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Long-term effects of ventilation tubes for persistent otitis media with effusion in children

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The otological, auditory and developmental effects of treatment with ventilation tubes were studied in a sample of 7–8-year-old Dutch children screened for otitis media with effusion (OME) serially at preschool age. Children treated with ventilation tubes were matched retrospectively for OME history, sex, and age with children who were not treated surgically. At the age of 7–8, abnormalities of the tympanic membrane were more prevalent in treated than in untreated ears. No significant differences were found in middle ear function and hearing in both groups. Some positive effects of early surgical intervention on specific developmental measures were found.

Keywords *otitis media with effusion ventilation tubes tympanic membrane middle ear function hearing language development*

Otitis media with effusion (OME) is a condition affecting most children temporarily in early life.^{1–3} Over the past two decades its treatment by ventilation tubes has become one of the most frequently performed operations in both Europe² and the USA.³ In 1991 some 52 000 patients were treated with ventilation tubes in The Netherlands, against 18 000 in 1975.⁴ Recently, doubts have been expressed concerning the necessity of such high numbers of operations.^{2,5} The main reason for treatment is immediate restoration of hearing in order to prevent or minimize developmental impairment. Current evidence regarding a causal link between OME and later linguistic and/or educational impairment is however not very strong.⁶ Furthermore, treatment with ventilation tubes could also have side-effects such as otorrhea and scarring of the tympanic membrane.⁷ The efficacy of ventilation tubes for OME therefore deserves further study.

In the recent Nijmegen Otitis Media Follow-up Study,^{8–12} the long-term structural and functional effects of OME and

its treatment with ventilation tubes were studied in a cohort of 946 children screened for OME serially at the ages of 2–4 years. For this study, an observational design was chosen to avoid ethical issues related to withholding ventilation tubes for the long time required for a randomized controlled trial. Consequently, the study could be criticized for an inability to distinguish between the effects of OME and its treatment. As an alternative way of testing the hypothesis that children with persistent OME benefit otologically and developmentally from early surgical treatment, we tried to approach the experimental design by carefully selecting and matching subsets from the original cohort. Children treated with ventilation tubes at the ages of 2–4 years were matched retrospectively with one or more untreated control children from the Nijmegen cohort, for OME duration at 2–4 years of age, season of screening, age and sex. This paper presents the otological and developmental outcome at ages 7–8 for these matched sets of children.

Materials and methods

PRESCHOOL SCREENING

Some 1328 children from a birth cohort of all children born in Nijmegen, The Netherlands, between 1 September 1982

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and 31 August 1983 ($n = 1439$) were screened for OME by tympanometry at 3-monthly intervals from 2 to 4 years of age.¹ Tympanograms were classified into four types according to Jerger's definitions.¹³ Only a type B tympanogram, defined as compliance < 0.2 ml or pressure < -400 daPa, was considered as evidence for OME. Causes for a type B tympanogram other than OME were excluded by otoscopy. Information about ENT disease between 0 and 2 years was collected retrospectively by means of a structured questionnaire.

INDICATIONS FOR SURGICAL TREATMENT

In The Netherlands, ventilation tubes are usually inserted when bilateral OME persists for a period of 3 months. Antibiotics are rarely prescribed for OME. Asymptomatic OME without noticeable hearing loss or symptoms of an acute infection can remain undetected and, thus, untreated for much longer.

FOLLOW-UP

In 1990, 946 children from the original study population, by then 7–8 years of age, participated in a follow-up study. Otomicroscopy, tympanometry, pure-tone audiometry and extensive language and educational testing were performed. Signs of ongoing middle ear disease such as OME, acute otitis media (AOM), otorrhea, a perforation or a ventilation tube still present were recorded. Otopathological sequelae related to OME and treatment with ventilation tubes such as atrophy, tympanosclerosis, atelectasis of the pars tensa,¹⁴ attic retraction¹⁵ or cholesteatoma were documented as well. Information on ENT-diseases at ages 4–8 was collected retrospectively by parental questionnaires, and where possible this information was verified by a search of medical records. Pure-tone hearing levels were measured at 0.5, 1, 2 and 4 kHz. Language ability and educational attainment were assessed in 305 children selected on the basis of their preschool tympanograms. Gen-

eral language ability was assessed by two subtests of the Dutch 'Taaltests voor Kinderen' (Language Tests for Children):¹⁶ the morphological Word Forms Production test (WFP) and the receptive Concealed Meaning test (CM). In both tests the total number of correct responses was recorded. Phonological ability was tested by a Phonemic Segmentation test (PS), a Sound Blending test (SB) and an Auditory Discrimination test (AD).¹¹ Educational achievement was assessed by a Word Recognition test (WR), a Sentence Verification test (SV) and a Spelling test.¹² In these six tests the proportion of correct responses was calculated. Non-verbal intelligence was tested by the Coloured Progressive Matrices test (CPM);¹⁷ raw scores were recorded.

