CARDIOLOGY GRAND ROUNDS

Presentation: The State of Atrial Fibrillation: Treatment Options, Iatrogenic Flutter Avoidance, and Left Atrial Appendage Management

Speaker: James L. Cox, MD

Evarts A. Graham Professor of Surgery Emeritus; Chief, Division of Cardiothoracic Surgery Emeritus; Washington University School of Medicine; Barnes-Jewish Hospital, St. Louis, MO

Dr. Cox is best known for his work in the field of cardiac arrhythmia surgery and the development of the Cox-Maze Procedure for the treatment of atrial fibrillation. His work in the field of arrhythmia surgery was supported by a personal RO1 NIH Grant continuously for over 25 years. Dr. Cox has trained many prominent surgeons in North America, South America, Europe and Asia and has served as the Guest Lecturer, Visiting Professor or Guest Surgeon over 450 times and in 30 countries. He has published over 350 peer-reviewed scientific articles and over 150 scientific abstracts and holds 30 patents on medical devices. Since retiring from clinical practice, Dr. Cox has been instrumental in the founding of six startup companies, four of which have subsequently been sold to larger companies, including Medtronic, St. Jude Medical and Johnson & Johnson.

Date: Monday, February 9, 2015, 7:00 – 8:00 AM
Location: ANW Education Building, Watson Room

OBJECTIVES
1. Evaluate approaches to left atrial appendage management.
2. Describe open and thoracoscopic approaches to treat atrial fibrillation.
3. Discuss strategies for avoiding peri-mitral atrial flutter.

ACCREDITATION
Physicians: This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Allina Health and Minneapolis Heart Institute Foundation. Allina Health is accredited by the ACCME to provide continuing medical education for physicians.

Allina Health designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nurses: This activity has been designed to meet the Minnesota Board of Nursing continuing education requirements for 1.2 hours of credit. However, the nurse is responsible for determining whether this activity meets the requirements for acceptable continuing education.

Others: Individuals representing other professional disciplines may submit course materials to their respective professional associations for 1.0 hours of continuing education credit.

DISCLOSURE STATEMENTS
Speaker: James L. Cox, MD, has declared the following financial relationships: Adagio Medical, AtriCure, CorMatrix, Harppon Medical and SentreHeart.

Planning Committee: Dr. Michael Miedema and Eva Zewdie have declared that they do not have any conflicts of interest associated with the planning of this activity. Dr. Robert Schwartz declared the following relationships - stockholder: Cardiomind, Interface Biologics, Aritech, DSI/Transoma, InstyMeds, Intvalve, Medtronic, Osprey Medical, Stout Medical, Tricardia LLC, CoAptus Inc, Augustine Biomedical; scientific advisory board: Abbott Laboratories, Boston Scientific, MEDRAD Inc, Thomas, McNerney & Partners, Cardiomind, Interface Biologics; options: BackBeat Medical, BioHeart, CHF Solutions; speakers bureau: Vital Images; consultant: Edwards LifeSciences.
The Current State of Atrial Fibrillation Treatment

James L. Cox, MD

Evarts A. Graham Professor of Surgery Emeritus
Chief, Division of Cardiothoracic Surgery Emeritus
Washington University School of Medicine
St. Louis, MO, USA

Global Prevalence of Atrial Fibrillation

Prevalence of atrial fibrillation and flutter (per 100,000) by region, 2010

The Electrophysiology of Atrial Fibrillation

Electrophysiology of Atrial Fibrillation


Normal Sinus Rhythm

How Atrial Fibrillation is Induced

How Atrial Fibrillation is Sustained
Paroxysmal Atrial Fibrillation (PAF)

- Self-Limiting Episode of Atrial Fibrillation

Non-Paroxysmal Atrial Fibrillation (N-PAF)

- Persistent or Permanent Episode of Atrial Fibrillation
Non-Paroxysmal Atrial Fibrillation (N-PAF)

