The Effect of Ventilation Tubes on Language Development in Infants With Otitis Media With Effusion: A Randomized Trial

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ABSTRACT. ***Objective.*** **To study the effectiveness of ventilation tubes on the language development in infants with persistent otitis media with effusion (OME). All existing studies addressed children 3 years of age or older. Currently, OME is detected and treated with ventilation tubes at a younger age. Because of the critical relationship between age, hearing, and language development, we conducted a study of the effects of ventilation tubes on language development in infants 1 to 2 years old with persistent OME.**

Design. **A multicenter, randomized, controlled trial (embedded in a cohort) with 2 treatment arms: 1) treatment with ventilation tubes (VT group; $n = 93$); or 2) with a period of watchful waiting (WW group; $n = 94$). Hearing loss and expressive and comprehensive language were assessed every 6 months, while tympanometry and otoscopy were performed every 3 months. Other factors with potential influence on language development were also included: adenoidectomy, hospital, attending day care, sex, age at randomization, educational level of the mother, upper respiratory infections, and the native country of the parents and older siblings. The trial was designed to allow for the detection of a mean difference in language development of 3 months or more between children allocated to the VT and WW groups.**

Results. **No relevant differences were found in expressive or comprehensive language between the 2 groups after adjustment for educational level of the mother, IQ of the child, and differences at baseline.**

A principal component analysis showed that in the VT group, the children with frequent complaints improved 1.6 months more in comprehensive language than those with no or some complaints. The children with favorable language stimulation, however, did not improve more than the children with less favorable stimulation. No differences were found for expressive language among the various clusters.

The probability to improve >3 months in comprehensive language was .48 (95% confidence interval [CI]: .29–.68) for children with highly educated mothers versus .09 (95% CI: .02–.30) for children whose mothers had a low educational level. In the WW group, these changes were .30 (95% CI: .14–.53) and .14 (95% CI: .04–.35), respectively. The probability to improve >4 months in expressive language was .52 (95% CI: .32– .71) for children with highly educated mothers versus .06 (95% CI: .01–.31) for children whose mothers had a low educational level. In the WW group these changes were .42 (95% CI: .23–.64) and .11 (95% CI: .03–.35), respectively. In addition, there were delays in expressive language in both groups compared with their age expected values.

The comprehensive language of the children who were effusion-free during the follow-up ($n = 54$) improved 1.5 months (95% CI: −.2–3.2) more than that of the children who had persistent effusion during the entire follow-up ($n = 28$). No differences were found for expressive language development.

Disregarding the intervention contrast, improvements in hearing seemed to be related to improvements in language development, especially in verbal comprehension.

Discussion. **In this study, we used the Reynell, Schlichting, and Lexi tests to study the relation between early persistent OME and language development. These tests are directly related to normal language, widely accepted, and validated. It cannot be ruled out that more specific measures such as auditory perception tests would have produced more differences between groups, but the focus was on general language development.**

A total of 10 children in the WW group received treatment with ventilation tubes during follow-up. A further 11 children dropped out during the trial. A sensitivity analysis with the 10 children who received ventilation tubes did not change the results, and baseline differences were not found between the 11 children who dropped out and those who completed the trial.

Conclusions. **In the total group of infants with persistent OME, ventilation tubes did not have any incremental effect on language development. Beneficial effect of treatment in individual patients or subgroups of patients can, however, not be excluded.** ***Pediatrics*** **2000;106(3). URL: http://www.pediatrics.org/cgi/content/full/106/3/e42;** ***randomized, controlled trial, otitis media with effusion, ventilation tubes, language development infants.***

ABBREVIATIONS. OME, otits media with effusion; ENT, ear, nose, and throat; VT group, ventilation tube group; WW group, watchful waiting group; SE, standard error; CI, confidence interval.

