Curr Pediatr Res 2022; 26 (11): 1678-1682 *ISSN 0971-9032*
www.currentpediatrics.com

Earwax and topic alpha-tocopherol acetate: The cerumenolytic action.

Domenico Testa*, Anna Donadio, Michele Andreotti, Giuseppe Massaro, Giovanni Motta

Department of Otorhinolaryngology, Head and Neck Surgery Unit, University of Campania "Luigi Vanvitelli", Napoli, Italy

Received: *01 November, 2022, Manuscript No. AAJCP-22-80694;* ***Editor assigned:*** *03 November, 2022, Pre QC No. AAJCP-22-80694(PQ);* ***Reviewed:*** *11 November, 2022, QC No. AAJCP-22-80694;* ***Revised:*** *21 November, 2022, Manuscript No. AAJCP-22-80694(R);* ***Published:*** *30 November, 2022, DOI:10.35841/0971-9032.26.11.1678-1682.*

Abstract

Objective: Cerumen (ear wax) is a physiologic secretion of ceruminous and sebaceous glands of the external ear canal. Its main function is lubricate the external auditory canal, creating a humid and warm environment. Cerumen usually, is expelled outside the ear canal to the movements of the jaw. Sometimes, however, in some people due to the shape of the ear canal or due to inappropriate cleaning maneuvers, ear wax can accumulate, causing an obstruction (plug). When treatment is indicated, there are three recommended ear wax removal methods: irrigation, manual removal, cerumenolytic agents.
Methods: For the study 137 patients were enrolled, age range 6-80 years old, mean 46.7, the subjects are divided in three groups standing the age and created a score in relation to the ear wax plug (0: Complete obstruction of external auditory canal; 1: Ear wax plug obstructing 2/3 of external auditory canal; 2: Ear wax plug obstructing 1/3 of external auditory canal; 3: Absence of ear wax). Each patient underwent topic treatment with alpha tocopherol acetate and polydecene (Filme Oto Spray), 3 puffs each external auditory canal, 3 times/day for 7/14 days. The aim of the treatment was to completely remove the ear wax plug in 7 days (primary endpoint) or in 14 days (secondary endpoint).
Results: Children and adolescent patients reached endpoints more than adults and older patients, with statistical significance ($p<0.05$).
Conclusion: The use of the composition of alpha-tocopherol acetate (vitamin E) and polydecene (Filme Oto Spray) allows to cleaning of the auditory canal and the complete visualization of the tympanic membrane, 7 days after the first application.

Keywords: Cerumen, Ear wax, Ceruminolytics, Alpha-tocopherol acetate, Tympanic membrane.

Accepted on 14th November, 2022

Main Points

- The use of alpha tocopherol acetate and polydecene (Filme Oto Spray) makes it possible to dissolve earwax plugs and visualize the tympanic membrane without the need of classic removal methods.
- Adults and children had greater compliance during therapy.
- The best ceruminolytic action was shown in young patients.

Introduction

Cerumen (ear wax), a physiologic secretion of ceruminous and sebaceous glands of the external ear canal, appears yellow-orange in color and it includes a mixture of squalene (6.4%), wax (9.3%) and cholesterol (9.6%) esters. Triacylglycerols (3%) free fatty acids (22.7%), and cholesterol (20.9%) including cholesterol esters (10%) and sulphates (0.9%) lay on the ear canal corneum stratum which continuously desquamates [1].

The main function of ear wax is to lubricate the external auditory canal, creating a humid and warm environment. Therefore, it filters out dust and small foreign particles, so that they cannot reach and damage the tympanic membrane and it provides initial protection from infectious agents such as bacteria, virus and fungi as well.

Cerumen is usually expelled outside the ear canal to the movements of the jaw. However, in some people due to the shape of the external ear canal or due to inappropriate cleaning maneuvers, ear wax can accumulate, causing an obstruction (plug). If ear wax plug completely occludes the ear canal, hearing impairment (transmissive hearing loss), sensation of "closed ear", autophony, ear pain, and tinnitus and in some cases imbalance, may occur [2].

