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IN-HOSPITAL AND LATE OUTCOMES OF SURGICAL VERSUS ENDOVASCULAR REPAIR OF SEVERE AORTIC STENOSIS IN NEWBORNS AND INFANTS

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With the purpose to present in-hospital and late results of balloon aortic valvuloplasty versus surgical aortic valvotomy in newborns and infants with severe aortic valve stenosis 58 consecutive newborns and infants with severe aortic valve stenosis. 47 (81 %) patients underwent balloon aortic valvuloplasty (Group I); 11(19 %) patients – surgical aortic valvotomy (Group II) were enrolled. Initial aortic systolic pressure gradient in Group I comprised 67.6±19 mm Hg; in Group II – 69±23 mm Hg. Both groups were compared with regard to the persistence or recurrence of postoperative aortic pressure gradients, valve insufficiency and necessity for valve-related re-interventions. Late outcomes studied on 36 months. Following balloon aortic valvuloplasty and surgical aortic valvotomy procedures were revealed significant decline of aortic systolic pressure gradient, and increase of left ventricular ejection fraction in both groups. On 12 months following endovascular balloon aortic valvuloplasty aortic pressure gradient increased in most patients, and aortic insufficiency began to increase.

Key words: aortic valve stenosis, surgical aortic valvulotomy, balloon valvuloplasty, infants.

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ГОСПІТАЛЬНІ ТА ВІДДАЛЕНІ РЕЗУЛЬТАТИ ХІРУРГІЧНОГО ТА ЕНДОВАСКУЛЯРНОГО ВІДНОВЛЕННЯ ТЯЖКОГО АОРТАЛЬНОГО СТЕНОЗУ В НОВОНАРОДЖЕНИХ І НЕМОВЛЯТ

З метою виявлення госпітальних і віддалених результатів балонної пластики аортального клапана порівняно з хірургічною вальвулопластикою аорти в новонароджених і немовлят із тяжким стенозом аортального клапана, у дослідження було включено 58 новонароджених і немовлят із тяжким стенозом аортального клапана. 47 (81 %) пацієнтам було виконано балонну пластику аортального клапана (група I); 11 (19 %) пацієнтам – хірургічну вальвулопластику аорти (група II). Початковий градієнт систолічного тиску в аорті в групі I становив 67,6±19 мм рт. ст.; у групі II – 69±23 мм рт. ст. Обидві групи порівнювали за збереженням або рецидивуванням післяопераційних градієнтів тиску в аорті, недостатністю клапана і необхідністю повторних втручань на клапані. Віддалені результати вивчалися через 36 місяців. Після балонної аортальної вальвулопластики і хірургічної аортальної вальвулопластики було виявлено значне зниження градієнта систолічного тиску в аорті і збільшення фракції викиду лівого шлуночка в обох групах. Через 12 місяців після ендоваскулярної балонної аортальної вальвулопластики градієнт тиску в аорті збільшився у більшості пацієнтів, і аортальна недостатність почала наростати.

Ключові слова: стеноз аортального клапана, хірургічна аортальна вальвулопластика, балонна вальвулопластика, немовлята.

Congenital aortic valve stenosis (AVS) is among the more common congenital heart diseases (CHD), accounting for 6 % of all CHD. When the stenosis is severe, it requires emergency intervention during the neonatal life or early infancy. This is undertaken either with a balloon aortic valvuloplasty (BAV) or surgical aortic valvotomy (SAV). Both options manifest a palliative approach with frequent necessity of re-interventions [5, 6].

Throughout the last decades clinicians have switched from one option to another, as both techniques evolved [3, 11, 12]. During surgical "open" heart valvotomy, the surgeon has direct access to the morphology of the aortic valve and can adapt surgical strategy to individual valvular anatomy. In contrast, endovascular BAV does not permit direct vision of the valve and tears aortic leaflets in a random way, usually at the weakest part of the valve and not necessarily at the level of the fused commissures. Despite its "blind" nature, BAV is now favored by most teams in the neonate and infants as a first-choice procedure, because of its greater facility to carry out. After BAV, there is a higher risk of significant aortic regurgitation but generally a lower risk of residual stenosis [6].

