ESC2023 - EP trials

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ADVENT

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

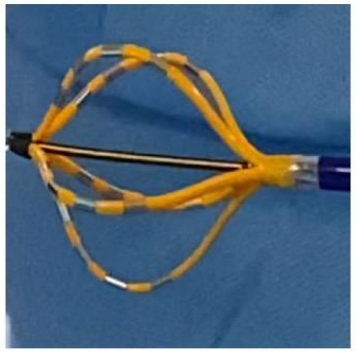
Pulsed field ablation (PFA)

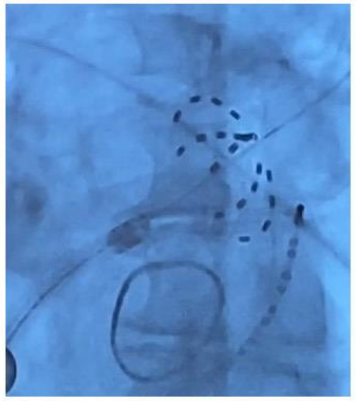
- Pulsed field ablation is a largely nonthermal energy approach that involves the use of micro second-scale, high-voltage electrical fields to cause irreversible electroporation and destabilization of cell membranes, a process that culminates in cellular necrosis.

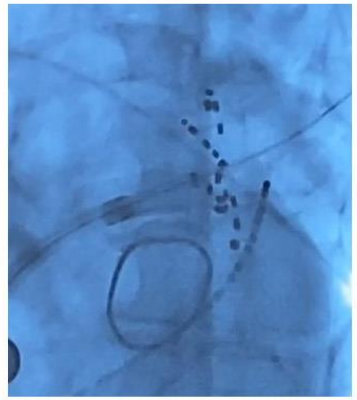
- Preclinical and clinical studies have shown that pulsed field ablation has a degree of ablative specificity that allows myocardial tissue to be preferentially ablated with limited effects on adjacent tissues such as the esophagus, phrenic nerve, and pulmonary vein tissue.

