Stented bovine jugular vein graft (Melody valve) for surgical mitral valve replacement in infants and children

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Objective: The options for mitral valve replacement in children with irreparable mitral valve disease have been limited to fixed-diameter prostheses that do not accommodate for somatic growth. We have modified an externally stented bovine jugular vein graft (Melody valve) for implantation in this cohort. Because it is not a fixed-diameter prosthesis, we hypothesized that the valve can be expanded in the catheterization laboratory as the child grows.

Methods: The medical records of patients who had undergone Melody valve implantation in the mitral or left atrioventricular valve position from 2010 to 2013 were reviewed.

Results: Eleven patients had undergone Melody valve implantation at a median age of 7 months (range, 2-28). The techniques of valve modification and implantation included stent shortening, adding a pericardial sewing cuff, intraoperative balloon expansion, and fixation of the distal stent to the inferior left ventricle wall. The valve was competent, with a low gradient acutely postoperatively in all patients. One patient died, and one required permanent pacemaker implantation. One patient developed valve dysfunction and required explantation. Two patients without a pericardial sewing cuff developed paravalvular leaks. One patient who had not undergone distal stent fixation developed left ventricular outflow tract obstruction. Three patients who had undergone subsequent catheter-based balloon expansion of the valve have continued to demonstrate acceptable valvular function.

Conclusions: The Melody valve has demonstrated acceptable short-term function. Implantation techniques to prevent left ventricular outflow tract obstruction (suture fixation of the distal stent) and paravalvular leaks (the addition of a pericardial cuff) should be considered. The Melody valve can be percutaneously expanded as the child grows. (J Thorac Cardiovasc Surg 2014;148:1443-9)

The options for mitral valve replacement (MVR) have been limited to stented mechanical and bioprosthetic valves and the Ross mitral operation. However, mechanical and bioprosthetic valves are only available in sizes >12 mm in diameter, precluding intra-annular implantation in neonates or infants with hypoplastic mitral annuli, and supra-annular implantation has been associated with poor outcomes.[1,2] Moreover, because these prostheses have a fixed diameter, early reoperation for replacement will be necessary, because they will fail to accommodate for somatic growth, and fixation of the annular diameter by the prosthesis will limit the ability to upsize the valve at reoperation.[2-4] The Melody valve (Medtronic, Minneapolis, Minn) is a stent-mounted valved bovine jugular vein graft that has been used for transcatheter pulmonary valve replacement.[5] The Melody valve has demonstrated competence for a wide range of internal diameters $\leq$22 mm. The short-term durability of this valve under systemic blood pressure has been acceptable.[6,7] We hypothesized that the Melody valve could be implanted into the mitral position at a small diameter, with the potential for percutaneous balloon expansion as the child grows.

METHODS

The institutional review board approved the present study. The patients' parents or guardians provided informed consent for MVR with the Melody valve prosthesis. A retrospective chart review was performed for patients who had undergone Melody valve implantation in the mitral or left atrioventricular valve position from 2010 to March 2013. The indications for replacement, implantation techniques, and short-term outcomes have been reported.

Preoperative Evaluation

The anteroposterior and lateral annular dimensions were obtained by echocardiography to determine the suitability for Melody valve placement. A 2.5-cm length from the midventricle to the mid-left atrium will be necessary to accommodate the valve. The annular diameter is obtained to determine the balloon size to be used during valve implantation.

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Abbreviations and Acronyms

AVC = atrioventricular canal
LV = left ventricular
LVOT = LV outflow tract
LVOTO = LVOT obstruction
MVR = mitral valve replacement

Valve Preparation

The Melody valve should be prepared before the initiation of cardiopulmonary bypass. The valve should be washed in saline, as specified by the manufacturer. The valve is approximately 2.5 cm long in its original configuration. For patients with small left ventricle, particularly infants, the valve can be shortened by trimming of the proximal and/or distal crowns. After trimming, the jugular vein wall should be reattached to the stent with interrupted sutures to prevent dehiscence. A strip of pericardium should be sutured around the exterior stent valve, midway between the base of the leaflet and the tips of the commissures (Figure 1, *A*) to facilitate suturing to the mitral annulus. Care should be taken to avoid injury to the valve leaflets, using intermittent infusion of saline to separate the valve leaflets from the valve sinuses. A sewing cuff would not be added in patients with an annular size < 12 mm, because the cuff could impede visualization. The valve should be compressed to the minimal diameter that will admit a balloon catheter (avoiding complete obliteration of the lumen). Care must be taken to avoid asymmetric compression of the stent graft.

