ORIGINAL ARTICLE

Developmental Outcomes after Early or Delayed Insertion of Tympanostomy Tubes

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ABSTRACT

BACKGROUND

To prevent later developmental impairments, myringotomy with the insertion of tympanostomy tubes has often been undertaken in young children who have persistent otitis media with effusion. We previously reported that prompt as compared with delayed insertion of tympanostomy tubes in children with persistent effusion who were younger than three years of age did not result in improved developmental outcomes at three or four years of age. However, the effect on the outcomes of school-age children is unknown.

METHODS

We enrolled 6350 healthy infants younger than 62 days of age and evaluated them regularly for middle-ear effusion. Before three years of age, 429 children with persistent middle-ear effusion were randomly assigned to have tympanostomy tubes inserted either promptly or up to nine months later if effusion persisted. We assessed developmental outcomes in 395 of these children at six years of age.

RESULTS

At six years of age, 85 percent of children in the early-treatment group and 41 percent in the delayed-treatment group had received tympanostomy tubes. There were no significant differences in mean (±SD) scores favoring early versus delayed treatment on any of 30 measures, including the Wechsler Full-Scale Intelligence Quotient (98±13 vs. 98±14); Number of Different Words test, a measure of word diversity (183±36 vs. 175±36); Percentage of Consonants Correct–Revised test, a measure of speech-sound production (96±2 vs. 96±3); the SCAN test, a measure of central auditory processing (95±15 vs. 96±14); and several measures of behavior and emotion.

CONCLUSIONS

In otherwise healthy children younger than three years of age who have persistent middle-ear effusion within the duration of effusion that we studied, prompt insertion of tympanostomy tubes does not improve developmental outcomes at six years of age.

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Among children in the United States, otitis media is the most commonly diagnosed illness after the common cold,[1] and myringotomy with the insertion of tympanostomy tubes is the most common operation beyond the newborn period.[2] An estimated 280,000 children younger than three years of age underwent the operation in 1996 (Kozak LJ: personal communication). Often the operation has been undertaken in young children to relieve persistent middle-ear effusion, out of concern that the commonly associated conductive hearing loss might have lasting adverse effects on the cognitive, speech, language, or psychosocial development of the children.[3-5] Supporting that practice have been official guidelines recommending the operation for otherwise healthy children in whom middle-ear effusion has persisted for as long as three months[6] or four months.[3]

In 1991, because of the limited and inconclusive evidence concerning the relation between otitis media during a child's early years and his or her later development[7-10] and because of the lack of evidence that the insertion of tympanostomy tubes favorably affected the development of children with persistent middle-ear effusion, we began a study to address these issues. Previously, we reported that among study participants younger than three years of age who had persistent effusion for the periods defined later in this article, early insertion of tympanostomy tubes, as compared with delayed insertion, did not result in improved developmental outcomes at three or four years of age.[11-13] This report describes developmental findings in these children at six years of age, when the findings are expected to be more predictive of the functioning of these children in later life.

METHODS

GENERAL PROCEDURES

The study included two main components. One was a randomized clinical trial in which children with persistent middle-ear effusion were assigned to undergo either prompt insertion of tympanostomy tubes or delayed insertion if effusion persisted. The other component consisted of a representative subgroup of children not meeting the randomization criteria and examined the relation between the cumulative duration of middle-ear effusion and the later developmental outcomes of the children. We have described the study procedures in detail previously.[11,14,15] In brief, from June 1991 through December 1995 we enrolled 6350 healthy infants who were 2 to 61 days of age at the following eight sites: Children's Hospital of Pittsburgh, Mercy Hospital of Pittsburgh, and two small-town and rural and four suburban private pediatric group practices in the Pittsburgh area. The study was approved by the institutional review boards of the two hospitals. Written informed consent was obtained from one or both parents or the guardians of each enrolled infant.

