Objectives

- Normal and Abnormal Heart Rhythms; AFib
- AFib Risk Factors
- Symptoms
- Complications of Untreated AFib
- Treatment Goals and Options

The Normal Heart

- The heart is a fist-sized muscle that pumps blood through the body 24 hours a day, 365 days a year, without rest.
- The normal heart is made up of four parts: two atria on the top of the heart (right atrium and left atrium), and two ventricles (right ventricle and left ventricle), the muscular chambers on the bottom that provide the major power to pump blood.
- The heart’s pumping action, or “heartbeat,” is directed by a complicated electrical system.

The 4 Chambers of the Heart

- The heart’s electrical system is responsible for creating the signals that trigger the heart to beat. These signals prompt the heart’s muscle to contract.
- With each contraction, blood is pumped throughout the body. The process begins in the upper chambers of the heart (atria), which pump blood into the lower chambers (ventricles). The ventricles then pump blood to the body and lungs.
- This coordinated action occurs because the heart is “wired” to send electrical signals that tell the chambers of the heart when to contract.
**Heart Disease**

- **Circulatory**
- **Structural**
- **Electrical**: Abnormal heart rhythms (arrhythmias); caused by problems with the electrical system
  - Heart rate may be too slow or too fast; may stay steady or become chaotic
  - Some arrhythmias are very dangerous and cause sudden cardiac death, while others may be bothersome but not life threatening.

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**Atrial Fibrillation**

- Atrial fibrillation (AFib) is the most common abnormal heart rhythm (arrhythmia).
- Emerging epidemic; today impacts more than 5.1 million people in US, expected to be 15.9 million by 2050.
- Incidence increases with age, AFib affects 12% of adults ≥ 75 years
- Estimated lifetime risk of 22-26%, or 1 in 4

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**Atrial Fibrillation**

- Can lead to symptoms that negatively impact the quality of life in some people.
- Others experience no symptoms at all.
- In general, not considered life threatening, however, left untreated, side effects of AFib can be life threatening, leading to stroke and heart failure.
- Identifying and treating AFib of paramount importance.
Atrial Fibrillation

- Atrial fibrillation happens when erratic or extra electrical signals throw off the heart's pacemaker.
- The atria (upper chambers of the heart) fibrillate (quiver or twitch quickly) and create an irregular rhythm.
- When the heart quivers instead of contracting rhythmically, blood can pool in the atria, and form blood clots.
- Excessive or irregular heartbeats can also overwork the heart muscle, leading to heart failure.

Sinus Rhythm  AFib

Sinus Rhythm                      AFib

AFib Classification

- **Paroxysmal**, or intermittent — episodes that come and go and last seven days or less
- **Persistent** — continuous AFib that lasts more than seven days
- **Longstanding persistent** — continuous AFib that lasts longer than one year
- **Permanent** — continuous AFib in which a decision has been made by the patient and the doctor not to try to restore normal sinus rhythm.
Causes of AFib

- Some people who are living healthy lives and have no other medical problems do develop Atrial Fibrillation
- AFib probably represents a common final endpoint of various disease states and medical conditions.
- Mechanisms/causes not entirely understood.
- Risk factors are known...

Risk Factors in AFib

- Age > 60
- Diabetes
- High Blood Pressure
- Coronary artery disease, prior heart attacks
- Congestive heart failure
- Structural heart disease (valve problems or congenital defects)
- Prior open-heart surgery
- Untreated atrial flutter (another type of abnormal heart rhythm)
- Thyroid disease
- Chronic lung disease
- Sleep apnea
- Obesity
- Excessive alcohol or stimulant use
- Serious illness or infection

Symptoms

- Many people with AFib feel no symptoms at all.
- Others can tell as soon as it happens.
- Symptoms of AFib are different for each person, often depends on age, the cause of the AFib (such as heart problems or other diseases), and on how much AFib affects the pumping of the heart.

