Outcome of Norwood and Damus-Kaye-Stansel procedures for univentricular congenital heart anomalies

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ABSTRACT

الأهداف: مراجعة تجربتنا مَع عمليتي نروود وداموس كاي ستانسل (DKS) في تصحيح عيوب متلازمة ضمور البطين الأيسر الخلقية (HLHS) والعيوب الخلقية وحيدة البطين (FSV) مع انسداد جهازي في مسلك التيار الخارجي (SOTO) في الجراحة القلبية لدى الأطفال.

الطريقة: أجريت دراسة ذات أثر رجعي خلال الفترة مابين يناير 2001م وحتى سبتمبر 2007م، في مركز الملك عبد العزيز لأمراض وجراحة القلب – الشؤون الصحية بالحرس الوطني – الرياض – المملكة العربية السعودية.

النَتائج: شملت الدراسة 28 مريضاً مصاب بمتلازمة ضمور البطين الأيسر الخلقية (HLHS) أو العيوب الخلقية وحدية البطين (FSV) في 18 مريض مع انسداد جهازي في مسلك التيار الخارجي (SOTO) في 10 مرضى. كان متوسط أوزانهم وأعمارهم (3.4±0.85kg) و (32±37) يوماً على التوالي. خضع جميع المرضى المدرجون في الدراسة بالمرحلة الأولى لعملية نروود والتي شَملتَ أمّا نروود كلاسيكي في 6/23 مرضى (21%) أو نروود معدّل بوصلة من البطين إلى الشريان الرئوي (RV–PA conduit) في 28/22 مريضاً (79%). بَعد المرحلة الجراحية الأولى، 23 مريض (82%) بَقوا على قيد الحياة، وجَميعهم باستثناء مَريضاً واحد خضعوا للجراحة بالمرحلة الثانية بوَصلة الوريد الأجوف العلوي بالشريان الرئوي (BCPA)، وكان مستوى النجاة بعد إتمام مرحلة التصحيح الثانية (91%)، أكمل أربعة مرضى المرحلة الثالثة (عملية فونتان) بنسبة نجاة (100%). كانت نسبة الوفيات خلال الـ7 سنوات من المتابعة (25%). جميع المرضى المتوفين كانوا مصابين بمتلازمة ضمور البطين الأيسر الخلقية (HLHS).

خاتمة: إنّ إجراءَ عملية نروود لمتلازمة ضمور البطين الأيسر (HLHS) والعيوب الخلقية القلبية وحيدة البطين ذات نتائج مقبولة عموماً، مع اختلاف النتائج باختلاف العيب الخلقي القلبي.

Objectives: To review the experience with Norwood and Damus-Kaye-Stansel (DKS) staged repair in the management of hypoplastic left heart syndrome (HLHS), or functional single ventricle (FSV) with systemic outflow tract obstruction (SOTO).

Methods: A retrospective study was conducted from a single center from January 2001 to September 2007 at the Cardiac Sciences Department, King Abdulaziz Cardiac Center, National Guard Health Affairs, Riyadh, Kingdom of Saudi Arabia. The cardiac departmental database was reviewed, together with the echocardiographic findings. Demographic data representing age and weight at operation, gender, cardiac anatomy, non-cardiac abnormalities, and operative details were collected.

Results: Twenty-eight patients with a diagnosis of HLHS were included in the study. The mean ± SD for weight was 3.4 ± 0.85 kg and 32 ± 37 days for age. All infants at our institution who underwent a Norwood or DKS surgery for HLHS, or other forms of FSV with SOTO were included. All included patients underwent first stage palliation consisting of either a classical Norwood procedure in 6/23 (21%) patients, or a modified Norwood with right ventricle to pulmonary artery (RV-PA) conduit in 22/28 (79%) patients. After first stage palliation, 23 patients (82%) survived, and all but one underwent second stage palliation with bidirectional cavopulmonary anastomosis (BCPA). The survival rate after second stage repair was 91%. Subsequently, 4 patients completed a third stage Fontan with 100% survival. All deceased patients had HLHS.

