Otitis externa

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ABSTRACT

INTRODUCTION: Otitis externa is thought to affect 10% of people at some stage, and can present in acute, chronic, or necrotising forms. Otitis externa may be associated with eczema of the ear canal, and is more common in swimmers, in humid environments, in people with narrow ear canals, in hearing-aid users, and after mechanical trauma. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical question: What are the effects of empirical treatments for otitis externa? We searched: Medline, Embase, The Cochrane Library, and other important databases up to October 2013 (BMJ Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). RESULTS: Nine studies were included. 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: oral antibiotics, specialist aural toilet, topical acetic acid, topical aluminium acetate, topical antibacterials, topical antifungals, topical corticosteroids, and combinations of these agents.

QUESTIONS

INTERVENTIONS

EMPIRICAL TREATMENTS FOR OTITIS EXTERNA

To be covered in future updates

Surgery for ear canal stenosis after otitis externa

Treatment for necrotising otitis externa

Footnote

*Based on consensus.

†Please see option on Antibacterials (topical; with or without corticosteroids), p 6 .

Key points

- Otitis externa is thought to affect 10% of people at some stage, and can present as acute, chronic, or necrotising forms. While milder forms of acute otitis externa are often short-lived isolated episodes, a substantial proportion of cases can persist for weeks or even months, despite intensive treatment. Once resolved, there is a significant risk of recurrence. Because of the risk of chronicity or recurrence, we have excluded studies with follow-up periods of less than 1 month; optimal treatment should not just transiently suppress early symptoms.

  Otitis externa may be associated with eczema or psoriasis of the ear canal or conchal bowl. It is more common in swimmers, in humid environments, in people with narrow ear canals, in hearing-aid users, and after mechanical trauma or ear syringing.

  The most common pathogens are *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

  Fungal overgrowth can occur, especially after prolonged antibiotic use.

- Topical aluminium acetate may be as effective as a topical antibacterial-corticosteroid at improving cure rates in people with acute otitis externa.

- Topical antibacterial agents are likely to improve signs and symptoms of otitis externa.

  Combining topical antibacterial agents and corticosteroids (methylprednisolone-neomycin drops) is likely to be more effective than placebo in reducing signs and symptoms of otitis externa over 28 days.

  We don't know whether any one topical antibacterial regimen should be used in preference to another.

- There is a lack of evidence for corticosteroids when used alone, however they are likely to be beneficial when used in combination with antibacterials.

  Consensus suggests that topical corticosteroids alone may reduce signs and symptoms of otitis externa, but few good-quality studies have been found assessing these agents alone in this population.

- There is a lack of evidence to demonstrate the benefit of specialist aural toilet use in otitis externa despite the fact there is consensus that it is likely to be beneficial and it is a key treatment used in the secondary care setting, particularly in cases where topical therapy alone has failed.
- We don't know whether topical antifungal agents improve symptoms of otitis externa. However, consensus would suggest that it is inferior as a first-line empirical agent, given that the most common pathogens implicated are bacterial; although, this may not be the case in tropical climates.
- Oral antibiotics have not been shown to be beneficial.

  Consensus suggests that adding oral antibiotics to topical anti-infective agents will not improve symptoms compared with topical agents alone.
- Topical acetic acid is likely to increase cure of otitis externa when used with topical anti-infective agents and corticosteroids, but is of unknown effectiveness when used alone.
- Preservatives in some topical ear products may potentially cause discomfort or contact dermatitis. Patient choice of generic topical ear drops may, therefore, be informed by the preservative used in a preparation.
- Overall, there is a relative lack of high-quality trials to assess each of these treatments, so meta-analysis is often not possible. In general, the outcomes of the various topical treatments available, and their combinations, are similar.
- Most of the studies have been performed in a secondary care setting, where aural toilet has also been provided. It is not clear how applicable these findings are to the primary care setting, where most cases of otitis externa are managed.

Clinical context

GENERAL BACKGROUND

Otitis externa is a common inflammatory (normally infective) condition affecting the external ear canal. It can usually be treated successfully in the primary care setting with ear drops.

FOCUS OF THE REVIEW

There is a wide range of available topical preparations used in clinical practice to treat otitis externa, including antiseptic agents, antibiotics, corticosteroids, antifungals, and combinations of these. The main purpose of this review is to identify the evidence base to support the use of these treatments in uncomplicated otitis externa.

COMMENTS ON EVIDENCE

We found numerous studies on the medical treatment of otitis externa but the majority are of poor quality, underpowered, lack blinding, or have inadequate follow-up to be of clinical value. There are also multiple potential interventions, which are often used in combination, so the evidence available to assess and compare individual interventions is generally limited.

SEARCH AND APPRAISAL SUMMARY

The update literature search for this review was carried out from the date of the last search, October 2007, to October 2013. 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, 38 records were screened for inclusion in the review. Appraisal of titles and abstracts led to the exclusion of 28 studies and the further review of 10 full publications. Of the 10 full articles evaluated, one systematic review was added at this update.

ADDITIONAL INFORMATION

This review also considers the improved efficacy of topical agents over oral antibiotics in uncomplicated otitis externa. In addition to topical ear drops, aural toilet (with microsuction or ear mopping) and the use of ear wicks to aid administration of topical therapy in patients with oedematous ear canals constitute common treatment interventions. Aural toilet is usually performed in the secondary care setting, often when topical treatment alone has failed. This treatment practice is included in this review. However, given the methodological difficulties of performing robust trials with a procedural intervention, the evidence is sparse.

