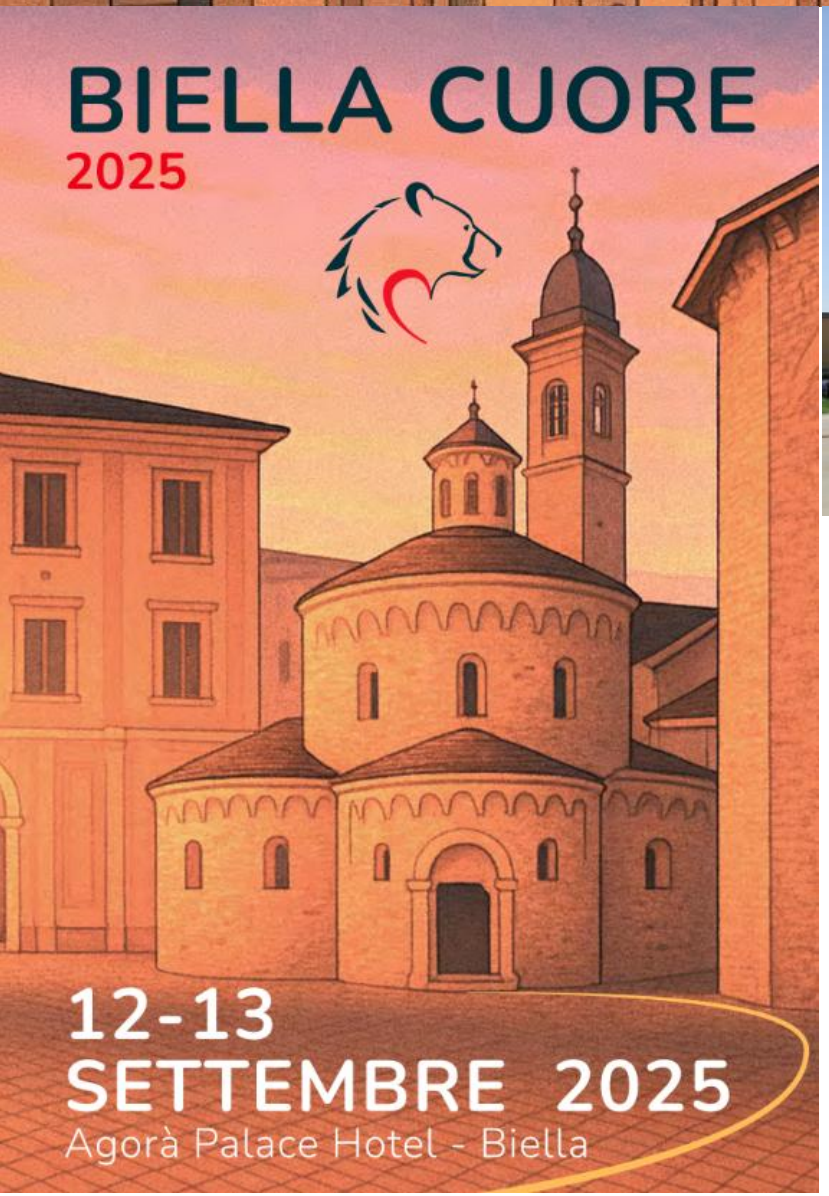
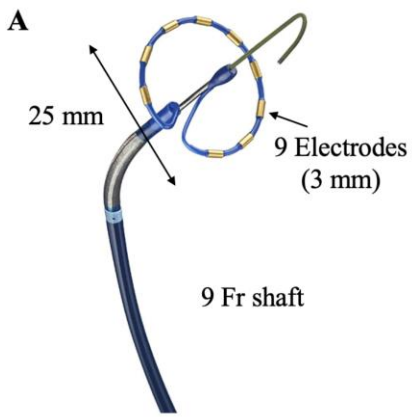
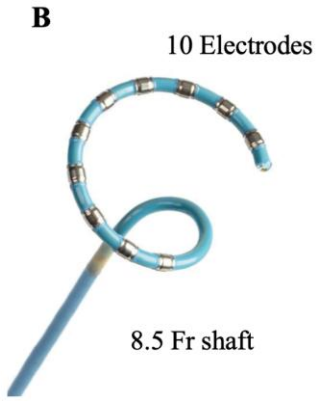
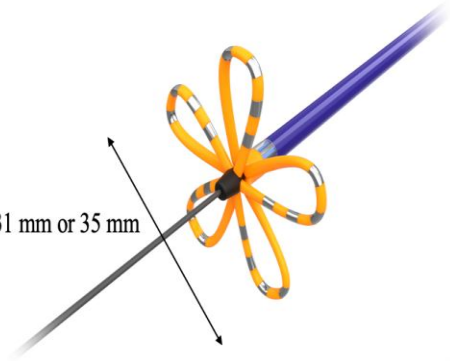


