

Otitis media with effusion in infants: Is screening and treatment with ventilation tubes necessary?

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Otitis media with effusion (OME) is one of the most common diseases in childhood; the annual health-related cost is estimated to be about \$2 billion in the United States.¹ The main line of treatment is surgical — the insertion of ventilation tubes² — the aim of which is to restore hearing to a normal level and so minimize language development problems.

So far, almost all effectiveness trials have included children aged 3 years or older. Children younger than this, among whom the prevalence at least of short-term OME is highest,³ form an increasing proportion of those treated with ventilation tubes. This is an important period for language development, and it has been assumed that screening and subsequent treatment of OME contribute to the prevention of communicative disorders.⁴

We recently conducted a trial involving a cohort of 30 099 children born in the eastern part of the Netherlands between January 1996 and April 1997. These infants had routine screening at age 9 months, and those who failed 3 consecutive tests were referred to 1 of 13 participating ear, nose and throat outpatient clinics for diagnosis and follow-up ($n = 1081$). The infants found to have persistent (4–6 months' duration) bilateral OME in subsequent observations were randomly assigned to treatment with ventilation tube insertion ($n = 93$) or watchful waiting ($n = 94$).⁵ We assessed their hearing, language development and quality of life after a 12-month follow-up period. In summary, we found that the children in the watchful waiting group suffered bilateral OME longer than those in the ventilation

tube group (277 days v. 142 days, $p < 0.001$). At 6 months' follow-up hearing levels in infants in the ventilation tube group were improved, but the magnitude and duration of the effect was limited. Among the children in the ventilation tube group, those with larger hearing deficits at randomization had greater improvements in hearing after the insertion of ventilation tubes than did children with better hearing thresholds. Treatment with ventilation tubes did not have a substantial incremental effect on both receptive and expressive language development or quality of life. Beneficial effects in individual patients or subgroups of patients cannot, however, be excluded.

So far, only a few adequately designed randomized controlled trials have been published on the effect of ventilation tubes on OME in young children. Most of these studies described the effect on hearing^{6–9} and reported short-term improvement, as was found in our trial. Maw and colleagues¹⁰ studied the effect of ventilation tubes on language development in children aged 3–4 years. At 9 months' follow-up, marginally significant differences were found in comprehensive and expressive language between the group receiving ventilation tubes and the group assigned to watchful waiting. However, 18 months after randomization, 85% of the children in the watchful waiting group had received ventilation tubes and the groups no longer differed. Paradise and colleagues¹¹ recently showed that prompt insertion of ventilation tubes in children with persistent otitis media did not measurably improve developmental outcomes at the age of 3 years. Other nonran-

domized studies involving children aged 3 years or less did not show any clear association between OME and speech and language development.^{12,13} Earlier studies on the effect of ventilation tubes on quality of life lacked a control group. Thus, our results are consistent with the findings reported by other investigators.

Several implications can be drawn for medical practice. Screening for hearing loss at the age of 9 months detected a large number of children with conductive hearing loss. However, treatment with ventilation tubes did not have any substantial effect on language development or quality of life in infants with bilateral, persistent OME detected through a population-based screening program, and so watchful waiting appears to be a reasonable approach. Thus, the chief prerequisite of screening¹⁴ was not met. There appears to be no reason to start screening programs solely for the purpose of detecting conductive hearing losses of typical severity and persistence in this age group.

Our negative findings do not necessarily mean that ventilation tubes would be ineffective in symptomatic or otherwise well-defined children. Our study design only permitted a statement about the effect of ventilation tubes on the entire group of infants detected by population-based screening at 9 months of age, not about infants with obvious complaints, those at high risk, those with upper respiratory tract complaints or children with comorbid sensorineural hearing loss or language impairment. Such children might well benefit from ventilation tubes, or from combinations of treatments. This, however, does not justify a policy of population-wide screening and subsequent intervention.

On the basis of current knowledge the following conclusions can be drawn:

- Screening programs for hearing loss at the age of 9 months will detect a large number of children with mild conductive hearing loss.
- Watchful waiting is a justifiable approach in young children, especially when there are no OME-related complaints.
- In individual cases with obvious complaints or hearing loss of at least 30 dB, or both, the clinician and the parents will need to make a choice from the available treatment options. They might consider ventilation tubes as an option, but adenoideotomy, antibiotic therapy and watchful waiting might be alternative (or supplementary) treatments.

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Contributors: Maroeska Rovers was responsible for the data collection, analyses and preparation of the manuscript. Koen Ingels planned the study and was the medical advisor of the trial. Gert Jan van der Wilt designed the protocol. Paul van den Broek and Gerhard Zielhuis were the supervisors of Maroeska Rovers and were involved in designing the trial. All of the authors commented on earlier drafts and approved the final version.

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Editor's note: A recommendation statement on screening children for otitis media with effusion appears on page 1092.