Results: Device deployment was attempted in all animals, of which 100% of NG-WM (6/6) and 75% of CG-WM (6/8) 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.

	CG-WM	NG-WM
Dogs	6	6
Total devices used	10	6
Full recaptures required in dogs	4	0
Partial recaptures in dogs	3	1
Peri-device jet (<2mm) in dogs	2	0

TCT-176

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

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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.

Imputed Placebo versus Observed WATCHMAN Ischemic Stroke Rate per 100 Patient - Years				
Study	Average CHADS2 Score WATCHMAN Patients	Imputed Untreated Control Event Rate	Observed WATCHMAN Ischemic Stroke Rate (95% CI)	Relative Risk Reduction
PROTECT AF	2.2	5.6 to 5.7	1.3 (0.9, 2.0)	77% (64%, 84%)
CAP	2.5	6.4	1.1 (0.8, 1.7)	83% (73%, 88%)
PREVAIL	2.6	6.6 to 6.7	2.5 (1.5, 4.3)	62% (35%, 77%)

TCT-177

Long-term follow-up after interventional left atrial appendage occlusion in a real world collective: Data from the ALSTER-LAA 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 ALSTER-LAA 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 TEE 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 availeable for 110 patients. Mean follow-up duration was 396 (±33) days. Mean age: 74.6 years (±0.9), CHA2DS2-VASc-Score 4.7 (±0.2), HAS-BLED score 3.7 (±0.1). In 109 patients (99%) LAA occlusion was successfully performed using the WATCHMAN® device. We observed two peri-procedural 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: • LAA occlusion with the WATCHMAN device can yield similar results in "real world" collective as in PROTECT-AF • 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 useage of NOACs

TCT-178

Atrial fibrillation in patients with aortic stenosis: is percutaneous left atrial appendage closure an option?

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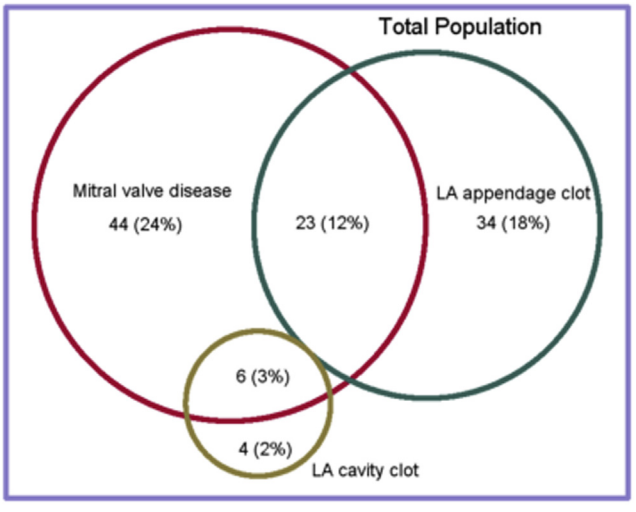
Background: Percutaneous Left atrial appendage (LAA) closure is emerging as a safe and effective alternative to medical anticoagulation for embolic event prophylaxis in non-valvular atrial fibrillation. However, the effectiveness of the procedure in patients with atrial fibrillation secondary to or associated valvular heart disease is not proven. We hypothesize that majority of patients with atrial fibrillation associated with severe aortic stenosis could be candidates for the procedure due to the location of thrombus being the LAA.
Methods: We queried our institutional echocardiography database from January 2003 to December 2012. All patients with aortic valve area less than 1.3 cm2 and who had a current episode or previous history of atrial fibrillation were considered for inclusion. Patients were excluded if no thrombus or echo contrast sludge was detected in the left atrium on trans-esophageal echocardiography (TEE). Descriptive statistics were used to summarize the data.
Results: Of the 185 patients who met the inclusion criteria, 73 (41%) patients also had an associated mitral valve disease. As shown in the attached figure 60% patients had a definitive thrombus visible on echocardiogram and only 2% of the patients who were free of associated mitral valve disease had a definitive thrombus detected in left atrial cavity.



Conclusions: Our analysis suggests that in patients with aortic stenosis, free of associated mitral valve disease, only a small number of thrombi are formed in left atrial cavity. This could imply that majority of these patients may benefit from percutaneous left atrial appendage closure.