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Moualed D, Masterson L, Kumar S, Donnelly N

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[Intervention Review]

Water precautions for prevention of infection in children with ventilation tubes (grommets)

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ABSTRACT

Background

Following middle ear ventilation tube (tympanostomy tube or grommet) insertion, most surgeons advise that a child's ears should be kept dry during the immediate postoperative period. Following the initial period some surgeons will permit swimming or bathing, whereas other surgeons will recommend ongoing water precautions. A large number of studies have been conducted to explore the association between water exposure and ear infections in children with ventilation tubes, however a range of differing conclusions exist regarding the need for water precautions and there is wide variation in clinical practice.

Objectives

To assess the effectiveness of water precautions for the prevention of ear infections in children with ventilation tubes (grommets), at any time while the tubes are in place.

Search methods

The Cochrane ENT Trials Search Co-ordinator searched the ENT Trials Register; Central Register of Controlled Trials (CENTRAL 2015, Issue 8); PubMed; EMBASE; CINAHL; Web of Science; Clinicaltrials.gov; ICTRP and additional sources for published and unpublished trials. The date of the search was 1 September 2015.

Selection criteria

Randomised controlled trials recruiting children (0 to 17 years) with ventilation tubes and assessing the effect of water precautions while the tubes are in place. We considered all forms of water precautions, including behavioural (i.e. avoidance or swimming/bathing restrictions) and mechanical (ear plugs/moulds or hats/bands).

Data collection and analysis

We used the standard methodological procedures expected by Cochrane. Our primary outcome measures were episodes of otorrhoea and adverse effects; secondary outcomes were antimicrobial prescriptions for ear infections, ventilation tube extrusion, surgical intervention to remove ventilation tubes and hearing outcomes.

Main results

Two randomised controlled trials recruiting a total of 413 patients met the criteria for inclusion in our review; one study had a low risk of bias and the other study had a high risk of bias.

Ear plugs versus control

One study recruited 201 children (aged six months to six years) who underwent myringotomy and ventilation tube insertion. The study compared an intervention group who were instructed to swim and bathe with ear plugs with a control group; the participants were followed up at one-month intervals for one year. This study, with low risk of bias, showed that the use of ear plugs results in a small but statistically significant reduction in the rate of otorrhoea from 1.2 episodes to 0.84 episodes in the year of follow-up (mean difference (MD) -0.36 episodes per year, 95% confidence interval (CI) -0.45 to -0.27). There was no significant difference in ventilation tube extrusion or hearing outcomes between the two study arms. No child required surgical intervention to remove ventilation tubes and no adverse events were reported.

Water avoidance versus control

Another study recruited 212 children (aged three months to 12 years) who underwent myringotomy and ventilation tube insertion. The study compared an intervention group who were instructed not to swim or submerge their heads while bathing with a control group; the participants were followed up at three-month intervals for one year. This study, with high risk of bias, did not show any evidence of a reduction or increase in the rate of otorrhoea (1.17 episodes per year in both groups; MD 0 episodes, 95% CI -0.14 to 0.14). No other outcomes were reported for this study and no adverse events were reported.

Quality of evidence

The overall quality (GRADE) of the body of evidence for the effect of ear plugs on the rate of otorrhoea and the effect of water avoidance on the rate of otorrhoea are low and very low respectively.

Authors' conclusions

The baseline rate of ventilation tube otorrhoea and the morbidity associated with it is usually low and therefore careful prior consideration must be given to the efficacy, costs and burdens of any intervention aimed at reducing this rate.

While there is some evidence to suggest that wearing ear plugs reduces the rate of otorrhoea in children with ventilation tubes, clinicians and parents should understand that the absolute reduction in the number of episodes of otorrhoea appears to be very small and is unlikely to be clinically significant. Based on the data available, an average child would have to wear ear plugs for 2.8 years to prevent one episode of otorrhoea.

Some evidence suggests that advising children to avoid swimming or head immersion during bathing does not affect rates of otorrhoea, although good quality data are lacking in this area. Currently, consensus guidelines therefore recommend against the routine use of water precautions on the basis that the limited clinical benefit is outweighed by the associated cost, inconvenience and anxiety.

Future high-quality studies could be undertaken but may not be thought necessary. It is uncertain whether further trials in this area would change the findings of this review or have an impact on practice. Any future high-quality research should focus on determining whether particular groups of children benefit more from water precautions than others, as well as on developing clinical guidelines and their implementation.

PLAIN LANGUAGE SUMMARY

Water precautions for prevention of infection in children with ventilation tubes (grommets)

Review question

Is there is any evidence to show that keeping ears dry after ventilation tube (grommet) insertion helps to prevent problems such as infections?

Background

Ventilation tubes are used to treat hearing loss due to glue ear, or to treat recurrent ear infections. Most surgeons agree that children's ears should be kept dry for a few weeks after the operation, but not all agree on whether ears need to be kept dry thereafter. Some

surgeons will allow children to swim and bathe without ear protection, whereas others will recommend ears be kept dry while tubes are in place.

Study characteristics

We included two studies, recruiting a total of 413 patients. One study looked at 201 children between six months and six years who had ventilation tubes inserted to treat glue ear or recurrent infections. Children were divided into two groups: one group was allowed to swim and bathe freely, the other group was instructed to wear ear plugs while swimming or bathing. Another study looked at 212 children between three months and 12 years who had ventilation tubes inserted (we do not know precisely what for). These children were divided into two groups: one group was allowed to swim and bathe freely, the other group was instructed not to swim and told to avoid putting their head under water when bathing.

Children in both studies were followed for about one year to see how many ear infections they had and if there were any other problems. We do not have any reason to be concerned about who funded these studies.

Key results

The main result we looked for was the effect that keeping ears dry had on ear infections, specifically ear discharge. One study showed that there was a small reduction in the likelihood of getting an ear infection in children who protected their ears from water with ear plugs when swimming or bathing. The effect of wearing ear plugs was to reduce the number of infections a child would have every year (on average) from 1.2 to 0.84. We think the results from this study are quite reliable.

Another study showed that there was no difference in the likelihood of children getting ear infections whether they were told to avoid swimming and putting their head under water, or whether they took no precautions at all. We are uncertain whether the results from this study are reliable.

Neither study showed any other important differences between the children who got their ears wet and those who kept them dry. There was no effect on how long the tubes stayed in place or on hearing (although these results were only measured in one study). No harm to any participant was reported in either study.

The evidence is current to September 2015.

Quality of the evidence

We graded the quality of evidence for the use of ear plugs as low, which means that "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".

We have graded the quality of evidence relating to water avoidance as very low ("we are very uncertain about the estimate").

Conclusion

The difference that wearing ear plugs makes appears to be very small and a child would have to wear them on average for almost three years to prevent one infection resulting in ear discharge.

It may be that telling children to avoid swimming and putting their head under water makes no difference to whether or not they get ear infections, but this is very uncertain. Current expert guidelines for clinicians therefore recommend against routinely using water precautions because the limited clinical benefit is outweighed by the associated cost, inconvenience and anxiety.

Future high-quality studies could be undertaken but may not be thought necessary. It is uncertain whether further trials in this area would change the findings of this review or have an impact on practice. Any future high-quality research should focus on determining whether particular groups of children benefit more from water precautions than others, as well as on developing clinical guidelines and their implementation.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Ear plugs compared with no ear plugs for the prevention of ventilation tube-associated infections

Patient or population: children (aged 6 months to 6 years) with ventilation tubes
Settings: developed healthcare settings
Intervention: use of ear plugs when swimming or bathing
Comparison: swimming and bathing without ear plugs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No ear plugs	Ear plugs				
Rate of otorrhoea (episodes per year) Follow-up: 1 year	The mean rate of otorrhoea was 1.2 episodes in the year of follow-up	The mean rate of otorrhoea in the intervention groups was 0.36 episodes per year lower (CI 0.27 to 0.45)	30% reduction in rate of otorrhoea (CI 23% to 38%)	172 (1)	⊕⊕◯◯[1] **low**	These results are based on a single study, which has low risk of bias

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: 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.
Very low quality: We are very uncertain about the estimate.

[1]Downgraded due to significant concerns regarding imprecision of the estimate (a relatively small number of participants in only a single study), and minor concerns regarding study design (risk of bias).

BACKGROUND

Following middle ear ventilation tube (tympanostomy tube or grommet) insertion, parents may ask for advice on the need for water precautions. The majority of surgeons advise that during the immediate postoperative period (weeks), a child's ears should be kept dry in order to prevent water contamination of the ears while healing. Following the initial period some surgeons will permit swimming or bathing with or without restrictions, whereas other surgeons will recommend ongoing water precautions (Basu 2007; Poss 2008).

Exposure to water during bathing or swimming may lead to otorrhoea (ear discharge) and this is the rationale for advocating water precautions. It is also possible for children to experience episodes of otorrhoea in the absence of water exposure, particularly in association with upper respiratory tract infections. Discharging ears can impair hearing, cause discomfort and may require treatment with oral or topical antibiotics.

Water precautions encompass a range of measures that may include avoidance of exposure to water, or use of a physical barrier such as ear plugs or a swimming hat. Restriction of swimming or bathing activities during childhood can have significant social or developmental implications, particularly for the acquisition of swimming skills in early life. Use of barrier methods such as ear plugs requires parental co-operation, has a financial cost and may be poorly tolerated by children.

