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THE PRESENT AND FUTURE

REVIEW TOPIC OF THE WEEK

Percutaneous Pulmonary Valve Implantation

Present Status and Evolving Future

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ABSTRACT

Due to recurrent right ventricular outflow tract (RVOT) dysfunction, patients with complex congenital heart disease of the RVOT traditionally require multiple surgical interventions during their lifetimes. Percutaneous pulmonary valve implantation (PPVI) has been developed as a nonsurgical alternative for the treatment of right ventricular to pulmonary artery stenosis or pulmonary regurgitation. PPVI has been shown to be a safe and effective procedure in patients with dysfunctional surgical RVOT conduits. In this population, PPVI has the potential to improve symptoms, functional capacity, and biventricular hemodynamics. However, limitations to the anatomical substrate and size of the RVOT currently restrict PPVI eligibility to less than one-quarter of patients with RVOT dysfunction. The current review discusses contemporary practices in PPVI, evidence supporting the procedure, and future technologies and developments in the field. (J Am Coll Cardiol 2015;66:2246–55) © 2015 by the American College of Cardiology Foundation.

The incidence of congenital heart disease (CHD) varies between 5 and 8 per 1,000 live births (1,2). In adulthood, the estimated prevalence is 1 in 150 people (3). Approximately 20% of newborns with CHD have anomalies in the pulmonary valve (PV) or right ventricular outflow tract (RVOT), such as tetralogy of Fallot, truncus arteriosus, or pulmonary atresia (4). For these patients, surgical repair of the RVOT within the first months of life is a lifesaving procedure (5). Surgical strategies for RVOT reconstruction include patch augmentation, bioprosthetic valves, and valved conduits (3,6). Long-term durability of surgical interventions for complex CHD of the RVOT is highly variable, depending on patient age and the type of tissue or material utilized (6,7). Ultimately, however, these patients are subject to progressive RVOT dysfunction due to several mechanisms, including pulmonary regurgitation (PR), somatic outgrowth, anastomotic stenosis of the conduit, valvular stenosis, conduit kinking, sternal compression, intimal proliferation, conduit calcification, and aneurysmal degeneration (6,8). Therefore, repeat surgical interventions are typically required over a lifetime. Although these procedures have a low mortality rate, they can be associated with significant morbidity, particularly with repeated operations

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(9,10). In this clinical context, percutaneous pulmonary valve implantation (PPVI) has been developed as a nonsurgical, less invasive alternative for the treatment of RVOT dysfunction. This paper will review the procedure, devices, indications, outcomes, complications, and future developments in PPVI.

DEVICES AND TECHNIQUE

Bonhoeffer et al. (11) first performed transcatheter PV implantation in 2000. Improvements to the device initially used by Bonhoeffer led to the development of the Melody transcatheter PV (Medtronic Inc., Minneapolis, Minnesota) (4,12), which consists of a bare-metal platinum-iridium stent (CP stent, NuMED, Inc., Hopkinton, New York) and a manually-sewn valved segment of bovine jugular vein (**Figure 1**). Currently, the Melody valve is available in diameters of 16 and 18 mm, which can be expanded to 18 or 20 mm, and 18, 20, or 22 mm, respectively. The device is crimped over a balloon-in-balloon catheter and delivered through a long 22-F sheathed balloon catheter (Ensemble Delivery System, Medtronic Inc.). The balloon-in-balloon technique allows for stepwise deployment, as the valve can still be repositioned after the inner balloon is inflated. The delivery system also includes a sleeve over the sheath to provide hemostasis at the insertion site (4,13).

