

Balloon and Mesh Catheter Ablation of Pulmonary Veins

ISHNE 2009

Atul Verma, MD FRCPC
Cardiology/Electrophysiology
Heart Rhythm Program, Division of Cardiology
Southlake Regional Health Centre
Newmarket, Ontario, Canada

September, 2009



Disclosures

- Moderate Support (honoraria, speaking bureau, research)
 - St Jude Medical International
 - Medtronic Canada
 - Biosense Webster
- Advisory Board
 - St Jude Medical International
 - Biosense Webster

Objectives

- Better understand where we are in the application of balloon and mesh technologies for ablation of pulmonary veins
- Assess the benefits and limitations of both approaches
- To characterize the type of patient where this technology will be best applied

Case 1

- 50 year old male
- Past medical history – appendectomy, hypertension
- 5 years of symptomatic paroxysmal atrial fibrillation
- Episodes last 3-4 hours and occur every week
- Failed propafenone and sotalol
- LA size is 43 mm in PLAX view
- You book him for AF ablation

Case 1

- Which of the following techniques would you use (assuming all were available to you)?
- A = point by point catheter-based PVI
- B = balloon-based cryoablation PVI
- C = mesh-based ablater PVI
- D = remote navigation based PVI

Case 2

- 50 year old male
- Past medical history – hypertension, hyperlipidemia, sleep apnea with CPAP
- 8 years of symptomatic paroxysmal atrial fibrillation which has become persistent
- Feels much better when cardioverted, but only lasts 2-3 weeks
- Failed sotalol, flecainide, and now dofetilide
- LA size is 48 mm in PLAX view
- You book her for AF ablation

Case 2

- Which of the following techniques would you use (assuming all were available to you)?
- A = point by point catheter-based ablation
- B = balloon-based cryoablation
- C = mesh-based ablater
- D = remote navigation based ablation

Balloon-Based Ablation

Arctic Front - Cryoballoon

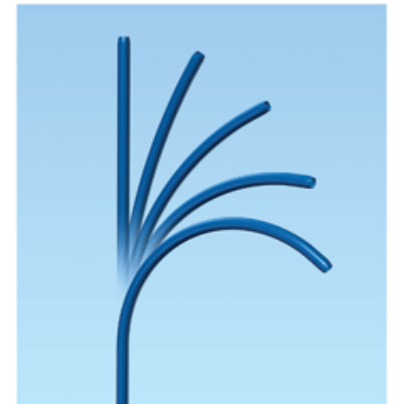
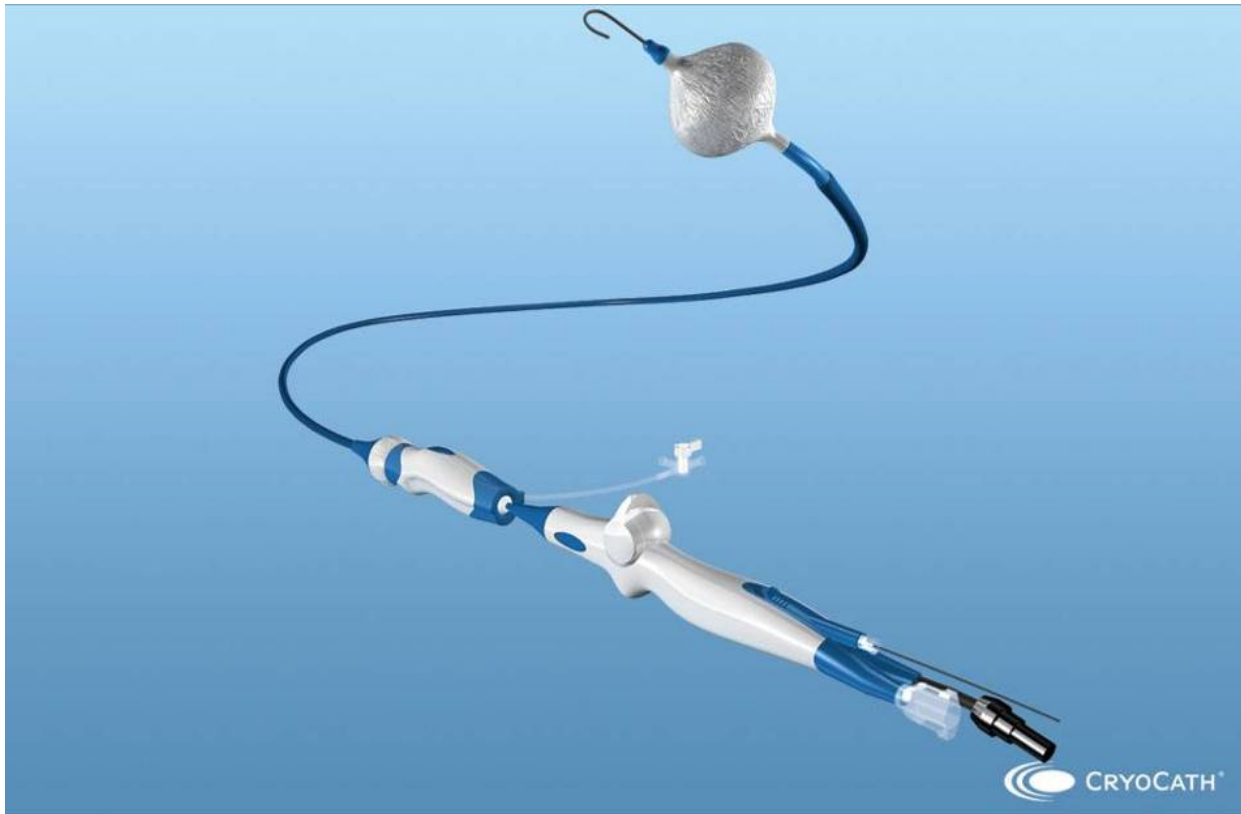


- **Investigational Device Exemption (IDE) Study ongoing and is not available for sale in the United States.**
- **The information provided does not constitute any safety and effectiveness claims.**



-
- **The Arctic Front Cardiac CryoAblation Catheter is intended for the treatment of patients suffering from paroxysmal atrial fibrillation (PAF). Adjunct devices (Freezor *MAX*) can be used with Arctic Front in the treatment of PAF.**

