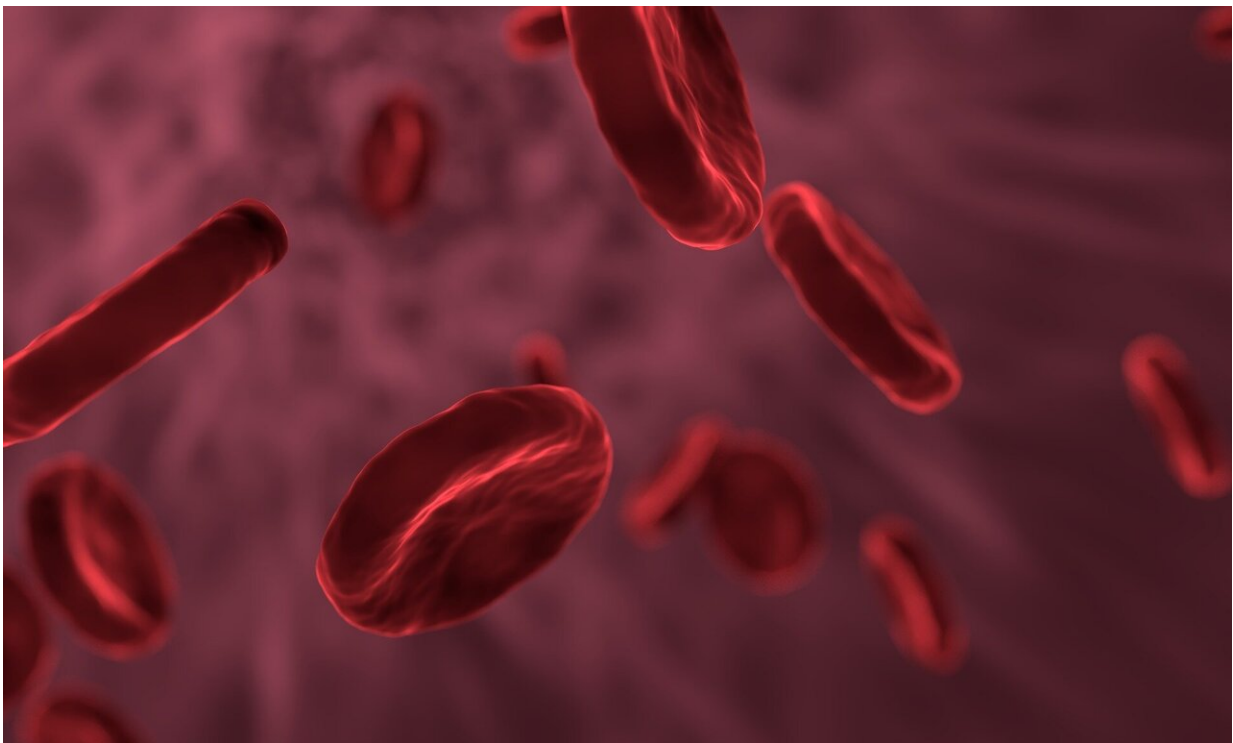


No increase in complications seen with perioperative administration of tranexamic acid

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Patients undergoing noncardiac surgery who received a single dose of tranexamic acid (TXA), which promotes blood clotting, at the beginning and end of their surgery had significantly less serious bleeding and

needed fewer blood transfusions compared with patients treated with a placebo, based on findings presented at the American College of Cardiology's 71st Annual Scientific Session. Researchers also observed no significant difference in the number of patients experiencing adverse events such as heart attacks, strokes or blood clots between the two patient groups.

"We saw an unequivocal benefit of treatment [with TXA] on preventing bleeding and blood transfusions, with no increased risk of complications," said P.J. Devereaux, MD, Ph.D., director of the Division of Perioperative Care at McMaster University in Hamilton, Canada, and the study's lead author. "Given the number of people worldwide who undergo [noncardiac surgery](#) every year and the frequency of postsurgical bleeding complications, this has the potential to help a lot of [patients](#), and I hope it will lead to a substantial change in practice."

Globally, about 300 million people undergo major noncardiac surgery every year. In an international observational study of 40,000 adults who underwent noncardiac surgery, major bleeding was the most common life-threatening post-surgical complication, accounting for 17% of deaths within 30 days after surgery. Post-surgical bleeding can also result in serious complications, such as heart attack, stroke or kidney damage.

Surgery accounts for at least 40% of all blood transfusions, at a time when the global demand for blood for transfusions outpaces the supply.

"If we could safely prevent post-surgical bleeding and reduce the need for blood transfusions, it would be a huge contribution to global health," Devereaux said.

TXA has been shown in previous large, randomized trials to prevent clinically significant bleeding after heart surgery and surgery for trauma or post-childbirth complications. Another large study, however, found

that patients with gastrointestinal bleeding who received TXA had an elevated risk for [blood clotting](#). For patients undergoing major noncardiac surgery (e.g., hip or knee replacement; general, vascular, urologic or spinal surgery), it has been unclear whether the benefit of TXA in reducing bleeding outweighed the risk of adverse events.

The Perioperative Ischemic Evaluation-3 (POISE-3) trial enrolled 9,535 patients aged 45 or older at 114 centers in 22 countries who were scheduled to undergo noncardiac surgery and had at least one risk factor that elevated their risk for post-surgical bleeding and vascular complications. Risk factors included: age over 70, undergoing major surgery, having fatty deposits in the arteries [atherosclerosis] and impaired kidney function. Patients' average age was 70 and 56% were men. Patients were randomly assigned to receive one intravenous dose of either TXA or a placebo at the beginning of their surgery, followed by a second dose at the end. No one directly involved in the trial—patients, their doctors or the people collecting trial data and adjudicating outcomes—knew which patients had received TXA or a placebo.

After 30 days, 11.7% of patients in the placebo group had experienced life-threatening, major or critical organ bleeding compared with 9.1% of those in the TXA group, a highly statistically significant difference, Devereaux said. Rates of adverse cardiovascular events, however, were similar in both groups (14.2% for patients who received TXA, 13.9% for those who received a placebo). The benefit of TXA treatment was consistent, regardless of the type of noncardiac surgery patients received and whether patients' hemoglobin (a component of red [blood](#) cells that carries oxygen to the body's organs) was normal or low before surgery.

"We have a clear, robust result showing that we can safely reduce postsurgical bleeding by giving just two doses of a readily available drug immediately before and after noncardiac [surgery](#)," Devereaux said.

"Moreover, it's a drug that we have a lot of experience with and in

different settings, and it's inexpensive."

A limitation of the study is that it did not meet its predetermined margin for determining that TXA was no less safe than the placebo. However, [statistical analysis](#) showed with a probability of more than 95% that the safety of TXA and placebo were similar. A beneficial reduction in bleeding risk must be weighed against a low probability of a small increase in the risk of a [heart attack](#), stroke or another cardiovascular adverse event, Devereaux said.

More information: Conference: accscientificsession.acc.org/

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