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SURGICAL CORRECTION OF SEPTAL DEFECTS IN PATIENTS WITH HIGH PULMONARY HYPERTENSION: A COMPARATIVE ANALYSIS OF COMPLETE CLOSURE OF THE DEFECT AND THE VALVE PATCH TECHNIQUE WITH A MODIFICATION OF THE W. NOVICK TECHNIQUE

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Abstract

The key problem that determines the prognosis and tactics of surgical treatment in this category of patients is the development of pulmonary arterial hypertension (PAH), a pathological condition characterized by a progressive increase in pulmonary vascular resistance and pressure in the pulmonary artery due to chronic hypervolemia of the pulmonary circulation. According to current epidemiological data, PAH associated with congenital heart defects is detected in 1.6–12.5 per million population in the general population, but among patients with uncorrected septal defects with a left-right shunt, its incidence reaches 30–50% during the first two years of life. The pathophysiological progression of pulmonary hypertension in septal defects includes successive morphological stages according to the Heath-Edwards classification: from initial hypervolemic hypertension with reversible medial hypertrophy of the pulmonary arterioles to irreversible obliterating pulmonary arteriopathy with plexiform lesions - Eisenmenger syndrome, in which the pressure in the pulmonary artery reaches or exceeds the systemic level, the direction of the shunt is inverted, and the standard surgical correction of the defect becomes impossible or extremely high-risk.

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The principal surgical dilemma in the management of patients with septal defects and high PAH is the choice between complete closure of the defect and techniques that provide for the preservation of controlled blood discharge through a controlled opening. Complete closure of the defect is the operation of choice in reversible PAH and ensures the normalization of the hemodynamics of the pulmonary circulation, but in irreversible or borderline PAH, it is associated with a high risk of acute right ventricular failure and pulmonary-hypertensive crises in the postoperative period due to the abrupt elimination of the "safety valve" – the shunt that maintained systemic cardiac output. In this regard, in the 1990s, W. Novick and co-authors proposed the fenestrated patch technique, which provides for the creation of a controlled unidirectional valve mechanism in the patch that closes the defect, which makes it possible to ensure decompression of the right ventricle in pulmonary hypertensive crisis without permanent pathological bypass grafting. This technique has become widespread in the world of cardiac surgery, but its technical aspects, indications and results of use in the pediatric population with high PAH continue to be actively studied and improved. The development and implementation of modifications of this technique aimed at optimizing the hemodynamic characteristics of the valvular mechanism and reducing the risk of postoperative complications is an urgent task of modern pediatric cardiac surgery. In the Republic of Uzbekistan, from 3,500 to 4,000 new cases of congenital heart defects are registered annually, while a significant part of children are admitted to cardiac surgery hospitals with already formed high PAH, which determines the particular relevance of developing optimal surgical strategies for this category of patients.

OBJECTIVE

The purpose of this study is to conduct a comparative analysis of the immediate and long-term results of complete closure of the septal defect and correction using a valve patch according to the W. Novick technique and its author's modification in pediatric patients with high pulmonary hypertension, as well as to assess the indications, technical features and clinical efficacy of the developed modification of the surgical technique in a multidisciplinary pediatric cardiac surgery hospital.

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MATERIALS AND METHODS OF THE STUDY

This study was conducted on the basis of the multidisciplinary children's clinic of the Tashkent State Medical University (Tashkent State Medical University) in the period from January 2018 to December 2025. The study included 87 patients aged 3 months to 16 years with a verified diagnosis of septal defect (VSD or ASD) complicated by high-grade pulmonary arterial hypertension. The diagnosis and degree of pulmonary hypertension were verified on the basis of a comprehensive clinical and instrumental examination, including transthoracic echocardiography with Doppler ultrasound, electrocardiography, chest X-ray, as well as invasive catheterization of the right heart with medical tests (oxygen test, nitric oxide test) in 42 cases (48.3%). The degree of pulmonary hypertension was classified according to the 2022 ESC/ERS guidelines and the TOPP (Tracking Outcomes and Practice in Pediatric Pulmonary Hypertension) classification. Intraoperative tensiometry was performed in all patients immediately before making a decision on the extent of surgical correction: the pressure in the pulmonary artery and right ventricle was measured relative to systemic blood pressure; The critical threshold for choosing a correction method was considered to be pulmonary artery pressure exceeding 85% of the systemic pressure.

