A 14-Year Prospective Follow-up Study of Children Treated Early in Life With Tympanostomy Tubes: Part 1: Clinical Outcomes

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Objective: To determine 14-year otological outcomes in young children treated with early insertion of ventilation tubes (VTs) for recurrent acute otitis media or otitis media with effusion (OME).

Design: Prospective 14-year follow-up.

Setting: Central Hospital of Central Finland, a tertiary care hospital.

Patients: Three hundred five consecutive infants and young children aged 5 to 16 months with otitis media were enrolled for early initial tympanostomy tube insertion. The final study group comprised 237 patients (77.7%) attending the 14-year checkup.

Main Outcome Measures: At the 14-year checkups, abnormal otological findings were recorded and results compared with those of the 5-year checkups.

Results: From 5 to 14 years' follow-up, the number of healed ears increased from 156 (65.8%) to 177 (74.7%), while the number of ears with abnormal outcomes decreased from 81 (34.2%) to 60 (25.3%). Of 156 healed ears, 142 (91.0%) remained healed, and 35 (43.2%) of 81 ears with abnormal outcomes healed. The proportion of abnormal outcomes was higher among ears with OME ($P = .02$) and with 3 or more VT insertions ($P < .001$). Repeated tympanostomy tube insertion was performed in 141 ears (59.5%), more often in those with OME ($P = .003$), and ear surgery was performed in 9 ears (3.8%), 8 with OME.

Conclusions: Early VT treatment is recommended for young children with recurrent acute otitis media or persistent OME. Parents should be informed of the long follow-up, of the possible need for repeated VT insertion, and of potential sequelae that sometimes necessitate surgical intervention. Patients healed after 5 years do not need further follow-up.


Otitis media (OM) is one of the most common diseases in early childhood necessitating physician office visits. Otitis media with effusion (OME) and recurrent acute otitis media (RAOM) form the main indications for insertion of ventilation tubes (VTs). In fact, myringotomy with insertion of VTs is the most common surgical procedure among young children in the United States. Nonetheless, many children treated early in life with VTs for RAOM or OME still need frequent checkups or active treatment for many years after the operation because of recurrent or chronic middle ear disease or sequelae. The short-term benefits in improved hearing are distinct. The tubes also reduce the incidence of RAOM and improve the quality of life of children with OME or RAOM. It is assumed that insertion of VTs is responsible for later changes in the tympanic membrane (TM), but the long-term sequelae are not well known. Furthermore, there are no extended long-term follow-up studies in the literature regarding young children treated with early insertion of VTs for OME or RAOM. This lack of systematic data has raised many questions and challenged the appropriateness of VT therapy. We now

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report the 14-year follow-up results of the same homogeneous group of young children treated with early insertion of VTs whose 5-year follow-up results were reported previously. In part 1, we present the clinical otological outcomes, while the audiological outcomes and general analysis of the results are reported in part 2.

This study commenced in 1983 at the Department of Ototorhinolaryngology of the Central Hospital of Central Finland. Consecutive children with OM were enrolled for early initial tympanostomy tube insertion during 1983 and 1984. The study was approved by the Research Committee of the Central Hospital of Central Finland. Oral informed consent was obtained from the parents of each child. The inclusion criteria were (1) a minimum of 2 episodes of RAOM within 3 months (RAOM group) or (2) signs of OME persisting after a minimum of 2 months (OME group). Children with a cleft palate or other major congenital anomalies were excluded, as were those older than 16 months and those with prior tympanostomy tube insertion or adenoidectomy.

Three hundred five children were enrolled in the study. The age at initial tympanostomy tube insertion ranged from 5 to 16 months (mean age, 10.1 months). The mean number of recurrences in the RAOM group (n=103) was 2.7, and the mean duration of OME in the OME group (n=202) was 2.2 months. The VTs (Shah vent Teflon tube, 1.1-mm inner diameter; Xomed, Jacksonville, Fla) were inserted under an operating microscope into an anteroinferior quadrant or a posteroinferior quadrant of the TM, based on ease of insertion according to the otomicroscope as presented previously, did not differ statistically significantly among patients who did or did not attend the 14-year checkup (χ²=5.6, \( P=0.057 \). The decision for ear surgery was made on a case-by-case basis. The indication for myringoplasty was a chronic and dry perforation of the TM; for tympanomastoidectomy, a chronically or repeatedly discharging ear. Follow-up of these children was continued for a minimum of 14 years and ended with the final checkup.

