Conclusions: LAA closure with the newer (fourth) generation WATCHMAN device is feasible and safe. The atriala distal end may reduce the incidence of pericardial effusion during implantation.

TCT-693
Development of in-vitro test methods for LAO-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 different 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.

Mitra Valve Disease and Treatment

Moscone West, 1st Floor

Tuesday, October 29, 2013, 3:30 PM-5:30 PM

Abstract nos: 694-706

TCT-694
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±1.3 to 1.1±1.1 (p<0.001), needing an average of 1.4 Clips±0.6. Cardiac output (CO) increased from 3.7±1 min⁻¹·1.1 to 4.7±1 min⁻¹·1.3 directly after the procedure (p=0.001). Stroke volume (SV) increased from 62.4±17.8 to 80.7±26.9 (p=0.001). Systolic pulmonary artery pressure (PAPs) increased slightly from 39.9±16.8 to 42.2±12.2 (p=0.005). Mean pulmonary pressure (PCWP, mean) fell from 16.8±11.7 to 15.7±11.6 (p=0.05) post MitraClip® (p<0.005). Left atrial pressure (LA, mean) was reduced significantly (p=0.001) from 16.1±16.6 to 13.2±16.1. 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 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. Results were comparable in men and women at the 6 month follow-up.

Conclusions: The MitraClip procedure shows a stable reduction of MR combined with a significant 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: All-Cause Mortality, 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+ to 4+ had undergone MC therapy at the University Heart Center Hamburg. All patients were adjudicated by heart team consensus as not operable or high surgical risk.

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=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 re-renal failure and MC failure in M, and failure and dilated cardiomyopathy in F. Rehospitalizations were frequent (M 54% and F 41% at 18 months), but did not significantly differ 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 (MLHQF). Logistic EuroScore was 22±16%; 82% pts were in NYHA class III/IV. Mean EF was 28±11%; LVEDD was 68±8. Mean cutoff of 14 points with MLHQF was used to define QoL restoration 1 year after the procedure (corresponding to the mean MLHQF observed in a NYHA I-II heart failure Italian population with mean age of 61 years).

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±1.3 to 1.1±1.1 (p<0.001), needing an average of 1.4 Clips±0.6. Cardiac output (CO) increased from 3.7±1 min⁻¹·1.1 to 4.7±1 min⁻¹·1.3 directly after the procedure (p=0.001). Stroke volume (SV) increased from 62.4±17.8 to 80.7±26.9 (p=0.001). Systolic pulmonary artery pressure (PAPs) increased slightly from 39.9±16.8 to 42.2±12.2 (p=0.005). Mean pulmonary pressure (PCWP, mean) fell from 16.8±11.7 to 15.7±11.6 (p=0.05) post MitraClip® (p<0.005). Left atrial pressure (LA, mean) was reduced significantly (p=0.001) from 16.1±16.6 to 13.2±16.1. 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 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. Results were comparable in men and women at the 6 month follow-up.
Results: Procedural success was 99% and 30-day mortality was 1.8%. Adverse events included: IABP support (13%), renal replacement therapy (6%), infections (3.6%). No cerebrovascular events or AMI occurred. Median length of hospital stay was 5 days. At discharge, 87% patients had MR ≤ 2+. At 1 year follow up was 34.7±10.4% (p=0.002 compared to baseline value). Actuarial survival at 1 year was 89.6±3.9%. Actuarial freedom from MR ≤ 2+ was 79.4±2%. At 1 year, MLHGF improved from 40.1±15 to 22.1±16 (p=0.0001). Complete QoL restoration at 1 year was achieved in 43% of the survivors. At multivariate analysis, preoperative value of serum pro-BNP<1600 pg/ml was identified as independent predictors of QoL restoration at 1 year (OR 0.2; p=0.03).

Conclusions: MitraClip therapy is a safe and effective therapeutic option for high-risk patients with FMR, leading to clinical and QoL improvements. Higher pro-BNP levels are associated with reduced likelihood of QoL restoration at 1 year.