Prolonged or Permanent Episode of Atrial Fibrillation

2 Categories of AF from Interventional Standpoint

- Paroxysmal AF
- Persistent AF
- Long-Standing Persistent AF
- Permanent AF
2 Categories of AF from *Interventional* Standpoint

**PAF**
- Paroxysmal AF

**N-PAF**
- Persistent AF
- Long-Standing Persistent AF
- Permanent AF

Isolate the Triggers

2 Categories of AF from *Interventional* Standpoint

**PAF**
- Paroxysmal AF

**N-PAF**
- Persistent AF
- Long-Standing Persistent AF
- Permanent AF

Isolate the Triggers

Interrupt the Rotors
Treatment Options for “Concomitant AF”

Treatment of Concomitant AF in USA

Under Treatment by Procedure

- **Coronary Artery Bypass with AF Diagnosis**
  - 55,000 (93%)
  - 4,000 (7%)

- **MV/Aortic Valve Procedures with AF Diagnosis**
  - 27,000 (61%)
  - 17,000 (39%)

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

Reasons Given for Not Treating Concomitant AF

2010 Survey of AATS Attendees

- Adds too much complexity to the primary procedure
- Added “on pump” time
- Reported results may not be reproducible in private practice
- Not willing to introduce any additional patient risks to primary procedure
- Lack of society consensus on patient selection, lesion set or energy source
Safety

Do we increase the operative risk by adding the Cox Maze III procedure to aortic valve replacement and coronary artery bypass surgery?

Ad N, Henry L, Hunt S, Holmes SD
Inova Heart and Vascular Institute, Cardiac Surgery Research, Falls Church, VA

“The addition of the Cox Maze III procedure did not convey an increase in major morbidity and perioperative risk.”
Safety

Incremental risk of the Cox-maze IV procedure for patients with atrial fibrillation undergoing mitral valve surgery
Saint LL, Damiano RJ Jr, Cuculich PS, Guthrie TJ, Moon MR, Munfakh NA, Maniar HS: Washington University in St. Louis, Barnes-Jewish Hospital, St. Louis, MO

“The addition of a Cox-maze IV procedure did not significantly affect the procedural mortality.”

Reasons Given for Not Treating Concomitant AF

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- **A Matter of Surgical Education**

2010 Survey of AATS Attendees

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**Randomized Trials of Surgical Ablation for AF in Patients Undergoing Mitral Surgery**

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<thead>
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<th>n</th>
<th>SURGERY</th>
<th>CONTROL</th>
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<td>95%</td>
<td>31%</td>
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<tr>
<td>Filho</td>
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<td>79%</td>
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<td>Doukas</td>
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<td>44%</td>
<td>5%</td>
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<tr>
<td>Lima</td>
<td>30</td>
<td>80%</td>
<td>40%</td>
</tr>
<tr>
<td>Deneke</td>
<td>30</td>
<td>80%</td>
<td>27%</td>
</tr>
<tr>
<td>Blomstrom-Lindquist</td>
<td>65</td>
<td>73%</td>
<td>43%</td>
</tr>
<tr>
<td>Chevalier</td>
<td>43</td>
<td>95%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Every randomized trial has shown a significantly better freedom from AF with surgical ablation!!

Courtesy of Ralph Damiano, MD
Survival following Mitral Valve Surgery


![Graph showing survival following mitral valve surgery with and without atrial fibrillation (AF).](image1)

Of the 47 patients, all patients were free of symptomatic AF at 10 years!

What About Coronary Artery Disease?

The long-term outcome of patients with coronary disease and atrial fibrillation undergoing the Cox maze procedure

Ralph J. Damiano, Jr, MD
Sydney L. Guyton, MD
Marc Bailey, RN
Sara
Joe
Joe

Of the 47 patients, all patients were free of symptomatic AF at 10 years!