We monitored children's middle-ear status at least monthly from the time of enrollment until three years of age. We used the term "middle-ear effusion" to encompass all types of otitis media in which effusion was present; we estimated the cumulative proportions of days that each child had unilateral effusion or bilateral effusion on the basis of diagnoses made at individual visits and interpolations for intervals between visits; and we conducted audiometric testing frequently when effusion was present. Since most testing was conducted with the use of speakers rather than earphones, results reflected function mainly in the better-hearing ear. We found hearing to be abnormal in approximately half the children with unilateral effusion and approximately three quarters of those with bilateral effusion.[11]

RANDOMIZED CLINICAL TRIAL

Children became eligible for the clinical trial if, from 61 days of age to 3 years of age, they had middle-ear effusion that appeared substantial in degree and that persisted, despite antimicrobial treatment, for 90 days in the case of bilateral effusion or 135 days in the case of unilateral effusion. Children with intermittent effusion for specified proportions of longer periods were also eligible, according to the criteria listed previously.[11] For example, a child was eligible if he or she had had bilateral effusion for at least 67 percent of the preceding 180-day period or unilateral effusion for at least 67 percent of the preceding 270-day period. Children who met one of these criteria and whose parents or guardians gave written consent were stratified according to practice site, age (in six-month categories), and whether they met the eligibility criteria on the basis of bilateral or unilateral effusion. They were then assigned randomly, within those strata and in balanced blocks of four children, to undergo insertion of tympanostomy tubes either promptly (the early-treatment group) or six months later if bilateral effusion persisted or nine months later if unilateral effusion persisted (the delayed-treatment group).

After consent had been obtained, designated nonclinical staff members made assignments with the use of separate, computer-generated lists of random numbers. Children assigned to the delayed-treatment group were able to receive tube insertion earlier if their parents requested the operation. Children for whom consent for randomization was withheld were offered tube insertion electively. Regardless of whether they underwent the surgery, they were then monitored less frequently but were scheduled for the same developmental testing procedures as those planned for the children who underwent randomization.

As anticipated, children in the early-treatment group had substantially less middle-ear effusion after randomization than children in the delayed-treatment group. For example, during the first 12 months after randomization, 45 percent of the children in the delayed-treatment group had middle-ear effusion for more than 50 percent of the days, as compared with 14 percent of the children in the early-treatment group.[11]

REPRESENTATIVE SUBGROUP

We randomly selected the comparison sample to represent the demographics of the study population as a whole and to represent a spectrum of children ranging from those with no middle-ear effusion to those just short of meeting the criteria for randomization. In these children, the estimated cumulative duration of effusion (unilateral and bilateral combined) ranged from no middle-ear effusion to 66 percent of their first year of life and to 45 percent of their first three years of life.[15]

DEVELOPMENTAL TESTS AND PROCEDURES

We assessed the cognitive, language, speech, and psychosocial development of the children with the use of formal tests, conversational samples, and parental questionnaires. We attempted to conduct assessments of the children as soon as possible after their sixth birthday, at times when hearing-level thresholds were 15 dB or less in each ear at 1000, 2000, and 4000 Hz. We used the following measures: the Wechsler Intelligence Scale for Children, third edition,[16] for intelligence; the Peabody Picture Vocabulary Test–Revised, Form M,[17] for receptive vocabulary; the SCAN test[18] for disorders of auditory processing of language; the Nonword Repetition Task[19] for phonologic memory; the Number of Different Words test[20,21] for vocabulary diversity; the Mean Length of Utterance in Morphemes test[21-23] for sentence length and grammatical complexity; the Percentage of Consonants Correct–Revised[21,24] for speech sound production; the Parenting Stress Index, Short Form,[25] for parent–child stress; and the parent and teacher versions of the Child Behavior Checklist[26] for behavior.

Details about test conditions, examiners, and procedures and the recording, transcription, and analysis of conversational samples have been described previously.[13,15,21] The examiners, transcriptionists, and analysts were blinded to the health histories (including receipt of tympanostomy tubes) and health insurance status of the children and the level of education of the mothers. Randomly selected samples of language constituting at least 10 percent of the total were subjected to second, independent transcription and analysis; interobserver reliability ranged from 91 to 94 percent.

