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Pharmacological and conservative interventions for ear discharge associated with grommets (ventilation tubes) outside the postoperative period (Protocol)

Javed F, van Dongen TMA, Waddell A, Venekamp RP, Schilder AGM

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[Intervention Protocol]

Pharmacological and conservative interventions for ear discharge associated with grommets (ventilation tubes) outside the postoperative period

Faisal Javed[1], Thijs MA van Dongen[2], Angus Waddell[3], Roderick P Venekamp[2], Anne GM Schilder[4]

[1]Severn Deanery, Great Western Hospital, Swindon, UK. [2]Department of Otorhinolaryngology & Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, Netherlands. [3]ENT Department, Great Western Hospital, Swindon, UK. [4]evidENT, Ear Institute, Faculty of Brain Sciences, University College London, London, UK

Contact address: Faisal Javed, Severn Deanery, Great Western Hospital, Swindon, UK. fjaveed@yahoo.com.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effectiveness and safety of various treatment strategies in patients with grommets who developed ear discharge.

BACKGROUND

Description of the condition

The insertion of grommets (also known as ventilation tubes or tympanostomy tubes) is one of the most common surgical procedures performed in children worldwide, with around 25,000 procedures performed in the UK (Position Paper ENT UK 2009), and almost 700,000 in the United States each year (Cullen 2009). The two main indications for this operation include restoration of hearing in children with persistent bilateral otitis media with effusion (also called 'glue ear') and prevention of further middle ear infections in children suffering from recurrent acute otitis media. Ear discharge (also called otorrhoea) is a common sequela in patients with grommets; it is generally considered to be a symptom of a middle ear infection whereby fluid that has built up in the middle ear drains through the grommet into the ear canal. Ear discharge associated with grommets is generally divided into early postoperative versus late ear discharge based on the time at which the condition occurs (with early postoperative ear discharge usually defined as ear discharge occurring within two weeks after insertion of the grommets). Estimations of the proportion of patients with grommets developing ear discharge range from 25%, in a meta-analysis of mainly observational studies, to 75% in a randomised controlled trial (Ah-Tye 2001; Kay 2001; van Dongen 2013). Ear discharge is most unpleasant, as it can smell bad, while the underlying middle ear infection may cause general illness, fever and pain. Ear discharge persisting for three days or more has a negative impact on children's quality of life (Rosenfeld 2000). Although most episodes of ear discharge in patients with grommets last days to weeks, some patients develop chronic ear discharge, which may be associated with considerable morbidity and hearing loss.

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Description of the intervention

Various interventions and combinations of interventions are used to treat ear discharge in patients with grommets. Broad-spectrum oral antibiotics, topical antibiotics with or without topical corticosteroids and initial observation are the most commonly used in daily clinical practice. Other (additional) interventions include suction of the discharging ear, saline rinsing and systemic or topical corticosteroids.

Several studies have shown that ENT surgeons tend to prescribe eardrops containing antibiotics with or without corticosteroids, while general practitioners (GPs) and emergency medicine physicians frequently prescribe oral antibiotics to these patients (Badalyan 2013; Bickerton 1988; Robb 1991). The fear of ototoxicity appears to be an important reason for physicians to refrain from treatment with topical antibiotics (Bickerton 1988). Aminoglycosides are considered potentially ototoxic, although the available evidence on this topic is of rather poor quality and ototoxicity is considered to be a rare complication given its frequent use (Pappas 2006; Phillips 2007). The use of chloramphenicol and polymyxin B eardrops has been associated with hair cell damage (Pappas 2006). Quinolone eardrops are considered to be non-ototoxic and are therefore frequently prescribed (Bagger-Sjöbäck 1992; Pappas 2006).

In this review we will assess the effectiveness and safety of the various interventions for ear discharge in patients with grommets. Treatment strategies for (the prevention of) ear discharge occurring shortly after the insertion of grommets (also called early postoperative ear discharge) are beyond the scope of this review and are addressed in a separate Cochrane review (Syed 2013).

How the intervention might work

Bacterial infection of the middle ear is thought to be the predominant cause of ear discharge. The bacteria involved in ear discharge in patients with grommets include the typical acute otitis media pathogens, such as *Streptococcus pneumoniae*, non-typeable*Haemophilus influenzae* and *Moraxella catarrhalis* (Dohar 2003; Ruohola 2006), but *Staphylococcus aureus* and *Pseudomonas aeruginosa* are also commonly found (Mandel 1994). Treatment of this condition is aimed at eradicating the bacterial infection and (topical) antibiotics are therefore predominantly prescribed. Topical antibiotics may have several potential advantages over oral antibiotics. First, antibiotic eardrops are delivered directly to the site of infection resulting in a higher local concentration of antibiotics. Second, antibiotic eardrops are (therefore) less likely to cause antimicrobial resistance compared to oral antibiotics (Weber 2004). Third, antibiotic eardrops mainly have minor side effects, such as local skin irritation or local allergy, while oral antibiotics are associated with systemic side effects including diarrhoea, nausea, rash, vomiting and potentially severe allergic reactions.

