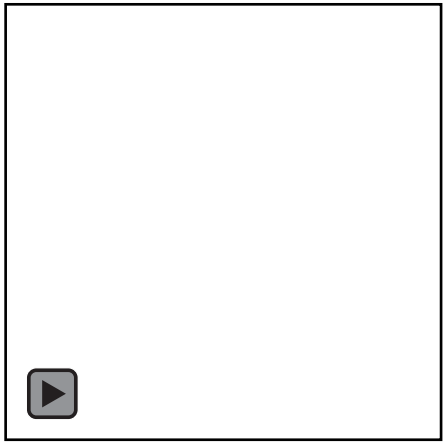

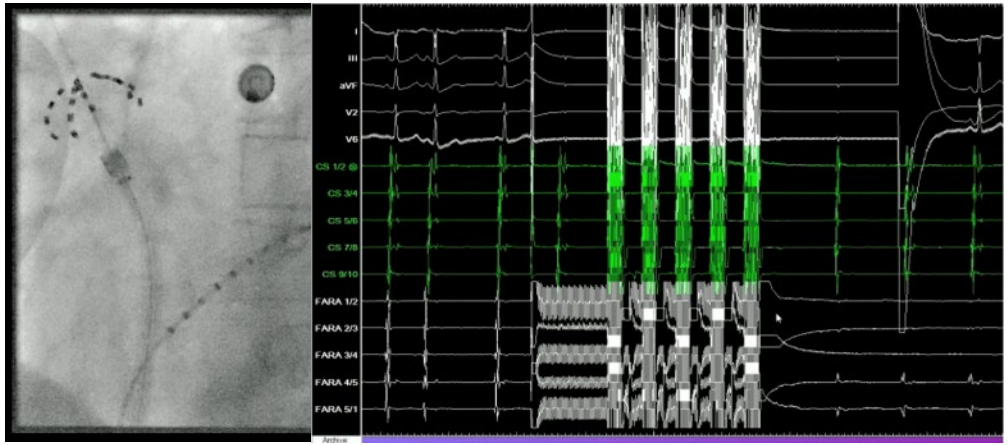

Radiofrequency	Cryoballoon	Pulsed field ablation
Pro: - Flexibility Contra: - Technically demanding - Esophageal lesions, tamponade	Pro: - Safety - Easy of use Contra: - One “does not fit all” - PNP	Pro: - Easy of use / fast / reproducible - No thermal lesions Contra: - Still limited long term data - Still limited data on rare complications

The multicentric experience using PFA

The Eu-Poria Study

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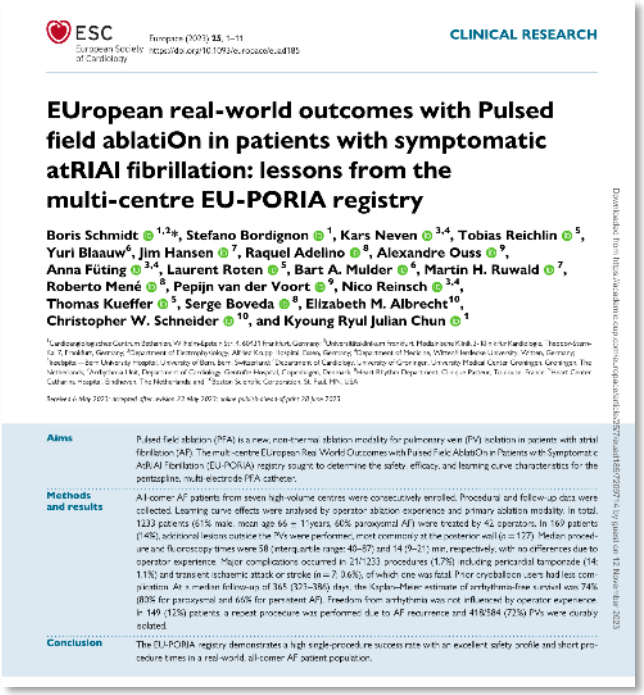

ESC European Society of Cardiology

Europace (2023) 25, 1–11 https://doi.org/10.1093/europace/euad185

CLINICAL RESEARCH

EUropean real-world outcomes with Pulsed field ablatiOn in patients with symptomatic atRIAl fibrillation: lessons from the multi-centre EU-PORIA registry

Boris Schmidt [1,2]*, Stefano Bordignon [1], Kars Neven [3,4], Tobias Reichlin [5], Yuri Blaauw[6], Jim Hansen [7], Raquel Adelino [8], Alexandre Ouss [9], Anna Füting [3,4], Laurent Roten [5], Bart A. Mulder [6], Martin H. Ruwald [7], Roberto Mené [8], Pepijn van der Voort [9], Nico Reinsch [3,4], Thomas Kueffer [5], Serge Boveda [8], Elizabeth M. Albrecht[10], Christopher W. Schneider [10], and Kyoung Ryul Julian Chun [1]

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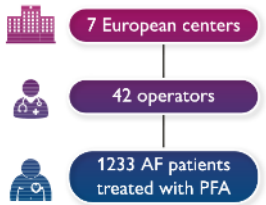
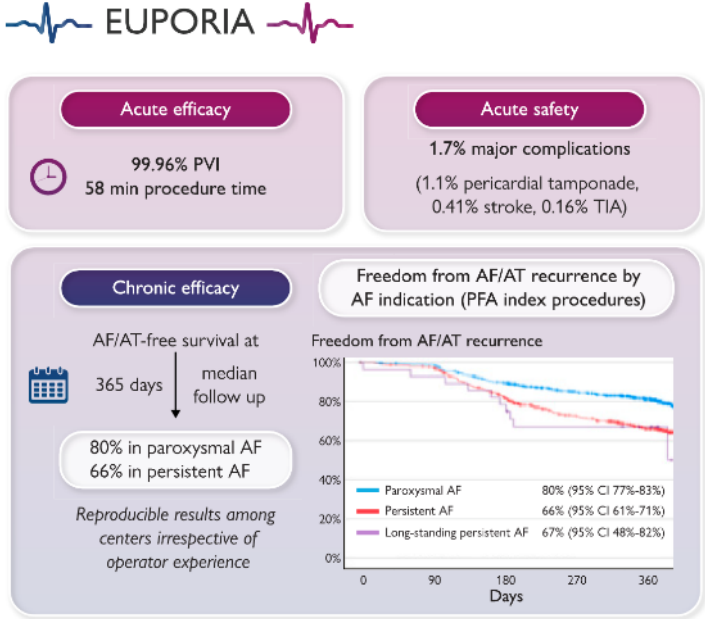
Methods and results All-comer AF patients from seven high-volume centres were consecutively enrolled. Procedural and follow-up data were collected. Learning curve effects were analysed by operator ablation experience and primary ablation modality. In total, 1233 patients (61% male, mean age 66 ± 11 years, 60% paroxysmal AF) were treated by 42 operators. In 169 patients (14%), additional lesions outside the PVs were performed, most commonly at the posterior wall (*n* = 127). Median procedure and fluoroscopy times were 58 (interquartile range 40–87) and 14 (9–21) min, respectively, with no differences due to operator experience. Major complications occurred in 21/1233 procedures (1.7%), including pericardial tamponade (14; 1.1%) and transient ischaemic attack or stroke (*n* = 7; 0.6%), of which one was fatal. Prior cryoballoon users had less complications. At a median follow-up of 365 (321–386) days, the Kaplan–Meier estimate of arrhythmia-free survival was 74% (80% for paroxysmal and 66% for persistent AF). Freedom from arrhythmia was not influenced by operator experience. In 149 (12%) patients, a repeat procedure was performed due to AF recurrence and 418/584 (72%) PVs were durably isolated.

Conclusion The EU-PORIA registry demonstrates a high single-procedure success rate with an excellent safety profile and short procedure times in a real-world, all-comer AF patient population.





Schmidt, Bordignon et al. Europace 2023

The multicentric experience using PFA

The Eu-Poria Study: the effect of operator experience with thermal energies

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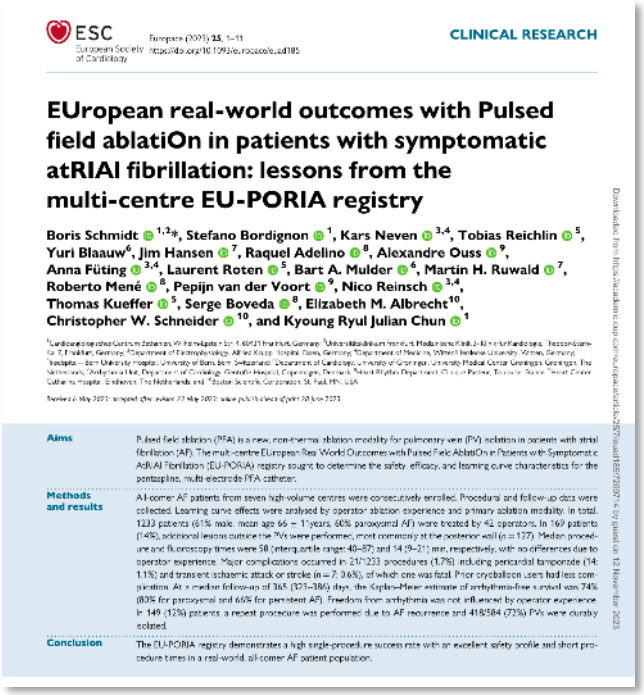

ESC European Society of Cardiology

Europace (2023) 25, 1–11 https://doi.org/10.1093/europace/euad185

CLINICAL RESEARCH

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Conclusion The EU-PORIA registry demonstrates a high single-procedure success rate with an excellent safety profile and short procedure times in a real-world, all-comer AF patient population.

