



UNIKLINIK
KÖLN

Vorhofflimmern

12.01.2022

HERZFOCUS Wiesbaden | Daniel Steven | Abteilung für Elektrophysiologie

Agenda

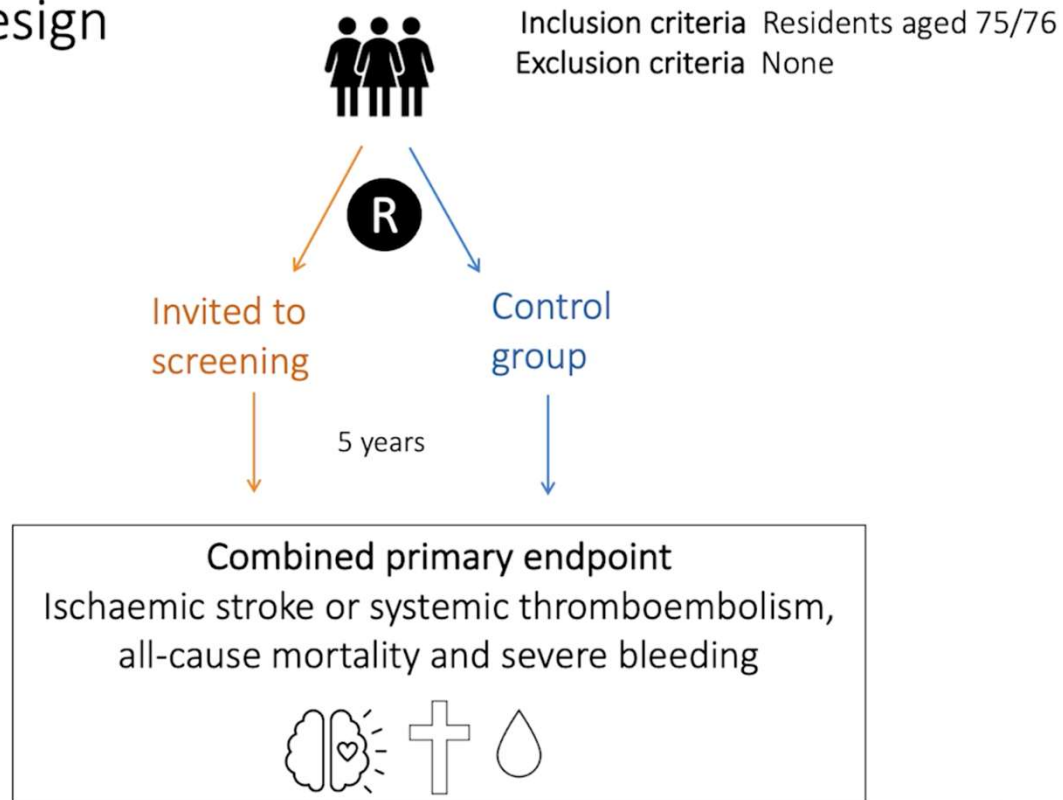
- Schlaganfallprophylaxe
- Prävention
- Mapping
- Ablation

Agenda

- Schlaganfallprophylaxe
- Prävention
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- Ablation

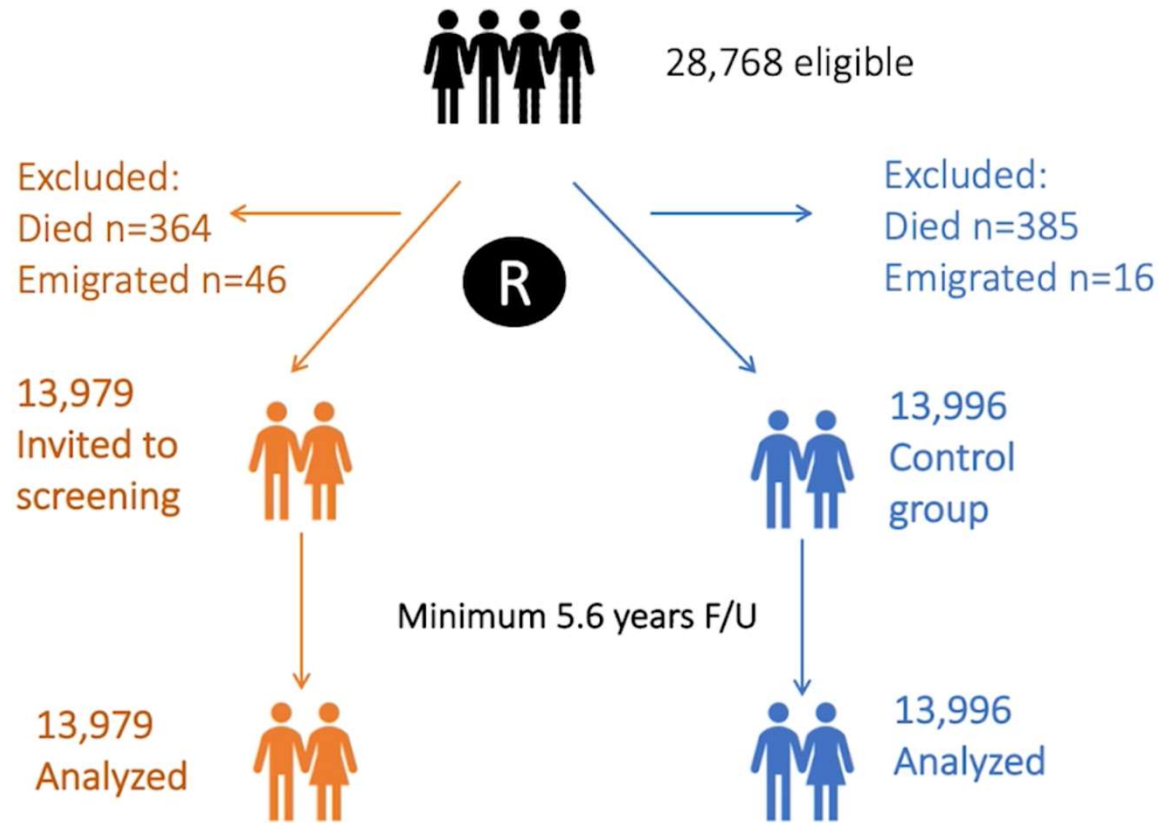
StrokeStop Studie

STROKESTOP - Design



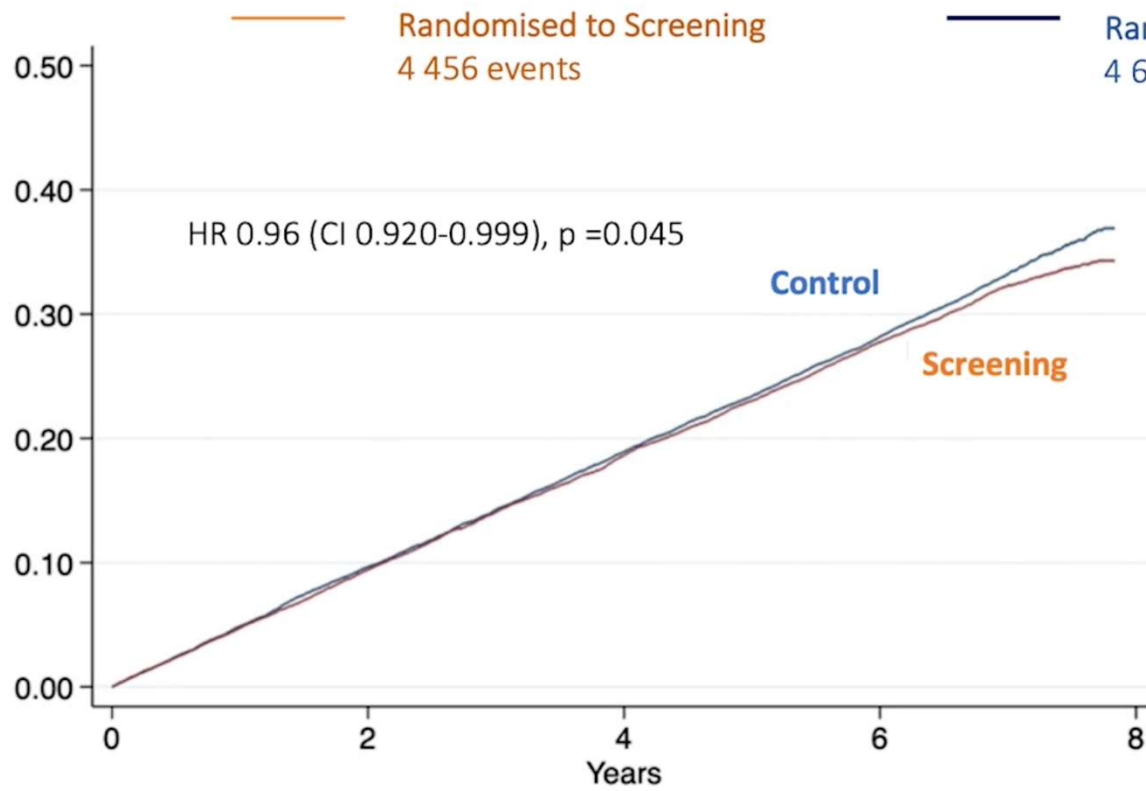
Svennberg et al. Lancet 10.1016/S0140-6736(21)01637-8

