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Management of Hypoplastic Left Heart Syndrome in Low-Resource Settings and the Ethics of Decision-Making

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Abstract

Hypoplastic left heart syndrome (HLHS) is possibly the most challenging congenital heart defect to confront in any setting. The highly specialized infrastructure and resources needed to treat HLHS is not available in many low-resource settings. However, low-resource settings must not be assumed to be synonymous with low- and middle-income countries as national income is not necessarily indicative of a country's prioritization of healthcare resources. Besides, a low-resource setting may be institution-specific as well as country-specific. We have stratified institutional capabilities for addressing the requirements of treatment for HLHS into five levels based on the capacity for diagnosis, intervention, and post-discharge monitoring. Depending on institutional capabilities, children born with HLHS in low-resource settings experience a spectrum of outcomes ranging from death without diagnosis to the hybrid or Norwood stage I palliation. The decision-making is ethically challenging when resources are scarce and economic efficiency must be considered in the context of distributive justice. Even in settings that would be classified as resource-rich where survival after surgery and quality of life afterward keep improving, not every parent would choose surgical intervention for their hypothetical child with HLHS.

Keywords

congenital heart disease, hypoplastic left heart syndrome, Norwood procedure, ethics, health economics

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Introduction

The resource requirements for safe and effective treatment of congenital heart disease (CHD) are substantial and even more so for a lesion like hypoplastic left heart syndrome (HLHS). HLHS is possibly the most resource-demanding lesion to treat in congenital heart surgery and presents overwhelming healthcare challenges in low-resource settings. Most consider low-resource settings synonymous with low- and middle-income countries (LMICs) using the gross domestic product (GDP) per capita as the deciding metric. Although this is generally true, national income is not always predictive of healthcare resources. The relationship between national income and healthcare investment is only moderate with significant variation, including superior outcomes in several countries with low GDP per capita.[1] Indeed, some countries rated as high-income, or higher income regions within a country, experience difficulties not entirely different from LMICs in resource allocation for CHD. Argentina is typically rated high income, yet some of its centers struggled with similar problems as LMICs for congenital heart surgery.[1]

So, what exactly is a low-resource setting? From the foregoing, the term must be defined in the context of the required service and the healthcare resources needed to provide it at a quality determined by current best practice. In that light, we propose that a low-resource setting may be institution-specific or country-specific and defines an institution or country where the capability to provide comprehensive treatment for a particular condition is restricted in scope and/or accessibility.

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Comprehensive treatment is determined by current best practice that yields the optimum survival and quality of life. In the case of HLHS, comprehensive treatment requires the availability of the full spectrum of surgical and interventional therapies with well-trained personnel in an environment with adequate error proofing. In addition, appropriate financial instruments must be in place for the needy to access the services.

The institutional resources required may be stratified into five levels within three domains (Table 1).[2] Institutions may have a partial or full complement of resources within the various domains of care—diagnostic, surgical/interventional, and post-discharge monitoring. In the institutions without diagnostic capabilities (Level 0), HLHS is usually mistaken for some other condition because of the lack of expertise. These institutions tend to be general hospitals without pediatric cardiology departments. These neonates either end up dead without a diagnosis or are referred to centers with cardiology departments as congenital heart disease. In the institutions that have the expertise to make the diagnosis but no surgical or interventional capability (Level 1), comfort measures only are adopted or a referral may be triggered if there is a facility within geographical and financial reach for intervention. Therapeutic resources provide the capability to perform a hybrid stage 1 palliation, a Norwood procedure, or transplantation (Level 2). The post-discharge care provided after the Norwood procedure requires special surveillance to manage this high-risk population. Interstage home monitoring (IHM) is a readily identifiable modifier of interstage mortality. It is characterized by discharge from hospital with parents trained to monitor enteral intake, infant scales and pulse oximeters for daily logs of weight and oxygen saturation for early recognition of "red flags" (resting SpO_2 75% or less; weight loss of 30 g; or failure to gain 20 g of weight during three days) and seeking medical advice on red flag detection.[3] This level (Level 3) of post-discharge care, an essential resource for best outcomes, is not available in all settings where the Norwood procedure is performed. The best performing centers caring for infants with HLHS have quality assurance measures (Level 4) that involve reporting to a central registry and regular outcomes evaluation for self-improvement (Table 1).

