Q J Med 2004; **97**:477–488
doi:10.1093/qjmed/hch082

Review

QJM

Impacted cerumen: composition, production, epidemiology and management

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Summary

In the UK, some 2.3 million people suffer cerumen ('ear wax') problems serious enough to warrant management, with approximately 4 million ears syringed annually. Impacted cerumen is a major cause of primary care consultation, and a common comorbidity in ENT patients, the elderly, infirm and people with mental retardation. Despite this, the physiology, clinical significance and management implications of excessive and impacted cerumen remain poorly characterized. There are no well-designed, large, placebo-controlled, double-blind studies comparing treatments, and accordingly, the evidence surrounding the management of impacted cerumen is inconsistent, allowing few conclusions. The causes and management of impacted cerumen require further investigation. Physicians are supposed to follow the edicts and principles of evidence-based medicine and clinical governance. Currently, in patients with impacted cerumen, the lack of evidence makes this impossible.

Introduction

Impacted cerumen ('ear wax') is common,[1] often causes unpleasant symptoms[2] and is occasionally associated with serious sequelae, including hearing loss, social withdrawal, poor work function and perforated eardrums.[3] Impacted cerumen is also a common comorbidity in secondary care populations, including ENT patients, the elderly infirm[30] and people with mental retardation.[27] Moreover, management of impacted cerumen in, for example, diabetics and immunocompromised subjects, can pose problems for secondary care physicians.[36] Occasionally, surgery is an appropriate treatment.

Clinicians have sought an effective means to remove impacted cerumen for centuries. For example, softening earwax with the specific intention of facilitating removal dates to the 18th century.[4] Since then, a large number of drugs to loosen impacted cerumen have been routinely used in general practice and as over-the-counter medications.

To review the published literature, we conducted an electronic search of the Medline, Embase, Health Star, Current Contents, NHSEED and Cochrane databases. The search terms for the databases included 'cerumen', 'ear wax' and 'hearing loss'. The abstracts of the publications identified by this search strategy were assessed, and other papers identified manually from the citations.

Despite excessive and impacted cerumen being common, the literature review presented in this

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paper suggests that its physiology, clinical significance and management implications remain poorly characterized. There are no well-designed, large, placebo-controlled, double-blind studies comparing treatments. The dearth of rigorous evidence negates any attempt at systematically assessing optimal management strategies, our original intention when planning this review. Indeed, the lack of rigorous evidence precluded a formal systematic review in any of the areas covered.

Therefore, we outline the current state of knowledge concerning the composition, production and genetics of cerumen. This paper also reviews the symptoms, causes and epidemiology of impacted cerumen, as well as the clinical studies assessing the efficacy of the different approaches to cerumen removal. The review presents a baseline from which further prospective trials can be designed. Indeed, we hope that this paper might act as a spur for further research into this common condition.

Cerumen composition and production

Cerumen production is, essentially, a consequence arising from a unique anatomical locale. The auditory canal is the only cul-de-sac of stratum corneum in the body. Therefore, physical erosion cannot routinely remove stratum corneum in the auditory canal during turnover. Cerumen offers a means to expel stratum corneum.

Cerumen is composed of desquamated sheets of corneocytes,[5] originating from the deep and superficial external auditory canal, mixed with glandular secretions. Keratin accounted for up to 60% of the cerumen plug in 20 patients with recurrent impacted earwax,[6] for example. During histological analysis of a further eight patients, long sheets of undivided keratin were isolated, the morphology of which resembled superficial stratum corneum of the normal skin in the deep recesses of the auditory canal. Hard plugs contain more keratin sheets than softer wax. In contrast, corneocytes in the softer wax seem to undergo expansion.[6]

Sebaceous and cerumenous glands in the auditory canal secrete lipids and peptides, respectively, into the cerumen. Hairs in the external third of the canal also produce glandular secretions that contribute to cerumen's composition.[2] The balance of secretions from the sebaceous and cerumenous glands varies between ethnic groups,[7] which might partly explain phenotypic differences in cerumen observed in different ethnic groups (see below). However, whether these phenotypic variations translate into clinically significant differences in the prevalence of impacted cerumen or treatment outcome, is unknown.

As a result of the sebaceous glands' secretions, cerumen's organic composition comprises saturated and unsaturated long-chain fatty acids, alcohols, squalene (which accounts for between 12% and 20% of the wax) and cholesterol (6–9%). Indeed, in about 15% of cases, an oily ring appears when cerumen is placed on filter paper.[8] However, cerumen lipid and amino acid composition seems to differ considerably from that expressed in the stratum corneum. For example, uncontaminated stratum corneum does not seem to express the squalene and wax esters (two of the sebaceous lipids in cerumen).[9]

A more detailed understanding of cerumen's composition could lead to a new generation of more effective treatments. However, we were unable to find evidence of rational drug design in this area.

