# Stage one Norwood procedure in an emerging economy: Initial experience in a single center

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#### ABSTRACT

Objective	:	The evolution of surgical skills and advances in pediatric cardiac intensive care has resulted in Norwood procedure being increasingly performed in emerging economies. We reviewed the feasibility and logistics of performing stage one Norwood operation in a limited-resource environment based on a retrospective analysis of patients who underwent this procedure in our institution.
Methods	:	Retrospective review of medical records of seven neonates who underwent Norwood procedure at our institute from October 2010 to August 2012.
Results	:	The median age at surgery was 9 days (range 5-16 days). All cases were done under deep hypothermic cardiopulmonary bypass and selective antegrade cerebral perfusion. The median cardiopulmonary bypass (CPB) time was 240 min (range 193-439 min) and aortic cross-clamp time was 130 min (range 99-159 min). A modified Blalock-Taussig (BT) shunt was used to provide pulmonary blood flow in all cases. There were two deaths, one in the early postoperative period. The median duration of mechanical ventilation was 117 h (range 71-243 h) and the median intensive care unit (ICU) stay was 12 days (range 5-16 days). Median hospital stay was 30.5 days (range 10-36 days). Blood stream sepsis was reported in four patients. Two patients had preoperative sepsis. One patient required laparotomy for intestinal obstruction.
Conclusions	:	Stage one Norwood is feasible in a limited-resource environment if supported by a dedicated postoperative intensive care and protocolized nursing management. Preoperative optimization and prevention of infections are major challenges in addition to preventing early circulatory collapse.
Keywords	:	Emerging economy, Norwood procedure, pediatric cardiac intensive care

## **INTRODUCTION**

Norwood procedure is the first stage surgical palliation for neonates with hypoplastic left heart syndrome (HLHS) and its variants. This complex procedure demands technical expertise, thorough understanding of the physiology of the Norwood

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circulation, intensive care backup, and a multispeciality approach to the perioperative management. Though there have been large series from various centers in the developed nations with good outcomes, this procedure has not become popular in the Indian scenario.<sup>[1]</sup> The relatively high mortality associated with this surgery, high resource utilization, lack of dedicated intensive care support, and inability of the family to accept the concept of staged palliation in view of the economic burden have all put surgeons on the back foot in performing this complex repair. However, early prenatal diagnosis, early referral to appropriate tertiary care centers, and better facilities for transport of sick neonates have created a more favorable environment for the surgical treatment of neonates with HLHS. We reviewed the clinical details and early postoperative

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outcomes of seven neonates who underwent Norwood procedure at our institute.

# **MATERIALS AND METHODS**

The study was conducted in a tertiary care pediatric cardiology center catering to a population of about 30 million in South India. The center is a tertiary care teaching hospital established with the purpose of serving the average citizen in the region. Neonatal heart surgeries are routinely performed in the center, with contemporary results comparable to international standards.<sup>[2]</sup> The study period was from October 2010 to August 2012. All neonates who underwent stage I Norwood operation were included in the present study. HLHS was defined as mitral or aortic stenosis or atresia (or both) in the presence of normally related great vessels, a hypoplastic left ventricle, and an intact ventricular septum. Patients who did not conform to these criteria but who had a duct-dependent parallel circulation, a non-septatable heart, and left ventricular outflow tract obstruction were considered to have variants of HLHS. The anatomical details of the patients are depicted in Table 1. Transthoracic echocardiography was the diagnostic modality used in all patients. Two patients had an antenatal diagnosis and planned delivery was undertaken at our center.

Data was collected by review of hospital records. Demographic data and intraoperative variables included age, weight, gender, cardiopulmonary bypass (CPB) time, and aortic cross-clamp (ACC) time. Postoperative outcomes studied included mortality, duration of mechanical ventilation, intensive care unit (ICU) stay, hospital stay, and blood stream infections. The average expenses incurred for the surgery was also reviewed. Demographic characteristics and outcomes were expressed as median and range.

#### **Preoperative care**

All patients were optimized in the ICU before the scheduled surgery. Prostaglandin (PGE1) infusion was

#### Table 1: Diagnosis

used to maintain the patency of ductus arteriosus at a dose of  $0.02-0.08 \ \mu g/kg/min$ . Six patients were on room air without supplemental oxygen before surgery. One patient was transported on ventilator with invasive lines and inotropes from a peripheral center. Fluids, electrolytes, and acid base status were maintained within normal limits during the preoperative period.

