

treated successfully (implantation of ≥ 1 Clip, MR $\leq 2+$ at discharge). Out of these, sufficient echocardiographic measurements after MC-implantation were available in 135 patients with degenerative MR (DMR) (moderate stenosis in 34.1%) and 284 patients with FMR (moderate stenosis in 20.4%). At baseline, the majority of patients presented with NYHA class III (69% of all patients) or IV (27% of all patients) without significant differences for MR aetiology. Cardiovascular risk factors were equally distributed at baseline within FMR and DMR subgroups. Device time and Clip-quantity were significantly higher in DMR-patients with moderate stenosis (implanted Clips ≥ 2 in 44.7% vs. 28.1% for no/mild stenosis, $p < 0.05$). There were no significant differences for FMR-subgroups. Quality of life improved significantly at 24-month follow-up. For DMR patients NYHA I/II was present in 68% of cases, whereas for FMR patients NYHA I/II was reported in 49%, NYHA III in 40%. Six-minute walk distance and Minnesota Living with Heart Failure Questionnaire scores improved significantly over all groups. For FMR patients with moderate stenosis, improvements in quality of life were less significant compared to baseline values. Kaplan-Meier analysis revealed no differences on long-term mortality rates neither for DMR (no/mild vs. moderate stenosis, log rank test, $p = 0.38$) nor for FMR (no/mild vs. moderate stenosis, log rank test, $p = 0.44$). For rehospitalization for heart failure, there again were no differences found after Kaplan-Meier analysis for both aetiologies (DMR: $p = 0.23$; FMR: $p = 0.98$).

Conclusion: This single-center, retrospective study failed to show an inferior long-term outcome in patients with a moderate mitral stenosis compared to patients with no/mild stenosis after successful treatment by MC-implantation. Pre-supposed this can be confirmed in larger cohorts, this finding could have a relevant impact on intra-procedural decision making.

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Evaluation of cystatin C and NGAL as predictors of mortality in patients undergoing percutaneous mitral valve repair

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Background: Percutaneous mitral valve repair (PMVR) is an interventional treatment option in patients with severe mitral regurgitation (MR) who have a high risk for open-heart surgery. Currently, risk stratification is partly based on clinical evaluation and the assessment of specific risk scores. In this regard, renal function is a major risk factor that is strongly associated with poor outcome in patients with MR and heart failure. Cystatin C, a cysteine protease inhibitor, has been used as a specific and sensitive biomarker of renal function. In addition, the neutrophil gelatinase-associated lipocalin (NGAL) is a sensitive biomarker that specifically indicates functional and structural kidney damage. The aim of the present study was to determine the predictive value of serum cystatin C and urinary NGAL as indicators of mortality in patients undergoing PMVR.

Methods: A total of 120 consecutive patients (age: 77.3 years [± 11.2]) undergoing PMVR were included in this study. PMVR was performed according to standard clinical practice using the mitralclip system. Venous blood and urinary samples for biomarker analyses were collected prior to PMVR. Samples were processed immediately and frozen at -80°C until assay. Physiological parameters, including the New York Heart Association (NYHA) class, medication use, safety events, and all-cause mortality, were followed over 12-month after the procedure.

Results: PMVR was performed successfully in all patients. Twelve months (median follow up: 317 days [IQR: 128; 427]) after PMVR there was an effective reduction in the severity of MR (MR grade: 3 [± 0.3] vs. 1.6 [± 0.6], $p < 0.001$), and an improvement in the NYHA class (class III vs. I-II, $p < 0.01$) was documented. Serum cystatin C (death: 2.4 mg/L [IQR: 1.7; 3.1] vs. alive: 1.7 mg/L [IQR: 1.3; 2.1], $p < 0.001$) and urinary NGAL (death: 242.0 ng/mL [IQR: 154.5; 281.5] vs. alive: 132.0 ng/mL [IQR: 107.0; 177.3], $p < 0.001$) levels were significantly higher in patients who died during the 12-month follow-up period. Elevated serum cystatin C and urinary NGAL values specifically predicted mortality after PMVR (AUCcystatinC: 0.719, $p < 0.001$; AUCNGAL: 0.761, $p < 0.001$). Importantly, cystatin C and NGAL were also strong predictors of mortality in a subgroup analysis of patients with normal creatinine levels (creatinine: 1.2 mg/dL; [IQR: 0.7; 1.7]) (AUCcystatin C: 0.78, $p < 0.001$; AUCNGAL: 0.832, $p < 0.001$).