DEFINITION Otitis externa is inflammation of the external ear canal, often with infection. This inflammation is usually generalised throughout the ear canal, so it is often referred to as 'diffuse otitis externa'. This review excludes localised inflammations, such as furuncles. Otitis externa has acute (<6 weeks), chronic (>3 months), and necrotising (malignant) forms. While milder forms of acute otitis externa are often short-lived isolated episodes, a substantial proportion of cases can persist for weeks or even months, despite intensive treatment. And, once resolved, there is a significant risk

of recurrence. It causes pain with aural discharge and associated hearing loss. [1] If the ear canal is visible, it appears red and inflamed. *Pseudomonas aeruginosa* and *Staphylococcus aureus* are the most frequent bacterial pathogens in otitis externa. Fungal overgrowth (e.g., with *Aspergillus niger* and *candida*) is also common, especially after prolonged antibiotic treatment. Chronic otitis externa may result in canal stenosis with associated hearing loss, for which it may be difficult to fit hearing aids. Necrotising otitis externa is defined by destruction of the temporal bone, usually in people with diabetes or in people who are immunocompromised, and can be life threatening. [2] Making an accurate diagnosis can be challenging, firstly to differentiate between otitis media and otitis externa (although these may co-exist) and secondly to decide on the most likely underlying cause (e.g., bacterial, fungal, dermatitis), so that the most appropriate treatment can be started. In this review, we look at the empirical treatment of only acute and chronic otitis externa. Topical treatment refers to drops, ointment, solution, cream, or spray. The population studied included adults and children.

INCIDENCE/ PREVALENCE

Otitis externa is common worldwide. The exact incidence is unknown, but 10% of people are thought to have been affected at some time. [3] The condition does affect children, but is more common in adults. It accounts for a large proportion of the workload in otolaryngology departments, but milder cases are often managed in primary care. [3]

AETIOLOGY/ RISK FACTORS

Otitis externa may be associated with dermatological disease of the ear canal and conchal bowl, such as eczema and, less commonly, psoriasis. It is more common in swimmers, in humid environments, in people with narrow external ear canals, in hearing-aid users, and after mechanical trauma or ear syringing. [4] Many clinicians suggest prophylactic measures for patients with recurrent otitis externa. These include water precautions to keep the ears dry, topical corticosteroids to treat underlying eczema, or regular antiseptic agents (e.g., acetic acid or aluminium acetate) to reduce the pH of the ear canal, thus maintaining an unfavourable milieu for microbes. The rationale for these measures is reasonable, given that moisture and eczema are risk factors for otitis externa. The evidence to determine the efficacy of these practices is, however, lacking and does not form part of this review.

PROGNOSIS

We found few reliable data. Many cases of otitis externa resolve spontaneously over several weeks or months. Acute episodes tend to recur, although risk of recurrence is unknown. Experience suggests that chronic inflammation affects a small proportion of people after a single episode of acute otitis externa and can, rarely, lead to canal stenosis. [1]

AIMS OF INTERVENTION

To improve or abolish symptoms; to prevent recurrence and complications, with minimal adverse effects.

OUTCOMES

Symptom improvement severity and duration of signs and symptoms (pain, discharge, hearing loss, redness); **cure rate** defined as complete resolution of signs and symptoms; **recurrence**; **quality of life**; and **adverse effects**.

METHODS

Search strategy *BMJ Clinical Evidence* search and appraisal October 2013. Databases used to identify studies for this systematic review include: Medline 1966 to October 2013, Embase 1980 to October 2013, The Cochrane Database of Systematic Reviews 2013, issue 2 (1966 to date of issue), Database of Abstracts of Reviews of Effects (DARE), and the Health Technology Assessment (HTA) database. **Inclusion criteria** Study design criteria for inclusion in this review were systematic reviews and RCTs published in English, at least single-blinded, and containing 20 or more individuals (at least 10 per arm), of whom more than 80% were followed up. The minimum length of follow-up required to include studies was 1 month. We decided to exclude studies with a minimum follow up period of less than 1 month because of the risk of the condition becoming chronic and recurrent, meaning that optimal treatment should not simply transiently suppress early symptoms. We excluded all studies described as 'open', 'open label', or not blinded unless blinding was impossible. *BMJ Clinical Evidence* does not necessarily report every study found (e.g., every systematic review). Rather, we report the most recent, relevant and comprehensive studies identified through an agreed process involving our evidence team, editorial team, and expert contributors. **Evidence evaluation** A systematic literature search was conducted by our evidence team, who then assessed titles and abstracts, and finally selected articles for full text appraisal against inclusion and exclusion criteria agreed a priori with our expert contributors. In consultation with the expert contributors, studies were selected for inclusion and all data relevant to this overview extracted into the benefits and harms section of the review. In addition, information that did not meet our predefined criteria for inclusion in the benefits and harms section, may have been reported in the 'Further information on studies' or 'Comment' section. **Adverse effects** All serious adverse effects, or those adverse effects reported as statistically significant, were included in the harms section of the overview. Prespecified adverse effects identified as being clinically important were also reported, even if the results

were not statistically significant. Although *BMJ Clinical Evidence* presents data on selected adverse effects reported in included studies, it is not meant to be, and cannot be, a comprehensive list of all adverse effects, contraindications, or interactions of included drugs or interventions. A reliable national or local drug database must be consulted for this information. **Comment and Clinical guide sections** In the Comment section of each intervention, our expert contributors may have provided additional comment and analysis of the evidence, which may include additional studies (over and above those identified via our systematic search) by way of background data or supporting information. As *BMJ Clinical Evidence* does not systematically search for studies reported in the Comment section, we cannot guarantee the completeness of the studies listed there or the robustness of methods. Our expert contributors add clinical context and interpretation to the Clinical guide sections where appropriate. **Data and Quality** 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). *BMJ Clinical Evidence* does not report all methodological details of included studies. Rather, it reports by exception any methodological issue or more general issue which may affect the weight a reader may put on an individual study, or the generalisability of the result. These issues may be reflected in the overall GRADE analysis. 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 empirical treatments for otitis externa?

OPTION ALUMINIUM ACETATE (TOPICAL)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- We found no direct information about whether topical aluminium acetate is more effective than no active treatment.
- Topical aluminium acetate may be as effective as a topical antibacterial-corticosteroid at improving cure rates in people with acute otitis externa.