Otitis media with effusion (OME), one of the most common diseases in early childhood, is associated with mild to moderate conductive hearing loss.[1,2] This hearing loss is presumed to have an adverse effect on language development.[2,3] The aim of the insertion of ventilation tubes is to restore hearing to normal levels and to prevent potential developmental problems.

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Evidence of an association between OME during very early childhood and (later) language developmental problems, however, remains elusive, because of conflicting results from previous studies.[2–4] Some authors found an association between otitis media and language development,[4–17] whereas others did not.[3,18–30] The conflicting findings may be caused by methodological limitations.[3,31–33] Some studies failed to confirm the duration and the severity of OME or did not measure hearing levels. Other studies used a retrospective design, included only a few cases, and/or included only a specific group of children. None of the studies accounted for other factors that might contribute to a child's language performance, such as the educational level of the mother or other demographic characteristics.[3,34]

A focus on young children is necessary because the essence and rates of language development in infants are different for infants and preschool children. First, speech and language develop more rapidly during the first 2 years of life than in subsequent years. Second, it has been argued that (intermittent) hearing loss because of OME has different effects on early and later language development[33] because one-to-one interaction typically for early childhood contrasted with communication in noise at later ages.

Adequately designed prospective studies on the effects of OME on development are few in number.[33] Currently, OME is detected and treated with ventilation tubes at a younger age,[35] so there is need for well-designed studies among young children.

Nonrandomized studies on children younger than 3 years old found mixed or contradictory results. Wright et al[20] did not find an association between OME and speech and language scores in children 2 years old. Friel-Patti and Finitzo[9] found effects on receptive language in 1-year-old children and effects on expressive language in 1½-year-old children; however, there were no effects during the other periods, ie, between 1 and 2 years old. Vernon-Feagans et al[36] and Roberts et al[16] found an association between OME and language development, but their analyses suggested that this association was probably confounded by the environment of the child (eg, educational level of the mother).

The accepted way to deal with such (unknown) confounding is to perform a randomized, controlled trial. Maw et al[37] recently performed such a trial on 186 children 3 to 4 years old. At 9 months of follow-up, marginally significant differences were found in comprehensive and expressive language between children in the surgery group and children in the watchful waiting group (WW group). However, 18 months after randomization, 85% of the children in the WW group had undergone surgery and the groups no longer differed. So far, no trials have been performed on children younger than 3 years of age.

We performed a randomized, controlled trial on the effect of treatment for OME on language development in infants 16 to 24 months old. Treatment with ventilation tubes was compared with watchful waiting in infants with persistent OME. Language development was tested at 6 and 12 months of follow-up.

METHODS

Patients

The trial is embedded in a cohort, which includes 30 099 children born in the Eastern part of The Netherlands between January 1, 1996 and April 1, 1997. These children were invited for routine hearing screening at 9 months old. For the purpose of the trial, those who failed 3 successive tests were referred to 1 of the 13 participating ear, nose, and throat (ENT) outpatient clinics for diagnosis and follow-up (n = 1081). The parents of infants found to be suffering from persistent (4–6 months) bilateral OME (confirmed by tympanometry and otoscopy) by the ENT surgeon in subsequent observations were invited to enter their child into our randomized, controlled trial (n = 386). Exclusion criteria were Down syndrome, schisis, asthma, cystic fibrosis, and sensorineural hearing loss. The children for whom informed consent was obtained were randomly allocated to 1 of 2 groups: the ventilation tube group (VT group; n = 93), treatment with ventilation tubes (Bevel Bobbins, Entermed BV, The Netherlands); or the WW group (n = 94), a period of watchful waiting. The 2 groups were followed for 1 year with language tests within 2 weeks after randomization (before treatment) and at 6 and 12 months after randomization.

Information on prognostic factors, such as educational level of the mother, attending day care, and the number of siblings, was obtained using a questionnaire completed by the parents during the first visit to the ENT clinic.[38] Information on other clinical symptoms, such as adenoidectomy before randomization, was obtained by means of a questionnaire completed by the ENT surgeon.