StrokeStop



Svennberg et al. Lancet 10.1016/S0140-6736(21)01637-8

StrokeStop Study



NNI 91

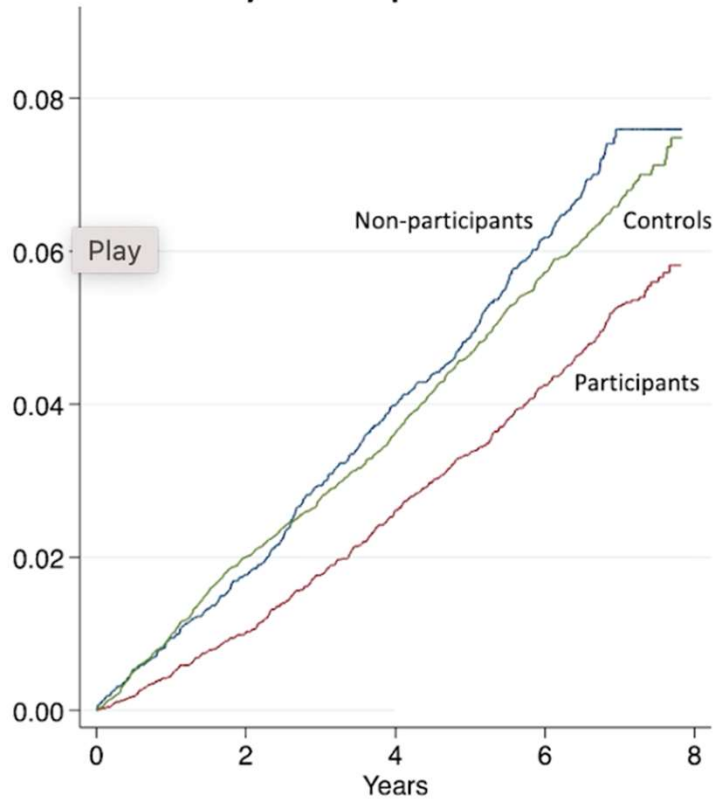
Primary combined endpoint
Ischaemic stroke, systemic
embolism, death from any
cause, haemorrhagic stroke or
hospitalisation for bleeding



Svennberg et al. Lancet 10.1016/S0140-6736(21)01637-8

As treated analysis

Secondary endpoint – As treated



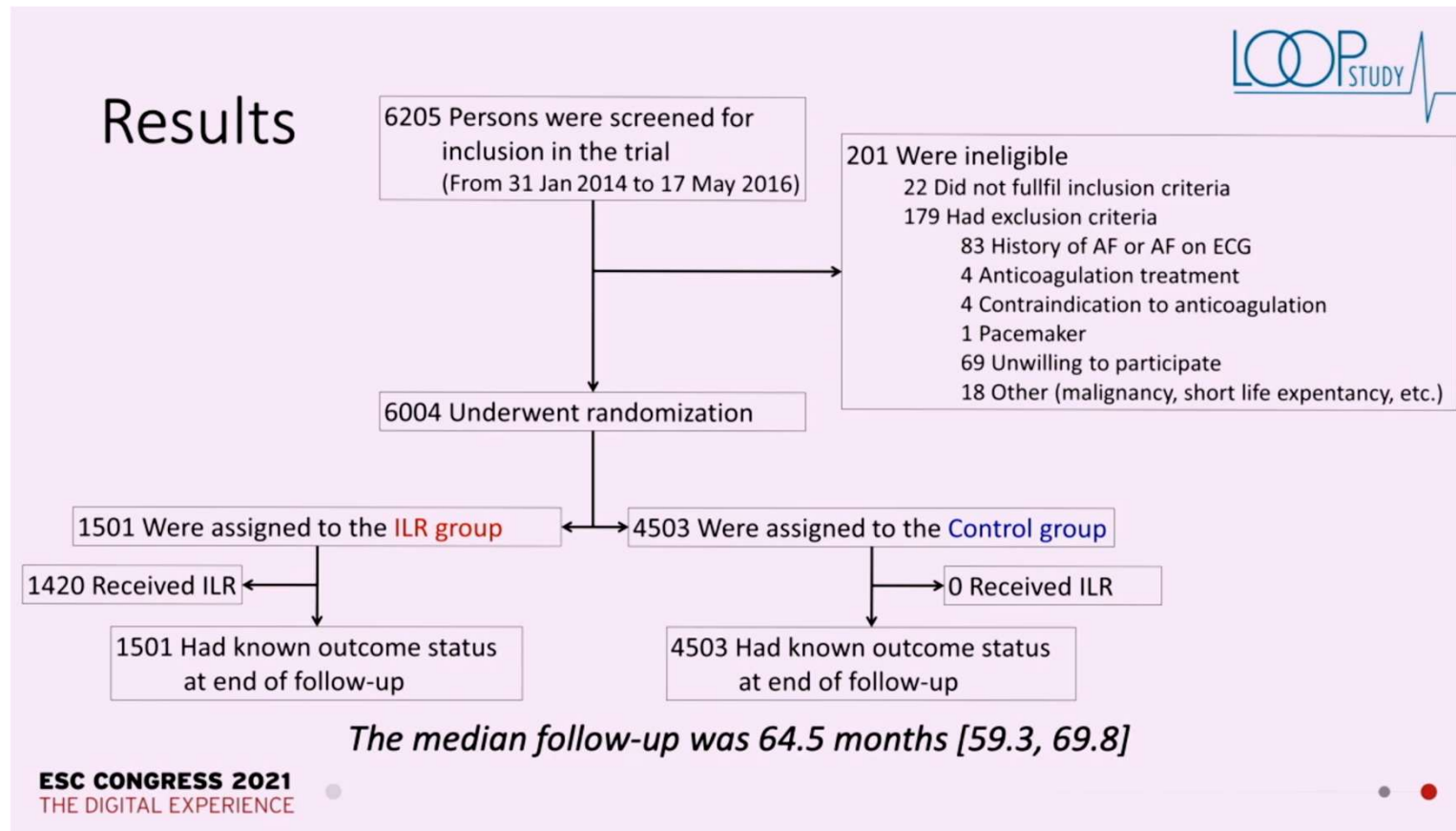
Participants vs. Controls
HR 0.76 (CI 0.68-0.87), $p < 0.001$

Secondary endpoint
Ischaemic stroke



Loop Study

> 70 Jahre, mindestens ein RF (TIA, HTN, DM, HF)

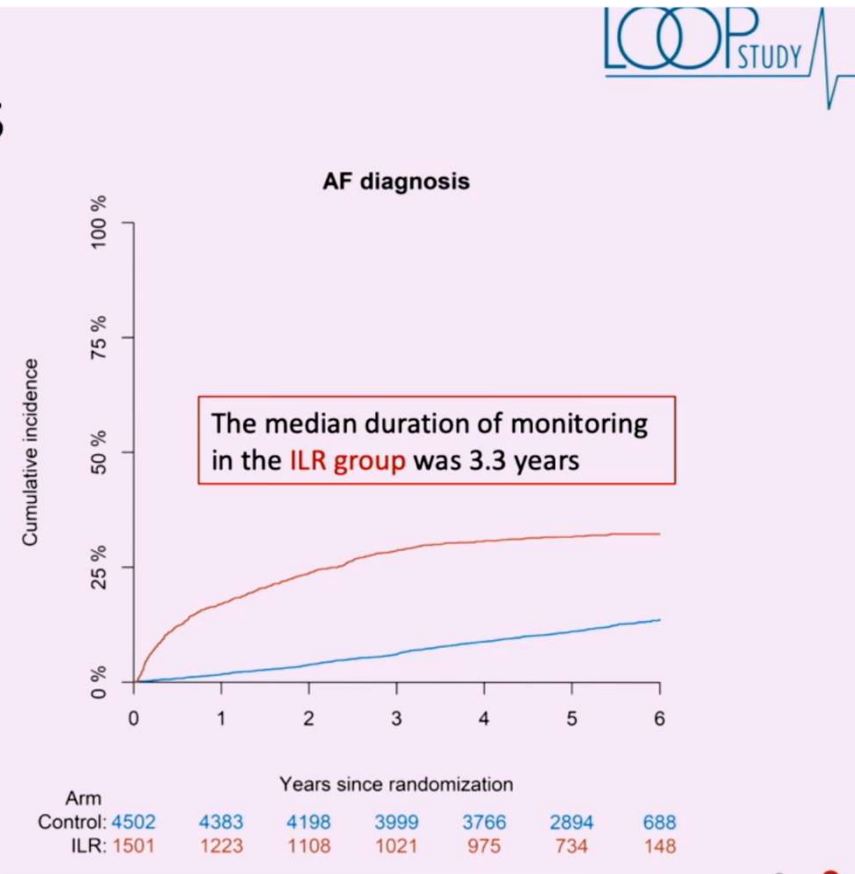


Loop Study

Results – AF Diagnosis

AF was diagnosed in 1,027 participants;
477 (32%) in the **ILR group** vs.
550 (12%) in the **Control group**

HR 3.17; 95% CI 2.81-3.59;
P<0.001



ESC CONGRESS 2021
THE DIGITAL EXPERIENCE

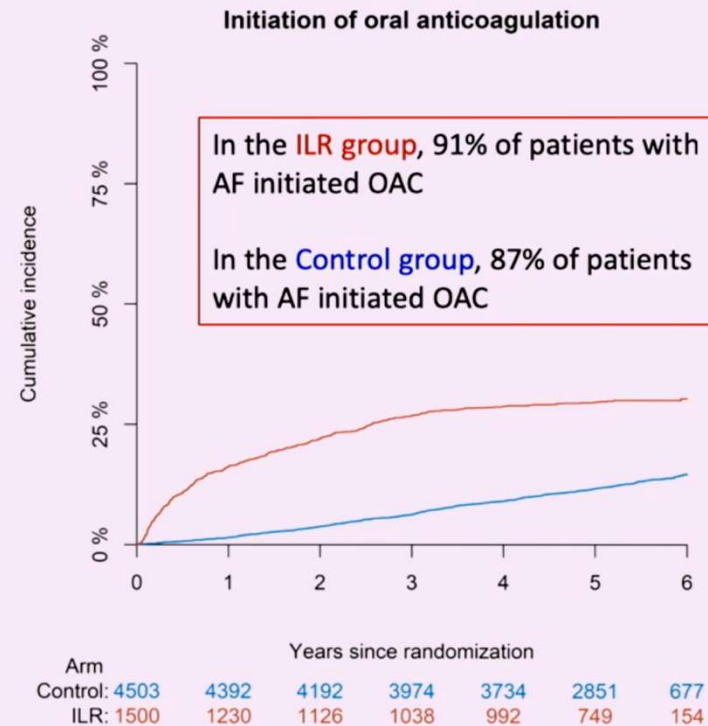
Loop Study



Results – Oral Anticoagulation

Oral anticoagulation (OAC) was initiated in 1,036 participants; 445 (30%) in the **ILR group** vs. 591 (13%) in the **Control group**