Among the possible risk factors predisposing to the formation of the ear wax plug are recognized [1-3]:

- Glandular hypersecretion of ear wax, often genetically determined.
- The introduction of water into the external auditory canal (at swimming in the pool or at the sea, showers or washing one's hair), due to hygroscopic ear wax properties leading to the formation of the plug.
- Age, the ear wax plug is formed more frequently in children and in the elderly. In children because the ceruminous glands are often hypertrophic and produce a greater amount

of ear wax in a small and not fully developed external ear canal; in the elderly as the ear wax becomes more and more dehydrated, dry and so difficult to push outside.

- The use of hearing aids (they make it difficult for the ear wax to get out keeping it in the depth of the external ear canal).
- Some dermatological clinical conditions increasing ear wax production and causing excessive skin peeling of the external auditory canal (psoriasis, seborrheic dermatitis, etc).
- The reduction of the caliber of the ear canal, which makes it difficult for the ear wax to get outside (exostosis, osteomas, and other malformations of the external auditory canal).
- The accumulation of dust.
- Excessive presence of traces (hairs) in the external auditory canal, which make it difficult to expel the ear wax.

Literature review

Wax plug formation affects about 12% of the general population, 10% of children and over 30% of the elderly, diagnosis is clinical by mean of otoscopy [1-3]. When treatment is indicated, there are three recommended ear wax removal methods: Irrigation, manual removal, cerumenolytic agents [4]. Irrigation, lukewarm water or a mixture of 50% water and 50% hydrogen peroxide is commonly used [5].

Manual removal is the method recommended by the American academy of Otolaryngology Head and Neck Surgery using the otomicroscope. The advantages of this method are the reduction of the risk infections because the ear canal is not exposed to irrigation and there is a direct view of the external ear canal [4-6].

Cerumenolytic agents are liquid solutions that help dilute, soften, and dissolve ear wax. These are generally water or oil-based drops, with various associated components (e.g., sodium bicarbonate, dimethylbenzene, peanut oil, olives and almonds). Generally, 4-5 drops are used two to three times a day for seven days. The aim of this research is to evaluate topic alpha-tocopherol acetate and polydecene (Filme Oto spray) ceruminolytic action without any mechanical removal.

Materials and Methods

It is a retrospective observational research. 137 patients, aged between 6 to 80 years old (mean age 46.7), referred to ENT Clinic of the University of Campania 'Luigi Vanvitelli' for ear wax plug were enrolled from September 2021 to June 2022. Each patient underwent ear, nose and throat clinical evaluation, in particular otoscopy and otomicroscopy, when needed.

The research includes three observational clinical phases

- **Time 0 (T_0):** First clinical evaluation, before topic treatment.
- **Time 1 (T_1):** Second clinical valuation, after 7 days of topic treatment with alpha tocopherol acetate and polydecene (Filme Oto Spray) 3 puff each external auditory canal for 3 times/day.
- **Time 2 (T_2):** Third and last clinical evaluation, after other 7 days of topic treatment, 3 puff each external auditory canal for 3 times/day (total 14 days of treatment from T0).

For clinical Otoscopic evaluation a score was used in order to analyze data in objective way

- **0:** Complete obstruction of external auditory canal.
- **1:** Ear wax plug obstructing 2/3 of external auditory canal.
- **2:** Ear wax plug obstructing 1/3 of external auditory canal.
- **3:** Absence of ear wax.

All patients selected for this study at time 0 had a complete obstruction of bilateral external auditory canal.

Excluded patients were affected by tympanic membrane perforation, external auditory canal malformation or neoformation such as exostosis or osteomas, inflammatory or infective diseases of external ear, patients previously undergoing otologic surgery or subjects referring hypersensitivity or allergy to alpha-tocopherol acetate or polydecene.

