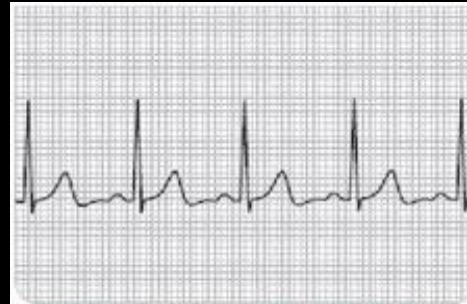
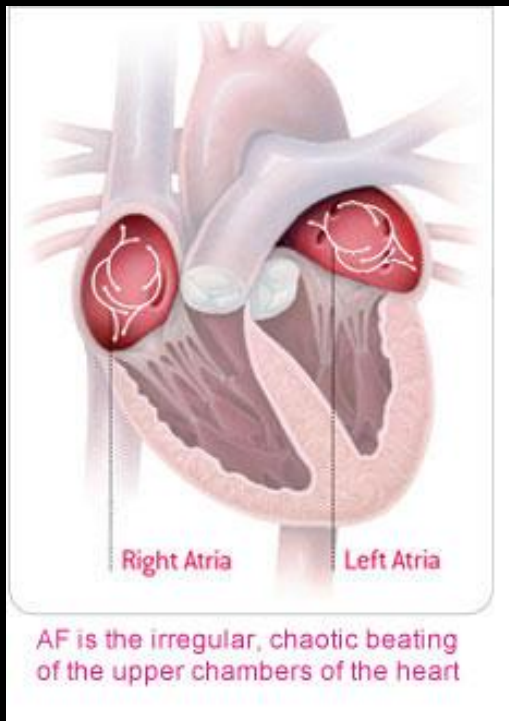


Boston Scientific Watchman

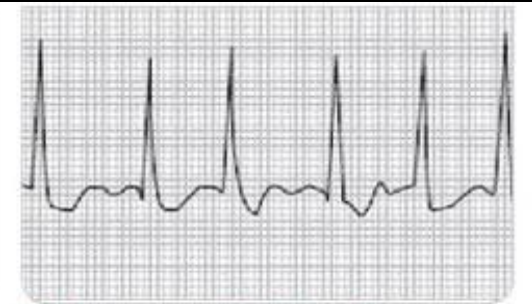
Left Atrial Appendage Closure Device

Janelle Martin Guerrero
CEPT 348 Presentation
Class of 2013

ATRIAL FIBRILLATION



ECG tracing a normal heart rhythm



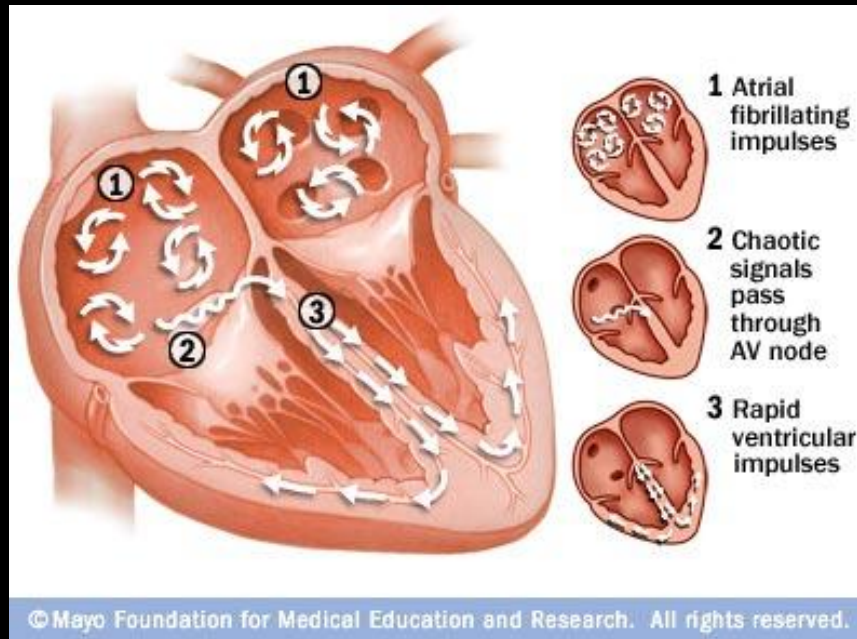
ECG tracing atrial fibrillation (AF).
The rhythm is irregular and erratic.

In patients with **Atrial Fibrillation (AF)**, blood tends to pool & form clots in an area of the heart called the **left atrial appendage (LAA)**.

- The **LAA** is a pouch-like extension located in the upper left chamber of the heart.
- A **blood clot** that breaks loose from this area may migrate through the blood vessels & eventually plug a smaller vessel in the brain or heart resulting in a stroke or heart attack. **20%** of all strokes are related to AF.
- Clinical studies show that the **majority** of blood clots in patients with AF are found in the LAA.

