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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.

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Table 2. Exclusion Criteria

Prior intracranial hemorrhage
Prior cardiac surgical procedure for left atrial appendage occlusion
Inability to complete transesophageal echocardiography
Mitral stenosis more than mild or significant aortic stenosis by echocardiography
Mitral regurgitation more than moderate
Mitral annular calcification (moderate or severe by echocardiogram)
Left atrial diameter >6.5 cm
Mobile or planar clot in the left atrium or left atrial appendage
Aortic plaque classified as complex according to mobility, ulceration, pedunculation, or thickness >4 mm by transesophageal echocardiography
Significant abnormality of the intra-atrial septum (such as aneurysm)
Prosthetic heart valve or inferior vena cava filter
Active endocarditis, infection, sepsis
History of immunodeficiency
Acute myocardial infarction, unstable angina, percutaneous coronary intervention, or coronary artery bypass grafting within 1 month
Symptomatic atherosclerotic carotid artery disease
Known hypercoagulability
Life expectancy <2 yrs
Requires warfarin for nonatrial fibrillation indication
Recent stroke (<2 months)
Abnormal laboratory findings (creatinine >2.5 mg/dl, platelets <100 k, hemoglobin <10 g/dl, white blood cell count <5,000)
Contraindication to aspirin or other medications prescribed
Pregnant or lactating women
Left ventricular thrombus or high risk for developing left ventricular thrombus, such as patients with a large dyskinetic left ventricular segment or aneurysm
Any other medical condition that, in the judgment of the investigators, made the patient a poor candidate for the procedure (e.g., esophageal varices, inability to lie flat for the procedure)

A total of 64 patients were enrolled at 9 sites in the U.S. and 1 Canadian site. Patient enrollment was completed November 18, 2003. Of the 64 subjects, 61 were implanted with the PLAATO system.

Procedure. The PLAATO system, used for percutaneous LAA transcatheter occlusion, has been described previously (1–4). Informed consent, baseline demographic data, and medical history were collected before treatment. Pre-evaluation TEE was performed within 48 h of the procedure. Before the procedure, all subjects received enteric-coated aspirin, clopidogrel (in case of intolerance, ticlopidine might have been substituted), and amoxicillin (or appropriate substitute). Once transseptal access was obtained, heparin was administered and supplemented as needed to maintain an activated clotting time of >250 s throughout the procedure. An angiogram of the LAA was done in the most appropriate 2 views (generally a right anterior cranial/oblique and an anterior/posterior angulation), and the appropriate occluder was selected after measurement of the LAA orifice diameter. Fluoroscopy, angiography, and intra-procedural echocardiography were used in the guidance of the delivery and evaluation of the implant. Intra-procedural echocardiography could be accomplished with TEE or intracardiac echocardiography. If intracardiac echocardiography was used, a phased array system with a color Doppler feature was employed. Final implant position was confirmed by cineangiography with contrast medium injections distal to the deployed device (in the LAA) and in the left atrium as well as by echocardiography. The TEE color Doppler was also used to assess for possible leaks around the implant's edges.

Post-procedure medication and follow-up. It was recommended that all subjects be given clopidogrel 75 mg once/day (or, if patient unable to take clopidogrel, then ticlopidine 250 mg twice/day) for a period of 4 to 6 weeks after the procedure. Subjects were directed to take enteric-coated aspirin, 325 mg/day indefinitely after the PLAATO procedure.

Follow-up visits were required at 1, 3, and 6 months and on an annual basis for 5 years after the procedure. Data collected during follow-up visits included a 12-lead electrocardiogram, administration of the National Institutes of Health Stroke Scale (NIHSS), complete blood count, and chest X-ray. In addition, the first 20 patients enrolled were to receive a TEE at the 1- and 6-month follow-up visits. Subjects who did not undergo a TEE had a transthoracic echocardiogram. Any adverse events were documented, and information regarding hospital stays and diagnostic testing were obtained and recorded during the follow-up period. An echocardiography core laboratory (Rhode Island Hospital, Providence, Rhode Island) independently analyzed all pre- and post-PLAATO procedure TEEs and transthoracic echocardiograms collected as part of the study. Implant seal of the LAA was assessed with a 5 grade scale (Table 3) from TEE images obtained immediately after procedure and at each follow-up visit. Follow-up compliance was 100% (61 of 61) at the 1-month visit and 98.2% (56 of 57) at the 1-year visit. The study was terminated while most subjects were in their fourth year of follow-up, before the 5-year visit. Subjects were followed for an average of 3.75 years.

