Balloon Cryo-Ablation For Atrial Fibrillation

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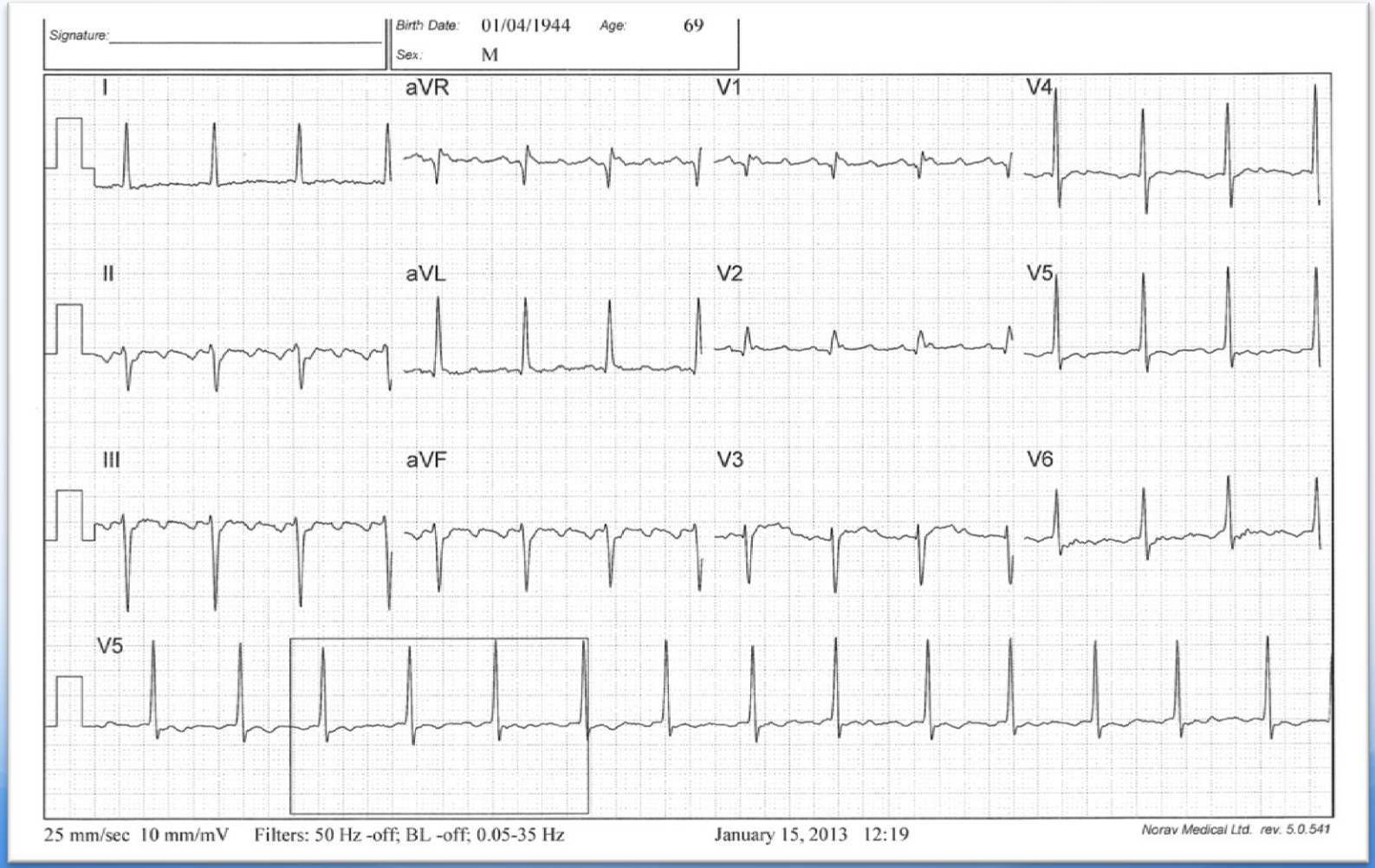
Disclosures

- Proctoring fee from Medtronic Israel

A.I. case study

- 68-year-old male patient.
- No structural heart disease.
- Paroxysmal AF since 2005.
- On Amiodarone and Warfarin since 2005.
- Cardioverted in 2007 and 2010.
- Presented with fatigue for a couple of months.

Atrial Flutter



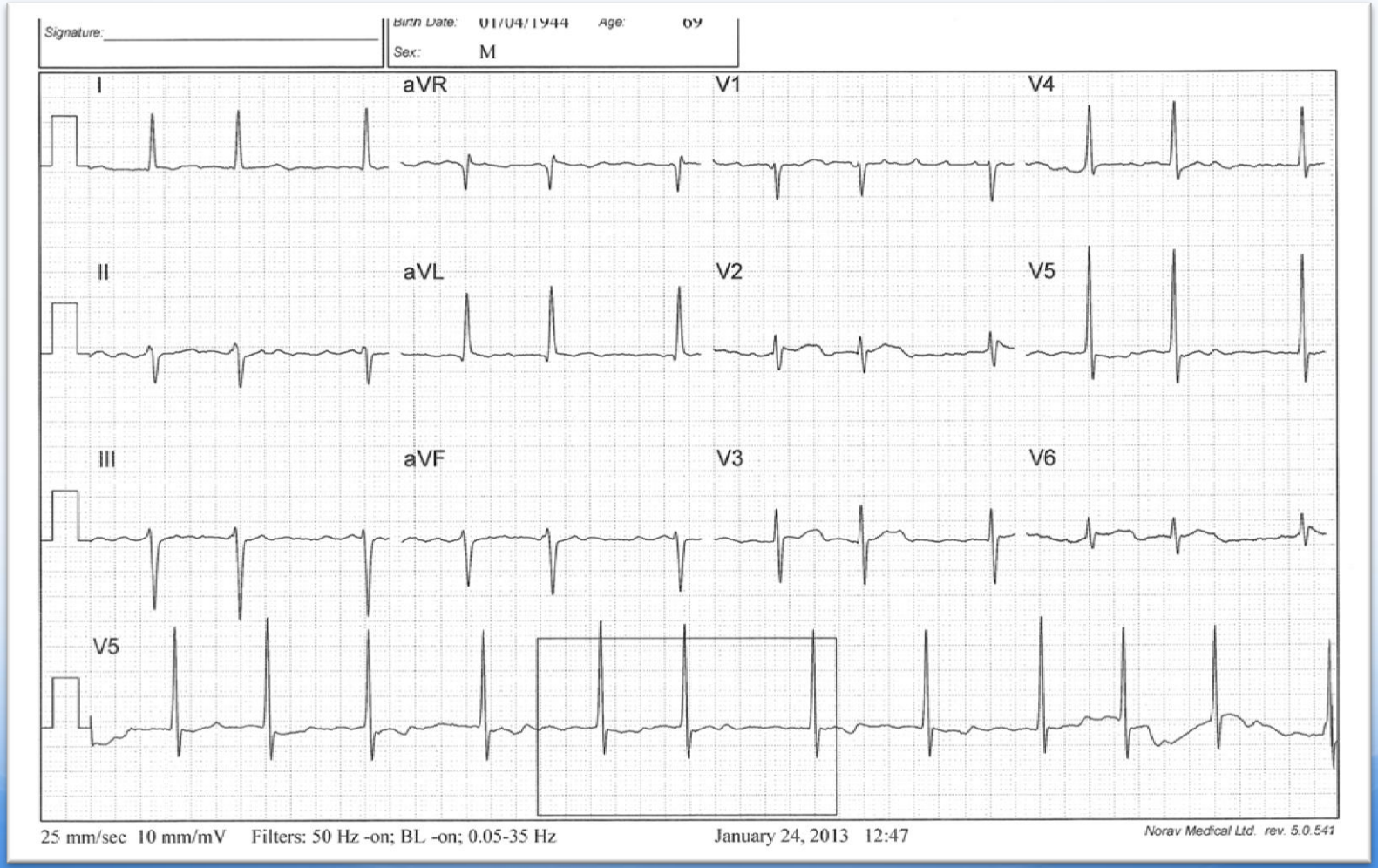
What would you do?

- Change / add medication?
- Cardioversion?
- Rate control?
- Flutter ablation?

Follow up

- Patient underwent successful Isthmus Block on 16.01.2013 and returned to sinus rhythm during RF ablation.
- Was discharged on Amiodarone and Warfarin because of the history of AF.
- Two days later, he presented in the EW with palpitations and the following ECG:

Atrial Fibrillation



What would you do?

- Change / add medication?
- Cardioversion?
- Rate control?
- AF ablation?

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 .

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

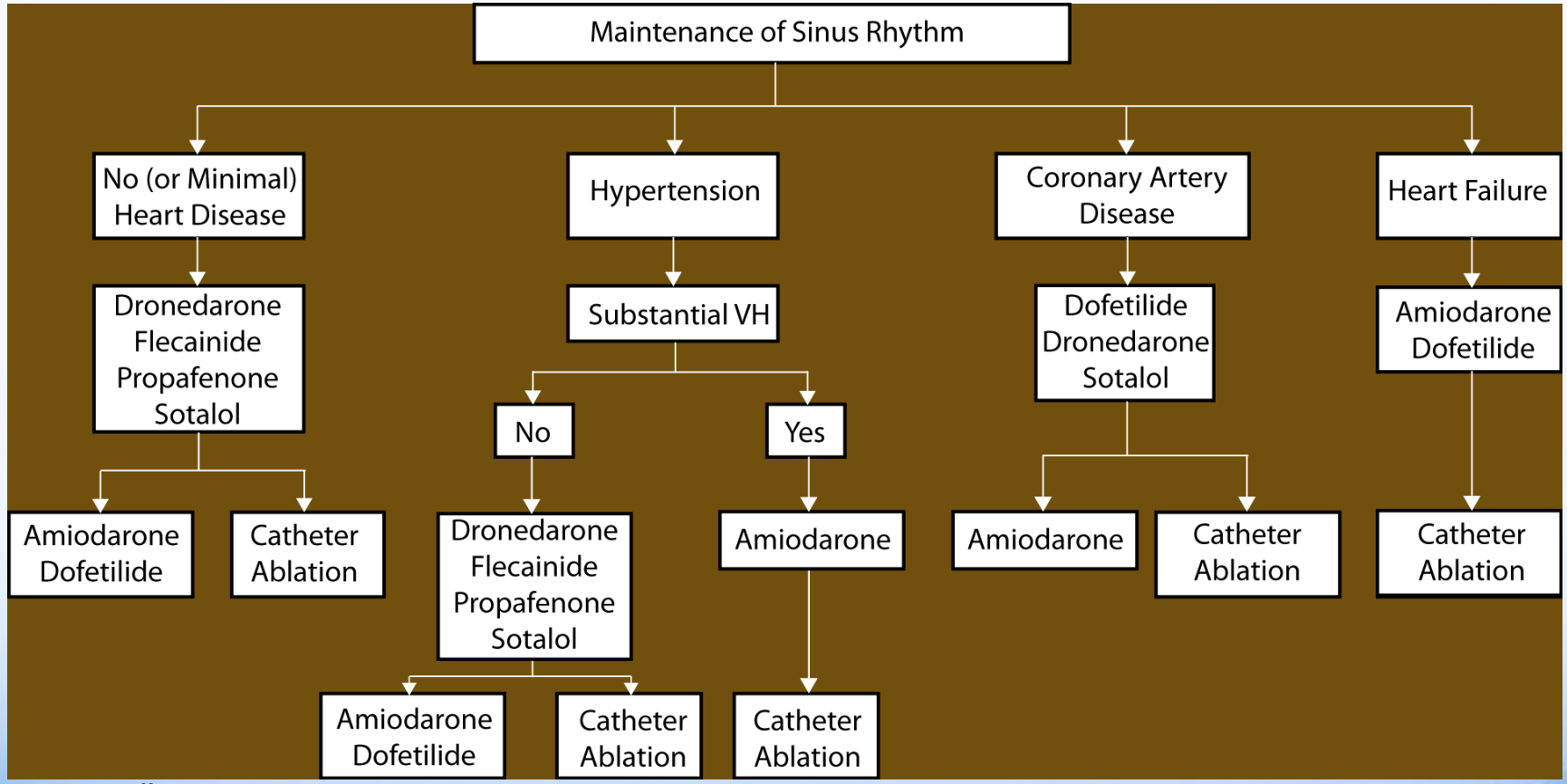
AFFIRM study
Circulation 2004

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

Atrial Fibrillation Ablation

Ultimate Rhythm Control ?