Blackshear J.L., Odell J.A., Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients with Atrial Fibrillation. Annals of Thoracic Surgery, 1996;61:755-759.

RISKS OF ATRIAL FIBRILLATION



Risks of Afib include:

- Stroke
- Cardiac Dysfunction
 - Increased LA pressure & volume
 - Decreased stroke volume
 - Shortened diastolic ventricular filling period
 - Regurgitation of AV valve
 - Irregular, rapid ventricular rate → potential LV systolic dysfunction
- Poor Quality of Life
- All-Cause Mortality

ATRIAL FIBRILLATION

Prevalence:

- 2.2 million people in the U.S. have Afib
 - Median age: **75** (65-85 are 70% of Afib population)
 - For those older than **40**, the prevalence averages **2.3%**
 - For those older than **65**, the prevalence averages **5.9%**
- Diseases associated with Afib include:
 - Heart disease, coronary artery disease, heart valve disease, hypertrophy cardiomyopathy, congenital heart disease, obesity, diabetes mellitus, metabolic syndrome, hyperthyroidism, chronic kidney disease and status post cardiac surgery

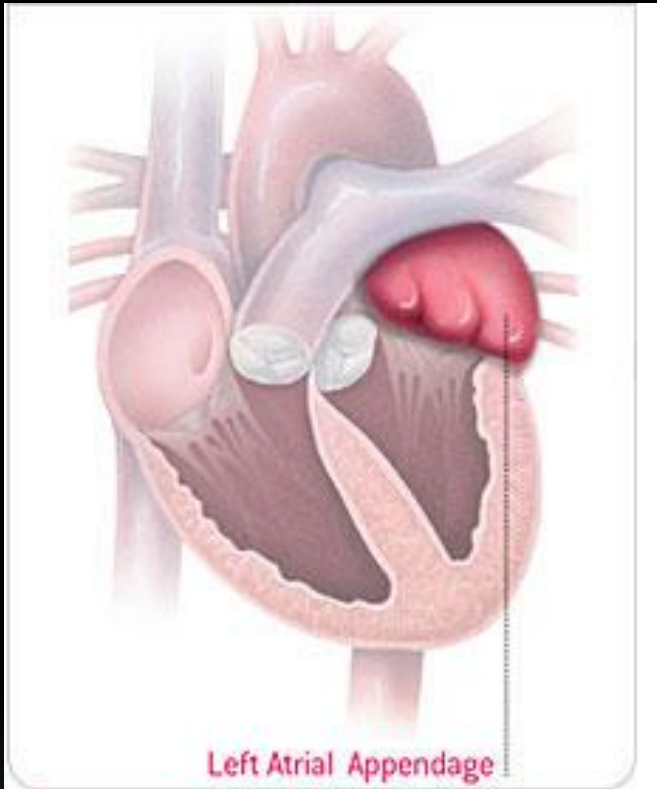
Risk Factors:

- Family history of CAD, polygenic & monogenic inheritance, birth weight, inflammation & infection, pericardial fat, autonomic dysfunction, prolonged QT interval, supraventricular tachycardias, decreased Mg levels, alcohol & caffeine, medications and decrease activity.

Afib & Stroke:

- A person with Afib is **five times** more likely to have a stroke than someone without Afib.
- **15%** of people who have a stroke, have Afib
- **3 out of 4** Afib-related strokes can be prevented

STROKE PREVENTION



The Left Atrial Appendage (LAA) is a pouch like extension on the left side of the heart

- Since the majority of blood clots are found in the LAA, it is believed that **closing off the appendage** may **reduce** the risk of stroke & potentially **eliminate** the need for long term anticoagulation therapy.
- The **WATCHMAN Left Atrial Appendage Closure (LAAC)** device is an alternative to anticoagulant therapy in patients with non-valvular AF.
- The **WATCHMAN LAAC** device is designed to **close off the LAA**, thus reducing the risk of stroke, CV death & systemic embolization, & potentially eliminating need for long term anticoagulation therapy.
- An obvious patient **benefit** is the elimination of anticoagulants, which may reduce bleeding-related-events such as bruising, nose bleeds, GI bleeding, or more importantly, hemorrhagic strokes.

WATCHMAN TECHNOLOGY



The **WATCHMAN LAAC** technology is a device-based solution designed to be permanently implanted **at or slightly distal** to the ostium of the LAA. It is intended to **trap** blood clots before they exit the LAA.

