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A Comparative Study of Distilled Water and Topical 4% Xylocaine-Distilled Water Combination as fast acting Cerumenolytic Agents

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ABSTRACT
Ear wax is frequent complaint reported in ENT OPD. There are various type of cerumenolytics are used to soften ear wax. One of these is water used as fast acting wax softener for quick removal of ear wax. While traditionally performed using distilled water, the addition of local anaesthetics such as 4% Xylocaine has been proposed to reduce discomfort and improve patient tolerance. This trial aims to compare the efficacy and patient satisfaction of ear cleaning using distilled water alone versus distilled water with 4% Xylocaine. A total of 294 patients with impacted cerumen were recruited and randomly assigned to one of two groups of control and intervention group: Group A or control group receiving ear cleaning post instillation of distilled water and Group B or intervention group receiving ear cleaning post instillation of distilled water mixed with 4% Xylocaine. Parameters including ease of wax removal, pain experienced during the procedure, and patient satisfaction were assessed using standardized scales. Additionally, adverse events such as trauma to the ear canal or tympanic membrane were recorded. Preliminary results suggest that the addition of 4% Xylocaine to distilled water may lead to improved patient comfort during ear cleaning without compromising efficacy. However, further analysis and a larger sample size are necessary to draw definitive conclusions. This study sheds light on potential advancements in ear wax removal in single setting without patient's discomfort.

INTRODUCTION

Earwax is a normally produced substance by the sebaceous glands of the ear canal in order to keep it greased and protect the ear from foreign bodies entering it. Ear canal has a special property by which the cerumen gets spirally pushed towards the external auditory meatus and the ear remains free from impaction, but in cases where there is large scale cerumen production the wax might get impacted and case symptoms like pain, fullness, decreased hearing, tinnitus, headache etc.[1,2].

Ear Wax Removal: Many different strategies have been tried over the years for earwax removal, but they basically fall into one of three categories: manual removal, irrigation, and chemical dissolution. Many patients will require a combination of all three stratagems[1-8].

Otitis Externa Definition: Otitis externa is a generalized condition of the skin of the external auditory canal. It is characterized by oedema and erythema associated with itch, pain and discharge[6].

Traditionally, ear cleaning has been performed using warm distilled water, which helps to soften and dislodge the wax. Despite its effectiveness, cerumen removal can be uncomfortable for patients, particularly when the wax is impacted or when the procedure is prolonged. To soften wax various type of wax softening drop available commercially but not only they are costly also required multiple visits.one method to overcome this use of water as fast acting agent to disintegrate the wax and remove after 15-30 minute after installation. In an effort to enhance patient comfort and tolerance, various modifications to the traditional ear cleaning technique have been explored. One such modification involves the addition of topical anaesthetics, such as lidocaine or Xylocaine, in water for installation in ear and removal under microscope with micro suction[9-10].

4% Xylocaine, a widely used topical anaesthetic in various ENT OPD minor procedure, acts by blocking the transmission of nerve impulses, thereby reducing pain sensation. By incorporating 4% Xylocaine, it is hypothesized that the procedure can be performed with less discomfort for the patient. Additionally, the anaesthetic properties of 4%Xylocaine may facilitate easier wax removal by reducing surface tension of the cerumen and relaxing the muscles of the ear canal thus, reducing reflexive responses such as the cough reflex.

Therefore, this randomised control trial aims to add that efficacy and patient satisfaction of cerumen removal using distilled water with 4% Xylocaine. This study seeks to provide valuable insights into the optimal approach for ear wax removal that prioritizes patient comfort and safety.

MATERIALS AND METHODS

Study Design: Randomised control trial. Written informed consent was obtained from all participants prior to enrolment.

Study Duration: The study is aimed at proving the usefulness of 4% xylocaine in ear wax removal in patients visiting the ENT department during April 2023 to September 2023 in determined days in a week.

