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Original Research Article

Outcomes of Balloon Dilatation in Isolated vs. Risk-Associated Pulmonary Stenosis: A Comparative Study

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Abstract: *Pulmonary valve stenosis (PVS) is a common congenital heart defect, with balloon pulmonary valvuloplasty (BPV) being the standard intervention. However, outcomes can vary significantly between isolated cases and those associated with additional risk factors, such as dysplastic valves or right ventricular hypoplasia.* ***Objective:*** *T.o compare the outcomes of balloon dilatation in isolated versus risk-associated pulmonary stenosis (PS).* ***Methodology:*** *This cross-sectional study was conducted from January to December 2024 at the Pediatric Cardiology Department of NICVD, Karachi. Patients of any age and gender with echocardiographicaly confirmed pulmonary valve stenosis (PVS) undergoing balloon pulmonary valvuloplasty (BPV) were included. Isolated PS was defined as severe doming valves without additional risk factors; risk-associated PS included dysplastic valves, critical PS, multilevel obstruction, or RV/valvular hypoplasia. Pre- and post-procedural clinical, echocardiographic, and hemodynamic data were recorded. Follow-up echocardiography was performed on day one and at one month. Data were analyzed using IBM-SPSS Statistics. For all inferential statics, p<0.05 was considered statistically significant.* ***Results:*** *Of 61 patients, 36 (59%) had isolated, and 25 (41%) had risk-associated pulmonary stenosis. Risk-associated cases had lower median age (1.5 vs 7.0 years; p=0.015), smaller annulus diameter (8.0 vs 15.0 mm; p<0.001), and higher cyanosis (64.0% vs 19.4%; p<0.001). Day-1 RVSP was higher (74.0 vs 65.5 mmHg; p =0.016), and cardiac arrest occurred only in the risk group (16.0%; p=0.013). By day-30, restenosis occurred exclusively in risk-associated cases (21.1% vs 0%; p=0.010). At day-30, mortality occurred in 2 cases (risk-associated PS).* ***Conclusion:*** *Balloon pulmonary valvuloplasty remains an effective therapeutic option for pulmonary stenosis. Patients with risk-associated features are more likely to experience higher residual RV pressures, greater regurgitant lesions, increased risk of cardiac arrest, and early restenosis.*

Keywords: Pulmonary stenosis, valvuloplasty, cardiac arrest, echocardiography, cyanosis, mortality

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Introduction

Pulmonary stenosis (PS) is obstruction between the right ventricle and the pulmonary artery at the level of the pulmonary valve, and its prevalence ranges between 0.6-0.8/1000 live-births (1). When it occurs with other congenital heart disease (CHD), PS occurs in approximately 50% of those born with any type of CHD. PS can be caused by isolated valvular (90%), subvalvular, peripheral (supravalvular) obstruction, or it could be related to congenital heart diseases of some other etiology (2). PS is valvular, sub-valvular (infundibular), or supra-valvular. Valvular stenosis is by far the most common type (3). Pulmonary valve stenosis (PVS) is usually congenital and caused by a malformed or dysplastic valve leaflet. Symptoms are uncommon in children and adolescents, but adults may experience dyspnea and fatigue. Exertional syncope may occur in severe cases, but sudden death is rare. Long-standing untreated obstruction may lead to tricuspid regurgitation (TR) and right ventricular failure (4). PVS in neonates, early infancy and childhood is a life-threatening condition. Severe PS is usually associated with reduced pulmonary flow, right ventricular hypertrophy and cyanosis, and with critical obstruction early congestive heart failure. The age of the patients at presentation is related to the severity of the obstruction. Patients who present with severe PS are usually found during the neonatal and infancy period. Patients who have a mild obstruction usually present during childhood and may be asymptomatic (5). Patients with severe PS should undergo treatment even if it is well tolerated and is asymptomatic at the beginning. This is due to the possibility of dangerous complications that may emerge if timely treatment is not used (6). Over the last few years, balloon pulmonary valvuloplasty (BPV) has become the treatment of choice for the relief of moderate to severe valvular pulmonic stenosis in neonates, infants, children, and adults (7). with minimally invasive techniques and positive outcomes, BPV has now become the preferred treatment option for patients with uncomplicated PS. The first trans-catheter BPV was done in 1982 by Kan et al (7). BPV has totally replaced the surgical pulmonary valvotomy and is the treatment of choice for moderate to severe valvular pulmonary stenosis in all age groups (8).The American Heart Association recommends pulmonary valvuloplasty for patients with critical valvar PS, valvar pulmonic stenosis, and clinically significant pulmonary valvar obstruction in the presence of RV dysfunction. Additionally, the AHA suggests that pulmonary valvuloplasty may be considered a palliative procedure in some cases of complex cyanotic congenital heart disease, such as tetralogy of Fallot (9, 10). Literature search showed that most of the data regarding the outcomes and efficacy of pulmonary valve ballooning has been from the developed world, and data from developing countries are limited (11, 12). Outcomes of balloon dilatation are different for patients with isolated PVS versus those with risk-associated PVS. This study might be helpful in providing clinicians with valuable insights into treatment decision-making for PVS. This study aimed to fill this knowledge gap by evaluating the outcomes of balloon pulmonary valvuloplasty in patients of all age groups. This study is also expected to shed light whether the presence of risk factors for PVS impact the outcomes of balloon dilatation compared to isolated PVS. The objective of study was to compare the outcomes of balloon dilatation in isolated versus risk-associated PS.