A large number of studies have been conducted to explore the association between water exposure and ear infections, however a range of differing conclusions exist regarding the need for water precautions. A recent trial provided evidence to support the hypothesis that water precautions help prevent ear infections (Goldstein 2005), whereas other trials have shown no benefit (Parker 1994; Salata 1996).

Description of the condition

Ventilation tube insertion is one of the most commonly performed surgical interventions. The operation is usually carried out under general anaesthetic at which time a small incision (cut) is made in the tympanic membrane (ear drum). A small artificial tube is placed through the incision in the tympanic membrane and remains in place for on average 12 months. The tube allows air to enter the middle ear, which prevents middle ear effusions and also prevents the build up of pus under pressure. Ventilation tubes do, however, breach a natural defence barrier, potentially resulting in ear infection by environmental contaminants (i.e. waterborne microbes).

Prior to ventilation tube insertion, otorrhoea occurs due to acute otitis media with tympanic membrane perforation. Following ventilation tube insertion, children may continue to suffer from otorrhoea to a greater or lesser extent. Otorrhoea may occur in the absence of symptoms of upper respiratory tract infection, and has been associated with exposure to water while bathing or swimming.

Ventilation tube-associated otorrhoea is quite common, with a meta-analysis of 23 studies showing that approximately 26% of patients are affected at some point (Kay 2001), although a recent large study of parent-reported otorrhoea suggests that the figure may be as high as 67% (van Dongen 2013). Discharge may be the only symptom, but some children suffer from pain or fever, and in some cases the tubes may become blocked or extrude early. Recurrent or chronic ventilation tube-associated otorrhoea is uncommon but can be associated with granulation tissue formation and the potential need for surgical removal of ventilation tubes (Kay 2001).

Description of the intervention

Water precautions include a range of 'behavioural' and 'mechanical' interventions. The simplest behavioural intervention is avoidance of water exposure, however total avoidance of water is impractical as bathing and hair washing will necessitate a minimum level of water exposure.

Restriction of exposure to particular types of water may be made on the basis of the potential to introduce infection to the middle ear. Some types of water may be regarded as more 'dirty' than others, for example public swimming pools or outdoor lakes. Similarly the properties of the water may have varying potential to pass via ventilation tubes into the middle ear. Soapy water may pass through ventilation tubes more easily due to the effect of decreased water surface tension (Pashley 1984).

Other behavioural interventions may be recommended, such as avoidance of head immersion during swimming, or avoidance of diving. These recommendations may be made on the basis that the penetration of water through the ventilation tube is more likely to occur at greater depths due to the effect of the increased water pressure (Herbert 1998).

The implementation of behavioural interventions to reduce water exposure in the above mentioned situations may take a number of forms, namely verbal advice from the medical team, written information detailing the recommendations or a more complex arrangement.

'Mechanical' interventions require the use of a physical barrier to prevent water entry into the ear canal. The most commonly used canal occlusive devices are ear plugs or swim moulds, which may come in a variety of materials and designs. Swimming hats or head bands may also be worn to minimise water exposure.

The implementation of mechanical interventions may again be carried out at a number of levels. Parents may be advised to purchase ear protection (specific products or devices may or may not be recommended), or ear protection may be provided. The advice may be verbal or written.

How the intervention might work

The mechanism for the proposed link between water exposure and middle ear infection is direct inoculation of environmental pathogens (i.e. waterborne bacterial contamination) through ventilation tubes, which breach the natural defence barrier of an intact tympanic membrane. Water precautions are thought to guard against infection by preventing this.

Why it is important to do this review

Ventilation tube insertion is a common surgical procedure and water exposure during bathing or swimming is universal. Middle ear infections are a common reason for seeking medical attention and there are significant health and financial implications. Interventions in the form of advocating water precautions can have lifestyle effects on children and should not be recommended without good evidence.

When the protocol for this review was published, there were no guidelines relating to the use of water precautions in children with ventilation tubes. Guidelines have since been issued by the American Academy of Otolaryngology (Rosenfeld 2013). There is wide variation in practice among otolaryngologists in dealing with this issue both in the UK (Basu 2007), and the USA (Poss 2008).

Many trials have been conducted to investigate the link between water exposure and middle ear infections. A majority of studies conclude that there is no evidence to support the use of water precautions; however there are few randomised controlled trials to provide high-quality evidence. Conclusions from meta-analyses have not supported the use of water precautions (Carbonell 2002; Lee 1999), however new research has since been published that may alter the outcome (Goldstein 2005).

Although two Cochrane reviews exist on the topic of post-ventilation tube otorrhoea, neither review addresses the efficacy of water precautions as an intervention. One review focuses on intra-operative interventions to prevent subsequent otorrhoea (Syed 2010). Another review compares pharmacological therapies for the treatment of established otorrhoea (Vaile 2006, currently being updated: Javed 2015). We believe, therefore, that our review may add meaningful new information to the debate.

OBJECTIVES

To assess the effectiveness of water precautions for the prevention of ear infections in children with ventilation tubes (grommets), at any time while the tubes are in place.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs).

Exclusion criteria:

- Studies utilising within-patient randomisation.

Types of participants

Children (aged 0 to 17) who underwent ventilation tube insertion for recurrent acute otitis media (rAOM) or otitis media with effusion (OME).

Exclusion criteria:

- Ventilation tubes inserted for other reasons, e.g. complex ear pathology.
- Children who were immunocompromised or had other co-morbidities predisposing to increased risk of middle ear infection or effusion, e.g. Down's syndrome.

Types of interventions

We considered the following intervention types:

- No intervention (control).

Behavioural interventions

- Water avoidance.
- Swimming/bathing restrictions, e.g. not allowed to bathe in dirty/soapy water.

Mechanical interventions

- Ear plugs/moulds.
- Swimming hats/bands.

This review allowed comparisons of any of the above interventions against each other. We expected the majority of studies to compare ear plugs/moulds against no intervention, as these are the two practices the authors had encountered most frequently.

The issue of compliance is particularly important for the above types of interventions as variations in compliance may significantly alter the outcomes of different studies. Unlike some pharmacological or operative interventions where it can be known with a high degree of certainty that an intervention has taken place, provision of advice on the use of water precautions may have variable compliance. Unknown or low levels of compliance may complicate measurement of the true treatment effect. For this reason this review assessed the efficacy of the provision of advice/instruction to undertake water precautions.

Types of outcome measures

We analysed the following outcomes in the review, but we did not use them as a basis for including or excluding studies.

Primary outcomes

- Episodes of otorrhoea
- Adverse effects

Secondary outcomes

- Antimicrobial prescriptions for ear infections
- Ventilation tube extrusion
- Surgical intervention to remove ventilation tubes
- Hearing outcomes

We assessed all outcomes in relation to the full duration of the study period, with the exception of hearing outcomes for which we sought baseline and endpoint data.

Search methods for identification of studies

The Cochrane ENT Trials Search Co-ordinator (TSC) conducted systematic searches for randomised controlled trials and controlled clinical trials. There were no language, publication year or publication status restrictions. The date of the search was 1 September 2015.

Electronic searches

The TSC searched:

- the Cochrane ENT Trials Register (searched 1 September 2015);
- the Cochrane Central Register of Controlled Trials (CENTRAL 2015, Issue 8);
- PubMed (1946 to 1 September 2015);
- Ovid EMBASE (1974 to 2015 week 35);
- Ovid CAB Abstracts (1910 to 2015 week 34);
- EBSCO CINAHL (1982 to 1 September 2015);
- LILACS, lilacs.bvsalud.org (searched 1 September 2015);
- KoreaMed (searched via Google Scholar 1 September 2015);
- IndMed, www.indmed.nic.in (searched 1 September 2015);
- PakMediNet, www.pakmedinet.com (searched 1 September 2015);
- Web of Knowledge, Web of Science (1945 to 1 September 2015);
- CNKI, www.cnki.com.cn (searched via Google Scholar 1 September 2015);
- ClinicalTrials.gov (searched via the Cochrane Register of Studies 1 September 2015);
- ICTRP, www.who.int/ictrp (searched 1 September 2015);
- ISRCTN, www.isrctn.com (searched 1 September 2015);
- Google Scholar, scholar.google.co.uk (searched 1 September 2015);
- Google, www.google.com (searched 1 September 2015).

In previous searches, we also searched BIOSIS Previews from 1926 to January 2014.

The TSC modelled subject strategies for databases on the search strategy designed for CENTRAL. Where appropriate, they were combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0, Box 6.4.b. (Handbook 2011). Search strategies for major databases including CENTRAL are provided in Appendix 1.

Searching other resources

We scanned the reference lists of identified publications for additional trials and contacted trial authors where necessary. In addition, the TSC searched PubMed, TRIP database, *The Cochrane Library* and Google to retrieve existing systematic reviews relevant to this systematic review, so that we could scan their reference lists for additional trials.

Data collection and analysis

Selection of studies

Two review authors independently scanned the titles and abstracts (when available) of all reports identified through the electronic searches. For studies that appeared to meet the inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision, we obtained the full report.

Two review authors independently assessed the full reports obtained from all the electronic and other methods of searching to establish whether the studies met the inclusion criteria or not. We resolved disagreements by discussion. Where resolution was not possible, a senior review author was consulted. All studies meeting the inclusion criteria underwent a 'Risk of bias' assessment and data extraction using a specially designed data extraction form. We recorded studies rejected at this or subsequent stages in the Characteristics of excluded studies table with reasons for the exclusion.

