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[Intervention Review]

**Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children**

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**ABSTRACT**

**Background**

Otitis media with effusion (OME; 'glue ear') is common in childhood and surgical treatment with grommets (ventilation tubes) is widespread but controversial.

**Objectives**

To assess the effectiveness of grommet insertion compared with myringotomy or non-surgical treatment in children with OME.

**Search methods**

We searched the Cochrane ENT Disorders Group Trials Register, other electronic databases and additional sources for published and unpublished trials (most recent search: 22 March 2010).

**Selection criteria**

Randomised controlled trials evaluating the effect of grommets. Outcomes studied included hearing level, duration of middle ear effusion, language and speech development, cognitive development, behaviour and adverse effects.

**Data collection and analysis**

Data from studies were extracted by two authors and checked by the other authors.

**Main results**

We included 10 trials (1728 participants). Some trials randomised children (grommets versus no grommets), others ears (grommet one ear only). The severity of OME in children varied between trials. Only one 'by child' study (MRC: TARGET) had particularly stringent audiometric entry criteria. No trial was identified that used long-term grommets.
Grommets were mainly beneficial in the first six months by which time natural resolution lead to improved hearing in the non-surgically treated children also. Only one high quality trial that randomised children (N = 211) reported results at three months; the mean hearing level was 12 dB better (95% CI 10 to 14 dB) in those treated with grommets as compared to the controls. Meta-analyses of three high quality trials (N = 523) showed a benefit of 4 dB (95% CI 2 to 6 dB) at six to nine months. At 12 and 18 months follow up no differences in mean hearing levels were found.

Data from three trials that randomised ears (N = 230 ears) showed similar effects to the trials that randomised children. At four to six months mean hearing level was 10 dB better in the grommet ear (95% CI 5 to 16 dB), and at 7 to 12 months and 18 to 24 months was 6 dB (95% CI 2 to 10 dB) and 5 dB (95% CI 3 to 8 dB) dB better.

No effect was found on language or speech development or for behaviour, cognitive or quality of life outcomes.

Tympanosclerosis was seen in about a third of ears that received grommets. Otorrhoea was common in infants, but in older children (three to seven years) occurred in < 2% of grommet ears over two years of follow up.

Authors’ conclusions

In children with OME the effect of grommets on hearing, as measured by standard tests, appears small and diminishes after six to nine months by which time natural resolution also leads to improved hearing in the non-surgically treated children. No effect was found on other child outcomes but data on these were sparse. No study has been performed in children with established speech, language, learning or developmental problems so no conclusions can be made regarding treatment of such children.

**PLAIN LANGUAGE SUMMARY**

**Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children**

Evidence suggests that grommets only offer a short-term hearing improvement in children with simple glue ear (otitis media with effusion or OME) who have no other serious medical problems or disabilities. No effect on speech and language development has been shown.

Glue ear is the build up of thick fluid behind the ear drum. It is a common childhood disorder, affecting one or both ears, and is the major cause of transient hearing problems in children. The insertion of grommets (ventilation or tympanostomy tubes) into the ear drum is a surgical treatment option commonly used to improve hearing in children with bilateral glue ear as unilateral glue ear results in minimal, if any, hearing disability. This review found that in children with bilateral glue ear that had not resolved after a period of 12 weeks and was associated with a documented hearing loss, the beneficial effect of grommets on hearing was present at six months but diminished thereafter. Most grommets come out over this time and by then the condition will have resolved in most children. The review did not find any evidence that grommets help speech and language development but no study has been performed in children with established speech, language, learning or developmental problems. Active observation would appear to be an appropriate management strategy for the majority of children with bilateral glue ear as middle ear fluid will resolve spontaneously in most children.

**BACKGROUND**

This is an update of a Cochrane Review first published in *The Cochrane Library* in Issue 1, 2005.

**Prevalence and symptoms**

Otitis media with effusion (OME) is the chronic accumulation of mucus within the middle ear and sometimes the mastoid air cell system. The prevalence is bimodal with the first and largest peak of 20% at two years of age and a second peak of approximately 16% at around five years of age (*Zielhuis 1990*). The first peak relates to episodes of OME that frequently follow acute otitis media and the second peak coincides with an increase in upper respiratory tract infections due to closer association with other children at school. Natural resolution of the OME is the most likely outcome, albeit there may be further episodes. In the majority of children, their
OME only causes a mild hearing impairment that is unlikely to be disabling and is of short duration. The clinical dilemma is how to identify children that are likely to have bilateral, persistent OME associated with a degree of hearing loss that is disabling and has the potential to impact on their health and development.

**Medical management**

A recent meta-analysis (Griffin 2006) and a review (Williamson 2010) have come to the conclusion that in childhood OME oral antibiotics, mucolytics and antihistamines with oral decongestants are not effective therapies. In addition, a recent trial of topical nasal steroids has shown these not to be effective (Williamson 2009). Oral steroids as a treatment for OME remain unproven and adverse effects include growth retardation (Thomas 2006). Thus currently there is no proven medical management for OME.

**Non-surgical options**

The use of bone conduction hearing aids on a head band is increasingly being advocated for children with craniofacial abnormalities associated with persistent ear disease over many years. These may be an option for the management of children with OME. Such aids have the advantage over conventional air-conduction aids in that there are no problems with ear mould fitting and there is no potential for inner ear damage due to excessive amplification if the OME resolves. Such aids appear to be acceptable to parents and children and require evaluation with an appropriate clinical trial. The only other alternative is auto-inflation with balloons using a commercial nose piece (e.g. Otovent®) (Perera 2006). The UK National Institute for Health Research Health Technology Assessment programme has invited applications for a clinical trial of these. Almost certainly a fairly high proportion of children with OME will be unable to comply with this treatment as compliance is age-related.

**Surgical options**

The Cochrane 2005 review of ‘Grommets for hearing loss associated with otitis media in children’ (Lous 2005) identified 13 randomised controlled trials and found that the benefit to hearing appeared to be small. Since then individual patient data from a UK Medical Research Council (MRC)-funded trial (MRC: TARGET 2001) of children (376 children aged 3.5 to seven years) with persistent bilateral OME and a minimum hearing impairment of 20 dB HL in both ears have been made available to us. This trial randomised children to treatment (rather than ears - see below) and included older children than the two previous studies in the 2005 review. In that review there were also three trials that randomised each ear of children in this age group to different treatments. Such 'by ear' studies, though valuable, cannot be generalised to clinical practice where you treat a child, i.e. it is conventional for both ears to receive the same treatment. Comparison of the ‘by child’ trials with the ‘by ears’ trials became an achievable and desirable objective, whilst the combination of the data from both types of trials was not considered to be meaningful.

The availability of these additional trial data allowed modification of the methods of the original 2005 Cochrane Review which included trials (or arms of trials) where children had adenoidectomy in addition to grommets. The adjuvant role of adenoidectomy is now being covered in another review (van den Aardweg 2010) and this provided us with the opportunity to concentrate on grommets as sole therapy.

The 2005 review had two primary outcomes: difference in hearing levels and presence or absence of fluid in the middle ear cavity or days with fluid. We felt that the presence of fluid should be a secondary outcome as it is the duration of the hearing impairment associated with fluid that increasingly is being recognised as the main symptom requiring management. Audiometric assessment of hearing has the advantage in a surgical trial of being relatively free from observer bias whereas the presence or otherwise of an effusion can be a biased observation. Having a primary outcome that is objective lowers the overall risk of bias and improves the quality of a surgical trial.

**OBJECTIVES**

To assess the effectiveness of grommet insertion compared with myringotomy or non-surgical treatment in children with OME.

**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

Randomised controlled trials.

**Types of participants**

Children aged 1 to 12 years with unilateral or bilateral otitis media with effusion. We included children if they had received short courses of analgesics or antibiotics for episodes of acute infection or in the pre-randomisation period. Decongestants could be used freely in any of the groups. Clinical diagnosis was by a combination of otoscopy (including pneumatic and microscopic), tympanometry and audiometry.
Types of interventions

Treatment in the form of grommet insertion in the tympanic membrane could be unilateral (randomisation by ears) with no surgery or myringotomy in the other ear as control, or bilateral (randomisation by children) with no surgery or myringotomy alone in the control group. The difference between the comparison groups was therefore only presence or absence of grommet insertion. The nongrommet treatment group could be (i) no therapy or (ii) conventional incisional myringotomy. In studies where patients in one arm of the trial received adenoidectomy, we excluded the adenoidectomy arm. The role of adenoidectomy in children with otitis media with effusion is evaluated in a separate Cochrane Review (van den Aardweg 2010).

Types of outcome measures

Primary outcomes

The primary outcome measure was difference in hearing level.

Secondary outcomes

Secondary outcome measures included the following effects (as measured by appropriate tests):
1. presence or absence of fluid in the middle ear or days with fluid;
2. language and speech development;
3. cognitive development;
4. behaviour;
5. quality of life and health utilities (general and specific, including impact on family and reported hearing difficulties);
6. repeat/revision surgery;
7. adverse effects, including tympanosclerosis, permanent perforation, otorrhoea, hearing loss, pars tensa atrophy and cholesteatoma.

Desirable time points of outcome assessment included one, three, six, nine, 12, 18 and 24 months, and five years.

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 22 March 2010, following previous searches in March 2003, August 2006 and June 2009.

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 Issue 3, 2010); PubMed; EMBASE; CINAHL; LILACS; KoreaMed; IndMed; PakMediNet; CAB Abstracts; Web of Science; BIOSIS Previews; CNKI; 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, TRIP database, 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. In previous searches, review authors’ own files were scanned for relevant studies.

Data collection and analysis

Selection of studies

Two review authors (GGB and MJB) scanned the abstracts of studies derived from the search to identify studies which loosely met the inclusion criteria. The same two authors obtained and reviewed the full texts of these articles and applied the inclusion criteria independently. Any differences in opinion about which studies to include in the review were resolved by discussion between the two authors. As the authors already knew several of the studies eligible for inclusion, we did not consider blinding practicable.

Data extraction and management

Two authors independently extracted data from the studies using standardised data forms. We extracted data to allow an intention-to-treat analysis. After all the data forms were completed, the first authors of the trials that might be included received a copy for comments if there was any doubt about the data. Where data were missing, we contacted the authors of the study requesting the missing data.
Assessment of risk of bias in included studies

GGB and MJB 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 2009):

- 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 5.0 (*RevMan* 2008), which involves describing each of these domains as reported in the trial and then assigning a judgement about the adequacy of each entry. This involved answering a pre-specified question whereby a judgement of ‘Yes’ indicates low risk of bias, ‘No’ indicates high risk of bias, and ‘Unclear’ indicates unclear or unknown risk of bias. Our assessments are presented in ‘Risk of bias’ tables (*Characteristics of included studies* (primary studies), Figure 1 (follow-up papers)) and a ‘Risk of bias’ summary and graph (Figure 2; Figure 3).

![Figure 1. 'Risk of bias' summary for follow-up papers.](image-url)
Figure 2. 'Risk of bias' graph: review authors’ judgements about each risk of bias item presented as percentages across all included studies.
Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

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Data synthesis

We carried out all the analyses on the basis of intention-to-treat. We used RevMan version 5.0 (RevMan 2008) to carry out the meta-analyses for comparable trials and outcomes. Since all outcome measures (i.e. mean hearing loss, time with effusion and language development) were continuous, we calculated mean differences (MD) or standardised mean differences (SMD) and their corresponding 95% confidence intervals (CIs).

