

Balloon Valvuloplasty as Percutaneous Intervention for Pulmonary Stenosis: Experience from a Tertiary Care Center

Jaywant Navale, Nikhil Borikar¹, Ajay Chaurasia¹, Parag Bawaskar¹, Kiran Narang¹, Chetan Bhandarkar¹, Kondaveeti Thirupathi Rao¹, Gayatri Autkar²

Department of Cardiology, Reliance Hospital, Navi Mumbai, ¹Department of Cardiology, Topiwala National Medical College and B. Y. L. Nair Charitable Hospital,

²Department of Radiology, Seth GS Medical College, Mumbai, Maharashtra, India

ORCID:

Jaywant Nawale: 0000-0003-1543-7216

Nikhil Borikar: 0000-0001-9654-9281

Ajay Chaurasia: 0000-0002-3989-0106

Parag Bawaskar: 0000-0002-9381-4294

Kiran Narang: 0000-0002-4008-7636

Chetan Bhandarkar: 0000-0002-0561-6248

Kondaveeti Thirupathi Rao: 0000-0003-2680-4296

Gayatri Autkar: 0000-0001-9843-009X

Abstract

Background: To assess immediate and intermediate outcomes of percutaneous balloon pulmonary valvuloplasty (BPV) in children and adults. **Materials and Methods:** This retrospective, single-center study included patients who had undergone balloon valvuloplasty for the treatment of moderate to severe pulmonary stenosis at a tertiary care center in India between May 2011 and July 2018. Clinical profile, echocardiographic details, procedural details, complications, short term, and intermediate results were assessed. **Results:** A total of 43 patients were assessed. The mean age of the study population was 13.87 ± 11.71 years. Of them, 21 (48.8%) patients were men and 30 (69.8%) patients were children/adolescents. Single-balloon technique was used in all the cases. Balloon/annulus ratio was 1.28 ± 0.04 . Immediate procedural success (Group 1) and partial procedural success (Group 2) were achieved in 26 (60.5%) and 17 (39.5%) patients, respectively. The right ventricular systolic pressure reduced from 117.70 ± 31.77 mmHg to 53.56 ± 13.29 mmHg postprocedure ($P < 0.001$). Peak-to-peak transvalvular gradient reduced from 102.81 ± 31.66 mmHg to 35.56 ± 12.47 mmHg postprocedure ($P < 0.001$). Intermediate follow-up was conducted for 2.61 ± 0.75 years (range: 2–4 years). At intermediate follow-up, peak-to-peak instantaneous gradient was 27.21 ± 5.80 mmHg. Restenosis, moderate, and severe pulmonary regurgitation were reported in 2 (7.1%), 4 (14.3%), and 2 (7.1%) patients, respectively. **Conclusion:** Percutaneous BPV is a safe and efficacious procedure for the treatment of moderate to severe pulmonary valve stenosis in children and adults. The procedure had excellent immediate and intermediate follow-up results.

Keywords: Balloon valvuloplasty, congenital heart disease, echocardiography, pulmonary regurgitation, pulmonary valve stenosis, pulmonary valve

INTRODUCTION

Pulmonary valve stenosis is one of the most prevalent congenital heart defects accountable for 5%–10% of all congenital heart diseases.^[1,2] It has an incidence of 0.6–0.8 per 1000 live births.^[3] Surgical valvotomy using the Brock method in 1948 was the first effort to treat pulmonary valve

obstruction. However, this was an invasive procedure.^[4] In 1982, Kan *et al.*^[5] introduced a safer non-invasive procedure to relieve pulmonary obstruction by inflation of a balloon catheter assembled across the stenotic pulmonary valve.^[6] Since then

Address for correspondence: Dr. Nikhil Borikar, Department of Cardiology, Topiwala National Medical College and B. Y. L. Nair Charitable Hospital, Mumbai - 400 008, Maharashtra, India. E-mail: nikhil01063@gmail.com

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balloon pulmonary valvuloplasty (BPV) is considered the treatment of choice for pulmonary valve stenosis irrespective of age or valvular morphology.^[7]

In this study, we retrospectively assessed the outcomes with BPV as a percutaneous therapy for pulmonary valve stenosis at a tertiary care center in India over a period of 8 years. In this study, we report immediate and intermediate follow-up results. Furthermore, this study analyzes the information regarding balloon/annulus ratio, balloon dilatation techniques, and various types of balloons.

