

Latest Treatments for Atrial Fibrillation

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BOULDER COMMUNITY HEALTH'S AFib Clinic at Boulder Heart

Our Passions

- Our Community
- Evidence-based care
- Quality of life
- Education and shared decision-making
- Cutting edge technology and resources

Our Approach

- Whole patient care
- Multispecialty team approach
- Collaborative decision-making
- Full spectrum of care
- Emphasis on comprehensive evaluation, individualized care planning, listening, education, and support

Our Goals

- Best possible outcomes (our 1st priority)
- Fewer ER visits
- Aggressive stroke prevention
- Streamlined, efficient access to care
- Lower costs for patients and families
- Supportive, connected care



Boulder Heart Atrial Fibrillation

Sameer Oza, M.D.



Atrial Fibrillation (AF or A Fib)

- Normal heart beat 60-120 bpm
- A Fib – Atria (upper chambers beat at upto 300 bpm)
- Not dangerous by itself, however
 - Risk of stroke due to blood flow stasis
 - Risk of weakening heart muscle due to fast heart rates

Atrial Fibrillation

- Most common arrhythmia in the US
- 2.3 million people in US have A Fib
- By age 65 y, 8 in 100 patients have A Fib
- Increases risk of stroke 500%

Types of Atrial Fibrillation

- Paroxysmal (comes and goes <7 days)
- Persistent (comes and goes > 7 days)
- Permanent (here to stay)

Risk factors for Afib

- Age > 60 y
- Diabetes
- Heart problems:
 - High blood pressure,
 - Structural heart disease (valves, congenital)
 - Coronary artery disease
 - Congestive heart failure
 - Prior heart surgery

Risk factors for AFib

- Thyroid disease
- Lung disease (COPD, sleep apnea)
- Excessive alcohol use
- Smoking (ARIC study – risk x 2)
- Endurance exercise

Symptoms of A Fib

- >50% patients have no symptoms
- Fatigue/lack of energy (most common) (“old age”)
- Palpitations (irregular/fast/slow)
- Shortness of breath
- Dizziness
- Chest discomfort

A Fib and Stroke

- Blood pooling
- Blood clotting
- Blood clot from heart → brain → interrupt blood flow to brain → stroke
- **15 of 100 strokes** caused by Afib
- 88,000 deaths and \$16 billion in additional costs to the U.S. healthcare system
- 3 out of 4 strokes caused by Afib can be prevented

A Fib and Cardiomyopathy

- Untreated A Fib →
- Multiple signals get through AV node →
- Ventricles beat fast
- Heart is a muscle → heart muscle fatigue
- Cardiomyopathy (weak heart muscle)
- Symptoms = congestive heart failure

Diagnosis of A Fib

- EKG (snapshot)
- Long term monitors (Holter, Event, MCOT)
- Implantable monitors
- Echocardiogram (Transthoracic or Transesophageal)

LINQ monitor



Treatment Options for A Fib

- 3 pillars of treatment
 - Prevent stroke
 - Rate control
 - Rhythm control
- 4th pillar - Risk factor modification

Prevent Stroke

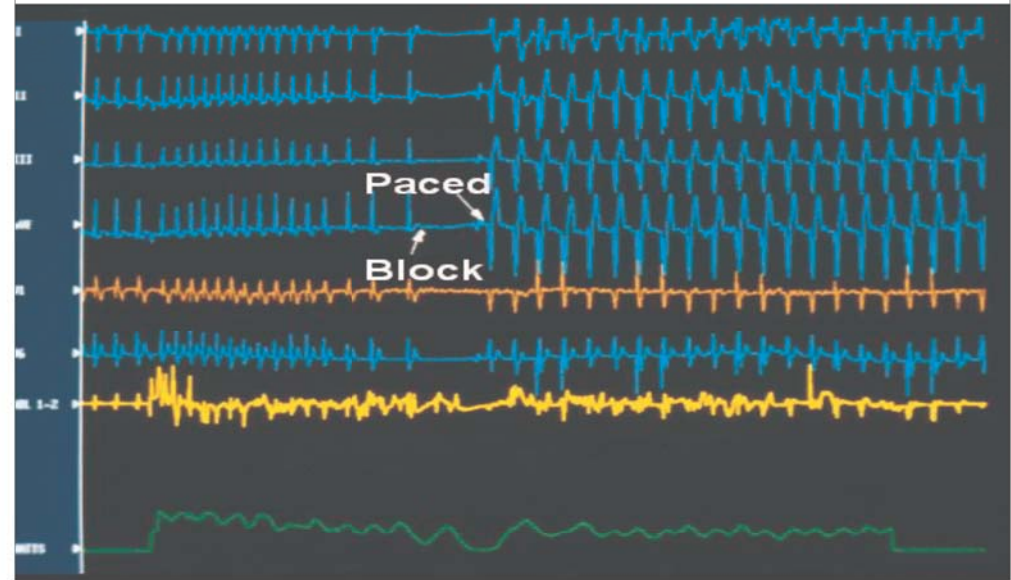
- Warfarin (Coumadin)
- DOAC (Direct oral anticoagulants) – Pradaxa, Xarelto, Eliquis
- Left atrial appendage
 - Remove left atrial appendage surgically
 - Left atrial appendage occlusion (Watchman)

Rate Control

- Drugs
 - Beta blockers
 - Calcium channel blockers
- Pacemaker + AV node ablation

Pacemaker + AV Node Ablation

- Used for patients with permanent atrial fibrillation with fast heart rates
- Pacemaker placed previously or at time of procedure
- AV node ablation
- Treatment of last resort



Rhythm Control

- DC Cardioversion (Effective 100%, 70% recurrence in 1 yr)
- Antiarrhythmic drugs (Effective ~ 40%)
 - Flecainide (Tambocor)
 - Propafenone (Rythmol)
 - Amiodarone (Cordarone)
 - Dofetilide (Tikosyn)
 - Sotalol
 - Dronedarone (Multaq)

Rhythm Control

- Ablation
 - Effectiveness based on type of Afib
 - 70-85% success rate for paroxysmal Afib

