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[Intervention Review]

Antihistamines and/or decongestants for otitis media with effusion (OME) in children

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ABSTRACT

Background

Otitis media with effusion (OME) is common and may cause hearing loss with associated developmental delay. Treatment remains controversial. The effectiveness of antihistamines, decongestants and antihistamine/decongestant combinations in promoting the resolution of effusions has been assessed by randomized controlled trials.

Objectives

The objective of this review is to determine whether antihistamine, decongestant, or combination therapy is effective in treating children who present with OME.

Search methods

The Cochrane Ear, Nose and Throat Disorders Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*, Issue 1 2006), EMBASE (1974 to 2006), MEDLINE (1951 to 2006) and a gray literature database were searched using a search strategy created by an experienced medical librarian. The date of the last search was March 2006. Reference lists from included studies and relevant reviews were searched by hand; pharmaceutical manufacturers of antihistamines and decongestants and first authors of included studies were contacted to identify other potentially relevant studies.

Selection criteria

Randomized controlled trials (RCTs) using antihistamines, decongestants or antihistamine/decongestant combinations as treatment for OME in children were selected. We excluded trials that randomized on the basis of acute otitis media (AOM) even though OME was also studied in follow up.

Data collection and analysis

Data were extracted from the published reports by two authors independently using standardized data extraction forms and methods. The methodological quality of the included studies was independently assessed by two authors. Dichotomous results were expressed as a relative risk with 95% confidence intervals using a fixed-effect model when homogeneous and a random-effects model when heterogeneous. Nearly all outcomes analysed were homogeneous. Continuous results were discussed qualitatively. Statistical analysis was conducted using RevMan software.

Main results

No statistical or clinical benefit was found for any of the interventions or outcomes studied. However, treated study subjects experienced 11% more side effects than untreated subjects (number needed to treat to harm = 9).

Authors' conclusions

Because the pooled data demonstrate no benefit and some harm from the use of antihistamines or decongestants alone or in combination in the management of OME, we recommend against their use.

PLAIN LANGUAGE SUMMARY**Antihistamines and/or decongestants do not help and may harm when used for symptoms of otitis media with effusion ('glue ear')**

Otitis media with effusion (OME), also known as glue ear or serous otitis media, is a condition in which there is fluid persisting in the middle ear. Many treatments have been suggested. This review summarizes the studies using antihistamines, decongestants or a combination of antihistamines and decongestants and finds no benefit for any of the short or long-term outcomes including resolution of the fluid, hearing problems, or the necessity of additional referral to specialists. Further, using these medications causes significant side effects, such as gastro-intestinal upset, irritability, drowsiness or dizziness in approximately 10% of patients. Therefore antihistamines, decongestants or antihistamine/decongestant combinations are not recommended treatments for OME. Watchful waiting is the best approach with consideration of referral for evaluation by an ENT consultant if symptoms persist beyond 12 weeks.