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The Analysis of the Risk Factors in the Arterial Switch Operation for Treatment of D-Transposition of the Great Arteries in One Pediatric Cardiac Center in Serbia

Mila Stajević Popović[1,2], Igor Šehić[2], Sergej Prijić[1,3], Vladislav Vukomanović[1,3], Jovan Košutić[1,3]

[1]University of Belgrade, School of Medicine, Belgrade, Serbia;
[2]Department of Pediatric Cardiothoracic Surgery, Institute for Mother and Child Health Care of Serbia "Dr Vukan Čupić", Belgrade, Serbia;
[3]Department of Pediatric Cardiology, Institute for Mother and Child Health Care of Serbia "Dr Vukan Čupić", Belgrade, Serbia

SUMMARY

Introduction The arterial "switch" operation has been the operation of choice for children born with D-transposition of the great arteries (D-TGA) for more than 30 years in countries with developed pediatric cardiac surgery program. After two decades of successful treatment of these children with the atrial "switch" corrections (Mustard or Senning operative techniques), the arterial "switch" operation (ASO) had been introduced as a routine technique in one pediatric cardiac center in Serbia.

Objective The aim of this study was the analysis of the identified risk factors involved with the ASO in the preoperative, operative and postoperative period and their impact on the survival of the operated children.

Methods A retrospective nonrandomized study of 52 operated patients with D-TGA by the ASO in the period between May 1, 2003 and December 31, 2011, divided into two groups. The data collection consisted of preoperative, operative and postoperative factors during the in-hospital stay and until the discharge from the hospital. Descriptive and differential statistical methods were used for analysis.

Results Ten individual risk factors were identified as significant for the immediate survival of children operated with the ASO technique.

Conclusion The arterial "switch" surgical operative technique is a complex neonatal/young infant procedure in which the preoperative status carried a significant risk as well as the surgical technique itself. These results differ from the results published throughout the world and are a representation of an evolutionary process of one center in Serbia starting the ASO procedure.

Keywords: D-transposition of the great arteries (D-TGA); arterial "switch"; risk factors

INTRODUCTION

The arterial "switch" operation (ASO) has been the operation of choice for surgical treatment of D-transposition of the great arteries (D-TGA) for more than three decades in the developed world reaching very high survival rates in the last 10 years [1]. The fate of these neonates in the developing/transitional countries has still remained a surgical challenge in the 21st century [2]. This department of pediatric cardiac surgery in Belgrade was founded in February 1982. Until 1992, the surgical correction of D-TGA was based on the Mustard and Senning modifications of the ASO. Compared to 38 mostly successful atrial switch operations, there were only five attempts with the arterial switch procedure with no survivors. Between 1997 and 2001, due to the collaboration of the hospital with a foreign humanitarian foundation, five neonates received the ASO, of which three survived. During the worst crisis in the modern history of Serbia, children with complex congenital heart disease and favorable outcomes for surgery were sent abroad for surgical treatment. Thus, between 1992 and 2005, about 50 neonates with D-TGA were operated on mostly in Great Britain with an impressive survival rate of 98%. The cost of one ASO procedure abroad exceeded the cost of 10 open heart surgeries in Serbia.

OBJECTIVE

The objective of this study was to show the commencement and evolution of the arterial switch program in our hospital with the identification of the most important risk factors for the survival of children treated by the ASO [3-6]. Since the beginning of this project, only four cases from our center had been sent abroad for surgery. They included two patients with D-TGA with left ventricular outflow tract obstruction (LVOTO) and two cases with complex coronary anatomy. Foreign guest surgeons operated on two patients – one with Taussig–Bing anomaly and the other with complex coronary anatomy.

