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Cerumen Impaction Removal in General Practices: A Comparison of Approved Standard Products

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Abstract

Background: Ear irrigation is a commonly used method for removing earwax in general practice. There is no firm evidence if no pre-treatment is as good as pre-treatment with various standard preparations. **Aim:** To assess the effectiveness of no pre-treatment compared to pre-treatment with commercially available cerumenolytics and to assess which preparation is best suited for pre-treatment. **Methods:** This is a pragmatic observational study of patients with cerumen treated from a single GP with 3 different preparations or no preparation prior to standardized ear irrigation. Generalized linear mixed models with logit link function were performed to assess the effectiveness of pre-treatment with different preparations and no pre-treatment. The models were adjusted for age group (<70, ≥ 70) and sex. **Results:** A total of 168 patients (298 ears, 58 % female, median age 65 years) consulted for obstructive cerumen, some of them several times. The cerumen was successfully removed in 70% (208/298). Comparing any preparation to no preparation (aggregated comparison), the odds ratio for complete clearance was 1.35 (95%confidence interval: 0.69-2.65). Comparing the preparations individually, the odds ratio of the docusate-sodium-based preparation was 1.87 (95% CI: 0.79-4.42) indicating a higher effectiveness. Although, not statistically significant. Ear irrigation was less successful for patients aged $\geq$ 70 years (OR = 0.48, 95% CI: 0.23-0.98). **Conclusions:** The aggregated comparison indicates a slight trend toward a higher effectiveness of any pre-treatment compared to no pre-treatment. The effect-size of docusate-sodium-based pre-treatment indicates a higher effectiveness of cerumen impaction removal. Nevertheless, superiority could not be shown conclusively according to the statistical significance given the restricted sample size.

Keywords

cerumen, ear irrigation, earwax removal, cerumenolytic agents, pre-treatment

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Background

Cerumen impaction causes symptoms such as hearing loss, ear noise or ear pain and is a common reason for consultation in general practice.[1,2] About 5% of adults, 10% of children and one-third of geriatric and cognitively impaired individuals are affected.[3,4] Cerumen becomes drier at an older age due to atrophy of the cerumen glands. This, together with the fact that hair in the ear canal becomes coarser with age, leads to a higher rate of cerumen impaction in elderly patients.[1,5] Furthermore, the natural self-cleaning mechanism can be inadequate and cerumen can become impacted, due to illness-related changes such as scaling skin disorders, for example, eczema and psoriasis, anatomical abnormalities of the ear canal and the routinely use of hearing aids or earplugs.[2] According to the *Clinical Practice Guideline: Earwax (Cerumen Impaction) of the American Academy of Otolaryngology- Head and Neck Surgery*, the following options are recommended for removing impacted cerumen: watchful-waiting, education,

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Table 1. Preparations Used for Pre-Treatment.

Preparation and German trade names	Constituents
Docusate-sodium-based	
Audilyse®	Dioctylnatriumsulfosuccinat, ethoxydiglycol, phenoxyethanol + caprylyglykol, water
Water-based	
Alvita®	Sterilized seawater (0.9% NaCl)
Oil-based	
Cerustop®	Caprilic/capric triglyceride, liquid paraffin, isostearyl isostearate, almond oil, PEG-40 sorbitan peroleate, Vitamin E

cerumenolytic agents, ear irrigation or other manual techniques for removing earwax (cerumen spoon, alligator forceps, suction, hook).[6] Earwax removal is one of the most frequently performed procedures in the head and neck area[7] and one of the few ENT procedures performed in primary care. Ear-nose-throat (ENT) specialists mainly use instruments to remove earwax. This procedure is fast, little time-consuming and rarely causes complications when performed by a well-trained practitioner.[1,8] If performed by a less experienced practitioner manual cerumen removal can cause ear canal trauma and perforation of the tympanic membrane.[9] Moreover, additional equipment such as headlamp or an ear microscope is needed to improve the safety of the manual removal.[10] Therefore, treatment with cerumenolytic agents and ear irrigation may be more suitable for general practitioners. According to a survey of 111 German general practitioners (GPs) in 2010, around 73% performed ear irrigation. In Germany, 21% of GPs reported that they infrequently use cerumenolytic agents.[11] In the UK, 97% of GPs and practice nurses advised pre-treatment prior to syringing the ear.[12] However, a Cochrane review concluded that there is no firm evidence whether or not one type pre-treatment with a cerumenolytic is more effective than another.[13] The aim of this study was to assess the effectiveness of no pre-treatment compared to pre-treatment with different preparations to aid the removal of earwax in adults and children and to assess which preparation is best suited for pre-treatment.

