Congenital cardiac defects involving the right ventricular outflow tract (RVOT) require initial surgical interventions as early as the neonatal period. These defects may include severe pulmonic valve stenosis, pulmonary atresia with or without ventricular septal defect, tetralogy of Fallot, transposition of the great arteries, and truncus arteriosus. In addition, congenital aortic valve defects can be corrected by placing the patient’s own pulmonary valve into the aortic position and using a homograft or bovine jugular vein in the pulmonic position (Ross procedure).

The initial surgical repair for these complex conditions, or repeated surgery for free pulmonary regurgitation, often includes the creation of an artificial right ventricle (RV)-to-main pulmonary artery (PA) connection (RV-PA conduit). Over time, these conduits are prone to develop valve dysfunction, leading to pulmonic regurgitation, stenosis, thrombosis, infections, and calcification. Such complications are not uncommon. There is clear evidence that pulmonary stenosis and regurgitation are associated with exercise intolerance, arrhythmias, heart failure, and an increased risk of sudden death.

Therefore, treatment of the obstruction with balloon dilatation and/or stent placement has been performed. RV-PA conduit stenting has been proven to decrease RV pressures and, potentially, prolong conduit lifespan. Nevertheless, this treatment option comes at the expense of free pulmonary regurgitation. Significant pulmonic regurgitation may result in the same cycle of progressive RV dilatation, RV dysfunction, atrial and ventricular arrhythmias, and sudden cardiac death. Although the appropriate timing for pulmonary valve replacement is an area of controversy, it can halt (and may reverse) such unfavorable outcomes and lead to improved symptoms, restore RV function, and decrease the incidence of arrhythmias.

However, this means that patients must undergo multiple open heart surgeries to reduce the hemodynamic burden on the RV. Patients may require three to five operations over a lifetime because the mean time to reoperation is approximately 10.3 years for xenografts and 16 years for homografts. Nevertheless, significant perioperative mortality exists as a result of advanced RV dysfunction in these patients. Reoperations are usually complex with mortality increasing with each reoperation.

Delaying repeat surgeries because of their associated morbidity and mortality must be weighed against the increased risks associated with deteriorating RV function. The need for repeat surgeries in this patient population, coupled with the surgical risks of mortality and morbidity, makes a percutaneous procedure to replace an obstructed and/or regurgitant pulmonic valve an attractive alternative. In 2000, Bonhoeffer et al reported the first experimental and clinical human appli-
cation of a percutaneous valve in the pulmonic position in a 12-year-old patient with a previously implanted conduit for pulmonary atresia. The conduit had developed severe stenosis and regurgitation. After the percutaneous pulmonic valve was placed, the patient had partial relief of the stenosis without evidence of pulmonic regurgitation.

Also, in 2005, in a compassionate use case, a percutaneous pulmonic valve (Sapien, Edwards Lifesciences, Irvine, CA) was placed in a 16-year-old boy with congenital severe aortic stenosis who had undergone a Ross procedure. After surgery, echocardiography demonstrated RVOT obstruction involving the pulmonic homograft, with a peak pressure gradient of 50 mm Hg. Due to the increased surgical risk in that patient to undergo a repeat operation, a percutaneous pulmonic valve implantation was performed. The homograft was initially stented to relieve the obstruction, and the Sapien valve was deployed inside the stent. Immediate and 1-month follow-up echocardiography revealed good valve function with no regurgitation. The patient did well clinically, with an improvement in symptoms. The patient had very good valve function 5 years after valve implantation.

Well over 1,500 patients have now received percutaneously placed pulmonic valves. This article describes the recent advances in our knowledge of percutaneous pulmonic valve implantation.

