

Video Article

The WATCHMAN Left Atrial Appendage Closure Device for Atrial Fibrillation

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Abstract

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting an estimated 6 million people in the United States¹. Since AF affects primarily elderly people, its prevalence increases parallel with age. As such, it is expected that 15.9 million Americans will be affected by the year 2050². Ischemic stroke occurs in 5% of non-anticoagulated AF patients each year. Current treatments for AF include rate control, rhythm control and prevention of stroke³.

The American College of Cardiology, American Heart Association, and European Society of Cardiology currently recommended rate control as the first course of therapy for AF³. Rate control is achieved by administration of pharmacological agents, such as β -blockers, that lower the heart rate until it reaches a less symptomatic state³. Rhythm control aims to return the heart to its normal sinus rhythm and is typically achieved through administration of antiarrhythmic drugs such as amiodarone, electrical cardioversion or ablation therapy. Rhythm control methods, however, have not been demonstrated to be superior to rate-control methods⁴⁻⁶. In fact, certain antiarrhythmic drugs have been shown to be associated with higher hospitalization rates, serious adverse effects³, or even increases in mortality in patients with structural heart defects⁷. Thus, treatment with antiarrhythmics is more often used when rate-control drugs are ineffective or contraindicated. Rate-control and antiarrhythmic agents relieve the symptoms of AF, including palpitations, shortness of breath, and fatigue⁸, but don't reliably prevent thromboembolic events⁶.

Treatment with the anticoagulant drug warfarin significantly reduces the rate of stroke or embolism^{9,10}. However, because of problems associated with its use, fewer than 50% of patients are treated with it. The therapeutic dose is affected by drug, dietary, and metabolic interactions, and thus requires detailed monitoring. In addition, warfarin has the potential to cause severe, sometimes lethal, bleeding². As an alternative, aspirin is commonly prescribed. While aspirin is typically well tolerated, it is far less effective at preventing stroke¹⁰. Other alternatives to warfarin, such as dabigatran¹¹ or rivaroxaban¹² demonstrate non-inferiority to warfarin with respect to thromboembolic events (in fact, dabigatran given as a high dose of 150 mg twice a day has shown superiority). While these drugs have the advantage of eliminating dietary concerns and eliminating the need for regular blood monitoring, major bleeding and associated complications, while somewhat less so than with warfarin, remain an issue¹³⁻¹⁵.

Since 90% of AF-associated strokes result from emboli that arise from the left atrial appendage (LAA)², one alternative approach to warfarin therapy has been to exclude the LAA using an implanted device to trap blood clots before they exit. Here, we demonstrate a procedure for implanting the WATCHMAN Left Atrial Appendage Closure Device. A transseptal cannula is inserted through the femoral vein, and under fluoroscopic guidance, inter-atrial septum is crossed. Once access to the left atrium has been achieved, a guidewire is placed in the upper pulmonary vein and the WATCHMAN Access Sheath and dilator are advanced over the wire into the left atrium. The guidewire is removed, and the access sheath is carefully advanced into the distal portion of the LAA over a pigtail catheter. The WATCHMAN Delivery System is prepped, inserted into the access sheath, and slowly advanced. The WATCHMAN device is then deployed into the LAA. The device release criteria are confirmed via fluoroscopy and transesophageal echocardiography (TEE) and the device is released.

Video Link

The video component of this article can be found at <http://www.jove.com/video/3671/>

Protocol

1. The WATCHMAN Device

1. The WATCHMAN device frame is constructed of nitinol (a nickel/titanium alloy) and is composed of 10 fixation anchors around the device perimeter that are designed to secure the device in the LAA (Figure 1).

A fabric cap, constructed out of fabric polyethyl terephthalate (PET) serves as a 160-micron filter and prevents harmful emboli from exiting during the healing process.

