Balloon Cryo-Ablation of Atrial Fibrillation

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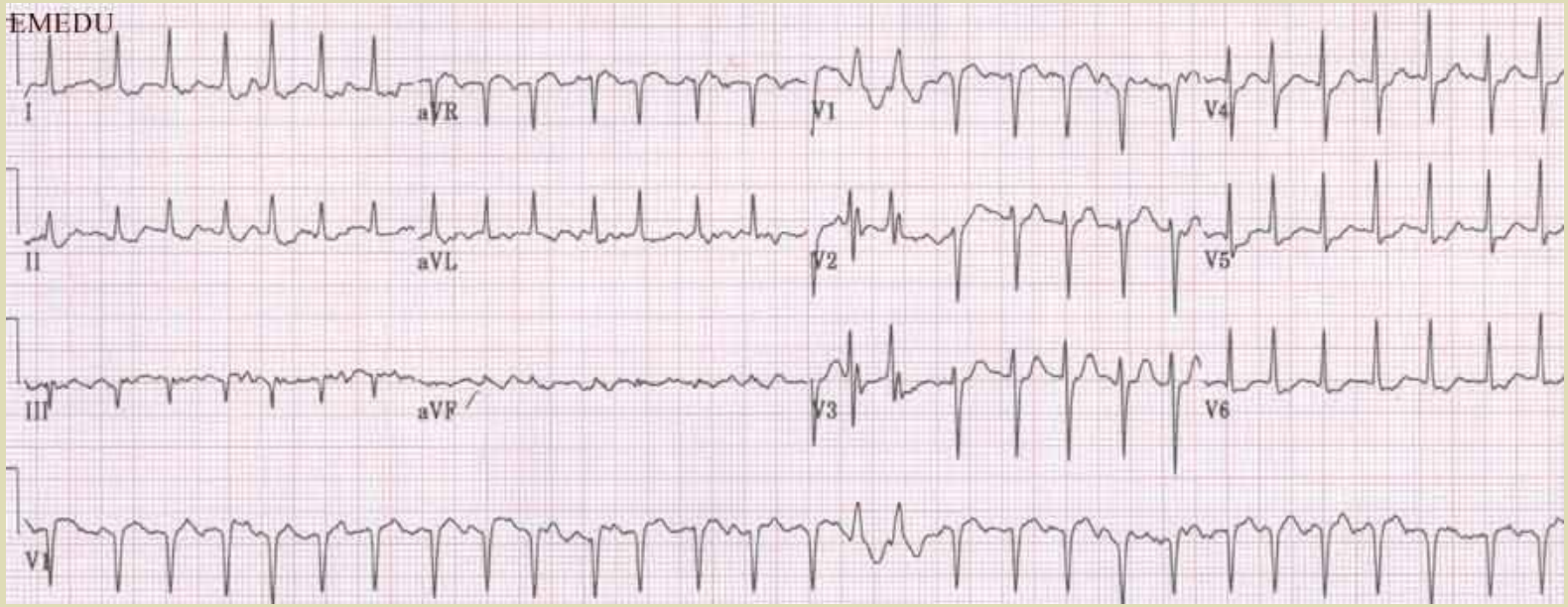
Shaare Zedek Medical Center

Ablate and Pace – Before Ablation



(AFFIRM) study

NEJM 2002, Circulation 2004

Age at enrollment	<0.0001	1.06	1.04	1.08
Coronary artery disease	<0.0001	1.65	1.31	2.07
Congestive heart failure	<0.0001	1.83	1.45	2.32
Diabetes	<0.0001	1.56	1.22	2.00
Stroke or TIA	<0.0001	1.54	1.17	2.05
Smoking	<0.0001	1.75	1.29	2.39
First episode of AFib	0.0067	1.27	1.01	1.58
Sinus rhythm	<0.0001	0.54	0.42	0.70
Warfarin use	<0.0001	0.47	0.36	0.61
Digoxin use	<0.0001	1.50	1.18	1.89
Rhythm-control drug	0.0005	1.41	1.10	1.83

(AFFIRM) study

Circulation 2004

- The presence of SR but not AAD use is associated with a lower risk of death.
- These results suggest that if an effective method for maintaining SR with fewer adverse effects were available, it might improve survival.

The Strategies of Treatment of Atrial Fibrillation (STAF) study

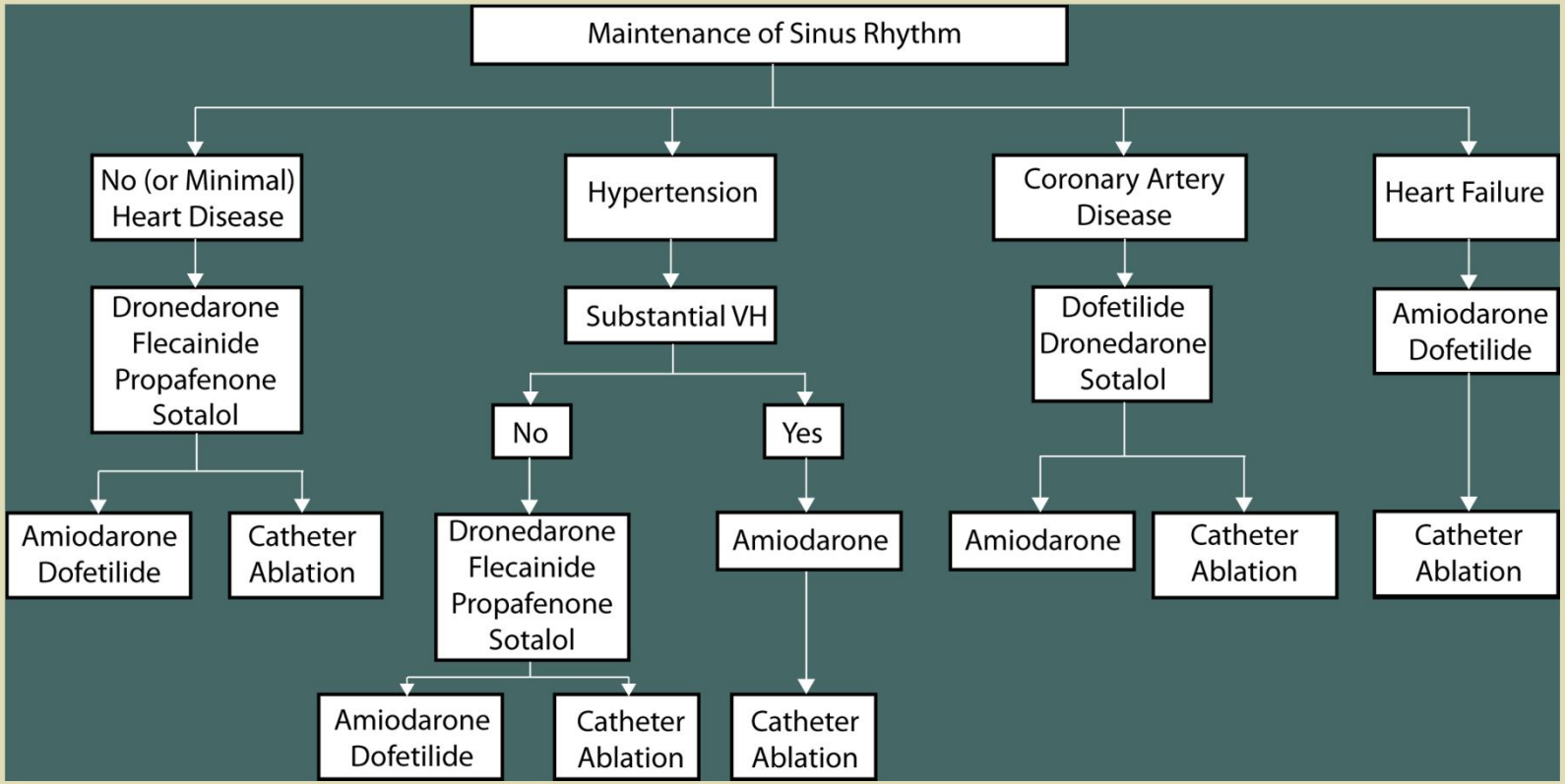
J Am Coll Cardiol. 2003;41(10):1690-1696

- No differences between rhythm-control and rate-control strategies regarding primary endpoints .
- All but one endpoint occurred during AF

Candidates for PV Isolation

- Symptomatic patients with PAF or persistent AF resistant to medical therapy
- No significant heart disease.
- No evidence of LA thrombus or thrombo-embolic phenomena
- Lone AF has best results

ACCF/AHA/HRS 2011 Guidelines Update Treatment of Atrial Fibrillation



"In some patients, especially young individuals with very symptomatic AF, ablation may be preferred over years of drug therapy."

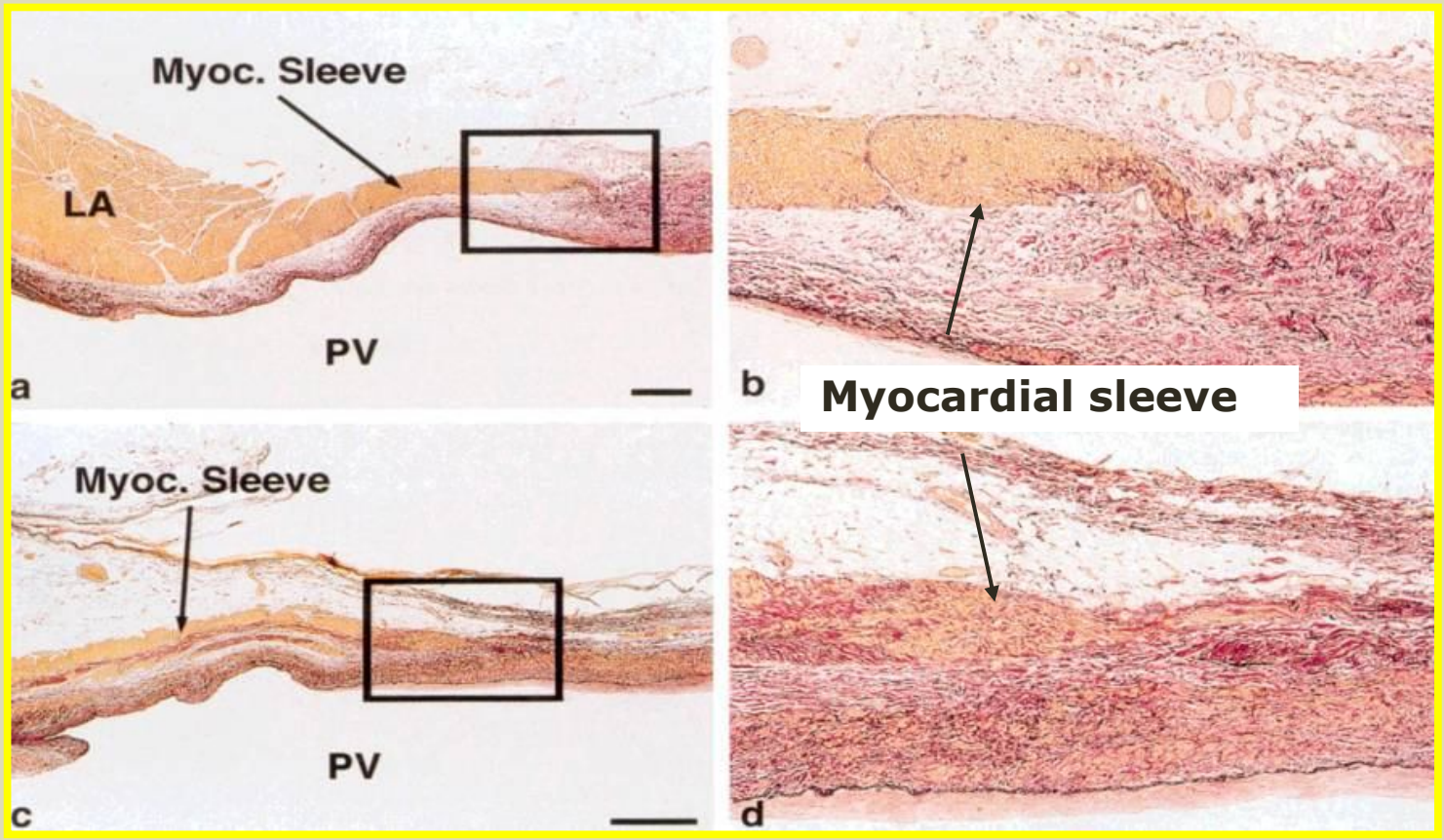
Wann LS. J Am Coll Cardiol. 2011 Jan 11;57(2):223-42.2011.

Knight B. HRS Practical Rate and Rhythm Management of Atrial Fibrillation. Updated January 2010.

Atrial Fibrillation Ablation

Ultimate Rhythm Control ?