A number of studies that compared BAV and SAV revealed almost identical results for both methods [3, 4, 7]. Comparing BAV and SAV, some authors demonstrate no differences on long-term survival or rate of aortic valve replacement, while pointing to higher rates of re-intervention following percutaneous BAV; others show the advantages of the surgical treatment marking significantly better rate of events-free survival (freedom from re-intervention and aortic valve replacement) following surgery [11]. Some reports comparing SAV versus BAV are limited by lack of adjustment for differences between groups [8].

During the first half of the last decade, usage of SAV in the UK has decreased in this population, but in the second half there has been an increase in the number of children undergoing SAV, translating in an increasing proportion relative to BAV [4].

Due to the accumulation of long-term results of both techniques, the approach to the treatment of AVS has become selective. Even today, despite the considerable experience of various clinics, there are no clear criteria for choosing BAV or SAV [2].

BAV and SAV are competing methods, and the choice of primary intervention is usually based on the preferences of a particular institution. The advantages of BAV are minimally invasive, fast, absence of prolonged anesthesia and hemotransfusions which are especially important in critic patients, and does not require anticoagulant therapy. During surgical correction, it is possible to perform not only repair of AVS under visual control, but also to perform plastic surgery to eliminate regurgitation on the valve, and repair concomitant congenital heart diseases, under necessity.

Some clinics today choose BAV as the first-line treatment for severe AVS in newborns and infants due to relatively low rate of mortality and complications [3, 4, 9], while others choose open SAV [11, 10]. On long-term monitoring, BAV more common than SAV follow with progressive aortic valve insufficiency or re-stenosis, requiring re-interventions. The development of scar tissue may promote re-stenosis as well.

The purpose of the study was to compare the immediate and long-term results of surgical versus endovascular balloon interventions for severe aortic valve stenosis in newborns and infants.

Materials and methods. From January 2006 to December 2018, 58 consecutive patients with severe AVS underwent endovascular and surgical treatment at the Amosov National Institution of Cardiovascular Surgery, Kyiv, Ukraine. Enrolled group included 43 boys (74 %), and 15 girls (26 %). All patients were separated in two groups: 4 (81 %) patients which underwent endovascular BAV comprised Group I; 11(19 %) patients who underwent SAV were included in Group II. Mean age of patients in Group I comprised 20±14.3 days; mean body weight – 3.4±1.5 kg. Mean age of patients In Group II was 125±72.4 days; mean body weight – 5.8±1.4kg.

In 23 (39.5 %) patients aortic valve stenosis was revealed prenatally and confirmed by Echo-exam immediately after birth. It must be emphasized that the rate of prenatally verified congenital critical aortic valve stenosis by fetal ultrasound is still low comprising 8.5 %.

Initial systolic pressure gradient via aortic valve in Group I varied from 30 to 114 mm Hg, mean 67.6±19mm Hg; initial systolic pressure gradient via aortic valve in Group II varied from 29 to 120 mm Hg, mean 69±23mm Hg.

All patients underwent ECG, chest radiography, echocardiography and bacteriological exams. In order to clarify concomitant congenital heart diseases CT-scan was performed in 5 (10.6 %) patients of Group I, and 2 (18.2 %) patients of Group II.

Concomitant congenital heart diseases were revealed in 19 (33.33 %) of 57 patients, with prevalence in Group II, unlike of Group I: 45.45 % versus 29.8 %, respectively.

10 (17.54 %) of 57 patients manifested with aortic arch hypoplasia with two-fold prevalence in surgical than endovascular group comprising 27.3 % vs. 14.9 %. Rate of concomitant atrial septal defects was almost equaled in both of groups, comprising in Group I and Group II 8.5 % vs. 9.1 %, respectively. Left ventricular hypoplasia, discrete subaortic stenosis and partial anomalous pulmonary venous return were prerogative of patients which underwent endovascular procedures. Initially all patients with severe aortic stenosis underwent intravenous prostaglandin treatment after birth post diagnosis in order to maintain a sufficient systemic perfusion via a patent ductus arteriosus. Inotropic medication, metabolic acidosis

repair, and ventilator support were indicated under necessity. After stabilization of the clinical status of newborn, SAV or endovascular BAV were performed.

