The Role of Shunt in The Norwood Procedure

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ABSTRACT

Introduction: In this study we observed that the effect of post-Norwood 3.5 mm modified BTS (mBTS) and 5 mm right ventricle to pulmonary (Sano modification) shunt models on clinical outcomes.

Patients and Methods: Fifty-four patients who were operated in our hospital between 2011 and 2020 years, were included in our study and this is a retrospective, observational, single-center case series study.

Results: The effect of shunt type on mortality was statistically significant, and the rate of death was lower in patients who used SANO type shunts (p < 0.05). The effect of vasoactive inotropic score (VISC score) on early mortality was significant, and VISC score was higher in the group with exitus (p < 0.05).

Conclusion: Although Sano shunt seems more preferred in Norwood, the experience of the surgeon and the center's experience may have led to variation in results at hypoplastic left heart syndrome. Nevertheless, it will be clinically important for studies to evaluate the long-term results between the two shunt types.

Key Words: Norwood procedure; shunt.

Norwood Prosedüründe Şantın Rolü

ÖZ

Giriş: Bu çalışmada, Norwood sonrası 3.5 mm modifiye BTS ile 5 mm sağ ventrikül/ pulmoner arter (Sano modifikasyonu) şant modellerinin klinik sonuçlar üzerindeki etkisi gözlemlenmiştir.

Hastalar ve Yöntem: Çalışmaya 2011-2020 yılları arasında hastanemizde ameliyat edilen 54 hasta dahil edilmiştir. Bu çalışma, geriye dönük, gözlemsel ve tek merkezli bir olgu serisidir.

Bulgular: Şant tipinin mortaliteye etkisi istatistiksel olarak anlamlı bulunmuştur ve SANO tipi şant kullanan hastalarda ölüm oranı daha düşüktür (p< 0.05). VISC skorunun erken mortaliteye etkisi anlamlı bulunmuştur ve VISC skoru eksituslu grupta daha yüksektir (p< 0.05).

Sonuç: Sano şant Norwood'da daha çok tercih edilmiş gibi görünse de cerrahın deneyimi ve merkezin deneyimi hipoplastik sol kalp sendromunda sonuçlarda farklılaşmaya yol açmış olabilir. Bununla birlikte, çalışmaların iki şant tipi arasındaki uzun vadeli sonuçları değerlendirmesi klinik olarak önemli olacaktır.

Anahtar Kelimeler: Norwood prosedürü; şant.

INTRODUCTION

Babies with hypoplastic left heart syndrome usually undergo a three-stage reconstruction that results in the fontan procedure. The first stage is the Norwood stage 1 procedure in which the hypoplastic aorta reconstructed aorta is connected to the proximal main pulmonary artery for systemic outlet of the right ventricle. Pulmonary flow is provided by a classical MBT shunt or RA-PA (Sano) shunt. After age of about 6 months, the shunt is removed in the second operation (stage II) and pulmonary blood flow is short-circuited by the anastomosis between the superior vena cava and the pulmonary artery. The Fontan procedure (stage III) is usually done when the child is between 18 and 48 months old. In this surgery, the blood flow from the inferior vena cava is directed to the pulmonary artery and the pulmonary and systemic circulations are separated⁽¹⁾.

No procedure has been discussed as much as the Norwood operation in the surgery of congenital heart diseases. With the increase in technique and experience, the results have also led to a dramatic improvement^(2.4).

The Norwood procedure with a modified Blalock-Taussig (MBT) shunt, the first palliative stage for single-ventricle lesions with systemic outflow obstruction, is associated with high



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© Copyright 2021 by Koşuyolu Heart Journal Available on-line at www.kosuyoluheartjournal.com mortality. The right ventricle-pulmonary artery (RV-PA) shunt may improve coronary flow but requires a ventriculotomy.

The most important developments in the past decade are the use of a right ventricle to pulmonary artery (RV-PA) shunt (Sano) as an alternative to the Blalock-Taussig (BT) shunt, as well as the "hybrid" use of bilateral pulmonary artery banding and ductal stenting.

