Transcatheter Pulmonary Valve Replacement in Patients With Congenital Heart Disease

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Transcatheter pulmonary valve replacement is now a feasible alternative to surgical pulmonary valve replacement in children and adults with dysfunctional right ventricular outflow conduits. Currently, 2 types of valves can be used for this application. This article provides an overview of the procedure and how it is performed, indications and contraindications for transcatheter pulmonary valve replacement, and short- and long-term outcomes. Nursing considerations mainly focus on educating patients, preventing bleeding and infection, monitoring renal function, and preventing injury to the catheter insertion site. This article enhances the knowledge of nurses working in cardiac catheterization laboratories and post-procedure recovery and cardiac units so that the nurses can anticipate interventions and understand the management of patients who have transcatheter pulmonary valve replacement. (Critical Care Nurse. 2018; 38[1]:30-37)

The estimated incidence of infants born with obstruction of the right ventricular tract is 1.6 per 1000 live births. Patients born with these lesions, which include tetrology of Fallot, pulmonary atresia, and truncus arteriosus, usually require surgical placement of a conduit or bioprosthetic valve in the right ventricular outflow tract (RVOT; Figure 1). Over time, the reconstructed RVOT can become dysfunctional, and stenosis or regurgitation can develop, leading to right ventricular dilatation, arrhythmias, and poor function. Thus, patients with RVOT conduits or bioprosthetic valves often require multiple surgeries in their lifetime to replace the failing valve. Each surgical intervention requires repeat sternotomy and cardiopulmonary bypass. Transcatheter pulmonary valves (TPVs) are now a feasible and much less invasive alternative to surgical RVOT repair or pulmonary valve replacement (PVR). TPVs are inserted through the femoral vein, and patients often remain in the hospital for 1 day. Use of TPVs offers the opportunity to delay and reduce the number of a patient’s future cardiac surgeries.
Pathophysiology

Several subsets of congenital heart defects involve RVOT obstruction. Infants and children born with these lesions undergo surgical PVR with conduits or bioprosthetic valves. Over time, these valves or conduits become stenotic or insufficient due to calcification of the valve or intimal proliferation. Persistent pulmonary valve regurgitation causes right ventricular dilatation and, eventually, right ventricular dysfunction. Tricuspid regurgitation develops as the annulus of the tricuspid valve dilates. Atrial and ventricular arrhythmias can occur, leading to right ventricular systolic dysfunction. As right ventricular function worsens, exercise intolerance and fatigue develop. Patients may experience other signs of right-sided heart failure, including swelling of extremities and liver congestion or hepatomegaly. Similarly, in patients with pulmonary conduit stenosis, right ventricular hypertrophy can develop. If obstruction remains severe and the right ventricle is pumping over a high-pressure gradient, the ventricle begins to dilate, and right ventricular function can worsen over time.

Guidelines for repeat PVR emphasize replacing the valve or conduit before the right ventricle becomes increasingly dilated. Once right ventricular dilatation has progressed beyond a certain threshold, the right ventricle may be unable to remodel. Because QRS prolongation greater than 180 milliseconds is considered a risk factor for arrhythmias and sudden death, PVR is often recommended when QRS duration is more than 140 milliseconds. Indications for TPV implantation are given in Table 1.

Development of TPVs

Philip Bonhoeffer first developed a TPV in the late 1990s. Bonhoeffer and his team began work on TPV implantation in lambs by replacing ovine valves with a bovine jugular vein sewn into a stent scaffold. On the basis of the success in valve replacements in an ovine model, Bonhoeffer et al performed the first human TPV implantation in 2000 in a 12-year-old boy with a history of pulmonary atresia and ventricular septal defect who had undergone a repair with closure of a ventricular septal defect and placement of an RVOT conduit at 4 years of age.