STATISTICAL ANALYSIS

We calculated the duration of middle-ear effusion in children beginning when they were 61 days of age. In the clinical trial, we assumed a priori that a difference of at least 0.33 SD on any outcome measure favoring the early-treatment group would be clinically important. For the study to have the ability to detect such differences at a power of 0.80, we calculated that 182 children would be needed in each group. Results of the trial were based on the intention-to-treat principle.

In the representative subgroup, the original sample size of 241 children was sufficient to detect correlations of 0.20, at a power of 0.71, between children's scores on developmental tests and their estimated cumulative proportions of days with middle-ear effusion, and correlations of 0.25 at a power of 0.91. Because correlations involving days with bilateral effusion differed little from correlations involving days with any effusion (i.e., bilateral or unilateral), all analyses presented here concern total days with any effusion.

We used two-tailed tests for all analyses and set statistical significance at $P \leq 0.05$. We used chi-square tests to evaluate differences in proportions among children in different groups. We used analysis of variance to test for differences between mean values, pairwise Pearson correlation analysis to test for correlations, and linear regression analysis to adjust for potentially confounding variables and to test for interactions.

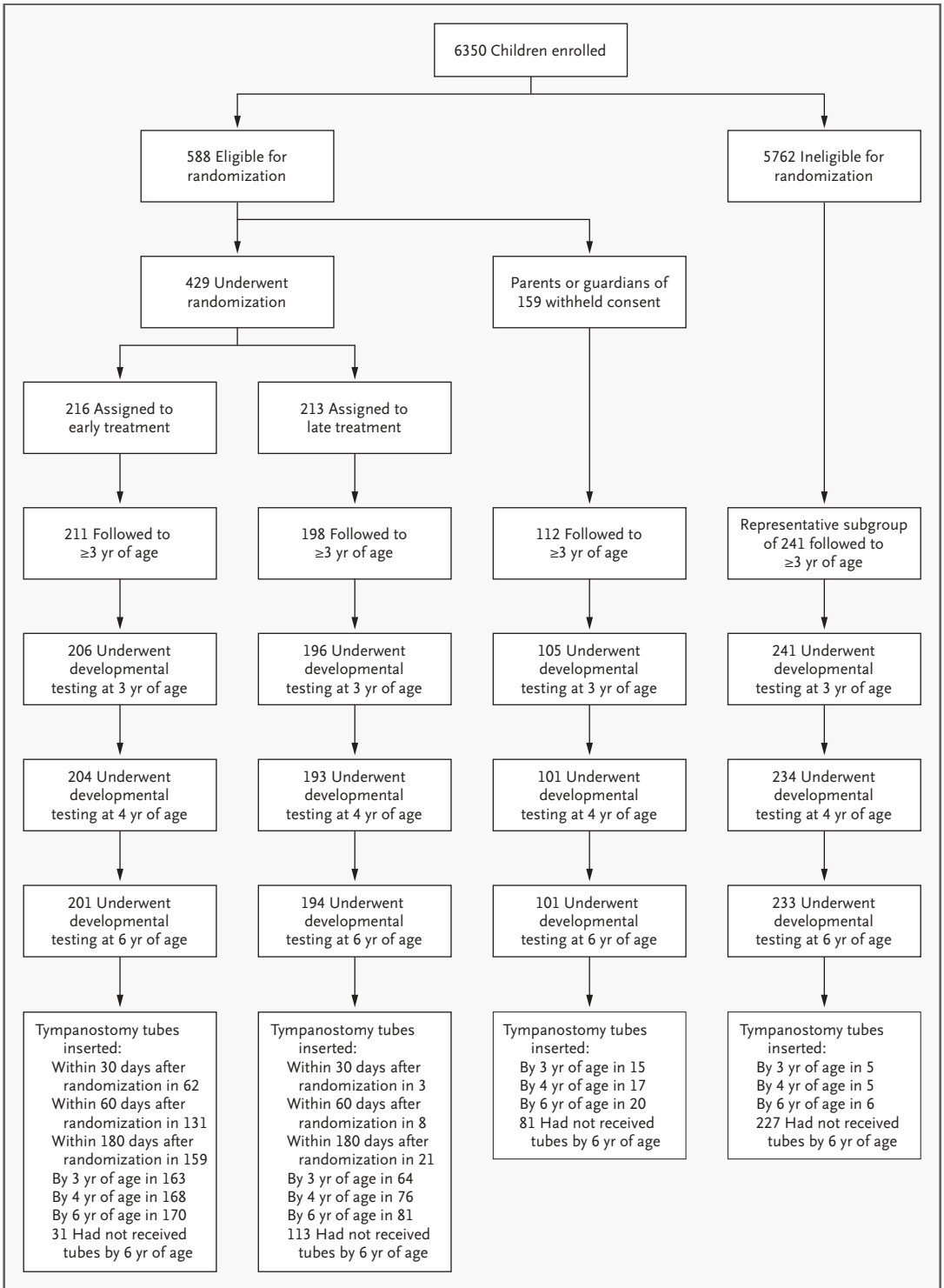

Figure 1. Enrollment, Randomization, and Follow-up of the Children and the Time of Insertion of Tympanostomy Tubes.
Two of the children who underwent developmental testing at six years of age — one in the early-treatment group of the clinical trial and one in the delayed-treatment group — were not tested at either three or four years of age.

RESULTS

STUDY SAMPLE AND TREATMENT GROUPS

Of 6350 children enrolled in the study, 588 eventually met the eligibility criteria for the clinical trial; of these, 429 children (73 percent) underwent randomization after their parents or guardians gave consent. A total of 395 (92 percent) of the children who underwent randomization, 101 of the 159 children (64 percent) whose parents or guardians declined randomization, and 233 of the 241 children (97 percent) in the representative subgroup underwent developmental testing at six years of age (Fig. 1).

