Grommets (ventilation tubes) for recurrent acute otitis media in children (Review)

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[Intervention Review]

Grommets (ventilation tubes) for recurrent acute otitis media in children

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ABSTRACT

Background

This is an update of a Cochrane Review first published in *The Cochrane Library* in Issue 4, 2008.

Acute suppurative otitis media is one of the most common infectious diseases in childhood. Recurrent acute otitis media is defined for the purposes of this review as either three or more acute infections of the middle ear cleft in a six-month period, or at least four episodes in a year. Strategies for managing the condition include the assessment and modification of risk factors where possible, repeated courses of antibiotics for each new infection, antibiotic prophylaxis and the insertion of ventilation tubes (grommets).

Objectives

To establish whether grommet insertion reduces the frequency of episodes of recurrent acute otitis media and the proportion of children with symptoms of ear disease.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the most recent search was 11 January 2011.

Selection criteria

Randomised controlled trials comparing grommet insertion versus control (antibiotics/other treatments/no treatment) for recurrent acute otitis media in children aged from 0 to 16 years.

Data collection and analysis

Two authors independently selected studies; three authors independently assessed study quality and extracted data. We synthesised data descriptively.

Main results

Two studies involving 148 children were included in the review. One of these studies, involving 95 children, showed that grommet insertion leads to a mean reduction of 1.5 episodes of acute otitis media in the first six months after treatment. This study also showed a significant increase in the proportion of children with no episodes of acute otitis media ($P < 0.001$) in the grommet group. The other included study also found a higher proportion of patients in the grommet group had no episodes of acute otitis media in the six months after intervention, but the difference did not reach statistical significance ($P = 0.16$).

Authors' conclusions

Grommets have a significant role in maintaining a 'disease-free' state in the first six months after insertion. Further research is required to investigate the effect beyond six months. Clinicians should consider the possible adverse effects of grommet insertion before surgery is undertaken.

PLAIN LANGUAGE SUMMARY

Grommets (ventilation tubes) for recurrent acute otitis media in children

Acute otitis media is a common disease of childhood, involving inflammation of the space behind the eardrum (the middle ear cleft). Episodes typically involve a fever and a build up of pus that stretches the eardrum causing severe pain. The drum may then rupture, relieving the pain, and a discharge of pus enters the ear canal. A small proportion of children suffer with recurrent acute otitis media, which is defined as either three or more acute infections of the middle ear cleft in a six-month period, or at least four episodes in a year.

One of the strategies used to treat this condition is the insertion of a miniature plastic ventilation tube (or grommet) into the eardrum, which prevents the painful accumulation of pus in the middle ear. This review aims to assess the evidence for the effectiveness of this treatment in reducing recurrent acute otitis media.

We searched for scientific studies which compared treating children with recurrent acute otitis media with either grommets or a non-surgical treatment such as antibiotics (or no treatment). In these studies, children with grommets in place were considered to have suffered an episode of acute otitis media if they had a discharge of pus from the ear.

Two suitable studies were found to be suitable for further analysis. The combined results from these two studies suggested that more children treated with grommets are rendered symptom-free in the six months following surgery compared to those who receive other treatments or no treatment. One of the two included studies, involving 95 children, showed that grommets reduce the number of episodes of acute otitis media in the first six months after surgery, by an average of 1.5 episodes per child.

When considering the size of this effect, it is important to bear in mind that the studies were not perfect in their design and execution. To be confident in these findings further high-quality research is required.

BACKGROUND

This is an update of a Cochrane Review first published in *The Cochrane Library* in Issue 4, 2008.

Definition and prevalence

Acute suppurative otitis media is one of the most common infectious diseases in childhood. In the United Kingdom around 30% of children aged under three years visit their general practitioner with acute otitis media each year; 97% will receive antimicrobial treatment (O'Neill 2006). About one in 10 children will have an episode of acute otitis media by three months of age (Froom 1997). It is the most common reason for outpatient antimicrobial treatment in the United States (Teele 1989).