Table 5 Outcomes by operator primary ablation modality

Primary ablation technology	Cryoballoon 13 operators 217 procedures	RF 11 operators 334 procedures	Both 18 operators 682 procedures	*P*-value
Procedural characteristics				
PVI only, *n* (%)	187 (86.2)	288 (86.2)	589 (86.4)	1.0000
3D mapping, *n* (%)	9 (4.2)	120 (35.9)	283 (41.5)	<0.0001
General anaesthesia, *n* (%)	60 (27.6)	44 (13.2)	146 (21.4)	<0.0001
Index PFA procedure	192 (88.4)	326 (97.6)	666 (97.7)	<0.0001
Type of AF				
Paroxysmal AF, *n* (%)	134 (61.8)	221 (66.2)	387 (56.7)	0.0136
Persistent AF, *n* (%)	72 (33.2)	109 (32.6)	276 (40.5)	0.0224
Long-standing persistent AF, *n* (%)	11 (5.1)	4 (1.2)	19 (2.8)	0.0246
Procedure times				
Skin-to-skin procedure time, min	59 (50–75)	71 (45–106)	51 (34–80)	<0.0001
Fluoroscopy time, min	15 (11–21)	18 (13–25)	11 (7–18)	<0.0001
Safety				
Complications, *n* (%)	4 (1.8)	15 (4.5)	26 (3.8)	0.2409
Stroke/TIA, *n* (%)	1 (0.5)	3 (0.9)	3 (0.4)	0.7685
Pericardial tamponade, *n* (%)	0	9 (2.7)	5 (0.7)	0.0058
Efficacy				
PV reconnection rate, *n* (%)	33/98 (33.7)	62/162 (38.3)	71/324 (21.9)	0.0004
Freedom from AF/AT at 12 months, *n* (%)	155/217 (71.4)	252/334 (75.4)	499/682 (73.2)	

Schmidt, Bordignon et al. Europace 2023

The multicentric experience using PFA

The Eu-Poria Study: 1 Y FU

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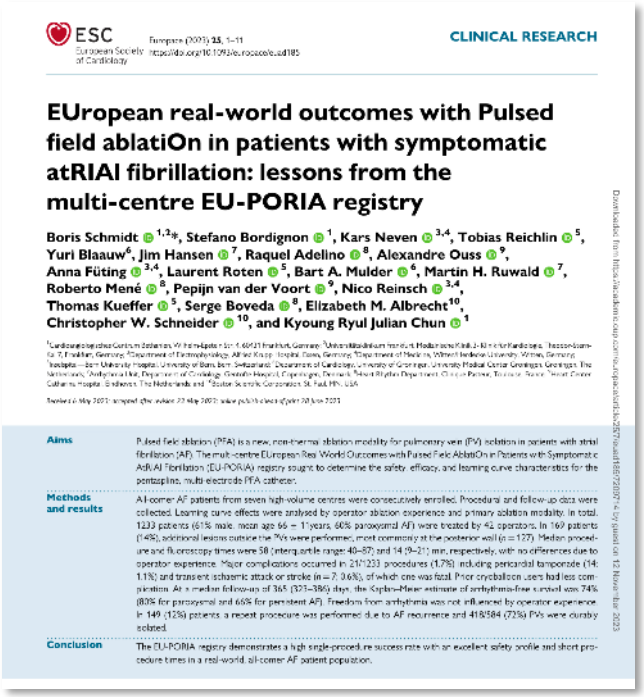

ESC European Society of Cardiology

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CLINICAL RESEARCH

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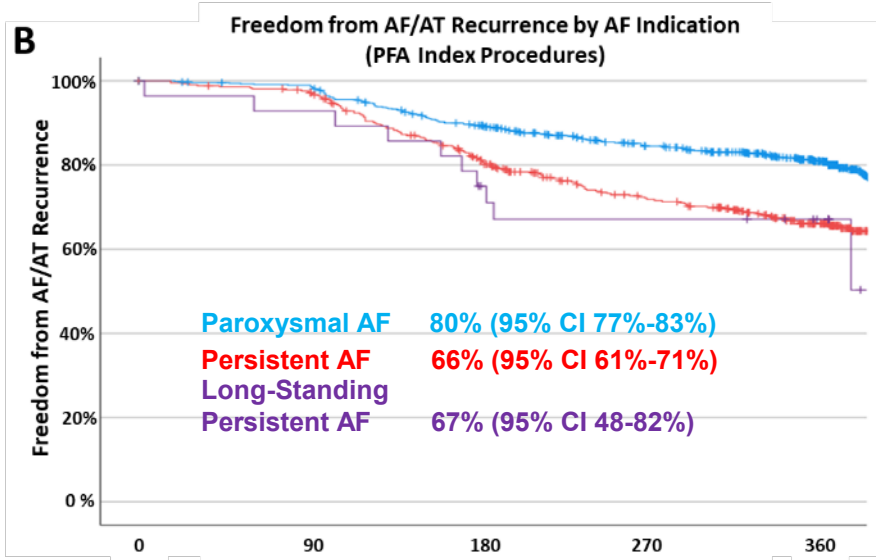

No. at Risk					
Paroxysmal AF	707	695	615	535	256
Persistent AF	426	410	327	259	134
LS Persistent AF	28	26	20	17	12

Schmidt, Bordignon et al. Europace 2023

Safety of PFA

Manifest 17K

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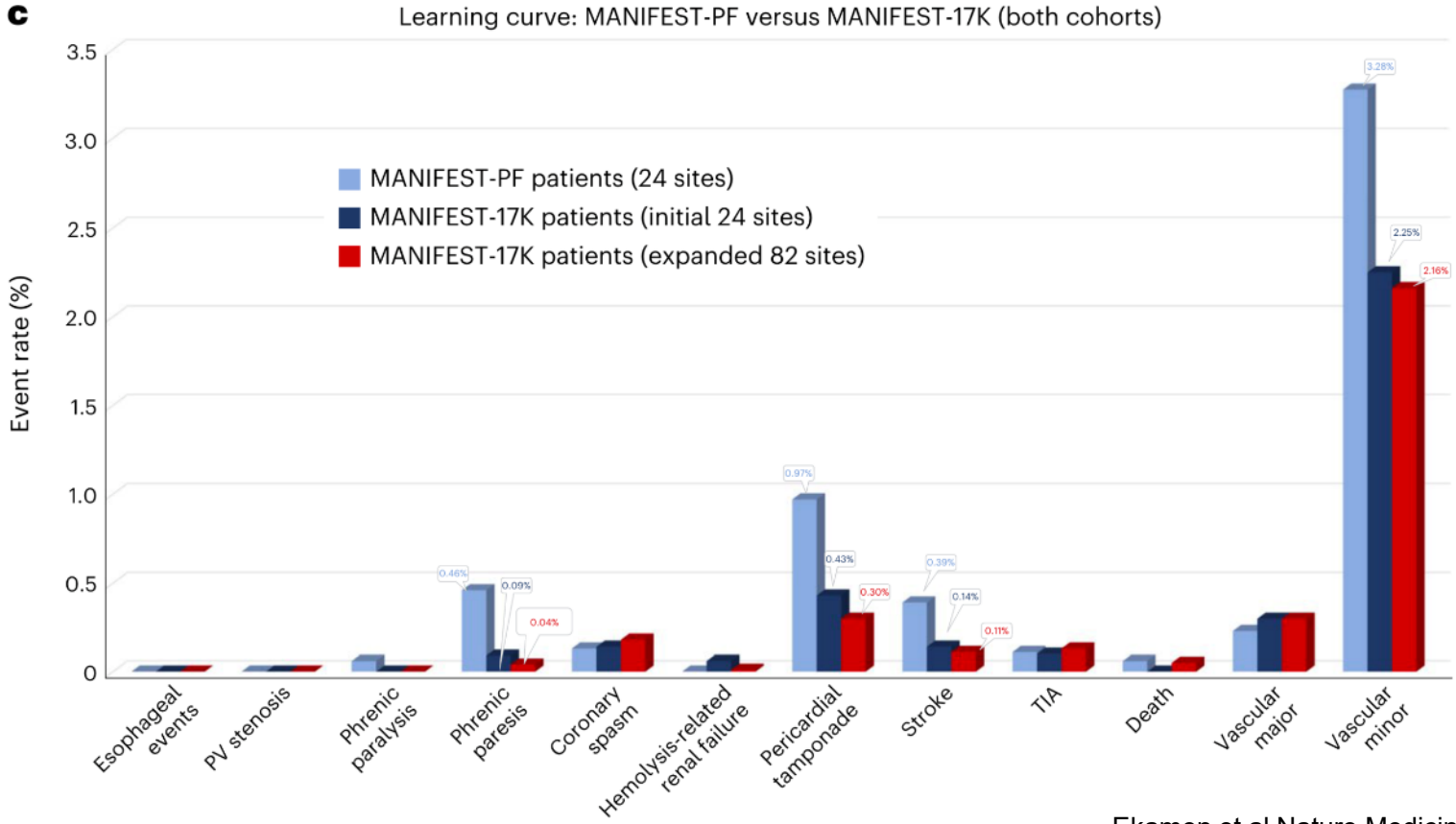