Benefits and harms

Aluminium acetate (topical) versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) [5] that found no RCTs on this comparison.

Aluminium acetate (topical) versus antibacterial-corticosteroid (topical):

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found one RCT on this comparison, which did not meet their inclusion criteria. [5] We have reported this RCT here with caveats (see Further information on studies). [6]

Symptom improvement

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

Cure rate

Aluminium acetate (topical) compared with antibacterial-corticosteroid (topical) Aluminium acetate drops may be as effective as antibacterial-corticosteroid drops at increasing cure rates or reducing time to clinical cure at 4 weeks in people with acute diffuse otitis externa (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Cure rate					
[6] RCT	126 people with any severity of acute diffuse otitis externa on otoscopy in a primary-care setting If present, people in both groups had discharge removed (no further details given on technique)	**Clinical cure rate , 4 weeks** 59/65 (91%) with aluminium acetate drops 49/61 (80%) with polymyxin-neomycin-hydrocortisone drops Each treatment given for 14 days	P >0.2 See Further information on studies	⟷	Not significant
Mean time to clinical resolution					
[6] RCT	126 people with any severity of acute diffuse otitis externa on otoscopy in a primary-care setting If present, people in both groups had discharge removed (no further details given on technique)	**Mean time to clinical resolution** 9.4 days with aluminium acetate drops 11.1 days with polymyxin-neomycin-hydrocortisone drops Each treatment given for 14 days	P >0.2 See Further information on studies	⟷	Not significant

Recurrence

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

Quality of life

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

Adverse effects

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

Aluminium acetate (topical) versus topical antibacterials alone, topical antifungals (with or without corticosteroids), topical corticosteroids alone, topical acetic acid, or oral antibiotics (with or without anti-infective agents [topical]), or specialist aural toilet:

We found no systematic review or RCTs.

Further information on studies

[6] This RCT was excluded by the systematic review [5] on the basis of it not being blinded. However, we found the issue of blinding to be unclear in the original RCT and have reported the data with the caveat that there is uncertainty over this issue. We have, therefore, deducted points on quality in the GRADE table. Our decision to continue to report this data has also been influenced by the lack of other trials on this intervention and the unlikelihood that this trial will be repeated. The RCT may be underpowered to identify a clinically important difference in efficacy between the two treatments used.

Comment: **Clinical guide**

Although we have not identified an RCT comparing topical aluminium acetate with no active treatment, the cure rates reported in the included RCT suggest that topical aluminium acetate is likely to be beneficial. [6] Topical aluminium acetate is often used for the treatment of fungal otitis externa, or as a prophylactic treatment of recurrent otitis externa. However, there is little evidence to confirm these beneficial effects. Aluminium acetate needs to be made up fresh because it degrades quickly, which may be a limiting factor for its use.

OPTION ANTIBACTERIALS (TOPICAL; WITH OR WITHOUT CORTICOSTEROIDS)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- Topical antibacterial agents are likely to improve signs and symptoms of otitis externa.
- We found no clinically important results about topical antibacterials alone compared with no active treatment in people with otitis externa.
- Combining topical antibacterial agents and corticosteroids (methylprednisolone-neomycin drops) seems to be more effective than placebo in reducing signs and symptoms of otitis externa over 28 days. The evidence for this is from one small RCT.
- We don't know whether any one topical antibacterial regimen should be used in preference to another.
- Topical antibacterial-corticosteroid may be as effective as topical aluminium acetate at improving cure rates in people with acute otitis externa, but this is from one small RCT.
- Topical dexamethasone-neomycin-polymyxin (topical antibacterial-corticosteroid) seems more effective at reducing the risk of recurrence at between 3 and 6 weeks in people with acute otitis externa compared with topical acetic acid, but evidence is from one RCT only.
- We don’t know whether topical antibacterial-corticosteroid and topical acetic acid-corticosteroid differ in effectiveness at reducing recurrence rates in people with otitis externa.
- Neomycin-dexamethasone-glacial acetic acid spray may be more effective at increasing the proportion of people with acute otitis externa who are clinically cured at 4 weeks compared with glacial acetic acid spray alone. The evidence for this is from one small RCT.

Benefits and harms

Topical antibacterials alone versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Topical antibacterials alone versus topical aluminium acetate, topical antifungals, topical corticosteroids, or oral antibiotics:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on these comparisons. [5]

Topical antibacterial-corticosteroids versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found two RCTs. [5] Both RCTs, as they are reported in the review, did not meet *BMJ Clinical Evidence* inclusion criteria for minimal length of follow-

up of 1 month. However, there was some lack of clarity reported in the review in the first RCT on the time of follow-up. Therefore, we report directly from the RCT with caveats (see Further information on studies). [7]

Symptom improvement

Topical antibacterial-corticosteroid compared with placebo Topical antibacterial-corticosteroid (methylprednisolone-neomycin drops) seems to be more effective at improving symptoms and signs of otitis externa at 28 days compared with placebo (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Symptom improvement					
[7] RCT	40 people in secondary care with mild, moderate, or severe acute/chronic diffuse otitis externa All people in the RCT had 'cleansing' of their external ear canals (details not reported)	**Symptoms and signs ('good' response) , 28 days** 11/20 (55%) with methylprednisolone-neomycin drops 2/20 (10%) with placebo Treatment given for 10 days	P <0.001	○○○	methylprednisolone-neomycin

Cure rate

No data from the following reference on this outcome. [7]

Recurrence

No data from the following reference on this outcome. [7]

Quality of life

No data from the following reference on this outcome. [7]

Adverse effects

No data from the following reference on this outcome. [7]

Topical antibacterials (with or without corticosteroids) versus each other:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) [5] that found seven RCTs relevant to this comparison. Three RCTs compared different topical antibacterial-corticosteroid with each other, three other RCTs compared topical antibacterial-corticosteroid with topical antibiotics, and one further RCT compared topical quinolone antibacterial with topical non-quinolone antibacterial. None of the seven RCTs included in the systematic review met *BMJ Clinical Evidence* inclusion criteria for minimal follow-up of 1 month. We found one additional RCT comparing different regimens of topical antibacterials (with corticosteroid) with each other. [8] This RCT was excluded from the systematic review because participants included people with chronic and acute otitis externa, and all six participants with the acute type were allocated the same intervention; however, we have reported it here with caveats.