Cerumen production seems to show neither discordance between sexes nor marked differences over the year. In one analysis,[10] cerumen triglyceride levels declined between November and July, although cholesterol levels remained constant. No sex-related differences emerged. The clinical significance of the change in triglyceride levels, if any, remains unknown. However, as mentioned below, the lack of marked differences over the year might offer one strand of circumstantial evidence *against* cerumen playing a clinically or biologically significant antibacterial role.

There is some evidence of genetic polymorphisms in cerumen phenotypes. Current evidence stratifies cerumen into two phenotypes: wet and dry. Wet cerumen, which is light or dark brown and sticky, is characterized by a relatively high concentration of lipid and pigment granules. Dry cerumen, which is grey or tan and brittle, tends to express lower levels of these components.[11] For example, dry wax contains around 20% lipid, compared to approximately 50% in wet cerumen. Other than this, the two forms show few other biochemical differences.[12]

The wet and dry cerumen phenotypes map to a one-gene trait on chromosome 16, at least in a study of eight Japanese families.[11] Inheritance seems to follow simple Mendelian rules. Thus, the allele encoding the wet form (W) is dominant over the dry form (w).[13] The wet cerumen phenotype tends to be most frequent in Caucasians and African Americans, with dry cerumen predominating in Asians and Native Americans. Dry cerumen also shows an 'intermediate frequency' among populations from Eastern Europe, the Middle East, the Pacific Islands and South Africa.[11,14] However, in our clinical practice, the dry form seems to be rare

among Asians living in North America or Europe. Rather, they seem to express the wet form. Further studies in Asians living in North America or Europe (as well as other populations) are needed to confirm or deny this clinical impression.

Furthermore, no firm data correlate phenotype, the risk of developing impacted cerumen and clinical outcomes with, for example, different agents. The differences in the biochemical composition of wet and dry cerumen might suggest that different drugs could be effective in different patient groups. However, there is no evidence to support this.

On the other hand, there is now a growing, although far from compelling, evidence base suggesting that adult and paediatric cerumens show several differences.[15] Firstly, paediatric cerumen might be moister than that in adults. As such, less hydration is needed for cell lysis than in adults. Secondly, the bolus of cerumen may be smaller in children than adults, so it is easier to disintegrate impacted wax in children than adults. Finally, the cerumen bolus in adults might be denser. This reflects the fact that cerumen has been present in the ear for longer and might be drier. Adults might also compact their wax with cotton buds.

Thus, strategies to remove cerumen might show different efficacy depending on age. There is some data that this is indeed the case (see Table 1). However, further studies are needed to characterize the optimum treatment strategies at different ages.

Cerumen microbiology

Apart from allowing desquamation, cerumen cleans and lubricates the canal,[2] trapping dirt and repelling water.[16] The traditional view holds that cerumen also protects the middle ear from bacterial and fungal infection. For example, some authorities[17] suggest retaining the cerumen barrier to bolster host defences against ear infections. However, the evidence that cerumen plays a biologically or clinically significant role in host defence seems relatively weak.

It might be expected, for example, that if cerumen played an important role bolstering host defence systems, its composition would alter in response to an infection. Perhaps exposure to bacteria would induce up-regulation of antibacterial components of cerumen. However, the cerumen of patients with otitis externa does not seem to contain more antibacterial polyunsaturated fatty acids than those without.[18] Moreover, in clinical practice our experience suggests that patients with otitis externa produce diminished amounts of cerumen. The reasons for this are unknown. However, this empirical observation supports suggestions that cerumen's only role is to provide a mechanism for excreting keratin.

Furthermore, if cerumen was important in host defence, production might change in response to infection risk. However, as mentioned above, cerumen production does not vary markedly over the year,[10] despite seasonal differences in the risk of infections.

Several other strands of evidence also fail to support suggestions that cerumen is associated with significant effects on host defence. For example, impacted cerumen exposed to water, possibly from shampoo or a chlorinated swimming pool, is associated with an increased infection risk.[2] Moreover, the consensus from microbiological studies seems to be that if anything, cerumen offers a rich medium supporting microbiological growth, with a mean of 10^6micro-organisms per millitre.[19]

Several studies[19–22] underscore cerumen's efficacy as a growth medium. Two examples suffice to exemplify this point. Firstly, in one study,[19] 66.6% of cerumen samples showed polymicrobial isolates, *Staphylococcus epidermidis* and *Corynebacterium* spp being the most common micro-organisms isolated from polymicrobial cultures. However, the authors also isolated *Candida albicans, Pseudomonas aeruginosa, P. stutzeri and S. aureus*. Secondly,[21] only 16/164 cerumen samples showed no growth. The remaining 148 specimens were colonized with 314 organisms, 291 of which were bacteria. *Turicella otitidis* and *Alloiococcus otitis* were isolated from 38 and 28 cerumen samples, respectively. The relatively high prevalence of these two bacteria, which is greater than in previous studies, might suggest that these bacteria are normal flora. The pattern from these studies, which encompass geographically diverse samples, is that cerumen supports bacterial growth, rather than being antibacterial.

