# Main Articles

# Tympanostomy in young children with recurrent otitis media. A long-term follow-up study

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# Abstract

A total of 305 children, five to 16 months of age, were treated from 1983–1984 with ventilation tubes - Shah vent Teflon tube – inserted under local anaesthesia for recurrent acute otitis media (RAOM) or otitis media with effusion (OME). The final study group comprised 281 children (92.1 per cent) monitored prospectively for five years, 185 in the OME-group and 96 in the RAOM-group. For the first insertion of tubes the average ventilation period was 15.4 months. Re-tympanostomy, with adenoidectomy simultaneously at the first time was performed in 99 ears (35.2 per cent); once in 27.0 per cent, twice in five per cent, and three times in 3.2 per cent. Mastoidectomy due to otorrhoea was performed in three ears (1.1 per cent). The children in the OME-group were at higher risk of repeated post-tympanostomy otorrhoea episodes than children in the RAOM-group. These episodes of otorrhoea during the first insertion of ventilation tubes significantly increased both the tube extrusion rate and the need for subsequent re-tympanostomies. No major complications were caused by the tympanostomy procedure as such. It is concluded that early tympanostomy is a safe procedure in young children with RAOM or OME. However, parents should be carefully informed of risks of post-tympanostomy otorrhoea and recurrent disease after insertion of ventilation tubes necessitating subsequent tube insertion, especially in children with OME.

Key words: Otitis media; Otitis media with effusion; Infant; Child; Middle ear ventilation; Follow-up studies

## Introduction

Since Armstrong in 1954 re-introduced a ventilation tube in the treatment of chronic secretory otitis media (Armstrong, 1954), it has become a generally accepted procedure. However, there are only a few studies concerning tympanostomy in the treatment of recurrent acute otitis media (RAOM) or otitis media with effusion (OME) in which most of the patients have been less than two years of age (Samuel et al., 1979; Gonzalez et al., 1986; Juola, 1988). Sederberg-Olsen et al. (1989) noted that if the insertion of a ventilation tube is decided upon, the operation should probably be carried out relatively early in life, when the complication rate and longterm results seem to be more acceptable. Qvarnberg (1981) and Juola (1988) also speculated that if tympanostomy is delayed too long, irreversible changes may develop in the middle ear cleft. On the other hand, the Swedish consensus conference -(1991) did not recommend tympanostomy for children less than one year of age because the procedure was regarded as difficult and complications were considered to be frequent. Usually ventilation tubes are inserted under general anaesthesia in young children, but in a study by Juloa (1988) the tubes were applied under local anaesthesia in children less than two years of age, without complications. Earlier we have shown (Valtonen *et al.*, 1997) that post-tympanostomy otorrhoea within seven days from the tympanostomy procedure indicate an advanced infectious process in the middle ear and mastoid rather than a complication of tympanostomy.

The purpose of this prospective second phase study was the further evaluation of the relevance of early tympanostomy in the treatment of RAOM or OME in young children, by monitoring and analyzing the functional profile of ventilation tubes during the five-year follow-up period.

# Materials and methods

This prospective five-year follow-up study commenced in 1983 at the Department of Otorhinolaryngology of Jyväskylä Central Hospital,

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Finland. The area has a population of some 250,000, and an annual birth rate of about 3,000. A total of 305 consecutive children with RAOM or OME were enrolled for primary tympanostomy, in 1983–1984. Children with a cleft palate or other major congenital anomalies were excluded as well as those more than 16 months of age, and prior tympanostomy or adenoidectomy. The final study group was formed by those 281 children (92.1 per cent) who could be followed-up for the planned five years.

At the start of the study 69 children (24.6 per cent) were five to eight months of age, 136 (48.4 per cent) were nine to 11 and 76 (27 per cent) were 12–16 months of age. The mean age was 10.1 months (five to 16 months). There was a predominance of boys; 58.4 per cent boys and 41.6 per cent girls. Despite the relatively short history of otitis media (mean 3.4 months), 274 children (97.5 per cent) had had at least three course of antibiotics for otitis media before the procedure.

For analyzing results, the worst ear of each child, based on otitis media history prior to and clinical middle ear status at the primary tympanostomy was used as representative of the child.