Conclusion: The Norwood procedure is applied to a heterogeneous group of patients with variable outcomes in certain subgroups. Patients with HLHS palliated with the Norwood procedure are at a greater risk for morbidity and mortality compared to those with other forms of FSV with SOTO.

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The Norwood procedure is the preferred palliative procedure for patients with hypoplastic left heart syndrome (HLHS), and can be applied to many congenital heart disorders that are characterized by the presence of a functional univentricle with systemic outflow tract obstruction (SOTO).[1,2] The outcome following the first stage Norwood procedure has improved following modifications in the surgical technique, better perioperative care, and improved anesthetic management.[3,4] Despite the continuing improvements in patient outcome, early survival rates for neonates requiring Norwood procedures remain lower than those in other neonates, with cardiac defects requiring neonatal repair other than Norwood.[5] Multiple factors play a role in the postoperative outcome of Norwood procedure, including low birth weight, prematurity, associated non-cardiac anomalies, and the presence of genetic syndromes. These factors were found to predict a poor outcome after first stage palliation.[3,5] There are additional factors that also contribute to early postoperative morbidity and mortality after a Norwood procedure, such as the severity of the cardiac anomaly, the complexity of surgical repair, hemodynamic fluctuations, difficulty in maintaining balanced systemic-pulmonary circulation, and postoperative myocardial dysfunction.[6,7] In addition to immediate perioperative morbidity and mortality, survivors of first stage palliation are still at risk for a later death that occurs frequently as a sudden and unexplained event.[8] Since the introduction of the Sano modification of the Norwood procedure, many authors have reported a better early outcome using the right ventricle to pulmonary artery conduit (RV-PA conduit) instead of a modified Blalock-Taussig shunt (BTS) as a source of pulmonary blood flow.[9,10] The currently existing data regarding the Sano modification of Norwood surgery includes mostly short- and mid-term results. The long-term outcome, however, is still unclear. Until now, there has been insufficient definitive evidence regarding the preferable type of Norwood operation that should be performed for HLHS.[11] The current study was undertaken to evaluate our institutional experience with the Norwood procedure in patients with HLHS, and other forms of functional single ventricle (FSV) with SOTO. Additionally, it was intended to evaluate potential predictors of early- and mid-term mortality.

Methods. This study is a single-center retrospective review encompassing the period from January 2001 until September 2007 at the Cardiac Sciences Department, King Abdulaziz Cardiac Center, National Guard Health Affairs, Riyadh, Kingdom of Saudi Arabia. All infants at our institution who underwent a Norwood or Damus-Kaye-Stansel (DKS) surgery for HLHS, or other forms of FSV with SOTO were included. The cardiac departmental database was reviewed together with the echocardiographic findings, and families who missed follow-up visits were contacted directly. This study was approved by our institutional research board. Demographic data representing age and weight at operation, gender, cardiac anatomy, non-cardiac abnormalities, and operative details were collected. An anatomic diagnosis was based on the review of echocardiography and operative findings. Hypoplastic left heart syndrome was defined as a normal segmental anatomy, intact ventricular septum, aortic and mitral atresia or stenosis, and hypoplasia of the left ventricle. Other forms of FSV with SOTO, observed in patients who underwent either Norwood or DKS procedures were classified as non-HLHS. Echocardiographic parameters, associated cardiac anomalies, and ventricular function were examined and collected. Operative parameters, including the type of surgery performed, deep hypothermic circulatory arrest time (if applicable), cardiopulmonary bypass time (CPB), and the source of pulmonary blood flow were also collected. Postoperative parameters included the presence or absence of an open sternum, the duration of mechanical ventilation, the length of stay in the intensive care unit, complications, and the length of hospital stay. The duration of patient follow-up and continuation to bidirectional cavopulmonary anastomosis (BCPA) or Fontan procedures were also recorded. All children received dexamethasone 1 mg/kg the night before, and the morning of the surgery. The operation was performed with standard cardiopulmonary bypass using innominate artery direct cannulation, and right atrial cannulation for venous return. Deep hypothermic circulatory arrest was required in certain complex cases. In the rest of the surgeries, selective brain perfusion at 30-50 ml/kg/min at a temperature of 24-26^{o}C was continued during arch reconstruction. Intermittent cold blood cardioplegia was given every 20 minutes for myocardial protection. The arch was reconstructed either with homograft, or with bovine pericardial patch. In patients who had modified BTS a 3.5-mm shunt was used, and in patients with RV-PA conduit, a 5-mm conduit was utilized. Atrial septostomy was carried out routinely. Weaning from the CPB was carried out by loading the patient with milrinone (50 mcg/kg) with an addition of epinephrine when needed. If sternal closure was not attainable, the sternum was left open for delayed closure, and the patient was transferred to the Pediatric Cardiac Intensive Care Unit. Any mortality that occurred within 30 days after surgery was defined as early mortality. Mortality that occurred after that period was characterized as late mortality.

