Early surgery compared with watchful waiting for glue ear and effect on language development in preschool children: a randomised trial

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Summary

Background Otitis media with effusion (OME) is the most common cause of hearing loss in children and is generally treated by elective surgery. We compared in children with persistent OME the effect on speech and language development of immediate surgery (ventilation-tube insertion) and watchful waiting before surgery.

Methods We did a randomised controlled trial with masked outcome assessment in Bristol Children's Hospital, Bristol, UK. We included 186 children born between April 1, 1991, and Dec 31, 1992, who had confirmed bilateral OME and bilateral hearing impairment of 25–70 dB of at least 3 months' duration. Children were randomly assigned surgery within 6 weeks (n=92), or 9 months of watchful waiting (n=90), after which bilateral tube insertion was done if required. We assessed hearing loss, expressive language, and verbal comprehension at 9 months and 18 months.

Findings At 9 months, standardised scores for expressive language and verbal comprehension differed between groups with marginal significance after adjustment for baseline differences (p=0·04 and p=0·028, respectively). At 9 months, verbal comprehension and expressive language skills in the watchful-waiting group were 3·24 months behind those in the early-surgery group. The watchful-waiting group was delayed on these two measures compared with their age-expected levels. 18 months after randomisation, 85% of children in the watchful-waiting group had received surgery and groups did not differ significantly.

Interpretation There is some benefit from ventilation-tube insertion for expressive language and verbal comprehension but the timing of surgery is not critical.

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Introduction

Persistent otitis media with effusion (OME), or glue ear, is the most common cause of hearing loss during childhood, and the most frequent cause for elective surgery in children. Persistent hearing loss of 25–30 dB hearing level for more than 3 months in both ears associated with symptoms has been suggested as an appropriate indication for surgery.[1] In the short term, the hearing deficit due to effusion in the middle ear is correctable by insertion of a ventilation tube. In the longer term, hearing gain after ventilation-tube insertion is not maintained. OME most frequently occurs between the ages of 1 year and 4 years and coincides with a period of rapid language acquisition. OME has, therefore, been suggested to have short-term or long-term effects on speech acquisition in young children.[2] Studies of the effects of OME on speech and language development have been flawed by design difficulties such as population selection,[3,4] failure to confirm the duration and severity or laterality of the OME, use of retrospective design, and inadequate sample size.

Moreover, the range and depth of tests of speech and language development used in trials hinder comparisons.[5] Therefore, although growing evidence supports the hypothesis that the temporary hearing loss which accompanies chronic OME may be associated with speech and language delay in many children,[6] confirmation is yet to be reported.[7,8] We did a randomised controlled trial to compare the effects of early surgery with watchful waiting of persistent OME on language development.

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Patients and methods

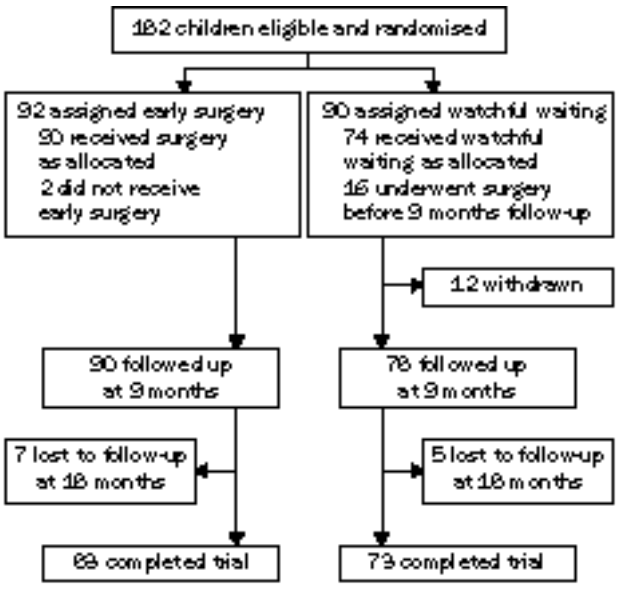
Patients

At baseline, children were seen in community clinics and confirmed to have bilateral OME (bilateral type B or C2 tympanograms and hearing loss of 25–70 dB hearing level, n=186). 3 months later, children were referred to consultant-run otolaryngology clinics. At this appointment we recruited children into our study. Inclusion criteria were: date of birth between April 1, 1991 and Dec 31, 1992; confirmation of bilateral OME by otoscopy and tympanometry; assessment of hearing loss; and disruptions to speech, language, learning, or behaviour. Exclusion criteria were cleft palate and syndromes such as Down's, Hunter's, or Hurler's. 182 children were enrolled (figure).

