
# IMPROVED PROCEDURAL EFFICACY OF PULMONARY VEIN ISOLATION USING THE NOVEL SECOND-GENERATION

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Domenico Catnzariti, Carlo Angheben, Maurizio Del Greco

Venice, October 18 2015

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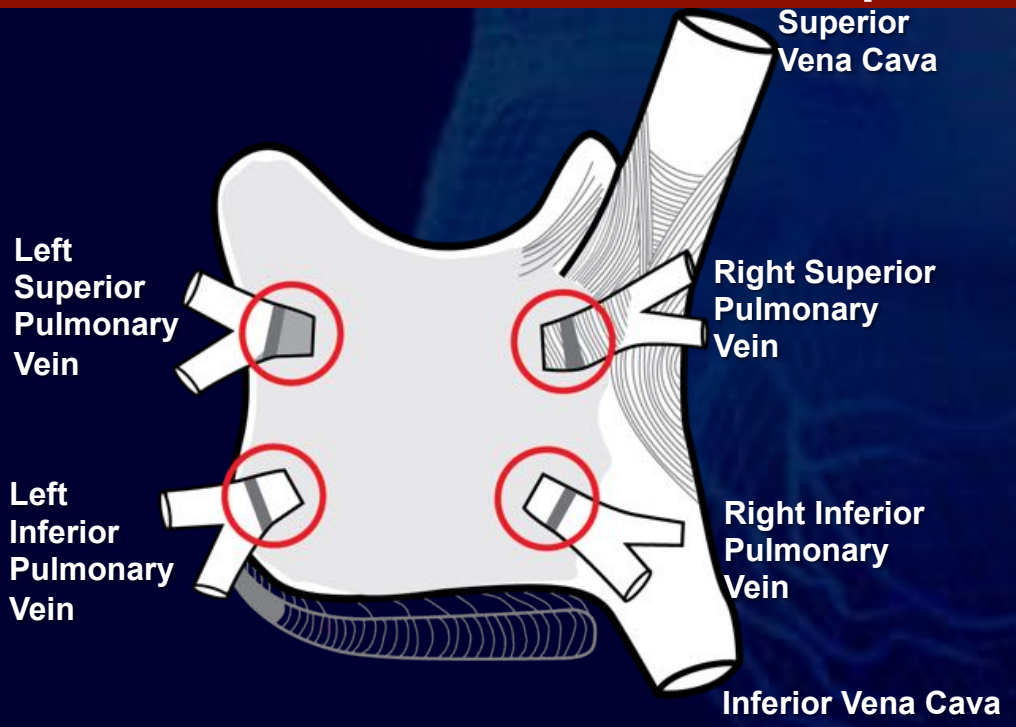
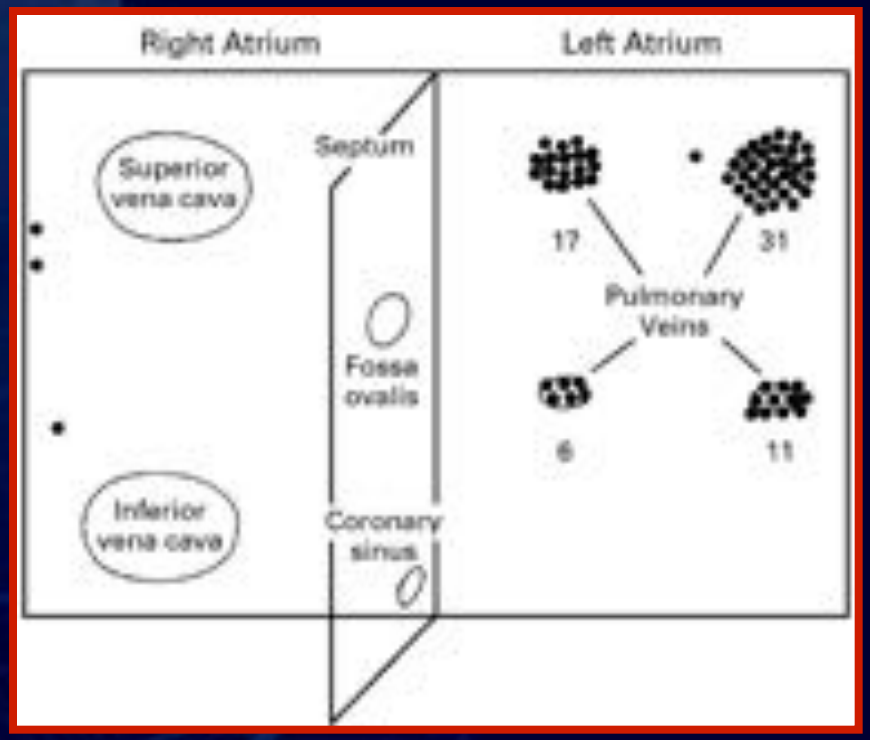
# Background - atrial fibrillation ablation

**2012 HRS/EHRA/ECAS Consensus Statement on catheter ablation of AF**

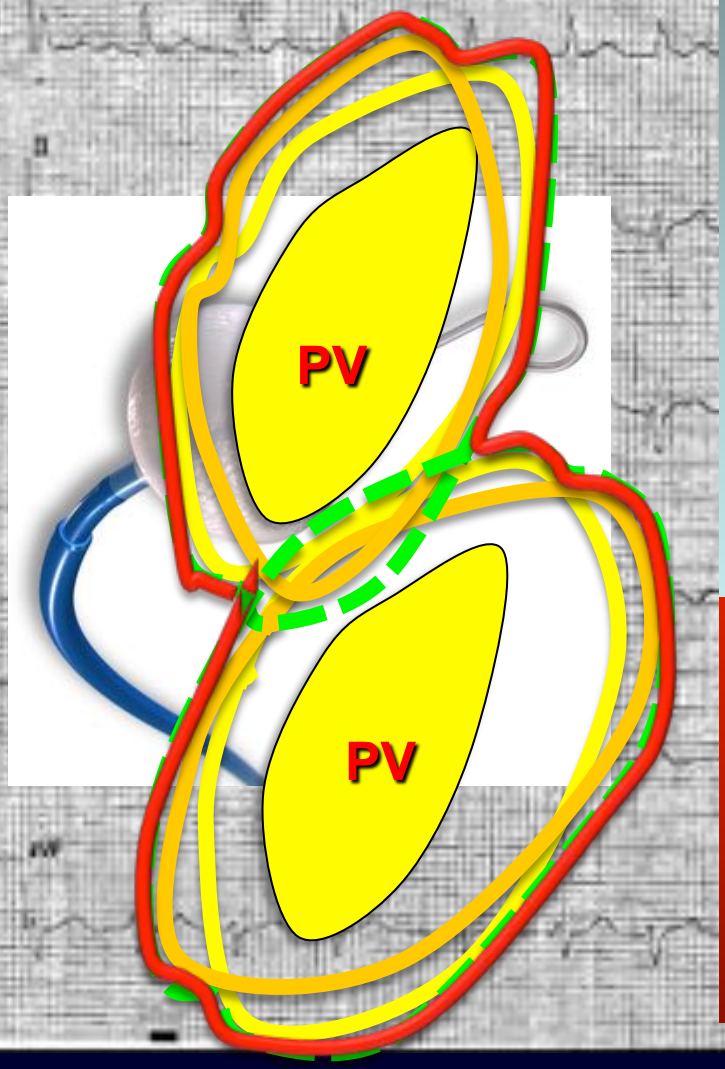
**"Ablation strategies which target the PVs and/or PV antrum are the cornerstone for most AF ablation procedures."**




Cappato et al., Circ Arrhythm Electrophysiol 2010;3;32-38
Calkins et al. *HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation.* Heart Rhythm 2012

