National Collaborating Centre for
Women's and Children's Health

Surgical management of otitis media with effusion in children

Clinical Guideline

February 2008

Funded to produce guidelines for the NHS by NICE

Surgical management of otitis media with effusion in children

National Collaborating Centre for Women's and Children's Health

Commissioned by the National Institute for Health and Clinical Excellence

Evidence tables

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RCOG Press

Evidence tables should be read in conjunction with the full guideline.

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Contents

Abbreviations

AOM	acute otitis media
CI	confidence interval
dB	decibel
dBA	A-weighted decibel scale measured on a sound level meter
dBHL	hearing level in decibels as measured on an audiometer
EL	evidence level (level of evidence)
ENT	ear, nose and throat
GDG	Guideline Development Group
HI	hearing impairment
Hz	hertz (unit of frequency; cycles per second)
ICER	incremental cost-effectiveness ratio
MEE	middle ear effusion
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPV	negative predictive value
OME	otitis media with effusion
PPV	positive predictive value
PTA	pure tone audiometry
QALY	quality-adjusted life year
RCT	randomised controlled trial
RD	risk difference
RR	relative risk
SD	standard deviation
SNHL	sensorineural hearing loss
TM	tympanic membrane
VT	ventilation tube

Evidence tables

Presentation of OME

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
Maw (1988)[13] {36960}	Prospective survey EL = 3	1) to identify the age at which hearing loss was first suspected in children with OME, 2) time of subsequent presentation in the hospital, 3) subjective presenting features of OME in an ENT department, and 4) identify the individual to whom the condition first presented or the method by which hearing loss was suspected	Total no. of patients = 280 Children between 2 and 11 years of age referred specifically to the ENT department of a tertiary hospital for consideration of treatment and inclusion in an ongoing study. The population included children with bilateral OME and significant hearing loss (severe disease group, *n* = 180) and where effusion cleared from one or both ears during the 3 month observation period (mild disease group, *n* = 100)	Comparison of features between severe and mild disease group *Age of suspected hearing loss (in %)* less than 3 years: 12.3 vs 5.2 3–5 years: 54.6 vs 41.2 5–7 years: 30.0 vs 45.4 more than 7 years: 3.1 vs 8.2 *Age of presentation in ENT department (in %)* less than 3 years: 0.6 vs 0 3–5 years: 15.9 vs 14.3 5–7 years: 55.3 vs 45.9 more than 7 years: 28.2 vs 39.8 *Subjective presenting feature of OME (in %)* Hearing impairment: 61.6 vs 66.3 Learning difficulty: 8.7 vs 0 Speech/language problems: 7.6 vs 4.2 Routine screening tests: 20.9 vs 27.4 *Individual or method of first suspecting hearing loss (in %)* Mother: 53.4 vs 48.4 Father: 1.7 vs 0 Teacher: 5.5 vs 2.1 GP: 2.2 vs 2.1 Routine screening tests: 20.0 vs 26.8 *Periodicity and seasonal variation of hearing loss (in %)* Intermittent: 23.0 vs 43.0	Source of funding: not given High risk of bias No control for confounding variables Incomplete information about the questionnaire (validity, piloting, application)

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				Continuous: 77.0 vs 57.0 Spring/Summer: 1.1 vs 2.0 Autumn/Winter: 43.5 vs 48.0	
Keles (2004)[18] {36973}	Prospective survey EL = 3	a) determine prevalence of OME b) analyse its effect on academic performance c) investigate correlation between frequency of OMEand BCG vaccination	Total no. of patients = 3675 Primary school children, clinically healthy, living in same region and with similar socio-economic status. First grade (n = 2042) and second grade (n = 1633). Mean age of first grade students: 84 (2.7) months, Male: 62% Mean age of second grade students: 96 (2.1) months, Male: 61.4% Exclusion criterion: Children with sinusitis, diabetes, immunodeficiency, and VT inserted.	*Prevalence of OME (first vs second grade)* 3.1% vs 1.5% ($P < 0.05$) *Males with OME (first vs second grade)* 59.3% vs 64% *Concordance between otoscopy and tympanometry in diagnosing OME (first vs second grade)* 93.7% vs 88% *Comparison of academic performance (students without OME vs with OME)* Bad 2.2% vs 3.3% Borderline 5.7% vs 6.7% Fair 30.5% vs 32.5% Good 37.2% vs 34.8% Very good 24.4% vs 22.4% $P > 0.05$ for all *Comparison of academic performance of OME cases (first vs second grade)* Bad 3.1% vs 4.0% Borderline 6.2% vs 8.0% Fair 35.9% vs 28.0% Good 34.3% vs 32.0% Very good 20.3% vs 28.0% $P > 0.05$ for all	Source of funding: not given Representative population Moderate chance of bias Questionnaire not validated, piloted.
Silva (1982)[14] New Zealand {36981}	Cohort study EL = 2+	Comparison of speech, language and motor development, intelligence, and behavioural characteristics of children with bilateral OME with those with no otological abnormalities.	Total no. of patients = 404 Children 5 years of age, born between April 1972 and March 1973, assessed for otological status every second year from the age of 3 years, similar socio-economic status Normal group (n = 357) Bilateral OME group (n = 47)	Comparison between normal group vs bilateral OME group – Mean score (SD) Speech articulation: 17.6 (3.92) vs 16.3 (4.88), P < 0.05 Verbal comprehension: 51.2 (6.41) vs 49.1 (5.27), P < 0.01 Verbal expression: 50.3 (7.18) vs 49.3 (5.84), P > 0.05 Intelligence quotient scores: 106.6 (16.14) vs 99.8 (15.4), P < 0.01 Motor development: 35.5 (8.19) vs 32.8 (7.87), P < 0.01	Funding: government Minimal chances of bias Confounding variables partially controlled Blinding of outcome assessors

