

Review Article

Percutaneous balloon valvuloplasty of pulmonary valve stenosis: state of the art and future prospects

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ABSTRACT

This study is aimed to delineate readers with an overview of percutaneous balloon pulmonary valvuloplasty (PBPV) of pulmonary valve stenosis (PVS) and highlighting outcome based on influential and recent studies. It has been four decades since Kan et al first introduce PBPV. Since then, PBPV has recognized as a gold standard therapy for PVS of all ages. Nowadays, PBPV is practiced for a broad range of indication such as PVS, PV dysplasia and pulmonary atresia. Typically, PBPV is recommended when gradient across the PV is >50 mmHg. The procedure involves the placement of one or more balloon catheters across the stenotic PV with the guidance of a guidewire; thereafter, inflation of the balloons is done by pressure, thus producing valvotomy. Nowadays, PBPV is done by echocardiographic guidance, but previously, it was done by fluoroscopic guidance. The main disadvantage of fluoroscopy was the radiation injury of patients. The recently recommended balloon/annulus ratio is 1.2 to 1.25. Following the procedure, the dramatic reduction of pressure gradient, free motion of the PV leaflets with less doming, the rise of cardiac output have been noted, whereas complications may occur but are unusual and minimal. Significant predictors of restenosis include balloon/annulus ratio <1.2 and immediate post-PBPV gradient ≥ 30 mmHg. Only a few percentages of patients needed repeat PBPV. Long-term follow-up results are surprisingly excellent. In conclusion, it is our opinion that PBPV is equally successful in patients of all ages, while worldwide recognized studies prove the safety, feasibility, and effectiveness. However, for early detection of any complication, life-long clinical follow-up is mandatory.

Keywords: Balloon pulmonary valvuloplasty, Congenital heart disease, Pulmonary insufficiency, Pulmonary stenosis

INTRODUCTION

Congenital heart disease (CHD) makes up nearly one-third of all significant congenital anomalies.¹ The birth prevalence of CHD is 9.410 per 1000 live births, which has been increasing since 1970.² The prevalence of congenital pulmonary stenosis (PS) is 8-10% (about 1 per 2000 live births worldwide) of all CHD.^{3,4} However, this

prevalence slightly higher in Asian countries compared to Europe and the United States.^{1,3} PS can be present isolated or associated with other CHD, such as ventricular septal defect, patent foramen ovale, atrial septal defect, and persistent ductus arteriosus. PS could be three types (a) valvular stenosis (most common), (b) supra-valvular and (c) sub-valvular (Table 1). Notwithstanding, there are three nonidentical morphologic types of valvular PS (Table 2).

Table 1: Types of PS with etiology.

Types	Level of obstruction	Etiology
Congenital	Supra-valvular	Hourglass deformity at the valve
		Pulmonary artery membrane
		Pulmonary artery stenosis
		Peripheral pulmonary artery stenosis
		Congenital rubella, Alagille, Williams, Noonan, and Keutel syndromes
	Valvular	Dome-shaped valve
		Dysplastic valve (Noonan syndrome)
		Unicuspid or bicuspid valve
	Sub-valvular/infundibular	Double-chambered right ventricle
		Secondary muscular hypertrophy in PS
		Tetralogy of Fallot, HOCM (Noonan syndrome)
		Tricuspid valve tissue
		Fibrous tag from IVC/SVC
Acquired/postoperative	Valvular	Aneurysm of Sinus of Valsalva
		Aneurysm of membranous septum
	Conduit stenosis	Native valve restenosis
		Prosthetic valve restenosis
		Peripheral arterial stenosis after systemic-pulmonary shunt procedure

HOCM: Hypertrophic obstructive cardiomyopathy, IVC: Inferior vena cava, SVC: Superior vena cava, PS: Pulmonary stenosis.

Table 2: Morphologic types of valvular PS.

Types	Description
Classic or typical “dome-shaped” pulmonary valve	characterized by a narrowed central orifice but a preserved mobile valve mechanism. The orifice usually central in location but occasionally eccentric; the orifice diameter can range from a pinhole to several millimeters. Calcification, although rare in early life, can occur in adults with typical PS. ^{4,5}
Dysplastic pulmonary valve	occurs in approximately 20% of cases, usually in Noonan syndrome. The leaflets are poorly mobile, and there is marked myxomatous thickening of the leaflets, with no commissural fusion.
Unicuspid or bicuspid pulmonary valve	is usually associated with Tetralogy of Fallot, and may or may not causing stenosis or regurgitation.