Arctic Front - Cryoballoon

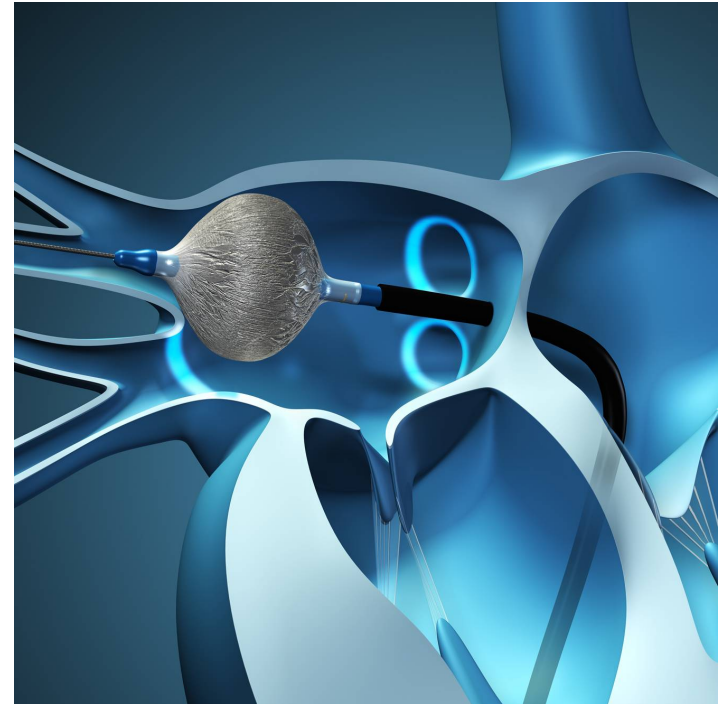


SOUTHLAKE
REGIONAL HEALTH CENTRE

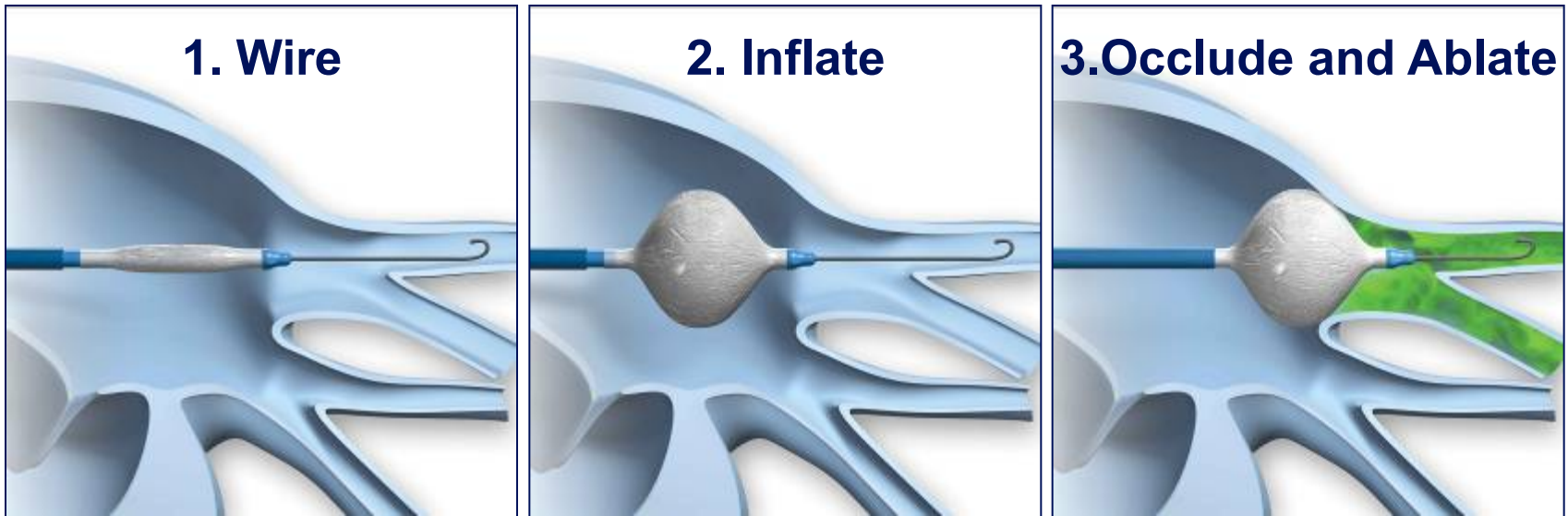
Arctic Front - Cryoballoon

23mm

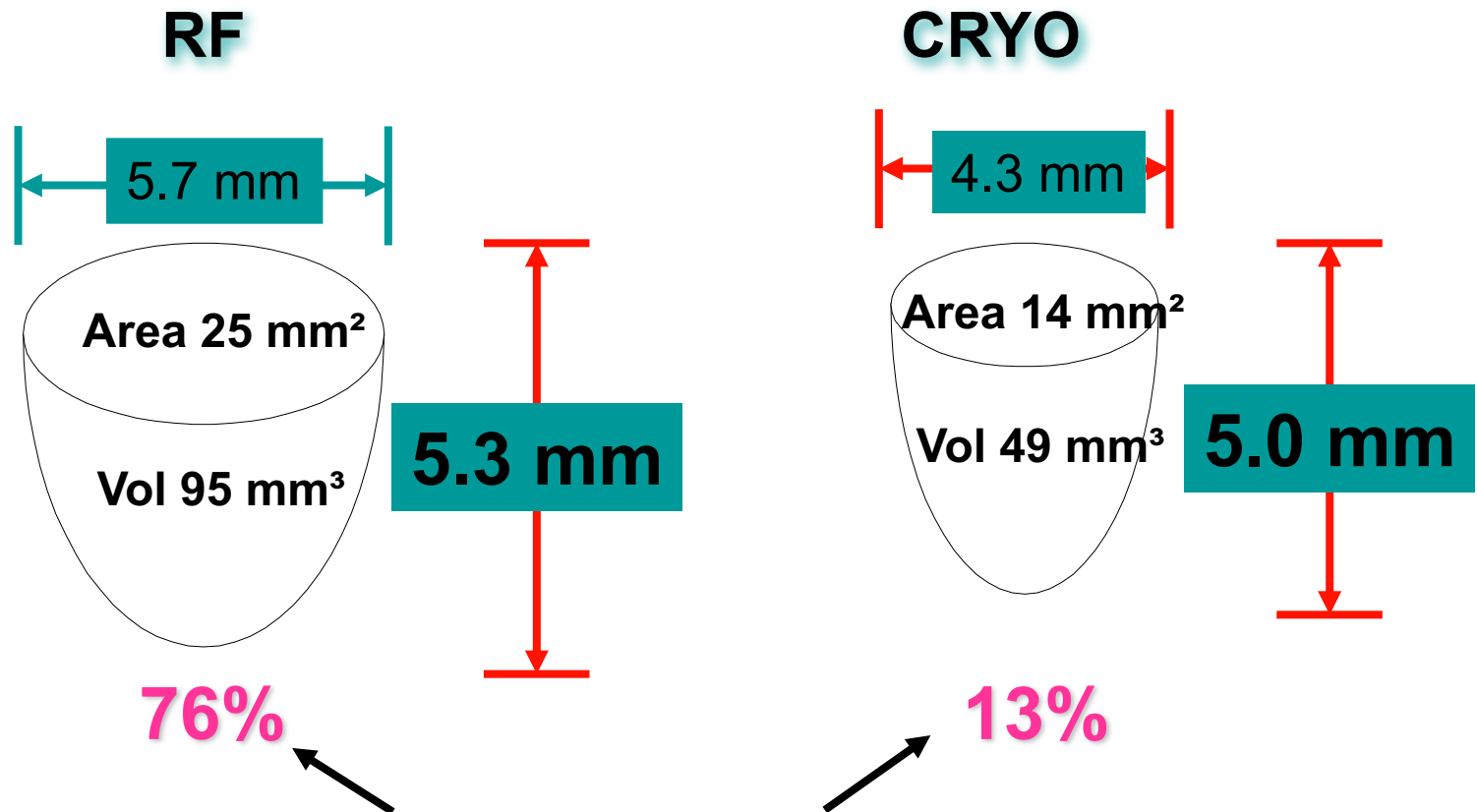
28mm



Arctic Front - Cryoballoon



Lower Incidence of Thrombus Formation with Cryoenergy Vs Radiofrequency Catheter Ablation

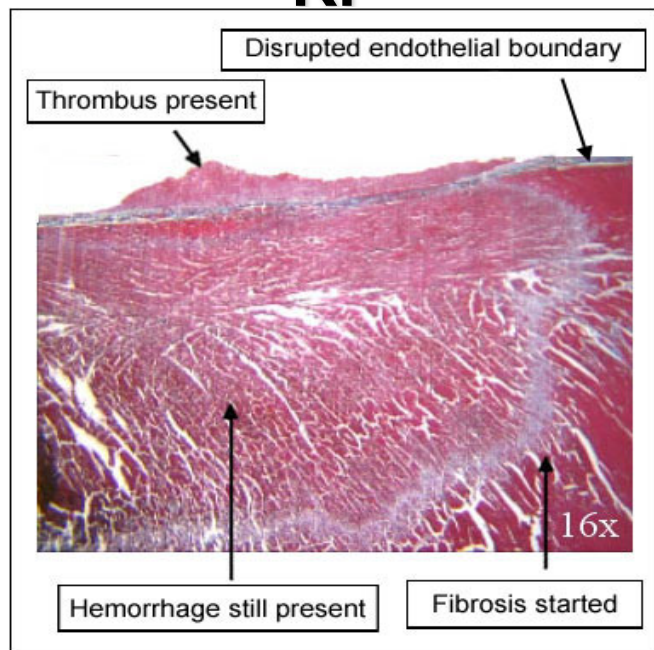


Incidence Of Thrombus

SOUTHLAKE
REGIONAL HEALTH CENTRE

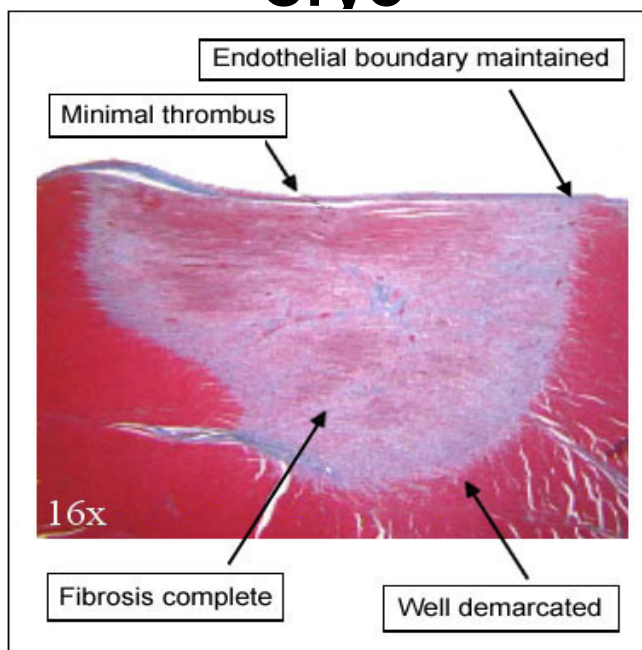
Effect on the Connective Tissue Matrix and Thrombogenicity

RF



**RF lesion at 1 week (Canine
+70° C - 50W • 60
seconds**

Cryo



**Cryolesion at 1 week (Canine
-75° C • 1 x 4
minutes**

Less
thrombogenic.

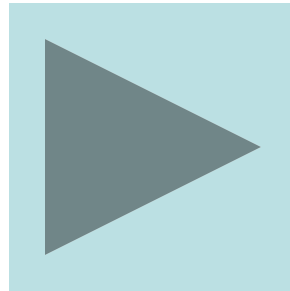
Less collateral
damage?
(no PV
stenosis,
esophagus?)

More
reversible
lesion?

