

ASE 2021 Original Science Presentations

PC-27

**The Mistral Chordal TV Repair Device Efficiently Reduces TR, Improves RV Systolic Function and Induces RV Reverse Remodeling: Echocardiographic Analysis**

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**Background:** The Mistral device is an investigational spiral-shaped device intended for percutaneous transcatheter repair by approximating the tricuspid leaflets, grasping together the chordae tendineae. We have recently reported the short-term significant improvement in TR severity and clinical impact in a single-center study. In the present study, we analyzed the short-term echocardiographic results of all Mistral devices implantations performed up to October 2020 as part of a FIM study. **Methods:** 17 patients with symptomatic severe, massive or torrential secondary TR from 4 different centers (Germany and Israel) have undergone a Mistral device implantation via femoral venous access, under TEE guidance. Baseline, 1 and 6 months trans-thoracic echo studies were analyzed by a core lab, which was blinded to on-site analysis. Measurements included TR severity assessment (visual TR grade, EROA, regurgitant volume, vena contracta diameter), right ventricular function (RV fractional area change (FAC), tricuspid annular peak systolic excursion (TAPSE), RV global longitudinal strain (RV GLS), and) and RV remodeling parameters (annular diameter, RV end diastolic diameter (RVEDD), tethering height). **Results:** No mortality nor device-related adverse event were reported through 6-months. TR reduction (of at least in 1 grade by integrative assessment) was apparent in 92% of patients at 6 months' follow-up. Remarkably, there was a significant improvement in all parameters of RV global systolic function at 6 months' follow-up (RV FAC by 29%, TAPSE by 15%) and of RV remodeling (RVEDD by 7% and tethering height by 25%). Changes were already apparent early after the procedure and progressed at 6 months' follow-up. **Conclusion:** In this ongoing FIM study, the Mistral device provided, beyond substantial TR reduction, a clinically important improvement in RV function and significant RV reverse remodeling. These may have also occurred due to the chordal repair approach inducing RV reverse remodeling, beyond the significant direct reduction in TR severity. Further studies should clarify the importance and mechanism of these findings.

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**Impact of Right Ventricular Stiffness on Discordance between Hemodynamic Parameter and Regurgitant Volume in Patients with Pulmonary Regurgitation**

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**Background:** Accurate detection of significant pulmonary regurgitation (PR) is critical in management of patients after right ventricular outflow (RVOT) reconstruction, because of its influence on adverse outcome. Although pressure half time (PHT) of PR velocity is one of the widely used echocardiographic marker of the severity, it is suggested to be seen in conditions with increased RV stiffness with mild PR. However, little has been reported about the exact characteristics of patients showing discrepancy between PHT and PR volume in this population. **Methods:** Echocardiography and cardiac magnetic resonance imaging (MRI) were performed in 98 patients after RVOT reconstruction (32±9 years old, Tetralogy of Fallot: 88%). PHT was measured from the continuous Doppler PR flow velocity profile and PHT<100 ms was used as a sign of significant PR. Presence of end-diastolic RVOT forward flow was defined as RV restrictive physiology. By using phase-contrast MRI, forward and regurgitant volumes through the RVOT were measured and regurgitation fraction (RF) was calculated. Significant PR was defined as RF≥25%. **Results:** Significant PR was observed in 77 of 98 patients. While PHT<100 ms well predicted significant PR with sensitivity of 95%, specificity of 52%, and C-index of 0.74, 10 patients showed shortened PHT despite RF<25% (discordant group). Tricuspid annular plane systolic excursion and LV ejection fraction were comparable between discordant group and patients showing PHT<100 ms and RF≥25% (concordant group). However, discordant group showed significantly smaller mid RV diameter (33.3±2.0 vs 38.3±0.7 mm, P=0.022) and higher prevalence of restrictive physiology (100% vs 43%, P<0.01) than concordant group. When mid RV diameter ≥33 mm and presence of restrictive physiology were added to PHT, the predictive value was significantly improved (sensitivity: 87%, specificity: 90%, and C-index: 0.93, P<0.001 vs PHT alone by multivariable logistic regression model). **Conclusion:** Patients with increased RV stiffness and non-enlarged RV showed short PHT despite mild PR. Although it has been expected, this was the first study to demonstrate the exact characteristics of patients showing discrepancy between PHT and PR volume in patients after RVOT reconstruction.

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**Natural History of Mitral Annulus Calcification and Calcific Mitral Valve Disease**

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**Background:** Mitral annulus calcification (MAC) is a common finding, but the natural history and risk for developing calcific mitral valve disease (CMVD) has been poorly defined. We sought to evaluate the progression rate of MAC and of the development of CMVD. **Methods:** Patients with at least mild MAC and paired echocardiograms at least one year apart between 2005 and 2019 were included. Progression rates from mild/moderate MAC to severe MAC and to CMVD (defined as severe MAC and significant mitral stenosis and/or regurgitation) were assessed, along with potential associations with sex and aortic valve stenosis (AS) progression. **Results:** A total of 11,605 patients (73±10 years, 51% male) with MAC (78% mild, 17% moderate, 5% severe) were included and had a follow up echocardiogram at 4.2±2.7 years. In patients with mild/moderate MAC on their initial echocardiogram, the incidence of severe MAC at 10 years was 33%. The incidence was higher in females than in males (41% vs. 24%, P<0.001, HR=1.3, P<0.001) and in patients with moderate vs. mild MAC (71% vs. 22%, P<0.001, HR=6.1, P<0.001, see Figure 1). The overall incidence of CMVD at 10 years was 10% (4%, 23% and 60% in patients with mild, moderate, and severe MAC, respectively, see Figure 2) and was predicted by female sex (15% vs. 5%, P<0.0001), even after adjustment for MAC severity (HR=1.9, P<0.001). Patients who progressed to severe MAC had larger increases in aortic valve mean pressure gradient (AV MPG) (+4.1±4.5 vs. +3.3±3.6 mmHg/year, P<0.001) that persisted after adjustment for age, sex, and baseline AV MPG. **Conclusion:** In this large patient cohort with MAC, progression to severe MAC is common and frequently results in CMVD. Female sex was associated with higher progression rates and an association between MAC and AS progression was observed. MAC and CMVD are expected to dramatically increase as the population ages and there is an urgent need to better understand the pathophysiology of MAC in order to develop effective preventative medical therapies.

**Progression to mitral annulus calcification (MAC) according to (A) sex and (B) sex and degree of mitral annulus calcification (MAC).** (A). At 10 years, 41% of female patients compared to 24% of male patients progressed to severe MAC. (B). Sex increased the risk of progression to severe MAC independent of MAC severity.

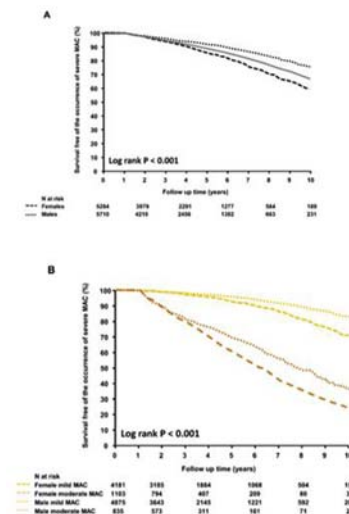


Figure 1