Transcatheter based cardiac surgical techniques are rapidly emerging and vibrant areas in today's medicine. Although surgical intervention has proven to be the ultimate curative method, recent studies indicate that transcatheter based techniques may provide a suitable and effective alternative to open-heart operations. In 1948, Sellors first performed a successfully closed trans ventricular instrumental pulmonary valvotomy.⁶ Then Swan and colleagues did surgical correction of PVS with intact ventricular septum by an open technique with circulatory arrest and hypothermia in about 1953.⁷ The transcatheter intervention has its origin back in 1956, introduced by Rubio and Limon.⁸ In 1979, Semb et al employed a balloon-tipped angiographic (Berman) catheter to produce a rupture of pulmonary valve commissures by rapidly withdrawing the inflated balloon across the PV.⁹ In 1982 by Kan et al, percutaneous balloon pulmonary valvuloplasty (PBPV) was performed on an 8-year-old child under fluoroscopic guidance to abate PVS by the radial forces of balloon inflation while balloon catheter positioned across the pulmonic valve.¹⁰

Kan et al applied Gruntzig et al technique for performing PBPV.¹¹ Since then, it has been practiced as the first-line treatment option for PVS worldwide because of its safety and effectiveness. But there was a possibility of radiation injury due to use of fluoroscopy. In 2016, Wang et al introduced first-in-human PBPV under echocardiographic guidance only.¹² Now a days, PBPV under echocardiographic guidance is gaining popularity because of no chance of radiation injury.

TECHNIQUES

Clinical indications

Surgical pulmonary valvotomy indicated when peak-to-peak gradient (PPG) ≥ 50 mmHg with standard cardiac index and indications for PBPV are comparable with that.⁴ However, PVS has been described as trivial (<25 mmHg), mild (25-39 mmHg), moderate (40-70 mmHg), and severe (>70 mmHg) based on the PPG across the PV with standard cardiac index.¹³ Therefore, Few

cardiologists suggest PBPV indicated when PPG moderate (≥ 40 mmHg) or right ventricular pressure of ≥ 50 mmHg. After meticulous evaluation of all the recognized studies, it is suggested that (I) there is only marginal reduction of right ventricular pressure if mild stenoses are dilated, (II) natural history evaluation revealed trivial and mild stenoses (PPG < 50 mmHg) are likely to remain mild at follow-up, and (III) increase in PPG can easily be identified by echocardiography during follow-up examination.^{4,12} Thereafter, The patient could undergo PBPV. Moderate-to-severe PVS is generally progressive, and if left untreated, will lead to symptoms of dyspnea, fatigue, and exercise intolerance. Commissural fusion is the most significant factor for effective post-PBPV clinical outcomes. For attaining optimum result, balloons that are 1.4-1.5 times the PV annulus should probably be applied in patients with dysplastic PV.¹⁴ In our opinion, performing PBPV in all patients including adults with moderate to severe PVS irrespective of the symptoms is judicious.¹⁵ Notwithstanding, PBPV is not indicated when systemic infection, overlying skin infection of the catheter insertion site, severe hemodynamic instability, and PV hypoplasia present.

Generally, neonates with critical PVS or PV atresia with intact ventricular septum present within the first week of life with cyanosis, duct-dependent pulmonary circulation, tricuspid regurgitation, and right-to-left shunting. Biventricular palliation is the current strategy for them. However, it is contraindicated when right ventricular dependent coronary arterial circulation and a severely hypoplastic right ventricle or tricuspid valve present.¹⁶ In our opinion, this strategy needs to evolve further.

Diagnosis and pre-operative preparation

Comprehensive studies such as clinical examination, chest radiography, electrocardiography, and TTE are performed for the diagnosis of PVS. When moderate to severe (PPG ≥ 50 mmHg) PVS is identified, cardiac catheterization and cine angiography are performed percutaneously to finalize the diagnosis.^{15,17} All patients have undergone routine pre-operative preparation, which includes routine blood investigations, blood coagulation profile, hepatic and renal function, and arterial blood gas analysis.¹⁷ It is prudent that every pros and cons of PBPV procedure explains to the patients or guardians, along with the fatal complications. Such written informed consent is painstaking when particular circumstances (acute fatal complications) occurs.

