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Original Research Article

A comparative study of sodium bicarbonate 5% and carbamide peroxide 6.5% as cerumenolytic agents

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ABSTRACT

Background: Earwax impaction is common and can cause symptoms such as hearing loss, discomfort, tinnitus, vertigo, and chronic cough. Removing impacted cerumen often improves hearing. Many cerumen-removal products exist but have limited efficacy, often requiring multiple doses over days. Sodium bicarbonate (5%) and carbamide peroxide (6.5%) are two important cerumenolytics. This study aimed to compare their effects on different degrees of wax obstruction.
Methods: This cross-sectional study at a tertiary ENT center included 148 adult patients with ≥50% bilateral ear canal occlusion (grades 3-4). Each patient received 5% sodium bicarbonate drops in one ear and 6.5% carbamide peroxide drops in the other, three times daily for four days. After 4 days, cerumen was removed by syringing and clearance outcomes were compared. Data were analyzed statistically with significance at $p \leq 0.05$.
Results: The mean age was 54±12.8 years, with a male predominance. Hearing loss was the most common symptom. Sodium bicarbonate demonstrated significantly more effective cerumen dissolution and clearance than carbamide peroxide ($p<0.05$). Complete clearance was achieved in 34.3% and 25.0% of ears treated with sodium bicarbonate and carbamide peroxide, respectively. Nearly half of sodium bicarbonate-treated ears (50.5%) were cleared with one syringing attempt, compared to about one-third with carbamide peroxide.
Conclusions: Sodium bicarbonate is a more effective option than carbamide peroxide for treating cerumen impaction in the external ear canal. By reducing blockage and symptoms, its use can improve patients' quality of life.

Keywords: Cerumen, Earwax, Sodium bicarbonate, Carbamide peroxide, Cerumenolytic agents

INTRODUCTION

Earwax is a normal secretion, the purpose of which is generally thought to be to protect the ear from particles entering the deeper part of the ear. Ear pain is most commonly brought on by impacted ear wax, or cerumen, which is a common presentation to the primary care physician.[1]

Between 2 and 6% of the US general population is thought to be affected by cerumen impaction. Cerumen impaction affects as much as 36% of people with mental impairment and as many as 65% of people over 65.[2-5]

It may be linked to transient hearing loss, discomfort, itching, tinnitus, external otitis, vertigo, and even a persistent cough. These clinical implications are significant for the overall health of the patients.[5] Hearing acuity can be momentarily reduced by up to 45 dB due to cerumen impaction.[6] This hearing loss can negatively affect an elderly person's quality of life by impairing their ability to communicate, think clearly, socialise, feel anxious or depressed, or even move around physically.[7,8] Studies have demonstrated that when impacted cerumen are removed, hearing greatly improves.[4,9] The two types of ear wax show an ethnicity/race correlation in which the dry type is dominantly seen in East Asians (95%), but rarely in Europeans and Africans (3%), and the mixed

type is more commonly seen in North Americans, Central Asia, and Turkey (30-50%).[10,11]

Currently, there are a number of cerumen removal products on the market. These include preparations that are water-based (acetic acid) or oil-based (almond oil) or non-oil-based (like propylene glycol) preparation.[12] Sadly, these preparations have little effect on dissolving cerumen impactions, and it frequently takes numerous dosages per day over a period of days to get acceptable outcomes.

These findings have spurred research into developing a more potent cerumenolytic agent, and researchers have discovered components that, when mixed together, can dissolve or break down human cerumen fast, efficiently, and safely. Out of these products, sodium bicarbonate (5%) and carbamide peroxide (6.5%) are important ones. In this study, we aimed to find out how commonly prescribed cerumenolytic agents (eardrops) containing carbamide peroxide and phenol glycol would affect patients with varying degrees of wax obstruction in terms of their cerumenolytic action.