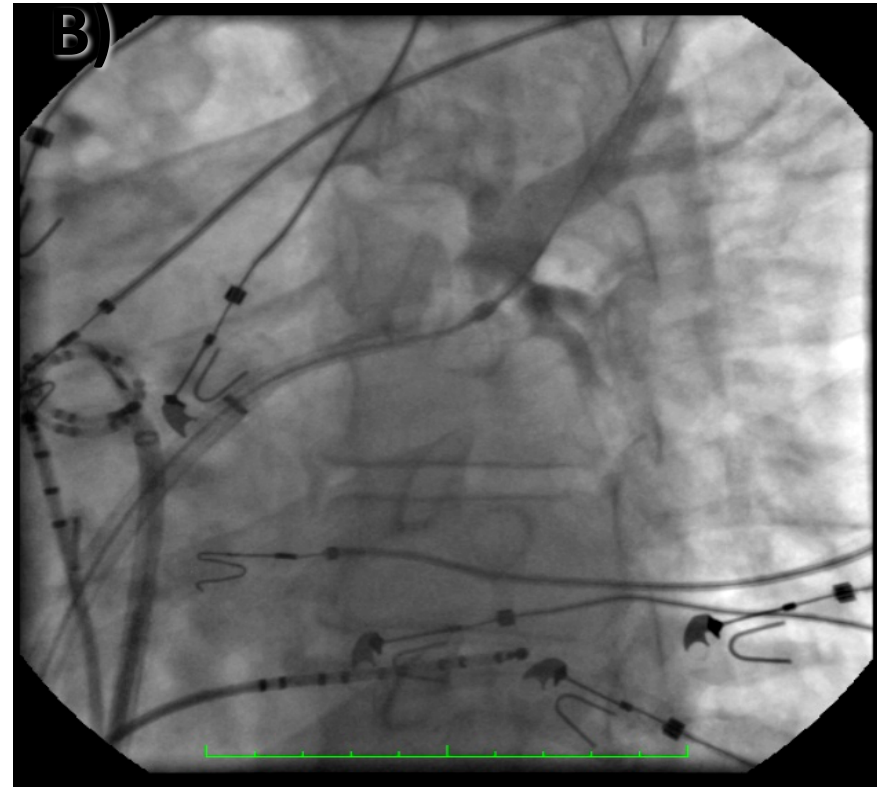
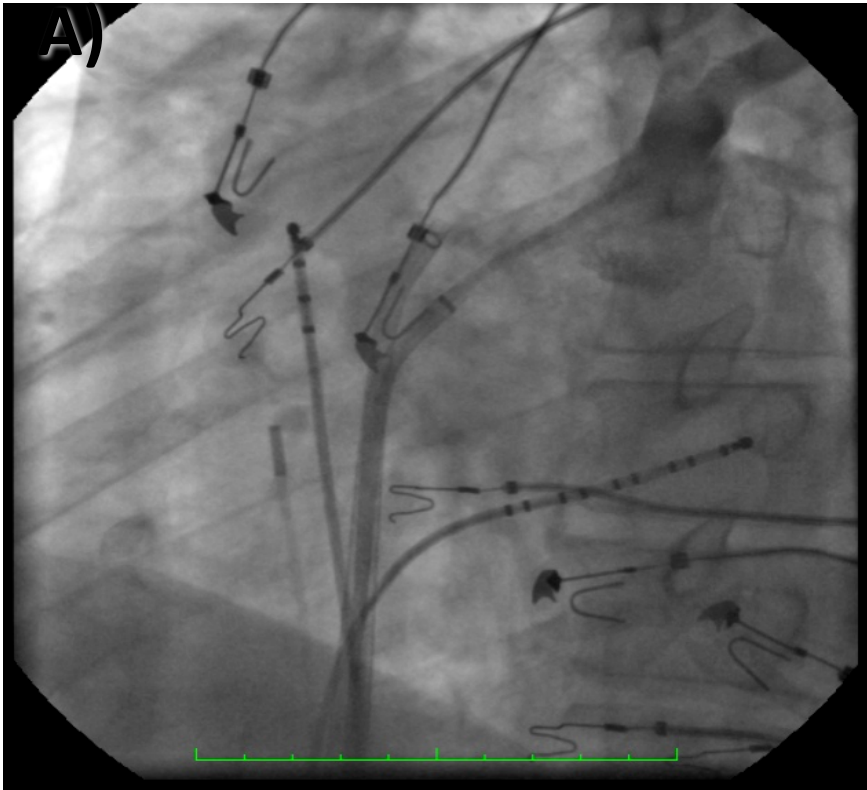


SOUTHLAKE
REGIONAL HEALTH CENTRE

Complete Occlusion is Key

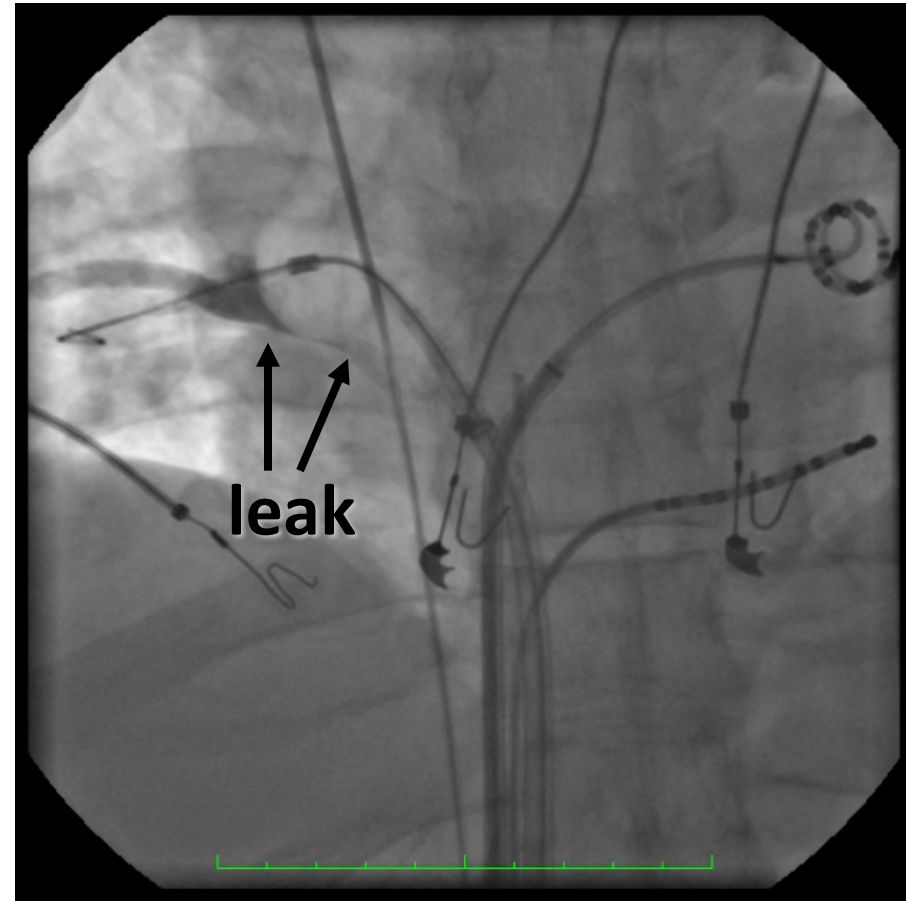
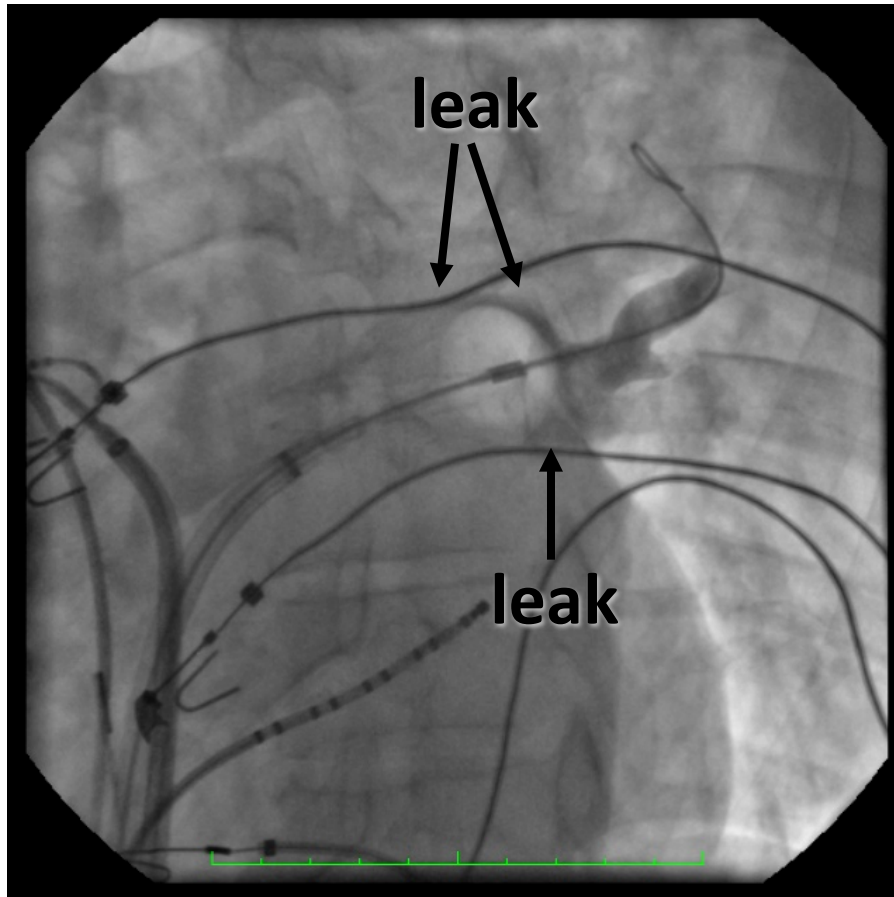


Occlusion is Key



- **Contact with entire PV ostium**
- **Blood flow halted = better cooling**
- **Circumferential lesion with single application**