Indeed, immunohistochemical studies suggest that antibody-mediated immune reactions, rather than cerumen, protect the external auditory canal from infection. The epidermis and dermis surrounding the sebaceous and cerumenous glands, as well as the piliary follicles, express cells capable of activating and sustaining local immune reactions, including IgA and IgG.[23] However, there is a need for further studies to characterize the nature of host defence in this unique anatomical site.

Impacted cerumen

Impacted cerumen is a common cause of consultation in primary care[24] and a common concurrent finding among secondary care populations.

Table 1 Summary of published clinical trial results involving pharmacological ceruminolytic agents

Authors	Study design	Subject details	Intervention	Results	Comments
Eekhof *et al.*[28]	Randomized controlled study	Patients with cerumen impaction attending a general practice	Water drops at body temperature for 15 min ($n=22$ patients)	Mean number of syringing attempts was 3.0 per patient	The use of water as a dispersant for impacted cerumen is quick and more convenient for the patient.
			Oil for three nights before sleeping ($n=20$ patients)	Mean number of syringing attempts was 2.4 per patient	
Lyndon *et al.*[4]	Open randomized study	Adult patients ($n=36$) with cerumen impaction attending a general practice	Audax ear drops for 4 days	39% of patients did not require syringing, 58% experienced easy syringing and 3% difficult syringing	A non-significant trend was observed showing less impaction post-treatment with Audax than with Earex. However, a significant difference was seen in favour of Audax for the frequency and ease of syringing ($p<0.005$).
			Earex ear drops for 4 days	21% of patients did not require syringing, 35% experienced easy syringing and 32% difficult syringing	
Chaput De Saintonge & Johnstone[47]	Double-blind comparison	Out-patients who had impacted wax and were considered suitable for syringing	Triethanolamine polypeptide oleate-condsate ear drops ($n=32$ ears)	20 had complete wax removal and 12 had partial wax removal	Triethanolamine polypeptide preparation needed a significantly smaller volume of water and resulted in less patient discomfort.
			Olive oil ($n=35$ ears)	21 had complete wax removal, 10 had partial wax removal and 4 had negligible wax removal	
Fahmy & Whitefield[48]	Controlled trial	Patients with cerumen impaction attending a hospital ENT department or general practice	5% urea hydrogen peroxide in glycerol (Exterol)	15% of ears treated with Exterol did not require syringing, whereas with glycerol, syringing was always necessary.	Exterol was significantly superior to both glycerol and Cerumol at dispersing wax completely and facilitating syringing ($p<0.001$).
			Glycerol control Cerumol	40% of ears treated with Exterol did not require syringing, compared to only 15% with Cerumol.	
Carr & Smith[15]	Randomized controlled trial	Adults ($n=33$) and children ($n=36$) presenting to a community family practice clinic who had cerumen occluding at least one external auditory canal	10% aqueous sodium bicarbonate	There was a 66% improvement.	There was no difference between the efficacy of the two treatments in reducing the amount of wax but both were more efficacious in children (96% improvement) than in adults (45% improvement)
			2.5% aqueous acetic acid	There was a 78% improvement.	
Jaffe & Grimshaw[49]	Randomized, double-blind controlled trial	Patients ($n=106$) with cerumen impaction attending a general practice	Otocerol drops for 3 days ($n=53$)	74% of patients required syringing and syringing was easy in 57% of the group	Otocerol was marginally better than Cerumol in all parameters evaluated.
			Cerumol drops for 3 days ($n=53$)	89% of patients required syringing and syringing was easy in 64% of the group	

