https://jlsb.science-line.com

Journal of Life Science and Biomedicine

Volume 14, Issue 4: 109-115; December 25, 2024

DOI: https://dx.doi.org/10.54203/jlsb.2024.11

Assessment of long-term hemodynamic changes following balloon valvuloplasty for pulmonary artery stenosis

Mirjamol Mirumarovich ZUFAROV, Miraziz Mirkamalovich UMAROV, and Raufbek Ravshanovich IBADOV

State Institution "Republican Specialised Scientific and Practical Medical Centre for Surgery named after academician V.Vakhidov", Tashkent, Uzbekistan

Corresponding authors's Email: miraziz4july@gmail.com

RESEARCH ARTICLE
PII: S225199392400011-14
Received: September 19, 2024
Revised: December 13, 2024
Accepted: December 15, 2024

ABSTRACT: Pulmonary artery stenosis (PAS) is a common congenital heart defect with a significant impact on the cardiovascular health of affected patients. Despite advancements in interventional cardiology, the long-term hemodynamic outcomes following balloon valvuloplasty (BV) for PAS remain insufficiently studied, especially in varying clinical and demographic subgroups. This knowledge gap necessitates further investigation. To assess long-term hemodynamic changes in patients with PAS after BV and analyze factors contributing to unsatisfactory outcomes. This single-center retrospective cohort study included 180 patients with PAS who underwent BV at the RSPPMCS named after Acad. V. Vakhidov between 2010 and 2022. Patients were categorized based on PAS type and baseline right ventricular systolic pressure (RVSP). Hemodynamic parameters were assessed using echocardiography and CT angiography. Kaplan-Meier survival analysis evaluated the durability of good and satisfactory outcomes. Statistical comparisons were made using t-tests and multivariate regression analysis, with p-values reported to three decimal places. Among the 180 patients, 144 (80.0%) had isolated valvular PAS, 27 (15.0%) had combined valvular-subvalvular PAS, and 9 (5.0%) had valvular-supravalvular PAS. Initial mean RVSP was 93.4±6.7 mmHg, which decreased significantly to 25.3±3.2 mmHg immediately post-BV ($p<0.001$). Long-term follow-up was achieved in 58 patients over five years, with mean RVSP stabilizing at 26.2±2.4 mmHg. Kaplan-Meier analysis revealed that 81.0% of patients maintained good outcomes at five years. Predictors of poor outcomes included inadequate balloon-to-annulus ratio (<1.2) and residual gradients ≥50 mmHg. Repeat BV improved outcomes in 100% of re-treated cases. BV demonstrates high efficacy in the long-term management of PAS, with sustained improvement in hemodynamics observed in most patients. Optimal balloon sizing remains critical to reducing residual gradients and ensuring long-term success. Further studies should explore additional predictors of restenosis to refine patient selection and procedural strategies.

KEYWORDS: Pulmonary artery stenosis; balloon valvuloplasty; hemodynamic outcomes; congenital heart defects; long-term follow-up.

INTRODUCTION

According to WHO data, congenital heart defects (CHDs) are detected in approximately 0.8–1.2% of newborns annually, with this rate increasing from 4 to 10 per 1,000 live births since 2000 [1]. The prevalence of CHDs at birth in Asia has been recorded at 9.3 per 1,000 live births (95% CI: 8.9–9.7), with a relatively high number of right ventricular outflow tract (RVOT) obstructions and fewer left ventricular outflow obstructions [2]. Pulmonary valve stenosis (PVS) is a typical and most commonly registered CHD, accounting for approximately 1.6% to 15% of cases [3]. Based on the location of the pulmonary artery narrowing, PVS is classified as valvular, subvalvular (infundibular), or supravalvular. Currently, valvular stenosis is the most prevalent form of the defect [4].

The development of X-ray endovascular surgery has opened a new chapter in the treatment of this severe patient category. The first report of successful percutaneous balloon pulmonary valvuloplasty (BPV) was made by Kan et al. [5] in 1982. Since then, this field has rapidly evolved in cardiac surgery centers worldwide, with published studies reporting favorable long-term prognoses. The methodological aspects of BPV for PVS have focused on the feasibility, safety, efficacy, and practicality of this technique [6].