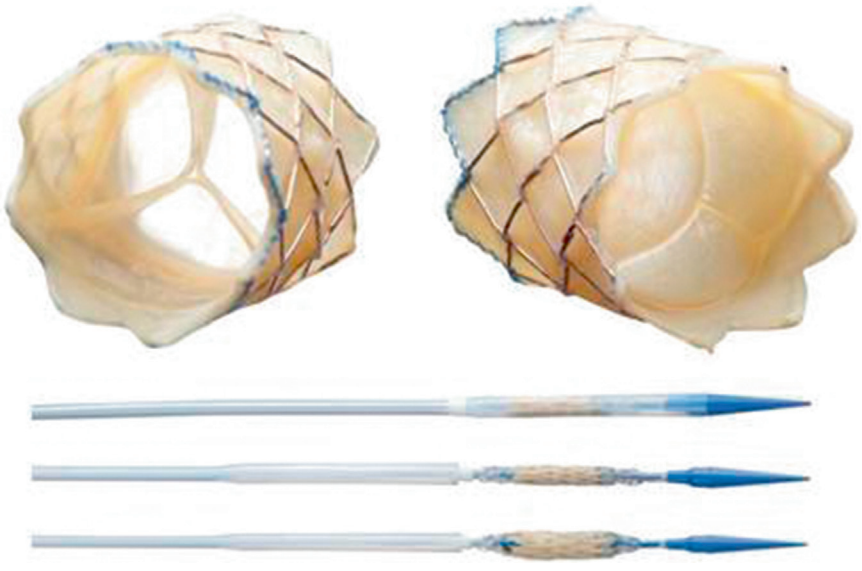
The Edwards Sapien Pulmonic transcatheter heart valve (Edwards Lifesciences, Irvine, California) is a trileaflet bovine pericardial tissue valve hand-sutured in a balloon-expandable, radiopaque, stainless-steel stent (**Figure 2**). It is available in 23 or 26 mm diameters that require 22- or 24-F delivery sheaths, respectively. This device contains a unique proximal sealing cuff designed to prevent paravalvular leaks. The valve is implanted using the Retroflex-3 delivery system (Edwards Lifesciences), which consists of a guiding catheter and a single-balloon catheter. A specialized tool is used to manually crimp the valve over the valvuloplasty balloon (13–15).

Careful pre-procedural assessment is vital for successful PPVI and requires collaboration from multimodality imaging specialists. Echocardiography is used for assessment of right ventricular (RV) and left ventricular (LV) systolic and diastolic function as well as chamber diameters. Conduit gradients and Doppler recordings are essential to estimate the severity of RVOT obstruction and/or PR (12,16,17). Cardiac

ABBREVIATIONS AND ACRONYMS

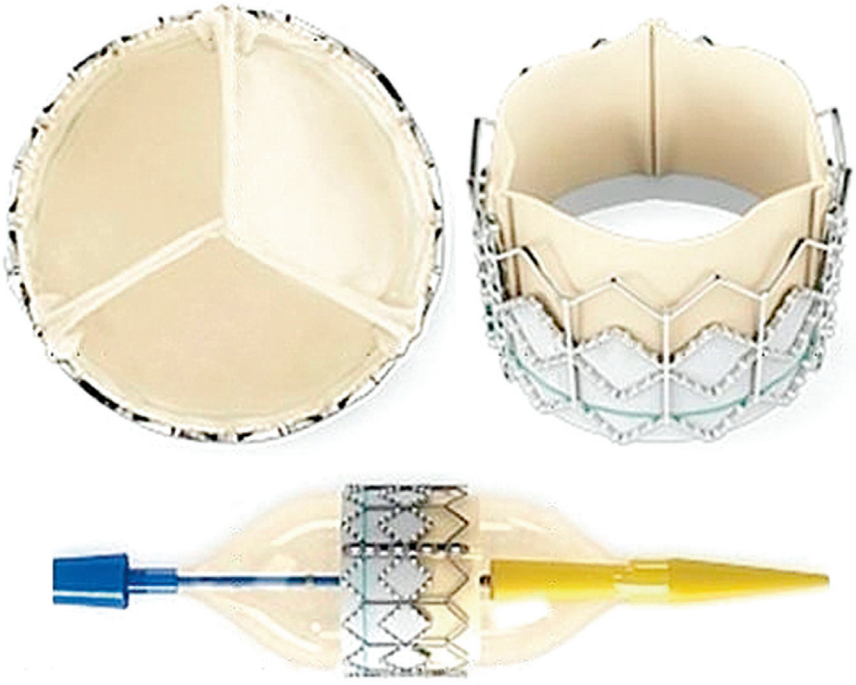
CHD = congenital heart disease
LV = left ventricle/ventricular
PA = pulmonary artery
PPVI = percutaneous pulmonary valve implantation
PR = pulmonary regurgitation
PV = pulmonary valve
RV = right ventricle/ventricular
RVOT = right ventricular outflow tract
SF = stent fracture

FIGURE 1 Melody Transcatheter Pulmonary Valve and Delivery System



Melody transcatheter pulmonary valve **(top)**: the valved segment of bovine jugular vein is hand-sewn to each node of the gold-brazed platinum-iridium stent. Ensemble transcatheter valve delivery system **(bottom)**: the **upper image** illustrates the sheath covering the valve, followed by withdrawal of the sheath and exposure of the valve; in the **bottom image**, the inner balloon is inflated prior to inflation of the outer balloon.