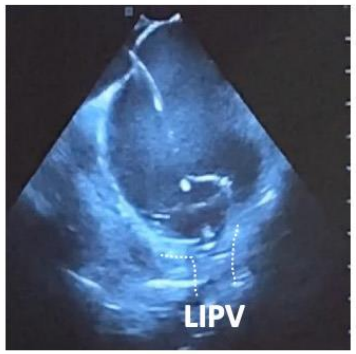
Basket

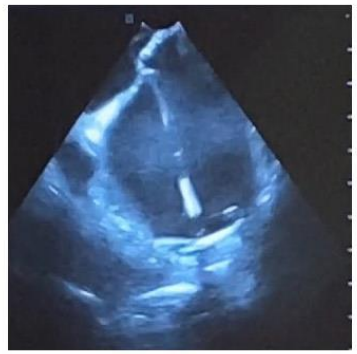
Flower

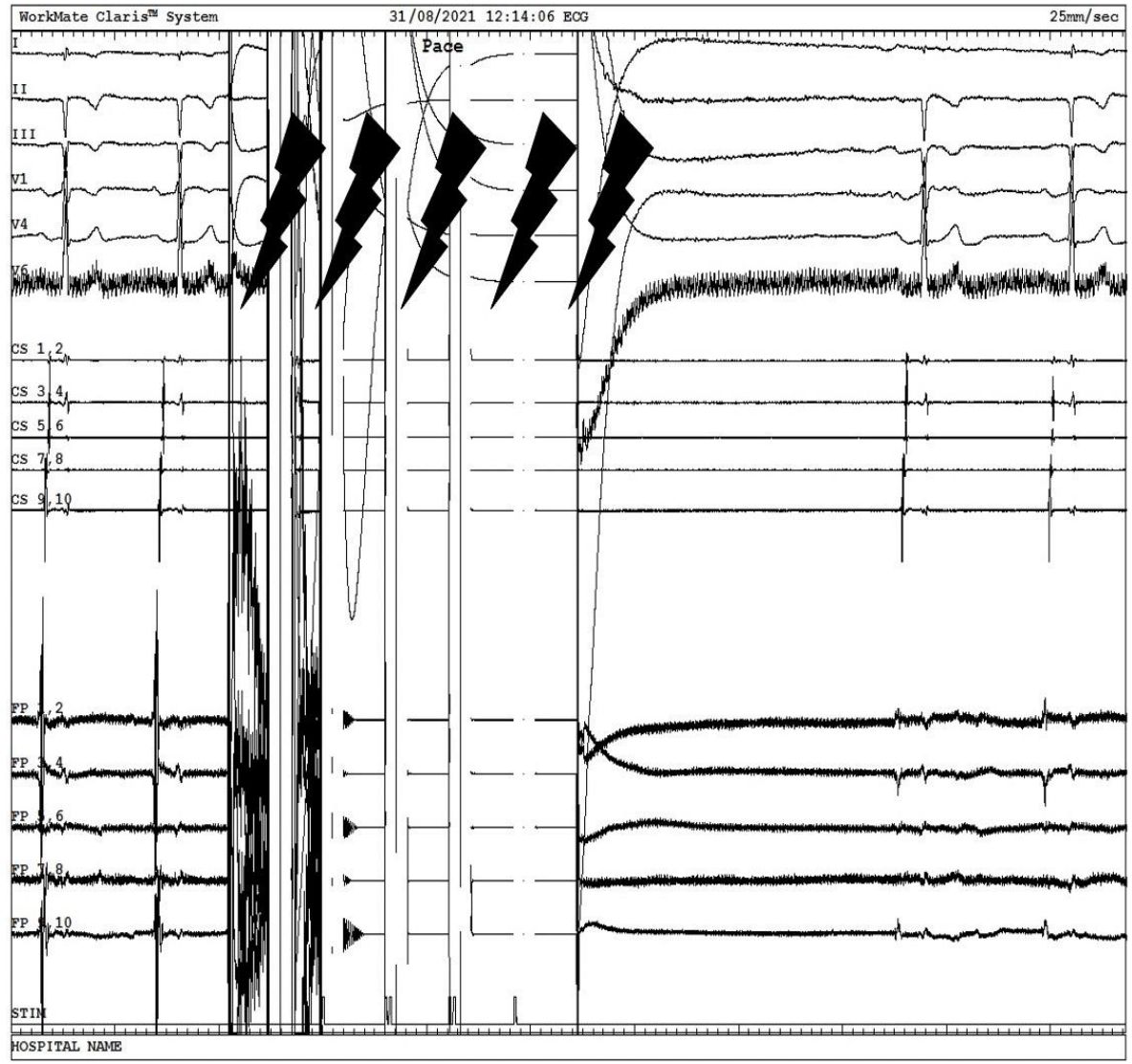




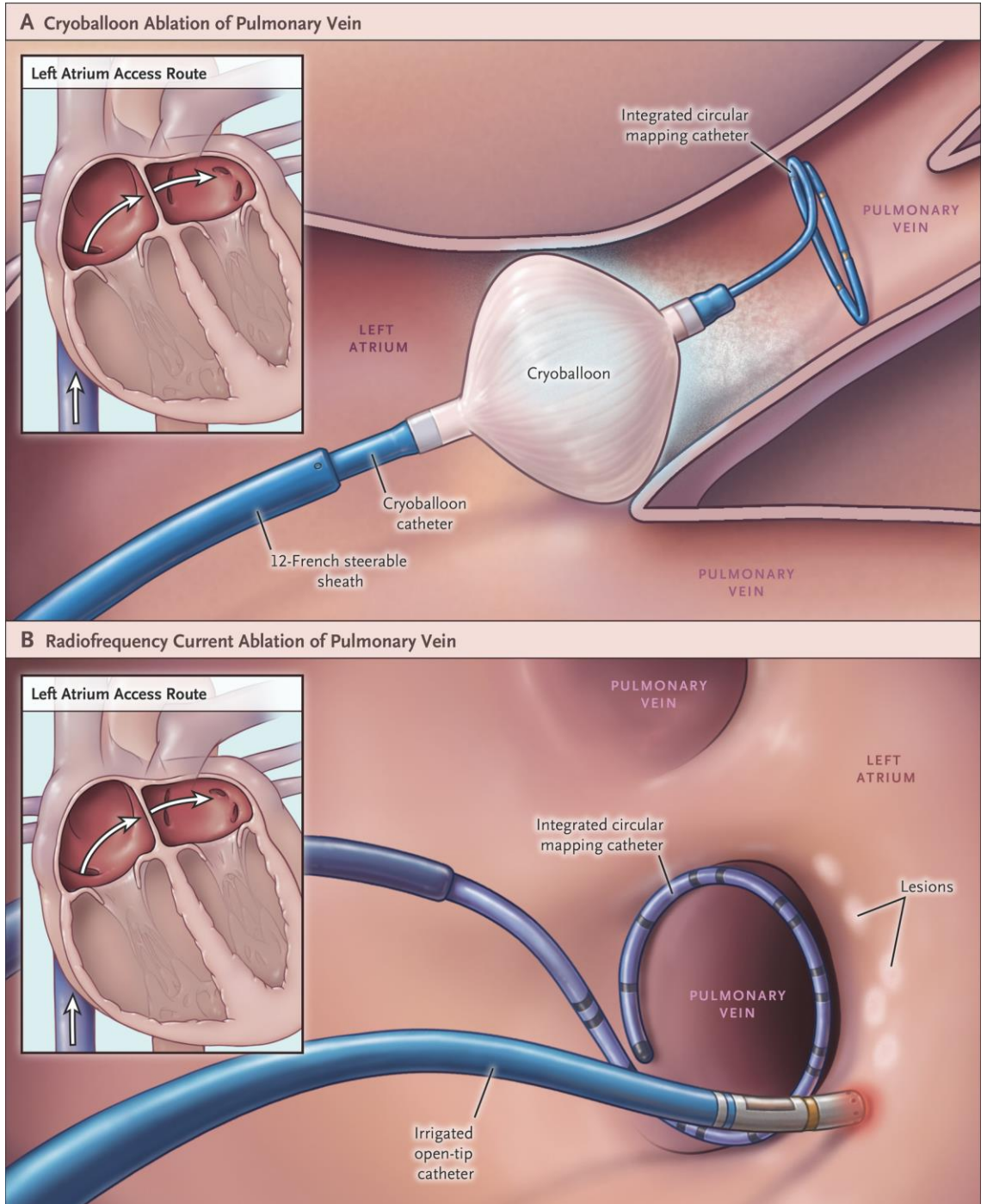




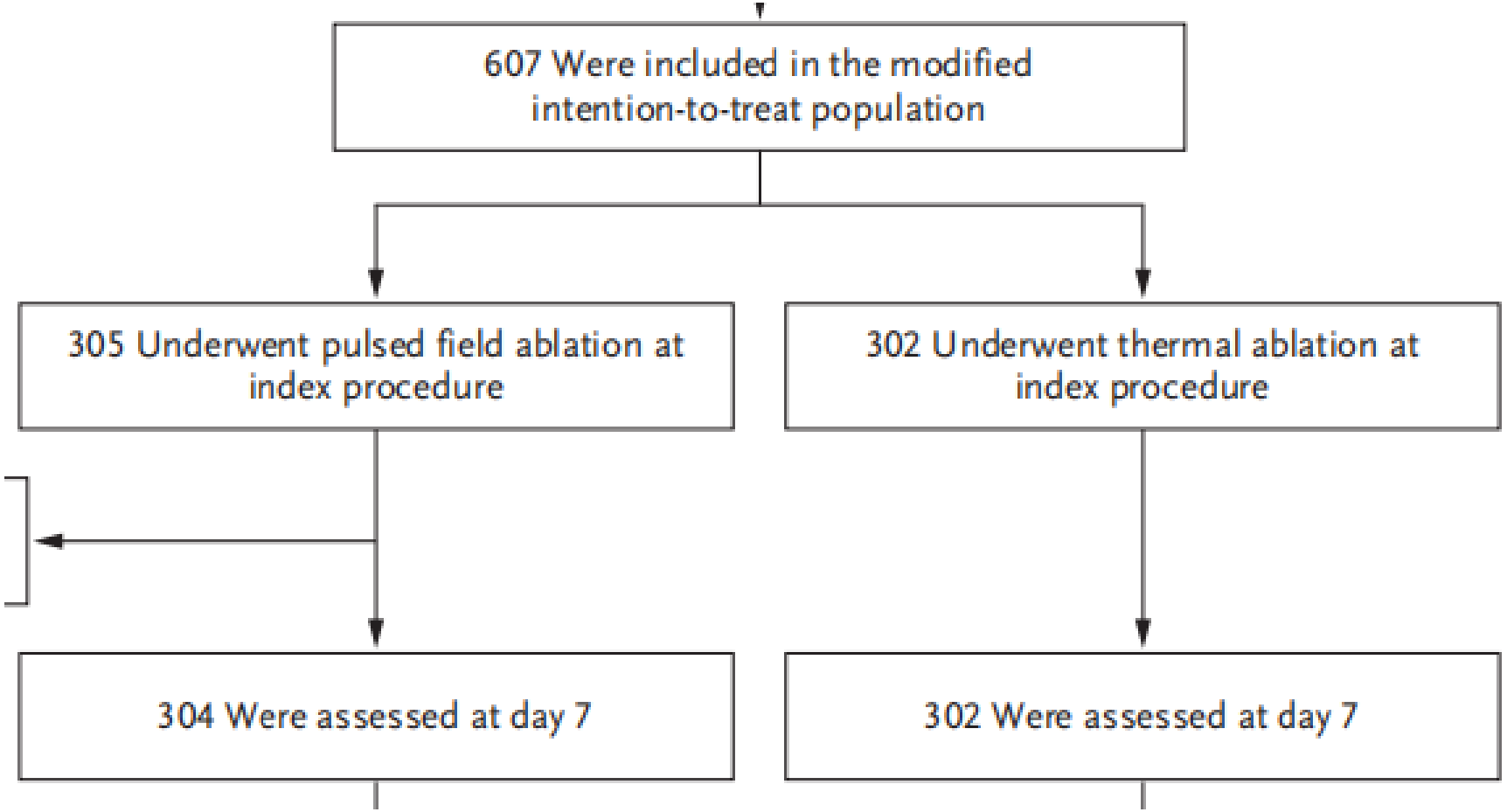