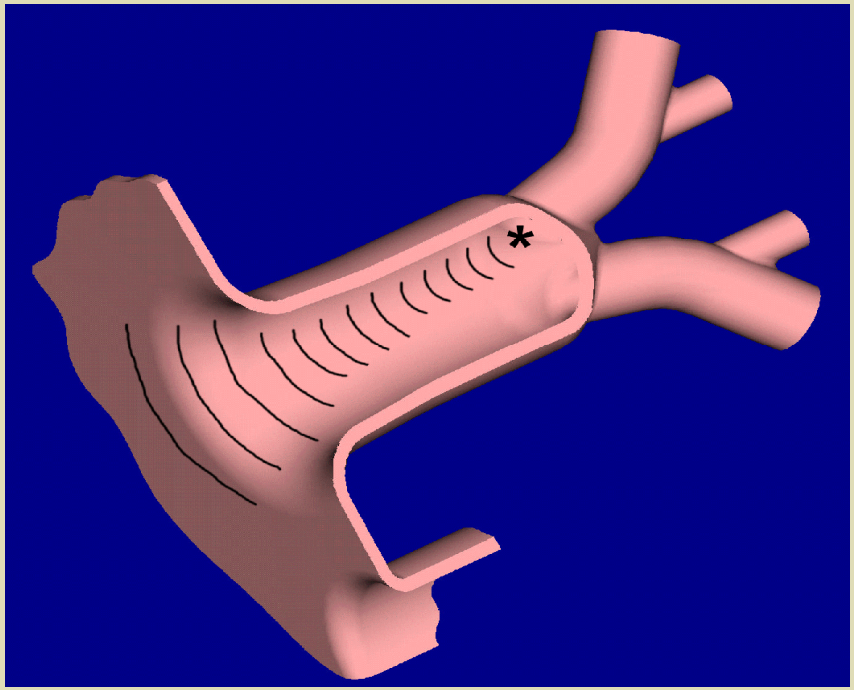
Microscopic Anatomy of Pulmonary Veins



Saito T, et al. J Cardiovasc Electrophysiol (2000) 11: 888

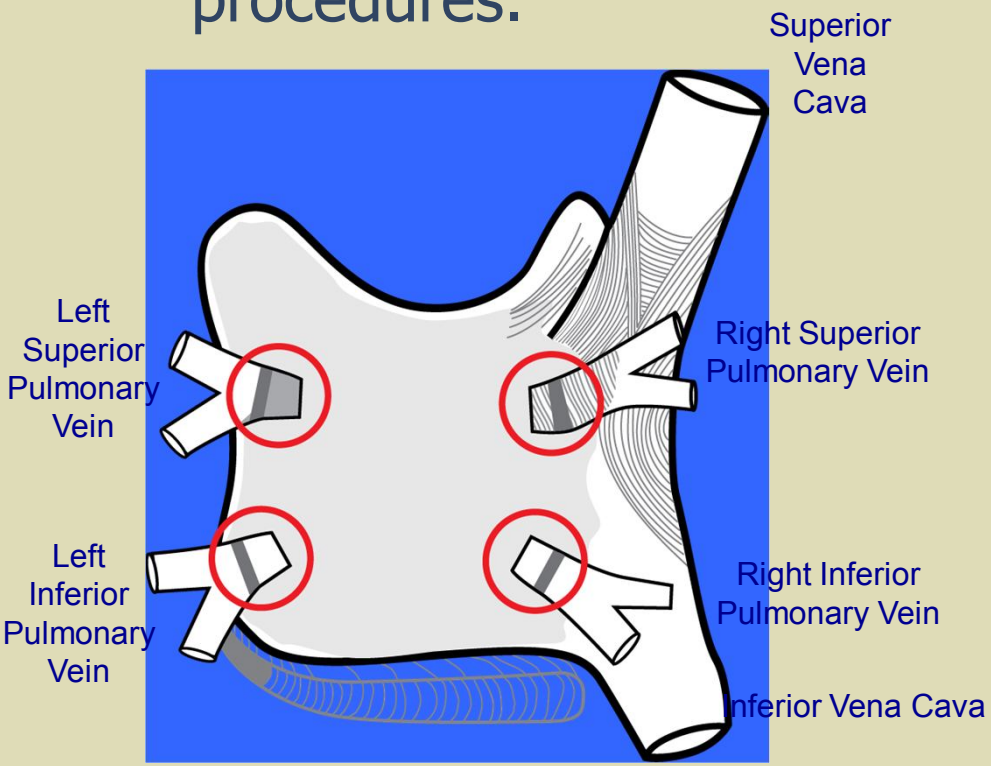
Focal Atrial Fibrillation - Concept

- Single very fast firing focus initiates chaotic activation of atria
- Proximal pulmonary veins focus location
- Elimination or isolation of pulmonary vein focus can cure Afib.



Pulmonary Vein Isolation (PVI) is the Cornerstone of AF Ablation

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



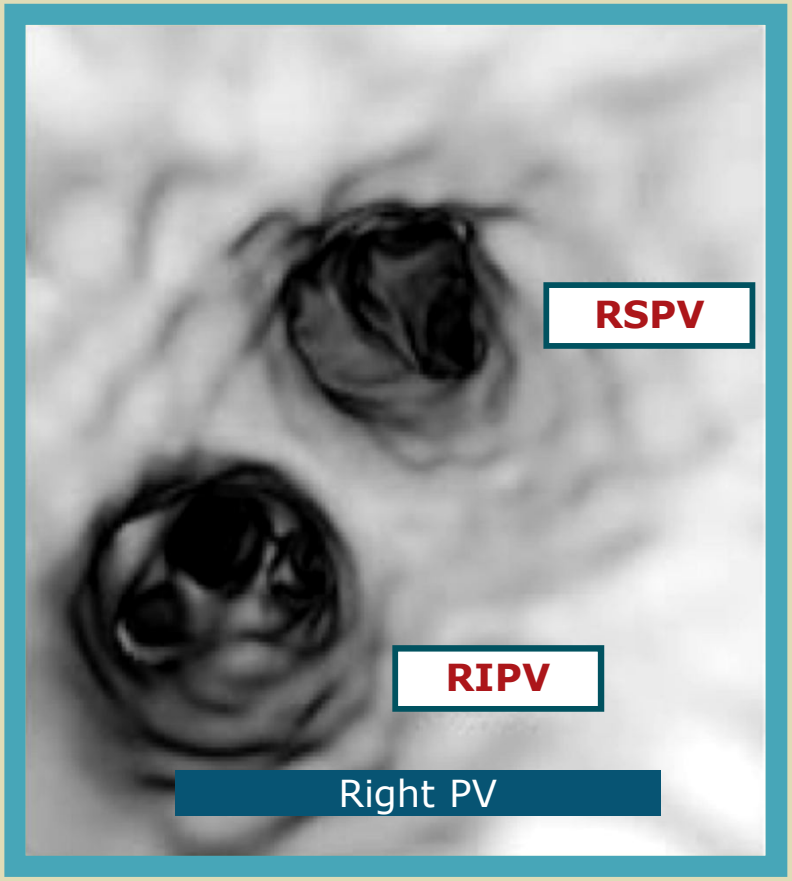
Each vein should be isolated independently

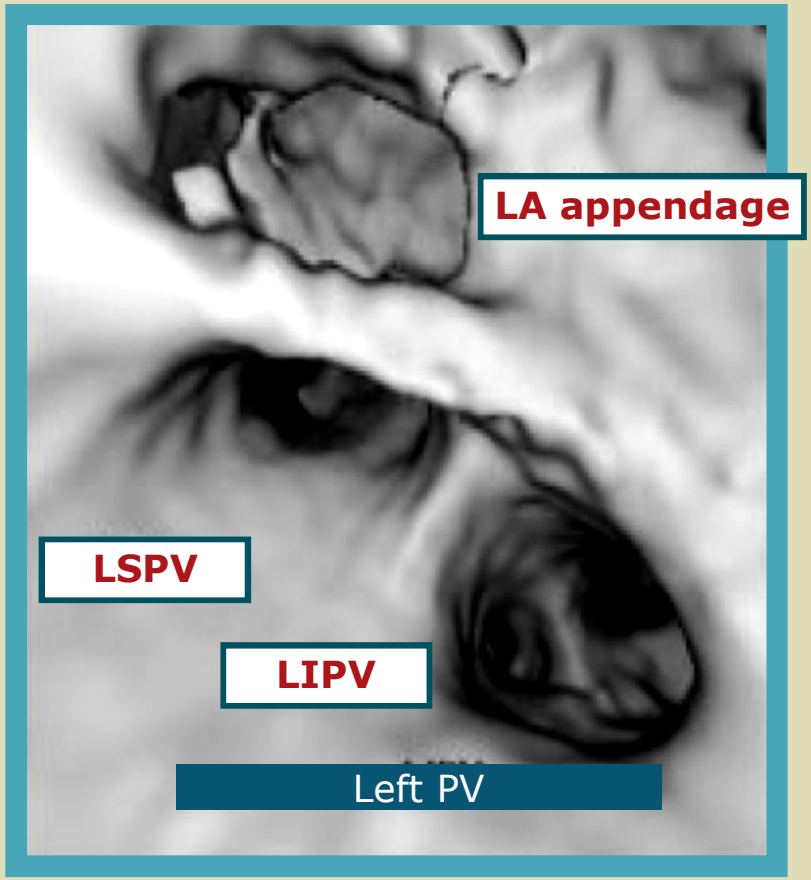
Complete electrical isolation should be the goal for targeted PVs and entrance and/or exit block should be demonstrated

Cappato et al., Circ Arrhythm Electrophysiol 2010;3;32-38 http://www.HRSonline.org/Policy/ClinicalGuidelines

2007 HRS Consensus Statement

Anatomy of the Pulmonary Veins

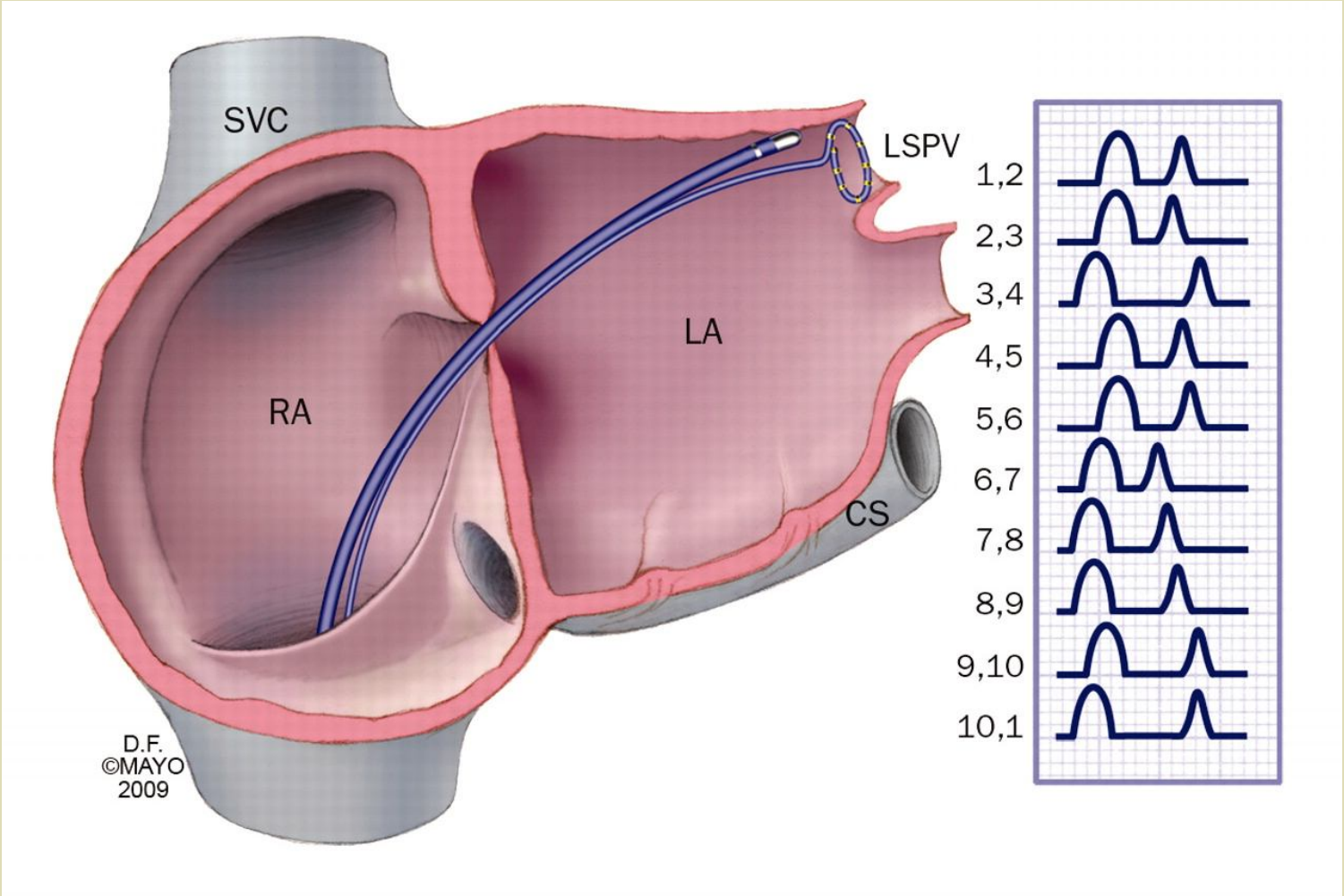




- Nuclear magnetic resonance image of the ostia of the right and left superior and inferior PVs and the left atrial appendage

Kato R, et al. Circulation (2003) 107: 2004

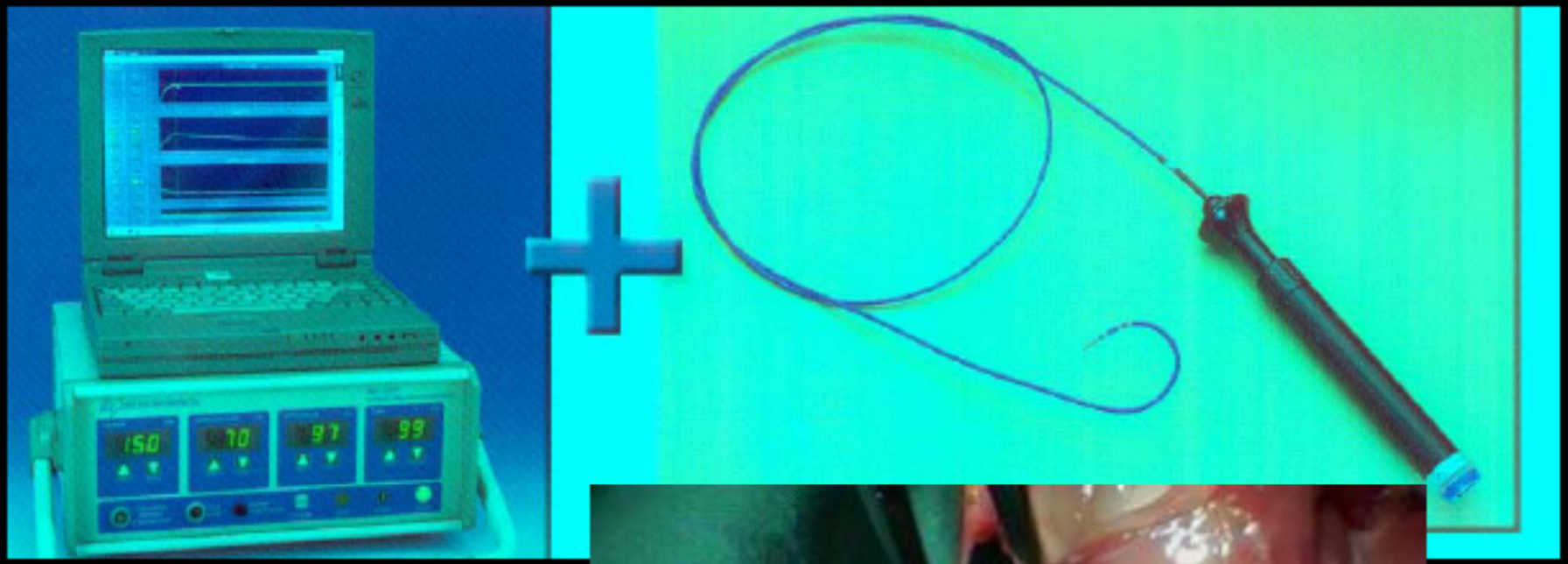
Pulmonary Vein Isolation is Currently the Most Common Ablation Technique Used for Atrial Fibrillation



