TCT-172

Aspirin monotherapy after left atrial appendage occlusion with the Amplatzer Cardiac Plug: results from the ACP Study Group Registry

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Background: To investigate the safety and efficacy of left atrial appendage occlusion (LAAO) with the Amplatzer Cardiac Plug (ACP) for stroke prevention in patients with atrial fibrillation (AF).

Methods: Data from consecutive patients treated in 22 centers were collected. Patients who underwent successful single LAAO and who were on aspirin monotherapy or no therapy at last follow-up were included in the study.

Results: A total of 627 patients (age 75.8 years) fulfilled the inclusion criteria. Of those, 579 were on aspirin (92%) and 48 received no treatment (8%) at last follow-up. The mean CHADS2/VASc score was 4.4 ± 1.5 (annual risk of thromboembolism = 5.6%±2.7%), and the mean HASBLED Score was 3.2 ±1.2 (annual risk of major bleeding = 5.7±3.9%). There were 3 strokes (0.5%), 1 transient ischemic attack (TIA) (0.2%), and 8 major bleedings (1.3%) in the periprocedural period. The median (IQR) follow-up was 16.2 (9.7-26.2) months, accumulating 981 patient years. A total of 21 deaths were reported during follow-up, which were not reported as device related. There were 3 strokes (0.5%), 6 TIAs (1.0%), and 5 major bleedings (0.8%) during follow-up. The annual rate of systemic thromboembolism was 1.33% (13981 patient-years), which is a 76.4% risk reduction compared to the annual predicted rate. The annual rate of major bleeding was 1.33% (13981 patient-years), which is a 76.5% risk reduction.

Conclusions: In this multicenter study, LAAO with the ACP and aspirin or no therapy at follow-up was effective in preventing thromboembolism, and was combined with a reduction of major bleeding events.

TCT-173

Percutaneous Closure of Left Atrial Appendage Guided by Intra-cardiac Echocardiography From the Left Atrium

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Background: Percutaneous left atrial appendage closure (LAAO) occlusion is commonly performed under general anesthesia and trans-esophageal echocardiography (TEE) guidance. Intra-cardiac echocardiography (ICE) offers several advantages over TEE for procedural guidance; however experience is limited with LAA occlusion. In previous reports of LAA closure under ICE guidance, ICE was performed from the right atrium or coronary sinus where complete visualization of the LAA anatomy is uncertain. We sought to evaluate the feasibility, efficacy and safety of LAA occlusion using ICE guidance from the left atrium (LA).

Methods: Twenty-three patients with AF, significant risk for stroke and long-term contra-indication for anticoagulation underwent LAA closure with the Amplatzer Cardiac PlugTM (St.Jude Medical Inc.) under conscious sedation and ICE guidance. The ICE catheter and ACP delivery sheath were advanced into the LA through separated trans-septal punctures. Baseline patient characteristics, procedural and follow-up data were prospectively recorded. Clinical and TEE follow-up was done at 3 months after the procedure. Procedural success was defined as the implantation of the closure device at the intended location at site with adequate post-procedural thromboembolic protection (grade 3 or more by ICE) occlusion

Results: Procedural success was achieved in 22 of 23 patients (96%) with a mean procedural time of 105 +/- 27 minutes; challenging anatomy was the reason of failure. Median hospital stay was 1 day. No major procedural complication occurred however two patients had TIAs during the procedure, which were not reported as device related. There were 3 strokes (0.5%), 6 TIAs (1.0%), and 5 major bleedings (0.8%) during follow-up. The annual rate of major bleeding (<0.5%), 6 TIAs (1.0%), and 5 major bleedings (0.8%) during follow-up. The annual rate of systemic thromboembolism was 1.33% (13981 patient-years), which is a 76.4% risk reduction compared to the annual predicted rate. The annual rate of major bleeding was 1.33% (13981 patient-years), which is a 76.5% risk reduction.

Conclusions: Initial experience suggests that LAA occlusion with the Amplatzer Cardiac PlugTM under ICE guidance from the left atrium in conscious patients is feasible, reproducible and safe.