Methods

Design and Patient Sample

This was a pragmatic practice based observational study carried out from October 2015 to February 2018 by one GP in the setting of his practice, in a nursing home as well as at patient homes. Patient complaints were hearing impairment or otological symptoms such as blocked ear sensation or otalgia. Only patients with an occluding cerumen (cerumen classification Manchaiah type 3) or fully occluding cerumen and debris (cerumen classification Manchaiah type 4) were included in the study.[14] An occluding cerumen was defined as soft and/or hard wax, with very little or no visualization of the tympanic membrane, but a gap between earwax and ear canal wall.[14] Fully occluding cerumen and debris were defined as a completely blocked ear canal with soft or hard wax and also with debris and no visualization of tympanic membrane.[14] Patients with contraindications such as known ear pathology, acute or chronic otitis media, previous eardrum injury, known eardrum defects and known or suspected allergic reactions to cerumenolytics were excluded.

Intervention

Patients were treated in consecutive groups with different commercially available preparations (drops or sprays) or no preparation prior to the ear irrigation with 500 ml water at body temperature. We classified the earwax removal solutions in docusate-sodium-based, water-based and oil-based according to the first (main) ingredient (Table 1). The preparations were applied by the GP 20 min prior to syringing the ear(s). Some patients were treated several times throughout the observation period and not always with the same ear and the same preparation. Success of the treatment (complete clearance; incomplete clearance/no clearance) and any side effects were documented.

For ear irrigation, a commercially available manual pressure flushing system (OtoClear® Ear Irrigation wash kit) was used.[15] It was a half-liter filling container with a finger lever pump, a temperature measuring strip and a 3-way disposable flushing nozzles. It was based on a modified household plastic spray bottle with a spray arm, on which the disposable nozzles are locked. With the finger lever pump a constant water pressure was guaranteed. A temperature measuring strip assured the right temperature of the rinsing water. A frequently underestimated side effect of ear irrigation is a vestibular caloric stimulation, which can occur if the irrigation fluid deviates only 1 to 2°C from the ideal temperature (37°C). Additionally, it fulfills hygienic requirements. The device was also used for external visits and for children.[15]

Data Analysis

We compared treatment success between the different treatment groups. The outcome variable *treatment success* (Yes/

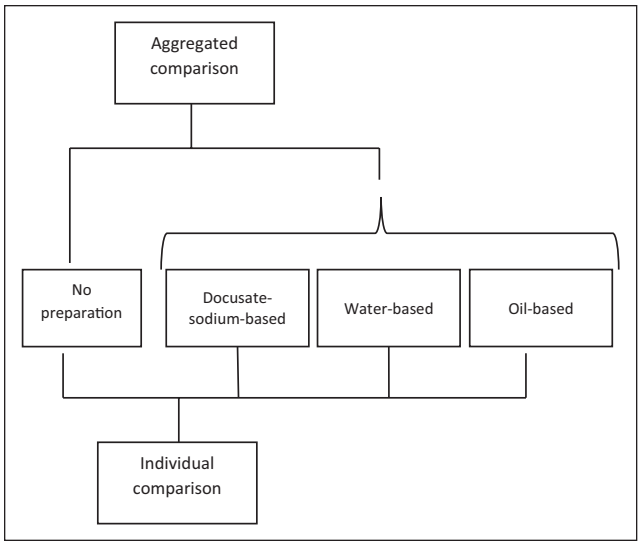

Figure 1. Data analysis comparing the different preparations.

No) was defined as the complete clearance of wax and the ability to see the tympanic membrane (successful treatment) or an incomplete clearance/no clearance of wax and therefore a blocked visualization of tympanic membrane (unsuccessful treatment). To account for the fact that some patients were treated more than once during the study period and some had both ears irrigated while others only one, also not always with the same preparation, we performed generalized linear mixed regression models with logit link function. To assess clustering in the data set we calculated the Intraclass Correlation Coefficient (ICC). The ICC in our study was 0.39, suggesting clustering.[16] Generalized linear mixed regression takes into account the clustered structure and the repeated measurements. The higher-level unit (patient) had its own intercept in the model and the subject-specific intercepts (ears) were used to measure the differences among no pre-treatment and pre-treatment with the different preparations. We first performed the regression comparing no pre-treatment with pre-treatment (aggregated comparison, Figure 1). In a second step, we performed the regression comparing the different preparations individually (Figure 1). Each model was adjusted for age group (<70, ≥ 70) and sex.