Ekamen et al Nature Medicine 2024

Emerging of new complications

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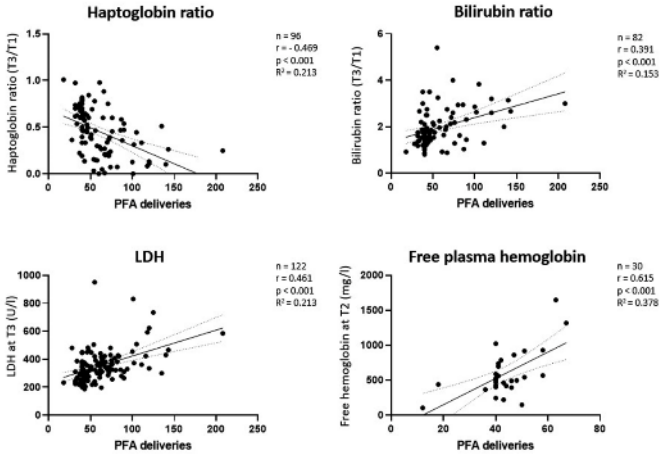
Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Characterization and Clinical Significance of Hemolysis After Pulsed Field Ablation for Atrial Fibrillation: Results of a Multicenter Analysis

Miruna A. Popa, MD; Sandrine Venier, MD; Roberto Meni, MD; Domenico Giovanni Della Rocca, MD, PhD; Frédéric Sacher, MD; Nicolas Derval, MD; Mélèze Hocini, MD; Stéphanie Duluc, PharmD, PhD; Guido Caluori, PhD; Stéphane Combes, MD; Jean-Paul Albenque, MD; Federica Sieda, MD; Bernhard Haller, Dr rer nat; Gian Battista Chierchia, MD, PhD; Carlo de Asmundis, MD, PhD; Pascal Defaye, MD; Serge Boveda, MD, PhD; Pierre Jais, MD



Popa et al. CIRCAE 2024

INVITED REVIEW OPEN ACCESS

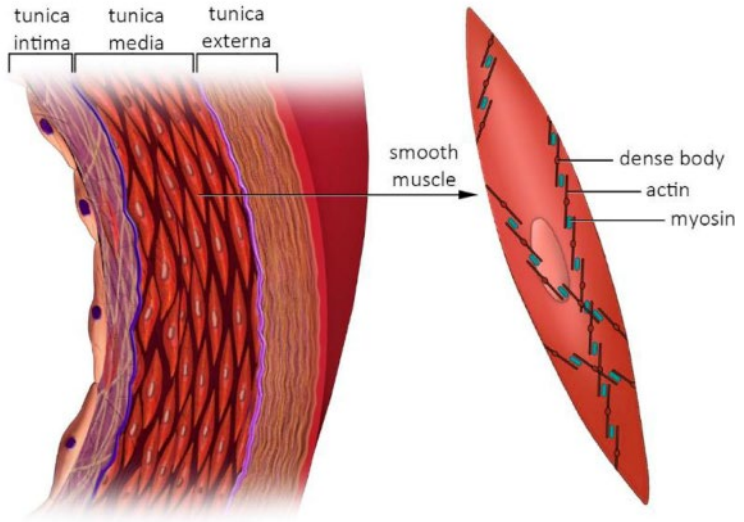
Coronary Spasm Due to Pulsed Field Ablation: A State-of-the-Art Review

David A. Ramirez | Kara Garrott | Ann Garlitski | Brendan Koop

Electrophysiology Research & Development, Boston Scientific Corporation, Marlborough, Massachusetts, USA

Correspondence: David A. Ramirez (David.Ramirez2@bsci.com)

Received: 31 July 2024 | **Accepted:** 16 October 2024



Ramirez et al. PACE 2024

The PFA revolution seems unstoppable

Even if non inferior does not mean superior

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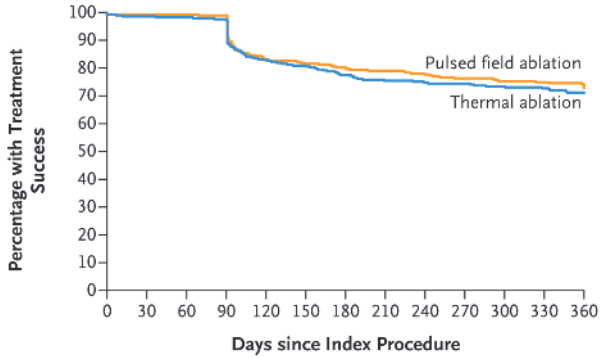
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation



No. at Risk

Pulsed field ablation	301	298	238	228	176
Thermal ablation	296	292	228	219	150

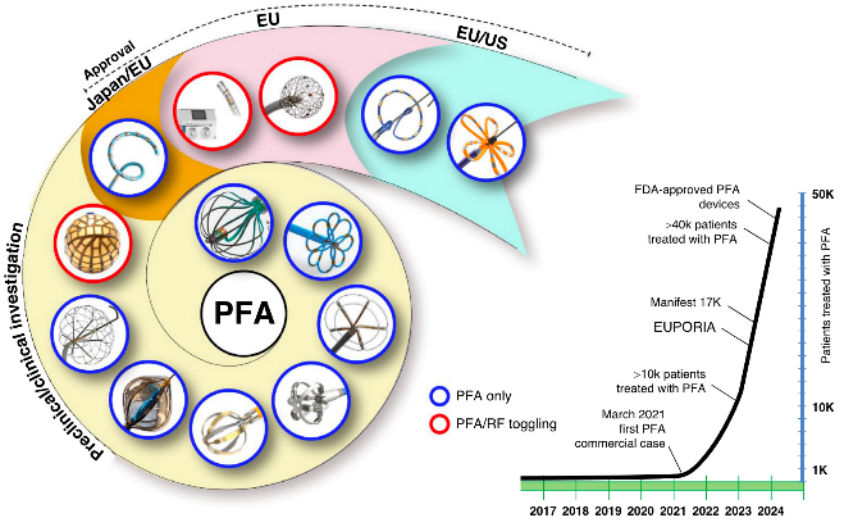
Treatment Success (%)

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

Reddy NEJM 2023

State-of-the-art pulsed field ablation for cardiac arrhythmias: ongoing evolution and future perspective

Kyoung-Ryul Julian Chun [1,2]*, Damijan Miklavčič [3], Konstantinos Vlachos [4], Stefano Bordignon [1], Daniel Scherr [5], Pierre Jais [4], and Boris Schmidt [1]



Chun et al. Europace 2024

The advent of toggling catheters

The new PFA and the “old” RFC together

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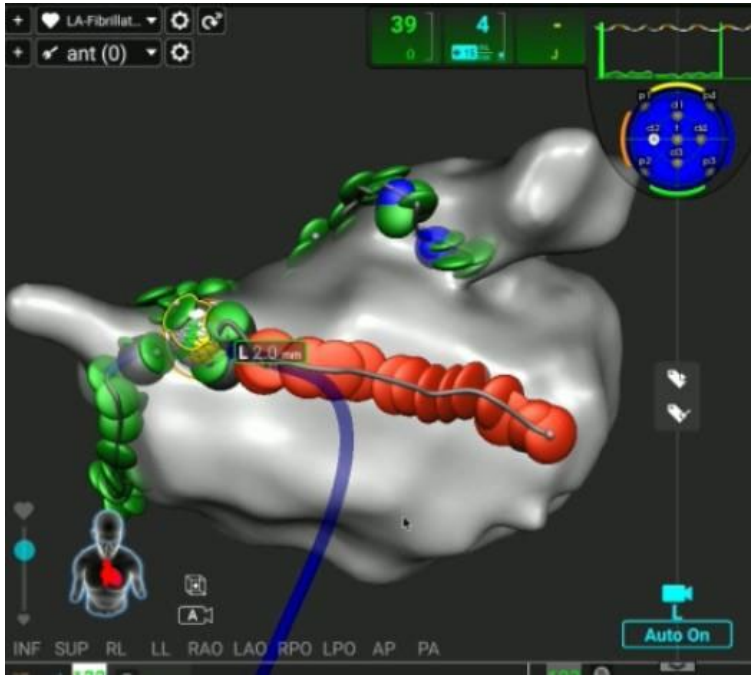


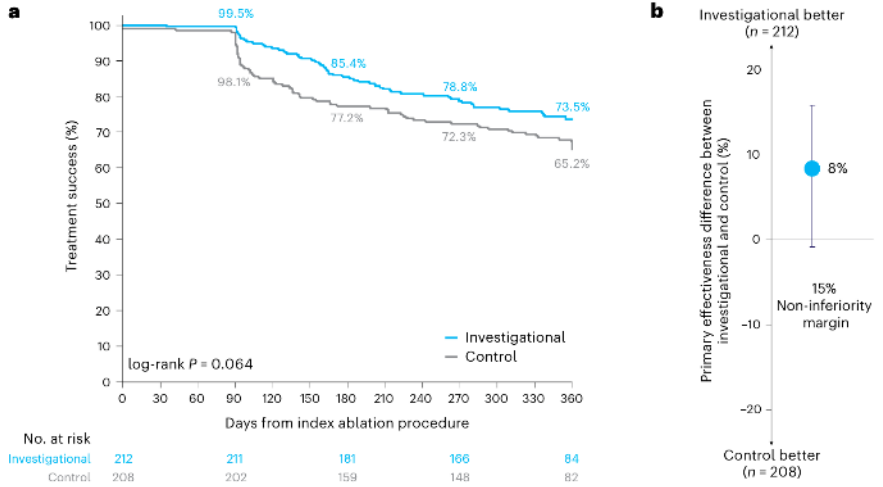
Personal image

nature medicine

Article

https://doi.org/10.1038/s41591-024-03022-6

Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial



Anter et al. Nature Medicine 2024

Was ist neu bei Vorhofflimmern? Neue Konzepte, energieformen, antikoagulation

Avoid Stroke

In the new guidelines

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Use locally-validated risk score or CHA_2DS_2-VA