The 237 patients who attended both the 5- and 14-year checkups formed the final study group. The children who dropped out before the end of the 14-year follow-up had moved to other parts of the country or abroad and could not be reached. We double-checked the medical files of all 237 patients from every health care facility they had visited for ear, nose, or throat diseases during the entire follow-up. At the 14-year checkup, the children were examined using pneumatic otoscope and otomicroscope by the same senior ototorhinolaryngologist (H.V.) according to the same principles as at the 5-year checkup. Abnormal otological findings (tympanosclerosis or atrophy of the TM, retractions of the pars flaccida [PF] and pars tensa [PT], presence of middle ear effusion or VTs in place, or perforations of the TM) and their localization were recorded. Herein, atrophy refers to a pseudomembranous or abnormally thin TM as seen on pneumatic otomicroscopy. Retractions of the PT were classified into one of the following 4 grades as presented by Sadé: grade I, a slight retraction of the TM; grade II, the TM touching the incus or stapes; grade III, the TM touching the promontorium; or grade IV, the TM adherent to middle ear structures. Retractions of the PF were classified according to the following system of Tos and Poulsen: grade I, retraction toward the neck of the malleus, not touching it; grade II, retraction to the neck of the malleus; grade III, retraction beyond the osseous annulus, with the bottom still visible; or grade IV, distinct resorption of the osseous annulus and retraction extending to the head of the malleus. In all ears with retraction, signs of keratin retention were sought. Whenever middle ear effusion was suspected, its presence was confirmed by myringotomy and aspiration. According to otological findings, the ears were classified into one of the following groups: TM perforation, VT in place, OME, retraction of the PT, retraction of the PF, or healed.

At the beginning of the study, the worse ear of each child was selected for analyzing the results. This selection was based on the OM history before the initial tympanostomy tube insertion (the number of RAOM episodes and duration of OME) and on the clinical status of the ear at the initial tympanostomy tube insertion (the amount of middle ear effusion and TM abnormalities). Data analysis and all statistical tests were performed using SPSS for Windows (version 11.5; SPSS Inc, Chicago, Ill). Dependencies between groups were explored by the χ² test for independence or, when needed because of small cell frequencies, by Fisher exact test. For a change in the clinical outcomes status, the marginal homogeneity test was applied. Linearity of initial clinical status among the OM groups was tested with the linear-by-linear association test.

Two hundred eighty-one (92.1%) of the 305 children with an initial tympanostomy tube insertion completed the 5-year follow-up, the first period of the study. The final study group comprised 237 children (77.7%) who continued through the second follow-up and attended the 14-year checkup. The mean age of these patients (57.0% boys) was 15.1 years (age range, 14.1-15.9 years), and the mean length of follow-up from the initial tympanostomy tube insertion was 14.2 years (range, 14.0-14.8 years). The clinical 5-year outcomes, based on ear examination results using pneumatic otoscope and otomicroscope as presented previously, did not differ statistically significantly among patients who did or did not attend the 14-year checkup (χ²=5.6, \( P=0.055 \); Fisher exact test). Therefore, the missing 14-year checkup outcomes can be considered independent of the observed 5-year outcomes, reducing the likelihood of missing data values obscuring the results.

During the 14 years, 141 (59.5%) of 237 ears had 1 VT insertion, 64 (27.0%) had 2 VT insertions, and 32 (13.5%) had at least 3 VT insertions (Table 1). Repeated tympanostomy tube insertion was performed significantly more often in ears with OME than with...
RAOM ($\chi^2 = 11.8, P = .003; \text{Pearson product moment correlation})$.

The clinical outcomes differed significantly between the 5- and 14-year checkups ($P < .001, \text{marginal homogeneity test}$), as seen in Table 2. The number of healed ears increased from 156 (65.8%) to 177 (74.7%), and the number of ears with abnormal findings decreased from 81 (34.2%) to 60 (25.3%). Of the 156 healed ears at the 5-year checkup, 142 (91.0%) remained healed at the 14-year checkup, and 35 (22.2%) of the 81 ears with abnormal outcomes at the 5-year checkup had healed. During the second follow-up, tympanostomy tube insertion was performed at least once in 17 (7.2%) of 237 ears, including 1 of 156 healed ears at the 5-year checkup, 2 of 17 ears with a grade I PT retraction, 11 of 20 ears with OME, 2 of 11 ears with a VT in place, and 1 of 11 ears with a PT perforation. Seven of the ears with a new VT insertion had previously had only the initial tube.

