*The Journal of Laryngology & Otology (2013), **127**, 1067–1070.*

doi:10.1017/S0022215113002375

MAIN ARTICLE

Finding the most effective cerumenolytic

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Abstract

Aim: To conduct an *in-vitro* study to determine the most effective topical cerumenolytic.

Method: Cerumen was collected from patients who attended the ENT out-patient clinic. The collected cerumen was formed into a homogeneous ball. Discs of wax were punched out and weighed to create samples of uniform shape and size. Each cerumen sample was placed in a tube which contained one of six test solutions. The tubes were observed at specific time points. Digital photographs were taken to record the degree of cerumen disintegration. The cerumen discs were then removed from the solutions, dried and re-weighed.

Results: Distilled water caused the greatest reduction in the mass of the cerumen disc. Cerumen placed in distilled water and in sodium bicarbonate solution showed substantial disintegration at 12 hours. Cerumen placed in solutions containing oil-based agents showed no visible sign of disintegration and no reduction in dried weight.

Conclusion: Distilled water resulted in the greatest degree of cerumenolysis. Oil-based cerumenolytics were ineffective.

Key words: Cerumen; Cerumenolytic Agents; In Vitro

Introduction

Cerumen is the brownish yellow, waxy secretion produced by the external auditory meatus. It is largely composed of desquamated sheets of keratinocytes. It also contains lipids and peptides which are secreted by the sebaceous and apocrine glands in the external auditory canal.[1] Cerumen acts as a lubricant and a hydrophobic protective layer on the meatal skin. It also contains lysosomal enzymes and immunoglobulins, which gives it bactericidal properties.[2,3]

Cerumen accumulation is normally asymptomatic. It can however prevent adequate clinical examination and cause conductive hearing loss.[3] Elderly patients are at increased risk of cerumen accumulation, as the sebaceous glands atrophy with age and the cerumen becomes dry.[3] One-third of elderly patients in nursing homes require removal of cerumen every year.[4] Hearing aids prevent the natural extrusion of cerumen, and patients with narrow external auditory canals and dermatological conditions are at increased risk of cerumen accumulation.

There are a range of devices and techniques used to mechanically remove cerumen: syringing, irrigation and suction with magnification.[4] Generally, mechanical removal is a safe procedure; however, there are reports of it causing severe otological trauma.[4]

Cerumenolytics are topical agents used to aid cerumen removal. They can be divided into oil-based and aqueous-based agents. Cerumenolytics work by hydrating the desquamated sheets of keratinocytes and by inducing keratolysis, causing disintegration of the cerumen.[5]

A wide range of cerumenolytics are available; however, it remains uncertain which are most effective. Limited clinical trials have been performed, but over 30 years ago (see below), so little current evidence is available. Olive oil and sodium bicarbonate preparations are still recommended in the *British National Formulary*, as they are simple remedies that do not contain organic solvents, which can irritate the skin of the external auditory canal.[6]

We aimed to conduct an *in-vitro* study to determine the most effective cerumenolytic, using over the counter, topical agents.

Method

Cerumen was collected by mechanical removal from patients who attended the otolaryngology out-patient clinic over a 2-week period and who were aged between 19 and 89 years old. Verbal consent for inclusion in the study was obtained. Patients with clinical evidence of external ear disease were excluded.

The collected cerumen was mixed and formed into a homogeneous ball and stored in an air-tight container at room temperature. The cerumen was rolled into a disc 3 mm thick. Smaller discs of cerumen were punched out using the end of an otoscope speculum (5 mm

Accepted for publication 2 April 2013 First published online 22 October 2013

TABLE I
AGENTS TESTED

No	Agent
1	Distilled water
2	Olive oil
3	Sodium bicarbonate BP 5%
4	Sofradex*
5	Urea + hydrogen peroxide 5% in glycerol
6	Vistamethasone†

*Dexamethasone 0.05%, framycetin sulphate 0.5% and gramicidin 0.005%. †Betamethasone sodium phosphate 0.1%. No = test number; BP = British Pharmacopoeia

diameter), to create samples of uniform shape and size. These discs were then weighed (using AND model GR120 scales; AND, Tokyo, Japan); discs weighing 0.030 g were selected. Each of these cerumen samples was placed into a tube which contained 5 ml of one of six over the counter cerumenolytic preparations. We tested two oil-based agents (olive oil, and urea hydrogen peroxide 5 per cent in glycerol) and four aqueous-based agents (distilled water, sodium bicarbonate, Sofradex (Sanofi-Aventis, Guildford, UK) and Vistamethasone (Cardinal Health Martindale Products, Brentwood, UK)) (see Table I).

