



HOSPITAL DE  
SANTAMARIA



IX Congresso  
Novas Fronteiras  
em Medicina  
Cardiovascular  
22 a 24 de Fevereiro 2019  
The Village Praia  
d'El Rey - Oeiras

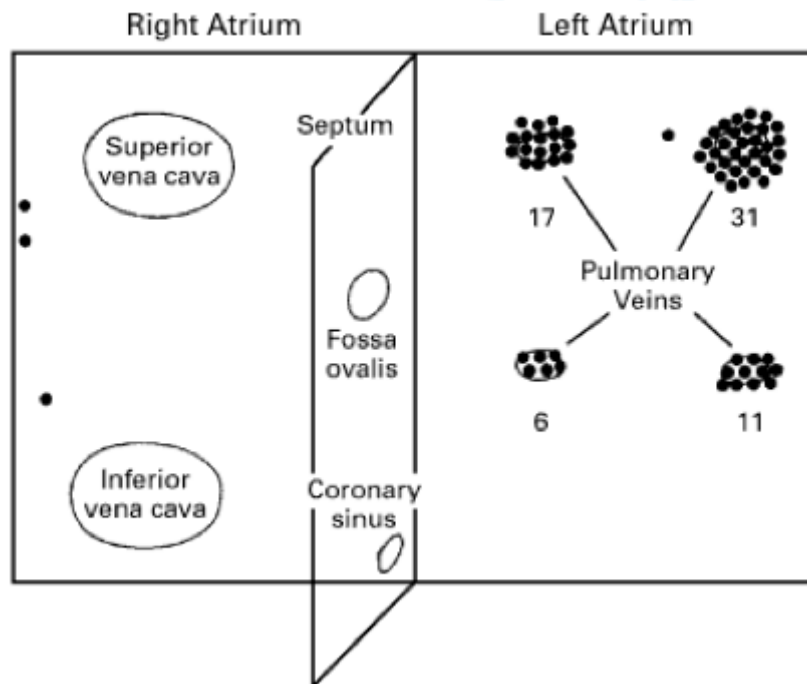
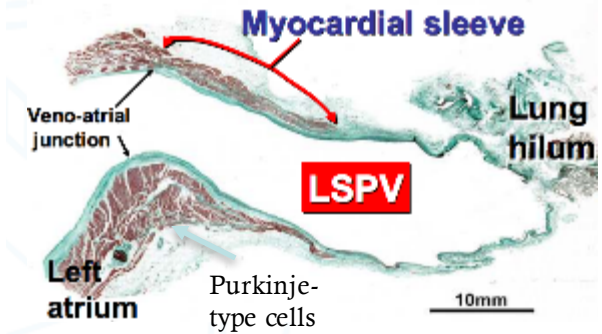
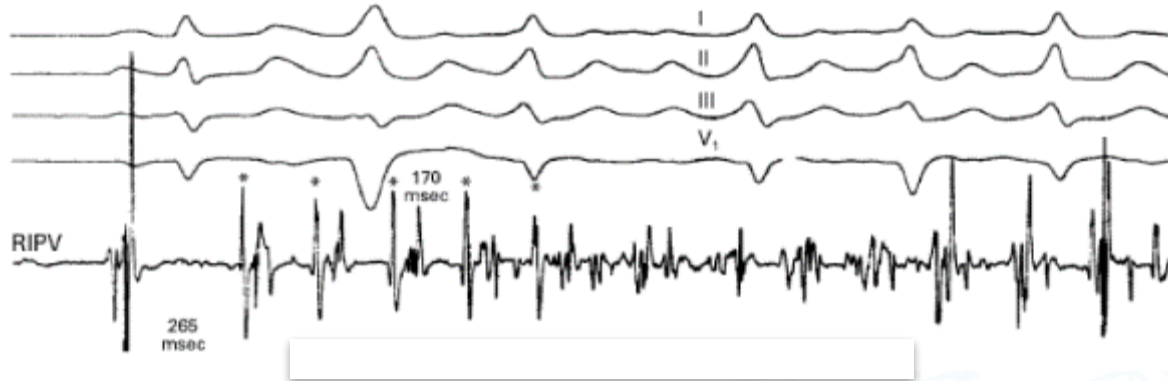
# “Single-shot” techniques for atrial fibrillation ablation

João de Sousa  
Serviço de Cardiologia  
Faculdade de Medicina de Lisboa  
CHULN, Hospital Universitário de Santa Maria





# Atrial fibrillation catheter ablation: PV foci



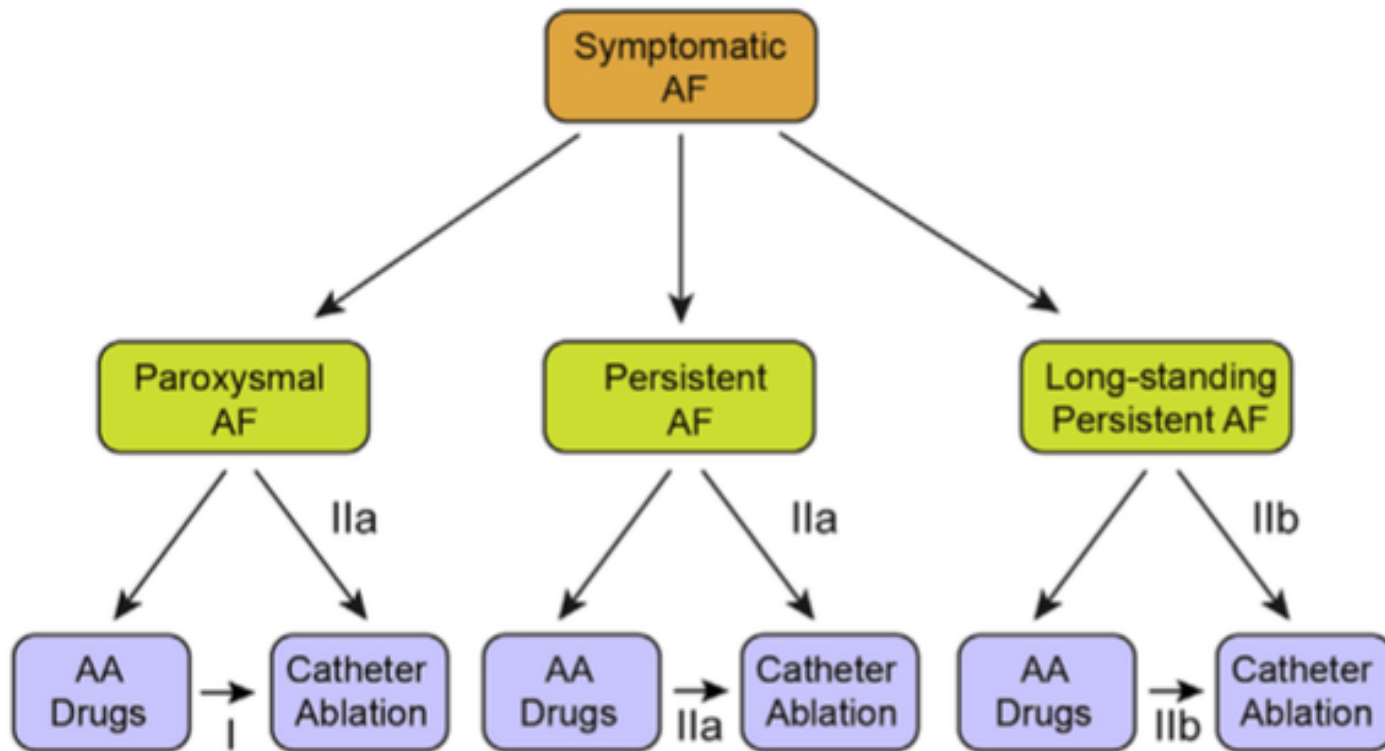
- AF triggers mostly localized in PV ostium (94%)



Haissaguerre M, et al.: Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins.  
*N Engl J Med* 1998;**339**: 659-666.



