Maxillary sinusitis in adults: an evaluation of placebo-controlled double-blind trials

Stalman W, van Essen G A, van der Graaf Y, de Melker R A

Authors' objectives
To assess the methodological quality of double-blind placebo-controlled randomised clinical trials (RCTs), regarding the effectiveness of antibiotic treatment in acute maxillary sinusitis in adults.

Searching
MEDLINE was searched from January 1966 to July 1996 using the keywords 'Respiratory Tract Infection' OR 'Sinusitis' AND 'Antibiotics'. In addition, the bibliographies of relevant articles were reviewed and the Cochrane Collaboration was consulted. The search strategy was limited to Dutch, English, French, German and Scandinavian studies.

Study selection
Study designs of evaluations included in the review
Placebo-controlled, double-blind randomised trials were included.

Specific interventions included in the review
Antibiotic treatments compared with placebo were included. Antibiotic regimens prescribed in the included trials were as follows: pivampicillin, 700 mg twice daily for 6 days; doxycyclin, 200 mg on day one then 100 mg for unspecified number of days, also weekly irrigations starting on day one; cyclacillin, 500 mg three times daily for 7 days.

Participants included in the review
Adults with acute maxillary sinusitis were included. Patient selection criteria for the included trials were as follows: purulent nasal discharge, nasal speech, malaise, headache and non-productive cough; macroscopic positive irrigation findings and homogeneous shadows of fluid levels on X-ray; purulent nasal discharge and positive culture in nasal secretion. Studies of the following were excluded: patients with chronic sinusitis, children under the age of 10 years, and otherwise unhealthy patients (tertiary care patients, those with immunodeficiency syndromes).

Outcomes assessed in the review
No specific outcomes were defined in terms of the review's inclusion criteria, but those assessed in the included trials were as follows: purulent nasal discharge, nasal speech, malaise, headache and non-productive cough; macroscopic changes in maxillary sinus secretion and rhinomanometric changes in ostrial patency; bacteriological culture of nasal secretion, signs and symptoms, changes in nasal cytology, and global clinical rating.

How were decisions on the relevance of primary studies made?
Two readers assessed the identified studies.

Assessment of study quality
The following criteria (incorporating 35 validity items), relating to both internal and external validity, were used: definition of population; adequate sample size; number of patients eligible and reject log; ethics; therapeutic intervention; placebo-control regimen; randomisation; blinding of patients and treatment team; testing of randomisation; withdrawals after randomisation; compliance; contamination (by other interventions); outcomes; adverse effects; and analysis. A scoring form of 35 validity items was used. For each item, a score of 1 was given if it was completely met, 0.5 if partially met, and 0 if not met at all. The highest possible score for each study was 35 for each reviewer. Four reviewers independently rated the studies, giving a maximum score of 140 for each study. The results were discussed in a consensus meeting. When consensus could not be reached, each reviewer scored as he/she believed was most appropriate. For each trial, the reviewers' total scores were summed and the percentages of the maximum attainable score were calculated. In addition, the reviewers' scores were summed per item and per group of items for each trial, and the percentages of the maximum attainable scores for each criterion were calculated. The pre- and post-consensus
scores were analysed for inter-rater agreement using the kappa statistic.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative summary.

How were differences between studies investigated?
Characteristics of the individual studies were discussed narratively.

Results of the review
Three RCTs (n=266) were included: of the 266 patients involved, 135 received antibiotics and 131 received placebo.

The external validity of all studies was low. One trial, conducted in a primary care setting, demonstrated no statistically-significant difference in recovery time following treatment with pivampicillin or placebo; this trial obtained 50% or more in 9 of the 15 internal validity criteria. Another trial demonstrated no superiority of doxycycline over placebo in patients attending an otolaryngology out-patients clinic; this scored 50% or more on 4 of the 15 internal validity items and 0% in 9 criteria. In an unknown setting, the third trial (55% for internal validity and a score of 50% or more in 6 of the 15 criteria) demonstrated the effectiveness of cyclacillin over placebo, measuring sinusitis using the normal bacterial flora of the nose. Effect sizes and p-values from the individual trials were not reported. The mean pre- and post-consensus inter-rater agreements were 0.53 (range: 0.48 - 0.70) and 0.91 (range: 0.83 - 1.0), respectively, indicating mediocre and excellent inter-rater reliability.

Authors' conclusions
At present, there is no evidence-based advice available to the general practitioner regarding antibiotic treatment of acute maxillary sinusitis.

CRD commentary
A stated aim of this review was to assess the methodological quality of trials, and the authors have carried out a detailed validity assessment of included studies. Pooling data using narrative methods was appropriate given the clinical heterogeneity of studies. Study selection criteria were defined for study design, participants, and interventions, but not for outcomes. The one trial suggesting effectiveness of antibiotic treatment attempted to measure sinusitis using the normal bacterial flora of the nose. The review's authors note that there is a lack of correlation between these outcomes, and suggest that no conclusions can be drawn. The search strategy was not adequate for a pharmacological review. The authors did not report accessing the EMBASE database and attempts to identify unpublished literature were unclear; thus, it is possible that relevant studies were omitted from the review. Some study details were provided in tables, but since effect sizes and p-values relating to outcomes were not reported, it was difficult to fully appreciate the review's findings. In terms of the systematic review process, two authors were involved in selecting studies but it was not stated whether decisions were made independently, or how disagreements were resolved. The number of reviewers involved in data extraction was not mentioned, nor whether any checking took place. This is an interesting systematic review, but methodological issues mean that the findings should be interpreted with caution.

Implications of the review for practice and research
Practice: The authors state that until further research becomes available, a restrictive policy seems justified, especially when the increased incidence of bacterial resistance is taken into account.
Research: The authors state that to determine the effectiveness of antibiotic treatment in acute maxillary sinusitis in adults, placebo-controlled double-blind randomised trials are required, conducted according to modern standards.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.