



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria

Auditorium
della Tecnica

9^a Edizione

30 Settembre

1 Ottobre

2022



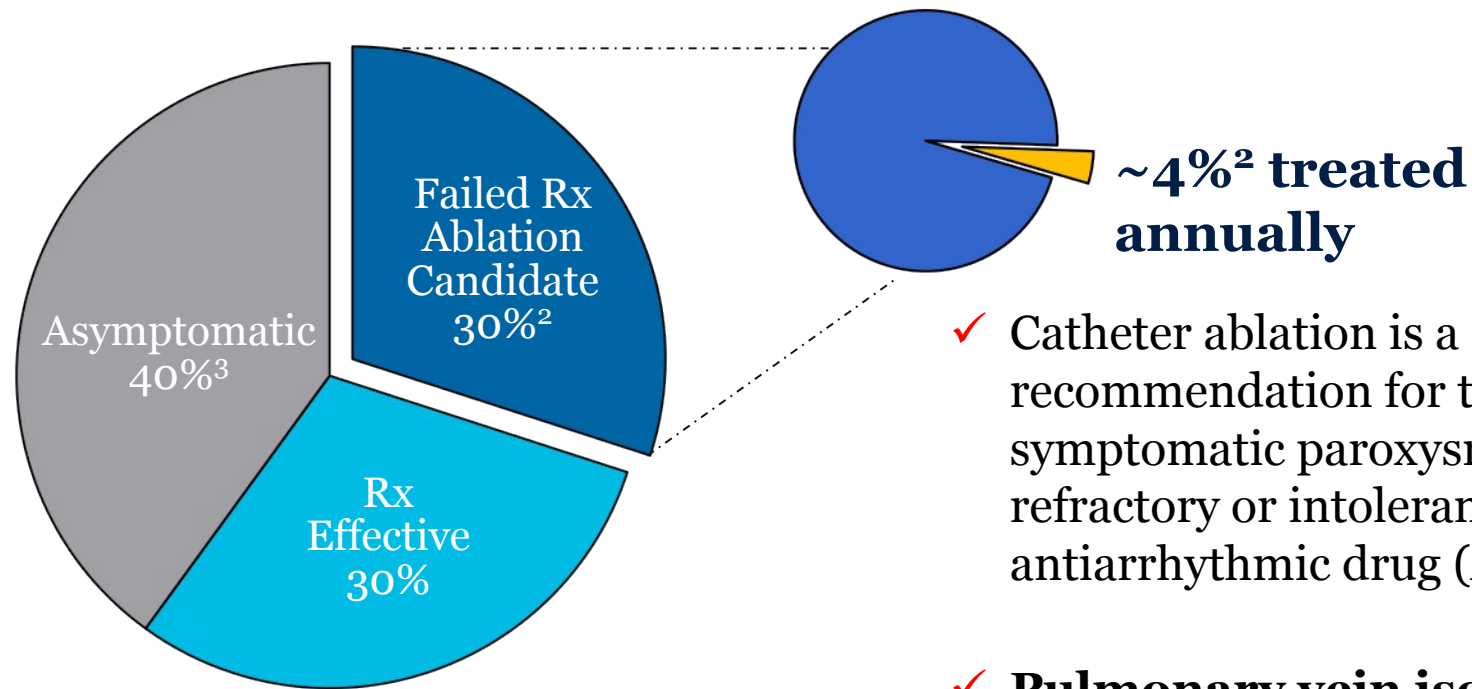
FIBRILLAZIONE ATRIALE: NOVITÀ TECNOLOGICHE PER IL TRATTAMENTO ABLATIVO

Valutazione prospettica di parametri biofisici con catetere multielettrodo a radiofrequenza come predittori a lungo termine per l'isolamento delle vene polmonari: confronto tra approccio guidato dal sistema di mappaggio e approccio guidato fluoroscopia

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Chairman of Electrophysiology Units GVM
Head of Arrhythmology Department
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AF Clinical/Referral Challenge



- ✓ Catheter ablation is a **Class I Level A** recommendation for treatment of symptomatic paroxysmal AF (PAF) refractory or intolerant to ≥ 1 Class I or III antiarrhythmic drug (AAD)⁴
- ✓ **Pulmonary vein isolation (PVI) is the cornerstone of AF ablation strategy⁵**
- ✓ Consensus guidelines and statements recommend PVI during the index CA procedure in **patients with PAF and persistent AF**

1. Rahman , et al. Nat. Rev. Cardiol. 2014; 11: 639–654

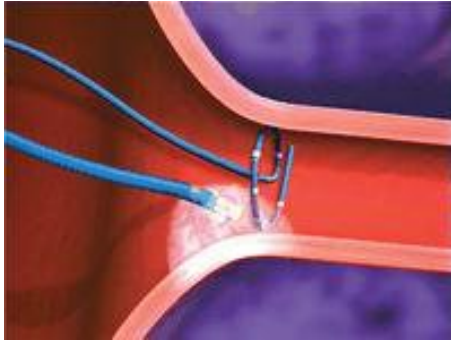
2. Wyse, et al. Circ. 1996; 93:1262-1277

3. Savelieva, et al. Pace. 2000; 23: 145-148

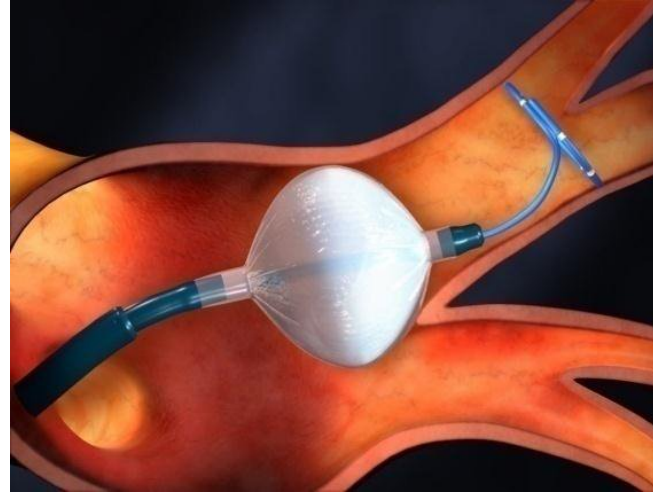
4. Calkins, H., et al. Heart Rhythm. 2012; 9(4): p. 632-696.e20