# Background - atrial fibrillation ablation




## CRYO

**'One Shot' technology**

- Ability to isolate the PV generally with 1-2 applications

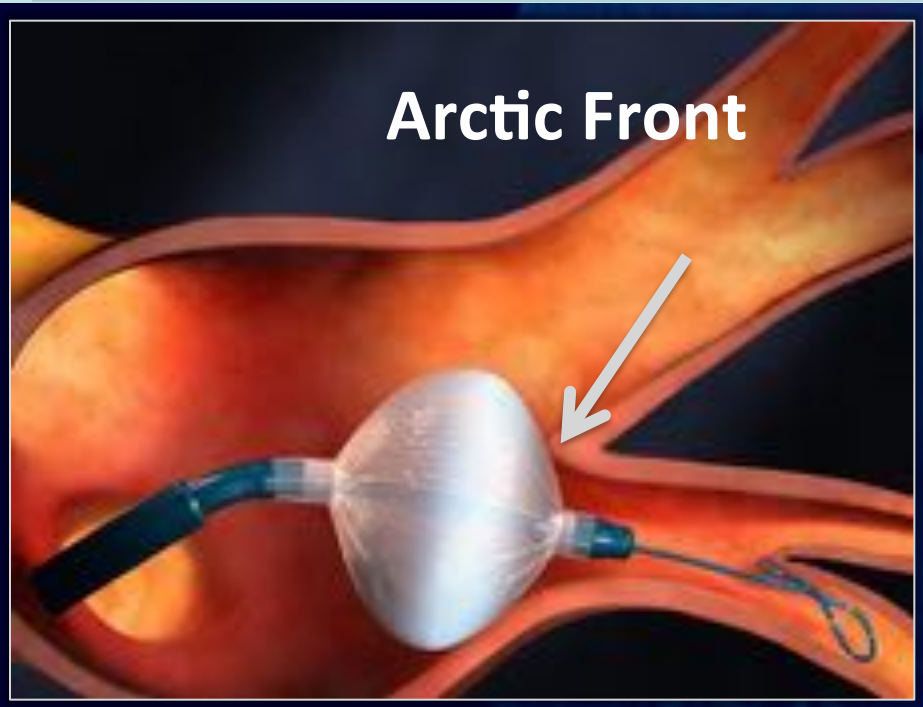
**Homogeneous lesion**

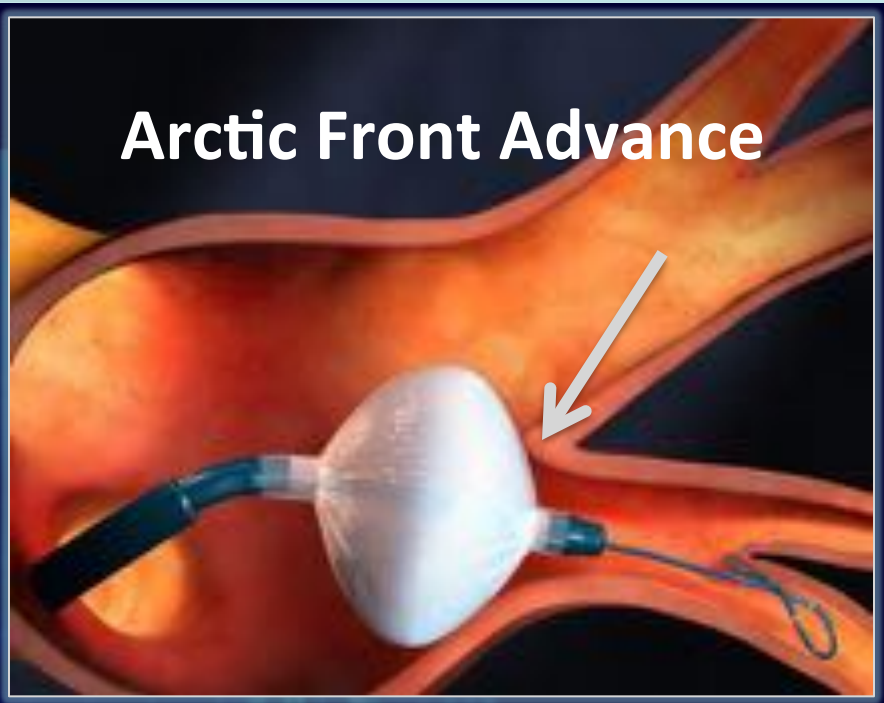
**Does not require 3D mapping**

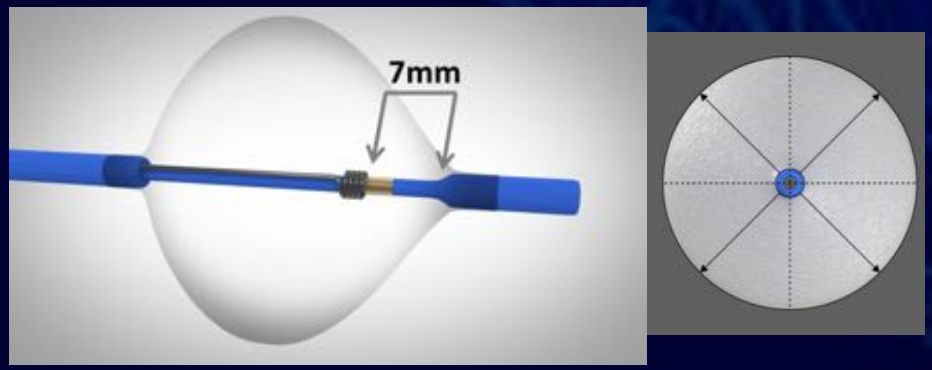
**No operator-dependance – faster learning curve**

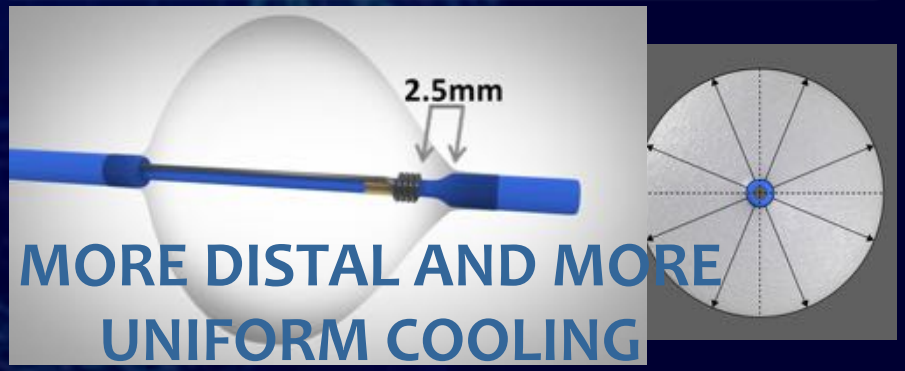
**First-generation cryoballoon (CB1) repeated freezing is often necessary**