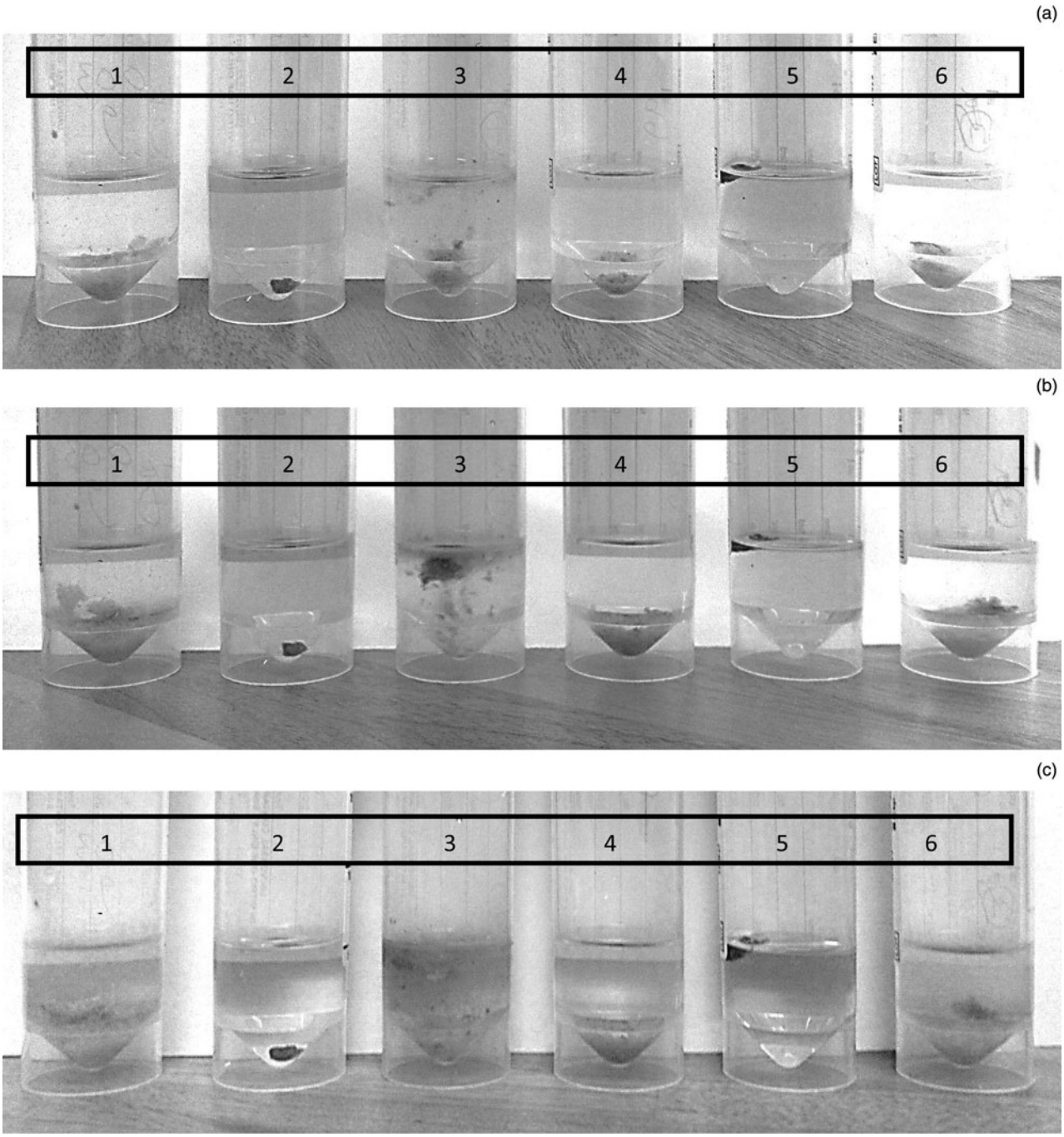

FIG. 1
Photographic evidence of cerumen disintegration at (a) 30 minutes, (b) 3 hours and (c) 12 hours. See Table I for identity of numbered solutions.

https://doi.org/10.1017/S0022215113002375 Published online by Cambridge University Press

The tubes were stored at room temperature and observed at 30 minutes, 3 hours and 12 hours. Digital photographs were taken to record the degree of cerumen disintegration. An individual blinded to the identity of the individual preparations recorded the degree of cerumen disintegration using a scale adapted from Fraser.[7] The cerumen discs were removed from the solutions at 12 hours, dried at room temperature for 48 hours and then re-weighed. The experiment was then repeated a further two times.

Results

Figure 1 shows photographic evidence of the cerumen disintegration. At 30 minutes (Figure 1a), the aqueous-based agents had caused slight disintegration of the cerumen, while the oil-based agents had not caused any visible change. At 3 hours (Figure 1b), partial disintegration of cerumen was seen in the aqueous-based agents, but no visible change was seen in the oil-based agents. At 12 hours (Figure 1c), the distilled water and the sodium bicarbonate solution had caused substantial disintegration of the cerumen, but the oil-based agents had still not caused any visible change to the cerumen.