Conclusion: Chronic kidney disease with impaired renal function is known to be associated with adverse cardiac events and poor prognosis in patients with MR and heart failure. In this study cystatin C and urinary NGAL were found to be predictors of long-term mortality in high-risk patients undergoing PMVR. Importantly, cystatin C and NGAL also predicted long-term mortality in patients with normal creatinine values. Thus, cystatin C and NGAL assessment may be helpful in the risk stratification in patients undergoing PMVR.

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Acute and chronic remodeling after interventional edge-to-edge repair of mitral regurgitation using cardiac magnetic resonance imaging

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Objectives: Given the frailty of patients receiving interventional edge-to-edge repair of mitral regurgitation (MR) using the MitraClip-system, optimal patient selection is desired.

Background: Several haemodynamic and echocardiographic studies suggest acute benefits for LV function and cardiac index (CI) following reduction in LV preload using the MitraClip. From a physiological point of view, MR reduction results in an increase in LV afterload. The impact of this afterload increase on LV and RV performance acutely as well the potential of positive remodelling during follow-up (FU) remain unclear.

Previous echocardiographic studies are limited by the inability to truly quantify effective ventricular stroke volume (SV) and atrioventricular valvular function. Aim of this prospective study was to assess the acute and late changes in left ventricular (LV) and right ventricular (RV) function using cardiac magnetic resonance (CMR) imaging as the considered reference standard in this setting

Methods: 38 Patients with severe symptomatic MR and high surgical risk (mean Euroscore II of 11.0 ± 6.6) underwent MitraClip-implantation and CMR imaging before (4 \pm 6 days), within 7 \pm 10 days and 196 \pm 23 days after the procedure.

Results: The reduction in MR fraction (pre vs. post/FU: 29 \pm 13% vs 15 \pm 11%/18 \pm 11%, $p \leq 0.001$ / $p = 0.001$) by MitraClip as well as symptom relief (pre vs FU: NYHA III-IV 84% vs. NYHA III+IV 16%, $p \leq 0.001$) was persistent over 6 months. The MR reduction is associated with an immediate significant reduction in LV preload and thereby LV end-diastolic volume, which was maintained during 6 months of FU (pre vs. post/FU: 114 \pm 34ml vs 105 \pm 34ml/104 \pm 36ml, $p \leq 0.001$ / $p = 0.05$). The acutely reduced LV EF (pre vs. post/FU: 42 \pm 14% vs 38 \pm 13%/43 \pm 16%, $p = 0.004$ / $p = 1.0$) and LV SV rose to pre clipping values in FU (pre vs. post/FU: 47 \pm 15ml vs 38 \pm 11ml/42 \pm 14ml, $p \leq 0.001$ / $p = 0.1$). LV CI however showed no significant differences (pre vs. post/FU: 2.14 \pm 0.5 l/min/m² vs 2.19 \pm 0.5 l/min/m²/2.17 \pm 0.5 l/min/m², $p = 1.0$ / $p = 1.0$).

RV volumes, function (pre vs. post/FU: 44 \pm 12% vs 46 \pm 10%/46 \pm 9%, $p = 1.0$ / $p = 0.7$), RV CI (pre vs. post/FU: 2.23 \pm 0.7 l/min/m² vs 2.53 \pm 0.6 l/min/m²/2.32 \pm 0.6 l/min/m², $p = 0.09$ / $p = 1.0$) and echocardiographically evaluated pulmonary artery pressures (pre vs. post/FU: 44 \pm 16 mmHg vs 36 \pm 13 mmHg/39 \pm 13 mmHg, $p = 0.17$ / $p = 0.49$), as well as the degree of tricuspid regurgitation (pre vs. post/FU: 15 \pm 16% vs 15 \pm 14%/11 \pm 13%, $p = 1.0$ / $p = 0.3$), remained unaffected. Therefore the afterload reduction may not be sufficient to trigger remodelling in these RVs with chronic adverse loading conditions.