For BAV we used balloon with diameter of 80 % of the aortic valve. If the procedure was uneffective, balloon was changed for increased diameter, but not exceeding diameter of the aortic valve ring. After BAV the systolic pressure gradient and aortic valve insufficiency were studied.

All patients in the surgical group (Group II) underwent on-pump interventions. Depending on the anatomy of the aortic valve, commissurotomy of fused native or pseudocommissures was performed, as well as removal of excess tissue of fibrotic and myxomatous altered valve leaflets. Intraoperatively, after CPB was switched off, transesophageal echocardiography performed to value residual pressure gradient and aortic valve incompetence.

All data obtained were analyzed statistically using descriptive statistics. The mean (M), standard deviation (σ2) of the mean numerical value and its standard error (m), as well as the minimum (min) and maximum (max) values of the series were calculated. Differences were considered statistically significant at $p<0.05$. Statistical processing was carried out using the Statgraphics Centurion 18 (USA) program.

Results of the study and their discussion. In Group I, in-hospital mortality comprised 8.5 % (n=4). In two patients, ICU-stay was complicated by bilateral pneumonia and sepsis. Both patients died on the 15th and 20th days following endovascular procedure from progressive respiratory and multiorgan failure. In third patient, left ventricular failure caused by severe left ventricular fibroelastosis on 5 days after birth. This patient died on the 2nd day following BAV. The fourth death caused by thromboembolism of the abdominal aorta resulted with acute renal infarction. This patient suffered from congenital dysplasia of both kidneys. The patient died on the 30th day after BAV. All fatalities were tied with initial severe clinical status of patients.

There were no deaths in Group II. 10 patients of group II underwent primary "open" aortic valvulotomy, and 1 patient underwent Ross-Konno procedure 15 days following BAV. CPB-time comprised 73±12min.(47–265 min.); aortic clamping time – 47±5min.(23–78 min.).

In 9 (81.8 %) patients of Group II revealed bi-leaflet aortic valve; in 2 patients (18.2 %) – a tricuspid one. The causes of aortic valve stenosis were fusion of the valve leaflets (with one or two pseudocommissures) in all patients; in 7 (63.6 %) patients – additionally diagnosed fibrotic leseion, and myxomatous thickened valve leaflets.

Intensive care unit (ICU)-complications in 16 (34 %) patients of Group I were predominantly manifested with cardiac (n=6), and respiratory (n=5) insufficiency. In 6 (54.5 %) patients of Group II, ICU-stay complicated with left ventricular dysfunction in 3 patients; exudative pleurisy in 1, and cardiac failure in one patient. The rate of complications following BAV and SAV comprised 34 % vs. 54.5 % respectively ($p<0.05$).

Echocardiographic examination was performed 24 hours after BAV and SAV, which confirmed a significant decrease in systolic pressure gradient in both groups. In Group I aortic pressure gradient reduced from initial 65.2±2.7 mmHg to 30.3±3 mmHg ($p<0.5$); in Group II – from 79.1±5.5 to 32.73±3.2 mmHg ($p<0.05$). In both groups, the mean aortic pressure gradient on discharge was the same: 30.3±3 mmHg in Group I vs. 32.73±3.2 mmHg in Group II (Table 1).

Table 1

ICU-stay complications in patients

Complications	Group I, BAV (n=47)	Group II, SAV (n=11)
Heart failure	6 (12.8 %)	1 (9.09 %)
Respiratory failure	5 (10.63 %)	-
Wound infection	0	-
LV dysfunction	0	3 (27.3 %)
Partial lung atelectasis	3 (6.38 %)	-
Hemotransfusions	2 (4.25 %)	1 (9.09 %)
Exudative pleurisy	-	1 (9.09 %)
Total	16 (34 %)	6 (54.5 %)

Note: BAV – balloon aortic valvuloplasty; SAV – surgical aortic valvulotomy.

Mean ventilator support following BAV vs. surgical interventions comprised 31±12h. vs. 38±16h. ($p<0.05$). ICU-stay, following BAV vs. surgical interventions varied from 2 to 40 days (mean 3 days) vs. 3 to 60 days (mean 5 days), respectively ($p<0.05$).