Outcome of Neonates Born With HLHS in Low-Resource Settings

Low-resource settings are clearly not homogenous. As previously outlined, resource capacities differ even within countries and may be further confounded by restricted financial and geographical accessibility. A typical case we encountered in 2008 in Ghana involved a 2.0 kg term neonate diagnosed at age seven days with HLHS. The SpO_2 was 89% (room air). The echocardiogram showed mitral stenosis and aortic atresia. There was a 6 mm ASD and a PDA of 4 mm. The institution had diagnostic capability but no prostaglandin or experience with the Norwood procedure (Level 1 capability). We sent a message to the closest institution on the continent (over 4,600 km away and 6 h commercial flying time) with therapeutic capability for HLHS in an attempt to figure out a solution. The parents, like the majority in the country, had no medical insurance to cover the treatment costs. The response was no surprise:

> This really is a major problem. Not sure it is worthwhile to operate even through the Foundation (a philanthropic organization); the costs are formidable, and the patient will need additional 2 operations. For the amount involved we could operate on about ten tetralogies; and cure them all! I regret and, am seriously saddened, having to use finance as an indication for acceptance and sincerely look forward to the day when this will not be necessary.

The majority of children born with HLHS in low-resource settings face similar circumstances—limited institutional capabilities, financial constraints, and vast distances to cover to reach the needed healthcare. What is the outcome of these children?

Death Before Diagnosis

Information regarding outcomes in low-resource settings is lacking and few centers report negative results. Presumably, the vast majority of such children do not receive a complete cardiac diagnosis and their deaths are attributed to causes other than HLHS. In Accra, Ghana, we studied patients born with CHD evaluated from 2011 to 2016 at the only tertiary cardiothoracic facility in the country. Among 2,497 patients with CHD studied in the period, only one had HLHS[4] when 137 cases per year would have been expected from a mean HLHS incidence of 0.178 per 1,000 live births.[5] It has been shown that diagnosis was unrecognized in life in 30% of all babies dying in infancy from CHD.[6] Reports specific to HLHS are lacking but it is likely a higher percentage of such neonates die without diagnosis.

Death After Receiving a Diagnosis

Some children in whom the management intent was not primarily comfort care still do not survive after the diagnosis is made. They are often high risk (low birthweight, low five-min Apgar score, or have other major congenital anomalies),[7] too ill to make it to the operating room or to a facility with treatment capabilities, inadequately resuscitated prior to transfer, or decompensate during transport or on arrival at the treatment facility prior to intervention. Pretransport and/or presurgical mortality occurs in low-resource settings where patients must travel long distances to reach care.[8] Birth near a center with Norwood capability results in lower pretransport and presurgical mortality. More than 36% of deaths in one institutional cohort occurred prior to stage 1 palliation.[9]

Comfort Care

Comfort care may be instituted when active surgical intervention is not the goal. In the context of CHD, comfort care has been defined as receiving no cardiac-directed therapy except

Table 1. Optimal Institutional Resources for HLHS Treatment.[a]

Domain	Resource level	Descriptors
Institutional Resources for Diagnosis	0. Inadequate for Diagnosis	Infrastructure and personnel for diagnosis are unavailable. Typically a facility lacking expertise for pediatric echocardiography. Missed HLHS diagnosis is the usual.
	1. Diagnosis of HLHS	Clinical evaluation, pulse oximetry, echocardiography, electrophysiological testing. Advanced imaging (cardiac CT, MRI) & cardiac catheterization.
Institutional Resources for Intervention	2. Surgery & Interventions:	Surgeons with expertise in hybrid procedures, the Norwood procedure, and transplantation.
	A. Hybrid S1P	Interventionists for cardiac catheterization and catheter-based interventions.
	B. Norwood S1P	Facilities for ECMO and mechanical assist devices.
	C. Transplantation	Transplant, immunology, and virology laboratories.
Post-discharge Monitoring	3. Inter-stage Home Monitoring	Program of comprehensive family training in monitoring of enteral intake with daily log of weight & SpO_2 and early recognition of red flag[b] symptoms.
	4. Institutional Quality Assurance	Computerized documentation of all procedures; listing of all major adverse events. Regular analysis of causes of mortality and morbidity; evaluation of long-term follow-up. Reporting to a Central Registry.