Sample size is was determined as per a pilot study conducted in the ENT department of a tertiary care hospital. Thus, a sample size of 294 patients included in the study, history taken from each patient and after permission from the patient was taken routine otolaryngology examinations were done including ear otoscopy, then we divided the sample in to two categories in a randomised manner with randomisation ratio of 1:1 and the study is double blinded with division as per the material used in ear, distilled water and distilled water with 4% xylocaine in a 1:1 ratio. Drops of distilled water and distilled water mixed with 4% xylocaine were dropped into the impacted ear of each group respectively and the auditory meatus blocked with a wet wad of cotton. After patient had waited for 30 minutes, attempts of wax removal were made under examining microscope using microsuction. In Group A, (control) The distilled water is installed into the ear canal, and wax was removed after 30 minutes using gentle microsuction and with forceps if needed. In Group B, (intervention) Topical 4% xylocaine with distilled water in 1:1 ratio is instilled into the ear canal, and wax was removed after 30 minutes using gentle microsuction and with forceps if needed.

Data collected by a questionnaire as age, gender, complain, any ear symptoms after which patients of both groups undergo ear irrigation followed by a visual analogue score for discomfort during the ear wax removal and follow up of the patient to determine improvements in adverse effects.

Inclusion Criteria:

- Any case with impacted ear wax.
- Both sex
- Patient above age 12 years.

Exclusion Criteria:

- Uncooperative patient.
- Diabetic patient.
- Any patient with previous ear surgery.
- Any patient with tympanic membrane perforation
- Any patient with external auditory canal infection.
- Patients with bilateral ear wax.

Questionnaire

1- History

Name: age: gender: male ☐ female ☐

Occupation: address: tel:

Complain:-

Diabetic yes ☐ no ☐

Hx of tympanic membrane perforation yes ☐ no ☐

Hx of ear trauma yes ☐ no ☐

Hx of ear surgery yes ☐ no ☐

smoker yes ☐ no ☐ if yes how much:

2- Examinations:

Findings

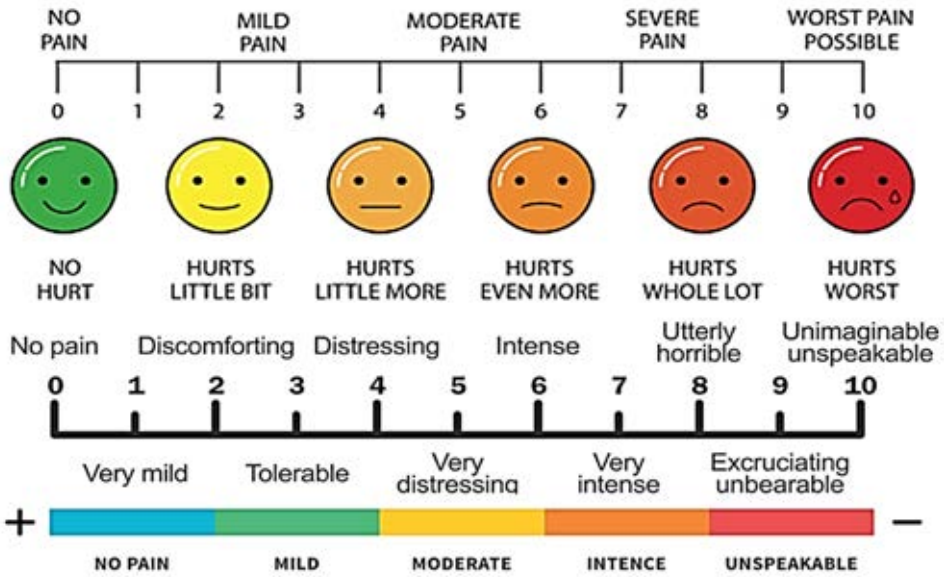
General:

Nose:

Throat:

Larynx:

Ear wax: ☐ unilateral ☐ bilateral



Follow up

Day/symptom	Ear pain	Ear itching	Decrease in hearing	Auricle redness
2nd				
5th				
7th				

Analysis: For both groups the mean for pain levels (95% confidence interval) was calculated and compared by testing the difference between means using a chi-square test. Data was analysed by latest version of the SPSS software.