Group I also manifested with significant increase of left ventricular ejection fraction (LVEF): from initial 48.21±3.1 % (18–75 %) to 60.2±1.67 % (55–75 %) on discharge. Unlike of Group I, in patients of Group II LVEF did not change significantly comprising from initially 65.82±4.33 % (59–75 %) to 67.82±2.9 % (65–85 %) on discharge.

LVEF was restored after BAV in all patients, and maintained at a sufficient level, confirming the effectiveness of BAV in patients with initial severe heart failure. Follow-up monitoring varied between 10–60 months (36±5 months).

Monitoring on 12 months following BAV, revealed increased aortic pressure gradient, unlike following SAV which manifested with good late results. Study of long-term outcomes revealed progressive aortic valve incompetence after BAV, than in patients underwent SAV (Table 2).

Table 2

Initial and late items following endovascular versus surgical interventions in patients with severe aortic stenosis

Item	Group I (n=47)	Group II (n=11)	P
Initial pressure gradient (mmHg)	65.2±2.7	79.1±5.5	<0.05
Pressure gradient following intervention	30.3±3	32.7±3.2	0.16
Pressure gradient over 12 months	38.2±3.5	31±2.8	0.28
Pressure gradient over 36 months	45.2±1.7	29.1±2.4	<0.05
Initial LVEF (%)	48.21±3.1	65.82±4.33	<0.05
LVEF following intervention	60.2±1.7	67.82±2.9	<0.05
LVEF at 12 months	62.3±1.9	67.2±2.1	0.26
LVEF at 36 months	65.2±2.4	68±1.9	0.08
Ventilator support (hours)	31±12	38±16	<0.05
ICU stay (days)	3	5	<0.05
In-hospital mortality	4 (8.5 %)	-	

Note: BAV – balloon aortic valvuloplasty; SAV – surgical aortic valvulotomy; LVEF – left ventricular ejection fraction; ICU – intensive care units.

Critical AVS implies a severe impairment of the left ventricle due to a high-grade stenosis and pressure overload of the left ventricle. Of note, there is no standardized definition for critical AVS. Aortic valve dysplasia and hypoplasia of the aortic annulus are the main causes. In most cases, the aortic valve has a unicuspid or bicuspid morphology due to congenital commissural fusions. Additional cardiac malformations may exist, such as aortic hypoplasia or coarctation of the aorta.

Trends of aortic valve incompetence in compared groups were presented in Fig. 1.

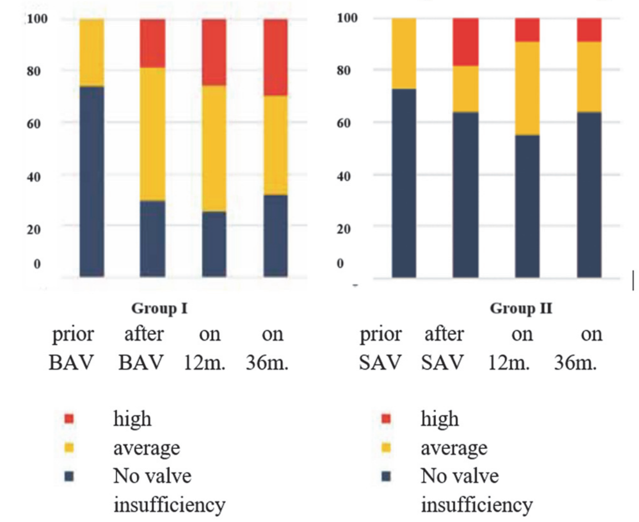

Fig.1. Trends of aortic valve incompetence in Group I and Group II.

Congenital critical AVS is a life-threatening disease requiring urgent treatment. First-line therapy remains a topic of controversy [9]. Management of these neonates is a complex and difficult problem. The spectrum of aortic valve and annular pathology, in addition to a variable degree of hypoplasia of the left heart, complicates treatment.

Critical AVS results in low-output heart failure due to left ventricular pressure overload with severely reduced left ventricular systolic function, left ventricular enlargement and eccentric dilatation, and mitral regurgitation. Endocardial fibroelastosis of the left ventricular may occur as well [3, 4]. Cardiomegaly and fetal hydrops may develop antenatally. However, clinical manifestations vary from mild symptoms to cardiogenic shock after birth [9].