2. The device comes in 5 different sizes: 21, 24, 27, 30, 33 mm, and the contoured shape of the device accommodates most LAA anatomy.
3. The WATCHMAN Transseptal Access System is available in double or single curve styles (14 French (F) Outer Diameter (OD) 4.7 mm), 12F Inner Diameter (ID)) with a 75 cm working length (Figure 2).
4. The device is preloaded (constrained) within the 12F delivery catheter. Note: The WATCHMAN delivery system is compatible with all 5 device sizes (12F OD) (Figure 3). Procedure:

2. TEE-Based Determination of WATCHMAN Device Size

1. Prior to starting the procedure, a transesophageal echocardiogram (TEE) is performed to document the absence of thrombi within the LAA and to determine the appropriate sized WATCHMAN device to be implanted. The recommended international normalized ratio should be ≥ 1.5 to perform the implantation procedure.
2. With the patient under conscious sedation (e.g. midazolam 2-5 mg), pass the ultrasound probe into the esophagus.
3. Confirm the absence of LA/LAA thrombus.
4. Assess the following LAA features: ostium size and shape, number of lobes, location, working length in the LAA, and pectinate features. The maximum LAA ostium size should be $>17\text{mm}$ or $<31\text{mm}$ to accommodate available WATCHMAN device sizes.
5. To do this, measure the LAA ostium in at least 4 TEE views. First measure the ostium at 0 degrees from the left coronary artery to a point 2 cm from tip of the left upper pulmonary vein limbus. Then measure it at 45, 90, and 135 degrees from the top of the mitral valve (MV) annulus to a point 2 cm from tip of the left upper pulmonary vein (LUPV) limbus.
6. Measure the approximate LAA usable length from the ostium line to the apex of the LAA. The available/useable LAA length should be equal to or greater than the largest distance measured.
7. To aid in planning the approach, categorize the LAA type: most can be categorized as "WindSock Type", "ChickenWing Type" or "Broccoli Type". With the LAA form categorized, the difficulty of the implantation procedure can be estimated.
8. The WindSock Type LAA, (Figure 4, left), is an anatomy in which one dominant lobe of sufficient length is the primary structure. The implantation procedure in most of these cases is relatively easy to perform.
9. The ChickenWing Type LAA is an anatomy whose main feature is a sharp bend in the dominant lobe of the LAA anatomy at some distance from the perceived LAA ostium (Figure 4, center).
10. If the proximal part longer than the widest diameter the implant procedure is straightforward. However, if the proximal part is shorter than the maximum width of the LAA orifice, the procedure may be complicated.
11. The Broccoli Type LAA is an anatomy whose main feature is an LAA that has limited overall length with more complex internal characteristics (Figure 4, right). When this anatomy is present, the device is often difficult to implant since there are several lobes to cover and the length of the LAA is limited.

3. Pre-Implantation Preparation

1. The WATCHMAN LAA Closure Device placement procedure should be performed under local or general anesthesia in a catheterization laboratory with diagnostic imaging equipment used to support the catheterization procedure.
2. Begin by preparing the catheterization lab for the procedure. The following equipment should be available:
3. A venous introducer, a standard transseptal access system (TAS), a 0.035" guidewire (e.g. Amplatz Super stiff 260cm) with exchange length/extra support, a pigtail catheter (4-5 F), a contrast syringe (60CC), and a mandatory pressurized saline bag with drip chamber/sterile line.
4. The appropriate WATCHMAN Access Sheath with corresponding dilator, single or double, the WATCHMAN Delivery System, and the optional WATCHMAN obturator, which is helpful in LAA anatomies with an acute bend.
5. It is recommended that a 5F arterial access sheath be used for pressure measurement, marking the aortic root during transseptal puncture, and quick complication management, if needed.
6. Also in case of complications the following materials should be available: a pericardiocentesis tray, a 14-16F sheath for device retrieval, a loop, biptome, coronary guiding catheters, a thrombectomy device (e.g. Medtronic export catheter), and a coronary guidewire.
7. In addition, the procedure requires a blood pressure monitor, an electrocardiography (EKG) device, and a pulse oximeter as a minimum for conscious sedation, plus supplementary airway devices such as a laryngeal mask airway (LMA), an endotracheal (ET) tube and laryngoscopes for emergencies.
8. The use of echocardiographic imaging is required, and transesophageal echocardiography is recommended. Biplane fluoroscopy should be used if it is available.
9. Once the room is ready, have the patient lay down flat on his or her back. Have the patient place his arms behind his head. Then strap the patient's arms and legs into place, taking care to avoid injury to the plexus of the arms.
10. For analgosedation administer 5 mg midazolam and 1% propofol according the patient's body weight. Then, administer a bolus of 1 mg/kg of propofol followed by continuous infusion of 5 to 10 mg / kg bodyweight per hour intravenously.
11. Immediately before the procedure begins, administer 20 mL of 1% lidocaine as a local anesthetic in the groin region.