Symptoms

- Feeling overtired or a lack of energy (most common)
- Pulse that is faster than normal or changing between fast and slow and feels irregular
- Shortness of breath
- Heart palpitations (feeling like your heart is racing, pounding, or fluttering)
- Trouble with everyday exercises or activities
- Pain, pressure, tightness, or discomfort in your chest
- Dizziness, lightheadedness, or fainting
- Increased urination (using the bathroom more often)
- Asymptomatic (No symptoms)
Diagnosing AFib

- Several tests can be done to check for a fast or irregular heartbeat, documentation of AFib
- Electrocardiogram (ECG)
- Holter monitor
- Event monitor
- Mobile cardiac monitoring
- Implantable loop recorders
- Smart phone apps/devices

AFib Complications

- If left untreated, the side effects of AFib can be potentially life threatening.
- Harder for the heart to pump blood effectively. With the blood moving more slowly, it is more likely to form clots.
- If clot is pumped out of the heart, it could travel to the brain and lead to a stroke.
- AFib is the cause of about 15 out of every 100 strokes, increases risk of stroke 5X
AFib Complications

- AFib can also cause a fast pulse rate for long periods of time, the ventricles are beating too fast.
- When the ventricles beat too fast for long periods of time, the heart muscle can become weak, called cardiomyopathy, can lead to heart failure and long-term disability.

Goals of AFib Treatment

1. Reduce stroke risk
2. Prevent fast heart beat (tachycardia) mediated heart failure (cardiomyopathy)
3. Reduce/relieve symptoms

- Modify underlying risk factors
- To help prevent these complications, medical treatment for AFib usually includes one medication to reduce the chance of blood clots and stroke, and another to keep the pulse from going too fast.

Treat the Risk Factors (if possible)

- Age > 60
- Diabetes
- High Blood Pressure
- Coronary artery disease, prior heart attacks
- Congestive heart failure
- Structural heart disease (valve problems or congenital defects)
- Prior open-heart surgery
- Untreated atrial flutter (another type of abnormal heart rhythm)
- Thyroid disease
- Chronic lung disease
- Sleep apnea
- Obesity
- Excessive alcohol or stimulant use
- Serious illness or infection
Treatment: Medications

Anti-clotting agents or anticoagulants (blood thinners) help prevent blood clots that can cause stroke.

- Anticoagulants, such as **Coumadin (warfarin)**, are commonly used for patients with atrial fibrillation or mechanical heart valves, requires periodic blood tests (INR) to ensure that the blood is appropriately thinned.

- Newer anticoagulants include **Pradaxa, Xarelto, Eliquis, and Savaysa**. Blood tests are not required with the newer anticoagulants.

Antiarrhythmic drugs decrease the frequency or severity of abnormal heart rhythms, known as arrhythmias. These medications include:

- **Beta blockers** - such as metoprolol, carvedilol, and atenolol
- **Calcium channel blockers** - such as verapamil and diltiazem
- **Potassium channel blockers** - such as amiodarone, sotalol, and tikoysn (also known as dofetilide)
- **Sodium channel blockers** such as flecaïnide and rhythmol (also know as propafenone)
Treatment: Cardioversion

- Cardioversion is a corrective procedure where an electrical shock is delivered to the heart to convert, or change, an abnormal heart rhythm (Afib) back to normal sinus rhythm.

![Heart Rhythm Comparison](image)

Treatment: Ablation

- Performed by an electrophysiologist (EP), a doctor specializing in diagnosing and treating heart rhythm disorders.
- Catheters (narrow, flexible tubes) are inserted into a blood vessel, often through a site in the groin (upper thigh) or neck, and guided through the vein until they reach the heart.
- Small electrodes on the tip of the catheters stimulate and record the heart’s activity.

Treatment: Ablation

- An electrophysiology study (EPS), allows the doctor to pinpoint the exact location of the short circuit.
- Once the location is confirmed, the short circuit is either destroyed or blocked (to prevent it from sending faulty signals to the rest of the heart).
- Done by sending energy through the catheters to destroy a small amount of tissue at the site.
- Energy may be either hot (radiofrequency energy), which cauterizes the tissue, or extremely cold, which freezes or “cryoablates” it.
Treatment: Pacemakers

- Artificial pacemakers: devices that are implanted into the body, just below the collarbone, to take over the job of the heart’s own electrical system and prevent slow heart rates.
- Size of a large wristwatch face, contains a computer with memory and electrical circuits, a powerful battery (generator), and special wires called “leads.”
- The generator creates electrical impulses that are carried by the leads to the heart muscle, signaling it to pump.
Treatment: Surgical Ablation

