Confronto a un anno di follow-up tra il catetere PFA circolare a nove elettrodi e i risultati della crioablazione in pazienti con FA

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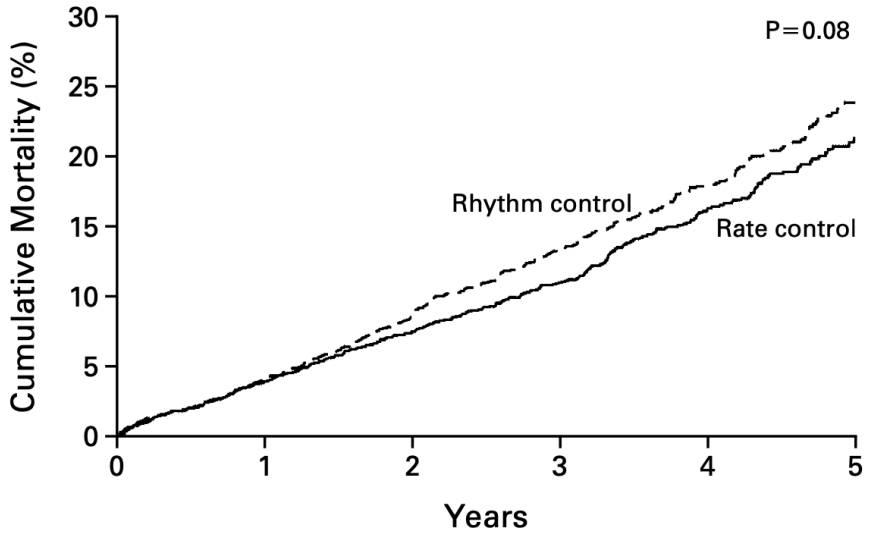
Rome
26 June 2026

AFFIRM trial

4060 pts with AF randomized to **rate** control or **rhythm** control



No. of Deaths		number (percent)				
Rhythm control	0	80 (4)	175 (9)	257 (13)	314 (18)	352 (24)
Rate control	0	78 (4)	148 (7)	210 (11)	275 (16)	306 (21)

No differences for the primary endpoint (**Death**)
Higher rates of any **hospitalization** with **AADs**

	AADs	Rate control	P-value
Death	356/2033 (26.7)	310/2027 (25.9)	0.08
Any Hosp	1374/2033 (80.1)	1220/2027 (73.)	<0.001

Wyse DG et al. NEJM. 200

Yesterday….

Non-permanent AF

Symptoms

↓

Rate Control

Symptoms

↓

Antiarrhythmics

Symptoms

↓

Ablation

….Today….