Results

Patient enrollment included 39 men (60.9%) and 25 women (39.1%) with an average age of 73 years (range 43 to 90 years). The majority of study patients had been diagnosed with AF for more than 3 years (33 of 64; 51.6%) upon study enrollment. The most prevalent reasons for being poor candidates for warfarin were excessive risk of falls, history of

Table 3. Echocardiographic Left Atrial Appendage Seal Grade Scale

Grade	Description by Echocardiography Core Lab
1	Severe leak, multiple jets of free flow
2	Moderate leak, >3 mm diameter jet
3	Mild leak, 1–3 mm diameter jet
4	Trace, <1 mm diameter jet
5	None

Table 4. $CHADS_2$ Category Distribution

$CHADS_2$ Category	Risk Factors	% PLAATO Patients (n = 64)
C	Congestive heart failure or left ventricular ejection fraction <40%	43.8% (28)
H	Hypertension	76.6% (49)
A	Age >75 yrs	45.3% (29)
D	Diabetes	23.4% (15)
S_2	Prior stroke/transient ischemic attack	68.8% (22)

PLAATO = Percutaneous Left Atrial Appendage Transcatheter Occlusion.

severe bleeding on warfarin, and inability to maintain a stable INR. Stroke risk estimates were calculated with the $CHADS_2$ stroke-risk index (6,7). Table 4 provides a distribution of the $CHADS_2$ categories within the PLAATO study population. Table 5 lists the $CHADS_2$ score distribution within the study population, along with each score's associated stroke risk.

Primary end point. The primary study end point of no occurrence of MAEs within 1 month of the index procedure was met by 63 of 64 (98.43%) patients. One patient had 2 events (cardiovascular surgery and death).

Secondary end points. Table 6 shows the secondary safety and effectiveness end points. No device failures or malfunctions occurred during the study. Eight strokes were reported in 8 patients throughout the course of the study. Five major strokes (present after 7 days or increased NIHSS by >4) occurred at the following times: 216; 979; 1,004; 1,043; and 1,586 days after procedure. Three minor strokes (resolved completely within 7 days or increased NIHSS by <3) occurred at the following times: 255, 274, and 689 days after procedure.

Echocardiography core laboratory results. A grade 3 or better score was needed to qualify as an effective seal of the LAA. Fifty-five of the 56 patients (98.2%) with assessable TEE data reached this end point. Follow-up TEE and chest X-ray assessments revealed stable implant position with no evidence of migration, erosion, or encroachment on surrounding structures and smooth healing on the left atrial-facing surface with no thrombus. Table 7 summarizes the echocardiographic core laboratory results.

A comparison of seal grades between the procedural and follow-up TEE assessments can be made in 23 subjects. Seal grades remained stable or improved in 17 of 23 subjects. Six of the 23 subjects (26%) had a degradation in seal grades during follow-up, but no seals were observed to degrade to more than a grade 3. The subject who did not have an effective seal (grade 2) of the LAA at the end of the implant procedure had a grade 4 seal at the 1-month follow-up assessment.

Adverse outcomes by $CHADS_2$ scores and seal grades. The $CHADS_2$ scores and LAA seal grades were evaluated among subjects with MAEs. The 1 subject who experienced a TIA was also included in this evaluation. The distribution of $CHADS_2$ within this group was similar to the total subject population. A $CHADS_2$ score of 3 was the most common, present in 33% of this group. Ten of the 18 subjects in this evaluation had follow-up TEEs performed, and only 2 of the 10 (20%) had a degradation in seal grade observed during follow-up. Only 1 event occurred within 6 months after the implant procedure. Among the 9 subjects in this group who experienced a neurological event (stroke or TIA), 7 have follow-up TEE data and only 1 had a degradation in seal grade. Table 8 summarizes the outcomes $CHADS_2$ scores and LAA seal grades in this group.