The ventilation tube (Shah vent Teflon tube, inner diameter 1.1 mm) was inserted under an operating microscope in the lower anterior or posterior quadrants of the tympanic membrane, bilaterally in 279/281 children. Local anaesthesia was used, by application with a cotton ball, soaked in anaesthetic solution (cocaine, phenol, menthol equal amounts), against the tympanic membrane for at least 30 minutes. Middle-ear effusion (MEE) was present in 185 children (OME-group); bilaterally in 113 (40.2 per cent) and unilaterally in 72 children (25.6 per cent), while 96 children (34.2 per cent) had no effusion (RAOM-group). Primarily, adenoidectomy was not done.

The children were examined by the otolaryngologist one week after the primary tympanostomy. The interval between later follow-up visits was three months when ventilation tubes were present and after that, six months. Every otorrhoea episode was registered per ear and each ventilation tube. The ventilation time of each ventilation tube was registered in months from its insertion to the time point when last observed to be open and in place or when removed. Ventilation tubes were removed from the tympanic membrane before the spontaneous extrusion only in the following cases: 1) it had been in place for more than three years with no problems during the last 12 months, 2) there was a perforation considerably larger than the ventilation tube, or 3) there was granulation tissue around the ventilation tube, resistant to local therapy.

After the extrusion of ventilation tubes an episode of acute otitis media (AOM) was treated with myringotomy and/or systemic antibiotics for 10 days. Adenoidectomy was performed during the presence of primary ventilation tubes if there was an otorrhoea episode for more than four weeks resistant to antibiotics and repeated cleaning of ear secretion, and ear drops. Adenoidectomy was always performed under general anaesthesia. If there was persistent otorrhoea despite adenoidectomy and antibiotic treatment, mastoidectomy was performed. Adenoidectomy with re-tympanostomy was performed if there had been at least three recurrences of AOM within the last three to four months or persistent OME after a trial with antibiotics and/or myringotomy. Re-tympanostomy was performed later under general or local anaesthesia according to the above indications. Shah vent tubes were generally used also for re-tympanostomy, except for Goode T-tubes in 18 unelected cases.

The final examination was performed at the outpatient department after a minimum of 60 months from the primary tympanostomy. The mean interval was 61.3 months (minimum 60 months, maximum 70 months). The mean age at the final follow-up visit was 72.3 months (67 to 82 months).

The data analysis and all statistical tests were performed using an SPSS/PC+ statistics program package. The two-way contingency tables were analysed using  $\chi^2$ -test for hypotheses of independence or homogeneity. Also, analyses of variance were used whenever relevant.

### Results

The ventilation tube extruded early, within two weeks post-operatively in five ears (1.8 per cent). The extrusion was into the tympanic cavity in one of them, spontaneous with otorrhoea in three and with no otorrhoea in one ear. In all these five ears a new ventilation tube was reinserted in accordance with the previously mentioned procedure and considered as an immediate continuation of the primary tube therapy.

Adenoidectomy was performed in 15 children (5.3 per cent) during the presence of the first ventilation tubes because of recurrent or prolonged posttympanostomy otorrhoea. During the follow-up new ventilation tubes were inserted in six of them (40 per cent). After the extrusion of first ventilation tubes, adenoidectomy was done (with no simultaneous retympanostomy) in 13 children (4.6 per cent); in five because of RAOM, in four because of obstructive adenoid hypertrophy, and in four children because of other reasons (recurrent respiratory infections, recurrent parotitis, or recurrent pharyngitis). Mastoidectomy was performed in three boys (1.1 per cent), two bilaterally and one unilaterally. The interval from the primary tympanostomy to mastoidectomy was 2.5, 13 and 19 months, respectively.