#### Anesthesia and cardiopulmonary bypass management

A high-dose narcotic inhalation based anesthetic technique was used during surgery. Fraction of inspired oxygen (FiO<sub>2</sub>) was titrated to 0.25-0.30 in the prebypass period to preserve the ductal flows. Arterial access was obtained through both the right radial artery and the femoral artery. The right radial artery was used for assessment of the cerebral perfusion pressure during selective antegrade cerebral perfusion. Central venous access was obtained through a 4-F double-lumen catheter (Arrow International, Inc., PA, USA) in the right internal jugular vein. The proximal port of the catheter was used to obtain venous samples for measuring superior venacava oxygen saturation ( $ScvO_2$ ). Methyl prednisolone was administered in a dose of 30 mg/kg to attenuate the systemic inflammatory response. Phenoxybenzamine was given at a dose of 1 mg/kg before the commencement of CPB to facilitate maximal reduction in systemic vascular resistance (SVR) and to promote uniform cooling of the patient. CPB was established by an arterial cannula placed through a 3.5 mm polytetraflouroethylene (PTFE) graft sewn to the base of the right subclavian artery and standard bicaval cannulation. Both branch pulmonary arteries were looped prior to commencement of CPB. In-patients with critical arch hypoplasia, an arterial cannula inserted into the main pulmonary artery (MPA) and later advanced to the ductus were used for lower body perfusion. CPB was managed using a membrane oxygenator (Dideco Lilliput, Sorin Group, Italy) and the infant was cooled to a temperature of 22°C. pH stat blood gas management was used during cooling. Hematocrit was maintained around 25-30%. Heart was arrested with cold blood

Patient	Diagnosis	Ascending aorta diameter in mm (Z score)	Nature of ASD	Tricuspid regurgitation	RV function
Case 1	HLHS, aortic atresia	4.5 (-8.3)	Unrestrictive	Mild	Normal
Case 2	DORV, subvalvar aortic stenosis, hypoplastic ascending aorta and arch, dilated PA from RV	4.2 (-8.7)	Restrictive	Nil	Normal
Case 3	Double-inlet left ventricle, hypoplastic arch, post subclavian coarctation of aorta	6.5 (-3.4)	Unrestrictive	Nil	Normal
Case 4	HLHS, hypoplastic left ventricle, aortic valve	6.5 (-4.1)	Restrictive	Nil	Normal
Case 5	HLHS, mitral/aortic atresia, hypoplastic ascending aorta	1.5 (–20.8)	Unrestrictive	Mild	Normal
Case 6	Common atrio-ventricular valve, aortic atresia, inlet VSD, hypoplastic arch, coarctation of aorta	4.1 (-8.6)	Unrestrictive	Nil	Normal
Case 7	Unbalanced atrio-ventricular canal defect, hypoplastic left ventricle, hypoplastic arch, inlet VSD	7.5 (-3.03)	Unrestrictive	Nil	Normal

HLHS: Hypoplastic left heart syndrome, DORV: Double outlet right ventricle, PA: Pulmonary artery, ASD: Atrial septal defect, RV: Right ventricle, VSD: Ventricular septal defect

cardioplegia infused into the aortic root after applying the cross clamp. Myocardial protection was maintained by intermittent doses of cold blood cardioplegia.

Once the target temperature was achieved, the ductus arteriosus was divided after removing the cannula in the MPA. The MPA was then divided and distal end sutured. Selective antegrade cerebral perfusion was initiated through the PTFE graft cannula after cross clamping the descending aorta and snaring the arch vessels. The flow rate was maintained at 15-25 ml/kg/min to maintain a mean perfusion pressure of 30 mm Hg measured from the right radial artery. Aortic arch augmentation was done using tanned pericardial patch with the proximal extent of the patch dictated by the degree of aortic hypoplasia. After de-airing, the descending aortic clamp was removed and distal circulation was maintained through the PTFE graft. After application of a side biting clamp, reconstruction of the proximal aorta and arch was done using the proximal MPA and tanned pericardial patch. The neoaorta was cannulated and the circulation through the PTFE graft discontinued. The proximal anastomosis of the Blalock-Taussig (BT) shunt was completed during the rewarming phase. Conventional ultrafiltration (CUF) was done during this period. All patients received a loading dose of milrinone at 50 µg/kg on pump before weaning off CPB to further reduce the SVR. Weaning from CPB was facilitated by inotropic support with epinephrine at 0.04-0.08  $\mu$ g/kg/min and milrinone at 0.7  $\mu$ g/kg/min. A higher FiO2 of 0.7-0.8 was used during weaning off CPB to address the high pulmonary vascular resistance (PVR) which is common in the immediate post bypass period. Modified ultrafiltration (MUF) was performed for 15 min to achieve a hematocrit of 45%. Sternum was electively stented in all patients.