TCT-174

Cardiac CT angiography is a useful non-invasive surveillance imaging test after percutaneous left atrial appendage closure

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Background: Left atrial appendage (LAA) device imaging after percutaneous closure for atrial fibrillation is important to assess for residual leak, device-associated thrombus, device positioning, surrounding structures, and pericardial effusion. Cardiac computed tomography angiography (CCTA) is well suited to assess these features non-invasively.

Methods: We report our pilot consecutive series of follow-up CCTA after LAA closure with the Amplatzer Cardiac Plug (ACP), Amulet, or Watchman devices, at Vancouver General Hospital. Patients were treated with aspirin indefinitely, and clopidogrel for 1-3 months following LAA closure. Transthoracic echocardiograms were routinely performed at 1 month and CCTA at 1-6 months post-procedure for clinical surveillance in this series of patients. Prospective cardiac-gated CCTA were performed with Toshiba 320-slice or Siemens 2nd generation 128-slice dual source scanners, and images were interpreted with the Vitrea software. GFR < 40 was an exclusion. We assessed for atrial-side device thrombus, residual contrast leak into the LAA, pericardial effusion, and device dimensions.

Results: Twenty-five patients underwent CCTA at a mean of 157 ± 143 days following LAA closures (13 ACP, 8 Amulet, and 4 Watchman). Average age was 75.5 ± 9.8 years, and CHADS2 score was 3.2 ± 1.3. All patients had concomitantly to anticoagulation for atrial fibrillation, and were treated with dual antiplatelet therapy for 3-6 months. Devices were visualized within the LAA on CCTA. No pericardial effusion was seen on CCTA follow-up. Only one patient had thrombus on the atria-side of the device. Sixty-five percent had residual leak into the LAA on CCTA at follow-up. Device measurements on CCTA and correlation to TEE measurement post-procedure and device dimensions were presented.

Conclusions: CCTA is a useful non-invasive imaging test for clinical surveillance after percutaneous LAA closure. Assessments of device position, atrial-side thrombus, pericardial effusion, and residual patency into the LAA are well visualized on CCTA. However, residual LAA patency is seen frequently on CCTA, and correlation to the degree of TEE residual leak should be further explored.

TCT-175

Preclinical Study of Novel Generation of Watchman for Left Atrial Appendage Occlusion

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Background: WATCHMAN is the most studied LAA device clinically with >2000 implantations and >5000 patient-years of follow-up. Currently, a new generation of Watchman has been designed to further improve implant performance. Similar to the current generation (CG-WM), the next generation (NG-WM) also has a self-expanding nitinol stent frame structure, which is covered with a permeable polyester fabric membrane and deployed with a 12F delivery catheter with 12F access sheath. The difference between the NG-WM includes 18 struts (vs. 10 in CG-WM), an atrumatic closed distal end (vs. open end in CG-WM), and reduced length of the NG-WM. The NG-WM can be redeployed after either full or partial re capture. In contrast, the CG-WM has to be replaced if a full recapture is needed. The present study aimed to test the NG-WM device in a canine LAA model.

Methods: A total of 14 dogs were used in the study. Under TEE at 0, 45, 90 and 135° views and x-ray guidance, both CG-WM and NG-WM were appropriately sized to be 10-20% larger than the LAA ostium.

Conclusion: NG-WM is feasible, reproducible and safe.
**Results:** Device deployment was attempted in all animals, of which 100% of NG-WM (60) and 75% of CG-WM (60) were successfully deployed. Two animals were excluded due to pericardial effusion and unfavorable LAA anatomy. All implanted animals were well tolerated the procedure and without adverse cardiac or systemic events. The table summarizes the overall deployment parameters between the two generation devices.

**Conclusions:** The next generation of the WATCHMAN device showed an improvement in the ease of implant. The NG-WM procedure required fewer device partial or full recaptures. Furthermore, the additional struts on the NG-WM device showed better seal with less leaks than the CG-WM, though neither device showed residual leaks in excess of 2 mm. Long-term assessment of device interaction with biologic systems and how the biologic system may affect the device study is ongoing.

