Left Atrial Appendage Occlusion With the WATCHMAN™ for Stroke Prevention in Atrial Fibrillation

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Atrial fibrillation (AF) is a major cause of stroke and systemic embolism. Although warfarin and the novel oral anticoagulants reduce thromboembolic risk, they are associated with an ongoing bleeding hazard, in addition to other limitations that deter their use. The left atrial appendage (LAA) appears to be the primary source of thrombus in AF; therefore, LAA closure represents a mechanical strategy for stroke prevention in these patients. The WATCHMAN™ LAA closure device (Boston Scientific, Natick, MA) is a nitinol-framed occluder that is implanted percutaneously under echocardiographic and fluoroscopic guidance. Data from two randomized clinical trials support the clinical efficacy of transcatheter LAA occlusion with the WATCHMAN and demonstrate that procedural safety has improved significantly since initial experience. This article summarizes the rationale, procedural technique, safety, and clinical efficacy of the WATCHMAN device in patients with AF at high risk for thromboembolic events.

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KEY WORDS

Atrial fibrillation • Stroke • Left atrial appendage • WATCHMAN

Atrial fibrillation (AF) is associated with an ongoing risk of stroke and systemic embolism. The prevalence of AF is increasing as the population ages, and has been referred to as a global epidemic.[1] Long-term oral anticoagulation is recommended for stroke prevention in AF patients at high-risk for thromboembolism according to clinical risk scores such as the $CHADS_2$ (congestive heart failure, hypertension, age ≥ 75 years, type 2 diabetes, prior stroke, transient ischemic attack, or thromboembolism [2 points]) and the CHA_2DS_2-VASc (congestive heart failure, hypertension, age ≥ 75 years [2 points], type 2 diabetes, prior stroke, transient ischemic attack, or thromboembolism [2 points]-vascular disease, age 65-74 years, female sex) models.[2] Although the non–vitamin-K-dependent oral anticoagulants (NOACs) are associated with similar or lower rates of bleeding than warfarin, the absolute risk of major bleeding with all these agents over the long-term is not negligible.

TABLE 1

Current Dataset for Left Atrial Appendage Occlusion With the WATCHMAN™ Device for Stroke Prevention in Nonvalvular Atrial Fibrillation

Study	Design	N	Patients
PROTECT-AF	Randomized clinical trial	707	OAC eligible
CAP	Continued access registry	460	OAC eligible
PREVAIL	Randomized clinical trial	407	OAC eligible
CAP2	Continued access registry	450[a]	OAC eligible
ASAP	Prospective multicenter registry	150	OAC ineligible

[a]As of 12/2013.
ASAP, ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology; CAP, Continuing Access to PROTECT-AF; CAP2, Continued Access to PREVAIL; OAC, oral anticoagulation; PREVAIL, Prospective Randomized Evaluation of the Watchman LAA Closure Device In Patients with Atrial Fibrillation Versus Long Term Warfarin Therapy; PROTECT-AF, WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation.
WATCHMAN™ is manufactured by Boston Scientific (Natick, MA).

Furthermore, a substantial proportion of AF patients who are candidates for oral anticoagulation are not treated because of this or other perceived risks.

The primary source of thromboembolism in AF patients appears to be the left atrial appendage (LAA).[3] Transcatheter LAA occlusion, by eliminating the nidus for thrombus formation, may reduce the thromboembolic risk in AF while abrogating the need for chronic anticoagulation, thereby eliminating the long-term bleeding risk observed with medical therapy. Several catheter-based devices have been developed to occlude or ligate the LAA. The WATCHMAN™ LAA occluder (Boston Scientific, Natick, MA) is a nitinol-based device that has been evaluated in two randomized clinical trials and several prospective registries, and is expected to be approved for use by the United States Food and Drug Administration (FDA) in 2014 (Table 1). This article summarizes the rationale, procedural technique, and safety and clinical efficacy of transcatheter LAA closure with the WATCHMAN device in patients with AF at high risk for thromboembolic events.

Transcatheter LAA occlusion, by eliminating the nidus for thrombus formation, may reduce the thromboembolic risk in AF while abrogating the need for chronic anticoagulation, thereby eliminating the long-term bleeding risk observed with medical therapy.