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



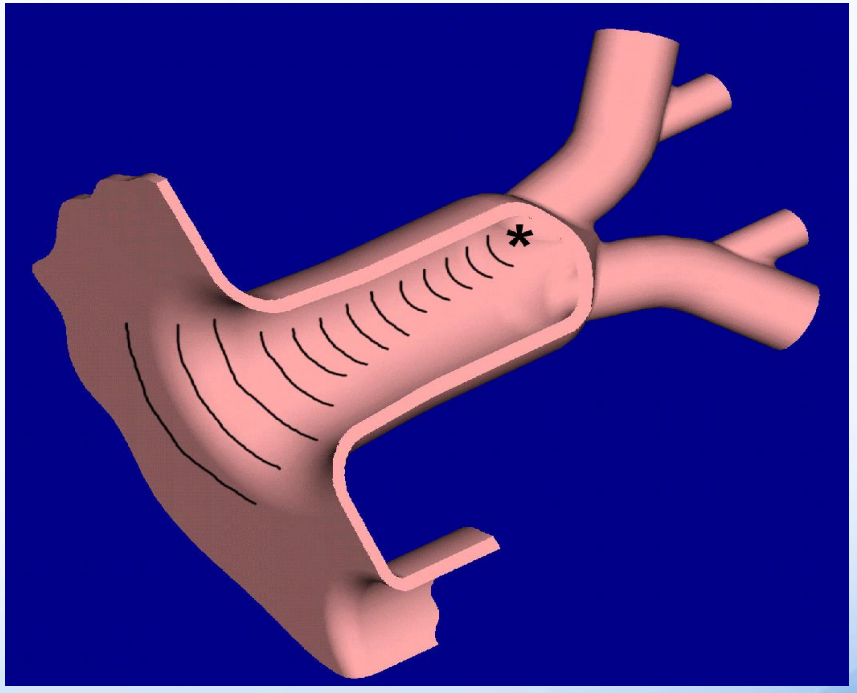
"In some patients, especially young individuals with very symptomatic AF, ablation may be preferred over years of drug therapy."

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

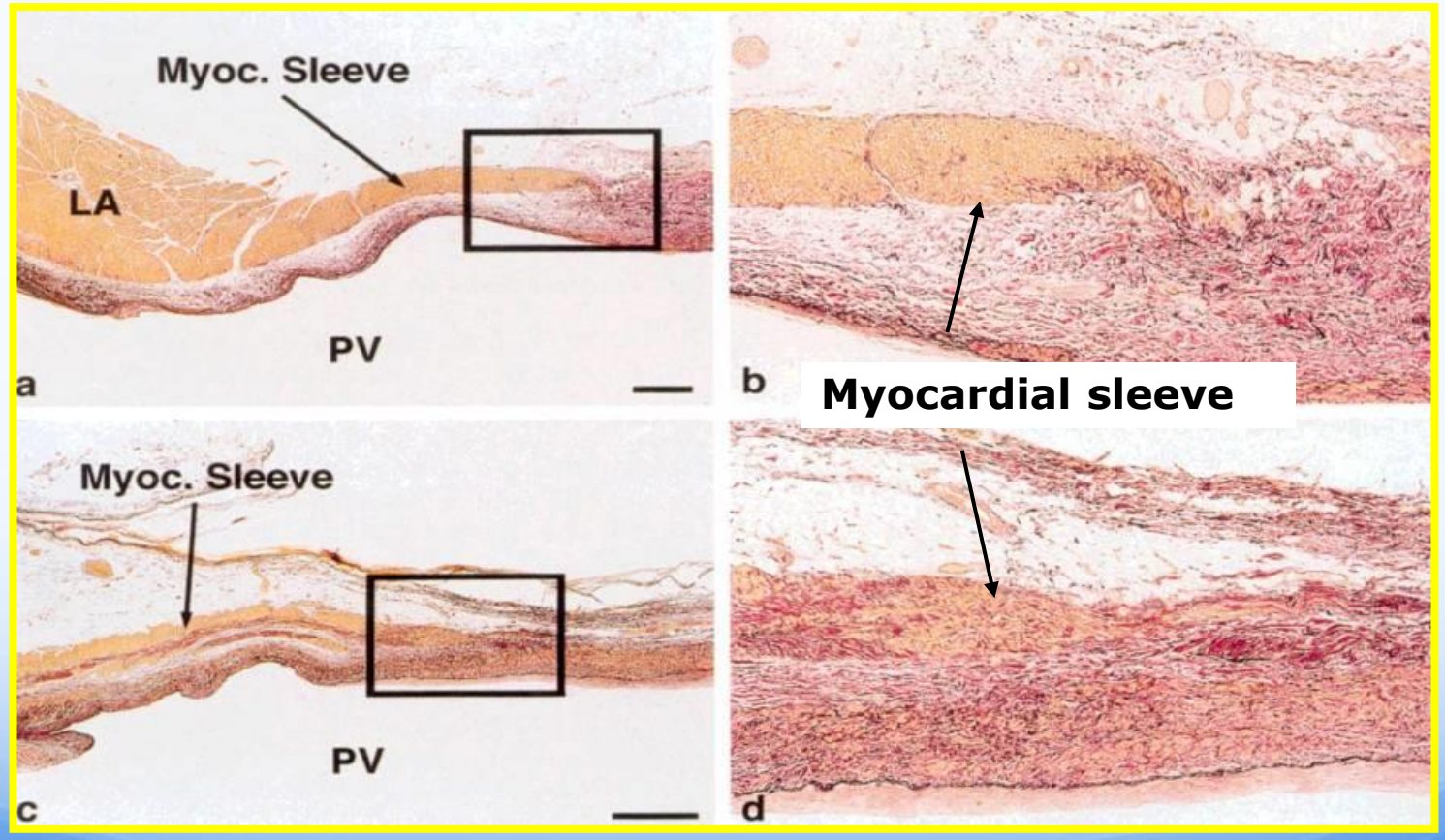
Knight B. HRS Practical Rate and Rhythm Management of Atrial Fibrillation. Updated January 2010.