The use of (topical) corticosteroids as an adjunctive therapy to antibiotic treatment is suggested to provide additional benefits in resolving the ear discharge by inhibiting the inflammatory cascade evoked in the middle ear as a result of the infection.

Since the middle ear infection that causes the ear discharge in patients with grommets may be self limiting over time, initial observation with or without daily suction (aural toilet) of the discharging ear(s) may also be a good alternative to treatment with antibiotics and/or corticosteroids.

Why it is important to do this review

The insertion of grommets is one of the most frequently performed surgical procedures in children and ear discharge is a common sequela (Ah-Tye 2001; Cullen 2009; Kay 2001; van Dongen 2013). The effectiveness of antibiotic eardrops with or without corticosteroids, systemic antibiotics and (saline) irrigation for the prevention of postoperative ear discharge in children has recently been reviewed (Syed 2013). The authors concluded that "if a surgeon has a high rate of postoperative ear discharge in children then either saline irrigation or antibiotic eardrops at the time of surgery would significantly reduce that rate". Still, even despite the use of effective prophylactic interventions, many children with grommets will develop ear discharge outside the immediate postoperative period and it is unknown if any of these interventions are also effective for this condition. Although most episodes of ear discharge in patients with grommets are acute and transient, some children develop chronic discharging ears, which may cause considerable morbidity and hearing loss (Acuin 2004; van der Veen 2006). As such, it is important to optimise treatment for this condition. A systematic review to assess the effectiveness of various interventions for ear discharge in patients with grommets is therefore warranted.

OBJECTIVES

To assess the effectiveness and safety of various treatment strategies in patients with grommets who developed ear discharge.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs), irrespective of the randomisation method and blinding procedure used.

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Types of participants

Patients of any age with grommets (irrespective of type) who developed ear discharge. We will exclude those who had grommets placed within the preceding two weeks.

Types of interventions

We will include all trials comparing the effectiveness and/or safety of at least two of the following interventions and comparators:

1. Initial observation with or without daily suction (aural toilet) of the discharging ear(s)
2. Oral antibiotics
3. Oral corticosteroids
4. Topical antibiotics with or without topical corticosteroids
5. Topical corticosteroids
6. Saline rinsing
7. Placebo (in the form of eardrops, oral suspension or tablets, depending on the 'active' intervention that is studied)

The main comparison of interest will be oral antibiotics versus topical antibiotics with or without topical corticosteroids.

We will include RCTs reporting on combined interventions (e.g. oral antibiotics plus topical antibiotics versus topical antibiotics only) only if they allow a direct comparison between one of the combined interventions and a control group and if the groups are not treated differently except for the therapy that is studied.

Types of outcome measures

We will analyse the primary and secondary outcomes listed below in this review, but we will not use these outcomes as a basis for including or excluding studies.

Primary outcomes

1. Proportion of patients with resolution of ear discharge at various time points (up to two weeks, two to four weeks and four to 12 weeks)
2. Adverse events likely to be related to the use of study medications (mainly ototoxicity, gastrointestinal symptoms and allergic reactions)
3. Serious complications related to middle ear infection including mastoiditis and intracranial complications

Secondary outcomes

1. Proportion of patients without ear pain and/or fever at two time points (one to seven days and seven to 14 days)
2. Proportion of patients with tube extrusion
3. Proportion of patients with tube blockage
4. Health-related quality of life, either measured as disease-specific quality of life using a validated instrument (e.g. Otitis Media-6 questionnaire) or generic quality of life using a validated instrument (e.g. EQ-5D; Infant Toddler Quality of Life Questionnaire; Child Heath Questionnaire). We will analyse disease-specific and generic health-related quality of life measures separately
5. Total duration of the ear discharge episode after randomisation
6. Proportion of patients with chronic ear discharge (duration longer than four weeks)
7. Number of recurrent ear discharge episodes during follow-up
8. Hearing levels as determined by audiometry

Search methods for identification of studies

The Cochrane Ear, Nose and Throat Disorders Group Trial Search Co-ordinator will conduct systematic searches for randomised controlled trials. There will be no language, publication year or publication status restrictions. We may contact original authors for clarification and further data if trial reports are unclear and we will arrange translations of papers where necessary.