OAC if CHA_2DS_2-VA score = 2 or more (Class I)

OAC if CHA_2DS_2-VA score = 1 (Class IIa)

Table 10 Updated definitions for the CHA_2DS_2-VA score

CHA_2DS_2-VA component		Definition and comments	Points awarded[a]
C	Chronic heart failure	Symptoms and signs of heart failure (irrespective of LVEF, thus including HFpEF, HFmrEF, and HFrEF), or the presence of asymptomatic LVEF ≤40%.[261–263]	1
H	Hypertension	Resting blood pressure >140/90 mmHg on at least two occasions, or current antihypertensive treatment. The optimal BP target associated with lowest risk of major cardiovascular events is 120–129/70–79 mmHg (or keep as low as reasonably achievable).[162,264]	1
A	Age 75 years or above	Age is an independent determinant of ischaemic stroke risk.[265] Age-related risk is a continuum, but for reasons of practicality, two points are given for age ≥75 years.	2
D	Diabetes mellitus	Diabetes mellitus (type 1 or type 2), as defined by currently accepted criteria,[266] or treatment with glucose lowering therapy.	1
S	Prior stroke, TIA, or arterial thromboembolism	Previous thromboembolism is associated with highly elevated risk of recurrence and therefore weighted 2 points.	2
V	Vascular disease	Coronary artery disease, including prior myocardial infarction, angina, history of coronary revascularization (surgical or percutaneous), and significant CAD on angiography or cardiac imaging.[267] OR Peripheral vascular disease, including: intermittent claudication, previous revascularization for PVD, percutaneous or surgical intervention on the abdominal aorta, and complex aortic plaque on imaging (defined as features of mobility, ulceration, pedunculation, or thickness ≥4 mm).[268,269]	1
A	Age 65–74 years	1 point is given for age between 65 and 74 years.	1

BP, blood pressure; CAD, coronary artery disease; CHA_2DS_2-VA, chronic heart failure, hypertension, age ≥75 years (2 points), diabetes mellitus, prior stroke/transient ischaemic attack/arterial thromboembolism (2 points), vascular disease, age 65–74 years; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; PVD, peripheral vascular disease.

[a]In addition to these factors, other markers that modify an individual's risk for stroke and thromboembolism should be considered, including cancer, chronic kidney disease, ethnicity (black, Hispanic, Asian), biomarkers (troponin and BNP), and in specific groups, atrial enlargement, hyperlipidaemia, smoking, and obesity.

Van Gelder et al. EHJ 2024

Avoid Stroke

In the new guidelines: it´s a matter of definition.

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A CHA_2DS_2-VA score of 1 should be considered an indicator of elevated thromboembolic risk for decisions on initiating oral anticoagulation.	IIa	C
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

Avoid Stroke

In device detected AF

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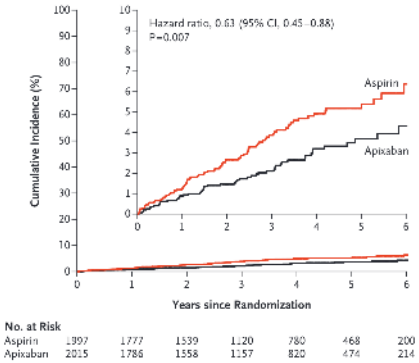
ARTESIA

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 JANUARY 11, 2024 VOL. 390 NO. 2

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. Stücherling, 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*



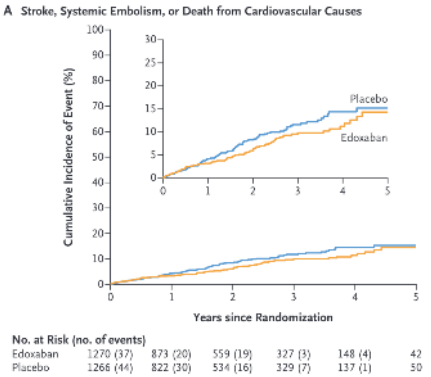
Pacemaker detected
subclinical AF
(6 min – 24 hrs)

NOAH

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 SEPTEMBER 28, 2023 VOL. 389 NO. 13

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 AHRE
(atrial rate > 170/min for ≥ 6)

Avoid Stroke

In device detected AF

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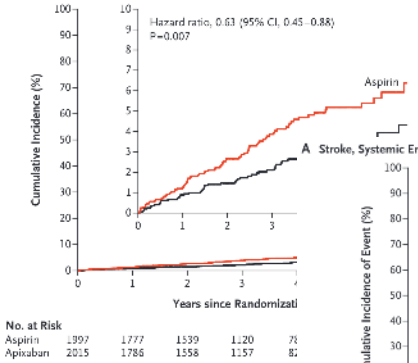
ARTESIA



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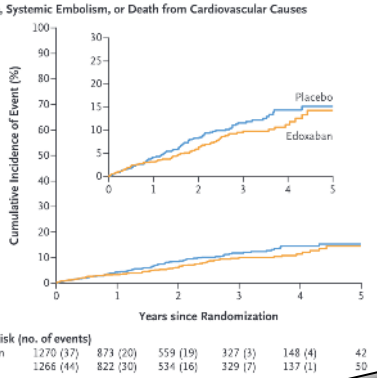

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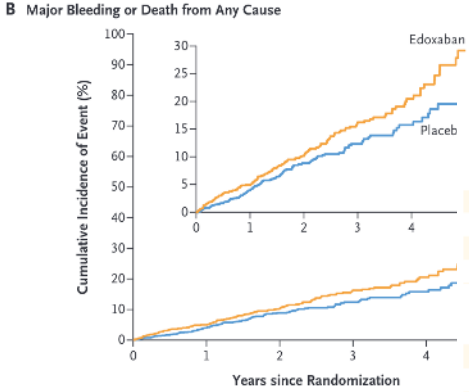
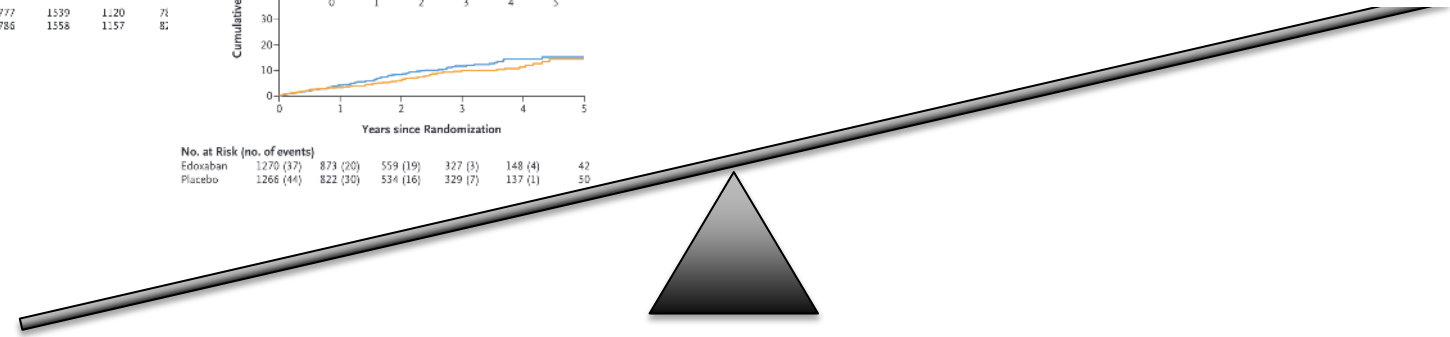


ARTESIA

Outcome	Apixaban (N=2015)		Aspirin (N=1997)	
	no. of patients with event	*%/patient-yr*	*no. of patients with event*	*%/patient-yr*
Stroke or systemic embolism	55	0.78	86	1.24
Stroke	55	0.78	84	1.21
Ischemic or unknown type†	45	0.64	71	1.02
Hemorrhagic	10	0.14	13	0.18
Major bleeding¶	106	1.53	78	1.12
Fatal bleeding	10	0.14	14	0.20
Symptomatic intracranial hemorrhage	17	0.24	23	0.33
Gastrointestinal bleeding	55	0.78	31	0.44
Transfusion performed	35	0.49	31	0.44



Favor DOACS

Against DOACS

Avoid Stroke

In device detected AF

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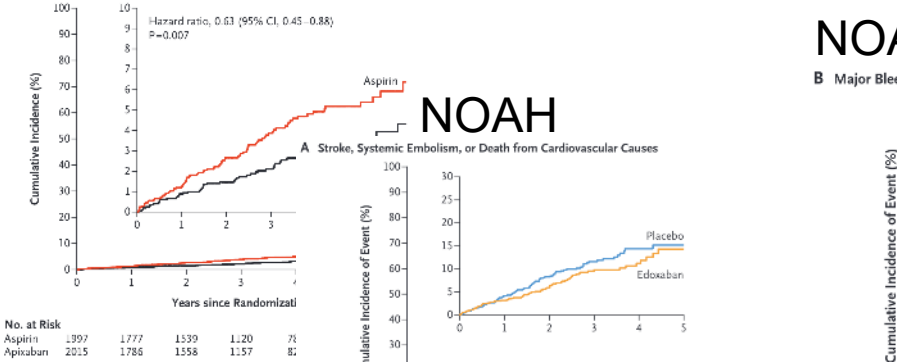