HR 2.72; 95% CI 2.41-3.08; P<0.001



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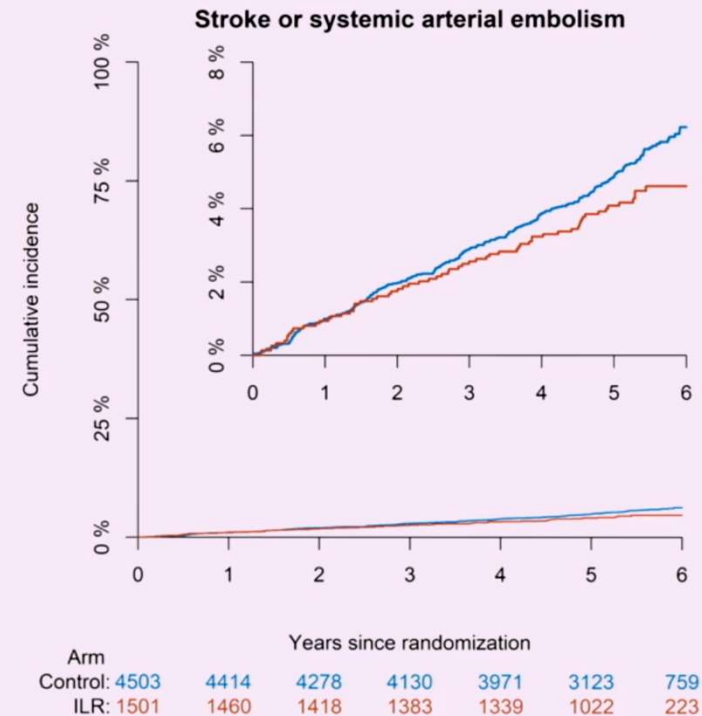


Loop Study

Results – Primary outcome

The primary outcome occurred in 318 participants (315 stroke, 3 systemic arterial embolism);
67 (4.5%) in the **ILR group** vs.
251 (5.6%) in the **Control group**

HR 0.80; 95% CI 0.61-1.05;
P=0.11



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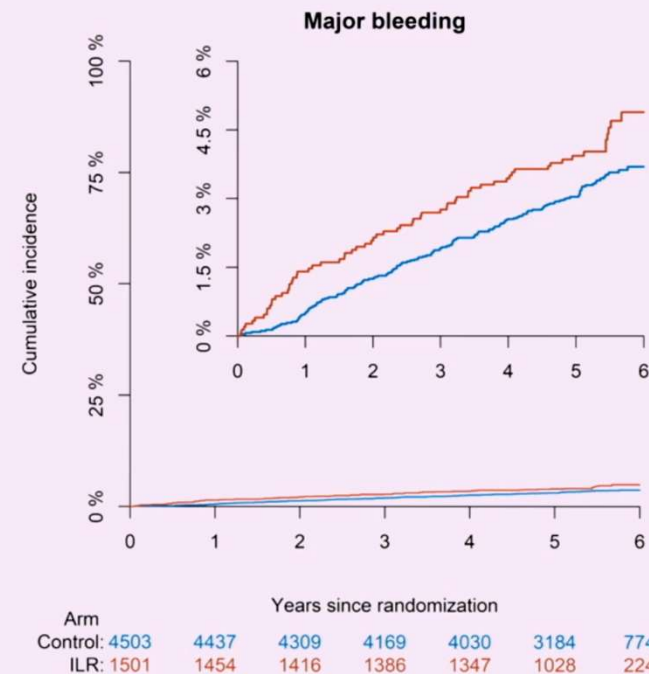
Loop Study

Results – Other outcome (I)

Major bleeding occurred in 221 participants;

65 (4.3%) in the **ILR group** vs.
156 (3.5%) in the **Control group**

HR 1.26; 95% CI 0.95-1.69;
P=0.11



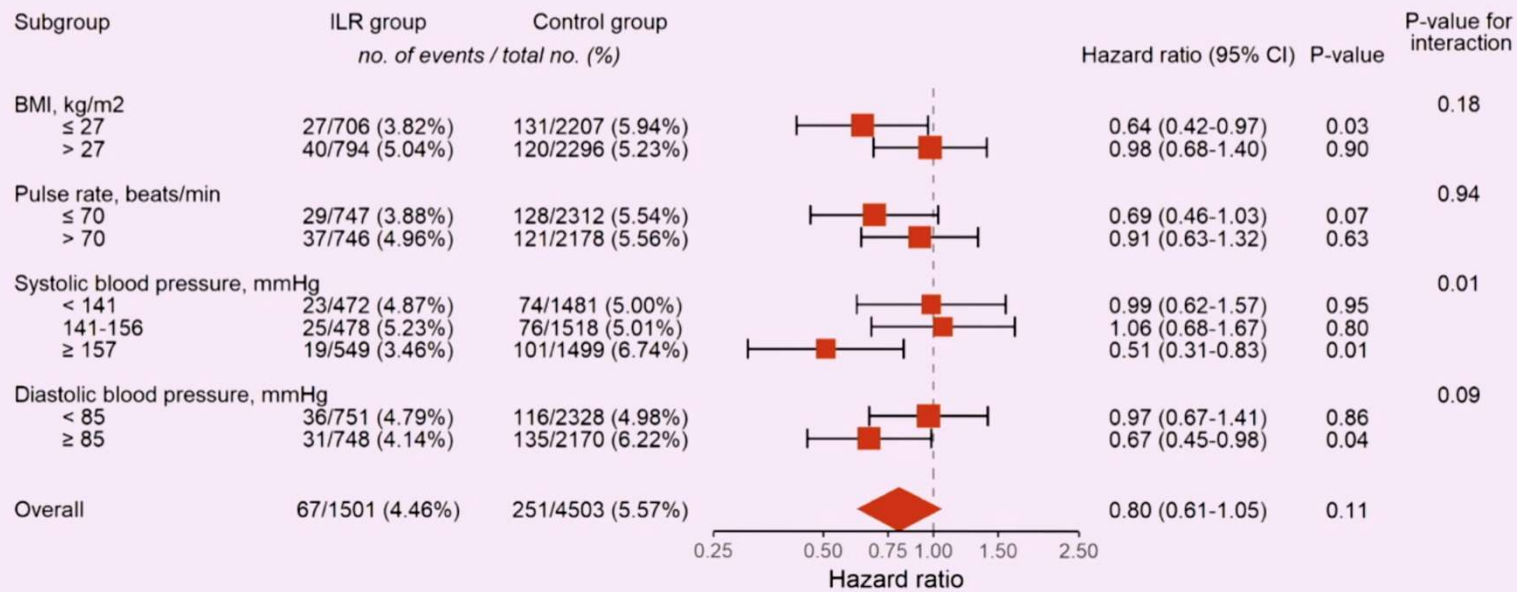
ESC CONGRESS 2021
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Loop Study



Results – Primary outcome, Subgroups

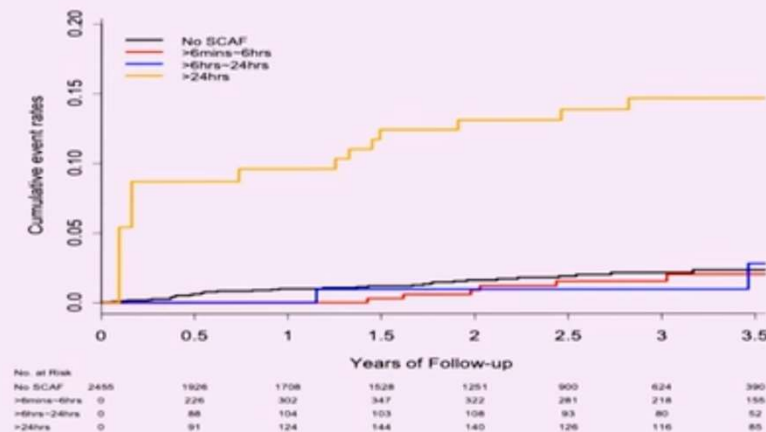


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Warum war Loop negativ?

- ASSERT trial: association of device detected AF and ischaemic stroke
- 2580 patients with hypertension, > 65 yrs, no AF, pacemaker or ICD
- Follow-up: 2.5 years
- Subclinical AF: > 6 min > 190 bpm



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Van Gelder, Healey for the ASSERT Investigators Eur Heart J 2017

NOAH AFNET 4

ARTESiA

Home Page About Us Participants Events News & Media Publications Guidelines Education Contact Us