The recently recommended balloon-to-annulus diameter ratio ranges from 1.2 to 1.25. Post-procedure, a sharp reduction in pressure gradients, free leaflet mobility with less doming, and an increase in cardiac output have been observed. Although complications may occur, they are rare and minimal [7].

Significant predictors of restenosis include a balloon-to-annulus ratio of <1.2 and a residual gradient of ≥30 mmHg immediately after BPV. Only 4–6% of patients require repeat BPV. The long-term follow-up results have been remarkably excellent. In conclusion, we consider BPV equally successful across all age groups, as globally recognized studies have demonstrated its safety, feasibility, and effectiveness [8].

To date, global practice has accumulated extensive experience with successful X-ray endovascular interventions (REIs) for PVS. In our country, this method was first introduced in 1996 at the RSPPMCS named after Acad. V. Vakhidov. The clinical material accumulated over 25 years and the established technological and methodological principles of REIs for patients with CHDs, particularly PVS, allow for a comprehensive evaluation of outcomes and the formulation of key treatment principles for this challenging patient category.

Objective

The objective of this study is to assess long-term hemodynamic changes following balloon valvuloplasty in patients with pulmonary artery stenosis and to identify factors influencing long-term outcomes and predictors of unsatisfactory results.

MATERIALS AND METHODS

The study was based on the treatment outcomes of 180 patients with pulmonary artery stenosis (PAS) and right ventricular outflow tract obstruction (RVOTO) who underwent various types of X-ray endovascular interventions (REIs) at the Republican Specialized Scientific Practical Medical Center of Surgery named after Acad. V. Vakhidov from 2010 to 2022.

Based on the type of pulmonary artery obstruction, patients were divided into the following groups (Table 2):

- With isolated valvular PAS – 144 patients (80.0%),
- With combined valvular-subvalvular PAS – 27 patients (15.0%),
- With combined valvular-supravalvular PAS – 9 patients (5.0%).

Table 1. Distribution of patients by gender and age

Age group	Male (n, %)	Female (n, %)	Total (n, %)
Infant (up to 1 year)	4 (2.2%)	4 (2.2%)	8 (4.4%)
Early childhood (1–3 years)	12 (6.7%)	8 (4.4%)	20 (11.1%)
Preschool age (4–7 years)	12 (6.7%)	16 (8.9%)	28 (15.6%)
School age (8–17 years)	24 (13.3%)	20 (11.1%)	44 (24.4%)
Young age (18–44 years)	28 (15.6%)	27 (15.0%)	55 (30.6%)
Middle age (45–59 years)	14 (7.8%)	11 (6.1%)	25 (13.9%)
Total	94 (52.2%)	86 (47.8%)	180 (100%)

Table 2. Distribution of patients by anatomical variants of pulmonary artery stenosis (PAS)

Anatomical Groups	n	%
Valvular PAS	144	80.0%
Valvular-subvalvular PAS	27	15.0%
Valvular-supravalvular PAS	9	5.0%
Total	180	100%

Citation: Zufarov MM, Umarov MM, and Ibadov RR. Assessment of long-term hemodynamic changes following balloon valvuloplasty for pulmonary artery stenosis. *J Life Sci Biomed,* 2024; 14(4): 109-115. DOI: https://dx.doi.org/10.54203/jlsb.2024.11

Based on the initial systolic pressure in the right ventricle (RV), patients were divided into four groups:

- With initial RV pressure up to 100 mmHg – 78 patients (43.3%);
- From 101 to 150 mmHg – 54 patients (30.0%);
- From 151 to 200 mmHg – 30 patients (16.7%);
- Above 200 mmHg – 18 patients (10.0%) (Figure 1).

All patients underwent a comprehensive clinical examination. For the verification of pathology, physical data, including complaints, medical history and objective indicators were recorded. Non-invasive diagnostic methods included electrocardiography (ECG), chest X-rays, echocardiography (EchoCG), Doppler echocardiography, and CT angiography.

Echocardiography (EchoCG)

It is used to identify PAS and detail its anatomical variant. The diagnosis of PAS is confirmed through Doppler echocardiography, which allows for the assessment of disease severity as follows:

- Mild: Peak gradient <36 mmHg (peak velocity <3 m/s);
- Moderate: Peak gradient 36–64 mmHg (peak velocity 3–4 m/s);
- Severe: Peak gradient >64 mmHg (peak velocity >4 m/s).

