The effectiveness of topical preparations for the treatment of earwax: a systematic review

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CRD summary
This review concluded that current evidence suggests little difference in the efficacy of water-based and oil-based preparations for the treatment of earwax. Non-water, non-oil-based preparations appear most effective for clearing earwax and improving syringing, but further research is needed. Given the limitations of the included studies, the authors were appropriately cautious in their conclusions.

Authors’ objectives
To determine the effectiveness of topical preparations for the treatment of earwax, both in clearing earwax without syringing and in aiding effective syringing.

Searching
MEDLINE, CINAHL, and the Cochrane Controlled Trials Register were searched until January 2004. The National Research Register and Clinical Evidence were searched in June 2003. The search terms were stated and no language restrictions were applied. The reference sections of all identified articles and additional reviews were checked for any further relevant articles. Experts and researchers in the field, some authors of the identified trials, and some manufacturers of the preparations were also contacted.

Study selection

- Study designs of evaluations included in the review
  Randomised controlled trials (RCTs) were eligible for inclusion in the review.

- Specific interventions included in the review
  Studies that assessed the use of drops for the treatment of earwax were eligible for inclusion. The included studies evaluated the water-based preparations Cerumenex, acetic acid, Colace, hydrogen peroxide, Molcer, sodium bicarbonate, Waxsol and Xerumenex; the oil-based preparations almond oil and Cerumol, Dioctyl-medo, Earex (same as Octocerol) and olive oil; and the non-water non-oil-based preparations Audax (same as Earex Plus) and Exterol (same as Otex).

- Participants included in the review
  The authors did not state which participants were eligible for inclusion in the review. It appears that any participants with earwax were included. The participants were adults and children presenting with earwax at hospitals, general practices, paediatric clinics, office practices, out-patient clinics, an emergency department, and a community and family practice. The participant selection criteria used in the primary studies were provided.

- Outcomes assessed in the review
  The authors did not state which outcomes were eligible for inclusion in the review. The main outcomes of the included studies were the number of participants with earwax clearance without syringing, and the number of participants with successful syringing. Different studies used varying definitions of successful syringing, including ease of syringing, clearance of wax, and visualisation of the tympanic membranes after treatment.

How were decisions on the relevance of primary studies made?
The identified trials were read independently and assessed for eligibility.

Assessment of study quality
The quality of each of the included studies was assessed in terms of reported generation of allocation sequence, allocation concealment, inclusion of all randomised patients, and blinding of the outcome assessors. Each of the quality
criteria were graded according to a 3-point scale. A trial was considered high quality if it obtained the maximum score on each of the four criteria. The identified trials were read independently and assessed for quality. Any differences in opinion were settled by negotiation.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. The data extracted were outcomes representing the success rate of earwax clearance without syringing, as stated by individual study authors, and the rate of successful syringing. The dosage and application of each preparation, and any adverse events were also recorded.

Odds ratios (OR) were calculated for each outcome in the included studies.

Methods of synthesis
How were the studies combined?
The studies were stratified according to the type of preparation used: water-based, oil-based, or non-water non-oil-based. The studies in each group were pooled using random-effects models, but only if the outcomes were sufficiently similar and the randomisation procedures were appropriate. Where pooling was not appropriate, a narrative synthesis of the results was undertaken.

How were differences between studies investigated?
The stratified analysis was used to analyse differences between water-based, oil-based, non-water non-oil-based treatments and no treatment. Water-based preparations were compared with one another, and oil-based preparations were compared with one another. Statistical heterogeneity was assessed in each of the pooled groups of studies using the Woolf Q statistic. Sensitivity analyses were used to assess the impact of low-quality trials on the pooled results.

Results of the review
Eighteen RCTs were included in the review. The total number of patients included in the review was not stated, as some primary studies reported the number of ears treated rather than the number of participants. At least 1,502 participants were included.

Treating earwax without syringing.

No statistically significant differences were found between no treatment, water-based treatments, oil-based treatments, and non-water non-oil-based treatments.

The pooling of 3 studies that compared the water-based treatments docusate sodium (Colace) and triethanolamine polypeptide (TEP) (Cerumenex) revealed no statistically significant differences between the two treatments. The pooling of 2 studies provided only weak evidence that TEP was more effective than normal saline (OR 4.6, 95% confidence interval, CI: 1.1, 18.5) and no evidence that docusate sodium was significantly more effective than saline.

One study found no statistically significant difference between the oil-based preparations Otocerol and Cerumol in removing the need for syringing.

In a comparison of all studies that investigated clearance of wax, there was a significant relationship between length of treatment and clearance of earwax (P<0.0001). Treatment for 4 days was found to be more effective than only one or 3 days of treatment.

Successful syringing.

There were no significant differences in the success of syringing with the use of water-based or oil-based preparations. Nor were there any significant differences among the different types of water-based preparations or among the oil-based preparations.
One study showed that the non-water non-oil-based preparation Audax was significantly more effective than the oil-based preparation Earex in aiding successful syringing, when applied twice daily for 4 days (OR 21.4, 95% CI: 2.6, 178.6). Another study showed that the non-water non-oil-based preparation carbamide peroxide was more effective in aiding successful syringing than the water-based preparation Cerumenex (OR 33.0, 95% CI: 9.5, 114.3).

One study found that the water-based treatment Xerumenex was more effective than no treatment in facilitating syringing the following day (OR 60.0, 95% CI: 6.6, 547.3).

In a comparison of all studies that investigated the success of syringing, there was no significant relationship between the number of days of treatment and the success rate.

Four trials were rated as high quality. Statistical heterogeneity was present among studies comparing docusate sodium and TEP (Q=6.8, d.f.=3, P=0.08) and studies comparing Dioctyl-medo and oil (Q=9.0, d.f.=2, P=0.01) in facilitating successful syringing. The removal of low-quality trials from the pooled analyses did not significantly affect the results.

**Authors' conclusions**
The current evidence suggests that there is little difference in the efficacy of water-based and oil-based preparations. Non-water non-oil-based preparations appear more effective for clearing earwax and improving syringing, but further research is needed.

**CRD commentary**
The authors set out a clear objective at the beginning of the review, although the inclusion criteria were only defined in terms of the intervention and study design. A thorough search was made of several databases, and an effort was made to contact experts for additional information, which might have helped reduce publication bias. The absence of language restrictions might also have helped reduce the risk of missing relevant articles. Appropriate criteria were used to assess the quality of the studies.

Given the clinical heterogeneity between the treatments, it was appropriate to stratify the studies according to preparation type. However, this resulted in the pooling of very small numbers of studies, which means that small differences between treatment types might not have been detected. Statistical heterogeneity was assessed, and sensitivity analyses were used to assess the effect of study quality on the results. The authors acknowledged that the external validity of the review was somewhat limited. The majority of the trials excluded patients with complications, such as otitis externa, so the findings are limited to people without such complications. In addition, some of the trials were rather old and treatments for earwax have since changed. Given the small number of participants and studies that were pooled, the authors were appropriately cautious in their conclusions and correctly highlighted the need for more high-quality research in this field.

**Implications of the review for practice and research**
**Practice:** The authors stated that for uncomplicated earwax, there may be no need to see a health professional and it may be more cost-effective to just use eardrops. Non-water, non-oil-based preparations appear to be most effective for this, but which particular preparation would be most effective is not yet known.

**Research:** The authors stated that more large, well-designed RCTs are needed to assess whether non-water non-oil-based preparations are actually more effective than water-based preparations, oil-based preparations, or water alone.

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