4. Implantation of the WATCHMAN Device

1. Once the patient is fully anesthetized, clean and prep the femoral vein region for cannulation.
2. Locate the femoral vein, and then insert the venous introducer of a standard transseptal access system medial to the femoral vein and into the femoral vein. Once it is in place, insert the 0.035" guidewire and vessel dilator into the femoral vein to access the heart.
3. Then, introduce a 5F sheath into the femoral vein. Place a pigtail catheter in the aortic root as a landmark and for pressure monitoring.
4. Advance the transseptal sheath and needle into the upper vena cava. Monitor the central venous pressure. Then, pull back the sheath with the needle until a tenting of the needle on the atrial septum is seen in the TEE.
5. Using TEE, identify the mid to lower part of the posterior septum. This is the optimal place for transseptal crossing. Recheck the position under fluoroscopy using the lateral view, then advance the needle and sheath into the left atrium and advance the sheath into the upper pulmonary vein.
6. Advance a 0.0035" stiff guidewire (e.g. Amplatz Super stiff 260 cm) into the left upper pulmonary vein and remove the transseptal access system, leaving the guidewire in place.
7. Administer heparin at 100 IU/kg bodyweight to obtain an activated clotting time (ACT) of 200-300 seconds. Monitor the ACT level every 30 minutes as needed.
8. Under sterile conditions, remove the WATCHMAN Access System and dilator from the packaging and inspect the entire system for damage.
9. Insert a syringe with saline into the side port of the WATCHMAN access sheath. Flush the unit with saline. Remove the syringe from the side port, and insert it into the end of the dilator and again flush with the remaining saline.
10. Next, advance the WATCHMAN access sheath and dilator over the guidewire into the left atrium remove the dilator while maintaining sheath position in the LUPV.
11. Flush the pigtail catheter and advance it over the wire and through the WATCHMAN access sheath. Then, remove the guidewire and connect a syringe with contrast dye to the pigtail.
12. To minimize the potential for introducing air within the sheath, allow bleed-back and then tighten the valve on the access sheath.