Focal Atrial Fibrillation - Concept

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

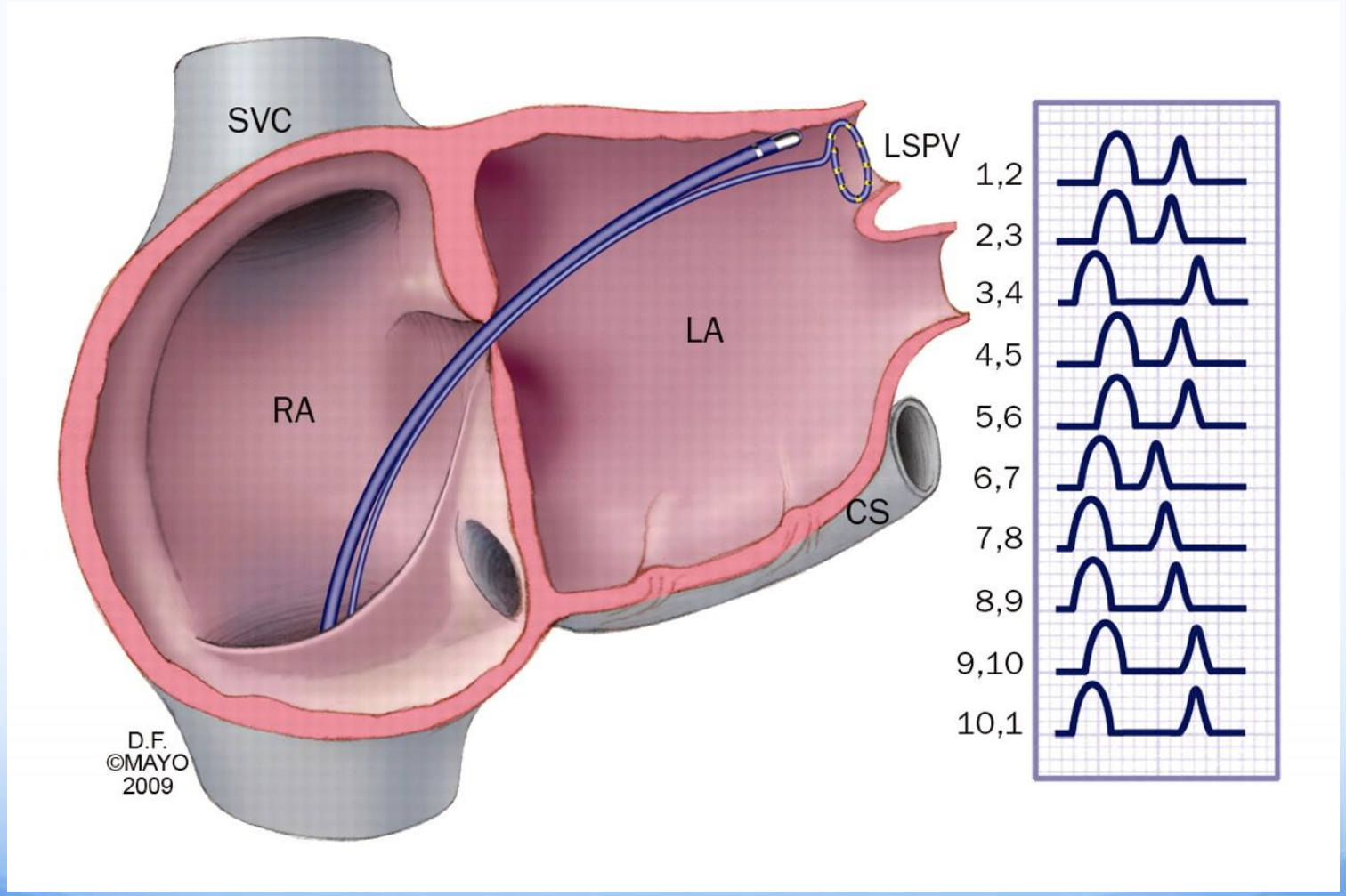


Microscopic Anatomy of Pulmonary Veins



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

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

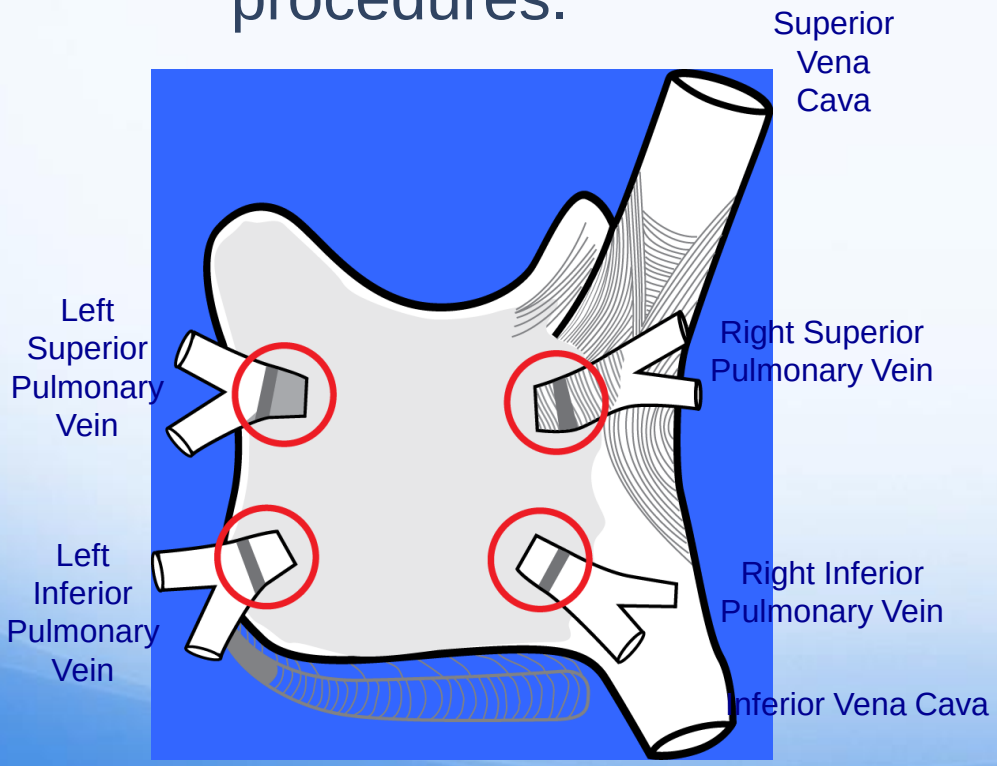


Crandall M A et al. Mayo Clin Proc. 2009;84:643-662

MAYO CLINIC
Mayo Clinic Proceedings

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."



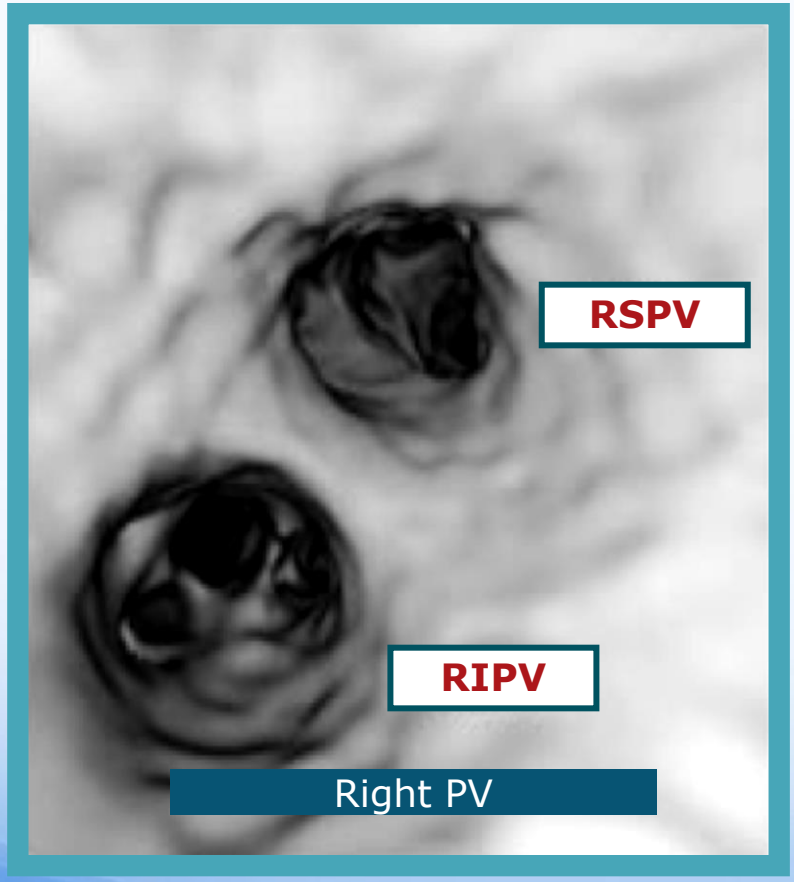
Each vein should be isolated independently

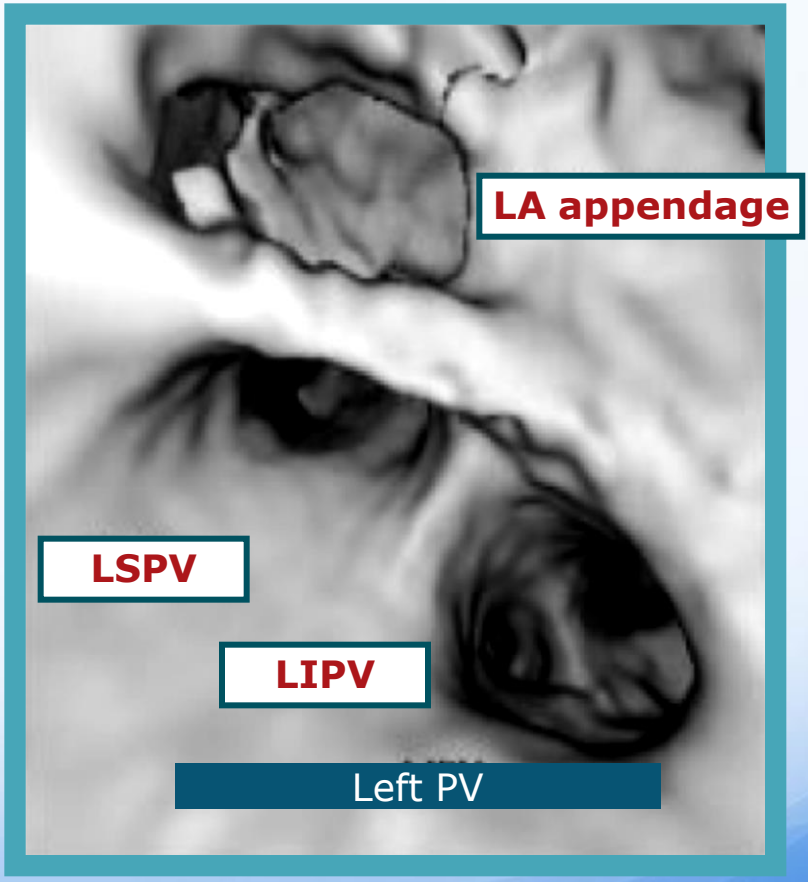
Complete electrical isolation should be the goal for targeted PVs and entrance and/or exit block should be demonstrated

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

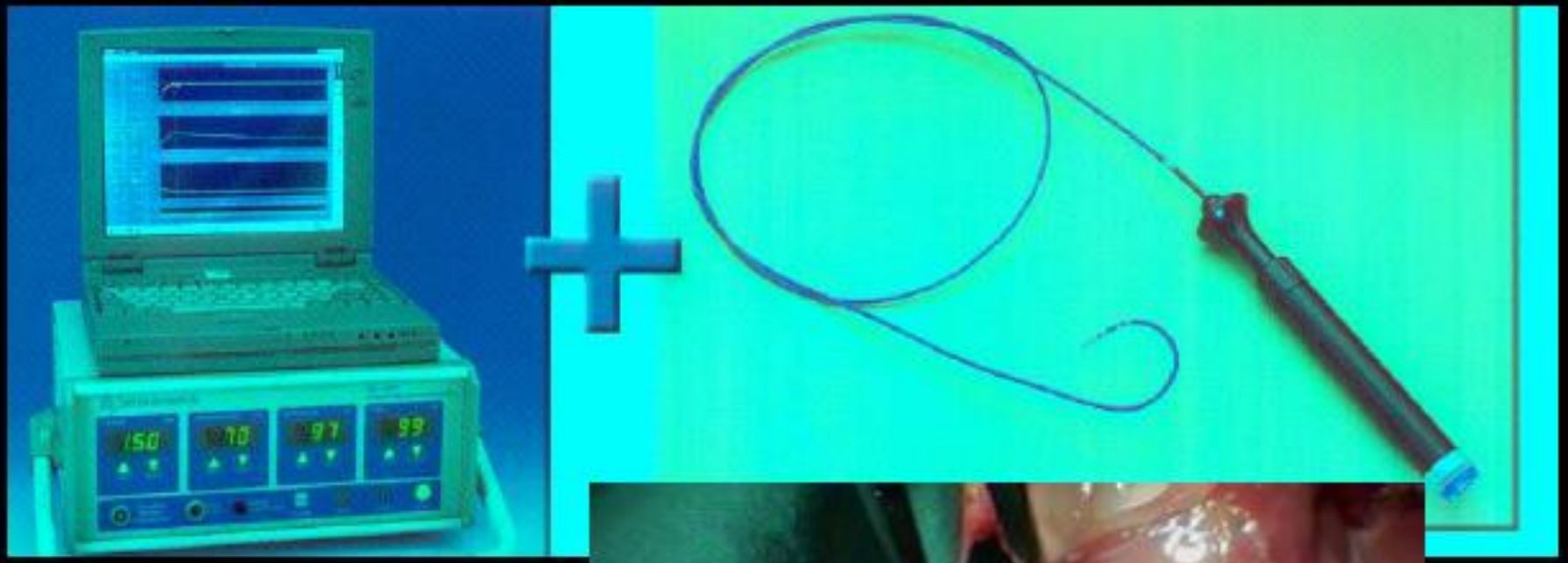




- Nuclear magnetic resonance image of the ostia of the right and left superior and inferior PVs and the left atrial appendage

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

Principle of Radiofrequency catheter ablation



RF-current: 300-500 kHz

No muscle stimulation

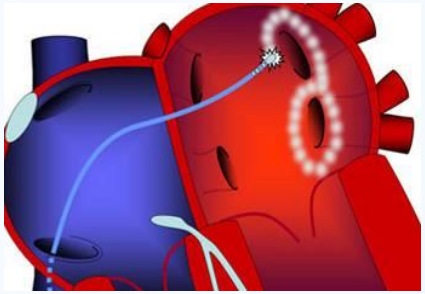
30-60 s delivery

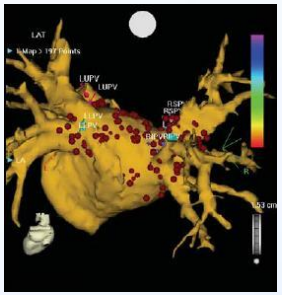
Heating of tissue at cath.tip

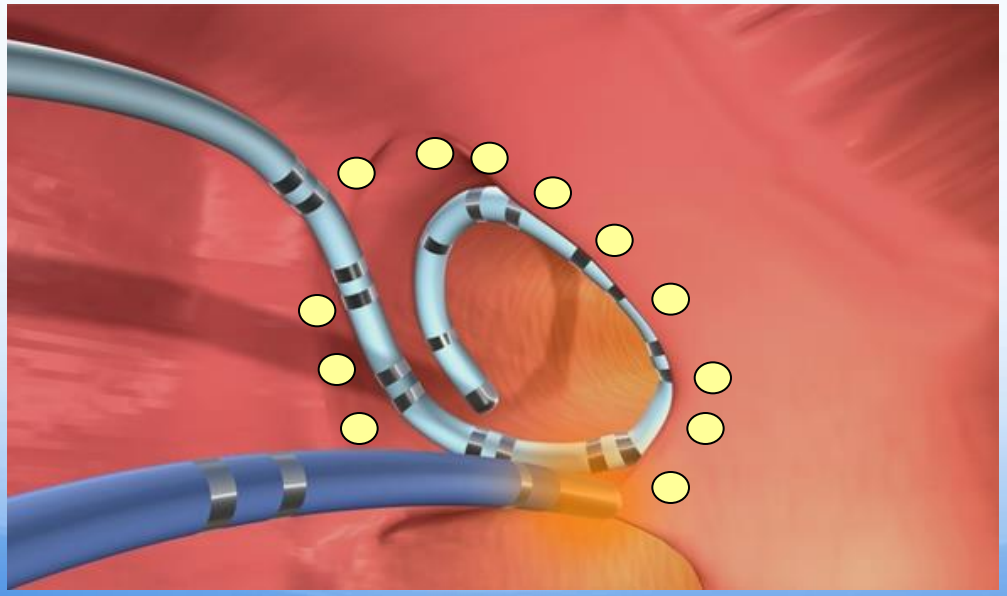
Coag.necrosis 8 x 4 x 4 mm

Challenges Using RF Focal Ablation Catheter to Isolate PV and Ablate Atrial Tissue

