



## **CERUMENOLYTIC AGENTS FOR CERUMEN IMPACTION TREATMENT: A SCOPING REVIEW**

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### **ABSTRACT**

**Background:** Cerumen impaction is a common condition all over the world. It is observed in around 5% of adults and has a higher prevalence in children, the elderly, and people with intellectual impairment. The management of cerumen impaction must be treated by general practitioners regarding insurance policies in Indonesia. Besides cerumen removal, in difficult cases for cerumen extraction, we can use cerumenolytic agents. **Objective:** This scoping review is to identify the current data on cerumenolytic drugs, emphasizing their effectiveness, safety profiles, and optimal treatment practices. **Methods:** Electronic databases were searched for medicinal treatment of cerumen impaction. The search technique entailed querying three esteemed databases—PubMed, SCOPUS, and ScienceDirect—utilizing the following search terms: (cerumen impaction) OR (cerumen prop)) OR (cerumen obturans)) OR (earwax) AND (cerumenolytic agent). **Results:** Ex vivo and in vitro studies demonstrated that carbamide peroxide had significantly more rapid cerumen degradation than phenol glycerol, distilled water was superior to commercial agents, and sodium bicarbonate surpassed docusate sodium and potassium hydroxide had the quickest disintegration among the agents studied. In vivo, investigations validated these patterns, with glycerin-hydrogen peroxide attaining the highest rates of tympanic membrane visualization and sodium bicarbonate demonstrating comparable efficacy to docusate sodium. **Conclusion:** Sodium bicarbonate was the most evaluated cerumenolytic agent, followed by docusate sodium and distilled water. There was no significant difference in weight growth or disintegration between sodium bicarbonate and docusate sodium, while wet cerumen exhibited a more rapid response than dry cerumen.

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### **BACKGROUND**

Cerumen, a combination of sebum and altered secretions from apocrine sweat glands, performs many defensive activities. It possesses antibacterial qualities that inhibit bacterial infiltration into the external ear canal's skin and serves as a barrier against foreign items or tiny animals entering the ear<sup>1</sup>. Under typical circumstances, cerumen does not build excessively in the ear canal due to the ear's self-cleaning process. This process is enabled by the inherent motions of the jaw during chewing or talking, along with the directed development of the skin in the ear canal, which collectively sustains a balanced level of cerumen<sup>2</sup>. During this process,

cerumen, together with desquamated epithelial cells and other detritus, is progressively conveyed outside and eliminated from the ear canal, maintaining its cleanliness and functioning.

Risk factors for cerumen impaction can be classified into non-avoidable and preventable categories. Non-preventable causes encompass structural characteristics such as constricted ear canals, increased cerumen production, aging, and cognitive impairments. Preventable risk factors frequently entail the inappropriate utilization of ear cleaning instruments, such as cotton swabs, which can unintentionally displace earwax farther into the ear canal, hence exacerbating the impaction. Symptoms



of cerumen impaction typically encompass a sense of ear fullness, otalgia, pruritus, imbalance, coughing, and diminished auditory acuity. Cerumen impaction is a prevalent auditory issue seen by general practitioners<sup>3</sup>. Nationally representative research in the United States indicated that 18.6% of those aged 12 and older and 32.4% of those aged 70 and older reported cerumen impaction<sup>4</sup>. These data highlight the considerable prevalence of cerumen impaction.

The management of prevalent cerumen impactions often entails a blend of mechanical, chemical, and irrigation techniques according to the patient's condition and preferences. Irrigation is a commonly employed method that entails flushing the ear canal with a warm solution to remove softened cerumen. This technique is readily available to general practitioners and emergency departments; nonetheless, it has hazards such as otitis externa or tympanic membrane injury if executed improperly<sup>5</sup>. For enhanced safety and precision in removal, manual extraction employs devices like curettes or suction under direct view (e.g., otoscopy). This method is especially advantageous for individuals with a history of ear surgery or tympanic membrane perforation since it reduces the risk of trauma<sup>6</sup>. When cerumen is too solidified, cerumenolytic drugs are frequently employed to soften the wax, therefore aiding in its removal. These medicines may also serve as an independent therapy to efficiently address cerumen impaction.

This scoping review aimed to map the existing evidence on cerumenolytics, considering the variability in study designs (e.g., differing methodologies, outcome measures, and populations), the lack of randomized controlled trials (RCTs), and the absence of consistent data amenable to meta-analysis. This review synthesizes existing literature to identify knowledge gaps and guide future research goals, including efficacy, safety, and clinical best practices.

## **METHODS**

### **Protocol**

This scoping review employs the exploratory methodological framework established by Arksey and O'Malley<sup>7</sup>, which is effective for mapping emerging evidence and detecting gaps in diverse literature. The research adhered to a five-step methodology: 1. defining the research question using

the Population-Concept-Context (PCC) framework (Population: individuals with cerumen impaction; Concept: application of cerumenolytic agents; Context: clinical and laboratory environments, encompassing in vitro, in vivo, and ex vivo investigations); 2. identifying relevant studies through systematic searches; 3. selecting eligible papers; 4. organizing data into structured tables; and 5. summarizing and reporting findings. A formal risk of bias assessment was not performed, as this is consistent with the exploratory intent of a scoping review, which seeks to delineate the extent of evidence rather than evaluate the quality of individual studies. The PRISMA Extension for Scoping Reviews (PRISMA-ScR) was utilized to guarantee methodological rigor and openness<sup>8</sup>. This method enabled a comprehensive synthesis of data while accepting diversity in study designs, results, and contexts—crucial factors due to the absence of standardized protocols in cerumenolytic research.