13. Under echocardiographic control, pull the sheath with the pigtail catheter back from the LUPV and turn it counterclockwise until it reaches the LAA. Note: Counterclockwise torque on the access system aligns the sheath more anterior. Clockwise torque on the access system aligns the sheath more posterior.
14. Once the pigtail catheter has reached the LAA, obtain angiography at a right anterior oblique (RAO) of 20-30°, caudal 20-30°.
15. Perform TEE with a minimum of a 0-135 degree sweep. This is most important when the sheath is advanced near the wall or apex of LAA and while advancing more distally in any anatomy.
16. Carefully manipulate the catheter/sheath in the most superior lobe in angiography around 2 o'clock, in TEE 135° the most right lobe.
17. To confirm LAA dimensions, use TEE to measure the maximum LAA dimensions in 4 views at 0, 45, 90 and 135 °as before.
18. Advance the pigtail catheter into the distal portion of the LAA under fluoroscopic guidance. Carefully advance the access sheath over the pigtail catheter, using the marker bands on the access sheath as a guide. The landing zone for the device is indicated by the most proximal marker band of the 33 mm, the middle marker of the 27 mm, or the proximal marker of the 21 mm WATCHMAN device. For the 24 mm and 30 mm devices, the landing zones are in between markers.
19. Select the appropriate sized WATCHMAN device based on the TEE measurements taken. Then, under sterile conditions, remove the appropriate sized WATCHMAN device from the packaging inspect it for damage. Open the hemostatic valve and retract the device about 1 cm to confirm the device is attached to the core wire.
20. Align the distal tip of the device with the marker band, and then push the device until the distal tip is aligned on the delivery catheter. Ensure that the WATCHMAN device does not protrude.
21. Attach a large 60 cc syringe and flush the system with saline several times to remove air fluid throughout the system. Then, submerge the tip of the delivery catheter in saline and tap it to remove bubbles.
22. Once the device is prepared, recheck the position of the access sheath by angiography. Loosen the access sheath valve and slowly remove the pigtail catheter from the sheath. Introduce the WATCHMAN device system.
23. To avoid introducing air, submerge the access sheath hub in saline or allow the sheath to back bleed. Then inject saline through the flush port so that it drips from the delivery catheter during introduction into access sheath.
24. Under fluoroscopic guidance, slowly advance the delivery catheter into the access sheath until the most distal marker band on the access sheath lines up with the marker band on the delivery catheter. Then, stabilize the delivery catheter.
25. Retract the access sheath and snap it onto the delivery catheter. Do not advance the access sheath once the delivery system has been snapped into the access sheath. Using fluoroscopy, reconfirm position of the delivery catheter tip.
26. If repositioning is required, remove the delivery system and reinsert the pigtail catheter to advance the access sheath into position.
27. Loosen the valve on the WATCHMAN delivery catheter. To deploy the device, observe the distal end of device to ensure that no forward advancement or repositioning relative to ostium occurs. Holding the deployment knob stationary, slowly retract the access sheath/delivery catheter assembly with a slow stable motion over a period of 3-5 seconds.
28. Leaving the core wire attached, withdraw the access sheath/delivery catheter assembly a few centimeters from the device to align it with the LAA.
29. Once the device has been deployed, use fluoroscopy and TEE to confirm the device release criteria have been met. These are: Position, Anchor, Size and Seal (PASS.)
30. POSITION: To confirm that the device was properly positioned, ensure that the plane of maximum diameter of the device is at or just distal to the orifice of the LAA, and that it spans the entire LAA ostium.
31. ANCHOR: To confirm the device is anchored in place, withdraw the access sheath/delivery catheter assembly 1 - 2 cm from the face of the device. Gently retract and release the deployment knob. The device and LAA should move in unison.
32. SIZE: To confirm the device size, measure the plane of the maximum diameter of the device using TEE in the standard 4 views 0, 45, 90, and 135 degrees, ensuring the threaded insert is visible. The device should be 80-92% of the original size.
33. SEAL: Using color Doppler, ensure that all of the lobes distal to device are sealed. Ideally, no color flow should be detected near the device. If a very small gap is visible between the wall of the left atrial appendage and the device, no adjustment is needed.
34. If there is a gap or jet around the device that is larger than 5 mm, the device should be repositioned or fully recaptured and replaced.
35. If all release criteria are met, move the access sheath/delivery catheter up to the face of the device and rotate the deployment knob 3-5 turns counterclockwise to release.
36. After release, perform angiography with contrast dye to document that the device is still in place. Then, using TEE, recheck the size and seal. Remove the sheath assembly from the left atrium.

5. Partial Implant Recapture

1. If the device is too distal in the LAA, advance the tip of access sheath/delivery catheter assembly up to the device. Do not unsnap.
2. Holding the deployment knob with the right hand, gently advance the access sheath/delivery catheter assembly over the shoulders of the device. Then, position the right thumb against the delivery catheter hub for stability.
3. Continue to advance the assembly up to, but not past the fixation anchors. Resistance will be felt as the device shoulders collapse. When resistance is felt a second time indicating anchor contact, stop, and tighten hemostasis valve.
4. Under fluoroscopic observation, pull back the device and sheath a few millimeters. Once the device is retracted, redeploy it as before.
5. Check to see if the release criteria have been met. If the release criteria have been met, release the device.

