

# eNeonatal Review

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## March 2007 VOLUME 4, NUMBER 7

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Congenital heart disease (CHD) is the most common life-threatening birth defect encountered in the NICU. While the incidence of these lesions has remained constant at around 8 per 1000, the methods of diagnosis and treatment have undergone tremendous change over the past several decades.

In this issue, we look at several recent articles that raise important questions for the perinatal care of these infants, reviewing subjects that are of broad scope and implication, but, in most cases, remain controversial. Four topics are highlighted: 1) the effect of prenatal diagnosis on outcomes in congenital heart disease, 2) fetal intervention for hypoplastic left heart syndrome, 3) prematurity, necrotizing enterocolitis and congenital heart disease, and 4) balloon atrial septostomy and neonatal stroke.

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March 15, 2009

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## Learning Objectives

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**At the conclusion of this activity, participants should be able to:**

- Describe the rationale for fetal intervention for Hypoplastic Left Heart Syndrome (HLHS).
- Discuss the risk factors for the development of necrotizing enterocolitis (NEC) in patients with congenital heart disease.
- Describe the risk factors for neonatal stroke in patients with transposition of the great arteries (TGA).

## Commentary

Fetal echocardiography at 18-22 weeks gestation has proven to be an extremely accurate screen for the detection of serious congenital heart disease, and an increasing percentage of cases are now diagnosed prenatally. Many newborn infants with CHD have already been examined several times by the cardiologist while in utero, and plans for medical or surgical interventions, once the diagnosis has been confirmed by postnatal echocardiogram, are often discussed in detail with parents well in advance of delivery. Potential benefits of fetal diagnosis include the identification of lesions that may require specific, life-saving interventions immediately after birth, the opportunity for parental counseling and education, and possibly, recognition of diseases that might benefit from medical or surgical interventions in utero. Four of the articles reviewed herein discuss the impact of prenatal diagnosis on outcome. In some regions, birth incidence of certain lesions has declined because of increased termination rates following prenatal diagnosis. With some diagnoses, such as transposition of the great arteries (TGA), prenatal diagnosis does not appear to confer significantly improved medical outcomes. However, for other lesions, fetal diagnosis appears to have a positive impact. These lesions, such as hypoplastic left heart syndrome (HLHS), have high potential for death if the infant discharged from the hospital prior to recognition of symptoms and referral for diagnosis and treatment. However, because of the changes in management and outcomes it provides, prenatal diagnosis by fetal echocardiography reduces the opportunities for pediatric residents to learn the signs and symptoms of critical CHD in the newborn, and may thus have an impact on training.

A trend in the treatment of congenital heart disease since the late 1980s has been to perform definitive, corrective repairs on younger and smaller infants, with the goal of establishing normal physiology as soon as possible to avoid co-morbidities resulting from palliative approaches or delayed interventions. The logical progression of this trend from child to newborn to premature infant has now taken the next step to the fetus. One particularly troublesome lesion complex has been the hypoplastic left heart syndrome (HLHS), in which the mitral valve, left ventricle, aortic valve, and aortic arch may all be critically small, and result in only one viable ventricle. The current therapeutic strategy for HLHS is extensive surgical palliation that eventually achieves an acceptable, though distinctly disadvantageous, univentricular circulation. It has long been speculated that at least part of the syndrome is the result of decreased flow across the left side of the heart in utero, resulting in hypoplasia of "downstream" structures. Due to the limited capacity for hyperplasia of myocardial cells after birth, there is relatively limited growth potential of a truly hypoplastic left ventricle after the first few months of life, even with improved flow. Fetal echocardiography has documented in several cases the development of HLHS from a relatively normal appearing left ventricle (LV) beginning at about 17-18 weeks gestation, most commonly noted when there is severe limitation of LV flow, such as in critical aortic stenosis<sup>[1]</sup>. Tworetzky and co-workers at The Children's Hospital in Boston have now reported their initial experience with fetal intervention on stenotic aortic valves in an effort to avoid the development of HLHS by

improving flow through the left heart during fetal life. The technique involves the collaboration of the interventional cardiologist, fetal echocardiographer, high-risk obstetrician, and perinatologist. One difficulty in evaluating the ultimate success of the strategy is in knowing which cases of fetal aortic stenosis are indeed destined to result in HLHS, and at what stage of development the fetal intervention must be performed in order to achieve the desired outcome. Other potential targets of fetal balloon interventions include restrictive patent foramen ovale in certain lesions, and critical pulmonary stenosis with resulting hypoplastic right ventricle. Infants born following these procedures will likely have unique medical needs in the NICU and, if eventually adopted as standard therapy, prenatal intervention may change the birth incidence of certain lesions.