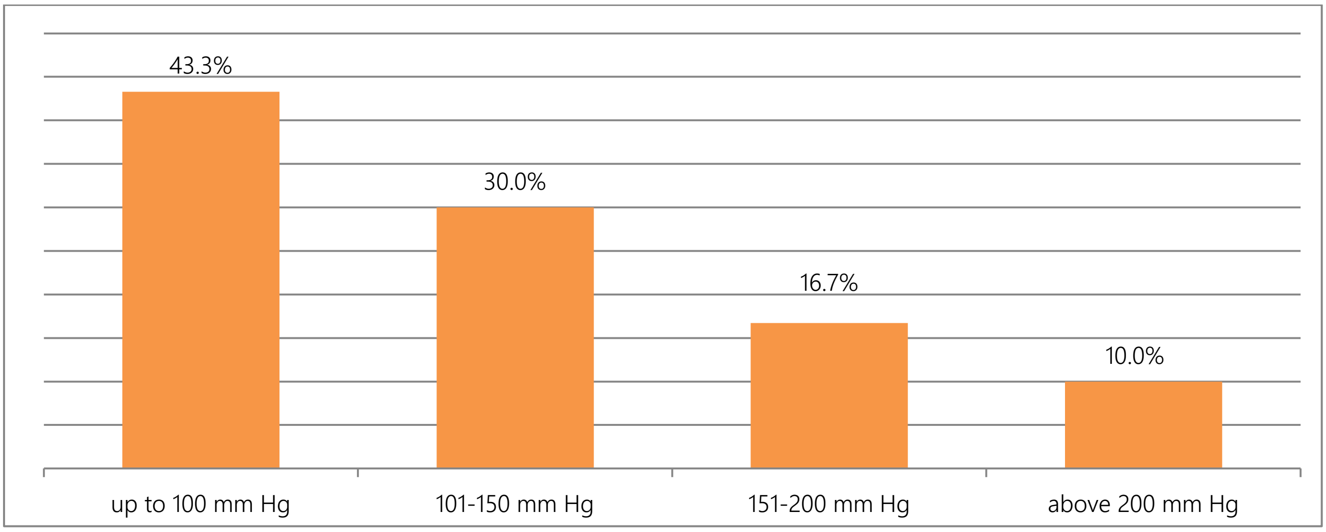

Figure 1. Distribution of Patients Based on the initial systolic pressure level in the right ventricle (RV).

RESULTS

At the intermediate follow-up (12 months after BPV), 128 patients (71.1%) were examined, while at the long-term follow-up (5 years after BPV), treatment efficacy was evaluated in 58 patients (32.2%) either at our center or on an outpatient basis in their local regions using echocardiography. Additionally, 14 patients (7.8%) underwent follow-up CT angiography of the pulmonary artery and right heart chambers. Repeat treatment was primarily administered to patients with a high residual pressure gradient (RPG) after BPV or minimal positive clinical dynamics.

Although BPV has become one of the most widely used methods for correcting PAS, the causes of unsatisfactory outcomes remain incompletely understood.

We undertook a study to evaluate the efficacy and analyze the causes of unsatisfactory results of BPV in PAS.

All patients demonstrated further improvements in overall health, exercise tolerance, and echocardiographic parameters. At the intermediate follow-up (12 months after BPV), the rate of unsatisfactory outcomes was 14.1% (18 out of 128), including 15 cases (11.7%) with RPGs exceeding 50 mmHg and 3 cases (2.3%) of pulmonary valve restenosis with gradients >50 mmHg (Fig. 2). These patients underwent repeat BPV using balloon catheters 1.2–1.5 times larger than the pulmonary valve annulus diameter. After repeat BPV, all patients achieved gradients below 50 mmHg.

Figure 2. Summary of balloon valvuloplasty outcomes for pulmonary artery stenosis.

The efficacy of BPV (good and satisfactory results) in patients with PAS, including repeat REI interventions, was 91.1% in the early period, 85.9% in the intermediate period, and 81.0% in the long-term period after BPV.

