Early surgery was better than watchful waiting for language development in children with persistent otitis media with effusion

Maw R, Wilks J, Harvey I, Peters TJ, Golding J. **Early surgery compared with watchful waiting for glue ear and effect on language development in preschool children: a randomised trial.** Lancet. 1999 Mar 20; 353:960-3.

Question

In children with persistent otitis media with effusion (OME), does early surgery lead to better language development than does watchful waiting?

Design

Randomised (concealed), single-blind (outcome assessor), controlled trial with 18-month follow-up.

Setting

A children's hospital in Bristol, England, United Kingdom.

Patients

182 children (mean age 3 y, 52% girls) who had bilateral OME confirmed by otoscopy and tympanometry; were born between April 1991 and December 1992; and had hearing loss and disruptions to speech, language, learning, or behaviour. Children with cleft palate or the Down, Hunter, or Hurler syndromes were excluded. Follow-up was 90% at 9 months and 84% at 18 months for language development outcomes.

Intervention

Children were allocated to early surgery within 6 weeks ($n = 92$) or watchful waiting with an outpatient appointment at 9 months ($n = 90$). Surgery was done by insertion of bilateral ventilation tubes. Children in the watchful-waiting group who were identified as needing surgery at the 9-month outpatient appointment received surgery within 6 weeks of that appointment.

Main outcome measures

Expressive language and verbal comprehension abilities were assessed by using the Reynell developmental language scales. Results were expressed as standardised scores (range −3.1 to 3.1, with 0 for age-appropriate performance) and age-equivalent scores.

Main results

After adjustment for potential baseline confounders, children in the early-surgery group had better verbal comprehension abilities ($P = 0.028$ for standardised scores, $P = 0.045$ for equivalent age scores) and better expressive language abilities ($P = 0.04$ for standardised scores) at 9 months than did children in the watchful-waiting group (Table). At 18 months, language development was similar in both groups, but by this time 85% of children in the watchful-waiting group had been treated with ventilation tubes.

Conclusions

In children who had otitis media with effusion, early surgery improved verbal comprehension and expressive language. Waiting 9 months for surgery had no deleterious effect on language development at 18 months, but few children were able to avoid having surgery.

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For correspondence: Mr. R. Maw, Department of Otolaryngology, St. Michaels Hospital, University of Bristol, Bristol BS8 2PR, England, UK. FAX 44-117-928-5117.

Early surgery vs watchful waiting for acute otitis media with effusion

Outcomes at 9 mo	Surgery	Control	Adjusted mean difference* (95% CI)
Verbal comprehension	−0.04	−0.35	0.39 (0.04 to 0.74)
Expressive language	−0.62	−1.00	0.42 (0.02 to 0.82)
			Adjusted geometric-means ratio† (CI)
Verbal comprehension	3.72	3.45	1.07 (1.00 to 1.15)
Expressive language	3.25	2.98	1.08 (0.99 to 1.17)

*Mean difference in standardised scores (range −3.1 to 3.1, with 0 for age-appropriate level).

†Geometric means of age-equivalent scores. Mean differences and geometric-means ratios were adjusted for age at randomisation, sex, and hearing at 4000 Hz of best hearing at randomisation.

Commentary

This important study by Maw and colleagues shows that a statistically significant difference exists in language development between children with OME who have earlier rather than later surgery, but this difference disappears by 18 months. The authors' interpretation—"there is some benefit from ventilation-tube insertion for expressive language and verbal comprehension but the timing of surgery is not critical"—is reasonable, given the methods used in the study and the data obtained. However, only 15% of children in the watchful-waiting group remained untreated at 18 months.

What we still do not know is what the language development of both groups of children would have been like without surgery. To those who feel that withholding surgery, earlier or later, would be unethical, there are some reassuring points to consider. First, one inclusion criterion was "disruptions to speech, language, learning, or behaviour," but we are told neither how many of these children had language problems at the outset nor how much of the language problem resulted from social class factors as opposed to hearing problems. Second, the authors acknowledge that the language assessment used "may not be entirely appropriate for the age group" studied. Third, although the results showed some statistically significant differences, the clinical significance of these differences is not described and may, in fact, not be important in the long run.

This study is a step in the right direction: It should reassure clinicians and parents that one need not rush into surgery. The definitive study showing whether any surgery is necessary in the long term is still anxiously awaited.

William Feldman, MD
University of Toronto
Toronto, Ontario, Canada