Grommets in otitis media with effusion: an individual patient data meta-analysis

CRD summary
This review attempted to identify subgroups of children with otitis media with effusion who would benefit most from ventilation tubes. The authors concluded that children younger than 3 years attending day-care, or older than 4 years with a hearing level of 25 dB HL or greater for at least 12 weeks, may benefit most. Considering the limitations of the review, the results should be treated with caution.

Authors' objectives
To identify which subgroups of children with otitis media with effusion (OME) would benefit most from treatment with ventilation tubes.

Searching
PubMed, the Cochrane Library and the proceedings of international symposia on recent advances in otitis media were searched.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), and studies where the treated ear was compared with the contralateral ear, were eligible for inclusion.

Specific interventions included in the review
Studies of short-term ventilation tubes compared with watchful waiting were eligible for inclusion.

Participants included in the review
Studies of children up to the age of 12 years with tympanometrically and/or otoscopically confirmed persistent bilateral OME were eligible for inclusion. The age of the participants at inclusion ranged from 1 to 9 years.

Outcomes assessed in the review
There were no specific inclusion criteria relating to the outcomes. The outcomes measured in the included studies were hearing (measured by audiometry; decibel hearing level, dB HL), time spent with effusion (measured by tympanometry), language development, mental development, behaviour and quality of life.

How were decisions on the relevance of primary studies made?
The authors stated that the integrity of randomisation and follow-up were checked, and that trial investigators were consulted when queries arose.

Assessment of study quality
The authors stated that the data were checked for consistency and plausibility, and that trial investigators or a statistician were consulted when queries arose. The authors did not state how validity was assessed, or how many reviewers performed the validity assessment.

Data extraction
Data relating to tympany, pure-tone audiometry or age-related hearing assessment, and language development measured using the Reynell test, were used. Mean time spent with effusion with 95% confidence intervals (CIs) were calculated from an interpolation from type B tympanograms during follow-up visits, with half of the number of days between visits being counted as days with effusion if effusion was present at one visit but absent at the other. The mean hearing
loss, measured by air conduction, pure-tone audiometry where possible, and standard error (SE) were calculated. Where children were randomised rather than ears, the average of both ears was used. Reynell language scores were expressed as standardised z scores. Scores of language development at 6 and 9 months were combined, as were those for 12 and 18 months.

**Methods of synthesis**

How were the studies combined?

The differences in mean time spent with effusion, hearing loss and language development between treatment and controls were tested using Student's t-test. A fixed-effect regression analysis was used to investigate the effect of ventilation tubes within subgroups of children, with the interventions as the independent variables and outcome measures as the dependent variables. All analyses were conducted on an intention-to-treat basis.

How were differences between studies investigated?

Separate analyses were conducted for trials that treated both ears and trials treating one ear. The efficacy of ventilation tubes was investigated by comparing results for children with functioning ventilation tubes and those with non-functioning or without ventilation tubes. The response to treatment of children with one versus two or more predisposing risk factors was also investigated.

**Results of the review**

Ten studies (n=2,347) met the inclusion criteria. Individual patient data could not be retrieved for 3 studies (n=1,116). Seven studies (n=1,231) were included in the review. The final follow-up ranged from 1 to 10 years.

**Time spent with effusion.**

The mean time spent with effusion was statistically significantly lower in children with ventilation tubes (19.7 weeks, 95% CI: 17.6, 21.9) than children in the watchful-waiting group (37 weeks, 95% CI: 34.9, 39.1) at the 12-month follow-up (557 children, P<0.001).

**Hearing level.**

The mean hearing level was statistically significantly better in children with ventilation tubes (26.6 dB HL, SE 1.0) than children in the watchful-waiting group (31.1 dB HL, SE 1.0) at the 6-month follow-up (574 children, P=0.001). However, there were no differences at 12 or 18 months' follow-up. Predictors of poor hearing at 6, 12 and 18 months included baseline hearing loss, attendance in day-care, age and season, and being breast fed. The fixed-effect regression analysis showed ventilation tubes were only differentially effective in children attending day-care, where the hearing level was 7 dB HL better in children with ventilation tubes.

In studies where one ear was treated and the contralateral ear was used as the comparator (160 children), hearing improved by 10 dB HL more in ears with ventilation tubes than in ears not treated at 6 months, and 7 dB HL at 12 months, when the hearing loss at baseline was 25 dB HL or more. When the hearing loss was less than 25 dB HL, the improvement in ears with ventilation tubes was 4 dB HL greater than control ears at the 6-month follow-up, and 3 dB HL at 12 months.

**Language development.**

There was no statistically significant difference in language development between children with ventilation tubes and children in the watchful-waiting group at 6/9 or 12/18 months' follow-up (381 children).

Children with more than one risk factor appeared to benefit slightly more from treatment with ventilation tubes than children with one risk factor.

**Authors' conclusions**

Treatment with ventilation tubes produced limited hearing improvement of short-term duration, whilst the tubes were in
situ and patent. Children 3 years or younger attending day-care, or 4 years and over with a hearing level of 25 dB HL or greater persisting for at least 12 weeks, may benefit more from treatment with ventilation tubes.

**CRD commentary**
The review question was clear in terms of the participants, intervention and study design. Relevant sources were searched, although the search was not extensive. Trial investigators or a statistician were contacted to resolve queries regarding data. It was unclear whether methods were used to reduce error and bias when selecting studies for the review. Individual patient data for 48% of the children evaluated in the studies that met the inclusion criteria could not be obtained and summary data for these children, which could have been used in a sensitivity analysis to investigate the effect of missing data, were not presented. The authors performed several subgroup analyses, but there appeared to be no formal assessment of heterogeneity. Considering the potential for selection bias, and the omission of data from a large number of children, the results should be treated with caution.

**Implications of the review for practice and research**
Practise: The authors suggested that an initial period of watchful waiting seems to be the appropriate management for most children with OME, as the benefits of ventilation tubes were small and related to the presence and patency of the tubes.

Research: The authors stated that the interaction between day-care attendance, infection load and treatment with ventilation tubes needed further study, as did the benefit of treatment in children with speech or language delays, behaviour and learning problems, Down's syndrome, and cleft palate.

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Record Status
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