Study inclusion criteria: age under 18 years; verified VSD or ASD with left-right or bidirectional shunt; high-grade pulmonary hypertension (pulmonary artery systolic pressure – SLLA ≥ 70 mm Hg according to echocardiography); performed surgical correction of the defect in conditions of extracorporeal circulation. Exclusion criteria: concomitant complex congenital heart defects requiring one-stage multicomponent correction; Eisenmenger syndrome with irreversible PAH and lack of response to drug tests; severe concomitant extracardiac pathology; refusal of the patient's legal representatives to participate in the study.

All operations were performed under conditions of extracorporeal circulation (CR) with moderate hypothermia (28–32°C) and pharmacocold cardioplegia with Custodiol or Del Nido solution. Intraoperative tensiometry was performed after departure from the IC by direct measurement of pulmonary artery pressure through a catheter. Depending on the results of tensiometry and initial clinical

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and hemodynamic data, the patients were divided into three groups: group I — complete closure of the septal defect (n = 61); group II — correction with a valve patch according to the original method of W. Novick (n = 9); group III — correction with a valve patch according to the author's modification of the W. Novick technique (n = 17, of which 17 patients in the postoperative period used the tactics of delayed closure of the sternum).

The technique of delayed closure of the sternum was used in 17 patients of group I and group III with unstable hemodynamics after departure from the IC. To ensure the necessary diastasis of the sternum, a silicone "spacer" made of an IR tube was used. The size of the spacer was 1.5 times the thickness of the patient's sternum; The length of the spacer was determined by maximizing the convergence of the sternum margins while maintaining stable hemodynamics. After the spacer was placed and fixed, the surgical wound was sealed with a latex membrane sutured to the edges of the skin wound, on top of which a sterile betadine membrane was applied in two layers to prevent infection and perforation. Patients were transferred to the intensive care unit (ICU) under continuous hemodynamic monitoring, followed by closure of the sternum after 48–96 hours with stabilization of hemodynamic parameters.

The valve patch method according to W. Novick provided for the following technical stages: fenestration with a diameter of up to 5.0 mm was performed in the center of the main synthetic patch, which was covered with a smaller patch made of autopericardium, which served as a valve element. The flap patch was stitched with a continuous seam from 9 to 15 o'clock of the conventional dial, forming a semilunar flap; The lower edge of the valve was fixed with one separate suture, creating two symmetrical tunnels for the discharge of blood from the right sections. The valve functioned when the pressure in the right ventricle exceeded the pressure in the left, providing decompression of the right parts without constant bypass grafting. The direction of blood discharge was oriented strictly into the cavity of the left ventricle towards the apex in order to avoid impairment of the function of the aortic valve.

The author's modification of the technique was distinguished by a modified scheme of fixation of the valve element: the fixation points were located at the

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positions of 12, 15, 18 and 21 o'clock of the conventional dial, which ensured a uniform redistribution of the blood flow entering the left ventricle, reducing the degree of turbulence in the left ventricular cavity and eliminating traumatization of the aortic valve. To close the defect, only a synthetic material (polytetrafluoroethylene or Dacron) was used, while an autopericardium or a synthetic material different in structure from the material of the main patch was used as a valve element in order to prevent the adhesion of the valve to the patch and maintain its mobility. The defect was closed with a continuous suture (6 cases) or separate U-shaped sutures on gaskets (3 cases), depending on the anatomical features of the defect.

