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Echocardiographic Assessment of Cardiac Phenotype Predicts Complications and Guides Intensive Care Management Following Pulmonary Valve Balloon Dilation in Neonates With Pulmonary Atresia/Critical Pulmonary Stenosis With Intact Ventricular Septum

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ABSTRACT

Introduction: Pulmonary valve balloon dilation (PVBD) has largely replaced surgical decompression as the preferred treatment for neonates with pulmonary atresia with intact ventricular septum (PAIVS) or critical pulmonary stenosis (CPS). This study aims to evaluate whether echocardiographic morphological and functional assessment can predict early complications and guide intensive care management following PVBD in this population.

Methods: We retrospectively analyzed 27 neonates with PAIVS or CPS who underwent PVBD between 2017 and 2023. Patients were divided into Group A (tripartite right ventricle [RV], developed infundibulum) and Group B (bipartite RV, hypoplastic infundibulum). Echocardiographic, catheterization, and clinical data were reviewed and compared.

Results: Group A had higher rates of transient left ventricular systolic dysfunction (92.9% vs. 15.4%, $p < 0.001$) and required more ventilatory and inotropic support. Group B was more prone to infundibular spasm (76.9% vs. 21.4%, $p = 0.004$) and often needed beta-blockers or additional pulmonary blood flow.

Conclusion: Echocardiographic RV phenotype is associated with specific post-PVBD complications and may help guide early post-procedural management.

1 | Introduction

Pulmonary Atresia with Intact Ventricular Septum (PAIVS) and Critical Pulmonary Stenosis (CPS) are ductal-dependent congenital heart diseases characterized by right ventricular (RV) outflow tract obstruction and variable degrees of right ventricular

hypoplasia. Currently, transcatheter pulmonary valve balloon dilation (PVBD), following pulmonary valve (PV) perforation if needed, is the preferred treatment in neonates with membranous PAIVS or CPS, provided RV anatomy is adequate, the tricuspid valve (TV) annulus z-score acceptable, and there is no RV-dependent coronary circulation [1, 2]. Over time, surgical

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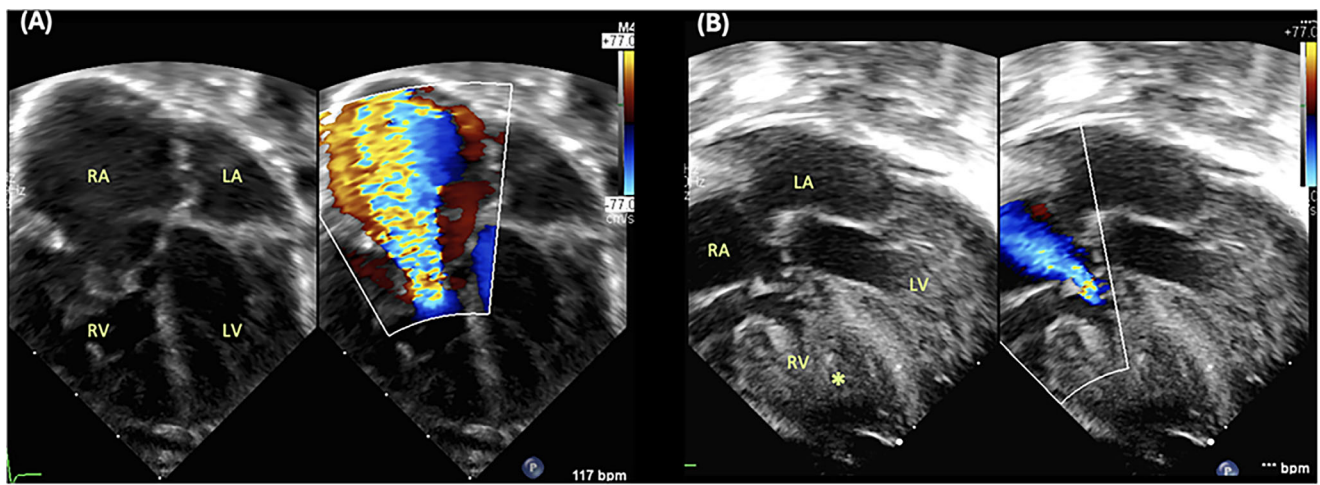


