Get in Rhythm.
Stay in Rhythm.

Atrial Fibrillation Patient Conference

HOSTED BY
StopAfib.org
For patients by patients

November 2, 2013
8:45 a.m. – 1:00 p.m.
Westin Dallas Park Central Hotel • Dallas, Texas

HEAR FROM THESE PHYSICIANS

ADAM R. SHAPIRA
MD, FACC, FHRS

KAMRAN A. RIZVI
MD, FHRS

JAY O. FRANKLIN
MD, FACC, FHRS

ROBERT C. KOWAL
MD, PHD, FHRS

WILLIAM BRINKMAN
MD

WORLD-RENOWNED AFIB EXPERT
Eric N. Prystowsky, MD, FHRS
ST. VINCENT HOSPITAL • INDIANAPOLIS, IN

FOUNDER STOPAFIB.ORG
Mellanie True Hills

$15
Fee includes afib-healthy breakfast & snacks

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Conference Agenda

8:00 – 8:45 am	Registration, Exhibits open, and Light Breakfast	
8:45 – 8:55 am	Welcome and Overview of the day	Mellanie True Hills
8:55 – 9:20 am	Overview of Afib and Why It Is a Problem	Adam Shapira, MD, FACC, FHRS
9:20 – 9:55 am	Treating Afib with Medications and Avoiding Strokes	Eric N. Prystowsky, MD, FHRS
9:55 – 10:10 am	Tips for Communicating with Your Doctor	Mellanie True Hills and Robert Kowal, MD, PhD, FHRS
10:10 – 10:30 am	Living with Afib	Mellanie True Hills
10:30 – 11:00 am	Refreshment Break and Exhibits	
11:00 – 12:00 pm	Treating Afib with Procedures	
	Catheter Ablation	
	▸ RF Catheter Ablation	Kamran A. Rizvi, MD, FHRS
	▸ Cryoballoon Catheter Ablation	Jay O. Franklin, MD, FACC, FHRS
	▸ New catheter ablation procedures (FIRM, laser balloon) and left atrial appendage (LAA) procedures	Robert Kowal, MD, PhD, FHRS
	Surgery including LAA	William T. Brinkman, MD
12:00 – 12:35 pm	Q & A with all Panel Experts	Moderated by Mellanie True Hills
12:35 – 12:45 pm	Wrap Up	Mellanie True Hills, StopAfib.org
12:45 pm	Meeting Adjourns	
1:00 pm	Exhibits close	

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Mellanie True Hills
Founder of StopAfib.org, Author, Survivor, and Patient Advocate

Following a brush with death in emergency heart surgery, and a subsequent close call with a stroke due to atrial fibrillation, Mellanie True Hills vowed to help others avoid heart disease and stroke.

She founded the non-profit American Foundation for Women's Health and StopAfib.org, a patient advocacy organization that informs and supports those living with atrial fibrillation. She speaks out about heart disease, stroke, and patient advocacy at medical conferences, hospital atrial fibrillation and women's events, and corporate events.

From partnering in Facing AFib featuring actress **Susan Lucci** and the AF Stat coalition featuring NBA Hall-of-Famer **Jerry West**, to following **Barry Manilow** at the podium in front of members of Congress, atrial fibrillation and stroke awareness are real passions for Mellanie. Through StopAfib.org, the most visited arrhythmia site, she raises awareness of atrial fibrillation to decrease afib-related strokes, improves the quality of life of those living with afib, and enhances communication with health-care providers.

Successes include creating Atrial Fibrillation Awareness Month and lobbying with other organizations to gain US Senate designation of September as National Atrial Fibrillation Awareness Month. She brings the voice of the atrial fibrillation patient community to think tanks, health policy discussions in Washington, DC and awareness-raising coalitions and partnerships worldwide. She is the author of the multiple award-winning book, *A Woman's Guide to Saving Her Own Life: The HEART Program for Health and Longevity*, and two best-sellers, *Intranet Business Strategies* (© Wiley) and *Intranet as Groupware* (© Wiley). She is a regular contributor on patient perspectives to medical publications and has been featured by hundreds of media around the globe.

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Adam Shapira, MD, FACC, FHRS

Dr. Shapira is the senior cardiac electrophysiologist at Advanced Heart Care, the director of The Heart Arrhythmia Center at The Heart Hospital Baylor Plano's Center for Advanced Cardiovascular Care, and a co-director of the electrophysiology laboratory at Hopkins County Memorial Hospital.

Dr. Shapira received his Bachelor of Arts degree in English literature from Princeton University, *cum laude.* He completed his medical training, internal medicine training and cardiology training between the University of Louisville and UT Southwestern.

Subsequently, he completed an additional two year fellowship in clinical cardiac electrophysiology at Loyola University in Chicago.

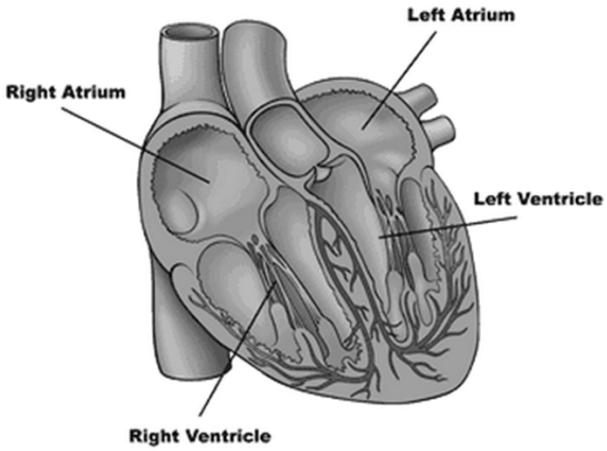
He is board certified by the American Board of Internal Medicine in the fields of clinical cardiology and clinical cardiac electrophysiology.

Dr. Shapira has a particular interest in atrial fibrillation ablation and has co-authored a book chapter about the safety concerns surrounding this procedure. He has also recently authored an overview article on catheter ablation of supraventricular arrhythmias for the journal American Family Physician.

An Introduction to Atrial Fibrillation

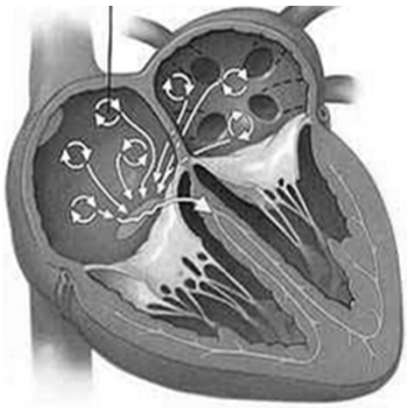
Adam R. Shapira, MD, FACC, FHRS
The Heart Hospital Baylor Plano
November 2nd, 2013

Atrial Fibrillation
Cardiac Anatomy

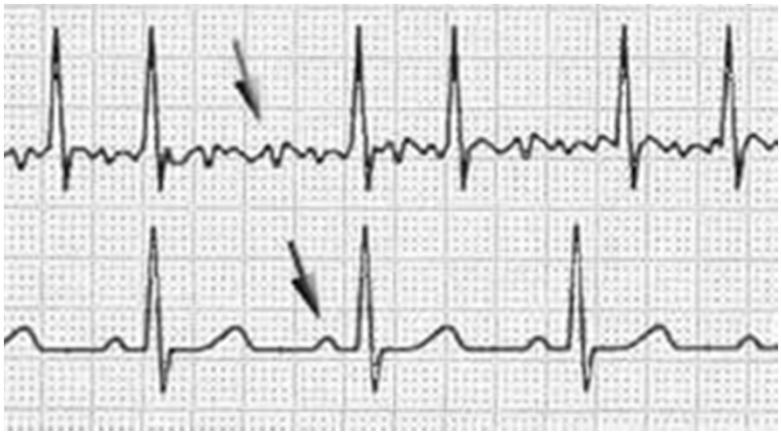


Atrial Fibrillation
Definition

Abnormal, chaotic electrical activity in the top two chambers of the heart



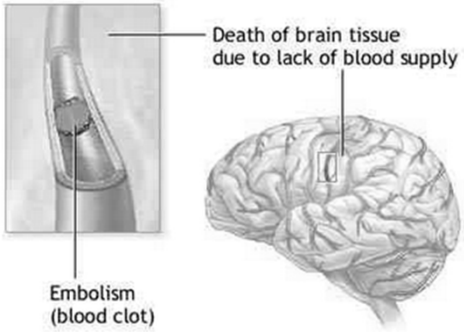
Atrial Fibrillation
Definition

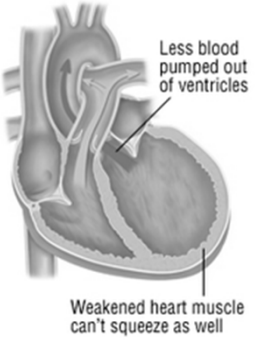


Atrial Fibrillation
Implications

What are the risks/dangers that accompany AF?

- Increased stroke risk
- Heart failure risk





Atrial Fibrillation
Implications: Stroke

CHADS2 Score

Clinical Parameter: CHADS2	Points
Congestive Heart Failure	1
High Blood Pressure	1
Age >/= 75years	1
Diabetes	1
Stroke History	2

CHADS2 Score	Annual Stroke Risk %
0	1.9
1	2.8
2	4.0
3	5.9
4	8.5
5	12.5
6	18.2

Atrial Fibrillation
Implications: Stroke
CHA_2DS_2-VASc Score

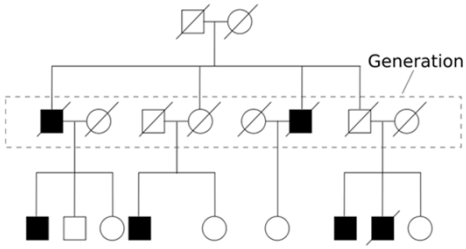
Clinical Condition	Points
Congestive Heart Failure	1
High Blood Pressure	1
Age >/=75	2
Diabetes Mellitus	1
Stroke history	2
Vascular disease	1
Age 65-74	1
Sex (female)	1

Score	Annual Stroke Risk %
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7
6	9.8
7	9.6
8	6.7
9	15.2

Atrial Fibrillation
Causes
Why do I have atrial fibrillation?

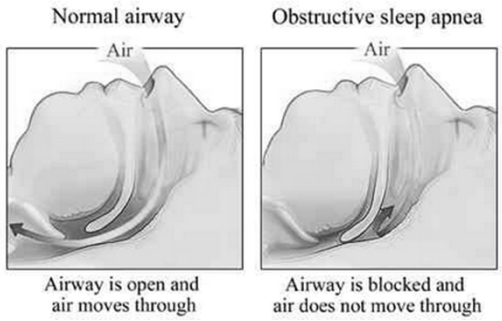
- Valvular heart disease
- High blood pressure
- Diabetes
- Heart Failure
- Hyperthyroidism
- Alcohol use
- Nervous system abnormality
- Genetic factors
- Cardiac surgery
- Chronic kidney disease
- Metabolic syndrome
- Obesity
- Hypertrophic cardiomyopathy
- Coronary artery disease
- Inflammation/Infection

Atrial Fibrillation
Role of Genetics



- Inherited risk of atrial fibrillation from a family member not completely understood
- Many genes likely play a role in causing atrial fibrillation

Atrial Fibrillation
Role of Sleep Apnea



- Decreased oxygen intake
- Blood pressure increases
- Treatment of sleep apnea can reduce AF occurrences

Atrial Fibrillation
Symptoms

What does AF feel like?

- Palpitations (uncomfortable awareness of heartbeat)
- Shortness of breath
- Chest pain
- Lightheadedness/dizziness
- Sweating
- Anxiety
- Rapid heart rates
- Fatigue
- Nausea

Atrial Fibrillation
Diagnosis

How do I know that I have AF?

- Symptoms
- ECG
- Holter Monitor
- Event Monitor

Atrial Fibrillation
Classification

What are the types of AF?

- Lone AF
- Paroxysmal AF
- Persistent AF
- Longstanding-persistent AF
- Chronic AF

Atrial Fibrillation
Framework for Thought

1. ANTICOAGULATION
2. RATE CONTROL
3. RHYTHM CONTROL

Eric N. Prystowsky, MD, FHRS

Dr. Prystowsky is a practicing Cardiologist with St. Vincent Medical Group, and Director of the Clinical Electrophysiology Laboratory at St. Vincent Indianapolis Hospital. He is also a Consulting Professor of Medicine at Duke University Medical Center.

Dr. Prystowsky is a graduate of Pennsylvania State University and the Mt. Sinai School of Medicine. He completed his internal medicine training at Mt. Sinai Hospital, New York City, and his training in cardiology and clinical electrophysiology at Duke University Medical Center, Durham, North Carolina.

From 1979 to 1986, Dr. Prystowsky was a full-time faculty member at the Indiana University School of Medicine, where he was Director of the Electrophysiology Laboratory. In 1986, he returned to Duke University as Professor of Medicine and Director of the Cardiac Arrhythmia Center. He joined The Care Group in 1988.

In addition to co-authoring two textbooks, *Cardiac Arrhythmias: An Integrated Approach for the Clinician; and Clinical Electrophysiology Review*, Dr. Prystowsky has also authored over 700 publications concerning cardiac arrhythmias. He is the Editor-in-Chief of *The Journal of Cardiovascular Electrophysiology* and is also on the editorial board of 16 journals, including *Circulation.*

Additionally, he is past chairman of the American Heart Association's Committee on Electrocardiography and Electrophysiology, past president of the Heart Rhythm Society, and past chairman of the Test Writing Committee for Clinical Electrophysiology for the American Board of Internal Medicine. He was given the Distinguished Alumni Award from Pennsylvania State University in 2007.

Eric Prystowsky, MD, FHRS

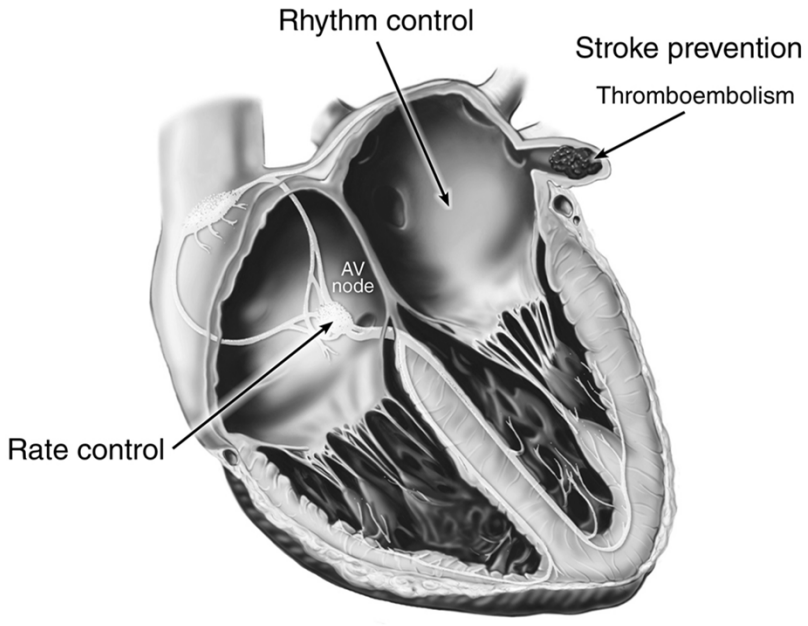
St. Vincent's Hospital
Indianapolis, IN

Conflict of Interest

- Consultant: Medtronic; Topera (stock)
- Board of Directors/Stock options: CardioNet; Stereotaxis
- Fellowship support: Boston Scientific; Medtronic; St Jude

Categories of A Fib

- Paroxysmal
- Persistent
- Long-standing persistent
- Permanent



Prime Directive in Management of Atrial Fibrillation

PRESERVE THE BRAIN

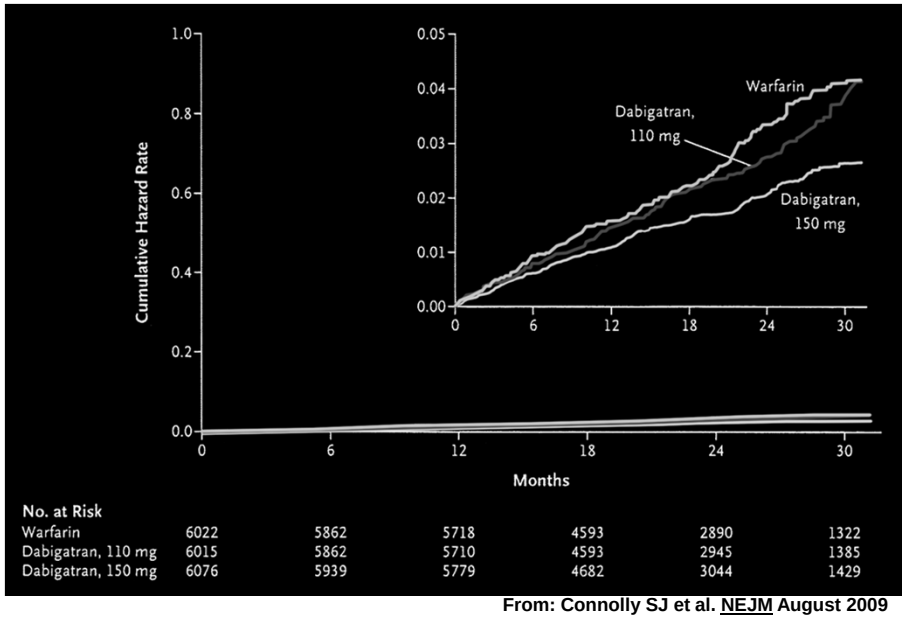
A.	Score
$CHADS_2$ acronym	
Congestive heart failure	1
Hypertension	1
Aged ≥75 years	1
Diabetes mellitus	1
Stroke/TIA/TE	2
Maximum score	6

B.	Score
CHA_2DS_2-VASc acronym	
Congestive heart failure/LV dysfunction	1
Hypertension	1
Aged ≥75 years	2
Diabetes mellitus	1
Stroke/TIA/TE	2
Vascular disease (previous MI, PAD, or aortic plaque)	1
Aged 65–74 years	1
Sex category (ie, female sex)	1
Maximum score	9