$CHADS_2$ outcomes. The mean $CHADS_2$ score in the study population was 2.6, resulting in an expected annual stroke/TIA rate of 6.6%. There are 239.9 patient-years reflected in the study data. Eight strokes and 1 TIA were reported, resulting in an annualized stroke/TIA rate of 3.8%, almost one-half (58%) of the expected stroke/TIA rate (Fig. 1).

NIHSS outcomes. National Institutes of Health Stroke Scale assessment scores were reviewed for all patients throughout their participation in the study. A majority (57.8%, 37 of 64) of the patients had no change in NIHSS assessment scores throughout the course of the study. Scores in 2 patients (3.1%) decreased ≤3 from prior visits during the study, whereas scores in 2 patients (3.1%) increased ≤3 from prior visits during the study. Scores in 12 patients (18.8%) increased and decreased ≤3 from any prior visit score during the study. Eight subjects (12.5%) had scores increase and decrease ≥3 from any prior visit score during the study. Only 12.5% of the study subjects demonstrated changes in NIHSS scores of 3 or greater throughout the course of the study, indicating that the majority of subjects had no significant changes in mental status during their participation in this study. All NIHSS scores improved at the 3- and 4-year follow-up visits compared with both the baseline and 6-month visits. Of the 8 patients who experienced strokes throughout the course of the study, 6 (75%) had no change in NIHSS assessment scores after their strokes. One patient had an increase ≤3 after the stroke. One patient experienced a stroke after the 4-year follow-up assessment, but the

Table 5. Baseline $CHADS_2$ Score Distribution

$CHADS_2$ Score	Associated Stroke Risk*	% PLAATO Patients (n = 64)
0	0.8%	0
1	2.2%	23.4% (15)
2	4.5%	31.2% (20)
3	8.6%	18.8% (12)
4	10.9%	17.2% (11)
5	12.3%	9.4% (6)
6	13.7%	0

*See reference (7).
PLAATO = Percutaneous Left Atrial Appendage Transcatheter Occlusion.

Table 6. PLAATO Secondary End Point Results

Secondary Safety End Points	Number of Procedures Meeting the End Point	Percentage
No MAEs during the hospital stay for the index procedure	64 of 65 procedures. One patient had 2 procedures; the first procedure was MAE-free. During the second procedure, the patient experienced 2 MAEs.	98.46%
Absence of mobile left atrial thrombus or MAEs within 6 (6) months of the index procedure		98.46%
Secondary Effectiveness End Points		
Device success: successful delivery and deployment of the PLAATO implant into the LAA or recapture and retrieval (if necessary.)	61 of 65 procedures. Three patients did not receive implants; 1 patient had 2 procedures.	93.85%
Procedural success: device success and no MAEs during the hospital stay of the index procedure		93.85%
Implantation success: successful delivery and deployment of the PLAATO implant into the LAA and the absence of MAEs within 1 (1) month of the index procedure		93.85%
Treatment success is defined as implantation success and LAA occlusion by echocardiography at 1 (1) month	22 of 22*	100%

*Only the first 20 patients were required by the protocol to have the seal leak assessed at the 1-month follow-up and therefore were the only patients analyzed for the treatment success end point.
LAA = left atrial appendage; MAE = major adverse event; PLAATO = Percutaneous Left Atrial Appendage Transcatheter Occlusion.

study was terminated before the subject's 5-year follow-up window (Fig. 2).

Adverse events. The CEC adjudicated a total of 18 MAEs for the study: 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. The CEC adjudicated a total of 263 SAEs for the study. The most common SAE reported was "congestive heart failure", which occurred 35 times among 12 patients, frequently in relation to an exacerbation of a pre-existing condition.