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				Maladaptive behavior (total 15 aspects): P < 0.05 for aspects of dependency, short attention span, weak goal orientation, restless, fidgety, destructive, often disobedient, and not liked by children	
Silva (1986)[15] New Zealand {36982}	Cohort study EL = 2+	Longitudinal follow-up of study by Silva *et al*. (1982)[14] Comparison of hearing, intelligence, language development, speech articulation, reading attainment, and behaviour problems of children with no otological abnormalities to those with bilateral OME	Total no. of patients = 367 Population same as in study by Silva *et al*. (1982)[14] Normal (*n* = 297 to 323) Bilateral OME group (*n* = 39 to 44)	<u>Comparison of normal vs bilateral OME group</u> *Mean hearing threshold levels (in dB)* 5 years: 4.6 vs 20.1 7 years: 10.0 vs 12.8 9 years: 8.7 vs 11.6 11 years: 7.9 vs 11.5 *P* < 0.001 for all *Mean Z scores for intelligence* 3 years: 0.04 vs −0.11 5 years: 0.11 vs −0.29 7 years: 0.10 vs 0.03 9 years: 0.10 vs 0.01 11 years: 0.05 vs −0.03 *P* = 0.202 (comparison of sums of means) *Mean Z scores for verbal comprehension* 3 years: 0.09 vs −0.21 5 years: 0.08 vs −0.36 7 years: 0.06 vs 0.04 9 years: 0.01 vs −0.14 *P* = 0.044 (comparison of sums of means) *Mean Z scores for verbal expression* 3 years: 0.08 vs −0.20 5 years: 0.03 vs −0.10 7 years: 0.08 vs −0.30 9 years: 0.09 vs −0.08 *P* = 0.030 (comparison of sums of means) *Mean Z scores for speech test* 5 years: 0.04 vs −0.41 7 years: 0.09 vs −0.34 9 years: 0.12 vs −0.46	Funding: Government Minimal chances of bias Confounding variables partially controlled Outcome assessors blinded

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				P = 0.0001 (comparison of sums of means) *Mean Z score for reading test* 7 years: 0.10 vs −0.30 9 years: 0.07 vs −0.21 11 years: 0.06 vs −0.25 *P* = 0.023 (comparison of sums of means) *Mean Z scores for behaviour (parents scale)* 5 years: −0.02 vs 0.34 7 years: −0.10 vs 0.19 9 years: −0.09 vs 0.13 11 years: −0.08 vs −0.01 Higher score indicate more behaviour problems *P* = 0.067 (comparison of sums of means) *Mean Z scores for behaviour (teachers' scale)* 5 years: −0.08 vs 0.26 7 years: −0.07 vs 0.49 9 years: −0.08 vs 0.25 11 years: −0.03 vs 0.24 Higher score indicate more behaviour problems *P* = 0.067 (comparison of sums of means)	
Peters (1994)[19] Netherlands {36983}	Cohort study EL = 2+	Evaluating the effect of OME on reading and spelling ability	Total no. of patients = 270 Children from a birth cohort who were screened between 2 to 4 years of age through quarterly tympanometry examination and later followed up at 7–8 years of age. OME group - with no treatment at 2–4 years (*n* = 151) Treated group - children with VT inserted at 2–4 years (*n* = 37) Control group, no OME (*n* = 82)	Comparison of mean scores (SD) between OME group vs Control grp *Spelling – for words* 64.1 (25.1) vs 70.4 (23.6) *P* < 0.05 *Spelling – for pseudowords* 60.4 (25.3) vs 66.7.4 (23.2) *P* < 0.001 *Spelling – one-minute test* 42.0 (19.9) vs 41.5 (17.5) *P* > 0.05 *Reading – comprehension for correct sentences*	Funding: Stichting Kinderpostzegels Nederland Minimal chances of bias Confounding variables controlled partially High drop-out rate

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				85.2 (12.9) vs 88.4 (12.2) $P > 0.05$ *Reading – comprehension for incorrect sentences* 84.7 (17.4) vs 86.1 (15.8) $P > 0.05$ Comparison of mean scores (SD) of teacher ratings between OME group vs Control group *Writing scale* 3.1 (1.0) vs 3.5 (1.0) $P < 0.05$ *Reading scale* 3.3 (0.8) vs 3.5 (0.9) $P > 0.05$ *Arithmetic scale* 3.0 (0.8) vs 3.2 (1.0) $P > 0.05$	
Gravel (2000)[16] USA {36992}	Cohort study EL = 2+	a) examine the effects of OME on hearing sensitivity during the first 3 years of life b) assess whether OME that resolves in 1 year has a long-term cumulative effect on hearing at later ages c) investigate patterns of OME and hearing loss as a function of gender, birth risk, and socioeconomic status	Total no. of patients = 114 Children enrolled in a hearing project by the age of 2.5 months with hearing assessment and middle-ear function evaluated every 2 months till 3 years of age. (males 52%, full-term 82%, African American 48%, SES mid to high 59%) Normal (n = 56) Bilaterally OME positive (n = 20) Unilaterally OME positive (n = 8) Mixed OME (n = 5) Infrequent OME (n = 25)	Difference between groups in mean average hearing levels *Year 1* $F(4,109) = 4.44$, $P = 0.002$) *Year 2* $F(4,109) = 17.2$, $P < 0.0001$) *Year 3* $F(4,109) = 12.28$, $P < 0.0001$) Difference in mean hearing levels (SD) between Normal and Bilateral OME group *Year 1* 13.9 (4.8) vs 20.0 (7.3) $P < 0.05$ *Year 2* 11.7 (3.4) vs 18.3 (4.4)	Funding: National Institutes of Health Moderate chance of bias Confounding variables controlled (partially) High drop-out rate