FIGURE 2 Edwards Sapien Pulmonic Valve and Delivery System



(Top) Edwards Sapien pulmonic valve: trileaflet bovine pericardium valve hand-sutured in a stainless-steel stent. **(Bottom)** Balloon dilation of the Sapien pulmonic valve mounted on the Retroflex delivery system.

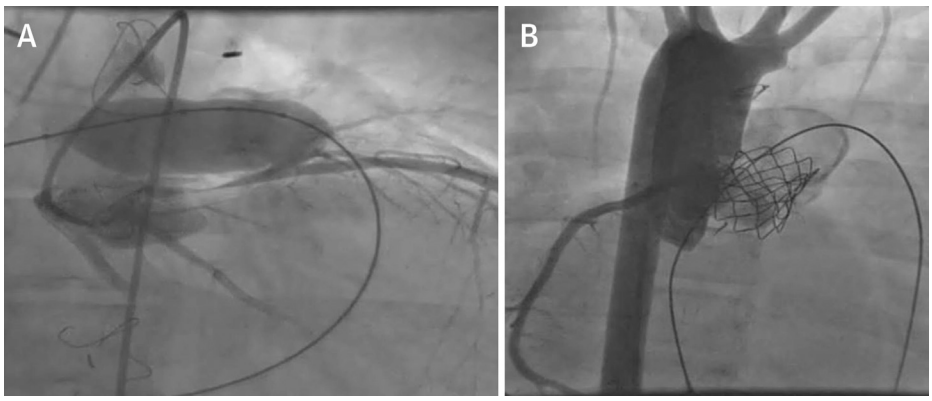
magnetic resonance imaging is indicated for evaluation of RV volume, RVOT morphology, and suitability for PPVI (12,17,18). PPVI is typically performed under general anesthesia through the femoral, jugular, or subclavian veins (16,17,19).

Due to variability in coronary anatomy among patients with complex CHD, approximately 5% of PPVI candidates are at risk for coronary compression after valve deployment and RVOT expansion (20). To avoid this potentially fatal complication (16,21), aortic or coronary angiography is routinely performed with simultaneous high-pressure balloon inflation in the valvular landing zone (17,20). PPVI is contraindicated if coronary flow is impaired by this maneuver (16) (**Figure 3**). In addition to evaluating the risk to the coronaries, balloon pre-dilation of the RVOT is often necessary to facilitate passage of the delivery system in calcified or highly stenotic surgical anatomies (22). Post-deployment balloon dilation, however, can theoretically lead to PR or cause damage to the valvular struts. Nevertheless, these findings have not been confirmed in clinical studies (22,23), and thus, post-dilation may be used to further expand the valve and improve hemodynamics in the presence of a significant residual RVOT gradient (24).

EFFICACY OUTCOMES

Overall, trials and registries of PPVI have included patients with surgical RVOT conduits who develop PR and/or RVOT stenosis. Regurgitation criteria in previous studies were moderate or severe PR associated with significant symptoms, RV dysfunction, and/or RV dilation (12,16,17); stenosis requirements included either gradient (typically >35 to 40 mm Hg) or RV to aortic pressure ratio (>0.67) (12,16,17,23). In dysfunctional surgical RVOT conduits, PPVI has been shown to normalize the RVOT gradient and resolve PR immediately after implantation (**Table 1**). In these patients, PPVI is also associated with significant improvements in functional capacity (14,19) and RV systolic function (18,23). The treatment of PR improves right-sided volume overload, resulting in a reduction of RV volumes, also known as reverse remodeling (14,16). Importantly, right-sided reverse remodeling has been associated with enhanced LV filling and higher LV end-diastolic volumes (18). Moreover, left-sided systolic function is also improved by PPVI, as observed by an elevation in LV stroke volume and aortic pressures following the procedure (18,19). Hemodynamic benefits of PPVI

FIGURE 3 Coronary Compression in Percutaneous Pulmonary Valve Implantation



(A) Coronary angiography reveals compression of the left anterior descending artery with balloon inflation in the valvular landing zone. **(B)** Aortic angiography demonstrates compression of the left main coronary artery by a deployed percutaneous pulmonary valve.

persist in intermediate and long-term follow-up (17-19,25,26).