Acute otitis media is an inflammatory process affecting the mucosa of the middle ear cleft, characterised by earache and fever. It can be caused by a number of viral and bacterial pathogens. The commonest viral pathogens are respiratory syncytial virus, adenovirus and influenza A. The commonest pathogenic bacteria are *Strep-*

tococcus pneumoniae, *Haemophilus influenza* type B and *Moraxella catarrhalis* (Bluestone 1988). If the inflammatory process is severe then the build-up of pus within the middle ear cleft leads to rupture of the tympanic membrane and discharge of pus (otorrhoea). Examination reveals a fractious child with a red, opaque and bulging eardrum. If the drum has ruptured then infected discharge is visible in the ear canal. The most reliable diagnostic criteria are ear pain (Goycoolea 1991), bulging of the tympanic membrane (Karma 1989) and recent discharge of pus (Leach 2006).

There is no World Health Organization definition of recurrent acute otitis media. We have adopted Goycoolea's definition which aims to separate patients with recurrent acute otitis media from those with otitis media with effusion, a related but different disease entity. Recurrent acute otitis media is defined as either three or more acute infections of the middle ear cleft in a six-month period or at least four episodes in a year. Patients should be disease-free between episodes in order to make the diagnosis (Goycoolea 1991).

Aetiology

Epidemiological studies of otitis media demonstrate that the first two years of life represent the greatest period of risk for the first as well as recurrent episodes of infection (Teele 1989). The greatest age-specific incidence is during the second six months of life, which coincides with the lowest level of serum immunoglobulin (antibody) concentrations. There is evidence to suggest that immunity is important. Breast milk, rich in maternal antibodies and capable of providing passive immunity, reduces the incidence of otitis media in the second six months of life (Paradise 1984). Furthermore, children prone to otitis media have lower immunoglobulin levels than controls, possibly reflecting a generalised reduction of the antibody response in these children (Veenhoven 2004). Environmental factors including passive smoking, bottle feeding, low socio-economic group and exposure to large numbers of other children have been causally implicated (Uhari 1996). A family history of recurrent ear disease, anatomical abnormalities of the palate and early onset of acute otitis media are all factors that have been associated with enhanced susceptibility to the recurrent condition.

Management

Management includes the assessment and modification of risk factors where possible. If found, any underlying cause is treated, although in the majority of cases a specific cause is not identified. The Greater Boston Collaborative Otitis Media Program demonstrated a protective effect of breastfeeding in children of breastfeeding age (Klein 1988). The American Academy of Pediatrics has recommended immunisation with 7-valent pneumococcal conjugate vaccine (PCV7) for children with recurrent or severe acute otitis media and children who have grommets for this condition (AAP 2000). However, a recent systematic review of randomised controlled trials on pneumococcal vaccination showed only a small effect on acute otitis media prevention in infancy that did not justify a large-scale vaccination programme (Jansen 2009). This may be because the target group has reduced immunological responsiveness (Teele 1989; Veenhoven 2004). Other strategies for managing the condition include repeated courses of antibiotics for each new infection as it presents, antibiotic prophylaxis and the insertion of ventilation tubes (grommets).

One systematic review of randomised controlled trials found that long-term antibiotic prophylaxis has a modest effect in preventing recurrences of acute otitis media (Williams 1993). This review identified 33 randomised controlled trials comparing antibiotics versus placebo to prevent recurrent acute otitis media and otitis media with effusion. Nine of the trials looked at recurrent otitis media alone. It was not clear which studies referred solely to children. The questions of which antibiotic to use, for how long, and how many episodes of acute otitis media justify treatment have not yet been adequately evaluated.

Concerns regarding the use of antimicrobial chemoprophylaxis include potential adverse drug reactions, the emergence of resistant pathogens (Casselbrant 1992), poor patient compliance and cost. Adverse drug reactions occur in up to 7% of children, but are predominately mild and include diarrhoea, vomiting and skin rashes.

Rosenfeld's meta-analysis of five randomised controlled trials reports that trans-tympanic ventilation tube (grommet) insertion is effective in reducing the frequency of attacks of acute otitis media in children with recurrent disease (Rosenfeld 2000). The validity of this conclusion is impaired by the inclusion of children with otitis media with effusion. Two of the five trials included patients with persistent middle ear effusion in addition to a history of recurrent acute otitis media, and a further two used the presence of otitis media with effusion on its own as an inclusion criterion. When considering the benefits of grommet insertion, the small risk of adverse events, such as anaesthetic complications, ear discharge and eardrum perforation following grommet extrusion should not be forgotten.