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				$P < 0.05$ *Year 3* 11.3 (2.7) vs 18.6 (6.2) $P < 0.05$ Average hearing levels across 3 years for 3 groups - normal, OME in year 1 only, OME in year 1 & 2 *Difference between groups* F (2,49) = 12.54 $P < 0.0001$ *Change in average hearing levels over time* F (2,48) = 26.21 $P < 0.0001$ Analysis of OME and hearing as a function of gender, birth risk status and socioeconomic status No difference $P > 0.05$ for all three variables	
Casselbrant (2000)[20] USA {36996}	Cohort study EL = 2+	To determine possible changes in vestibular and balance test results associated with a history of recurrent or persistent OME, but without any concurrent effusion.	Total no. of patients = 71 Children aged 4 years free of middle ear effusion at the time of testing, enrolled in an earlier study at the age 24–35 months and with monthly evaluation of middle ear status. Mean age 48.6 months, boys 59%, white 67.6%. Group A with no significant history of middle ear effusion (n = 31) Group B with significant history of middle ear effusion (n = 40)	Comparison of Mean (SD) of gain in Rotational Testing *Stimulus at 0.02 Hz, 50/sec* 0.55 (0.15) vs 0.49 (0.19) $P = 0.10$ *Stimulus at 0.1 Hz, 50/sec* 0.64 (0.15) vs 0.54 (0.17) $P = 0.06$ *Stimulus at 0.1 Hz, 150/sec* 0.57 (0.14) vs 0.44 (0.13) $P = 0.007$ Comparison of Mean (SD) of phase degrees in Rotational Testing phase *Stimulus 0.02 Hz, 50/sec* 23.1 (8.5) vs 28.0 (7.8)	Funding: Part of thesis Moderate chances of bias Confounding variables not adjusted High drop-out rate

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				P = 0.10 *Stimulus 0.1 Hz, 50/sec* 7.7 (3.7) vs 8.3 (3.9) *P* = 0.62 *Stimulus 0.1 Hz, 150/sec* 9.4 (5.6) vs 9.8 (4.9) *P* = 0.78 <u>Comparison of Mean (SD) of asymmetry in degrees/sec in Rotational testing</u> *Stimulus 0.02 Hz, 50/sec* 1.50 (0.84) vs 1.89 (1.30) *P* = 0.54 *Stimulus 0.1 Hz, 50/sec* 2.94 (2.29) vs 1.65 (1.27) *P* = 0.07 *Stimulus 0.1 Hz, 150/sec* 2.70 (1.8) vs 2.09 (1.71) *P* = 0.30 <u>Comparison of Moving posture platform testing</u> No difference in Normalized EquiTest scores for 6 conditions tested between Group A and Group B (*P* > 0.10 for all conditions)	
Roberts (2004)[17] {37009}	Systematic Review/Meta-Analysis EL = 2+	Comparison of receptive language, expressive language, vocabulary, syntax, language use, and speech.	Prospective studies or RCT with documented OME or associated hearing loss before the age of 5 years, and with measured outcomes. Total no. of included studies = 14 studies (both correlational and individual group comparison studies)	*Receptive language vs OME and hearing loss at 3 years (3 correlation studies)* R (95% CI) = - 0.03 (- 0.27, 0.22) *P* = 0.81 *Receptive language vs OME and hearing loss at 2–5 years (7 group studies)* R (95% CI) = - 0.24 (- 0.41, - 0.07) *P* = 0.003	Source of funding: Government Detailed description of methodology Quality appraisal of individual studies not done Meta-analysis of similar studies done

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				Receptive language vs OME and hearing loss at 1–2 years (3 correlation studies) R (95% CI) = - 0.17 (- 0.29, - 0.05) *P* = 0.005 *Expressive language vs OME and hearing loss at 3 years (3 correlation studies)* R (95% CI) = - 0.07 (- 0.22, 0.08) *P* = 0.35 *Expressive language vs OME and hearing loss at 2–5 years (6 group studies)* R (95% CI) = - 0.24 (- 0.41, - 0.07) *P* = 0.006 *Expressive language vs OME and hearing loss at 1–2 years (3 correlation studies)* R (95% CI) = - 0.30 (- 0.43, - 0.16) *P* < 0.001 *Receptive vocabulary vs OME at 3 years (4 correlation studies)* R (95% CI) = - 0.05 (- 0.23, 0.13) *P* = 0.56 *Receptive vocabulary vs OME at 3 years (4 group studies)* R (95% CI) = - 0.16 (- 0.37, 0.05) *P* = 0.144 *Expressive vocabulary vs OME at 3–5 years (3 correlation studies)* R (95% CI) = - 0.05 (- 0.16, 0.05) *P* = 0.192 *Expressive syntax vs OME at 3–5 years (3 correlation studies)* R (95% CI) = - 0.07 (- 0.18, 0.04) *P* = 0.330 *Speech development vs OME at 3 years (3 group studies)* R (95% CI) = - 0.15 (- 0.32, 0.01) *P* = 0.065	

