

Brief description of patient problem/setting (summarize the case very briefly)

28 YOF with no PMHx who presents to clinic with right ear “popping sensation” and intermittent pain x 2 weeks. She reports cleaning the ear very often with Qtips. She denies recent travel or swimming.

Search Question: Clearly state the question (including outcomes or criteria to be tracked)

In adults with ear discomfort secondary to cerumen impaction, does treatment with cerumenolytic drops compared to irrigation alone lead to faster or more complete symptom resolution?

Question Type: What kind of question is this? (boxes now checkable in Word)

- Prevalence Screening Diagnosis
- Prognosis **Treatment** Harms

Assuming that the highest level of evidence to answer your question will be meta-analysis or systematic review, what other types of study might you include if these are not available (or if there is a much more current study of another type)? Please explain your choices.

- If meta-analysis or systematic review are not available, I would include randomized controlled trials (RCTs), as they provide strong evidence for comparing treatment comparisons while minimizing bias. Randomization ensures equal distribution of patient characteristics between groups, allowing differences in symptom resolution to be attributed to the intervention (irrigation vs drops) itself.

PICO search terms:

P	I	C	O
Adult	<u>Cerumenolytic drops</u>	Irrigation	Symptom resolution
Adult patients	Ear drops	Ear irrigation	Symptom relief
Cerumen			Fast symptom relief
Cerumen impaction			
Ear wax			
Ear discomfort			
Ear pain			

Search tools and strategy used:

Please indicate what data bases/tools you used, provide a list of the terms you searched together in each tool, and how many articles were returned using those terms and filters. Explain how you narrow your choices to the few selected articles.

Results found:

PubMed

Cerumen AND Irrigation OR Ear drops: 1,687 results

- Filters: 10 years, RCT, systematic review, meta analysis: 108 results

Cerumen AND Ear pain AND Irrigation OR Cerumenolytic drops: 24 results

- Filters: 10 years, RCT, systematic review, meta analysis: 2 results

Ear wax AND Irrigation OR Ear drops AND Symptom relief: 36 results

- Filters: 10 years, RCT, systematic review, meta analysis: 6 results

Google scholar

Irrigation vs ear drops for cerumen impaction

- Filters: since 2022, sort by relevance, reviewed articles: 11 results

Irrigation vs cerumenolytic drops in adult patients with cerumen: 39 results

- Filters: since 2022: 2 results

Symptomatic relief in patients with cerumen impaction with irrigation vs ear drops: 59 results

- Filters: since 2022, sort by relevance, reviewed articles: 5 results

Fast symptomatic relief in patients with cerumen impaction with irrigation vs ear drops: 245 results

- Filters: any time, sort by relevance, reviewed articles: 43 results

Identify at least 3 articles (or other appropriate reputable sources) that answer your specific question with the highest available level of evidence (you will probably need to look at more than 3 articles to get the 3 most focused and highest level articles to address your question). Please make sure that they are Medline indexed.

Please post the citation and abstract for each article (to include the journal and authors' names and date) and say why you chose it. Please also note what kind of article it is (e.g. meta-analysis, cohort study, or independent blind comparison with gold standard of diagnosis, etc.). At the bottom of each abstract, please comment on what your key points are from this article (including any points or concepts included in the article, but not present in the abstract – i.e. make the concepts understandable to the reader). Please note that if the evidence is not in the abstract, you must clearly summarize the evidence in your posting.

Citation: Clegg, A. J., Loveman, E., Gospodarevskaya, E., Harris, P., Bird, A., Bryant, J., Scott, D. A., Davidson, P., Little, P., & Coppin, R. (2010). The safety and effectiveness of different methods of earwax removal: A systematic review and economic evaluation. *Health Technology Assessment*, 14(28), 1–192. <https://doi.org/10.3310/hta14280>

Type of article: Systematic review and economic evaluation

Background: Build-up of earwax is a common reason for attendance in primary care. Current practice for earwax removal generally involves the use of a softening agent, followed by irrigation of the ear if required. However, the safety and benefits of the different methods of removal are not known for certain.

Objectives: To conduct evidence synthesis of the clinical effectiveness and cost-effectiveness of the interventions currently available for softening and/or removing earwax and any adverse events (AEs) associated with the interventions.