MATERIALS AND METHODS

Study design and patient population

This was a retrospective, single-center study of patients who had undergone balloon valvuloplasty for the treatment of moderate to severe pulmonary stenosis at a tertiary care center in India. During the period between May 2011 and July 2018, a total of 43 patients were identified and enrolled in the study. Patients were taken for BPV based on echocardiographic findings of peak instantaneous gradient >60 mmHg or mean gradient >40 mmHg in asymptomatic patients and peak instantaneous gradient >50 mmHg or mean gradient >30 mmHg in symptomatic patients. Patients with pulmonary regurgitation of mild or grade II severity were eligible to undergo BPV and were included in the study. None of the patients had pulmonary regurgitation of moderate or severe degree on color Doppler. Patients who had atrial septal defect (ASD) and patent foramen ovale were also included in the study. The exclusion criteria were patients who had undergone balloon valvuloplasty as palliative treatment for cyanosis or ventricular septal defect. The study was retrospective in nature; therefore, Institutional Ethics Committee approval was not obtained for the procedure. Written informed consent for the procedure and data release was obtained from all patients before the procedure.

Data collection

All patients underwent an electrocardiogram, chest X-ray, and 2D echocardiography with color Doppler after analysis of symptoms and clinical characteristics. A retrospective analysis of baseline characteristics, hemodynamics, complications, and follow-up was performed. Twenty-eight (65.1%) patients were followed up for >2 years. The severity of pulmonary valve stenosis was quantified by continuous-wave Doppler. Maximum instantaneous gradient was calculated with the help of Bernoulli's equation using maximum velocity obtained. The presence and severity of pulmonary regurgitation were assessed by color Doppler after analysis of the regurgitant jet and its width at the origin.

Study procedure

Antibiotic prophylaxis was given before the start of the procedure. The procedure was done under local anesthesia in adults and adolescents while general anesthesia was given to children. The femoral vein access was obtained in all

patients. In addition, femoral arterial access was obtained for hemodynamic monitoring. Unfractionated heparin was administered to maintain activated clotting time >250 s.

Right heart catheterization was routinely performed in all patients. The right ventriculogram was taken in lateral projection using a pigtail catheter to measure pulmonary annulus size in diastole at leaflet hinge points and to rule out infundibular obstruction [Figure 1]. Peak-to-peak systolic gradient was measured between the right ventricle (RV) and pulmonary artery using an end-hole catheter. The stenosed pulmonary valve was crossed with a 0.035 "guidewire and then exchanged with a 0.035" stiff guide wire of 260 cm length with the help of an end-hole catheter. After the measurement of the transvalvular gradient, appropriately sized balloon was selected depending on pulmonary annular size. The size of the balloons used for valvuloplasty was 1.2–1.4 times the pulmonary annulus size with a standard balloon size being 1.25 times greater than the annulus size. Higher balloon sizes were reserved for unyielding pulmonary valves which had suboptimal results with lower balloon sizes. Different types of balloons were utilized for valvuloplasty depending on patient subset, operator choice, and availability. Different balloons used for valvuloplasty were namely Tyshak Mini (NuMed, Hopkinton, NY), Z-Med (NuMed, Hopkinton, NY), Admiral Xtreme (Medtronic, Minneapolis, MN), Andratec (Koblenz, Germany) and Inoue balloon (Toray Industries, Japan) [Figure 2]. Inoue balloon was advanced over a 0.025 "coiled wire whilst the rest of the balloons were advanced over a 0.035" 260 cm extra stiff guide wire (Cook Amplatz) [Figure 3]. The balloon was positioned midway over the stenotic pulmonary valve and inflated with dilute contrast till the disappearance of the waist. Following dilation and removal of the balloon, the transvalvular gradient was measured again. In addition, the right ventriculogram was done to assess the severity of pulmonary regurgitation and any evidence of infundibular obstruction. Further dilation with balloon or upsizing of the balloon was done after the assessment of transvalvular gradient.



