Review Article

Balloon pulmonary valvuloplasty with percutaneous transluminal mitral commissurotomy balloon in pulmonary stenosis

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Abstract

Pulmonary stenosis is common and accounts for 5%–12% of all congenital heart diseases. Echocardiography is the mainstay for evaluating pulmonary stenosis due to its easy availability, reproducibility and non-invasive nature. American Heart Association/American College of Cardiology (AHA/ACC) guideline recommends balloon pulmonary valvuloplasty in patients with moderate to severe valvular pulmonary stenosis. Due to its advantages over other balloons, Inoue and Accura balloon, balloons especially designed for Percutaneous Transluminal mitral commissurotomy can be used for successful balloon pulmonary valvuloplasty.

Introduction

Pulmonary stenosis (PS) accounts for 5%–12% of all congenital heart diseases and its incidence is 0.6–0.8 per 1000 live births.[1,2,3] It may also be diagnosed in adults, with an incidence of 0.12 per 1000 adults.[4] Though PS can be found in all ages of patients, in large series, it occurs most commonly in younger ages.[5,6] PS commonly coexist with other complex defects like tetralogy of Fallot, double-outlet right ventricle, ventricular septal defect, tricuspid atresia, transposition of the great arteries, etc.[7] but can occur independently. In most of the cases it is congenital and is due to fusion of commissures leading to "doming" of the valve leaflets and rarely may be due to dysplastic leaflets.[8] Most children and adults with mild-to-moderate PS remain asymptomatic and do not progress, whereas those with severe PS may experience dyspnea and fatigue. Some develop symptoms of right heart failure (peripheral edema, fatigue, and dyspnea), and rarely patients present with exertional angina, syncope, or sudden death.[9,10] The amount of degree of stenosis guides the age at presentation and therefore patients may be symptomatic in early childhood.[11] However, it is not uncommon to encounter among adult patients where predominant symptoms are dyspnea, effort intolerance, and rarely syncope.[9]

Diagnosis of PS

Echocardiography is the mainstay for evaluating PS due to its easy availability, reproducibility and non-invasive nature. It allows visualization of the pulmonic valve and surrounding structures compared to other imaging studies. A transthoracic echocardiogram is sufficient in most cases.[12,13]

Doppler studies using echocardiography provide flow gradients, which are used to grade severity. Guidelines from the European Association of Echocardiography, the American Society of Echocardiography, the American Heart Association, the American College of Cardiology (AHA/ACC), and the European Society of Cardiology have been summarized below.[14,15,16,17]

Mild stenosis: Peak Doppler gradient across the valve less than 36 mm Hg or Doppler jet velocity less than 3m/sec.

Moderate stenosis: Peak Doppler gradient across the valve 36 to 64 mm Hg, Doppler jet velocity 3 m/sec to 4m/sec.

Severe stenosis: Peak Doppler gradient across the valve greater than 64 mm Hg, Doppler jet velocity greater than 4m/sec.

Cardiac catheterization and pulmonary angiography are typically not required to diagnose PS due to echocardiography's efficacy and its safety profile.

Treatment / Management

According to the American Heart Association/American College of Cardiology (AHA/ACC) guideline, in case of a domed pulmonic valve with moderate to severe valvular stenosis and less than moderate pulmonic valve regurgitation, balloon pulmonary valvuloplasty (BPV) is recommended.[18] Otherwise, surgical repair is recommended for those who are ineligible for BPV or who have failed it. This includes patients with severe PS and an associated hypoplastic pulmonary annulus, severe pulmonary regurgitation (PR), sub-valvular PS or supravalvular PS. Surgery is also preferred for most dysplastic valves and when there is associated severe tricuspid regurgitation or other cardiopathy that warrants operative intervention.[18,19]

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Treatment depends on the severity of flow restriction across the pulmonary valve and the valve anatomy. The American Heart Association and American College of Cardiology have recommended the following management plans in their 2018 guidelines.[20]

Asymptomatic patients with a peak Doppler gradient of less than 30 mm Hg can be followed up every 5 years with an electrocardiogram and Doppler echocardiography.

Asymptomatic patients with a peak Doppler gradient greater than 30 mm Hg can be followed up every 2 to 5 years with Doppler echocardiography.