Methods: From 1993 to 2002, 47 patients undergoing operations for ischemic heart disease underwent a concomitant Cox maze III procedure. All patients underwent coronary bypass grafting, and 13 patients underwent coronary bypass grafting plus a mitral valve repair. Follow-up was performed by means of mail and telephone questionnaires with both the patients and their cardiologists. All patients who had any history of arrhythmias or who were taking medications had their rhythms documented by electrocardiogram.

*J Thorac Cardiovasc Surg* 2003;126:2016-21

Courtesy of Ralph Damiano, MD
Mitral Surgery and Concomitant Maze Procedure


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%)

Courtesy of Ralph Damiano, MD
i WANT THIS TO BUILD
Jim DiBiasi, 9/10/2011
Freedom from Long-Term Strokes


![Freedom from Long-Term Strokes Graph](image)

Fewer Long-Term Thromboembolic and Valve-Related Complications


![Fewer Long-Term Complications Graph](image)
Decrease in *All* Cardiac Complications


Improved Long-Term Survival

Reasons Given for Not Treating Concomitant AF

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- Lack of society consensus on patient selection, lesion set or energy source

Inaccurate

Lack of society consensus on patient selection, lesion set or energy source
**Consensus Recommendation of Societies**

2012 Consensus Statement on Surgical AF:

“It is advisable that all patients with documented AF referred for other cardiac surgeries undergo a left or biatrial procedure for AF at an experienced center, unless it...will add significant RISK...”

Heart Rhythm Society  
American College of Cardiology  
American Heart Association  
Society of Thoracic Surgeons  
European Heart Rhythm Association  
European Cardiac Arrhythmia Society

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**Consensus Recommendation of ISMICS**

“Concomitant surgical ablation is recommended .... to increase the incidence of sinus rhythm both at short- and long-term follow-up .... to improve ejection fraction and exercise tolerance .... to reduce the risk of stroke and thromboembolic events .... and to improve long-term survival.”
Treatment of Concomitant AF in USA

CABG, AVR, or MVRr patients who also have Atrial Fibrillation

2013 STS National Adult Cardiac Surgery Data Base

CABG Patients

CABG patients who also have Paroxysmal AF

- Surgical Options:
  - PV Isolation
  - Maze Procedure
CABG Patients

N-PAF

- Surgical Options:
  - Maze Procedure

CABG patients who also have Non-Paroxysmal AF

AVR Patients

PAF

- Surgical Options:
  - PV Isolation
  - Maze Procedure

AVR patients who also have Paroxysmal AF
**AVR Patients**

- Surgical Options:
  - Maze Procedure

**Mitral Valve Surgery Patients**

- Mitral patients who also have **Paroxysmal AF**
- Mitral patients who also have **Non-Paroxysmal AF**

- Surgical Options:
  - Maze Procedure
The Maze-IV Procedure

Potential Macro-Reentrant Circuits in N-PAF

Atypical Left Atrial Flutter
“Peri-Mitral Atrial Flutter” (iatrogenic)

2 Possible Routes Across LA Isthmus

Classic Atrial Flutter Wave

LA Myocardium
Coronary sinus
Potential Macro-Reentrant Circuits in N-PAF

Why PV Isolation is not enough for N-PAF
Objective of the Maze Lesions

How to Prevent Postoperative Peri-Mitral Atrial Flutter
The Left Atrial Isthmus

Precise Placement of Coronary Sinus Lesion

The Coronary Sinus Lesion must be placed in the same plane as the atriotomy.
Precise Placement of Coronary Sinus Lesion

The Coronary Sinus Lesion must be placed in the same plane as the atriotomy.

Failure

Atriotomy to Mitral Annulus
Coronary Sinus Lesion

Precise Placement of Coronary Sinus Lesion

The Coronary Sinus Lesion must be placed in the same plane as the atriotomy.
The First Case of Peri-Mitral Flutter
Coronary Sinus Hexa-Polar Catheter

Failure of Mitral Line/Coronary Sinus Lesion
Treatment Options for “Stand-Alone AF”

Success Rate of Catheter Ablation for Stand-Alone AF

Long-term single procedure efficacy of catheter ablation of atrial fibrillation.