Data extraction and management

Two review authors extracted data independently using specially designed data extraction forms. We piloted the data extraction forms on several papers and modified them as required before use. We discussed any disagreements and consulted a senior review author where necessary. When necessary, we contacted authors for clarification or missing information.

For each trial we recorded the following:

- year of publication, country of origin and source of study funding;
- details of the participants including demographic characteristics, indication for surgery, and criteria for inclusion and exclusion;
- details of the type of intervention and nature of implementation;
- details of the outcomes reported including method of assessment, timing and duration of follow-up, and assessment of compliance with the intervention.

Assessment of risk of bias in included studies

DM and LM undertook assessment of the risk of bias of the included trials independently with the following taken into consideration, as guided by the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011):

- sequence generation;
- allocation concealment;
- blinding;
- incomplete outcome data;
- selective outcome reporting; and
- other sources of bias.

We used the Cochrane 'Risk of bias' tool in RevMan 5.3 (RevMan 2014), which involves describing each of these domains as reported in the trial and then assigning a judgement about the adequacy of each entry: 'low', 'high' or 'unclear' risk of bias.

Measures of treatment effect

For the primary outcome measure 'episodes of otorrhoea', results were reported in the form of count and rate data. We extracted data in the form in which it had been reported. We compared results between studies by means of rate data, i.e. average number of episodes of otorrhoea per patient, per unit time. We expected to analyse the secondary outcome measure 'antimicrobial prescriptions for ear infections' in the same way, however no data were available.

We intended to extract adverse effects data in the form provided and to make comparisons using appropriate statistical methods. No adverse events were reported therefore this was not required.

The secondary outcomes 'ventilation tube extrusion' and 'surgical intervention to remove ventilation tubes' represent dichotomous outcomes and we expected to extract data to determine risk ratios. Only one paper reported on ventilation tube extrusion and this in the form of time-to-event rather than dichotomous data. We have therefore extracted these data in the form reported, and would expect to analyse data from future studies in the same way if possible to allow comparison. No patient required surgical intervention to remove ventilation tubes, therefore no data were available.

The secondary outcome 'hearing outcomes' represents continuous data, which we extracted in the form reported. We anticipated the pure-tone average to be the most likely unit of analysis; therefore comparisons between studies, if appropriate, would be by difference in means (no standardisation required). However, only one paper reported hearing outcomes and did so by stating that speech awareness/recognition thresholds were 20 dB or less for all children.

For all outcome measures, we calculated confidence intervals (95%) to demonstrate the range within which the true treatment measure is likely to lie.

Unit of analysis issues

There were no unit of analysis issues in this review. For future updates of this review we will interpret results from cluster-randomised trials and cross-over trials with caution, and we will only include them for analysis if (in our opinion) potential sources of bias have been addressed and controlled for. We will include studies with multiple treatment groups if two arms of the study differ only by the intervention we intend to assess, i.e. water precautions. We will assess the results from studies with multiple treatment groups for the possibility of confounding factors.

Dealing with missing data

We contacted the authors of studies to request missing data, which were valuable in reaching study conclusions. We analysed studies on an intention-to-treat basis.

Assessment of heterogeneity

Meta-analysis was not possible in this review. For future updates of this review we will conduct meta-analyses only if there are studies of similar comparisons reporting the same outcome measures. We will perform assessment of heterogeneity using the Chi^2 test with a P value of 0.1 to increase the power of the test (we anticipate that there will be only a few studies with relatively small numbers of participants). We will assess inconsistency across studies using the I^2 statistic, with the thresholds for interpretation as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011).

Assessment of reporting biases

Insufficient studies were included to allow for a meaningful assessment of reporting bias. For future updates of this review we intend to construct a funnel plot and interpret the results as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011).

Data synthesis

Meta-analysis was not possible in this review. It is not known whether there is natural variation in the true value of the intervention effect. We anticipate that there may be variation in the

treatment effect based on the knowledge that some interventions (e.g. ear moulds/plugs) are available in different forms that are not identical in design. There may therefore be variation in treatment effect that results from subtle differences in the design and manufacture of ear plugs/moulds. For future updates to this review we will carry out meta-analysis both in accordance with a random-effects model and with a fixed-effect model to assess whether the method of meta-analysis chosen has any bearing on the outcome.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis was not possible in this review, as subgroup data were not available. For future updates to this review, where possible, we will perform subgroup analysis to determine whether there is any variation in outcome between children who have undergone ventilation tube insertion for different underlying pathologies, i.e. OME versus rAOM. We will perform further subgroup analysis if different studies use similar strategies for grouping participants. We will investigate heterogeneity using the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011).

Sensitivity analysis

Sensitivity analysis was not possible in this review, as no meta-analysis was performed. For future updates we intend to undertake sensitivity analysis to determine the effect of eligibility criteria, data analysed and analysis methods. Where we have identified trials that may be of value but are excluded from the analysis for failure to declare patient details (e.g. indication for surgery) or low follow-up rate, we will analyse the data again with each paper included to determine what influence it has on the estimate of treatment effect.

Where arbitrary values are assigned to determine thresholds for inclusion or analysis, we intend to re-analyse the data with different values either side of our chosen value to determine whether our decisions have influenced the outcome of the review:

- lengths of time constituting a distinct episode of otorrhoea (duration of otorrhoea, time between episodes);
- follow-up rate and review interval.

GRADE and 'Summary of findings' table

We used the GRADE approach to rate the overall quality of evidence. The quality of evidence reflects the extent to which we are confident that an estimate of effect is correct and we will apply this in the interpretation of results. There are four possible ratings: high, moderate, low and very low. A rating of high quality of evidence implies that we are confident in our estimate of effect and that further research is very unlikely to change our confidence in the estimate of effect. A rating of very low quality implies that any estimate of effect obtained is very uncertain.

The GRADE approach rates evidence from RCTs that do not have serious limitations as high quality. However, several factors can lead to the downgrading of the evidence to moderate, low or very low. The degree of downgrading is determined by the seriousness of these factors:

- study limitations (risk of bias);
- inconsistency;
- indirectness of evidence;
- imprecision; and
- publication bias.

We have included a 'Summary of findings' table, constructed according to the recommendations described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011). The 'Summary of findings' table includes the primary outcome, episodes of otorrhoea.

RESULTS

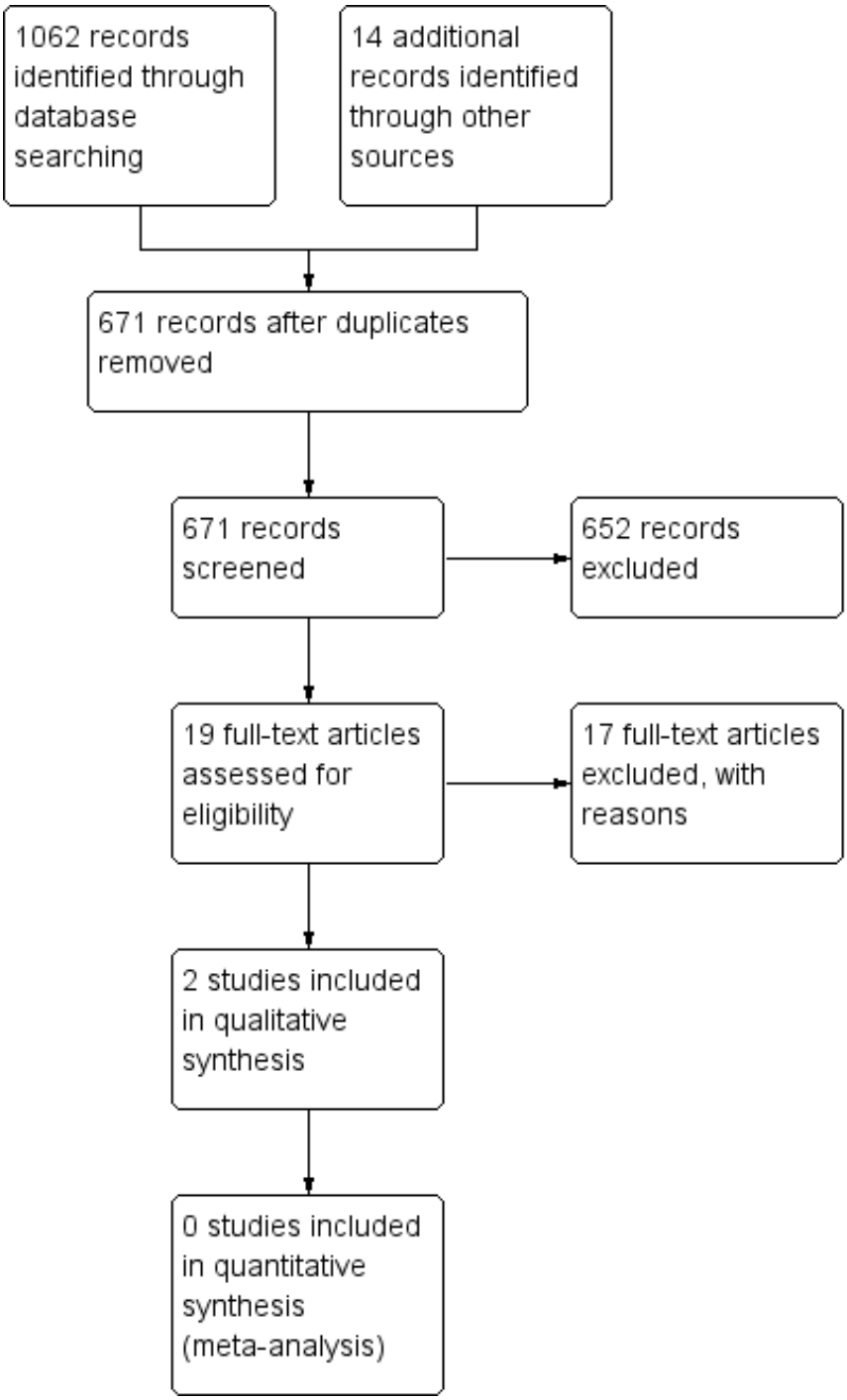
Description of studies

(See Characteristics of included studies and Characteristics of excluded studies for descriptions of individual studies).