Direct comparisons between surgical intervention and PPVI have not been performed. PPVI has been accepted as a therapeutic alternative to RVOT conduit dysfunction under the premise that it is a safe and effective procedure (**Central Illustration**), with the potential to avoid or delay open-heart surgery and its associated morbidity. Therefore, it is particularly important to consider reintervention rates of PPVI, as transcatheter procedures are not without risk. Overall, freedom from reintervention after PPVI has been reported above 90%, 80%, and 70% in follow-up periods of approximately 1, 2, and 4 years, respectively (17,19,22,25). Recently published data from the U.S. Investigational Device Exemption trial reported 5-year freedom from reintervention and explant of 76% ± 4% and 92% ± 3%, respectively (26). Factors associated with reinterventions include a high post-PPVI residual RVOT gradient (17,26) and stent compression or recoil after valve deployment (22). Pre-stenting of the RVOT (22,26) and increasing operator experience (17) have been associated with longer freedom from reintervention. Given the lack of sufficient long-term data, it is not currently known whether all patients with PPVI will ultimately require repeat procedures, as occurs in surgical conduits (**Table 1**).

COMPLICATIONS

Fracture of the percutaneous valve stent frame has been reported in up to 30% of PPVI cases (27,28). Stent fractures (SFs) are categorized according to the classification by Nordmeyer et al. (27) as follows (**Figure 4**): type I, no loss of stent integrity; type II, loss of stent integrity; and type III, separation or embolization of the fractured segment. Although a common complication, the majority of SFs are nonclinically relevant type I fractures, which are usually diagnosed by routine radiography or fluoroscopy (22,28). Nevertheless, RVOT obstruction secondary to SF remains the most common cause for reintervention after PPVI (17,19). Type I fractures are typically managed conservatively and followed regularly, as they can progress to more advanced fractures (22). Type II and III fractures can be successfully treated with valve-in-valve procedures, although type III SFs may require surgical management in the case of distal strut embolization (16,17,29).

Risk factors associated with percutaneous PV SF include: younger age; higher pre- and post-procedural RVOT gradient; smaller angiographic conduit diameter; stent recoil or compression after deployment; and valve position directly under the sternum (22,27,30). Deployment of 1 or more balloon-expandable stents in the RVOT prior to PPVI, a technique known as pre-stenting, has been shown to decrease the incidence of SF (22) and prolong freedom from fracture-related reinterventions (28). Although pre-stenting increases fluoroscopy time (28), the additional bare-metal stent also serves as a landmark and landing zone for valve placement (15,28,31). PPVI is usually performed in the same procedure, but can be done in a staged intervention 2 to 3 months after pre-stenting to allow for stent endothelial ingrowth (31).

The risk of infective endocarditis following PPVI has been estimated at 2.4% per patient-year (32). More than one-half of cases do not directly involve the implanted PV, and most respond to antibiotics without

TABLE 1 Summary of Clinical Studies in Percutaneous Pulmonary Valve Implantation

First Author, Year (Ref. #)	Country	Time Period	N	Age (yrs)	Weight (kg)	Follow-Up (Months)	Valve	Procedure Success*	Reinterventions†	PR‡	SF (SF-r)†	RVOT Tear or Rupture†	Improved Findings in Addition to RVOT Stenosis and PR
Armstrong et al., 2014 (36)	United States	July 2010 to July 2012	101	19.9	59.4	12	Melody	98%	2 surgical 0 transcatheter	0	7 (1)	6	NYHA functional class, tricuspid regurgitation
Butera et al., 2013 (23)	Italy	October 2007 to October 2010	63	24	60	30	Melody	93.6%	3 surgical 2 transcatheter	1	10 (2)	1	RV/Ao, RVEDV, RVEF, RVESV, RVSP
Cheatham et al., 2015 (26)	United States	January 2007 to January 2010	150	19	NA	54	Melody	NA	8 surgical 28 transcatheter	1	50 (25)	1	Exercise capacity, NYHA functional class
Eicken et al., 2011 (16)	Germany	December 2006 to July 2010	102	21.5	63	11.7	Melody	NA	2 surgical 9 transcatheter	NA	5 (3)	0	RV/Ao, RVEDV
Haas et al., 2013 (15)	Germany	NA	22	21.7	56.5	5.7	SAPIEN	95.5%	1 transcatheter	0	NA	NA	NYHA functional class, PA pressures, RVSP
Kenny et al., 2011 (14)	United States, United Kingdom	April 2008 to May 2010	36	30.3	73.4	6	SAPIEN	97.1%	3 surgical 1 transcatheter	1	0	NA	NYHA functional class, PA pressures, RV/Ao, RVEDV, RVSP
Khambadkone et al., 2005 (18)	France, United Kingdom	January 2000 to September 2004	59	16	56	9.8	Melody	98.3%	8 surgical 5 transcatheter	1	7 (2)	2	Exercise capacity, LVEDV, LVSV, NYHA functional class, RVEDV
Lurz et al., 2008 (17)	France, United Kingdom	September 2000 to February 2007	155	21.2	NA	28.4	Melody	NA	23 surgical 22 transcatheter	2	32 (9)	4	PA pressures, RVSP
McElhinney et al., 2010 (19)	United States	January 2007 to August 2009	136	19	NA	NA	Melody	99.1%	1 surgical 10 transcatheter	0	25 (9)	2	Ao pressure, NYHA functional class, RV/Ao, RVEDV, RV mass