Leak = Incomplete Lesions



Case Study: Cryoballoon

Optimizing Occlusion



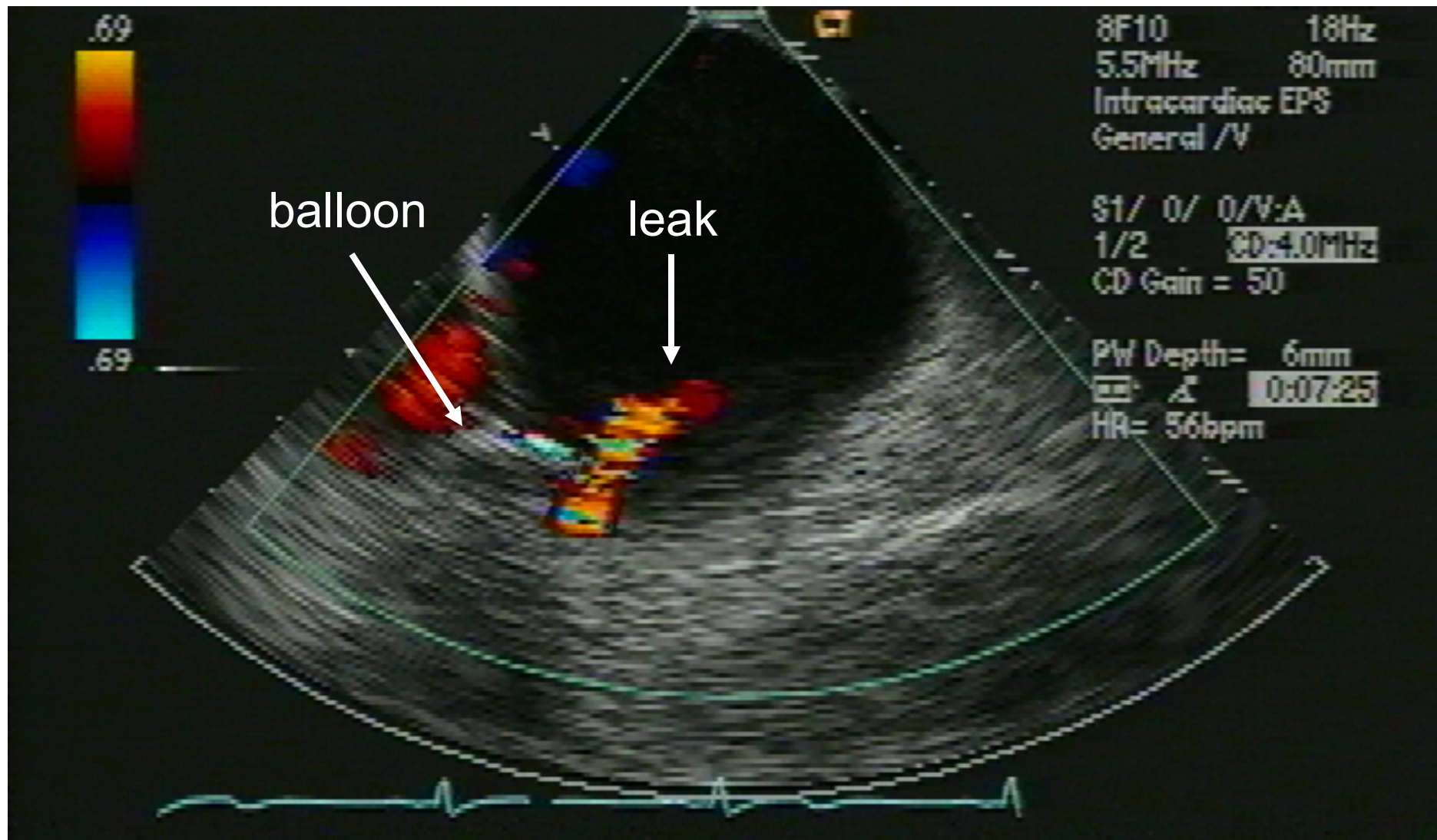
**Incomplete LSPV occlusion with
leak of contrast into the atrium
(Guide wire in inferior branch)**



SOUTHLAKE
REGIONAL HEALTH CENTRE

Courtesy Marc Dubuc, MD

ICE Monitoring for Leak



Optimizing Occlusion



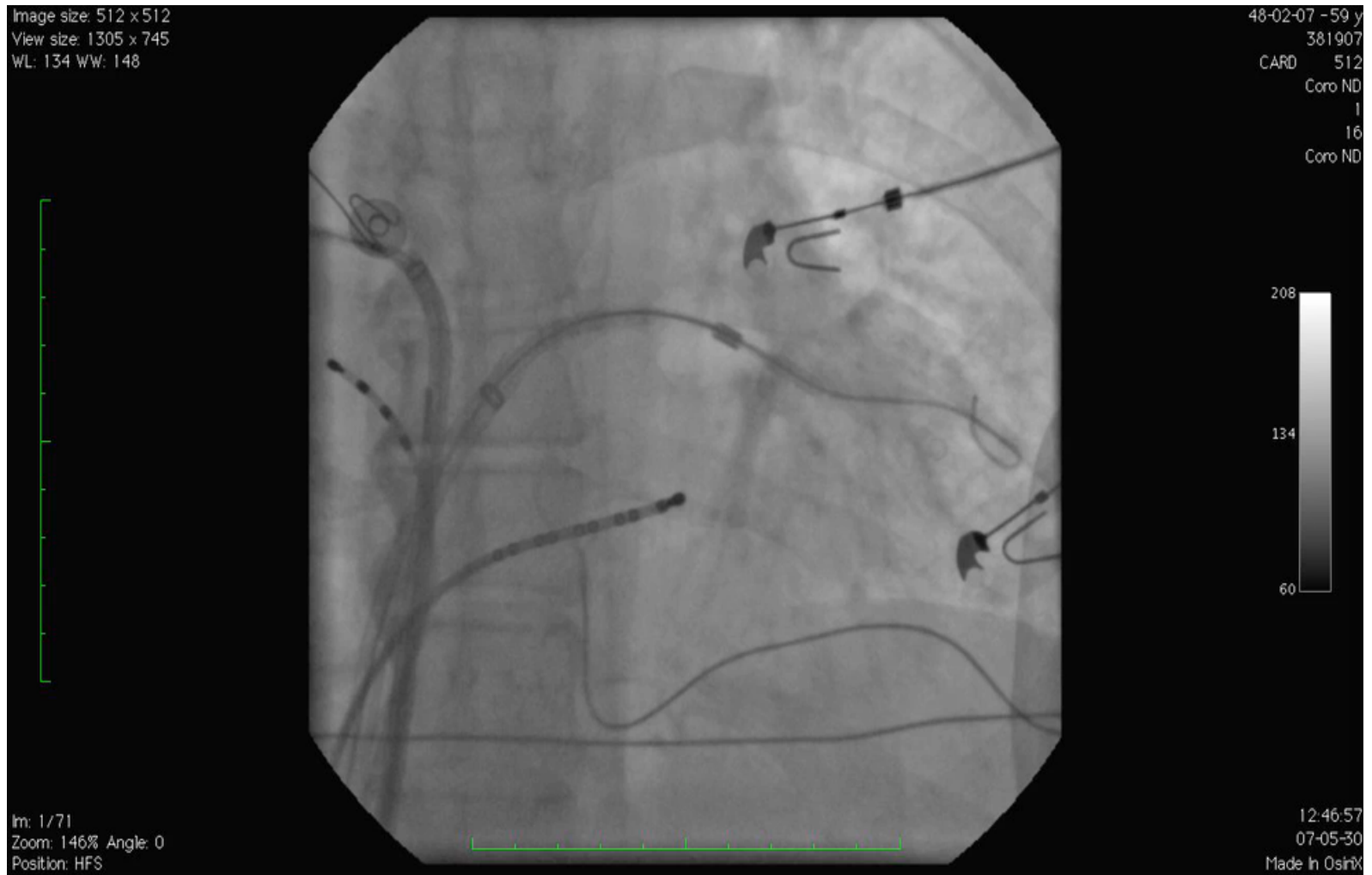
**Incomplete LSPV occlusion with
leak of contrast into the atrium
(Guide wire in superior branch)**