Correspondence to:
Mila STAJEVIĆ POPOVIĆ
Department of Pediatric Cardiothoracic Surgery
Institute for Mother and Child Health Care of Serbia
"Dr Vukan Čupić"
Radoja Dakića 6-8, 11070 Belgrade
Serbia
mila.stajevic@yahoo.com

METHODS

Outcome analyses of the patients who had undergone the ASO from May 2003 until December 2011 were included in the study. The surgical team of the hospital had performed a total number of 52 ASOs in an eight-year period, 50 cases were operated on by one senior pediatric cardiac surgeon and two cases by a visiting surgeon. Six anesthesiologists and three perfusionists were involved in the operative procedures. The performing cardiac surgeon had had surgical training abroad in a total duration of two and a half years, while the assistant cardiac surgeons were also trained abroad for a one-year period in a center which performed the ASO on a routine basis. Our cardiac surgery center did not have access to extracorporeal membrane oxygenation (ECMO) support in this period.

This is a retrospective nonrandomized study which has been approved by the Ethical Committee of the hospital. Data includes complete documentation, including patient history notes, operative and postoperative charts, discharge letters and follow-up examinations of a period of minimum 12 months. As the purpose of this study was to show the evolution of the ASO through two periods, the identified time spans were from May 1, 2003 until December 31, 2007 (Group I) and from January 1, 2008 until December 31, 2011 (Group II). The group periods were determined by adoption of an intra- and perioperative protocol in January 2008 containing the revised preoperative, operative and postoperative techniques, as well as by the introduction of new anesthesiologists who underwent training in neonatal cardiac anesthesia. The Yacoub–Radley-Smith [7] coronary classification was used for determining the coronary anatomy.

The statistical methods used for data analysis were the following: descriptive (groups and tables, arithmetic mean, standard deviation) and differential (variation coefficient, ANOVA – analysis of variance, Pearson's χ^2 test, Fisher's exact test, 95% confidence interval and logistic regression analysis).

Data collection and analysis: The total number of patients, age of the patients at the time of surgery, sex distribution, patient body mass, conjoint cardiac and non-cardiac anomalies, anatomic subsets of D-TGA, the preoperative patient status (interventions and mechanical ventilation, inotropic support), the length of induction of anesthesia, operative and cardiopulmonary bypass techniques, preoperative, operative and immediate postoperative laboratory results (hemoglobin, base excess and lactate values). Intra operative complications, postoperative open sternum, immediate postoperative course (low cardiac output syndrome ECG ischemia, arrhythmias, bleeding, respiratory complications, infection, neurological complications), as well as the total and yearly mortality were also included as examined parameters.

The size of the left ventricle was not analyzed as a separate factor because of the incoherent descriptions of this entity ("border line", "banana shaped", "relatively normal" etc.). The patients were all operated on regardless of the left ventricular size as they had no other option of treatment opposed to the imminent death outcome.

RESULTS

The total number of children operated on was 52. Group I consisted of 28 children, Group II of 24 children. Male to female ratio was 36 to 16. The average incidence of the D-TGA babies compared to the total number of the patients who underwent surgery was 4.57% (0.85% to 7.81%). There were 44 "simple" D-TGAs with intact ventricular septum (84.6%), eight children with "complex" anatomies – seven babies with D-TGA with ventricular septal defect (VSD, 13.5%) and one child with a Taussig–Bing anatomy (1.9%). One baby had coarctation of the aorta (1.9%), seven children (13.4%) had associated non-cardiac anomalies (hematological, gastrointestinal, renal and central nervous system anomalies). The time of surgery was between seven and 123 days of life ("simple" D-TGA with intact interventricular septum, D-TGA+VSD, Taussig–Bing, and one late "two stage" switch), with four children operated in the first week of life (7.69%), 17 children operated in the second week of life (32.69%), 10 in the third week of life (19.23%), 17 after the third week of life (32.69%) and four after the age of two months (3.84%). Patient distribution according to the body mass was as following: 11 children weighed between 2,500 g and 3,000 g (21.15%), 15 babies between 3,000 g and 3,500 g (28.84%) and 26 babies were heavier than 3,500 g (50%). All the babies were born after the 37th gestational week, apart from two who were born in the 35th and 36th gestational week.