## Indications for Catheter Ablation of Symptomatic Atrial Fibrillation



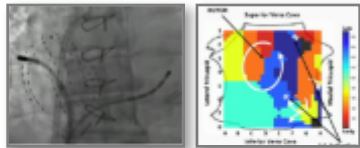
H Calkins et al: 2017 HRS/EHRA/ECAS/APHRs/SOLACE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Journal of Arrhythmia 33 (2017);369-409



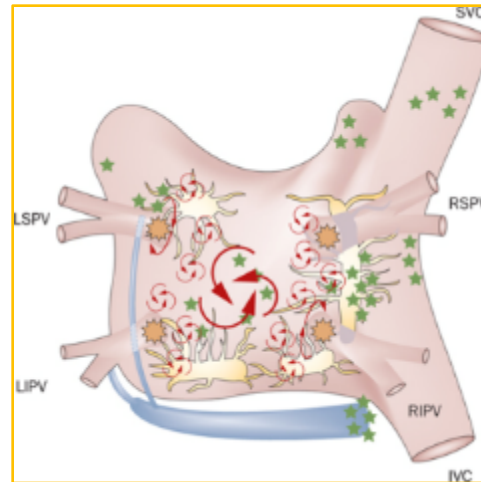


## Ablation strategy

### Pulmonary Vein Isolation (PVI)



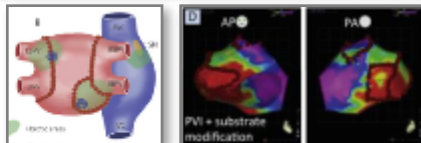
#### PVI + Rotor ablation (endocardium / surface mapping)



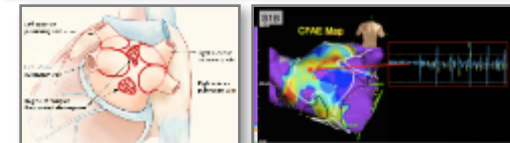
#### PVI + LA linear lesions (roof, posterior wall, mitral isthmus)



#### PVI + encircling low voltage areas (fibrosis)



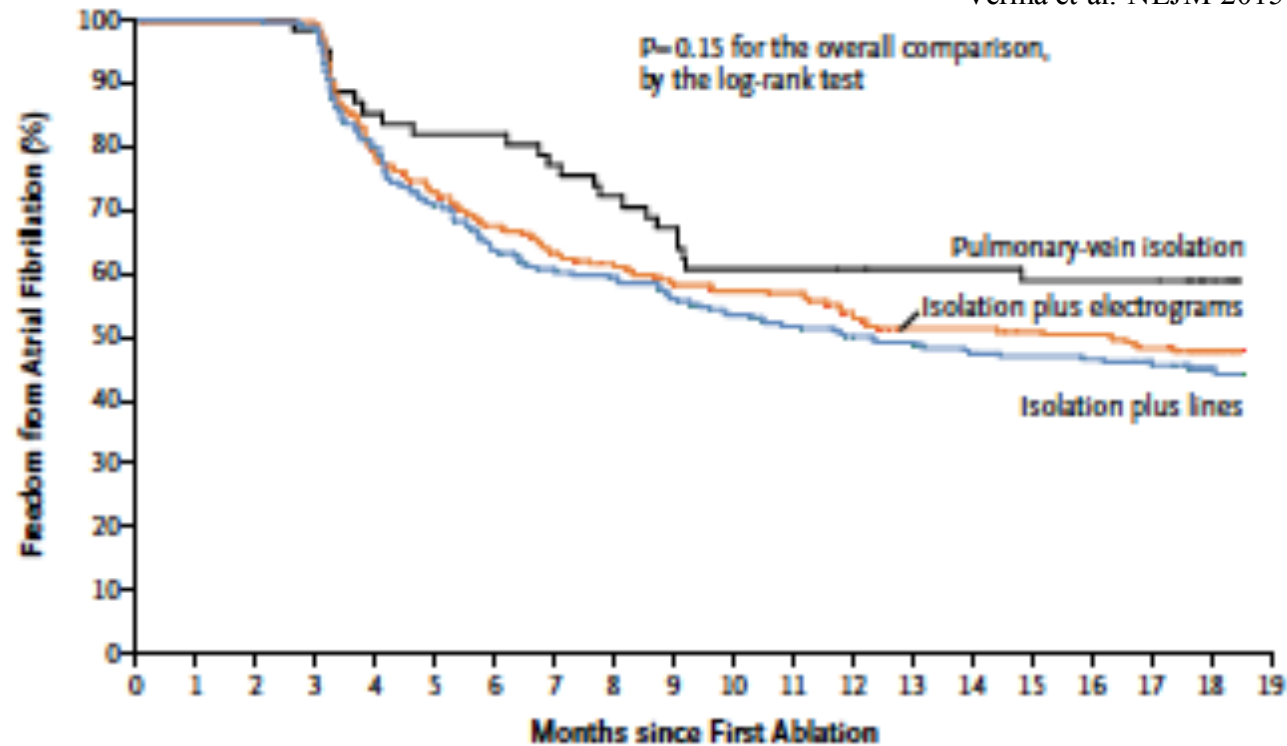
#### PVI + CFAEs (fractionated electrograms)





## Star-II AF Trial

Verma et al: NEJM 2015



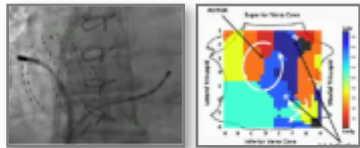
### No. at Risk

|                             |     |     |     |     |     |    |
|-----------------------------|-----|-----|-----|-----|-----|----|
| Pulmonary-vein isolation    | 61  | 60  | 50  | 41  | 36  | 23 |
| Isolation plus electrograms | 244 | 242 | 161 | 137 | 124 | 72 |
| Isolation plus lines        | 244 | 240 | 152 | 133 | 115 | 57 |

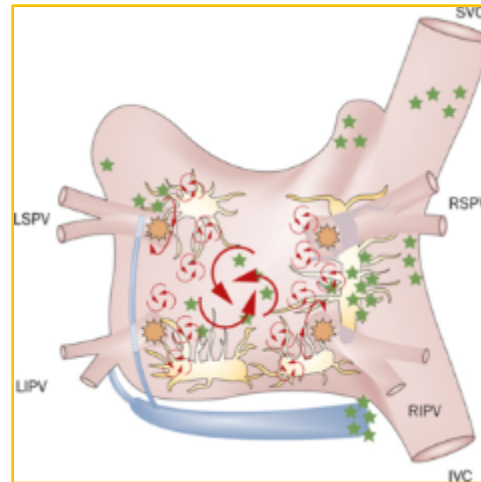


## Ablation strategy

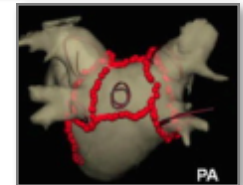
### Pulmonary Vein Isolation (PVI)



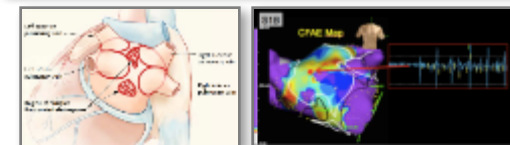
### PVI + Rotor ablation (endocardium / surface mapping)