Crandall M A et al. Mayo Clin Proc. 2009;84:643-662

MAYO CLINIC
Mayo Clinic Proceedings

Principle of Radiofrequency catheter ablation



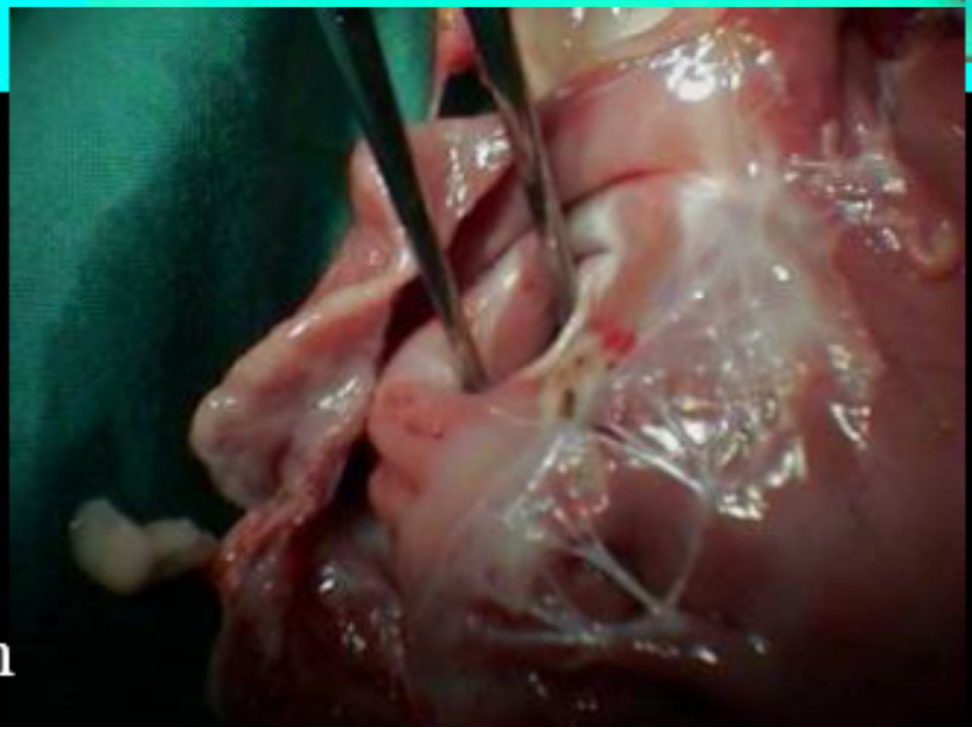
RF-current: 300-500 kHz

No muscle stimulation

30-60 s delivery

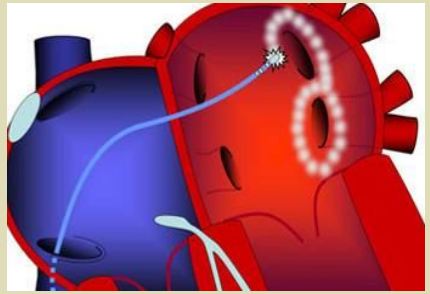
Heating of tissue at cath.tip

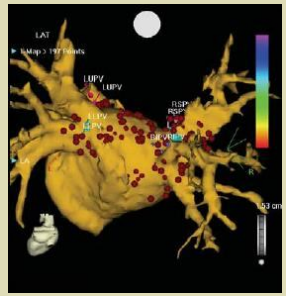
Coag.necrosis 8 x 4 x 4 mm

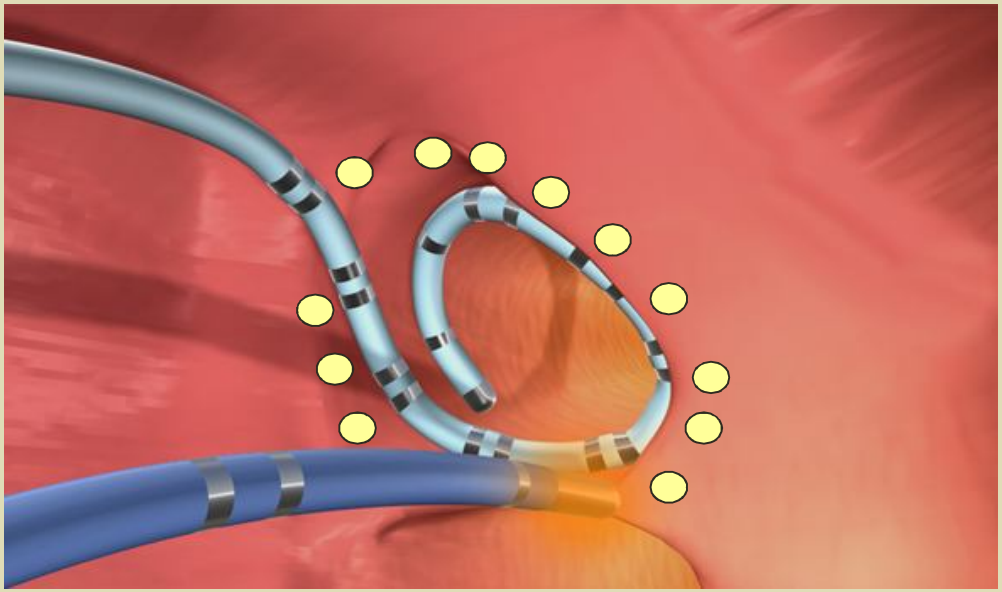


RF Focal Ablation Catheter to Isolate PV and Ablate Atrial Tissue

- Patient anatomy and atrial tissue depth is variable
- Cardiac contractions make maintaining position difficult
- Catheter force varies with position in heart
- Technically challenging
- Good lesions require transmurality
- Successful procedure requires *contiguous* lesions

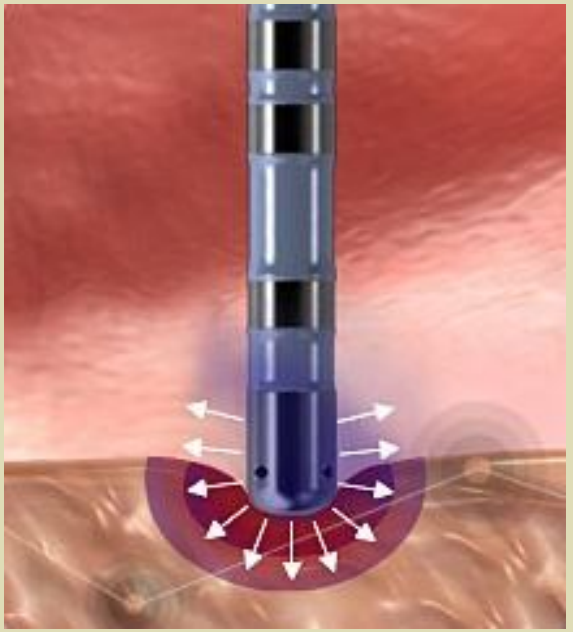






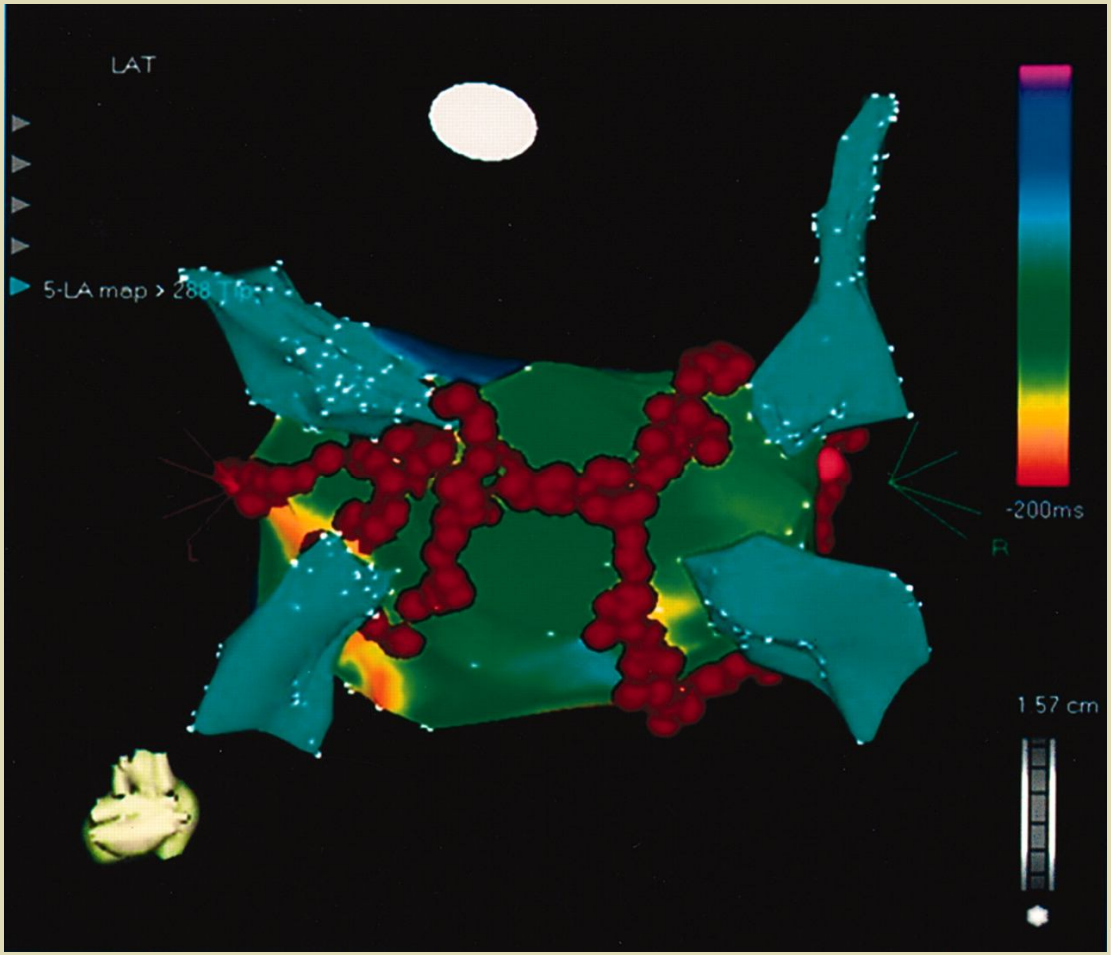
Clinical Issues with RF Focal Ablation Catheter

- Risk of perforation
- Uncontrolled energy delivery
- Esophageal damage
- Char/coagulum formation
- Inconsistent results
- Time consuming point-by-point ablation



Cappato R, et al. *Circulation*. 2005;111:1100-1105.

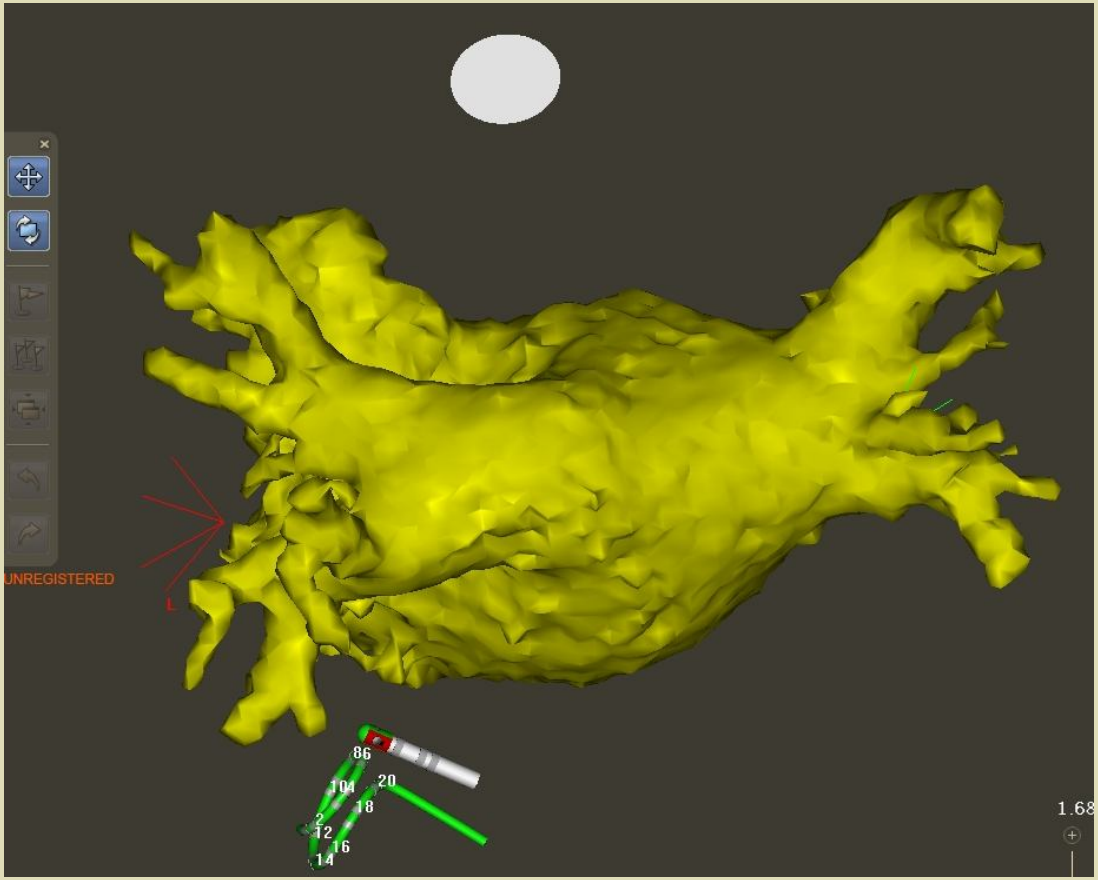
Ablation Approach for Patients with Persistent Atrial Fibrillation