Catheter ablation for atrial fibrillation: are results maintained at 5 years of follow-up?

Catheter ablation of long-standing persistent atrial fibrillation: 5-year outcomes of the Hamburg Sequential Ablation Strategy.
Success Rate of Catheter Ablation for Stand-Alone AF

![Graph showing success rate of catheter ablation for stand-alone AF.](image)

- **Multiple Catheter Ablations**
- **Single Catheter Ablation**
Success Rate of Catheter Ablation for Stand-Alone AF

Success Rate of Catheter Ablation for Stand-Alone AF

Percent Freedom from AF

0 5 10 15

Years

0 50 100

Multiple Catheter Ablations

63

45

Single Catheter Ablation

29

20

Success Rate of Catheter Ablation for Stand-Alone AF

Percent Freedom from AF

0 5 10 15

Years

0 50 100

Multiple Catheter Ablations

63

45

~50% at 5 years

Single Catheter Ablation

29

20

~25% at 5 years
Hybrid Procedures

The 2012 HRS Guidelines define hybrid procedures as:

“…a joint AF ablation procedure performed by electrophysiologists and cardiac surgeons either as part of a single “joint” procedure or performed as two pre-planned separate ablation procedures separated by no more than six months of time.”

1. Surgery and catheter ablation at a single “joint” setting
2. Initial catheter ablation followed by surgery at a later date
3. Initial surgery followed by catheter ablation at a later date
Staged Surgery/Catheter Hybrid

Percent Freedom from AF

90% with Surgery as Initial Procedure

50% with Catheter Ablation as Initial Procedure (Multiple Catheter Ablations)

Limitations of Previous “Minimally Invasive” Approaches

General Anesthesia
Endotracheal Intubation
Dual-Lumen Intubation
Cardiopulmonary Bypass
Systemic Heparinization
Individual Deflation of Lung(s)
Bilateral Pericardiotomies
Postop Chest Tubes

Still too invasive!
Contemporary Thoracoscopic Surgery for AF

Hybrid Maze Procedure

Off-Pump

90-Day Blanking Period

90-Day Blanking Period

Follow-up

6m
Initial Thoracoscopic Procedure

Documented *Left Atrial* Macro-Reentrant Circuits in N-PAF
Left Atrial Lesions

Radiopaque Vascular Clips
Documented **Right Atrial** 
Macro-Reentrant Circuits in N-PAF

**Right Atrial Lesions**
Completed Initial Thoracoscopic Surgery

This is NOT a complete Maze procedure.

Followup Catheter Ablation
Followup Catheter Ablation

Followup Catheter Ablation
Followup Catheter Ablation

Followup Catheter Ablation
Followup Catheter Ablation

Followup Catheter Ablation

Final Hybrid Maze Procedure

This IS a complete Maze procedure.
**Why the Future should be Hybrid Maze Procedures**

1. Outcomes for the catheter ablation of AF will not improve until better catheter tools are developed.

1. New off-pump thoracoscopic procedures make surgery a viable option as the initial treatment for Stand-Alone AF, provided there is an obligatory follow-up catheter ablation.

1. Such a “Hybrid Maze Procedure” should produce outcomes equal those for the open-heart surgical Maze Procedure.

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**Should the Left Atrial Appendage be Closed?**
The LAA and Strokes

All Strokes (100%)

90% Ischemic

20% are Associated with AF

95% of Detected Thrombi are in the LAA

10% Hemorrhagic

= 130,000 Strokes / yr (US)

Patients with AF are 5 times more likely to have a stroke than patients without AF

Why the LAA and not the RAA?

