Ear wax

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ABSTRACT

INTRODUCTION: Ear wax only becomes a problem if it causes a hearing impairment or other ear-related symptoms. Ear wax is more likely to accumulate and cause a hearing impairment when normal extrusion is prevented; for example, by the use of hearing aids, or by the use of cotton buds to clean the ears. Ear wax can visually obscure the ear drum, and may need to be removed for diagnostic purposes. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical question: What are the effects of methods to remove ear wax? We searched: Medline, Embase, The Cochrane Library, and other important databases up to July 2014 (BMJ Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). RESULTS: We found 10 studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: ear irrigation (syringing); manual removal (other than ear irrigation); wax softeners prior to irrigation; and wax softeners alone.

QUESTIONS

INTERVENTIONS

Footnote

*Although we found no RCTs, there is consensus that irrigation is effective at removing ear wax.

Key points

- Ear wax only becomes a problem if it causes a hearing impairment, or other ear-related symptoms.

  Ear wax is more likely to accumulate and cause a hearing impairment when normal extrusion is prevented (for example, by hearing aids or by the use of cotton buds to clean the ears).

  Ear wax can visually obscure the ear drum, and may need to be removed for diagnostic purposes.
- For such a commonly occurring condition, there is little high-quality evidence available to guide practice. All procedures for removing wax should be essentially pain free.
- Ear irrigation (syringing) is generally considered to be effective, but evidence is limited.

  Irrigation is usually performed using a motorised pump with a governable pressure.

  Ear irrigation may be associated with vertigo and tympanic membrane perforation in some people. Pain, damage to the skin of the ear canal, and otitis externa are other possible adverse effects.

  Ear irrigation may rarely cause permanent deafness; therefore, people with hearing in only one ear should not have this ear irrigated.
- Other mechanical methods of removing ear wax by trained staff using instruments, such as microsuction, are probably effective, although the evidence is limited.

  Mechanical removal of wax with suction, probes, or forceps is considered effective, but can cause trauma to the ear canal, depending on the experience and training of the operator and the adequacy of visualisation.
- Overall, we found limited high-quality evidence on the effects of proprietary wax softeners.
- With regard to the use of wax softeners prior to irrigation, we found very weak evidence that wax softeners may be better than no treatment.

  However, we found no good evidence that wax softeners improved wax clearance after irrigation compared with saline.

  We found no good evidence that any one type of wax softener was better than any other type of wax softener.
- With regard to the use of wax softeners alone, we found very weak evidence that wax softeners may be better than no treatment.

  We found no consistent evidence that wax softeners alone improved wax clearance compared with sterile water or normal saline.

  We also found no good evidence that any one type of wax softener was better than any other type of wax softener.

Clinical context

GENERAL BACKGROUND

Ear wax only becomes a problem if it causes a hearing impairment or other ear-related symptoms. The accumulation of wax occurs for many different reasons, including the over- or under-production of its constituent components, a failure to self-clear because of slow skin migration, or mechanical issues such as the use of cotton buds or hearing aids.

FOCUS OF THE REVIEW

If wax needs to be removed, there are various options available. These include: irrigation (syringing with unregulated manual syringes should no longer be used); the use of wax softeners/solvents alone; the use of wax softeners prior to irrigation; and the manual removal of wax by use of an oto-endoscope and small instruments or a binocular microscope with suction and micro instruments. This review examines this commonly occurring and important condition and identifies what RCT evidence is available on the effects of these different interventions.

COMMENTS ON EVIDENCE

We found few RCTs on the effects of ear irrigation and manual removal techniques. We found two systematic reviews which performed a meta-analysis on RCTs which examined the effects of different wax softeners/solvents. One review categorised ear drops into three groups in order to pool data (water-based, oil-based, and non-water, non oil-based), while another review did not use this classification. The reviews included RCTs that examined the effects of wax softeners/solvents used alone or prior to irrigation compared with no treatment, saline, sterile water, as well as different wax softeners/solvents versus each other. Overall, many of the included RCTs had weak methods, which limited the robustness of any conclusions that could be drawn.

SEARCH AND APPRAISAL SUMMARY

The update literature search for this review was carried out from the date of the last search, June 2007, to July 2014. For more information on the electronic databases searched and criteria applied during assessment of studies for potential relevance to the review, please see the Methods section. After deduplication and removal of conference abstracts, 14 records were screened for inclusion in the review. Appraisal of titles and abstracts led to the exclusion of five studies, and the further review of nine full publications. Of the nine full articles evaluated, one systematic review was updated (which related to two different treatment options) and one systematic review and two further RCTs were added at this update.

ADDITIONAL INFORMATION

Irrigation relies on getting water past the wax in the ear canal, so that it builds up deep to the wax and then pushes it outwards. Thus, if the wax is completely occluding the canal, this technique can easily make matters worse by impacting the wax against the tympanic membrane. If there are pre-existing changes to the tympanic membrane, damage can occur; so there are many contra indications to irrigation. Oto-endoscopes give a monocular view of the ear canal and practice is needed with instrumentation to become competent at wax removal without trauma. Binocular microscopes give a stereoscopic view and are probably the safest way of dewaxing an ear, especially when suction is used, but are expensive and users need training.

DEFINITION

The external ear canal in adults is about 24 mm long. The outer third has cartilaginous and soft tissue walls, while the deep two-thirds has continuous bony walls. There is no soft tissue between the ear canal skin and the bone, and this gives the ear canal resonance properties that enhance the usual range of sounds we hear at the tympanic membrane. To prevent the deep ear canal becoming filled with dead skin cells, this skin is migratory and moves from the deep canal outwards. In the outer part of the canal are modified sweat glands (ceruminous glands), which secrete a modified sweat that has bacteriocidal and fungicidal properties, and sebaceous glands that produce an oily material and usually discharge in the hair follicles at the outside of the canal. Wax is a mixture of all three components, with keratin being predominant. Overall wax is sticky, waterproof, and protective, and there should be a thin coating of wax near the external opening of the canal. To cause a significant conductive hearing loss, the wax must completely occlude the ear canal. However, partial blockage of the canal alters the resonant properties and the quality of the hearing. Accumulation can reduce the efficiency of hearing aids. When wax gets wet, the keratin swells and can lead to the sudden onset of complete occlusion of the canal and a hearing loss. The wet, dead keratin can become infected and an otitis externa develop. Wax may obscure the view of the tympanic membrane and may need to be removed for diagnostic reasons. Impacted wax can become adherent to the ear canal skin and tympanic membrane and make removal more difficult. Since the deep ear canal may be wider than the opening, a large plug of dry, hard wax deep in the canal can be particularly difficult to remove. If wax needs to be removed, then various options are available:

irrigation (syringing with unregulated manual syringes should no longer be used), wax softeners/solvents, irrigation following wax softeners, mechanical removal, or microsuction.