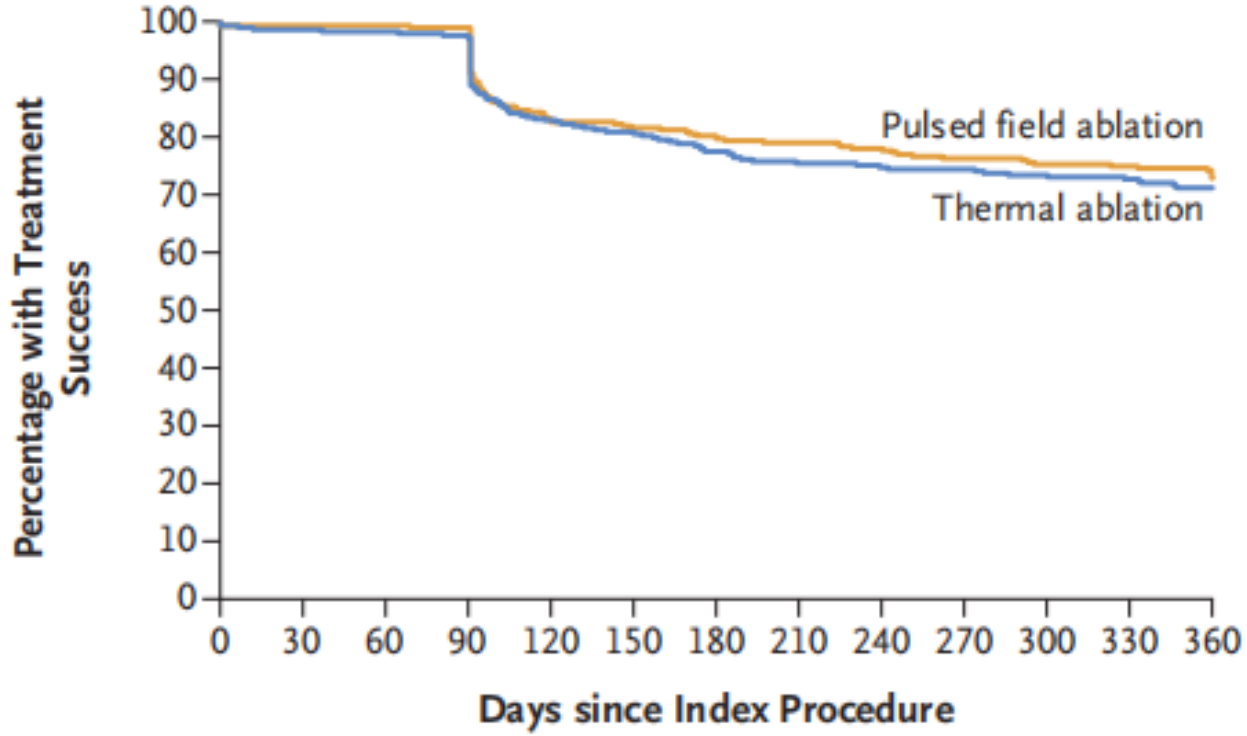


Thermal energy



The study included refractory PAF pts





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

Figure 2. Efficacy Outcomes of Pulsed Field Ablation as Compared with Thermal Ablation.