TABLE I

ventilation time of the first ventilation tube and later Retympanostomies/ears (%)

Ventilation time of the first VT	Number of re-tympanostomies			
	0	1	2–3	
≤12 months	59 (49.6)	45 (37.8)	15 (12.6)	
13–18 months >18 months	68 (70.1) 55 (84.6)	23 (23.7) 8 (12.3)	$   \begin{array}{c}     6 & (6.2) \\     2 & (3.1)   \end{array} $	
Total	182 (64.8)	76 (27.0)	23 (8.2)	

THE TIME INTERVALS OF RE-TYMPANOSTOMIES FROM THE PRIMARY TYMPANOSTOMY				
Number of ears with re-tympanostomy				
Time interval	First re-tympanostomy	Second-third re-tympanostomy	All	
≤12 months	30	1	30*	
13-24 months	40	6	46	
25-36 months	22	5	27	
≥37 months	7	17	24	
Total	99	29	127	

TABLE II

\*Both the second and third ventilation tube was inserted in one ear during the first year

The ventilation time for the first ventilation tube was two to 61 months, with a mean of 15.4 months. During the follow-up re-tympanostomy was performed in 99 ears (35.2 per cent): once in 76 and two to three times in 23 ears (Table I). The time intervals from the primary tympanostomy to re-tympanostomies are presented in Table II. The first reinsertion was carried out in 30 of the 99 ears (30.3 per cent) within 12 months and in 92 ears (92.9 per cent) within three years from the primary tympanostomy. The shorter the ventilation time of the first ventilation tube, the more frequently re-tympanostomy was needed ( $\chi^2 = 24.7$ , DF = 4, p = 0.0001) (Table I). A significant correlation ( $\chi^2 = 20.8$ , DF = 4, p = 0.0003) was found between the number of myringotomies performed prior to primary tympanostomy and retympanostomies during the follow-up (Table III). The ears with initial OME had significantly more often ( $\chi^2 = 13.7$ , DF = 2, p = 0.001) episodes of posttympanostomy otorrhoea (Table IV) and greater need ( $\chi^2 = 16.2$ , DF = 2, p = 0.0023) of subsequent re-tympanostomies (Table V) than those with RAOM. The relative frequency for otorrhoea episodes during the first ventilation tubes (episodes per 12 months) was 1.38. It was significantly higher (Analysis of variance, p = 0.0028) in ears with a tube functional less than 13 months (1.78) than in those with 13-18 months (1.10) or longer than 18 months (1.05). Otorrhoea episodes during the presence of first ventilation tubes correlated significantly  $(\chi^2 = 10.8, DF = 4, p = 0.029)$  to re-tympanostomies performed after their extrusion (Table VI).

The age of the children had no effects on the otorrhoea or re-tympanostomy rate.

During the follow-up a ventilation tube was removed from 24/281 ears (8.5 per cent): five of them were primary and 19 subsequent tubes. The reasons for removal were persistent granulation tissue in seven, a large TM perforation in seven,

TABLE III
MYRINGOTOMIES PRIOR TO PRIMARY TYMPANOSTOMY AND LATER RE-
TYMPANOSTOMIES/EARS (%)

		. ,	
Number of myringotomies prior to	Number of re-tympanostomies		
primary tympanostomy	0	1	2–3
0-2	50 (79.4)	7 (11.1)	6 (9.5)
3–5	117 (64.3)	55 (30.2)	10 (5.5)
6-11	15 (41.7)	14 (38.9)	7 (19.4)
Total	182 (64.8)	76 (27.0)	23 (8.2)

TABLE IV POST-TYMPANOSTOMY OTORRHOEA EPISODES AND DIAGNOSIS AT THE PRIMARY POST-TYMPANOSTOMY/EARS (%)

Diagnosis at primary tympanostomy	Post-tympanostomy otorrhoea episodes during the primary ventilation tube			
	0	12	>2	
RAOM	46 (47.9)	34 (35.4)	16 (16.7)	
OME	48 (25.9)	91 (49.2)	46 (24.9)	
Total	94 (33.5)	125 (44.5)	62 (22.0)	

and a ventilation tube with no spontaneous extrusion in 10 ears. Out of the 76 ears with one retympanostomy, a Goode-T tube was removed from 11/18 ears (61.1 per cent) and a Shah vent tube from two out of 58 ears (3.5 per cent). Granulation tissue in conjunction with a ventilation tube was found in 16/281 ears (5.7 per cent): with the first tube in five out of 281 ears (1.8 per cent) and with later tubes in 11/99 ears (11.1 per cent).