Non-permanent AF

Symptoms

↓

Rate Control

Symptoms

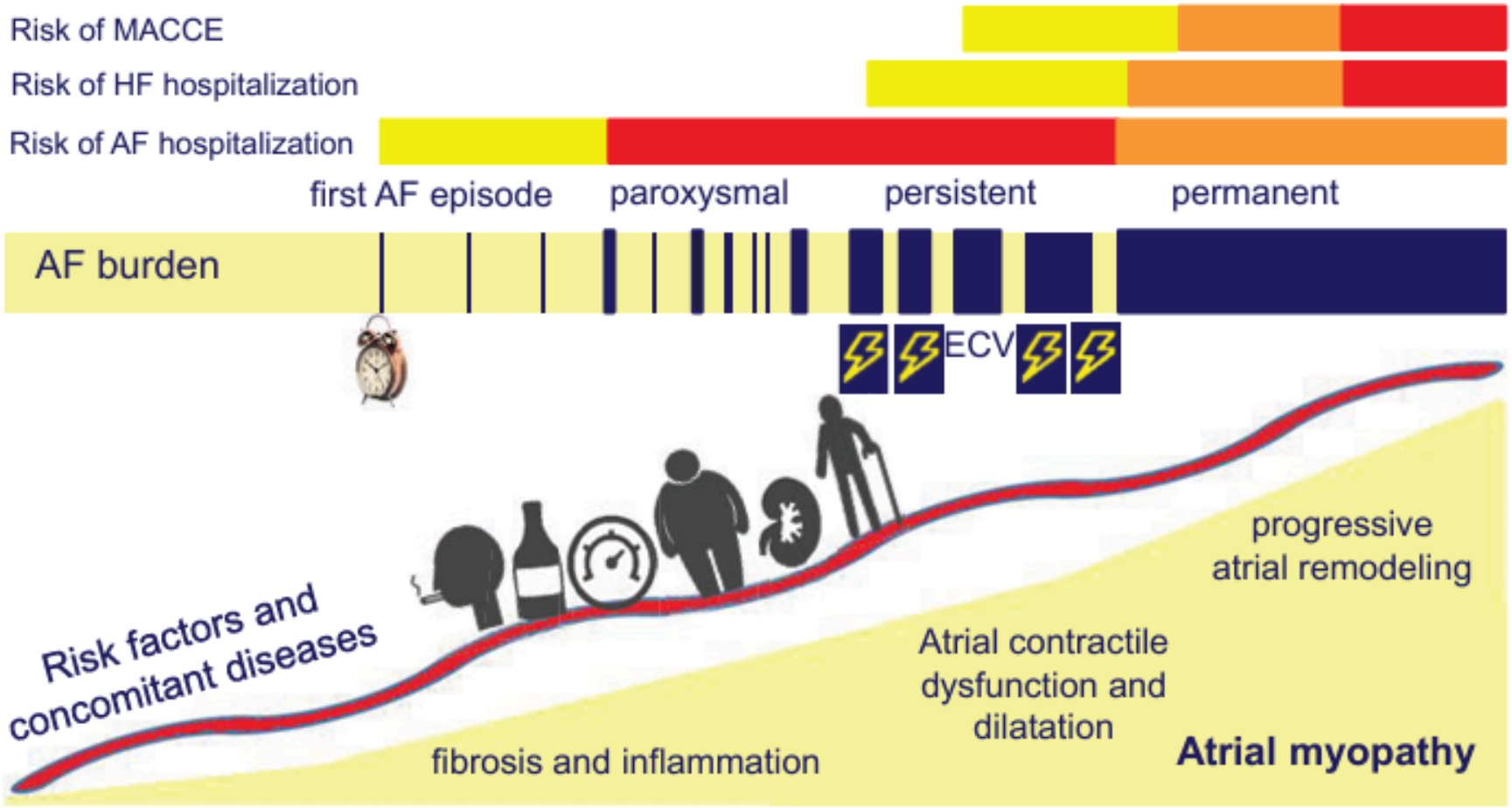
↓

Rhythm + Rate control

↓ ↓

AAD | Ablation

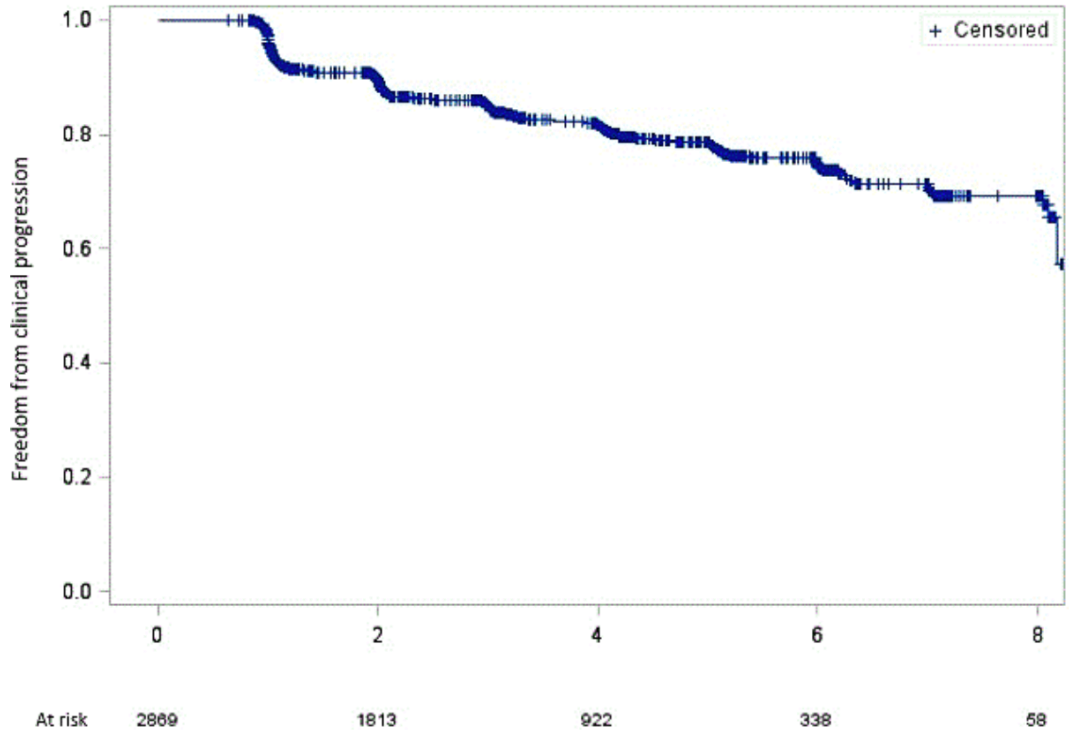
AF as a progressive disease



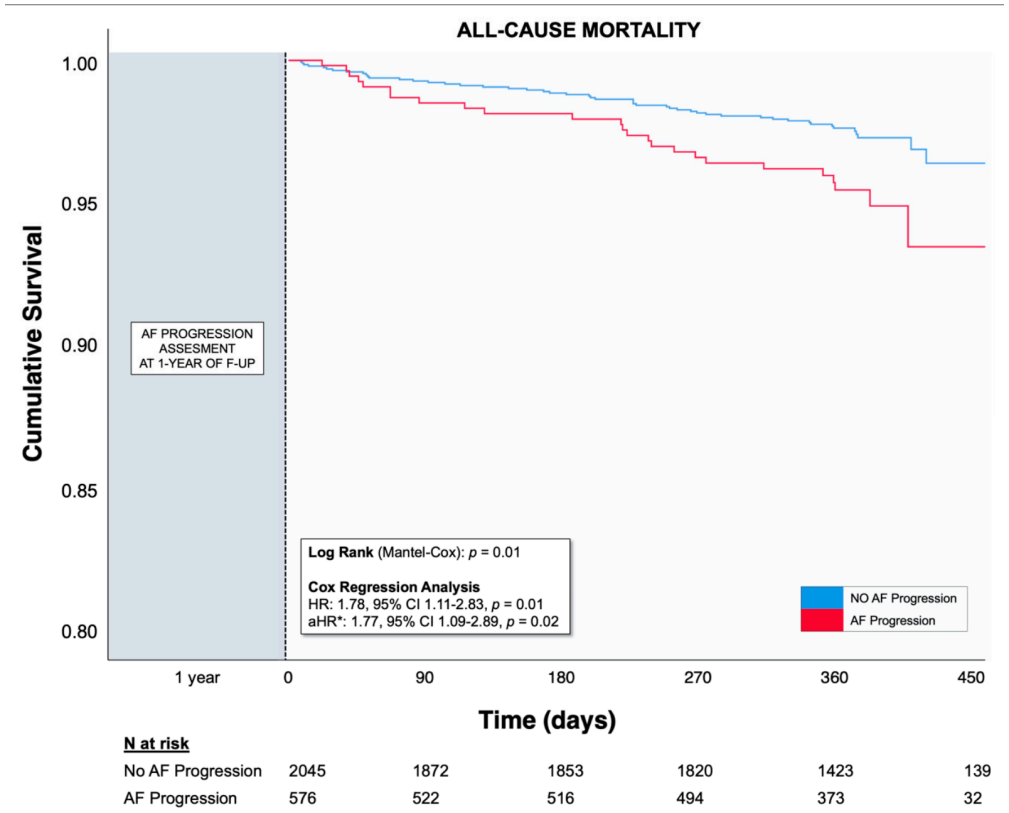
Freedman B et al. Eur Heart J Supplements. 2020

Impact of AF Progression

16.0% of AF pts have clinical **AF progression** (BEAT-AF + Swiss AF)



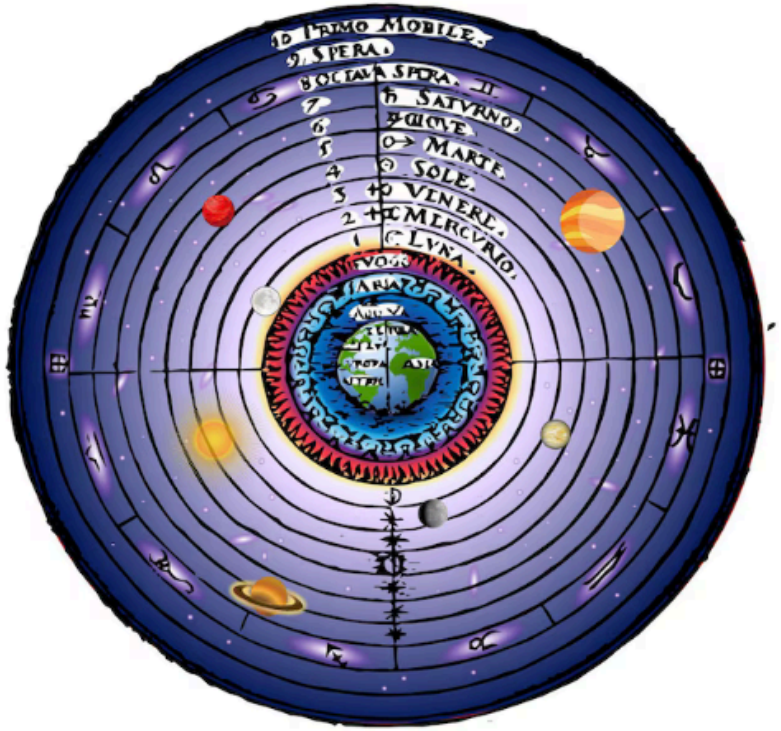
22.1% of AF patients had progression and had higher risk of outcomes (EORP-AF Long Term)



Blum S et al. JAHA. 2019

Vitolo M et al. JCM. 2023

....Tomorrow(?)