Table 1 shows selected demographic characteristics of the children who were tested. In the clinical trial, there were no significant differences in characteristics between the tested children in the early-treatment and delayed-treatment groups, or between the 395 children who were tested and the 34 children who were not. Table 2 shows pertinent clinical characteristics of the children who underwent randomization; there were no significant differences between groups. In 684 of the 729 children tested (94 percent), testing was completed within two months after their sixth birthday. The mean scores of the participants in the study on all developmental measures are shown in Table 3.

CLINICAL TRIAL

There were no significant differences between the early-treatment and the delayed-treatment groups, except for a moderately higher score among the children in the delayed-treatment group on the Nonword Repetition Task (76±10 vs. 74±10, $P<0.05$). Results were materially unchanged after adjustment for the age in months when testing occurred and, in the case of measures of language samples, for

Table 1. Demographic Characteristics of the Children Who Underwent Testing, According to Study Component.*

Characteristic	Randomized Clinical Trial (N=395)	Group for Whom Consent for Randomization Was Withheld (N=101)	Representative Subgroup (N=233)
		no. of children (%)	
Location of study site			
Urban	192 (49)	69 (68)†	58 (25)†
Small town or rural	143 (36)	17 (17)	88 (38)
Suburban	60 (15)	15 (15)	87 (37)
Sex			
Male	225 (57)	55 (54)	117 (50)
Female	170 (43)	46 (46)	116 (50)
Race or ethnic group‡			
Black	143 (36)	52 (51)§	38 (16)†
White	241 (61)	45 (45)	192 (82)
Other or indeterminate	11 (3)	4 (4)	3 (1)
Maternal level of education			
Less than high school	52 (13)	20 (20)	22 (9)†
High-school graduate	310 (78)	71 (70)	162 (70)
College graduate	33 (8)	10 (10)	49 (21)
Health insurance status			
Medicaid	252 (64)	73 (72)	75 (32)†
Private	140 (35)	27 (27)	154 (66)
None	3 (1)	1 (1)	4 (2)

* Because of rounding, percentages may not sum to 100.
† $P<0.001$ for the comparison with the distribution of children who underwent randomization.
‡ Race or ethnic group was assigned by the interviewer.
§ $P<0.01$ for the comparison with the distribution of children who underwent randomization.