#### Discussion

The OM history of children in the present study corresponds to the recurrent or relapsing pattern presented by Donaldson et al. (1990). A minority of children had a recurrent pattern; repetitive acute middle-ear infections with a healthy period between acute phases, and the majority had a relapsing pattern; repetitive acute infections with MEE present even between acute episodes. During the present study myringotomy was used in the treatment of OM when the child had severe pain and/or markedly MEE. Antibiotics were used, and they were the only treatment in milder cases. This treatment strategy seemed to be insufficient in the present study material which corresponds to some four per cent of children less than one year of age born in the hospital district of Jyväskylä Central Hospital.

The ventilation tube, primarily always a Shah vent tube, was inserted under local anaesthesia. There were practically no complications or side-effects caused by the procedure or anaesthetic. Contrary to the recommendations of the Swedish consensus conference (1991) the procedure cannot be considered technically very difficult, not even when performed under local anaesthesia, in children less than one year of age. The same conclusion was also made by Juola (1988) and Sederberg-Olsen *et al.* (1989). This procedure should always be done in cooperation with the children's parents. Today, modern anaesthetic methods and new short-acting

TABLE V DIAGNOSIS AT PRIMARY TYMPANOSTOMY AND SUBSEQUENT RE-TYMPANOSTOMIES/EAPS (%)

TIMI ANOSTOMIES/EARS (70)				
Diagnosis at	Number of re-tympanostomies			
tympanostomy	0	1	2–3	
RAOM OME	74 (77.1) 108 (58.4)	20 (20.8) 56 (30.3)	2 (2.1) 21 (11.3)	
Total	182 (64.8)	76 (27.0)	23 (8.2)	

TABLE VI POST-TYMPANOSTOMY OTORRHOEA EPISODES DURING THE FIRST VENTILATION TUBE AND THE NUMBER OF RE-TYMPANOSTOMIES/ EARS (%)

Post-tympanostomy	Number of re-tympanostomies			
during the first VT	0	1	2–3	
0	69 (73.4) 80 (64.0)	23 (24.5) 33 (26.4)	2(2.1) 12(9.6)	
>2	33 (53.2) <sup>*</sup>	20 (32.3)	9 (14.5)	
Total	182 (64.8)	76 (27.0)	23 (8.2)	

anaesthetic drugs make it possible to safely perform tympanostomy in small children also even with spontaneous breathing and without endotracheal intubation, on an out-patient basis.

The functional time of ventilation tubes depends partly on its type. The mean durations for conventional, short-term tubes have varied from 5.5 months to 10.7 months (Kokko, 1974; Barfoed and Rosborg, 1980; Rothera and Grant, 1985; Virolainen, 1986; Weigel et al., 1989) and for long-term tubes, e.g. Goode-T tubes from 20.6 months to 35 months (Weigel et al., 1989; Bulkley et al., 1991; Prichard et al., 1992). In this study the average ventilation time for the primary Shah vent tubes was 15.4 months, 57.7 per cent staying functional more than 12 months. Gibb and Mackenzie (1985) presented that virtually all Shah vent tubes were functional at six months, but the extrusion rate accelerated rapidly between nine and 15 months, every tube having been extruded by 18 months. The ventilation time for Goode-T tubes in our study was 31.7 months, in average. A longer tube function was found for virgin over previously intubated ears by Leopold and McCabe (1980) but no difference was found by Kokko (1974). We did not find any difference in ventilation times between the first and second Shah vent tubes (the average 12.1 months, respectively) in the ears tympanostomized twice.

In some cases the tube does not extrude spontaneously or it has to be removed for other reasons. The extrusion rate for conventional tubes was found to be 90 per cent by Virolainen (1986) and 80–93 per cent during the first two years of follow-up by Weigel *et al.* (1989). Correspondingly, the extrusion rate for Goode-T tubes was found to be 31 per cent during the first two years of follow-up by Weigel *et al.* (1989), 28 per cent in 30 months by Rothera and Grant (1985), and 16.9 per cent in 19.8 months by Prichard *et al.* (1992). In our study the extrusion rates for second ventilation tubes were: 96.5 per cent and 38.9 per cent for Shah vent and Goode-T tubes, respectively.