# Background - atrial fibrillation ablation



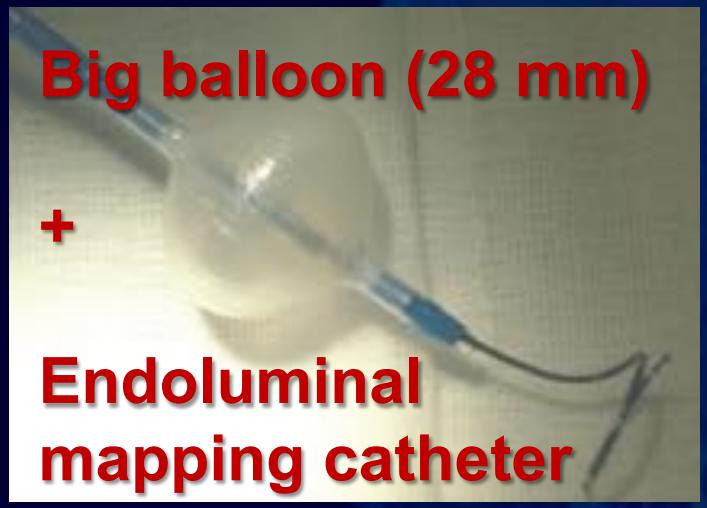



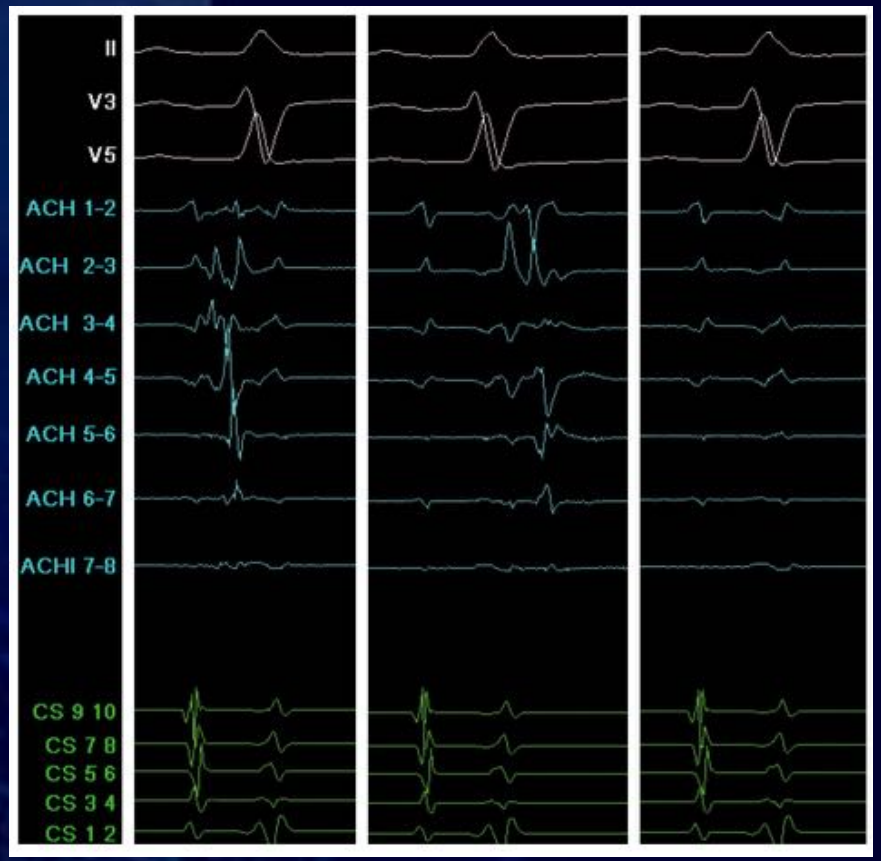
# AIM

**Investigate the impact of the novel CB2 on procedural efficacy of cryoballoon PV isolation (CB-PVI)**

# METHODS:

## *"Single-catheter procedure"*




Delay | Increased Delay | Isolation

# ICE in our electrophysiology laboratory

## All Cryoablation

1. Guide in atrial transseptal puncture


2. Identification and prevention of procedural complications


3. Achieve Cryoballoon PV Occlusion

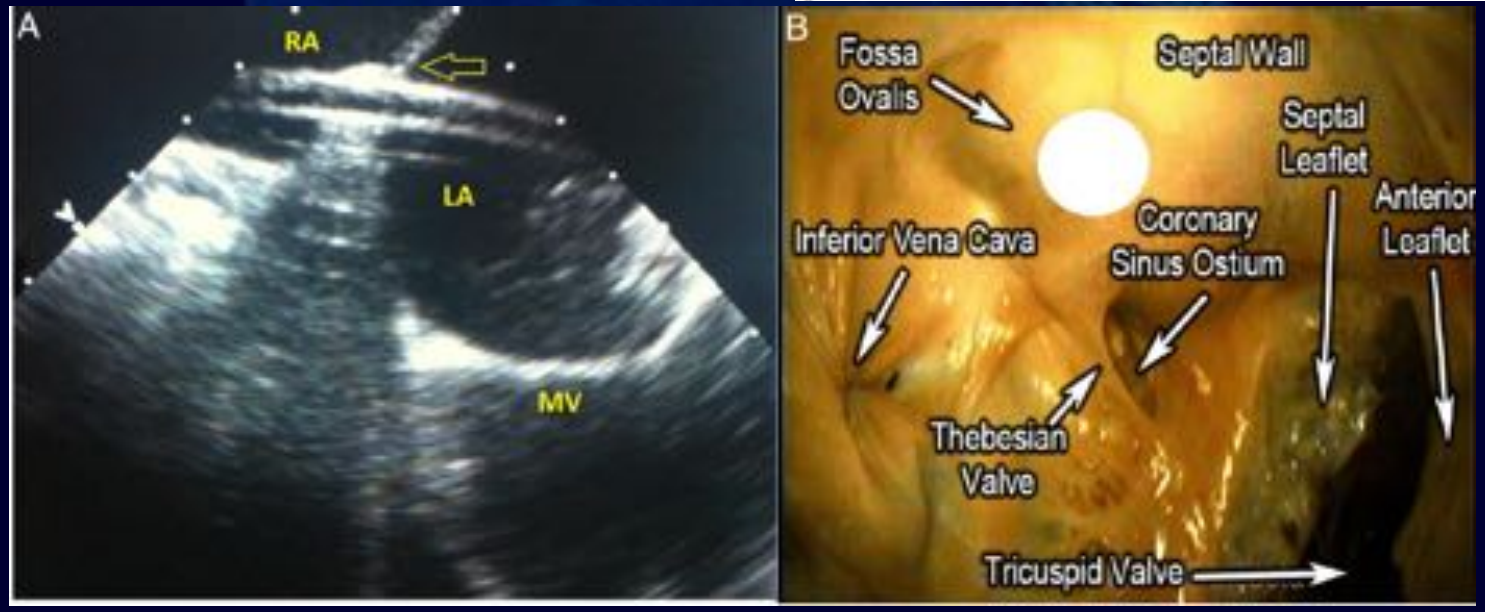

CONTEMPORARY REVIEW

# Best practice guide for cryoballoon ablation in atrial fibrillation: The compilation experience of more than 3000 procedures

Wilber Su, MD, FHRS,* Robert Kowal, MD, FHRS,† Marcin Kowalski, MD, FHRS,‡ Andreas Metzner, MD, FHRS,§ J. Thomas Svinarich, MD, FHRS,‖ Kevin Wheelan, MD, FHRS,† Paul Wang, MD, FHRS**

(Heart Rhythm 2015;12:1658–1666)

contact with the inferior aspects of the PVs. We highly recommended using ICE to improve the safety of transseptal catheterization. ICE will also provide early detection of complications (eg, catheter-related thrombus and pericardial) in ablation cases. The location of the transseptal access is best at the lower third of the septum and anterior reach at the plane of ICE where the mitral valve is in view (Figure 2).



**Indian Pacing Electrophysiol. J.** 2012;12(6)
In press
Indian PACING and ELECTROPHYSIOLOGY Journal

**Original Article**

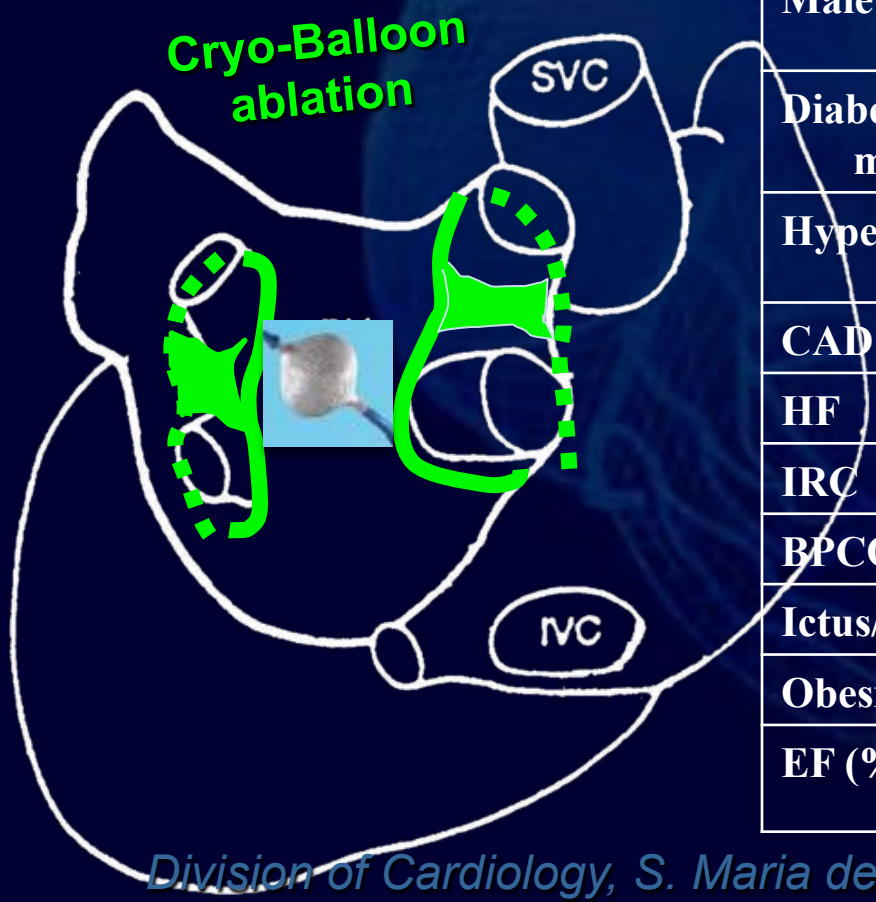
# Usefulness of Contrast Intracardiac Echocardiography in Performing Pulmonary Vein Balloon Occlusion during Cryo-ablation for Atrial Fibrillation

Domenico Catanzariti, MD[1], Massimiliano Maines, MD[1], Carlo Angheben, MD[1], Maurizio Centonze, MD[2], Claudio Cemin, MD[1], Giuseppe Vergara, MD[1]
[1]Division of Cardiology, S Maria del Carmine Hospital, Rovereto (TN), Italy; [2]Department of Radiology, S Chiara Hospital, Trento, Italy

| | All (n=30) | Group 1 (n=15) | Group 2 (n=15) | P |
|---|---|---|---|---|
| Procedure time (minutes) | 138±20 | 152±19 | 127±16 | P<0.05 |
| Number of applications | 11.4±3.2 | 10.8±2.6 | 12.0±3.6 | P=n.s. |
| fluoroscopy time (minutes) | 34±8 | 43±9 | 30±12 | P<0.05 |
| use of contrast (ml) | 140±62 | 190±47 | 88±26 | P<0.001 |

# METHODS: Population

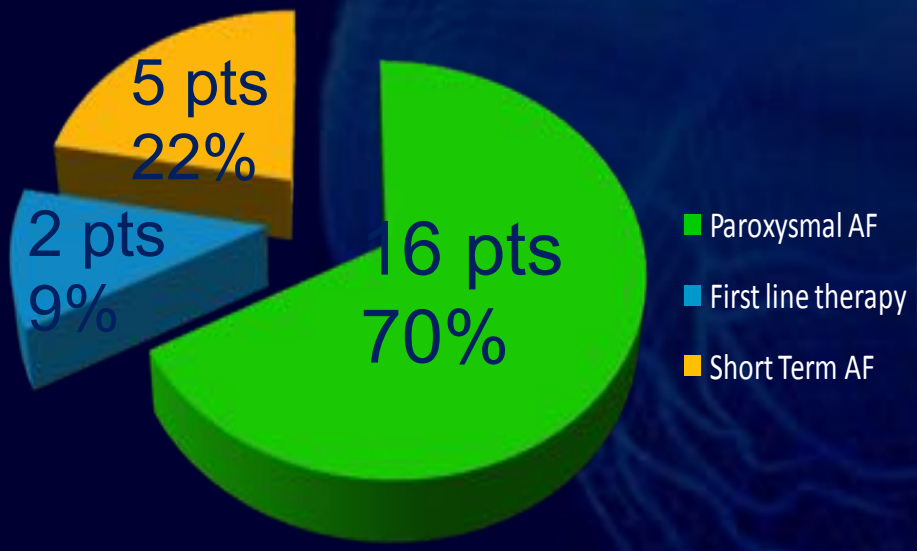
PAROXYSMAL OR SHORT-TERM PERSISTENT ATRIAL FIBRILLATION
**(sep 2011 – feb 2014)**