The effectiveness of various treatments in controlling recurrent acute otitis media in children without an underlying cause is not well-established. This review investigates the effectiveness of grommet insertion compared to treatments used in the management of recurrent acute otitis media. We excluded trials in which a middle ear effusion is the only clinical feature of recurrent acute otitis media in patients studied.

OBJECTIVES

To establish whether grommet insertion reduces the frequency of episodes of recurrent acute otitis media and the proportion of

children with symptoms of ear disease.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials.

Types of participants

Children aged from birth to 16 years with recurrent acute otitis media meeting the definition of the disease specified by Goycoolea 1991: either three or more acute infections of the middle ear cleft in a six-month period or at least four episodes in a year. Patients should be disease-free between episodes.

Types of interventions

Grommet insertion versus control (antibiotics/other treatments/ no treatment) for the treatment of recurrent acute otitis media.

Types of outcome measures

The primary outcome measures were a reduction in the frequency of episodes of acute otitis media and the proportion of children with recurrent acute otitis media following treatment.

Secondary outcome measures were:

- a change in symptom scores for otalgia and otorrhoea;
- an alteration in the frequency of otalgia and otorrhoea;
- number of days at nursery/school lost secondary to acute otitis media.

Search methods for identification of studies

We conducted systematic searches for randomised controlled trials. There were no language, publication year or publication status restrictions. The date of the last search was 11 January 2011, following a previous search in 2008.

Electronic searches

We searched the following databases from their inception for published, unpublished and ongoing trials: the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 4); PubMed; EMBASE; CINAHL; LILACS; KoreaMed; IndMed; PakMediNet; CAB Abstracts; Web of Science; BIOSIS Previews; ISRCTN; ClinicalTrials.gov; ICTRP and Google.

We modelled subject strategies for databases on the search strategy designed for CENTRAL. Where appropriate, we combined subject strategies with 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 5.0.2, Box 6.4.b. (Handbook 2009)). 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, we searched PubMed, TRIPdatabase, NHS Evidence - ENT & Audiology and Google to retrieve existing systematic reviews relevant to this systematic review, so that we could scan their reference lists for additional trials. We searched for conference abstracts using the Cochrane Ear, Nose and Throat Disorders Group Trials Register.

Data collection and analysis

Study selection

No trials that included a treatment and a control group that met the inclusion criteria were excluded. We screened abstracts initially to find studies which met our inclusion criteria. We obtained full-text articles. Two authors (SM and CLH) independently applied the inclusion criteria. Any differences over which studies to include were settled by reference to a third author (DAN).

Data extraction

SM, CLH and DAN independently extracted data. We used standardised, pre-piloted data extraction forms. We extracted the following data: age, sex, symptoms, signs, medication, treatment, follow up duration and length of history prior to treatment.

Quality assessment

Studies included in the review underwent quality assessment performed independently by all authors adapting the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2006). We assessed and graded five components of quality:

- method of treatment assignment;
- allocation concealment;

- reporting of participants by allocated group;
- follow up; and
- outcome assessment.

Treatment assignment

We included studies of grades A, B and C, i.e. we excluded trials in which randomisation was not mentioned.

Allocation concealment

We included studies of grades A and B, i.e. the allocation concealment was adequate or unclear.

Blinding

We included all studies as this is a review of studies involving a surgical intervention, which invariably leaves clinically detectable postoperative signs. The outcome assessors cannot be reliably blinded to grommet insertion if any objective evaluation of patients' ears is undertaken.

Reporting of participants by allocated group

We included studies of grade A, i.e. the progress of all randomised children in each group was described.

Follow up

We included studies in which at least 70% of subjects had outcomes measured. We excluded studies in which a more significant proportion of patients were lost to follow up from the analysis but described these in the Discussion. Our initial intention was to impose a minimum follow-up interval of 12 months. In practice we accepted six months in view of the narrow age group affected by recurrent acute otitis media and the data available in the literature.

Outcome assessment

We included studies of grade A, i.e. those in which all patients had standardised assessment.