INDICATIONS

Percutaneous pulmonary valve implantation (PPVI) is a new treatment option in patients with dysfunctional conduits. Currently, the aim of PPVI is to prolong the lifespan of RV-PA conduits, thereby postponing open heart surgery, while at the same time improving the patients’ clinical conditions and preventing complications that may result from conduit dysfunctions. There are clinical and morphological (anatomical) criteria that are applied to judge patient suitability for PPVI. The clinical indications for PPVI as adapted from the conventional criteria for surgical reintervention and the common indications for the bare-metal stenting of conduits are as follows:

- PPVI is indicated for severe pulmonary regurgitation and any of the following:
  - Symptoms or decreased exercise tolerance
  - Moderate to severe RV dysfunction
  - Moderate to severe RV enlargement
  - Development of symptomatic or sustained atrial and/or ventricular arrhythmias
  - Moderate to severe tricuspid regurgitation
- PPVI is indicated for residual RVOT obstruction and any of the following:
  - Residual RVOT obstruction with peak instantaneous echocardiography gradient > 50 mm Hg (mean, > 30 mm Hg)
  - Residual RVOT obstruction with RV/aortic pressure ratio > 0.7
  - Residual RVOT obstruction with progressive and/or severe dilatation of the right ventricle with dysfunction
  - Electrocardiographic evidence of QRS prolongation. A value > 180 milliseconds is viewed to be a harbinger of ventricular arrhythmias and sudden death.
- Due to the concern of optimal timing of valve replacement and the impact on the RV size and functional recovery (and to eliminate symptoms and prevent lethal arrhythmias), an additional criterion is added based on cardiac magnetic resonance imaging (MRI) that precisely defines the degree of pulmonary regurgitation, RV function, and RV end-diastolic volume as an indication for PPVI. This includes one of the following: RV end-diastolic volume (> 150 mL/m²), RV ejection fraction < 40%, or pulmonary regurgitant fraction > 40%.

Candidates for PPVI must also fulfill the anatomic requirements necessary for safe anchoring of the percutaneous valve. Therefore, we chose patients with a conduit between the RV and PA because this environment offers the ideal properties for performing PPVI. In contrast, native or patched outflow tracts after surgical repair for tetralogy of Fallot tend to be dilated and dynamic and therefore do not provide a secure implantation site. Finally, the conduit size at the time of implantation plays a major role in device selection. However, on occasion, smaller conduits may dilate with time, and it is possible to implant a larger valve than the one implanted at the time of surgery.

CLINICAL EVALUATION

The aim of clinical evaluation of patients with conduit dysfunction is to determine which patients will need PPVI and to decide if the conduit is anatomically suitable for implantation. The operative report must be studied in detail to have a full understanding of the anatomy of the outflow tract and to avoid device dislodgement. The size of the conduit at the time of surgical implantation must be known. Any comment regarding the proximity of the coronary arteries to the RVOT must be studied carefully.

Initial functional assessment must also be determined. The use of cardiopulmonary exercise testing is encouraged to assess the degree of exercise limitation in an objective fashion. Measurements of oxygen consumption and anaerobic threshold can be performed, and it is encouraged to follow such parameters after valve implantation.
Transthoracic echocardiography is performed to assess RV size, function, and systolic pressure (if possible), as well as RVOT gradient and the degree of pulmonic and tricuspid regurgitation.

MRI and/or computed tomographic (CT) angiography may be used to assess morphologic suitability for PPVI. Assessment of valve function, degree of obstruction and regurgitation, and RVOT diameter are also obtained by MRI/CT. Furthermore, these imaging modalities delineate the relationship of the intended implantation site with the origin of the pulmonary artery branches and coronary arteries.

Catheterization laboratory assessment includes systemic and pulmonary pressure measurements and angiography to assess the degree of pulmonic regurgitation and/or obstruction. The gradient across the conduit is also measured. Aortic root angiography and/or selective left coronary artery angiography is performed simultaneously with balloon inflation at the site of valve implantation. There have been a few cases of coronary artery compression and ischemia during stent/valve implantation at the intended site. Therefore, this step is crucial before stent implantation.

THE DEVICES

Currently, there are two available percutaneous pulmonary valves that can be implanted in dysfunctional conduits: the Melody valve (Medtronic, Inc., Minneapolis, MN) received US Food and Drug Administration approval under humanitarian device exemption status in January 2010, and the Sapien transcatheter heart valve (THV) (Edwards Lifesciences) is still undergoing clinical trials. We will discuss each device regarding their structure, indications, and limitations.