Children were assigned early surgery (n=92), which was performed within 6 weeks of randomisation, or watchful waiting (n=90), and given an outpatient appointment 9 months later. A second assessment was made 18 months after randomisation.

Methods

Tympanometry and hearing tests at randomisation and 9-month and 18-month follow-up visits were done by audiological scientists



Trial profile

	Early treatment (n=88)	Watchful waiting (n=72)
Characteristics at birth		
Full-term	80 (92%)	65 (90%)
Preterm	7 (8%)	7 (10%)
Mean (SD) birthweight (g)	3528 (667)	3475 (744)
Breastfed	55 (63%)	47 (65%)
Maternal smoking during pregnancy	34 (40%)	26 (36%)
Characteristics during childhood		
Current smokers in household	40 (47%)	35 (49%)
Childhood allergies present	10 (12%)	6 (8%)
Recurrent sore throat/tonsillitis	35 (42%)	31 (44%)
Maternal characteristics		
Qualifications		
None	14 (16%)	15 (21%)
CSE/'O' level	35 (40%)	25 (35%)
'A' level/Tech	22 (25%)	18 (26%)
Degree	16 (19%)	13 (18%)
Employed	37 (43%)	27 (38%)
White	84 (95%)	69 (96%)
Number of children in home		
1	11 (13%)	12 (17%)
2	47 (53%)	28 (39%)
⩾3	30 (34%)	31 (44%)
7-month hearing-test result		
Passed	31 (37%)	22 (34%)
Not passed	53 (63%)	42 (66%)
Not tested	1 (1%)	1 (1%)
Missing data	3 (3%)	7 (10%)

Table 1: **Comparisons of questionnaire data between groups at randomisation**

or technicians who were masked to the children's treatment status. Hearing assessment was done by pure-tone audiometry, automated McCormick toy tests, or both. We classified tympanometry results by Fiellau Nikolajsen's modification of Jerger's classification.[9] All tests were done in soundproof rooms. Pneumatic otoscopic assessment was also done by an otolaryngologist at these times.

Surgery was by insertion of bilateral ventilation tubes. In children with clinical evidence of nasal obstruction because of adenoid enlargement, adenoidectomy was also done. The watchful-waiting group were advised that if the need for an operation was recognised at the 9-month assessment, surgery would be done within 6 weeks of that date. In the early-surgery group, if hearing difficulty returned, otoscopy showed recurrence of effusions, with type B or C2 tympanograms during follow-up, tube reinsertion would be performed, if desired, within 6 weeks. Parents were advised to contact the trial office if their child's hearing or behaviour began to deteriorate. 9 months and 18 months after randomisation, in addition to otoscopy, tympanometry, and hearing tests, the Reynell development language scales[10] were administered by a trained tester who was also unaware of treatment status. The Reynell test assesses expressive language and verbal comprehension abilities in children aged 6 months to 6 years and takes into account sex, social class, and position in the family. Reynell scores are available as age-standardised and equivalent age. At randomisation and 9-month assessment, the Griffiths mental development scale[11] was used. The scales assess general childhood development from birth to age 8 years, Our main outcome measures were verbal comprehension and use of expressive language.

We obtained approval from the Bristol and District Health Authority Research Ethics Committee and recruited children between November, 1993, and January, 1996.

Test	Early surgery (n=92)	Watchful waiting (n=78)
Pure-tone audiometry	46 (50%)	32 (41%)
Distraction	28 (30%)	29 (37%)
McCormick	11 (12%)	10 (13%)
Other (performance/VRA)	7 (8%)	5 (6%)
No details	0	2 (3%)

VRA=visual reinforced audiometry.