6. Full Implant Recapture

1. If the device was placed too proximal to the LAA ostium or the device release criteria are not met, fully recapture the device.
2. Advance the tip of the assembly up to the face of the device. Again, do not unsnap. Holding the deployment knob with the right hand, gently advance the assembly over shoulders of device. Position the right thumb against delivery catheter for stability.
3. Continue to advance the assembly until device is completely collapsed and recaptured. Resistance will be felt as device shoulders collapse.
4. Withdraw the device until the distal tines are proximal to marker band. Then tighten the hemostasis valve.
5. While maintaining position, unsnap the delivery system from the access sheath. Then, slowly remove the delivery system. Insert a pigtail catheter and/or obturator to reposition access sheath in LAA if necessary.

7. Post-Procedure

1. Once proper placement of the device has been confirmed, remove the sheath. Local hemostasis should be obtained.
2. Following the procedure, check for hematoma and/or bleeding at regular intervals according to institutional guidelines. The patient should be monitored intensively.

3. Continuous blood pressure, heart rate, O₂ saturation should be measured until the patient is awake.
4. Once the patient is awake, perform a neurological examination. The patient should be monitored for at least 6 hours with blood pressure and heart rate monitoring.
5. The patient should remain on warfarin and 81mg aspirin for a minimum of 45 days following the implant procedure (internal normalized ratio (INR) 2.0-3.0). The patient should be administered antibiotic prophylaxis per the American Heart Association's guidelines. NOTE: Post procedure heparin is not recommended.
6. The patient may be hospitalized overnight and discharged the next day. ATTE is typically performed before dismissal.
7. At 45 days, assess the WATCHMAN device placement using TEE. Cessation of warfarin is at physician discretion, if the LAA is closed completely and thrombus on the device was ruled out. If flow is noted around the device greater than 5 mm, consideration should be given to keep the patient on warfarin until it has decreased to less than 5 mm.
8. Patients ceasing warfarin should begin clopidogrel 75mg and aspirin daily through 6 months post-implant and continue taking aspirin daily indefinitely.
9. Prescribe appropriate endocarditis prophylaxis for 6 months following implantation. Continuing endocarditis prophylaxis beyond 6 months is at physician discretion.

8. Outcome/Representative Results

The PROTECT-AF clinical trial was performed to compare the safety and effectiveness of the implantation of the WATCHMAN device to that of warfarin treatment. 707 eligible patients were randomly assigned in a 2:1 ratio to either percutaneous closure of the LAA with subsequent discontinuation of warfarin (intervention; n=463) or to warfarin treatment (control; n=244).

As seen in Figure 5, the primary efficacy event rate (assessed by a primary composite endpoint of stroke, cardiovascular death, and systemic embolism) was compared in patients undergoing LAA closure with the WATCHMAN device (intervention group) and patients undergoing warfarin therapy (control group). The primary efficacy event rate was 3.0 per 100 patient-years (95% credible interval [CrI] 1.9-4.5) in the intervention group and 4.9 per 100 patient-years (2.8-7.1) in the control group. The ischemic stroke rate was 2.2 (1.2-3.5) in the intervention group and 1.6 (0.6-3.0) in the control group. The cardiovascular/unexplained death rate was 0.7 (0.2-1.5) in the intervention group and 2.7 (1.2-4.4) in the control group. The hemorrhagic stroke rate was 0.1 (0.0-0.5) in the intervention group and 1.6 (0.6-3.1) in the control group. The systemic embolism rate was 0.3 (0.0-0.8) in the intervention group and 0 in the control group. Taken together, this reflects a 38% decrease in cardiovascular adverse events demonstrating that LAA closure is not inferior to warfarin therapy.