Table 1 - Comparison between the classical and the modified Norwood groups (N=28).

Characteristics	Classical Norwood n=6	Modified Norwood n=22	*P*-value
HLHS number (%)	5 (83)	13 (59)	>0.05
Non-HLHS number (%)	1 (16.7)	9 (41)	>0.05
Age at first surgery, days	21.3 ± 11.3	34.6 ± 41.8	0.4
Weight at first surgery (kg)	3.2 ± 0.38	3.4 ± 0.9	0.64
Presence of restrictive PFO	3 (50)	7 (31.8)	0.634
Mean CBP time, minutes	168.3 ± 71.5	154 ± 53.8	0.114
Circulatory arrest used number (%)	3 (50)	3 (13.6)	0.05
Mean ventilation, hours	120.3 ± 111.8	278.3 ± 255.3	0.15
Mean ICU length of stay, days	10.7 ± 11.2	20 ± 15.3	0.17
Mean hospital length of stay, days	10 ± 11.2	22.9 ± 12	0.08
Need to leave sternum open	3 (50)	19 (86.4)	0.09
Septicemia (%)	1 (16.7)	9 (41)	0.37
Arrhythmia (%)	1 (16.7)	8 (36.4)	0.63
Chylothorax number (%)	1 (16.7)	-	0.214
Reintervention	1 (16.7)	4 (18.2)	0.017
Mortality after first stage surgery	3/6 (50.0)	2/22 (22.0)	
Mortality after second stage surgery	0/6	2/19 (10.0)	
Overall mortality	3/6 (50)	4 (18.2)	0.114

HLHS - hypoplastic left heart syndrome, PFO - patent foramen ovale, CBP - cardiopulmonary bypass time, ICU - intensive care unit

Table 2 - Details of patients who required reintervention and the type of reintervention performed.

Patient number	Diagnosis	Primary Operation	Reintervention
1	HLHS	Norwood, MBTS	TV repair
2	HLHS	Norwood, RV-PA conduit	Conduit replacement because of conduit stenosis
3	DILV, TGA, hypoplastic AA, CoA	Norwood, RV-PA conduit	False aneurysm resection, take down of conduit and placement of BTS, balloon dilatation of Re CoA
4	HLHS	Norwood, RV-PA conduit	Balloon dilatation of recoarctation
5	HLHS	Norwood, RV-PA conduit	CoA balloon dilatation

CoA - coarctation of the aorta, DILV - double inlet left ventricle, hypoplastic AA - hypoplastic ascending aorta, HLHS - hypoplastic left heart syndrome, MBTS - modified Blalock-Taussig shunt, PFO - patent foramen ovale, RV-PA conduit - right ventricle to pulmonary artery conduit, TGA - transposition of the great arteries, TV - tricuspid valve

All statistical analysis was performed with SPSS version 16.0 software. Data were expressed as mean±SD or median and range when appropriate. Data were analyzed with unpaired t test, or chi-square (or Fisher's exact test when appropriate). A p-value of less than 0.05 were considered significant.

