Acquired pulmonic valve disease is extremely rare. It has been associated with intravenous drug use, causing infective endocarditis, carcinoid rheumatic disease, external compression by a tumor, or sinus of Valsalva aneurysm. The majority of pulmonic valvular dysfunction is associated with congenital heart disease. Pulmonic stenosis or regurgitation (native valve or conduit) is a primary component of many congenital lesions and can also manifest after some repair strategies. Given the improvements in surgical and medical care, many of these congenital patients are now reaching adulthood. Therefore, a percutaneous approach to replacement (implantation) of the dysfunctional valve is an attractive alternative to repeated surgical procedures.

SURGICAL CORRECTION

Congenital defects involving the right ventricular outflow tract may require surgical interventions as early as the neonatal period. Surgical implantation of a pulmonic valve can improve symptoms, restore right ventricular function, and decrease the incidence of arrhythmias. Surgeons use one of three valves to implant in the pulmonic position: a homograft from a cadaver, a cloth tube with a valve sewn inside, or the more recent Contegra graft (bovine jugular vein with a valve inside) (Medtronic, Inc., Minneapolis, MN). On rare occasions, some surgeons implant a prosthetic valve in that position; however, it is not recommended to do so. The primary mode of failure of all these artificial valves/conduits is stenosis or regurgitation.

However, on occasion, it can be a combined pathology of stenosis and regurgitation. Patients may require three to five operations over a lifetime, because the mean time for a repeat operation is 10.3 years for xenografts and 16 years for homografts. However, significant perioperative mortality exists due to advanced right ventricular dysfunction in these patients. Controversy also exists regarding optimal timing for pulmonary valve replacement. Delaying repeat surgeries due to their associated morbidity and mortality must be weighed against the increased risks associated with deteriorating right ventricular dysfunction. Thus, a nonsurgical, percutaneous approach is appealing.

The first experimental percutaneous pulmonary valve implantation was performed by Bonhoeffer in 1999. He used the bovine jugular vein with a valve inside, and he sutured it inside a CP stent (NuMed, Inc., Hopkinton, NY). The valve was mounted over a BiB balloon catheter (NuMed, Inc.) and delivered to the target area using a 22-F delivery sheath. The first human implantation was performed by Bonhoeffer in 2000. Since then, this valve was acquired by Medtronic.

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and renamed the Melody valve. More than 900 patients worldwide have received this valve, and a feasibility trial to assess safety, procedural success, and short-term effectiveness was just concluded in the United States. The second valve that is being used in the pulmonic position is the Edwards Sapien THV.

PULMONIC REGURGITATION

Regurgitation of the pulmonic valve was previously considered benign.10 In recent years, however, detrimental effects have been described, including irreversible right ventricular remodeling, decreased exercise capacity, arrhythmias, and sudden cardiac death. Therefore, an aggressive approach to pulmonary regurgitation is warranted. Moreover, an earlier approach would, in theory, lessen the secondary lesions associated with chronic pulmonary regurgitation, such as worsened tricuspid regurgitation and right atrial enlargement, which may predispose the patient to supraventricular tachycardias.

Additionally, the Edwards Sapien THV is being evaluated in the COMPASSION trial for its safety and efficacy in the pulmonic position in three cardiac centers in the United States. The Edwards pulmonic valve made its clinical debut in 2005 in a 16-year-old boy with congenital aortic stenosis, who had undergone a Ross procedure with subsequent homograft stenosis.11 This valve has been in development for 8 years and is the same valve used by Alain Cribier, MD, in the first human case of percutaneous transcatheter implantation of an aortic valve prosthesis.12 The current leaflet material is bovine pericardium, and the three valve leaflets are hand-sewn to a stainless steel, tubular, slotted, balloon-expandable stent. The valve is available in two sizes: 23 and 26 mm. The delivery sheath required is 22 to 24 F. At the time of implantation, the stent valve is mounted and crimped onto conventional balloon dilation catheters using a crimper. The Edwards Sapien THV is also simultaneously undergoing evaluation for both transapical and transfemoral aortic valve replacement in critical aortic stenosis in the PARTNER trial.

One advantage of the Edwards Sapien THV over the Melody valve is the ability to deliver this valve in large homografts up to 26 mm.
Our group is currently involved in the COMPASSION trial, and our initial results are promising, with no patient having more than trivial to mild regurgitation after implantation. There has been no mortality in our cohort of patients (unpublished data). The current inclusion/exclusion criteria include the patient’s weight (> 35 kg) with a dysfunctional homograft (regurgitation and/or stenosis). The size of the homograft must be at least 20 mm and no larger than 27 mm. However, if the homograft is larger but with significant stenosis and it can be stented, the valve can be implanted. Other inclusion/exclusion criteria pertain to venous access (patent femoral vessels), no history of endocarditis within 6 months of the procedure, and no prosthetic valve in the left side of the heart.

At the time of evaluation, the patient undergoes extensive testing, including a physical examination and electrocardiography, chest x-ray, and magnetic resonance imaging to assess the right ventricle function, volume, and pulmonary regurgitant fraction, as well as a computed tomography angiogram to assess the location of the coronary arteries and their proximity from the right ventricular outflow tract. There have been cases of coronary compression during stent implantation in homografts in the pulmonary position.13-15

The procedure is performed under general anesthesia with or without echocardiographic monitoring. We prefer to perform intracardiac echocardiographic monitoring. Both femoral veins are accessed percutaneously, and the left femoral artery is cannulated to perform coronary angiography. Routine right and left heart catheterization is performed to assess the gradient across the homograft, and then angiography is performed in the conduit to assess the degree of regurgitation and/or narrowing. In almost all cases, the homograft is stented to get rid of any narrowing and also to use the stent as a landing zone for the valve. The valve’s height is 14 to 16 mm. Stenting the homograft with a longer stent facilitates valve positioning and may decrease the chance of future strut fracture of the stent valve. After implantation, repeat transvalvular pressure measurement and angiography allows for the assessment of residual regurgitation. At the end of the procedure, hemostasis is achieved. In our last eight cases, we used a preclosure vascular device (Perclose Proglide, Abbott Vascular, Santa Clara, CA) for the large sheath in the vein and direct pressure for the smaller sheath in the vein and artery. Patients are maintained on 81 mg aspirin daily for 6 months, and they are discharged home the next day.

Figure 1 demonstrates the angiographic steps of valve implantation in a patient with a homograft dysfunction.

**CONCLUSION**

A percutaneous approach to the pulmonic valve is a viable alternative to surgical repair. In the United States, ongoing trials to determine the safety, feasibility, clinical outcomes, and long-term efficacy are currently underway. Furthermore, there may be significant financial savings using this approach with the presumed decrease in perioperative morbidity and interim clinical deterioration if repeat procedures are required.

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