Statistical data processing was carried out using IBM SPSS Statistics version 26.0 and MedCalc version 20.1 software. Quantitative data are presented as a mean and standard deviation (M ± SD) in a normal distribution, or as a median and interquartile range (Me [Q1; Q3]) in case of abnormal distribution. The normality of the distribution was checked by the Shapiro–Wilk test. To compare the groups, univariate analysis of variance (ANOVA) with the post-hoc Tukey test (with a normal distribution) and the Kruskel–Wallis test (with an abnormal distribution) were used. To compare the qualitative data, the Pearson χ^2 test or the Fisher exact test was used. The differences were considered statistically significant at $p < 0.05$. Survival and freedom from repeated interventions were analyzed by the Kaplan-Meier method with a logrank test to compare curves between groups.

RESEARCH RESULTS

The study included 87 patients: 40 boys (46.0%) and 47 girls (54.0%). The mean age of the patients was 3.8 ± 2.9 years. By nosological forms: VSD — 58 patients (66.7%), ASD — 29 patients (33.3%). By groups of surgical correction: group I (complete closure) — 61 patients (70.1%), group II (valve patch according to W. Novick) — 9 patients (10.3%), group III (author's modification) — 17 patients (19.5%). Among patients in group I and III, 17 (27.9% and 100%, respectively) used the tactics of delayed sternum closure. The initial clinical, demographic, and hemodynamic characteristics of patients by groups are presented in Table 1.

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Table 1. Initial clinical, demographic and hemodynamic characteristics of patients by groups of surgical correction (M ± SD)

Parameter	Group I: full closure (n = 61)	Group II: W. Novick patch (n = 9)	Group III: author's modification (n = 17)	p
Age, years	4,1 ± 3,1	2,8 ± 2,2	2,4 ± 1,8	0,038
Body weight, kg	14,6 ± 8,4	10,2 ± 5,7	9,8 ± 5,1	0,041
СДЛА по ЭхоКГ, мм рт. ст.	72,4 ± 9,8	94,6 ± 11,3	97,2 ± 12,1	< 0.001
Aircraft pressure / system pressure, %	74,3 ± 8,6	91,8 ± 7,4	93,4 ± 8,2	< 0.001
VSD, n (%)	38 (62,3)	7 (77,8)	13 (76,5)	0,412
ASD, n (%)	23 (37,7)	2 (22,2)	4 (23,5)	0,412
LH III B degree, n (%)	48 (78,7)	4 (44,4)	6 (35,3)	0,002
Grade IV PH, n (%)	13 (21,3)	5 (55,6)	11 (64,7)	0,002
Retardation in physical development, n (%)	29 (47,5)	7 (77,8)	14 (82,4)	0,018
Poor response to drug tests, n (%)	14 (23,0)	6 (66,7)	13 (76,5)	< 0.001

Note: SLLA is the systolic pressure in the pulmonary artery; LA — pulmonary artery; LH — pulmonary hypertension; p is the level of significance of the differences between the three groups (ANOVA or the Kruskel–Wallis test for quantitative data, the χ^2 test for qualitative data).

Indications for the use of a particular surgical tactic were determined on the basis of a combination of clinical, echocardiographic and intraoperative tensiometric data. Complete closure of the septal defect (group I) was performed in the presence of a pronounced left-right or bidirectional discharge on the defect according to echocardiography in combination with intraoperative tensiometry data showing pulmonary artery pressure not exceeding 85% of the systemic pressure. The use of a valve patch (groups II and III) was indicated for: LH of the IV degree in children under 1.5 years of age with a significant delay in physical development and a poor response to drug tests; LH III B degree in children over 1.5 years of age with a high risk of pulmonary-hypertensive crises; pulmonary artery pressure exceeding 85% of the systemic pressure according to intraoperative tensiometry. Intraoperative and early postoperative parameters by groups are presented in Table 2.