5. Raviele et al. J Cardiovasc Electrophysiol, 2012;23:890-923

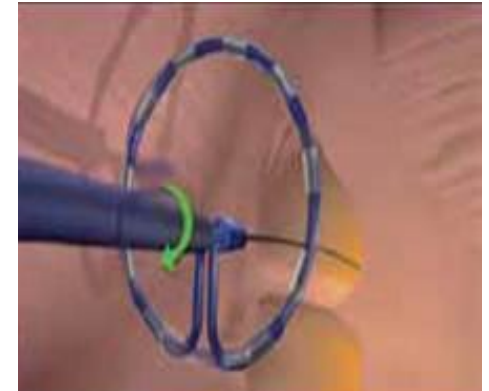
Different Technology for CA of AF



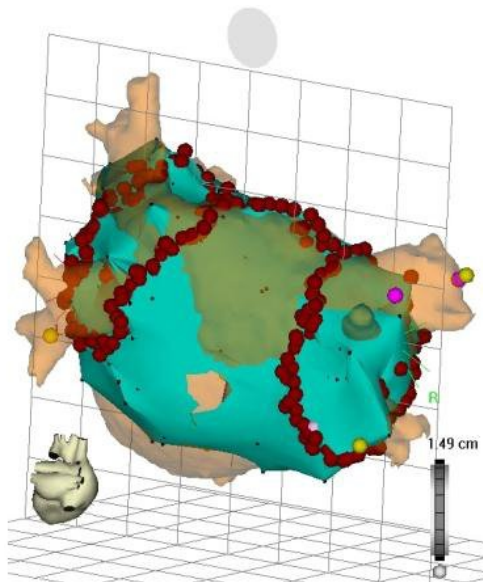
Segmental Ostial CA



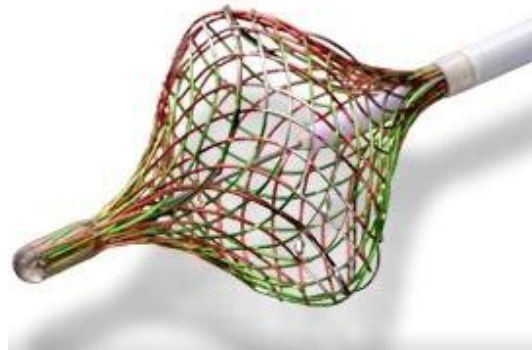
CRYOABLATION



PVAC



Circumferential Ostial CA



MESH



Cardiofocus

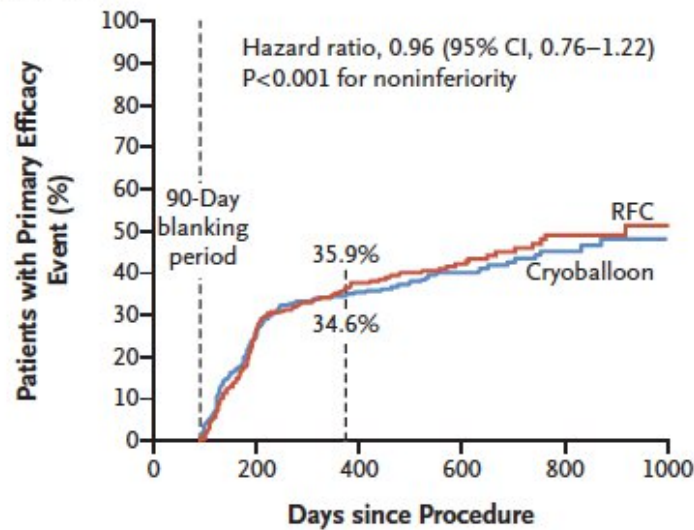
Afib Ablation: Results

- ✓ Clinical Variability (Afib type; cardiomyopathy; atrial remodeling; LV dysfunction, atrial fibrosis)
- ✓ Ablation Strategy
- ✓ Acute and Long-term evaluation of results (antiarrhythmic drugs; diagnostics)
- ✓ Different EP Lab Experience

Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation

Karl-Heinz Kuck, M.D., Josep Brugada, M.D., Alexander Fürnkranz, M.D., Andreas Metzner, M.D., Feifan Ouyang, M.D., K.R. Julian Chun, M.D., Arif Elvan, M.D., Ph.D, Thomas Arentz, M.D., Kurt Bestehorn, M.D., Stuart J. Pocock, Ph.D., Jean-Paul Albenque, M.D., Ph.D., and Claudio Tondo, M.D., Ph.D., for the FIRE AND ICE Investigators*

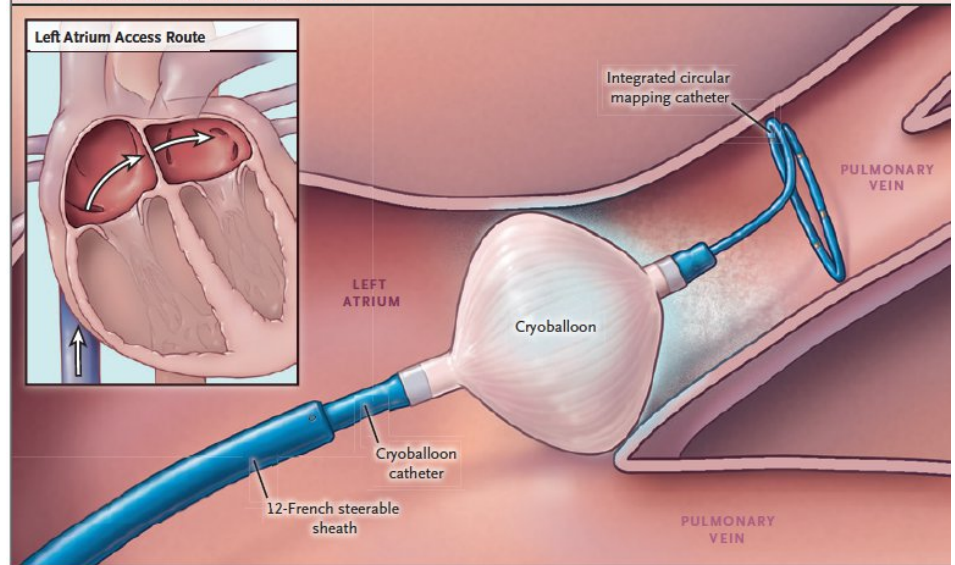
A Primary Efficacy End Point



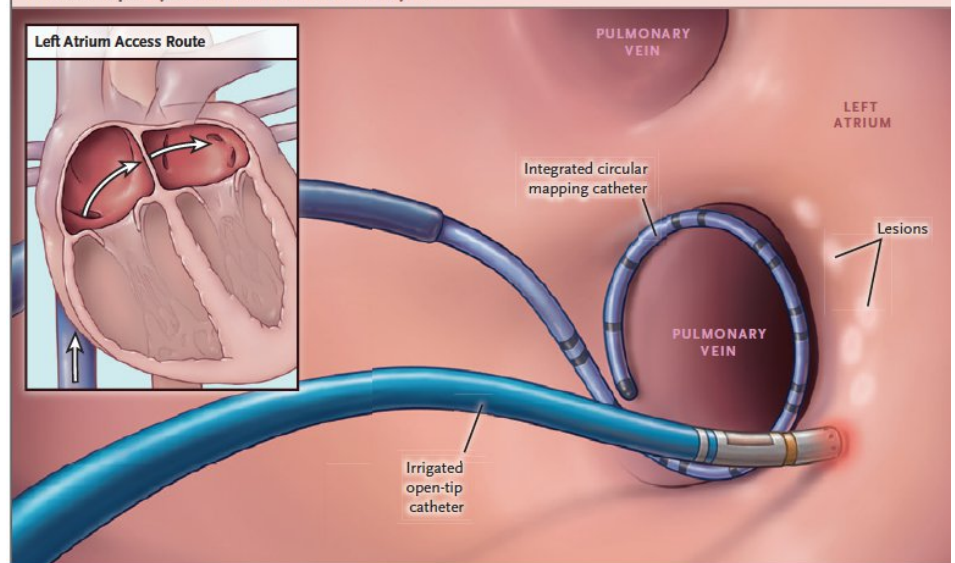
No. at Risk
Cryoballoon
RFC

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

A Cryoballoon Ablation of Pulmonary Vein



B Radiofrequency Current Ablation of Pulmonary Vein

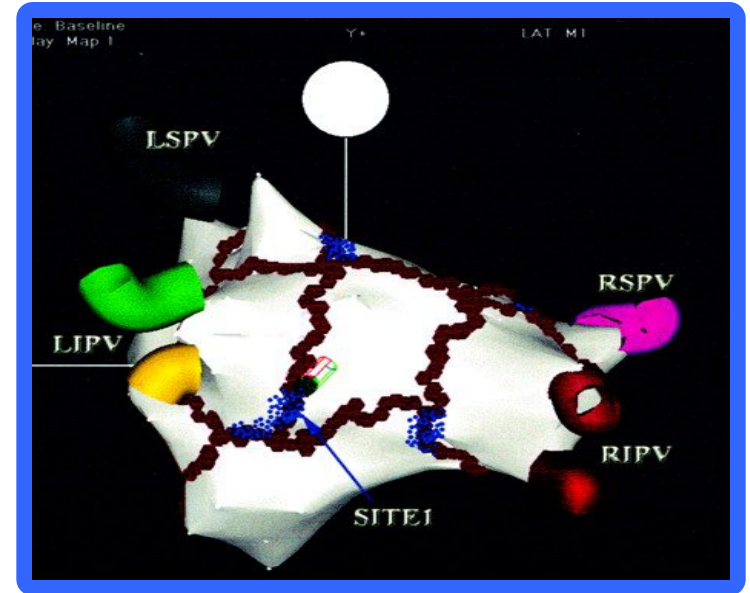


Cryoablation vs RF Catheter Ablation



28 mm **CRYOBALLON**
LA electroanatomic map

(area of electrical isolation, mean of **40+/-**
3.9% of the map's surface)