Figure 1: Classic doming pulmonary valve stenosis

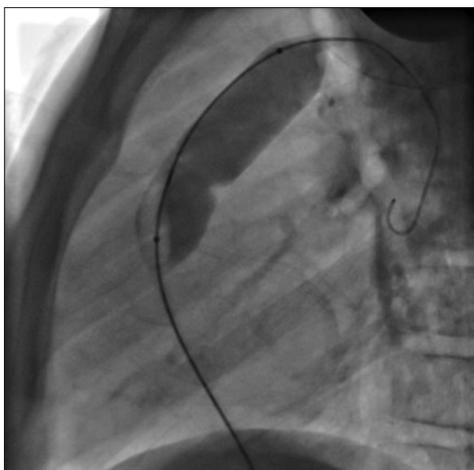


Figure 2: Centering of waist of balloon over stenotic pulmonary valve during inflation

After the procedure, the sheath was removed and hemostasis was achieved. Patients were shifted to intensive care unit and were observed closely. Transthoracic echocardiography was done before discharge and at follow-up. Patients who had suboptimal results with postprocedure peak to peak systolic gradient >36 mmHg were prescribed oral beta-blocker therapy.

Study definitions

Procedural success was defined as fall in peak-to-peak systolic gradient between the RV and pulmonary artery immediate postprocedure to a value <36 mmHg. Partial procedural success was defined in cases in which peak-to-peak systolic gradient did not decrease to <36 mmHg immediately postprocedure and there was reduction in gradient during follow-up to a value <36 mmHg. Pulmonary valve restenosis was defined as re-elevation of peak instantaneous gradient on echocardiography to >50 mmHg after initial successful reduction in transvalvular gradient to <36 mmHg.^[8,9]

Statistical analysis

Continuous variables were expressed as means with standard deviations and categorical variables as counts and percentages. Continuous variables were compared with Student's *t*-test. A $P \leq 0.05$ was considered statistically significant. All data were processed using the Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) program version 15.0.

Ethical statement

The study was retrospective in nature; therefore, Institutional Ethics Committee approval was not obtained for the procedure. Written informed consent for the procedure and data release was obtained from all patients prior to the procedure.

RESULTS

Baseline characteristics

A total of 43 patients underwent balloon valvuloplasty for pulmonary valve stenosis. The patient age was 13.87 ± 11.71 years (range: 6 months–52 years). There was

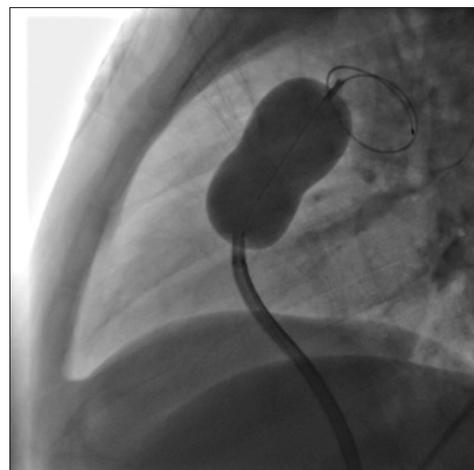


Figure 3: Balloon valvuloplasty using Inoue balloon

an almost equal distribution of men and women; 21 (48.8%) men and 22 (51.2%) women. The study predominantly involved ($n = 30$, 69.8%) children and adolescents. Of the study group, most ($n = 40$, 93.0%) had exercise intolerance. Three patients had a history of presyncope/syncope. Cyanosis was present in two cases as a result of reversal of shunt across ASD. The most frequently observed anomalies were ASD ($n = 4$, 9.3%) and facial dysmorphism ($n = 3$, 7.0%). Down syndrome was observed in 1 patient (2.3%). None of the cases in the study had Noonan syndrome while 1 patient had dysplastic pulmonary valve stenosis. The right ventricular systolic dysfunction was present in 4. The baseline characteristics and associated anomalies are shown in Table 1.