INCIDENCE/ PREVALENCE

We found four surveys of the prevalence of impacted wax. [1] [2] [3] [4] The studies were carried out in a variety of populations, and used a variety of definitions of impacted wax. Prevalence ranged from 7% to 35%. It is unclear how these figures relate to prevalence in the general population.

AETIOLOGY/ RISK FACTORS

Accumulation of wax occurs for many different reasons relating to the over- or underproduction of the three major components, a failure to self-clear because of slow skin migration especially in the dermatitides, or because of mechanical issues such as the use of cotton buds or hearing aid moulds.

PROGNOSIS

Most ear wax emerges from the external canal spontaneously; one small RCT that included a no-treatment group found that 32% of ears with impacted wax showed some degree of spontaneous resolution after 5 days (26% described as moderately clear; 5% described as completely clear). [5] Without impaction or adherence to the drum, there is likely to be minimal, if any, hearing loss.

AIMS OF INTERVENTION

To relieve symptoms or to allow examination, especially of the tympanic membrane, by completely removing impacted wax or visually obstructing wax; and to ease wax removal.

OUTCOMES

Treatment success proportion of people (or ears) with relief of hearing loss or discomfort; subjective assessment of amount of wax remaining after use of wax softeners prior to cleansing; proportion of people requiring mechanical removal to improve symptoms; degree of visualisation of the tympanic membrane; perceived ease of mechanical removal (measured, for example, by the volume of water used to accomplish successful syringing). **Adverse effects**.

METHODS

BMJ Clinical Evidence search and appraisal July 2014. The following databases were used to identify studies for this systematic review: Medline 1966 to July 2014, Embase 1980 to July 2014, and The Cochrane Database of Systematic Reviews 2014, issue 6 (1966 to date of issue). Additional searches were carried out in the Database of Abstracts of Reviews of Effects (DARE) and the Health Technology Assessment (HTA) database. We also searched for retractions of studies included in the review. Titles and abstracts identified by the initial search, run by an information specialist, were first assessed against predefined criteria by an evidence scanner. Full texts for potentially relevant studies were then assessed against predefined criteria by an evidence analyst. Studies selected for inclusion were discussed with an expert contributor. All data relevant to the review were then extracted by an evidence analyst. Study design criteria for inclusion in this review were: published systematic reviews and RCTs in the English language, at least single-blinded, and containing more than 20 individuals (10 in each arm) of whom more than 80% were followed up. There was no minimum length of follow-up. We excluded all studies described as 'open', 'open label', or not blinded unless blinding was impossible. We included RCTs and systematic reviews of RCTs where harms of an included intervention were assessed, applying the same study design criteria for inclusion as we did for benefits. In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the MHRA, which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 23). The categorisation of the quality of the evidence (high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the Clinical Evidence population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION What are the effects of methods to remove ear wax?

OPTION EAR IRRIGATION (SYRINGING)

- For GRADE evaluation of interventions for Ear wax, see table, p 23 .
- Ear irrigation (syringing) is generally considered to be effective, but evidence is limited.
- Ear irrigation may be associated with vertigo and tympanic membrane perforation in some people. Pain, damage to the skin of the ear canal, and otitis externa are other possible adverse effects.

- There are many contraindications to ear irrigation (for further information, see Clinical guide, p 3); in particular, it should not be performed in an only hearing ear.

Benefits and harms

Ear irrigation versus no treatment:

We found one systematic review (search date 2008), which found no RCTs comparing ear irrigation alone with no treatment. [6] We found no subsequent RCTs. However, there is consensus that ear irrigation is effective at removing wax but may be associated with adverse effects (see Comment).

Ear irrigation with prior water instillation versus ear irrigation without prior water instillation:

We found one systematic review (search date 2008), [6] which found one RCT. [7] We have reported from the RCT directly. [7] We found no subsequent RCTs.

Treatment success

Ear irrigation with prior water installation compared with ear irrigation without prior water instillation Water instilled in the ear 15 minutes before irrigation may be more effective at reducing the volume of water needed to syringe the ear clear of wax compared with no treatment. However, evidence was weak (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Volume of water needed to clear the ear					
[7] RCT	26 people, 39 ears	**Mean volume of water needed to clear the ear** 187 mL with water instillation (ear filled with warm tap water for 15 minutes) prior to syringing 635 mL with no treatment After water instillation, the ear was syringed until visibly clear of wax	P = 0.043 Possible bias; for full details see Further information on studies	○○○	prior water instillation

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[7] RCT	26 people, 39 ears	**Adverse effects** with water instillation (ear filled with warm tap water for 15 minutes) prior to syringing with no treatment After water instillation, the ear was syringed until visibly clear of wax The RCT reported that one person experienced transient dizziness after syringing No other adverse effects reported			

Further information on studies

[7] The RCT was not blinded, which may have introduced bias, as the outcome reported depended on the visual subjective assessment of when the ear was clear of wax, and irrigation was done manually rather than by a standardised electronic device.

Comment: The review included two further RCTs that were outside the inclusion criteria for this *BMJ Clinical Evidence* review. [6] One RCT (39 people) compared a skin oil versus no treatment after earwax removal to evaluate recurrence, while the other RCT (237 people) compared a combination of sodium bicarbonate ear drops plus irrigation by a practice nurse versus sodium bicarbonate ear drops plus self-treatment using a bulb syringe. [6]

Ear irrigation versus no treatment

Although we found no RCTs, there is consensus that ear irrigation is effective at clearing wax. One large prospective observational study (952 ears in 622 subjects) of all people attending an ear, nose, and throat (ENT) clinic for ear irrigation between December 1999 and June 2001 found that the most common complications were vertigo, and perforation of the tympanic membrane (vertigo: 1 [0.2%]; tympanic membrane perforation: 1 [0.2%]; further details, including details of denominators for adverse effects, not reported; other adverse effects not reported). [8] This study was undertaken in an ENT clinic, and adverse-event rates may not be generalisable to other settings. Other reported complications of ear irrigation include pain, damage to the skin of the external canal with haemorrhage, and otitis externa. [9]

Clinical guide

Care must be taken in selecting people suitable for ear irrigation. The UK NICE guidance for ear irrigation includes a long list of contraindications, cautions, and warnings for ear irrigation. [10] Importantly, people with hearing in only one ear should not have their hearing ear irrigated due to the rare but serious risk of permanent deafness. Other contraindications include people with: perforation of the tympanic membrane or mucus discharge from the ear within past 12 months; grommets in place; a history of ear surgery; cleft palate (repaired or not); acute otitis externa with oedematous ear canal and painful pinna; middle ear infection in the past 6 weeks; or a foreign body in the ear. Furthermore, people must be able to co-operate; therefore, irrigation is not suitable for people who are confused or agitated, young children, and some people with learning difficulties. Irrigation should also be avoided in people who have experienced previous problems with irrigation (pain, perforation, severe vertigo). Irrigation may aggravate symptoms in people with a history of recurrent otitis externa or tinnitus.

