Surgical Management Has Little Effect On Neurodevelopmental Outcomes

/PRNewswire/ -- In the largest multicenter clinical trial of children undergoing early-stage surgery for single-ventricle heart defects, differences in intraoperative management did not significantly affect neurodevelopmental outcomes at 14 months of age. Instead, the strongest influences were innate patient characteristics and general medical morbidity during the child's first year of life.

Children born with hypoplastic left-heart syndrome (HLHS) and related single-ventricle defects have long been known to be vulnerable to developmental impairments, and researchers suspected that variations in heart shunts and in cardiopulmonary bypass might affect outcomes. However, the study leaders concluded that substantial improvements in neurodevelopmental outcomes are "likely to require interventions that occur outside the operating room." For example, because infants delivered closer to term had better neurodevelopmental outcomes, the researchers suggest postponing elective delivery from 37 weeks to 39 or 40 weeks might benefit patients.

Researchers from 15 hospitals in the National Heart, Lung, and Blood Institute's Pediatric Heart Network published these results from the Single-Ventricle Reconstruction (SVR) trial online March 28 in the journal Circulation. The lead author was Jane W. Newburger, M.D., M.P.H., of Children's Hospital Boston.

The SVR trial, sponsored by the National Heart, Lung and Blood Institute, is the largest prospective study of children undergoing the Norwood procedure, the first in a series of three staged surgeries used for this complex, life-threatening heart defect. The trial compared outcomes after the Norwood procedure for two types of heart shunt: the Blalock-Taussig shunt and the right-ventricular-to-pulmonary artery (RV-to-PA) shunt. The current study reported on an important secondary trial outcome, neurodevelopment assessed at 14 months of age.

The study leaders hypothesized that children in the RV-to-PA shunt group would fare better in neurodevelopmental tests, reasoning that cerebral blood flow was improved compared to that provided by the Blalock-Taussig shunt. However, neurodevelopmental delay remained common in both groups, a finding that was "discouragingly similar" to results from earlier studies, said J. William Gaynor, M.D., pediatric cardiothoracic surgeon at The Children's Hospital of Philadelphia and senior author of the study. Factors such as the presence of genetic syndromes, lower maternal education and lower birth weight led to lower development scores.

The current study included infants from 15 participating centers, recruited between May 2005 and July 2008. The researchers evaluated 321 infants at 14 months of age. Neurodevelopment was assessed using the Bayley Scales of Infant

Development Second Edition, a standardized assessment of cognitive and motor development, with two scores: the Psychomotor Development Index (PDI) and the Mental Development Index (MDI).

MDI scores for the infants who had the Norwood procedure were significantly lower than in the general population, and PDI scores for the cohort were profoundly lower-greater than 2 standard deviations lower in 44 percent of the patients. Infants with both shunt types had similar developmental scores. No characteristics such as center volume or surgeon volume had an effect on PDI or MDI scores, nor did the type of perfusion. The subgroup of patients with the highest PDI and MDI scores, as well as a shorter post-operative hospital stay, were children with no genetic syndrome and birth weights higher than 2.5 kg (5.5 lbs.).

The authors suggested that birth weight might be improved by postponing the time of elective delivery to 39 to 40 weeks. Recent studies have shown that babies with critical congenital heart disease were delivered electively as early as 37 weeks.

The study team found that infants with more post-operative complications tended to have worse neurodevelopmental outcomes. "Between Norwood discharge and age 12 months, a greater number of complications were also associated with worse development, a novel finding that highlights ongoing brain vulnerability and opportunities for intervention," said Newburger. Longer recovery times and prolonged mechanical ventilation may involve other factors during hospitalization, such as adverse events, low cardiac output, poor feeding or comorbidities.

"The finding that postnatal factors had only modest effects on neurodevelopment is consistent with growing evidence that the risk for adverse neurodevelopmental outcomes begins in the prenatal period," added Gaynor. Patients with HLHS have a high rate of abnormal cerebral development and smaller head size, suggesting that genetic factors and epigenetic changes contribute to brain abnormalities. Researchers have identified abnormalities in fetal cerebral blood flow and in brain metabolism and microstructure, all indicative of brain immaturity in fetuses and neonates with this heart defect. These delays in brain maturation, said Gaynor, may increase the infant's vulnerability to circulatory injury in the brain during the operative period.

Further studies may reveal interventions that improve neurodevelopmental outcomes in these children, conclude the authors. In addition to discouraging elective deliveries before 39 weeks, they suggest evaluating further measures to protect the brain from hemodynamic instability before and after the surgery, and improving developmental support after the infant is discharged following the Norwood procedure.

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