NATIONAL PEDIATRIC CARDIOLOGY
Quality Improvement Collaborative | a JCCHD initiative

Research Explained

Key Findings: Comparison of Shunt Types in the Norwood Procedure for Single-Ventricle Lesions

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The *New England Journal of Medicine* published a study in May 2010: "Comparison of Shunt Types in the Norwood Procedure for Single-Ventricle Lesions".

The NPC-QIC Research and Publication Committee has reviewed this article and a summary of the findings can be found below.

Main Finding from this Study:

While there has been great improvement in care for patients with hypoplastic left heart syndrome and other similar single ventricle lesions that require the Norwood procedure, these patients are still at great risk. When the Norwood procedure is performed there are 2 different ways blood can be supplied to the lungs. A right ventricular-to-pulmonary artery shunt (RVPAS) is placed directly from the right side of the heart to the pulmonary arteries by making a cut in the heart muscle. A modified Blalock-Taussig shunt (MBTS) is placed from an artery that supplies the head and arm to the pulmonary arteries. Each shunt has advantages and disadvantages. The MBTS may cause less blood to flow to the heart muscle through the coronary arteries, but the RVPAS may not allow the pulmonary arteries to grow well and makes a scar on the muscle of the heart. It was not known if one of these shunts were better than the other.

This study describes a comparison of two groups who were randomly assigned to get one shunt type or the other at the time of their Norwood surgery. The authors of this study concluded that in infants undergoing the Norwood procedure, survival without requiring a heart transplant was better at 1 year of age in those receiving a RVPAS than those receiving a MBTS.

About this study:

- **Why is this study important?**

  This was a very important study because doctors at many different medical centers worked together to find answers to questions that could not be answered by one medical center alone. This is the first time that this type of study was successfully performed in congenital heart surgery, and has helped usher in a new era of cooperation between centers in doing research to improve outcomes in these patients. The number of patients at any single center would not be large enough to be certain that difference are not just based on random events or differences between individual patients, but rather based on an effect of one particular intervention or another. Statistical calculations may be used to correct for individual differences, but can only be used when the groups of patients studied are large. Many other studies have come from the information collected in this study because so many different medical centers

worked together to contribute information. This study was also the first fair comparison between shunt types because patients were randomly assigned to a type of shunt. This means that in such a large group, any difference seen between those with the two types of shunts is most likely due to the type of shunt.

In addition, this is a very large group of patients with this heart defect about whom we have a lot of very good baseline information. It will be very valuable to continue to follow them over time, even for their entire lives.

- **How was this study performed?**

This study enrolled patients from 2005-2008 who required the Norwood procedure at 15 medical centers in the United States and Canada. The patients were randomly assigned to one shunt type when they had their Norwood surgery. They were followed after surgery for 12 to 52 months depending on when they entered the study. The main comparison was how many from each group survived to 1 year of age without needing a heart transplant. In addition, they compared how many catheterization procedures each group underwent and the function of the hearts by echocardiogram (echo) for each group.

- **What were the results of the research?**

  - 275 patients with MBTS were compared to 274 patients with RVPAS.
  - At 1 year of age the RVPAS had more patients alive without needing a heart transplant (74%) than the MBTS group (64%).
    - When they followed the patients they could for longer than 1 year the difference between the groups disappeared.
    - At centers that did a lot of Norwood procedures every year there was no difference between shunt types even at 1 year.
  - The group getting the RVPAS underwent more catheterization procedures than the MBTS group, mostly to perform interventions to increase the size of the pulmonary arteries.
  - At the end of the study there was no difference between shunt groups in the function of their heart by echo.

- **What are the limitations of this study?**

This study went on for many years and patients were enrolled at different times so they were followed for different lengths of time. The main comparisons between groups were made when all patients were about 1 year old. This may not be long enough to know which shunt type is better. Differences at 3 years were also examined and published recently[1]. These data confirm that differences seen at 1 year did not continue. The number of patients alive without heart transplant was very similar between the two groups (67% for RVPAS vs. 61% for MBTS), even though cardiac function by echo was a little better

in the MBTS group and those in the RVPAS group underwent more catheter procedures. A further extension of this trial is ongoing to see what happens at 6 years old.

Differences in many features of patients might be studied, but deciding which are important (other than survival without heart transplant) is difficult. As well, many differences in how patients are treated at different centers can be seen. But since the patients were randomly sorted into groups for comparison based only on the type of shunt they received and not other aspects of care (such as using a certain medication), conclusions about other aspects of care would be very difficult.

- **What are the takeaway messages considering the results and limitations of this study?**

  For the 1st year of life, survival without heart transplant is better in those who get a Norwood with RVPAS than those who get a MBTS. After that, there is not a clear advantage to have one shunt over another, but as they continue to collect more information over time, new knowledge may be gained. The group that had RVPAS had smaller pulmonary arteries and underwent more catheterization interventions to try to improve the size of their pulmonary arteries.

[1] Newburger JW, Sleeper LA, Frommelt PC, Pearson GD, Mahle WT, Chen S, Dunbar-Masterson C, Mital S, Williams IA, Ghanayem NS, Goldberg CS, Jacobs JP, Krawczeski CD, Lewis AB, Pasquali SK, Pizarro C, Gruber PJ, Atz AM, Khaikin S, Gaynor JW, Ohye RG; Pediatric Heart Network Investigators. Transplantation-free survival and interventions at 3 years in the single ventricle reconstruction trial. Circulation. 2014 May 20;129(20):2013-20.