OPTION MANUAL REMOVAL (OTHER THAN EAR IRRIGATION)

- For GRADE evaluation of interventions for Ear wax, see table, p 23 .
- Other mechanical methods of removing ear wax by trained staff using instruments, such as microsuction, are probably effective, although the evidence is limited.
- Mechanical removal of wax with suction, probes, or forceps is considered effective but can cause trauma to the ear canal, depending on the experience and training of the operator and the adequacy of visualisation.
- We found no clinically important results about mechanical methods compared with no treatment or alternative treatments in removal of ear wax.

Benefits and harms

Mechanical methods alone versus no treatment or alternative treatment:

We found one systematic review (search date 2008), [6] which found no RCTs comparing mechanical methods alone with no treatment or alternative treatment (see Comment). We found no subsequent RCTs.

Endoscopic vision versus microscopic vision to assist mechanical dewaxing:

We found one systematic review (search date 2008), [6] which found one RCT that compared using an endoscope with using a microscope to aid vision in mechanical de-waxing. [11] We have reported directly from the RCT. [11]

Treatment success

Endoscopic vision compared with microscopic vision We don't know how endoscopic vision and microscopic vision compare at increasing treatment success rates in mechanical de-waxing in people with a build-up of wax which prevents inspection of the tympanic membrane (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful de-waxing					
[11] RCT	100 people in secondary care with ear wax preventing inspection of the tympanic membrane	**Proportion of people successfully de-waxed after one procedure** 45/50 (90%) with endoscopic vision 48/50 (96%) with microscopic vision Mechanical de-waxing was carried out using a Jobson-Horne probe, wax hook, or crocodile forceps, or suction with a Zoellner sucker People who failed treatment in assigned group crossed over to the other group; see Further information on studies for full details	Significance not assessed Possible bias; for full details see Further information on studies		

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[11] RCT	100 people in secondary care with ear wax preventing inspection of the tympanic membrane	**Median pain score on a 100 mm visual analogue scale from 0 (no pain) to 100 (very painful)** 5 with endoscopic vision 25 with microscopic vision Mechanical de-waxing was carried out using a Jobson-Horne probe, wax hook, or crocodile forceps, or suction with a Zoellner sucker People who failed treatment in assigned group crossed over to the other group; see Further information on studies for full details	P = 0.002 Possible bias; for full details see Further information on studies	○○○	endoscopy
[11] RCT	100 people in secondary care with ear wax preventing inspection of the tympanic membrane	**Median discomfort score on a 100 mm visual analogue scale from 0 (no discomfort) to 100 (very uncomfortable)** 3.5 with endoscopic vision 10 with microscopic vision Mechanical de-waxing was carried out using a Jobson-Horne probe, wax hook, or crocodile forceps, or suction with a Zoellner sucker People who failed treatment in assigned group crossed over to the other group; see Further information on studies for full details	P = 0.075 Possible bias; for full details see Further information on studies	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[11] RCT	100 people in secondary care with ear wax preventing inspection of the tympanic membrane	**Traumatisation to the skin of the canal causing a minor bleed** 1/50 (2%) with endoscopic vision 1/50 (2%) with microscopic vision Mechanical de-waxing was carried out using a Jobson-Horne probe, wax hook, or crocodile forceps, or suction with a Zoellner sucker People who failed treatment in assigned group crossed over to the other group; see Further information on studies for full details	Possible bias; for full details see Further information on studies		

Mechanical methods after use of wax softeners:

See option on Wax softeners, p 15 .

Further information on studies

[11] People who failed with initial treatment were crossed over to the other group; after second de-waxing, intention-to-treat analysis found that only 2/50 (4%) of people in the endoscopic vision group and 1/50 (2%) of people in the microscopic vision group required ceremunolytics before subsequent de-waxing. Potential bias: the study was open label, which may have introduced bias into the results of the levels of discomfort and pain experienced by the participants. Randomisation was by opaque envelope.

Comment: Endoscopic vision uses a wide-angled, rigid Hopkins type rod to see into the ear canal. The benefits are that a very good view is obtained, but the view is two-dimensional and depth perception is reduced. With discrete lumps of wax this is a very useful technique, although training is needed. For canals completely occluded by wax, the endoscopic approach is limited (as is irrigation). The microscopic view uses a binocular microscope with three-dimensional vision and depth perception, although the immediate field of view is not as good as with the endoscope. In trained hands, microsuction is capable of removing all wax, even if some solvents or lubricants need to be used to allow wax adherent to the ear canal or tympanic membrane to be gently removed.

OPTION WAX SOFTENERS PRIOR TO IRRIGATION

- For GRADE evaluation of interventions for Ear wax, see table, p 23 .
- Overall, the benefits of wax softeners are unknown when used prior to irrigation.
- We found evidence from one small, weak study that wax softeners may improve wax clearance after irrigation compared with no treatment.
- However, we found no good evidence that wax softeners were more effective than saline at improving wax clearance after irrigation.
- We also found no good evidence that any one type of wax softener was consistently better than any other type of wax softener at improving wax clearance after irrigation.