We obtained approval from the ethical committees of all 13 participating hospitals.

Methods

A balanced allocation procedure was used to increase the comparability at baseline. In this trial, 187 children were balanced over 5 prognostic factors: sex, age, season at randomization, educational level of the mother, and hospital.

The Reynell test[39] was used to measure comprehensive language development, while the Schlichting test[40] was used for the expressive language development. These tests were administered by a speech therapist. Scores were obtained as age-standardized and equivalent age. We also used the Lexi test[40] for the expressive language development. This test consists of words that appear in normal language; the parents are asked to mark the words that their child speaks spontaneously.

Hearing was assessed with a portable visual reinforcement audiometry set, which was developed especially for this study and has been described in detail elsewhere.[41] Otoscopy was performed by the ENT surgeon. Tympanometry was classified according to Jerger,[42] while OME was classified according to the Maastrichts' Otitis Media With Effusion Study protocol.[43]

A test for IQ, Bayley developmental scales,[44] was included because IQ interacts with language development.

Other factors with potential influence on language development were also included: adenoidectomy before randomization, hospital, attending day care, sex, age at randomization, educational level of the mother, upper respiratory infections, native country of the parents, and older siblings.

The trial was designed to allow for the detection of a mean difference in language development of 3 months or more between children allocated to the VT and WW groups as measured by the Reynell-test at 12 months of follow-up.

Statistical Analysis

All analyses were performed based on intention to treat. Language development was expressed as the difference between equivalent age in months and real age in months. Differences in language development at 0, 6, and 12 months, as well as the difference between 12 and 0 months of follow-up between groups, were tested with the Student's t test for independent groups.

To adjust for potential confounders and to study possible effect modifiers, we performed regression analysis with the following basis model:

M($\triangle$language after 12 months of follow-up) = $\beta_0 + \beta_1 \times$ treatment $+ \beta_2 \times$ confounders $+ \beta_3 \times$ treatment $\times$ effect modifiers.

Potential confounders and/or effect modifiers were: adenoidectomy before randomization (yes/no), hearing loss at baseline (dB), IQ of the child at baseline (low/middle/high), day care (yes/no), hospital (1–13), sex (male/female), age at randomization (≥20/>20), educational level mother (low/middle/high), season at randomization (winter/spring/summer/autumn), common colds since birth (≤4/>4), older siblings (yes/no), and native country of the parents (The Netherlands/other).

The models were built in 2 directions: 1) starting with univariate analysis followed by a multivariate model with the relevant factors; and 2) starting with a model with all potential confounders, plus all possible effect modifiers, and then deletion of the irrelevant factors.

We also made logistic models to analyze the probability that a child would improve >3 months, 4 months, and 170 words on the Reynell, Schlichting, and Lexi tests, respectively. The dichotomization of improvements was based on the P75. The models can be described by:

$$\mathrm{logit}(P) = \alpha + \beta_1 \times \text{treatment} + \beta_2 \times \text{confounders} + \beta_3 \times \text{treatment} \times \text{effect modifiers}.$$

To reduce the number of variables in subgroup analyses, we performed principal component analysis: a model with 2 components summarizing several clinical factors (adenoidectomy before randomization, frequent common colds, OME before randomization, and fever and/or earache as indications of acute otitis media); a model indicating the degree of auditive stimulation (educational level of the mother, older siblings, attending day care, and the IQ of the child). Two clinical components occur (Table 1): 1) children with no or some complaints, and 2) children with frequent complaints. Two clusters were also apparent for the predisposing factors (Table 2): 1) the low-chance children (children with a lower IQ and with a mother with a low educational level, and 2) the high-chance children (children with higher IQ and with a mother with a high educational level).

RESULTS

A total of 187 children were randomized: 93 children to the VT group and 94 to the WW group. Mean language development and patient characteristics are shown in Table 3. The parents of 19 infants withdrew immediately after randomization. During the trial, an additional 11 children dropped out: 8 from the WW group and 3 from the VT group. Furthermore, 10 children in the WW group were treated with ventilation tubes.