The outcomes of BPV largely depend on the correct selection of the balloon catheter size, which is the primary factor for reducing the pressure gradient between the RV and PA, both immediately after BPV and in the long term. Properly performed BPV in patients with combined valvular-subvalvular PAS leads to regression of RVOT obstruction in the long-term follow-up.

Analysis of follow-up echocardiography and CT angiography at various periods after BPV (Fig. 3) showed a statistically significant difference in the mean residual pressure gradient (RPG) between the RV and PA. The initial mean RPG was 93.4±6.7 mmHg (range: 44–232 mmHg), which decreased immediately after BPV to 25.3±3.2 mmHg (range: 14–58 mmHg). In the intermediate period, the mean RPG was 29.4±3.8 mmHg (range: 16–62 mmHg), and in the long-term period, it was 26.2±2.4 mmHg (range: 16–42 mmHg).

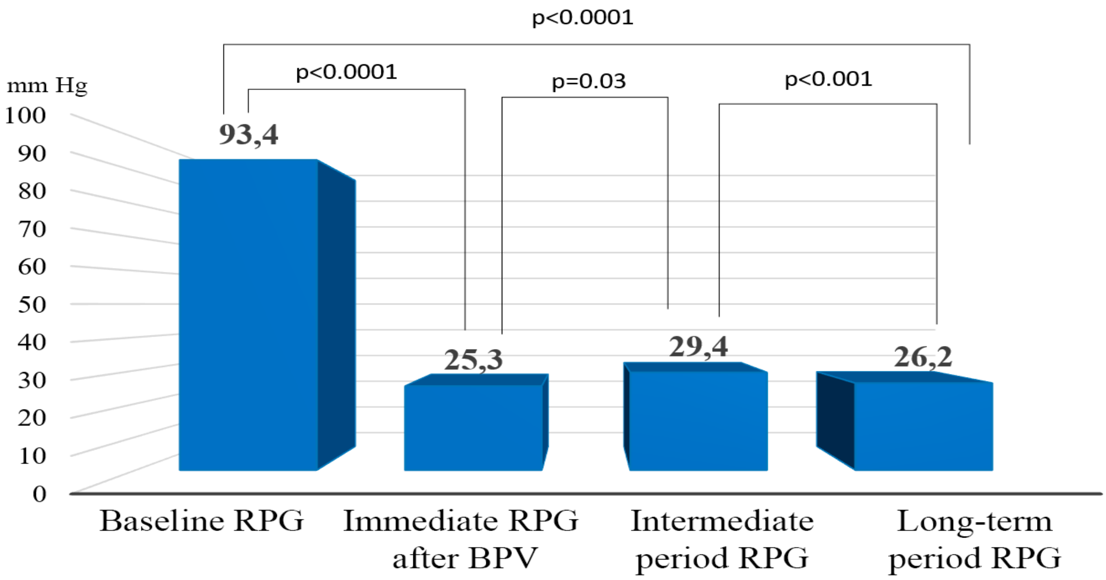

Figure 3. Comparative assessment of mean RPG values following BPV in patients with PAS across different study periods.

Citation: Zufarov MM, Umarov MM, and Ibadov RR. Assessment of long-term hemodynamic changes following balloon valvuloplasty for pulmonary artery stenosis. *J Life Sci Biomed,* 2024; 14(4): 109-115. DOI: https://dx.doi.org/10.54203/jlsb.2024.11

A Kaplan-Meier analysis was conducted on censored data to evaluate the durability of good and satisfactory outcomes, accounting for patients who were lost to follow-up or had varying observation periods (Fig. 4).

After accounting for 40 patients lost to follow-up within 6 months post-BPV, the retention rate of good outcomes was 88.6% (124 out of 140 re-examined patients). Among these, the same 16 patients who had unsatisfactory results with RPGs exceeding 50 mmHg immediately after BPV remained under observation.

At 12 months post-BPV, the frequency of good outcomes was 85.9% (110 out of 128 re-examined patients).

For patients with unsatisfactory results, the RPG ranged from over 50 mmHg to less than 60 mmHg. In 15 out of 18 cases, a watchful waiting strategy was employed, with echocardiographic monitoring every six months. In the remaining three cases with RPGs exceeding 64 mmHg, as previously noted, repeat BPV was performed with good outcomes.