### **Search Strategy**

The search technique entailed querying three esteemed databases—PubMed, SCOPUS, and ScienceDirect—utilizing the following search terms: (cerumen impaction) OR (cerumen prop) OR (cerumen obturans) OR (earwax)) AND (cerumenolytic agent). This technique was created to encompass all pertinent publications on cerumenolytic research. A standardized search methodology was consistently employed across all databases to guarantee comprehensiveness and consistency.

### **Eligibility Criteria**

The inclusion criteria for this review are as follows: Studies were removed based on title if they were duplicates in other databases, not available in English, or did not mention cerumenolytic agents. Additionally, papers were removed based on abstract if they were not completely available or not published in full. Further exclusions during the full-text review phase were publications with duplicate data, studies published more than 10 years ago, and those limited to review or meta-analysis designs. This methodology guaranteed that the review concentrated on relevant, high-quality, and up-to-date literature.



## RESULTS

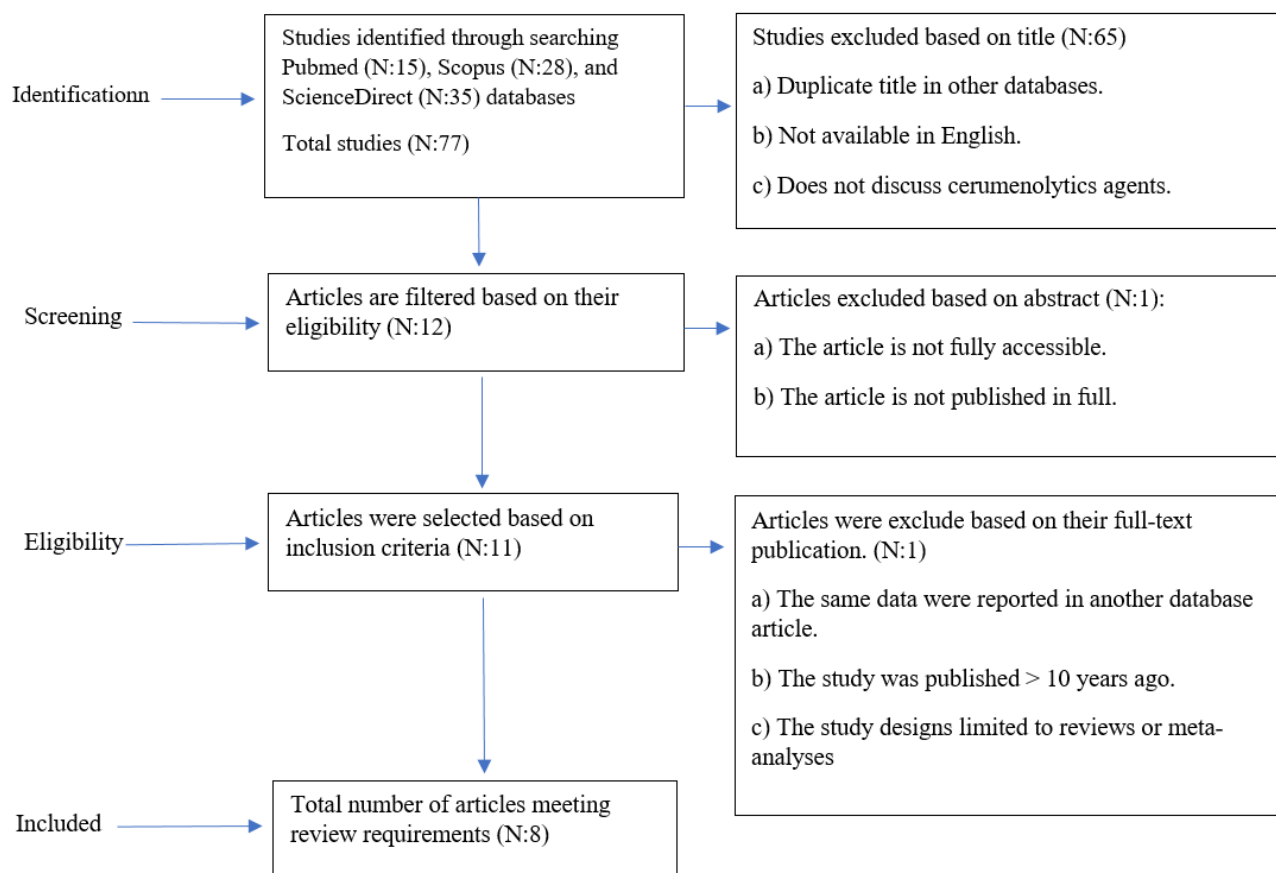
### Search results

The search technique entailed querying three esteemed databases—PubMed, SCOPUS, and ScienceDirect—utilizing the following search terms: (cerumen impaction) OR (cerumen prop) OR (cerumen obturans) OR (earwax)) AND (cerumenolytic agent). The literature search was conducted on February 11, 2025. This technique was created to encompass all relevant publications on cerumenolytic research. A standardized search methodology was consistently employed across all databases to guarantee comprehensiveness and consistency (Fig 1).

