

Chapter 32: Step-by-Step Guide for Pulmonary Valve Replacement with the Melody Transcatheter Pulmonary Valve

Brian H. Morray, MD, Zachary L. Steinberg, MD, Thomas K. Jones, MD, FACC

Division of Pediatric Cardiology, Seattle Children's Hospital, University of Washington School of Medicine, Seattle, WA

The Melody transcatheter pulmonary valve (TPV) is a glutaraldehyde-treated bovine jugular vein sewn within a platinum-iridium stent. Worldwide, over 10,000 Melody (Medtronic Inc., Minneapolis, MN) valves have been implanted to date. The initial U.S. Melody TPV trial was limited to patients with dysfunctional right ventricular outflow tract (RVOT) conduits ≥ 16 mm in original diameter and weighing ≥ 30 kg¹. The trial was later expanded to include patients with dysfunctional bioprosthetic valves (BPV) with manufacturer-specified inner diameter of 18 to 20 mm². The Melody TPV received formal approval from the Food and Drug Administration (FDA) in 2015. The technical aspects of TPV replacement (TPVR) have evolved over time, resulting in improved valve durability and expanded patient populations including smaller patients, smaller conduits and BPVs, and implantation in native outflow tracts³⁻⁵.

Pre-intervention assessment

Vascular Access

Vascular access is typically obtained in the femoral vessels, although vascular occlusions, small patient size or challenging catheter course may require alternative sites of access such as the internal jugular vein or a periventricular approach. Femoral venous access is obtained with or without the aid of ultrasonography, and a 7-Fr introducer sheath is placed. Femoral arterial access is obtained and a 5-Fr sheath is placed for arterial pressure monitoring, blood gas sampling and coronary angiography during compression testing. The use of vascular pre-closure devices is often employed in the femoral vein to assist with hemostasis at the conclusion of the case although this practice varies by center. Our default approach when using transfemoral access has been to deploy two suture mediated closure systems (Perclose ProGlide, Abbott Laboratories, Abbott Park, IL) for venous pre-closure. Additional venous access is typically not necessary but may be indicated for additional procedures.

Hemodynamic Assessment

A comprehensive hemodynamic assessment of the right heart is performed using a balloon-tipped end-hole catheter, carefully documenting the degree and levels of RVOT obstruction. This data should be integrated into the pre-procedural assessment to ensure that the patient meets criteria for TPVR. A retrograde left heart catheterization is performed to document left-sided hemodynamics. This is often helpful to identify diastolic dysfunction in patients who have had prior surgeries for left heart obstructive lesions (i.e. Ross procedure) or have a systemic right ventricle in patients with an LV to PA conduit. The pigtail angiographic catheter can then be used to perform the initial assessment of the aortic root and coronary arteries.

Angiography

RVOT angiography is typically performed with biplane fluoroscopy with an angiographic catheter in the RV or RVOT. This provides detailed anatomic information about the level of obstruction as well as the degree of conduit calcification. Fluoroscopic projections will vary depending on the conduit orientation but often a right anterior oblique (RAO) and cranial projection for the anterior-posterior (AP) camera and 90° left anterior oblique projection (LAO) for the lateral camera will provide adequate visualization of the RVOT (Figure 1). An additional strategy for angiographic assessment of the RVOT is to establish wire position in a lower lobe branch pulmonary artery and perform the angiographic assessment over the wire using a Multitrack angiographic catheter (B. Braun Medical Inc., Bethlehem, PA). This approach is preferable when there is challenging RVOT anatomy and abandoning an established catheter position in the branch pulmonary arteries is not desirable.

The relationship of the aortic root and coronary arteries to the RVOT is then assessed with aortic root angiography and/or selective coronary artery angiography. If there is any concern about the proximity of the coronary arteries to the RVOT, coronary artery compression testing with simultaneous RVOT balloon angioplasty and coronary artery angiography (aortic root angiography or selective coronary angiography) should be performed in order to simulate the effect that conduit dilation and stent implantation will have on the coronary arteries. In most patients, it is the left main coronary artery or left anterior descending coronary artery that are in close proximity to the RVOT.