Surgical valvuloplasty

Surgical relief of PS was one of the first congenital heart operations and was described independently by Sellors and Brock in 1948.[21,22] This first surgical procedure consists of a closed transventricular pulmonary valvotomy via the RV outflow tract. The Brock technique dilates and cuts the stenotic pulmonary valve and likely the pulmonary infundibulum using a valvulotome and dilators through a purse string in the RV below the native valves.[23,24] However, this was an invasive procedure.[25] It was the treatment of choice in the pre-percutaneous era, which now has been replaced by less invasive balloon valvuloplasty since 1980.[9,26,27,28,29,30] Relieving the stenosis by splitting the valve leaflets is efficient but this relief occurs at the cost of PR, leading to right ventricular dilatation and tricuspid regurgitation. Nowadays surgical valvuloplasty is reserved for those patients with a hypoplastic pulmonary annulus, diminutive main pulmonary artery, or dysplastic pulmonary valves. In these patients, surgical repair is required to excise thickened and obstructive valve leaflets and place a transannular patch. Surgery is also the intervention of choice for patients with sub-valvular and supravalvular PS.[21,31,32]

Balloon pulmonary valvuloplasty (BPV)

The first attempt to relieve pulmonary valve obstruction by the transcatheter method was done in the early 1950s by Rubio-Alverez et al. and Rubio and Limon-Lason[33,34] they used a ureteral catheter with a wire to cut open the stenotic pulmonary valve. In 1979, Semb et al.[33] first introduced nonsurgical dilatation of stenotic pulmonary valve by balloon technique in a pediatric patient. They employed a balloon-tipped angiographic (Berman) catheter to produce a rupture of pulmonary valve commissures by rapidly withdrawing the inflated balloon across the pulmonary valve. Later in 1982, Pepine et al first described successful BPV in an adult patient.[34]

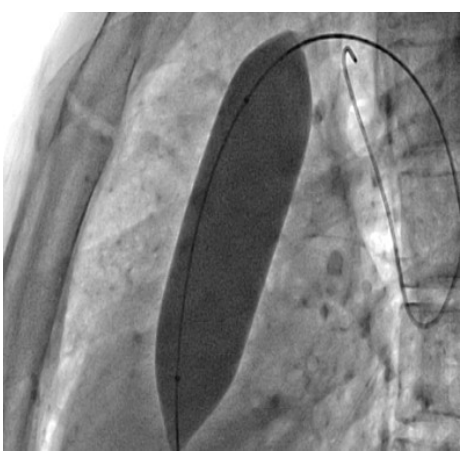

Figure 1. *BPV with Tyshak Balloon*

Kan et al.[29] applied the technique of Gruntzig et al.[35] to relieve pulmonary valve obstruction by the radial forces of balloon inflation of a balloon catheter positioned across the pulmonic valve. This static balloon dilatation technique is currently employed throughout the world in the treatment of PS.[30] It has become the gold standard treatment for hemodynamically significant PS. It offers excellent long-term results thus making it safe and effective.[36]

Since 1982, BPV has been carried out successfully to date with only minor modifications like the double-balloon technique, Inoue balloon and Accura balloon.[37,38] The percutaneous dilation of the pulmonary valve with a balloon is currently considered the therapeutic modality of choice in the treatment of PS in any age group and any valvular morphology.[33] BPV is the earliest percutaneous balloon dilatation procedure and until now it has remained the most successful of all percutaneous balloon valvuloplasty procedures.[40]

The double-balloon technique was first reported by Al Kasab et al in 1987. [41] Using two balloons may permit a small amount of blood flow between them even during full dilatation, leading to fewer hemodynamic changes.[42] The Tyshak series of balloons (NuMed, Hopkintown, NY) have been specifically designed for BPV and ongoing modifications have been made to reduce the profile of the balloon catheter, while maintaining the resistance to balloon rupture.[43] Currently, it is the most commonly used by interventional cardiologists for BPV.[43] The biggest disadvantage of the Tyshak balloon is the melon seeding effect and maintaining its position while inflation especially if the size is small. The potential risk with the longer balloon is an injury to the tensor apparatus of the tricuspid valve and occasional complete heart block due to atrioventricular node injury.[9]

Inoue (Toray Industries, Inc., Houston, TX) and Accura balloon (Vascular Concept, Essex, UK), balloons are especially designed for Percutaneous Transluminal mitral commissurotomy (PTMC). The use of the Inoue balloon for BPV which was first reported by Lau et al[38] in 1993 also has advantages over the single-balloon technique because it is size-adjustable, making stepwise dilatation possible. Due to its short inflation deflation time and self-positioning characters it helps to prevent balloon instability and minimizes the potential injury to RV infundibulum or main PA.[44] The safety of the Inoue balloon for BPV was first demonstrated by Chen et al. among adult patients. They concluded that patients with congenital PS who present in late adolescence or adult life can be treated with excellent short-term and long-term results similar to those in young children. The Inoue-Balloon Catheter is manufactured of polyvinyl chloride with a balloon attached to the distal end. The balloon is two latex layers between which is polyester micromesh. The catheter is supplied in a 12F diameter with a length of 70 cm; the length of each balloon is 2.5 cm (un-stretched). Two proximally positioned stopcocks accomplish balloon inflation and catheter venting. A stainless-steel tube is used to stretch and slenderize the balloon prior to insertion.

