Indication, Patient Selection, and Referral Pathways for Left Atrial Appendage Closure

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KEYWORDS

• Atrial fibrillation • Left atrial appendage • WATCHMAN • LARIAT • Amulet • Thromboembolism • Anticoagulation

KEY POINTS

- Left atrial appendage closure (LAAC) is a viable alternative to oral anticoagulation therapy (OAC) for patients with nonvalvular atrial fibrillation who are considered poor candidates for long-term oral anticoagulation.
- Current consensus on LAAC indications, patient, and device selection.
- Patient selection for this procedure continues to evolve with growing expertise, technology, and ongoing clinical investigation on its use in various patient populations.
- We propose a model for appropriate referral system for patients undergoing LAAC for favorable clinical outcomes.

INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia encountered by clinicians with evidence suggesting an increasing prevalence and incidence worldwide.[1–3] Thromboembolic stroke related to AF with associated morbidity and mortality remains a challenge for diverse reasons.[4] One of the main challenges is the risk of bleeding associated with pharmacotherapy. The incidence of AF, risk of stroke, and risk of bleeding increase with age, creating a difficult situation. The overall prevalence of AF is 1%. Out of all patients with AF, 70% are 65 and older and 45% are 75 years and older, respectively. The prevalence of AF ranged from 0.1% among adults less than 55 years of age to 9% in those 80 years of age and older.[5] In the setting of nonvalvular AF, 90% of thrombi are located within the left atrial appendage (LAA).[6] Left atrial fibrosis and inflammation in patients with AF is particularly intense in the LAA and may account for this finding. Oral anticoagulation therapy (vitamin K antagonists [VKA] or non-VKA oral anticoagulants [NOAC]) has long been used for prevention of thromboembolism in patients with AF and remains the first-line

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therapy.[7,8] In some patients, challenges arise either starting or continuing oral anticoagulation (OAC) therapy. Patients are at increased risk of bleeding events secondary to OAC therapy, especially life-threatening intracranial hemorrhage (ICH) and gastrointestinal bleeding. In the past decade, NOACs have emerged as a safer and more effective alternative than VKA[9–12] but the risk of bleeding with anticoagulation remains because the risk factors for thromboembolism and bleeding are largely driven by an overlapping set of comorbidities.[13] Approximately 50% of patients with AF who have a guideline indication for OAC therapy end up not being on any form of OAC therapy for diverse reasons.[14] In recent years, there has been a focus on development and implementation of nonpharmacologic measures to prevent cardioembolic events and fulfill a clinical need for a significant proportion of patients. LAA occlusion, including endocardial and epicardial devices, has emerged as an attractive and promising alternative to OAC therapy.

METHODS OF LEFT ATRIAL APPENDAGE CLOSURE AND CLINICAL EVIDENCE SUPPORTING LEFT ATRIAL APPENDAGE CLOSURE

Currently there are two main approaches for LAAC: surgical and percutaneous.

Surgical Methods/Approach

Surgical methods/approach includes open surgical approaches and minimally invasive thoracoscopic technique. In 2015, a meta-analysis of two randomized trials and five observational studies of surgical LAAC in the setting of cardiac surgery (n = 3653 patients) was done and showed that LAAC is associated with a lower incidence of stroke at 30-day follow-up (0.95 vs 1.9%; odds ratio [OR], 0.46; P = .005) and last follow-up (1.4 vs 4.1%; OR, 0.48; P = .01).[15]

Based on available data, current European Society of Cardiology and American Heart Association/American College of Cardiology guidelines make a suggestion that surgical excision of the LAA may be considered in patients undergoing cardiac surgery or thoracoscopic AF surgery (grade IIb recommendation with level B and C evidence, respectively).[8,16]

Data from multiple studies, however, have raised concerns about efficacy of surgical LAAC techniques, especially suture exclusion. Kanderian and colleagues[17] reported an overall success rate of 40% for LAAC, with surgical excision achieving higher success rates (73%) than suture exclusion (23%), after a mean follow-up of 8.1 $\pm$ 12 months. Unsuccessful LAAC was defined as the presence of a patent LAA, excluded LAA with persistent flow, or a remnant LAA. An active LAA thrombus was present in 41% and 0% of unsuccessful LAA exclusion and excision, respectively. Cullen and colleagues,[18] in a retrospective 1-month follow-up data after surgical LAAC, showed a residual communication from LAA in 37% of cases with an active thrombus present in 28% of all patients and 47% of patients with incomplete LAAC. The safety of anticoagulation discontinuation in patients after surgical LAAC is uncertain, especially if a transesophageal echo (TEE) is not performed to confirm successful closure and the absence of an LAA thrombus.

Newer techniques, such as the epicardial AtriCure Atriclip system (Atricure, West Chester, OH) (Fig. 1), used during open or thoracoscopic surgery, have improved the success rates of LAA exclusion. A multicenter evaluation of the Atricure clip reported a more than 98% closure rate at 3-month follow-up TEE/computed tomography angiography.[19]

Percutaneous Methods/Approach

WATCHMAN device

The safety and efficacy of the WATCHMAN device (Boston Scientific Corp, Marlborough, MA) was evaluated in two randomized trials: the PROTECT AF study (Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) followed by the PREVAIL (Prospective Randomized Evaluation of the Watchman LAA Closure Device in Patients with Atrial Fibrillation vs Long-Term Warfarin Therapy) study (Fig. 2).[20–23]

The PREVAIL study and CAP registry reported an improvement in implant success rate (90.9% PROTECT AF to 94.3% CAP to 95.1 % PREVAIL; P = .04) and a significant decline in iatrogenic complications (periprocedural) indicating improvement in operator experience and training with time. All 7-day procedural complication rates declined from 8.7% in PROTECT AF trial to 4.2% and 4.5% (P = .004), as reported from CAP and PREVAIL data, respectively. The rate of pericardial effusion requiring surgery dropped from 1.6% in PROTECT AF trial to 0.2% and 0.4% (P = .03) in CAP and PREVAIL data, respectively.[22]

Based on the results of PROTECT AF and PREVAIL, the WATCHMAN device was approved by the US Food and Drug Administration (FDA) in March 2015 for patients with nonvalvular AF for whom long-term anticoagulation is indicated, but who have a rational reason for not adhering to such therapy. These patients must be able to tolerate warfarin for at least