Coronary Artery Compression Testing

Prior to performing coronary artery compression testing or any other RVOT intervention it is important to establish stable wire position in a lower lobe branch PA with a stiff wire such as the Amplatz Super Stiff, (Boston Scientific Corp., Marlborough, MA), Lunderquist (Cook Medical, Bloomington, IN) or Meier wire (Boston Scientific Corp., Marlborough, MA). Compression testing should be performed with a non-compliant angioplasty balloon containing dilute contrast inflated to a diameter that closely approximates the desired final diameter of the RVOT. With the balloon inflated in the RVOT, simultaneous coronary angiography is performed in steep caudal and 90° LAO projections (Figure 2). Compression testing may result in complete obstruction of coronary blood flow or more subtle compression of the coronary artery. If there is concern for coronary artery compression the procedure should be concluded. Compression testing is not necessary in every case but is positive in 5-6% of cases and certain patients are at increased risk of compression⁶. Similarly, aortic root compression has been reported and should be evaluated if there is concern about the relationship of the RVOT to the aortic root as compression by the RVOT can result in increasing aortic valve insufficiency or the formation of a traumatic aortopulmonary fistula^{7,8}.

Conduit or bioprosthetic valve preparation

If there is no coronary artery compression the next step is to proceed with conduit preparation for valve implantation. The use of compliant sizing balloons to evaluate the dimensions of the RVOT is more commonly done with BPVs to determine the true inner diameter of the valve and is not necessary with a calcified or stenotic conduit. It is typically at this juncture that any concomitant procedures such as

balloon pulmonary angioplasty or pulmonary artery stent implantation are performed prior to conduit dilation and TPVR. Before any interventions are performed, intravenous (IV) unfractionated heparin is administered to maintain an activated clotting time (ACT) > 250 seconds. IV antibiotics are also administered and given at regular intervals for up to 24 hours after the conclusion of the case.

Conduit pre-dilation and stent implantation are crucial steps to ensure the success of the procedure. In the early experience, recurrent RVOT obstruction associated with Melody valve stent fracture (MSF) was the most common indication for reintervention². Follow-up studies have demonstrated improved freedom from MSF when TPVR is performed within an intact RVOT stent or BPV⁹. Bare metal stents (BMS) such as the Palmaz XL (Palmaz Scientific, Dallas, TX) and IntraStent Max LD (eV3 Inc., Plymouth, MN) are hand crimped onto low-pressure delivery balloons such as the BiB balloon (NuMed, Hopkinton, NY) or higher pressure balloons such as the Z-Med (B. Braun Medical Inc., Bethlehem, PA) or Atlas balloons (Bard Peripheral Vascular, Tempe, AZ).

The femoral venous sheath is upsized to an 18-Fr sheath. Through this sheath, 12-Fr or 14-Fr long sheaths can be advanced over the wire into the RVOT to aid in stent delivery and allow for rapid angiographic assessment of stent position before and after deployment. Stent recoil is common, particularly in small or heavily calcified conduits and multiple overlapping stents may be required to achieve a conduit diameter sufficient for valve implantation. After each stent placement, hemodynamic and angiographic assessments of the RVOT are made to ensure adequate relief of conduit obstruction (Figure 3). Stent implantation prior to TPVR within a BPV is not commonly performed as the valve sewing ring provides adequate support for the TPV. Polytetrafluoroethylene (PTFE) covered Cheatham-Platinum stents (NuMed, Hopkinton, NY) are available and have demonstrated efficacy in the treatment or prevention of conduit tears or injury that occur during pre-dilation or BMS stent implantation. Estimates of conduit injury during TPVR range from 6% to 22% although most tears are confined to the perivascular space surrounding the conduit lumen and unconfined tears leading to significant bleeding, emergent surgery or death are uncommon^{10, 11}.