Good results were maintained at the following rates:

- 88.1% (111 out of 126 re-examined) at 18 months post-BPV,
- 88.5% (108 out of of 122) at 24 months,
- 88.2% (97 out of 110) at 30 months,
- 86.5% (83 out of 96) at 36 months (5 out of 13 unsatisfactory outcomes had pulmonary regurgitation >15%), and
- 84.5% (71 out of 84) at 42 months.

At five years post-BPV, 58 patients were evaluated, with good outcomes preserved in 81.0% (47 out of 58). In the remaining 11 cases, pulmonary regurgitation >15% was observed.

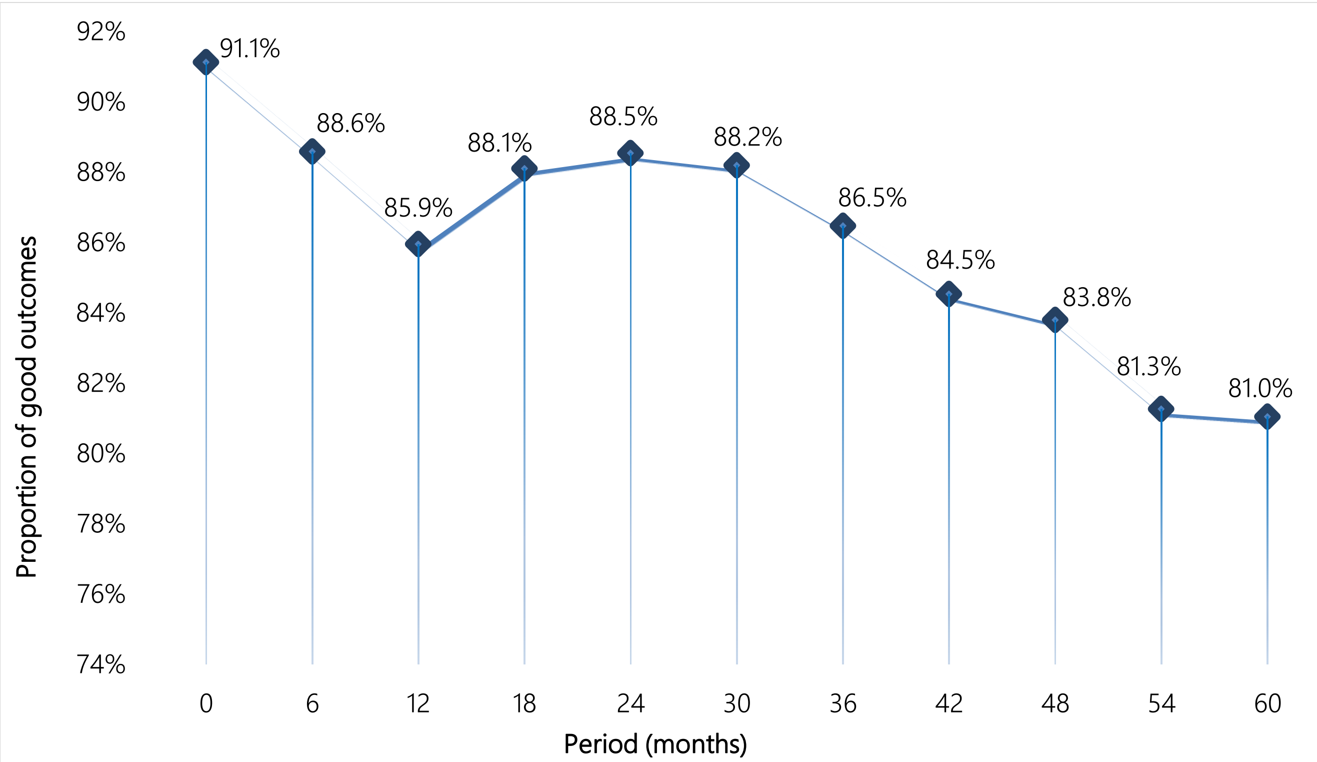

Figure 4. Analysis of the durability of good and satisfactory BPV outcomes for PAS over various study periods

DISCUSSION

The evaluation of long-term hemodynamic changes following balloon valvuloplasty (BPV) for pulmonary artery stenosis (PAS) underscores the efficacy of this procedure in reducing transvalvular pressure gradients and improving right ventricular function. Despite the promising outcomes, some patients experience complications, such as pulmonary regurgitation, necessitating ongoing monitoring and, in some cases, repeat interventions. These findings emphasize the need to optimize patient selection criteria and refine procedural techniques.

