“LIVING WITH ATRIAL FIBRILLATION”

With new thinking
more is possible…

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Orlando Health Heart Institute: Cardiology
October 7, 2017

Disclosures

Boston Scientific

Biotronik

Medtronic

St Jude

INTRODUCTION

A. Case Study
B. Epidemiology
C. Mechanisms
D. Pharmacologic Therapies
E. Non- Pharmacologic Therapies
F. Thromboembolism & Stroke Prevention
G. Conclusion
H. Live, hands on demonstration of an ablation leading to HRS certification

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Case Study

- 60 yo female with with past h/o paroxysmal atrial fibrillation initially diagnosed in 2010. She presents to her primary cardiologists office with AF manifested as palpitations, fatigue and increasing anxiety x 4 hours. Her episodes are often triggered by emotional stress, and spontaneously terminates in less than 24 hours. She is directly admitted to the hospital.
- On arrival her heart rate varies from 100 – 150 bpm ,

  and BP ~ 100/ 50 mmHg and she is visibly anxious.
- Her previous work up has included a stress test negative for ischemia and a 2D echo showing preserved LV function.

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Case Study

- CHA2DS2Vasc – 1 (female)
- She had previously tried and failed diltiazem, metoprolol, flecainide and most recently drodenarone.

- **What would you do next ?**

A. Try rate control and xanax.
B. Try another anti-arrhythmic agent
C. Cardiovert and discharge home.
D. Consult your friendly neighborhood electrophysiologist

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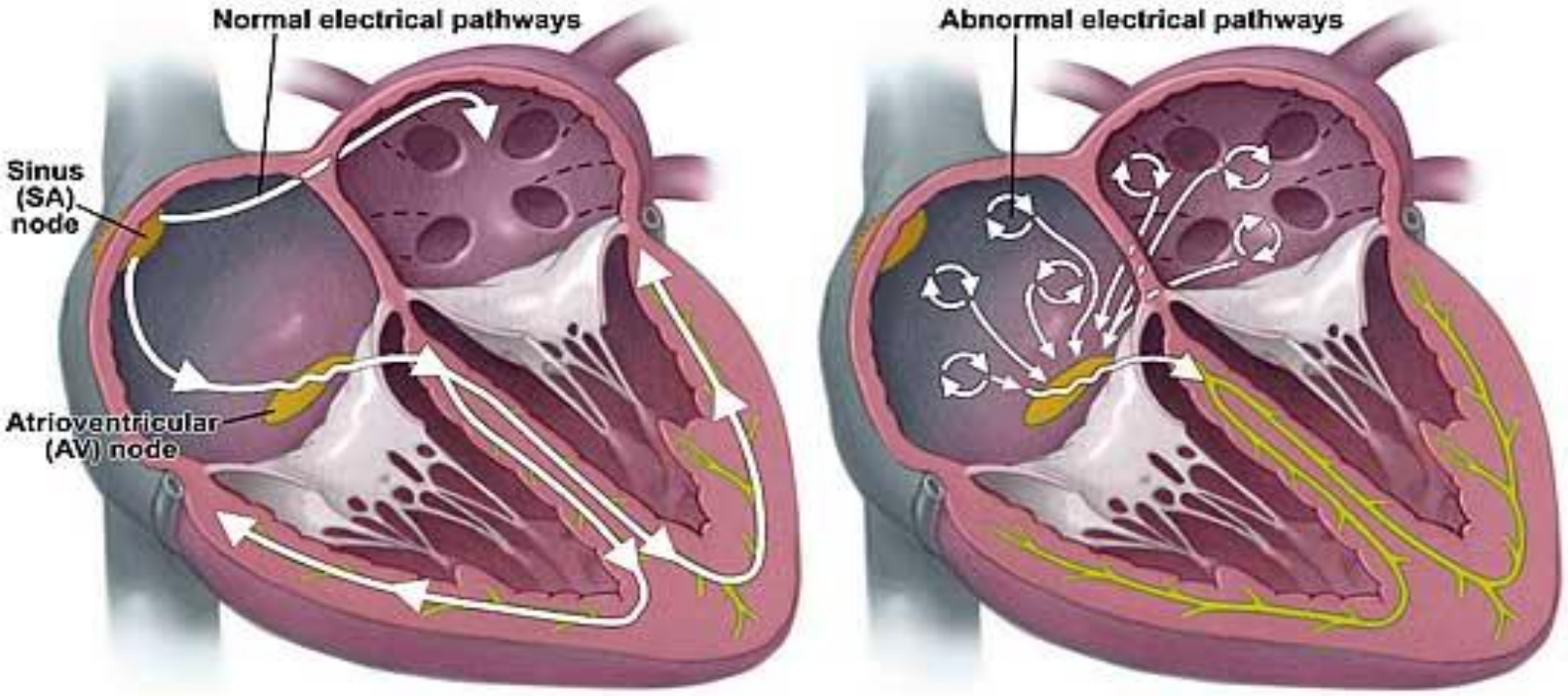
Atrial Fibrillation

Definition :

This is a supraventricular tachycardia with uncoordinated atrial activation and therefore ineffective atrial contractions.

- Irregular atrial activity – due to chaotic electrical activity in both atria (~300-350 bpm)
- Irregular ventricular activity (~150-200 bpm) driven by atrial activity.
- Absence of distinct repeating P waves.
- Atrial blood pooling and risk of clot formation

What is Atrial Fibrillation?



Atrial Fibrillation

Types of Atrial Fibrillation:

Paroxysmal AF: Last a short time (usually less than 24 hrs.) and can occur on and off for many years.

Persistent AF: Longer than 7 days, not self terminating

Permanent AF: Longer than 1 year and *resistant* to cardioversion

Lone AF: ***Any of the above*** without structural heart disease

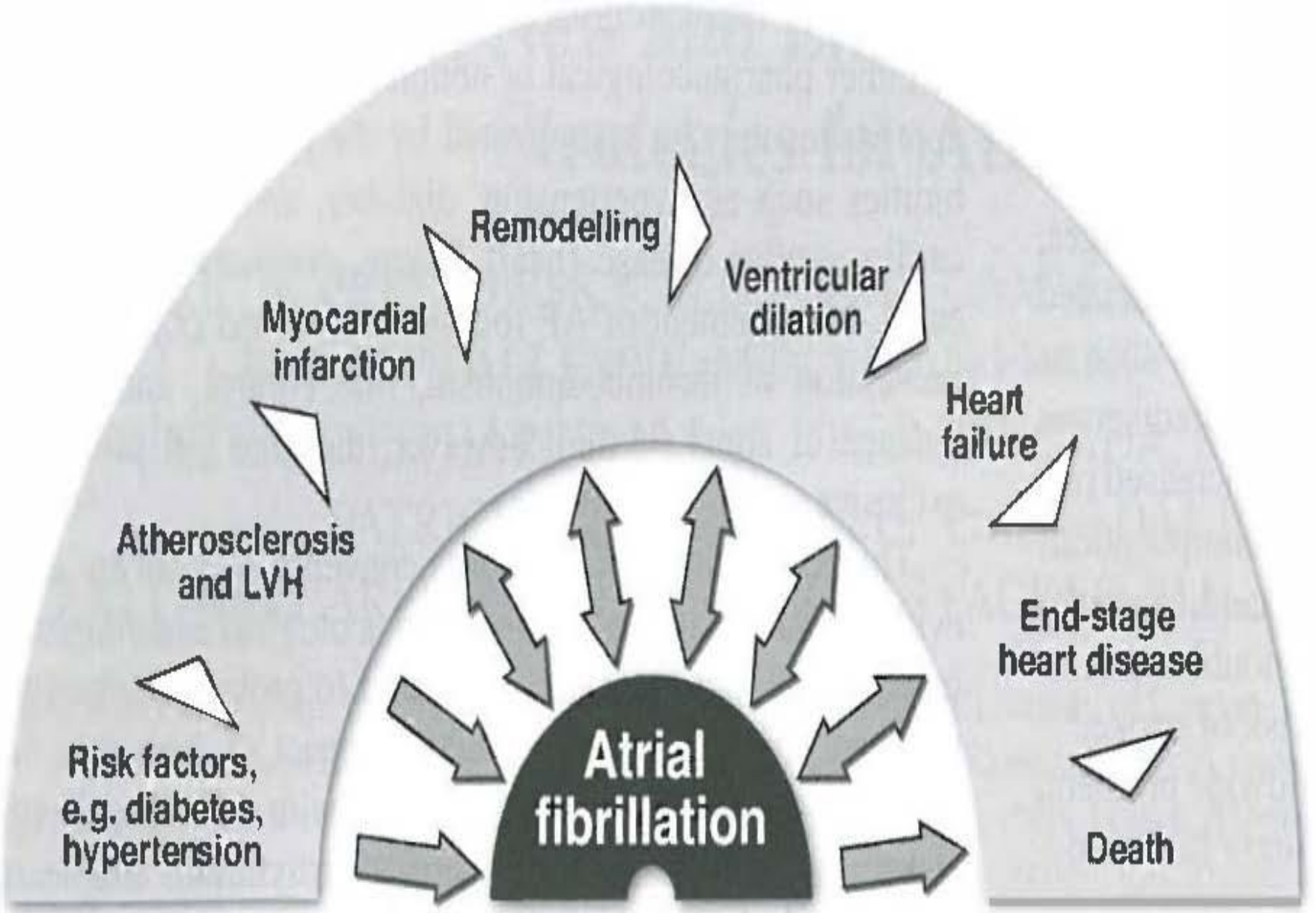
Atrial Fibrillation

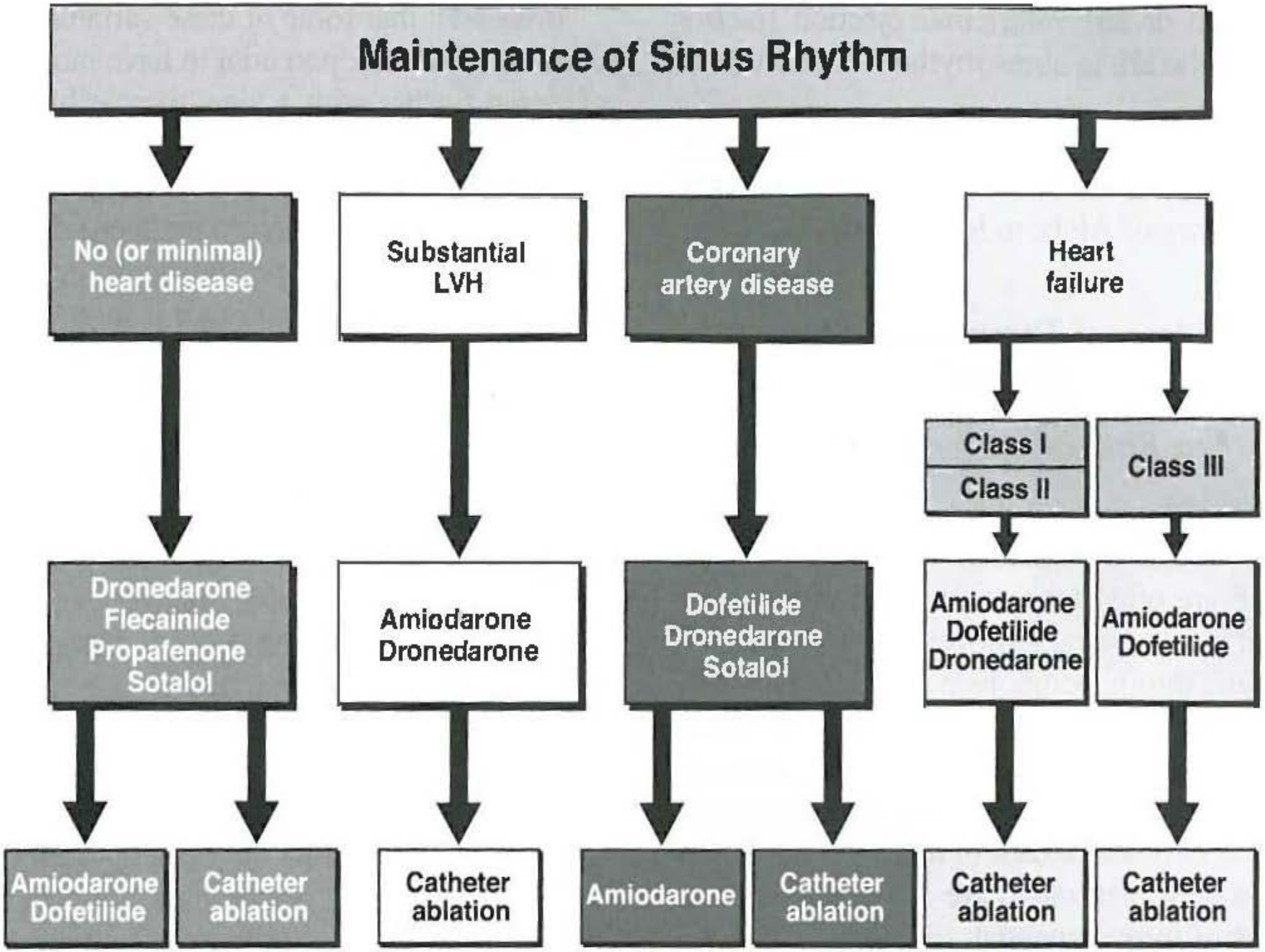
Treatment strategies for AF can be either pharmacologic or non pharmacologic.

Both approaches may be complicated by comorbidities such as HTN, DM, or other preexisting CV comorbidities (ie CAD,PVD & HF).

Management focuses on 4 broad objectives:

1. Rate Control
2. Prevention of thromboembolism
3. Maintenance of sinus rhythm
4. Treatment of risk factors (CV comorbidities)


Remodelling
Ventricular dilation
Myocardial infarction
Heart failure
Atherosclerosis and LVH
End-stage heart disease
Risk factors, e.g. diabetes, hypertension
Atrial fibrillation
Death


Maintenance of Sinus Rhythm
No (or minimal) heart disease
Substantial LVH
Coronary artery disease
Heart failure
Class I
Class II
Class III
Dronedarone
Flecainide
Propafenone
Sotalol
Amiodarone
Dronedarone
Dofetilide
Dronedarone
Sotalol
Amiodarone
Dofetilide
Dronedarone
Amiodarone
Dofetilide
Amiodarone
Dofetilide
Catheter ablation
Catheter ablation
Amiodarone
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Catheter ablation

Atrial Fibrillation

Mechanisms of Atrial Fibrillation

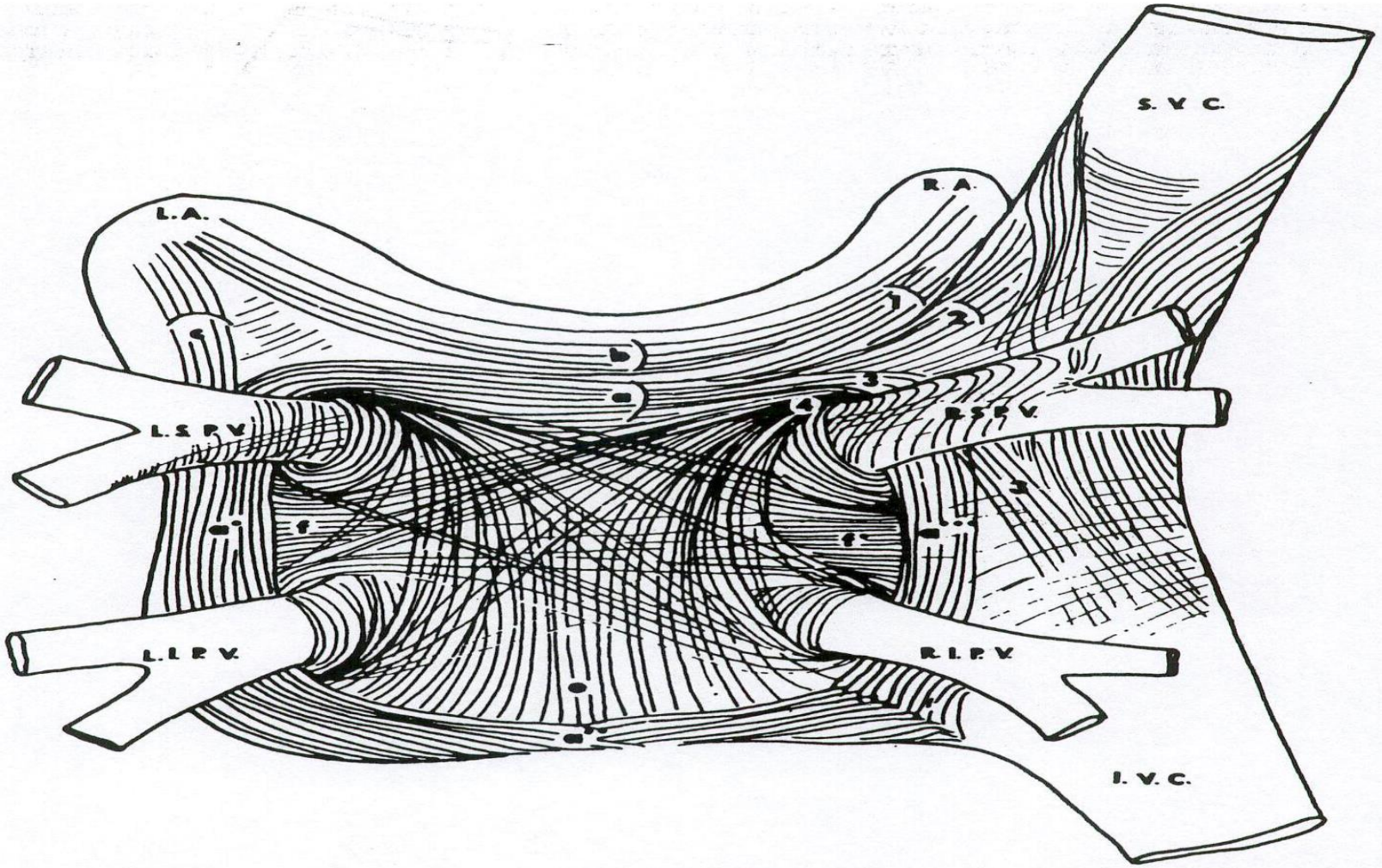
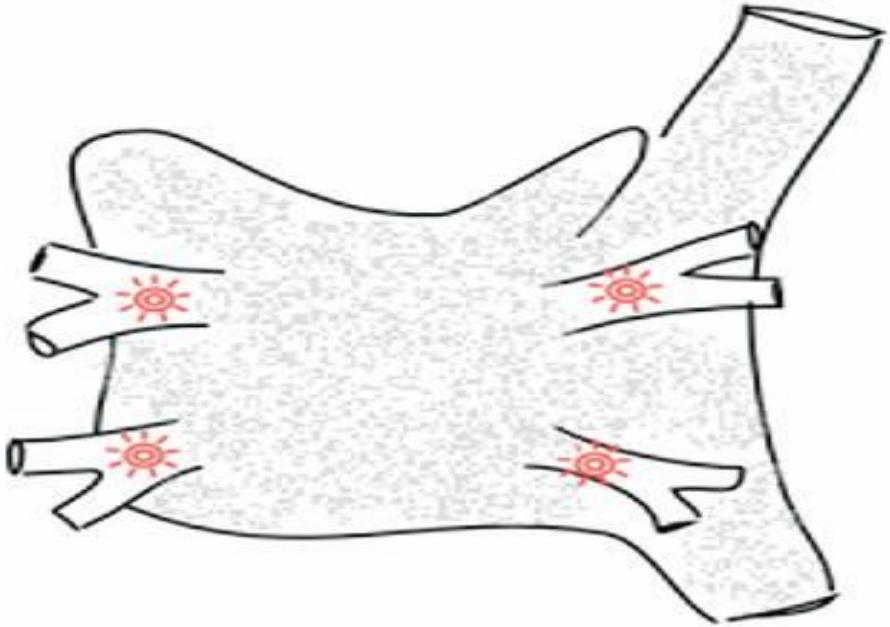
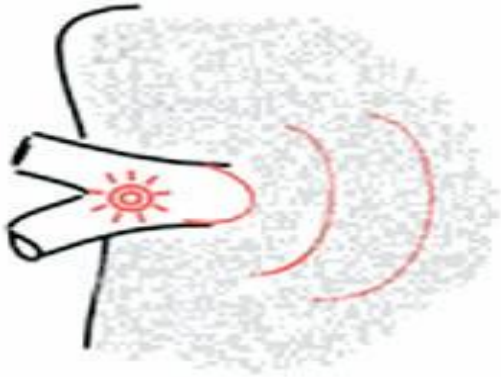
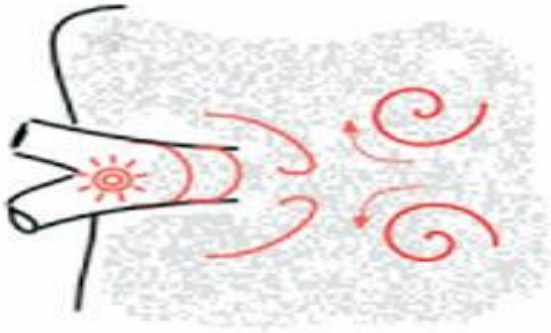