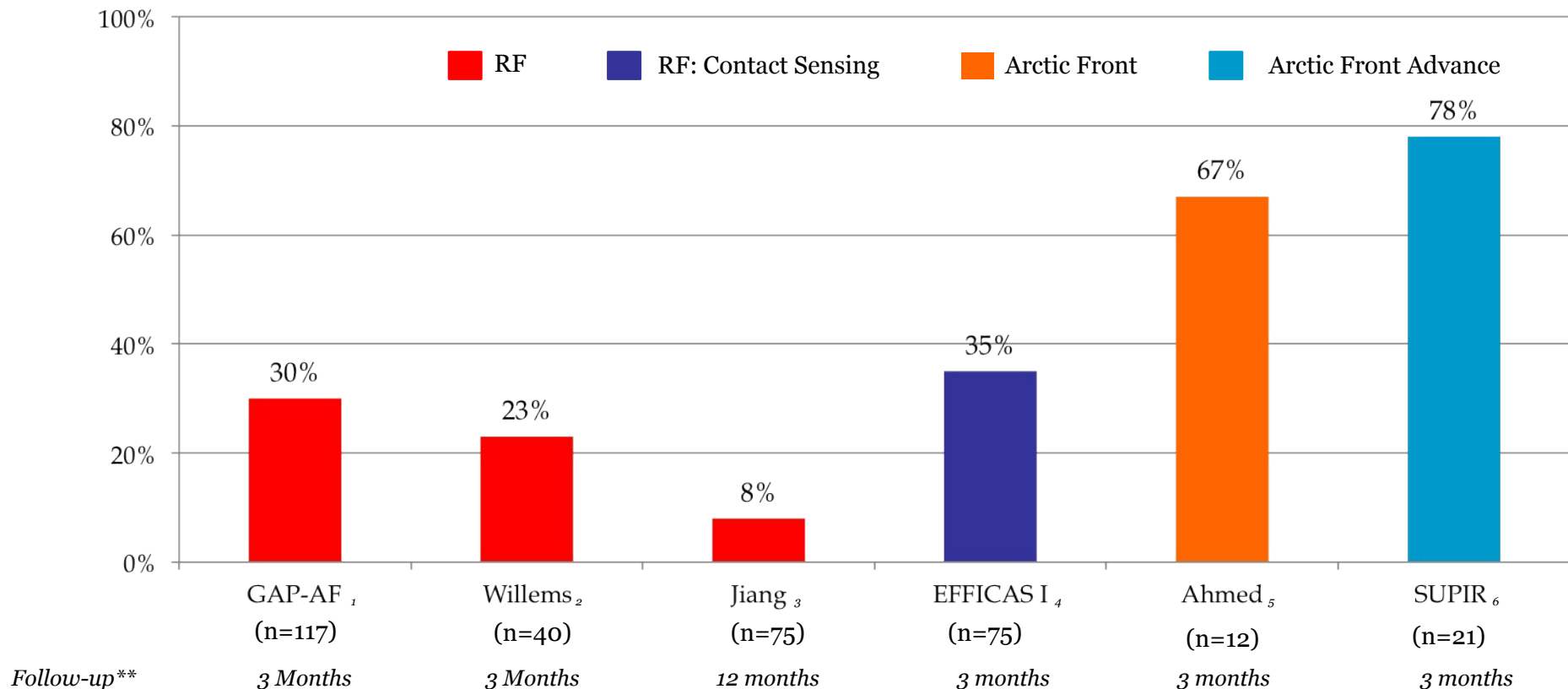


CARTO 3D
LA electroanatomic map

PV Lesion Durability with RF and Cryo

PV re-conduction Using Repeat Electrophysiology and Mapping

% of Patients with PVI* During Remapping Procedure



¹Late Breaking Clinical Trials session I at the EHRA EUROPACE 2013 meeting in Athens, Greece

²Williems, et al. J Cardiovasc Electrophysiol 2010; 21(10):1079-84.

³Jiang, et al. Heart Rhythm. 2014;11(6):969-76

⁴Neuzil et al. Circ Arrhythm Electrophysiol.(2):327-33

⁵Ahmed, et al. J Cardiovasc Electrophysiol, 2010;21(7):731-7,

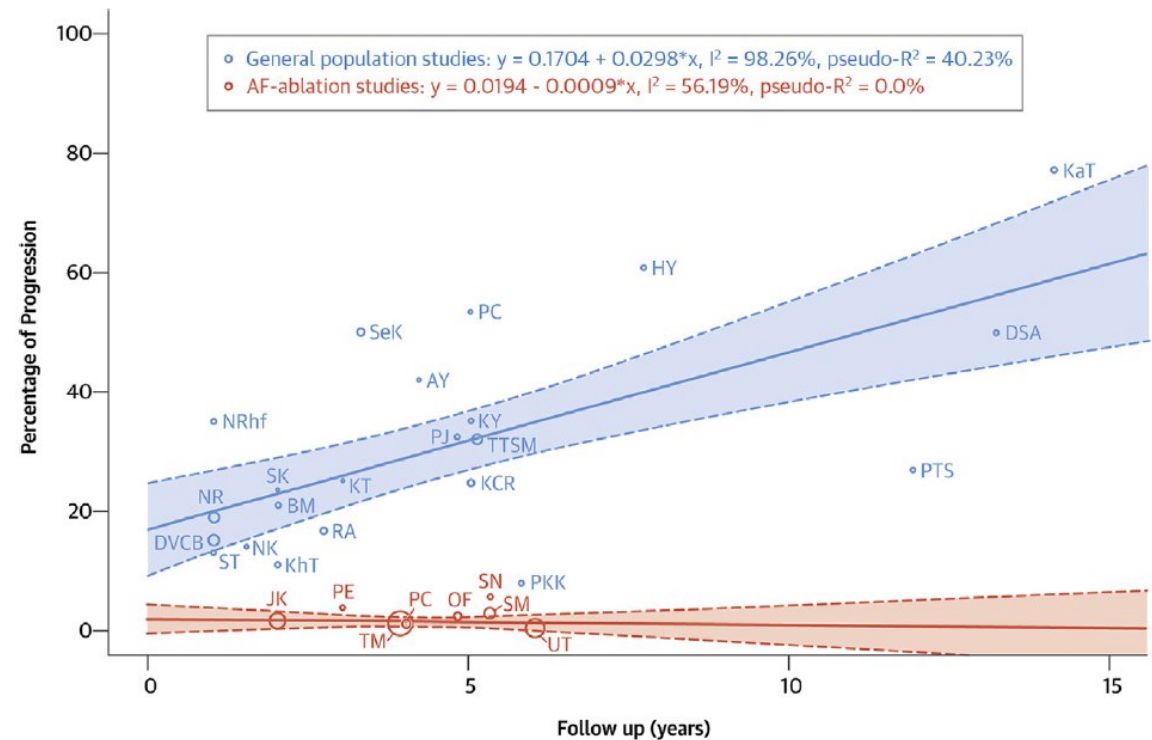
⁶Petru, et al. International Symposium on Progress in Clinical Pacing 2014

Preventing Progression Of AF

HOW TO TREAT?