Citation: Zufarov MM, Umarov MM, and Ibadov RR. Assessment of long-term hemodynamic changes following balloon valvuloplasty for pulmonary artery stenosis. *J Life Sci Biomed,* 2024; 14(4): 109-115. DOI: https://dx.doi.org/10.54203/jlsb.2024.11

One of the most consistent findings across studies is the significant reduction in pressure gradients after BPV. For example, in the study by Vinelli-Arzubiaga et al. [9] the mean transvalvular gradient decreased from 61.7 mmHg to 17 mmHg, representing a substantial improvement. Similarly, Hansen et al. reported a significant drop in mean gradients from 56 mmHg to lower levels post-procedure. These findings suggest that BPV is highly effective in alleviating the obstruction at the pulmonary valve, thereby reducing the workload on the right ventricle [10].

Long-term studies, with follow-up periods ranging from 1 to 25 years, indicate sustained benefits in the majority of patients. For instance, Khalaf et al. [11] found that 85.96% of patients-maintained pressure gradients below 36 mmHg over an extended follow-up period. However, the durability of these results is influenced by factors such as the severity of the initial stenosis and the balloon-to-annulus ratio used during the procedure. Moderate pulmonary insufficiency was observed in approximately 29% of patients in the long term [10], raising questions about the trade-off between reducing stenosis and preserving valve function.

Pulmonary regurgitation is a frequently reported complication following BPV. Sirico et al. [12] noted an increase in mild regurgitation from 8% pre-procedure to 29% post-procedure. While mild regurgitation is often clinically insignificant, the progression to severe regurgitation, observed in 17% of patients in long-term follow-ups [9], can negatively impact cardiac function and quality of life.

Re-interventions are required in a subset of patients, primarily due to residual stenosis or significant regurgitation. Hansen et al. [10] reported a re-intervention rate of approximately 13%, highlighting the need for careful procedural planning and follow-up. Predictors of re-intervention include a suboptimal balloon-to-annulus ratio (<1.2) and high residual gradients immediately post-procedure.

CONCLUSIONS AND RECOMMENDATIONS

Thus, the mean RPG after BPV for PAS showed a statistically significant difference from baseline values ($p<0.0001$), averaging 29.4±3.8 mmHg (range: 16–62 mmHg) in the intermediate period (12 months post-BPV) and 26.2±2.4 mmHg (range: 16–42 mmHg) in the long-term period. Kaplan-Meier survival curves for maintaining good BPV outcomes in PAS demonstrated the high efficacy of X-ray endovascular interventions over the long term, with good results observed in 88.5% of cases at 2 years, 81.0% at 3 years, and 84.5% at 5 years. Unsatisfactory outcomes were characterized by the development of clinically insignificant pulmonary regurgitation.

DECLARATIONS

Corresponding author

Correspondence and requests for materials should be addressed to Miraziz M. Umarov; E-mail miraziz4july@gmail.com; Phone: +998998141513; ORCID: https://orcid.org/0009-0004-2063-020X

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Acknowledgements

This work was supported by Republican Specialized Hospital Zangiota-1, Tashkent, Uzbekistan.

Authors contributions

All authors contributed equally to this work.

Funding support

None.

Competing interests

All authors declare that they have no conflict of interest.

Ethical approval

The review board and ethics committee of Republican Specialized Hospital Zangiota-1 approved the study protocol and informed consents were taken from all the participants.

REFERENCES

[1] World Health Organization. Cardiovascular diseases (CVDs). Available at: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds), May 21, 2019.