Radiofrequency Ablation

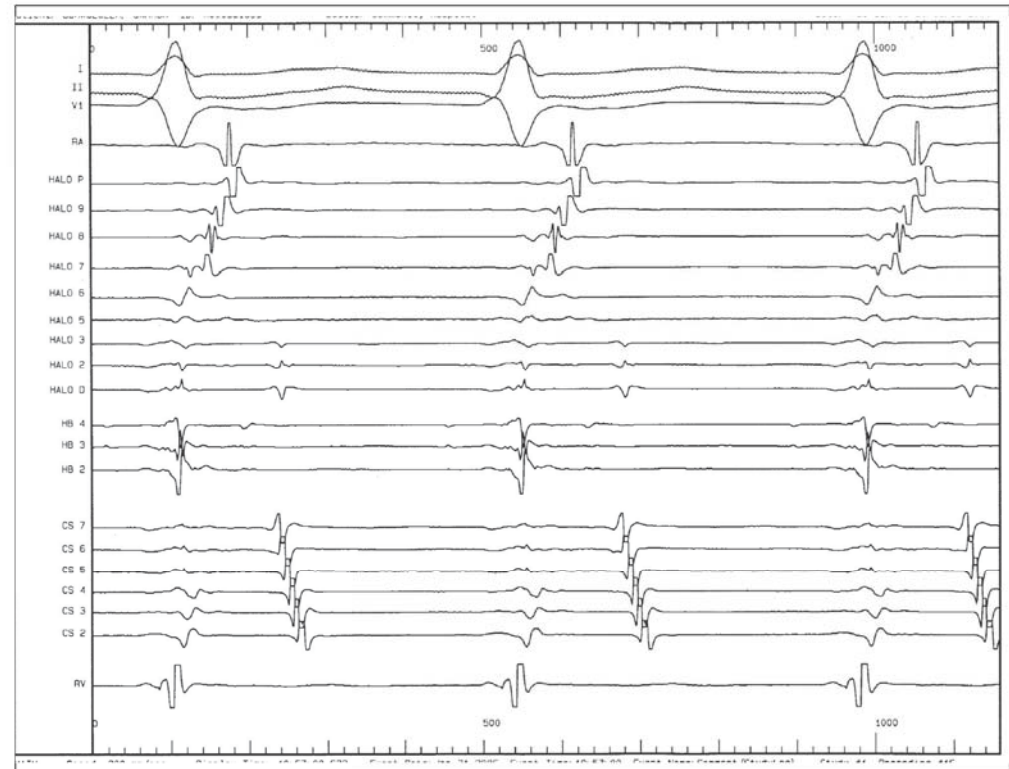
- Catheters – narrow, flexible plastic tubes are inserted into veins through a site in the groin.
- Catheters are directed to the heart using fluoroscopy (live X-Rays).
- Once the catheter reaches the heart, electrodes along the catheter gather data and a variety of electrical measurements are made. The data pinpoints the location of the faulty electrical site.

Mapping

- Mapping is done before ablation.
- Mapping = finding source of arrhythmia
- Types:
 - Conventional mapping
 - 3D mapping

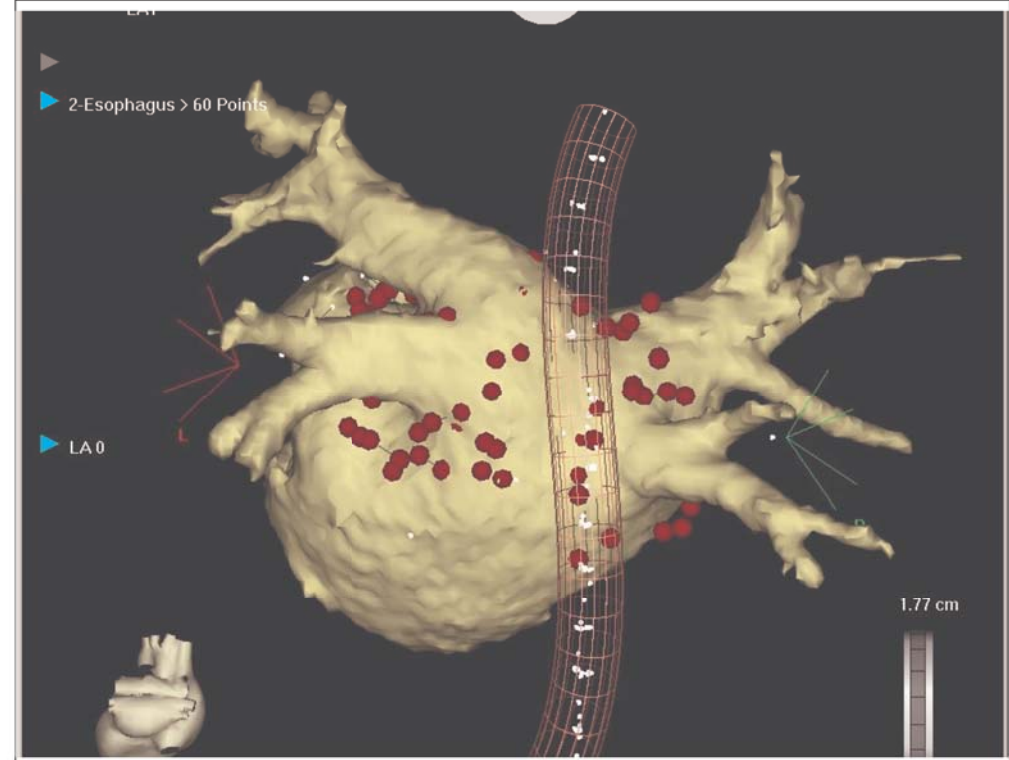
Conventional Mapping

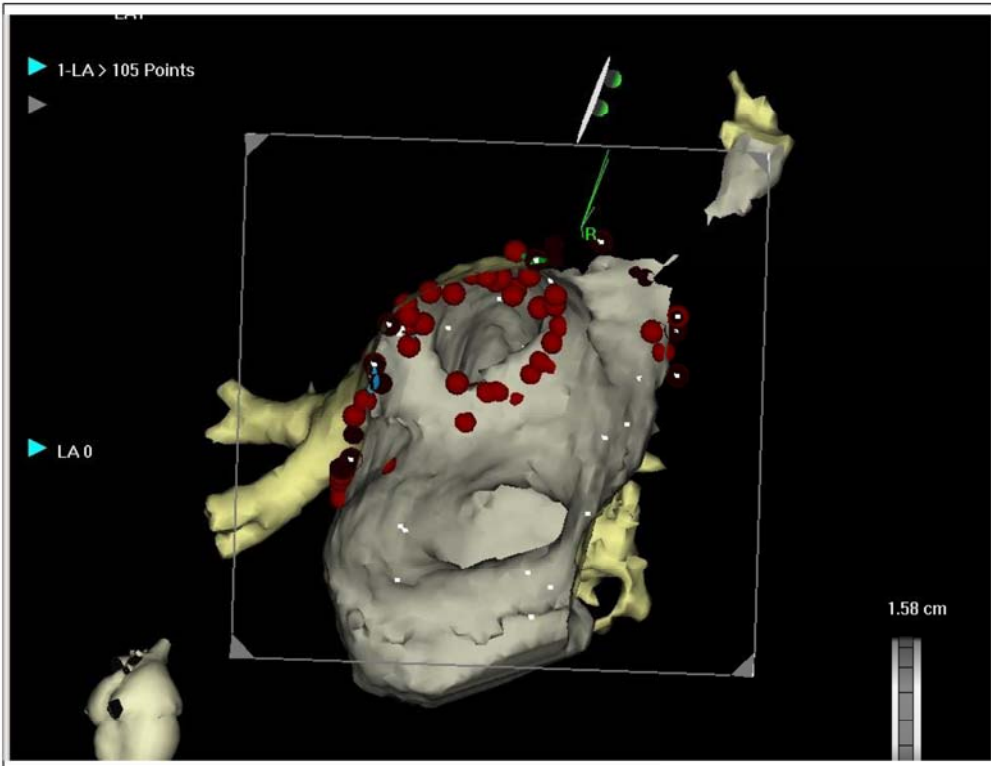
- Uses fluoroscopy (live X-ray) and catheters with platinum electrodes that records electrical activity from different portions of the heart muscle



3D Mapping

- Similar in concept to a GPS system
- Uses magnetic and electrical fields
- Electrical activity at each point in that space is simultaneously recorded
- CT integration of data





Cryo-balloon Ablation

myAFib.org

Boulder Heart Atrial Fibrillation

Srinivas Iyengar, M.D.