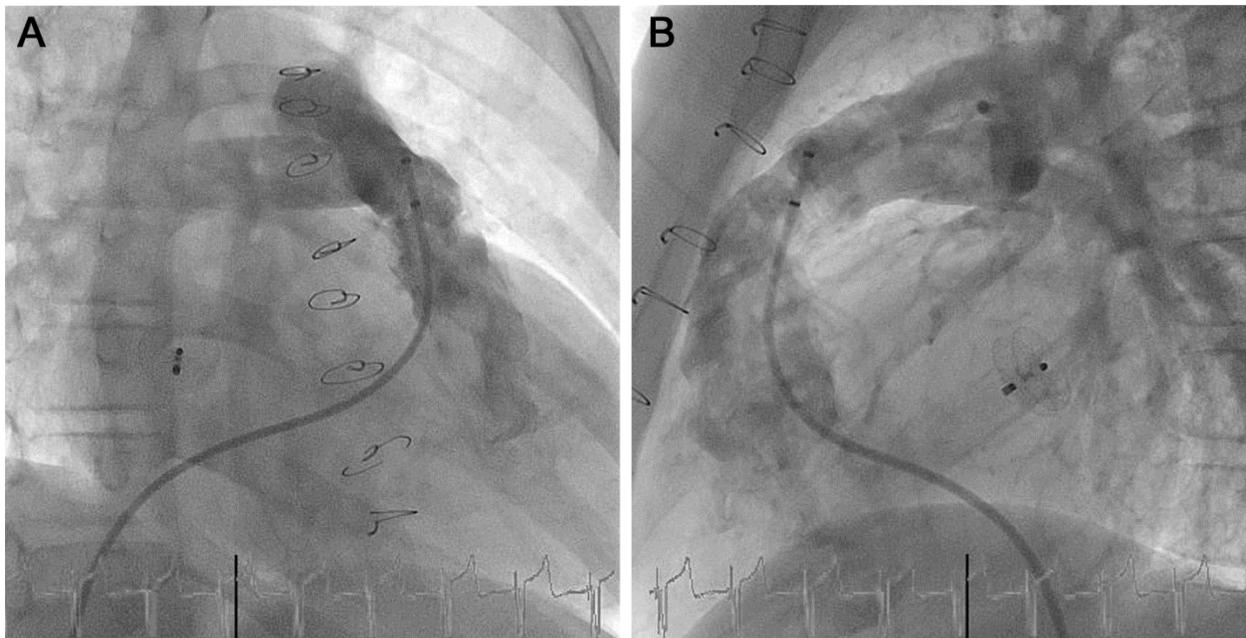
Transcatheter valve replacement

Once an adequate conduit diameter has been achieved, Melody TPVR is performed. The valve is inspected and washed in 2 sterile saline baths. It is then hand-crimped onto the delivery balloon housed within the Ensemble Delivery System (Medtronic Inc., Minneapolis, MN). Care is taken to confirm the appropriate valve orientation (Figure 4). The delivery system comes with 3 outer balloons sizes (18, 20, 22mm) and has a 22-Fr maximum outer diameter. Selection of the proper delivery balloon size is based on the measured conduit diameter following pre-dilation and stent placement. The measured outer diameter of the valve and stent complex is approximately 2 mm larger than the rated nominal diameter of the valve after expansion. For valve deployment, inflation of the outer balloon is rated up to 4 atmospheres on the 18 and 20 mm Ensemble delivery systems and 3 atmospheres on the 22 mm delivery system.

Following deployment, repeat hemodynamics and pulmonary artery angiography generally demonstrate significant reductions in RVOT gradient and a competent pulmonary valve (Figure 5). Post-dilation of the TPV is typically not necessary although it can be performed safely without damaging the

