Stroke prevention in atrial fibrillation is an important consideration. Treatment with anticoagulant medications is the most common approach to stroke prevention. Left atrial occlusion devices offer a non-pharmacologic alternative to anticoagulant medications.

Stroke is the most serious complication of atrial fibrillation. The estimated incidence of stroke in non-treated patients with atrial fibrillation is 5% per year. Stroke associated with atrial fibrillation is primarily embolic in nature, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of atrial fibrillation treatment.

Stroke occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in atrial fibrillation leads to blood stasis in the left atrium, and this low flow state increases the risk for thrombosis. The area of the left atrium with the lowest blood flow in atrial fibrillation, and, therefore, the highest risk of thrombosis, is the left-atrial appendage (LAA). It has been estimated that 90% of left-atrial thrombi occur in the LAA.

The main treatment for stroke prevention in atrial fibrillation is anticoagulation, which has proven efficacy. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications have recently received U.S. Food and Drug Administration (FDA) approval for this indication and have demonstrated noninferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, there is an increased risk of bleeding. Also,
warfarin requires frequent monitoring and adjustments, as well as lifestyle changes. Dabigatran does not require monitoring. However, unlike warfarin, the antithrombotic effects of dabigatran are not reversible with any currently available hemostatic drugs.

Surgical removal, or exclusion, of the LAA is often performed in patients with atrial fibrillation who are undergoing open heart surgery for other reasons. Percutaneous LAA closure devices have been developed as a nonpharmacologic alternative to anticoagulation for stroke prevention in atrial fibrillation. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation.

Several versions of LAA occlusion devices have been developed. The WATCHMAN® left atrial appendage system (Boston Scientific, Maple Grove, MN) is a self-expanding nickel titanium device. It has a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, utilizing venous access and transseptal puncture to enter the left atrium. Following implantation, patients are anticoagulated with warfarin or alternate agents for approximately 1-2 months. After this period, patients are maintained on antiplatelet agents (i.e., aspirin and/or clopidogrel) indefinitely. The Cardioblate® closure device developed by Medtronic Corp. is currently being tested in clinical studies. The Amplatzer® cardiac plug (St. Jude Medical, Minneapolis, MN), is FDA-approved for closure of atrial septal defects but has not received FDA approval for LAA closure device. The Percutaneous LAA Transcatheter Occlusion (PLAATO) device (eV3, Plymouth, MN) has also been evaluated in research studies but has not received FDA approval.

**Regulatory Status**

There are currently no percutaneous LAA closure devices with FDA approval. The WATCHMAN® device was considered for FDA approval in 2009 based on the results of the Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients with Atrial Fibrillation (PROTECT-AF) randomized controlled trial. While the FDA advisory panel for this topic voted in favor of approval, the FDA did not grant final approval after concluding that further studies of efficacy and safety were necessary.

**Policy**

The use of percutaneous left-atrial appendage closure devices for the prevention of stroke in atrial fibrillation is considered **investigational**

**Policy Guidelines**

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FirstCarolinaCare Insurance Company, Inc. is a wholly-owned subsidiary of FirstHealth, Inc.
Effective in 2012, there is a specific CPT category III code for this procedure:

0281T: Percutaneous transcatheater closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation.

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Rationale

This policy was created in 2011 and updated periodically with literature review. The most recent update with literature review covers the period of January 2011 through January 2012.

Literature review

The evidence on the efficacy of left-atrial appendage (LAA) closure devices consists of numerous case series and one randomized controlled trial (RCT) comparing LAA closure to warfarin anticoagulation.