The modern concept of treatment of congenital aortic stenosis comprises surgical methods as well as a catheter intervention. After the pioneering works percutaneous BAV became the first-line therapy for the initial treatment of congenital aortic stenosis. Therapy costs became lower and patients comfort higher [1].

Currently, most of centers have experience, and practice with both options, preferring one of them with the best outcomes. This is summarized in a recent meta-analysis, with only four single-center and two multicenter comparative reports, compared with 12 reports of a single technique, as presented in a recent meta-analysis by G.D. Hill, et al. (2016). Authors compared two interventions and involving 2,368 patients revealed no significant difference in long-term survival or freedom from aortic valve replacement between the two groups. However, higher rates of re-intervention were observed in the BAV group [7].

Originally, it was reported that the progression of aortic insufficiency is not a problem in the first decade after the procedure [3]. Moreover, data from the early studies that compared percutaneous BAV and SAV revealed almost identical results for both methods [4, 7]. It seemed that the outcome of treatment of congenital AVS is more related to the disease itself than to the method of treatment. Percutaneous BAV thus became a logical choice for initial intervention. Our midterm results [8] however, indicated that aortic insufficiency after BAV is indeed a problem; namely, it is frequent and progressive. Also, recurrent aortic valve stenosis developed in a considerable number of patients and contributed to the need for frequent surgical aortic valve interventions in the mid to long term after BAV. The actuarial probability of survival from any valve re-intervention was 89.9 %, 85.9 %, and 82 % on 10, 20, and 30 years after first BAV, respectively. At the same time events-free survival comprised 59.9 %, 35.2 %, and 26.7 % on 10; 20, and 30 years after first BAV, respectively [8].

IMPACT study (Improving Pediatric and Adult Congenital Treatments), the largest study of its kind from the USA, described 1,026 isolated BAV procedures with success rates 70.9 % for noncritical AVS and 62.7 % for critical AVS [1]. The IMPACT study revealed an in-hospital death of 1.5 % for noncritical AVS and 10.0 % for critical AVS and the fact that major adverse events of 9.6 % for the non-critical AVS group and 27.3 % for the critical AVS group [2].

Study of leading predictors of unfavorable late outcomes following endovascular BAV of aortic valve in newborns and infants tied with age at procedure, and features of valve morphology. Christensen AH, et al. (2022) studied late outcomes of BAV on 7.1 (3.3–11) years in 139 infants (of them 48 % neonates) with median age of 33days (7–84 days) and weight 4.0 kg (3.4–5.1 kg), noted that the underlying anatomy of aortic valve, and resulting hemodynamic consequences are more important for prognosis of late outcomes following BAV in newborns and infants than the child's age alone. The child's age below 1 month was significant predictor of re-intervention (HR [95% CI]: 2.1 [1.1-4.1]; P=0.032) [3].

Highlighted features of aortic valve morphology responsible for late outcomes: higher aortic annulus Z–score was predictive for severe aortic regurgitation ($p<0.05$) and lower aortic annulus Z–score for insufficient gradient reduction ($p<0.05$), and lower balloon-to-annulus ratio were predictive of a need for re-valvuloplasty ($p<0.001$). Left ventricular dysfunction n or arterial duct dependency; unicommissural aortic valve were predictive of both worse survival and survival free from any reintervention ($p<0.001$) [3, 8]. Anyway, despite of prevalence rate of aortic pressure gradient recurrency, and necessity in re-interventions, unlike SAV, endovascular BAV is choice of option in newborns and infants with severe aortic stenosis.

The limitations of our study are the retrospective approach as well as the limited number of patients, which was based on both the low incidence of congenital critical AVS and the single center analysis.

Conclusions

1. Group I also manifested with significant increase of left ventricular ejection fraction: from initial 48.21±3.1 % (18–75 %) to 60.2±1.67 % (55–75 %) on discharge.

2. Unlike of Group I, in patients of Group II left ventricular ejection fraction did not change significantly comprising from initially 65.82±4.33 % (59–75 %) to 67.82±2.9 % (65–85 %) on discharge.