### Study characteristic

The studies reviewed comprised diverse research methodologies, including ex vivo experiments ( $n = 2$ )<sup>9,10</sup>, in vitro investigations ( $n = 4$ )<sup>11-14</sup>, and in vivo clinical trials ( $n = 3$ )<sup>9,15,16</sup>.

Study settings are varied from laboratory-based research to clinical contexts. A cumulative total of 1,518 people were included in the research, with sample sizes ranging from 12 to 1,243 persons. The average age of participants ranged from 3 to 91 years, including both pediatric Soy et al. (2015) and adult demographics. Gender distribution was documented in 5 of 8 investigations, with females constituting 55.8% ( $n = 732$ ) of participants, while males comprised 44.2% ( $n = 580$ ). Fullington et al. (2017) observed a male preponderance of 79%, but other research exhibited more balanced or female-majority cohorts.



**Figure 1.** PRISMA flow chart. Eight studies were included in this systematic review



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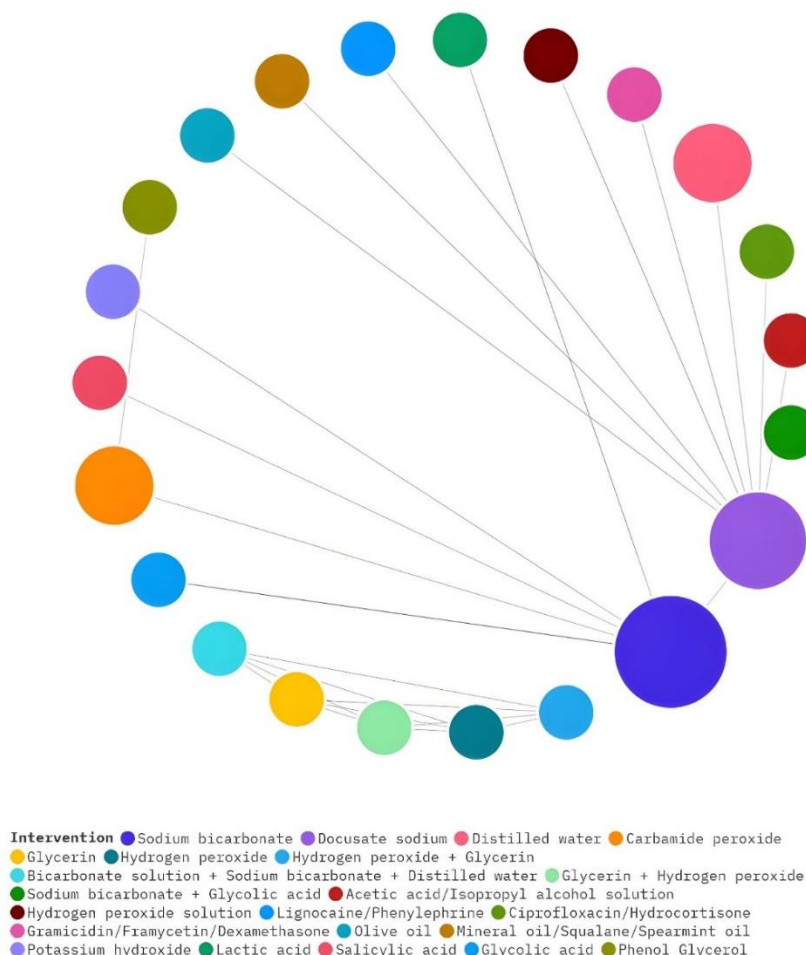
### Primary outcome

Eight studies were included in the assessment of wax removal after the use of cerumenolytic drugs. Sodium bicarbonate (n = 4) was the most commonly evaluated cerumenolytic agent, followed by docusate sodium (n = 3) and distilled water (n = 2) (Fig 2).

The analyzed studies showed clear variations in cerumenolytic effectiveness among experimental models (Table 1). Ex vivo studies demonstrated that carbamide peroxide (CP) facilitated significantly more rapid cerumen degradation (total degradation within 40 minutes) than phenol glycerol, which resulted in only moderate degradation<sup>9</sup>. Additionally, distilled water surpassed commercial agents (e.g.,

Waxsol®) in effectiveness for softening and dissolving cerumen ( $p < 0.05$ ).

Tynan, 2020. In vitro investigations repeatedly demonstrated sodium bicarbonate's efficacy, with Srisukhumchai et al, 2020 showing enhanced turbidity and cholesterol dissolution compared to docusate sodium, while Anh, 2022 observed potassium hydroxide's quick action, achieving considerable disintegration within 2 hours. Chongkolwatana et al, 2025 observed no significant difference in weight growth or disintegration between sodium bicarbonate and docusate sodium, while wet cerumen exhibited a more rapid response than dry cerumen ( $p < 0.001$ ).