Anesthesia and endovascular access

Regarding anesthesia, institutional practices should be respected. Generally, PBPV is performed with local anesthetic [2% Lidocaine (3-4.5 mg/kg)] or sedative cocktail [midazolam (0.05-0.1 mg/kg IV) and/ or Fentanyl (0.5-1.0 mg/kg IV)] or by ketamine, given

intramuscularly or orally according to the patient's age.⁴ General anesthesia (propofol) with endotracheal ventilation is used in young age patients. Most cardiologists prefer a femoral venous route. Notwithstanding, other routes such as jugular, axillary, transhepatic, and transumbilical also used successfully when femoral venous access not possible or in infants.¹⁸⁻²¹

Per-operative evaluation and monitoring

Per-operative oxygen saturation, blood pressure, heart rate, respiration, and electrocardiograph should be monitored. It is judicious to set an arterial line (no. 3 French in infants, no. 4 French in children, and no. 5 French in adolescents and adults) into the femoral artery to monitor the arterial blood pressure (continuously) and arterial blood gas analysis (intermittently). For evaluating the severity of the PVS, the pressure gradient across the PV is measured when the cardiac index is within the normal range. PV area is not usually used as an indicator of the severity of PVS. However, Cobra catheter or Right coronary catheter or Glidecath catheter or Berman angiographic catheter or Multipurpose catheter is alternatively used for pass-through the PV. It is prudent to measure right ventricular and femoral artery pressures because when right ventricular peak systolic pressure 75% of systemic peak systolic pressure, then it is reckoned that there is significant PVS.⁴ Previously, a cine angiogram under fluoroscopy was performed for evaluation PVS just before balloon dilatation. Nowadays, PBPV is performing under echocardiographic guidance.¹² Therefore, now per-operative echocardiography is used for evaluation of PVS just before balloon dilatation.

PBPV procedure

The entire procedure is performed cardiac operation room while the patient is placed in the supine position. A cardio-pulmonary bypass team should remain on-call/standby. Firstly, after heparinization (100 units/kg), a femoral sheath is inserted into the femoral vein by puncturing the femoral vein. This sheath can be up-sized if it does not accommodate the selected balloon. The distance from the right parasternal third intercostal space to the puncture site was measured; this distance is called "working distance" for catheter insertion. Then, a catheter (no. 4-6 French) is introduced into the femoral vein (Figure 1A) via the sheath to the right atrium, with the length not exceeding the working distance. Now, the catheter tip is rotated toward the tricuspid valve to guide the guidewire for entering into the right ventricle (Figure 1B). Then, again the catheter tip is rotated toward the PV and advanced across the PV along with the guidewire. However, the tip of the catheter should be kept in the pulmonary artery for facilitating the insertion of the balloon catheter across the PV.

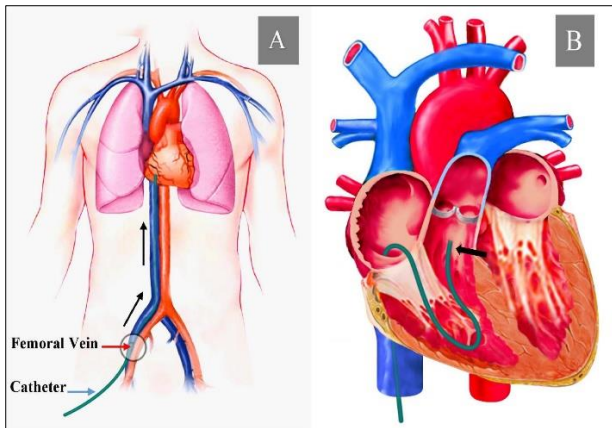


Figure 1: (A) Catheter (blue arrow) insertion into the femoral vein (red arrow) and black arrow showing direction of catheter, (B) Catheter tip is toward the pulmonary valve (black arrow).