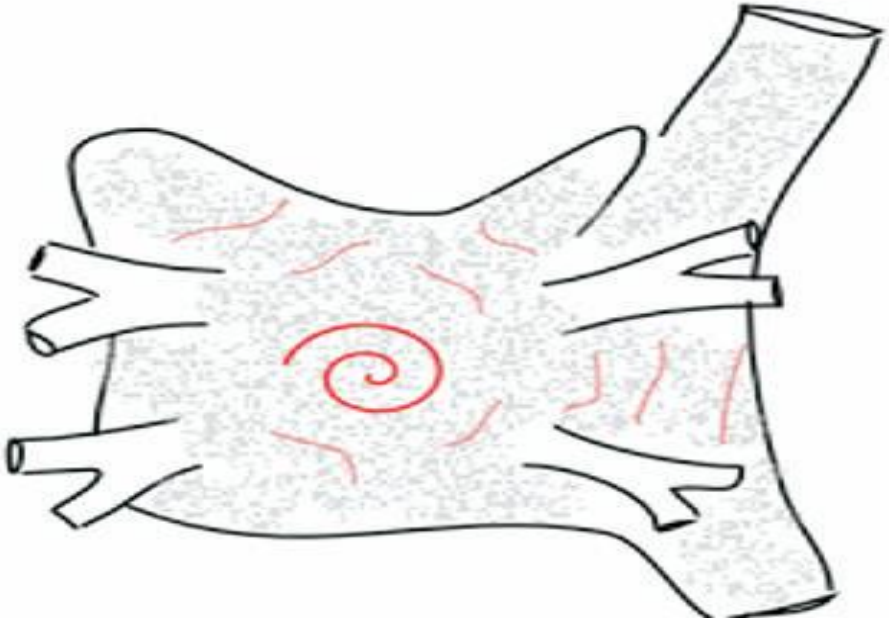
Figure 1

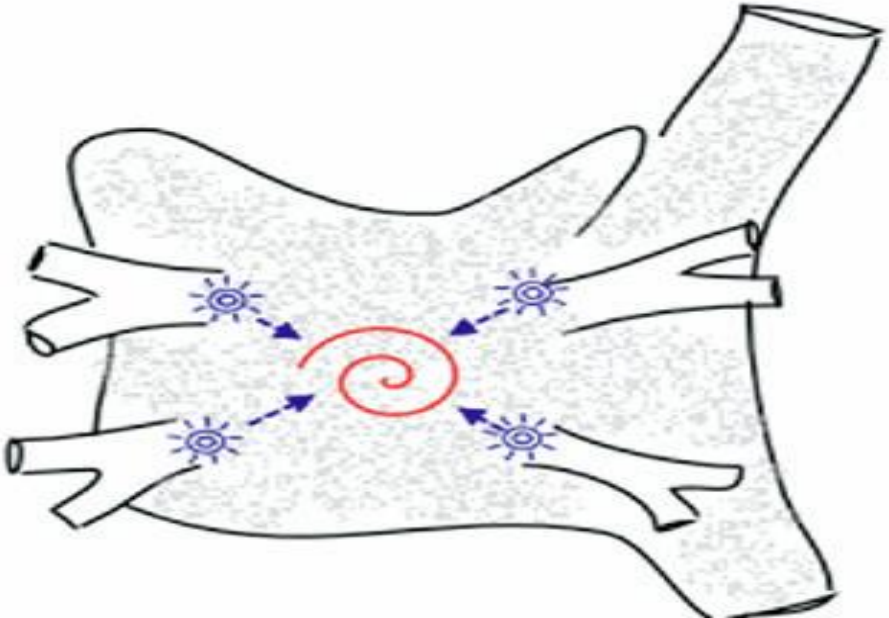
The common pattern of the superficial myocardial fibers of the left atrium (posterior aspect). A main circular fascicle (a, a', a'', and a''') runs peripherally around the area of the openings of the pulmonary veins. An interatrial fascicle (b) runs between the right (RA) and the left (LA) atrium. Some fibers (c) descend from the left atrium into the left part (a') of the main circular fascicle. Circular fibers leaving the main fascicle turn around the openings of the pulmonary veins, forming sphincter-like structures; other fibers extend over the veins as myocardial sleeves. Loops of fibers coming from the atrium are seen over the right superior pulmonary vein (R.S.P.V.) and returning to the atrium. Oblique, vertical (e), and transverse (f, f') fascicles of fibers are also seen on the posterior atrial surface. L.A. = left atrium; R.A. = right atrium; S.V.C. = superior vena cava; I.V.C. = inferior vena cava; R.S.P.V. = right superior pulmonary vein; L.S.P.V. = left superior pulmonary vein; R.I.P.V. = right inferior pulmonary vein; L.I.P.V. = left inferior pulmonary vein.