SELECTION OF SUBJECTS AND DATA ANALYSIS

For each child of the original cohort ($n = 1328$) treated with ventilation tubes at 2–4 years of age, control children were sought who had had an equal or more persistent OME experience, but without having received surgical treatment. For that purpose, all surgically treated children (56/1328) were classified by age, season of screening, sex and the number of type B tympanograms found at the preschool screening. For each of these children, all available controls of the same age, season of screening, sex, and with a similar number of type B tympanograms were selected manually from the records (see example in Table 1).

Subsequently, the OME experience was calculated as the percentage of type B tympanograms out of all available tympanograms at 2–4 years (maximum 9). This so-called OME duration score was calculated for right and left ears separately, and ranged from 0 to 100%. In the presence of a ventilation tube, the tympanogram was excluded as no valid measurement could be obtained. The corresponding tympanogram (the same screening period) of the control children was excluded as well. Matching for OME experience was considered to be adequate when the duration score of the ear of the control

Table 1. Examples of selection of subjects for otomicroscopic and auditory comparisons

Matched pairs	Sex	Group*	Tympanogram type†		OME duration score (%)‡	
			Right ear	Left ear	Right ear	Left ear
Subject 1	M	07	BBTTTBCBB	BBTTTCCBB	83	67
Control 1a	M	07	BBBCBBCBB	BBBCBBCBB	83	83
Subject 2	F	06	BCMBBBTTCB	BCBBBBTTCB	71	75
Control 2a	F	06	BCBBBBBBB	CACBBCCB	88	50
Control 2b	F	05	BBBBBCBAB	CACACCACC	75	0

* Group (01–24) refers to date of birth and month of screening (a difference of 1 month was allowed).

† Tympanogram type A, C₁ or C₂ (C) and B (Jerger's classification), M = missing, T = ventilation tube present.

‡ OME duration score = percentage of type B tympanograms out of all available tympanograms. If a ventilation tube is present (T), the tympanogram is excluded. The corresponding tympanogram in the control children is excluded as well.

child was equal to or higher than that of the surgically treated child. This was to ensure that those children treated with ventilation tubes had not had more persistent disease than their untreated controls (as is often the case in observational studies).

For the otomicroscopic and auditory comparisons, data were analysed per ear and are presented for the right ear only.

For the developmental comparisons, data were analysed per child. These children had had bilateral OME for at least 3 months at preschool age, and the OME duration scores of both left and right ears of the controls had to be equal to or higher than those of the children treated with ventilation tubes.

For binomial distributed outcome variables, χ^2 tests were used; when the expected count was less than 5, Fisher's exact tests were used. For ordinal variables *t*-tests or Wilcoxon tests were used. Finally, multivariate regression analyses were performed to control for possible confounders. Two-tailed *P*-values <0.05 were considered to indicate statistical significance.

Results

STUDY POPULATION

From the original cohort of 1328 children, 56 children treated with ventilation tubes between 2 and 4 years of age were matched with 102 controls for age, season of screening, sex and, provisionally, for the number of type B tympanograms at 2–4 years of age. Table 2 shows how, as a result of various exclusion criteria, this number was reduced to a population of 29 children treated with ventilation tubes and 34 control children.

For the treated children, the analyses are restricted to a

Table 2. Composition of the study population

Treated with VT	Controls untreated	Excluded	Exclusion criteria*
56	102		
↓	↓	38	No follow-up data available
46	74		
↓	↓	45	OME duration score† in controls lower than in treated ear
32	43		
↓	↓	12	VT inserted at 4–8 years in control
29	34‡		

* Exclusion of a control child usually resulted in the exclusion of a surgically treated child and vice versa.