Table 2. Clinical Characteristics of the Tested Children Who Underwent Randomization.*

Characteristic	Early-Treatment Group (N=201)	Delayed-Treatment Group (N=194)
	no. of children (%)	
Year of life during which randomization criteria were met		
First	81 (40)	78 (40)
Second	92 (46)	94 (48)
Third	28 (14)	22 (11)
Laterality and sequence of middle-ear effusion serving as the basis for meeting randomization criteria		
Bilateral, continuous	40 (20)	33 (17)
Bilateral, discontinuous	38 (19)	34 (18)
Unilateral, continuous	33 (16)	30 (15)
Unilateral, discontinuous	90 (45)	97 (50)
Hearing test abnormal on ≥1 occasion before randomization†		
Yes	164 (82)	140 (72)
No	22 (11)	32 (16)
Results incomplete or unreliable, or children not tested	15 (7)	22 (11)
Percent of time with bilateral middle-ear effusion in the 6-month period before meeting randomization criteria‡		
≤25	30 (15)	40 (21)
26–50	79 (39)	67 (35)
51–75	77 (38)	76 (39)
76–99	12 (6)	8 (4)
100	3 (1)	3 (2)
Percent of time with bilateral middle-ear effusion in the 6-month period before meeting randomization criteria, in the subgroup of children meeting the criteria on the basis of unilateral effusion‡§		
≤25	30 (24)	39 (31)
26–50	57 (46)	53 (42)
51–75	35 (29)	32 (25)
76–99	1 (1)	3 (2)
100	0	0
Hearing thresholds at time of developmental testing at 6 yr of age		
Protocol-specified criteria met¶	180 (90)	181 (93)
Protocol-specified criteria not met	19 (9)	11 (6)
Audiometric results incomplete or child's hearing not tested	2 (1)	2 (1)
Middle-ear effusion status at time of developmental testing at 6 yr of age		
None	177 (88)	170 (88)
Unilateral	15 (7)	20 (10)
Bilateral	7 (3)	3 (2)
Indeterminate	2 (1)	1 (<1)

* There were no significant differences in characteristics between the two treatment groups. Because of rounding, percentages may not sum to 100.
† On the basis of data obtained from children in the study who had no effusion,[27] abnormal hearing tests were defined as an auditory brainstem–response threshold >20 dB hearing level (HL) or a pure-tone average >25 dB HL up to the age of 10 months, >20 dB HL from 10 to 23 months, and >15 dB HL from the age of 2 years onward.
‡ For the 63 children (29 in the early-treatment group and 34 in the delayed-treatment group) who met the criteria before 9 months of age, the period extended from 61 days of age (the starting point for data analysis) to the date the criteria were met.
§ There were 123 children in the early-treatment group and 127 in the delayed-treatment group.
¶ The criteria consisted of a hearing-level threshold of ≤15 dB at 1000, 2000, and 4000 Hz.