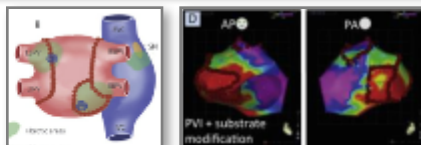
### PVI + LA linear lesions (roof, posterior wall, mitral isthmus)

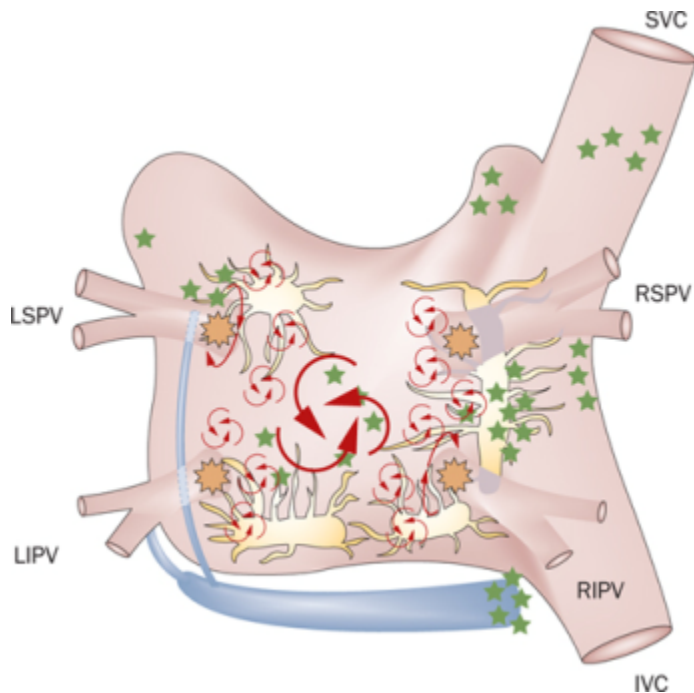
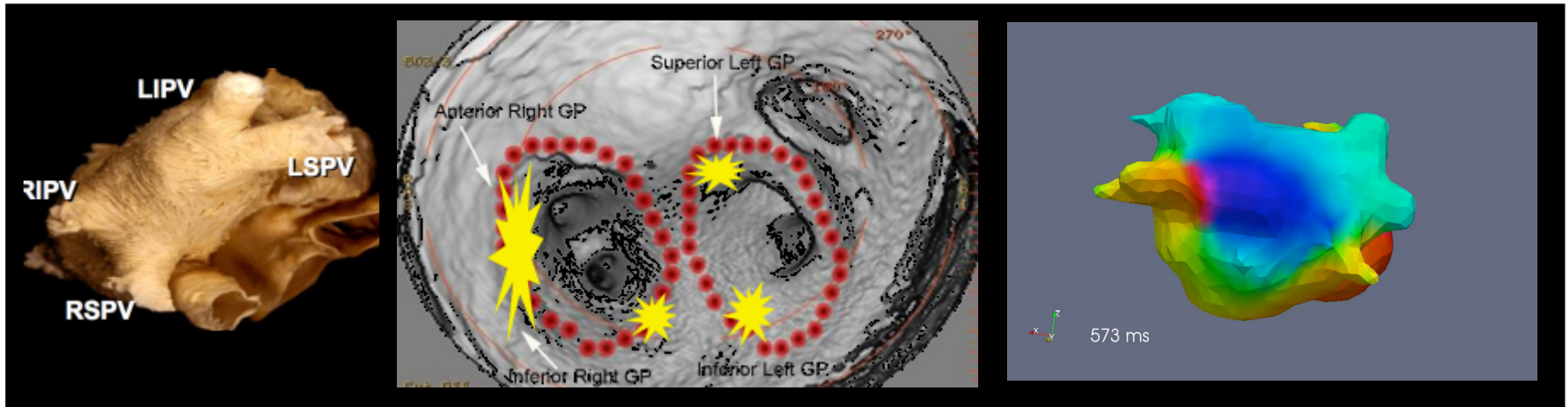


### PVI + CFAEs (fractionated electrograms)



### PVI + encircling low voltage areas (fibrosis)

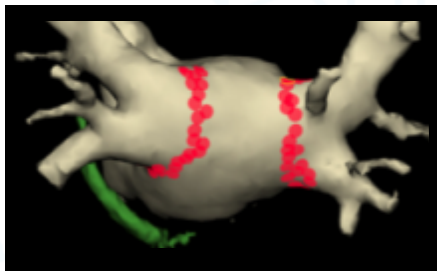
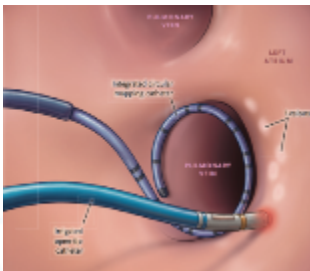




- **AF Triggers** localized in PV in 94% of paroxysmal atrial fibrillation patients
- **Additional Triggers** frequently localized in PV antrum
- **Rotors** localized in PV antrum
- **Autonomic ganglionar plexus** localized in PV ostium proximity

- **Pulmonary Vein Isolation (PVI)** is the key element in paroxysmal or short duration persistent atrial fibrillation ablation.

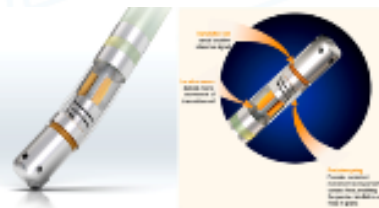
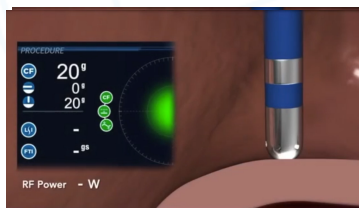
## Point-by-Point Ablation