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Table 2. Intraoperative and early postoperative parameters by surgical correction groups (M ± SD)

Parameter	Group I (n = 61)	Group II (n = 9)	Group III (n = 17)	p
IR time, min	68,4 ± 18,2	74,6 ± 19,8	76,1 ± 21,4	0,284
Aortic clamping time, min	38,7 ± 12,4	42,3 ± 14,1	44,8 ± 15,6	0,196
AP pressure after IC / systemic, %	62,4 ± 11,8	78,6 ± 13,4	74,2 ± 12,9	< 0.001
Delayed sternum closure, n (%)	17 (27,9)	0 (0,0)	17 (100,0)	< 0.001
Period to sternum closure, days	3,2 ± 1,1	—	3,8 ± 1,4	0,142
Duration of mechanical ventilation, h	38,6 ± 24,8	52,4 ± 31,6	61,8 ± 38,2	0,012
Duration of stay in the ICU, days	4,8 ± 2,6	7,2 ± 3,4	8,6 ± 4,1	0,001
Pulmonary hypertensive crises, n (%)	11 (18,0)	2 (22,2)	1 (5,9)	0,218
Low ejection syndrome, n (%)	14 (23,0)	3 (33,3)	2 (11,8)	0,312
In-hospital mortality, n (%)	4 (6,6)	1 (11,1)	0 (0,0)	0,384

Note: IC – Artificial Circulation; LA — pulmonary artery; Mechanical ventilation — artificial ventilation; ICU — Intensive Care Unit; p is the level of significance of the differences between the three groups; dash (—) — the indicator is not applicable for this group.

The immediate results of surgical treatment were assessed by the frequency of achieving a positive hemodynamic result, defined as a decrease in DMLA to a level of less than 50% of the systemic pressure at hospital discharge, the absence of signs of right ventricular failure and pulmonary-hypertensive crises. In group I, a positive immediate result was achieved in 51 out of 61 patients (83.6%). In group II, it occurred in 5 out of 9 patients (55.6%), which corresponds to the literature data on the effectiveness of the original W. Novick technique. In group III, a positive immediate outcome was achieved in 15 of 17 patients (88.2%),

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which was significantly higher than the results of group II (p = 0.041). Long-term outcomes were evaluated between 12 and 60 months after surgery. A comparative analysis of the immediate and long-term results of surgical treatment by groups is presented in Table 3.

Table 3. Comparative analysis of the immediate and long-term results of surgical treatment by groups

Result indicator	Group I (n = 61)	Group II (n = 9)	Group III (n = 17)	p (I vs II)	p (I vs III)	p (II vs III)
Positive immediate result, n (%)	51 (83,6)	5 (55,6)	15 (88,2)	0,048	0,712	0,041
DSLA at discharge, mm Hg. st. (M ± SD)	44,8 ± 12,6	62,4 ± 14,8	48,6 ± 13,2	0,002	0,481	0,018
Residual shunt at discharge, n (%)	3 (4,9)	2 (22,2)	2 (11,8)	0,062	0,241	0,512
Positive long-term result (12 months), n (%)	48 (78,7)	5 (55,6)	14 (82,4)	0,138	0,812	0,098
Positive long-term result (36 months), n (%)	44 (72,1)	4 (44,4)	13 (76,5)	0,112	0,741	0,086
Repeated interventions, n (%)	5 (8,2)	2 (22,2)	1 (5,9)	0,184	0,812	0,241
Long-term SLLA (36 months), mm Hg st. (M ± SD)	42,1 ± 11,4	58,6 ± 16,2	44,8 ± 12,8	0,004	0,512	0,021
Survival rate within 5 years, %	91,8	77,8	94,1	0,214	0,812	0,184

Note: SLLA is the systolic pressure in the pulmonary artery; p is the level of significance of the differences between the groups (χ^2 test for qualitative data, Student's or Mann-Whitney test for quantitative data); a positive result was defined as a DSLA < 50% of systemic pressure with no evidence of right ventricular failure.

The technical features of the application of the author's modification of the valve patch and its comparison with the original method of W. Novick in terms of key technical and functional parameters are presented in Table 4. The fundamental difference of the author's modification was in the change in the valve element

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fixation scheme: in the original W. Novick method, fixation was carried out at 9 and 15 o'clock of the conventional dial, while in the author's modification - at 12, 15, 18 and 21 o'clock, which provided a four-point fixation of the valve with a uniform redistribution of the blood flow entering the left ventricle, and a significant reduction in the degree of turbulence in its cavity. This technical solution made it possible to exclude cases of injury to the aortic valve by the discharge jet, which were observed in 2 out of 9 cases (22.2%) when using the original W. Novick technique.