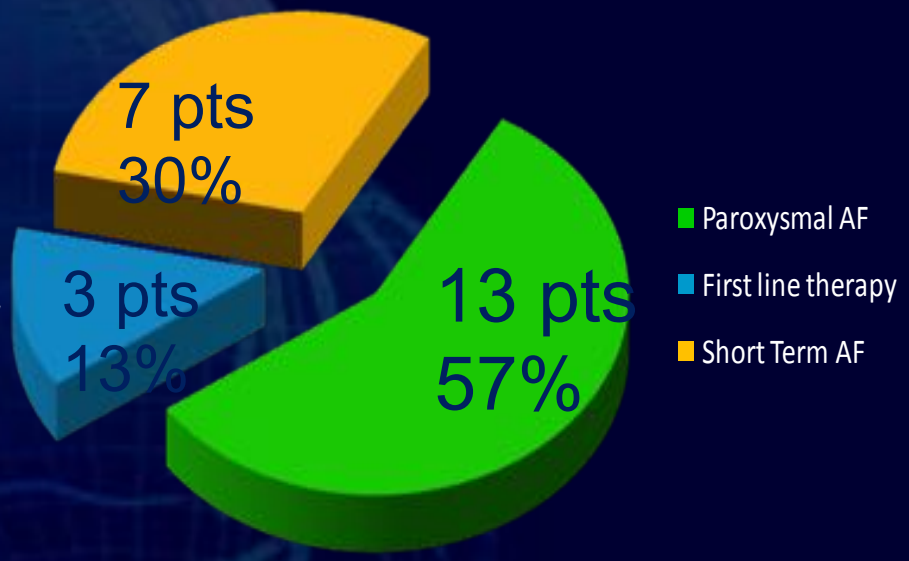

| | ALL 46 pts | CB1 23 pts | CB2 23 pts |
|---|---|---|---|
| Age (years) | 65±13 | 66±9 | 65±6 |
| Male Gender | 37 (80%) | 19 | 18 |
| Diabetes mellitus | 3 (7%) | 1 | 2 |
| Hypertension | 24 (52%) | 11 | 13 |
| CAD | 5 (11%) | 3 | 2 |
| HF | 2 (4%) | 1 | 1 |
| IRC | 4 (9%) | 2 | 2 |
| BPCO | 3 (7%) | 1 | 2 |
| Ictus/TIA | 3 (7%) | 1 | 2 |
| Obesity | 15 (33%) | 6 | 9 |
| EF (%) | 60.2±3.9 | 59.9±2 | 60.7±3 |

# METHODS: Population

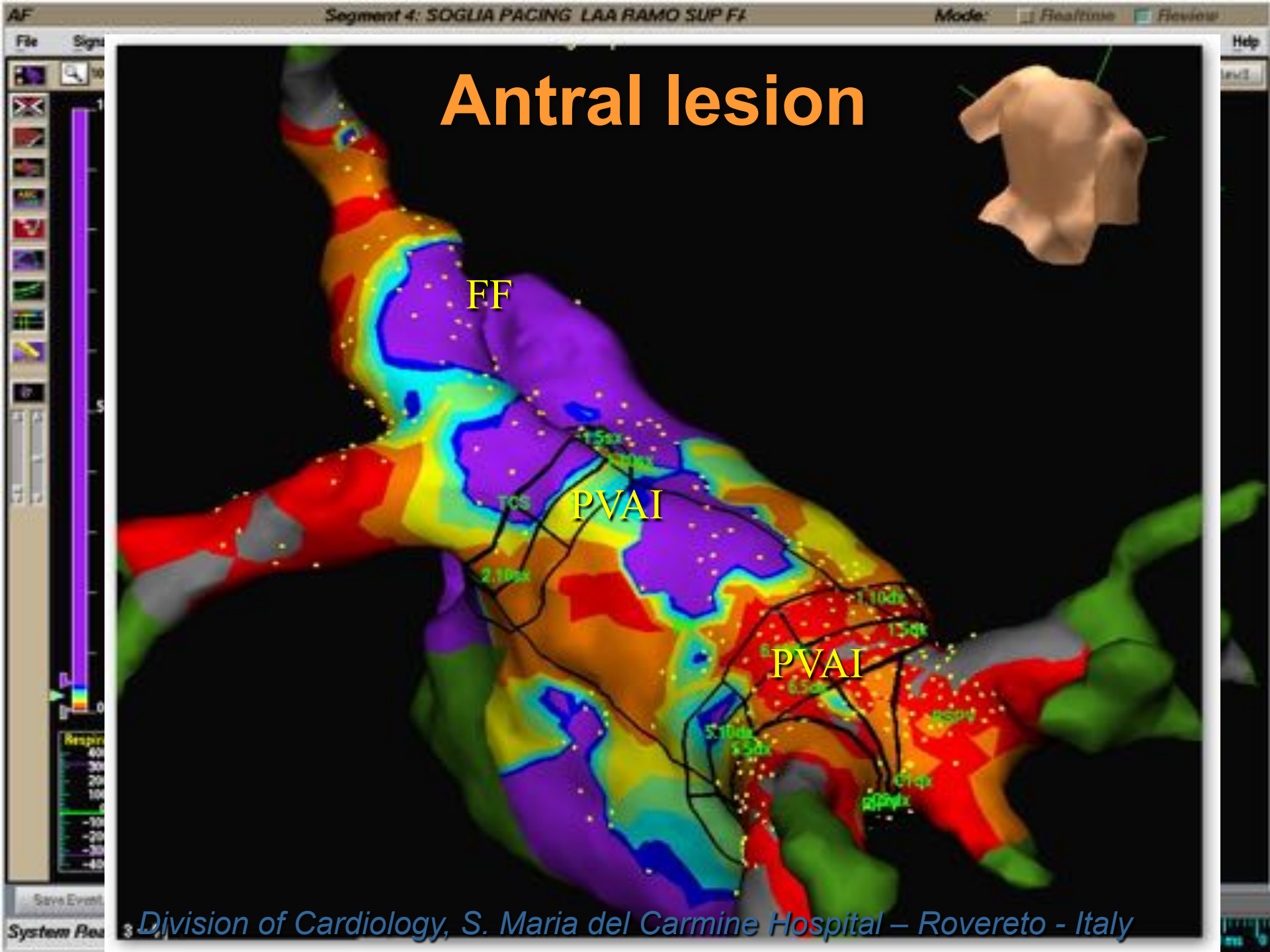
## CB1 Ablation indication



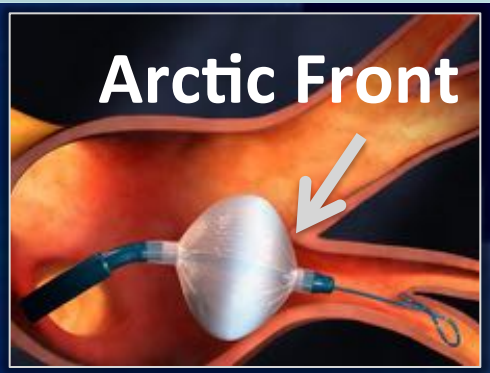

## CB2 Ablation indication



# Antral lesion



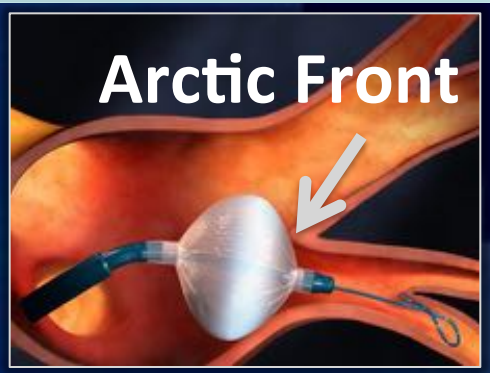
# RESULTS





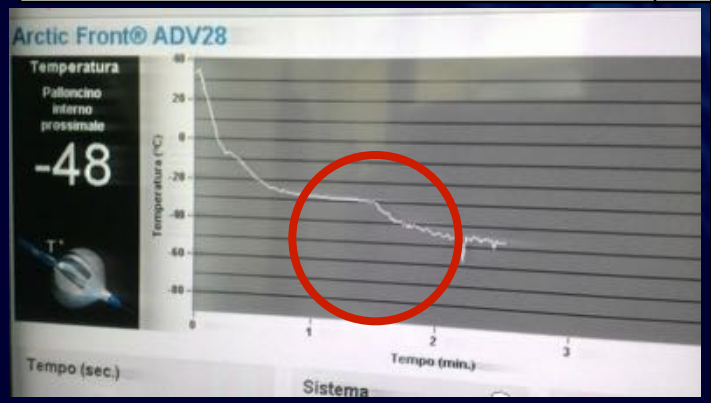
| | CB1 (300 s application time) | CB2 (240 s application time) | P |
|---|---|---|---|
| Patients (number) | 23 | 23 | - |
| single-shot PVI rate (%) | 56 | 85 | < 0.01 |
| procedure duration (min) | 190 ± 26 | 139 ± 32 | < 0.01 |
| fluoroscopy exposure time (min) | 35.7 ± 8.3 | 23.4 ± 5.4 | P=0.01 |
| Time to PVI (seconds) | 68 ± 28 | 49 ± 26 | |