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
Higson (2005)[22] {36958}	Qualitative Study EL = 2++	To quantify similarities and differences in how the signs, symptoms, and developmental impact of OME are attributed and construed between teachers, parents and ENT surgeons.	Total no. of patients = 450 Primary school teachers of children aged between 3 and 7 years in two educational authorities (n = 118) ENT specialists - random sample (n = 178) Parents - attending one of four ENT departments of tertiary level hospitals (n = 67), visiting their GP's for advice on OME (n = 28), and through publication in a parenting magazine (n = 48) or newspaper (n = 11).	<u>Weighting to Language and education</u> *Overall trend* teachers > surgeons > parents $P < 0.004$ for teachers > surgeons & teachers > parents <u>Weighting to Hearing</u> *Overall trend* parents > teachers > surgeons $P < 0.004$ for parents > teachers & parents > surgeons <u>Weighting to Behaviour</u> *Overall trend* teachers > parents > surgeons $P < 0.004$ for teachers > surgeons & parents > surgeons <u>Weighting to Balance</u> *Overall trend* surgeons > parents > teachers $P < 0.004$ for surgeons > parents & surgeons > teachers	Source of funding: Not given Comments: Good quality descriptive study
Bennett, Haggard (1999)[21] UK {37015}	Longitudinal Cohort study EL = 2+	To find association between a history of middle ear disease and psychosocial outcomes.	Total no. of patients at 5 years = 12000 and total no. of patients at 10 years = 5000 All births in the UK between 5 and 11 April 1970, with data available for evaluating the exposure and outcome variables at 5 and 10 years of age. Prevalence of ear discharge 11.5% and of hearing difficulty 8.4%.	<u>Effect (SD units) of hearing difficulty on continuous behavior scores (parent reported) at 5 years</u> *Crude effect* Antisocial: 0.13 Neurotic: 0.22 Hyperactive: 0.19 Poor conduct: 0.08 *Adjusted effect* Antisocial:0.12 (0.06, 0.18) Neurotic: 0.22 (0.14, 0.25) Hyperactive: 0.19 (0.12, 0.25) Poor conduct: 0.07 (0.01, 0.13) <u>Effect (SD units) of ear discharge on continuous behaviour scores (parent reported) at 5 years</u> *Crude effect* Antisocial: 0.15 Neurotic: 0.20 Hyperactive: 0.13	Source of funding: Not given Exposure indirectly related to OME Chance of information bias Confounding variables partially controlled

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				Poor conduct: 0.14 *Adjusted effect* Antisocial:0.08 (0.03, 0.13) Neurotic: 0.14 (0.09, 0.19) Hyperactive: 0.07 (0.02, 0.13) Poor conduct: 0.07 (0.02, 0.12) Effect (odds ratio) of hearing difficulty on dichotomous behaviour scores (parent reported) at 5 years *Crude effect* Antisocial:1.41 (1.20, 1.70) Neurotic: 1.53 (1.27, 1.80) Hyperactive: 1.53 (1.27, 1.84) Poor conduct: 1.37 (1.13, 1.66) *Adjusted effect* Antisocial:1.44 (1.18, 1.76) Neurotic: 1.52 (1.26, 1.85) Hyperactive: 1.56 (1.29, 1.89) Poor conduct: 1.37 (1.12, 1.67) *P* value < 0.01 for all	
Sheahan (2003)[73] {37527}	Prospective Survey EL = 3	To examine the incidence, natural history, treatment, and outcome of middle ear disease in children with cleft palate	All subjects with cleft lip and palate registered on the database at a children's hospital (*n* = 584). The response rate to the questionnaire was 68.0% (397/584) and the medical records of these children were also reviewed to get more information. Final sample size = 359, [178 children (49.6%) with cleft palate only, 62 (17.3%) with cleft lip only, and 119 (33.1%) with both]. Median age = 7 years (range 5 months – 27 years) 191 (53.2%) males, 168 (46.8%) females	Incidence of middle ear disease & intervention – cleft lip only vs cleft palate only vs cleft lip and palate *H/O any ear problem* 16% vs 68% vs 76% *H/O recurrent ear infections* 8% vs 45% vs 46% *H/O VT insertion* 3% vs 56% vs 61% *H/O ≥ 2 ventilation tubes* 2% vs 38% vs 37% *Tympanoplasty/Mastoidectomy*	Source of funding: Not given Moderate chance of bias Confounding variables not controlled No details about questionnaire validity

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				2% vs 9% vs 7% *Below normal hearing* 3% vs 30% vs 29% <u>Incidence of age-related middle ear disease in children with cleft palate only or cleft lip and palate</u> *H/O any ear problem, H/O ear infections & H/O VT insertion* years: 31%, 11% & 3% 2–3 years: 54%, 23% & 37% 4–6 years: 86%, 59% & 64% 7–9 years: 75%, 44% & 66% 10–12 years: 95%, 65% & 83% 13–15 years: 79%, 56% & 79% 16+ years: 79%, 52% & 64% *Ear problems in preceding year & current hearing below normal* years: 25% & 14% 2–3 years: 37% & 20% 4–6 years: 56% & 40% 7–9 years: 44% & 31% 10–12 years: 46% & 46% 13–15 years: 26% & 24% 16+ years: 21% & 24% <u>% of subjects with below normal current hearing related to age of onset of ear problems</u> 0 years: 52% 1 year: 45% 2 years: 45% ≥ 3 years: 32% <u>Relationship between number of VT insertion and subjects with current hearing level below normal</u> *One vs None* 18.5% vs 11.3%	