Data analysis

The authors extracted data independently and synthesised data descriptively. An initial qualitative comparison of all the individually analysed studies examined whether pooling of results (meta-analysis) was reasonable. This took into account differences in study populations, inclusion/exclusion criteria, interventions, outcome assessment and estimated effect size.

In future updates of this review, should suitable data be available, we will subject the results from studies that meet the inclusion criteria and report any of the outcomes of interest to meta-analysis. We will calculate the summary weighted risk ratio and 95% confidence interval (fixed-effect model) by the Mantel-Haenszel method which weights studies by the number of events in the control group (using the Cochrane statistical package, Review Manager (RevMan) version 5.1 (RevMan 2011)).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

We identified five randomised controlled trials, of which two (Gebhart 1981; El-Sayed 1996) fulfilled the inclusion criteria. Attempts to contact the lead authors of all five studies to clarify ambiguities in the papers were either unsuccessful, or the author contacted was unable to provide clarification.

Included studies

Both Gebhart 1981 and El-Sayed 1996 were included as they met minimum quality standards.

Methods

Both included studies were randomised controlled trials. The methods of randomisation are not explained, and we were unsuccessful in contacting the authors for further details.

Participants

Gebhart 1981 studied 108 children and El-Sayed 1996 studied 68. All were under the age of three, and had a history of at least three episodes of acute purulent otitis media in the six months prior to referral.

Interventions

The children in Gebhart 1981 received either tympanostomy tubes or no treatment. Those in El-Sayed 1996 received either tympanostomy tubes or sulfamethoxazole and trimethoprim syrup, 12 mg/kg per day, administered once daily for six months.

Outcome measures

1. Episodes of acute otitis media.
Gebhart 1981 saw recruited children at one-month intervals and additionally if the parents suspected acute otitis media. A diagnosis of acute otitis media during the study period was made on the basis of symptoms of behavioural change, fever or upper respiratory tract infection, together with signs of erythema and reduced tympanic membrane mobility in the control group, or discharge in the grommet group. El-Sayed 1996 saw patients at two-month intervals, and between times if the parents suspected acute otitis media. In the control group, a diagnosis of acute otitis media depended on acute onset earache and inflammatory otoscopic findings with or without discharge. In the grommet group, the diagnosis was contingent on ear discharge.
2. The secondary outcome measures given above were not reported in either study.

Excluded studies

We excluded trials due to problems with the interventions chosen (Casselbrant 1992; Gonzalez 1986; Le 1991) and absence of attrition rate data (Gonzalez 1986). Further details can be found in the table of Characteristics of excluded studies.

Risk of bias in included studies

The method of randomisation and allocation is not mentioned in either paper. The authors were both contacted twice in writing but did not respond. Both papers have been included as the authors have been given the benefit of the doubt according to our protocol. Progress of all randomised children is described by Gebhart 1981. El-Sayed 1996 includes a total of 53 of a potential 68 in the results. Of those initially approached, eight were not randomised due to parental preference for grommets. It is not clear whether these children have been included in the results, making Gebhart 1981 the better quality study.

Effects of interventions

The results from Gebhart 1981 and El-Sayed 1996 are shown in Table 1 and Table 2, respectively. Both Gebhart and El-Sayed presented data categorically, drawing a distinction between no episodes of acute otitis media and one or more episode. In Gebhart's paper, the difference in the number of children who had no episodes of acute otitis media in the two groups was significant at $P < 0.001$, suggesting a highly significant role for grommets in maintaining a 'disease-free' state. The difference is in the same direction in El-Sayed 1996 , but the result is not significant ($P = 0.16$ using the Chi^2 test).
From Gebhart's paper it is possible to calculate the mean number of episodes of acute otitis media per child in each group (0.67 for the grommet group, 2.2 for controls over six months). Grommet insertion leads to a mean reduction of 1.5 episodes of acute otitis media in the first six months after treatment (a reduction of approximately 70%).
The short duration of follow up covers the period when the grommets might be expected to be in situ. There is no information in these papers about the long-term sequelae of grommet insertion.