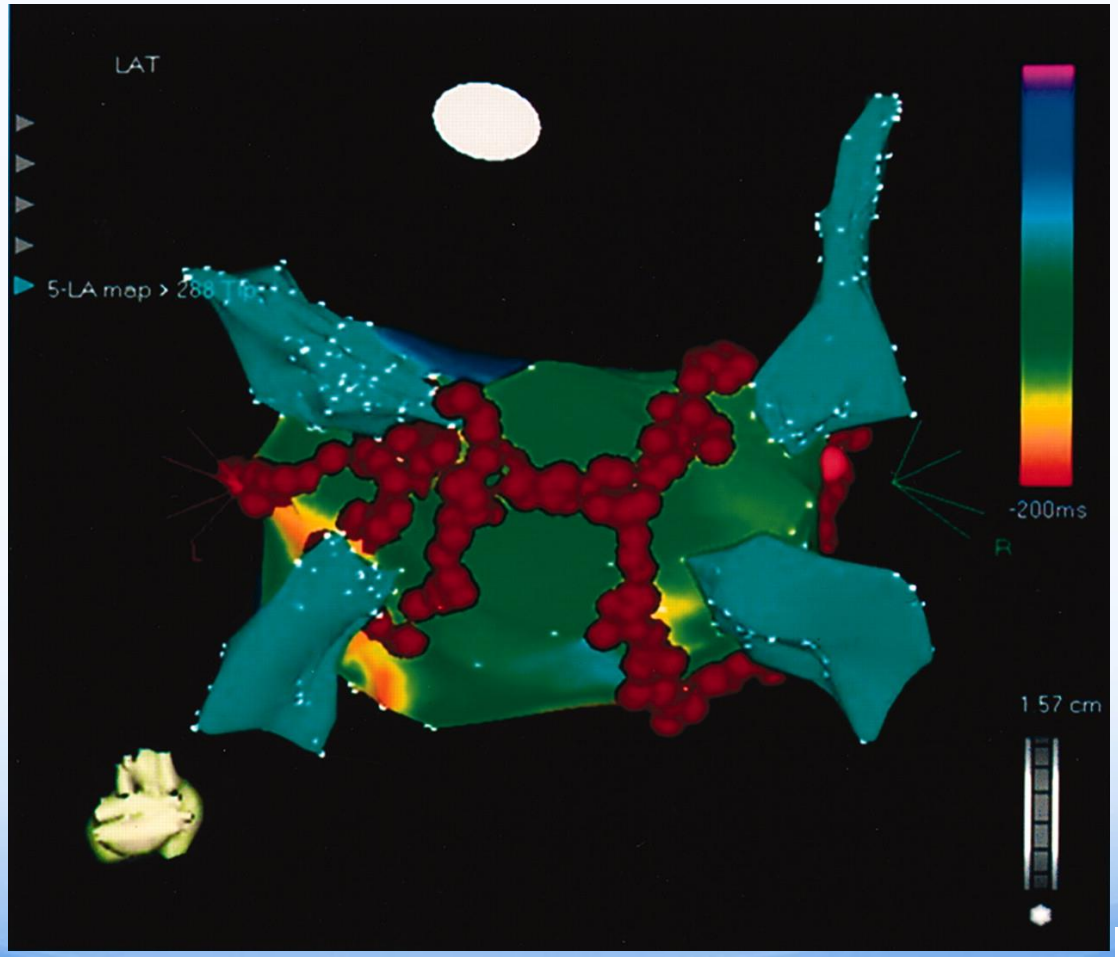
- Patient anatomy and atrial tissue depth is variable
- Cardiac contractions make maintaining position difficult
- Catheter force varies with position in heart
- Technically challenging
- Good lesions require transmurality
- Successful procedure requires *contiguous* lesions







Ablation Approach for Patients with Persistent Atrial Fibrillation

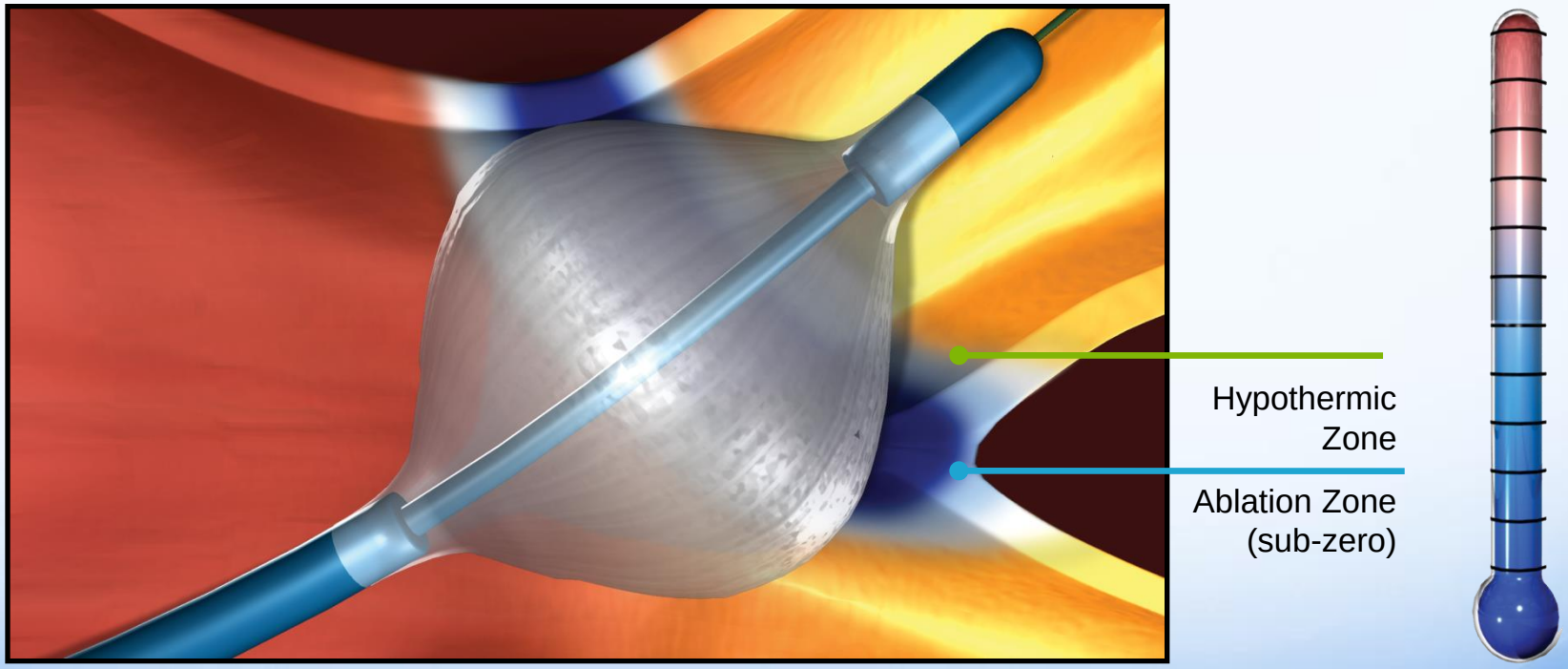


Crandall M A et al. Mayo Clin Proc. 2009;84:643-662

Advantages of Cryo energy

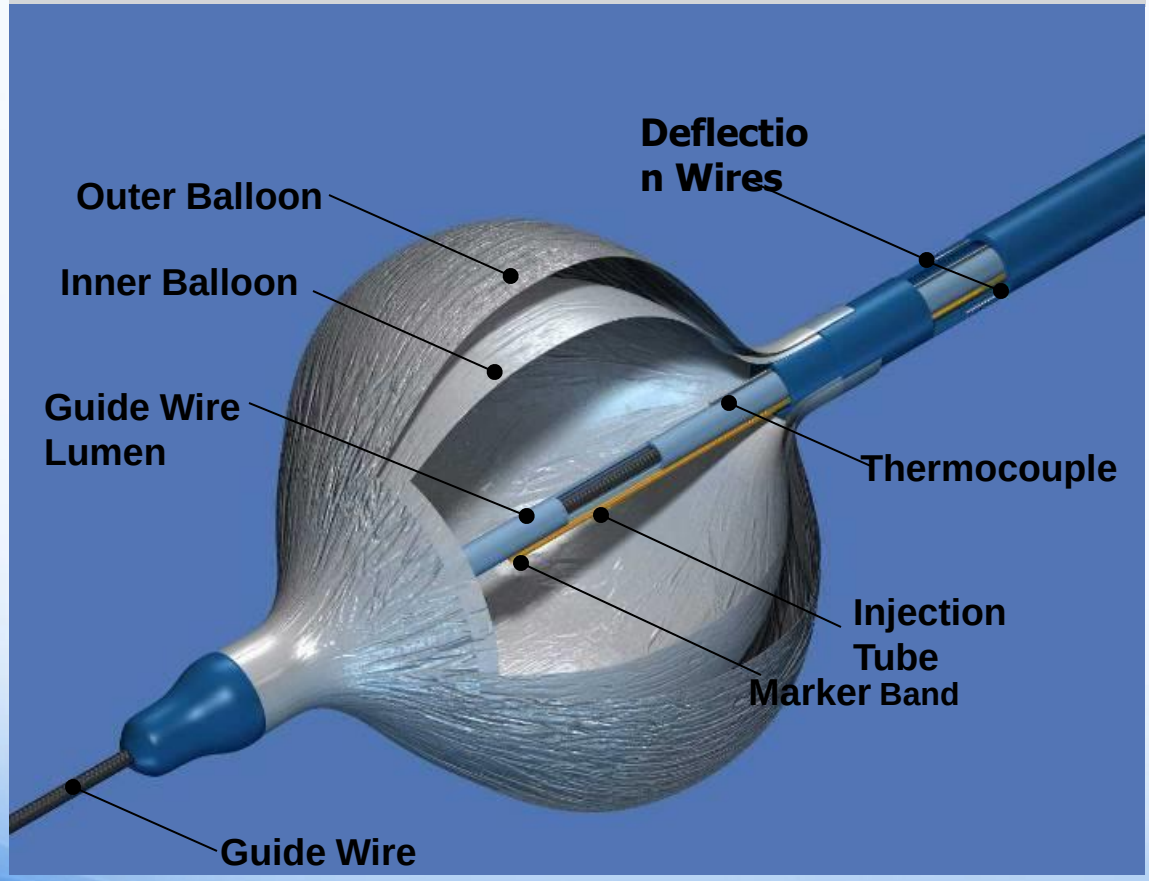
- Minimal disruption of endothelium
  - Minimal thrombus production
- Maintenance of extracellular matrix - no collagen denaturation
  - No collagen shrinkage known to occur with thermal injury
  - Advantageous within venous structures - CS or PV's

