A quasi-randomised controlled trial of water as a quick softening agent of persistent earwax in general practice

J A H Eekhof, G H de Bock, S Le Cessie and M P Springer

SUMMARY

Background: *Earwax is a common problem in general practice. The incidence of complaints owing to earwax in general practice in the Netherlands is 39.3 per 1000 patients.*

Aim: *To determine the feasibility of a strategy using water as a quick dispersant for persistent earwax, compared with the usual strategy using oil as a dispersant for three days in a general practice setting.*

Design of study: *Practice based, prospective controlled intervention study.*

Setting: *Forty-two patients (59 ears) in four general practices in the Netherlands.*

Method: *Patients with persistent earwax were randomised into an intervention group and a control group. For patients in the intervention group, water drops at body temperature were dropped into the impacted ear and the auditory meatus was blocked with a wet wad of cotton. After the patient had waited for 15 minutes in the waiting room a series of attempts at syringing was completed. Patients in the control group received the usual strategy and were instructed to soften the earwax with oil each night before sleeping and to block the auditory meatus with a wad of cotton, for three days. They were asked to come back after three days for the second attempt of syringing. For both strategies the mean number of syringing attempts (and 95% confidence interval) was calculated and compared by testing the difference between the means using a t-test for independent samples. All ears in which the wax was still persistent after another five syringing attempts were given the value of 6 in the calculations.*

Results: *The mean number of syringing attempts needed per patient in the intervention group was 3.0 (95% CI = 2.4 to 3.6) and for the control group, the mean was 2.4 (95% CI = 1.7 to 3.1). The difference between means (0.6, 95% CI = 0.3 to 1.5) was not statistically significant (*P = *0.18).*

Conclusion: *A patient with persistent earwax can stay in the waiting room following the initial series of five attempts at syringing, with water instilled in the ear canal. After 15 minutes, the earwax is removed as easily as in the usual strategy using oil instilled for three days. The strategy using water as a dispersant for persistent earwax is quick and more convenient for the patient.*

Keywords: *earwax; ear syringing; softening agent.*

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Introduction

EARWAX is a common problem in general practice. The incidence of complaints owing to earwax in general practice in the Netherlands is 39.3 per 1000 patients.[1] Although syringing is not a recommended method, according to otolaryngologists, it is by far the most common method of removing earwax; it is used by 95% of general practitioners (GPs).[2] For most patients the earwax can be easily removed during the initial visit. In a few cases the wax is very impacted and extremely difficult to remove, even after several attempts at syringing. For these patients an additional strategy is necessary. The usual advice is to soften the persistent earwax with a ceruminolytic and to return within a few days for another attempt at syringing. In the Netherlands, as well as in the United Kingdom, most GPs prescribe (olive) oil as a ceruminolytic agent for persistent earwax.[2] *In vitro* studies have proven that (olive) oil appeared to be almost totally ineffective as an earwax dispersant.[3,7] In some of these studies, water – which was originally intended as a control substance – surprisingly proved to be one of the fastest working and most effective agents.[3-5] This prompted our study to investigate an alternative strategy for a quick dispersant of persistent earwax, by comparing the use of water with the usual strategy of using oil, for three days.

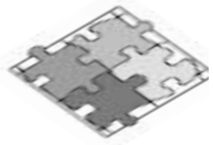
Method

The study was performed in four general practices with a total of 14 000 patients. All patients who visited the practice in the period from July 1997 to October 1997 with complaints resulting from earwax were offered syringing. The syringing was done in a standardised manner (Box 1).

Reasons for not offering syringing were tympanic membrane perforation, middle ear operation, otitis externa, swimming within the previous 72 hours or having used ceruminolytics within the previous 72 hours. After each attempt at syringing the auditory canal was checked with an auriscope and the extent of blocking of the auditory canal was noted (obstruction levels of 0–25%, 25–49%, 50–74% and 75–100%). Persistent earwax was defined as earwax that was still persistent (more than 75%) after five attempts at syringing. A total of 130 patients (224 ears) were treated for earwax.

In 42 patients (31 right and 28 left ears) the earwax was still persistent (more than 75%) after five syringes. Informed consent was requested from these 42 patients (20 men, mean age = 51 years, standard deviation [SD] = 16). All 42 patients agreed and were included in the study. The patients were randomised into an intervention group (n = 22, year of

HOW THIS FITS IN



What do we know?
In-vitro studies have proen that water is much more effective than oil as an earwax dispersant.

What does this paper add?
When earwax is still persistent after several syringing attempts, the earwax can be easily removed after waiting for 15 minutes with water in the ear.

Manual ear syringing[8]

- The procedure was explained to the patient.
- An ear syringe of 100 cc was used.
- The syringe was filled with tap water at body temperature.
- The patient held a receptacle below the ear to be syringed.
- The tip of the nozzle of the syringe was advanced into the patient's external auditory meatus.
- Traction of the auricle in an upwards and backwards direction to straighten the auditory canal.
- The flow of the syringe into the auditory meatus was directed towards the roof of the canal.
- After each time the syringe was emptied, the canal was checked for the persistence of wax.
- This process was repeated five times.