The type of catheter may vary according to PV anatomy. After that, the guidewire is withdrawn, and a soft J-tipped (0.014-0.035-inch diameter), exchange-length, and extra stiff guidewire is inserted through the already placed catheter. Now, the catheter is withdrawn. The selection of the guidewire diameter is dependent on the selected balloon dilatation catheter. In complicated cases, a super-stiff (“Amplatz” Boston Scientific), short, soft-tipped guidewire can be used. Now, the selected balloon catheter (BALT, Inc., Montmorency, France) is advanced along the guidewire and positioned across the PV (Figure 2A) and is inflated with 6-8 atmospheres pressure or manufacture recommended pressure using operator’s hand or any of the commercially available inflators for no more than 8 seconds until disappearance of the balloon waist (Figure 2B). Repeated balloon inflation (3-5 times) can be needed for obtaining optimum dilatation of PV and a significant reduction of the pressure gradient across PV until ≤ 30 mmHg. During balloon dilatation, systemic systolic pressure is maintained within 60 mmHg. If the balloon waist is not positioned correctly across the PV, the position of the balloon is repositioned, and the balloon dilatation procedure repeated. Sequential balloon dilation can be needed in neonates or severe PVS by a different size balloon catheter.²¹ On achievement of acceptable pulmonary transvalvular pressure gradient, the balloon catheter, guidewire, and sheath are withdrawn. Nowadays, all this procedure is done by echocardiographic guidance, but previously, this was done by fluoroscopic guidance.¹²

OTHER INTRAPROCEDURAL DETAILS

The activated clotting times (ACT) are measured intermittently (20-25 minutes) and maintained between 200 and 250 seconds for the long-time consuming complicated cases. In our opinion, it is judicious to administer prophylactic antibiotics for the prevention of bacterial endocarditis.

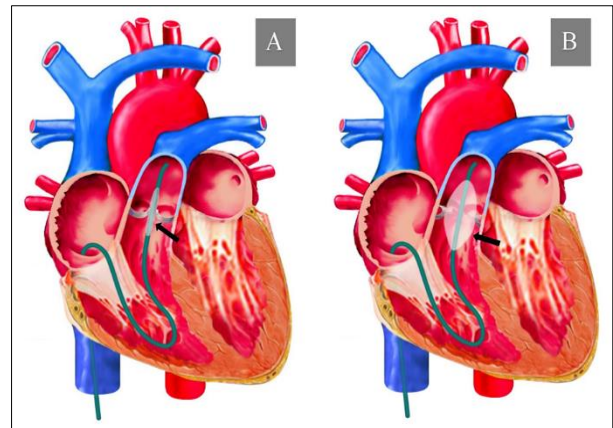


Figure 2: (A) The balloon catheter is positioned across the pulmonary valve (black arrow), (B) The balloon catheter is inflated (black arrow) with pressure, thus producing valvotomy.

SELECTION OF BALLOON ANGIOPLASTY CATHETER

Types of catheters

Balloon catheter has been modified and updated in size and shape since its evolution. In the past, several balloon catheters were used for PBPV. Later, more sophisticatedly designed balloon catheter such as Nucleus-X (B.Braun), Tyshak I, II, Z-Med I, II and Mullins catheters (NuMed); Diamond, Ultrathin (Boston Scientific); Marshal (Meditech); Maxi LD, OptaLP, OptaPro, and PowerFlex (Cordis Endovascular), and others were used. Nowadays, BALT (France) and Tyshak II (NuMed) balloon catheters mostly used due to their low profile, allowing balloons passage through small diameter sheaths and effortless tracking over the guidewire.

Balloon diameter

In the past, the balloon diameter recommendation was 1.2-1.4 times of PV annulus on the basis of immediate and follow-up clinical outcome.²² However, PBPV with a bigger diameter (1.5 times of PV annulus) can damage the PV annulus.²³ Notwithstanding, bigger balloons can be used in dysplastic PV cases.¹⁴ Later, some authors report pulmonary insufficiency at late follow-up who underwent PBPV with bigger balloons.^{17,24,25} After meticulous evaluation, it is now recommended that smaller balloon/annulus ratio (1.2:1.25) provide excellent long-term clinical outcomes.^{17,26}

Balloon length

It is judicious to use 20, 30, and 40 mm long balloon catheters for neonates and infants, children and adolescents, and adults, respectively.⁴ It is hazardous to maintain the balloon waist across the PV if smaller is used. However, longer balloons may impinge on the

tricuspid valve and can cause tricuspid insufficiency or on the conduction system and can cause heart block.^{27,28}

Number of balloons

Some authors suggest to use double balloon by calculating effective balloon size when PV annulus bigger.²⁹ However, the clinical outcome of double balloon dilatation is comparable with single balloon dilatation.³⁰ Triple balloon valvuloplasty is also reported by some authors, but the effectiveness is not proven yet.³¹

