
Atrial Fibrillation A Brief Overview!!

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Presenter Disclosure Information

Financial Disclosures

- Significant Research Support: National Cardiovascular Database Registry (NCDR and AHA)

Typical EP Patient.....A Metabolic



Atrial Fibrillation

- What is Atrial Fibrillation
- Is all AF similar?
- Rate Control Strategy.....It's so much Easier!!
- Rhythm Control
 - Anti-arrhythmic Drugs
 - Cardioversion
 - Ablation
- Stroke Prevention in Atrial Fibrillation
 - Who is a candidate for anticoagulation
 - Watchman Device

Man vs. the Beast!!

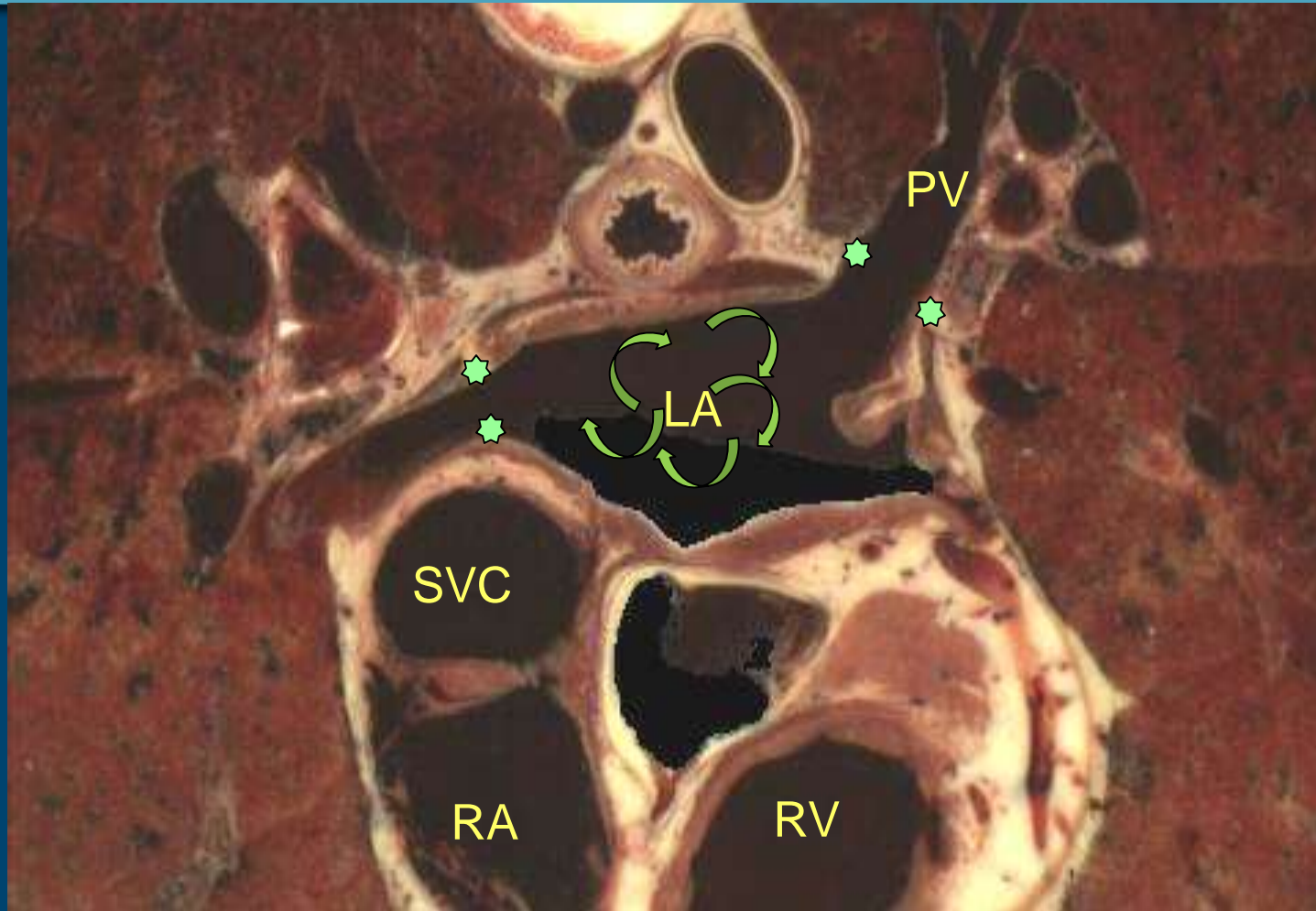


Atrial Fibrillation

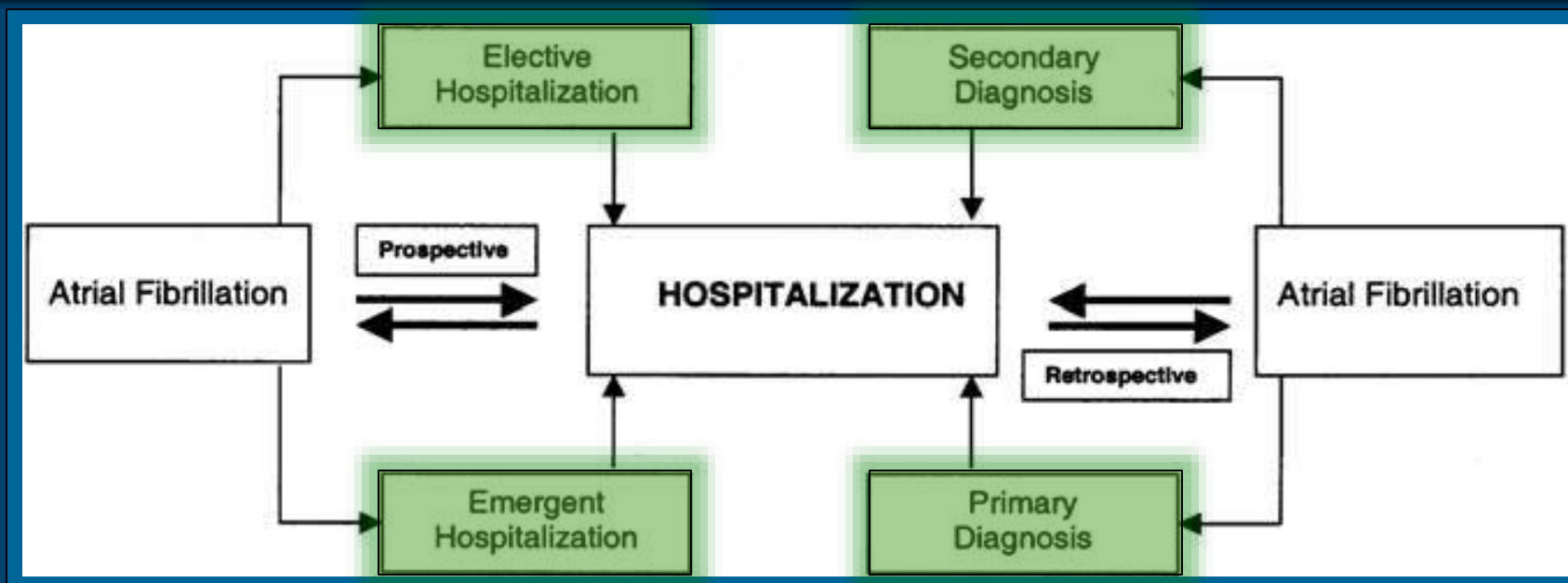
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Atrial Fibrillation

An Interplay of Substrate & Triggers



Atrial Fibrillation, Hospitalization & Direct Costs



- Outpatient costs: \$ 1.8 billion
- Inpatient Costs (Principal Diagnosis): \$ 2.9 billion
- Inpatient costs (incremental as a co-morbidity): \$ 2.0 billion
- **TOTAL ESTIMATED (2005): \$ 6.7 billion and growing**

CHF-AF: A Double Whammy!

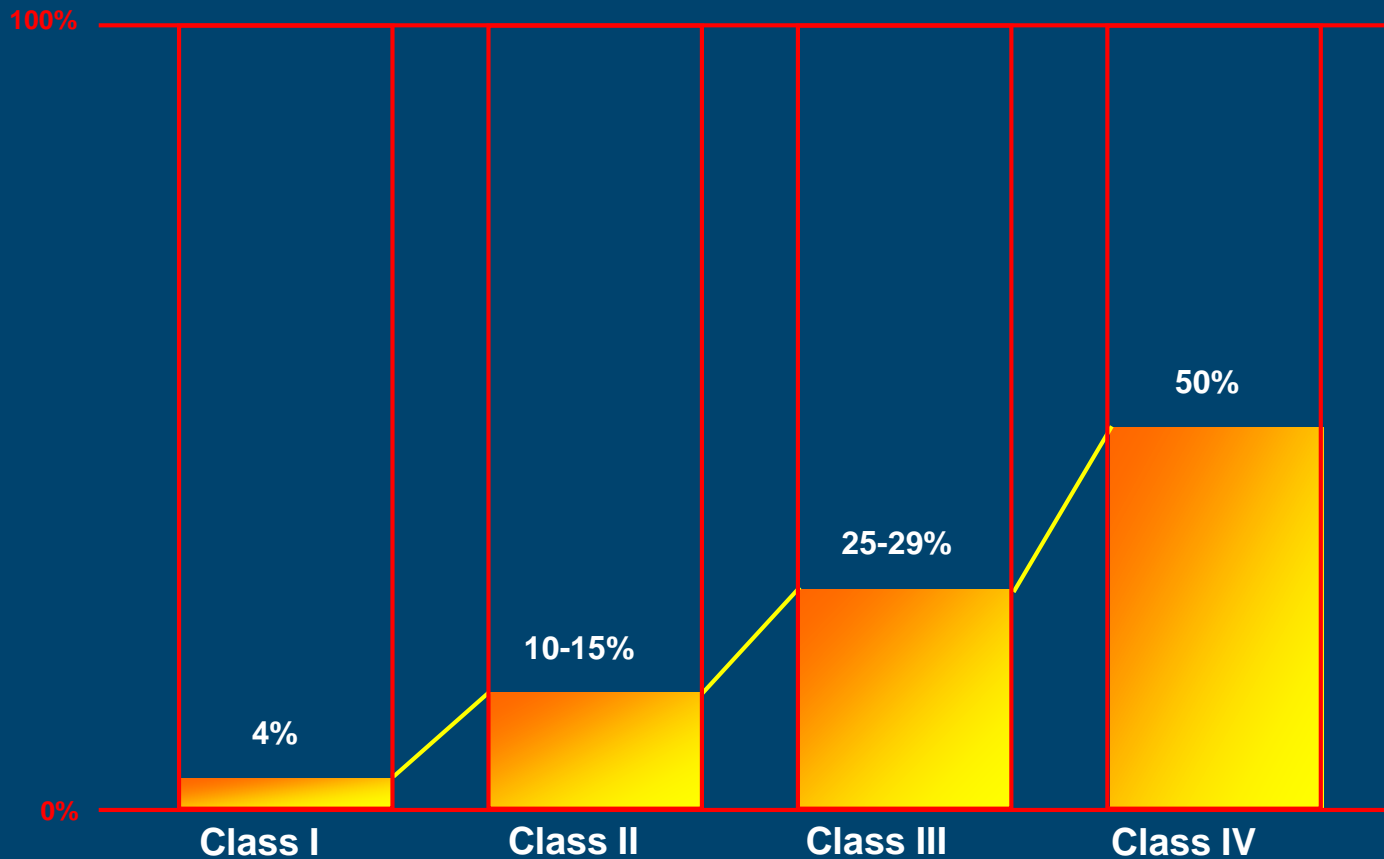
TABLE 2. Cox Multivariable Proportional Hazards Models Examining the Impact of the Comorbid Condition on Mortality

Models	Men, Adjusted HR (95% CI)	Women, Adjusted HR (95% CI)
Comorbid condition as a time-dependent variable		
(A) Mortality after AF		
Impact of incident CHF	2.7 (1.9 to 3.7)*	3.1 (2.2 to 4.2)*
(B) Mortality after CHF		
Impact of incident AF	1.6 (1.2 to 2.1)†	2.7 (2.0 to 3.6)*

The combination of AF and HF irrespective of which comes first is associated with a further 2-3 fold increase in mortality

Atrial fibrillation burden increases with severity of heart failure

Incidence of Atrial Fibrillation by NYHA Class

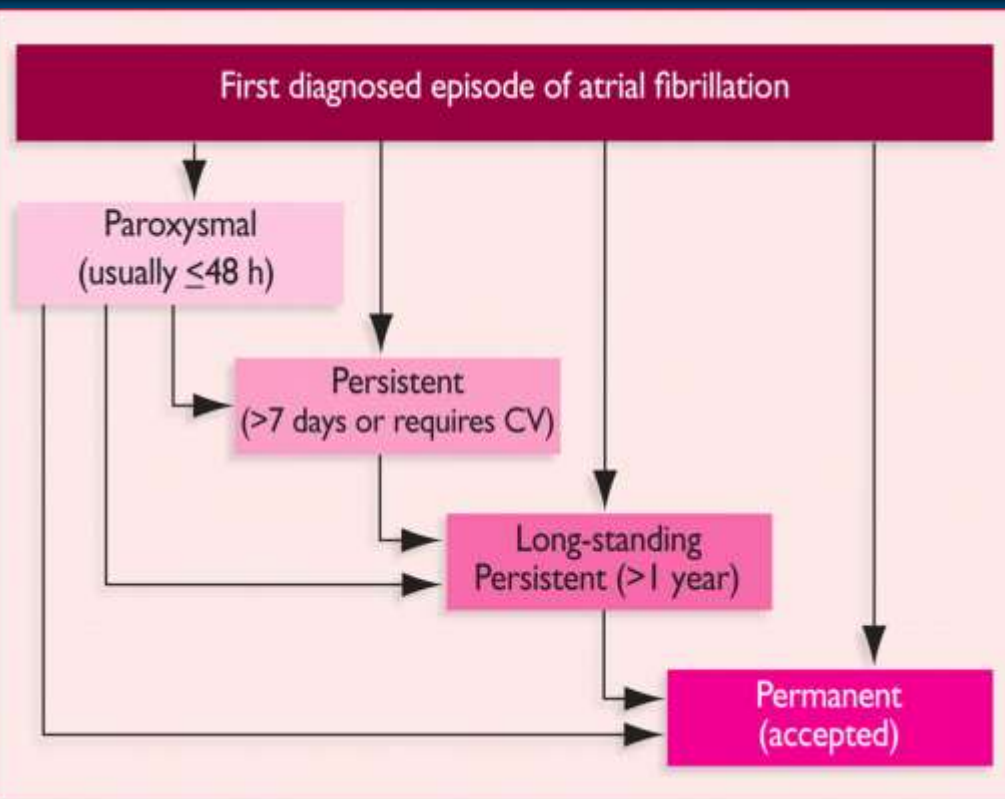


Despite prevalence, no clear standards for treating this complicated group of patients

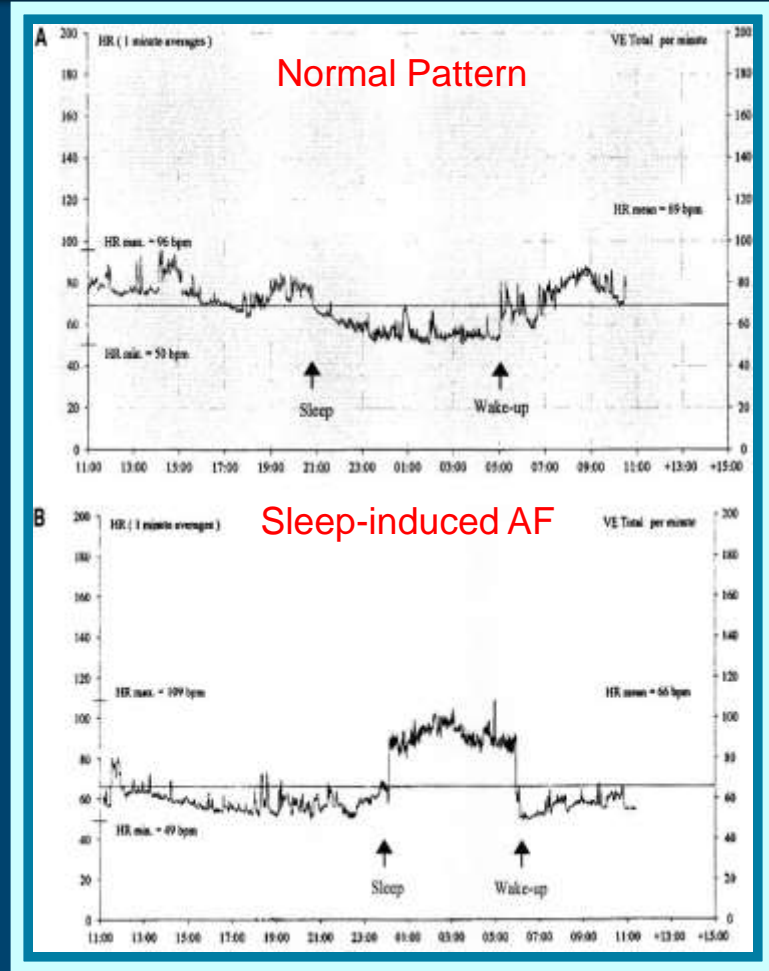
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Defining AF: Individualizing Treatment Approaches



- Mechanistic
 - Adrenergic
 - Vagal (sleep-induced)

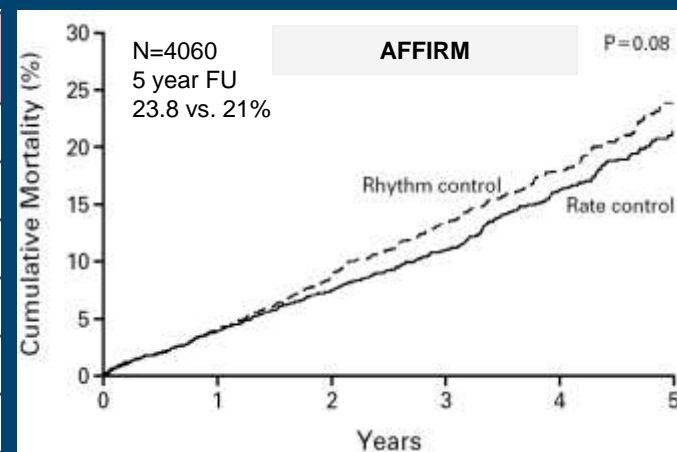


Atrial Fibrillation

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Rate Control: where do we stand?

