Ventilation tubes in infants increase the risk of otorrhoea and antibiotic usage

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Abstract. Ventilation tubes in infants increase the risk of otorrhoea and antibiotic usage. 1) Problem/objective: The effect of ventilation tubes on acute otitis related symptoms (otorrhoea, earache, and fever) and on antibiotic usage was investigated in children with persistent otitis media with effusion, as part of a multicenter, randomised, controlled clinical trial.
2) Methodology: One hundred-eighty-seven children were randomly placed into either a watchful waiting group (WW group) (n = 94) or a group treated with ventilation tubes (VT group) (n = 93). Both groups were followed for 12 months. Data were collected from parental reports and from medical files kept by the attending ENT-surgeons.
3) Results: There were significant differences in the reported frequency of otorrhoea (but not of earache or fever) between both groups during follow-up, i.e. children in the VT group had more episodes of otorrhoea than the children in the WW group (p < 0.003). As a consequence, children in the VT group had been prescribed antibiotics more often.
4) Conclusions: Young children treated with ventilation tubes due to persistent otitis media with effusion have a higher risk of developing otorrhoea because of the tubes, and they have a higher risk of needing treatment with antibiotics.

Introduction

Otitis media (OM) is defined as inflammation of the mucosa of the middle ear and it presents with a wide variation in clinical appearance. The term otitis media with effusion (OME) refers to effusion in the middle ear without any acute symptoms, whereas Acute Otitis Media (AOM) refers to the same condition with acute symptoms such as pain, fever, and possibly otorrhoea. OM is a pathological condition that has periods of both effusion and acute exacerbations. When the effusion persists for more than 3 months, the otitis is called chronic or persistent. Children with chronic or recurrent OM (OME or AOM) are often treated by having ventilation tubes inserted, although an increasing number of reports have advocated a wait and see policy, especially in young children. The aeration achieved by permanent drainage and ventilation is believed to prevent acute exacerbations. On the other hand, tubes are considered to be one of the causative factors in tympanosclerosis, permanent tympanic perforations, and chronic discharge. In the long-term, more cases of tympanosclerosis, retraction, and atrophy were found in tube-treated ears than in untreated ears with chronic OME or recurrent AOM. In addition, tubes might facilitate the occurrence of an acute infection, presenting either in the form of otorrhoea or AOM. Tubes may act as a “porte d’entrée” for infectious agents or they may drain the residual chronic inflammation exudate from the middle ear mucosa. Tubes that are inserted to treat recurrent AOM and aeration might have a favourable effect on the middle ear condition, but there are indications that the incidence of otorrhoea increases after tubes have been inserted. For instance, in a group of 173 young children who had tympanostomy-tube placement for persistent middle-ear effusion, the proportion of children who developed 1 or more episodes of otorrhoea increased progressively, reaching 75% after 12 months. In addition, when discharge exuding through the tympanostomy tube lumen occurred in patients in that study, it was treated with oral antimicrobial drugs and/or ototopical antibiotic suspension.

We studied otitis related symptoms like otorrhoea, earache, fever, as well as the usage of antibiotics in a randomised, con-
trolled clinical trial in children aged 1-2 years. Children were placed into a group treated with ventilation tubes or into a group subjected to a watchful waiting policy.

Patients and Methods

This analysis is based on information from patients who took part in a large randomised, controlled, multicenter trial in the Eastern part of the Netherlands. The primary aim of the trial was to investigate the effect of early treatment with ventilation tubes on hearing, language development, and quality of life in infants with persistent bilateral OME who failed a population-based screening test at the age of 9 months. It was not necessary to have a clinically significant loss of hearing or to suffer recurrent acute periods of otitis media. Parents were asked to give consent for their child to participate in the randomised, controlled trial. The Ethical Committees of all 13 participating hospitals approved the protocol. Details of this trial have been described elsewhere.10,11

The trial population consisted of 187 young children with persistent OME; 93 infants were treated with ventilation tubes (VT group) (mean age 19.5 months; SE = 1.7) and 94 infants were subjected to a watchful waiting policy (WW group) (mean age 19.4 months; SE = 1.9). All the children were followed at three month intervals for one year. During the visits, the parents were asked to complete a questionnaire to provide data on the occurrence of otorrhoea, earache, and fever. Medical records of the attending ENT surgeons were used for supplementary information. Parents also filled out a diary every day with data on visits to the general practitioner, prescriptions, and/or use of ear drops and antibiotics, periods of illness, and otorrhoea.

The difference between the two groups was largest at 6 months, i.e. 9.9% (95% CI 4-16%) in the WW group versus 49.4% (95% CI 39-60%) in the VT group, and decreased gradually in the months thereafter. No differences were found with respect to earache and fever.

Results

At the time of the 3 month follow-up visit, 13 (15%) of the children in the VT group were diagnosed with OME, indicating that the tubes were already malfunctioning or had been extruded. At the time of the 6, 9, and 12 month follow-up visits, these percentages were 29, 27, and 27%, respectively. In the WW group 77, 66, 57, and 53% of the children had bilateral OME at the time of the 3, 6, 9, and 12 month of follow-up visits, respectively.

