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Searching for the Holy Grail among ear drops

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Abstract

Introduction and aim of the study: Ear wax plays many roles in maintaining ear health, such as cleansing, shielding, and lubricating the external auditory canal. Sometimes, when earwax obstruction occurs, for example as a result of improper hygiene procedures (such as using cotton swabs), it can cause a number of disorders ranging from discomfort to even loss of hearing. In such cases, various methods can be used to remove the cerumen impaction. One of these and also the most commonly used, involves the usage of ear drops, which can contain different active substances (water-based compounds, oil-based compounds, a combination of oil and water-based compounds, and non-water, non-oil solutions). The aim of our study is to present current state of knowledge about effectiveness of various types of ear drops in wax cleaning.

Material and methods: Our review is based on the analysis of materials collected in Pubmed", „Google Scholar" and other scientific articles using keywords: „earwax", cerumen impaction", „cerumenolytics", „ear drops", „cerumen", „earwax solvents", „wax solvents".

Conclusions: Despite numerous studies, the Holy Grail has not been found among ear drops. The majority conducted studies did not show that any of the cerumenolitics were superior to the others in a statistically significant way. The only result that was statistically significant was the one showing a higher effectiveness of 2.5% sodium bicarbonate compared to docusate sodium. Further research is needed.

Key words: cerumenolytic agents; cerumen; hygiene

INTRODUCTION AND PURPOSE

Personal hygiene is instilled from infancy; however, ear hygiene appears to be a contentious issue among a considerable portion of the populace, irrespective of educational background. It is essential to emphasise that the manner in which ear cleaning is conducted, rather than the mere act itself, holds significant consequence, as auditory health can be compromised by unsanitary or injudicious personal practices[1].

Many people assume that earwax forms as a result of dust and dirt accumulation[2]. It is pertinent to acknowledge that a regulated presence of cerumen is beneficial in maintaining optimal aural health[3], as this endogenously secreted substance fulfils roles in cleansing, shielding, and lubricating the external auditory canal[4]. Concomitantly, the innate self-cleaning mechanism of the ear engenders the entrapment and subsequent expulsion of particulate matter, including dust and dirt, along a medial to lateral axis within the ear canal. This process is facilitated by the combined actions of epithelial migration and movements of the jaw[5,6].

The normal migratory process can be disrupted by narrowing or blockage of the ear canal due to anatomical variations, infections, or dermatological conditions[7]. Also foreign objects placed in the ear, such as cotton swabs, tree sticks, towel tips, roller pen points [8], can irritate the ear canal, leading to chronic changes in the skin and disrupting the normal migratory process of the epithelium[7]. It is noteworthy that ear bud-type headphones or hearing aids can also contribute to the impaction of cerumen deeper within the auditory canal[5], however, no significant correlation has been demonstrated between hearing aid use and earwax impaction so far.[9]

Cerumen impaction, also known as earwax blockage, occurs when earwax accumulates and obstructs the ear canal, resulting in discomfort, itching, and even hearing loss[10]. It is noteworthy that 8,9% of hearing loss is caused by wax impaction[11]. Due to the decline in ceruminous gland activity as people age, resulting in a drier and slower-migrating wax, earwax impaction is found in approximately 57% of older individuals, contrasting sharply with the 5% prevalence in younger, healthier adults[7]. In case of cerumen impaction patients tend to self-clean ears with cotton buds[12] which is not only unnecessary but also potentially hazardous, and it has been widely criticized by otolaryngologists worldwide[13]. This stems from extensively documented issues such as injury (like perforation of the eardrum), earwax build-up, external ear inflammation (otitis externa) and retention of foreign objects[14–16]. What is surprising: in a study of health workers in Nigeria, 94% of them were found to be self-cleaning their ears[17].

STATE OF KNOWLEDGE

Initially, cerumen impaction is commonly managed with ear drops[18]. This kind of eardrops are called cerumenolytics[19]. Cerumenolytics are used as pre-treatment drops or sprays help to soften the hardened wax, making it easier to remove[20]. A prevailing issue is that earwax is frequently left untreated due to the misconception that using pre-treatment softeners alone is adequate[20]. Using cerumenolytic agents increases the likelihood of cerumen clearance compared to not treating[7]. They can be divided according to the main active substance: water-based compounds (such as sodium bicarbonate), oil-based compounds (such as olive oil), a combination of oil and water-based compounds, and non-water, non-oil solutions (such as carbamide peroxide and glycerol)[21]. Water and water-based agents act as cerumenolytics by hydrating and subsequently breaking down the corneocytes in earwax. Conversely, oil-based preparations work by lubricating and softening the earwax without breaking it apart[22]. The exact mechanism by which non-oil, non-water-based ear drops manage earwax has not been determined by in vitro studies[23]. In cases where usage of cerumenolytics fails, options like irrigation (washing out the wax with water) or microsuction (using a vacuum while observing through a microscope) can be pursued for extraction impacted cerumen[18].

