

Adding intranasal fluticasone to cefuroxime resolved acute rhinosinusitis

Dolor RJ, Witsell DL, Helkamp AS, et al., for the Ceftin and Flonase for Sinusitis (CAFFS) Investigators. Comparison of cefuroxime with or without intranasal fluticasone for the treatment of rhinosinusitis. The CAFFS Trial: a randomized controlled trial. *JAMA*. 2001 Dec 26;286:3097-105.

QUESTION

In patients with acute rhinosinusitis and a history of chronic or recurrent sinus symptoms, is the addition of intranasal fluticasone to cefuroxime more effective than the addition of placebo for prompting recovery?

DESIGN

Randomized {allocation concealed*}†, blinded (clinicians, patients, data collectors and {outcome assessors}†),* placebo-controlled trial with 8-week follow-up.

SETTING

12 primary care and 10 otolaryngology sites in the United States.

PATIENTS

95 patients who were ≥ 18 years of age (median age 38 to 41 y, 68% women) with recurrent or chronic sinusitis requiring antibiotic therapy. All patients were required to have evidence of sinus infection on either plain film radiography or nasal endoscopy. Exclusion criteria were previous sinus surgery, sinus lavage in the past 7 days, nasal polyposis, recurrent moderate epistaxis, chronic bacterial sinusitis with antimicrobial therapy failure, intranasal corticosteroid use in the past 14 days, long-term corticosteroid or immunosuppressive agent use, immunocompromised state, allergy to cephalosporins or penicillins, antibiotic use in the past 7

days, or potential for pregnancy. 92 patients (97%) were included in the analysis.

INTERVENTION

All patients received cefuroxime axetil, 250 mg twice daily for 10 days, and 2 puffs of xylometazoline hydrochloride per nostril twice daily for 3 days, after which they were allocated to fluticasone propionate, 2 puffs of 200 μg ($n = 47$), or placebo ($n = 48$) for 21 days.

MAIN OUTCOME MEASURES

Clinical success. Patients reported by telephone interview whether they were cured or much improved using a 6-point scale (cured, much improved, somewhat improved, no change, somewhat worse, and much worse). Secondary outcomes were health status and quality-of-life changes measured by the Sinonasal Outcome Test-20 (SNOT-20) and the Short Form-12 (SF-12).

MAIN RESULTS

Analysis was by intention to treat. More patients who received fluticasone than pla-

cebo achieved clinical success ($P = 0.009$) (Table) and reached it in fewer days (median 6.0 vs 9.5 d, $P = 0.01$). The fluticasone and placebo groups did not differ for changes on the SNOT-20 (change from baseline to 56 days -1.0 vs -1.0 , $P = 0.54$) or changes on the SF-12 survey (change from baseline to day 21 physical component score 7.8 vs 4.6, $P = 0.39$, and mental component score 2.4 vs 1.4, $P = 0.21$).

CONCLUSION

In patients with acute rhinosinusitis and a history of chronic or recurrent sinus symptoms, the addition of intranasal fluticasone to cefuroxime was more effective than the addition of placebo in achieving cure or improvement.

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*See Glossary.

†Information provided by author.

Fluticasone vs placebo added to cefuroxime for acute rhinosinusitis at 8 weeks‡

Outcome	Fluticasone	Placebo	RBI (95% CI)	NNT (CI)
Clinical success	94%	74%	27% (6 to 58)	6 (3 to 19)

‡Abbreviations defined in Glossary; CI for RBI calculated from data in article.

COMMENTARY

In the United States, an estimated 3 million patients per year are treated for symptoms suggestive of acute rhinosinusitis (1). Currently, physicians are advised to diagnose the condition by clinical criteria (1) and to use amoxicillin or trimethoprim-sulfamethoxazole as first-line treatment agents (2). Such adjunctive agents as topical decongestants and corticosteroids have been considered by many to be useful but have been less thoroughly investigated than have antibiotics (2).

The patients in the study by Dolor and colleagues were not previously healthy persons with an isolated episode of acute sinusitis. One third to one half had a known diagnosis of allergic illness in addition to recurrent or chronic sinusitis. About one quarter showed only mucosal thickening on radiography (Dolor RJ. Personal communication), a finding that is nonspecific and often seen in allergic or viral illness (3).

This study does not prove that fluticasone speeds resolution of acute bacterial sinusitis unrelated to atopy. However, these conditions frequently coexist, and differentiating between them may be difficult. The

addition of fluticasone (and perhaps 3 days of xylometazoline) to first-line antibiotics in clinically diagnosed sinusitis is now a better validated option, especially if a history of recurrent episodes or underlying allergy exists.

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