Melody Transcatheter Pulmonary Valve

The Melody transcatheter pulmonary valve is composed of a bovine jugular venous valve and a balloon-expandable stent (Figure 1). The stent (CP stent, NuMed, Inc., Hopkinton, NY) is made of a platinum-iridium wire welded together with gold. The length of the stent is 34 mm and can be cramped down to a diameter of 6 mm. When expanded, the competence of the trileaflet valve is maintained at a large range of diameters (16–22 mm). For implantation, the valved stent is cramped onto a balloon-in-balloon, front-loading delivery system (Ensemble, Medtronic, Inc.). The stent is covered by a retractable sheath during delivery and is uncovered prior to implantation by pullback of the sheath. Although there is only one device size, the delivery system is available with an outer balloon diameter of 18, 20, or 22 mm. The Melody valve can only be expanded to 22 mm in diameter, thus limiting its use to patients with conduits that are 22 mm or smaller. The smallest conduit size that can be treated is 16 mm, as long as the 18-mm valve can be implanted.

Sapien THV

The Sapien THV consists of three bovine pericardial leaflets that are hand-sewn to a tubular, slotted, stainless steel, balloon-expandable stent (Figure 2). A fabric-sealing cuff covering the lower portion of the stent facilitates a seal with the calcified conduit and prevents paravalvular leaks. The leaflet material has been designed and treated to maximize longevity. Specifically, the leaflet geometry is designed to reduce leaflet stress and maximize coaptation, and the pericardial tissue is processed with the same Thermafix anticalcification treatment used in the Carpentier-Edwards Perimount Magna surgical valves (Edwards Lifesciences). Currently, the Sapien valve is available in 23- and 26-mm-diameter sizes, with heights of 14.5 and 16 mm, respectively (Figure 2).

Comparison

The Sapien THV is available in larger sizes than the current Melody system and therefore may be offered to patients with larger conduits. However, the Melody delivery system is less bulky and uses a retractable sheath that protects (covers) the valve until the operator is ready to deploy the valve at the desired position. The Sapien THV delivery system is bulkier, making it potentially more difficult to implant especially in patients with tortuous RVOTs, and it does not use a covering sheath. Once the Sapien THV exits its delivery sheath, it is difficult (if not impossible) to retract the valve inside the delivery sheath. Therefore, careful consideration must be given to the likelihood of procedural success before attempting PPVI using the Sapien THV. Newer generations of the Sapien...
THV delivery system and changes to the stent material (from stainless steel to a cobalt-chromium alloy; Sapien XT, Edwards Lifesciences) will permit the delivery profile and sheath size to be markedly reduced and will expand the valve size range to include 20-, 23-, 26-, and 29-mm-diameter valves.

**CLINICAL EXPERIENCE**

In 2005, Khambadkone et al\(^2\) published their results using the Bonhoeffer bovine jugular valve (which eventually became the Melody valve) in 59 patients undergoing PPVI. Valve implantation was performed successfully in 58 patients. The median patient age was 16 years, and most patients \((n = 36)\) had tetralogy of Fallot. After valve implantation, the patients had a significant decrease in RV systolic pressure, outflow tract gradient, and pulmonic regurgitation. MRI showed a significant decrease in pulmonic regurgitant fraction and RV diastolic volume.

Clinical trial data evaluating the Melody valve were recently published.\(^2\) At five United States centers, 124 patients with dysfunctional conduits underwent valve implantation from January 2007 to August 2009. Immediately after valve implantation, there was a reduction in the RV pressure from 65.3 to 41.5 mm Hg, and the peak gradient across the conduit decreased from 37 to 12 mm Hg. One patient died from intracranial hemorrhage after coronary artery dissection, and one valve was explanted after conduit rupture. At 6-month follow-up, the RV pressure was 55 ± 14.6 mm Hg compared to 73.5 ± 17.9 mm Hg \((P = .001)\) before intervention. Also, the gradient was 20 ± 8.6 mm Hg compared to 33.4 ± 15 mm Hg before intervention \((P = .001)\). Furthermore, the RV end-diastolic volume was 172.7 ± 76.3 mL/m\(^2\) compared to 205.8 ± 90.2 mL/m\(^2\) before intervention \((P = .001)\), as determined by MRI. There was improvement in New York Heart Association class at 6 months, which was maintained at 2 years in most patients.