Benefits and harms

Water-based wax softeners prior to irrigation versus no treatment:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]). The reviews had slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water and non-oil-based,

and pooled data on this basis (see Comment). [12] The second review did not use this categorisation. [13] The third review did not pool data. [6] Two reviews identified one small RCT comparing water-based softeners with no treatment. [12] [6] For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Water-based wax-softeners compared with no treatment Water-based proprietary wax-softeners may be more effective than no treatment at facilitating removal of ear wax by irrigation. However, this trial used a non-standard syringe intervention, and evidence was weak (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful irrigation (syringing)					
[12] Systematic review	45 people Data from 1 RCT	**Successful syringing** 75% with triethanolamine polypeptide/propylene glycol/chlorbutol/water (water base)-based proprietary preparation 5% with no treatment Absolute numbers not reported The ear drops were instilled at night, and people syringed their own ears the following morning Method of randomisation and allocation concealment were unclear, as was the baseline compatibility of treatment groups [12] [6]	OR 60 95% CI 6.6 to 547.3 The confidence limits are wide, and blinding in the RCT was inadequate	●●●	water-based proprietary preparation

No data from the following reference on this outcome. [13]

Adverse effects

No data from the following reference on this outcome. [12] [13] [6]

Water-based wax softeners prior to irrigation versus saline:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]). The reviews had slightly different inclusion criteria and reported a slightly different analysis. The earlier review categorised ear drops as being water-based, oil-based, or non-water and non-oil-based, and pooled data on this basis (see Comment). [12] The second review did not use this categorisation. [13] The third review did not pool data. [6] The third review [6] included one RCT [14] which was excluded from the second review. [13] The third review [6] included one further RCT reported at that time as an abstract, which has subsequently been published in full. [15] We have reported directly from both RCTs. [14] [15] For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Water-based wax-softeners compared with saline We don't know how water-based wax softeners and saline compare at facilitating removal of ear wax by irrigation (syringing) (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful irrigation (syringing)					
[12] Systematic review	91 people 2 RCTs in this analysis	**Successful syringing** 21/47 (45%) with triethanolamine polypeptide-based proprietary preparation	OR 0.5 95% CI 0.2 to 1.2 See also [13]	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		27/44 (61%) with normal saline			
[13] Systematic review	77 people 2 RCTs in this analysis	**Wax cleared after first irrigation** 9/36 (25%) with triethanolamine polypeptide-based proprietary preparation 15/41 (37%) with normal saline This analysis included the same 2 RCTs as assessed for successful irrigation by an earlier review [12]	OR 0.54 95% CI 0.20 to 1.48	⟷	Not significant
[12] Systematic review	93 people 2 RCTs in this analysis	**Successful syringing** 23/49 (47%) with docusate-based proprietary preparation 27/44 (61%) with normal saline	OR 0.5 95% CI 0.2 to 1.2 See also [13]	⟷	Not significant
[13] Systematic review	83 people 2 RCTs in this analysis	**Wax cleared after first irrigation** 10/42 (24%) with docusate-based proprietary preparation 15/41 (37%) with normal saline This analysis included the same 2 RCTs as assessed for successful irrigation by an earlier review [12]	OR 0.51 95% CI 0.19 to 1.34	⟷	Not significant
[14] RCT **3-armed trial**	74 people	**Wax clearance after irrigation** with triethanolamine polypeptide-based proprietary preparation with saline Absolute results not reported Agents were instilled for up to 2 15-minute applications followed by irrigation The remaining arm evaluated a carbamide peroxide-based proprietary preparation	P = 0.37	⟷	Not significant
[14] RCT **3-armed trial**	74 people	**Wax clearance after irrigation** with carbamide peroxide-based proprietary preparation with saline Absolute results not reported Agents were instilled for up to 2 15-minute applications followed by irrigation The remaining arm evaluated a triethanolamine polypeptide-based proprietary preparation	P = 0.06	⟷	Not significant
[15] RCT **3-armed trial**	89 people	**Complete tympanic membrane visualisation achieved after application of the wax solvent, with or without irrigation , final success rate** 16/29 (55%) with potassium carbonate/ethyl acohol/glycerol 480/thymol proprietary preparation 12/28 (43%) with saline	OR 1.6 95% CI 0.6 to 4.7 P = 0.35 This analysis based on univarate logistic regression	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		Instilled 15 minutes before examination for irrigation The remaining arm assessed an oil-based preparation			

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[14] RCT **3-armed trial**	74 people	**Pruritus** 1/24 (4%) with triethanolamine polypeptide-based proprietary preparation 2/26 (8%) with carbamide peroxide-based proprietary preparation 0/24 (0%) with saline Agents were instilled for up to 2 15-minute applications followed by irrigation	Significance not assessed		
[14] RCT **3-armed trial**	74 people	**Discomfort** 0/24 (0%) with triethanolamine polypeptide-based proprietary preparation 0/26 (0%) with carbamide peroxide-based proprietary preparation 1/24 (4%) with saline Agents were instilled for up to 2 15-minute applications followed by irrigation	Significance not assessed		
[14] RCT **3-armed trial**	74 people	**Contact dermatitis** 1/24 (4%) with triethanolamine polypeptide-based proprietary preparation 0/26 (0%) with carbamide peroxide-based proprietary preparation 0/24 (0%) with saline Agents were instilled for up to 2 15-minute applications followed by irrigation	Significance not assessed		
[15] RCT **3-armed trial**	89 people	**Adverse events** with potassium carbonate/ethyl acohol/glycerol 480/thymol proprietary preparation with saline The RCT reported that there were no adverse events in the trial			

No data from the following reference on this outcome. [12] [13] [6]

Water-based wax softeners versus oil-based wax softeners prior to irrigation:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]). The reviews had slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water and non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] The review with the earlier search date [12] found five RCTs comparing various proprietary water-based preparations (including plain water) and oil-based preparations, and pooled data. For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Water-based wax-softeners compared with oil-based wax-softeners Water-based wax-softeners and oil-based wax-softeners seem to be equally effective at facilitating removal of ear wax by irrigation (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful irrigation (syringing)					
[12] Systematic review	523 people 5 RCTs in this analysis	**Successful syringing** 249/318 (78%) with water-based preparations 161/205 (79%) with oil-based preparations	OR 1.0 95% CI 0.6 to 1.6	⟷	Not significant

No data from the following reference on this outcome. [13] [6]

Adverse effects

No data from the following reference on this outcome. [12] [13] [6]

Water-based wax softeners versus each other prior to irrigation:

We found three systematic reviews (search date 2004; [12] 2008 [6] [13]). The reviews had slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water and non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Water-based wax-softeners compared with each other We don't know how water-based wax softeners compare with each other at facilitating removal of ear wax by irrigation (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful irrigation (syringing)					
[12] Systematic review	190 people 4 RCTs in this analysis	**Successful syringing** 63/98 (64%) with docusate sodium 46/92 (50%) with triethanolamine polypeptide	OR 1.9 95% CI 0.7 to 5.0 See below	⟷	Not significant
[13] Systematic review	78 people 2 RCTs in this analysis	**Wax cleared after first irrigation** 9/36 (25%) with triethanolamine polypeptide-based proprietary preparation 10/42 (24%) with docusate-based proprietary preparation	OR 1.06 95% CI 0.37 to 3.07 This analysis included 2 of the 4 RCTs included in the above analysis [12]	⟷	Not significant