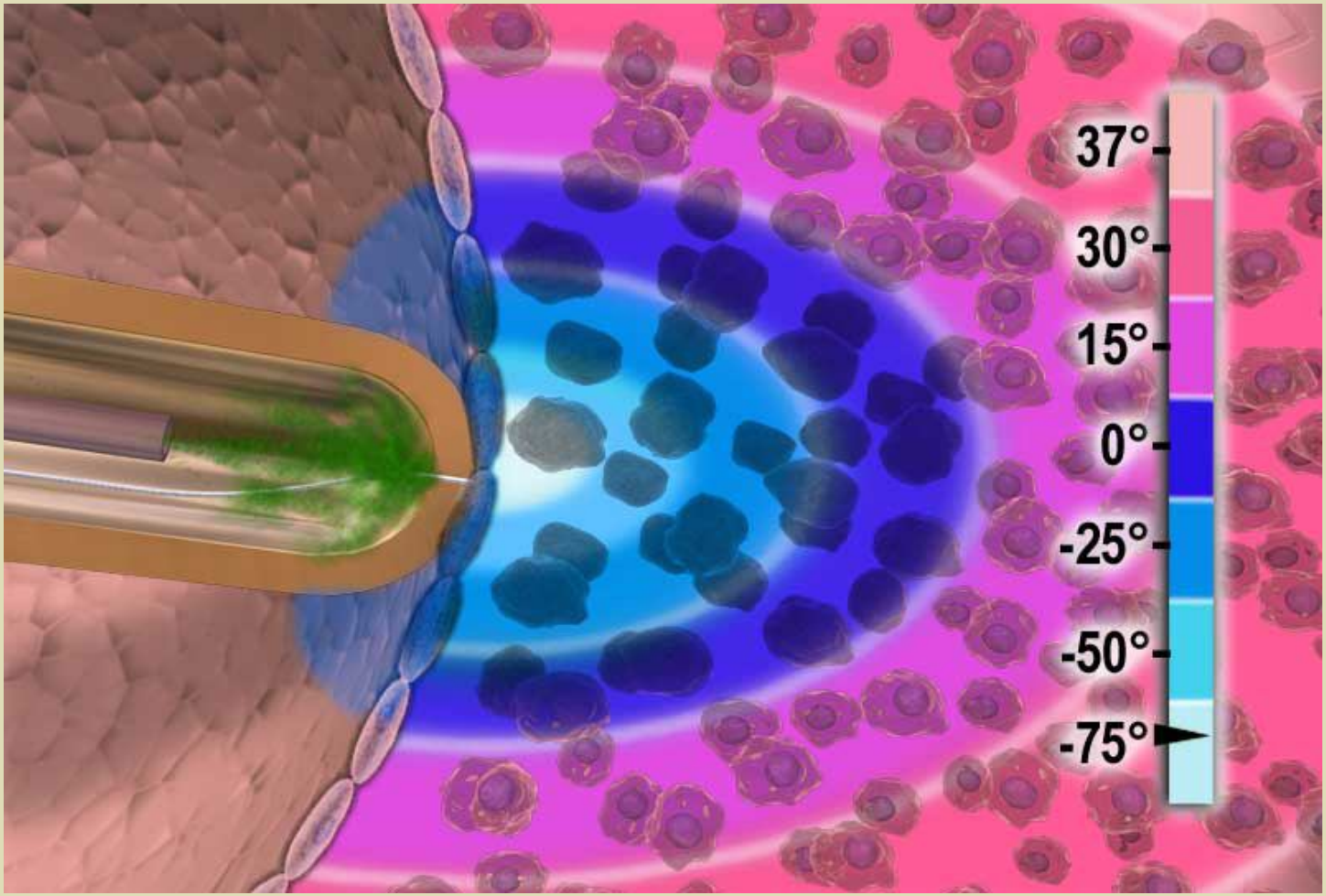
Crandall M A et al. Mayo Clin Proc. 2009;84:643-662

MAYO CLINIC
Mayo Clinic Proceedings

CT Image Segmentation



Catheter Cryoablation

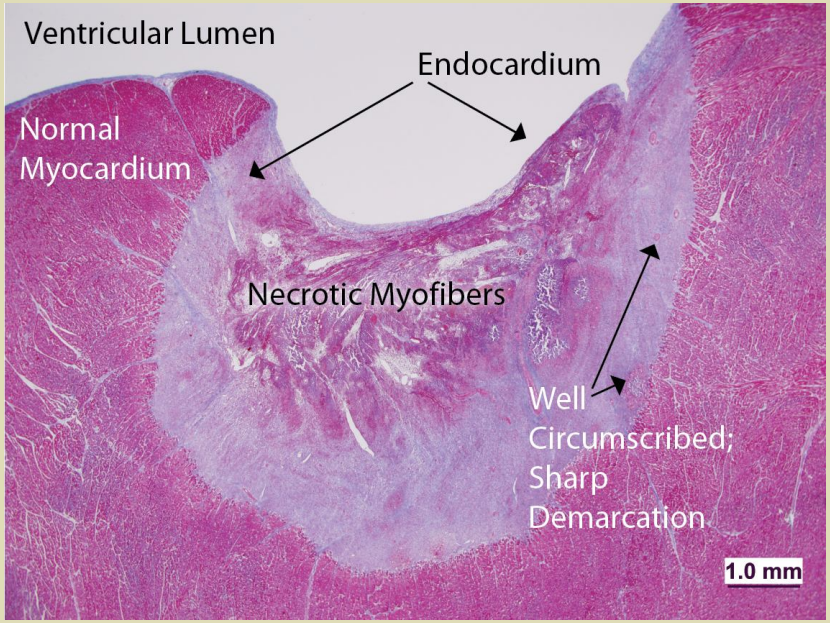


Advantages of Cryothermy

- Minimal disruption of endothelium
  - Minimal thrombus production
- Maintenance of extracellular matrix - no collagen denaturation
  - No collagen shrinkage known to occur with thermal injury
  - Advantageous within venous structures - CS or PV's

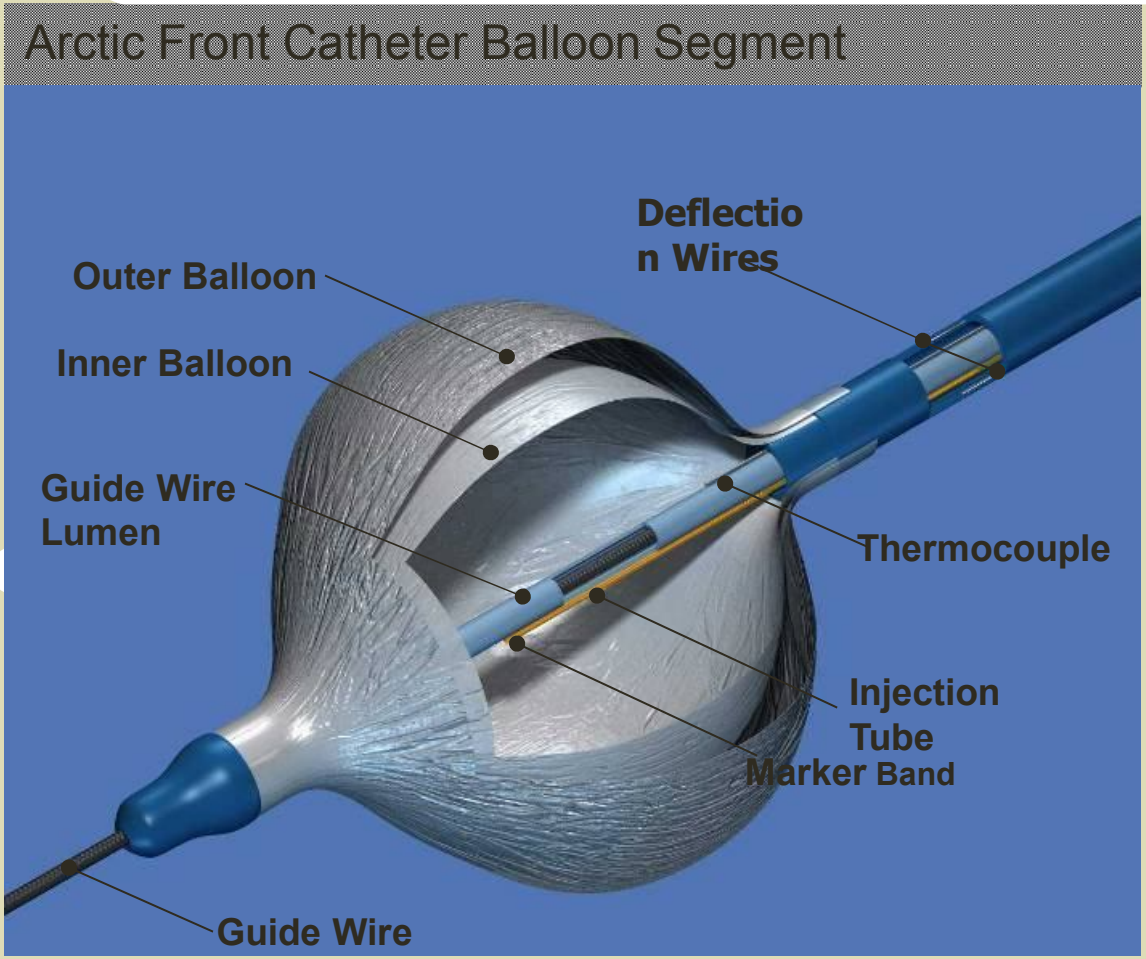
Histological Effect on the Connective Tissue Matrix

- Cryoadhesion improves contact and stability
- Preserves the extracellular matrix and endothelial integrity[1]
- Decreases risk of thrombus formation[1]
- Demonstrates well demarcated lesions[1]



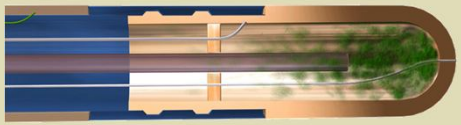
[1] Sarabanda AV, et al. *J Am Coll Cardiol*. 2005;46:1902-1912.

Arctic Front® Catheter Design

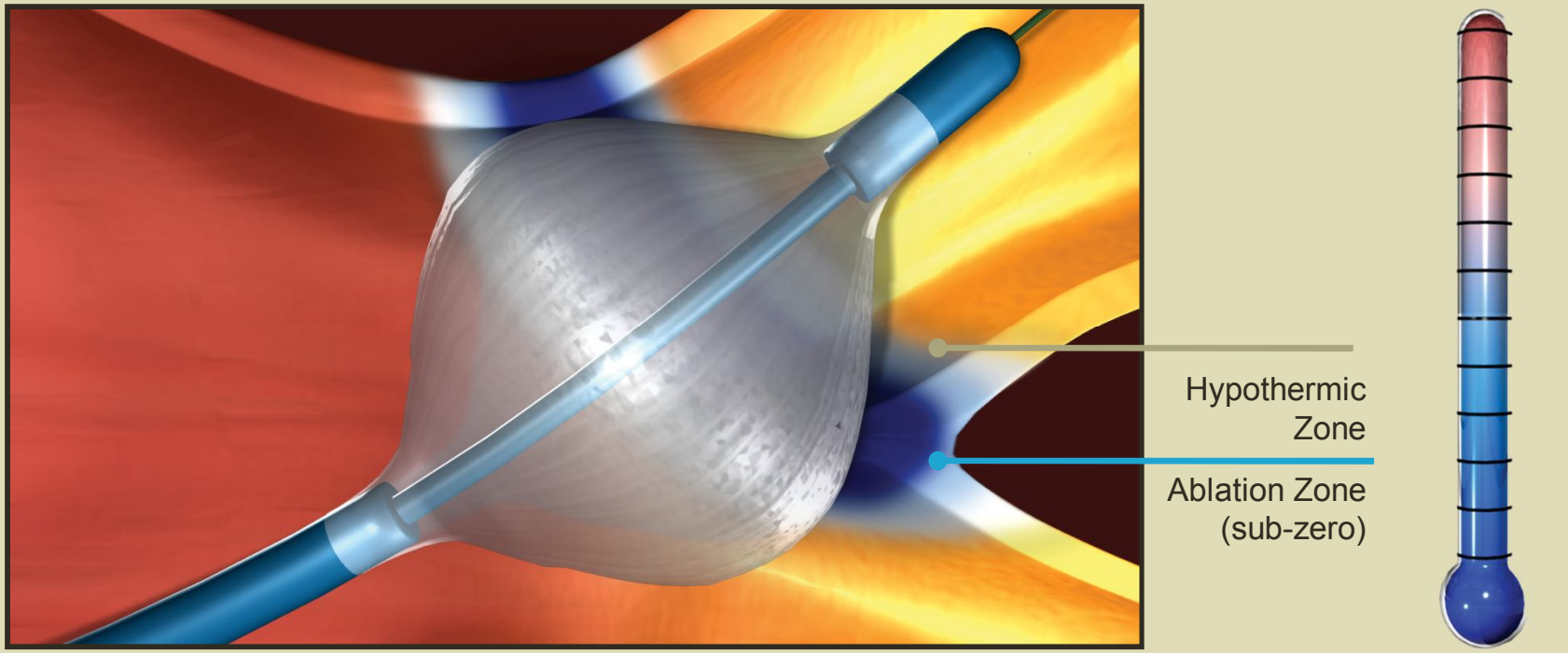


- Pressurized N_2O delivered through ultrafine injection tube
- Straightforward positioning: over-the-wire, steerable, good visibility
- Several safety mechanisms: double balloon, pressure and flow monitoring, blood detection

