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Adenoidectomy for otitis media with effusion (OME) in children

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Abstract

Background

Otitis media with effusion (OME) is an accumulation of fluid in the middle ear cavity, common amongst young children. The fluid may cause hearing loss. When persistent, it may lead to developmental delay, social difficulty and poor quality of life. Management of OME includes watchful waiting, autoinflation, medical and surgical treatment. Adenoidectomy has often been used as a potential treatment for this condition.

Objectives

To assess the effects (benefits and harms) of adenoidectomy, either alone or in combination with ventilation tubes (grommets), for otitis media with effusion (OME) in children.

Search methods

The Cochrane ENT Information Specialist searched the Cochrane ENT Register; Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE; Ovid Embase; Web of Science; ClinicalTrials.gov; ICTRP and additional sources for published and unpublished trials. The date of the search was 20 January 2023.

Selection criteria

We included randomised controlled trials and quasi-randomised trials in children aged 6 months to 12 years with unilateral or bilateral OME. We included studies that compared adenoidectomy (alone, or in combination with ventilation tubes) with either no treatment or non-surgical treatment.

Data collection and analysis

We used standard Cochrane methods. Our primary outcomes were determined following a multi-stakeholder prioritisation exercise and were: 1) hearing, 2) otitis media-specific quality of life and 3) haemorrhage. Secondary outcomes were: 1) persistence of OME, 2) adverse effects, 3) receptive language skills, 4) speech development, 5) cognitive development, 6) psychosocial skills, 7) listening skills, 8) generic health-related quality of life, 9) parental stress, 10) vestibular function and 12) episodes of acute otitis media. We used GRADE to assess the certainty of evidence for each outcome.

Although we included all measures of hearing assessment, the proportion of children who returned to normal hearing was our preferred method to assess hearing, due to challenges in interpreting the results of mean hearing thresholds.

Main results

We included 10 studies (1785 children). Many of the studies also used concomitant interventions for all participants, including insertion of ventilation tubes or myringotomy.

We report results for our main outcome measures at the longest duration of follow-up available. Further details of additional outcomes and time points are reported in the review.

1) Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting (three studies)

After 12 months there was little difference in the proportion of children whose hearing had returned to normal but the evidence was very uncertain (adenoidectomy 68%; no treatment 70%; risk ratio (RR) 0.97, 95% confidence interval (CI) 0.65 to 1.46; number

needed to treat (NNT) 50; 1 study; 42 participants). There is risk of haemorrhage from adenoidectomy, but the absolute risk appears small (1/251 receiving adenoidectomy compared to 0/229, Peto odds ratio (OR) 6.77, 95% CI 0.13 to 342.54; 1 study; very low-certainty evidence). The risk of persistent OME may be slightly lower after two years in those receiving adenoidectomy (65% versus 73%), but again the difference was small (NNT 13, RR 0.90, 95% CI 0.81 to 1.00; 3 studies; 354 participants; very low-certainty evidence).

2) Adenoidectomy (with or without myringotomy) versus non-surgical treatment

We did not identify any studies for this comparison.

3) Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes (four studies)

There was a slight increase in the proportion of ears with a return to normal hearing after six to nine months (57% adenoidectomy versus 42% without, RR 1.36, 95% CI 0.98 to 1.89; 1 study; 127 participants (213 ears); very low-certainty evidence). Adenoidectomy may give an increased risk of haemorrhage, but the absolute risk appears small, and the evidence was very uncertain (2/416 with adenoidectomy compared to 0/375 in the control group, Peto OR 6.68, 95% CI 0.42 to 107.18; 2 studies; 791 participants). The risk of persistent OME was similar for both groups (82% adenoidectomy and ventilation tubes compared to 85% ventilation tubes alone, NNT 34, RR 0.96, 95% CI 0.86 to 1.07; low-certainty evidence).

4) Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube (two studies)

Slightly more children returned to normal hearing after adenoidectomy, but the confidence intervals were wide (57% versus 46%, NNT 9, RR 1.24, 95% CI 0.79 to 1.96; 1 study; 72 participants; very low-certainty evidence). Fewer children had persistent OME after 12 months (43% compared to 75%, RR 0.57, 95% CI 0.38 to 0.86; 2 studies; 189 participants).

5) Adenoidectomy and ventilation tubes versus no treatment/watchful waiting (two studies)

We did not identify data on the proportion of children who returned to normal hearing. However, after two years, the mean difference in hearing threshold for those allocated to adenoidectomy was -3.40 (95% CI -5.54 to -1.26; 1 study; 211 participants; very low-certainty evidence). There may be a small reduction in the proportion of children with persistent OME after two years, but the evidence was very uncertain (82% compared to 90%, NNT 13, RR 0.91, 95% CI 0.82 to 1.01; 1 study; 232 participants). We noted that many children in the watchful waiting group had also received surgery by this time point.

6) Adenoidectomy and ventilation tubes versus non-surgical treatment

We did not identify any studies for this comparison.

Authors' conclusions

When assessed with the GRADE approach, the evidence for adenoidectomy in children with OME is very uncertain. Adenoidectomy may reduce the persistence of OME, although evidence about the effect of this on hearing is unclear. For patients and carers, the most important hearing outcome is a return to normal hearing, but few studies measured this outcome. We did not identify any evidence on disease-specific quality of life. There were few data on adverse effects, in particular postoperative bleeding, but there are recognised risks of adenoidectomy, including the potential for haemorrhage, which should be carefully considered when choosing a treatment strategy for children with OME. Future studies should aim to determine which children are most likely to benefit from treatment, rather than offering interventions to all children.

Plain language summary

Adenoidectomy for glue ear in children

Key messages

We are uncertain whether surgery to remove the adenoids (adenoidectomy) improves hearing for children with glue ear, because the evidence is not robust.

Adenoidectomy may slightly reduce the number of children who have glue ear after one to two years of follow-up, but we do not know the effect of this on hearing or quality of life.

We know that there may be harms from surgery, such as a risk of bleeding. However, there was not enough information in the studies to know how often this may occur.

What is OME?

Glue ear (or 'otitis media with effusion', OME) is a relatively common condition affecting young children. Fluid collects in the middle ear, which may cause hearing impairment. As a result of their poor hearing, children may be behind in their speech and may have difficulties at school.

How is OME treated?

Most of the time OME does not need any treatment, and the symptoms will get better with time. In children with persistent OME, different treatments have been used, including medications or surgery (insertion of grommets, with or without adenoidectomy). The adenoids are lumps of tissue at the back of the nose (above the roof of the mouth), which help the body to fight infection.

What did we want to find out?

We wanted to identify whether adenoidectomy was better than no treatment, or other types of treatment (such as medicines), for children with OME.

We also wanted to see if there were any unwanted effects associated with having an adenoidectomy.

What did we do?

We searched for studies that compared adenoidectomy with either no treatment, or a different treatment, in children with OME. We compared and summarised the study results, and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We included 10 studies that involved 1785 children. We did not identify any studies that compared adenoidectomy to medical treatment - only studies that compared adenoidectomy to no adenoidectomy. All the evidence we found was thought to be uncertain, because of issues with how the studies were conducted, and the relatively small number of people included.

We are uncertain to what extent adenoidectomy has an effect on hearing.

Adenoidectomy may reduce the number of children with persistent OME after one to two years of follow-up, but the difference may be small.

We did not find any evidence about quality of life, so we do not know if adenoidectomy has any impact on this.

Few studies reported any information about possible harms of treatment. We know that bleeding is a risk with any surgery. As part of this review we found that two children out of 416 who received adenoidectomy suffered from significant bleeding, compared to no children (out of 375) who did not have an adenoidectomy.

What are the limitations of the evidence?

As the evidence was uncertain, we cannot be sure if adenoidectomy gives any benefit for children with OME. We also found very little information about harms of adenoidectomy,

although we know that there are likely to be some risks associated with undergoing surgery.

How up-to-date is this evidence?

The evidence is up-to-date to January 2023.

Summary of findings

Summary of findings 1

Adenoidectomy (with or without myringotomy) compared to no treatment/watchful waiting for otitis media with effusion (OME) in children

Adenoidectomy (with or without myringotomy) compared to no treatment/watchful waiting for otitis media with effusion (OME) in children

Patient or population: children with otitis media with effusion (OME)
Setting: outpatient
Intervention: adenoidectomy (with or without myringotomy)
Comparison: no treatment/watchful waiting

Outcomes	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)			Certainty of the evidence (GRADE)	What happens
		With no treatment/watchful waiting	With adenoidectomy (with or without myringotomy)	Difference		
Hearing: proportion with normal hearing - up to 12 months № of participants: 42 (1 RCT)	RR 0.97 (0.65 to 1.46)	70.0%	67.9% (45.5 to 100)	2.1% fewer (24.5 fewer to 32.2 more)	⊕⊖⊖⊖ Very low[1,2]	The evidence is very uncertain about the effect of adenoidectomy on the likelihood of returning to normal hearing up to 12 months, when compared with no treatment or watchful waiting.
Presence or persistence of OME - over 12 months № of participants: 354 (3 RCTs)	RR 0.90 (0.81 to 1.00)	72.6%	65.4% (58.8 to 72.6)	7.3% fewer (13.8 fewer to 0 fewer)	⊕⊖⊖⊖ Very low[3,4]	The evidence is very uncertain about the effect of adenoidectomy on persistence of OME over 12 months, when compared with no treatment or watchful waiting.
Adverse event: haemorrhage № of participants: 480 (1 RCT)	One trial reported postoperative haemorrhage in 1/251 who received adenoidectomy (this includes those who received adenoidectomy plus VT), compared to 0/229 who did not undergo adenoidectomy (Gates 1989).				⊕⊕⊕⊖ Moderate[5]	Adenoidectomy probably increases the risk of postoperative haemorrhage, but the size of the risk is uncertain.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1]Downgraded by two levels for risk of performance and detection bias.

[2]Downgraded by two levels for very serious imprecision as the optimal information size (OIS) was not reached (< 300 events), and two decision thresholds were crossed by the confidence interval (RR 0.80 and 1.25)

[3]Downgraded by two levels for risk of bias, due to the potential for performance, detection and attrition bias.

[4]Downgraded by one level for serious imprecision as the OIS was not reached (< 300 events).

[5]This outcome was not downgraded for risk of bias, as recording of haemorrhage was considered sufficiently objective to be at little risk of performance and detection bias. However, we downgraded by one level for serious imprecision, as we were not able to estimate an effect size, and relied on a narrative synthesis.

Summary of findings 2

Adenoidectomy and bilateral ventilation tubes compared to bilateral ventilation tubes only for otitis media with effusion (OME) in children

Adenoidectomy and bilateral ventilation tubes compared to bilateral ventilation tubes only for otitis media with effusion (OME) in children

Patient or population: children with otitis media with effusion (OME)
Setting: outpatient
Intervention: adenoidectomy and bilateral ventilation tubes
Comparison: bilateral ventilation tubes only

Outcomes	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)			Certainty of the evidence (GRADE)	What happens
		With bilateral ventilation tubes only	With adenoidectomy and bilateral ventilation tubes	Difference		
Hearing: return to normal hearing at 6-9 months № of participants: 127 (1 RCT, 213 ears assessed)	RR 1.36 (0.98 to 1.89)	41.6%	56.5% (40.7 to 78.5)	14.9% more (1.1 fewer to 36.9% more)	⊕⊖⊖⊖ Very low[1,2]	Adenoidectomy may slightly increase the proportion of children in whom hearing returns to normal at 6-9 months, but the evidence was very uncertain.
Presence/persistence of OME - over 12 months № of participants: 254 (1 RCT)	RR 0.96 (0.86 to 1.07)	85.3%	81.9% (73.3 to 91.2)	3.4% fewer (11.9 fewer to 6 more)	⊕⊖⊖⊖ Very low[3,4]	The evidence is very uncertain about the effect of adenoidectomy with bilateral ventilation tube on persistence of OME beyond 12 months follow-up, when compared to bilateral ventilation tube alone.
Adverse event: haemorrhage № of participants: 791 (2 RCTs)	Peto OR 6.68 (0.42 to 107.18)	2/416 children	0/375 children	0.5% more (CI not calculable)	⊕⊕⊖⊖ Low [5]	Adenoidectomy may increase the risk of postoperative haemorrhage, but the size of the risk is uncertain.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1]Downgraded by two levels for very serious risk of bias, due to the potential for performance and detection bias.

[2]Downgraded by one level for serious imprecision, as the optimal information size was not reached (< 400 participants).

[3]Downgraded by two levels for very serious risk of bias, due to the potential for performance, detection and attrition bias.

[4]Downgraded by one level for serious imprecision, as the optimal information size was not reached (< 300 events).

[5]This outcome was not downgraded for risk of bias, as recording of haemorrhage was considered sufficiently objective to be at little risk of performance and detection bias. However, we downgraded by two levels for very serious imprecision, due to the extremely wide confidence intervals for the effect size.

Summary of findings 3

Adenoidectomy and unilateral ventilation tube compared to unilateral ventilation tube only for otitis media with effusion (OME) in children

Adenoidectomy and unilateral ventilation tube compared to unilateral ventilation tube only for otitis media with effusion (OME) in children

Patient or population: children with otitis media with effusion (OME)
Setting: outpatient
Intervention: adenoidectomy and unilateral ventilation tube
Comparison: unilateral ventilation tube only

Outcomes	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)			Certainty of the evidence (GRADE)	What happens
		With unilateral ventilation tubes only	With adenoidectomy and unilateral ventilation tube	Difference		
Hearing: proportion of children with hearing returned to normal (12 months - medium-term) - normal hearing ≤ 15 dB № of participants: 72 (1 RCT)	RR 1.24 (0.79 to 1.96)	45.7%	56.7% (36.1 to 89.6)	11.0% more (9.6 fewer to 43.9 more)	⊕⊖⊖⊖ Very low[1,2]	The evidence is very uncertain about the effect of adenoidectomy plus unilateral ventilation tube on return to normal hearing at 12 months, when compared to unilateral ventilation tube only.
Presence or persistence of OME - 3 years - long-term) № of participants: 74 (1 RCT)	RR 0.67 (0.35 to 1.29)	40.5%	27.2% (14.2 to 52.3)	13.4% fewer (26.4 fewer to 11.8 more)	⊕⊖⊖⊖ Very low [2] [3]	The evidence is very uncertain about the effect of adenoidectomy plus unilateral ventilation tube on persistence of OME at 3 years, when compared to unilateral ventilation tube only.

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1]Downgraded by one level for a risk of performance bias.

[2]Downgraded by two levels for very serious imprecision, as the optimal information size (OIS) was not reached (< 300 events), and two decision thresholds were crossed by the confidence interval (RR 0.80 and

1.25).

[3]Downgraded by two levels for a risk of performance and detection bias.

Summary of findings 4

Adenoidectomy and ventilation tubes compared to no treatment/watchful waiting for otitis media with effusion (OME) in children

Adenoidectomy and ventilation tubes compared to no treatment/watchful waiting for otitis media with effusion (OME) in children

Patient or population: children with otitis media with effusion (OME)
Setting: outpatient
Intervention: adenoidectomy and ventilation tubes
Comparison: no treatment/watchful waiting

Outcomes	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)			Certainty of the evidence (GRADE)	What happens
		With no treatment/watchful waiting	With adenoidectomy and ventilation tubes	Difference		
Hearing: hearing threshold (at 2 years - long-term) № of participants: 211 (1 RCT)	—	The mean hearing threshold was 18.2 dB	—	MD 3.4 lower (5.54 lower to 1.26 lower)	⊕⊖⊖⊖ Very low[1,2]	The evidence is very uncertain about the effect o adenoidectomy plus ventilation tubes on the hearing threshol at 2 years, when compared to no treatment/watchf waiting.
Presence/persistence of OME (at 2 years - long-term) № of participants: 232 (1 RCT)	RR 0.91 (0.82 to 1.01)	89.7%	81.6% (73.6 to 90.6)	8.1% fewer (16.1 fewer to 0.9 more)	⊕⊖⊖⊖ Very low[2,3]	The evidence is very uncertain about the effect o adenoidectomy plus ventilation tubes on persistence of OME at 2 years, when compared to no treatment/watchf waiting.
Adverse event: haemorrhage № of participants: 416 (2 RCTs)	Two studies reported the number of children who returned to operating theatre to control haemorrhage after adenoidectomy. In one study, this applied to one child of 251 (this includes those who received adenoidectomy plus myringotomy) (Gates 1989). In the other trial, the number was one child of 165 (TARGET).				⊕⊕⊕⊖ Moderate[4]	Adenoidectomy likely increases the risk of postoperative haemorrhage.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1]Downgraded by two levels for risk of bias, due to the potential for performance and detection bias.

[2]Downgraded by one level for serious imprecision, as the optimal information size was not reached (< 400 participants for continuous outcomes, < 300 events for dichotomous outcomes).

[3]Downgraded by two levels for very serious risk of bias, due to the potential for performance, detection and attrition bias.

[4]This outcome was not downgraded for risk of bias, as recording of haemorrhage was considered sufficiently objective to be at little risk of performance and detection bias. However, we downgraded by one level for serious imprecision, as we were not able to estimate an effect size, and relied on a narrative synthesis.

Background

Description of the condition

Otitis media with effusion (OME) is a common condition in early childhood. The condition, also known as 'glue ear' and serous otitis media, is defined as "the presence of fluid in the middle ear without signs or symptoms of acute infection" (Rosenfeld 2016).

A key clinical feature of OME is hearing loss, due to decreased mobility of the tympanic membrane and consequent loss of sound conduction (Rosenfeld 2016). When hearing loss persists, this may affect speech and language development, and lead to behavioural problems in some children (NICE 2008). Other symptoms that may be attributable to OME include balance (vestibular) problems and ear discomfort (Rosenfeld 2016). When symptoms persist, they may lead to poor school performance and affect a child's daily activities, social interactions and emotions, possibly leading to a poorer quality of life for the child (Rosenfeld 2000).

It is thought that up to 80% of children have had OME by the age of four years but a decline in prevalence is observed for children beyond six years of age (Williamson 2011). Most episodes of OME in children resolve spontaneously within three months, however approximately 35% of children will have more than one episode of OME and, furthermore, 5% to 10% of episodes will last for more than a year (Rosenfeld 2016). Children with OME following an episode of untreated acute otitis media have a 59% rate of resolution by one month rising to 74% by three months, while children with newly diagnosed OME of unknown duration demonstrate a resolution rate of 28% by three months and up to 42% by six months (Rosenfeld 2003). The condition is more prevalent in children with Down syndrome or cleft palate (Flynn 2009; Maris 2014). Atopy has been considered a potential risk factor for OME in children (Kreiner-Møller 2012; Marseglia 2008; Zernotti 2017).

Diagnosis of OME is typically by clinical examination including (pneumatic) otoscopy and/or tympanometry in primary care. Following diagnosis, there will often be a period of active observation, for at least three months. During the observation period the care provider may offer a non-surgical intervention such as hearing aids or autoinflation. The National Institute for Health and Care Excellence (NICE) and the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) do not currently recommend the use of antibiotics, antihistamines, decongestants or corticosteroids for OME as there is insufficient evidence to suggest that they are effective treatments (NICE 2008; Rosenfeld 2016). If OME has not resolved within the three-month observation period, the child may be referred for further management/active intervention. This may include hearing aid provision or review by an ENT surgeon for consideration for myringotomy, ventilation tubes insertion and/or adenoidectomy. The choice of active intervention varies considerably. Earlier active intervention may be considered for children at increased risk of developmental difficulties (see Rosenfeld 2016 for a list of 'at-risk' factors).

This Cochrane Review focusses on adenoidectomy, either alone or in combination with ventilation tubes, as a treatment for OME. It forms part of a suite of five reviews of OME treatment, which will address those interventions identified in a prioritisation exercise as being most important and in need of up-to-date Cochrane Reviews, namely ventilation tubes, adenoidectomy, autoinflation, topical and oral steroids, and antibiotics (Cochrane ENT 2020).

Description of the intervention

The adenoid is a mass of lymphoid tissue in the postero-superior wall of the nasopharynx. Adenoidectomy, that is surgical removal of the adenoid, is performed in children to treat

persistent OME and recurrent episodes of acute otitis media (AOM) (Schilder 2016). The adenoid may be visualised via the mouth with a mirror or via the nose with an endoscope and is removed under general anaesthetic. Techniques for adenoidectomy vary. The traditional method is 'cold steel' curettage, however suction diathermy and other techniques are increasingly used. These involve direct visualisation of the adenoid tissue and have a reported reduced risk of bleeding. Adenoidectomy may be most beneficial for children with persistent OME aged four or more years (Boonacker 2014).

Guideline evidence focusses on the combination of adenoidectomy and ventilation tubes, rather than adenoidectomy alone. NICE recommends "adjuvant adenoidectomy for children over 4 years of age as it improves the efficacy of ventilation tubes" (NICE CKS 2021). This recommendation parallels those of an international consensus on the management of OME (Simon 2018), which recommends considering adjuvant adenoidectomy in recurrent OME, for associated nasal obstruction, or in older children (over four years of age). Adenoidectomy is recommended in particular for those who require repeat ventilating tube surgery (Rosenfeld 2016). For children under four years old, adenoidectomy is not recommended, unless there is a distinct indication, such as nasal obstruction or chronic adenoiditis (Rosenfeld 2016). French guidelines recommend adenoidectomy (unless contraindicated by velar abnormality or clotting disorders) for children aged four years or over who have enlarged adenoids (Blanc 2018).

How the intervention might work

The adenoid serves as a "nasopharyngeal reservoir of respiratory pathogens and, when enlarged, may cause obstruction of the nasal airway and impair Eustachian tube function" (Schilder 2016). In addition, the location of the adenoid tissue and, in particular, contact with the torus tubarius, may play a role in the causation of OME (Skoloudik 2018). Thus adenoidectomy may work by removing a bacterial reservoir and a site of chronic inflammation, which may be obstructing Eustachian tube function. However, there is some uncertainty around the precise mode of action of this intervention.

Why it is important to do this review

A Cochrane Review assessing the effects of adenoidectomy for recurrent AOM and persistent OME in children was published in 2010 (van den Aardweg 2010). This review compared the following interventions:

- adenoidectomy (with or without myringotomy) with non-surgical treatment or myringotomy alone;
- adenoidectomy with unilateral tympanostomy tube versus unilateral tympanostomy tube only;
- adenoidectomy with bilateral ventilation tubes versus bilateral ventilation tubes only.

Searches were run to March 2009 and the review included 14 studies. The authors found a significant beneficial effect of adenoidectomy on resolution of middle ear effusion, but only a small benefit to hearing.

A scoping search undertaken in 2020 identified 12 abstracts of randomised controlled trials published since the Cochrane Review. There has also been an National Institute for Health Research (NIHR) Health Technology Assessment (HTA) report that includes an individual patient data meta-analysis of adenoidectomy with or without ventilation tubes for children with OME (Boonacker 2014), and six systematic reviews published since the Cochrane Review (Berkman 2013; Cheong 2012; Mikals 2014; Tian 2014; Wallace 2014; Williamson 2011). A prioritisation exercise undertaken in 2020 identified a review of adenoidectomy, with or without ventilation tubes, as a top priority (Cochrane ENT 2020). It is timely to update the evidence.

Objectives

To assess the effects (benefits and harms) of adenoidectomy, either alone or in combination with ventilation tubes (grommets), for otitis media with effusion (OME) in children.

Methods

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) and quasi-randomised trials (where trials were designed as RCTs, but the sequence generation for allocation of treatment used methods such as alternative allocation, birth dates and alphabetical order). We included studies that randomised by participant or by cluster. We did not identify any cross-over trials for inclusion in this review.

Types of participants

The population of interest was children aged 6 months to 12 years with unilateral or bilateral OME. If a study included children aged younger than 6 months and older than 12 years, we only included the study if the majority of children fit our inclusion criteria or if the trialists present outcome data by age group. We included all children regardless of any comorbidity such as Down syndrome or cleft palate, although many trials specifically excluded children with these co-morbidities.

Clinical diagnosis of OME was confirmed by oto(micro)scopy or tympanometry or both. We included studies where children had OME for at least three months.

Types of interventions

Intervention

Adenoidectomy, either alone or in combination with ventilation tubes.

Comparator

We assessed the following comparisons:

- adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting;
- adenoidectomy (with or without myringotomy) versus non-surgical treatment;
- adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only;
- adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only;
- adenoidectomy and ventilation tubes versus no treatment/watchful waiting;
- adenoidectomy and ventilation tubes versus non-surgical treatment.

If study participants received other treatments in addition to the main intervention (for example intranasal steroids, oral steroids, antibiotics, mucolytics or decongestants) we planned to include these studies if both arms of the study received identical treatment. However, this was not the case for the included studies.