The number of alternative/additional treatments were either equally distributed (adenoidectomy) over both groups, or the children in the VT group received slightly more (antibiotics and nose drops), compared with the WW group.

The mean age of the children at randomization was 19.5 months (standard error [SE]: 1.7) in the VT group and 19.4 months (SE: 1.9) in the WW group.

The mean hearing levels (measured over 500, 1000, 2000, and 4000 Hz) in the best ear at randomization were 46.4 dB A (SE: 1.1) in the VT group and 43.4 dB A (SE: 1.2) in the WW group.

At 6 months of follow-up the improvement in hearing levels in the VT group was 10.2 dB versus 4.6 dB in the WW group; at 12 months of follow-up, these values were 13.1 dB and 8.5 dB, respectively.[45]

At 3, 6, 9, and 12 months of follow-up, 14.6%, 29.3%, 26.9%, and 26.6% of the children in the VT group were diagnosed with bilateral OME, respectively. In the WW group, these percentages were 77.2%, 65.9%, 57.3%, and 53.2%, respectively. In the WW group, 25 children (26.6%) were diagnosed as having bilateral OME at all visits, while 10 children (10.7%) only had 1 episode of bilateral OME. In the VT group, 3 children (3%) were diagnosed as having bilateral OME at all visits, while 44 (47.3%) were only diagnosed as having bilateral OME before insertion of the tubes.

TABLE 1. Two Clusters Formed by Means of a Principal Component Analysis With Two Components (Explained Variation = 5%)

	Cluster 1 No/Some Complaints	Cluster 2 Frequent Complaints
Groups		
VT group	62 (50.0%)	49 (49.1%)
WW group	62 (50.0%)	28 (50.9%)
Sex		
Male	69 (55.7%)	35 (63.6%)
Female	55 (44.4%)	20 (36.4%)
Adenoidectomy		
Yes	5 (4.0%)	11 (20.0%)
No	119 (96.0%)	44 (80.0%)
Fever		
Yes	8 (6.5%)	49 (89.1%)
No	116 (93.6%)	6 (10.9%)
Earache		
Yes	31 (25.0%)	55 (100%)
No	93 (75.0%)	0 (0%)
Common colds	3.8	4.7
Hearing level at T = 0 (dB)	44.6	45.4

TABLE 2. Two Clusters Formed by Means of a Principal Component Analysis With Two Components*

	Cluster 1 Low Change	Cluster 2 High Change
Groups		
VT group	70 (50.7%)	20 (47.6%)
WW group	68 (49.3%)	22 (52.4%)
Sex		
Male	86 (62.3%)	19 (45.2%)
Female	52 (37.7%)	23 (54.8%)
Day care		
Yes	11 (8.0%)	36 (85.7%)
No	127 (92.0%)	6 (14.3%)
Older siblings		
Yes	122 (88.4%)	27 (64.3%)
No	16 (11.6%)	15 (35.7%)
Educational level mother		
Low	47 (34.1%)	0 (0%)
Middle	74 (53.6%)	14 (33.3%)
High	17 (12.3%)	28 (66.7%)
IQ of the child		
Low	61 (43.3%)	3 (7.7%)
Middle	49 (34.8%)	11 (28.2%)
High	31 (22.0%)	25 (64.1%)

* Explained variation = 8%.