- ✓ Systematic review in general population (primarily medical therapy only) vs. catheter ablation studies
- ✓ Weighted progression from paroxysmal to persistent or permanent AF by follow-up duration
- ✓ The percentage of AF progression increases over time (i.e., with longer follow up duration) in general population studies (n = 21), but remains flat in AF-ablation studies (n = 8)

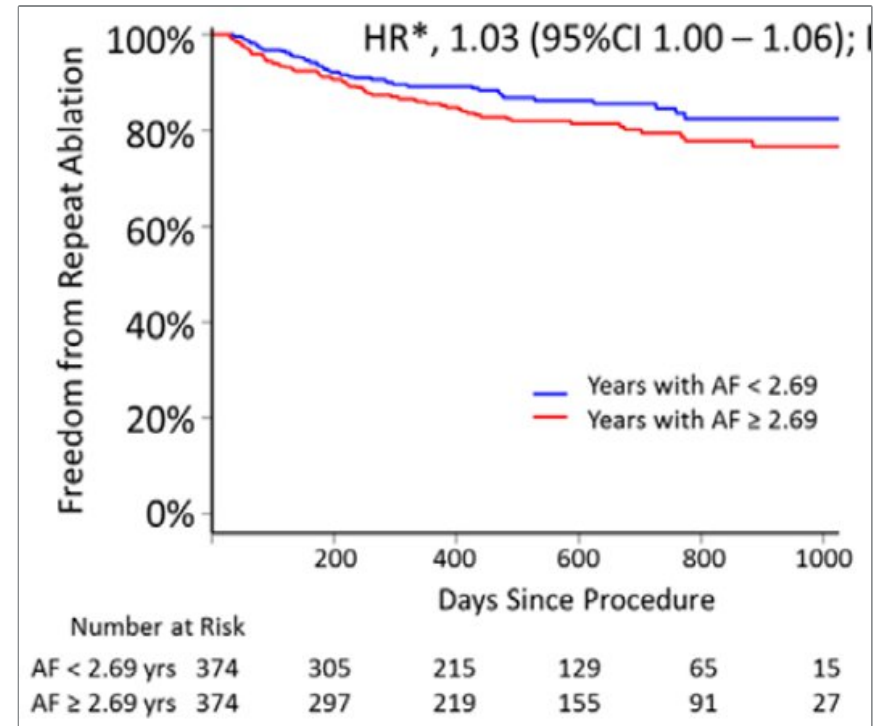
Ablation reduces the percentage of AF progression vs. medical therapy alone



Proietti et al. A systematic review on the progression of paroxysmal to persistent atrial fibrillation: shedding new light on the effects of catheter ablation. JACC: Clinical Electrophysiology. 2015; 1(3):105-115.

Earlier ablation Decreases the Risk of Repeat Ablation – Fire and Ice

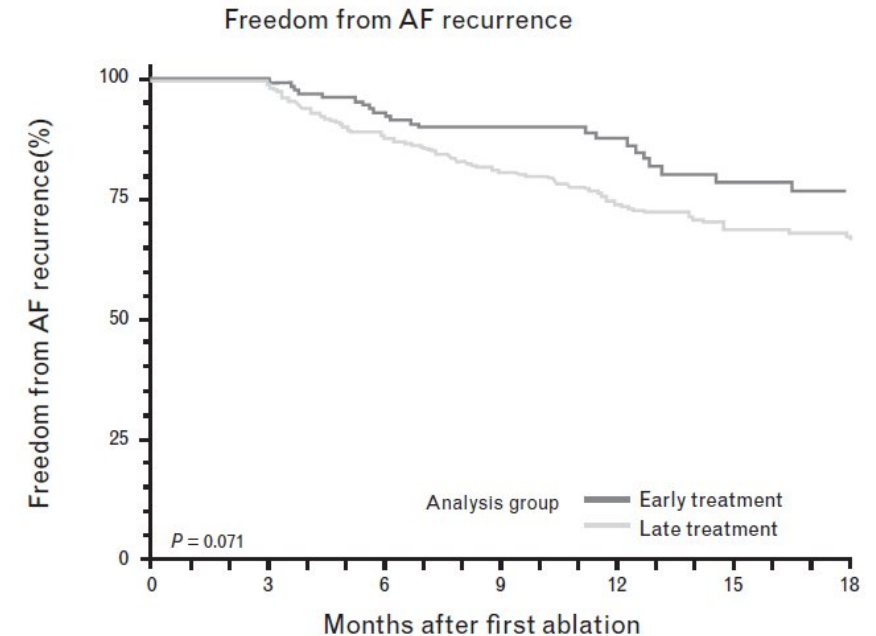
- ✓ 750 subjects with symptomatic PAF:
 - ✓ Refractory to class I or III antiarrhythmic drugs
 - ✓ Cryoballoon or RF catheter ablation
- ✓ Each additional year between AF diagnosis and ablation procedure was associated with a 3% increased risk of repeat ablation (HR = 1.03; P = 0.039)
- ✓ Higher freedom of AF predictor for patients who did not undergo cardioversions



Earlier Ablation Decreases Risk of AF Recurrence

1STOP ITALIAN CRYOBALLOON REGISTRY

- ✓ **130 (25%)** patients in the **early treatment group** (≤ 15 months post-AF diagnosis)
- ✓ **380 (75%)** patients in the **late-treatment group** (> 15 months post-AF diagnosis)
- ✓ **Freedom from AF recurrence** at a mean follow-up of ~ 16 months was:
 - ✓ **78.5% in the early-treatment group**
 - ✓ **68.4% in the late-treatment group**



| | | | | | | | |
|-----------------|-----|-----|-----|-----|-----|-----|-----|
| No. at risk | | | | | | | |
| Early treatment | 130 | 129 | 121 | 89 | 70 | 48 | 36 |
| Late treatment | 380 | 377 | 334 | 240 | 179 | 131 | 104 |

Risk of AF recurrence in the multivariable analysis was significantly higher in the late-treatment group (HR: 1.77, 95% CI: 1.00-3.13; $P = 0.048$)

Cryo-FIRST: Multicenter Randomized (1:1) Controlled Trial

218

First-Line
Patients with
Symptomatic
PAF

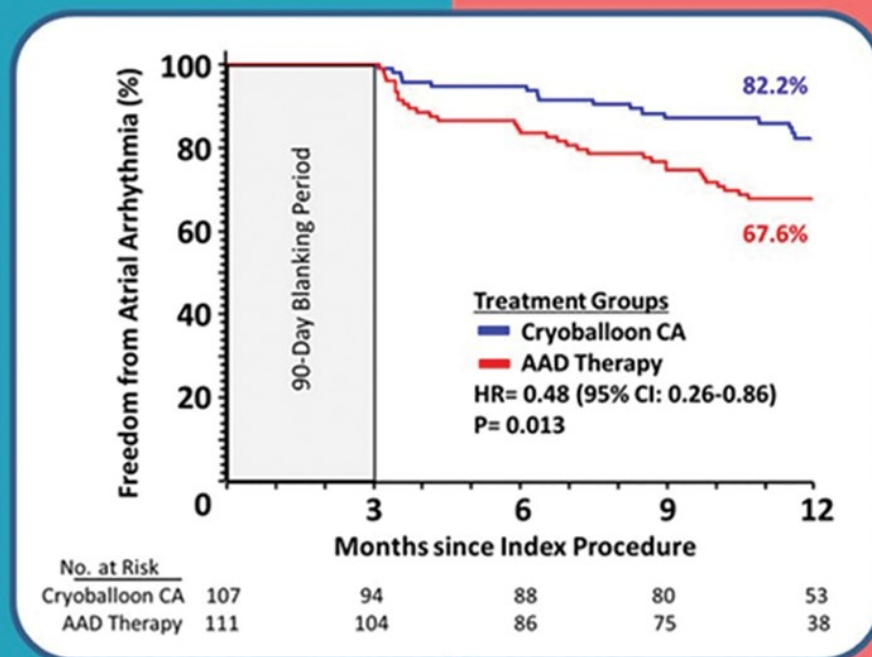
**CRYOBALLOON CATHETER
ABLATION (CA) WITH
ARCTICFRONT ADVANCE
N=107**