Balloon characteristics

Balloon/annulus ratio was 1.28 ± 0.04 mm. Single-balloon technique was followed in all the cases. Tyshak mini and Inoue were the most commonly used balloons in 28 (65.1%) and 10 (23.2%) cases, respectively. Single inflation was sufficient in majority ($n = 28$, 65.1%) while double and triple inflations were required in 8 (18.6%) and 2 (4.7%) cases, respectively. Balloons were stepped up in size in 7 cases (16.2%). The balloon characteristics are demonstrated in Table 2.

IMMEDIATE RESULTS

Right ventricular systolic pressure was reduced from 117.70 ± 31.77 mmHg to 53.56 ± 13.29 mmHg postprocedure. Pulmonary artery systolic pressure increased from 14.65 ± 1.90 mmHg to 17.79 ± 1.99 mmHg postprocedure. Peak-to-peak transvalvular gradient reduced from 102.81 ± 31.66 mmHg to 35.56 ± 12.47 mmHg postprocedure. Procedural success was achieved in 26 (60.5%) cases whilst partial procedural success was achieved in 17 (39.5%) cases. Moderate pulmonary regurgitation occurred in 4 cases while infundibular obstruction was observed in 8 cases. Depending on whether peak-to-peak transvalvular gradient fell to a value less than or more than 36 mmHg postprocedure, patients were retrospectively divided into two groups: Group 1 with

Table 1: Baseline characteristics of study population

Characteristics	n=43, n (%)
Age, (mean±SD, years)	13.87 ± 11.71
Male	21 (48.8)
Female	22 (51.2)
Children/adolescents	30 (69.8)
Adults	13 (30.2)
Symptoms	
Exercise intolerance	40 (93.0)
Syncope/presyncope	3 (7.0)
Cyanosis	2 (4.7)
Right heart failure	1 (2.33)
Associations	
Atrial septal defect	4 (9.3)
Right ventricle dysfunction	4 (9.3)
Facial dysmorphism	3 (7.0)
Patent ductus arteriosus	1 (2.33)
Mental retardation	1 (2.33)
Deafness	1 (2.33)
Down syndrome	1 (2.33)
Noonan syndrome	0

SD: Standard deviation

Table 2: Balloon characteristics

Parameter	n=43
Balloon characteristics	
Balloon size (mean±SD, mm)	18.86 ± 4.67
Pulmonary annulus mean±SD, mm)	14.79 ± 3.69
Balloon/annulus ratio, (mean±SD)	1.28 ± 0.04
Balloon dilation characteristics	
Single-balloon technique	
Admiral	6 (13.09)
Tyshak mini	28 (65.1)
Z med II	2 (4.7)
Andratec	4 (9.3)
Inoue	10 (23.2)
Step-up balloons	7 (16.2)
Number of inflations	
Single	28 (65.1)
Double	8 (18.6)
Triple	2 (4.7)

SD: Standard deviation

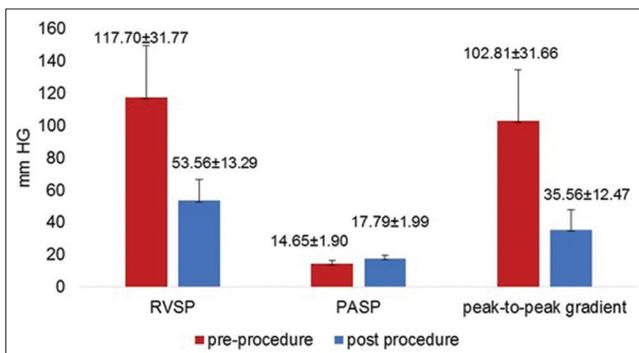


Figure 4: Immediate procedural results

complete procedural success ($n = 26$) and Group 2 with partial procedural success ($n = 17$). The immediate procedural results are illustrated in Figure 4.

