

Pulmonary valve replacement using the Medtronic Mosaic bioprosthetic mitral valve: A single institution's experience.

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*Background:* The Mosaic bioprosthesis is a third-generation stented porcine valve. The objective of this study was to evaluate the long term hemodynamic performance and clinical outcomes in patients undergoing pulmonary valve replacement (PVR) using the Mosaic mitral valve at our institution.

*Methods:* 67 patients underwent PVR using a Mosaic valve between January 1, 2002 and December 31, 2012. We compared pre- and post-operative LVEF (%), PV mean and peak gradient (mmHg) measured by echo, as well as RVEDVI (ml/m<sup>2</sup>), RVESVI (ml/m<sup>2</sup>), and RVEF (%) measured by MRI. Time at follow-up evaluation ranged from one to ten years post implant. Mean follow-up time post implant was 3.1 years (SD=2.2, min=0.1, max=9.8). Comparisons were made using mixed linear regression models to account for repeated measures within patients. Models were adjusted for time since implant.

*Results:* Mean age at implant was 19.8 years [SD=5.9, range=11 to 37 years] and mean weight was 66.1 kg [SD=16.7, range 34-119 kg]. 40 patients (60%) had repaired Tetralogy of Fallot and 42 (63%) were male. Preoperatively, 47 (70%) had severe pulmonary insufficiency, and 30 (30%) had moderate or moderate to severe insufficiency. 55 patients (82%) received a 25mm valve and 12 (18%) received a 27mm valve. Early complications included 2 reoperations for bleeding (9 hours and 1 day post-op). The valves were followed up for structural valve deterioration (SVD). One patient had significant SVD and required transcatheter PVR 6 yrs post implant. Early and late mortality was 0. To date, no reoperation for redo PVR has been necessary. Compared to pre-implant measures in 55 patients (n=139 exams), adjusted LVEF increased by 8.0% (SE=1.9, p<.0001), PV mean gradient increased 8.5 mmHg (SE=2.8, p=0.003), and PV peak gradient increased 10.3 mmHg (SE=5.0, p=0.04). Compared to pre-implant measures in 47 patients (n=55 exams), RVEDVI decreased 54.1 ml/m<sup>2</sup> (SE=9.5, p=0.002), and RVESVI decreased 23.0 ml/m<sup>2</sup> (SE=8.1, p=0.03) at 1-7 years post implant. There was no significant change in RVEF (%) (-3.6%, SE=2.4, p=0.18).

*Conclusions:* In this cohort of young adults requiring PVR for sequelae of repaired congenital heart disease, the hemodynamic performance measures and clinical outcomes associated use of the Mosaic bioprosthesis are excellent. A multi-institutional cohort with longer follow-up is required to definitively characterize late hemodynamic and clinical performance of the valve.