**ANTIARRHYTHMIC
DRUG (AAD) THERAPY
N=111**

82.2%

67.6%



**60% Reduction in the Incidence Rate
of Symptomatic Palpitations with
Cryoballoon CA**

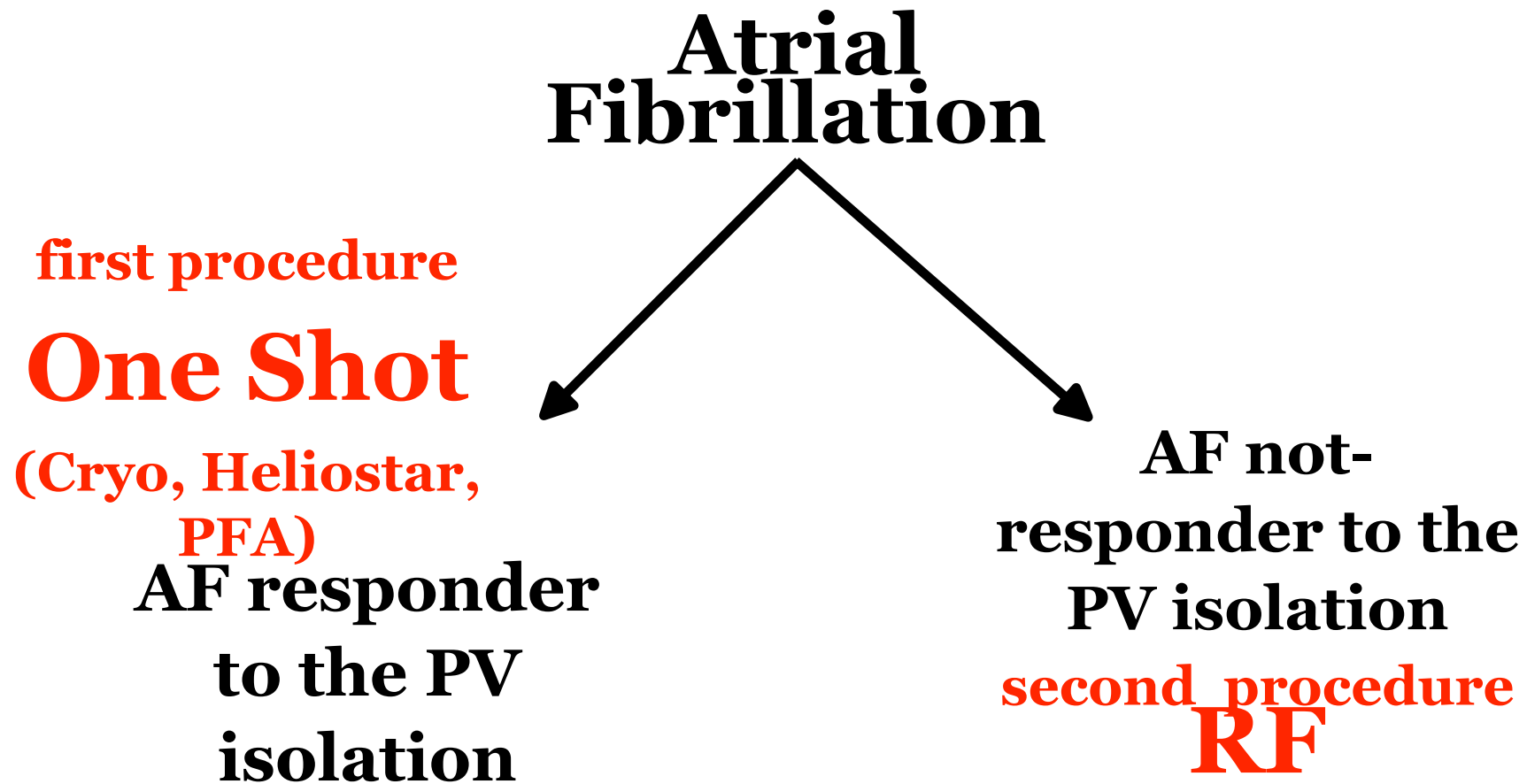
**No Difference in the Incidence Rate
of Serious Adverse Events**



**Cryoballoon CA Results in Superior Efficacy Compared to AAD Therapy and has a
Comparable Safety Profile in Treatment Naïve Patients with
Symptomatic Paroxysmal AF**

AF Ablation

Maria Cecilia Hospital Approach



LA dim > 60 mm indication for **Hybrid Ablation (staged)**

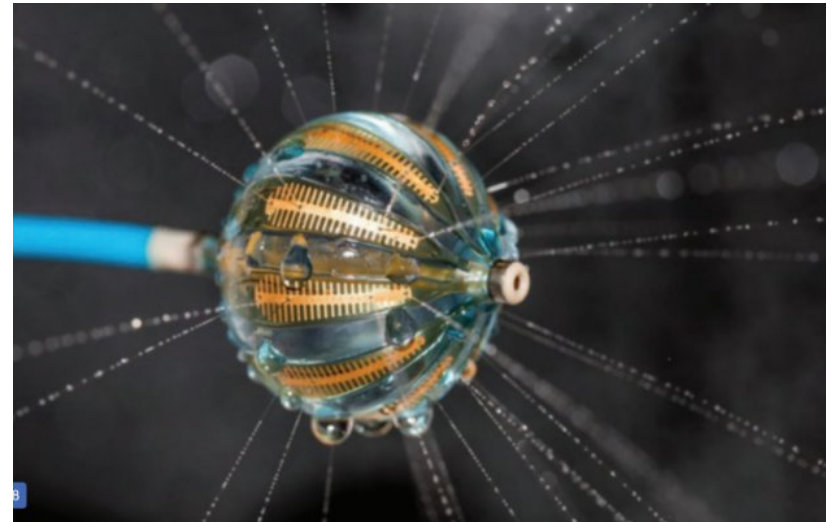
New Ablation Catheter Technologies



POLARx™ Cardiac Cryoablation System



PFA - FARAPULSE



Helios II multi-electrode RFA

HELIOSTAR

Balloon Ablation Catheter Platform Overview



HELIOSTAR™ Balloon Ablation Catheter



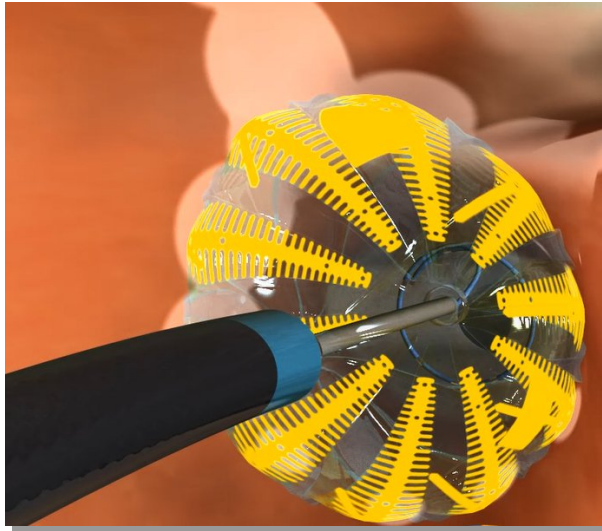
LASSOSTAR™ NAV Catheter



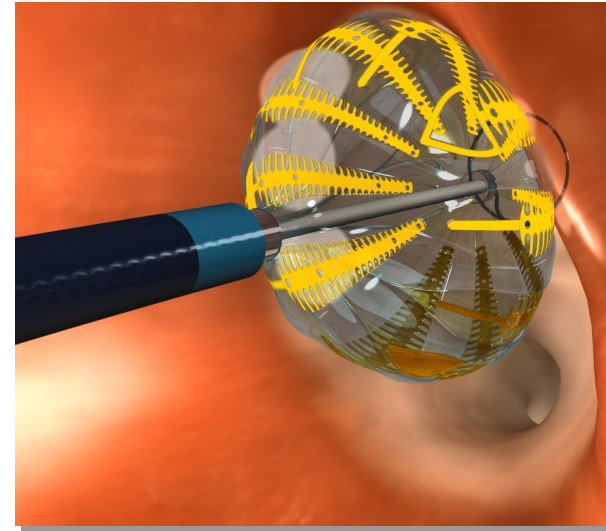
GUIDESTAR™ Deflectable Sheath

Balloon Electrodes

- ✓ Independently controlled, irrigated electrodes to improve safety and lesion quality
- ✓ Flexibility to perform circumferential or segmental ablation (1)



