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MINI-FOCUS ISSUE: PERCUTANEOUS LAA CLOSURE

Left Atrial Appendage Ligation in Nonvalvular Atrial Fibrillation Patients at High Risk for Embolic Events With Ineligibility for Oral Anticoagulation

Initial Report of Clinical Outcomes

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ABSTRACT

OBJECTIVES This study sought to assess long-term clinical outcomes in adults with nonvalvular atrial fibrillation (AF) who are ineligible for oral anticoagulation therapy and underwent left atrial appendage (LAA) ligation with the Lariat device.

BACKGROUND LAA exclusion has been used to prevent thrombus formation within the LAA in AF patients and is believed to decrease the risk of cardioembolic events.

METHODS LAA ligation with the Lariat device was performed in 139 patients with nonvalvular AF. LAA closure was verified during the procedure by LA angiography and transesophageal echocardiography. A follow-up transesophageal echocardiography was performed at 30 to 45 days post-procedure. After the procedure, patients received aspirin only, clopidogrel only, aspirin plus clopidogrel, or no antithrombotic drugs. Patients did not receive transition oral anticoagulation therapy post-LAA ligation. Patients were followed for LAA closure and adverse events, including stroke, systemic events, and death.

RESULTS Acute closure was accomplished in 138 of 139 treated patients (99%). In 1 patient, a posterior lobe was partially closed. At the day-30 to day-45 transesophageal echocardiography (n = 127), 114 (90%) had complete LAA closure, and 13 (10%) had a 2- to 4-mm leak. There were no leaks ≥5 mm. The periprocedural adverse event rate was 11.5%, including 2 cardiac perforations and 1 death due to pulmonary embolus. Over a mean follow-up of 2.9 ± 1.1 years, the event rate for the composite endpoint of stroke and systemic embolism was 1.0% per year (n = 4). The combined stroke, embolism, and death of any cause event rate was 2.8% (n = 11) per year.

CONCLUSIONS The findings from this analysis of post-procedure event rates suggest that LAA ligation with the Lariat device effectively closes the LAA and may be a beneficial approach to reduce the risk of embolic events in AF patients ineligible to oral anticoagulation therapy. However, future randomized clinical trials are needed to verify these results and to determine device and procedural safety. (J Am Coll Cardiol EP 2015;1:465–74) © 2015 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

ASA = aspirin

CT = computed tomography

LAA = left atrial appendage

OAC = oral anticoagulation

RV = right ventricle

TEE = transesophageal echocardiography

Atrial fibrillation (AF) is the most common arrhythmia in the world, with an estimated prevalence of 3 million in the United States (1,2). AF is associated with a significant, increased risk of morbidity and mortality associated with a 5-fold increase in the frequency of stroke (1). The risk of embolic stroke in the general population increases with age, and in people over the age of 75 years, AF is among the most important causes of embolic stroke (2).

Currently, chronic oral anticoagulation (OAC) treatment is the most frequently used prophylactic approach in patients with AF at high risk of thromboembolic events (3,4). However, as many as 20% of patients with AF cannot take OAC therapy (5–7), and the risk of bleeding events while on OAC therapy can lead to increased death and disability (8–10). Although the newer OAC medications have been shown to be either noninferior or superior to warfarin therapy with equivalent or decreased bleeding events (11–16), there remains a yearly 2% to 3% incidence of major bleeding (11–16). These OAC-contraindicated patients have limited or no options (17–19) and present a significant health care problem should a cardioembolic stroke occur (20,21).

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The Watchman device results from PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with AF), the CAP (Continued Access PROTECT AF) registry, and long-term follow-up from Protect AF demonstrate that exclusion of the LAA is noninferior to warfarin therapy, can be implanted into the LAA with reasonable safety, and has mortality benefits when compared with warfarin therapy (22–24). However, in the United States, the Watchman device for LAA exclusion requires OAC therapy for at least 45 days to prevent thrombus formation on the device (22). Therefore, use of the implantable LAA exclusion devices would not mitigate the risk of bleeding in patients with contraindications to OAC therapy.

The Lariat suture delivery device (SentreHeart, Inc., Redwood City, California) is a percutaneous endocardial/epicardial approach for LAA exclusion (25,26). The LAA ligation approach with the Lariat suture delivery device provides a potential alternative to AF patients at high risk of thromboembolic events that have contraindications to OAC therapy. The present study assessed safety, long-term clinical efficacy of stroke prevention, and death.

METHODS

This prospective multicenter observational study includes 5 clinical sites: CardioVascular Center Frankfurt CVC (Frankfurt, Germany), St. Luke's Hospital (Houston, Texas), John Paul II Hospital (Krakow, Poland), St. Mary's Hospital (San Francisco, California), and the University of California, San Francisco (San Francisco, California). All participants provided written informed consent, and the protocol was approved by the institutional review board of each institution. Study objectives were as follows: 1) to determine the effectiveness of LAA closure with the Lariat device; 2) to assess procedural and 30-day periprocedural safety; and 3) to obtain long-term clinical follow-up.

Pre-specified 30-day periprocedural adverse events included the following: 1) bleeding requiring transfusion; 2) cardiac perforation; 3) cardiac tamponade; 4) cerebrovascular accident; 4) chest pain/discomfort; 5) death; 6) device breakage; 7) inability to remove device; 8) infection; 9) myocardial infarction; 10) pericardial effusion; 11) pericarditis lasting >2 days; 12) pleural effusion; 13) pneumothorax/hemothorax; 14) pulmonary edema; 15) pulmonary embolism; 16) renal failure requiring renal replacement therapy; 17) stroke—ischemic; 18) stroke—hemorrhagic; 19) systemic embolism; 20) transesophageal echocardiography (TEE) complication; 21) thrombosis; 22) transient ischemic attack; 23) vascular damage; 24) vascular access complications; 25) ventricular fibrillation; and 26) ventricular tachycardia.

Defined composite clinical endpoints include the following: 1) stroke and systemic embolism; and

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