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				OR: 1.78 (P = 0.198) *Two vs None* 42.6% vs 11.3% OR: 5.82 (P = 0.000) *Three or more vs None* 60% vs 11.3% OR: 12.25 (P = 0.000) Relationship between number of VT insertion and subjects with surgery for chronic OM *One vs None* 5.6% vs 3.2% OR: 1.76 (P = 0.46) *Two vs None* 4.3% vs 3.2% OR: 1.33 (P = 0.74) *Three or more vs None* 21.5% vs 3.2% OR: 8.23 (P = 0.000)	

Diagnosis of OME

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
Anteunis (1999)[23] {37318}	Diagnostic study EL = II	Full-term infants (birthweight 2500–4500 gms and gestational age 38–42 weeks) and preterm infants (birthweight under 1500 gms and gestational age under 33 weeks) recruited from newborn ward and intensive care unit respectively at birth, and examined every 3 months until the age of 24 months. (Full-term infant–parent pairs = 150, preterm infant–parent pairs = 66)	1) Parental reporting on OME vs OME diagnosed clinically Parental reporting about OME assessed by a questionnaire asking questions on the period since preceeding examination. OME confirmed clinically by otoscopy and tympanometry (by an otolaryngologist and an audiologist) 2) Parental reporting on AOM vs AOM diagnosed clinically 3) Parental reporting on HI vs HI diagnosed clinically	<u>Comparison 1 in Full-term infants</u> Sensitivity: 16.5% Specificity: 92.8% PPV: 67.3% NPV: 55.2% *When parents informed about OME presence in previous visit* Sensitivity: 19.6% Specificity: 89.1% PPV: 73.7% NPV: 41.7% *When parents informed about OME absence in previous visit* Sensitivity: 12.8% Specificity: 94.5% PPV: 56.8% NPV: 66.0% <u>Comparison 1 in Preterm infants</u> Sensitivity: 18.2% Specificity: 88.3% PPV: 68.4% NPV: 43.8% *When parents informed about OME presence in previous visit* Sensitivity: 20.9% Specificity: 88.2% PPV: 82.6% NPV: 29.4%	Unselected population Validity of questionnaire – not specified Tests and reference standard adequately described Tests and reference tests done by trained personnel Blinding – not specified Results not given for AOM and HI as not relevant to guideline question

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				When parents informed about OME absence in previous visit Sensitivity: 13.2% Specificity: 92.7% PPV: 55.6% NPV: 60.7%	
Babonis (1991)[41] {37255}	Diagnostic study EL = I b	Children scheduled for elective myringotomy and pressure equalization tube placement due to persistent MEE for 4 months, recurrent OM (three in previous 6 months or five in a year), or recurrent OM unresponsive to prophylactic antibiotics (*n* = 120, ears = 240) Age range: 6 months – 10 years 9 months 139 males	1) Portable tympanometry by one of the authors vs Myringotomy Threshold: Type B 2) Acoustic otoscopy /reflectometry by one of the authors vs Myringotomy Threshold: > 5 RU	Comparison 1 (*n* = 220) Prevalence: 53.6% (118/220) Sensitivity: 78.0% (92/118) Specificity: 82.3% (84/102) PPV: 83.6% (92/110) NPV: 76.4% (84/110)	Selected population Tests done immediately prior to the reference standard (exact timing not specified) Adequate description of test and reference standard Blinding – Yes Acoustic otoscopy not relevant to the guideline question
Cantekin (1980)[37] {37325}	Diagnostic study EL = II	Patients scheduled for myringotomy and insertion of tympanostomy tubes on the basis of history of recurrent AOM or persistent MEE or both (*n* = 333, ears = 599) Age range: 7 months – 15 years 203 males, 130 females	1. Pneumatic otoscopy by two otolaryngologists (A & B) vs Myringotomy Threshold: Present, absent or inflammation without effusion or equivocal 2. Tympanometry and middle ear (ME) muscle reflex by an audiologist and independently classified by two investigators vs Myringotomy Threshold: ME muscle reflex threshold ≤ 105 dB measured using different quantitative criterion (ambient pressure / peak pressure, stimulus frequency 1000 / 2000)	Comparison 1 excluding equivocal data (Examiner A) Prevalence: 62.2% (230/370) Sensitivity: 97.0% (223/230) Specificity: 81.4% (114/140) PPV: 89.6% (223/249) NPV: 94.2% (114/121) Comparison 1 excluding equivocal data (Examiner B) Prevalence: 57.4% (201/350) Sensitivity: 87.6% (176/201) Specificity: 80.5% (120/149) PPV: 85.8% (176/205) NPV: 82.7% (120/145)	Selected population Test and reference standard done within 1 hour Adequate description of test and reference standard Blinding – Not specified Data not given for tympanometry as combination of thresholds used.
Capper (1987)[27] {37279}	Diagnostic study EL = II	Children presenting with glue ear (*n* = 125, ears = not specified, Visits = 331)	Tuning fork tests (Rinne and Weber) at 512 Hz by one of the authors vs PTA by an experienced	Rinne test (all age groups) Sensitivity: 87.0% Specificity: 55.0%	Selected population Time interval between test and reference standard not