Table 3. Serious and Nonserious Adverse Events.*

Event	Serious Adverse Events†		Serious or Nonserious Adverse Events‡	
	Pulsed Field Ablation (N = 305)	Thermal Ablation (N = 302)	Pulsed Field Ablation (N = 305)	Thermal Ablation (N = 302)
	number of patients (percent)			
Any event	6 (2.0)§	4 (1.3)	7 (2.3)§	6 (2.0)
Death	1 (0.3)	0	1 (0.3)	0
Myocardial infarction	0	0	0	0
Persistent phrenic-nerve palsy	0	0	0	2 (0.7)
Stroke	0	1 (0.3)	0	1 (0.3)
TIA	1 (0.3)	0	1 (0.3)	0
Systemic thromboembolism	0	0	0	0
Cardiac tamponade or perforation	2 (0.7)	0	2 (0.7)	0
Pericarditis	1 (0.3)	0	2 (0.7)	0
Pulmonary edema	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)
Vascular-access complication	1 (0.3)	2 (0.7)	1 (0.3)	2 (0.7)
Heart block	0	0	0	0
Gastric motility or pyloric spasm	0	0	0	0
Pulmonary vein stenosis	0	0	0	0
Atrioesophageal fistula	0	0	0	0

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ORIGINAL ARTICLE

Catheter Ablation in End-Stage Heart Failure with Atrial Fibrillation

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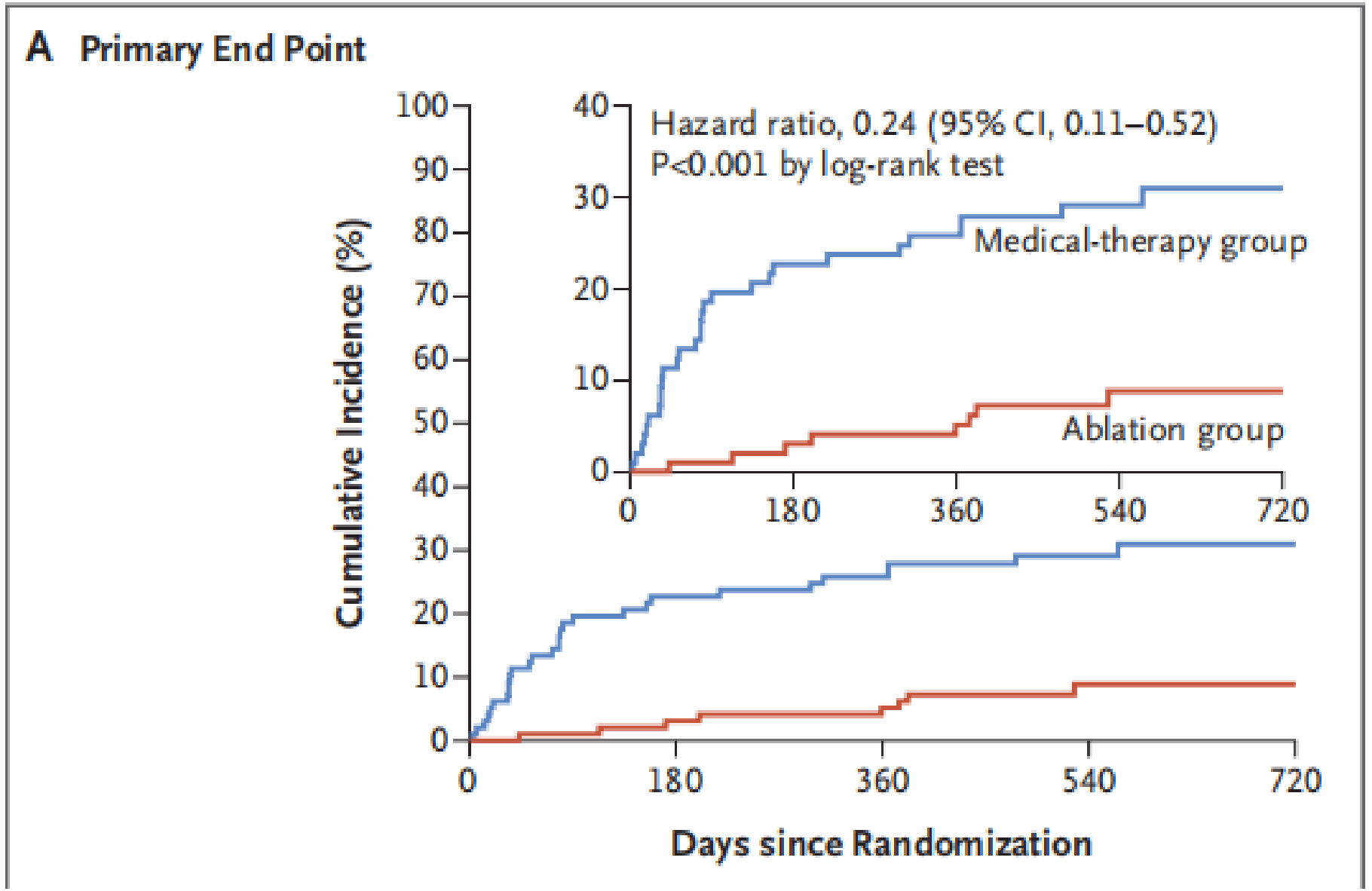
CASTLE-HTx