Verbal Comprehension

Figure 1 shows the children's comprehensive language development. Language development in the VT group increased more than that in the WW group, but there was also a baseline difference. At baseline, the WW group had a language development that was .3 month (95% confidence interval [CI]: −.3–.95) behind their age score, while the VT group score was .9 month (95% CI: .35–1.5) behind their age score. At 6 and 12 months of follow-up, both group scores were better than the age scores. At 12 months of follow-up, the children in the WW

TABLE 3. Mean Language Development in Months (Equivalent Age − Real Age) and Patient Characteristics

	Number	VT	WW	Reynell T = 0	Reynell T = 6	Reynell T = 12	Reynell Δ12	Schlichting T = 0	Schlichting T = 6	Schlichting T = 12	Schlichting Δ12
Groups											
VT group	93	93	—	−.91	.11	.87	1.78	−2.49	−2.13	−1.27	1.35
WW Group	94	—	94	−.31	.51	.59	.77	−1.97	−1.06	−.16	1.88
Sex											
Male	110	55	55	−.94	.01	.36	1.28	−2.52	−2.30	−1.39	1.24
Female	77	38	39	−.14	.72	1.23	1.27	−1.79	−.58	.17	2.12
Eduction mother*											
Low	46	23	23	−1.77	−1.93	−2.14	−.43	−3.07	−3.79	−3.95	−1.06
Middle	92	45	47	−.45	.52	1.19	1.56	−1.85	−1.31	−.48	1.55
High	49	25	24	.26	2.14	2.77	2.47	−2.16	−.02	1.91	4.02
Season at T = 0											
Spring	43	20	23	−1.19	.38	−.48	.71	−2.44	−1.98	−1.93	.51
Summer	47	23	24	−1.21	−.49	.27	1.56	−2.60	−2.05	−1.95	1.34
Autumn	59	31	28	.27	.25	1.52	.96	−1.71	−1.11	.31	1.85
Winter	38	19	19	−.61	1.27	1.50	2.08	−2.39	−1.32	.47	2.76
Age at T = 0											
<20 mo	145	72	73	−.46	.74	.88	1.29	−2.02	−1.21	−.81	1.34
≥20 mo	42	21	21	−1.14	−1.18	.22	1.22	−2.90	−2.90	−.33	2.69
District											
1	11	7	4	.09	1.91	1.73	1.64	−1.45	−1.45	−.10	.80
2	125	62	63	−.69	.23	.92	1.50	−2.15	−2.15	−.24	2.14
3	25	13	12	−.84	.52	−.38	.33	−2.43	−2.43	−2.75	.23
4	26	11	15	−.35	−.16	.45	.95	−2.69	−2.69	−1.18	1.32
IQ*											
Low	66	35	31	−2.68	−2.47	−2.48	.24	−4.30	−4.30	−4.27	.21
Middle	62	29	33	−.68	.58	1.73	2.29	−2.16	−2.16	−.36	2.18
High	58	28	30	1.81	3.21	3.35	1.42	−.03	−.03	2.53	2.45

* The language scores over the subgroups of the educational level of the mother as well as over the subgroups of the IQ of the child were significant ($P < .05$) for all measurements.

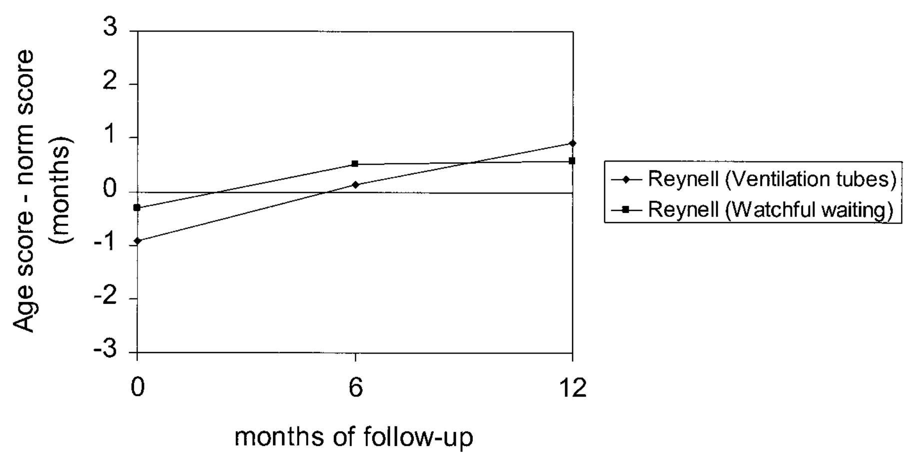

Fig 1. Comprehensive language development (equivalent age − real age in months).

group had improved .8 month (95% CI: −.1–1.6), while the children in the VT group had improved 1.8 months (95% CI: 1.0–2.6).