Results of the search

Our search, updated in September 2015, identified a total of 1076 references (including 14 references obtained by searching the reference and citation lists of relevant studies), which dropped to 671 after removal of duplicates. From these, a review of the titles and abstracts highlighted 19 studies as being potentially relevant. We excluded 17 studies (see Excluded studies for reasons). We are not aware of any ongoing studies and there are no studies awaiting assessment. See Figure 1 for a flow chart depicting the search history.

Figure 1. Process for sifting search results and selecting studies for inclusion



Included studies

Only two studies met the inclusion criteria for our review (Goldstein 2005; Parker 1994). See Characteristics of included studies.

Design

Both included studies were prospective randomised controlled trials. Goldstein 2005 was an investigator-blinded trial of ear plugs (canal occlusion) versus a control group. Participants were followed up at monthly intervals for one year and "whenever there was an intercurrent ear, nose, or throat problem, including otorrhoea". Parker 1994 was an unblinded trial that assessed the effect of advice to avoid swimming and head immersion while bathing versus a control group. Participants were followed up at three-monthly intervals for a period of one year.

It should be noted that Parker 1994 also reports data for a cohort of patients who were initially allocated to the non-swimming group but chose to swim with water precautions (ear plugs). The results for these patients have not been included in the discussion and we feel they do not warrant inclusion in this review as patients self allocated to the intervention. For the purposes of numerical analysis these patient have been treated as having dropped out of the non-swimming arm of the study.

Participants

Goldstein 2005 recruited 201 children (aged six months to six years) who underwent myringotomy and ventilation tube insertion for rAOM (79%) or OME (21%). Parker 1994 recruited 212 children (aged three months to 12 years) who underwent myringotomy and ventilation tube insertion (information on indications for surgery is not provided). Both studies were conducted in the United States.

Interventions

Goldstein 2005 assessed the effect of canal occlusion in the form of ear plugs. Children in the intervention group were instructed to swim and bathe with ear plugs (no bathing caps were used). Compliance with ear plugs was assessed by means of a calendar completed by the parents. Children in the control group were allowed to swim and bathe without ear plugs. Children in both groups were advised not to dive or swim deeply underwater. Parker 1994 assessed the effect of advice to restrict swimming and bathing behaviour. The intervention group were instructed not to swim or submerge their heads while bathing, whereas children in the control group were allowed to swim and bathe without precautions.

Outcomes

Both studies recorded episodes of otorrhoea as the primary outcome measure. In the Goldstein 2005 study all episodes of otorrhoea were confirmed by examination by a clinician, whereas the Parker 1994 study utilised a combination of examination, case note review, diaries, mailed questionnaires and telephone contact to establish episodes of otorrhoea. Goldstein 2005 additionally collected data for time to ventilation tube extrusion and hearing outcomes.

Excluded studies

We have deliberately listed and described a large number of studies in this section (Characteristics of excluded studies), as although in certain cases it is clear the inclusion criteria are not met, these studies are often referred to in the literature relating to the need for or efficacy of water precautions (including in previous meta-analyses: Carbonell 2002 and Lee 1999).

One excluded study warrants further discussion as it initially appears to be relevant to the review (Gilbert 1994). In this study 24 children with ventilation tubes were allowed to swim with the right ear protected and the left ear unprotected. Episodes of otalgia or otorrhoea were the main outcome measures. Allocation of the intervention to the right ear only is a form of pseudo-randomisation, which in this context probably carries a low risk of bias. The use of the contralateral ear in the same patient as a control is the main reason for exclusion of this study. We feel that each ear cannot be regarded as a 'closed system'; otorrhoea or infection on one side has the potential to affect the other ear and therefore the two 'arms' of the study are not independent.

Risk of bias in included studies

There is variability in the risk of bias between the two included studies (see Characteristics of included studies 'Risk of bias' tables for details and Figure 2 for a summary).

Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

Overall we found the Goldstein 2005 study to have a low risk of bias. This study has low risk of bias for allocation concealment, blinding of outcome, selective reporting and other sources of bias, although we acknowledge that there is an unclear risk of bias in relation to sequence generation, blinding of participants and incomplete outcome data.

We found the Parker 1994 study to have an overall high risk of bias. This study has high risk of bias for allocation concealment, blinding of outcome assessment and incomplete outcome data, there is an unclear risk of bias for allocation concealment and blinding of participants, and there is a low risk of bias for selective reporting and other sources of bias.

Allocation

Goldstein 2005 described block randomisation of participants but unfortunately no detail is available on the method of sequence generation. We are satisfied that allocation concealment was adequate based on the method of central randomisation. Parker 1994 utilised pseudo-randomisation by social security/medical record number, which compromised allocation concealment and introduced a risk of selection bias.

Blinding

Neither study blinded participants, as this was not possible due to the nature of the intervention. Lack of participant blinding is unlikely to influence actual rates of otorrhoea, however patient perception of the need to keep ears dry may potentially influence reporting of symptoms. Both studies describe blinding of investigators at the assessment stage, however there is an increased risk of bias in the Parker 1994 study due to the method of randomisation, which may have unmasked group allocation.

Incomplete outcome data

Both studies had an overall one-year follow-up rate in the region of 50%. Goldstein 2005 presents some follow-up data for 85% of participants and there is equal loss to follow-up between the study groups. Parker 1994 has an increased drop-out rate for the non-swimming group. See Characteristics of included studies for further details.

Selective reporting

All outcome measures stated in the methods section of the published papers were reported in the results. We found no evidence to suggest that the studies were at risk of bias from selective outcome reporting, although we did not have the full protocols available for review.

Other potential sources of bias

We found no evidence to suggest that the studies were at risk of bias from other sources.

Effects of interventions

See: **Summary of findings for the main comparison**; **Summary of findings 2**

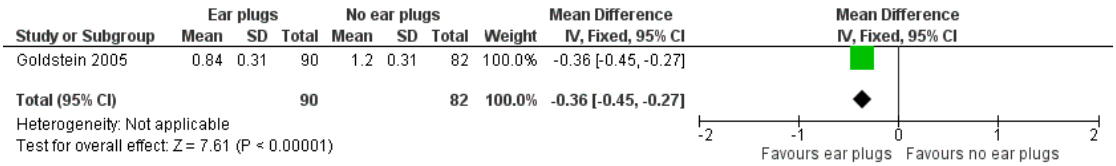
Ear plugs versus control

Primary outcomes

Episodes of otorrhoea

Goldstein 2005 did not find a statistically significant difference between groups in the number of children having at least one episode of otorrhoea (56% of patients in the control group and 47% of the 'ear plugs' group had at least one episode during the study period). There was, however, a statistically significant difference in the rate of otorrhoea between the groups with the control group averaging 0.10 episodes per month compared to a reduced rate in the 'ear plugs' group of 0.07 episodes per month (P value = 0.05). The effect of the intervention therefore is a 0.36 episode reduction (95% confidence interval (CI) -0.27 to -0.45) in the annual rate of otorrhoea (Analysis 1.1; Figure 3).

Figure 3. Forest plot of comparison: 1 Effect of ear plugs, outcome: 1.1 Rate of otorrhoea (annual).



This study collected data on compliance with the intervention, which is critical to quantifying accurately the treatment efficacy. Analysing the results adjusting for compliance shows a slight apparent increase in the efficacy of the intervention as would be expected if the treatment effect were genuine (monthly rate of otorrhoea when ear plugs worn < 10% of time = 0.09, cf when ear plugs worn > 90% of time = 0.06, P value = 0.04). Further outcome data are available in Table 1. The overall quality of evidence for this comparison is low as measured using the GRADE criteria (Summary of findings for the main comparison).

Adverse effects

Goldstein 2005 reported that no patients had adverse effects in either group.

Secondary outcomes

Antimicrobial prescriptions for ear infections

No data are presented for this outcome.

Ventilation tube extrusion

Goldstein 2005 found that there was no significant difference in time to ventilation tube extrusion between the two groups ('ear plugs' group (left: 14.5 months, right: 14.2 months), control group (left: 14.1 months, right: 14.2 months)).

Surgical intervention to remove ventilation tubes

Goldstein 2005 reported that no patients required surgical removal of ventilation tubes in either group.

Hearing outcomes

Goldstein 2005 reported that no patients had adverse hearing outcomes in either group.