- Freezor® *MAX* operates on similar principles



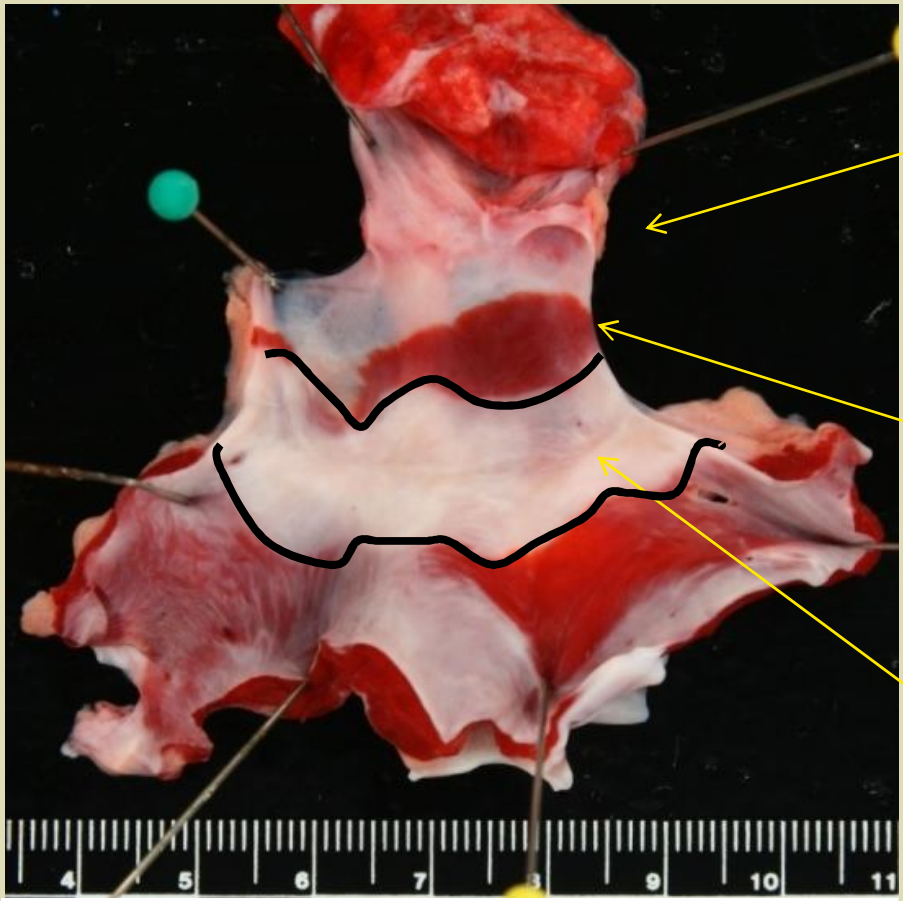
Cryoablation



Circumferential Lesion at LA-PV Junction

Towards the lungs

Towards the left atrium



Lesion outline from Arctic Front Catheter 23 mm ablation in swine LA-PV junction (45-day survival). PV is cut open longitudinally and flattened out. Top of image: PV and its branches; Bottom: LA. TTC staining.

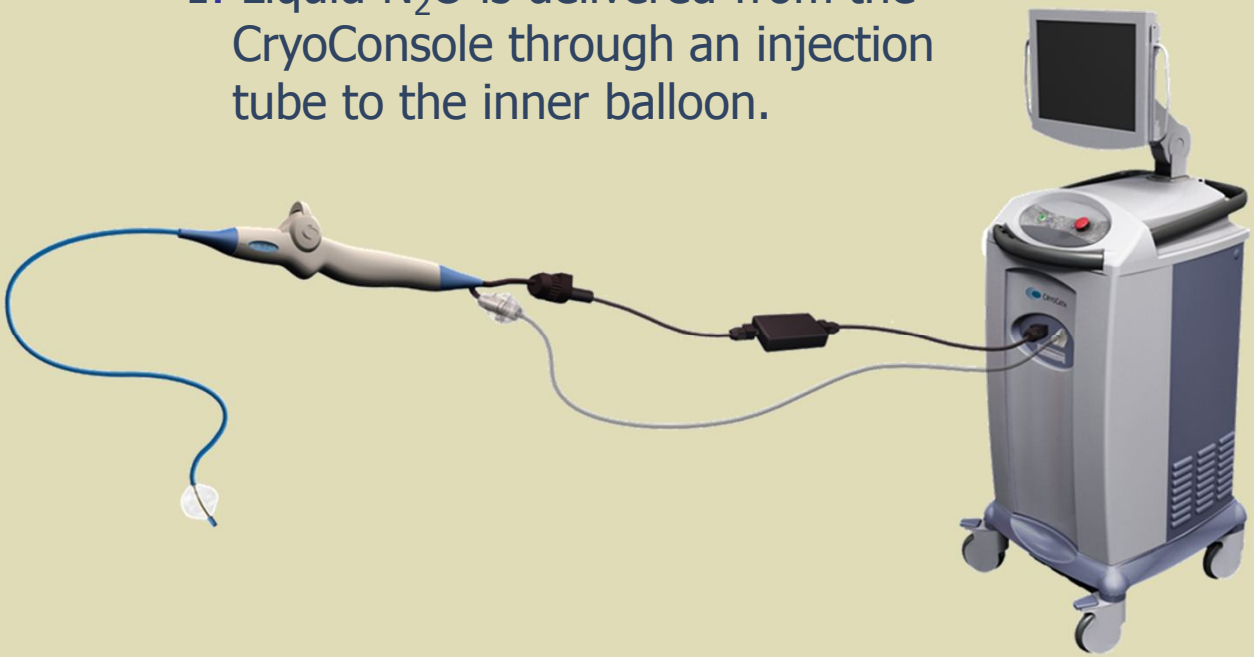
Pulmonary vein tissue, transition between collagen and muscular sleeve

Muscular pulmonary veins sleeve distal to the lesion

Contiguous lesion performed by Arctic Front® Catheter

How the Arctic Front® Cardiac CryoAblation System Works

1. Liquid N_2O is delivered from the CryoConsole through an injection tube to the inner balloon.



2. Inside the balloon the liquid N_2O vaporizes and absorbs heat from the surrounding tissue.

3. The vapor is returned to the console through a lumen maintained under vacuum.

4. The CryoConsole controls safe delivery of N_2O to the catheter and return of the vapor. Numerous safety systems mitigate potential hazards.

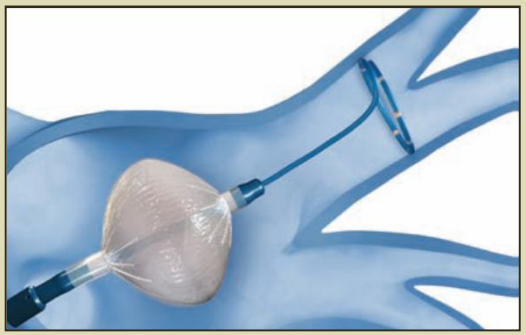
Arctic Front PV Isolation

Achieve™ Mapping Catheter

- Achieve is an intracardiac electrophysiology diagnostic catheter which can be deployed through the Arctic Front® guide wire lumen.
- Available in 15 mm and 20 mm loop diameters.
- Both diameters are compatible with 23 mm and 28 mm Arctic Front.

How Arctic Front® Balloon Catheter and Achieve™ Work?

1. Access targeted vein

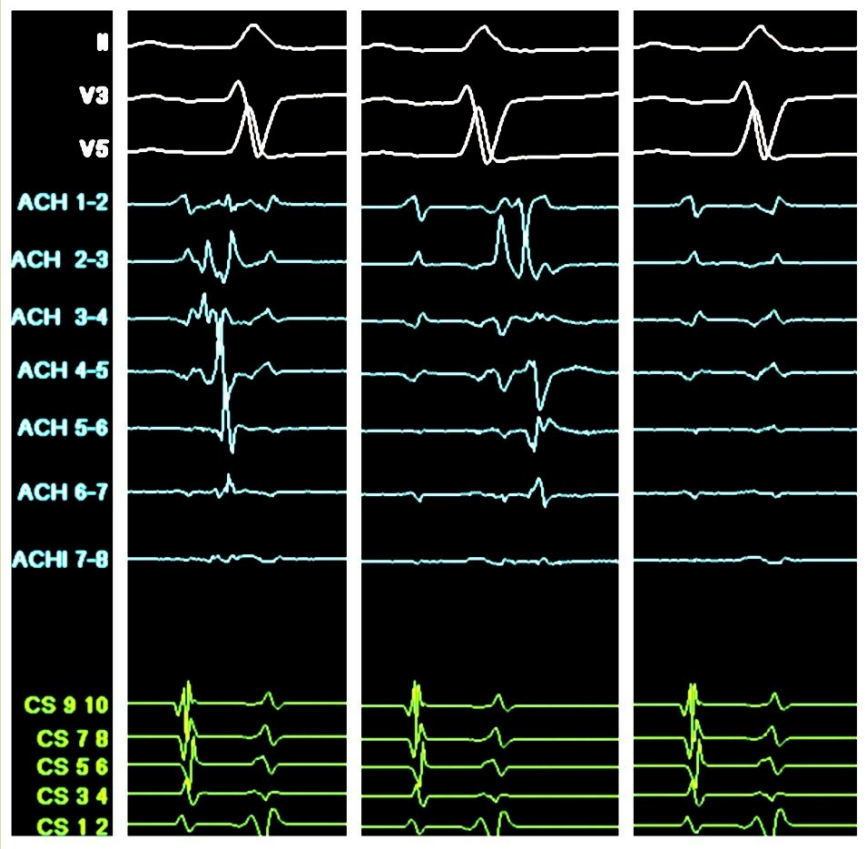


2. Inflate and position

3. Occlude and ablate

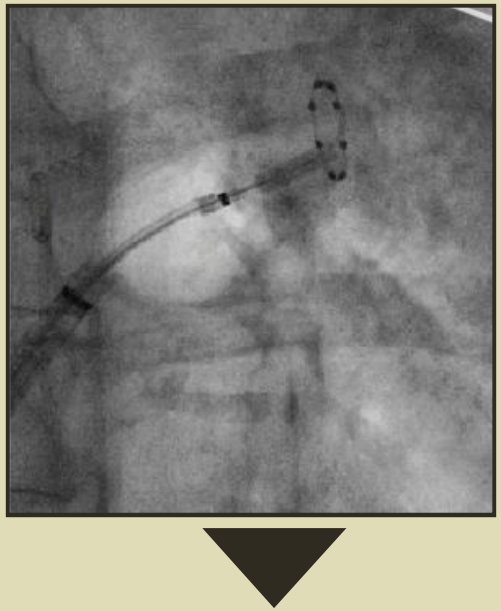
4. Assess PVI

Assessment of Real-Time PV Isolation



Delay **Increased Delay** **Isolation**

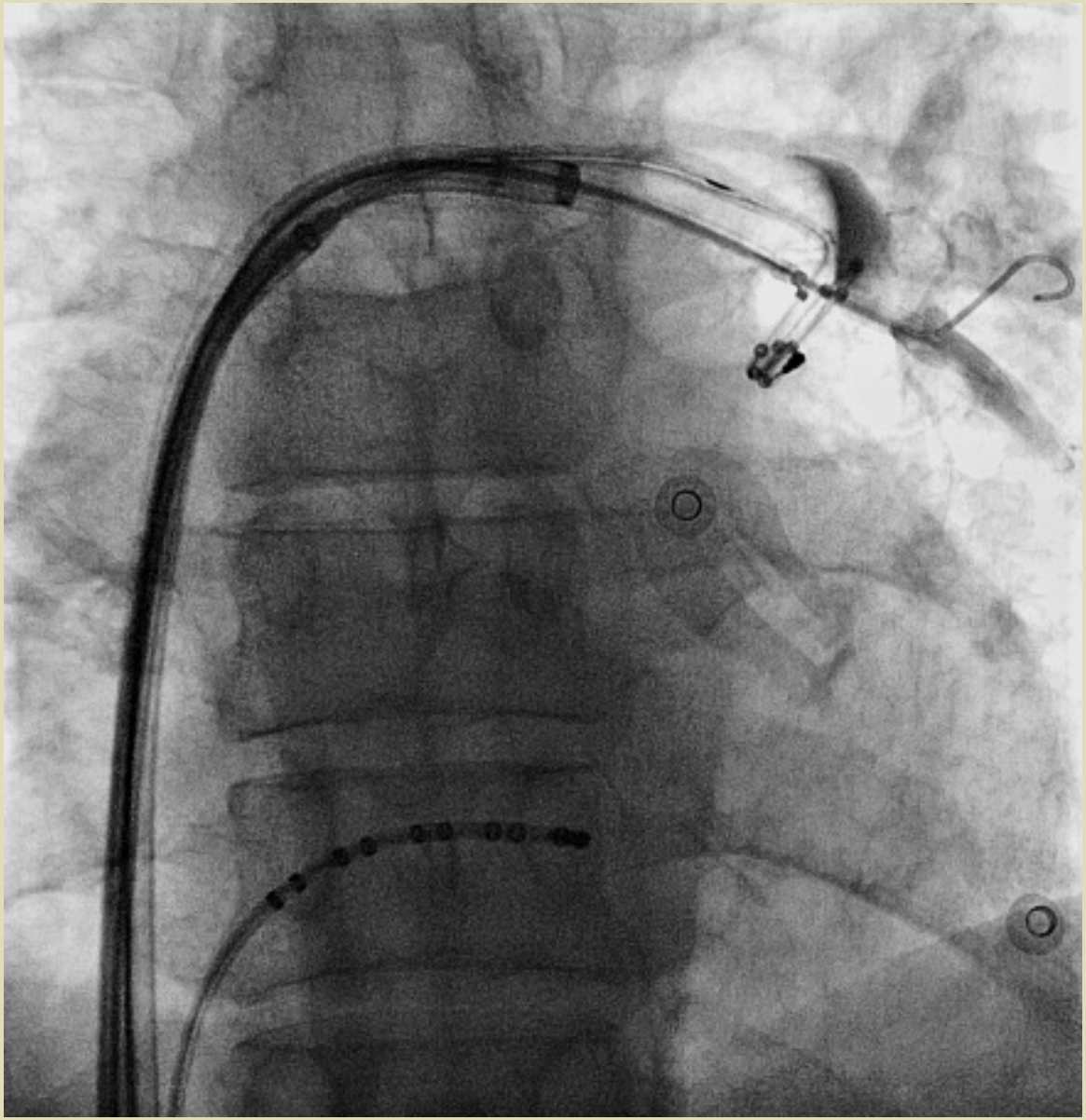
- Achieve™ mapping catheter allows for real-time assessment of PV isolation during cryoablation with Arctic Front®

