

Comparison of Three Different Ceruminolytic agents (Soda-Bicarbonate, Almond Oil & Normal Saline) with Respect to their Efficacy

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ABSTRACT

Objective: To compare the efficacy of three ceruminolytic agents for cerumen impaction with respect to its ease of complete removal via suctioning or probe.

Study Design: A comparative prospective study.

Place and duration of Study: This study was conducted carried out at the outpatient department of ENT, Abbasi Shaheed hospital, Karachi from November 2010 to March 2011.

Patients and Methods: A comparative prospective study of 75 adult patients with cerumen impaction in either or both of the ears carried out at the outpatient department of ENT, Abbasi Shaheed hospital, Karachi. The study was done after taking the consent of the patients. All the adult patients of age 18 years or greater, of either sex with the symptoms in the ear(s) because of cerumen which was hard/dry and difficult to remove were included in the study. Those of age less than 18 years and not having any symptomatology because of the cerumen or with soft wax which was easy to clean were not included in the study. The study was carried out from November 2010 till March 2011. The patients with problematic, difficult to remove cerumen or cerumen impaction with symptoms were divided in to three groups: Group A, Group B and Group C; all having equal number of cases that is 25 each. In group A they were given soda-bicarbonate in glycerin based ear drops; in group B almond oil and group C the normal saline for instillation in ear. The doses and timings for drops were equal in all the group and it was 3 drops in the affected ear every 6-hourly for 1-week. They were counselled that the dose should not be missed and they have to lay down for 5 minutes so that drops are absorbed and does not come out of the ear. After one week they were called in the OPD, their ear(s) were assessed with respect to the cerumen softening and ease of removal, either via probe or suctioning, was compared with the completeness of removal of impacted cerumen for the three groups.

Result: Ease and completeness of cerumen removal was 80% in group A, followed by 60% for group C and 20% for group B.

Conclusion: We found soda-glycerin to be superior to almond oil and normal saline as ceruminolytic agent.

Key Words: cerumen; ear-wax; cerumen impaction; ceruminolytic agents

INTRODUCTION

Cerumen or ear-wax production is a normal healthy phenomenon of the external auditory canal (EAC) with myriad of functions, which under normal circumstances, is expected to be extruded from the ear canal by the "conveyor-belt phenomenon" of lateral migration. Although there is no study but some people are 'wax producers', and others remain wax free without much maintenance. Accumulation of cerumen, caused by failure of self cleaning mechanism is one of the most common reason that a patient seek medical care for ear related problems.^{1, 2} Excessive or impacted cerumen is present in one in 10 children, one in 20 adults and more than one-third in geriatric and developmentally delayed populations.³⁻⁵ In United States about 12 million people seek medical care annually for problematic cerumen, resulting in nearly eight million cerumen removal procedures.^{6, 7} In Netherlands the incidence of complaints owing to ear wax in general practice is 39.3 per 1000 patients.⁸

Unfortunately in our part of the country no such records or data exists to know the current status and magnitude of this problem.

Cerumen impaction is when an accumulation of it is associated with symptoms, prevents assessment of ear(s) or both.⁹ Impacted cerumen can arise from a number of causes for instance anatomical changes of EAC, keratosis obturans and failure in separation of keratinocytes. Possibly people prone to recurrent episodes of cerumen impaction do not express sufficient quantities of an unidentifiable 'keratinocyte attachment destroying substance'.¹⁰ There is no local study available to judge the magnitude of this problem in our part of the country although international studies are abundant. Impacted cerumen clears completely in 5% of the patients without any treatment, while a further 26% of patients show a moderate improvement after 5 days without treatment.

Cerumen removal may be attempted by irrigation of the EAC, with or without the use of ceruminolytics; by

ceruminolytics alone; by manual removal via probe, curette, forceps or suctioning.

Manual removal via curette is a long recognized method for ear cleaning and is generally considered safe and effective but there are no trials to compare it with other methods for efficacy and safety.¹¹ It requires the presence of a co-operative patient!

Irrigation may be attempted alone or with a ceruminolytic pre-treatment. There are different irrigation systems available for office-use. One study has shown that irrigation alone was effective approximately 70% of the times.⁷

Ceruminolytics are broadly divided in to three categories: (1) water based; (2) oil based and (3) non-water, non-oil based.^{7, 12-14} Table 1 illustrates the different types of ceruminolytic agents and their effects.

PATIENTS AND METHODS

A comparative prospective study of 75 adult patients with cerumen impaction in either or both of the ears

carried out at the outpatient department of ENT, Abbasi Shaheed hospital, Karachi. The study was done after taking the consent of the patients. All the adult patients of age 18 years or greater, of either sex with the symptoms in the ear(s) because of cerumen which was hard/dry and difficult to remove were included in the study. Those of age less than 18 years and not having any symptomatology because of the cerumen or with soft wax which was easy to clean were not included in the study. The study was carried out from November 2010 till March 2011. The patients with problematic, difficult to remove cerumen or cerumen impaction with symptoms were divided in to three groups: Group A, Group B and Group C; all having equal number of cases that is 25 each. In group A they were given soda-bicarbonate in glycerin based ear drops; in group B they were given almond oil as ear drops and the group C they were given normal saline for instillation in ear.