SOUTHLAKE
REGIONAL HEALTH CENTRE

Courtesy Marc Dubuc, MD

Optimizing Occlusion

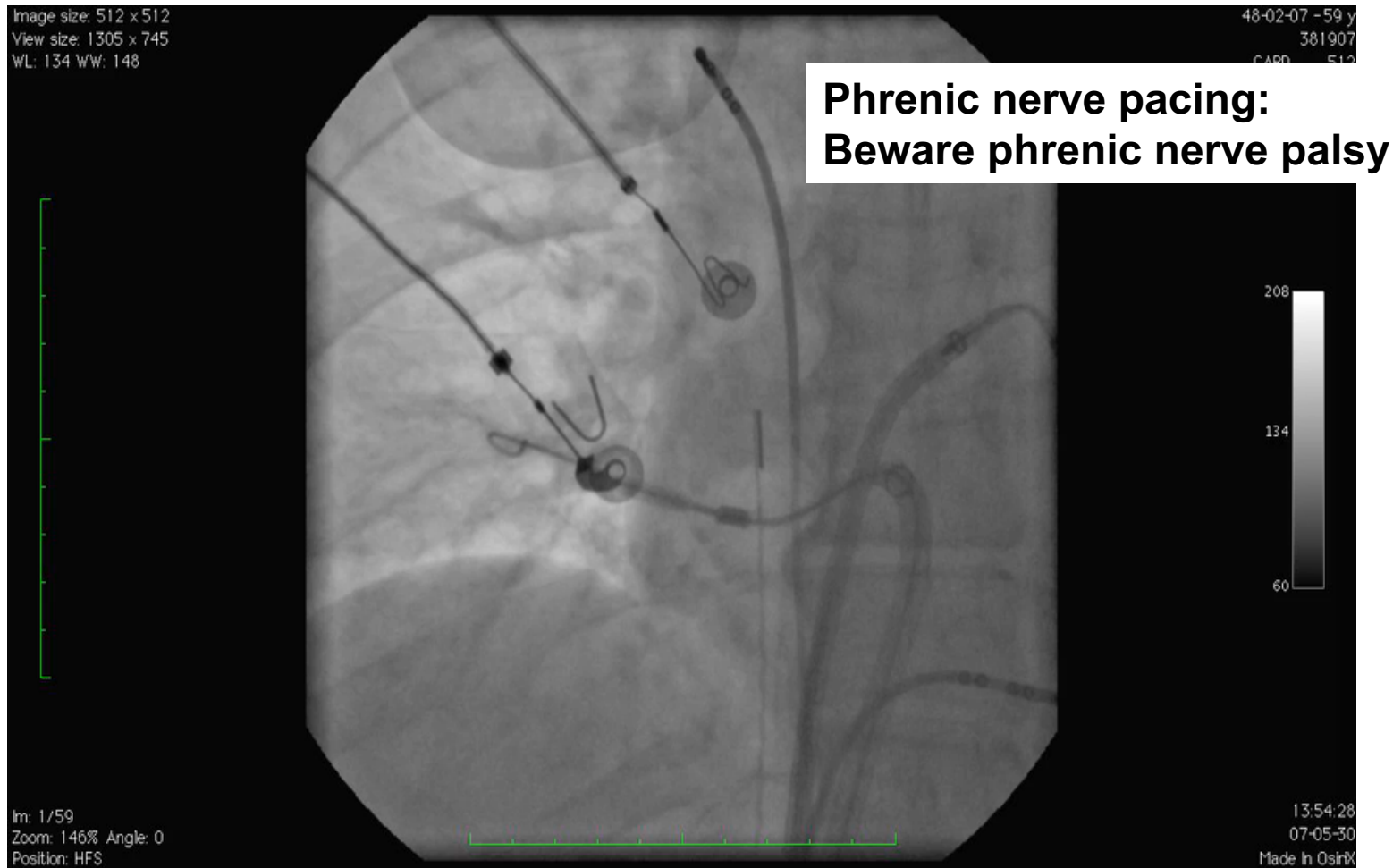


**Complete LIPV occlusion with no
leak of contrast into the atrium**



Courtesy Marc Dubuc, MD

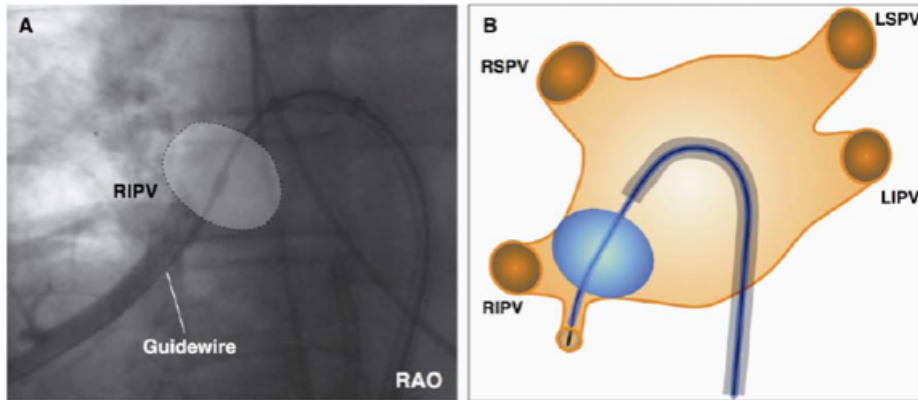
Cryoablation and Right Pulmonary Veins



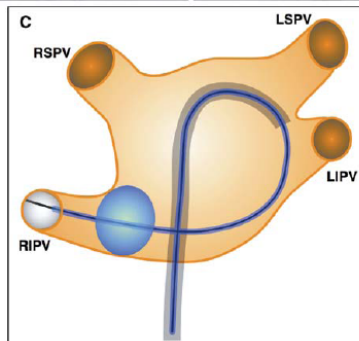
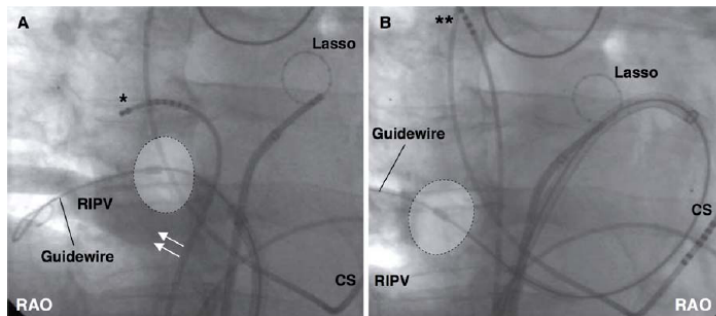
Complete RIPV occlusion with no leak of contrast into the atrium and pacing the phrenic nerve with a quadripolar catheter

Courtesy Marc Dubuc, MD

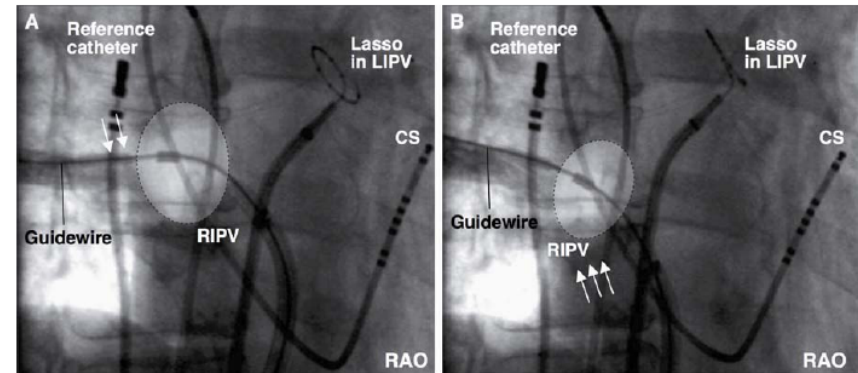
Inferior PVs can be a Challenge



“Hockey stick” technique



“Big loop” technique



“Pull down” technique

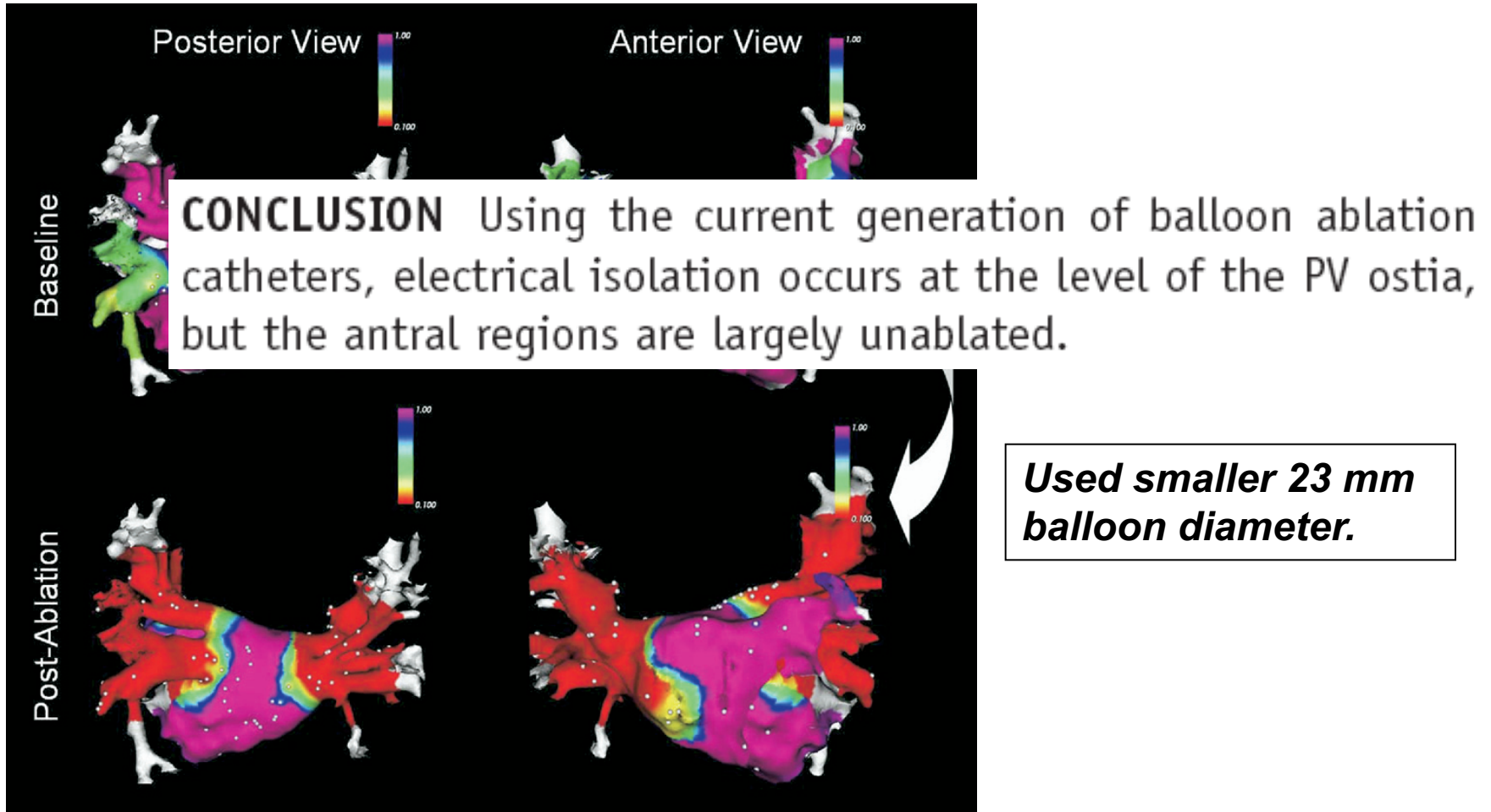
Clinical Results - Cryoballoon

	Number of pts	Type of AF	Acute Success	F/U (days)	Outcomes	Comments/ Complicat'n
Chun, Kuck et al, 2009 (28 mm)	27	100% parox, lone AF	98% PVs isolated except 2 RIPVs	271	70% cure (TTM)	3 PNPs – recovered 0,28,384 d
Van Belle et al, 2008	139	100% parox, lone AF	100% PVs w/ balloon & cath	457	59% cure (1,2 proc)	4 PNPs – recov 6 mo
Malmborg et al, 2008	40	80% parox, 18% parox/persist	91% had PVI w/ ball & cath	270	45% cure off drug, 53% on	2 PNPs, 2 dysphagia
Neumann et al, 2008	346	85% parox, 15% persist	97% had PVI w/ ball & cath	Median 365 (76% >6mo)	74% parox, 42% persist, some loss f/u (7d Holter)	24 PNPs, mostly w/ 23 mm, resolve <1y
Klein et al, 2008	21	100% parox	95% of PVs isolated	172	86% (Holter)	3 PNPs

