

**Comparative study of the efficacy of topical steroid and antibiotic combination therapy versus oral antibiotic alone when treating acute rhinosinusitis**

Dear Editors,

This is in reference to a very well written article titled ‘Comparative study of the efficacy of topical steroid and antibiotic combination therapy versus oral antibiotic alone when treating acute rhinosinusitis’ by El-Hennawi *et al.*<sup>1</sup> The study design is well thought of and I must commend the authors for undertaking such a novel study. However, there seem to be some flaws in the study design and I would like to highlight them.

Acute sinusitis is a common condition and a sample size of just 40 patients does not seem to be appropriate to derive a conclusion about its treatment. The sample size should be larger and more representative.

The authors compared oral amoxicillin to topical ofloxacin and steroid combination. This creates a treatment bias, as both groups received different treatments; therefore, comparing them is not correct. Moreover, no culture was performed of the nasal secretions to determine the sensitivity pattern of the organisms causing sinusitis. This creates a bias as it is possible that the organisms causing sinusitis in the ‘amoxicillin group’ may not be sensitive to it at all, which can also affect the outcome of the study.

The efficacy of ofloxacin irrigations in preventing bacterial biofilms has been reported.<sup>2</sup> However, there are no reports of the efficacy of ‘topical’ ofloxacin in acute sinusitis. It is not clear how the dose of 5 drops every 8 hours has been calculated and seems to be arbitrary. Another consideration concerns the usage of ofloxacin either as topical drops or as topical irrigations.

In view of the above arguments against the present study design, I would recommend that a prospective randomised study with a larger sample size be designed before a definite conclusion is made. The investigators should culture the secretions, and divide patients into two groups that are given same antibiotic either orally or topically.

If the efficacy of topical antibiotics is established, another randomised study can be designed that has two groups: one that is given topical antibiotic alone and one given a topical antibiotic and steroid combination.

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**References**

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- 2 Ezzat WF, Fawaz SA, Rabie H, Hamdy TA, Shokry YA. Effect of topical ofloxacin on bacterial biofilms in refractory post-sinus

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*Authors’ reply*

Dear Editors,

We are so glad to hear of the interest in our work titled ‘Comparative study of the efficacy of topical steroid and antibiotic combination therapy versus oral antibiotic alone when treating acute rhinosinusitis’. I would like to reply to the comments made in the above-mentioned letter.

First, we shall address the comment ‘sample size of just 40 patients does not seem to be appropriate to derive a conclusion...’. Before we start any study, we determine the sample size based on a previously calculated standard international equation, and we respect the number obtained from the equation. In our study, optimal sample size was calculated according to the following equation:<sup>1</sup>

$$n = P(100 - P)/A^2 \times F(1 - a)$$

Where  $n$  = sample size,  $A = 0.1$  when  $F(1 - a) = 0.10$ , and  $P$  = prevalence of acute bacterial rhinosinusitis. Hence, when calculated with the desired confidence level of 95 per cent and standard error of 5 per cent, with prevalence of acute bacterial rhinosinusitis (‘ $P$ ’) at 2 per cent,<sup>2</sup> where  $A = 0.1$  and  $F(1 - a) = 0.10$ , the optimal sample size was 20 patients for each group. We could not change the results by increasing the sample size as we have to respect the methodology rules.

With regard to the second comment ‘The authors have compared oral amoxicillin to topical ofloxacin and steroid combination. This creates a treatment bias...’, our aim was to clinically evaluate the effects of a topical antibiotic and steroid combination therapy administered intranasally, versus an oral antibiotic used alone, when treating acute rhinosinusitis. The investigation of an intervention requires that a control group is compared to the study group, and the logical control group is the standard, widely used and internationally accepted reference. For this intervention, the logical control was amoxicillin, as used in our study. Amoxicillin is a first-line therapy in patients suspected of having acute bacterial sinusitis because of its general effectiveness, safety, tolerability, low cost and narrow spectrum.<sup>3</sup> Hence, there was no bias here, as we compared the efficacy of the variable of interest (topical antibiotic and steroid) with the standard, widely used and internationally recommended (by most guideline agencies) treatment for acute rhinosinusitis, which acted as the baseline or control.

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