But what else does AF cause?

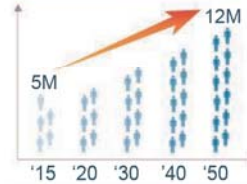
- Stroke!!
- The left atrial appendage (LAA) which is in the left atrium can collect blood which forms clots that can break free in patients with AF
- That's why we place patients with AF who have elevated risks for stroke on blood thinners



AF is a Growing Problem Associated with Greater Morbidity and Mortality

AF = most common cardiac arrhythmia, and growing

AF increases risk of stroke



~5 M people with AF in U.S., expected to more than double by 2050¹

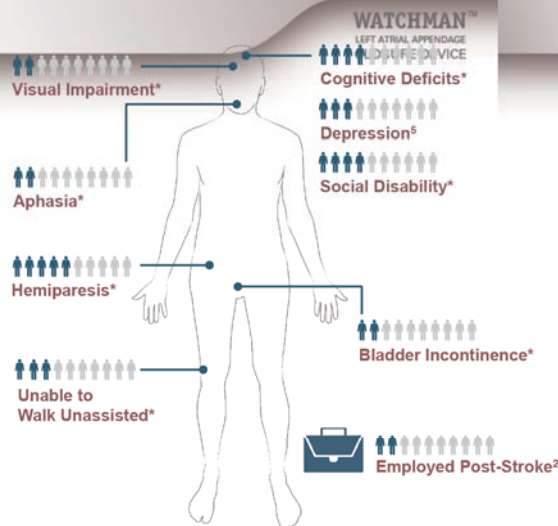
5x greater risk of stroke with AF²

- Higher stroke risk for older patients and those with prior stroke or TIA
- 15-20% of all strokes are AF-related
- AF results in greater disability compared to non-AF-related stroke

1. Go AS, et al, Heart Disease and Stroke Statistics—2013 Update: A Report From the American Heart Association. Circulation. 2013; 127: e6-e245.
2. Holmes DR, *Seminars in Neurology* 2010;30:528-536.
Wolf PA et al, Duration of Atrial Fibrillation and the Imminence of Stroke: The Framingham Study, *Stroke* 1993; 14:664-667

AF-related strokes are debilitating

- Stroke
- #1 cause of adult disability worldwide¹
- AF-related Stroke
- 1.5X higher disability^{3**}
- 2X higher mortality^{3**}
- 70% result in death or permanent disability⁶

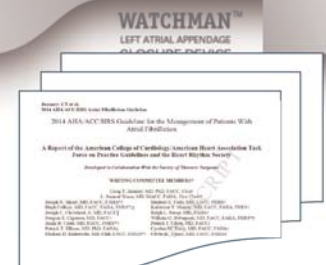


¹at 6 months post-stroke⁴
^{**}compared with stroke patients without AF

¹Chee and Tan, *Med J Malaysia* 69.3 (2014): 119-23. ²Sreedharan et al. *Journal of the neurological sciences* 332.1 (2013): 97-101. ³Lamas et al. *Stroke* 32.2 (2001): 392-398. ⁴Kelly-Hayes et al. *Journal of Stroke and Cerebrovascular Diseases* 12.3 (2003): 119-126. ⁵Loo and Gan. *International Journal of Stroke* 7.2 (2012): 165-167. ⁶Holmes DR, *Seminars in Neurology* 2010;30:528-536.

2014 ACC/AHA/HRS Treatment Guidelines to Prevent Thromboembolism in Patients with AF

- Assess stroke risk with CHA₂DS₂-VASc score
 - Score 1: Annual stroke risk 1%, oral anticoagulants or aspirin may be considered
 - Score ≥2: Annual stroke risk 2%-15%, oral anticoagulants are recommended
- Balance stroke risk reduction benefit vs. bleeding risk



2014 AHA/ACC/HRS Guideline for the Management of Patients with AF

CHA ₂ DS ₂ VASc Score	Recommendation
0	No anticoagulant
1	Aspirin (81-325 mg daily) or warfarin (INR 2-3)
≥2	Oral anticoagulants are recommended (warfarin (INR 2-3), dabigatran, rivaroxaban or apixaban)

January, CT, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation. *JACC*. 2014; doi: 10.1016/j.jacc.2014.03.022

Anticoagulant Therapy Carries Risk of Intracerebral Hemorrhage or Death



Spontaneous intraparenchymal bleed



Hemorrhagic transformation

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

SH-433401-AC DEC2016

Validated Scoring Systems to Assess Stroke Risks

CHA₂DS₂VASc Score (Stroke Risk)³

Condition	Points	Score	Yearly Stroke Risk (%)		
			No Warfarin	With Aspirin ²	With Warfarin ²
C Congestive heart failure	1	0	0	0	0
H Hypertension (SBP>160)	1	1	1.3	1.0	0.5
A ₂ Age ≥ 75 years	2	2	2.2	1.8	0.8
D Diabetes mellitus	1	3	3.2	2.6	1.1
S ₂ Prior stroke, TIA or thromboembolism	2	4	4.0	3.2	1.4
V Vascular disease (PAD, MI)	1	5	6.7	5.4	2.3
A Age 65-74 years	1	6	9.8	7.8	3.4
Sc Sex category (Female)	1				
TOTAL POINTS					

3. Chest. 2010 Feb;137(2):263-72.

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Validated Scoring Systems to Assess Bleeding Risks

HAS-BLED Score (Bleeding risk with warfarin)⁴

Condition	Points	Score	Yearly Major Bleeding Risk %
H Hypertension	1	0	1.13
A Abnormal renal/liver function (1 pt each)	1 or 2	1	1.02
S Hemorrhagic Stroke	1	2	1.88
B Bleeding history or disposition	1	3	3.74
L Labile INRs	1	4	8.70
E Elderly	1	5+	Not well validated
D Current drugs (medication) or alcohol use (1pt each)	1 or 2		
TOTAL POINTS			

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Bleeding Risk Increases Over Patients' Lifetime

HAS-BLED Score	Annual % Bleed Risk*	10-Year Bleeding Risk (%)**
0	0.9	8.6
1	3.4	29.2
2	4.1	34.2
3	5.8	45.0
4	8.9	60.6
5	9.1	61.5

** Assumes constant risk despite increasing age and bleeding risk is independent from bleeding risk in previous years

* Lip. JACC (2011)

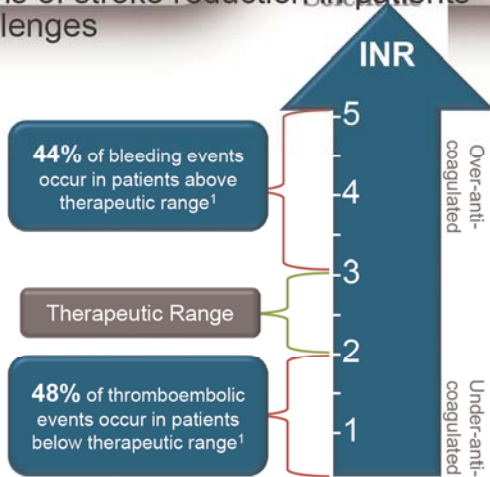
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4. Chest. 2010 Nov;138(5):1093-100.

