Early stenosis of Medtronic Mosaic porcine valves in the aortic position

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The third-generation Medtronic Mosaic porcine bioprosthesis (Medtronic Inc, Minneapolis, Minn) was introduced in 1994. The valve leaflets are fixed in glutaraldehyde at zero pressure (applying equal pressure to the inflow and outflow ends of the valve), the root is dilated to a pressure of 40 mm Hg ("physiologic fixation"), the fixed tissue is treated with α -aminooleic acid (a long-chain fatty acid that binds to the aldehyde fractions of the glutaraldehyde-preserved porcine tissue) to reduce calcification, and the tissue is mounted on a Hancock II (Medtronic Inc) flexible stent made of acetyl copolymer covered with Dacron fabric.^{1,2}

CLINICAL SUMMARY

The Medtronic Mosaic porcine valve has been reported to be both reliable and durable over time.¹⁻⁴ The alarmingly early stenosis of an implanted Medtronic Mosaic porcine valve (Medtronic) necessitating its replacement prompted a review of the Medtronic Mosaic valves implanted in patients at the Washington University School of Medicine.

Approval from the Washington University Human Research Protection Office was obtained to perform this review. Patients with valvular stenosis with endocarditis (N = 1) or end-stage renal disease (N = 1) were excluded.

RESULTS

Between August 17, 2001, and December 5, 2005, 122 Medtronic Mosaic valves were implanted in patients at the Washington University School of Medicine in the aortic (106), mitral (6), tricuspid (9), or both aortic and mitral (1) positions. Four of 106 patients with valves implanted in the aortic position were found to have early (3–44 months) development of severe stenosis necessitating replacement. Table 1 summarizes the patient information for the 4 patients described. Figure 1 depicts valves explanted from patients B and D. These valves have the strikingly similar appearance of thickened material resulting in immobility of the leaflets. Of note, they were implanted by 2 different surgeons.

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DISCUSSION

Early (2-year follow-up) results after implantation of the Medtronic Mosaic porcine valve reported appropriate valve function and no primary structural valve failure.¹ Follow-up at 6 years by Jamieson and colleagues³ documented 4 cases of structural valve deterioration (2 aortic and 2 mitral) after the implantation of 657 Medtronic Mosaic porcine valves. However, no patients aged more than 60 years had aortic structural valve deterioration in this review. Freedom from structural valve deterioration in the aortic position at 8.5 years has been reported

FIGURE 1. A, Medtronic Mosaic (Medtronic Inc, Minneapolis, Minn) porcine aortic valve explanted after 14 months from patient B after significant stenosis was diagnosed. B, Medtronic Mosaic porcine aortic valve explanted after 3 months from patient D after significant stenosis was diagnosed.

TABLE 1. Clinical data in 4 patients in whom early (3–44 months) valvular stenosis developed

Patient	Year of implant	Implant position and size	Indexed effective orifice area (EOA/BSA in cm ² /m ²)	Indication for explantation (aortic valve gradients in mm Hg)	Months implanted	Age at redo operation (y)	Operative findings
A	2002	Aortic, 23 mm	1.51/1.81 = 0.83	Aortic stenosis (AVA 1.0 cm ²), peak 44, mean 26	44	76	Thickened leaflets, small perforation 1 leaflet
B	2003	Aortic, 23 mm	1.51/1.99 = 0.76	Aortic stenosis (AVA 0.7 cm ²), peak 88, mean 45	14	74	Thickened leaflets (Figure 1, A)
C	2004	Aortic, 23 mm	1.51/1.83 = 0.83	Aortic stenosis (AVA 0.7 cm ²), peak 100, mean 60	19	70	Thickened leaflets, pannus
D	2007	Aortic, 25 mm	1.69/1.90 = 0.89	Aortic stenosis, peak 65, mean 42	3	73	Thickened leaflets, pannus (Figure 1, B)

AVA, Aortic valve area; BSA, body surface area; EOA, effective orifice area.

to be 97.4% by Botzenhardt and colleagues⁴ and 87.1% at 10 years by Riess and colleagues.² In the review by Riess and colleagues, there was no structural valvular deterioration at 10 years in patients aged more than 65 years.²

Improved valve durability in patients aged more than 65 years in reported studies^{2,3} was not seen in our patients. All 4 patients were aged more than 68 years at the time of implant, and all were aged 70 years or more at the time of the redo operation.

Patient–prosthesis mismatch was excluded as a cause of early stenosis because the indexed effective orifice area was greater than 0.75 cm²/m² in all 4 patients. Explanted valves were examined by a pathologist at the Washington University School of Medicine and by a pathologist after return of the valves to Medtronic Inc, and no cause for the stenosis could be determined in any case. The cause of early

valvular stenosis, whether it is related to patient factors or valve factors, remains unclear.

CONCLUSIONS

Continued close and long-term follow-up of patients receiving the Medtronic Mosaic porcine valve is imperative.

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Tricuspid valve regurgitation after heart transplantation

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Tricuspid valve regurgitation (TR) after orthotopic heart transplantation (OHT) is of concern owing to its correlation with right ventricular dysfunction and mortality.¹

Studies show that the bicaval anastomosis technique decreases the incidence TR when compared with biatrial techniques.² More recent studies show that modified surgical techniques, such as tricuspid valve annuloplasty or a modified inferior vena cava anastomosis, may alleviate moderate and severe TR after transplantation.^{3,4}

This study examines the long-term natural history of TR after OHT.