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CLINICAL RESEARCH

Percutaneous Left Atrial Appendage Occlusion for Patients in Atrial Fibrillation Suboptimal for Warfarin Therapy

5-Year Results of the PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) Study

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Objectives The aim of this study was to determine 5-year clinical status for patients treated with percutaneous left atrial appendage transcatheter occlusion with the PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) system.

Background Anticoagulation reduces thromboembolism among patients with nonvalvular atrial fibrillation (AF). However, warfarin is a challenging medication due to risks of inadequate anticoagulation and bleeding. Thus, PLAATO was evaluated as a treatment strategy for nonwarfarin candidate patients with AF at high risk for stroke.

Methods Sixty-four patients with permanent or paroxysmal AF participated in this observational, multicenter prospective study. Primary end points were: new major or minor stroke, cardiac or neurological death, myocardial infarction, or requirement for cardiovascular surgery related to the procedure within 1 month of the index procedure. Patients were followed for up to 5 years.

Results Thirty-day freedom from major adverse events rate was 98.4% (95% confidence interval: 90.89% to >99.99%). One patient, who did not receive a PLAATO implant, experienced 2 events within 30 days (cardiovascular surgery, death). Treatment success was 100% 1 month after device implantation. At 5-year follow-up, there were 7 deaths, 5 major strokes, 3 minor strokes, 1 cardiac tamponade requiring surgery, 1 probable cerebral hemorrhage/death, and 1 myocardial infarction. Only 1 event (cardiac tamponade) was adjudicated as related to the implant procedure. After up to 5 years of follow-up, the annualized stroke/transient ischemic attack (TIA) rate was 3.8%. The anticipated stroke/TIA rate (with the $CHADS_2$ scoring method) was 6.6%/year.

Conclusions The PLAATO system is safe and effective. At 5-year follow-up the annualized stroke/TIA rate in our patients was 3.8%/year, less than predicted by the $CHADS_2$ scoring system. (J Am Coll Cardiol Intv 2009;2:594–600) © 2009 by the American College of Cardiology Foundation

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The PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) feasibility study was a nonrandomized, prospective, 10-center study in which 64 patients with permanent or paroxysmal atrial fibrillation (AF) who were at high risk for developing thromboembolic events underwent percutaneous left atrial appendage (LAA) transcatheter occlusion. Patient enrollment was completed November 18, 2003. Previous reports have documented early clinical experience from this study and a sister study in

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Europe (1–4). The feasibility study in Europe required follow-up for only 1 year and consequently is not included in this report of long-term outcomes. One small study of 11 patients reported reduction of predicted stroke at 3-year follow-up (5). We report the 5-year outcomes of patients enrolled in this North American study.

Methods

Eligible subjects were patients with permanent or paroxysmal AF who were at high risk for developing thromboembolic events or stroke, who were not candidates for long-term anticoagulation with warfarin. Candidates had to meet the following inclusion criteria to be eligible: not a candidate for warfarin therapy (defined as having a contraindication to warfarin based on warfarin product label, including history of severe bleeding on warfarin therapy, excessive risk of fall or hemorrhage, or the inability to maintain a stable international normalized ratio (INR) as defined by an INR >3.5 and/or <1.5 on 2 or more measurements in the prior 1 year unless due to a warfarin initiation period), chronic (>3 months) continuous or paroxysmal nonrheumatic AF, able to undergo transesophageal echocardiography (TEE), candidate for emergency cardiac surgery (if required), able to complete the study follow-up program and provide informed consent. All patients had to have a total high-risk ($CHADS_2$ [congestive heart failure, hypertension, age, diabetes, previous stroke]) (6,7) score of 2 or more or presence of at least 1 high-risk echocardiographic risk factor, according to the criteria in Table 1. Specific exclusion criteria are listed in Table 2.

The primary study end point was the occurrence of major adverse events (MAEs) within 1 month of the index procedure. A MAE was defined as new major or minor stroke, cardiac or neurological death, myocardial infarction, or requirement for cardiovascular surgery related to the PLAATO procedure.

Secondary safety end points were: MAEs during the hospital stay for the index procedure, and presence of mobile left atrial thrombus or MAEs within 6 months of the index procedure. Secondary effectiveness end points were: device success (successful delivery and deployment of the PLAATO implant into the LAA or recapture and retrieval if necessary); procedural success (Device Success and no MAEs during the hospital stay of the index procedure); implantation success (successful delivery and deployment of the PLAATO implant into the LAA and the absence of MAEs within 1 month of the index procedure); and treatment success (implantation success and LAA occlusion by TEE at 1 month).

Abbreviations and Acronyms

AF = atrial fibrillation
INR = international normalized ratio
LAA = left atrial appendage
MAE = major adverse event
NIHSS = National Institutes of Health Stroke Scale
SAE = serious adverse event
TEE = transesophageal echocardiography
TIA = transient ischemic attack

A Clinical Events Committee (CEC) comprising invasive and noninvasive cardiologists and neurologists in clinical practice adjudicated in a blinded fashion all complications reported during the study. All events were designated as related to the device, implantation procedure, or study requirements; not related to the device or implantation procedure; or the relation was unknown. Adjudicated adverse events were categorized as MAEs, serious adverse events (SAEs), or adverse events. The CEC adjudication was the final determination of an event.

Table 1. High-Risk Clinical and Echocardiographic Inclusion Criteria

Score	High-Risk Clinical Inclusion Criteria
2	A prior history of transient ischemic attack or stroke more than 2 months before the index procedure
1	Diagnosed with congestive heart failure, with an episode within the prior 100 days (refer to the New York Heart Association definition in Section 15.0) or left ventricular ejection fraction <40% by cardiac catheterization, radionuclide venogram, or echocardiogram
1	Patient has a history of systolic hypertension >160 mm Hg
1	Patient has Type I or Type II diabetes mellitus
1	Patient is ≥65 yrs of age
1	Patient has a history of coronary artery disease, defined as previous myocardial infarction or known coronary stenosis ≥50%
	High-Risk Echocardiographic Inclusion Criteria
	Patient displays high-risk characteristics on transesophageal echocardiography examination, defined as: left atrial appendage velocity ≤20 cm/s or moderate or dense spontaneous echocardiographic contrast in the left atrial appendage.