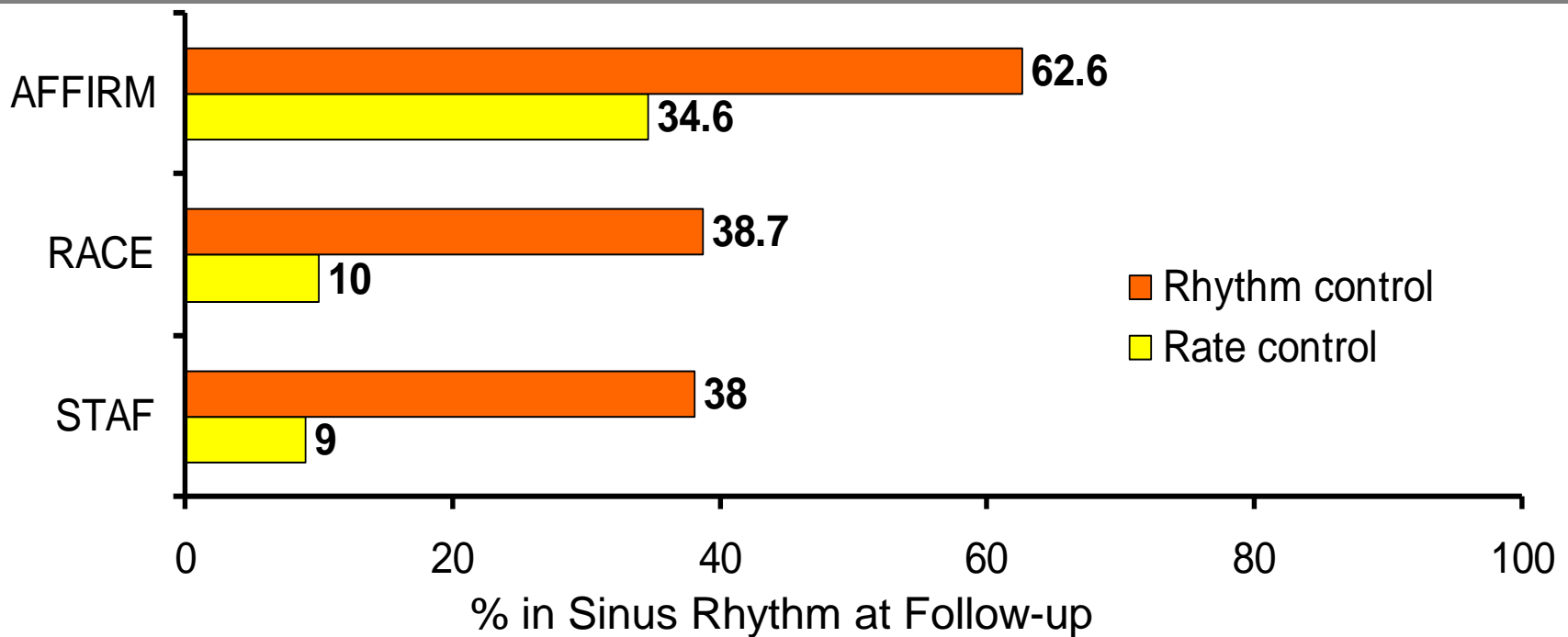
Trial	Deaths from all causes (in rate/rhythm)	Deaths from cardiovascular causes	Deaths from non-cardiovascular causes	Stroke
PIAF (2000)	4	1/1	1 ^a	ND
AFFIRM (2002)	666 (310/356)	167/164	113/165	77/80
RACE (2002)	36	18/18	ND	ND
STAF (2003)	12 (8/4)	8/3	0/1	1/5
HOT CAFÉ (2004)	4 (1/3)	0/2	1/1	0/3
AF-CHF (2008)	228/217	175/182	53/35	11/9



- Most patients in Drug Arm did not maintain NSR
- Excluded younger patients
- Stopped anticoagulation if AAD led to NSR
- Most common drug used Amiodarone

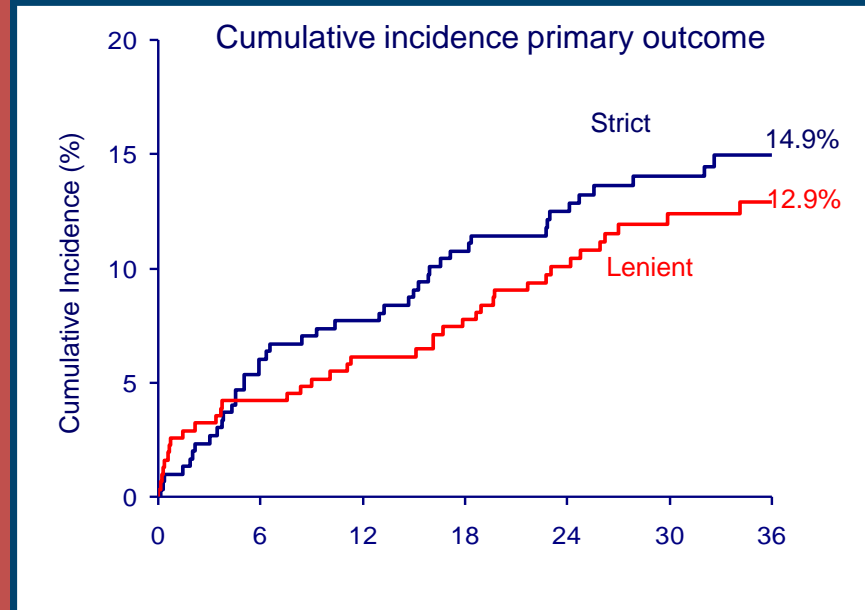
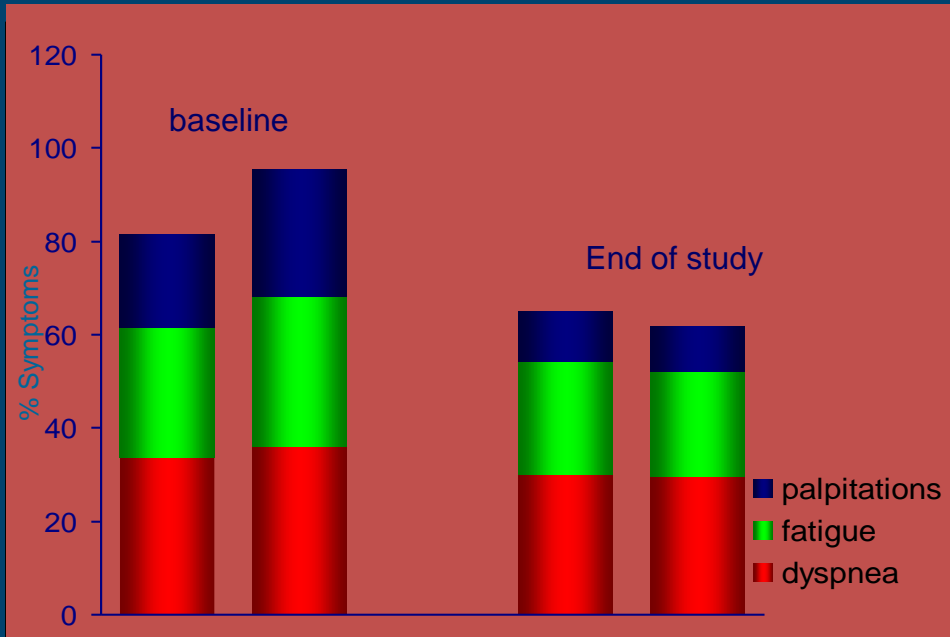
Sinus Rhythm versus Rate control: Not tested

Efficacy of Anti-arrhythmic Drugs in Rhythm vs. Rate Control



RACE 2:

Rate Control Efficacy in Permanent Atrial Fibrillation



- The RACE II study shows that lenient rate control is not inferior to strict rate control
- Lenient rate control is more convenient since fewer outpatient visits, fewer examinations, lower doses and less often combination of drugs are needed

Rate Control Conclusions

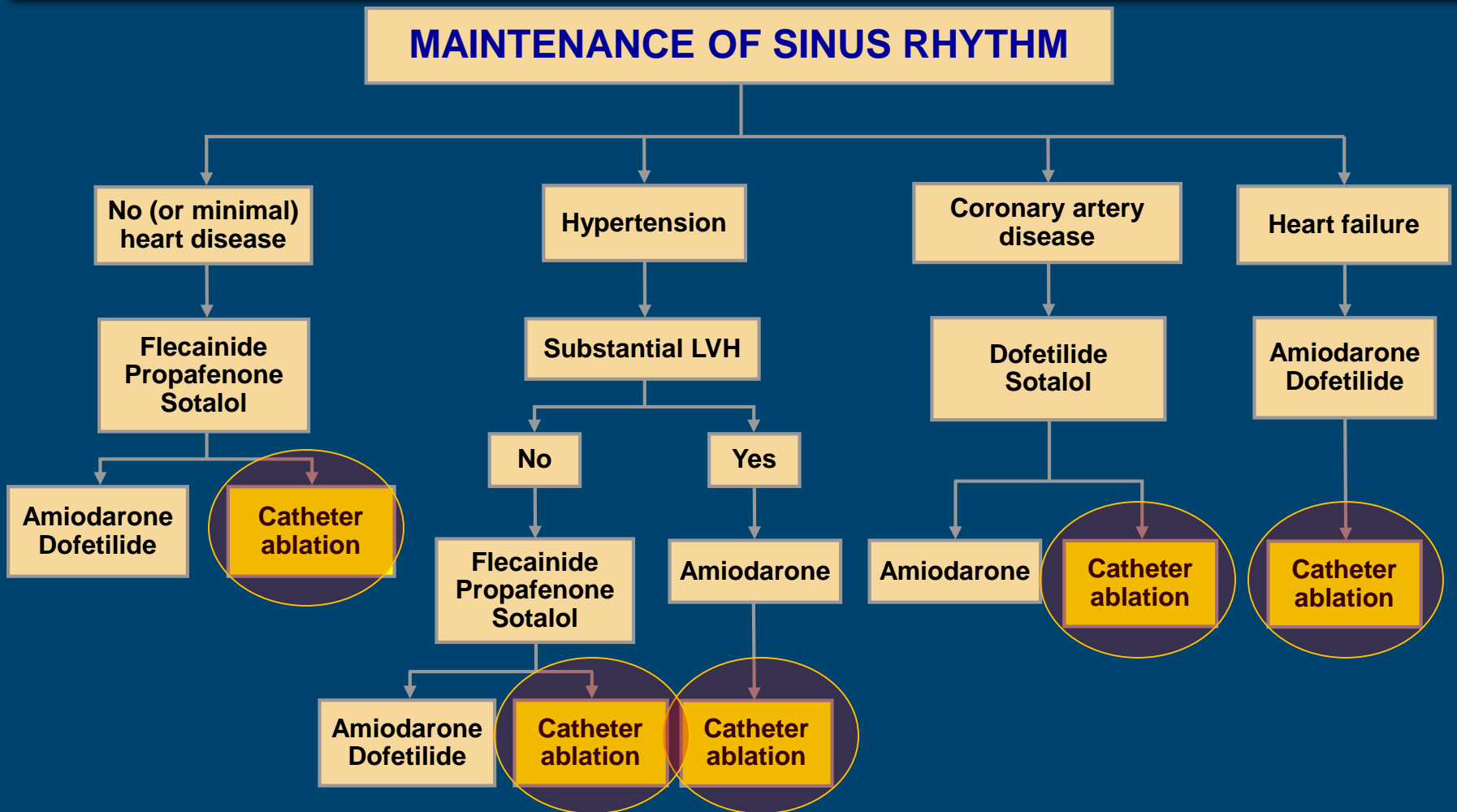
Some take home points:

- Rate therapy equivalent to Rhythm control for hard endpoints
- Quality of life not entirely comparable
- Age cut-offs important
 - **Age <65 yrs not tested for rate control**
- Adverse effects of AAD may offset benefits of SR
- Lenient rate control <110 BPM reasonable if **LVEF is Normal**

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2013 ACC/AHA/ESC Guidelines: Treatment Algorithms for AF



Cardioversion

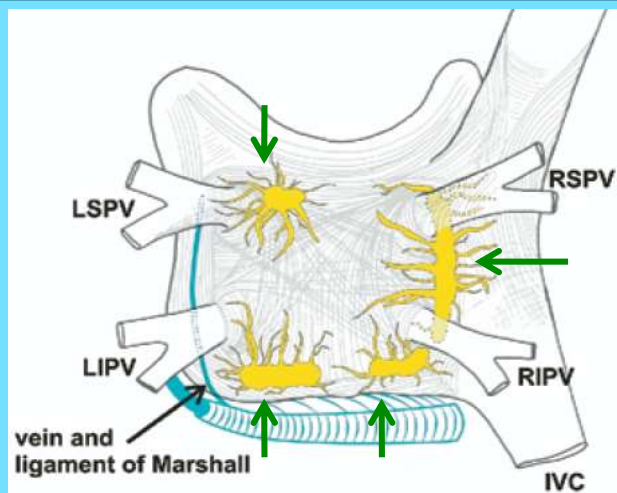
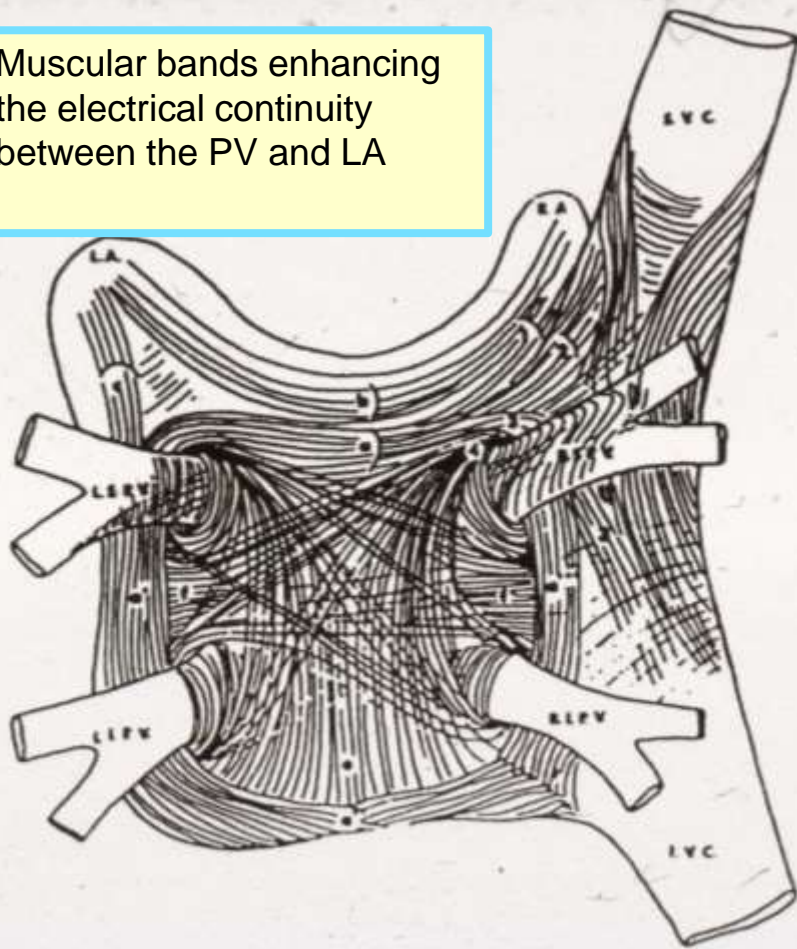
- It's a mere resetting of the short circuits
- TEE
 - If >48 hours from onset of atrial fibrillation
 - Inadequate anticoagulation
 - INR <2 in the 3 weeks prior to cardioversion
 - Non-Compliance with NOACS
- 4 weeks of Anticoagulation after cardioversion
 - Must no matter what the CHADS2 score

