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Grommets may decrease the recurrence of acute otitis media, compared to active monitoring.

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Clinical question: Is the use of grommets (ventilation tubes) in children with recurrent acute otitis media (AOM) safe and effective?

Context: AOM is a very common childhood disease. For most children, this is a sporadic disease, but an important group suffer from recurrent AOM, which is defined as three or more episodes in six months or four or more episodes in one year. AOM is accompanied by pain, illness, sleep disturbances and time lost from school.

This Cochrane review collected trials which compared bilateral grommet insertion, with or without concurrent adenoidectomy, with active monitoring, antibiotic prophylaxis or placebo, in children below 16 years old. The primary outcomes of this review were the proportion of children without recurrence of AOM at three to six months follow-up and persistent tympanic membrane perforation as adverse event.

Summary of the results: This review identified five trials, with a total of 805 children. Four of the trials were published before 1996. Study populations were quite comparable, consisting of children generally under the age of 3 years who had had at least 3 episodes of AOM in the previous 6 months. Two studies compared grommets to active monitoring, three compared grommets to antibiotic prophylaxis (amoxicilline, sulfamethoxazole-trimethoprim or sulfisoxazole) and two compared grommets to placebo. None of the studies included adenoidectomy in both the intervention and control groups.

When compared to active monitoring, two studies suggest that grommets may increase the likelihood of not having a AOM recurrence, either within 6 months (1 study with 95 participants: 46% for grommets versus 5% for active monitoring, RR[^]: 9.49, 95% CI from 2.38 to 37.8), or within 12 months (1 study with 200 participants: 48% for grommets versus 34% for monitoring, RR: 1.41, 95% CI from 1.00 to 1.99). The evidence was downgraded to low quality because of methodological limitations and small sample size.

When compared to antibiotic prophylaxis, a meta-analysis of 2 studies including only 96 participants suggest that children receiving grommets were more likely to have no recurrence of AOM within 6 months (60% for grommets versus 35% for antibiotics, RR 1.68 with 95% CI from 1.07 to 2.65). In this case, however, evidence was downgraded to very low quality because of high risk of bias of one of the studies and because of small sample size. Exclusion of this study led to non-significant results. Therefore, the benefits of grommets compared to prophylactic antibiotics remain uncertain.

In terms of possible adverse effects of grommets, only two trials reported the number of persistent tympanic membrane perforations. Reported incidences were low (0/54 in one study and 3/76 or 4% in the other).

Remarks: The evidence from RCT's about the efficacy and safety of grommets in young children with recurrent AOM is of low (compared to active monitoring) to very low (compared to antibiotic prophylaxis or placebo) certainty.

In addition, applicability of the results in current clinical practice is limited by the fact that these studies were conducted prior to the widespread use of the pneumococcal vaccine, which altered the bacteriology and epidemiology of AOM. It is unclear how this might influence the results from these studies.

Finally, in the available studies severity of AOM recurrences was not taken into account as an outcome, ignoring the possibility that grommets may decrease the degree of symptoms and the duration of recurrences.

Conclusion: In young children with recurrent AOM, grommets may increase the likelihood of remaining free from recurrences after 6 to 12 months, compared to active monitoring, but the effects compared to antibiotic prophylaxis and placebo are uncertain. Although adverse effects have been poorly studied, the risk of persistent tympanic perforation may be low.

Implications for practice: The available evidence is too weak to unequivocally advise for or against grommets in children with recurrent AOM. A large, high-quality RCT on this topic in the era of widespread pneumococcal vaccination is required to make more reliable conclusions.

Reference: Venekamp RP, Mick P, Schilder AG, Nunez DA.. Grommets (ventilation tubes) for recurrent acute otitis media in children. Cochrane Database Syst Rev. 2018 May 9;5:CD012017.

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* CI = confidence interval

^ RR = relative risk