3D – Carto™, NavX™



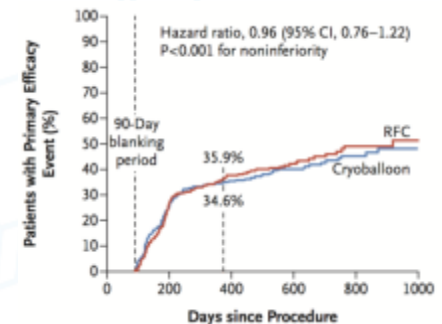
Contact monitoring



## “Single-shot” Techniques



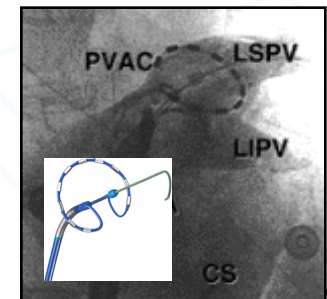
Cryoablation



Kuck KH. N Engl J Med. 2016

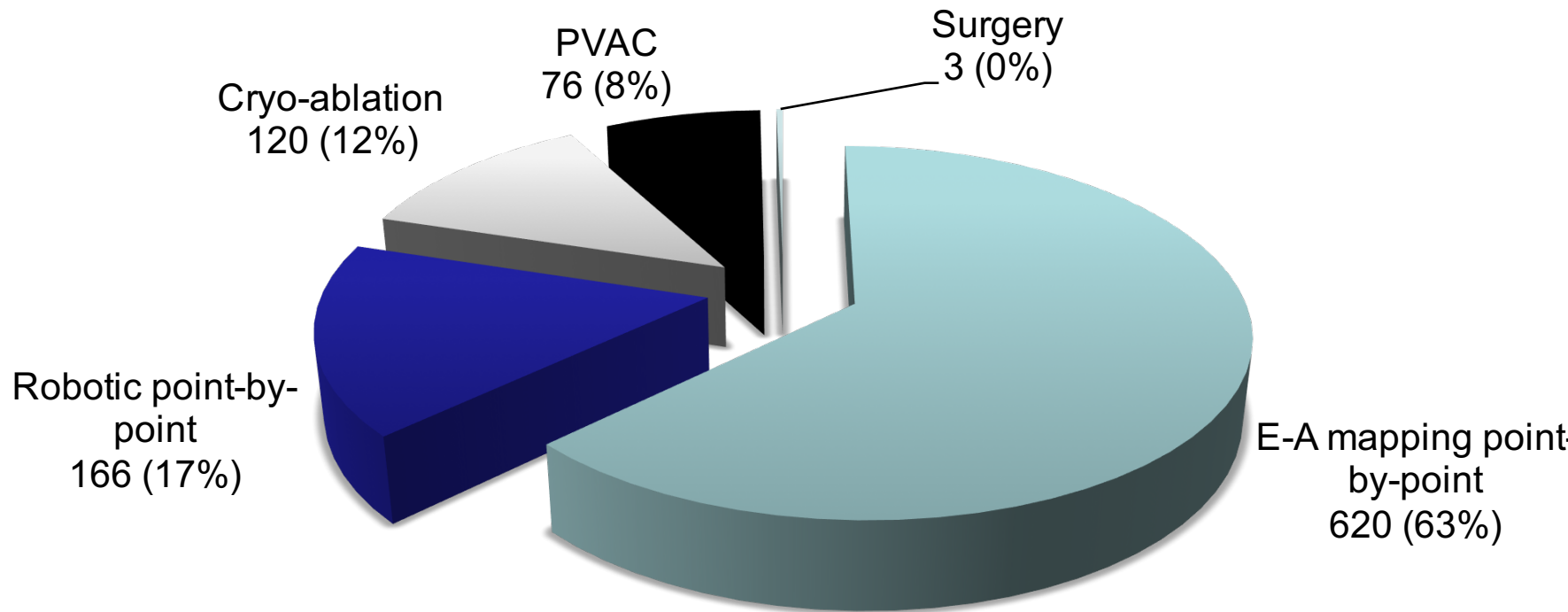
**PVAC**

Pulmonary Vein  
Ablation Catheter





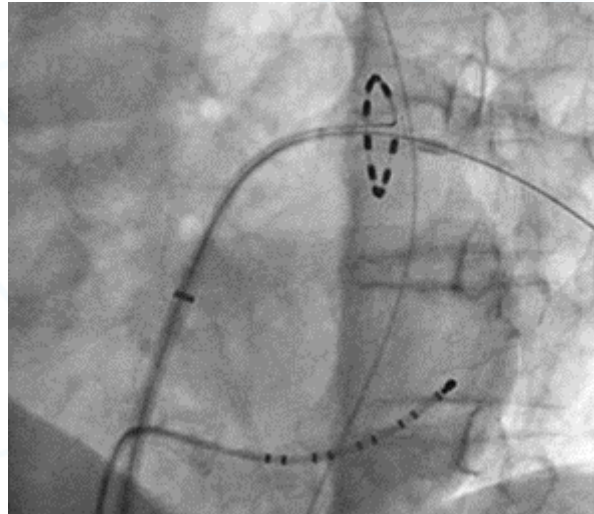
## AF Ablation techniques – APAPE 2017



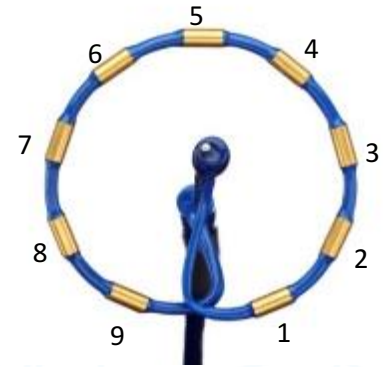
985 patients, representing 97% AF ablation procedures

- Increase success
    - Less “gaps”
  - Easier
    - Less catheters
    - One trans-septal puncture
  - Faster
    - Simultaneous lesions
  - Less complications
  - Less expensive
  - Less operator-dependent
- Problems
    - Anatomic variations
      - Common ostia
      - Accessory veins
    - Need for additional lesions
      - Atrial Flutter
      - Non-PV triggers
    - Collateral damage

# PVAC:PVI technique



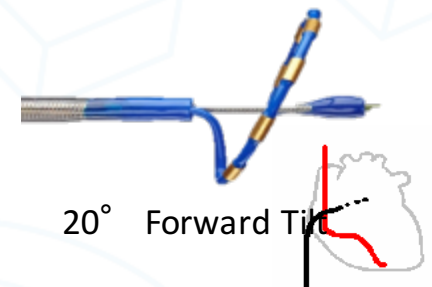
## GOLD



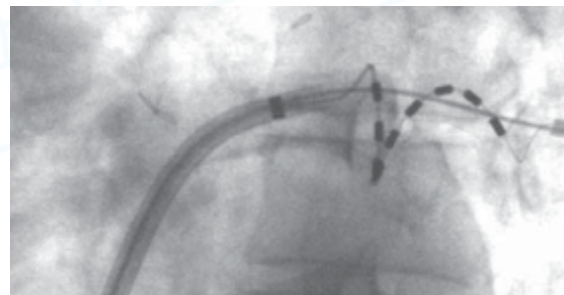
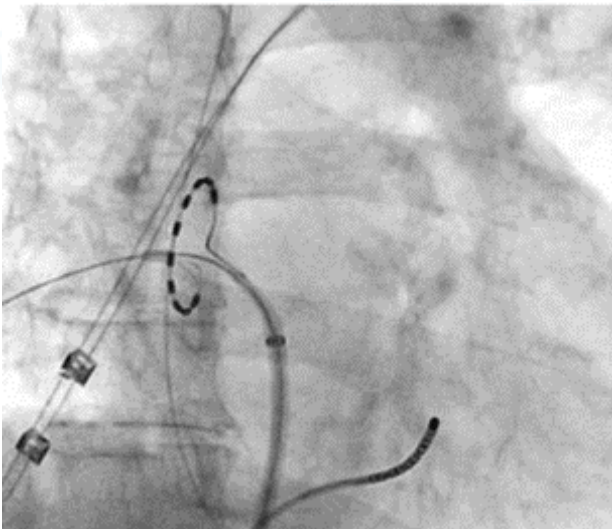
9 Electrodes



3.75mm Spacing



20° Forward Tilt





## Patient Applications Edit View Input Tools Options Help



## Meta-Analysis of Contemporary Atrial Fibrillation Ablation Strategies

Irrigated Radiofrequency Versus Duty-Cycled Phased  
Radiofrequency Versus Cryoballoon Ablation

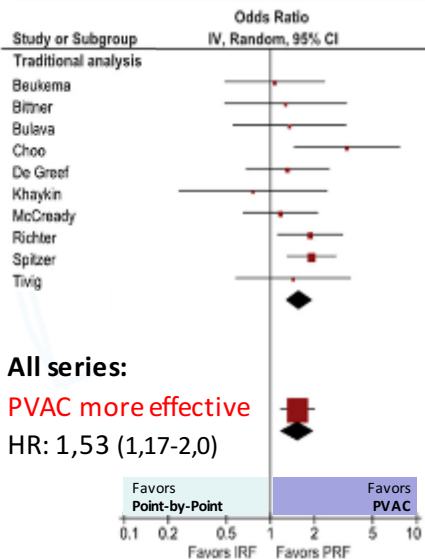
Peter Kabunga, MBChB,<sup>a,b</sup> Kevin Phan, BSc(Adv),<sup>b,c</sup> Hakeem Ha, BMed,<sup>c</sup> Raymond W. Sy, MBBS, PhD<sup>a,b</sup>

- 3 RCT comparison PVAC *versus* Point-by-Point, total of 370 pts (larger had 188 patients)
- Only paroxysmal AF in 2 RCT
- Short-F-U duration (máx: 12 m)