Keane *et al.*[50]	Randomized, double-blind controlled trial	Adult in-patients ($n=113$) with cerumen impaction	No treatment (38 ears)	32% of ears were moderately or completely clear of impacted wax	There were no statistically significant differences between sterile water, sodium bicarbonate and cerumol. However, all three treatments were significantly better than no treatment.
			Sterile water drops for 5 days (38 ears)	53% of ears were moderately or completely clear of impacted wax	
			Sodium bicarbonate drops for 5 days (39 ears)	46% of ears were moderately or completely clear of impacted wax	
			Cerumol drops for 5 days (40 ears)	60% of ears were moderately or completely clear of impacted wax	
Singer *et al.*[51]	Randomized, double-blind controlled trial	Patients ($n=50$) attending a university-based emergency department requiring removal of cerumen to visualize the tympanic membrane	Triethanolamine polypeptide ($n=23$ patients)	35% of all patients (0% of children <5 years) had completely visualized ears after treatment with or without irrigation	Docusate sodium was more effective, allowing complete or partial visualization of the tympanic membrane in most patients after a single application.
			Docusate sodium ($n=27$ patients)	82% of all patients (90% of children <5 years) had completely visualized ears after treatment with or without irrigation	
Dummer *et al.*[52]	Single-blind randomized study	Adult patients ($n=50$) with cerumen impaction attending a general practice	Audax ear drops for 4 days	85% of patients developed softer wax and 58% of patients with abnormal hearing experienced an improvement in objective hearing	Both treatments were effective but there was no significant difference between them. However, patients who had abnormal hearing before treatment had a significantly greater improvement in objective hearing after treatment with Audax ($p<0.05$).
			Cerumol ear drops for 4 days	87% of patients developed softer wax and 15% of patients with abnormal hearing experienced an improvement in objective hearing	
Fraser[53]	Randomized double-blind controlled trial in which sodium bicarbonate was used in one ear and one of the other five treatments was used in the other ear	Geriatric patients ($n=124$ patients) attending hospital	Cerumol drops for 3 days	30% improvement in ease of syringing	Cerumol was the only treatment significantly better than sodium bicarbonate in facilitating ear syringing. Additionally, Cerumol was significantly better than both dioctyl ear capsules and Xerumenex ($p<0.05$), but there was no significant difference between Cerumol, olive oil and Waxsol.
			Olive oil drops for 3 days	24% improvement in ease of syringing	
			Waxsol drops for 3 days	18% improvement in ease of syringing	
			Xerumenex drops 15–30 min before syringing	11% worsening in ease of syringing	
			Dioctyl ear capsules for 3 days	12% worsening in ease of syringing	

Impacted cerumen can cause a variety of symptoms[2] including itching, pain, hearing loss, tinnitus, dizziness and increased infection risk. Furthermore, untreated impacted wax can lead to 'hearing loss, social withdrawal, poor work function and even mild paranoia'. Some patients with impacted wax present with perforated eardrums.[3] In most cases, the latter is self-induced—cerumen by itself cannot cause perforation. Nevertheless, perforation can in turn, lead to perilymph fistula: a tear or opening in the round or oval cochlear windows, which can cause nystagmus, neurosensory hearing loss and tinnitus. Moreover, tinnitus can occur if cerumen is severely impacted against the eardrum and then is suddenly released.[3]

Impacted cerumen can arise from a number of causes. Firstly, certain anatomical changes (such as stenosis in the external auditory meatus) can promote impacted cerumen. Moreover, keratosis obturans (a disease characterized by increased keratin production) can lead to a variety of symptoms, including erosion of the bony cartilaginous wall, infections and hearing loss. This appears to be the external auditory canal equivalent of middle-ear cholesteatoma, since sheets of undisturbed and unbroken keratin are produced without any fatty content.[25,6] The external meatus can become markedly enlarged in patients with keratosis obturans,[14] which can lead to severe cerumen accumulation.[14]

More commonly, impacted cerumen might arise from a failure in the separation of keratinocytes that normally occurs in the external auditory canal as part of skin turnover. As noted above, hard cerumen plugs consist of more keratin sheets than softer wax. Moreover, corneocytes in softer wax seem to undergo expansion. Possibly, people prone to recurrent episodes of impacted cerumen do not express sufficient quantities of an unidentified 'keratinocyte attachment destroying substance'.[6] However, further studies are required to identify the nature of this substance, as well as any role in influencing the risk of impaction as well as therapeutic outcomes.

Other research suggests that carotenoids might contribute to the pathogenesis of impacted cerumen. (Obviously, this hypothesis is not mutually exclusive with the above suggestion.) Experimental administration of retinoids increases epidermal hyperplasia and cerumenous gland activity. Such changes could promote cerumen production and increase the likelihood that the wax will become impacted. Certainly, cerumen contains carotenoids, although their role in the pathogenesis of impacted cerumen requires further confirmation.[2]

Finally, there is a need to educate patients to prevent behavioural factors that can contribute to impacted cerumen. For example, using cotton buds to clean the canal can lead to impacted cerumen. In one study, cotton-tipped swabs were associated with 75% of cerumen occlusion on the left side, but not on the right side in paediatric patients. However, the study did not show a causal relationship between the use of cotton-tipped swabs and impacted cerumen. Clearly, however, such swabs do not necessarily clear cerumen from the external canal.[26] Any future prospective studies of cerumen removal strategies need to take account of such behavioural factors.