Conclusion: In severely compromised patients, marked reduction in MR by MitraClip implantation does not result in improved CI and effective biventricular forward flow in 6 months FU. Further studies are needed to enhance our understanding of LV volume overload reduction, to refine patient selection for MR reduction therapies in markedly compromised patients.

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Effects of levosimendan therapy in patients with severe functional mitral regurgitation and chronic heart failure undergoing mitralclip implantation: a single-centre experience

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Background and purpose: Percutaneous mitral valve repair (PMVR) has been introduced as a valuable therapy in high surgical risk patients with functional mitral regurgitation (FMR) who are not responding to medical treatments. Our aim was to assess clinical, functional and prognostic impact of peri-procedural levosimendan administration in patients with FMR undergoing PMVR

Methods: Between December 2009 and August 2016, 94 consecutive patients with FMR who underwent PMVR at our centre were enrolled in a prospective registry. In order to identify two comparable groups of patients, 27 patients not receiving levosimendan (No-L-group) were selected for the analysis matching by propensity score with those treated with levosimendan (L-group). Propensity score was calculated by using a logistic regression model including age, gender, Log EuroSCORE and EuroSCORE II values, history of diabetes mellitus, coronary artery disease and cardiac surgery, values of glomerular filtration rate, left ventricle (LV) ejection fraction and systolic pulmonary artery pressure (sPAP) (C-statistic 0.76)

Results: Baseline demographics and echocardiographic variables were similar between the two groups (No-L-group vs L-group). Surgical risk was comparable: EuroSCORE II and STS PROM (6.3 (3–17.1) vs 4.9 (2.9–12.1), $p = 0.89$; 4.4 (2.3–6.6) vs 4.2 (2.1–8.1), $p = 0.59$). 79% of patients were in NYHA classes III to IV with high BNP values (median 1022.4 pg/ml). The overall study population showed enlarged left chambers with severely reduced LV systolic function (mean LV ejection fraction 31%) without significant differences between groups.

Right chambers dimensions and RV (right ventricle) systolic function were also similar in both groups. Acute procedural success was similarly high with no differences in procedural time and hospital and long-term outcome. Survival at 1 year (84.0±7.3% vs 77.9±8.1%; HR0.56, 95% CI: 0.16–1.94, $p=0.36$), 1-year survival free from cardiovascular death (87.3±6.8% vs 83.7±7.4%; HR0.60, 95% CI: 0.14–2.68, $p=0.51$) and free from readmission due to cardiac disease (76.6±8.4% vs 76.6±8.4%; HR0.69, 95% CI: 0.24–2.00, $p=0.46$) were comparable. Interestingly, patients treated with levosimendan showed higher value of RV TDI peak S-wave velocity at discharge (10.7±3.0 vs 13.0±4.1 cm/sec, $p=0.03$; respectively). None other echo parameters differed among groups after PMVR. Compared with baseline measurements, LV end diastolic volume decreased significantly after PMVR in both groups ($p=0.04$ and $p=0.004$, respectively in No-L-group and L-group) whereas, LV end diastolic diameter, sPAP and RV TDI peak S-wave velocity showed a significant improvement after PMVR only in the L-group ($p=0.05$, $p=0.0004$ and $p=0.03$; respectively)

Conclusion: The present study shows that peri-procedural administration of levosimendan in patients with end-stage heart failure undergoing Mitraclip implantation for severe FMR is safe and might be associated with significant RV functional improvement representing a valid therapeutic strategy

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Anaemia is a predictor of mortality in patients with mitral regurgitation undergoing transcatheter edge-to-edge mitral valve repair

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Background: Anaemia is common among patients with cardiac disease. In the patients who undergoing cardiac intervention treatments, anaemia is an independent risk factor of death and poor clinical outcomes.