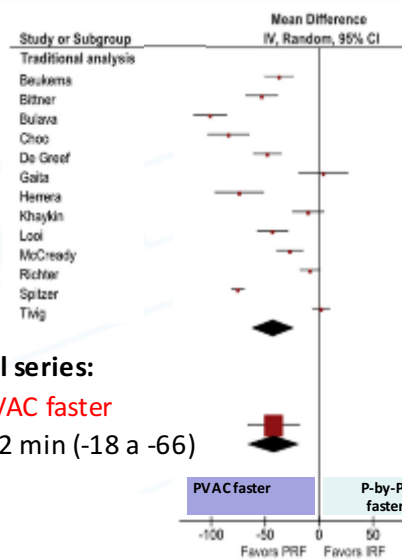
TABLE 1 Summary of Included Studies

| First Author (Ref. #)  | Country of Origin | Year | Strategy                   | Study Type(s) | PRF (n) | IRF (n) | PAF (n) | PsAF (n) | Follow-Up (months) |
|------------------------|-------------------|------|----------------------------|---------------|---------|---------|---------|----------|--------------------|
| PRF vs. IRF            |                   |      |                            |               |         |         |         |          |                    |
| McCready et al. (10)   | UK                | 2014 | PRF vs. WACA               | RCT, P        | 94      | 94      | 188     | 0        | 12                 |
| Zellerhoff et al. (13) | Germany           | 2014 | Modified PRF vs. WACA*     | OS, P         | 31      | 30      | 29      | 32       | NA                 |
| Spitzer et al. (14)    | Germany           | 2014 | PRF vs. WACA + Lines       | OS, R         | 388     | 151     | 392     | 147      | 24                 |
| De Greef et al. (15)   | Belgium           | 2014 | PRF vs. WACA               | OS, P         | 79      | 82      | 97      | 64       | 36                 |
| Richter et al. (16)    | Austria           | 2013 | PRF vs. WACA + Lines       | OS, P         | 120     | 120     | 148     | 92       | 12                 |
| Looi et al. (23)       | UK                | 2013 | PRF vs. WACA or Ostial PVI | OS, P         | 75      | 128     | 203     | 0        | >18                |
| Tivig et al. (17)      | Switzerland       | 2012 | PRF vs. WACA + Lines       | OS, P         | 209     | 211     | 298     | 122      | 18                 |
| Khaykin et al. (18)    | Canada            | 2012 | PRF vs. WACA               | OS, P         | 31      | 19      | 50      | 0        | >12                |
| Beukema et al. (19)    | the Netherlands   | 2012 | PRF vs. Ostial PVI         | OS, P         | 89      | 96      | 185     | 0        | 12                 |
| Herrera et al. (20)    | Germany           | 2011 | PRF vs. WACA               | OS, P         | 24      | 27      | 31      | 20       | NA                 |
| Gaita et al. (21)      | Italy             | 2011 | PRF vs. Ostial PVI         | OS, P         | 36      | 36      | 72      | 0        | NA                 |
| Choo et al. (22)       | UK                | 2011 | PRF vs. WACA + Lines       | OS, P         | 38      | 71      | 73      | 36       | 6                  |
| Bittner et al. (11)    | Germany           | 2011 | PRF vs. WACA               | RCT, P        | 40      | 40      | 44      | 36       | 8                  |
| Bulava et al. (12)     | Czech Republic    | 2010 | PRF vs. WACA               | RCT, P        | 51      | 51      | 102     | 0        | 7                  |

### Ablation Success

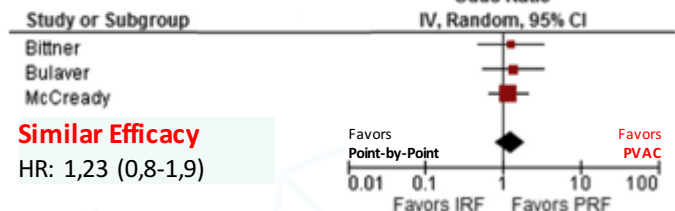


### Procedure Duration

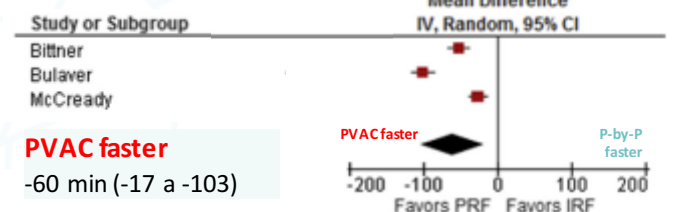


### Only Randomized Controlled Trials

#### Ablation success

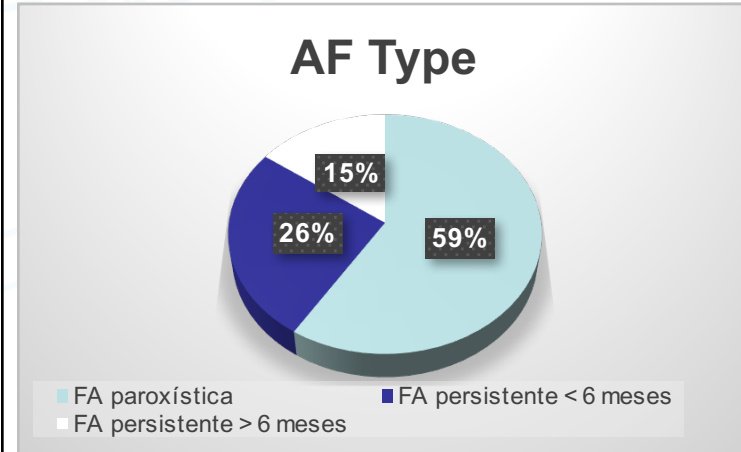


#### Procedure duration



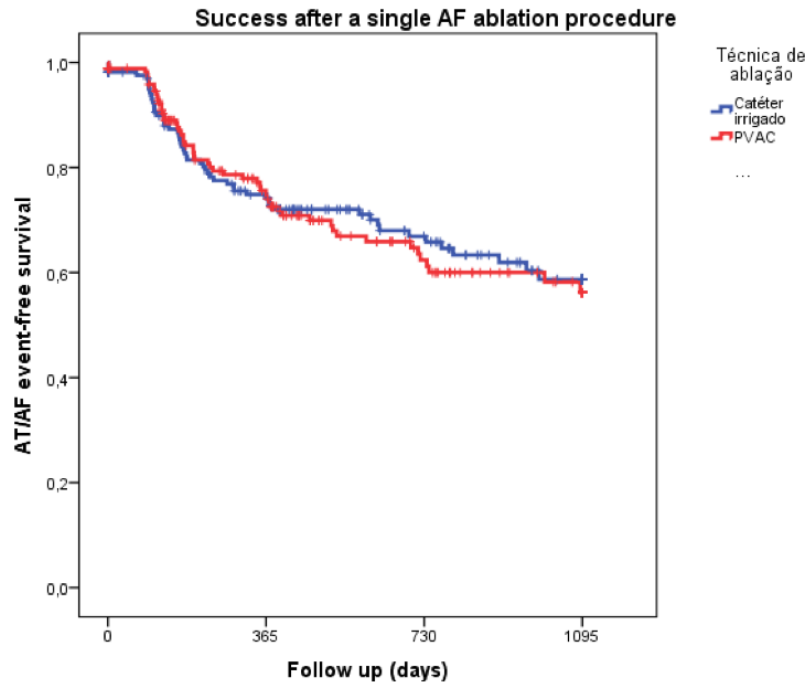
## PVI with a multipolar duty-cycle catheter (PVAC): randomised controlled trial