Table No.1: Different Ceruminolytic agents^{7, 12-14}

Category/Agent	Dosing	Use	Comments
1) Water based			
10% Triethanolamine Polypeptide	Fill EAC 15-30 minutes before irrigation	Soften cerumen before irrigation	Irritating; can't be used for prolonged periods
Docusate Sodium	Fill EAC with 1mL of IT for 15-30 seconds	Soften cerumen before irrigation	-----
3% Hydrogen Peroxide	Fill EAC for 15-30 seconds	Soften cerumen before irrigation	If not completely removed bubbling may hamper tympanic membrane visualization
2.5% Acetic Acid	Fill EAC with 2-3cc twice daily for 14 days	Home based treatment	More effective in children
10% Soda Bicarbonate	Fill EAC with 2-3cc prior to irrigation or alternatively for 3-14 days at home without irrigation	Soften cerumen before irrigation or home based treatment	More effective in children
Water or Saline	Instill water or saline & wait for 15minutes then do irrigation	Soften cerumen before irrigation	-----

Table 1 (Continued)

2) Oil Based			
Olive Oil; Almond Oil; Mineral Oil	3-Drops in the EAC at night for 3-days	Soften cerumen before irrigation	-----
Arachis Oil; Rectified Camphor Oil	4-Drops in the EAC, twice daily for upto 3/4-days	Soften cerumen before irrigation	-----
3) Non-Water, Non-Oil Based			
Carbamide Peroxide	5-10 drops, twice daily in the EAC for upto 7-days	Soften cerumen before irrigation or home based treatment	-----
Propylene Glycol; 50% Choline Slaicylate & Glycerol; 0.5% Chlorbutol	Put 3-drops in EAC, twice daily for 4-days	Soften cerumen before irrigation	Branded formulations aren't available in Pakistan

The doses and timings for drops were equal in all the groups and it was 3 drops in the affected ear every 6-hourly for 1-week. It was thoroughly explained to them that the dose should not be missed and they have to lie down for 5 minutes, with the ears with drops in up position, so that the drops are properly absorbed and

RESULT

Total number of cases were 75 (n=75 patients) with males being 40 (53.33%) in number and females 35 (46.66%) in number (table 2). In our study we found that the maximum response in terms of softening of cerumen and completeness of removal with ease (80% of the cases) was observed with the group A with soda-glycerin ear drops. It was followed by the group C with

does not come out. After one week time they were called in the OPD, their ear(s) assessed with respect to the cerumen softening, ease of removal either via probe or suctioning and the completeness of removal of impacted cerumen among the patients in the three groups.

normal saline as ear drops in which the success rate for ease and completeness of removal was 60% and group B with almond oil as ear drops on third number with success rate of only 20% (table 3).

Table No.2: Male & female patients (n=75 patients)

Males	40 (53.33%)
Females	35 (46.66%)

Table No.3: Effects of ceruminolytic agents (soda glycerin, almond oil & saline) in each of the three groups

<i>Effects observed (25 patients in each group)</i>		
Softening of cerumen (In -----No. of patients)	No effect of cerumen softening (In ----- No. patients)	Ease and completeness of removal (In-----No. of patients)
Group A – Soda Bicarbonate-glycerin ear drops		
22 (88%)	03 (12%)	20 (80%)
Group B – Almond oil as ear drops		
15 (60%)	10 (40%)	05 (20%)
Group C – Normal saline as ear drops		
19 (76%)	06 (24%)	15 (60%)

DISCUSSION

In one systemic review of topical ceruminolytics, the investigators concluded that triethanolamine was better than saline and that longer treatment with cerumen softener was better than shorter treatment duration. The review also found that the effect of docusate sodium was not statistically superior or different from saline or triethanolamine. Although longer treatment duration appeared to increase the

effectiveness of the ceruminolytics alone, overall effectiveness is still uncertain because of limitations of the evidence.¹⁵ The same study also suggested that the use of ceruminolytic agents may improve irrigation by as much as 97%. A study by Eekhof JAH and colleagues⁷ concluded that water is more effective than several of the proprietary agents in facilitating the cerumen removal. In one in-vitro study conducted by Andaz and colleagues¹⁶ found water to be the most effective dispersant. In this model, olive oil seemed almost ineffective. In our study the almond oil was almost in-effective. In the same study the agents like urea-hydrogen-peroxide, sodium bicarb, and docusate sodium all showed levels of efficacy between that of water and olive oil. In another study para-dichloro-benzene emerged as the most effective agent, closely followed by soda-bicarb, while 2.5% acetic acid fared moderately and normal saline emerged as the least effective.¹⁷ This is in contrast to our study which showed normal saline is 2nd best after the soda-glycerin ear drops! In a report by Wilson S¹⁸, he states that docusate sodium is the most effective ceruminolytic agent followed by triethanolamine and olive oil. By his report, carbamide

peroxide was labeled as the least effective. Singer and associates¹⁹ also found the docusate sodium to be effective but according to Whatley et al²⁰ amongst docusate sodium and triethanolamine none was superior. In our part of the world many of the agents aren't available as ear drops and from our armamentarium soda-glycerin seems the most effective ceruminolytic and that it comes cheap also makes it a good choice as people easily can afford it while almond oil is not readily available and is not the preferred 'ear-drops' by the patients!

Unfortunately the international trials have used ceruminolytics which are not available here so we limited our study to agents which can readily be obtained by the patients and is affordable!

CONCLUSION

The evidence regarding the pharmacological management of impacted cerumen is sparse and inconsistent and also that there is no consensus concerning the treatment of choice, or whether formulations designed to loosen the cerumen impaction are any better than water. Our study again is but small so can the result be extrapolated to a more wide scale population remains to be seen. It is hoped that this study regarding the cerumen impaction and ceruminolytic agents might open some new debates and perhaps in near future a consensus regarding the optimal management and stratification of ceruminolytics based on their efficacy can be produced.

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