Types of outcome measures

We analysed the following outcomes in the review, but we did not use them as a basis for including or excluding studies. We assessed all outcomes at very short term (< 6 weeks for postoperative adverse events), short term (</= 3 months), medium term (> 3 months to </= 1 year) and long term (> 1 year) follow-up.

Primary outcomes

- Hearing:

    - proportion of children whose hearing has returned to normal, with normal hearing defined as 20 dB HL or less (assessed using age-appropriate tests);
    - hearing threshold.

It was anticipated that trial data for these outcomes would be derived from a variety of assessment methods. To avoid loss of important evidence, we extracted all such data for analysis. However, we gave consideration to the appropriateness of pooling different types of data in meta-analysis. Our selection of primary outcomes was based principally upon clinical importance, but also permits applicability across a variety of age-appropriate assessment methods and considers the types of outcome data that are most likely to be available. Accordingly, we regard the proportion of participants whose hearing has returned to normal as the most important measure of hearing impact. We considered medium- and long-term outcome data as the most clinically important.

- Disease-specific quality of life measured using a validated instrument, for example:
    - OM8-30 (Haggard 2003);
    - Otitis Media-6 (Rosenfeld 1997).
- Adverse events - serious haemorrhage and its consequences.

Secondary outcomes

- Presence/persistence of OME.
- Adverse events - measured by the number of participants affected.
    - Tympanic membrane changes, such as:
        - atrophy;
        - atelectasis or retraction;
        - myringosclerosis;
        - tympanosclerosis.
    - Patient-related:
        - recurring haemorrhage;
        - transient postoperative velopharyngeal insufficiency;
        - pain;
        - infection;
        - lip/tooth/tongue injury;
        - velopharyngeal reflux/nasal escape;
        - other surgical complications.
- Receptive language skills, measured using a validated scale, for example:
    - Peabody Picture Vocabulary Test - Revised (Dunn 2007);
    - Reynell Developmental Language Scales (relevant domains) (Reynell 1985);
    - Preschool Language Scale (PLS) (relevant domains) (Zimmerman 1992);
    - Sequenced Inventory of Communication (SCID) (relevant domains) (Hedrick 1984).
- Speech development, or expressive language skills, measured using a validated scale, for example:
    - Schlichting test (Schlichting 2010);
    - Lexi list (Schlichting 2007);
    - Reynell Developmental Language Scales (relevant domains) (Reynell 1985);
    - PLS (relevant domains) (Zimmerman 1992);
    - SCID (relevant domains) (Hedrick 1984).

- Cognitive development, measured using a validated scale, for example:
  - Griffiths Mental Development Scales (Griffiths 1996);
  - McCarthy General Cognitive Index (McCarthy 1972);
  - Bayley Scales of Infant and Toddler Development (Bayley 2006).
- Psychosocial outcomes, measured using a validated scale, for example:
  - Social Skills Scale of the Social Skills Rating System (Gresham 1990);
  - Child Behaviour Checklist (Achenbach 2011);
  - Strengths and Difficulties Questionnaire (Goodman 1997);
  - Pediatric Symptom Checklist (Jellinek 1988).
- Listening skills, for example listening to stories and instructions effectively. Given that there are few validated scales to assess listening skills in children with OME, we will include any methods used by trialists.
- Generic health-related quality of life assessed using a validated instrument, for example:
  - EQ-5D (Rabin 2001);
  - TNO AZL Children's QoL (TACQOL) (Verrips 1998);
  - TNO AZL Pre-school children QoL (TAPQOL) (Fekkes 2000);
  - TNO AZL Infant Quality of Life (TAIQOL) (TNO Prevention 1997);
  - Infant Toddler Quality of Life Questionnaire (ITQOL) (Landgraf 1994);
  - Child Heath Questionnaire (CHQ) (Landgraf 1996).
- Parental stress, measured using a validated scale, for example:
  - Parenting Stress Index (Abidin 1995).
- Vestibular function:
  - balance;
  - co-ordination.
- Number of doctor-diagnosed AOM episodes within a specified time frame.

These outcomes were identified as the most important in two studies that aimed to develop a core outcome set for children with OME (Bruce 2015; Liu 2020). As this review forms part of a suite of reviews of interventions for OME, not all outcomes are relevant for all reviews.

Search methods for identification of studies

The Cochrane Ear, Nose and Throat Disorders Group's Information Specialist conducted systematic searches for randomised controlled trials and controlled clinical trials. There were no language, publication year or publication status restrictions. We contacted original authors for clarification and further data if trial reports were unclear and we arranged translations of papers where necessary. The date of the search was 20 January 2023.

Electronic searches

The Information Specialist searched:

- the Cochrane ENT Register (searched via the Cochrane Register of Studies to 20 January 2023;
- the Cochrane Central Register of Controlled Trials (CENTRAL) (searched via the Cochrane Register of Studies to 20 January 2023);

- Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (1946 to 20 January 2023);
- Ovid EMBASE (1974 to 20 January 2023);
- Web of Science, Web of Science (1945 to 20 January 2023);
- ClinicalTrials.gov, www.clinicaltrials.gov:
    - searched via the Cochrane Register of Studies to 20 January 2023;
    - searched via www.clinicaltrials.gov to 20 January 2023;
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP), https://apps.who.int/trialsearch/:
    - searched via the Cochrane Register of Studies to 20 January 2023;
    - searched via https://apps.who.int/trialsearch/ 20 January 2023.

The Information Specialist modelled subject strategies for databases on the search strategy designed for CENTRAL. The search strategies were designed to identify all relevant studies for a suite of reviews on various interventions for Otitis Media with Effusion. Where appropriate, they were combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the Technical Supplement to Chapter 4 of the *Cochrane Handbook for Systematic Reviews of Interventions* version 6.1) (Lefebvre 2021). 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. The Information Specialist also ran non-systematic searches of Google Scholar to retrieve grey literature and other sources of potential trials.

We did not perform a separate search for adverse effects. We considered adverse effects described in included studies only.

Data collection and analysis

Selection of studies

The Cochrane ENT Information Specialist used Cochrane's Screen4Me workflow to help assess the search results. Screen4Me comprises three components:

1. Known assessments – a service that matches records in the search results to records that have already been screened in Cochrane Crowd and been labelled as 'a RCT' or as 'not a RCT'.
2. The machine learning classifier (RCT model) (Wallace 2017), available in the Cochrane Register of Studies (CRS-Web), which assigns a probability of being a true RCT (from 0 to 100) to each citation. For citations that are assigned a probability score below the cut-point at a recall of 99% we will assume these to be non-RCTs. For those that score on or above the cut-point we will either manually dual screen these results or send them to Cochrane Crowd for screening.
3. Cochrane Crowd is Cochrane's citizen science platform where the Crowd help to identify and describe health evidence. For more information about Screen4Me and the evaluations that have been done, please go to the Screen4Me website on the Cochrane Information Specialist's portal and see Marshall 2018, McDonald 2017, Noel-Storr 2018 and Thomas 2017.

At least two review authors independently screened titles and abstracts retrieved by the search to identify potentially relevant studies. At least two review authors then independently evaluated the full text of each potentially relevant study to determine whether it met the inclusion/exclusion criteria for this review. Any differences were

resolved by discussion and consensus, with the involvement of a third author where necessary.

Screening eligible studies for trustworthiness

Two review authors appraised all studies meeting our inclusion criteria for trustworthiness using a screening tool developed by Cochrane Pregnancy and Childbirth. This tool includes specified criteria to identify studies that are considered sufficiently trustworthy to be included in the review (see Appendix 2 and Figure 1). For any studies assessed as being potentially 'high risk', we attempted to contact the study authors to obtain further information or address any concerns. We had planned to exclude these studies from the review if we were unable to contact the authors, or there was persisting uncertainty about the study. However, when using the trustworthiness tool, there were only five studies where we had no concerns (Dempster 1993; Fiellau-Nikolajsen 1982; Gates 1989; Maw 1983; TARGET).

All of the remaining studies had at least some concerns, although this was often due to a paucity of information rather than a specific concern over trustworthiness:

- We were unable to identify prospective trial registration for three studies (Hao 2019; Jabeen 2019; Xu 2016).
- Three studies reported full follow-up, without explanation to indicate how this was achieved (Luo 2007; Sagnelli 1990; Xu 2016).
- Xu 2016 also indicated that equal numbers of participants were randomised to each group, without a description of blocked randomisation.
- Finally, Hao 2019 provided details of complete cases only, so we were unable to assess the number randomised to each group, or assess whether full follow-up was achieved.

We were unsure whether this high level of studies with concerns reflected a genuine problem with the data from these studies, or whether the assessment tool was perhaps too sensitive. We note that this tool - and others used for the same purpose - has not yet been validated.

Consequently we decided to include all of the studies in the main analyses of this review, but we did investigate the effect of excluding studies with concerns over trustworthiness on the overall results (see Sensitivity analysis).

Data extraction and management

At least two review authors (of KG, CM, AP, RC, KW) independently extracted outcome data from each study using a standardised data collection form. Where a study had more than one publication, we retrieved all publications to ensure complete extraction of data. Any discrepancies in the data extracted by the two authors were checked against the original reports, and differences were resolved through discussion and consensus, with recourse to a third author where necessary. If required, we contacted the study authors for clarification. We included key characteristics of the studies, such as the study design, setting, sample size, population and the methods for defining or collecting outcome data in the studies.

We extracted data on study findings according to treatment assignment, irrespective of whether study participants complied with treatment or received treatment to which they were randomised.

In addition to extracting pre-specified information about study characteristics and aspects of methodology relevant to risk of bias, we extracted the following summary statistics for each study and outcome:

- For continuous data: the mean values, standard deviation and number of patients for each treatment group at the different time points for outcome measurement. Where endpoint data were not available, we extracted the values for change-from-baseline data instead. If values for the individual treatment groups were not

reported, where possible we extracted summary statistics (e.g. mean difference) from the studies.

- For binary data: we extracted information on the number of participants experiencing an event, and the number of participants assessed at that time point. If values for the individual treatment groups were not reported, where possible we extracted summary statistics (e.g. risk ratio) from the studies.
- For ordinal scale data: we did not include any data from an ordinal scale in this review.

We pre-specified time points of interest for the outcomes in this review. Where studies reported data at multiple time points, we took the longest available follow-up point within each of the specific time frames. For example, if a study reported an outcome at 4 months, 8 months and 12 months of follow-up, then the 12-month data are included for the time point > 3 months to ≤ 1 year.

Assessment of risk of bias in included studies

At least two authors (of KG, CM, AP, RC, KW) undertook assessment of the risk of bias of the included studies independently, with the following taken into consideration, as guided by the *Cochrane Handbook for Systematic Reviews of Interventions* (Handbook 2011):

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

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

Measures of treatment effect

We summarised dichotomous data - such as presence of OME - as risk ratios (RR) and 95% confidence intervals (CI), and we summarised continuous data as a mean difference (MD) and 95% CI. For the outcomes presented in the summary of findings tables, we also provide both the relative and absolute measures of effect.

Unit of analysis issues

For this review we anticipated that the unit of analysis would be the child. However, some studies reported findings by ear, therefore we have used both the child and ear as the unit of analysis. See Appendix 3 for further details.

Dealing with missing data

We attempted to contact study authors by email where data on an outcome of interest to the review were not reported but the methods described in the paper suggested that the outcome was assessed. We did the same if not all data required for meta-analysis were reported. If standard deviation data were not available, we approximated these using the standard estimation methods from P values, standard errors or 95% CIs (if these are reported), as detailed in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021).

Assessment of heterogeneity

We assessed clinical heterogeneity by examining the included studies for potential differences between them in the types of participants recruited, interventions or controls used, and the outcomes measured. We assessed statistical heterogeneity by considering

both the I^2 statistic, which calculates the percentage of variability that is due to heterogeneity rather than chance (with values over 50% suggesting substantial heterogeneity) and the P value from the Chi^2 test (Higgins 2021).

Assessment of reporting biases

We assessed reporting bias as within-study outcome reporting bias and between-study publication bias.

Outcome reporting bias (within-study reporting bias)

We assessed within-study reporting bias by comparing the outcomes reported in the published report against the study protocol or trial registry, whenever this could be obtained. If the protocol or trial registry entry was not available, we compared the outcomes reported to those listed in the methods section. If results are mentioned but not reported adequately in a way that allows analysis (e.g. the report only mentions whether the results were statistically significant or not), bias in a meta-analysis is likely to occur. We then sought further information from the study authors. If no further information could be found, we noted this as being a 'high' risk of bias when the risk of bias tool is used. If there was insufficient information to judge the risk of bias we noted this as an 'unclear' risk of bias (Handbook 2011).

Publication bias (between-study reporting bias)

We planned to produce a funnel plot to explore possible publication biases, if we were able to pool 10 or more studies in a single analysis. However, this was not possible, as too few studies were included in the meta-analyses.

Data synthesis

Where two or more studies report the same outcome we performed a meta-analysis using Review Manager 5 (RevMan 2014). We report pooled effect measures for dichotomous outcomes as a risk ratio (RR) using the Mantel-Haenszel methods. For continuous outcomes measured using the same scales we report the mean difference (MD). We used a random-effects model.

Where it was not possible to pool the findings from studies in a meta-analysis, we have presented the results of each study and provide a narrative synthesis of findings.

Subgroup analysis and investigation of heterogeneity

We proposed the following subgroup analyses if sufficient data were available in trial reports:

- children with mild hearing loss versus moderate or worse;
- children with allergy versus those without (using the trialists' own definition);
- children aged up to four years versus children aged four years and older;
- children with previous adenoidectomy versus those without previous adenoidectomy;
- children with previous ventilation tubes versus those without ventilation tubes;
- children with Down syndrome;
- different adenoidectomy techniques;
- intervention of interest with concomitant treatment versus intervention of interest without concomitant treatment.

However, we did not find any data suitable for conducting these subgroup analyses. No studies provided subgroup data for children with different features (for example, for those with mild hearing loss, compared to those with moderate or worse hearing loss). Many of the trials did not provide sufficient background information (for example on hearing level) for us to conduct subgroup analysis at the level of the individual study. Where data were

provided, trials often recruited a mixed population that encompassed all subgroups (for example, most trials recruited children aged 2 to 12 years, not specifically children aged < 4 years, or ≥ 4 years).

Sensitivity analysis

We carried out sensitivity analyses to assess whether our findings were robust to decisions made regarding the analyses and inclusion of studies. We performed sensitivity analyses to assess the following:

- the impact of the model chosen: we compared the results of any pooled analyses to that obtained using a fixed-effect model;
- the inclusion of studies at high risk of bias: we compared the results including all studies versus excluding studies at overall high risk of bias, that is four or more of the seven domains of bias are rated as high risk (see Assessment of risk of bias in included studies). This only applied to one study (Gates 1989).
- exclusion of studies considered to have concerns over trustworthiness, as assessed by the trustworthiness tool (Figure 1). This applied to five studies (Hao 2019; Jabeen 2019; Luo 2007; Sagnelli 1990; Xu 2016).

The results of these analyses are presented in Table 1.

Summary of findings and assessment of the certainty of the evidence

Two independent authors (KG, CM) used the GRADE approach to rate the overall certainty of evidence using GRADEpro GDT (https://gradepro.org/). The certainty of evidence reflects the extent to which we are confident that an estimate of effect is correct, and we applied this in the interpretation of results. There are four possible ratings: high, moderate, low and very low. A rating of high certainty of evidence implies that we are confident in our estimate of effect and that further research is very unlikely to change our confidence in the estimate of effect. A rating of very low certainty implies that any estimate of effect obtained is very uncertain.

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

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

When assessing imprecision, we used a minimally important difference of a risk ratio (or odds ratio) of 0.8 or 1.25 for dichotomous outcomes. For most continuous data we considered a minimally important difference to be half of the standard deviation for the control/comparator group. The exception to this was hearing thresholds, where a difference of 10dB HL was used as the minimally important difference.

We included a summary of findings table, constructed according to the recommendations described in Chapter 14 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021), for the following comparisons:

- adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting;
- adenoidectomy (with or without myringotomy) versus non-surgical treatment;
- adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only;
- adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only;
- adenoidectomy and ventilation tubes versus no treatment/watchful waiting;

- adenoidectomy and ventilation tubes versus non-surgical treatment.

We included the following four outcomes in the summary of findings tables:

- hearing;
- disease-specific quality of life;
- presence/persistence of OME;
- adverse events - serious haemorrhage and its consequences.

Results

Description of studies

Results of the search

The searches (January 2023 and September 2021) retrieved a total of 7441 records. This reduced to 4157 after the removal of duplicates. The Cochrane ENT Information Specialist sent all 4157 records to the Screen4Me workflow. The Screen4Me workflow identified 68 records as having previously been assessed: 50 had been rejected as not RCTs and 34 had been assessed as possible RCTs. The RCT classifier rejected an additional 1514 records as not RCTs (with 99% sensitivity). The Cochrane Crowd assessed the remaining 2443 references, rejecting 1313 as not RCTs and identifying 1130 as possible RCTs. Following this process, the Screen4Me workflow had rejected 2877 records and identified 1280 possible RCTs for title and abstract screening.

	Possible RCTs	Rejected
Known assessments	34	50
RCT classifier	2559	1514
Cochrane Crowd	1130	1313
Total	1280	2877

We identified 76 additional duplicates. We screened the titles and abstracts of the remaining 1204 records. We discarded 886 records and assessed 318 full-text records. We subsequently discarded an additional 230 records and identified an additional five duplicates.

We excluded 49 records (linked to 45 studies) with reasons recorded in the review (see Excluded studies).

We included 10 studies (28 records) where results were available (Dempster 1993; Fiellau-Nikolajsen 1982; Gates 1989; Hao 2019; Jabeen 2019; Luo 2007; Maw 1983; Sagnelli 1990; TARGET; Xu 2016). We subsequently identified two additional papers for Fiellau-Nikolajsen 1982.

We identified two ongoing studies. See Characteristics of ongoing studies for further details.

We identified four studies that remain in awaiting assessment because we did not have enough information to determine eligibility (Diacova 2016; Marshak 1980; Maw 1986; Tawfik 2002).

A flow chart of study retrieval and selection is provided in Figure 2.

Included studies

See Table 2 for a summary of the features of included studies, and Characteristics of included studies for a full description of each study.

Study design

All of the studies included were described as randomised controlled trials. Six studies included two randomised groups, comparing adenoidectomy with no adenoidectomy,

often with concomitant interventions for both groups, such as myringotomy or ventilation tubes (Fiellau-Nikolajsen 1982; Hao 2019; Jabeen 2019; Luo 2007; Sagnelli 1990; Xu 2016). Four studies included additional intervention arms:

- Dempster 1993 was a four-arm RCT (the main comparison was of adenoidectomy versus no adenoidectomy. In addition all children had a ventilation tube inserted in one ear, to allow a comparison of ventilation tube versus none).
- Gates 1989 was also a four-arm RCT (comparing adenoidectomy plus myringotomy to myringotomy alone, as well as adenoidectomy plus bilateral ventilation tubes to bilateral ventilation tubes alone).
- Maw 1983 included three arms. For this review we have included data for the comparison or adenoidectomy versus no adenoidectomy. An additional arm considered the combined effect of adenotonsillectomy.
- TARGET was a three-arm RCT, which compared adenoidectomy to both adenoidectomy plus ventilation tubes, and to watchful waiting. We have included both of these comparisons.

Participants

Three studies were conducted in the UK (Dempster 1993; Maw 1983; TARGET), and three were conducted in China (Hao 2019; Luo 2007; Xu 2016). One study was conducted in each of the following countries: Denmark (Fiellau-Nikolajsen 1982), Italy (Sagnelli 1990), Pakistan (Jabeen 2019) and the USA (Gates 1989).

The sample size ranged from 45 participants (Fiellau-Nikolajsen 1982) to 578 participants (Gates 1989). Most of the studies recruited young children, with a range between 2 and 12 years.

Many the studies did not require children to have a specified level of hearing loss in order to enter the trial. For those studies that did, different levels of hearing impairment were required:

- Dempster 1993 recruited children with a hearing threshold on pure tone audiometry of ≥ 25 dB HL and an air-bone gap of ≥ 15 dB.
- Jabeen 2019 included children with a hearing threshold of > 20 dB HL.
- Luo 2007 included children with a hearing threshold of > 25 dB HL.
- Maw 1983 recruited participants with > 25 dB HL loss in both ears at one or more frequency.
- TARGET included children where the hearing threshold for the better ear was > 20 dB HL (averaged across 0.5, 1, 2 and 4 kHz) and with an air–bone gap > 10 dB.

Interventions and comparisons

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting

We identified three studies for this comparison (Fiellau-Nikolajsen 1982; Gates 1989; Sagnelli 1990). All compared adenoidectomy plus myringotomy to myringotomy alone.

Comparison 2: Adenoidectomy (with or without myringotomy) versus non-surgical treatment

We did not identify any studies for this comparison.

Comparison 3: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only

We identified four studies for this comparison (Gates 1989; TARGET; Hao 2019; Jabeen 2019).

Comparison 4: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only

We identified two studies for this comparison (Dempster 1993; Maw 1983). Where relevant, we assessed outcomes for the un-operated ear (i.e. the ear without the ventilation tube).

Comparison 5: Adenoidectomy and ventilation tubes versus no treatment/watchful waiting

We identified two studies for this comparison (Gates 1989; TARGET). Both trials also provided data for other comparisons (described above, comparisons 1 and 3).

Comparison 6: Adenoidectomy and ventilation tubes versus non-surgical treatment

We did not identify any studies for this comparison.

Outcomes

Hearing was assessed differently between the studies.

Return to normal hearing

Three studies provided some information on the return to normal hearing. This was described by Dempster 1993 as reaching a hearing threshold of < 15 dB HL. Fiellau-Nikolajsen 1982 also reported on the proportion of children who achieved a composite outcome of a type A tympanogram, normal otomicroscopy and normal middle ear reflexes, combined with 'normal hearing', although no definition of normal hearing was provided. Luo 2007 also used a composite outcome measure, including a return to normal hearing thresholds (0 to 25 dB HL on pure tone audiometry), together with resolution of symptoms and type A tympanogram. We acknowledge that these measures may underestimate the proportion of children who return to normal hearing, as children whose hearing was normal, but who still had tympanometric changes or other symptoms, will not be included.

Final hearing threshold

Several studies reported on the final hearing threshold, or the change in hearing threshold, using pure tone audiometry (Dempster 1993; Hao 2019; Maw 1983; TARGET). Sagnelli 1990 also indicated that mean final hearing threshold was assessed, but gave very little information regarding how this was measured.

The study Gates 1989 did not report on either the proportion of children who returned to normal hearing, or the mean final hearing threshold. Instead, the authors calculated the proportion of time with any hearing loss. We were unable to include these data in a meta-analysis. Xu 2016 also assessed participants hearing using pure tone audiometry, but the data were reported graphically, and summary statistics for the entire group were not reported. We were unable to use the results in this review.

Persistent OME

Again, studies assessed this outcome in various ways. Two studies defined persistent OME using a type B tympanogram (Dempster 1993; Xu 2016), and two further studies used a "non-type A tympanogram", i.e. type B or C (Fiellau-Nikolajsen 1982; Sagnelli 1990). Gates 1989 and Maw 1983 used a combination of tympanometry and otoscopy to identify persistent OME, whilst Jabeen 2019 indicated that only otoscopic assessment was carried out. Hao 2019 used a composite outcome measure, reported as the number of children who were not 'cured' - children with no symptoms, no effusion and normal hearing.

Adverse effects

Few studies provided any information on adverse effects. Furthermore, where a description of adverse events was provided, this often did not include a comparison of the relevant groups for this review. For example, studies that randomised children to received adenoidectomy (or not) and ventilation tubes (or not) provided details on the adverse events in those who received ventilation tubes, but not for those receiving adenoidectomy (Gates 1989; TARGET).

Acute otitis media

A single study reported on this outcome, and provided information on the number of episodes of acute otitis media during six months of follow-up (Fiellau-Nikolajsen 1982).

Excluded studies

We excluded 49 records (linked to 45 studies). The main reasons for exclusion are listed below.