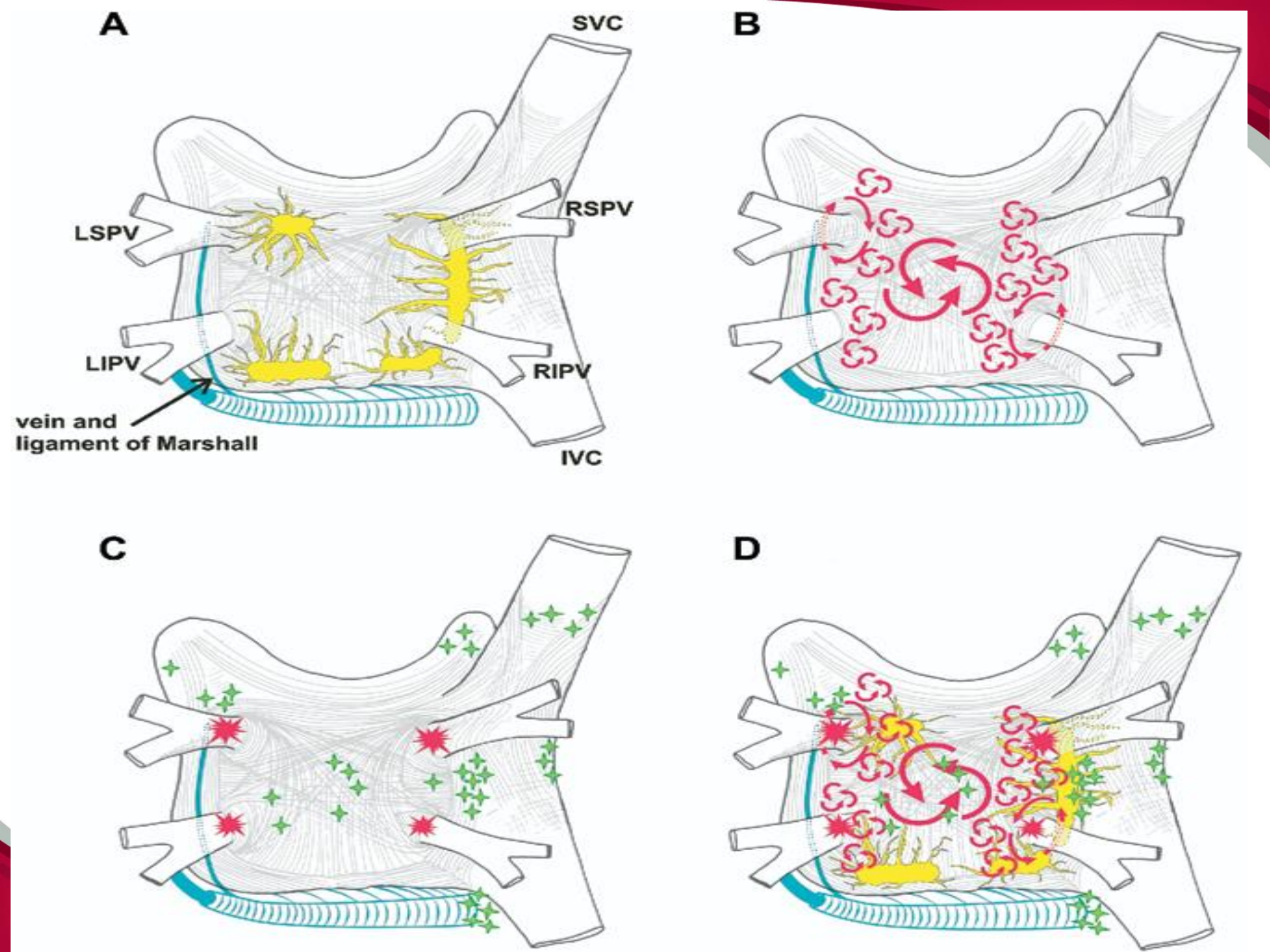











A
SVC
RSPV
LSPV
LIPV
RIPV
vein and
ligament of Marshall
IVC
B
C
D

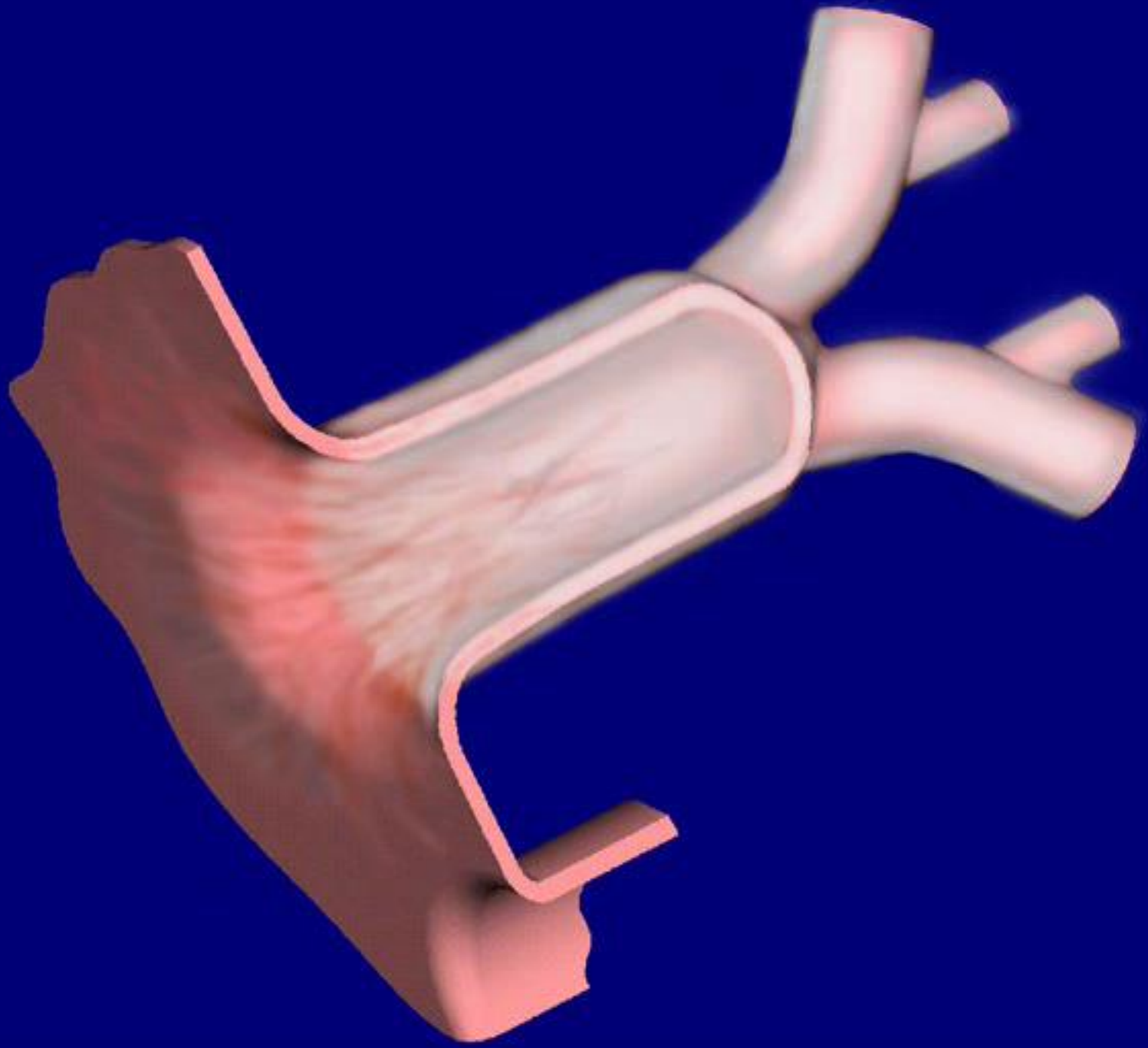
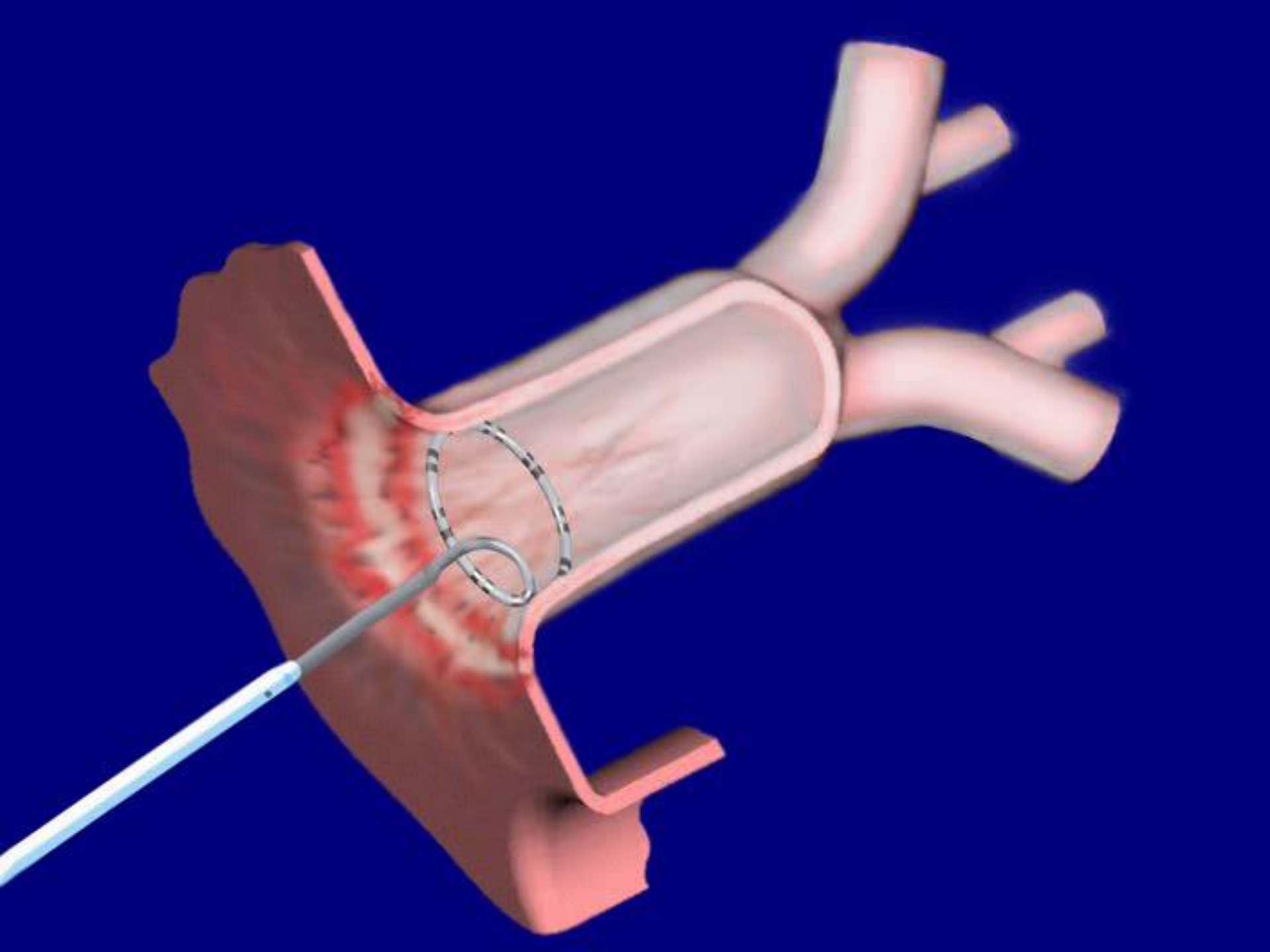
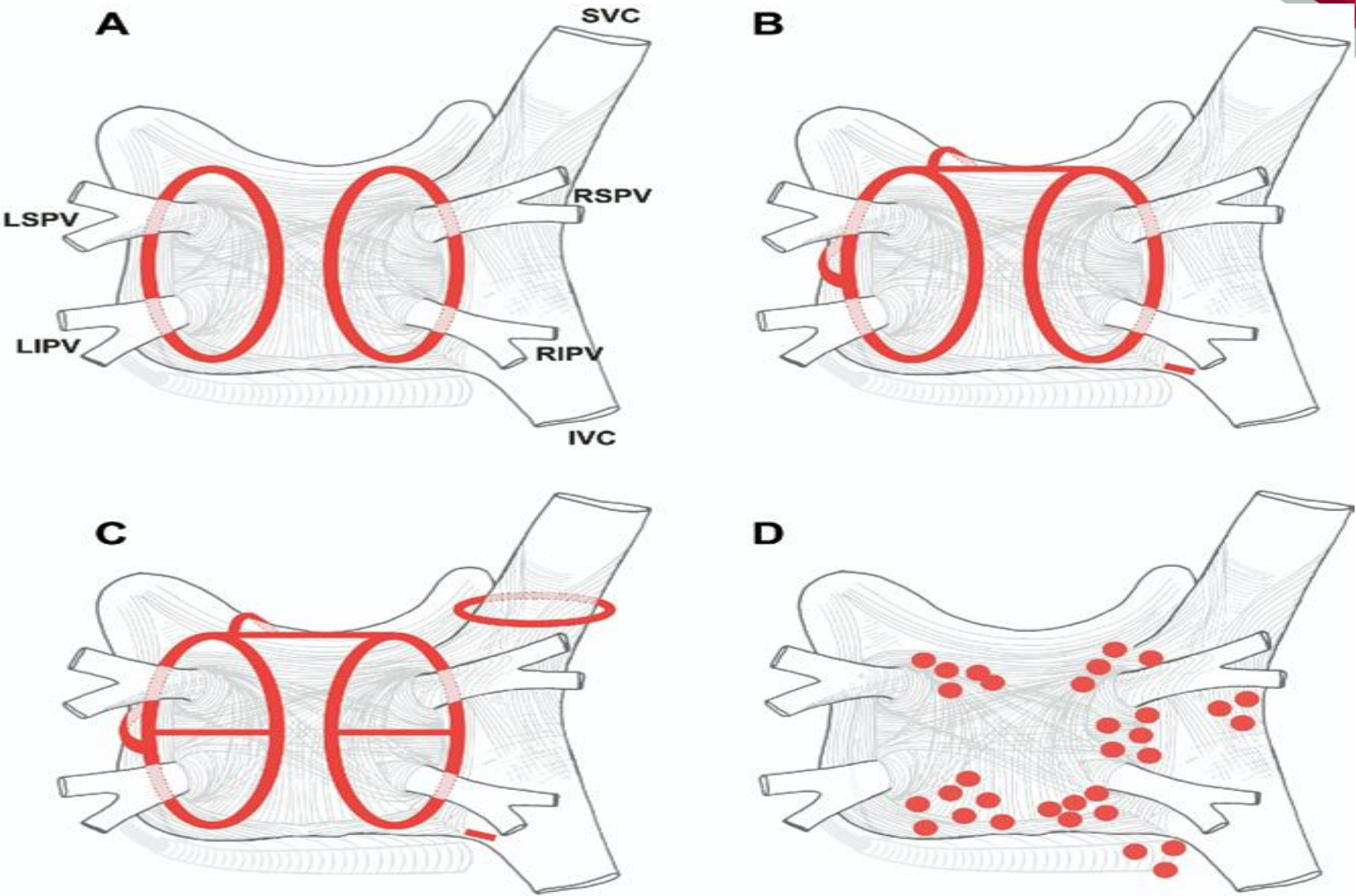
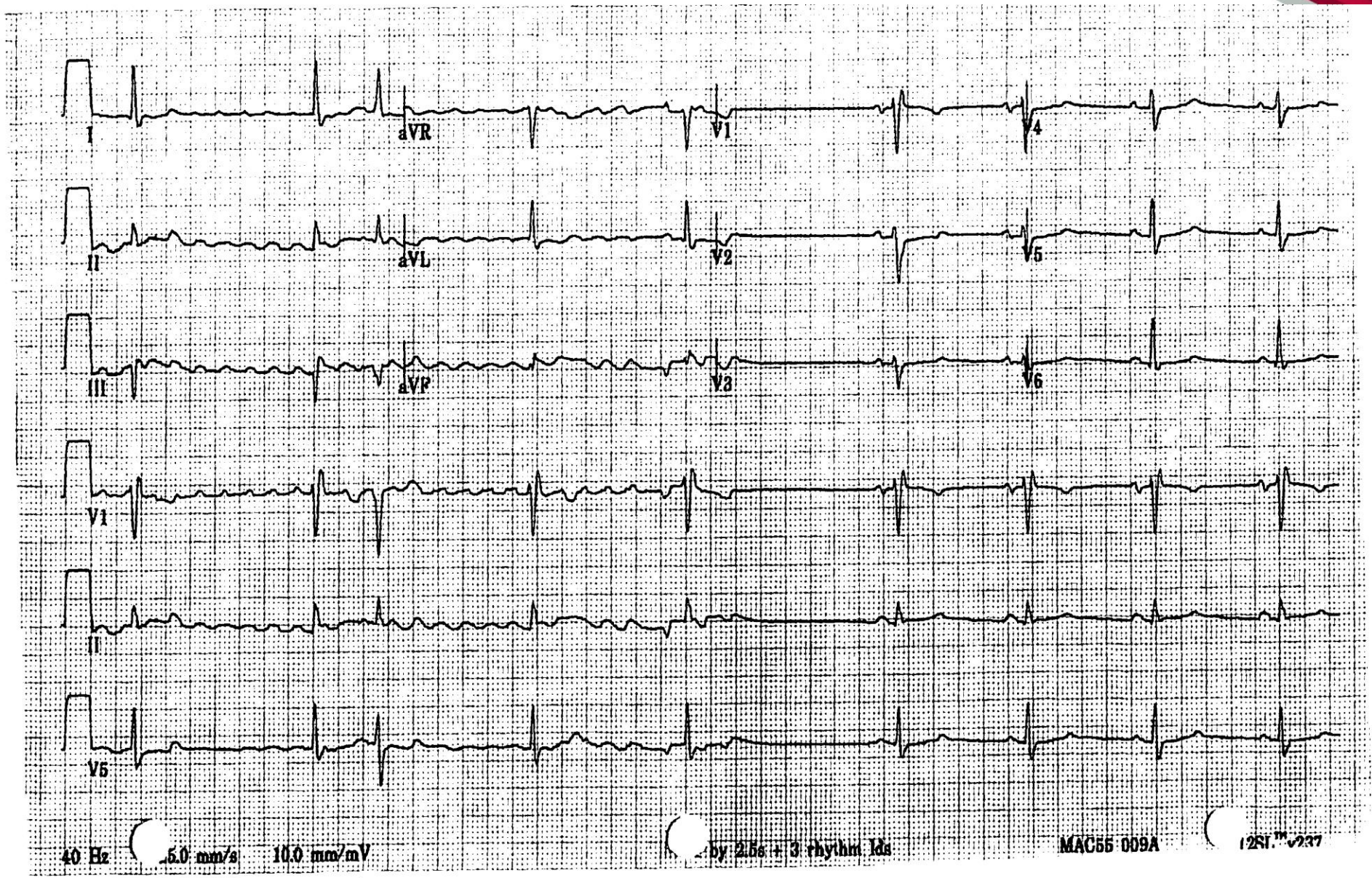


FIGURE 15–4. Initiation of atrial fibrillation by a premature atrial contraction (PAC) originating from the right superior pulmonary vein (RSPV). After the second sinus beat, there is a high-frequency pulmonary vein (PV) potential *(first star)* in the RSPV that precedes the onset of the ectopic P wave. The low-frequency atrial potential follows the PV potential associated with the PAC but precedes the PV potential associated with the sinus beats, indicating a reversal of the activation sequence. A second high-frequency PV potential *(second star)* follows the first by 160 msec. I, II, III, and V1 are surface electrocardiographic leads. dist, distal; prox, proximal; LIPV, left inferior pulmonary vein; RA, right atrium. *(From Haissaguerre M, Jais P, Shah DC, et al.: Catheter ablation of chronic atrial fibrillation targeting the reinitiating triggers. J Cardiovasc Electrophysiol 11:2-10, 2000, with permission.)*



AF Ablation Patterns




I
aVR
V1
V4
II
aVL
V2
V5
III
aVF
V3
V6
V1
II
V5
40 Hz
10.0 mm/mV
by 2.5s + 3 rhythm lds
MAC55 009A

Paroxysmal Atrial Fibrillaton

Catheter Ablation vs Antiarrhythmic Drugs for AF: A4 Study

- Randomized, multicenter comparison with PAF having failed at least 1 AAD.
- Primary endpoint was absence of AF between 3 -12 months.
- Ablation technique was PV isolation
- N= 112 pts (53 CA tx vs 59 AAD)
- Results: At 1 year 23% in the AAD arm vs 89% in the CA arm had no recurrence of AF ($p<0.0001$)
- Symptom score, exercise capacity & QoL were higher in the ablation group.
- Conclusion: Catheter ablation was superior to antiarrhythmic therapy in regards to maintenance of SR & improvement in sxs, exercise capacity and QoL. Jais et al Circ 2008;118:2498

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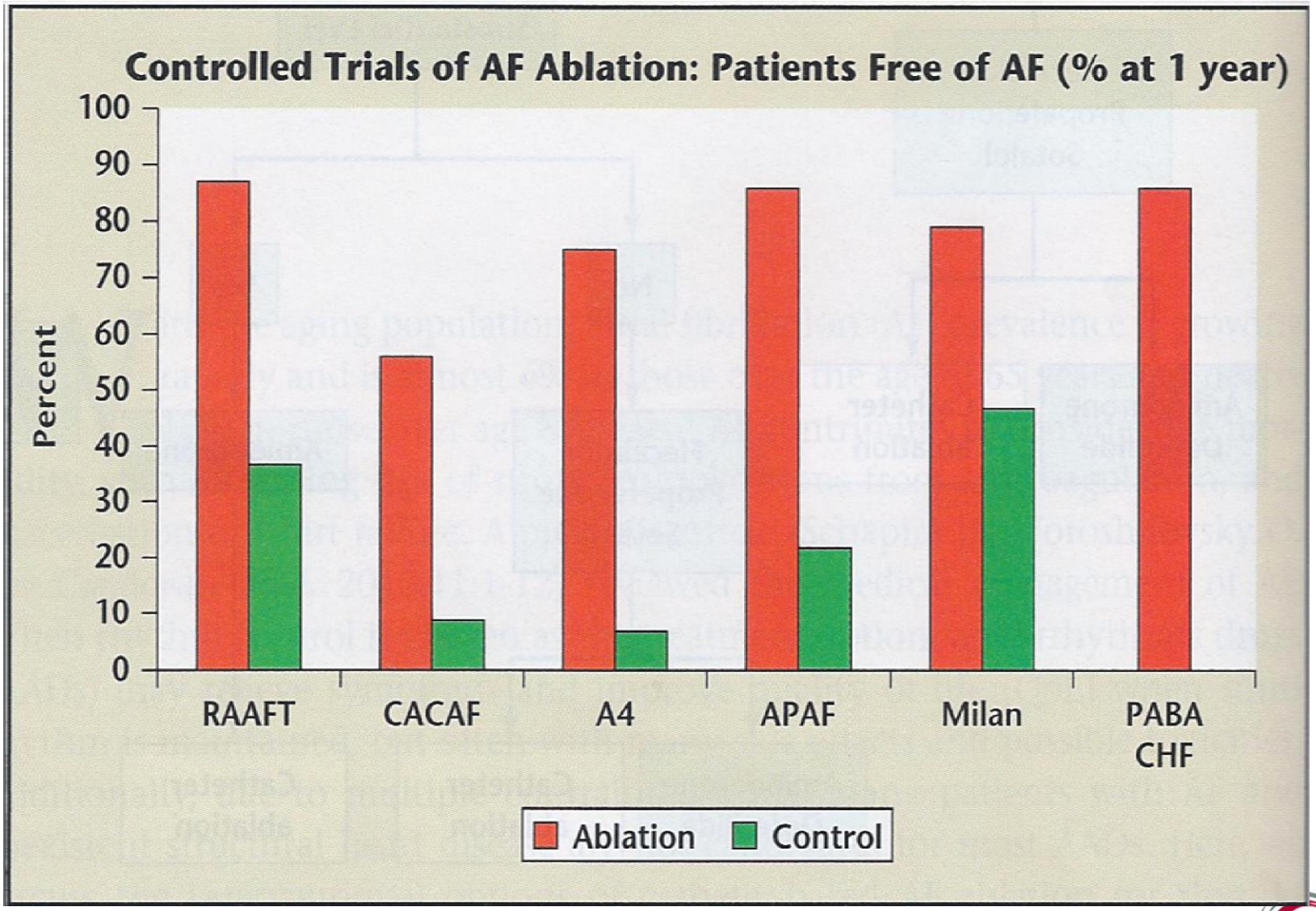
Therapies

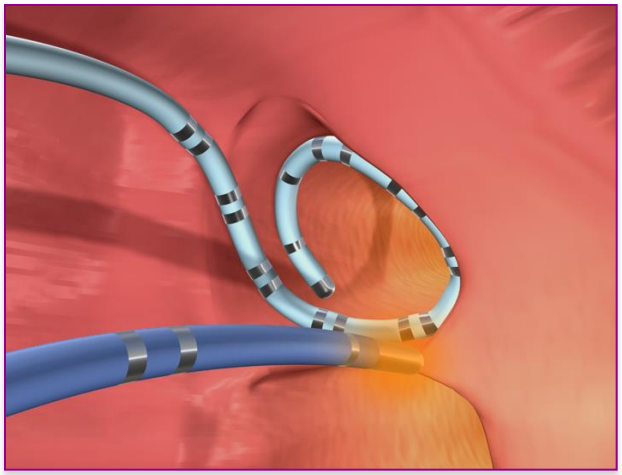


Therapies

Nair et al (*JCE 2009*) published a meta analysis of 6 randomized trials comparing RFA vs AAD tx in pts with AF. These studies showed a 65% decrease in the risk of AF recurrence @ 1 year with an ablation strategy.

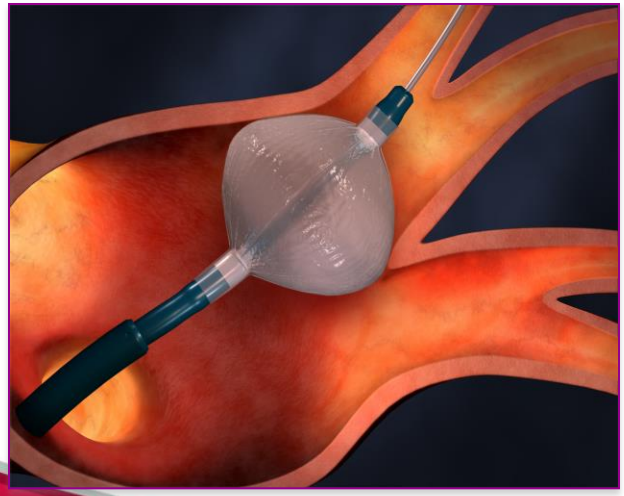
Thermocool Study Group : Randomized, prospective, multicenter study of pts with symptomatic AF who have failed at least one drug trial. Primary endpoint was freedom from symptomatic AF recurrence. *Wilber et al* (JAMA 2010)

Point-by-Point Technique vs Balloon Technique



Point-by-point approach:

Electrophysiologists have to ablate many times to achieve Pulmonary Vein Isolation



Cryoballoon approach:

The balloon can create a continuous line of scar tissue all the way around the pulmonary vein with just a few applications