Purpose: This study aims to find the relationship between of pre-procedural anaemia and outcomes in patients with mitral regurgitation (MR) after receiving MitraClip therapy.

Methods: A retrospective single study was conducted in 241 consecutive severe MR patients who were successfully treated by MitraClip. Haemoglobin level (Hb) was measured before the procedure. Anaemia was defined according to world health organization definition as a Hb level of less than 12 g/dL for women and less than 13 g/dL for men. The clinical outcomes were compared between patients with or without anaemia.

Results: Anaemia was found in 53.9% of the patients. Mean Hb was 11.1±1.2 g/dL in anaemic group and 13.7±0.9 g/dL in non-anaemic group. The anaemic patients had found to be older, higher surgical risk, more severe symptom, more frequent history of ischaemic stroke, higher incidence of previous open heart surgery, and worse renal function. According to baseline echocardiographic findings, pulmonary artery pressure was significant higher among anaemic patients. However, no differences were observed in severity and etiology of MR, left ventricular, and left atrial dimension, as well as ejection fraction between both groups. The anaemic patients had similar periprocedural outcome compared to non-anaemic patients. At 24-month (mean follow-up of 564.7±229.2 days), all-cause mortality rate was 30.0% in anaemic group compared to 15.3% in non-anaemic group ($p=0.007$). The composite of all-cause death, mitral valve surgery, and hospitalisation from heart failure was significant higher in anaemic group (46.2% vs 27.9%, $p=0.004$). Cox proportional hazards model showed anaemia was an independent predictor of all-cause death at 24-month follow-up (hazard ratio 2.17, 95% confidence interval 1.14–4.14, $p=0.018$).

Clinical outcomes at 24-month follow up

Outcomes	Non-anaemia (n=111)	Anaemia (n=130)	p value
All-cause death (%)	17 (15.3)	39 (30.0)	0.007
MV surgery (%)	6 (5.4)	7 (5.4)	0.994
Hospitalisation from CHF (%)	15 (13.5)	32 (24.6)	0.030
MR grade 3+ or 4+ (%)	29 (26.1)	28 (21.5)	0.404
Death, MV surgery, or CHF (%)	31 (27.9)	60 (46.2)	0.004

MV = mitral valve; CHF = congestive heart failure; MR = mitral regurgitation.

Conclusions: Anaemia is frequently found in MR patients undergoing MitraClip procedure. This study demonstrates that pre-procedural anaemia is strongly related to mortality rate and poor outcomes during mid-term follow-up.

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Galectin-3 and ST-2 as predictors of therapeutic success in high-risk patients undergoing percutaneous mitral valve repair (MitraClip)

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Background: Percutaneous mitral valve repair (PMVR) is an interventional treatment option in patients with severe mitral regurgitation (MR) who have a high risk for open-heart surgery. Although PMVR is safe and feasible, there is currently limited information about predictors of clinical outcome and procedural success. Galectin-3 (Gal-3), a member of the lectin family, and ST-2, a member of the

interleukin-1 family, are synthesized and secreted in response to increased cardiac volume and pressure overload and enhanced myocardial wall stress. Gal-3 and ST-2 induce fibrotic alterations and are up-regulated in severe MR and left ventricular dysfunction. Importantly, these biomarkers are known to be predictive of cardiovascular events and mortality in patients with heart failure. The aim of the present study was to examine the diagnostic and prognostic value of Gal-3 and ST-2 as specific indicators of therapeutic success in high-risk patients undergoing PMVR.

Methods: A total of 212 consecutive patients (age: 77.5 [±8.1] years) undergoing PMVR were included in this study. PMVR was performed according to standard clinical practice using the MitraClip system. Procedural success was defined as a reduction of MR by ≥2 grades. Venous blood samples for biomarker analysis were collected prior to PMVR. Samples were processed immediately and frozen at -80 °C until assay. Physiological parameters, including the New York Heart Association (NYHA) class, medication use, safety events, and all-cause mortality, were followed over 12 months.