Epidemiology of impacted cerumen

Several studies assessing the epidemiology of impacted cerumen show that the condition is common. For example, between 2% and 6% of the general population suffers from impacted cerumen.[27] A large study of 1507 patients screened for adult hearing loss found suspected occluding wax in 2.1% of subjects.[1] Based on these figures, we estimated that between 1.2 million and 3.5 million people in the UK suffer from impacted cerumen. Clearly, therefore, impacted cerumen will be a comorbidity in many secondary care patients.

Not all these patients consult a health care professional because of impacted cerumen. Around 39.3 per 1000 patients in the population consult their GP for problems related to impacted cerumen. This suggests an incidence of cerumen problems serious enough to warrant management in 3.9% of the population receiving primary health care,[28] or 2.3 million people. However, no literature was found characterizing any anthropological, psychological, socio-economic or medical factors influencing a patient's decision to consult for the symptoms of impacted cerumen. Such factors could help needs assessments in primary care.

Against this background, a Scottish study[24] eloquently highlights the scale of the problem posed by impacted cerumen in general practice. The authors surveyed 289 general practitioners in Lothian about cerumen removal and gained a response rate of 92%. The high response rate suggests that GPs are interested in cerumen removal and, perhaps, that current strategies are less than ideal. In this survey, the number of patients presenting with impacted cerumen varied between five and >50 a month. The reasons for such marked differences are not entirely clear. This further underscores the need for a study assessing the reasons why some patients decide to present for treatment. On average, however, each GP saw nine patients with impacted cerumen, although almost 13%

of those that replied saw at least 21 patients a month. About half (50.7%) saw 10 or fewer patients for cerumen removal a month.

Such surveys are prone to recollection bias. Nevertheless, the survey provides an 'order of magnitude' estimate of the health care burden associated with impacted cerumen in Scotland. The GPs managed a population of around 650 000 people, and the researchers estimated that some 44 000 ears are syringed each year in this population. Assuming the same proportion applies to the whole UK population of around 59 million, approximately 4 million ears are syringed annually. This suggests that impacted cerumen poses a considerable burden on primary care health services.

Certain groups also seem especially prone to develop impacted cerumen. For example, ear disease and hearing impairment seem to be disproportionately common among elderly people. In one survey,[29] 8% of 32 656 patients aged at least 75 years reported 'a lot' of difficulty hearing. Forty-two per cent reported 'a lot' or 'a little' difficulty. Twenty-six per cent (3795) of the 14 877 who underwent a whispered hearing test failed. However, wax removal reversed hearing loss in 343 of the 3795 patients (9%) who failed the whisper test. Overall, 23% of subjects who underwent the test still failed after wax removal. Although regression to the mean and a practice effect might contribute to the reduced failure rate on the second test, syringing seems to improve hearing in some older people. Indeed, another study[24] found that removing occlusive wax improved hearing by a mean of 5 dB.

The prevalence of hearing loss and impacted cerumen seems to be higher among those living in nursing homes than in their community-dwelling peers. Indeed, in one paper[30] almost 40% of people in nursing homes showed impacted cerumen. In part, the increased prevalence among the elderly reflects the use of hearing aids, which stimulate cerumen production and inhibit outflow. This suggests that a patient's age and functional status in studies of epidemiology, interventions and burden of illness needs careful consideration.

Patients with mental retardation also appear to be especially prone to developing impacted cerumen. In one study, 20% of mentally retarded patients showed excessive wax, while 8% suffered from impacted cerumen associated with conductive hearing loss. Moreover, more than half of patients with mental retardation showed excessive or impacted cerumen that caused some occlusion a year later.[27] In a study of 70 elderly people with intellectual disability, most patients (no figure cited) needed impacted cerumen removed 'often every year'.[31]

The reasons for the increased prevalence of impacted cerumen among people with mental retardation are not clear. However, anatomical differences in the structure of the canal (for example, associated with trisomy 21) or excessive cerumen production may play, at least, contributory roles.[27] Again, the association between mental retardation and excessive cerumen production requires further analysis, not least because very few people with mental retardation visit a clinician because of cerumen impaction.