*Defined by Armstrong et al. (36) as the percentage of subjects with a transcatheter pulmonary valve placed in the desired location, with no more than mild PR, an RV-PA peak-to-peak gradient <35 mm Hg by angiography, and freedom from explantation at 24 h post-implantation. †Absolute number of patients with complications during follow-up. ‡Absolute number of patients with moderate or severe pulmonary regurgitation on latest follow-up.

Ao = aortic; LVEDV = left ventricular end-diastolic volume; LVSV = left ventricular stroke volume; NA = not available; NYHA = New York Heart Association; PA = pulmonary artery; PR = pulmonary regurgitation; RV = right ventricle; RV/Ao = right ventricular to aortic pressure ratio; RVEDV = right ventricular end-diastolic volume; RVEF = right ventricular ejection fraction; RVESV = right ventricular end-systolic volume; RVOT = right ventricular outflow tract; RVSP = right ventricular systolic pressure; SF = absolute number of stent fractures; SF-r = stent fractures requiring reintervention

the need for reintervention (32). However, infective endocarditis can also lead to valve explantation (16,17), need for a second PPVI (32), or even sepsis-related mortality (32). A high residual RVOT gradient, the resulting turbulence, and in situ thrombosis have been implicated in the pathophysiology of post-PPVI endocarditis (33). Noncompliance with recommended antibiotic prophylaxis is also commonly reported in transcatheter PV endocarditis (18,23). Mortality associated with PPVI is rare and is most often related to comorbidities, rather than the procedure itself (17,23).

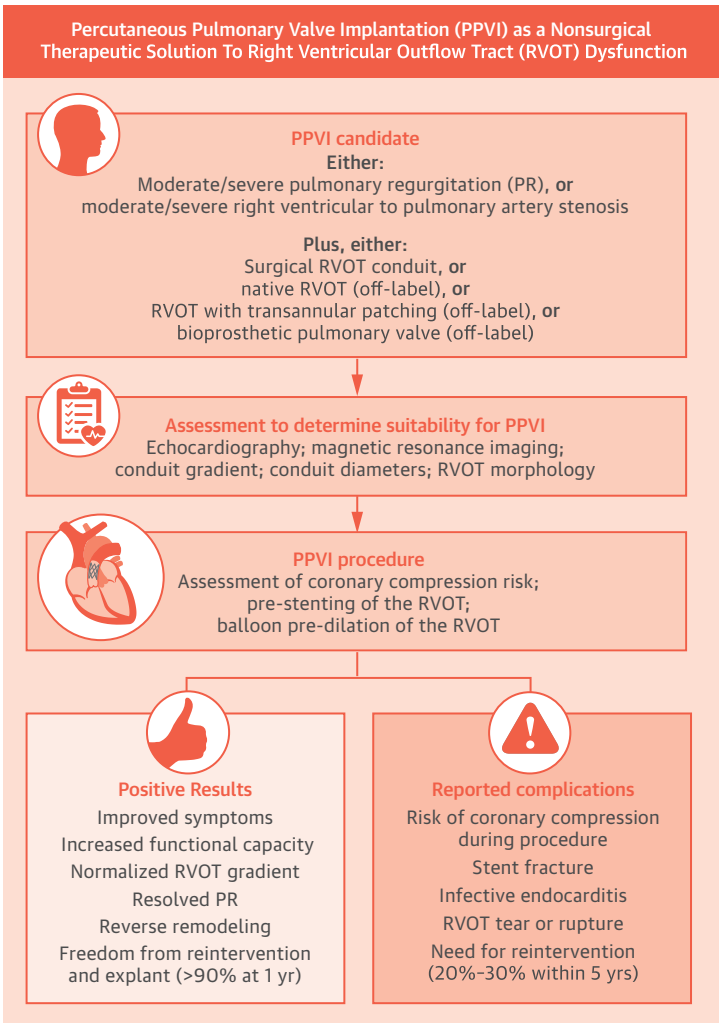
Pre- and post-deployment balloon dilations have the potential to cause a tear or rupture in the RVOT. Risk factors include heavy RVOT calcification and a homograft substrate (34). Although the incidence of such complications has been reported to be as high as 9% (34), most cases are not associated with hemodynamic compromise and can be successfully managed with a covered stent (35). In the Melody valve post-approval study, 6 of 101 patients experienced a confined conduit tear, all of which resolved with covered stent placement (36). Rarely, surgical conduit replacement may be required after a rupture (22). Other complications that can potentially demand urgent surgical conversion are rare, and include valve migration or embolization (14,23), pulmonary artery (PA) occlusion or rupture (28), and coronary artery compression (37).