- Twelve studies were not randomised controlled trials (Becker 1992; Gibson 1996; Hornigold 2008; Iino 1989; MRC Multicentre Otitis Media Study 2004; Paradise 1997; Parker 1989; Parlea 2012; Sagara 2003; Shubich 1996; Stenstrom 2005; Worley 2007).
- Nineteen studies recruited an incorrect population, including:
    - 10 studies in which the duration of OME was unknown, or was definitely less than three months (Black 1986; Black 1990; Brown 1978; Bulman 1984; Hammaren-Malmi 2005; Markou 2004; NCT00629694; Rohail 2006; Roydhouse 1980; Shishegar 2007);
    - eight studies in which participants had recurrent acute otitis media, not OME (Casselbrant 2009; Ferrara 2005; Kujala 2012; Mandel 1992; Niemi 2015; Paradise 1980; Paradise 1990; Rynnel-Dagoo 1978);
    - one study where participants had acute otitis media (Mattila 2003).
- Twelve studies where an intervention other than adenoidectomy was assessed. Some of these studies were relevant for other reviews in this suite (Ardehali 2008; Choung 2008; El Begermy 2022; Elkholy 2021; Marchisio 1998; Maw 1993; Maw 1999; NCT04584073; Popova 2010; Sujatha 2015; Tao 2020; Velepic 2011).
- Two studies with an incorrect comparator:
    - Le 1991, where concomitant treatments were not identical between the intervention and control groups.
    - NCT04302337, which compares two different techniques of adenoidectomy.

Risk of bias in included studies

All the studies included in this review had at least some concerns regarding the risk of bias. See Figure 3 for a summary of the risk of bias across all included studies, and Figure 4 for details of the risk of bias for individual studies.

Allocation

We rated only one study at low risk for this domain. TARGET provided sufficient description of the process used for randomisation and allocation concealment to have confidence that the risk of selection bias was low. The remaining studies either failed to provide any description of the randomisation procedure (other than to state that 'random' methods were used), or did not provide information on concealment of group allocation (or both).

Blinding

There was a risk of bias performance and detection bias for all the studies included, as no studies indicated that participants or study personnel were blinded to the intervention received. Most studies also provided no indication that outcome assessors were blinded to the intervention group, or we could be confident that outcome assessors were aware of the group allocation.

Incomplete outcome data

Five studies reported either complete follow-up, or had only a small amount of attrition (Fiellau-Nikolajsen 1982; Jabeen 2019; Luo 2007; Sagnelli 1990; Xu 2016). For some studies we noted higher rates of attrition, but were uncertain if this was substantial enough to impact the overall results (Dempster 1993; Maw 1983; TARGET). Hao 2019 did not report loss to follow-up in sufficient detail for us to judge if there was a risk of

bias for this domain. The study Gates 1989 had substantial attrition (33%), which we considered introduced a risk of bias to the results, although we note that features of those who dropped out were similar to those who completed follow-up.

Selective reporting

We rated three studies at low risk of selective reporting bias, as it appeared that all pre-specified outcomes were fully reported (Jabeen 2019; Maw 1983; TARGET). For many studies we did not have sufficient information to judge whether this was the case, therefore we rated this domain at unclear risk of bias (Dempster 1993; Fiellau-Nikolajsen 1982; Luo 2007; Sagnelli 1990; Xu 2016). Gates 1989 provided incomplete data for some outcomes (such as persistent perforation), and Hao 2019 did not report long-term follow-up data (despite carrying out follow-up for three years). We therefore rated these studies at high risk of selective reporting bias.

Other potential sources of bias

We rated two studies at high risk of other bias, due to very limited duration of follow-up, which may be insufficient to fully assess the effect of the intervention (Fiellau-Nikolajsen 1982; Jabeen 2019). We rated Hao 2019 at high risk due to the exclusion of children who did not complete full follow-up. We also rated TARGET at high risk, due to a failure of reporting economic and developmental outcomes (which were planned to be assessed). We rated the remaining studies at either low (Maw 1983) or unclear risk of bias for this domain (Dempster 1993; Gates 1989; Luo 2007; Sagnelli 1990; Xu 2016).

Effects of interventions

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting

We identified three studies for this comparison (Fiellau-Nikolajsen 1982; Gates 1989; Sagnelli 1990).

Hearing

No study reported the hearing threshold at specified follow-up times, although Sagnelli 1990 stated that "No differences were found in the audiometric thresholds" (quote from translation).

Proportion of children whose hearing has returned to normal

Fiellau-Nikolajsen 1982 reported a composite outcome measure, which assessed the number of children with "normal otomicroscopy and normal hearing at audiometry and tympanogram type A and presence of middle ear reflexes". A definition of normal hearing was not provided, and we note that this outcome may underestimate the number of participants with normal hearing (as additional participants may have normal hearing, but fail to meet the remaining three criteria). See Appendix 3 for further details on analysis of this outcome.

Up to three months

The proportion of children whose hearing had returned to normal was reduced in those who received adenoidectomy, but the confidence intervals were very wide (absolute effect 14% for those receiving adenoidectomy, compared to 25% for those receiving no treatment, risk ratio (RR) 0.55, 95% confidence interval (CI) 0.15 to 2.00; 1 study; 42 participants; Analysis 1.1; very low-certainty evidence).

Up to 12 months

There was little difference in the proportion of children whose hearing had returned to normal between those who received adenoidectomy and those who did not (absolute effect 68% for those receiving adenoidectomy, compared to 70% for those with no

treatment, RR 0.97, 95% CI 0.65 to 1.46; 1 study; 42 participants; Analysis 1.1; very low-certainty evidence).

Serious adverse event: haemorrhage

Only Gates 1989 reported on the number of children who experienced a postoperative haemorrhage. This was reported for all children undergoing adenoidectomy in the study (additional arms of this study considered adenoidectomy with bilateral ventilation tubes, and bilateral ventilation tubes alone - see Comparison 3). There was one occurrence of a postoperative haemorrhage in the group that received adenoidectomy, compared to no occurrences in the comparator group (1/251 compared to 0/229, Peto odds ratio (OR) 6.77, 95% CI 0.13 to 342.54; 1 study; 480 participants; Analysis 1.2; very low-certainty evidence).

Presence or persistence of OME

Up to three months

Fiellau-Nikolajsen 1982 and Sagnelli 1990 reported on tympanometry findings in the ears of affected children. Data were reported according to the ears affected (not the number of children). This does not account for the correlation between outcomes in two ears of the same individual, therefore we accounted for this in the analysis by adjusting the sample size accordingly (see Appendix 3 for details). At three months, slightly fewer children had ongoing effusion in the adenoidectomy group with a RR of 0.83 (95% CI 0.61 to 1.13, absolute effects 65% with persistent OME in the adenoidectomy group compared to 79% in the control group; 2 studies; 117 participants; I^2 = 40%; Analysis 1.3; low-certainty evidence). We conducted a sensitivity analysis to explore the impact of the sample size adjustment, analysing the data as if there was complete correlation between ears of the same individual (Analysis 1.4), and as if there was no correlation between ears (Analysis 1.5), but the effect on the estimates was very small.

Up to 12 months

At three months, slightly fewer children had ongoing effusion in the adenoidectomy group with a RR of 0.65 (95% CI 0.36 to 1.15, absolute effects 23% with persistent OME in the adenoidectomy group compared to 36% in the control group; 2 studies; 117 participants; I^2 = 0%; Analysis 1.3; very low-certainty evidence).

Over 12 months

Gates 1989 reported on the number of children who developed a recurrent effusion over the course of two years - these data appear to be cumulative (i.e. not specifically reporting the number with an effusion at exactly two years). Data were also reported using tympanometry findings by Fiellau-Nikolajsen 1982 and Sagnelli 1990. The risk of persistent OME was slightly lower in those receiving adenoidectomy, but the difference may be small (RR 0.90, 95% CI 0.81 to 1.00, absolute effects 65% with persistent OME in the adenoidectomy group compared to 73% in the control group; 3 studies; 354 participants; I^2 = 0%; Analysis 1.3; very low-certainty evidence).

Gates 1989 also reported on the proportion of follow-up time spent with an effusion, which was reduced in those who received adenoidectomy (mean difference (MD) -0.19, 95% CI -0.25 to -0.12; 1 study; 237 participants; Analysis 1.6; very low-certainty evidence). This approximates to a reduction of around 140 days (4.5 months) over the two-year follow-up period.

Number of doctor-diagnosed acute otitis media episodes within a specified time frame

Fiellau-Nikolajsen 1982 reported the mean number of episodes of otalgia experienced by children in each group over a six-month period. We considered that these episodes were likely to represent acute otitis media in this population of children, although acknowledge that this may not be certain. Those receiving adenoidectomy had 0.23 fewer episodes in a six-month period (95% CI from -0.71 fewer to 0.25 more; 1 study; 42 participants; Analysis 1.7; very low-certainty evidence).

Adverse events

Very little information was available regarding possible adverse effects of treatment. Fiellau-Nikolajsen 1982 and Sagnelli 1990 did not report on adverse events - we are unsure whether this was because none occurred, or simply because they were not reported.

Tympanic membrane perforation

Gates 1989 reported some information on persistent tympanic membrane perforation, but this was not reported according to the randomisation of adenoidectomy versus no adenoidectomy. Instead, they reported that 3/181 children who received myringotomy and 3/208 children who received ventilation tubes suffered from persistent tympanic membrane perforation.

Other aural complications

Gates 1989 also reported one occurrence of necrosis of the long process of the incus for a child who received ventilation tubes. Again, it was not specified whether this child received adenoidectomy or no adenoidectomy.

Other outcomes

We did not identify any evidence on the following outcomes: disease-specific quality of life, receptive or expressive language skills, cognitive development, psychosocial outcomes, listening skills, generic health-related quality of life, parental stress or vestibular function.

Comparison 2: Adenoidectomy (with or without myringotomy) versus non-surgical treatment

We did not identify any studies for this comparison.

Comparison 3: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only

We identified six studies for this comparison (Gates 1989; TARGET; Hao 2019; Jabeen 2019; Luo 2007; Xu 2016).

Hearing

Return to normal hearing

Up to 12 months

Luo 2007 reported on the return to normal hearing as part of a composite measure. The authors reported the proportion of children in whom OME was 'cured' - with a return to normal hearing (speech frequency hearing range on pure tone audiometry of 0 to 25 dB HL), type-A tympanogram and resolution of symptoms. We acknowledge that this may not be an accurate estimate of effect - partly as children with PTA results of 25 dB HL may not be regarded as having 'normal hearing' (our protocol required a hearing threshold of < 20 dB HL), but also because children with normal hearing despite abnormal tympanometry results would not be included. These data were analysed at the level of the individual ear, rather than the child (see Appendix 3 for details). There was a slight increase in the proportion of ears with a return to normal hearing for those who received adenoidectomy (57% compared to 42%, RR 1.36, 95% CI 0.98 to 1.89; 1 study; 127 participants (213 ears); Analysis 2.1; very low-certainty evidence). Adjusting for the correlation between ears of the same individual with different correlation coefficients made little difference to the estimates (see Analysis 2.5; Analysis 2.6).

Final hearing threshold

Two studies reported information on final hearing threshold (Hao 2019; TARGET).

Up to three months

The mean difference in final hearing threshold was -0.79 (95% CI -1.99 to 0.41; 2 studies; 409 participants; I^2 = 0%; Analysis 2.2; very low-certainty evidence).

Up to 12 months

The mean difference in final hearing threshold was -2.18 (95% CI -5.25 to 0.88; 2 studies; 405 participants; I^2 = 78%; Analysis 2.2; very low-certainty evidence). There was considerable heterogeneity in this analysis, but the effect direction was similar for both studies, and the difference between the groups is likely to be trivial.

Over 12 months

The mean difference in final hearing threshold was -3.90 (95% CI -6.12 to -1.68; 1 study; 217 participants; Analysis 2.2; very low-certainty evidence).

Serious adverse event: haemorrhage

As described above, Gates 1989 provided some data on the incidence of haemorrhage following adenoidectomy for all participants in this study. TARGET also reported the occurrence of one postoperative haemorrhage following adenoidectomy. This gives an absolute risk of 2/416 in those who received adenoidectomy compared to 0/375 in the control group (Peto OR 6.68, 95% CI 0.42 to 107.18; 2 studies; 791 participants; very low-certainty evidence).

Presence or persistence of OME

Four studies provided data for this outcome (Gates 1989; Hao 2019; Jabeen 2019; Luo 2007).

Up to three months

Jabeen 2019 reported a considerable reduction in the number of children with persistent OME for those who received adenoidectomy (absolute effect 10% in children receiving adenoidectomy compared to 70% in children receiving ventilation tubes alone, RR 0.14, 95% CI 0.06 to 0.37; 1 study; 80 participants; Analysis 2.3; very low-certainty evidence).

Up to 12 months

Hao 2019 and Luo 2007 used a composite outcome score to assess the number of participants who did not have complete disappearance of symptoms and middle ear effusion, and recovery of hearing. This may over-estimate the number of participants with persistent OME, as children with persisting hearing problems or other symptoms are also included. However, we assumed that it was likely that this was a reasonable estimate of those with persistent OME. The risk of persistence was similar between those who received and did not receive adenoidectomy (absolute effect 45% in those with adenoidectomy compared to 55% in the control group, RR 0.81 95% CI 0.63 to 1.05; 2 studies; 311 participants; Analysis 2.3; very low-certainty evidence).

Over 12 months

As described above, Gates 1989 reported on the number of children who developed a recurrent effusion over the course of two years - these data appear to be cumulative (i.e. not specifically reporting the number with an effusion at exactly two years). The risk of recurrent effusion was slightly lower in those receiving adenoidectomy, but the difference may be small (82% compared to 85%, RR 0.96, 95% CI 0.86 to 1.07, very low-certainty evidence). Gates 1989 also reported on the proportion of follow-up time spent with an effusion, which was reduced in those who received adenoidectomy (MD -0.09, 95% CI -0.15 to -0.04). This approximates to a reduction of around 66 days (two months) over the two-year follow-up period.

Adverse events

Four studies did not provide any information regarding adverse events (Hao 2019; Jabeen 2019; Luo 2007; Xu 2016).

Gates 1989 reported a small amount of information on tympanic membrane perforation and other aural complications - these are reported above, under Comparison 1.

TARGET only reported adverse events according to the receipt of ventilation tubes or no ventilation tubes, not according to treatment with adenoidectomy. These data were also reported using a per protocol analysis, rather than on an intention-to-treat basis. For completeness, we include the data here. Of 635 ears that had a ventilation tube inserted, eight had a persistent perforation for at least six months after any surgery. Subsequent record search showed that in the four who attended a post visit 7 appointment, all had healed. Similarly, six of seven perforations recorded at visits 5 or 6 and that could be checked at a subsequent visit had resolved. Lasting perforations are therefore rare but at worst there could be as many as 0.8% (5/635). Tympanosclerosis was seen in 20% (128 of 635) ears where a ventilation tube was inserted versus none in un-operated ears.

Comparison 4: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only

We identified two studies for this comparison (Dempster 1993; Maw 1983). Where relevant, we assessed outcomes for the un-operated ear (i.e. the ear without the ventilation tube).

Hearing

Return to normal hearing

Up to 12 months

Dempster 1993 reported the number of children in whom hearing returned to normal (classed as < 15 dB HL). Slightly more children experienced a return to normal hearing in the group who received adenoidectomy (57% compared to 46%, RR 1.24, 95% CI 0.79 to 1.96; 1 study; 72 participants; Analysis 3.1; very low-certainty evidence). As our protocol specified normal hearing as ≤ 20 dB HL, we conducted a sensitivity analysis to see if the effect estimate changed using the next band of hearing provided by the authors (< 25 dB HL). The beneficial effect was still present, but the effect size was reduced (RR 1.05, 95% CI 0.83 to 1.33; Analysis 3.1).

Hearing threshold

Up to 12 months

Both studies reported either the final hearing threshold, or the change in hearing threshold at up to 12 months. The mean difference in hearing threshold for those with adenoidectomy was -5.36 (95% CI -10.16 to -0.56; 2 studies; 154 participants; I^2 = 44%; Analysis 3.2; very low-certainty evidence).

Presence or persistence of OME

Both studies provided data for this outcome.

Up to three months

Maw 1983 reported that fewer children receiving adenoidectomy had persistence or presence of OME at three months follow-up (48% compared to 82%, RR 0.58, 95% CI 0.38 to 0.91; 1 study; 53 participants; Analysis 3.3; very low-certainty evidence).

Up to 12 months

Both studies reported at this time point. The RR for presence or persistence of OME in those receiving adenoidectomy was 0.57 (95% CI 0.38 to 0.86, 43% compared to 75%; 2 studies; 189 participants; Analysis 3.3; very low-certainty evidence). We included OME as assessed by tympanometry from Dempster 1993. However, inclusion of data as assessed otoscopically made little difference to the results (RR 0.58, 95% CI 0.37 to 0.89).

Over 12 months

Maw 1983 reported that fewer children receiving adenoidectomy had persistence or presence of OME at 12 months follow-up (27% compared to 41%, RR 0.67, 95% CI 0.35 to 1.29; 1 study; 74 participants; Analysis 3.3; very low-certainty evidence).

Other adverse events

Maw 1983 did not report on adverse events.

Dempster 1993 found the risk ratio for tympanosclerosis in those receiving adenoidectomy (and a unilateral ventilation tube) was 1.34 (95% CI 0.75 to 2.39; 46% in adenoidectomy plus unilateral ventilation tubes versus 34% unilateral ventilation tube only; 1 study; 72 participants; Analysis 3.4; very low-certainty evidence).

Dempster 1993 also reported persistent perforation/retraction. At 12 months, the risk ratio for perforation/retraction for those undergoing adenoidectomy plus ventilation tube insertion was 1.89 (95% CI 0.37 to 9.69; 1 study; 72 participants; Analysis 3.5; very low-certainty evidence).

Comparison 5: Adenoidectomy and ventilation tubes versus no treatment/watchful waiting

We identified two studies with data for this comparison. Both studies also provided data for other comparisons (described above, Comparisons 1 and 3). It should be noted that the study Gates 1989 compared adenoidectomy and ventilation tubes to myringotomy. For the purposes of this analysis we have assumed this is equivalent to no intervention. TARGET compared adenoidectomy and ventilation tubes to watchful waiting. However, it should be noted that 57% of children in the watchful waiting group subsequently received surgery (either ventilation tubes alone or ventilation tubes plus adenoidectomy) during the course of the two-year follow-up.

Hearing

Hearing threshold

Up to three months

TARGET reported the hearing threshold at three months. The mean difference was -12.70 in favour of adenoidectomy (95% CI -14.88 to -10.52; 1 study; 222 participants; Analysis 4.1; very low-certainty evidence).

Up to 12 months

At 12 months the mean difference was -3.40 in favour of adenoidectomy (95% CI -6.00 to -0.80; 1 study; 211 participants; Analysis 4.1; very low-certainty evidence).

Over 12 months

At 24 months the mean difference was also -3.40 in favour of adenoidectomy (95% CI -5.54 to -1.26; 1 study; 211 participants; Analysis 4.1; very low-certainty evidence).

Presence or persistence of OME

One study provided data for this outcome (Gates 1989).

Over 12 months

As described above, Gates 1989 reported on the number of children who developed a recurrent effusion over the course of two years - these data appear to be cumulative (i.e. not specifically reporting the number with an effusion at exactly two years). The risk of recurrent effusion was slightly lower in those receiving adenoidectomy, but the difference may be small (82% compared to 90%, RR 0.91, 95% CI 0.82 to 1.01; 1 study; 232 participants; Analysis 4.2; very low-certainty evidence). Gates 1989 also reported on the proportion of follow-up time spent with an effusion, which was reduced in those who received adenoidectomy (MD -0.23, 95% CI -0.29 to -0.17; Analysis 4.3; very low-certainty evidence). This approximates to a reduction of around 168 days (5.4 months) over the two-year follow-up period.

Other adverse events

Other adverse events reported by Gates 1989 and TARGET are described above (under Comparisons 1 and 3).

Comparison 6: Adenoidectomy and ventilation tubes versus non-surgical treatment

We did not identify any studies for this comparison.

Discussion

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting

The effect of adenoidectomy on the return to normal hearing was very uncertain, and we did not identify any data on the final hearing threshold for children who had undergone adenoidectomy. We did not identify any data on disease-specific quality of life. There is a chance of haemorrhage from adenoidectomy, but the absolute risk of this is likely to be small, and the evidence was very uncertain. Adenoidectomy may have a small beneficial effect on the resolution of OME - fewer children who received adenoidectomy had persistent effusion at up to three months (low-certainty evidence) and up to 12 months of follow-up (very low-certainty evidence). The effect of adenoidectomy on acute otitis media was very uncertain.

Comparison 2: Adenoidectomy (with or without myringotomy) versus non-surgical treatment

We did not identify any studies for this comparison.

Comparison 3: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only

All the evidence for this comparison was very low-certainty. There was a slight increase in the proportion of ears with return to normal hearing after six to nine months of follow-up, but very little difference in mean hearing threshold (after 3, 12 and 24 months). There is risk of haemorrhage from adenoidectomy, but the absolute risk of this may be small, although the evidence was very uncertain. At three months there may be a reduction in persistent OME for those receiving adenoidectomy, but this effect was not seen after longer-term follow-up (12 months and two years), when there was a trivial difference between the groups.

Comparison 4: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only

All the evidence for this comparison was very low-certainty. There was a slight increase in the proportion of ears with return to normal hearing after 12 months of follow-up, but little difference in mean hearing threshold (after 12 months). Fewer children who received adenoidectomy had a persistent effusion at up to 3 months, 12 months and 3 years of follow-up, but the evidence was all very uncertain.

Comparison 5: Adenoidectomy and ventilation tubes versus no treatment/watchful waiting

At up to three months there may be an improvement in mean hearing threshold for those who received adenoidectomy plus ventilation tubes, but the evidence was very uncertain.

This effect was much smaller after one and two years of follow-up, but it should be noted that many children in the control group had also received surgery by this time. There may be a small reduction in the proportion of children with persistent OME after two years of follow-up, but again the evidence was uncertain and the difference may not be large.

Comparison 6: Adenoidectomy and ventilation tubes versus non-surgical treatment

We did not identify any studies for this comparison.

Overall completeness and applicability of evidence

In keeping with other reviews in this suite, we noted that very few studies reported our preferred outcome measure for hearing - the number of children who returned to normal hearing. We have concerns that assessment of hearing using the mean difference in final hearing threshold (or mean change in hearing threshold) may not be the most appropriate way to assess hearing. OME has a high spontaneous resolution rate. Consequently, we would anticipate that the change in hearing threshold for most children will be similar across the groups, as many children will improve with or without treatment. Therefore, even if a subset of children had substantial benefit from the intervention, the overall mean difference between the two groups would appear to be small. When assessed using the mean difference, the marked benefit seen in a subgroup of participants is ‘diluted’ by the children who get better regardless of treatment. Therefore, an apparently small mean difference between the two groups may actually be consistent with a substantial change in the number of children in whom hearing returns to normal.

It is difficult to interpret the data from some of the studies included in this review, due to the high level of cross-over between the allocated groups. For example, when comparing adenoidectomy and ventilation tubes to watchful waiting (Comparison 5) we noted that 57% of children allocated to watchful waiting in the TARGET study actually received surgery during the follow-up period. It is perhaps unsurprising then that the apparent beneficial effect of surgery on hearing seen after three months disappears after longer-term follow-up.

The results of this review should be assessed in conjunction with those of the companion review regarding the use of ventilation tubes for OME. It is possible that there are synergistic effects of ventilation tubes and adenoidectomy when treating OME.

Quality of the evidence

We considered most of the evidence included in this review very low-certainty. This was predominantly due to concerns over the risk of bias in the studies included, particularly the risk of performance and detection bias. However, many studies also had unclear ratings for the risk of selection bias, attrition bias or reporting bias. In addition, many of the studies included relatively few participants, which led to wide confidence intervals and imprecision in the overall effect estimates.

Potential biases in the review process

We have attempted to minimise the potential for bias during the review process by adhering to the *Cochrane Handbook for Systematic Reviews of Interventions* throughout the conduct of this review. We conducted comprehensive searches, and ensured that study selection, data extraction and GRADE assessment were carried out by at least two independent authors, to ensure reproducibility of findings.

Agreements and disagreements with other studies or reviews

The results of this review are largely in keeping with the previous Cochrane Review on this topic (van den Aardweg 2010), which identified a beneficial effect of adenoidectomy on the resolution of OME, but no evidence of a benefit to hearing. However, there are some differences in the conduct of the two reviews. Our protocol specified that we would only include studies where children had a duration of OME of at least three months. In addition, we focused on children with OME and not recurrent acute otitis media. This resulted in the exclusion of some studies that were included in the previous Cochrane Review. In accordance with current Cochrane standards we have now used the GRADE approach to assess the certainty of the evidence; the previous Cochrane review on this topic pre-dated the GRADE criteria. This approach means that our conclusions appear less certain than the previous review, but it should be noted that the evidence has not changed, it is simply that we are looking at the data with a new approach.

Authors' conclusions

Implications for practice

Evidence on the proportion of children whose hearing returns to normal, our preferred outcome measure for hearing, was scarce. However, adenoidectomy may slightly reduce the persistence of otitis media with effusion (OME), when used either alone or in addition to ventilation tubes.

