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# Outcome of Balloon Valvuloplasty in Children with Pulmonary Valve Stenosis – Multi-Center Experience

**Mohamed Abdelsaboor[1], Amal Mahmoud El-Sisi[2], Saud M. Elsaughier[*3], Mohamed Nashat Moawed[1], Naggeh Mohammed Mahmoud[3]**

Departments of [1]Pediatrics and [3]Cardiology, Cardiology, Faculty of Medicine, Aswan University, Egypt

Department of [2]Pediatrics, Faculty of Medicine, Cairo University, Egypt

***Corresponding author:** Saud M. Elsaughier, **Mobile**: (+20)01157166779, **E-mail**: soud_elsoughier_66@yahoo.com

## ABSTRACT

**Background:** Pulmonary valve stenosis (PS) is a prevalent congenital heart disorder in children, and symptoms include chest distress, dyspnea, cyanosis, and heart failure in its severe criteria. **Objective:** To learn more about the short-term results of balloon pulmonary valvuloplasty in children who had severe pulmonary stenosis.

**Patients and methods:** Between January 2015 and December 2018, a 4-year cross-sectional study was conducted in various centers across Egypt, with funding from the "Dar Al Orman charity". We included 146 Children varied from 5 months to 17 years of either sex diagnosed as severe pulmonary stenosis' case with doming valve with mean value of peak pressure gradient across the pulmonary valve of 74 mmHg on echocardiography. Patients were intervened with balloon-valvuloplasty. **Results:** There were 74 (50.7%) men and 72 (49.3%) women among the 146 patients. The average age was 5.34 (SD 0.5) years. On echocardiography, the mean pre-cath gradient via the pulmonary valve was 74.44 (SD 9.5) mmHg. The mean pressure gradient across PV was 19.54 (SD 1.9) mmHg after the intervention, (P-value 0.001). Before intervention, the pulmonary valve annulus on echocardiography varied from 8.5 to 20 mm, with a mean of 13.44 (SD 3.2) mm. Most patients (89%) had no complications. Only 2 (1.4%) patients had severe pulmonary valve regurgitation, and 1 (0.7%) patient had right ventricular outflow tract perforation (0.7%). **Conclusion:** Balloon pulmonary valvuloplasty is the preferred treatment for stenosis of the pulmonary valve in people of all ages, and it has few side effects.

**Keywords:** Pulmonary valve stenosis, Pulmonary valvuloplasty, Outcome, Children.

## INTRODUCTION

Pulmonary valve stenosis (PS) is a prevalent congenital heart disorder in children. It could be asymptomatic with an incidental outcome of a symptomatic or murmur with cyanosis, dyspnea, malfunction in severe stenosis, and chest pain [(1)]. **Patel *et al.*** [(2)] found that the pulmonary valve stenosis' incidence was 3.1%. PS is said to be more prevalent in Asian nations than in Western nations like Europe and United States [(3-5)].

PS occur alone or conjugated with other congenital heart diseases (CHDs) involving a ventricular septal defect, patent ductus arteriosus, patent foramen ovale, or atrial septal defect. PS is divided into three subtypes: sub valvular stenosis, most valvular stenosis, and supra valvular stenosis [(6)].

Treatment of choice for children with severe, intensive, or moderate PS is pulmonary balloon valvuloplasty, which is an effective and safe method [(7)]. **Kan *et al.*** [(8)] performed the first trans-catheter balloon pulmonary valvuloplasty (BPV) in 1982, and pulmonary valvuloplasty has since become the desired approach for simple PS patients with minimally invasive strategies and favorable findings.

The majority of the information on the outcomes and effectiveness of pulmonary valve ballooning comes from developed nations, but information from developing nations is scarce. The purpose of this study is to gain knowledge about the pulmonary valvuloplasty's outcomes in children with PS in low-resource settings in a number of centers along through Egypt that are all endorsed by the "Al Orman charity."