- Comparative study with conventional therapy (point-by-point, irrigated-tip).
- Ablation strategy: PVI + cavo-tricuspid isthmus in patients with at. flutter history
- Patient monitored: Event-recorder at 3, 6 and every 12 months
- Ablation success: freedom from AF or sustained supraventricular arrhythmia (> 30 secs)

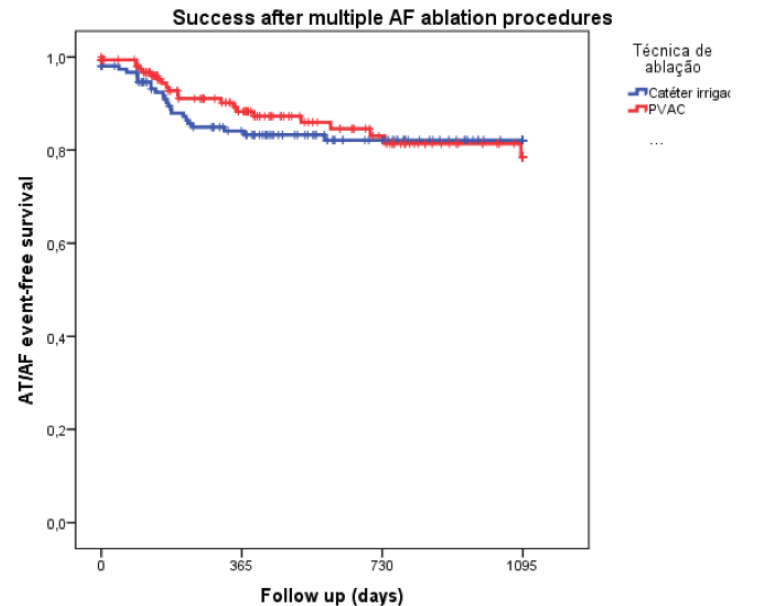


| N= 354 pts (67,5 male, 58±12 yo) | PVAC (n=179) | Conv. (n=175) | p     |
|----------------------------------|--------------|---------------|-------|
| Acute isolation                  | 98,3%        | 93,1%         | ns    |
| Complications (all)              | 4,9%         | 7,8%          | ns    |
| Hemopericardium                  | 0%           | 4,6%          | 0,013 |
| CVA                              | 1,3%         | 0%            | ns    |
| Procedure duration               | 136 min      | 230 min       | 0,01  |
| X-ray duration                   | 24,4 min     | 27,1 min      | ns    |

## RESULTS: follow-up 36 months



Single ablation success: 68%



Multiple ablation success: 85,8%

- Conclusion:

- PVAC multipolar catheter in comparison to conventional ablation therapy, is equally effective to obtain PVI, but is associated with shorter procedure duration and decreased tamponade risk.
- The incidence of clinically manifest stroke has to be monitored

# PVAC: Multicenter Gold AF Registry

- 12-Month efficacy outcome
- Prospective, observational, multi-center study
- 1054 patients, median age 62, 67.6% male, BMI=27, CHA2DS2-VASc = 2.
- 70.2% Paroxysmal AF, 26.5% Persistent AF, 3.3% long standing Persistent AF.

| N= 1054 pts             |                  |
|-------------------------|------------------|
| Median RF applications  | N=23             |
| Mean procedure time     | 107.0 ± 39.5 min |
| Mean Fluor. time        | 25.0 ± 15.5 min  |
| Cath lab time           | 154.7 ± 49.3 min |
| Acute PVI               | 94,3% (977/1036) |
| 30 day-complication     | 2,8% (n=30)      |
| 12 months AF recurrence | 22,3%            |

## Conclusion:

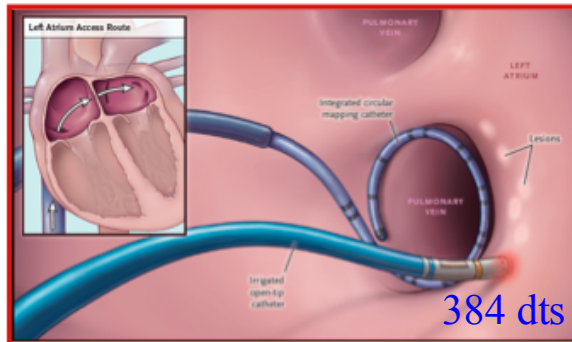
- 22.3% AF recurrence rate at 12 months
- Reduction in arrhythmia related symptoms and improved quality of life were observed.
- Periprocedural complication rate of 3%



## Arctic Front Advance

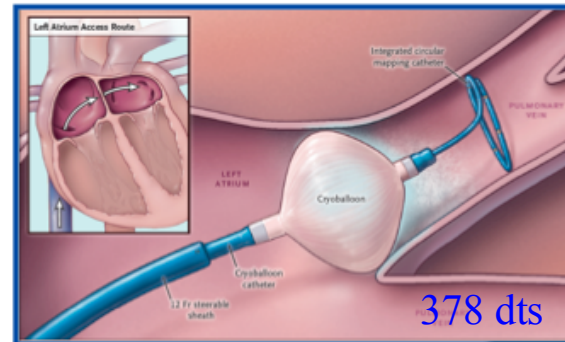
### FIRE AND ICE AF Clinical Trial

- **RFC Ablation (“FIRE”)**
  - Power was not to exceed
    - 40 W at A/I aspect
    - 30 W at P/S aspect
  - 3D electroanatomical mapping



### Methods

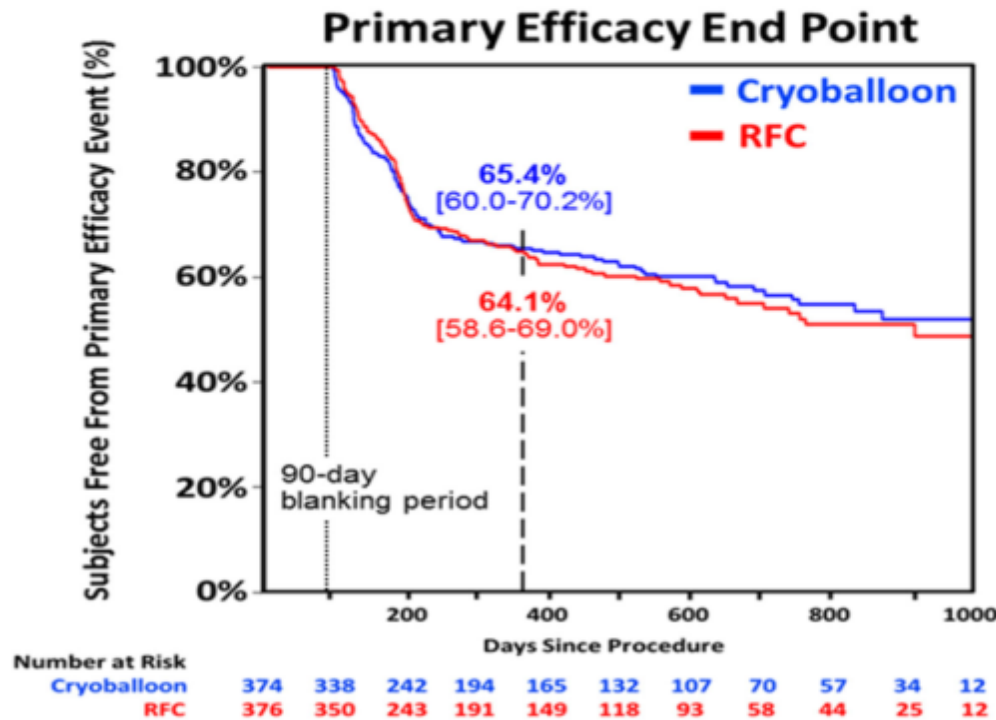
- **Cryoballoon Ablation (“ICE”)**
  - Max. freeze duration of 240s recommended
  - Bonus freeze after isolation recommended
  - Phrenic nerve pacing required



