Does early detection of otitis media with effusion prevent delayed language development?

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Abstract

Objective—To consider whether earlier detection of otitis media with effusion (OME) in asymptomatic children in the first 4 years of life prevents delayed language development.

Methods—MEDLINE and other databases were searched and relevant references from articles reviewed. Critical appraisal and consensus development were in accordance with the methods of the Canadian Task Force on Preventive Health Care.

Results—No randomised controlled trials assessing the overall screening for OME and early intervention to prevent delay in acquiring language were identified, although one trial evaluated treatment in a screened population and found no benefit. The “analytic pathway” approach was therefore used, where evidence is evaluated for individual steps in a screening process. The evidence supporting the use of tools for early detection such as tympanometry, microtympanometry, acoustic reflectometry, and pneumatic otoscopy in the first 4 years of life is unclear. Some treatments (mucolytics, antibiotics, steroids) resulted in the short term resolution of effusions as measured by tympanometry. Ventilation tubes resolved effusions and improved hearing. Ventilation tubes in children with hearing loss associated with OME benefited children in the short term, but after 18 months there was no difference in comparison with those assigned to watchful waiting. Most prospective cohort studies that evaluated the association between OME and language development lacked adequate measurement of exposure or outcome, or suffered from attrition bias. Findings with regard to the association were inconsistent.

Conclusions—There is insufficient evidence to support attempts at early detection of OME in the first 4 years of life in the asymptomatic child to prevent delayed language development.

Keywords: otitis media with effusion; language development disorders; speech disorders; child development

Otitis media with effusion (OME) is common, with a prevalence of about 20% at age 2 years. It is often asymptomatic. Some studies have found an association between OME and delayed language development, and this finding has led to the implementation of programmes for earlier detection of OME, although the evidence supporting attempts at earlier detection has been questioned. Clinicians conducting periodic health examinations or child health surveillance may question whether attempts at earlier diagnosis of OME should be included as a routine part of these examinations. Using the methods of the Canadian Task Force on Preventive Health Care, we considered the evidence for and against assessing asymptomatic children for OME. Our focus was the first 4 years of life because this is the period of most rapid language acquisition.

Methods

The “causal (analytic) pathway” approach considers evidence for an entire programme for early detection; if this is not available, evidence is considered for each step in an analytic pathway (fig 1). Regarding programmes for earlier detection of OME, the analytic pathway involved examining evidence for the effectiveness of screening the general population for OME in the first 4 years of life to prevent delayed language development (step 1). If such evidence was lacking, the remaining steps in the pathway were considered as follows:

- Is there a suitable tool for early detection (step 2)?
- Is treatment effective in clearing effusions (step 3)?
- Does treating OME improve language related outcomes (step 4)?
- Is there is an association between OME and delayed language development (step 5)?

The guidelines for rules of evidence established by the Canadian Task Force on Preventive Health Care were used to classify the quality of study designs in a hierarchical fashion (box 1).
## Canadian Task Force on Preventive Health Care: levels of evidence and grades of recommendations

**QUALITY OF PUBLISHED EVIDENCE**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tr>
<td>I</td>
<td>Evidence from at least one properly randomised controlled clinical trial</td>
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<tr>
<td>II-1</td>
<td>Evidence from well designed controlled trials without randomisation</td>
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<tr>
<td>II-2</td>
<td>Evidence from well designed cohort or case–control analytic studies, preferably from more than one centre or research group</td>
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<tr>
<td>III-3</td>
<td>Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could also be included here</td>
</tr>
<tr>
<td>III</td>
<td>Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees</td>
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### MEDLINE was searched from 1966 to July 2000, focusing on screening (in general and in the early years), treatment (and subsequent language related outcomes), and the relation between OME and language delay. Key search terms used included otitis media with effusion (OME), middle ear effusion, developmental disabilities, learning disorders, child development, language development disorders, speech disorders, mass screening, sensitivity, and specificity. The Cochrane database of systematic reviews and controlled trials register, as well as the NHS centre for reviews and dissemination database were also searched for relevant studies and meta-analyses. Further studies were identified from manual searching of the indexes of studies identified by electronic searchers, from indexes of review studies, and from the index of the systematic review by the New Zealand health technology assessment clearing house for health outcomes and health technology assessment (http://nzhta.chmeds.ac.nz/screen.htm). If a meta-analysis of suitable quality was found, only relevant individual trials published after the meta-analysis were sought.