DISCUSSION

In both Gebhart 1981 and El-Sayed 1996, presence or absence of otitis media with effusion (OME) did not preclude inclusion in the study. Our protocol excluded trials requiring only OME for inclusion, but we felt that the presence of OME between attacks of acute otitis media was acceptable, as the middle ear effusion associated with acute otitis media can take up to three months to clear in practice. It is therefore likely that a proportion of children who meet the inclusion criteria for frequency of recurrent acute otitis media attacks will have a middle ear effusion during the asymptomatic interval at the point of study recruitment. These children are unlikely to differ fundamentally from those with acute otitis media who did not have OME at inclusion.

The study designs differed in that Gebhart gave no treatment to the control group, whereas El-Sayed gave prophylactic antibiotics. We felt that this prevented pooling of the results into one table. In other respects, the studies were broadly similar in design. The studies recruited children with an upper age limit of three, reviewing them at regular intervals (monthly in the case of Gebhart, every two months for El-Sayed) and at the parents' request if acute otitis media was suspected. Both studies provided a brief description of the symptoms and signs used to diagnose acute otitis media. A purulent discharge was taken to signify an episode of acute otitis media in children with grommets. In children without tubes, inflammatory findings at otoscopy were required by both authors.

The number of patients free from acute otitis media in the included studies is higher in the grommet group. El-Sayed did not report the total number of episodes occurring in both groups. The size of the effect of grommet insertion on the frequency of recurrent acute otitis media is therefore based wholly on Gebhart's work. Although Casselbrant 1992 was an excluded study (see below), this paper also found that grommet insertion reduced the rate of acute otitis media.

Randomisation is mentioned but not detailed in either Gebhart or El-Sayed. There is some inconsistency in the number of children quoted to have been enrolled in El-Sayed's study, with the implication that some non-randomised children may have been included in the analysis. While the results of El-Sayed 1996 show no statistically significant effect of grommet insertion on the number of episodes of acute otitis media, the data from Gebhart 1981 do demonstrate a statistically significant difference.

There were no adverse events associated with grommet insertion described in these studies. However, clinicians should bear in mind the possible complications and sequelae of grommet insertion, such as anaesthetic complications, otorrhoea and tympanic membrane scarring or perforation. These should be weighed up against the possible complications of acute otitis media, which include all of the above bar anaesthetic complications, plus sensorineural hearing loss, mastoiditis and meningitis.

Excluded studies

The study Le 1991 was not included for further analysis for several reasons. The inclusion criteria for entry were two or more breakthrough episodes of acute otitis media in a three-month course of prophylactic antibiotics, which departs from those adopted by other studies. In addition, Le randomised each of a patient's ears to receive or not receive a grommet, preventing comparison of his data with that of other authors. The diagnosis of an episode of acute otitis media during the study period was delegated to a community physician, and the criteria for this diagnosis were not explicitly stated.

We excluded Gonzalez 1986 because there were no data given about the attrition rate from the study, and because the protocol for patients receiving grommets was changed during the study; initially patients were given a postoperative course of ear drops, but this practice was subsequently discontinued.

The data from Casselbrant 1992 were not included in this review as patients in the antibiotic and control group who developed acute otitis media or OME during the trial underwent surgical management by middle ear drainage as part of the protocol.

AUTHORS' CONCLUSIONS

Implications for practice

This review concludes that in children of three years and under with recurrent acute otitis media, grommets reduce the number of episodes of acute otitis media in the first six months after surgery. In addition, more children treated with grommets are rendered symptom-free in the six months following surgery compared to controls.

The effect size is small in terms of total number of episodes of recurrent acute otitis media but in both studies more than 50% of children were acute otitis media free after grommet insertion, while no more than a handful were rendered acute otitis media free in the antibiotic arm. Clinicians should take into account an individual patient's circumstances, the possible adverse effects of grommet insertion and the potential complications of acute otitis media.