Box 1. Description of syringing methodology used in the study.

birth was even) and control group (n = 20, year of birth was odd) which means that in a patient with both ears having persistent earwax, both ears were treated with the same strategy. We randomised patients instead of ears because it was impractical to offer individual patients different treatments for different ears. For all ears the number of syringing attempts needed to remove the earwax was noted. A difference of two syringing attempts between the mean of intervention and control group was found to be clinically significant. Thirteen people were therefore needed in each group (with α = 0.1, β = 0.2, and an estimated SD of 1.5). With groups of 20 and 22 patients, a difference of 1.6 between means would be statistically significant.

For patients in the intervention group, drops of water at body temperature were dropped into the impacted ear and the auditory meatus was blocked with a wet wad of cotton. After the patient had waited for 15 minutes in the waiting room, a series of attempts at syringing was made. Patients in the control group received the usual strategy and were instructed to soften the earwax with oil each night before sleeping and to block the auditory meatus with a wad of cotton, for three days. They were asked to return after three days for a second attempt at syringing.

Analysis

For both strategies the mean number of syringing attempts (and 95% confidence interval [95% CI]) was calculated and compared by testing the difference between the means, using a *t*-test for independent samples. For patients with persistent earwax in both ears, the mean number of syringing attempts needed for both ears in one patient was used for the calculations. All ears in which the wax was still persistent after another five syringing attempts were given the value of 6 in the calculations. Data for this study were analysed using SPSS for Windows 9.0. The Medical Ethics Committee of the Leiden University Medical Centre approved the design and requested informed consent from all participants.

Results

In the intervention group the mean number of syringing attempts needed was 3.0 (95% CI = 2.4 to 3.6) for the control group the mean was 2.4 (95% CI = 1.7 to 3.1). The difference between these means (0.6; 95% CI = -0.3 to 1.5) was not statistically significant (P = 0.18). Note that even when the real difference was 1.5 (outermost value confidence interval), it is fewer than two syringing attempts and not clinically significant. There were two patients with one ear in which, after five syringing attempts, the earwax was still present: one patient from the intervention group and one patient from the control group.

Discussion

No clinically significant differences were found between the alternative strategy, with water as a quick softening agent, compared with the usual strategy. The implication is that if there is persistent earwax after five syringing attempts then the patient does not have to go home and use oil for three days before coming back for a further attempt at syringing.

Table 1. Number of syringes needed per patient to remove the earwax[a].

Mean number of syringing attempts needed per patient	Number of patients in which the earwax was removed after each attempt at syringing	
	Intervention (n = 22)	Control (n = 20)
1	4	6
1.5	1	2
2	2	5
2.5	3	1
3	2	2
3.5	4	0
4	2	0
5	3	4
6	1	0
Mean (95% CI)	3.0 (2.4–3.6)	2.4 (1.7–3.1)

[a]For patients having persistent earwax in both ears, the mean of the number of syringing attempts needed for both ears in one patient was used for the calculations.

Staying in the waiting room with water in the ear, for 15 minutes after the initial attempt at syringing, led to comparable results.

Randomising patients by year of birth (odd or even) is probably not the most robust method because operators could have known in advance in which group a patient would be randomised. Nevertheless, the operators did not know in advance in which of the 130 patients the earwax was still persistent after the first five attempts at syringing. All 42 patients with persistent earwax after the first of five syringing attempts were included in the study.

We did not study patient acceptability in comparing the two strategies. Some patients spontaneously mentioned that they would rather have the complaint dealt with on one visit than to return after three days. We have not chosen for an inactive control group. If, in the 42 included patients the treatment (the first of five syringing attempts) turned out to be unsuccessful, then it was deemed unacceptable to send them home without any further treatment. Further studies must reveal if a second out of five syringing attempts, consecutive to the first attempt, is just as effective as waiting for 15 minutes.

The difference between the substances of water and oil made a blind study unfeasible. The choice was made to instil water for 15 minutes rather than for three days, since an *in vitro* study has shown that earwax is largely disintegrated in water within 15 minutes.[5] The prolonged use of water in the external ear canal may cause softening of the skin and secondary otitis externa. It is also impractical to keep an ear canal completely filled with water over a longer period. Using oil for a period of 15 minutes was not considered feasible because there is no evidence to suppose that oil takes any effect within this time.

Although otolaryngological textbooks do not generally consider ear syringing to be the optimum method for earwax removal, it is the method most commonly employed in general practice. Manual earwax syringing is a relatively safe procedure; it is easy to learn and may give gratifying results.[8] This is demonstrated by the results in three-quarters of the ears in our study, in which fewer then five syringing attempts were needed to remove the earwax. For the remainder, an additional treatment with a dispersant was necessary. Whereas otolaryngologists report that they frequently see complications as a result of syringing, none of the participating patients in our study had any complaints. The experience of the otolaryngologists can probably be explained by the 'iceberg phenomenon': they only encounter the few cases in which syringing leads to complications, out of a large total population.

Our study showed that water proves to be a quick and effective dispersant for earwax, not only *in vitro* but also in daily practice with real patients. The alternative strategy using water yielded similar results to the strategy of instilling oil for three days and returning to the practice afterwards. Using water as a quick dispersant for persistent earwax is a more convenient treatment for the patient.

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