## PATIENTS AND METHODS

### Study population

**A** retrospective study of 146 PS children who received BPV was carried out; done in different centers all-over Egypt in four years in the period between January, 2015 and December, 2018, sponsored by "Dar Al Orman charity". Individuals of either sex diagnosed with severe PS associated with doming pulmonary valve and aged 17 years or less at the time of intervention met the inclusion criteria. PS patients without hemodynamic compromise, who had a patent atrial septal defect (ASD), atrial septal defects (ASDs), ventricular septal defects (VSDs), or patent ductus arteriosus (PDA), were involved in the study. Children with mild PS who did not require intervention, syndromic characteristics, other related congenital cardiac anomalies needing surgery, and other heart disorders related to hemodynamic compromise were all ruled out.

### Definition

In this study, the transpulmonary pressure gradient was utilized to conduct a quantitative evaluation of PS intensity. PS severity was ascertained utilizing 2006 ACC/AHA recommendations for valvular heart disease management [(9)].

### Data collection

Blood tests, biochemistry, cardiac catheterization, hepatic and kidney function, 12-lead electrocardiogram (ECG), coagulation time, chest



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radiography, arterial blood gas, transthoracic echocardiography (TTE), and angiography were all completed by all patients prior to surgery.
Outcome included the immediate results whether successful achievements or complication as well as the follow-up data till one-year post-procedure. Age, gender, pre-cath echocardiography, post-ballooning pulmonary valve (PV) gradient, cath pulmonary valve annulus, and follow-up gradient on echocardiography at 3, 6, and 12 months have all been recorded. Complications during the procedure were also recorded.

**Echocardiographic data**
The PV morphology and the velocity flow, the peak PVS gradient, the right ventricular dimensions, the tricuspid regurgitation's degree and pulmonary valve, and the left ventricular dimensions and function were all investigated utilizing standard M-mode and two-dimensional echocardiographic view points, and also color Doppler and continuous-wave Doppler. The transpulmonary flow velocity curve was used to quantify the maximum peak instantaneous systolic pressure gradient by utilizing the simplified Bernoulli equation ($\triangle p= 4v^2$).

**Cardiac catheterization and angiography**
For right cardiac catheterization, venous access was usually gained through the femoral vein, in which the balloon floating catheter or pig tail was inserted. A single balloon was used for all of the procedures. RV-PA PSEG, pulmonary artery (PA) systolic pressure, and right ventricular (RV) systolic pressure were all obtained from the preliminary PBPV cardiac catheterization and postoperative findings.

**Ethical consent:**
**An approval of the study was obtained from Aswan University Academic and Ethical Committee. Informed consent was obtained from written informed consent was taken from guardians of the children for participation in the study, after being informed about the aims and process of the study as well as applicable objectives. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.**

**Statistical analysis:**
The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 23 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Categorical variables are conveyed as frequency with percentage while continuous variables are described as median and mean with interquartile range (IQR). The categorical variables were contrasted utilizing the Fisher's exact or Chi-square test. To contrast continuous variables among groups, the Wilcoxon rank-sum test was utilized. While adjusting for potential confounding variables, a logistic regression analysis was utilized to recognize the PR severity and restenosis' independent risk factors. The confidence intervals (CI) and odds ratios (OR) were calculated. The Kaplan-Meier curve was used to assess the likelihood of repetitive PBPV or surgical intervention. P value $\leq 0.05$ was considered significant.

## RESULTS

**Patients' baseline characteristics**
A total of 146 patients were included in the study. Female subjects represented 50.7% (74 patients) and male subjects represented 49.3% (72 patients). The mean age of the studied subjects was 5.34 (SD 0.5) years, and the age ranged from 5 months to 17 years; Mode is one year (the most frequently encountered age) with 52 subjects of one year age and younger. The mean weight of the studied subjects was 19.56 (SD 1.4) kg (ranged from 5 to 69 Kg), and the mean height was 123 (SD 13.9) Cm (range 62-169 Cm). A total of 126 subjects were asymptomatic (86.3%) while 20 subjects were symptomatic by shortness of breath with activity (13.7%). The mean pressure gradient across the pulmonary valve by transthoracic echocardiography (TTE) was 74.4 (SD 9.5) mmHg.