Comparison of different cerumenolytics

Many studies have been carried out to determine the most effective cerumenolytic. The main active substances were compared according to different expected effects, in different environments and in different combinations. Table 1. presents comparison of the effects of any active treatment or group of cerumenolytics (water-based and oil-based) with no treatment or groups among themselves. The most basic comparison - active treatment vs. no treatment - shows an advantage for any active treatment (RR 4,09; 95% CI: 1.00-16.80)[5,24]. When comparing specific groups of cerumenolytics the studies indicated that oil-based treatment have a 41% higher odds of achieving the total elimination of cerumen to no preparation (OR 1.41; 95% CI: 0.59-3.34), while comparison of water-based versus no treatment suggests no difference in the odds of achieving the desired outcome (OR 0.99; 95% CI: 0.43-2.31)[25]. Another comparison suggests a potential fourfold increase in the likelihood of the completed clearance of cerumen with water or saline compared to no treatment. usage of water or saline alone provided no advantage over no treatment (RR 4.00; 95% CI: 0.91-17.62)[5,24]. However, verification of the effectiveness of any active treatment (other than water or saline) versus water or saline shows a relative risk of 1.30, which indicates a 30% higher likelihood of the total earwax clearance while using any active treatment (other than water or saline) (RR 1.30; 95% CI: 0.65-2.62)[5,24,26,27]. However, a comparison of oil-based vs non-oil-based cerumenolytics revealed a 15% lower likelihood of the desired outcome with oil-based treatments compared to non-oil-based cerumenolytics (RR 0.85; 95% CI: 0.48-1.49)[5,24,26–29]. Unfortunately, none of these results presented above were statistically significant[5,24–29].

IN VIVO STUDIES	
Group of cerumenolytics **vs** **no treatment/other group**	**Result**
Active treatment vs No treatment	RR 4.09 (95% CI: 1.00-16.80)[5,24]
Oil-based vs No-preparation	OR 1.41 (95% CI: 0.59-3.34)[25]
Water-based vs No-preparation	OR 0.99 (95% CI: 0.43-2.31)[25]
Water or saline vs No treatment	RR 4,00 (95% CI: 0.91-17.62)[5,24]
Any active treatment (other than water or saline) vs Water or saline	RR 1.30 (95% CI: 0.65-2.62)[5,24,26,27]
Oil - based vs **Non-oil-based cerumenolytics**	RR 0.85 (95% CI: 0.48-1.49)[5,24,26–29]

Table 1. Comparison of the effects of any active treatment or group of cerumenolytics (water-, oil-based) with no treatment or groups among themselves. Elements showing greater effectiveness are marked in bold. (RR – Relative Risk, OR – Odds Ratio, CI - Confidence Interval)

Comparison of active substances in vivo

A range of substances and products were compared under in vivo conditions (Table 2). Studies compared the efficacy in unblocking impacted earwax or the effectiveness of ear syringing performed after administration of cerumenolytics. Docusate sodium appears to give better results than no treatment (OR 1.87; 95% CI: 0.79-4.42)[25], while compared to 2.5% sodium bicarbonate it shows slightly less effectiveness (SR 1.10; 95% CI: 0.94–1.29)[30]. In contrast, a comparison of docusate sodium (presented under the trade name Colace®) to triethanolamine polypeptide (trade name Ceruminex®) shows that Ceruminex® might be slightly more effective than Colace® (RR 0.81; 95% CI: 0.38-1.72)[5,26,27,29]. Comparison of Dioctyl-medo® (containing dioctyl sodium sulphosuccinate as the active substance) vs Maize Oil Base showed to be similarly effective (OR 0.6; 95% CI: 0.2-2.4)[23,31]. Cerumol® (whose active ingredients are peanut oil, chlorobutanol and para-dichlorobenzene) has the same effect as sodium bicarbonate (RR 1.10; 95% CI: 0.47-2.55)[5,24], but slightly worse than Otocerol® (phenazone and sodium carbonate) (OR 1.3; 95% CI: 0.5-3.4)[28] or Audax® (choline salicylate, ethylene oxide-polyoxypropylene glycol, glycol and glycerol) (OR = 1.1; 95% CI: 0.5 to 2.4)[32]. Moreover Earex® (arachis oil, almond oil and rectified camphor oil) is as effective as Audax® (choline salicylate, ethylene oxide-polyoxypropylene glycol, glycol and glycerol)[5,33]. A comparison of the effectiveness of the products Colace® (docusate sodium), Ceruminex® (triethanolamine polypeptide) and saline showed no significant difference[27]. When comparing three products such as Auro® (carbamide peroxide and anhydrous glycerin) versus Cerumol® (triethanolamine polypeptide) versus CleanEars® (mineral oil (paraffin), squalane and spiramint oil), it was shown that only in the CleanEars® group a complete resolution of obstruction in both ears was achieved[34]. None of these studies showed a statistically significant advantage for any of the substances.