Studies were excluded for the following reasons:
- assessment of exposure that was retrospective or inadequate;
- use of samples other than the general population, for example studies that included only graduates of neonatal units, children with cleft palate, high risk children in day care, or specific ethnic groups;
- evaluation of OME after the first 4 years of life;
- findings published in abstract form or in conference proceedings only.

The evidence was systematically reviewed using the methods of the Canadian Task Force on Preventive Health Care. Two authors extracted information from and assessed the quality of the individual studies. The task force of expert clinicians/methodologists from a variety of medical specialities used a standardised evidence based method for evaluating the effectiveness of screening interventions. The full methodology is described by Woolf *et al.*

## Results

### STEP 1: DOES SCREENING THE GENERAL POPULATION OF CHILDREN IN THE FIRST 4 YEARS OF LIFE PREVENT DELAYED LANGUAGE DEVELOPMENT?

We identified no trials assessing the entire screening process for OME (early detection and intervention), where subjects were randomised to be screened and treated if early abnormality is detected, or not screened. However, one trial assessed the impact of screening a general population of children aged 2 years and those with persistent effusions invited to participate in a randomised trial. Owing to small numbers, the study lacked sufficient power to detect a clinically important effect.

Three other “screening” studies were excluded because audiometry was the screening tool and subjects were not randomised. Two of these studies focused on older children. Three studies were excluded because referral rate was the outcome measure. Given the lack of evidence for or against screening for OME in the general population, we then explored the remaining steps in the analytic pathway (fig 1).

### STEP 2: IS THERE A SUITABLE TOOL FOR EARLY DETECTION?

#### Hearing tests

Not all children with OME suffer important hearing loss so an effective tool that directly evaluates hearing loss caused by OME would be ideal. However, manoeuvres that examine hearing deficits—such as audiograms or distraction tests—are not yet useful for early detection. The former tests are not often feasible in children less than 4 years of age and are resource intensive, while the latter are not sufficiently sensitive.

#### Tympanometry

In presurgery populations, several studies found sensitivities and specificities for tympanometry of above 80%. In studies involving populations with a lower prevalence of OME that use otoscopy as the gold standard, sensitivities of around 80% and specificities of more than 90% were reported. Two studies assessed tympanometry in a community setting using pneumatic otoscopy as the gold standard. The sensitivities were 65% and 95%, and the specificities were 65% and 80%. Microtympanometry compared well with standard tympanometry. As not all children with effusions suffer hearing loss, tympanometry is therefore a surrogate measure for hearing loss. Positive predictive values ranged from 49% to 66% for a hearing loss greater than or equal to 25dB (over 0.5, 1, and 2 kHz) after an abnormal tympanogram in referred populations.
Acoustic reflectometry
Reported sensitivities and specificities of acoustic reflectometry varied widely.23 37-48 However, the performance of the newer reflectometers approaches that of tympanometers.23 41

Pneumatic otoscopy
A review of five studies comparing pneumatic otoscopy with fluid present at the time of surgery found a mean sensitivity of 89% and a mean specificity of 80%.49 In one study, pneumatic otoscopy identified less than half the effusions noted on computed tomography.50 In a comparison with tympanometry in a primary care setting, where the prevalence of OME was 31%, otoscopy had a sensitivity of 76% and a specificity of 87%.51

Decisions based on a combination of manoeuvres, tympanometry, and middle ear muscle reflex measures have high sensitivities and specificities,52 53 but this approach is resource intensive and has not been tested for use in clinical practice.54

Problems with tools for early detection
When assessing the properties of manoeuvres used for the early detection of OME, fluid found in the middle ear at the time of surgery is often considered the gold standard, rather than hearing loss associated with OME in primary care. As the prevalence of OME affects positive and negative predicative values of these manoeuvres, it is important that such characteristics be examined in community samples.55 Children in presurgery samples may also differ from those considered for early detection in other important variables such as age, duration of OME, and related conditions.