Methodology

This cross sectional-study was conducted at the Pediatric cardiology department of National Institute of Cardiovascular Diseases (NICVD) Hospital Karachi, Pakistan during January 2024 to December 2024. Approval was obtained from the institutional ethical review board of NICVD (IRB#42/2023) before the commencement of this study. All the patients undergoing BPV in NICVD during the study period were included. Non-probability, consecutive sampling technique was used. Inclusion criteria were patients of any gender and age, diagnosed with PVS through echocardiography, and underwent BPV, regardless of whether they had isolated (dysfunctional, dooming) or risk associated PS . Exclusion criteria were patients with multiple CHDs or who underwent BPV or other treatments concurrently. The patients who had a prior history of congenital heart surgery, received valvuloplasty for PVS in the native valve, tissue bioprosthetic valve, or right ventricle to pulmonary artery valve conduit were also excluded. Isolated PS was named as dysfunctional (thickened and dooming) pulmonic valve with severe PS without risk factors. Risk associated PS was patients with dysplastic valve, critical PS, multiple level obstruction, branch PS, RV dysfunction, small annulus size, small RV, small TV, small PA sizes, and severe TR. Informed and written consents were obtained from patients or their parents/caregivers. Among patients fulfilling eligibility criteria, demographics and clinical information were documented. Trans-thoracic echocardiography pre-procedure findings were used as for standard echocardiographic views in addition to color doppler and continuous-wave doppler. The presence and intensity of PR were assessed by color flow mapping. All BPV procedures were performed as per standard protocols and details of type of anesthesia used (local, conscious, or general), the RV pressure, the pulmonary artery pressure (PAP), and the degree of PVS (mild, moderate or severe) were noted. PS severity was determined based on cut-off values recommended by the 2018 ACC/AHA guidelines.[13] In addition to the balloon size to annulus ratio, the shape (doming or dysplastic) and annulus of the valve on the RV angiography at left lateral projection, the presence or absence of TR, and the balloon's length were documented. For pulmonary valve instantaneous gradient and RV function, RVOT obstruction, pericardial effusion, TR (mild, moderate, severe), and pulmonary regurgitation (PR), results of post-procedural echocardiogram performed on day one and on one month follow up were recorded (mild, moderate, severe). *The data collected* were analyzed using IBM-SPSS Statistics, version 26.0. For all quantitative variables, median and interquartile range (IQR) were calcualted as data were non-normally distributed. The frequencies and percentages were computed for all *Qualitative* variables. Mann-Whiteny U test was used to compare quantitiatve data, while chi-square test or Fisher's exact test were used to compare qualitative data. For all inferential statistics, p<0.05 was considered statistically significant.