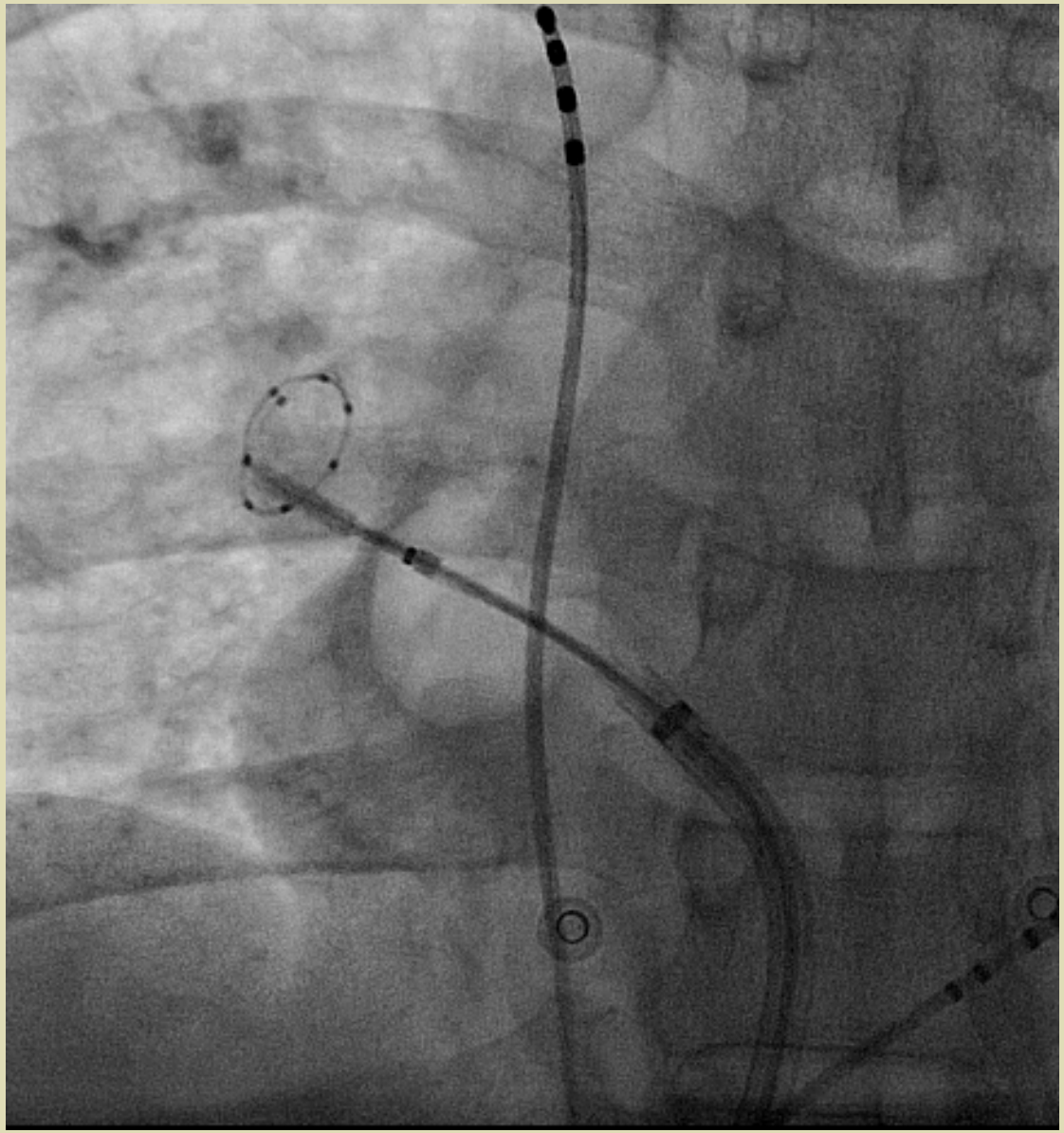


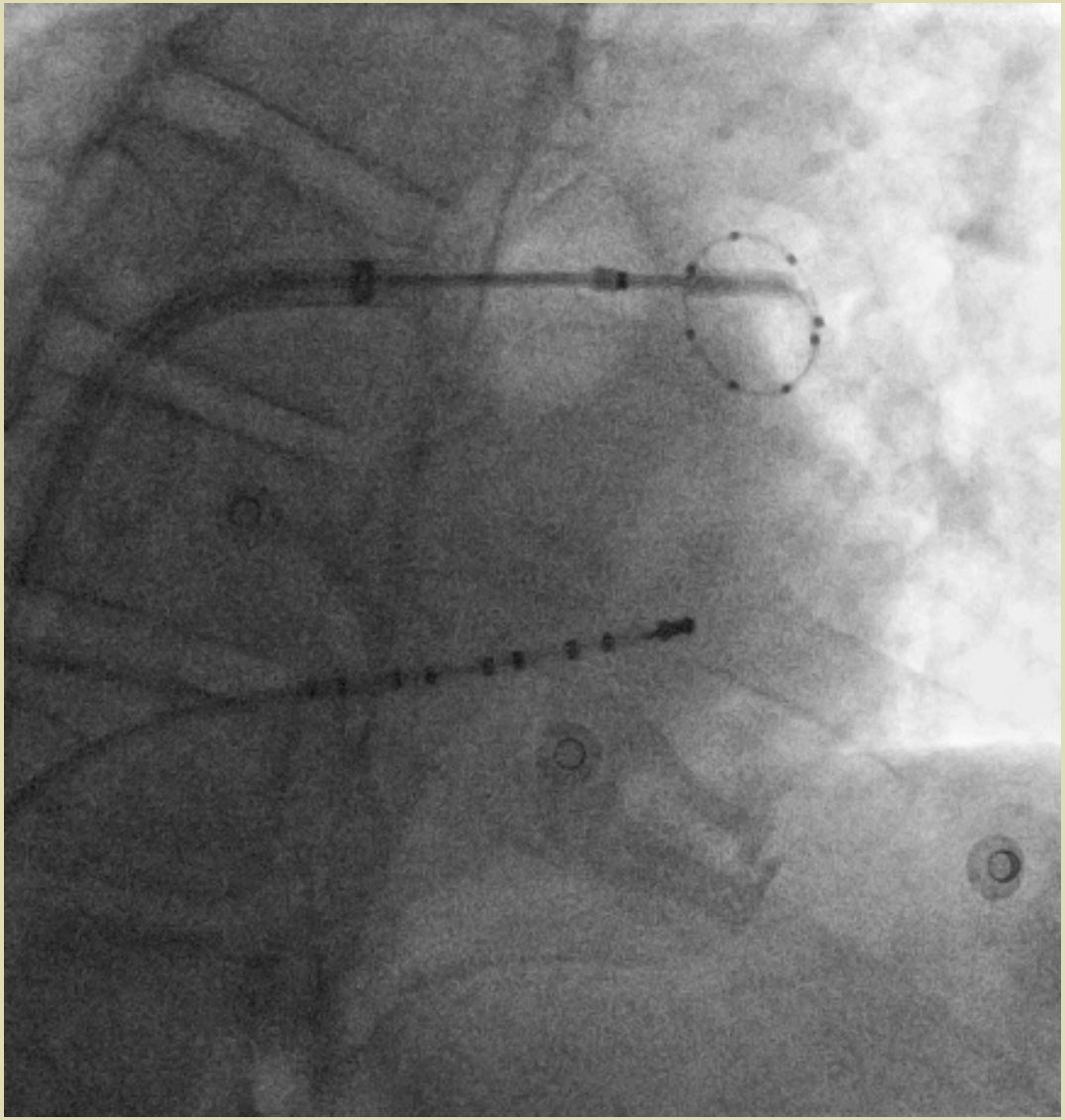
Arctic Front is positioned against the LIPV ostium, with Achieve positioned to assess PV isolation

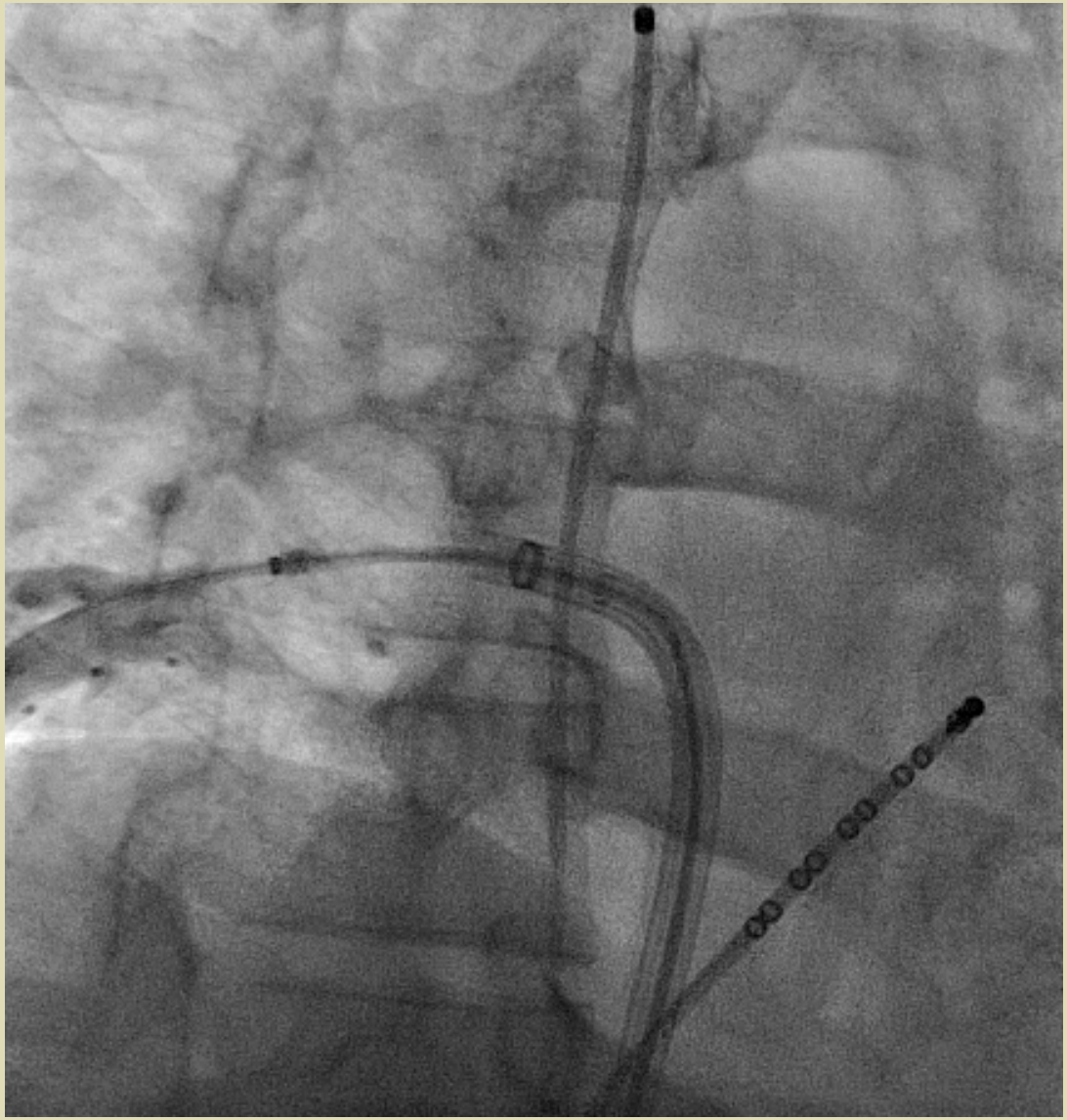
Images: Courtesy of Dr. Schwagten, ZNA Middelheim, Belgium (above) and Dr. Vogt, Herz- und Diabeteszentrum NRW, Germany (right)