Unmet Clinical Needs With Current Treatment Strategies

Anticoagulation with warfarin or NOACs is the current standard of care for stroke prevention in high-risk patients with AF.[2] The clinical decision to treat with oral anticoagulation can be guided by the $CHADS_2$ and the CHA_2DS_2-VASc scores, which provide an estimated yearly risk of thromboembolic events based on a particular individual's comorbidities (Tables 2 and 3). Oral anticoagulation is generally recommended in patients with $CHADS_2 \geq 1$ with an additional risk factor. The CHA_2DS_2-VASc score incorporates patient sex and the presence of peripheral vascular disease, and provides greater weight for elderly age, which enables the score to better identify patients who are truly at low risk and who may not require anticoagulation (ie, those with CHA_2DS_2-VASc = 0).[4]

Although oral anticoagulation reduces thromboembolic risk, there are several challenges to its routine use in clinical practice. Warfarin therapy has several limitations, including a narrow therapeutic window, a wide variation in metabolism and numerous food and drug interactions, a requirement for regular laboratory

TABLE 2

The $CHADS_2$ Model for Thromboembolic Risk in Atrial Fibrillation

Characteristic	Points
Congestive heart failure	1
Hypertension	1
Age ≥ 75 y	1
Type 2 diabetes	1
Stroke or transient ischemic attack	2

Patients with a summed score of 0 through ≥ 6 have an estimated 1.9%, 2.8%, 4.0%, 5.9%, 8.5%, 12.5%, and 18.2% yearly risk of a thromboembolic event, respectively. Adapted from Fuster V et al.[2]

TABLE 3

The CHA_2DS_2-VASc Model for Thromboembolic Risk in Atrial Fibrillation

Characteristic	Points
Congestive heart failure	1
Hypertension	1
Age 65-74 y	1
Age ≥ 75 y	2
Type 2 diabetes	1
Stroke or transient ischemic attack	2
Vascular disease	1
Female sex	1

Patients with a summed score of 0 through 9 have an estimated 0%, 1.3%, 2.2%, 3.2%, 4%, 6.7%, 9.8%, 9.6%, 6.7%, and 15.2% yearly risk of a thromboembolic event, respectively.

monitoring and dose adjustment, and slow pharmacodynamic onset and offset. The NOACs (dabigatran, rivaroxaban, apixaban, and edoxaban) are advantageous in that they have a consistent pharmacodynamic profile and monitoring is not required. Large, randomized clinical trials have demonstrated that the NOACs are either noninferior or superior to warfarin in reducing stroke or systemic embolism with similar or lower rates of major hemorrhage, with the exception of gastrointestinal bleeding, which is greater with all the NOACs except apixaban, for which the risk of gastrointestinal bleeding is similar.[5-8] Importantly, the efficacy of the NOACs compared with warfarin was driven by reductions in hemorrhagic stroke; the rates of ischemic strokes were similar or only modestly reduced.

Despite their potential advantages, there are several challenges with the NOACs, including cost, lack of widely available antidotes, and issues with long-term compliance. Moreover, the absolute yearly risk of major bleeding with these agents is not small (Table 4), and the overall bleeding hazard must be interpreted in the context of a therapy that may be administered for years to decades. In addition, patients with prior bleeding events and those who are thought to be at high bleeding risk were either excluded or not well represented in the randomized trials of the NOACs,[9] so the safety and efficacy of NOACs in this difficult patient population has not been defined. A mechanical strategy that reduces the risk of stroke but eliminates the need for long-term compliance with medication and the ongoing risk of bleeding, therefore, has several advantages.

WATCHMAN Device Characteristics

The WATCHMAN is a parachute-shaped device consisting of a nitinol frame and a polyethylene terephthalate fabric membrane cap that faces the body of the left atrium (Figure 1). Small tines, projecting toward the proximal cap, line the circumference of the distal portion and serve to anchor the device within the trabeculae of the LAA. The device is connected to a delivery cable via a threaded insert within the proximal cap. There are five available sizes (21 mm, 24 mm, 27 mm, 31 mm, and 33 mm), which correspond to the broadest diameter of the device (located at the

The WATCHMAN is a parachute-shaped device consisting of a nitinol frame and a polyethylene terephthalate fabric membrane cap that faces the body of the left atrium.

TABLE 4

Major Bleeding Rates in the Randomized Trials of the Novel Anticoagulants

Trial	Drug	Rate (%/y)
RE-LY	Dabigatran (150 mg BID)	3.11
ROCKET-AF	Rivaroxaban	3.6
ARISTOTLE	Apixaban	2.13
ENGAGE-AF	Edoxaban	2.75

Major bleeding definitions were as follows: RE-LY: clinically overt with reduction in hemoglobin ≥ 2 g/dL, transfusion ≥ 2 U, or symptomatic bleeding in a critical area or organ; ROCKET-AF: clinically overt with fatal outcome, critical site, reduction in the hemoglobin level ≥ 2 g/dL, transfusion ≥ 2 U, or permanent disability; ARISTOTLE and ENGAGE-AF: clinically overt with decrease in hemoglobin ≥ 2 g/dL or transfusion of ≥ 2 U, occurring at a critical site, or resulting in death. ARISTOTLE, Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation; ENGAGE-AF, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation; RE-LY, Randomized Evaluation of Long-Term Anticoagulation; ROCKET-AF, Rivaroxaban Once-daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation.