Stroke Treatment Option: Warfarin

Warfarin is an effective means of stroke reduction in patients with AF but can present challenges

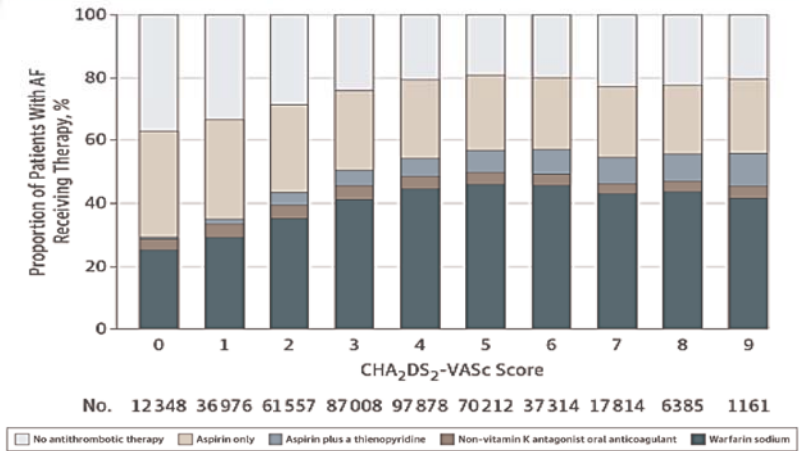
- Many patients spend a significant amount of time outside of the therapeutic range.
- Warfarin tops the list for emergency hospitalizations for adverse drug events in older Americans²



¹ Oake N, et al. *Can Med Assoc J*. 2007;176(11):1589-1594
² Budnitz, MD, MPH, et al. *Annals of Internal Medicine*. 2007;147(11): 229

Oral Anticoagulation is Standard of Care, but Compliance a Challenge

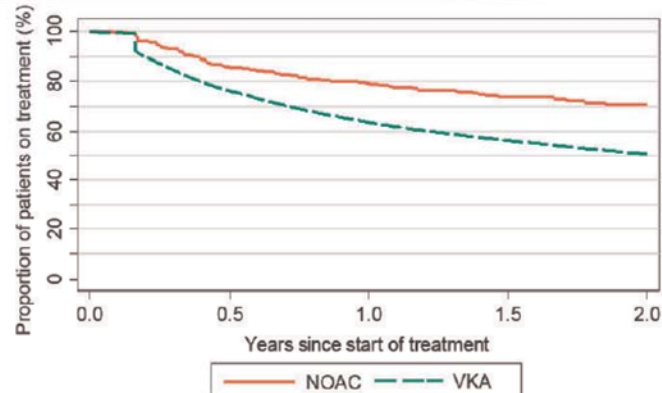
Use of OACs in AF Patients peaks at ~50%, use declines with increasing risk



1. Hsu, J et al. *JAMA Cardiol*. Published online March 16, 2016. doi:10.1001/jamacardio.2015.0374

Despite NOAC Adoption and Ability to Switch NOACs, Adherence to Anticoagulation Remains a Challenge

~30% of NOAC patients stop taking any drug at 2 years



	0.0	0.5	1.0	1.5	2.0
NOAC	914	651	342	139	41
VKA	12307	8453	5762	3915	2506

Martinez C, et al. *Thromb Haemost*. 2015 Dec 22;115(1):31-9.

Challenge: Adherence and Major bleed rates with Novel Oral Anticoagulants (NOACs)

Treatment	Study Drug Discontinuation Rate	Major Bleeding (rate/year)
Rivaroxaban ¹	24%	3.6%
Apixaban ²	25%	2.1%
Dabigatran ³ (150 mg)	21%	3.3%
Edoxaban ⁴ (60 mg / 30 mg)	33 % / 34%	2.8% / 1.6%
Warfarin ¹⁻⁴	17 – 28%	3.1 – 3.6%

For those that remain adherent, there is an annual compounding bleeding risk

¹Connolly, S. *NEJM* 2009; 361:1139-1151 – 2 yrs follow-up (Corrected) ²Patel, M. *NEJM* 2011; 365:883-891 – 1.9 yrs follow-up, ITT ³Granger, C. *NEJM* 2011; 365:981-992 – 1.8 yrs follow-up, ⁴Gaugliano, R. *NEJM* 2013; 369(22): 2093-2104 – 2.3 yrs follow-up.

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only

Non-Valvular Atrial Fibrillation (NVAF), Stroke, and Current Treatment Options

- AF is a Growing Problem Associated with Greater Morbidity and Mortality
 - 5x increased risk of stroke
 - 90% of clots formed in LA come from LAA
- Current treatments with warfarin or NOACS are effective, but many patients stop taking the medications
 - ~1 in 4 patients discontinue blood thinners after 2 years
- Anti-coagulation bleeding risk compounds over time; may not be viable as a long-term solution for some patients

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Connection Between NVAF-Related Stroke and the Left Atrial Appendage

AF Creates Environment for Thrombus Formation in Left Atrium

- Stasis-related LA thrombus is a predictor of TIA¹ and ischemic stroke².
- In non-valvular AF, >90% of stroke-causing clots that come from the left atrium are formed in the LAA³.



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1. Stoddard et al. Am Heart J. (2003); 2. Goldman et al. J Am Soc Echocardiogr (1999)
3. Blackshear JL, Odell JA, Annals of Thoracic Surg (1996)

WATCHMAN LAAC Device Overview

Boston Scientific



Designed specifically for the left atrial appendage

- Nitinol frame radially expands to maintain position in LAA
- 10 fixation anchors engage LAA tissue for stability and retention
- Polyethylene terephthalate (PET) membrane designed to block emboli from exiting the LAA

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PROTECT AF: WATCHMAN Disabling Stroke Reduction Superior to Warfarin

Significant Reduction in Disabling Strokes

PROTECT AF	Event Rate (per 100 pt-yrs)		Rate Ratio (95% CrI)	Posterior Probabilities, %	
	WATCHMAN N=463	Warfarin N=244		Non-Inferiority	Superiority
Stroke (all)	1.5	2.2	0.68 (0.42, 1.37)	>99	83
Disabling	0.5	1.2	0.37 (0.15, 1.00)	>99	98
Non-disabling	1.0	1.0	1.05 (0.54, 2.80)	89	34

