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