TCT-697
Outcomes from MitraClip Therapy in Functional Compared to Degenerative Mitral Regurgitation: Multi-centre Experience from the MitraClip Asia-Pacific Registry (MARS)
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1National University Heart Centre, Singapore, Singapore, 2National Heart Centre Singapore, Singapore, Singapore, 3University of NSW, Darlinghurst, Australia.
Methods: From October 2008, 109 patients underwent MitraClip for FMR at our Institution. All patients underwent a standardized prospective data collection pathway.
Results: Patients were 27 ID (24.2%) and 82 IS (75.2%). Groups did not differ in age (p=0.13), NYHA (p=0.16) and pro-BNP (p=0.47). ID were slightly “lower-risk” due to less comorbidities: STS mortality 8.2% vs 11.5% (p=0.06), RED 5% vs 17% (p=0.0008), COPD 1% vs 32.9% (p=0.02), mean creatinine 1.3±0.5 vs 1.65±0.9 mg/dl (p=0.04), inotropic support 0% vs 7.9% (p=0.03). ID however had a more impaired QoL (mean MLHGF 48±16 vs 37±13, p=0.0008; SF-36 F 29.1±7 vs 35.8, p=0.004; SF36-M 38.9±19 vs 39.9; 6MWT 168±76 vs 202±109, p=0.08) and a deeper heart dysfunction: mean EF 24.9±9 vs 30.1±11% (p=0.02; EDD 69±7 vs 67±8 mm (p=0.20). Implantation was successful in 100% vs 98.8% (p=0.56) and multiple clips were used in 77.8% vs 67% (p=0.19) of ID and IS respectively. Residual MR 22% vs 11% (p=0.26). There was no difference in procedural time, post-operative stay of length and complications (all p>0.05). In-hospital mortality was 0% in ID vs 2% IS patients (p=0.41). Twenty-two ID and 64 IS reached 1-year follow-up: survival was 86.4% vs 90.6% (p=0.57), MR 2% 78% vs 80% (p=0.81) respectively. Similar outcomes were also observed regarding NYHA (18% vs 9%, p=0.26), MLHGF (26±17 vs 21±17, p=0.16), SF-36 F (41±11 vs 44±9, p=0.14), SF36-M (47±11 vs 48±10, p=0.30) and 6MWT (336±94 vs 329±78, p=0.59). All improvements were statistically significant compared to baseline, both in ID and IS (all p<0.05). At 1 year ID and IS had similar EDD (60±10 vs 63±8, p=0.21), but improvement appeared significant only in IS patients (p=0.19 vs p=0.0004). EF recovery was also reduced in the ID vs IS (26±6 ± 5±11, p=0.0016; respectively p=0.13 and p=0.0036 against baseline).
Conclusions: MitraClip therapy is in ID and effective in MR reduction and symptoms relief at 1 year, providing similar outcomes compared to IS. Ventricular remodelling and EF recovery however appear to be reduced in the ID setting.

TCT-700
Percutaneous Vs Surgical Repair For Degenerative Mitral Regurgitation In Octogenarians.
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Methods: Since October 2008, 46 octogenarians underwent isolated mitral repair for DMR at our Institution using MitraClip or standard surgery. A retrospective comparison was conducted.
Results: MitraClip was performed in 24 (52.2%) and surgery in 22 (44.8%) cases. Baseline features for MitraClip and surgery respectively included: mean age 84.7±3.4 vs 81.8±1.6 years (p=0.0004), median STS mortality 8.4 vs 5.7 (p=0.02), NYHA II 70.8% vs 40.9% (p=0.04), mean creatinine 1.2±0.3 vs 0.9±0.3 mg/dl (p<0.009), chronic obstructive pulmonary disease 33% vs 9% (p=0.04). The groups did not differ in mitral annular geometry in both functional and degenerative MR. The actual impact of these geometrical changes on procedural success and durability of MR reduction requires further investigation.

References
MitraClip Therapy In Ischemic Vs Ischemic Dilated Cardiomyopathy, A Single Center Experience.
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Background: MitraClip therapy is emerging as a viable option for high-risk patients with mitral regurgitation (MR). The comparison between MitraClip outcomes in ischemic (ID) and (IS) ischemic MR.
Methods: From October 2008, 109 patients underwent MitraClip for FMR at our Institution. All patients underwent a standardized prospective data collection pathway.
Results: Patients were 27 ID (24.2%) and 82 IS (75.2%). Groups did not differ in age (p=0.13), NYHA (p=0.16) and pro-BNP (p=0.47). ID were slightly “lower-risk” due to less comorbidities: STS mortality 8.2% vs 11.5% (p=0.06), RED 5% vs 17% (p=0.0008), COPD 1% vs 32.9% (p=0.02), mean creatinine 1.3±0.5 vs 1.65±0.9 mg/dl (p=0.04), inotropic support 0% vs 7.9% (p=0.03). ID however had a more impaired QoL (mean MLHGF 48±16 vs 37±13, p=0.0008; SF-36 F 29.1±7 vs 35.8, p=0.004; SF36-M 38.9±19 vs 39.9; 6MWT 168±76 vs 202±109, p=0.08) and a deeper heart dysfunction: mean EF 24.9±9 vs 30.1±11% (p=0.02; EDD 69±7 vs 67±8 mm (p=0.20). Implantation was successful in 100% vs 98.8% (p=0.56) and multiple clips were used in 77.8% vs 67% (p=0.19) of ID and IS respectively. Residual MR 22% vs 11% (p=0.26). There was no difference in procedural time, post-operative stay of length and complications (all p>0.05). In-hospital mortality was 0% in ID vs 2% IS patients (p=0.41). Twenty-two ID and 64 IS reached 1-year follow-up: survival was 86.4% vs 90.6% (p=0.57), MR 2% 78% vs 80% (p=0.81) respectively. Similar outcomes were also observed regarding NYHA (18% vs 9%, p=0.26), MLHGF (26±17 vs 21±17, p=0.16), SF-36 F (41±11 vs 44±9, p=0.14), SF36-M (47±11 vs 48±10, p=0.30) and 6MWT (336±94 vs 329±78, p=0.59). All improvements were statistically significant compared to baseline, both in ID and IS (all p<0.05). At 1 year ID and IS had similar EDD (60±10 vs 63±8, p=0.21), but improvement appeared significant only in IS patients (p=0.19 vs p=0.0004). EF recovery was also reduced in the ID vs IS (26±6 ± 5±11, p=0.0016; respectively p=0.13 and p=0.0036 against baseline).
Conclusions: MitraClip therapy is in ID and effective in MR reduction and symptoms relief at 1 year, providing similar outcomes compared to IS. Ventricular remodelling and EF recovery however appear to be reduced in the ID setting.