Results

During the study period, a total of 61 patients fulfilled the eligiblity criteria and were analyzed. There were 31 (50.8%) females, and the median (IQR) age was 7.00 (1.00-18.00) years. Of the 61 patients who underwent balloon valvuloplasty for PS, 36 (59%) had isolated PS while 25 (41%) had risk-associated PS. Males predominated in the isolated group (n=23, 63.9%) but were significantly fewer in the risk-associated group (n=7, 28.0%) (p=0.006). The median age was significantly higher in the isolated group (7.00 years [IQR, 0.25–21.00]) compared with the risk-associated group (1.50 years [IQR, 0.18–9.50]) (p=0.015), and a similar pattern was observed for weight (20.00 kg vs 9.00 kg; p=0.001). The median oxygen saturation was significantly lower among the risk-associated group (77.00% vs 97.00%; p<.001), with cyanosis more prevalent (64.0% vs 19.4%; p<.001). Shortness of breath was more frequent in the isolated group (69.4% vs 44.0%; P = .047). Pre-procedural echocardiographic data revealed a smaller pulmonary annulus diameter in the risk-associated group (8.00 (6.00-9.50) mm vs 15.00 (9.00-16.00) mm; p<0.001). Moderate TR was more common in risk-associated cases (32.0% vs 5.6%; p=0.014). Table-1 is showing details about the comparison of baseline demographic, clinical and electrocardiograph features among patients with isolated versus risk associated PS. Procedural data showed that general anesthesia was used exclusively in the risk-associated group (12.0%; p=0.040), and the balloon-annulus ratio was significantly lower among patients of risk-associated PVS (11.50 vs 14.00; P = .016). No intra-procedural mortality was recorded in any of the cases. Table-2 is showing comparison of procedures details among patients with isolated versus risk associated PS. On day-1 following balloon valvuloplasty, the median peak pulmonary valve gradient decreased in both groups, with no significant difference between isolated and risk-associated PS (27.00 mmHg vs 33.50 mmHg; p=0.649). The median RVSP remained significantly higher in the risk-associated group (74.00 (60.00-100.00) mmHg vs 65.50 (50.00-75.00 mmHg; p=0.016). Pulmonary artery systolic pressure (p=0.701), and post-procedure annulus diameter (p=0.074) were comparable across groups. TR (24.0% vs 8.3%, p=0.149), and PR (25.0% vs 5.7%, p=0.104) were more frequently moderate among risk-associated patients but these differences were not statistically significant. Minor complications such as vascular occlusion (8.3% vs 4.0%), hematoma (5.6% vs 4.0%), and minor RVOT perforation (2.8% vs 4.0%) occurred in both groups without significant variation. Cardiac arrest occurred in 4 patients (16.0%) in the risk-associated group, with none in the isolated group (p=0.013). On day-1, mortality was reported in 1 (4.0%) patient from the risk-associated group, while no deaths occurred in the isolated group (p=0.226). Table-3 is showing comparison of post-procedural hemodynamic parameters, and complications at day-1 among patients with isolated versus risk associated PS.

By day-30, 59 patients remained available for follow-up, with 2 deaths in the risk-associated group due to cardiac arrest. Among survivors, mild TR remained the predominant finding in both groups (87.1% in isolated vs 94.7% in risk-associated; p=0.364), with no cases of severe regurgitation. PR was generally mild, although moderate cases were slightly more frequent in the risk-associated group (10.5% vs 6.5%; p=0.532). Minor vascular complications such as vascular occlusion (10.5% vs 3.2%; p=0.313), and local hematoma (10.5% vs 0%; p=0.072) were more frequent in the risk-associated group, although differences were not statistically significant. Minor RVOT perforation was reported in only 1 (3.2%) patient from the isolated group. Restenosis occurred exclusively in the risk-associated group (21.1% vs. 0%; p=0.010). Comparison of hemodynamic parameters, and complications at day-30 among patients with isolated versus risk associated PS are shown in table-4.