CURRENT GUIDELINES, INDICATIONS, AND CONTRAINDICATIONS

On the basis of much of the aforementioned evidence, the 2010 guidelines from the European Society of Cardiology and Association for European Pediatric Cardiology recommend PPVI with the same indications as surgical PV replacement (38). In symptomatic patients, these guidelines endorse intervention when the RV systolic pressure is above 60 mm Hg (tricuspid regurgitation velocity >3.5 m/s) and/or when there is moderate or severe PR. PPVI is also indicated in asymptomatic patients with severe RVOT stenosis and/or severe PR in the presence of decreased exercise capacity, progressive RV dilation, progressive RV systolic dysfunction, progressive tricuspid regurgitation, RV systolic pressure >80 mm Hg, or sustained ventricular or atrial arrhythmias (38).

A 2011 scientific statement from the American Heart Association, American Academy of Pediatrics, and Society of Cardiovascular Angiography and Interventions assigned a Class IIa recommendation (Level of Evidence: B) for PPVI in patients with a RV-to-PA conduit in the presence of moderate to severe pulmonary regurgitation or stenosis, provided that

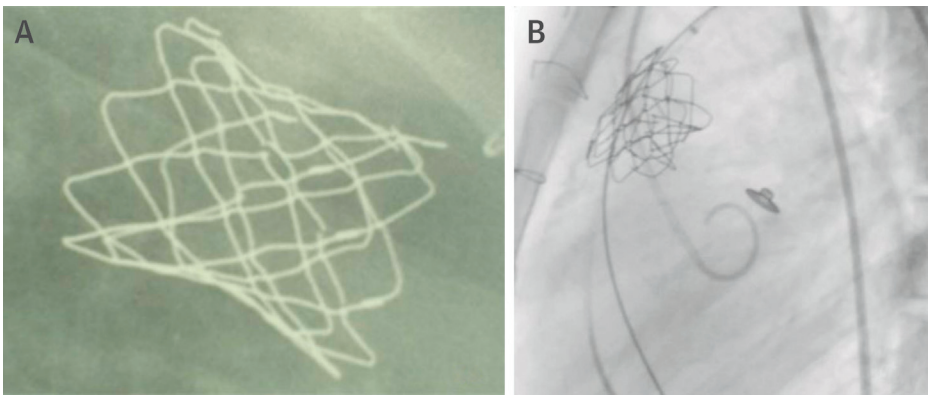
CENTRAL ILLUSTRATION PPVI: Overview of Contemporary Practices and the Evolving Future



Ansari, M.M. et al. J Am Coll Cardiol. 2015; 66(20):2246–55.

Candidates for PPVI include patients with moderate to severe PR or right ventricle-to-pulmonary artery stenosis with a previous surgical RVOT conduit. Future techniques and devices have the potential to expand routine PPVI eligibility to patients with native RVOTs, as well as those with RVOT diameters that are either smaller or larger than currently available devices. Pre-procedural assessment includes detailed imaging of the RVOT to determine gradients, diameters, and morphology. Prior to valvular deployment, the risk of coronary compression is evaluated with aortic/coronary angiography and simultaneous high-pressure balloon inflation in the RVOT. Although fracture of the valvular stent frame can lead to recurrent obstruction, approximately three-quarters of patients have freedom from reintervention at 5 years. PPVI improves clinical symptoms and hemodynamic parameters associated with RVOT dysfunction, with the potential benefit to avoid or delay open heart surgery and its associated morbidity. PR = pulmonary regurgitation; PPVI = percutaneous pulmonary valve implantation; RVOT = right ventricular outflow tract.