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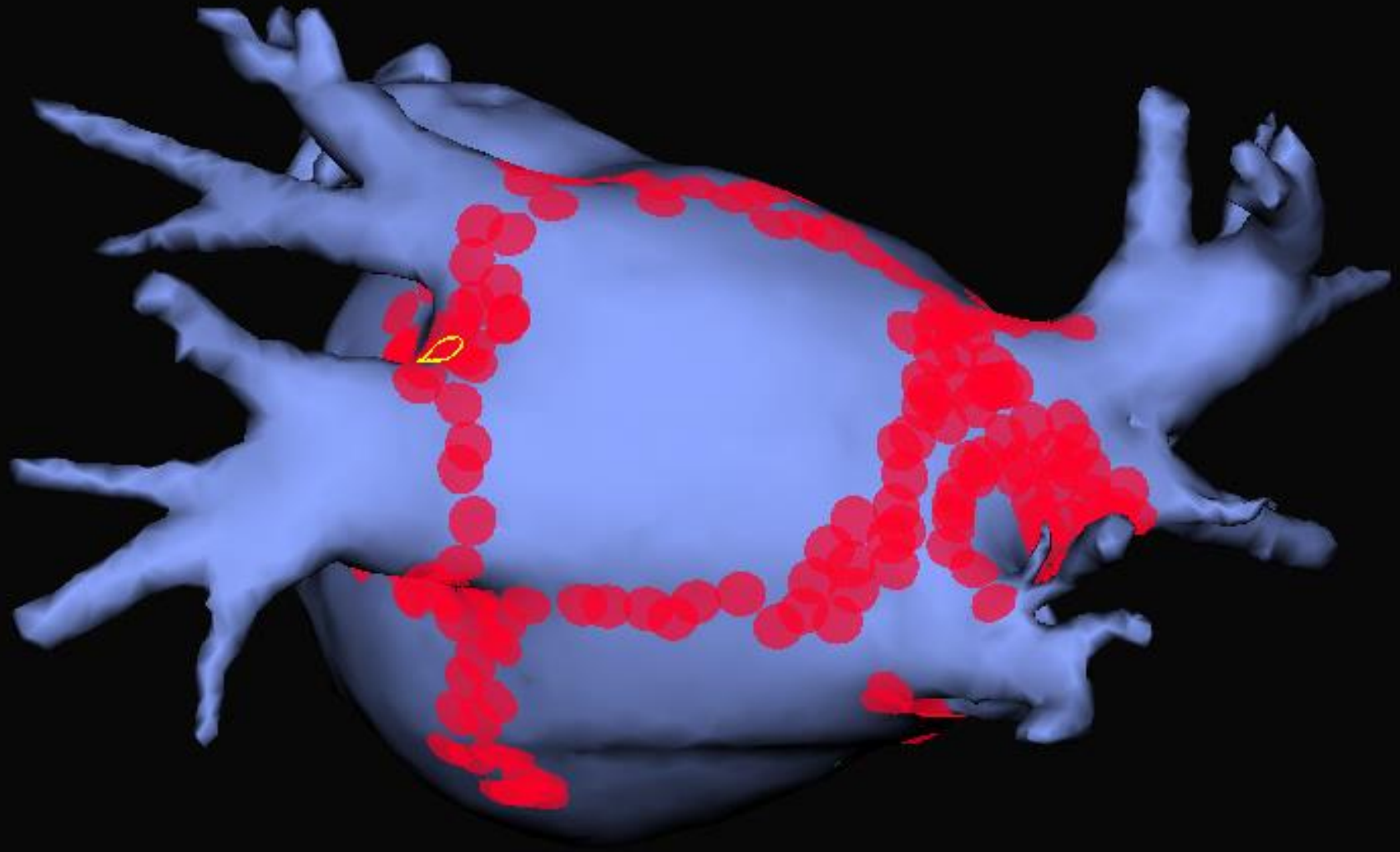
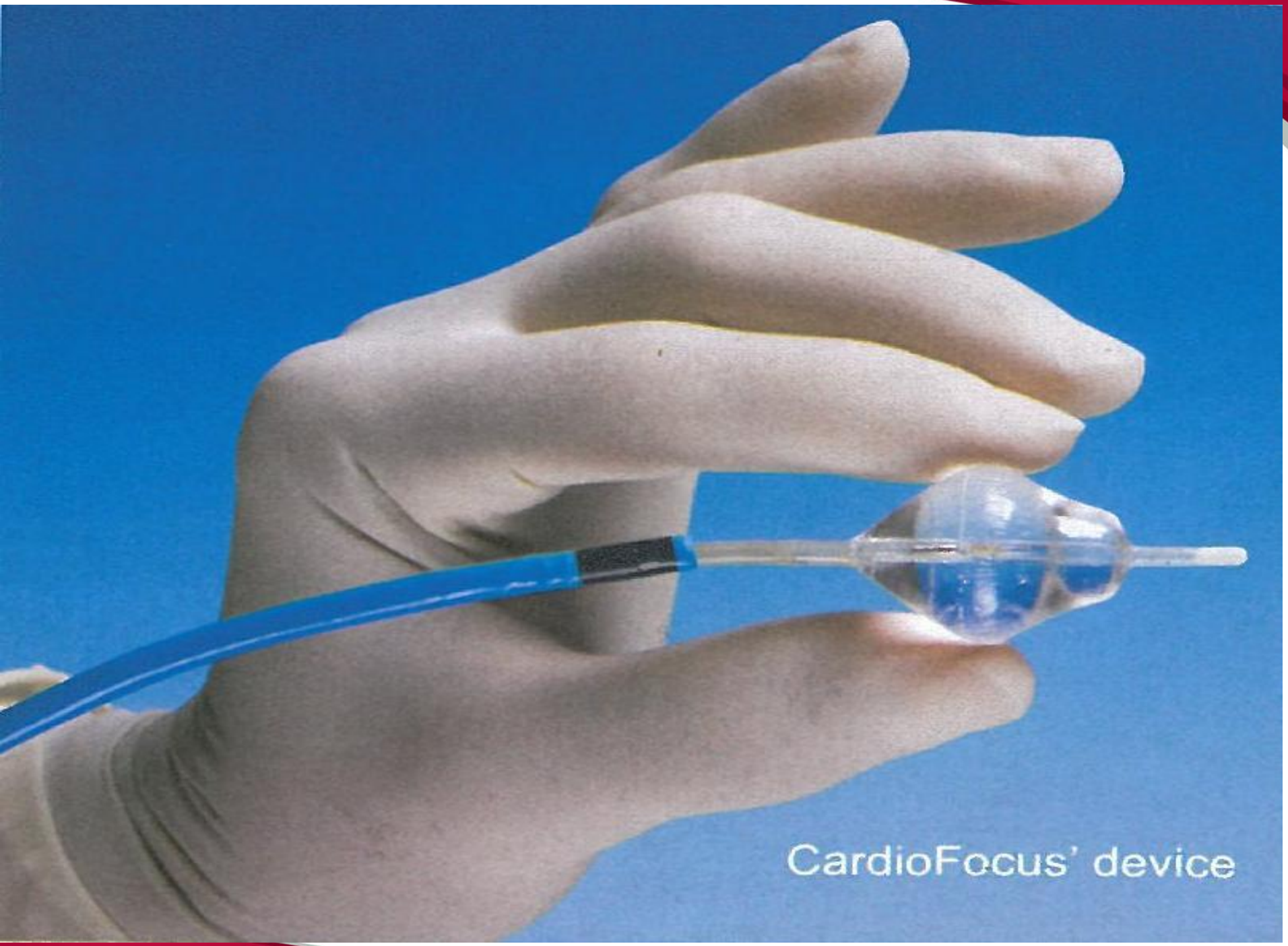
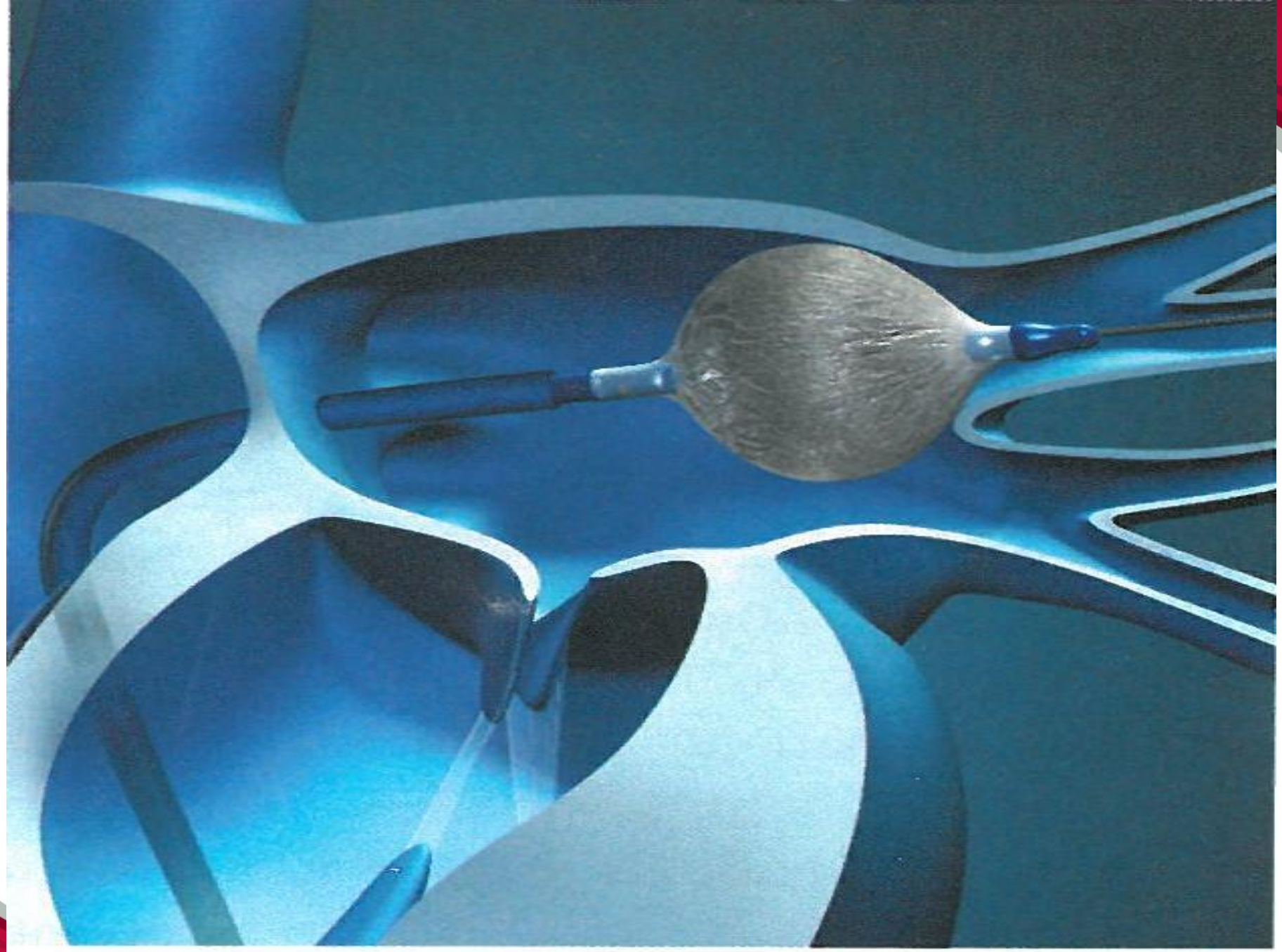



CardioFocus' device



Arctic Front catheter

Cryoablation

Atrial Fibrillation

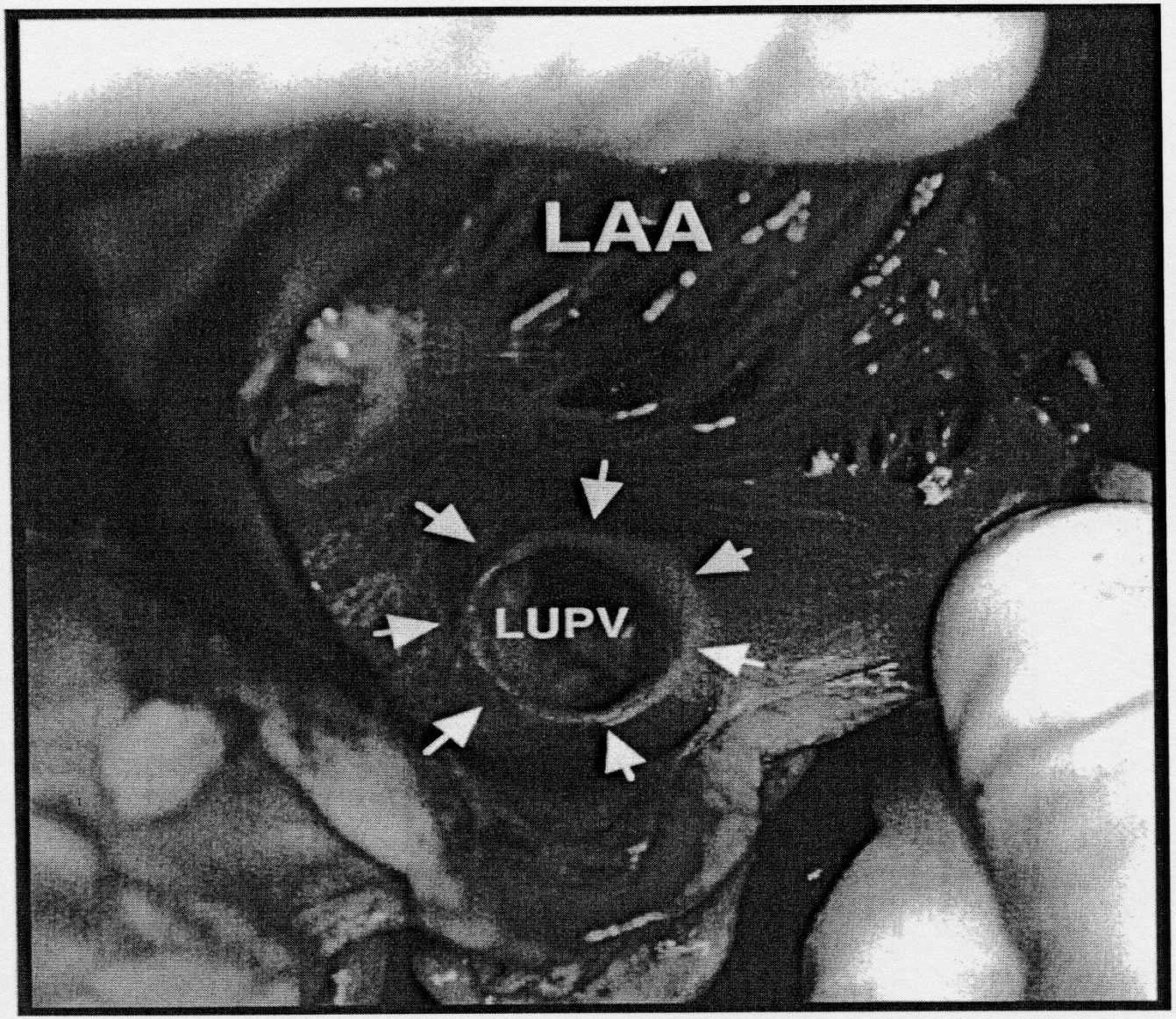
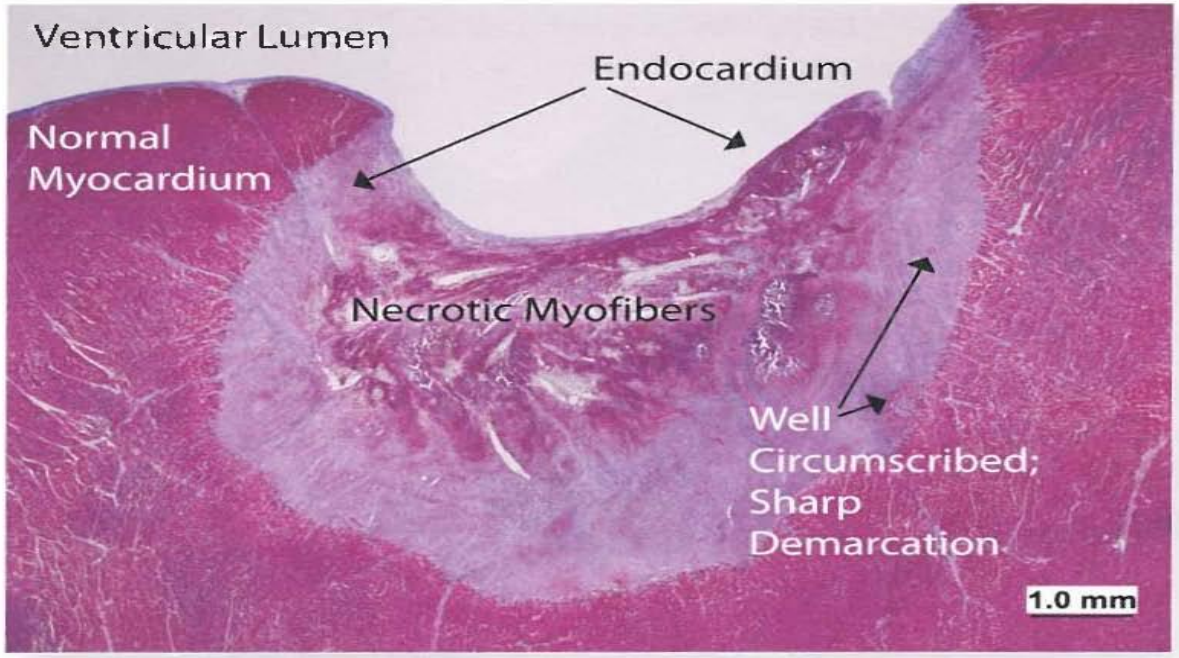


Fig. 10. *In another specimen, a circumferential lesion (arrows) was created with ultrasound around the base of the left upper pulmonary vein (LUPV) in a pig. LAA: left atrial appendage.*

Benefits of Cryoablation

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



7-day old ventricular ablation lesions in swine hearts created using Freezor® *Xtra* 6 mm tip CryoAblation catheter.

STOP AF

Sustained Treatment of Paroxysmal Atrial Fibrillation

The first, randomized, controlled study using Arctic Front® Cardiac CryoAblation Catheter

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Medtronic Inc, Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.

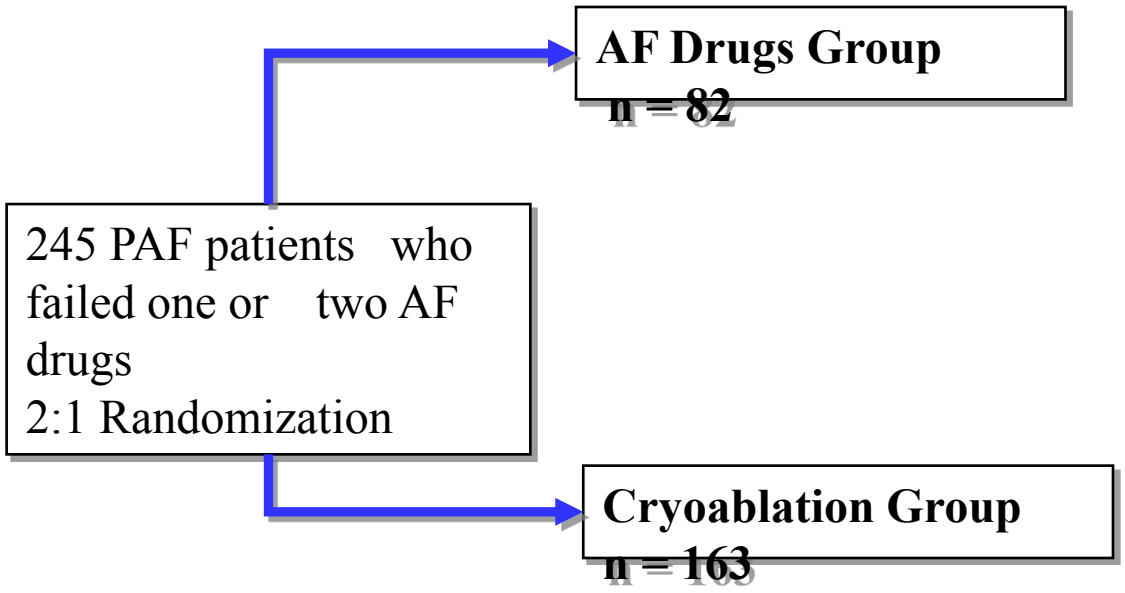
STOP AF – Study Objective[1]

- To confirm the safety and effectiveness of the Arctic Front Cardiac CryoAblation System when used to treat patients with drug refractory* Paroxysmal Atrial Fibrillation (PAF).

* Failed one or two of the following three antiarrhythmic drugs: flecainide, propafenone, or sotalol.

[1] Medtronic Inc., Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.

STOP AF – Trial Design[1]



26 centers in the United States and Canada

[1] Medtronic Inc, Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.