The published case series are primarily small and intended to establish safety and feasibility of the device. (1-6) A larger case series of 143 patients from Europe was published in 2011. (4) This series reported that successful implantation was achieved in 96% (137/143) of patients and that serious complications occurred in 7.0% (10/143). Complications included stroke (n=3), device embolization (n=2), and pericardial effusion (n=5). Another larger series was reported by Reddy et al., (5) primarily focusing on the adverse event rate from a registry of 460 patients who received the WATCHMAN® device. Serious pericardial effusion occurred in 2.2% of patients, and there were no deaths or periprocedural strokes reported. Bayard et al. (1) reported on 180 patients with nonrheumatic atrial fibrillation and a contraindication to warfarin and who were treated with the Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO) device. Placement was successful in 90% of patients. Two patients died within 24 hours of the procedure (1.1%), and 6 patients had cardiac tamponade (3.3%), with 2 requiring surgical drainage. During a follow-up of 129 patient-years, there were 3 strokes, for a rate of 2.3% per year. Other case reports and small case series report complications, including multiple reports of thrombus formation at the site of device placement. (7-9)

The PROTECT-AF study (10) was a randomized, unblinded trial that evaluated the noninferiority of an LAA closure device compared to warfarin for stroke prevention in atrial fibrillation. The trial randomized 707 patients from 59 centers in the U.S. and Europe to the WATCHMAN® device or warfarin treatment in a 2:1 ratio. Mean follow-up was 18 +/- 10 months. The primary efficacy outcome was a composite endpoint of stroke (ischemic or hemorrhagic), cardiovascular or unexplained death, or systemic embolism. There was also a primary safety outcome, which was...
a composite endpoint of excessive bleeding (intracranial or gastrointestinal [GI] tract bleeding) and procedure-related complications (pericardial effusion, device embolization, or procedure-related stroke).

The primary efficacy outcome occurred at a rate of 3.0 per 100 patient-years in the LAA closure group compared to 4.9 per 100 patient-years in the warfarin group (rate ratio [RR]: 0.62; 95% credible interval [CrI]: 0.35-1.25). Based on these outcomes, the probability of noninferiority was greater than 99.9%. For the individual components of the primary outcome, cardiovascular/unexplained death and hemorrhagic stroke were higher in the warfarin group. In contrast, ischemic stroke was higher in the LAA closure group at 2.2 per 100 patient-years compared to 1.6 per 100 patient-years in the warfarin group (RR: 1.34; 95% CrI: 0.60-4.29).

The primary safety outcome occurred more commonly in the LAA closure group, at a rate of 7.4 per 100 patient-years compared to 4.4 per 100 patient-years in the warfarin group (RR: 1.69; 95% CrI: 1.01-3.19). The excess in adverse event rates for the LAA closure group were primarily the result of early adverse events associated with placement of the device. The most frequent type of complication related to LAA closure device placement was pericardial effusion requiring intervention, which occurred in 4.8% of patients (22/463).

Ongoing clinical trials

There are currently a number of additional ongoing clinical trials of LAA closure devices. (11) Of several studies listed online at ClinicalTrials.gov, (12) there is one randomized, controlled trial (Evaluation of the Watchman® LAA Closure Device in Patients with Atrial Fibrillation Versus Long-term Warfarin Therapy [PREVAIL trial]; NCT01182441) of LAA closure versus warfarin using the WATCHMAN® device. Eligibility for PREVAIL includes a CHADS score (a clinical risk prediction score of atrial fibrillation-related stroke) of 2 or greater, or a CHADS score of 1 with other indicators of high risk, indicating a patient population with a higher risk of stroke compared to the PROTECT-AF trial. This trial plans to enroll 475 patients with an estimated completion date of November 2015. Other nonrandomized, single-group studies are in progress evaluating the safety and efficacy of various LAA closure devices.

Summary

LAA occlusion devices are nonpharmacologic alternatives to anticoagulation for patients with atrial fibrillation. Currently, there are no devices that have FDA-approval for this indication. Case series have demonstrated that these devices can be successfully implanted percutaneously in most patients. Complications such as pericardial effusion and tamponade are reported in available studies at a rate of 2-5%. Periprocedural stroke has been reported uncommonly. One randomized, controlled trial compared the WATCHMAN® device to warfarin and reported noninferiority on a composite outcome of stroke, cardiovascular/unexplained death, or systemic embolism after 2 years of follow-up. There were a higher number of complications in the LAA closure group, primarily due to early complications associated with the device placement. Longer term outcomes past 2 years have not been reported. Given the lack of FDA approval and the limited data regarding impact on net health outcome, use of left atrial appendage closure devices is considered investigational.

References:


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Left Atrial Appendage Closure Device