† Percentage of type B tympanograms in right ear out of all available tympanograms for that ear at 2–4 years of age.

‡ Treated: 12 girls; 17 boys; controls; 13 girls; 21 boys.

rather mildly affected group; the final selection of 29 children had a mean OME duration score of 59%, as opposed to 67% for the 46 children for whom follow-up data were available.

As a result of our strict matching criteria regarding OME duration (see Materials and methods), the mean OME duration score was about 20% higher in control children than in the surgically treated children (80% versus 59%; Wilcoxon test, *P* = 0.002). In the first 2 years of life three surgically treated children had a positive OME history and one child had ventilation tubes inserted before the age of 2, as opposed to none of the controls. In the period between the end of the preschool screen and follow-up, i.e. between the ages of 4 and 8, 19 (66%) of the surgically treated children had a positive OME history as opposed to eight (24%) of the controls (χ^2 = 10.7, *P* = 0.001). During these years, 16 (55%) children who had had ventilation tubes inserted between 2 and 4 years of age had at least one other set of tubes inserted.

ACTIVE MIDDLE EAR DISEASE

The prevalence of ongoing middle ear disease at follow-up is presented in Table 3. A ventilation tube was still present in more than 10% of the surgically treated children. As the presence of a ventilation tube most probably indicates a state of OME, if not treated, there was no significant difference regarding the presence of OME in the two groups.

OTOPATHOLOGICAL SEQUELAE

The abnormalities of the tympanic membrane related to OME or treatment with ventilation tubes are presented in Table 4. All ears with signs of ongoing middle ear disease or ventilation tubes still present were excluded from this analysis, because changes of the tympanic membrane cannot be visualized clearly until middle ear effusion and inflammatory changes have disappeared.

Cholesteatoma or serious retraction of the pars flaccida were not observed. Often a combination of tympanic membrane abnormalities was found. In contrast with the prevalence of active middle ear disease, as presented in Table 3, Table 4 shows that otopathological sequelae were more prevalent in treated than in untreated ears.

PURE-TONE AUDIOMETRY

Figure 1 shows the mean air-conduction levels at 0.5, 1, 2 and 4 kHz for the right ears of treated and control children. This figure shows a trend for the control children to hear better than the surgically treated children. The difference in hearing levels between the two groups ranged from 1.8 to 3.9 dB at various frequencies. The pure-tone average hearing level at 0.5–4 kHz was 11.4 and 8.1 dB (*t*-test, *P* = 0.19) for treated and control ears, respectively.

Because these hearing levels are likely to be affected by the

Table 3. Signs of active middle ear disease, perforation or ventilation tube present at 7–8 years of age ($n = 63$)

Group	Otomicroscopic findings: n (percentage of group total)					Total
	OME	AOM	Otorrhea	Perforation	VT present	
Treated with VT $n = 29$	2 (7.1)	2 (7.1)	3 (10.3)	2 (7.1)	3 (10.7)	8 (28.6)
Control $n = 34$	7 (20.6)	0 (0)	0 (0)	0 (0)	0 (0)	7 (20.6)
P value*	0.2	0.2	0.09	0.2		0.5

* χ^2 or Fisher's exact test.

Table 4. Otopathological sequelae at 7–8 years of age: 15 right ears with signs of active middle ear disease or a VT present excluded ($n = 47$)†

Group	Otomicroscopic diagnosis: n (percentage of group total)			Total
	Tympanosclerosis	Atrophy	Atelectasis stage ≥ 2	
Treated with VT $n = 20$	9 (45.0)	15 (75.0)	1 (5.0)	17 (85.0)
Control $n = 27$	3 (11.1)	3 (11.1)	0 (0)	4 (14.8)
P value*	0.008	<0.001	0.2	<0.001

* χ^2 or Fisher's exact test.

† One treated child with incomplete data regarding active middle ear disease was excluded as well.