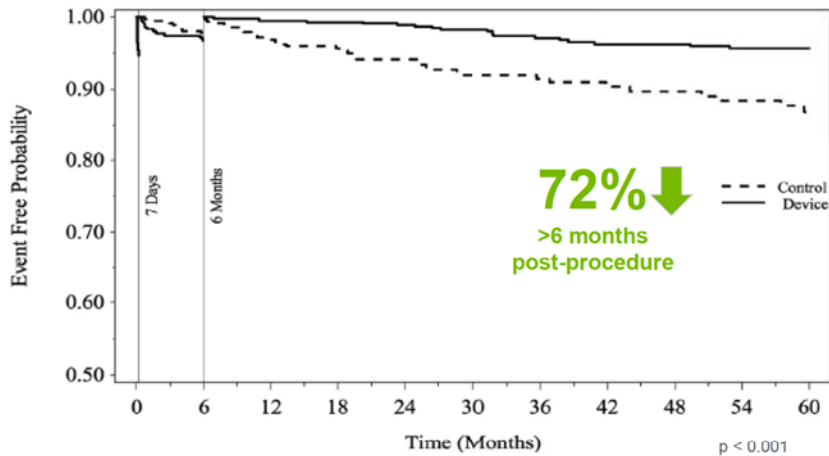
Disabling stroke defined as Modified Rankin Score 3-6

Bayesian – Posterior prob for NI must be ≥97.5%; Posterior Prob for Superiority must be >95%
Reddy, et al. JAMA, 2014

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WATCHMAN Major Bleeding Reduction Superior to Warfarin 6-months Post Procedure

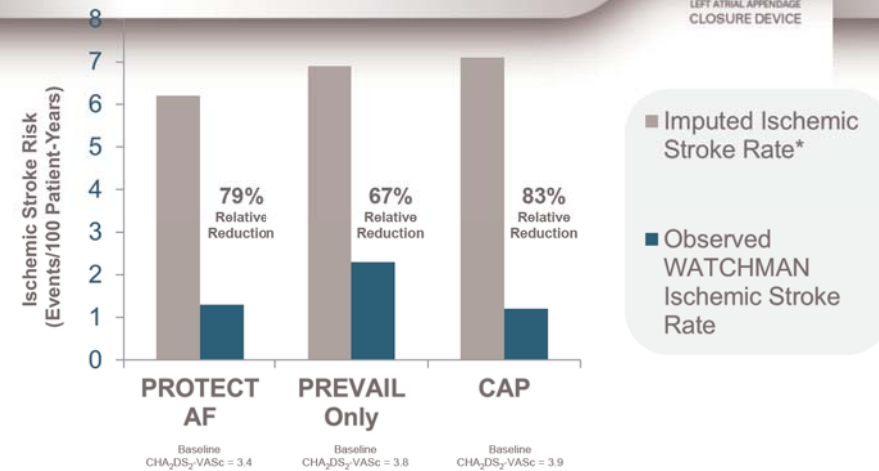
Freedom of Major Bleeding Over 3 Adjunctive Pharmacotherapy Intervals



Price, M. J., V. Y. Reddy, et al. JACC: CV Interv 2015; 8(15): 1925-1932

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WATCHMAN Reduced Ischemic Stroke Compared to No Therapy



* Imputation based on published rate with adjustment for CHA₂DS₂-VASc score (3.0); Olesen JB. Thromb Haemost (2011)

FDA Oct 2014 Panel Sponsor Presentation. Hanzel G, et al. TCT 2014 (abstract)

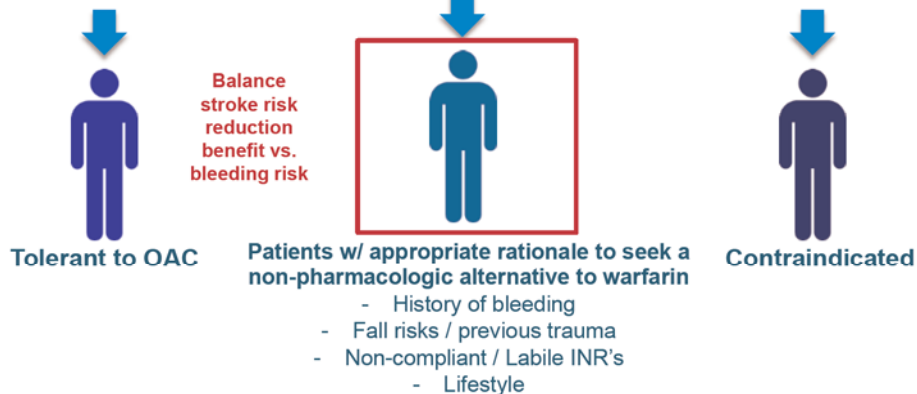
Results from different clinical investigations are not directly comparable. Information provided for educational purposes only

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Patient Populations

Non-Valvular A-Fib Population

High Risk for Stroke (CHA₂DS₂-VASc ≥ 2)



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But what if I need both ablation and ligation?

- Alternatives therapies exist and work!
- Surgical procedures can be performed which can address both issues
- Also, not every patient is a candidate for Watchman (too big, too large)—surgery can also address these individuals

Boulder Heart Atrial Fibrillation

Bryan Mahan, D.O.



BOULDER HEART ATRIAL FIBRILLATION CLINIC

Bryan Mahan, D.O.
Cardiothoracic Surgery
Sameer Oza, M.D.
Electrophysiology
Srinivas Iyengar, M.D.
Structural Heart
Sam Aznaurov, M.D.
Electrophysiology



ATRIAL FIBRILLATION CLINIC

- PATIENT CENTERED COMPREHENSIVE APPROACH TO IRREGULAR HEART RYTHMS
- BEST PRACTICE AND PROTOCOL DRIVEN CARE WITH NATIONAL DATA ENTRY AND OUTCOME AND COMPARISON
- SINGLE POINT OF ENTRY INTO AN INTEGRATED, CENTRALIZED SYSTEM
- TEAM APPROACH TO ALL ASPECTS OF EVALUATION AND TREATMENT COMPRISED OF NURSE EDUCATORS, PHYSICIANS, PATIENT NAVIGATORS, SCHEDULERS AND ADMINISTRATORS
- HIGHLY EXPERIENCED AND SKILLED MEDICAL AND SURGICAL TEAM



ATRIAL FIBRILLATION

- MOST COMMON SUSTAINED ARRHYTHMIA
- PREVALENCE AND INCIDENCE ARE INCREASING
- LIFETIME RISK >40 AT 25% (16% IN ABSENCE OF CV DISEASE)
- 3-6% ACUTE HOSPITAL ADMISSIONS (CHF, CAD, LONE, POST-OP)
- 1.5/1.9 men/women odds ratio for death
- 20-30% all acute stroke admits found to be in AF