Our aim is to observe the effect of post-Norwood 3.5 mm modified BTS and 5 mm right ventricle to pulmonary (Sano modification) shunt models on clinical outcomes.

PATIENTS and METHODS

Fifty-four patients who were operated in our hospital from 2011 to 2020 were included in our study and this is a retrospective, observational, single-center case series study. Patients' gestational age, gender, weight, hospitalization time, preoperative echocardiographic data and PDA size, procedure applied, preoperative and postoperative SpO₂ values, CPB and PCC duration, intraoperative volume balances, VISC scores were evaluated. Twenty-four (44.4%) of the patients were female, 30 (55.6%) were male. Nine (16.7%) patients were preterm/SGA (small for gestational age) delivery and 45 (83.3%) patients were after term pregnancy. Average birth weight is 3296 ± 486.6 gram. The duration of intensive care unit stay is 31.22 ± 3.81 days. CPB times average 218.27 ± 10.92 minutes. PCO durations are on average 90.89 ± 5.51 minutes. It resulted with exitus in 17 (31.5%), and survival was in question in 37 (68.5%) patients. The average VISC scores of the patients are 22.11 \pm 6.97. Preoperative and postoperative SpO₂ values average 90.97 \pm 3.77 and 81.11 \pm 5.85, respectively. Central veno-arterial ECMO support was required in 7 (12.9%) patients. The mean CPB balance of the patients is -131.28 ± 110.50 mL, and the peroperative volume balance is 156.31 ± 54.43 mL.

The first postoperative 30 days are taken as basis for early mortality. Preterm or SGA delivery is defined as preterm or sga babies whose gestation week is below 37th week or whose birth weight is below the 10th percentile according to the week of gestation. Echocardiographic data were used when defining PDA dimensions.

Ethics committee approval was obtained for the study. It was conducted retrospectively, observing the ethical rules, in accordance with the Declaration of Helsinki.

IBM SPSS STATISTICS v24 program was used for statistical analysis. While evaluating the study data, descriptive statistical methods (Average, Standard Deviation, Median, Frequency, Ratio, Minimum, Maximum) were used. Chi-Square test was applied with categorical data. Mann-Whitney U test was used for numerical data analysis that did not conform to normal distribution on categorical data, independent sample t test used on other group. Spearman test was used for correlation analysis in numerical data. Logistic regression analysis was used to investigate the effect of parameters on exitus.

RESULTS

Fifty-four patients were included in the study and their mean birth weight was 3296 ± 486.6 kg. The duration of intensive care unit stay is 31.22 ± 3.81 days.

Preterm or Sga delivery has no significant effect on early mortality (p> 0.05). There is no significant effect on early mortality of patients in the preoperative period (p> 0.05). The effect of shunt type on mortality is significant and the exitus rate is less in patients where sano type shunt is used (p< 0.05)

Likewise, there is no statistically significant difference between birth weight and patients with early death (p> 0.05). There is no significant difference between babies born preterm, according to therm borns, between intraoperative or postoperative period of going to ecmo, maybe it can be assessed in terms of LCOS.

There was a statistically significant difference between the groups who died and survived in terms of length of stay in the intensive care unit (p< 0.05). Preoperative SpO_2 level also has no statistically significant effect on exitus (p< 0.05). VISC score had a significant effect on early mortality, and VISC score was significantly higher in the group with exitus (p< 0.05).

There is a significant positive correlation between the length of stay in the intensive care unit and birth weight, and the correlation coefficient is r=0.32 and it is weakly correlated (p<0.05).