Virchow’s Triad:

1. Hypercoagulability
   - Same in LAA and RAA

2. Tissue Injury
   - Same in LAA and RAA

3. Stasis
   - Worse in LAA
Anatomy of RA Appendage

Right Atrial Appendage

Tricuspid Annulus

Anatomy of LA Appendage

LSPV  LPA  R.P.A.

LAA  PT.

SVC  RSPV

LA  L.A.

LV  IVC

MV
No Stasis

• Favorable for prevention of stroke in meta-analyses and RCTs.

• Disadvantages: Warfarin-related bleeding.

Fuster V et al., ACC/AHA/ESC 2006 guidelines for the management of patients with AF. Circulation. 2006;114:e257-354

Gold Standard - Warfarin

• Only 1/3 of patients with AF have sufficient anticoagulant therapy!
Patient Compliance

Swedish Stroke Registry
(21,077 stroke survivors)

Glader E et al.; Stroke 2010, 41: 397-401

LAA Closure Devices

Percutaneous
0. PLAATO Device
1. WATCHMAN Device
2. Amplatzer Plug
3. LARIAT Device

Surgical
1. “Tiger Paw”
2. AtriClip
LAA Closure Devices

Percutaneous
1. PLAATO Device
2. WATCHMAN Device
3. Amplatzer Plug
4. LARIAT Device

Surgical
1. “Tiger Paw”
2. AtriClip

The WATCHMAN Device
The Amplatzer Plug

Epicardial LAA Closure Devices

Percutaneous

0. PLAATO Device
1. WATCHMAN Device
2. Amplatzer Plug
3. LARIAT Device

Surgical

1. “Tiger Paw”
2. AtriClip
The Percutaneous LARIAT Device
The Surgical AtriClip

The Surgical AtriClip
Evidence that LAA Closure Decreases Stroke in Patients with AF
The Left Atrial Appendage Occlusion (LAAOS) Study

1. Epicardial Suture Closure of the LAA
   - Residual LA-LAA connection in 57% (failures)

2. Surgical Stapling of the LAA
   - Residual “pouch” of >1cm in 38% (failures)

“However, closure by either method reduced the incidence of stroke from 5.6% to 2.6% when compared to screened but non-randomized, non-occluded patients.”

Healey et al: Am Heart J 2005

Personal Series of Maze Patients

All Patients
100%

Previous T.E. 20%

No Previous T.E. 80%
### Early Postoperative Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Postop Arrhythmias</td>
<td>37 %</td>
</tr>
<tr>
<td>Postop Fluid Retention</td>
<td>6 %</td>
</tr>
<tr>
<td>Perioperative TIA</td>
<td>0.6 %</td>
</tr>
<tr>
<td>Perioperative Stroke</td>
<td>0.6 %</td>
</tr>
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### Comparative Perioperative Stroke Rate

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Stroke Rate</th>
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<tbody>
<tr>
<td>CABG + MVR</td>
<td>LAA Closed</td>
</tr>
<tr>
<td>CABG + AVR</td>
<td></td>
</tr>
<tr>
<td>CABG + MV Repair</td>
<td></td>
</tr>
<tr>
<td>AVR + MVR</td>
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</tr>
<tr>
<td>MV Repair</td>
<td></td>
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<tr>
<td>MVR</td>
<td></td>
</tr>
<tr>
<td>AVR</td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td></td>
</tr>
<tr>
<td>Maze + Above</td>
<td></td>
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</tbody>
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Risk Factors for Stroke due to Atrial Fibrillation

- **High Risk**
  - 1) Advanced Age
  - 2) Hypertension
  - 3) Diabetes Mellitus
  - 4) Congestive Heart Failure
  - 5) Ischemic Heart Disease
  - 6) Previous Stroke and/or TIA

- **Low Risk**

*Arch Intern Med, 1994*

Risk Factors for Stroke due to Atrial Fibrillation

- **High Risk**
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  - D Diabetes Mellitus
  - C Congestive Heart Failure
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  - S Previous Stroke and/or TIA