METHODS

This study was a cross-sectional observational study, carried out in the department of ENT of SKIMS medical college and hospital Bemina, Srinagar, Jammu and Kashmir from May 2023 to April 2024. A total of 148 patients with cerumen were included in the study, after obtaining ethical clearance from the institutional ethics committee. Consent was taken from all patients after informing about the nature and purpose of the study. All parameters within the scope of this study were assessed in these patients with impacted or non-impacted ear wax. A comprehensive proforma was used for each patient interview, and the results of the examination and history were meticulously recorded. Scores 1 through 4 represented the different levels of occlusion: no cerumen in the ear canal, little cerumen in the ear canal, partial occlusion of the ear canal walls, and complete obstruction of the ear canal with or without impaction in the current study only grade 3 and 4 patients were included.[16] For the individuals to be enrolled, the ear canal had to have at least 50% cerumen impaction. Males and females over 18 years who were not pregnant and having earwax in both the ears were enrolled in the study.

Patients were excluded if they had any history of ear surgery or tympanostomy tubes, a non-intact tympanic membrane, or an active ear infection (otitis externa or media). Additionally, those with conditions that could compromise safe cerumen removal or confound the results (such as chronic otitis or an immunocompromised state) were not included.

Patients administered sodium bicarbonate (5%) and carbamide peroxide (6.5%) three times a day (five drops each time) for four days. The same patient's left and right ears, respectively, were treated with sodium bicarbonate and carbamide peroxide to examine their effects under somewhat identical circumstances and to minimise the impact of structural and genetic variations in cerumen. After 4 days, patients were called for removal of ear wax. Then the time for removal of cerumen was recorded and compared between the two medications.

Degree of obstruction between the left and the right EAC was compared by independent t-test which showed no significant difference indicating the reliability of the data provided. Data was entered in SPSS software version 22 and analysed. The time of cerumen removal was also compared by independent t-test between the two medications. Chi-square test was applied to see the association between variables. Data were reported in mean±SD, and $p \leq 0.05$ was considered significant.

RESULTS

Among the 140 patients (280 ears) included in the study, 78 (55.71%) were men and 62 (44.29%) were women. The mean age of patients was 54±12.8 years. A fully occluding cerumen (type 4) was found in 64.3% (90/140) of the ears and an occluding cerumen (type 3) in 35.7% (50/140). Table 1 shows the age and sex distribution of patients with ear wax. Most common age group affected by earwax is >60 years of age among adult patients. The association of age and gender with occurrence of cerumen was found to be significant in this study.

Most common symptoms of cerumen blockage were decreased hearing found in 148 ears (52.9%), followed by fullness of ear in 120 ears (42.9%) and tinnitus in 112 ears (40.0%) (Table 2). Itching was observed in 84 ears (30.0%). Patients also complained of sound of water being trapped after showering or swimming and that was observed in 62 ears (22.1%). Other minor symptoms were irritation and earache/tingling/pain found in 35 (12.5%) and 18 (6.4%) ears respectively.

Table 3 shows frequency of sodium bicarbonate and carbamide peroxide applied and its outcome as complete clearance or incomplete clearance of cerumen. As can be seen, ears in which sodium bicarbonate was used, complete clearance was seen in 96 (34.3%) cases. Incomplete clearance was seen in 184 (65.7%) patients. Carbamide peroxide has found to be having lower complete clearance rate as compared to sodium bicarbonate. Seventy (25.0%) ears were found to be having complete clearance and in 210 (75.0%) ears clearance was not complete. The clearance rate was found to be significantly associated with type of ear drops used.

Table 4 shows ears which received sodium bicarbonate needed lower number of attempts of syringing to extrude the cerumen mass. Out of 184 ears, 1 attempt was required in 93 ears, 2 attempts were required in 79 ears and 3 or more attempts were required in 12 ears. The ears which received carbamide peroxide needed 1 attempt in

80 cases, 2 attempts in 100 cases and 3 or more attempts in 30 cases. The association of number of attempts of syringing and type of cerumenolytic drop used was found to be statistically significant.