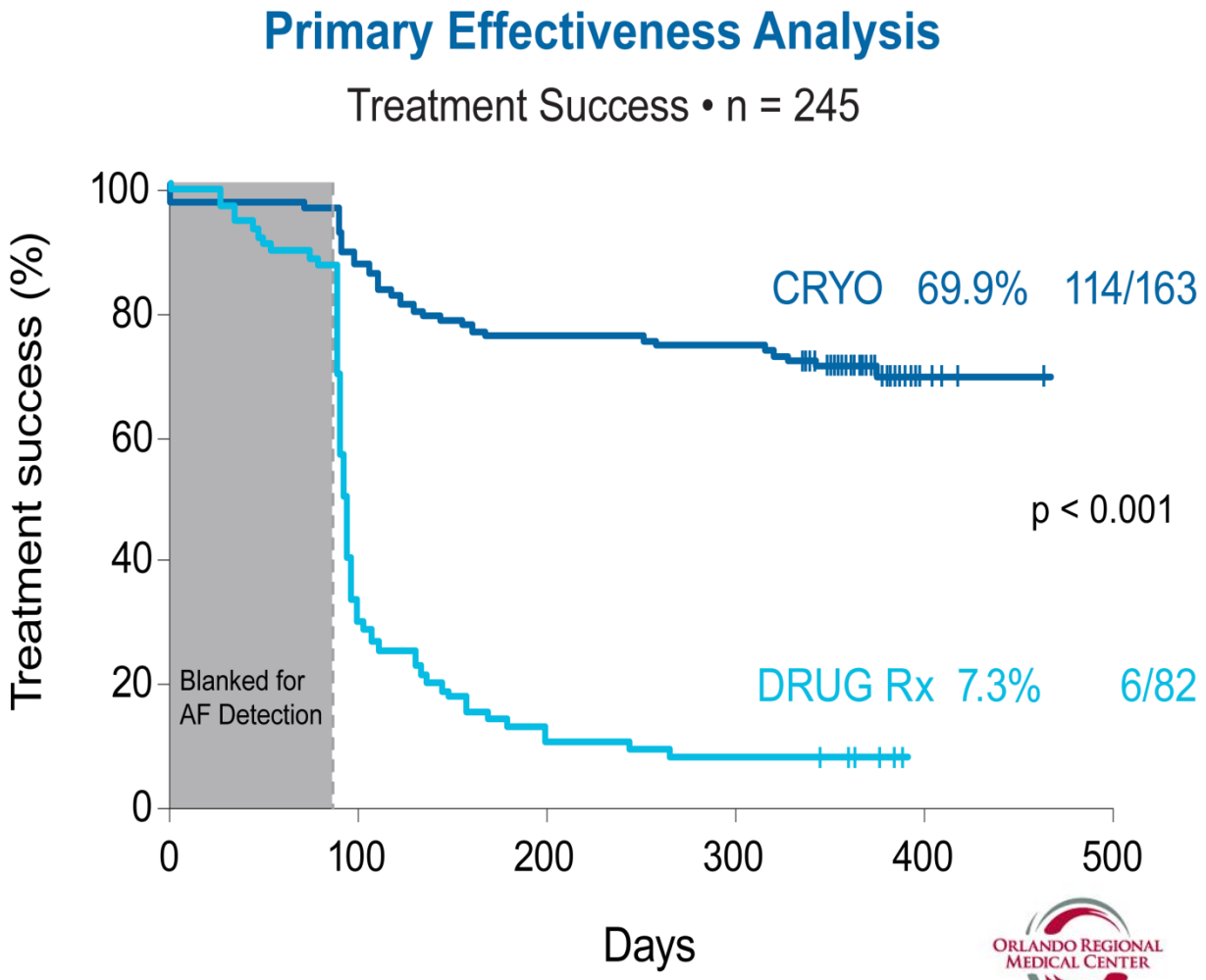
69.9% of Patients Achieved Treatment Success at 12 Months[1]

Defined as:

- **Acute Procedural Success**

AND

- **Freedom from chronic treatment failure**
  - No detectable AF post-blanking
  - No use of non-study AF drug
  - No AF intervention



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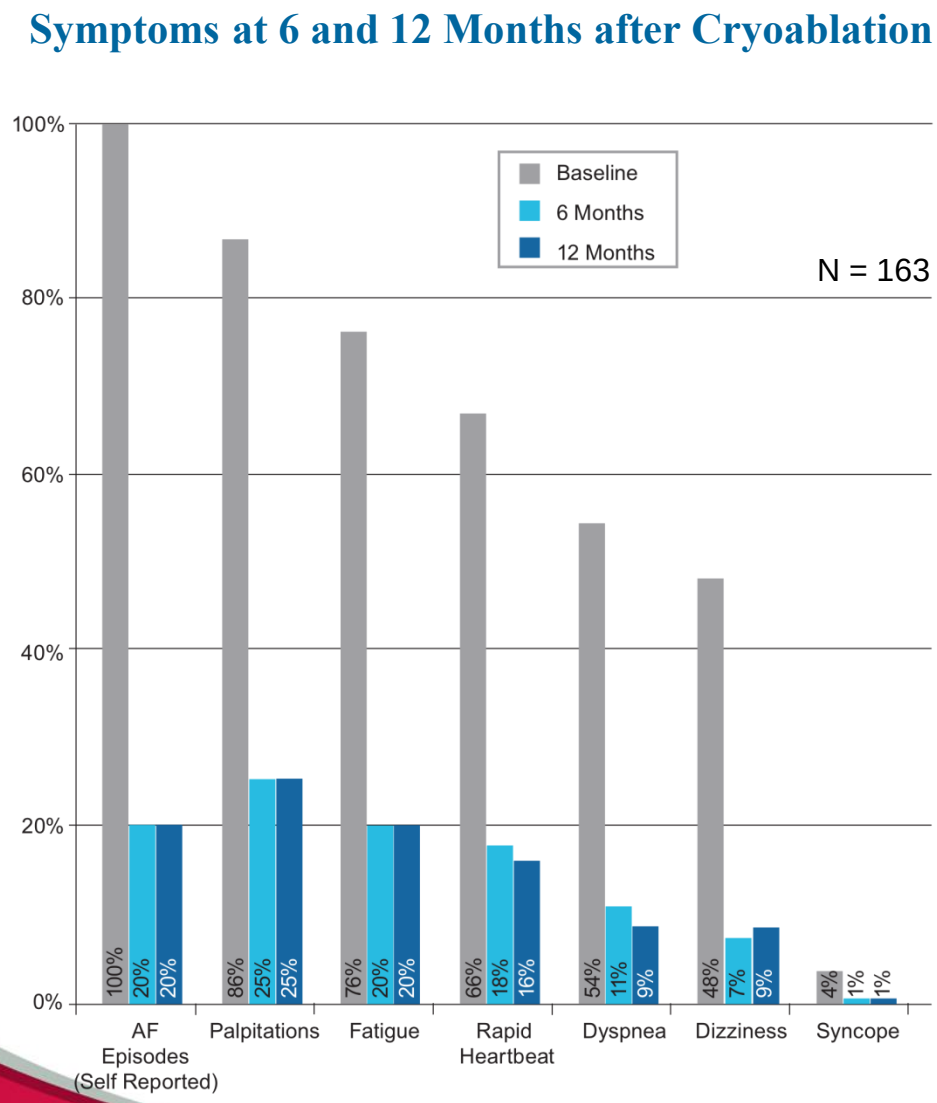
Significant Reduction in AF Symptoms[1]



- Symptom reduction sustained throughout the 12-month follow-up period
- 80% of patients reported no AF symptoms at 12 months

[1] Medtronic Inc, Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.

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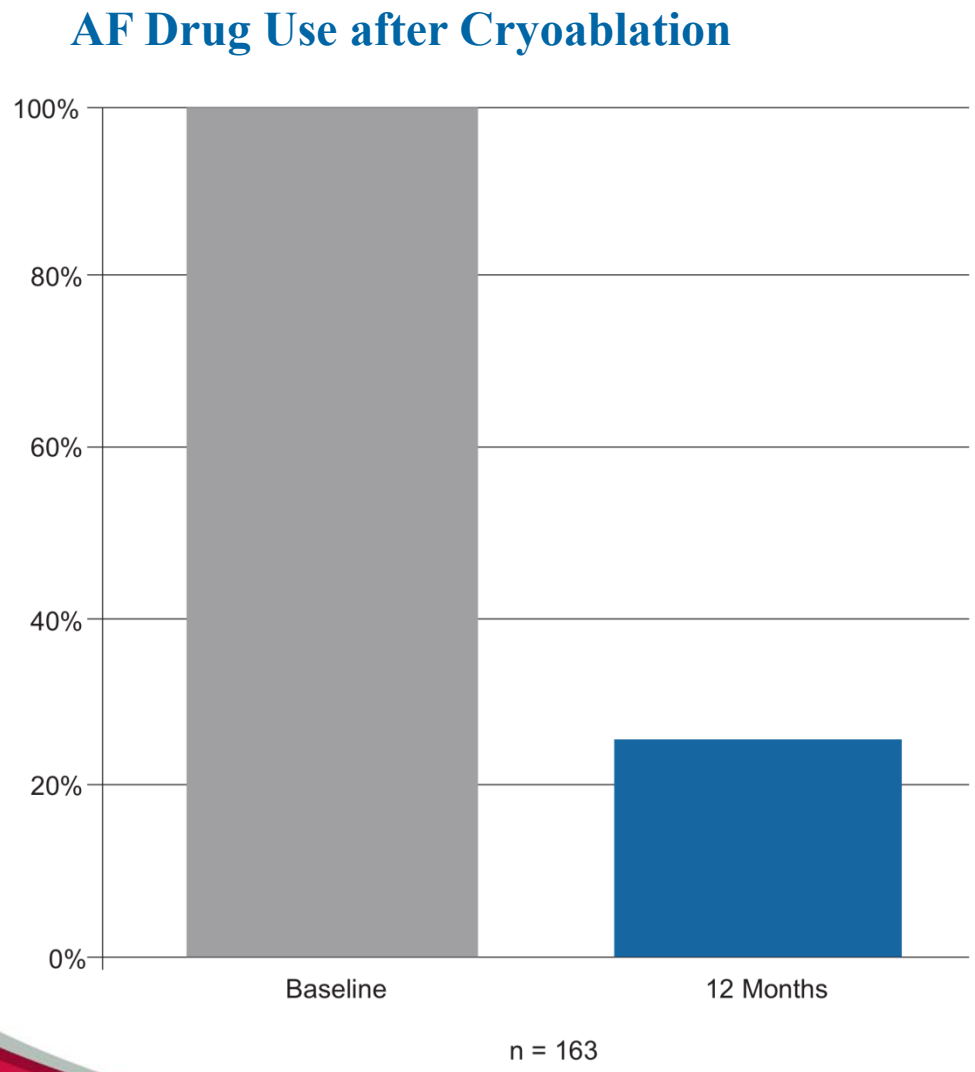
Significant Reduction in AF Drug Use[1]



74% of Patients Off AF Drugs at 12 Months

[1] Medtronic Inc, Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.

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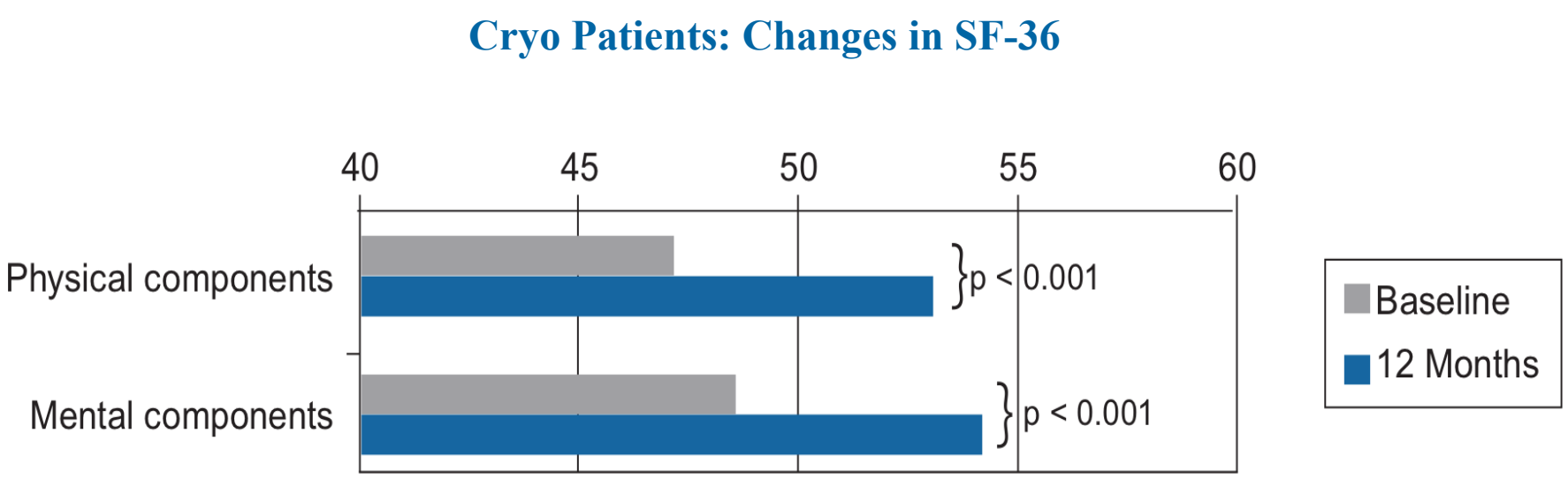
Improved Quality of Life[1]



- Physical components score improved by 6.0 points*
- Mental components score improved by 5.6 points*

*Any change in the score of more than 5 points is seen as a clinically relevant improvement in the quality of life.[2]

[1] Medtronic Inc, Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.

[2] Ware JE, Snow KK, Kosinski M, Gandek, B. *SF-36 Health Survey manual and interpretation guide*. Boston, MA: New England Medical Center, The Health Institute, 1993.

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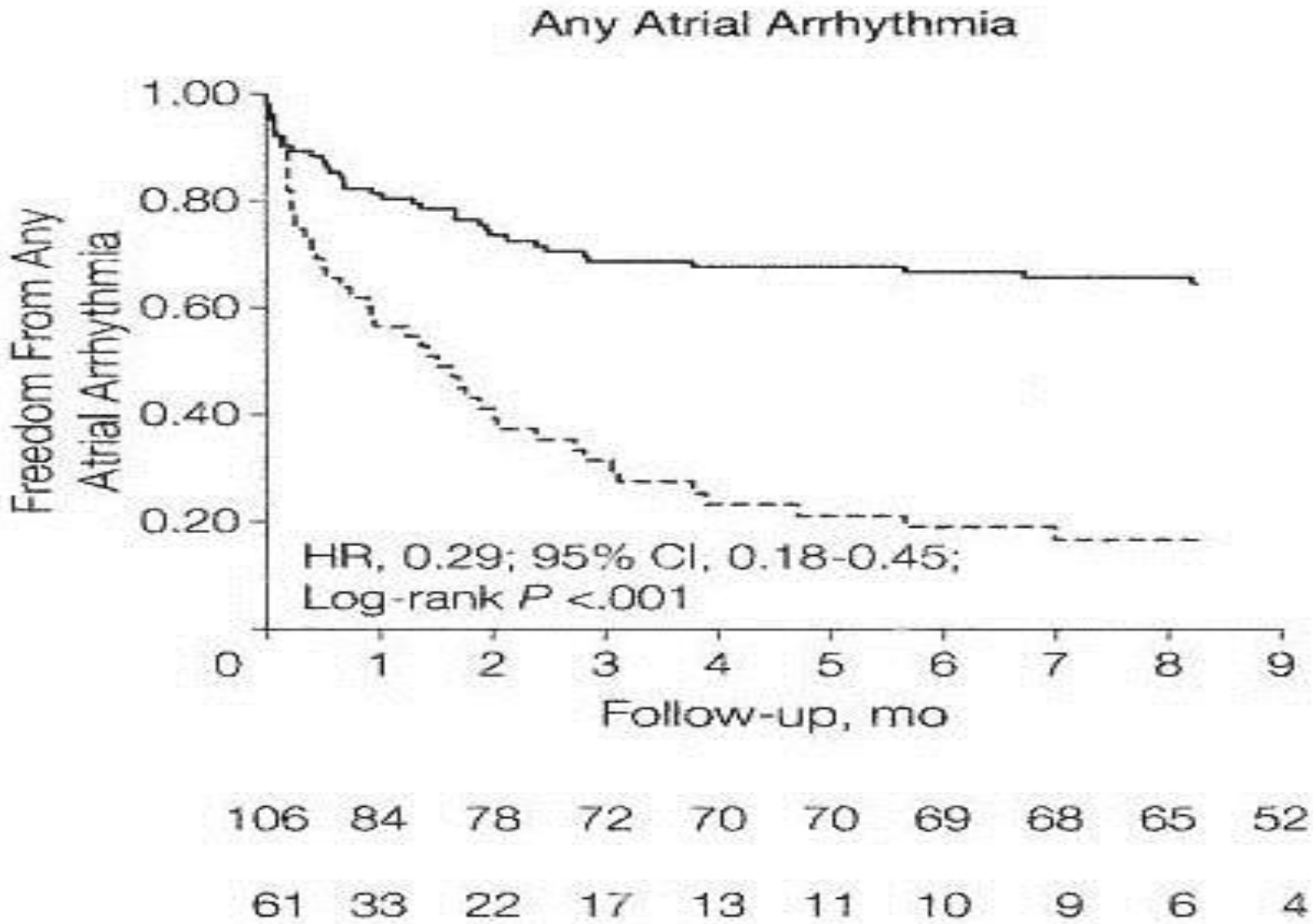
Any Atrial Arrhythmia
Freedom From Any Atrial Arrhythmia
1.00
0.80
0.60
0.40
0.20
HR, 0.29; 95% CI, 0.18-0.45;
Log-rank P <.001
0
1
2
3
4
5
6
7
8
9
Follow-up, mo
106 84 78 72 70 70 69 68 65 52
61 33 22 17 13 11 10 9 6 4

Therapies

Thermocool Study Group:

Patients with frequent symptomatic paroxysmal AF unresponsive to drug therapy, RFCA resulted in significantly better outcomes vs continued attempts at rhythm control with alternative anti-arrhythmic agents.

Outcomes included substantial decrease in the risk of recurrent atrial arrhythmias & clinically meaningful improvement in symptoms & QOL.

Atrial Fibrillation Therapies

Reynolds et al *(Circ Arrhythmia Electrophysio 2009)*

Evaluated the cost effectiveness of CA compared to AAD Tx for pts with paroxysmal AF.