Table 3: **Audiological tests done at randomisation**

Statistical analysis

The distributions of the two versions of the Reynell data showed that parametric statistics were appropriate for the standardised score in its original form, with log transformation for the (positively skewed) equivalent age scores. For age score, therefore, we calculated geometric means and compared groups by independent-sample t test, with results presented as ratios of geometric means. For verbal comprehension and expressive-language assessment we used a two-sided 5% level of significance. At this significance level, 170 children would yield 80% power to detect differences of 0·43 SDs for these outcome measures. We adjusted for baseline confounders with ANCOVA. All analyses were done by intention to treat.

Results

182 children entered the study. Between randomisation and 9-month follow-up, eight (4·4%) children in the watchful-waiting group withdrew at parental request and four (2·2%) were excluded because of severe learning difficulties related to late diagnosis of syndromic disorders. Of the 16 children assigned watchful waiting who had surgery early, six children were referred for surgery by the consultant otolaryngologist or the parents opted for private surgery, and ten were admitted, unknown to the investigators under a hospital waiting-list initiative (figure).

The mean age of the children at randomisation was 2·96 years (SD 0·84) in the early-surgery group (range 1·17–4·62) and 2·93 years (0·87) in the watchful-waiting group (1·31–4·69). 49 (53%) and 45 (58%) children in the two groups were girls. At randomisation, 160 parents completed self-administered questionnaires (table 1). The Griffiths mental development scales[11] were completed at randomisation to assess baseline comparability between the two groups. The groups did not differ for any of the six subscales or in the general quotient (table 2).

Audiology, tympanometry, and otoscopy

Audiology and tympanometry data were available for 170 participants (table 3). Hearing was measured at a range of frequencies (250–8000 Hz), but sufficient data for comparison were available only at 4000 Hz because of the young age of the children. Data were available at this frequency for individual ears in 78 (85%) children in the early-surgery group and in 59 (75%) of the watchful-waiting group. The two groups did not differ significantly for mean hearing loss (dB) at 4000 Hz, tympanometry, or otoscopic findings for right and left ears and best and

Griffiths scales	Randomisation		9-month follow-up		95% CI for difference	p
	Early surgery (n=77)	Watchful waiting (n=65)	Early surgery (n=85)	Watchful waiting (n=75)		
Locomotor	98·21	99·17	103·68	102·04	−4·26 to 7·54	0·58
Personal-social	102·54	100·28	105·99	100·91	0·21 to 9·95	0·04
Hearing and speech	100·28	95·92	109·67	104·69	−2·68 to 12·64	0·20
Eye-hand coordination	102·82	100·68	102·60	101·42	−3·81 to 6·16	0·64
Performance	108·60	104·07	113·41	115·28	−8·29 to 4·54	0·56
Practical reasoning	95·99	98·05	103·54	101·14	−3·83 to 8·62	0·45
General quotient	101·45	99·84	106·48	104·25	−2·58 to 7·04	0·36

Table 2: **Mean scores for Griffiths mental development scales at randomisation and 9-month follow-up**

	Early surgery (n=92)				Watchful waiting (n=78)			
	Right ear	Left ear	Best ear	Worst ear	Right ear	Left ear	Best ear	Worst ear
Mean hearing loss (dB) at 4000 Hz (n=135)	38·6	37·9	32·9	42·5	38·6	40·5	34·9	42·8
Tympanometry (n=334)*								
C1	0	0	N/A	N/A	1	0	N/A	N/A
B/C2	89	90	N/A	N/A	75	77	N/A	N/A
Unclassified	1	0	N/A	N/A	1	0	N/A	N/A
Observed fluid behind drum (n=312)*	82	80	N/A	N/A	75	75	N/A	N/A

N/A=not applicable. *Two ears.

Table 4: **Audiological, tympanometric, and otoscopic results at randomisation**

worst ears at randomisation (table 4). 96% of the early-surgery and 99% of the watchful-waiting groups' tympanograms were type B. Otoscopic data were available for 159 children (83 early-surgery, 76 watchful waiting). 104 (65%) children were examined by the consultant otolaryngologist and 55 (35%) by a senior registrar in otolaryngology. All examined participants had fluid in the middle ear, but only two (1·2%) had discharge at randomisation. Data were missing for children who had obstructive wax in the ear canal.