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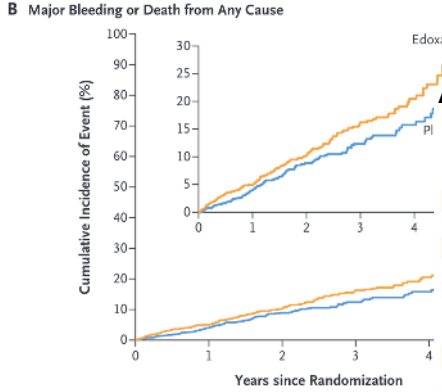

ARTESIA

Outcome	Apixaban (N=2015) no. of patients with event	Apixaban (N=2015) %/patient-yr	Aspirin (N=1997) no. of patients with event	Aspirin (N=1997) %/patient-yr
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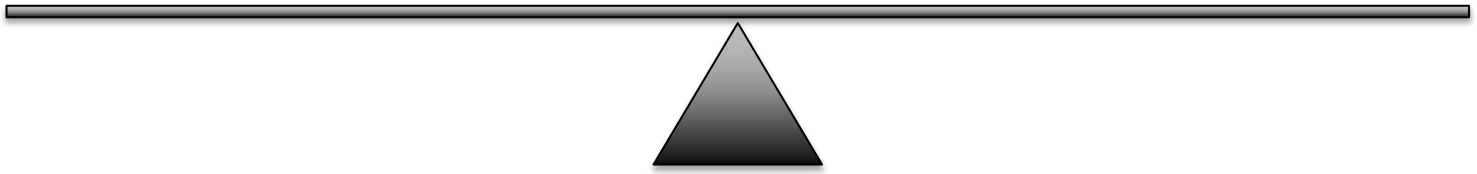

Favor DOACS

Against DOACS

Conclusions

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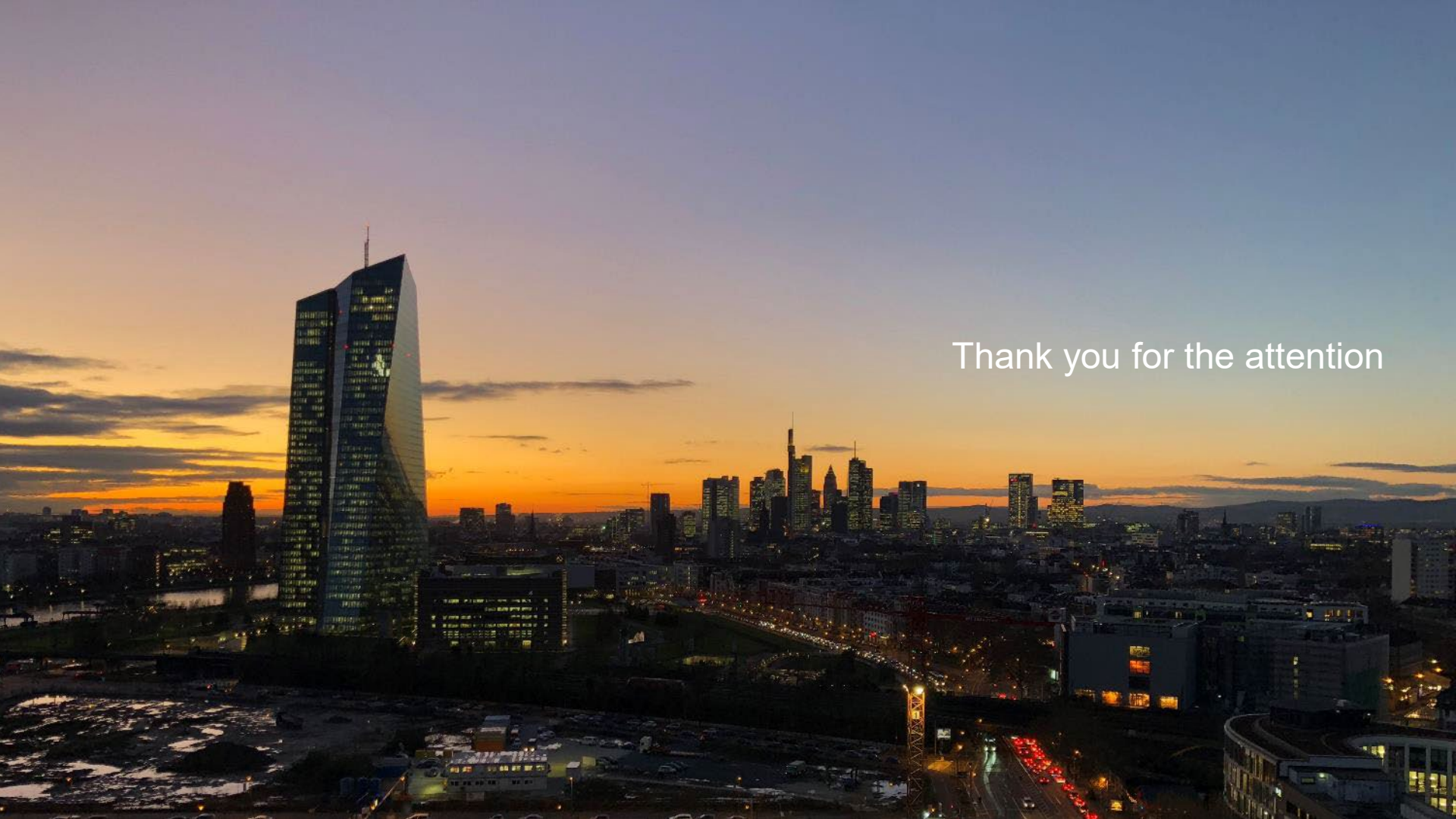
- New concepts
  - The new guidelines “introduced” the CARE concept
  - EP is still looking for a strategy to increase the success rate beyond PVI
    - Alcohol ablation and AI guided EGM ablation showed promising results

- New energy forms
  - PFA revolution is there
  - We need post market analysis to detect rare complications

- Anticoagulation
  - We still do not know how to prevent stroke in device detected AF


Thank you for the attention

Avoid Stroke

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

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 11, 2024 VOL. 390 NO. 2

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*

ABSTRACT

BACKGROUND

Subclinical atrial fibrillation is short-lasting and asymptomatic and can usually be detected only by long-term continuous monitoring with pacemakers or defibrillators. Subclinical atrial fibrillation is associated with an increased risk of stroke by a factor of 2.5; however, treatment with oral anticoagulation is of uncertain benefit.

METHODS

We conducted a trial involving patients with subclinical atrial fibrillation lasting 6 minutes to 24 hours. Patients were randomly assigned in a double-blind, double-dummy design to receive apixaban at a dose of 5 mg twice daily (2.5 mg twice daily when indicated) or aspirin at a dose of 81 mg daily. The trial medication was discontinued and anticoagulation started if subclinical atrial fibrillation lasting more than 24 hours or clinical atrial fibrillation developed. The primary efficacy outcome, stroke or systemic embolism, was assessed in the intention-to-treat population (all the patients who had undergone randomization); the primary safety outcome, major bleeding, was assessed in the on-treatment population (all the patients who had undergone randomization and received at least one dose of the assigned trial drug, with follow-up censored 5 days after permanent discontinuation of trial medication for any reason).

RESULTS

We included 4012 patients with a mean (±SD) age of 76.8±7.6 years and a mean CHA_2DS_2-VASc score of 3.9±1.1 (scores range from 0 to 9, with higher scores indicating a higher risk of stroke); 36.1% of the patients were women. After a mean follow-up of 3.5±1.8 years, stroke or systemic embolism occurred in 55 patients in the apixaban group (0.78% per patient-year) and in 86 patients in the aspirin group (1.24% per patient-year) (hazard ratio, 0.63; 95% confidence interval [CI], 0.45 to 0.88; P=0.007). In the on-treatment population, the rate of major bleeding was 1.71% per patient-year in the apixaban group and 0.94% per patient-year in the aspirin group (hazard ratio, 1.80; 95% CI, 1.26 to 2.57; P=0.001). Fatal bleeding occurred in 5 patients in the apixaban group and 8 patients in the aspirin group.

CONCLUSIONS

Among patients with subclinical atrial fibrillation, apixaban resulted in a lower risk of stroke or systemic embolism than aspirin but a higher risk of major bleeding. (Funded by the Canadian Institutes of Health Research and others; ARTESIA ClinicalTrials.gov number, NCT01938248.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Healey can be contacted at jeff.healey@phri.ca or at the Population Health Research Institute, McMaster University, 237 Barton St. E., Hamilton ON L8L 2X2, Canada.

*A full list of the ARTESIA investigators is provided in the Supplementary Appendix, available at NEJM.org.