The total proportion of TM resections increased slightly during the second follow-up, from 39 (16.5%) to 52 (21.9%) of 237 ears, mainly because of OME and VT therapy at the end of the first follow-up. In some ears, a PT resection had switched to a PF resection and vice versa. Four (25.0%) of 16 ears with a PT resection had healed. The grade of resection remained the same in 10 (62.5%) of the 16 ears and increased in 2 (12.5%). Twelve (52.2%) of 23 ears with a PT resection had healed, and in 9 ears (39.1%) the grade of resection remained the same (7 ears) or had decreased (2 ears), while in 1 (4.3%) the retraction had progressed. Among the ears with a PT resection, 1 ear (4.3%) had OME.

Table 2 shows that 11 (55.0%) of 20 ears with OME at the 5-year checkup had healed, while 8 (40.0%) had a TM resection, of low grade in most cases, including 1 patient with myringoplasty and 1 with modified radical mastoidecomy and tympanoplasty (patients 108 and 55, respectively, in Table 3). The latter had a grade II resection in the posterosuperior quadrant of the PT in addition to OME at the 5-year checkup and, despite repeated tympanostomy tube insertion, the resection progressed to cholesteatoma. One (5.0%) of the 20 ears with OME at the 5-year checkup had OME (Table 2).

Among 11 ears with a VT in place at the 5-year follow-up, 2 (18.2%) had healed at the 14-year checkup and 7 (63.6%) had developed a TM resection, of low grade in most cases. In 1 ear, OME was present, and in another a PT perforation of the TM was present. During the first follow-up, 3 ears (patients 67, 107, and 187 in Table 3) underwent mastoidecomy because of chronic or recurrent discharge. Two of these (patients 107 and 187) were healed at the 5- and 14-year checkups, but 1 (patient 67) required 2 revision operations during the second follow-up. Two of the patients with a VT insertion during the second follow-up needed ear surgery later (patient 108 who underwent myringoplasty and patient 55 who underwent modified radical mastoidecomy with tympanoplasty for retraction cholesteatoma). Five of 11 children with a PT perforation at
the 5-year follow-up were operated on during the second follow-up, including 3 (patients 10 and 317 once and patient 199 twice) with myringoplasty, 1 (patient 165) with tympanomastoidectomy, and 1 (patient 67) with 2 revision operations who had undergone mastoidectomy during the first follow-up.

As presented in Table 2, 6 (54.5%) of 11 ears with a PT perforation of the TM at the end of the first follow-up had healed, 3 of them (patients 165, 199, and 317 in Table 3) after ear surgery and another 3 spontaneously during the second follow-up. Two ears had a TM retraction, 1 ear (patient 67) had inactive adhesive OM after several ear operations, and 3 ears still had a PT perforation, 1 of them (patient 10) after myringoplasty.

At the 14-year checkup, abnormal clinical outcomes occurred significantly more often in the ears that had received 3 or more VTs during the 14 years ($\chi^2=32.1$, $P<.001$; Fisher exact test) (Table 4). The difference reflects mainly the greater presence of PT retractions and perforations. As seen in Table 5, there was a trend toward more frequent abnormal outcomes, especially retractions and OME, in the ears with initial OME compared with RAOM ($\chi^2=5.4$, $P=.02$; linear-by-linear association test). Moreover, in the entire cohort of 237 patients, 9 patients (3.8%) underwent ear surgery during follow-up; 8 originally had OME (Table 3).