Preoperatively, echocardiography was performed in all patients, and cardiac catheterization in four children who required assessment of the pulmonary vascular resistance. Fifty children (96.15%) had Rashkind balloon atrioseptostomy prior to surgery and seven patients had been mechanically ventilated (13.46%). No patients required preoperative inotropic support. Two patients (3.84%) had preoperative sepsis, two (3.84%) patients had preoperative intracranial hemorrhage and nine (17.3%) had chest infections.

The described coronary artery patterns were as following: 38 children (73.07%) had the normal coronary artery anatomy (Sinus 1 – left coronary artery and circumflex artery, Sinus 2 – right coronary artery), two patients (3.84%) had "inverted" coronary anatomy (Sinus 1 – right coronary artery, Sinus 2 – left coronary artery + circumflex artery), eight patients (15.38%) had the circumflex artery coming out of the Sinus 2 with the right coronary artery, one patient was with the single ostium anatomy (1.92%) and three patients (5.76%) with other coronary artery patterns. We had no patients with intramural coronary arteries.

Six anesthesiologists were involved in the ASO procedures. The length of the induction of anesthesia (length of time between intubation and skin incision) was less than 60 minutes in 13 children (25%), between 60 and 90 minutes in 22 children (42.30%) and over 90 minutes in 17 children (32.7%).

The standard "arterial switch" technique (transection of the great arteries, coronary artery transfer, reconstruction of the great arteries with the Lecompte maneuver, atrial septal defect (ASD), VSD closure, reconstruction of the pulmonary artery with autologous pericardium) was applied to all cases. Single venous atrial cannulation was used in all cases except children with D-TGA+VSD. Myocardial arrest was achieved after aortic cross clamping with cold crystalloid cardioplegia (the initial dose of 30 ml/kg BW and 20 ml/kg BW when repeated) and topical cooling with ice slush. Deep hypothermic circulatory arrest was applied in the first nine patients (the first period) in order to close the ASD and was subsequently abandoned, replacing the circulatory arrest with the suction collection of the venous return during the ASD closure or bi-caval cannulation (43 patients). Deep hypothermia below 22°C was applied in 20 patients, 22 patients were operated on at the temperature of 24°C and 10 at the temperature of 28°C. The myocardial ischemic time ("cross-clamp" time) was shorter than 90 minutes in nine patients, between 90 and 100 minutes in 11 patients, between 100 and 110 minutes in 18 patients and longer than 110 minutes in 14 patients. The length of the cardiopulmonary bypass was shorter than 150 minutes in 22 cases, 12 babies needed between 150 and 180 minutes of cardiopulmonary bypass (CPB) support, nine babies between 180 and 210 minutes and nine babies above 210 minutes. All patients were conventionally ultrafiltrated during the operative procedure (100%), and 30 patients had modified ultrafiltration post CPB. Thirty-four patients received aprotinin during and after CPB until it was withdrawn from use. We have analyzed the hemoglobin (Hb) values immediately before and after CPB: 33 patients had lower Hb values than 10 g/l prior to CPB, 18 had Hb values between 10 and 13 g/l and one above 13 g/l. The immediate postoperative CPB (prior to modified ultrafiltration) Hb values were: two patients had Hb values lower than 10 g/l, 31 had Hb between 10 and 13 g/l, and 19 children had Hb higher than 13 g/l. The arterial base excess prior to the open heart procedure was 0 to -5 mmol/l in 46 patients, and lower than -5 mmol/l in six babies. Post CPB, 34 patients had arterial base excess between 0 and -5 mmol/l, and the values were lower than -5 mmol/l in 18 patients.