Because of Bonhoeffer’s promising results with TPV replacements (tPVRs), Medtronic developed the Melody valve (Medtronic Inc; Figures 2 and 3), which was...
based on the TPV prototype of Bonhoeffer and his colleagues. Between 2007 and 2010, the Melody valve was implanted in more than 150 patients who had RVOT conduit stenosis or insufficiency at 5 centers in the United States under an investigational device exemption. In 2010, the Melody valve was approved by the Food and Drug Administration for use in the RVOT position in patients with dysfunctional conduits.7

The Melody valve is available in sizes 18, 20, and 22 mm. The valve can be underexpanded to 16 mm and overexpanded to 24 mm. Overall, multiple studies8-13 have indicated that by decreasing pulmonary insufficiency or relieving stenosis, implantation of the Melody valve is effective in postponing the need for surgical intervention in patients with RVOT conduit failure. Initially, the predominant adverse effect associated with the Melody valve was stent fracture of the valve.8,14,15 Stent fracture was as high as 21% in patients without prestenting.8,15 Prestenting the conduit before Melody valve implantation reduced the occurrence of stent fracture.11 The other major adverse event was endocarditis, with an incidence of 3% of cases in 4 years, spurring the recommendation for lifelong prophylaxis for subacute bacterial endocarditis in patients who received a Melody valve.8,10,15

Because of the limitations of available sizes (18-22 mm) of the Melody valve, the Sapien valve (Edwards Lifesciences; Figure 4) was introduced for use in the pulmonic area. The Sapien valve is a transcatheter heart valve approved for the aortic position and is often used as a surgical alternative in elderly patients with multiple

### Table 1 Indications and contraindications for transcatheter pulmonary valve implantation in RVOT

<table>
<thead>
<tr>
<th>Indications</th>
<th>Contraindications</th>
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<tbody>
<tr>
<td>Existence of a full (circumferential) RVOT conduit that was ≥ 16 mm in</td>
<td>Venous anatomy unable to accommodate a 22-F introducer sheath</td>
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<tr>
<td>diameter when originally implanted</td>
<td>Unfavorable RVOT for good stent anchorage</td>
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<td>AND</td>
<td>Severe RV outflow obstruction that cannot be dilated by balloon</td>
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<td>Dysfunctional RVOT conduits with a clinical indication for intervention</td>
<td>Obstruction of the central veins</td>
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<td>AND</td>
<td>Clinical or biological signs of infection</td>
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<td>Regurgitation: ≥ moderate regurgitation 3+ by TTE or pulmonary regurgitant</td>
<td>Active endocarditis</td>
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<td>fraction ≥ 40% by cardiac MRI</td>
<td>Known allergy to aspirin or heparin</td>
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<tr>
<td>AND/OR</td>
<td>Pregnancy</td>
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<tr>
<td>Stenosis: mean RVOT gradient ≥ 35 mm Hg by TTE</td>
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<tr>
<td>RV dysfunction and dilatation (indexed RV end-diastolic volumes &gt; 150 mL/m²)</td>
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<tr>
<td>QRS &gt; 140 milliseconds</td>
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<tr>
<td>Atrial and ventricular tachyarrhythmia</td>
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Abbreviations: MRI, magnetic resonance imaging; RV, right ventricular; RVOT, right ventricular outflow tract; TTE, transthoracic echocardiography.
comorbid conditions that preclude surgical aortic valve replacement. The Sapien XT valve can be used in RVOT conduits or bioprosthetic valves sized 23, 26, and 29 mm (Table 2), increasing the number of patients eligible for tPVR. The first implantation of a Sapien valve in the pulmonic position was performed in 2005 in a 16-year-old patient with a 24-mm homograft conduit with conduit insufficiency. Early results from an international multicenter trial indicated that implantation of a Sapien valve in right ventricle to pulmonary artery conduits leads to restoration of conduit function with a decrease in right ventricle to pulmonary artery conduit gradient and minimal insufficiency.

**Indications and Contraindications for tPVR**

Indications for tPVR are based on indications for surgical PVR, because currently no published guidelines for tPVR are available. The major indication for tPVR is conduit dysfunction evidenced by at least moderate stenosis or regurgitation (Table 1). Right ventricular dilatation and dysfunction, prolonged QRS (>140 milliseconds), atrial and ventricular tachyarrhythmias, manifestations of right-sided-heart failure (dyspnea on exertion, edema), and/or exercise intolerance are also considered indications for tPVR.

Major contraindications include current infection or endocarditis and pregnancy (Table 1). The size or anatomy of the RVOT, including a severely stenotic or calcified conduit that cannot be safely dilated or a dilated conduit greater than 29 mm that is too large for a transcatheter heart valve, may preclude tPVR. Coronary compression testing is performed during the procedure. If any angiographic evidence of coronary compression is detected, the tPVR cannot be performed. Smaller or younger patients are often not good candidates for tPVR because of the sheath size.