Surgical Technique

The mitral valve should be approached transeptally through a right atriotomy. Valve replacement should be undertaken if the mitral valve has been deemed irreparable. The posterior leaflet and supporting subvalvular apparatus should be completely resected, but the anterior leaflet should only be partially resected to elongate the distance between the valve and the left ventricular (LV) outflow tract (LVOT), particularly in patients with an atrioventricular canal (AVC) defect. Consideration should be given to anterior chord-sparing valve replacement. Most patients will require removal of the subvalvular apparatus to accommodate the length of the valve. The annulus is sized with dilators.

The prepared and compressed valve is placed in the LV inflow tract. To prevent LVOT obstruction (LVOTO), the ventricular end of the valve should be fixed to the posterior inferior wall of the left ventricle (Figure 1, *B*). The valve stent is secured to the muscle of the posterior LV wall using a single figure-of-eight polypropylene suture, without pledgets. We have preferred not to fix it to a chordal structure or papillary muscle, because that can still permit unfavorable mobility of the valve toward the LVOT. We have not observed disruption of this suture resulting in loss of downward canting of the Melody valve.

The valve should be anchored to the mitral annulus using a single continuous circumferential suture or multiple adjacent interrupted mattress sutures. Patients undergoing fixation with the continuous suture technique should undergo valve expansion before knot tying. The Melody valve should be expanded to 4 atm using catheterization balloons to a size not more than 1 mm greater than the annulus diameter measured using echocardiography. The inflow segment of the valve should be inspected to ensure that the pulmonary veins are not obstructed, and the valve leaflets should be tested with saline. The interatrial septum can be reconstituted using either autologous or bovine pericardium, increasing the capacity of the left atrium. We now maintain fenestration (with a 2.7-mm punch) of the atrial septal defect patch in all patients. The opening will provide easy access to the left atrium for catheterization to assess hemodynamics and image and perform dilation on the Melody valve, as necessary. In addition, many of these children are known to have poor LV compliance because of underlying disease, and the fenestration will allow echocardiographic estimation of the transseptal gradient and, thus, the left atrial pressure.

An echocardiogram should be performed intraoperatively to assess the function of the prosthetic valve, rule out paravalvular leaks and LVOTO, and assess ventricular function, specifically, regional wall motion abnormalities in the circumflex territory.

Postoperative Care

The current practice has been to anticoagulate patients with heparin at a therapeutic dose (adjusting to an heparin level > 0.5 U/mL) until aspirin therapy (5-10 mg/kg/d) can be initiated. Aspirin responsiveness is tested using the Verify Now system (Accumetrics, Inc, San Diego, Calif) to ensure <550 aspirin reaction units. Nonresponders should be treated with clopidogrel. Antibiotic prophylaxis should be administered to all patients until the chest tubes have been removed. All patients should undergo echocardiographic evaluation before discharge. Cardiac catheterization will be scheduled for 3 to 6 months postoperatively or sooner, if the echocardiographic evaluation suggests an increasing transmitral gradient.

RESULTS

Eleven patients underwent Melody valve implantation (Table 1). The median age at implantation was 7 months (range, 2-28). Of the 11 patients, 8 were <12 months old. The median weight was 5.2 kg (range, 3.5-13.6). Of the 11 patients, 3 had an AVC defect, 1 had ischemic mitral regurgitation, and 7 had congenital mitral stenosis. All patients had undergone mitral or left atrioventricular valve repairs that had failed, and 1 patient had had bioprosthetic valve failure. The median number of previous surgical and/or catheter-based interventions was 3 (range, 3-6). The indication for MVR was severe mitral stenosis in 4 patients and severe mitral regurgitation in 7.

The operative details are provided in Table 1. Melody valve modification included addition of a pericardial sewing cuff in 6 patients, removal of the proximal stent crowns in 5, removal of the distal stent crowns in 5, and aggressive resection of the LVOT-facing sinus in 1 patient. The native anterior leaflet with its subannular apparatus was preserved in 2 patients. The anterior leaflet was partially preserved in 5 patients. Fixation of the distal stent to the posterior left ventricle was performed in 7 patients. The maximum balloon size used for Melody valve expansion in the operating room was 9 to 16 mm (median, 14). The interatrial septum was reconstituted with patch material in 10 patients and fenestrated in 7. The immediate postoperative transvalvular gradient ranged from 2 to 7 mm Hg (median, 4), with mild or less mitral regurgitation in all patients. Two patients had mild LVOTO. Small paravalvular leaks were observed in 7 patients.

At a median follow-up of 3 months (range, 1-20), 1 patient had died. This patient had had heterotaxy, upstairs-downstairs ventricles, a double outlet right ventricle and an AVC defect, and ventricular dysfunction and had undergone biventricular repair. He had required extracorporeal membrane oxygenation for severe ventricular dysfunction. The patient subsequently underwent