We calculated the summary weighted risk differences and 95% CIs (random-effects model) by the Mantel-Haenszel method, which weighs studies by the number of events in the control group.

Results

Description of studies

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

Results of the search

The original searches for this review (2003) identified 581 potentially relevant abstracts. Many of the studies were excluded for methodological reasons, e.g. they were not randomised controlled trials. Studies which focused on the use of grommets in adults were also excluded. Other excluded studies considered the effectiveness of adenoidectomy rather than grommets (see 'Characteristics of excluded studies' table).

For the update of this review new searches were carried out in August 2006, June 2009 and March 2010. In total, after removal of duplicates and sifting, these searches retrieved 188 references. After scanning the titles and abstracts we discarded a further 12 references. One study is awaiting assessment as it is unclear from the published paper whether it is a randomised study and we are attempting to establish contact with the authors (Rohail 2006). We excluded three studies as they were randomised controlled trials which did not meet one or more inclusion criteria of this review (Casselbrant 2009; Koopman 2004; Shishegar 2007) (see Excluded studies below). Four new references were included - all were longer-term follow-up reports of studies already included in the previous review (Maw 1999; Paradise 2001). One study previously listed as 'ongoing' is now formally included in the review following the release of unpublished data by the principal investigator (MRC: TARGET 2001). We also searched for systematic reviews so that we could scan their references for further studies. Ten reviews were found, but no additional studies were identified.

The non-surgical treatments identified in these searches included 'watchful waiting/active monitoring' and antibiotics. We found no randomised controlled trial in which hearing aids or other non-surgical treatments in combination with grommets had been evaluated.

Included studies

The included studies used a range of designs and outcome measures (see also Characteristics of included studies table). All trials identified used short-term grommets.

Designs of the included studies:

- A. Randomised by ears to right or left (unilateral) grommet:
  - Maw 1979-86
  - Black 1990
  - Dempster 1993

- B. Randomised by children to bilateral grommets or no grommets:
  - Gates 1987
  - Rach 1991
  - Mandel 1992
  - Maw 1999
  - Rovers 2000
  - MRC: TARGET 2001
  - Paradise 2001

A: Studies randomised by ears to unilateral grommet insertion

These three studies were all randomised controlled trials conducted in secondary care in which the participating children had bilateral OME. The two ears were randomised, i.e. all children had a unilateral grommet inserted in one ear and no surgery or myringotomy in the other ear. These studies were designed to elucidate the effect of treatment with a grommet on hearing and the duration of OME. In studies where children were also randomised to have or not have adenoidectomy, the adenoidectomy children are excluded from the analysis. The outcome measure was the difference in hearing between the ears treated with a grommet and the contralateral control ears.

Black 1990 included 149 children undergoing surgery for bilateral OME on the basis of 'clinical judgement'. The duration of OME was not documented. The mean preoperative hearing level was about 28 dB HL. As well as being randomised to receive adenoidectomy or not, all children were randomised to myringotomy or no myringotomy in the ear without a grommet. The study therefore comprised four different groups: 1) adenoidectomy and myringotomy in one ear, 2) adenoidectomy and no surgery in one ear...
Studies randomised by children to bilateral or no grommets insertion

These seven studies were all randomised controlled trials conducted in secondary care in which the participating children had bilateral OME. The participating children were randomised to either bilateral grommets or ‘watchful waiting/active monitoring’ (i.e. no grommets or late grommets). In one study this was in combination with randomisation to adenoidectomy or no adenoidectomy (Gates 1987). Five later studies did not include adenoidectomy (Mandel 1992; Maw 1999; Paradise 2001; Rach 1991; Rovers 2000). A further trial (MRC TARGET 2001) had a third adenoidectomy arm and these children were excluded from the analysis. The studies used a variety of outcome measures (hearing, time with hearing loss, time with effusion, language and cognitive development, and quality of life).

The Gates 1987 study (reported further in Gates 1989 - see Gates 1987 for reference) included 491 children aged four to eight with persistent effusion for more than 60 days. At surgery between 57% and 68% had bilateral effusion, 21% to 30% had unilateral effusion and 11% to 16% had no effusion at surgery. The children were randomised to four groups: 1) myringotomy only, 2) grommets only, 3) adenoidectomy and myringotomy and 4) adenoidectomy and grommets. Children in the last two groups are not considered in this review. Preoperative mean hearing was between 26 and 31 dB HL in the four groups. The relevant reported outcomes were: time with hearing loss ≥ 20 dB HL (three frequency pure tone average) in the better and poorer ears, and time with effusion (otoscopy and tympanometry). Complications were reported. Rach 1991 randomised 52 children aged two to four (mean three years three months). The children had bilateral flat type B tympanograms at two examinations three months apart and were randomised to: 1) grommets or 2) ‘watchful waiting/active monitoring’. About two-thirds of the children had OME for more than six months at randomisation. The study examined the effect of grommets on language development (differences in comprehension and expressive language) after six months and did not report any audiometric results. Summary results from the same study are also reported in Zielhuis 1989 (see Rach 1991 for reference). At the age of seven to eight years 37 of the children were re-evaluated with tests of language, reading and spelling (Schilder 1993).

Mandel 1992 included 111 children with unilateral or bilateral OME for at least two months and excluded children with a mean hearing level of more than 24 dB HL. All children were treated with antibiotics for two weeks before inclusion. Only 59% had bilateral OME at randomisation and the mean hearing level in the worst ear was 24 dB, which means that the children were less affected than in most of the other studies. Children were randomised to three groups: 1) grommets, 2) myringotomy and 3) no surgery. Ninety-seven children (87%) were followed up for three years to evaluate treatment failure (persistent OME bilaterally for four months or unilateral for six months). Hearing level was only reported in about one-third of the children. Only results on hearing from the grommet and no surgery group are included in this review. Other outcomes were treatment failure in the first year, episodes of acute otitis media, days with OME in the first year, and episodes of otorrhoea.

Maw 1999 included 182 children with bilateral OME, disruptions to speech, language or behaviour, and bilateral hearing loss (25 dB HL or poorer at 4000 Hz only) for at least three months. The children were randomised to: 1) immediate surgery (bilateral
ventilation tube insertion and adenoidectomy if needed) and 2) 'watchful waiting/active monitoring' for at least nine months. The mean age at randomisation was three years. Hearing data were only available for about 80% and only at 4000 Hz because of the young age of the children. Individual patient data were made available by Maw and for the meta-analysis (below) four frequency averages were used. Data on 79% of participants were available at nine months. Mean hearing levels in the ears were between 38 and 40 dB. More than 95% had type B tympanograms. During the nine months, 16 in the 'watchful waiting/active monitoring' group underwent surgery and two in the surgery group did not receive early surgery. Outcomes measured were differences between groups in verbal comprehension and expressive language after nine months. The results at 18 months follow up are excluded because a total of 59 children (76%) in the 'watchful waiting/active monitoring' group had grommets inserted. In other papers reporting aspects of the same study, one (Wilks 2000) examined the effect of early treatment with grommets on behavioural problems and a second (Hall 2009) developmental outcomes in the same cohort up to age seven years (see Maw 1999 for references). The loss to follow up rates were high.

MRC: TARGET 2001, the UK MRC-funded TARGET study ("Trial of Alternative Regimens in Glue Ear Treatment"), randomised 376 children aged 3.7 to seven years with documented persistent bilateral otitis media with effusion over a three-month period and a hearing loss of at least 20 dB HL in both ears. Allocation was into three groups: 122 to active observation, 126 to bilateral grommets and 128 to bilateral grommets with adjuvant adenoidectomy. Several outcomes were evaluated at three, six, 12, 18 and 24 months and those relevant to this review were hearing level, repeat/revision surgery and adverse effects as judged by otoscopy.

Rovers 2000 embedded a randomised controlled trial in a cohort of 30,099 children invited for routine hearing screening at the age of nine months. The 187 participating children had failed three successive hearing screening tests and were suffering from persistent (four to six months) bilateral OME (confirmed by tympanometry and otoscopy). The children were randomised to: 1) insertion of grommets or 2) 'watchful waiting/active monitoring'. Mean visual reinforced audiometry hearing level in the best ear at randomisation was 46 dB HL in the grommets group and 43 dB HL in the 'watchful waiting/active monitoring' group, and mean age at randomisation was 19 months. The outcomes measured included hearing, tests of language and quality of life at six and 12 months. Hearing and quality of life were reported in separate publications (see Rovers 2000, 2001 references: Ear and Hearing and Archives of Disease in Childhood, respectively).

Paradise 2001 randomised 429 children (aged 0 to 3 years) who had developed OME for 90 days bilaterally or 135 days unilaterally. Allocation was to one of two groups: 1) grommets inserted as soon as possible or 2) delayed surgery (up to nine months later if still needed). Eighteen per cent had bilateral middle ear effusion for 90 days; 16% unilateral for 135 days or intermittent middle ear effusion (19% bilateral; 47% unilateral) for specified proportions of longer periods (e.g. bilateral for 67% of the last 180 days; unilateral for 67% of the last 270 days). The outcomes measured were hearing, developmental testing (cognition, receptive language, expressive language) at the age of three years, reports of parental stress and child behaviour. In April 2003 the group published more details about the outcomes in relation to pre-randomisation illness patterns and hearing levels (Paradise 2003a), and in August 2003 results from the developmental assessment at the age of four years (Paradise 2003b). Further follow up was reported at five years (Johnston 2004), six years (Paradise 2005) and nine to 11 years of age (Paradise 2007) (see Paradise 2001 for all references).

Excluded studies

Details of all the excluded studies are in the Characteristics of excluded studies table. All the participants in Casselbrant 2009 received adenoidectomy and for this reason we excluded the study from the review. Koopman 2004 compared laser myringotomy with grommets; there was no 'watchful waiting/active monitoring' group. Moreover, the aim of the study was to assess the effectiveness of laser myringotomy and we felt this was not necessarily comparable with conventional myringotomy. We have excluded three studies that were included in the previous version of this review because all patients also underwent adenoidectomy (Brown 1978; Richards 1971; To 1984).

Risk of bias in included studies

The quality of randomisation in each study is set out in the Characteristics of included studies table. The first three items (adequate sequence generation, allocation concealment and blinding) apply to all subsequent papers reporting other aspects of the trial. The last three items (incomplete outcome data addressed, free of selective reporting and free of other bias) are not necessarily those of the first paper but reflect our summary assessment of the set of papers reporting the study in its entirety. Figure 1 presents the results of our assessment of the risks of bias as reported in each individual paper and these issues are dealt with individually in the discussion that follows.

In all the developmental studies the assessors were blinded to allocation group. All five developmental studies and MRC: TARGET 2001 described the problem of cross-over between groups. All the 'by child' studies reported detailed information on analysis for potential confounders, even when proper randomisation was done: namely MRC: TARGET 2001, Paradise 2001 and Rovers 2000.

