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**Research Explained**

Transcatheter palliation with pulmonary artery flow restrictors in neonates with congenital heart disease: Feasibility, outcomes, and comparison with historical hybrid stage I cohort

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ABOUT THIS STUDY

The goal of this study is to evaluate a less invasive palliative procedure for high-risk infants as an alternative to a surgical procedure during the neonatal period.

**Why is this study important?**

* Neonates with complex congenital heart disease are at risk for excessive pulmonary blood flow which can be detrimental.
* Excessive pulmonary blood flow in neonates can lead to poor outcomes including pulmonary edema (excessive fluid in lungs) and low cardiac output (inadequate delivery of blood to body systems).
* Typically, babies with single ventricle anatomy who are initially dependent on their ductus arteriosus for pulmonary blood flow are palliated with a surgical stage I operation (Norwood operation)
	+ Hybrid stage I (hS1) procedure (ductal stent and pulmonary artery band placement) is used for higher risk neonates at most centers.
* Some neonates with complex congenital heart disease undergo surgical repair or palliation with pulmonary artery band placement.
	+ Pulmonary artery band placement is a surgical procedure where bands are wrapped around the outside of the pulmonary arteries to limit the amount of blood flow into the lungs.
* These procedures (Norwood operation, hybrid stage 1, complete surgical repair, and pulmonary artery band placement) all require open-chest surgical procedures, sometimes requiring cardiopulmonary bypass, and are associated with significant potential risks to the baby.
* Some high-risk babies with additional risk factors (prematurity, low birth weight, decreased cardiac function) may benefit from a less invasive, catheter-based intervention to limit pulmonary blood flow.
* Catheter based placement of a pulmonary flow restrictor (PFR) within the pulmonary arteries is a relatively newer approach that has been performed with limited data on outcomes.

**How was this study performed?**

* This study was done at Boston Children’s Hospital with a review of patients who have undergone placement of pulmonary artery flow restrictors (PFR) between December 2021 and March 2023.
* The outcomes for these babies were then compared to outcomes for a group of babies that had undergone a hybrid stage 1 palliation (ductal stent and pulmonary artery bands) at Boston Children’s Hospital from January 2012 to March 2023.
* The procedure to place a pulmonary flow restrictor requires the operator to customize the hole within the restrictor.

* + Various types, shapes, and sizes of fenestrations (holes) were used over time with adjustments made to optimize the flow through the hole.
* Acute (immediate) effectiveness of the pulmonary flow restrictor was assessed by echocardiography during the procedure in addition to an assessment of the pressure in the pulmonary arteries past the flow restrictor.

**What were the results of the study?**

* 17 babies had pulmonary flow restrictors implanted during the study period.
* The babies were mostly male (70.5%) and white (58.9%).
* Most of the babies had single ventricle anatomy and physiology (88%) and considered high-risk surgical candidates, with the most common diagnosis being hypoplastic left heart syndrome (65%).
* Factors which categorized the babies as high-risk included:
	+ Intact or restrictive atrial septum (9 babies)
	+ Abnormal coronary connections to the ventricle (4 babies)
	+ Prematurity (9 babies)
	+ Genetic syndrome or other congenital defects (4 babies)
* All attempts at placement of pulmonary flow restrictors were successful, for a total of 36 devices in the 17 babies.
* At a median period of 6 months (range 4-11 months), 13 babies (76%) were able to successfully undergo planned surgery.
* The total mortality (death rate) from all causes was 35% with 4 babies before their target surgery and 2 after surgery.
* The estimated survival in these babies at 3 and 6 months was 82% and 69% respectively.
* As a comparison, the study looked at and compared outcomes to a group of 36 high-risk babies that had undergone either a hybrid stage 1 procedure (23 babies) or a pulmonary flow restrictor palliation (13 babies) procedure.
* There were no significant differences in demographic characteristics (gender, ethnicity, weight) between the two groups.
* Comparison of these groups showed a significant difference in survival rate from all causes in the pulmonary flow restrictor group (59%) versus the surgical hybrid group (30%) at 6 months follow-up.

**What were the limitations of the study?**

* The study was a retrospective (evaluating and looking back on past cases and their outcomes) review.
* Because use of pulmonary flow restrictors is relatively new, there is very limited data on their use and outcomes associated with them.
* The numbers of babies who underwent either pulmonary flow restrictor or hybrid stage 1 for the period studied was low.
* This study only looked at babies at a single center (one hospital), so the results might not apply to all centers, particularly centers with lower overall surgical and catheterization volumes.

**What it all means**

* Use of pulmonary flow restrictors is a safe, feasible, and effective means to bridge certain high-risk babies to surgery at a later time when they are more clinically stable to undergo surgery with 76% of patients bridged safely.
* There was an overall low complication rate associated with transcatheter placement of pulmonary flow restrictors with no deaths related to the procedure.
* In comparison to babies who are bridged with a hybrid stage 1, the babies who underwent pulmonary flow restrictor placement had a lower overall 6-month mortality.