Results. During the study, 28 children underwent either the Norwood (23 patients) or DKS (5 patients) procedure. There were 17 males and 11 females. Two (7%) children were born prematurely at a gestational age between 34 and 36 weeks. A prenatal diagnosis of congenital heart disease was noted in 2 (7%) cases. Eighteen (64%) patients had HLHS, and 10 (36%) patients had some form of FSV with SOTO.

Overall, there were 18 (64%) patients with a functional single right ventricle morphology (all HLHS patients), while 10 (36%) had a functional single left ventricle morphology (all non-HLHS patients). Restrictive patent foramen oval (PFO) was present in 10 patients (36%). Significant extra-cardiac anomalies or genetic syndromes, including Down syndrome, Goldenhar syndrome, and anal atresia, were present in 3 patients (11%). The mean ± SD for age was 32 ± 37 days (7-158 days) and weight at the first palliative surgery was 3.4 ± 0.85 kg (2.4-7 kg). Twenty-one

Table 3 - Comparison between the deceased and the survivors.

Parameters	Survived n=21	Deceased n=7	*P*-value
Type of Norwood surgery			0.14
Modified	18	4	
Classical	3	3	
Mean age at first surgery, days	29 ± 32	39 ± 53	0.54
Mean weight at first surgery, kg	3.5 ± 0.93	3.1 ± 0.5	0.43
Presence of restrictive PFO, (%)	5 (24)	5 (71)	0.06
Presence of extra-cardiac anomalies, (%)	1 (5)	2 (28)	0.59
Mean CPB, minutes	129 ± 33	202 ± 32	0.001
Mean cross clamp time (minutes)	59 ± 20	73 ± 33	0.19
Deep hypothermic circulatory arrest (%)	3 (50)	2 (9)	0.36
Mean ventilation, hours	230 ± 209	289 ± 331	0.58
Mean ICU length of stay, days	17.5 ± 12	19.3 ± 22.6	0.79
Mean length of hospital stay, days	22. 5 ± 10.5	23 ± 17	0.6
Incidence of septicemia, (%)	8 (4)	2 (29)	1.0
Incidence of arrhythmia, (%)	5 (24)	4 (57)	0.37
Sternum open (%)	19 (90)	3 (43)	0.02

PFO - patent foramen ovale, CBP - cardiopulmonary bypass time, ICU - intensive care unit

(75%) patients were less than one month of age at the time of surgery. The classical Norwood procedure using modified BTS was performed in 6 patients (21%), and the modified Norwood procedure with RV-PA conduit was performed in 22 patients (79%). The demographic and perioperative data, with comparisons between classical and modified Norwood cases, are summarized in **Table 1**. During the postoperative intensive care, delicate manipulations were necessary to control pulmonary and systemic vascular resistance. Ventilator settings were adjusted to maintain arterial oxygen saturations between 70% and 85% and carbon dioxide levels from 40-50 mm Hg, depending on the pulmonary to systemic blood flow (Qp/Qs) calculation. The inotropic drugs commonly used were milrinone, dopamine, and epinephrine, to maintain an appropriate mean systemic blood pressure according to age. Patients were extubated after a mean period of 10.2 ± 10 days (2 hours - 34 days). The mean length of stay in the pediatric cardiac intensive care unit was 15 ± 14 days. The most commonly encountered complications in the ICU were a low cardiac output state in 18 (64%) patients requiring multiple inotropic supports, the development of infection in 10 (36%) patients, and arrhythmias in 9 (32%) patients. Extracorporeal membrane oxygenation (ECMO) support was utilized in one patient (3.6%). The mean length of the hospital stay was 23 ± 11 days (8-46