We did not identify any data on behavioural, psychosocial and developmental outcomes, and evidence on adverse effects of treatment was sparse. It should be recognised that there are risks associated with any surgical procedure, and these should be carefully considered when contemplating the use of adenoidectomy for OME.

Implications for research

This review forms part of a suite of five reviews that consider intervention for OME (Galbraith 2022; MacKeith 2022a; MacKeith 2022b; Mulvaney 2022; Mulvaney 2022a). Here we present implications for research in this field which are shared across the suite of reviews:

1. As OME is a fluctuating condition with high rates of resolution and recurrence, and a highly variable impact on children, clinical trials (and, in particular, randomised controlled trials) may not be the research design of choice. Instead, evidence may be better obtained from surgical or clinical registries (for example, see Schmalbach 2021) or prospective cohort studies, with the use of 'big data'. These data sets may also be used to help identify subgroups of children who are at greater risk of persistent disease or long-term consequences of OME. A clearer understanding of possible subgroups of children is needed to better target interventions to those who need them most, whilst avoiding over-treatment for those in whom spontaneous resolution is anticipated.
2. Adverse effects of interventions are important and should always be assessed. However, randomised controlled trials are also not the best method to consider these, especially when events are rare. Observational studies with longer follow-up and larger numbers of participants are needed to provide more robust evidence on the frequency of side effects.
3. It is encouraging that a core outcome set has been developed in this field (Bruce 2015; Liu 2020). Guidance on *how* to measure the different outcomes would also be helpful for future research.
4. Comparison of mean hearing thresholds is widely used in research to assess the impact of different interventions on hearing. However, this outcome measure risks underestimating the potential impact of interventions on hearing. Small changes in mean hearing thresholds may be consistent with a substantial improvement in the number of children whose hearing returns to normal, particularly in a condition with a high spontaneous resolution rate. We would encourage researchers to assess hearing with the proportion of children in whom hearing returns to normal, in preference to mean hearing thresholds.

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Data and analyses

Comparison 1

Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Hearing: proportion with normal hearing	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1.1 Up to 3 months	1	42	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.15, 2.00]
1.1.2 Up to 12 months	1	42	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.65, 1.46]
1.2 Haemorrhage	1	480	Peto Odds Ratio (Peto, Fixed, 95% CI)	6.77 [0.13, 342.54]
1.3 Presence or persistence of OME	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.3.1 Up to 3 months	2	117	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.61, 1.13]
1.3.2 Up to 12 months	2	117	Risk Ratio (M-	0.65 [0.36, 1.15]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
			H, Random, 95% CI)	
1.3.3 Over 12 months	3	354	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.81, 1.00]
1.4 SENSITIVITY ANALYSIS: Presence or persistence of OME (complete correlation between ears)	3	501	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.81, 0.98]
1.4.1 Up to 3 months	2	88	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.64, 1.18]
1.4.2 Up to 12 months	2	88	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.33, 1.24]
1.4.3 Over 12 months	3	325	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.82, 1.00]
1.5 SENSITIVITY ANALYSIS: Presence or persistence of OME (no correlation between ears)	3	765	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.81, 0.96]
1.5.1 Up to 3 months	2	176	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.63, 1.09]
1.5.2 Up to 12 months	2	176	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.43, 1.10]
1.5.3 Over 12 months	3	413	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.81, 0.99]
1.6 Time with effusion	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
1.6.1 Over 12 months	1		Mean Difference (IV, Random, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
1.7 Number of episodes of AOM over 6 months	1		Mean Difference (IV, Random, 95% CI)	Subtotals only	

Comparison 2

Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Return to normal hearing	1	160	Risk Ratio (M-H, Random, 95% CI)	1.36 [0.98, 1.89]
2.2 Hearing: hearing threshold	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.2.1 Up to 3 months	2	409	Mean Difference (IV, Random, 95% CI)	-0.79 [-1.99, 0.41]
2.2.2 Up to 12 months	2	405	Mean Difference (IV, Random, 95% CI)	-2.18 [-5.25, 0.88]
2.2.3 Over 12 months	1	217	Mean Difference (IV, Random, 95% CI)	-3.90 [-6.12, -1.68]
2.3 Presence/persistence of OME	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.3.1 Up to 3 months	1	80	Risk Ratio (M-H, Random, 95% CI)	0.14 [0.06, 0.37]
2.3.2 Up to 12 months	2	344	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.63, 1.05]
2.3.3 Over 12 months	1	254	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.86, 1.07]
2.4 Time with effusion	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2.4.1 Over 12 months	1		Mean Difference (IV,	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
			Random, 95% CI)		
2.5 SENSITIVITY ANALYSIS: Return to normal hearing ICC 0	1	213	Risk Ratio (M-H, Random, 95% CI)	1.40 [1.06, 1.86]	
2.6 SENSITIVITY ANALYSIS: Return to normal hearing ICC 1	1	128	Risk Ratio (M-H, Random, 95% CI)	1.43 [0.99, 2.06]	
2.7 SENSITIVITY ANALYSIS: Presence/persistence of OME ICC 0	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only	
2.7.1 Up to 3 months	1	80	Risk Ratio (M-H, Random, 95% CI)	0.14 [0.06, 0.37]	
2.7.2 Up to 12 months	2	397	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.64, 1.02]	
2.7.3 Over 12 months	1	254	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.86, 1.07]	
2.8 SENSITIVITY ANALYSIS: Presence/persistence of OME ICC 1	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only	
2.8.1 Up to 3 months	1	80	Risk Ratio (M-H, Random, 95% CI)	0.14 [0.06, 0.37]	
2.8.2 Up to 12 months	2	312	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.64, 1.05]	
2.8.3 Over 12 months	1	254	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.86, 1.07]	
2.9 Haemorrhage	2	791	Peto Odds Ratio (Peto, Fixed, 95% CI)	6.68 [0.42, 107.18]	

Comparison 3

Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
3.1 Hearing: proportion of children with hearing returned to normal (medium-term)	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only	
3.1.1 Normal hearing ≤15 dB.	1	72	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.79, 1.96]	
3.1.2 SENSITIVITY ANALYSIS: Normal hearing < 25 dB.	1	72	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.83, 1.33]	
3.2 Hearing: Hearing threshold	2	154	Mean Difference (IV, Random, 95% CI)	-5.36 [-10.16, -0.56]	
3.2.1 Up to 12 months	2	154	Mean Difference (IV, Random, 95% CI)	-5.36 [-10.16, -0.56]	
3.3 Presence or persistence of OME	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only	
3.3.1 Up to 3 months	1	53	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.38, 0.91]	
3.3.2 Up to 12 months. Dempster data from tympanometry	2	189	Risk Ratio (M-H, Random, 95% CI)	0.57 [0.38, 0.86]	
3.3.3 Over 12 months	1	74	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.35, 1.29]	
3.3.4 SENSITIVITY ANALYSIS: Up to 12 months. Dempster data from otoscopy	2	189	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.37, 0.89]	
3.4 Adverse events: tympanosclerosis	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected	
3.5 Adverse events: perforation/retraction	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected	

Comparison 4

Adenoidectomy and ventilation tubes versus no treatment/watchful waiting

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
4.1 Hearing: hearing threshold	1		Mean Difference (IV, Random, 95% CI)	Totals not selected	
4.1.1 Up to 3 months	1		Mean Difference (IV, Random, 95% CI)	Totals not selected	
4.1.2 Up to 12 months	1		Mean Difference (IV, Random, 95% CI)	Totals not selected	
4.1.3 Over 12 months	1		Mean Difference (IV, Random, 95% CI)	Totals not selected	
4.2 Presence/persistence of OME	1	232	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.82, 1.01]	
4.2.1 Over 12 months	1	232	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.82, 1.01]	
4.3 Time with effusion	1		Mean Difference (IV, Random, 95% CI)	Totals not selected	
4.3.1 Over 12 months	1		Mean Difference (IV, Random, 95% CI)	Totals not selected	

History

Protocol first published: Issue 4, 2022

Contributions of authors

Samuel MacKeith: drafted the protocol. Screened the search results and selected studies. Reviewed the analyses and reviewed and edited the text of the review.

Caroline A Mulvaney: drafted the protocol. Screened the search results and selected studies, conducted data extraction, carried out statistical analyses and GRADE assessment. Drafted the text of the review.

Kevin Galbraith: drafted the protocol. Screened the search results and selected studies, conducted data extraction, carried out statistical analyses and GRADE assessment. Drafted the text of the review.

Katie Webster: screened the search results and selected studies, conducted data extraction and carried out statistical analyses. Drafted the text of the review.

Aye Paing: conducted data extraction. Reviewed the analyses and reviewed and edited the text of the review.

Rachel Connolly: conducted data extraction. Reviewed the analyses and reviewed and edited the text of the review.

Tal Marom: reviewed the protocol. Reviewed the analyses and reviewed and edited the text of the review.

Mat Daniel: reviewed the protocol. Reviewed the analyses and reviewed and edited the text of the review.

Roderick P Venekamp: co-wrote and edited the protocol. Reviewed the analyses and reviewed and edited the text of the review.

Anne GM Schilder: co-wrote and edited the protocol. Reviewed the analyses and reviewed and edited the text of the review.

Editorial and peer reviewer contributions

[To be completed after peer review/sign-off] Cochrane ENT supported the authors in the development of this review.

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): [NAME, AFFILIATION];
- Managing Editor (selected peer reviewers, collated peer reviewer comments, provided editorial guidance to authors, edited the article): [NAME, AFFILIATION];
- Copy Editor (copy editing and production): [NAME, AFFILIATION];
- Peer reviewers (provided comments and recommended an editorial decision): [NAME, AFFILIATION] (clinical/content review)*, [NAME, AFFILIATION] (consumer review), [NAME, AFFILIATION] (methods review), [NAME, AFFILIATION] (search review). [NUMBER] of additional peer reviewers provided [CLINICAL/CONTENT/CONSUMER/METHODS/SEARCH] peer review, but chose not to be publicly acknowledged.

Declarations of interest

Samuel MacKeith: treats patients with OME in his NHS and private practice and is Assistant Co-ordinating Editor of Cochrane ENT but was not involved in the editorial process for this review.

Caroline A Mulvaney: none known.

Kevin Galbraith: none known.

Katie Webster: none known.

Aye Paing: none known.

Rachel Connolly: none known.

Tal Marom: none known.

Mat Daniel: has a financial interest in Aventamed, a company that produces a ventilation tube insertion device.

Roderick P Venekamp: is an Editor for Cochrane Acute Respiratory Infections and Cochrane ENT, but had no role in the editorial process for this protocol.

Anne GM Schilder: Professor Anne Schilder was joint Co-ordinating Editor of Cochrane ENT until April 2020, but had no role in the editorial process for this protocol. Her evidENT team at the UCL Ear Institute is supported by the National Institute of Health Research (NIHR) University College London Hospitals (UCLH) Biomedical Research Centre (BRC), with research projects being supported by the NIHR, Wellcome Trust, RNiD, ENT UK and industry. She is the National Specialty Lead for the NIHR Clinical Research Network ENT and Surgical Specialty Lead for ENT for the Royal College of Surgeons of England's Clinical Research Initiative. In her role as director of the NIHR

UCLH BRC Deafness and Hearing Problems Theme, she advises CRO, biotech and pharma companies in the hearing field on clinical trial design and delivery.

Sources of support

Internal sources

- No sources of support provided

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Differences between protocol and review

In our protocol we planned to use the Trustworthiness Tool developed by Cochrane Pregnancy and Childbirth to determine which studies would be included in the main analyses (MacKeith 2022b). As described in the text, we used this tool to assess the studies, but did not use it to determine whether a study should be included in the main analysis.

Characteristics of studies

Characteristics of included studies [ordered by study ID]

Dempster 1993

Study characteristics	
Methods	Four-arm, parallel group RCT with 12 months of follow-up. Randomisation by child for adenoidectomy. Then randomisation by ear for VT, i.e. all children received a ventilation tube in one ear; half of the children received adenoidectomy. The comparison of interest in this review is: • Adenoidectomy and unilateral ventilation tube insertion versus unilateral ventilation tubes only

Participants	**Setting:**
	Single centre study from Glasgow, UK.
	Sample size:
	• **Number randomised:** 78 participants total
	• **Number completed:** 72 participants total
	Participant (baseline) characteristics:
	• **Age:**
	  ◦ Adenoidectomy group: mean 5.9 years (SD 1.4)
	  ◦ No adenoidectomy group: mean 5.7 years (SD 1.2)
	• **Gender:**
	  ◦ Adenoidectomy group: 17 male: 20 female
	  ◦ No adenoidectomy group: 23 male: 12 female
	• **Hearing threshold, mean (SD):**
	  ◦ Adenoidectomy group
	  ▪ ear with VT inserted: 31.4 (9.1) dB HL
	  ▪ ear without VT: 32.4 (9.3) dB HL

	◦ No adenoidectomy group: ▪ ear with VT inserted: 33.0 (6.7) dB HL ▪ ear without VT: 32.4 (7.1) dB HL **Inclusion criteria:** Children aged between 3.5 and 12 years with otoscopic evidence of bilateral OME that satisfied the following criteria on 2 assessments 12 weeks apart: • Pure tone air conduction thresholds average over 0.5, 1 and 2 kHz of ≥ 25 dB HL • Air-bone gap over 0.5, 1 and 2 kHz of ≥ 15 dB • Type B tympanogram **Exclusion criteria:** • Previous adenoidectomy or aural surgery • Additional symptoms requiring surgical interventions e.g. recurrent sore throat • Cleft palate
Interventions	**Intervention:** Adenoidectomy with unilateral VT n=37 **Comparator:** No adenoidectomy with unilateral VT n=35
Outcomes	**Primary outcomes relevant to this review:** • **Hearing** ◦ Proportion of ears with hearing returned to normal ◦ Mean final hearing threshold (air conduction and air-bone gap) ◦ Mean change in hearing threshold • **Disease-specific quality of life** ◦ Not reported • **Adverse event** ◦ Haemorrhage **Secondary outcomes relevant to this review:** • **Presence/persistence of OME: proportion of children with persistence of OME** ◦ Proportion of ears with persistence of OME (otoscopy and tympanometry) • **Other adverse effects** ◦ Proportion of ears with perforation/retraction ◦ Proportion of ears with tympanosclerosis
Funding sources	No details given.
Declarations of interest	No details given.
Notes	Research integrity checklist: • No retractions or expressions of concern were identified • Trial was published prior to 2010, therefore prospective registration was not required. • Baseline characteristics are not excessively similar across the groups. • Plausible loss-to-follow-up was reported. • No implausible results were identified. • Different numbers of participants were randomised to each group.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	No details provided on how allocation sequence was generated.
Allocation concealment (selection bias)	Low risk	"These 78 children were then admitted to hospital within ten days and randomly allocated by a serially numbered envelope system..."
Blinding of participants and personnel (performance bias) All outcomes	High risk	No information provided on blinding of participants and personnel. There is a strong possibility that participants and personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	“At six and 12 months post-surgery, the presence or absence of otitis media in the non-grommeted ear was record by the validated otoscopist who was blind as to whether adenoidectomy had been performed and by tympanometry.” There was no report of blinding for either tympanometric or audiometric assessment. The outcomes are not sufficiently objective to discount the possibility of ascertainment bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Six children defaulted either at the six or 12 month assessment visits, leaving 72 (92 per cent) children with complete clinical, audiometric and tympanometric data for the pre-operative and these post-operative visits." Six of the 78 (8%) randomised children were lost to follow-up. The distribution of those six across groups is not reported. Precise reasons for losses to follow-up were not reported. It is therefore difficult to judge the potential for attrition bias.
Selective reporting (reporting bias)	Unclear risk	No protocol or trial registration was found. The published paper reports all expected outcomes.
Other bias	Unclear risk	It is unclear whether (for VT versus no treatment) comparisons were made within each individual child. The data are presented as if comparisons were made at whole trial arm level, as in a parallel group trial. There could therefore be a unit of analysis error, which could result in spuriously wide confidence intervals.

Fiellau-Nikolajsen 1982

Study characteristics	
Methods	Parallel group RCT with up to 21 months of follow-up. Randomisation by child. Comparison of interest: • adenoidectomy plus myringotomy versus myringotomy alone

Participants	**Setting:**
	Single centre study from Denmark.
	Sample size:
	• **Number randomised:** 45 participants
	• **Number completed:** 42 participants
	Participant (baseline) characteristics:
	• **Age:**
	  ◦ Adenoidectomy group: mean 47.4 months (no SD)
	  ◦ No treatment group: mean 47.7 months (no SD)
	• **Gender:**
	  ◦ Adenoidectomy group:
	  ▪ 8 males
	  ▪ 12 females
	  ◦ Myringotomy group:
	  ▪ 13 males
	  ▪ 9 females
	Inclusion criteria:

	Children with abnormal tympanometry, i.e. a flat curve (type B tympanogram) or a middle ear pressure ≤ - 100 mm H20 (type C tympanogram) at all four tests in Aug 1978, Sep 1978, Nov 1978 and Feb 1979. **Exclusion criteria:** Not reported.
Interventions	**Intervention** Adenoidectomy and myringotomy n=20 **Comparator** Myringotomy alone n= 22

Outcomes	**Primary outcomes relevant to this review:**
	• **Hearing**
	  ◦ Proportion of hearing returned to normal (composite outcome of normal hearing at audiometry, type A tympanogram, normal otomicroscopy and presence of middle ear reflexes) at 3, 6, and 21 months
	• **Disease-specific quality of life**
	  ◦ Not reported
	• **Adverse event**
	  ◦ Not reported
	Secondary outcomes relevant to this review:
	• **Presence/persistence of OME: proportion of children with persistence of OME**
	  ◦ Number of children who did not have a type A tympanogram at 3, 6 and 21 months.
	• **Other adverse effects**
	  ◦ Not reported
	• **Episodes of acute otitis media**
	  ◦ Number of episodes over 6 months follow-up.

Funding sources	"This study was supported by the Danish Medical Research Council, grants 512-10525, 512- I5724, and 522-911."
Declarations of interest	None declared.
Notes	**Research integrity checklist:** • No retractions or expressions of concern were identified • Study was published prior to 2010, therefore prospective registration not required. • Baseline characteristics were not excessively similar. • Plausible loss-to-follow-up was reported. • No implausible results were identified. • Different numbers were allocated to each group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“Twenty children had myringotomy with adenoidectomy and 22 children myringotomy without adenoidectomy, decided by blind, random allocation (sealed envelopes). The envelopes, which contained an equal number of cards with and without the word “adenoidectomy” were randomly allotted to the children prior to the operation…” The allocation sequence is described as random, but the precise process was not reported: There is no mention of stratification or minimisation, but the possibility that such methods might have been employed is raised by the statement that “Our series was fairly modest in size, owing to the demands made on controlling variables such as age, race, domicile, season, and duration of pathology.” However, given the description of

		treatment allocation, this more likely refers to initial recruitment prior to randomisation.
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes were used, but there is no report of sequential numbering, or other methods of ensuring concealment such as opacity of the envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No information provided on blinding of participants and personnel. It is not possible to blind surgeons. There is a strong possibility that participants and personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of 44 children undergoing treatment, 42 (95%) completed follow-up.
Selective reporting (reporting bias)	Unclear risk	“All 42 were followed up by impedance audiometry, pure tone audiometry, and otomicroscopy 1 month, 3 months and 6 months postoperatively. This systematic and purely observational follow-up examinations were discontinued after the 6-month test in August 1979, but all 42 children had long-term follow-up in November 1980, twenty-one months after surgery". It is unclear which data were collected 21 months post-operatively. It is evident that some data were collected because tympanogram types are reported at that time-point.
Other bias	High risk	The length of follow-up (maximum 6 months) with full data was brief, and could lead to detection bias.

Gates 1989

Study characteristics	
Methods	Parallel group RCT with 2 years of follow-up Randomisation by child. Comparisons of interest for this review are: • Adenoidectomy plus myringotomy versus myringotomy alone • Adenoidectomy plus bilateral ventilation tubes versus bilateral ventilation tubes alone

Participants	**Setting:**
	Multicentre study, conducted in the USA.
	Sample size:
	• **Number randomised:** 578 participants
	• **Number completed:** 389 participants
	Participant (baseline) characteristics:
	• **Age: reported as proportion of children aged 4.5 to 6 years**
	  ◦ Adenoidectomy plus ventilation tubes: 74%
	  ◦ Adenoidectomy plus myringotomy: 73%
	  ◦ Ventilation tubes: 69%
	  ◦ Myringotomy: 69%
	• **Gender: reported as proportion male**
	  ◦ Adenoidectomy plus ventilation tubes: 58%
	  ◦ Adenoidectomy plus myringotomy: 59%
	  ◦ Ventilation tubes: 58%
	  ◦ Myringotomy: 61%
	• **Proportion with bilateral disease**
	  ◦ Adenoidectomy plus ventilation tubes: 58%
	  ◦ Adenoidectomy plus myringotomy: 57%

	◦ Ventilation tubes: 64% ◦ Myringotomy: 68% **Inclusion criteria:** Children aged 4-8 years with persistent fluid in the middle ear for 60 days after a 10-day course of erythromycin ethyl succinate and sulfisoxazole, and a 30-day course of pseudoephedrine hydrochloride. **Exclusion criteria:** Otologic conditions other than OME and advanced or irreversible changes of the tympanum (e.g., perforation, cholesteatoma, or atelectasis)
Interventions	**Intervention A** Adenoidectomy + myringotomy = 151 **Comparator** Myringotomy =127 **Intervention B** Adenoidectomy + VT = 150 **Comparator** VT = 150
Outcomes	**Primary outcomes relevant to this review:** • **Hearing** ◦ Only assessed as the proportion of time with any hearing loss. The number of visits in which a child had a hearing threshold of ≥20 dB, (using the three-frequency, pure-tone average) was divided by the number of visits made, and weighted for the number of visits made. This proportion was determined for each child and averaged for each group. These data were not included in the review. • **Disease-specific quality of life** ◦ Not reported • **Adverse event** ◦ Haemorrhage **Secondary outcomes relevant to this review:** • **Presence/persistence of OME: proportion of children with persistence of OME** ◦ Persistence was determined using an algorithm based on otoscopy and tympanometry. Also reported as the proportion of time with an effusion. • **Other adverse effects** ◦ Not reported
Funding sources	
Declarations of interest	
Notes	**Research integrity checklist:** • No retractions or expressions of concern were noted • This trial was conducted before 2010, therefore prospective registration was not required. • Baseline characteristics of the groups are not excessively similar. • Plausible loss-to-follow-up was reported • No implausible results were reported. • Equal numbers of participants were not recruited to each group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequence generation was based on random number tables. Patients were stratified according to age, sex, ethnic group and previous placement of tympanostomy tube.

Allocation concealment (selection bias)	Unclear risk	No details on allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not possible to blind surgeons. Parents of children were informed of treatment allocation. There is a strong possibility that participants and personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Despite otoscopists being blind to treatment allocation and outcome data, treatment allocation would be obvious in instances when a VT is visible. Otoscopic assessments have a degree of subjectivity.
Incomplete outcome data (attrition bias) All outcomes	High risk	Despite losses to follow-up being of similar proportions across groups, and despite the characteristics of those losses being similar to those who were not lost to follow-up, the very high attrition rate of 189/578 (33%) constitutes a major loss of data, exceeding the effect size for outcomes relating to persistence of effusion.
Selective reporting (reporting bias)	High risk	One or more outcomes of interest in the review (e.g., perforation, tube extrusion) are reported incompletely. The time point at which some outcomes are assessed is not clearly stated.
Other bias	Unclear risk	The parents of 27 of the 491 randomised children (5.5%) chose a treatment other than that to which their child was randomised. Re-treatment also resulted in interventions to which children were not originally randomised.

Hao 2019

Study characteristics	
Methods	Parallel group RCT with 6 months of follow-up. Randomisation by child. The comparison of interest in this review is: • Adenoidectomy and bilateral ventilation tube insertion versus bilateral ventilation tubes alone

Participants	**Setting:**
	Single centre study from China.
	Sample size:
	• **Number randomised:** Not reported - only data for complete cases are presented.
	• **Number completed:** 184 participants
	Participant (baseline) characteristics:
	• **Age:**
	  ◦ Adenoidectomy group: mean 5.03 years (SD 0.95)
	  ◦ No adenoidectomy group: mean 5.21 years (SD 1.02)
	• **Gender:**
	  ◦ Adenoidectomy group: 63 male: 35 female
	  ◦ No adenoidectomy group: 55 male: 31 female
	• **Hearing threshold**
	  ◦ Adenoidectomy group: mean 34.84 dB HL (SD 12.93)
	  ◦ No adenoidectomy group: mean 34.56 dB HL (SD 12.88)
	Most participants had Grade 2 or 3 adenoid hypertrophy.
	Inclusion criteria:
	Aged 3-6 years, with a confirmed diagnosis of OME (type B or C tympanogram). Failure of conservative treatment. Provided written, informed consent.
	Exclusion criteria:
	Mixed sensorineural and conductive hearing loss, craniofacial abnormalities, children with incomplete follow-up data. Ventilation tubes removed/extruded before 6 months.