APIXABAN FOR THE REDUCTION OF THROMBO-EMBOLISM IN PATIENTS WITH DEVICE-DETECTED SUB-CLINICAL ATRIAL FIBRILLATION

ARTESiA Study Participation

Top 10 European Sites
Top 10 North American Sites
NEW Training Modules

Twitter

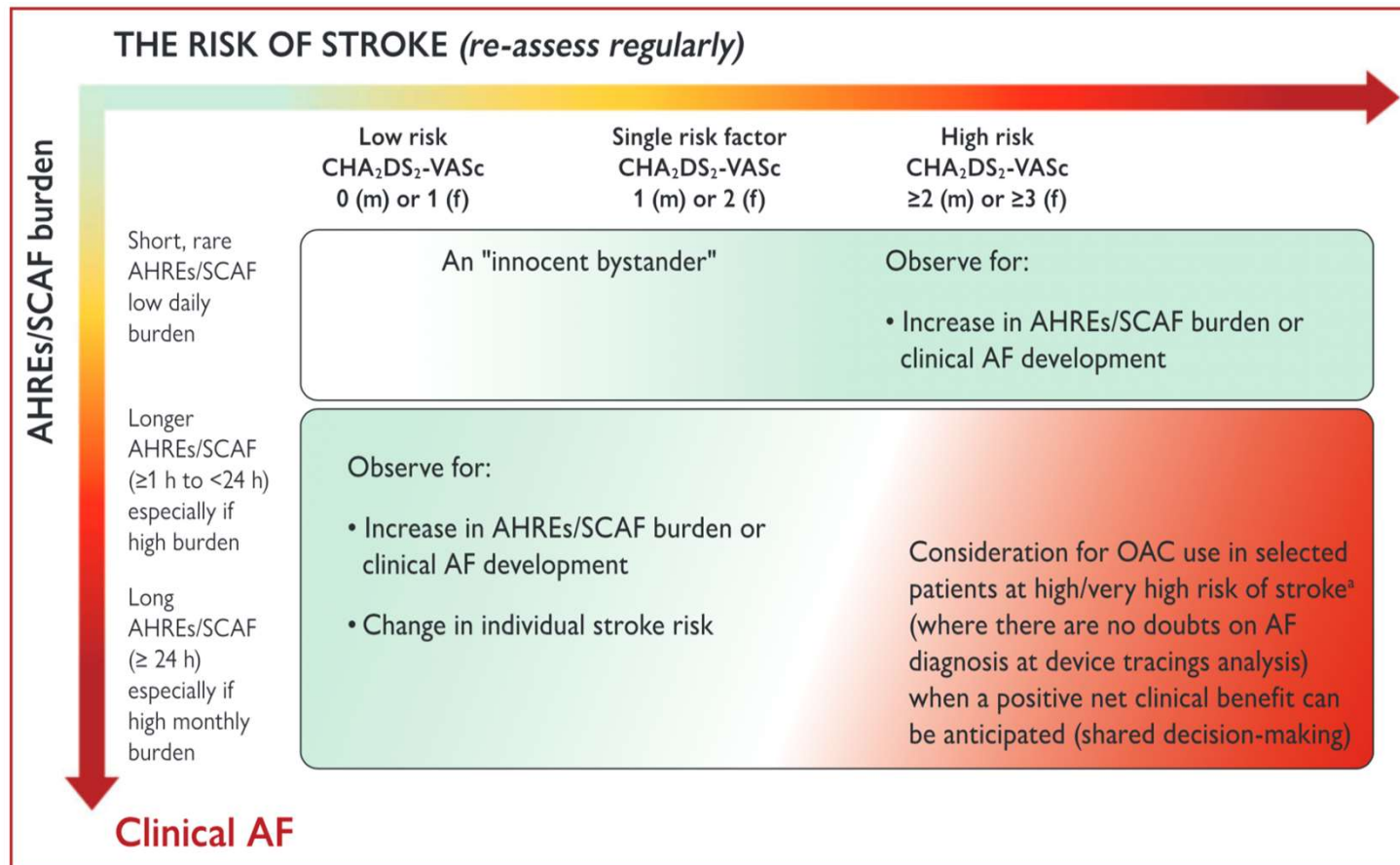
The ARTESiA Trial 🇨🇦 @Artesia_RCT
Congratulations #ARTESiA Dr. Laurence Sterns & Study Team Caitlin, Tanner & Riley from Victoria BC on enrolling the 1000th

NOAH - AFNET 6

Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High rate episodes



Leitlinienempfehlungen



©ESC 2020

Prague- 17 Studie

PRAGUE-17 Randomized Clinical Trial



• 402 High-Risk AF Pts → Randomized
CHA₂DS₂-VASc = 4.7 ± 1.5

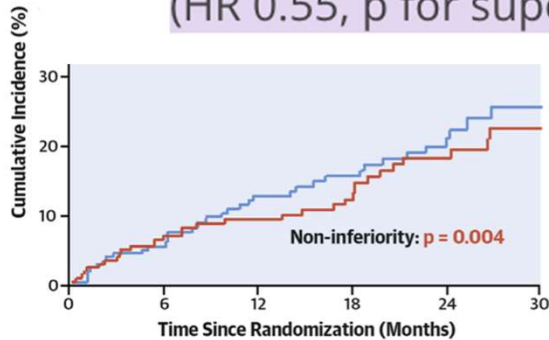


Summary:

- LAAC DOAK nicht unterlegen

Long-term results, median of 3.5 years:

- For the primary outcome, left atrial appendage occlusion was noninferior to a NOAC (HR 0.81, p for superiority = 0.27, p for noninferiority = 0.006).
- For clinically relevant bleeding, left atrial appendage occlusion was superior to a NOAC (HR 0.55, p for superiority = 0.039).



All-Stroke/TIA	1.00 (0.40-2.51)	0.99
CV Death	0.75 (0.34-1.62)	0.46
Major + NMCR Bleeding		
All	0.81 (0.44-1.52)	0.51
Nonprocedural	0.53 (0.26-1.06)	0.07

Procedure duration, min	60 (45-85)
Fluoroscopy, min	11 (6-16)
Device type	
Amulet	111 (61.3)
Watchman	65 (35.9)
Watchman-FLX	5 (2.8)
Procedures requiring >1 device	17 (9.4)

Osmancik P. JACC 2020 Jun 30;75(25):3122-3135.

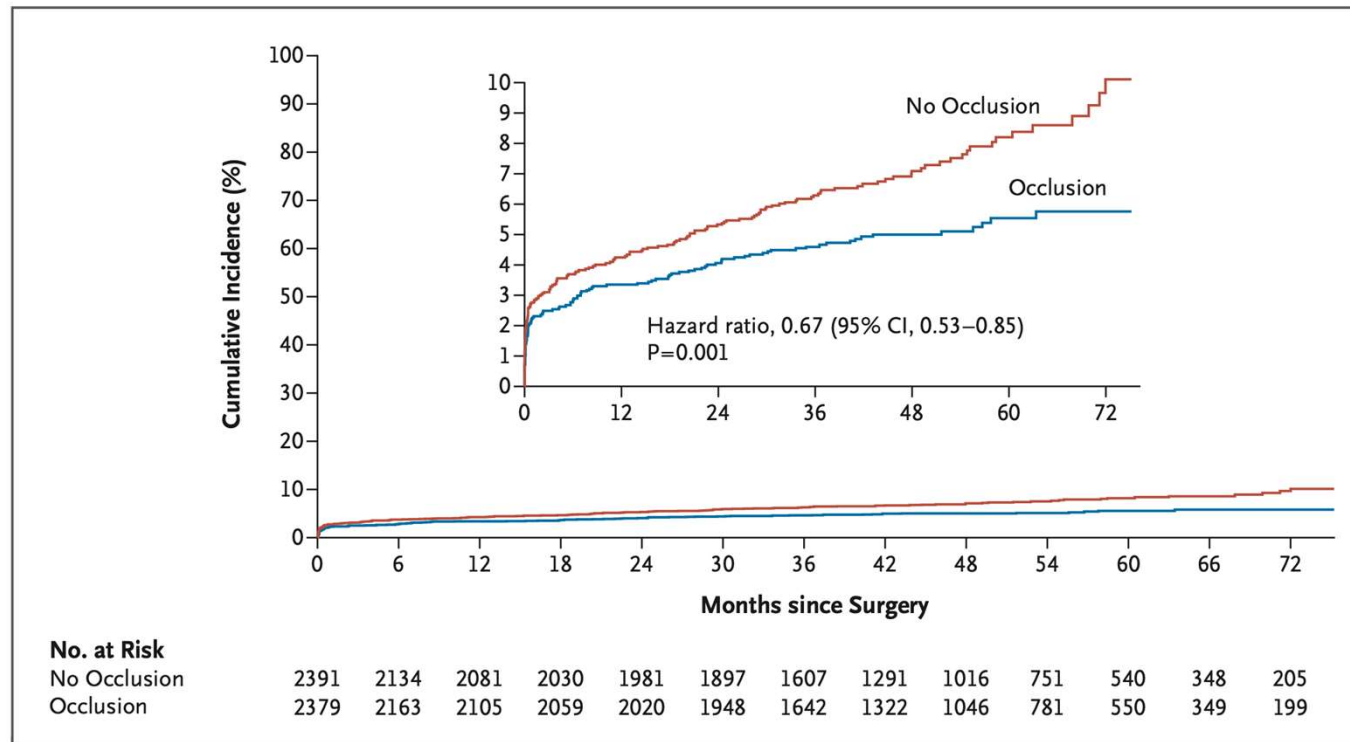


Operativer LAA Verschluss

Variable	Occlusion (N = 2379)	No Occlusion (N = 2391)
Participants		
Age — yr	71.3±8.4	71.1±8.3
Male sex — no. (%)	1617 (68.0)	1601 (67.0)
Type of atrial fibrillation — no. (%)		
Permanent	692 (29.1)	707 (29.6)
Persistent	577 (24.3)	508 (21.3)
Cardiac surgery		
Surgical procedure performed — no. (%)		
Isolated CABG	482 (20.3)	522 (21.8)
Isolated valve replacement	552 (23.2)	572 (23.9)
Other	1344 (56.5)	1296 (54.2)
Any valve procedure		
Mitral	856 (36.0)	880 (36.8)
Aortic	837 (35.2)	858 (35.9)
Tricuspid	397 (16.7)	427 (17.9)
Pulmonic	2 (0.1)	4 (0.2)
Any aortic procedure	146 (6.1)	134 (5.6)
Concomitant surgical ablation of atrial fibrillation — no. (%)	809 (34.0)	753 (31.5)
Received assigned procedure — no. (%)	2131 (89.6)	2262 (94.6)

Whitlock et al. N Engl J Med 2021;384:2081-91.

Operativer LAA Verschluss



Whitlock et al. N Engl J Med 2021;384:2081-91.