ACC.16

- Multicentric, randomized, experient operators
- Paroxysmal AF refractory to AA drugs
- Primary efficacy: sustained atrial arrhythmia, need AA drugs, re-ablation
- Safety: death, cerebrovascular events, SAE
- Follow-up: 1,5 years





## Modified ITT analysis

- HR [95% CI] = 0.96 [0.76-1.22];  $p = 0.0004$
- Non-inferiority hypothesis met
- Superiority test:  $p = 0.74$

| Efficacy End Point Type          | Cryo (N=374) | RFC (N=376) |
|----------------------------------|--------------|-------------|
| Recurrent atrial arrhythmia      | 80           | 87          |
| Antiarrhythmic drug prescription | 51           | 49          |
| Re-ablation                      | 7            | 7           |

Complicações: Crio – 40 (10,2%); RF – 51 (12,8%) – HR 0,78,  $p=0,24$

FIRE AND ICE  
AF Clinical Trial

## Key Treatment-Related Serious Adverse Events

| Event (N, %)                                 | RFC (n=376) | Cryoballoon (n=374) |
|----------------------------------------------|-------------|---------------------|
| Groin Site Complication*                     | 16 (4.3%)   | 7 (1.9%)            |
| Atrial Flutter/Atrial Tachycardia**          | 10 (2.7%)   | 3 (0.8%)            |
| Phrenic Nerve Injury unresolved at discharge | 0           | 10 (2.7%)***        |
| Unresolved at 3 months                       | 0           | 2 (0.5%)            |
| Unresolved at > 12 months                    | 0           | 1 (0.3%)            |
| Cardiac Tamponade/Pericardial Effusion       | 5 (1.3%)    | 1 (0.3%)            |
| Stroke/TIA                                   | 2 (0.5%)    | 2 (0.5%)            |
| Atrial Septal Defect                         | 1 (0.3%)    | 0                   |
| Esophageal Ulcer                             | 0           | 1 (0.3%)            |
| Pericarditis                                 | 0           | 1 (0.3%)            |
| Atrioesophageal Fistula                      | 0           | 0                   |
| Pulmonary Vein Stenosis                      | 0           | 0                   |

\* Includes vascular pseudoaneurysm, AV fistula, device-related infection, hematoma, puncture site hemorrhage, groin pain

\*\* Serious (e.g. hospitalization) and causally related to the therapeutic intervention (e.g. ablation-induced or drug-induced)

\*\*\* 8 resolved by 3 month visit, 1 resolved by 6 months visit, 1 unresolved after 12 month visit



## FIRE AND ICE

AF Clinical Trial

## Procedural Characteristics

| Time Measurement (minutes) | RFC (n=376) * | Cryoballoon (n=374) * | P-value** |
|----------------------------|---------------|-----------------------|-----------|
| Procedure Time***          | 140.9 ± 54.9  | 124.4 ± 39.0          | <0.0001   |
| LA Dwell Time***           | 108.6 ± 44.9  | 92.3 ± 31.4           | <0.0001   |
| Fluoroscopy Time           | 16.6 ± 17.8   | 21.7 ± 13.9           | <0.0001   |

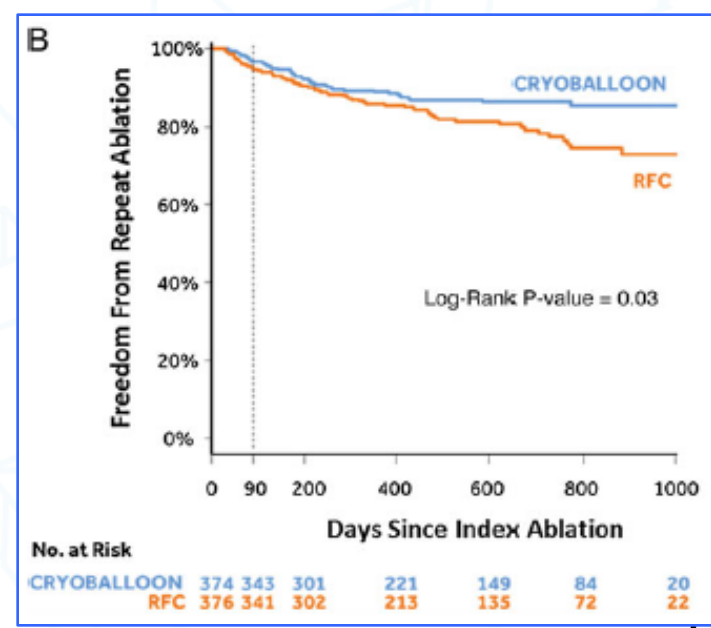
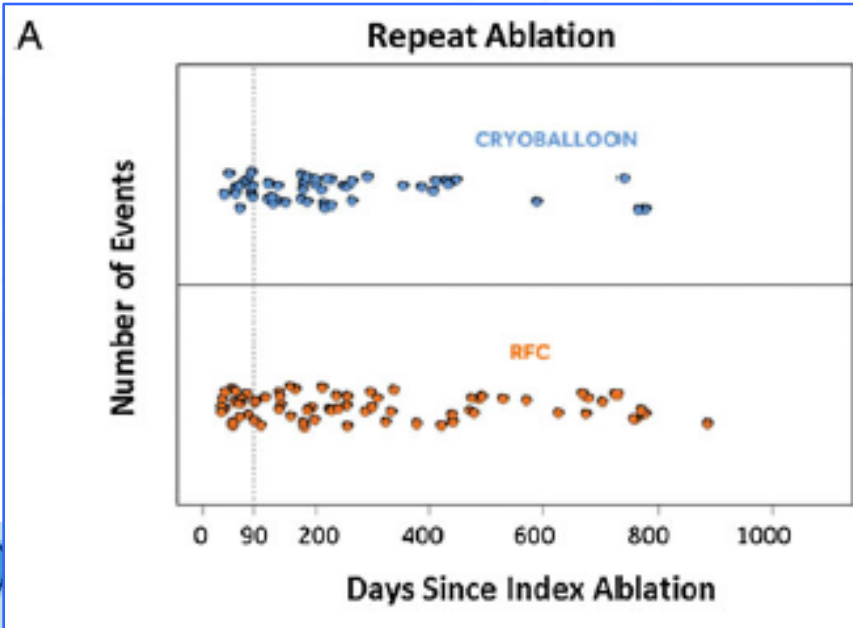
\* Calculations based on mITT

\*\* t-test

\*\*\* Protocol required 30-min waiting period after last application to assess PVI

**Table I** Summary of rehospitalization data

|                                   | Total number of events; subjects with events |                  | Hazard ratio (95% CI) | P-value |
|-----------------------------------|----------------------------------------------|------------------|-----------------------|---------|
|                                   | Cryoballoon (n = 374)                        | RFC (n = 376)    |                       |         |
| All-cause rehospitalizations      | 210; 122 (32.6%)                             | 267; 156 (41.5%) | 0.72 (0.57–0.91)      | 0.01    |
| Cardiovascular rehospitalizations | 139; 89 (23.8%)                              | 203; 135 (35.9%) | 0.61 (0.47–0.80)      | <0.01   |
| Repeat ablations                  | 49; 44 (11.8%)                               | 70; 66 (17.6%)   | 0.65 (0.45–0.95)      | 0.03    |
| Direct-current cardioversions     | 13; 12 (3.2%)                                | 28; 24 (6.4%)    | 0.49 (0.25–0.98)      | 0.04    |