Indications for Catheter Ablation

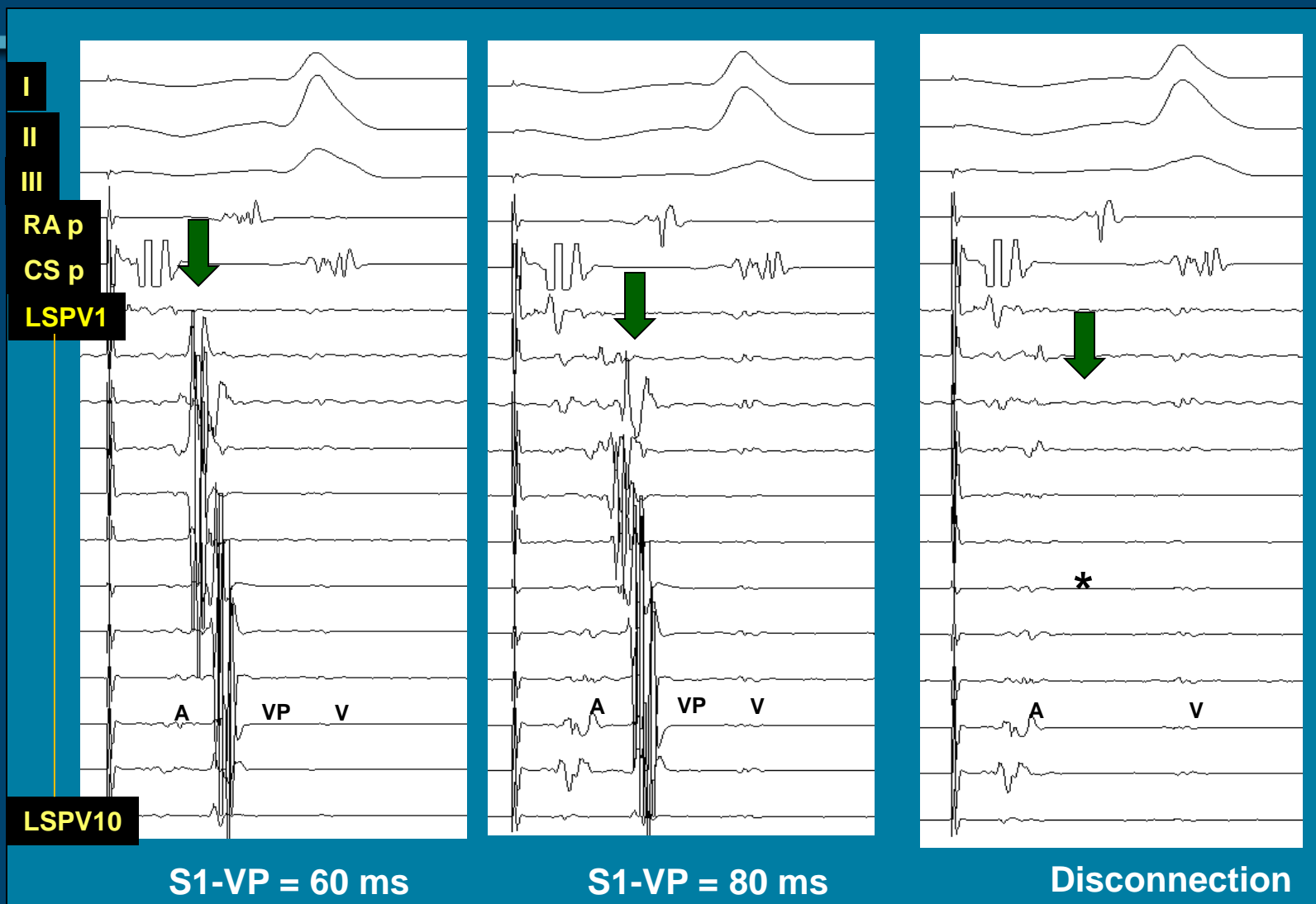
- **Symptomatic** atrial fibrillation **refractory** or intolerant to at least one Class I or III antiarrhythmic medication
- Selected symptomatic patients with **heart failure** and/or reduced ejection fraction

Pulmonary Veins & Autonomic Ganglia

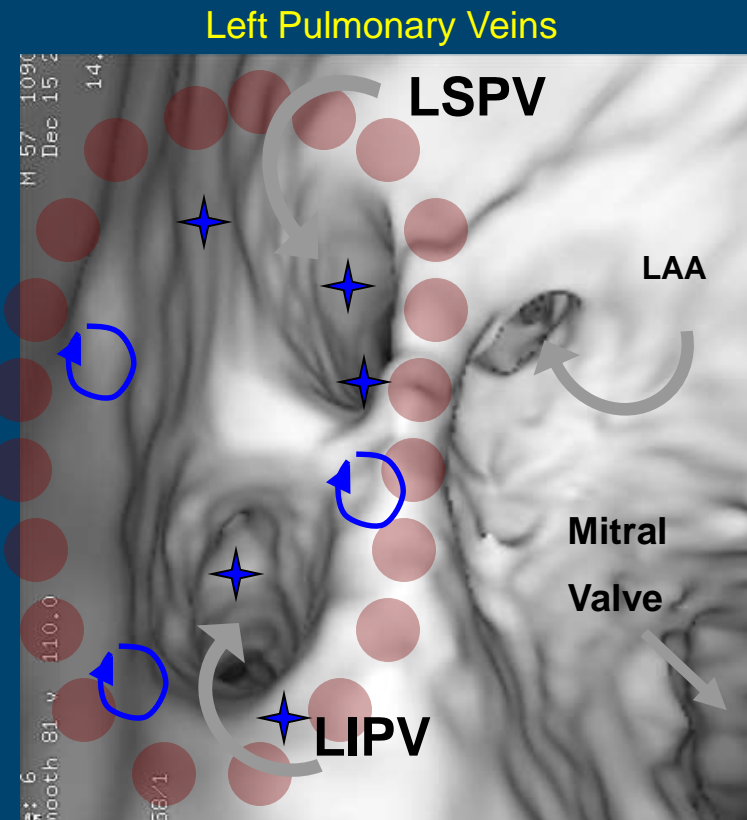
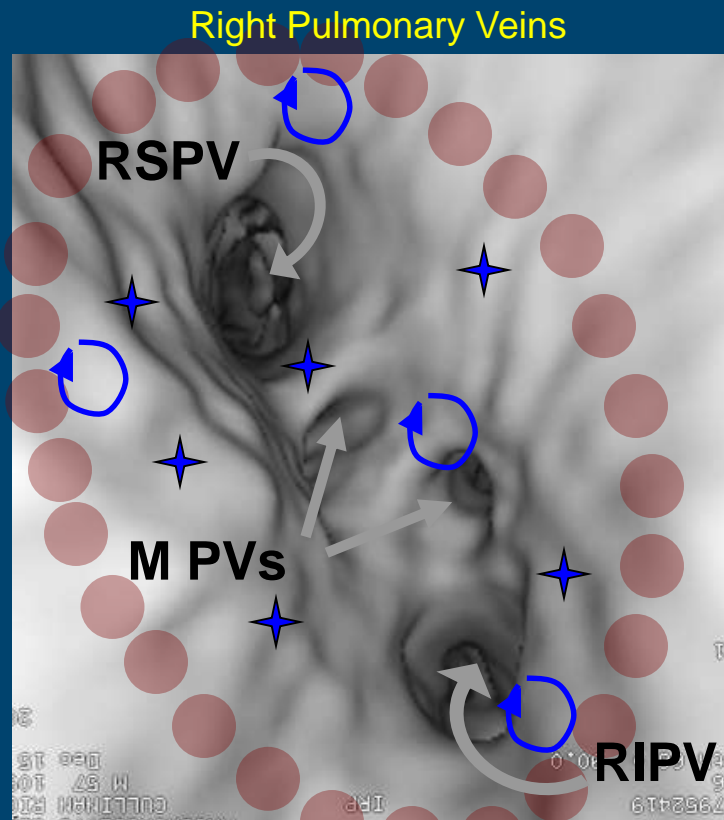
Muscular bands enhancing the electrical continuity between the PV and LA



Cornerstone of AF: Isolating the Pulmonary Vein



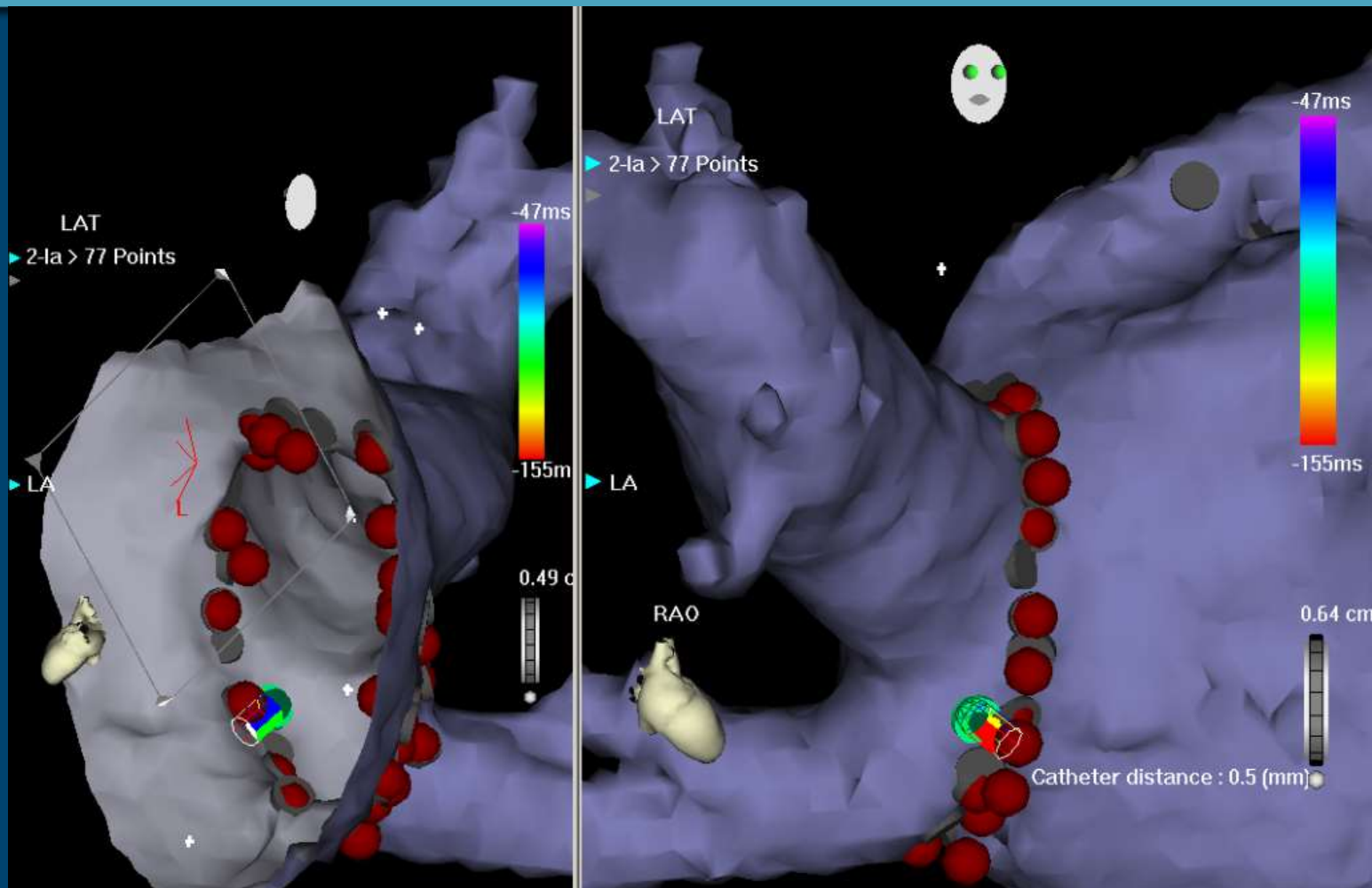
Catheter Ablation (Internal view)



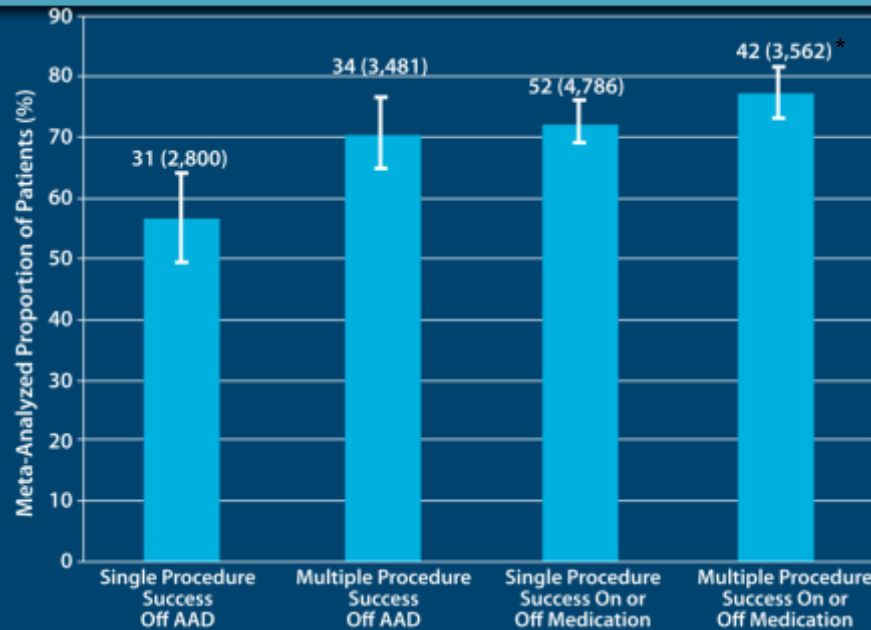
Endoscopic View of the LA and the Pulmonary Veins

Image Integration

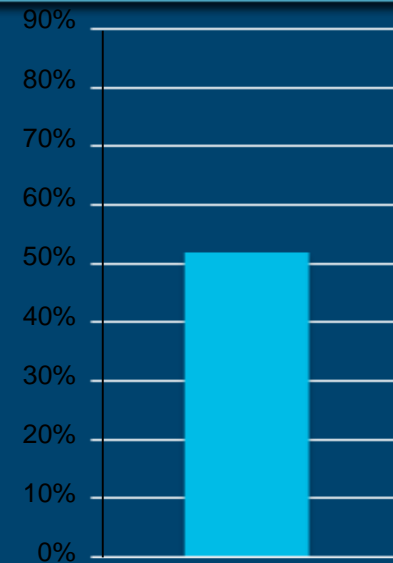
Intra-procedural display of Ablation points



Published Catheter Ablation Success Rates Compare Favorably to Antiarrhythmic Drugs