The study patients were divided into three groups standing the age

- **Group A:** Children and adolescents, age range 3–18 years, 44 patients (23 M and 21 F), age 13.4.
- **Group B:** 47 patients (23 M and 24 F) age range 18 and 60 years, age 49.7.
- **Group C:** 46 patients (24 M and 22 F) aged over 60, mean age 68.2.

The objective of the treatment was to completely remove the ear wax plug in 7 days (primary endpoint) or in 14 days (secondary endpoint), reaching score from 0 to 3. For statistical analysis, the Anova one-way was used within the groups and between the three groups: A, B and C group. P-values<0.05 were considered statistically significant. The analyses were carried out with statistics 8.0.3.

Results

Reached scores after 7 days and 14 days of topic treatment with alpha tocopherol acetate and polydecene (Filme Oto Spray) are resumed in Table 1. Topic treatment was effective in the reduction of the ear wax in all patients and in most cases the removal was complete only 7 days of therapy.

(A)			
Scores	**Group A**	**Group B**	**Group C**
T_1–7 days of topic treatment	44 patients	47 patients	46 patients
0	4	8	13
1	4	9	7
2	5	7	4

3	31 (70.45%)	23 (48.93%)	22 (47.82%)
(B)			
Scores	Group A	Group B	Group C
T_2 –14 days of topic treatment	44 patients	47 patients	46 patients
0	0	1	6
1	2	8	9
2	5	10	8
3	37 (84.09%)	28 (59.5%)	23 (50%)

Table 1. Scores reached after 7 days (A) and 14 days (B) of topic treatment with alpha tocopherol acetate and polydecene (Filme Oto Spray) in patients group A, B and C. T_1: First time phase; T_2: Second time phase.

Group A patients reached endpoints more than Group B and C ones, with statistical significance ($p<0.05$) (Tables 2 and 3).

Data summary				
Patients	**Number**	**Mean**	**Std. Dev.**	**Std. Error**
Group A	44	2.4318	0.9976	0.1504
Group B	47	1.9574	1.1788	0.1719
Group C	46	1.7826	1.3319	0.1964
Anova summary				
Sources	Degrees of freedom	Sum of squares	Mean square	p-value
Between groups	3	10.1059	5.053	0.0292
Within groups	134	186.5421	1.3921	
Total	137	196.6481		

Table 2. Statistic results at T_1, after 7 days of topic treatment with alpha-tocopherol acetate (fime oto spray).

Data summary				
Patients	**Number**	**Mean**	**Std. Dev.**	**Std. Error**
Group A	44	2.7727	0.6048	0.0912
Group B	47	2.2553	0.9661	0.1409
Group C	46	2.0217	1.1252	0.1659
Anova summary				
Sources	Degrees of freedom	Sum of squares	Mean square	p-value
Between groups	3	13.2345	6.6172	0.0007
Within groups	134	115.6361	0.863	
Total	137	128.8706		

Table 3. Statistic results at T_2, after 14 days of topic treatment with alpha-tocopherol acetate (Filme Oto Spray).

Analysing Table 1, we can see that group A already permits a complete visualization of the tympanic membrane in 70.45% at T_1 (7 days after the start of therapy); the percentage increases to 84.09% at T_2. Group B and C in contrast to group A at T_1 allow visualization of the tympanic membrane in just under half of the subjects (48.93% and 47.82% respectively) and subsequently at T_2 a slight increase can be seen in both groups (group B: 59.5%, group C: 50%). The group A compared to groups B and C have higher percentages, which means that the young age favors the effectiveness of Filme Oto Spray in removing the plug of earwax and thus allowing visualization of the tympanic membrane.

Discussion

Earwax plugs are very annoying and cause a lowering of the hearing threshold causing troubles in interpersonal relationships, it is therefore very important to prevent and treat this pathology. The use of ear washes has some side effects in several patients it can cause a sense of dizziness and damage of the tympanic membrane so, before using this method, it would be better to set up a ceruminolytic therapy. Only after therapy, an auricular lavage can be performed, which will be easier due to the action of the ceruminolytic.