Non-permanent AF

Rate Control

Rhythm + Rate control

AAD

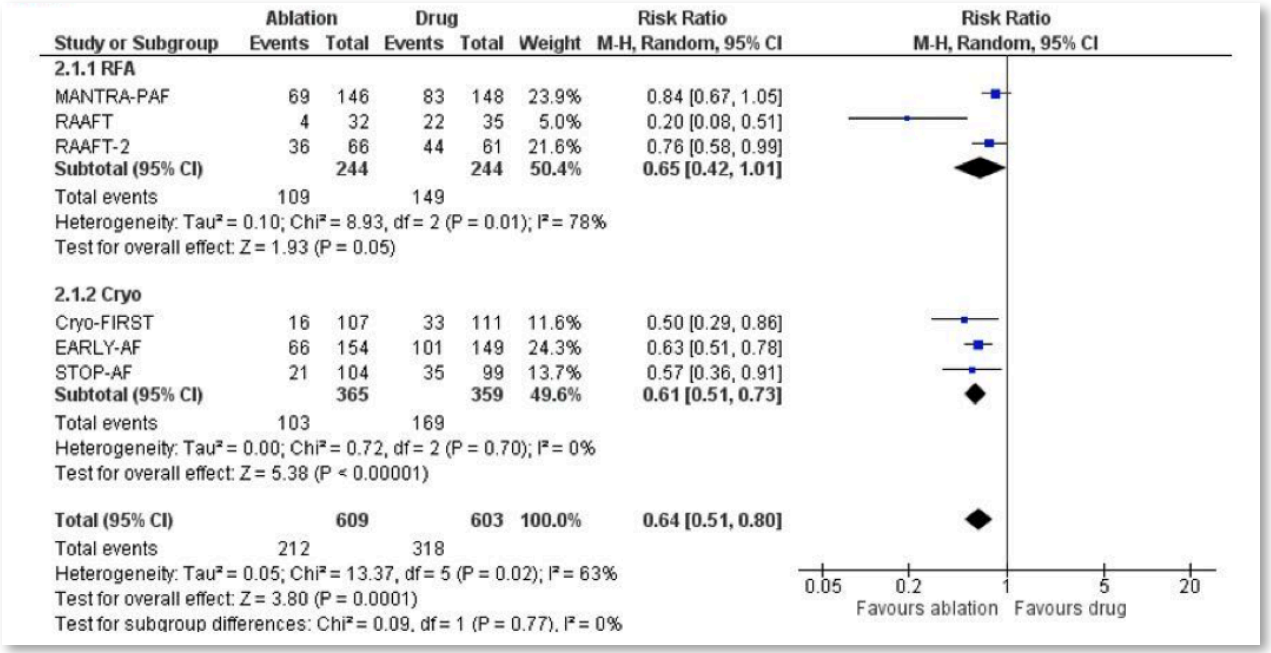
Ablation

Poor rhythm control

AF ablation and outcomes

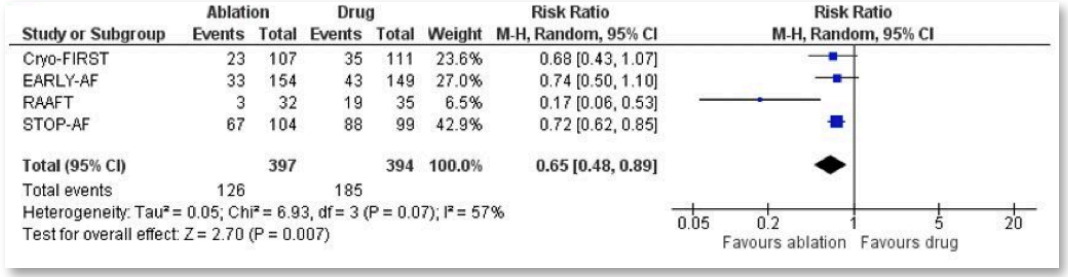
Recurrence of AT

-36% probability of AF recurrence with ablation as first line vs AAD



Health care utilization

-35% probability of Health care utilization vs AAD



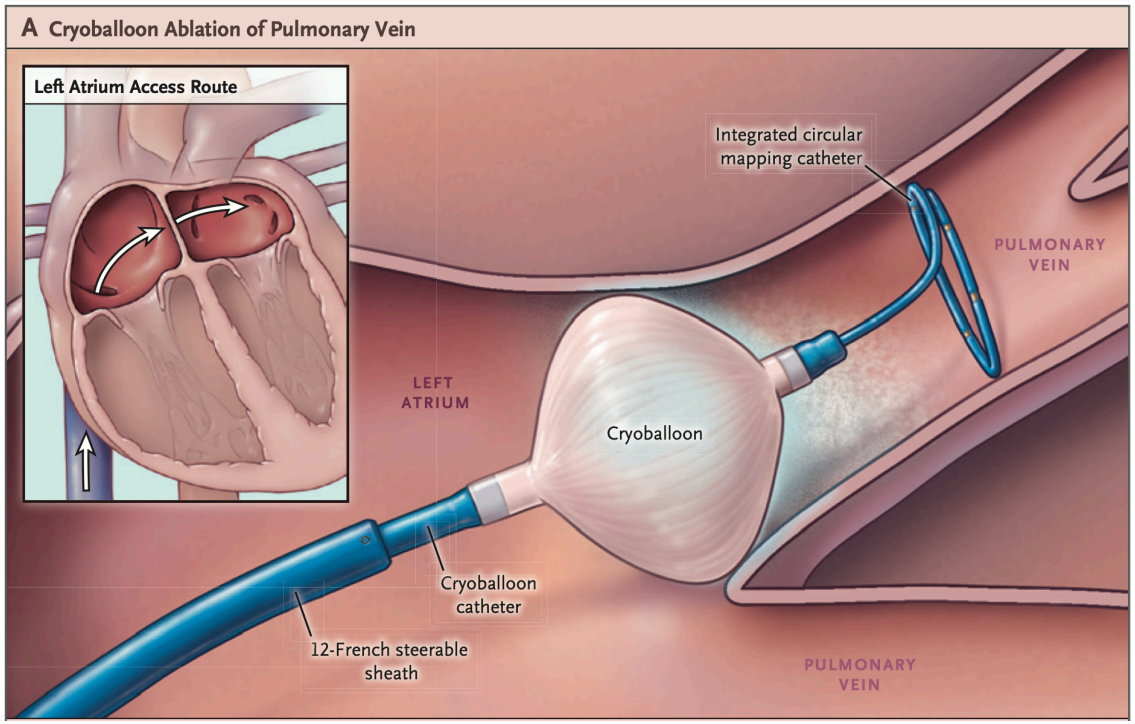
Imberti JF et al. Heart. 2022

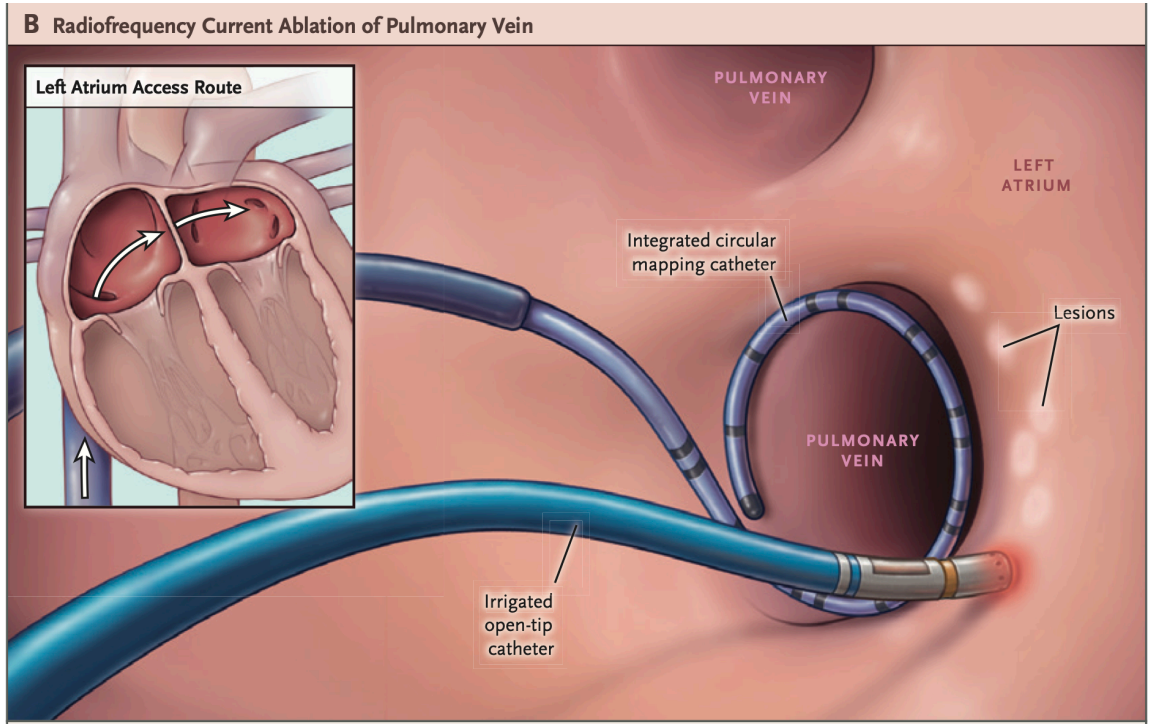
Which technique?

Background: FIRE and ICE

Randomized clinical trial enrolling **762** patients

378 **cryoballoon** vs **384 Radiofrequency**

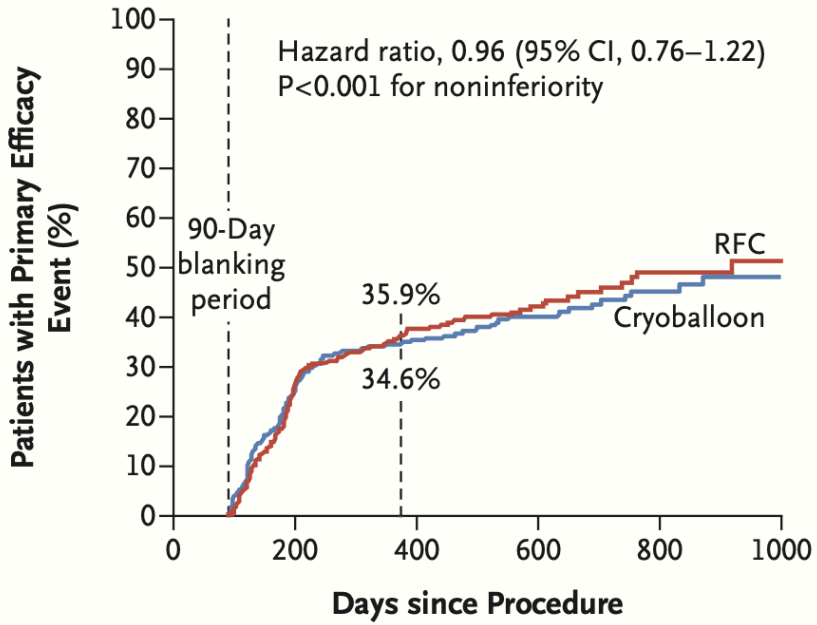




Kuck KH et al. NEJM. 2016

FIRE and ICE trial

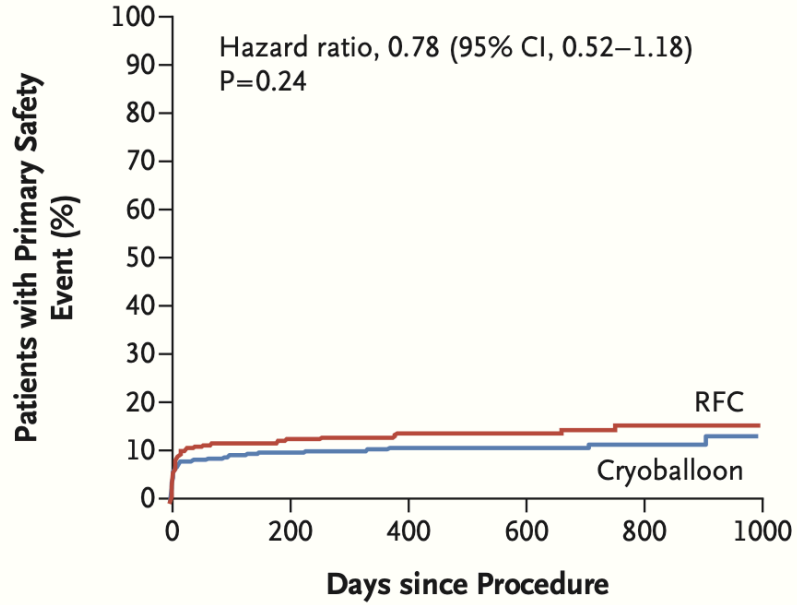
A **Primary Efficacy End Point**



No. at Risk

Cryoballoon	374	338	242	194	165	132	107	70	57	34	12
RFC	376	350	243	191	149	118	93	58	44	25	12