Baloon Cryoablation



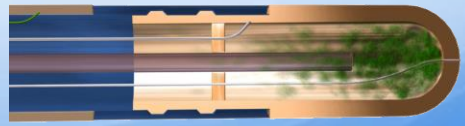
Arctic Front® Catheter Design

Arctic Front Catheter Balloon Segment



- 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

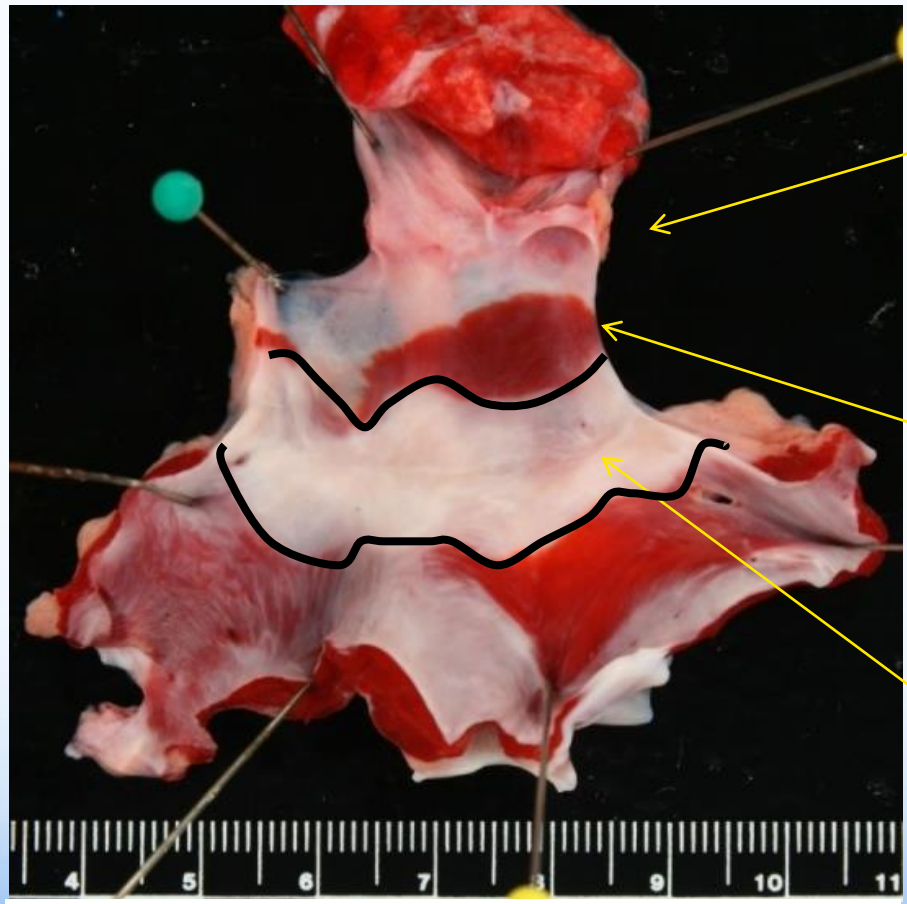
- Freezor® *MAX* operates on similar principles



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.

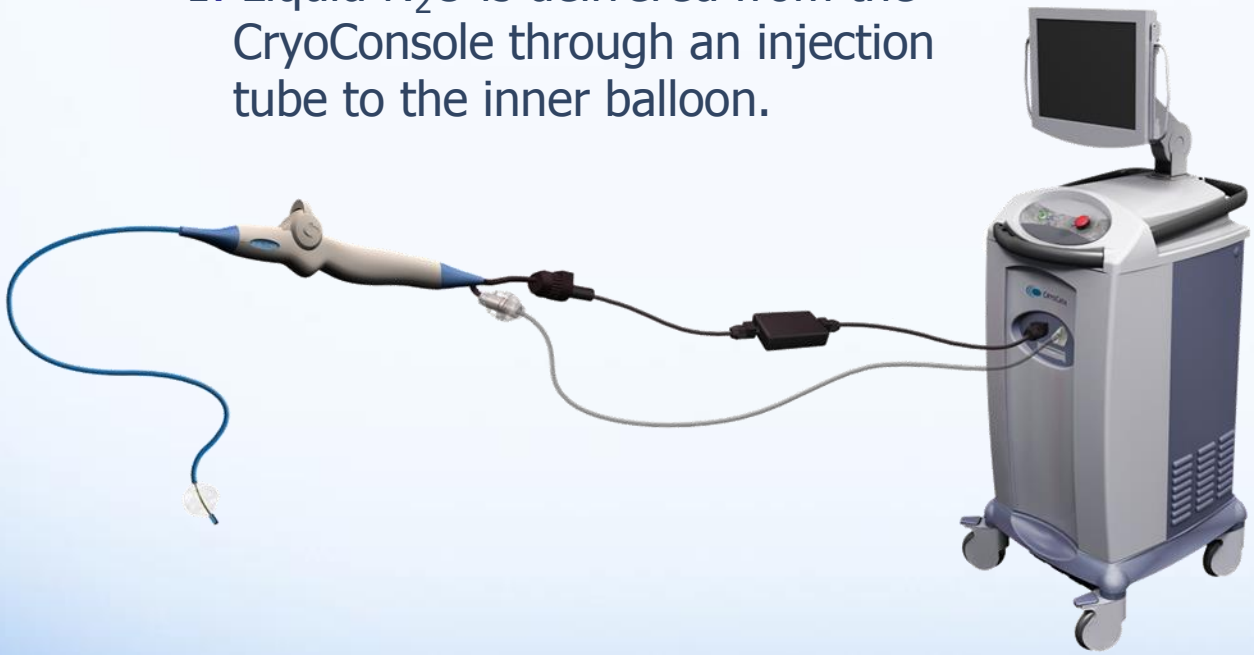
Pulmonary vein tissue, transition between collagen and muscular sleeve

Muscular pulmonary veins sleeve distal to the lesion

Contiguous lesion performed by Arctic Front® Catheter

How the Arctic Front® Cardiac Cryo-Ablation 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.

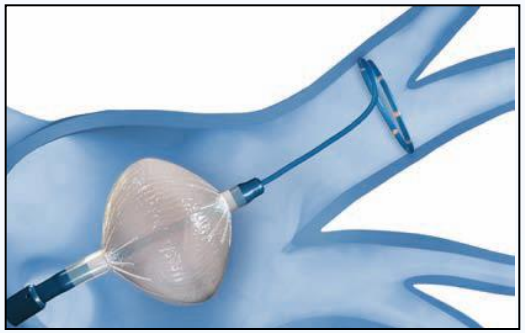
Arctic Front PV Isolation

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.

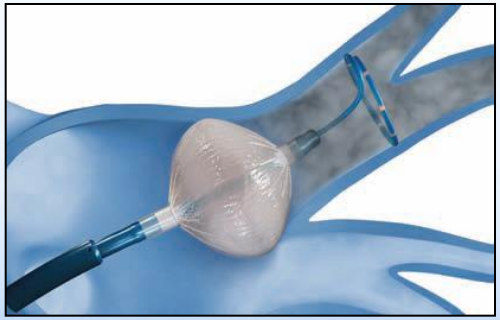
How Arctic Front® Balloon Catheter and Achieve™ Work?