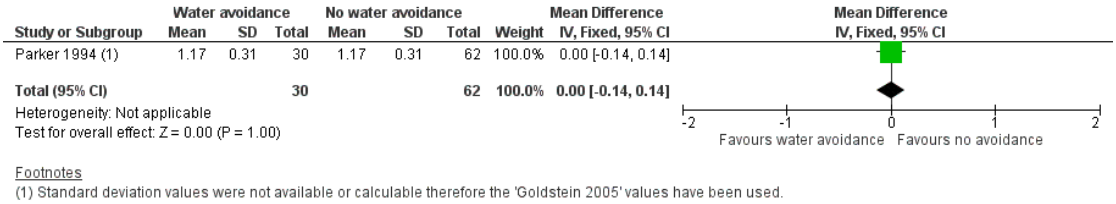
No swimming or head submersion during bathing versus control

Primary outcomes

Episodes of otorrhoea

Parker 1994 did not find a statistically significant difference between groups in the number of children having at least one episode of otorrhoea (68% of patients in the control group and 60% in the non-swimming group had at least one episode during the study period). There was no significant difference in the rate of otorrhoea between the two groups, with both groups averaging 1.17 episodes per year. The effect of the intervention, therefore, is no difference (95% CI -0.14 to 0.14) in the annual rate of otorrhoea (Analysis 2.1; Figure 4). Some caution must be taken with interpretation of the 95% confidence interval in this case as it was not possible to calculate standard deviations for the study data and therefore we have used Goldstein 2005 values. Further outcome data are available in Table 2. The overall quality of evidence for this comparison is very low as measured using the GRADE criteria (Summary of findings 2).

Figure 4. Forest plot of comparison: 2 Effect of avoiding swimming and head immersion during bathing, outcome: 2.1 Rate of otorrhoea (annual).



Footnotes
(1) Standard deviation values were not available or calculable therefore the 'Goldstein 2005' values have been used.

Adverse effects

No data are presented for this outcome.

Secondary outcomes

Antimicrobial prescriptions for ear infections

No data are presented for this outcome.

Ventilation tube extrusion

No data are presented for this outcome.

Surgical intervention to remove ventilation tubes

No data are presented for this outcome.

Hearing outcomes

No data are presented for this outcome.

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

Water avoidance compared with no water avoidance for the prevention of ventilation tube-associated infections

Patient or population: children (aged 3 months to 12 years) with ventilation tubes
Settings: developed healthcare settings
Intervention: advice to avoid swimming or head immersion during bathing
Comparison: no water avoidance

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No water avoidance	Water avoidance				
Rate of otorrhoea (episodes per year) Follow-up: 1 year	The mean rate of otorrhoea was 1.17 episodes per year	The mean rate of otorrhoea in the intervention groups was unchanged (CI -0.14 to 0.14)	No change in the rate of otorrhoea (CI -12% to 12%)	92 (1)	⊕◯◯◯[1] **very low**	These results are based on a single study, which has high risk of bias

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: 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.
Very low quality: We are very uncertain about the estimate.

[1]Downgraded due to significant concerns regarding imprecision of the estimate (a relatively small number of participants in only a single study), and significant concerns regarding study design (risk of bias).

DISCUSSION

Summary of main results

There are only two randomised controlled trials that assess the efficacy of water precautions for the prevention of otorrhoea in children with ventilation tubes. One study assessed the efficacy of wearing ear plugs, and another study assessed the efficacy of avoiding swimming and head immersion during bathing. Collectively the studies recruited 413 children, however a significant overall loss to follow-up means that one-year data (the stated endpoint for both studies) are only available for 188 children. The two included studies differ in their conclusions regarding the efficacy of water precautions for the prevention of otorrhoea.

One study, with low risk of bias, showed that the use of ear plugs while swimming and bathing resulted in a small but statistically significant reduction in the rate of otorrhoea (from 0.10 to 0.07 episodes per month) (Goldstein 2005). The reduction of 0.36 episodes per child-year would mean that to prevent one episode of otorrhoea, a child would have to wear ear plugs for 2.8 years, or 5.6 children would have to wear ear plugs for six months.

One study, with high risk of bias, assessed the effect of avoiding swimming and head immersion during bathing and did not show any evidence of a reduction in the rate of otorrhoea (Parker 1994). The limitations of this study included inadequate allocation concealment and an unequal loss to follow-up between the two arms of the study. Although patients in the experimental arm of this study avoided swimming and head submersion during bathing, no other form of water precautions were used during bathing and so water exposure may have occurred.

Neither study showed any evidence of adverse effects associated with the use of water precautions.

It should be noted that Parker 1994 also reported data for a cohort of patients who were initially allocated to the non-swimming group but chose to swim with water precautions (ear plugs). The results for these patients have not been included in the discussion and we feel that they do not warrant inclusion in this review as patients self allocated to the intervention.

Data from one study did not show any evidence of an effect of water precautions in relation to our secondary outcome measures, ventilation tube extrusion or hearing outcomes (Goldstein 2005).

Overall completeness and applicability of evidence

The overall quantity of data on which to base robust conclusions is limited. This is primarily due to the low number of studies meeting the criteria for inclusion in this review.

The evidence supporting a reduction in episodes of otorrhoea when ear plugs are worn comes from one study, which recruited participants aged six months to six years in the United States (Goldstein 2005). It is uncertain whether the results can be extrapolated to older children or other geographical areas, or whether the results would equally apply to patients excluded from that study (immunocompromised, craniofacial syndrome including cleft, prior ear surgery other than for ventilation tubes). It should be noted that in this study both groups were advised not to swim deeply underwater. The indications for surgery may impact on the applicability of the evidence as the majority of children in this study were operated on for recurrent acute otitis media, unlike in the UK where the majority of operations are done for otitis media with effusion. It is unknown what difference this might make.

The evidence suggesting that there is no change in episodes of otorrhoea when children avoid swimming or head immersion is based on one study, which recruited participants aged three months to 12 years in the United States (Parker 1994). Again, it is uncertain whether the results can be extrapolated to older children or other geographical areas. Moreover, it should be noted that in this study participants in one arm avoided swimming, however no water precautions (other than avoiding head submersion) were used during bathing.

The two studies on which the evidence is based used different types of ventilation tubes and this variable may potentially have an impact on the efficacy of the interventions. In particular, we would consider the internal diameter and length of the ventilation tubes to be of potential relevance as these factors influence the hydrostatic pressure required for water to enter the middle ear. The findings of the studies may not be applicable to patients with different types of ventilation tubes, especially if their dimensions vary significantly from the ones used in the included studies.

No data are available on methods of ear protection other than ear plugs (cf swimming caps), and no data are available relating to the secondary outcome measure antimicrobial prescriptions. Other outcomes that are important to patients and their parents, such as pain, fever and patient/parent satisfaction, were similarly not measured in either study.

Quality of the evidence

At an individual study level there is variation in the risk of bias between the two included studies (see Characteristics of included studies; Figure 2). We judged Goldstein 2005 to have an overall low risk of bias due to a sound study design and detailed reporting of methods and results, whereas Parker 1994 has an overall high risk of bias due to limitations in study design and incomplete outcome data.

The overall strength of the body of evidence relating to the efficacy of water precautions is limited due to the paucity of data. The strength of the evidence (as assessed using GRADE) for the use of ear plugs to prevent otorrhoea is low as it is based on a single study with low risk of bias (Goldstein 2005). The strength of the evidence for the avoidance of swimming or head immersion when bathing to prevent otorrhoea is very low as it is based on a single study with high risk of bias (Parker 1994).

Potential biases in the review process

Although the review placed no restriction on the language of publication, it is possible that some non-English language publications have been missed by our search strategy.

We have chosen to focus only on randomised controlled trials and in doing so we have consciously excluded a large body of evidence gathered from non-randomised or uncontrolled trials (see Characteristics of excluded studies). The excluded trials may contain valid data that could have influenced the findings of this review.

The decision to exclude Gilbert 1994 on the basis of within-patient randomisation could potentially introduce bias as it was not explicitly stated at the protocol stage. The reason for excluding Gilbert 1994 is stated in the Excluded studies section: each ear cannot be regarded as a 'closed system' and therefore the two 'arms' of the study are not independent. We intend to apply the same decision-making for future updates to this review.

Agreements and disagreements with other studies or reviews

Two previous meta-analyses have not shown any evidence of increased otorrhoea in children who swim without water precautions (Carbonell 2002; Lee 1999). Both of the previously published meta-analyses pre-dated the Goldstein 2005 study and therefore the results of this study were not included.

The previous meta-analyses include several studies excluded from this review, the details of which are listed in Characteristics of excluded studies. We mainly excluded the studies due to lack of control/intervention groups, or lack of randomisation. Carbonell 2002 included Arcand 1984, Becker 1987, Chapman 1980, Cohen 1994, Francois 1992, Gilbert 1994, Parker 1994, Salata 1996, Sharma 1986, and Smelt 1984, whereas Lee 1999 included Becker 1987, Parker 1994, Salata 1996, Sharma 1986, and Smelt 1984.

Recent guidelines from the American Academy of Otolaryngology, Rosenfeld 2013, acknowledge the findings of Goldstein 2005 and identify it as the only high-quality study in this field. However, the guidelines recommend against the routine use of water precautions on the basis that the limited clinical benefit is outweighed by the associated cost, inconvenience and anxiety.

AUTHORS' CONCLUSIONS

Implications for practice

The baseline rate and morbidity associated with ventilation tube otorrhoea is usually low and therefore careful prior consideration of the efficacy, costs and burdens of any intervention aimed at reducing this rate is required.

While there is some evidence to suggest that wearing ear plugs reduces the rate of otorrhoea in children with ventilation tubes, clinicians and parents should understand that the absolute reduction in the number of episodes of otorrhoea appears to be very small and is unlikely to be clinically significant. Based on the data available, an average child would have to wear ear plugs for 2.8 years to prevent one episode of otorrhoea.