C **Primary Safety End Point**



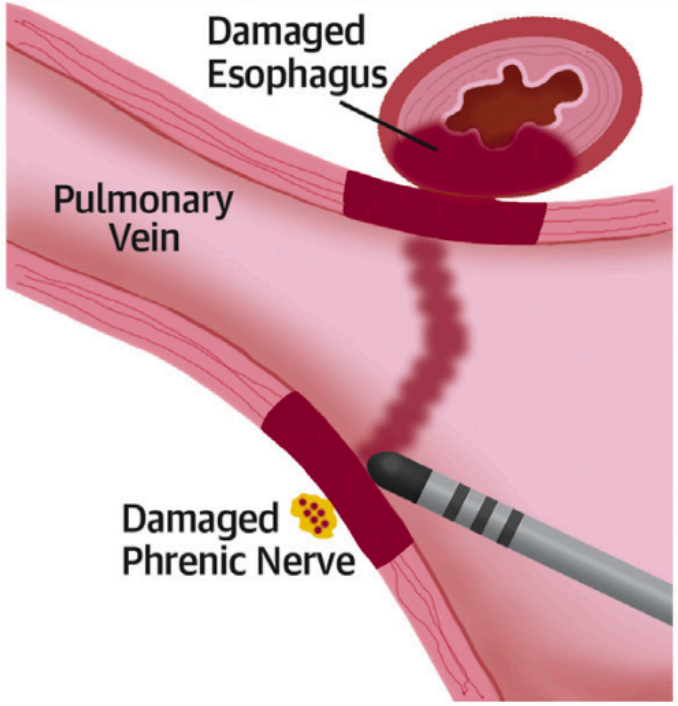
No. at Risk

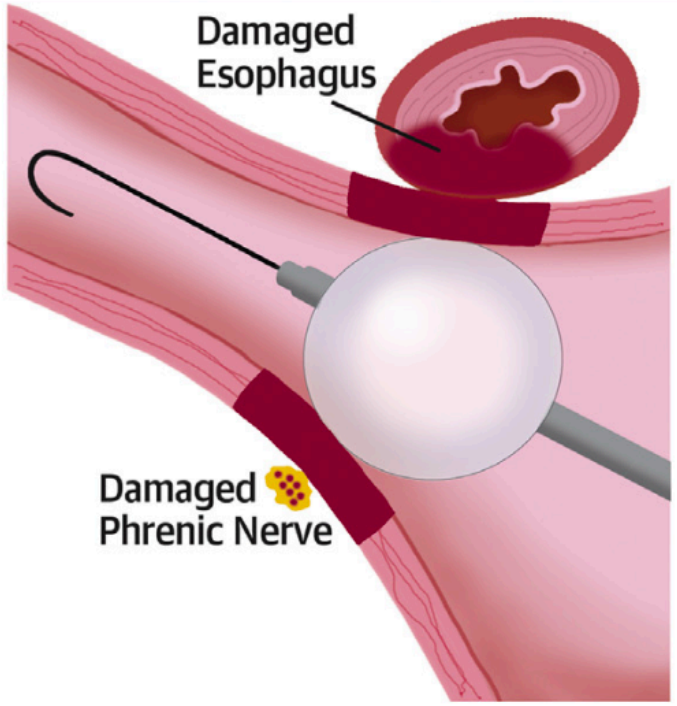
Cryoballoon	374	323	298	261	229	189	159	117	94	55	21
RFC	376	315	292	247	215	176	146	110	87	52	27

Kuck KH et al. NEJM. 201

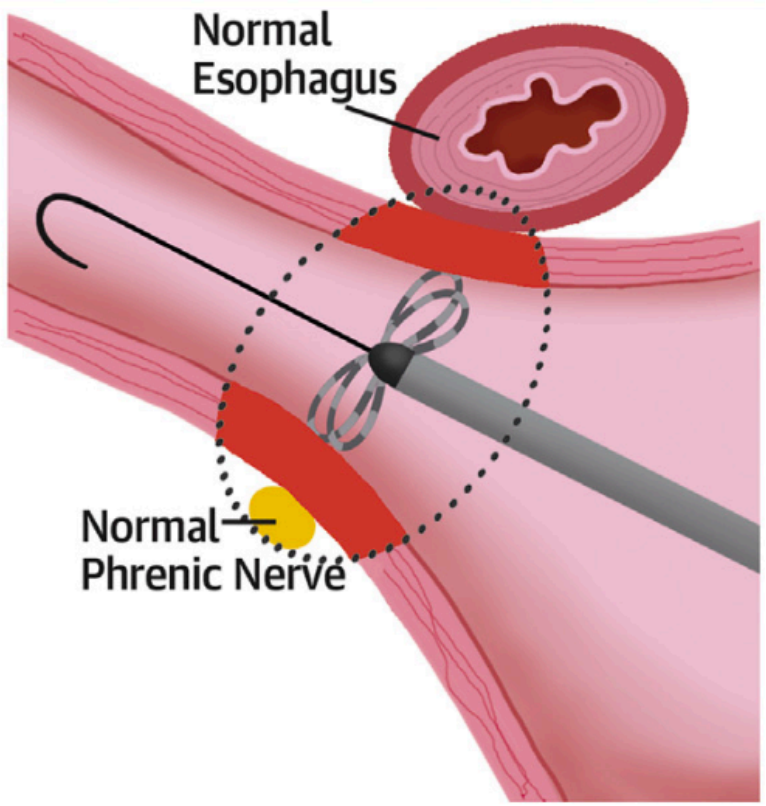
Thermal vs non thermal ablation

Thermal ablation





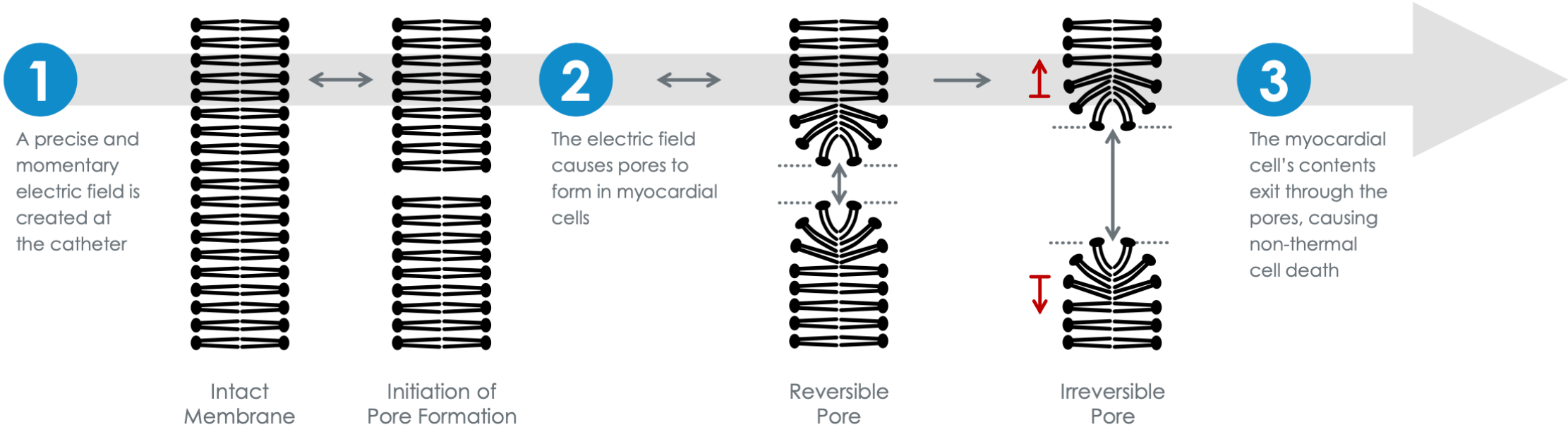
Non-Thermal ablation



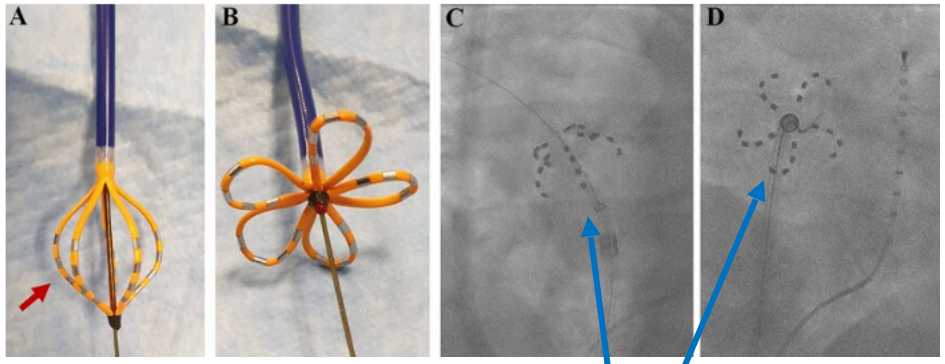
Adapdted from Reddy VY et al. JACC. 2

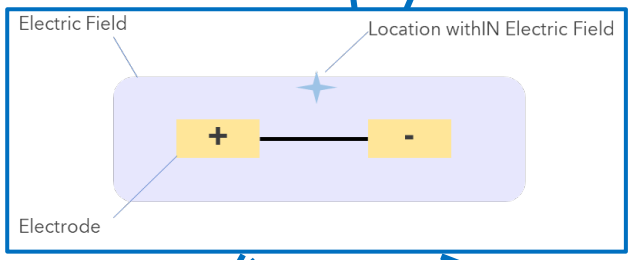
Mechanism of damage

Irreversible Electroporation:
cell membrane pore formation & cell death occurs with sufficient electric field