It consists of a **three part system**:

- 1) transseptal access sheath
- 2) delivery catheter
- 3) implantable device

WATCHMAN LAA CLOSURE DEVICE



- What is it? A self-expanding **nitinol frame** structure with **fixation barbs** & a permeable polyester fabric that covers the **atrial facing** surface of the device.
- How is it implanted? The device is preloaded within a delivery catheter.
- Can it fit any LAA? **WATCHMAN LAAC** device is available in 5 sizes to accommodate the unique anatomy of each patient's LAA. Size selection is based on LAA measurements obtained via Fluoro & TEE in multiple angles (0°, 45°, 90°, 135°).
- Is it MRI compatible? It has been determined to be Magnetic Resonance (MR) **conditional**, meaning a patient with this device can be scanned safely if the static magnetic field is **3-Tesla or less** & spatial gradient field is **720-Gauss/cm or less**.
- Contraindications include: the presence of intracardiac thrombus, atrial septal repair closure device, or the any other established contraindications for percutaneous &/or catheterization interventions.
- Precautions: Patients should be fully heparinized throughout the procedure with ACT of **200-300s** after transeptal puncture. Device embolization risk exists with cardioversion **< 30 days** following implantation & therefore, device position must be verified post cardioversion.

WATCHMAN ACCESS SHEATH



Single Curve



Double Curve

The **WATCHMAN** access sheath is utilized to gain access into the LAA & serves as a conduit for the delivery catheter. It is available in both a **single** curve (90° angle) & **double** curve distal tip configuration.

WATCHMAN PROCEDURE

- <http://www.youtube.com/watch?v=ZFWMB42Y0KE>
- A transoesophageal echocardiogram (TEE) is performed to measure the LAA to determine which size WATCHMAN device to be implanted.
- After the inter-atrial septum is crossed using a standard transseptal access system, the WATCHMAN access sheath & dilator are advanced over a guidewire into the LA.
- The access sheath is then carefully advanced into the distal portion of the LAA over a pigtail catheter.
- The WATCHMAN delivery system is prepped, inserted into the access sheath, & slowly advanced under fluoroscopic guidance.
- The WATCHMAN device is then deployed into the LAA.

DEPLOYMENT OF WATCHMAN IN LAA



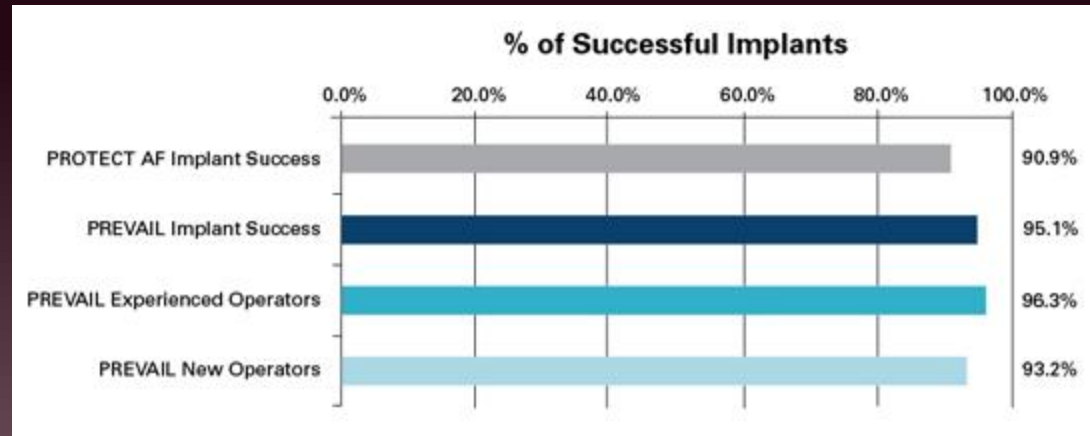
- Placement of the **WATCHMAN** is confirmed via fluoroscopy & prior to releasing the device.
- Also, following implantation, a **TEE** is performed to judge completeness of **closure** & the presence of **blood clots**.
- It takes about **45 days** for an **endothelial layer** to grow over the device.

PROTECT AF Study:

- The PROTECT AF clinical trials' primary efficacy endpoints were all stroke, CV death & systemic embolism.
- A total of 800 patients were enrolled in the study from February 2005 – June 2008 at 59 centers in the United States & Europe.
- All study patients were required to complete follow-up assessments at 45 days, 6 months, 9 months, 12 months & semi-annually thereafter for the duration of the study.
- Patients who were assigned to the WATCHMAN group & successfully implanted, maintained Warfarin therapy for 45 days following the procedure.
- 4-year follow-up data showed that WATCHMAN LAAC device was statistically superior to warfarin for reducing the relative risk of the composite primary endpoint of CV death, all stroke & systemic embolization, as well as both all-cause mortality & CV mortality.
- Long-term efficacy reveals that WATCHMAN is a viable alternative to chronic warfarin therapy for stroke reduction in non-valvular AF patients.
- To date, more than 2000 patient with 4800 patient-years of follow-up have been studied in clinical trials of the WATCHMAN device.