In this study, factors that may affect early mortality were investigated. There was no significant effect on exitus between babies born preterm or SGA and the normal patient group (p > 0.05). Likewise, the effect of birth weight on early mortality was not statistically significant (p> 0.05). There was no significant difference between the patients who were intubated and operated during the preoperative preparation period and those who were followed up extubated (p > 0.05). Preoperative and postoperative SpO2 values had no significant effect on early mortality (p > 0.05). The effect of shunt type on mortality was statistically significant, and the rate of death was lower in patients who used SANO type shunts (p < 0.05). The effect of VISC score on early mortality was significant, and VISC score was higher in the group with exitus (p < 0.05). There is a significant positive correlation between the duration of stay in the intensive care unit and birth weight, and the correlation coefficient is r= 0.32 and it is weakly correlated (p< 0.05). Factors that may have an effect on early mortality were examined and the effect of VISC score, shunt type and lenght of intensive care unit stay on mortality was analyzed.

Table 1. Categorical variables that have an impact on mortality							
Parameters	Variables	Frequency	Percent				
Pretermorsga	Term	45	83.3				
	Preterm or SGA	9	16.7				
Gender	Female	24	44.4				
	Male	30	55.6				
ECMO	Without ECMO	47	87				
	ECMO	7	13				
Preoperative	Extubated	39	72.2				
respiratory status							
	Intubated	15	27.8				
Type of shunt	SANO	40	74.1				
	BT SHUNT	14	25.9				
Total		54	100				

ECMO= Extracorporeal membran oxigenator, BT SHUNT= Blalock -Taussing Shunt, SGA= Small for gestational age.

Table 2. Numerical variables that affect mortality									
Descriptive statistics									
Parameters	Range	Minimum	Maximum	Mean	SD				
Lenght of ICU stay (/h)	128	1	129	31.22	28.00				
ACC (min)	161	40	201	90.61	27.64				
CPB (min)	271	134	405	218.19	54.78				
VISC score	34	13	47	22.11	6.98				
Preoperative SpO ₂	20	79	99	90.97	3.78				
CPB balance (/mL)	585	-485	100	-131.28	110.51				
intraoperative balance (/mL)	1200	-200	1000	51.43	156.32				
Birth weight (/gram)	2150	2350	4500	3296.3	486.70				
POSTOPEXT	30	0	30	10.59	10.46				

ACC= Aortic cross clamp time, CPB= Cardiopulmonary by-pass time, VISC score= Vasoactive inotropic score, SD: Standard deviation.

Categorical variables affecting mortality are given in Table 1, numerical variables affecting mortality are listed in Table 2, and chi-square analysis with categorical data affecting mortality is given in Table 3.

DISCUSSION

The Norwood procedure is a surgical technique for hypoplastic left heart syndrome (HLHS) that includes staged surgeries. The advantages of the two shunt models applied in the first stage of this procedure over each other have been discussed for a long time. In the Norwood procedure, instead of the modified Blalock-Taussig shunt (mBTS), the right ventricular to pulmonary artery shunt (SANO) provides better results in early and inter-stage mortality rates⁽⁵⁻⁸⁾. The problems that may arise regarding ventriculotomy in Sano are uncertain⁽¹⁾.

In the follow-up of the shunt methods of our patients who underwent the Norwood operation, we did not observe any difference in the need for aortic arch and shunt intervention according to the groups. There was no difference between the groups in terms of the need for an early Glenn operation. Some reports do not point to any advantage of RV-PA⁽⁶⁾; however, the only randomized, multicenter study showed better survival with RV-PA 10 months after Norwood⁽⁹⁾. The SANO method is reported to be a more suitable method for Fontan⁽¹⁰⁾. One of the potential explanations for a better survival rate and a more stable postoperative course is a higher diastolic blood supply and a higher coronary artery perfusion information obtained with the RV-PA method⁽¹¹⁾. Considering that coronary perfusion is provided from the hypoplastic aorta, the Sano modified Norwood stage 1 surgery for pulmonary artery blood supply makes the coronary perfusion less affected⁽¹²⁾.

