乳児の心臓奇形に対する二つの術式の成績の比較は複雑な結果であった

乳児における重症の中隔欠損に対する新たなシャント術は1年生存率を改善するが合併症が多い

New shunt procedure for correcting severe heart defect in infants improves survival to one year, but has more complications

心臓が重度に未発達な状態で生まれた小児は新たなシャント術を施行されることにより1歳まで生存する確率が上昇するが、この方法は長期において最も安全な方法ではない可能性があると2009年American Heart Association学会で発表された。この初めての手技の新たな方法は、機能している右室を肺動脈へつなぐ右室から肺動脈(RV-to-PA)へのシャントを用いる。従来の方法はBlalock-Taussigシャント(MBTS)変法を用い、大動脈を肺動脈につなぐ。ある15施設のトライアルで555人の小児(男児61%、白人73%)をRV-PAシャントまたはMBTS術を施行する群に無作為に割り付けた。12ヵ月後に心臓手術を必要とせずに生存している乳児は、RV-PAシャント群においてMBTS群と比較し、有意に多かった(74%対64%、p=0.01)。RVからPAへのシャントは合併症が多く、240のインターベンションを必要とした(乳児100人当たり87.6)。MBTS群においては心血管系のインターベンションを必要とする例がはるかに少なかった(183人、乳児100人当たり66.5%、p=0.006)。平均2年後には、MBTSと比較したRV-PAシャント術の移植を必要としない生存率の有益性は消失し、その差は有意ではなくなった(68%対62%、p=0.14)。

Full Text

Infants born with a severely underdeveloped heart are more likely to survive to their first birthday when treated with a new shunt procedure - yet it may not be the safest surgery long term, according to research presented at the American Heart Association's Scientific Sessions 2009.

Babies born with a critically underdeveloped left side of their hearts require three surgeries to correct the problem. A portion of the first operation, the Norwood Procedure, includes a connection to deliver blood from the heart to the pulmonary arteries feeding the lungs so that blood can pick up oxygen. There are currently two ways it can be done:

- The new modification of the Norwood utilizes a right ventricle to pulmonary artery (RV-to-PA) shunt to connect the functioning right ventricle to the pulmonary artery.
- The traditional version uses a modified Blalock-Taussig shunt (MBTS), which connects the aorta (the major blood vessel delivering blood from the heart to the body) to the pulmonary artery.

In a 15-center trial by the Pediatric Heart Network, 555 infants (61 percent male, 73 percent Caucasian) were randomized to receive either the RV-to-PA shunt or MBTS procedure.

In the first results from the study, the researchers reported:

- At 12 months, significantly more babies survived without requiring a heart transplant with the RV-to-PA shunt (74 percent) compared to the MBTS (64 percent, p=0.01).
- The RV-to-PA shunt had more complications, necessitating 240 interventions (87.6 for every 100 babies), for example, to make adjustments to the shunt or use balloons or stents to keep it open. Far fewer cardiovascular interventions were needed (183, or 66.5 for every 100 babies) in the MBTS group (p=0.006).
- At an average of two years, the transplant-free survival advantage of RV-to-PA (68 percent) over MBTS (62 percent) had diminished and was no longer significant (p=0.14).

"Early results seem to favor the RV-PA shunt, but by two years there is no longer any survival advantage," said Richard G. Ohye, M.D., lead author of the study and associate professor of surgery at the University of Michigan Medical School in Ann Arbor. "It is still unknown which will turn out to be better over the long term."

For example, the children still must undergo other stages of surgical repair to increase the amount of oxygen in their blood. Good pulmonary artery growth is important in the success of this procedure. In the results so far, overall pulmonary artery growth was significantly greater after the MBTS.

"Ongoing surveillance as these children grow and undergo the final surgical procedure will be very important to determine the proper roles of the shunts," Ohye said.

Although rare, having a single working ventricle is the most common severe congenital heart defect. "Just 25 to 30 years ago, this defect was uniformly fatal," Ohye said. "Now babies are treated with a series of three surgeries, but many still die, even when treated at experienced centers."

Each shunt procedure has theoretical advantages, but researchers previously didn't have hard evidence about which option to choose. The downside of the MBTS is that it takes blood away from the arteries feeding the heart muscle. The RV-to-PA shunt doesn't do this, but requires an incision into the baby's only working ventricle, creating scarring that might interfere with its later function.

"Roughly 50 percent of surgeons use each type, but we truly don't know which is better because there has never been a study," Ohye said. "In fact, there has never been a multi-center, randomized clinical trial performed in congenital heart surgery. This trial sets a new standard for using evidence-based medicine to evaluate new procedures in congenital heart surgery."

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