In 2010, Boone et al\(^2\) published their results using the Sapien THV in 10 patients undergoing PPVI. Valve implantation was performed successfully in seven patients. The patients ranged in age from 16 to 52 years, and most patients underwent the Ross procedure. After valve implantation, the patients had a significant decrease in RV systolic pressure, outflow tract gradient, and pulmonic regurgitation.

Also in 2010, results were presented for the COMPASSION trial, a United States multicenter, prospective, non-randomized feasibility study of the percutaneous placement of the Sapien THV in the pulmonic position.\(^2\) A total of 33 patients (male, 73%; mean age, 30 years; age range, 11.3–72 years) underwent an attempt at valve implantation. Thirty patients successfully received the Sapien valve (93%). There was no procedure-related mortality, and there was significant improvement in symptoms and a marked decrease in RV systolic pressure and pulmonary regurgitation. The survival rate at 30 days and 1 year was 100%; the major adverse cardiac and cerebrovascular events rate was 3.6% both at 30 days and at 1 year.

**STANDARD PROCEDURE TECHNIQUE**

The PPVI procedure may be performed under general anesthesia with or without transesophageal echocardiographic guidance. In selected patients, the use of moderate sedation and intracardiac echocardiographic guidance may be an option. Access is achieved via the right femoral vein. However, the jugular vein may be used if the femoral vessels are occluded. After full hemodynamic assessment, angiography is performed to assess the function of the conduit and to measure the length of the narrow segment. Before valve implantation, most operators deploy a bare-metal stent in the homograft. This stent should be balloon-expandable and have the capacity to be dilated to 22 to 24 mm. The presence of the stent in the homograft acts as a landing zone for the new valve and may decrease the incidence of stent fracture.

After the stent is implanted, repeat hemodynamic assessment and angiography are performed to evaluate the result. It is important to note that any residual gradient > 15 mm Hg should not be accepted prior to valve deployment. Therefore, if the gradient is higher, aggressive dilatation with high-pressure balloons (Mullins, NuMed, Inc.) or the Atlas balloon (Bard Peripheral Vascular, Inc., Tempe, AZ) should be performed to lower this gradient. If the stent is ready and no significant gradient exists, the proper size sheath is
inserted using careful gradual dilation of the femoral vein. The valve is crimped onto a balloon delivery system, and the valve-balloon system is delivered using an antegrade technique under fluoroscopic guidance. It is crucial to use the stiffest exchange-length guidewires available for better tracking of the delivery system through the tortuous pathway from the femoral vein to the target area. We have been using the Meier wire (Boston Scientific Corporation, Natick, MA), and some operators use the Lunderquist wire (Cook Medical, Bloomington, IN).

Immediately after valve implantation, repeat measurements of gradient and angiographic assessment of pulmonic regurgitation and obstruction are obtained. Additional balloon dilatations to relieve any residual gradient may be performed using high-pressure balloons. Echocardiography is done immediately after the procedure to assess valve competence without a wire across. Furthermore, echocardiography with MRI and/or CT angiography are performed at selected intervals to assess valve function and results. Figure 3 illustrates the steps of the PPVI procedure using the Sapien valve, and Figure 4 shows the steps of implantation with the Melody valve.

COMPLICATIONS

Factors that place certain patients at high risk during PPVI can be found in the Contraindications and Exclusions sidebar. Further, complications uniquely associated with the use of percutaneous pulmonic valves include those listed in the following paragraphs.