Implications for research

Further methodologically rigorous research is needed to confirm the effect of grommets on recurrent acute otitis media, and to investigate the effect beyond six months.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

El-Sayed 1996

Methods	Randomised controlled trial, method unclear
Participants	Age: under 3 years; mean at entry 19.7 months (chemoprophylaxis), 19.9 months (tube) Sex: tube = 55% male, chemoprophylaxis = 55% male Symptoms: acute onset of earache Signs: no tube = inflammatory otoscopic findings with or without otorrhoea; tube = discharge Medication: on diagnosis of AOM during study period, cefaclor for 10 days Follow up duration: 6 months at 2-month intervals and if AOM suspected Length Hx: not specified; treated once dx of AOM made
Interventions	Tympanostomy tubes versus sulfamethoxazole and trimethoprim
Outcomes	Primary = number of episodes of AOM All patients had standardised assessment Follow up: 53/68 (78%) reported Trial ran for 6 months only
Notes	"Presence or absence of otitis media with effusion... did not preclude participation in the study..." therefore controversial (see Gebhart sheet) Randomisation mentioned, but not detailed. Methods: "8 of 64 not randomised" (i.e. 56 randomised). Results: "of a total of 68 children entered the study, 53 completed 6 month follow-up". Hence numbers inconsistent, and results imply non-randomised children included in analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Gebhart 1981

Methods	Randomised controlled trial, method unclear
Participants	Age: under 3 years; mean at entry 18.5 months (no tube), 21.2 (tube) Sex: tube = 66% male; no tube = 61% male Symptoms: behavioural change, fever, URTI Signs: no tube = erythema of entire TM and reduced mobility, +/- sequelae; tube = discharge Medication: on diagnosis of AOM during study period, ampicillin, or if allergic to penicillin, erythromycin and sulphonamide for 10 days Follow up duration: 6 months at 1-month intervals and if AOM suspected Length Hx: not specified; treated once diagnosis of AOM made. If diagnosis in doubt,

Gebhart 1981 (*Continued*)

	patients seen daily until confirmed or refuted
Interventions	Tympanostomy tubes versus no treatment
Outcomes	Primary = number of episodes of AOM Progress of all 95 randomised children described All patients had standardised assessment; 88% have outcomes but trial ran for 6 months only, therefore should be rejected by original criteria, accepted by our later amendment
Notes	"Presence or absence of otitis media with effusion... did not preclude inclusion in the study. .." Our protocol explicitly excludes trials requiring only OME for inclusion (Background section, penultimate paragraph), but also states that "patients should be disease-free between episodes" (under Types of participants). Decision therefore depends on whether disease is defined as OME or AOM

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	B - Unclear

AOM: acute otitis media
OME: otitis media with effusion
TM: tympanic membrane
URTI: upper respiratory tract infection

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

Study	Reason for exclusion
Casselbrant 1992	ALLOCATION: Randomised controlled trial PARTICIPANTS: Goycoolea definition of recurrent acute otitis media, and no evidence of middle ear effusion at entry INTERVENTIONS (EXCLUDED): Tympanostomy tubes versus amoxicillin versus placebo tablet, but non-grommet group had myringotomy for culture swab OUTCOME MEASURES: Primary - number of episodes of acute otitis media
Gonzalez 1986	ALLOCATION: Randomised controlled trial PARTICIPANTS: Unsure. "Presence or absence of otitis media with effusion... did not preclude inclusion in the study..." Our protocol explicitly excludes

(*Continued*)

	trials requiring only OME for inclusion (Background, penultimate paragraph), but also states that "patients should be disease-free between episodes" (under Types of participants). Decision therefore depends on whether disease is defined as OME or acute otitis media INTERVENTIONS (EXCLUDED): Tympanostomy tubes versus sulfisoxazole versus placebo. However, in the tube group postoperative ear drops were given initially, but "were discontinued later in the study" OUTCOME MEASURES (EXCLUDED): Number of children recruited not included
Le 1991	ALLOCATION: Randomised controlled trial PARTICIPANTS (EXCLUDED): Included children who had suffered 2 or more break-through episodes of acute otitis media during a 3-month course of prophylactic antibiotics INTERVENTIONS (EXCLUDED): Randomises treatments to ears rather than patients, so cannot compare with other studies OUTCOME MEASURES: Primary = number of episodes of acute otitis media

OME: otitis media with effusion

DATA AND ANALYSES

Comparison 1. > 1 episode of acute otitis media

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Acute otitis media	2	148	Odds Ratio (M-H, Fixed, 95% CI)	0.18 [0.08, 0.42]

Analysis 1.1. Comparison 1 > 1 episode of acute otitis media, Outcome 1 Acute otitis media.

