generation WATCHMAN LAA closure device. Of the 36 patients, the new device was implanted in 34 (94.4%). In two patients (5.6%), device closure was attempted but unsuccessful due to an unfavorable LAA anatomy (early separation into multiple lobes in one and acute LAA angulation in the second). In these cases closure was performed successfully with a different closure system. Though in eight patients partial and in fourteen full recaptures were needed prior to final release, there was no pericardial effusion. Mean procedural time was 50 ± 45 minutes. No device-related adverse events occurred during the procedure and accurate device placement was achieved in all implanted patients. During the follow-up of 12 months, three ischemic strokes (8.3%), one hemorrhage stroke (2.7%), one TIA (2.7%) and three deaths (8.7%) occurred. Device-associated thrombus formation was seen in one patient (2.7%) at the six-month follow-up treated with low molecular weight heparin.
Conclusions: LAA closure with the newer (fourth) generation WATCHMAN device is feasible and safe. The atraumatic distal end may reduce the incidence of pericardial effusion during implantation.

TCT-693

Development of in-vitro test methods for LAA-occlusion devices

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Background: Recent study results present left atrial appendage (LAA) occluders as an alternative to oral anticoagulation for stroke prevention in patients with atrial fibrillation. Several devices with different designs (specifically different anchoring methods and diameters) are being tested in clinical and animal trials with good results. Device anchoring and achieving sufficient seal remain challenges, considering the diverse morphologies of the LAA, but must be achieved in order to prevent residual flow and possible associated thrombotic events. There are currently no standard guidelines or norms for in-vitro assessment and comparability of LAA occluders and their function.
Methods: In order to design a test system for the in-vitro assessment of LAA occluder function, a design study and review of literature and CT-data were performed. Additionally, anatomical studies on LAAs of porcine hearts were performed to better incorporate the surface structure and mechanical properties into the test setup.
Results: A modular in-vitro test system with the possibility of integrating exact physiological models of the LAA was developed. The system allows for integration and exchange of different LAA morphologies cast from silicone or native animal anatomies and has the possibility to assess permeability, seal and anatomical fit of LAA occluders.
Conclusions: Standardized tests are essential during the establishment of novel device based therapies, to ensure comparability and the fulfillment of basic requirements. The in-vitro test setup for LAA occluders presented here allows for assessment and optimization of LAA occluders.

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Acute Hemodynamic effects of the MitraClip® System. Focus on grade of MR, stroke volume, LA-, PA- and PCW- pressure. Analyzing 330 MitraClip procedures at the AK St. Georg, Hamburg

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Background: Hemodynamic changes after MitraClip® procedure are rarely described till today. Aim of this work was to improve the understanding of the acute hemodynamic effects.
Methods: Till today more than 330 Patients have been treated with the MitraClip® System at the AK St. Georg in Hamburg. Hemodynamics have been evaluated with Swan Ganz catheterization and thermodilution method directly before and after Clipping. The functional result was assessed 6 weeks, 6 months and 12 months after the MitraClip® procedure.
Results: 314 out of 330(95.2%) patients could be treated successfully (MR post ≤2). 30 day mortality was 7%. MR was reduced significantly from 3.0(±0.3) to 1.1(±1.1) ($p<0.001$), needing an average of 1.4 Clips(±0.6). Cardiac output(CO) increased from 3.7l/min(±1.1) to 4.7l/min(±1.3) directly after the procedure ($p<0.001$). Stroke volume(SV) increased from 62.4ml(±18.7) to 80.7ml(±26.9) ($p<0.001$). Systolic pulmonary artery pressure (PAPs) increased slightly from 39.9mmHg(±12.5) to 42.2mmHg(±12.2) ($p<0.05$). Wedge pressure (PCWP, mean) fell from 16.8mmHg(±7.8) before to 15.7mmHg(±6.5) post MitraClip® ($p<0.05$). Left atrial pressure (LA, mean) was reduced significantly ($p<0.001$) from 16.1mmHg(±6.9) to 13.2mmHg(±6.1). Grade of dyspnea by NYHA fell significantly as well (3.2(±0.5) baseline, 2.1(±0.7) after 6 months and 2.2(±0.6) after 12 months), $p<0.001$. Grade of MR assessed by echo was reduced stable and significantly from 3.1(±0.3) before to 1.1(±0.6) directly after and 1.8(±0.7) after 6 months, $p<0.001$.
Conclusions: The MitraClip procedure shows a stable reduction of MR combined with a stable improvement of the clinical symptom dyspnea. We've shown that this non open chest treatment of MR improves the CO and SV of up to 27% while reducing LA pressure significantly. If these findings have a prognostic impact is part of running investigation.