Device Instability and/or Dislodgement

This complication may be managed with percutaneous device retrieval and redeployment, if possible, or may require urgent surgery. Therefore, such procedures should be performed at centers in which surgical backup is available.24

Coronary Artery Compression Due to Stent Placement

Coronary artery compression can be avoided by performing careful MRI/CT angiography before the procedure to assess the distance between the conduit (and site of stent valve implantation) and the coronary artery ostia. In addition, at the time of the procedure, the operator should perform balloon inflation in the RVOT during aortic root and/or selective coronary angiography.
Pulmonary Artery Obstruction
Right or left pulmonary artery obstruction can be avoided by careful preprocedural MRI/CT assessment and meticulous stent and valve placement using fluoroscopy and angiography at the time of implantation. The stent should be positioned away from the origin of either pulmonary artery branch.

Homograft Rupture
Factors related to rupture include the degree of deterioration of the conduit (eg, severe calcification) and aggressive oversizing of balloon dilatations. The importance of appropriate sizing using multiple imaging modalities (eg, MRI/CT, echocardiography, balloon sizing angiography) cannot be overemphasized. Furthermore, the availability of covered stents for bailout in such circumstances is of crucial importance.

Stent Fracture
To date, there have been no reported stent fractures using the Sapien valve in either the pulmonic or aortic position (with more than 7,500 implants in the aortic position). However, with the Melody valve, there has been up to a 30% stent fracture rate at 6-month follow-up.21 This complication may lead to an increase in RVOT gradient and RV pressure.25 The incidence of this complication was as high as 21% in one series using the Melody valve.26 In this series, repeat interventions were performed after PPVI, predominantly because of stent fractures. Nordmeyer et al25 have devised risk stratification, systemic classification, and an anticipatory management strategy to effectively manage stent fracture after PPVI. Stent fracture has decreased dramatically after implantation of a bare-metal stent in the conduit before deployment of the Melody valve.

Because of the acute and potentially catastrophic risks...
of using emerging technologies, such as PPVI, a multidisciplinary approach involving close collaboration between cardiologists and surgeons is vital. A skilled and responsive surgical backup team is mandatory when proceeding with valve implantation. Our institution uses a hybrid suite as an additional means of expedited surgical transition. A hybrid suite permits a quick transition to a surgical procedure without the need for patient transport if emergent rescue surgery is required. At the end of the procedure, the femoral vein can be repaired surgically, if needed.

In our center, we have been using two techniques to quickly achieve hemostasis. The first approach involves preclosure of the vessel with a vascular closure device. We deploy (“preclose”) two Perclose systems (Abbott Vascular, Santa Clara, CA), one positioned at the 10 o’clock position and the other at the 2 o’clock position. At the end of the procedure, both sutures are applied, and in all of our cases, very good results were achieved. For the second approach, we have applied the figure-of-eight suture, and this also works well.

**SPECIAL POINTS**

**Learning Curve Effect**

As with any new procedure, there is a steep learning curve that affects clinical outcomes. Lurz et al\(^{26}\) observed 155 patients with stenosis and/or regurgitation and resultant RV failure who underwent PPVI between September 2000 and February 2007. Overall, there was a significant reduction in RVOT gradient and RV systolic pressure. Freedom from repeat transcatheter intervention was 95% at 10 months and 70% at 70 months; survival at 83 months was 96.9%. When the investigators separated the patients into two cohorts—the first 50 patients versus the remaining 105—they found a significant increase in reoperations in the first 50 patients than in the subsequent patient group: 16 of 50 patients in the first group underwent device explantation compared to five of 105 patients in the second group (\(P < .001\)).

Additionally, the incidence of procedural complications was 6% (three of 50 patients) in the first cohort and 2.9% (three of 105 patients) in the second cohort.