Success Rates Catheter Ablation

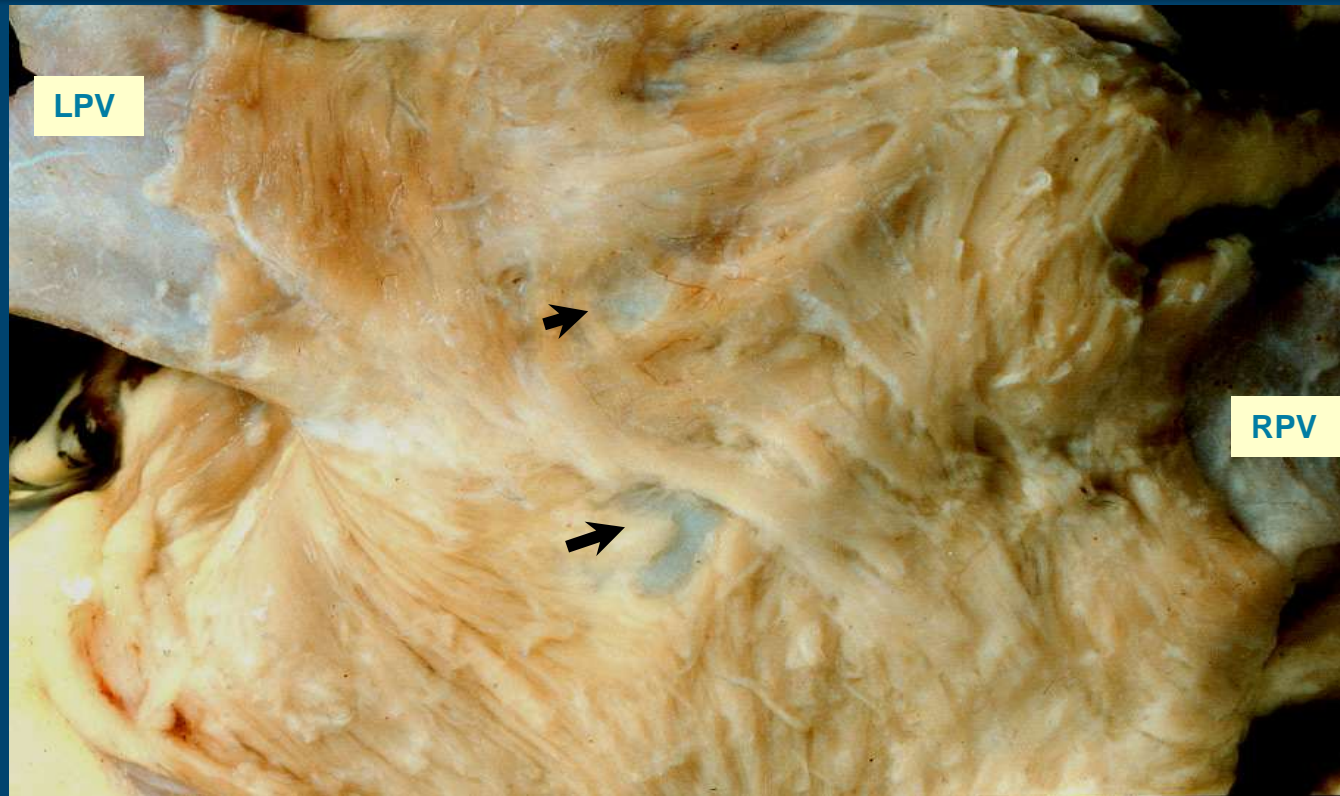


Success Rate AADs

Meta Analysis of Radiofrequency Ablation and Antiarrhythmic Drug Studies

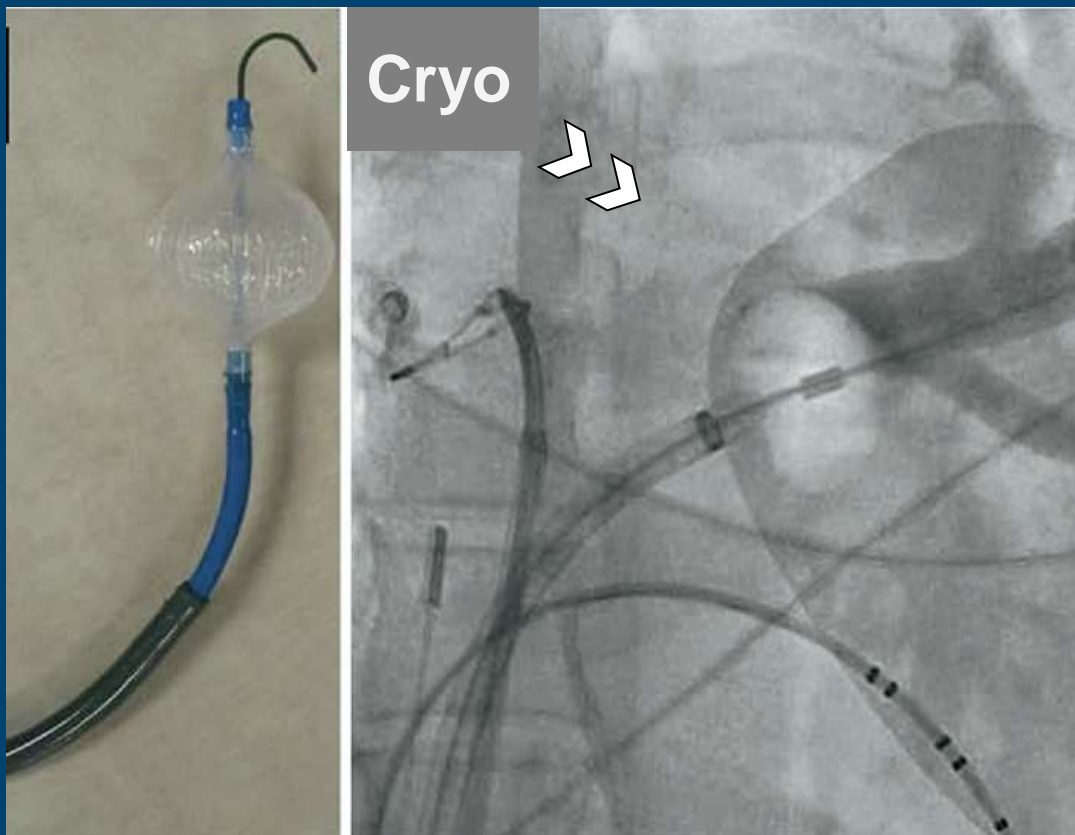
- Success rates were higher for ablation than drugs
- Ablation success rates represent a mixed population of paroxysmal (69.8%), persistent (14.9%) and longstanding persistent (13.9%)
- Adverse events were rarer but more severe for ablation – 5% vs. 30% for AAD

Variability in Left Atrial Wall Thickness



- Need to put into perspective the potential for cardiac perforation, collateral damage and venous stenosis

Cryoballoon Ablation



- Arctic Front System
 - Inflation cycle
 - Ablation cycle
 - Thawing cycle
- 23 & 28 mm balloon
- Cryo-refrigerant
- Single lesion PV isolation at 90%
- ICE-guided
- 4-min lesion
- Safety needs evaluation

How Arctic Front Advance™ Cryoballoon and Achieve® Mapping Catheter Work

1. Access targeted vein



2. Inflate and position



3. Occlude and ablate

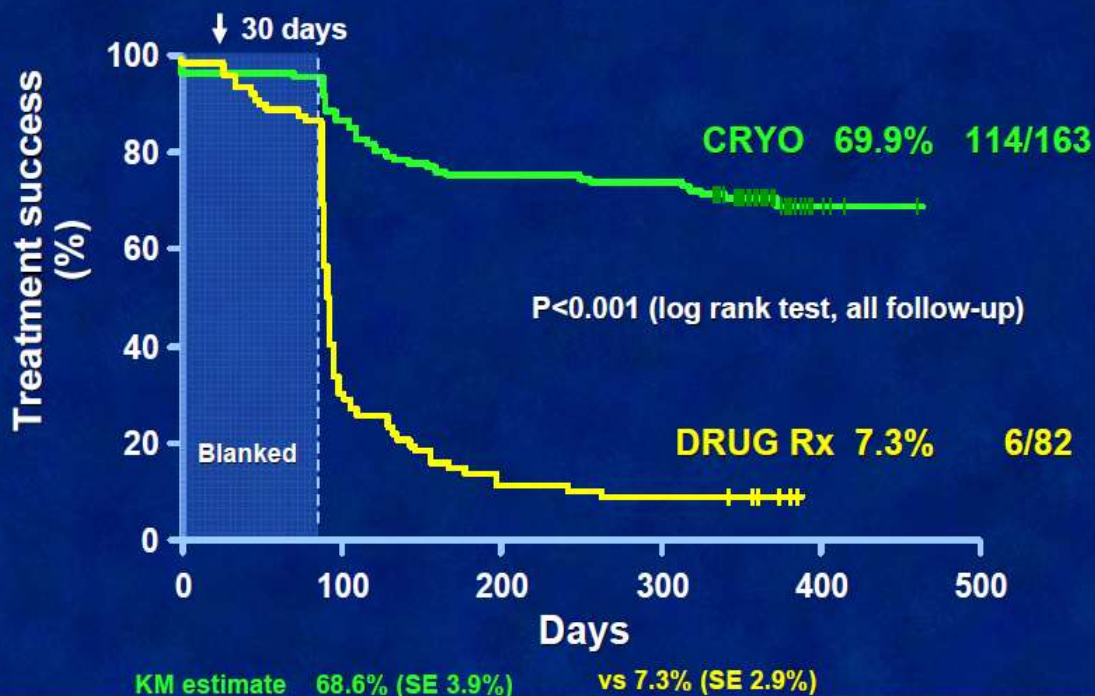


4. Assess PVI



STOP-AF Results

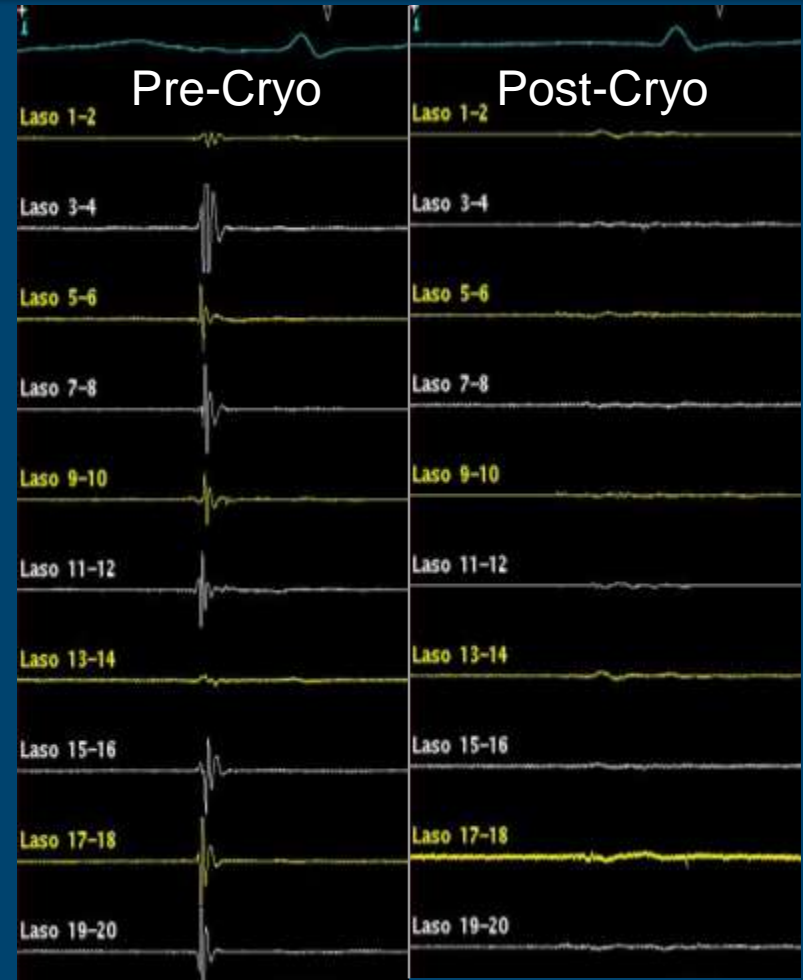
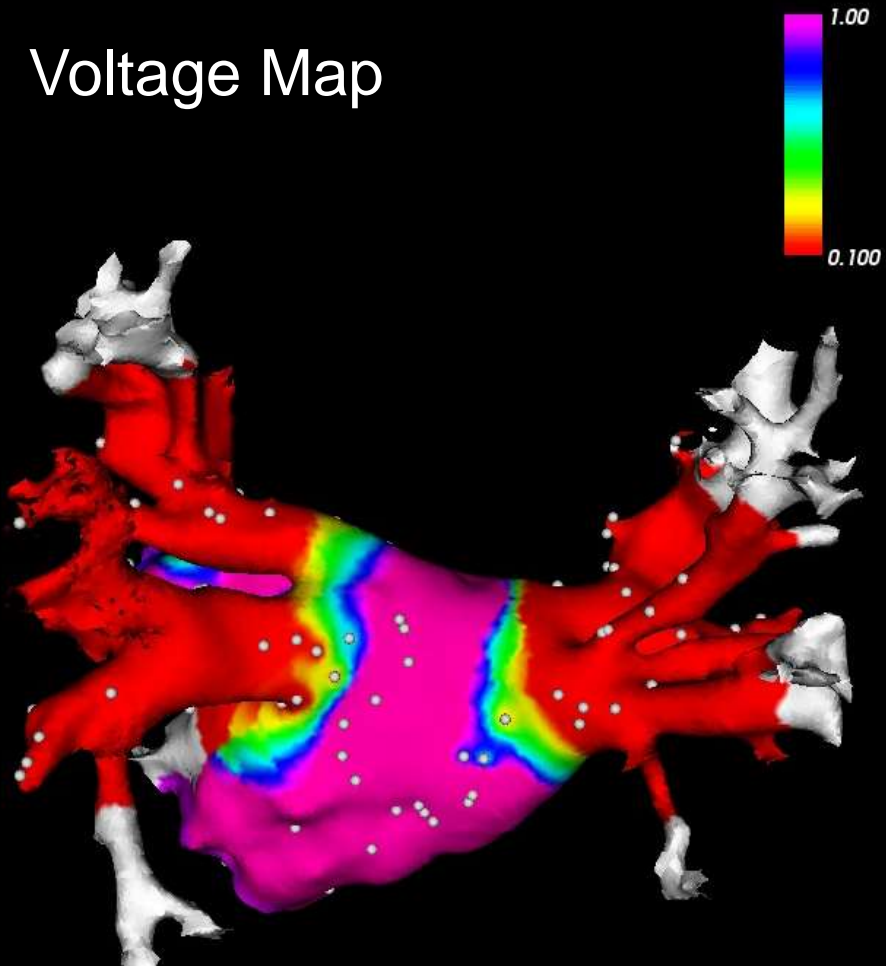
Treatment Success



- Cryo-ablation is feasible and effective
- FDA approved
- Issues:
 - Phrenic nerve palsy
 - Pulmonary vein stenosis

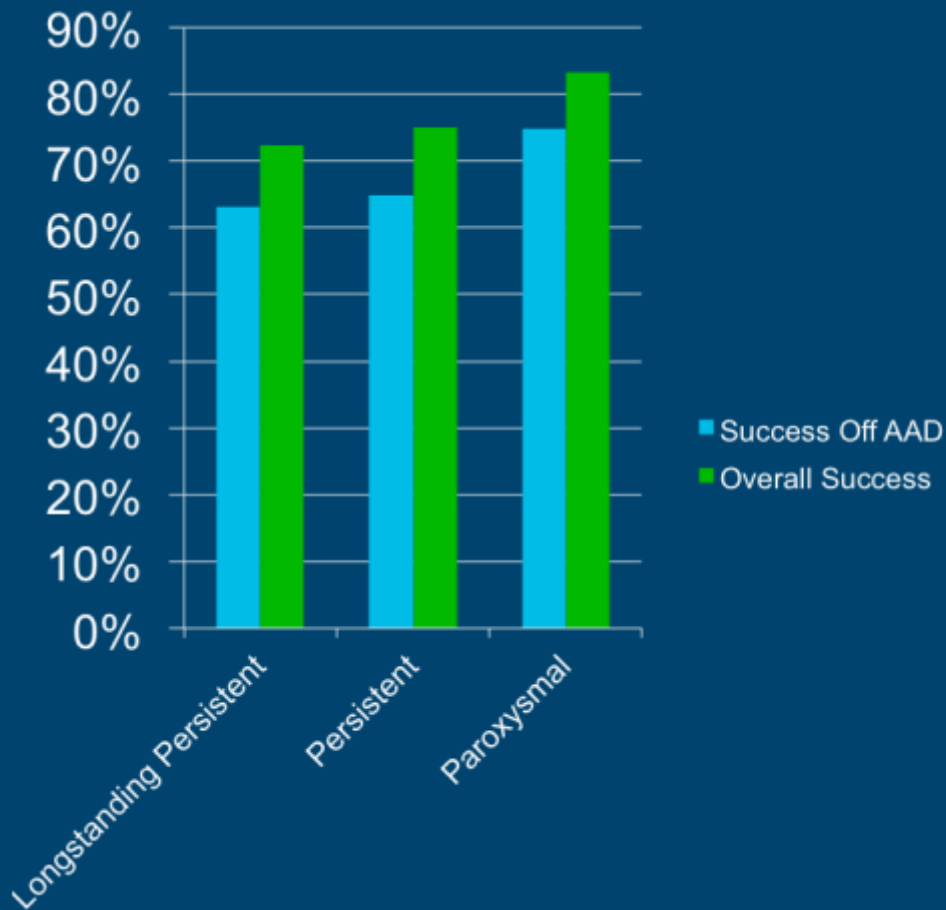
Cryo Ablation (post-ablation)