- **Cox maze (III) procedure** is an open-heart surgery done by a cardiothoracic surgeon using a "cut-and-sew" procedure to scar the tissue.
- **Maze procedure** is a surgical ablation done by a cardiothoracic surgeon. It uses the same open-heart procedure as Cox maze III, but uses an energy source to scar the tissue. It is typically combined with other heart surgery.
- **Mini maze procedure** is a minimally-invasive surgical ablation that uses an energy source to scar the tissue. It doesn’t require opening the chest, so it has a shorter recovery time.
- Dr. Sun

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Treatment: Alternatives to Blood Thinners

- Left atrial Appendage Ligation/Exclusion strategies
- Dr. Azam and Dr. Sun

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Summary

- AFib, most common arrhythmia, emerging epidemic
- Symptoms are highly variable
- Detection and treatment are key to prevent complications
- Various treatment options available

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Thank You

Questions?

Resources
- [http://www.stopafib.org/](http://www.stopafib.org/)
- Heart Rhythm Society
  - [http://www.hrsonline.org/Patient-Resources/](http://www.hrsonline.org/Patient-Resources/)
Percutaneous Treatment Options for Stroke Risk Reduction

Salman M. Azam MD
COR Healthcare Medical Associates
Torrance Memorial Medical Center

Disclosures

• Consultant and Proctor for Edwards Lifesciences

AF is a Growing Problem Associated with Greater Morbidity and Mortality

AF = most common cardiac arrhythmia, and growing

~5 M people with AF in U.S., expected to more than double by 2050

5x greater risk of stroke with AF

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

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

• Assess stroke risk with CHA₂DS₂-VASc score
  – Score 1: Annual stroke risk 1%, oral anticoagulants or aspirin may be considered
  – Score ≥2: Annual stroke risk 2%-25%, anticoagulants are recommended

• Balance benefit vs. bleeding risk
Oral Anticoagulation is Standard of Care, but Not Ideal for All

**Warfarin**
- Bleeding risk
- Daily regimen
- High non-adherence rates
- Regular INR monitoring
- Food and drug interaction issues
- Complicates surgical procedures

**Novel Oral Anticoagulants**
- Bleeding risk
- Daily regimen
- High non-adherence rates
- Complicates surgical procedures
- Lack of reversal agents
- High cost


Introducing the WATCHMAN™ LAAC Device

A first-of-its-kind, proven alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular AF.

Most studied LAAC therapy, only one proven with long-term data from randomized trials or multi-center registries.

Comparable stroke risk reduction, and statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death compared to warfarin over long-term follow-up.


With the WATCHMAN™ LAAC Closure Device

- Minimally Invasive, Local Solution
- Available sizes: 21, 24, 27, 30, 33 mm diameter
- Intra-LAA design
  - Avoids contact with left atrial wall to help prevent complications
- Nitinol Frame
  - Conforms to unique anatomy of the LAA to reduce embolization risk
  - 10 active fixation anchors - designed to engage tissue for stability
- Proximal Face
  - Minimizes surface area facing the left atrium to reduce post-implant thrombus formation
  - 160 micron membrane PET cap designed to block emboli and promote healing
- Warfarin Cessation
  - 92% after 45 days, >99% after 12 months
  - 95% implant success rate

1. Holmes, DR et al. JACC 2014; Vol. 64, No. 1
The WATCHMAN™ LAAC Device is the most studied LAAC device and the only one proven with long-term data from randomized trials or multi-center registries:

- Five studies, >1400 patients, nearly 6000 patient-years of follow-up

The WATCHMAN Device can be implanted safely, enables patients to discontinue warfarin and reduces AF stroke risk comparably to warfarin:

- 95% implant success rate
- >92% warfarin cessation after 45 days, >99% after 1 year

WATCHMAN™ therapy demonstrated comparable stroke risk reduction, and statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death compared to warfarin over long-term follow-up:

- 32% in all cause stroke
- 83% in hemorrhagic stroke
- 63% in disabling stroke
- 56% in cardiovascular death


Most Studied LAAC Device. Only One with Long-Term Clinical Data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PROTECT AF</th>
<th>CAP Registry</th>
<th>PREVAIL Registry</th>
<th>CAP2 Registry</th>
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<td>407</td>
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Patient Risk Factors Across Trials