Symptom improvement

No data from the following reference on this outcome. [8]

Cure rate

Topical antibacterials (with or without corticosteroid) compared with each other We don't know which antibiotic (with or without corticosteroid) is more effective at improving clinical cure rates, although there is evidence from one small RCT of faster resolution of signs and symptoms of moderate to severe acute or chronic diffuse otitis externa by 1 month with topical triamcinolone-neomycin compared with hydrocortisone-neomycin-polymyxin B (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Resolution					
[8] RCT	People (76 ears) with moderate-severe acute or chronic diffuse otitis externa on otoscopy, in a secondary-care setting All people received microsuction if discharge was present	**Resolution , 1 month or until resolution of all symptoms and signs** 27/34 (79%) with triamcinolone-neomycin 10/21 (48%) with hydrocortisone-neomycin-polymyxin B Randomisation was by people, but analysis was by ears; the total number of people randomised unclear 38 people (55 ears) included in this analysis Each treatment given for 10 days	P <0.01	○○○	triamcinolone-neomycin

Recurrence

No data from the following reference on this outcome. [8]

Quality of life

No data from the following reference on this outcome. [8]

Adverse effects

No data from the following reference on this outcome. [8]

Topical antibacterial-corticosteroids versus topical aluminium acetate:
See option on Topical aluminium acetate, p 4 .

Topical antibacterial-corticosteroid versus topical acetic acid:

See option on Topical acetic acid, p 14 .

Topical antibacterial-corticosteroid versus topical acetic acid-corticosteroid:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found one RCT. [5] The RCT reported on clinical cure rates but at a shorter time than *BMJ Clinical Evidence* inclusion criteria of a minimum of 1 month, it also reported on recurrence rates at 3 to 6 weeks, which we have included below.

Symptom improvement

No data from the following reference on this outcome. [5]

Cure rate

No data from the following reference on this outcome. [5]

Recurrence

Topical antibacterial-corticosteroid versus topical acetic acid-corticosteroid We don't know whether topical antibacterial-corticosteroid and topical acetic acid-corticosteroid differ in effectiveness at reducing recurrence rates in people with otitis externa. We only found one RCT which found no significant difference (low-quality evidence)

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recurrence					
[5] Systematic review	213 people (aged >17 years) with acute otitis externa, primary care setting Data from 1 RCT RCT was 3-armed trial, other arm assessed acetic acid alone Ear cleaning was performed on initial visit; a wick was inserted for 24 hours if ear canal was swollen and repeated as necessary	**Recurrence, assessed by telephone , day 42** 15/57 (26%) with acetic acid-triamcinolone drops 14/68 (21%) with polymyxin B-neomycin-dexamethasone drops Treatment duration 21 days No ITT analysis	OR 1.38 95% CI 0.60 to 3.17 P =0.45	⟷	Not significant

Quality of life

No data from the following reference on this outcome. [5]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[5] Systematic review	213 people (aged >17 years) with acute otitis externa, primary care setting Data from 1 RCT RCT was a 3-armed trial; other arm assessed acetic acid alone Ear cleaning was performed on initial visit; a wick was inserted for 24 hours if ear canal was swollen and repeated as necessary	**Adverse effects** with acetic acid-triamcinolone drops with polymyxin B-neomycin-dexamethasone drops Absolute results not reported 74% of people reported at least one adverse effect, including local burning, pain, and inflammation	Difference among groups reported as not significant P value not reported	⟷	Not significant

Topical antibacterial-corticosteroid-acetic acid versus topical acetic acid alone:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found one RCT comparing topical antibacterial-corticosteroid-acetic acid spray with topical acetic acid spray. [5]

Symptom improvement

No data from the following reference on this outcome. [5]

Cure rate

Topical antibacterial-corticosteroid-acetic acid compared with topical acetic acid alone Neomycin-dexamethasone-glacial acetic acid spray may be more effective at increasing the proportion of people with acute otitis externa who are clinically cured at 4 weeks compared with glacial acetic acid spray alone (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Clinical cure					
[5] Systematic review **3-armed trial**	53 adults in secondary care with acute otitis externa on otoscopy Data from 1 RCT All people included in the study [9] received aural toilet before randomisation to treatment and at 2 weeks if active disease present Subgroup analysis; full population in RCT were people with acute otitis externa or an infected mastoid cavity (109 people; see Further information	**Clinical cure , 4 weeks** 18/21 (86%) with neomycin-dexamethasone-glacial acetic acid spray 12/32 (38%) with glacial acetic acid spray alone Treatment duration: 2 weeks initially; a further 2 weeks treatment if not cured after the initial 2 weeks	OR 0.10 95% CI 0.02 to 0.41 P =0.0014	●●●	neomycin-dexamethasone-glacial acetic acid spray

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	on studies for more details)				

Recurrence

No data from the following reference on this outcome. [5]

Quality of life

No data from the following reference on this outcome. [5]

Adverse effects

No data from the following reference on this outcome. [5]

Further information on studies

[7] The RCT reported response to treatment at 28 days. The systematic review includes this RCT but reports a possible lack of clarity on follow-up. [5] The review analysed data from this RCT for the outcome: 'clinical resolution ('good response'): day 5 or day 10 (? - unclear).' For this outcome, the review reports a favourable response for topical antibiotic-corticosteroid (methylprednisolone-neomycin) compared with placebo (OR 11.00, 95% CI 2.00 to 60.57, P = 0.0059). We have not reported direct from the systematic review as its interpretation of time of follow-up does not meet *BMJ Clinical Evidence* inclusion criteria, but we have retained our reporting from the original RCT. The RCT did not clearly define how people were randomised, gave no definition of otitis externa, and did not state any exclusion criteria.