#### Postoperative management

All patients were managed according to standardized institutional protocols. Mechanical ventilation was initiated at  $FiO_2$  of 0.7-0.8 and gradually titrated to a lower level (0.3-0.4) as the lung compliance and PVR normalized. All patients were ventilated in the pressure-controlled volume guaranteed (PCV-VG) mode, with a tidal volume of 6-8 ml/kg, a positive end expiratory pressure (PEEP) of 5 cm H<sub>2</sub>O, and a respiratory rate adjusted to achieve a partial pressure of carbon dioxide (PCO<sub>2</sub>) of 35-40 mm Hg. The perioperative ventilatory and hemodynamic management targeted a pulmonary to systemic blood flow (Qp/Qs) of 1-1.5, arterial oxygen saturation (SaO<sub>2</sub>) of 75-85%, ScvO<sub>2</sub>  $\ge$  50%, and arterio venous oxygen content difference  $\leq 5$ . A mean arterial pressure (MAP) of 40-45 mm Hg and a central venous pressure of 4-8 mm Hg were considered acceptable. Arterial and proximal superior venacaval sampling was done at two hourly intervals in the initial 12 h and thereafter at 4-6 h to optimize the systemic every 4 h and time trends were obtained for the first 48 h. Deep sedation was maintained by a continuous infusion of fentanyl at 1-2 µg/kg/h and intermittent doses of midazolam. Neuromuscular blockade was maintained with vecuronium as required. A negative fluid balance was achieved with an infusion of frusemide at 1-2 mg/kg/day to reduce edema and facilitate chest closure. Heparin infusion was used at 5-10 U/kg/h to maintain the shunt patency. Sternal closure was done on first or second postoperative day (POD). Decision to wean from mechanical ventilation was taken after ensuring hemodynamic stability after chest closure, adequate negative fluid balance, and a decrease in edema. A postoperative screening echocardiogram was routinely performed before weaning to assess ventricular function, atrio-ventricular valve regurgitation, and shunt patency. Patients were weaned off mechanical ventilation as appropriate to nasal continuous positive airway pressure (CPAP) and then to nasal cannula.

and pulmonary circulations. The Qp/Qs was calculated

Enteral feeding was initiated on POD1 with trophic feeds and gradually escalated to full feeds to achieve a caloric goal of 120-140 kcal/kg/day and a protein intake at 2-2.5 g/kg/day. Aspirin therapy was started at 5 mg/kg after sternal closure. Weaning of inotropes and de-intensification was done 24-48 h after extubation. Weight charts were maintained in the postoperative period to track the nutritional status. Patients were discharged from ICU after weaning off oxygen and establishing breast feeds. Since the interstage mortality is high for Norwood procedure, all patients were regularly followed up at the outpatient department initially at 2 weeks after discharge and thereafter at monthly intervals till the second stage operation. We did not employ home monitoring by oxymetry due to practical issues. A computerized tomographic (CT) scan of the thorax was done in addition to echocardiographic evaluation in those patients who underwent the second stage palliation.

## **RESULTS**

A total of 7 (3 male and 4 female) patients underwent stage I Norwood operation at our center during the study period. The median age at operation was 9 (5-16) days. There were no pre-term neonates. The median weight was 3 kg (range 2.24-3.60 kg). The median weight was 3 kg (range 2.24-3.60 kg). The median birth weight was 3.20 kg (range 2.16-3.60 kg).

The median CPB time was 240 min (range 193-439 min) and ACC time was 130 min (range 99-159 min). The median duration of mechanical ventilation was 117 h (range 71-243 h) and ICU stay was 12 days (range 5-16 days). Median hospital stay was 30.5 days (range 10-36 days).

The median Qp/Qs trends show that a duration of nearly 12 h was required to reach the targeted levels of 1-1.2 [Figure 1]. The blood lactate trends in the early postoperative period showed initial high levels in the first 4 h with a subsequent declining trend and a gradual stabilization to less than 2 mmol/L in 24 h [Figure 2]. However, in the patient who had a poor outcome in the early postoperative period, the lactate levels persistently remained above 6 mmol/L for nearly 10 h after surgery.