Interventions	**Intervention:**

	Adenoidectomy + VT n=98 children (188 ears) **Comparator:** VT alone n=86 children (166 ears)

Outcomes	**Primary outcomes relevant to this review:**
	• **Hearing**
	  ◦ Mean final hearing threshold (air conduction) at 3 and 6 months
	• **Disease-specific quality of life**
	  ◦ Not reported
	• **Adverse event**
	  ◦ Haemorrhage
	Secondary outcomes relevant to this review:
	• **Presence/persistence of OME: proportion of children with persistence of OME**
	  ◦ Only reported as number of children who were not 'cured' - a composite outcome, including children with no symptoms, no effusion and normal hearing.
	• **Other adverse effects**
	  ◦ Not reported

Funding sources	"This research was supported by the Beijing municipal Administration of Hospitals Clinical medicine development of special funding support (XM201409) by the Beijing municipal Administration of Hospitals Clinical medicine development of special funding support and (ZYLX201508)."
Declarations of interest	The authors declared no conflict of interest.
Notes	**Research integrity checklist:** • No retractions or expressions of concern were identified • No prospective trial registration was identified. • Baseline characteristics of the groups were not excessively similar. • No implausible results were noted. • No information was available on loss to follow-up, as data are only reported for those with complete follow-up. • The number randomised to each group was not reported.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"All patients were randomly divided into the observation group (group A) and the control group (group B)." No details are given.
Allocation concealment (selection bias)	Unclear risk	No details are given.
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not possible to blind surgeons. There is a strong possibility that participants and personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details are given.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting to permit judgement.
Selective reporting (reporting bias)	High risk	Patients were followed up for one and a half years to three and a half years. However, data were reported for only 3 months, 6 months and

		one year post-operatively. No protocol or trial registration was found so it is unclear whether there was selective reporting.
Other bias	High risk	One of the exclusion criteria for the study was “children with incomplete clinical follow-up data”. Therefore it is not known whether the children who did not attend the follow-up visits were different in terms of baseline characteristics and/or outcomes from the children who did attend. We do not know if the excluded children were equal across both treatment groups.

Jabeen 2019

Study characteristics	
Methods	Parallel group RCT with 3 months of follow-up. Randomisation by child. The comparison of interest to this review is: • Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only

Participants	**Setting:**
	Single centre study from Pakistan.
	Sample size:
	• **Number randomised:** 80 participants
	• **Number completed:** 80 participants
	Participant (baseline) characteristics:
	• **Age:**
	  ◦ Only reported for the entire cohort: mean 7.65 years (SD 3.5)
	• **Gender:**
	  ◦ Adenoidectomy group: 17 male: 23 female
	  ◦ No adenoidectomy group: 6 male: 34 female
	• **Hearing threshold, mean (SD):**
	  ◦ Only reported for the entire cohort: 30% had >25dBHL hearing loss
	Inclusion criteria:
	Aged 3-5 years with unilateral or bilateral middle ear effusion (>20dBHL hearing loss and Type B tympanogram).
	Exclusion criteria:
	Craniofacial abnormalities, e.g. cleft lip or Down's syndrome. History of surgery of adenoids or ears. Type A tympanogram.

Interventions	**Intervention:** Myringotomy + VT + adenoidectomy n=40 **Comparator:** Myringotomy + VT n=40

Outcomes	**Primary outcomes relevant to this review:**
	• **Hearing**
	  ◦ Not reported
	• **Disease-specific quality of life**
	  ◦ Not reported
	• **Adverse event**
	  ◦ Not reported
	Secondary outcomes relevant to this review:
	• **Presence/persistence of OME: proportion of children with persistence of OME**
	  ◦ Proportion of ears with persistence of OME (otoscopy)

	• **Other adverse effects** ◦ Not reported
Funding sources	No details provided.
Declarations of interest	No declaration is made.
Notes	**Research integrity checklist:** • No retractions or expressions of concern were identified • No prospective trial registration was identified. • Baseline characteristics were not excessively similar between the groups. • No loss to follow-up was reported. • No implausible results were noted. • A lottery method was used to allocate participants, therefore we may expect equal numbers in each group.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"80 children were selected by non-probability consecutive sampling." This appears to refer to enrolment. “Patients were selected by lottery method” appears to refer to the method of random allocation. There is insufficient information about the sequence generation process to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Insufficient information about the sequence generation process to permit judgement.
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not possible to blind surgeons. There is a strong possibility that participants and personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	High risk	“Both groups were followed for 3 months post op for recurrence of disease on otoscopy, first by the trainee and then by the supervisor.” Some outcomes could be influenced by lack of blinding of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up in either group.
Selective reporting (reporting bias)	Low risk	No protocol or trial registration available but all pre-specified outcomes were reported
Other bias	High risk	A follow-up of 3 months is too brief to truly assess any effect from interventions.

Luo 2007

Study characteristics	
Methods	Parallel group, two-arm randomised controlled study with 6 to 9 months of follow-up.

Participants	**Setting:**
	Single centre study from China.
	Sample size:
	• **Number randomised:** 127 participants
	  ◦ 64 participants (110 ears) in the intervention group
	  ◦ 63 participants (103 ears) in the control group
	• **Number completed:** 127 participants
	Participant (baseline) characteristics:
	Only reported for the full cohort.
	• **Age**
	  ◦ average age 7.3 years (range 4-13 years)
	• **Gender**
	  ◦ 65 males

	◦ 62 females • **Hearing threshold** ◦ Air conduction hearing loss ranged from 25 to 45dB. **Inclusion criteria:** Children aged 4-13 years old diagnosed with unilateral or bilateral OME for at least 3 months, all with adenoid hypertrophy. **Exclusion criteria:** None reported.
Interventions	**Adenoidectomy group:** Randomised: n = 64 participants. Children received adenoidectomy and ventilation tube insertion (presumed to the affected ear(s) only but this is not explicit). **Control group:** Randomised: n = 63 participants. Children received ventilation tube insertion (again, presumably to any affected ear(s), but this is not explicit).
Outcomes	**Primary outcomes relevant to this review:** • **Hearing** ◦ Not reported • **Disease-specific quality of life** ◦ Not reported • **Adverse event** ◦ Not reported **Secondary outcomes relevant to this review:** • **Presence/persistence of OME: proportion of children/ears with persistence of OME** ◦ Not reported **Other outcomes reported in the study:** The only reported outcome is a composite measure of 'efficacy', which includes an assessment of symptoms, hearing and tympanometry. We are unable to determine from this the actual number of children who showed an improvement/change in the specific outcomes of relevance to this review. It is not clear how children who improved in some measures - but not others - would have been categorised.
Funding sources	Not described in the translation.
Declarations of interest	Not described in the translation.
Notes	**Research integrity checklist:** • No retractions/expressions of concern were noted • This study was published before 2010, therefore prospective registration was not required. • Limited baseline characteristics are reported, and we are unable to compare the groups. • Full follow-up was reported, and no reasons are given for this. • No implausible results were identified. • Slightly different numbers of participants were randomised to each group.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote, from translation: "The 127 patients were randomly divided into two groups, namely the experimental group and the control group." Comment: No further information available.
Allocation concealment (selection bias)	Unclear risk	Quote, from translation: "The 127 patients were randomly divided into two groups, namely the experimental group and the control group." Comment: No further information available.

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and study personnel would have been aware of treatment allocation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Open-label trial. Outcome assessors are presumably aware of group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full follow-up was reported.
Selective reporting (reporting bias)	Unclear risk	No protocol is available to assess.
Other bias	Unclear risk	Insufficient details to determine whether an additional source of bias exists.

Maw 1983

Study characteristics	
Methods	Parallel group RCT with 3 years of follow-up. Randomisation by child for adenoidectomy. Then randomisation by ear for VT, i.e. all children received a ventilation tube in one ear; half of the children received adenoidectomy. The comparison of interest in this review is: • Adenoidectomy and unilateral ventilation tube insertion versus unilateral ventilation tubes only

Participants	**Setting:**
	Single centre study from the UK.
	Sample size:
	• **Number randomised:** 145 participants
	• **Number completed:** 74 participants total
	Participant (baseline) characteristics:
	Not reported for all randomised participants.
	• **Age:**
	  ◦ Adenoidectomy plus VT group: mean 5.16 years (SD 1.31)
	  ◦ No adenoidectomy group: mean 5.31 years (SD 1.22)
	• **Gender:**
	  ◦ Adenoidectomy group: 36 male: 11 female
	  ◦ No adenoidectomy group: 32 male: 24 female
	• **Hearing threshold, mean (SD):**
	  ◦ Adenoidectomy group
	  ▪ 33.2 dB HL (SD 6.74)
	  ◦ No adenoidectomy group:
	  ▪ 32.4 dB HL (SD 7.97)
	Inclusion criteria:
	Aged 2-9 years. Significant subjective hearing loss. Pneumatic otoscopic confirmation of bilateral OME. Impedance studies not showing a Type A curve (98% Type B, 2% Type C). In excess of 25 dB audiometric hearing loss in each ear at one or more frequencies on pure tone audiometry or free field hearing. assessment.
	Exclusion criteria:
	Exclusion criteria were not reported as such. However, exclusions were described because of:
	• Pre-operative assessment less than 3 months
	• Upper airway obstruction from gross adenoidal hyperplasia
	• Asymmetrical hearing loss

	• Suspected additional sensorineural hearing loss
Interventions	**Intervention:** Adenoidectomy with unilateral VT n=70 **Comparator:** Unilateral VT only n=75

Outcomes	**Primary outcomes relevant to this review:**
	• **Hearing**
	  ◦ Mean final hearing threshold (operated and un-operated ear are reported. We used data from the ear *without* the ventilation tube, as the focus of this review was on the efficacy of adenoidectomy)
	• **Disease-specific quality of life**
	  ◦ Not reported
	• **Adverse event**
	  ◦ Not reported
	Secondary outcomes relevant to this review:
	• **Presence/persistence of OME: proportion of children with persistence of OME**
	  ◦ Proportion of ears with persistence of OME (otoscopy and tympanometry) - again, for the ear without the ventilation tube.
	• **Other adverse effects**
	  ◦ Not reported

Funding sources	Not reported
Declarations of interest	Not reported
Notes	**Research integrity checklist:** • No retractions or expressions of concern were identified • Trial was published prior to 2010, therefore prospective registration was not required. • Baseline characteristics are not excessively similar across the groups. • Plausible loss-to-follow-up was reported. • No implausible results were identified. • Different numbers of participants were randomised to each group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"From tables of random numbers, the children were allocated as follows: adenotonsillectomy 47; adenoidectomy 47; no-surgery 56."
Allocation concealment (selection bias)	Unclear risk	The method of concealment is not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Surgeons could not be blinded. There is a strong possibility that personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	High risk	"The accuracy of A. R. M. (the clinical investigator) in otoscopic diagnosis has been assessed and reported previously." The lead researcher undertook the pneumatic otoscopy. Blinding of audiometric and tympanometric assessments was not reported and therefore assessments are unlikely to be blinded. Audiometry is open to subjective assessment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The attrition rate was similar in each group of interest (24% and 23% at one year, and 53% and 52% at three years, in the adenoidectomy plus unilateral VT group and the unilateral VT group, respectively). The

		reasons for attrition were largely unreported and could have been related to the outcomes of interest.
Selective reporting (reporting bias)	Low risk	No published protocol has been found and it appears that all pre-specified outcomes are reported.
Other bias	Low risk	None identified.

Sagnelli 1990

Study characteristics	
Methods	Parallel group RCT with up to 15 months of follow-up Randomisation by child, ear unit of analysis. The comparison of interest in this review is: • Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting
Participants	**Setting:** Single centre study from Italy. **Sample size:** • **Number randomised:** 46 participants • **Number completed:** 46 participants (presumed, number with complete follow-up not explicit) **Participant (baseline) characteristics:** • no baseline characteristics are reported **Inclusion criteria:** Children aged 6-7 who had a type B or C tympanogram for at least 3 months, despite medical therapy (details of the medical therapy are not provided). **Exclusion criteria:** None reported.
Interventions	**Intervention:** Adenoidectomy plus myringotomy n=22 **Comparator:** Myringotomy alone n=24

Outcomes	**Primary outcomes relevant to this review:**
	• **Hearing**
	  ◦ Article states “No differences were found in the audiometric thresholds”. No data reported. No information on methods of assessment.
	• **Disease-specific quality of life**
	  ◦ Not reported
	• **Adverse event**
	  ◦ Not reported
	Secondary outcomes relevant to this review:
	• **Presence/persistence of OME: proportion of children with persistence of OME**
	  ◦ Proportion of ears with persistence of OME (type B or C tympanogram)
	• **Other adverse effects**
	  ◦ Not reported

Funding sources	No information provided.
Declarations of interest	No information provided.
Notes	**Research integrity checklist:** • No retractions or expressions of concern were noted • This study was conducted prior to 2010, therefore prospective registration was not required

	• No baseline characteristics are reported, therefore we cannot assess for excessive similarity between the groups. • Follow-up is not fully described, but appears to be complete, and no reasons are given for this. • No implausible results were identified. • Different numbers of participants were randomised to the two groups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Paper states that children were randomly and blindly divided into two groups but no details on methods used for randomisation.
Allocation concealment (selection bias)	Unclear risk	Paper states that children were randomly and blindly divided into two groups but no details are given on methods used for allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Surgeons could not be blinded. There is a strong possibility that personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on blinding of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	It appears that there is no loss to follow-up or missing data.
Selective reporting (reporting bias)	Unclear risk	No protocol is available for assessment. Some outcomes e.g. audiometry are only reported narratively, precluding their use in the review.
Other bias	Unclear risk	This is difficult to assess as we are using a translation for our data extraction.

TARGET

Study characteristics

Methods	3 arm, multi centre parallel group RCT, with randomisation by child and 2 year follow-up. For this review we have included data relevant to the comparison of adenoidectomy plus bilateral ventilation tubes with bilateral ventilation tubes, and the comparison of adenoidectomy plus ventilation tubes versus watchful waiting.

Participants	**Location:** UK, 11 sites
	Setting of recruitment and treatment: Otorhinolaryngology Departments
	Study dates: April 1994 to January 1998
	Sample size:
	• **Number randomised:** 376 [126 Bilateral VT (VTs), 128 VT with Adenoidectomy (VTs + ad), 122 watchful waiting (WW)]
	• **Number completed:** 321 [109 Bilateral VT (VTs), 109 VT with Adenoidectomy (VTs + ad), 103 watchful waiting (WW)
	Participant (baseline) characteristics:
	• Age (mean (SD) months):
	  ◦ VTs 62.5 (10.2)
	  ◦ VTs + ad 64.5 (10.3)
	  ◦ WW 62.9 (10.4)
	• Gender:
	  ◦ VTs M 60/126 (48%) F 66/126 (52%)
	  ◦ VTs + ad M 61/128 (48%) F 67/128 (52%)
	  ◦ WW M 62/122 (51%) F 60/122 (49%)
	• Hearing threshold at baseline (at visit 2) (mean (SD) dB):
	  ◦ VTs 32.2 (6.0)

	◦ VTs + ad 31.7 (6.4) ◦ WW 33.5 (6.4) • AOM episodes (> 6 per year): ◦ VTs 5/126 (4%) ◦ VTs + ad 5/127 (4%) ◦ WW 8/122 (7%) **Inclusion criteria:** • children aged between 3.25 and 6.75 years • referred primarily for otological or hearing reasons • first visit, with no previous ear or adenoid surgery • bilateral type B + B or B + C2 tympanogram combination • better ear HL > 20 dB HL averaged across 0.5, 1, 2 and 4 kHz and air–bone gap > 10 dB • criteria met on two qualifying visits separated by a 12-week period of watchful waiting. **Exclusion criteria:** • children with cranio-facial structural abnormalities, severe systemic disease (e.g. diabetes) and non-OME ear disease (e.g. perforation) • where consultant or parent was unduly concerned over a child's speech/language, behaviour, otalgia or nose/throat problems, the child could be managed outside TARGET. • previous VT/adenoid surgery, outside age limits, not accompanied by parent/guardian, other medical exclusion, significant family language problems, parent refusing to take part in study, child unable/unwilling to do audiometry, administrative problems, family/social reasons and protocol mishaps, particularly early in the trial.
Interventions	**Bilateral VTs:** Bilateral Shepard VTs were inserted following myringotomy and fluid aspiration **Bilateral VT with adenoidectomy:** Bilateral ventilation tubes were inserted, as above, and adenoidectomy was performed by curettage **Watchful waiting (WW):** Children were not allocated to any surgery. However, over the 2-year follow-up period 57% of participants in this group actually underwent surgery.
Outcomes	Mean final hearing threshold • Air conduction thresholds at 0.5, 1.0, 2.0 and 4.0 kHz in each ear at every visit were summarised as the 4-frequency average binaural hearing thresholds Mean change in hearing from baseline Adverse events: • perforation • haemorrhage • tympanosclerosis • functioning VT
Funding sources	Medical Research Council. Trial Registration Number: ISRCTN35793977.
Declarations of interest	Authors reported "None to declare".
Notes	**Research Integrity Checklist:** • No retraction notices identified. • Prospective registration not applicable for earliest publications (published before 2010). Registration was noted for the most recent publication. • Baseline characteristics were not excessively similar between the groups. • Plausible loss to follow-up was reported. • No implausible results.

	• Numbers allocated to each group are not identical.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“For each centre, the first five children were randomised according to a computer-generated random number sequence. Thereafter, the minimisation procedure balanced the treatment allocations across four dichotomous factors: boy, girl; <5.25, >5.25 years old at initial visit; manual, non-manual occupation of head of household and baseline hearing <25 dB HL, >25 dB HL.”
Allocation concealment (selection bias)	Low risk	"Randomisation was performed by telephone call from the nurse⁄research assistant to the statistician at the MRC Institute of Hearing Research and allocation immediately communicated to the parent,” and “This basis of minimisation was not divulged to centres and may be regarded as completely concealed.”
Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not possible to blind surgeons. There is a strong possibility that participants and personnel can identify which treatment a participant received and hence change their behaviour as a result.
Blinding of outcome assessment (detection bias) All outcomes	High risk	“Audiometry was performed by audiologists, independently of the otolaryngologist and research nurse. Clinic pressures meant that these testers, whilst not blinded in the strictest sense, were not aware of the child’s allocation, nor in a position to be influenced by such information were it present.”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Losses to follow-up were 55/376 randomised (14.6%) overall, 19/122 (15.6%) in the medical management group, 17/126 (13.5%) in the VT group and 19/128 (14.8%) in the VT+Ad group. Complete data were available for only 76/122 (62.3%), 85/126 (67.5%) and 92/128 (71.9%) in the medical management, VT and VT+Ad groups respectively. Reasons for losses to follow-up after randomisation were not reported.
Selective reporting (reporting bias)	Low risk	Published protocol does not report pre-specified outcomes. However these are detailed in the trial registration. All are reported
Other bias	High risk	In the trial registration, the title of the study is: “Trial of alternative regimens in glue ear treatment - effectiveness of surgery for otitis media with effusion in 3.5-7 year olds using multiple developmental and economic measures combined with classical clinical measures”. However little developmental and no economic outcome data has been published. Few details given on scales used to assess some outcomes such as quality of life. Publication bias may be a possibility, with the trial accepted for publication due its funding source.

Xu 2016

Study characteristics	
Methods	Parallel group, randomised controlled trial.
Participants	**Setting:** Single centre, from a University hospital in China. **Sample size:** • **Number randomised:** 126 participants (63 to each group) • **Number completed:** 126 participants (63 to each group) **Participant (baseline) characteristics:** • **Age:** not reported • **Gender:** 78 males and 48 females **Inclusion criteria:** Aged 4-12 years with recurrent OME for at least 3 months. **Exclusion criteria:** Not reported.
Interventions	**Adenoidectomy and ventilation tubes**

	N = 63. Endoscopic tympanostomy combined with nasal endoscopic adenoidectomy. **Ventilation tubes only** N = 63. Children were treated with tympanostomy under an otoendoscope. **Concomitant interventions administered to both groups:** In addition to tympanostomy, "All patients in the two groups received conventional antibiotics to prevent infection after the operation, and mucus-thinning agents and nasal glucocorticoids were used."

Outcomes	**Primary outcomes relevant to this review:**
	• **Hearing**
	  ◦ Pure tone hearing thresholds were assessed after surgery. However, the timing of assessment was unclear, and the data are not reported in a manner suitable for analysis.
	• **Disease-specific quality of life**
	  ◦ Not reported
	• **Adverse event**
	  ◦ Not reported
	Secondary outcomes relevant to this review:
	• **Presence/persistence of OME: proportion of children/ears with persistence of OME**
	  ◦ Tympanogram type B. However, the timing of follow-up is unclear, therefore these data were not included in a meta-analysis.
	Other outcomes reported in the study:
	• Time to complete healing
	• Time to resolution of middle ear effusion
	• Recurrence

Funding sources	Not reported in translation.
Declarations of interest	Not reported in translation.
Notes	**Research integrity checklist:** • No retractions/expressions of concern were noted • No prospective registration was identified. • Limited baseline characteristics are reported, and we are unable to compare the groups. • Full follow-up was reported, and no reasons are given for this. • No implausible results were identified. • Equal numbers of participants were randomised to each group.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote (from translation): "A total of 126 children with recurrent OME were randomly divided into Observation Group (63 cases) and Control Group (63 cases)" Comment: no information on generation of random sequence.
Allocation concealment (selection bias)	Unclear risk	Quote (from translation): "A total of 126 children with recurrent OME were randomly divided into Observation Group (63 cases) and Control Group (63 cases)" Comment: no information on concealment of allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No information is provided regarding blinding. We assume that participants and study personnel were aware of the group allocation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No information is provided regarding blinding. We assume that outcome assessors were aware of the group allocation.

Incomplete outcome data (attrition bias) All outcomes	Low risk	Full follow-up is reported.
Selective reporting (reporting bias)	Unclear risk	No protocol was identified with which to compare the report.
Other bias	Unclear risk	Insufficient information to assess.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ardehali 2008	INTERVENTION: treatment with antibiotics, and is relevant for another review in this suite XXX
Becker 1992	ALLOCATION: not randomised
Black 1986	PARTICIPANTS: wrong patient population - participants did not have OME for at least 3 months duration.
Black 1990	PARTICIPANTS: unknown duration of OME
Brown 1978	PARTICIPANTS: unknown duration of OME
Bulman 1984	PARTICIPANTS: wrong patient population
Casselbrant 2009	PARTICIPANTS: had RAOM as well as OME
Choung 2008	INTERVENTION: treatment with steroids, and is relevant for another review in this suite XXX
El Begermy 2022	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Elkholy 2021	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Ferrara 2005	PARTICIPANTS: had RAOM
Gibson 1996	ALLOCATION: not randomised
Hammaren-Malmi 2005	PARTICIPANTS: did not have OME of at least 3 months duration
Hornigold 2008	ALLOCATION: not randomised
Iino 1989	ALLOCATION: not randomised
Kujala 2012	PARTICIPANTS: had RAOM
Le 1991	COMPARISONS: wrong comparison
Mandel 1992	PARTICIPANTS: wrong patient population
Marchisio 1998	INTERVENTION: treatment with antibiotics, and is relevant for another review in this suite XXX
Markou 2004	PARTICIPANTS: unknown duration of OME
Mattila 2003	PARTICIPANTS: had AOM
Maw 1993	INTERVENTION: patients had adenotonsillectomy
Maw 1999	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
MRC Multicentre Otitis Media Study 2004	ALLOCATION: not randomised
NCT00629694	PARTICIPANTS: unknown duration of OME
NCT04302337	INTERVENTION: comparing two types of adenoidectomy
NCT04584073	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Niemi 2015	PARTICIPANTS: wrong patient population
Paradise 1980	PARTICIPANTS: wrong patient population
Paradise 1990	PARTICIPANTS: did not have OME
Paradise 1997	ALLOCATION: not randomised
Parker 1989	ALLOCATION: not randomised
Parlea 2012	ALLOCATION: not randomised
Popova 2010	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Rohail 2006	PARTICIPANTS: unknown duration of OME
Roydhouse 1980	PARTICIPANTS: wrong patient population
Rynnel-Dagoo 1978	PARTICIPANTS: wrong patient population
Sagara 2003	ALLOCATION: not randomised
Shishegar 2007	PARTICIPANTS: wrong patient population

Study	Reason for exclusion
Shubich 1996	ALLOCATION: not randomised
Stenstrom 2005	ALLOCATION: not randomised
Sujatha 2015	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Tao 2020	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Velepic 2011	INTERVENTION: treatment with ventilation tubes, and is relevant for another review in this suite XXX
Worley 2007	ALLOCATION: not randomised

Characteristics of studies awaiting classification [ordered by study ID]

Diacova 2016

Methods	—
Participants	—
Interventions	—
Outcomes	—
Notes	Extensive efforts to obtain full text were unsuccessful. The information available is ambiguous in that it defines the design as ‘a prospective observational study’ but then goes on to describe random treatment assignment.

