



The Watchman Device: An Alternative Treatment in Atrial Fibrillation

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Abstract

Stroke prevention is an important aspect in the management of Atrial Fibrillation (AFib). The 2019 Guideline for Management of Patients with Atrial Fibrillation recommends DOACs as first line, but warfarin is also still widely used. These medications are effective but their systemic effect on the body require careful monitoring to avoid serious adverse events, contraindications, and other drug-drug interactions. As a result, many patients do not adhere or cannot tolerate the medications, therefore physicians continue to search for alternatives. The latest focus has been on the Watchman Device, a device that essentially seals off the left atrial appendage closure (LAAC). The LAAC is an area in the heart where blood clots often form in patients with AFib. The Watchman device prevents the clots in this area from escaping, lowering the risk of stroke. Though the Watchman device has been shown to be an effective non-pharmacological substitute, careful patient consideration remains an emphasis when choosing treatment. Staying informed and knowing what treatment options are available, along with understanding the patient and his/her preferences, can aid in deciding on the most effective option to prevent stroke.



Atrial fibrillation (AFib) affects approximately 2.7–6.1 million people in the United States.¹ While some patients are asymptomatic, others may experience symptoms such as tachycardia, heart palpitations, dizziness, fatigue or shortness of breath.¹ One of the greatest concerns with AFib is that AFib increases a person's risk for stroke by four to five times when compared to people who do not have AFib.¹

Treatment

The American Heart Association (AHA) treatment goals for atrial fibrillation (Afib) are reducing the heart rate < 80 bpm (rate control), restoring the heart to a normal rhythm (rhythm control), preventing thromboembolism, reducing the risk of developing stroke or heart failure, and preventing additional heart rhythm problems.² Rate control is preferred over rhythm control.² The need for anticoagulation therapy is determined by the CHA₂DS₂-VASc score. The score is calculated by scoring the following risk factors: congestive heart failure (CHF), hypertension, age ≥ 65, diabetes, stroke, vascular disease (heart attack, peripheral artery disease, or aortic plaque), and female sex.² Adults between 65 and 74 receive one point for their score, while age over 74 receive two points. A CHA₂DS₂-VASc ≥ 2 for men and ≥ 3 for women indicates the need for anticoagulation. According to the AHA Afib treatment guidelines, there are several options used to treat Afib: medications, nonsurgical procedures, and surgical procedures.²

Medications, for most patients, are the most preferred method of treatment.³ Medication options may include anticoagulants, rate control medications, and

rhythm control medications.³ Anticoagulants, such as warfarin, Direct Oral Anticoagulants (DOACs), and aspirin are prescribed to prevent and treat blood clots.² Beta blockers, non-dihydropyridine calcium channel blockers (non-DHP CCB), digoxin, and amiodarone can be all used for rate control.² The AHA guidelines recommend a beta-blocker or non-DHP CCB as first-line therapy for paroxysmal, persistent, or permanent Afib.² Sodium channel blockers (lidocaine, procainamide, flecainide) and potassium channel blockers (amiodarone, dronedarone, dofetilide) can be used for rhythm control.² Amiodarone is usually reserved when other methods are unsuccessful or contraindicated.³ The heart rhythm can be more difficult to control, especially if patients are untreated for an extended period of time.³

Nonsurgical procedures used to treat Afib are electrical cardioversion or ablation.² Electrical cardioversion uses an electrical shock to reset the heart to a normal rhythm. The procedure is similar to defibrillation, but uses much lower energy. The risk with cardioversion is that it may free loose clots from the heart and into the blood vessels. Therefore, transesophageal echocardiography (TEE) is also recommended to check for blood clots in the atria before the procedure.^{3,5} Ablation is a nonsurgical, catheter-based procedure used when medications or cardioversion is not preferred or effective.³ Ablation can be done by radiofrequency, laser, or cryotherapy to scar problematic areas of the heart that cause irregular rhythm.³ The common sites for ablation in Afib are the pulmonary vein and AV node.³ Ablation is generally safe, but there is an increased risk of Afib returning within a few months and the patient would



have to repeat the procedure or take rhythm control medication.⁶

There are also surgical procedures for the treatment of Afib, which includes implanting a pacemaker and open-heart maze surgery, that are last line treatment.³ A pacemaker is usually implanted under the skin and sends electrical signals to maintain a steady contracting rhythm. Open-heart maze surgery is a complex procedure in which a surgeon creates small incisions in the upper part of the heart.³ The incisions are then stitched together causing scar tissue to form, which interferes with the transmission of electrical impulses that can cause Afib.³ Normal heartbeat is usually restored in these procedures but they are invasive and possess risks such as infection or developing new arrhythmias.^{7,8}

Pathophysiology

Recently in 2015, the FDA approved a new medical intervention called the WATCHMAN device.⁹ The WATCHMAN device may serve as an alternative for patients who cannot tolerate the use of oral anticoagulants or who do not qualify/failed surgical procedures to restore normal sinus rhythm. To understand the importance of the WATCHMAN device, the pathophysiology of AFib should first be reviewed. The heart acts as a pump with its own very sophisticated electrical system. Disrupting the electrical system leads to heart rhythm issues, such as AFib. In normal electrical conductance, the sinoatrial (SA) node sends signals to the atrioventricular (AV) node and there is normal rhythm. However, when a patient has AFib, there are signals in the atria that are originating in areas of the heart other than the SA node. The signals spread through the atria in a rapid, disorganized way. The

result is a very fast and irregular contraction of the atria in a quivering manner.

