New Technique Improves Success Rates For Infant Surgery

Pediatric researchers report that a recently introduced surgical procedure offers infants with severely underdeveloped hearts a better chance at surviving during their first year of life, in comparison to the standard surgery. Heart surgeons from 15 centers in the federally sponsored Pediatric Heart Network studied the outcomes in 549 newborns who received a complex series of surgeries for hypoplastic left heart syndrome (HLHS).

“This landmark study is the largest clinical trial ever performed in congenital heart surgery, and the first randomized trial comparing two surgical procedures for congenital heart defects,” said senior author J. William Gaynor, M.D., a pediatric cardiothoracic surgeon at The Children's Hospital of Philadelphia, and co-principal investigator of the study, which will appear in the *New England Journal of Medicine*.

The lead author and principal investigator of this study, called the Single Ventricle Reconstruction (SVR) Trial, was Richard G. Ohye, M.D., head of the Pediatric Cardiovascular Surgery Division of the University of Michigan.

Occurring about once in every 100 live births, congenital heart disease is the most common birth defect. It includes a broad variety of structural abnormalities, but HLHS is among the most severe forms. In HLHS the left ventricle is smaller and unable to function. Without treatment, it’s fatal in the first few days of life.

Starting in the 1980s, surgeons developed surgical procedures for HLHS that have allowed increasingly more children born with a single functioning ventricle to survive. The intervention involves three planned surgeries, beginning in the newborn period and extending to 18 to 36 months of age.

This SVR trial compares two techniques used in the initial, riskiest stage of surgery, called the Norwood procedure. As part of the Norwood procedure, surgeons implant a shunt to re-route blood from the malformed heart to the pulmonary artery, which supplies the lungs.

The traditional surgical approach is to use a modified Blalock-Taussig (MBT) shunt, which carries blood from an artery branching off the aorta to the pulmonary artery. The newer technique, sometimes known as the Sano procedure or the right ventricle-pulmonary artery (RVPA) shunt, links the right ventricle to the pulmonary artery. If either technique fails, the only alternative is a heart transplant.

In the current trial, researchers randomized infants who required the Norwood procedure to two groups. Twelve months after the surgery, 74 percent of infants with the RVPA shunt survived and didn't require a heart transplant, compared to 64

percent of infants with the MBT shunt. The RVPA group did, however, undergo a higher rate of complications requiring unintended interventions, such as needing stents or balloons to keep the shunt open. After the first year, rates for transplantation-free survival were the same for both groups. The researchers will continue to follow the children in the study over a longer period to further analyze patient outcomes for the two types of shunts.

Beyond survival, patient outcomes include quality-of-life issues. As medical and surgical advances have improved survival rates for children born with heart defects, caregivers have been able to focus on long-term effects of their disease and its treatment. In particular, children with complex congenital heart disease (CHD) are at greater risk of neurodevelopmental problems. As these children reach school age, they tend to have higher rates of academic, behavioral and coordination difficulties, as compared to their peers.

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