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**TCT-176**

Comparison of Imputed Placebo Versus Observed Ischemic Stroke Rates in the Watchman Trials Represents a Significant Risk in Reduction

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**Background:** Left atrial appendage closure (LAAC) is, intuitively, an attractive strategy to reduce stroke risk in atrial fibrillation. Although the PROTECT-AF trial demonstrated superiority of the WATCHMANTM LAAC device over warfarin at four years, there is little data regarding ischemic stroke protection of LAAC therapy in patients unable or unwilling to take warfarin. We sought to assess the effectiveness of the device for stroke risk reduction compared to the imputed placebo event rate, that is, the expected ischemic stroke rate without anticoagulation therapy, based on CHADS2 score, in three separate device trials.

**Methods:** The imputed placebo event rate in the trials (PROTECT AF, CAP, PREVAIL) was calculated using the average CHADS2 score in each study. The expected event rate, which is well validated in the literature, was compared with the observed ischemic stroke rate in the device arm of each individual trial.

**Results:** Patients from PROTECT AF (n=463), CAP (n=566) and PREVAIL (n=407) were analyzed. The average CHADS2 score and imputed placebo event rate per 100 patient-years were 2.2 (5.6-5.7), 2.5 (6.4), and 2.6 (6.6-6.7) in PROTECT AF, CAP, and PREVAIL, respectively. The relative risk reduction for ischemic stroke was 77%, 83%, and 62%, respectively (Table).

**Conclusions:** In this analysis, LAAC with WATCHMAN is associated with a significant reduction in ischemic stroke compared with an expected event rate derived from the CHADS2 score. The relative risk reduction is similar to that seen in the historical trials comparing warfarin to placebo, suggesting LAAC may provide a reduction in stroke risk for patients not receiving anticoagulation therapy.

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**TCT-177**

Long-term follow-up after interventionia left atrial appendage occlusion in a real world collective: Data from the ALSTAR-LA Registry and comparison with results from the ARISTOTLE trial

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**Background:** Patient selection and postinterventional anticoagulation after WATCHMAN implantation varies widely between centers and national guidelines. Clinical data are available mainly for relatively low risk patients and only in comparison to warfarin, whereas direct oral anticoagulants gain an increasing role in clinical practice. Here, we present follow-up data after WATCHMAN® implantation in a high-risk population in terms of safety and efficacy from our all-comers ALSTAR-LA registry and compare these to subgroup analyses from the ARISTOTLE trial showing safety and efficacy of apixaban in patient at particular high risk for stroke and bleeding events.

**Methods:** Postinterventional anticoagulation according to the individual bleeding risk and conducted either with warfarin, DAPT or low-dose DOACS. Follow-up after 3 months and regular clinical follow-ups thereafter.

**Results:** Between 2010 and April 2014, 196 patients were treated with WATCHMAN® devices in our center, regular follow-up data is available for 110 patients. Mean follow-up duration was 396 (±33) days. Mean age: 74.6 years (±9.9), CHADS2 VASc-Score 4.7 (±0.2), HAS-BLED score 3.7 (±1.0). In 109 patients (99%) LAAC occlusion was successfully performed using the WATCHMAN® device. We observed two periprocedural strokes (1.8%), one device embolization (0.9%) and three relevant pericardial effusions (2.7%). In addition, we observed 2 strokes, 9 CV or unknown deaths and 2 major bleedings as endpoints during our follow-up (rates shown in figure 1). The combined safety endpoint (procedure-related stroke, bleeding, pericardial effusion, device embolization and major bleeding) and combined efficacy endpoint (stroke, systemic embolism and cardiovascular/unknown death) are calculated as in PROTECT-AF.

**Conclusions:** LAAC occlusion with the WATCHMAN device can yield similar results in “real world” collective as in PROTECT-AF. No NOACs are not an effective alternative to VKA for patients at high bleeding risk. Comparison with high-risk subgroups from NOAC trials (ARISTOTLE) imply, that WATCHMAN will keep its significance even with increasing usage of NOACs.