Liu et al. did a retrospective analysis of outcomes following BPV in children using the single balloon and adults using the Inoue balloon, long term results were similar to single balloon among the pediatric population. Gradients were not significantly different from that obtained at one-month follow-up in children, over a follow-up of 15 years.[46] Similarly, Lanjewar et al. showed excellent mid-term results of Inoue balloon in adolescents and adults with isolated pulmonary stenosis. They encountered an increase in pulmonary regurgitation by one grade in 53.2%.[10]

Limitations of the Tyshak balloon were addressed by Inoue catheter for BPV. A stepwise dilation of the pulmonary valve is not possible with the fixed size Mansfield/Tyshak catheter and more than one balloon catheter is required to achieve optimum results thus preventing cumbersome exchanges of balloons. The hemodynamic compromise is also minimized due to the short balloon inflation/deflation cycle of approximately 3 to 5 seconds allowing fast hemodynamic recovery. The Inoue balloon catheter in slenderized form has a small profile and can be percutaneously inserted into the femoral vein without the use of a sheath.[44] In the standard over-the-wire technique, the Inoue catheter after slenderizing over the metal stylet is advanced over its accompanying 0.02500 floppy-tipped stainless-steel guidewire.

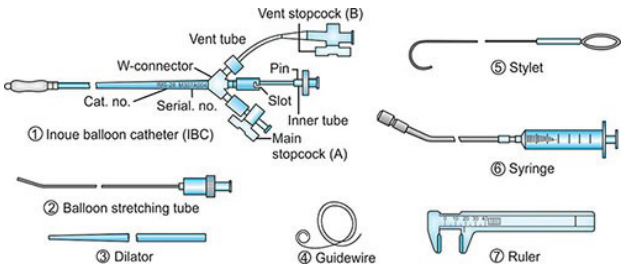

Figure 2. *Innoue balloon and it's accessories*

Accura balloon which was also originally developed for PTMC is being used for BPV. It offers various advantages over other balloons used in BPV. Firstly because of its peculiar expansile shape, it achieves a stable position across the stenosed valve and there are very less chances of slipping during inflation, secondly it can be expanded to a variable diameter that helps in achieving stepwise dilatation.[9] During inflation, it becomes a balloon floatation catheter because the distal inflated portion assumes the shape of dog bone when engaged across the valve and subsequently proximal part gets inflated. This provides perfect anchorage for the valve dilation and prevents any slippage either proximal or distal. During terminal inflation, the waist expands and achieve perfect commissurotomy.[11,47]

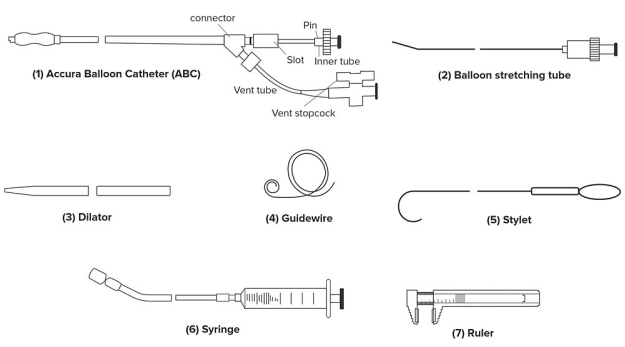

Figure 3. *Accura balloon and its accessories*

Although Inoue and Accura balloons are fundamentally similar, Accura balloons have advantage over the Inoue balloons in its better trackability.[9] As their pressure and volume relationship are unique, Accura balloons can deliver more stable and higher pressure when inflated within the standard diameter range. Therefore, it achieves better splitting of commissures at the same pressure compared to the Inoue balloon. Balloon sizes attainable with Inoue and Accura balloons are +4 and +3 mm respectively from their lowest given diameter. Also, recommended contrast dilution with Inoue and Accura balloons are 1:4 and 1:6-8 respectively which means that deflation time is lesser with the Accura balloon. Another advantage is that this balloon can be tracked with ease over either a dedicated left atrial wire or an extra stiff Amplatz wire. Appropriate size balloon prevents pulmonary leak and at the same time relieves obstruction.[9] In our center we have successfully performed BPV with Inoue balloon as well as ASD device closure in a single patient.[48]

Recommendations for BPV[20]

BPV is recommended for the following:

Asymptomatic patients with a domed pulmonary valve and a peak Doppler gradient greater than 60 mm Hg.

Symptomatic patients with a domed pulmonary valve and a peak Doppler gradient greater than 50 mm Hg or a mean Doppler gradient greater than 30 mm Hg.