[9] The RCT carried out an ITT analysis (assigned explicit allocation of poor outcome to those not completing the protocol). The systematic review [5] reported that the methods for sequence code generation and outcome assessment were not described clearly in the RCT.

Comment: **Clinical guide**

In current UK practice, most clinicians would use a combination of topical antibiotic plus corticosteroid agent for 1 to 2 weeks initially, as first-line treatment of acute otitis externa. Some argue that microbial swabs should be taken at first attendance to tailor antimicrobial treatment in persisting cases, but this is supported by only anecdotal evidence. Most clinicians use swabs only in persistent or recurrent cases. If there are concerns of a possible underlying tympanic membrane perforation, then a topical quinolone may be used in preference to other potentially ototoxic antibiotic preparations. However, in an acute ear infection with discharge, it may be difficult to differentiate between an external- and middle-ear infection. We do not know if quinolones are as effective as aminoglycosides in treating middle-ear infections. In the UK, the consensus opinion is that aminoglycoside/corticosteroid combination therapy can be used if limited to a course of less than 2 weeks. It may be that the lack of a corticosteroid/quinolone combined agent and the lack of a quinolone that is licensed for use in the ear in the UK has discouraged the use of quinolones. Clinicians giving corticosteroids in combination with quinolones are required to write two separate prescriptions, which may also affect patient compliance.

OPTION ANTIFUNGALS (TOPICAL; WITH OR WITHOUT CORTICOSTEROIDS)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- We don't know whether topical antifungal agents improve symptoms of otitis externa. However, consensus would suggest that it is inferior as a first-line empirical agent, given that the most common pathogens implicated are bacterial; although, this may not be the case in tropical climates.
- We found no direct information about whether topical antifungals are more effective than no active treatment in people with otitis externa.
- We found no direct information about topical antifungals (alone or in combination with other anti-infective agents or corticosteroids) compared with oral antibiotics, topical corticosteroids, topical aluminium acetate drops, topical acetic acid, or other topical anti-infective agents in people with otitis externa.

Benefits and harms

Topical antifungals (with or without corticosteroids, or in combination with oral antibiotics) versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Topical antifungals (with or without corticosteroids, or in combination with oral antibiotics) versus topical aluminium acetate, topical antibacterials, topical corticosteroids, topical acetic acid, or oral antibiotics:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Comment:

The systematic review [5] found one RCT comparing antibiotic-corticosteroid drop with antibiotic-corticosteroid-antifungal drop in people with otitis externa, and one RCT comparing antifungal-antibiotic-corticosteroid ointment on a wick with antiseptic-astringent solution on a wick in people with severe acute otitis externa. Both RCTs did not meet *BMJ Clinical Evidence* inclusion criteria. The systematic review stated that *candida*, *aspergilla,* and other fungi are found in around 80% of tropical cases of otitis externa; however, much of the data come from temperate climates where the proportion is 10% to 20% of cases, and as such the results may not be generalisable to other geographical locations.

Clinical guide

There is little evidence assessing the use of topical antifungal agents in acute otitis externa as it is not a first-line treatment in most countries. Fungal otitis externa may be suspected by otoscopic examination findings of hyphae or spores (e.g., *Aspergillus niger* and *candida albicans*), or by swab cultures. People with fungal otitis externa have often had previous prolonged courses of a combination of corticosteroid plus antibiotic agents. In this group of patients, it may be appropriate to use topical antifungal agents or other antiseptic agents, such as aluminium acetate or acetic acid. Antiseptic agents have the advantage that they are not ototoxic or allergenic, meaning they are probably safer, particularly in the long term. However, anecdotal evidence suggests they may cause more discomfort, which may lead to poor compliance and resultant poor efficacy.

OPTION CORTICOSTEROIDS (TOPICAL)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- There is a lack of evidence for corticosteroids when used alone, however they are likely to be beneficial when used in combination with antibacterials. Please see option on Antibacterials (topical; with or without corticosteroids), p 6 for the evidence on antibacterials used in combination with corticosteroids.
- Consensus suggests that topical corticosteroids alone may reduce signs and symptoms of otitis externa, but good-quality studies assessing these agents alone in this population are lacking.
- All RCTs reported in this option include corticosteroids that have been given in combination with another agent. We found no direct information from RCTs meeting our inclusion criteria about whether topical corticosteroids alone are better than placebo in the treatment of people with otitis externa.

Benefits and harms

Topical corticosteroids alone versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5] We found one additional RCT with short follow-up assessing the effects of budesonide drops (please see Comment section, p 12). [10] It was excluded by the systematic review because it studied participants with eczematous otitis externa. [5]

Topical corticosteroids alone versus each other, topical aluminium acetate, topical antibacterials, topical antifungals, topical acetic acid, or oral antibiotics:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on these comparisons. [5]

Low- versus high-potency corticosteroids:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on these comparisons. [5]

Topical antibacterial-corticosteroids versus placebo:

See option on Topical antibacterial agents (with or without corticosteroids), p 6 .

Topical antibacterial-corticosteroid versus topical acetic acid alone:

See option on Topical acetic acid, p 14 .

Topical antibacterial-corticosteroid versus topical acetic acid-corticosteroid:

See option on Topical antibacterial agents (with or without corticosteroids), p 6 .

Topical antibacterial-corticosteroid versus topical aluminium acetate:

See option on Topical aluminium acetate, p 4 .

Topical antibacterial-corticosteroid-acetic acid versus topical acetic acid alone:

See option on Topical antibacterial agents (with or without corticosteroids), p 6 .

Topical corticosteroid-acetic acid versus topical acetic acid:

See option on Topical acetic acid, p 14 .