A.	Adjusted stroke rate (% per year)
$CHADS_2$ score*	
0	1·9%
1	2·8%
2	4·0%
3	5·9%
4	8·5%
5	12·5%
6	18·2%

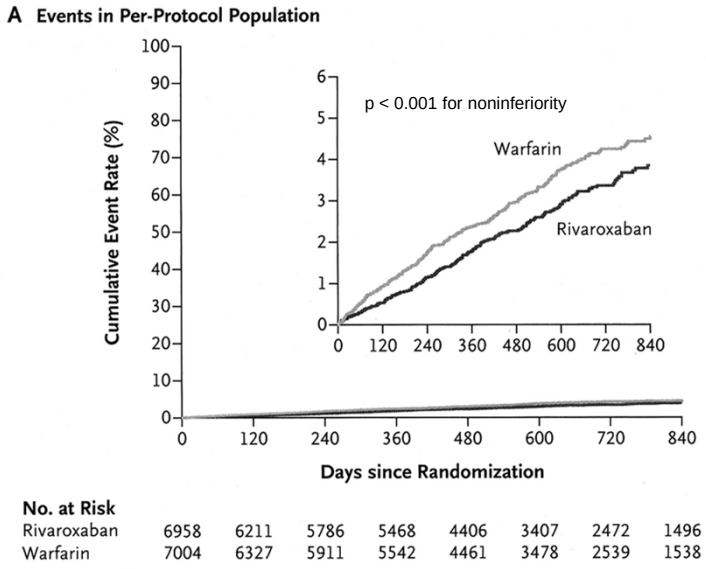
B.	Adjusted stroke rate (% per year)
CHA_2DS_2-VASc score†	
0	0%
1	1·3%
2	2·2%
3	3·2%
4	4·0%
5	6·7%
6	9·8%
7	9·6%
8	6·7%
9	15·2%

Primary Outcome of Stroke or Systemic Embolism in (RE-LY)



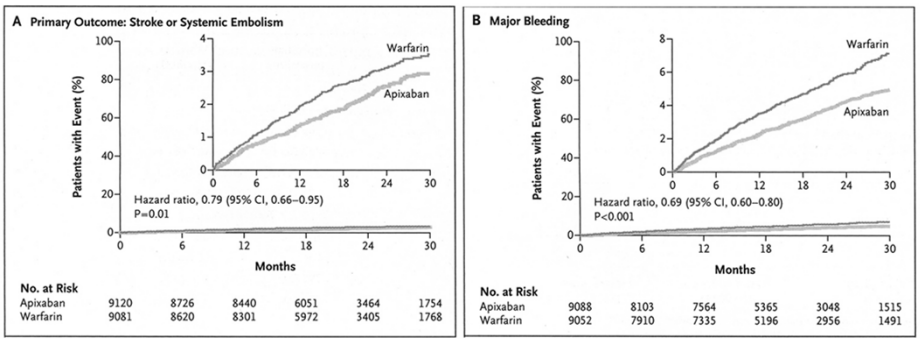
From: Connolly SJ et al. NEJM August 2009

Stroke or Systemic Embolism in ROCKET AF



From Patel MK et al. NEJM 2011; 365: 883-91

Primary and Safety Outcomes in ARISTOTLE (Apixaban in A. Fib)



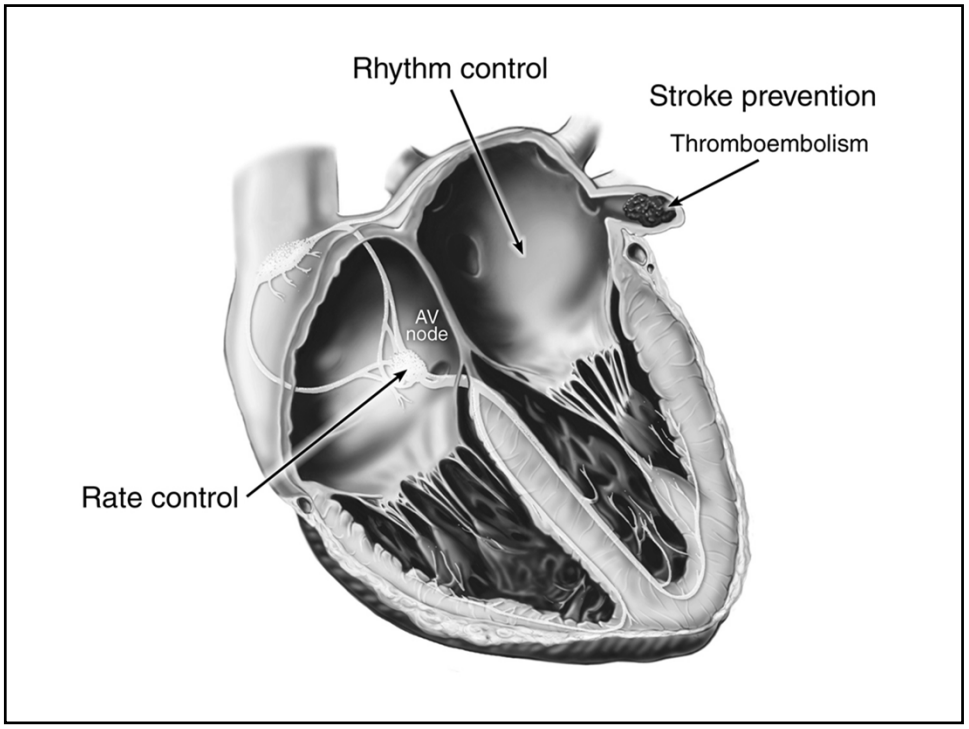
From: Granger CB et al. NEJM 2011; 365: 981-92

Cost of INR Testing

- **INR determination: $231.00**
- **Minimum yearly cost (1/month): $2,772.00**

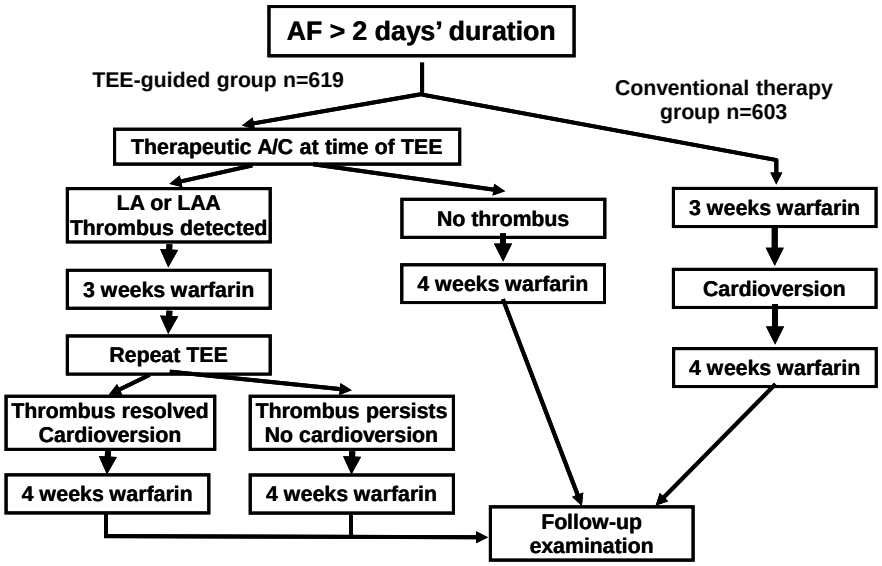
HAS-BLED Score for Major Bleeding Risk

- Hypertension
- Abnormal Liver/Renal Function
- Stroke History
- Bleeding Predisposition
- Labile INRs
- “Elderly” (Age ≥65)
- Drugs/Alcohol Usage



Cardioversion of AF

TEE Guidance: ACUTE Study Protocol

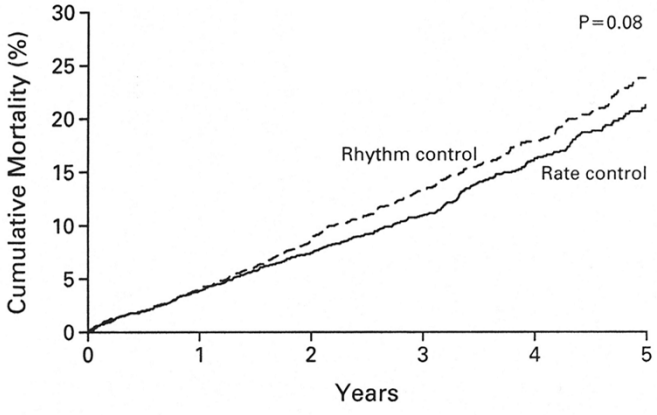


Klein et al. N Engl J Med. 2001;344:1411-1420.

Treatment Strategy for Atrial Fibrillation

Rate versus Rhythm

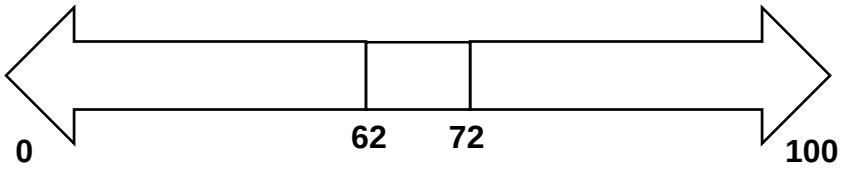
Rate Versus Rhythm Control in Patients with A. Fib (AFFIRM)



No. of Deaths		number (percent)				
Rhythm control	0	80 (4)	175 (9)	257 (13)	314 (18)	352 (24)
Rate control	0	78 (4)	148 (7)	210 (11)	275 (16)	306 (21)

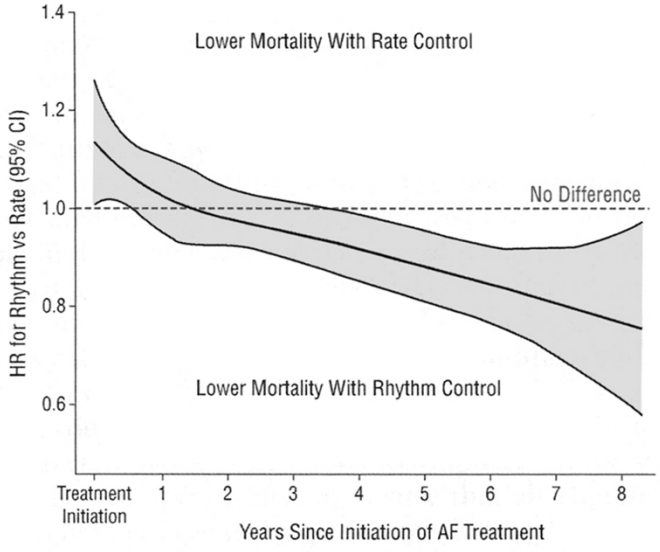
From: AFFIRM investigators NEJM 2002; 347:1825

"Documented" Safety of Persistent Atrial Fibrillation



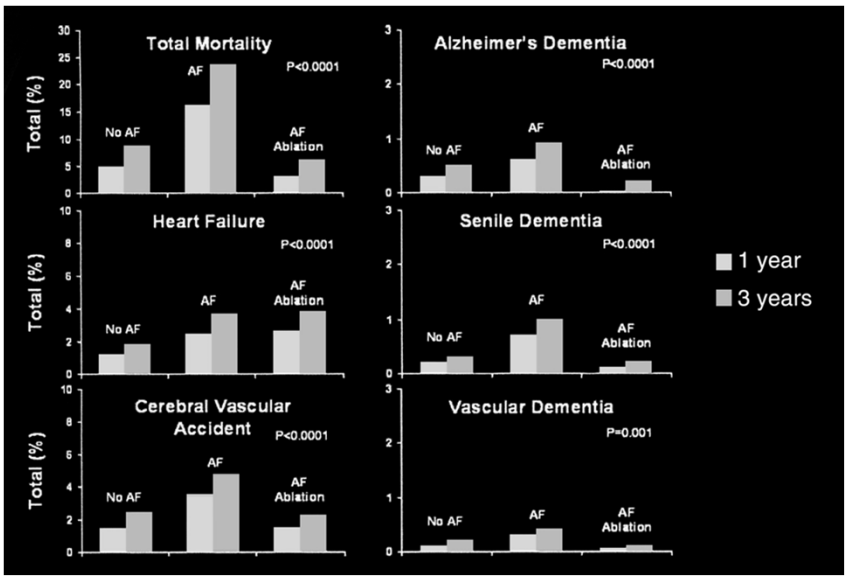
AGE

Effect on Rhythm vs. Rate Control Therapy on Mortality Over Time



From: Ionescu-Ittu R et al. Arch Intern Med 2012; 172: 997

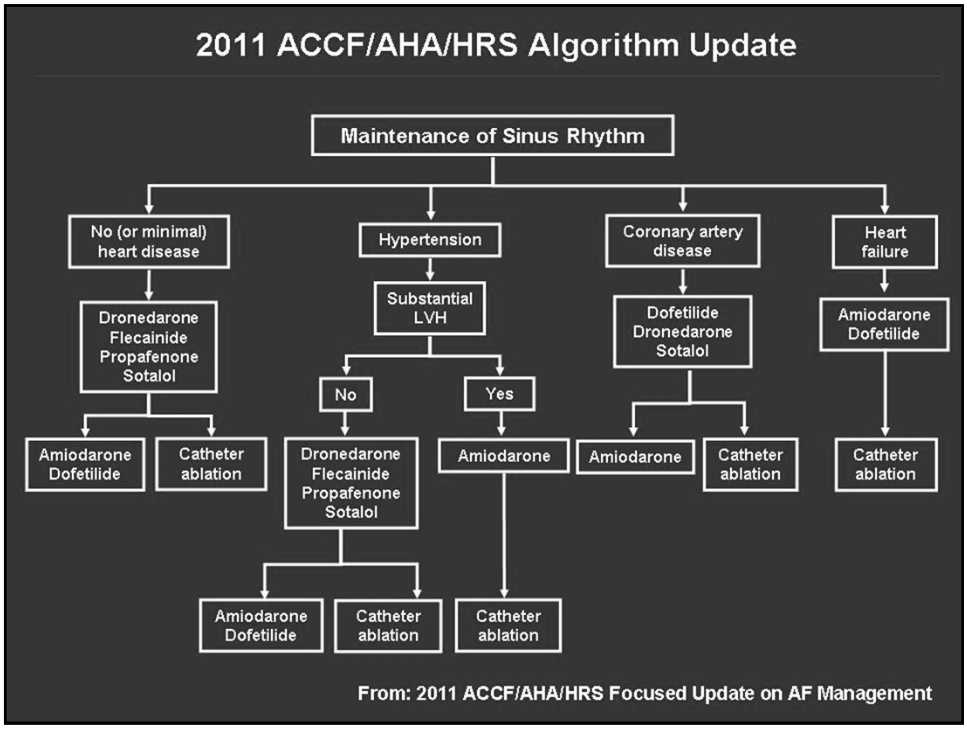
Long-term Outcomes in Patients With AF; AF/RFA; No AF History



From: Bunch TJ et al. J Cardiovasc Electrophysiol 2011; 22: 839

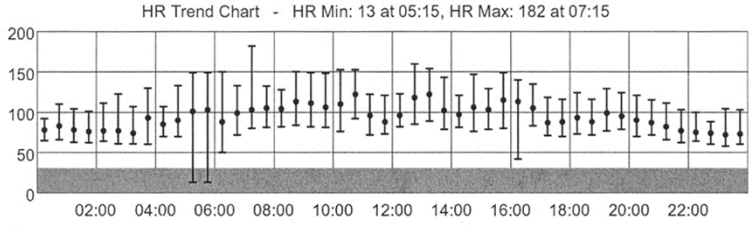
ACC/AHA/ESC 2006 Management Guidelines for Atrial Fibrillation

" Selection of an appropriate agent is based first on safety…"

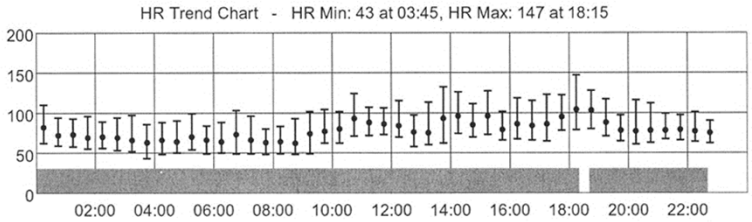


Rate Control

A. Control



B. Toprol XL 50mg/day



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Robert Kowal, MD, PhD, FHRS

Dr. Robert Kowal graduated from Yale University and received his MD and PhD degrees from UT Southwestern Medical Center. He completed his medical internship, residency and cardiology fellowship at Harvard Medical School/Brigham and Women's Hospital and went on to study cardiac electrophysiology.

He currently practices at Baylor Heart and Vascular Hospital. While performing a broad spectrum of device implantation procedures, from pacemakers to multi-lead defibrillators, his main focus is the management of complex arrhythmias such as atrial fibrillation and ventricular tachycardia. His approaches involve both non-invasive medical therapy and catheter-based ablation procedures.

He has been and is currently involved in research on many cutting-edge technologies including cryoballoon ablation and FIRM mapping for atrial fibrillation, left atrial appendage closure and the role of renal denervation in the treatment of arrhythmia.

He has taken a national leadership role serving on the Board of Trustees at the Heart Rhythm Society and is on the editorial board of several scientific journals.

Getting the Most From Your Doctors

Who Do I See?
When Do I See Them?

Robert C. Kowal, MD/PhD
Baylor Heart and Vascular Hospital
VP and Medical Director, Best Care and Clinical Integration, Baylor Quality Alliance.

The Doctor Taking Primary Responsibility for Your AF Depends On ***How It Was Discovered***

- Diagnosis by Primary Care MD/GP/FP in the office setting.
  - Often they will be the ones to manage AF.
- Emergency Room/Hospital Based
  - Often cardiologist will be directly consulted and assume care.