Some evidence suggests that advising children to avoid swimming or head immersion during bathing does not affect rates of otorrhoea, although good quality data are lacking in this area. Currently, consensus guidelines therefore recommend against the routine use of water precautions on the basis that the limited clinical benefit is outweighed by the associated cost, inconvenience and anxiety (Rosenfeld 2013).

Implications for research

Future high-quality studies could be undertaken but may not be thought necessary. It is uncertain whether further trials in this area would change the findings of this review or have an impact on practice. Any future high-quality research should focus on determining whether particular groups of children benefit more from water precautions than others, as well as on developing clinical guidelines and their implementation.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Goldstein 2005

Methods	**Allocation:** randomised controlled trial **Design:** prospective, investigator-blinded Children undergoing bilateral myringotomy and ventilation tube insertion for rAOM or OME were randomised into 2 groups (ear plugs versus no ear plugs) and followed up monthly for 1 year "... and whenever there was an intercurrent ear, nose, or throat problem, including otorrhoea" The primary outcome measure, episodes of otorrhoea "were all documented by physician visit, we did not rely on history. Otorrhea had to be visualized in the canal" (Goldstein 2014) Compliance with ear protection was assessed by means of a calendar completed by the parents
Participants	**Number:** 201 **Age:** 6 months to 6 years (80% aged 6 months to 3 years, 20% aged 4 to 6 years) **Gender:** 119 boys, 82 girls **Setting:** study conducted at the Children's Hospital of Pittsburgh, Pennsylvania (United States of America) **Eligibility criteria:** children who underwent myringotomy and ventilation tube insertion for rAOM (79%) or OME (21%) **Exclusion criteria:** children who were immunocompromised, had a craniofacial syndrome or cleft palate, or who had undergone prior ear surgery (other than ventilation tube placement) were excluded **Baseline characteristics:** all children had "fluoroplastic Armstrong Grommet-type tympanostomy tubes placed"
Interventions	**Intervention group:** (n = 103). The intervention group were instructed to swim and bathe with ear plugs "Children using ear plugs were fitted with a soft, plastic, prefabricated ear plug (Doc's Proplugs, International Aquatic Trades, Inc., Santa Cruz, CA) or, if their ear canals were too small, with a moldable silicone ear plug (Insta-Putty, Insta-Mold Products, Inc., Oaks, PA). Bathing caps were not used." **Comparator group:** (n = 98). The control group were allowed to swim and bathe without ear plugs **Use of additional interventions:** there were no restrictions on the frequency or location of swimming; children in both groups were advised not to dive or swim deeply underwater
Outcomes	**Primary outcomes:** - Incidence of otorrhoea - Rate of otorrhoea **Secondary outcomes:** - Time to tube extrusion - Hearing level - Adverse events Participants were followed up at monthly intervals for 1 year

Goldstein 2005 (*Continued*)

Funding sources	The paper acknowledges GlaxoSmithKline, Alcon Laboratories and Allergan "for their generous contribution of oral and topical antibiotics used in the present study"
Declarations of interest	There are no declarations of interest other than those listed above under funding sources
Notes	**Participants lost to follow-up:** see 'Risk of bias' table - incomplete outcome data Although not reported in the paper, we found no significant difference between study groups in the numbers of children excluded from the study within 1 year due to blocked or extruded tubes; analysis performed using 2-tailed fisher's exact test (3/103 'ear plugs' versus 7/98 control, P value = 0.20)

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Children were stratified by age (< 4 and ≥ 4) and diagnosis (rAOM and OME) and were then assigned "randomly in blocks of four to one of two groups" No detail is given in the paper on the method of sequence generation and this is not described further in the study protocol
Allocation concealment (selection bias)	Low risk	Correspondence with the author states: "The patients were recruited by one of the physicians and then the nurse practitioner or medical assistant made the group assignment ... The ENT clinic was adjacent to the ENT research center, so once the patient was recruited from the clinic they went over to the ENT research center for group assignment. There was no way for the investigator to know what group the child would be put in." (Goldstein 2014)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants is not possible due to the nature of the intervention. We feel the lack of participant blinding is unlikely to influence actual rates of otorrhoea, however patient perception of the need to keep ears dry may potentially influence reporting of symptoms and for this reason we have graded the risk of bias as unclear The paper states "Investigators were blinded as to the group to which the child was assigned"

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Correspondence with the author states: "The investigators (3 physicians) were blinded to patient group when examining the children." (Goldstein 2014) There is a potential for study group allocations to be revealed to investigators by the participants at follow-up visits due to the lack of blinding of participants, however we judge this to be low risk
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	85% (172/201) of children attended for at least 1 follow-up visit with similar follow-up rates between the 2 main study groups (84% 'ear plugs' group versus 87% control group) There is significant loss to follow-up at the stated endpoint of the study (1 year) with 50% (52/103) patients in the 'ear plugs' group achieving ≥ 12 months follow-up compared to 45% (44/98) in the 'no ear plugs group'. Mean follow-up time was 9.4 months for the 'ear plugs' group and 9.1 months for the control group While the loss to follow-up is similar between groups and short-term results are available for a majority of patients, we feel the degree of long-term loss to follow-up represents an unclear risk of bias 7 children in the 'ear plugs' group and 3 children in the control group were excluded before completion of the study due to bilateral blocked or extruded tubes. 4 children in the control group were excluded from the study due to being categorised as 'treatment failures' (> 3 episodes of otorrhoea in 6 months or > 4 episodes of otorrhoea in 12 months). The paper states "Children withdrawn from the study early were included in the analysis for the duration of their participation" We feel that patients who were lost to follow-up or excluded have been addressed and that related data have been handled appropriately
Selective reporting (reporting bias)	Low risk	All initially stated outcome measures were reported. In relation to excluded patents the paper states that "Children withdrawn from the study early were included in the

Goldstein 2005 (*Continued*)

		analysis for the duration of their participation."
Other bias	Low risk	The paper acknowledges GlaxoSmithKline, Alcon Laboratories and Allergan "for their generous contribution of oral and topical antibiotics used in the present study". Further correspondence with the author states "several pharmaceutical companies donated antibiotics to be used for studies done in the ENT Research Center. We often gave the parents the medications for otorrhea so it certainly can be viewed as compensation for study participation. In general, the donated antibiotics did not influence the choice of treatment as we had protocols on how the otorrhea was to be treated." (Goldstein 2014) We do not feel this would result in an increased risk of bias

Parker 1994

Methods	**Allocation:** randomised controlled trial **Design:** prospective Children undergoing ventilation tube placement were randomised into swimming and non-swimming groups and followed up at 3-monthly intervals for 1 year The primary outcome measure, episodes of otorrhoea "was obtained by examination, review of outpatient records, patient diaries, mailed questionnaires, and direct telephone contact" Patients initially assigned to the non-swimming group who were non-compliant and elected to swim with 'water precautions' (canal occlusion) were included in the study and analysed as a separate group
Participants	**Number:** 212 **Age:** 3 months to 12 years **Gender:** not specified **Setting:** 2 adjacent hospitals in Portsmouth, Virginia (USA) **Eligibility criteria:** children who underwent myringotomy and ventilation tube insertion (the indications for surgery are not stated) **Exclusion criteria:** no exclusion criteria are stated **Baseline characteristics:** "The majority of tubes were Teflon Sheehy collar buttons (Xomed-Trease, Jacksonville, FL)"
Interventions	**Intervention group:** (n = 30). The intervention group were instructed not to swim or submerge their heads while bathing **Comparator group:** (n = 62). The control group were allowed to swim and bathe without precautions **Use of additional interventions:** both groups were provided calendars to record swim-

	ming, bathing and otorrhoea. Results for an additional group "swimming with precautions" (n = 15) were reported and comprised a group of patients who were originally allocated to the no swimming group but who then decided to swim and use water precautions (canal occlusion)
Outcomes	**Primary outcomes** - Incidence of otorrhoea - Rate of otorrhoea **Secondary outcomes** - None Participants were followed up at 3-monthly intervals for a period of 1 year
Funding sources	There are no declared sources of funding
Declarations of interest	There are no declarations of interest
Notes	This study had a high loss to follow-up rate (50%) and number of methodological sources of bias as outlined below in the 'Risk of bias' table 15 patients initially allocated to the non-swimming group chose to swim and use water precautions (canal occlusion). These patients were analysed as a separate group and not included in the non-swimming group as might be expected with an 'intention-to-treat' analysis We feel that the results from the 'swimming with precautions' group need to be interpreted with caution: as this group has not followed the initially stated methodology and is not subject to randomisation, we have not included them in the analysis for this review

Risk of bias ***Risk of bias***

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The paper states: "Patients ... were randomized into a swimming or nonswimming group based on the last digit of their social security number". Correspondence with the author states that patients were allocated into groups on the basis of "odd versus even" (Tami 2014). This is a method of pseudo-randomisation and may introduce bias
Allocation concealment (selection bias)	High risk	The paper states: "Patients ... were randomized into a swimming or nonswimming group based on the last digit of their social security number" Correspondence with the author states "the social security number, at least at the time of our study, was the number used for the medical record number. So, yes, it would have been available at the time of recruit-