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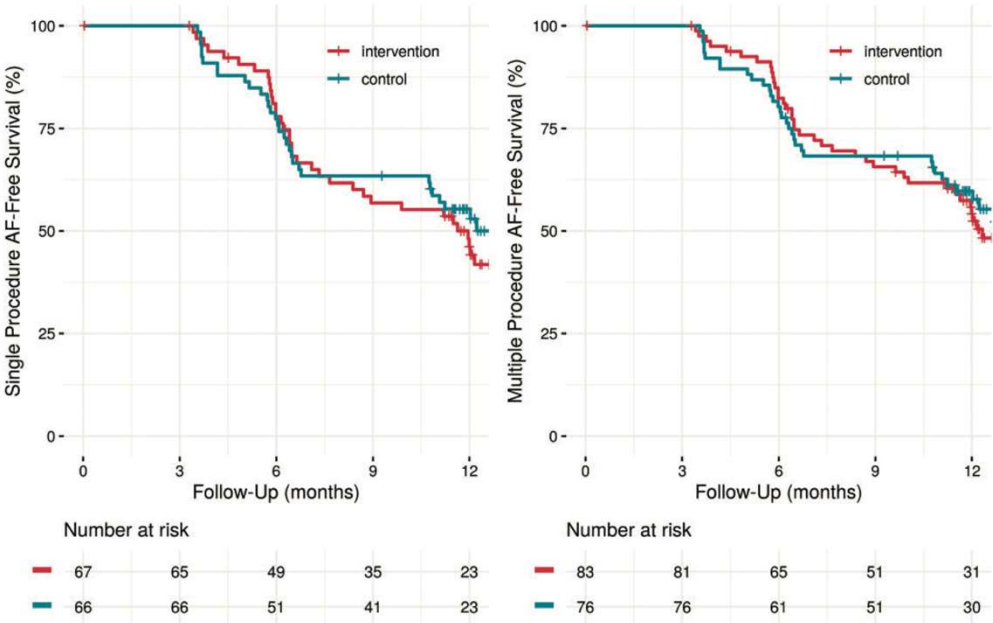
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Gewichtsreduktion

Supervised Obesity Reduction Trial for AF ablation patients: results from the SORT-AF trial

Nele Gessler^{1,2,3}, Stephan Willems ^{1,3,4,*†}, Daniel Steven ⁵, Jens Aberle⁶,
 Ruken Oezge Akbulak^{1,3}, Nils Gosau^{1,3}, Boris A. Hoffmann⁷, Christian Meyer ^{3,8,9},
 Arian Sultan⁵, Roland Titz^{3,10}, Julia Vogler^{3,10}, Peter Wohlmuth¹¹, Susanne Scholz^{1,2},
 Melanie A. Gunawardene^{1,3}, Christian Eickholt^{1,3}, and Jakob Lüker⁵



- Gewichtsreduktion erhöht die AF Freiheit
- Gewichtsreduktion schwer zu halten

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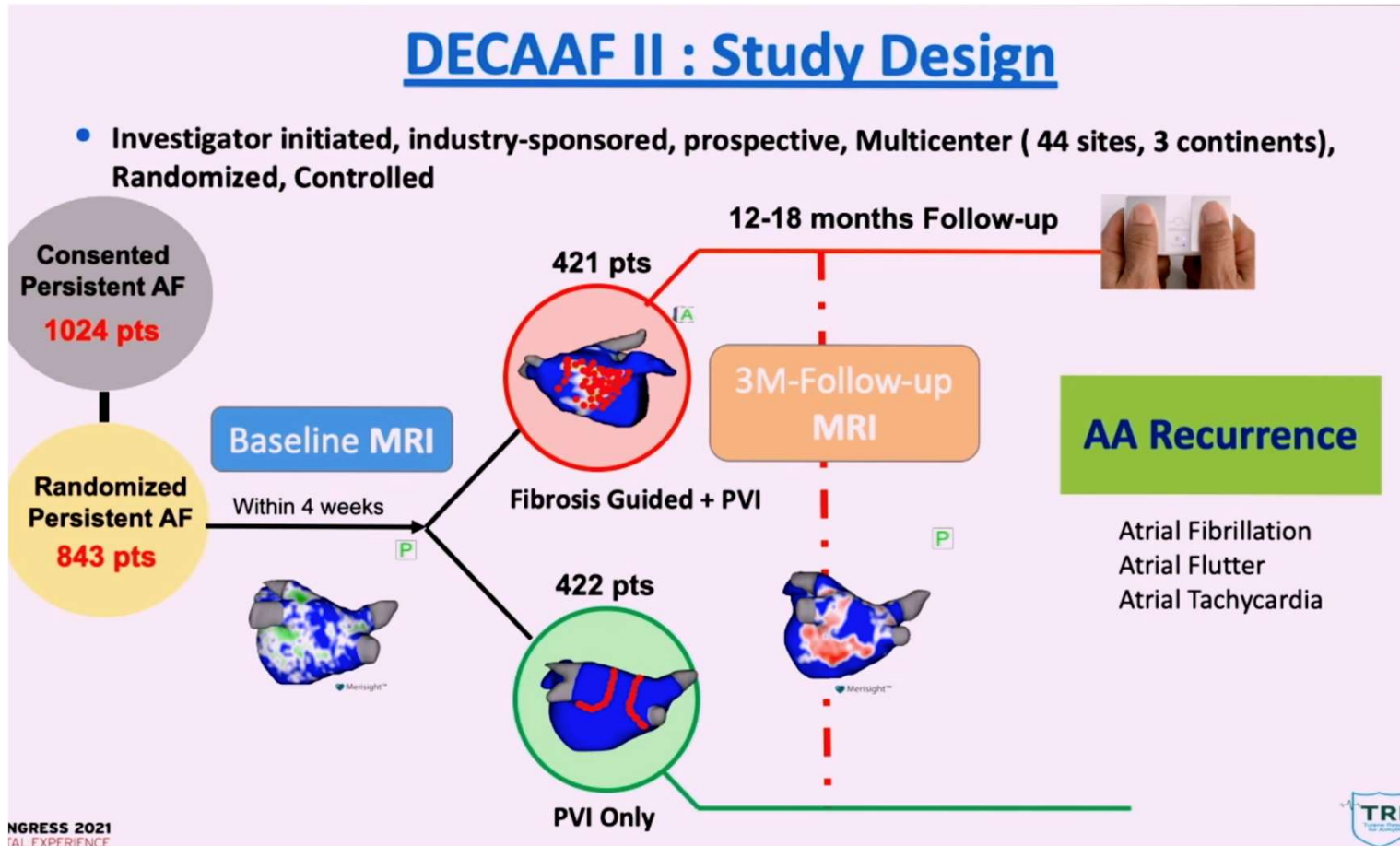
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Was machen wir nach der PVI?

Posterior Wall ablation	IIb
High dose isoproterenol	IIb
Dominant frequency guided ablation	IIb
Linear lesions	IIb
Substrate- based ablation	IIb
Complex fractionated electrogram	IIb
Rotorablation	IIb
Autonome Ganglien	IIb

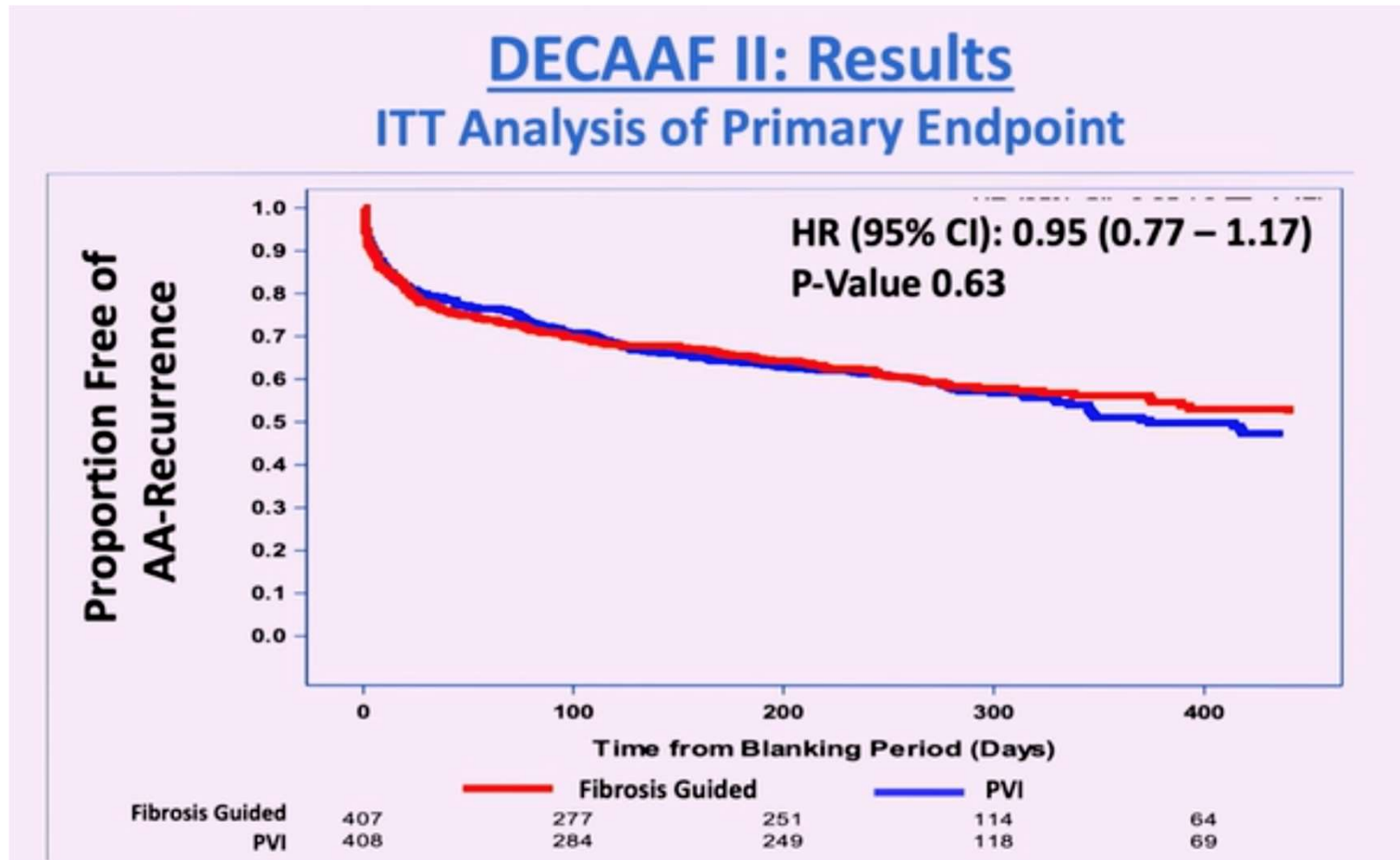
Calkins et al. 10.1093/europace/eux275

Decaaf II



Marrouche ESC 2021

Decaaf II -outcome



Marrouche ESC 2021

Safety outcome

DECAAF II: Results

Safety Outcomes within 30 Days Post Ablation

Safety Outcomes	Fibrosis-Guided		Conventional PVI	P-Value
	N (%)	N (%)	N (%)	
Bleeding requiring transfusion	1 (0.2%)	0 (0%)	0 (0%)	0.485
Heart Failure	1 (0.2%)	0 (0%)	0 (0%)	0.485
Pulmonary Vein Stenosis	0 (0%)	0 (0%)	0 (0%)	NA
Stroke/TIA	6 (1.5%)	0 (0%)	0 (0%)	0.013
Death	2 (0.5%)	0 (0%)	0 (0%)	0.235
Perforation/Tamponade	5 (1.2%)	5 (1.2%)	5 (1.2%)	1.000