The authors noted two factors contributing to these improved results in the second group. First, the incidence of residual gradients was reduced, partly because of increased confidence over time in postdilating implanted valves. Second, patient selection improved based on a better understanding of the implantation site (careful assessment of conduit type, RVOT morphology, and distensibility). In fact, device dislodgement at the time of valve implantation occurred only among the first 50 patients (seen in two patients). In addition to the learning curve effect, the impact of revised stent-valve design cannot be underestimated. An adverse outcome noted in the series by Lurz et al\(^{26}\) was caused by the hammock effect—poor stent-valve apposition in the midportion of the valve (in seven patients) —leading to in-stent stenosis. This defect has been corrected in the current generation of this device, and no hammock effect events occurred after redesigning the device.

**Delayed Improvement in Valve Hemodynamic Performance**

In 2008, Ródes-Caubau et al\(^{27}\) reported the case of a 21-year-old woman who underwent PPVI (with the Melody valve) for treatment of a severely stenotic pulmonary homograft. Although no significant change in transvalvular gradient was appreciated immediately after the procedure, there was major improvement in hemodynamic valve performance at 3-month follow-up (>60% decrease in transvalvular gradient and >30% increase in pulmonary valve area). Possible reasons for delayed hemodynamic improvement are the presence of perivalvular edema/hematoma and inflammation after valve implantation, which regressed over time, and long-term exposure to pulsatile transvalvular flow and intraluminal radial forces, optimizing three-dimensional configuration of the valve and improvement of valve-opening kinetics. The authors recommend repeat echocardiographic examination at 3 months before concluding that a procedure is a failure and warrants reintervention.

**Durability and Structural Integrity**

The issue of prosthesis durability must also be considered in a discussion about PPVI. We have limited data on the durability of the Sapien THV prosthesis in the pulmonary position, but in our few patients who have been followed for 3.5 years, the gradient across the valve itself remains low with no evidence of pulmonary insufficiency.

**CONTRAINDICATIONS AND EXCLUSIONS**

Contraindications and exclusions to PPVI include:

- Patients with a history of endocarditis or other active infection within 6 months of the procedure should not undergo valve implantation.
- RVOT size precluding appropriate stent valve delivery (depending on the delivery system used).
- Venous occlusion prohibiting percutaneous access via the femoral or jugular approach.
- Vessel size and characteristics that would preclude safe placement of a 22- to 24-F introducer sheath. However, hopefully with further miniaturization of technology and perhaps a periventricular approach, smaller children may be eligible for this technology.

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The valve gradient has increased slightly over the course of follow-up, but the increase remains clinically insignificant. Furthermore, this increase is similar to the one reported by Lurz et al in their longer-term follow-up series (peak velocity increased from 2.64 ± 0.6 m/s at 1 month after implantation to 2.89 ± 0.74 m/s at 2 years). The durability of the Melody valve is unclear but appears to be reasonable in the medium term based on data from 155 patients who were followed for an average of 28.4 months. In these patients, the survival rate was 96.9% at 83 months, and freedom from reoperation was 73% at 70 months.

The issue of structural integrity must be considered. There have been more than 7,500 Sapien THV implants placed worldwide in the aortic position without reports of structural valve failure. However, the rate of fracture when the Sapien valve is implanted in the pulmonary position remains to be seen. Percutaneous valves that are placed in the pulmonary position may be more susceptible to fracture (due to extrinsic forces and other factors) than percutaneous valves that are placed in the aortic position. When using the Melody valve, stent fracture has been the leading cause for reoperation.

**ALTERNATIVE APPROACHES: PERVERVENTRICULAR SURGICAL TECHNIQUES**

In addition to the traditional surgical approach and the aforementioned percutaneous transfemoral approach, alternate techniques for pulmonic valve placement are possible. One option is a perventricular approach, with entry via the right ventricle. The main advantage of this technique over a traditional surgical approach is the ability to avoid a full cardiopulmonary bypass. This is an important consideration in patients who have complex congenital anatomy, multiple previous surgeries, or multiple comorbidities but whose anatomy is not suitable for a percutaneous transfemoral/transjugular approach.