Marshak 1980

Methods	—
Participants	—
Interventions	—
Outcomes	—
Notes	Unable to obtain full-text

Maw 1986

Methods	—
Participants	—
Interventions	—
Outcomes	—
Notes	Unable to obtain full-text

Tawfik 2002

Methods	—
Participants	—
Interventions	—
Outcomes	—
Notes	Unable to obtain full-text

Characteristics of ongoing studies [ordered by study ID]

ACTRN12611000380998

Study name	Surgery for otitis media in Indigenous Australian children
Methods	Multi-centre parallel group study.
Participants	**Inclusion criteria**

	Indigenous & non-indigenous children aged 3-10 years living in remote Australian communities, with OME or recurrent acute otitis media for greater than 3 months who have failed medical treatment. Glue ear (immovable tympanic membrane) determined by tympanometry & otoscopy plus mild or moderate conductive hearing impairment (>15dB in soundproof room or >25db in non-sound proof room). **Exclusion criteria** Children with conditions which may predispose to post-op complications e.g.: cleft palate, Downes syndrome, generalised immunological conditions
Interventions	**Intervention A:** Adenoidectomy with ventilation tubes **Intervention B:** Adenoidectomy with myringotomy **Comparator:** Medical treatment (antibiotics) as clinically indicated
Outcomes	Primary outcome: • Prevalence of OME (assessed with audiometry, tympanometry and video-otoscopy) after 12 months Secondary outcomes: • Proportion of children with an improvement of 10dB or more in hearing impairment over at least 2 frequencies after 12 months • Presence of aural discharge • Tympanic membrane perforation • Culture and sensitivity of aural and nasal swabs • Antibody responses
Starting date	Anticipated: 1/8/2014
Contact information	Katie Davis katie.davis@unimelb.edu.au
Notes	We note that thi study was planned to start in 2014. The trial registration was updated in 2020, but we do not know if this planned study is going ahead. We also note that the study population includes a mixture of children with OME and recurrent acute otitis media. Therefore it may not be relevant for this review (depending on whether subgroup data for those with OME can be obtained).

NCT05545345

Study name	Adjuvant adenoidectomy for the treatment of chronic OME in children
Methods	Parallel group RCT
Participants	Estimated enrollment 380 children. **Inclusion criteria:** Children aged 4-12 years with OME (middle ear effusion detected by otoscopy with Type B or C tympanometry and symptoms/signs of OME for >3 months). Documented hearing loss ≥20dB (average threshold of 500Hz, 1000Hz and 2kHz in pure tone audiometry) and adenoid hypertrophy (A/N ratio> 0.5 in lateral radiography of the nasopharynx). **Exclusion criteria:** Cleft palate or other systemic disorders. Patients diagnosed with other nose, sinuses or ear diseases that are eligible for surgical treatment. Patients are diagnosed with sleep apnoea, tonsil hypertrophy or scheduled for tonsillectomy. History of tympanostomy tube placement. Infection of the upper respiratory tract or acute rhinosinusitis over the past 7 days. Sensorineural hearing loss.
Interventions	Intervention: Adenoidectomy and ventilation tube placement. Comparator: Ventilation tubes alone.
Outcomes	**Primary Outcome Measures:** • Rate of OME recurrence, 1 year after tube removal • Proportion of patients who need repeated tube insertion, 1 year after tube removal **Secondary Outcome Measures:**

	• The number of acute otitis media attacks, 1 year after tube removal • Rate of otorrhoea, 2 years after tube removal • Change of pure tone audiometry thresholds compared with baseline, 2 years after tube removal • Change of questionnaire score. Otitis Media-6 score ranges from 6 to 42, and higher scores mean worse outcomes. Pediatric Sleep Questionnaire score ranges from 0 to 22, and higher scores mean worse outcomes. 2 years after tube removal • Complications related to interventions of this study, 2 years after tube removal • Costs of OME-related visits and treatment, until study completion, an average of 2 years
Starting date	Anticipated start date September 2022, but note that recruitment does not yet appear to have started (clinicaltrials.gov website accessed 27.2.2023).
Contact information	Huiqian Yu, yhq925@163.com Fangzhou Yu, 13301050317@fudan.edu.cn
Notes	—

Appendices

Appendix 1. Search strategies

The search strategies were designed to identify all relevant studies for a suite of reviews on various interventions for otitis media with effusion.

CENTRAL (CRS)	Cochrane ENT Register (CRS)	MEDLINE (Ovid)
1 MESH DESCRIPTOR Otitis Media with Effusion EXPLODE ALL AND CENTRAL:TARGET 2 ("otitis media" adj6 effusion):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET 3 (OME):TI,TO AND CENTRAL:TARGET 4 (Secretory otitis media):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET 5 (Serous otitis media):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET 6 (Middle-ear effusion):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET 7 (glue ear):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET 8 (middle-ear perfusion):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET 9 MESH DESCRIPTOR Otitis Media AND CENTRAL:TARGET 10 (otitis media):TI,TO AND CENTRAL:TARGET 11 #9 OR #10 AND CENTRAL:TARGET 12 (((effusion or Recurrent or persistent or serous or secretory or perfusion) adj3 otitis)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET	1 MESH DESCRIPTOR Otitis Media EXPLODE ALL AND INREGISTER 2 ("otitis media" OR OME OR "glue ear" OR middle-ear effusion OR middle-ear perfusion):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER 3 #1 OR #2 4 (effusion or Recurrent or persistent or serous or secretory or perfusion):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER 5 #3 AND #4	1 exp Otitis Media with Effus 2 ("otitis media" adj6 effusion 3 OME.ti. 4 Secretory otitis media.ab,ti 5 Serous otitis media.ab,ti. 6 Middle-ear effusion.ab,ti. 7 Glue ear.ab,ti. 8 middle-ear perfusion.ab,ti. 9 Otitis Media/ 10 otitis media.ti. 11 9 or 10 12 ((effusion or Recurrent or or serous or secretory or per adj3 otitis).ab,ti. 13 11 and 12 14 1 or 2 or 3 or 4 or 5 or 6 o 13 15 randomized controlled tria 16 controlled clinical trial.pt. 17 randomized.ab. 18 placebo.ab. 19 drug therapy.fs. 20 randomly.ab. 21 trial.ab. 22 groups.ab. 23 15 or 16 or 17 or 18 or 19 21 or 22 24 exp animals/ not humans 25 23 not 24

13 #11 AND #12 AND CENTRAL:TARGET 14 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #13 AND CENTRAL:TARGET		26 14 and 25
Embase (Ovid)	**Web of Science (Web of knowledge)**	**Trial registries (CR**
1 exp secretory otitis media/ 2 ("otitis media" adj6 effusion).ab,ti. 3 OME.ti. 4 Secretory otitis media.ab,ti. 5 Serous otitis media.ab,ti. 6 Middle-ear effusion.ab,ti. 7 glue ear.ab,ti. 8 middle-ear perfusion.ab,ti. 9 otitis media/ 10 otitis media.ti. 11 9 or 10 12 ((effusion or Recurrent or persistent or serous or secretory or perfusion) adj3 otitis).ab,ti. 13 11 and 12 14 1 or 2 or 4 or 5 or 6 or 7 or 8 or 13 15 (random* or factorial* or placebo* or assign* or allocat* or crossover*).tw. 16 (control* adj group*).tw. 17 (trial* and (control* or comparative)).tw. 18 ((blind* or mask*) and (single or double or triple or treble)).tw. 19 (treatment adj arm*).tw. 20 (control* adj group*).tw. 21 (phase adj (III or three)).tw. 22 (versus or vs).tw. 23 rct.tw. 24 crossover procedure/ 25 double blind procedure/ 26 single blind procedure/ 27 randomization/ 28 placebo/ 29 exp clinical trial/ 30 parallel design/ 31 Latin square design/ 32 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 33 exp ANIMAL/ or exp NONHUMAN/ or exp ANIMAL EXPERIMENT/ or exp ANIMAL MODEL/ 34 exp human/ 35 33 not 34 36 32 not 35 37 14 and 36	11 #10 AND #9 Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 10 #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 9 TS=(randomised OR randomized OR randomisation OR randomisation OR placebo* OR (random* AND (allocat* OR assign*)) OR (blind* AND (single OR double OR treble OR triple))) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 8 (TI=(otitis media)) AND TS= ((effusion or Recurrent or persistent or serous or secretory or perfusion) NEAR/3 otitis) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 7 TOPIC: ((middle-ear perfusion)) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 6 TOPIC: ((glue ear)) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 5 TOPIC: ((Middle-ear effusion)) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 4 TOPIC: ((Serous otitis media)) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 3 TOPIC: ((Secretory otitis media)) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 2 TITLE: (OME) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years 1 TOPIC: ("otitis media" NEAR/6 effusion) Indexes=SCI-EXPANDED, CPCI-S Timespan=All years	1 ("otitis media" OR OME OR ear" OR middle-ear effusion middle-ear perfusion):AB,EH,KW,KY,MC AND CENTRAL:TARGET 2 (effusion or Recurrent or p serous or secretory or perfusion):AB,EH,KW,KY,MC AND CENTRAL:TARGET 3 #1 AND #2 4 http*:SO AND CENTRAL:T 5 (NCT0* or ACTRN* or ChiC DRKS* or EUCTR* or eudra IRCT* or ISRCTN* or JapicC JPRN* or NTR0* or NTR1* o NTR3* or NTR4* or NTR5* o NTR7* or NTR8* or NTR9* o or UMIN0*):AU AND CENTRAL:TARGET 6 #4 OR #5 7 #3 AND #6
ClinicalTrials.gov	ICTRP	
(EXPAND[Concept] "otitis media" OR EXPAND[Concept] "glue ear" OR	(otitis media AND effusion) OR glue ear OR middle-ear effusion OR middle-ear	

middle-ear) AND (effusion OR Recurrent OR persistent OR serous OR secretory OR perfusion) | Interventional Studies	perfusion	

Appendix 2. Tool for screening eligible studies for scientific integrity/trustworthiness

This screening tool has been developed by Cochrane Pregnancy and Childbirth. It includes a set of predefined criteria to select studies that, based on available information, are deemed to be sufficiently trustworthy to be included in the analysis.

Criteria questions	Assessment		Comments and concerns
	High risk	Low risk	
Research governance			
Are there any retraction notices or expressions of concern listed on the Retraction Watch Database relating to this study?	Yes	No	
Was the study prospectively registered (for those studies published after 2010) If not, was there a plausible reason?	No	Yes	
When requested, did the trial authors provide/share the protocol and/or ethics approval letter?	No	Yes	
Did the trial authors engage in communication with the Cochrane Review authors within the agreed timelines?	No	Yes	
Did the trial authors provide IPD data upon request? If not, was there a plausible reason?	No	Yes	
Baseline characteristics			
Is the study free from characteristics of the study participants that appear too similar? (e.g. distribution of the mean (SD) excessively narrow or excessively wide, as noted by Carlisle 2017)	No	Yes	
Feasibility			
Is the study free from characteristics that could be implausible? (e.g. large numbers of women with a rare condition (such as severe cholestasis in pregnancy) recruited within 12 months)	No	Yes	
In cases with (close to) zero losses to follow-up, is there a plausible explanation?	No	Yes	
Results			
Is the study free from results that could be implausible? (e.g. massive risk reduction for main outcomes with small sample size)?	No	Yes	
Do the numbers randomised to each group suggest that adequate randomisation methods were used (e.g. is the study free from issues such as unexpectedly even numbers of women 'randomised' including a mismatch between the numbers and the methods, if the authors say 'no blocking was used' but still end up with equal numbers, or if the authors say they used 'blocks of 4' but the final numbers differ by 6)?	No	Yes	
For abstracts only:			
Have the study authors confirmed in writing that the data to be included in the review have come from the final analysis and will not change?	No	Yes	

Appendix 3. Analysis details

Some data for the studies Fiellau-Nikolajsen 1982 and Sagnelli 1990 were reported according to affected ears, rather than affected participants.

Ears of the same individual are likely to respond similarly to treatment, and therefore some correlation is to be expected. However, the extent of this correlation is unknown.

Proportion of children with normal hearing (Fiellau-Nikolajsen 1982)

Data on normal hearing are reported according to the ears in which an effusion was identified during myringotomy. The numbers reported do not match with the total number of participants randomised in this trial.

20 participants received adenoidectomy; hearing data for 22 ears are reported.

22 participants did not receive adenoidectomy; hearing data for 20 ears are reported.

The authors state "Moreover, the cumulated recovery rate for the 42 ears which were found to contain effusion at myringotomy proved independent of the type of operation". It is therefore unclear whether this is a data entry error in the article (and the hearing data are presented for the wrong group), or whether some ears were found not to have an effusion at myringotomy in the no-adenoidectomy group, and some children in the adenoidectomy group had bilateral disease.

We have analysed these data as if they were reported per participant, as it is unclear how many (if any) ears relate to the same participant in this analysis. However, this may result in artificially narrow confidence intervals if more than one ear from the same individual has been included in the results.

Presence/persistence of OME (Fiellau-Nikolajsen 1982; Sagnelli 1990)

Some data from these trials were reported for each ear of every participant. This applies to data on the presence of OME, as assessed by tympanometry. Accounting for the correlation between ears of the same participant requires analysis as if this were a cluster-randomised trial, with a cluster size of 2 (2 ears per participant).

To calculate the design effect (according to the methods in the Handbook 2011), we calculate

1 + ([M-1] x ICC)

Where M = average cluster size, and ICC = intracluster correlation coefficient.

If we assume an ICC of 0.50 this gives us:

1 + ([2-1] x 0.5) = 1.5, i.e. the design effect is 1.5.

As part of a sensitivity analysis, we also considered the situation where there was complete correlation between the ears (i.e. an intracluster correlation coefficient of 1, giving a design effect of 2) and no correlation between the ears of an individual.

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Figures and tables

Additional tables

Table 1

Sensitivity analyses

Outcome	Main analysis result (95% CI)	Sensitivity analysis	Sensitivity analysis result (95% CI)
Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting			
1.3.1 Persistence of OME up to 3 months	RR 0.83 (0.61 to 1.13)	Exclusion of studies with concerns over trustworthiness	RR 0.68 (0.45 to 1.04)
1.3.1 Persistence of OME up to 3 months	RR 0.83 (0.61 to 1.13)	Fixed-effect model	RR 0.82 (0.65 to 1.03)
1.3.2 Persistence of OME up to 12 months	RR 0.65 (0.36 to 1.15)	Exclusion of studies with concerns over trustworthiness	RR 0.60 (0.23 to 1.56)
1.3.2 Persistence of OME up to 12 months	RR 0.65 (0.36 to 1.15)	Fixed-effect model	RR 0.65 (0.36 to 1.15)
1.3.3 Persistence of OME over 12 months	RR 0.90 (0.81 to 1.00)	Exclusion of studies with concerns over trustworthiness	RR 0.90 (0.82 to 1.00)
1.3.3 Persistence of OME over 12 months	RR 0.90 (0.81 to 1.00)	Exclusion of studies at high risk of bias	RR 0.76 (0.47 to 1.22)
1.3.3 Persistence of OME over 12 months	RR 0.90 (0.81 to 1.00)	Fixed-effect model	RR 0.88 (0.78 to 0.99)
Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only			
2.2.1 Hearing threshold up to 3 months	MD -0.79 (-1.99 to 0.41)	Exclusion of studies with concerns over trustworthiness	MD -0.80 (-2.49 to 0.89)
2.2.1 Hearing threshold up to 3 months	MD -0.79 (-1.99 to 0.41)	Fixed-effect model	MD -0.79 (-1.99 to 0.41)
2.2.1 Hearing threshold up to 12 months	MD -2.18 (-5.25 to 0.88)	Exclusion of studies with concerns over trustworthiness	MD -3.90 (-6.34 to -1.46)
2.2.1 Hearing threshold up to 12 months	MD -2.18 (-5.25 to 0.88)	Fixed-effect model	MD -1.66 (-2.97 to -0.35)
2.3.2 Persistence of OME up to 12 months	RR 0.81 (0.63 to 1.05)	Fixed-effect model	RR 0.81 (0.65 to 1.00)
Adenoidectomy and unilateral ventilation tubes versus unilateral ventilation tubes only			
3.2 Hearing: Hearing threshold up to 12 months	MD -5.36 (-10.16 to -0.56)	Fixed-effect model	MD -5.45 (-9.03 to -1.86)
3.3.2 Presence or persistence of OME up to 12 months	RR 0.57 (0.38 to 0.86)	Fixed-effect model	RR 0.55 (0.42 to 0.72)

CI confidence interval; MD mean difference; RR risk ratio

Table 2

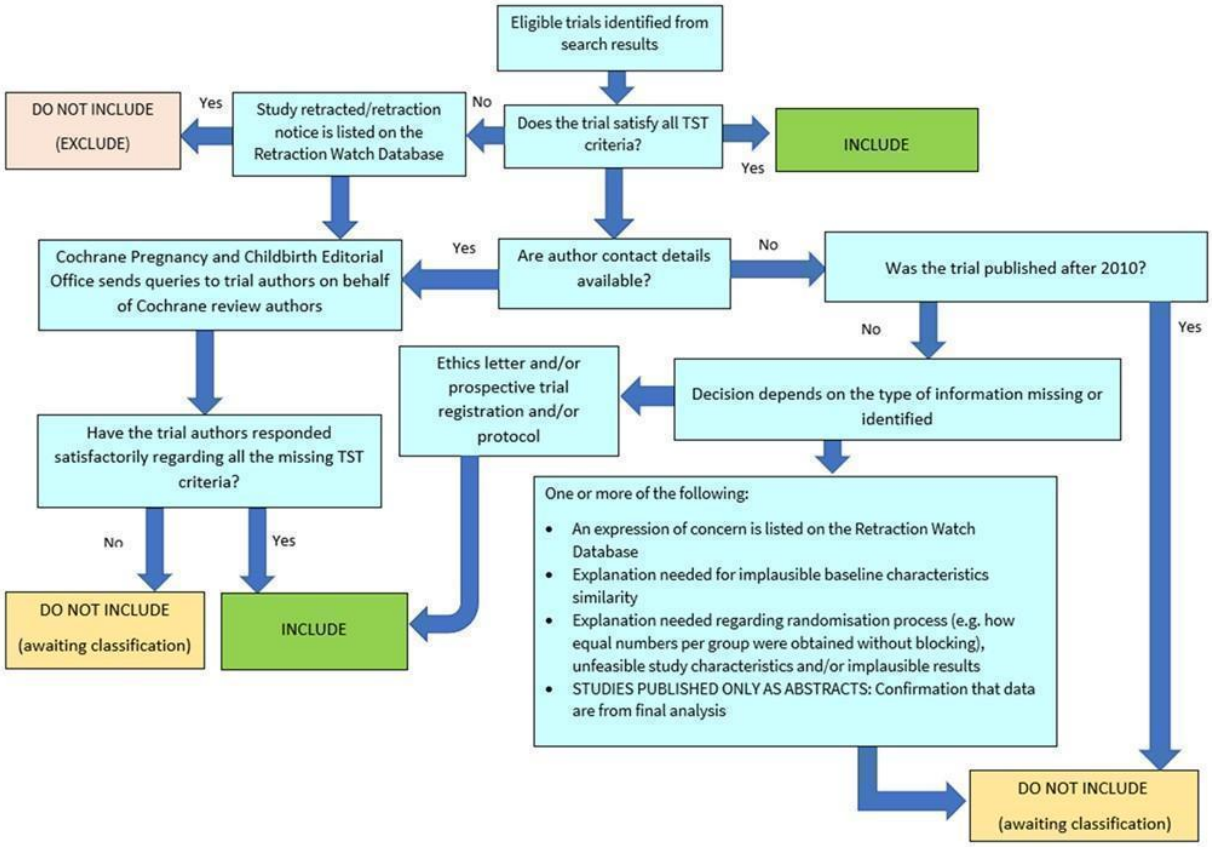
Study features

Study	Participants	Setting	Intervention	Comparator	Concomitant treatment	Follow-up (main outcomes reported at this time)	Notes
Dempster 1993	Children aged 3.5-12 years with bilateral OME and hearing loss (PTA ≥25dBHL) for at least 3 months (n = 78)	Single centre, UK	Adenoidectomy	No adenoidectomy	All children in the trial received a ventilation tube in one ear.	12 months	
Fiellau-Nikolajsen	Children with type B	Single centre,	Adenoidectomy	No adenoidectomy	All children received	21 months	

1982	tympanogram or middle ear pressure ≤-100mmH_2O for at least 3 months (n = 45)	Denmark			myringotomy		
Gates 1989	Children aged 4-8 years with persistent OME for 60 days after a 10-day course of erythromycin and sulfisoxazole, and a 30-day course of pseudoephedrine hydrochloride (n = 578)	Multicentre, USA	Adenoidectomy plus myringotomy or Adenoidectomy plus bilateral ventilation tubes	Myringotomy or Bilateral ventilation tubes		2 years	4-arm trial.
Hao 2019	Children aged 3-6 years with OME (n = 184)	Single centre, China.	Adenoidectomy	No adenoidectomy	Bilateral ventilation tubes	6 months	Additional follow-up was reported, but not for outcomes of relevance to this review.
Jabeen 2019	Children aged 3-5 years with unilateral or bilateral OME (n = 80)	Single centre, Pakistan.	Adenoidectomy	No adenoidectomy	Bilateral ventilation tubes	3 months	
Luo 2007	Children aged 4-13 years old diagnosed with unilateral or bilateral OME, all with adenoid hypertrophy (n = 127)	Single centre, China.	Adenoidectomy	No adenoidectomy	Bilateral ventilation tubes.	9 months	
Maw 1983	Children aged 2-9 years with bilateral OME (n = 145)	Single centre, UK	Adenoidectomy	No adenoidectomy	All children in the trial received a ventilation tube in one ear.	3 years	
Sagnelli 1990	Children aged 6-7 with OME (n = 46)	Single centre, Italy	Adenoidectomy	No adenoidectomy	All children received myringotomy	15 months	
TARGET	Children aged 3.25 to 6.75 with bilateral OME (n = 376)	Multicentre, UK	Adenoidectomy plus bilateral ventilation tubes	Bilateral ventilation tubes alone or Watchful waiting		2 years	
Xu 2016	Children aged 4-12 years with OME (n = 126)	Single centre, China	Adenoidectomy	No adenoidectomy	All children received ventilation tubes - it is unclear whether this was	Not stated.	Note, we have been unable to include any data from this study in

					unilateral or bilateral.		the review.