PFA: esperienze di real life

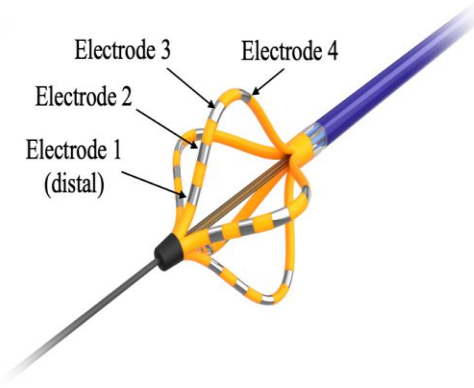
Dr. Ruggero Maggio



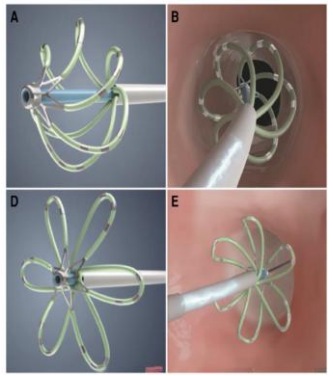


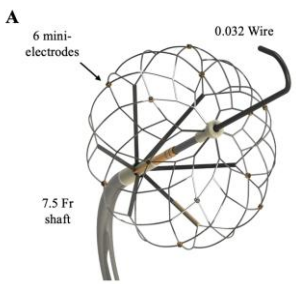


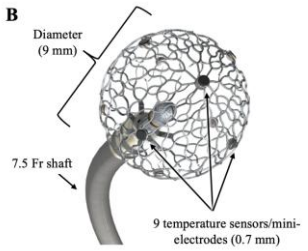
Fully deployed "flower" configuration

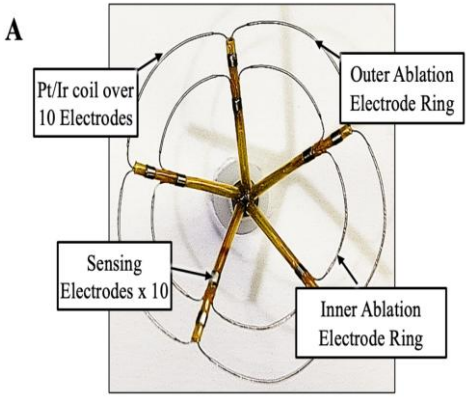


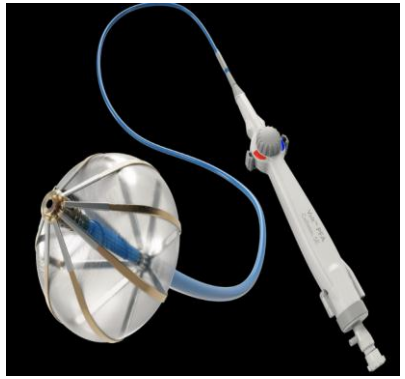
Partially deployed "basket" configuration

