Article Appraisal

Article: Effect of Oral Dexamethasone Without Immediate Antibiotics vs. Placebo on Acute Sore Throats in Adults: A Randomized Clinical Trial

Date of Journal Club: June 1st, 2017

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Background and Study Objective(s):
Sore throat is a common patient presentation in the emergency department setting. A large proportion of these patients receive antibiotics despite the low risk of suppurative complications and limited symptomatic benefit. We need to find an effective alternative to antibiotics, and while studies have assessed the effectiveness of steroids and antibiotics combined, evidence is lacking for exclusive steroid use for sore throat in primary care patients. This study, termed the TOAST trial (Treatment Options without Antibiotics for Sore Throat) aimed to assess the clinical effectiveness of oral corticosteroids for acute sore throat in the absence of antibiotics in an outpatient general practice setting.

Study Design:
This is a randomized, placebo-controlled, double-blind trial conducted at 42 family practices in South and West England. It included patients 18 years of age and older presenting to a primary care clinician with acute symptoms of sore throat and pain with swallowing. The clinician must have judged the sore throat to be caused by an infection, but not requiring immediate antibiotics. After throat swabs, the clinician had to decide between no antibiotics or delayed antibiotics. Patients were then randomized to take 10mg of dexamethasone or a placebo. The primary outcome was complete resolution of sore throat at 24 hours, and secondary outcomes included complete resolution of sore throat at 48 hours, subsequent antibiotics use, additional pain medications, and time off work and school.

Results:
A single dose of oral dexamethasone did not significantly increase the proportion of participants reporting complete resolution of their sore throat at 24 hours, regardless of receiving a delayed antibiotic prescription. Of those assigned to dexamethasone, 22.6% had complete symptom resolution at 24 hours, compared with 17.7% of placebo, an absolute risk difference of 4.7% (-1.8 to 11.2). At 48 hours, those in the no-antibiotic prescription group experienced were significantly more likely to have complete resolution of their sore throat with a statistically significant difference of 8.7% corresponding to a number needed to treat of 12. There were no differences in those
offered a delayed prescription. There were no significant differences in any other secondary outcomes. There were 5 serious adverse events, 2 in the dexamethasone group and 3 in the placebo group.

Validity of Results:
The results of this study were generally considered valid. In particular, all clinically important outcomes were considered, participants were analyzed in the groups to which they were randomized, blinding was employed, and the treatment arm groups were similar. One consideration is that this study was powered based on a previous Cochrane review to detect a modest effect size. It is possible that a larger study would be able to reveal a significant difference. Previous meta analyses and systematic reviews have demonstrated the combination of antibiotics and corticosteroids to lead to a threefold complete resolution of sore throat by 24 hours compared to placebo. While this study did not combine antibiotics and steroids like most previous research, the discrepancy between previous research results and this study call the results into question.

Generalizability of Results:
This study took place in the general practice setting, and patients who required immediate antibiotics were excluded. Both of these factors would lead to inclusion of patients of lower acuity than those presenting to the average emergency department in Canada. Furthermore, this study did not include children, who comprise a large proportion of patients presenting with sore throat.

The Bottom Line:
In relatively healthy adults with a sore throat not requiring immediate antibiotics, I would offer steroids and employ shared decision making to determine if dexamethasone was a good fit for the patient. I would say something like: “A recent study found that about 9% more patients with a sore throat were pain free at 48 hours and about 5% more patients were pain free after 24 hours after taking a single dose of steroids. There are virtually no side effects of a single dose of steroids, however many people prefer not to take a medication that that don’t absolutely need. With this information, how would you like to proceed?”