Table 3. Scores on Developmental Tests at Six Years of Age.*

Test	Randomized Clinical Trial (N=395)				Group for Whom Consent for Randomization Was Withheld (N=101)		Representative Subgroup (N=233)	
	Early-Treatment Group (N=201)		Delayed-Treatment Group (N=194)		95% CI†			
	mean score	*(no. of children)*	*mean score*	*(no. of children)*		*mean score*	*(no. of children)*	*mean score*	*(no. of children)*
Formal tests‡								
Wechsler Intelligence Scale for Children								
Full-scale IQ	98±13	(199)	98±14	(194)	−3.0 to 2.5	97±14	(101)	105±14	(233)
Verbal IQ	98±13	(199)	98±14	(194)	−2.8 to 2.6	97±13	(101)	104±14	(233)
Performance IQ	98±14	(201)	99±15	(194)	−3.2 to 2.5	97±15	(101)	105±15	(233)
Peabody Picture Vocabulary Test	94±14	(200)	94±20	(193)	−3.6 to 3.2	93±16	(100)	104±15	(233)
SCAN test	95±15	(178)	96±14	(177)	−4.6 to 1.5	96±14	(96)	100±15	(231)
Nonword Repetition Task	74±10	(182)	76±10	(176)§	−4.1 to 0.1	74±11	(97)	79±11	(216)
Conversational samples‡									
Number of Different Words	183±36	(188)	175±36	(186)	0.0 to 14.4	177±43	(98)	180±36	(225)
Mean Length of Utterance in Morphemes	3.9±0.8	(188)	3.8±0.7	(186)	−0.1 to 0.2	3.9±0.8	(98)	3.9±0.7	(225)
Percentage of Consonants Correct	96±2	(188)	96±3	(185)	−0.5 to 0.4	96±2	(98)	96±2	(226)
Parent-reported inventories¶									
Parenting Stress Index, Short Form									
Parental Stress subscale	22±7	(194)	23±8	(189)	−2.1 to 1.0	21±7	(94)	21±7	(231)
Parent–Child Dysfunctional Interaction subscale	19±6	(194)	19±7	(189)	−1.5 to 1.2	18±6	(94)	17±6	(231)
Difficult Child subscale	25±8	(194)	25±9	(189)	−1.5 to 1.9	24±7	(94)	23±7	(231)
Total Stress score	66±19	(194)	66±22	(189)	−4.5 to 3.7	63±18	(94)	62±17	(231)
Child Behavior Checklist									
Withdrawn scale	53±5	(197)	52±5	(193)	−0.8 to 1.0	52±4	(93)	52±4	(229)
Somatic Complaints scale	53±5	(197)	53±5	(193)	−1.5 to 0.4	53±5	(93)	53±5	(229)
Anxious/Depressed scale	52±5	(197)	52±3	(193)	−0.3 to 1.3	52±4	(93)	52±5	(229)
Social Problems scale	53±6	(197)	53±5	(193)	−0.2 to 2.0	53±5	(93)	52±4	(229)
Thought Problems scale	53±6	(197)	53±6	(193)	−1.2 to 1.1	54±6	(93)	52±4	(229)
Attention Problems scale	54±6	(197)	54±6	(193)	−1.3 to 1.0	54±6	(93)	52±4	(229)
Delinquent Behavior scale	54±6	(197)	54±6	(193)	−1.2 to 1.2	54±5	(93)	53±4	(229)
Aggressive Behavior scale	55±7	(197)	54±7	(193)	−1.1 to 1.7	54±6	(93)	53±5	(229)
Total Problems score	49±11	(197)	48±11	(193)	−1.5 to 2.7	48±10	(93)	46±10	(229)

the total numbers of words and of utterances in the sample. There were no significant interactions to suggest that outcomes differed in relation to whether children met the randomization criteria of the study during their first, second, or third year of life; whether they met the criteria on the basis of bilateral continuous middle-ear effusion, unilateral continuous effusion, bilateral discontinuous effusion, or unilateral discontinuous effusion; and, in the 358 children who received hearing tests during one or more episodes of effusion before undergoing randomization, whether one or more of those tests gave abnormal results (as defined in Table 2) or showed a pure-tone average threshold of 30 dB or more or 40 dB or more. (Thresholds of 31 to 50 dB constitute moderate hearing loss.[28])

Among the children who underwent randomization, mean scores for those who actually received tympanostomy tubes before three years of age (irrespective of treatment assignment) as com-

Table 3. (Continued.)

Test	Randomized Clinical Trial (N=395)			Group for Whom Consent for Randomization Was Withheld (N=101)	Representative Subgroup (N=233)
	Early-Treatment Group (N=201)	Delayed-Treatment Group (N=194)	95% CI†		
Teacher-reported inventory¶					
Child Behavior Checklist					
Withdrawn scale	53±6 (192)	54±7 (186)	–1.7 to 1.0	53±6 (93)	52±5 (222)
Somatic Complaints scale	52±4 (192)	52±5 (186)	–1.3 to 0.5	51±4 (93)	52±4 (222)
Anxious/Depressed scale	52±4 (192)	53±5 (186)	–1.7 to 0.3	52±4 (93)	53±4 (222)
Social Problems scale	54±5 (192)	53±6 (186)	–0.8 to 1.4	53±5 (93)	52±4 (222)
Thought Problems scale	52±6 (192)	52±6 (186)	–0.9 to 1.4	53±6 (93)	51±4 (222)
Attention Problems scale	56±8 (192)	55±8 (186)	–0.8 to 2.3	55±8 (93)	53±5 (222)
Delinquent Behavior scale	54±6 (192)	53±5 (186)	–0.4 to 1.9	54±7 (93)	52±4 (222)
Aggressive Behavior scale	55±8 (192)	54±7 (186)	–1.0 to 2.0	55±9 (93)	53±5 (222)
Total Problems score	49±11 (192)	48±11 (186)	–1.2 to 3.3	49±11 (93)	46±10 (222)