The Doctor Taking Primary Responsibility for Your AF Will Usually Treat Based on ***How You Feel***

- If you have minimal symptoms or do not know you have AF, your primary care/GP/FP may be the principle person managing your AF.
- What prompts referral?
- What prevents referral?

Why is That?

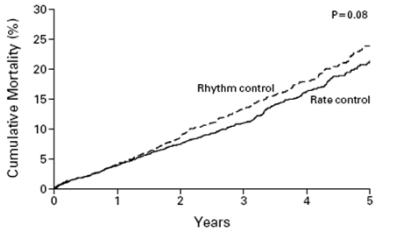
- Care has several components
  - Stoke prevention
  - Rate management
  - Symptom/rhythm management
- Most primary care providers will manage stroke prevention and rate management …..but not rhythm management.

What Prompts Referral by a Primary Care Provider?

- Patient age
  - Under 50 (outliers: most studies do not apply)
  - Complex medical conditions
  - History of other heart disease
  - High heart rate that is difficult to control
  - Ongoing symptoms despite treatment

The AFFIRM Trial is often Cited to Justify a Minimalist Approach to AF

AFFIRM compared a strategy of rate control only to a strategy to maintain SR among 5000 patients with *minimal symptoms* due to AF



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Rate control	0	78 (4)	148 (7)	210 (11)	275 (16)	306 (21)

The AFFIRM trial *does not* tell us that AF patients do not do better in sinus rhythm!

Pieces of AF Management

- Stroke Prevention
  - Blood thinners
    - Warfarin/Coumadin
    - Rivaroxaban/Xarelto
    - Apixaban/Eliquis
  - Devices (in the future)
  - The problem with Aspirin and/or Plavix
- Rate Control
  - Routine medications (most)
  - Pacemaker therapy with AV node ablation (few)
- Rhythm Management
  - Complex medications
    - Anti-arrhythmic drugs
  - Catheter Ablation
  - AF surgery
  - Combination approaches
- Timing can be critical
  - Duration of AF is an important predictor of response to treatment.

When Do I Want to See a Specialist?

- When you are not sure that stroke risk is being properly addressed.
- When you feel limited by your AF and you doctor tells you they have nothing else to offer.
- When you do not feel like you are getting answers to your questions and concerns.
- But...

Problems with Specialists

- There are many unknowns and “black boxes” with AF. No doctor has all the answers. Avoid the problem of perpetual dissatisfaction.
- The more specialists you see, the more likely you will have more complex therapy whether you need them or not.
- Doctors love engaged patients….to a point.

It is a Balance!

Be sure you are armed with with most information possible and that your options are presented completely.

Living with Atrial Fibrillation

Mellanie True Hills, Founder and CEO, StopAfib.org

Communicating with Your Doctor

- Prepare for appointments
- Tell your doctor if you don't understand
- Bring an advocate
- Be open about how afib affects you
- Don't overwhelm your doctor with data
- Ask for resources

StopAfib.org

Resources — Patient Card

StopAfib.org is HON Code Certified by the Health on the Net Foundation

StopAfib.org

StopAfib.org

- Search for info
- Sign up for newsletter alerts about new stories
- Find afib services
- Learn about afib
- Access blog and discussion forum
- HON Certified

We comply with the HONcode standard for trustworthy health information: verify here. HON CODE CERTIFIED 01/2011

StopAfib.org

Get Started Learning About Afib

Afib News and Videos

- Latest afib news and research
- Reports from medical conferences
- Video interviews with top afib experts
- Input from Global Medical Advisory Board
- Afib news feeds

Patient and Caregiver Resources

Atrial Fibrillation General Resources

- American Heart Association Atrial Fibrillation Information
- American Stroke Association
- American College of Cardiology Cardiosmart Heart Patient Resources
- AntiCoagulation Europe
- Atrial Fibrillation Association UK
- Atrial Fibrillation Association US
- Cleveland Clinic AF Center
- Clot Care Anticoagulation Resource
- European Heart Rhythm Association
- Everyday Health Atrial Fibrillation Center
- Healthline Atrial Fibrillation Resources
- Heart Rhythm Society Atrial Fibrillation Patient Site
- Journal of Atrial Fibrillation
- Mayo Clinic Atrial Fibrillation
- MedicineNet.com Atrial Fibrillation Index
- Medline Plus Interactive Afib Tutorial
- Medscape Atrial Fibrillation Resource Center
- National Blood Clot Alliance
- National Stroke Association Atrial Fibrillation Information
- Society of Thoracic Surgeons
- The AFIB Report
- TheHeart.org Arrhythmia/EP Site
- WebMD Atrial Fibrillation Health Center

Atrial Fibrillation Coalitions and Reports

- Action for Stroke Prevention — How Can We Avoid a Stroke Crisis in Europe, October 2012, Atrial Fibrillation-Related Stroke: An Avoidable Burden, October 2012, Atrial Fibrillation-Related Stroke across Europe: A Preventable Problem, October 2012, Atrial Fibrillation-Related Stroke across the Asia-Pacific Region: A Preventable Problem, October 2012, Atrial Fibrillation-Related Stroke across Latin America: A Preventable Problem, October 2012, How Can We Avoid a Stroke

StopAfib.org

Glossary

A

- Ablate
- Ablation
- Amiodarone
- Angina
- Angiotensin II
- Angiotensin-converting enzyme (ACE) inhibitors
- Angiotensin II receptor blockers (ARBs)
- Antiarrhythmic drugs
- Anticoagulant
- Anticoagulation
- Antiplatelet drugs
- Antithrombotic drugs
- Anterior
- Antrum
- Antrum Pulmonary Vein Ablation
- Apixaban
- ARISTOTLE Study
- Arrhythmia
- Asymptomatic
- Atherosclerosis
- Atrial remodeling
- Atrial volume
- Atrioventricular (AV) node
- AV junctional ablation
- AV node ablation

Ablate — Eliminate tissue around the pulmonary veins or at other sources of erratic electrical signals that cause the irregular heartbeat.

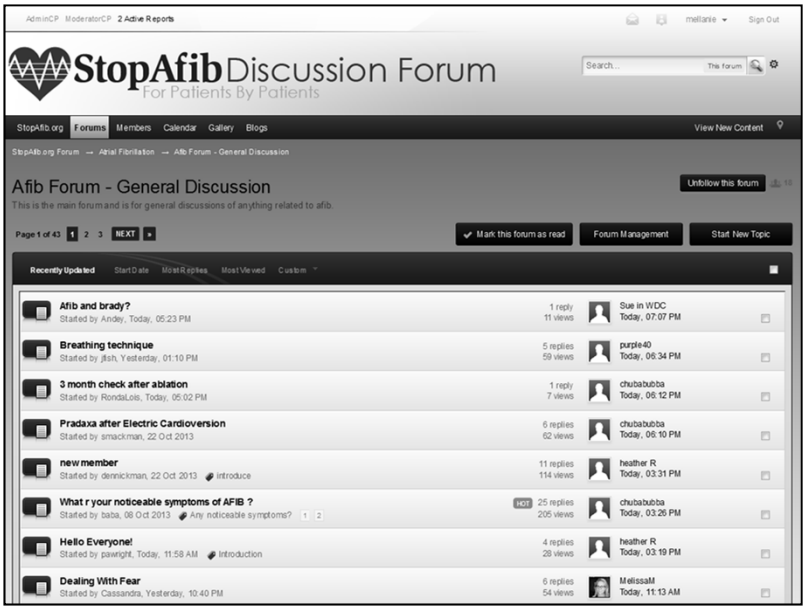
Ablation — A procedure that eliminates tissue around the pulmonary veins or at other sources of erratic electrical signals that cause the irregular heartbeat.

Amiodarone — An antiarrhythmic medication used for atrial and ventricular irregular heartbeats. It is considered the most effective antiarrhythmic drug, but can cause serious side effects, including thyroid damage, liver problems, or kidney problems or failure. Other possible side effects include lung and breathing problems, respiratory distress, vision problems, diaphragm paralysis, nervous system damage, severe hair loss, speech loss, cognitive problems, and death. Oral dose amiodarone has many brand names that differ in various countries. Brand names in the US are Cordarone and Pacerone.

StopAfib.org

AtrialFibrillationBlog.com

Forum.StopAfib.org



Social Media

Facebook.com/stopafib

YouTube.com/stopafib

Twitter.com/stopafib

Bit.ly/stopafibgp

StopAfib.org

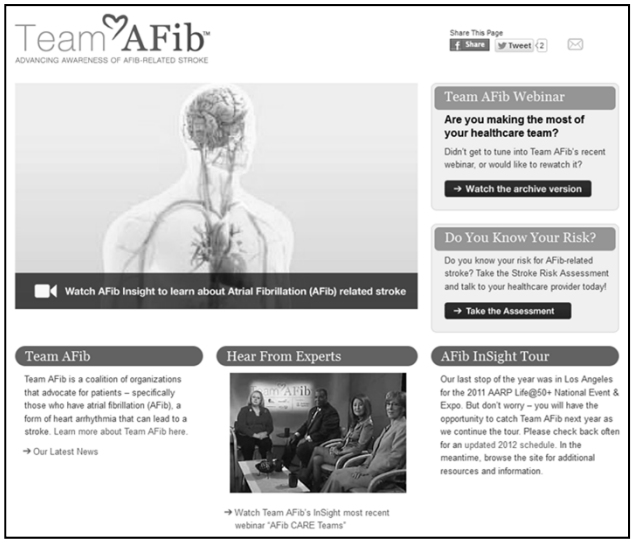
Help Caregivers Understand

"Because AF is not considered immediately life threatening, friends, coworkers, & family members may not appreciate its effect on the patient, may minimize the patient's condition, or dismiss the concerns & symptoms of the patient altogether."

Source: Living with Atrial Fibrillation, Journal of Cardiovascular Nursing

StopAfib.org

Patient and Caregiver Info



- See AFib CARE Team webinar to understand role of caregivers
- See AFib Insight video to understand afib-related strokes

www.TeamAFib.com

StopAfib.org

Frequently Overlooked Relationships

- Sleep apnea
- Autoimmune diseases
  - Celiac disease/gluten intolerance
  - Psoriasis
  - Rheumatoid arthritis

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Sleep Apnea and Afib

Odds of Irregular Heartbeat Are 18 Times Higher After Sleep Apnea Episode

Sleep Apnea Multiplies Risk of Arrhythmias Like Atrial Fibrillation

October 31, 2009 5:21 AM CT

By Peggy Noonan and Mellanie True Hills

New research shows sleep apnea, a disorder that disrupts breathing during sleep, increases the risk of having arrhythmias.

Severe Obstructive Sleep Apnea Predicts Atrial Fibrillation Ablation Failure, New Study Says

July 6, 2010 8:05 AM CT

By Peggy Noonan and Mellanie True Hills

Roughly half of those who have obstructive sleep apnea (OSA) also have atrial fibrillation (AF). In obstructive sleep apnea, the airway becomes blocked during sleep, which causes interruptions in breathing.

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Autoimmune Diseases and Afib

- Increased afib risk shown in those with autoimmune disorders, such as Graves' disease, celiac disease, and psoriasis[1]
- Afib is more frequent in those with rheumatoid arthritis
- Paroxysmal afib and multiple sclerosis sometimes found together[1]
- Autoimmune antibodies, inflammation, and fibrosis are associated with afib[2]

Hypothesis: Atrial Fibrillation is an autoimmune disorder[2]

[1] Lee et al. Heart Rhythm 2012;9:e2-e3
[2] Schairer and Levis, Heart Rhythm 2012;9:e2

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Common Issues

- Alcohol
- Caffeine
- Dehydration
- Air pollution and chemicals
- Stress
- Exercise
- Diet – sugar, flour, salt

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Vitamins and Supplements

- Why doctors don't address supplements
- Bring your supplement list to doctor visits
- What is known about supplements for afib
  - Fish oil/Omega-3s
  - Magnesium and potassium

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Gender Matters: Why Afib is More Fatal For Women

EP Insights

Gender Matters:
Why Afib is More Fatal for Women

StopAfib.org

A Matter of Trust: How to Build Adherence with Afib Patients

Patient Perspectives

A Matter of Trust: How to Build Adherence with Afib Patients

Patient Perspectives from the Sixth Annual Western AF Symposium

StopAfib.org

Bridging the Afib Communications Gap

ATRIAL FIBRILLATION UPDATE APRIL 2015

Bridging the Afib Communications Gap:

Afib Patient Perspectives from the Fourth Annual Western AF Symposium

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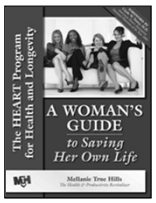
For patients by patients

www.StopAfib.org



EP Insights

Gender Matters: Why Afib is More Fatal for Women

Figure 1: StopAfib.org founder Mellanie True Hills is an afib survivor who believes that better communication between afib patients and healthcare providers leads to better care.

$CHADS_2$ Score

Letter	Clinical Characteristic	Points Awarded
C	Congestive heart failure	1
H	Hypertension	1
A	Age ≥75	1
D	Diabetes mellitus	1
S_2	Stroke/TIA/TE	2
	Maximum score	**6**

TIA = transient ischemic attack; TE = thromboembolism
0 points = low risk
1 point = intermediate risk
2 or more points = high risk
Annual Adjusted Stroke Rate
0 points = 1.9%
1 point = 2.8%
2 points = 4%
3 points = 5.9%
4 points = 8.5%
5 points = 12.5%
6 points = 18.2%

CHA_2DS_2-VaSc Score

Letter	Clinical Characteristic	Points Awarded
C	Congestive heart failure/LV dysfunction	1
H	Hypertension	1
A_2	Age ≥75	2
D	Diabetes mellitus	1
S_2	Stroke/TIA/TE	2
V	Vascular disease	1
A	Age 65 – 74	1
Sc	Sex category (i.e. female sex)	1
	Maximum score	**9**

LV = left ventricular; TIA = transient ischemic attack; TE = thromboembolism; vascular disease = prior myocardial infarction, peripheral artery disease, or aortic plaque
0 points = low risk
1 point = intermediate risk
2 or more points = high risk
Annual Adjusted Stroke Rate
0 points = 0%
1 point = 1.3%
2 points = 2.2%
3 points = 3.2%
4 points = 4.0%
5 points = 6.7%
6 points = 9.8%
7 points = 9.6%
8 points = 6.7%
9 points = 15.2%

Figure 2: The two main stroke risk assessment tools are $CHADS_2$ and CHA_2DS_2-VASc. As part of the CHA_2DS_2-VASc score, the female gender is included as a risk factor. Source: Assessing Stroke and Bleeding Risk in Atrial Fibrillation: Consensus Statement on Appropriate Anticoagulant Use.[26] http://bit.ly/afib-consensus

Mellanie True Hills, Speaker and CEO, StopAfib.org
Decatur, Texas

In recent years, there have been many revelations about heart disease and how it specifically affects women. Research has shown that women frequently have different symptoms of a heart attack than men, and women are often worse off after a heart attack.[1]

Not surprisingly, the diagnosis, symptoms, and treatments of atrial fibrillation (afib) can differ for women, too. One stark, potentially deadly difference: in women 20 to 79 years old, the risk of stroke is 4.6-fold greater in women than men.[2] In addition, mortality for women with afib is up to 2.5 times greater than that for men.[3]

Afib affected approximately 2.66 million people in the United States in 2010, according to the U.S. Centers for Disease Control. And the numbers will only climb. With the aging Baby Boomer population, estimates from the Centers for Disease Control indicate that afib will affect 12 million people by 2050.[4] Afib sufferers have a five-fold increase in stroke risk compared to the general population. The numbers for women tell a dire story:

- Each year, in the United States, about 55,000 more women than men have strokes.[5]
- Stroke is the fourth leading cause of death for women.[5]
- Women account for more than 60 percent of stroke-related deaths.[5]
- After age 75, which is the median age for afib onset, 60 percent of those with afib are women.[5]
- Afib risk in women increases over men when patients have other conditions, such as diabetes mellitus, congestive heart failure, hypertension,

HAS-BLED Score

Letter	Clinical Characteristic	Points Awarded
H	Hypertension	1
A	Abnormal renal &/or liver function (1 point each)	1 or 2
S	Stroke history	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (age ≥ 65)	1
D	Drugs or alcohol (1 point each)	1 or 2
	Maximum score	**9**

Hypertension = systolic BP≥160 mmHg; Abnormal renal function = presence of chronic dialysis or renal transplantation or serum creatinine≥200µmol/L; Abnormal liver function = chronic hepatitis disease (e.g., cirrhosis) or biochemical evidence of significant hepatic derangement (e.g., bilirubin>2x upper limit of normal, in association with AST/ALP/ALP>3x upper limit normal, etc.); Bleeding = previous bleeding history or predisposition to bleeding (e.g., bleeding diathesis, anemia, etc.); Labile INRs = unstable/high INRs or poor time in therapeutic range (e.g., <60%); Drugs or alcohol = concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatories, or alcohol abuse, etc.; INR = international normalized ratio
Annual Adjusted Bleeding Rate
0 points = 1.13%
1 point = 1.02%
2 points = 1.88%
3 points = 3.74%
4 points = 8.70%
5 points = 12.50%
Any score = 1.56%

Figure 3: The HAS-BLED tool helps healthcare providers accurately weigh the risks of bleeding from anticoagulants versus benefits of stroke prevention. Source: Assessing Stroke and Bleeding Risk in Atrial Fibrillation: Consensus Statement on Appropriate Anticoagulant Use.[26] http://bit.ly/afib-consensus

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valvular disease, and myocardial ischemia.[6]
- There have been greater declines in stroke death rates among men than in women.[6]

We celebrate the differences between men and women, but as far as afib and stroke are concerned, the differences can be deadly. Women are also more likely to experience longer symptomatic episodes, more frequent recurrences, and significantly higher ventricular rates during afib.[7] Interestingly, women with type B blood have a 17 percent increase in stroke risk compared to men.[8]

Like the revelations about women and heart disease, these differences may surprise many healthcare providers. The differences also extend to how women afib patients are viewed by some healthcare providers. Too many times, women with afib symptoms are dismissed as having panic attacks or being stressed and not taken seriously. However, afib in women can be much more serious. When healthcare providers know about the differences in risk, diagnosis, and treatment, they can provide the best possible treatment to female afib sufferers.

