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Medtronic Mosaic Porcine Bioprosthesis: A Potential New Mode of Structural Valve Deterioration

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Objectives:

Pathological findings of structural valve deterioration (SVD) with the Medtronic Mosaic porcine bioprosthesis was evaluated to demonstrate specific anatomical features. Mosaic was introduced in 1999 with alpha-oleic acid tissue fixation and stress-free physiological treatment to advance durability. Clinical performance of the Mosaic in aortic and mitral valve replacement (AVR, MVR) was presented to the Society for Heart Valve Disease in 2007. Freedom from SVD at 10yrs was 95.4±2.0% (Actual freedom 97.2±1.2%) and for mitral valve replacement 85.6±8.5% (92.0±4.5%).

Method:

The bioprosthesis was implanted in 1176 procedures between 1994 and 2003: AVR-706, MVR-470. Mean age of AVR patients was 70.8±10.8yrs and MVR, 71.0±9.3yrs (p=0.783). The total cumulative follow-up was: AVR-3801.1yrs and MVR-2124.7yrs (98.1% complete). SVD was reported in AVR 21 and MVR 8 by both reoperative and pathological evaluation (7 and 6, respectively) and by clinical evaluation (14 and 2, respectively). There was also suspicion of SVD in 29 AVR where the effective orifice area index median (early) was 0.91cm²m² and at the latest follow-up echocardiogram examination was 0.47cm²m².

Results:

Of 13 cases that were identified at reoperation or autopsy, 5 were examined in one of the three participating, affiliated teaching hospitals. Predominant mode of clinical failure was regurgitation with operative and pathological findings of leaflet tears. There were no cases of extensive dystrophic calcification. 4 prostheses were examined radiographically and found to have extensive calcification in the region of the commissures at the junction with the aortic wall of the prosthesis. Of the 2 cases, this finding accompanied leaflet tears and the final pathological diagnosis of SVD. 2 cases had similar radiographic findings in the region of the commissures and 1 had evidence of lesser degrees of calcification in the leaflet cusps: both these cases have pathological findings compatible with infective endocarditis. The fifth case demonstrated only stent-post dehiscence.

Conclusions:

SVD with this prosthesis has been demonstrated to have leaflet tears with accompanying extensive calcification at the region of the commissures. When potential infective endocarditis complicated the pathological interpretations, there was still extensive calcification at the commissures. The literature provides evidence that alpha-oleic acid is more protective of the cuspal leaflets than of the aortic wall. Consideration must be given to whether the pathologically demonstrated features are a manifestation of that reported evidence.