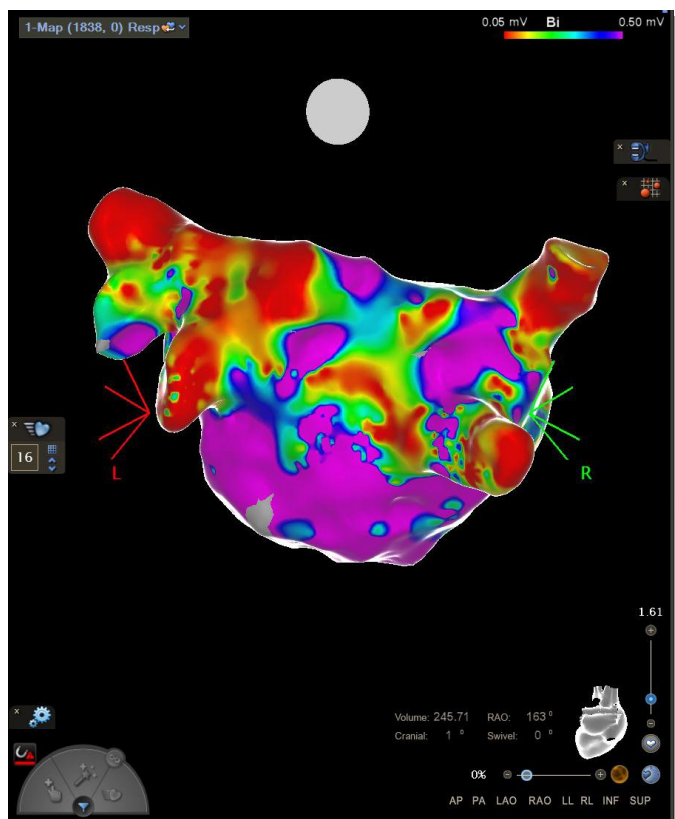
Circumferential



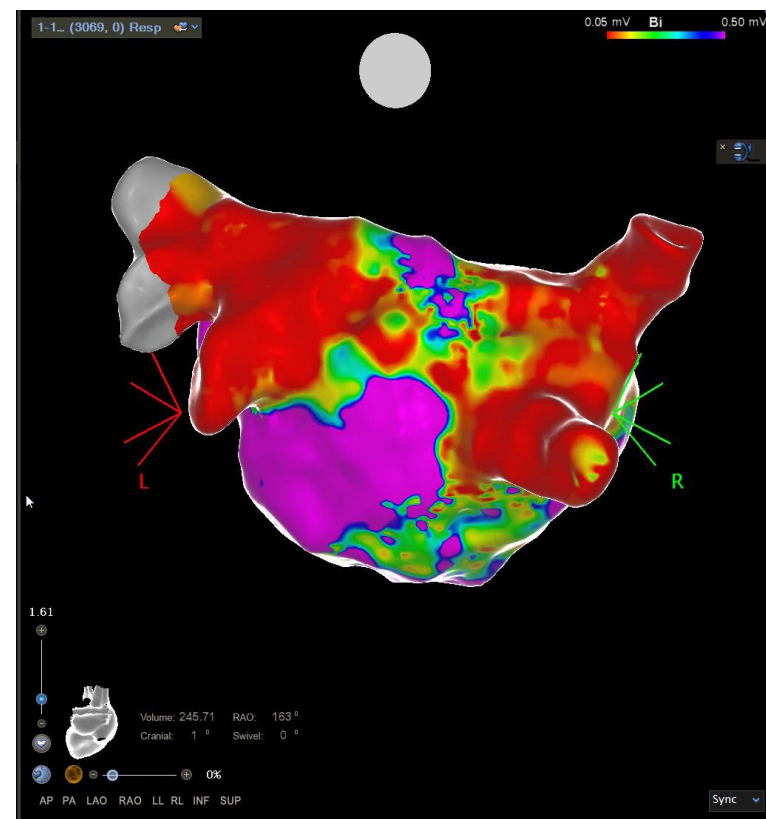
Segmental

LASSOSTAR™ NAV Integration with CARTO™ 3 System

- ✓ Generate left atrial anatomy with LASSOSTAR™ NAV Catheter and may reduce fluoroscopy use¹
- ✓ Perform post-ablation voltage mapping to confirm pulmonary vein isolation¹



Pre-Ablation Voltage



Post-Ablation Voltage

1 - Biosense Webster, Inc. Internal Design Validation Test Report (TR-0022056, June 27, 2017).

Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO™ 3 System User Guide regarding recommendations for fluoroscopy use.

Pellegrino, P.L., Brunetti, N.D., Gravina, D., Sacchetta, D., De Sanctis, V., Panigada, S., Di Biase, L., Di Biase, M., and Mantica, M. (2013). Nonfluoroscopic mapping reduces radiation exposure in ablation of atrial fibrillation. *Journal of cardiovascular medicine* 14, 528-533.

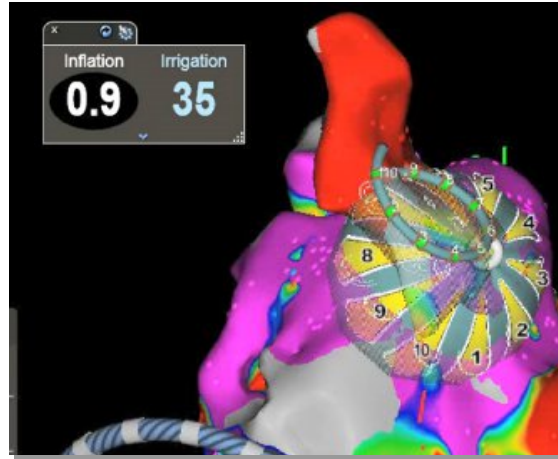
Earley, M.J., Showkathali, R., Alzetani, M., Kistler, P.M., Gupta, D., Abrams, D.J., Horrocks, J.A., Harris, S.J., Sporton, S.C., and Schilling, R.J. (2006). Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial. *Eur Heart J* 27, 1223-1229