Age was 12.16 ± 10.39 and 16.47 ± 13.38 ($P = 0.243$) for Group 1 and Group 2, respectively. Balloon/annulus ratio was 1.28 ± 0.04 and 1.27 ± 0.03 ($P = 0.347$) for Group 1 and Group 2, respectively. The preprocedure right ventricular systolic pressure was 98.96 ± 19.10 mmHg in Group 1 and 146.35 ± 25.26 mmHg in Group 2 ($P < 0.001$). Postprocedure right ventricular systolic pressure was 44.62 ± 7.86 mmHg in Group 1 and 67.24 ± 6.19 mmHg in Group 2 ($P < 0.001$). Preprocedure peak to peak gradient was 84.12 ± 18.96 mmHg in Group 1 and 131.41 ± 25.14 mmHg in Group 2 ($P < 0.001$). Postprocedure peak-to-peak gradient was 26.92 ± 5.98 mmHg in Group 1 and 48.76 ± 6.77 mmHg in Group 2 ($P < 0.001$). The procedural results are shown in Table 3 and Figures 5a and b.

Intermediate follow-up results

An analysis of patients with at least 2 years' follow-up was available for 28 (65.1%) patients with a mean follow-up period of 2.61 ± 0.75 years. At this follow-up, the right ventricular systolic pressure was 40.2 ± 6.4 mmHg and peak instantaneous gradient was 27.21 ± 5.8 mmHg. Restenosis was reported in 2 (7.1%) patients. Moderate pulmonary regurgitation was seen in 4 (14.3%) patients, while severe pulmonary regurgitation was seen in 2 (7.1%) patients. The intermediate follow-up results are given in Table 4.

DISCUSSION

Transcatheter BPV is an established procedure for relief of pulmonary stenosis. In the current study, BPV could be performed in all the cases. There was an effective fall in transvalvular gradient to <36 mmHg in majority of patients which translated into immediate procedural success rate in 26 (60.5%) patients. Partial procedural success was achieved in 17 (39.5%) patients. These outcomes adequately demonstrate the efficacy of this technique in children, adolescents, and adults.

Immediate procedural success was 60.5% in our study. This fits within the range of 54%–87.1% suggested by previous authors.^[4,7,10,11] Hatem *et al.*^[4] and Lanjewar *et al.*^[12] reported that patients unable to obtain immediate success had a greater severity of pulmonary stenosis highlighted by a significantly greater pulmonary transvalvular gradient and right ventricular systolic pressure than those who achieved immediate success. This observation is reflected in our study for parameters such as right ventricular systolic pressure (98.96 ± 19.10 mmHg vs. 146.35 ± 25.26 mmHg) and peak-to-peak pulmonary transvalvular gradient (84.12 ± 18.96 mmHg vs. 131.41 ± 25.14 mmHg) for the immediate and partially successful groups, respectively. No significant difference between the two groups in terms of age, sex, balloon/annulus ratio, and degree of reduction in the pulmonary transvalvular gradient was observed. Despite suboptimal initial results in patients of the partial procedural success group, the further reduction in transvalvular gradient

Table 3: Procedural results

Parameter	Group 1 (n=26)	Group 2 (n=17)	P
Age (mean±SD, years)	12.16 ± 10.39	16.47 ± 13.38	0.243
Balloon/annulus ratio (mean±SD, mm)	1.28 ± 0.04	1.27 ± 0.03	0.347
Preprocedure right ventricular systolic pressure (mean±SD, mmHg)	98.96 ± 19.10	146.35 ± 25.26	<0.001
Postprocedure right ventricular systolic pressure (mean±SD, mmHg)	44.62 ± 7.86	67.24 ± 6.19	<0.001
Preprocedure pulmonary artery systolic pressure (mean±SD, mmHg)	14.46 ± 1.86	14.94 ± 1.98	0.425
Postprocedure pulmonary artery systolic pressure (mean±SD, mmHg)	17.35 ± 2.13	18.47 ± 1.59	0.070
Preprocedure peak to peak gradient (mean±SD, mmHg)	84.12 ± 18.96	131.41 ± 25.14	<0.001
Postprocedure peak to peak gradient (mean±SD, mmHg)	26.92 ± 5.98	48.76 ± 6.77	<0.001