## NEW RESEARCH PAPERS

### Single-Procedure Outcomes and Quality-of-Life Improvement 12 Months Post-Cryoballoon Ablation in Persistent Atrial Fibrillation

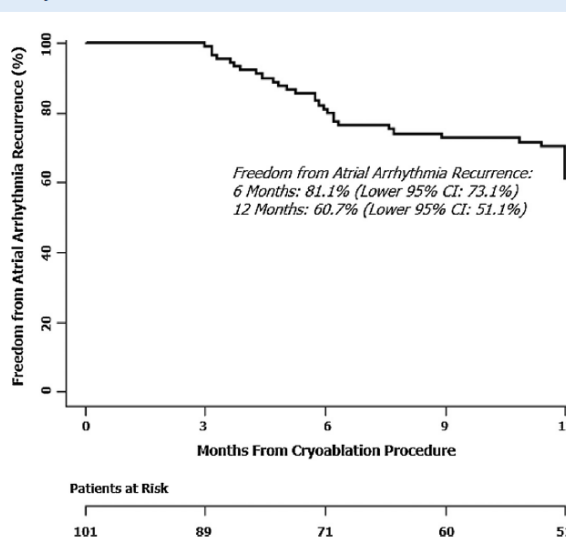
Results From the Multicenter CRYO4PERSISTENT AF Trial

Serge Boveda, MD,<sup>a</sup> Andreas Metzner, MD,<sup>b</sup> Dinh Q. Nguyen, MD,<sup>c</sup> K.R. Julian Chun, MD,<sup>d</sup> Konrad Goehl, MD,<sup>e</sup>  
Georg Noeller, MD,<sup>f</sup> Jean-Claude Deharo, MD,<sup>g</sup> George Andrikopoulos, MD,<sup>h</sup> Tillman Dahme, MD,<sup>i</sup>  
Nicolas Lellouche, MD,<sup>j</sup> Pascal Defaye, MD<sup>k</sup>

**TABLE 1** Patients' Baseline Characteristics (N = 101)

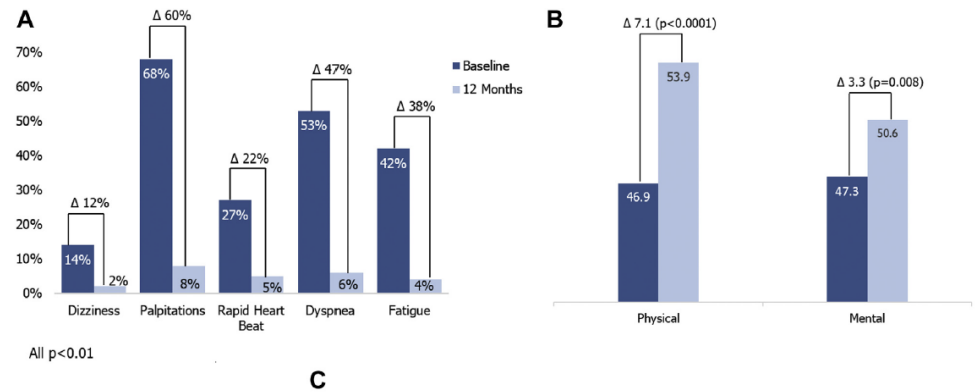
|                                        |              |
|----------------------------------------|--------------|
| Male                                   | 75 (74.3)    |
| Age, yrs                               | 61.8 ± 10.5  |
| PerAF onset, days                      | 120.6 ± 98.0 |
| CHA <sub>2</sub> DS <sub>2</sub> -VASc | 1.6 ± 1.3    |
| BMI, kg/m <sup>2</sup>                 | 28.2 ± 4.2   |
| Systolic BP, mm Hg                     | 129.9 ± 14.0 |
| Diastolic BP, mm Hg                    | 82.0 ± 11.1  |
| LAD, mm                                | 43 ± 5       |
| LVEF, %                                | 56 ± 8       |
| Coronary artery disease                | 5 (5.0)      |
| Hypertension                           | 63 (62.4)    |
| Type II diabetes                       | 5 (5.0)      |
| Dyslipidemia                           | 20 (19.8)    |
| Smoking                                | 22 (21.8)    |
| Alcoholism                             | 4 (4.0)      |
| Prior DCCV <12 months                  | 51 (50.5)    |
| Prior stroke/transient ischemic event  | 4 (4.0)      |
| NYHA functional classification         |              |
| Subject does not have heart failure    | 46 (45.5)    |
| I                                      | 23 (22.8)    |
| II                                     | 26 (25.7)    |
| III                                    | 5 (5.0)      |
| IV                                     | 0 (0.0)      |
| Not reported                           | 1 (1.0)      |

**FIGURE 2** Freedom From Atrial Fibrillation, Atrial Flutter, Atrial Tachycardia Recurrence



Kaplan-Meier curve of time to first atrial fibrillation, atrial flutter, or atrial tachycardia recurrence. Subjects with a primary endpoint >12 months from index cryoballoon ablation had their time to primary endpoint set to 12.0 months. CI = confidence interval.

**FIGURE 3** Arrhythmia-Related Symptoms, QoL, and EHRA AF Symptom Score



Δ: (B) 36-Item Short Form Health Survey (SF36) quality-of-life (QoL) improvement (baseline to cryoballoon (AF) symptom score reduction (baseline to 12 months)).

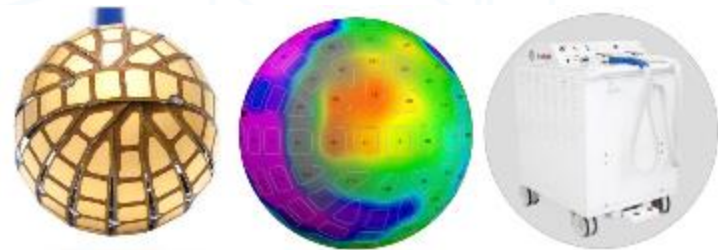
**TABLE 3** Major Adverse Events (N = 101)

|                                |         |
|--------------------------------|---------|
| Vascular pseudoaneurysm        | 2 (2.0) |
| Transient ST-segment elevation | 1 (1.0) |
| Pericardial effusion/tamponade | 1 (1.0) |
| PNI at discharge               | 0 (0.0) |
| Stroke/TIA                     | 0 (0.0) |
| Pulmonary vein stenosis        | 0 (0.0) |
| AE fistula                     | 0 (0.0) |
| Death                          | 0 (0.0) |
| Total                          | 4 (4.0) |

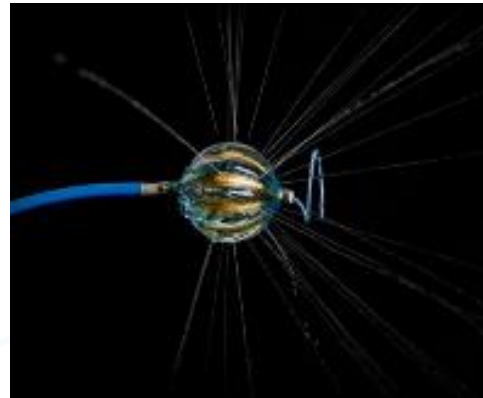
- Laser balloon



- RF balloon
  - Kardia



- Heliostar



🎬 In what patients is classic point-by-point ablation with mapping system still needed?

🎬 AF re-ablation

🎬 Ablation of AF + A. Flutter

🎬 Ablation of AF with an identified trigger

🎬 AT / PAB

- Conclusion:
  - For PVI in AF ablation, single-shot techniques are easier, faster, less operator dependente and equally effective as conventional ablation therapy
  - In the future single-shot techniques will be dominant in the PVI for AF ablation initial attempt