### Table 3. Ear Surgery During the 14-Year Follow-up

<table>
<thead>
<tr>
<th>Patient No./Sex</th>
<th>Initial Otitis Media Type</th>
<th>5-y Outcome</th>
<th>No. of Ventilation Tubes Inserted</th>
<th>Ear Surgery</th>
<th>14-y Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/F</td>
<td>OME</td>
<td>Perforation of the TM</td>
<td>2</td>
<td>MPL</td>
<td>Perforation of the TM</td>
</tr>
<tr>
<td>55/M</td>
<td>OME</td>
<td>OME</td>
<td>2</td>
<td>Modified radical ME</td>
<td>Grade I PT retraction</td>
</tr>
<tr>
<td>67/M</td>
<td>OME</td>
<td>Perforation of the TM</td>
<td>4</td>
<td>ME* + TME twice</td>
<td>Grade IV PT retraction</td>
</tr>
<tr>
<td>107/M</td>
<td>OME</td>
<td>Healed</td>
<td>4</td>
<td>ME*</td>
<td>Healed</td>
</tr>
<tr>
<td>108/M</td>
<td>OME</td>
<td>Healed</td>
<td>2</td>
<td>MPL</td>
<td>Grade I PT retraction</td>
</tr>
<tr>
<td>187/F</td>
<td>Recurrent acute otitis media</td>
<td>Perforation of the TM</td>
<td>2</td>
<td>TME</td>
<td>Healed</td>
</tr>
<tr>
<td>199/M</td>
<td>OME</td>
<td>Perforation of the TM</td>
<td>2</td>
<td>MPL twice</td>
<td>Healed</td>
</tr>
<tr>
<td>317/M</td>
<td>OME</td>
<td>Perforation of the TM</td>
<td>1</td>
<td>MPL</td>
<td>Healed</td>
</tr>
</tbody>
</table>

Abbreviations: F, female; M, male; ME, mastoidectomy; MPL, myringoplasty; OME, otitis media with effusion; PT, pars tensa; TM, tympanic membrane; TME, tympanomastoidectomy.

*During the first 5 years.

### Table 4. Otological 14-Year Outcomes With Respect to Inserted Ventilation Tubes (First Included)*

<table>
<thead>
<tr>
<th>14-y Otological Outcome</th>
<th>No. of Ears</th>
<th>Healed</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Otitis Media With Effusion</th>
<th>Perforation of the Tympanic Membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>141 (59.5)</td>
<td>114 (80.9)</td>
<td>5 (3.5)</td>
<td>2 (1.4)</td>
<td>15 (10.6)</td>
<td>2 (1.4)</td>
<td>1 (0.7)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>2</td>
<td>64 (27.0)</td>
<td>48 (75.0)</td>
<td>1 (1.6)</td>
<td>0</td>
<td>12 (18.8)</td>
<td>0</td>
<td>2 (3.1)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>3</td>
<td>32 (13.5)</td>
<td>15 (46.9)</td>
<td>2 (6.3)</td>
<td>0</td>
<td>6 (18.8)</td>
<td>7 (21.9)</td>
<td>1 (3.1)</td>
<td>1 (3.1)</td>
</tr>
<tr>
<td>Total</td>
<td>237 (100.0)</td>
<td>177 (74.7)</td>
<td>8 (3.4)</td>
<td>2 (0.8)</td>
<td>33 (13.9)</td>
<td>9 (3.8)</td>
<td>4 (1.7)</td>
<td>4 (1.7)</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage).

### Table 5. Otological Outcomes at the 14-Year Follow-up With Respect to the Initial Otitis Media Type*

<table>
<thead>
<tr>
<th>Initial Otitis Media Type</th>
<th>No. of Ears</th>
<th>Healed</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Grade I</th>
<th>Grade II</th>
<th>Otitis Media With Effusion</th>
<th>Perforation of the Tympanic Membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent acute otitis media</td>
<td>79 (33.3)</td>
<td>67 (84.8)</td>
<td>2 (2.5)</td>
<td>0</td>
<td>8 (10.1)</td>
<td>0</td>
<td>0</td>
<td>2 (2.5)</td>
</tr>
<tr>
<td>Otitis media with effusion</td>
<td>158 (66.7)</td>
<td>110 (69.6)</td>
<td>6 (3.8)</td>
<td>2 (1.3)</td>
<td>25 (15.8)</td>
<td>9 (5.7)</td>
<td>4 (2.5)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Total</td>
<td>237 (100.0)</td>
<td>177 (74.7)</td>
<td>8 (3.4)</td>
<td>2 (0.8)</td>
<td>33 (13.9)</td>
<td>9 (3.8)</td>
<td>4 (1.7)</td>
<td>4 (1.7)</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage).

Earlier findings after the first follow-up showed that in one third of the ears, the otological outcomes were abnormal 5 years after tympanostomy tube insertion. Many questions remained unanswered, including the follow-
ing: Do TM retractions heal, improve, or progress? Do PT perforations heal spontaneously or require surgery? In the case of OME and VT therapy, do ears normalize with time? We planned this 14-year prospective follow-up study to answer these questions. The 14-year period was chosen because after then many children may move elsewhere for secondary education. Nearly 78% of the children could be followed up for 14 years, which is an exceptionally high percentage and gives an opportunity for reliable interpretation of the results.