* Plus–minus values are means ±SD.
† The 95 percent confidence interval (CI) is for the difference in mean scores (early-treatment group minus delayed-treatment group).
‡ Higher scores indicate more favorable results. In the Wechsler Intelligence Scale for Children, third edition,[16] the number of correct responses is calculated. The normative mean verbal IQ, performance IQ, and full-scale IQ are each 100±15. In the Peabody Picture Vocabulary Test–Revised,[17] the number of correct responses is calculated. The normative mean score is 100±15. For the SCAN Screening Test for Auditory Processing Disorders[18] to be completed successfully, the hearing level has to be normal. A composite score is calculated from the number of correctly understood distorted words, speech in the presence of background noise, and different words presented simultaneously to the two ears. The normative mean score is 100±15. In the Nonword Repetition Task,[19] in standardized phonologic strings of increasing length (one, two, three, and four syllables) in nonsense words, the percentage of phonemes repeated correctly is calculated. Values shown are limited to children with values for all four lengths of strings. In the Number of Different Words test,[20,21] from a computer-assisted analysis of the transcribed sample, all first-occurrence word roots, ignoring inflectional morphemes, are counted in all utterances. In the Mean Length of Utterance in Morphemes test,[21-23] from a computer-assisted analysis of the transcribed sample, the mean length of all utterances that were both complete and intelligible is calculated. In the Percentage of Consonants Correct–Revised test,[21,24] from a computer-assisted analysis of the phonetically transcribed sample, the first 100 first-occurrence words in the transcript are analyzed for the percentage of intended consonants that are articulated correctly. Speech-sound substitutions and omissions are scored as incorrect and speech-sound distortions as correct.
§ $P<0.05$ for the comparison with the early-treatment group.
¶ Higher scores indicate less favorable results. In the Parenting Stress Index, Short Form,[25] the parent rates the parent–child dyad on 36 items in three subscales in terms of the degree of agreement with each statement ("strongly agree," "agree," "not sure," "disagree," or "strongly disagree"). The total of the scores on the subscales is the total stress score. The normative mean scores are 26±7 for the Parental Stress subscale; 19±5 for the Parent–Child Dysfunctional Interaction subscale; 26±7 for the Difficult Child subscale; and 71±15 for the Total Stress score. For the Child Behavior Checklist,[26] a parent and a teacher independently rate the overall behavioral and emotional problems of the child by responding to 120 items and scoring each statement as "not true," "somewhat or sometimes true," or "very or often true." The results are organized into eight specific scales. Scores on the eight scales and a Total Problems score are calculated and converted to T scores. The normative mean T score on each scale and for Total Problems is 50±10.

pared with mean scores for those who did not showed only one significant difference: the mean score on the Nonword Repetition Task was higher among the children who had not received tubes (76±10 vs. 74±11, P=0.04). There were no significant differences between the mean scores of children who underwent randomization and those of children for whom randomization was declined or, in the latter group, between the mean scores of children who received tympanostomy tubes and those who did not.

REPRESENTATIVE SUBGROUP

In the representative subgroup, unadjusted correlations between the scores on each outcome measure and the cumulative duration of middle-ear effusion in the children during their first, second, and third years of life and during their first two years and first three years of life were all less than 0.25; most were less than 0.10 and most were nonsignificant. Exceptions consisted of significant negative correlations (range, –0.13 to –0.18) between the percentage of days with effusion during one or more of

those age periods and scores on the Peabody Picture Vocabulary Test–Revised and the Mean Length of Utterance in Morphemes test, and significant positive correlations (range, 0.13 to 0.22) between percentages of days with effusion and scores on all subscales of the Parenting Stress Index, Short Form, and on certain scales of the parent and teacher versions of the Child Behavior Checklist.