Serum lactate levels have been available since 2007 and have been analyzed in a total of 25 patients. Lactate levels prior to CPB were below 2 mmol/l in two patients, 2–5 mmol/l in 16 patients, 5–7 mmol/l in three patients and above 7 mmol/l in one patient. The children ended the operation with the lactate levels 2–7 mmol/l in 17 cases, in five cases the levels were 5–7 mmol/l and three babies had lactate levels higher than 5 mmol/l.

Intraoperative complications were described as technical (due to failures in equipment) and were registered in one patient (faulty cardioplegia delivery), and 18 patients had intraoperative complications in the form of bleeding, problems in lung ventilation, ECG ischemia, arrhythmias. Four children required reanastomoses of the coronary arteries.

Twenty-eight babies were weaned off CPB during the first attempt, 16 needed a single period of myocardial reperfusion and in eight cases three or more attempts were necessary to cease the cardiopulmonary bypass.

Postoperatively, a total of 31patients had open sternum which was reapproximated after the hemodynamic stabilization and weaning from adrenaline support. The first 48 hours of the postoperative care were uneventful in 21 patients (40.38%), seven (13.46%) had signs of severe low cardiac output syndrome, temporary ischemia on the ECG was registered in six patients (11.53%), reversible arrhythmias were registered in eight patients (15.38%), prolonged bleeding requiring surgical re intervention in three babies (5.76%), ventilation problems (pulmonary hypertensive crises, recurrent atelectases and pneumothoraces) in nine (17.3%), infection was registered in three patients (5.76%) and neurological disturbances in one child (1.92%).

The overall mortality was 36.53%, the mortality in the first period, between 2003 and 2007, was 46.4% and 25% between 2008 and 2011. There was no mortality (0%) in the last 11 cases (September 2010 to December 2011).

The initial statistical analysis has identified 10 significant risk factors which were crucial for the survival of babies with D-TGA operated on using the ASO in our institution:

a) The total mortality in the period between 2003 and 2007 was 46.4%. Concerning the age, the operation itself was not found to be a statistically significant risk factor in this group, where the average age was 21.7 days, but after extrapolating the patients with D-TGA+VSD and the child who had a "two stage" switch procedure, the older patients had higher mortality rates;

b) Regarding coronary anatomy, it was abnormal in 12 patients, where the suboptimal surgical transfer significantly affected the final outcome in both groups;

c) Regarding the intra operative hypothermia – deep hypothermic circulatory arrest – the first 19 cases were operated on under deep hypothermia of 17°C to 19°C with periods of deep hypothermic circulatory arrest, which had significantly affected the final result of the patients;

d) The length of CPB longer than 180 minutes affected our patients, resulting in higher mortality rates. The length of cross-clamp time was not found to be a significant risk factor (an average of 101.4 minutes in the first phase versus 93.8 minutes in the second phase). The prolonged CPB times were related exclusively to myocardial reperfusion periods or revisions of the bleeding from the anastomotic sites;

e) The arterial base excess values at the END of surgery were found to be in direct correlation with the length of the operative procedure and intraoperative and postoperative low cardiac output syndrome resulting with fatal outcomes;

f) Preoperative hemoglobin values were found to influence the final outcome whether in the form of a preoperative anemic baby or limited exsanguination during induction of anesthesia and introduction of venous and arterial lines or frequent arterial gas analysis;

g) Postoperative hemoglobin values are mostly related to the perfusion techniques, amount of prime volume, type of oxygenator and types of ultrafiltration during surgery – degree of hemodilution during CPB;

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h) Concerning the length of induction of anesthesia (time of intubation to the skin incision in minutes), insertion of one arterial line, one or two central venous lines, peripheral venous line and urinary catheter took various lengths of time. The length of this procedure was directly proportional to the clinical state of the newborn regarding body temperature, peripheral vasoconstriction with repercussions on the blood pH, increased values of serum lactates and lower arterial base excess values. This parameter directly influenced the final outcome of our patients;

i) Number of attempts of CPB weaning directly influenced the eventual fatal outcome (low cardiac output, capillary leak, increased overload and distension of the myocardium, pulmonary edema);

j) Ischemic ECG changes lasting more than two minutes on the standard monitoring device (V1-6, aVR, aVL, aVF) during CPB weaning implied a suboptimal coronary transfer. The changes unequivocally indicated a coronary transfer revision. The hazardous situations were manipulations of the great vessels during revisions of bleeding sites (kinking of the miniature coronary arteries) or compression of the coronaries with excessive quantities of topical hemostatic agents.