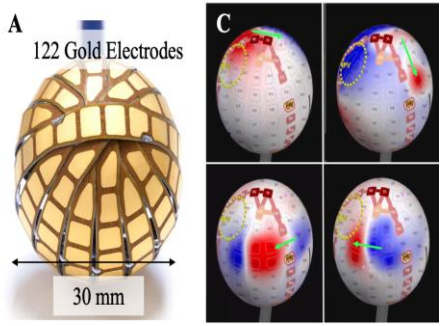










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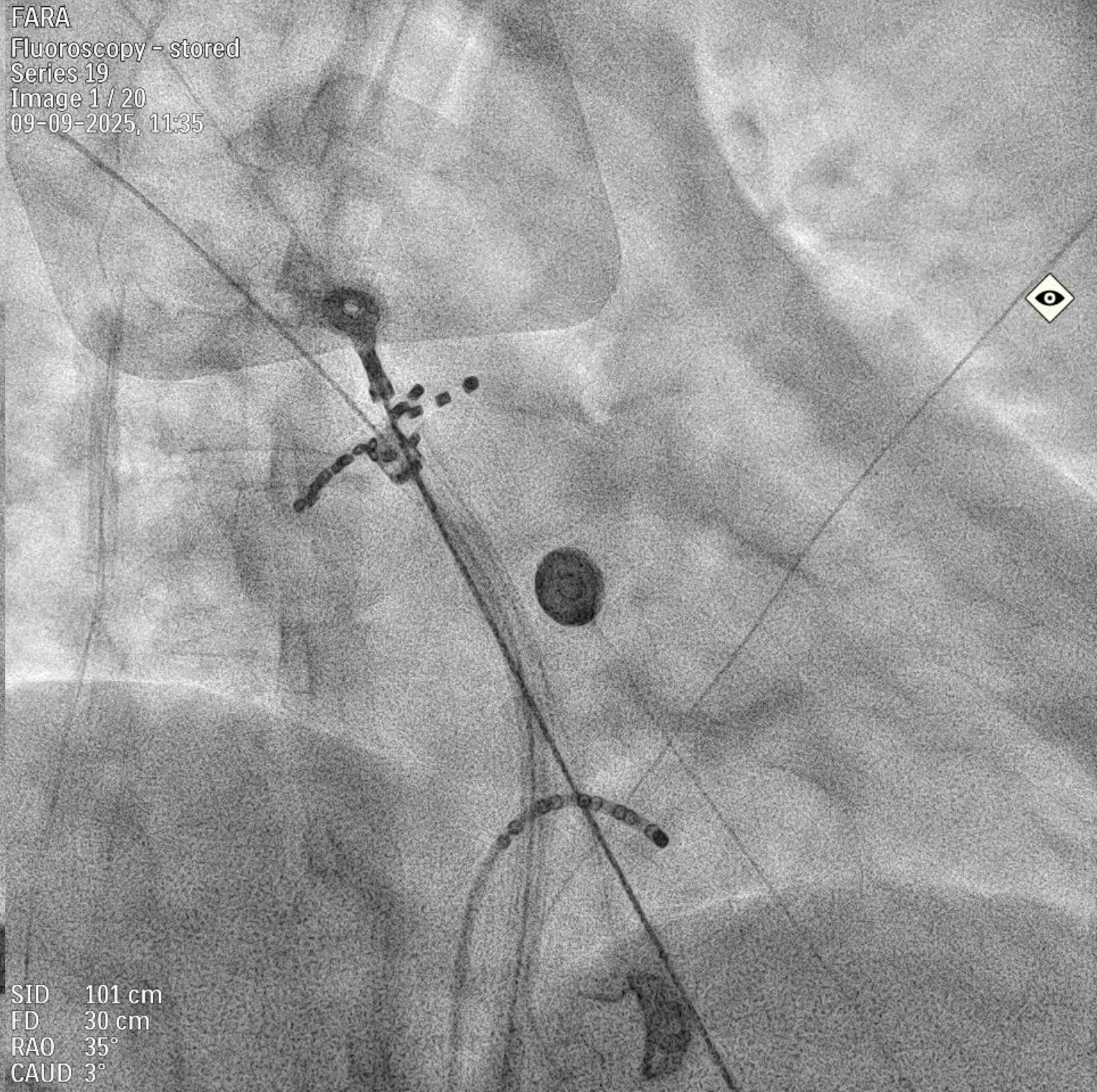
FD 30 cm
RAO 1°
CAUD 3°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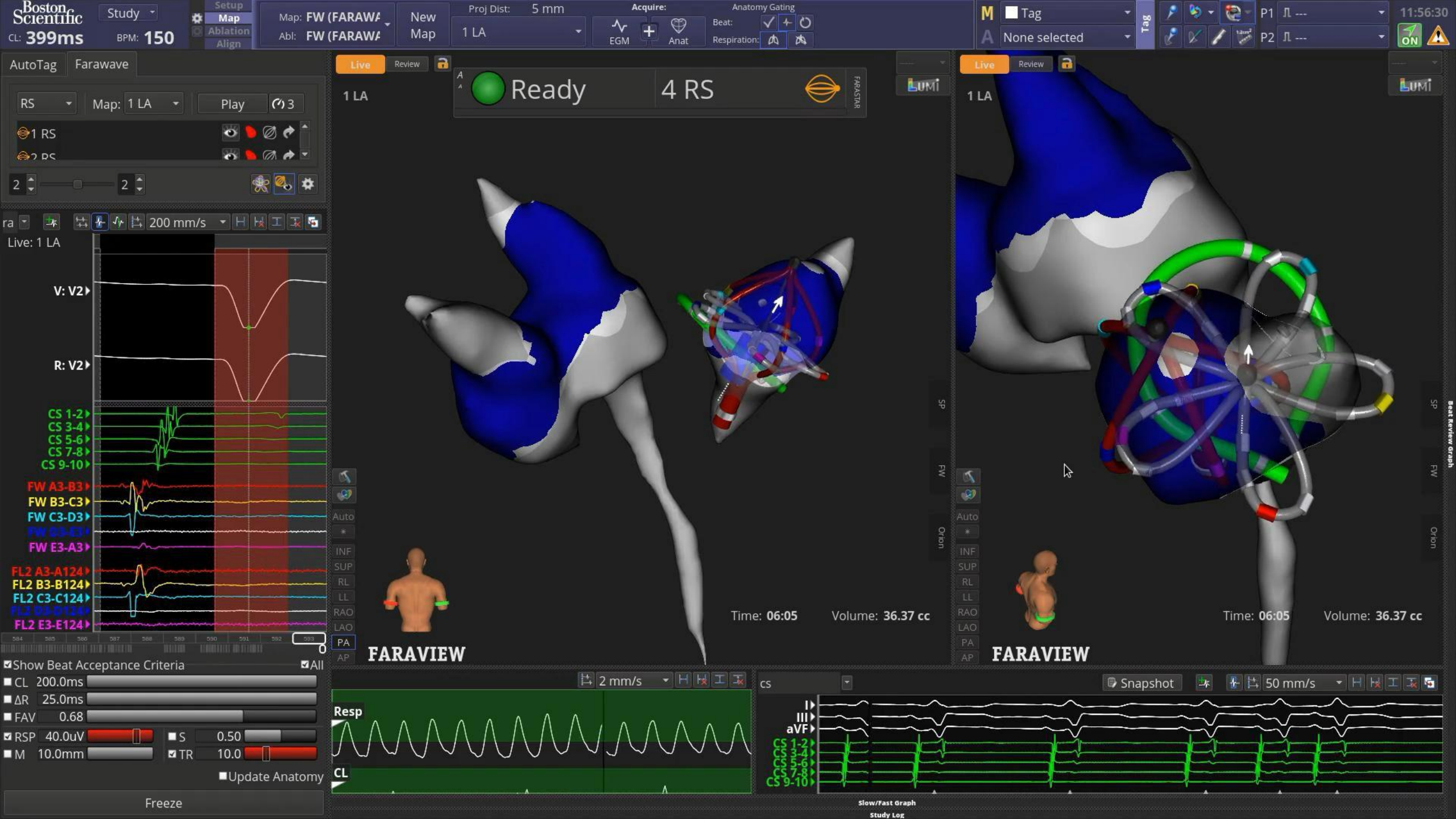
Boston Scientific
Study
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BPM: 150
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Ablation
Align
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Abl: FW (FARAWA
New Map
Proj Dist: 5 mm
1 LA
Acquire:
EGM
Anat
Anatomy Gating
Beat:
Respiration:
M
Tag
A
None selected
Tag
P1
P2
11:56:30
ON
AutoTag
Farawave
RS
Map: 1 LA
Play
3
1 RS
2
2
ra
200 mm/s
Live: 1 LA
V: V2
R: V2
CS 1-2
CS 3-4
CS 5-6
CS 7-8
CS 9-10
FW A3-B3
FW B3-C3
FW C3-D3
FW D3-E3
FW E3-A3
FL2 A3-A124
FL2 B3-B124
FL2 C3-C124
FL2 D3-D124
FL2 E3-E124
Show Beat Acceptance Criteria
All
CL 200.0ms
ΔR 25.0ms
FAV 0.68
RSP 40.0uV
S 0.50
M 10.0mm
TR 10.0
Update Anatomy
Freeze
Live
Review
1 LA
Ready
4 RS
FARASTAR
LUMI
Auto
INF
SUP
RL
LL
RAO
LAO
PA
AP
SP
FW
Orion
Time: 06:05
Volume: 36.37 cc
FARAVIEW
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1 LA
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FW
Orion
Beat Review Graph
Time: 06:05
Volume: 36.37 cc
FARAVIEW
2 mm/s
Resp
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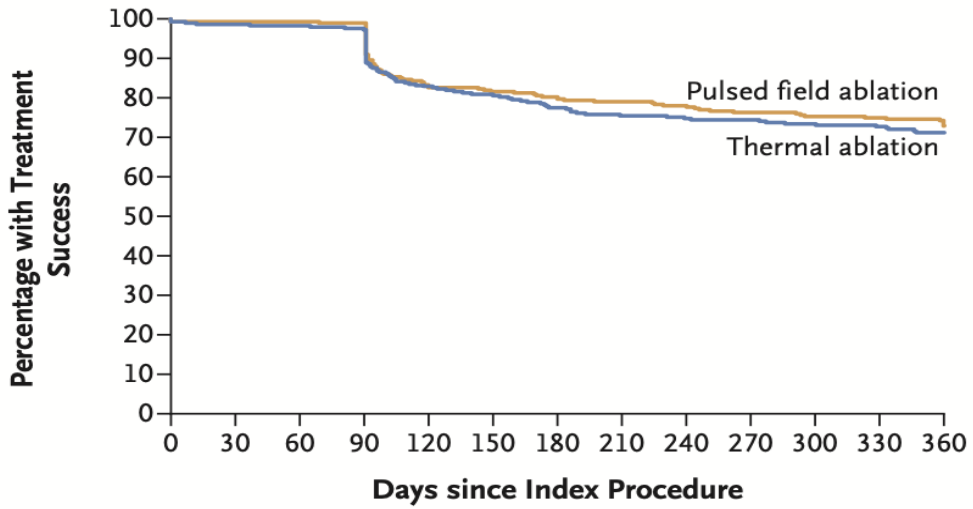
cs
Snapshot
50 mm/s
I
III
aVF
CS 1-2
CS 3-4
CS 5-6
CS 7-8
CS 9-10
Slow/Fast Graph
Study Log