Electronic searches

Published, unpublished and ongoing studies will be identified by searching the following databases from their inception:

- Cochrane Register of Studies Online (search to date);
- Ovid MEDLINE (1946 to date);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (1946 to date);
- PubMed (as a top up to searches in Ovid MEDLINE) (1946 to date);
- Ovid EMBASE (1974 to date);
- EBSCO CINAHL (1982 to date);
- LILACS (search to date);
- KoreaMed (search to date);
- IndMed (search to date);
- PakMediNet (search to date);
- Web of Knowledge, Web of Science (1945 to date);
- ISRCTN (http://www.isrctn.com/) (search to date);
- ClinicalTrials.gov (www.clinicaltrials.gov) (search via the Cochrane Register of Studies to date);
- ICTRP (search to date);
- Google Scholar (search to date);
- Google (search to date).

The subject strategies for databases will be modelled on the search strategy designed for CENTRAL (Appendix 1). Where appropriate, these will be combined with subject strategy adaptations of the highly sensitive search strategy designed by The Cochrane Collaboration 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)).

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Searching other resources

We will scan the reference lists of identified publications for additional trials and contact trial authors if necessary. In addition, the Trial Search Co-ordinator will search PubMed, TRIPdatabase, *The Cochrane Library* and Google to retrieve existing systematic reviews relevant to this systematic review, so that we can scan their reference lists for additional trials. We will search for conference abstracts using the Cochrane Ear, Nose and Throat Disorders Group Trials Register and EMBASE.

Data collection and analysis

Selection of studies

Two review authors will independently screen the titles and abstracts found by the searches and scan reference lists of relevant studies and systematic reviews to assess potential relevance for full review. The same review authors will independently review the full text of potentially relevant studies against the pre-defined inclusion and exclusion criteria. Any disagreements will be resolved by discussion with a third review author.

Data extraction and management

Two review authors will independently extract data from the included trials using a standardised data extraction form. We will extract the following information from each trial:

1. Study characteristics: setting, design, method of data-analysis.
2. Participants: study population, number of participants in each group, patient characteristics including age, gender, ethnicity, duration of ear discharge prior to enrollment, number of discharging ears at baseline and main indication for tube insertion.
3. Interventions: type of intervention and comparison used including dosage, duration and route of administration.
4. Outcomes: primary and secondary outcomes recorded, adverse events including adverse effects likely to be related to the use of study medications and serious complications of middle ear infection.

If a study provides more than one data point within the same time period (e.g. data on the proportion of patients with resolution of ear discharge at 5 and 10 days of follow-up), we will use the data point with the shortest duration of follow-up. If a study reports both parental and otoscopic observations, we will use the latter as this is the considered the most objective method of diagnosing resolution or persistence of middle ear infection (ear discharge) in children.

Any disagreements in data extraction will be resolved by discussion with a third review author.

Assessment of risk of bias in included studies

Two review authors will independently assess the methodological quality of the included trials and any disagreements will be resolved by discussion with a third review author. We will perform 'Risk of bias' assessment by using the 'Risk of bias' tool described in Chapter 8 of the*Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011). We will judge the following domains as high, low or unclear risk of bias:

- sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of participants and personnel (performance bias);
- blinding of outcome assessment (detection bias);
- incomplete outcome data (attrition bias);
- selective outcome reporting (reporting bias);
- other sources of bias.

We will present the results of the 'Risk of bias' assessment in a 'Risk of bias' graph and a 'Risk of bias' summary.

Measures of treatment effect

We will express dichotomous outcomes as risk ratios (RRs) and risk differences (RDs) with accompanying 95% confidence intervals (CIs) and we will calculate the number needed to treat to benefit (NNTB). We propose to express continuous outcome variables either as mean differences (MDs), if reported on the same scale, or as standardised mean differences (SMD), if different continuous scales were used, with accompanying 95% CIs.

Unit of analysis issues

In the case of cluster-randomised trials, we will use analysis techniques that take into account the effect of clustering, as described in Chapter 16 of the*Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011).

Dealing with missing data

One trial author will contact the corresponding trial authors of the included trials to try to obtain additional information in case of missing data. For continuous outcomes, we will calculate missing statistics, such as standard deviations (SDs), from other available statistics (e.g. P values) according the methods described in Chapter 7 of the*Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011).

Assessment of heterogeneity

We will assess the level of clinical diversity by reviewing the included trials for potential differences between trials in study populations, interventions or comparisons used and outcomes measured. We will assess statistical heterogeneity for each outcome using the Chi^2 test, with a significance level set at P value < 0.10,

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and the I^2 statistic, with I^2 values of 50% or more suggesting substantial statistical heterogeneity (Handbook 2011).