Parker 1994 (*Continued*)

		ment" (Tami 2014) In theory this introduces risk of bias at the selection stage
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants is not possible due to the nature of the intervention. We feel lack of participant blinding is unlikely to influence actual rates of otorrhoea, however patient perception of the need to keep ears dry may potentially influence reporting of symptoms and for this reason we have graded the risk of bias as unclear No mention is made in the paper of blinding of investigators, however correspondence with the author states "the investigators doing the follow-up were blinded to the study" (Tami 2014)
Blinding of outcome assessment (detection bias) All outcomes	High risk	No mention is made in the paper of blinding of investigators, although correspondence with the author states: "the investigators doing the follow-up were blinded to the study". However, as outlined above in relation to allocation concealment, use of the social security/medical record number for allocation could potentially unmask patient groups. The author states: "I suspect that they could have deduced that, although I don't specifically remember" (Tami 2014)
Incomplete outcome data (attrition bias) All outcomes	High risk	50% (107/212) of patients were available for 1-year follow-up (62 patients in the swimming group and 45 patients initially allocated to the non-swimming group). No data are available on the numbers of patients initially allocated to each study group so it is not possible to accurately determine the proportion lost to follow-up for each study group. Assuming approximately equal distribution between groups, it would appear that loss to follow-up is greater for the non-swimming group Of the 45 patients initially allocated to the non-swimming group who attended for follow-up, 15 dropped out of the non-swimming group and were reported to have used water precautions (canal occlusion) while swimming. These 15 patients were

Parker 1994 (*Continued*)

		analysed as a separate group We have graded incomplete outcome data as high risk of bias due to the overall loss to follow-up and an apparent increased drop-out rate for the non-swimming group
Selective reporting (reporting bias)	Low risk	All initially stated outcome measures were reported. No interim data are presented for patients lost to follow-up. No data are presented relating to ventilation tube extrusion, hearing outcomes or adverse events; we assume that this was probably not collected
Other bias	Low risk	This study was "performed in part under the United States Navy Clinical Investigation Programme". We are not aware of any reason why this would introduce bias

rAOM: recurrent acute otitis media
OME: otitis media with effusion

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Arcand 1984	**2 arms of study differ with respect to 2 separate interventions** (one of which is water precautions); not possible to determine which intervention led to observed effects Description of study: randomised trial of 1000 children undergoing ventilation tube insertion. A 'closed canal' group undertook water precautions with canal occlusion and bathing cap, whereas an 'open canal' group took no water precautions and used antimicrobial drops on the evening of water exposure
Becker 1987	**No randomisation** Description of study: non-randomised trial of 85 children who underwent ventilation tube insertion. Parental choice to allow child to either swim without water protection, swim and bathe with water protection, or abstain from swimming and bathe with water protection. Otorrhoea episodes and swimming habits were recorded at 2-monthly follow-up
Chapman 1980	**No randomisation. No intervention** Description of study: observational prospective cohort study of 112 children who underwent ventilation tube insertion. Children were allowed to swim without water precautions if they wished. Otorrhoea rates and swimming habits were determined at follow-up visits over a 6-month period

(*Continued*)

Cohen 1994	**No randomisation. 2 concurrent interventions** Description of study: non-randomised trial of 42 children who underwent ventilation tube insertion. Self selected swimmers were allowed to 'surface swim' without water precautions provided antimicrobial drops were used that evening; non-swimmers acted as the control group. Otorrhoea was measured as the main outcome
De Vries 1984	**No randomisation. No control group. Does not assess effect of water precautions** Description of study: non-randomised trial of 88 children who underwent ventilation tube insertion for middle ear effusions. Children were permitted to swim provided antimicrobial drops were used on the evening of water exposure. Numbers of swimming episodes and otorrhoea episodes were recorded
El Silimy 1986	**No randomisation. No intervention** Description of study: prospective cohort study of 100 children (50 swimmers, 50 non-swimmers) who underwent ventilation tube insertion. Episodes of otorrhoea and bacteriological analysis of ear discharge were measured over a 6-month period
Francois 1992	**No randomisation. No intervention** Description of study: prospective cohort study of 210 children who underwent ventilation tube insertion in 5 study centres. Children were allowed to swim without water precautions. Otorrhoea rates and swimming habits were determined at mean 6-month follow-up [Original paper unavailable - above data extracted from summary letter published in *BMJ* (1992); 304(6829): 778-9]
Gilbert 1994	**Pseudo-randomised, self controlled trial** Description of study: 24 children with ventilation tubes were allowed to swim with the right ear protected and left ear unprotected. Episodes of otalgia or otorrhoea were the main outcome measures
Jaffe 1981	**No randomisation. No control group. Does not assess effect of water precautions** Description of study: non-randomised trial of 100 children who underwent ventilation tube insertion for middle ear effusions. Children were permitted to swim providing antimicrobial drops were used on the evening of water exposure. Otorrhoea rates and adverse events are the recorded outcome measures
Johnson 1977	**Pseudo-randomised trial. No control group** Description of study: pseudo-randomised trial of 35 patients requiring ear protection for bathing (not restricted only to patients with ventilation tubes). Patients assigned sequentially to 4 different types of ear plugs; no control group without ear protection. Otorrhoea and signs of infection were outcome measures
Kaufmann 1999	**No randomisation** Description of study: non-randomised trial of 86 children who underwent ventilation tube insertion. Children were assigned to either: swimming without water precautions or swimming with canal occlusive water protection. Children were assigned to groups on the basis of parental preference
Lounsbury 1985	**No control group** Description of study: prospective cohort study of 113 children with ventilation tubes. Swimming was permitted without water precautions but with restrictions to bathing. Swimming habits and otorrhoea episodes were recorded
Salata 1996	**No randomisation** Description of study: non-randomised trial of 533 children undergoing ventilation tube insertion. Children assigned to either: no water precautions, no water precautions and prophylactic antimicrobial drops, use of ear

(*Continued*)

	moulds during swimming, or no swimming. Children were assigned to groups on the basis of parental preference
Sharma 1986	**No randomisation. No intervention** Description of study: prospective cohort study of 130 children who underwent ventilation tube insertion. Children were allowed to swim without water precautions if they wished. Otorrhoea rates and swimming habits were recorded at follow-up visits until ventilation tube extrusion
Smelt 1984	**No randomisation. No intervention** Description of study: prospective cohort study of 119 children who underwent ventilation tube insertion for secretory otitis media. Children were allowed to swim without water precautions if they wished. Otorrhoea episodes and swimming habits were recorded at 2-monthly follow-up
Wang 2009	**No intervention** Description of study: prospective cohort study of 14 children with ventilation tubes. Presence of water in ear canal and otorrhoea episodes were assessed after swimming without water precautions
Wight 1987	**No intervention** Description of study: retrospective cohort study of 43 children who underwent ventilation tube insertion for OME. A range of data were collected, including swimming status and otorrhoea rates

OME: otitis media with effusion

DATA AND ANALYSES

Comparison 1. Ear plugs versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Rate of otorrhoea (annual)	1	172	Mean Difference (IV, Fixed, 95% CI)	-0.36 [-0.45, -0.27]

Comparison 2. No swimming or head submersion during bathing versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Rate of otorrhoea (annual)	1	92	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.14, 0.14]

Analysis 1.1. Comparison 1 Ear plugs versus control, Outcome 1 Rate of otorrhoea (annual).

Review: Water precautions for prevention of infection in children with ventilation tubes (grommets)

Comparison: 1 Ear plugs versus control

Outcome: 1 Rate of otorrhoea (annual)

Study or subgroup	Ear plugs N	Mean(SD)	No ear plugs N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Goldstein 2005	90	0.84 (0.31)	82	1.2 (0.31)		100.0 %	-0.36 [-0.45, -0.27]
Total (95% CI)	**90**		**82**			**100.0 %**	**-0.36 [-0.45, -0.27]**

Heterogeneity: not applicable

Test for overall effect: Z = 7.61 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 2.1. Comparison 2 No swimming or head submersion during bathing versus control, Outcome 1 Rate of otorrhoea (annual).

Review: Water precautions for prevention of infection in children with ventilation tubes (grommets)

Comparison: 2 No swimming or head submersion during bathing versus control

Outcome: 1 Rate of otorrhoea (annual)

Study or subgroup	Water avoidance		No water avoidance		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI		IV,Fixed,95% CI
Parker 1994 (1)	30	1.17 (0.31)	62	1.17 (0.31)		100.0 %	0.0 [-0.14, 0.14]
Total (95% CI)	**30**		**62**			**100.0 %**	**0.0 [-0.14, 0.14]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P = 1.0)

Test for subgroup differences: Not applicable

(1) Standard deviation values were not available or calculable therefore the 'Goldstein 2005' values have been used.