Summary of deaths. There were 17 reported deaths throughout the course of this study. A death was classified as an MAE when the cause of death was either cardiac or neurological. Of the 17 adjudicated deaths, 8 were categorized as MAEs and 9 as SAEs. All of the deaths were categorized as unrelated to the device or procedure and were related to patient comorbidities (e.g., renal failure, congestive heart failure).

Discussion

This study supports the use of the PLAATO system for percutaneous LAA transcatheter occlusion. The primary study end point rate (98.43%) demonstrates that use of the PLAATO system provided an acceptably safe means of percutaneous LAA transcatheter occlusion in patients with AF who were suboptimal candidates for anticoagulation with warfarin. More than 98% of patients had satisfactory LAA sealing by echocardiographic core laboratory assess-

Table 7. Echocardiography Core Laboratory Assessment of LAA Occlusion

	Procedure		1-Month*		6-Month*	
Grade	n	%	n	%	n	%
1	0	0.00	0	0.00	0	0.00
2	1	1.79	0	0.00	0	0.00
3	12	26.79	5	22.73	1	5.88
4	29	51.79	13	59.09	13	76.47
5	11	19.64	4	18.18	3	17.65
Total	56	100.00	22	100.00	17	100.00
Not assessable†	2	3.33	1	4.35	0	0
Data missing‡	2	3.33	0	0.00	1	5.56

Percentages are based on the number of patients with assessable echocardiographic data. *Follow-up transesophageal echocardiography (TEE) exams were only required for the first 20 subjects enrolled in the study. †The PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) Study device was not assessable during the TEE exam. ‡LAA occlusion grade was unreadable on the TEE exam or not recorded.
LAA = left atrial appendage.

Table 8. $CHADS_2$ Scores and LAA Seal Grades in Patients With MAEs/TIA

Patient ID	$CHADS_2$ Score	LAA Seal Grade			Days After Procedure	Adjudication Description
		Procedure	1-Month	6-Month		
115-007	4	NA	NA	NA	27	Probable cerebral hemorrhage, death
101-003	1	3	3	4	216	Major stroke
113-001	2	4	4	3	255	Minor stroke—probable
107-012	5	3	NA	NA	274	Minor stroke
101-002	3	5	4	4	342	Sudden death
101-005	1	3	5	4	354	TIA
115-003	3	5	NA	NA	370	Death
123-002	3	NA	NA	NA	581	Death
109-002	3	4	NA	NA	682	Death
115-006	4	4	NA	NA	689	Minor stroke
109-001	4	3	3	4	979	Major stroke
107-002	3	4	5	4	1004	Major stroke
107-001	2	4	4	4	1043	Major stroke
115-015	5	4	NA	NA	1174	Death
110-001	4	5	4	5	1216	Death
121-002	2	4	4	3	1342	Death
123-008	3	4	NA	NA	1399	Myocardial infarction
101-007	4	4	5	NA	1586	Major stroke

LAA = left atrial appendage; MAE = major adverse event; TIA = transient ischemic attack.

ment. This was not a randomized study, but one can speculate whether LAA occlusion with the PLAATO device impacted the incidence of stroke in our patients. On the basis of the $CHADS_2$ score, our study patients had an expected annual stroke/TIA risk of 6.6%. With up to 5 years of follow-up, the actual stroke/TIA rate was 3.8%/year—a 42% reduction.