In Afib, the heart works less efficiently as a pump. Blood flow within the heart chambers have slowed so stagnant blood flow occurs and blood clots can form, causing stroke associated with AFib. For patients with Afib, over 90% of stroke causing clots that originated in the heart are formed in a structure called the left atrial appendage (LAA).¹⁰ This small pouch resides on the left side of the heart. The clots that form in the LAA may break away into an arterial highway and travel directly into the brain. As the blood vessels branch off and become finer, the clot will block further blood flow to the brain. The nerve cells in these area of the brain are deprived of oxygen and die. This complication is known as an ischemic stroke. Since clots that are formed in the heart are rather large, ischemic stroke caused by AFib can be fatal or cause permanent disabilities.

The WATCHMAN Device

The WATCHMAN device is a 2015 FDA-approved left atrial appendage closure (LAAC) device for reducing the risk of stroke in non-valvular AFib patients.¹¹ Performed in a one-time procedure, the WATCHMAN is an implant that fits directly in the left atrial appendage to permanently seal it off to prevent blood clots from escaping.¹¹ Roughly the size of a quarter, the WATCHMAN is created from light and compact materials commonly used in other medical device implants such as nickel or titanium.¹¹ To implant this device, a small incision is made in the upper leg to allow a catheter to be inserted, such as in a standard stent procedure.¹¹ Then, the WATCHMAN device is guided into the LAA of the heart; this procedure takes about an hour with patients

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under general anesthesia.¹¹ Patients who receive this procedure normally stay overnight in the hospital and go home the following day.¹¹

Following the WATCHMAN implant procedure, patients are typically given warfarin up to 45 days after the procedure until the LAA is permanently sealed off.¹¹ Over 45 days, the tissue of the heart will grow over the implant, forming a barrier against future blood clots.¹¹ Once this tissue has efficiently grown to cover the implant, warfarin will be stopped and clopidogrel will be initiated, as well as aspirin to be taken orally for the next six months.¹¹ Once the six months has been completed, aspirin will likely be recommended on an ongoing basis to ensure maximal reduction in the risk of thrombi development.¹¹

In a recent clinical trial by EWOLUTION, the WATCHMAN was implanted successfully in 98.5% of patients with no flow or minimal residual flow achieved in 99.3% of patients.⁴ More than 60,000 the WATCHMAN procedures have been executed worldwide and did not have the same high bleeding risk as patients using long-term warfarin therapy.¹¹ Important safety information in the EWOLUTION study revealed risks that were associated with the general implant procedure, as well as use of the device. Such risks included, but were not limited to: accidental heart puncture, air embolism, arrhythmias, anemia, anesthesia risks, allergic reactions, excessive bleeding, blood clot or air bubbles in the lungs or other organs, renal failure, stroke, thrombosis, and in rare cases, death.¹¹ Therefore, patients must talk with their physician prior to initiating the WATCHMAN device to make sure the WATCHMAN is right for them.

There has also been data on the overall prevention of stroke and decreased mortality rates with the WATCHMAN device. The data from two randomized studies (PROTECT-AF and PREVAIL) and multiple registries formed the basis for the FDA's approval as the only endovascular device indicated for stroke prevention.¹² In the PROTECT-AF study, the WATCHMAN device was shown to be noninferior to warfarin for overall stroke prevention but superior in respect to a decrease in hemorrhagic stroke and long-term bleeding, and to be associated with a reduction in all-cause mortality.¹² The meta-analysis of PROTECT-AF and PREVAIL also showed similar all-cause stroke or systemic embolization rates between the WATCHMAN and warfarin, with lower hemorrhagic stroke and cardiovascular mortality with the WATCHMAN.¹²



Knowledge Check: True or False? The Watchman device is the only endovascular device that is FDA approved for stroke prevention.

Answer: True

Conclusion

As an alternative to chronic anticoagulant therapy, the WATCHMAN device is becoming more widely used in the treatment of Afib as more literature has becomes available. Patients who have been on long-term anticoagulants may be concerned with the risk of side effects and

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increased drug interactions with other medication therapies. In addition, a higher amount of bleeding episodes may be a reasonable justification for seeking an alternative intervention. Regarding warfarin, bleeding risks greatly impacts the patient's life and there is the need to periodically check INR, go to follow-up visits, and have constant wary of diet and activities. On the contrary, the WATCHMAN is a one-time permanent implant and does not have the same high bleeding risk as patients using long-term oral anticoagulants. If patients are at a high-risk of bleeding or have increased bleeding complications due to lifestyle factors, they may benefit from the WATCHMAN device and be further assessed as candidates for the implant procedure. In conclusion, the new development of the WATCHMAN device may serve as an effective alternative in AFib treatment and provide an overall more healthful quality of life.



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