3. SAV or BAV both are effective approach for severe aortic valve stenosis in newborns and infants with good in-hospital outcomes. Unlike surgical interventions, endovascular BAV more often mark with progressive tend either of re-stenosis, or valve incompetence on 12–36 months later procedure. Nevertheless, despite of these disadvantages, endovascular BAV could be useful like a first-line treatment in newborns and infants with severe aortic valve stenosis, resulting in left ventricular relief, clinical stabilization, and a time gain until cardiac surgery. Nevertheless, it seems advisable to choose first-line therapy according to the experience of the treatment team.

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NON-STRABISMIC ANOMALIES OF THE EYES IN PRESCHOOL CHILDREN AND THE DEVELOPMENT OF A TRIPLEX ULTRASOUND EXAMINATION

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The purpose of the study was to elucidate the profile of non-strabismic binocular vision dysfunction and its relationship with intraorbital hemodynamic features in preschool children. The prospective study conducted on 1000 patients diagnosed with transient ischemic attack in the neonatal period of life, according to the clinical characteristics of the transition from infancy to the preschool stage of life. These patients were examined dynamically (3 months–3 years, and then from 3 to 6 years): determinations of eye refraction, dynamic refraction, the state of the inner membranes of the eyes, the level of constant potentials of the cerebral cortex of brain. The ophthalmic artery blood flow, the vasomotor supply of the eyes, optical-vestibular sensitivity and neuroplasticity variants are assessed. The most common non-strabismic disorders of binocular vision were accommodation spasm (39.0 %), convergence insufficiency (13.6 %), convergence excess (9.1 %), accommodation insufficiency (15.9 %), basic exophoria (3.5 %), basic esophoria (6.1 %), and inferior oblique muscle hyperfunction (6.4 %).

Key words: binocular vision, non-strabismic disorders, accommodation, transient ischemic attack, children.

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ЗМІНИ ОРГАНА ЗОРУ, НЕ ПОВ'ЯЗАНІ ЗІ СТРАБІЗМОМ, У ДІТЕЙ ДОШКІЛЬНОГО ВІКУ ТА РОЗРОБКА ТРИПЛЕКСНОЇ МЕТОДИКИ УЛЬТРАЗВУКОВОЇ ДІАГНОСТИКИ

Метою дослідження було з'ясування профілю нестрабізмічної дисфункції бінокулярного зору та її зв'язку з особливостями інтраорбітальної гемодинаміки у дітей дошкільного віку. Проспективне дослідження проведено на 1000 пацієнтах із діагнозом минущі гострі порушення мозкового кровообігу в неонатальному періоді життя за клінічними ознаками в період переходу від дитячого до дошкільного етапу життя. У цих пацієнтів проводилося динамічне обстеження (з 3 місяців до 3 років, а потім з 3 до 6 років): визначення рефракції ока, динамічної рефракції, стану внутрішніх оболонок очей, рівня постійних потенціалів кори великих півкуль головного мозку. Оцінювали кровотік очноямкової артерії, вазомоторне постачання очей, оптико-вестибулярну чутливість і варіанти нейропластичності. Найпоширенішими нестрабізмічними порушеннями бінокулярного зору були спазм акомодації (39,0 %), недостатність конвергенції (13,6 %), надлишок конвергенції (9,1 %), недостатність акомодації (15,9 %), базова екзофорія (3,5 %), базова езофорія (6,1 %) і гіперфункція нижнього косого м'яза (6,4 %).

Ключові слова: бінокулярний зір, нестрабізмічні порушення, акомодація, транзиторна ішемічна атака, діти.

Formation of the visual organ, development and improvement of visual functions, age-related increase in visual acuity and the ability to perceive the depth and life of a child and continues until 16–18 years. The main point of such development is the formation of the optical system of the eye, visual acuity and binocular perception functions. Detailed knowledge of age-related features is necessary for early detection of pathology, since they require immediate treatment and, in case of untimely diagnosis, lead to irreversible disorders [14]. Accommodation and binocular vision disorders are the second most common visual impairments in the clinical pediatric population after refractive errors [10]. These dysfunctions are collectively termed Non-Strabismic Binocular Vision Abnormalities (NSBVA). NSBVA mainly affects