Multivariate analysis showed that the educational level of the mother, IQ of the child, and language development at baseline were confounders. In Table 4, the estimates of this model are shown. After adjustment for these factors, the children in the VT group improved .7 month (95% CI: −.3–1.7) more than the children in the WW group ($P = .18$).

In Table 5, the estimates of the logistic model are shown. In this model, the probability to improve >3 months in the VT group was .48 (95% CI: .29–.68) for children with highly educated mothers versus .09 (95% CI: .02–.30) for children whose mothers had a low educational level. In the WW group, these chances were .30 (95% CI: .14–.53) and .14 (95% CI: .04–.35), respectively.

TABLE 4. Final Linear Model With Development of Verbal Comprehension (Reynell) as Dependent Variable at 12 Months' Follow-Up*

Covariable	Estimate	SE	*P* Value
Intercept	−.19	.67	
Treatment effect			
Watchful waiting	−.71	.53	.18
Ventilation tubes (reference)	—	—	—
Language at T = 0	−.53	.11	.0001
Educational level mother			
High	.86	.65	.19
Middle (reference)	—	—	—
Low	−2.10	.65	.002
IQ of the child			
High	2.92	.83	.0006
Middle	2.86	.68	.0001
Low (reference)	—	—	—

* $n = 173$; 86 children in the WW group and 87 in the VT group.

TABLE 5. Logistic Model With an Improvement of More Than Three Months (Reynell) as Dependent Variable*

Covariable	Estimate	SE	*P* Value
Intercept	−.59	.32	
Treatment effect			
Watchful waiting	−.51	.47	.28
Ventilation tubes (reference)	—	—	
Educational level mother			
High	.50	.53	.34
Middle (reference)	—	—	—
Low	−1.72	.81	.03
Treatment × educational level			
Watchful waiting × high	−.25	.80	.75
Watchful waiting × low	.97	1.08	.37
Others (reference)	—	—	—

* *n* = 173; 86 children in the WW group and 87 in the VT group.

The principal component analyses with 2 components showed that in the VT group, the children with frequent complaints (cluster 2; Table 1) improved 1.6 months more than those with no or some complaints ($P = .20$). However, the VT group children with favorable language stimulation (cluster 2; Table 2) did not improve more than the children with less favorable stimulation ($P = .4$).

Expressive Language

Figure 2 shows expressive language development. During the whole follow-up, the 2 groups had scores that were behind their age scores. The overall increases in expressive language were 1.9 (95% CI: .65–3.1) and 1.4 (95% CI: .2–2.5) months in the WW and VT groups, respectively.

Again, language development at baseline, educational level of the mother, and IQ were confounders in the multivariate analysis. The estimates of this model are shown in Table 6. After adjustment for the confounding factors, the children in the WW group improved 1 month more than those in the VT group ($P = .17$).

In Table 7, the estimates of the logistic model are shown. In this model, the probability of an improvement of 4 months or more in the VT group was .52 (95% CI: .32–.71) for children with highly educated mothers versus .06 (95% CI: .01–.31) for children whose mothers had a lower level of education. In the WW group, these chances were .42 (95% CI: .23–.64) and .11 (95% CI: .03–.35), respectively.