FIGURE 1 | Four-chamber view in neonates with pulmonary atresia and intact ventricular septum. (A) Group A: The right ventricle is tripartite with mild hypertrophy. The tricuspid valve is severely dysplastic, featuring an annular diameter within normal limits and severe regurgitation. Note the marked dilation of the right atrium. (B) Group B: The right ventricle is bipartite and markedly hypertrophied (*). The tricuspid valve has a hypoplastic annulus and exhibits mild-to-moderate regurgitation. LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle.

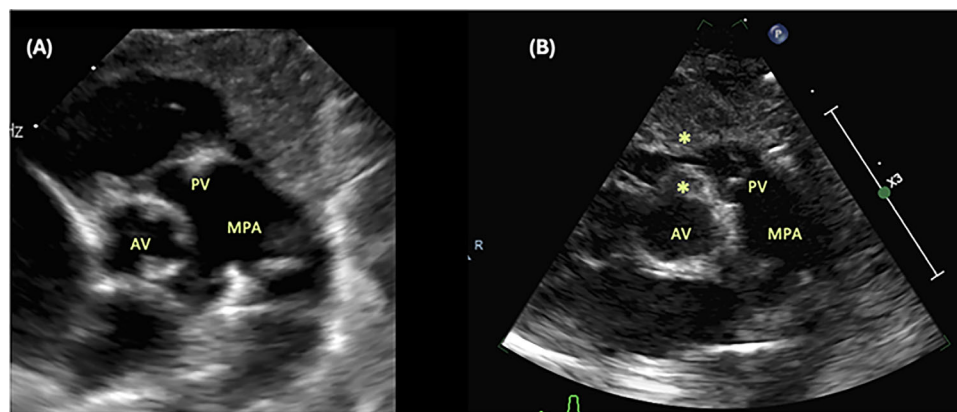


FIGURE 2 | Short-axis view in neonates with pulmonary atresia and intact ventricular septum. (A) Group A: The infundibulum is patent and well-developed. (B) Group B: The infundibulum is hypoplastic due to marked hypertrophy of its muscular walls and the infundibular septum (*). AV, aortic valve; MPA, main pulmonary artery; PV, pulmonary valve.

decompression \pm Blalock-Taussig shunt has been largely replaced by PVBD, with a significant reduction in morbidity and mortality [3–5]. RV morphology, TV annulus size, and coronary anomalies are key prognostic and management factors [6–10]. While therapeutic strategies based on RV morphology have been well described [1, 10, 11], little is known about post-procedural pharmacologic and intensive care approaches according to different cardiac phenotypes. The aim of this study is to assess whether echocardiographic morphological and functional analysis can predict complications, clinical outcomes, and the type of intensive treatment required soon after PVBD in patients with PAIV and CPS.

2 | Methods

2.1 | Study Population and Patients' selection

We retrospectively analyzed newborns diagnosed with either PAIVS or critical PS (requiring prostaglandin infusion) treated

with transcatheter PV valvuloplasty \pm PV radiofrequency perforation at our institution between October 2017 and August 2023. Patients were divided into two groups (Group A and Group B) based on the morphology of the RV and the Infundibulum.

Group A patients had a mildly hypertrophic but tripartite RV, and a well-developed, patent infundibulum. Group B included patients with a borderline, bipartite RV, with a markedly attenuated pars trabeculata, and a hypoplastic infundibulum due to various degrees of subvalvular pulmonary muscle overgrowth (Figures 1, 2).

Neonates older than 1 week at cardiac catheterization and with a severe, but non-ductal-dependent PV stenosis, were excluded from the study. Patients with a RV-dependent coronary circulation, those who underwent surgical RV decompression and univentricular palliation, were also excluded. The study was approved by the Institutional Review Board of Bambino Gesù Children's Hospital, Rome.