Adverse effects

No data from the following reference on this outcome. [12] [13] [6]

Oil-based wax softeners versus saline prior to irrigation:

We found one systematic review (search date 2008) [6] which included one RCT reported as a conference abstract, which has subsequently been published in full. [15] We have reported directly from the RCT. [15]

Treatment success

Oil-based wax softeners compared with saline We don't know how oil-based wax softeners compare with saline at facilitating removal of ear wax by irrigation (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful irrigation (syringing)					
[15] RCT **3-armed trial**	89 people	**Complete tympanic membrane visualisation achieved after application of the wax solvent, with or without irrigation , final success rate** 21/32 (66%) with chlorbutanol/phenol/turpentine/ethyl alcohol based proprietary preparation 12/28 (43%) with saline Instilled 15 minutes before examination for irrigation The remaining arm evaluated a water-based preparation	OR 2.5 95% CI 0.9 to 7.2 P = 0.08 This analysis based on univarate logistic regression	⟷	Not significant

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[15] RCT **3-armed trial**	89 people	**Adverse effects** with with chlorbutanol/phenol/turpentine/ethyl alcohol based proprietary preparation with saline The RCT reported that there were no adverse events in the trial			

Oil-based wax softeners versus each other prior to irrigation:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]), which between them identified four RCTs. The reviews had slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water and non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Oil-based wax softeners compared with each other We don't know how oil-based wax-softeners compare with each other at facilitating removal of ear wax by irrigation (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Successful irrigation (syringing)					
[13] Systematic review	106 people Data from 1 RCT	**Successful syringing** with turpentine oil/chlorbutanol/parachlorbenzene/arachis oil proprietary preparation with almond oil/arachis oil/rectified camphor oil proprietary preparation Absolute results not reported	Reported as not significant P value not reported	⟷	Not significant
[12] Systematic review	275 people 3 RCTs in this analysis	**Successful syringing** 93/136 (68%) with dioctyl sodium sulphosuccinate-based softener 98/139 (70%) with maize oil base or olive oil-based softener	OR 0.6 95% CI 0.2 to 2.4	⟷	Not significant

Adverse effects

No data from the following reference on this outcome. [12] [13] [6]

Non-water, non-oil based wax softeners versus water-based preparations prior to irrigation:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]). The reviews had slightly different inclusion criteria. The earlier review categorised ear drops as being water based, oil based, or non-water and non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] Two reviews included the same single RCT. [12] [6] For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Non-water, non-oil-based wax softeners compared with water-based preparations Non-water, non-oil-based wax softeners may be less effective than water-based preparations. However, evidence was weak and limited to one small study (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Wax removal					
[12] Systematic review	80 ears, number of people not reported Data from 1 RCT	**Removal of wax (all or most of wax)** 88% with triethanolamine polypeptide (water base)-based proprietary preparation (applied 30 minutes prior to syringing) 18% with carbamide peroxide (non-water, non-oil base)-based proprietary preparation Absolute results not reported The RCT had unclear randomisation, allocation concealment, and blinding [12]	OR 33.0 95% CI 9.5 to 114.3	●●●	water-based proprietary preparation

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		Some baseline characteristics were unclear [6]			

No data from the following reference on this outcome. [13]

Adverse effects

No data from the following reference on this outcome. [12] [13] [6]

Wax softeners alone versus wax softeners plus irrigation:

We found one RCT, which compared oily drops with oily drops plus irrigation and assessed improvement in hearing. [16] For adverse effects of wax softeners, see option on Wax softeners alone, p 15 .

Treatment success

Wax softeners plus irrigation compared with wax softeners alone Wax softeners plus irrigation may be more effective than wax softeners alone at improving hearing after removal of wax (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Improvement in hearing					
[16] RCT	116 people attending ear syringing clinics	**Improvement in hearing** with oily drops (not further defined) plus syringing with oily drops (not further defined) alone Absolute results not reported The RCT did not relate improvements in hearing to amount of wax removed People attended the clinic for a variety of reasons, including blocked ears (78%), hearing problems (72%), noises in ears (33%), itchy ears (29%), dizziness (16%), and ear pain (14%)	Difference in mean improvement in hearing 6.9 dB, 95% CI 3.8 dB to 10.1 dB P value not reported Possible bias; for full details see Further information on studies	○○○	oily drops plus syringing

Adverse effects

No data from the following reference on this outcome. [16]

Further information on studies

[15] The method of randomisation or allocation concealment was not stated. Although the trial was described as single-blind, it was not clear whether outcome assessment was blinded.

[16] Oily drops may impair baseline hearing level, which may have biased the results in favour of intervention. This makes the RCT difficult to interpret.

Comment: One review [12] categorised ear drops into three groups, water-based; oil-based; and non-water, non-oil-based, in order to pool data. Both the first and second reviews noted that the included RCTs were of limited methodological quality. [12] [13] See Comment for Wax softeners alone, p 15 . The third review had broader inclusion criteria than the other two reviews and included 22 RCTs and 4 CCTs for all interventions (including trials of drops, irrigation, and other mechanical removal). [6] The review noted that overall (including all studies in the review) there was little consistency among included studies. There were variations in the characteristics of people recruited and the extent of the earwax problem; there was limited discussion of baseline characteristics; and many studies were published in a short paper format, with some being published over 20 years ago. [6] It noted that it is likely in current practice than an irrigator rather than a metal syringe will be used, but syringes were used in many of the studies or it may not be clear as the terms 'syringing' and 'irrigation' may sometimes have been used interchangeably. [6] The third review also included an economic analysis which we have not reported here.

OPTION WAX SOFTENERS ALONE

- For GRADE evaluation of interventions for Ear wax, see table, p 23 .
- Overall, the benefits of wax softeners are unknown when used alone.
- We found limited evidence from one small study that wax softeners alone may improve wax clearance compared with no treatment.
- However, we found no consistent evidence that wax softeners alone were more effective than sterile water or normal saline at improving wax clearance.
- We also found no good evidence that any one type of wax softener was consistently better than any other type of wax softener at improving wax clearance.