Relatively low levels of agreement among potential manoeuvres for early detection have been reported.49 Interobserver reliability has also been found to be moderate.57 58

These problems with candidate tools for early detection are compounded by the recurrent and fluctuating nature of OME: it is only long term OME that warrants treatment; a single measure of any type will fail to document clinically relevant chronicity. Children with positive tests would need to begin a period of observation with repeated testing.

STEP 3: IS TREATMENT EFFECTIVE IN CLEARING OME?

Mucoactive drugs
A meta-analysis concluded that patients with OME receiving oral S-carboxymethyl cysteine or its lysine salt versus placebo benefited by avoiding surgical intervention 2.31 times more often (95% confidence interval (CI), 1.28 to 4.2; p < 0.01), and by reverting to normal tympanograms more often (odds ratio 2.25 (95% CI, 0.97 to 5.22); p = 0.058).59 Longer term effects such as recurrences were not reported. Studies included placebo and no treatment controls, but outcome assessors were blinded to treatment condition. In all but one of the six individual studies considered, confidence intervals for odds ratios included unity. The single study showing benefit included 19 subjects for analysis; the odds ratio favouring mucolytics was 18.92 (95% CI, 2.03 to 177.6).

Antibiotics
Williams and colleagues’ meta-analysis examined the effectiveness of antibiotic prophylaxis of recurrent otitis media and found a rate difference of 0.11 favouring antibiotic treatment (95% CI, 0.03 to 0.19).60 Studies examining outcomes at one month following antibiotic treatment of OME had a rate difference favouring antibiotics of 0.16 (95% CI, 0.03 to 0.29). Studies without a placebo control group showed greater antibiotic effect than placebo controlled trials. Three studies evaluated hearing. There were no significant differences in outcomes between the groups that received placebo compared with antibiotics in studies of longer term outcome of OME, that is from six weeks to 11 months after starting treatment (rate difference 0.06 (95% CI, −0.03 to 0.14)).

Other meta-analyses also found that antibiotics promoted the resolution of OME in the short term.64 65

Since these meta-analyses were done, there have been three further relevant trials confirming that antibiotics have an effect on preventing recurrent acute otitis media52 and in promoting the short term resolution of OME.63 64 Long term effects on language were not assessed, and side effects of antibiotic treatment were reported in 44% of antibiotic treated versus 22% of control children in one study of treatment of OME.65

Steroids
The Agency for Health Care Policy and Research (now known as the Agency for HealthCare Research and Quality) found contradictory evidence for steroid treatment alone or in combination with an antibiotic and did not recommend the use of steroids for OME.54 A previous meta-analysis found that children receiving steroids for 7 to 14 days were 3.6 times more likely than placebo controlled subjects to have both ears free of effusion at the end of treatment (95% CI, 2.2 to 4.1).66 However, there was significant heterogeneity of results, and the studies generally involved small samples (range 22 to 60). Since these meta-analyses, a trial showed benefit from adding oral steroid to antibiotic treatment after two weeks, but this advantage was no longer apparent at six weeks and six months.66

Topical (intranasal) steroid combined with an oral antibiotic was effective in clearing effusions in the short term, but by 12 weeks of treatment differences in most outcomes were no longer statistically significant.57

Surgery
A systematic review of well designed randomised controlled trials examining the effectiveness of surgical interventions for OME concluded that ventilation tubes and adenoidectomy alone or in combination were equally effective.19 Meta-analysis was not possible because of variability across studies. On the
basis of three studies, the authors estimated that the magnitude in reduction of hearing loss was on average 12dB at 6 months and under 6 dB after 12 months following surgery. There was a large variation in effect between children. Myringotomy alone, tonsillectomy alone, or combinations of the two were ineffective interventions. Ventilation tube insertion was noted to lead to tympanosclerosis and slightly increased the incidence of chronic perforation and cholesteatoma. Risks of surgery included exposure to an anaesthetic, possible psychological trauma, and a slight risk of haemorrhage after adenoidectomy. Between 20% and 35% of those receiving ventilation tubes experienced ear discharge, which was persistent in 5% of cases.