ORIGINAL ARTICLE

Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation

Vivek Y. Reddy, M.D., Edward P. Gerstenfeld, M.D., Andrea Natale, M.D., William Whang, M.D., Frank A. Cuoco, M.D., Chinmay Patel, M.D., Stavros E. Mountantonakis, M.D., Douglas N. Gibson, M.D., John D. Harding, M.D., Christopher R. Ellis, M.D., Kenneth A. Ellenbogen, M.D., David B. DeLurgio, M.D., Jose Osorio, M.D., Anitha B. Achyutha, M.Tech., M.S.E., Christopher W. Schneider, M.Eng., Andrew S. Mugglin, Ph.D., Elizabeth M. Albrecht, Ph.D., Kenneth M. Stein, M.D., John W. Lehmann, M.D., M.P.H., and Moussa Mansour, M.D., for the ADVENT Investigators*



NEJM 2023;389:1660-167

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Pulsed Field Ablation (N=305)	Thermal Ablation (N=302)†
Age — yr	62.4±8.7	62.5±8.5
Sex — no. (%)		
Male	202 (66.2)	195 (64.6)
Female	103 (33.8)	107 (35.4)
Body-mass index‡	28.3±4.6	29.0±4.8
Race or ethnic group — no. (%)§		
American Indian or Alaska Native	0	1 (0.3)
Asian	6 (2.0)	5 (1.7)
Black	4 (1.3)	11 (3.6)
Native Hawaiian or other Pacific Islander	1 (0.3)	2 (0.7)
White	286 (93.8)	272 (90.1)
Unknown or declined to disclose	8 (2.6)	11 (3.6)
CHA_2DS_2-VASc score¶	1.7±1.2	1.7±1.2
Concomitant clinical conditions — no. (%)		
Coronary artery disease	32 (10.5)	51 (16.9)
Congestive heart failure: NYHA class I or II	59 (19.3)	59 (19.5)
Diabetes	33 (10.8)	32 (10.6)
Dyslipidemia	133 (43.6)	141 (46.7)
Hypertension	174 (57.0)	159 (52.6)
Sleep apnea	81 (26.6)	88 (29.1)
Previous stroke or TIA	12 (3.9)	15 (5.0)
Years since first diagnosis of paroxysmal atrial fibrillation	3.8±6.2	3.3±4.5
Any antiarrhythmic drug at baseline — no. (%)‖	301 (98.7)	300 (99.3)
Class I	115 (37.7)	101 (33.4)
Class II**	174 (57.0)	201 (66.6)
Class III	70 (23.0)	72 (23.8)
Class IV	79 (25.9)	66 (21.9)
Any anticoagulant — no. (%)	305 (100)	301 (99.7)
Nonwarfarin oral anticoagulant	303 (99.3)	300 (99.3)
Vitamin K antagonist	2 (0.7)	1 (0.3)

ESC European Society of Cardiology
Europace (2024) **26**, euae103
https://doi.org/10.1093/europace/euae103

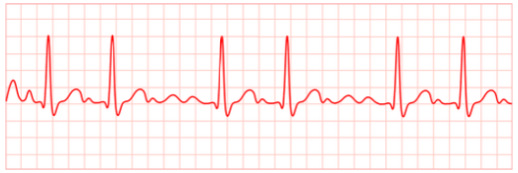
Comparing pulsed field electropo and radiofrequency ablation for t of paroxysmal atrial fibrillation: d and rationale of the BEAT PARO randomized clinical trial