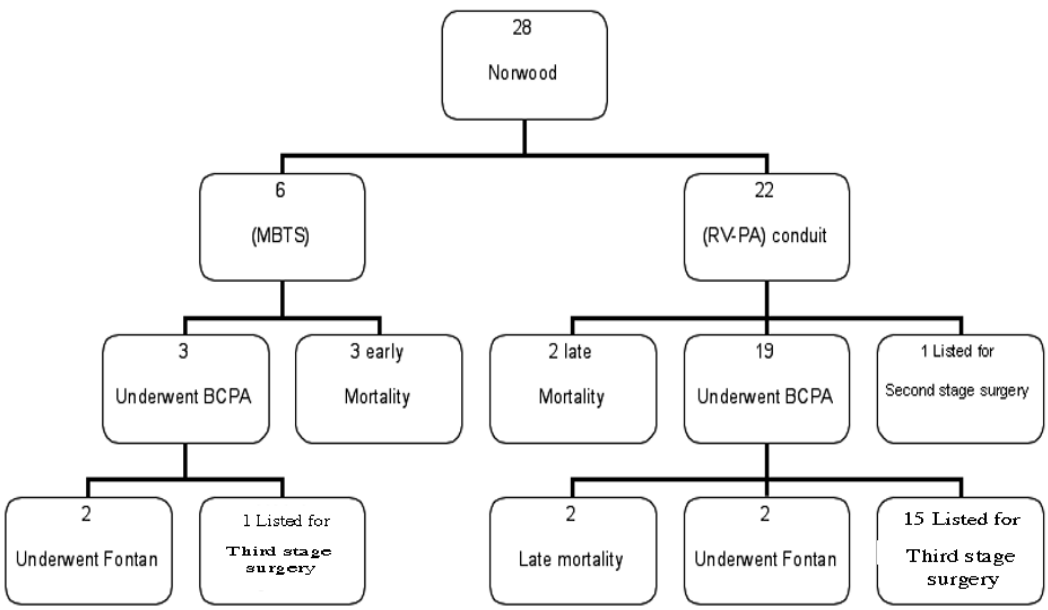

Figure 1 - Flow diagram of the total number of patients and their outcomes. The overall mortality during the study period was 25% (7/28). BCPA - bidirectional cavopulmonary anastomosis.

days). The mean follow-up period for all patients was 18 ± 16 months (1-6 years). Five patients (18%) required reintervention during the follow-up period (**Table 2**). The overall mortality after the first stage was 18% (5/28 patients), which consisted of 3 early and 2 late mortality. The majority of the hospital mortality occurred early in our period of study (2000-2001). The most common cause of early death was low cardiac output state in the immediate postoperative period. Three of the deceased patients underwent a classical Norwood operation and died soon after surgery. The fourth patient had a modified Norwood procedure and died 63 days post-surgery. The fifth patient died suddenly at home, 5 months after his modified Norwood surgery (**Figure 1**). Although there was a noticeable difference between patients who underwent classical (3/6) (50%), and modified Norwood (4/22) (22%) procedures, in terms of the mortality after a first stage surgery, the difference was not statistically significant. Twenty-two of the 23 survivors (96%) underwent second stage palliation (BCPA) after an average period of 5 months from the first stage surgery. Two of these patients died suddenly at home after discharge from the hospital. Both of these 2 patients who died following the second stage surgery had a modified Norwood as initial palliation and HLHS as initial diagnosis. Out of the 20 second stage survivors, 18% of the patients underwent Fontan completion at a mean time of 34 months from the second stage surgery (range 30-48 months) with 100% survival (**Figure 1**). The remaining survivors are being followed and listed for future surgery. During the study period, 5 patients died after first stage palliation, and 2 died after second stage palliation. The overall mortality rate during the 7-year study was 7/28 (25%). A comparison between the surviving and deceased patients is outlined in **Table 3**.

Discussion. The early and late outcomes for children with HLHS or FSV with SOTO have improved steadily since the introduction of the Norwood procedure 25 years ago,[1,2] With the introduction of the Sano modification to the Norwood procedure with RV-PA conduit, many authors have reported distinct improvements in early outcomes following first stage palliation for HLHS.[7,10,12]

