

Research Explained

Research Explained

Sinai C. Zyblewski, MD and Richard James, parent

Reintervention following stage 1 palliation: A report from the NPC-QIC Registry

Authors: Matthew W. Buelow, MD, Nancy Rudd, NP, Jena Tanem, NP, Pippa Simpson, PhD, Peter Bartz, MD, Garick Hill, MD

Published in *Conventional Heart Disease* 2018 Aug 10 [Epub ahead of print]

About this Study

Why is this study important?

- Single ventricle heart disease with narrowing of the main artery where it leaves the heart (aortic arch hypoplasia) has high risk for medical complications and early death.
- Problems with the heart after stage 1 surgery (residual lesions), are associated with prolonged hospital stays, longer time on life support, and early death
- Some of the worst residual lesions are narrowing (coarctation) of the aorta and blockage of blood as it tries to leave the left atrium (atrial septal restriction).
- These problems often need to be fixed with either catheter-based procedures or more surgery.

How was this study performed?

- Data for patients who were already enrolled in the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) Registry were used ~~analyzed~~.
- Patients were included in the study if they had one of the two most common stage 1 surgeries (either a modified Blalock-Taussig (BT) or right ventricular to pulmonary artery (RV-PA) shunt), went home after that stage 1 surgery, and completed their stage 2 surgery or died between June 2008 and July 2014.
- Centers that enrolled fewer than 10 patients into the NPC-QIC database were not used in this study.
- What this study tried to find out:
 1. Describing what kinds of re-intervention procedures were used and how often they happened. Re-intervention was defined as catheter-based procedures and additional surgery between stage 1 and stage 2 surgeries.
 2. Determining the risk factors for developing heart problems (residual lesions) after stage 1 surgery, and if the type of surgery made a difference (BT vs RV-PA).
- Data about the patients' medical history and hospital course were also collected.

What were the results of the research?

Study population characteristics

- 1156 patients were included in the study.
- 466 patients (40%) had a stage 1 surgery ~~palliation~~ with a BT shunt. 691 patients (60%) had a stage 1 surgery with an RV-PA shunt.
- 616 patients (53%) had a problem that was seen before the surgery (such as ECMO, metabolic acidosis, need for ventilator, kidney injury, arrhythmia, brain injury/seizures, need for cardiac catheterization).
- 869 patients (75%) had hypoplastic left heart syndrome and it was the most common diagnosis.
- 179 patients (15%) had a restrictive atrial septum prior to stage 1 surgery.
- 580 patients (50.2%) required more procedures after stage 1 surgery.

Re-intervention by shunt type

- Of the 466 patients in the BT shunt group, 245 (52.5%) required more procedures.
- Of the 691 patients in the RV-PA shunt group, 335 (48%) required more procedures.
- The patients in the BT shunt group had more procedures than patients in the RV-PA shunt group (23% vs. 16%).
- Between the stage 1 and stage 2 surgeries, there was no difference between the two groups in the need for extra procedures and surgeries.

Types and timing of re-intervention

Stage 1 hospitalization:

- Patients with an RV-PA shunt needed fewer surgeries or catheter interventions to fix problems with the main artery compared to patients with a BT shunt (surgical aortic arch revision 0.002% vs. 2% and catheter-based aortic arch intervention 0.3% vs 3.6%).
- However, patients with an RV-PA shunt had more shunt problems to fix with a catheter procedure compared to patients with a BT shunt (46% vs 27%).

Interstage period:

- Patients with an RV-PA shunt had decreased risk of aortic arch surgical revision (5% vs 17%) and decreased risk of catheter-based aortic arch intervention (42% vs 59%) when compared to patients with a BT shunt.
- Patients with an RV-PA shunt needed fewer surgeries on the shunt compared to patients with a BT shunt (5% vs 11%).
- Patients with an RV-PA shunt needed more catheter-based interventions compared to patients with a BT shunt, including procedures on the shunt itself (20% vs 3%), on the pulmonary arteries (16% vs 5%), and on the aorto-pulmonary collaterals (32 vs 12%).

Stage 2 palliation:

- At the time of stage 2 palliation, there were no significant differences in re-intervention between the shunt groups.

Risks for re-intervention

- The presence of pre-operative arrhythmia or any other pre-operative risk factor were associated with reduced risk for having a re-intervention.
- Being on a ventilator after an operation for more than 2 weeks was associated with the need for more procedures or surgery.

What are the limitations of this study?

- Because of the limitations of studies that look at data from the past, this study was not able to see what directly caused the need for extra procedures and surgeries.
- This study did not use higher risk patients who either died before they left the hospital or stayed in hospital until stage 2 surgery.
- Specific reasons for re-intervention, exact timing of re-interventions, and complete pre- and post-intervention data were not collected.
- This study was unable to find out how re-intervention affects risk for death.
- The study was unable to find out if hospitals did procedures and medical care differently from each other.

What it all means

- Between the first two main surgeries (stage 1 and stage 2), babies often need to have more procedures and surgery.
- In this study, early re-intervention during the stage 1 hospitalization occurred more frequently in patients having a BT shunt. These interventions were usually surgeries and catheter procedures on the aorta.
- Between the stage 1 and stage 2 surgeries, patients with a BT shunt more often had catheter-based and surgical interventions on the aorta. Patients with an RV-PA shunt had more catheter-based intervention on the shunt, pulmonary arteries, and aorto-pulmonary collaterals.
- This study was unable to determine if re-intervention was due to poorly performed surgery, better detection of residual lesions, or more aggressive treatment of possible complications.
- This study was unable to find out if a need for more surgery or procedures made a difference in whether a child lived or died.