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Role of mometasone furoate nasal spray as an adjunct treatment of acute sinusitis

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To the Editor:

Nasal corticosteroids are commonly used as an adjunct in the treatment of acute sinusitis, although clinical data supporting this use are limited.¹ Results of a trial intended to assess the efficacy of adding mometasone furoate nasal spray (MFNS) 400 µg twice daily to amoxicillin clavulanate for 21 days in patients with acute sinusitis were recently published in this Journal.² The authors concluded that MFNS provides added benefit to treatment with antibiotics for acute sinusitis. We believe that certain design flaws in this trial limit such a definite conclusion.

The patient subset on which the conclusions are based is problematic. The study reports data on 407 patients who met "evaluation criteria." Except for medication compliance, no other evaluation criteria are mentioned, nor does the article state whether any criteria were prespecified. There is no presentation of results from an intent-to-treat population. Data obtained from an "evaluatable" subset of patients, which was not defined a priori, are subject to important bias.

The symptoms used for patient enrollment and for efficacy assessment are also problematic. Many of the symptoms used (purulent rhinorrhea, congestion, postnasal drip, headache, facial pain, and cough) are as reflective of uncomplicated rhinitis as of sinusitis. The protocol did not require the presence of symptoms for a specified duration for enrollment. Clinicians do not typically make a diagnosis of acute sinusitis unless symptoms are present for at least 1 week, and some authorities recommend that symptoms be present for at least 3 weeks.¹

It should also be noted that the difference in the total symptom score can be primarily attributed to symptoms related to congestion (congestion, facial pain, and headache). This limits the interpretation of the results because decongestants—which are typically used by clinicians to treat acute sinusitis—were not allowed in the study, and nasal corticosteroids are known to be effective in controlling congestion associated with rhinitis. Objective assessments of sinusitis by CT scans showed no difference between the treatment arms. From all these considerations, it is possible that the small numerical difference in total symptom score between the two treatment arms was driven by patients with rhinitis who benefited from MFNS therapy and not by a specific effect of MFNS on sinusitis. Finally, the efficacy analysis in this study was based on symptom scores recorded on days 1 through 15, whereas the duration of treatment was 21 days. It would be preferable to assess efficacy over the full 21 days of treatment. Given the limitations stated above, we believe that the authors' conclusion that MFNS 400 µg twice daily is an effective adjunct treatment to antibiotics for sinusitis is not supported by this study.

In addition to the efficacy concerns, we note that the total daily dose of MFNS used in the study is 4 times the dose approved for allergic rhinitis.³ The authors do not provide a rationale for such a high dose in studying the treatment of acute sinusitis. High doses of MFNS are likely to be associated with increased nasal and, potentially, systemic adverse events. Efficacy of lower doses should be explored in any additional examination of the role of MFNS in treating sinusitis.

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