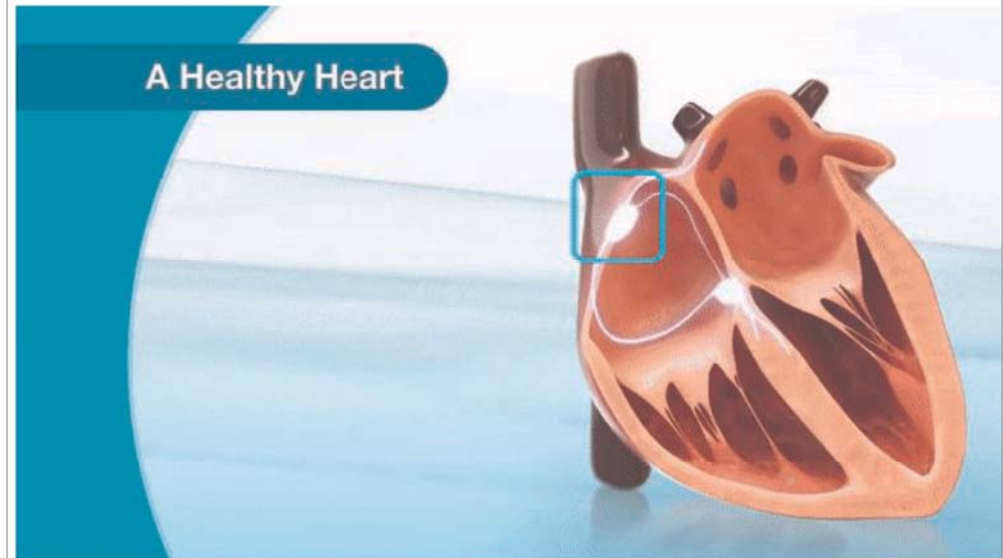
MANAGEMENT OPTIONS

MEDICAL

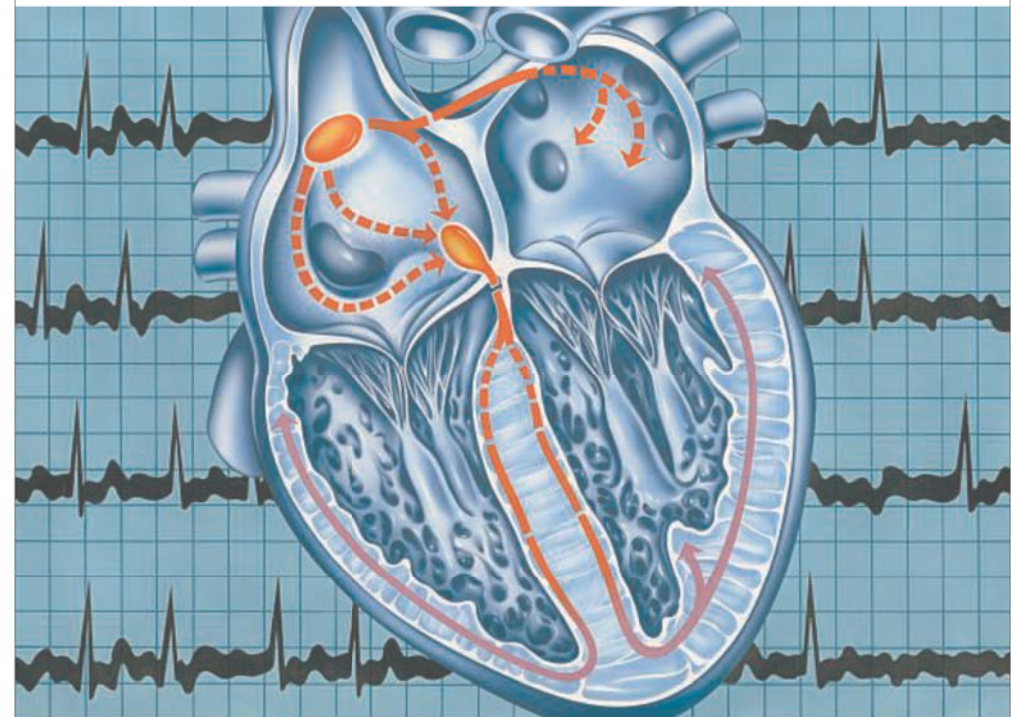
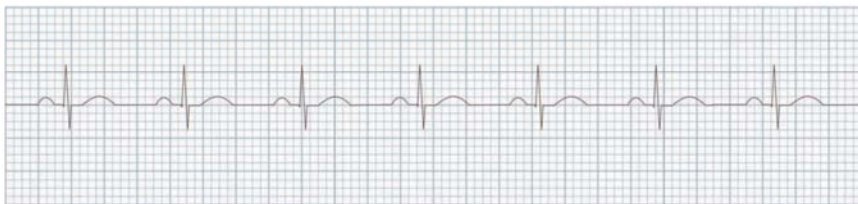
- RHYTHM CONTROL
- RATE CONTROL
- ANTICOAGULATION

INTERVENTIONAL

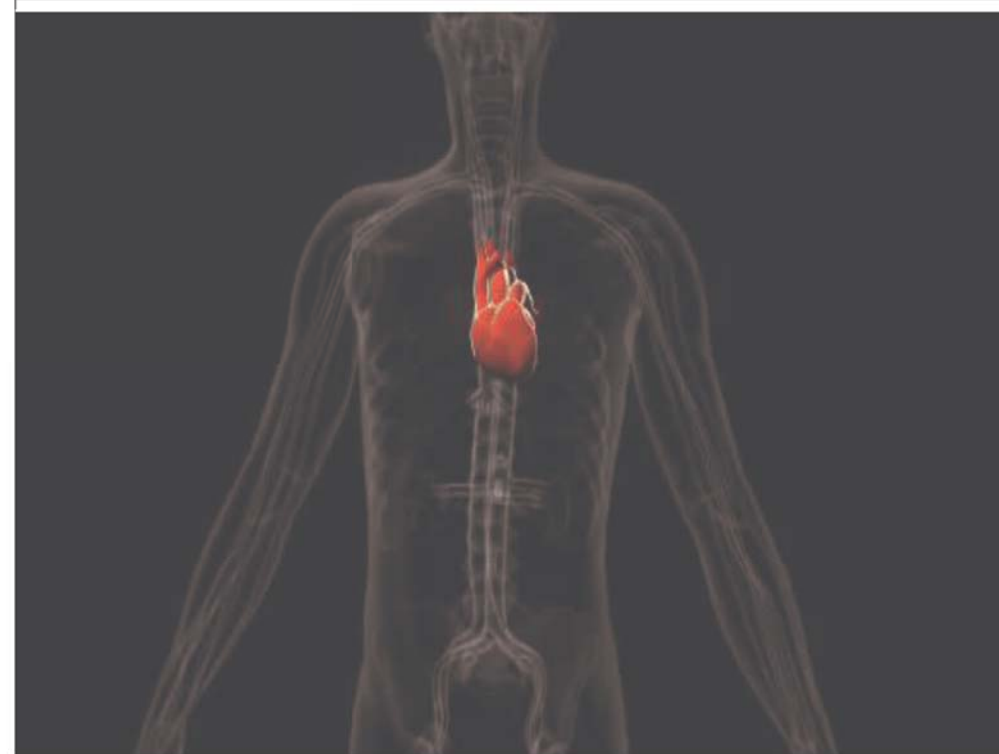
- CATHETER
 - PULMONARY VEIN ABLATION
 - AV NODE ABLATION
 - WATCHMAN
 - OTHER
- SURGICAL(non-pharmacologic)
 - COX-MAZE IV
 - LAA CLOSURE
 - HYBRID