Voltage Map



HYBRID AF ABLATION

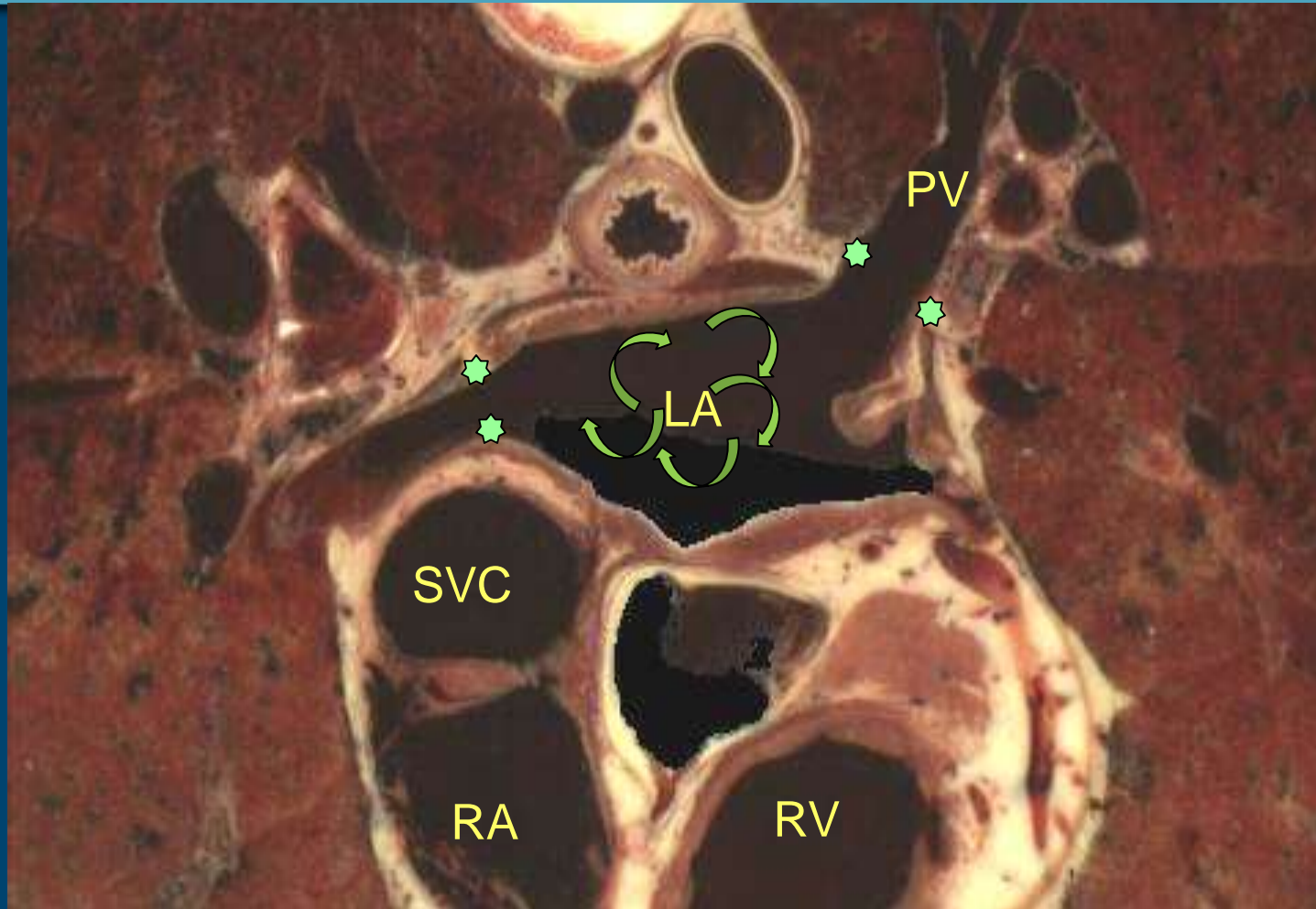
Catheter Ablation Success Rates Are Highest in Paroxysmal AF



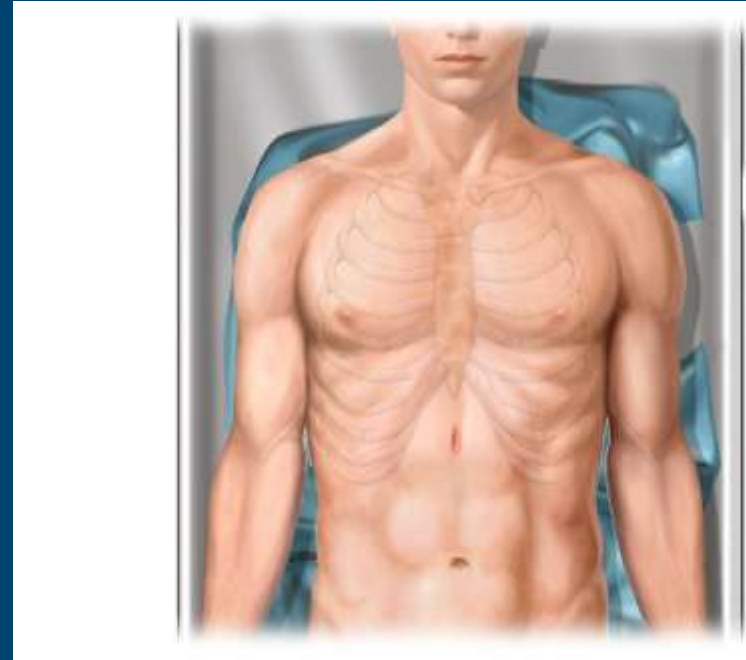
- Ablation of paroxysmal AF was associated with a 35% and 66% larger probability of success as compared to ablation of persistent and longstanding persistent AF, respectively
- Earlier referral for catheter ablation may lead to higher success rates

Atrial Fibrillation

An Interplay of Substrate & Triggers



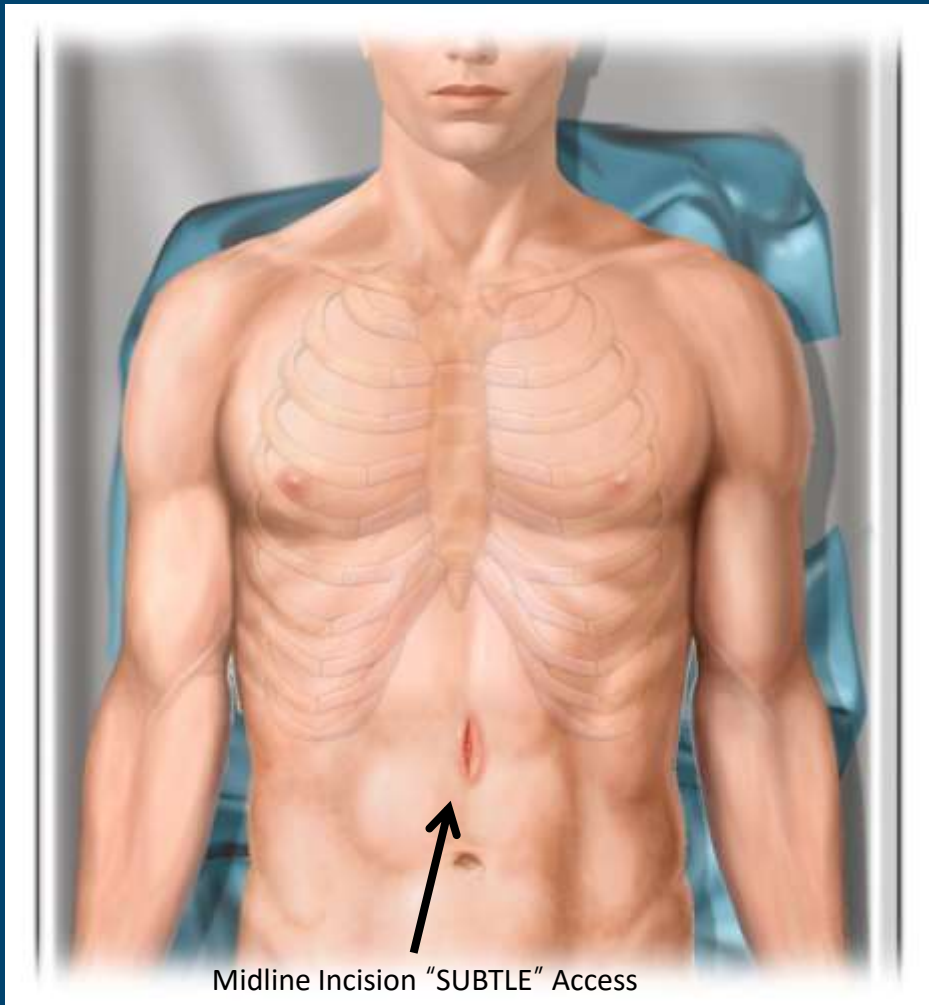
SUBTLE™ Closed Chest Access



SUBTLE™ access enables a transdiaphragmatic approach that provides the ability to access the posterior region of a beating heart. The closed chest approach offers surgeons direct visualization to the posterior of a beating heart through endoscopes, enabling the ability to create bi-atrial, linear lesions without chest incisions or ports.

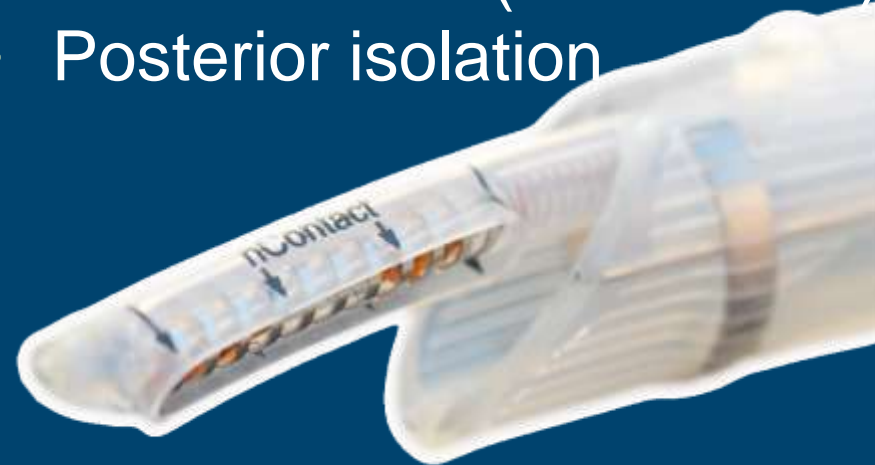
SUBTLE™ Closed Chest Access

Addressed Technical Limitations



Midline Incision "SUBTLE" Access

- Better ablation device design / ability to create complete lesions
- Direct visibility (endoscopic)
- Better access (SUBTLE™)
- Posterior isolation

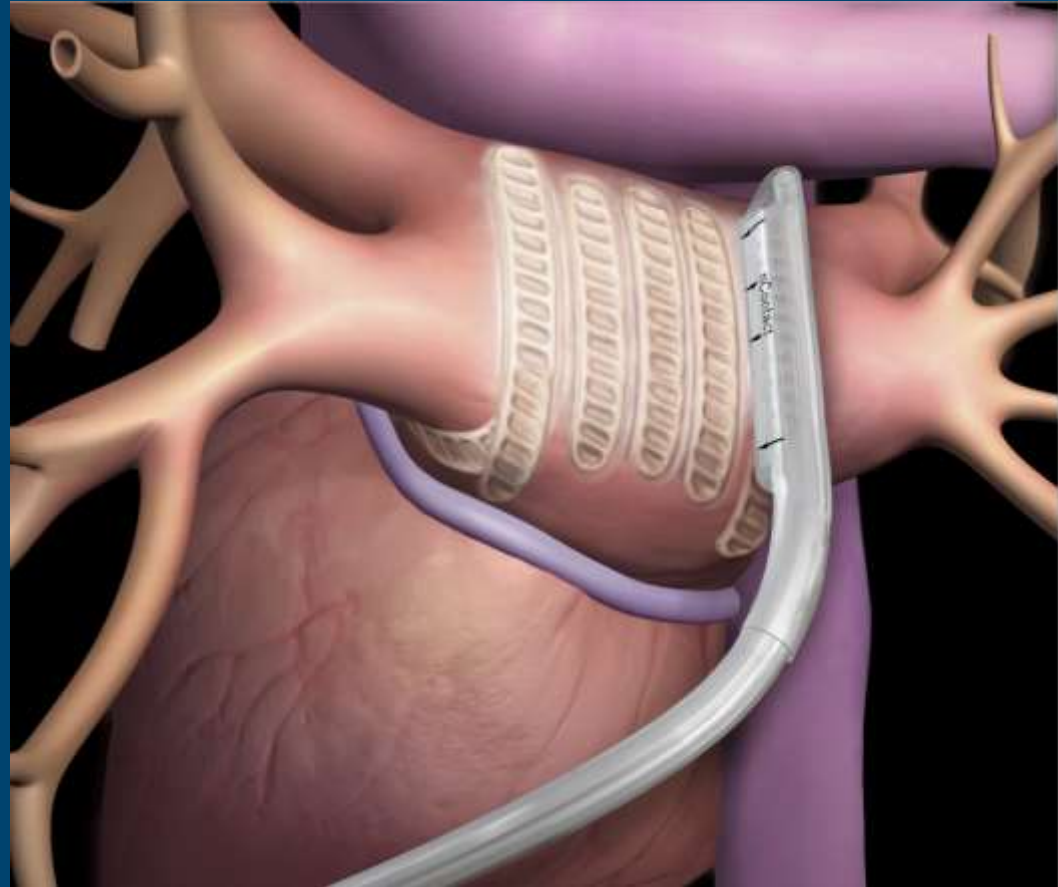


Electrosilencing Posterior Left Atrium

Direct Visibility

- AF Foci Located Along PV Tissue
- Posterior LA Derives Embryologically from PVs
- PVI Does Not Address Reentrant Circuits
- Need to Ablate Posterior LA to Prevent Wavelets