Abbreviations: ECMO, extracorporeal membrane oxygenation; S1P, stage 1 palliation; SpO_2, oxygen saturation measured with a finger pulse oximeter.
[a]Adapted from reference 2.
[b]Red flag symptoms—SpO_2 ≤75% or unanticipated increase to ≥90%, or weight loss of 30 g, or failure to gain 20 g of weight during three days.[3]

prostaglandin E_2.[10] It aims at relieving suffering and distress of the child and parents by providing support psychological, emotional, and bereavement support.

Tshiamo Mogajane at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in South Africa documented 15 neonates admitted with HLHS between 2006 and 2014.[11] CMJAH is a tertiary-level facility with a cardiology and cardiac surgery service. The prognosis of HLHS in that institution was notably poor as neonatal cardiac surgery and heart transplantation is not available: the neonates with HLHS were offered comfort measures only, and all died.

A Mexican study reported on 54 neonates diagnosed prenatally with left ventricular outflow tract abnormalities including 38 with HLHS.[12] There was one termination and two intrauterine deaths. Postnatally, 17 were offered comfort care and three were submitted to the Norwood procedure with one survivor. The others (15) had associated anomalies and were excluded from the analysis. The authors concluded that HLHS carries more than 95% risk of perinatal death in countries with suboptimal postnatal management and little or no experience with surgical palliation.

Hybrid Stage I Palliation

Although the hybrid theatre is often found in advanced economies, its availability in some middle-income economies has provided the stage for the hybrid stage I palliation of HLHS. This approach was adopted by Cuaso and coworkers in the Philippines, a setting with limited success at performing the Norwood procedure.[13] The authors indicate that in the Philippines, multiple attempts at Norwood stage I palliation had been made with no previous survivors. Without prostaglandin for initial stabilization of ductal blood supply to the lungs and limited neonatal cardiopulmonary bypass experience, the hybrid approach was considered the best option for initial management of the patient. They performed bilateral pulmonary artery banding, stenting of the arterial duct, and balloon atrial septostomy. The neonate survived to hospital discharge. In another low-resource setting in north-eastern Brazil,[14] the hybrid approach was adopted as initial palliation for HLHS based on lower cost, no requirement for cardiopulmonary bypass, and limited experience with the Norwood procedure. From 2012 to 2015, eight neonates with HLHS were treated by this approach. The median age and weight at the time of the procedure was two days and 3.15 kg, respectively. The median length of stay in intensive care unit was six days. There were no in-hospital deaths, but two late deaths occurred following hospital discharge. Four patients have undergone the second stage of the surgical treatment of HLHS.[14] The hybrid approach thus served as a viable option in settings where results of the Norwood procedure were suboptimal but facilities existed for the hybrid approach. Others have safely performed the hybrid stage I palliation for a hypoplastic left heart condition (aortic atresia with ventricular septal defect) in a two-month-old infant using minimal resources in a conventional catheterization laboratory.[15]

Norwood Stage I Palliation

Substantial numbers of neonates with HLHS are born in low-resource settings, but data on outcomes of the relatively few centers performing the Norwood stage I palliation are sparse.