RESULTS

Mean of patients experiencing mild pain in control is 1.78±0.233 with S.D. 0.84 and in intervention group 1.58±0.272 with S.D. 0.80. Mean of patients experiencing moderate pain in control is 4.82±0.264 with S.D. 0.78 and in intervention group 4.66±0.533 with S.D. 0.81. Mean of patients experiencing severe pain in control is 7.71±0.518 with S.D. 0.69 and in intervention group mean is 7±0 with S.D. 0. Mean of patients experiencing worst pain in control group and intervention group is 5. The results in both groups are thus comparable (P value is <0.00001).

In patients having severe pain worst pain score procedure was abandoned and commercially available cerumilytics prescribed for five days and wax removal was done after five days.

DISCUSSION

In our study clinically significant difference in pain score of two group was found. we came across that the percentage of no pain in control group is 33.33% (49) while in intervention group is 68.71%

Table 1: Male/female preponderance

Group	Total	Male	%	Female	%
Control	147	85	57.83	62	42.17
Intervention	147	70	47.62	77	52.38
Total	294	155	52.72	139	47.27

Table 2: Age Distribution

Group	16-30 year	31-45 year	46-60 year	61 and above
Control	34	61	36	16
Intervention	36	52	42	17
Total samples	70	113	78	33
percentage	23.80	38.43	26.53	11.22

Table 3: Pain score

Group	No pain (0)	Mild pain (1-3)	Moderate pain (4-6)	Severe pain (7-9)	Worst pain (10)
Control	49	51	35	7	5
Mean	0	1.78	4.82	7.71	10
Intervention	101	34	9	2	1
mean	0	1.58	4.66	7	10

Table 4: Ear Symptoms

Day /symptoms	Ear pain	Ear itching	Auricle redness	Total of cases	%
Control	12	13	5	30	20.41%
Intervention	17	14	6	37	25.17%

(101), mild pain seen in 34.69% (51) with mean pain score 1.78±0.233 with S.D. 0.84 and in intervention group mild pain is seen in 23.13% (34) with mean pain score is 1.58±0.272 with S.D. 0.80. Moderate pain is seen control group 23.81% (35) with 4.82±0.264 with S.D. 0.78 and in intervention group moderate pain seen in 6.12% (9) with mean pain score 4.66±0.533 with S.D. 0.81. Sever pain in control group is 4.76% (7) with mean pain score is 7.71±0.518 with S.D.0.69 and in intervention group sever pai seen in 1.36% (2) with mean pain score7±0 with S.D. 0. Worst pain is seen in 3.40% (5) with mean pain score 10 while only. 68% (1) in intervention group. The result is in both groups are thus comparable (P value is <0.00001) hence it can be said that 1:1 4% xylocaine with distilled water is significantly better agent for fast acting wax solvent.

In our study male (52.72%) preponderance was noticed over females (47.27%). In our study the main age group is (31-45 year) i.e. 47 cases out of 138 in percentage (34.05%) this may reflect the age of growth and stress of life in our country, the second age group is 46-60 year i.e. 43 cases out of 138 in percentage (31.15%), this may reflect that the above-mentioned age group neglected their health and had a habit of repeated[1] cleaning (Table 1).

12 patients develop delayed pain in control group and 17 in intervention group which is mild in nature and subside by simple analgesics. In control group 13 patients develop itching and 5 patients develop ear canal congestion which subside without medication while in intervention group 14 patients develop itching and 6 develop congestion of canal which subside without medication. No patients develop decreased hearing in post intervention period. Post intervention mild pain, itching and ear canal congestion is slightly more common in intervention group may be xylocaine anaesthetised skin of ear canal made it more prone to minor trauma (Table 2 and 3).

Overall pain levels were significantly less ($p<0.00001$) during the ear cleaning process making the ear cleaning process more satisfying to the patient and also comfortable for the doctor. This increased overall patient compliance (Table 4).

CONCLUSION

Concerning wax percentage, no male to female preponderance in our study. The commonest age group present with wax is (31-45 year). As a fast-acting wax softener distilled water with 4% xylocaine is better than distilled water by decreasing percentage of discomfort and pain during the ear wax removal process in single visit.

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