In this study, the overall survival rate after the first stage palliation was 82%. During our initial experiences, we had significant early hospital mortality in the subgroup of patients palliated with the classical Norwood surgery. We observed a significant improvement in hospital survival after the introduction of the Sano modification of the Norwood procedure, but this change was not statistically significant, which is probably due to the small size of the study group. Late mortality, however, remains a concern after both procedures. In comparison with the classical Norwood procedure, studies have shown that in the immediate postoperative period, patients who underwent a modified Norwood operation tended to have a higher diastolic blood pressure, decreased hemodynamic fluctuations, and potentially better coronary blood flow with a more physiological pulsatile pulmonary blood flow.[6,10,13] Furthermore, some authors have suggested that the advantages of a modified Norwood operation are not only limited to the short-term outcome but also include the mid-term outcome, in which there was lower inter-stage mortality, as compared to the classical Norwood operation.[14] Recently, some authors indicated that despite the improvement in diastolic blood pressure after the modified Norwood operation, there were no significant differences in the early outcomes among patients who underwent a modified versus classical Norwood procedure for HLHS.[13,15] In our study, although it consists of a small group of patients, all of the early mortality was among patients palliated with the classical Norwood procedure (3/7), while all of the late mortality was among patients palliated with the modified Norwood procedure (4/7). Potential predictors of early mortality in patients with HLHS include low birth weight, restrictive patent foramen ovale, the presence of associated extra-cardiac defects, chromosomal abnormalities, the presence of additional cardiac defects, prolonged CPB time, and the need for deep hypothermic circulatory arrest.[3,5,16] In our study, the deceased patients had HLHS (7/7), late presentation beyond the first month of age (1/7), associated extracardiac and genetic anomalies (2/7), longer bypass and cross clamp time, and restrictive PFO (5/7). The presence of a restrictive PFO has been shown to increase mortality rates among patients with HLHS palliated with the Norwood procedure. Despite the presence of the mentioned risk factors in most of the deceased patients in our study, they did not reach statistical significance, which could again be due to the small sample size (**Table 3**). The avoidance of hypothermic circulatory arrest through selective brain perfusion significantly improves postoperative hemodynamics and helps to reduce hospital mortality after the modified Norwood procedure.[5] In our study, 2 of the deceased patients (28%), and 3 of the survivors (19%) were operated with deep hypothermic circulatory arrest. Although the difference was not statistically significant, we observed a trend toward better postoperative recovery in those managed without hypothermic circulatory arrest.

One concern is related to the potential risk of late patient death during the first year of life among those who survived the initial surgery. In the current study, 3 patients had a late mortality and died during the inter-stage periods (one after the first stage Norwood and 2 after the BCPA). Multiple factors may be responsible for the unexplained late deaths, including coronary

insufficiency, arrhythmias, ventricular dysfunction, residual arch obstruction, pulmonary artery distortion, restrictive atrial septal defect, shunt malfunction, and inadequate pulmonary blood flow.[5,14] Five of our patients required additional re-interventions in the form of co-arctation balloon dilatation, right ventricular outflow tract (RVOT) aneurysm resection with replacement of the RV-PA conduit with a modified BTS, or atrioventricular valve repair. There was a trend toward a higher rate of reintervention among the HLHS group, as 4 out of 5 patients who required reintervention had HLHS (**Table 2**). Associated cardiac defects, particularly the presence of coarctation of the aorta and atrioventricular valve insufficiency are risk factors for reintervention.[2,5]

There are certain limitations to our study. It is a retrospective single-center study including a small number of patients. Patients were not randomized to receive either the classical or modified Norwood procedure. The small number of cases, particularly among the classical Norwood group, makes it difficult for us to reach any definite statistical conclusions regarding the preferred type of surgery.

In conclusion, Norwood procedure is currently applied to a heterogeneous group of patients with variable results in certain subgroups. Early survival rates for patients undergoing the Norwood procedure continue to improve, especially in patients with a normal birth weight without associated anomalies. Patients with HLHS palliated with the Norwood procedure are at a greater risk for morbidity and mortality, as compared to those with other forms of FSV with SOTO. In our setting, the modified Norwood procedure had a better early outcome than the classical Norwood method. The presence of extra cardiac problems and restrictive PFO is a potential risk factor for morbidity and mortality. Inter-stage mortality remains a concern, even in cases of the modified Norwood surgery. Further studies and follow-up are required to determine the optimal surgical approach in children with HLHS or FSV with SOTO.

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