Logistic regressional analysis of the statistically significant results showed that the three most important risk factors in our series were: deep intraoperative hypothermia (lower temperatures than 20°C – higher mortality – odds ratio 0.020), hemoglobin levels at the end of the surgical procedure (levels lower than 10 g/l – higher mortality – odds ratio 0.024) and the length of the introduction of anesthesia (induction longer than 90 minutes – higher mortality – odds ratio 0.012), (Tables 1 and 2).

Table 1. Logistic regressional analysis of the data

Variable	Score	DF	Significance
Phase I (2003–2007)	2.559	1	0.110
Sex	0.279	1	0.598
Body mass (g)	0.036	1	0.850
Age (days)	0.588	1	0.443
Balloon atrioseptostomy	1.198	1	0.274
Ventricular septal defect	0.004	1	0.951
Preoperative mechanical ventilation	1.481	1	0.224
Preoperative conjoint anomalies	0.322	1	0.571
Coronary anatomy	5.255	1	0.022*
Degree of intraoperative hypothermia (°C)	6.186	1	0.013*
Ischemic myocardial time (min)	0.167	1	0.683
Deep hypothermic circulatory arrest	4.261	1	0.039*
CPB (min)	11.250	1	0.001*
Modified ultrafiltration	1.307	1	0.253
Conventional ultrafiltration	1.246	1	0.264
Diuresis after CPB	0.004	1	0.951
Aprotinin	0.742	1	0.389
Arterial BE preoperatively	0.530	1	0.467
Arterial BE postoperatively	2.151	1	0.142
Hgb preoperatively	2.969	1	0.085
Hgb postoperatively	4.953	1	0.026*
Introduction of anesthesia (min)	16.131	1	0.000*
Weaning from CPB	6.061	1	0.014*
Open sternum	0.964	1	0.326
ECG ischemia	2.655	1	0.103

* statistically significant

DF – degree of freedom; CPB – cardiopulmonary bypass; BE – base excess; ECG – electrocardiogram

DISCUSSION

The routine performance of the arterial switch procedure in the surgical treatment of D-TGA in one of the two pediatric cardiac surgical centers in Serbia had commenced nearly 20 years after the first introduction of this operation in the developed world. The current mortality rate for the so-called "simple" D-TGA is less than 5% in most Western European and USA centers [6]. High cardiac surgical neonatal mortality, among others, of those operated on using the ASO, caused a great scandal in the United Kingdom ("Bristol Case") between 1990 and 1995. The inquiry found an "old boys" culture among doctors, a lax approach

Table 2. Further logistic regressional analysis of the significant factors

Variable	B	SE	Wald	DF	Sig.	OR	95.0% CI for OR	
							Lower	Upper
Phase I (2003–2007)	-7.007	4.976	1.983	1	0.159	0.001	0.000	15.576
Coronary anatomy	-1.370	0.789	3.017	1	0.082	0.254	0.054	1.192
Degree of intraoperative hypothermia	5.475	2.358	5.393	1	0.020*	238.6*	2.3*	24233.5*
Deep hypothermic circulatory arrest	0.565	2.994	0.036	1	0.850	1.759	0.005	622.089
Length of CPB (min)	-1.238	0.954	1.684	1	0.194	0.290	0.045	1.881
Arterial BE postoperative	-2.346	1.901	1.523	1	0.217	0.096	0.002	3.974
Hemoglobin preoperative	1.603	1.738	0.851	1	0.356	4.968	0.165	149.777
Hemoglobin postoperative	5.549	2.456	5.103	1	0.024*	257.0*	2.1*	31684.0*
Length of induction of anesthesia	4.413	2.144	4.236	1	0.040*	82.5*	1.2*	5519.4*
Intraoperative problems	-0.052	0.847	0.004	1	0.951	0.949	0.181	4.991
Weaning from CPB	-0.953	1.026	0.863	1	0.353	0.386	0.052	2.879
ECG ischemia	-2.180	5.028	0.188	1	0.665	0.113	0.000	2154.65