Clinical Results

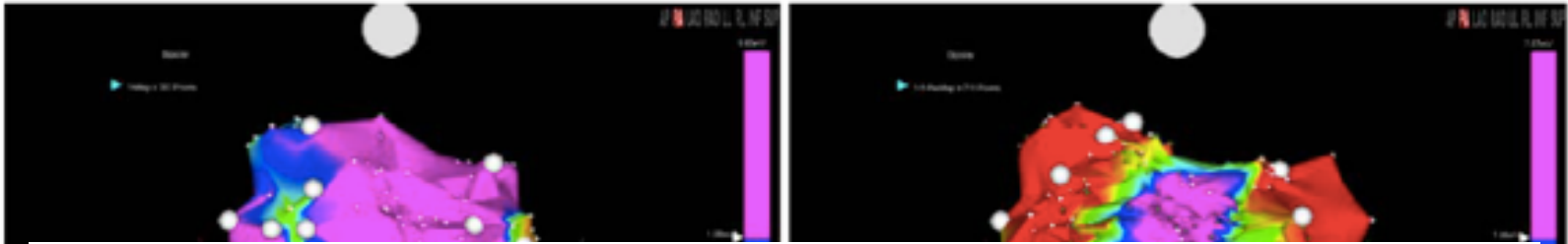
- Predominantly paroxysmal, lone AF population
- Most of these done by skilled operators
- Success rates of traditional catheter ablation 75%-90% after 1-2 procedures in this population
- Success rates seem a bit lower
- Follow-up duration is limited
- Risk of PNP – but most resolve within 6-12 mo
- Faster, shorter procedure

Level of Isolation – Ostial or Antral?



Reddy et al, Heart Rhythm 2008

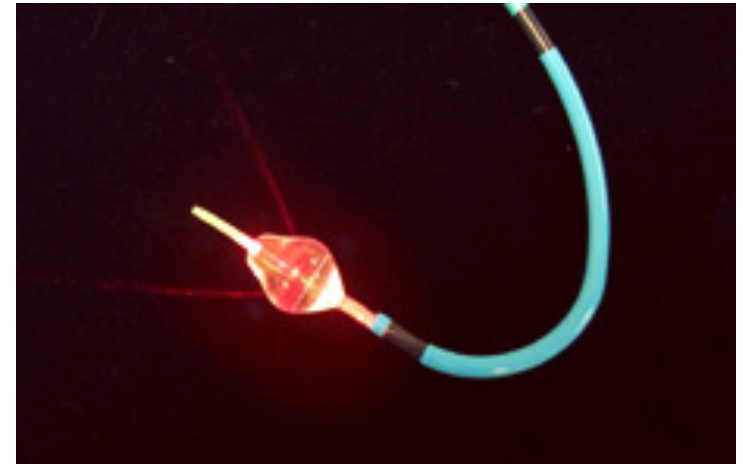
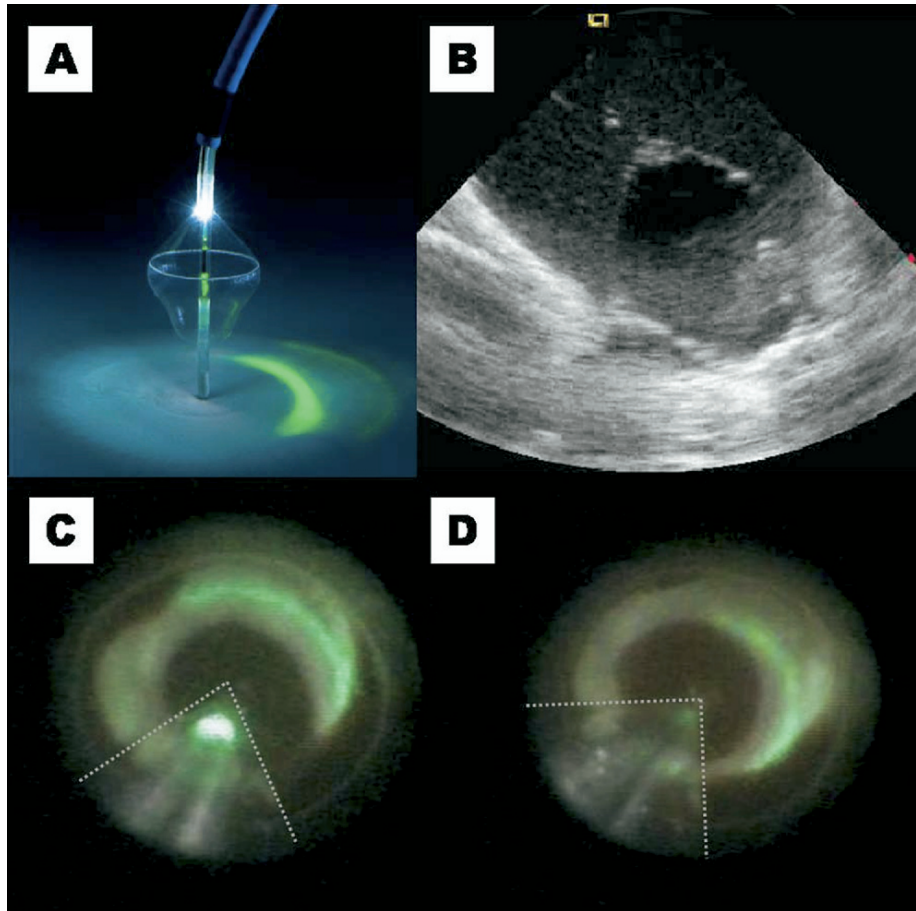
Level of Isolation – Ostial or Antral?



Conclusions In cryoballoon PVI, the majority of the veins undergo antral isolation. Veins with a diameter larger than the balloon, are isolated ostially. In individual cases, the left atrial activation sequence appears to be altered after ablation.

***Used larger 28 mm
balloon diameter.***

Cardiofocus – Laser Balloon



Diode laser system
Endoscope viewer - reusable

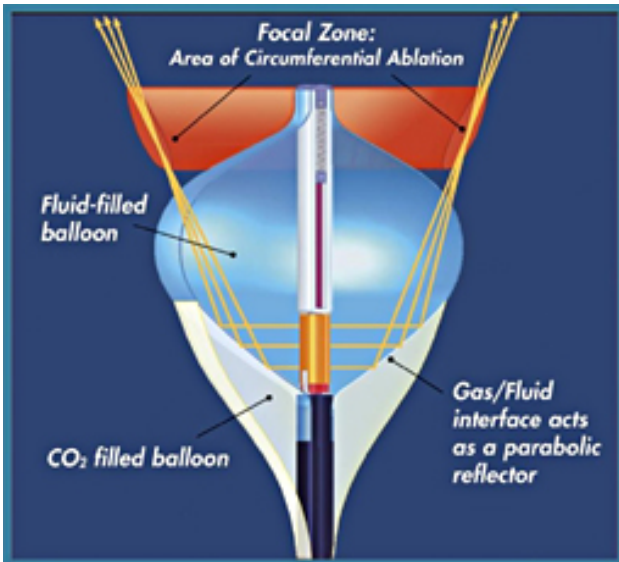
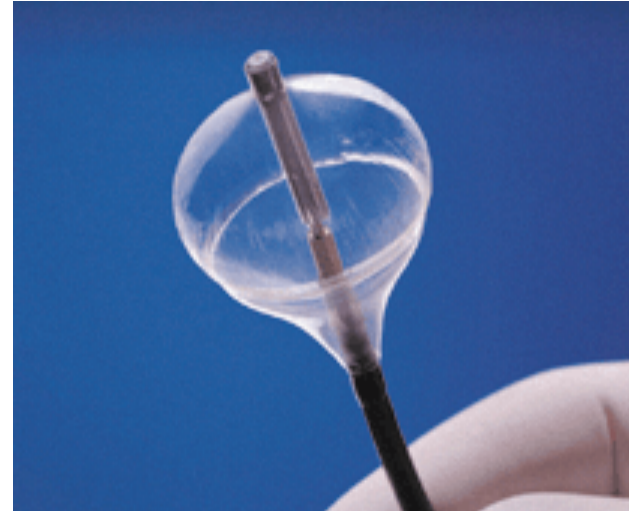
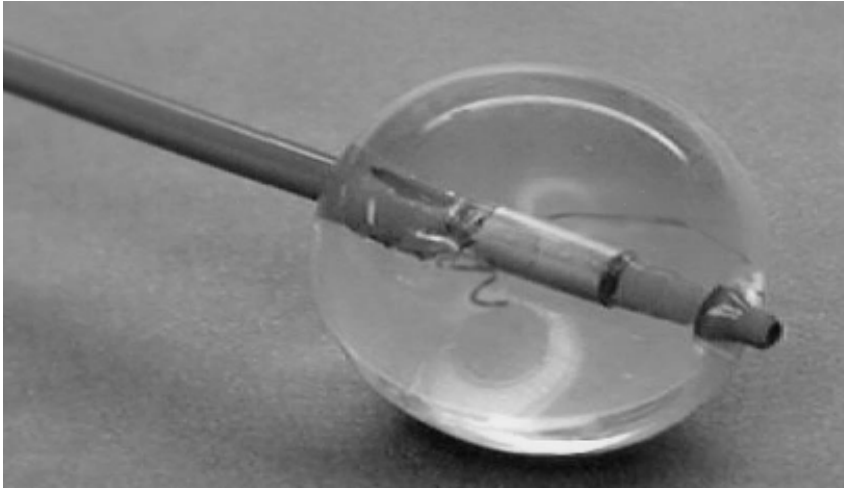
From Reddy et al, Heart Rhythm 2008

