Pre-op steroids to prevent nausea do not significantly increase post-op bleeding

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Tonsillectomy is exceedingly common, with a reported increase in tonsillectomy rates in children younger than 15 years from 287,000 to 530,000 per year over the past decade. Although safe, adenotonsillectomy can result in significant complications, such as aspiration and bleeding. Complications are infrequent, but because tonsillectomy is so common, the absolute number of children experiencing tonsillectomy complications is formidable.

Corticosteroids are often given to children undergoing tonsillectomy to reduce postoperative nausea and vomiting; however, previous research has suggested that corticosteroids may increase the risk of hemorrhage during and after surgery. Researchers from the Massachusetts Eye and Ear, Boston, Naval Medical Center Portsmouth, Virginia, and colleagues set to determine the effect of dexamethasone, a corticosteroid, on bleeding. They found that administration of the dexamethasone to children during a tonsillectomy was not associated with excessive, serious bleeding events following surgery compared to patients who received placebo. Their findings are reported in the September 26 issue of *JAMA*.

A recent randomized trial studying the dose response of perioperative dexamethasone to postoperative nausea and vomiting [PONV] in children undergoing tonsillectomy was prematurely terminated due to an increased risk of postoperative hemorrhage. The outcomes of the trial suggested that a single dose of intraoperative dexamethasone significantly increased post-tonsillectomy hemorrhage events. In light of

these findings, there is a need to reassess the safety profile for dexamethasone when used during tonsillectomy," the authors write.

"This was a troubling study as it ran counter to our own American Academy of Otolaryngology, Head and Neck Surgery guidelines recommending steroids after tonsillectomy to reduce nausea and vomiting, as well as against the Cochrane Group data suggestions," said Senior Author Christopher Hartnick, M.D., co-director of Mass. Eye and Ear's Pediatric Airway/Swallowing/Voice Center and Harvard Medical School Associate Professor, Otology and Laryngology, "It went against the experience of a majority of practitioners who have routinely used steroids for years without finding an elevated bleeding rate. But the only way of testing this was through a randomized trial."

Dr. Hartnick, along with Thomas Q. Gallagher, M.C., U.S.N., of the Naval Medical Center Portsmouth, Va., and colleagues performed a clinical trial (NTC01415583) to examine bleeding events in children associated with dexamethasone use during tonsillectomy. The multicenter, randomized trial included 314 children ages 3 to 18 years undergoing tonsillectomy without a history of bleeding disorder or recent corticosteroid medication use. The study was conducted between July 2010 and December 2011 with 14-day follow-up. The researchers tested the hypothesis that dexamethasone would not result in 5 percent more bleeding events than placebo using a noninferiority (outcome not worse than treatment compared to) statistical design. Patients received a single perioperative dose of dexamethasone or an equivalent volume of saline.

The primary outcome measured was rate and severity of post-tonsillectomy hemorrhage in the 14-day postoperative period using a bleeding severity scale (level I, self-reported or parent-reported postoperative bleeding; level II, required inpatient admission for postoperative bleeding; or level III, required reoperation to control postoperative bleeding).

One hundred fifty-seven children (median [midpoint] age, 6 years) were randomized into each study group, with 17 patients (10.8 percent) in the dexamethasone group and 13 patients (8.2 percent) in the placebo group reporting bleeding events. The overall rate of bleeding events for all levels was 30 out of 314 (9.6 percent). The researchers found that in an intention-to-treat analysis, the rates of level I bleeding were 7.0 percent (n = 11) in the dexamethasone group and 4.5 percent (n = 7) in the placebo group; rates of level II bleeding were 1.9 percent (n = 3) and 3.2 percent (n = 5), respectively; and rates of level III bleeding were 1.9 percent (n = 3) and 0.6 percent (n = 1), respectively.

"The dexamethasone treatment failed to show noninferiority for the level I bleeding, but did demonstrate that the bleeding rate with dexamethasone is not more than 5 percent greater than that with placebo (noninferiority) for both level II and III bleeding events. The data was stratified for primary vs. secondary bleeding events and a decrease in level II and level III bleeding events in both groups was noted," the authors write.

"In conclusion, in this prospective, randomized study of 314 children undergoing tonsillectomy, perioperative dexamethasone administration was not associated with more level II or III bleeding events than placebo as shown by noninferiority. Increased subjective (level 1) bleeding events caused by dexamethasone could not be excluded because the noninferiority threshold of 5 percent was crossed," the authors write.

More information: *JAMA*. 2012;308[12]:1221-1226.

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