Video 1. <http://www.atritech.net/animation.html>



Figure 1. The WATCHMAN Device. The WATCHMAN device is a nitinol cage with a polytetrafluoroethylene membrane on the surface, and fixation anchors around the perimeter

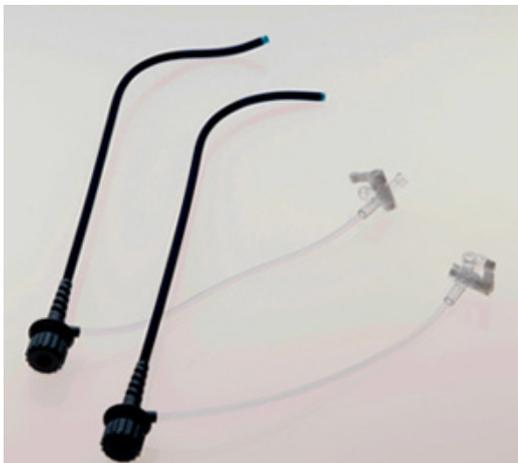


Figure 2. Transseptal Access System. The WATCHMAN introduction sheath is available with double and single curve for different anatomical situations.

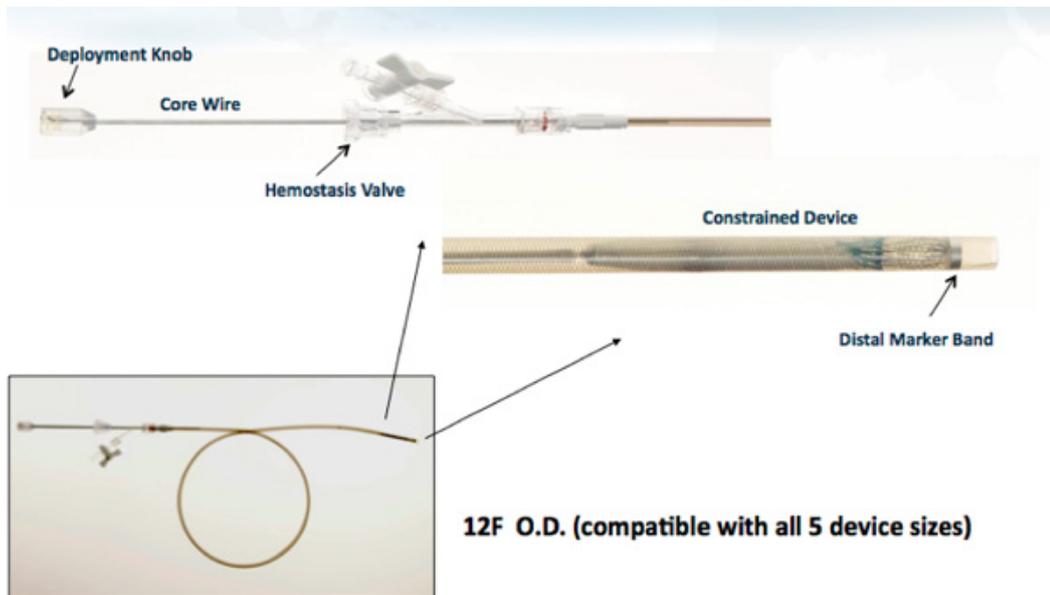
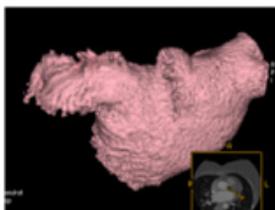
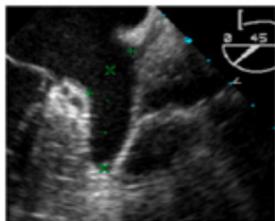
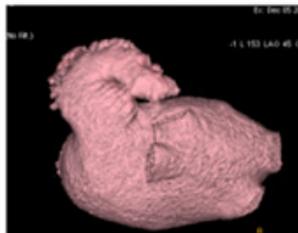
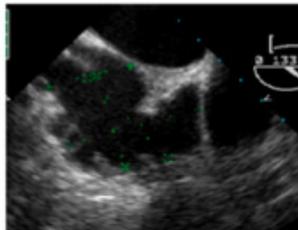


Figure 3. WATCHMAN Delivery system. The WATCHMAN device is constrained within the delivery system, which is compatible with all 5 device sizes.