Benefits and harms

Wax softeners versus no treatment:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]), which used slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water, non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] All the reviews [12] [13] [6] identified the same RCT. [5]

Treatment success

Water-based and oil-based wax softeners compared with no treatment Water-based and oil-based wax softeners may be more effective at completely clearing wax compared with no treatment. However, evidence was weak and the result was of borderline significance (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Wax clearance					
[5] RCT **4-armed trial**	97 people, 155 ears, older people in hospital with impacted wax In review [12] [13] [6]	**Proportion of ears with complete wax clearance** 9/40 (22%) with arachis oil/chlorbutol/*p*-dichlorobenzene (oil-based) wax softener 2/38 (5%) with no treatment Ear drops were used for 5 days The remaining arms evaluated a water-based wax softener and sterile water Analysis not by intention to treat; for full details see Further information on studies	P <0.05 for oil-based wax softener *v* no treatment Result was of borderline significance	○○○	wax softener

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		Sterile water found to be more effective than no treatment; see Further information on studies for full details			
[5] RCT **4-armed trial**	97 people, 155 ears, older people in hospital with impacted wax In review [12] [13] [6]	**Proportion of ears with complete wax clearance** 8/39 (21%) with sodium bicarbonate/glycerol/sterile water (water-based) wax softener 2/38 (5%) with no treatment Ear drops were used for 5 days The remaining arms evaluated an oil-based wax softener and sterile water Analysis not by intention to treat; for full details see Further information on studies Sterile water found to be more effective than no treatment; see Further information on studies for full details	P <0.05 for water-based wax softener *v* no treatment Result was of borderline significance	○○○	wax softener

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[12] Systematic review	Population details not reported	**Adverse effects** with wax softeners The review did not report any adverse effects directly attributable to ear drops in 3 identified RCTs, but noted that some people had pain (10 people) or bleeding (1 person) on subsequent syringing			
[13] Systematic review	Population details not reported	**Adverse effects** with wax softeners The review noted that general harms described with ear drops included sensitivities to the constituents of some drops, increased hearing loss, and dizziness if the drops were too cold			

Wax softeners versus sterile water:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]), which used slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water, non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] All the reviews [12] [13] [6] identified the same RCT. [5]

Treatment success

Wax softeners compared with sterile water We don't know whether water-based and oil-based wax softeners are more effective than sterile water at clearing wax (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Wax clearance					
[5] RCT **4-armed trial**	97 people, 155 ears, older people in hospital with impacted wax In review [12] [13] [6]	**Proportion of ears with complete wax clearance** 9/40 (22%) with arachis oil/chlorbutol/*p*-dichlorobenzene (oil-based) wax softener 8/39 (21%) with sodium bicarbonate/glycerol/sterile water (water-based) wax softener 8/38 (21%) with sterile water alone Ear drops were used for 5 days The remaining arm evaluated no treatment Analysis not by intention to treat; for full details see Further information on studies	Among-group difference reported as not significant P value not reported	⟷	Not significant

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[12] Systematic review	Population details not reported	**Adverse effects** with wax softeners The review did not report any adverse effects directly attributable to ear drops in 3 identified RCTs, but noted that some people had pain (10 people) or bleeding (1 person) on subsequent syringing			
[13] Systematic review	Population details not reported	**Adverse effects** with wax softeners The review noted that general harms described with ear drops included sensitivities to the constituents of some drops, increased hearing loss, and dizziness if the drops were too cold			

Water-based wax softener versus saline:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]), which used slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water, non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6]

Treatment success

Water-based softeners compared with normal saline Water-based proprietary preparations containing triethanolamine polypeptide may be more effective at clearing wax compared with saline, but we don't know whether softeners containing sodium docusate are more effective than saline at clearing wax (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Wax clearance					
[12] Systematic review	91 children 2 RCTs in this analysis	**Proportion of children whose ears were completely clear** 11/47 (23%) with triethanolamine polypeptide (water base)-based softener 3/44 (7%) with normal saline Ear drops were applied as a single installation, and ears were assessed after 15 minutes	OR 4.6 95% CI 1.1 to 18.5 Potential bias (see Further information on studies for full details) The later review performed the same numerical analysis of the 2 RCTs, although it calculated a slightly different summary statistic (OR 3.77, 95% CI 1.18 to 12.04)	●●○	water-based wax softener
[12] Systematic review	91 children 2 RCTs in this analysis	**Proportion of children whose ears were completely clear** 6/49 (12%) with sodium docusate (water base)-based softener 3/44 (7%) with normal saline Ear drops were applied as a single installation, and ears were assessed after 15 minutes	OR 1.9 95% CI 0.4 to 8.8 Potential bias (see Further information on studies for full details) The later review performed the same numerical analysis of the 2 RCTs, although it calculated a slightly different summary statistic (OR 1.90, 95% CI 0.48 to 7.46)	⟷	Not significant

Adverse effects

No data from the following reference on this outcome. [12] [13] [6]

Water-based wax softeners versus each other:

We found three systematic reviews (search date 2004; [12] 2008 [13] [6]). The reviews used slightly different inclusion criteria. The earlier review categorised ear drops as being water-based, oil-based, or non-water, non-oil-based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6]

Treatment success

Water-based wax softeners compared with each other We don't know how water-based wax softeners compare with each other at clearing wax (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Wax clearance					
[12] Systematic review	146 ears (number of people not clear) 3 RCTs in this analysis	**Proportion of ears clear of wax , 15 minutes** 11/76 (14%) with docusate sodium (water-based) 13/70 (19%) with triethanolamine polypeptide (water-based) Single installation of softeners	OR 0.8 95% CI 0.2 to 2.8 See below	⟷	Not significant
[13] Systematic review	96 people 2 RCTs in this analysis	**Syringing not necessary** 6/45 (13%) with docusate-based proprietary preparation 11/51 (21%) with triethanolamine polypeptide-based proprietary preparation	OR 1.77 95% CI 0.62 to 5.11 Included 2 of the 3 RCTs included in the above analysis [12]	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[12] Systematic review	69 people, 138 ears Data from 1 RCT	**Wax clearance** with aqueous sodium bicarbonate (water-based) with acetic acid (water-based) Absolute results not reported	Reported as not significant P value not reported	⟷	Not significant

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[12] Systematic review	Number of people/ears not clear	**Adverse effects** with water-based softeners 1 included RCT reported 2 cases of 'stinging' with acetic acid drops (further details not reported) 2 included RCTs found single cases of irritation, smell, and buzzing noise, with different proprietary agents 1 included RCT reported 6 cases of otitis externa with different ear drops			

Non-water, non-oil wax softener versus oil-based wax softener:

We found two systematic reviews (search date 2004; [12] 2008 [6]). The reviews identified one RCT comparing non-water, non-oil-based softeners with oil-based softeners. [12] [6] We found one subsequent RCT. [17]