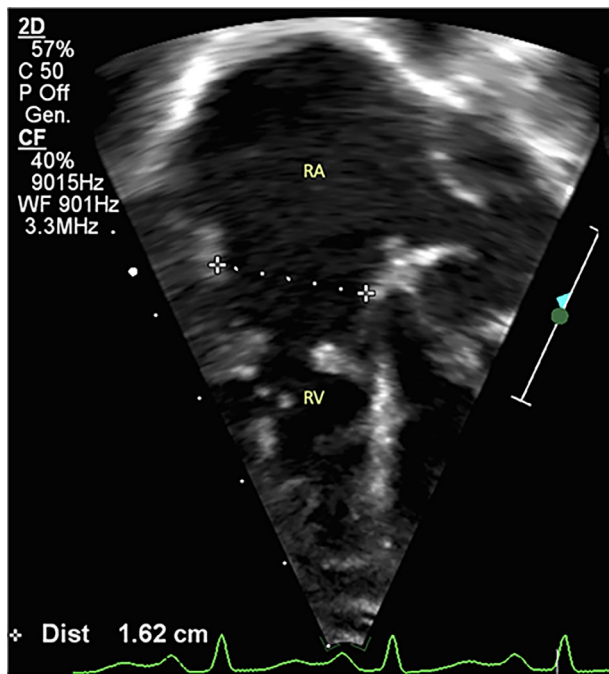


FIGURE 3 | Tricuspid valve annulus measurement. The tricuspid annular diameter is measured at the leaflet hinge points during diastole, corresponding to the maximal annular size. RA, right atrium; RV, right ventricle.

2.2 | Echocardiography and Cardiac Catheterization

Neonatal echocardiograms before and after transcatheter PV valvuloplasty, cardiac catheterizations and clinical records were analyzed. Echocardiograms were performed using a Philips EPIQ CVx ultrasound machine with 8 and 12 MHz probes. A complete echocardiographic assessment, including morphological and functional analysis as described below, was performed before and within 14 days after PVBD. Following cardiac catheterization, the echocardiogram with the lowest LV ejection fraction (EF) was analyzed. Annular diameters and z-scores were measured for atrioventricular valves in the four-chamber view (See Figures 3), for the aortic valve (AV) in the long-axis view and for the PV in the short-axis view. RV systolic pressure was estimated from the tricuspid regurgitant jet velocity using the modified Bernoulli equation. RV systolic function was assessed by measuring TAPSE (tricuspid annular plane systolic excursion) and TV S' (tricuspid valve annular systolic velocity) from the apical four-chamber view. TAPSE represents the longitudinal displacement of the TV annulus during systole, TV S' reflects its peak systolic velocity on tissue Doppler. Clips from four-chamber view and short-axis view were imported into an offline speckle-tracking analysis software (2D cardiac performance analysis, TomTec Imaging Systems, GmbH; Munich, Germany). The software automatically traced the endocardial borders for a single cardiac cycle, after which subsequent manual adjustments were made by a single investigator to optimize tracking accuracy, and automatically calculated peak LV global longitudinal strain (GLS) and EF. Infundibular spasm was defined on echocardiographic assessment as dynamic narrowing of the infundibulum with high-velocity flow (≥ 2.5 m/s) and a late-peaking, dagger-shaped Doppler profile, consistent

with dynamic infundibular obstruction. Cardiac catheterization data were collected from reports generated after the procedures and included pre- and post-PVBD RV systolic pressure, systolic aortic pressure, and ratio of RV systolic pressure to systolic aortic pressure.

2.3 | Statistical Analysis

Continuous variables were presented as mean (standard deviation) or median (interquartile range) as appropriate, while categorical variables were presented as frequency (percentage). Comparisons between the two groups were made using the Wilcoxon rank sum test or unpaired *t*-test for continuous variables and Fisher's exact test for categorical variables. Data were analyzed using SPSS Statistics 28.0 (IBM; Armonk, NY, USA) statistical software.