TCT-695

A Gender-Specific Look at MitraClip Therapy in Surgical High-Risk Patients: Acute and Long-Term Outcomes

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Background: In Europe, MitraClip (MC) therapy for significant mitral regurgitation (MR) is increasingly being performed, particularly in elderly patients at high surgical risk. Outcomes emphasizing differences between men and women are lacking. We present a high-volume single-center retrospective analysis of outcomes according to gender.
Methods: By 01/2013, 361 consecutive patients (75 ± 9 years, 227 men [M; 63%], 134 women [F; 37%]) with MR 3+/4+ had undergone MC therapy at the University Heart Center Hamburg. All patients were adjudicated by heart team consensus as not amenable to surgery.
Results: Baseline conditions were significantly more adverse in M than in F, with higher log. EuroSCORE, lower LVEF, and higher prevalence of cardiomyopathy, hypercholesterolemia, diabetes, coronary artery disease, renal failure, and functional MR in the former. Procedures were successful (discharge MR ≤2+) in 207 M (91%) and 118 F (88%, p=NS). Follow-up information was available in 205 M (90%) and 116 F (87%) at a median of 12.7 (range, 0.3-41) and 13.6 (0.4-39) months, respectively (p=NS). No significant differences in the prevalence of MR ≤2+ and of NYHA functional class ≤II were observed at 12 months (MR: M 91%, F 85%; NYHA: M 60%, F 50%) and 24 months (MR: M 91%, F 80%; NYHA: M 62%, F 49%). Overall, cumulative survival was not different between M and F (p[logrank]=0.12), but survival curves diverged significantly in favor of F after 12 months (p=0.03 by landmark analysis). Independent predictors of death on multivariate Cox regression analysis were renal failure and MC failure in M, yet renal failure and dilated cardiomyopathy in F. Rehospitalizations were frequent (M 54% and F 41% at 18 months), but not significantly different between M and F. MC failure was predictive of rehospitalizations in both genders.
Conclusions: MC therapy appears to be equally effective, acutely as well as in the long term, in M and F at high surgical risk. Increased mortality after 1 year in M is likely related to higher comorbidity and poorer LV function and requires further study.

TCT-696

Pre-operative pro-BNP levels predict quality of life restoration 1 year after MitraClip treatment in heart failure patients with severe functional Mitral Regurgitation

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Background: The aim of this study is to investigate the predictors of quality of life (QoL) restoration 1 year after MitraClip implantation in heart failure patients with FMR in our single center experience.
Methods: From October 2008, 109 consecutive patients with FMR underwent MitraClip implantation (mean age 69±9 years). FMR was ischemic in 75%. All patients underwent standardized assessment of mitral valve anatomy and functional status. Preprocedural QoL was assessed by Minnesota Living with Heart Failure Questionnaire (MLHFQ). Logistic EuroScore was 22±16%; 82% pts were in NYHA class III-IV. Mean EF was 28±11%; LVEDD was 68±8 mm. A cut-off of 14 points with MLHFQ was used to define QoL restoration 1 year after the procedure (corresponding to the mean MLHFQ observed in a NYHA I-II heart failure Italian population with mean age of 61 years).

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