ASSESSING STROKE AND BLEEDING RISK

To assess the stroke risk of those with afib and the need for anticoagulants, many healthcare providers use the $CHADS_2$ and CHA_2DS_2-VASc scoring tools (Figure 2) to help gauge the risk of stroke and determine whether to prescribe anticoagulants. However, the $CHADS_2$ tool fails to consider women's apparent greater stroke risk.

For those who have a $CHADS_2$ score of 0 or 1, meaning that anticoagulants may not be deemed necessary, considering their CHA_2DS_2-VASc score may provide a more accurate assessment of their true stroke risk. It incorporates vascular disease, another age range (65 to 74 years), an additional weighting for being 75 years or older, and the female gender.[9] Therefore, using only the $CHADS_2$ tool for women (and some men) who are a $CHADS_2$ score of 0 or 1 could be a disservice to them.

When deciding whether to use anticoagulants, some healthcare providers also weigh bleeding risk. One commonly used tool that helps gauge this risk is the HAS-BLED scoring tool that takes into account major bleeding risk factors, such as **H**ypertension, **A**bnormal kidney or liver function, **S**troke, **B**leeding, **L**abile INR (unstable or high INRs, or poor time in the therapeutic range), **E**lderly, and **D**rugs or alcohol. For more information about the HAS-BLED scoring tool, see Figure 3.[10] Using these tools can help optimize afib patient care.

POTENTIAL MISPERCEPTIONS ABOUT WOMEN AND AFIB

Healthcare providers have to be careful about afib-related misperceptions and clarify them for patients. Some media reported that a recent Danish study concluded that females with atrial fibrillation weren't at greater risk of a stroke. These news outlets didn't read the full study, because the authors clearly stated that for there to be no additional stroke risk, women must be younger than 65 and have no other stroke risk factors aside from afib. In other words, they must truly have lone afib.

The study authors noted that the European Society of Cardiology (ESC) guidelines (Figure 4) advise that female patients with afib take oral anticoagulants, except those who meet the "age <65 and lone AF criterion." Female patients under 65 with just one minor risk factor, and those between 65 and 74 years of age with no additional risk factors, should be on oral anticoagulants. While these Danish study results contradict the recommendations in the guidelines because they did not find females aged less than 75 to have excess risk when compared to males, the study authors still recommended sticking to the ESC guidelines because so many other studies have reported otherwise.[11]

This bears emphasis: the study authors recommended that anticoagulation is not needed only for women 65 and younger with lone afib. If women have other stroke risk factors, such as diabetes, high blood pressure, or heart disease, making them a CHA_2DS_2-VASc score of 2 or more, they clearly need anticoagulants. To say otherwise irresponsibly jeopardizes women's lives.

Afib affects immediate risks and the long-term prognosis of women differently than men. An analysis from the Euro Heart Survey for Afib found that women with afib have more than double the thromboembolism risk of men with afib.[12] In addition, a Swedish study found that the rate of ischemic stroke in afib patients younger than 65 years of age was 47 percent higher in women than men.[13] What's worse: women overall have a significantly higher risk of afib-related stroke than men and are more likely to live with stroke-related disability. As you might imagine, women who have these stroke-related disabilities have a significantly lower quality of life.[6]

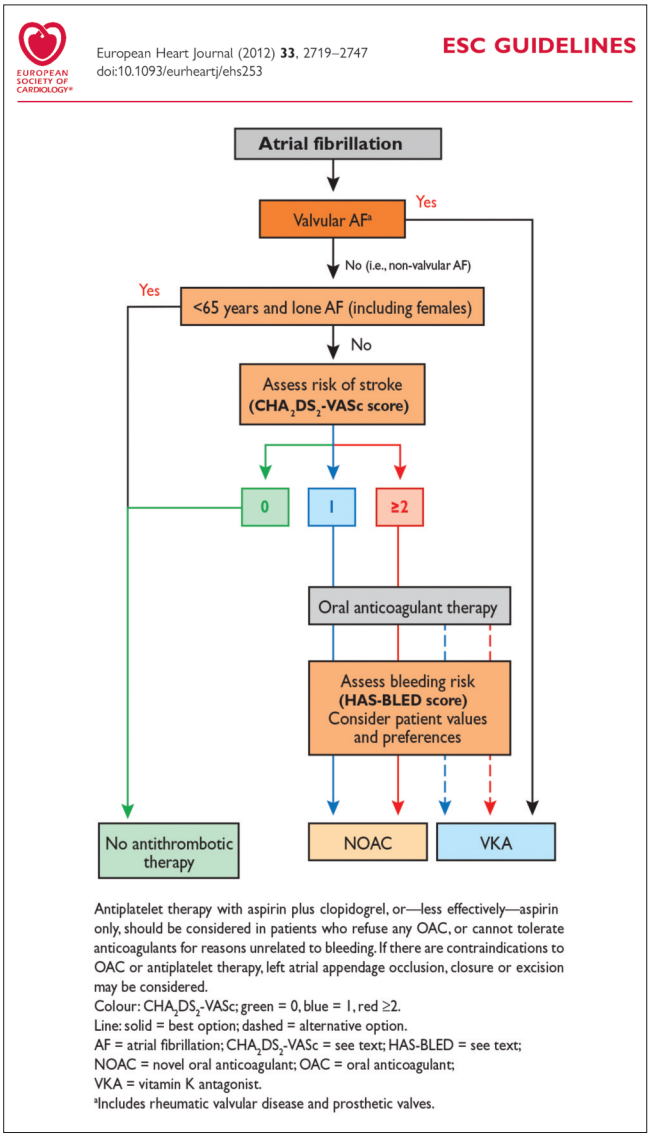

Figure 4: The European Society of Cardiology advises oral anticoagulants for female patients with afib except those who meet the "age <65 and lone AF criterion." So female afib patients under 65 with just one minor risk factor, and those between 65 and 74 years of age with no additional risk factors, should be on oral anticoagulants. [With permission of Oxford University Press (UK) (c) European Society of Cardiology, www.escardio.org/guidelines. A. John Camm et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: An update of the 2010 ESC Guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association. *Eur Heart J.* (2012) 33(21): 2719-2747, doi:10.1093/eurheartj/ehs25, Fig. 1].[27]

SOURCES OF AFIB-RELATED GENDER DIFFERENCES

While not all of the sources of afib differences between men and women are known, researchers have found some very specific afib-related differences. For example, blood pressure (BP) is strongly associated with afib in women, and systolic BP is a better predictor in women than diastolic BP.[14]

continued on page 36

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Gender Matters

Continued from page 35

These differences between men and women with afib may be based in physiology, vascular biology, genetics, hormones, or thromboembolic factors. Certainly, menstrual cycles and hormones play a role in women.[6] Biomarkers for inflammation, such as high-sensitivity C-reactive protein, soluble intercellular adhesion molecule-1, and fibrinogen, have been associated with afib in women with a history of heart disease.[15] Women also live longer than men, placing them in the susceptible age range for afib for a longer amount of time.[16]

Social and psychological differences between men and women also relate to afib. For example, we know that cardiovascular events are more common among women who have high-stress jobs.[17] Although heavy alcohol consumption is associated with higher risk of afib among men, there is no such association in women.[18]

Another critical difference is communication. Women communicate differently than men, and understanding those differences can go a long way to helping your afib patients. For ideas of ways to better talk with afib patients, especially women, see the sidebar "Improving Communication with Afib Patients."

RATE AND RHYTHM TREATMENT DIFFERENCES FOR WOMEN WITH AFIB

To control arrhythmia, medications are typically prescribed. Other treatments include catheter ablation and surgical ablation procedures. But there are differences in treatment, too.

Research shows that women are prescribed beta blockers and digoxin (rate control drugs) more often, whereas men are more often prescribed class I or class III anti-arrhythmic drugs (rhythm control drugs).[13]

What are the implications of these treatment differences? Women may be left in afib longer without treatment because the condition may not be viewed as worthy of treatment in women. Or women may just be left on rate control, which doesn't treat the condition or the symptoms, some of which may be inaccurately attributed to aging instead of afib. For many, rate control leads to a lower quality of life as these medications may leave them fatigued and even "in a fog."

What's absolutely tragic: being left on rate control long term, and in afib, may allow fibrosis to continue to build in their hearts, increasing their stroke risk. While we don't know what causes women's greater stroke risk, perhaps delayed treatment or less aggressive treatment in women plays a role.

ANTICOAGULATION AND BLEEDING DIFFERENCES

There are differences related to anticoagulants, too. Women, especially those 75 years or older, have a higher risk of stroke than men, regardless of their use of warfarin.[19] Women's adherence to anticoagulants isn't an issue, either. While some research shows that women are less adherent to medications for some chronic conditions, that doesn't appear to be the case for warfarin adherence. When it comes to warfarin, men have been found to have lower warfarin adherence rates than women.[20] Women are also at a higher risk than men for afib-related thromboembolism when off of warfarin.[21]

Another significant difference: women on warfarin spend more time outside of the therapeutic range than men. In a recently published study, on average, women were outside of the therapeutic range 40 percent of the time compared to men's 37 percent. Women also spent more time below the therapeutic range, putting them at more risk for ischemic stroke, at 29 percent compared to 26 percent in men.[22]

Patient self-monitoring of warfarin should help women stay in therapeutic range. However, one study found more men than women (56 percent vs. 44 percent) were referred for self-monitoring, leading to the question of whether women are referred for self-monitoring less often.[23]

One of the most frustrating aspects of this issue has been discovering that women are sometimes told to "just take aspirin because you're a $CHADS_2$ score of 1, with just one risk factor, so you are at low risk," when in fact the latest guidelines (Figure 4) indicate that having a single risk factor beyond afib increases a woman's stroke risk and that she should consider an anticoagulant.

Even more frustrating is when women 75 or over are automatically considered to be a "fall risk," regardless of their physical condition, and thus are not considered for an anticoagulant and then often go on to have a stroke. Warfarin is superior to aspirin in reducing the risk of stroke, especially in women, as it reduces the risk by 84 percent in them compared to 60 percent in men.[6] However, women over 75 years old were 54 percent less likely to receive warfarin and twice as likely to receive aspirin. Aspirin is associated with a significantly decreased stroke

Figure 5: StopAfib.org (http://bit.ly/epStart) contains many resources for healthcare providers and patients. The site includes a doctor finder, afib-related news and videos, a newsletter, and a discussion forum to connect patients.

Figure 6: By handing out StopAfib.org patient cards, healthcare providers can connect patients to a wealth of information and sources of support. Contact us at http://www.stopafib.org/contact.cfm to receive some patient cards.

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risk in men (44 percent), but the risk reduction in women is about half of that (23 percent).[12]

While aspirin is currently part of the U.S. afib guidelines, many of the other afib guidelines have withdrawn aspirin for prevention of afib-related strokes.

But what may be even better news for women is that stroke reduction results of the newer novel oral anticoagulants are even stronger than warfarin.

When looking to prescribe anticoagulant medication to women, additional risk of bleeding shouldn't be a concern. Studies have shown bleeding risk for men and women to be about the same.[20] This is another one of those perceptions that needs to change.

OTHER TREATMENT DIFFERENCES

Some other differences in afib treatment for women include:

- Electrical cardioversion is used significantly less frequently in women.[24]
- Procedures are usually recommended only after more antiarrhythmic drugs in women than in men.[6]
- Despite similar outcomes, women with afib are referred for catheter ablation less often or later than men.[6]
- Women are over-represented in AV node ablation and under-represented in catheter ablation, according to data from a small, private practice study.[25]

We need more studies to determine if the greater stroke risk for women is due to physiological differences or treatment differences, or both. In the meantime, by being aware of these differences in afib between men and women, medical professionals can design a safer, more effective, and personalized approach to managing afib.

Electrophysiology professionals, cardiologists, and GPs can have a huge positive impact by recognizing these differences in diagnosing and treating atrial fibrillation in women. Wouldn't you want that kind of care for your mom, grandmother, sister, daughter, or spouse? ■

IMPROVING COMMUNICATION WITH AFIB PATIENTS

Women communicate differently from men. Doctors may not comprehend how much afib symptoms are affecting women's quality of life. Often, doctors' instructions may not have been understood. Or, perhaps, the significance of the drug wasn't completely conveyed or comprehended. Remember, the more vague medication instructions are, or the more difficult it is to incorporate with other meds, the worse adherence will be. Here are a few tips for improving communications with afib patients:

- Put yourself in the patient's heart.
- Slow it down and speak clearly and simply. Especially when afib patients are initially diagnosed, they may not be able to process information as quickly.
- Cut down on medical jargon. Don't assume patients understand the jargon, as they probably don't.
- Don't just ask "How are you doing?" Instead ask: "What can't you do now that you could do before afib?"
- Listen for what is said, and what is not said, and ask clarifying questions. Some women communicate with emotion rather than facts, so you may have to listen closely to distill symptoms and side effects from what is said.
- Define options. When describing potential treatment options, be as descriptive as possible and assess whether the patient understands what you said. Yes, I know you have limited time, but you can refer them to StopAfib.org to learn more.
- Be a team. Explore treatment options together. Work with patients to understand their lifestyle and find the best type of treatment to fit it.

This is an area that I want to greatly expand upon to help you eliminate some of your frustrations in dealing with complex and often difficult afib patients. I am creating an email newsletter to share tips to help you engage and empower your patients. If you're interested, just give me your email address at http://bit.ly/engagepatients. Wouldn't it be nice to enjoy treating your afib patients!

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Kamran A. Rizvi, MD, FHRS

Dr. Kamran Rizvi’s undergraduate studies took place at Tulane University in New Orleans. His medical training took place at the University of Chicago Pritzker School Of Medicine.

Dr. Rizvi's initial training was in Internal Medicine with a highly competitive Fellowship in Cardiology at UT-Southwestern Medical School in Dallas. He then completed two years of specialized Cardiac Electrophysiology training at the University of Utah focusing on atrial fibrillation ablation, working with Dr. Nassir Marrouche.

Dr. Rizvi has published and presented research on topics such as atrial fibrillation and exercise capacity.

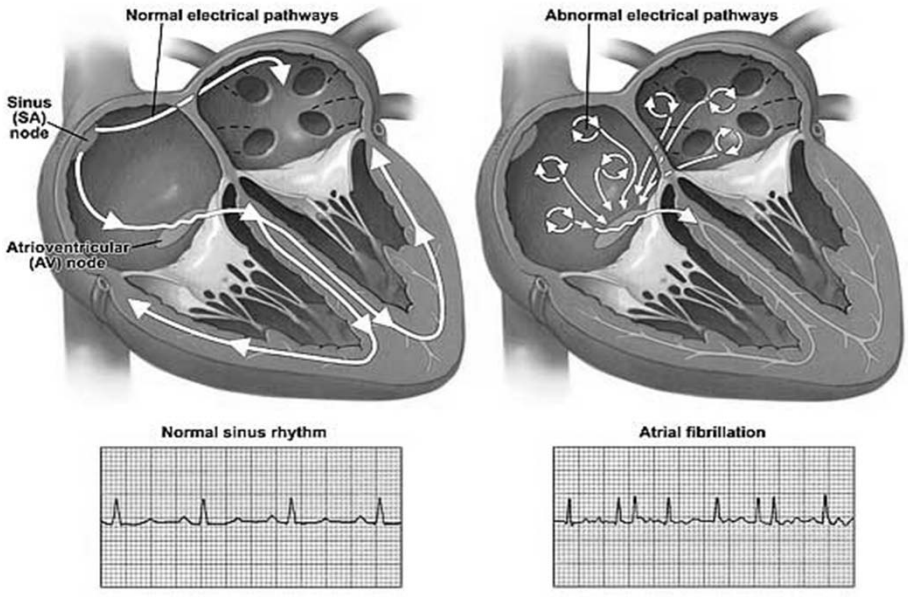
He is board certified in Internal Medicine, Cardiology and Cardiac Electrophysiology.