**SUBTLE Access Enables
Visualization & Ablation of
Posterior LA**

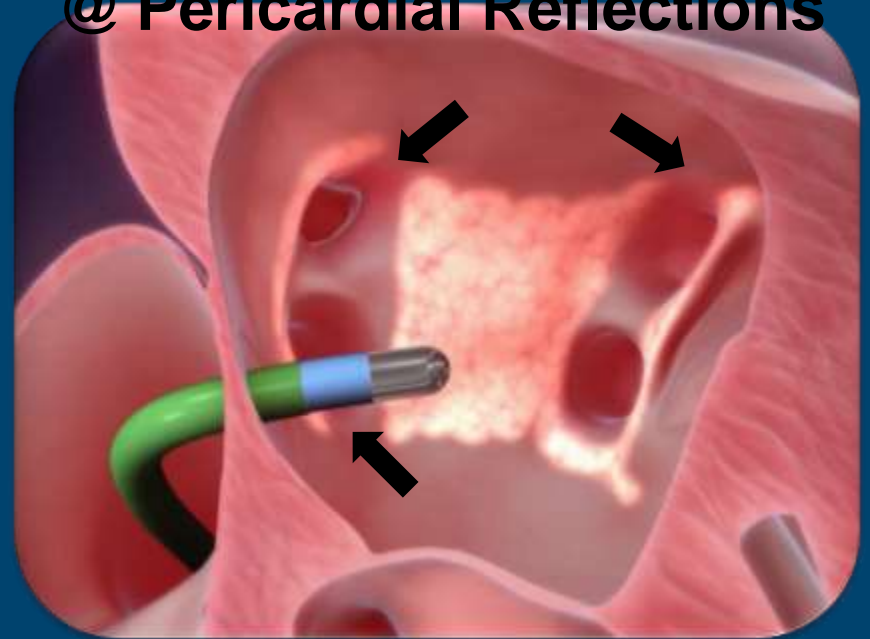


Percutaneous Endocardial Ablation

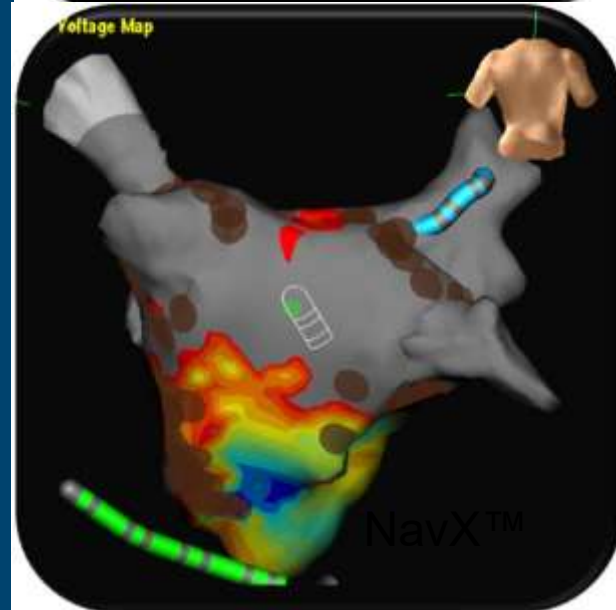
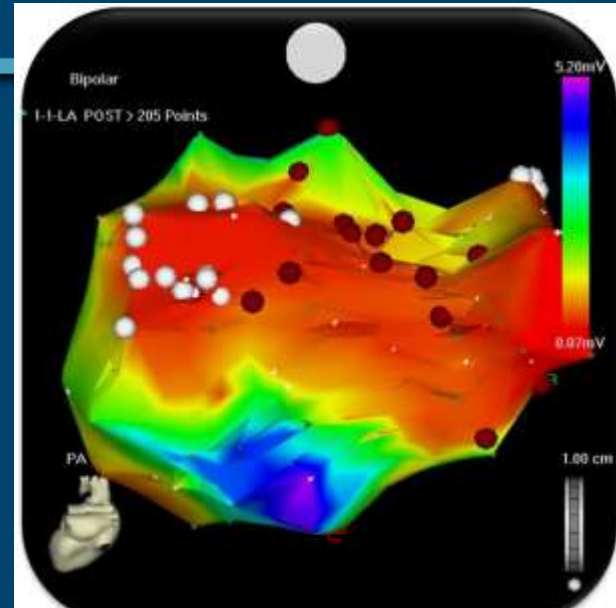
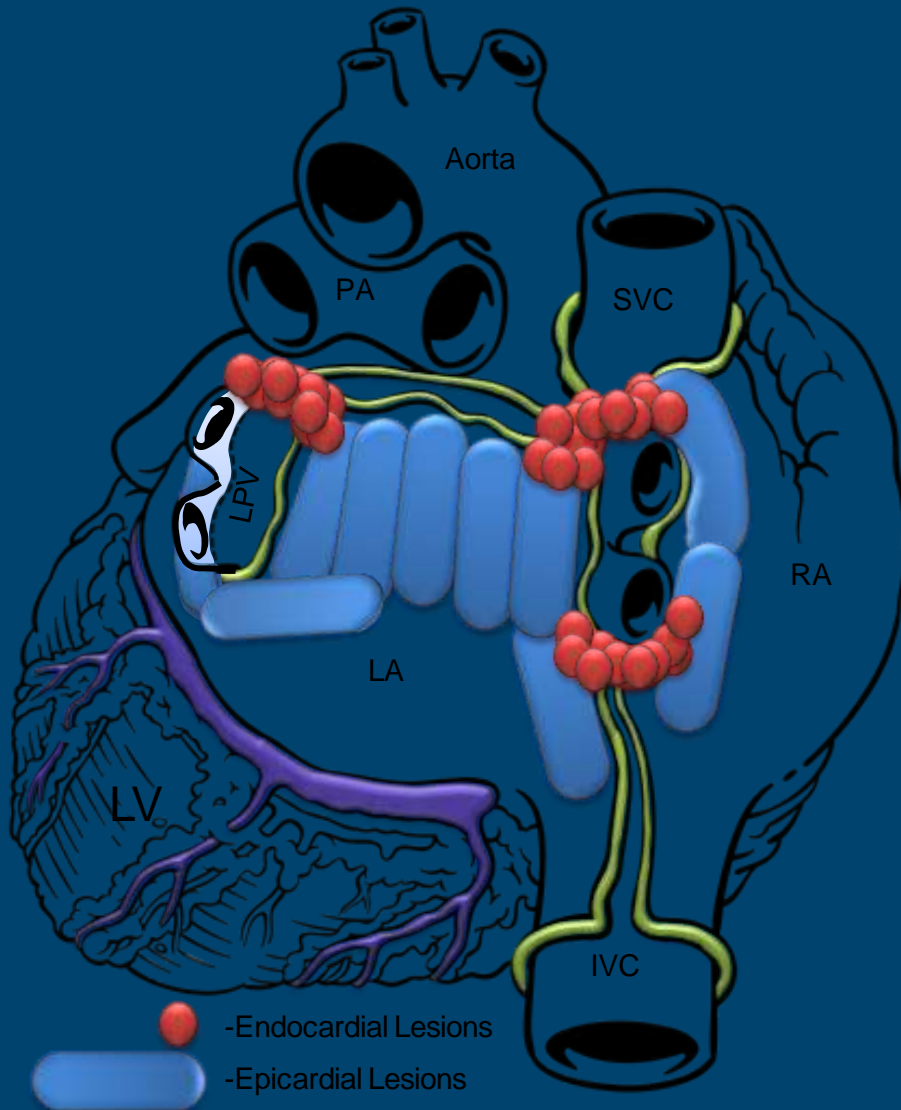
**Percutaneous
Access**



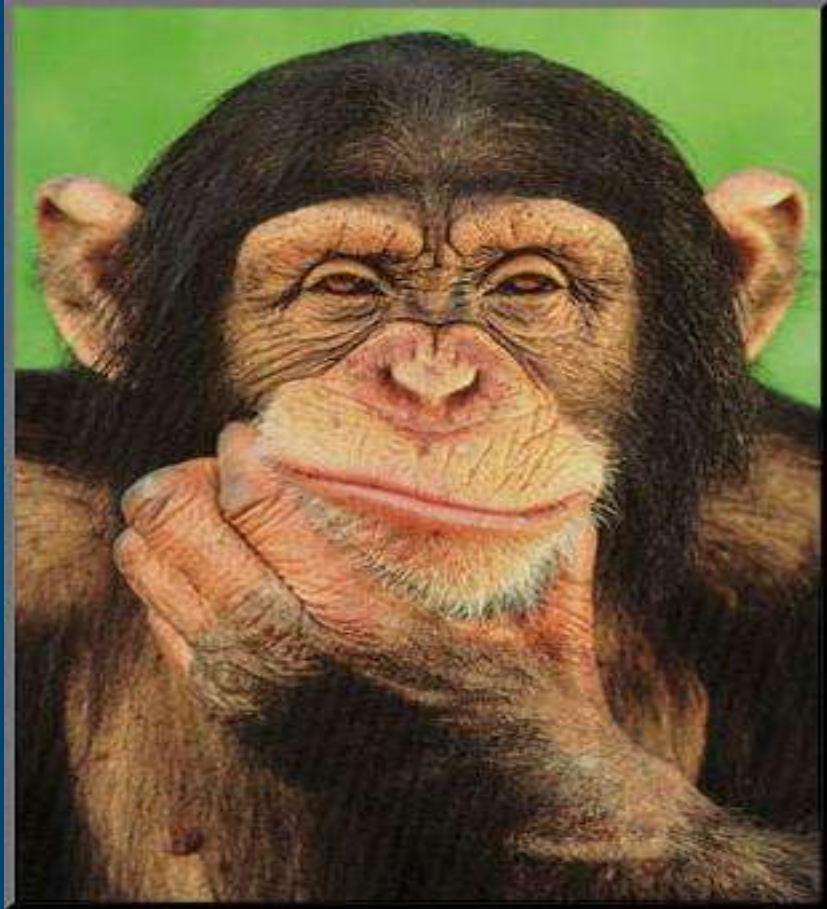
**Breakthrough Locations
@ Pericardial Reflections**



Multidisciplinary Strategy *Leveraging Best Techniques*







**Interesting.....How about
this Watchman
device...what's the
deal.....?**

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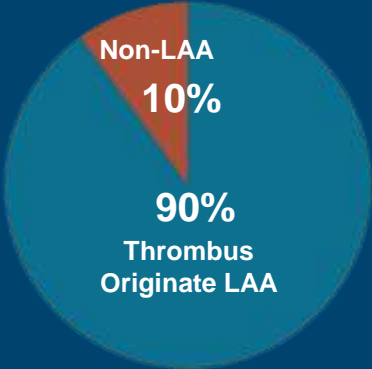
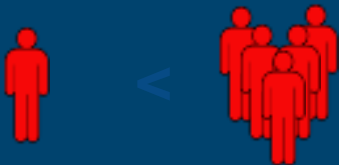
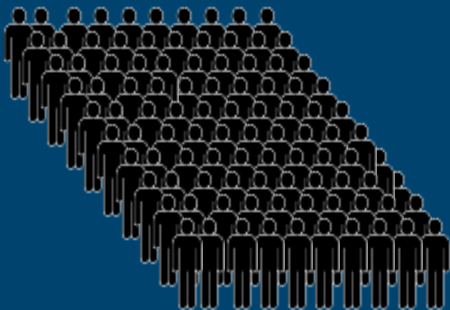
Atrial Fibrillation Population, Stroke Risk and the Left Atrial Appendage

AFib is the most common cardiac arrhythmia

AFib increases risk of stroke

Blood clots form in the left atrial appendage

Many patients are unprotected



> 5M
people with AFib in the US

5x
greater risk of stroke with AFib¹

>90%
of stroke in AFib is caused by blood clots that form in the left atrial appendage²

30 - 40%
of patients are unwilling or unable to take Warfarin

Stroke is more severe for patients with AF, as they have a 70% chance of death or permanent disability¹

¹ Holmes DR. *Seminars in Neurology*. 2010;30:528-536
² Blackshear JL, Odell JA., *Annals of Thoracic Surgery*. 1996;61:755-759

Left Atrial Appendage AFib and Thrombus Formation

Fibrillation causes blood to stagnate in the LAA



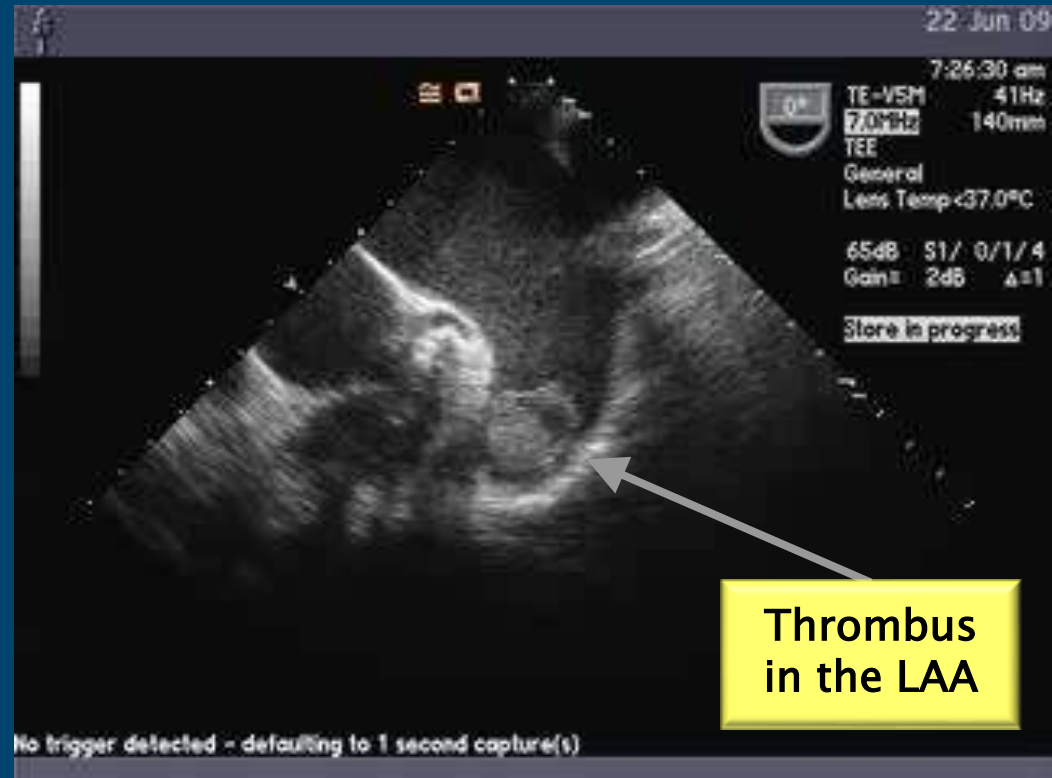
The stagnant blood becomes an ideal environment for a thrombus or blood clot to form



The blood clot, or portion of it, dislodges from the LAA and travels through arterial system



The embolism lodges itself in the blood vessels of the brain, restricting blood flow and causing a stroke



New Drugs: Major Bleeding and Hemorrhagic Stroke Rates

Study	Treatment	Major Bleeding	Hemorrhagic Stroke
RE-LY ¹	Dabigatran (110 mg)	2.71%	0.12%
	Dabigatran (150 mg)	3.11%	0.10%
	Warfarin	3.36%	0.38%
ROCKET-AF ²	Rivaroxaban	3.6%	0.5%
	Warfarin	3.4%	0.7%
ARISTOTLE ³	Apixaban	2.13%	0.24%
	Warfarin	3.09%	0.47%

1 Connelly SJ et al, *NEJM* 2009;361:1139-51

2 Patel MR et al, *NEJM* 2011;365:883-91

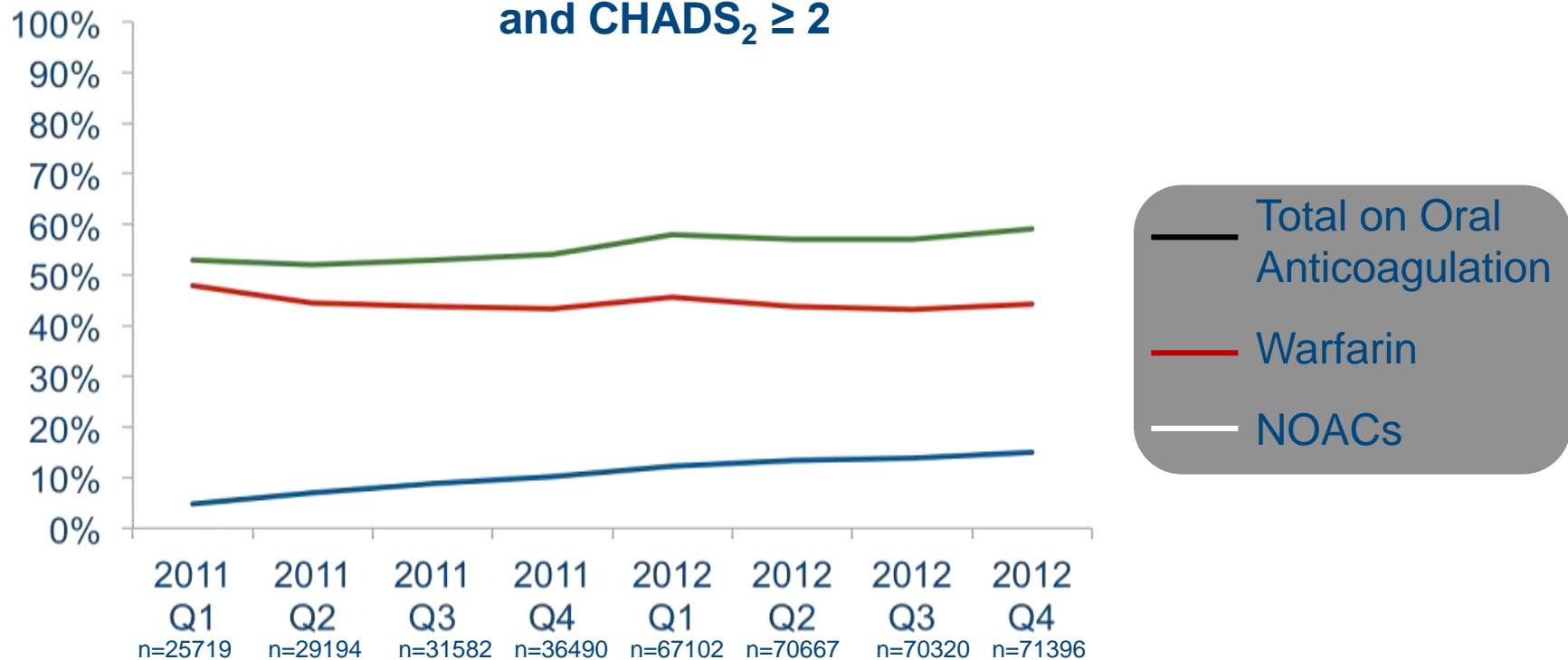
3 Granger J. et al, *NEJM* 2011;365:981-92

Despite Increasing NOAC Adoption, Overall Rate of Anticoagulation in High Risk NVAF Patients has Not Improved



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Anticoagulant Use in Patients with NVAF and CHADS₂ ≥ 2

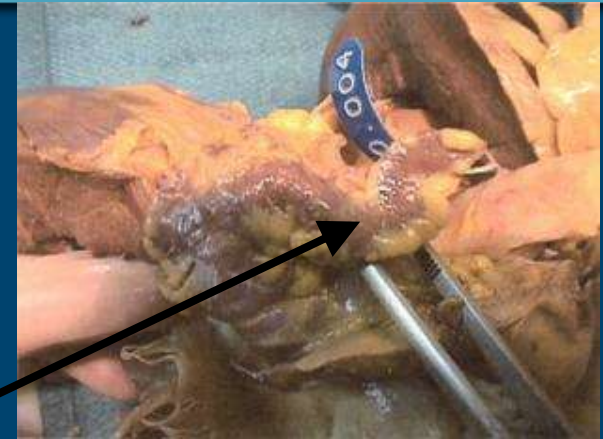


Results from the NCDR PINNACLE Registry¹

1. Jani, et al. Uptake of Novel Oral Anticoagulants in Patients with Non-Valvular and Valvular Atrial Fibrillation: Results from the NCDR-Pinnacle Registry. ACC 2014

Interventions on LAA: Why Mixed Success? LAA Anatomy

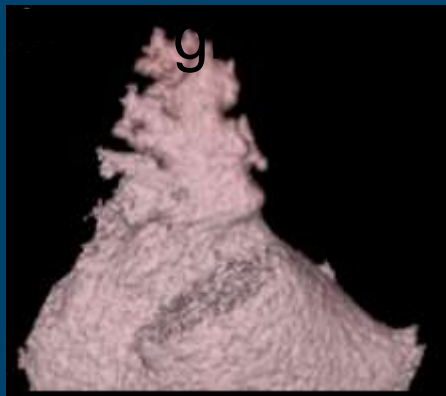
- LAA forms during the third week of gestation and serves as the left atrium in the fetus
 - Adult LAA is the about the size of a thumb
 - Ostium range may range from 10 - 40mm



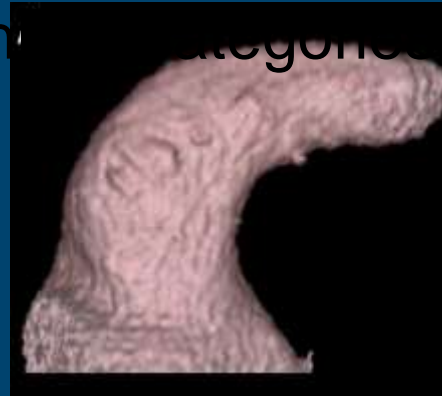
Left Atrial Appendage

LAA anatomy varies in shape.