Since this systematic review, further reports from one of the studies showed that the median duration of OME was reduced by surgery, especially by the combination of a tube and adenoidectomy. However, a recent study of adenoidectomy and adenotonsillectomy for recurrent acute otitis media showed short term and limited efficacy in preventing episodes of acute otitis media and in reducing the estimated proportion of time with effusions.

Other interventions
Auto-inflation (including nose blowing) has limited applicability in young children. A meta-analysis found studies of autoinflation to be of variable and low quality; its use was not recommended for clinical practice. The role of non-steroidal anti-inflammatory drugs may be explored in larger, well designed studies. In two underpowered, placebo controlled trials, there was a non-significant trend favouring treatment with these agents.

A pilot study found a non-significant trend in favour of homeopathic treatment versus usual care for OME.

A meta-analysis of studies of antihistamines combined with decongestant treatment showed no effect on resolution of OME.

STEP 4: DOES TREATING OME IMPROVE LANGUAGE RELATED OUTCOMES?
The studies assessing language related outcomes are summarised in table 1.

A randomised controlled trial examined the effect of treatment on language related outcomes in children recruited to the trial at the time of their first appointment at an otolaryngology clinic. Bilateral effusions and hearing loss were documented prospectively for at least 3 months, after which children were randomised to receive ventilation tubes within 6 weeks, or, if required, after a period of 9 months of “watchful waiting”. Nine months after randomisation, those assigned to the watchful waiting group had verbal comprehension and expressive language skills that were 3.24 months behind those in the early surgery group. Eighteen months after randomisation, 85% of the watchful waiting group had undergone tube insertion, and the groups no longer differed significantly with regard to language related outcomes.

As outlined in table 1, the remaining studies included five controlled cohort studies. The sample sizes ranged from 25 to 58 participants; the findings regarding the effect of treatment on language ability were conflicting.

STEP 5: IS OME ASSOCIATED WITH DELAYED LANGUAGE DEVELOPMENT?
Table 2 summarises the 13 groups of studies identified that considered the effect of OME on language acquisition during the first 4 years of life.

Two studies had high internal validity. Lous and Fiellau-Nikolajsen and Lous et al screened more than 90% of two separate entire birth cohorts in a Danish municipality; follow up was achieved for more than 65% of the children in both cohorts who had significant OME. In these studies, cases were carefully matched with controls. No lasting effects from OME were found. However, outcome was measured at age 8 years, by which time children who had experienced OME may have caught up with their unaffected peers. In one of the studies, follow up evaluation involved only the silent reading word test.

The remaining 11 study groups had methodological flaws that posed substantial threats to internal validity. Only three studies documented hearing loss associated with effusions. Reports from studies of the Nijmegen cohort suffered from possible attrition bias. Although documentation of OME was comprehensive and screening occurred at regular intervals, no attempt was made to follow up all screened subjects with language related assessments. For example, Peters and colleagues did not indicate how subjects were selected for language assessment from the original sample screened for exposure to OME. The extent of subject overlap across studies was not clear: it appeared that some children might have been included in more than one report of outcomes. If this was the case, the studies could not be considered independent. Few significant differences in language outcomes attributable to OME were found, despite multiple comparisons.

Paradise and colleagues report follow up for a subsample of children enrolled in their ongoing study. Children from diverse backgrounds were enrolled by the age of 2 months and middle ear status was monitored at least monthly with hearing tests for those with ongoing OME. Children in this cohort who met inclusion criteria for a trial of treatment with ventilation tubes became ineligible. The remaining children represented a broad range of exposure to OME. They were randomly selected from the remaining cohort for evaluation of language development, speech, and sound production at 3 years of age. The percentage of variance in scores for receptive vocabulary and verbal aspects of cognition explained by time with OME in the first year of life, beyond that explained by sociodemographic variables, ranged from 1.2% to 2.9%. There were no significant correlations between time with OME and scores on measures of spontaneous expressive language,
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addressed the question of early detection in the

terrible investigation, few studies have directly

evaluate a statistically significant association between exposure to otitis media and language delay at age 2 years. A further evaluation of a non-random subsample found that the risk of delayed language development depended on average hearing levels during exposure to OME.