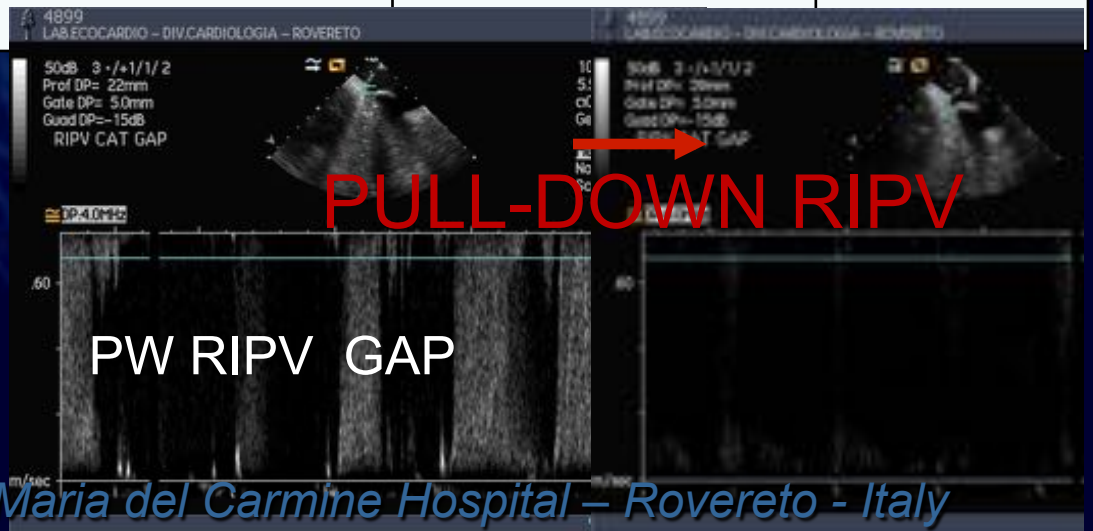
# RESULTS



| | CB1 | CB2 | P |
|---|---|---|---|
| Patients (number) | 23 | 23 | - |
| Need of pull-down maneuver (%) | 16 | 4 | < 0.01 |



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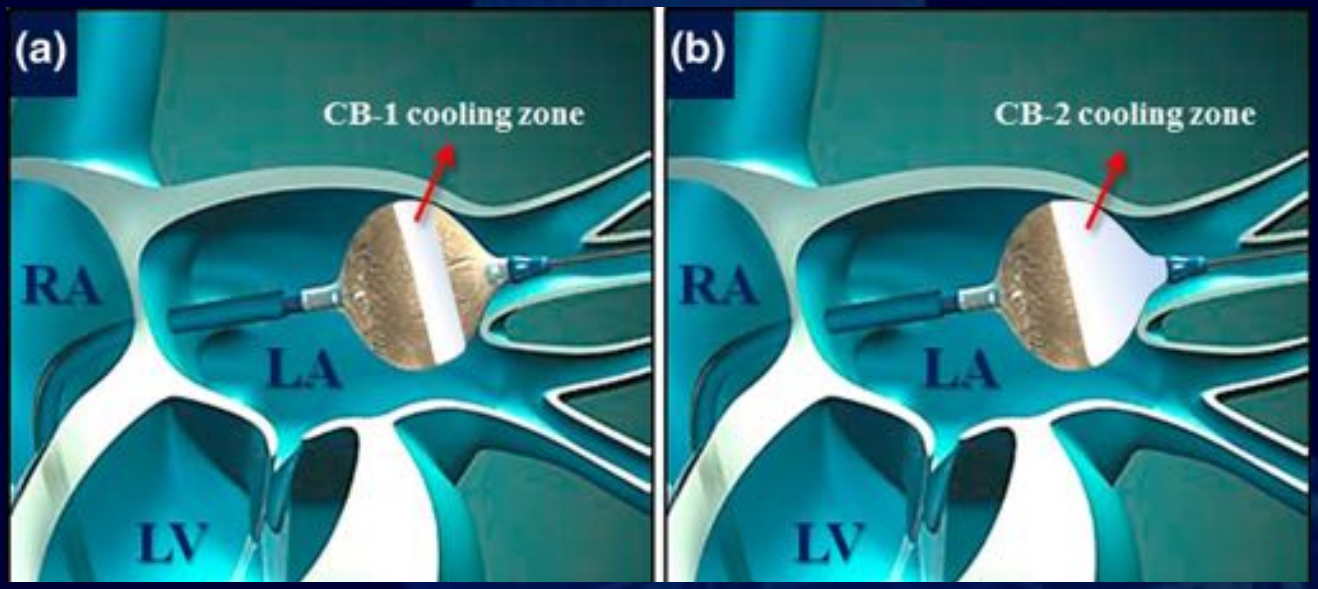
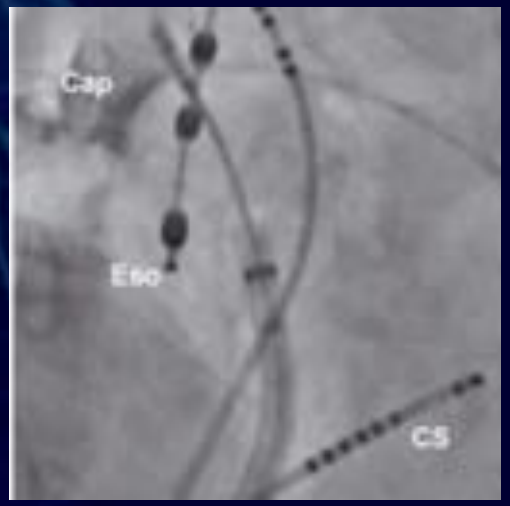
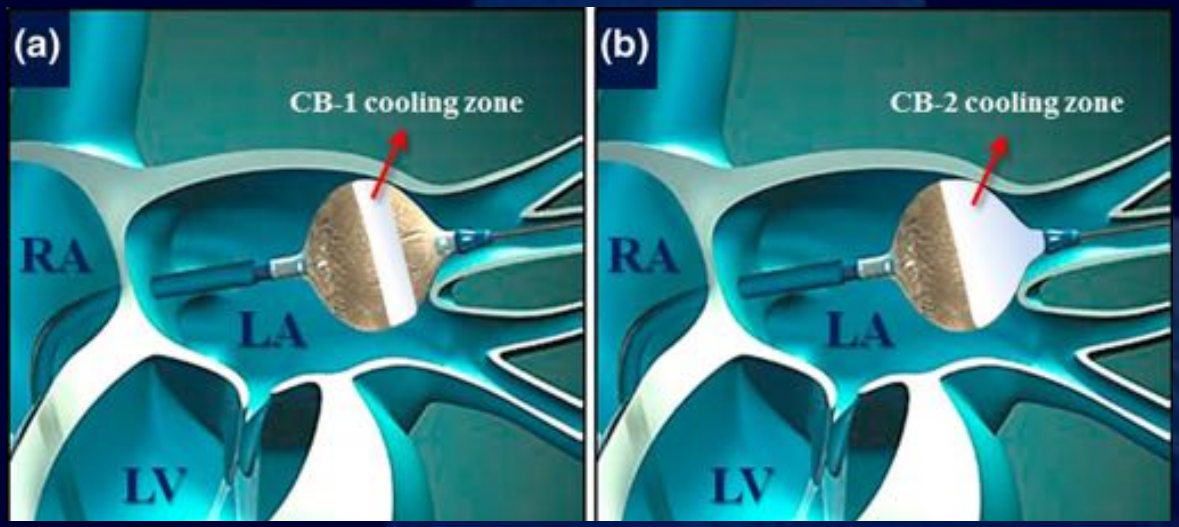







The improved efficacy of the CB-2G may be explained by an increased area of balloon-tissue contact with optimal cooling.
Furthermore, improved cooling of the nose may give rise to more extensive ice formation within the PV as demonstrated by the stable ice cap phenomenon.