Figure 1



The Cochrane Pregnancy and Childbirth Trustworthiness Screening Tool

Figure 2

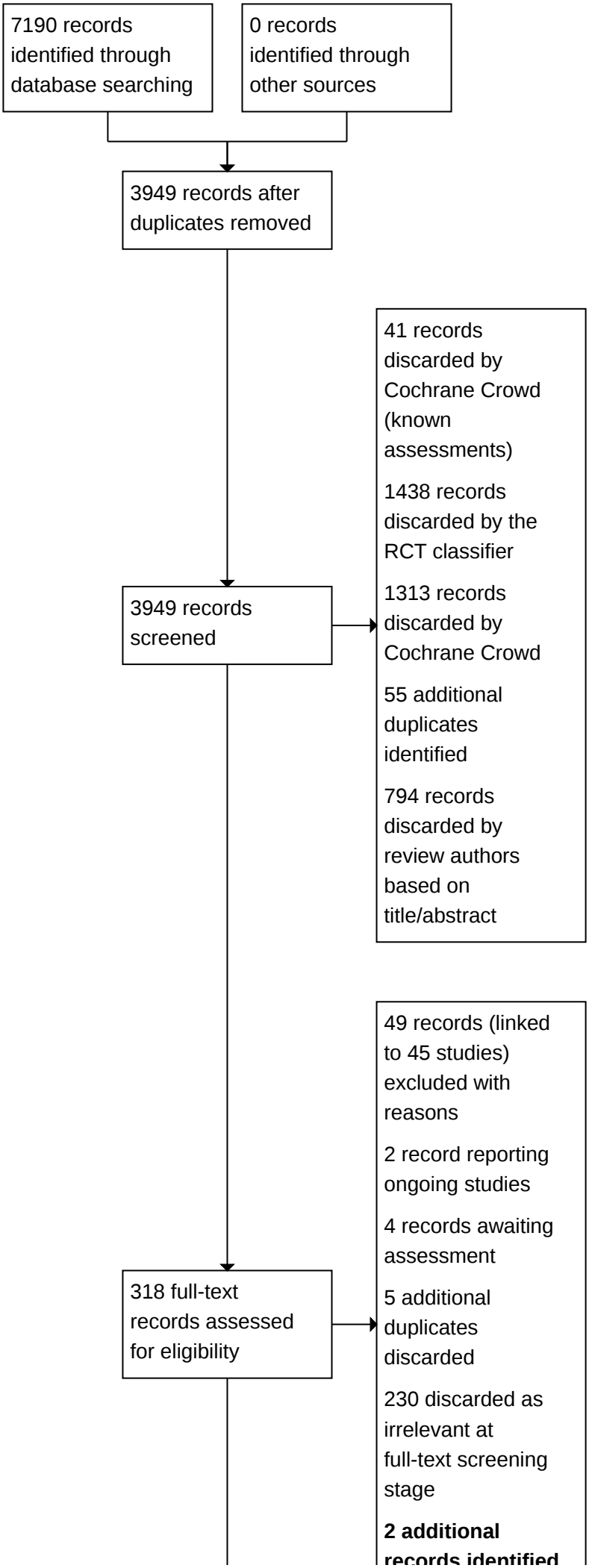

7190 records identified through database searching
0 records identified through other sources
3949 records after duplicates removed
3949 records screened
41 records discarded by Cochrane Crowd (known assessments)
1438 records discarded by the RCT classifier
1313 records discarded by Cochrane Crowd
55 additional duplicates identified
794 records discarded by review authors based on title/abstract
318 full-text records assessed for eligibility
49 records (linked to 45 studies) excluded with reasons
2 record reporting ongoing studies
4 records awaiting assessment
5 additional duplicates discarded
230 discarded as irrelevant at full-text screening stage
2 additional records identified

Figure 3

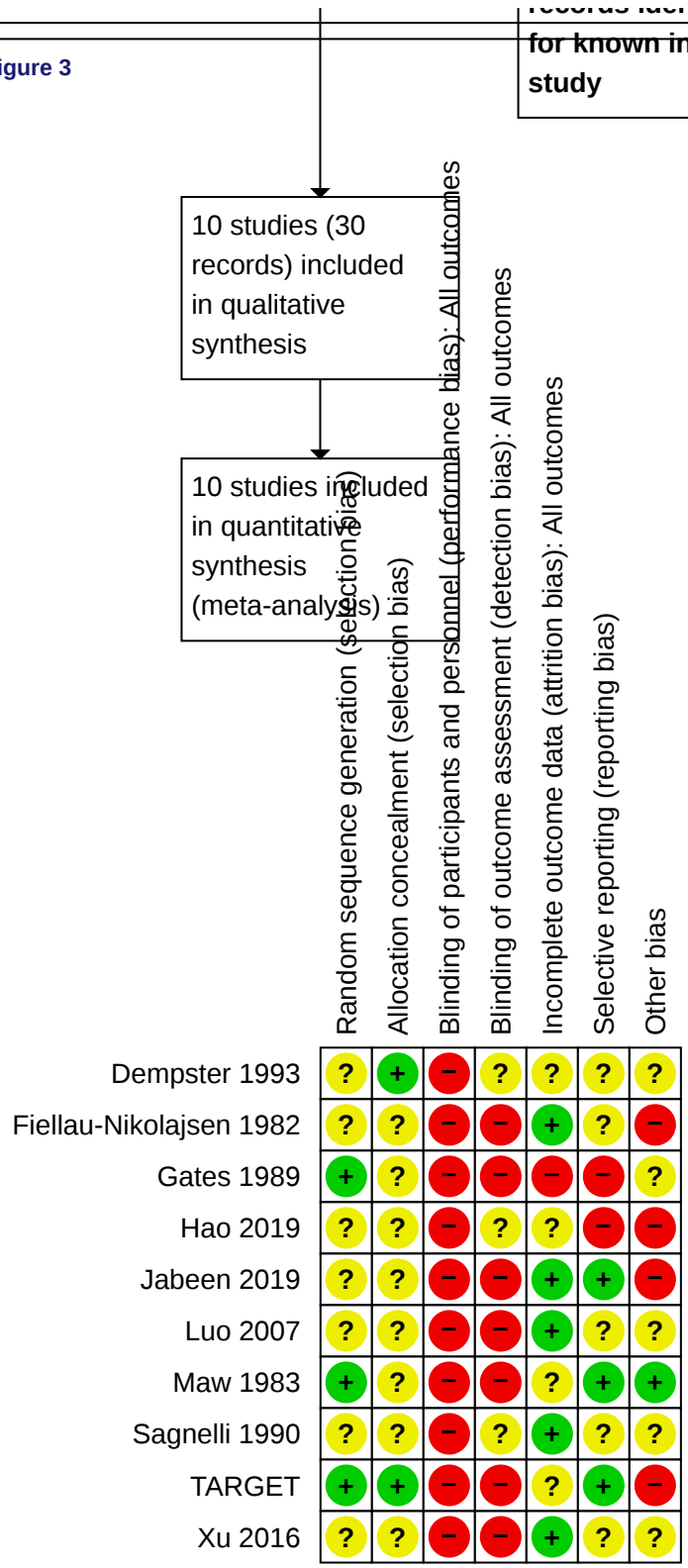
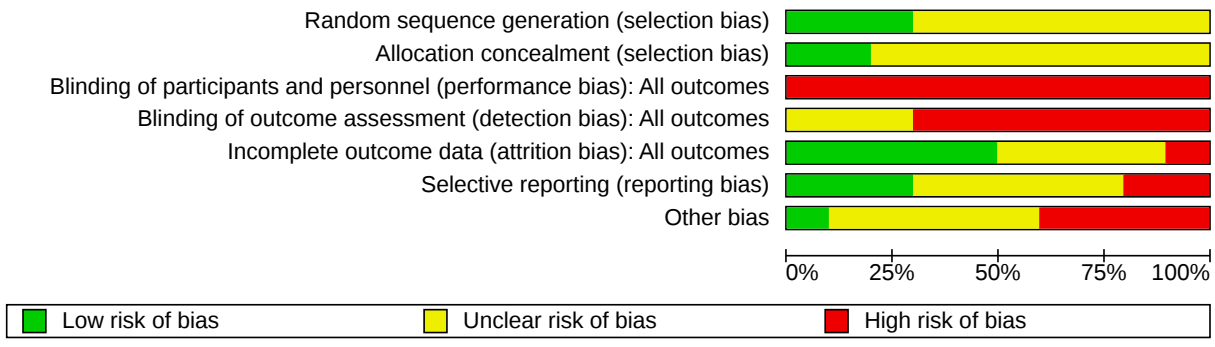
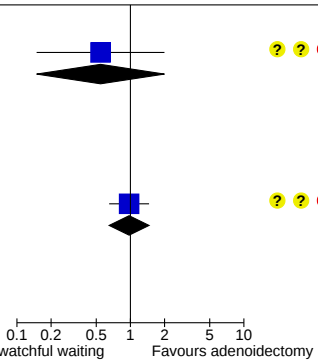


Figure 4



Analysis 1.1

Study or Subgroup	Adenoidectomy Events	Total	No treatment/watchful waiting Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
1.1.1 Up to 3 months								
Fiellau-Nikolajsen 1982 (1)	3	22	5	20	100.0%	0.55 [0.15 , 2.00]		? ? − − + ? −
Subtotal (95% CI)		**22**		**20**	**100.0%**	**0.55 [0.15 , 2.00]**		
Total events:	3		5					
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.92 (P = 0.36)								
1.1.2 Up to 12 months								
Fiellau-Nikolajsen 1982 (2)	15	22	14	20	100.0%	0.97 [0.65 , 1.46]		? ? − − + ? −
Subtotal (95% CI)		**22**		**20**	**100.0%**	**0.97 [0.65 , 1.46]**		
Total events:	15		14					
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.13 (P = 0.90)								



Footnotes

(1) Data from 3 months. See appendix for analysis details. Reported as a composite outcome.
(2) Data from 6 months. See appendix for analysis details. Reported as a composite outcome.

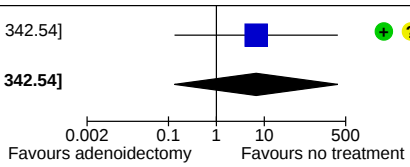
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 1: Hearing: proportion with normal hearing

Analysis 1.2

Study or Subgroup	Adenoidectomy Events	Total	No treatment Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI	Peto Odds Ratio Peto, Fixed, 95% CI	Risk of Bias A B C D E F G
Gates 1989 (1)	1	251	0	229	100.0%	6.77 [0.13 , 342.54]		+ ? − − − − ?
Total (95% CI)		**251**		**229**	**100.0%**	**6.77 [0.13 , 342.54]**		
Total events:	1		0					
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.96 (P = 0.34)								
Test for subgroup differences: Not applicable								



Footnotes

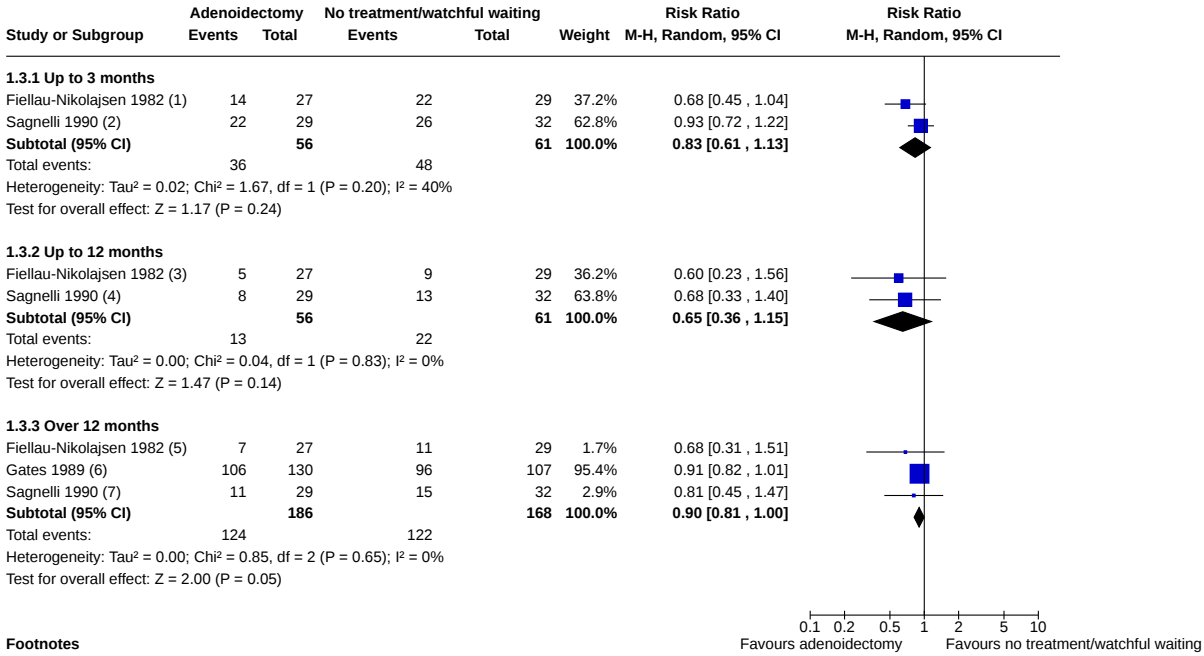
(1) Data for all children undergoing adneoidectomy (or not), regardless of co-intervention.

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 2: Haemorrhage

Analysis 1.3

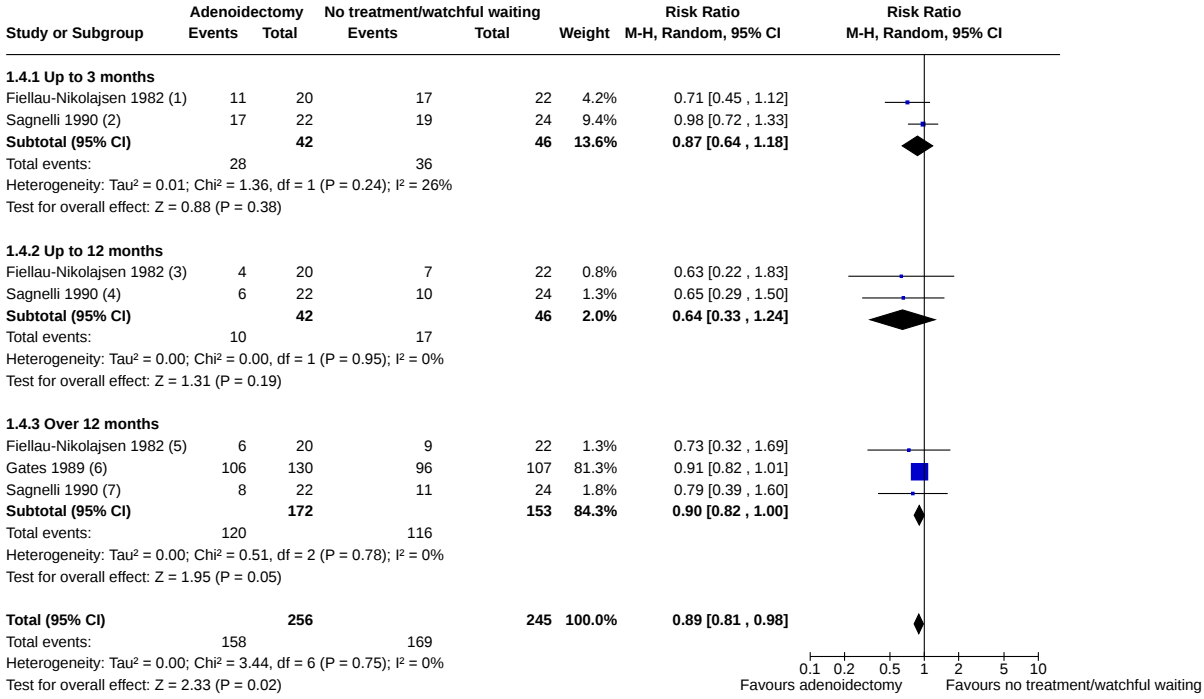


Footnotes

(1) At 3 months. Sample size adjusted with design effect 1.5. See Appendix for details. Type B or C2 tympanogram.
(2) At 3 months. Sample size adjusted with design effect 1.5. See Appendix for details. Type B or C tympanogram.
(3) At 6 months. Sample size adjusted with design effect 1.5. See Appendix for details. Type B or C2 tympanogram.
(4) At 6 months. Sample size adjusted with design effect 1.5. See Appendix for details. Type B or C tympanogram.
(5) At 21 months. Sample size adjusted with design effect 1.5. See Appendix for details. Type B or C2 tympanogram.
(6) Adenoidectomy plus myringotomy versus myringotomy. Stated as number with recurrent effusion at up to 2 years. Assumed to be cumulative.
(7) At 15 months. Sample size adjusted with design effect 1.5. See Appendix for details. Type B or C tympanogram.

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 3: Presence or persistence of OME

Analysis 1.4



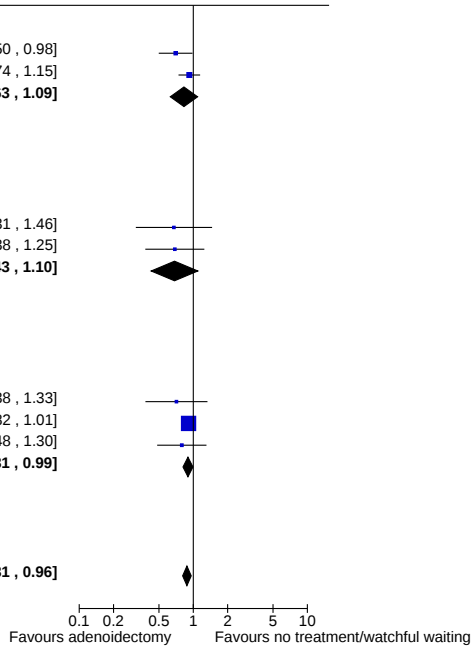
Footnotes

(1) At 3 months. Sample size adjusted assuming complete correlation between ears. Type B or C2 tympanogram.
(2) At 3 months. Sample size adjusted assuming complete correlation between ears. Type B or C tympanogram.
(3) At 6 months. Sample size adjusted assuming complete correlation between ears. Type B or C2 tympanogram.
(4) At 6 months. Sample size adjusted assuming complete correlation between ears. Type B or C2 tympanogram.
(5) At 21 months. Sample size adjusted assuming complete correlation between ears. Type B or C2 tympanogram.
(6) Stated as number with recurrent effusion at up to 2 years. Assumed to be cumulative.
(7) At 15 months. Sample size adjusted assuming complete correlation between ears. Type B or C tympanogram.

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 4: SENSITIVITY ANALYSIS: Presence or persistence of OME (complete correlation between ears)

Analysis 1.5

Study or Subgroup	Adenoidectomy Events	Total	No treatment/watchful waiting Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.5.1 Up to 3 months						
Fiellau-Nikolajsen 1982 (1)	21	40	33	44	6.5%	0.70 [0.50 , 0.98]
Sagnelli 1990 (2)	33	44	39	48	15.8%	0.92 [0.74 , 1.15]
Subtotal (95% CI)		**84**		**92**	**22.2%**	**0.83 [0.63 , 1.09]**
Total events:	54		72			
Heterogeneity: Tau² = 0.02; Chi² = 1.95, df = 1 (P = 0.16); I² = 49%						
Test for overall effect: Z = 1.34 (P = 0.18)						
1.5.2 Up to 12 months						
Fiellau-Nikolajsen 1982 (3)	8	40	13	44	1.3%	0.68 [0.31 , 1.46]
Sagnelli 1990 (4)	12	44	19	48	2.1%	0.69 [0.38 , 1.25]
Subtotal (95% CI)		**84**		**92**	**3.4%**	**0.68 [0.43 , 1.10]**
Total events:	20		32			
Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.97); I² = 0%						
Test for overall effect: Z = 1.58 (P = 0.11)						
1.5.3 Over 12 months						
Fiellau-Nikolajsen 1982 (5)	11	40	17	44	1.9%	0.71 [0.38 , 1.33]
Gates 1989 (6)	106	130	96	107	69.4%	0.91 [0.82 , 1.01]
Sagnelli 1990 (7)	16	44	22	48	3.0%	0.79 [0.48 , 1.30]
Subtotal (95% CI)		**214**		**199**	**74.4%**	**0.90 [0.81 , 0.99]**
Total events:	133		135			
Heterogeneity: Tau² = 0.00; Chi² = 1.22, df = 2 (P = 0.54); I² = 0%						
Test for overall effect: Z = 2.10 (P = 0.04)						
Total (95% CI)		**382**		**383**	**100.0%**	**0.88 [0.81 , 0.96]**
Total events:	207		239			
Heterogeneity: Tau² = 0.00; Chi² = 5.55, df = 6 (P = 0.48); I² = 0%						
Test for overall effect: Z = 2.91 (P = 0.004)						
Test for subgroup differences: Chi² = 1.44, df = 2 (P = 0.49), I² = 0%						



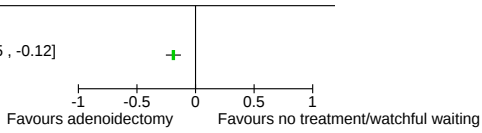
Footnotes

(1) At 3 months. Analysis conducted according to ears affected, not children. Type B or C2 tympanogram.
(2) At 3 months. Analysis conducted according to ears affected, not children. Type B or C tympanogram.
(3) At 6 months. Analysis conducted according to ears affected, not children. 95% CI will be artificially small. Type B or C2 tympanogram.
(4) At 6 months. Analysis conducted according to ears affected, not children. Type B or C tympanogram.
(5) At 21 months. Analysis conducted according to ears affected, not children. 95% CI will be artificially small. Type B or C2 tympanogram.
(6) Stated as number with recurrent effusion at up to 2 years. Assumed to be cumulative.
(7) At 15 months. Analysis conducted according to ears affected, not children. Type B or C tympanogram.

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 5: SENSITIVITY ANALYSIS: Presence or persistence of OME (no correlation between ears)

Analysis 1.6

Study or Subgroup	Adenoidectomy Mean	SD	Total	No treatment/watchful waiting Mean	SD	Total	Mean Difference IV, Random, 95% CI
1.6.1 Over 12 months							
Gates 1989	0.302	0.25	130	0.491	0.252	107	-0.19 [-0.25 , -0.12]



Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 6: Time with effusion

Analysis 1.7

Study or Subgroup	Adenoidectomy Mean	SD	Total	No treatment/watchful waiting Mean	SD	Total	Mean Difference IV, Random, 95% CI
Fiellau-Nikolajsen 1982 (1)	0.45	0.801257	20	0.68	0.789399	22	-0.23 [-0.71 , 0.25]

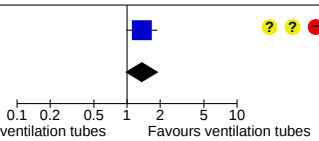
Footnotes

(1) Mean number of episodes in a 6-month period.

Comparison 1: Adenoidectomy (with or without myringotomy) versus no treatment/watchful waiting, Outcome 7: Number of episodes of AOM over 6 months

Analysis 2.1

Study or Subgroup	Adenoidectomy plus ventilation tubes Events	Total	Ventilation tubes Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
Luo 2007 (1)	47	83	32	77	100.0%	1.36 [0.98 , 1.89]		? ? − − + ? ?
Total (95% CI)		**83**		**77**	**100.0%**	**1.36 [0.98 , 1.89]**		
Total events:	47		32					



Heterogeneity: Not applicable
Test for overall effect: Z = 1.87 (P = 0.06)
Test for subgroup differences: Not applicable

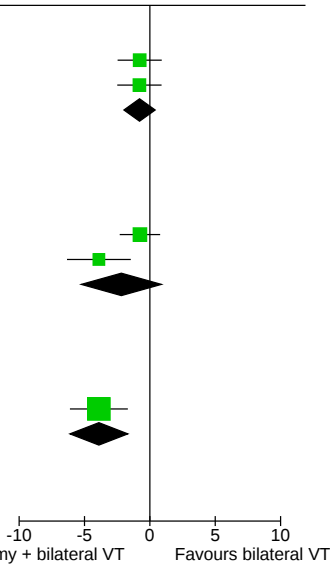
Footnotes
(1) At 6-9 months. Adjusted data to account for correlation between ears ICC = 0.5. See Appendix.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 1: Return to normal hearing

Analysis 2.2

Study or Subgroup	Adenoidectomy + VT Mean	SD	Total	VT Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
2.2.1 Up to 3 months									
Hao 2019 (1)	15.54	5.7	98	16.32	5.94	86	50.2%	-0.78 [-2.47 , 0.91]	
TARGET (2)	13.6	6	116	14.4	6.9	109	49.8%	-0.80 [-2.49 , 0.89]	
Subtotal (95% CI)			**214**			**195**	**100.0%**	**-0.79 [-1.99 , 0.41]**	
Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.99); I² = 0%									
Test for overall effect: Z = 1.29 (P = 0.20)									
2.2.2 Up to 12 months									
Hao 2019 (3)	14.52	5.42	98	15.28	5.27	86	54.7%	-0.76 [-2.31 , 0.79]	
TARGET (4)	17.1	9.1	111	21	9.4	110	45.3%	-3.90 [-6.34 , -1.46]	
Subtotal (95% CI)			**209**			**196**	**100.0%**	**-2.18 [-5.25 , 0.88]**	
Heterogeneity: Tau² = 3.84; Chi² = 4.54, df = 1 (P = 0.03); I² = 78%									
Test for overall effect: Z = 1.40 (P = 0.16)									
2.2.3 Over 12 months									
TARGET (5)	14.8	7.7	109	18.7	8.9	108	100.0%	-3.90 [-6.12 , -1.68]	
Subtotal (95% CI)			**109**			**108**	**100.0%**	**-3.90 [-6.12 , -1.68]**	
Heterogeneity: Not applicable									
Test for overall effect: Z = 3.45 (P = 0.0006)									

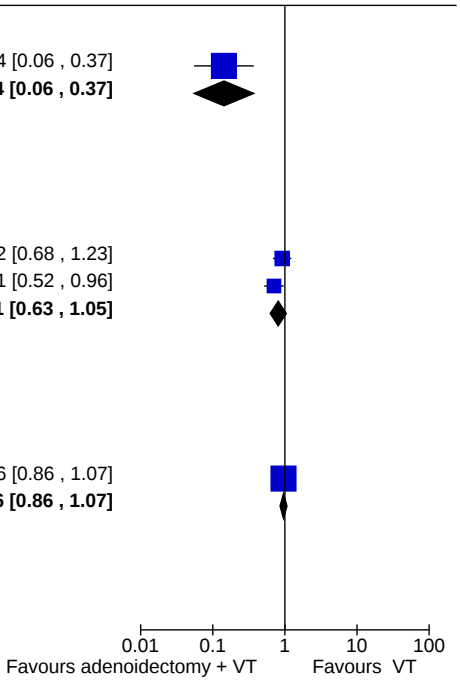


Footnotes
(1) Data from 3 months.
(2) Data are average hearing at 3 months follow-up.
(3) Data from 6 months.
(4) Data are average hearing at 12 months follow-up.
(5) Data are average hearing at 24 months follow-up.