Comment: There is very little evidence to support the use of topical corticosteroids alone in the treatment of acute otitis externa. One double-blind RCT with a short follow-up period compared budesonide

drops with placebo drops in a secondary-care setting for 7 days. [10] It found that budesonide drops significantly improved symptoms and signs compared with placebo after 10 days (change from baseline in a global clinical score ranging from 0 [no symptoms/signs] to 3 [severe symptoms/signs]: –2.29 with budesonide v +0.23 with placebo; P = 0.001). The RCT found that a similar proportion of people using budesonide and placebo had adverse effects, including external ear canal disorders (sticky ear canal, ear wax), headache, and dizziness (10/30 [33%] with budesonide *v* 9/30 [30%] with placebo; significance not reported). [10] Multiple studies have looked at topical corticosteroids used in combination with other agents, primarily antibacterials, where they seem likely to be of benefit.

Clinical guide

In current UK practice, most clinicians would use a combination of topical corticosteroid plus antibiotic agent for 1 to 2 weeks initially, as first-line treatment of acute otitis externa. Some argue that microbial swabs should be taken at first attendance to tailor antimicrobial treatment in persistent cases, but this is supported by only anecdotal evidence. Most clinicians use swabs only in persistent or recurrent cases. If there are concerns of a possible underlying tympanic membrane perforation, then a topical quinolone may be used in preference to other potentially ototoxic antibiotic preparations. However, in an acute ear infection with discharge, it may be difficult to differentiate between an external- and middle-ear infection. We do not know if quinolones are as effective as aminoglycosides in treating middle-ear infections. In the UK, the consensus opinion is that aminoglycoside/corticosteroid combination therapy can be used if limited to a course of under two weeks. It may be that the lack of a corticosteroid/quinolone combined agent in the UK, and the lack of a quinolone that is licensed for use in the ear, has discouraged the use of quinolones. Clinicians giving corticosteroids in combination with quinolones are required to write two separate prescriptions, which may also affect patient compliance.

OPTION ACETIC ACID (TOPICAL)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- We found no direct information about whether topical acetic acid is better than no active treatment.
- We found very few RCTs comparing acetic acid with other active interventions.
- Topical acetic acid seems less effective than topical antibacterial-corticosteroid (dexamethasone-neomycin-polymyxin) at reducing the risk of recurrence (assessed at day 42) in people with acute otitis externa, but evidence is from one RCT only.
- We don't know whether topical acetic acid and acetic acid-corticosteroid differ in their effectiveness at reducing the risk of recurrence (assessed day 42) in people with acute otitis externa.
- Glacial acetic acid spray alone may be less effective than neomycin-dexamethasone-glacial acetic acid spray (topical antibacterial-corticosteroid-acetic acid) at increasing the proportion of people with acute otitis externa who are clinically cured at 4 weeks, but evidence is from one RCT only.

Benefits and harms

Topical acetic acid versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Topical acetic acid versus topical aluminium acetate, topical antibacterial alone, topical antifungals, topical corticosteroids, or oral antibiotics:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Topical acetic acid versus topical antibacterial-corticosteroid:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found three RCTs comparing a topical antiseptic with a topical antibacterial-corticosteroid. [5] Only one of the RCTs met *BMJ Clinical Evidence* inclusion criteria for minimal length of follow-up of 1 month.

Symptom improvement

No data from the following reference on this outcome. [5]

Cure rate

No data from the following reference on this outcome. [5]

Recurrence

Topical acetic acid compared with topical antibacterial-corticosteroid Topical acetic acid seems less effective at reducing the risk of recurrence (assessed at day 42) in people with acute otitis externa compared with topical dexamethasone-neomycin-polymyxin (moderate-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recurrence					
[5] Systematic review	213 people (aged >17 years) with acute otitis externa, primary care setting Data from 1 RCT RCT was a 3-armed trial; the third arm assessed triamcinolone-acetic acid drops Ear cleaning was performed on initial visit; a wick was inserted for 24 hours if ear canal was swollen and repeated as necessary	**Recurrence assessed by telephone , day 42** 21/47 (45%) with acetic acid 14/68 (21%) with dexamethasone-neomycin-polymyxin drops Treatment duration 21 days No ITT analysis	OR 3.12 95% CI 1.37 to 7.09 P =0.0068	●●○	dexamethasone-neomycin-polymyxin

Quality of life

No data from the following reference on this outcome. [5]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[5] Systematic review	213 people (aged over 17 years) with acute otitis externa, primary care setting Data from 1 RCT RCT was a 3-armed trial; the third arm assessed	**Adverse effects** with acetic acid with dexamethasone-neomycin-polymyxin drops Absolute results not reported 74% of people reported at least one adverse effect, including local burning, pain, and irritation	Difference among groups reported as not significant P value not reported	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	triamcinolone-acetic acid drops Ear cleaning was performed on initial visit; a wick was inserted for 24 hours if ear canal was swollen and repeated as necessary				

Topical acetic acid versus topical acetic acid-corticosteroid:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found one RCT comparing topical acetic acid with topical acetic acid-corticosteroid. [5]

Symptom improvement

No data from the following reference on this outcome. [5]

Cure rate

No data from the following reference on this outcome. [5]

Recurrence

Topical acetic acid compared with topical acetic acid-corticosteroid We don't know whether topical acetic acid differs in its effectiveness at reducing the risk of recurrence (assessed at day 42) in people with acute otitis externa compared with topical acetic acid-corticosteroid (low-quality evidence). [5]

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Recurrence					
[5] Systematic review	213 people (aged >17 years) with acute otitis externa, primary care setting Data from 1 RCT RCT was a 3-armed trial; other arm assessed dexamethasone-neomycin-polymyxin Ear cleaning was performed on initial visit; a wick was inserted for 24 hours if ear canal was swollen and repeated as necessary	**Recurrence assessed by telephone , day 42** 21/47 (45%) with acetic acid 15/57 (26%) with triamcinolone-acetic acid Treatment duration 21 days No ITT analysis	OR 0.44 95% CI 0.19 to 1.01 P =0.052	⟷	Not significant

Quality of life

No data from the following reference on this outcome. [5]

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[5] Systematic review	213 people (aged >17 years) with acute otitis externa, primary care setting Data from 1 RCT RCT was a 3-armed trial; the third arm assessed dexamethasone-neomycin-polymyxin Ear cleaning was performed on initial visit; a wick was inserted for 24 hours if ear canal was swollen and repeated as necessary	**Adverse effects** with acetic acid with triamcinolone-acetic acid Absolute results not reported 74% of people reported at least one adverse effect, including local burning, pain, and irritation	Difference among groups reported as not significant P value not reported	⟷	Not significant

Topical acetic acid versus topical antibacterial-corticosteroid-acetic acid:
See option on Topical antibacterial agents (with or without corticosteroids), p 6 .