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<th>CAP Registry</th>
<th>PREVAIL Registry</th>
<th>CAP2 Registry</th>
<th>p-value</th>
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<td>2.6 ± 1.0</td>
<td>2.7 ± 1.1</td>
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<td>CHADS2, Risk Factors (% of Patients)</td>
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<td></td>
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<tr>
<td>CHF</td>
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<td>23.3</td>
<td>19.1</td>
<td>27.1</td>
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<td>Hypertension</td>
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<td>88.8</td>
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<td>Age ≥ 75</td>
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<td>53.6</td>
<td>51.8</td>
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<td>Diabetes</td>
<td>26.3</td>
<td>32.4</td>
<td>24.9</td>
<td>33.7</td>
<td>0.001</td>
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<tr>
<td>Stroke/TIA</td>
<td>18.5</td>
<td>27.8</td>
<td>30.4</td>
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<td>&lt;0.0001</td>
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<tr>
<td>CHADS2-VASc</td>
<td>3.5 ± 1.6</td>
<td>3.9 ± 1.5</td>
<td>4.0 ± 1.2</td>
<td>4.5 ± 1.3</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Results in animal models may not necessarily be indicative of clinical outcomes.
Implant Success & Warfarin Cessation

PROTECT AF: Implanted success = 91%
CAP: Implanted success = 94%
PREVAIL: Implanted success = 95%

*p = 0.04

Warfarin Cessation

Study | 45-day | 12-month
PROTECT AF | 87% | >93%
CAP | 96% | >96%
PREVAIL | 92% | >99%

PREVAIL Implant Success

No difference between new and experienced operators

Experienced Operators
- n=26
- 96%
New Operators
- n=24
- 90%

*p = 0.04


Favorable Procedural Safety Profile:
7-Day Safety Events

Patients with Safety Event (%)
PROTECT AF (n=232)
1st Half: 3.9%
2nd Half: 4.8%
CAP (n=231)
1st Half: 4.1%
2nd Half: 4.1%
PREVAIL (n=566)
1st Half: 3.9%
CAP2 (n=269)
1st Half: 3.9%
2nd Half: 4.8%

Learning Curve

Favorable Procedural Safety Profile:
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PROTECT AF (n=232)
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2nd Half: 4.1%
PREVAIL (n=566)
1st Half: 3.9%
CAP2 (n=269)
1st Half: 3.9%
2nd Half: 4.8%

WATCHMAN™ PROTECT AF Study Overview

Study Design & Objective
Prospective, randomized (2:1), non-inferiority trial of LAA closure vs. warfarin in non-valvular AF patients for prevention of stroke

Primary Endpoint
Efficacy: Composite end point of stroke, cardiovascular death or systemic embolization
Safety: Major bleeding, device embolization or pericardial effusion

Statistical Plan
All analyses by intention-to-treat
Bayesian (stratified for CHADS2, score): Primary Efficacy and Safety endpoints Cox Proportional: All Secondary Analyses

Patient Population
n = 707
Mean CHADS2 = 2.2, CHA2DS2-VASc = 3.5

Key Inclusion Criteria
Paroxysmal / Persistent / Permanent AF
CHADS ≥ 1 (93% had a CHA2DS2-VASc Score ≥2)
Eligible for long-term warfarin therapy

Mean Follow-Up
2,717 patient-years, 48 months

Number of Sites
59 in the United States and Europe
Enrollment Feb 2005 – June 2008

PROTECT AF: Final, 5-Year Primary Efficacy Events Consistent with 4-Year Results

<table>
<thead>
<tr>
<th>Event Rate (per 100 Pt-Yrs)</th>
<th>Rate Ratio (95% CI)</th>
<th>Posterior Probability</th>
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<tr>
<td>Watchman</td>
<td>Warfarin</td>
<td>Non-inferiority</td>
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<td>Primary efficacy</td>
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<tr>
<td>Stroke (all)</td>
<td>1.5</td>
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<tr>
<td>Systemic embolism</td>
<td>0.2</td>
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<tr>
<td>Death (CV/unexplained)</td>
<td>1.0</td>
<td>3.3</td>
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Source: FDA Oct 2014 Panel Sponsor Presentation
### Stroke & Systemic Embolism