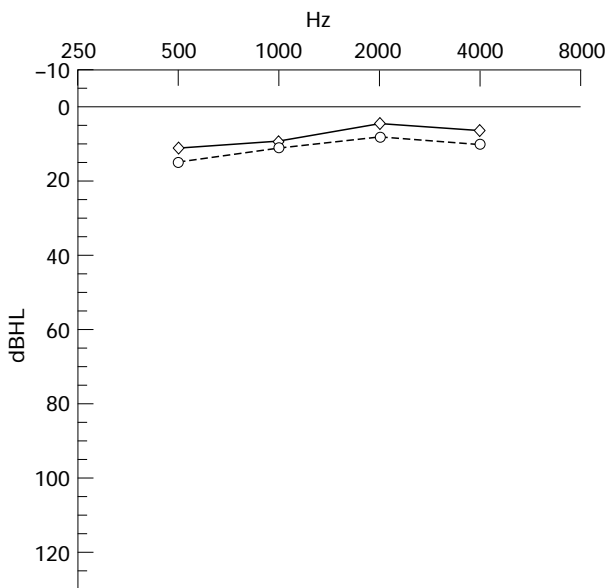


Figure 1. Mean air-conduction levels at 7–8 years of age; $n = 57$ (three children with a congenital sensorineural hearing loss >60 dB and three controls excluded). Average air-conduction level at 0.5–4 kHz (SD) for treated and control children: 11.4 dB (10.5) and 8.1 (6.9 dB) respectively. \circ = treated; \diamond = untreated.

presence of active middle ear disease (see Table 3) and changes of the tympanic membrane (see Table 4), these variables were corrected for in a multiple regression analysis. After correction for active middle ear disease (OME, AOM, otorrhea, perforation and VT still present), the difference in hearing (pure-tone average at 0.5–4 kHz) between surgically treated and

control ears was 2.6 dB ($P = 0.21$). Further correction for changes of the tympanic membrane (tympanosclerosis, atrophy and atelectasis) reduced this difference to 1.2 dB ($P = 0.53$).

LANGUAGE AND EDUCATIONAL ACHIEVEMENT AT FOLLOW-UP

Of the 32 children selected for the developmental analyses (for selection see Materials and methods), three children who repeated a grade and two corresponding matched children were excluded because the educational tests were designed for children of higher grades. This resulted in a sample of 13 children treated with ventilation tubes and 14 untreated controls.

Table 5 shows that potential confounders and/or effect modifiers such as the education level of the parents, educational intervention or intelligence scores did not differ significantly between the two groups.

Table 6 presents the mean scores for the two groups on the language and educational tests. The surgically treated children did not score significantly better than their controls on any of the tests.

Although the differences presented in these tables were not statistically significant, Table 5 shows a trend in favour of the controls for non-verbal intelligence, hearing and the frequency of educational intervention. Table 6 shows a trend in favour of the surgically treated children for all tests, except for the Sound Blending test. In addition to this, exploratory analyses showed that children who had received speech therapy and/or

Table 5. Some characteristics of the study sample for developmental evaluations ($n = 27$)

Characteristics	Treated $n = 13$	Controls $n = 14$
Boys/girls	7/6	8/6
Mean OME duration score right ear	73%	85%*
Mean OME duration score left ear	70%	72%
Pure-tone average at 0.5–4.0 kHz (SD)	14.0 dB (12.8)	8.4 dB (7.7)
Education of mother low†	7	6
Education of father low†	4	3
Speech therapy	4	2
Remedial teaching	2	1
Mean CPM score‡ (SD)	24.6 (4.0)	26.3 (4.0)

* t -test, $P = 0.08$.

† Up through secondary school.

‡ Coloured Progressive Matrices test, raw score.

Table 6. Language and educational test scores related to treatment ($n = 27$)

Tests	Treated $n = 13$	Controls $n = 14$
	Mean score (SD)	Mean score (SD)
<i>Language measures</i>		
Word forms production*	27.8 (3.9)	25.7 (3.6)
Concealed meaning	24.2 (4.1)	24.0 (4.5)
Phonemic segmentation	0.81 (0.10)	0.76 (0.13)
Sound blending	0.86 (0.14)	0.90 (0.15)
Auditory discrimination	0.88 (0.10)	0.85 (0.13)
<i>Reading</i>		
Word recognition	0.95 (0.05)	0.93 (0.10)
Sentence verification	0.88 (0.09)	0.86 (0.16)
<i>Spelling</i>		
Spelling test	0.77 (0.17)	0.70 (0.24)

* One control with invalid test score and one corresponding treated child excluded.

remedial teaching tended to perform less well on the non-verbal intelligence test and the language and educational tests than those who had not received this help. Therefore, these variables were tested for confounding in a regression model. Language and educational test results were used as continuous dependent variables. Treatment, educational intervention, and average pure-tone hearing level at 0.5–4.0 kHz (< and > 5 dB) were used as dichotomous independent variables.