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
		Age range: not specified (but results given for 4–5, 5–6, and 7–10 years) Exclusions: child with known or suspected sensorineural hearing loss, unreliable results on PTA	audiologist Threshold: Rinne negative for a positive test Weber – lateralized to bad ear	<u>Rinne test (4 – 5 years)</u> Sensitivity: 80.0% Specificity: 50.0% <u>Weber test (all age groups)</u> Sensitivity: 65.0% Specificity: 75.0%	specified Test and reference standard described in details Reference test – not a standard one Blinding – Yes Other diagnostic test results unknown as no data provided
Fiellau-Nikolajsen (1980)[44] {37281}	Diagnostic study EL = I b	Children with persistent type B or C tympanogram during 4 screenings done within six month period, and referred for surgery (*n* = 44, ears = 88) Age range: 42 – 54 months 23 male, 21 female	Tympanometry (operator not specified) vs Myringotomy Threshold: Different thresholds used for a positive test – compliance value ≤ 0.1, 0.2, 0.3, 0.4, 0.5, 0.6 or ≥ 0.7, gradient < 0.025, 0.050, 0.075, 0.10, 0.125, 0.150 or ≥ 0.150, and Type B or C2 as abnormal	*Compliance < 0.1 as threshold* Prevalence: 52.3% (46/88) Sensitivity: 19.6% (9/46) Specificity: 100.0% (42/42) PPV: 100.0% (9/9) NPV: 53.2% (42/79) *Compliance < 0.2 as threshold* Prevalence: 52.3% (46/88) Sensitivity: 45.6% (21/46) Specificity: 95.2% (40/42) PPV: 91.3% (21/23) NPV: 61.5% (40/65) *Compliance < 0.3 as threshold* Prevalence: 52.3% (46/88) Sensitivity: 34.8% (16/46) Specificity: 23.8% (10/42) PPV: 33.3% (16/48) NPV: 25.0% (10/40) *Gradient < 0.1 as threshold* Prevalence: 52.3% (46/88) Sensitivity: 91.3% (42/46) Specificity: 54.8% (23/42) PPV: 68.8% (42/61) NPV: 85.2% (23/27) *Type B or C2 as threshold* Prevalence: 52.3% (46/88) Sensitivity: 91.3% (42/46)	Selected population Test done within 30 minutes of the reference standard Adequate description of test and reference standard Blinding – Yes Results calculated from the data given in the study

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				Specificity: 88.1% (37/42) PPV: 89.4% (42/47) NPV: 90.2% (37/41)	
Grimaldi (1976)[33] {37277}	Diagnostic study EL = III	Children referred by otologists with presumptive diagnosis of MEE, and undergoing myringotomies as an outpatient procedure (*n* = 120, ears = 209) Age group: not specified	1) Otoscopy by otologists vs Myringotomy Threshold: Effusion probable, possible or unlikely 2) Audiometry by an audiologist vs Myringotomy Threshold: not given 3) Tympanometry by an audiologist vs Myringotomy Threshold: not given	<u>Comparison 1 with possible cases as false positive</u> Prevalence: 73.7% (154/209) Sensitivity: 85.7% (132/154) Specificity: 87.3% (48/55) PPV: 95.0% (132/139) NPV: 68.6% (48/70) <u>Comparison 1 with possible cases as true positive</u> Prevalence: 73.7% (154/209) Sensitivity: 98.0% (151/154) Specificity: 36.4% (20/55) PPV: 81.2% (151/186) NPV: 87.0% (20/23)	Selected population Time interval between test and reference standard not specified Test and Reference test described in details Blinding – Yes for audiometry and tympanometry, but not specified for otoscopy Other diagnostic test results (comparison 2 and 3) unknown as no data provided
Haapaniemi (1997)[31] {37297}	Diagnostic study EL = III	School children of 1, 4, and 8 grades for hearing screening according to the recommendations of the Finnish National Board of Health. (*n* = 687, ears = not specified) Age range: 6 – 9 years for grade 1, 10 – 12 years for grade 4, and 13 – 15 years for grade 8.	1) Pure tone audiometry (PTA) at 0.25, 0.5, 1, 2, 3, 4, 6, 8 kHz (operator not specified) vs Tympanocentesis Threshold: Hearing loss > 15 and 20 dB 2) Tympanometry and stapedius reflex (operator not specified) vs Tympanocentesis Threshold: Different thresholds – peak pressure -100, -150 and -200 daPa, admittance of 0.3 ml, different gradients, and Type B curve.	<u>Comparison 1 with subjects as unit of measure</u> *Threshold > 15 dB* Prevalence: 4.2% (29/687) Sensitivity: 82.8% (24/29) Specificity: 82.7% (544/658) PPV: 17.4% (24/138) NPV: 99.1% (544/549)	Representative population Time interval between tests and reference standard not specified Not clear whether tympanocentesis done in all subjects Blinding – not specified Data not extractable for 20 dB threshold on PTA, and different thresholds used for tympanometry.
Harris (2005)[38] {37330}	Diagnostic study EL = II	Children seeking medical treatment for suspected middle ear disease (*n* = 21, ears = 35) Age range: 1 – 10 years 13 boys, 8 girls	1. Pneumatic otoscopy by otolaryngologist vs Myringotomy Threshold: Mobility normal, decreased or no mobility.	<u>Comparison 1 with decreased and no mobility as positive test</u> Prevalence: 62.8% (22/35) Sensitivity: 90.9% (20/22) Specificity: 69.2% (9/13)	Selected population Test done immediately before reference standard (exact time not mentioned) Adequate description of test