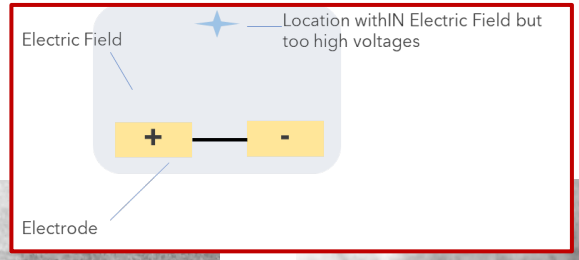


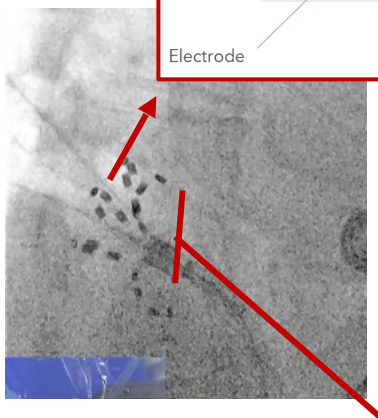
Theoretically

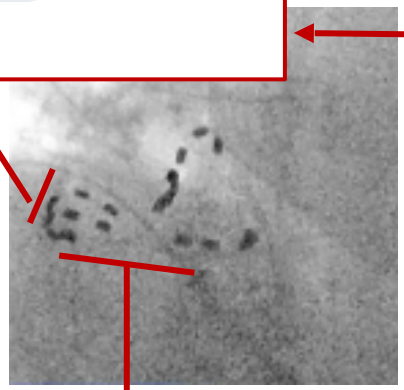


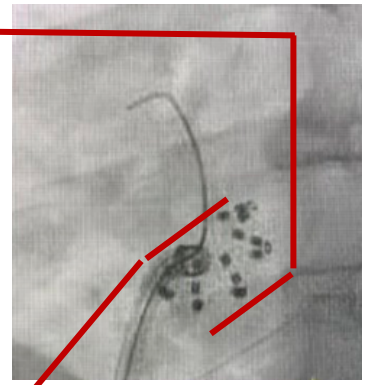


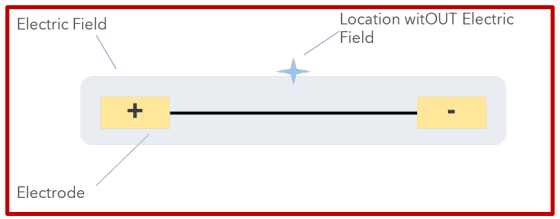
In real world – clinical practice

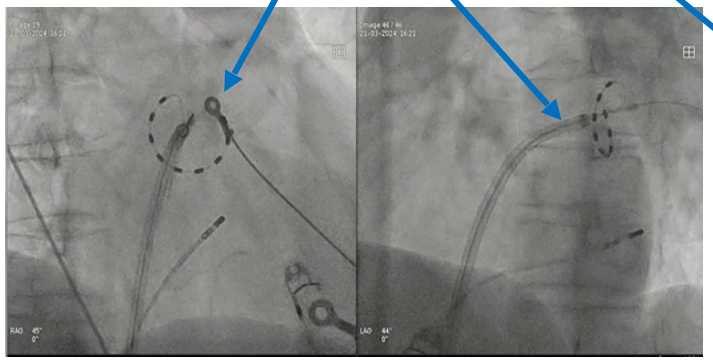


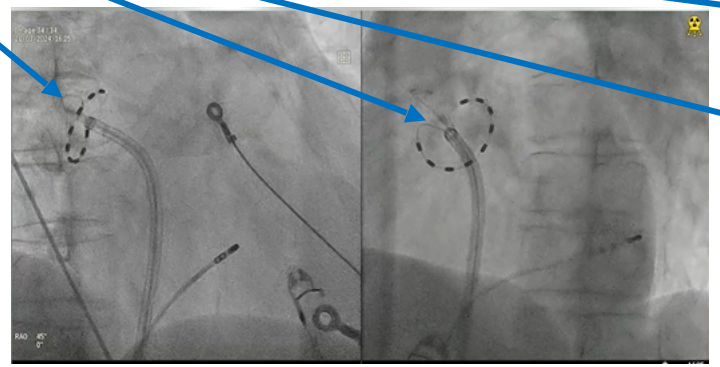


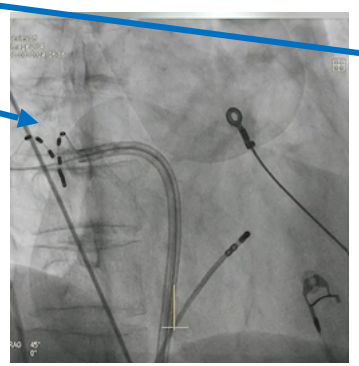


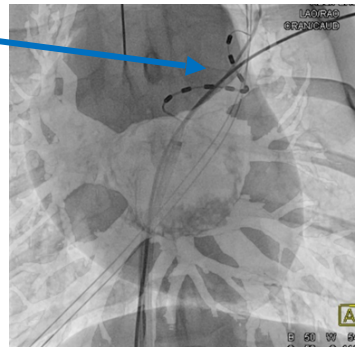








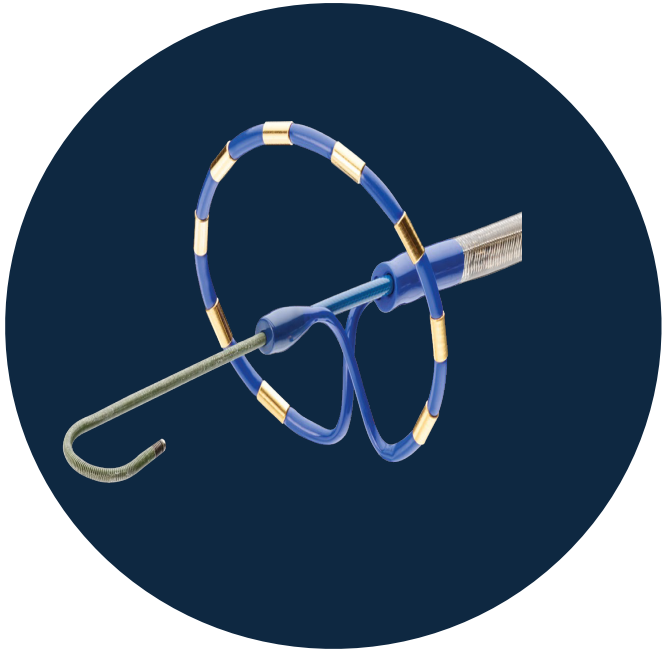




The impact of the catheter design

Persistent atrial fibrillation treatment key catheter's features

- Size
- Easy manuverability
- Omogenous electric field (fixed electrodes spacing)
- Safety Features

