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Up to 11 years of experience with the Melody valved stent

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Objective To report up to11 years follow up after Melody® valve implantation in pulmonary position.

Methods Single institution non randomized prospective observational study. All patients discharged with a Melody valve in pulmonary position from 2006 until the end of 2017 (n = 186) were included. Follow-up consisted of 1,3, 6, 12 month followed by annual visits. Clinical evaluations, chest radiography and standard echocardiography were performed.

Results: 190 Melody valved stents were implanted in 186 patients. Mean age 19.4 y (std 13.1), 66.7% male. Indication : stenosis (45%), regurgitation (33%) and mixed (22%). Basic diagnosis: tetralogy of Fallot (54%), Ross (18%), truncus arteriosus (6%), DORV (9%), pulmonary stenosis (13%). Pre-stenting was performed in all except the initial four patients. In stenotic lesions there was an immediate reduction of the gradient mean 66 > 23 mmHg PIG with slow increase to 36±12 mmHg PIG after 11 years. In dominant regurgitation there was t reduction from median 4/4 to 0/4, progressing to maximal 2/4 after 11 years. Stent fractures were observed in 8.4% of patients mean 4.2±2.6 years after implantation; only 1 had a grade III fracture where the clinician decided for redo PPVI. Re-interventions included surgical removal in 8 (4.3%), redo PPVI in 5 (2.7%) and balloon angioplasty to accommodate for somatic growth in 8 (4.3%). Re-interventions were performed mean 4±2.5 years after implantation. Endocarditis was diagnosed in 19 (10.2%) patients a median of 2.3 years (range: 0.7–8.8) after Melody implantation. Nine got sterilized (47,4%), 3 got redo PPVI (15.8%) and 7 were surgically removed (36.8%). Three patients showed thickened wall of the valved stent with inceased gradient but without signs of endocarditis. There were 3 deaths, none were procedure or valve related.

Conclusions: The Melody valve shows a good preserved leaflet function up to 11 years after implantation as well in stenotic as in regurgitant lesions. The main reason for redo PPVI or surgical removal is endocarditis, although in half of the patients with endocarditis no re-intervention was needed. Stent fractures are observed but lead very exceptionally to intervention.