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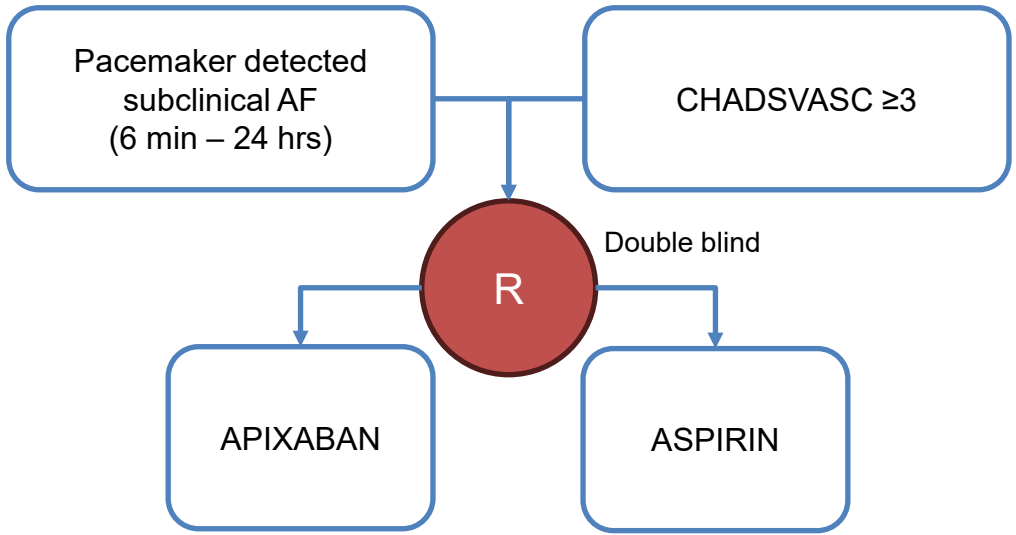

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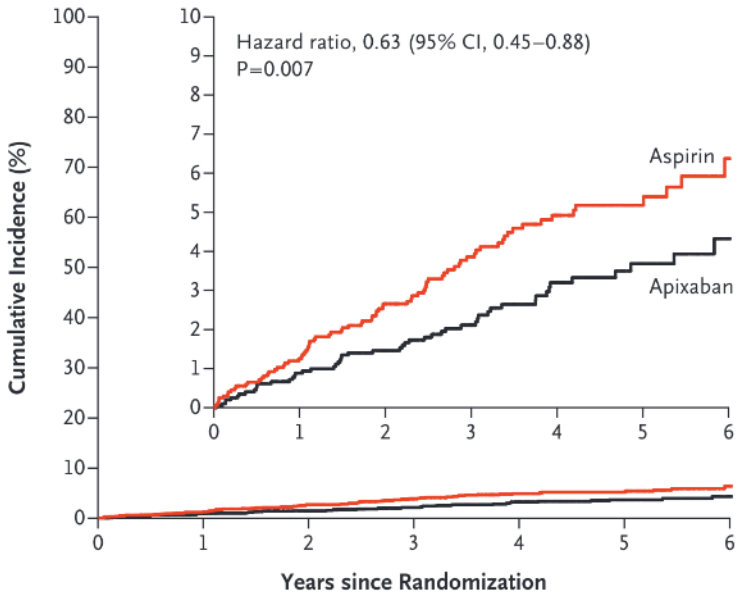

No. at Risk							
Aspirin	1997	1777	1539	1120	780	468	200
Apixaban	2015	1786	1558	1157	820	474	214

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Avoid Stroke

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

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Outcome	Apixaban (N=2015)		Aspirin (N=1997)		Hazard Ratio (95% CI)	P Value
	no. of patients with event	%/patient-yr	no. of patients with event	%/patient-yr		
Stroke or systemic embolism	55	0.78	86	1.24	0.63 (0.45–0.88)	0.007
Stroke	55	0.78	84	1.21	0.64 (0.46–0.90)	
Ischemic or unknown type†	45	0.64	71	1.02	0.62 (0.43–0.91)	
Hemorrhagic	10	0.14	13	0.18	0.76 (0.33–1.73)	
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)	

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Avoid Stroke

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

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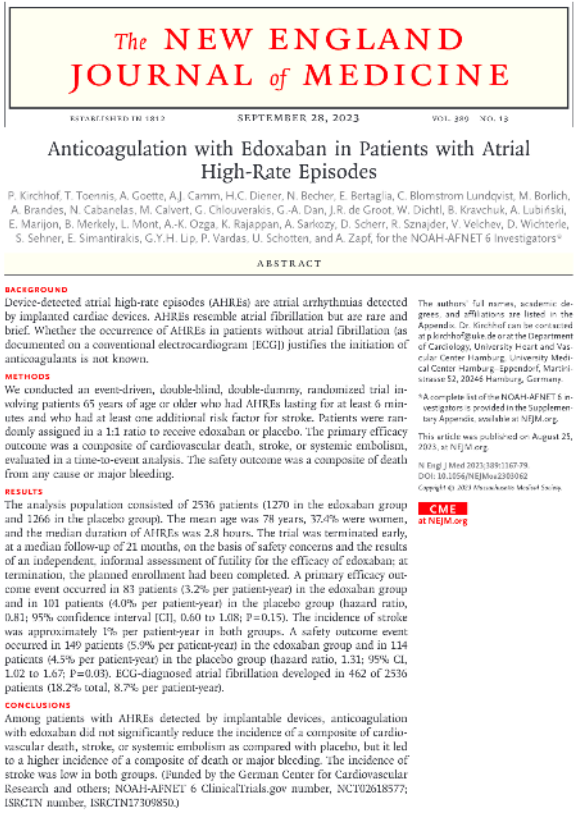

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 28, 2023 VOL. 389 NO. 13

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*

ABSTRACT

BACKGROUND

Device-detected atrial high-rate episodes (AHREs) are atrial arrhythmias detected by implanted cardiac devices. AHREs resemble atrial fibrillation but are rare and brief. Whether the occurrence of AHREs in patients without atrial fibrillation (as documented on a conventional electrocardiogram [ECG]) justifies the initiation of anticoagulants is not known.

METHODS

We conducted an event-driven, double-blind, double-dummy, randomized trial involving 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. Patients were randomly assigned in a 1:1 ratio to receive edoxaban or placebo. The primary efficacy outcome was a composite of cardiovascular death, stroke, or systemic embolism, evaluated in a time-to-event analysis. The safety outcome was a composite of death from any cause or major bleeding.

RESULTS

The analysis population consisted of 2536 patients (1270 in the edoxaban group and 1266 in the placebo group). The mean age was 78 years, 37.4% were women, and the median duration of AHREs was 2.8 hours. The trial was terminated early, at a median follow-up of 21 months, on the basis of safety concerns and the results of an independent, informal assessment of futility for the efficacy of edoxaban; at termination, the planned enrollment had been completed. A primary efficacy outcome event occurred in 83 patients (3.2% per patient-year) in the edoxaban group and in 101 patients (4.0% per patient-year) in the placebo group (hazard ratio, 0.81; 95% confidence interval [CI], 0.60 to 1.08; P=0.15). The incidence of stroke was approximately 1% per patient-year in both groups. A safety outcome event occurred in 149 patients (5.9% per patient-year) in the edoxaban group and in 114 patients (4.5% per patient-year) in the placebo group (hazard ratio, 1.31; 95% CI, 1.02 to 1.67; P=0.03). ECG-diagnosed atrial fibrillation developed in 462 of 2536 patients (18.2% total, 8.7% per patient-year).

CONCLUSIONS

Among patients with AHREs detected by implantable devices, anticoagulation with edoxaban did not significantly reduce the incidence of a composite of cardiovascular death, stroke, or systemic embolism as compared with placebo, but it led to a higher incidence of a composite of death or major bleeding. The incidence of stroke was low in both groups. (Funded by the German Center for Cardiovascular Research and others; NOAH-AFNET 6 ClinicalTrials.gov number, NCT02618577; ISRCTN number, ISRCTN17309850.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Kirchhof can be contacted at p.kirchhof@uke.de or at the Department of Cardiology, University Heart and Vascular Center Hamburg, University Medical Center Hamburg–Eppendorf, Martinistrasse 52, 20246 Hamburg, Germany.

*A complete list of the NOAH-AFNET 6 investigators is provided in the Supplementary Appendix, available at NEJM.org.

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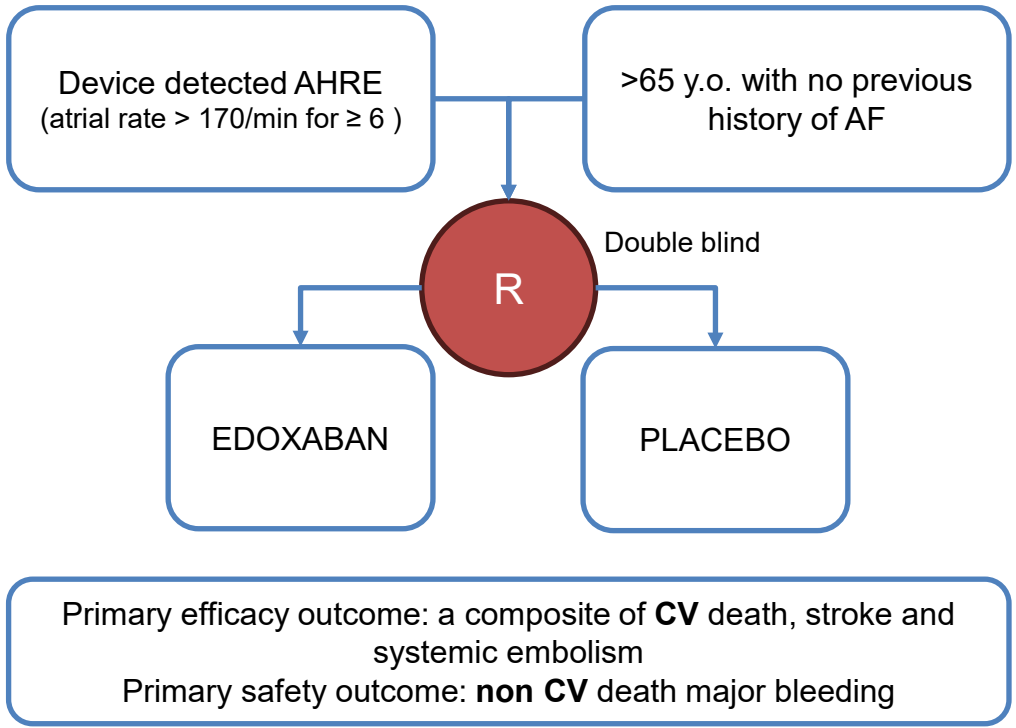

Primary efficacy outcome: a composite of **CV** death, stroke and systemic embolism
Primary safety outcome: **non CV** death major bleeding

Kirchhof et al. NEJM 2023

Avoid Stroke

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

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The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Kirchhof can be contacted at p.kirchhof@uke.de or at the Department of Cardiology, University Heart and Vascular Center Hamburg, University Medical Center Hamburg–Eppendorf, Martinistrasse 52, 20246 Hamburg, Germany.