Separate analyses on each of the otitis related symptoms (otorrhoea, earache, fever) showed that the frequency of otorrhoea was significantly different between the two groups at all the follow-up visits (3, 6, 9, and 12 months post randomisation) (Figure 1, Table 1).
The cumulative proportion of children with one or more episodes of otorrhoea can be derived from Table 2. After 12 months, 38% (95% CI 28-48%) of children in the WW group had suffered otorrhoea. In the VT group, the percentage of children with one or more episodes of otorrhoea was 83% (95% CI 75-91%) (p = 0.001).

In the WW group, 39 courses of antibiotic treatment were prescribed to 21 children (22%; 95% CI 14-30%), and of those, 11 children received antibiotics at least twice. In the VT group, 61 courses of antibiotic treatment were prescribed to 32 children (34%; 95% CI 24-44%), and of those, 19 children received antibiotics at least twice. Antibiotic ear drops were used in 9 children in the WW group (10%; 95% CI 4–16%), and of those, 4 children used more than one course. In the VT group, 57 children (39%; 95% CI 29-49%) used antibiotic ear drops, and of those, 38 children were prescribed more than one course.

Discussion

This trial found that there was a remarkable increase in the proportion of children with otorrhoea in the VT group. The largest difference in discharge from the ear was seen at the 6 month follow-up visit. For example, nearly 50% of the children had discharge in the VT group vs. 10% in the WW group. Otorrhoea after VT placement does not resemble spontaneous eruption of middle ear pus; thus, discharge from a ventilation tube might be the consequence of residual secretions or hyperreactive (sterile) mucus production. In theory, post-intubation otorrhoea can also result from acute or persistent infection in the middle ear mucosa, inflammatory external canal disease, or from a reaction to the tube as a foreign body. However, as both groups in this study were similar with respect to the underlying disease, and otorrhoea was more frequent in the VT group for a long time after insertion of the tubes, our results suggest that post-intubation otorrhoea is caused by the tubes and not by an inflamed status of the mucosa. This statement is supported by the observation that the tubes in this study were extruded in the second half of the follow-up period and the prevalence of otorrhoea subsequently decreased (Figure 1, Table 1).

In this study the cumulative proportion of patients with otorrhoea (83%) after tympanostomy-tube placement was much larger than that found by Goldstein et al. and Mangat et al. In both of those studies, otorrhoea occurred in about 20% of the children with ventilation tubes. Our results agree with those of Ah-Tye et al., who demonstrated episodes of otorrhoea in 83% of children with tubes in place after 18 months. These differences might be explained by the differences in the ages of the children studied in each of these trials. Young children, like those in our trial, appear to be at much higher risk, probably because they have a less mature immune system.

Even if we cannot be sure about the etiology of otorrhoea, it is reasonable to apply treatment based on the number of courses of antibiotics prescribed. In contrast to the United States, there are no official guidelines in the Netherlands for the prescription of oral antimicrobial drugs in case of otorrhoea after tube placement. However, our study demonstrates that more antimicrobial drugs and drops are prescribed as a result of infections caused by ventilation tubes. It is interesting to note that in the trial antibiotics were a substantial part of the total medical cost and were partly responsible for the higher costs incurred by the VT group. The results did not show any positive effect on the occurrence of other symptoms of AOM such as earache or fever. By contrast we demonstrated an increased frequency of adverse effects, such as otorrhoea and use of antibiotics. This will lead to increased morbidity and costs, which are not justified by long term beneficial effects.

Although otorrhoea was easily recognised by the parents and recalled at the three month visits, the validity of the data in this study may be questioned. Parents may have missed the signs of discharge or forgotten to mention it, which would result in an underestimation of the frequency of the symptoms. Antibiotics which may have been prescribed for other reasons, may have decreased the frequency of otorrhoea, and otitis

### Table 2

<table>
<thead>
<tr>
<th>Otorrhoea Episodes</th>
<th>WW group</th>
<th>VT group</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 episodes</td>
<td>58 (62%)</td>
<td>16 (17%)</td>
</tr>
<tr>
<td>1 episode</td>
<td>23 (24%)</td>
<td>28 (30%)</td>
</tr>
<tr>
<td>2 episodes</td>
<td>8 (9%)</td>
<td>26 (28%)</td>
</tr>
<tr>
<td>≥ 3 episodes</td>
<td>5 (5%)</td>
<td>23 (25%)</td>
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</table>
related symptoms. However, it is unlikely that the observed differences in otorrhoea and in use of antibiotics between the two groups were due to observation bias. Children in both groups were seen after identical time intervals and were subjected to identical examination procedures.

Young children treated with ventilation tubes due to persistent otitis media with effusion have an increased risk of developing otorrhoea because of the tubes, and thus are more likely to be treated with antibiotics. Results from the multi-centre randomised controlled trial showed that ventilation tubes had a beneficial effect on hearing in the short term (6 months), but this effect largely disappeared in the long term (12 months). Ventilation tubes did not improve language development or quality of life. We therefore recommend initial observation as a standard procedure in young children with persistent OME, that failed a population based screening test.

References


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