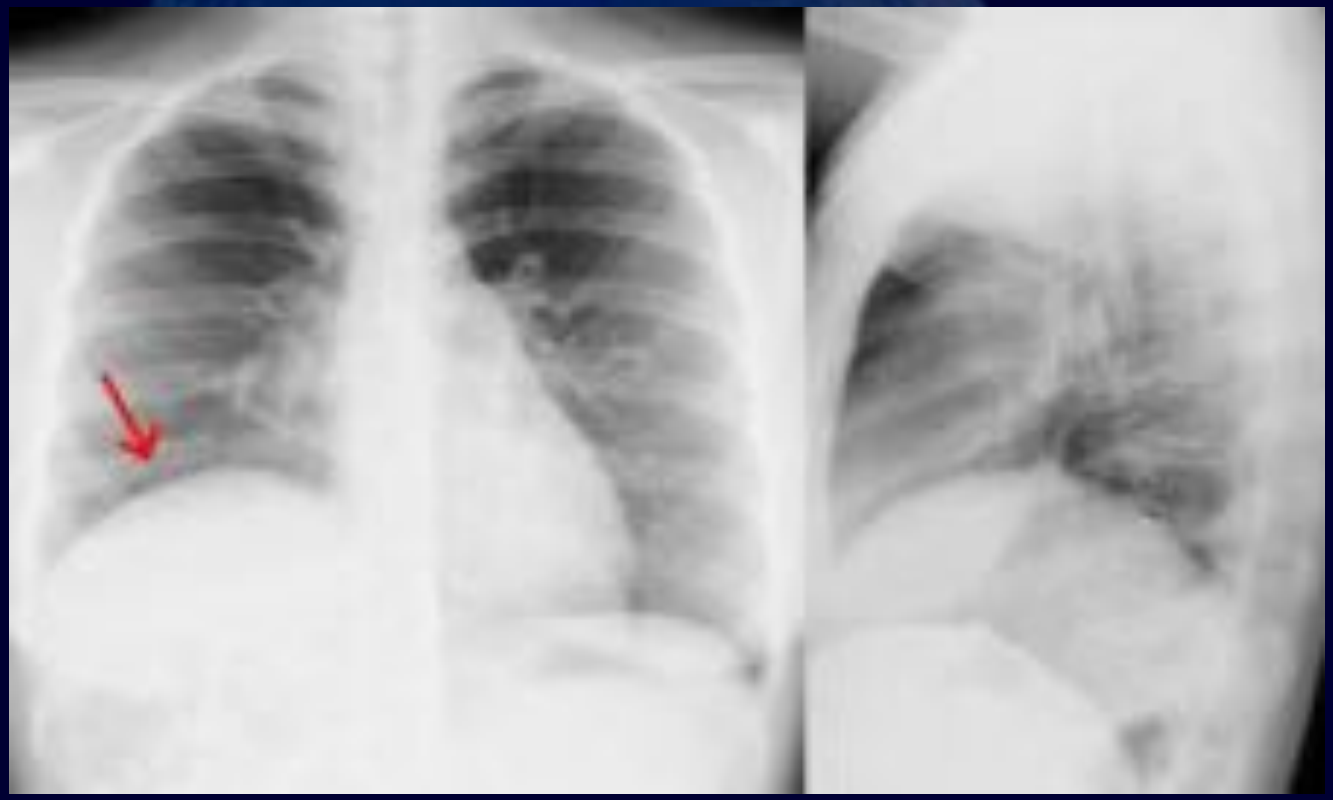
# RESULTS




The improved efficacy of the CB-2G may be explained by an increased area of balloon-tissue contact with optimal cooling. Furthermore, improved cooling of the nose may give rise to more extensive ice formation within the PV as demonstrated by the stable ice cap phenomenon.

# RESULTS: complications

Only 1 transient paralysis (few hours) of phrenic nerve in CB1group



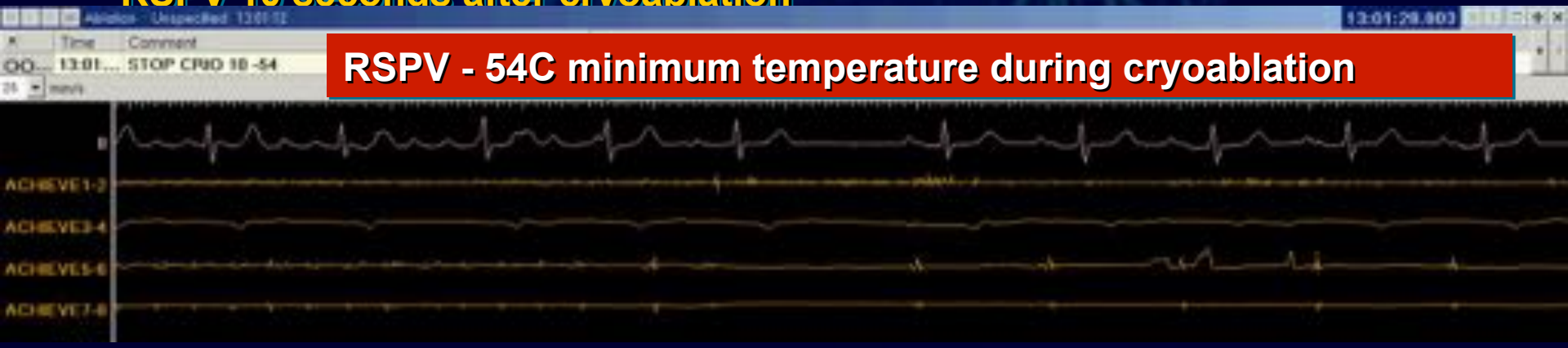
# RESULTS: complications

Only 1 transient paralysis (few hours) of phrenic nerve in CB1group

# RESULTS

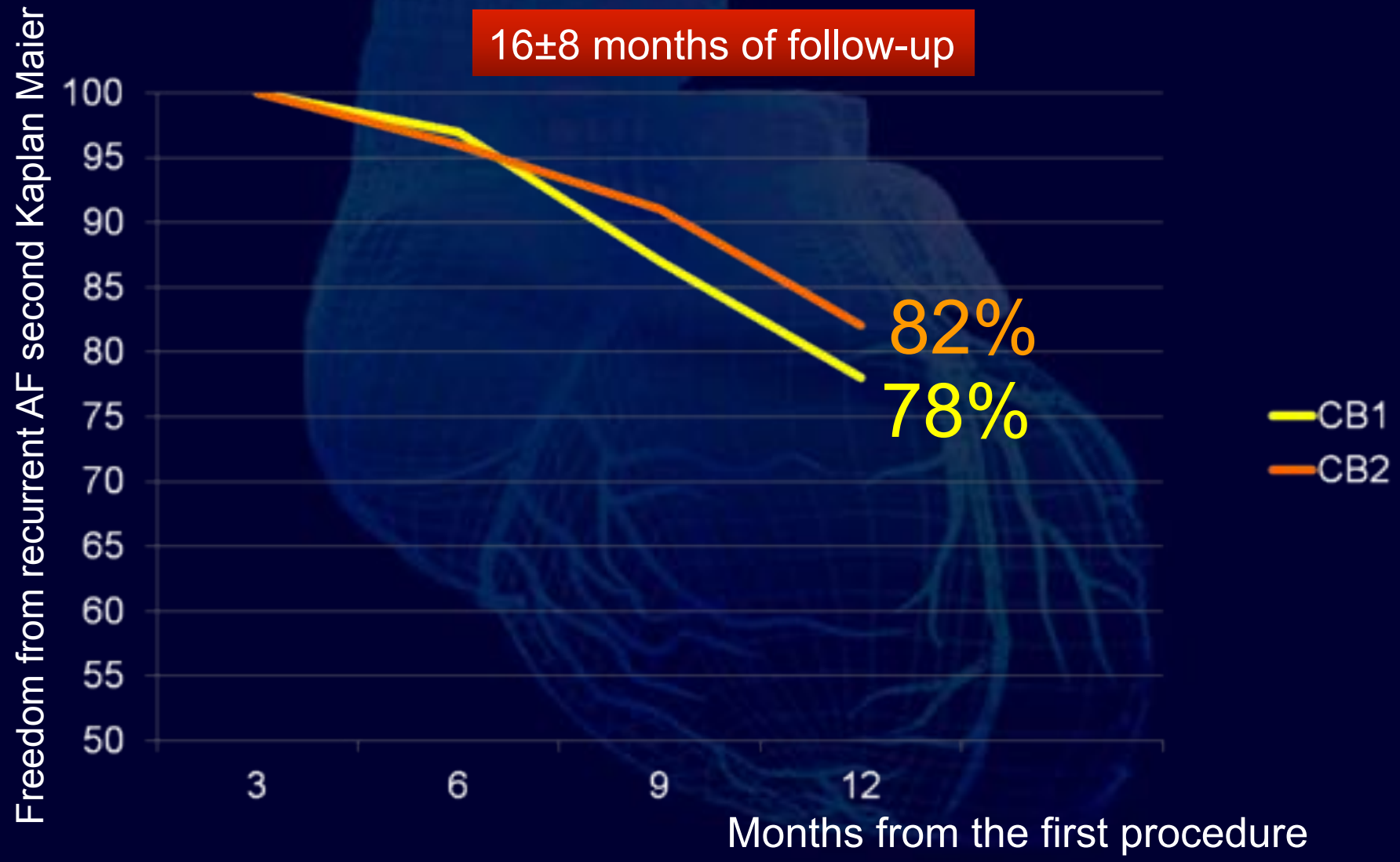
Acute procedural success was 100% in both groups


RSPV 10 seconds after crvoablation




RSPV - 54C minimum temperature during cryoablation

# RESULTS: follow-up



# Literature

## Improved Procedural Efficacy of Pulmonary Vein Isolation Using the Novel Second-Generation Cryoballoon

ALEXANDER FÜRNKRANZ, M.D.,* STEFANO BORDIGNON, M.D.,* BORIS SCHMIDT, M.D., MELANIE GUNAWARDENE,* BRITTA SCHULTE-HAHN, M.D.,* VERENA URBAN, M.D.,* FRANK BODE, M.D.,† BERND NOWAK, M.D.,* and JULIAN K. R. CHUN, M.D.*