They concluded that in pts with drug refractory PAF, catheter ablation is a reasonably cost effective therapy compared with AAD tx based on QOL & avoidance of future health care costs.

TactiCath™ Catheter Clinical Evidence

- Comprehensive set of multi-center clinical studies[6,7,10,11,12] on contact force sensing
- First to provide guidelines for contact force management intended to improve isolation[6,7] of pulmonary veins in AF ablation
- Continued focus on clinical publications

TOCCATA[10,11]

- Safety and feasibility of Force Sensing
- Importance of average Contact Force
- Demonstrated that contact force monitoring during the ablation of AF correlates with clinical outcome

EFFICAS II[7]

- Significantly better outcome when using Contact Force recommendations

EFFICAS I[6]

- Established Contact Force recommendations
  - Minimum Contact Force
  - Minimum Force Time Integral

TOCCASTAR[12]

- Effectiveness and safety with TactiCath™ ablation catheter
- Provided indication for treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation

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- Effectiveness and safety with TactiCath™ ablation catheter
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TactiCath™ Catheter Clinical Evidence

- Comprehensive set of multi-center clinical studies[6,7,10,11,12] on contact force sensing
- First to provide guidelines for contact force management intended to improve isolation[6,7] of pulmonary veins in AF ablation
- Continued focus on clinical publications

TOCCATA[10,11]

- Safety and feasibility of Force Sensing
- Importance of average Contact Force
- Demonstrated that contact force monitoring during the ablation of AF correlates with clinical outcome

EFFICAS II[7]

- Significantly better outcome when using Contact Force recommendations

EFFICAS I[6]

- Established Contact Force recommendations
  - Minimum Contact Force
  - Minimum Force Time Integral

TOCCASTAR[12]

- Effectiveness and safety with TactiCath™ ablation catheter
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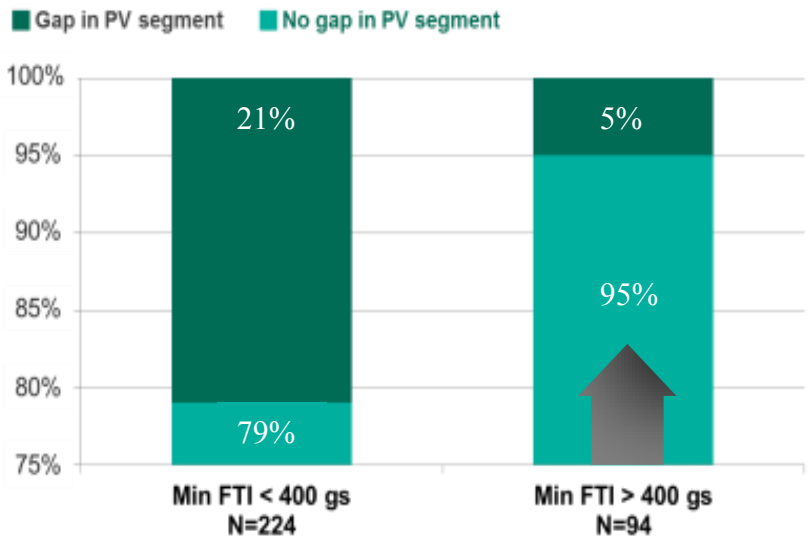
Clinical Evidence: Efficacy

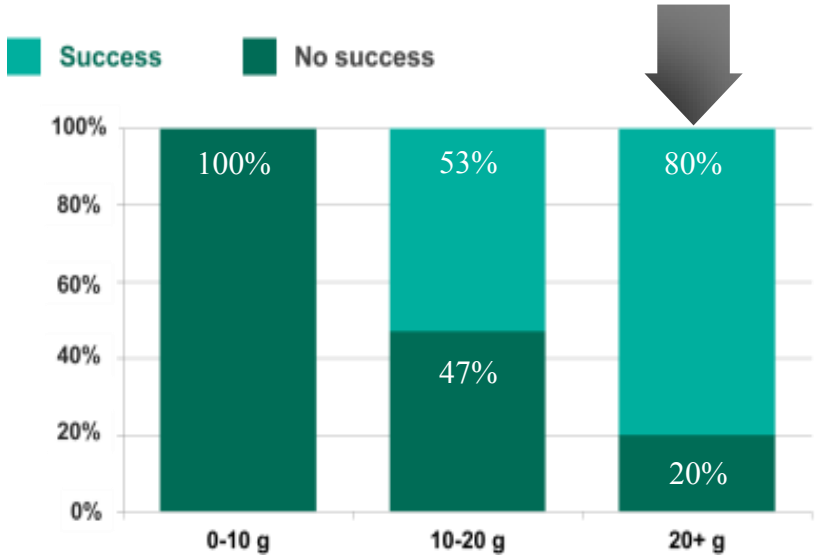
Using appropriate contact force during ablations may lead to:

1. Improved isolation rate at 3M[6]



Target minimum FTI of 400 g-s[6]

2. Improved clinical outcome at 12M[11]



Target Contact Force of 20 g[11]

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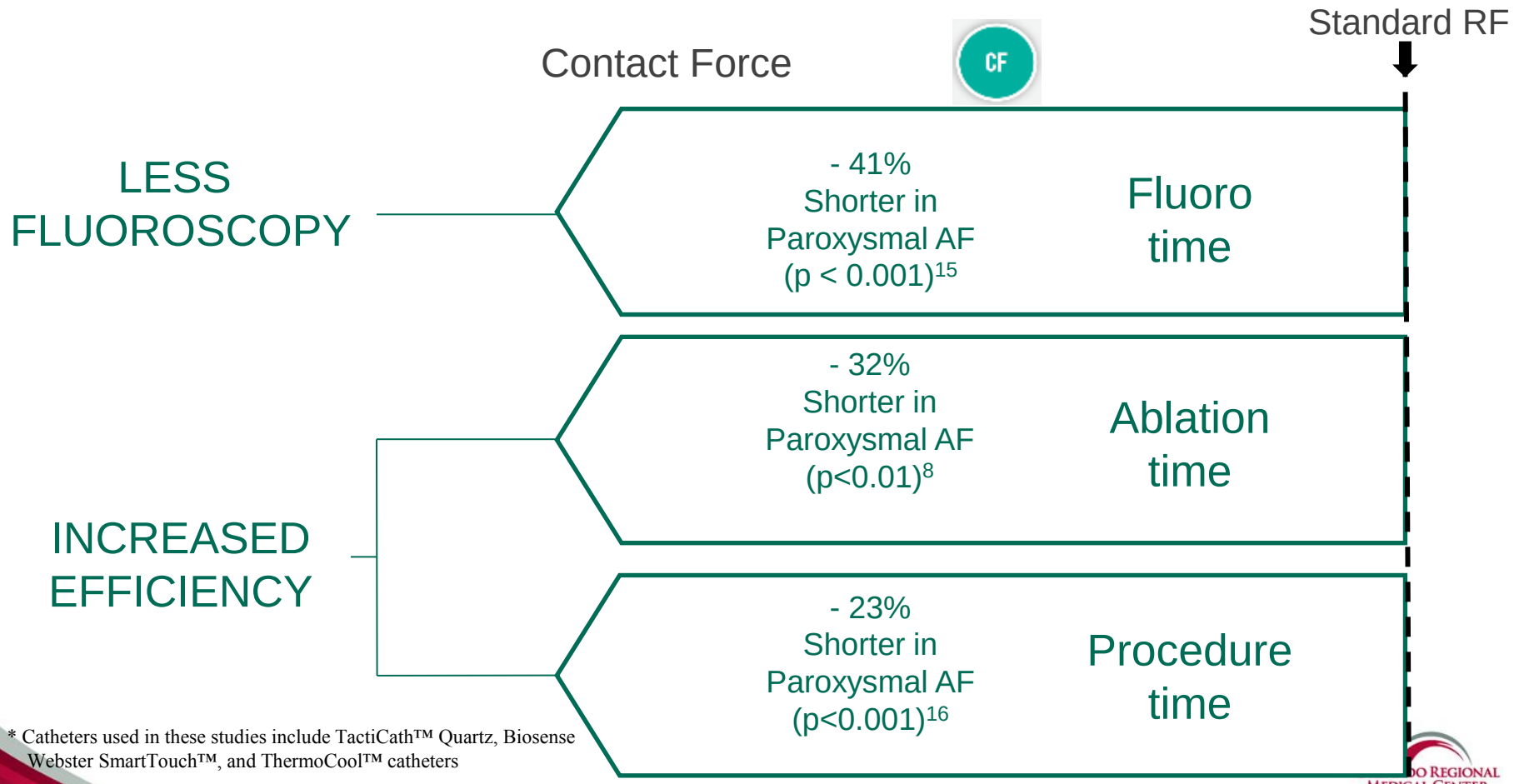
The Value of Contact Force – Inside the

Use of contact force sensing catheters for the treatment of atrial fibrillation may also increase efficiency within the EP lab.[14,15]



* Catheters used in these studies include TactiCath™ Quartz, Biosense Webster SmartTouch™, and ThermoCool™ catheters

Summary

Use of contact force recommendations may lead to reduced recurrence of AF[6,7,11]			
→	Target	CF	20 g with range (10g, 30g)[6,11]
→	Min	CF	10 g for any ablation points[6,11]
→	Min	FTI	400 g-s for any ablation points[6]
→	ONE SHOT: Transmurality should be achieved in one shot[6]		

- Contact force-sensing technology provides further information to physicians during PV isolation procedures.
- St. Jude Medical can provide tools and clinical evidence on contact force.
- When contact force recommendations are used appropriately, they may:
  - Increase quality of performed ablations[6,11]
  - Improved outcomes for AF patients[11]

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The FIRE AND ICE Trial

Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation

Primary Endpoint and Secondary Analyses Results

(ClinicalTrials.gov NCT01490814)

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Study Overview

- Compare the safety and efficacy of PVI by either:
  - **Cryoablation**, n=374 **(**Arctic Front™ catheters) guided by fluoroscopy OR
  - **RFC ablation**, n=376 **(**THERMOCOOL® catheters) guided by CARTO® 3D mapping system

- Primary Efficacy Endpoint*: Time to first documented recurrence of AF>30s/AT/AFL, prescription of AAD, or re-ablation

- Primary Safety Endpoint*: Time to first all-cause death, all-cause stroke/TIA or treatment-related serious AEs (e.g. phrenic nerve injury, atrioesophageal fistula, etc.)

* Predefined analyses

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

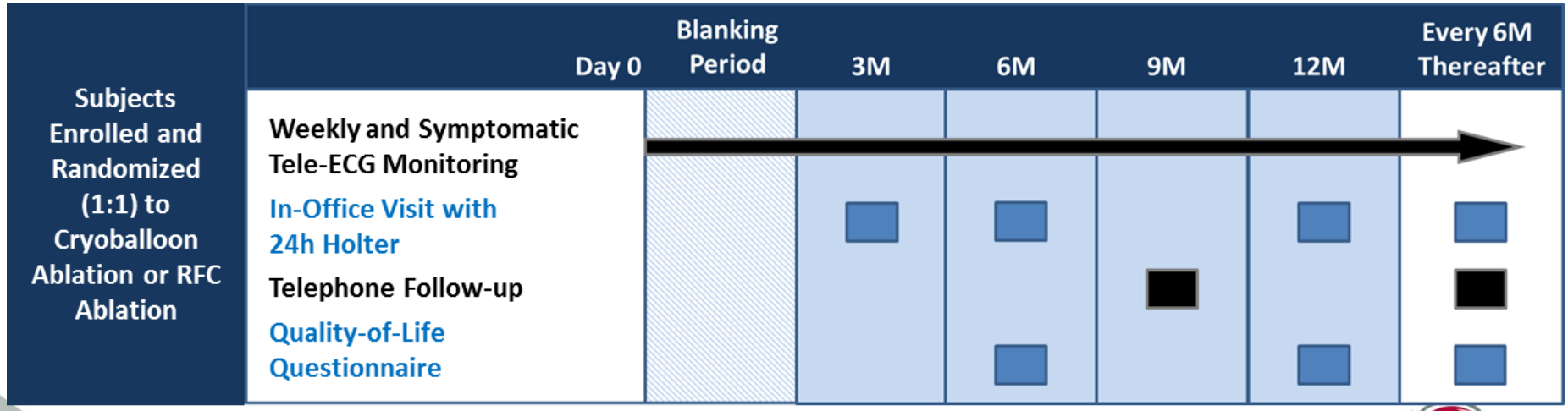
Study Methods

Key Inclusion Criteria

- Symptomatic PAF
- Prior AAD failure
- ≥ 18 & ≤ 75 years of age

Key Exclusion Criteria

- Previous LA ablation or surgery
- PCI, MI within 3M of enrollment
- Stroke/TIA within 6M of enrollment
- LVEF < 35%
- LA diameter > 55mm



Mean follow-up 1.5 years, Maximum follow-up duration of 33 months

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

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Study Methods

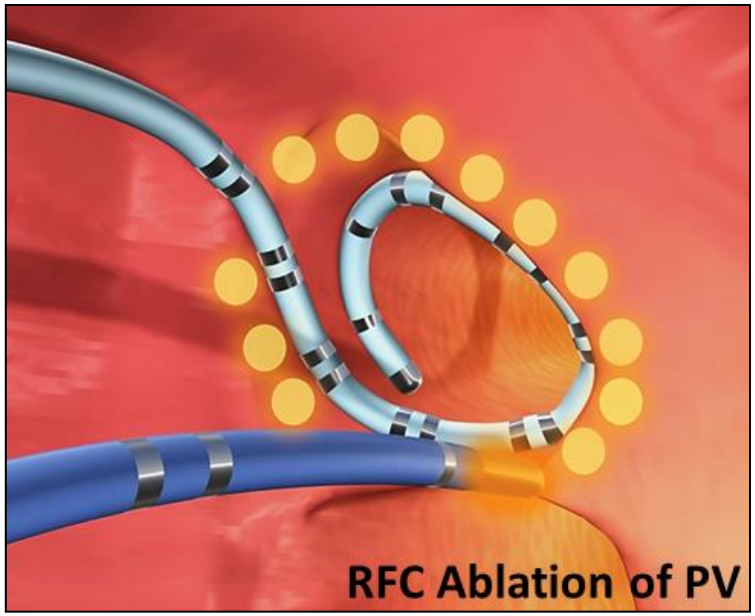
- Investigators must have documented experience
  - ≥ 50 cases with either technology; each center had to provide at least one investigator proficient in both techniques
  - ≥ 10 cases before introduction of advanced-generation catheters
- PVI-only approach (CTI flutter ablation allowed, no additional lines or CFAE ablation)
- Must confirm PV isolation with a mapping catheter
- AADs discontinued after 90 day blanking period

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

Catheter Groups

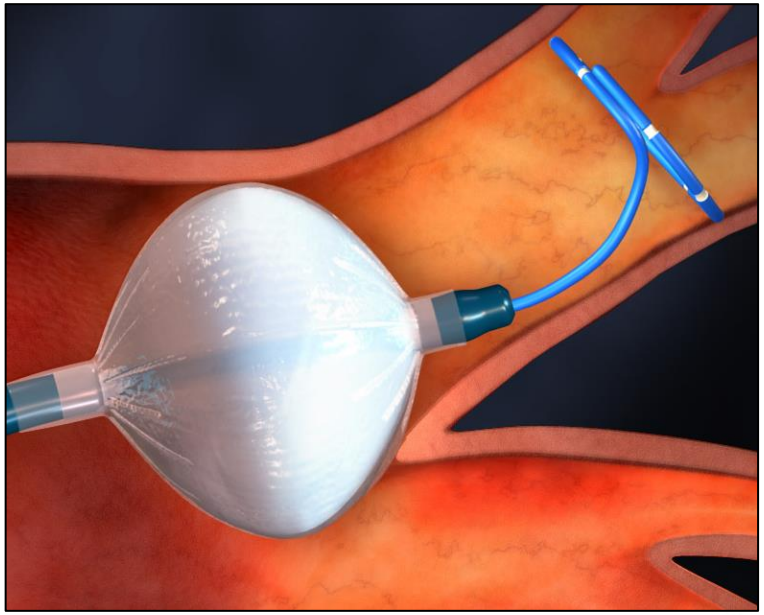
RFC Ablation ("FIRE")

- Power was not to exceed
  - 40 Watts at A/I aspect
  - 30 Watts at P/S aspect
- 3D electroanatomical mapping



Cryoballoon Ablation ("ICE")

- Max. freeze duration of 240s recommended
- Bonus freeze after isolation recommended
- Phrenic nerve pacing required



Cryoballoon Ablation of PV

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

Patient Demographics and Follow-up

	RFC (n=376)	Cryoballoon (n=374)	P-value*
Age, years	60.1 ± 9.2	59.9 ± 9.8	0.83
Men, n (%)	236 (63)	221 (59)	0.30
BMI, kg/m^2	27.8 ± 4.5	28.0 ± 4.7	0.66
CHA_2DS_2-VASc Score, n (%)			0.19**
0	67 (17.8)	58 (15.5)	
1	109 (29.0)	108 (28.9)	
2	97 (25.8)	95 (25.4)	
3	62 (16.5)	60 (16.0)	
4	33 (8.8)	40 (10.7)	
5	7 (1.9)	10 (2.7)	
6	1 (0.3)	3 (0.8)	
Years Since First PAF Diagnosis	4.7 ± 5.3	4.6 ± 5.1	0.97
Left Atrial Diameter, mm	40.6 ± 5.8	40.8 ± 6.5	0.58
Previous DC Cardioversion	23.4%	23%	0.89
Systolic Blood Pressure, mm Hg	134.8 ± 18.9	133.6 ± 18.0	0.40
Diastolic Blood Pressure, mm Hg	78.9 ± 10.6	78.8 ± 11.5	0.83

Patient Follow-up		
	RFC (n=376)	Cryoballoon (n=374)
Visits	2007 / 2372 (85%)	2006 / 2317 (87%)
Mean F/U Time	1.54 ± 0.79 years	1.54 ± 0.80 years
Total F/U Time	577 patient years	576 patient years
Weekly Tele-ECG	60.0%	58.1%