The two studies by Teele and colleagues should be considered to be one study as the reports followed essentially the same children at different times. Duration of OME was calculated by extrapolation from the number of episodes of acute otitis media. Those followed up at 3 years were not randomly selected from the original cohort, and less than 10% of those initially recruited underwent language assessments at the follow up points. At 3 years of age, children with OME had lower scores on the three tests used to assess speech and language. At the 7 year follow up, the relation between time with OME and language was significant in two of nine comparisons.

Kinshkowy and colleagues explored the association between recurrent otitis media and language outcomes. As in the studies by Teele and colleagues, inferences were made about exposure meticulously, but the sample numbers were small (n = 36, 46, and 36), and it was not clear if their studies were independent.

The findings supported the “cumulative effects model,” in that an association was identified but there was probably insufficient power to detect a clinically important difference (step 1 in the analytic pathway).

Various manoeuvres for early detection are available, but performance has not been adequately assessed in community settings, where the prevalence and severity are lower than in presurgery groups. Indeed, manoeuvres have to be evaluated against each other in this setting, where it is not possible to use the gold standard of documented hearing loss associated with the presence of middle ear fluid found at tympanocentesis (step 2 in the analytic pathway). No single reading can give an indication of chronicity, which is crucial in a condition that fluctuates and is often self-limiting.

Most treatments were evaluated in populations identified through usual care. Studies of antibiotics have shown some short term benefit in clearing effusions (step 3 in the analytic pathway), but long term resolution of effusions has not been demonstrated. Antibiotics helped to reduce recurrences of acute otitis media. Evidence for benefit in the short and medium term must be considered in the context of rising bacterial resistance, side effects, and lack of evidence for long term improvement in hearing in children with OME. A meta-analysis of trials of mucolytics suggests possible short term benefit. Surgical management alone or in combination cleared fluid and improved hearing—a systematic review showed ventilation tubes and adenoidectomy were equally effective, with some evidence suggesting the combination was better than either procedure alone. Treatment effectiveness studies generally used intermediate outcomes of effectiveness, such as resolution of OME based on tympanometry. Thus it is not known whether early detection of OME with subsequent treatment using methods other than ventilation tubes prevents adverse language outcomes.

There is good evidence that treatment of OME with ventilation tubes compared with watchful waiting improves language outcomes at 9 months (step 4 in the analytic pathway). However, by 18 months, differences were no longer apparent. This was a study of management among children referred to an otolaryngology clinic and not an evaluation of additional interventions for earlier detection. Consequently, this trial does not provide evidence to support attempts at earlier detection of OME.

With regard to step 5 in the analytic pathway, in five study groups there was no association between OME and language outcomes, while

Discussion

Although the association between OME and language development has undergone considerable investigation, few studies have directly addressed the question of early detection in the first 4 years of life. The analytic pathway approach is therefore particularly important to consider when examining the evidence for or against early detection.

We identified no randomised controlled trials examining the overall process of screening for OME in the first 4 years of life with a preventive manoeuvre for adverse language outcomes. However, one trial screened children and then randomised those with persistent effusions to be treated with ventilation tubes or not. No effect on language was identified but there was probably insufficient power to detect a clinically important difference (step 1 in the analytic pathway).

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With regard to step 5 in the analytic pathway, in five study groups there was no association between OME and language outcomes, while
in eight study groups a minority of analyses showed a significant association. Socio-demographic variables appeared to account for more of the variance in measures of language development than exposure to OME. There was substantial variability across study groups in measurement of exposure (severity, laterality, associated hearing loss, and persistence of OME) and in outcome, and many of the studies had major methodological weaknesses. For example, not all children with effusions suffer from significant hearing loss, a factor that is often considered as the causal link between OME and language delay; a wide range of language and developmental outcomes was used, and the clinical importance of results obtained with these measures was not clear; and interpretation of significant findings was difficult because of the broad array of language tests used without accompanying information about the clinical importance of change scores. In addition, there was a high rate of intervention for OME in the studies, which may have affected the outcomes.