Management of impacted cerumen

In rare cases, surgery may be appropriate for impacted cerumen. For example, if a patient suffers from meatal stenosis (bony cartilagenous narrowing of the external auditory canal) then migration or clearance of cerumen would be prevented. M-meatoplasty may offer a successful treatment strategy. In one study[32] using this approach in 125 patients, the median satisfaction score on a ten-point scale was 9 (where 10 was very good). Only 1.5% of subjects developed post-operative wound infections.

In primary care, however, there are two approaches to removing impacted cerumen: curettage and irrigation. Each approach is associated with risk and benefits. Using a curette allows a clinician to view the procedure and the lack of water lowers infection risk. However, using a curette requires considerable skill.[30] Irrigation, on the other hand, is simpler, requires fewer materials and is less likely to damage the eardrum. As a result, irrigation tends to be the treatment of choice for impacted cerumen in primary care.

In a survey of GPs,[24] 95% of doctors used syringing to remove impacted cerumen. Four per cent used a Jobson Horne probe, while the remainder referred patients directly to hospital outpatient clinics. Oil was the most popular substance for syringing, used in 70% of procedures. Cerumol and bicarbonate were used in 13 and 8.2% of procedures, respectively. However, as mentioned later in this review, such choices are not based on firm evidence. Only 19% of the GPs surveyed always performed earwax removal. The other GPs routinely referred patients to their practice nurse—another reason why syringing is the treatment of choice. However, nurses typically receive no instruction about syringing.

Moreover, earwax removal, even with syringing, is not necessarily innocuous. If a patient has

a perforated eardrum, water and infections can enter the middle ear. Residual water can also promote infection.[30] Indeed, ear syringing can be associated with several potentially serious complications.[24] In the aforementioned GP survey, 38% of those that responded reported experiencing a total of 127 complications associated with cerumen removal. Failure of cerumen removal accounted for 29% of complications. Otitis externa (17%), eardrum perforation (15%) and damage to the external canal (12%), emerged as the next most common adverse events. Pain, vertigo, otitis media and discovered perforation each accounted for fewer than 10% of the complications.[24] However, recollection bias might skew these results and a prospective study is warranted to fully characterize the risks.

Furthermore, cleaning the external auditory meatus could be hazardous. The literature suggests that between 10 and 20% of traumatic tympanic membrane perforations arise from mechanical damage and 'very frequently by unprofessional attempts' to clean the meatus.[33] The risk that the tympanic membrane could rupture during ear irrigation depends on the integrity of the eardrum. Normal tympanic membranes in cadavers rupture at an over-pressure of between 0.5 and 2.0 atmospheres. The difference highlights the large variation in membrane strength between individuals. For example, atrophic tympanic membranes can rupture at a much lower overpressure, between 0.3 and 0.8 atmospheres. Moreover, the membrane's tensile strength declines with advancing age.[34] In another study, a metal syringe generated median maximum overpressures of 240 mmHg. This is not sufficient to rupture normal tympanic membranes, but might be enough to rupture atrophic tympanic membranes.[33]

Tympanic membrane rupture can be associated with considerable inner ear damage. In three case reports, for instance, oral jet irrigation perforated the eardrum, led to ossicular disruption, round and oval window fistulae and subluxation of the stapedial footplate. Furthermore, in 25 fresh cadavers, oral jet irrigation ruptured the tympanic membrane in 6% of cases. A third of these occurred at full power. Two-thirds occurred when the jet irrigation was a third of full power.[35]

In nine of 24 patients (37.5%) with invasive external otitis media, infection emerged following removal of impacted cerumen by irrigation under pressure. Eight patients suffered from diabetes, the other subject had undergone head-and-neck irradiation. The authors suggested that people with diabetes and immunocompromised subjects should not undergo irrigation for impacted cerumen.[36] Finally, a case history[37] supports the anecdotal evidence that severe audiovestibular loss can follow ear syringing to remove cerumen.

Agents to loosen impacted cerumen

Against this background, agents that loosen cerumen seem to offer the only effective, relatively well-tolerated management alternative to physical removal. Indeed, softeners are often sufficient to treat mild cases of impacted cerumen, as well as reducing the need for surgical removal in more severe cases.[4] Softeners can be used in conjunction with syringing. However, there are no well-designed, large, placebo-controlled, double-blind studies comparing the various agents and strategies to loosen impacted cerumen.

In vitro studies

A few *in vitro* studies have assessed the effectiveness of cerumenolyics. Firstly, there is evidence that water might be more effective than several proprietary agents in facilitating cerumen removal.[28] Furthermore, an *in vitro* study[38] that originally intended using water as a control found that it was the most effective dispersant. In this model, olive oil seemed to be almost ineffective. Cerumol, Exterol, sodium bicarbonate, Waxsol and Travasept all showed levels of efficacy between that of water and olive oil.