Unfortunately, the combination of severe congenital heart disease and prematurity is commonplace. The specific issues that complicate the management of these infants include lower birth weight, which may negatively impact the surgical and interventional catheter options available; higher risk of lung disease, which can have a deleterious effect, particularly on the univentricular heart; and a higher risk of neurological and gastrointestinal complications. While several studies have shown acceptable survival rates for cardiac surgery done on low birth weight critically ill neonates, morbidity is high<sup>[2-4]</sup>. On the other hand, delaying surgery to achieve weight gain has not been shown to lessen mortality or morbidity, although it is often attempted. Enteral feeds, while usually given in this setting to maximize somatic growth, can result in gastrointestinal injury, particularly in the setting of decreased gut perfusion, as is often the case in CHD with increased pulmonary blood flow at the expense of systemic flow. Dees et al reviewed the outcomes of premature infants with congenital heart disease and found a high percentage of associated syndromes and risk of NEC, while McElhinney et al found certain types of cardiac lesions to have a higher risk than others, particularly in the setting of prematurity. These data support the theory that decreased gut perfusion results in a higher risk of NEC.

The most common cause of severe cyanosis in the neonate is transposition of the great arteries, a condition in which the aorta arises from the right ventricle and the pulmonary artery from the left ventricle. The advent of the balloon atrial septostomy (BAS) procedure to improve systemic oxygenation (by Dr. William Rashkind in 1965) resulted in a dramatic increase in early survival of infants with TGA, and the procedure remains a standard technique, now often done in the NICU with echocardiographic guidance. Neurological outcomes in patients following repair of TGA have been extensively researched via several large, prospective studies that focused mainly on intraoperative and postoperative variables as predictors of outcome<sup>[5-7]</sup>. While these studies show generally favorable outcomes, they also report a higher prevalence of learning disabilities and behavioral problems. In a pair of articles by Miller et al and McQuillen et al, BAS was noted to be associated with abnormal findings on preoperative brain MRI. It is unclear why neurological injury may result from BAS, but presumably small thrombotic or air emboli, either from the septostomy itself or associated with placement of the venous sheath, may be involved. Whether the routine application of this common, life-saving practice should continue unmodified is now in question.

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## EFFECT OF PRENATAL DIAGNOSIS ON OUTCOMES IN CONGENITAL HEART DISEASE

(For non-journal subscribers, an additional fee may apply for full text articles.)

Bartlett JM, Wypij D, Bellinger DC et al. **Effect of Prenatal Diagnosis on Outcomes in D-Transposition of the Great Arteries.** *Pediatrics*. 2004; 113: 335-340.

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Khoshnood B, De Vigan C, Vodovar V et al. **Trends in Prenatal Diagnosis, Pregnancy Termination, and Perinatal Mortality of Newborns With Congenital Heart Disease in France, 1983-2000: A Population-Based Evaluation.** *Pediatrics* 2005; 115: 95-101.

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Tworetzky W, McElhinney DB, Reddy VM et al. **Improved Surgical Outcome After Fetal Diagnosis of Hypoplastic Left Heart Syndrome.** *Circulation* 2001; 103: 1269-1273.

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Mahle WT, Clancy RR, McGaurn SP et al. **Impact of Prenatal Diagnosis on Survival and Early Neurologic Morbidity in Neonates with the Hypoplastic Left Heart Syndrome.** *Pediatrics*. 2001; 107: 1277-1282.

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Ultrasonography has become the standard of care in the United States for screening of fetal anomalies. This technology has developed rapidly, such that many cardiac lesions are now easily identified during routine obstetrical screening, and mothers suspected of having a fetus with CHD are typically referred to the pediatric cardiologist for further delineation of cardiac anatomy and counseling. Many lesions are now fully defined with surprising accuracy in utero. These trends might be expected to have a major impact on the care of patients with congenital heart disease.