**Procedure**

The TPV implantation is performed in the cardiac catheterization laboratory, generally with a local anesthetic to the femoral sites but also with general anesthesia. Antibiotics are given prophylactically. Heparin boluses are administered throughout the procedure to maintain an activated clotting time greater than 200 seconds. The intervention is performed with fluoroscopic guidance. Hemodynamic and angiographic assessment of the right ventricle to pulmonary artery conduit is performed to determine the baseline pressure gradient and degree of pulmonary regurgitation across the conduit. The minimum diameter of the conduit is also determined from the angiograms obtained in 2 orthogonal planes. Coronary angiography to detect possible coronary compression is performed before RVOT intervention. Serial balloon dilation of the RVOT to the desired stent size is performed. Coronary angiography is performed again to assess for signs of coronary compression. With the RVOT expanded to the desired size, the implantation area is typically prestented with a bare metal stent. The metal stent creates a landing zone for the transcatheter heart valve and reduces the risk of TPV stent fracture. If the patient has a bioprosthetic valve, prestenting is not required because the ring of the bioprosthetic valve supports the TPV.

The Melody valve is deployed by using an Ensemble delivery system (Medtronic; Figure 5). The delivery system consists of a balloon-in-balloon catheter with a
retractable sheath. The valve is typically crimped by hand on the delivery ensemble.\textsuperscript{7} Before the valve is crimped, its orientation should be verified by using a blue suture on the valve.\textsuperscript{20} The delivery system is introduced through the femoral vein and advanced toward the implantation site. Once it is in position, the sheath is removed, and the 2 balloons are inflated, thereby deploying the valve. The delivery system is then deployed, and pressure measurements are again obtained. Angiography of the RVOT is repeated to assess compliance of the valve.

Deployment of a Sapien valve differs from deployment of a Melody valve in the delivery ensemble used. The valve is crimped on the NovaFlex+ (Edwards Lifesciences) delivery system (Figure 6). As with the Melody valve, the Sapien valve is advanced through the femoral vein to the implantation site. Hemodynamic parameters are remeasured after deployment to assess the gradient across the RVOT. Angiography of the RVOT is performed.

After TPV deployment, if the activated clotting time is less than 200 seconds, the sheaths are removed in the catheterization laboratory. Hemostasis is achieved by using either a vascular closure device or a figure 8 suture.\textsuperscript{6} The patient is admitted to a telemetry unit for overnight observation. In most centers, a transthoracic echocardiogram, chest radiograph, and electrocardiogram are obtained within 24 hours to reevaluate valve placement.\textsuperscript{4} Patients do not require anticoagulation therapy after tPVR, although antiplatelet therapy with aspirin is often recommended.\textsuperscript{20}

**Procedural Complications**

Conduit or pulmonary artery rupture can be a devasting complication of tPVR.\textsuperscript{7,8,18,20} Rupture would be detected by evidence of a hemothorax on fluoroscopy, blood in endotracheal tube, or pericardial effusion.\textsuperscript{7} Small conduit tears can be contained with balloon occlusion, covered stent placement, or deployment of a Melody valve (which is a covered stent).\textsuperscript{7} If bleeding cannot be contained, emergent surgical intervention would be required. Another potential complication is TPV embolization, which may require surgical removal of the valve.\textsuperscript{7,18} Stent fracture of a Melody valve occurred during initial trials; however, presenting of the RVOT conduit has ameliorated that risk.\textsuperscript{8,11,14,15} Stent fracture can be visualized with radiography and may be suspected if stenosis of the transcatheter heart valve occurs. Placement of another bare-metal stent and reimplantation of the transcatheter heart valve (valve-in-valve) inside the fractured valve are a feasible solution that can be used to postpone surgical reintervention.\textsuperscript{7} Coronary artery compression is a major risk that can also result in death.\textsuperscript{7} Assessment for coronary compression before deployment of a stent or a transcatheter heart valve is necessary. Coronary angiography is performed after deployment to assess for impingement.

Bleeding and hematoma at the catheterization site are major risks immediately after transcatheter heart
valve replacement because of the large-bore (22F) sheath used for deployment of the device.7 Endocarditis has been reported in several patients and is a particular risk in patients with a history of endocarditis.7 Antibiotic prophylaxis during the procedure and lifelong prophylaxis for subacute bacterial endocarditis are also recommended.