NORMAL SINUS RHYTHM



ATRIAL FIBRILLATION



FRACTURED INSULATION “A SHORT IN THE SYSTEM”



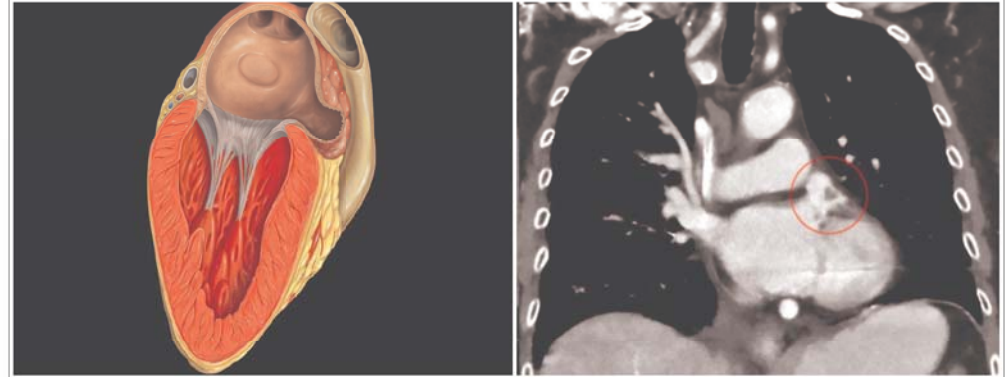
WHEN DO YOU OFFER SURGERY FOR ATRIAL FIBRILLATION

1. Most commonly done if patient is coming to heart surgery for something else (coronary artery bypass, aortic valve replacement, mitral valve repair, etc) and has a history of atrial fibrillation
2. Has failed medical therapy and catheter ablations, may be considered an option
3. Eliminate the left atrial appendage, an alternative to Watchman

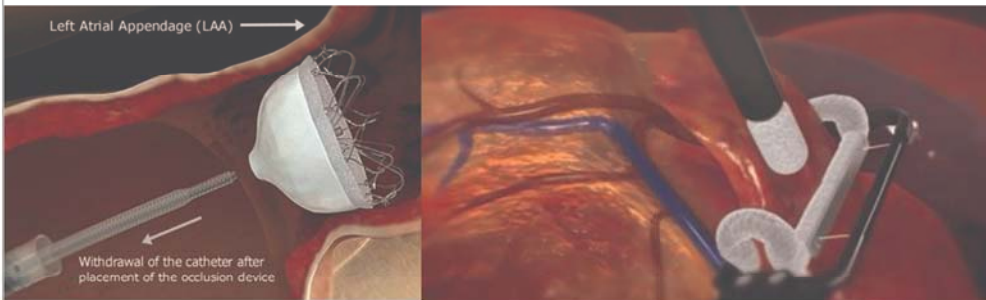
SURGICAL OPTIONS FOR ATRIAL FIBRILLATION

1. ELIMINATE LEFT ATRIAL APPENDAGE
2. THORACOSCOPIC HYBRID MAZE
3. COX-MAZE 4

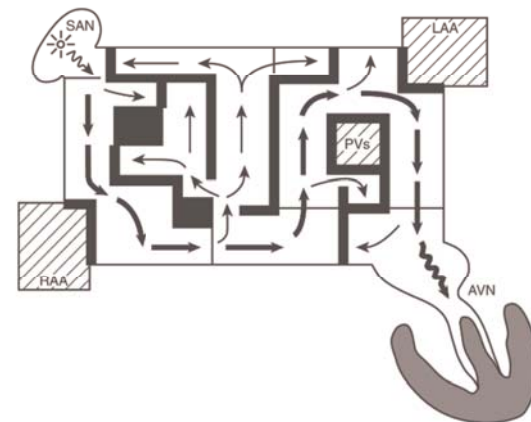
LEFT ATRIAL APPENDAGE OVER 90% OF STROKES ORIGINATE IN LAA



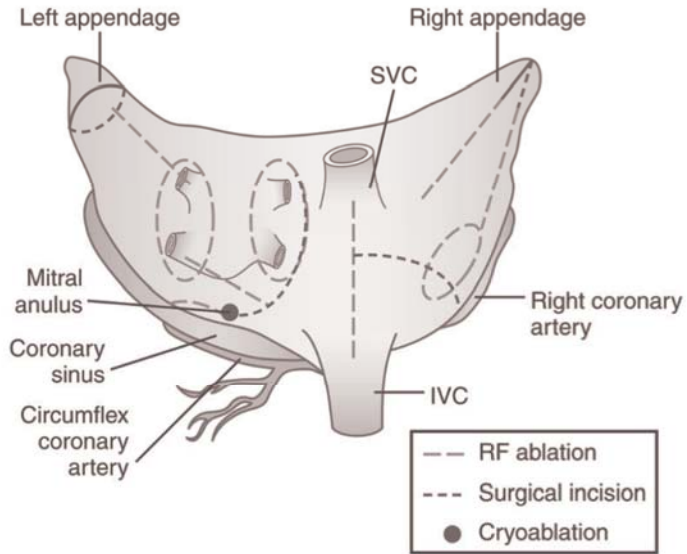
SURGERY FOR LAA MANAGEMENT ALONE



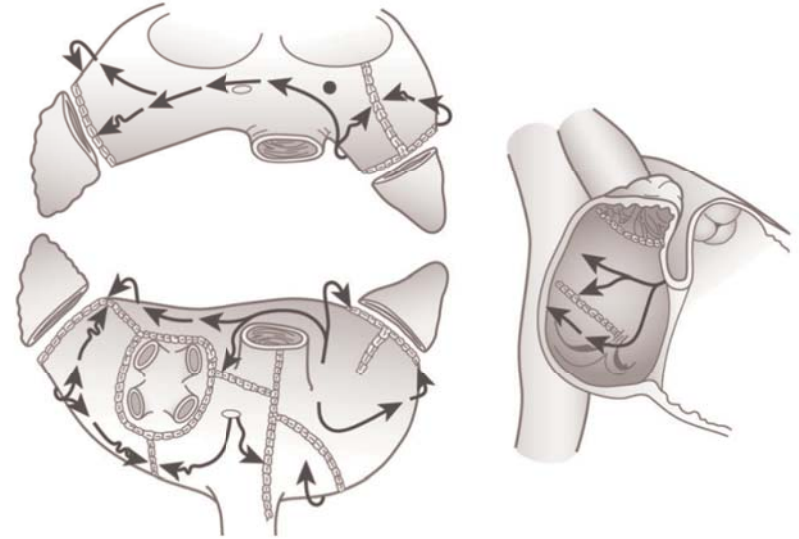
PURPOSE OF ALL “MAZE” SURGERY CREATE A PATHWAY FOR NORMAL ELECTRICAL IMPULSE BETWEEN UPPER AND LOWER CHAMBERS OF THE HEART