While prenatal diagnosis has affected the management and outcomes of CHD, it has done so in a disease-specific manner. Bartlett et al describe the experience at Children’s Hospital Boston, where prenatal diagnosis for patients with d-transposition of the great arteries has not been shown to greatly affect management. Although there were mild differences in infant characteristics and earlier surgery in the prenatally diagnosed group, there were no differences in operative mortality or in neurological outcomes at one year. Therefore, prenatal diagnosis from a purely medical outcomes standpoint did not show a great advantage. However, this finding does not take into account the potential benefit to families from knowing about and anticipating surgery. The international experience is somewhat different: as described by Khoshnood et al, a prenatal diagnosis of d-TGA was found to lower the risk of mortality in the first week of life by 15% in France.

For more challenging lesions such as the hypoplastic left heart syndrome (HLHS), prenatal diagnosis has more substantially affected both the decision to terminate pregnancy as well as the outcomes of infants brought to term. The experience of several centers has recently been published. Tworetzky et al from the University of California, San Francisco found that patients who were diagnosed prenatally were less likely to undergo surgery than patients who were diagnosed postnatally. Since the rate of intervention of live born infants is similar among prenatally versus postnatally diagnosed children, the difference is solely due to the rate of pregnancy termination (which was 33% in their study). The researchers found a similar trend internationally: in France, during 1995 to 2000, 63% of pregnancies having fetuses with a prenatal diagnosis of HLHS were terminated. This same study found that pregnancy termination in France for simpler lesions such as tetralogy of Fallot, coarctation of the aorta, and d-TGA was quite uncommon. All fourteen prenatally diagnosed infants who went to surgery survived, compared to survival of only 25 of 38 postnatally diagnosed children. Further, prenatally diagnosed children were less likely to have preoperative acidosis, tricuspid regurgitation, and ventricular dysfunction.

Mahle et al at the Children’s Hospital of Philadelphia published their experience with 216 patients with HLHS. Children with a prenatal diagnosis were delivered more often in a tertiary care hospital and were started on prostaglandins sooner. Although overall hospital mortality rates were similar, multivariate analysis

demonstrated that prenatal diagnosis was associated with fewer adverse neurologic events (odds ratio 0.46), defined as seizure or coma.

In summary, the weight of evidence from these studies seems to indicate that prenatal diagnosis has had a positive effect on preoperative management, operative mortality, and neurological outcomes in patients with CHD, especially in high risk lesions such as HLHS.

## FETAL INTERVENTION FOR HYPOPLASTIC LEFT HEART SYNDROME

(For non-journal subscribers, an additional fee may apply for full text articles.)

Tworetzky W, Wilkins-Haug LE, Jennings RW et al. **Balloon Dilation of Severe Aortic Stenosis in the Fetus; Potential for Prevention of Hypoplastic Left Heart Syndrome, Candidate Selection, Technique, and Results of Successful Intervention.** *Circulation*. 2004; 110: 2125-2131.

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The hypoplastic left heart syndrome is one of the most challenging and devastating congenital heart malformations: even with optimal surgical management the mortality rate for HLHS approaches 25-30% for the first five years of life. In addition, those children who do survive have lifetime cardiac disability. Increased surveillance of fetal heart disease has led to the recognition that HLHS progresses from equal ventricular size to left ventricular hypoplasia during the late second to early third trimester. This observation has led a small group of physicians to attempt to alter the natural history of HLHS by in utero dilation of the severely stenotic aortic valve.

Tworetzky et al recently published their report on the largest program for fetal intervention for HLHS undertaken. Fetal aortic valvular dilation was offered to 24 mothers whose fetuses had severe aortic stenosis. Intervention was only offered to fetuses after three independent echocardiographers assigned a high probability of progression to HLHS. Twenty fetuses underwent attempted balloon dilation of aortic stenosis; the report describes the initial findings as well as the technical advances made during the time of the study.

The procedure involves entry of a small catheter through the maternal abdominal wall, through the fetal chest wall, and directly into the left ventricular apex. If successful, a guide wire is passed directly out the left ventricular outflow tract, a small balloon is deployed over the wire, and the stenotic aortic valve is balloon dilated. The authors reported a technically successful procedure in fourteen out of twenty patients. Complications to the fetus were relatively common. There was demise in two fetuses within days after successful intervention and one demise a day after an unsuccessful intervention. There was one pre-viable delivery in a fetus 3 weeks after the procedure. There were no significant maternal complications.