3 | Results

3.1 | Patients' Characteristics and Neonatal Echocardiographic Examination

Among the 27 patients analyzed, 14 were assigned to Group A and 13 to Group B. A total of 21 patients had a prenatal diagnosis of PAIVS or CPS. The median follow-up time was 16 months (IQR 12–46 months), and no deaths occurred.

Patients in Group A had a significantly larger TV annulus diameter compared to patients in Group B, both in absolute value (11.8 ± 2.3 vs. 9.5 ± 1.8 , $p = 0.007$) and z-score (0.73 ± 1.3 vs. -1.50 ± 1.0 , $p < 0.001$) terms. The PV annulus diameter was also significantly larger in patients in Group A. No significant differences were found between the two groups regarding the MV and AV annuli, the degree of tricuspid regurgitation, and RV systolic pressure. All comparisons are shown in Table 1.

3.2 | Cardiac Catheterization

The age at PVBD was comparable in both groups. There were no significant differences observed in pre- and post-PVBD RV systolic pressure, aortic systolic pressure, or the ratio of RV systolic pressure to aortic systolic pressure between the two groups. Detailed cardiac catheterization data are provided in Table 2.

Echocardiographic Functional Assessment, Clinical Management, and Outcomes After PVBD: Radiofrequency perforation of the PV was performed in 8 out of 27 patients, 5 in Group A and 3 in Group B. The median age at PV valvuloplasty was 2.5 days (IQR 2–4 days). Before PVBD, Group A showed better right ventricular systolic function with significantly higher TAPSE (0.8 ± 0.2 vs. 0.6 ± 0.2 cm, $p = 0.016$) and TV S' (6.5 ± 1.5 vs. 4.6 ± 1.0 cm/s, $p = 0.001$). Post-PVBD, TV S' remained significantly higher in Group A (6.7 ± 1.2 vs. 5.0 ± 0.9 cm/s, $p < 0.001$), while TAPSE showed a non-significant trend (0.9 ± 0.3 vs. 0.6 ± 0.5 cm, $p = 0.076$). Before cardiac catheterization, patients in both groups exhibited good left ventricular (LV) systolic function, with normal EF and GLS

TABLE 1 | Echocardiographic measurements of atrioventricular and semilunar valves annuli.

Parameter	Group A (n = 14)	Group B (n = 13)	p value
TV annulus (mm)	11.8 (2.3)	9.5 (1.8)	0.007
TV annulus (z-score)	0.7 (1.3)	−1.5 (1.0)	<0.001
MV annulus (mm)	12.3 (1.5)	11.4 (1.4)	0.157
MV annulus (z-score)	1.1 (0.9)	0.9 (0.8)	0.511
MV/TV	1.1 (0.2)	1.3 (0.3)	0.101
AV annulus (mm)	7.3 (0.8)	6.9 (0.9)	0.393
AV annulus (z-score)	0.5 (0.3)	0.3 (0.2)	0.429
PV annulus (mm)	6.5 (0.7)	5.4 (0.9)	0.004
PV annulus (z-score)	−1.0 (0.9)	−2.0 (0.6)	0.006
AV/PV	1.0 (0.1)	1.3 (0.1)	0.009

Note: Comparison of echocardiographic parameters in Group A (tripartite right ventricle with mild hypertrophy) and Group B (bipartite right ventricle with hypoplastic infundibulum). Significant differences are observed in tricuspid and pulmonary valve measurements.

Abbreviations: AV, aortic valve; MV, mitral valve; PV, pulmonary valve; TV, tricuspid valve.

TABLE 2 | Hemodynamic changes before and after pulmonary valve balloon dilation in Groups A and B during cardiac catheterization.