*A complete list of the NOAH-AFNET 6 investigators is provided in the Supplementary Appendix, available at NEJM.org.

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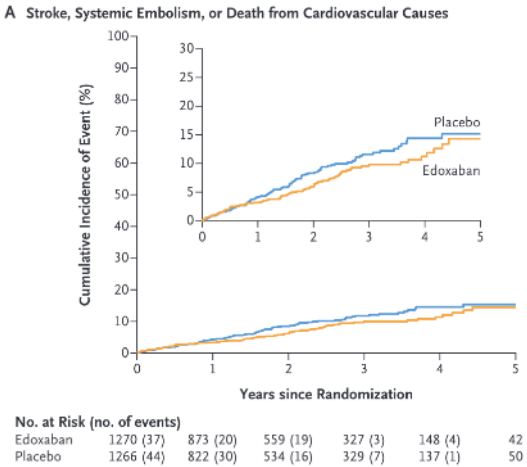

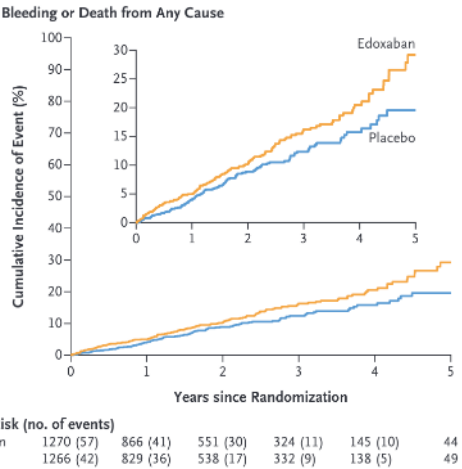

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Astro AF Trial

Randomization after confirmed durable PVI

RESEARCH ARTICLE | Originally Published 7 October 2024

Ablation Strategies for Repeat Procedures in Atrial Fibrillation Recurrences Despite Durable Pulmonary Vein Isolation: The Prospective Randomized ASTRO AF Multicenter Trial

Kerk Schmidt, MD; Stéphane Bordignon, MD; Andreas Metzner, MD; Philipp Sommer, MD; Dan Gilhofer, MD; Etienne Dalmo, MD; Matthias Busch, MD; ... and K.-R. Julian Chun, MD

Circulation • New online • https://doi.org/10.1161/CIRCULATIONAHA.124.069993

197 GIFT ACCESS

Abstract

BACKGROUND:

Ablation strategies for patients with symptomatic atrial fibrillation and isolated pulmonary veins vary and their effects on arrhythmia recurrence remain unclear. A prospective randomized German multicenter trial sought to compare 2 ablation strategies in this patient cohort.

METHODS:

Patients with atrial fibrillation despite durable pulmonary vein isolation were randomly assigned at 7 centers to undergo low-voltage area ablation using 3-dimensional mapping and irrigated radiofrequency current ablation (group A) or empirical left atrial appendage isolation (LAAI) using the cryoballoon followed by staged interventional left atrial appendage closure (group B). The primary end point was freedom from atrial tachyarrhythmias between 91 and 365 days after index ablation. The study was powered for superiority of LAAI compared with low-voltage area.

RESULTS:

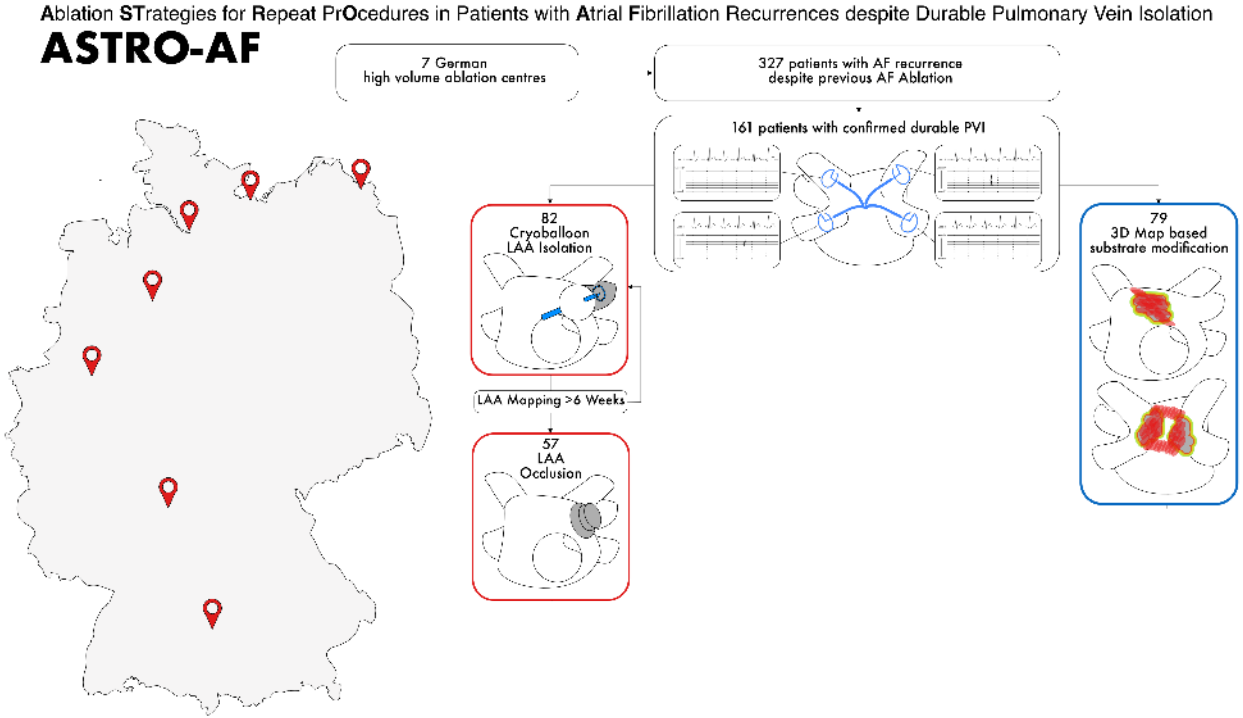
Patients (40% women; mean age, 68.8±6 years) with paroxysmal (32%) or persistent atrial fibrillation (68%) were randomized to undergo low-voltage area ablation (n=79) or cryoballoon-guided LAAI (n=82). After a planned interim analysis, enrollment was halted for futility on January 10, 2023. In the LAAI group, 77 of 82 left atrial appendages were successfully isolated with subsequent left atrial appendage closure in 57 patients. Procedure-related complications occurred in 4 (5%) and 11 (13.5%) patients in group A and B, respectively (P=0.10). The median follow-up was 387 days (interquartile range, 359–378). The Kaplan-Meier point estimate for freedom from atrial tachyarrhythmias was 51.7% (CI, 40.9%–65.4%) for group A and 56.5% (CI, 44.4%–69.2%; P=0.8069) for group B.

CONCLUSIONS:

The current study did not detect superiority of cryoballoon-guided LAAI over low-voltage area ablation in patients with atrial fibrillation despite durable PVI.

REGISTRATION:

URL: https://www.clinicaltrials.gov; Unique identifier: NCT04056390



Schmidt, Bordignon … Chun Circulation 2024

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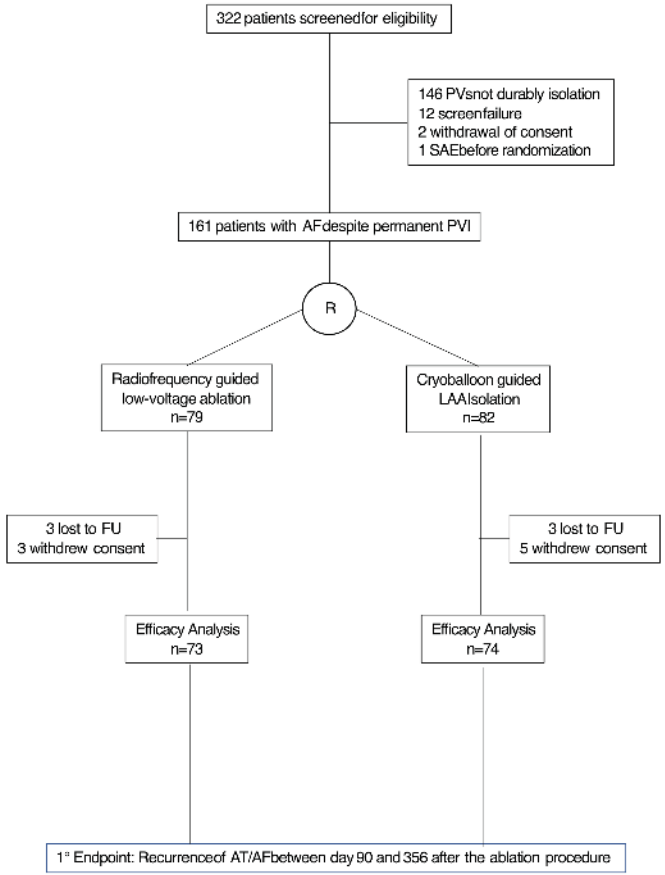

