

Giving steroids during bypass surgery shows no benefit, some harm

March 31 2014

Giving patients steroids at the time of heart surgery does not improve health outcomes and appears to put them at greater risk of having a heart attack in the days following surgery, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session. The finding, which stems from the largest randomized trial in cardiac surgery ever conducted, challenges a practice that many surgeons have used for decades.

"Based on these results, we suggest that [steroids](#) should not be used prophylactically during cardiac surgeries that require the use of cardiopulmonary bypass," said Richard Whitlock, M.D., associate professor of cardiac surgery at McMaster University, and lead investigator of the study.

Cardiopulmonary bypass, or the "heart-lung machine," is a technology that is instrumental in performing surgery for [coronary heart disease](#) and other heart conditions. More than half a million [cardiac procedures](#) are performed annually in the United States.

Steroids have been shown to reduce the body's inflammation reaction during and following the use of the heart-lung machine, though until recently no studies had evaluated whether using steroids actually improves patient outcomes. A survey conducted at the start of the trial suggests patients are currently given steroids in about 25 percent of medical centers worldwide. The use of steroids varies by country, hospital and surgeon.

"As cardiovascular disease continues to climb, cardiac surgery has become a common operation worldwide," Whitlock said. "Trying to improve the outcome for these patients is clearly imperative, and it is important to re-evaluate practices for which there is a lack of evidence and potential for harm. This study shows that administering steroids during cardiac surgery requiring bypass can cause harm."

The study involved more than 7,500 patients who underwent cardiac surgery with the use of the heart-lung machine in one of 82 participating medical centers across 18 countries spanning North America, South America, Europe, the Middle East and Asia. Half the patients were randomly assigned to receive methylprednisolone, a common steroid used to prevent inflammation, and half received a placebo. Health outcomes were assessed 30 days after surgery.

The study failed to meet both of its co-primary endpoints in that it did not show a significant benefit of steroid treatment over placebo in terms of either the overall rate of death or a composite metric that included death, heart attack, stroke, new renal failure or respiratory failure.

However, a pre-specified examination of the study's secondary endpoints, which included the rate of heart attacks, revealed that patients who received the methylprednisolone faced a 15 percent greater risk of death or heart attack and a 21 percent greater risk of heart attack alone, a pattern that was consistent across all subgroups. Of the study's 7,500 participants, 927 had a heart attack and 332 died.

The biological explanation for the increased rate of heart attack is not clear, Whitlock said, adding that the finding is specific to prophylactic steroids – those given solely as prophylaxis during cardiac surgery requiring the heart-lung machine, and not for any other medical reason. The results do not suggest steroids should be stopped in cardiac surgery patients who are already taking them for other reasons.

A 2012 study of 4,000 cardiac procedures in patients of a lower risk profile in the Netherlands also found steroids had no effect on death, heart attack, stroke, new renal failure or respiratory failure. That study, however, suggested a benefit of steroids in the sub-group of high-risk patients, a finding that was not reflected in the present study.

The hospitals that participated in the trial have launched two new studies to examine other aspects of cardiac surgery.

"This trial has helped us establish a large network of surgical centers to answer important questions about cardiac surgery in a very rigorous way," Whitlock said.

Provided by American College of Cardiology

Citation: Giving steroids during bypass surgery shows no benefit, some harm (2014, March 31) retrieved 27 April 2024 from
<https://medicalxpress.com/news/2014-03-steroids-bypass-surgery-benefit.html>

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