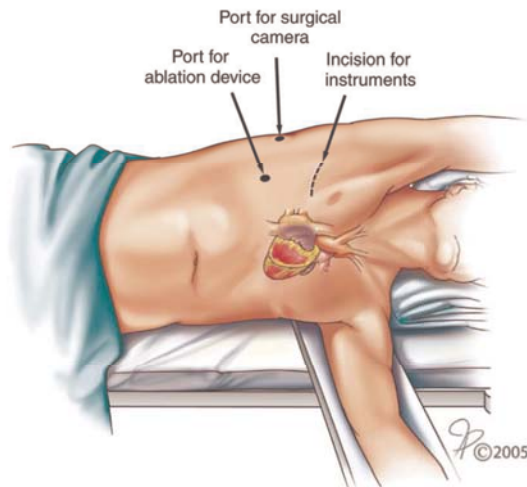
MAZE



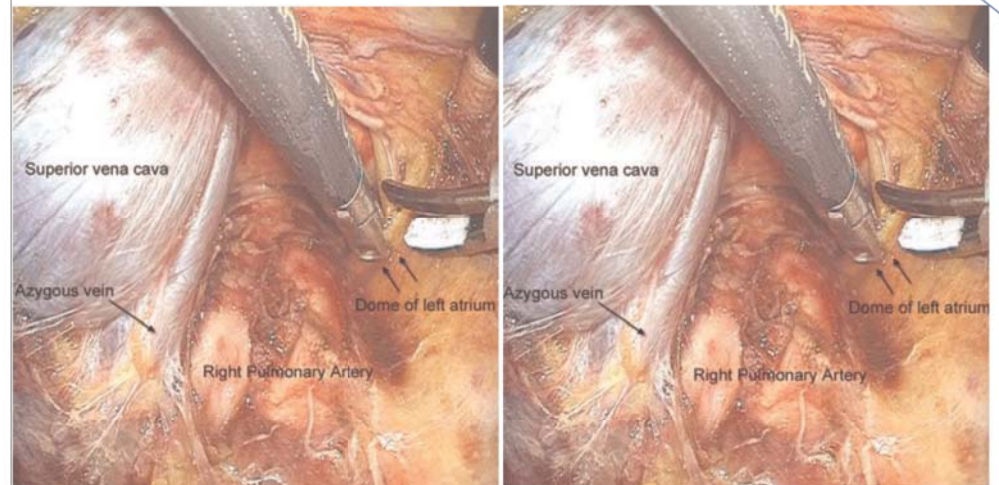
MAZE



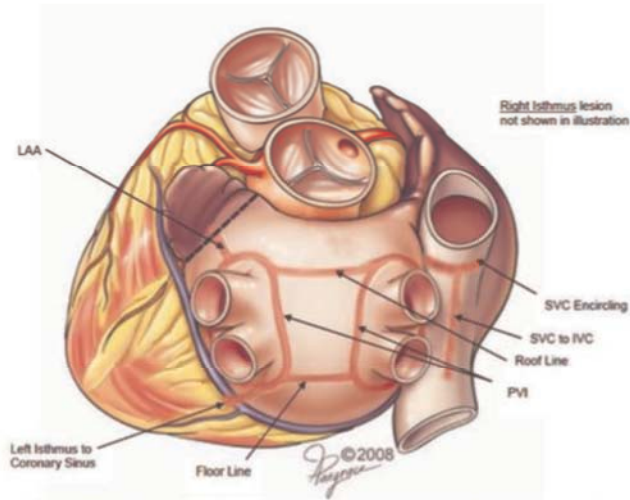
HYBRID MAZE - THORACOSCOPIC



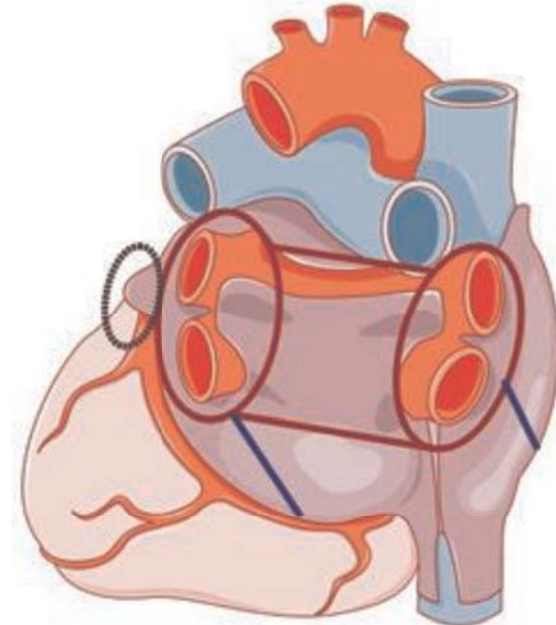
THORACOSCOPIC APPROACH



HYBRID COX-MAZE SURGICAL ABLATION



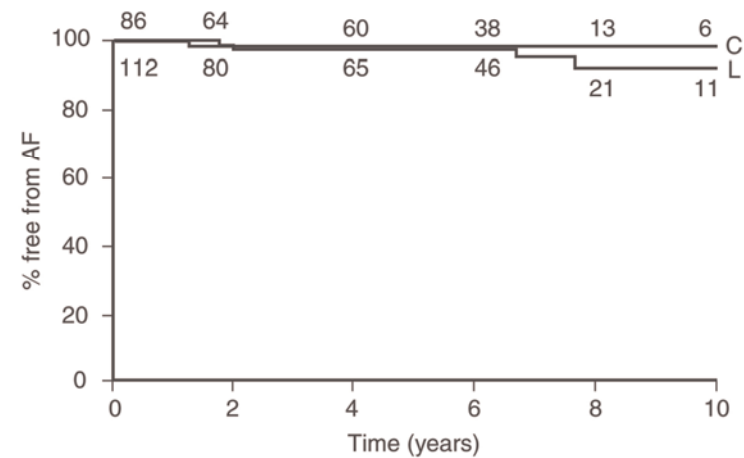
DEEP AF Epicardial Lesion set



COX-MAZE IV SURGERY

- GOLD STANDARD FOR SUCCESS, GREATER THAN 93% AT 1 YEAR
- REQUIRES HEART-LUNG MACHINE, STERNOTOMY OR MINIMALLY INVASIVE APPROACH
- USUALLY DONE WHEN HAVING HEART SURGERY FOR SOMETHING ELSE (CABG, VALVE SURGERY, ETC.)
- CAN BE DONE ALONE IN SPECIFIC SITUATIONS

COX-MAZE IV



COX-MAZE IV SURGERY

- SYMPTOMATIC IMPROVEMENT
- 95% LONG TERM SUCCESS
- IMPROVE LONG TERM SURVIVAL IN PATIENTS UNDERGOING OTHER HEART SURGERY
- ELIMINATE NEED FOR ANTICOAGULATION
- THROMBOEMBOLIC RISK DECREASED BY RESECTION OF LAA

AF

- ? MARKER FOR LONG TERM INCREASE IN MORTALITY OVER THOSE WHO DON'T DEVELOP AF
- Recent data documenting improved survival in patients having heart surgery when atrial fibrillation is addressed at the time of surgery as opposed to leaving it alone

Thank You!



Boulder Heart, 303-872-6899