RADIOFREQUENCY ABLATION FOR ATRIAL FIBRILLATION

Kamran A. Rizvi, MD, FHRS
Board Certified Cardiac Electrophysiologist

ARRHYTHMIA MANAGEMENT
THE HEART RHYTHM SPECIALISTS

The Heart Hospital
Baylor Plano
Joint ownership with physicians

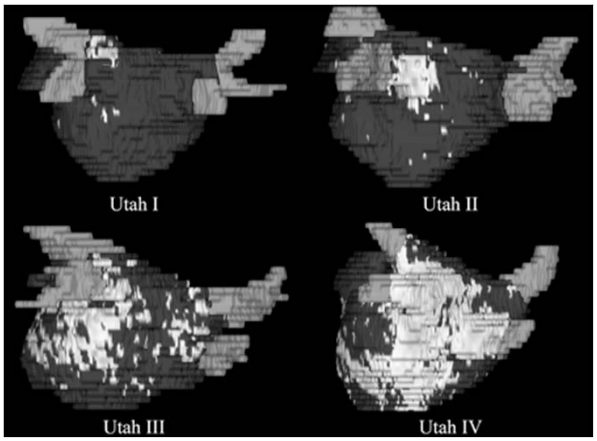


General Strategies for A.fib Control (simplified)

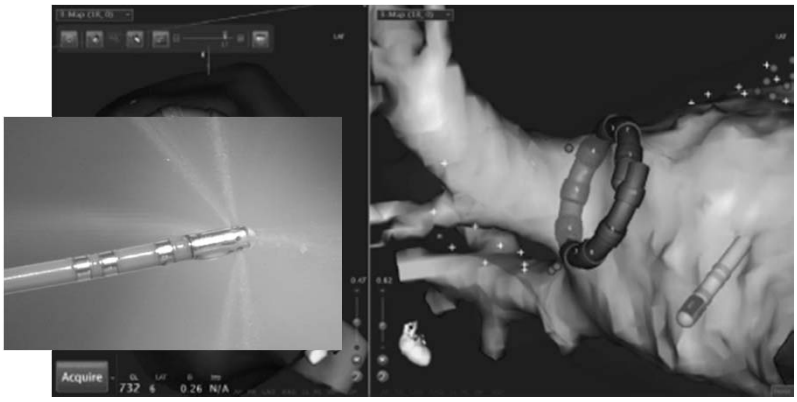
- Plan “A”
  - Medical therapy/Lifestyle Modifications
- Plan “B”
  - Atrial fibrillation Ablation
    - Radiofrequency Energy
    - Cryo Ablation
- Plan “C”
  - Pacemaker/AV Nodal Ablation
    - Typically reserved for patients with chronic a.fib and elevated heart rates
    - Can be preferred plan in some patients
- Blood thinners
  - All AFib strategies require stroke risk management

“Stages” of A.fib

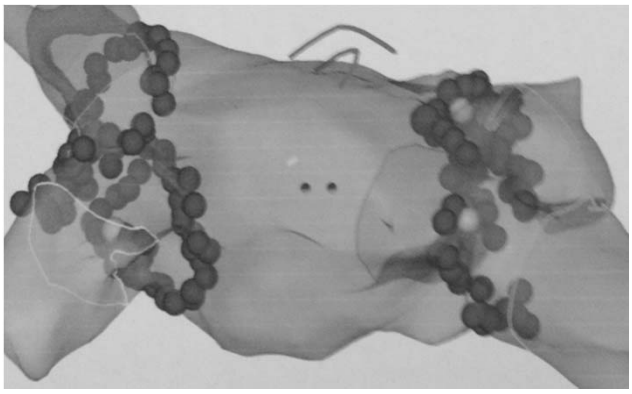
- Intermittent (paroxysmal) to persistent to permanent
- Correlates with microscopic changes at the tissue level



RF AFIB ABLATION



Typical Ablation for A.fib with Radiofrequency energy



Red circles represent areas where heat energy was applied to isolate the areas that tend to trigger A.fib

Pre Ablation Testing

- Trans-esophageal echocardiogram (TEE) required pre-procedure in most cases
  - Rules out a pre-existing blood clot in the atrium
- Cardiac CT Scan or Cardiac MRI
  - Defines the anatomy of the left atrium and pulmonary veins
    - Rules out anomalies
    - Can help create 3D geometry of left atrium to aid ablation

Afib Ablation Procedure Details 1

- Nothing to eat the night prior
- May need to stop heart related mediations prior
  - Anti-Arrhythmic Medications
    - (i.e. betapace, amiodarone, flecanide)
    - These medicines typically should “Wash out” prior to the ablation
  - Blood Thinners
    - Ask your doctor his preference regarding blood thinners and when/if to stop them
    - May need to temporarily be on IV blood thinners

Afib Ablation Procedure Details 2

- Typically takes 3 hours (2-4 hour range)
- General anesthesia used in majority of cases
- Multiple catheters are placed in the veins in the groin
  - Ablation catheter, mapping catheter, ultrasound catheter
- Post procedure all catheters are removed
- Bedrest for 4-6 hours afterwards
- Typically an overnight stay
  - Occasionally additional nights are required

Afib Ablation Results

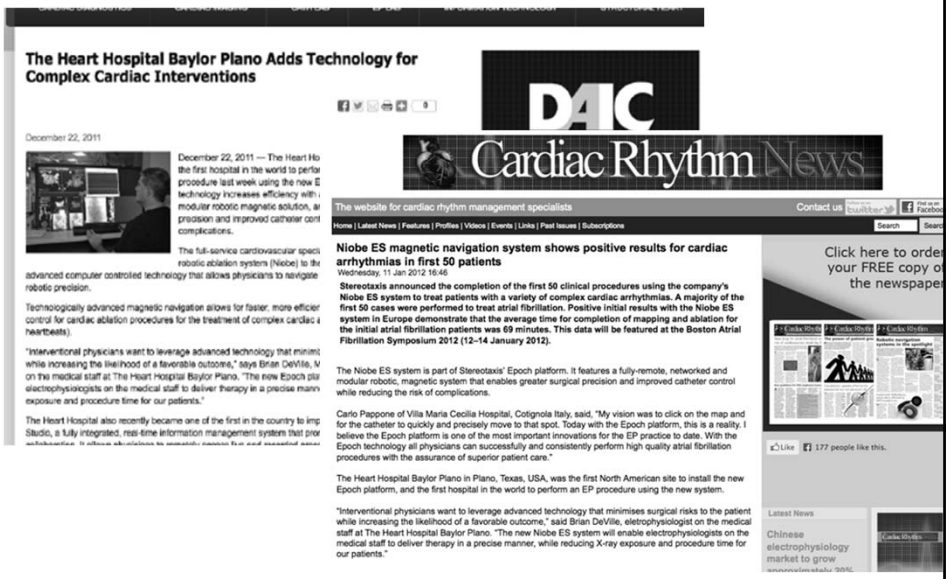
Single procedure success rate 70-80% for intermittent atrial fibrillation

- Major complication rate approximately 1-2%
  - Total complication rate 3-5% (mainly access site related)
  - Bleeding, hematoma (small collection of blood underneath the skin), groin related complications, effusion (fluid around the heart)
  - Rare (<1%): stroke, heart attack, atrio-esophageal fistula (abnormal connection between heart and food tube)
- Re-do ablation required 25% of the time

Afib Research at The Heart Hospital Baylor Plano

- Physicians at THHBP are at the forefront of research and clinical development.
  - Major scientific journals
  - International medical meetings.
- Nationally recognized researchers
  - Large dollar grants from government agencies that support novel medical research.
  - National Institutes of Health
  - American Heart Association

Remote Navigation – First in the world!



The Heart Hospital Baylor Plano Adds Technology for Complex Cardiac Interventions

December 22, 2011

December 22, 2011 — The Heart Ho
the first hospital in the world to perfo
procedure last week using the new E
technology increases efficiency with
modular robotic magnetic solution, a
precision and improved catheter cont
complications.

The full-service cardiovascular speci
robotic ablation system (Niobe) to the
advanced computer controlled technology that allows physicians to navigate
robotic precision.

Technologically advanced magnetic navigation allows for faster, more efficie
control for cardiac ablation procedures for the treatment of complex cardiac
heartbeats).

"Interventional physicians want to leverage advanced technology that minim
while increasing the likelihood of a favorable outcome," says Brian DeVille, M
on the medical staff at The Heart Hospital Baylor Plano. "The new Epoch pla
electrophysiologists on the medical staff to deliver therapy in a precise mann
exposure and procedure time for our patients."

The Heart Hospital also recently became one of the first in the country to imp
Studio, a fully integrated, real-time information management system that pro

DAIC

Cardiac Rhythm News

The website for cardiac rhythm management specialists

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Niobe ES magnetic navigation system shows positive results for cardiac arrhythmias in first 50 patients

Wednesday, 11 Jan 2012 16:46

Stereotaxis announced the completion of the first 50 clinical procedures using the company's Niobe ES system to treat patients with a variety of complex cardiac arrhythmias. A majority of the first 50 cases were performed to treat atrial fibrillation. Positive initial results with the Niobe ES system in Europe demonstrate that the average time for completion of mapping and ablation for the initial atrial fibrillation patients was 69 minutes. This data will be featured at the Boston Atrial Fibrillation Symposium 2012 (12–14 January 2012).

The Niobe ES system is part of Stereotaxis' Epoch platform. It features a fully-remote, networked and modular robotic, magnetic system that enables greater surgical precision and improved catheter control while reducing the risk of complications.

Carlo Pappone of Villa Maria Cecilia Hospital, Cotignola Italy, said, "My vision was to click on the map and for the catheter to quickly and precisely move to that spot. Today with the Epoch platform, this is a reality. I believe the Epoch platform is one of the most important innovations for the EP practice to date. With the Epoch technology all physicians can successfully and consistently perform high quality atrial fibrillation procedures with the assurance of superior patient care."

The Heart Hospital Baylor Plano in Plano, Texas, USA, was the first North American site to install the new Epoch platform, and the first hospital in the world to perform an EP procedure using the new system.

"Interventional physicians want to leverage advanced technology that minimises surgical risks to the patient while increasing the likelihood of a favorable outcome," said Brian DeVille, eletrophysiologist on the medical staff at The Heart Hospital Baylor Plano. "The new Niobe ES system will enable electrophysiologists on the medical staff to deliver therapy in a precise manner, while reducing X-ray exposure and procedure time for our patients."

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Like 177 people like this.

Latest News

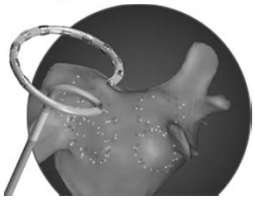
Chinese electrophysiology market to grow

A Fib Research at THHBP

- CABANA Trial
  - Large NIH funded study

- ACP Trial
  - Appendage occlusion

- reMARQable Study
  - Circular ablation



The Heart Hospital Baylor Plano
Joint ownership with physicians

Among others…..

Thank you for your attention!

Kamran A. Rizvi, MD FHRS

Arrhythmia Management
1820 Preston Park Suite 1450
Plano, TX 75093
Denton and McKinney Satellite Offices
Office Number: 972-964-0363

The Heart Hospital Baylor Plano
Joint ownership with physicians

Arrhythmia Management
The Heart Rhythm Specialists

Jay O. Franklin, MD, FACC, FHRS

A clinical cardiac electrophysiologist practicing with Cardiology Consultants of Texas in Dallas at Baylor since 1988, Dr. Franklin's primary interests include catheter ablation of arrhythmias and device management of heart rhythm abnormalities. Dr. Franklin sees patients at CCT's Dallas clinic at the Baylor University Medical Center clinic and at the Waxahachie clinic.

Dr. Franklin is Board Certified in Internal Medicine, Cardiovascular Disease and Cardiac Electrophysiology. He is currently conducting several clinical research trials and has published a number of articles that have appeared in widely respected journals. He is also involved in important research projects to advance medical knowledge of cardiology. He has been named as a "Texas Super Doctor" by *Texas Monthly* magazine. Dr. Franklin was recently named by Patients' Choice Award 2012 as "Best of the Best". Dr. Franklin has received this distinction for five years in a row. He was also named a **Super Doctor for 2010** by Texas Monthly Magazine.

Dr. Franklin received his medical degree from Texas A&M University College of Medicine, College Station and Temple where he also served his internship in Internal Medicine. He fulfilled his residency and chief residency in Internal Medicine at the University of Louisville in Kentucky. He then completed a fellowship in Cardiovascular Medicine at the University of Missouri in Columbia and a fellowship in Cardiac Electrophysiology at the Cardiovascular Research Institute, University of California in San Francisco. Dr. Franklin is a Fellow of American College of Cardiology and the North American Society of Pacing and Electrophysiology.

Cryoballoon Ablation

Jay Olen Franklin, MD, FACC, FHRS
Clinical Cardiac Electrophysiology
Cardiology Consultants of Texas/HTPN
Baylor Heart and Vascular Hospital

1

Atrial Fibrillation Treatment Goals and Options

- **Treatment Goals:**
  - Restoration and maintenance of sinus rhythm:
    - Reduce risk of blood clots and stroke
    - Alleviate disabling symptoms of rapid and inefficient heart beats
- **Treatment Options:**
  - Heart rhythm drugs
  - Surgery (Maze procedure)
  - Catheter ablation (correcting rhythms with invasive procedures)
    - Ablate and pace
    - AV node modification
    - Pulmonary Vein Isolation: RF ablation or cryoablation
  - Devices (pacemakers)
  - Cardioversion (shocks to restore normal rhythm)

2

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

Patients that continue to have symptomatic atrial fibrillation should be considered for atrial fibrillation ablation (pulmonary vein isolation)

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

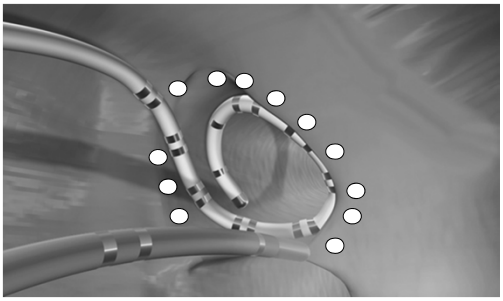
Wann LS. J Am Coll Cardiol. 2011 Jan 11;57(2):223-42.2011.

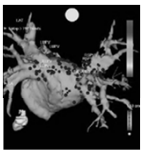
* Knight B. HRS Practical Rate and Rhythm Management of Atrial Fibrillation. Updated January 2010. http://www.hrsonline.org/Policy/ClinicalGuidelines/upload/2010_rate-rhythm_guide1.pdf

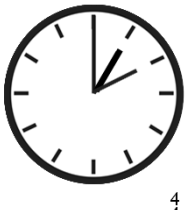
3

RF Catheter Ablation

- Patients are structurally varied
- Beating heart makes maintaining position difficult
- Catheter pressure varies with position in heart
- Technically challenging and slow to perform
- Need full thickness heating for permanent effect
- Successful procedure requires overlapping scars



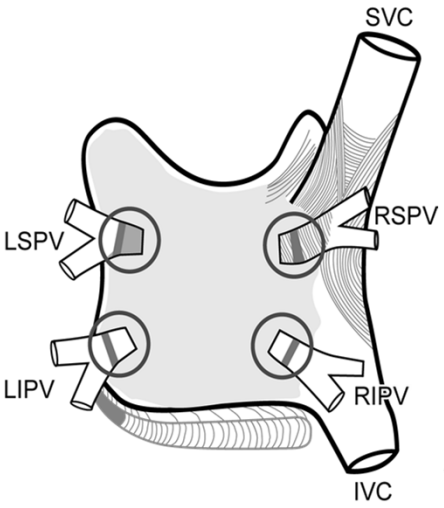




4
4

Pulmonary Vein Isolation (PVI) is the Cornerstone of AF Ablation . . .

2012 HRS (Heart Rhythm Society) Consensus Statement



"Ablation strategies which target the PVs are the cornerstone for most AF ablation procedures."

Majority of AF ablation procedures target PV isolation

Calkins H, et al. *Heart Rhythm*. April 2012;9(4):632-696.

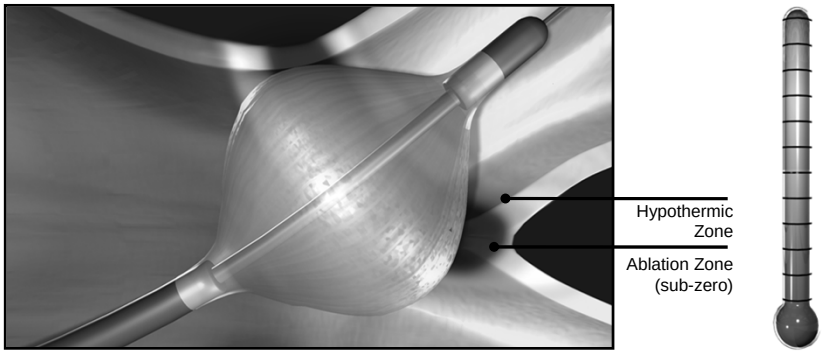
. . . and Cryoballoon Ablation Now a Standard Treatment for AF Ablation

2012 HRS Consensus Statement

"… point-by-point RF energy and Cryoballoon ablation are the two standard ablation systems used for catheter ablation of AF today . . ."

Calkins H, et al. *Heart Rhythm*. April 2012;9(4):632-696.

Properties of Cryoablation

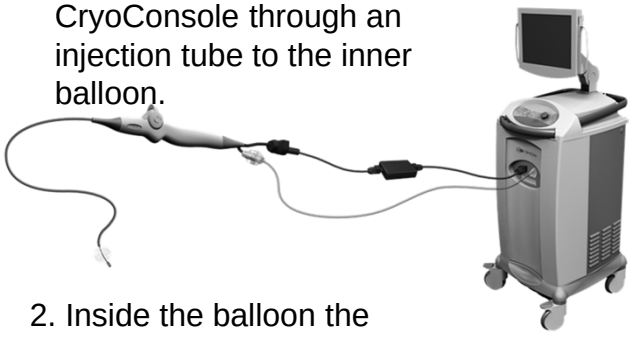


- Ablates at the point of balloon contact
- Freezes tissue to create permanent scar
- Freezing to tissue holds catheter in place in heart

7

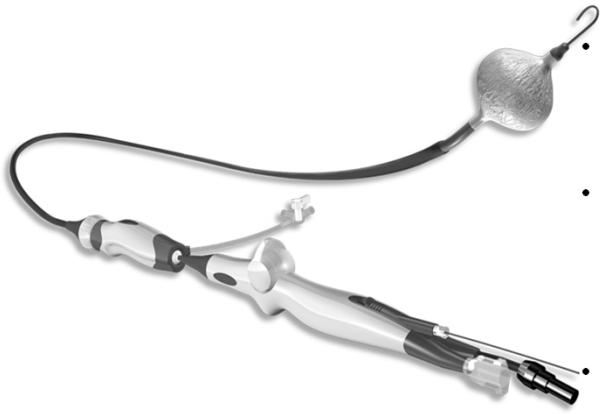
How the Arctic Front® Cardiac CryoAblation System Works

1. Liquid N_2O (nitrous oxide) is delivered from the CryoConsole through an injection tube to the inner balloon.
2. Inside the balloon the liquid N_2O vaporizes and absorbs heat from the surrounding tissue.
3. The vapor is returned to the console through a lumen (tube) maintained under vacuum.
4. The CryoConsole controls safe delivery of N_2O to the catheter and return of the vapor. Numerous safety systems mitigate potential hazards.