The mean pre-procedure right ventricular (RV) systolic pressure by transthoracic echocardiography (TTE) was 89.3 (SD 8.9) mmHg. The mean pre-procedure pulmonary artery (PA) pressure by transthoracic echocardiography (TTE) was 11.7 (SD 2.3) mmHg.

The valvular pulmonary stenosis was presented as solitary lesion in 126 (86.3%) subjects and associated with other cardiac lesions in 20 (13.7%) subjects. Eight (5.6%) of these subjects had secundum ASD. Four (2.7%) of these subjects had patent ductus arteriosus. Four (2.7%) of these subjects had ventricular septal defects. The Mean pulmonary valve annulus diameter by transthoracic echocardiography (TTE) was 13.44 (SD 3.2 mm), ranging from 8.5- 20mm **(Table 1).**

**Table (1): Patients' baseline characteristics.**

| Variable | Mean (Range/ %) |
|---|---|
| **Age (Years)** | 5.34 ± 0.5 |
| **Weight (Kg)** | 19.56 ± 1.4 |
| **Height (Cm)** | 123.61 ± 13.9 |
| **Gender** | |
| **Females** | 74 (50.7%) |
| **Males** | 72 (49.3%) |
| **Peak echocardiographic PVS gradient (mmHg)** | 74.44 ± 9.5 |
| **Pulmonary annulus diameter (mm)** | 13.44 ± 3.2 (8.5 - 20) |
| **Balloon/annulus ratio** | 1.26 ± 0.06 (1.15 – 1.40) |
| **Clinical symptoms** | 126 (86.3%) |
| **Other Cardiac Lesions** | 20 (13.7%) |

The mean balloon size utilized for PV dilatation was 17 mm ranging from 10 to 25 mm. The mean Balloon/Annulus ratio was 1.26 (SD 0.06), with a variation of 1.15-1.40 and median of 1.25. Tyshak II balloon was used in 143 (95.9%) subjects and Z-Med balloon was used in 3 (2.1%) subjects **(Table 2).**

**Table (2): Balloon-related features of the studied BPV sample.**

| Variable | Category | n = 146 |
|---|---|---|
| **Balloon Type** | TYSHAK II | 143 (97.9%) |
| | Z-MED | 3 (2.1%) |
| **Balloon Size** | Mean ± SD | 17.00 ± 4.3 |
| | Median (Range) | 15 (10 - 25) |
| **Balloon/Annulus Ratio** | Mean ± SD | 1.26 ± 0.06 |
| | Median (Range) | 1.25 (1.15 - 1.40) |

**Immediate results of percutaneous balloon pulmonary valvuloplasty**

The mean value of mean pulmonary artery pressure (MPA) before and immediately after BPV was 11.7 (SD 2.3) mmHg and 13.40 (SD 2.4) mmHg, respectively. The mean systolic right ventricular pressure (SRV) before and immediately after BPV was 89.33 (SD 8.9) mmHg and 43.05 (SD 7.8) mmHg, respectively. The mean value of peak pressure gradient across the pulmonary valve (PV) before balloon valvoplasty (BBV) and immediately after balloon valvoplasty (IABV) was 74.44 (SD 9.5) mmHg and 19.54 (SD 1.9) mmHg, respectively. The IABV value had dropped to less than the half BBV value in 140 (95.9%) subjects. Pulmonary valve regurgitation immediately after balloon valvoplasty was noted to be mild in 116 (79.5%) subjects, moderate in 28 (19.2%) subjects, severe in 2 (1.4%) subjects **(Table 3).**

**Table (3): Immediate outcomes of BPV**

| Variable | Category | n = 146 | P-value |
|---|---|---|---|
| **Systolic RV mmHg** | Pre- | 89.33 ± 8.9 | <0.001* |
| | Immediately-Post | 43.05 ± 7.8 | |
| **Mean PAP mmHg** | Pre- | 11.07 ± 2.3 | <0.001* |
| | Immediately-Post | 13.40 ± 2.4 | |

The total incidence of complications was 11% (16 subjects). No deaths happened. Perforation of right ventricular outflow tract (RVOT) was reported in 1 (0.7%) subject. Severe pulmonary valve regurgitation (PR) was reported in 2 (1.4%) subjects.