**Fig 2.** Network graph for the primary outcome: Circles represent each of the cerumenolytics, and the sizes of circles indicate the total numbers of included studies evaluating the respective cerumenolytic



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**Table 1.** Summary of articles included in review

| Author (Year)             | Country       | Intervention  | Population/ Model  | Study Design  | Results  | Outcome Assessed  |
|---------------------------|---------------|---|--|---|--|---|
| Soy et al, 2015           | Not specified | Group 1 (40 cc glycerin), group 2 (40 cc 3% hydrogen peroxide) group 3 (20 cc 3% hydrogen peroxide + 20 cc glycerin) group 4 (10% bicarbonate solution - 4 g bicarbonate + 40 cc distilled water), and group 5 (10 cc glycerin + 10 cc 3% hydrogen peroxide). | In vivo: 1.243 pediatric patients (3–16 yrs)<br>In vitro: cerumen from 20 patients | Single-center, prospective, double-blind (in vivo + in vitro) | In in vitro study, no group attained complete dissolution within the first 24 hours. Complete resolution was seen in group 1 and group 3 at hour 72, in group 2 and group 5 at hour 48, in group 4 at hour 72, and in the control group at hour 120. In in vivo study, Total visualization of the tympanic membrane was greatest in group 5 (73.5%) on day 3, succeeded by group 3 (62.3%), group 2 (57.1%), Group 1 (50.2%), and group 4 (44.3%). At 96 hours, group 5 attained the greatest removal rate of 76%, and by 120 hours, 92.1% of patients in group 5 had their cerumen plugs entirely eliminated. | TM visualization, removal coefficient, pain (ACCS scale)<br>In vitro dissolution over 5 days period |
| Fullington et al, 2017    | Not specified | Novel dual-action cerumenolytic solutions (bicarbonate + glycolic acid)   | 30 ears from 19 adults (mean age 64.8 yrs)   | Prospective single-arm clinical trial (In vivo)               | This study indicates that dual-action cerumenolytic solutions are exceptionally successful in dissolving cerumen, particularly when used in conjunction with irrigation, and are especially appropriate for moderate to severe impaction.  | Clearance rate, TM visibility, adverse events, patient satisfaction                                 |
| Piromchai et al, 2020     | Not specified | Sodium bicarbonate versus docusate sodium   | 91 adults (18–85 yrs)  | Randomized Controlled Trial (In vivo)                         | Both treatments were efficacious and well tolerated, with sodium bicarbonate exhibiting a somewhat greater success rate and reduced suction time, however this difference lacked statistical significance.   | TM visibility, cleaning time, adverse effects   |
| Srisukhumchai et al, 2020 | Thailand      | Docusate sodium versus 2.5% sodium bicarbonate  | 18 gr pooled cerumen (36 aliquots) from ENT clinic patients                        | In vitro experimental study                                   | 2.5% sodium bicarbonate has a higher cerumenolytic effect than docusate sodium.  | Optical absorbance (350nm, 400nm), cholesterol levels,  |
| Tynan et al, 2020         | Australia     | Water-based, Oil-based, and Non-water/non-oil-based   | Cerumen from 12 ENT clinic patients  | Prospective ex vivo study                                     | Water-based agents were found to be the most effective. Oil-based cerumenolytics commonly used in the outpatient setting were found to be ineffective. Distilled water was the most effective agent across most consistencies, raising questions about the worth of expensive cerumenolytic products.  | Dissolving/softening indices for different cerumen consistencies                                    |





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|-----------------------------|----------|--|--|--|---|--|
| Anh et al, 2022             | Thailand | 7.5% sodium bicarbonate, 5% potassium hydroxide, 10% lactic acid, 3% salicylic acid, 10% glycolic acid, and distilled water. | 36 untreated dry impacted cerumen samples                            | In vitro study                         | Potassium hydroxide showed the fastest cerumenolytic activity, dissolving a moderate amount of cerumen at 30 minutes, while glycolic acid and salicylic acid caused no visible changes in the cerumen samples. Samples treated with potassium hydroxide and sodium bicarbonate exhibited higher degrees of disintegration compared to samples treated with distilled water (odds ratio and 95% CI: 273.237 [0.203-367 470.4] and 1.129 [0.002-850.341], respectively). The greatest reduction in cerumen weight was associated with the use of sodium bicarbonate; however, this result did not reach statistical significance. | Dissolution degree over time, undissolved weight at 12 hours |
| Chongkol watana et al, 2025 | Thailand | 2.5% sodium bicarbonate versus 0.5% sodium docusate  | Cerumen from otolaryngology clinic patients (>18 yrs; wet/dry types) | In vitro study                         | Both treatments had comparable disintegration effects, with no significant differences seen at any time period ( $p = 0.749$ ). Subgroup analysis indicated no significant differences for wet ( $p = 0.584$ ) or dry ( $p = 0.076$ ) cerumen. Wet cerumen exhibited markedly higher breakdown than dry cerumen at both 15 and 60 minutes ( $p < 0.001$ ). The study concluded that 2.5% sodium bicarbonate and 0.5% sodium docusate exhibited equivalent efficacy in augmenting cerumen weight and facilitating disintegration, with wet cerumen demonstrating a more expedited response to treatment compared to dry cerumen. | Weight gain, disintegration (15 min to 24 hours)             |
| Asgari et al, 2024          | Iran     | Phenol glycerol 6.4% (PG) versus carbamide peroxide 6.5% (CP)  | In vivo: 29 patients (9–78 yrs)<br>Ex vivo: 30 cerumen samples       | Ex vivo and in vivo experimental study | Ex vivo studies indicated (CP) higher effectiveness, exhibiting instantaneous cerumen breakdown (grade 1) upon contact and complete dissolution (grade 4) after 40 minutes, whereas (PG) necessitated 20 minutes to commence degradation (grade 1) and achieved only partial dissolution (grade 2) in the same duration. Clinically, ears treated with CP exhibited a quicker average removal time ( $54.1 \pm 31.77$ sec) in comparison to PG ( $67.1 \pm 35.54$ sec), however this difference lacked statistical significance.  | Cerumen degradation, removal time                            |