Review: Grommets (ventilation tubes) for recurrent acute otitis media in children

Comparison: 1 > 1 episode of acute otitis media

Outcome: 1 Acute otitis media

Study or subgroup	Treatment n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
El-Sayed 1996	11/31	12/22		30.6 %	0.46 [0.15, 1.40]
Gebhart 1981	29/54	39/41		69.4 %	0.06 [0.01, 0.27]
Total (95% CI)	**85**	**63**		**100.0 %**	**0.18 [0.08, 0.42]**
Total events: 40 (Treatment), 51 (Control)					
Heterogeneity: Chi^2 = 4.72, df = 1 (P = 0.03); I^2 =79%					
Test for overall effect: Z = 4.04 (P = 0.000054)					
Test for subgroup differences: Not applicable					

ADDITIONAL TABLES

Table 1. Tabulated results: Gebhart 1981

Gebhart 1981	Grommet	No grommet	Total
No AOM	25*	2*	27
AOM once or more	29	39	68
Total	54	41	95

Table 1. Tabulated results: Gebhart 1981 (*Continued*)

* Chi² test shows this difference is significant at P < 0.001

AOM: acute otitis media

Table 2. Tabulated results: El Sayed 1996

El Sayed 1996	Grommet	No grommet	Total
No AOM	20	10	30
AOM once or more	11	12	23
Total	31	22	53
A Chi² test shows that the above results are not statistically significant (P > 0.05)			

APPENDICES

Appendix 1. Search strategies

CENTRAL	Cochrane Ear Nose and Throat Disorders Group Trials Register (ProCite database)	PubMed	EMBASE (Ovid)
#1 RAOM OR AOM #2 OTITIS MEDIA explode all trees (MeSH) #3 OTITIS NEXT MEDIA #4 MASTOIDITIS OR TYMPANITIS #5 SEROUS NEXT OTITIS OR SECRETORY NEXT OTITIS #6 #1 OR #2 OR #3 OR #4 OR #5 #7 OTITIS explode all trees (MeSH) #8 OTITIS	(raom OR recur* OR reoccur* OR relaps* OR recrudes* OR persist*) AND (grommet* OR tub* OR ventilation)	#1 "Middle ear ventilation" [Mesh] OR (middle [tiab] AND ear [tiab] AND ventilation [tiab]) OR grommet* [tiab] OR tubulation [tiab] OR ((ventilation [tiab] OR tympanonstomy [tiab] OR "middle ear" [tiab] OR tympanic [tiab]) AND tube* [tiab]) #2 ("otitis" [Mesh] OR otitis [tiab] OR inflamm* [tiab] OR infect* [tiab]) AND ("ear, middle" [Mesh] OR (middle [tiab] AND ear [tiab])) #3 "Otitis Media" [Mesh] OR	1 raom.tw. 2 aom.tw. 3 exp otitis media/ 4 ((SEROUS or SECRETORY or Media) and otitis).tw. 5 (MASTOIDITIS or TYMPANITIS).tw. 6 2 or 3 or 4 or 5 7 exp otitis/ 8 (otitis or inflamm* or infect*).tw. 9 7 or 8 10 middle ear/ 11 (middle and ear).tw.

(*Continued*)

#9 INFLAMM* OR INFECT* #10 #7 OR #8 OR #9 #11 EAR, MIDDLE explode all trees (MeSH) #12 MIDDLE NEXT EAR* #13 #11 OR #12 #14 #10 AND #13 #15 #6 OR #14 #16 MIDDLE EAR VENTILATION single term (MeSH) #17 MIDDLE NEXT EAR NEXT VENTILATION #18 GROMMET* OR TUBULATION #19 (VENTILATION OR TYMPANOSTOMY OR MIDDLE NEXT EAR OR TYMPANIC) NEAR TUBE* #20 #16 OR #17 OR #18 OR #19 #21 #15 AND #20		OR aom [tiab] OR (otitis [tiab] AND media [tiab]) OR mastoiditis [tiab] OR tympanitis [tiab] OR ((serous [tiab] OR secretory [tiab]) AND otitis [tiab]) #4 recur* [tiab] OR reoccur* [tiab] OR relaps* [tiab] OR recrudescence* [tiab] OR persist* [tiab] #5 (#2 OR #3) AND #4 #6 raom [tiab] #7 #5 OR #6 #8 #1 AND #7	12 10 or 11 13 9 and 12 14 6 or 13 15 exp recurrent disease/ 16 (recur* or reoccur* or relaps* or recrudescence* or persist*).tw. 17 15 or 16 18 14 and 17 19 1 or 18 20 exp tympanostomy tube/ 21 (grommet or tubulation).tw. 22 (MIDDLE and EAR and VENTILATION).tw. 23 ((VENTILATION or TYMPANOSTOMY or (MIDDLE and EAR) or TYMPANIC) and TUBE*).tw. 24 20 or 21 or 22 or 23 25 19 and 24