Significant tricuspid valve regurgitation (TR) was reported in 1 (0.7%) subject. Moderate tricuspid valve regurgitation (TR) was reported in 2 (1.4%) subjects. local hematoma was reported in 4 (2.7%) subjects. Vascular occlusion was reported in 6 (4.1%) subjects **(Table 4).**

**Table (4): Post-procedure Complications and plans of the studied BPV sample.**

| Variable | Category | n = 146 |
|---|---|---|
| **Complications** | No | 130 (89%) |
| | Vascular Occlusion | 6 (4.1%) |
| | TR | 5 (3.5%) |
| | Local Haematoma | 4 (2.7%) |
| | RVOT Perforation | 1 (0.7%) |
| **Post-PR** | No | 0 (0%) |
| | Mild | 116 (79.5%) |
| | Moderate | 28 (19.2%) |
| | Severe | 2 (1.4%) |

**Follow-Up**

**Echocardiographic results**

The mean value of peak pressure gradient across the PV before BBV and IABV was 74.44 (SD 9.5) mmHg and 19.54 (SD 1.9) mmHg, respectively. The mean values of peak pressure gradient across the pulmonary valve at 3-month, 6-month and 1-year follow up were 20.1 (SD 2.8) mmHg, 22 (SD 2.4) mmHg and 24.4 (SD 2.1) mmHg, respectively. Right ventricular hypertrophy (RVH) degree at 3-month follow up was mild in 88 (60.2%) subjects, moderate in 56 (38.4%) subjects, and severe in 2 (1.4%) subjects. At 6-month follow up, there was no right ventricular hypertrophy (RVH) in 4 (2.7%) subjects, mild RVH in 132 (90.4%) subjects and moderate in 14 (9.6%) subjects with no subjects with severe degree RVH. At 1-year follow up, there was no RVH in 76 (52.1%) subjects, mild RVH in 56 (38.4%) subjects and moderate in 14 (6.9%) subjects **(Table 5).**

**Table (5): Pressure gradients across the pulmonary valve, immediate & follow-up results**

| Variable | Category | n = 146 | P-value* | P-value** |
|---|---|---|---|---|
| **PV Peak PG** | BBV (I) | 74.44 ± 9.5 | < 0.001 | I vs. II < 0.001 |
| | | | | I vs. III < 0.001 |
| | IABV (II) | 19.54 ± 1.9 | | I vs. IV < 0.001 |
| | | | | I vs. V < 0.001 |
| | 3-months (III) | 20.11 ± 2.8 | | II vs. III =0.221 |
| | | | | II vs. IV = 0.021 |
| | 6-months (IV) | 22.03 ± 2.4 | | II vs. V < 0.001 |
| | | | | III vs. IV = 0.011 |
| | 1-year (V) | 24.38 ± 2.1 | | III vs. V < 0.001 |
| | | | | IV vs. V = 0.009 |

**Residual stenosis and restenosis during follow-up**

Twenty-one subjects needed balloon pulmonary valve redilatation (14.4), 18 (12.3%) of them had undergone balloon redilatation till the time of data collection **(Table 6).**

**Table (6): Re-intervention plans among the studied subjects.**

| Variable | Category | n = 146 |
|---|---|---|
| **Need for Re-dilatation** | **Yes** | 21 (14.4%) |
| | **No** | 125 (85.6%) |
| **Re-dilatation Done** | **Yes** | 23 (15.8%) |
| | **No** | 123 (84.2%) |
| **Need for Surgery** | **Yes** | 4 (2.7%) |
| | **No** | 142 (97.3%) |

## DISCUSSION

Since 1982[8], BPV is a primary method that has been extensively utilized for PS medication. Many studies have debated the safety, effectiveness, practicality, and feasibility of this approach. We conducted a retrospective review of 146 pediatric subjects definitively diagnosed with PS, and all study participants had undergone BPV. The centers hosting the catheterization processes are numerous and widely distributed across the Egyptian four-corners. They included governmental university hospitals (Cairo, Ain-Shams, Mansoura, Tanta, Assiut, Sohag, Aswan, etc), also included private universities, insurance hospitals and general hospitals of Ministry of Health and Population.