* statistically significant

B – beta coefficient; SE – standard error ; Wald – Wald test; DF – degree of freedom; Sig. – significance; OR – odds ratio; CI – confidence interval; CPB – cardiopulmonary bypass; BE – base excess; ECG – electrocardiogram to safety, secrecy about doctors' performance and a lack of monitoring by the hospital managements [8, 9]. Although certain authors posed questions about introducing the ASO in countries with lower volume departments (less than 150 procedures per year) and the unacceptability of the "learning curves" for individual surgeons (EACTS recommendations), no acceptable alternative solutions have been given for countries which could not fully meet the EACTS standards [10]. Although some neighboring countries reported the management of children with congenital heart disease (needing complex operative treatment) by linking to geographically close experienced hospitals, "twinning" of cardiac surgery centers had not been a realistic option in our case. Most of the surgeons who had been invited to participate on this basis could not, or would not, commit themselves for any longer period of time to such a project. In his legendary article "Human factors and cardiac surgery", de Leval [11, 12] was amongst the first authors who addressed nonsurgical issues dealing with the ASO. In our local circumstances in 2003, we felt that the introduction of the ASO in our center, after more than 10 years of catastrophic socio-economic conditions, was completely justified, especially as the budget of the Serbian National Health Service was drained by the D-TGA patients who were sent abroad for surgery. Our results show that beside the obvious suboptimal surgical performance in the coronary artery transfer, there were also other, very significant risk factors which were associated with the preoperative conditions of the children and preoperative and operative procedures and perfusion techniques. These risk factors are very rarely mentioned in the literature [13]. In our circumstances, they could be easily explained by the training, experience and organization of the nonsurgical staff. The cardiac surgeons have had exposure to this surgical technique and postoperative management during their training abroad, while the other members of the team had no such training and therefore no experience with neonates with complex congenital heart disease. The second period (2008–2011) demonstrated a dramatic fall in the mortality rate by nearly 50% and a consecutive series of 11 patients with no mortality regardless of the anatomic complexity (between 2010 and 2011). This came as a result of having established certain protocols. On the local level they were: a) identifying the most skilled nonsurgical members of the team (regardless of the department hierarchy or the "old boy" culture) to be involved in the ASOs; b) obligatory postponing the surgery for a minimum of 24 hours if the induction of anesthesia took more than 90 minutes, the lactate levels exceeded 5 mmol/l, or in case of obvious clinical deterioration of the child (hypothermia, low hemoglobin, desaturation) [13]: c) revision of the perfusion techniques (exclusion of deep hypothermic circulatory arrest, the shift towards higher intraoperative temperatures and more intensive filtering of the prime volumes) [14]. Personal surgical experience with the coronary transfer was also a crucial factor in the second period [15].

Interestingly enough, the patients' age at surgery was not a prominent risk factor in our series but it was related to a longer intensive care and hospital stay. The size of the left ventricle was not assessed as a separate risk factor because of the incomplete documentation or "descriptive" values for most of our patients. The associated cardiac (VSD, coarctation of aorta) and noncardiac conjoint anomalies or conditions did not influence the outcomes of the ASO [16]. A higher incidence of "simple" D-TGAs was recorded in our series compared to the complex types, but this can be explained by a number of patients who were regarded as high-risk cases (four known cases) and had been sent abroad for surgery through the National Health Service or were privately funded in the mentioned period. A patient with a "simple" D-TGA conjoint with Hemophilia A was successfully operated on in our center and a paper on this case was published. This was the youngest ever reported patient with Hemophilia A surviving cardiopulmonary bypass [17].