ADDITIONAL TABLES

Table 1. Goldstein 2005: Outcomes

Outcome measured	Result (as reported in the study unless otherwise stated)
Incidence of otorrhoea	47% (42/90) of children in the 'ear plugs' group had 1 or more episode of otorrhoea during the study period compared to 56% (46/82) in the control group (P value = 0.21)
Rate of otorrhoea	The monthly rate of otorrhoea in the 'ear plugs' group was 0.07 compared to 0.10 in the control group (P value = 0.05)
Tube extrusion	There was no significant difference in time to tube extrusion between the 2 study groups ('ear plugs' group (left: 14.5 months, right: 14.2 months), control group (left: 14.1 months, right: 14.2 months))
Other	No children in the 'ear plugs' group were classified as 'treatment failures' (> 3 episodes of otorrhoea in 6 months or > 4 episodes of otorrhoea in 12 months) compared to 4 children (5%) in the control group (P value = 0.05). No adverse hearing outcomes were reported in either group Further analysis to adjust for compliance compares the control group (including 'low compliance' (< 10% ear plug use) 'ear plugs' patients) with 'high compliance' (> 90% ear plug use) 'ear plug' patients. These findings replicated those of the main study groups Correspondence with the author: "No patient required surgical intervention to remove the tubes at the time of study participation" and " ... there were no additional adverse events other than those mentioned" (Goldstein 2014)

Table 2. Parker 1994: Outcomes

Outcome measured	Result (as reported in the study unless otherwise stated)
Incidence of otorrhoea	68% (42/62) of children in the swimming group experienced otorrhoea compared to 60% (18/30) in the non-swimming group, which was "not statistically significant". *(Our analysis of figures provided using two-tailed fisher's exact test shows P value = 0.49).* The incidence of otorrhoea in the 'swimming with precautions' group was 86.7% (13/15)
Rate of otorrhoea	The annual rate of otorrhoea in both the swimming group and the non-swimming group was 1.17. The annual rate of otorrhoea in the 'swimming with precautions' group was 3.07; the authors judge that this represents a "statistically significant increased number" (P value < 0.005)
Other	No data are presented relating to ventilation tube extrusion, hearing outcomes or adverse events

APPENDICES

Appendix 1. CENTRAL search strategy

CENTRAL	PubMed	EMBASE (Ovid)
#1 MeSH descriptor: [Middle Ear Ventilation] explode all trees #2 grommet* or tubulation or middle next ear near ventilat* #3 (ventilat* or tympanostomy or middle next ear or tympanic) near tube* #4 ear* near insert* near tube* #5 #1 or #2 or #3 or #4 #6 MeSH descriptor: [Water] this term only 1334 #7 MeSH descriptor: [Baths] explode all trees #8 MeSH descriptor: [Swimming] explode all trees #9 MeSH descriptor: [Immersion] explode all trees #10 MeSH descriptor: [Swimming Pools] explode all trees #11 MeSH descriptor: [Fresh Water] explode all trees #12 MeSH descriptor: [Oceans and Seas] explode all trees #13 MeSH descriptor: [Seawater] explode	#1 "Middle Ear Ventilation"[Mesh] #2 ((tympanostomy OR (middle AND ear) OR tympanic) AND tube*) #3(ear* AND ("tube insert*" OR "tubes insert*" OR "ventilation tube*" OR "ventilating tube*" OR "tube ventilat*" OR "tubes ventilat*")) #4 (grommet* OR tubulation OR (middle AND ear AND ventilat*)) #5 (#1 OR #2 OR #3 OR #4) #6 "Water"[Mesh:NoExp] #7 "Baths"[Mesh] #8 "Swimming"[Mesh] #9 "Fresh Water"[Mesh] #10 "Swimming Pools"[Mesh] #11 "Immersion"[Mesh] #12 "Oceans and Seas"[Mesh] #13 "Seawater"[Mesh] #14 (water* or swim* or shower* or bath* or dry or wash* or clean* or dive or diving or rinsing or rinse or nonswim*) #15 (immers* or submers* or submerg* or	1 exp middle ear ventilation/ 2 (grommet* or tubulation or (middle adj6 ear adj6 ventilat*)).tw 3 ((ventilat* or tympanostomy or (middle adj6 ear) or tympanic) adj6 tube*).tw 4 (ear* adj6 insert* adj6 tube*).tw. 5 1 or 2 or 3 or 4 6 water/ 7 exp bath/ 8 exp swimming/ 9 exp water immersion/ 10 exp immersion/ 11 exp swimming pool/ 12 exp fresh water/ 13 exp sea/ 14 exp sea water/ 15 (water* or swim* or shower* or bath* or dry or wash* or clean* or dive or diving or rinsing or rinse or nonswim*).tw 16 (immers* or submers* or submerg* or lake* or pond* or creek* or pool* or river* or freshwater* or sea* or ocean* or seawa-

(*Continued*)

all trees #14 water* or swim* or shower* or bath* or dry or wash* or clean* or dive or diving or rinsing or rinse or nonswim* #15 immers* or submers* or submerg* or lake* or pond* or creek* or pool* or river* or freshwater* or sea* or ocean* or seawater* or ingress #16 MeSH descriptor: [Ear Protective Devices] explode all trees #17 (ear and protect*) or ear mould* or ear mold* or ear plug* or earplug* or earmold* or earmould* or Canal occlusive devis* or physical barrier* or (cotton and (vaseline or "petroleum jelly")) #18 #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 #19 #5 and #18 #20 MeSH descriptor: [Middle Ear Ventilation] explode all trees and with qualifiers: [Adverse effects - AE] #21 #19 or #20	lake* or pond* or creek* or pool* or river* or freshwater* or sea* or ocean* or seawater* or ingress) #16 "Ear Protective Devices"[Mesh] #17 ((ear and protect*) or "ear mould*" or "ear mold*" or "ear plug*" or earplug* or earmold* or earmould* or "Canal occlusive devis*" or "physical barrier*" or (cotton and (vaseline or "petroleum jelly"))) #18 (#6 OR #7 OR #8 Or #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18) #19 (#5 AND #18) #20 "Middle Ear Ventilation/adverse effects"[Mesh] #21 (#19 OR #20)	ter* or ingress).tw 17 ((ear and protect*) or "ear mould*" or "ear mold*" or "ear plug*" or earplug* or earmold* or earmould* or "Canal occlusive devis*" or "physical barrier*" or (cotton and (vaseline or "petroleum jelly"))).tw 18 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 19 5 and 18
CINAHL (EBSCO)	**Web of Science (Web of Knowledge)**	**ICTRP**
S1 (MH "Middle Ear Ventilation") S2 TX (tympanostomy OR (middle AND ear) OR tympanic) AND tube* S3 TX (ear* AND ("tube insert*" OR "tubes insert*" OR "ventilation tube*" OR "ventilating tube*" OR "tube ventilat*" OR "tubes ventilat*")) S4 TX (grommet* OR tubulation OR (middle AND ear AND ventilat*)) S5 S1 OR S2 OR S3 OR S4 S6 (MH "Water") S7 (MH "Bathing and Baths") S8 (MH "Swimming") S9 (MH "Oceans and Seas") S10 TX water* or swim* or shower* or bath* or dry or wash* or clean* or dive or diving or rinsing or rinse or nonswim* S11 TX immers* or submers* or submerg* or lake* or pond* or creek* or pool* or river* or freshwater* or sea* or ocean* or seawater* or ingress S12 (MH "Ear Protective Devices") S13 TX (ear and protect*) or "ear mould*" or "ear mold*" or "ear plug*" or earplug*	#1 TS=(grommet* or tubulation or (middle NEAR/6 ear NEAR/6 ventilat*)) #2 TS=((tympanostomy or (middle NEAR/6 ear) or tympanic) NEAR/6 tube*) #3 TS=(ear* NEAR (insert* OR ventilat*) NEAR/6 tube) #4 #3 OR #2 OR #1 #5 TS=(immers* or submers* or submerg* or lake* or pond* or creek* or pool* or river* or freshwater* or sea* or ocean* or seawater* or ingress) #6 TS=(water* or swim* or shower* or bath* or dry or wash* or clean* or dive or diving or rinsing or rinse or nonswim*) #7 TS=((ear and protect*) or "ear mould*" or "ear mold*" or "ear plug*" or earplug* or earmold* or earmould* or "Canal occlusive devis*" or "physical barrier*" or (cotton and (vaseline or "petroleum jelly"))) #8 #7 OR #6 OR #5 #9 #8 AND #4	grommet OR grommets OR tympanostomy tubes OR ventilation tubes OR tympanostomy tube OR ventilation tube OR ear ventilation insert AND ear AND tube

(*Continued*)

or earmold* or earmould* or "Canal occlusive devis*" or "physical barrier*" or (cotton and (vaseline or "petroleum jelly")) S14 S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 S15 S5 AND S14 S16 (MH "Middle Ear Ventilation/AE") S17 S15 OR S16		

CONTRIBUTIONS OF AUTHORS

Daniel Moualed (DM) conceived, designed and managed the review.

DM and Liam Masterson (LM) screened the titles and abstracts.

DM and LM organised retrieval of papers.

DM and LM screened the retrieved papers against the inclusion criteria, appraised the quality of the papers and extracted data.

DM and LM obtained additional data on published studies.

DM entered data into RevMan and was responsible with LM for data management for the review and analysis of the data.

Sanjiv Kumar (SK) and Neil Donnelly (ND) provided a methodological and clinical perspective.

DECLARATIONS OF INTEREST

DM declares no competing interests.

LM declares no competing interests.

SK declares no competing interests.

ND declares no competing interests.

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Internal sources

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- National Institute for Health Research, UK.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods section has been re-written in the past tense and updated to refer to the methods as applied to this version of the review.

The methods section subheading Types of outcome measures previously stated "Studies were eligible for inclusion provided they measured at least one of the primary or secondary outcome measures below." In keeping with new MECIR guidelines this has been changed to "We analysed the following outcomes in the review, but we did not use them as a basis for including or excluding studies."

Timeframes have been added to the objectives and outcome measures section of the protocol.

Studies utilising within-patient randomisation will be excluded from future updates to this review in keeping with the decision-making applied to Gilbert 1994, as outlined in Excluded studies.

INDEX TERMS

Medical Subject Headings (MeSH)

*Baths; *Ear Protective Devices; *Middle Ear Ventilation [instrumentation]; *Swimming; *Water; Bacterial Infections [*prevention & control]; Ear Diseases [*prevention & control]; Randomized Controlled Trials as Topic

MeSH check words

Child; Child, Preschool; Humans; Infant