Criteria for Optimal Balloon Placement



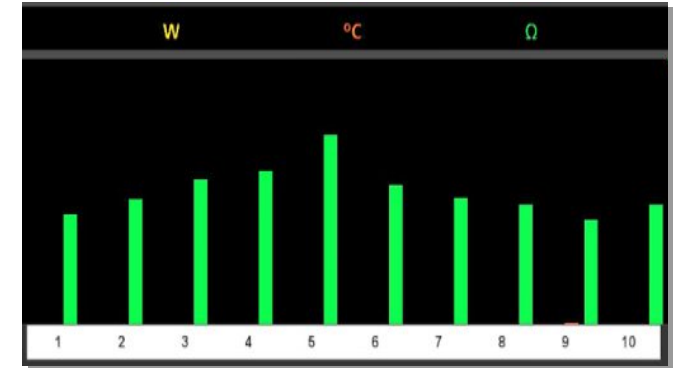
CO-AXIAL

HELIOSTAR™ Balloon
Ablation Catheter in axis
with the vein



INFLATED

Inflation Index > 0.8¹



OPTIMAL BALLOON INDICATORS

Impedance Range, Temperature
Max²

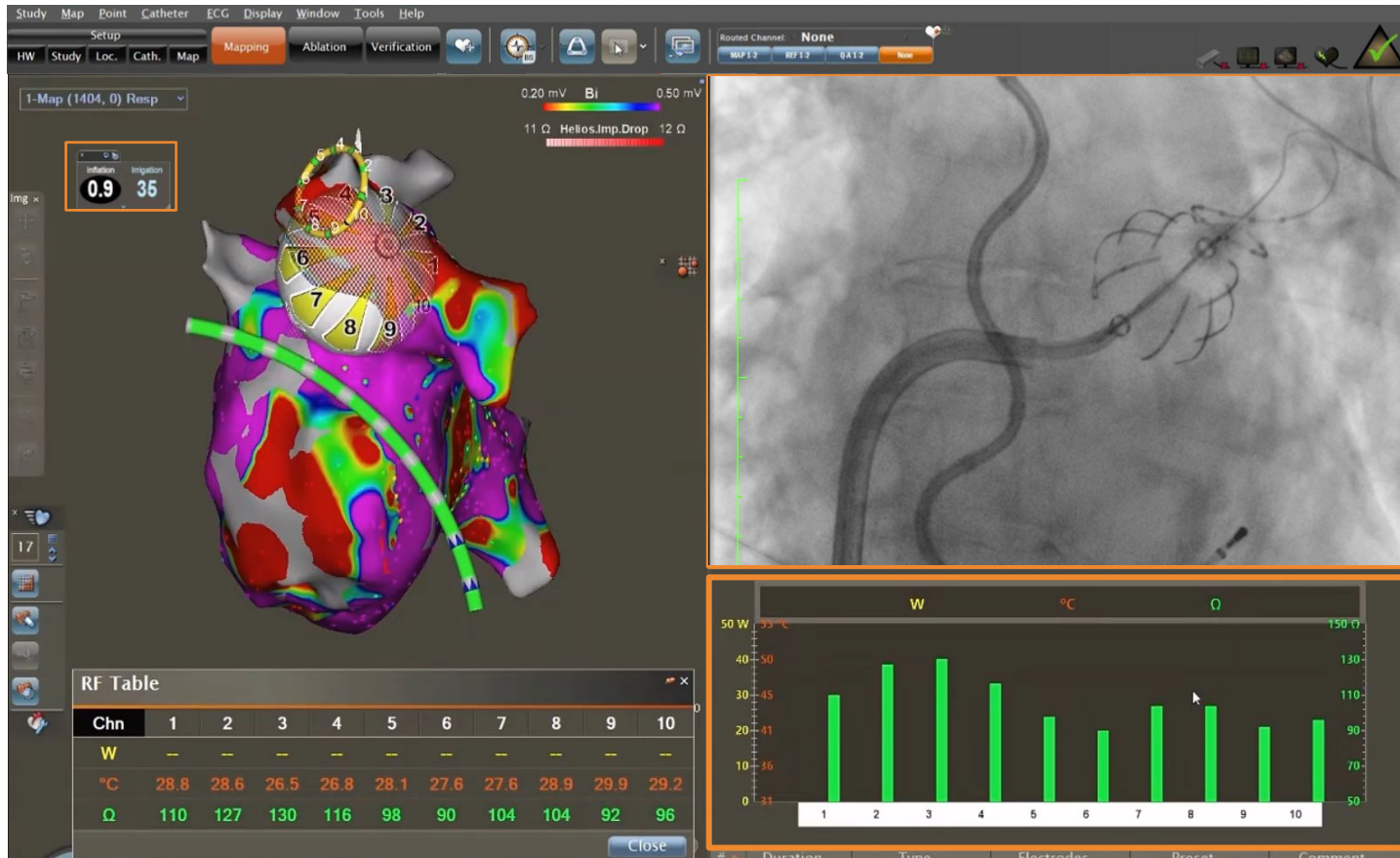
Pre-ablation indicators: 85-130 Ω ; Below 31 °C

1 - Almorad A, Chierchia GB, Pannone L, et al. The optimized clinical workflow for pulmonary vein isolation with the radiofrequency balloon [published online ahead of print, 2021 Nov 18]. J Interv Card Electrophysiol. 2021;10.1007/s10840-021-01094-9.

doi:10.1007/s10840-021-01094-9

2 - REP 14285 – Analysis of HELIOSTAR Balloon Alignment Indicators

Optimal Balloon Positioning on CARTO™ 3 System



Play
video

Post-Ablation Indicators of Lesion Formation

Impedance Drop $\geq 12 \text{ Ohms}^1$

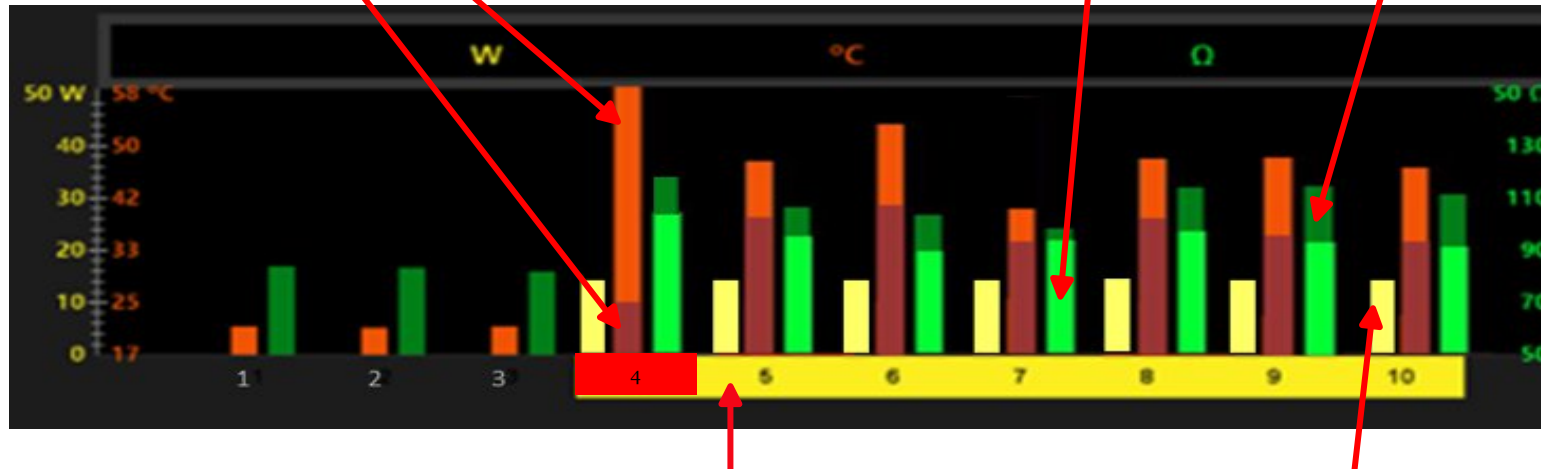
Temperature Rise $\geq 6^\circ \text{ C}^1$

If impedance drop $< 12 \text{ Ohms}$ or temperature rises $< 6^\circ \text{ C}$, consider segmental consolidation application¹

Real-time Graph Viewer During Ablation

Bright red bar = real-time temperature
Dark red bar = baseline temperature

Bright green bar = real-time impedance
Dark green bar = baseline impedance



Color indicates parameter at maximum value.
Yellow = Maximum power reached
Red = Maximum temperature reached
Black = RF to electrode is disabled

Yellow bar = real-time power

Visualization of Impedence and Temperature Drop during ablation for each electrode

HELIOSTAR™ BALLOON ABLATION CATHETER

CLINICAL SUMMARY EVIDENCE

RADIANCE Study^{1,2}

- ✓ Incidence of primary AE 2.6% with no PV stenosis or atrio-esophageal fistula
- ✓ 81.8% RIPVs succeeded in first-pass isolation
- ✓ Overall acute reconnection rate 4.6%
- ✓ 86.4% freedom from documented atrial arrhythmia at 12 months (on/off AAD)

SHINE Study³

- ✓ Procedure time: 87.6 min
- ✓ LA balloon dwell time 40.3±16.7 min
- ✓ Fluoroscopy time 10.9±9.1 min
- ✓ Incidence of post-ablation SCL: 9.7%
- ✓ 1.2% primary AE with no PV stenosis or atrio-esophageal fistula
- ✓ 72,2% freedom from symptomatic AF/AFL/AT recurrence at 12 months