SD: Standard deviation

Table 4: Intermediate follow up results

Parameter	n=28
Follow up period (mean±SD, years)	2.61±0.75
Number of patients available for follow up period >2 years	28 (65.1)
Right ventricular systolic pressure, before procedure (mean±SD, mmHg)	120.89±31.37
Right ventricular systolic pressure, after procedure (mean±SD, mmHg)	55.46±14.23
Right ventricular systolic pressure, at follow up - echo derived (mean±SD, mmHg)	40.2±6.4
Peak to peak gradient, before procedure (mean±SD, mmHg)	106.36±30.88
Peak to peak gradient, after procedure (mean±SD, mmHg)	37.39±13.57
Peak instantaneous gradient, at follow up - echo derived (mean±SD, mmHg)	27.21±5.80
Restenosis, n (%)	2 (7.1)
Moderate pulmonary regurgitation, n (%)	4 (14.3)
Severe pulmonary regurgitation, n (%)	2 (7.1)

SD: Standard deviation

to <36 mmHg was attained with beta-blocker therapy during the intermediate follow-up period. Notwithstanding, this observation in intermediate follow-up, it implies that earlier intervention in natural history of severe pulmonary stenosis would result in lower residual gradient with consequent beneficial effects on the right ventricular hypertrophy.

It is a common occurrence for hypertrophied infundibular muscles to go into spasm after BPV. Numerous studies have reported this complication.^[13-17] The consequence of this complication is a significant residual gradient despite adequate dilatation of the pulmonary valve. Hence, if only immediate results are considered, outcomes may be skewed by this

complication. However, this is not a permanent complication as infundibular obstruction gradually regresses within the follow-up period. Secondary infundibular hypertrophy may contribute to the obstruction present postvalvuloplasty but it resolves after relief of obstruction. This process of regression is a dynamic process and may rapidly regress on the administration of oral beta-blockers.^[10,13,14]

Numerous modern approaches to BPV implement a single- or double-balloon technique. Double-balloon technique may be used in the case of larger annular size. It maintains continuous blood flow eliminating chances of hypotension. However, the pitfall of double or triple balloons includes additional venous access, prolonged procedural time, stretch-induced injury to vessels, balloon slippage and more frequent injury to the pulmonary valve.^[18,19] We were comfortable with single-balloon technique in our patients and all the procedures utilized single-balloon technique. In addition, we found the sequential balloon technique very useful whilst dealing with a number of patients. The technique is very useful during procedures involving very severe stenosis or presence of RV dysfunction when there is transient hypotension during catheter advancement or balloon dilation. In such cases, rapid catheter manipulation and rapid balloon inflation-deflation are desirable. We used short and small diameter low profile balloons for initial valve dilation so as to get better control of hemodynamics while final valvuloplasty was done by larger diameter balloons.

A variety of balloons were utilized for the procedure depending on patient subset, operator choice, and availability. Among these, the most important factor was the availability of different balloons. In the initial years of the study period, Tyshak and Admiral Balloons were easily available while Andratec balloons were available in the later period. Inoue balloons were used especially in the presence of larger pulmonary annulus size in adults. These balloons conferred several advantages over other balloons. Flexible, short, and self-positioning characters of these balloons minimize injury to the RV outflow tract and main pulmonary artery. Adjustable inflation permits stepwise dilation reducing the risk of over-dilation of the pulmonary valve.^[11,17,20] Further, short inflation-deflation cycle of approximately 5S takes care of hemodynamic compromise during inflation.

Twenty-eight patients were analyzed for the intermediate results of the balloon valvuloplasty. These patients were followed up for 2–4 years. Successful relief of obstruction was sustained in majority of the patients in intermediate period. Restenosis was seen in only 2 cases (1 at 2 years and the other at 3 years of follow-up). In 1 of these cases of restenosis, partial relief of obstruction with residual gradient was seen immediately postprocedure. Risk factors for recurrence identified in a study of 36 cases were balloon/pulmonary valve annulus ratio <1.2 and immediate postvalvuloplasty gradient >30 mmHg.^[21] Dysplastic pulmonary valves and pulmonary valve hypoplasia did not seem to have any influence on recurrence in this study. In addition