8

Arctic Front® Cryoballoon Catheter



- Available in 23 mm (1 inch) and 28 mm (1 1/8 inch) for different patient sizes
- FlexCath® Steerable Sheath (delivery tube or catheter) helps position Cryoballoon at each of the four pulmonary veins
- Balloon's shape eliminates the need for point-by-point ablation, and complex mapping/navigation

9 ®

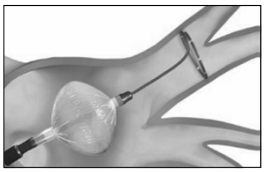
Achieve™ Mapping Catheter (Lasso Catheter)

- Achieve is an intracardiac (inside the heart) electrophysiology diagnostic catheter (fancy mapping wire used with the Cryoballoon)
- Available in 15 mm and 20 mm loop diameters

10

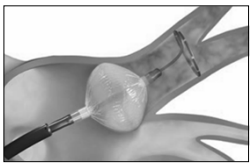
How Arctic Front® Balloon Catheter and Achieve™ Work

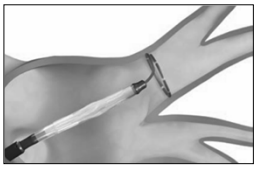
1. Access targeted vein



2. Inflate and position

3. Occlude and freeze/ ablate

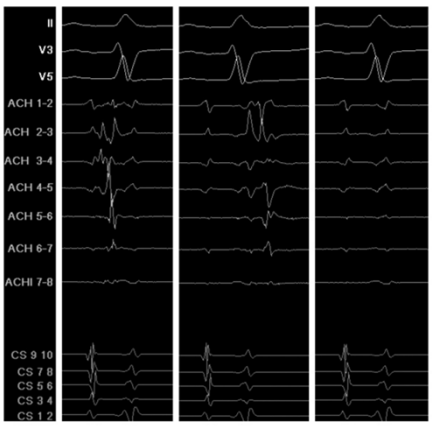




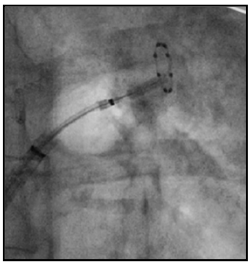
4. Assess PVI

11

Assessment of Real-Time PV Isolation



- Achieve™ mapping catheter allows for real-time assessment of PV isolation during cryoablation with Arctic Front®



Arctic Front is positioned against the LIPV, with Achieve positioned to assess PV isolation

Images: Courtesy of Dr. Schwagten, ZNA Middelheim, Belgium (above) and Dr. Vogt, Herz- und Diabeteszentrum NRW, Germany (right)

12

Cryoballoon Freezing a Pulmonary Vein

Video Presentation

13

Europe and STOP AF Trials Overall Conclusions

Cryoablation with the Arctic Front® System:

1. Effectively treats PAF that fails drug therapy
2. Is a safe procedure
3. Is a straightforward, efficient procedure
4. Treatment success improves with physician training and experience
5. Has shorter procedure times, compared to conventional RF ablation procedures (European Trials)

14

Why Cryoballoon?

- Cryoballoon
  - Faster
  - Less risky (3.1% complications)
  - As good or better than RF
  - Easier for patient and physician
  - One transeptal puncture
  - No 3D mapping
- Radiofrequency
  - Tedious and slow (3-6 hours)
  - Higher risk (6% complications)
  - Variable success
  - Technically challenging
  - Two transeptal punctures
  - Requires 3D mapping

15

Cryoballoon Ablation What to expect before:

- Anticoagulation (blood thinners)
- Heart rhythm medications
- CT scan or MRI scan of heart (left atrium)
- TEE (transesophageal echocardiogram) immediately prior to ablation
- Echocardiogram and stress testing

16

Cryoballoon Ablation
What to expect during/after:

- Several hour procedure
- General anesthesia
- Overnight stay in hospital on monitor
- Resumption of blood thinner
- Resumption of heart rhythm meds
- Occasional recurrence of PAF in first one to three months after procedure
- 20% need for second procedure
- 70% chance of long-term prevention of PAF

17

Catheter Ablation Complications

- Bleeding, bruising, blood clots, stroke
- Phrenic Nerve Damage – injury to nerve the controls breathing/diaphragm
  - More common with cryoballoon, usually resolves
- Pulmonary vein stenosis (narrowing)
  - Less common with cryoballoon
  - May require stenting
- Esophageal injury
  - Less common with cryoballoon
  - May be fatal

18

Cryoballoon Ablation Recovery

- Up and ambulatory evening of procedure
- Resumption of anticoagulation (blood thinners)
- Resumption of heart rhythm medications
- Rapid return to normal activities
- Limits on bending, squatting, lifting for a week
- Return to work 1-7 days after procedure

19

Why Not Cryoballoon?

- Persistent or Permanent AF?
- Patients that need more than pulmonary vein isolation (linear ablation scars, atrial flutter ablation, etc.)
- Previous cryoballoon ablation

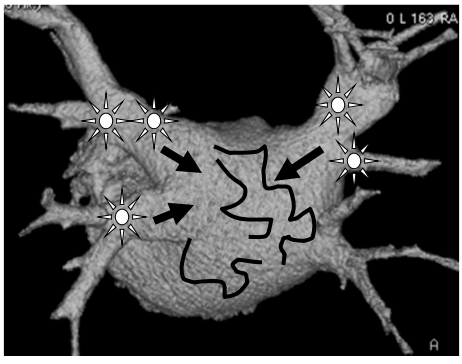
20

New Procedures to Treat AF

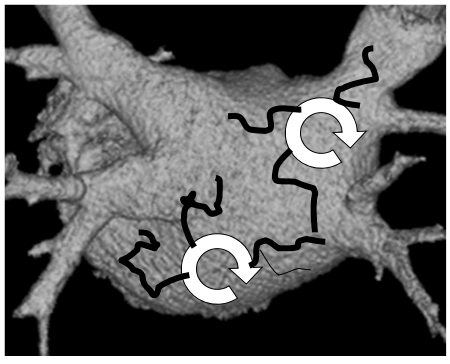
Robert C. Kowal, MD/PhD
Baylor Heart and Vascular Hospital
VP and Medical Director, Best Care and
Clinical Integration, Baylor Quality Alliance

Ablation Targets in AF

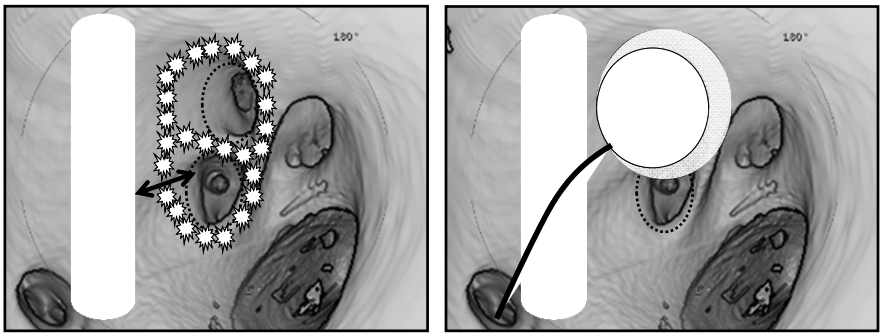
Paroxysmal AF



Persistent AF

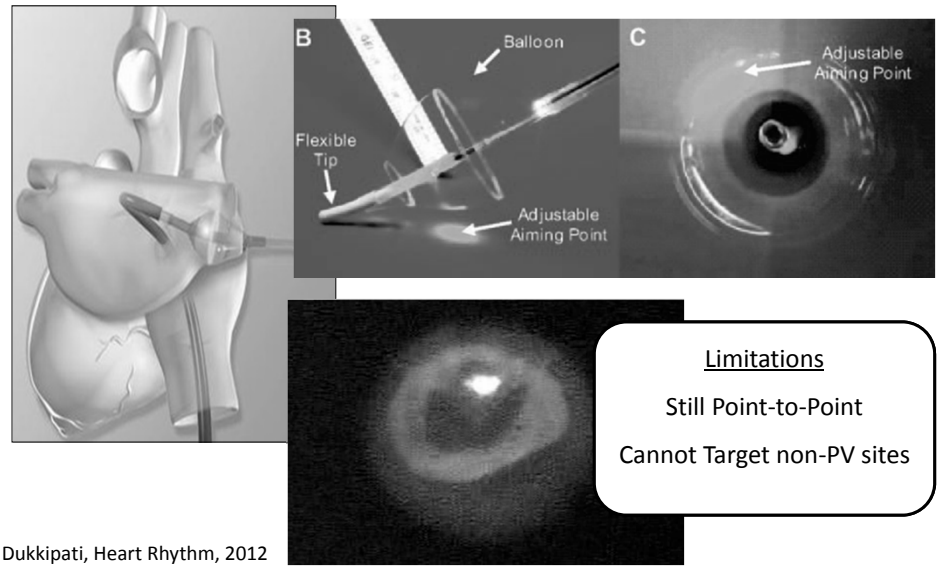


Current Approaches to Pulmonary Vein Isolation (PVI)



Limitation	Point-by-point RF	Cryoballoon
Gaps in ablation spots	+++	+/-
"See" where ablating	-	-
Ablate other AF targets	+	-

Laser Balloon: An Alternative



Limitations

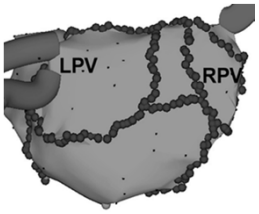
Still Point-to-Point

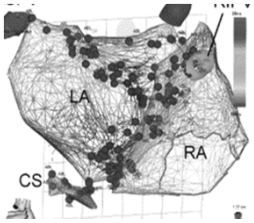
Cannot Target non-PV sites

Dukkipati, Heart Rhythm, 2012

Persistent/Longstanding AFF

Strategies with Traditional RF

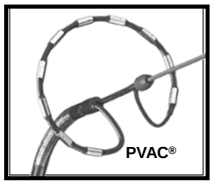


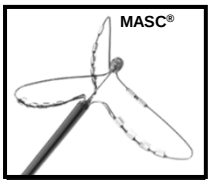


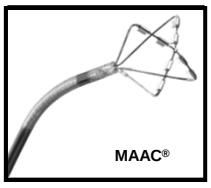
- Linear lesions are difficult and often incomplete with gaps.
- CFAE (AF sites throughout the atria) are poorly defined.
- Complications increase with increasing amount of RF.
- High incidence of LA flutter, short circuits in the atria formed when gaps are present between ablation sites.

Specialized RF Catheters

Cycled, Phased RF





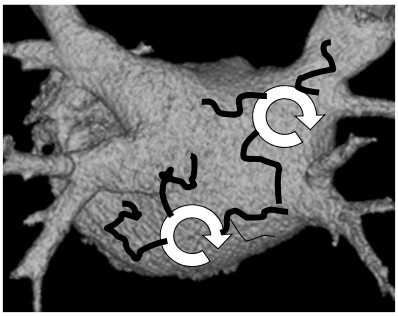


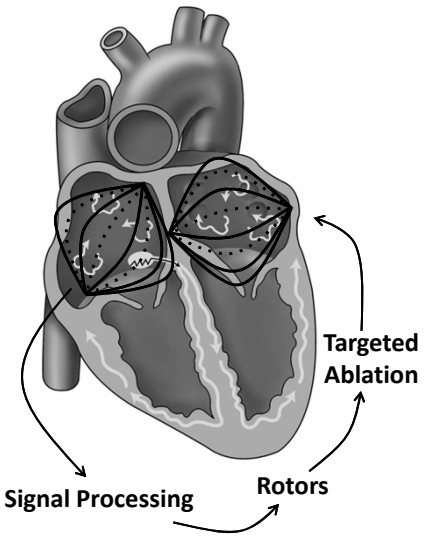
- Combined tool set to target variety of sites.
- Designed to create circular, linear and regional lesions.
- 6-month results: 67.4% for persistent AF.
- FDA requiring 2nd safety study due to silent brain lesions seen following ablation procedures.

Limitation

No ability to map AF sites away from the pulmonary veins.

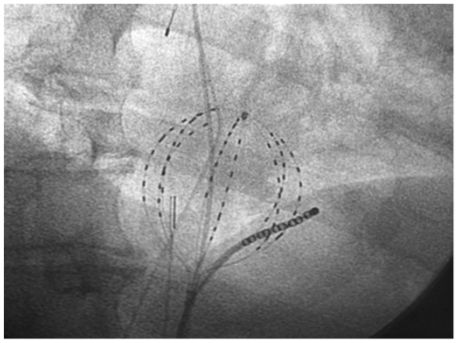
Specific Mapping of AF

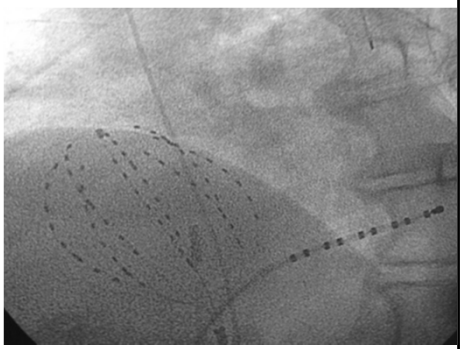




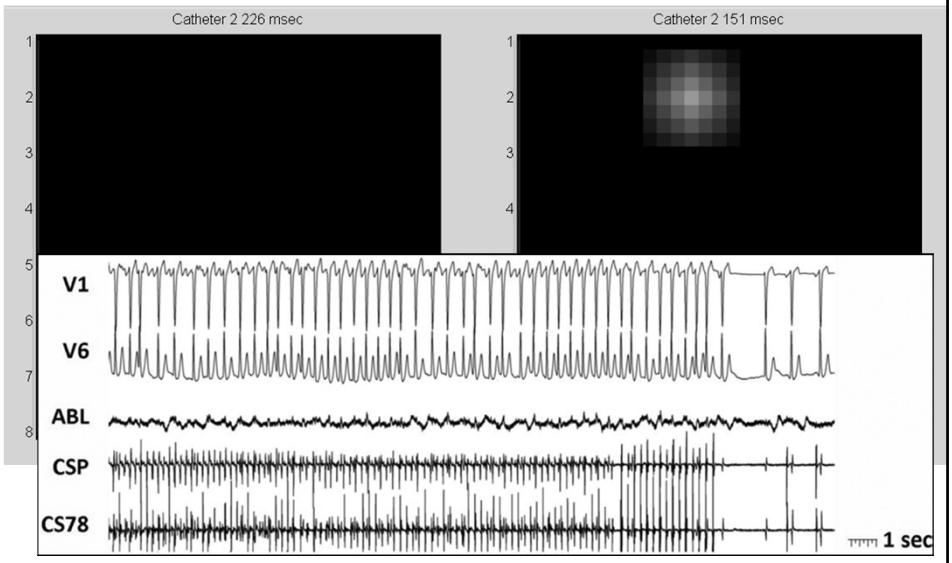
FIRM Mapping: Right Atrium

Focal Impulse and Rotor Modulation



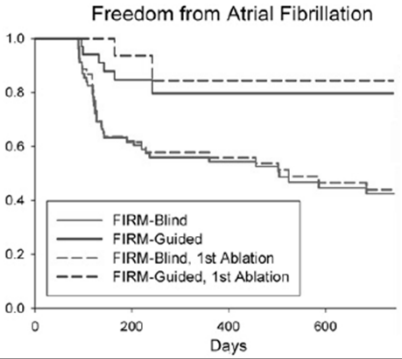


52 yo with PAF having undergone 3 prior PVI procedures



CONFIRM Trial

- 92 subjects with AF
- (66% - 81% persistent)
- Pulmonary Vein Isolation vs. FIRM + Pulmonary Vein Isolation
- Non-randomized



Limitations

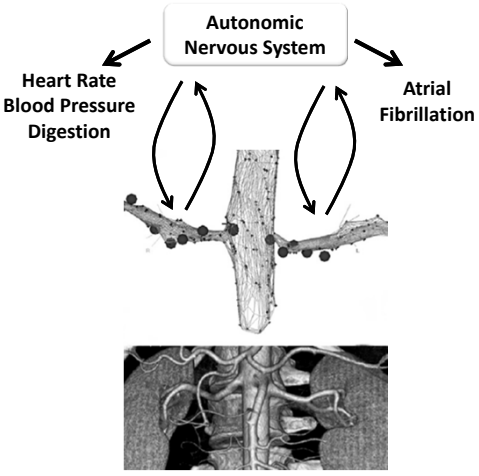
Current Basket Technology Poor

No randomized data

Narayan, JACC. 2012

Are We Treating the Right Organ

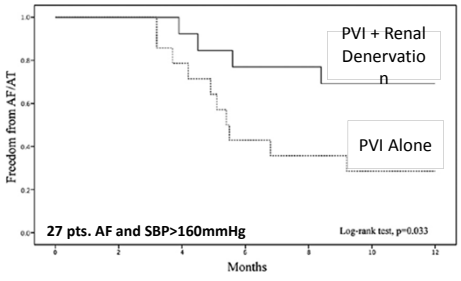
Combining Renal Denervation with AF Ablation

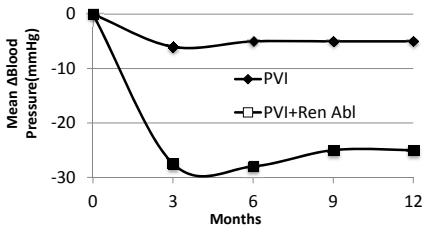


- 27 patient with AF (18 persistent)
- SBP > 160 mmHg on 3 medications
- Compared traditional pulmonary vein isolation (PVI) to PVI plus Renal Denervation.

Pokusholav, JACC. 2012

Should We Target More Than the Heart

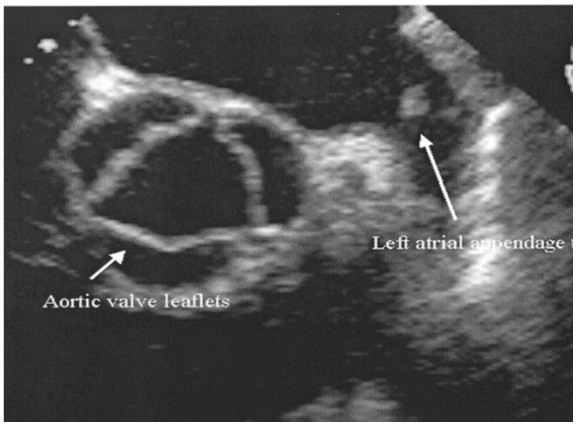


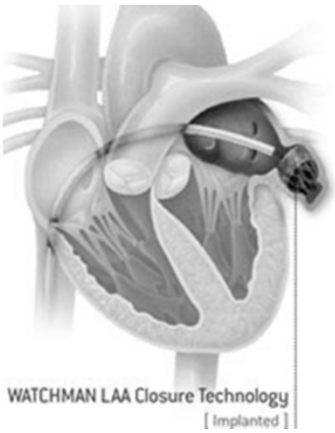


Baylor Heart and Vascular is currently enrolling in H-FIB and will be adding new trials that combine AF ablation with renal denervation.