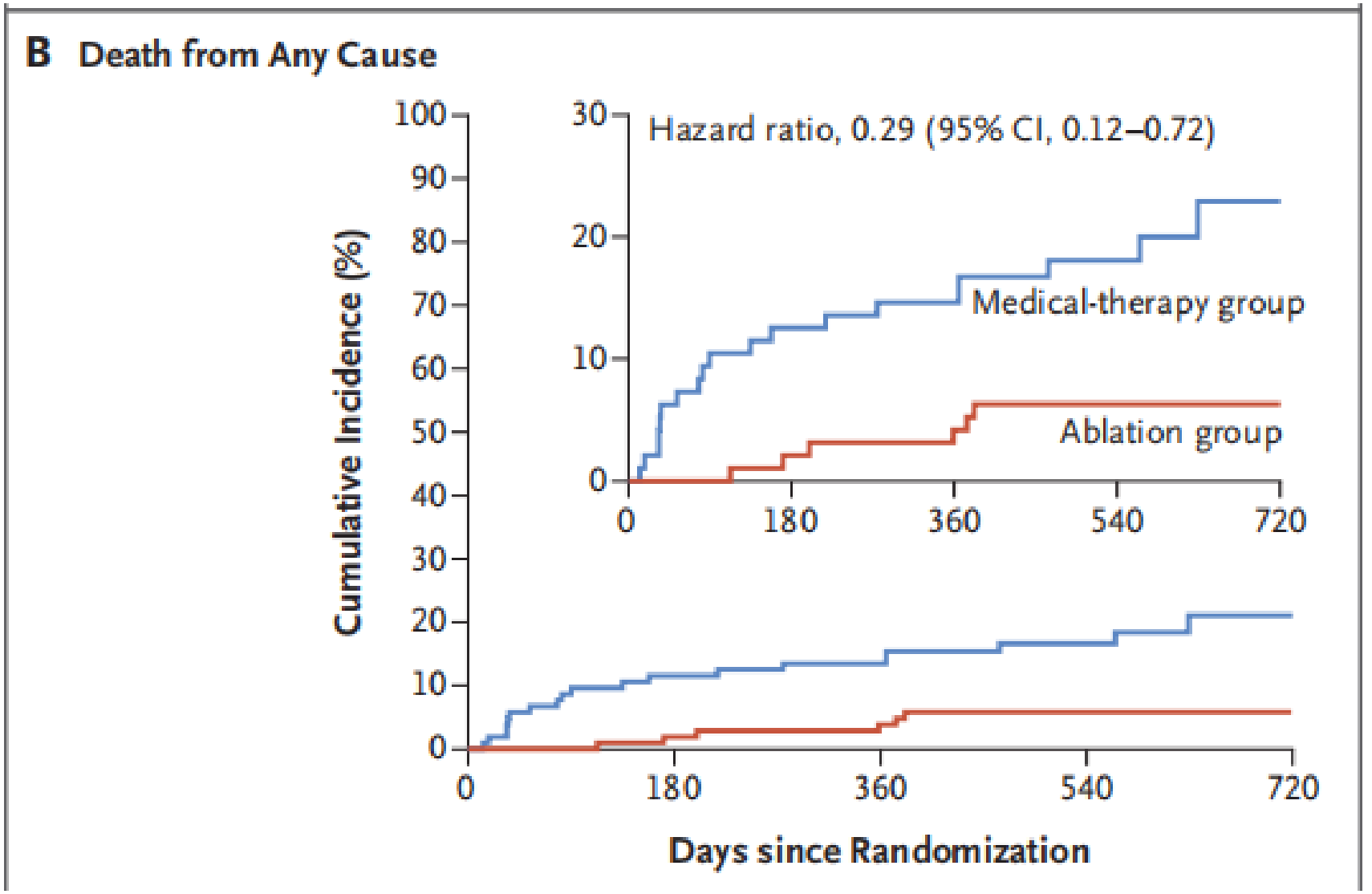
- Catheter Ablation for Atrial Fibrillation in Patients with End-Stage Heart Failure and Eligibility for Heart Transplantation:

- Trial to assess the safety and efficacy of catheter ablation in patients with end-stage heart failure and symptomatic atrial fibrillation who were referred for evaluation for heart transplantation or implantation of a left ventricular assist device.

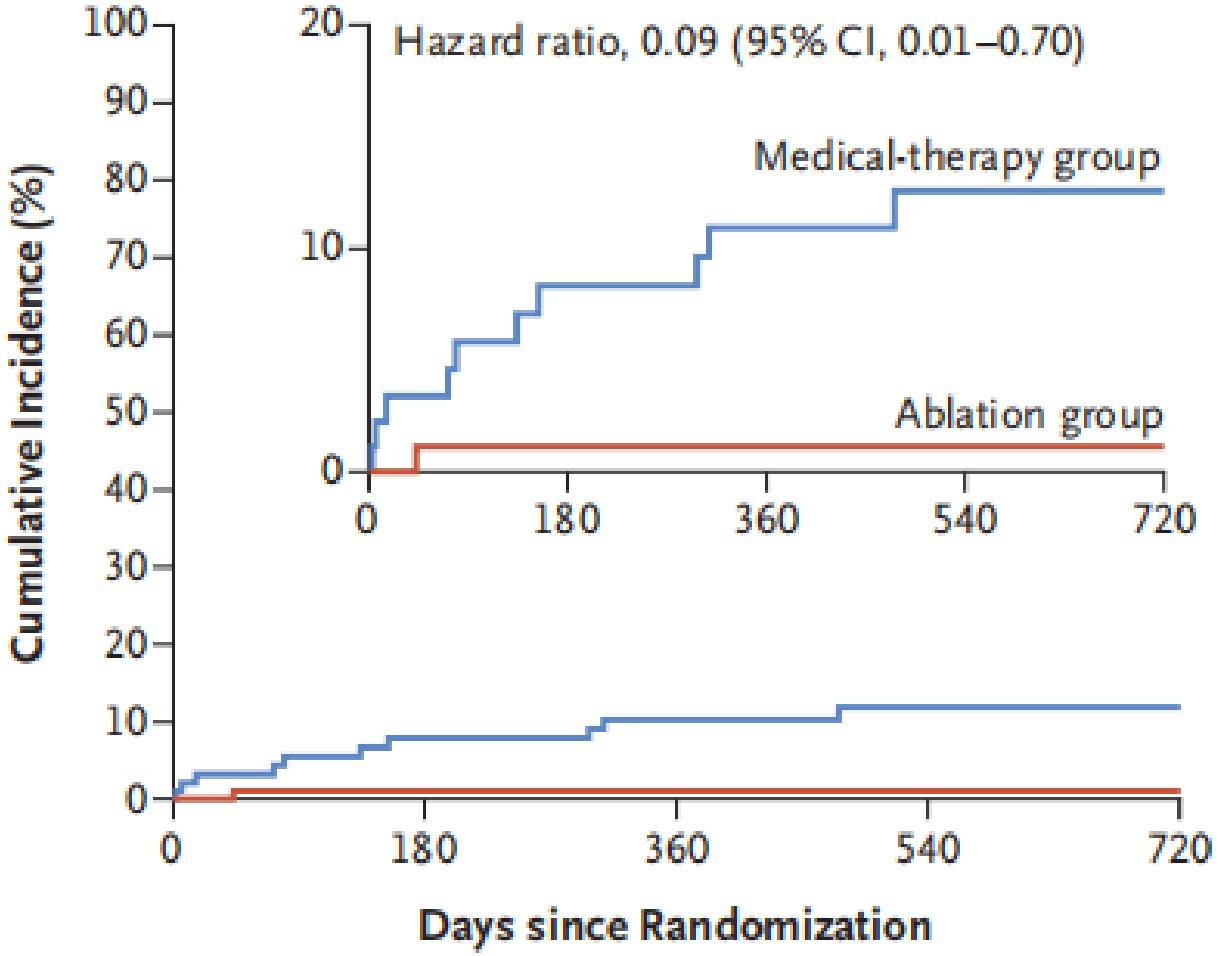
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Ablation Group (N=97)	Medical-Therapy Group (N=97)
Age — yr	62±12	65±10
Male sex — no. (%)	85 (88)	72 (74)
Body-mass index†	28±4	28±5
NYHA functional class — no. (%)‡		
II	33 (34)	28 (29)
III	52 (54)	54 (56)
IV	12 (12)	15 (15)
Left ventricular ejection fraction — %	29±6	25±6
Type of atrial fibrillation — no. (%)		
Paroxysmal	28 (29)	31 (32)
Persistent	54 (56)	54 (56)
Long-standing persistent: duration of >1 yr	15 (15)	12 (12)
Duration of atrial fibrillation — yr	4±5	3±4
History of cardioversion — no. (%)	64 (66)	62 (64)
Heart rate — beats/min	80±21	82±20
Cause of heart failure — no. (%)		
Ischemic	37 (38)	39 (40)
Nonischemic	60 (62)	58 (60)