Analysis of the successful interventions provided some promising data. Growth of the mitral valve, aortic valve, and ascending aorta occurred in successfully dilated fetuses, compared to the unsuccessfully dilated and no intervention control cases. On the other hand, there was not significant growth in the left ventricular dimensions when averaged among successfully intervened patients. The authors emphasize that three infants of the fourteen with successful interventions were born with two ventricles as proof of principle. Although there were no infants born with two ventricles among either the unsuccessful interventions or those who declined procedures, the total numbers were small. There were only six live born infants in the latter group versus nine successfully dilated live born infants (three were still in utero at the time of the report). In order to evaluate these data, a larger group of fetuses with an early echocardiographic assignment of HLHS would need to be followed.

Despite the inherent shortcomings of this observational study, this report provides promising data for fetal interventional cardiology. As these types of technologies progress, neonatologists will likely encounter patients on whom fetal cardiac procedures have been performed. These infants may well have new complications and pose new challenges in the neonatal period.

## PREMATURITY, NECROTIZING ENTEROCOLITIS, AND CONGENITAL HEART DISEASE

(For non-journal subscribers, an additional fee may apply for full text articles.)

Dees E, Lin H, Cotton RB, et al. **Outcome of Preterm Infants with Congenital Heart Disease.** *J. Pediatrics* 2000; 137: 653-9.

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McElhinney DB, Hedrick HL, Bush DM et al. **Necrotizing Enterocolitis in Neonates With Congenital Heart Disease: Risk Factors and Outcomes.** *Pediatrics* 2000; 106: 1080-1087.

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An unfortunately common scenario encountered by neonatologists and pediatric cardiologists is the dilemma of the child with CHD who also has the misfortune of being born prematurely. A study by Dees et al nicely summarizes the outcomes of a large group of premature neonates with congenital heart disease. Associated congenital and genetic malformations were common in this group of patients, with 32% having associated congenital syndromes. In terms of morbidity, premature neonates with congenital heart disease were almost twice (1.7) as likely to develop necrotizing enterocolitis (NEC). Interestingly, the rate of intraventricular hemorrhage was lower by half than in neonates without congenital heart disease. Perhaps unsurprisingly, the rate of in-hospital mortality was higher for preterm patients with congenital heart disease than for premature infants or infants with congenital heart disease alone.

Although NEC occurs more frequently in premature infants with congenital heart disease, term infants with congenital heart disease are also at risk from this disease. McElhinney et al reviewed 643 neonates admitted to their institution with a diagnosis of congenital heart disease. Among these neonates the rate of NEC was 3.3%, a ten-fold increase over the general population of newborns, but a lower risk than prematurity. Not every neonate was equally at risk: using multivariate analysis, the diagnosis of hypoplastic left heart syndrome, truncus arteriosus, or aortopulmonary window were independently associated with the diagnosis of NEC. The data were analyzed in a case control manner, finding earlier gestational age at birth (36.7 +/- 2.7 weeks versus 38.1 +/- 2.3 weeks) and episodes of low cardiac output or clinical shock to be significantly associated with NEC by multivariate analysis. Although high dose prostaglandin was significantly associated in univariate analysis with NEC, this association became nonsignificant upon controlling for other factors. These data strongly imply that NEC within the population of congenital heart disease patients is a perfusion phenomenon. Patients with the diagnoses of HLHS, truncus arteriosus, and aortopulmonary window all share the characteristics of widened pulse pressure and low diastolic pressure due to large amounts of systemic runoff into the pulmonary vascular bed. Doppler of the descending aorta in these patients often shows reversal of flow in diastole, a risk factor for mesenteric hypoperfusion. Importantly, preoperative feeding, timing of feeding, and type of feeding (breast milk or formula) had no influence on the incidence of NEC in this population. Hospital mortality was not found to be greater with the diagnosis of NEC, likely due to the stronger influence that congenital heart disease had on overall mortality. However, among patients who developed NEC and died, the deaths were attributable directly to NEC -- implying that NEC is an important cause of mortality in neonates with CHD.