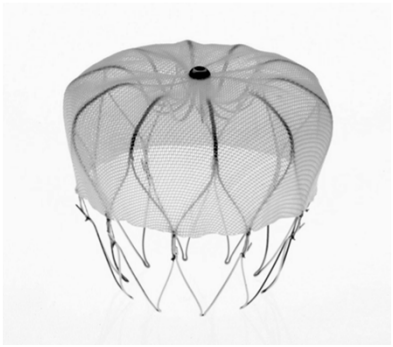
Pokusholav, JACC. 2012

Origin of Stoke in AF



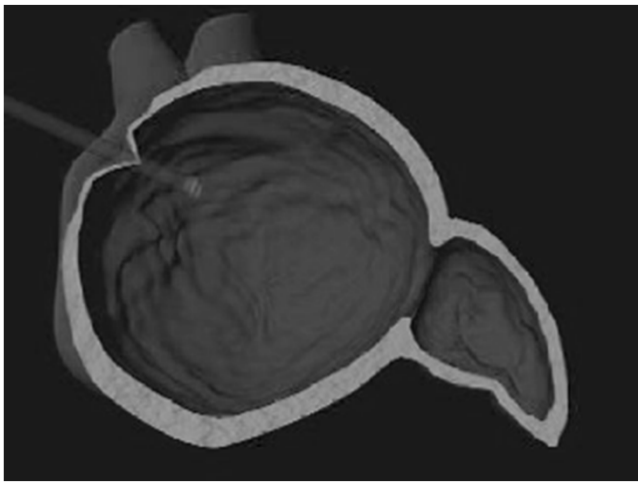


Left Atrial Occlusion Device

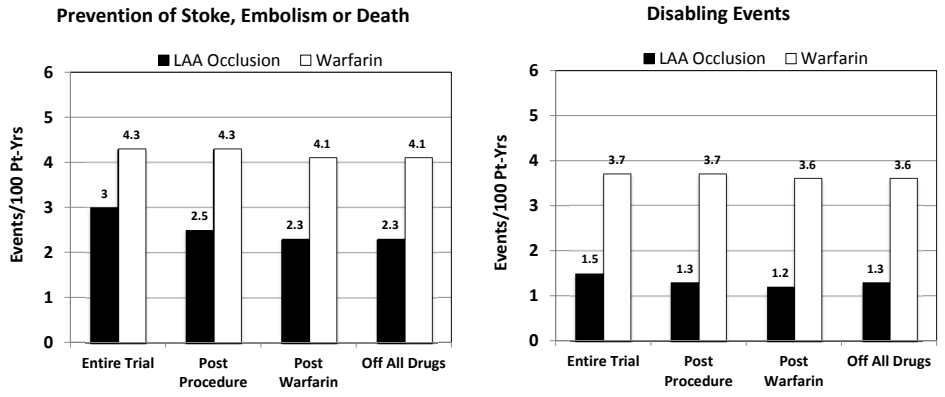


Nitinol frame with a fabric cap
- Available in 5 sizes (21 – 33mm)
- Fixation barbs around device perimeter engage LAA tissue
- Contour shape accommodates most LAA anatomy

Implantation of the Watchman Device



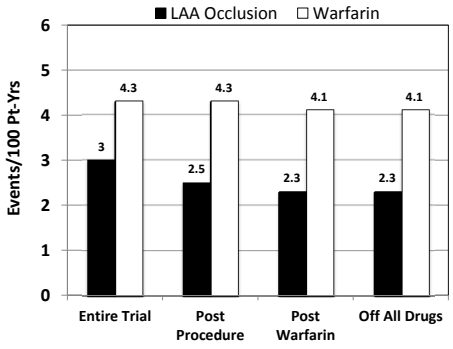
Results with Watchman



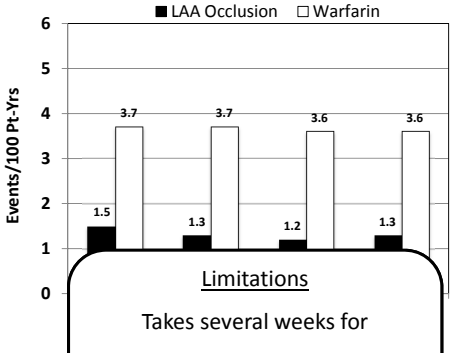
Reddy, Circulation, 2013

Results with Watchman

Prevention of Stoke, Embolism or Death



Disabling Events



Limitations

Takes several weeks for appendage to close

Implant Complications

Not yet FDA approved

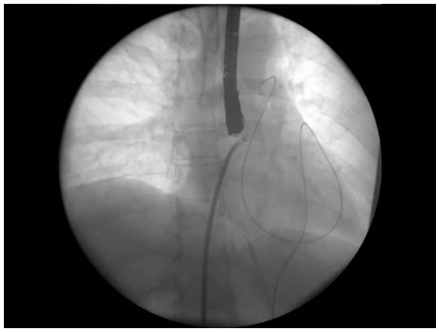
Reddy, Circulation, 2013

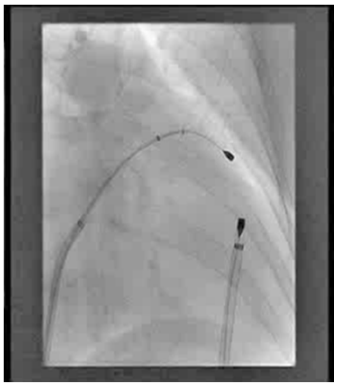
Left Atrial Appendage Occlusion

- Alternative Approaches
  - Minimize hardware
  - Immediate result
  - No need for Oral Anticoagulant Therapy bridging (in theory)

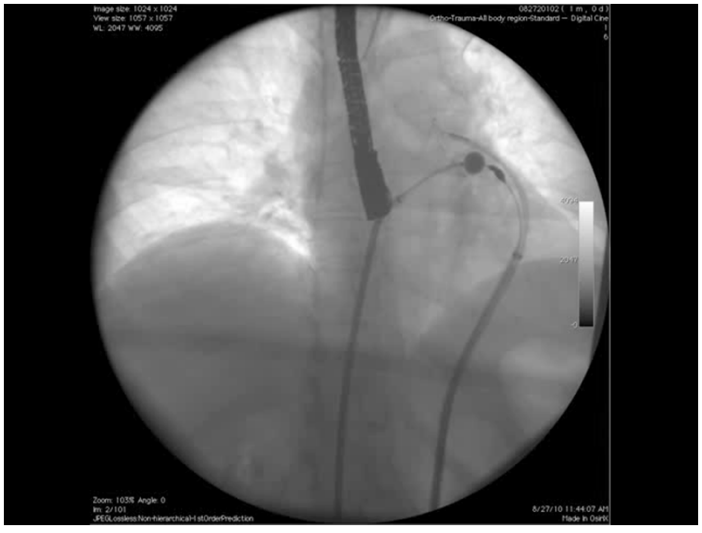
Lariat

LARIAT Left Atrial Appendage Closure

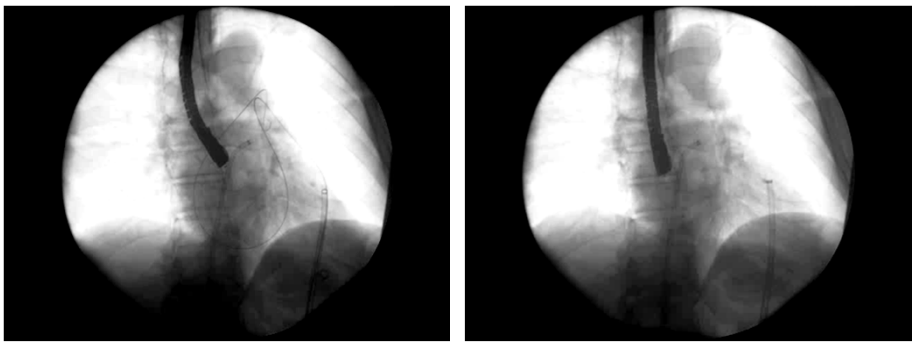




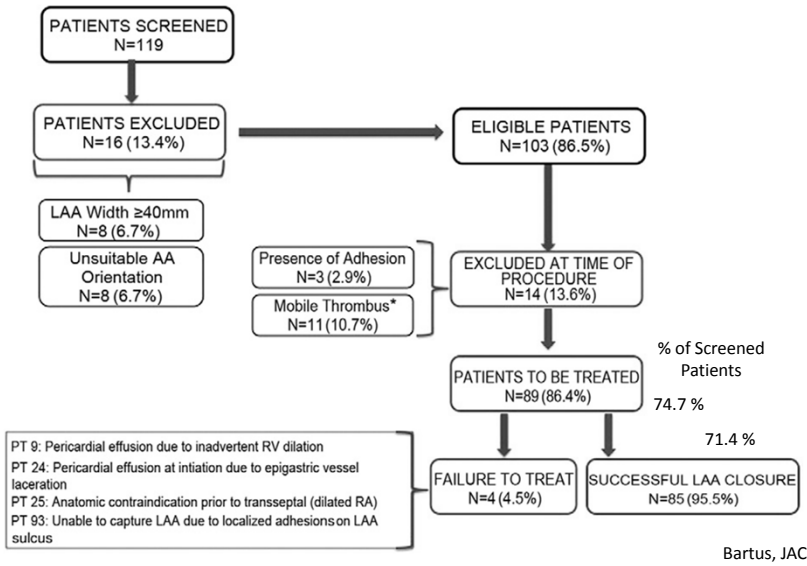
Delivering the Snare



Before/After

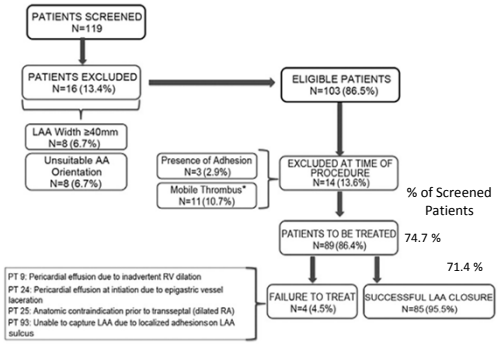


Lariat LAA Closure



Bartus, JACC, 2012

Lariat LAA Closure



Time	Closure or <1mm leak (TEE)
End of procedure (n=85)	82 (96%)
1 day post (n=85)	81 (95%)
30 days (n=85)	81 (95%)
90 days (n=65)	77 (95%)
1 year (n=65)	64 (98%)

Limitations

Complex Skill Set

Pericarditis

Not yet FDA approved

Bartus, JACC, 2012

Who Should Have Left Atrial Closure

Watchman

- Warfarin-eligible patients with 2 stroke risk factors.
- Warfarin ineligible patients with 2 stroke risk factors.
- No comparison with newer blood thinners.
- FDA likely to approve for high-risk warfarin eligible patients.

LARIAT

- No trials vs. warfarin or other anticoagulants.
- Thus far, reserved for those patients at high risk for stroke who cannot take a blood thinning agent.

Summary

- New ablation tools are under development to simplify ablation energy delivery and pinpoint where to ablate; this holds promise for increasing efficacy and limiting complications.
- Left atrial appendage occlusion devices will offer new options to those at high risk for stroke. Stroke prevention with blood thinners will evolve into a “Stroke Prevention Strategy” that could be a medication or device.

William T. Brinkman, MD

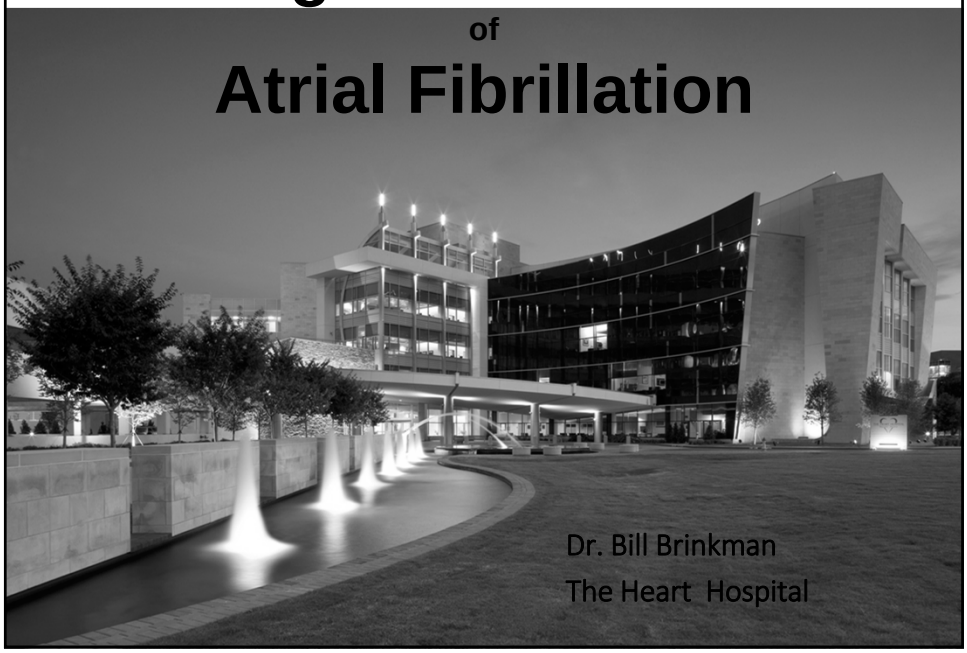
Dr. Brinkman is a board-certified thoracic surgeon. He received his medical degree from Emory University School of Medicine, Atlanta GA; and a general surgery residency at Emory University School of Medicine.

He then completed a cardiothoracic surgery residency at Brigham and Women's Hospital, Boston MA; and a thoracic aortic fellowship at the Hospital at the University of Pennsylvania, PA.

An active researcher, Dr. Brinkman has been an investigator in the Placement of Aortic Transcatheter Value (PARTNER) trial, PARTNER II trial, DISSECTION, and Cardiothoracic Surgical Trials Network (CTSN) trials, directed by the National Institutes of Health.

Dr. Brinkman has authored more than 30 articles in peer-reviewed journals and has presented his work at regional and national meetings. A recent publication is "*Influence of Surgeon Volume on Outcomes with Aortic Value Replacement",* in the January 2012 issues of the Annals of Thoracic Surgery.

Surgical Treatment
of
Atrial Fibrillation



Introduction
&
Concomitant Maze

Risks Associated with Atrial Fibrillation

- A-Fib increases stroke rate 3 – 5 times
  - 15% of all strokes
- A-Fib increases death rate 2 fold
- congestive heart failure due to progressive deterioration of lower chamber function
- The longer a patient is in A-Fib, the more difficult it is to treat and eliminate the rhythm

Classification of AF

- The latest classification divides AF into three types:
  - Paroxysmal
  - Persistent
  - Long standing persistent

  OR
  - Intermittent
  - Continuous

.

A Different Way to Classify AF

- Lone A-Fib
- Concomitant A-Fib
  - Valve Disease
  - Coronary Artery Disease
  - Septal Defects
  - Other

Three Consequences of A-Fib

- Loss of "Atrial Kick" → decreased pumping
- Stasis of blood in quivering atria
  - Clot formation
  - May go downstream blocking an artery
  - Stroke
- Rapid Ventricular Response
  - No time to relax and fill
  - Decreased pumping

Problems Associated with Atrial Fibrillation

- Feeling of “Not well being”, “impending doom”
  - Accompanies rapid heart beat
- Palpitations, Fluttering in Chest
- Lethargy, Fatigue, “Washed Out”, Short of Breath with Exertion
  - ***Out of proportion to activity***
  - Related to decreased amount of blood pumped
    - Fast rate causes decreased filling of heart
    - Loss of atrial priming “kick”
- Stroke
- Slow Deterioration of Ventricles over years

Treatment Options

Just FIVE basic treatment choices

1. Shock to normal Rhythm
2. Accept the A-Fib & prevent the complications
3. Catheter Ablation
4. Minimal Access (thorascopic) surgical ablation
5. Cox Maze III

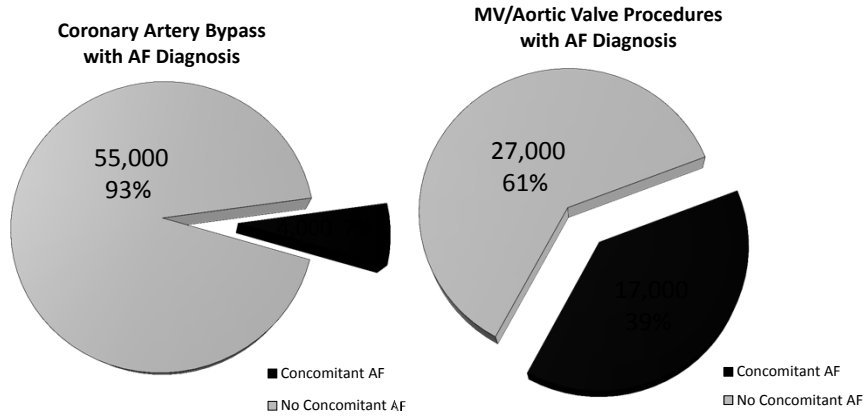
Treatment Options for Atrial Fibrillation

1. Cardioversion
   - Pharmacological
   - Electrical (shock)
2. Rate Control & Anticoagulation
   - Slow heart to allow adequate filling of lower chambers
   - Prevent stroke from blood clots
3. Cox Open Chest Maze-III
   - Electrical contraction waves spread from one muscle cell to another
   - In atrial fibrillation these electrical waves are chaotic
   - Electricity can't cross scars
   - Series of "Scars" surgically placed on upper chambers to channel the electrical waves
   - Big operation usually reserved for "concomitant" A-Fib
     - On heart-lung machine
     - Heart arrested

Concomitant Maze

- With Valve surgery
- With coronary surgery
- With other.