Web of Science/BIOSIS Previews (Web of Knowledge)	**CINAHL (EBSCO)**	**CAB Abstracts (Ovid)**	**ICTRP**
#1 TS=((middle AND ear AND ventilation) OR grommet* OR tubulation OR ((ventilation OR tympanonstomy OR (middle AND ear) OR tympanic) AND tube*)) #2 TS=((otitis OR inflamm* OR infect*) AND middle AND ear) #3 TS=(aom OR (otitis AND media) OR mastoiditis OR tympanitis OR ((serous OR secretory) AND otitis)) #4 #3 OR #2 #5 #4 AND #1 #6 TS=(recur* OR reoccur* OR relaps* OR recrudescence* OR persist*) #7 #6 AND #5	S1 (MH "Otitis Media+") S2 TX (serous OR secretory OR media) AND otitis S3 TX tympanitis OR mastoiditis S4 S1 or S2 or S3 S5 (MH "Ear, Middle+") S6 TX (middle AND ear) S7 S5 or S6 S8 TX (inflamm* OR infect* OR otitis) S9 S7 and S8 S10 S4 or S9 S11 (MH "Recurrence") S12 TX recur* OR reoccur* OR relaps* OR recrudes* OR persist* S13 S11 or S12 S14 S10 and S13	1 raom.tw. 2 aom.tw. 3 ((SEROUS or SECRETORY or Media) and otitis).tw. 4 (MASTOIDITIS or TYMPANITIS).tw. 5 2 OR 3 OR 4 6 (otitis or inflamm* or infect*).tw. 7 (middle and ear).tw. 8 6 AND 7 9 5 OR 8 10 (recur* or reoccur* or relaps* or recrudescence* or persist*).tw. 11 9 AND 10 12 1 OR 11 13 (grommet or tubulation).tw.	grommet* OR ventilation AND tub* OR tubulation OR otitis AND ventilation OR middle AND ear AND ventilation

(*Continued*)

#8 TS=raom #9 #1 AND #8 #10 #7 OR #9	S15 (MH "Middle Ear Ventilation") S16 TX grommet* OR tubulat* S17 TX middle AND ear AND ventilation S18 TX (VENTILATION OR TYMPANOSTOMY OR MIDDLE ADJ EAR OR TYMPANIC) AND tube* S19 S15 or S16 or S17 or S18 S20 TX raom S21 S14 or S20 S22 S19 and S21	14 (MIDDLE and EAR and VENTILATION).tw. 15 ((VENTILATION or TYMPANOSTOMY or (MIDDLE and EAR) or TYMPANIC) and TUBE*).tw. 16 13 OR 14 OR 15 17 12 AND 16	

WHAT'S NEW

Last assessed as up-to-date: 10 January 2011.

Date	Event	Description
13 January 2011	New search has been performed	We ran new searches in January 2011, however no new studies meeting our inclusion criteria were identified

HISTORY

Protocol first published: Issue 2, 2004

Review first published: Issue 4, 2008

Date	Event	Description
24 July 2008	Amended	Converted to new review format.

DECLARATIONS OF INTEREST

The authors are all practising otolaryngologists.

SOURCES OF SUPPORT

Internal sources

- North Bristol NHS Trust and University of Bristol, UK.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Middle Ear Ventilation; Acute Disease; Otitis Media, Suppurative [*therapy]; Randomized Controlled Trials as Topic; Recurrence

MeSH check words

Child; Humans