[2] Pan F, Li J, Lou H et al .Geographical and Socioeconomic Factors Influence the Birth Prevalence of Congenital Heart Disease: A Population-based Cross-sectional Study in Eastern China. Curr Probl Cardiol. 2022 Nov; 47(11):101341. https://doi.org/10.1016/j.cpcardiol.2022.101341

[3] van der Linde D, Konings EE, Slager MA, et al. Birth prevalence of congenital heart disease worldwide: a systematic review and meta-analysis. J Am Coll Cardiol 2011;58:2241–7. https://doi.org/10.1016/j.jacc.2011.08.025

[4] Cuypers JA, Witsenburg M, van der Linde D, Roos- Hesselink JW. Pulmonary stenosis: update on diagnosis and therapeutic options. Heart. 2013;99(5):339- 347. https://doi.org/10.1136/heartjnl-2012-301964

[5] Kan JS, White RI, Mitchell SE, Gardner TJ. Percutaneous balloon valvuloplasty: a new method for treating congenital pulmonary- valve stenosis. N Engl J Med. 1982; 307(9):540- 542. https://doi.org/10.1056/NEJM198208263070907

[6] Morray BH, McElhinney DB. Semilunar Valve Interventions for Congenital Heart Disease: JACC State-of-the-Art Review. J Am Coll Cardiol. 2021 Jan 5;77(1):71-79. https://doi.org/10.1016/j.jacc.2020.10.052; PMID: 33413944.

[7] Baumgartner H., De Backer J., Babu-Narayan S.V. et al. Рекомендации ESC по ведению взрослых пациентов с врожденными пороками сердца 2020. Рабочая группа Европейского общества кардиологов (ESC) по ведению взрослых пациентов с врожденными пороками сердца [ESC Guidelines for the Management of Adult Patients with Congenital Heart Defects 2020. The European Society of Cardiology (ESC) Task Force on the Management of Adult Patients with Congenital Heart Defects]. Российский кардиологический журнал [Russian Journal of Cardiology] 2021;26(9):4702 Клинические Рекомендации [Clinical Practice Guidelines]. https://doi.org/10.15829/1560-4071-2021-4702; ISSN 1560-4071. https://russjcardiol.elpub.ru

[8] Bonow R- O, Blase- A C, Kanu C, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing Committee to Revise the 1998 guidelines for the management of patients with valvular heart disease) developed in collaboration with the Society of Cardiovascular Anesthesiologists endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. J Am Coll Cardiol. 2006;48(3):e1- e148.

[9] Vinelli-Arzubiaga, D. (2022). Outcomes of percutaneous balloon pulmonary valvuloplasty in pulmonary valve stenosis in the pediatric population in a single center, Lima - Peru. Archivos Peruanos de Cardiología y Cirugía Cardiovascular, 3(2), 60–68. https://doi.org/10.47487/apcyccv.v3i2.208

[10] Hansen, R. L., Naimi, I., Wang, H., Atallah, N., Smith, F. C., Byrum, C. J., Kveselis, D. A., Leonard, G. T., Devanagondi, R., & Egan, M. (2019). Long-term outcomes up to 25 years following balloon pulmonary valvuloplasty: A multicenter study. Congenital Heart Disease, 14(6), 1037–1045. https://doi.org/10.1111/CHD.12788

[11] Khalaf, O. Z., Yaseen, M. J., & Hasan, S. N. (2022). Long-term results of balloon pulmonary valvuloplasty in pediatric age group in surgical specialty teaching hospital/cardiac center/Hawler. World Journal of Biology Pharmacy and Health Sciences, 11(2), 17–22. https://doi.org/10.30574/wjbphs.2022.11.2.0088

[12] Sirico, D., Spigariol, G., Mahmoud, H. T., Fonte Basso, A., Reffo, E., Biffanti, R., Sabatino, J., Di Candia, A., Castaldi, B., & Di Salvo, G. (2022). P151 Right ventricular mechanics in patients affected by pulmonary valve stenosis, before and after percutaneous pulmonary valvuloplasty. European Heart Journal Supplements, 24(Supplement_C). https://doi.org/10.1093/eurheartj/suac012.145

Citation: Zufarov MM, Umarov MM, and Ibadov RR. Assessment of long-term hemodynamic changes following balloon valvuloplasty for pulmonary artery stenosis. *J Life Sci Biomed,* 2024; 14(4): 109-115. DOI: https://dx.doi.org/10.54203/jlsb.2024.11