At 9-month follow-up, audiology and tympanometry data were available for 167 children. 80 (89%) right ears and 81 (90%) left ears in the early-surgery group, and 56 (72%) and 59 (76%), respectively, in the watchful-waiting group had data available at 4000 Hz. 31 children in the early-surgery group had no ventilation tubes in left or right ears compared with 63 for each ear in the watchful-waiting group. For those with tubes, in the early-surgery group, they were functioning in 29 right and 35 left ears, and in the watchful-waiting group, seven right and eight left ears. The difference in mean hearing loss in the early-surgery group compared with the watchful-waiting group was non-significant for best ears (15·0 *vs* 17·5 dB [−10·0 to −0·001], p=0·079) but significant for the worst ears (25·0 *vs* 35·0 dB [−10·0 to −0·0010], p=0·049).

62 (78%) of 79 children in the early-surgery group had at least one middle ear without fluid at 9-month follow-up, compared with 23 (32%) of 72 in the watchful-waiting group (difference in proportions 47% [32–61]). Tympanometry results showed that 51 (70%) of 73 children in the early-surgery group had at least one good ear (type A, C1, or patent grommets) compared with 22 (30%) of 73 in the watchful-waiting group (40% [25–55]). Otoscopic and tympanometric clearance of OME was, therefore, significantly better in the early-surgery group than in the watchful-waiting group.

Language development

Two children in the early-surgery group did not attend at 9-month follow-up and Reynell data were, therefore, available for 87 children in this group, and for 77 in the watchful-waiting group. The two groups were similar for examiners, mean duration of test (early surgery 28·9 min, watchful waiting 28·1 min), and the child's age at testing. The child's performance during the Reynell test was taken to be typical by 95% of parents. 5% of children were, however, recorded as being silent during most of the test, and the examiner described a further 28 (20%) as being difficult to understand. At 18 months, Reynell data were available for 81 in the early-surgery group and 71 in the watchful-waiting group (table 5). The Reynell developmental language scales can be expressed as standardised scores between −3·1 and 3·1, in which 0 would be an age-appropriate performance, or by equivalent age scores, in which a score of 5·0 would, for example, show that a child performed at the levels expected of a child aged 5 years.

Verbal comprehension on the Reynell test with allowance for potential baseline confounders differed with only marginal significance. In the early-surgery group, verbal comprehension abilities were at a level expected for the age of the children, but for the watchful-waiting group, levels were a mean of 3·72 months behind that expected (table 5).

For expressive language, the early-surgery group had better scores than the watchful-waiting group, although

	Early surgery mean score	Watchful waiting mean score	Comparison (95% CI)	p	Comparison (95% CI) adjusted for potential baseline confounders*	p
Verbal comprehension at 9 months						
n	87	77	. .	. .	. .	. .
Chronological age (years)	3·73	3·76	. .	. .	. .	. .
Standardised score	−0·04	−0·35	0·31 (−0·03 to 0·66)†	0·07	0·39 (0·04 to 0·74)†	0·028
Equivalent age (years)‡	3·72	3·45	1·08 (0·95 to 1·22)§	0·23	1·07 (1·00 to 1·15)§	0·045
Expressive language at 9 months						
n	87	76	. .	. .	. .	. .
Chronological age (years)	3·73	3·76	. .	. .	. .	. .
Standardised score	−0·62	−1·00	0·37 (−0·01 to 0·76)†	0·059	0·42 (0·02 to 0·82)†	0·04
Equivalent age (years)‡	3·25	2·98	1·09 (0·95 to 1·24)§	0·22	1·08 (0·99 to 1·17)§	0·091
Verbal comprehension at 18 months						
n	81	71	. .	. .	. .	. .
Chronological age (years)	4·53	4·58	. .	. .	. .	. .
Standardised score	0·39	0·13	0·26 (−0·08 to 0·60)†	0·14	0·17 (−0·21 to 0·56)†	0·37
Equivalent age (years)‡	4·99	4·75	1·05 (0·95 to 1·16)§	0·36	1·04 (0·97 to 1·13)§	0·26
Expressive language at 18 months						
n	81	71	. .	. .	. .	. .
Chronological age (years)	4·53	4·58	. .	. .	. .	. .
Standardised score	−0·07	−0·38	0·31 (−0·07 to 0·69)	0·11	0·14 (−0·28 to 0·56)	0·51
Equivalent age (years)‡	4·99	4·75	1·05 (0·95 to 1·16)	0·36	1·04 (0·94 to 1·14)	0·44

*Age at randomisation, sex, hearing at 4000 Hz of best hearing at randomisation (total sample size decreased to 125). †Difference between means. ‡Geometric means (log transformation). §Ratio of geometric means.