Nico Erhard[1]*, Eric Frison [2], Julien Asselineau[2], Besma A Serge Boveda [3], Hubert Cochet [4], Isabel Deisenhofer Anne Gimbert[6], Josef Kautzner [7], Sebastien Knecht [8], Petr Neuzil [10], Marine Rousset [6], Daniel Scherr [11], Christopher W. Schneider[12], Maxime Sermesant [13,14], D and Pierre Jaïs [4]; on behalf of the BEAT-AF Study group

BEAT AF

BEAT PAROX-AF
randomized clinical trial

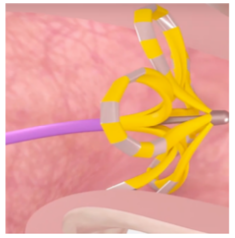
292 patients with drug-resistant paroxysmal AF
1:1 Randomization



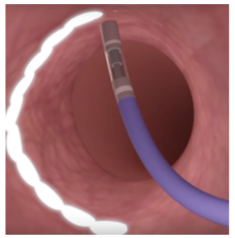
9 European clinical centres
(France, czechia, germany, austria, belgium)

Intervention

PFA PVI, high-voltage pulsed energy (2000 V) ≥ 8x per vein in two configurations (Farapulse, boston Scientific©)



RF PVI, using contact force catheter (CLOSE protocol, CARTO©, smart touch)



Aim and endpoint

Superiority of PFA over RF on 1-year, single-procedure, off-drug absence of atrial arrhythmia recurrence