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

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Primary Endpoint Results

ACC and New England Journal of Medicine

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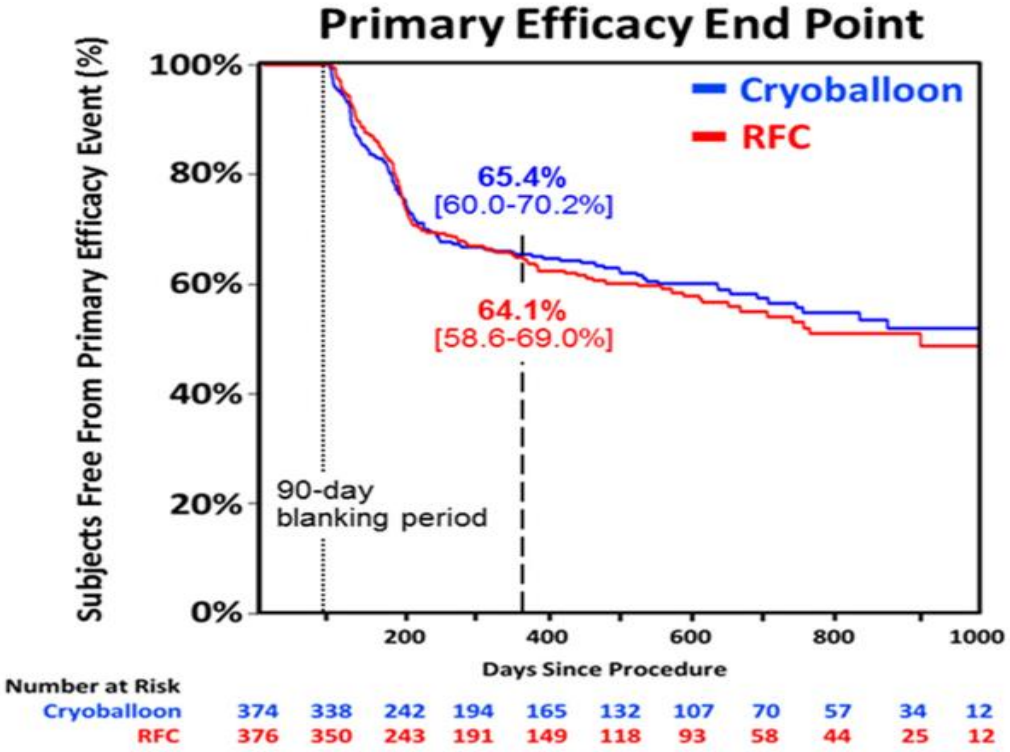
Primary Efficacy Endpoint Met



- Non-inferiority hypothesis met
- HR [95% CI] = 0.96 [0.76-1.22]; p = 0.0004
- 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

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

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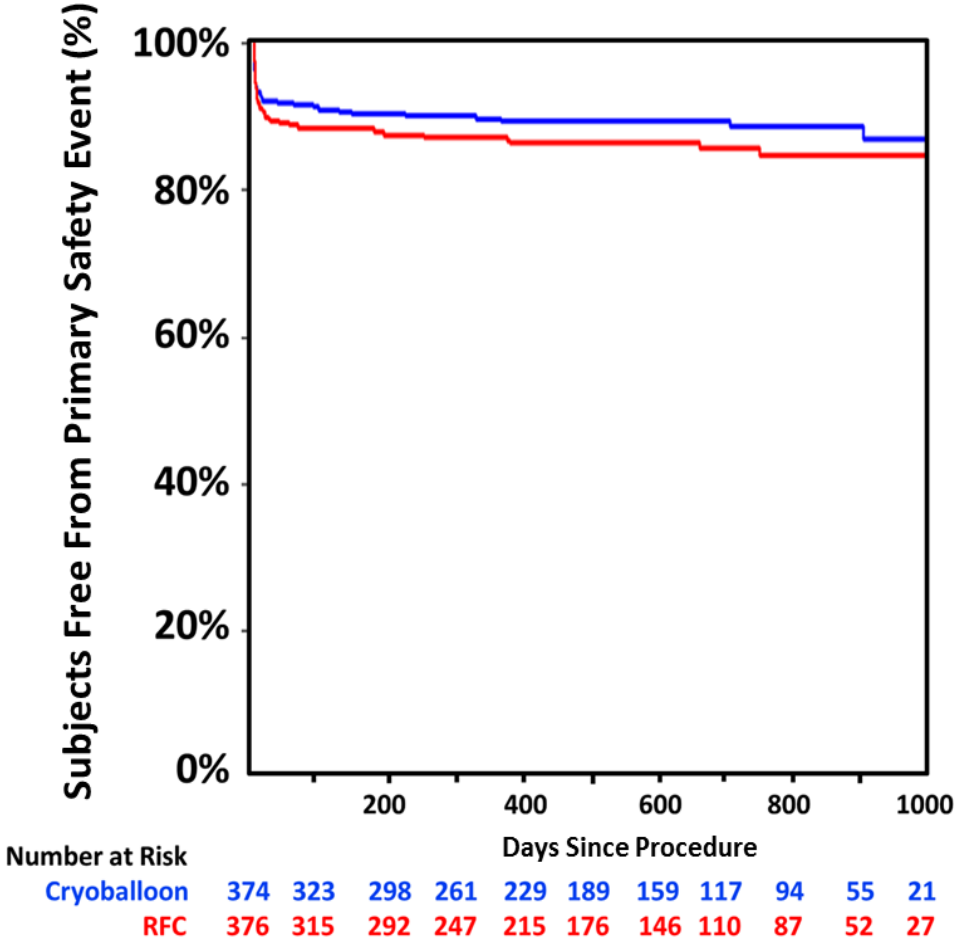
Primary Safety Endpoint Met



Safety Event Type	RFC (n=376)	Cryoballoon (n=374)
All-cause death*	0	2
All-cause stroke/TIA	2	2
Arrhythmia-related SAE	13	8
Non-arrhythmia-related SAE	36	28
Total	51	40

*One death (at day 366) was of unknown cause; one death (at day 95) was associated with sepsis and was determined by autopsy to be a non-cardiac related death

HR [95% CI] = 0.78 [0.52-1.18]; p = 0.24

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

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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 (0%)	10 (2.7%)***
Unresolved at 3 months	0 (0%)	2 (0.5%)
Unresolved at > 12 months	0 (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 (0%)
Esophageal Ulcer	0 (0%)	1 (0.3%)
Pericarditis	0 (0%)	1 (0.3%)
Atrioesophageal Fistula	0 (0%)	0 (0%)
Pulmonary Vein Stenosis	0 (0%)	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*

Kuck KH, et al. *N Engl J Med.* 2016; 374(23): 2235-45.

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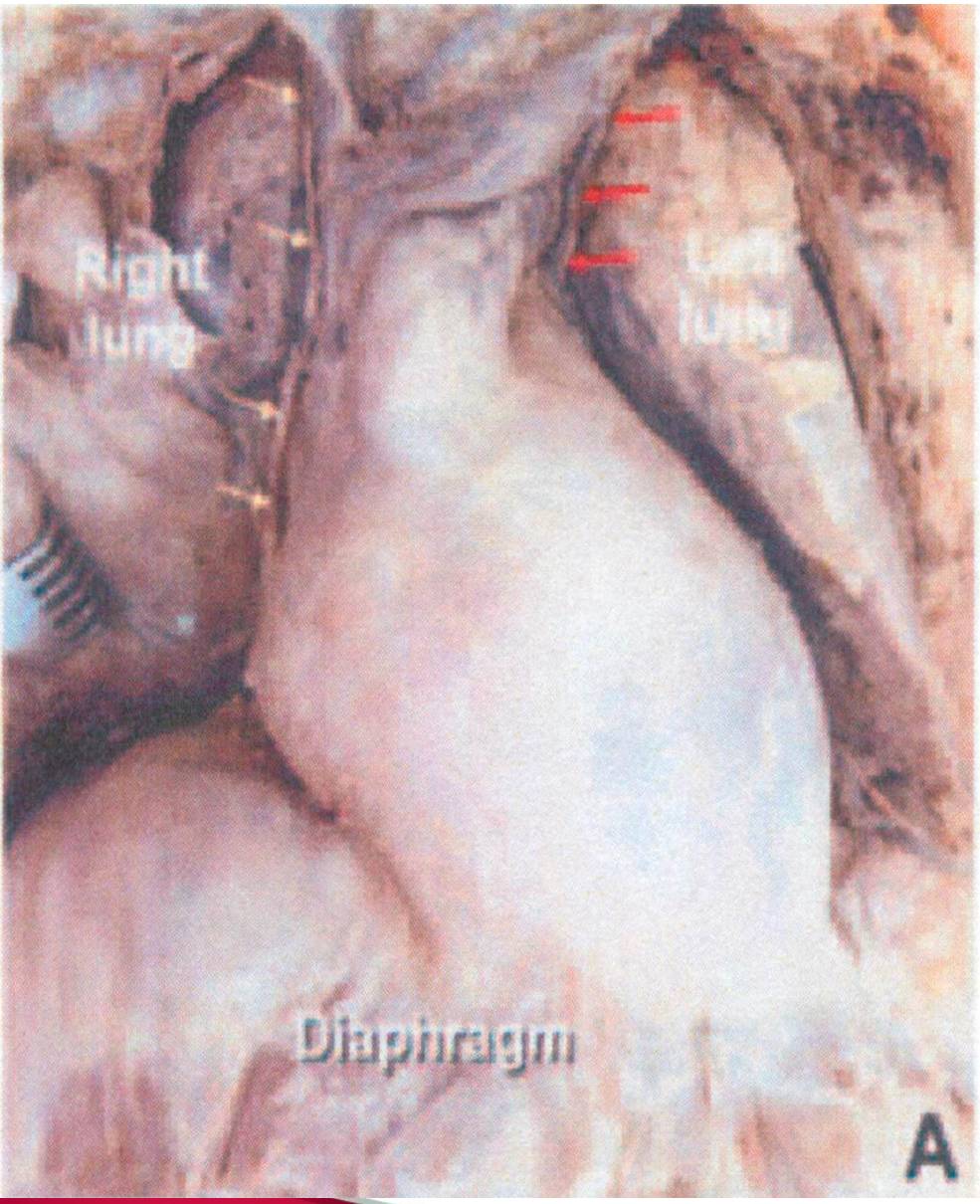
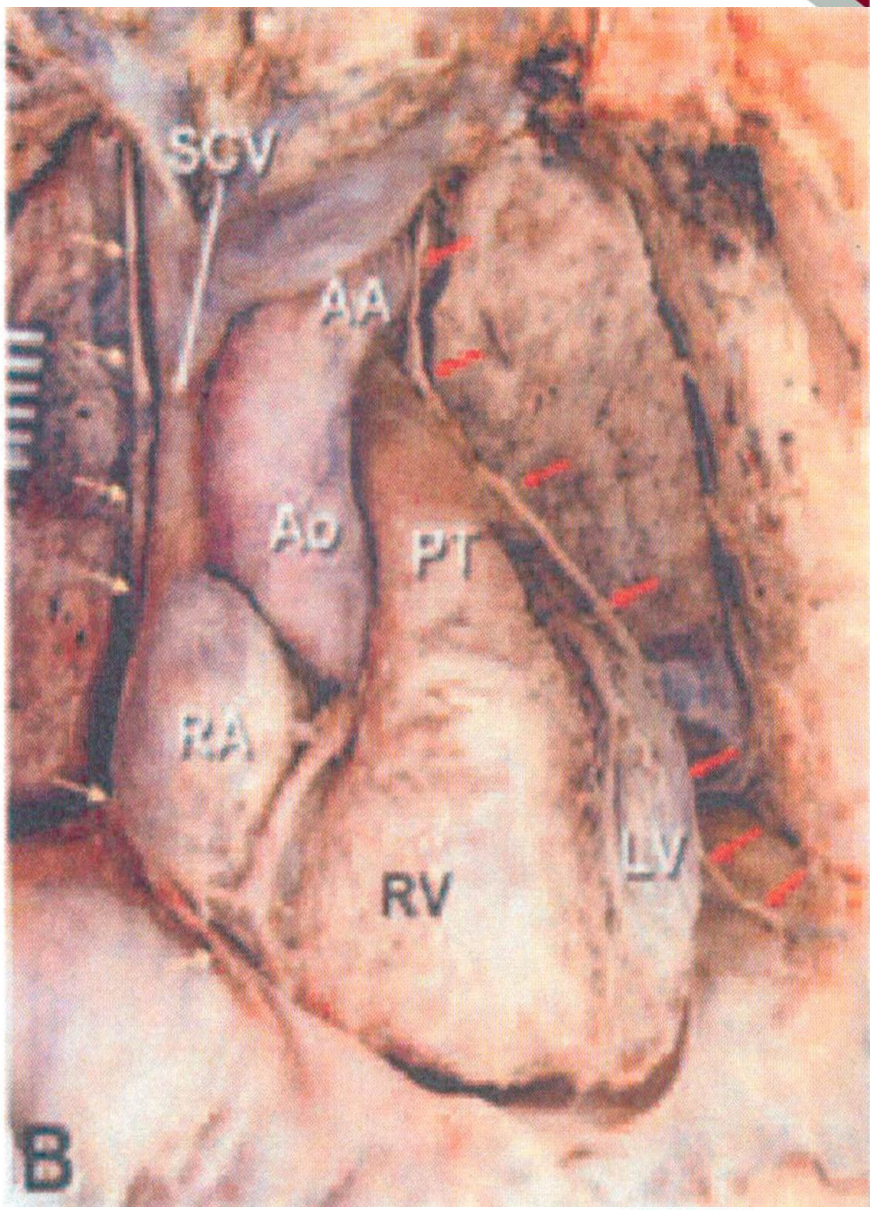
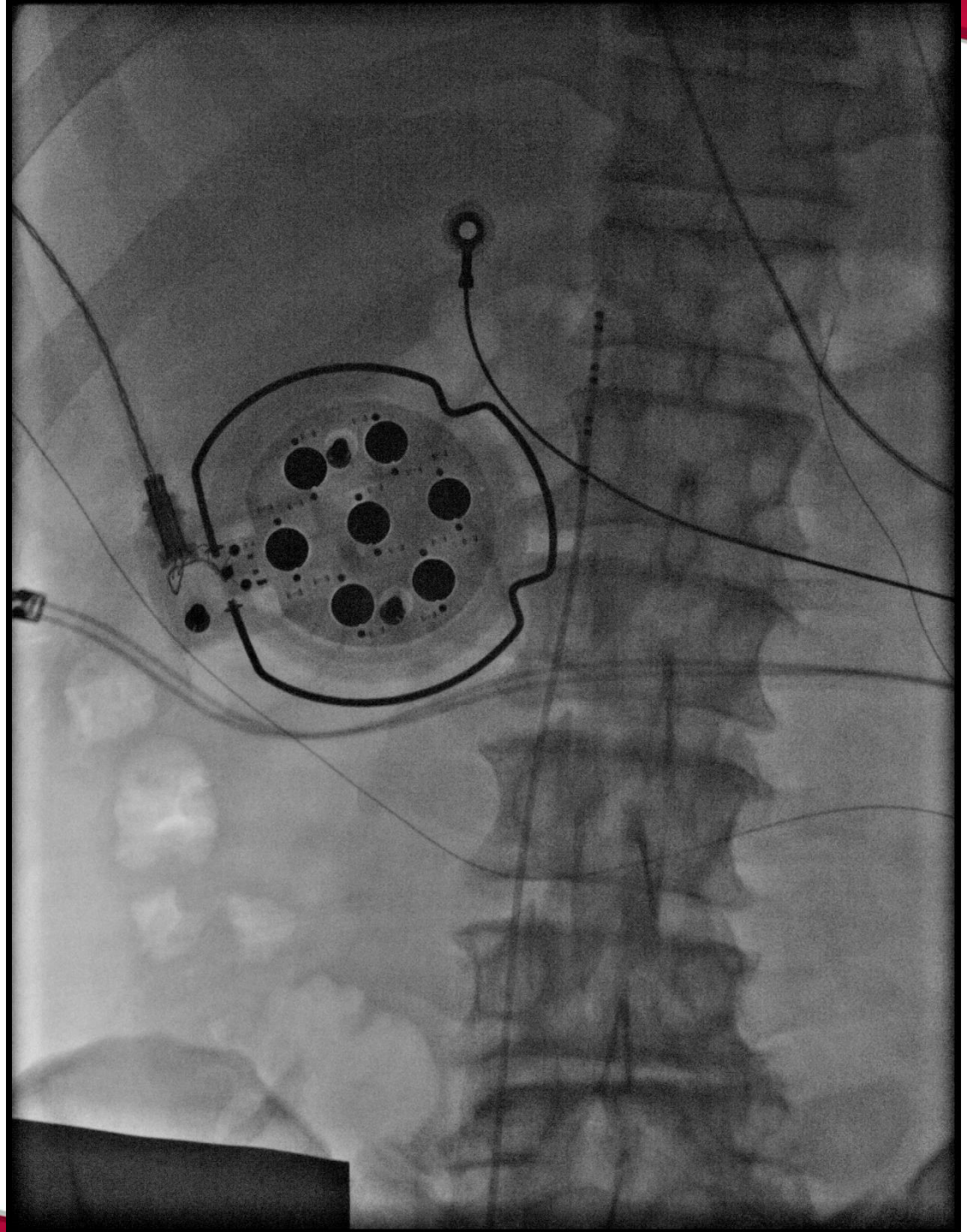
Phrenic Nerves







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Secondary Analyses Results

Cardiostim and European Heart Journal

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Secondary Analysis Background

Secondary analyses included:

- Cardiovascular hospitalization* (including AF hospitalization†)
- Repeat ablation*
- Quality-of-life*
- All-cause hospitalization
- Direct current cardioversion (DC Cardioversion)

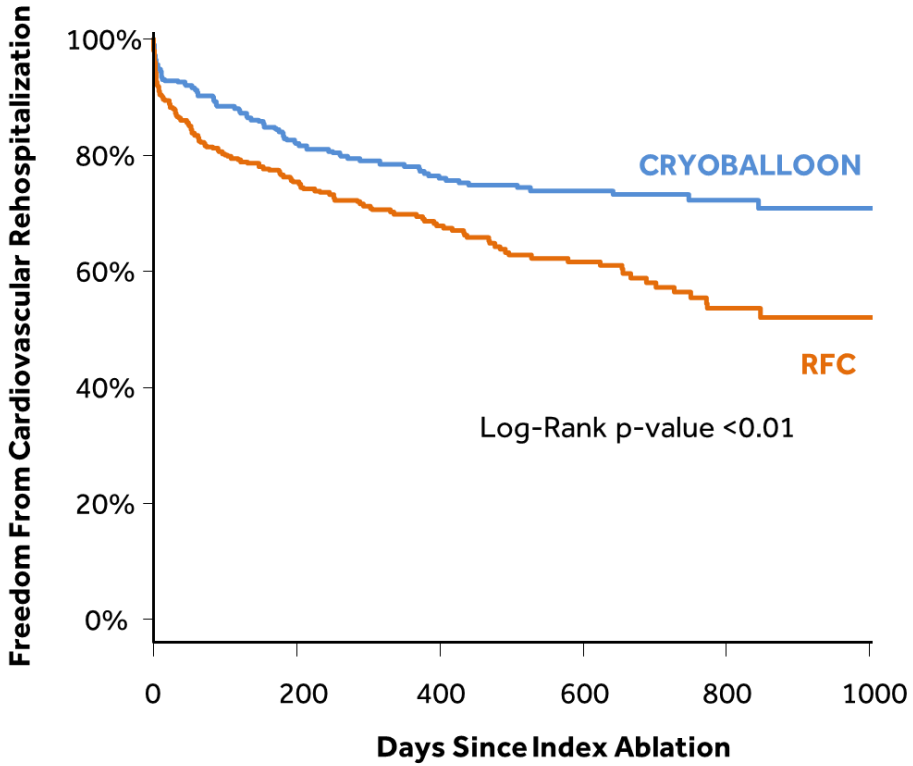
* Predefined secondary analyses
† Not predefined but included in supplementary analyses

Kuck KH, et al. Eur Heart J. 2016; Oct 7;37(38):2858-2865.