Marrouche ESC 2021

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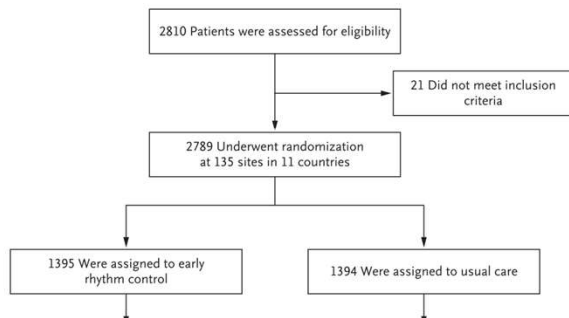
- Schlaganfallprophylaxe
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Early Rhythm Control

ORIGINAL ARTICLE

Early Rhythm-Control Therapy in Patients with Atrial Fibrillation

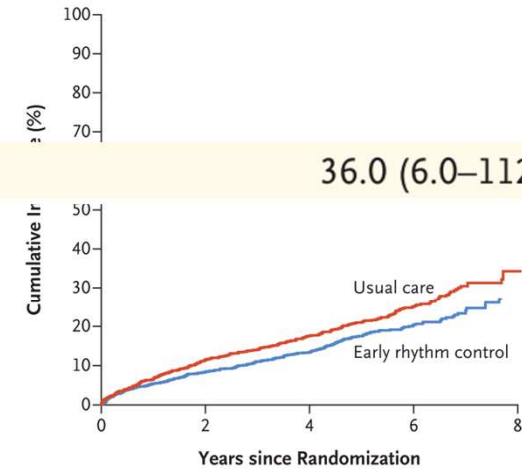
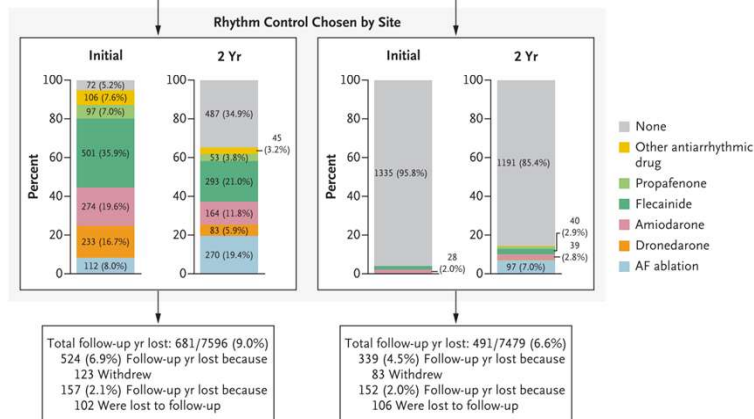
P. Kirchhof, A.J. Camm, A. Goette, A. Brandes, L. Eckardt, A. Elvan, T. Fetsch, I.C. van Gelder, D. Haase, L.M. Haegeli, F. Hamann, H. Heidbüchel, G. Hindricks, J. Kautzner, K.-H. Kuck, L. Mont, G.A. Ng, J. Rekosz, N. Schoen, U. Schotten, A. Suling, J. Taggeselle, S. Themistoclakis, E. Vettorazzi, P. Vardas, K. Wegscheider, S. Willems, H.J.G.M. Crijns, and G. Breithardt, for the EAST-AFNET 4 Trial Investigators*



Median days since atrial fibrillation diagnosis (IQR)‡

36.0 (6.0–114.0)

36.0 (6.0–112.0)



No. at Risk

	0	2	4	6	8
Usual care	1394	1169	888	405	34
Early rhythm control	1395	1193	913	404	26

The first primary outcome was a composite of death from cardiovascular causes, stroke, or hospitalization with worsening of heart failure or acute coronary syndrome.

Early AF

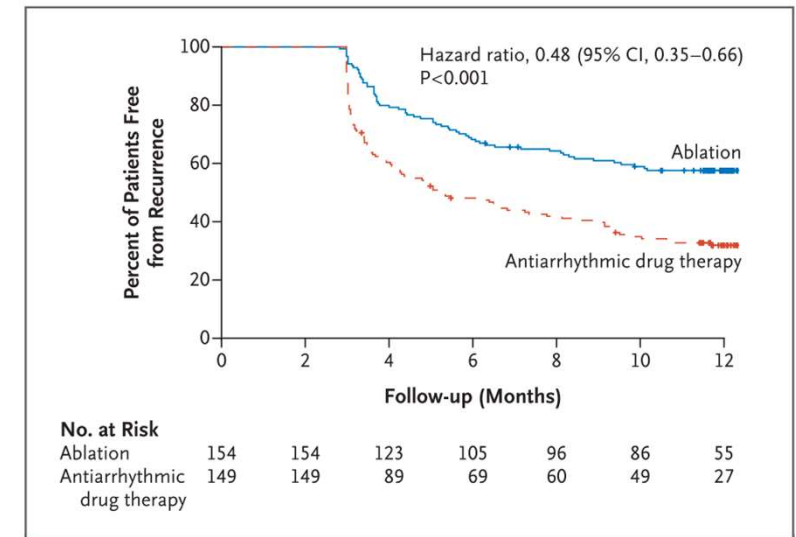
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Ablation Group (N=154)	Antiarrhythmic Drug Group (N=149)
Age — yr	57.7±12.3	59.5±10.6
Male sex — no. (%)	112 (72.7)	102 (68.5)
BMI†	30.9±14.2	29.7±9.3
Obesity — no. (%)‡	56 (36.4)	53 (35.6)
Tobacco use	8 (5.2)	10 (6.7)
Blood pressure — mm Hg		
Systolic	129.1±18.1	129.3±15.7
Diastolic	78.4±10.6	78.0±9.8
Median yr since diagnosis of atrial fibrillation (IQR)	1 (0–3)	1 (0–4)
Paroxysmal atrial fibrillation — no. (%)	147 (95.5)	140 (94.0)
Symptomatic atrial fibrillation episodes/mo — median (IQR)	3 (1–10)	3 (1–10)
Previous cardioversion — no. (%)	56 (36.4)	63 (42.3)
Quality-of-life scores		
AFEQT score§	61.4±19.7	57.4±20.6
EQ-5D score¶	0.77±0.26	0.75±0.26
EQ-VAS score	75.4±14.5	74.4±16.5
CCS-SAF score of 3 or 4 — no. (%)**	84 (54.5)	84 (56.4)

ORIGINAL ARTICLE

Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation

Jason G. Andrade, M.D., George A. Wells, Ph.D., Marc W. Deyell, M.D., Matthew Bennett, M.D., Vidal Essebag, M.D., Ph.D., Jean Champagne, M.D., Jean-Francois Roux, M.D., Derek Yung, M.D., Allan Skanes, M.D., Yaariv Khaykin, M.D., Carlos Morillo, M.D., Umjeet Jolly, M.D., Paul Novak, M.D., Evan Lockwood, M.D., Guy Amit, M.D., Paul Angaran, M.D., John Sapp, M.D., Stephan Wardell, M.D., Sandra Lauck, Ph.D., Laurent Macle, M.D., and Atul Verma, M.D., for the EARLY-AF Investigators*



Andrade et al 10.1056/NEJMoa2029980

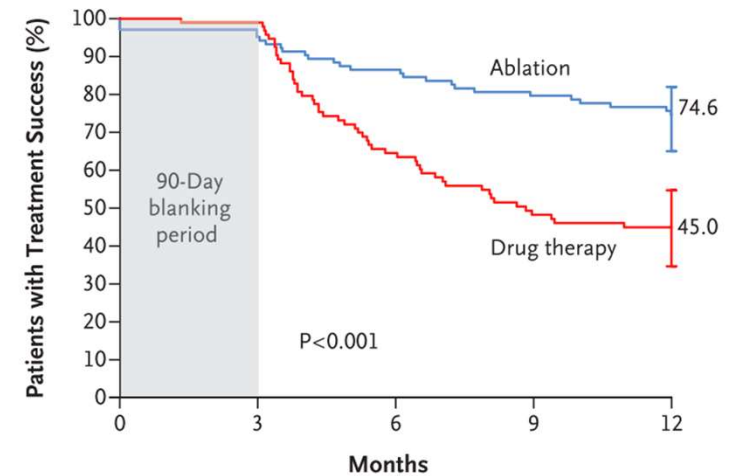
Stop AF First

Cryoballoon Ablation as Initial Therapy for Atrial Fibrillation

Oussama M. Wazni, M.D., Gopi Dandamudi, M.D., Nitesh Sood, M.D., Robert Hoyt, M.D., Jaret Tyler, M.D., Sarfraz Durrani, M.D., Mark Niebauer, M.D., Kevin Makati, M.D., Blair Halperin, M.D., Andre Gauri, M.D., Gustavo Morales, M.D., Mingyuan Shao, Ph.D., Jeffrey Cerkenik, M.S., Rachelle E. Kaplon, Ph.D., and Steven E. Nissen, M.D., for the STOP AF First Trial Investigators*

Table 1. Characteristics of the Patients.*

Characteristic	Ablation (N=104)	Drug Therapy (N=99)
Age — yr	60.4±11.2	61.6±11.2
Male sex — no. (%)	63 (61)	57 (58)
Time since paroxysmal atrial fibrillation onset — yr	1.3±2.5 [†]	1.3±2.3 [‡]
Left atrial diameter — mm	38.7±5.7	38.2±5.4 [‡]
Left ventricular ejection fraction — %	60.9±6.0	61.1±5.9 [‡]