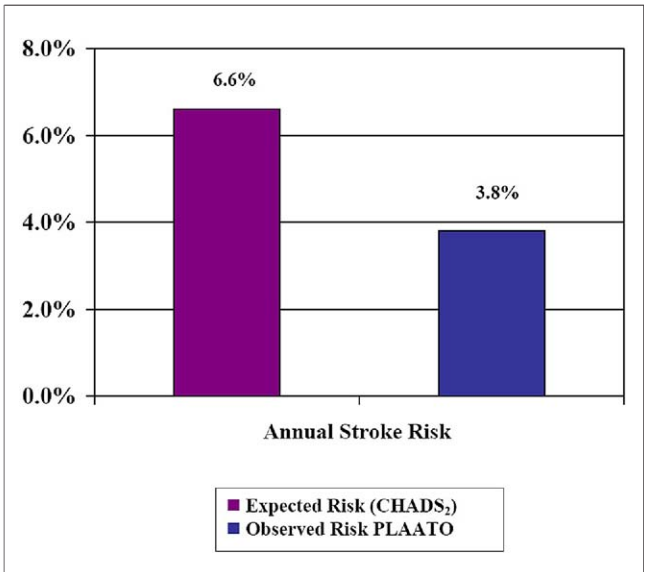
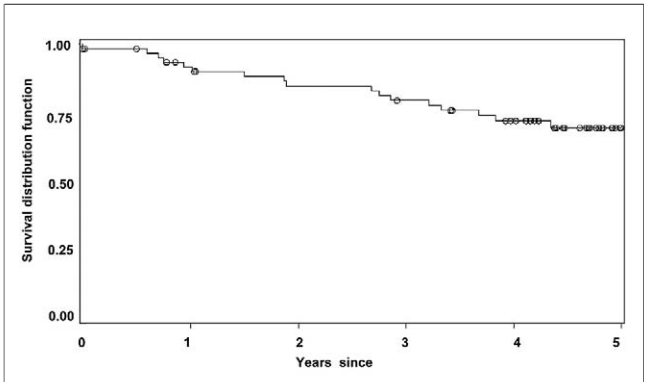


Figure 1. Difference Between the Expected Versus Observed Stroke/TIA Rates in the PLAATO U.S. Feasibility Study

The **purple bar** represents the expected stroke/transient ischemic attack (TIA) rate calculated from the patient population $CHADS_2$ score (6.6%). The actual observed stroke/TIA rate was 3.8% (depicted by the **blue bar**). PLAATO = Percutaneous Left Atrial Appendage Transcatheter Occlusion.



Years after Index Procedure	0	1	2	3	4	5
# At Risk	64	54	48	44	36	12 *
# Censored	0	5	7	8	12	35
# Events	0	5	9	12	16	17 †
% MAE Event Free	100%	91.8%	84.8%	79.5%	72.1%	69.5%

Figure 2. Kaplan-Meier Analysis of Time to MAE

The **table** depicts the number of years after the index procedure, the actual number of patients at risk at each year end, the number of events, and the percentage of patients free of major adverse events (MAEs). *12 subjects completed the 5-year follow-up visit prior to early study termination; †17 subjects had a total of 18 MAEs. One subject experienced 2 MAE events. **Solid line** = product-limit estimate curve; **circles** = censored objectives. PLAATO = Percutaneous Left Atrial Appendage Transcatheter Occlusion.

Although the safety and effectiveness of the PLAATO system was demonstrated, there are at present no plans to pursue a pivotal study of the PLAATO system. However, the recently completed PROTECT-AF (Embolic Protection in Patients with Atrial Fibrillation) Trial is such a pivotal, randomized trial (8). This trial uses the Atritech (Plymouth, Minnesota) "Watchman" device for LAA occlusion. The Watchman device differs in design from the PLAATO device. However, the initial trial findings reported at the American College of Cardiology Annual meeting in 2009 indicate that LAA occlusion with the Watchman device is not inferior to warfarin therapy and might be superior in terms of the incidence of hemorrhagic stroke in follow-up. On the basis of these findings, if Food and Drug Administration approval is given, it would lead to the availability of a transcatheter LAA occlusion device that could be used for patients that are suboptimal candidates for warfarin therapy long-term.

Study limitations. Because this was a safety and feasibility study, it was not randomized, and the patient numbers were small. However, each patient did serve as his/her own "control", which makes the data more easily interpretable.

Conclusions

Use of the PLAATO system is safe and effectively occludes the LAA. Although this was not a randomized study, the stroke/TIA rate was 3.8%/year in a population of patients in which the anticipated stroke/TIA rate was 6.6% over a 5-year follow-up period—a 42% reduction.

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Key Words: atrial fibrillation ■ left atrial appendage ■ PLAATO ■ stroke ■ transcatheter.