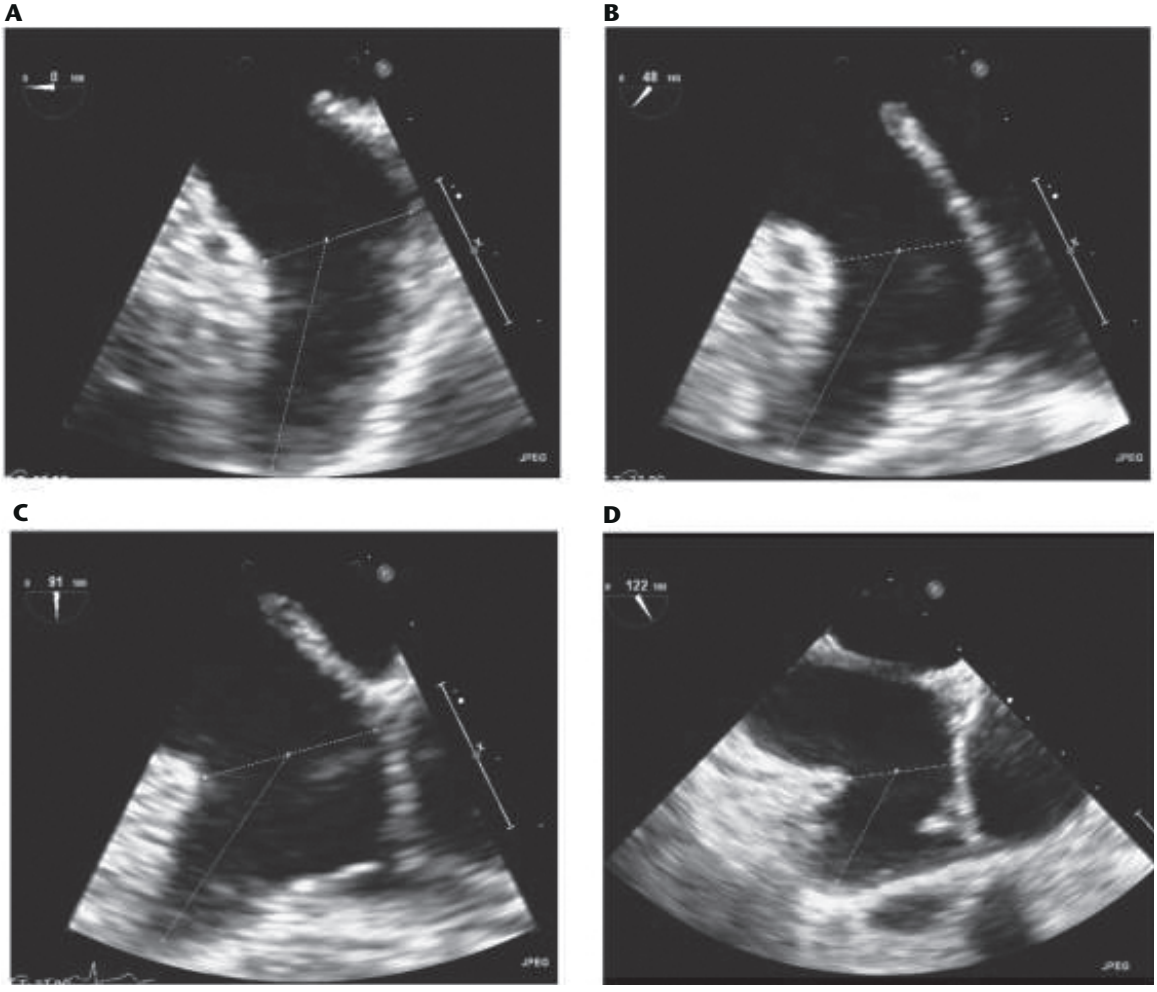
Figure 1. WATCHMAN™ left atrial appendage closure device. The WATCHMAN consists of a nitinol frame and a polyethylene terephthalate fabric membrane cap that faces the body of the left atrium. Small tines line the circumference of the distal portion and serve to anchor the device within the trabeculae of the left atrial appendage. WATCHMAN™ is manufactured by Boston Scientific (Natick, MA).

proximal shoulders). The length of the device is approximately equal to this diameter. The device is provided preloaded within a delivery system that is introduced through a 14F double- or single-curved access sheath placed within the LAA. Device implantation is guided by a combination of transesophageal echocardiography (TEE) and fluoroscopy. If required, the device is fully retrievable prior to release from the delivery cable.