TABLE 6. Final Model With Development of Verbal Expression (Schlichting) as Dependent Variable at 12 Months' Follow-Up*

Covariable	Estimate	SE	*P* Value
Intercept	−3.55	.98	.0004
Treatment effect			
Watchful waiting	.96	.71	.18
Ventilation tubes (reference)	—	—	—
Language at T = 0	−.88	.13	.0001
Educational level mother			
High	1.80	.86	.04
Middle (reference)	—	—	—
Low	−2.26	.91	.01
IQ of the child			
High	5.21	1.06	.0001
Middle	3.47	.94	.0003
Low (reference)	—	—	—

* *n* = 158; 78 children in the WW group and 80 in the VT group.

TABLE 7. Logistic Model With an Improvement of More Than Four Months (Schlichting) as Dependent Variable*

Covariable	Estimate	SE	*P* Value
Intercept	−1.71	.44	
Treatment effect			
Watchful waiting	1.16	.55	.4
Ventilation tubes (reference)	—	—	—
Educational level mother			
High	1.79	.61	.0003
Middle (reference)	—	—	—
Low	−1.13	1.12	.31
Treatment × educational level			
Watchful waiting × high	−1.56	.83	.06
Watchful waiting × low	−.40	1.39	.77
Others (reference)	—	—	—

* *n* = 158; 78 children in the WW group and 80 in the VT group.

No differences were found between the various clusters (Tables 1 and 2). The children in the WW group improved from 60 to 267 words on the Lexi test, versus an improvement from 55 to 253 words in the VT group ($P = .66$). After adjustment for the educational level of the mother, IQ of the child, and language development at baseline, the children in the WW group improved 8 words more than the children in the VT group ($P = .32$). The probability of achieving considerable improvement on the Lexi test (ie, >170 words) was equal within the 2 groups and within the various subgroups.

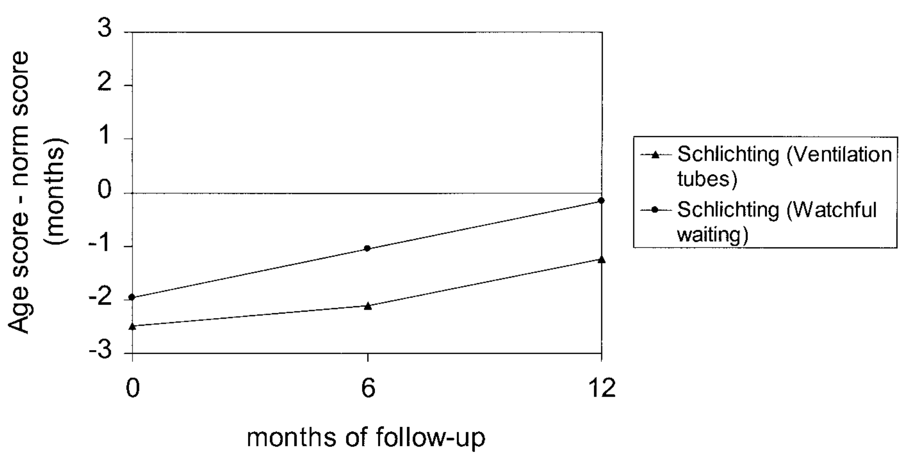

Fig 2. Expressive language development (equivalent age − real age in months).

Maximum Contrast

Spontaneous resolution and recurrence of OME obscured the contrast between the 2 groups to some extent. To test our causal model (hearing loss attributable to OME influences language development), we compared the children with effusion during the entire follow-up ($n = 28$) with the children who were effusion-free during follow-up ($n = 54$). The comprehensive language of children who were effusion-free during follow-up improved 1.5 months (95% CI: −.2–3.2) more than that of the children who had persistent effusion. No differences were found for expressive language development.