A Primary End Point
Cumulative Incidence (%)
100
90
80
70
60
50
40
30
20
10
0
0
180
360
540
720
Days since Randomization
Hazard ratio, 0.24 (95% CI, 0.11–0.52)
P<0.001 by log-rank test
Medical-therapy group
Ablation group
40
30
20
10
0
0
180
360
540
720


B Death from Any Cause
Cumulative Incidence (%)
100
90
80
70
60
50
40
30
20
10
0
0
180
360
540
720
Days since Randomization
Hazard ratio, 0.29 (95% CI, 0.12–0.72)
Medical-therapy group
Ablation group
30
20
10
0
0
180
360
540
720

C **Implantation of a Left Ventricular Assist Device**



Conclusion

- In the CASTLE-HTx trial, catheter ablation of atrial fibrillation plus medical therapy in patients with end-stage heart failure who were referred for transplantation evaluation was associated with a lower likelihood of a composite of death from any cause, implantation of a left ventricular assist device, or urgent heart transplantation than medical therapy alone.

10.1161/CIRCULATIONAHA.123.066485

Safety of Switching from a Vitamin K Antagonist to a Non-Vitamin K Antagonist Oral Anticoagulant in Frail Older Patients with Atrial Fibrillation: Results of the FRAIL-AF Randomized Controlled Trial

Pateints:

- Age ≥75 years currently managed on INR-guided VKA treatment for AF ; a Groningen Frailty Indicator (GFI) ≥3.

- Exclusion: valvular AF ; an eGFR below 30 ml/min/1.73 m2

- Patients were randomized to switch:
  - to a NOAC-based treatment strategy :stop VKA and start NOAC if INR is below 1.3.
  – or to the control group : continue with INR-guided VKA management (2.0 and 3.0).

Results

- ITT population included 662 patients that switched from a VKA to a NOAC and 661 patients that continued with INR_guided VKA management.

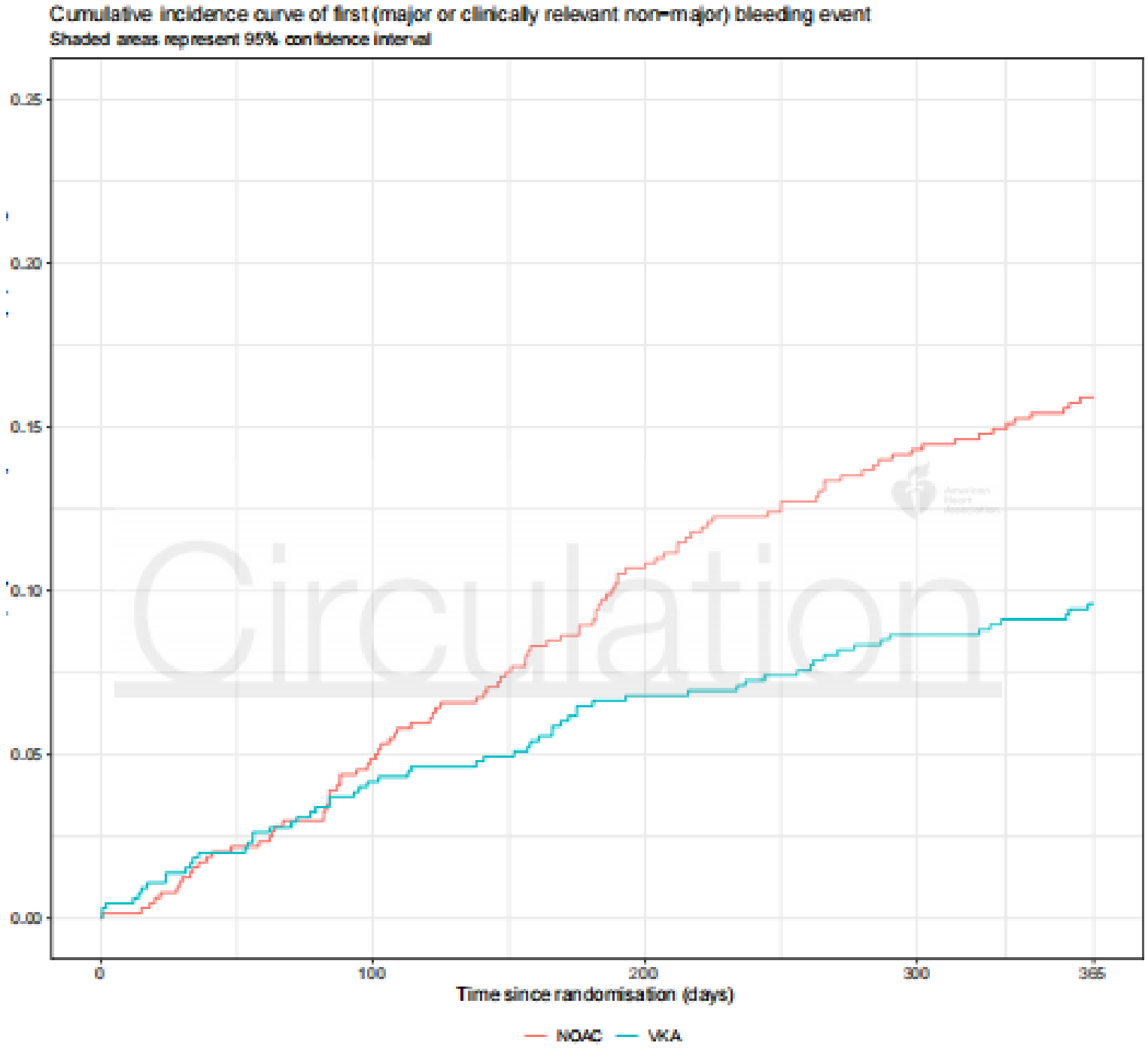
- 8.6% patients were switched to dabigatran,