Table-1: Comparison of baseline demographic, clinical and electrocardiograph features among patients with isolated versus risk associated pulmonary stenosis (N=61)

Characteristics		Isolated pulmonary stenosis (n=36)	Risk associated pulmonary stenosis (n=25)	P-value
Gender	Male	23 (63.9%)	7 (28.0%)	0.006
	Female	13 (36.1%)	18 (72.0%)	
Age in years		7.00 (0.25-21.00)	1.50 (0.18-9.50)	0.015
Weight in Kg		20.00 (5.00-53.00)	9.00 (4.00-14.00)	0.001
SpO_2 (%)		97.00 (97.00-99.00)	77.00 (68.00-95.00)	<0.001

Arrhythmia		4 (11.1%)	1 (4.0%)	0.319
Cyanosis		7 (19.4%)	16 (64.0%)	<0.001
Shortness of breath		25 (69.4%)	11 (44.0%)	0.047
Peak pulmonary valve gradient (mmHg)		77.00 (72.00-130.00)	125.00 (85.00-140.00)	0.058
Pulmonary annulus diameter (mm)		15.00 (9.00-16.00)	8.00 (6.00-9.50)	<0.001
Right ventricular systolic pressure (mmHg)		110.00 (88.75-146.00)	125.00 (75.00-146.00)	0.618
Pulmonary artery systolic pressure (mmHg)		25.00 (24.00-30.00)	26.50 (20.00-30.00)	0.667
Degree of pulmonary valve stenosis	Mild	4 (11.0%)	-	0.210
	Moderate	4 (11.1%)	4 (16.0%)	
	Severe	28 (77.8%)	21 (84.0%)	
Degree of tricuspid regurgitation	None	2 (5.6%)	-	0.014
	Mild	32 (88.9%)	17 (68.0%)	
	Moderate	2 (5.6%)	8 (32.0%)	

Table-2: Comparison of procedural details among patients with isolated versus risk associated pulmonary stenosis (N=61)

Characteristics		Isolated pulmonary stenosis (n=36)	Risk associated pulmonary stenosis (n=25)	P-value
Anesthesia type	General	-	3 (12.0%)	0.040
	Local	33 (91.7%)	22 (88.0%)	
	Conscious	3 (8.3%)	-	
Balloon annulus ratio		14.00 (11.00-16.25)	11.50 (7.00-15.50)	0.016
Balloon type	Osypka	4 (11.1%)	1 (4.0%)	0.414
	Tayshak II	1 (2.8%)	-	
	Valvar	31 (86.1%)	24 (96.0%)	

Table-3: Comparison of post-procedural hemodynamic parameters, and complications at day-1 among patients with isolated versus risk associated pulmonary stenosis (N=61)

Characteristics		Isolated pulmonary stenosis (n=36)	Risk associated pulmonary stenosis (n=25)	P-value
Peak pulmonary valve gradient (mmHg)		27.00 (25.00-45.00)	33.50 (25.00-43.75)	0.649
Right ventricular systolic pressure (mmHg)		65.50 (50.00-75.75)	74.00 (60.00-100.00)	0.016
Pulmonary artery systolic pressure (mmHg)		25.00 (24.00-30.00)	29.00 (20.00-33.75)	0.701
Pulmonary annulus diameter (mm)		14.00 (11.00-16.00)	10.00 (7.50-16.00)	0.074
Degree of tricuspid regurgitation	None	5 (13.9%)	5 (20.0%)	0.149
	Mild	28 (77.8%)	14 (56.0%)	
	Moderate	3 (8.3%)	6 (24.0%)	
Pulmonary regurgitation	None	4 (11.1%)	2 (8.3%)	0.104
	Mild	29 (82.9%)	16 (66.7%)	
	Moderate	2 (5.7%)	6 (25.0%)	
Vascular occlusion		3 (8.3%)	1 (4.0%)	0.504
Local hematoma		2 (5.6%)	1 (4.0%)	0.782
Minor RVOT perforation		1 (2.8%)	1 (4.0%)	0.792
Infundibular stenosis		8 (22.2%)	7 (28.0%)	0.565
Anesthesia complications		1 (2.8%)	1 (4.0%)	0.792
Need for BT shunt		-	1 (4.0%)	0.226
Arrhythmia		-	1 (4.0%)	0.226
Cardiac arrest		-	4 (16.0%)	0.013
Mortality		-	1 (4.0%)	0.226

Table-4: Comparison of hemodynamic parameters, and complications at day-30 among patients with isolated versus risk associated pulmonary stenosis (N=50)