On the educational level, our further measures had included sending anesthesiologists, intensivists, nurses and perfusionists abroad for shorter or longer periods of time (two weeks to three months) and retraining them in cardiac anesthesia and perfusion. Operating with foreign cardiac surgeons, when possible, in cases with complex anatomic subsets of D-TGA, was also a helpful option in two cases.

CONCLUSION

The successful surgical outcome of the neonates with D-TGA operated on using the ASO is influenced by many nonsurgical factors. With due respect, most of the criteria recommended by the European Association of Cardio-Thoracic Society (EACTS) could not be implemented in a country ruined by civil war and sanctions, at least in the first half of the program. After installing optimal conditions for neonatal cardiac surgery, a period of about five years had been necessary to establish a successful protocol for surgical treatment of children with D-TGA by the ASO in our center. This entailed parallel training of surgeons, and nonsurgical staff (anesthesia, perfusion, intensive care physicians, and nursing staff). The results from the second pediatric cardiac surgery center in Belgrade with their middle term follow-up results also prove that this procedure can be recognized as the operation of choice for babies with D-TGA in Serbia [18].

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Анализа фактора ризика артеријске „свич“ операције у лечењу Д-транспозиције великих крвних судова срца у једном педијатријском кардиолошком центру у Србији

Мила Стајевић Поповић[1,2], Игор Шехић[2], Сергеј Пријић[1,3], Владислав Вукомановић[1,3], Јован Кошутић[1,3]

[1]Универзитет у Београду, Медицински факултет, Београд, Србија;
[2]Служба за педијатријску кардиоторакалну хирургију, Институт за здравствену заштиту мајке и детета Србије „Др Вукан Чупић“, Београд, Србија;
[3]Одељење за испитивање и лечење болести срца и крвних судова, Институт за здравствену заштиту мајке и детета Србије „Др Вукан Чупић“, Београд, Србија

КРАТАК САДРЖАЈ

Увод Артеријска „свич“ операција (АСО) је хируршка техника избора код деце рођене са Д-транспозицијом великих крвних судова (*D-TGA*) већ више од тридесет година у земљама с развијеним педијатријским кардиохируршким програмом. Након две деценије успешног лечења ових болесника хируршким техникама по Мустарду или Сенингу, АСО је уведена као рутинска хируршка техника у једном педијатријском кардиохируршком центру у Србији.

Циљ рада Циљ истраживања је био да се препознају и анализирају фактори ризика АСО пре, током и после хируршког лечења деце са *D-TGA*, те њихов утицај на преживљавање оперисане деце.

Методе рада Ретроспективна студија је обухватила 52 болесника са *D-TGA* (сврстана у две групе) који су оперисани применом АСО између 1. маја 2003. и 31. децембра 2011. године. Током истраживања анализирани су подаци о преоперационом, операционом и постоперационом току за време боравка у болници, односно амбулантних контролних прегледа. У обради података коришћене су методе дескриптивне и диференцијалне статистике.

Резултати Десет посебних фактора ризика је идентификовано као значајно у непосредном преживљавању деце оперисане техником артеријског „свича“.

Закључак АСО је сложена хируршка процедура која се примењује током неонаталног, односно раног одојеначког доба, где преоперационо стање детета носи значајне ризике као и сам хируршки захват. Наши резултати су донекле разликују од објављених резултата у свету и представљају одраз развојног процеса једног кардиохируршког центра у Србији у примени АСО.

Кључне речи: транспозиција великих артерија; артеријска „свич“ операција; фактори ризика

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