In 2008, Al Qethamy et al reported the placement of a bovine tissue valve using a perventricular approach in a 3-year-old boy with a previous tetralogy of Fallot repair who was considered high risk for prolonged cardiopulmonary bypass. After median sternotomy, an 18-mm Contegra 200 pulmonary valve (Medtronic, Inc.) was transfixed inside an 18-mm X 2.8-cm CP stent. The stent-valve device was introduced via a small purse-string suture that was placed at the lower end of the RVOT patch, and the stent-valve composite was expanded to 22 mm in the pulmonic valve position. The patient tolerated the procedure well, and postoperative echocardiography showed normal RV function with no paravalvular leakage or pulmonic regurgitation.

In 2007, Schreiber et al reported the use of the No-React treated porcine pericardium valve (Shelhigh Inc., Union, NJ) in six patients with previous tetralogy of Fallot correction. All patients (ages, 9–27 years) had severe pulmonic regurgitation without significant RVOT obstruction. After median sternotomy, the porcine valve, mounted inside a self-expandable stent, was introduced just below the RVOT without the use of cardiopulmonary bypass. External sutures were used at the proximal and distal valve sites to ensure fixation of the valve. The implantations were uneventful. One patient exhibited paravalvular leakage requiring replacement with a homograft after 2 days. At 6- and 12-month follow-up, the remaining patients showed no more than mild pulmonary regurgitation. The mean RV end-diastolic volume indexed decreased from 143 ± 23 to 94 ± 18 mL/m², as determined by MRI. The mean MRI RV ejection fraction increased from 46% ± 9% to 58% ± 27%. In addition to avoiding cardiopulmonary bypass, this valve allows implantation of prostheses with diameters > 22 mm.

In 2010, Cubeddu and Hijazi reported a case of a patient who underwent attempted placement of a Sapien THV in the pulmonic position. Due to severe scoliosis, the valve migrated proximally upon inflation of the balloon. The operators managed to retrieve the valve via a venovenous loop and positioned it in the right atrium. During surgery, the migrated valve was removed under inflow occlusion without cardiopulmonary bypass, and at the same time, a perventricular approach was used to implant a 26-mm Sapien THV in the intended position and had a very good result.

PPVI can spare the need for additional or repeat high-risk surgical procedures. Select studies have documented patients with nine to 10 repeat surgeries due to disease recurrence. In addition to the costs and risks of each surgical intervention, clinical deterioration between procedures may lead to worsening clinical status. Although surgical valve implantation reduces RV diastolic and systolic volumes in patients who are treated late, studies have shown a lack of improvement in RV ejection fraction and exercise capacity in patients undergoing late surgery. The use of a percutaneously placed pulmonic valve may lead to earlier intervention in these patients, before irreversible RV dysfunction develops.

**FUTURE DEVELOPMENTS**

Experimental work is underway to address percutaneous valve replacement in larger RVOTs. One advance has been the development of a self-expandable stent that allows downsizing of the diameter of the RVOT to the biologically available valve size. However, the main limitation is the frequently tortuous pulmonary anatomy that may affect correct stent deployment. A second alternative that has been proposed is a hybrid approach involving cooperation between surgeons and interventionists. By means of a left thoracotomy, the RVOT is banded using...
two radiopaque rings, and subsequently, the valved stent is implanted percutaneously or by a percutaneous approach. This method avoids cardiopulmonary bypass while ensuring a stable valve position. An alternative strategy that we have also contemplated is the implantation of an expandable conduit at the time of initial repair, which could be dilated as the child grows, with subsequent treatment using a percutaneous valve when dysfunction develops. These strategies remain experimental, having only been performed in animal models, in which the anatomy of the native RVOT is more favorable than in patients who have undergone previous surgery.

SUMMARY
PPVI has been shown to have a significant impact on RVOT physiology in patients with regurgitation and/or obstruction after repair of congenital heart defects. Improvements have been noted in symptoms, exercise capacity, RV volumes, and RV systolic and diastolic function. Further patient enrollment and clinical follow-up are ongoing to assess clinical improvement, freedom from adverse cardiac events, and the longevity of percutaneously implanted pulmonic valves.

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