Table 5: **Mean standardised and equivalent age scores for verbal comprehension and expressive language at 9 and 18 months**

less significantly so (table 5). The expressive abilities of the two groups were, however, lower than that expected from a reference population. The watchful-waiting group were 9·36 months or 1 SD lower than age-expected levels, and the early-surgery group at 5·76 months or more than 0·5 SD lower than expected. The scores at 18 months were closer to the norms for this age-group.

Surgery

43 (55%) children in the watchful-waiting group received bilateral ventilation tubes according to protocol within 6 weeks of 9-month follow-up. In addition, ten children (14%) in this group were included in a waiting-list initiative and received surgery before 9 months, against protocol, and a further six underwent surgery privately or because symptoms persisted.

Retreatment was required before 18-month follow-up in 17 (18%) children in the early-surgery group and in three in the watchful-waiting group. At 18 months, six (7%) children in the early-surgery group and ten (13%) in the watchful-waiting group were scheduled for retreatment with ventilation tubes.

Only 11 (15%) of the 73 children followed up at 18 months in the watchful-waiting group were not given ventilation tubes. Conversely, two children assigned early surgery did not receive ventilation tubes after re-examination immediately before the operation.

Discussion

We designed our trial to overcome many of the shortcomings of previous studies.[12,13] Persistence of the middle-ear disorder for at least 3 months before randomisation had been confirmed objectively with tympanometry. Our study was randomised and included a watchful-waiting group, 85% of whom were judged to require surgery by the end of monitoring. We found a slight effect of OME on verbal comprehension, and a moderate delay in expressive language at 9 months in the watchful-waiting group compared with the early-surgery group. Concurrent hearing thresholds provide a plausible mechanism for these observations. Overall, some benefit can be accrued from surgery, but the timing of surgery is not critical. Moreover, having a 9-month follow-up enabled avoidance of surgery in a few children for at least 18 months. We did not assess the effect of adenoidectomy and no child received a hearing aid.

Critical periods for speech acquisition have been proposed, but whether the current level of hearing rather than a history of hearing difficulty is important in determining performance in language tests has not been confirmed.[14] The ages of 1 year and 4 years have been suggested as critical for acquisition of phonological and semantic development, respectively. There may be a relation, mediated by hearing between OME and language, even during the first year of life.[14] Furthermore, the relation may change over time. At some times, OME may affect hearing and language and at other times only hearing may be affected. Why some children with OME do not develop language delay is not known, and further studies are required. Various interactions with other factors may adversely affect some children more than others in language development. OME may affect performance of competitive listening and have an additive effect with other factors, such as intrinsic central processing or extrinsic socioeconomic grouping. Children's potential may be lessened by OME and have a more striking effect on children in higher socioeconomic groups. Auditory deficits may result in decreased listening skills, and poor listening may affect ability to read and spell. The Reynell language development scales have been correlated with the Illinois test of psycholinguistic abilities,[15] but they may not be entirely appropriate for the age-group that we studied. If verbal deficit persists, however, our study suggests that the expressive component of language would be more likely to be affected than verbal comprehension by factors related to hearing deficit.

Ventilation tubes resolve OME in the short term. We showed that 9 months after this treatment, the expressive language of children was worse than the average for the age, but after 18 months the difference was no longer apparent. This finding supports similar differences in language and behaviour previously reported in longitudinal studies of older children.[16] We found also that if children with persistent OME are left untreated, expressive language development can be delayed. We found no detrimental effect from a longer period of review before surgery, with the advantage that some children avoid the distress of hospital admission and surgery.

Contributors

All investigators participated in trial design, conduct, analysis, and the writing of the paper, and took part in regular meetings before, during, and after completion of the trial.

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