- **Low Risk**

*Analysis of pooled data: Arch Intern Med, 1994*
**Strokes Following the Maze Procedure**

- **CHA\textsubscript{2}DS\textsubscript{2}-VASc Risk Stratification**

- **YEARS after onset of Atrial Fibrillation**

- **% Predicted Stroke**

- **CHADS\textsubscript{2}VASc Risk Stratification**

- **68 Predicted Strokes**

- **1 Observed Stroke**

**Long-Term Freedom from Stroke**

- **65% not anticoagulated**

- **All had LAA Closed**

- **99.3%**

**Damiano, et al: JTCVS, 2003**
Potential Consequences of LAA Closure

1. Improved results of catheter ablation and surgery for AF
   - Isolates atrial triggers that can induce PAF
   - Isolates atrial rotors that can perpetuate Non-PAF

2. Decrease in Atrial Natriuretic Peptide (ANP)
   - Negligible if RAA remains intact
   - Temporary, even if decreased slightly

3. Decrease in left atrial “contraction”
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**Triggers and Reentry in LAA**
Map of a Trigger in the LAA

Benussi et al., Circulation 2011

Up to 30% of AF may come from the LAA

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Potential Consequences of LAA Closure

Left Atrial Isolation Procedure

[Diagram showing DVI, NSR, and LAA]
Potential Consequences of LAA Closure

CONCLUSION:

- Loss of LA “contraction” had no effect on cardiac hemodynamics
- Therefore, loss of LAA “contraction” has no effect on cardiac hemodynamics

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Atrial Fibrillation Cost Analysis

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<tr>
<th>Cost</th>
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<tr>
<td>Aspirin</td>
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<tr>
<td>Aspirin with Clopidogrel</td>
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<tr>
<td>Warfarin (not including INR monitoring)</td>
</tr>
<tr>
<td>Dabigatran</td>
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<tr>
<td>Cost of INR</td>
</tr>
<tr>
<td>Moderate to severe ischemic neurological event (admission)</td>
</tr>
<tr>
<td>Moderate to severe ischemic neurological event (long term)</td>
</tr>
<tr>
<td>Major bleeding without residua</td>
</tr>
<tr>
<td>Hemorrhagic stroke (admission)</td>
</tr>
<tr>
<td>Hemorrhagic stroke (long term)</td>
</tr>
</tbody>
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Shah et al., Circulation. 2011
Atrial Fibrillation Cost Analysis

The prevalence, impact and economic implications of atrial fibrillation in stroke: What progress has been made?
Andrew NE, Thrift AG, Cadilhac DA

*Neuroepidemiology* 2013;40:227-239

“Unless action is taken to improve detection of AF and reduce its consequences, a considerable increase in the social and economic burden associated with AF-related stroke is likely.”

“Missing the Point”

“Because the LAA is the site of 95% of detected thrombi, this structure should be removed from circulation when possible during cardiac surgery in patients at risk of developing postoperative AF.”

What about the 3 million patients who *already* have atrial fibrillation?
Recognition of the Problem
LAA Publications from 1948 - 2011

Who should receive LAA closure?

1. Patients with AF who cannot take anticoagulants
2. Patients undergoing catheter ablation for AF
3. Patients with AF who are not candidates for intervention
4. Patients undergoing cardiac surgery with a history of AF
5. All patients undergoing cardiac surgery?
6. Patients with subclinical AF?
Summary

1. Proper closure of the LAA virtually eliminates stroke associated with atrial fibrillation.

2. LAA Closure with *Epicardial Devices* may improve the results of catheter ablation and surgery for the treatment of AF.

3. There are no known adverse effects of closing the LAA.

4. LAA closure in patients with AF will almost certainly reduce future health care costs.

1. Perhaps we should close the LAA anytime we can get our hands on it!

Thank You