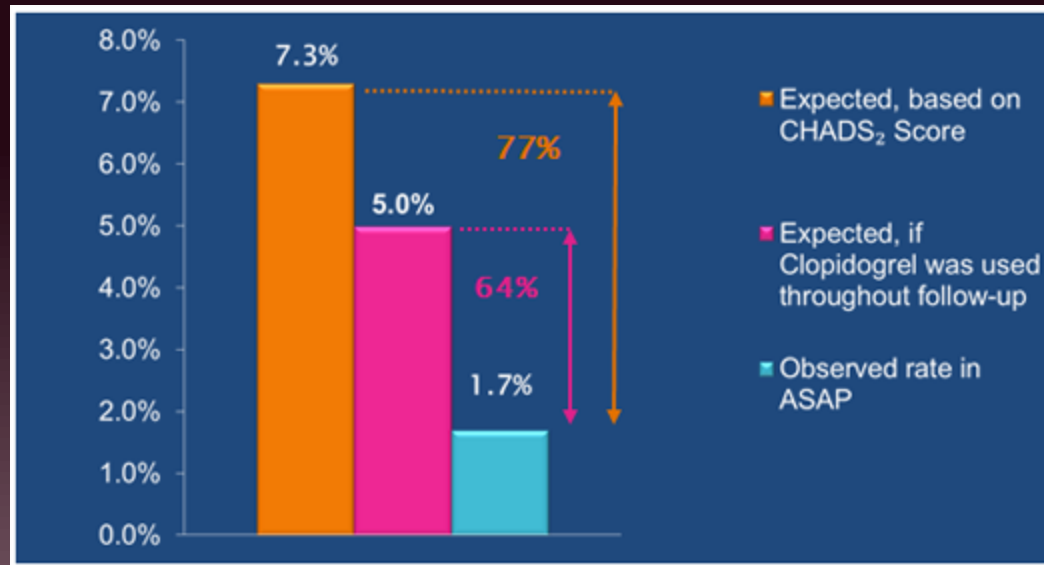
PREVAIL Study:

- Positive results from the **PREVAIL** trial demonstrated acute procedure & device-related risks *remained low* for the WATCHMAN LAAC device.
- Evidence revealed the Watchman device can be successfully implanted by *new* operators.
- Results showed *low complication* rates with both new & experienced operators & significantly *lower complications* than the early stage of the **PROTECT AF** trial.
- WATCHMAN is the only *device-based* alternative to anticoagulation that has undergone *rigorous* scientific study. Results of the **PREVAIL** trial added to the wealth of previously published data which confirmed the utility of **WATCHMAN** as an option for the *reduction of stroke in high risk patients*.



ASAP Registry:

- The *ASAP registry*, a non-randomized feasibility study, was designed to assess the safety & efficacy LAA closure in non-valvular AF patients *ineligible* for warfarin therapy.
- LAAC with the *WATCHMAN* device produced a significant *reduction* in the expected *ischemic stroke rate* for patients contraindicated to warfarin.
- The *ASAP registry* demonstrated a *77% reduction* in ischemic stroke in warfarin contra-indicated patients vs. Aspirin alone & a *64% reduction* vs. Aspirin & Clopidogrel.



WATCHMAN ADVERSE EVENTS

WATCHMAN Adverse Events:

- The main **adverse events** related to this procedure include:
 - pericardial effusion
 - incomplete LAA closure
 - dislodgement of the device
 - blood clot formation on the device requiring prolonged oral anticoagulation
 - the general risks of catheter-based techniques (such as air embolism)
 - The LA anatomy can also preclude use of the device in some patients
- Following implantation, a **TEE** must be performed to judge completeness of **closure** & the presence of **blood clots**.
- Patients need to use low dose **aspirin** indefinitely, & prolonged **clopidogrel** can be prescribed as well.
- **Oral anticoagulants** are needed following implantation of the WATCHMAN device to allow blood vessel lining to form around the device (**endothelialization**). Endothelium growth typically takes **45 days**.
- There are concerns regarding the role of the LAA in **thirst regulation & water retention** because it is an important source of **atrial natriuretic factor**. Preserving the RAA **might** attenuate this effect.

References

- WATCHMAN Left Atrial Appendage Closure Device website:
<http://www.bostonscientific.com/watchman-eu/>
- “Prevalence, Age Distribution, and Gender of Patients with Atrial Fibrillation”; Drs. Feinberg, Blackshear, Laupacis, Kronmal & Hart. Arch Intern Med; 2013 Mar 13; 155(5): 469-73
- Journal of the American College of Cardiology website:
<http://content.onlinejacc.org/journal.aspx>