Assessment of reporting biases

We will search the internet and ClinicalTrials.gov (http://clinicaltrials.gov) for available study protocols to determine whether outcomes reported in the included trials were pre-defined and whether all outcomes listed in the study protocol were reported in the publication. If there are sufficient trials, we propose to assess reporting bias by using funnel plots.

Data synthesis

We will perform available case analyses, so using data for every participant for whom the outcome was obtained, according to the intention-to-treat (ITT) principle (i.e. analysing participants in the groups to which they were originally allocated). We will perform meta-analyses in the absence of substantial clinical diversity. We will use a fixed-effect meta-analysis where no statistical heterogeneity is present. We will use the more conservative random-effects (DerSimonian and Laird) model if statistical heterogeneity is detected but not resolved by subgroup or sensitivity analyses.
In primary analysis, we propose to pool data for the interventions that are listed as a separate category under the Types of interventions heading. As such, we will primarily combine data for topical antibiotics only and topical antibiotics plus corticosteroids (#4) if sufficient data are available. We will analyse separately data from trials reporting on combined interventions (e.g. oral antibiotics plus topical antibiotics versus topical antibiotics only).

Subgroup analysis and investigation of heterogeneity

We propose to perform subgroup analysis for the following categories:

- age (children versus adults);
- duration of ear discharge prior to randomisation (four weeks or less versus more than four weeks);
- number of discharging ears at baseline (unilateral versus bilateral discharge);
- main indication for tube insertion (recurrent acute otitis media versus persistent otitis media with effusion);
- type of topical treatment used (topical antibiotics only versus topical antibiotics plus corticosteroids).

Sensitivity analysis

We propose to perform a sensitivity analysis in which only trials judged as low risk of bias (based on a low risk in the key domains affecting bias including allocation concealment and incomplete outcome data) are included.

GRADE approach and 'Summary of findings'

We will use the GRADE approach to rate the overall quality of evidence for each outcome. We will rate the quality of evidence as high, moderate, low or very low. We will rate evidence from RCTs that do not have serious limitations as high quality. However, we may downgrade the quality of evidence to moderate, low or very low based on the following factors:

- study limitations (risk of bias);
- indirectness of evidence (directness of evidence);
- imprecision (precision of results);
- inconsistency (consistency of results);
- publication bias (existence of publication bias).

We will include a 'Summary of findings' table for the main comparison of interest (oral antibiotics versus topical antibiotics with or without topical corticosteroids), which we will construct according to the recommendations described in Chapter 10 of the*Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011).

ACKNOWLEDGEMENTS

Louise Vaile, Tim Williamson and Gordon J Taylor were co-authors of the original review.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Middle Ear Ventilation] explode all trees
#2 grommet* or tubulation
#3 middle next ear near ventilat*
#4 (ventilat* near tube*) and ((otitis near media) or OME or ear)
#5 (tympanostomy or middle next ear or tympanic) near tube*
#6 ear* near insert* near tube*
#7 #1 or #2 or #3 or #4 or #5 or #6
#8 MeSH descriptor: [Cerebrospinal Fluid Otorrhea] explode all trees
#9 liquorrh* or liquorh* or otoliquorrh* or otoliquorh*
#10 suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or Mucopurulen* or wet or moist or weep*
#11 infect* or obstruct*
#12 (acute near otitis near media) or AOM or AOMT
#13 #8 or #9 or #10 or #11 or #12
#14 #7 and #13
#15 MeSH descriptor: [Middle Ear Ventilation] explode all trees and with qualifier(s): [Adverse effects - AE]
#16 #14 or #15

CONTRIBUTIONS OF AUTHORS

Drafting of protocol: all authors

Screening search results: FJ, TMAvD

Extracting data: FJ, TMAvD

Assessing risk of bias: FJ, TMAvD

Entering data into RevMan: FJ, TMAvD

Carrying out analysis: FJ, TMAvD

Interpreting the analysis: all authors

General advice on the review: all authors

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DECLARATIONS OF INTEREST

FJ, AW declare no conflicts of interests in the current work.

AGMS is joint Co-ordinating Editor of the Cochrane Ear, Nose and Throat Disorders Group.

RPV is an Editor of the Acute Respiratory Infections Group.

TMAvD, RPV and AGMS are authors of a trial that may be included (van Dongen 2014). To avoid any potential conflicts of interest, the two other review authors will review eligibility and perform data extraction and 'Risk of bias' assessment for this study.

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Internal sources

- No sources of support supplied

External sources

- National Institute for Health Research (NIHR), UK.

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NOTES

This review has been split from 'Interventions for ear discharge associated with grommets (ventilation tubes)' (Vaile 2006), which is now out of date. Vaile 2006 will be withdrawn on completion of the current review.

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