Parameter	Group A (n = 14)	Group B (n = 13)	p value
Pre-PVBD RVSP (mmHg)	90 (22)	83 (23)	0.470
Pre-PVBD SBP (mmHg)	62 (7)	58 (6)	0.136
Pre-PVBD RVSP/SBP	1.4 (0.3)	1.5 (0.5)	0.917
Post-PVBD RVSP (mmHg)	48 (11)	46 (9)	0.622
Post-PVBD SBP (mmHg)	61 (7)	52 (6)	0.114
Post-PVBD RVSP/SBP	0.8 (0.2)	0.8 (0.1)	0.719

Note: No significant differences were observed between the groups in the RVSP or SBP following the procedure.

Abbreviations: PVBD, pulmonary valve balloon dilation; RVSP, right ventricular systolic pressure; SBP, systolic blood pressure.

values. After PVBD, 13 out of 14 patients in Group A developed transient LV systolic dysfunction (13 [92.9%] group A vs. 2 [15.4%] group B, $p < 0.001$) at a median post-procedure time of 3 days (IQR 2–6 days). The median duration of LV dysfunction was 4 days (IQR 3–5 days). Statistically significant differences were observed between the two groups regarding both EF ($45\% \pm 7\%$ group A vs. $58\% \pm 9\%$ group B, $p = 0.001$) and GLS ($-17.1\% \pm 4\%$ group A vs. $-20.4\% \pm 3\%$ group B, $p = 0.025$). A significantly higher number of patients in Group B compared to Group A developed infundibular reaction with muscle spasm after PV valvuloplasty (3 [21.4%] group A vs. 10 [76.9%] group B, $p = 0.004$). All patients in Group A were treated with an inodilator (milrinone or levosimendan), while 9 out of 10 patients in Group B were treated with a beta-blocker (intravenous esmolol followed by oral

TABLE 3 | Clinical outcomes and post-operative findings.

Parameter	Group A (n = 14)	Group B (n = 13)	p value
Radiofrequency perforation	5 (35.7)	3 (23.1)	0.472
LV dysfunction	13 (92.9)	2 (15.4)	<0.001
Pre-PVBD EF (%)	64 (6)	63 (8)	0.695
Pre-PVBD GLS (%)	20.2 (2.7)	19.7 (3.6)	0.663
Post-PVBD EF (%)	45 (7)	58 (9)	0.001
Post-PVBD GLS (%)	17.1 (4.0)	20.4 (3.2)	0.025
Pre-PVBD TAPSE (cm)	0.8 (0.2)	0.6 (0.2)	0.016
Pre-PVBD TV S' (cm/s)	6.5 (1.5)	4.6 (1.0)	0.001
Post-PVBD TAPSE (cm)	0.9 (0.3)	0.6 (0.5)	0.076
Post-PVBD TV S' (cm/s)	6.7 (1.2)	5.0 (0.9)	<0.001
Inotropes	13 (92.9)	5 (38.5)	0.004
Infundibular spasm	3 (21.4)	10 (76.9)	0.004
β -blocker	2 (14.3)	10 (76.9)	0.006
Post-PVBD Severe PR	5 (35.7)	6 (46.2)	0.691
Post-PVBD Moderate TR	7 (50.0)	5 (38.5)	0.431
PDA Stent/BT shunt	2 (14.2)	4 (30.8)	0.316
Mechanical ventilation (hours)	36 (14)	15 (7)	<0.001
Gastrointestinal complications	4 (28.6)	0 (0)	0.098
CICU (days)	17 (8)	21 (13)	0.470
Hospitalization (days)	30 (9)	34 (13)	0.409

Note: Clinical outcomes and complications following pulmonary valve balloon dilation. Group A patients exhibited higher rates of transient left ventricular dysfunction, while Group B patients were more likely to experience infundibular spasm and require beta-blocker therapy.

Abbreviations: BT, Blalock-Taussig; CICU, cardiac intensive care unit; EF, ejection fraction; GLS, global longitudinal strain; PDA, patent ductus arteriosus; PR, pulmonary regurgitation; PVBD, pulmonary valve balloon dilatation; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; TV S', tricuspid valve annular systolic velocity.

propranolol). In our cohort, before discharge, due to persistent desaturation and inability to wean off prostaglandins, 6 patients of group B required an additional source of pulmonary blood flow (4 patients underwent stenting of the ductus arteriosus and 2 underwent a Blalock-Taussig shunt).