Methods: Two reviewers screened titles and abstracts for eligibility. Inclusion criteria were applied to the full text or retrieved papers and data were extracted by two reviewers using data extraction forms developed a priori. Any differences were resolved by discussion or by a third reviewer. Study criteria included: interventions - all methods of earwax removal available and combinations of these methods; participants - adults/children presenting requiring earwax removal; outcomes - measures of hearing, adequacy of clearance of wax, quality of life, time to recurrence or further treatment, AEs and measures of cost-effectiveness; design - randomised controlled trials (RCTs) and controlled clinical trials (CCTs) for clinical effectiveness, cohort studies for AEs and cost-effectiveness, and costing studies for cost-effectiveness. For the economic evaluation, a deterministic decision tree model was developed to evaluate three options: (1) the use of softeners followed by irrigation in primary care; (2) softeners followed by self-irrigation; and (3) a 'no treatment' option. Outcomes were assessed in terms of benefits to patients and costs incurred, with costs presented by exploratory cost-utility analysis.

Results: Twenty-six clinical trials conducted in primary care (14 studies), secondary care (8 studies) or

other care settings (4 studies), met the inclusion criteria for the review - 22 RCTs and 4 CCTs. The range of interventions included 16 different softeners, with or without irrigation, and in various different comparisons. Participants, outcomes, timing of intervention, follow-up and methodological quality varied between studies. On measures of wax clearance Cerumol, sodium bicarbonate, olive oil and water are all more effective than no treatment; triethanolamine polypeptide (TP) is better than olive oil; wet irrigation is better than dry irrigation; sodium bicarbonate drops followed by irrigation by nurse is more effective than sodium bicarbonate drops followed by self-irrigation; softening with TP and self-irrigation is more effective than self-irrigation only; and endoscopic de-waxing is better than microscopic de-waxing. AEs appeared to be minor and of limited extent. Results of the exploratory economic model found that softeners followed by self-irrigation were more likely to be cost-effective [24,433 pounds per quality-adjusted life-year (QALY)] than softeners followed by irrigation at primary care (32,130 pounds per QALY) when compared with no treatment. Comparison of the two active treatments showed that the additional gain associated with softeners followed by irrigation at primary care over softeners followed by self-irrigation was at a cost of 340,000 pounds per QALY. When compared over a lifetime horizon to the 'no treatment' option, the ICERs for softeners followed by self-irrigation and of softeners followed by irrigation at primary care were 24,450 pounds per QALY and 32,136 pounds per QALY, respectively.

Conclusions: Although softeners are effective, which specific softeners are most effective remains uncertain. Evidence on the effectiveness of methods of irrigation or mechanical removal was equivocal. Further research is required to improve the evidence base, such as a RCT incorporating an economic evaluation to assess the different ways of providing the service, the effectiveness of the different methods of removal and the acceptability of the different approaches to patients and practitioners.

Key points:

- Cerumenolytic agents are more effective than no treatment, and no single cerumenolytic was consistently superior to others
- Wet irrigation is more effective than dry irrigation
- Cerumenolytic + irrigation is generally more effective than irrigation alone

I chose this article because it is a systematic review with economic evaluation, which represents a higher level of evidence compared to individual RCTs. Using a systemic review that synthesizes data from multiple trials provides reliable evidence to support conclusions about whether cerumenolytics, irrigation alone, or combination therapy is most effective, which is very relevant to my PICO question. Further, the study specifically examines whether cerumenolytics improve effectiveness compared to irrigation alone and whether combining the two leads to better outcomes, including symptom relief.

Citation: Michaudet, C., & Malaty, J. (2018, October 15). Cerumen impaction: Diagnosis and management. *American Family Physician*, 98(8), 525–529. <https://www.aafp.org/pubs/afp/issues/2018/1015/p525.html>

Type of article: Evidence based review article

Abstract: Cerumen is a normal protective secretion in the ear canal that may accumulate and become impacted, leading to symptoms such as hearing loss, itching, or pain). The article reviews indications, diagnosis, treatment options such as cerumenolytic agents and irrigation, and contraindicated methods. It also discusses patient factors that modify management decisions.

Methods & Materials: Authors performed a narrative clinical review drawing from a PubMed search using terms such as “cerumen,” “cerumen impaction,” “earwax” and “earwax removal.” They included meta-analyses, RCTs, clinical trials, and clinical reviews from major evidence databases and systematic review sources.

Results: Cerumen impaction should be treated when it causes symptoms. Effective treatments include cerumenolytic agents, irrigation with or without cerumenolytic pretreatment), and manual removal. There is no strong evidence that shows superiority of one approach over another. Cotton swabs should be avoided due to potential harm.

Conclusion: Multiple treatment options are effective for cerumen disimpaction, and no single method is clearly superior. Treatment should be chosen based on patient factors, contraindications, and available resources. Clinicians should assess after the first removal attempt, and refer if multiple attempts fail or if symptoms persist after clearing impaction.