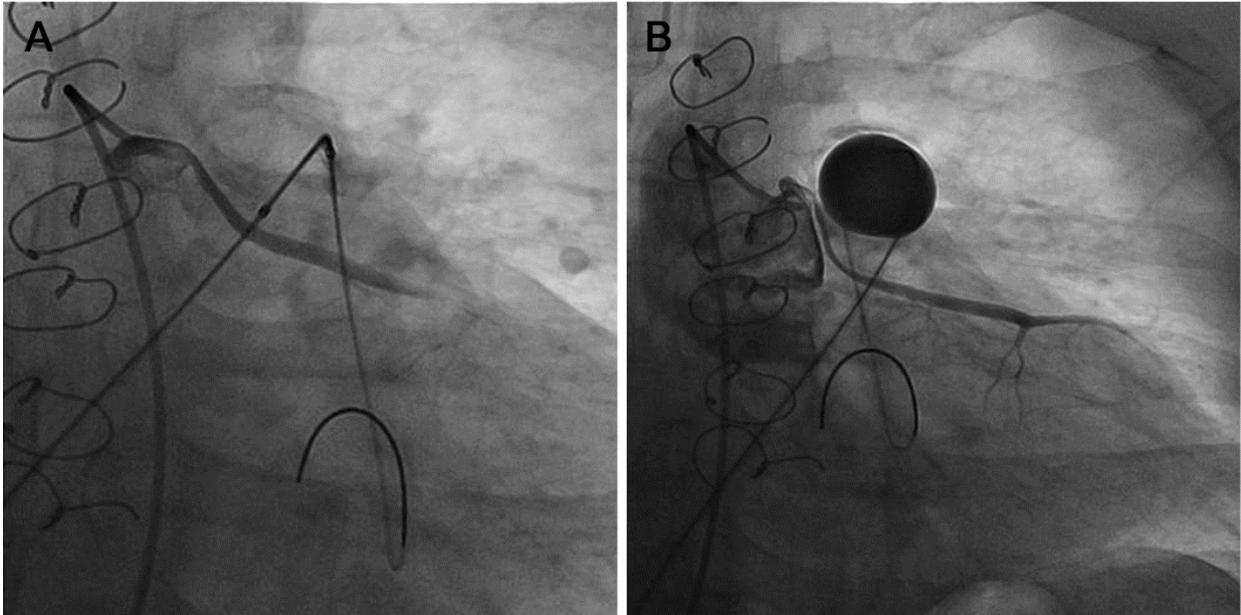
valve leaflets if adequate gradient relief has not been achieved. At the discretion of the operator additional imaging with intracardiac echocardiography (ICE) is sometimes performed to evaluate TPV function and for the presence of perivalvular leak. The patient is admitted for overnight observation and echocardiogram prior to discharge. Most patients will receive a brief course of prophylactic intravenous antibiotics started during the case and discontinued prior to discharge. Anticoagulation practices vary by center and patient, but most patients will be discharged on daily aspirin indefinitely as long as the TPV remains in place.

Figure 1



(A) Right ventricular outflow tract angiogram in a right anterior oblique (RAO) and cranial projection. The length of the RVOT and the bifurcation of the pulmonary arteries are nicely demonstrated.
(B) Lateral or 90° left anterior oblique (LAO) projection of the same angiogram also demonstrates the length of the conduit.

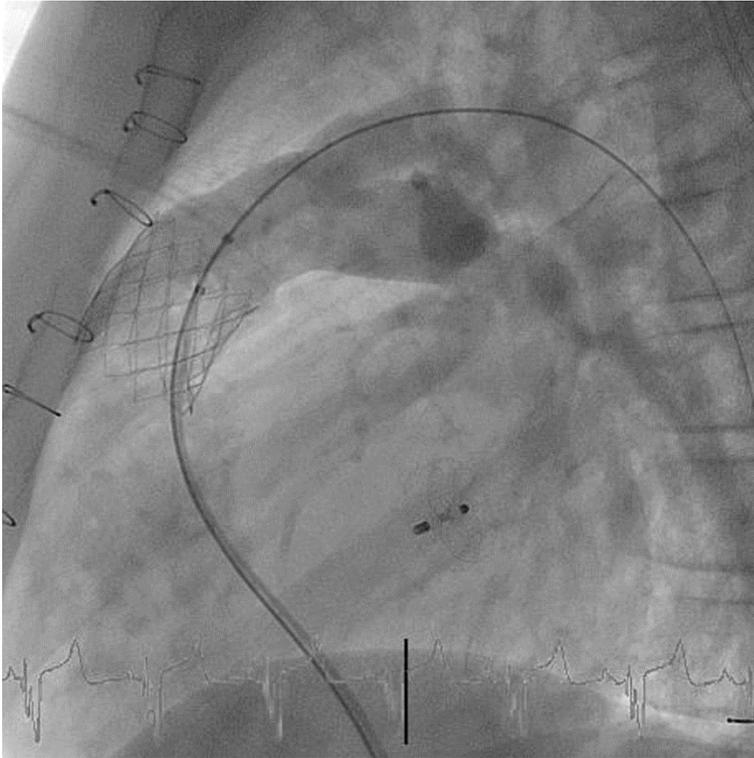
Figure 2



(A) Selective left coronary artery angiogram in a steep caudal projection looking down the long axis of the RVOT, which is marked by the wire. There is no evidence of coronary artery distortion or compression.