IN VIVO STUDIES	
Compared substances	**Result**
Docusate sodium vs No preparation	OR 1.87 (95% CI: 0.79-4.42)[25]
2.5% Sodium bicarbonate vs Docusate sodium	SR 1.10 (95% CI: 0.94–1.29)[30]
Dioctyl-medo® vs **Maize Oil Base**	OR 0.6 (95% CI: 0.2-2.4)[23,31]
Colace® vs Ceruminex®	RR 0.81 (95% CI: 0.38-1.72)[5,26,27,29]
Cerumol® vs Sodium bicarbonate	RR 1.10 (95% CI: 0.47-2.55)[5,24]
Otocerol ® vs Cerumol®	OR 1.3 (95% CI: 0.5-3.4)[28]
Audax ® vs Cerumol®	OR 1.1 (95% CI: 0.5 to 2.4)
Audax® vs Earex ®	RR 1.40 (95% CI: 0.57-3.44)[5,33]
Colace® vs Ceruminex® vs Saline	No significant difference[27]

Auro ® vs Cerumol® vs **CleanEars ®**	RR 0.71 (95% CI: 0.39-1.30)[5]

Table 2. Comparison of specific cerumenolytics in vivo. Elements showing greater effectiveness are marked in bold. A list of the active ingredients of the products listed in the Table 2 is provided below the table. Both the names of the products and the list of the most important active substances have been taken directly from the publication. (RR – Relative Risk, OR – Odds Ratio, CI - Confidence Interval, SR- Success Ratio)

List of active substances of products listed in the Table 2:

- Audax® (choline salicylate, ethylene oxide-polyoxypropylene glycol, glycol and glycerol)
- Auro ® (carbamide peroxide and anhydrous glycerin)
- Ceruminex® (triethanolamine polypeptide)
- Cerumol® (arachis oil, chlorobutanol and para-dichlorobenzene)
- CleanEars ® (mineral oil (paraffin), squalane and spiramint oil)
- Colace® (docusate sodium)
- Dioctyl-medo® (dioctyl sodium sulphosuccinate)
- Earex ® (arachis oil, almond oil and rectified camphor oil)
- Otocerol ® (phenazone and sodium carbonate)

In vitro comparison

In in vitro studies, a number of substances and their effects on wax degradation were compared (Table 3). In one study, active substances were compared to distilled water - it was shown that 5% potassium hydroxide and 7.5% sodium bicarbonate had higher odds ratio than distilled water, but lactic acid had lower odds ratio than distilled water[35]. In contrast, 5%

potassium hydroxide had higher odds ratio than 7.5% sodium bicarbonate (OR 242.078; 95% CI: 0.183-319 851.9)[35]. In another in vitro study, the use of Cerumol® (arachis oil, chlorobutanol and para-dichlorobenzen)e prior to ear rinsing was shown to achieve better syringing results than the use of dioctyl (OR 5.8; 95% CI 0.6 to 283.5) or olive oil (OR 0.5, 95% CI 0.008 to 10.4)[36]. Results mentioned above were also not statistically significant and therefore their validity cannot be clearly established. The only result that was statistically significant was the one showing a higher effectiveness of 2.5% sodium bicarbonate compared to docusate sodium[37].

IN VITRO STUDIES	
Compared substances	**Result**
5% Potassium hydroxide vs Distilled water	OR 273.237 (95% CI: 0.203-367 470.4)[35]
7.5% Sodium bicarbonate vs Distilled water	OR 1.129 (95% CI: 0.002-850.341)[35]
5% Potassium hydroxide vs 7.5% Sodium bicarbonate	OR 242.078 (95% CI: 0.183-319 851.9)[35]
10% Lactic acid vs Distilled water	OR 0.017 (95% CI:<0.001-18.415)[35]
Cerumol® vs Dioctyl	OR 5.8 (95% CI: 0.6-283.5)[23,36]
Olive oil vs Cerumol ®	OR 0.5 (95% CI: 0.008-10.4)[23,36]

2.5% Sodium bicarbonate vs Docusate sodium	The statistically significant difference implies that 2.5% sodium bicarbonate has greater efficacy in dissolving cerumen than does docusate sodium[37].