**INTERPRETATION**

On the basis of these findings we conclude that there is insufficient evidence to make recommendations for or against the use of tympanometry, microtympanometry, acoustic refectionometry, and pneumatic otoscopy for the earlier detection of OME in the general population of children up to 4 years of age. There is insufficient evidence to recommend early detection of OME in children in the first 4 years of life to prevent delayed language development.

These conclusions were also reached by the Canadian Task Force on Preventive Health Care. The US Agency for Health Care and Policy Research expert panel did not make a recommendation about early detection of OME.26 The New Zealand health technology assessment clearing house for health outcomes and health technology assessment (http://nzhta.chmeds.ac.nz/screen.htm) stated that it was not possible to conclude whether or not screening programmes for OME in preschool children are an effective health strategy. The report by Haggard and Hughes for the United Kingdom Department of Health recommended against extending preschool screening for OME.25

**FUTURE RESEARCH**

Tools for early detection should be evaluated in settings of low prevalence. Future studies on the identification, effects, and treatment of OME should document hearing loss associated with OME prospectively over time. Unilateral OME is unlikely to result in hearing loss warranting intervention, and laterality should be reported. Outcomes should include behavioural assessments (for example, measures of concentration) as well as language assessments. The reliability and validity of these outcome measures should be described, and clinically important differences specified. Regarding screening the general population for OME, a randomised controlled trial which allocates children at the level of exposure to strategies for early detection would be necessary to determine the effectiveness of the overall screening process (early detection and subsequent management) in preventing language delay. However, such a resource intensive trial is not justified without evidence that OME causes clinically important deficits in language and other developmental outcomes that can be reduced with treatment.

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16 Luckner J. Application of pass fail criteria to middle ear screening results. ASHMJ 1990;23:539–40.
Glue ear, grommets, and adenoids

In the USA in 1996 about 280,000 children under the age of 3 years had tympanostomy tubes inserted but there is still debate about the effects of these procedures. Two papers in the New England Journal of Medicine have addressed the timing of tube insertion and the effect of removing the adenoids at the same time.

In Pittsburgh (Jack L Paradise and colleagues. New England Journal of Medicine 2001;344:1179–87) 6350 babies were studied from the age of 2–61 days. They had at least monthly pneumatic otoscopy and tympanometry up to the age of 3 years. Four hundred and twenty-nine children developed persistent (90 days if bilateral, 135 days if unilateral) middle ear effusion and were randomised to either early (as soon as possible) tympanostomy tube insertion or delayed insertion (dependent on persistence of effusion up to 9 months later). By the age of 3 years the rate of tympanostomy tube insertion was 82% (early group) v 34% (delayed group) but there were no significant differences between the two groups on tests of speech, language, cognition, and psychosocial development. These authors conclude, from these and other data, that tympanostomy tube insertion in children of this age group and with middle ear effusions of this duration produces no evident benefit by the age of 3 years (though it is possible that benefit could become apparent on testing the children when they are older). Children with more severe hearing loss or more severe ear disease might benefit from early tympanostomy.

In Toronto (Peter C Coyte and colleagues. Ibid: 1188–95) a retrospective study included over 37,000 children who had tympanostomy tubes inserted between 1995 and 1997. They found that children who had had concomitant adenoidectomy (or adenotonsillectomy) were about half as likely to need reinsertion of tympanostomy tubes or to need readmission for “conditions related to otitis media”. Adenoidectomy most benefited children aged 3 years or over.

An editorial (Ibid: 1241–2) calls for longer term follow up of the children in the first of these studies and points to difficulties in assessing the clinical implications of the second.

When should tympanostomy tubes be inserted? What are the benefits to be expected? What harm might it cause? Should adenoidectomy be performed at the same time? The debate will continue.
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