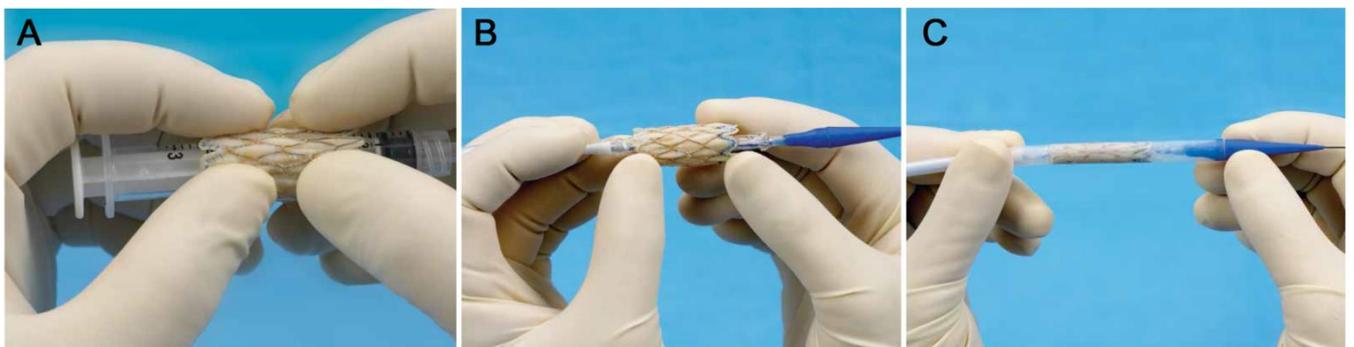
(B) In the same projection with a balloon inflated in the RVOT, selective left coronary artery angiography clearly demonstrates compression and distortion of the left main coronary artery.

Figure 3



RVOT angiography following placement of a Palmaz XL (Palmaz Scientific, Dallas, TX) stent. The stent covers the narrowest portion of the RVOT as seen in the lateral projection and serves as a landing zone for the Melody TPV.

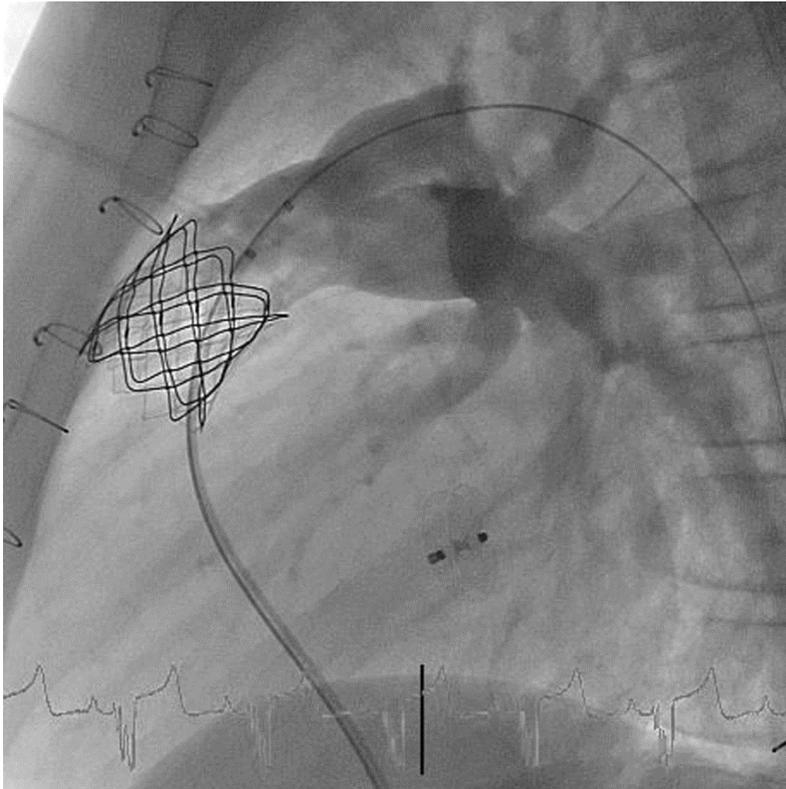
Figure 4



the delivery system.