Table 3. The comparison of the results of in vitro studies on the effectiveness of wax degradation by cerumenolytics. Active substances of Cerumol®: arachis oil, chlorobutanol and para-dichlorobenzene. (OR – Odds Ratio)

Ex vivo and in vivo

One study was performed under both in vivo and ex vivo conditions(Table 4). It compared the effects of Carbamide peroxide and Phenol glycerin ex vivo considering the degree of earwax degradation over time intervals and in vivo comparing the correlation of time and outer ear canal obstruction depending on the substance used. The ex vivo experiment revealed that noticeable alterations occurred promptly upon exposure of earwax to carbamide peroxide. In contrast, changes in earwax exposed to phenol glycerin became apparent only after an incubation period of 20 minutes at 37 degrees Celsius. Moreover despite the fact that cerumen removal took less time in the EAC treated with Carbamide peroxide (54.10±31.77) compared to that treated with Phenol glycerin (67.10±35.54), this variance did not demonstrate statistical significance. Linear regression analysis revealed a noteworthy correlation between the degree of obstruction in the ear treated with phenol glycerin and ear treated with Carbamide peroxide and the time required for cerumen removal, with coefficients of $r=0.40$, $P=0.02$ and $r=0.37$, $P=0.05$ respectively[21].

BOTH EX VIVO AND IN VIVO STUDIES	
Compared substances	**Result**
Carbamide peroxide vs Phenol glycerin	Model coefficient= 0.45 coefficient=0.17; p-value=0.02[21]

Table 4. The comparison of the results of in vitro and in vivo studies on the effectiveness of wax degradation by cerumenolytics.

SUMMARY

Despite numerous studies attempting to determine if one type of cerumenolytic is more effective than another, there is no high-quality evidence to support a definitive conclusion, leaving the question unresolved[5]. The only result that was statistically significant was the one showing a higher effectiveness of 2.5% sodium bicarbonate compared to docusate sodium.

Both water-based and oil-based solutions are equally effective for aiding successful ear syringing and are presumably more effective than no treatment, with success rates as high as 97%[23]. Individuals who underwent pre-treatment exhibited a 35% increased likelihood of achieving complete cerumen clearance in comparison to those who did not undergo pre-treatment[25]. Moreover another systematic review found weak evidence suggesting that using a cerumenolytic agent, either alone or before irrigation, was more effective than no treatment or irrigation alone in clearing cerumen impaction[38]. Using a water-based (including plain water) or oil-based preparation immediately, followed by syringing 15-30 minutes later, appears to be as effective as applying eardrops for several days before syringing. Non-water and non-oil-based solutions tend to be less effective in this scenario. However, there is one non-water, non-oil-based solution that has proven to be much more effective than an oil-based one when used over several days[23]. Additionally, a separate review indicated that using a cerumenolytic followed by self-irrigation at home was the most cost-effective approach compared to using a cerumenolytic with professional irrigation or no treatment at all (the cost of no treatment was considered to be the continued hearing loss if left untreated)[39].

In vitro studies suggest that using a true cerumenolytic is more effective for disintegrating earwax compared to an oil-based lubricant, and that a longer treatment duration tends to increase efficacy[4]. In addition the research indicates that water-based cerumenolytics work better than organic ones[40].

On the other hand NICE, while not recommending any specific product, suggests using softening agents for up to five days before earwax removal. There is a lack of systematic studies comparing the effectiveness of various durations of ear drop use or the use of drops versus sprays[20]. As there is no evidence that any cerumenolytic agent is more effective than water or saline, water and saline should be the first choice. In cases where water or saline is ineffective, mineral oil or docusate sodium should be used as a second-line cerumenolytic agent[19]. However, it should be emphasised that there is no evidence showing that using saline or water alone is better than not treating the earwax at all[5].

Cerumenolytics are typically safe to use; however, they should be avoided in cases of a perforated eardrum or a history of ear surgery, such as the insertion of tympanostomy tubes. Common side effects include local irritation and rash[41]. Other possible side effects include discomfort, temporary hearing loss, dizziness[4]. Extended use may result in a superinfection[41]. Inorganic solutions such as saline appear to have the lowest likelihood of causing a local skin reaction when used as a cerumenolytic[4].

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Conflict of interest

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