Our results show that during the 14 years a second VT was placed in 59.5% of ears, but 3 or more tubes were placed in only 13.5%. Repeated tympanostomy tube insertion was performed significantly more often among the ears with initial OME compared with RAOM, indicating a more severe disease process and longer recovery in ears with OME, as also shown by Tos et al.11 and Boston et al.18 During the second follow-up, repeated tympanostomy tube insertion became necessary in only 7.2% of ears, indicating that the healing process continued with time in most ears, as noted also by Daly et al.19

At the 14-year checkups, no ear had a VT in place. Three quarters of the ears were healed, and major TM retractions were rare. Otitis media with effusion was present in 1.7%, and a TM perforation was present in 1.7%. The end results were poorer in cases of OME compared with RAOM, the differences being explained by more frequent and more advanced TM retractions, as well as continuing OME. The outcomes also deteriorated with increasing number of VTs used, especially in cases of 3 or more VT insertions. As healing of the middle ear cleft progresses to a certain point, new episodes of OME no longer seem to develop.19 There remains a risk of TM perforations, at times necessitating surgical closure, in 3.4% of instances in our series. It is impossible to ascertain whether TM perforations are due to the disease or the treatment, but perforations as a pure complication of VT therapy are rare.

After the first 5 years, the healed ears remained almost invariably healed. The retractions of the TM seemed to be interconnected to some degree, changing from PF to PT retractions and vice versa. Similar types of changes were seen also by Tay et al.20 They noted, as did Tos et al.,11 a growing incidence of severe retractions in children treated with tympanostomy tube insertion at an older age. Progression was rarely observed in the present study, but in one case it led to a retraction cholesteatoma in the posterosuperior portion of the PT, facing the lower lateral attic and posterior pouch. About half of the TM retractions healed during the second follow-up, especially those in the PF. A process leading to an adhesive TM was verified in 1 ear, which required several surgical treatments, beginning with mastoidectomy early during the first follow-up. Otitis media with effusion at the 5-year checkup necessitated a new VT in 53.0% of ears with OME, while the others resolved spontaneously with time. At the 14-year checkup, most of these ears were healed or showed only minor-grade TM retraction. Of the ears with a VT in place at the 5-year checkup, fewer than one fifth were healed, and in one third at least a grade II PT retraction, OME, or TM perforation remained. Of the TM perforations, 45.5% remained chronic and required ear surgery during the second follow-up, including myringoplasty or tympanomastoidectomy. At the final checkup, more than a half of these were healed, while a quarter had a persisting TM perforation.

In general, based on the total outcomes 14 years after treatment as presented in Table 4 and Table 5, children with OME and RAOM are in need of long-term follow-up. One fourth of the patients in the present series showed sequelae of varying severity after 14 years of observation or treatment. This group had otological changes that can be attributed to deficient aeration, still present in some patients at the final checkup. This is in accord with a recent histopathologic study22 that showed that VTs do not necessarily cure the disease process beyond the mesotympanum, which in the presence of a VT may appear normal. Partial or full blockage of the posterior pouch, the separate aeration pathway to Prussak space, impedes drainage of secretions and may lead to the development of fibrotic obliteration of the space and cause an irreversible retraction of Shrapnell membrane. These changes may remain local, benign, and stable but, in the presence of nondrained inflammatory fluid, may lead to the development of a papillary ingrowth cholesteatoma or, because of a deep retraction, may lead to retention of keratin.23 In the present series, PF retractions of grade II or higher were seen at the end of the 14-year follow-up in 2 (0.8%) of 237 ears. Whether these retractions will remain stable or the disease will progress in some ears is unknown. Pars tensa retractions were more frequent, with grade II or higher observed in 9 ears (3.8%). In these, further progress would more likely lead to adhesive OM. However, invagination of the posterosuperior portion of the PT may lead to development of cholesteatoma, following a retraction process in the lower lateral attic, as seen in patient 55 in Table 3 in this series. Therefore, patients with a retraction of the PF or PT need a long follow-up.19 On the other hand, the results from the present series suggest that, if the ear appears healed after 5 years, which is the case for most patients, follow-up can be discontinued.

CONCLUSIONS

We recommend early VT therapy as the treatment of choice in young children with persistent OME or RAOM. However, before institution of therapy, parents should be informed of the possible need for repeated VT insertion, of the long follow-up, and of potential sequelae, especially TM perforations, that sometimes necessitate surgical intervention.

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REFERENCES