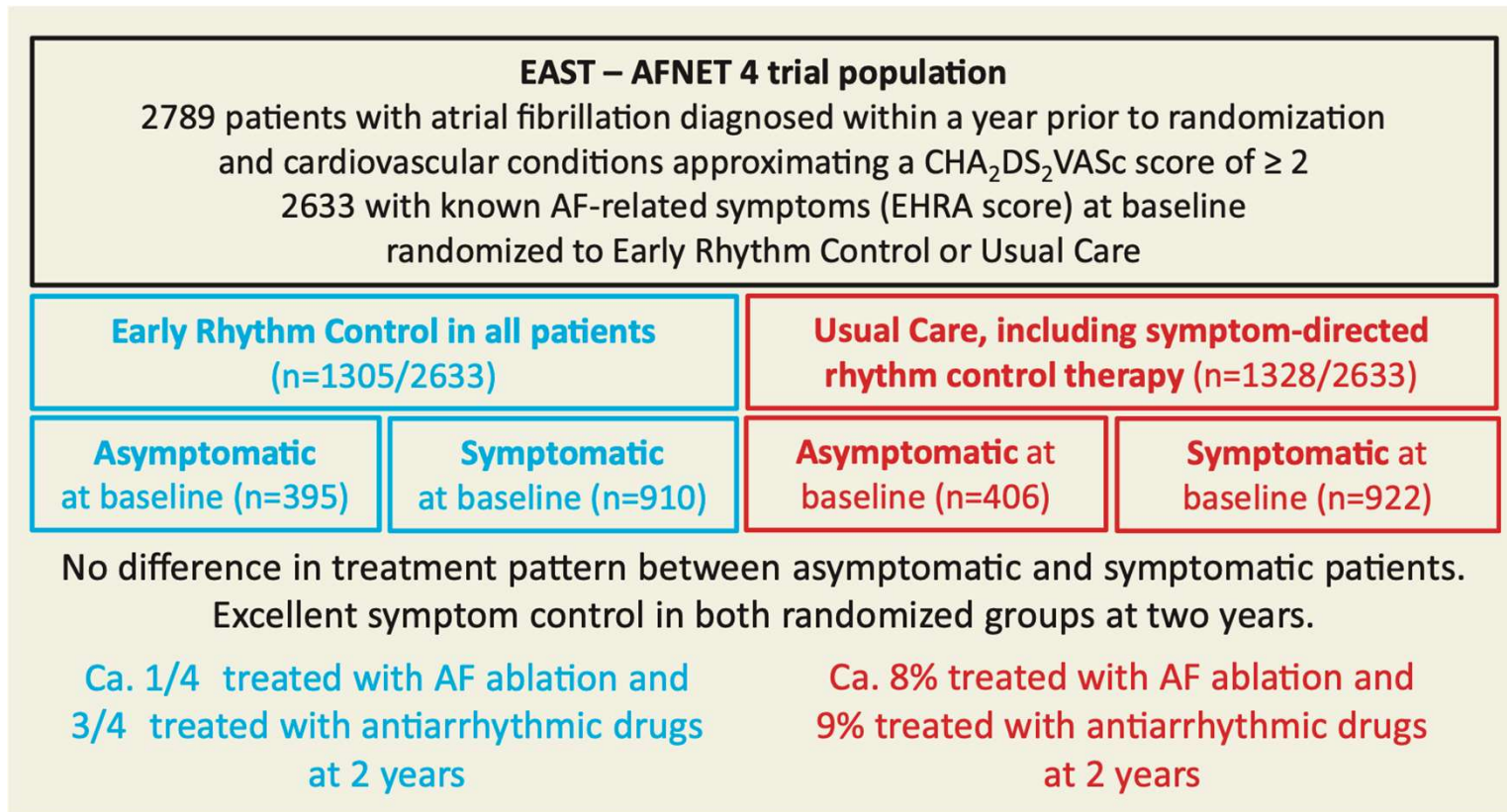


No. at Risk

Ablation	104	99	88	81	70
Drug therapy	99	93	60	44	39

Wazni et al. 10.1056/NEJMoa2029554

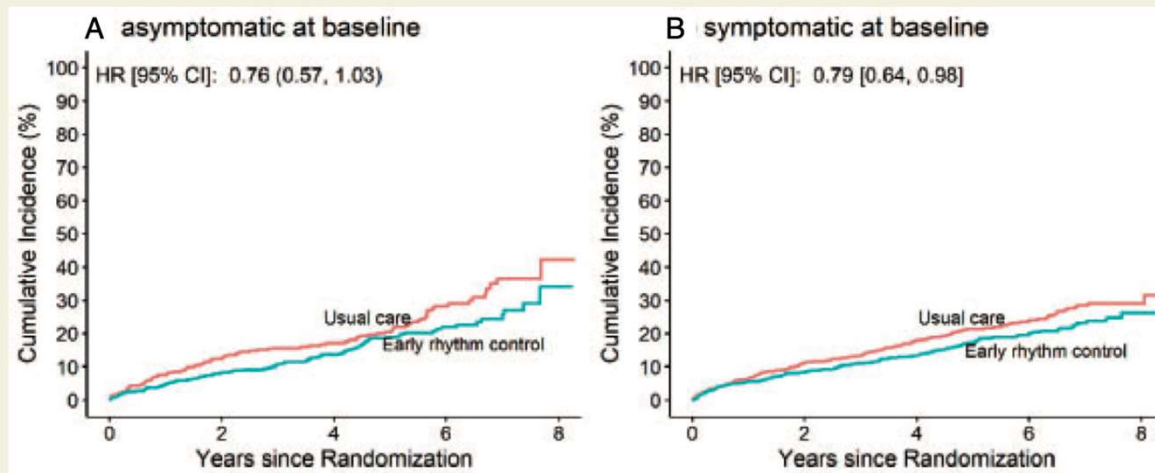
EAST AFNET 4



Willems et al. 10.1093/eurheartj/ehab593

EAST AFNET 4

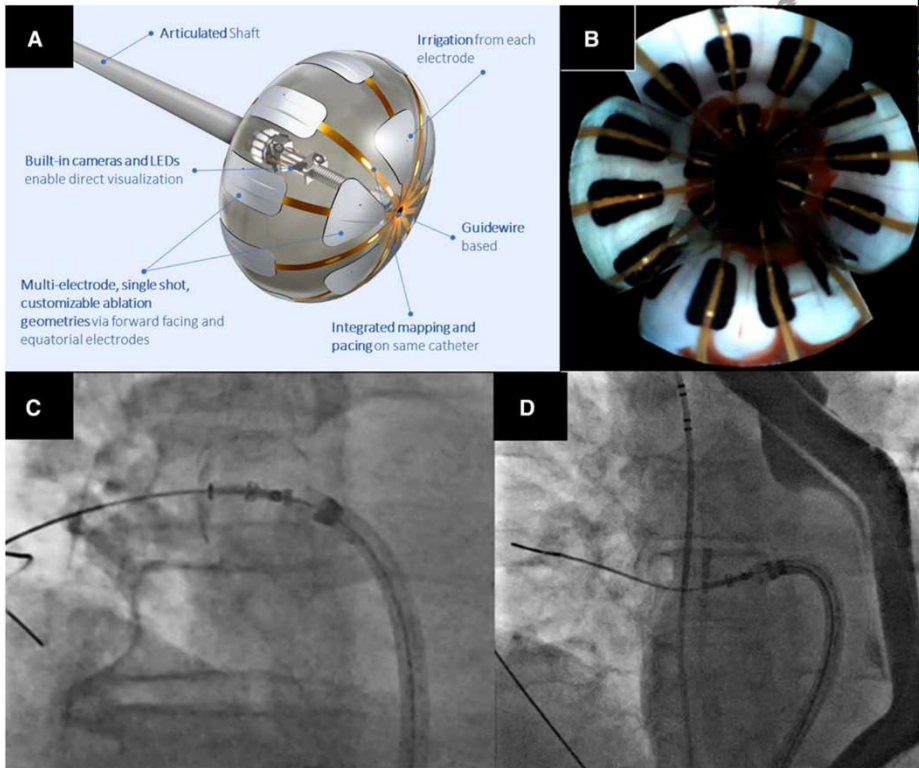
Similar reduction of cardiovascular death, stroke, or hospitalisation for heart failure or acute coronary syndrome in symptomatic and asymptomatic patients



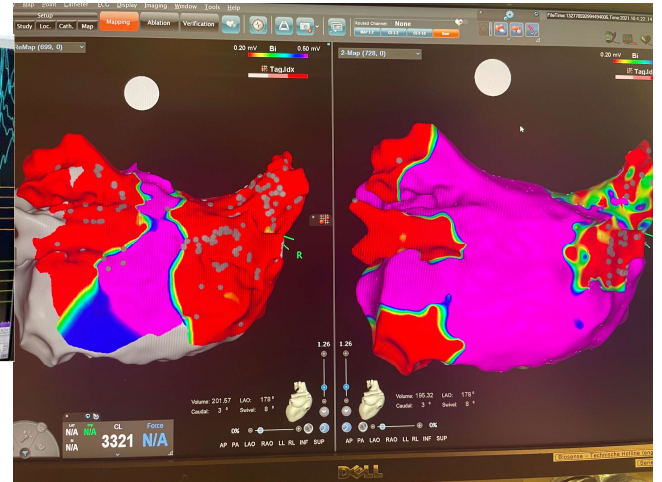
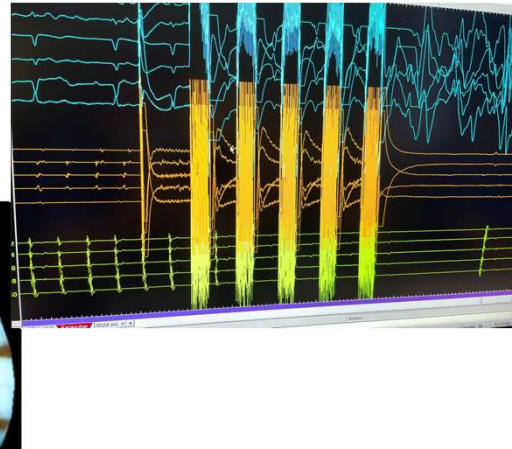
Our findings support the systematic, early initiation of rhythm control therapy in asymptomatic patients with atrial fibrillation and concomitant cardiovascular conditions.