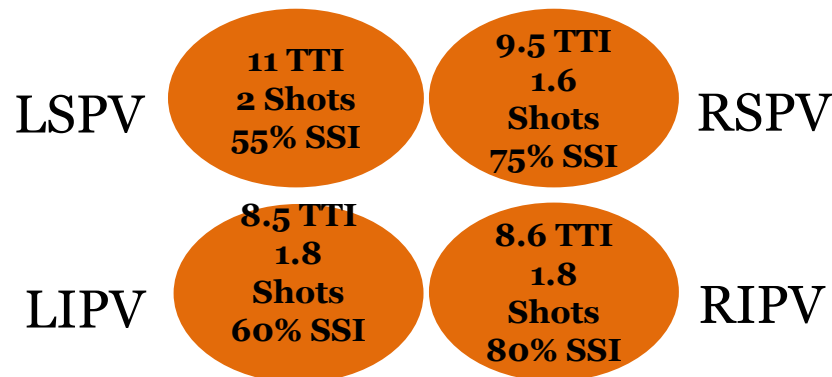
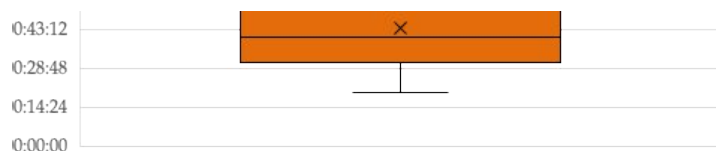
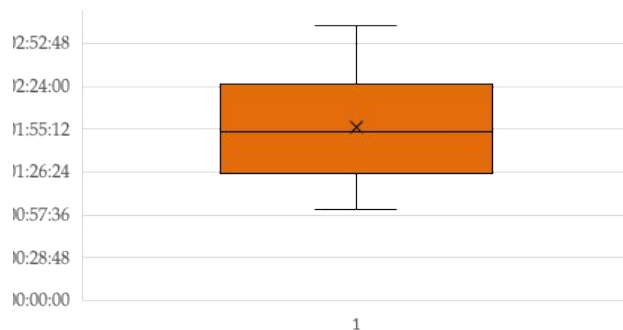
1. Reddy V et al. "PV Isolation with a Novel Multielectrode Radiofrequency Balloon Catheter that Allows Directionally-Tailored Energy Delivery: Short-Term Outcomes from a Multicenter First-in-Human Study (RADIANCE)" *Circ Arrhythm Electrophysiol* 2019 Dec; 12(12):e007541.

2. Dhillon G et al. "Use of a multi-electrode radiofrequency balloon catheter to achieve pulmonary vein isolation in patients with paroxysmal atrial fibrillation: 12-Month outcomes of the RADIANCE study" *J Cardiovasc Electrophysiol*. 2020 Jun;31(6):1259-1269.

3. Schilling R et al. "Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: 1-year outcomes from SHINE" *Europace*. 2020 Jan 15:euaa382 (E-pub ahead of print)

HELIOSTAR™ Balloon Ablation Catheter

MARIA CECILIA HOSPITAL Experience (20 Pts)



3 Notes on current EE results:

- ✓ Looking for the **best Workflow** to reach PVI (i.e., extreme workflow for RIPV)
- ✓ Importance of the correct position of the balloon for PVI to **avoid contrast injection**
- ✓ Impressive **Time To Isolation** and **signals visualization** on the balloon electrodes



PROSPECTIVE EVALUATION OF BIOPHYSICAL PARAMETERS AS LONG-TERM PREDICTORS OF PVI WITH MULTI-ELECTRODE RF CATHETER: COMPARISON BETWEEN FLUOROSCOPY-GUIDED AND CARTO-GUIDED APPROACH (MERCY STUDY)

Clinical Study Design

This is a prospective, single-center, research study designed to evaluate the acute achievement of pulmonary vein (PV) isolation with HELIOSTAR Balloon catheter using prospectively the pre-ablation indicators of optimal electrode positioning in comparison with standard positioning evaluated by fluoroscopy visualization and contrast injection and the optimized biophysical parameters as predictors of long-term efficacy

Sixty patients undergoing catheter ablation will be enrolled and divided **in two different group (A and B)**

PROSPECTIVE EVALUATION OF BIOPHYSICAL PARAMETERS AS LONG-TERM PREDICTORS OF PVI WITH MULTI-ELECTRODE RF CATHETER: COMPARISON BETWEEN FLUOROSCOPY-GUIDED AND CARTO-GUIDED APPROACH (MERCY STUDY)

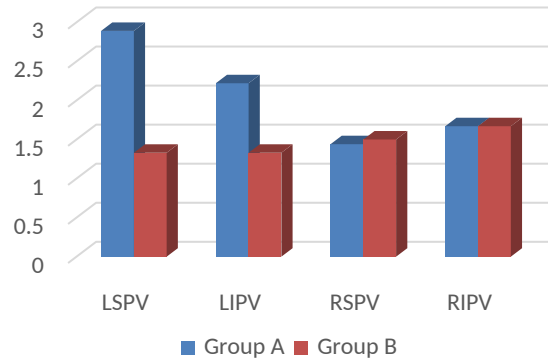
Group A (FLUOROSCOPY-GUIDED):

- ✓ **Vessel occlusion from grade 0 (very poor occlusion) to grade 4 (perfect occlusion) in two different fluoroscopic projections;**
- ✓ All biophysical parameters and signals of HELIOSTAR will be hidden on CARTO 3D mapping system;
- ✓ The correct inflation of the Balloon will be validated only by fluoroscopy system;
- ✓ The LASSOSTAR circular decapolar mapping catheter should be used to obtain PV potential recordings for real-time monitoring before and during the ablation.

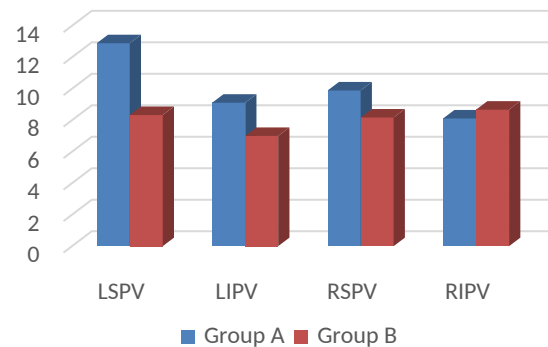
Group B (CARTO-GUIDED):

- ✓ **Coaxial alignment of the Balloon to achieve electrode contact before each RF session will be evaluated on CARTO non fluoroscopic system;**
- ✓ **Pre-ablation indicators of optimal electrode positioning:** baseline impedance range 90-110 Ohms, impedance variability across ten electrodes ≤ 20 Ohms, baseline electrode temperature $\leq 31^{\circ}\text{C}$, baseline temperature variability $\leq 3^{\circ}\text{C}$;
- ✓ At the end of each RF session, analyzing the post RF indicators, it will be considered a **good lesion if impedance drop ≥ 12 Ohm and temperature rise $\geq 6^{\circ}\text{C}$ are obtained;**
- ✓ **inflation of the Balloon should be a value ≥ 0.8 ;**
- ✓ The ablation will also be guided by the visualization and the monitoring of the vein potentials to the ostium on the LASSOSTAR circular decapolar mapping catheter and the signals of HELIOSTAR.

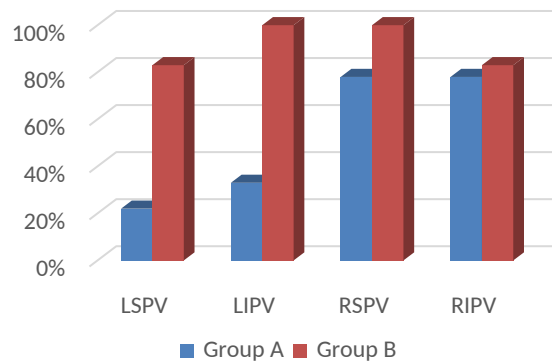
TOTAL APPLICATION



TTI MEDIUM (sec)



SINGLE SHOT ISOLATION



MERCY STUDY

9 Patients **Group A** and 6 Patients **Group B**

- ✓ number of applications **Group A** > **Group B** thanks to the occlusion of the vein verified by the biophysical parameters of the contact between electrode-ostium;
- ✓ in the left veins is more important than in the right veins to ensure the contact of the electrodes for a higher success rate of single shot isolation
- ✓ when the pre-ablation indicators of optimal electrode positioning are satisfied, the TTI is always in the range of 8-12s

Conclusion

- ✓ **PVI remains the cornerstone of PAF ablation**
- ✓ Novel tools might render the procedures safer and faster
- ✓ Early ablation therapy of PAF seems to yield excellent results on a short-mid term F-Up
- ✓ The complication rate might be lower in younger patients
- ✓ **the PVI procedure was safe, effective, and efficient** with regards to the treatment of patients with paroxysmical and persistent AF
- ✓ **Patient selection is the best predictor of success!**