Results

Participant Characteristics and Descriptive Statistics

A total of 298 ears from 168 patients (58% (98/168) female, median age 65, age range 4-104 years) were treated. A fully occluding cerumen (type 4) was found in 89% (264/298) of the ears and an occluding cerumen (type 3) in 11% (34/298). Table 2 shows how many times no pre-treatment and pre-treatment with the different preparations were applied as well as the frequencies the earwax was successfully removed. In 70% (208/298) of cases the earwax was successfully removed. A complete clearance of earwax was achieved in 64% of cases when no pre-treatment was applied. The highest complete clearance rate was achieved with the docusate-sodium-based preparation (83%) (Table 2). There were 5 caloric induced nystagmus due to incorrect water temperature while rinsing the ear and one auditory canal irritation, which was probably caused by the ear irrigation tip.

Aggregated Comparison of No Pre-Treatment with Pre-Treatment

Those with pre-treatment had 35% higher odds (OR = 1.35; 95% CI: 0.69-2.65) of complete clearance of cerumen compared to those with no pre-treatment. Adjusting for age and sex did not change the result. Neither the unadjusted odds nor the adjusted odds were significant. Males had a 13% higher odds ratio compared to females (OR = 1.13; 95% CI: 0.53-2.43). The successful removal of earwax was less likely in patients aged ≥ 70 years (OR = 0.47, 95% CI: 0.23-0.97).

Individual Comparison

Comparison of docusate-sodium-based, oil-based and water-based preparations with no preparation. Comparing the preparations individually with no preparation, the docusate-sodium-based preparation had, with 1.87 (95% CI: 0.79-4.42), the highest odds ratio. Followed by the oil-based preparation with OR = 1.41 (95% CI: 0.59-3.34) and the water-based preparation (OR: 0.99; 95% CI: 0.43-2.31) (Table 3). The interpretation of the results did not differ when adjusting for age and sex. The odds of complete clearance for males were 10% higher compared to females, (95% CI: 0.51-2.38). Ear irrigation was less successful for patients aged ≥ 70 years (OR = 0.48, 95% CI: 0.23-0.98).

Discussion

Main Results

In about 3 out of 4 cases, earwax was successfully removed. The aggregated comparison showed a 35% higher odds in successful clearance of cerumen using a preparation. Comparing the preparations individually, the odds ratio of the docusate-sodium-based preparation was 1.87 (95% CI: 0.79-4.42) indicating a higher effectiveness. Although, not statistically significant. Complete clearance of wax was less likely in patients aged ≥ 70 years.

Interpretation of the Results and Comparison with Literature

In accordance with a systematic review from 2004, about 3 out of 4 ear irrigations were successful.[17] According to the

Table 2. Frequency of Different Preparations and No Preparation Applied and Divided into Successful Clearance and Unsuccessful Clearance of Ear Wax.

	Total ears, n (%)	Number of subjects, n (%)[a]	Complete clearance, n (%)	Incomplete clearance/no clearance, n (%)
No preparation	78 (26.2)	52	50 (64)	28 (36)
Docusate-sodium-based	69 (23.2)	47	57 (82.6)	12 (17.4)
Water-based	71 (23.8)	44	47 (66.2)	24 (33.8)
Oil-based	80 (26.8)	50	54 (67.5)	26 (32.5)

[a]Some subjects were treated more than once and not always the same ear as well as not always the same preparation.

Table 3. Crude and Adjusted Generalized Linear Mixed Regression Models with Log Link Function, Modeling the Probability of Complete Clearance of Wax, with Reference Group = No Preparation, n = 298.