Willems et al. 10.1093/eurheartj/ehab593

„New tools on the block“



Reddy et al., 2021, JACC EP



Daniel Steven
@danielsteven_ep

First Heliostar procedures @UKKoeln: First time combination of RF ablation and balloon technology. A learning curve certainly applies, however results are already impressive on the first day! @woerjon @JvdBruck @AriSultanEP @LukerJakob @karlo_ep @jongichun



ORIGINAL ARTICLE

Pulmonary Vein Isolation With a Novel Multielectrode Radiofrequency Balloon Catheter That Allows Directionally Tailored Energy Delivery

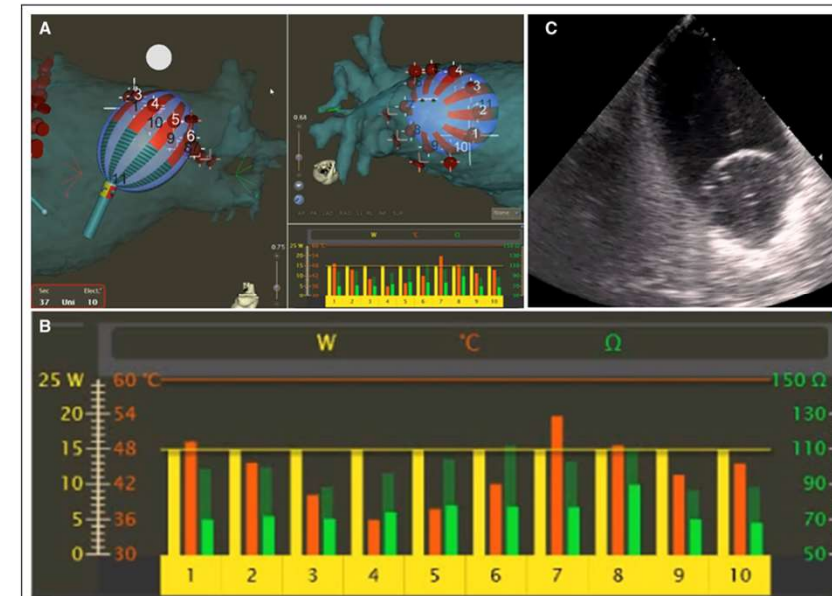
Short-Term Outcomes From a Multicenter First-in-Human Study (RADIANCE)

Table 2. Procedural Details (Table view)

	Study Cohort (n=39)
No. of RF applications per patient (mean±SD)	7.3±2.62
Patients with routine bonus lesions, n (%)	18/39 (46.2%)
Overall procedure duration, min (mean±SD, n=35)	101.6±29.4
Ablation procedure time,* min (mean±SD, n=35)	36.7±17.1
Fluoroscopy duration, min (mean±SD, n=36)	17.4±10.14
Balloon dwell time, min (mean±SD, n=36)	40.5±11.5
Total saline delivered, mL (mean±SD, n=37)	1450.8±540.7
Saline delivered via the RFB, mL (mean±SD, n=37)	885.9±425.3
PV isolation outcomes	
PVs isolated with the RFB alone, %	100 (152/152)
PVs isolated with 1st application by RFB, %	79.6 (109/137)
PVs reconnected with adenosine, %	4.6 (7/150)

RFB indicates radiofrequency balloon; PV, pulmonary vein.

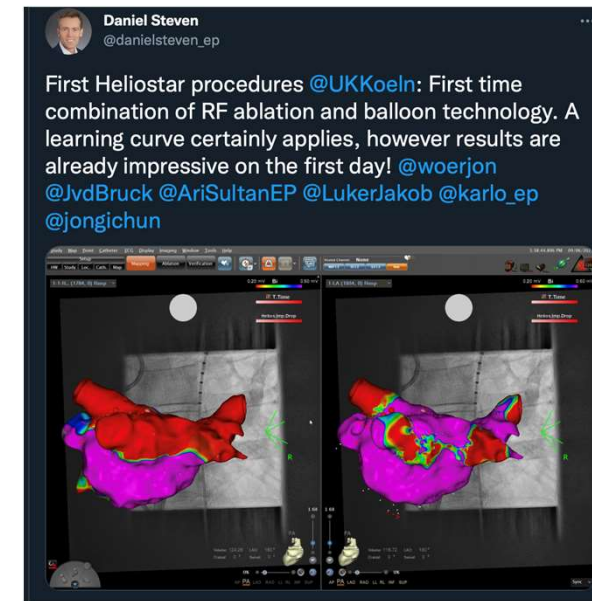
* Defined as the time transpiring from the start of the first application to the end of the last application.



Single shot RF Ablation

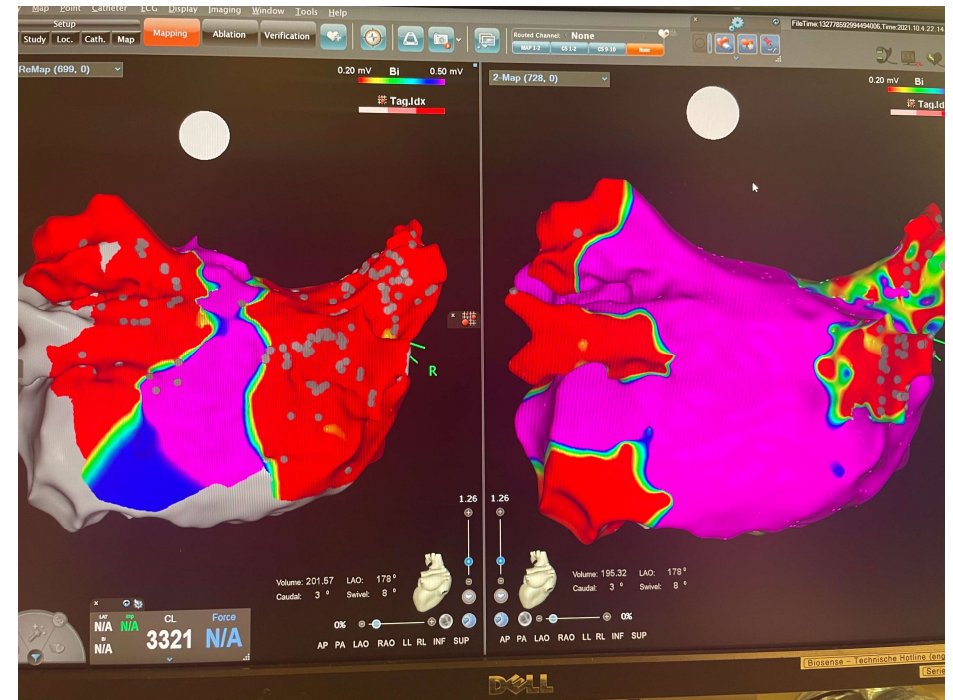
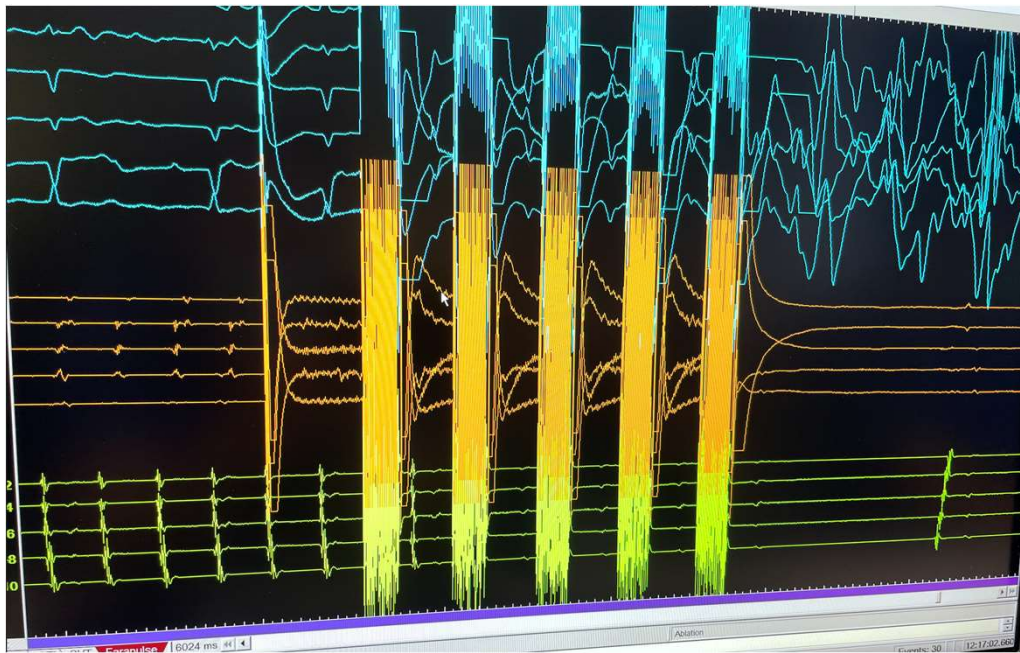


	Heliostar	HPSD
Anzahl Patienten	17	38
RF Abgabe/ Vene (à 60s)	2,8	n/a
Ösophagus (mean max Temp. °C)	40,2	39,5
Prozedurdauer(min)	111±28	100±25
Zeit im LA	90±23	80±26
Fluorotime (min)	17±4	13±5
Freiheit von AF @ 3 months (%)	100	79





Farapulse



Zusammenfassung

Effektivität LAA Verschluss weiterhin unklar

Patienten, für die ein Screening effektiv ist, müssen noch besser stratifiziert sein

Weitere Studien zur Einordnung der AHRE am Horizont

Frühe Rhythmuskontrolle kann harte Endpunkte auch bei asymptomatischen Patienten beeinflussen

Katheterablation als first line Therapie sehr effektiv



rhythmologie@uk-koeln.de



[danielsteven_ep](https://twitter.com/danielsteven_ep)



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