**TABLE 2**

Procedural Parameters

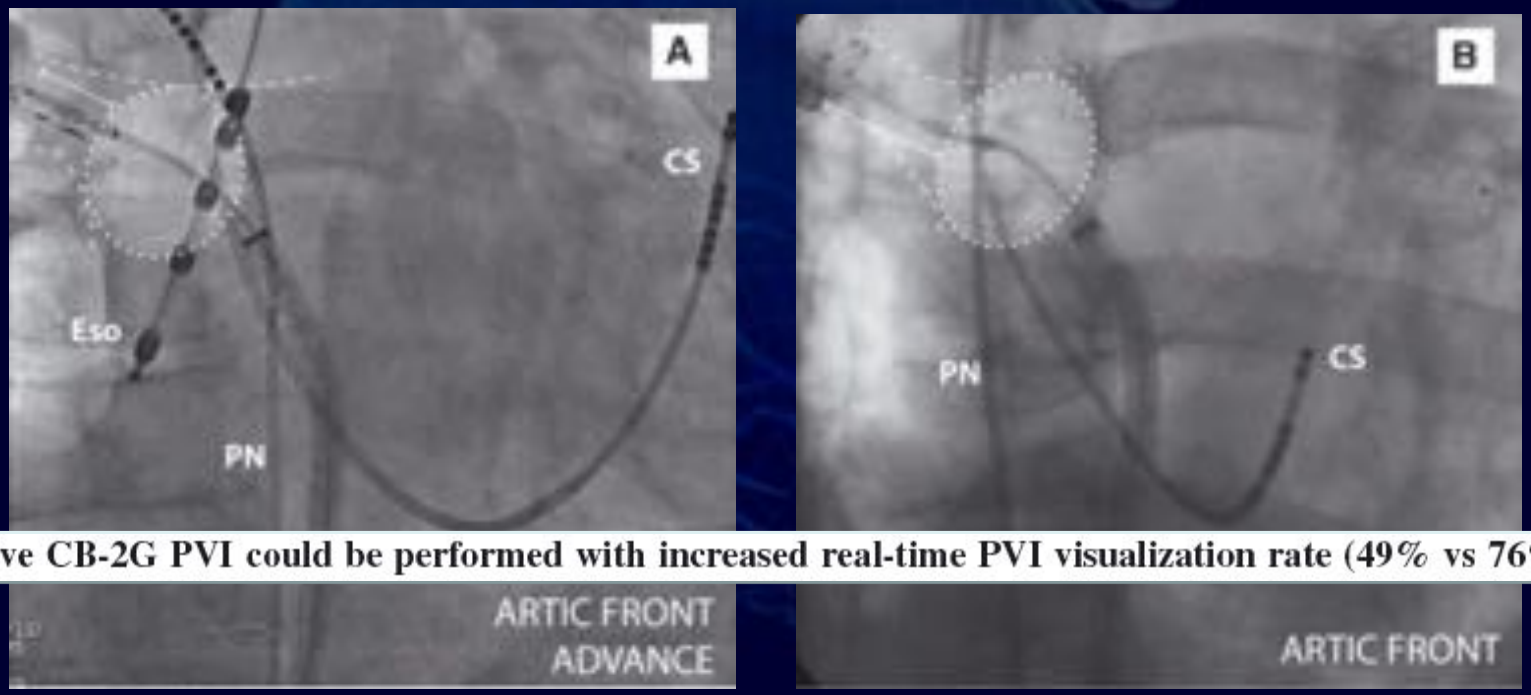
| | CB-1G | CB-2G | P Value |
|---|---|---|---|
| Balloon applications per vein (excluding bonus) | 1.8 ± 1.2 | 1.3 ± 0.8 | <0.001 |
| Distance to achieve proximal electrode (mm) | 18 ± 8 | 12 ± 5 | <0.001 |
| $T_{PVI}$ (seconds) | 79 ± 60 | 52 ± 36 | 0.049 |
| Procedure duration (minutes) | 128 ± 27 | 98 ± 30 | <0.001 |
| Fluoroscopy exposure (minutes) | 19.5 ± 7.4 | 13.4 ± 5.3 | 0.001 |
| Contrast medium (mL) | 134 ± 33 | 120 ± 34 | n.s. |

# Literature

## Improved Procedural Efficacy of Pulmonary Vein Isolation Using the Novel Second-Generation Cryoballoon

ALEXANDER FÜRNKRANZ, M.D.,* STEFANO BORDIGNON, M.D.,* BORIS SCHMIDT, M.D., MELANIE GUNAWARDENE,* BRITTA SCHULTE-HAHN, M.D.,* VERENA URBAN, M.D.,* FRANK BODE, M.D.,† BERND NOWAK, M.D.,* and JULIAN K. R. CHUN, M.D.*

From the *Cardioangiologisches Centrum Bethanien, Medizinische Klinik III, Markus Krankenhaus, Frankfurt am Main; and †Universitätsklinikum Medizinische Klinik II, Lübeck, Germany




Effective CB-2G PVI could be performed with increased real-time PVI visualization rate (49% vs 76% P < 0.001

# Literature

## Comparison of the First and Second Cryoballoon

### High-Volume Single-Center Safety and Efficacy Analysis

**Table 2. Procedural Data**

| | CBG1 (n=364 Patients) | CBG2 (n=120 Patients) | *P* Value |
|---|---|---|---|
| Total procedure time, min | 185±49 | 175±45 | 0.038 |
| LA time, min | 139±40 | 124±39 | <0.001 |
| Fluoroscopy time, min | 34±12 | 29±11 | <0.001 |
| Acute PVI with CB only | 1469/1471 (99.86) | 476/476 (100) | 0.43 |
| Focal touch-ups per vein | 2/1471 (0.14) | 0/476 (0) | 1.0 |
| Mean number of applications per patient | 12.1±3.3 | 11.6±2.5 | 0.06 |
| Mean number of applications per vein | 2.98±1.2 | 2.82±1.1 | 0.007 |
| Mean number of applications until PVI | 1.45±0.81 | 1.28±0.64 | 0.001 |
| Feasibility real-time PV potential recording | 456/1471 (31) | 208/476 (44) | 0.0001 |
| Early reconduction | 38/1471 (2.6) | 2/476 (0.42) | 0.0023 |
| CB use | | | |
| 23-mm CB only | 118/364 (32) | 41/120 (34) | 0.74 |
| 28-mm CB only | 32/364 (9) | 54/120 (45) | 0.0001 |
| 23+28-mm CB | 208/364 (58) | 25/120 (21) | 0.0001 |
| Freeze abortion because of low BT | 6/364 (1.65) | 4/120 (3.33) | 0.27 |

# Literature

**Table 2** Procedural and follow-up characteristics ($n = 306$)

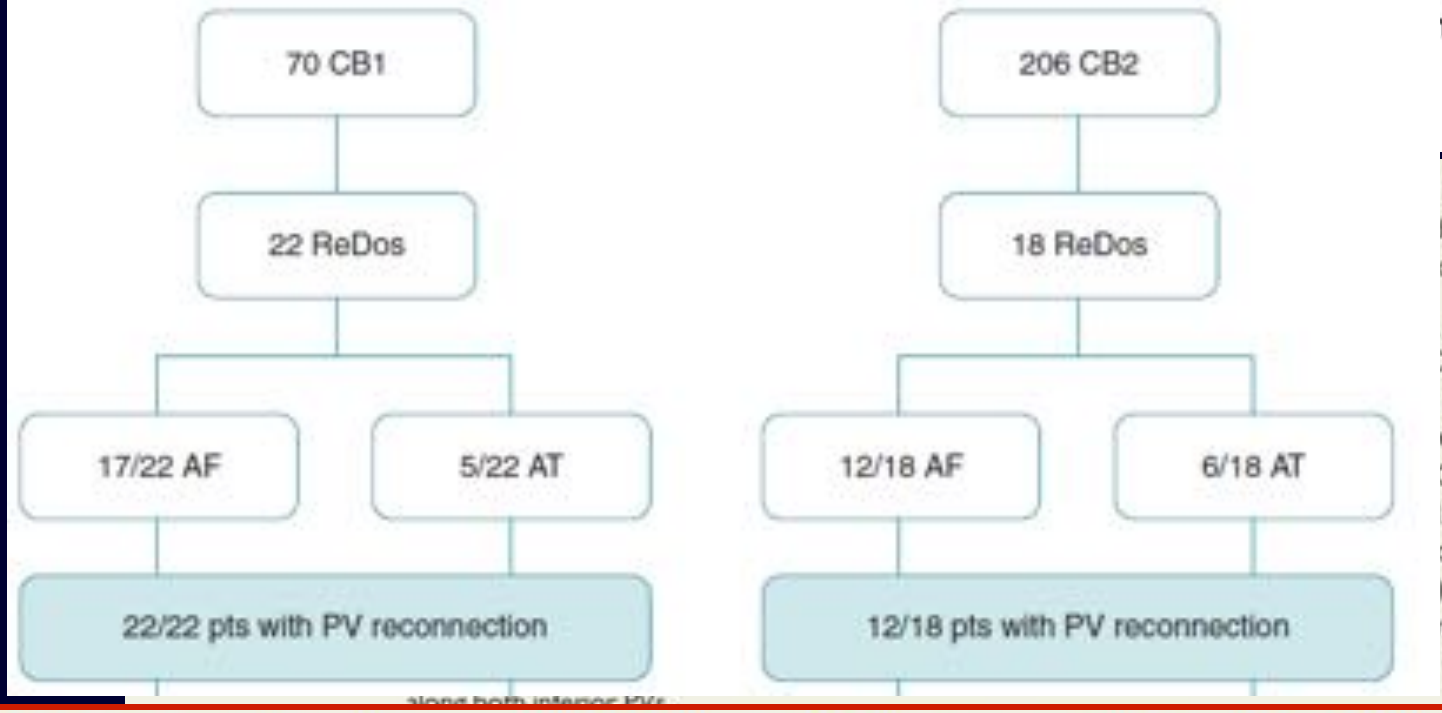
| | Arc-CB ($n = 197$) | Arc-Adv-CB ($n = 109$) | *P* value |
|---|---|---|---|
| Anatomical features | | | |
| Number of pulmonary veins, median (range) | 4.0 (3–6) | 4.0 (3–7) | NS |
| Pulmonary vein abnormality, n (%) | 17 (15.60) | 29 (14.70) | NS |
| Left common PV, n (%) | 70 (35.50) | 37 (34.00) | NS |
| Right common PV, n (%) | 7 (3.50) | 4 (3.60) | NS |
| Procedural details | | | |
| Acute procedural success n (%) | 766/770 (99.50) | 433/435 (99.50) | NS |
| Cumulative time of procedure (minutes) | 75.61 ± 12.64 | 66.67 ± 9.52 | <0.001* |
| Fluoroscopy time (minutes) | 16.22 ± 1.62 | 12.96 ± 2.69 | <0.001* |
| Median temperature reached during cryoballoon applications (°C) | | | |
| RSPV | 46 (44–49) | 48 (47–49) | NS |
| RIPV | 42 (39–45) | 44 (42–45) | |
| LSPV | 51 (45–56) | 52 (46–55) | |
| LIPV | 46 (42–51) | 48 (45–52) | |
| Cumulative time of cryoballoon applications (s) | | | |
| RSPV | 645.00 ± 101.00 | 519.58 ± 89.87 | <0.001* |
| RIPV | 512.14 ± 133.29 | 462.64 ± 158.44 | 0.010* |
| LSPV | 659.77 ± 120.02 | 536.40 ± 87.88 | <0.001* |
| LIPV | 627.29 ± 164.06 | 545.00 ± 93.28 | <0.001* |
| Cryoballoon application/PV, median (range) | 2 (2–5) | 2 (2–4) | NS |
| Vagal reactions n (%) | 75 (38.07) | 55 (50.45) | 0.036* |
| Procedure-related complications n (%) | | | |
| Tamponade requiring percutaneous drainage | 1 (0.50) | 0 (0) | NS |
| Femoral AV fistula requiring surgical/interventional repair | 2 (1.00) | 1 (0.90) | NS |
| Phrenic nerve palsy | 5 (2.54) | 9 (8.26) | 0.040* |
| Haematoma/pseudoaneurysm | 4 (2.00) | 2 (1.80) | NS |
| Post-procedural pericardial effusion n (%) | 14 (7.1) | 8 (7.3) | NS |
| Follow-up parameters | | | |
| Follow-up time (months) | 30 (23–38) | 10 (8–13) | <0.001* |
| Early recurrence n (%) | 36 (18.27) | 12 (11.01) | NS |

