4 year outcomes in a prospective evaluation of transcatheter mitral valve-in-valve, valve-in-ring and valve-in-mitral annular calcification: results from the MITRAL trial

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Background: The MITRAL Trial (Mitral Implantation of TRAns catheter valVes) evaluates the safety and feasibility of balloon-expandable aortic transcatheter heart valves in patients with severe mitral valve disease with mitral annular calcification (MAC), failed surgical rings or failed bioprostheses.

Purpose: We sought to evaluate 4-year outcomes of patients enrolled in the MITRAL trial.

Methods: This is a prospective study that enrolled 91 high surgical risk patients at 13 sites in the U.S. 30 patients underwent Mitral Valve-in-Valve (MViV), 30 Valve-in-Ring (MVIR) and 31 Valve-in-MAC (ViMAC). 4-year outcomes of these patients were evaluated in this analysis. Primary endpoints and key serious adverse events including deaths were adjudicated by an independent Clinical Events Committee. Cardiac computed tomography (CT) and echocardiographic images were evaluated by independent CT and Echocardiographic Core Laboratories.

Results: Mean age was 74.3±8.9 years. Most patients undergoing MViV and ViMAC were female (MViV=63.3%, MVIR=36.7% and ViMAC=71%). Mean STS score was 9.2±6.6% (MViV 10.2±6.5%, MVIR 8.7±4.7%, ViMAC=8.6±8.2%). All-cause mortality at 4 years was higher for ViMAC and MVIR: MViV=6.9% (cardiovascular 3.4%), MVIR=48.1% (cardiovascular 18.5%), ViMAC=51.9% (cardiovascular 29.6%), p=0.002 (Figure 1). At 4 years, all survivors had ≤1+ mitral regurgitation and most had none or trace mitral regurgitation (MViV=87.5, MVIR=33.3% and ViMAC=100%). Mean mitral valve gradients remained stable (MViV=5.9±2.2 mmHg, MVIR=6.6±5.1 mmHg, ViMAC=5.1±1.0 mmHg), Figure 2. Most survivors experienced significant improvement of symptoms and were in NYHA class I-II at 4-year follow-up (MViV=78.9%, MVIR=66.7% and ViMAC=66.7%).

Conclusions: MViV is associated with excellent outcomes at 4 years. MVIR and ViMAC were associated with higher mortality at 4 years. However, most survivors in all groups experienced sustained improvement of symptoms and stable THV performance at 4 years. Whether survival bias had an impact on THV performance and improved symptoms at follow-up is not known and deserves further evaluation.