Implantation Procedure

A comprehensive baseline TEE evaluation of the LAA is required prior to LAA occlusion to (1) exclude the presence of thrombus within the appendage, and

Figure 2. Preprocedural transesophageal echocardiographic (TEE) assessment of the left atrial appendage (LAA). Prior to the procedure, TEE is performed to exclude the presence of LAA thrombus and to confirm LAA anatomy is feasible for occlusion. The diameter and depth of the LAA is measured at 0°, 45°, 90°, and 135° (Panels **A, B, C,** and **D,** respectively). The diameter of the LAA is defined as the distance from a point just distal to the left circumflex artery to approximately 1 to 2 cm from tip of the left upper pulmonary vein limbus.



(2) define the size and shape of the appendage in order to assist in the selection of the appropriately sized device. The LAA is imaged at 0°, 45°, 90°, and 135°. In each plane, the diameter of the LAA mouth is measured, defined as the distance from the mitral annulus (just below the left circumflex artery) to approximately 2 cm below the tip of the ridge of the left upper pulmonary vein. The length of the LAA is measured from this line to the tip of the primary lobe (Figure 2).

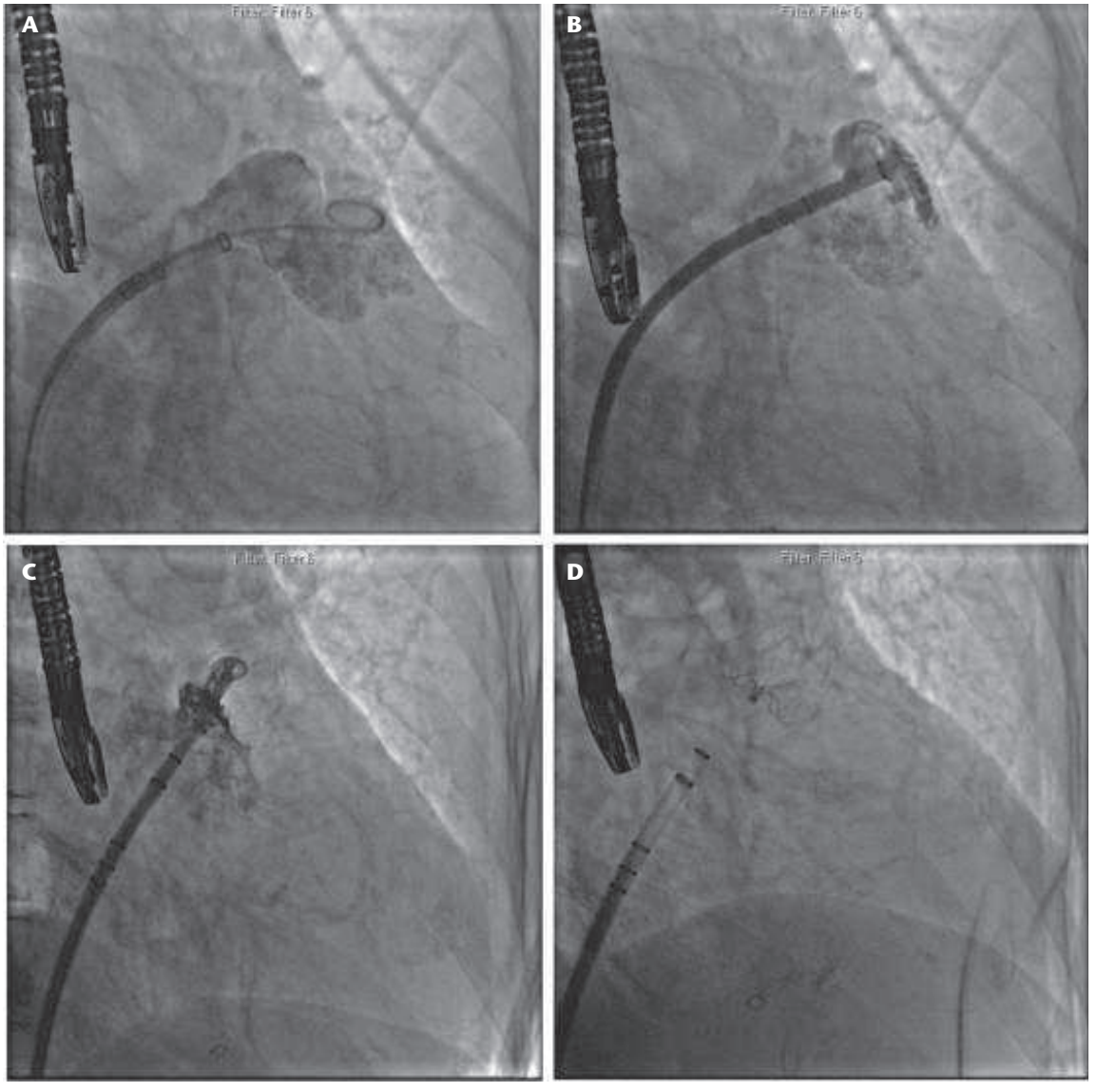
A transseptal puncture is performed under echocardiographic guidance using standard techniques. A posterior and inferior puncture is preferred as this will provide a coaxial approach to the LAA, which is an anterior and superior structure. The 14F delivery sheath is advanced deeply into the LAA over a diagnostic pigtail catheter. The appropriate-sized device is selected through a combination of TEE and fluoroscopic measurements, and is advanced to the tip of the delivery sheath, whereupon the sheath is withdrawn and the device deployed and released if the appropriate criteria on TEE and fluoroscopy are met (Figures 3 and 4).