(C) The valve is then further crimped over the delivery balloon and the sheath is advanced over the valve while flushing the sheath with saline to clear it of air.

Figure 5



A final angiogram in the main pulmonary artery following valve deployment demonstrates a competent valve in stable position within the RVOT.

References:

1. Zahn EM, Hellenbrand WE, Lock JE and McElhinney DB. Implantation of the melody transcatheter pulmonary valve in patients with a dysfunctional right ventricular outflow tract conduit early results from the u.s. Clinical trial. *J Am Coll Cardiol.* 2009;54:1722-9.
2. McElhinney DB, Hellenbrand WE, Zahn EM, Jones TK, Cheatham JP, Lock JE and Vincent JA. Short- and medium-term outcomes after transcatheter pulmonary valve placement in the expanded multicenter US melody valve trial. *Circulation.* 2010;122:507-16.
3. Berman DP, McElhinney DB, Vincent JA, Hellenbrand WE and Zahn EM. Feasibility and short-term outcomes of percutaneous transcatheter pulmonary valve replacement in small (<30 kg) children with dysfunctional right ventricular outflow tract conduits. *Circ Cardiovasc Interv.* 2014;7:142-8.
4. Gillespie MJ, Rome JJ, Levi DS, Williams RJ, Rhodes JF, Cheatham JP, Hellenbrand WE, Jones TK, Vincent JA, Zahn EM and McElhinney DB. Melody valve implant within failed bioprosthetic valves in the pulmonary position: a multicenter experience. *Circ Cardiovasc Interv.* 2012;5:862-70.

5. Meadows JJ, Moore PM, Berman DP, Cheatham JP, Cheatham SL, Porras D, Gillespie MJ, Rome JJ, Zahn EM and McElhinney DB. Use and performance of the Melody Transcatheter Pulmonary Valve in native and postsurgical, nonconduit right ventricular outflow tracts. *Circ Cardiovasc Interv.* 2014;7:374-80.
6. Morray BH, McElhinney DB, Cheatham JP, Zahn EM, Berman DP, Sullivan PM, Lock JE and Jones TK. Risk of coronary artery compression among patients referred for transcatheter pulmonary valve implantation: a multicenter experience. *Circ Cardiovasc Interv.* 2013;6:535-42.
7. Lindsay I, Aboulhosn J, Salem M and Levi D. Aortic root compression during transcatheter pulmonary valve replacement. *Catheter Cardiovasc Interv.* 2016;88:814-821.
8. Kenny D, Holoshitz N, Turner D and Hijazi ZM. Aortopulmonary fistula after transcatheter pulmonary valve replacement. *Circ Cardiovasc Interv.* 2013;6:e67-8.
9. McElhinney DB, Cheatham JP, Jones TK, Lock JE, Vincent JA, Zahn EM and Hellenbrand WE. Stent fracture, valve dysfunction, and right ventricular outflow tract reintervention after transcatheter pulmonary valve implantation: patient-related and procedural risk factors in the US Melody Valve Trial. *Circ Cardiovasc Interv.* 2011;4:602-14.
10. Hainstock MR, Marshall AC, Lock JE and McElhinney DB. Angioplasty of obstructed homograft conduits in the right ventricular outflow tract with ultra-noncompliant balloons: assessment of therapeutic efficacy and conduit tears. *Circ Cardiovasc Interv.* 2013;6:671-9.
11. Bishnoi RN, Jones TK, Kreutzer J and Ringel RE. NuMED Covered Cheatham-Platinum Stent for the treatment or prevention of right ventricular outflow tract conduit disruption during transcatheter pulmonary valve replacement. *Catheter Cardiovasc Interv.* 2015;85:421-7.