Porcine small intestine submucosa cylinder valve for mitral and tricuspid valve replacement

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An ideal pediatric valve replacement remains elusive. Mechanical valves are not available in the smallest sizes and require anticoagulation. The smallest bioprosthetic valves are 19 mm and tend toward early failure in children. Melody valves (Medtronic, Minneapolis, Minn; bovine jugular vein) have been used in several positions.¹ Handmade CorMatrix cylinder valves (CorMatrix, Roswell, Ga; porcine small intestinal submucosa) in the tricuspid and mitral positions have been reported in small series of children.²⁻⁴ The cylinder valve has been used in 19 adult patients with tricuspid valve (TV) endocarditis⁵ and is undergoing a clinical trial of a factory-produced CorMatrix cylinder valve for adult TV replacement. We report 2 pediatric patients in whom CorMatrix cylinder valves were implanted.

CLINICAL SUMMARY

Patient 1

A 15-month-old (10 kg) male patient with pulmonary atresia with intact ventricular septum, after 2 balloon pulmonary valvuloplasty procedures, followed by a TV repair and transannular patch placement, presented with severe tricuspid regurgitation (TR), tricuspid stenosis, and pulmonary regurgitation. An initial attempt at re-repair resulted in continued severe TR, and the decision was made to replace the valve. His TV annulus was 20 mm. Although this was large enough for a bioprosthetic valve, its poor performance in this age group is well known. The advantage of future dilatations of a Melody valve was limited to only a few millimeters. Therefore, we proceeded with off-label use of CorMatrix to form a cylinder valve as an alternative. This also could allow future placement of a transcatheter valve.

The edge of the CorMatrix valve was folded over approximately 3 mm to form a double-layered “sewing ring.” A cylinder was created by sewing the patch over a 20-mm dilator. The length of the cylinder was 24 mm (1.2× diameter), as described previously.⁴ The distal cylinder was sutured to the 3 papillary muscles using

MV replacement with CorMatrix cylinder valve (CorMatrix Cardiovascular Inc, Roswell, Ga).

Central Message

CorMatrix (CorMatrix Cardiovascular Inc, Roswell, Ga) (small intestinal submucosa) cylinder valves in the tricuspid and mitral positions in pediatric patients provide a simple and reproducible alternative with acceptable short-term outcomes.

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pledgeted mattress polypropylene sutures. The “sewing ring” was sutured to the annulus using a running polypropylene suture. On filling the ventricle, there was central regurgitation. The procedure was repeated with a new cylinder that was 35 mm (1.7× diameter) in length, resulting in a competent valve. A pulmonary allograft was placed from the right ventricle to the pulmonary artery (Figure 1).

Postoperative transesophageal echocardiogram (TEE) showed mild TR, valve annulus 14 mm (z score −1), and a mean inflow gradient of 3 mm Hg. He was discharged on postoperative day 5. The echocardiogram at 6 months showed mild TR with a valve annulus of 14 mm (z −1.2) and a mean inflow gradient of 3 mm Hg. He remains asymptomatic 11 months after surgery.

Patient 2

A 5-week-old (3 kg) male patient, born prematurely at 34 weeks, with critical aortic stenosis, after fetal and postnatal balloon valvuloplasty, presented with moderate aortic stenosis and regurgitation, mitral stenosis, endocardial fibroelastosis, and severe pulmonary hypertension. The mitral annulus was 12 mm.

Intraoperatively, the mitral valve (MV) was found to be thickened and dysplastic with commissural and subvalvar

FIGURE 1. A, Schematic representation showing the CorMatrix cylinder valve (CorMatrix Cardiovascular Inc, Roswell, Ga) in the tricuspid position in patient 1. The valve is sutured to the annulus using running polypropylene suture and to the 3 papillary muscles using pledgeted mattress polypropylene sutures. The right ventricle-to-pulmonary artery conduit is shown. B and C, Apical 4-chamber echocardiographic view from this patient demonstrating the CorMatrix valve in the tricuspid position both open and closed, respectively.

fusion. An MV repair, an endocardial fibroelastosis resection, and a Ross–Konno procedure were performed. Post-operative TEE demonstrated severe mitral regurgitation

(MR). Therefore, the MV was replaced with a 14-mm factory-produced CorMatrix cylinder valve. The valve length was trimmed to 20 mm ($1.5\times$ diameter). The

FIGURE 2. A, Schematic representation showing the CorMatrix cylinder valve in the mitral position in patient 2 (after Ross–Konno procedure). B and C, Apical 4-chamber echocardiographic view from this patient demonstrating the CorMatrix valve in the mitral position both open and closed, respectively.

proximal end was sutured to the mitral annulus, and the distal end was sutured to the papillary muscles (Figure 2).

Postoperative TEE demonstrated mild MR, annulus size of 8 mm (z score -2.3), and a mean inflow gradient of 3 mm Hg. He was discharged on postoperative day 20. Echocardiogram at 9 months showed mild MR, annulus size of 10 mm (z score -2.9), and mean inflow gradient of 5 mm Hg. Both patients 1 and 2 are receiving aspirin.

DISCUSSION

Pediatric valve replacement remains a challenge. This novel application of a handmade or factory-produced cylinder valve of CorMatrix provides a potential alternative.

One of the unattained goals for pediatric applications is growth potential. In ovine models, explanted CorMatrix valves show progressive endothelialization, tissue remodeling, and integration at the host–tissue interface.^{6,7}

Unfortunately, this regenerative potential has not been replicated in humans. Explanted CorMatrix patches used in valve repairs have not shown native tissue regeneration. CorMatrix patches placed within the right atrium for a mean of 21 months before explantation failed to demonstrate any native tissue ingrowth.⁸

CONCLUSIONS

Regardless of the regenerative potential of the CorMatrix cylinder valve or lack thereof, the valve provides a useful alternative in this challenging population. Short-term

results are promising. In the study by Nelson and colleagues,⁸ although no native tissue ingrowth occurred, there was minimal calcification and the patches remained pliable, which bodes well for valve function. The true role of the cylinder valve for pediatric patients will require expanded experience and longer-term follow-up.

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