Key points:

- Cerumen impaction is common, especially in adult patients
- Diagnosis requires otoscopic visualization of ear wax causing symptoms or interfering with assessment
- Many treatment options such as cerumenolytics, irrigation, and manual removal are effective in cerumen removal and evidence doesn't strongly favor one over the other
- Self treatments such as cotton swabs should be avoided
- Benefits of home irrigation with drops vs clinician irrigation are similar in adults when they are properly instructed, although limited evidence

I chose this article because it directly addresses management options for cerumen impaction, including the main two included in my PICO question: cerumenolytic drops and irrigation. Although the article is an evidence based review rather than a RCT, meta analysis or systematic review, it synthesizes evidence from multiple RCTs and systematic reviews, providing a broad overview of current best practices in primary care. Based on the results of this review, my PICO question is addressed in that neither ear irrigation nor cerumenolytic drops are shown to be superior to one another, suggesting that both treatment modalities are effective for managing impaction.

Citation: Meyer F, Preuß R, Angelow A, Chenot J-F, Meyer E, Kiel S. Cerumen Impaction Removal in General Practices: A Comparison of Approved Standard Products. *Journal of Primary Care & Community Health*. DOI: 10.1177/2150132720973829. <https://journals.sagepub.com/doi/full/10.1177/2150132720973829>

Type of article: Observational Study

Abstract:

Background: Ear irrigation is a commonly used method for removing earwax in general practice. There is no firm evidence if no pre-treatment is as good as pre-treatment with various standard preparations.

Aim: To assess the effectiveness of no pre-treatment compared to pre-treatment with commercially available cerumenolytics and to assess which preparation is best suited for pre-treatment.

Methods: This is a pragmatic observational study of patients with cerumen treated from a single GP with 3 different preparations or no preparation prior to standardized ear irrigation. Generalized linear mixed models with logit link function were performed to assess the effectiveness of pre-treatment with different preparations and no pre-treatment. The models were adjusted for age group (<70, ≥70) and sex.

Results: A total of 168 patients (298 ears, 58 % female, median age 65years) consulted for obstructive cerumen, some of them several times. The cerumen was successfully removed in 70% (208/298). Comparing any preparation to no preparation (aggregated comparison), the odds ratio for complete clearance was 1.35 (95%confidence interval: 0.69-2.65). Comparing the preparations individually, the

odds ratio of the docusate-sodium-based preparation was 1.87 (95% CI: 0.79-4.42) indicating a higher effectiveness. Although, not statistically significant. Ear irrigation was less successful for patients aged ≥ 70 years (OR=0.48, 95% CI: 0.23-0.98).

Conclusions: The aggregated comparison indicates a slight trend toward a higher effectiveness of any pre-treatment compared to no pre-treatment. The effect-size of docusate-sodium-based pre-treatment indicates a higher effectiveness of cerumen impaction removal. Nevertheless, superiority could not be shown conclusively according to the statistical significance given the restricted sample size.

Key points:

- Pre-treatment with cerumenolytics may improve the effectiveness of irrigation compared with none, but this study did not show statistically significant benefit.
- Docusate sodium had the highest effect size estimate among agents tested, but not statistically significant
- Age ≥ 70 was shown to negatively influence the success of irrigation
- Results are limited by sample size and the observational (non-randomized) study

I chose this study because it directly evaluated the added value of cerumenolytic agents before irrigation, fitting my PICO question. Although the study wasn't randomized and didn't measure symptom resolution specifically, it focused on procedural success of cerumen removal with pre-treatment of cerumenolytics vs no pre-treatment. This provided foundational evidence for the effectiveness of cerumenolytics in clinical practice, which was a key component of the "Intervention vs Comparison" portion of my question.

What is the clinical "bottom line" derived from these articles in answer to your question?

Based on the three articles I included, there is no strong, high-quality evidence demonstrating that cerumenolytic drops alone are superior to irrigation alone in achieving faster or more complete symptom resolution in adults with cerumen impaction. Cerumenolytics are more effective than no treatment and may facilitate wax softening and removal. Irrigation is also an effective method of cerumen clearance. Some evidence shows that combination therapy (cerumenolytic drops followed by irrigation) may improve success rates in removing earwax compared to irrigation alone, although no single method has been shown to be superior in regard to overall clinical outcomes or symptom relief. Although my PICO's "Outcome" included symptom resolution, the studies focused primarily on cerumen clearance rather than patient reported symptom relief. Overall, either method of cerumen removal (irrigation or cerumenolytics) are reasonable first line options, and treatment choice should be guided by patient factors, safety considerations, and clinical setting.