In vivo, results mirrored some laboratory findings while emphasizing clinical subtleties. Soy et al, 2015 noted that the combination of glycerin and hydrogen peroxide (Group 5) attained the greatest tympanic membrane visibility rate (73.5% by Day 3) and nearly complete removal (92.1% by 120 hours), consistent with its quick in vitro breakdown. Likewise, Piromchai et al, 2020 documented elevated but non-significant success rates for sodium bicarbonate (91.11%) compared to docusate sodium (82.61%). Fullington et al, 2017 revealed that dual-action glycolic acid formulations resulted in a total of 53% dissolved following irrigation, highlighting the synergy between chemical and mechanical techniques

Study settings are varied from laboratory-based research to clinical contexts. A cumulative total of 1,518 people were included in the research, with sample sizes ranging from 12 to 1,243 persons. The average age of participants ranged from 3 to 91 years, including both pediatric Soy et al. (2015) and adult demographics. Gender distribution was documented in 5 of 8 investigations, with females constituting 55.8% (n = 732) of participants, while males comprised 44.2% (n = 580). Fullington et al. (2017) observed a male preponderance of 79%, but other research exhibited more balanced or female-majority cohorts.

### **Categorization of Interventions and Assessed Outcomes**

The reviewed studies demonstrated comprehensive methodologies for classifying therapies and evaluating effects in cerumenolytic research. Interventions were predominantly categorized by chemical composition, with water-based agents (sodium bicarbonate, hydrogen peroxide) receiving the most extensive examination<sup>11,14</sup>, succeeded by oil-based agents (olive oil) and non-water/non-oil agents (carbamide peroxide)<sup>10</sup>. Dual-component formulations, such as glycerin-hydrogen peroxide combinations, exhibited enhanced clinical efficacy<sup>14</sup>, whilst innovative glycolic acid-based treatments revealed encouraging outcomes<sup>15</sup>.

Measures of outcome show considerable variation between experimental and clinical investigations. In vitro studies mainly utilized quantitative measures such as spectrophotometric

absorbance<sup>11</sup>, variations in cerumen weight<sup>13</sup>, and dissolution grading scales<sup>9</sup>. The laboratory assessments demonstrated the enhanced cerumenolytic efficacy of sodium bicarbonate, evidenced by increased turbidity<sup>11</sup> and expedited grade 4 degradation<sup>9</sup>. Clinical trials highlighted patient-centered outcomes, including tympanic membrane visualization rates<sup>14,16</sup>, and therapy duration<sup>9</sup>. Notably, carbamide peroxide exhibited markedly accelerated ex vivo degradation (complete dissolution in 40 minutes compared to phenol glycerol's partial dissolution after 72 hours)<sup>9</sup>, yet its clinical benefit in removal time (54.1 seconds versus 67.1 seconds) did not reach statistical significance, underscoring the intricate translation of laboratory results to clinical application.

### **Mechanism of Action**

Cerumenolytic agents are topical formulations intended to aid in the extraction of impacted cerumen by modifying its physical characteristics. Their mode of action involves softening, fragmenting, or dissolving cerumen, therefore facilitating its spontaneous evacuation or simplifying physical extraction. Aqueous solutions (e.g., saline, hydrogen peroxide) rehydrate the dehydrated keratin and lipid constituents, hence reducing viscosity and rigidity<sup>17</sup>. Chemical disruptors such as carbamide peroxide break down into hydrogen peroxide and urea, producing oxygen bubbles that mechanically disturb the cerumen matrix and dissolve it<sup>18</sup>. Surfactants like docusate sodium emulsify lipids, whereas oil-based compounds (e.g., olive oil) lubricate and soften cerumen, facilitating its natural evacuation<sup>19</sup>. Effervescent responses facilitate the displacement of cerumen by mild pressure, aiding physiological clearance systems<sup>18</sup>.