Clinical Outcomes

Efficacy

The clinical efficacy of LAA occlusion with the WATCHMAN has been explored in two randomized, noninferiority Bayesian clinical trials: the WATCHMAN

Figure 3. WATCHMAN™ implantation. **(A)** Left atrial appendage (LAA) angiography through a pigtail catheter telescoped within the WATCHMAN delivery sheath, which was introduced into the left atrium via a posterior-inferior transseptal puncture. **(B)** The delivery sheath is advanced deep within the left atrial appendage over the pigtail catheter to avoid traumatizing the thin-walled appendage, and a device size is chosen based on transesophageal echocardiographic measurements and fluoroscopic markers on the delivery sheath, which correspond with the estimated landing zone of different sized devices. **(C)** The WATCHMAN is deployed within the LAA, and angiography through the delivery sheath demonstrates appropriate position and seal. Contrast material penetrates through the WATCHMAN since it is covered with a 160 µm filter. **(D)** Device is released from its delivery cable. WATCHMAN™ is manufactured by Boston Scientific (Natick, MA).



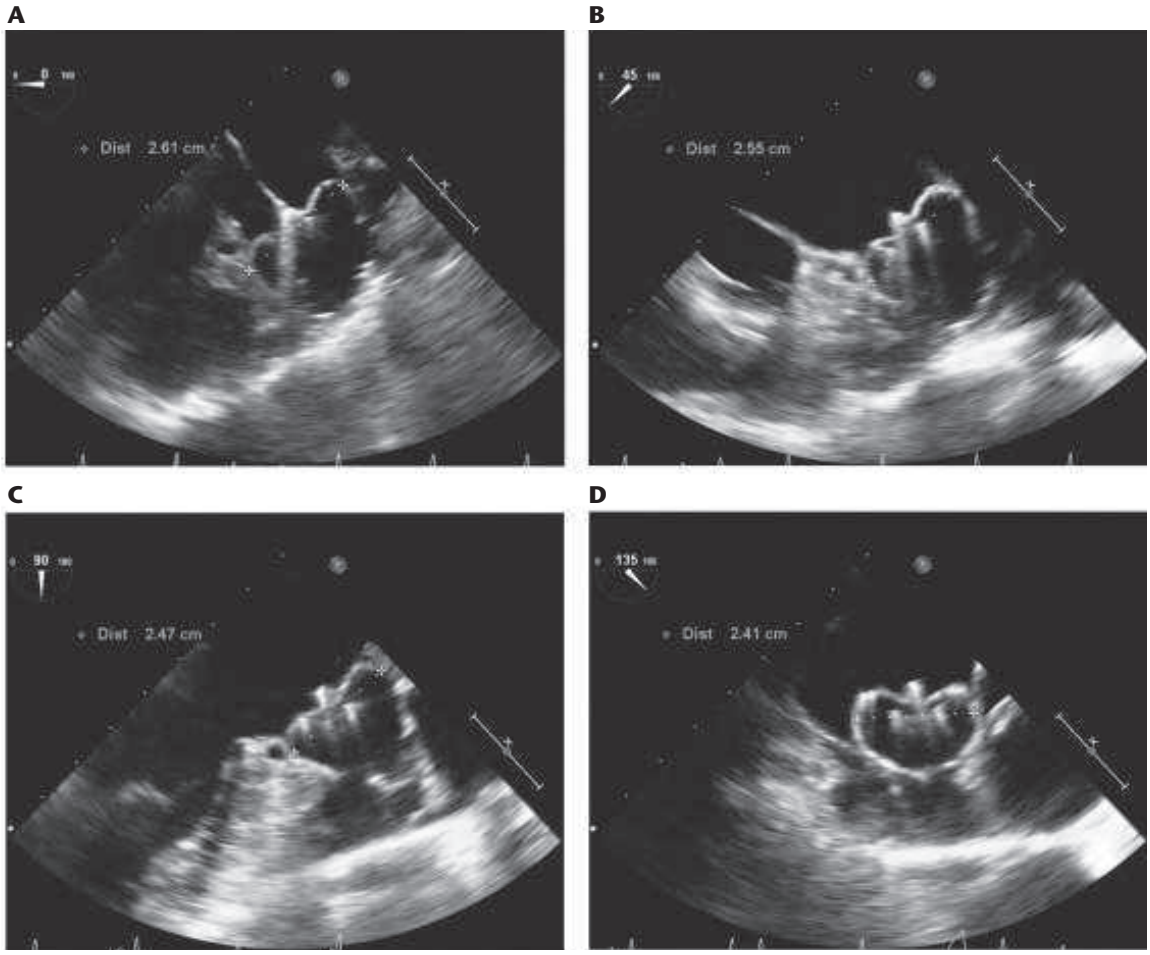


Figure 4. Postprocedural transesophageal echocardiographic (TEE) assessment of WATCHMAN™ implantation. After deployment, the device is assessed at 0°, 45°, 90°, and 135° (Panels A, B, C, and D, respectively). Compression is determined by measuring the distance across the shoulders of the device. If compression and position are adequate, the left atrial appendage sealed by color Doppler and fluoroscopy, and the device well anchored according to a "tug test," the device is released. WATCHMAN™ is manufactured by Boston Scientific (Natick, MA).

Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation (PROTECT-AF) trial,[10] followed by the Prospective Randomized Evaluation of the Watchman LAA Closure Device In Patients with Atrial Fibrillation Versus Long Term Warfarin Therapy (PREVAIL) study[11] (Table 5). PROTECT-AF randomly assigned 707 patients with paroxysmal, persistent, or permanent AF with $CHADS_2$ scores ≥ 1 who were candidates for long-term oral anticoagulation to either WATCHMAN implantation or warfarin anticoagulation.[10] PREVAIL was a smaller study designed to further explore the safety and efficacy of the device. A total of 407 patients with AF who were eligible for anticoagulation and had $CHADS_2$ scores ≥ 2 or $= 1$ with an additional risk factor were randomly assigned to either WATCHMAN implantation or warfarin anticoagulation.[11] In both studies, patients assigned to the device arm were treated with warfarin anticoagulation and daily aspirin for 6 weeks, at which time a TEE was performed. If the TEE findings were adequate (ie, peridevice leak < 5 mm), warfarin was discontinued and aspirin and clopidogrel prescribed for 5 more months, followed by indefinite aspirin therapy.

In PROTECT-AF, the WATCHMAN device was deemed noninferior to warfarin anticoagulation at 18-month follow-up for the primary efficacy endpoint of cardiovascular death, any stroke, and systemic embolism (3.0% [95% credible interval (CrI), 1.9-4.5] vs 4.9% [95% CrI, 2.8-7.1]). Among the patients randomly assigned to warfarin, the time in therapeutic range was 66%, similar to that of the control arms within the NOAC trials.[5-8] The WATCHMAN device was still noninferior to warfarin at a mean follow up of 2.3 ± 1.1 years, at which time the event rates continued to favor the device arm (rate ratio [RR], 0.71; 95% CrI, 0.44-1.30]).[12] All-cause mortality was significantly reduced in patients with the WATCHMAN device at 4 years after implantation, although

TABLE 5

Comparison of the Study Designs of the PROTECT-AF and PREVAIL Randomized Clinical Trials