  50.2% to rivaroxaban,

  17.4% to apixaban,

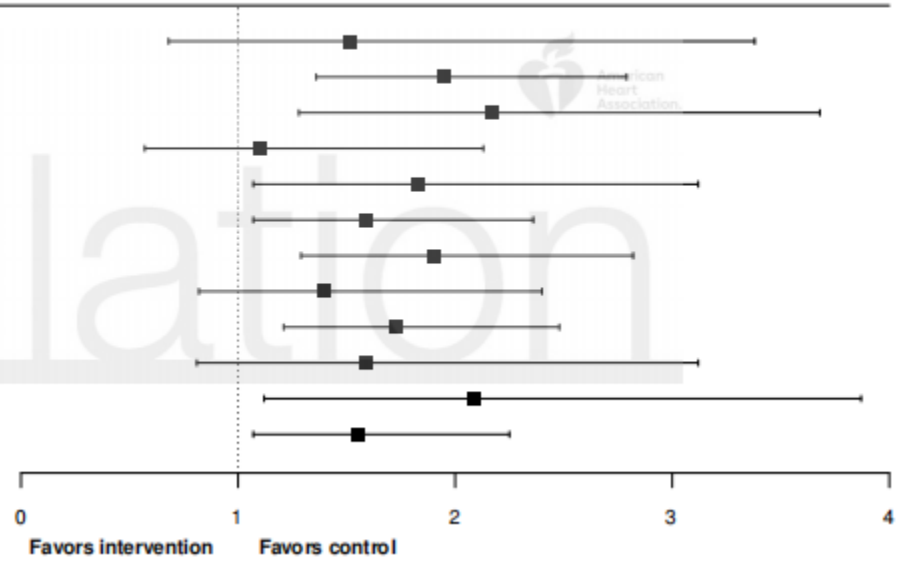
  16.5% to edoxaban.

Characteristic*	NOAC (n=662)	VKA (n=661)
Age – yr. (SD)	83.0 (5.1)	82.8 (5.1)
Female sex – no. (%)	274 (41.4%)	239 (36.2%)
Type of atrial fibrillation		
Paroxysmal atrial fibrillation – no. (%)	170 (25.7%)	201 (30.4%)
Persistent atrial fibrillation – no. (%)	63 (9.5%)	57 (8.6%)
Permanent atrial fibrillation – no. (%)	340 (52.7%)	335 (50.7%)
Unknown – no. (%)	89 (13.4%)	68 (10.3%)
Duration of atrial fibrillation – yr. (SD)	12.0 (9.2)	13.0 (9.9)
Groningen Frailty Indicator – score (IQR)	4 (3-6)	4 (3-6)
Groningen Frailty Indicator 3 (%)	170 (25.7%)	171 (25.9%)
Groningen Frailty Indicator ≥4	492 (74.3%)	490 (74.0%)
Groningen Frailty Indicator domain		
Use of ≥4 different types of medication	589 (89%)	581 (87.9)
Complaints of memory	237 (35.8%)	261 (39.5%)
Unable to walk around the house	112 (16.9%)	112 (16.9%)
Problems due to of impaired vision	297 (44.9%)	279 (42.2%)
Problems due to of impaired hearing	380 (57.4%)	353 (53.4%)
CHA_2DS_2-VASc score (IQR)	4.0 (3.0-5.0)	4.0 (3.0-5.0)
Heart failure – no. (%)	129 (19.5%)	150 (22.7%)
Hypertension – no. (%)	365 (55.1%)	336 (50.8%)
Diabetes – no. (%)	140 (21.1%)	140 (21.2%)
History of major bleeding – no. (%)	105 (15.9%)	88 (13.3%)
History of thromboembolic event – no. (%)	139 (21.0%)	117 (17.7%)
Active cancer – no. (%)	44 (6.6%)	35 (5.3%)
Liver cirrhosis – no. (%)	3 (0.5%)	5 (0.8%)
Body-mass index (SD)	27.4 (6.0)	27.4 (11.7)
eGFR mL/min/1.73 m^2 (SD)	62.5 (15.8)	62.7 (15.6)
Off-label reduced NOAC dose (%)	44 (6.6%)	-
Concurrent platelet inhibitor use – no. (%)	16 (2.4)	13 (2.0)


Cumulative incidence curve of first (major or clinically relevant non-major) bleeding event
Shaded areas represent 95% confidence interval
0.25
0.20
0.15
0.10
0.05
0.00
0
100
200
300
365
Time since randomisation (days)
NOAC
VKA