Another technique for removing earwax plugs is the manual removal that use the microscope and speculums to allows visualization and localization of the earwax plug in the external ear canal; thanks to the use of surgical instruments such as a curette loop or spoon to an aspirator we could practice the remove of the earwax plug. The use of this technique involve that the patient is steady still and compliant precisely to avoid the risk of iatrogenic tympanic perforation.

The use of such invasive techniques, as ear washing rather than the removal of earwax under microscopic vision can be very difficult and dangerous in uncooperative patients, such as children and some categories of adults. The topical applications with combination of alpha tocopherol acetate and polydecene (Filme Oto Spray) has given very satisfactory results in ceruminolytic action. This research analyzed its cerumenolytic propriety. Alpha tocopherol acetate (vitamin E) is used in ear nose and throat practice standing to its anti-inflammatory, antioxidant and restorative action [7,8].

Many ceruminolytics effective in removing ear wax plugs impacted by the ear canal are reported in the literature, and in most cases additional manual maneuvers is required. These pharmaceutical preparations are preferred for patients with very hard ear wax [9-11]. Furthermore, it has been observed that the association urea+hydrogen/peroxide+glycerol are better than saline solution or simple water in the clearance of ear wax without additional invasive manual maneuvers. Ceruminolytics based on sodium bicarbonate and paradichlorobenzene is followed by mechanical removal, compared to normal saline solutions. Glycerol-based ceruminolytics, sodium docusate, almond oil, hydrogen peroxide+glycerol and peanut oil+chlorobutanol +paradichlorobenzene have been found to be significantly effective in terms of ceruminolytic action [9-14].

In another study, conducted by Singer et al. comparing the efficacy between docusate sodium solution and triethanolamine polypeptide drops, it is found that docusate sodium was more effective especially in patients younger than 5 years of age, but despite this, most patients were treated later with ear lavage to allow visualization of the tympanic membrane [15].

Although several researches studied type of cerumenolytic and its effectiveness, there is no high-quality evidence to arrive to a conclusion about comparisons among these molecules action [12-20]. The present study analyzed 137 patients, 76 patients (55.4%) reached score 3 (absence of ear wax) after 7 days of topic treatment with alpha-tocopherol acetate (Filme Oto Spray), of them 31 subjects (70.45%) were children and adolescent aged between 3 and 18 years old, 23 (48.93%) and 22 patients (47.82%) had an age respectively between 18 and 60 years old and over 60 years old.

After 14 days of topic treatment, 88 patients (64.2%) reached score 3 (absence of ear wax after therapy); of them 37 patients (84.09%) were in Group A, 28 (59.5%) and 23 subjects (50%) were respectively in the Group B and C. Data had statistical significance. During the study, no patients reported any side effects after using the drug. The use of spray was accepted by all patients especially by the parents of the younger patients who found it easy to be administered and with satisfactory compliance. Adults also preferred the use of ear spray therapy over traditional washing techniques for earwax plug removal [21].

Conclusion

The data collected prove that the use of the composition of alpha-tocopherol acetate and polydecene (Filme Oto Spray) allows the cleaning of the auditory canal and the visualization of the tympanic membrane after 7 days after the first application. Younger individuals respond better to spray therapy than older individuals; in addition the patients are more compliant in using topical treatment than using invasive methods. Thanks also to the results obtained, and the use of alpha-tocopherol acetate with polydecene in spray therapy in children is more accepted than classical invasive methods. Topic treatment was effective in reducing the ear wax in all patients and in most cases the removal was complete and after only 7 days of local therapy.