Table 7 shows that educational intervention confounded the relationship between surgical treatment and the score on the Word Forms Production test, a test considered to be a good indicator of a general language factor.¹⁶ Children treated early with ventilation tubes scored higher on this test than their untreated controls, and children who had received some

Table 7. Multivariate regression model with Word Forms Production test as dependent variable* ($n = 25$)†

Variable	Parameter estimate	Standard error	P value
Intercept	26.4	0.92	0.0001
Treated with VT	3.0	1.3	0.03
Speech therapy and/or remedial teaching	−4.8	1.5	0.005

* $R^2 = 0.36$; $F(2, 22) = 6.19$; $P = 0.007$.

† One control with invalid test score and one corresponding treated child excluded.

form of educational intervention scored lower than those who had not received this. A similar effect of educational intervention and surgical treatment was found for performance on the Auditory Discrimination test (see Table 8).

Furthermore, the Auditory Discrimination test score was affected by the hearing ability of the children at the time of testing: children with a pure-tone average hearing level of > 5 dB performed less well on this test than those with better hearing. This implies that the finding that some more surgically treated children had received educational intervention, and had poorer hearing than their untreated controls obscured the outcome on the WFP and AD test. After controlling for these confounders, children treated early with ventilation tubes performed slightly but significantly better on these two tests.

Discussion

In this population, no long-term beneficial effect of ventilation tubes on middle ear function or hearing could be demonstrated. Neither were tubes efficacious in preventing the changes of the tympanic membrane related to OME from developing. Some positive effects of early surgical intervention, however, were found on specific developmental measures.

The number of children included in the present analysis is

Table 8. Multivariate regression model with Auditory Discrimination test as dependent variable* ($n = 27$)

Variable	Parameter estimate	Standard error	P value
Intercept	0.93	0.03	0.0001
Treated with VT	0.08	0.03	0.03
Speech therapy and/or remedial teaching	−0.14	0.04	0.001
Pure-tone average at 0.5–4 kHz > 5 dB	−0.10	0.03	0.009

* $R^2 = 0.50$; $F(3, 23) = 7.68$; $P = 0.001$.

small, certainly when related to the original screening population of more than 1000 children. Adequate comparison of treated and untreated groups required strict matching for OME experience as well as season, age and sex—factors that may affect the course of OME and susceptibility for its sequelae. As a result, the number of children and thus the statistical power dropped dramatically. Similar numerical problems have been experienced in prospective trials of OME.^{1,5}

In contrast with the 2–4 year period in which the control children were at least as much affected by OME as the treated children, OME histories at 0–2 years and 4–8 years of age were more often positive in the treated children than in the controls. As the latter data were collected retrospectively by means of questionnaires, they may be affected by memory bias. It is remarkable that so many children (55%) who were treated with ventilation tubes at 2–4 years of age received another set of tubes at a later age. It is possible that initial surgical intervention for OME makes parents more aware of the child's ear and hearing status and increases the likelihood that a recurrence of OME will lead to further surgical treatment.

In this study, we found no considerable differences in the prevalence of active middle ear disease at follow-up between the groups. Like others, however, we found a strong correlation between the presence of atrophy and tympanosclerosis and treatment with ventilation tubes.^{7,18} The present otoscopic findings are consistent with those previously reported on the original population from which this sample was taken.⁸

In the long term, the difference in hearing between treated and untreated children was small and of little clinical importance (<5 dB at speech frequencies). This supports the opinion that the tympanic membrane changes related to OME and tubes have little auditory consequence.^{9,18,19}

In general, no substantial differences in general language performance and educational attainment between the groups were found. This agrees with previously reported data on our cohort,^{11,12,20} as well as the view of Haggard and Hughes⁶ and Roberts *et al.*,²¹ that early OME does not have a major impact on later linguistic and educational performance. After controlling for some important confounders, however, surgically treated children performed somewhat better on a general language ability test and an auditory discrimination test. It is not clear whether this may be attributed to the early insertion of tubes or to the fact that surgically treated children live in a more supportive environment. With so many variables affecting language development and communication skills, there is a need for further well-designed and controlled long-term studies of OME.

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