9-1-2021

2-year outcomes for transcatheter repair in patients with functional mitral regurgitation from the CLASP study

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Recommended Citation

Kourkoveli P, Mazimba S, Hage A, Goldschmidt M, Simmons L, Moe G, Cowger J, Mishkin J, Marcoff L, Toma M, and Grayburn P. 2-year outcomes for transcatheter repair in patients with functional mitral regurgitation from the CLASP study. Eur J Heart Fail 2021; 23(SUPPL 2):242.

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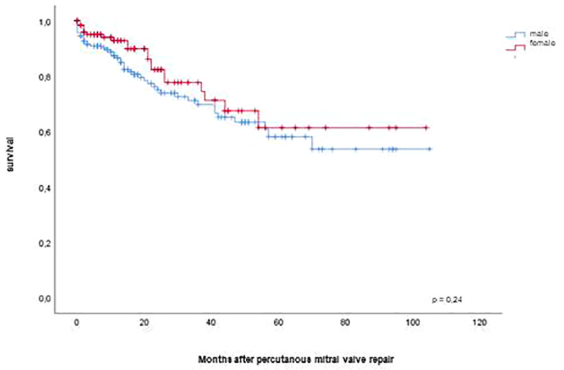

Kaplan Mayer survival curves

Results: Twohundered and fifteen (58%) of he patients were male. They experienced more frequent previous myocardial infarction (29% versus 16%, P < 0.05), previous PCI (54% versus 32%, P < 0.05) or previous aortocoronary bypass operation (22% versus 10%, P < 0.05). Men were more frequent diabetics (22% versus 15%, p = 0.08), and smokers (27% versus 8%, P < 0.05). NYHA classification (NYHA III/IV 77% men versus 89% women) and severity of MR (MR IV 63% men versus 58% women) were comparable. Functional MR was more frequent in men (47% versus 35%). Procedural success was 91% in men and 93% in women. Treatment was equally effective in terms of procedural result and residual MR in women and men and complication rates were low..Women showed less improvement in functional NYHA classification after mitraclip treatment compared to men. However no significant differences between male and female patients were found in mortality (figure), re-intervention and operative mitral vlave repair.
Conclusion: Percutaneous mitral valve repair is safe and effective for treatment of significant MR with equal postprocedural results and mortality rates in men and women.

2-year outcomes for transcatheter repair in patients with functional mitral regurgitation from the CLASP study

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On behalf of: The CLASP Study Investigators
Funding Acknowledgements: Type of funding sources: Private company. Main funding source(s): Edwards Lifesciences

Background: Transcatheter mitral valve repair has emerged as a favourable option in patient care for treating functional mitral regurgitation (FMR) with a need for longer term data. We herein report two-year outcomes from the FMR group of the multicentre, prospective, single arm CLASP study with the PASCAL transcatheter valve repair system.
Methods: Patients with symptomatic, clinically significant FMR ≥3+ as evaluated by the core laboratory and deemed candidates for transcatheter repair by the local heart team were eligible for the study. Follow-up was conducted at 30 days, one year, and two years with echocardiographic outcomes evaluated by the core laboratory at all timepoints and major adverse events (MAEs) evaluated by an independent clinical events committee to one year (site-reported thereafter).
Results: Eighty-five FMR patients were treated with mean age 72 years, 55% male, 65% in NYHA Class III-IVa, 37% LVEF, and 100% MR grade ≥3+. Successful implantation was achieved in 96% of patients. MAEs included one cardiovascular mortality (1.2%) and one conversion to mitral valve replacement surgery (1.2%) at 30 days, and two reinterventions between 30 days and two years. Kaplan-Meier (KM) estimates for survival were 88% at one year and 72% at two years. Freedom from heart failure (HF) rehospitalization KM estimates were 81% at one year and 78% for two years. The reduction in annualized HF hospitalization rate was 81% at two years (p < 0.001). MR ≤1+ was achieved in 73% of patients at 30 days, 75% at one year, and 84% at two years; MR ≤2+ was achieved in 96% of patients at 30 days, 100% at one year, and 95% two years (all p < 0.001). Mean LVEDV of 199 mL at baseline decreased by 9 mL at 30 days (p=0.039), 29 mL at one year (p < 0.001), and 31 mL at two years (p < 0.001). NYHA class I/II was achieved in 87% of patients at 30 days, 86% at one year, and 88% at two years (all p < 0.001). Six-minute walk distance (6MWD) improved by 22 m at 30 days (p=0.004) and 40 m at one year (p=0.003). Kansas City Cardiomyopathy Questionnaire (KCCQ) score improved by 16 points at 30 days and one year (all p < 0.001).
Conclusions: In the CLASP study, the PASCAL transcatheter valve repair system demonstrated sustained favourable outcomes at two years in patients with FMR. Results showed a high survival rate of 72% and freedom from HF rehospitalization of 78% at two years. An 81% reduction in annualized HF hospitalization rate was observed. At two years, sustained MR reduction of MR ≤2+ was achieved in 95% and MR ≤1+ in 84% of patients, with evidence of left ventricular reverse remodelling. Improvements in functional status were significant and sustained at two years. The CLASP IIF randomized pivotal trial is ongoing.