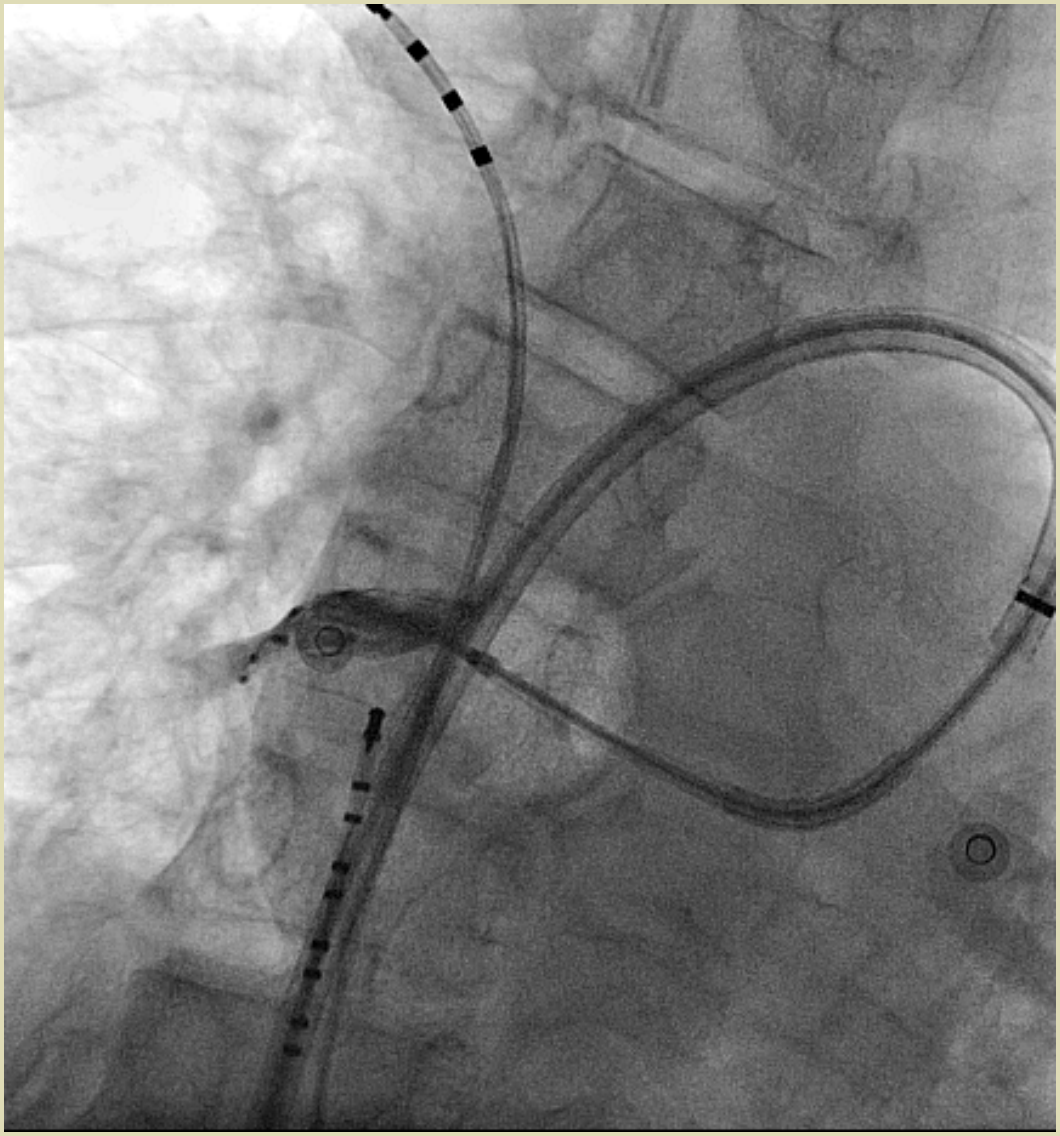
CT Image of Pulmonary Veins







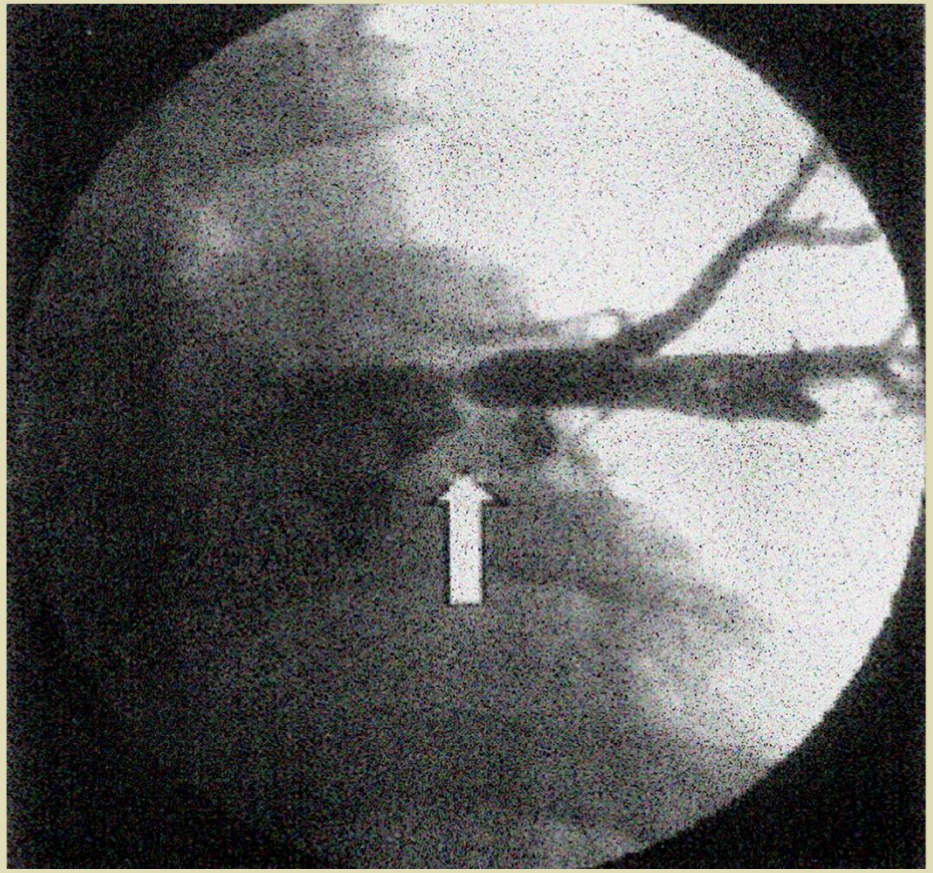




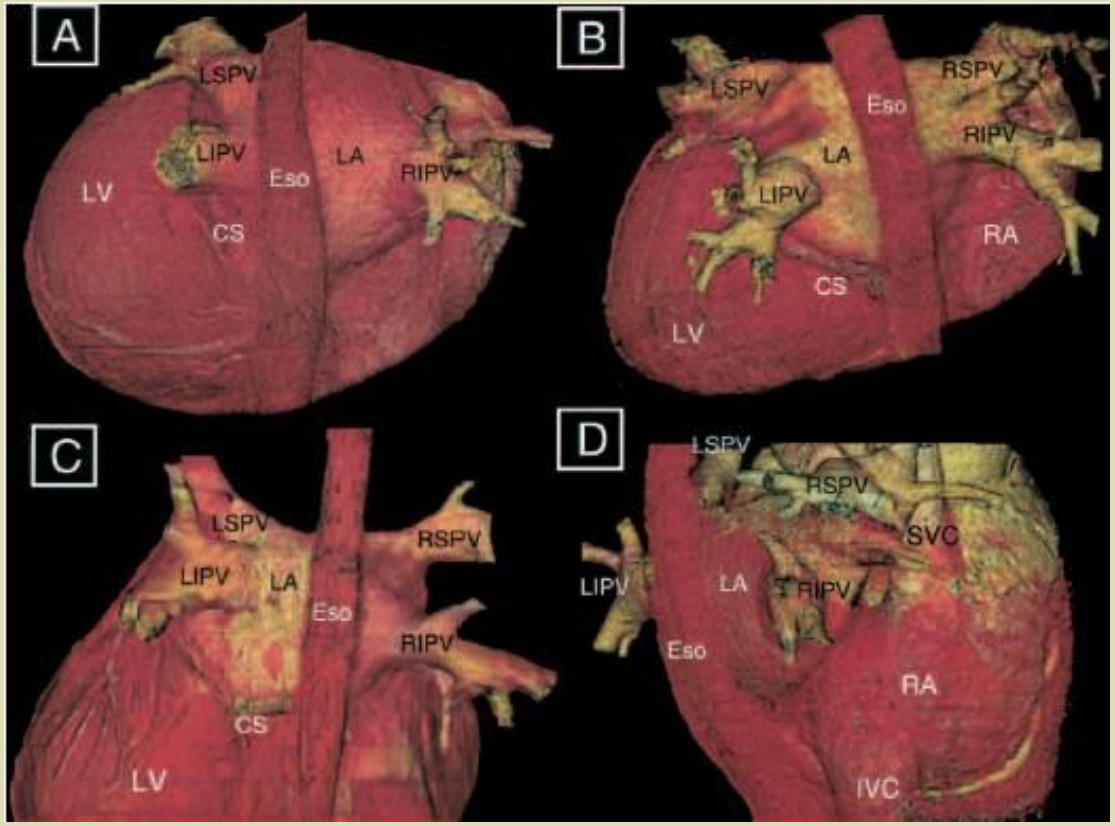
Potential Complications of AF Ablation

- Pulmonary vein stenosis -> 5%
- Atrio-esophageal fistula -> 0.5%
- Diaphragmatic palsy -> 10%

Pulmonary Vein Stenosis



CT Analysis of the LA and Esophagus



Lemola K, et al. Circulation (2004) 110: 3655

Phrenic Nerve Palsy

Solutions ?

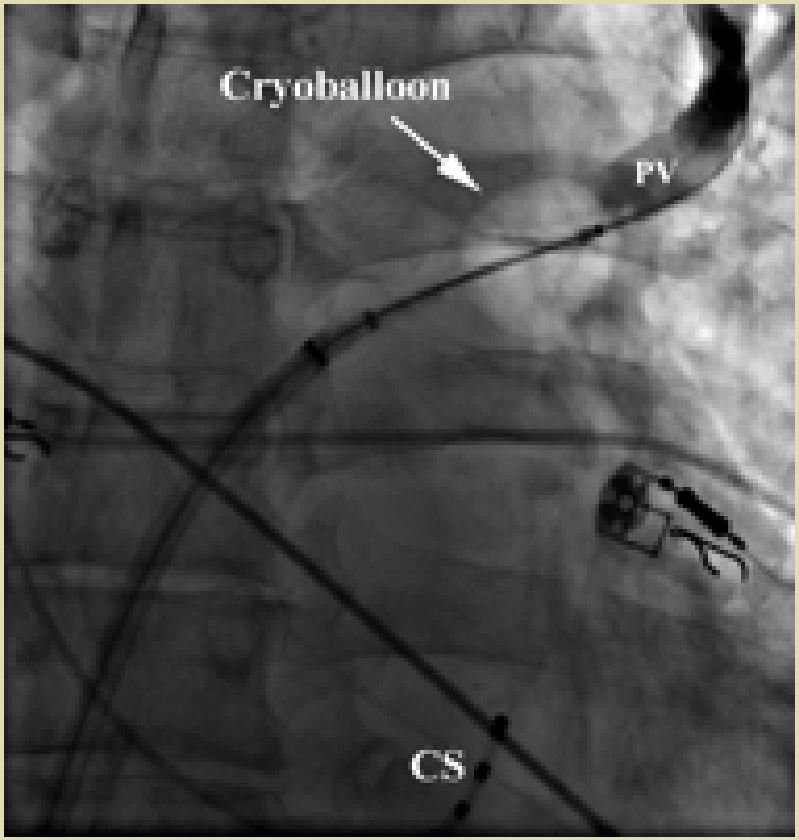
Ablate within the Left Atrium

Not in the Pulmonary veins !