Schidlow and coworkers reported on single ventricle palliation in LMICs using data from the International Quality Improvement Collaborative for Congenital Heart Disease (IQIC) between 2010 and 2014. Data were collected from 32 centers; 11 (34%) performed Norwood stage I palliations. The 2,543 procedures reported included 5% (127) stage 1 Norwood palliations. Specific outcome data for the Norwood were not reported but survival was 89% for the entire single ventricle cohort.[16]

Ismail and coworkers in Saudi Arabia described a setting with problems obtaining timely access to tertiary care facilities where transfer of a neonate with HLHS may take several weeks,

a shortage of intensive care beds, and a limited number of centers performing the Norwood procedure.[17] They reported 145 patients who underwent the Norwood procedure between 2003 and 2018. Median age at surgery was 29 days. Four Norwood procedures were performed in 2004 with 50% mortality, increasing to 15 Norwoods in 2017 with 7% mortality.[17]

In an initial single-center report from southwest India covering the period 2010 to 2012, Balachandran and coworkers analyzed their experience of seven patients with HLHS who underwent the Norwood procedure: there were two operative deaths.[8] In a subsequent report from the same institution over the period 2011 to 2018, 569 neonatal cardiac operations were performed, including 21 Norwood procedures. Early mortality associated with the Norwood was not specifically reported but for the entire neonatal cardiac surgery cohort overall in-hospital mortality was 7.0%. Thus, a growing experience (and possibly improved results) with the Norwood has been gained in this limited resource setting.[18] That notwithstanding, some have questioned the logic of consuming large resources in providing care that is only palliative to a minority of infants with HLHS in a land where hundreds of thousands of children die every year of diarrhea, malnutrition, and infectious disorders.[19] Ethical issues surrounding staged reconstruction of HLHS and the attendant resource requirements are common, and not only limited to low-resource settings.

The Ethics of HLHS Treatment (or Nontreatment)

If evidence-based treatment is available for a condition, there should be no debate regarding whether that treatment should be offered to a neonate deemed in need of the treatment. But this is not what is always observed in the case of HLHS. In low-resource settings where institutional capabilities are only at levels 0 or 1, comfort care is often the only option available and so no ethical dilemmas usually arise. But in settings where other options are available, especially where the results of the stage 1 palliation are good, some believe it ought to be intuitive that treatment be offered without even bringing up comfort care in the informed consent discussion.

Economic Efficiency Versus Distributive Justice in Low-Resource Settings

In low-resource settings with some surgical or interventional capability, the key ethical question is the economic justification for performing the Norwood procedure. Obviously, resources devoted to running a single ventricle program will yield substantially more lives saved and at the higher quality if committed instead to lower cost interventions for simpler, more prevalent, and "curable" defects.[20] This is the "best outcomes" approach based on economic or allocative efficiency. Unsurprisingly, this position has nearly unassailable support among healthcare experts and health economists in low-resource settings. The counter argument is one of distributive justice which posits that every child deserves a fair chance at treatment regardless of the cost—the "fair chances" approach. As one can imagine, in low-resource settings the "best outcomes" versus "fair chances" debate almost always ends up on the economic efficiency desk. But when resources are devoted to the treatment of neonates with HLHS in economies where resources are scarce and the distribution glaringly uneven as is the case in India, critical debate often ensues.[19,21,22] The arguments are not difficult to grasp: Dean and coworkers showed in a 2011 study[23] of 1,941 neonates that stage 1 palliation had a median length of stay (LOS) of 25 days and charges of $214,680. If one factors the costs of Stage 2 and stage 3 palliation (Glenn and Fontan procedures, respectively)—median LOS and charges of eight days and $82,174 and 11 days and $79,549, respectively, the enormity of the resource requirements becomes obvious. Primary neonatal transplantation had an LOS of 87 days and charges of $582,920. To be fair, these costs relate to procedures performed in the United States using data from the University of Virginia Health System Consortium, an alliance of 101 academic medical centers and 178 affiliated hospitals. The corresponding procedural costs in places like India may be lower: Balachandran and coworkers[8] reported median expenses incurred for the Norwood procedure was Rs. 360,000 (range Rs. 210,000-380,000) which is US dollar;4,819 ($2,811-5,086) using a conversion rate of US $1 = Rs. 74.71. The overall expenses for the stage one Norwood procedure in this setting was 1.6 times the average cost of other neonatal heart surgeries like the arterial switch operation, largely because of a longer ICU stay. These healthcare costs, as has been argued, may be reduced by indigenization, innovation, training of manpower, and teamwork.[21] As reported by Balachandran and coworkers,[8] the direct material costs do not sound prohibitively high, but the economic efficiency argument is that unlike the situation in developed countries, resources consumed for the management of HLHS come at the expense of children with correctable lesions.[19]