Europace (2015) 17, 725–731
doi:10.1093/europace/euu331

CLINICAL RESEARCH
*Ablation for atrial fibrillation*

# High rate of durable pulmonary vein isolation after second-generation cryoballoon ablation: analysis of repeat procedures

**Stefano Bordignon, Alexander Fürnkranz, Laura Perrotta, Daniela Dugo,**
**…midt,**




by a high rate of recovered
h recurrent atrial tachyar-
of chronic PVI and PV con-

B1 PVI (28 mm) were en-
performed. The rates of
een CB1 and CB2. Antral
Of 206 patients (CB2), 18
l PVs were electrically iso-
duction. Of 71 PVs [1 left
was characterized by the
red with CB1, CB2 ablation
the greatest improvement

Second-generation cryoballoon atrial fibrillation ablation is associated with a high rate of durable PVI in patients with ATa recurrence. The RSPV represents the PV with the greatest risk for left atrium–pulmonary vein reconnection.

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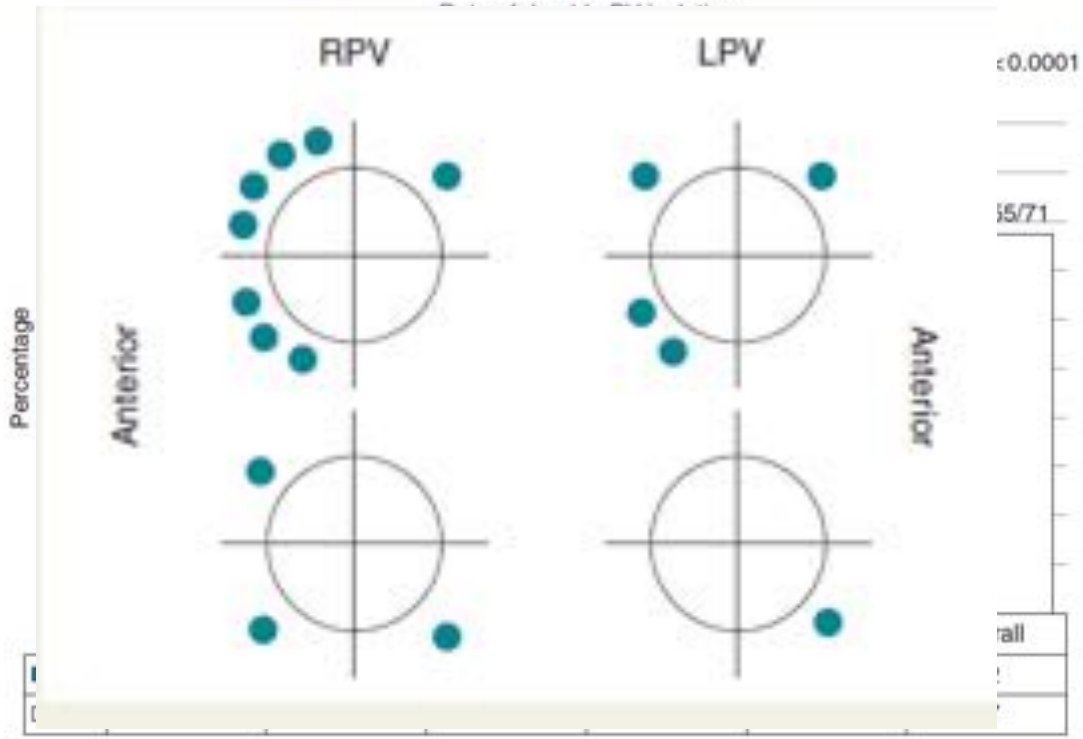
# High rate of durable pulmonary vein isolation after second-generation cryoballoon ablation: analysis of repeat procedures

**Stefano Bordignon, Alexander Fürnkranz, Laura Perrotta, Daniela Dugo, Athanasios Konstantinou, Bernd Nowak, Britta Schulte-Hahn, Boris Schmidt, and Kyoung Ryul Julian Chun***




Second-generation cryoballoon atrial fibrillation ablation is associated with a high rate of durable PVI in patients with ATa recurrence. The RSPV represents the PV with the greatest risk for left atrium–pulmonary vein reconnection.

# Literature

## Acute procedural and cryoballoon characteristics from cryoablation of atrial fibrillation using the first- and second-generation cryoballoon: a retrospective comparative study with follow-up outcomes

Arash Aryana · Shemsa Morkoch · Sean Bailey · Hae W. Lim · Rahmani Sara · André d'Avila · P. Gearoid O'Neill

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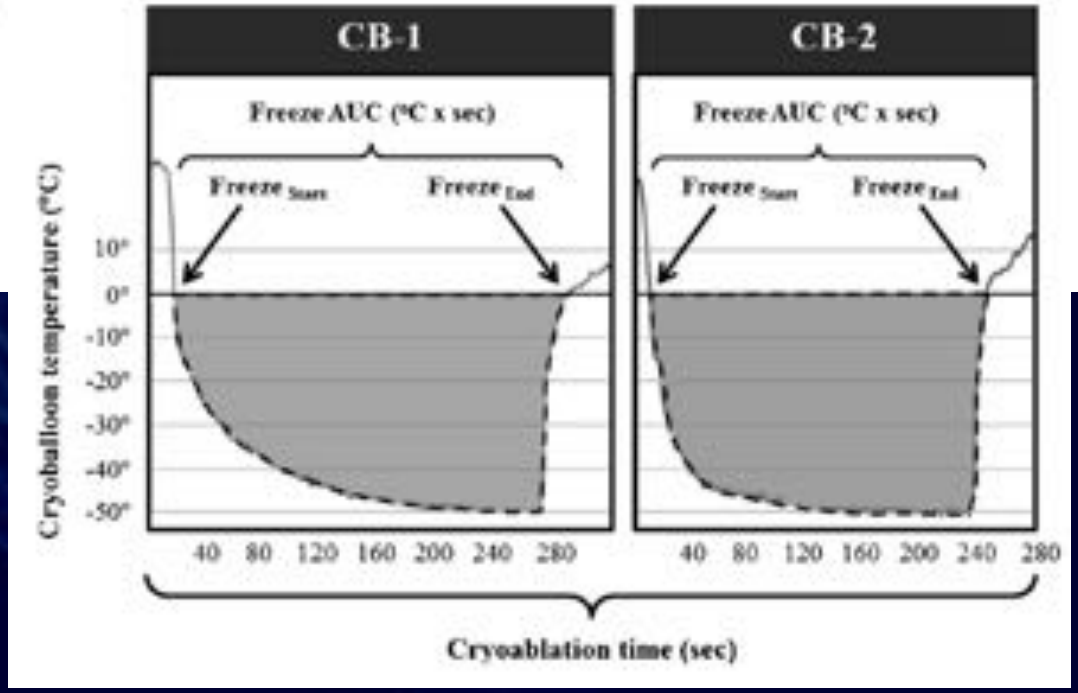

# CONCLUSION

THE CB2 SIGNIFICANTLY IMPROVED PROCEDURAL EFFICACY COMPARED TO THE CB1

- high rates of single-shot isolation
- shortened procedure duration and fluoroscopy exposure time.
- PV mapping during cryoablation was possible in the majority of PVs using the CB2 and this may provide the opportunity to adjust application time and number individually
- safety profile is similar.