Cardiofocus – Laser Balloon

- Not much published data
- Abstract presented at AHA 2007
- 30 pts with paroxysmal AF
- Acute isolation achieved in 91% of PVs
- 70% AF-free 6 mo, 67% AF-free 12 mo
- 2 on antiarrhythmics (60% success off drugs)
- 3 adverse events (not specified)

Circulation, Supplement II, Vol 116, No 16 October 16, 2007, 2440 pp II-536

HIFU Balloon



- High Frequency Focused Ultrasound
- Reflected off a saline gas interface
- Forward focused in a ring pattern

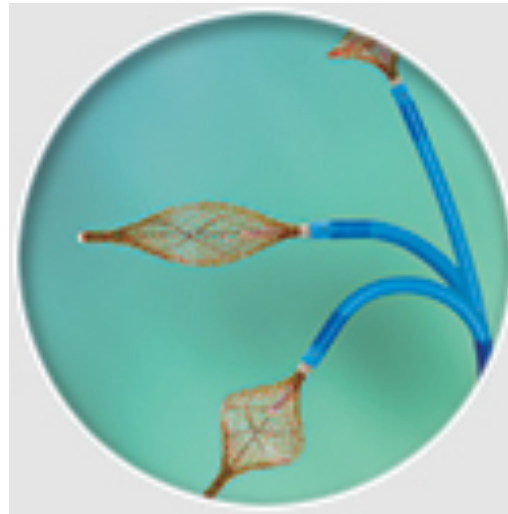
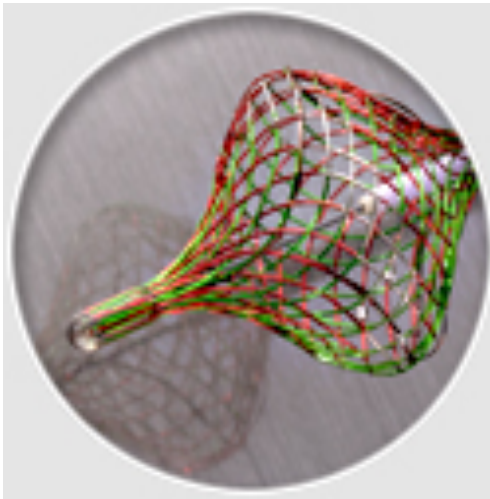
HIFU Balloon

- Nakagawa et al, JCE 2007 (n=27)
 - 87% acute PV isolation, 59% AF-free at 12 months
 - 1 phrenic nerve palsy
- Schmidt et al, Heart Rhythm 2007 (n=15)
 - 89% acute PV isolation, 58% AF-free at 12 months
 - 2 permanent phrenic nerve palsies
- US Pivotal Trial (n=240)
 - Started Jan 2007, 25 enrolling centers
 - Approx 69 patients enrolled – study halted May 2008 to investigate serious adverse events



Mesh Ablator

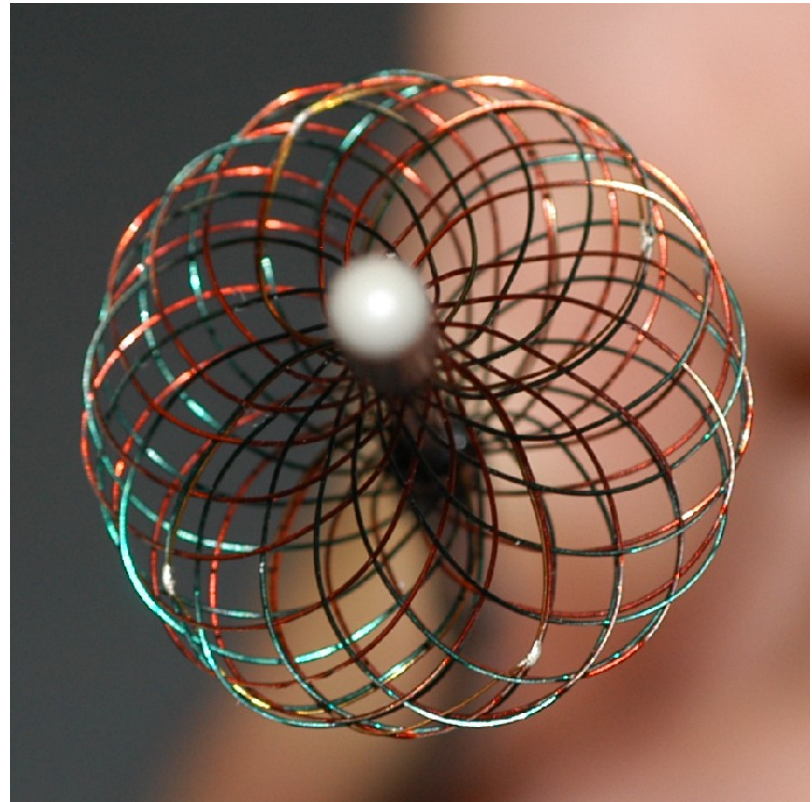
Bard HD – Mesh Ablator Catheter



SOUTHLAKE
REGIONAL HEALTH CENTRE

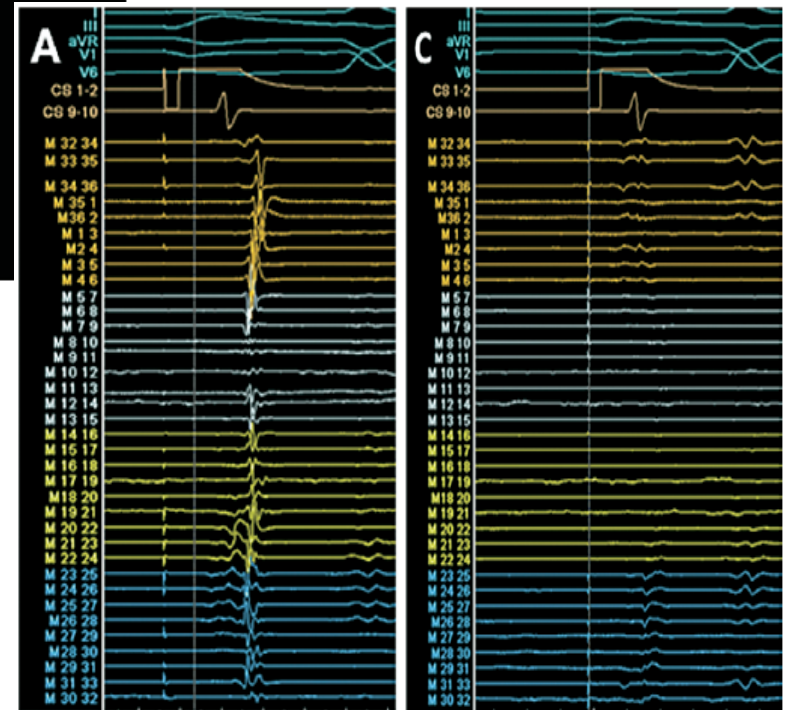
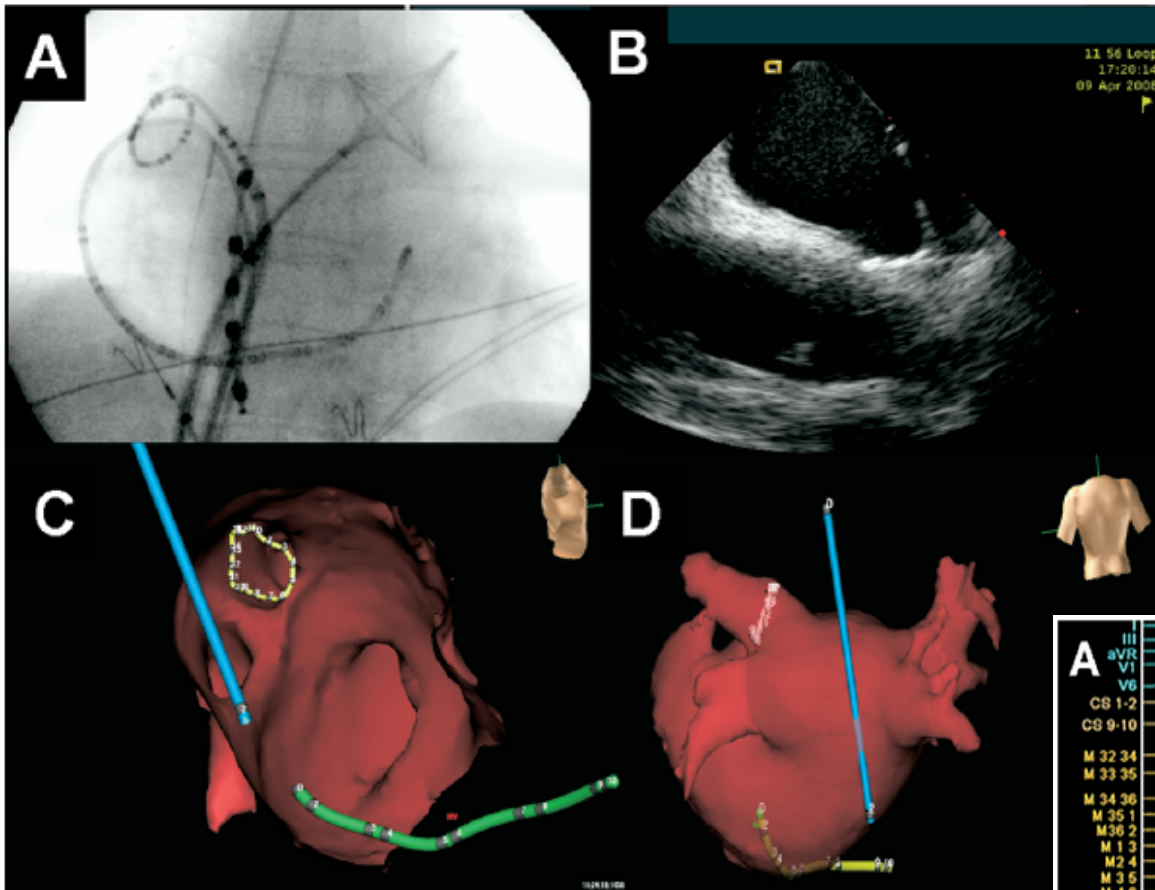
Bard HD – Mesh Ablator Catheter