Table 1: Age and gender-wise distribution of patients with impacted ear wax.

Age group (in years)	Males	Females	Total	Chi-square	P value
18-30	18	18	36	10.884	0.012
31-45	13	21	32		
46-60	13	11	24		
>60	34	12	48		
Total	78	62	140		

Table 2: Baseline ear specific symptom of cerumen blockage.

Variables	Yes, N (%)	No, N (%)
Diminished auditory perception	148 (52.9)	132 (47.1)
Fullness of ear	120 (42.9)	160 (57.1)
Tinnitus (ringing or noise in the ear)	112 (40.0)	168 (60.0)
Itching	84 (30.0)	196 (70.0)
Sound of water being trapped after showering or swimming	62 (22.1)	218 (77.9)
Irritation	35 (12.5)	245 (87.5)
Earache, tingling or pain	18 (6.4)	262 (93.6)

*Total 280 years from 140 subjects

Table 3: Frequency of sodium bicarbonate and carbamide peroxide applied and divided into successful clearance and unsuccessful clearance of ear wax.

Methods	Total ears	N	Complete clearance (%)	Incomplete clearance (%)	Chi-square	P value
Sodium bicarbonate	280	140	96 (34.3)	184 (65.7)	5.788	0.016
Carbamide peroxide	280	140	70 (25.0)	210 (75.0)		

Table 4: Attempts of syringing required to extrude the cerumen mass.

Methods	Total ears	N	Attempts of syringing required to extrude the cerumen mass, N (%)			Chi-square	P value
			1	2	3		
Sodium bicarbonate	184	92	93 (50.5)	79 (42.9)	12 (6.5)	6.286	0.043
Carbamide peroxide	210	105	80 (38.1)	100 (47.6)	30 (14.3)		

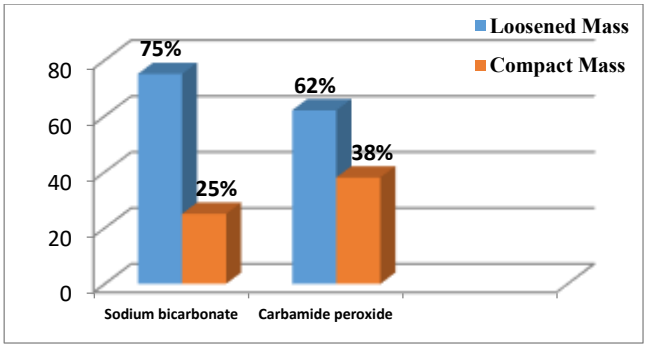

Figure 1: Appearance of the removed cerumen.

Figure 1 shows the appearance of removed cerumen after sodium bicarbonate and carbamide peroxide drops instillation. As can be seen, 75% of the ears receiving sodium bicarbonate has loosened mass of cerumen while 25% has compact mass. With ears receiving carbamide peroxide, the percentage of loosened cerumen and compact cerumen is 68% and 32% respectively. The association of type of ear drop and appearance of cerumen was found to be statistically non-significant (p=0.272).

DISCUSSION

According to 2017 American academy of otolaryngology guideline on cerumen 'there are a limited number of well controlled, high quality, homogenous studies demonstrating the efficacy of topical agents'. This study used an *in vivo* methodology to examine the impact of two ear drops on the degradation alterations of cerumen. In the current study the mean age of patients was found to be 54±12.8 years with male predominance (55.71%). Another study in USA by Fullington et al also found male predominance (79%) in their study with higher mean age (64.8±12.3 years).[16] The proportion of fully occluding cerumen (type 4) was 64.3% of the ears and an occluding

cerumen (type 3) in 35.7% in the present study. In a single-centre study in one region of the UK, the prevalence of partially occluding or totally occluding earwax was reported to be 43%. In contrast to the current study, this study also suggested that prevalence of earwax tends to decrease with age and there is no difference in prevalence between gender.[17]

Otolaryngologists frequently see symptoms associated with ear wax, and they spend a significant amount of time extracting impacted or non-impacted cerumen from the external auditory canal. The most common complaints related to cerumen impaction in current study was found to be decreased hearing and fullness of ear followed by fullness of ear. Similar results were obtained by Fullington et al in their study in USA.[16] Minor symptoms were irritation and earache/tingling/pain found in 35 (12.5%) and 18 (6.4%) ears respectively.