Structural variation of balloons

Unifoil single balloon blocks PV annulus completely during inflation; usually, it augments systemic hypoperfusion. For this, some authors suggest to use Bifoil or Trefoil balloons.^{32,33} But, in reality, there is no gap between the balloon and the PV annulus because a bigger size balloon is used for PBPV. Besides, some authors reported PBPV by using the Inoue balloon.³⁴ However, the effectiveness of using Bifoil or Trefoil or Inoue balloon is not well documented. Therefore, it is prudent to use a single balloon with short inflation period (5-6 seconds) but repeated (3-5 times) inflation. Very recently, in 2018, Kilic, Teoman, et al, successfully performed PBPV using an hourglass-shaped V8 balloon catheter (new type).³⁵

Post-operative evaluation

Following balloon dilation, the pressure gradient across the PV, right ventricular pressures, the degree pulmonary and tricuspid insufficiency are assessed. However, repeat dilatation with a 2 mm bigger balloon than the previous balloon is warranted when PPG > 30 mmHg. After that, all the patient remains under close monitoring. An electrocardiogram and an echocardiogram are usually done in the very next morning. Thereafter, at 1, 3, 6, 12 months, the post-operative clinical follow-up is recommended.

COMPLICATIONS

Immediate

PBPV is a significantly safe procedure. Post-operative immediate complications are remarkably minimal. The VACA registry revealed only 0.24% death rate and 0.35% major complication rate from the 822-PBPV cases of 26 institutions.³⁶ This study is sufficient enough to prove the safety profile of PBPV. However, with the advent of modern medicine, the complications rate of PBPV is lower than before. Notwithstanding, some early postoperative complications are tabulated below (Table 3).

However, few of these complications can be inevitable; meticulous pre-operative preparation and per-operative scrupulous concentration to the procedure may preclude

or downgrade the complications. Nonetheless, post-procedure monitoring is mandatory.

At follow-up

After careful evaluation of recognized studies, it is observed that usually, the patients present with femoral venous occlusion, restenosis of the PV, and pulmonary insufficiency at the follow-up period. Generally, neonates and infants are present with femoral venous obstruction, and it accounts for 7 to 19%.³⁸ Restenosis of PV may occur in about 8-10% of patients.³⁹ whereas, long-term follow-up data demonstrates that the frequency and severity of pulmonary insufficiency rise with time up to 41-88%.^{17,24,25}

RESULTS

Immediate

Following the procedure, the dramatic fall of PPG across the PV and right ventricular peak systolic pressure along with a slight increase in pulmonary artery pressure occurs while the cardiac output remains unchanged or it may improve. The PV leaflets open more freely with less doming, and the width of blood jet flowing through PV increases. Right ventricular function is improved significantly with the reduction of tricuspid insufficiency and right-to-left shunt.

In some cases of prolong severe PVS and resultant right ventricular hypertrophy, the alleviation of the PVS unmasks the presence of the infundibular obstruction; thus, a significant gradient may still be present.⁴⁰ In this case, the infundibular stenosis must be treated with aggressive fluid management and β -adrenergic blockade. Follow-up evaluation has shown that this infundibular stenosis regress within weeks to months.^{40,41} However, most of the patients discharge from the hospital within 24-48 hours.

Mid-term follow-up

At mid-term follow-up (usually categorized as <2.5 years), the pressure gradient across the PV was below the safety level.^{17,38} Notwithstanding, the PV restenosis, (categorized when PPG>50 mmHg) was observed in 8-10% patients.⁴² Therefore, repeat PBPV is performed for those restenosis patients. However, it is recommended to perform surgery when the patients present with dysplastic PV annulus, dysplastic PV leaflets, hypoplastic PV, and significant supra-valvular pulmonary artery stenosis; as because these are the important factors for the restenosis.⁴

Predictors of restenosis

After meticulous evaluation of worldwide recognized studies, two major risk factors for restenosis were detected (immediate post valvuloplasty PPG \geq 30 mmHg and balloon/pulmonary valve annulus ratio <1.2). In our

opinion, it is judicious to use conservative size balloon (balloon: annulus ratios 1.2 to 1.25) for attaining gradient level <30 mmHg during the intervention. However, there are some other presage factors for restenosis, such as PVS associated with other complex heart diseases, dysplastic PV annulus, dysplastic PV leaflets, hypoplastic PV, and earlier study year.