The duration of intensive care unit stay was comparable between the two groups, with no significant difference in total hospitalization days (30 ± 9 days in Group A vs. 34 ± 13 days in Group B, $p = 0.409$). Patients in Group A required a significantly longer duration of mechanical ventilation following cardiac catheterization (36 ± 14 h vs. 12 ± 7 h in Group B, $p < 0.001$). Gastrointestinal complications, including abdominal distension and pre-necrotizing enterocolitis, were more frequent in Group A, although this difference did not reach statistical significance (4 [28.6%] vs. 0 [0%], $p = 0.091$). A detailed comparison of outcomes is presented in Table 3.

4 | Discussion

We demonstrated that echocardiographic assessment of RV anatomy plays a crucial role in patient stratification and in predicting complications, different pathophysiological patterns, and therefore, treatment strategies after PV valvuloplasty. Group A patients exhibit a normal TV and PV annulus diameter, a tripartite RV with mild hypertrophy, and a patent, well-developed infundibulum. Transient LV systolic dysfunction was observed in almost all Group A patients, typically emerging within a few days after PVB and resolving within 3 to 5 days. This finding aligns with the study by Ronai et al., who described a similar pattern in neonates with well-developed RVs. Among the risk factors identified, a higher TV z-score was significantly associated with LV dysfunction. Several mechanisms have been proposed to explain this phenomenon, including altered ventricular-ventricular interaction following acute RV decompression, transient myocardial ischemia due to coronary steal, and abrupt changes in LV loading conditions, particularly in the presence of a patent ductus arteriosus (PDA) [12]. In a subsequent study by the same group, strain imaging showed that the most affected myocardial segments were septal, further supporting the hypothesis that interventricular dependence plays a key role in this reversible dysfunction [13].

Consistent with these findings, in our cohort, nearly all patients with adequately sized RVs developed some degree of LV systolic dysfunction. During this phase, the coexistence of antegrade flow through the opened PV and retrograde flow through a still-PDA may contribute to transient LV overload, especially as the PDA is expected to close within a few days after stopping prostaglandin. LV systolic dysfunction, combined with diastolic runoff through the PDA, results in reduced cardiac output and impaired systemic oxygen delivery.

Clinically, this scenario poses risks such as systemic hypoperfusion, mesenteric ischemia, necrotizing enterocolitis, and pulmonary volume overload [14]. Therefore, our management strategies are centered around three key interventions:

1. **Mechanical Ventilation:** Used for up to several days post-cardiac catheterization to minimize oxygen consumption.
2. **Inodilators:** Administered (e.g., milrinone or levosimendan) to support LV function, decrease systemic vascular resistance, and enhance oxygen delivery and cardiac index [15, 16].
3. **Diuretics:** Utilized based on the degree of pulmonary congestion and tricuspid regurgitation.

Patients are reintroduced to feeding very gradually due to the heightened risk of mesenteric hypoperfusion. A few days following the procedure, as systolic function improves, extubation is generally performed, with most patients experiencing an excellent long-term prognosis.

In contrast, patients in group B present with hypertrophy and varying degrees of reduction in the trabecular portion of the RV. The infundibulum also tends to be more hypoplastic and is prone to spasm and increased hypertrophy following PVB. The clinical manifestations in these patients are largely dictated by the severity of RV hypertrophy and diastolic dysfunction [10,