A summary of our risk of bias assessments can be found in the 'Risk of bias' graph (Figure 2), 'Risk of bias' summary (Figure 3) and 'Risk of bias' summary of follow-up papers (Figure 1).
Effects of interventions

We believe that the results of any hearing improvement in the individual child are more important than improvement in hearing in individual ears. So far in this review we have reported the details of the ‘by ear’ studies first as historically these were the first that were undertaken. However, in subsequent parts of this review we will examine the effects of hearing ‘by child’ first.

Hearing levels by child

Individual patient data (IPD) meta-analysis could be performed on hearing levels using data from three of the seven trials that randomised by child (Maw 1999; MRC: TARGET 2001; Rovers 2000) because in each case individual patient data were made available to us by the trialists. The other four studies (Gates 1987; Mandel 1992; Paradise 2001; Rach 1991) did not provide mean hearing levels in their papers so are not included in the meta-analysis.

The results of meta-analyses at six to nine months (Analysis 1.1) and 12 months (Analysis 1.2) follow up show that grommets were mainly beneficial in the first six months. At six to nine months follow up the mean hearing level in the children treated with grommets (n = 271) was 4.2 dB better (95% CI 2.4 to 6.0 dB) than the mean hearing levels of those in the ‘watchful waiting/active monitoring’ group (n = 252) (Figure 4). At 12 months follow up no differences in mean hearing levels were found primarily due to natural resolution (Figure 5).

Figure 4. Forest plot of comparison: 1 Hearing levels by child, outcome: 1.1 By child hearing levels at 6 to 9 months follow up.

Figure 5. Forest plot of comparison: 1 Hearing levels by child, outcome: 1.2 By child hearing levels at 12 months follow up.

We did not combine the 18-month follow-up data since most children in the ‘watchful waiting/active monitoring’ group in the Maw 1999 study received grommets between nine and 18 months, and mean hearing at 18 months was only measured in 45% of the randomised children. In MRC: TARGET 2001, though follow up was around 80% of children, about 60% that still had bilateral OME in the ‘watchful waiting/active monitoring’ group at 18 months had switched to surgery.

All three studies in this meta-analysis used ‘short-term’ grommets which progressively become extruded or non-functioning and thus give lesser potential benefit. MRC: TARGET 2001 reported 79%, 55%, 18%, 8% and 3% functioning on otoscopy and tympanometry at 3, 6, 12, 18 and 24 months (MRC: TARGET 2001, 2003).
However, the proportion of children eligible for revision surgery because of a persistent bilateral hearing average of at least 25 dB HL was 4%, 8%, 16%, 18% and 15% respectively. MRC: TARGET 2001 gave earlier data at three months where the mean hearing levels in the children treated with grommets (n = 109) and the watchful waiting group (n = 106) were 14.4 and 26.3 dB HL; that is a difference of 11.9 dB (95% CI 9.6 to 14.2 dB). At baseline, the mean hearing level in both groups was 33 dB HL. The corresponding levels at six months were 17.5 dB HL in the children with grommets (n = 106) versus 23.1 dB HL in the watchful waiting children (n = 105). At 12 months the hearing levels were 21.0 dB HL in the grommet children (n = 110) versus 20.5 dB HL in the watchful waiting children (n = 100).

**Hearing levels by ears**

Data on mean hearing levels from all studies that randomised by ears, i.e. one ear was treated with a grommet and the other with 'watchful waiting/active monitoring', could be combined in a meta-analysis (Black 1990; Dempster 1993; Maw 1979-86). The results of these meta-analyses (Analysis 2.1; Analysis 2.2) showed similar effects to the trials that randomised children in the first 12 months but benefit was maintained in the second year in the one trial that reported at that time. At four to six months follow up the mean hearing level in the treated ears (n = 115) was 10.1 dB (95% CI 1.1 to 19.1 dB) better than in the contra-lateral control ears (n = 115) (Figure 6). At seven to 12 months follow up the mean hearing level in the treated ears (n = 117) was 5.2 dB (95% CI 0.1 to 10.4 dB) better than in the contra-lateral control ears (n = 117) (Figure 7). Only one 'by ear' trial (Black 1990) followed children up for 24 months and found the mean hearing level in the grommet ears (n = 36) was 2.1 dB (95% CI -2.6 to 6.8 dB) better than the contra-lateral ears (n = 36).

**Figure 6. Forest plot of comparison: 2 Hearing levels by ears, outcome: 2.1 By ear hearing levels at 4 to 6 months follow up.**

**Figure 7. Forest plot of comparison: 2 Hearing levels by ears, outcome: 2.2 By ear hearing levels at 7 to 12 months follow up.**

**Time with effusion**

We were able to combine the data on time with effusion from three trials for both the first year (Mand 1992; Paradise 2001; Rovers 2000) and the first two years (Gates 1987; Mand 1992; Paradise 2001). The results of these meta-analyses (Analysis 3.1; Analysis 3.2)
showed a small but significant beneficial effect in those treated with grommets. In the first and first two years after randomisation the children treated with grommets spent 32% (95% CI 17% to 48%) and 13% (95% CI 8% to 17%) less time with effusion as compared to those in the ‘watchful waiting/active monitoring’ group, respectively.

Impact on child health and development
The global impact of OME on the child’s life, and on several key aspects of their development, is regarded as clinically highly important and has been investigated in randomised studies that use a variety of different outcomes (for example, proxy parental reported measures, age-specific child tests (e.g. of comprehension), or auditory performance tests (e.g. speech in noise)). Domains considered most relevant include speech and language, cognition and mental development, behaviour, impact on the family, physical health, reported hearing difficulty, and their overall effect on quality of life and functioning.

Four randomised studies that have been followed up as cohorts evaluated both specific and general developmental outcomes. The trials identified were clinically heterogeneous, with a large number of outcomes for which there are concerns. Age-related test reliability and validity also restricted the meta-analyses available, which were only possible for some of the speech and language tests. Time to follow up ranged widely from immediately post-surgery to eight years after in some children (who had received grommets when aged three years) (Paradise 2001, 2007 reference).

Language and speech development
We were able to combine the data on language development from three trials that used the same outcome measurement in a meta-analysis (Maw 1999; Rach 1991; Rovers 2000).

The results of these meta-analyses (Analysis 4.1; Analysis 4.2; Figure 8; Figure 9) did not show a beneficial effect of grommets regarding comprehensive and expressive language development as compared to ‘watchful waiting/active monitoring’. Another trial that used different outcome measures (Paradise 2001) did not find a beneficial effect of early insertion of grommets as compared to ‘watchful waiting/active monitoring’ at the ages of three, four and nine to 11 years.

Figure 8. Forest plot of comparison: 4 Language development, outcome: 4.1 Comprehensive language development (measured with the Reynell test) at 6 to 9 months follow up.

Figure 9. Forest plot of comparison: 4 Language development, outcome: 4.2 Expressive language development (measured with Reynell, Schlichting) at 6 to 9 months follow up.
### Cognitive development
Two randomised trials, those of Maw 1999 and Paradise 2001 (2007 reference), did not find significant differences between groups on the Griffiths mental scale and McCarthy cognitive index (both general scales).

### Behaviour
Maw 1999 did not find any differences in the Richman score between early and delayed surgery groups at 18 months (Maw 1999, 2000 reference). This measure is a general behavioural measure based on 12 items predictive of behavioural problems. Although emotional problems were noted more often by teachers in children in the delayed group in a later analysis of the same cohort (Maw 1999, 2009 reference), this is not a reliable finding because of methodological weaknesses. Specifically, the loss to follow up at age seven years (approximately four years post-baseline) was high, as were the number of measures used, and the study was also underpowered. In the Paradise cohort at 2001 and 2007 a child behaviour checklist was used and was not significantly different between groups at either time point (Paradise 2001, 2001 and 2007 references).

### Quality of life and health utilities
Rovers 2000 did not find a significant quality of life improvement using the TAIQOL scale at either six or 12 months post-randomisation between groups (Rovers 2000, 2001 reference (Archives of Disease in Childhood)). The OM8-30 is an otitis media-specific health measure developed from TARGET children but has yet to be fully reported as an outcome from the TARGET study.

### Repeat/revision surgery
Three 'by child' studies reported revision surgery rates. Gates 1987 reported that 28% of children allocated to grommets alone had surgical retreatment in the two-year follow-up period and Maw 1999 reported 25% repeat/revision surgery in the 18-month follow-up period. The revision surgery figure in MRC: TARGET 2001 was 35% over a two-year period. Of these, 77% had bilateral hearing thresholds > 20 dB HL and the other 33% other indications. This overall percentage of 35% that had repeat/revision surgery is little different from the 33% that became eligible because their thresholds were > 20 dB HL following their bilateral ventilation tube becoming non-functioning. However, around a third of such eligible children did not have revision surgery.

### Adverse effects of grommets

#### Tympanosclerosis
One 'by ear' and one 'by child' study reported the otoscopic presence of tympanosclerosis. Dempster 1993 found this present at one year in 38% of ears that had had grommets versus 1% of ears that had no grommets. MRC: TARGET 2001 at 24 months reported an incidence of 27% of tympanosclerosis in grommet ears versus 0% in those that had not had one.

#### Perforation and otorrhoea
The majority of ears heal spontaneously following grommet extrusion but in some, particularly if the ear is prone to episodes of acute otitis media, a perforation persists. The only data in included trials are from MRC: TARGET 2001 where at 24 months two of 634 (< 1%) had a persistent perforation. Otorrhoea only occurred in fewer than 15 of the 634 (2%) ears at any time in the 24-month follow-up period in ears that had grommets. This is in contrast to the Rovers 2000 study in which the participants were much younger infants. In that study the incidence of otorrhoea peaked at six months in 49% (95% CI 39% to 60%) of grommet ears compared with 10% (95% CI 4% to 16%) of non-grommet ears (Rovers 2000, 2005 reference). In the Gates study of children aged four to eight years, where there was a high incidence of acute otitis media in the non-grommet ear of 11%, the grommet ear had an incidence of around 27% (Gates 1987, 1989 reference).

#### Long-term hearing loss
The early treatment group in Paradise 2001 had an increased risk difference of 28% (95% CI 20% to 36%) more tympanic membrane abnormalities than the late treatment group. They reported in the later follow-up paper that ears with tympanic membrane abnormalities had between -0.3 and 3.0 dB lower hearing levels compared with tympanic membranes without abnormalities (Paradise 2001, 2004 reference). Two to five years after treatment with grommets no significant hearing difference was found. In some of the studies a new grommet was inserted if fluid recurred after extrusion of the original tube. This could have biased the results. Information on other complications was inconclusive because of few studies.

## Discussion

### Summary of main results

#### Hearing
The children in our IPD meta-analysis of the trials randomising children and not ears were towards the more severe end of a spectrum of children with OME; they had persistent, bilateral
effusions with well-documented hearing levels. In these children, treatment with grommets has a small beneficial effect on both the mean hearing levels and the time with effusion. The magnitude of the hearing benefit is greatest at three months, being in the region of 12 dB, but this drops at six to nine months to only 4 dB. This later figure is within the test/retest error for audiometry in an individual child.