In our study, complete clearance was seen in 34.3% of ears in which sodium bicarbonate was used. Incomplete clearance was seen in 65.7% ears. Carbamide peroxide has found to be having lower complete clearance rate as compared to sodium bicarbonate. This is supported by an *in vitro* study in which cerumen disintegration was found to be more with sodium bicarbonate than carbamide peroxide.[18] Overall, research indicates that aqueous preparations work better than oil-based preparations to disrupt human cerumen. Furthermore, bicarbonate formulations have demonstrated better efficacy for causing the disintegration of cerumen *in vitro*.[19-21] However, *in vitro* studies have their own limitation. The incubations were carried out at room temperature and the outcomes may differ at natural body temperatures. A prospective randomized clinical trial is needed to validate these findings. The outcomes of a systematic review and randomized clinical trial which indicated no discernible differences between the preparations, do not support our findings.[22,23]

In our study sodium bicarbonate was found to be most effective with maximum proportion of ears (50.5%) getting cleared of cerumen mass with a single attempt of syringing. This is in comparison to the result of a study done by Nair.[24] The ears which received carbamide peroxide needed 1 attempt in 38.1% cases, 2 attempts in 47.6% cases and 3 or more attempts in 14.3% cases. The association of number of attempts of syringing and type of cerumenolytic drop used was found to be statistically significant as found by Nair also.[24] In the current study, ceruminous mass in the EAC has been softened as compared to the hard impacted cerumen prior to administration of drops. The softening could be seen by appearance of removed cerumen after sodium bicarbonate and carbamide peroxide drops instillation. In this study, 3/4th of the ears receiving sodium bicarbonate has loosened mass of cerumen while 25% had compact mass. With ears receiving carbamide peroxide, the percentage of loosened cerumen and compact cerumen was 68% and 32% respectively. This finding is similar to the results of Robinson and Hawke's *in vitro* investigation, which showed that sodium bicarbonate solution was most effective in causing wax plug disintegration.[25] An *in vitro* study conducted by Bellini also demonstrated sodium bicarbonate to be more effective than others in producing disintegration of wax plug *in vitro*.[26] It is also comparable to the study conducted by Fraser et al who found that sodium bicarbonate is a better ceruminolytic agent than others except 2% paradichlorobenzene.[27] Similar results were seen in the study conducted by Keane et al.[28]

Limitations

Limitations include the relatively small sample size (148 patients) and single-center design, both of which may limit the generalizability of our findings. Additionally, this was an open-label observational study without randomization, so lack of blinding could introduce observer or patient bias. Symptom relief was assessed subjectively, with no objective measures (such as audiometry) to confirm improved hearing. We also did not include a water or no-treatment control group, which prevents comparison with spontaneous clearance rates. Finally, the outcomes were short-term, and no follow-up was done to assess if differences in efficacy or symptom relief were sustained.

CONCLUSION

Cerumen impaction is a prevalent and serious medical condition. Based on the current research, sodium bicarbonate is suggested as a better option for treatment of patients with EAC obstruction caused by cerumen impaction than carbamide peroxide. As a result, cerumen related hearing loss and symptoms could be prevented which will improve overall quality of life. This could reduce or eliminate the need for intervention from a physician. People can use it as maintenance/routine hygiene product, before the onset of symptoms or before symptoms became too severe. However, due to the small sample size, the statistical significance did not allow for a clear demonstration of superiority. Further *in vivo* studies are required.

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