Melody Valve for Mitral Valve Replacement

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In certain pediatric patients with irreparable mitral valve disease, mitral valve replacement is necessary. One option for replacement in a child with small annulus is off label use of the Melody valve for mitral replacement. The device modifications and implantation technique are described, and focus on maneuvers to prevent perivalvular leak and left ventricular outflow tract obstruction. Short term results are acceptable, but long term performance of this valve in this position is still unknown.

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Introduction

Options for mitral valve replacement in children with irreparable mitral valve are limited, particularly for annular size less than 15 mm. Recent experience with a bovine jugular vein graft (Melody® valve) for mitral replacement has demonstrated acceptable short-term results. Advantages of this valve include favorable effective orifice area index and potential for subsequent expansion by percutaneous catheter-based balloon dilation as the child grows. Certain design features of the device make it favorable for implantation into the right ventricular outflow tract yet make it less favorable for implantation into the mitral position. The length of the device (2.3-2.5 cm) predisposes it to protrusion into the left ventricle (LV), leading to left ventricular outflow tract obstruction (LVOTO). The device lacks a sewing cuff to anchor the device to the mitral annulus. Modification of the device and specific implantation techniques are described to allow implantation and avoid LVOTO.

Disclaimer: This article describes off-label use of a device (Melody® valve). Long-term performance of this device in this position has not been determined, and its use should be considered investigational. Although institutional policies regarding off-label use of a device vary, we have pursued approval from institutional review board before approaching families with this option. During discussions and parental consent process, clear statement regarding the off-label use of the device is provided.

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Preparation of the Melody Valve

Figure 1 If mitral valve replacement is expected, preparation of the device on the back table before institution of cardiopulmonary bypass (CPB) limits the duration of cross-clamp and CPB. The goals of modification of the Melody are to facilitate surgical implantation and minimize risk of LVOTO. The sewing cuff is added externally to the stent in its midsection. Although we have used bovine pericardium, any expandable material (ePTFE, autologous pericardium) can be utilized. With the fully expanded 18 or 16-mm valve washed for 3 minutes, a 3-mm ring of pericardium is cut with an inner diameter equivalent to the diameter of the Melody valve is secured to the stent using interrupted sutures (shown). Sutures should not penetrate the conduit material itself, as this could lead to entrapment of the valve leaflets themselves or perforation of the extremely thinned-walled conduit material. ePTFE = polytetrafluoroethylene.
Our preference to avoid any disruption of the stent structure supporting the valve apparatus. However, shortening of the valve or excision of part of the valve adjacent to the LVOT may be necessary in certain patients with small LV dimensions, particularly in neonates and infants with LV hypoplasia. The LV long- and short-axis dimensions measured by preoperative echocardiogram can be used to plan the preparation of the prosthesis. If shortening or resection of the stent material adjacent to the LVOT is considered, the remaining conduit material should be secured to the remaining intact stent (B and D).
Figure 3 Through a median sternotomy, CPB is established through aortic and dual venous cannulation. The mitral valve is exposed through a transseptal approach (shown). CPB = cardiopulmonary bypass.
Figure 4 The posterior leaflet and chordal attachments are resected. Chordal attachments of the anterior leaflet may be preserved to prevent deviation of the implanted valve into the LVOT. Preservation of the portion of the anterior leaflet adjacent to the LVOT creates distance between the prosthesis and the LVOT. In a patient with AV canal defect, closure of the cleft prevents suture of the prosthesis directly to the ASD or VSD patches. During resection of the leaflet material, a small rim of leaflet is left intact on the annulus to avoid injury to conduction and coronary artery during implantation. Hegar dilators are used to size the annulus following leaflet resection and help determine the balloon size to be used for valve expansion. ASD = atrial septal defect; VSD = ventricular septal defect.
To prevent tilting of the Melody valve into the LVOT during systole, the distal aspect of the stent is fixed to the endocardium of the LV free wall abutting the diaphragm. Suture is passed through the endocardium approximately 1.5 cm apical to the mitral annulus, and then passed through one of the tines of the distal stent. Before tying this suture, the Melody valve prosthesis is compressed over a balloon catheter or 5-mm hegar dilator to allow passage through the mitral annulus. A knot pusher device may be necessary to secure the tie as space between the prosthesis and the annulus is limited.
Next, the sewing ring of the valve is secured to the prepared mitral annulus. A single continuous circumferential suture or multiple interrupted sutures may be utilized. If continuous suture is used, it is not tied until the valve is eventually dilated to the desired size (described later). To prevent or minimize the risk of perivalvular leak, a second purse string suture on the atrial side of the mitral annulus—that does not pass through the sewing cuff—can be placed and tied down following valve expansion.
Finally, serial balloon dilation of the valve to the desired size is performed. Balloon size is chosen based on preoperative measurement of the annulus size by echocardiogram and intraoperative sizing. Balloon size of 1 mm + AP annular dimension by echocardiogram has yielded satisfactory results in our experience. Undersizing may result in perivalvular leak and valve instability, whereas oversizing may lead to LVOTO, coronary artery compression, or heart block. The balloon is carefully inserted through the central lumen of the valve, which was kept patent by compression of the valve over the dilator or balloon. AP = anteroposterior.

Care must be taken during the initial balloon insertion to avoid shear injury to the fragile leaflets within. The balloon is inflated to 4 atm and inspected to ensure that the stent has been dilated uniformly. Often, the balloon must be advanced or retracted and redilated to ensure uniform dilation. To prevent LVOTO in a neonate or hypoplastic LV, tapered dilation can be performed by dilating the LV end of the valve with a smaller balloon than is used to dilate the atrial end of the valve.

During the final dilation, the balloon is maintained at 4 atm inflation while any remaining circumferential continuous sutures are tightened. Keeping the balloon dilated during this step prevents inadvertent compression of the valve. Although the valve protrudes into the left atrium, pulmonary vein compression obstruction has not been observed. The valve is tested to ensure free mobility of all 3 leaflets. During deairing, external manual compression of the LV should be minimized to avoid compression of the stent valve. The LV is filled with saline to maximize air displacement before atrial septal closure and minimize need for external cardiac massage. A small-bore LV vent is placed across the valve to assist subsequent deairing.

Aspirin is the only long-term anticoagulation therapy, and the child is maintained on heparin until aspirin is initiated. Antiplatelet effect is confirmed with Verify Now or TEG Platelet mapping.

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To facilitate subsequent percutaneous catheter access to the left atrium, the atrial septal defect is closed with a patch of bovine pericardium and a 4-mm central fenestration. The right atriotomy is closed, the heart deaired, and the cross-clamp removed. An echocardiogram is performed after discontinuation of bypass to confirm absence of perivalvular leaks or LVOTO.

Figure 8
Results

The Melody valve appears to function well at short-term follow-up, with complications including LVOTO in 10% of patients.\textsuperscript{1,2} Balloon expansion of the valve at up to 4 years following implantation has been successful at preserving valvular competence and low gradient. Reoperation for perivalvular leak and LVOTO remains a concern and requires close follow-up. Perivalvular leaks and LVOTO can be managed with transcatheter techniques, whereas severe LVOTO may require reoperation.\textsuperscript{3} Future development of a device that is specifically designed for implantation into the mitral position with sewing cuff and shorter profile may reduce the incidence of perivalvular leaks and LVOTO.

References