1. Access targeted vein



2. Inflate and position

3. Occlude and ablate



4. Assess PVI

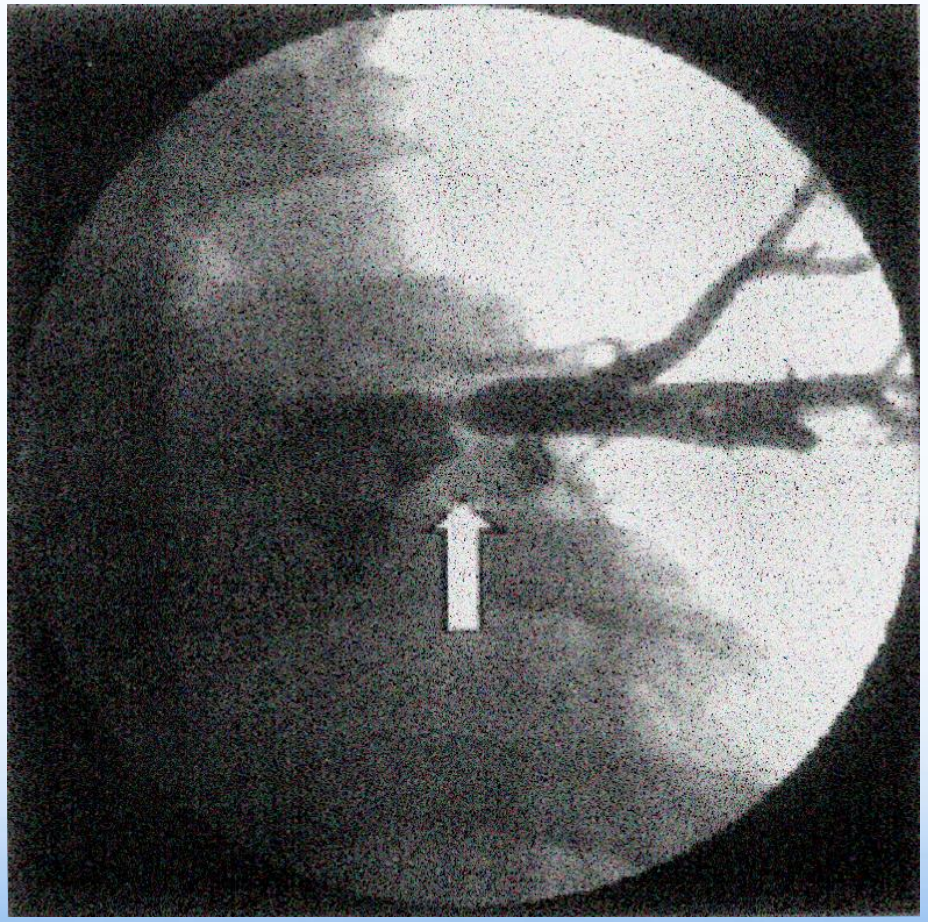
32

Pulmonary Vein Isolation

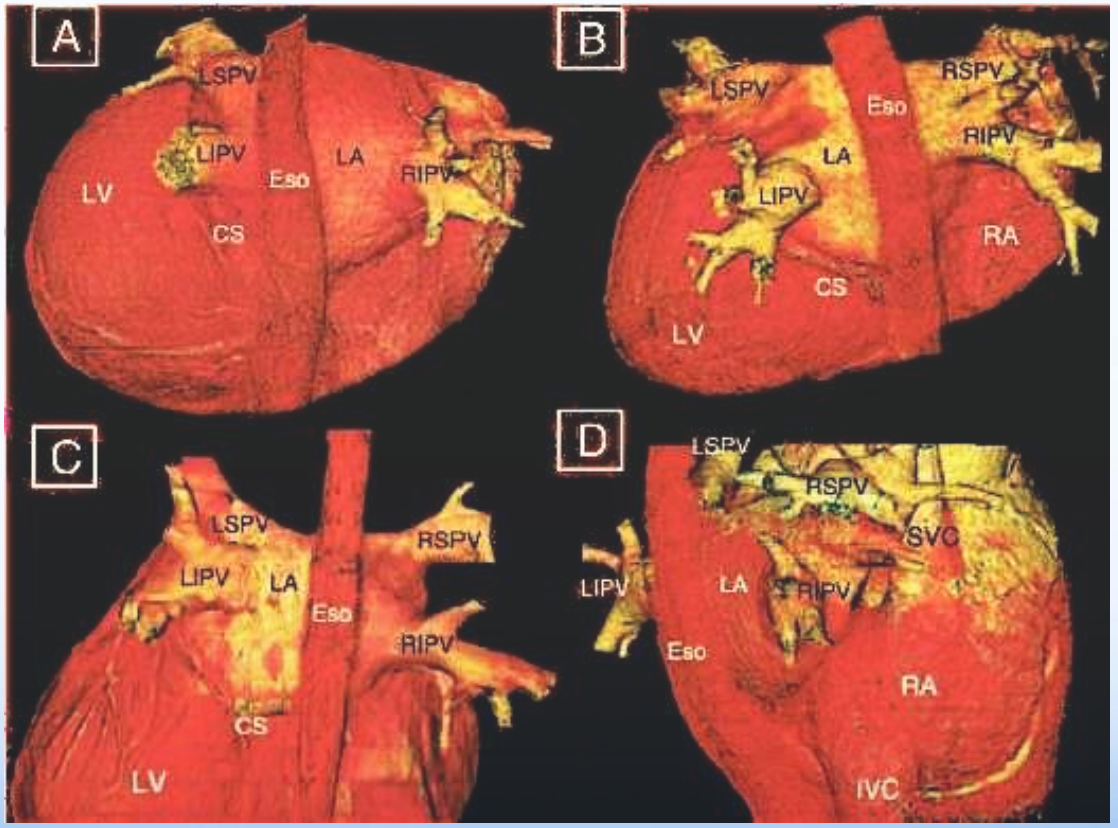
Potential Complications of AF Ablation

- Pulmonary vein stenosis → 5%
- Atrio-esophageal fistula → 0.5%
- Phrenic nerve 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**

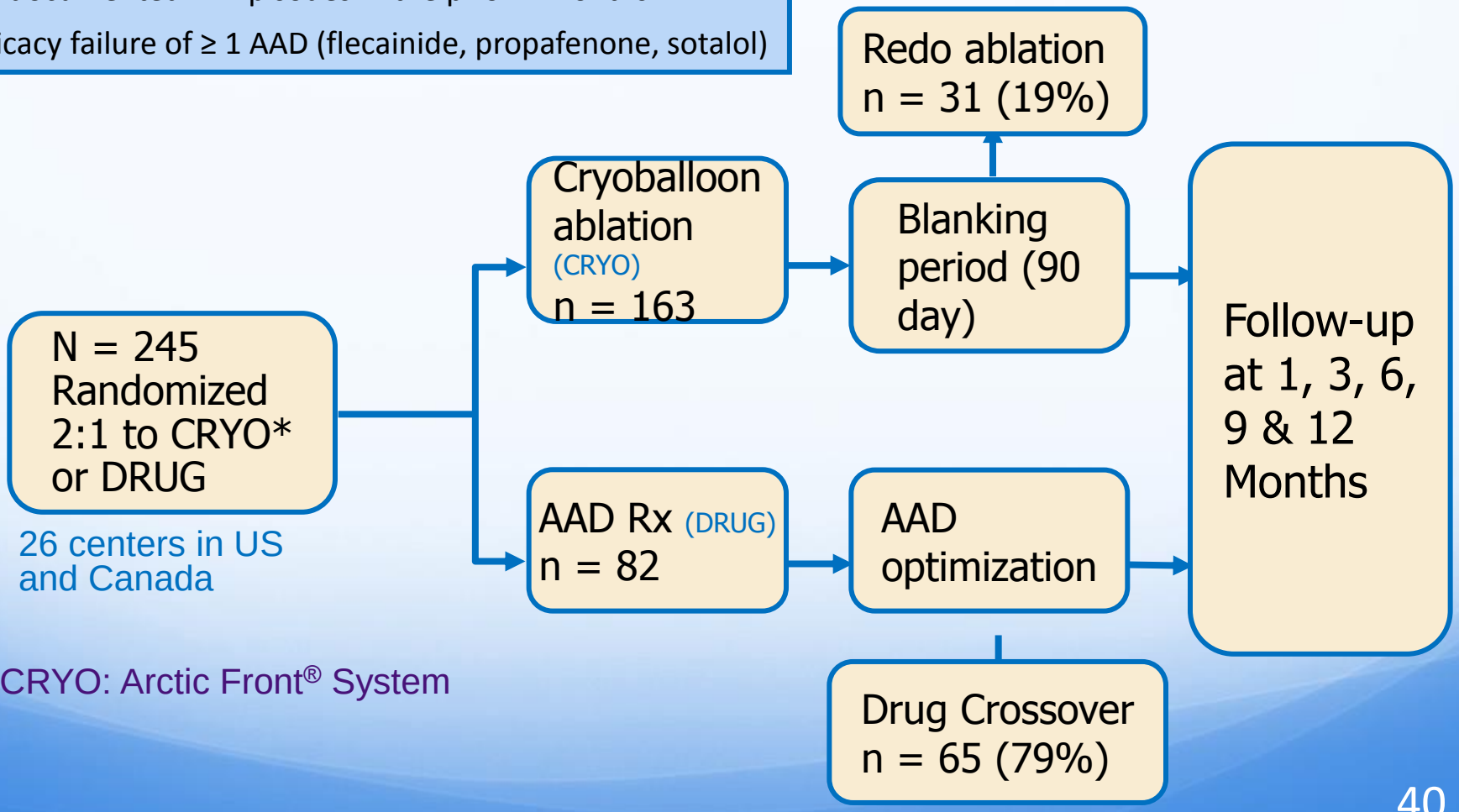
  Not in the Pulmonary veins !

- **Pace the Phrenic Nerve**
- **Monitor Esophageal Temperature**

STOP AF Trial
Sustained Treatment of Paroxysmal Atrial Fibrillation

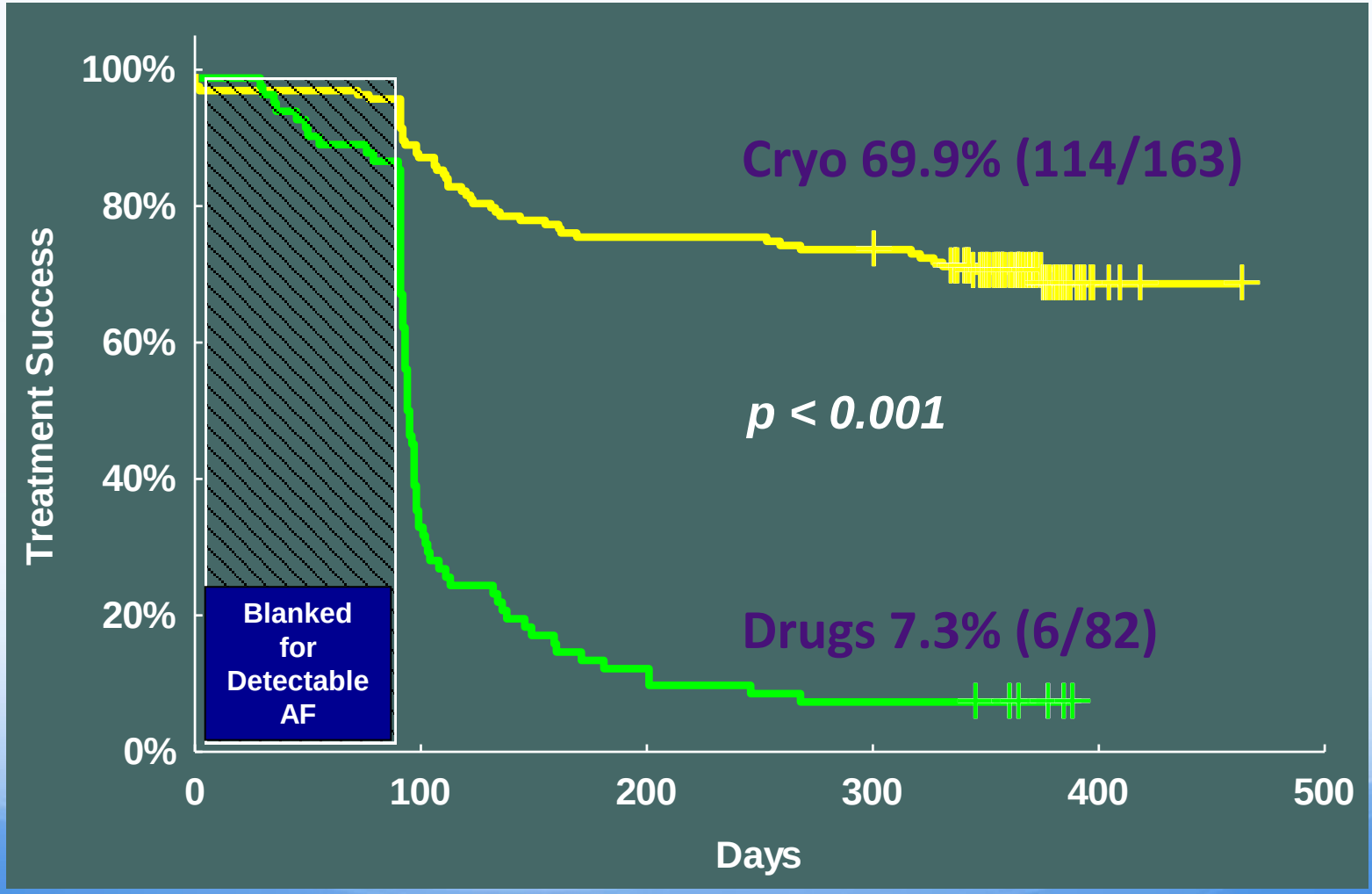
Inclusion Criteria:

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

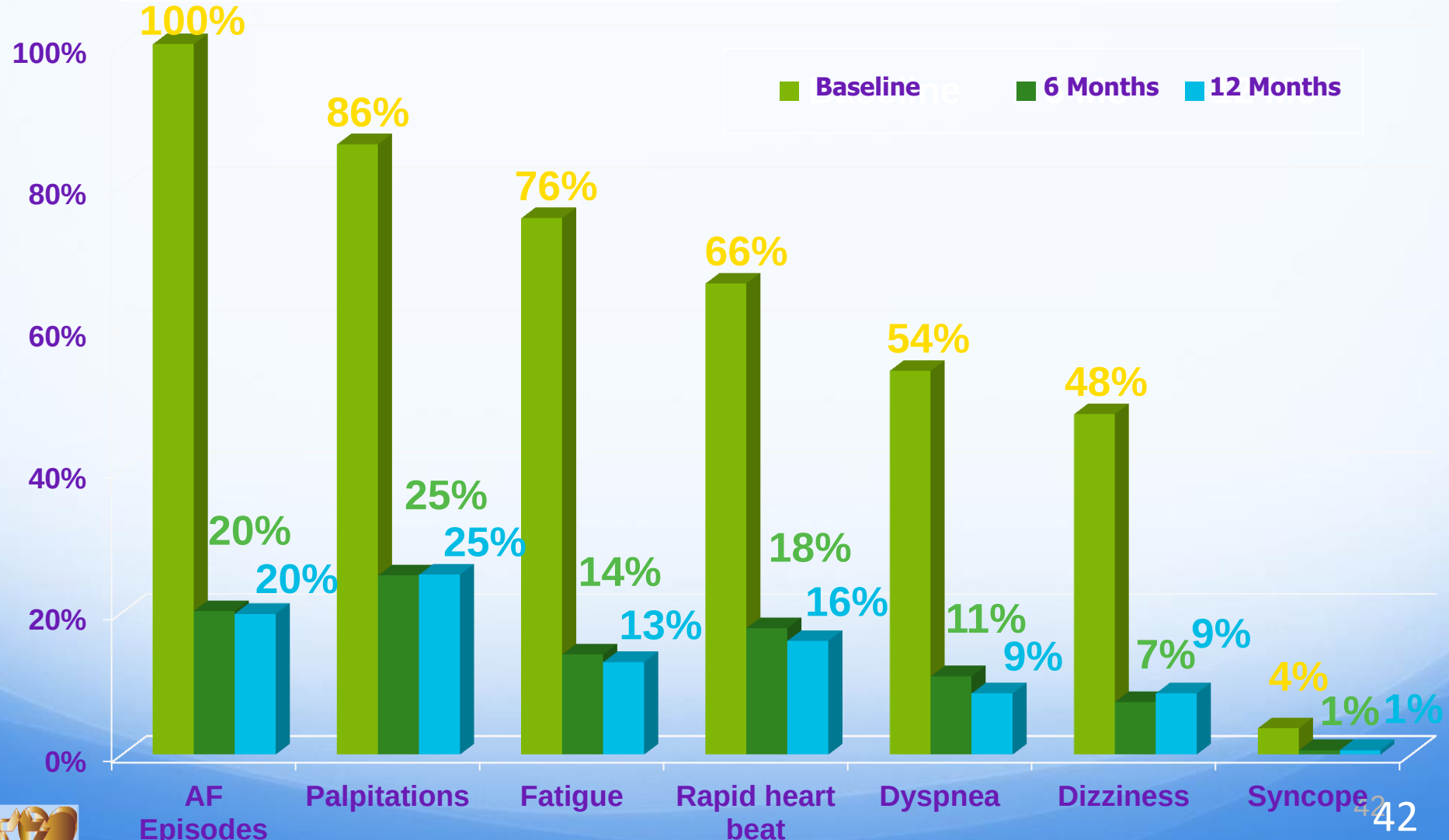


* CRYO: Arctic Front® System

STOP AF Trial - Results



AF Symptoms at 12M: CRYO Subjects



US Continued Access Protocol (CAP)

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

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%
- One patient had a second ablation procedure using RF. At this time, the root cause of the PV stenosis is under review.

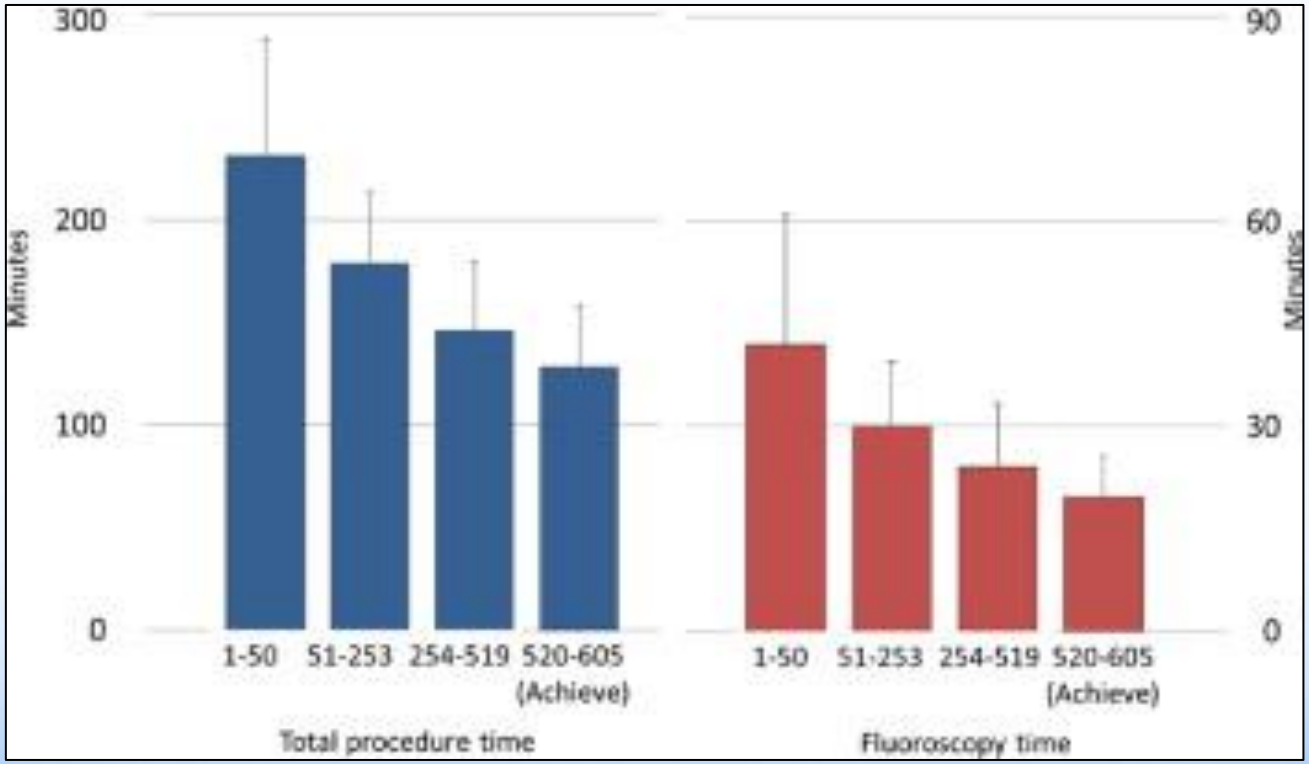
Long Term Follow up – Vogt at al

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 data 12< 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



Long Term Follow up – Neumann at al

Europace 2013

- In a prospective European single-center study, 163 patients underwent PVI with a cryo-balloon. Five years success rate after a single ablation procedure was 53%.
- Up to 11% of the patient experienced phrenic nerve palsy, all reversible within 9 months.

Back to our patient…

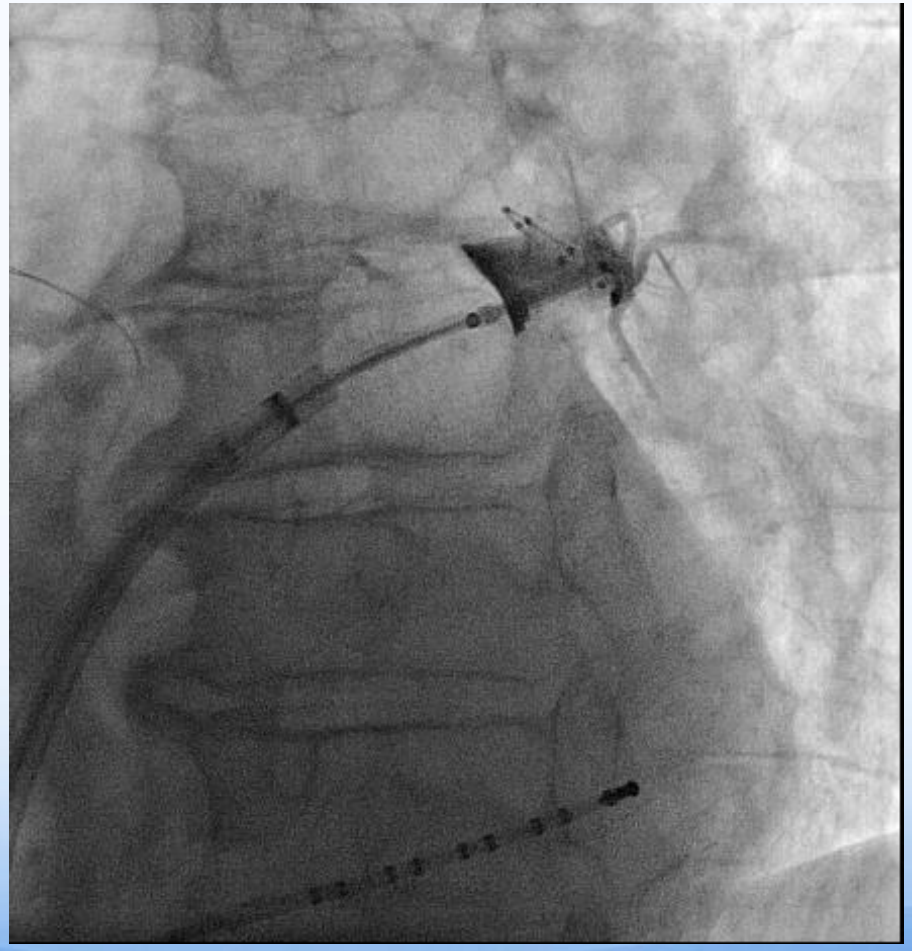
- He underwent successful Isolation of 4 PV's on 13.03.2013

Shaare Zedek Ablation Protocol

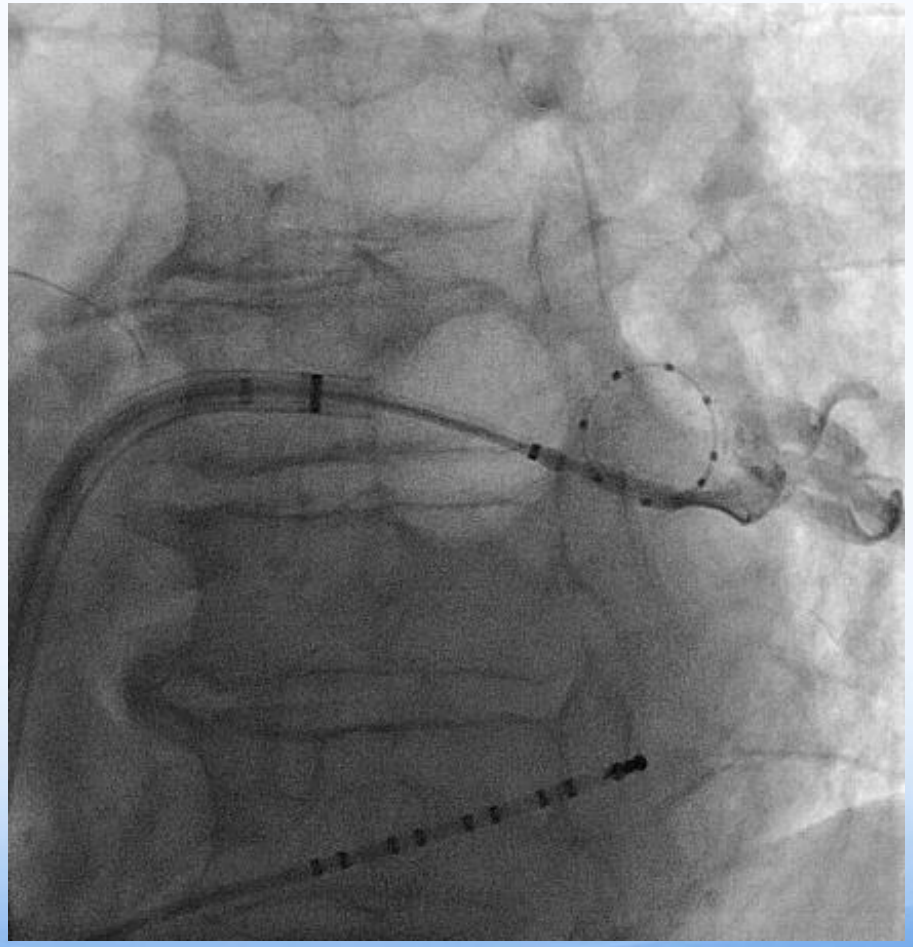
- Cardiac CT and Trans-Esophageal Echocardiography were performed the day before the procedure.
- Cardiac CT images underwent segmentation using the Ensite Velocity system (St. Jude Medical) to obtain a 3-D picture of the LA and assess the PVs diameters.
- A single trans-septal puncture was performed and a deflectable sheath (FlexCath, Medtronic) was advanced into the LA.
- A 28 mm only Cryo-balloon (Arctic Front, Medtronic) was advanced over a 20 mm lasso catheter (Achieve, Medtronic) placed through its central lumen.
- Rt. phrenic nerve stimulation was performed during ablation of the right PVs.
- The esophageal temperature was monitored during ablation.