Long-term follow-up

Many reports revealed that the long-term clinical outcome after PBPV is excellent.^{17,42-45} Some of the significant studies done on infants, children, and adolescents are tabulated below (Table 4). However, a total of 823 patients underwent PBPV, and 822 were followed-up up to 16.8 years after the Intervention. Surprisingly, 78.8% of patients were free from clinically significant PV restenosis up to the end of the follow-up

period. However, only 6.9% of patients required repeat PBPV because of the clinically significant residual gradient. The only 7.8% of patients underwent a surgical procedure (right ventricular outflow tract reconstruction). The most delightful point is, only 0.9% of patients developed severe pulmonary insufficiency during the follow-up period. However, some other independent risk factors identified for an optimum long-term clinical outcome such as young age at initial PBPV, smaller/dysplastic PV annulus, dysplastic PV leaflets, PV hypoplasia, too smaller/larger balloon/annulus ratio, significant residual gradient just after PBPV, and the higher initial pulmonary valvular PPG. Therefore, it is our opinion that PBPV is a safe and effective procedure that provides long-term (not lifelong) relief from moderate-to-severe PVS if the patients present with typical PV anatomy.

Table 3: Immediate postoperative complications of PBPV.

Less common complications	Rare complications
Systemic hypotension	Balloon rupture at high balloon inflation pressures
Transient bradycardia	Tear of tricuspid valve papillary muscle
Cardiac arrest	Tear of pulmonary artery
Cerebrovascular accident	Complete right bundle branch block
Pulmonary regurgitation	Transient or permanent heart block
Hemorrhage from puncture site	Acute lung injury ³⁷
Infundibular obstruction	Ventricular arrhythmia

Table 4: Long-term follow-up results after successful PBPV.

Variable	Study year	Patients number/ study years	Follow-up (years)	Long-term freedom from restenosis	Repeat PBPV	RVOT Surgery	Severe pulmonary insufficiency
McCordle (VACA) ⁴²	1994	533 (1981-86)	1-8.7	399/533	40/533	44/533	0/533
Berman et al ⁴³	1999	107 (1985-98)	0.5-10	101/106	2/106	3/106	6/106
Peterson et al ⁴⁴	2003	92 (1969-00)	1.6-9.2	79/92	6/92	7/92	1/92
Karagoz et al ⁴⁵	2009	50 (1988-08)	0.008-16.8	32/50	5/50	10/50	0/50
Qian et al ¹⁷	2015	41 (1999-05)	9-15	37/41	4/41	0/41	0/41
Total		823		648/822 (78.8%)	57/822 (6.9%)	64/822 (7.8%)	7/822 (0.9%)

PBPV: Percutaneous balloon pulmonary valvuloplasty, RVOT: Right ventricular outflow tract.

FUTURE PROSPECT

Since its evolution in 1982, PBPV remains as the gold standard first-line treatment option for moderate to severe PVS in all age group patients. After that, some authors describe hybrid procedure (combined surgical and interventional approach) for balloon pulmonary valvuloplasty.^{46,47} However, some other authors describe transthoracic per-ventricular balloon pulmonary valvuloplasty under echocardiographic guidance instead of using percutaneous approach.^{48,49}

Nowadays, it is possible to detect structural heart defects in a fetus as early as 20 weeks of gestation. However, those babies born with complex CHD are died very early age of life or suffered lifelong. It would be a great help for them if we could have been performed intervention in the fetal period. However, it is delightful that very few authors tried to perform pulmonary balloon valvuloplasty on the fetus.⁵⁰ Although the clinical outcome of fetal intervention was not optimum, it was a great leap forward and lion-hearted endeavor. Therefore, several important issues now need to be studied to move forward with fetal intervention on the PV such as clear detail identification

of PVS by echocardiography in the gestational period, is this intervention can reverse the process of right ventricular hypoplasia, and is it entirely safe and effective for both mother and fetus. All of these issues are under study. If these issues will be solved, surely it would be recognized as a blockbuster in the medical field and great help for humankind.

CONCLUSION

Undoubtedly, PBPV is the best and gold standard therapy for obstructive PV diseases, while several worldwide recognized studies prove the feasibility, safety, and effectiveness. However, recent studies recommend to use conservative sized balloon catheter (balloon: annulus ratios 1.2 to 1.25) to reduce long-term complications. Notwithstanding, new technological improvement will certainly increase the number of patients who can be successfully treated with this minimally invasive intervention in the future.

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