Characteristics		Isolated pulmonary stenosis (n=36)	Risk associated pulmonary stenosis (n=23)	P-value
	None	3 (8.3%)	-	0.364

Degree of tricuspid regurgitation	Mild	30 (83.3%)	21 (91.3%)	
	Moderate	3 (8.3%)	2 (8.7%)	
Pulmonary regurgitation	None	4 (11.1%)	5 (21.7%)	0.532
	Mild	29 (80.6%)	16 (69.6%)	
	Moderate	3 (8.3%)	2 (8.7%)	
Vascular occlusion		1 (2.8%)	2 (8.7%)	0.313
Local hematoma		-	2 (8.7%)	0.072
Minor RVOT perforation		1 (2.8%)	-	0.420
Infundibular stenosis		5 (13.9%)	6 (26.1%)	0.241
Restenosis		-	4 (17.4%)	0.010

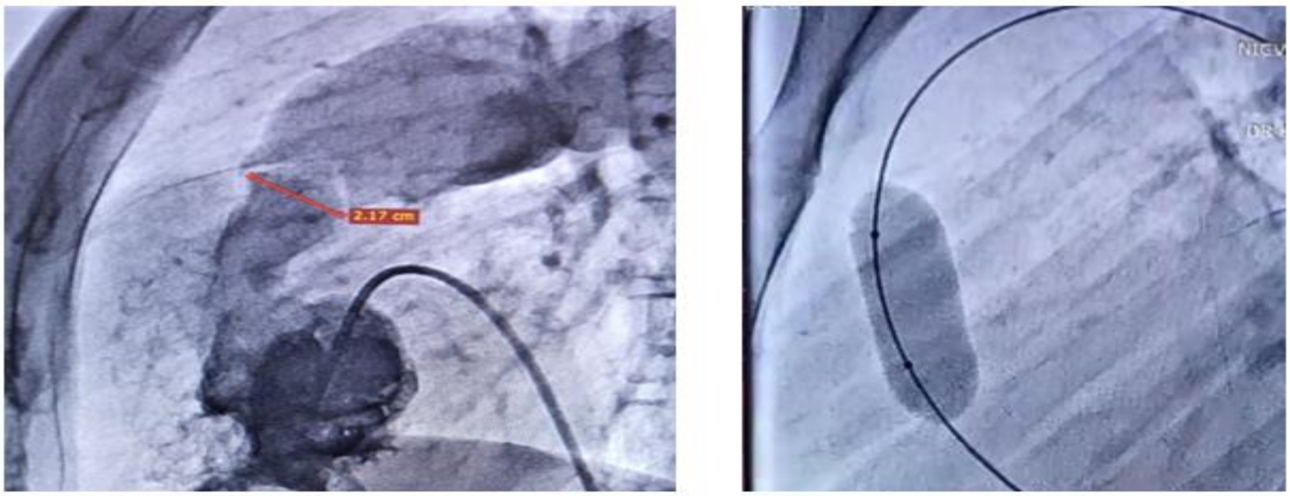

Figure 1: Right ventricle angiogram left lateral projection of 12 years female diagnosed with isolated severe pulmonary stenosis. Post balloon dilation pressure gradiant decrease from 70mmhg to 20mmhg. No pulmonary regurgitation.