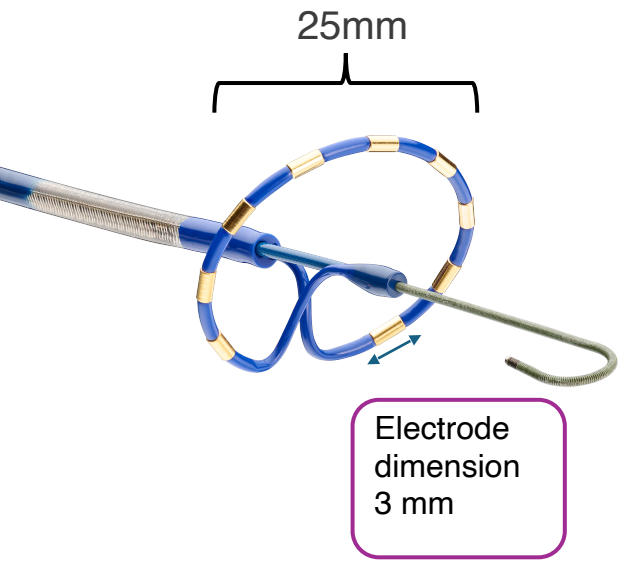


9 Fr

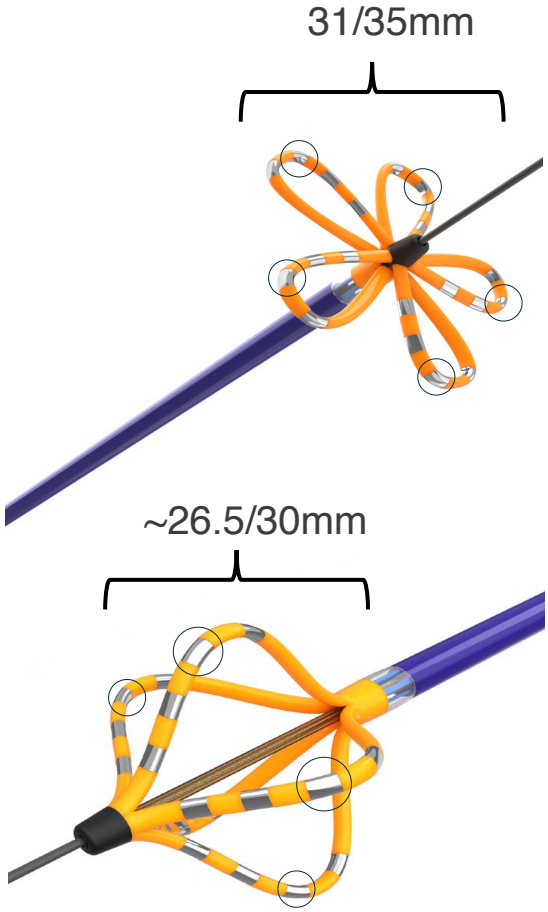
8.5 Fr

Catheter Technical Specifications

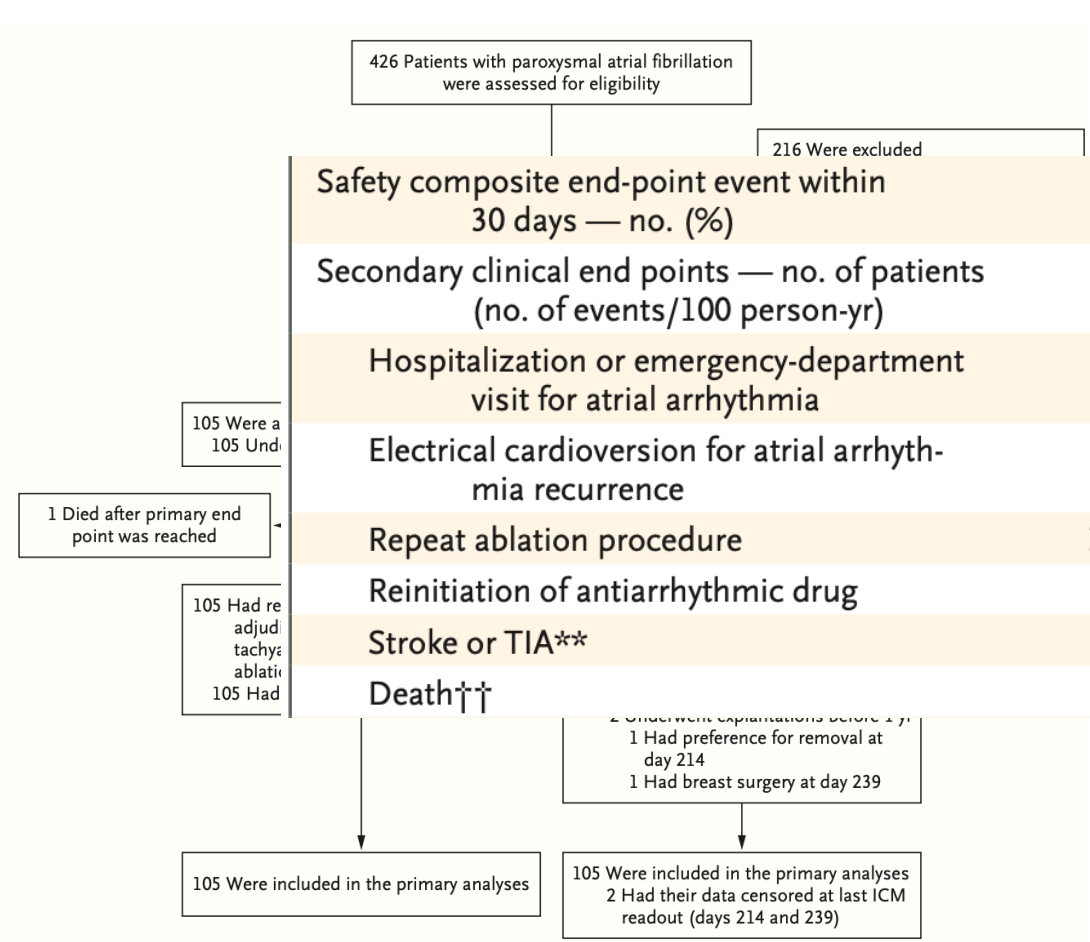
- Relaible signals recording (overcame stunning effect)



PulseSelect™		Farawave™
Over-the-wire, PVI, Fixed circular catheter	**Catheter Description**	Over-the-wire, PVI, Basket and Flower configuration
25mm	**Array sizes**	31mm 35mm
Biphasic	**PFA Waveform**	Biphasic
Bipolar	**Vectoring**	Bipolar
9.8 Fr Deflectable Bi-directional	**Shaft description**	12.8 Fr Non-Deflectable
10Fr sheath Bi-directional	**Sheath description**	13Fr sheath Uni-directional
0.032” J-tip	**Guidewire**	0.035” J-tip
9 ablation electrodes	**Number of electrodes**	20 ablation electrodes
9 mapping electrodes	**Mapping electrodes**	5 mapping electrodes
No	**Irrigation Required**	No
8 applications minimum	**Dosing Strategy per vein**	8 applications minimum



Single shot CHAMPION trial



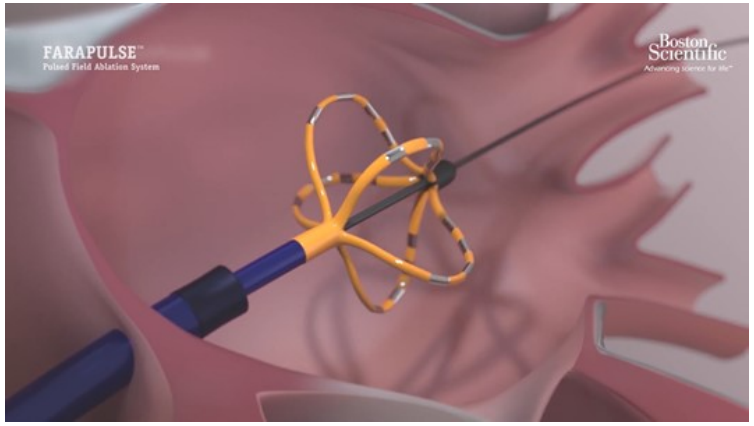
Safety composite end-point event within 30 days — no. (%)	1 (1.0)	2 (1.9)	—	0.50 (0.05 to 5.43)‖
Secondary clinical end points — no. of patients (no. of events/100 person-yr)				
Hospitalization or emergency-department visit for atrial arrhythmia	2 (1.9)	8 (7.6)		0.25 (0.05 to 1.15)
Electrical cardioversion for atrial arrhythmia recurrence	2 (1.9)	4 (3.8)		0.50 (0.09 to 2.68)
Repeat ablation procedure	16 (15.2)	10 (9.5)		1.60 (0.76 to 3.37)
Reinitiation of antiarrhythmic drug	3 (2.9)	3 (2.9)		1.00 (0.21 to 4.86)
Stroke or TIA**	1 (1.0)	2 (1.9)		0.50 (0.05 to 5.46)
Death††	1 (1.0)	0		NA

Among patients with symptomatic paroxysmal atrial fibrillation, PFA was noninferior to cryoballoon ablation with respect to the incidence of a first recurrence of atrial tachyarrhythmia, as assessed by continuous rhythm monitoring. (Funded by Inselspital and others; SINGLE SHOT CHAMPION ClinicalTrials.gov number, NCT05534581.)

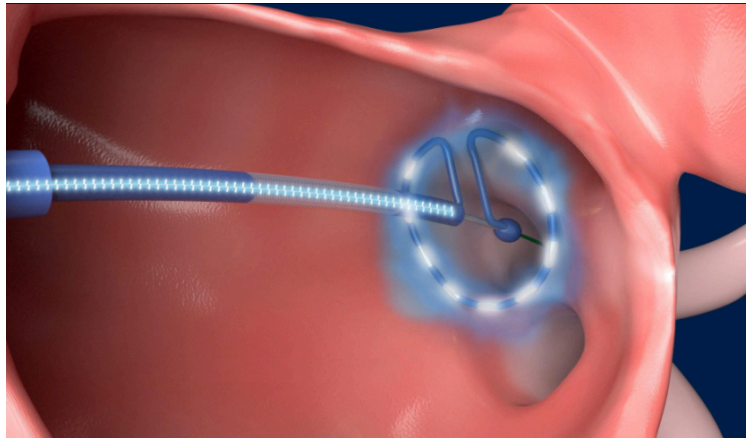
Reichlin T et al. NEJM. 202

In Modena?

FARAPULSE ™ - Boston



PULSELECT ™ - Medtronic



SOFARE Milestones

Milestone	Date
Protocol designed	September 5, 2023
1° Regulatory Approval	March 12, 2023
1° Site activation	March 12, 2023 -> Modena
Patient enrollment	Ongoing (Now 128)
Target: enrollment complete	Late 2028
Projected: Follow-up complete	Late 2029

SOFARE Study design

SOFARE is a prospective, multicenter, observational registry that aim to enroll consecutive patients > 18 years old undergoing AF ablation with any of available tecniques

Inclusion criteria

- Age >18 years
- Documented atrial fibrillation onfirmed by a specialist during a visit within 12 months from enrollment
- Has undergone atrial fibrillation ablation
- Life expectancy > 12 months
- Informed consent signature

Outcomes

Primary objectives

1. Number of AF recurrences during follow-up
2. Number of re-ablation procedures for AF

Secondary objectives

1. Identify predictors of AF recurrence
2. Identify predictors of re-ablation for AF
3. Identify complications related to AF ablation
4. Assess the impact of ablation on patient symptoms using dedicated scores