- In one patient study of 932 AF patients¹ LAAs were



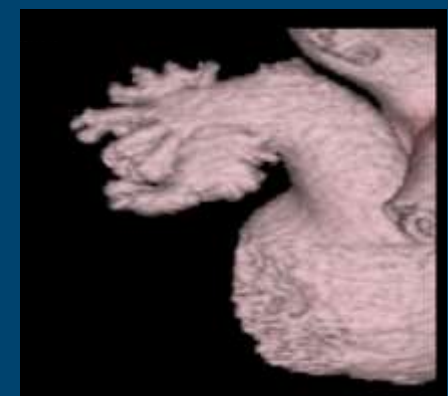
Cactus (30%)



Chicken Wing (48%)

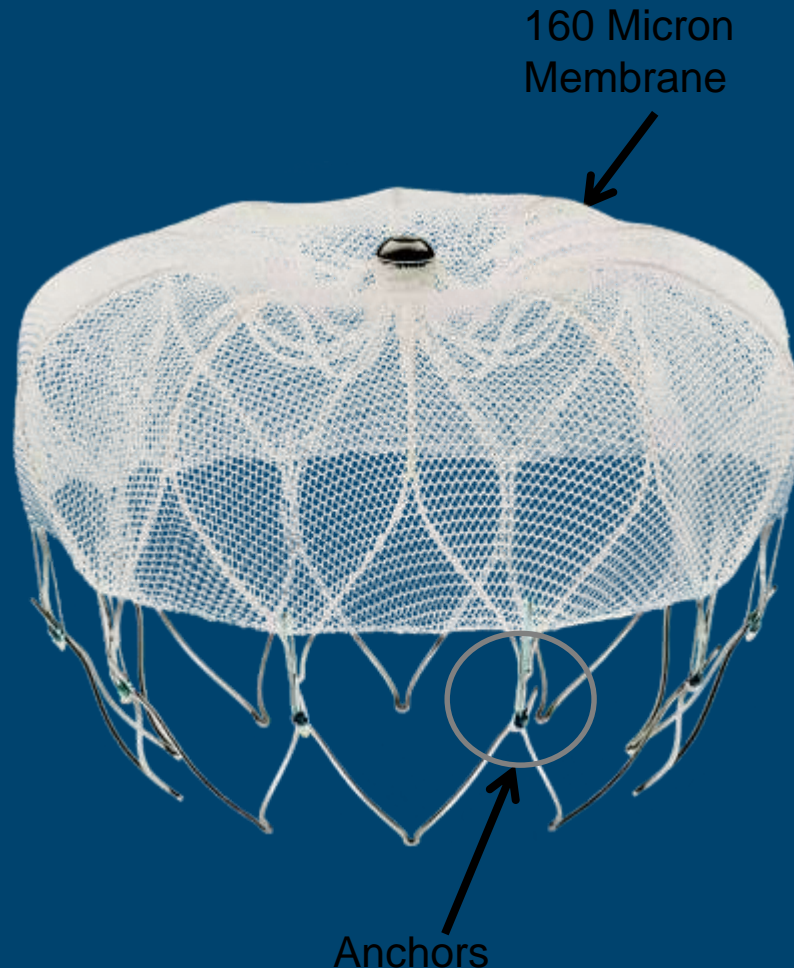


Windsock (19%)



Cauliflower (3%)

WATCHMAN™ LAAC - Device Overview



Nitinol Frame

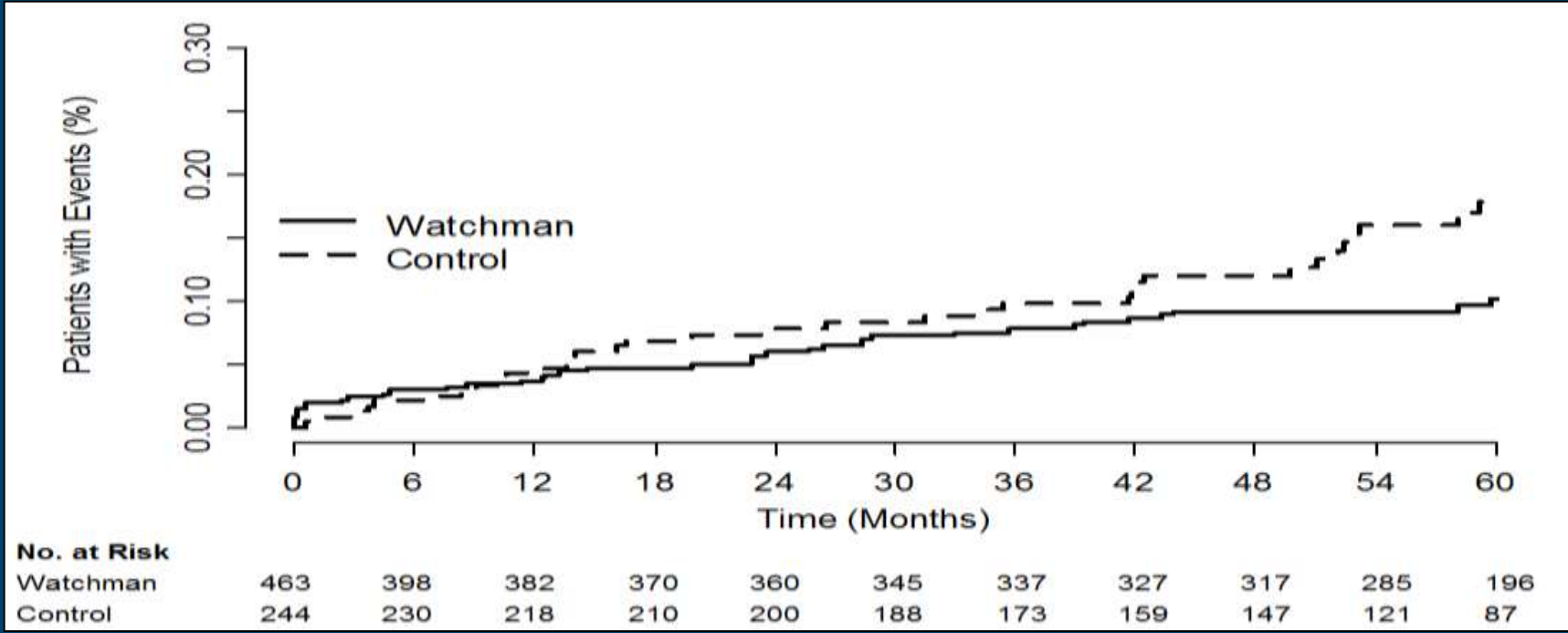
- Radially expands to maintain position in LAA
- Available sizes:
 - 21, 24, 27, 30, 33 mm (diameter)
- 10 Active fixation anchors around device perimeter engage LAA tissue for stability and retention
- Contour shape accommodates most LAA anatomies

160 Micron Membrane

- Polyethylene terephthalate (PET) cap
- Designed to block emboli from exiting the LAA
- Intended to promote healing process

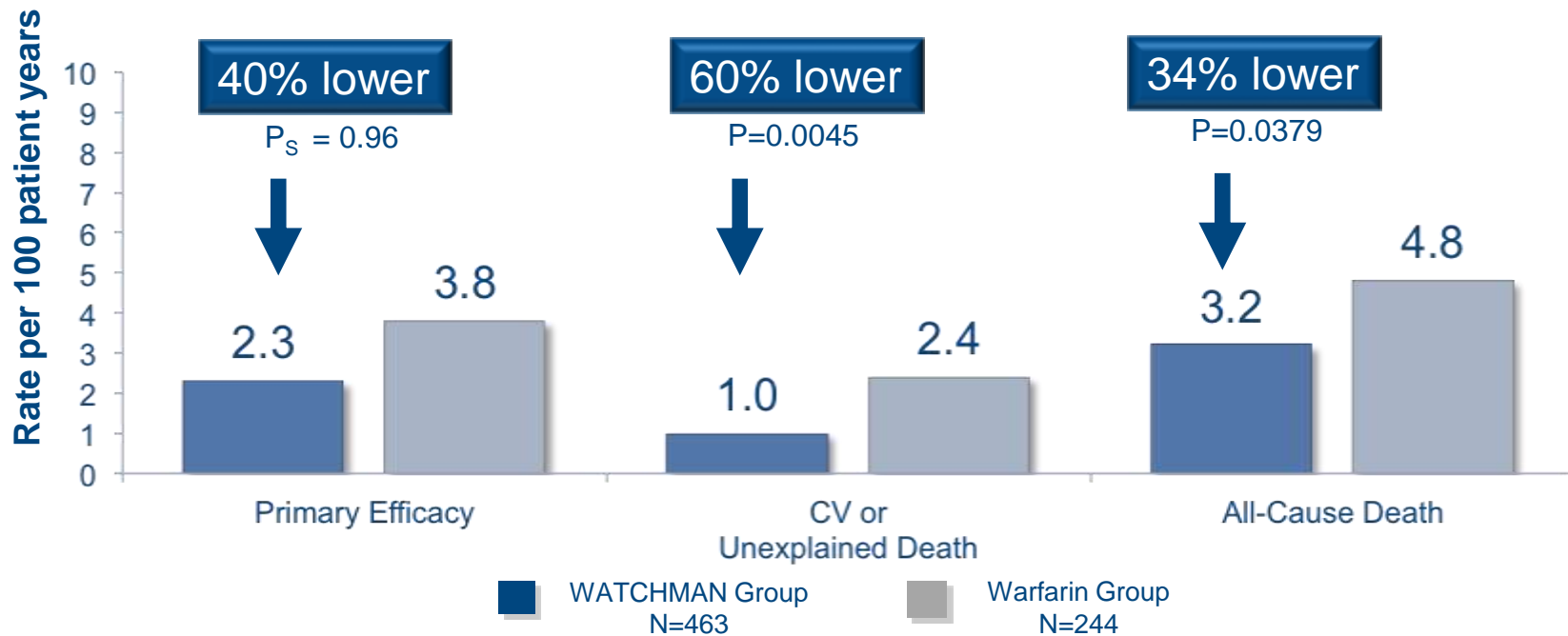
PROTECT AF 4 Year Follow Up: Primary Efficacy Endpoint

Event	Watchman Group (n = 463)		Warfarin Group (n = 244)		Rate Ratio (Watchman/Warfarin) (95% CrI)	Posterior Probabilities	
	Events/ Patient-Years	Observed Rate (Events per 100 Patient-Years) (95% CrI)	Events/ Patient-Years	Observed Rate (Events per 100 Patient-Years) (95% CrI)		Non- inferiority	Superiority
Primary Efficacy Endpoint	39/1720.2	2.3 (1.7, 3.2)	34/900.8	3.8 (2.5, 4.9)	0.60 (0.41, 1.05)	>0.999	0.960



PROTECT AF Long Term (4 Year Follow-up)

Events in PROTECT AF trial at 2,621 patient years



P_s = Posterior Probability for Superiority

All three endpoints met statistical superiority

FDA APPROVAL March 2015

- FINAL INDICATION
- The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:
- Are at increased risk for stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.



ATRIAL FIBRILLATION WELLNESS PROGRAM

Risk Factors for Atrial Fibrillation

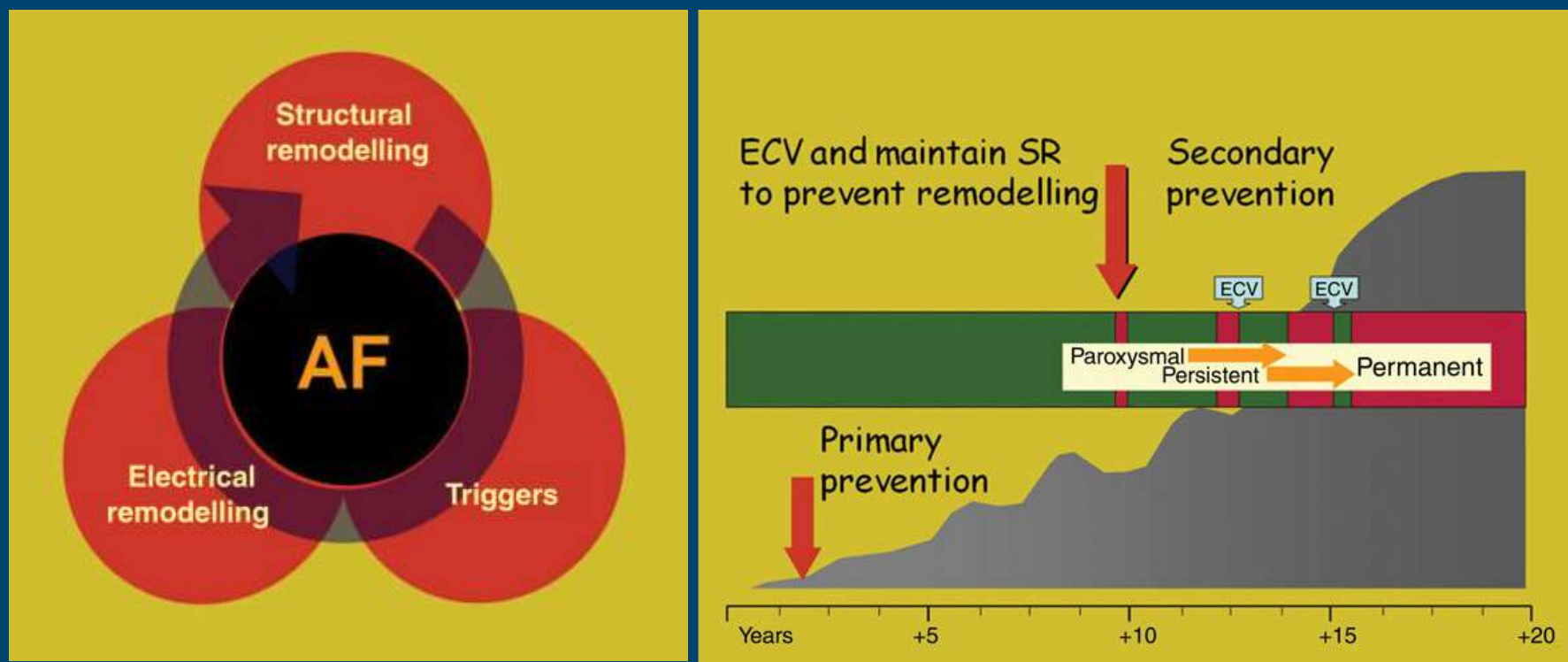
Validated risk factors, concomitant cardiovascular conditions	Hazard ratio
Age	
Benjamin <i>et al.</i> M/F per 10 years ⁹	2.1/2.2
Furberg <i>et al.</i> per 7 years ¹¹	1.03
Psaty <i>et al.</i> ¹²	1.1
Verdecchia <i>et al.</i> per 10 years ¹³	1.8 PAF 2.9 CAF
DeVos <i>et al.</i> ¹⁴	1.6*
Schnabel <i>et al.</i> ¹⁵	2.3
Gami <i>et al.</i> ¹⁶	2.0
Aviles <i>et al.</i> ¹⁷	1.4
Marcus <i>et al.</i> ¹⁸	1.1/1.1
Chamberlain <i>et al.</i> ¹⁹	2.1–5.9
Male gender	
Benjamin <i>et al.</i> M/F per 10 years ⁹	1.5
Furberg <i>et al.</i> per 7 years ¹¹	–
Schnabel <i>et al.</i> ¹⁵	1.9
Gami <i>et al.</i> ¹⁶	2.7
Gammage <i>et al.</i> ²⁰	2.4
Aviles <i>et al.</i> ¹⁷	1.7
Marcus <i>et al.</i> ¹⁸	1.6/1.7
Chamberlain <i>et al.</i> ¹⁹	1.9
Validated risk factors, concomitant cardiovascular conditions	Hazard Ratio
Hypertension	
Benjamin <i>et al.</i> ⁹	1.5/1.4
Furberg <i>et al.</i> ¹¹	1.4
Krahn <i>et al.</i> ²¹	1.4
Psaty <i>et al.</i> ¹²	1.1
DeVos <i>et al.</i> ¹⁴	1.5*
Schnabel <i>et al.</i> ¹⁵	1.2
Treated hypertension	1.8
Rosengren <i>et al.</i> ²²	1.7
Treated hypertension	2.1
Gammage <i>et al.</i> ²⁰	1.4
Aviles <i>et al.</i> ¹⁷	1.3
Conen <i>et al.</i> ²³	
Syst 130–140/140–160/>160	1.4/1.7/2.2
Diast 85–90/90–95/>95	1.3/1.5/1.5
Thomas <i>et al.</i> ²⁴ Achieved blood pressure: syst < 120 and > 140: J shaped curve	2/2
Marcus <i>et al.</i> ¹⁸	1.5
	2.1
Chamberlain <i>et al.</i> ¹⁹	1.4/2.2
Valvular heart disease	
Benjamin <i>et al.</i> ⁹	1.8/3.4
Furberg <i>et al.</i> ¹¹	3.2
Krahn <i>et al.</i> ²¹	3.2
Psaty <i>et al.</i> ¹²	2.2
Heart failure	
Benjamin <i>et al.</i> ⁹	4.5/5.9
Furberg <i>et al.</i> ¹¹	2.8