Because scores on most measures were most favorable among the most socioeconomically advantaged children (as indicated by the location of the study site, maternal level of education, and health insurance status) and scores on measures of language and speech were significantly higher in girls than in boys, we performed analyses adjusting for these variables and for hearing thresholds at the time of testing (categorized as within or above protocol-specified limits). Most of the correlations that were significant in unadjusted analyses remained significant (data not shown). However, the percent of the variance in scores explained by time with middle-ear effusion beyond that explained by demographic variables was low, ranging from 1.8 to 4.9 percent.

DISCUSSION

The present findings in children who had persistent middle-ear effusion during their first three years of life indicate that prompt insertion of tympanostomy tubes had no demonstrable beneficial effect on their developmental outcomes at six years of age. These findings reinforce our findings in the study participants at three and four years of age and extend those findings to include results of measures newly applied at six years of age. These measures consisted of a test for deficits in central auditory processing, considered by some authors to constitute the underlying basis of many learning problems[29] and by others to be caused by persistent early-life otitis media[30]; a formal test of intelligence; and teachers' ratings of the behavior of the children.

Other authors have observed that measures of intellectual function[31] and measures of language[32] become increasingly predictive of later IQ as age increases from two to approximately six years, after which predictability levels off, and that both IQ and parents' and teachers' reports of behavior during school-age years correlate with later academic performance.[33,34] Therefore, it seems likely that the results we obtained in the children at six years of age will correlate with the functioning of the children later. To determine whether developmental effects not discernible by 6 years of age might become apparent later, we are currently testing the children at 9 to 11 years of age with the use of measures of literacy, attention, and related skills.

On all of the 30 measures we applied, we found no significant differences in scores favoring the early-treatment group over the delayed-treatment group in the clinical trial. For 26 of the measures, the associated 95 percent confidence intervals afforded assurance that the presence of any difference of 0.33 SD or larger favoring the early-treatment group would probably have been detected. In children in the representative subgroup, correlations between the cumulative duration of middle-ear effusion in the first three years of life and developmental outcomes were, as we had found at earlier ages,[13,15,35] generally weak and in most instances nonsignificant. For the few significant associations found, the percent of variance in the results explained by time with effusion beyond that explained by demographic variables was negligible. The findings in the clinical trial suggest that these associations reflect chance, residual confounding, or both.

Citing our findings in children who underwent randomization at three years of age,[11,12] a clinical practice guideline recently issued by representatives of the American Academy of Family Physicians, the American Academy of Otolaryngology–Head and Neck Surgery, and the American Academy of Pediatrics recommends that otherwise healthy children with persistent otitis media with effusion, instead of undergoing tube insertion, "should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected."[36] Our findings support the recommendation not to insert tubes simply on the basis of persistent effusion and seem generally applicable to children in primary care settings in whom middle-ear effusion is an isolated condition.

As we have noted previously,[11,13] these findings cannot be generalized to children who are not otherwise healthy or who have handicapping conditions such as sensorineural hearing loss, cleft palate, or Down's syndrome, or to children with periods of effusion longer than those we studied, or to children whose effusion is consistently accompanied by moderately severe (rather than the more usual

mild-to-moderate) hearing loss. However, both clinical experience and our previously reported findings[13] suggest that relatively few children in circumstances similar to those of the children in our trial will have periods of effusion substantially longer than those of the participants in the trial.

In summary, our findings in children who were six years of age, consistent with our results when they were three and four years of age, show that the insertion of tympanostomy tubes for persistent otitis media with effusion in the first three years of life, within the duration of effusion that we studied, does not improve the developmental outcomes of the children at those ages. These data, together with the risks posed by the insertion of tubes,[37-40] provide clear support for managing the treatment of such children conservatively.

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