Pace the Phrenic Nerve

Monitor Esophagial Temperature

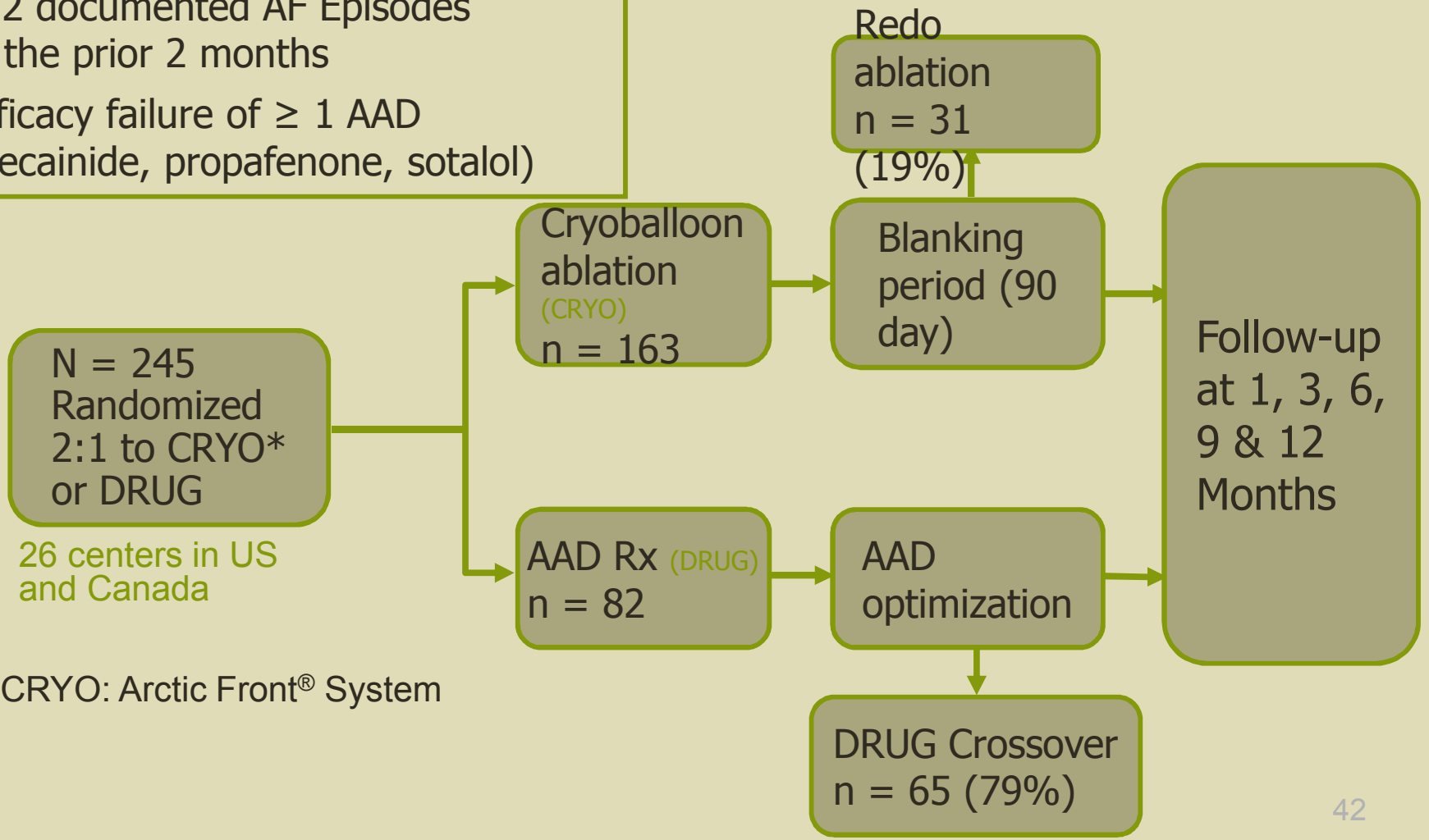
Cryo-Ablation of Left Upper PV



STOP AF Trial
Sustained Treatment of Paroxysmal Atrial Fibrillation

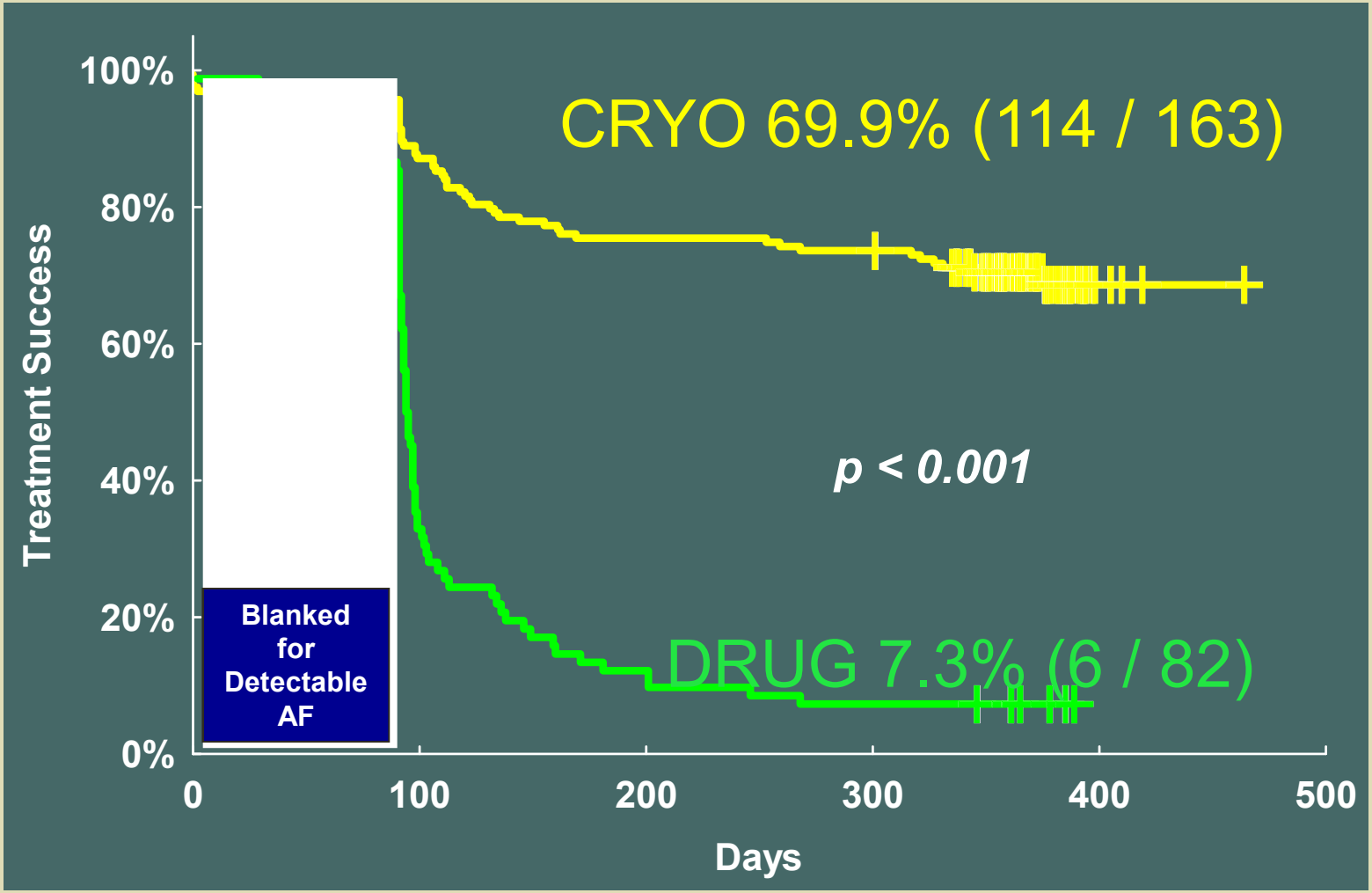
Key Inclusion Criteria:

- ≥ 2 documented AF Episodes in the prior 2 months
- Efficacy failure of ≥ 1 AAD (flecainide, propafenone, sotalol)

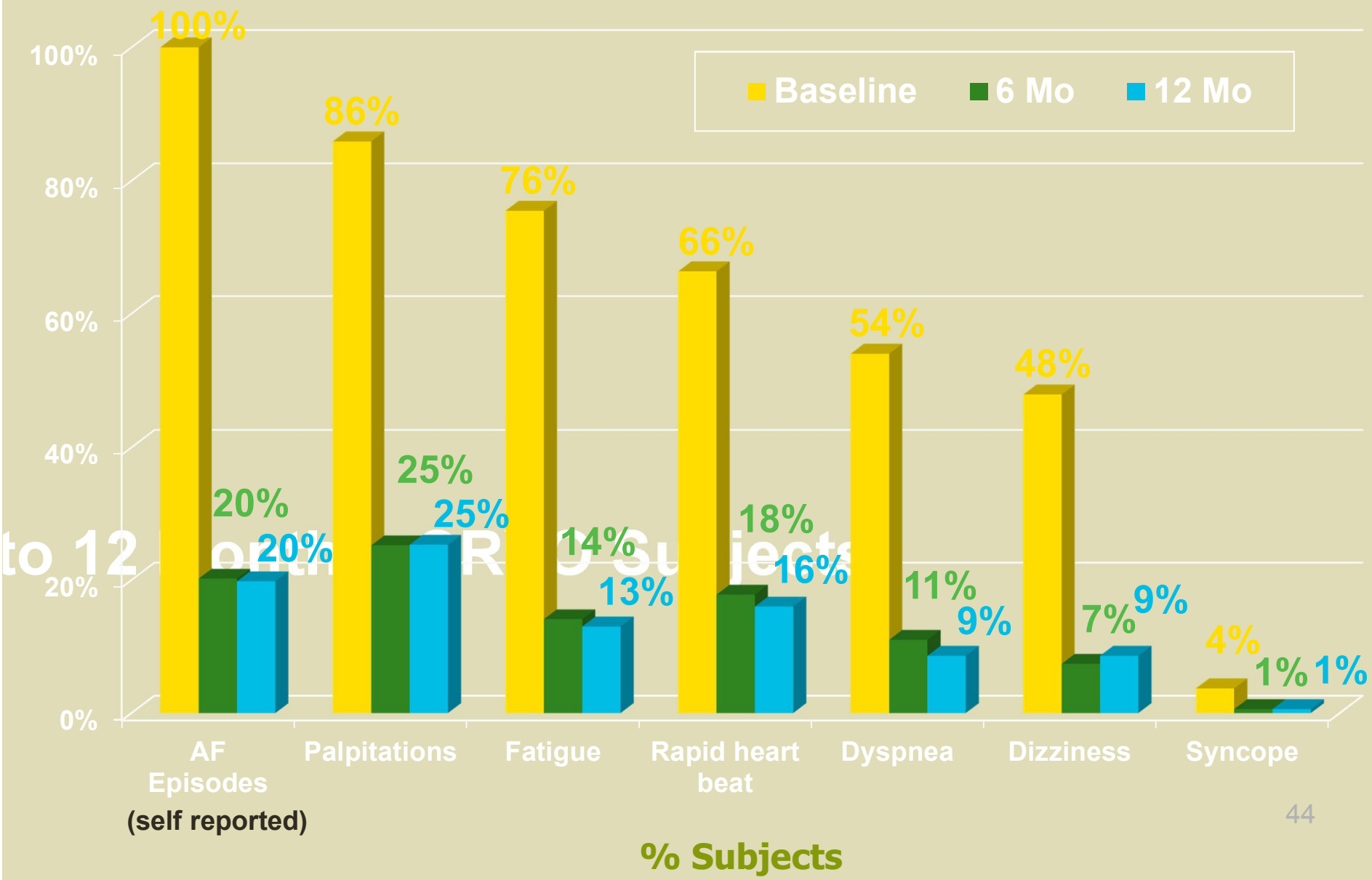


* CRYO: Arctic Front® System

STOP AF Trial - Results



AF Symptoms to 12 Months



US Continued Access Protocol

- Single-arm, non-randomized study (followed STOP AF)
  - 80 subjects
  - 12 centers
- Purpose to continue evaluating
  - Safety and efficacy of Arctic Front® system
    - Follow-up at 1,3,6,12 months and 2,3,4,5 years post-cryoablation procedure
  - The impact of experience on the learning curve
- The chronic success rate of Cryoballoon ablation increases with experience
  - 12-month efficacy increased from 69.9% to 71%

CAP AF Safety Summary

- Phrenic nerve injury risk decreased from 11.2% in STOP AF to 4.8% in CAP AF
- Pulmonary vein stenosis decreased from 3.1% to 1.3%
  - Patient had a second ablation procedure using RF.

Long Term Follow up – Vogt at al

JACC December 2012

- PV isolation was achieved without touch-up in 91.1% of patients, using the smaller balloon in 26.7%, the larger balloon in 25.6%, and both balloons in 47.7% of patients.

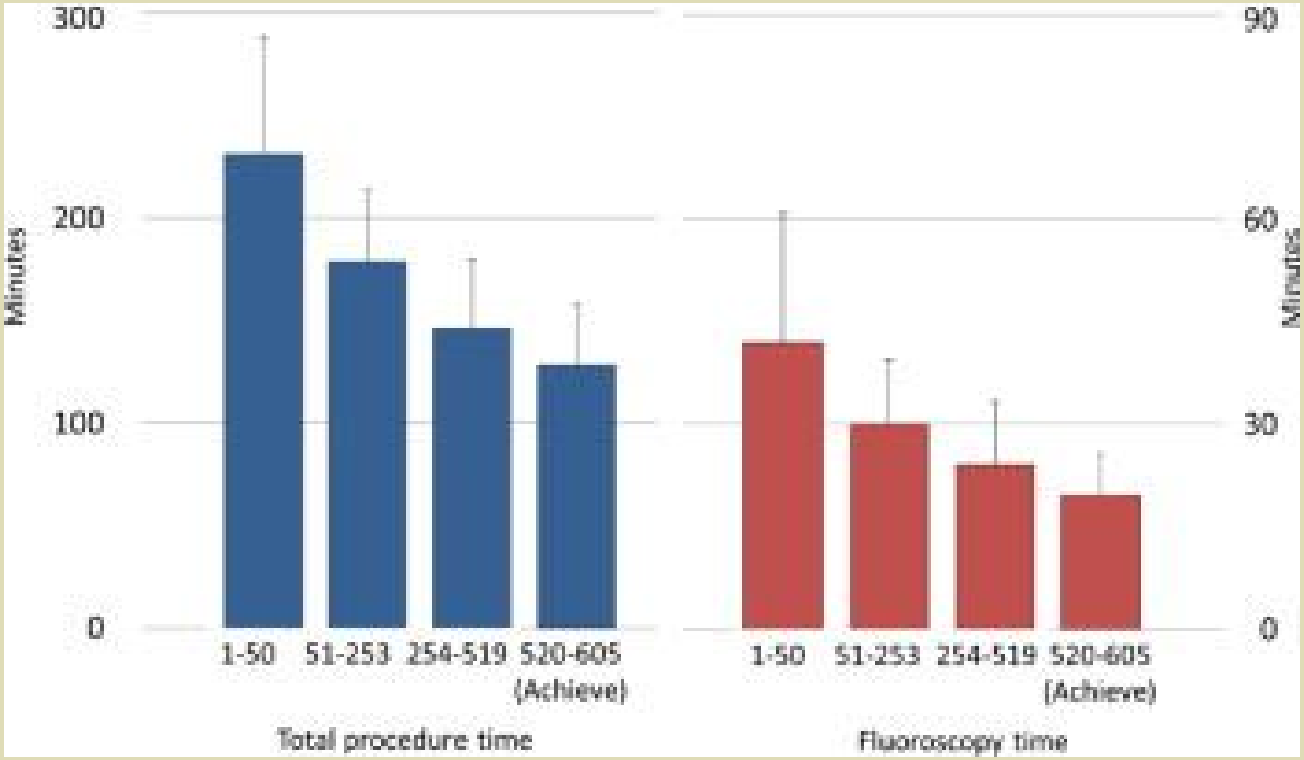
- Long-term follow-up data12< months (median 30 months; interquartile range 18 to 48 months) were available for 451 patients.

- 278 patients (61.6%) were free of AF recurrence with no need for repeat procedures after the 3-month blanking period. Rates of freedom from AF after 1, 2, and 3 repeat procedures were 74.9%, 76.2%, and 76.9%, respectively.

- Use of the smaller balloons or both balloons produced the highest rates of long-term freedom from AF. Phrenic nerve palsy occurred in 12 patients (2%), resolving within 3 to 9 months.

Long Term Follow up – Vogt at al

JACC 2012



Shaare Tzedek Experience

- Between July and November 2012, cryo-ablation with a 28 mm balloon was performed in 10 patients (age 59 ± 8, 6 with drug refractory paroxysmal AF, 3 with persistent AF and 1 with left atrial tachycardia.
- 34 of 37 PV's (91.9%) were successfully isolated. The right inferior PV was not isolated in 3 patients.
- Radiation time was 76 ± 29 min, it is expected to drop with the learning curve.
- Sinus rhythm was maintained in in 80% of patients, however follow up is still too short (108 days, range 24-182).

Shaare Tzedek Experience

- No PV narrowing, right phrenic nerve palsy or atrio-esophagial fistula occurred during cryo-balloon ablation.
- There were no significant complications.
- One patient had a mild to moderate amount of pericardial fluid the day after the procedure, which subsided within 48 hours.

Conclusions

Cryoablation with the Arctic Front® System:

- Effectively treats drug refractory PAF
- Is a safe and efficient procedure
- Has shorter procedure times, compared to RF ablation procedures (European Trials)