This hearing benefit is very similar to the benefit seen in the randomisation by ear studies. In these, at four to six months the benefit was 10 dB and at seven to 12 months 5 dB. Because of this any cross-over to surgery from 'watchful waiting/active monitoring' in the 'by child' studies has had an effect that is marginal at most. The reduction in benefit over time is understandable because of natural resolution of the OME in the non-operated children. It is a coincidence that the time that this occurs is when an increasing proportion of the grommets becoming non-functioning. What is less obvious is why, prior to six months, the hearing improvement is not greater in children whose mean hearing level is in the region of 30 dB HL. One factor of interest, previously reported from TARGET data (MRC: TARGET 2001, 2003 reference), may be deduced from observing that at three months, where only ears with functioning grommets were analysed, the residual air-conduction thresholds were 11.9 dB HL (95% CI 11.2 to 12.4 dB HL) and there was an air-bone gap of 13.5 dB (95% CI 12.5 to 14.5 dB). This persistent conductive defect, seen even when grommets are in situ and functioning, was postulated to be due to mucosal oedema around the ossicular chain that had not been resolved by ventilating the middle ear with the grommet. It is also recognised that even after resolution of otoscopic and tympanometric fluid there is still a small conductive hearing loss which persists for many years (de Beer 2004; Caye-Thomasen 2008).

Time with effusion

This outcome, in comparison to hearing levels, has several weaknesses. It is calculated from whether fluid was present or not at postoperative time intervals that vary by study. As otoscopy is part of the assessment of whether fluid is present, blindness as to the presence of a grommet or its sequelae is not possible.

Impact on child health and development

No effects were found regarding the impact of grommets on the potential sequelae which have been studied and reported in this review. These include speech and language development at periods up to 11 years, cognitive development and behaviour. The lack of quality of life improvement in the Rovers study may be partly explained by the fact that most children did not have any quality of life problems at baseline. Furthermore, they used a generic quality of life measure which has not been validated for otitis media, whereas other specific otitis media quality of life measurements are now available.

This lack of effect on any of the developmental scales, however, raises a question as to whether the magnitude of improvement in hearing reported above is likely to make any material difference to these outcomes. The answer to this has not been evaluated but an effect is unlikely.

This raises the further question as to whether in the long-term there are any detrimental effects in the vast majority of children with otitis media, even at the more severe end of a spectrum of persistence and hearing loss. The hypothesis here being that the hearing-deprived period is rapidly compensated for by the flexibility of development in children. No study that randomised children to grommets versus 'watchful waiting/active monitoring' demonstrated a significant effect on any developmental outcome in either group compared with 'normal' non-otitis media with effusion controls.

Revision surgery

All the trials reported in this review used 'short-term' grommets. Papers that report revision/repeat surgery rates (Gates 1987; Maw 1999; MRC: TARGET 2001) suggest that around 30% of children that have had grommets have re-operations. Revision surgery is done for many reasons apart from persistence of a hearing impairment. Good quality data on the proportion of children that are eligible because of persistence of a hearing impairment are not available. The data from the adenoidectomy arm in these trials suggest that the repeat/revision surgery rate can be reduced to around 10% if adjuvant adenoidectomy is performed at the same time as grommet insertion.

Adverse effects of grommets

This review confirms many previous reports from other studies that grommets are associated with tympanosclerosis in around a third of ears (Kay 2001).

Children with established otitis media with effusion treated with grommets in the age group three to seven years are not likely to have otorrhoea postoperatively or develop permanent perforations. This is in contrast to younger children and different indications, such as recurrent acute otitis media, where both have a higher incidence and necessitate intervention.

Long-term hearing loss

Two studies have now followed up children with OME for more than a decade, de Beer 2004, a cohort study, found a persistent small (<2 dB HL) conductive hearing impairment in non-surgically managed OME children compared with non-OME children (<0 dB HL). Children that had had grommets had poorer hearing (5 to 10 dB HL) than those that had not had grommets. Caye-Thomasen 2008 followed up OME children where the right ear had a grommet and the left ear a myringotomy and found
that there was a persistent hearing impairment (~8 dB HL) but no difference between the right and left ears.

Overall completeness and applicability of evidence

The included studies in large part address the question we posed at the outset of the review. Some of the participants in the trials included in the earlier version of this review were characterised by potentially mild disease. That is, the entry criteria for the individual studies did not require participants to have had marked disease (as determined by hearing levels) that persisted over a long period (two evaluations, a fixed interval apart prior to study entry).

In contrast the current review does include studies enrolling children with persistent OME and a documented hearing impairment over a wide range. However, we note that the more severely affected children (MRC: TARGET 2001) do not seem to have significantly different results compared to others (Maw 1999; Rovers 2000; Analysis 1.1; Analysis 1.2; Analysis 1.3).

Subgroups that might benefit more from treatment with grommets include those with speech or language delays, behaviour and learning problems, Down's syndrome, or children with cleft palate. These could not be studied in this review as these subgroups were excluded in all included individual trials.

No evidence was available concerning some outcomes that we felt to be important and were included in our protocol.

How do the results of this review fit into the context of current practice? There is wide variation both within and between countries in the rates at which grommets are inserted. In some countries, relatively stringent criteria are recommended by national guidelines. In the UK, for example, NICE guidance (NICE 2008) suggests grommets be considered in children (without special risk factors) with a type of persistent bilateral disease and hearing loss that is slightly more severe than in children in the TARGET trial. Our review suggests that even in such children, the measured hearing improvement is very modest. The NICE guidelines provide a caveat that the audiological criteria may be less where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. The studies examined in this review did not necessarily include children with marked developmental, social or educational problems so the results of the review cannot be applied to these children, nor indeed to those specifically excluded from the individual studies - children with Down's syndrome or cleft lip and palate, for example.

Quality of the evidence

The three 'by child' studies providing the primary hearing outcomes in this review had no bias likely to impact upon the hearing outcomes for the meta-analysis. The three 'by ear' studies reporting hearing levels were also of high quality in this respect, with non-consequential risks of bias.

The three 'by child' studies reporting language and speech development were all of high quality and assessed as at minimal risk of bias.

Potential biases in the review process

To capture all trials relevant to this review, both published and unpublished, we used an extensive search strategy which included more than 14 databases and was subject to no language or publication restrictions. It is possible that studies may have been missed, but unlikely.

Study selection and quality assessment were both undertaken by two authors independently and we have used the Cochrane Collaboration 'Risk of bias' method to ensure transparent assessment and reporting of study quality.

We have been successful in our attempt to obtain and include unpublished data. This review now includes considerable data from the MRC: TARGET 2001 trial which had not previously been in the public domain.

Agreements and disagreements with other studies or reviews

Several other Cochrane Reviews on treatments for otitis media have been published. A review on the effect of adenoidectomy (van den Aardweg 2010) showed that adenoidectomy in combination with a unilateral grommet has a small beneficial effect on the resolution of OME and hearing compared to a unilateral grommet only. The results of studies of adenoidectomy with or without myringotomy versus non-surgical treatment or myringotomy only, and those of adenoidectomy in combination with bilateral grommets versus bilateral grommets only, also showed a small beneficial effect of adenoidectomy on the resolution of the effusion. However, since the benefit of all surgery to hearing is small, the authors conclude that the risks of operating should be weighed against the potential benefits, which is in agreement with our findings and conclusion.

Our results are also in agreement with the results of a meta-analysis of individual patient data (Rovers 2005), which was performed to identify subgroups of children with OME that might benefit more than others from treatment with grommets. Significant interactions (beneficial effects) were found in young children that grow up in an environment with a high infection load (e.g. children attending day-care) and in older children with a hearing level of 25 dB or greater in both ears for at least 12 weeks. No final conclusion could be drawn on other subgroups that might benefit more, such as children with speech and language delays, behaviour and learning problems, Down's syndrome and children with cleft palate, since these children were not included in the individual studies.
AUTHORS’ CONCLUSIONS

Implications for practice

This 2010 update of the review has clarified several issues regarding grommets that were raised in the 2005 review. Adenoidectomy in conjunction with grommets is considered in another Cochrane Review (van den Aardweg 2010).

All included trials used short-term grommets in children with documented bilateral OME persistent over at least 12 weeks, with age-related thresholds at the more severe end of the spectrum. Older children aged three to seven years with hearing levels of at least 40 dB HL in both ears remain unreported.

It would be helpful if children more likely to benefit from grommets could be identified. The Rovers 2005 individual patient meta-analysis of ‘by ear’ studies, mentioned above, concluded that grommets might be used in older children with a hearing level of 25 dB HL or greater in both ears persisting for at least 12 weeks. This review has replicated that finding.

We also replicated the Rovers 2005 finding that the same audiometric criteria cannot be confirmed as a ‘cut-off’ point to predict benefit based on the ‘by child’ studies we report here. We have calculated that grommets give a 2 to 6 dB benefit to children at six to nine months. At this time a high proportion of the short-term grommets are non-functioning but the OME has sufficiently resolved not to merit repeat/revision surgery.

The question here is whether this magnitude of hearing improvement merits a surgical operation. This is a matter of judgement as to what benefit would accrue to an individual child from a mean improvement of 10 to 14 dB at three months and 2 to 6 dB at six to nine months, given the ‘starting point’ (specific hearing levels) in that child. In making the judgement it has to be remembered that the degree of hearing impairment is associated with greater likelihood of persistence. Data from the TARGET trial show that children with the poorest hearing levels at the outset had the greatest chance of persistence of middle ear fluid and hearing loss (MRC: TARGET 2001, Browning 2001b reference).

The relatively short-term benefit to hearing of short-term grommets might suggest that longer-term grommets would be more appropriate. This is not the case as the main reason for the small benefit at six to nine months is primarily because of resolution of the OME in the non-surgical children. Correspondingly, short-term grommets are appropriate for the majority of children to give hearing benefit for six months, the time by which the majority of children will have resolved spontaneously.

Implications for research

Despite the efforts of many researchers and patients over more than 25 years there is still uncertainty around the best management strategy for children with OME. Current work to increase our understanding of the basic science underlying this process (including genetics, aetiology, microbiology and immunology) is to be welcomed, as are endeavours to develop novel therapeutic strategies using new technologies.

Clinical research has thus far focused primarily on the commonest interventions (medical treatments and surgery in the form of grommets, with or without adenoidectomy) and on standard patients with mild or moderate disease. This leaves a number of important questions.

The studies included in this review exclude children with other disorders - cleft lip and palate or Down's syndrome, for example - or children with more severe and persistent hearing loss (40 dB HL+). To undertake randomised controlled trials in these groups may be difficult because of a perceived absence of equipoise and the obvious difficulties and expense of such a study design.

Future studies may consider the appropriateness of measuring hearing using pure tone thresholds in quiet. A 'speech in noise' test might be a more appropriate method of assessing eligibility and outcomes as it may more accurately reflect the child’s disability. Whilst this is an objective measure that merits serious consideration we are uncertain whether or not the modest benefit on pure tone thresholds found in this review would be associated with significant improvements in the results of speech in noise tests.

Future research might also look at the optimal period of ‘watchful waiting/active monitoring’. What would be the effect of extending the currently accepted period from three to six months before considering surgery? This policy is as justified as the current three months of ‘watchful waiting/active monitoring’ during which time around 50% of children with bilateral OME and a hearing impairment will resolve. If a second three-month active observation period were to be recommended during this time a further - 50% would resolve spontaneously (MRC: TARGET 2001, Browning 2001b reference). To make such a policy acceptable to parents the waiting period has to be an active period and research could usefully evaluate the best ‘active monitoring’ strategy.