The **WindSock Type LAA** is an anatomy in which one dominant lobe of sufficient length is the primary structure.



The **ChickenWing Type LAA** is an anatomy whose main feature is a sharp bend in the dominant lobe of the LAA anatomy at some distance from the perceived LAA ostium.



The **Broccoli Type LAA** is an anatomy whose main feature is an LAA that has limited overall length with more complex internal characteristics.

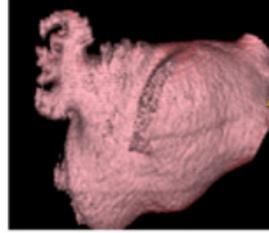


Figure 4. LAA Typing. (Left) The WindSock Type LAA is an anatomy in which one dominant lobe of sufficient length is the primary structure. (Center) The ChickenWing Type LAA is an anatomy whose main feature is a sharp bend in the dominant lobe of the LAA anatomy at some distance from the perceived LAA ostium. (Right) The Broccoli Type LAA is an anatomy whose main feature is an LAA that has limited overall length with more complex internal characteristics.

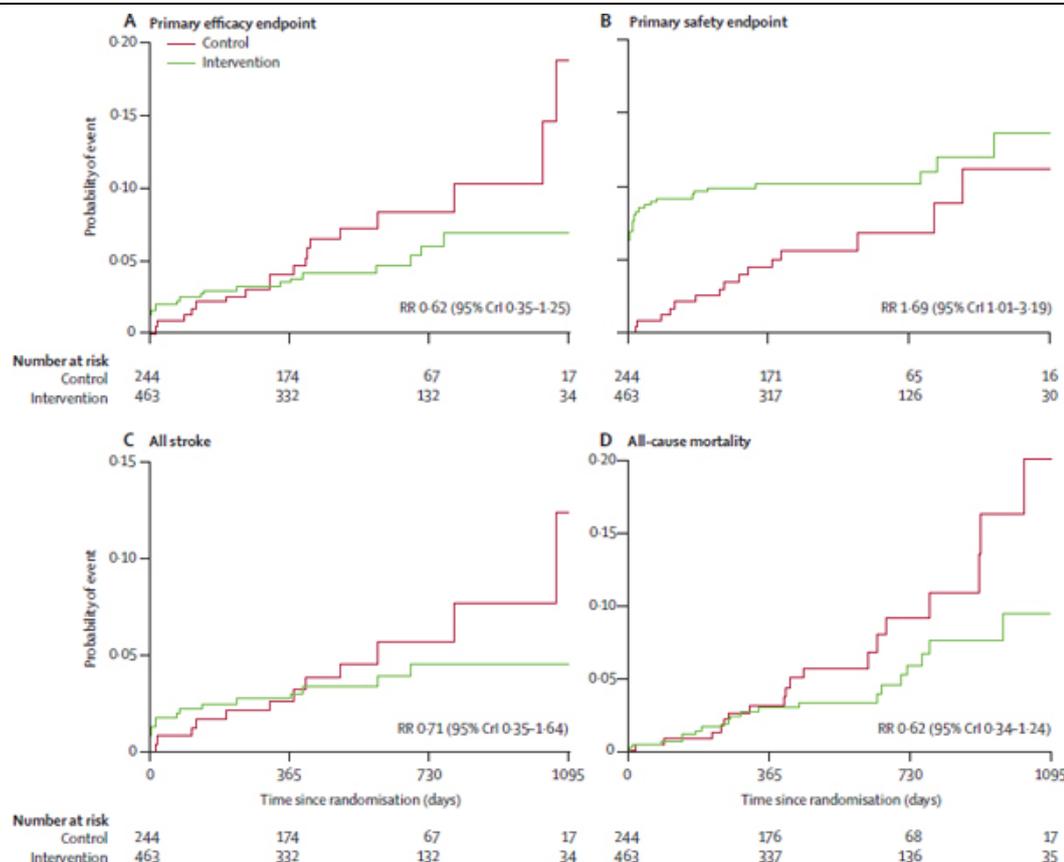


Figure 5. Kaplan-Meier curves of incidence of study endpoints in intervention and control groups. RR=rate ratio. Incidence probabilities for the intention-to-treat analyses are shown with time calculated as the days since randomization for the primary efficacy endpoint (A), the primary safety endpoint (b), all stroke (C), and all-cause mortality (D). [Click here for larger figure.](#)

Maximum LAA Ostium (mm)	Device Size (mm)
	<i>(uncompressed diameter)</i>
17-19	21
20-22	24
23-25	27
26-28	30
29-31	33

Table 1. Determining proper device selection. The device sizing is based on the maximum LAA diameter. The maximum LAA ostium size should be >17mm or <31mm to accommodate available device sizes. The available/useable LAA length should be equal to or greater than the ostium.

Discussion

The procedure for percutaneous implantation of the WATCHMAN left atrial appendage closure device described here, has been shown in clinical trials to be feasible¹⁶, non-inferior to warfarin therapy², and safe¹⁷. Though in all studies there was a higher rate of complications in the group receiving the implant^{2,16,17}, data from the PROTECT AF trial and CAP registry study, which assessed safety, suggests that the complications associated with implantation of the WATCHMAN can be largely attributed to operator inexperience. The frequency of safety event rates was initially high, but decreased over time¹⁷.