Table II quantifies the degree of cerumen disintegration in the six test solutions, while Table III presents the dried weight of the cerumen disks following exposure to the test solutions. Figure 2 shows the percentage disintegration of cerumen caused by each of the six test solutions.

Discussion

In the present study, distilled water was the most effective cerumenolytic as it produced the greatest reduction in the weight of the cerumen test disc. Both the distilled water and the sodium bicarbonate solution caused substantial cerumen disintegration at 12 hours. The two aqueous-based agents had a much greater effect than the four oil-based cerumenolytics. The latter agents resulted in substantially less visible cerumen disintegration, and negligible (if any) decrease in the dried weight of the cerumen disc.

TABLE II
DEGREE OF CERUMEN DISINTEGRATION OVER TIME

Agent	Time elapsed		
	30 min	3 hr	12 hr
Distilled water	+	++	+++
Olive oil	–	–	–
Sodium bicarbonate	+	++	+++
Sofradex	+	++	++
Urea + hydrogen peroxide	–	–	–
Vistamethasone	+	++	++

Adapted with permission.[7] Min = minutes; hr = hours; + = slight disintegration; ++ = partial disintegration; +++ =substantial disintegration; – = no visible change

TABLE III
DRIED WEIGHT OF CERUMEN

Agent	Weight (g)			
	Trial 1	Trial 2	Trial 3	Mean
Distilled water	0.002	0.001	0.001	0.001
Olive oil	0.030	0.029	0.030	0.030
Sodium bicarbonate	0.004	0.006	0.007	0.006
Sofradex	0.005	0.008	0.009	0.007
Urea + hydrogen peroxide	0.030	0.030	0.028	0.030
Vistamethasone	0.008	0.006	0.007	0.007

In 2009, a Cochrane systematic review of trials of cerumenolytics identified eight clinical trials, all with small numbers of participants.[3] The reviewers concluded that there was no evidence that any one cerumenolytic was preferable to any other. Mehta (1985), Horowitz (1968) and Fraser (1970) found oil-based cerumenolytics to be less effective than aqueous-based cerumenolytics.[7–9] Fraser's *in-vivo* study found that Cerumol (arachis oil and chlorobutanol; Thornton & Ross, Huddersfield, UK) was a more effective cerumenolytic than sodium bicarbonate; however, Cerumol contains the skin irritants turpentine and dichlorobenzene.[7] Hinchcliffe (1955) noted that Cerumol caused significantly more aural discomfort than other topical preparations.[10] More recently, Bellini (1989) and Chalishazar (2007) discovered water to be a very effective cerumenolytic.[11,12]

- **Topical cerumenolytics are used to aid cerumen removal**
- **Many types are available but their relative efficacy is uncertain**
- **In this study, distilled water was the most effective cerumenolytic**
- **Oil-based cerumenolytics were relatively ineffective**
- **Use of distilled water as a cerumenolytic would be cheaper for both patients and hospitals**

The use of water as a cerumenolytic would have financial benefits for both patients and the National Health Service, reducing both expenditure on cerumenolytics and the time spent mechanically removing cerumen. In addition, mechanical cerumen removal is not without risk. It can be traumatic, causing bleeding of the external auditory canal and perforation of the tympanic membrane, and can also lead to an increased number of infections. Prolonged exposure of the ear to water is associated with otitis externa.[11]

The present investigation was limited by being an *in-vitro* study. The samples were kept at room temperature; however, the physiological temperature of the external auditory canal is higher. This may have

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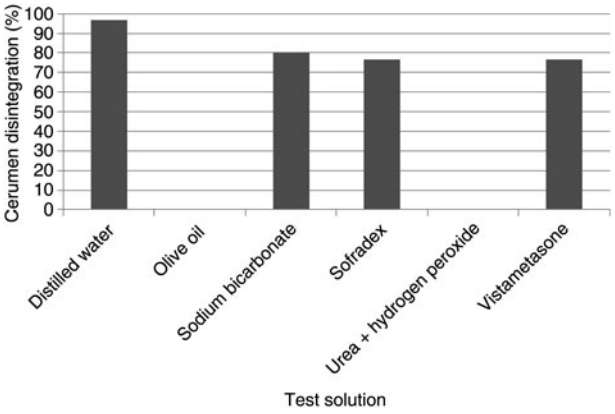

FIG. 2
Mean percentage cerumen disintegration caused by each test solution.

affected the cerumenolytic potential of the agents tested. The cerumen samples were from multiple patients, although differences in cerumen consistency were overcome by mixing the difference samples into one homogeneous ball. The study constituted an up to date, experimental trial using a variety of over the counter, topical agents, some of which had not previously been tested.

Conclusion

In the present study, distilled water caused the greatest degree of cerumenolysis. Oil-based cerumenolytics were relatively ineffective. A future, *in-vivo* study is required to assess the efficacy of distilled water as a cerumenolytic agent and to monitor for any adverse effects.

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Ms C Saxby takes responsibility for the integrity of the content of the paper
Competing interests: None declared