Hearing Level

As mentioned above, the causal model of this study was that effusion results in hearing loss, which was expected to influence language development. By comparing the language development of the children in the VT group with that of the children in the WW group, we only studied the effect of OME on language development. To study the effect of hearing levels on language development, we made another linear model with the improvement in hearing at 12 months of follow-up as the independent variable. After correction for the language difference at baseline, the educational level of the mother and the IQ of the child, the children with the greatest improvement in hearing had the best comprehensive language development: $\beta = -.05$ (SE: .02; $P = .01$), which means that with every dB improvement in hearing, comprehensive language development improved .05 month. For expressive language, the β-estimate was also −.05 (SE: .03), but this estimate could not be distinguished from chance ($P = .10$).

It should be noted that the original intervention contrast was disregarded in this analysis and in the maximum contrast analysis.

DISCUSSION

In this trial, there was no difference in language development between young children who received ventilation tubes and those who underwent watchful waiting. This is dissimilar to the study by Maw et al[37] who reported a marginal effect of otitis media treatment on language development. This might be attributable to some differences between the trials. First, the children in the Bristol trial were older (3 years old vs 19 months old in our study). Second, the children in our trial were selected based on failing the Ewing screening and had no obvious complaints, whereas the children in the trial by Maw et al[37] were included because of disruptions in speech, language, learning, or behavior. Third, Maw et al[37] did not adjust for important covariables, such as the educational level of the mother and IQ of the child. In their articles, as Roberts et al and Vernon-Feagans et al[16,30,34,36,46] suggested that it is important to account for any factors that might contribute to a child's language performance and, therefore, might interact with the treatment effect.

Verbal comprehension improved from below standard to about the standard level during the trial. The children in the VT group did not improve substantially more than those in the WW group. Verbal expression, however, remained below standard, which is in agreement with the findings of Maw et al.[37] It should be noted that it takes a child ~5 months to produce the words once he/she comprehended them.[47] The follow-up in our study might have been too short to demonstrate an effect on verbal expression in the core analyses as well as in analyzing the maximal contrast.

In this study, we used the Reynell, Schlichting, and Lexi tests to study the relation between early persistent OME and language development. These tests are directly related to normal language, widely accepted, and validated. It cannot be ruled out that more specific measures (such as auditory perception tests) would have produced more differences between groups, but the focus was on general language development.

Surprisingly, despite balanced randomization, there was a difference in language development between the VT group and the WW group at baseline. This difference can be explained partly by 19 parents who had given informed consent but withdrew their child immediately after hearing the result of the balanced randomization procedure. These children were excluded from the analyses; 15 had originally been randomized to the VT group and 4 to the WW group. Audiometry data on these 19 children showed that the 4 children randomized to the WW waiting group had poorer mean hearing levels than did the remaining children in the WW group. To adjust for this baseline difference, language development at randomization was taken into account in the analysis.

The educational level of the mother seemed to be an important covariable in our model, despite the balanced allocation procedure over this factor. This can be explained based on the children who were withdrawn immediately after randomization. Although the resulting imbalance was small, we had to adjust for this factor in our multivariate model.

Ten children in the WW group received treatment with ventilation tubes during follow-up. An additional 11 children dropped out during the trial period. If these children differed from the other children, the intention-to-treat analysis would have led to an underestimation of the effect. However, no differences in language development were found at baseline between the 10 children who received ventilation tubes during follow-up and those who remained in the WW group, or between the 11 children who dropped out and those who completed the trial. In sensitivity analyses, the 10 children who received ventilation tubes were not analyzed at all or they were analyzed as treated; the results did not change.

CONCLUSION

Ventilation tubes did not have a substantial incremental effect on language development in the total group of infants with persistent OME. In agreement with the language model of Roberts and Vernon-Feagans,[33] hearing improvement seemed to have an incremental effect on language development. In this model, hearing loss was the causal variable, but there were also moderating variables, such as the educational level of the mother, parental sensitivity, child IQ, and child temperament. It is possible that the parents of children with persistent OME and hearing loss compensate for negative effects of impaired hearing on language development. In our study, we tried to find such subgroups, but no relevant differences were found. Because this might be attributable to a power problem, a meta-analysis is advocated on datasets of trials that adequately documented the potential modifiers.

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