Follow-up

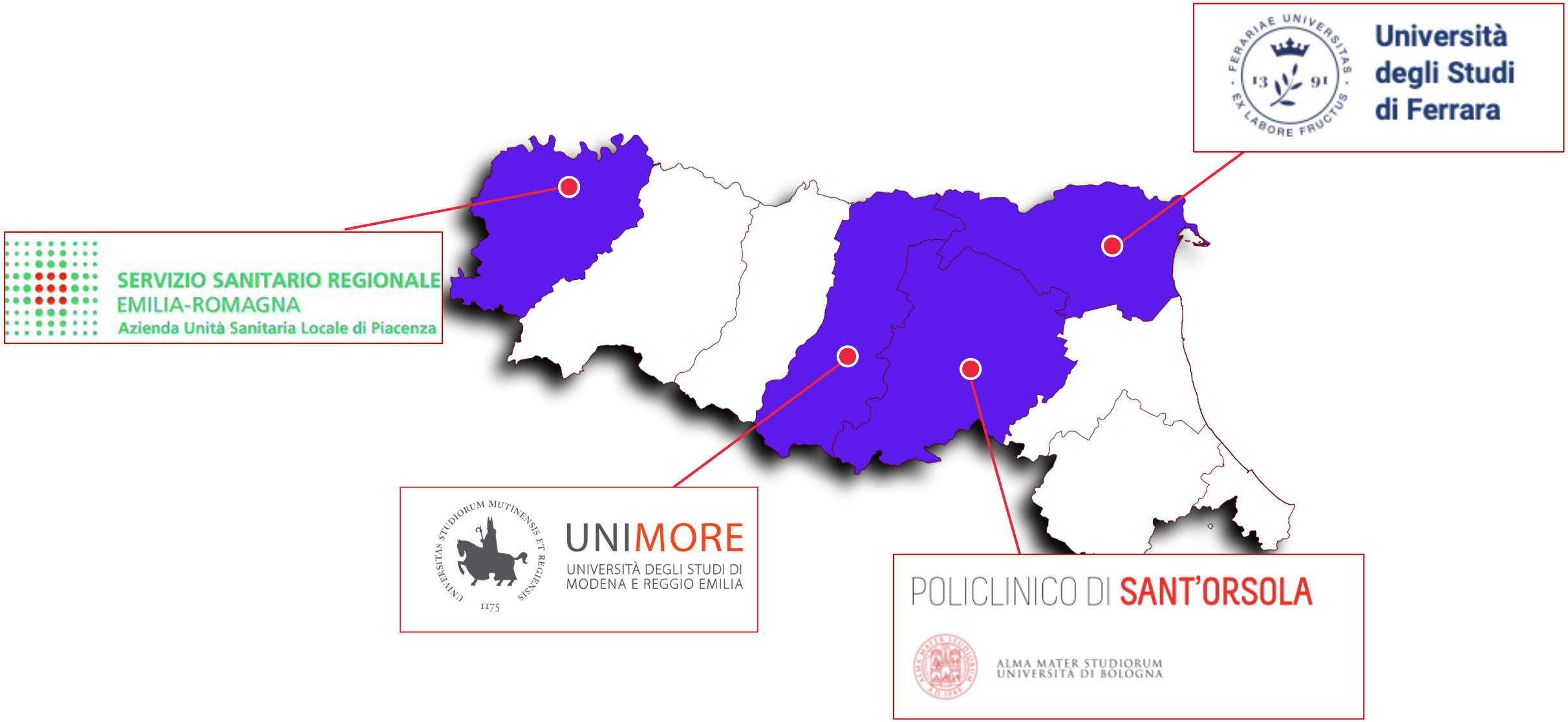
Pre specified follow up

1. 3 months
2. 12 months
3. 24 months

Timepoints

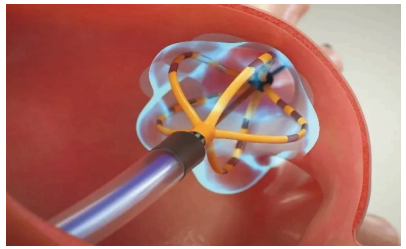
1. End of enrollment 31-12-2028
2. End of follow-up
3. 31-12-2029

SOFARE Consortium

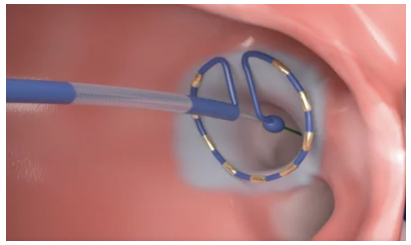


RESULTS: study population

128 patients



79 patients: FARAPULSE
(Boston)



49 patients: PulseSelect
(Medtronic)

Similar age, CV comorbidities and CHA_2DS_2-VASc score

75 Paroxysmal AF
53 Persistent AF

	Circular (PulseSelect)	Pentaspline (FARAPULSE)	p
n	49	79	
Age (median [IQR])	59.00 [54.00, 68.00]	61.00 [54.50, 66.00]	0.951
Females (%)	15 (30.6)	20 (25.3)	0.653
BMI (median [IQR])	26.30 [24.22, 29.09]	25.80 [23.35, 29.37]	0.818
Metabolic Category (%)			0.567
- **Normalweight**	18 (36.7)	34 (43.0)	
- **Overweight**	22 (44.9)	28 (35.4)	
- **Obese**	9 (18.4)	17 (21.5)	
LAVI max (median [IQR])	39.00 [29.00, 50.50]	33.75 [27.38, 44.25]	0.114
PALS (median [IQR])	30.00 [21.25, 36.75]	23.50 [20.00, 29.50]	0.039
EFLA (median [IQR])	48.00 [38.00, 58.00]	46.00 [36.00, 55.75]	0.353
LVEF (median [IQR])	58.00 [55.00, 63.00]	59.00 [55.00, 61.50]	0.792
CHA_2DS_2-VASc (median [IQR])	1.00 [1.00, 2.00]	1.00 [0.50, 2.00]	0.359
Heart failure (%)	3 (6.1)	7 (8.9)	0.824
CAD (%)	2 (4.1)	3 (3.8)	1.000
Hypertension (%)	28 (57.1)	38 (48.1)	0.416
Diabetes (%)	1 (2.0)	11 (13.9)	0.054
Thromboembolic event (%)	1 (2.0)	3 (3.8)	0.974
HAS-BLED (median [IQR])	0.00 [0.00, 1.00]	0.00 [0.00, 1.00]	0.831
Persistent AF	15 (30.6)	24 (30.4)	1.000
ECV (%)	35 (71.4)	58 (73.4)	0.967
Ablation (%)	6 (12.2)	9 (11.4)	1.000
EHRA class baseline (%)			0.064
- **I**	0 (0.0)	4 (5.1)	

RESULTS: procedural duration and left atrial dwell time

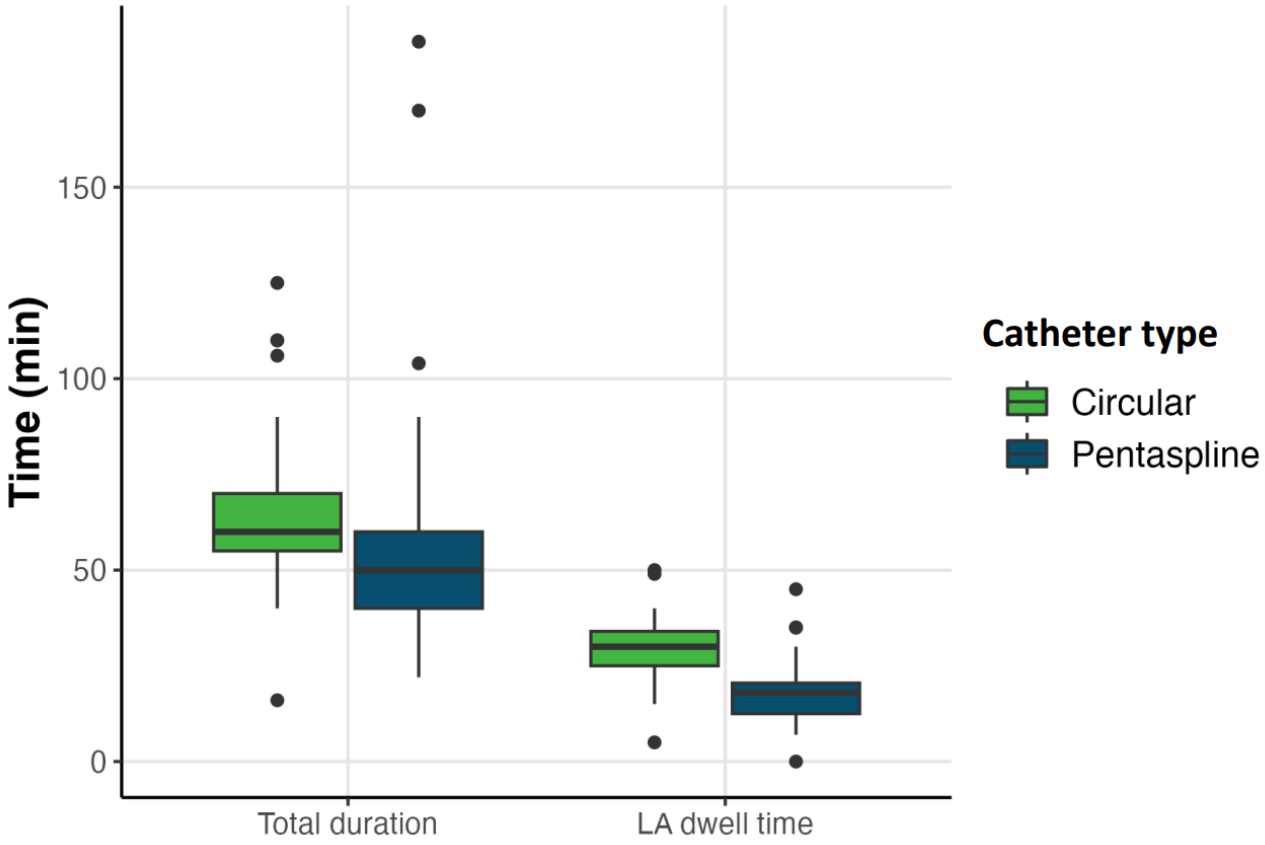
The median **procedural time** and the **left atrial dwell time** were significantly **longer** in group treated with the **circular** ablation **catheter** compared to the group treated with the pentaspline ablation catheter

Circular catheter

- Median procedure times: **60 minutes** (IQR [55.0-70.0], $p < 0.001$)
- Median LA dwell time: **30 minutes** (IQR [25.0-34.0], $p < 0.001$)

Pentaspline catheter

- Median procedure times: **50 minutes** (IQR [40.0-60.0], $p < 0.001$)
- Median LA dwell time: **18 minutes** (IQR [12.5-20.5], $p < 0.001$)



RESULTS: rates of periprocedural complication

Total complication prevalence was **7.8%**

No significant differences in the rate of **serious adverse events** in circular ablation catheter group vs pentaspline ablation catheter group

The most observed adverse event was **bleeding complication** (3.9%)

No deaths were reported.