There were two deaths in our series. One patient had severe gram-negative septicemia and capillary leak syndrome. This patient had been transported from overseas. Surgery was opted only after the indicators of sepsis showed significant downward trends and hemodynamics could be maintained with minimal supports. The combined effect of poor preoperative status and prolonged bypass might have contributed to the adverse outcome. This patient also had a prolonged CPB time due to a technical issue with the right coronary artery with requirement of higher inotrope support during weaning off CPB. Postoperatively he developed fulminant septicemia with septic shock. The second child who had died was a high-risk anatomical subset with aortic atresia, mitral atresia, and an extremely narrow ascending aorta and arch. This patient had developed ventricular dysfunction after discharge with mild residual arch obstruction and could not be salvaged. This child presented with late-onset ventricular dysfunction and died during the second hospital admission.

Four patients had blood stream sepsis with gram-negative bacilli. Among these, two patients had preoperative sepsis. In three patients, the sepsis was contained with appropriate antibiotic therapy and inotrope management. One patient (early death) succumbed to fulminant sepsis and septic shock. One patient developed deep sternal wound infection which required vacuum drainage and resuturing. One patient developed abdominal distension with signs of intestinal obstruction. Laparotomy revealed a stricture in the proximal ileum, which was addressed by resection and anastomosis. This child required parenteral nutrition for a week till normal enteral feeding could be re-established.

The median expenses incurred for the surgery was Rs. 360,000 (range Rs. 210,000-380,000).

Four out of five surviving patients have successfully completed stage II palliation with bidirectional Glenn shunt. All are currently doing well on follow-up.

### **DISCUSSION**

Norwood operation is a challenging endeavor for the pediatric cardiac ICU. The goal of surgery is to provide unobstructed arch flows, unrestricted flows across the atrial septal defect, and a reliable source of pulmonary blood flow.<sup>[3]</sup> There is a significant learning curve both for surgery and postoperative intensive care.

Evidence has accumulated on the beneficial effects of phenoxybenzamine in optimizing SVR for this complex physiology. It appears to ameliorate postoperative fluctuations in SVR and reduces the incidence of early circulatory collapse after Norwood procedure.<sup>[4,5]</sup> Afterload reduction also facilitates higher pump flow rates during CPB resulting in better tissue perfusion. At our institute, we regularly follow the practice of adding phenoxybenzamine at a dose of 1 mg/kg prior to initiation of CPB.

Surgical and perfusion techniques for Norwood operation have evolved substantially during the last two decades. Our center routinely employs deep hypothermia at 22°C-24°C with selective antegrade cerebral perfusion during this

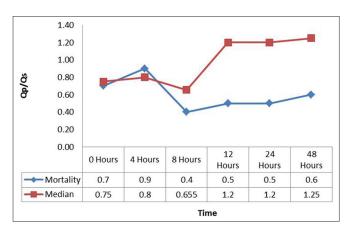


Figure 1: Qp/Qs trends in the first 48 h after surgery. The red line indicates the median values of the entire group. The lowest values are recorded at around 8 h, followed by a progressive improvement to 1-1.2 by 24 h. The blue line indicates the Qp/Qs trends of the patient who had early postoperative death

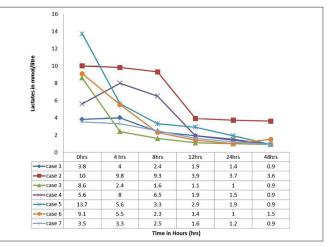


Figure 2: Lactate trends in the first 48 h after surgery. There is a steady clearance of lactates, which returns to <2 mmol/L by 24 h. However, lactate clearance was impaired in the patient who did not survive (red line)

stage. Selective cerebral perfusion with low flows may reduce the likelihood of neurological complications.<sup>[6,7]</sup>

The source of pulmonary blood flow following a Norwood procedure can be through a BT shunt or through a right ventricle (RV) to pulmonary artery (PA) conduit. The purported benefit of the RV-PA conduit (Sano modification) has been the avoidance of diastolic run off and coronary artery steal, as well as a better balance between the systemic and pulmonary circulation.<sup>[8]</sup> Universal acceptance of the Sano modification has been hindered by concerns regarding systolic and diastolic myocardial performance following ventriculotomy, atrio-ventricular valve function, and ventricular arrhythmias.<sup>[9,10]</sup> The pulmonary blood flow was routinely provided by a modified BT shunt at our institute.

Recognizing the proven benefits of ultrafiltration techniques (removing inflammatory mediators and reduction of extravascular lung water and myocardial edema,<sup>[11,12]</sup>) we use both CUF and MUF for achieving a target hematocrit of 45% and above.