Treatment success

Non-water, non-oil-based softeners compared with oil-based softeners We don't know how non-water, non-oil-based proprietary preparations and oil-based preparations compare at clearing wax (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Wax clearance					
[12] Systematic review	50 people, 100 ears Data from 1 RCT	**Wax clearance (reduction in wax in more than 50% of ears)** with choline salicylate/glycerol/ethyleneoxide-polyoxypropylene glycol (non-water non-oil-based) with arachis oil/chlorbutol/*p*-dichlorobenzene (oil-based) Absolute results not reported	OR 1.1 95% CI 0.5 to 2.4 P value not reported	⟷	Not significant
[17] RCT **3-armed trial**	38 people, 76 ears	**Mean difference between pre- and post-treatment occlusion scores (0 = no occlusion, 1 = <50% occluded, 2 = >50% occluded, 3 = complete occlusion)** 1.92 with carbamide peroxide/anhydrous glycerine-based softener (non-water non-oil base)	P value not reported Reported as 'no difference' regarding the degree of occlusion between the 3 treatment groups		

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		1.46 with arachis oil/chlorobutanol/dichlorobenzene-based softener 2.30 with mineral oil/paraffin/squalane/spearmint oil-based softener			

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[12] Systematic review	Number of people/ears not clear	**Adverse effects** with water-based softeners 2 included RCTs found single cases of irritation, smell, and buzzing noise, with different proprietary agents 1 included RCT reported 6 cases of otitis externa with different ear drops			

Oil-based wax softeners versus each other:

We found three systematic reviews (search date 2004; [12] 2008; [13] [6] see Comment). The reviews used slightly different inclusion criteria. The earlier review categorised ear drops as being water based, oil based, or non-water non-oil based, and pooled data on this basis (see Comment). [12] The later review did not use this categorisation. [13] The third review did not pool data. [6] The reviews identified one RCT comparing oil-based preparations with each other. [12] [13] [6]

Treatment success

Oil-based softeners compared with each other Oil-based preparations containing arachis oil/almond oil/rectified camphor oil may be more effective at reducing the need for irrigation compared with an oil-based preparation containing arachis oil/chlorobutol/*p*-dichlorobenzene. However, evidence was weak and limited to one small study (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Need for irrigation (syringing)					
[12] Systematic review	106 people Data from 1 RCT	**Proportion of people not requiring syringing** 26% with arachis oil/almond oil/rectified camphor oil (oil base)-based softener 11% with arachis oil/chlorobutol/*p*-dichlorobenzene (oil base)-based softener Absolute numbers not reported The RCT had unclear randomisation, allocation concealment, and blinding [12] [6]	OR 2.8 95% CI 1.0 to 8.0	●●○	arachis oil/almond oil/rectified camphor oil-based softener

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[12] Systematic review	106 people	**Adverse effects ('mainly pain/irritation'; no further details reported)** 7 people with arachis oil/almond oil/rectified camphor oil (oil-base)-based softener 10 people with arachis oil/chlorbutol/*p*-dichlorobenzene (oil-base)-based softener Absolute results not reported No further details reported	Significance not assessed		

Further information on studies

[5] *Sterile water versus no treatment* the RCT found that sterile water improved rate of wax clearance compared with no treatment (complete clearance of ears: 8/38 [21%] with sterile water *v* 2/38 [5%] with no treatment; P <0.05; result was of borderline significance). *Analysis* of 113 people initially randomised, data were only presented for the 97 (86%) people who completed the trial. The analysis was not by intention to treat.

[12] In one RCT (48 children) that included the analysis for water-based wax-softener versus saline, not all ears were completely occluded at baseline, which may have introduced bias if the proportion with partial obstruction was different between groups. [13]

Comment: One review categorised ear drops into three groups (water-based, oil-based, and non-water, non-oil-based) in order to pool data. [12] The rationale was that the mechanism of action between these three groups is different, and those with similar properties or constituents have a similar mechanism of action. [12] Some RCTs reported water or saline as control or placebo. However, water or saline may or may not be inert in these circumstances. [5] [7] Where water or saline has been used as a comparator, we have stated this and not used the term control or placebo. The first and second reviews noted that, overall, the included RCTs were of poor or modest methodological quality. [12] [13] Most included trials did not use rigorous methods of randomisation, and did not control for degree of ear canal occlusion at randomisation. In many, blinding was unclear or inadequate. [12] Many trials were sponsored by companies that manufactured only one of the products being tested, but the possibility of publication bias (failure to publish unfavourable results) has not been assessed. The inclusion criteria for the RCTs were not always clear: many stated that the participants had impacted wax, without defining this. We found no good evidence about the optimal duration of treatment. The second review concluded that, because of the heterogeneous, poor-quality trials, it was difficult to offer any definitive recommendations on the effectiveness of cerumenolytics for the removal of symptomatic ear wax. [13] The review further concluded that it was uncertain if any one type of drop was better than any other. The third review concluded that, from the available evidence, it was not possible to say any one type of softener is superior in clearing earwax with or without subsequent irrigation. [6]

GLOSSARY

Impacted wax Wax that has been compressed in the ear canal, completely obstructing the lumen. In practice, many RCTs define impaction as the presence of symptoms associated with wax obscuring the ear drum.

Obstructing wax Wax that obscures direct vision of the ear drum.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Ear irrigation (syringing) One systematic review added. [6] Categorisation unchanged (trade-off between benefits and harms).

Manual removal (other than ear irrigation) One systematic review added. [6] Categorisation unchanged (unknown effectiveness).

Wax softeners alone One systematic review updated [13], one systematic review added, [6] and one RCT added. [17] Categorisation unchanged (unknown effectiveness).

Wax softeners prior to irrigation One systematic review updated [13] and one systematic review [6] and one RCT added. [15] Categorisation unchanged (unknown effectiveness).