Are there any alternatives to grommets other than ‘watchful waiting/active monitoring’ that have not been evaluated? There are two that need serious consideration. In the UK hearing aids are sometimes used for children with persistent conductive hearing losses due to OME. They appear to be accepted by the children that use them with a remarkable degree of equanimity, are free of the risks associated with surgery and have the potential for raising hearing levels more than grommets because the residual air-bone gap associated with grommets can be closed. Risks include over-amplification after resolution of OME and battery ingestion. Their provision and maintenance by paediatric hearing healthcare professionals ensures that the children also receive a high degree of active monitoring. Any trial evaluating their use would need to understand and be aware of this when selecting the appropriate control group. The other management strategy that requires eval-
auto-inflation with mechanical devices such as the Otovent®. Previous trials have been equivocal and were not reported on an intention-to-treat basis. Children that could not auto-inflate were excluded from the analysis (Perera 2006).

ACKNOWLEDGEMENTS

This is an update of a review original conceived and authored by one of us - Professor Jørgen Lous - and co-authored by five others. We acknowledge the debt we owe to two authors who did not participate in the update (Jens Felding and Therese Ovesen), as well as the significant role Jørgen Lous played in the original review. We thank the Foundation for Research in General Practice and the Danish health system for financial support and are also grateful for support from the Institute and Research Unit of General Practice, Århus University, The Research Fund of Århus University, the Institute of Public Health and the University of Southern Denmark, all for the original review.

We acknowledge important discussions in Melbourne with Melissa Wake during the early stages of this review.

We are grateful to the lead investigators of the following trials for making data available for the meta-analysis performed for this review: Black 1990; Dempster 1993; Maw 1979-86; Maw 1999; MRC: TARGET 2001; Paradise 2001; Rach 1991; Rovers 2000.

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Dempster 1993 (published data only)

Gates 1987 (published data only)

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Maw 1979-86 (published data only)
Maw AR. Personal correspondence (e-mail) regarding study design July 2010.

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Professor Mark Haggard. Personal communication October 2009 to August 2010.
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**Paradise 2001** (published data only)


**Rach 1991** (published data only)


**Rovers 2000** (published data only)


**References to studies excluded from this review**

**Ah-Tye 2001** (published data only)


**Bonding 1985** (published data only)

Brown 1978  [published data only]

Bulman 1984  [published data only]

Casselbrant 2009  [published data only]

Johnson 2000  [published data only]

Koopman 2004  [published data only]

Le 1991  [published data only]

Lildholdt 1983  [published data only]

Mandel 1989  [published data only]

Paradise 1997  [published data only]

Richards 1971  [published data only]

Roydhouse 1980  [published data only]

Schilder 1993  [published data only]

Shishegar 2007  [published data only]

To 1984  [published data only]

**References to studies awaiting assessment**

Rohail 2006  [published data only]

**Additional references**

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de Beer 2004

Griffin 2006

Handbook 2009

Kay 2001

NICE 2008
National Collaborating Centre for Women's and Children's Health (Commissioned by the National Institute for Health and Clinical Excellence). Surgical management

Perera 2006

RevMan 2008

Rovers 2005

Thomas 2006

van den Aardweg 2010

Williamson 2009

Williamson 2010

Zielhuis 1990

References to other published versions of this review

Lous 2005

* Indicates the major publication for the study.
## Characteristics of included studies  [ordered by study ID]

### Black 1990

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT (randomised by ears)</th>
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<tr>
<td>Participants</td>
<td>149 children undergoing surgery for bilateral OME on the basis of 'clinical judgement' Age 4 to 9 years</td>
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<tr>
<td>Interventions</td>
<td>Shepard ventilation tube in one ear versus myringotomy in the other ear; half had adenoidectomy (data from the adenoidectomy arm are not included in this review)</td>
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<td>Outcomes</td>
<td>At 7 weeks, 6, 12 and 24 months: Hearing (mean hearing loss of 3 worst-heard frequencies) Tympanometry Parents' opinion Adverse effects</td>
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<tr>
<td>Notes</td>
<td>73% middle ear effusion 24% of treated ears without OME at operation Unilateral tube study All had myringotomy in control ears</td>
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### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
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<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>Shuffled non-numbered envelopes</td>
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<td>Allocation concealment?</td>
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<td>Blinding?</td>
<td>Yes</td>
<td>Objective audiometric outcome</td>
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<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>85% seen at 12 months 61% seen at 24 months but these data are not reported in the review</td>
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<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>-</td>
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<td>Free of other bias?</td>
<td>Yes</td>
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### Dempster 1993

| Methods | RCT (randomised by ears): unilateral Shepard grommets  
<table>
<thead>
<tr>
<th></th>
<th>RCT (randomised by children): adenoidectomy versus no adenoidectomy</th>
</tr>
</thead>
</table>
| Participants | 78 children referred for hearing loss; bilateral OME for 3 months or more  
|          | Age 3 to 12 years |
| Interventions | All had tube in one ear versus no surgery  
|              | 37 had adenoidectomy, 35 had no adenoidectomy |
| Outcomes | Mean hearing loss at 6 and 12 months  
|          | Tympanometry  
|          | Adverse effects |
| Notes | 100% middle ear effusion at surgery |

#### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Serial numbered envelopes</td>
</tr>
</tbody>
</table>
| Blinding?  
| All outcomes | Yes | Objective hearing and tympanometric outcome |
| Incomplete outcome data addressed?  
| All outcomes | Yes | 92% complete data |
| Free of selective reporting? | Yes | - |
| Free of other bias? | Yes | - |

### Gates 1987

| Methods | RCT (randomised by children) Shepard grommets versus no grommets  
<table>
<thead>
<tr>
<th></th>
<th>RCT (randomised by children) adenoidectomy versus no adenoidectomy</th>
</tr>
</thead>
</table>
| Participants | 491 children referred with at least 2 months unilateral or bilateral OME  
|          | Age 4 to 8 years  
|          | All treated with an antibiotic and decongestant before inclusion |
| Interventions | 1) Myringotomy only, 2) grommets only, 3) adenoidectomy and myringotomy, and 4) adenoidectomy and grommets  
|              | 255 had adenoidectomy and 236 had no adenoidectomy  
|              | 125 and 129 had grommets; 130 and 107 had no grommets |
### Gates 1987

#### Outcomes
- Time with effusion (otoscopy and tympanometry)
- Time with hearing loss ≥ 20 dB (3 frequency pure tone average)
- Surgical retreatments

#### Notes
- 298 bilateral OME, 123 unilateral OME, and 70 had no OME
- 27 children (6%) received a treatment other than the one assigned
- Many children also had acute otitis media
- See also Gates 1989 ([Gates 1987](#)) for reference which adds no additional audiometric or other data pertinent to this review

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Table of random numbers</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Allocation in blocks of 16 by statistician</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>Main outcome was time with effusion; an otoscopic diagnosis. Secondary outcomes of hearing and surgical treatments are objective</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>No</td>
<td>A very high proportion of children (~60%) were not followed up. Only ~3% attended for more than 4 or more out of the potential 7 scheduled visits</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>No</td>
<td>A high proportion of the children had recurrent acute otitis media as evidenced by an 11% rate of otorrhoea in ears that had no grommet inserted</td>
</tr>
</tbody>
</table>

### Mandel 1992

#### Methods
- Balanced RCT (randomised by children); 3 groups

#### Participants
- 111 children referred for OME; all with unilateral or bilateral OME for 2 months or more (n = 37, 39, 35); mean hearing level in worst ear 24 dB
- Age 7 months to 12 years
- 59% had bilateral OME at randomisation
- All treated with antibiotics for 2 weeks before inclusion
- Children with a mean hearing level > 35 dB excluded
## Interventions
Bilateral Armstrong grommets versus bilateral myringotomy versus no surgery
None had adenoidectomy

## Outcomes
Hearing SRT
SAT
Treatment failure in first year
Days with OME
Episodes of AOM
Episodes of otorrhoea

## Notes
Balanced by age and duration of OME
High cross-over makes assessment difficult

## Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Unclear</td>
<td>-</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>“Randomly assigned, within strata to...”</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Unclear</td>
<td>Primary outcome was middle ear fluid defined using an algorithm of otoscopy and tympanometry</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>87% follow up at 2 years</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

## Maw 1979-86

| Methods                      | RCT (randomised by ears); unilateral Shepard tube
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RCT (randomised by children); adenotonsillectomy versus adenoidectomy versus neither</td>
</tr>
</tbody>
</table>
| Participants                 | 150 children referred with long-standing bilateral OME (mean duration 18 months) with symmetrical hearing loss in excess of 25 dB HL
|                              | Age 2 to 9 years                                  |
| Interventions                | All had unilateral Shepard tube; 47 had tonsillectomy, 47 had adenoidectomy and 56 had neither |
| Outcomes                     | Hearing (mean of frequencies tested dB and change in mean hearing threshold) Effusion resolved |
Maw 1979-86  (Continued)

| Notes | 13 patients (8%) excluded at operation because no fluid found at myringotomy or because contralateral ear suspected to be dry. See Maw 1993 and Maw 1994 (Maw 1979-86 for references) for long-term results; not all data available at all time points for each ear. |

<table>
<thead>
<tr>
<th><strong>Risk of bias</strong></th>
<th><strong>Authors' judgement</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Tables of random numbers</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Sealed envelopes opened in theatre</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Yes</td>
<td>Audiometry is the outcome reported in this review. Otoscopy for the presence of OME was not used in the analysis of time with effusion</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>75% audiometry at 12 months</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>Yes</td>
<td>-</td>
</tr>
</tbody>
</table>

**Maw 1999**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT (randomised by children)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>182 children with bilateral OME, disruption in speech, language or behaviour, and hearing loss (25 dB or poorer at 4000 Hz only) for at least 3 months, referred to hospital. Mean age 2.9 years. 83 + 73 = 156 completed the trial. Children with congenital syndromes were excluded.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Bilateral Shepard or Shah grommets versus ‘watchful waiting/active monitoring’ (9 months)</td>
</tr>
</tbody>
</table>
| Outcomes | Hearing  
Verbal comprehension  
Expressive language (Reynell Expressive Language Scales - revised)  
Retreatment surgery |
| Notes | 18 children did not receive the randomised treatment. See also Wilks 2000 and Hall 2009 (Maw 1999 for references) |

Risk of bias
### Maw 1999 (Continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Tables of random numbers</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Sealed envelopes opened by third party</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Yes</td>
<td>Language outcomes and audiometry ‘done masked of treatment’</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>88% completed the trial</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>Yes</td>
<td>The 18-month hearing data are not relevant as the design of the study was that ‘watchful waiting/active monitoring’ was only for 9 months. At 18 months 85% of these children had grommets. These data are not included in the review hence the data reported are free of bias</td>
</tr>
</tbody>
</table>

### MRC: TARGET 2001

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT (randomised by child); 3 arms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>376 children qualified on 2 occasions, 3 months apart, with better ear hearing level &gt; 20 dB HL with tympanometrically confirmed bilateral otitis media with effusion Age aged 3.5 to 7 years Children with a hearing loss of 40 dB or greater in their better hearing ear were not obliged to be randomised</td>
</tr>
<tr>
<td>Interventions</td>
<td>'Watchful waiting/active monitoring’ versus bilateral Shepard grommets versus bilateral grommets with adenoidectomy 376 children were randomised: 122 to further ‘watchful waiting/active monitoring’, 126 to bilateral grommets and 128 to bilateral grommets with adenoidectomy</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Follow up 3, 6, 12, 18 and 24 months Binaural mean hearing level Reported hearing difficulty Quality of life (parent and child) Behaviour General health OM8-30 Repeat/revision surgery Adverse otoscopic effects</td>
</tr>
</tbody>
</table>
## Notes

No peer reviewed paper reporting any of the above outcomes has been published despite the trial being completed by 2000.