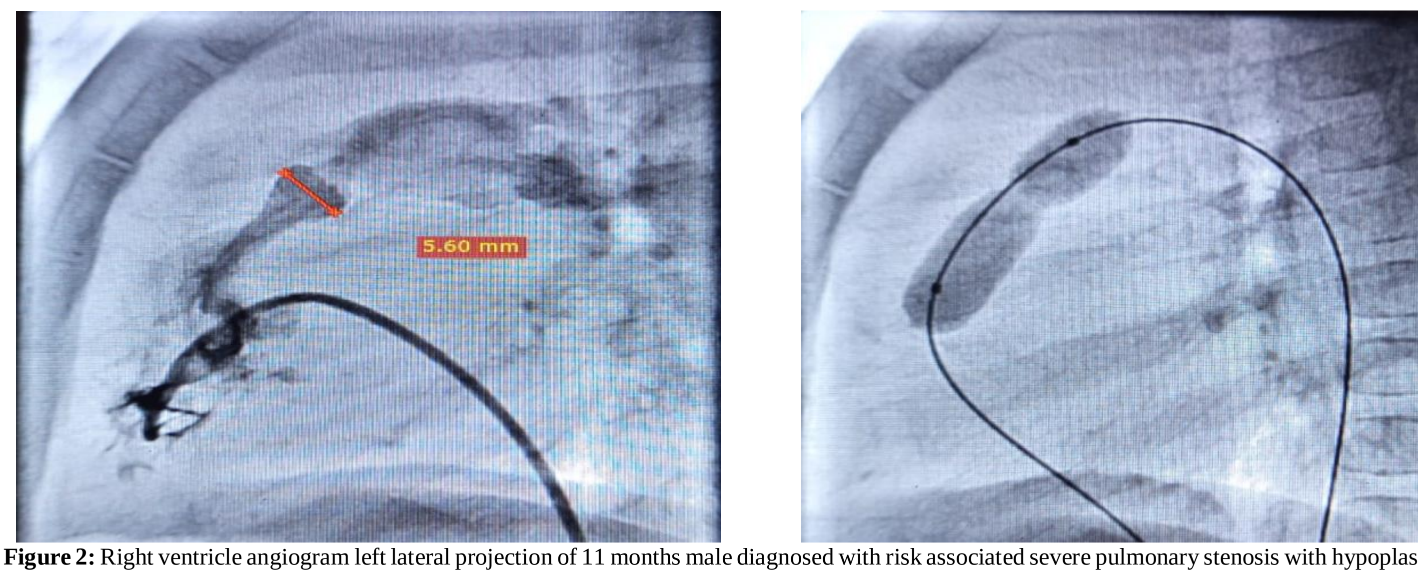

Figure 2: Right ventricle angiogram left lateral projection of 11 months male diagnosed with risk associated severe pulmonary stenosis with hypoplastic pulmonic valve. Post balloon dilation pressure gradiant decrease from 120 mmhg to 32mmhg. No pulmonary regurgitation

Discussion

The baseline demographic and clinical characteristics differed significantly between the two groups. Patients with isolated PS had a higher median age (7.00 years vs 1.50 years) and weight (20.00 vs 9.00 kg), reflecting the relatively milder clinical course that often permits delayed presentation. Risk-associated PS, presented earlier and more often with cyanosis and reduced oxygen saturation (median SpO_2 77.00% vs 97.00%). These findings are consistent with those of Devanagondi et al, (14). who reported that patients with critical PS and smaller body surface areas had more severe hemodynamic compromise and were more likely to develop moderate or greater PR at follow-up.

This study also observed a markedly smaller pulmonary annulus diameter in the risk-associated group (8.00 vs. 15.00 mm), which correlated with higher pre- and post-procedural RVSP, and greater procedural complexity. This aligns with observations by Karagoz et al (15). Who reported that cases with annular hypoplasia (median Z-score −2.6) undergoing balloon dilation required tailored strategies to avoid procedural complications and to achieve effective palliation? Balloon-annulus ratios were significantly lower in the risk-associated group (11.50 vs 14.00) in this study, an observation consistent with Rao S (16). Who in a systematic review suggested that optimal balloon/annulus ratios (1.2 to 1.25) are crucial for reducing restenosis without increasing the risk of PR. General anesthesia was utilized exclusively in the risk-associated group, possibly reflecting more complex anatomy, younger age, and lower body weight necessitating airway protection. This mirrors findings from studies by Mini et al, (17). And Sluysmans et al, (18). Which highlighted that patients with complex PS anatomy, including those with tetralogy of Fallot or critical valve anatomy, required more advanced procedural planning and anesthetic management. No intraoperative mortality was observed in either group, indicating the overall safety of the procedure across the spectrum of PS.