REFERENCES

1. Kalantan KA, Abdulghani H, Al-Taweel AA, et al. Use of cotton tipped swab and cerumen impaction. *Ind J Otol* 1999;5:27–31.
2. Minja BM, Machemba A. Prevalence of otitis media, hearing impairment and cerumen impaction among school children in rural and urban Dar es Salaam, Tanzania. *Int J Pediatr Otorhinolaryngol* 1996;37:29–34.[PubMed]
3. Swart SM, Lemmer R, Parbhoo JN, et al. A survey of ear and hearing disorders amongst a representative sample of Grade 1 school children in Swaziland. *Int J Pediatr Otorhinolaryngol* 1995;32:23–34.[PubMed]
4. Lewis-Cullinan C, Janken JK. Effect of cerumen removal on the hearing ability of geriatric patients. *J Adv Nurs* 1990;15:594–600.[PubMed]
5. Keane EM, Wilson H, McGrane D, et al. Use of solvents to disperse ear wax. *Br J Clin Pract* 1995;49:71–72.[PubMed]
6. Clegg AJ, Loveman E, Gospodarevskaya E, et al. The safety and effectiveness of different methods of earwax removal: a systematic review and economic evaluation. *Health Technol Assess* 2010;14:1–192. Search date 2008.[PubMed]
7. Pavlidis C, Pickering JA. Water as a fast acting wax softening agent before ear syringing. *Aust Fam Physician* 2005;34:303–304.[PubMed]
8. Ogunleye AOA, Awobem AA. Trends in ear syringing in Ibadan, Nigeria. *Afr J Med Sci* 2004;33:35–37.[PubMed]
9. Sharp JF, Wilson JA, Ross L, et al. Ear wax removal: a survey of current practice. *BMJ* 1990;301:1251–1253.[PubMed]
10. National Institute for Health and Care Excellence. Clinical knowledge summaries: earwax - scenario: ear irrigation. May 2012. Available at http://cks.nice.org.uk/earwax#!scenario:1 (last accessed 18 December 2014).
11. Pothier DD, Hall C, Gillett S. A comparison of endoscopic and microscopic removal of wax: A randomised clinical trial. *Clin Otolaryngol* 2006;31:375–380.[PubMed]
12. Hand C, Harvey I. The effectiveness of topical preparations for the treatment of earwax: a systematic review. *Br J Gen Pract* 2004;54:862–867.[PubMed]
13. Burton MJ, Doree CJ. Ear drops for the removal of ear wax. In: The Cochrane Library, Issue 6, 2014. Chichester, UK: John Wiley & Sons, Ltd. Search date 2008.
14. Roland PS, Eaton EA, Gross RD, et al. Randomized placebo-controlled evaluation of Cerumenex and Murine earwax removal products. *Arch Otolaryngol Head Neck Surg* 2004;130:1175–1177.[PubMed]
15. Caballero M, Navarrete P, Prades E, et al. Randomized, placebo-controlled evaluation of chlorobutanol, potassium carbonate, and irrigation in cerumen removal. *Ann Otol Rhinol Laryngol* 2009;118:552–555.[PubMed]
16. Memel D, Langley C, Watkins C, et al. Effectiveness of ear syringing in general practice: a randomised controlled trial and patients' experiences. *Br J Gen Pract* 2002;52:906–911.[PubMed]
17. Oron Y, Zwecker-Lazar I, Levy D, et al. Cerumen removal: comparison of cerumenolytic agents and effect on cognition among the elderly. *Arch Gerontol Geriatr* 2011;52:228–232.[PubMed]

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Disclaimer

GRADE **Evaluation of interventions for Ear wax.**

Important outcomes			Treatment success						
Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
What are the effects of methods to remove ear wax?									
1 (26) [7]	Treatment success	Ear irrigation with prior water instillation versus ear irrigation without prior water instillation	4	–3	0	0	0	Very low	Quality points deducted for sparse data, lack of blinding, subjective assessment of outcome, and manual irrigation
1 (100) [11]	Treatment success	Endoscopic vision versus microscopic vision to assist mechanical dewaxing	4	–3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and blinding flaws
1 (45) [12]	Treatment success	Water-based wax softeners prior to irrigation versus no treatment	4	–3	0	–1	+2	Low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods; effect size points added for OR >5; directness point deducted for non-standard syringe method
at least 5 (at least 256) [12] [13] [14] [15]	Treatment success	Water-based wax softeners prior to irrigation versus saline	4	–2	0	0	0	Low	Quality points deducted for weak methods and incomplete reporting of results
5 (523) [12]	Treatment success	Water-based wax softeners versus oil-based wax softeners prior to irrigation	4	–1	0	0	0	Moderate	Quality point deducted for weak methods
4 (190) [12] [13]	Treatment success	Water-based wax softeners versus each other prior to irrigation	4	–2	0	0	0	Low	Quality points deducted for sparse data and weak methods
1 (60) [15]	Treatment success	Oil-based wax softeners versus saline prior to irrigation	4	–2	0	0	0	Low	Quality points deducted for sparse data and weak methods
4 (381) [12] [13]	Treatment success	Oil-based wax softeners versus each other prior to irrigation	4	–2	0	0	0	Low	Quality points deducted for incomplete reporting of results and weak methods
1 (unclear) [12]	Treatment success	Non-water, non-oil based wax softeners versus water-based preparations prior to irrigation	4	–3	0	–1	2	Low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods; directness point deducted for unclear population/baseline; effect size points added for OR >5
1 (116) [16]	Treatment success	Wax softeners alone versus wax softeners plus irrigation	4	–3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and for possible bias
1 (97) [5]	Treatment success	Wax softeners versus no treatment	4	–3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods
1 (97) [5]	Treatment success	Wax softeners versus sterile water	4	–3	0	0	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods
2 (91) [12] [13]	Treatment success	Water-based wax softener versus saline	4	–2	0	0	0	Low	Quality points deducted for sparse data and weak methods

Important outcomes			Treatment success						
Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
4 (unclear) [12] [13]	Treatment success	Water-based wax softeners versus each other	4	–2	0	0	0	Low	Quality points deducted for incomplete reporting of results and weak methods
2 (88) [12] [17]	Treatment success	Non-water, non-oil wax softener versus oil-based wax softener	4	–3	0	0	0	Very low	Quality points deducted for sparse data, weak methods, and incomplete reporting of results
1 (106) [12] [13]	Treatment success	Oil-based wax softeners versus each other	4	–3	0	0	1	Low	Quality points deducted for sparse data, incomplete reporting of results, and weak methods; effect size point added for OR >2

We initially allocate 4 points to evidence from RCTs, and 2 points to evidence from observational studies. To attain the final GRADE score for a given comparison, points are deducted or added from this initial score based on preset criteria relating to the categories of quality, directness, consistency, and effect size. Quality: based on issues affecting methodological rigour (e.g., incomplete reporting of results, quasi-randomisation, sparse data [<200 people in the analysis]). Consistency: based on similarity of results across studies. Directness: based on generalisability of population or outcomes. Effect size: based on magnitude of effect as measured by statistics such as relative risk, odds ratio, or hazard ratio.