The authors report that, in general, infants with CHD born prematurely had worse outcomes and were more likely to develop necrotizing enterocolitis than infants with prematurity alone. In addition to the risk that prematurity confers, infants with CHD seem to have a propensity for developing NEC even when born at term. This risk may be related to specific hemodynamic features which place the mesentery at high risk of hypoperfusion. Neonatologists must therefore be vigilant in monitoring and treatment of NEC in this patient population.

## BALLOON ATRIAL SEPTOSTOMY AND NEONATAL STROKES

(For non-journal subscribers, an additional fee may apply for full text articles.)

Miller SP, McQuillen PS, Vigneron DB et al. **Preoperative Brain Injury in Newborns with Transposition of the Great Arteries.** *Ann Thor Surg* 2004; 77: 1698-706.

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McQuillen PS, Hamrick SE, Perez MJ, et al. **Balloon Atrial Septostomy is Associated With Preoperative Stroke in Neonates With Transposition of the Great Arteries.** *Circulation* 2006; 113: 280-285.

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A lower level of cognitive ability and various aspects of developmental delay have long been observed in children who survive surgery for congenital heart disease, and the mechanisms of neurological insult in these patients have been the subject of intense research. Preoperative conditions such as cyanosis and respiratory distress, operative insults of bypass and circulatory arrest, and postoperative instability with disturbances in

ventilation and oxygenation have all been implicated in neurological trauma.

Two reports have recently shed light onto the amount of neurologic injury that occurs in the preoperative period, typically during time spent in the NICU. In the report by Miller et al, 10 consecutive neonates were subjected to preoperative and postoperative MRI scans to assess the sequence of neurologic injury in surgical repair of TGA. Also performed was MR spectroscopic imaging (MRSI) of the basal ganglia, thalamus, and corticospinal tracts. The authors report that MRSI of lactate/choline, a measure of oxidative metabolism, was higher in newborns with TGA versus normal newborns, a finding consistent with the hypoxic condition of the preoperative brain in TGA physiology. Not anticipated was a 40% rate of focal injury discovered preoperatively, with only one neonate having new damage documented after surgery. The focal findings on MRI were infarct, white matter damage, intraventricular hemorrhage, and/or a combination of these lesions. The data in this study were quite surprising, as conventional wisdom would have held that major neurologic morbidity would be associated with surgery and the immediate post-surgical period.

An intriguing study recently published by McQuillen et al sought to extend these findings by analyzing the risk factors involved in preoperative neurological damage among a group of 29 newborns with transposition of the great arteries, studied using MRI before corrective surgery. Twelve patients were found to have preoperative brain injury. Although severe desaturation occurred in these patients, no patients had evidence of basal ganglia damage or watershed infarcts. Birth weight, Apgar score, resuscitation score, PGE1 use, lowest oxygen saturation recorded, and lowest base deficit were not associated with preoperative brain injury. The only factor found to be significantly associated with preoperative neurological injury was the performance of balloon atrial septostomy (BAS). Of the 29 neonates studied, all 12 with brain injury were among the 19 patients who underwent preoperative BAS. The injuries were apparently unrelated to the BAS technique, including site of cannulation (umbilical versus femoral) as well as duration of catheterization before MRI.

This useful information, if confirmed in larger studies, will likely change the preoperative management of many cyanotic neonates. While the precise clinical prognostic value of these MRI changes is not fully understood at this time, it is generally agreed that these are pathologic changes. Pediatric cardiologists may therefore be more likely to accept somewhat lower postnatal saturations in order to avoid performing BAS in selected patients. In addition, some interventionalists may consider anticoagulation during BAS in order to lessen the risk of thromboembolic events. Whether this strategy will have a positive impact on long-term neurological outcomes is unknown.

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At the conclusion of this activity, participants should be able to:

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- Dr. Nogee has indicated a financial relationship of grant/research support with Forest Laboratories and has received an honorarium from Forest Laboratories.
- Dr. Lawson has indicated a financial relationship of grant/research support from the NIH. He also receives financial/material support from Nature Publishing Group as the Editor of the Journal of Perinatology.
- Dr. Lehmann has indicated a financial relationship in the form of honorarium from the Eclipsys Corporation.

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