References

1. Bortz Jeffrey T, Wertz Philip W, Downing Donald T. Composition of cerumen lipids. J Am Acad Dermatol 1990; 23(5): 845–849.
2. Guest JF, Greener MJ, Robinson AC, et al. Impacted cerumen: Composition, production, epidemiology and management. QJM 2004; 97(8): 477-88.
3. Sridharan K, Sivaramakrishnan G. Cerumenolytics with or without manual extraction for impacted earwax: A network meta-analysis of randomised clinical trials. Clin Otolaryngol 2021; 46(3): 464-473.
4. Sharvill J. Ear wax removal and core services in general practice. BMJ 2021; 374: n2077.
5. Michaudet C, Malaty J. Cerumen impaction: Diagnosis and management. Am Fam Physician 2018; 98(8): 525-529.
6. Shope TR, Chen CP, Liu H, et al. Randomized trial of irrigation and curetting for cerumen removal in young children. Front Pediatr 2019; 7: 216.
7. Testa D, Marcuccio G, Lombardo N, et al. Role of α-tocopherol acetate on nasal respiratory functions: Mucociliary clearance and rhinomanometric evaluations in primary atrophic rhinitis. Ear Nose Throat J 2021; 100(6): NP290-NP295.
8. Testa D, Marcuccio G, Panin G, et al. Nasal mucosa healing after endoscopic sinus surgery in chronic rhinosinusitis of elderly patients: Role of topic alpha-tocopherol acetate. Aging Clin Exp Res 2017; 29(Suppl 1): 191-195.
9. Meyer F, Preu R, Angelow A, et al. Cerumen impaction removal in general practices: A comparison of approved standard products. J Prim Care Community Health 2020; 11: 2150132720973829.
10. Anh NQ, Numthavaj P, Bhongmakapat T. Comparison of the cerumenolytic activities of new and currently used agents. Ear Nose Throat J 2021; 29: 145561320986060.
11. Piromchai P, Laohakittikul C, Khunnawongkrit S, et al. Cerumenolytic efficacy of 2.5% sodium bicarbonate versus docusate sodium: A randomized, controlled trial. Otol Neurotol 2020; 41(7): e842-e847.
12. Aaron K, Cooper TE, Warner L, et al. Ear drops for the removal of ear wax. Cochrane Database Syst Rev 2018; 7(7): CD012171.
13. Kenwright S. Removal of ear wax in primary care: Be wary about which services are withdrawn and which patients are affected. BMJ 2020; 371: m3952.
14. Horton GA, Simpson MTW, Beyea MM, et al. Cerumen management: An updated clinical review and evidence-based approach for primary care physicians. J Prim Care Community Health 2020; 11: 2150132720904181.
15. Singer AJ, Sauris E, Viccellio AW. Ceruminolytic effects of docusate sodium: A randomized, controlled trial. Ann Emerg Med 2000; 36(3): 228-32.
16. Sugiura S, Yasue M, Sakurai T, et al. Effect of cerumen impaction on hearing and cognitive functions in Japanese older adults with cognitive impairment. Geriatr Gerontol Int 2014; Suppl 2: 56-61.
17. Pavlidis C, Pickering JA. Water as a fast acting wax softening agent before ear syringing. Aust Fam Physician 2005; 34: 303-304.
18. Prowse SJ, Mulla O. Aural microsuction for wax impaction: Survey of efficacy and patient perception. J Laryngol Otol 2014; 128: 621-625.
19. Testa B, Testa D, Mesolella M, et al. Management of chronic otitis media with effusion: The role of glutathione. Laryngoscope 2001; 111(8): 1486-1489.
20. Leong AC, Aldren C. A non-randomized comparison of earwax removal with a “do-it-yourself” ear vacuum kit and

a jobson-horne probe. Clin Otolaryngol 2005; 30(4): 320-323.

21. Petrosino V, Motta G, Tenore G, et al. The role of heavy metals and Polychlorinated Biphenyls (PCBs) in the oncogenes is of head and neck tumors and thyroid diseases: A pilot study. Bio Metals 2018; 31(2): 285-295.

***Correspondence to:**

Domenico Testa

Department of Otorhinolaryngology Head and Neck Surgery Unit

University of Campania “Luigi Vanvitelli”

Napoli

Italy

E-mail: domenico.testa@unicampania.it