	PROTECT-AF	PREVAIL
Study design	Randomized, noninferiority	Randomized, noninferiority
Control arm	Warfarin	Warfarin
Size	N = 707	N = 407
Risk criteria for inclusion	$CHADS_2 \geq 1$	$CHADS_2 \geq 2$ (or = 1 with additional risk factor)
Sites	United States and Europe	United States; at least 25% new operators
Primary efficacy endpoint	CV death, any stroke, or SE	Coprimary: CV death, any stroke, or SE Coprimary: ischemic stroke or SE ≥ 7 d postprocedure
Primary safety endpoint	Bleeding or any device/ procedure-related event (serious PE, device embolism, or stroke)	Death, ischemic stroke, SE or procedure-related events requiring major intervention within 7 days of the procedure
Last reported follow-up	4 y	18-mo

CV, cardiovascular; PREVAIL, Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device in Patients with Atrial Fibrillation Versus Long-Term Warfarin Therapy; PROTECT-AF, WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation; SE, systemic embolism.

this observation must be considered exploratory and hypothesis generating.[13] Outcomes in the subsequent PREVAIL trial were analyzed using a Bayesian model-based rate of an event occurring within 18 months. The rates of cardiovascular death, any stroke, or systemic embolism were similar between the WATCHMAN device and warfarin anticoagulation (0.064 vs 0.063, RR, 1.07; 95% CrI, 0.57-1.89), but the device did not achieve noninferiority because the upper bound of the 95% CrI for the 18-month RR was not lower than the prespecified noninferiority margin of 1.75.[11] The results of this endpoint must also be considered in the context of a lower-than-expected event rate among the patients randomly assigned to warfarin.

Several analyses from the PROTECT-AF and PREVAIL trials provide insight into the validity of the mechanistic hypothesis that occlusion of the LAA suffices to eliminate thromboembolic risk in the absence of oral anticoagulation. Landmark analyses of PROTECT-AF confined to the periods after the procedure and after termination of warfarin therapy in the device arm demonstrated that fewer efficacy events occurred in the patients receiving the WATCHMAN compared with those treated with oral anticoagulation.[12] In PREVAIL, the rate of ischemic stroke or systolic embolism occurring more than 7 days after randomization—the coprimary endpoint—was noninferior to the WATCHMAN compared with chronic oral anticoagulation (18-month event rate 0.0253 vs 0.0200; risk difference, 0.0053; 95% CrI, −0.0190-0.0273).[11] The totality of the data, therefore, supports the contention that LAA occlusion can prevent longer-term ischemic events in the absence of chronic anticoagulation.

All-cause mortality was significantly reduced in patients with the WATCHMAN device at 4 years after implantation, driven by reductions in hemorrhagic stroke, although this observation must be considered exploratory. . .

Safety

A key potential benefit with LAA occlusion is the elimination of long-term bleeding hazard posed by chronic oral anticoagulation. However, this hazard is replaced by procedural risk. In PROTECT-AF, the rate of the major safety endpoint (excessive bleeding or a procedure-related complication) at 18 months was more frequent in the patients randomly assigned to the WATCHMAN compared with those on warfarin (RR 1.69; 95% CrI, 1.01-3.19).[10] Among the patients in the device group, serious device-related pericardial effusion (requiring drainage or surgical intervention) occurred in 4.8% and procedure-related ischemic stroke occurred in 1.1%, predominantly due to air embolism. However, longer follow-up illustrates the impact of the ongoing bleeding hazard

TABLE 6

Comparison of Procedural Outcomes in Device Patients Within the PROTECT-AF and PREVAIL Randomized Clinical Trials

	PROTECT-AF	PREVAIL	*P* Value
Implant success	90.9	95.0	.01
All 7-d procedural complications	8.7	4.4	.005
PE requiring surgery	1.6	0.4	.004
PE with pericardiocentesis	2.4	1.5	.326
Procedure-related stroke	1.1	0.4	.007

PE, pericardial effusion; PREVAIL, Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device in Patients with Atrial Fibrillation Versus Long-Term Warfarin Therapy; PROTECT-AF, WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation.

with anticoagulation: by 4 years, the rates of overall safety events in the two arms were similar, primarily due to "catch-up" among the patients randomly assigned to warfarin anticoagulation.[13]

Prospective and randomized data show that procedural safety has significantly improved since this initial experience, likely due to technical modifications and increased communal experience (Table 6). In the PREVAIL trial, approximately 40% of patients were treated by operators without prior WATCHMAN experience; however, the device arm met the performance goal for procedural and device safety prespecified by the sponsor and the FDA. In addition, procedural success was significantly improved compared with the PROTECT-AF experience, and procedural safety, including the incidence of serious pericardial effusions and procedural stroke, was significantly reduced. This improved safety profile was consistent with observations from the prospective continuing access registry that followed the PROTECT-AF trial.[14] This diminished procedural hazard with current technique and training may further tilt the balance of safety and efficacy toward the WATCHMAN device over the longer term, although it must be confirmed with continuing follow-up from the PREVAIL trial and continued access registries.