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<th>Device/Anticoagulant</th>
<th>N</th>
<th>CHADS2</th>
<th>Primary Endpoint</th>
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<tr>
<td>PROTECT AF 1yr</td>
<td>Watchman N=463</td>
<td>244</td>
<td>2.2</td>
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<td></td>
<td>Warfarin N=244</td>
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<td></td>
<td>CAP Watchman N=566</td>
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<tr>
<td></td>
<td>RE-LY Dabigatran N=6076</td>
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<td>0.2621 pt yr</td>
</tr>
<tr>
<td></td>
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<td>Warfarin N=7036</td>
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### Cardiovascular Mortality

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<tr>
<td></td>
<td>Warfarin N=244</td>
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**PROTECT AF 4-Year Results in JAMA**

WATCHMAN™ Met Criteria for both Noninferiority and Superiority for the Primary Composite Endpoint Compared to Warfarin

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<td></td>
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<tr>
<td></td>
<td>ARISTOTLE Apixaban N=9120</td>
<td>9120</td>
<td>2.1</td>
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<tr>
<td></td>
<td>Warfarin N=9081</td>
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<td>2.1</td>
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<tr>
<td></td>
<td>ENGAGE AF Edoxaban N=7035</td>
<td>7035</td>
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<tr>
<td></td>
<td>Warfarin N=7036</td>
<td></td>
<td>2.8</td>
<td></td>
</tr>
</tbody>
</table>

**PROTECT AF/PREVAIL Pooled Analysis:**

Less Bleeding with WATCHMAN™ Device 6 Months Post-Implant

- **HR = 0.29, p<0.001**
- 71% Relative Reduction in Major Bleeding after cessation of anti thrombotics
Pooled PROTECT AF and PREVAIL
Efficacy Endpoint by Subgroup

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>&lt;75</td>
<td>0.910</td>
</tr>
<tr>
<td>≥75</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.679</td>
</tr>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>CHADS2 score</td>
<td></td>
</tr>
<tr>
<td>≤3</td>
<td>0.758</td>
</tr>
<tr>
<td>&gt;3</td>
<td></td>
</tr>
<tr>
<td>CHA2DS2-VASc score</td>
<td></td>
</tr>
<tr>
<td>≤4</td>
<td>0.271</td>
</tr>
<tr>
<td>&gt;4</td>
<td></td>
</tr>
<tr>
<td>HAS-BLED</td>
<td></td>
</tr>
<tr>
<td>≤2</td>
<td>0.098</td>
</tr>
<tr>
<td>&gt;2</td>
<td></td>
</tr>
<tr>
<td>History of TIA stroke</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0.023</td>
</tr>
</tbody>
</table>

Hazard Ratio (95% CI)

WATCHMAN™ Device Reduces Ischemic Stroke Over No Therapy

- Imputed Ischemic Stroke Rate
- Observed WATCHMAN Ischemic Stroke Rate

WATCHMAN™ Indications for Use

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

WATCHMAN is not intended to be a broad replacement for Oral Anticoagulants (OAC)

Slide courtesy from David R. Holmes, Jr. MD

FDA WATCHMAN Approval

Post Approval Study

- Prospective single arm study of 1,000 participants with the WATCHMAN device
- TWO year follow-up
- Data linkage to CMS database for long-term surveillance from years 3 to 5 post implant

WATCHMAN Novel Surveillance

- NCDR surveillance through 12 months post-implant for >1,000 patients
- NOT participating in the New Enrollment Study
- Linkage of data to CMS for long-term surveillance annually through 5 years post-implant

Slide courtesy from David R. Holmes, Jr. MD
**ASAP (Aspirin Plavix) Study**

- **Rate of success with implantation in warfarin contraindicated patients**
  - 94.7% successfully implanted
  - Avg. Procedure Time = 51.5 mins

- **Study Details**
  - Patients history of hemorrhagic & bleeding tendencies or a warfarin hypersensitivity
  - 150 patients, 4 European centers
  - Average CHADS$_2$ = 2.8
  - Post procedure anti-platelet regimen
    - Clopidogrel through 6 months
    - Aspirin indefinitely
  - Patients followed to 2 years
    - Follow-up @ 3, 6, 12, 18 & 24 months
    - TEE at 3 and 12 months
  - Average follow-up was 14.4 months