The allocative efficiency implied by the "best outcomes" approach needs to be considered in the light of distributive justice. In a two-stage survey assessing the importance of costs in setting health-care priorities, public opinion suggested that it was unfair to discriminate against patients with a high cost-to-treat illness.[24] The majority maintained this view regardless of the obvious implications of economic inefficiency, implying that the concern with allocative efficiency, as usually envisaged by healthcare experts and economists, is not shared by the general public. Thus, the choice between single ventricle palliation and surgery for "curable" defects does not appear to be a mutually exclusive one, even in low-resource settings. Policymakers therefore, have to find a way to do a bit of both, using different weights as appropriate for the local context.

Is Comfort Care a Reasonable Option When Outcomes Are So Good?

The ethical debate is different in adequately resourced settings where the question is: "should non-intervention (comfort care)

be offered as an option to parents of neonates with HLHS?" Against offering comfort care as an option, the following arguments have been made[25]—most high-volume centers now report early surgical mortality rates of less than 10% to 15%; short- and long-term outcomes of the Fontan procedure continue to improve and children with HLHS are at no greater risk of mortality or short-term morbidity following the Fontan procedure than other children with complex congenital heart defects and a functionally single ventricle; currently, most children with HLHS are in mainstream education with normal cognitive abilities; and nonintervention is inconsistent with the approach taken for essentially all other complex medical conditions in neonates and children including near drowning, acute lymphocytic leukemia, head trauma, insulin-dependent diabetes, pulmonary atresia, or transposition of the great arteries. The question proponents of this position will always ask is "How good must the results of intervention be before comfort care is no longer reasonable?"

On the other hand, the proponents of comfort care as an option even in centers with all the resources available (level 4 capability) have made equally important arguments[26]: the process of informed consent stipulates that parents must be well informed in terms of the treatment option the practitioner believes is most appropriate, discussing all reasonable alternatives including what to expect if life-prolonging treatment is declined; surveys have found many parents believe that the burdens of the interventions for HLHS outweigh the early and late benefits; it is in the child's best interest to pursue care that minimizes suffering without prolonging life; and many parents (including physicians) choose or would choose comfort care if their own hypothetical child had HLHS, making it a reasonable option regardless of the surgical outcomes. Reasonableness, is here based on the "reasonable person" standard, defined as any act that a competent person might rationally perform.

The arguments notwithstanding, the available data suggest that decisions regarding management for infants with HLHS are not predominantly based on surgical survival but seems to be swayed substantially by the perceived suffering an infant ought to endure to attain the prolongation of life associated with the multiple surgical procedures.[27]

Conclusion

Low-resource settings are neither homogenous nor synonymous with LMICs. They are best defined in country- or institution-specific terms regarding the capabilities available to address a specific health condition. In the context of HLHS, neonates born in low-resource settings either die without diagnosis or succumb to pretransport or presurgical decompensation, die receiving comfort care, or undergo hybrid stage 1 or Norwood stage 1 palliation with acceptable results in the institutions that have reported results. Regardless of the setting, ethical dilemmas are encountered in the treatment choices caregivers and parents face. In low-resource settings where the Norwood is available, staged reconstruction of HLHS continues to attract criticism regarding allocative efficiency. Where the Norwood procedure is not available, comfort care continues to be viewed as a sign of economic disadvantage. In adequately resourced settings where "everything" including transplantation seems to be available and surgical outcomes continue to improve, data suggest that doctors (including pediatric cardiologists and cardiac surgeons) are no more likely to predict that they would choose surgery for their own hypothetical infant with HLHS. The HLHS treatment and ethics terrain continue to evolve, and what is current today may become antiquated tomorrow.

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