Granulation tissue was found with a ventilation tube in some five per cent of the ears, rarely with the primary tubes. The tube had to be removed in less than half of the ears with granulation. The corresponding percentages presented by Juola (1988) and Lildholdt (1983) were some 50 per cent and 100 per cent, respectively.

After the extrusion of ventilation tubes, attacks of AOM or chronic OME recur in some cases and retympanostomy has to be considered. In our study retympanostomy with simultaneous adenoidectomy for the first time was performed in 35.2 per cent of the ears; once in 27 per cent, twice in five per cent and three times in 3.2 per cent. The ventilation tube is suggested to substitute the Eustachian tube function but its normalization may take a long time, even years and therefore, recurrences have to be expected and should not be considered as complications (Muenker, 1980). The re-tympanostomy rates per ear varied between different follow-up studies from 12.5 per cent (Virolainen, 1986) to 61 per cent (Barfoed and Rosborg, 1980). The differences may depend on study populations, re-tympanostomy indications, other performed operations, or followup times. The re-tympanostomy rate in our study (35.2 per cent of the ears) is in the middle of the presented frequencies. On the other hand, the frequency of the third or fourth tympanostomy (8.2 per cent of the ears) is considerably lower than presented in other follow-up studies; 20.3 per cent by Kokko (1974), 27.5 per cent by Karma et al. (1982), 36 per cent by Koivuniemi (1988), and 42 per cent by Barfoed and Rosborg (1980). In some cases mastoidectomy became necessary. In our study it was performed in three children (1.1 per cent), due to otorrhoea. Mastoidectomy rates in other follow-up studies varied from 1.4 to 7.5 per cent (Karma et al, 1982; Palva et al., 1985; Sipilä, 1991).

Opinions of the benefits of adenoidectomy in the treatment of OME and especially in the prophylaxis of RAOM are controversial. Although it is recommended by many, the mechanisms behind its favourable effect are not completely understood (Gates et al., 1987). It was recommended by Paradise et al. (1990) on an individualized basis for children who develop recurrent OM after the extrusion of the ventilation tube and by Gates et al. (1987) for children, four to eight years of age, who are severely affected by chronic OME. The Finnish consensus conference (Karma et al., 1987) recommended adenoidectomy as a measure to prevent recurrent AOM in otitis-prone children based on clinical evidence of its favourable effects on preventing recurrent attacks of AOM. It is not generally recommended for children less than 18 months of age (Cotton et al., 1984) and most of the studies concerning adenoidectomy have been conducted in children more than three years of age. Our policy was to perform adenoidectomy always upon the first re-tympanostomy and during the presence of first tubes (primary adenoidectomy), if there was therapy-resistant otorrhoea (15)children). Retympanostomy was performed afterwards for six of them (40 per cent). So, adenoidectomy did not totally prevent the need for re-tympanostomy.

In the present study the need for re-tympanostomy was highest during the first three years of follow-up, significantly diminishing after that. By Muenker (1980) of all recurrences 93 per cent occur within two years after the tube insertion. For an individual child it is impossible to predict if new tubes will be needed after the extrusion of the first tubes. However, our results suggest certain factors which behind an unfavourable may be outcome. Myringotomy was actively performed at the time of the study and can be considered as a measure of severity of symptoms and signs of otitis media. Several myringotomies needed before the primary tympanostomy appeared to be a significant risk factor for a recurrent disease and need for retympanostomy after the first insertion of ventilation tubes. The same was also true for the ears with OME upon the primary tympanostomy. The ears with OME initially had post-tympanostomy otorrhoea episodes more often during the presence of first ventilation tubes than those with RAOM. These repeated episodes of otorrhoea were associated with earlier tube extrusion and a higher re-tympanostomy rate

### Conclusion

Our study shows that ventilation tubes can be placed in young children without per- or immediate post-operative complications. However, we found that persistent OME in young children with or without acute otitis media episodes prior to tympanostomy is relatively often associated with post-tympanostomy otorrhoeas, increasing the likelihood of tube extrusion too early and the need for the insertion of subsequent ventilation tubes.

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