Limited data have been made available for meta-analysis for this review.

Good follow up.

High proportion of cross-over to surgery from 'watchful waiting/active monitoring'; 43% in the first year and 57% by the end of the second year.

## Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated sequence</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>Eligible children allocated by telephone from administrative office</td>
</tr>
<tr>
<td>Blinding? All outcomes</td>
<td>Yes</td>
<td>Primary outcome objective pure tone thresholds</td>
</tr>
<tr>
<td>Incomplete outcome data addressed? All outcomes</td>
<td>Yes</td>
<td>80% follow up at 2 years. Imputation of missing data</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>No</td>
<td>Apart from hearing levels no 'by child' outcomes have been reported or made available</td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>No</td>
<td>The time lapse since trial completion is 10 years. The reasons for the absence of peer reviewed publications have not been explained. Cross-over from control arm is an intention-to-treat aspect and should not be considered a bias</td>
</tr>
</tbody>
</table>

## Paradise 2001

### Methods

RCT (randomised by children) after screening 6350 children for OME.

### Participants

588 children (9.2%) met the inclusion criteria; 429 randomised: 216 and 213

Age 0 to 3 years

18% had bilateral effusion for 90 days; 16% unilateral effusion for 135 days or intermittent effusion (19% bilateral; 47% unilateral) for specified longer periods.

### Interventions

Early or delayed (up to 9 months) insertion of Teflon bi-flanged grommets.

### Outcomes

Days with OME

Hearing

Developmental testing (cognition (McCarthy Scale of Children's Abilities), receptive language (Peabody Picture Vocabulary Test-Revised), expressive language (Number of Different Words, Mean Length of Utterance in Morphemes, Percentage of Consonants Correct-Revised) at 3 years.
Paradise 2001  (Continued)

<table>
<thead>
<tr>
<th>Notes</th>
<th>Reports of parental stress (Parents Stress Index) and child behaviour (Child Behaviour Checklist)</th>
</tr>
</thead>
<tbody>
<tr>
<td>402 underwent developmental testing</td>
<td>37 + 66 children did not receive the randomised treatment</td>
</tr>
<tr>
<td>63% had unilateral OME and 66% discontinuous OME</td>
<td>See also Paradise 2003 (3 papers), 2004, 2005, 2006, 2007 (Paradise 2001 for references)</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Computer-generated random numbers</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>In blocks by designated non-clinical staff</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Yes</td>
<td>Objective developmental tests</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes</td>
<td>94% follow up when 3 years of age</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>Yes</td>
<td>-</td>
</tr>
</tbody>
</table>

### Rach 1991

<table>
<thead>
<tr>
<th>Methods</th>
<th>Balanced RCT (randomised by children) after screening 1439 children for OME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>288 children (20%) met the screening criteria; 84 (5.8%) were eligible for the trial; only 52 children were randomised; 43 completed Age 2 to 4 years; mean 39 months Non-Dutch speaking children and children with multiple illnesses and cognitive defects were excluded</td>
</tr>
<tr>
<td>Interventions</td>
<td>Bilateral Donaldson grommets versus no surgery ('watchful waiting/active monitoring' for at least 9 months)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Verbal comprehension at 6 months Expressive language at 6 months (Dutch version of Reynell Developmental Language Scales - revised)</td>
</tr>
<tr>
<td>Notes</td>
<td>Balanced allocation on age, gender, treatment hospital and result of first language test Some results published in Zielhuis 1989 (see Rach 1991 for reference)</td>
</tr>
</tbody>
</table>

### Risk of bias

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<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes</td>
<td>Randomised balanced allocation procedure with a reference in a statistical journal</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>“the first 5 children were randomised; each subsequent child was allocated to the treatment group which would lead to the smallest imbalance...”</td>
</tr>
<tr>
<td>Blinding?</td>
<td>Yes</td>
<td>Objective language testing</td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Unclear</td>
<td>No child appears to have been lost to follow up</td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>Yes</td>
<td>-</td>
</tr>
</tbody>
</table>

**Rovers 2000**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Balanced RCT (randomised by children) after screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>30,099 invited for screening, 386 (1.3%) had at least 4 to 6 months with OME 187 children who had failed 3 successive hearing screening tests with persistent (4 to 6 months) bilateral OME confirmed by tympanometry and otoscopy were randomised Age 16 to 24 months (mean 19 months at randomisation)</td>
</tr>
<tr>
<td>Interventions</td>
<td>Bilateral Bevel Bobbins grommets versus ‘watchful waiting/active monitoring’</td>
</tr>
</tbody>
</table>
| Outcomes                                   | Hearing loss
Verbal comprehension (Reynell) and expressive language (Schlichting) both expressed as mean language development in months |
| Notes                                      | Balanced allocation on age, gender, season, mother’s education and hospital Follow up at 6 and 12 months At 12 months 3 children in the grommets group and 8 children in the ‘watchful waiting/active monitoring’ group were lost to follow up 10 children in the ‘watchful waiting/active monitoring’ group received grommets during the year More detailed information about the effect of grommets on hearing and quality of life is published in 2 later papers (2001) Details on otorrhoea are reported in a later paper (Ingels 2005 - see Rovers 2000 for reference) |

**Risk of bias**
### Item | Authors’ judgement | Description
--- | --- | ---
Adequate sequence generation? | Yes | Balanced allocation procedure
Allocation concealment? | Yes | Centrally located randomised list; allocation by telephone call to central location
Blinding? | Yes | Language tests and hearing are objective measures
All outcomes | | 
Incomplete outcome data addressed? | Yes | 11 (6%) of 187 were lost to follow up in the first year
All outcomes | | 
Free of selective reporting? | Yes | -
Free of other bias? | Yes | -

AOM: acute otitis media; OME: otitis media with effusion; SAT: speech awareness threshold; SRT: speech recognition threshold; RCT: randomised controlled trial

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonding 1985</td>
<td>Allocation: Non-randomised study; all right ears had grommets</td>
</tr>
<tr>
<td>Brown 1978</td>
<td>Allocation: Randomisation of ears unclear Participants: 60 children with bilateral OME Interventions: All children had adenoidectomy whereas we were interested in grommets versus 'watchful waiting/active monitoring'</td>
</tr>
<tr>
<td>Bulman 1984</td>
<td>Allocation: Randomised; not concealed Participants: Not all participants had bilateral OME. Only 6 weeks with preoperative middle ear effusion Interventions:</td>
</tr>
<tr>
<td>Allocation</td>
<td>Participants</td>
</tr>
<tr>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Randomised</td>
<td>Children 24 to 47 months of age, with a history of bilateral middle ear effusion for at least 3 months, unilateral for 6 months or longer or unilateral for 3 months after extrusion of a tympanostomy tube, unresponsive to recent antibiotic</td>
</tr>
<tr>
<td>Originally designed as a RCT, but changed to an observational cohort study because of parental resistance to randomise the children. 698 enrolled at birth, 379 assessed at the age of 3 and 198 at the age of 7 years</td>
<td></td>
</tr>
<tr>
<td>Randomised</td>
<td>208 children 24 to 47 months of age, with a history of bilateral middle ear effusion for at least 3 months, unilateral for 6 months or longer or unilateral for 3 months after extrusion of a tympanostomy tube, unresponsive to recent antibiotic</td>
</tr>
<tr>
<td>Randomised (by ears)</td>
<td>Unilateral treatment with ventilation tube in 13 children with bilateral persistent middle ear effusion and 44 children with bilateral recurrent acute otitis media. Data from the 2 groups are impossible to separate</td>
</tr>
<tr>
<td>Inadequately randomised and inadequate concealment (randomised by birthday)</td>
<td></td>
</tr>
<tr>
<td>Randomised</td>
<td>Study included middle ear effusion and recurrent acute otitis media. Data could not be separated. Five different treatment groups: 3 without hearing loss and 2 with hearing loss</td>
</tr>
<tr>
<td>Non-randomised observational study</td>
<td></td>
</tr>
</tbody>
</table>
Richards 1971  
**Allocation:**
Randomised (by ears)
**Participants:**
57 children (aged 4 to 12 years) with bilateral OME
**Interventions:**
All children had adenoidectomy whereas we were interested in grommets versus 'watchful waiting/active monitoring'

Roydhouse 1980  
**Allocation:**
Non-randomised, case-control study (concerning the grommets)

Schilder 1993  
**Allocation:**
Randomised
**Participants:**
47 children (aged 7 to 8 years) with OME
**Interventions:**
Almost all children randomised to 'watchful waiting/active monitoring' at the age of 4 years were treated with grommets before the age of 8 years

Shishegar 2007  
**Allocation:**
Randomised (by ear)
**Participants:**
30 children (aged 4 to 8 years) with OME
**Interventions:**
All children had adenoidectomy whereas we were interested in grommets versus 'watchful waiting/active monitoring'

To 1984  
**Allocation:**
Randomised (by ear)
**Participants:**
54 children (aged 47 months to 14 years) with OME
**Interventions:**
All children had adenoidectomy whereas we were interested in grommets versus 'watchful waiting/active monitoring'

OME: otitis media with effusion

**Characteristics of studies awaiting assessment**  
[ordered by study ID]
**Rohail 2006**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Described as “random allocation” but method not specified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>40 patients up to 12 years of age; inclusion criteria not specified</td>
</tr>
<tr>
<td>Interventions</td>
<td>Medical versus surgical treatment - not specified</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Resolution of OME, hearing, adverse effects</td>
</tr>
<tr>
<td>Notes</td>
<td>ENT Department, Jinnah Hospital, Lahore, Pakistan</td>
</tr>
</tbody>
</table>
### Comparison 1. Hearing levels by child

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 By child hearing levels at 6 to 9 months follow up</td>
<td>3</td>
<td>523</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-4.20 [-4.00, -2.39]</td>
</tr>
<tr>
<td>2 By child hearing levels at 12 months follow up</td>
<td>2</td>
<td>328</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-0.41 [-2.37, 1.54]</td>
</tr>
<tr>
<td>3 By child hearing levels at 18 months follow up</td>
<td>2</td>
<td>283</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-0.02 [-3.22, 3.18]</td>
</tr>
</tbody>
</table>

### Comparison 2. Hearing levels by ears

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 By ear hearing levels at 4 to 6 months follow up</td>
<td>3</td>
<td>230</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-10.08 [-19.12, -1.05]</td>
</tr>
<tr>
<td>2 By ear hearing levels at 7 to 12 months follow up</td>
<td>3</td>
<td>234</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-5.18 [-10.43, 0.07]</td>
</tr>
</tbody>
</table>

