

The Melody™ valved stent: up to 10 years of experience

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Introduction : The Melody valve became commercially available in 2006. It has been shown to be a safe and effective intervention, but medium term results are still being gathered. The evaluation of the valve function and its risks from a prospective ongoing registry.

Methods: single center experience; all data are collected from a dedicated prospective registry started in 2006. 97% are pre-stented until stiff tube. The analyzed data: leaflet function (echocardiography), re-interventions, mortality, endocarditis (modified Duke's criteria) and stent fractures (chest X-ray).

Results: 159 valves were implanted 2006-2016 in 158 patients. The indication was stenosis 44%, regurgitation 33% and mixed 23%; male/female ratio was 2:1, the mean age at implant was 19.6 y (3.5 – 81.6). Original conduit diameter had shrunken to mean 19 mm and was re-expanded to 22 mm.

1/ Overall survival was 98 % at 10 years, no procedural or valve related deaths.

2/ Graft survival was 92.1% at 10 years; re-intervention overall 11% : explantation of valve in 4.4% (endocarditis n=6, subvalvular stenosis n=1); repeat PPVI was 1.9% and balloon dilation for somatic growth 5%.

3/ Endocarditis occurred in 9.4% (15/159) with a freedom from endocarditis of 78% at 10 y. The maximal annual incidence of endocarditis was 3.3% in 2015 with a steep decline after changes in behaviour. Mean age at endocarditis was 18.2y (8.1–45.6), male 87%.

4/ Chest X-ray was performed in 87% of the patients showing a stent fracture in 8 % median 2.9 y (0.4–6.9) after implant. In no patients the fractures had hemodynamic significance.

5/ Valve function: a/ RVOT obstruction: mean RVOT PIG 65 ± 17 mmHg at implant drops to 23 ± 11 mmHg post implant and is 38 ± 17 mmHg 10 y later. B/ Indication regurgitation : median 4/4 at implant drops to 0/4 post and is 1-2/4 at 10 y follow-up.

Conclusions: Ten year follow-up of the Melody™ valved stent shows good long term preservation of the valve function. We observed no replacement for intrinsic valve dysfunction except endocarditis (3.8%). The Melody valve is competitive with surgical conduits despite a higher incidence of SBE.