Preparation	Crude model odds ratio (95% CI)	Adjusted model odds ratio (95% CI)
No preparation	1 [Reference]	1 [Reference]
Docusate-sodium-based	1.87 (0.79-4.42)	1.88 (0.79-4.49)
Water-based	0.99 (0.43-2.31)	1.04 (0.45-2.42)
Oil-based	1.41 (0.59-3.34)	1.32 (0.55-3.13)
Sex		
Female	-	1 [Reference]
Male	-	1.10 (0.51-2.38)
Age group		
<70	-	1 [Reference]
≥70	-	**0.48 (0.23-0.98)**

Note. Statistically significant results are displayed bold.

relative numbers (Table 2) the docusate-sodium-based preparation were with 83% better in complete clearance of earwax compared to no preparation, water-based and oil-based preparation with 64%, 66% and 67%, respectively. According to the generalized linear mixed regression, the effect size of docusate-sodium-based preparation indicates a higher effectiveness. However, given the restricted sample size, our results could not show superiority of docusate-sodium preparation according to the statistical significance. Our results are not in line with the results of a randomized clinical trial[18] and a systematic review,[13] where no significant difference between the preparations were found.

Other factors such as consistency of the cerumen and anatomic variations of the ear canal (eg, too narrow, too wide, too tortuous or surfer's ear) may play an important role. We did not collect these data in our study.

A randomized trial of ear irrigation in children compared different irrigation methods and devices.[19] Successful cerumen removal was achieved without cerumenolytic pre-treatment in 71% of participants using the same spray bottle irrigation device we used in our study. In our study, successful cerumen removal without pre-treatment was achieved in 64% of cases. The RCT found no difference in successful cerumen removal among the different irrigation methods tested. However, the spray bottle device was postulated to be particularly safe because its structure prevents deep penetration into the ear canal and water streams are aimed to the sides of the ear canal rather than directly at the tympanic membrane.[19] Using a syringe, constant water pressure cannot be guaranteed and depth and placement is difficult to control.[19]

The age-group ≥70 showed less success in complete clearance of cerumen. This can be explained by physiological age-related structural changes in the ear canal and earwax. According to the literature,[13] we had a small number (n = 6) of short-term and minor side effects. There were handling errors during the actual rinsing (because of an incorrect temperature control of the water n = 5; auditory canal irritation probably caused by the ear irrigation tip n = 1).

Strengths and Limitations

This is, to our knowledge, the largest study on earwax removal exceeding in each treatment arm the number of subjects of randomized controlled trials included in the Cochrane review on the subject. This was a pragmatic practice based observational study comparing 4 different treatment strategies. We believe risk of selection bias is low since patients were assigned consecutively and independently of age, sex or other individual characteristics and settings to one treatment. We also believe that risk of performance bias is low since only one GP, also trained in ENT, performed the ear irrigation with the same device and therefore reduced the chance that the ear irrigation differed in technique and

success. The manually operated pump mechanism was able to generate regulated and reproducible water pressure.[15] Therefore, it was possible to objectively compare the washing results within the examined groups, either in general practice as well as in patients or nursing homes.

One limitation of this study is that sample size of treatment groups was not calculated or predetermined. The treating GP switched between subgroups after reaching an approximate number of 60-80 ears. Therefore, treatment groups do not have exactly the same size and sample size may be too low to support the effect size. There has been only little research on safety and effectiveness of ear irrigation devices, which limits the discussion of this topic, but it also might be a strength of this study.

Conclusion

The aggregated comparison indicates a slight trend toward a higher effectiveness of any pre-treatment compared to no pre-treatment. The effect-size of docusate-sodium-based pre-treatment indicates a higher effectiveness of cerumen impaction removal. Nevertheless, superiority could not be shown conclusively according to the statistical significance given the restricted sample size.

Author's Contribution

FM* and RP* contributed equally to this project and should be considered co-first authors. FM initiated and planned the examination, recruited the patients, carried out the clinical measures in practice, assessed the success and contributed to the preparation of the manuscript. RP and SK were major contributors in writing the manuscript and management of study. EM was involved in data collection. SK, JFC, AA and RP analyzed and interpreted the data. All authors finalized, provided critical review, and approved the final manuscript.

Declaration of Conflicting Interests

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Ethics Approval

According to a decision of the Ethics Committee of the Bavarian State Medical Association, examinations for quality assurance (routine medical duties, control, management, security of current common practice, patient care) with anonymized data (no code list available, no personal reference can be made) are not subject to consultation (decision of 11.06.2019).

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