The method presented here highlights several critical steps in preventing procedural complications. During the pilot study, three safety events occurred as a result of device failure. In two subjects the device embolized, and in one subject the wire fractured during the implantation procedure. Though these events occurred in first generation devices, and have not occurred in the second-generation device, the WATCHMAN system should always be thoroughly examined before use¹⁶.

The most common complications associated with the procedure are pericardial effusions needing intervention and air embolism. Analysis of imaging data suggests that the serious pericardial effusions in the PROTECT AF trial were caused by operator error during transeptal puncture, by the manipulation of the WATCHMAN device or by manipulation within the LAA with the sheath to reach an optimal implantation procedure. By using a pigtail catheter the risk for perforation of the LAA by the tip of the sheath can be strongly reduced. One pericardial effusion most likely resulted from a vigorous "tug test" performed to check stability of the device in the LAA. For this reason, it is critical to use TEE and fluoroscopy throughout the procedure to monitor the implantation process. When checking for stability, contrast should be injected into the LAA to visualize the chamber, or the process should be continually monitored with TEE. With observation, no further tug-related effusions have been observed. Procedure-related stroke occurred in 3 cases as a result of air embolism from the large 12F transeptal access sheath. Therefore, it is critical to be diligent in properly flushing the sheath ensure that air is not trapped within the sheath¹⁷. Also, fasting prior to the procedure can lead to

dehydration resulting in a low left atrial pressure during the implantation procedure, which can cause air embolism. Therefore, prior to deploying the device, saline should be infused to increase the patient's left atrial pressure to about 10 mmHg.

Despite the higher rate of safety-events with LAA occlusion compared to warfarin treatment, the overall outcome with regard to morbidity/mortality with LAA occlusion was improved¹⁷. Closure of the left atrial appendage is therefore a promising effective alternative to continual warfarin therapy in patients with non-valvular atrial fibrillation.

Disclosures

Dr. Möbius- Winkler, Dr. Dähnert and Prof. Schuler participated in the protect AF Trial.

Dr. Möbius-Winkler works as proctor for WATCHMAN Implantation for Atritech Inc. and Boston Scientific.

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