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 2: Hearing: hearing threshold

Analysis 2.3

Study or Subgroup	Adenoidectomy + VT Events	Total	VT Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
2.3.1 Up to 3 months						
Jabeen 2019 (1)	4	40	28	40	100.0%	0.14 [0.06 , 0.37]
Subtotal (95% CI)		**40**		**40**	**100.0%**	**0.14 [0.06 , 0.37]**
Total events:	4		28			
Heterogeneity: Not applicable						
Test for overall effect: Z = 4.01 (P < 0.0001)						
2.3.2 Up to 12 months						
Hao 2019 (2)	46	98	44	86	51.9%	0.92 [0.68 , 1.23]
Luo 2007 (3)	35	83	46	77	48.1%	0.71 [0.52 , 0.96]
Subtotal (95% CI)		**181**		**163**	**100.0%**	**0.81 [0.63 , 1.05]**
Total events:	81		90			
Heterogeneity: Tau² = 0.01; Chi² = 1.43, df = 1 (P = 0.23); I² = 30%						
Test for overall effect: Z = 1.62 (P = 0.11)						
2.3.3 Over 12 months						
Gates 1989 (4)	102	125	110	129	100.0%	0.96 [0.86 , 1.07]
Subtotal (95% CI)		**125**		**129**	**100.0%**	**0.96 [0.86 , 1.07]**
Total events:	102		110			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.79 (P = 0.43)						



Footnotes

(1) Recurrence of disease at 3 months, as assessed by otoscopy.

(2) Unclear if data are from 3 or 6 months f/up. Composite outcome, including symptom, effusion and hearing. See text.

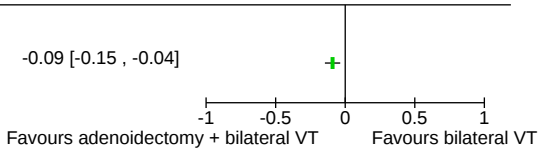
(3) 6-9 months. Composite outcome including tympanometry, symptoms and hearing. See text. Reported per ear and adjusted using ICC of 0.5.

(4) Recurrent effusion at up to 2 years. Assumed to be cumulative.

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 3: Presence/persistence of OME

Analysis 2.4

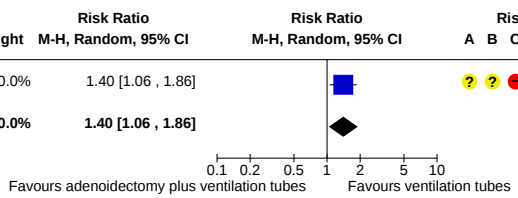
Study or Subgroup	Adenoidectomy + VT Mean	SD	Total	VT Mean	SD	Total	Mean Difference IV, Random, 95% CI
2.4.1 Over 12 months							
Gates 1989	0.258	0.212	125	0.349	0.235	129	-0.09 [-0.15 , -0.04]



Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 4: Time with effusion

Analysis 2.5

Study or Subgroup	Adenoidectomy plus ventilation tubes Events	Total	Ventilation tubes Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
Luo 2007 (1)	63	110	42	103	100.0%	1.40 [1.06 , 1.86]	? ? − − + ? ?
Total (95% CI)		**110**		**103**	**100.0%**	**1.40 [1.06 , 1.86]**	
Total events:	63		42				
Heterogeneity: Not applicable							
Test for overall effect: Z = 2.35 (P = 0.02)							
Test for subgroup differences: Not applicable							



Footnotes

(1) At 6-9 months. Adjusted data to account for correlation between ears - see Appendix. ICC 0.

Risk of bias legend

(A) Random sequence generation (selection bias)

(B) Allocation concealment (selection bias)

(C) Blinding of participants and personnel (performance bias)

(D) Blinding of outcome assessment (detection bias)

(E) Incomplete outcome data (attrition bias)

(F) Selective reporting (reporting bias)

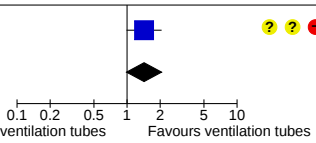
(G) Other bias

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 5: SENSITIVITY ANALYSIS: Return to normal hearing ICC 0

Analysis 2.6

Study or Subgroup	Adenoidectomy plus ventilation tubes Events	Total	Ventilation tubes Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
Luo 2007 (1)	38	66	25	62	100.0%	1.43 [0.99 , 2.06]		? ? − − + ? ?
Total (95% CI)		**66**		**62**	**100.0%**	**1.43 [0.99 , 2.06]**		
Total events:	38		25					

Heterogeneity: Not applicable
Test for overall effect: Z = 1.90 (P = 0.06)
Test for subgroup differences: Not applicable



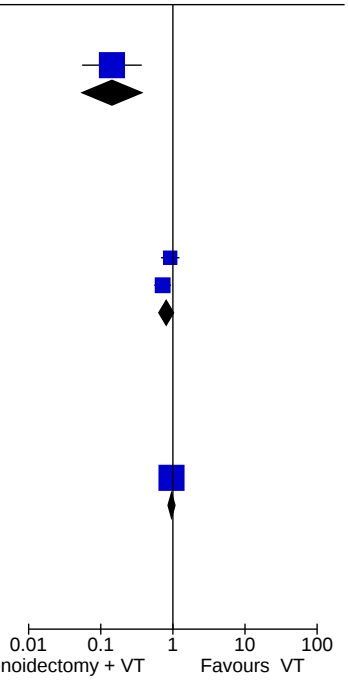
Footnotes
(1) At 6-9 months. Adjusted data to account for correlation between ears - see Appendix. ICC 1.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 6: SENSITIVITY ANALYSIS: Return to normal hearing ICC 1

Analysis 2.7

Study or Subgroup	Adenoidectomy + VT Events	Total	VT Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
2.7.1 Up to 3 months							
Jabeen 2019 (1)	4	40	28	40	100.0%	0.14 [0.06 , 0.37]	
Subtotal (95% CI)		**40**		**40**	**100.0%**	**0.14 [0.06 , 0.37]**	
Total events:	4		28				
Heterogeneity: Not applicable							
Test for overall effect: Z = 4.01 (P < 0.0001)							
2.7.2 Up to 12 months							
Hao 2019 (2)	46	98	44	86	46.7%	0.92 [0.68 , 1.23]	
Luo 2007 (3)	47	110	61	103	53.3%	0.72 [0.55 , 0.94]	
Subtotal (95% CI)		**208**		**189**	**100.0%**	**0.81 [0.64 , 1.02]**	
Total events:	93		105				
Heterogeneity: Tau² = 0.01; Chi² = 1.39, df = 1 (P = 0.24); I² = 28%							
Test for overall effect: Z = 1.79 (P = 0.07)							
2.7.3 Over 12 months							
Gates 1989 (4)	102	125	110	129	100.0%	0.96 [0.86 , 1.07]	
Subtotal (95% CI)		**125**		**129**	**100.0%**	**0.96 [0.86 , 1.07]**	
Total events:	102		110				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.79 (P = 0.43)							

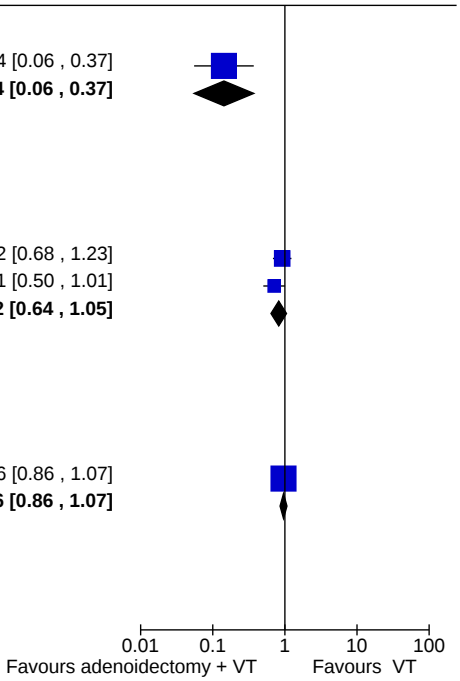


Footnotes
(1) Recurrence of disease at 3 months, as assessed by otoscopy.
(2) Unclear if data are from 3 or 6 months f/up. Composite outcome, including symptom, effusion and hearing. See text.
(3) 6-9 months. Composite outcome including tympanometry, symptoms and hearing. See text. Reported per ear and adjusted using ICC of 0.
(4) Recurrent effusion at up to 2 years. Assumed to be cumulative.

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 7: SENSITIVITY ANALYSIS: Presence/persistence of OME ICC 0

Analysis 2.8

Study or Subgroup	Adenoidectomy + VT Events	Total	VT Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
2.8.1 Up to 3 months						
Jabeen 2019 (1)	4	40	28	40	100.0%	0.14 [0.06 , 0.37]
Subtotal (95% CI)		**40**		**40**	**100.0%**	**0.14 [0.06 , 0.37]**
Total events:	4		28			
Heterogeneity: Not applicable						
Test for overall effect: Z = 4.01 (P < 0.0001)						
2.8.2 Up to 12 months						
Hao 2019 (2)	46	98	44	86	56.8%	0.92 [0.68 , 1.23]
Luo 2007 (3)	28	66	37	62	43.2%	0.71 [0.50 , 1.01]
Subtotal (95% CI)		**164**		**148**	**100.0%**	**0.82 [0.64 , 1.05]**
Total events:	74		81			
Heterogeneity: Tau² = 0.01; Chi² = 1.20, df = 1 (P = 0.27); I² = 17%						
Test for overall effect: Z = 1.55 (P = 0.12)						
2.8.3 Over 12 months						
Gates 1989 (4)	102	125	110	129	100.0%	0.96 [0.86 , 1.07]
Subtotal (95% CI)		**125**		**129**	**100.0%**	**0.96 [0.86 , 1.07]**
Total events:	102		110			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.79 (P = 0.43)						



Footnotes

(1) Recurrence of disease at 3 months, as assessed by otoscopy.

(2) Unclear if data are from 3 or 6 months f/up. Composite outcome, including symptom, effusion and hearing. See text.

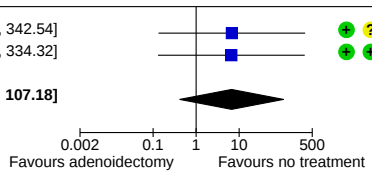
(3) 6-9 months. Composite outcome including tympanometry, symptoms and hearing. See text. Reported per ear and adjusted using ICC of 1.

(4) Recurrent effusion at up to 2 years. Assumed to be cumulative.

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 8: SENSITIVITY ANALYSIS: Presence/persistence of OME ICC 1

Analysis 2.9

Study or Subgroup	Adenoidectomy plus bilateral VTs Events	Total	Bilateral VTs Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI	Risk of Bias A B C D E F G
Gates 1989 (1)	1	251	0	229	50.0%	6.77 [0.13 , 342.54]	+ ? − − − − ?
TARGET	1	165	0	146	50.0%	6.59 [0.13 , 334.32]	+ + − − ? + −
Total (95% CI)		**416**		**375**	**100.0%**	**6.68 [0.42 , 107.18]**	
Total events:	2		0				
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.99); I² = 0%							
Test for overall effect: Z = 1.34 (P = 0.18)							
Test for subgroup differences: Not applicable							



Footnotes

(1) Data for all children undergoing adneoidectomy (or not), regardless of co-intervention.

Risk of bias legend

(A) Random sequence generation (selection bias)

(B) Allocation concealment (selection bias)

(C) Blinding of participants and personnel (performance bias)

(D) Blinding of outcome assessment (detection bias)

(E) Incomplete outcome data (attrition bias)

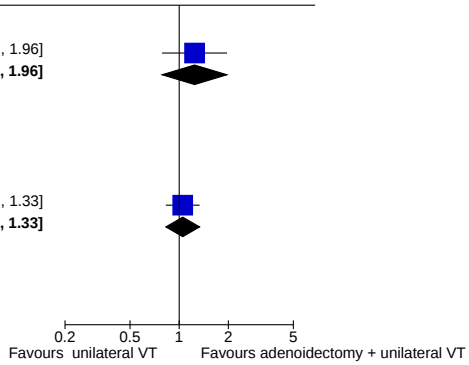
(F) Selective reporting (reporting bias)

(G) Other bias

Comparison 2: Adenoidectomy and bilateral ventilation tubes versus bilateral ventilation tubes only, Outcome 9: Haemorrhage

Analysis 3.1

Study or Subgroup	Adenoidectomy plus unilateral VT Events	Total	Unilateral VT Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
3.1.1 Normal hearing ≤15 dB.						
Dempster 1993 (1)	21	37	16	35	100.0%	1.24 [0.79 , 1.96]
Subtotal (95% CI)		**37**		**35**	**100.0%**	**1.24 [0.79 , 1.96]**
Total events:	21		16			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.93 (P = 0.35)						
3.1.2 SENSITIVITY ANALYSIS: Normal hearing < 25 dB.						
Dempster 1993 (2)	30	37	27	35	100.0%	1.05 [0.83 , 1.33]
Subtotal (95% CI)		**37**		**35**	**100.0%**	**1.05 [0.83 , 1.33]**
Total events:	30		27			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.41 (P = 0.68)						



Footnotes

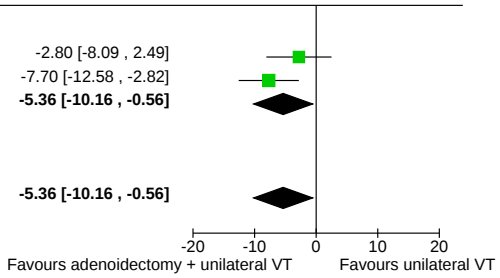
(1) At 12 months. Analysis per child for ears without a grommet. Normal hearing ≤15 dB.

(2) At 12 months. Analysis per child for ears without a grommet. Normal hearing < 25 dB.

Comparison 3: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only, Outcome 1: Hearing: proportion of children with hearing returned to normal (medium-term)

Analysis 3.2

Study or Subgroup	Adenoidectomy + unilateral VT Mean	SD	Total	Unilateral VT Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
3.2.1 Up to 12 months								
Dempster 1993 (1)	-16.8	10.7	37	-14	12.1	35	47.8%	-2.80 [-8.09 , 2.49]
Maw 1983 (2)	19.7	10.36	35	27.4	12.13	47	52.2%	-7.70 [-12.58 , -2.82]
Subtotal (95% CI)			**72**			**82**	**100.0%**	**-5.36 [-10.16 , -0.56]**
Heterogeneity: Tau² = 5.27; Chi² = 1.78, df = 1 (P = 0.18); I² = 44%								
Test for overall effect: Z = 2.19 (P = 0.03)								
Total (95% CI)			**72**			**82**	**100.0%**	**-5.36 [-10.16 , -0.56]**
Heterogeneity: Tau² = 5.27; Chi² = 1.78, df = 1 (P = 0.18); I² = 44%								
Test for overall effect: Z = 2.19 (P = 0.03)								
Test for subgroup differences: Not applicable								



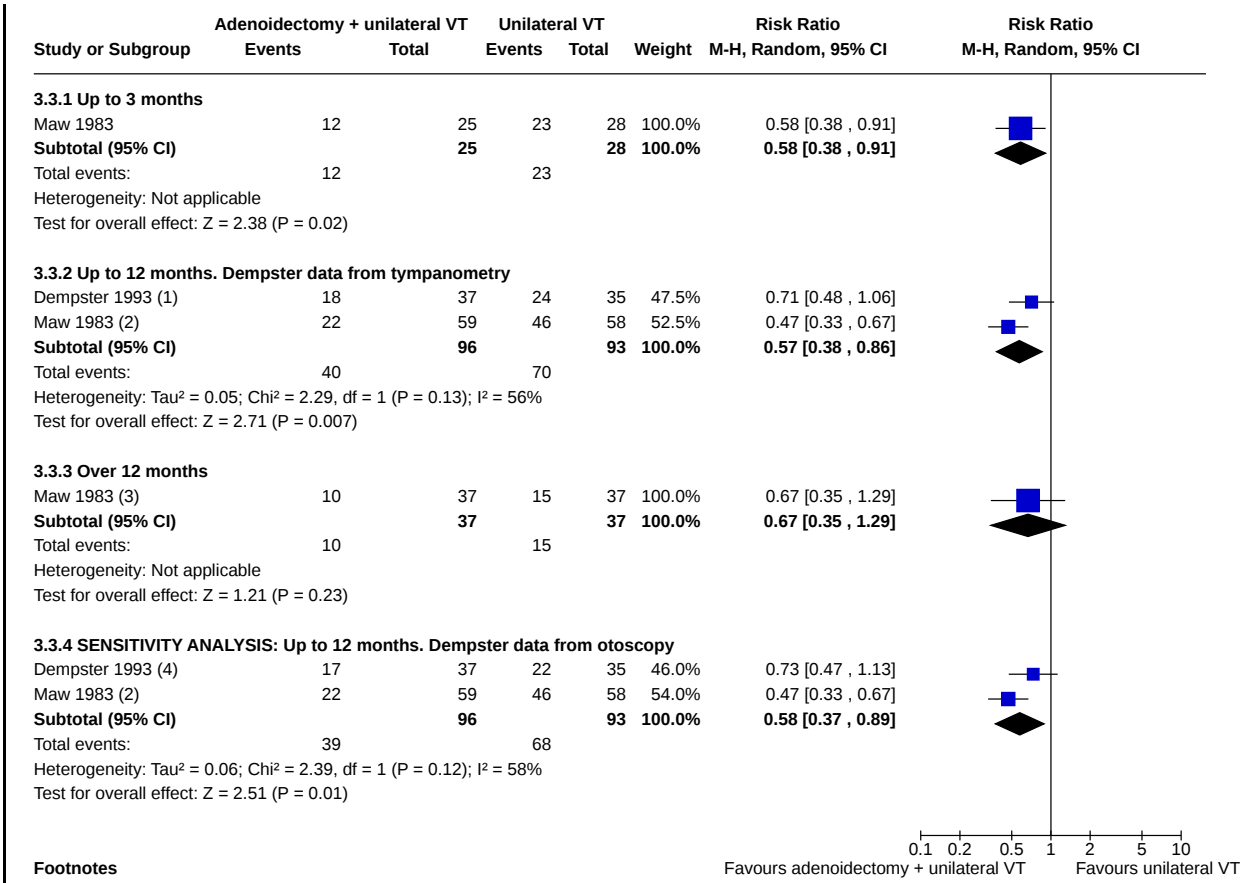
Footnotes

(1) Change from baseline. Data at 12 months. Air conduction threshold. Ear without a VT.

(2) Final hearing threshold at 12 months. Ear without a VT.

Comparison 3: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only, Outcome 2: Hearing: Hearing threshold

Analysis 3.3

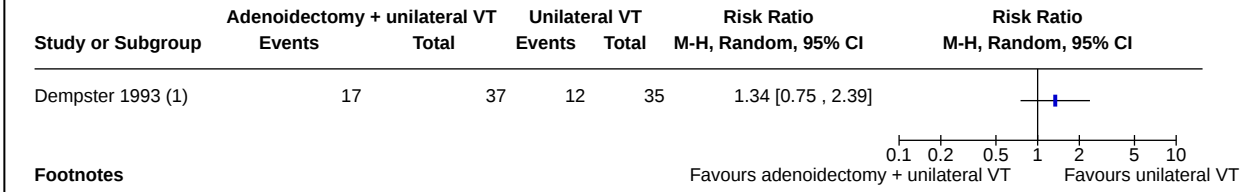


Footnotes

(1) Data from 12 months, by tympanometry. From ear without the VT.
(2) Data from 12 months. Unoperated ear assessed.
(3) At 3 years.
(4) Data from 12 months, by otoscopy. From ear without the VT.

Comparison 3: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only, Outcome 3: Presence or persistence of OME

Analysis 3.4

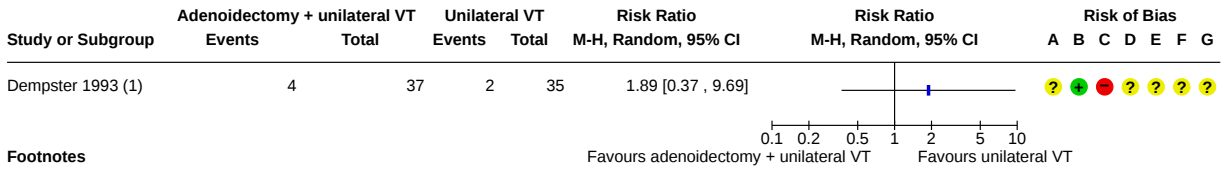


Footnotes

(1) Includes ears with VT and without VT. N.B. numerator in control group may be 11, not 12.

Comparison 3: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only, Outcome 4: Adverse events: tympanosclerosis

Analysis 3.5



Footnotes

(1) Includes ears with VT

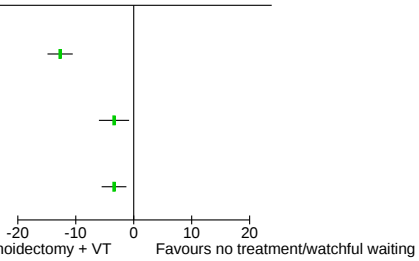
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 3: Adenoidectomy and unilateral ventilation tube versus unilateral ventilation tube only, Outcome 5: Adverse events: perforation/retraction

Analysis 4.1

Study or Subgroup	Adenoidectomy + VT Mean	SD	Total	No treatment/watchful waiting Mean	SD	Total	Mean Difference IV, Random, 95% CI
4.1.1 Up to 3 months							
TARGET	13.6	6	116	26.3	9.9	106	-12.70 [-14.88 , -10.52]
4.1.2 Up to 12 months							
TARGET (1)	17.1	9.1	111	20.5	10.1	100	-3.40 [-6.00 , -0.80]
4.1.3 Over 12 months							
TARGET (2)	14.8	7.7	109	18.2	8.1	102	-3.40 [-5.54 , -1.26]



Footnotes

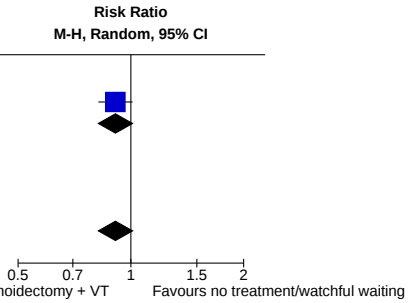
(1) Data are average hearing at 12 months follow-up.

(2) Data are average hearing at 24 months follow-up.

Comparison 4: Adenoidectomy and ventilation tubes versus no treatment/watchful waiting, Outcome 1: Hearing: hearing threshold

Analysis 4.2

Study or Subgroup	Adenoidectomy + VT Events	Total	No treatment/watchful waiting Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
4.2.1 Over 12 months						
Gates 1989 (1)	102	125	96	107	100.0%	0.91 [0.82 , 1.01]
Subtotal (95% CI)		**125**		**107**	**100.0%**	**0.91 [0.82 , 1.01]**
Total events:	102		96			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.77 (P = 0.08)						
Total (95% CI)		**125**		**107**	**100.0%**	**0.91 [0.82 , 1.01]**
Total events:	102		96			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.77 (P = 0.08)						
Test for subgroup differences: Not applicable						



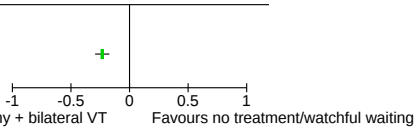
Footnotes

(1) Recurrent effusion at up to 2 years. Assumed to be cumulative.

Comparison 4: Adenoidectomy and ventilation tubes versus no treatment/watchful waiting, Outcome 2: Presence/persistence of OME

Analysis 4.3

Study or Subgroup	Adenoidectomy + VT Mean	SD	Total	No treatment/watchful waiting Mean	SD	Total	Mean Difference IV, Random, 95% CI
4.3.1 Over 12 months							
Gates 1989	0.258	0.212	125	0.491	0.252	107	-0.23 [-0.29 , -0.17]



Comparison 4: Adenoidectomy and ventilation tubes versus no treatment/watchful waiting, Outcome 3: Time with effusion