TCT-722
Predictors for acute increase of cardiac output in patients undergoing MitraClip procedure
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BACKGROUND MitraClip procedure is a valid alternative in high surgical risk patients with severe mitral regurgitation (MR). Predictors for acute increase of cardiac output (CO) after MitraClip have not been studied. We aim to analyze predictors for cardiac output (CO) improvement.

METHODS From January 2014 to May 2015, 108 consecutive high surgical risk patients with moderate or severe MR underwent mitral valve repair with MitraClip device. CO before and after the procedure was measured by thermo-dilution in all patients and an increase ≥25% was defined as relevant.

RESULTS Out of 108 patients (mean age 76 ± 7 yrs, 69.4% male), 45 (42%) had an increase ≥ 25% of CO. Patients with CO increase ≥ 25% significantly more often presented with a residual MR ≤ C (p=0.01) and had a lower baseline CO (2.0 ± 0.8 L/min vs 2.7 ± 1.0 L/min, p=0.002). Patients with no relevant increase in CO had a higher rate of previous PCI (57% vs 36%, p=0.017) and of COPD (22% vs 7%, p=0.024). Mean left ventricular ejection fraction was similar in patients with compared to without CO increase (44 vs 42%, p=0.656). Binary logistic regression analysis identified residual MR ≤ C (p=0.007), low baseline CO (p=0.048), absence of previous PCI (p=0.034) and absence of COPD (p=0.026) as independent predictors for an increase ≥ 25% of CO.

CONCLUSIONS Acute CO improvement after MitraClip is not only predicted by a good procedure outcome but also by patient’s comorbidity and baseline CO.

KEYWORDS Mitral Valve Repair, Mitraclip, Mitral regurgitation

TCT-723
Evaluation Of The Mitralign Percutaneous Anulloplasty System (MPAS) For The Treatment Of Functional Mitral Regurgitation (FMR): 6 Month Results
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BACKGROUND An estimated 4 million people in Europe and 4 million people in the United States have significant mitral valve insufficiency, also known as mitral regurgitation, with an annual incidence of 250,000.1 Approximately 50,000 of these patients undergo surgery each year.2 Mitral valve insufficiency, if left untreated, is associated with chronic volume overload, which leads to heart muscle dysfunction, development of congestive heart failure (CHF) and thus increased morbidity and mortality. Mitral valve regurgitation (MR) has proven to increase the risk of mortality in patients with CHF, a disease affecting more than 25 million worldwide. As MR worsens, so does CHF and, hence, risk of mortality. Compared to CHF patients with no MR, mild MR increases risk of mortality at 5 years by 18% and moderate to severe MR by 53%.3 Treatment for MR is performed to better a patient’s prognosis. Mitral valve repair is considered superior to mitral valve replacement because of lower operative mortality, improved late survival, a reduced risk of endocarditis, fewer thromboembolic complications.1,4,5,6,7,8 There is also a growing body of evidence that supports early mitral valve repair instead of valve replacement for significant mitral regurgitation. Early benefits of repair include shorter hospital stays, less need for antiaggregation therapy, and lowered in-hospital mortality and complication rates.

METHODS It has been proposed two goals of treatment of patients for FMR should be to slow or reverse LV remodeling and to improve the patient’s symptoms or functional class.9 The Mitrailign Percutaneous Anulloplasty System (MPAS) is a novel device for percutaneous mitral valve repair. The mechanism of treatment for the MPAS is to deliver pledges to the posterior mitral annulus and subsequently plicate (pull together) the annulus to reduce annular circumference. (Figure 1) The Mitrailign MPAS study is a prospective, single-arm, multi-center, first-in-human study using the Mitrailign MPAS and enrolled FMR patients including those considered high risk for surgery. Patient demographics are presented in Table 1. The Primary Safety Endpoint for the study is all major adverse events (MAE) within 30 days post index procedure.

MAE is defined as occurrence of any of the following: Mitral valve related cardiac surgery/intervention, myocardial infarction, cardiac tamponade, stroke, or device/procedure-related death. The Primary Performance Endpoint of this study is defined as freedom from mitral valve-related cardiac surgery/intervention, and freedom from device and/or procedure-related death within 6 months; and freedom from an increase in ventricular diameter at 6 months.

RESULTS At 30 days freedom from all-cause mortality was 92.2%. At six months, the annular dimensions of the mitral valves were significantly reduced in both the A-P and S-L directions by -0.35 ± 0.4 cm, p<0.01, and -0.32 ± 0.3 cm, p<0.01, respectively.

CONCLUSIONS The MPAS is safe/effective

KEYWORDS Mitral regurgitation, Mitral regurgitation, functional, Mitral valve repair

TCT-724
Efficacy of percutaneous left atrial appendage closure to prevent thromboembolic events in atrial fibrillation patients with high stroke and bleeding risk
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BACKGROUND The randomized PROTECT AF trial demonstrated non-inferiority of left atrial appendage (LAA) closure to oral anticoagulation with warfarin. Current guidelines on the management of atrial fibrillation patients with high stroke risk and contraindications for long-term oral anticoagulation give a class IIb recommendation for LAA closure. Data on the efficacy of LAA closure in patients at high risk for ischemic stroke and bleeding events however are limited. We evaluate the efficacy and safety of LAA closure with the Amplatzer cardiac plug (St. Jude Medical) or the Watchman LAA closure device (Boston Scientific) in a consecutive series of high risk non-valvular atrial fibrillation patients with either contraindications to long-term oral anticoagulation or at high bleeding risk.

METHODS A series of 101 consecutive non-valvular atrial fibrillation patients (age 74.7±7.5 years) at high risk for stroke (CHA2DS2-VASc Score 4.4±1.6) and high bleeding risk (HAS-BLED Score 4.2±1.3) received LAA closure with either the Watchman left atrial appendage system (38 patients) or the Amplatzer cardiac plug (63 patients). Average size of the LAA closure device was 25.0±3.7 mm (range 16-33 mm). Dual antiplatelet therapy with aspirin 100 mg od and clopidogrel 75mg od was recommended for the first 3-6 month after device implantation, followed by long-term antiplatelet therapy with aspirin 100mg od. No anticoagulation was recommended after device implantation. Mean follow-up was 400 days. Transesophageal echocardiography was done 3 and 12 month after LAA closure.

RESULTS Procedure related serious complications were seen in 2 patients with pericardial tamponade, requiring pericardiocentesis. One patient (1%) had a transient ischemic attack at day 299 post implantation and two patients (2%) suffered from ischemic stroke (day 1 and day 398). Respectively, the expected annual stroke rate according to CHA2DS2-VASc Score would have been 4.0 to 6.7%. While on recommended antiplatelet therapy bleeding occurred in 12/101 patients (12%). The average HAS-BLED Score for these patients was 5.3±1.5 (range 4-7). During long-term follow-up after discontinuation of dual antiplatelet therapy two additional bleeding events (2.4%) occurred. In contrast the expected annual bleeding rate according to HAS-BLED Score ranged between 8.7 to 12.5%.

CONCLUSIONS Left atrial appendage closure in patients with non-valvular atrial fibrillation and high risk for stroke and bleeding events effectively prevented stroke and reduced cerebral ischemic events compared to expected stroke rate according to CHA2DS2-VASc Score