*Rate of implantation success in contraindicated patients.*

---

**Left Atrial Appendage Closure**

**What Have We Learned**

- LAAC is stable at least to 5 years with improving risk/benefit ratio
- Documented to have clinically reduction (40-50%) reduction in CV/unexplained death
- Associated with clinically significant less long term bleeding post procedure compared with warfarin
- As effective as warfarin in preventing the composite of stroke/systemic embolization

---

**Left Atrial Appendage Closure**

**What Have We Learned**

- The hypothesis that in patients with nonvalvular atrial fibrillation that stroke results from LAA thrombus is correct
- Benefit of LAA occlusion remains stable
- >90% of patients can be taken off of warfarin without harm and some patients may never need warfarin at all if they receive a device
- There is a learning curve, the more you do, the better you are at doing it.

---

**Left Atrial Appendage Closure With the Watchman Device in Patients With a Contraindication for Oral Anticoagulation**

- **Conclusions**: LAA closure with the Watchman device can be safely performed without a warfarin transition, and is a reasonable alternative to consider for patients at high risk for stroke but with contraindications to systemic oral anticoagulation.
Left Atrial Appendage Closure
What Have We Learned

• Does not prevent strokes from non LAA strokes
• > 90% of patients can be taken off of warfarin without harm and some patients may never need warfarin at all if they receive a device
• Being studied in expanded patient groups including those in whom anticoagulation is contraindicated and patients undergoing PVI

EWOLUTION Registry
- Endpoints: Additional information in real-world setting
- Est. Enrollment: Up to 5,000 patients
- Target Follow-up Duration: 2 years
- Sites: 75 international centers

WATCHMAN Asia Pacific (WASP) Registry
- Endpoints: Additional information in real-world setting
- Est. Enrollment: 300 patients
- Target Follow-up Duration: 2 years
- Sites: 10 sites in Asia Pacific region

WATCHMAN Post Approval Study
- National registry

Surgical Treatments for Atrial Fibrillation

Jack C.J. Sun, MD, MS, FRCSC
Medical Director, Cardiothoracic Surgery
Torrance Memorial Medical Center
Assistant Professor of Cardiothoracic Surgery
Keck School of Medicine of USC
Overview

- The problem of A-fib
- Traditional surgical ablation
- Concomitant surgical ablation
- Minimally invasive hybrid ablation (CONVERGENT)

The Problem of A-Fib

- Most common arrhythmia: 2.2 million people in U.S.
- Age 40-70s have incidence of 0.5%-10%
- 31% NOT associated with heart disease
- Death RR = 1.5 men, 1.9 women
- AF causes ~15% of all strokes

The Problem of A-Fib

- >80% of aberrant impulses that cause afib come from pulmonary veins
- >90% of emboli from afib come from left atrial appendage
- Antiarrhythmic drug therapy failure: 50% at 1y 84% at 2y
- Coumadin is cumbersome & can cause bleeding
- NOA is expensive & can cause bleeding

Traditional Surgical Ablation
- Cox-Maze III (1995) = “the gold standard”
- Sternotomy, CPB
- 99% success rate reported by Cox

Cox-Maze IV Ablation
- Surgical procedure that eliminates atrial fibrillation
- Done in combination with open heart procedure (eg. Mitral valve surgery, Coronary bypass)
- Lesions/scars in left & right atria (radiofrequency & cryoablation)
- Lesions trap Afib electrical impulses & stop them from spreading

Traditional Surgical Ablation
- Not done anymore for lone AFib
- Complex & invasive
- High rate of permanent pacemaker requirement

Concomitant Surgical Ablation
- Rates of preoperative A-Fib:
  - CABG 6.9%
  - AVR 15.6%
  - MVR 31.7%
- ~11% open heart surgery patients
Concomitant Surgical Ablation

- Cons of not performing concomitant ablation:

  >90% stay in Atrial Fibrillation

  2-3x higher risk for Stroke at 6-8y

  1.5-2x higher risk for death at 5y

Figure 2. Right atrial lesions of the Cox maze IV procedure: (A) three right atrial lesions; (B) incision in body of right atrium; (C) lesion to superior vena cava; (D) lesion to inferior vena cava; (E) cryolesion to tricuspid annulus at the 2-o’clock position; and (F) incision in right atrial appendage and cryolesion to tricuspid annulus at the 10-o’clock position.
### Concomitant Surgical Ablation