BPV's immediate, intermediate-, short-, and long-term efficiency and safety in various centers have been documented in various studies [10-13]. **Hong *et al.*[14]** noted a 6.4% (10 of 158) restenosis rate and a 3.7% (6 of 158) re-intervention rate in a prior study, indicating BPV was chosen as the primary intervention because it was both protected and minimally invasive. **Hansen *et al.*[15]** recently published a multicenter study with the lengthiest follow-up period of nearly up to 25 years, in which 83% of study participants (n = 207) had a significant reduction in PS after preliminary BPV, while 17% considered repeat intervention necessary.

An overall of 146 subjects were involved in the study, with 72 males expressing 49.3% and 74 females expressing 50.7% of the studied patients. These results are comparable to those reported in the study of **Razzaghi *et al.*[16]** that demonstrated the slight overall female dominance of CHDs (50.6%).

The studied subjects' mean age was 5.34 years and the age variation is from 5 months to 17 years. The smallest baby in our study weighed 5 kg, while the heaviest was 69 kg, with a mean of 19.56 (SD 1.4) kg.

Initially, echocardiography was used to acquire the haemodynamic data's majority from patients with pulmonary valve stenosis. As per **Gielen *et al.* [17],** Doppler echocardiography allows for the stenosis estimation in all age groups.

As per echocardiographic collected data prior to balloon pulmonary valvuloplasty, the mean pressure gradient via the pulmonary valve in all age categories was roughly 74.49.5 mmHg (the pressure gradient is 55 mmHg at the lowest point and 110 mmHg at the highest point).

BPV was tried in all individuals with a peak-to-peak systolic gradient equivalent to or higher than 45 mmHg at catheterization. This requirement is reliable with the majority of available research, which recognizes a peak-to-peak gradient less than 50 mmHg like an absolute sign for BPV [18].

The mean balloon/pulmonary valve annulus ratio was 1.26 (SD 0.06), with a range of 1.15-1.40 and a median of 1.25, which was consistent with the majority of published research in this field. **Rao [19]** also suggested that the balloon size can evaluate by both long- and short-term consequences. Balloons bigger than 1.5 times the pulmonary valve annulus can have a negative impact on the RVOT; additionally, these balloons provide no additional benefit over balloons 1.2-1.4 times the annular size and should not be utilized. Large balloons with a 1.4:1.5 balloon/annulus ratio can still be employed to dilate dysplastic pulmonary valves.

The balloon size was calculated by measuring the pulmonary valve's maximum internal diameter from hinge point to hinge point throughout systole on a right ventricular angiogram with magnification adjustments, as per **Handoka and El-Eraky [18].**

Interventional cardiologists prefer Tyshak II balloons because they offer the broadest variation of diameters and balloon sizes in this catheter's line, according to **Rao [19]** Tyshak II balloons were utilized in 143 (97.9%) of the subjects in our study.

The peak-to-peak systolic pressure gradient across the pulmonary valve was decreased significantly in this study, from 74.44 (SD 9.5) mmHg to 19.54 (SD 1.9) mmHg. This finding is consistent with **Behjati *et al.* [20],** who found that the peak-to-peak systolic pressure gradient across the pulmonary valve was reduced from 83.28 (SD 32) mmHg to 19.3 (SD 14.2) mmHg.

We considered balloon pulmonary valvuloplasty is successful when the pressure gradient across the pulmonary valve is reduced to half or less of its pre-catheterization value. Furthermore, **Rao [19]** defined an effective intervention as one that reduced stenosis by at minimum 50% of its initial value. Other researchers may consider the intervention is successful, when the transvalvular peak gradient drops to <36 mmHg [18].