Continued

Diabetes	
Benjamin <i>et al.</i> ⁹	1.4/1.6
Furberg <i>et al.</i> ¹¹	–
Gammage <i>et al.</i> ²⁰	2
Marcus <i>et al.</i> ¹⁸	1.5
	2.1
Chamberlain <i>et al.</i> ¹⁹	1.9
Coronary artery disease (MI)	
Benjamin <i>et al.</i> ⁹	1.4/–
Furberg <i>et al.</i> ¹¹	–
Krahn <i>et al.</i> ²¹	3.6
Psaty <i>et al.</i> ¹²	1.4
Gami <i>et al.</i> ¹⁶ <65 years	2.7
Tsang <i>et al.</i> ⁸	2.2
Marcus <i>et al.</i> ¹⁸	2.2
	3.6

Sleep apnoea syndrome	
Stevenson <i>et al.</i> ³⁸ 2008	3.0
Gami <i>et al.</i> ¹⁶ only <65 years	3.3
Gami <i>et al.</i> ³⁹	2.2
Subclinical hyperthyroidism	
Sawin <i>et al.</i> ⁴⁰ (relative risk)	3.1
Gammage <i>et al.</i> ²⁰	
Cappola <i>et al.</i> ⁴¹	
Heeringa <i>et al.</i> ⁴²	1.9
Alcohol consumption (often excessive)	
Conen <i>et al.</i> ⁴³	1.5
Rosengren <i>et al.</i> ²²	1.3
Mukamal <i>et al.</i> ⁴⁴ former	1.3
Kadoma <i>et al.</i>	
Chronic kidney disease	
Iguchi <i>et al.</i> ⁴⁵	
Baber <i>et al.</i> ⁴⁶	1.9
Asselbergs <i>et al.</i> ⁴⁷ albuminuria	1.5
Go <i>et al.</i> ⁴⁸	1.9
Horio <i>et al.</i> ⁴⁹	1.4*
Competitive or athlete-level endurance sports	
Mont <i>et al.</i> ³⁷	22.8
Abdulla <i>et al.</i> ⁵⁰ meta-an	5.3
Aizer <i>et al.</i> ⁵¹ 5–7 days/week	1.7
Molina <i>et al.</i> ⁵²	8.8
Elosua <i>et al.</i> ⁵³	2.9

AF: Recognizing the Continuum



- AF begets AF
- Ionic and structural remodeling

Lifestyle Modification

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Heart Rhythm Disorders

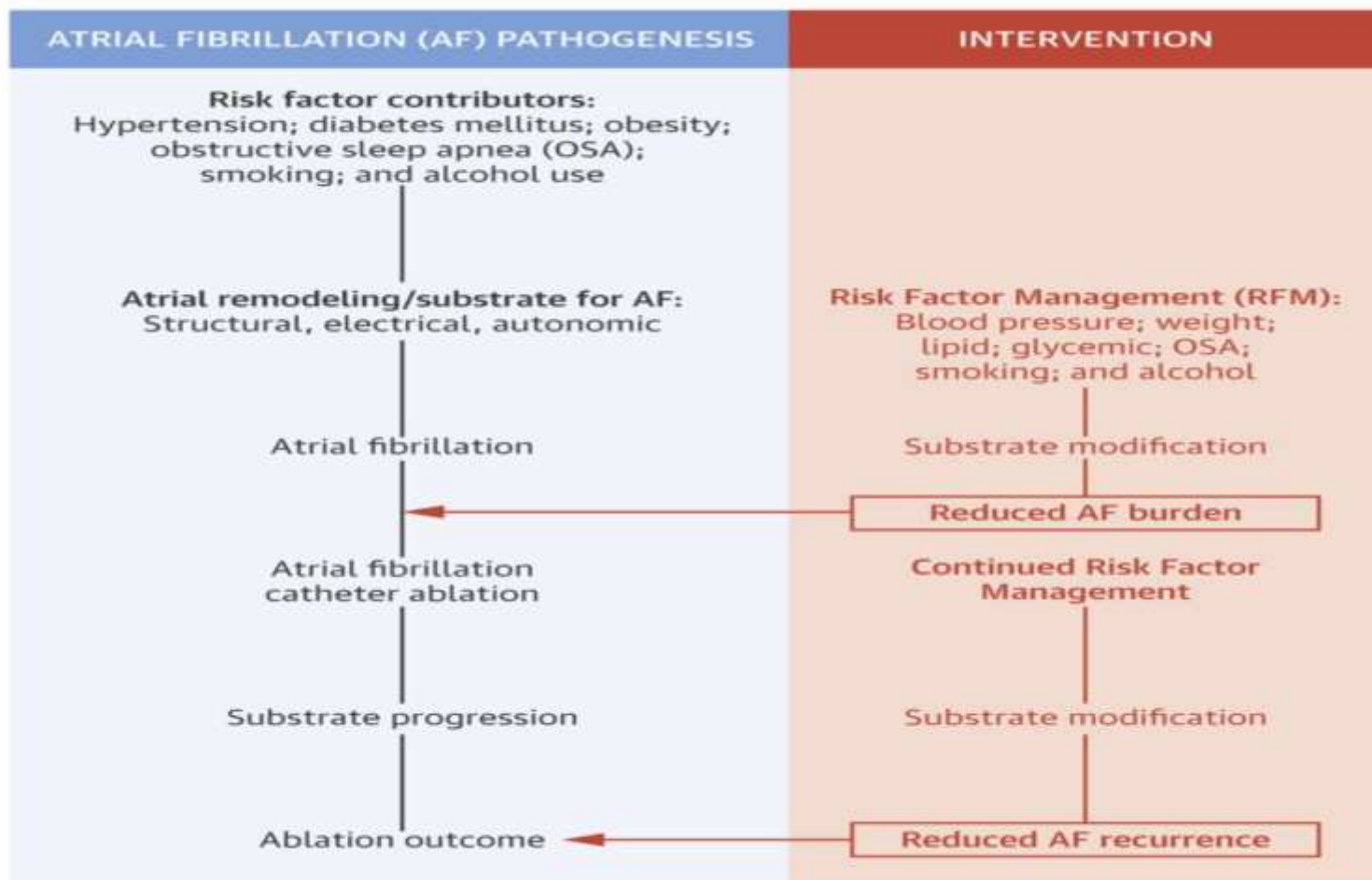
Effect of Yoga on Arrhythmia Burden, Anxiety, Depression, and Quality of Life in Paroxysmal Atrial Fibrillation

The YOGA My Heart Study

Dhanunjaya Lakkireddy, MD,* Donita Atkins, RN,* Jayasree Pillarisetti, MD,* Kay Ryschon, MS,†
Sudharani Bommana, MPhil,* Jeanne Drisko, MD,‡ Subbareddy Vanga, MBBS, MS,§
Buddhadeb Dawn, MD*

Kansas City, Kansas; Omaha, Nebraska; and Newark, Delaware

Aggressive Risk Factor Reduction Study for Atrial Fibrillation and Implications for the Outcome of Ablation: The ARREST-AF Cohort Study

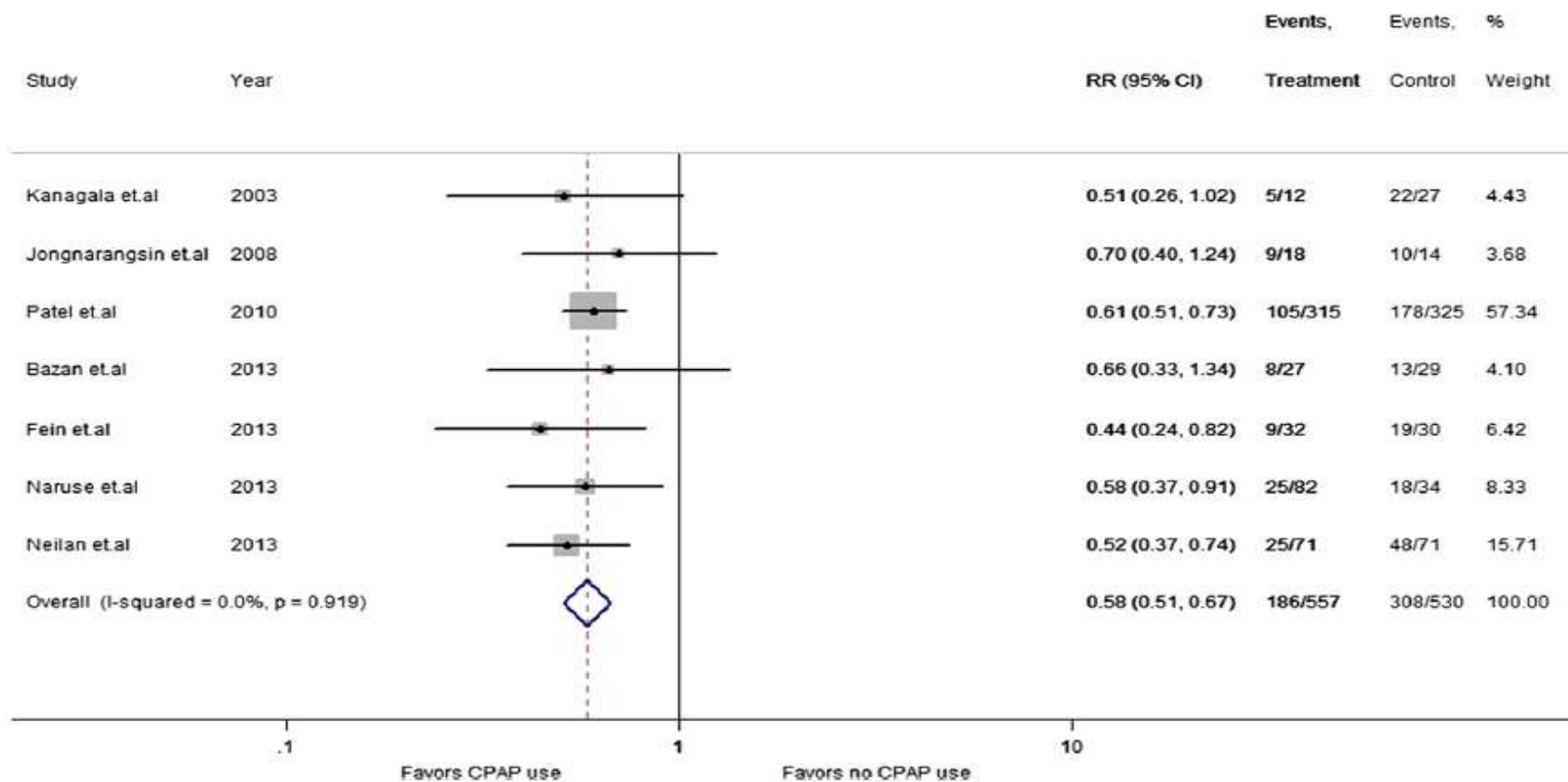


Effect of Obstructive Sleep Apnea Treatment on Atrial Fibrillation Recurrence

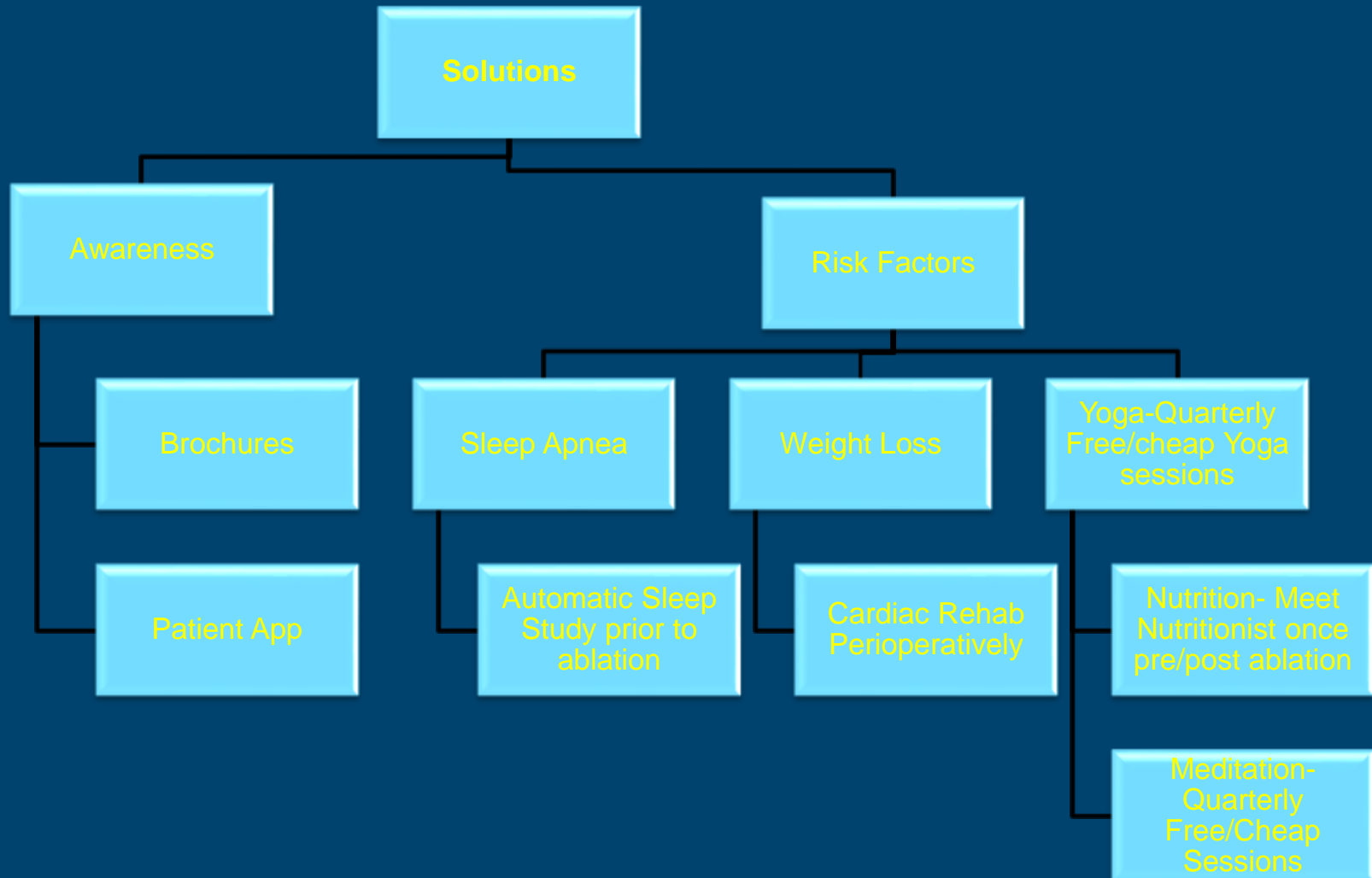
A Meta-Analysis

Ashish Shukla, MD, MPH, Anthony Aizer, MD, MSc, Douglas Holmes, MD, Steven Fowler, MD, David S. Park, MD, PhD, Scott Bernstein, MD, Neil Bernstein, MD, Larry Chinitz, MD

FIGURE 2 Forest Plot to Compare AF Recurrence in Users Versus Nonusers of CPAP In Patients With OSA



Patient Related



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Atrial Fibrillation (AFib) is an abnormal heart rhythm characterized by a rapid and irregular heart beat. Risk factors include high blood pressure, sleep apnea, obesity, poor diet and exercise habits, smoking and heart disease. The Atrial Fibrillation Wellness Program is a unique approach to disease management that combines the latest technology and cutting-edge procedures with a strong focus on lifestyle modification to prevent and decrease the burden of AFib.

With a particularly high rate of AFib in the South Coast region, the Atrial Fibrillation Wellness Program seeks to educate patients and the local physician community on the prevention and management of this disorder. This comprehensive program is designed to help identify high-risk patients and streamline their access to care, offering the tools to help reduce the risk for AFib through education, exercise and lifestyle changes, and social supports.

Our Doctors



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- Cardiac Rehabilitation
- Electrophysiology & Heart Rhythm Services
- Heart Failure Clinic
- Open Heart Surgery
- Structural Heart/Valve Clinic
- Vascular Surgery and Endovascular Services

Questions