- 36 pole design – allows for detailed PV signal mapping
- Delivers RF energy to multiple poles simultaneously – temperature controlled
- Pulsed RF energy delivery – contiguous lesions, prevents overheating and char
- Does not occlude blood flow – mesh design



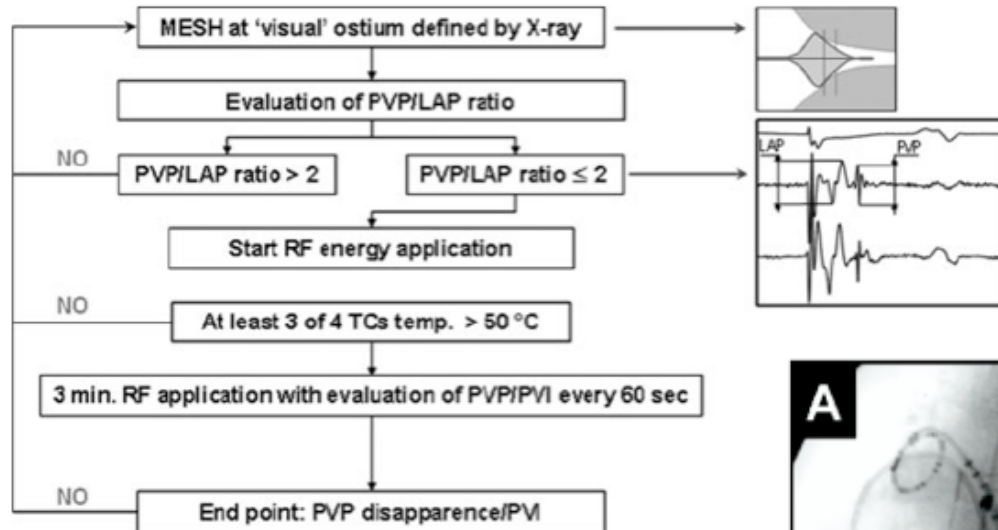
SOUTHLAKE
REGIONAL HEALTH CENTRE

Bard HD – Mesh Ablator



From Mansour et al, Heart Rhythm 2008

Positioning the Mesh

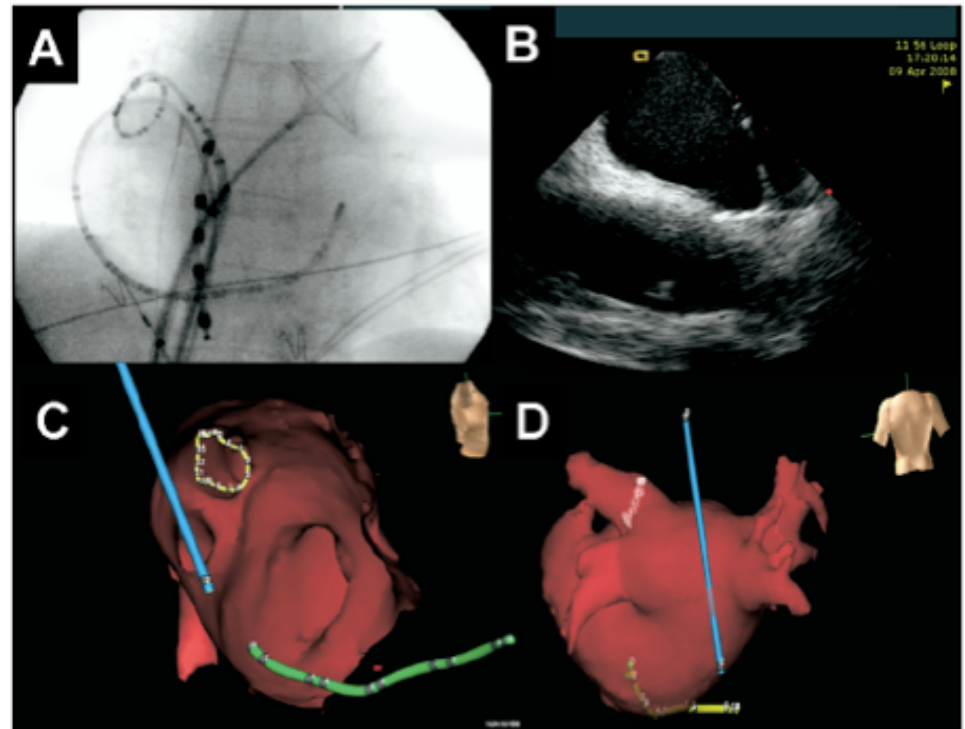


Use fluoroscopy with PV angiography, signals (look for atrial and PV signals).

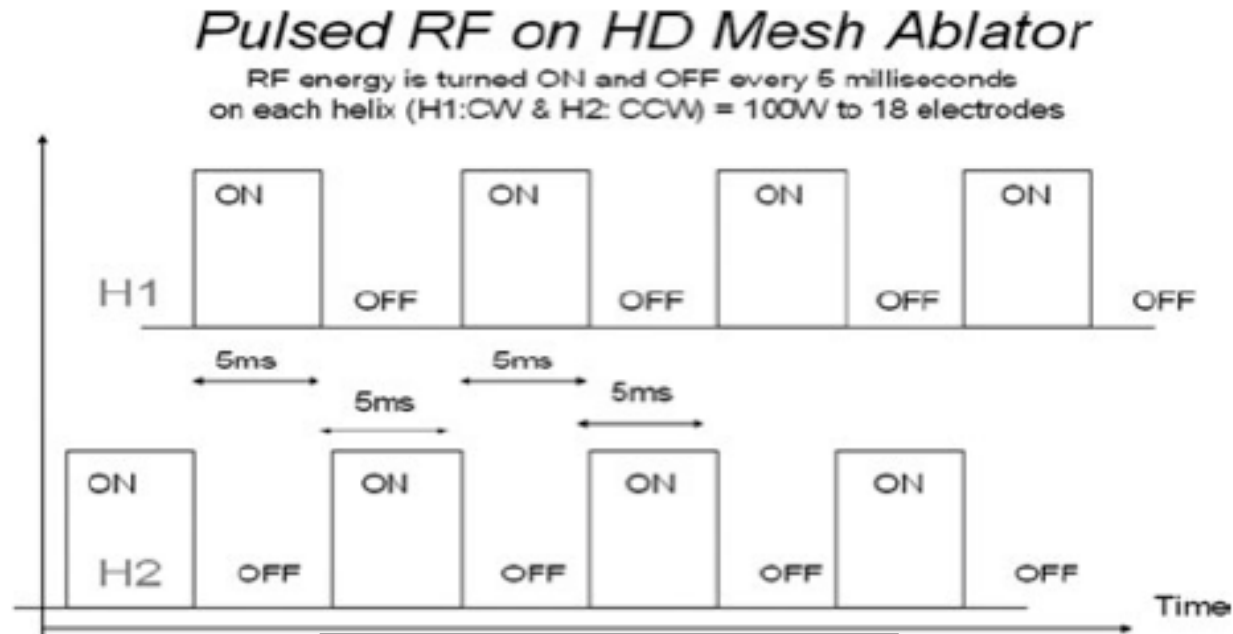
From DeFillipo et al, JCE 2009

Can also use ICE or electroanatomical mapping system.

From Mansour et al, HR 2008



RF Delivery



Meissner et al, JCE 2009

Delivered unipolar, pulsed in 5 ms pulses and delivered in alternating fashion to half of the electrodes followed by the other half. Deliver max 80-100 W to a target temp of 55-60 C. Look at 4 thermocouples – if temp is target in 3 of 4, continue for 300 sec. If not, adjust position.

Clinical Results – Mesh Ablator

	Number of pts	Type of AF	Acute Success	F/U (days)	Outcomes	Comments/ Complicat'n
Mansour et al, 2008	20	100% parox, lone AF	63% of PVs isolated, rest req usual abl'n	0	No longer term outcome	No complic'ns
DeFillipo et al, 2009	17	10 parox, 7 persistent	All PVs isolated, but only 47% RIPV	330	64% in sinus on drugs	No complic'ns
Meissner et al, 2009	26	14 parox, 12 persistent	94% of PVs isolated	90	65% in sinus by symptoms	No complic'ns
Steinwender et al, 2009	26	100% parox, lone AF	97% of PVs isolated	3-6 mos	57-60% in sinus	1 tamponade

- On average, about 9-12 min RF required per PV.
- Average procedure duration is about 3-4 hours.
- Average fluoro time was about 31-42 mins.

Mesh Ablator

- Success rates not as high as balloon technology
- Procedural and fluoro times are longer
- Very small number of patients studied
- Larger trials are required

Summary

- Balloon and mesh based technologies are promising avenues
- At this point, balloon technologies are further ahead in success and procedural efficiency
- Results not quite as good as traditional ablation and mostly limited to pure paroxysmals
- Further clinical evaluation/trials required to assess where these will “fit” in therapeutic armamentarium