Freedom From Cardiovascular Rehospitalization

34% Fewer CV Rehospitalizations in the Cryoballoon Group vs Radiofrequency Group

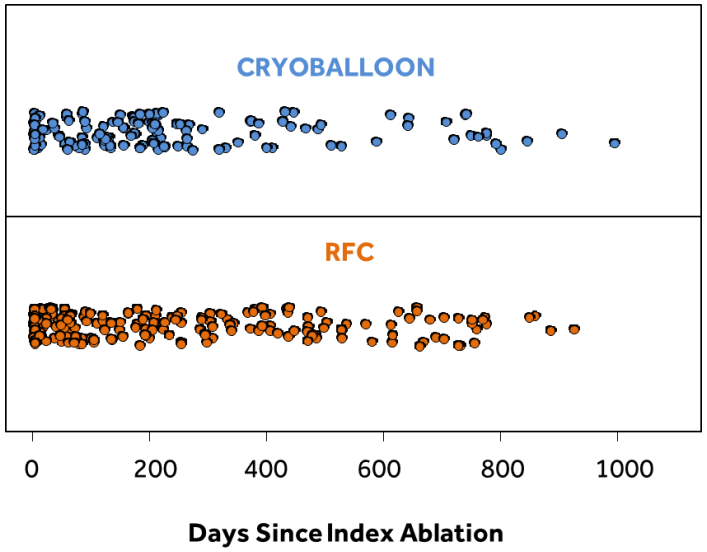
Event Free Survival



Number at Risk

CRYOBALLOON	374	271	190	126	68	15
RFC	376	250	167	102	52	14

Total Events



Cryo: 139 events in 89 subjects (89/374; **23.8%**)

RFC: 203 events in 135 subjects (135/376; **35.9%**)

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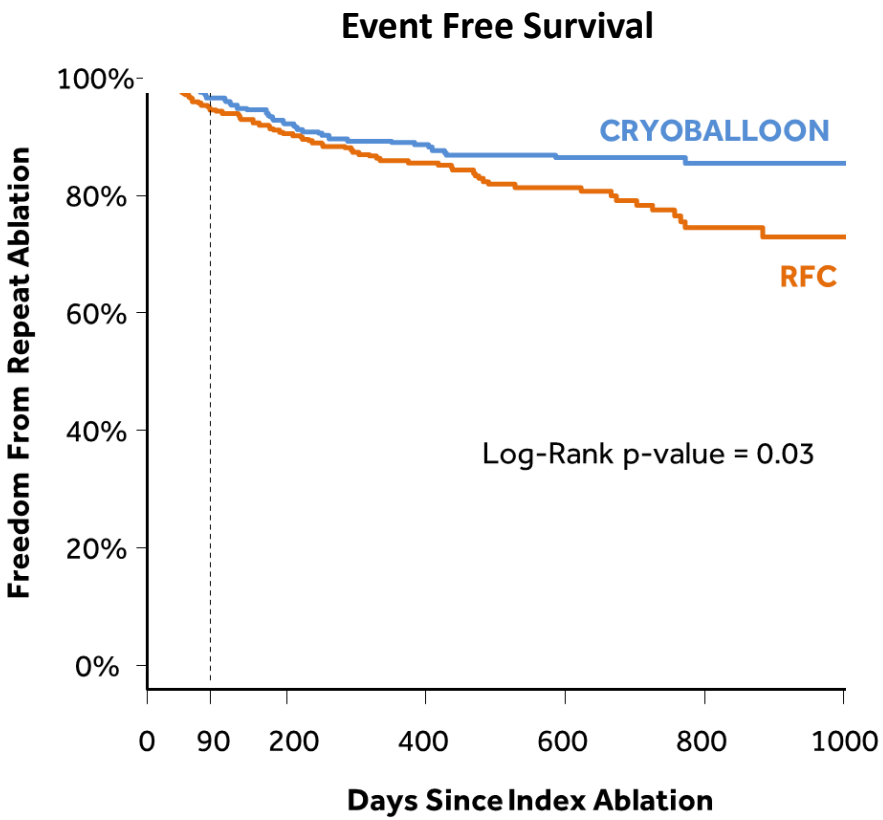
Kuck KH, et al. Eur Heart J. 2016; Oct 7;37(38):2858-2865.

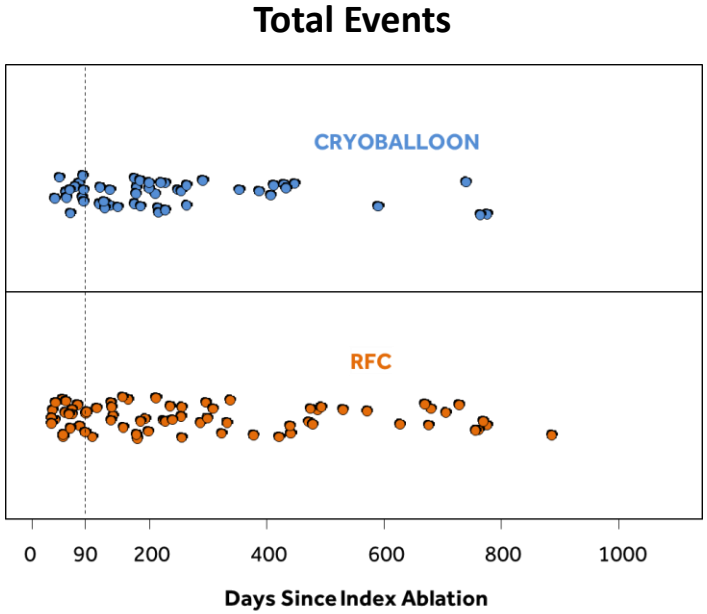
Freedom From Repeat Ablation

33% Fewer Repeat Ablations in the Cryoballoon Group vs Radiofrequency Group



Number at Risk

CRYOBALLOON	374	343	301	221	149	84	20
RFC	376	341	302	213	135	72	22



Cryo:49 events in 44 subjects (44/374; **11.8%**)

RFC:70 events in 66 subjects (66/376; **17.6%**)

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Kuck KH, et al. Eur Heart J. 2016; Oct 7;37(38):2858-2865.

FIRE AND ICE Conclusions

Primary Endpoints: PVI by Cryoballoon ablation was found to be non-inferior to PVI by RFC ablation in terms of efficacy and safety, but had shorter and more consistent procedure times[1]

Secondary Analyses: Subjects treated with Cryoballoon compared to RFC had significantly fewer reinterventions and rehospitalizations:[2]

- Cardiovascular hospitalizations - 34% Fewer
- Repeat ablations - 33% Fewer
- All-cause hospitalizations - 21% Fewer
- Direct current cardioversions - 50% Fewer
- Both patient groups demonstrated improved quality-of-life scores after an AF ablation[2]

These analyses have important implications on daily clinical practice

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1. Kuck KH, et al.. *N Engl J Med*. 2016; 374(23): 2235-45. *2.* Kuck KH, et al. *Eur Heart J* (2016) First published online: 5 July 2016

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FIRE AND ICE Conclusions

Health Economic Analysis

- Payer costs for Cryoballoon were lower than for RFC and driven by differences in repeat ablations and CV rehospitalizations
- Savings persisted across the three healthcare systems analyzed

Predictors of Outcomes

- Female gender and a baseline history of DCCV were independently associated with increased primary endpoint rates
- Female gender and hypertension were independently associated with increased CV rehospitalization rates
- Cryoballoon ablation was associated with significantly less CV rehospitalizations in patients with a baseline history of DCCV, and in patients with a baseline CHA2DS2-VASc score of 0 or 1

Kuck KH, et al. The Fire and Ice: Late-breaking Clinical Trial Presentation at APHRS 2016 October 13; Seoul, Korea

Case Study

- CHA2DS2Vasc – 1 (female)
- She had previously tried and failed diltiazem, metoprolol, flecainide and most recently drodenarone.

- **What would you do next ?**

A. Try rate control and xanax.
B. Try another anti-arrhythmic agent
C. Cardiovert and discharge home.
D. Consult your friendly neighborhood electrophysiologist

78

Shopping Days

Left until

Christmas

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Persistent Atrial Fibrillation

- Surgical data support the isolation not only the PV's but also the whole posterior LA. Success rates ~ 93% for pts with "lone AF" & 86% among those with persistent AF.

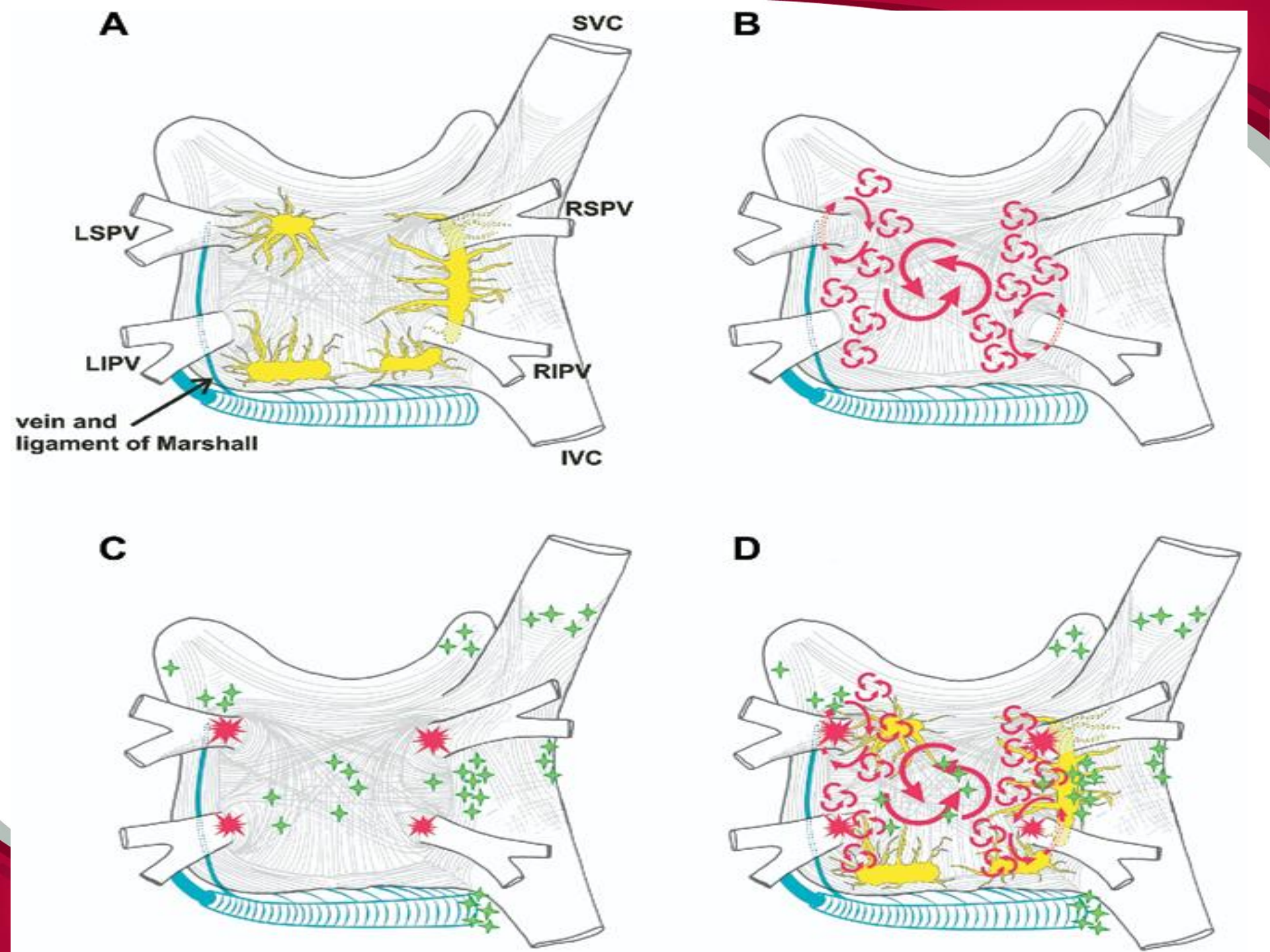
  Sueda et al Ann Thorac Surg 1997;63: 1070

- Non PV foci commonly originate from the PV ostium or posterior LA.

- Posterior wall arrhythmogenic substrates include triggers, reentrant circuits & ganglionic plexi. Isolating the posterior wall may interrupt these sympathetic & parasympathetic innervations.

  Lim et al Circ 2003;107:3176 Katritsis et al Heart Rhythm 2011;8:672

  Pappone et al Circ 2004;109:327 Yamaguchi et al Circ J 2010;74: 1096


A
SVC
RSPV
LSPV
LIPV
RIPV
vein and
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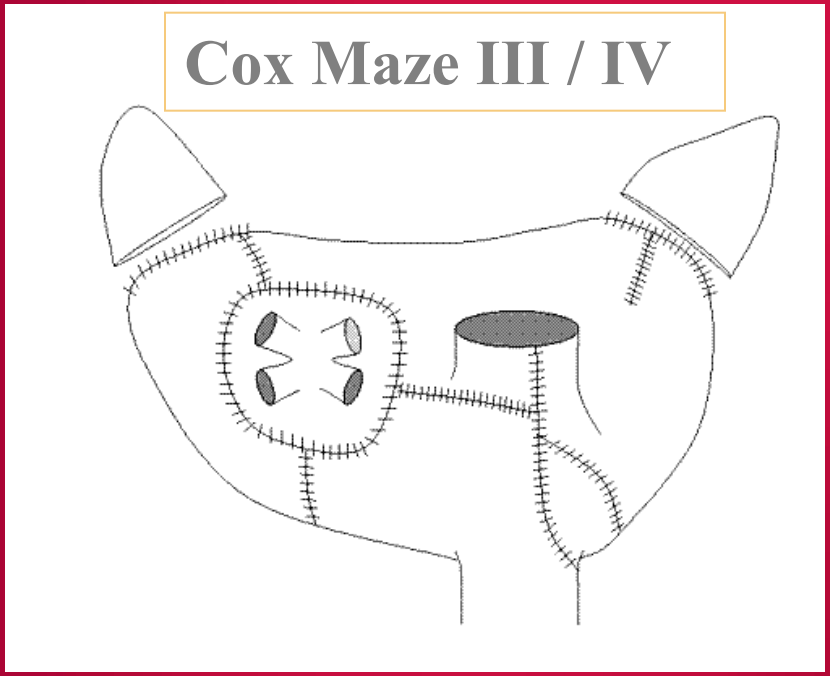
IVC
B
C
D

How do we know that an RF surgical maze is effective?



-Based on the original Cox Maze Gold Standard (>90%)

-IV uses RF for most of the lesions

-Complex

-Sternotomy / CPB

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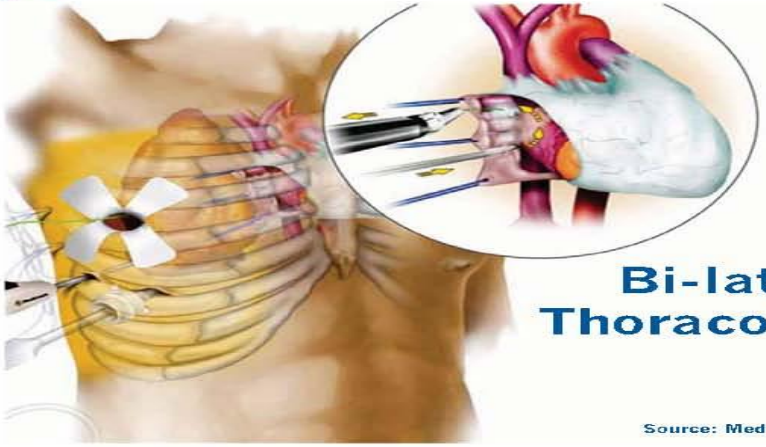
POTENTIAL CLOSED CHEST ADVANTAGES:
DRIVES CARDIOLOGY REFERRALS AND PATIENT RECEPTIVENESS

Closed Chest SUBTLE Approach



Bi-lateral Thoracotomies

Source: Medronic, Inc.

Persistent Atrial Fibrillation

- Pericardioscopy provides endoscopic access to and visualization of the beating epicardial surface through the central tendon of the diaphragm without the need for cardiopulmonary bypass or chest incisions. Kiser et al Innovations 2008;3:117
- This procedure can be done outside the CV OR suite, in a hybrid room in collaboration with electrophysiologists to provide an endocardial ablation pattern. Hence …"The Convergent Procedure" Kiser et al Heart Surg forum 2010;13:e317

Persistent Atrial Fibrillation

- **Conclusion:**
  - The success any treatment for persistent AF is dependent upon the transmurality & contiguity of the ablation lines & the completeness of the lesion pattern.
  - The inability to obtain a high degree of success with the current minimally invasive surgical approaches or the percutaneous catheter techniques has led to this Convergent/Hybrid Procedure.
  - This multidisciplinary approach integrates the advantages of both cardiac surgery and electrophysiology.

Persistent Atrial Fibrillation

- The convergence of technologies & expertise allows:
  1. Creation of complete endo/epicardial ablation patterns without the need for chest incisions or cardiopulmonary bypass.
  2. Provide intraoperative metrics to confirm procedural success.
  3. Encourage integrated patient care by cardiac surgery and EP
  4. Potentially decreases hospital stay & the number of repeat ablations.

Atrial Fibrillation

- Conclusion:
- AF contributes to considerable morbidity with increasing risk of stroke, complications from anticoagulation and exacerbation of heart failure.
- The discovery of underlying mechanisms have allowed for the evolution of newer antiarrhythmic agents, anticoagulants and techniques of ablation based on the identification of specific targets.