### Comparison 3. Time with effusion

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Time (proportion) with effusion in first year</td>
<td>3</td>
<td>574</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-0.32 [-0.48, -0.17]</td>
</tr>
<tr>
<td>2 Time (proportion) with effusion in first two years</td>
<td>3</td>
<td>426</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>-0.13 [-0.17, -0.08]</td>
</tr>
</tbody>
</table>
### Comparison 4. Language development

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Comprehensive language development (measured with the Reynell test) at 6 to 9 months follow up</td>
<td>3</td>
<td>394</td>
<td>Std. Mean Difference (IV, Random, 95% CI)</td>
<td>0.09 [-0.21, 0.39]</td>
</tr>
<tr>
<td>2 Expressive language development (measured with Reynell, Schlichting) at 6 to 9 months follow up</td>
<td>3</td>
<td>393</td>
<td>Mean Difference (IV, Random, 95% CI)</td>
<td>0.03 [-0.42, 0.49]</td>
</tr>
</tbody>
</table>

#### Analysis 1.1. Comparison 1 Hearing levels by child, Outcome 1 By child hearing levels at 6 to 9 months follow up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 1 Hearing levels by child

Outcome: 1 By child hearing levels at 6 to 9 months follow up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>IV(Random,95% CI)</td>
<td></td>
<td>IV(Random,95% CI)</td>
</tr>
<tr>
<td>Maw 1999</td>
<td>79 25.7 (10.9)</td>
<td>63 29.5 (12.9)</td>
<td>18.8 %</td>
<td>-3.80 [-7.79, 0.19]</td>
<td></td>
</tr>
<tr>
<td>MRC: TARGET 2001</td>
<td>106 17.5 (8.2)</td>
<td>105 23.1 (10.1)</td>
<td>43.1 %</td>
<td>-5.60 [-8.08, -3.12]</td>
<td></td>
</tr>
<tr>
<td>Rovers 2000</td>
<td>86 35.9 (8.9)</td>
<td>84 38.7 (8.9)</td>
<td>38.1 %</td>
<td>-2.80 [-5.48, -0.12]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>271</td>
<td>252</td>
<td>100.0 %</td>
<td>-4.20 [-6.00, -2.39]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.35; Chi² = 2.31, df = 2 (P = 0.32); I² = 13%
Test for overall effect: Z = 4.56 (P < 0.00001)
Test for subgroup differences: Not applicable
### Analysis 1.2. Comparison 1 Hearing levels by child, Outcome 2 By child hearing levels at 12 months follow up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 1 Hearing levels by child

Outcome: 2 By child hearing levels at 12 months follow up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>IV, Random, 95% CI</td>
<td></td>
<td>IV, Random, 95% CI</td>
</tr>
<tr>
<td>MRC: TARGET 2001</td>
<td>110 21 (9.4)</td>
<td>100 20.5 (10.1)</td>
<td>54.4% 0.50 [-2.15, 3.15]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rovers 2000</td>
<td>37 33.2 (7.2)</td>
<td>81 34.7 (7.9)</td>
<td>45.6% -1.50 [-4.39, 1.39]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>147</td>
<td>181</td>
<td>100.0% -0.41 [-2.37, 1.54]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 1.00, df = 1 (P = 0.32); I² = 0%

Test for overall effect: Z = 0.41 (P = 0.68)

Test for subgroup differences: Not applicable

### Analysis 1.3. Comparison 1 Hearing levels by child, Outcome 3 By child hearing levels at 18 months follow up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 1 Hearing levels by child

Outcome: 3 By child hearing levels at 18 months follow up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>IV, Random, 95% CI</td>
<td></td>
<td>IV, Random, 95% CI</td>
</tr>
<tr>
<td>Maw 1999</td>
<td>45 19.6 (8.7)</td>
<td>37 21.5 (8.5)</td>
<td>43.0% -1.90 [-5.64, 1.84]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRC: TARGET 2001</td>
<td>103 21.1 (10.2)</td>
<td>98 19.7 (10.4)</td>
<td>57.0% 1.40 [-1.45, 4.25]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>148</td>
<td>135</td>
<td>100.0% -0.02 [-3.22, 3.18]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 2.57; Chi² = 1.89, df = 1 (P = 0.17); I² = 47%

Test for overall effect: Z = 0.01 (P = 0.99)

Test for subgroup differences: Not applicable
Analysis 2.1. Comparison 2 Hearing levels by ears, Outcome 1 By ear hearing levels at 4 to 6 months follow-up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 2 Hearing levels by ears

Outcome: 1 By ear hearing levels at 4 to 6 months follow-up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Mean (SD)</th>
<th>Mean (SD)</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td></td>
<td>IV, Random</td>
<td>95% CI</td>
<td>IV, Random</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black 1990</td>
<td>35</td>
<td>35</td>
<td>19 (10)</td>
<td>24.8 (10)</td>
<td>-5.80</td>
<td>33.5 %</td>
<td>-10.49, -1.11</td>
</tr>
<tr>
<td>Dempster 1993</td>
<td>35</td>
<td>35</td>
<td>15.8 (10.3)</td>
<td>21.1 (11.7)</td>
<td>-5.30</td>
<td>32.8 %</td>
<td>-10.46, -0.14</td>
</tr>
<tr>
<td>Maw 1979-86</td>
<td>45</td>
<td>45</td>
<td>17.5 (9.79)</td>
<td>36.5 (11.87)</td>
<td>-19.00</td>
<td>33.7 %</td>
<td>-23.50, -14.50</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>115</td>
<td>115</td>
<td></td>
<td></td>
<td>-10.08</td>
<td>100.0 %</td>
<td>-19.12, -1.05</td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 57.7$; $\text{Chi}^2 = 21.49$, df = 2 ($P = 0.00002$); $I^2 = 91$

Test for overall effect: $Z = 2.19$ ($P = 0.029$)

Test for subgroup differences: Not applicable
### Analysis 2.2. Comparison 2 Hearing levels by ears, Outcome 2 By ear hearing levels at 7 to 12 months follow up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: Hearing levels by ears

Outcome: By ear hearing levels at 7 to 12 months follow up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
</tr>
<tr>
<td>Black 1990</td>
<td>35</td>
<td>21.6 (10)</td>
<td>35</td>
<td>26 (10)</td>
<td>33.3 %</td>
</tr>
<tr>
<td>Dempster 1993</td>
<td>35</td>
<td>17.6 (11.2)</td>
<td>35</td>
<td>18.4 (10.6)</td>
<td>31.7 %</td>
</tr>
<tr>
<td>Maw 1979-86</td>
<td>47</td>
<td>17.5 (8.61)</td>
<td>47</td>
<td>27.4 (12.13)</td>
<td>35.0 %</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>117</td>
<td>27.2 (11.8)</td>
<td>117</td>
<td>27.2 (11.8)</td>
<td><strong>100.0 %</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 15.81; Chi² = 7.57, df = 2 (P = 0.02); I² = 74%
Test for overall effect: Z = 1.93 (P = 0.053)

### Analysis 3.1. Comparison 3 Time with effusion, Outcome 1 Time (proportion) with effusion in first year.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: Time with effusion

Outcome: Time (proportion) with effusion in first year

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
</tr>
<tr>
<td>Mandel 1992</td>
<td>36</td>
<td>0.17 (0.3)</td>
<td>35</td>
<td>0.64 (0.3)</td>
<td>29.1 %</td>
</tr>
<tr>
<td>Paradise 2001</td>
<td>159</td>
<td>0.29 (0.2)</td>
<td>157</td>
<td>0.48 (0.21)</td>
<td>36.9 %</td>
</tr>
<tr>
<td>Rovers 2000</td>
<td>93</td>
<td>0.36 (0.3)</td>
<td>94</td>
<td>0.7 (0.3)</td>
<td>34.1 %</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>288</strong></td>
<td><strong>0.25 (0.2)</strong></td>
<td><strong>286</strong></td>
<td><strong>0.38 (0.2)</strong></td>
<td><strong>100.0 %</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.02; Chi² = 20.32, df = 2 (P = 0.000004); I² = 90%
Test for overall effect: Z = 4.08 (P = 0.0000045)
Test for subgroup differences: Not applicable
**Analysis 3.2. Comparison 3 Time with effusion, Outcome 2 Time (proportion) with effusion in first two years.**

**Review:** Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

**Comparison:** 3 Time with effusion

**Outcome:** 2 Time (proportion) with effusion in first two years

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment (tubes)</th>
<th>Control (no tubes)</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
<td>IV,Random,95% CI</td>
</tr>
<tr>
<td>Gates 1987</td>
<td>129</td>
<td>0.35 (0.24)</td>
<td>107</td>
<td>0.49 (0.25)</td>
<td>46.6 %</td>
</tr>
<tr>
<td>Mandel 1992</td>
<td>36</td>
<td>0.33 (0.3)</td>
<td>35</td>
<td>0.51 (0.3)</td>
<td>9.5 %</td>
</tr>
<tr>
<td>Paradise 2001</td>
<td>57</td>
<td>0.3 (0.18)</td>
<td>62</td>
<td>0.4 (0.18)</td>
<td>44.0 %</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>222</strong></td>
<td><strong>204</strong></td>
<td></td>
<td></td>
<td><strong>100.0 %</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 0.0, \ Chi^2 = 1.38, df = 2 (P = 0.50); I^2 = 0.0$

Test for overall effect: $Z = 5.76 (P < 0.00001)$
Analysis 4.1. Comparison 4 Language development, Outcome 1 Comprehensive language development (measured with the Reynell test) at 6 to 9 months follow up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: Language development

Outcome: Comprehensive language development (measured with the Reynell test) at 6 to 9 months follow up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Std. Mean Difference</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>IV,Random,95% CI</td>
<td></td>
</tr>
<tr>
<td>Maw 1999</td>
<td>87 -0.04 (1.02)</td>
<td>77 -0.35 (0.98)</td>
<td>39.6 %</td>
<td>0.31 [ 0.00, 0.62 ]</td>
</tr>
<tr>
<td>Rach 1991</td>
<td>22 0.17 (0.61)</td>
<td>21 0.11 (0.55)</td>
<td>18.3 %</td>
<td>0.10 [ -0.50, 0.70 ]</td>
</tr>
<tr>
<td>Rovers 2000</td>
<td>93 -0.06 (0.95)</td>
<td>94 0.06 (1.05)</td>
<td>42.0 %</td>
<td>-0.12 [ -0.41, 0.17 ]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>202</td>
<td>192</td>
<td>100.0 %</td>
<td>0.09 [ -0.21, 0.39 ]</td>
</tr>
</tbody>
</table>

Heterogeneity: Tau^2 = 0.03; Chi^2 = 3.96, df = 2 (P = 0.14); I^2 = 49%

Test for overall effect: Z = 0.59 (P = 0.55)
Analysis 4.2. Comparison 4 Language development, Outcome 2 Expressive language development (measured with Reynell, Schlichting) at 6 to 9 months follow up.