Under-Treatment by Procedure…..
going to an A-Fib Center may be important



(ICD-9 427.31)

Source: Agency for Health Care Quality and Research (AHRQ)
Cost and Utilization Project Nationwide Inpatient Sample 2009

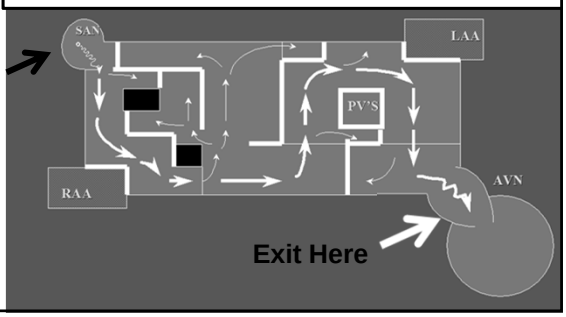
Risks of Untreated AF in Cardiac Surgery Patients

CABG	• > 20% increase in mortality by 10 yrs • Increased post op morbidity (2 X stroke)
Aortic Valve	• Worse late survival (RR = 1.5) • More post op stroke (16% vs. 5%) and CHF (25% vs. 10%)
Mitral Valve	• 18% difference in survival by 10 yrs • Increase in late cardiac events/stroke (32% difference)

Remember…

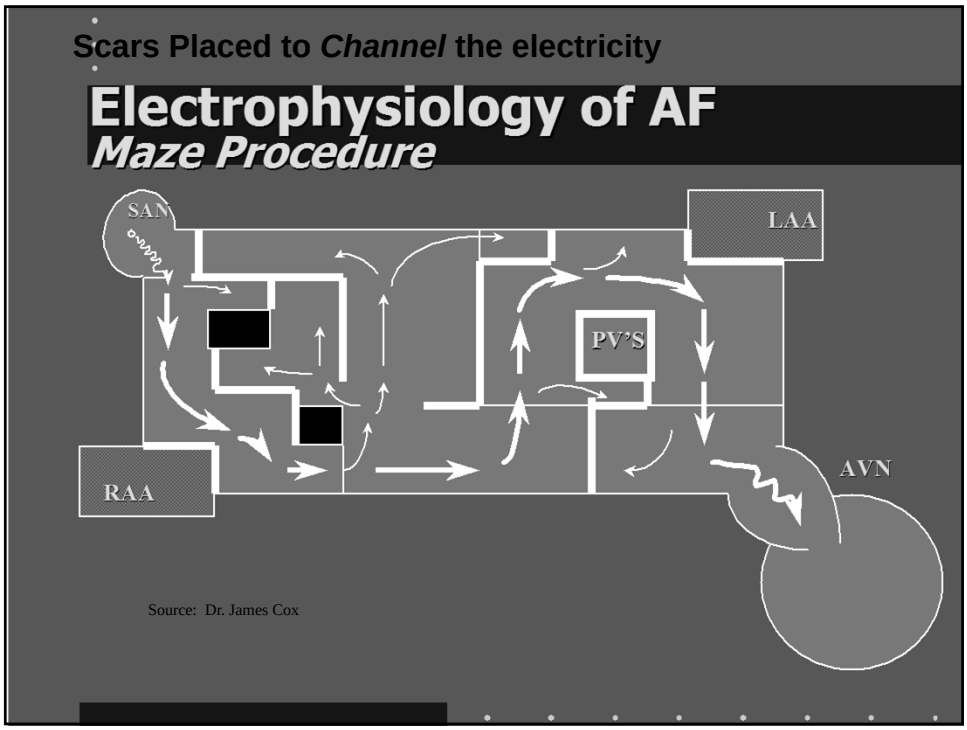
- **Electricity Spreads from Cell to Cell**
- **ELECTRICITY CANNOT CROSS A SCAR**
- **A Series of Scars Can *direct the flow of electricity***
- **Just like the <u>Maze</u> in the Sunday paper**

Enter Here



With permission, J.Edgerton

Scars Placed to *Channel* the electricity



Classic Cox Maze

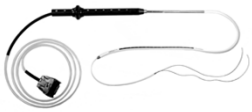
- Goal is to create strategically placed scars to channel the electricity
- All Lines (Scars) were formed by cutting the tissue and sewing it back together
- Called “Cut and Sew”
- But Cut and Sew is highly morbid
- Many of the Cut and Sew lines are now made by burning or freezing the tissue to create a linear scar
- A Burst of enabling technology produced *many new energy sources* to kill a line of tissue

With permission, J.Edgerton

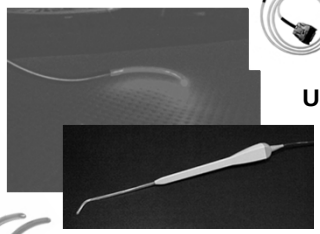
Technologies for Surgical Ablation: The search for the perfect energy source

Bipolar Radiofrequency

Microwave

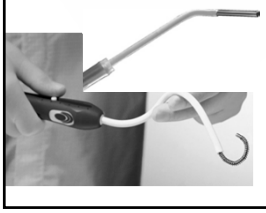


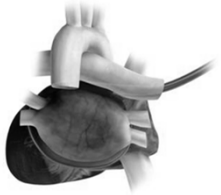
Laser



Unipolar Radiofrequency

Cryoablation





High frequency ultrasound

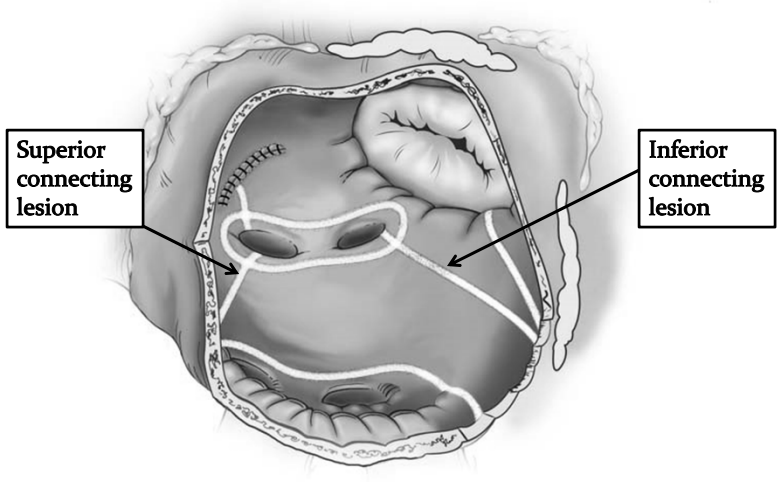
Most of these energy sources didn't work…

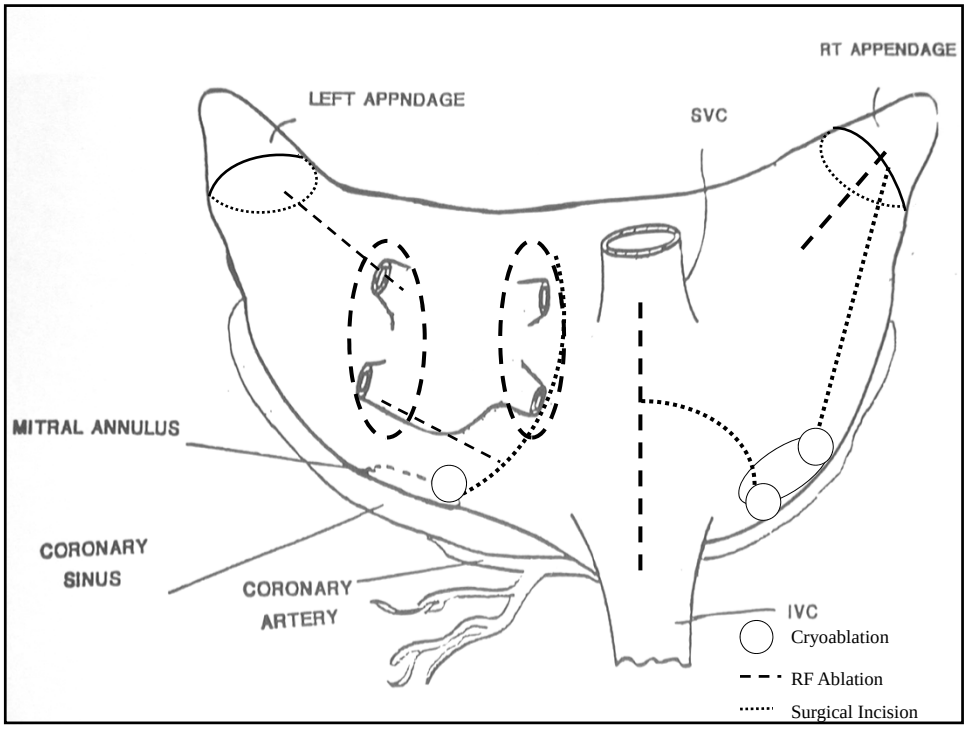
What works:

- **Scissors**
- **Radiofrequency**
- **Cryo**

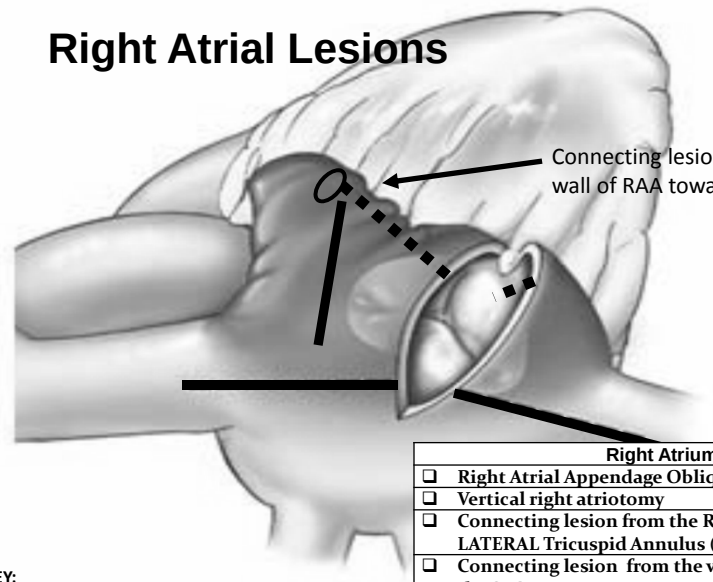
With permission, J.Edgerton

Left Atrial Lesions of the Cox-Maze IV





Right Atrial Lesions



Right Atrium
❑ Right Atrial Appendage Oblique
❑ Vertical right atriotomy
❑ Connecting lesion from the RAA Oblique to the LATERAL Tricuspid Annulus (10 o'clock position)
❑ Connecting lesion from the vertical atriotomy to the SVC
❑ Connecting lesion from the vertical atriotomy to the IVC
❑ Connecting lesion from the vertical atriotomy to the MEDIAL Tricuspid Annulus (2 o'clock position)

KEY:
Blue lines represent typical clamp lesions.
Orange lines represent typical cryo lesions.
Purple oval represents RAA incision.

Maze III
Cox Series

- **38% have episodic a-fib for 3 months postoperatively**
- **1.2% long-term failure rate (Cox)**
- **15% new pacemakers**
- **98% had right atrial transport**
- **93% had left atrial transport (documented by: MRI, AV vs. V Pacing, or Echo)**

Maze III
Cleveland Clinic

- **1% Mortality**
- **6% new pacemaker**
- **90.4% in SR at 3 years**
- **No late embolic events**

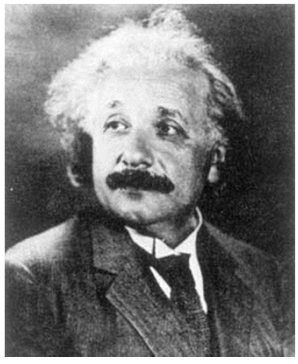
Maze III
Mayo Clinic

- 1.4% mortality
- 3.2% new pacemaker
- 5% failure for paroxysmal AF
- 10-20% failure for chronic AF with enlarged atria

Minimal Access Thorascopic Maze

Treatment Options for Atrial Fibrillation

1. Cardioversion
   - Pharmacological
   - Electrical (shock)
2. Rate Control & Anticoagulation
   - Slow heart to allow adequate filling of lower chambers
   - Prevent stroke from blood clots
3. Cox Open Chest Maze-III
4. Catheter Ablation
   - AV node ablation and Pacemaker
   - Pulmonary Vein Isolation
5. Closed Chest Maze
   - Pulmonary Vein Isolation
   - Atrial Appendage Removal
   - Selective Autonomic Denervation
   - Additional linear lesions for Persistent forms of AF



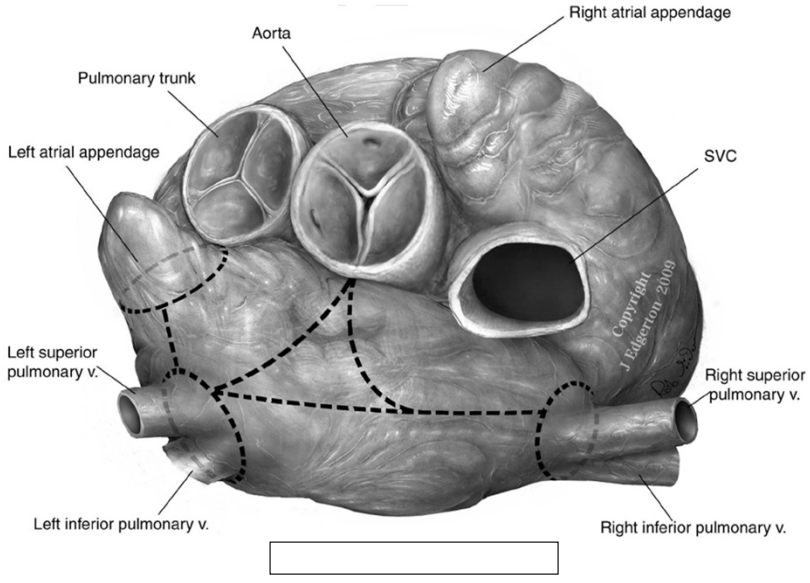
“Imagination is more important than knowledge”

Albert Einstein

Minimal Access Techniques

- **Non-sternotomy**
- **Minimally invasive incision**
- **Progressed to Totally Thorascopic**
- **Beating heart**
- **Transmural lesions**

The Dallas Connection



Closed Chest Minimal Access Maze

- Closed-chest, beating heart
- Endoscopic visualization
- Complete electrical isolation of pulmonary veins
- Left Atrial Appendage exclusion
- Selective Denervation
- Additional Connecting Lines in Persistent AF

One Year Results Totally Thoracscopic Maze with Dallas Lesion Set

	All Patients	Paroxysmal	Persistent	LSP
# Patients	68	30	17	21
Follow-up (mos)	12.9 ± 7.0 (median 12.1)	12.5 ± 6.6 (median 12.4)	11.2 ± 5.5 (median 12.6)	14.8 ± 8.5 (median 11.8)
Success	75.0% (51/68)	86.7% (26/30)	71.0% (12/17)	61.9% (13/21)

Surgical Procedural Evolution
The Future

- 2004: Minimally Invasive Pulmonary Vein Isolation, Wolf
- 2005: Targeted Partial Autonomic Denervation, Jackman
- 2006: The Trigone Connection, **THE DALLAS LESION SET**
- 2007 Demonstrate Block of Linear Lesions and Determine Midterm Outcomes with Extended Lesion Set
- 2008: Develop Easier Method of Confirmation of Block of Linear Lesions
- 2008 - 2009: Totally endoscopic approach
- 2010- 2011: Hybrid Endocardial/Epicardial Approach
- 2012: Staged Hybrid

Hybrid Rationale

- Surgeons are very good at making lines
- EPs excel at “spot welding”

- A surgeon may fail to penetrate the endocardium
- The EP may fail to penetrate the epicardium

- Surgeons have difficulty mapping for completeness
  - Constrained by pericardial reflections
  - Cognitive deficit
- EPs Excel at mapping for success
  - Formally trained, & mature enabling technology
  - Full access to entire LA and better tools


StopAfib.org

Get in Rhythm.
Stay in Rhythm.

Atrial Fibrillation Patient Conference

HOSTED BY StopAfib.org
For patients by patients

November 2, 2013
8:45 a.m. – 1:00 p.m.
Westin Dallas Park Central Hotel • Dallas, Texas

Conference Agenda

8:00 – 8:45 am	Registration, Exhibits open, and Light Breakfast	
8:45 – 8:55 am	Welcome and Overview of the day	Mellanie True Hills
8:55 – 9:20 am	Overview of Afib and Why It Is a Problem	Adam Shapira, MD, FACC, FHRS
9:20 – 9:55 am	Treating Afib with Medications and Avoiding Strokes	Eric N. Prystowsky, MD, FHRS
9:55 – 10:10 am	Tips for Communicating with Your Doctor	Mellanie True Hills and Robert Kowal, MD, PhD, FHRS
10:10 – 10:30 am	Living with Afib	Mellanie True Hills
10:30 – 11:00 am	Refreshment Break and Exhibits	
11:00 – 12:00 pm	Treating Afib with Procedures	
	Catheter Ablation	
	▸ RF Catheter Ablation	Kamran A. Rizvi, MD, FHRS
	▸ Cryoballoon Catheter Ablation	Jay O. Franklin, MD, FACC, FHRS
	▸ New catheter ablation procedures (FIRM, laser balloon) and left atrial appendage (LAA) procedures	Robert Kowal, MD, PhD, FHRS
	Surgery including LAA	William T. Brinkman, MD
12:00 – 12:35 pm	Q & A with all Panel Experts	Moderated by Mellanie True Hills
12:35 – 12:45 pm	Wrap Up	Mellanie True Hills, StopAfib.org
12:45 pm	Meeting Adjourns	
1:00 pm	Exhibits close	