BPV is not as effective in most dysplastic valves as in domed valves, thus making surgery the preferred option. However, in patients with dysplastic valves, balloon valvuloplasty may be reasonable in the following cases:

Asymptomatic patients with a dysplastic pulmonary valve and a peak Doppler gradient greater than 60 mm Hg or a mean Doppler gradient greater than 40 mm Hg

Symptomatic patients with a dysplastic pulmonary valve and a peak Doppler gradient greater than 50 mm Hg or a mean Doppler gradient greater than 30 mm Hg

BPV with PTMC balloon

As the pulmonary annulus is small in children it may not be suitable to use PTMC balloon in children. BPV can be done in adolescent and adults if the balloon size required for BPV is suitable. BPV with PTMC balloon is done under local anesthesia with prior informed consent. As per standard protocol, intravenous heparin is given at a total dose of 100U/kg after sheath insertion. A 5F/6F right femoral arterial access may be obtained for pressure monitoring. A standard diagnostic right heart catheterization to measure RV and PA pressure is performed. Right ventriculography in the left lateral view usually done using Pigtail catheter of appropriate size. This helped in assessing the pulmonary annulus, the presence of systolic doming and ruling out sub-valvular obstruction. The pulmonary annulus diameter is measured from hinge to hinge during systole. A good Echocardiogram can avoid measurement of RV and PA pressure measurement and also the RV gram.

A 6F Judkins Right (JR) catheter is then introduced into the right heart over a 0.032 "double-length angled tip guide wire and placed distal to the stenotic pulmonary valve. Over the JR catheter A 270 cm, 0.02500 floppy-tipped stainless steel (Springer) guide wire (with the coiled end straightened as much as possible) is anchored distally in the dilated PA, followed by removal of the JR catheter. A 14F dilator, part of the Inoue balloon catheter system, is used to dilate the venous groin access for facilitating passage of the balloon catheter. A 12F Inoue balloon catheter is prepared, with its balloon segment made air-free, stretched and slenderized by insertion of 18G silver metal tube. If Accura balloon is being used, an extra stiff Amplatz wire can be used instead of A 270 cm, 0.02500 floppy-tipped stainless steel (Springer) guide wire/LA wire.

Balloon size for BPV with Innoue and Accura balloon is size like the Tyshak balloon. The initial recommendations were to use balloons that are 1.2–1.4 times the pulmonary valve annulus.[30] These recommendations are formulated on the basis of immediateas well as follow- up results.[43,49,50,51,52] Balloons larger than 1.5 times the pulmonary valve annulus should not be used because it may damage right ventricular out flow tract.[53] Furthermore, such large balloons do not have advantage beyond that produced by balloons that are 1.2–1.4 times the annular size.[51,52] However, large balloons with balloon/annulus ratio of 1.4:1.5 may be used when dilating dysplastic pulmonary valves.[54]

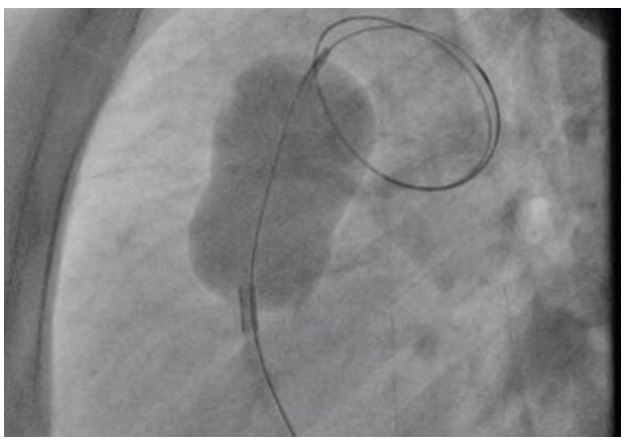

Figure 4. *BPV with PTMC balloon.*

The Innoue or Accura balloon catheter is inserted over the guide wire into the right femoral vein without a sheath and advanced into the right atrium, right ventricle and into the RVOT. After the balloon catheter reaches the level of RVOT, the metal tube is removed which allows the balloon to resume its more flexible natural shape. The balloon catheter is then maneuvered across the stenotic valve with slight clockwise rotation. The distal half of the balloon is inflated with diluted contrast agent (dilution, 1:4). Initial inflation is performed with a balloon size 1 -2mm less than its maximal capacity. While the floppy tipped guide-wire is stabilized, the catheter is pulled back until the middle portion of the balloon was is positioned just across the pulmonic valve. The balloon is fully inflated and then quickly deflated. Repeat inflation with increased balloon diameters (0.5 ml increments) can be done until the waist is abolished. Abolition of the balloon "waist "is used as the endpoint of the procedure. The deflated balloon is then removed keeping the guidewire in the PA. The guidewire permits the repositioning of a catheter into the distal pulmonary artery for pull-back pressure measurement.

In conclusion, Inoue and Accura balloons which are especially designed for PTMC can be used for successful BPV in suitable cases of PS, due to its advantages over other balloons,

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