Topical acetic acid-corticosteroid versus topical antibacterial-corticosteroid:
See option on Topical antibacterial agents (with or without corticosteroids), p 6 .

Comment: There is very little good-quality evidence on the efficacy of acetic acid in otitis externa. One small RCT suggests that acetic acid alone (glacial acetic acid spray) may be less effective than an antibacterial-corticosteroid-acetic acid combination at increasing the proportion of people with acute otitis externa who are clinically cured at 4 weeks (see option on Topical antibacterial agents [with or without corticosteroids], p 6) and there are no data comparing it with placebo.

Clinical guide
Glacial acetic acid spray is available over-the-counter in the UK and, while there are few studies to demonstrate its efficacy, the consensus view is that it may be of benefit in mild cases of acute otitis externa that may not present to primary or secondary care. It appears unlikely to be of significant harm. The low pH may cause more pain or irritation than corticosteroids or antibiotics.

OPTION ANTIBIOTICS (ORAL)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- Oral antibiotics have not been shown to be beneficial.

- We found no clinically important results from RCTs about whether oral antibiotics are better than no active treatment or topical anti-infective agents in people with otitis externa.

Benefits and harms

Oral antibiotics versus placebo:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Oral antibiotics versus topical aluminium acetate, topical antibacterials, topical antifungals, topical corticosteroids, or topical acetic acid:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Comment:

The systematic review [5] only found one RCT that included oral antibiotics. [11] This RCT compared an oral antibiotic plus topical non-quinolone antibiotic-corticosteroid (10 days treatment) with topical quinolone antibiotic-corticosteroid (7 days treatment) for simple acute otitis externa with follow up of 2 to 3 weeks. It found no significant difference between the treatment groups in response to treatment (P = 0.5109). There were no serious treatment-related adverse events with either treatment. The authors of the review concluded, "Topical treatments alone, as distinct from systemic ones, are effective for uncomplicated acute otitis externa". [5]

Clinical guide

Although there is little evidence on the role of oral antibiotics, the consensus view is that topical antibiotic-corticosteroid treatments are sufficient and more effective than oral antibiotics in uncomplicated otitis externa. Topical treatments have the added benefit of avoiding the potential adverse effects of systemic antibiotics.

OPTION ANTIBIOTICS (ORAL) PLUS ANTI-INFECTIVE AGENTS (TOPICAL)

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- Consensus suggests that adding oral antibiotics to topical anti-infective agents will not improve symptoms compared with topical agents alone.
- We found no clinically important results from RCTs about whether oral antibiotics in combination with a topical anti-infective agent are better than a topical anti-infective agent alone in people with uncomplicated otitis externa.

Benefits and harms

Oral antibiotics plus topical antibacterial versus topical antibacterial alone:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Oral antibiotics plus topical antifungal versus topical antifungal alone:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Further information on studies

[5] The systematic review found one RCT comparing an oral antibiotic (amoxicillin) plus topical non-quinolone antibiotic-corticosteroid with topical quinolone antibiotic-corticosteroid for simple acute otitis externa. It found no significant difference between the treatment groups in response to treatment (P = 0.5109). There were no serious treatment-related adverse events with either treatment.

Comment: **Oral antibiotics plus topical antifungal-antibacterial-corticosteroid versus oral placebo plus topical antibacterial-corticosteroid-antifungal** One double-blind RCT with a short follow-up period compared 5 days of oral trimethoprim-sulfamethoxazole (co-trimoxazole) with placebo in a primary-care setting. [12] Both groups also received repeated applications of ointment containing triamcinolone, neomycin, and gramicidin, and had suction of the external canal if discharge was present. The RCT found no significant difference between groups in symptom severity scores, duration of symptoms, or cure rate (improvement in mean symptom severity score on scale ranging from 1 [no symptoms] to 5 [severe symptoms]: 0.72 with added oral co-trimoxazole *v* 0.69 with added placebo, P >0.4; mean duration of symptoms: 3.1 days with added oral co-trimoxazole *v* 3.1 days with placebo, P >0.5; cure rates: 18/47 [38%] with added oral co-trimoxazole *v* 21/53 [40%] with placebo, P >0.8). The RCT gave no information on adverse effects. The authors of the systematic review on interventions for acute otitis externa concluded, "Topical treatments alone, as distinct from systemic ones, are effective for uncomplicated acute otitis externa". [5]

Clinical guide

There is consensus that adding oral antibiotics to topical anti-infective agents will not confer additional benefit in people with uncomplicated otitis externa.

OPTION SPECIALIST AURAL TOILET

- For GRADE evaluation of interventions for Otitis externa, see table, p 23 .
- We found no direct information from RCTs about whether specialist aural toilet is more effective than no active treatment.
- Despite the lack of evidence, there is consensus that specialist aural toilet is likely to be beneficial and it is considered a key treatment in the secondary care setting, particularly where topical therapy alone has failed.