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
			2. Tympanometry at conventional frequency of 226 Hz, and also high frequency 678 and 1000 Hz (test operator not specified) vs Myringotomy Threshold: At 226 Hz – Type B and Type B or C. At 678 and 1000 Hz – Gelfand criterion.	PPV: 83.3% (20/24) NPV: 81.8% (9/11) Comparison 2 at 226 Hz (Threshold - Type B) Prevalence: 62.8% (22/35) Sensitivity: 54.5% (12/22) Specificity: 100.0% (13/13) PPV: 100.0% (12/12) NPV: 56.5% (13/23) Comparison 2 at 226 Hz (Threshold - Type B or C) Prevalence: 62.8% (22/35) Sensitivity: 81.8% (18/22) Specificity: 61.5% (8/13) PPV: 78.3% (18/23) NPV: 66.7% (8/12) Comparison 2 at 678 Hz Prevalence: 62.8% (22/35) Sensitivity: 95.5% (21/22) Specificity: 53.8% (7/13) PPV: 77.8% (21/27) NPV: 87.5% (7/8) Comparison 2 at 1000 Hz Prevalence: 62.8% (22/35) Sensitivity: 100.0% (22/22) Specificity: 53.8% (7/13) PPV: 78.3% (22/28) NPV: 100.0% (7/7)	and reference standard Blinding – Yes
Jonathan (1989)[32] {37519}	Diagnostic study EL = III	Children admitted for routine myringotomies including in some cases adenoidectomy and/or tonsillectomy (*n* = 64, ears = 128) Age range: 3 – 14 years 35 boys, 29 girls A control group also recruited, but findings not relevant to the	1) Otoscopy (examiner not specified) vs Myringotomy Threshold: Normal or abnormal appearance 2) PTA (examiner not specified) vs Myringotomy Threshold: Hearing loss > 15 dB	Comparison 1 Compliance rate: 88.0% Sensitivity: 100.0% (80/80) Specificity: 28.0% (9/32) PPV: 77.7% (80/103) NPV: 100.0% (9/9) Comparison 3 Compliance rate: 80.0%	Selected population Time interval between test and reference standard not specified Test and Reference test described in details Blinding – Not specified Other diagnostic test results (comparison 2 and 3) unknown as no data provided

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
		guideline question	at all frequencies 3) Tympanometry (examiner not specified) vs Myringotomy Threshold: Flat tympanogram	Sensitivity: 90.0% Specificity: 52.0% <u>Comparison 2</u> Compliance rate: 93.0% Sensitivity: 86.0% Specificity: 86.0%	
Karma (1989)[39] {37284}	Diagnostic study EL = II	Children followed for otitis episodes in two urban areas in Finland (*n* = 2911, Ear related visits = 11804) Group A: seen by an otolaryngologist in one area (*n* = 1688, visits = 5949) Group B: seen by a paediatrician in second area (*n* = 1223, visits = 5855)	1. Pneumatic otoscopy by the two examiners vs Myringotomy Threshold: Different tympanic membrane findings (colour, position, mobility) with and without acute symptoms. Colour – red, distinctly red, cloudy, abnormal Position – bulging, retracted, abnormal Mobility – impaired distinctively or slightly.	<u>Comparisons for findings without acute symptoms</u> *Colour – cloudy (Group A)* Prevalence: 68.8% (408/593) Sensitivity: 92.9% (379/408) Specificity: 98.4% (182/185) PPV: 99.2% (379/382) NPV: 86.3% (182/211) *Colour – cloudy (Group B)* Prevalence: 69.1% (345/499) Sensitivity: 69.0% (238/345) Specificity: 87.7% (135/154) PPV: 92.6% (238/257) NPV: 55.8% (135/242) *Colour – abnormal (Group A)* Prevalence: 68.8% (408/593) Sensitivity: 97.6% (398/408) Specificity: 92.9% (172/185) PPV: 99.2% (398/411) NPV: 94.5% (172/182) *Colour – abnormal (Group B)* Prevalence: 69.1% (345/499) Sensitivity: 81.2% (280/345) Specificity: 79.2% (122/154) PPV: 89.7% (280/312) NPV: 65.2% (122/187) *Position – bulging (Group A)*	Unselected population Test done before the reference standard (exact time not mentioned) Adequate description of test and reference standard Blinding – No Results calculated from the data given in the study