Patients Intolerant to Anticoagulation

Stroke prevention strategies are particularly challenging in patients who are intolerant to anticoagulation or in whom anticoagulation is contraindicated. The ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology (ASAP) was a prospective, multicenter, observational study performed outside of the United States that examined clinical outcomes with the WATCHMAN device in 150 patients with nonvalvular AF who were ineligible for warfarin therapy.[15] After implantation, patients were treated with clopidogrel for 6 months and aspirin indefinitely. At a mean follow-up of 14.4 ± 8.6 months, the rate of all-cause stroke or systemic embolism was 2.3% per year, significantly less than the expected rate of 7.3% per year based on $CHADS_2$ scores. Although these findings are encouraging, a larger dataset is required to adequately define the role and appropriate postprocedural medical regimen of the WATCHMAN in AF patients who cannot tolerate oral anticoagulants.

Other Transcatheter LAA Occlusion Technology

Several other LAA occlusion devices are currently being evaluated or are in use for the purpose of stroke prevention in AF. The Amplatzer Cardiac Plug™ (ACP; St. Jude Medical, Minneapolis MN), like the WATCHMAN LAA occluder, is a nitinol-based device that is delivered through a delivery sheath that is manipulated into the LAA via a transseptal puncture. Data regarding safety and efficacy are limited to relatively small observational studies from outside the United States.[16-19] A large, randomized clinical trial comparing the safety and efficacy of the ACP with oral anticoagulation was recently halted given the pending FDA approval of the WATCHMAN device. To date, a new study design has not been announced. The LARIAT® device (SentreHEART, Redwood City, CA) enables the percutaneous ligation of the LAA through the delivery of a surgical suture via a combined transseptal and subxiphoid approach.[20] This device received 510(k) clearance by the FDA for the approximation of soft tissue. To date, this approach has been explored in a few relatively small observational studies that were not sufficiently powered to assess clinical efficacy.[20, 21] The most common procedural safety events with the LARIAT are major bleeding and serious pericardial effusions. Larger trials are required to define the safety and efficacy of this device for stroke prevention in AF. In sum, although the WATCHMAN experience supports the concept of LAA occlusion as a therapeutic strategy for

stroke prevention, the safety and efficacy of other devices must be determined.

Conclusions

AF is a growing health care problem within the aging population of the United States. AF is associated with an ongoing risk of thromboembolic stroke and systemic embolism, primarily due to stasis and thrombus formation within the LAA. Although effective at stroke prevention, oral anticoagulation with warfarin and the NOACs suffer from several challenges, including medication compliance and an ongoing hazard of major bleeding. The WATCHMAN device is a nitinol-framed device with polyester cap delivered through a transseptal puncture and placed within the LAA using fluoroscopic and echocardiographic guidance. In the PROTECT-AF trial, LAA occlusion with the WATCHMAN followed by 6 weeks of warfarin was noninferior to long-term warfarin therapy for the prevention of cardiovascular death, any stroke, or systemic embolism. Device implantation was associated with an early procedural hazard, but at long-term follow-up, overall safety events were similar to warfarin due to the ongoing hazard of oral anticoagulation. The subsequent continued-access registry and the PREVAIL randomized trial demonstrate that, with newer techniques and training, procedural safety has significantly improved compared with earlier experiences. The totality of the data supports that closure of the LAA with the WATCHMAN device is a reasonable alternative to long-term warfarin therapy for AF patients at high risk for thromboembolic events. ■

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MAIN POINTS

- Atrial fibrillation (AF) is a major cause of stroke and systemic embolism. Warfarin and the non–vitamin-K-dependent oral anticoagulants reduce thromboembolic risk, although they are associated with an ongoing bleeding hazard, in addition to other challenges that limit their use.
- The left atrial appendage (LAA) appears to be the primary source of thrombus in AF. Transcatheter LAA occlusion, by eliminating the nidus for thrombus formation, may reduce the thromboembolic risk in AF while reducing or eliminating the need for chronic anticoagulation, thereby eliminating the long-term bleeding risk observed with medical therapy.
- The WATCHMAN device is a nitinol-framed device with polyester cap delivered through a transseptal puncture and placed within the LAA using fluoroscopic and echocardiographic guidance.
- Clinical trial data support that closure of the LAA with the WATCHMAN device is a reasonable alternative to long-term warfarin therapy for AF patients at high-risk for thromboembolic events.

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