Benefits and harms

Specialist aural toilet versus no aural toilet:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs on this comparison. [5]

Different types of specialist aural toilet versus each other:

We found one systematic review (search date 2009; 19 RCTs; 3382 people) that found no RCTs meeting *BMJ Clinical Evidence* inclusion criteria on this comparison. [5] We found one additional RCT. [13]

Cure rate

Different types of specialist aural toilet compared with each other We don't know whether ear wicks plus anti-infective drops are more effective than gauze impregnated with an anti-infective agent at increasing cure rates at 4 weeks in people with moderate to severe acute diffuse otitis externa (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Cure rate					
[13] RCT	94 people with moderate to severe acute diffuse otitis externa on otoscopy in a secondary-care setting	**Resolution rate , 4 weeks** 30/47 (64%) with ear wick 33/47 (70%) with ribbon gauze Resolution was defined as absence of symptoms and signs	P = 0.58	⟷	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		See Further information on studies for details of treatment regimens			

Symptom improvement

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

Recurrence

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

Quality of life

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

Adverse effects

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

Further information on studies

[13] The RCT compared an ear wick plus anti-infective drops (framycetin-gramicidin-dexamethasone or flumetasone) removed after 3 days with ribbon gauze impregnated with anti-infective ointment (framycetin-gramicidin or triamcinolone-gramicidin-neomycin-nystatin) removed after 3 days.

Comment: Many of the trials included in the systematic review [5] include ear cleaning as a co-intervention for all participants (11 out of the 19 trials). The majority of trials took place in a specialist secondary care setting (only 2 out of the 19 trials were in a primary care setting). Generally, aural toilet is less likely to be available in a primary care setting. The authors of the review concluded, "The findings may not be wholly generalisable to primary care".

Clinical guide
Aural toilet is frequently used in secondary care in cases where the ear canal is blocked by a significant quantity of debris, usually infected desquamated skin. It is assumed that physical removal of this skin, usually by suction under microscopy, is helpful by allowing topical medications to reach the underlying infected and inflamed ear canal skin. In addition, severe cases of acute otitis externa often result in oedema of the ear canal skin and consequent closure of the ear canal lumen. This results in severe pain and makes it impossible to apply topical treatments. Insertion of a wick can facilitate opening of the lumen and application of topical medications. Aural toilet may also be required to obtain a view of the tympanic membrane and differentiate between otitis externa, different forms of otitis media, and cholesteatoma.

Although it would be possible to perform a double-blind RCT for this procedure (*v* sham), the widely assumed efficacy and rationale for its use might deem it unethical, meaning the evidence base for this treatment intervention is unlikely to change.

GLOSSARY

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.

Specialist aural toilet Technique (microsuction, non-surgical debridement) used to clear the ear canal, usually performed in a secondary care, specialist setting. It includes dry mopping of the ear canal or suction. This can be performed using a head light or microscope, which allows cleaning of the more medial areas of the ear canal.

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

SUBSTANTIVE CHANGES

Acetic acid (topical) One systematic review added. [5] Categorisation unchanged (unknown effectiveness).

Aluminium acetate (topical) One systematic review added. [5] Evidence re-evaluated. Categorisation unchanged (likely to be beneficial).

Antibacterials (topical; likely to be beneficial with or without corticosteroids) One systematic review added. [5] Evidence re-evaluated. Categorisation unchanged (likely to be beneficial).

Antibiotics (oral) One systematic review added. [5] Categorisation unchanged (unknown effectiveness).

Antibiotics (oral) plus anti-infective agents (topical) Title clarified. One systematic review added. [5] Categorisation unchanged (unlikely to be beneficial [by consensus]).

Antifungals (topical; with or without corticosteroids) One systematic review added. [5] Categorisation unchanged (unknown effectiveness).

Corticosteroids (topical) One systematic review added. [5] Evidence re-evaluated. Categorisation changed from 'likely to be beneficial' to ''unknown effectiveness'.

Specialist aural toilet One systematic review added. [5] Evidence re-evaluated. Categorisation changed from 'unknown effectiveness' to 'likely to be beneficial' by consensus.

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GRADE **Evaluation of interventions for Otitis externa.**

Important outcomes			Cure rate , Quality of life, Recurrence , Symptom improvement						
Studies (Participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of empirical treatments for otitis externa?									
1 (126) [6]	Cure rate	Aluminium acetate (topical) versus antibacterial-corticosteroid (topical)	4	–3	0	0	0	Very low	Quality points deducted for sparse data, lack of clarity on blinding, and lack of power to detect clinically important differences between groups
1 (40) [7]	Symptom improvement	Topical antibacterial-corticosteroids versus placebo	4	–3	0	–1	0	Very low	Quality points deducted for sparse data, unclear method of randomisation, and no definition of otitis externa or exclulsion criteria given; directness point deducted for use of co-intervention (ear cleaning)
1 (38) [8]	Cure rate	Topical antibacterials (with or without corticosteroids) versus each other	4	–2	0	–1	0	Very low	Quality points deducted for sparse data and weak methods; directness point deducted for use of co-intervention (microsuction)
1 (125) [5]	Recurrence	Topical antibacterial-corticosteroid versus topical acetic acid-corticosteroid	4	–2	0	0	0	Low	Quality points deducted for sparse data and no ITT analysis
1 (53) [5]	Cure rate	Topical antibacterial-corticosteroid-acetic acid versus topical acetic acid alone	4	–2	0	–1	0	Very low	Quality points deducted for sparse data and for weak methods; directness point deducted for use of co-intervention (aural toilet)
1 (115) [5]	Recurrence	Topical acetic acid versus topical antibacterial-corticosteroid	4	–2	0	0	+1	Moderate	Quality points deducted for sparse data and no ITT analysis; effect-size point added for odds ratio of >2 to 5
1 (104) [5]	Recurrence	Topical acetic acid versus topical acetic acid-corticosteroid	4	–2	0	0	0	Low	Quality points deducted for sparse data and no ITT analysis
1 (94) [13]	Cure rate	Different types of specialist aural toilet versus each other	4	–1	0	–1	0	Low	Quality point deducted for sparse data; directness point deducted for disparity in active agents used

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.