### **Efficacy**

The investigations presented showed comparable effectiveness results across ex vivo, in vitro, and in vivo models, but with significant variation between experimental and clinical outcomes. In ex vivo and in vitro experiments, carbamide peroxide (CP) showed enhanced cerumenolytic efficacy, attaining total breakdown (Grade 4) after 40 minutes. In contrast, phenol glycerol (PG) achieved only moderate degradation (Grade 2) in the same duration<sup>9</sup>. Sodium bicarbonate surpassed docusate sodium in



spectrophotometric evaluations ( $p < 0.001$ ) and cholesterol solubilization<sup>11</sup>, although potassium hydroxide demonstrated the quickest disintegration (30 minutes) among the agents studied<sup>12</sup>. In vivo, investigations validated these patterns, with glycerin-hydrogen peroxide mixtures attaining the highest rates of tympanic membrane visualization (73.5% by Day 3, 92.1% by Day 5)<sup>14</sup> and sodium bicarbonate demonstrating comparable efficacy to docusate sodium (success rates: 91.11% vs. 82.61%,  $p = 0.23$ )<sup>16</sup>.

### Adverse Effect

Four in vivo studies documented adverse effects, with just two detailing specific occurrences<sup>15,16</sup>. Piromchai et al, 2020 reported no significant side effects associated with either 2.5% sodium bicarbonate or docusate sodium; nevertheless, one instance of minor ear irritation (2/10 on VAS) was recorded in the sodium bicarbonate cohort. Likewise, Fullington et al, 2017 documented few side effects, noting a singular occurrence of moderate ear pruritus linked to their innovative glycolic acid-based formulation. The remaining studies either failed to observe adverse effects<sup>9</sup> or did not specifically document them<sup>14</sup>. No significant problems (e.g., otitis externa) were reported in the investigations, indicating the overall safety of cerumenolytic medicines when utilized as instructed. The scant reporting of patient-centered outcomes, specifically pain reduction (0/4 studies) and quality-of-life enhancements (0/4 studies), underscores a significant evidence deficiency.

## DISCUSSION

### Summary

Our review indicates considerable discrepancies in the efficacy of different cerumenolytic drugs. The glycerin-hydrogen peroxide combination exhibited enhanced clinical efficacy, attaining 73.5% tympanic membrane visualization by Day 3 and complete cerumen removal in 92.1% of patients by 120 hours, thereby establishing it as the most effective dual-action remedy for moderate to severe impactions. In comparison investigations, 2.5% sodium bicarbonate showed consistently superior cerumenolytic effects compared to docusate sodium; nevertheless, this difference did not achieve statistical significance ( $p = 0.749$ ). Sodium bicarbonate significantly decreased

cerumen weight and demonstrated improved disintegration relative to distilled water (OR: 1.129 [0.002-850.341]). Water-based agents consistently surpassed oil-based alternatives, with distilled water being identified as one of the most efficacious agents in many trials, undermining the cost-benefit justification for costly proprietary goods. Potassium hydroxide had the most rapid commencement of action in vitro, attaining considerable dissolution within 30 minutes, but glycolic and salicylic acids displayed minimal activity. Ex vivo testing showed that carbamide peroxide (CP) outperformed phenol glycerol (PG), attaining instantaneous Grade 1 degradation and total dissolution (Grade 4) after 40 minutes. In contrast, PG exhibited only partial degradation (Grade 2) in the same period.

### Clinical and Practical Implications

The management of cerumen impaction necessitates a comprehensive approach that prioritizes efficacy, safety, and accessibility, especially in environments with limited access to ENT experts, such as Indonesia. General practitioners, typically without specific expertise in manual cerumen extraction, may improve their practice by integrating cerumenolytic drugs. These agents, predominantly aqueous (e.g., sodium bicarbonate, hydrogen peroxide) or lipid-based (e.g., olive oil, glycerin) solutions, dissolve earwax, hence simplifying removal and may diminish the necessity for invasive methods such as manual extraction or irrigation. Research indicates that cerumenolytics may be equally successful as mechanical techniques while also reducing the risk of damage to the ear canal, a frequent consequence of poor ear cleaning<sup>17,20</sup>.

Manual extraction (via suction or curettage) and irrigation are the most established therapies, especially for severe impactions; nevertheless, their efficacy is significantly contingent upon the clinician's expertise. Studies demonstrate that irrigation and manual extraction produce similar outcomes for cerumen removal and patient comfort<sup>21</sup>. Cerumenolytics provide a less skill-dependent option, rendering them especially beneficial in primary care environments lacking ENT expertise. For example, dual-action compounds (e.g., glycerin and hydrogen peroxide) have shown enhanced effectiveness,





achieving total cerumen breakdown in more than 90% of instances when used with irrigation<sup>15</sup>.

### Age Analysis

Cerumen impaction exhibits a distinct age-dependent epidemiology and necessitates age-specific therapeutic strategies. The problem impacts around 10% of children<sup>22</sup>, 5% of healthy people<sup>23</sup>, and significantly increases to 57-60% among elderly persons, especially in institutional care environments<sup>15,24</sup>. Pediatric cases derive significant advantages from water-based cerumenolytics such as sodium bicarbonate or hydrogen peroxide solutions, which attain clearance rates exceeding 90% while reducing discomfort, owing to the naturally softer cerumen and narrower ear canals in children<sup>15,25</sup>.

In the general adult population, dual-action water-based solutions (e.g., sodium bicarbonate with hydrogen peroxide) show superior efficacy with 73-92% success rates<sup>15</sup>. However, elderly patients present unique challenges due to age-related physiological changes, including atrophied cerumen glands, coarser ear canal hair, and impaired natural clearance mechanisms<sup>3,26</sup>, often resulting in drier, harder wax that may initially require oil-based softeners before gentle removal<sup>27</sup>. The high prevalence among nursing home residents (up to 60%) and individuals with intellectual disabilities (19-36%)<sup>26</sup> underscores the need for tailored protocols that account for reduced self-care capacity and increased vulnerability to complications.