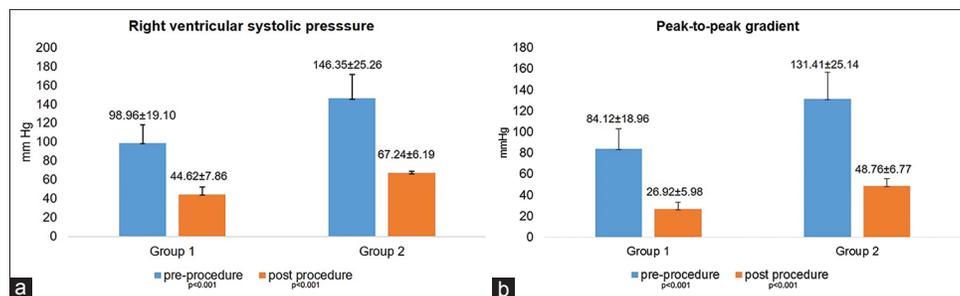


Figure 5: (a) Right ventricular systolic pressure pre and post procedure. (b) Peak-to-peak gradient pre and post procedure

to these two factors large multi-institutional valvuloplasty and angioplasty of congenital anomalies (VACA) registry also found earlier study year, small valve annulus, and postsurgical or complex pulmonary stenosis as predictive factors for restenosis.^[9] Depending on these studies and our experience, it can be concluded that larger balloons should be used to reduce valvular gradient to <36 mmHg for longer-lasting results. However, the use of larger balloons for valvuloplasty comes at the price of more chances of pulmonary regurgitation in the long term. Although mild pulmonary regurgitation was seen in as many as 23 patients, hemodynamically significant pulmonary regurgitation was found in follow-up in 6 patients. Among them, 2 patients had severe pulmonary regurgitation at the end of 4 years of follow-up. However, there was no significant volume overload or systolic dysfunction of RV. These cases will require further follow-up for any adverse consequences in future. The prevalence of pulmonary regurgitation has been reported to be 40%–90% in literature which roughly corresponds to our study.^[8,22–25] Majority of the cases in these studies did not require valve replacement due to the absence of volume overload except few exceptions.^[22] Berman *et al.*^[23] suggested young age, higher degrees of obstruction, large balloon/annulus ratio, use of noncompliant balloons, and low postdilatation peak-to-peak systolic pressure gradient as factors contributing to the development of pulmonary regurgitation. Another study of 68 cases found that use of larger balloon with balloon/annulus ratio >1.3:1 was associated with the development of pulmonary regurgitation at follow-up.^[23] Depending on these experiences Rao *et al.* recommend a balloon/annulus ratio of 1.2–1.25 instead of previously recommended 1.2–1.4 ratio as optimal choice for balloon selection for achieving adequate relief of obstruction with least incidence of significant pulmonary regurgitation at follow-up.^[6]

Complications in our study were limited to 27 cases of acute pulmonary regurgitation, 8 cases of infundibular obstruction, 2 cases of vasovagal syncope and only 1 case of femoral vein thrombosis. Hatem *et al.*^[4] reported complications of dissection of the inferior vena cava, 2 cases of convulsions during balloon inflation, two cases of atrial fibrillation, one case of rupture of tricuspid valvular apparatus and 1 case of cardiac arrest. Similarly, Amoozgar *et al.*^[3] reported 2 cases of cardiac arrest and 1 case each of detachment of the cover of the hydrophilic catheter, mild pericardial effusion, sepsis, supraventricular tachycardia, and umbilical vein dissection. Further acute

pulmonary regurgitation not requiring surgical management is a common occurrence.^[10] BPV is a safe, effective, and less invasive alternative in comparison to surgical valvotomy. Significant residual gradient after valvuloplasty recedes gradually with regression of infundibular hypertrophy over time. Less than moderate pulmonary regurgitation develops in most cases, but rarely requires surgical treatment. The incidence of restenosis is truly low.

Study limitations

The first limitation of our study is retrospective collection of data. The second limitation is the small study population size.

CONCLUSION

Percutaneous BPV is a safe and efficacious procedure for the treatment of moderate to severe pulmonary valve stenosis in children/adolescents and adults. The procedure yielded excellent immediate and intermediate follow-up results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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