Secondly, Bellini [45] compared four cerumenolytic agents bought from a chemist (Cerumol, Waxsol, Earex and store's own) and sodium bicarbonate ear drops, olive oil, distilled water and acetone. The authors assessed disintegration of 40 mg cerumen pellets over two hours. Waxsol, the store's own brand and distilled water all caused 'substantial disintegration' of the plug. Indeed, the authors suggested that dioctyl sodium sulphosuccinate may be unnecessary, with the water base being the active ingredient. However, this was, again, a subjective evaluation and a quantitative assessment is needed to test this hypothesis.

Finally, Mehta[46] compared Cerumol, Waxsol, Exterol, Earex and Xerumenex on the disintegration of a cerumen plug collected and homogenized from several patients. After 24 h, Waxsol was the only product to produce complete disintegration. However, the clinical relevance of a 24 h exposure is debatable. Nevertheless, Waxsol also remained the most effective after 15 and 30 min, producing 'substantial disintegration' of the plug. The remaining products produced only 'slight disintegration'. The study can be criticized, since the sample 'shape of a pea' might not be clinically relevant,

the assessment was qualitative and the samples were pooled. However, it suggests that Waxsol may be more effective.

Clinical studies

A number of clinical studies assess the efficacy and safety of cerumen softeners. However, there is a need for further well designed, large, placebo-controlled, double-blind studies.

An analysis of docusate sodium enrolled 302 patients in whom cerumen either partially or completely blocked the tympanic membrane. One group received either docusate sodium or mineral oil before irrigation. Another group underwent either irrigation only or received a solution of vinegar and alcohol after irrigation. The amount of irrigation needed did not differ between the two groups. In other words, tap water (at body temperature) irrigation proved as effective as pre-treatment with a softener for uncomplicated cerumen. The treatment is quick and requires only a single visit to a clinician. Thus, the paper advocates water as the treatment of choice for impacted cerumen.[39]

However, not all publications concur that water is the treatment of choice. For example, one study found that the only truly effective ceruminolytics had an aqueous base. In this study, a 10% solution of sodium bicarbonate emerged as the most effective ceruminolytic. In contrast, ceruminolytics that had an organic base showed little ceruminolytic effect.[40] However, another paper remarks that water and bicarbonate solution can swell the cerumen plug by 100%. This could 'wedge' the plug into the ear, hindering removal. Furthermore, the formation of cerumen crumbs, formed by head movements, can facilitate the removal of wax from the canal.[41]

In common with the other papers reviewed in Table 1, factors such as recurrence, infections, repeat visits to GPs to properly remove the impacted cerumen are not fully taken into account in the studies cited above. As a result, the conclusion that water is the treatment of choice should be viewed with extreme caution. These factors also precluded any systematic analysis of the evidence.

Indeed, numerous factors conspire to complicate a systematic analysis aside from any pharmacological differences. Impacted cerumen clears completely in 5% of patients without any treatment, while a further 26% of patients show a moderate improvement after five days without treatment.[42] Moreover, numerous intrinsic and external factors seem to influence efficacy, some of which are alluded to below. In addition, patient education may be important to maximize outcomes. For instance, some patients might not apply the drops for long enough before syringing. Moreover, patients may not allow them to soak into the external meatus for long enough before standing up.[14]

Despite these limitations, a number of papers purport to advocate other agents as effective treatments for cerumen removal. However, the evidence is often mixed and inconsistent. To take one example, docusate sodium (dioctyl sodium sulphosuccinate), widely used as a stool softener, offers a 'highly effective' means of removing cerumen. No side-effects emerged over five years' clinical experience.[43] However, in another study[44] docusate sodium in maize oil did not offer any 'outstanding advantages' in aiding earwax removal compared to maize oil control. Indeed, the average volume of water used was higher in the active group compared to controls: 111 and 81 ml, respectively. Furthermore, 80% and 58% of the wax was easy to remove in the control and docusate sodium groups, respectively.

Table 1 summarizes the published clinical trials involving pharmacological cerumenolytic agents. It is difficult to draw any firm conclusions from this evidence—as noted above, there is a need for large, placebo-controlled, double-blind studies. Only one rigorous review[42] was found that examined the evidence for the best treatment for impacted cerumen. This paper concluded that docusate sodium administered 15 min before irrigation was the most effective method for aiding cerumen removal in a single visit. However, the studies lacked irrigation-only arms. Triethanolamine and olive oil were the next most effective treatments; carbamide peroxide was the least effective.