Optimal management must, therefore, consider not just the chemical properties of cerumenolytics but also age-specific anatomical variations, cerumen consistency, and individual patient capabilities to ensure safe and effective treatment across all age groups<sup>3,23</sup>. These findings highlight the importance of developing evidence-based, age-stratified clinical guidelines for cerumen management in primary care settings.

### Strengths and limitations

This review offers significant insights into the effectiveness and safety of several cerumenolytic drugs via a systematic examination of existing literature. The incorporation of various study designs (ex vivo, in vitro, and in vivo) enhances the generalizability of results. In contrast, the study with a direct comparison of agents (e.g., sodium

bicarbonate versus docusate sodium) facilitates clinically pertinent conclusions. The assessment also emphasizes significant developments, including the enhanced performance of water-based agents compared to oil-based alternatives and the effectiveness of dual-action formulations such as glycerin-hydrogen-peroxide.

However, several limitations must be recognized. The exclusion of non-English studies and grey literature may have created linguistic and publishing biases, potentially overlooking crucial data. Secondly, the review failed to examine various quantities of cerumenolytics or durations of administration, which are essential parameters affecting therapy success. The inability to do quantitative meta-analysis hindered statistical data gathering and restricted findings about comparative efficacy. Additional limits encompass considerable variety in study designs, notably changes in research methodologies, outcome measures, and cerumen categorization systems (wet versus dry), which hindered direct comparisons among studies. Numerous prior studies also exhibited a deficiency in uniform reporting (e.g., non-compliance with CONSORT recommendations), hence complicating quality evaluation. These constraints underscore the necessity for more stringent, standardized trials that systematically assess dose methods and treatment durations while including varied demographics and cerumen types.

### CONCLUSION

We summarized cerumenolytics agents to soften impacted cerumen safely and facilitate subsequent removal procedures using glycerin, hydrogen peroxide, sodium bicarbonate, sodium docusate, phenylephrine, distilled water, mineral oil, lactide acid, salicylic acid, and carbamide peroxide. The choice of cerumenolytic agents should consider patient circumstances, individual risks, and potential outcomes, ensuring that the selected approach balances efficacy with safety.

The investigations presented showed comparable effectiveness results across ex vivo, in vitro, and in vivo models, but with significant variation between experimental and clinical outcomes. In ex vivo and in vitro experiments, carbamide peroxide showed enhanced cerumenolytic efficacy than phenol glycerol, sodium bicarbonate surpassed docusate



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sodium, and potassium hydroxide demonstrated the quickest disintegration among the agents studied. In vivo, investigations validated these patterns, with glycerin-hydrogen peroxide mixtures attaining the highest rates of tympanic membrane visualization and sodium bicarbonate demonstrating comparable efficacy to docusate sodium. Nonetheless, further study is required to formulate standardized treatment protocols and to evaluate long-term safety outcomes.

In summary, the current research landscape concerning cerumenolytics reveals crucial gaps, particularly in the areas of comparative effectiveness among agents, the safety of irrigation procedures, and the integration of telemedicine in cerumen management. Addressing these deficits through targeted investigations could significantly enhance clinical practices in managing cerumen impaction effectively and safely.

#### **ETHICAL APPROVAL**

There is no ethical approval.

#### **CONFLICTS OF INTEREST**

There is no conflict of interest related to materials and publication in this study.

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#### **AUTHOR CONTRIBUTIONS**

AHS designing of the study, collecting data and synthesis the article. AW, RF, DD review and editing the article.

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#### **REFERENCES**

1. Schwartz SR, Magit AE, Rosenfeld RM, Ballachanda BB, Hackell JM, Krouse HJ, et al. Clinical Practice Guideline (Update): Earwax (Cerumen Impaction) Executive Summary. *Otolaryngology - Head and Neck Surgery* (United States). 2017 Jan 1;156(1):14–29.
2. Alrajhi MS, Alim BM, Aldokhayel SD, Zeitouni LM, Tawil LK Al, Alzahrani FA. Knowledge, attitudes, and practices pertaining to cotton-bud usages and the complications related to their misuse among outpatients in an ear, nose, and throat clinic. *Journal of Nature and Science of Medicine*. 2019 Oct 1;2(4):220–5.
3. Meyer F, Preuß R, Angelow A, Chenot JF, Meyer E, Kiel S. Cerumen Impaction Removal in General Practices: A Comparison of Approved Standard Products. *J Prim Care Community Health*. 2020;11.
4. Tolan MM, Choi JS, Tibesar MT, Adams ME. Cerumen impaction: Prevalence and associated factors in the United States population. *Laryngoscope Investig Otolaryngol*. 2024 Apr 1;9(2).
5. Michaudet C, Malaty J. Cerumen Impaction: Diagnosis and Management [Internet]. Vol. 98. 2018. Available from: [www.aafp.org/aafp](http://www.aafp.org/aafp)
6. Justin Sevy AO, Hohman MH, Singh Affiliations A. Cerumen Impaction Removal Continuing Education Activity. 2023.
7. Arksey H, O'Malley L. Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology: Theory and Practice*. 2005 Feb;8(1):19–32.
8. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. Vol. 169, *Annals of Internal Medicine*. American College of Physicians; 2018. p. 467–73.
9. Asgari A, Asgari HR, Ghorbanlou M, Dobakhti F, Ghorbanian MA. Cerumenolytic Effects of Carbamide Peroxide in Patients with Ear Wax Obstruction. *Iran J Otorhinolaryngol*. 2024 Mar 1;36(2):415–20.
10. Tynan T, Griffin A, Whitfield BCS. An ex vivo comparison of over-the-counter cerumenolytics for ear wax. Vol. 3, *Australian Journal of Otolaryngology*. AME Publishing Company; 2020.
11. Srisukhumchai C, Kasemsiri P, Rattanaanekchai T, Srirompotong S, Yordpratum U, Sakolsinsiri C. A comparative in vitro study on the cerumenolytic effect of docusate sodium versus 2.5% sodium bicarbonate using UV-visible absorption spectroscopy. *J Otol*. 2020 Sep 1;15(3):99–102.