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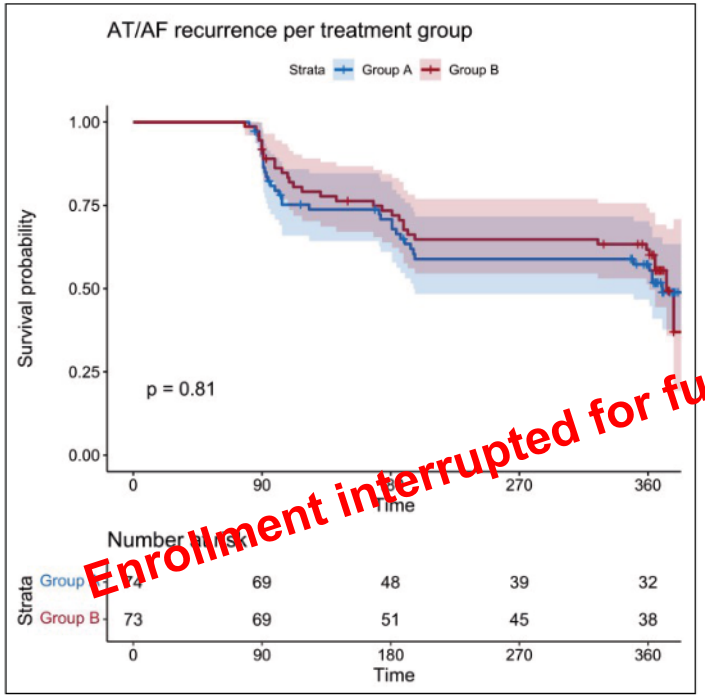
Table 3. Procedural Complications

Characteristics	Substrate modification (n=79)	Cryoballoon-guided LAAI and LAAC (n=82)	*P* value
Death	0	0	
Stroke	0	1 (1.2)	1.0
LAA thrombus	0	2 (2.4)	0.4970
Pericardial effusion	2 (2.6)	4 (4.9)	0.6819
Pericardial effusion requiring intervention	1 (1.3)	4 (4.9)	0.3676
Access site complication	1 (1.3)	2 (2.4)	1.0
Infection	1 (1.3)	1 (1.2)	1.0
Other	0	1 (1.2)	1.0
Total	4 (5.0)	11 (13.4)	0.1022



Enrollment interrupted for futility

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Avoid stroke after AF ablation

A role for LAA Occlusion?

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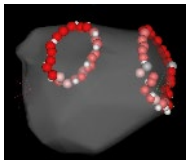
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

O.M. Wazni, W.I. Saliba, D.G. Nair, E. Marijon, B. Schmidt, T. Hounshell, H. Ebelt, C. Skurk, S. Oza, C. Patel, A. Kanagasundram, A. Sadhu, S. Sundaram, J. Osorio, G. Mark, M. Gupta, D.B. DeLurgio, J. Olson, J.E. Nielsen-Kudsk, L.V.A. Boersma, J.S. Healey, K.P. Phillips, F.M. Asch, K. Wolski, K. Roy, T. Christen, B.S. Sutton, K.M. Stein, and V.Y. Reddy, for the OPTION Trial Investigators*



1600 pts

CHADSVASC ≥2-3

R

803 pts

Watchman

NOACs

797 pts

- Primary safety endpoint (superiority): non procedure related major or clinically relevant bleeding
- Primary efficacy end point (noninferiority): composite of death from any cause, stroke, or systemic embolism at 36 months.
- Secondary end point (noninferiority): major bleeding, including procedure-related bleeding, through 36 months.

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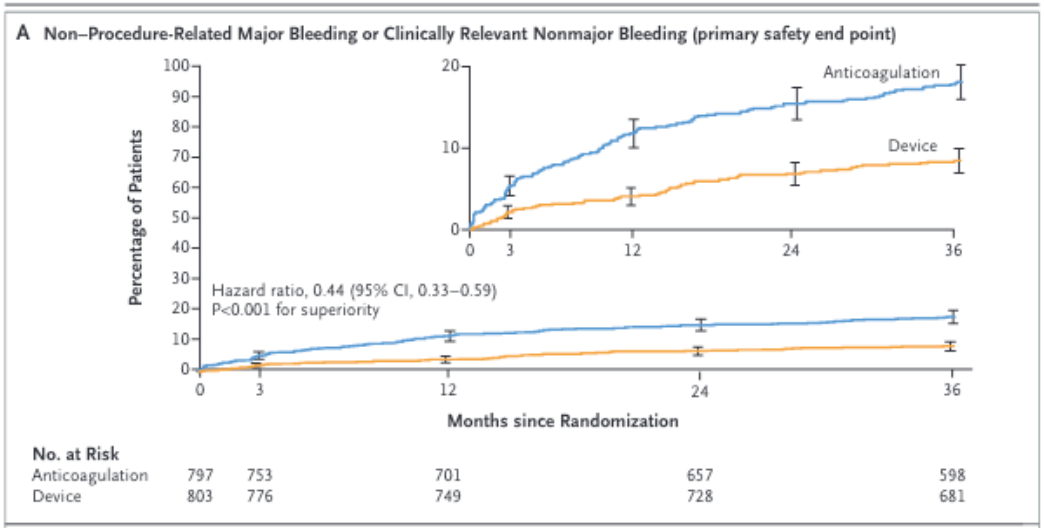

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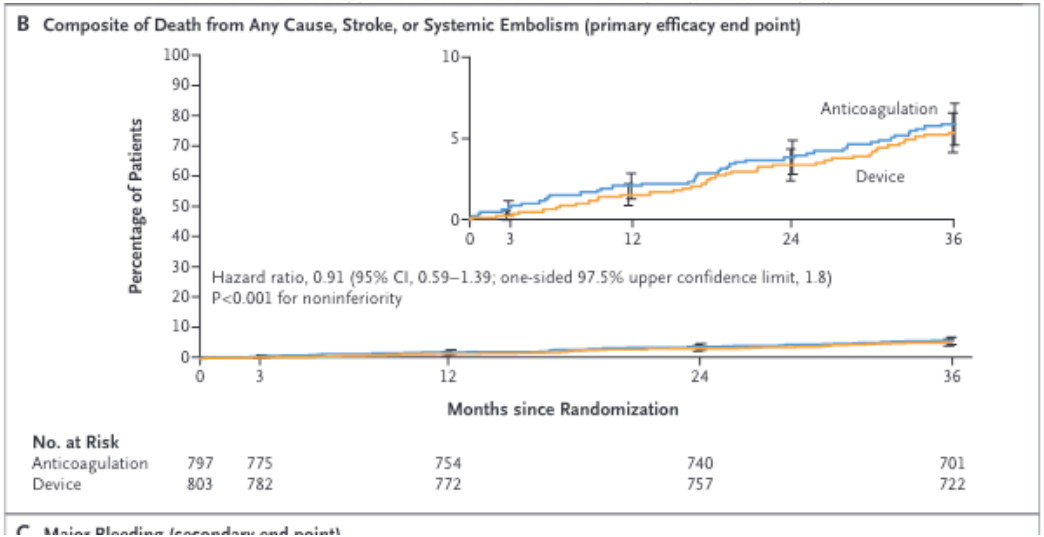

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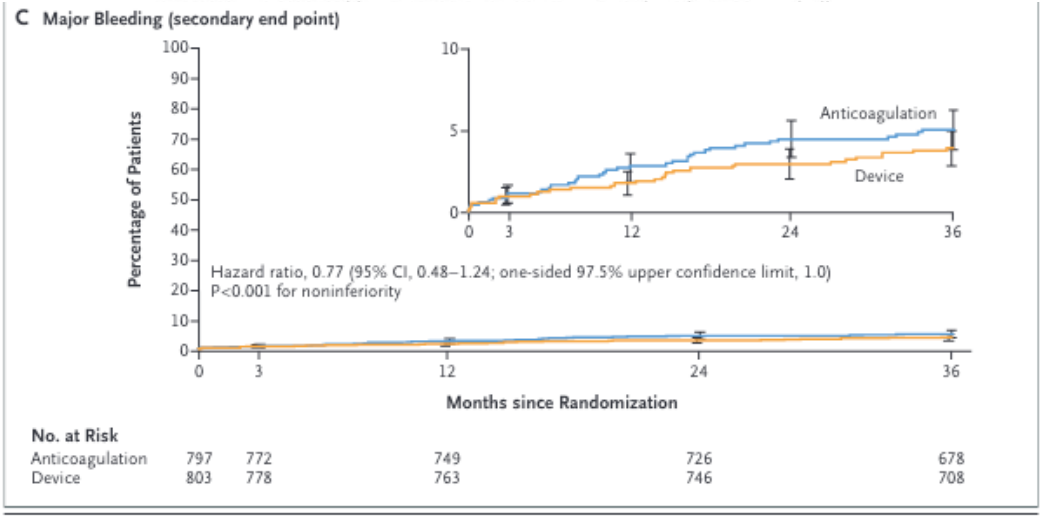

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