In the early postoperative management, the cornerstone of managing the postoperative Norwood circulation is to manipulate the SVR. The vasodilator effects of phenoxybenzamine during CPB and postoperative inotropic support with milrinone complement each other to provide the necessary afterload reduction. As the shunt acts as a fixed resistor in the circuit, ventilator manipulations to optimize PVR is usually not necessary.<sup>[13]</sup> It has clearly been shown that high  $FiO_2$  and alkalosis does not predispose to significant hemodynamic instability or need for increased vasopressor support in Norwood patients.<sup>[14]</sup>

In our series, the analysis of Qp/Qs trends clearly depicts that an initial period of nearly 12 h is needed for stabilization to a desired level of 1-1.2 [Figure 1]. This may be due to the fact that in the immediate post bypass period, the PVR is high due to effects of CPB, presence of extravascular lung water, and intrinsically elevated PVR of the neonatal circulation. The lowest level of Qp/Qs was noted around 8-10 h postoperatively, which corresponds to the nadir of low cardiac output normally encountered in the postoperative period. A practical approach which we have evolved from our experience is to initiate ventilation with higher  $FiO_2$  (0.7-0.8) and titrate to lower levels as the lung compliance and saturation spontaneously improve in the postoperative period following normalization of PVR. In infants with multiple intracardiac shunts, where a true mixed venous sample cannot be drawn, the superior venacaval blood has been suggested to closely approximate the mixed venous blood.[13] Tweddell and colleagues in a study of 35 neonates concluded that continuous ScvO<sub>2</sub> monitoring can identify the risk factors for poor outcome and hemodynamic instability in the early postoperative phase after Norwood procedure.<sup>[15]</sup>

The role of lactate as a predictor for adverse outcomes after cardiac surgery is well known. The analysis of lactate trends in our series shows that majority of patients had been able to successfully clear blood lactate levels to <2 mmol/L in 12 h. One patient who died in early postoperative period had persistently elevated lactate levels in the first 24 h. Our data are supported by a retrospective study of 221 patients where inability to clear lactate levels to less than 6.76 mmol/L in the first 24 h was found to be a significant predictor of mortality.<sup>[16]</sup>

Blood stream infections were a major concern in our patients. This was reflected in postoperative outcomes as mortality in one patient and prolonged ICU and hospital stay in two patients. Preoperative ICU stay, need for mechanical ventilation, and invasive monitoring and suboptimal conditions of transport from peripheral centers could have contributed to the risk of infections in these vulnerable neonates.

The concept of staged palliation of HLHS had not been a priority in developing nations where the focus had been on health care delivery to reach a greater proportion of children with heart disease.[17] Parents often fail to understand the concept of structural heart disease requiring multiple staged repairs. The birth of a child with a congenital heart disease itself can turn out to be a trigger for family conflicts. The pediatric cardiology team at our center had been meticulous in devoting significant time and effort to counsel the entire family regarding the treatment prospects. For the initial period, we chose those families who had a fair degree of awareness about the disease process. Those parents who showed a substantial degree of commitment to offer the best possible therapy to the child in spite of financial constraints also prompted us to undertake this repair in a couple of neonates with partial bearing of expenses by the institute. Surgery was not opted in those children with major associated congenital anomalies and genetic syndromes. We did not consider hybrid procedure in any of the patients.

Prenatal diagnosis of HLHS has several specific advantages that include improved counseling, directed and planned deliveries at specialized centers, and reduced perioperative morbidity.<sup>[18,19]</sup> These advantages may be even greater in emerging economies where neonatal transport is poorly developed.

The postoperative management of a Norwood physiology was a relatively novel challenge to our intensivists and primary care nurses. Retraining of nurses to pick up early fluctuations in SVR and PVR was taken up. Posters were placed near the child regarding how to manage various combinations of  $\text{ScvO}_2$  and  $\text{SaO}_2$  and derive the Qp/Qs. Meticulous attention was also given to managing postoperative feeding in these children.

In our series, the overall expenses for the stage one Norwood procedure was 1.6 times the average cost of other neonatal heart surgeries like arterial switch operation, largely because of a longer ICU stay. Much of the longer ICU stay may be reduced once the learning curve is overcome. A proactive attitude from the critical care team toward cost containment in terms of minimizing the use of consumables, optimizing laboratory investigations, and appropriate early de-intensification may allow further reduction in costs.

## CONCLUSIONS

Norwood operation is technically feasible in a limited-resource environment if supported by meticulous pre-operative optimization, protocolized nursing care, and intense postoperative hemodynamic monitoring. Minimizing perioperative infective complications can further improve outcomes and reduce the economic burden of this complex surgery. This treatment modality can be offered to motivated families in institutions with good surgical expertise, multispeciality services, and a dedicated pediatric cardiac intensive care backup.

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