A

LotosPFA ™

PFA Catheter

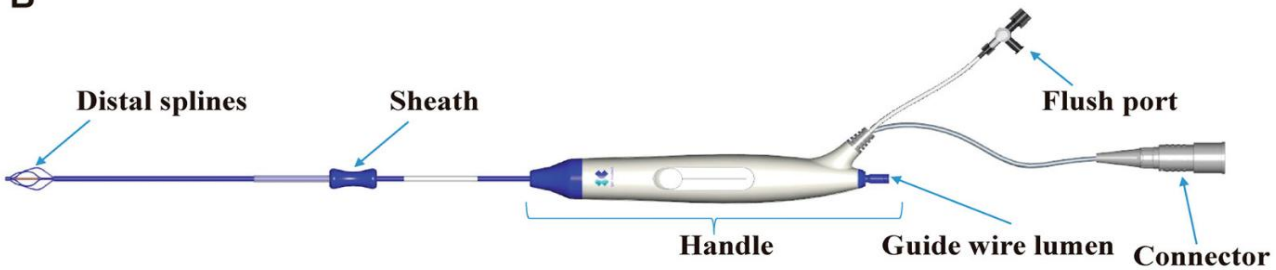
InBridge ™

Steerable Sheath

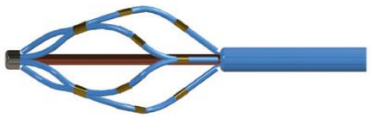
InRythm ™

PFA Generator

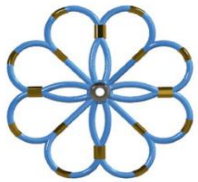
B



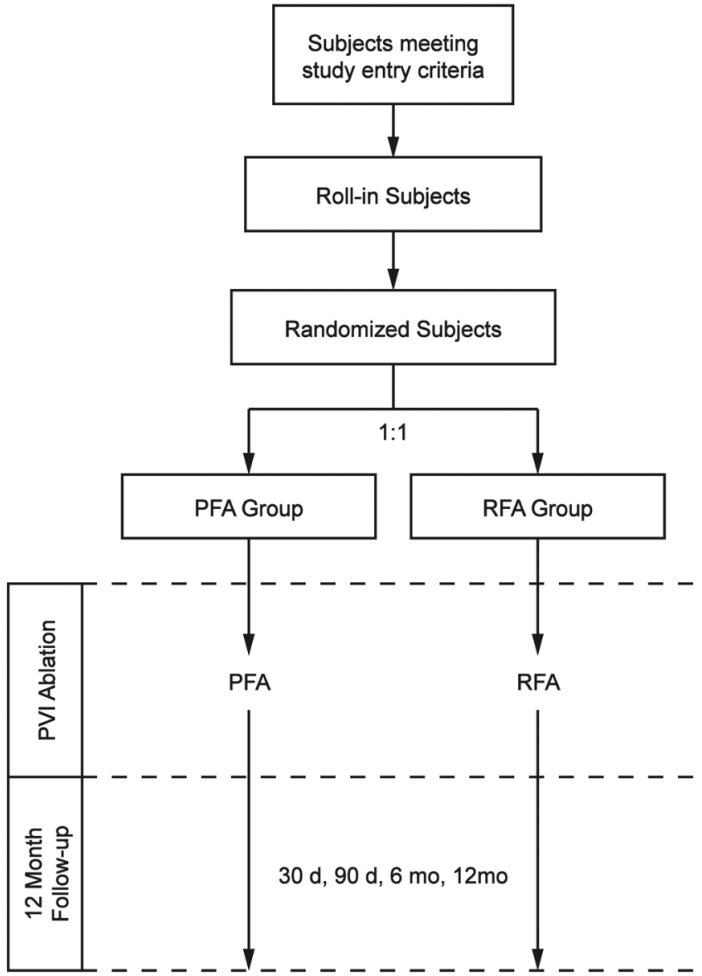
C

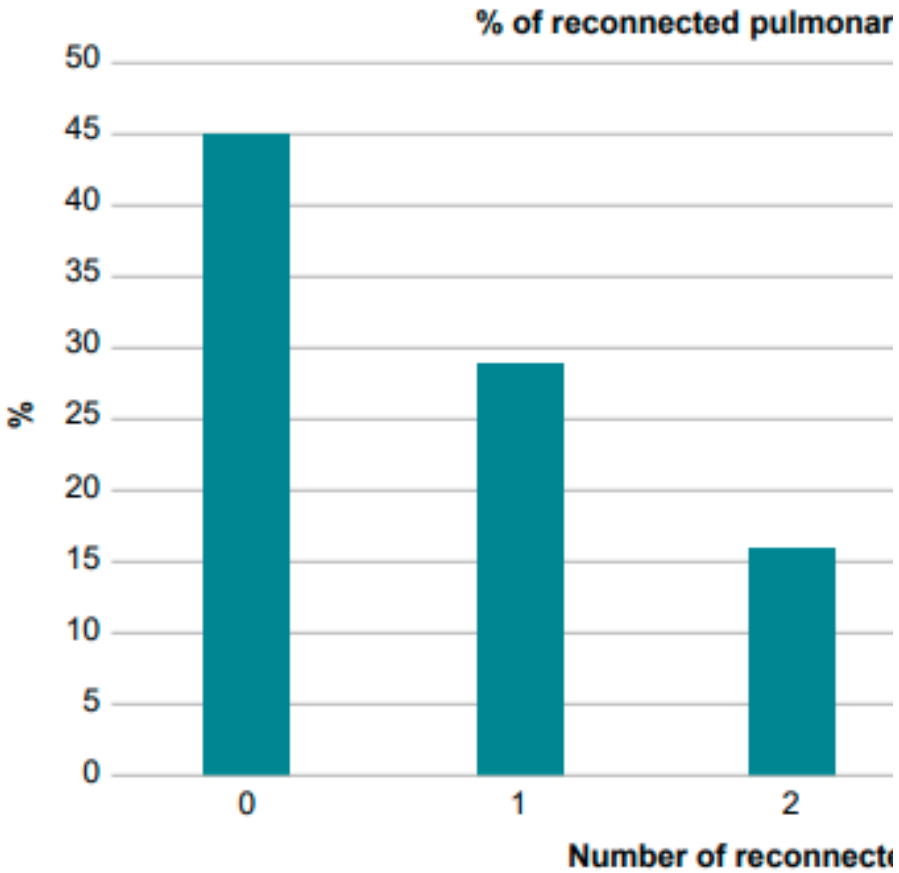


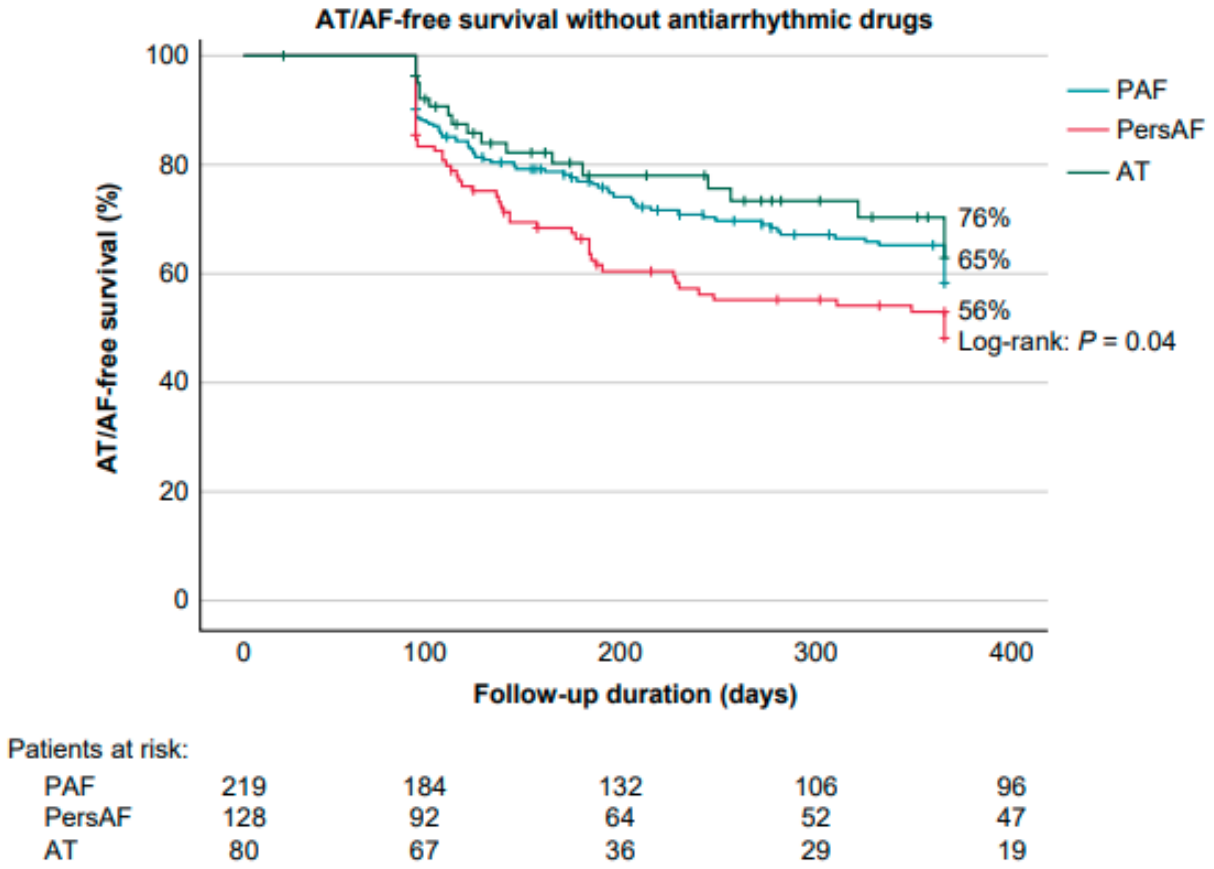
Spindle pose 8~20mm



Lotos pose 28mm, 31mm







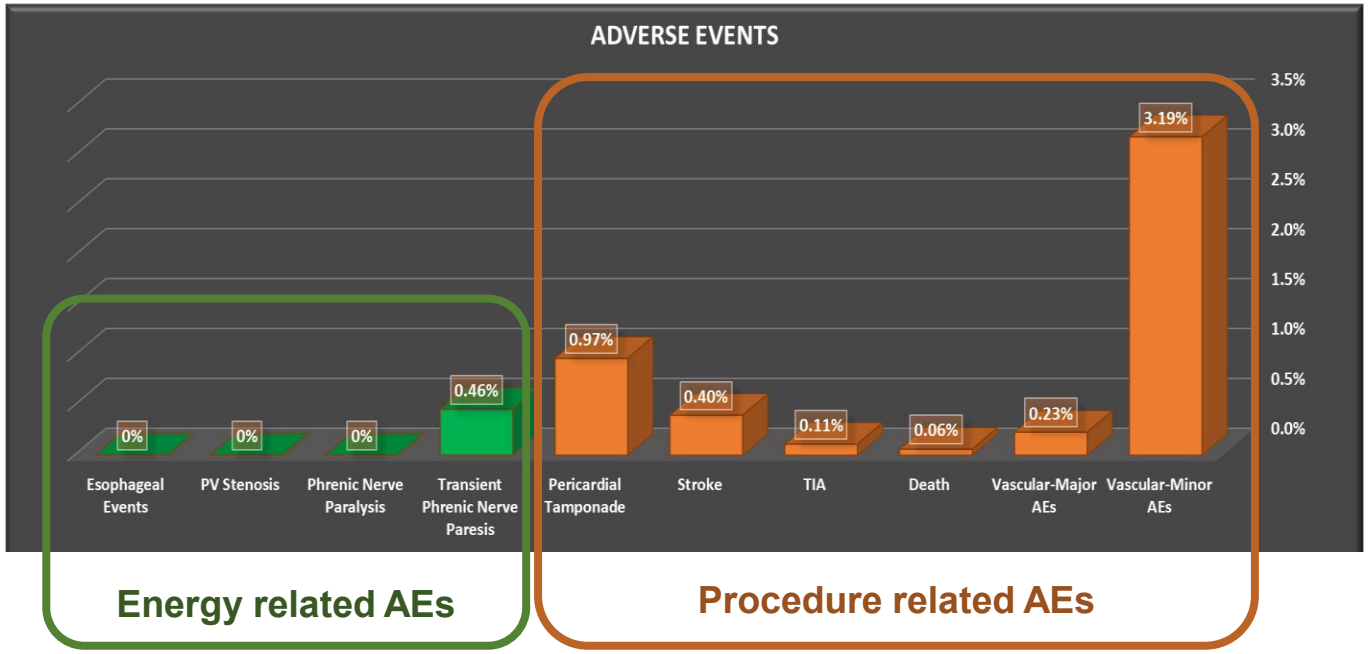
Patients at risk:

PAF	219	184	132	106	96
PersAF	128	92	64	52	47
AT	80	67	36	29	19

Manifest PF. Safety

In the 1,758-patient cohort:

- Major complication rate was 1.6% (n = 29)
- Minor complication rate was 3.87% (n = 68)



	N (%)
Major Complications	**29 (1.6%)**
Esophageal Fistula	0
Esophageal Dysmotility	0
Pulmonary Vein Stenosis	0
Pericardial Tamponade	17 (0.97)
Percutaneous Treatment	13 (0.74)
Surgical Treatment	4 (0.23)
Stroke	7 (0.40) *
Phrenic Nerve Injury (persistent) †	0
Vascular complications requiring surgery	4 (0.23)
Coronary artery spasm	1 (0.06)
Death	1 (0.06) *

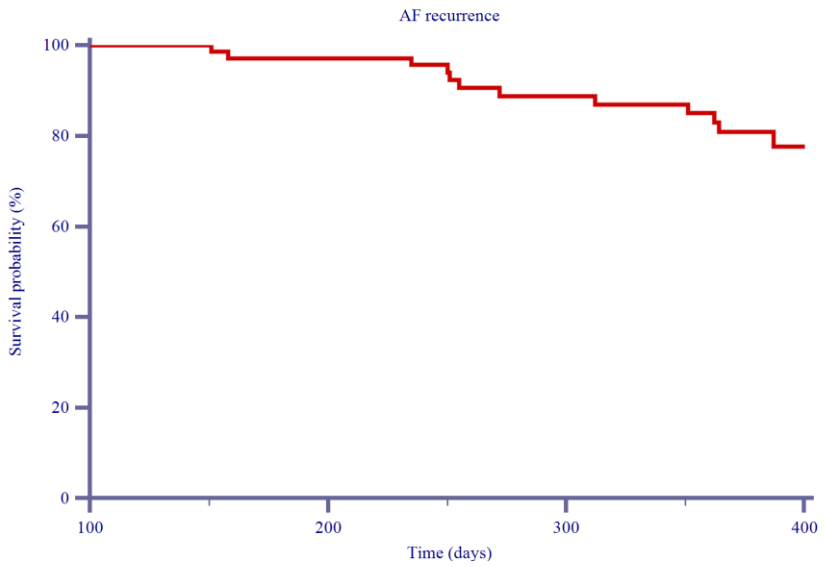
† Defined as persisting beyond hospital discharge.