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>MV+SA Events</th>
<th>MV Events</th>
<th>Total Events</th>
<th>Weight</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
<th>Year</th>
<th>Year 2000-2004</th>
<th>Year 2005-2009</th>
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<tbody>
<tr>
<td></td>
<td>Total Events</td>
<td>Weight</td>
<td>Odds Ratio</td>
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<td></td>
<td>MV</td>
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<td></td>
<td>Subtotal</td>
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</table>

**Take Home Message**

If you have Afib & are having open heart surgery: 

Make sure your surgeon does an ablation!
Minimally Invasive Hybrid Atrial Fibrillation Ablation (CONVERGENT)

- Combine benefits of surgery & catheter ablation
- Two-step procedure
- Less invasive than traditional heart surgery
- More successful than catheter ablation alone

Long-Term Success for the Convergent Atrial Fibrillation Procedure: 4-Year Outcomes

Borut Gersak, MD, PhD, and Matevž Jan, MD
University of Ljubljana School of Medicine, and Department of Cardiovascular Surgery, University Medical Center Ljubljana, Ljubljana, Slovenia

ADULT CARDIAC

Repeat ablation was observed 1 year after the convergent

85% of patients were in SR, with 61% in SR off AADs. No

who received both epicardial and endocardial compo-

2013. Ninety-

ections, and 1 required reisolation of only the superior

Persistent 12 (16)

4 2 (3)

3 12 (16)

0 16 (21)

Clinical presentation at follow-up for patients (n

fliemed

28.9

¼

DS

2

ned by the Heart Rhythm

DS

¼

C21

¼

C20

¼

C6

¼

Bar, CA) were used for endocardial ablation at a

mond Bar, CA) were used for endocardial ablation at a

injury or ulceration of the esophagus has been detected.

components of the procedure; (2) injection of saline into

implemented, and included (1) esophageal temperature

previously and included two esophageal

6 months, 75% at 1 year, 70% at 2 years, 60% at 3 years, and

years, 71% at 3 years, and 79% at 4 years. Prevention of

Table 1. Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>56.6 ± 10.1 (31–79)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>28.9 ± 4.0 (20.2–42.3)</td>
</tr>
<tr>
<td>Preoperative left atrium, cm</td>
<td>4.7 ± 0.5 (3.2–5.7)</td>
</tr>
<tr>
<td>Preoperative LVEF, %</td>
<td>59.2 ± 12.0 (28–84)</td>
</tr>
<tr>
<td>Atrial fibrillation duration, years</td>
<td>5.2 ± 4.5 (1–25)</td>
</tr>
<tr>
<td>Atrial fibrillation type</td>
<td></td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Persistent</td>
<td>12 (16)</td>
</tr>
<tr>
<td>Longstanding persistent</td>
<td>60 (79)</td>
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Table 2. Clinical Presentation at Each Follow-Up Visit

<table>
<thead>
<tr>
<th>Follow-Up Visit</th>
<th>Sinus Rhythm</th>
<th>Sinus Rhythm, No Interventions</th>
<th>Sinus Rhythm, No AADs</th>
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</thead>
<tbody>
<tr>
<td>6 months</td>
<td>88 (59/67)</td>
<td>85 (57/67)</td>
<td>60 (40/67)</td>
</tr>
<tr>
<td>12 months</td>
<td>85 (52/61)</td>
<td>77 (47/61)</td>
<td>61 (37/61)</td>
</tr>
<tr>
<td>24 months</td>
<td>85 (49/58)</td>
<td>66 (38/58)</td>
<td>62 (36/58)</td>
</tr>
<tr>
<td>36 months</td>
<td>84 (43/51)</td>
<td>73 (37/51)</td>
<td>73 (37/51)</td>
</tr>
<tr>
<td>48 months</td>
<td>81 (29/36)</td>
<td>72 (26/36)</td>
<td>69 (25/36)</td>
</tr>
</tbody>
</table>

Values are percent (n/N).
AAD = antiarrhythmic drug.

What about the left atrial appendage?
Summary

- Atrial Fibrillation associated with worse quality of life, complications, & death
- Atrial fibrillation affects people more as they age
- Cutting edge therapies for afib
- Multidisciplinary approach
- Minimally invasive & maximum results
Questions?