Although both groups demonstrated a significant reduction in peak pulmonary valve gradients by day-1, the residual RVSP remained higher in the risk-associated group (74.00 vs 65.50 mmHg; p=0.016). Residual gradients and RV pressures are known to predict restenosis and RV dysfunction, as shown in previous work by Hong et al, (19). Where a residual peak gradient >30 mmHg was associated with higher restenosis risk and requirement for reintervention. The most striking difference in this study was observed in early complications. Cardiac arrest occurred exclusively in the risk-associated group (16.0%; p=0.013), and day-1 mortality was reported in one patient from this group. By day-30, mortality had increased to 6 patients in the risk-associated group compared to 4 in the isolated PS group, indicating that the presence of additional risk features carries prognostic implications beyond the immediate post-procedural period. These findings are in line with those of Devanagondi et al (14). And Geggel et al, (20). Who noted higher adverse event rates among patients with central pulmonary artery involvement, critical PS, or low body surface area?

Despite effective pressure relief in both groups, PR and TR emerged as important considerations. Moderate PR was more common among risk-associated cases both at day-1 (25.0% vs 5.7%) and at day-30 (10.5% vs 6.5%). While these differences were not statistically significant, these suggest a tendency for more severe valvular sequelae in patients with complex anatomy. This supports long-term studies by Harrild et al (21). Who demonstrated that PR fraction >15% was associated with lower peak VO_2 and RV dilation on cardiac MRI, suggesting subclinical cardiopulmonary compromise that may evolve over time. Restenosis by day-30 occurred exclusively in the risk-associated group (21.1%, p=0.010), further affirming the structural and functional vulnerability of this subgroup. This finding is consistent with Hong et al (19). Who identified balloon-annulus ratio and residual pressure gradient as independent predictors of restenosis during medium-term follow-up? Patients with restenosis shared common features such as small annuli, RV hypoplasia, and moderate TR, supporting the concept that multifactorial anatomic and hemodynamic characteristics contribute to suboptimal outcomes in this cohort. The frequency of vascular complications (hematoma and occlusion), RVOT perforation, and infundibular stenosis was low overall and did not significantly differ between the two groups. These data reflect procedural safety when BPV is performed in experienced centers and with adherence to catheter-based protocols, as described by Amoozgar et al (22). And Ali et al (23).

Clinical implications of present findings are significant. These emphasize the need for risk stratification when selecting patients for BPV. While BPV remains an effective and generally safe intervention for isolated PS, those with risk-associated features may benefit from more tailored preprocedural planning, closer postprocedural surveillance, and possibly adjunctive strategies such as staged interventions or early surgical referral. The association between lower balloon-annulus ratios and restenosis reinforces the importance of careful sizing, particularly in patients with dysplastic valves or small annuli. Given the observed differences in RVSP, TR, and PR, echocardiographic follow-up should focus not only on transvalvular gradients but also on RV remodeling and regurgitant severity.

There are several limitations to this study. It was conducted in a single national tertiary care cardiac center, which may limit generalizability to centers with differing resources or patient populations. The follow-up duration was limited to 30 days; longer-term follow-up is necessary to assess outcomes such as sustained PR, RV dysfunction, exercise intolerance, and the need for reintervention. Due to the observational cross-sectional nature of the study, potential confounding factors such as inter-operator variability, genetic syndromes, and anatomic complexities were not fully controlled. Advanced imaging modalities such as cardiac MRI were not utilized to assess RV function or quantify regurgitation, limiting the ability to correlate hemodynamic changes with structural remodeling. Subgroup sizes were modest, which may affect the power to detect certain differences, particularly in complication rates. Despite these limitations, the study provides valuable insights into the differential impact of BPV in children with isolated versus risk-associated PS. By evaluating clinical, echocardiographic, procedural, and early post-intervention parameters in parallel, the findings offer a comprehensive view of the unique challenges and risks associated with more complex PS variants.

Conclusion

BPV remains an effective therapeutic option for PS. Patients with risk-associated features are more likely to experience higher residual RV pressures, greater regurgitant lesions, increased risk of cardiac arrest, and early restenosis.

This study underscore the importance of risk stratification and individualized procedural planning in optimizing BPV outcomes. Future studies with long-term follow-up and advanced imaging are warranted to refine management strategies and improve outcomes in this high-risk population.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-NIKR-124-23)

Consent for publication

Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

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Review of Literature, Data entry, Data analysis, and drafting article.

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All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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