12. Anh NQ, Numthavaj P, Bhongmakapat T. Comparison of the Cerumenolytic Activities of New and Currently Used Agents. *Ear Nose Throat J*. 2022 Feb 1;101(2):31S-36S.
13. Chongkolwatana C, Sureepong P, Chansomboon K, Kasemsuk N, Srisawat C. In vitro comparison of cerumenolytic efficacy: 2.5 % sodium bicarbonate versus 0.5 % sodium docusate based on cerumen weight gain. *American Journal of Otolaryngology - Head and Neck Medicine and Surgery*. 2025 Mar 1;46(2).
14. Soy FK, Ozbay C, Kulduk E, Dundar R, Yazici H, Sakarya EU. A new approach for cerumenolytic treatment in children: In vivo and in vitro study. *Int J Pediatr Otorhinolaryngol*. 2015 Jul 1;79(7):1096–100.
15. Fullington D, Song J, Gilles A, Guo X, Hua W, Anderson CE, et al. Evaluation of the safety and efficacy of a novel product for the removal of impacted human cerumen. *BMC Ear Nose Throat Disord*. 2017 Jun 2;17(1).
16. Piromchai P, Laohakittikul C, Khunawongkrit S, Srirompotong S. Cerumenolytic Efficacy of 2.5% Sodium Bicarbonate Versus Docusate Sodium: A Randomized, Controlled Trial. *Otology and Neurotology*. 2020 Aug 1;41(7):e842–7.
17. Clegg AJ, Loveman E, Gospodarevskaya E, Harris P, Bird A, Bryant J, et al. The safety and effectiveness of different methods of earwax removal: A systematic review and economic evaluation. *Health Technol Assess (Rockv)*. 2010;14(28).
18. Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, et al. Clinical practice guideline: Cerumen impaction. *Otolaryngology - Head and Neck Surgery*. 2008 Sep;139(3 SUPPL.2).
19. Aaron K, Cooper TE, Warner L, Burton MJ. Ear drops for the removal of ear wax. Vol. 2018, *Cochrane Database of Systematic Reviews*. John Wiley and Sons Ltd; 2018.
20. Ahmed S. Association of Dermatological Conditions of External Ear with the Use of Cotton Buds. *Journal of Enam Medical College*. 2014.
21. Yobel S. Comparison Of The Effectiveness Of Irrigation and Manual Extraction Techniques On The Comfort Level Of Serumen-Impacted Patients Using The Kolcaba Comfort Theory Approach. *Adi Husada Nursing Journal*. 2023 Jun 19;9(1):9.
22. Adegbiji W, Alabi B, Olajuyin O, Nwawolo C. Earwax impaction: Symptoms, predisposing factors and perception among Nigerians. *J Family Med Prim Care*. 2014;3(4):379.
23. Horton GA, Simpson MTW, Beyea MM, Beyea JA. Cerumen Management: An Updated Clinical Review and Evidence-Based Approach for Primary Care Physicians. Vol. 11, *Journal of Primary Care and Community Health*. SAGE Publications Inc.; 2020.
24. Manchaiah V, Arthur J, Williams H. Does hearing aid use increase the likelihood of cerumen impaction? *Korean J Audiol*. 2015;19(3):168–71.
25. Sridharan K, Sivaramakrishnan G. Cerumenolytics with or without manual extraction for impacted earwax: A network meta-analysis of randomised clinical trials. Vol. 46, *Clinical Otolaryngology*. Blackwell Publishing Ltd; 2021. p. 464–73.
26. Sugiura S, Yasue M, Sakurai T, Sumigaki C, Uchida Y, Nakashima T, et al. Effect of cerumen impaction on hearing and cognitive functions in Japanese older adults with cognitive impairment. *Geriatr Gerontol Int*. 2014;14(SUPPL2):56–61.
27. Yang EL, Macy TM, Wang KH, Durr ML. Economic and demographic characteristics of cerumen extraction claims to medicare. *JAMA Otolaryngol Head Neck Surg*. 2016 Feb 1;142(2):157–61.