Results: PMVR was performed without severe complications in all patients. After PMVR there was a significant reduction in the severity of MR (MR grade: 3 (±0.3) vs. 1.6 (±0.6); $p<0.001$), and an improvement in the NYHA class (class III vs. I-II, $p<0.01$) was documented. Low baseline Gal-3 (PMVRsuccess: 22.0 ng/mL [IQR: 17.3; 30.9] vs. PMVRfailure: 30.6 ng/mL [IQR: 24.8; 42.3]; $p<0.001$) and ST-2 (PMVRsuccess: 900.0 pg/mL [IQR: 619.5; 1114.5] vs. PMVRfailure: 1728.0 pg/mL [IQR: 1051.3; 1930.1]; $p<0.001$) levels were associated with successful MR reduction after PMVR. In addition, ROC analysis identified low baseline Gal-3 and ST-2 levels as predictors of therapeutic success after PMVR (AUC Gal-3: 0.721 [0.64; 0.803], $p<0.001$; AUC ST-2: 0.807 [0.741; 0.872], $p<0.001$).

Conclusions: Gal-3 and ST-2 are associated with enhanced myocardial pressure and volume overload, increased wall stress, and fibrotic alterations in patients with MR. In this study, low baseline Gal-3 and ST-2 levels were predictive of therapeutic success in high-risk patients undergoing PMVR. Accordingly, high-risk patients with myocardial fibrotic alterations might not benefit from PMVR.

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Ex-vivo pathological models of mitral and tricuspid regurgitation for realistic clinical training and new treatment approaches evaluation

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Background/Introduction: Emerging percutaneous treatment options for the mitral and tricuspid valve strongly rely on, in the contrast to the conventional surgery, the biomechanical interaction between the device and the dynamically changing configurations of the valve, subvalvular apparatus and ventricle. Hence, the procedure success depends on, primarily, the overall alternation introduced by the procedure and, secondly, on an operator's experience. The complex anatomical structures of the mitral and tricuspid valve require realistic tools for preliminary treatments' feasibility studies as well as clinician training.

Purpose: The aim was to develop realistic ex-vivo models of valvular pathologies incorporated in reliable beating heart conditions compatible with the standard guiding imaging techniques to be used as in-the-lab clinicians training or new treatment evaluation tools.

Methods: Experimental methods to induce following valvular pathologies in an ex-vivo porcine passive beating heart were developed: mitral regurgitation of functional (FMR) and degenerative origin (DMR) and functional tricuspid regurgitation (FTR). The methods to obtain the pathological models in the experimental setting followed their clinically recognized mechanisms. The FMR was achieved by mechanically dilating the mitral annulus and/or mechanical displacement of the papillary muscles. The DMR was simulated by chordae tendinae cutting. The FTR model exploited the tendency of the right ventricle to dilate under pressure in the laboratory conditions. Competent tricuspid valve was obtained by placing constrain bands externally to the right ventricle at the annulus and papillary muscle levels.

Results: Moving from the baseline to the pathological conditions caused hemodynamic alternations evidenced as significant drop of cardiac output by 33±11%,

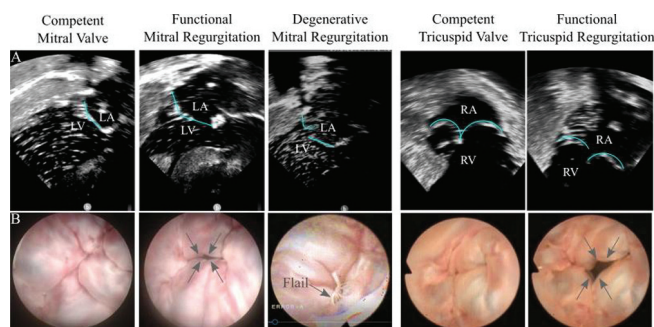


Figure 1