

Steroids during surgery may not be helpful for infants having heart bypass

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The largest clinical trial ever conducted in infants younger than age 1 undergoing heart surgery with cardiopulmonary bypass found that administering steroids during surgery did not improve post-operative

outcomes compared to placebo, according to preliminary late-breaking research to be presented at the American Heart Association's Scientific Sessions 2022. The meeting, held in person in Chicago and virtually, Nov. 5–7, 2022, is a global exchange of the latest scientific advancements, research and evidence-based clinical practice updates in cardiovascular science.

According to the American Heart Association's 2022 Heart Disease & Stroke Statistical Update, approximately 40,000 children in the U.S. every year undergo [heart surgery](#) to treat congenital heart defects. Despite major medical advances, congenital [heart disease](#) requiring [surgery](#) during infancy is still considered high risk with potential for complications, including neurological injuries, [respiratory failure](#) with need for tracheostomy, cardiac arrest or the need for machines to assist with blood circulation and oxygenation after surgery. These outcomes are often associated with severe systemic inflammatory responses, which may contribute to worse post-operative outcomes.

"In an effort to reduce this inflammatory reaction and to improve post-operative outcomes, some [health care professionals](#) administer steroids during surgery, while others believe that the side effects of steroids outweigh the benefits," said lead study author Kevin D. Hill, M.D., M.S., a professor of pediatrics at Duke University Pediatric and Congenital Heart Center in Durham, North Carolina.

Previous studies have found wide variability among clinicians, with some routinely administering steroids during infant heart surgery, some routinely avoiding steroids and others employing a selective approach depending on the complexity of the case and the patient's age.

"Professionals have been debating the use of steroids during infant heart surgery for decades with relatively little evidence to support their safety or effectiveness," Hill said. "Due to the difficulties in enrolling children

in [clinical trials](#), there have been only three randomized, controlled trials of steroid use in [infants](#) with heart disease reported over the past five years, and the results are conflicting."

Researchers examined data from the Society of Thoracic Surgeons Congenital Heart Surgery Database to evaluate the safety and effectiveness of steroids in infants younger than 12 months of age undergoing heart surgery. The STeroids to Reduce Systemic inflammation after infant heart Surgery (STRESS) Trial compared the administration of steroids at initiation of cardiopulmonary bypass vs. [placebo](#) on combined clinical outcomes, including post-operative complications, hospital length of stay and mortality. They also compared individual outcomes in a secondary analysis.

This study was conducted at 24 centers across the U.S., and a total of 1,200 infants were enrolled, representing the largest trial ever conducted in children undergoing heart surgery. Approximately half of the patients were female, 16% were Black infants and 12% were Hispanic children, "which is representative of the U.S. population of children undergoing heart surgery," Hill said. The average age at the time of surgery was four months, and more than 30% of patients were younger than 30 days old at the time of surgery.

After obtaining informed consent from parents, half of the infants were randomly assigned to receive a single dose of steroids during surgery while the other half received a placebo. The primary analysis of the results, after adjusting for baseline characteristics, showed no significant difference in post-operative outcomes between those receiving steroids or placebo.

The secondary analysis found that patients receiving steroids had lower odds of bleeding requiring another operation.

"When we analyzed the primary endpoint using a different approach known as the 'win ratio,' there was evidence that steroids provided a small net benefit," Hill said, but other outcomes were comparable for the two groups including mortality, post-operative infections and the need for [mechanical ventilation](#) and length of hospital stay:

- The mortality rate among the infants who received steroids was 2.0% compared to 2.8% in the placebo group.
- The rate of mortality or major post-operative complications combined was 17.2% for the steroid group vs. 20.3% of those in the placebo group.
- Post-operative infection complications occurred in 5.2% of those who received steroids compared to 4% of the placebo group.
- 6.8% of the steroid group needed prolonged mechanical ventilation compared to 8.5% of the placebo group.
- The average hospital length of stay for infants who received steroids was 10 days, compared to 11 days for those in the placebo group.
- Infants in the steroid group were more likely to have high blood sugar, which is a known side effect of steroids, with 19% of infants requiring insulin within 24 hours of surgery. In comparison, 6.7% of the infants in the placebo group required insulin within 24 hours of surgery.

The investigators' review of all outcome components concludes that steroid administration may hold a small benefit for some infants.

"Although our primary analysis did not find a difference in outcomes for those treated with steroids, there were enough secondary signals indicating a benefit that the consensus of our investigative team, including multiple pediatric cardiologists and congenital heart surgeons, is that steroids may offer a small benefit," Hill said.

"Every day, clinical decisions have to be made, and for infants needing heart surgery, there may not be sufficient evidence to support the treatments. There is a need for more studies to determine the optimal dose and to evaluate which children might benefit more than others," he added. "There is also a need to evaluate whether lower doses of steroids may offer similar benefits but with less risk of hyperglycemia."

The study's limitations included that more than a quarter of the trial participants were administered steroids after surgery, more commonly among those in the placebo group. "This may have masked some of the effectiveness of prophylactic [steroids](#)," Hill said.

More information: Link to session [abstract](#)

Provided by American Heart Association

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