This review[42] also concluded that urea (5%) hydrogen peroxide in glycerol was the most efficacious regimen for facilitating removal between visits and reducing the amount of irrigation needed. However, there was only one placebo-controlled trial; the studies lacked rigorous randomization; and the degree of cerumen impact was poorly defined. The following were all less efficacious than urea hydrogen peroxide in glycerol, but were of similar efficacy to one another: sterile water; sodium bicarbonate in glycerol; 2% acetic acid; ethylene oxide polyoxypropylene; arachis oil, chlorobutanol and p-dichlorobenzene.

We concur with the impression from this analysis that the evidence surrounding the pharmacological management of impacted cerumen is inconsistent, and few conclusions can be drawn. There is clearly a need for a definitive assessment of the most effective pharmacological strategy for cerumen removal.

Discussion and conclusions

Impacted cerumen is common. We provisionally estimate that between 1.2 m and 3.5 m people in the UK suffer from impacted cerumen. Moreover, 2.3 m people suffer cerumen problems serious enough to warrant management. Approximately 4 m ears are syringed annually. These provisional estimates require confirmation in formal epidemiological studies.

Patients with impacted cerumen require effective treatment. The literature shows that impacted cerumen often causes unpleasant symptoms and is occasionally associated with serious sequelae. Moreover, treatment can produce worthwhile objective improvements. For example, in one study, removing occlusive wax improved hearing by a mean of 5 dB.[24] However, the lack of published evidence suggested that the physiology, clinical significance and management implications associated with excessive and impacted cerumen remain poorly characterized. For example, we were unable to confirm or deny our empirical experience suggesting that normalization of cerumen indicates an improvement in ear health.

Part of the reason for our inability to confirm or deny empirical experience using only the published evidence base results from the large number of outstanding issues identified by our review. For example, more detailed analysis of cerumen's composition and the differences, especially in lipid and amino acid composition, from stratum corneum[9] would be valuable. The agents currently used seem to have arisen more from empirical experience than from rational design. Determining the qualitative and quantitative differences between these agents could lead to a new generation of more effective treatments specifically designed for cerumen removal. It might also help understand variations in outcomes.

Such studies could also determine whether adult and paediatric cerumens show clinically or biologically significant differences; an inference from the current data.[15] Strategies to remove cerumen might show different efficacies depending on age (see Table 1). Appreciating these differences could help optimize treatment strategies.

Many fundamental issues also remain to be addressed. For example, there is some evidence of genetic polymorphisms in cerumen phenotypes. Further studies are needed to determine if phenotype correlates with the risk of developing impacted cerumen and clinical outcomes. Moreover, identification and significance of the 'keratinocyte attachment destroying substance'[6] and cerumen carotenoids are needed. Once the identity and role of these substances have been characterized, it should be possible to target treatments that could further enhance outcomes.

We conclude that the evidence supporting a traditional view that cerumen plays a biologically or clinically significant role in host defence seems relatively weak. Indeed, the consensus from microbiological studies seems to be that if anything, cerumen offers a rich medium supporting microbiological growth. This concurs with our clinical experience. In cases of otitis externa, cerumen levels are depleted. As the condition improves, levels of cerumen return to normal. These findings suggest that cerumen's only role is to expel stratum corneum.

Cerumen removal is important in the clinical management of patients in primary and secondary care. GPs, for example, seem to be interested in cerumen removal, exemplified by the high response rate to a questionnaire about current practice. This may reflect the combination of a considerable clinical workload arising from impacted cerumen, and the lack of strong evidence on treatment. In particular, a dearth of rigorous evidence negates any attempt at a systematic assessment of optimal management strategies. The evidence surrounding the pharmacological management of impacted cerumen is inconsistent, and few conclusions can be drawn. Similarly, there is no consensus concerning the treatment of choice, or even whether formulations designed to loosen cerumen offer any benefit over water. We were also unable to identify any formal cost effectiveness studies comparing the different approaches to cerumen removal. There is clearly a need for a definitive assessment of the most cost-effective and clinically efficacious pharmacological strategy for cerumen removal.

In conclusion, the causes and management of impacted cerumen require further investigation. It is hoped that this review presents a baseline from which further prospective trials can be designed. Indeed, this review might act as a spur for further research into this common primary care condition. Physicians are supposed to follow the edicts and principles of evidence-based medicine and clinical governance. Currently, for impacted cerumen the lack of evidence makes this impossible.

Acknowledgements

The preparation of this review was funded by an unrestricted grant from Alcon Laboratories Ltd. The authors have no conflicts of interests that are directly relevant to the content of this manuscript. The authors thank Susan Varney and Francis Ruiz

for their invaluable insight and contributions to this review. We would also like to thank the anonymous reviewers for their comments.

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