According to measurements of total air kerma (kinetic energy released in matter) and dose area product, patients who undergo TPV placement are exposed to a greater amount of radiation during the isolated procedure than are patients who have cardiac catheterization procedures.22 Exposure to high-dose radiation can lead to skin erythema, dermal atrophy, hair loss, and cataracts and may increase the future risk for cancer.22-24

Nursing Considerations

The care of patients during and after tPVR centers on maintaining hemostasis and preventing infection. Patients undergoing TPV implantation are typically evaluated by a pediatric or congenital cardiologist as outpatients and have tests such as magnetic resonance imaging, echocardiography, baseline electrocardiography, radiography, and laboratory values. Most patients are treated as outpatients and are admitted for overnight observation after TPV placement. Preprocedural considerations include assessing the results of baseline laboratory tests, confirming the patient’s ABO-Rh blood group, and assessing vital signs.

Baseline renal function should be determined. Patients receive large doses of contrast material, placing them at risk for acute kidney injury. The risk is higher for patients with chronic renal disease and diabetes. These patients may require hydration with isotonic saline before tPVR and hydration afterward to prevent contrast-induced nephropathy. Some centers may recommend using isotonic sodium bicarbonate or acetylcysteine for renal prophylaxis. Urine output and creatinine level should be monitored after the procedure.

Patients with RVOT conduits are at risk for rupture or tearing of the conduit, depending on the degree of conduit calcification.13,25 Perforation of the pulmonary artery during positioning of the wire is also a risk. Cardiac catheterization nurses should ensure that blood is available in the cardiac catheterization laboratory in the event of conduit tear and bleeding or perforation of the pulmonary artery. If conduit tear or perforation occurs, the interventionist may have to deploy a covered stent or may deploy a Melody valve to contain the tear and bleeding. Briefing or a huddle before the tPVR may help staff in the catheterization laboratory understand the patient’s particular anatomy, anticipate possible complications, and have appropriate equipment ready.

Immediately after the valve replacement, frequent monitoring of the catheterization site is required to assess for bleeding or hematoma, because the valve is delivered through a large-bore sheath. Typically, the site is monitored every 15 minutes for the first hour, then every 30 minutes for 2 hours, and then hourly until the patient is allowed to ambulate. Vital signs should be assessed at the same intervals. Patients should be positioned supine without leg adduction for a minimum of 6 hours. Fluctuation in blood pressure and heart rate can indicate retroperitoneal bleeding and should be reported to a physician or an interventionist. Patients require activity restrictions, including isometric activity and weight lifting, for 2 to 4 weeks to protect the femoral catheterization site and prevent bleeding or hematoma formation after discharge.

Patients undergoing tPVR may have underlying arrhythmias and preexistent right bundle branch block due to previous ventriculotomy. Patients should be monitored via telemetry for potential arrhythmias. New arrhythmias after tPVR are rare.

Antibiotics are typically given before implantation of a TPV and then for 24 hours after the procedure. Nurses should educate patients on the need for lifelong prophylaxis for subacute bacterial endocarditis as well as signs and symptoms of endocarditis such as fever. Active infection or endocarditis is a contraindication for tPVR.

Patients undergoing tPVR are exposed to large doses of radiation and accordingly should receive education about the risk of radiation exposure. Patients who have received skin doses greater than 2 Gy or a cumulative lifetime dose greater than or equal to 3 Gy are at risk for more adverse effects than are patients with less radiation exposure. After tPVR, patients should be monitored for skin erythema, because this sign can be an early indication of high exposure to radiation. Before discharge, patients should be
instructed to assess for skin reddening and pruritus.24 No clear data are available on management of postprocedure erythema; however, applications of aloe vera and Biafine topical emulsion are often used, although no randomized controlled trials have been done to verify the efficacy of these materials.24

Conclusion

The tPVR procedure is an emerging method for treating patients with RVOT dysfunction after surgical repair. The procedure is safe and feasible. This technique can potentially decrease the number of surgeries a patient will require in a lifetime. Uses for the technology involved in tPVR are expanding to include transcatheter intervention of mitral and tricuspid valves. As experience with the Melody and Sapien valves increases, so will development of improved implantation techniques to reduce patient morbidity after these procedures and increase the length of time before repeat surgical or catheter-based interventions are needed. CCN

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None reported.

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