CT Image of Pulmonary Veins

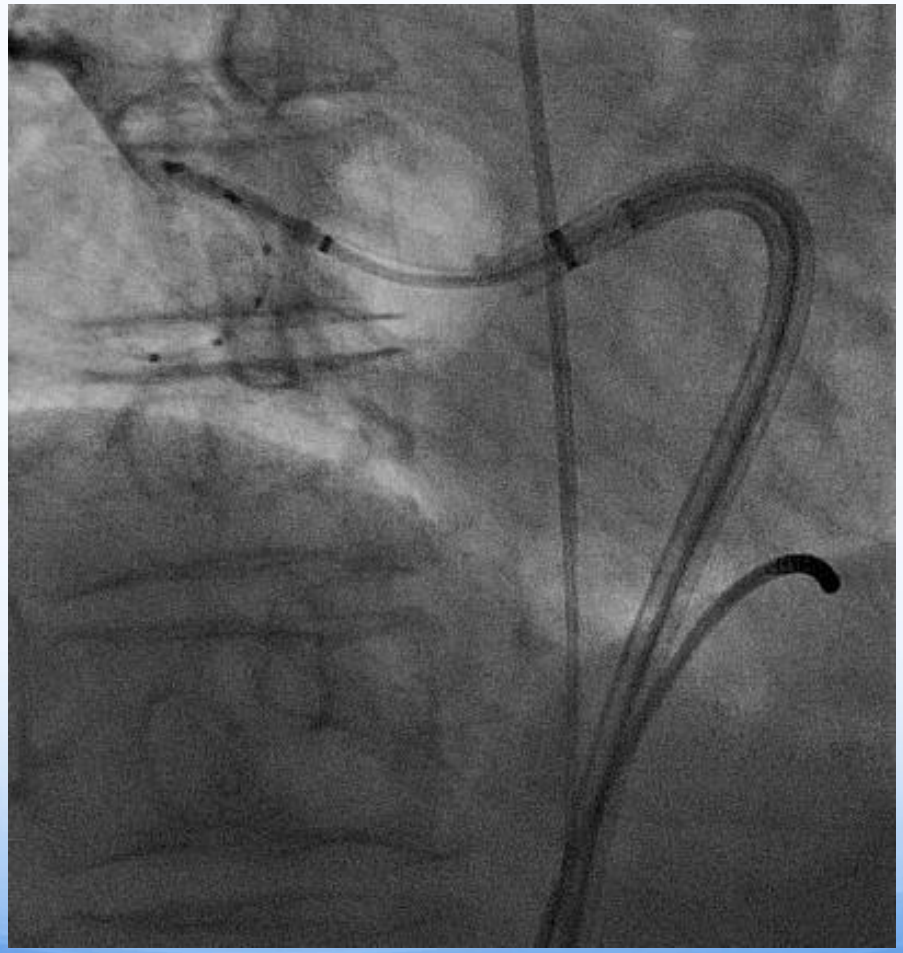
Cryo-Ablation of LSPV



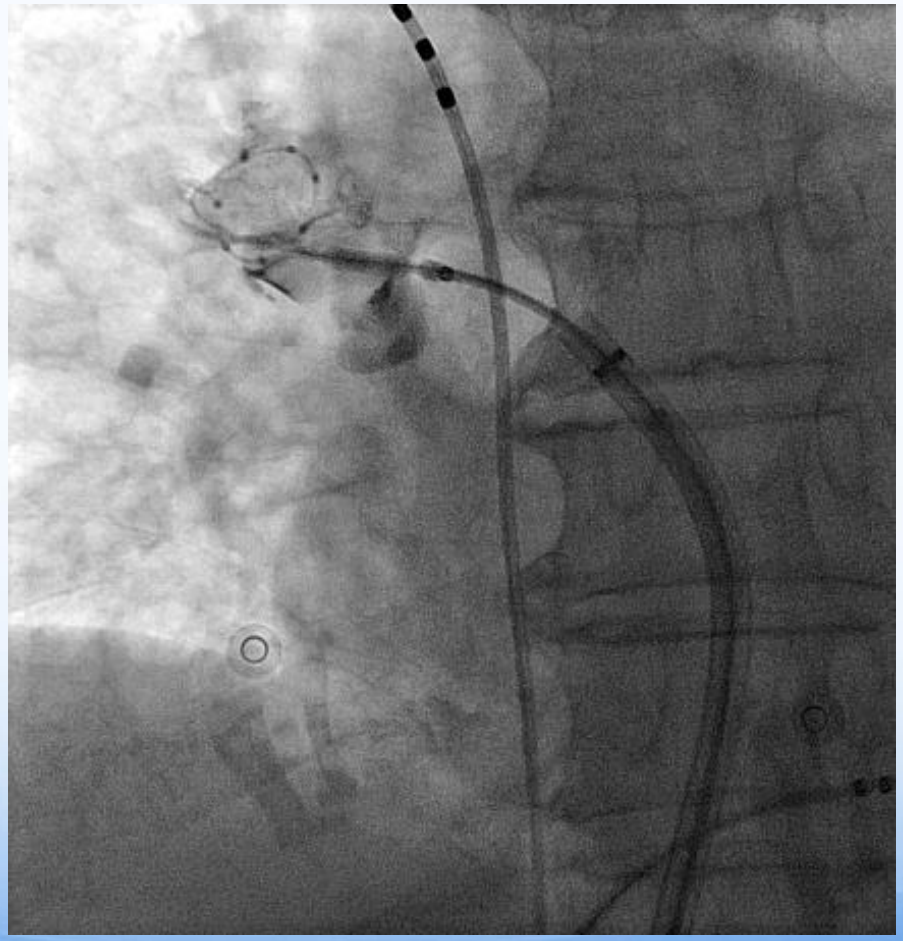
Cryo-Ablation of LIPV



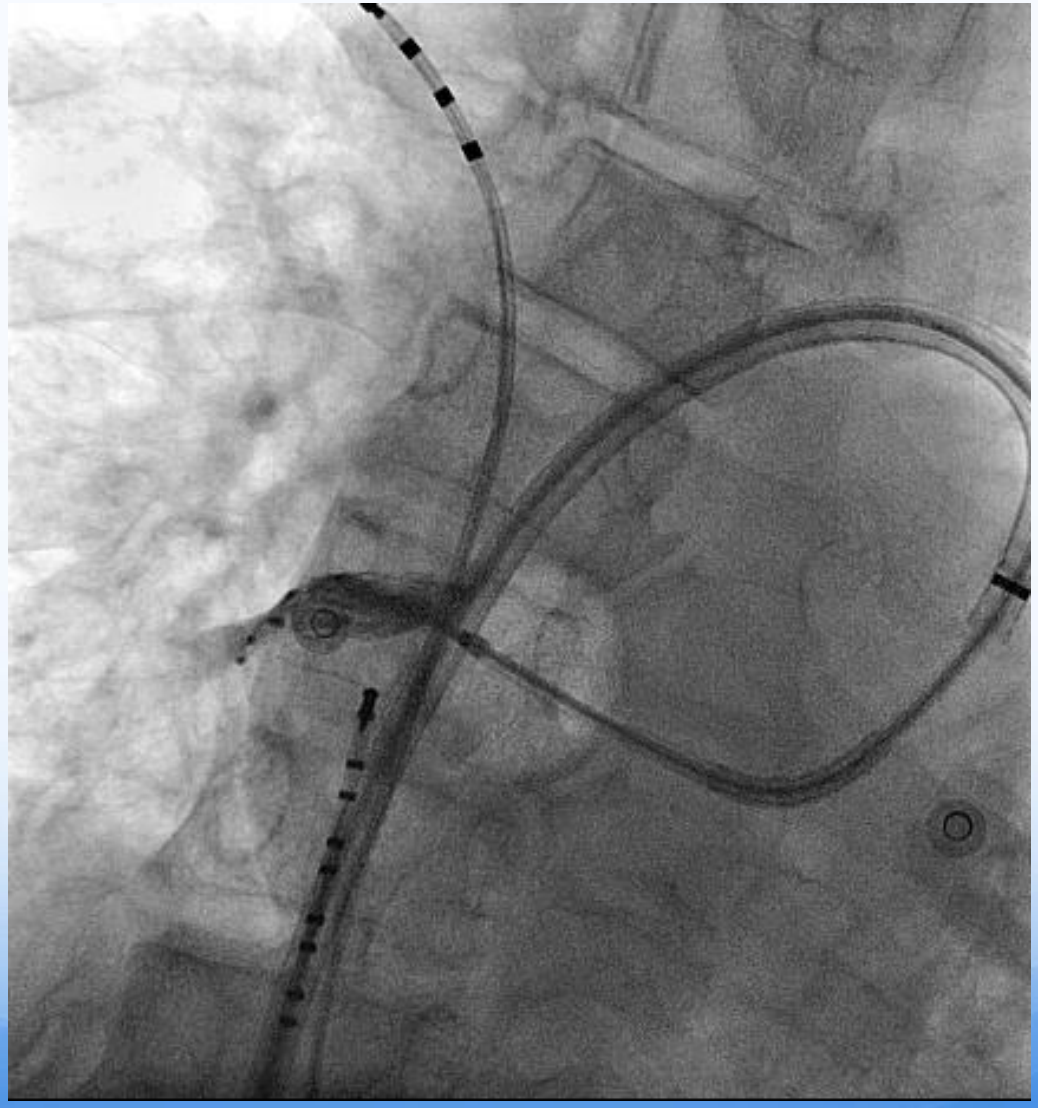
Cryo-Ablation of RIPV



Cryo-Ablation of RSPV



Cryo-Ablation of RIPV – Big Loop



Pulmonary Vein Isolation

Shaare Zedek Experience

- Between July 2012 & May 2013, cryo-ablation was performed in 18 patients (age 56 [22-68]) for whom at least one AAD has failed: 12 with paroxysmal AF, 5 with persistent AF and 1 with left atrial tachycardia.
- 66 of 70 PV's (94.3%) were successfully isolated. The right inferior PV was not isolated in 4 patients: 1 -not attempted, 1 - technical issue, 2 - unsuccessful.
- Radiation time was 70 ± 32 min (dropping with learning curve).
- After the 3 months blanking period, sinus rhythm was maintained in 80% of patients, follow up averaging 193 days (range 72-325).

Shaare Zedek Experience

Complications:

- Phrenic nerve palsy occurred in 1 patient (5.6%) and lasted for 30 minutes.
- Two patients had a minor pericardial effusion.
- No PV stenosis or esophageal fistula.

Conclusions

Cryoablation with the Arctic Front System:

- Effectively treats drug refractory PAF or early persistent AF.
- Is a safe and efficient procedure.
- Has shorter procedure times compared to RF ablation according to large published trials.
- Further follow up is needed to assess the long-term success rate.

Our Patient?

- So far in Sinus Rhythm… (3 months and 4 days)