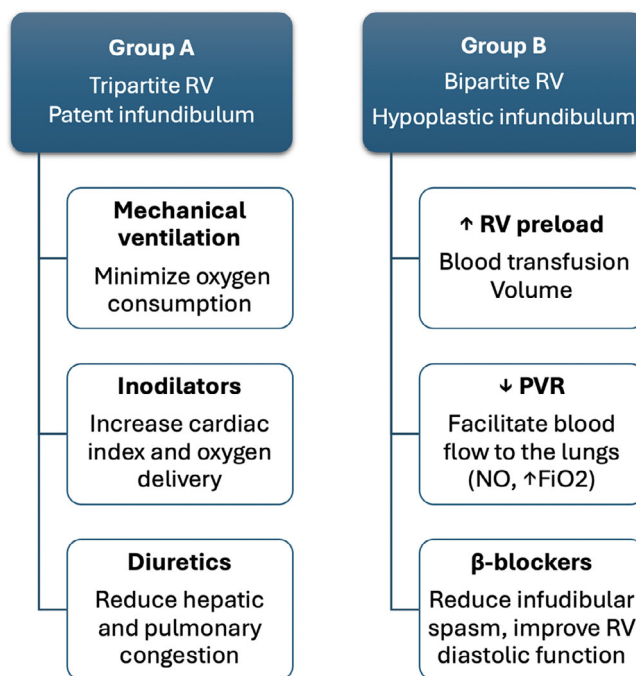


FIGURE 4 | Post-procedural management strategies based on right ventricular morphology. Therapeutic approaches for Group A (tripartite RV) and Group B (bipartite RV) neonates with pulmonary atresia and intact ventricular septum, highlighting key interventions tailored to RV morphology. RV, right ventricle.

17]. The infundibulum in Group B is often markedly hypertrophied and narrowed, making it more susceptible to dynamic obstruction during balloon dilation. We believe that this muscular hyperreactivity leads to transient infundibular spasm, triggered by sudden mechanical stretching and irritation during PVB. This is supported by the echocardiographic finding of dynamic narrowing with a late-peaking, dagger-shaped Doppler profile, consistent with significant subvalvular obstruction. Discontinuation of prostaglandins can lead to severe cyanosis. Therapeutic management in these cases includes:

1. **Optimizing RV Preload:** Achieved through volume resuscitation and blood transfusions.
2. **Beta-Blockers:** Administered to mitigate infundibular spasm and improve right ventricular compliance.
3. **Maintaining Low Pulmonary Vascular Resistance:** Potentially achieved by increasing fractional inspired oxygen or administering nitric oxide.

At this stage, treatment decisions are guided by arterial saturation levels following PDA closure. If systemic arterial saturation remains above 70%–75%, the patient is managed with chronic oral beta-blocker therapy. However, if saturation falls below 70% for at least 1 week despite optimal medical therapy and at least two attempts to discontinue prostaglandins, we consider the addition of an accessory pulmonary flow source, initially through ductus arteriosus stenting (Figures 4). Beta-blockers are commonly employed in pediatrics for hypertrophic cardiomyopathy, where they reduce outflow tract obstruction and enhance diastolic function and filling time [18, 19]. Despite their broad use,

no studies have specifically evaluated their efficacy in patients with PAIVS/CPS. Additionally, the mechanisms allowing some hypertrophied, bipartite RVs to sustain right cardiac output and undergo progressive growth remain unclear. In many cases, despite effective decompression and adequate flow through the TV, often facilitated by the presence of a small atrial septal defect, diastolic dysfunction persists, necessitating further surgery or interventions over time [20].

Interestingly, we observed no significant difference between the two patient groups in terms of average length of stay in the intensive care unit or overall duration of hospitalization. Despite substantial internal variability within each cardiac phenotype, both groups face distinct but equally complex complications and management challenges.

4.1 | Limitations of the Study

This study has several limitations. First, its retrospective design and single-center setting may limit the generalizability of the findings. Second, the sample size, although meaningful given the rarity of PAIVS and CPS, remains relatively small. Nevertheless, the use of shared protocols and consistent echocardiographic assessment within a single institution may have helped mitigate some variability. Future multicenter prospective studies are needed to confirm these findings and improve generalizability.

5 | Conclusion

RV phenotype is closely associated with distinct early complications following PVB. Tripartite RVs were associated with transient left ventricular dysfunction, while bipartite RVs showed a higher incidence of infundibular spasm and need for additional pulmonary blood flow. Early imaging-based stratification may help optimize immediate post-procedural management.

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