Our result is the effect of shunt type on mortality was statistically significant, and the rate of death. In a multicentre study of 15 clinics written by Ohye et al. 12 months after randomization, the survival without transplantation was higher with the Sano shunt than with the MBT shunt⁽¹⁾. However, there were more attempts and complications in the Sano shunt was lower in patients who used SANO type shunts⁽¹⁾.

Mroczek et al. reported that "although establishing the same systemic blood flow, the total work of the right ventricle was lower in the patient after Norwood procedure with 5 mm RV-PA conduit compared with the 3.5 mm mBTS⁽¹³⁾. Also in the BTS group, Qp/Qs ratio was higher". The most important finding is the fact that systolic blood pressure and right ventricular blood pressure and its wall tension were higher in the BTS model. It seems that RV-PA benefited from a different work of the right ventricle and apparently a lower oxygen demand, mainly when the systolic function of the right ventricle was decreased⁽¹³⁾.

RV-PA shunt has been shown to provide better early outcomes, a lower incidence of ventilator manipulations, a lower tendency of heart failure-induced collapses, and a lower incidence of extracorporeal life support (ECLS)⁽¹⁴⁾. This was mainly attributed to coronary insufficiency, which was thought to be related to the diastolic outflow to the pulmonary circulation associated with the continuous outflow nature of the shunt. Therefore, the RV-PA Shunt (RVPAS) technique was developed as an alternative to BTS by Sano et al.⁽¹⁵⁾.

Using long-term follow-up data of up to 6 years, the current meta-analysis showed that despite initial survival benefits of

Table 3. Chi-square analysis with categorical data affecting mortality									
Parameters	Variable	Exitus	%	Alive	%	р			
Preterm or SGA	Term	14	31.1	31	68.9	0.896			
	Preterm or SGA	3	33.3	6	66.7				
Preoperative ent	Extubated	14	35.9	25	64.1	0.26			
	Intubated	3	20.0	12	80.0				
Type of shunt	SANO	9	22.5	31	77.5	0.041			
	BT SHUNT	5	38.5	9	61.5				
ECMO	Without ECMO	17	36.2	30	63.8	0.055			
	ECMO	6	85.7	1	14.2				
Gender	Female	8	33.3	16	66.7	0.793			
	Male	9	30.0	21	70.0				
ECMO: Extracorporeal memb	ran oxigenator, BT SHUNT: Blalock-T	aussing Shunt, SGA: Sn	hall for gestational as	re.					

RVPAS, there is a gradual equalization of survival starting at 2 years after the Norwood stage 1 procedure (S1P). This is confirmed by analysis of survival between stages, showing better survival for RVPAS between S1P and S2P but equal survival for the two shunt types between S2P and S3P. This is chronologically consistent with annual survival data, as S2P is typically performed at 4-6 months of age, whereas S3P is performed at 3-6 years of age⁽¹⁶⁾. Many subsequent studies have confirmed this and showed significantly higher diastolic and therefore coronary perfusion pressures in RVPAS compared to patients with mBTS^(17,18). The other noteworthy finding of the present meta-analysis is that long-term survival beyond 2 years was equivalent between patients initially palliated with RVPAS and mBTS. Several single cohort studies also were reported similar results(19,20).

Most of the studies were retrospective observational. Moreover, the experience of the surgeon and the center's experience may have led to variation in results at HLHS. As we reported in our clinic's article on previous Norwood surgeries, clinical experience improves clinical outcomes⁽²¹⁾. Nevertheless, it will be clinically important for studies to evaluate the longterm results between the two shunt types.

Ethics Committee Approval: This study was approved by the Institutional Research Ethical Committee of Kartal Koşuyolu High Specialization Training and Research Hospital (Decision no: 2021/7/501, Date: 13.07.2021).

Informed Consent: Informed consent was obtained.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept/Design - NC, HC; Analysis/Interpretation - NÇ, HC; Data Collection - EA; Writing - NÇ, HC; Critical Revision -NC, HC; Statistical Analysis - FY; Overall Responsibility - NC, HC; Final Approval - All of authors.

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