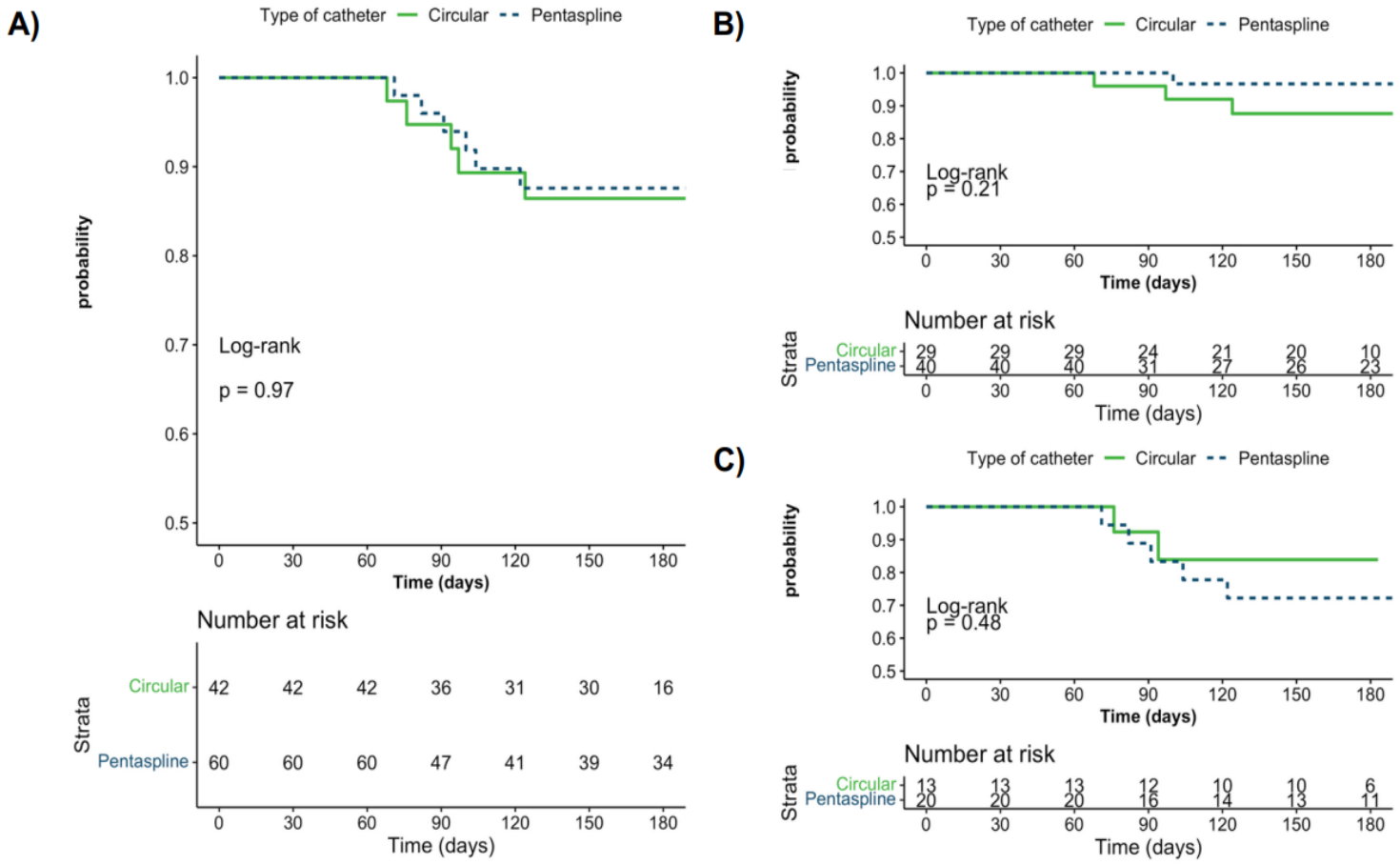
	Circular (PulseSelect)	Pentaspline (FARAPULSE)	p
n	49	79	
SAE (%)	6 (12.2)	4 (5.0)	0.667
Type of complication (%)			0.400
None	43 (87.8)	75 (94.9)	
Bleeding	3 (6.1)	2 (2.5)	
Cardiac tamponade	1 (2.0)	0 (0.0)	
Cardiac perforation	0 (0.0)	0 (0.0)	
Pericardial effusion	0 (0.0)	0 (0.0)	
Phrenic nerve injury	0 (0.0)	0 (0.0)	
Phrenic nerve paralysis	0 (0.0)	0 (0.0)	
Esophageal injury	0 (0.0)	0 (0.0)	
Mycardial infarction	0 (0.0)	1 (1.3)	
Cardiac arrest	0 (0.0)	0 (0.0)	
Pericarditis	0 (0.0)	0 (0.0)	
Stroke	0 (0.0)	0 (0.0)	
Delirium post-anesthesia	2 (4.0)	1 (1.3)	

Results: with 60 days of blanking period

103 (80.4%) patients (43 [87.8%] that underwent PFA with PulseSelect vs 60 [75.9%] with FARAPULSE) completed the **6 months follow up** visit.

Recurrence of AF, was observed in **8 cases (18.6%)** in the subgroup treated with the **circular catheter** and recorded in **13 cases (21.7%)** in the subgroup treated with the **Pentaspline catheter** (P=0.80).

Kaplan-Meier analysis showed a **higher** risk of **recurrence** for patients with **persistent AF** compared to paroxysmal AF, with no difference according to the type of catheter used.



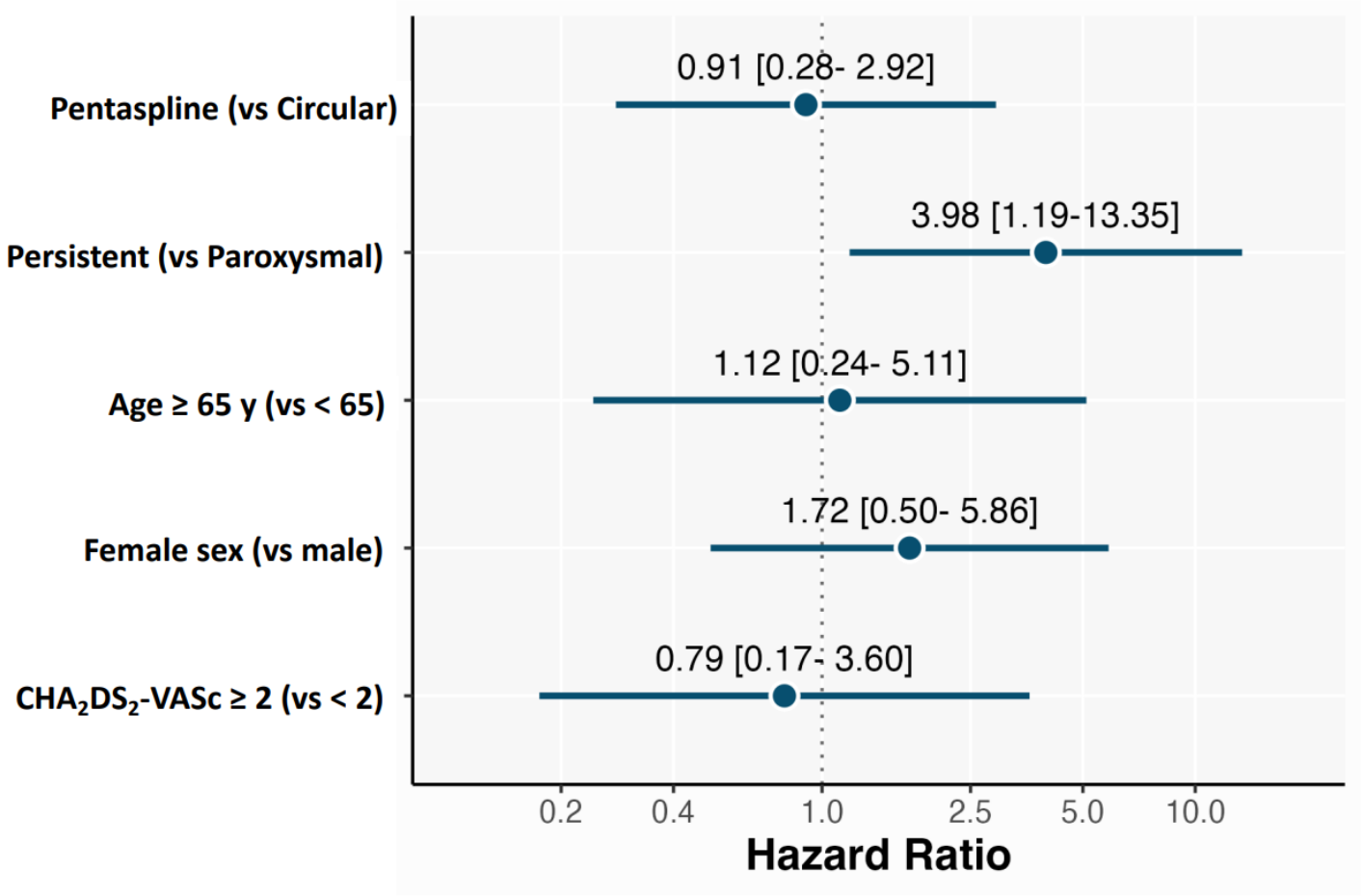
A) All patients; B) Patients with paroxysmal AF; C) Patients with persistent AF.

RESULTS: predictors of recurrence in the SOFARE cohort

Recurrent AF rates are **similar** between the two **PFA systems**

Risk of **recurrence** was **higher** for patients with **persistent AF** compared to paroxysmal AF (HR 3.98 [95% C.I. 1.19 – 3.35], p=0.025

No difference in the **risk of recurrence** was found for **age** ≥ 65 years vs. < 65 years (HR 1.12 [95% C.I. 0.24 – 5.11], p=0.88), female **sex** vs. male (HR 1.72 [95% C.I. 0.50 – 5.86], p=0.38), and **CHA2DS2-VASc** ≥ 2 vs < 2 (HR 0.79 [95% C.I. 0.17 – 3.60], p=0.76).



Grazie a tutti e all’equipe