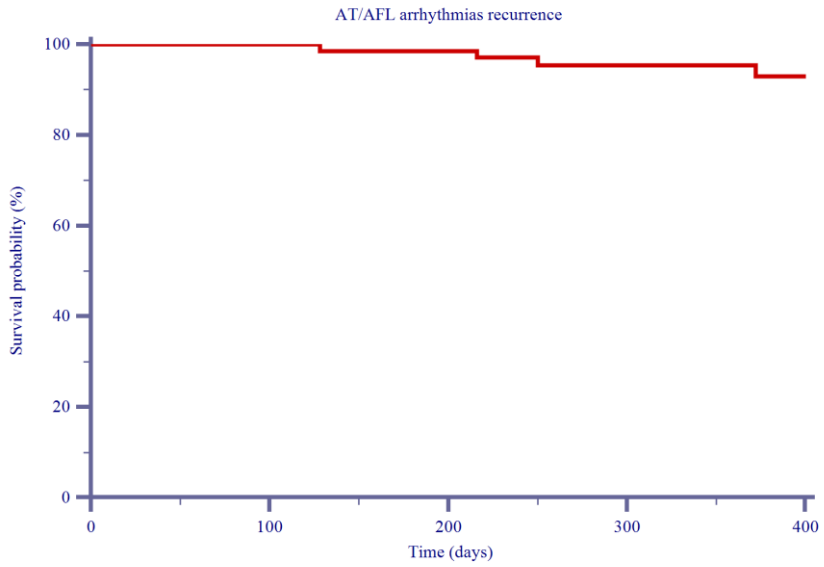
	N (%)
Minor Complications	**68 (3.87%)**
TIA	2 (0.11)
Phrenic Nerve Injury (transient) §	
Transient Effect	8 (0.46)
Vascular	
Hematoma	43 (2.45)
Pseudoaneurysm	4 (0.23)
AV Fistula	3 (0.17)
Other	6 (0.34)
Other complications	
Hemoptysis Requiring Bronchoscopy	1 (0.06)
Persistent Dry Cough x 6 wks	1 (0.06)

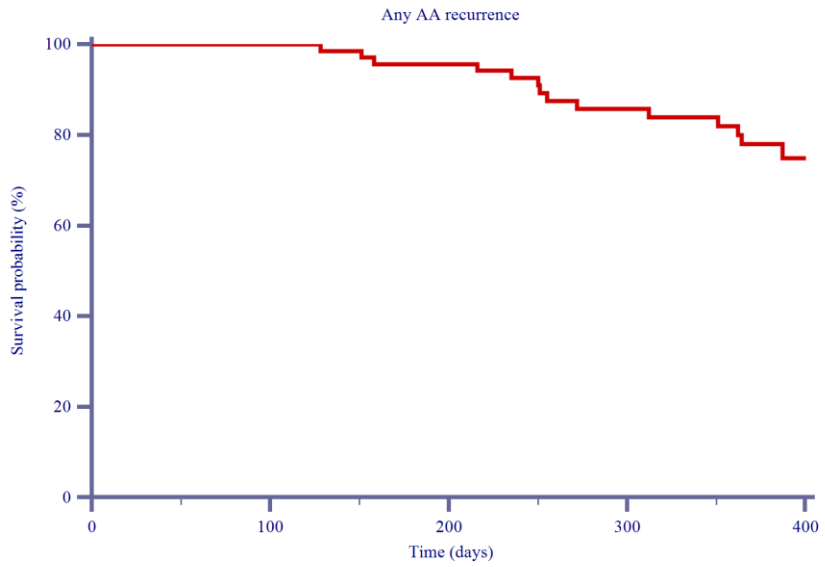
Parameter	N = 203
Age, year	64±9
Female gender	30.9%
AF type - Paroxysmal AF - Persistent AF - Long standing AF	 - 42.7% - 57.3% - 26.3%
LVEF, %	56±9
CAD	14.2%
CKD	8.1%
COPD	3.7%
Cancer history	10.3%
Sleep apnea	4.1%
Diabetes	10.7%
Hypertension	66.5%
CHA2DS2VAs, n	2 [1-3]

Parameter	N = 203
Procedure type - De novo - Repeated	 - 87.7% - 12.3%
Ablation approach - PVI only - Additional lesion set	 - 55.7% - 44.3%
3D mapping	22.3%
Lab occupancy tyme, min	90 [80-100]
Skin-to-skin time, min	64 [60-75]
Fluoroscopy time, min	14 [11-19]
Radiation exposure, Gy*cm2	10 [5-26]
Total number of PFA deliveries, n	40 [32–52]
PFA deliveries at PVs, n	36 [32-40]
PFA deliveries outside PVs, n	12 [10-16]

1 (0.5%) major complication (cardiac tamponade)







Outcome measure (n=70)	Overall	Paroxysmal	Persistent	PVI only	PVI+*
AF recurrence during blanking period (90 days)	4.3%	8%	2.2%	2.2%	4.0%
AF recurrence	17.1%	12.0%	20.0%	8.9%	32.0%
AT/AFL recurrence	5.7%	4.0%	6.7%	0.0%	16.0%
Any Atrial Arrhythmia recurrence	20%	16.0%	22.2%	8.9%	40.0%

*primarily driven by repeated ablation (50% AA recurrence in redos)

Conclusioni

Efficacia clinica simile a RF

Sicurezza maggiore per esofago, stenosi vene polmonari e nervo frenico. Ablazione della parete posteriore **sicura**, efficacia da valutare

Tempi di procedura e di sala ridotti

GRAZIE PER L'ATTENZIONE