In estimated 95.9% of our research group (140 patients), the pressure gradient across the pulmonary valve was reduced to further than 50% of pre-catheterization values, whereas in approximately 17.9% of our research group, the pressure gradient was reduced to 30% to lower than 50% of pre-catheterization attributes (25 patients). In 4 patients, the

post-dilatation pressure gradient dropped to a level equal or more than the half of pre-cath measurement. It was statistically significant improvement in the pressure gradient's degree across the pulmonary valve (P-value <0.001).

In this work, individuals had a substantial decrease in the right ventricular systolic pressure varying 89.33 (SD 8.9) mmHg to 43.05 (SD 7.8) mmHg instantly after balloon pulmonary valvuloplasty. It is in line with **El-Saeidi *et al.* [21]** in a large study demonstrated significant decrease in the right ventricular systolic pressure varying 107.81 (SD 30.88) mmHg to 54.92 (SD 20.74) mmHg and also in right ventricular systolic pressure – pulmonary artery pressure varying 86.43 (SD 25.66) mmHg to 28.15 (SD 16.68) mmHg instantly after balloon pulmonary valvuloplasty.

Our success rate is approximately 95.9% (140/146). **Jaing *et al.* [22]** reported that the success rate was 90%. The immediate success rate was 89.6% with **Yin *et al.* [23].** The possible cause of this difference may be due to the selection bias in our study.

Our study results, as well as those of previous studies, showed that BPV is effective in the pulmonary valve stenosis treatment.

Nonetheless, **Larry [24]** states that most researchers have found that 15–30% of individuals with initially efficient BPV may demonstrate evidence of significant residual or frequent RVOT obstruction via 1-2 years, while initial success does not guarantee that the pressure gradient will remain constant. Numerous BPV procedures benefit many of these patients. Nevertheless, the RVOT or pulmonary valve's surgical resection may be required in up to 10% of patients. This result affirms that successful cases should be closely monitored.

About 17.1% (25 patients) in our study group developed pulmonary valve restenosis, 14.1% (21 patients) were scheduled for second balloon dilation via repeat catheterization, 2.7% (four individuals) were regarded for surgical valvotomy, and 2 of them had supravalvular PS components. This result is equivalent to that of **Peterson *et al.* [25],** who discovered the development of restenosis in 13 (14.1%) of patients who had undergone BPV; 6 individuals were re-dilated, and 7 individuals required surgery (their study involved 108 patients with a mean age of 3.6 years). According to **Yin *et al.* [23],** reported 16.6% of 193 individuals with follow-up data with residual stenosis or restenosis after initial BPV, with 9 needing re-intervention.

In aspects of BPV complications, we observed approximately 11% (16 patients) throughout the catheterisation technique. The majority of them were minor hiccups. One patient (0.7%) had a perforation of the RVOT, which culminated with a small amount of pericardial effusion (resolved spontaneously). One patient had severe TR post-procedure and needed repeated close follow up for possibility of surgical intervention later-on. Other complications were either transient or not major in nature, including moderate TR, local hematoma or transient vascular occlusion that has been resolved at early follow-up check. **Tggart *et al.* [26]** reported that 11% of the 89 individuals in the pediatric study group had periprocedural complications (10 patients), but the most prevalent complexity was RVOT perforation/pericardial effusion (3 patients).

**Larry [24]** noted that attempts to treat PS with BPV have resulted in a wide range of complications over the years. The accessible BPV catheters in initial reports from the 1980s were significantly stiffer and larger than the current generation of catheters. Vascular issues such as retroperitoneal haematomas and iliac vein avulsions have been reported in the past, but these should be greatly uncommon with the valvuloplasty catheters' new generation.

**Study Limitations:** The study's retrospective nature, and also the relatively short follow-up duration, make clinical data gathering insufficient. As a result of these limitations, future work will necessitate a more comprehensive assessment. Nonetheless, this study can be used as a foundation for future research.

**In conclusion,** BPV is an efficient and protected procedure for moderate to severe PS, according to our research. In children, the short and intermediate outcomes are outstanding. As a result, for children with valvular pulmonary stenosis, BPV can be regarded the preferred treatment.

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