FIGURE 4 SF Complications in Percutaneous Pulmonary Valve Implantation



(A) Chest radiography demonstrates percutaneous pulmonary valve stent fractures (SFs) without compromising stent integrity (type I SF). **(B)** Chest radiography illustrates a type II SF, characterized by architectural distortion and loss of stent integrity, without separation of the fractured segment.

clinicians adhere to the inclusion/exclusion criteria for each available valve (39). PPVI is currently not recommended in native or patch-augmented RVOTs and in conduits <16 mm in diameter. Absolute contraindications include active infection, occluded central veins, and coronary compression observed with RVOT balloon dilation (38,39).

FUTURE DEVELOPMENTS

OFF-LABEL USE. Currently, indications for PPVI are limited to dysfunctional surgical RVOT conduits (including left heart disease with prior Ross procedure), with dilated diameters between 18 to 22 mm and 23 to 26 mm for the Melody and Sapien valves, respectively (13,14,40). However, it is estimated that <20% of patients with CHD and RVOT dysfunction meet these restricted criteria (31,41). The majority of patients with the potential to benefit from PPVI have an off-label indication for the procedure, including native or large patch-augmented RVOTs, bioprosthetic valves, or small-diameter conduits (<16 mm) (**Central Illustration**).

Boshoff et al. (31) reported 23 off-label cases of PPVI, including 8 patients with conduit-free patch-augmented RVOTs, 2 native PV stenosis, and 13 undersized conduits. The peak RVOT gradient was significantly decreased, and no more than mild PR was observed in a mean follow-up of 1.2 years. Repeat interventions due to restenosis were required in 2 patients. There were no vascular complications, SF, or valve migration during follow-up. Meadows et al. (42) found resolution of the peak RV-to-PA gradient following successful PPVI in 31 patients with native or nonconduit dysfunctional RVOTs. Similarly encouraging results have been observed in transcatheter valve-in-valve implantation within failed bioprosthetic valves. Gillespie et al. (43) reported 104 cases of PPVI in bioprosthetic valves. At 1-year median follow-up, restenosis was observed in 4 patients, whereas none had more than mild PR. Two SFs were identified during follow-up, neither of which required RVOT reintervention. Overall, freedom from reintervention was >90% at 2 years, and there was no procedure-related mortality.

The use of approved devices for off-label indications has been associated with an increased incidence of complications, as compared with standard indications (44). Furthermore, there are liability and ethical concerns with off-label device use (31). However, there are instances where devices and procedures are clinically indicated on the basis of the published medical data and/or standards of practice in the medical community, but remain off-label according to regulatory agencies (31,44). In such cases, patients can be deprived of effective treatment strategies if device use is strictly restricted to standard "on-label" indications. Developments in PPVI technology and larger clinical studies in patients with native, undersized, or nonconduit RVOTs will likely expand the "on-label" indications for PPVI in the near future. Meanwhile, physicians considering an off-label procedure must evaluate clinical appropriateness on a case-by-case basis. This decision requires a careful assessment of patient preferences, guided by an informed decision-making process,

as well as a review of safety and efficacy outcomes data published in similar patients.

TECHNIQUES AND DEVICES

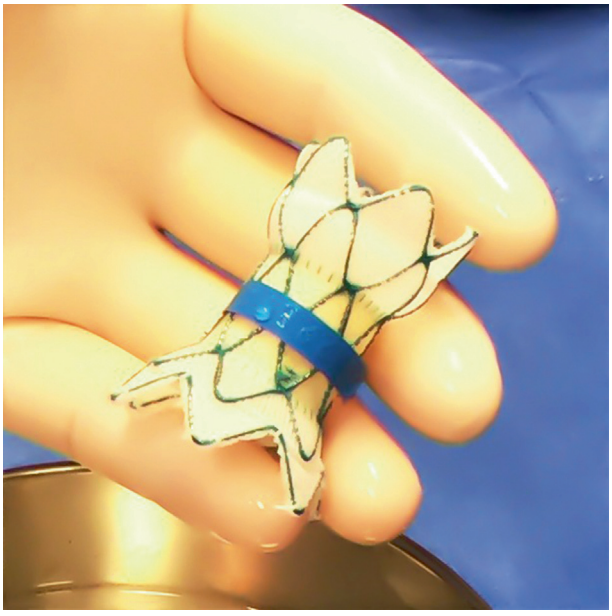
A number of innovative strategies have been studied in an effort to expand the population eligible for PPVI, particularly in patients with large RVOT diameters. If effective in oversized RVOTs, these new techniques and devices have the potential to expand PPVI indications to more than 50% of dysfunctional RVOTs (41). In 2010, Schievano et al. (45) reported the successful deployment of a transcatheter self-expanding PV. This device, later called the Native Outflow Tract device (Medtronic, Inc.), has completed enrollment in an ongoing Investigational Device Exemption trial. It has an hourglass contour (**Figure 5**), with larger diameters at the proximal and distal ends and a smaller diameter in the center, where a porcine pericardial valve sits. The self-expanding nature of the nitinol stent has the potential, in theory, to improve valvular stability in heterogeneous RVOT morphologies (46).