Subgroup analysis

	NOAC n	IR (no. of events)	VKA n	IR (no. of events)	HR (95% CI)
Dabigatran	57	13.6 (7)	661	10.5 (62)	1.52 (0.68 – 3.38)
Rivaroxaban	332	20.8 (61)	661	10.5 (62)	1.95 (1.36 – 2.79)
Apixaban	115	19.5 (20)	661	10.5 (62)	2.17 (1.28 – 3.68)
Edoxaban	109	11.1 (11)	661	10.5 (62)	1.10 (0.57 – 2.13)
Age ...85	233	20.3 (39)	217	10.9 (21)	1.83 (1.07 – 3.12)
Age ...84	429	16.5 (62)	444	10.2 (41)	1.59 (1.07 – 2.36)
Males	388	20.4 (67)	422	10.5 (40)	1.90 (1.29 – 2.82)
Females	274	14.2 (34)	239	10.3 (22)	1.40 (0.82 – 2.40)
eGFR ...50	518	18.1 (80)	519	10.3 (48)	1.73 (1.21 – 2.48)
eGFR ...49	144	16.5 (21)	142	10.9 (14)	1.59 (0.81 – 3.12)
GFI 3	170	21.2 (31)	171	9.7 (15)	2.09 (1.12 – 3.87)
GFI ...4	492	16.6 (70)	490	10.7 (47)	1.55 (1.07 – 2.25)



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Conclusion

- Among frail older AF patients, switching INR_guided VKA-management to a NOAC based treatment strategy was associated with a 69% increase in major and/or CRNM bleeding complications.
- Event rates for thrombo-embolic events, major bleeding in isolation, hemorrhagic stroke, or the composite of hemorrhagic and ischemic stroke were low in both treatment arms,

BUDAPEST CRT Upgrade trial:Upgrade to cardiac resynchronisation therapy benefits heart failure patients with pacing

BUDAPEST CRT Upgrade was the first trial to compare the efficacy and safety of a CRT upgrade, compared to ICD alone, in HFrEF patients with a pacemaker or ICD and intermittent or permanent RV pacing.

Study population

HFrEF patients

- with ejection fraction ≤35%
- had received a pacemaker or ICD >6 months previously
- had HF symptoms
- had a wide paced QRS complex
- had a high burden of RV pacing
- treated with guideline-directed medical therapy

Patients were excluded if they were eligible for CRT according to current guidelines

Where?

7 countries

17 sites

Who and what?

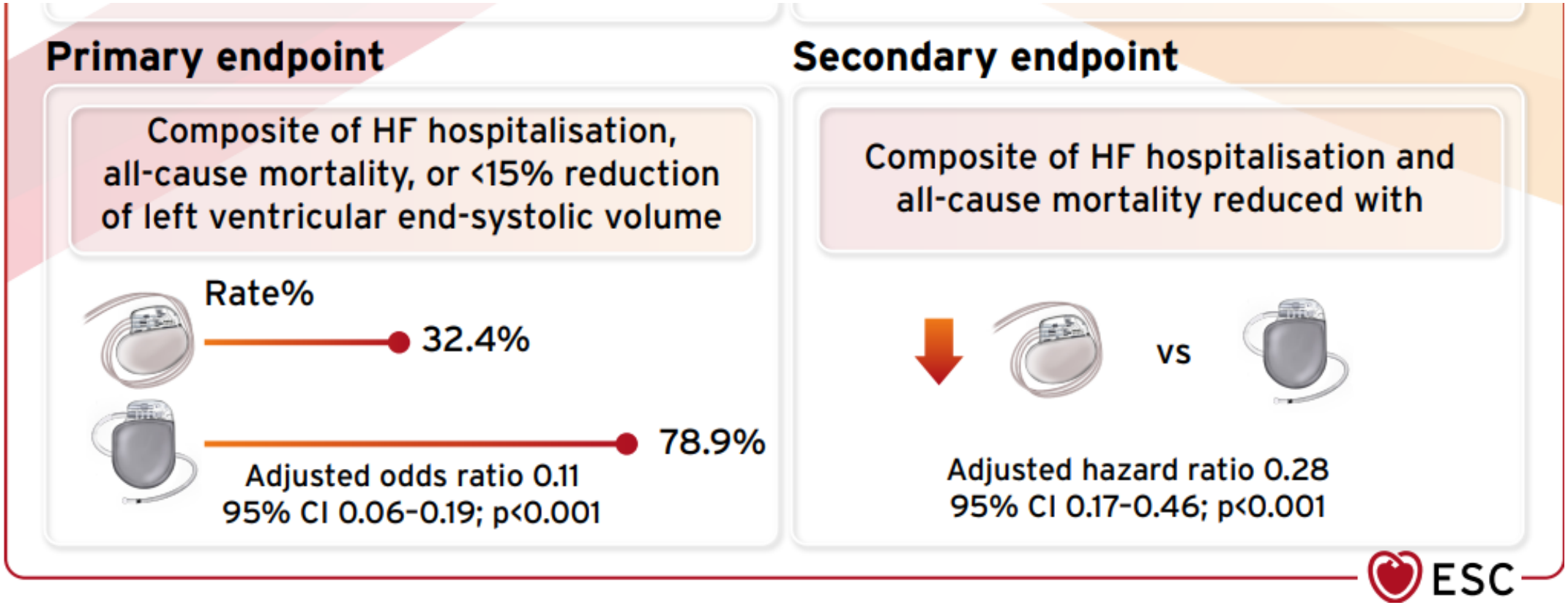
360 patients

randomised 3:2

CRT-D upgrade

ICD

Median follow-up ▶ 12.4 months



LV morphological and functional response according to echocardiography also favoured CRT-D compared to ICD

Safety

- The incidence of procedure- or device-related complications was similar between the two arms: CRT-D group 12.3% vs. ICD group 7.8%.

- The occurrence of major ventricular arrhythmias was substantially lower in the CRT-D arm [0.5%] compared to the ICD arm patients [14.5%].

Conclusions

- The findings support performing an CRT upgrade in patients with redued EF and intermittent or permanent RV pacing.

- CRT upgrade should be performed immediately without deferring the procedure to a later date (e.g. battery replacement) to avoid or reduce the risk of further adverse events such as mortality, heart failure hospitalisation or LV remodelling.