Review: Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children

Comparison: 4 Language development

Outcome: 2 Expressive language development (measured with Reynell, Schlichting) at 6 to 9 months follow up

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Control</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maw 1999</td>
<td></td>
<td>87</td>
<td>-0.62 (1.27)</td>
<td>76</td>
<td>-1</td>
<td>(1.25)</td>
<td></td>
<td>32.4%</td>
<td></td>
</tr>
<tr>
<td>Rach 1991</td>
<td></td>
<td>22</td>
<td>0.29 (0.75)</td>
<td>21</td>
<td>0.18</td>
<td>(0.64)</td>
<td></td>
<td>31.3%</td>
<td></td>
</tr>
<tr>
<td>Rovers 2000</td>
<td></td>
<td>93</td>
<td>-0.18 (1.19)</td>
<td>94</td>
<td>0.17</td>
<td>(0.74)</td>
<td></td>
<td>36.3%</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td></td>
<td>202</td>
<td></td>
<td>191</td>
<td></td>
<td></td>
<td>0.03 [-0.42, 0.49]</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.13; Chi² = 9.57, df = 2 (P = 0.01); I² = 79%

Test for overall effect: Z = 0.13 (P = 0.90)

Test for subgroup differences: Not applicable

APPENDICES

Appendix 1. Search strategies

<table>
<thead>
<tr>
<th>CENTRAL</th>
<th>PubMed</th>
<th>EMBASE (Ovid)</th>
<th>CINAHL (EBSCO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 MeSH descriptor Otitis Media with Effusion explode all trees</td>
<td>#1 &quot;Otitis Media with Effusion&quot;[Mesh]</td>
<td>1 exp chronic otitis media/ or exp secretory otitis media/</td>
<td>S1 (MH &quot;Otitis Media with Effusion&quot;)</td>
</tr>
<tr>
<td>#2 MeSH descriptor Ear, Middle explode all trees with qualifier: SE</td>
<td>#2 &quot;Ear, Middle/secretion&quot;[Mesh]</td>
<td>2 Middle Ear Effusion/ 3 Effusion/ and Middle Ear/ 4 ((glue and ear) or (otitis and media) or (middle and ear and effusion*) or (otitis and effusion*) or (nonsuppurative and otitis) or (non and suppurative and otitis)).tw.</td>
<td>S2 TX (glue AND ear) or TX (otitis AND media) or TX (middle AND ear AND effusion*)</td>
</tr>
<tr>
<td>#3 (glue NEXT ear) OR (otitis NEXT media) OR (middle NEXT ear NEAR effusion*) OR (otitis NEAR effusion*) OR (nonsuppurative NEXT otitis) OR (non NEXT suppurative NEXT otitis)</td>
<td>#3 (glue [tiab] AND ear [tiab]) OR (otitis [tiab]) AND media [tiab]) OR (middle [tiab] AND ear [tiab] AND effusion* [tiab]) OR (otitis [tiab] AND effusion* [tiab]) OR (nonsuppurative [tiab] AND otitis [tiab]) OR (non [tiab] AND suppurative [tiab] AND otitis [tiab])</td>
<td>5 (typanitis or (serous and otitis) or (secretory and otitis)).tw. 6 ((mucoid* and otitis) or (mu-</td>
<td>S3 TX (nonsuppurative AND otitis) or TX (non AND suppurative AND otitis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

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#4 tympanitis OR (serous NEAR otitis) OR (secretory NEAR otitis)
#5 (mucoid* NEAR otitis) OR (mucous* NEAR otitis) OR (sero NEXT muco* NEAR otitis) OR (otitis NEAR serosa)
#6 (mucoid* NEAR middle NEXT ear*) OR (mucous NEAR middle NEXT ear*) OR (seromuco* NEAR middle NEXT ear*) OR (sero NEXT muco* NEAR middle NEXT ear*) OR (otitis NEAR serosa)
#7 (adhesive NEAR otitis) OR (exudative NEAR otitis)
#8 (OME OR SOM) AND (otitis OR ear*)
#9 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8)
#10 MeSH descriptor Middle Ear Ventilation explode all trees
#11 grommet* OR tubulation OR middle NEXT ear NEAR ventilat*
#12 (ventilat* OR tympanostomy OR middle NEXT ear OR tympanic) AND (middle and ear* AND effusion*) OR (otitis and effusion*) OR (nonsuppurative and otitis) OR (non and suppurative and otitis)
#13 ear* NEXT insert* NEAR tube*
#14 (#10 OR #11 OR #12 OR #13)
#15 (#9 AND #14)

Web of Science | BIOSIS Previews (Ovid) | CAB Abstracts (Ovid) | ISCTRN (mRCT)
---|---|---|---
#1 TS=((glue and ear) or (otitis and media) or (middle and ear and effusion*) or (otitis and effusion*) or (nonsuppurative and otitis) or (non and suppurative and otitis))
#2 TS=(tympanitis or (serous tympanitis [tiab] OR (serous [tiab] AND otitis [tiab]) OR (secretory [tiab] AND otitis [tiab]))
#5 (adhesive [tiab] AND otitis [tiab]) OR (exudative [tiab] AND otitis [tiab])
#6 (OME [tiab] OR SOM [tiab]) AND (otitis [tiab] OR ear*)
#7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
#8 #9 OR #10
#9 #9 OR #10
#10 "Middle Ear Ventilation"[Mesh]
#11 grommet* [tiab] OR tubulation [tiab] OR (middle AND ear* AND ventilat* [tiab])
#12 (ventilat* [tiab] OR tympanostomy [tiab] OR (middle [tiab] AND ear* [tiab] OR tympanic [tiab])) AND tube* [tiab])
#13 ear* [tiab] AND (otitis [tiab] OR ear* [tiab])
#14 (#10 OR #11 OR #12 OR #13)
#15 (#9 AND #14)

Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

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Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

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(Continued)

and otitis) or (secretory and otitis))

#3 TS=((mucoid* and otitis) or (mucous and otitis) or (seromuco* and otitis) or (sero and muc* and otitis) or (otitis and serosa))

#4 TS=((mucoid* and middle and ear*) or (mucous and middle and ear*) or (seromuc* and middle and ear*))

#5 TS=((adhesive and otitis) or (exudative and otitis))

#6 TS=((OME or SOM) and (otitis or ear*))

#7 TS=(grommet* or tubulation or (middle and ear and ventilat*))

#8 TS=(ventilat* or tympanostomy or (middle and (ear or tympanic)) and tube*)

#9 TS=(ear* and insert* and tube*)

#10 #6 OR #5 OR #4 OR #3 OR #2 OR #1

#11 #9 OR #8 OR #7

#12 #11 AND #10

tis) or (secretory and otitis)).tw.

3 ((mucoid* and otitis) or (mucous and otitis) or (seromuco* and otitis) or (sero and muc* and otitis) or (otitis and serosa)).tw.

4 ((mucoid* and middle and ear*) or (mucous and middle and ear*) or (seromuc* and middle and ear*)).tw.

5 ((adhesive and otitis) or (exudative and otitis)).tw.

6 ((OME or SOM) and (otitis or ear*)).tw.

7 1 OR 2 OR 3 OR 4 OR 5 OR 6

8 (grommet* or tubulation or (middle and ear and ventilat*)).tw.

9 ((ventilat* or tympanostomy or (middle and (ear or tympanic)) and tube*).tw.

10 (ear* and insert* and tube*).tw.

11 8 OR 9 OR 10

12 7 AND 11

2 (typanitis or (serous and otitis) or (secretory and otitis)).tw.

3 (mucoid* and otitis) or (mucous and otitis) or (seromuco* and otitis) or (sero and muc* and otitis) or (otitis and serosa)).tw.

4 ((mucoid* and middle and ear*) or (mucous and middle and ear*) or (seromuc* and middle and ear*)).tw.

5 ((adhesive and otitis) or (exudative and otitis)).tw.

6 ((OME or SOM) and (otitis or ear*)).tw.

7 1 OR 2 OR 3 OR 4 OR 5 OR 6

8 (grommet* or tubulation or (middle and ear and ventilat*)).tw.

9 ((ventilat* or tympanostomy or (middle and (ear or tympanic)) and tube*).tw.

10 (ear* and insert* and tube*).tw.

11 8 OR 9 OR 10

12 7 AND 11

WHAT'S NEW

Last assessed as up-to-date: 21 March 2010.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
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<tbody>
<tr>
<td>22 March 2010</td>
<td>New citation required and conclusions have changed</td>
<td>Following new searches in March 2010 the review was updated. We included one new study (MRC: TARGET 2001 - unpublished data) and new data from several long-term follow-up reports of studies already included in the review (Maw 1999; Paradise 2001). The authorship of the review also changed in 2010.</td>
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HISTORY

Protocol first published: Issue 3, 1999
Review first published: Issue 1, 2005

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<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
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<tr>
<td>21 October 2008</td>
<td>Amended</td>
<td>Converted to new review format.</td>
</tr>
</tbody>
</table>

CONTRIBUTIONS OF AUTHORS

GEORGE G BROWNING: Invited to lead the data evaluation and writing team for this updated review. Drafting of abstract, plain language summary, background. Selection of studies. Appraisal of trial risk of bias. Revision surgery and adverse events outcomes. Writing final review.

MAROESKA ROVERS: Comments on the protocol, literature search and the draft review. Data extraction and analysis. Hearing outcomes. Writing final review.

IAN WILLIAMSON: Comments on the protocol, literature search and the draft review. Data extraction. Developmental outcomes. Writing final review.

JØRGEN LOUS: Lead author of original review, review of draft update.


DECLARATIONS OF INTEREST

GEORGE G BROWNING was the lead clinician but not the principal investigator for the MRC: TARGET 2001 study and has been involved in the data analysis and writing up of all the currently cited MRC Multi-centre Otitis Media Study Group papers.

MAROESKA ROVERS was the lead investigator and author for the papers cited under Rovers 2000. She was also involved as an advising epidemiologist in the MRC: TARGET 2001 study and is therefore co-author on most MRC Multi-centre Otitis Media Study Group papers. Furthermore, she has participated in workshops and educational activities on otitis media for GlaxoSmithKline.

JØRGEN LOUS in 2008 received funds for research for otitis media related subjects from Oticon Fonden (Oticon foundation) the owner of Interacoustic A/S Assens, Denmark. Interacoustic make tympanometers, audiometers and other acoustic equipment.

SOURCES OF SUPPORT

Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children (Review)

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Internal sources

- The Institute and Research Unit of General Practice, Århus University, Denmark.
- Århus University Research Foundation, Denmark.
- Institute of Public Health, University of Southern Denmark, Denmark.

External sources

- The Foundation for Research in General Practice and the Health Care System, Denmark.
- UK National Institute for Health Research Cochrane Review Incentive Scheme, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The following changes were made at the update of the review in 2010:

Objectives

- We have added assessment of adverse effects as an objective of the review.

Types of interventions

- We have excluded arms/trials where children also had adenoidectomy, as this is now covered in a separate review (van den Aardweg 2010).

Types of outcome measures

- 'Presence or absence of fluid in the middle ear cavity or days with fluid' has been changed from a primary to a secondary outcome measure.
- We have added a new outcome measure: 'Repeat/revision surgery'.
- Desirable time points for outcome assessment have been changed to one, three, six, nine, 12, 18 and 24 months, and five years.

Quality/risk of bias assessment

- We have adopted the Cochrane Collaboration 'Risk of bias' tool for assessment of study quality.

INDEX TERMS

Medical Subject Headings (MeSH)

Hearing Loss [etiology; *surgery]; Middle Ear Ventilation [adverse effects; *methods]; Otitis Media with Effusion [complications; *surgery]; Randomized Controlled Trials as Topic
MeSH check words
Child; Child, Preschool; Humans; Infant