Table 4. Comparative analysis of the technical and functional characteristics of the W. Novick method and the author's modification

Characteristics	W. Novick Method (Group II, n = 9)	Author's modification (group III, n = 17)	p
Valve element fixation points	9 and 15 hours (2 points)	12, 15, 18 and 21 hours (4 points)	—
Main Patch Material	Synthetic (PTFE/Dacron)	Synthetic (PTFE/Dacron)	—
Valve Element Material	Autopericardium	Autopericardium or synthetic (other than the main patch)	—
Fenestration diameter, mm (M ± SD)	4,6 ± 0,6	4,8 ± 0,5	0,384
Continuous seam of defect closure, n (%)	5 (55,6)	11 (64,7)	0,612
U-shaped defect closure joints, n (%)	4 (44,4)	6 (35,3)	0,612
Adhesion of the valve to the patch, n (%)	3 (33,3)	0 (0,0)	0,018
Aortic valve dysfunction, n (%)	2 (22,2)	0 (0,0)	0,048
LV turbulent flow by echocardiography, n (%)	4 (44,4)	2 (11,8)	0,062
Self-closure of fenestration within 12 months, n (%)	3 (33,3)	8 (47,1)	0,484

Note: PTFE is polytetrafluoroethylene; LV — left ventricle; Echocardiography – echocardiography; p is the level of significance of the differences (χ^2 criterion for qualitative data, Student's criterion for quantitative data); dash (—) — statistical comparison is not applicable for this parameter.

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CONCLUSIONS:

A study conducted on the basis of the Multidisciplinary Children's Clinic of the Tashkent State Medical University, which included 87 pediatric patients with septal defects and high pulmonary hypertension, made it possible to formulate the following main conclusions. Complete closure of the septal defect remains the operation of choice in patients with high but reversible pulmonary hypertension with pulmonary artery pressure not exceeding 85% of the systemic pressure according to the data intraoperative tensiometry, and provides a positive immediate result in 83.6% of cases; At the same time, 27.9% of patients in this group required the use of the tactics of delayed closure of the sternum using a silicone spacer, which made it possible to stabilize hemodynamics and avoid lethal outcomes associated with acute right ventricular failure. The use of valvular patches according to the original W. Novick technique in the most severe category of patients with grade IV LH and pulmonary artery pressure exceeding 85% of the systemic pressure provided a positive immediate result only in 55.6% of cases, which indicates the need to improve this technique in relation to the pediatric population with extremely high pulmonary hypertension. The author's modification of the valve patch technique, which provides for a four-point fixation of the valve element at positions 12, 15, 18 and 21 o'clock of the conventional dial using a valve material different from the material of the main patch, demonstrated a significantly higher direct efficiency compared to the original W. Novick method (88.2% vs. 55.6%; p = 0.041), as well as a significant decrease in the frequency of valve-to-patch adhesion (0% vs. 33.3%; p = 0, 018) and complete elimination of aortic valve dysfunction (0% vs. 22.2%; p = 0.048) due to turbulent discharge flow. Uniform redistribution of the blood flow entering the left ventricle during four-point valve fixation is the key hemodynamic advantage of the proposed modification, which reduces turbulence and protects the structures of the left ventricular outlet tract. The tactics of delayed sternum closure using a silicone spacer and a sealing latex-betadine membrane is a safe and effective method of managing patients with unstable postoperative hemodynamics, which allows you to gain time for the adaptation of the pulmonary vascular bed to new hemodynamic conditions. Thus, a differentiated

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approach to the choice of a method of surgical correction of septal defects based on intraoperative tensiometry data, with the use of the author's modification of the valvular patch in patients with extremely high pulmonary hypertension and the tactics of delayed closure of the sternum with unstable hemodynamics, ensures the optimization of the immediate and long-term results of surgical treatment of this severe category of patients and can be recommended for widespread use in pediatric cardiac surgery centers.

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