The Venus P Valve (Venus Medtech, Shanghai, China) is another novel self-expanding percutaneous pulmonary device. It is composed of a trileaflet porcine pericardial valve mounted on a covered nitinol stent frame. It is manually crimped onto a delivery system that ranges from 14- to 22-F, depending on valvular size, which varies from 20 to 32 mm. Small case series have demonstrated short-term safety and efficacy of PPVI with the Venus P Valve (47,48). Given the applicability of this device in large patch-augmented RVOTs, it may play an important role in the future of PPVI if favorable results are confirmed in clinical trials. Similarly, the Sapien XT (Edwards Lifesciences) 29-mm valve may also become an alternative for large-diameter RVOTs, although this valve has not yet been sufficiently studied in the pulmonary position. Percutaneous devices for RVOT size reduction have been successfully implanted in sheep with enlarged RVOTs (49,50), but remain to be tested in humans. Other advanced techniques have been successfully performed in sporadic cases of patients with highly-complex RVOT anatomy, including Melody valve implantation in bilateral PA (51), and a PA "jailing" technique, in which overlapping uncovered bare-metal stents were deployed from a PA branch down to the RVOT as an anchor for PPVI (52).

The patient population suitable for PPVI is also somewhat limited by the large-profile sheaths required for the procedure (22- to 24-F). Berman et al. (35) reported good procedural hemodynamic outcomes in 25 patients <30 kg (median age 8 years; median weight 21.4 kg) who underwent PPVI. Inability to advance the delivery sheath prevented valve implantation in 1 patient. In addition, another patient developed an abdominal hematoma secondary to trauma from crossing the delivery system through the femoral-caval junction. Low-profile devices are currently being developed, and will likely make the procedure safer in younger pediatric patients.

In conformity with a heart team approach for structural heart disease interventions (53), hybrid procedures with mutual collaboration from cardiac surgery and interventional cardiology will likely shape the future of PPVI. A hybrid approach allows for minimally invasive surgical techniques (54,55) and permits structural heart disease interventionalists to collaborate in planning the most favorable surgical RVOT substrate, in anticipation of potential future transcatheter procedures.

FIGURE 5 The Native Outflow Tract Transcatheter Pulmonary Valve



This valve (Medtronic Inc., Minneapolis, Minnesota) has an hourglass contour, with larger diameters in the proximal and distal ends. This self-expandable, porcine pericardial valve has the potential to expand percutaneous pulmonary valve implantation to patients with large-diameter outflow tracts.

TIMING OF INTERVENTION

Prior to the development of PPVI, patient and/or physician concerns for repeated surgical procedures had the potential to delay interventions for RVOT dysfunction, often compromising ventricular recovery

and placing patients at an increased risk for sudden cardiac death (4,56,57). Borik et al. (58) recently demonstrated that younger patients with RVOT dysfunction derive the most benefit from PPVI. The authors found an incremental improvement in LV ejection fraction, oxygen consumption, and RV end-diastolic volume with younger age, concluding that early PPVI is associated with better hemodynamic results. Strategies for safer and more durable transcatheter PVs will likely shift medical decisions toward earlier percutaneous valve implantation in the future (34,59).

CONCLUSIONS

PPVI has been consolidated as a safe and effective nonsurgical therapeutic alternative for RVOT dysfunction. In patients with stenotic or regurgitant surgical RVOT conduits, PPVI has a high procedural success rate, with immediate and durable resolution of RV-to-PA gradient as well as a very low incidence of post-procedure PR (**Central Illustration**). Less than 25% of patients who undergo PPVI will require repeat interventions in a 5-year period, most commonly secondary to a fracture in the percutaneous valve stent frame. Future developments in the field aim to reduce the incidence of complications, improve freedom from reintervention rates, and, most importantly, expand the population eligible for this elegant procedure. Clinical studies in off-label populations, innovative devices, and new techniques will likely expand the indications to native RVOTs, small-diameter conduits, and oversized patched RVOTs.

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