MicroRNA assessment in secondary mitral regurgitation - evidence for remodelling mechanisms at a cellular level

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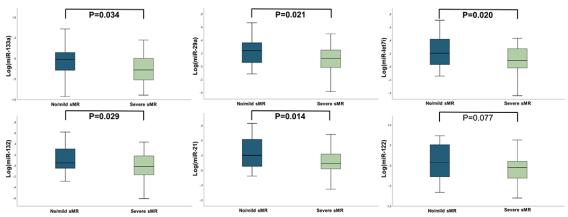
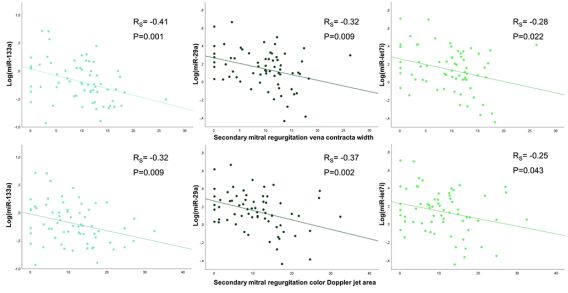
Funding Acknowledgements: Type of funding sources: Foundation. Main funding source(s): FWF - Austrian Science Fund

Background: Secondary mitral regurgitation (sMR) is associated with adverse outcome in patients with heart failure with reduced ejection fraction (HFrEF), possibly driven through malignant cardiac remodelling. MicroRNAs (miRNA/miR), small non-coding RNAs involved in post-transcriptional gene regulation, have recently been associated with the development of fibrosis and hypertrophy. This study therefore sought to assess the differences in miRNA-profiles in patients with severe sMR compared to matched disease controls, the correlation of circulating miRNAs with sMR severity as well as the prognostic implications of miRNA-levels in patients with HFrEF and severe sMR.
Methods: Sixty-six patients with HFrEF were included in this pilot study. Forty-four patients with severe sMR were matched to disease controls with no/mild sMR in a 2:1 ratio. A comprehensive panel of miRNAs (miR-21, miR-29a, miR-122, miR-132, miR-133a, and miR-let7i) was measured using real time polymerase chain reaction and related to echocardiographic assessment of sMR severity.
Results: The profiles of miR-21, miR-29a, miR-132, miR-133a, and miR-let7i differed significantly between patients with severe sMR and HFrEF controls (for all P < 0.05). Moreover, we observed significant correlations of circulating miR-133a (r=−0.41, p = 0.001), miR-29a (r=−0.32, p = 0.009), and miR-let7i (r=−0.28, p = 0.022) with sMR vena contracta width. Elevated levels of miR-133a conveyed an increased risk for cardiovascular death and/or heart failure hospitalisations with and adjusted HR of 1.85 (95% CI 1.24-3.13, p = 0.004). Furthermore, Kaplan-Meier-Analysis revealed a significantly higher risk for the above-mentioned outcome in patients with severe sMR and miR-133a-levels above the median (Log-rank p = 0.03).
Conclusions: This study unveils distinct pathophysiologic mechanisms at a cellular level in patients with severe sMR compared to patients with no/mild sMR. We observed significant differences in miRNA-profiles and strong correlations of miRNAs with surrogates of sMR severity, supporting the concept that sMR drives adverse cardiac remodelling in heart failure. Finally, elevated levels of miR-133a convey an increased risk for morbidity and mortality in patients with HFrEF and severe sMR, potentially implying advanced myocardial damage.



MicroRNA-profiles in sMR



Association between miRNAs and sMR