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				Prevalence: 68.8% (408/593) Sensitivity: 45.1% (184/408) Specificity: 98.9% (183/185) PPV: 98.9% (184/186) NPV: 44.9% (183/407) *Position – bulging (Group B)* Prevalence: 69.1% (345/499) Sensitivity: 18.3% (63/345) Specificity: 99.4% (153/154) PPV: 98.4% (63/64) NPV: 35.2% (153/435) *Position – abnormal (Group A)* Prevalence: 68.8% (408/593) Sensitivity: 55.4% (226/408) Specificity: 94.0% (174/185) PPV: 95.4% (226/237) NPV: 48.9% (174/356) *Position – abnormal (Group B)* Prevalence: 69.1% (345/499) Sensitivity: 50.4% (174/345) Specificity: 90.4% (138/154) PPV: 91.6% (174/190) NPV: 44.7% (138/309) *Mobility – abnormal(Group A)* Prevalence: 68.8% (408/593) Sensitivity: 98.8% (403/408) Specificity: 90.3% (167/185) PPV: 95.7% (403/421) NPV: 97.1% (167/172) *Mobility – abnormal(Group B)* Prevalence: 69.1% (345/499) Sensitivity: 93.6% (323/345) Specificity: 71.4% (110/154) PPV: 88.0% (323/367)	

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				NPV: 83.3% (110/132)	
Lo (2006)[25] {37296}	Diagnostic (Nested case-control) study EL = III	Subjects taken from population-based OME screening survey of schoolchildren – positive screens and random sample of negative screens re-examined after 2–3 wks (n = 276) *Inclusion criterion:* cases and controls with (a) parental consent; (b) parental response to questionnaire; (c) of Chinese descendants; (d) 6–7 years of age; and (e) with PTA results *Cases:* positive screen subjects with effusion on microscopy or abnormal tympanometry with average air-bone gap of 10 dB in at least one of the ears (n = 117, 59.8% bilateral OME, 69 boys and 48 girls) *Controls:* negative screen with normal otoscopy and tympanogram during re-examination (n = 159, 91 boys and 68 girls)	Self-administered questionnaire sent to parents prior to screening, and a binary choice question asking about hearing impairment. Otoscopy and tympanometry performed for screening, and re-examination included history, microscopy, repeated tympanometry and stapedius reflex testing, and standard PTA. OME diagnosed during re-examination 1) Parental suspicion of hearing loss vs OME 2) Parental suspicion of hearing loss vs actual hearing loss obtained from PTA PTA threshold for hearing loss > 25 dB	Average PTA hearing threshold level in cases = 17 dB (range 3.8–40.0 dB) Children diagnosed with MEE = 117 Children with average PTA threshold > 25 dB = 17 <u>Comparison 1</u> Prevalence: 42.4% (117/276) Sensitivity: 19.7% (23/117) Specificity: 96.9% (154/159) PPV: 82.1% (23/28) NPV: 62.1% (154/248) P < 0.001 for chi-square test parental suspicion vs OME <u>Comparison 2</u> Prevalence: 6.2% (17/276) Sensitivity: 11.8% (2/17) Specificity: 90.0% (233/259) PPV: 7.1% (2/28) NPV: 94.0% (233/248) P < 0.686 for chi-square test parental suspicion vs PTA findings	Questionnaire – not validated Test and reference standard performed by trained personnel Blinding – not specified Adequate description of tests and reference standard
Mitchell (1990)[30] {37314}	Diagnostic study EL = III	Consecutive admissions of children with suspected glue ear (n = 50, ears = 100) Age range: 6 months – 14 years	1) Pure tone audiometry (PTA) at 500, 1 kHz and 2 kHz (operator not specified) vs Myringotomy Threshold: Hearing loss ≥ 20 dB 2) Tympanometry (operator not specified) vs Myringotomy Threshold: Type B	<u>Comparison 1 (n = 67)</u> Prevalence: 67.5% (51/67) Sensitivity: 80.4% (41/51) Specificity: 68.7% (11/16) PPV: 89.1% (41/46) NPV: 52.4% (11/21) <u>Comparison 2 (n = 84)</u> Prevalence: 77.4% (65/84) Sensitivity: 87.7% (57/65) Specificity: 52.6% (10/19) PPV: 86.4% (57/66) NPV: 55.6% (10/18)	Selected population Tests and reference standard done within 24 hours Tests and reference standard not described in details. Blinding – not specified

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
Nozza (1992)[45] {37303}	Diagnostic study EL = I b	Children admitted to the same-day surgery unit of a children's hospital for myringotomy and tube placement (*n* = 61, ears = 111) Age range: 1 – 8 years Data not given for second part of this study as comparison with non-reference standard (comparison of tympanometry with pneumatic otoscopy in an unselected group of children)	Tympanometry by an audiologist vs Myringotomy Threshold: Different thresholds used alone and in combination – acoustic reflex present/absent, gradient ≤ 0.1 or 0.2, and peak admittance ≤ 0.1, 0.2, 0.3 or 0.4	*Acoustic reflex absent (n = 103)* Prevalence: 73.8% (76/103) Sensitivity: 88.2% (67/76) Specificity: 85.2% (23/27) PPV: 94.4% (67/71) NPV: 71.9% (23/32) *Gradient ≤ 0.2* Prevalence: 73.0% (81/111) Sensitivity: 91.4% (74/81) Specificity: 70.0% (21/30) PPV: 89.2% (74/83) NPV: 75.0% (21/28) *Peak admittance ≤ 0.2* Prevalence: 73.0% (81/111) Sensitivity: 55.6% (45/81) Specificity: 93.3% (28/30) PPV: 95.7% (45/47) NPV: 43.8% (28/64) *Peak admittance ≤ 0.3* Prevalence: 73.0% (81/111) Sensitivity: 72.8% (59/81) Specificity: 80.0% (24/30) PPV: 90.8% (59/65) NPV: 52.2% (24/46) *Peak admittance ≤ 0.4* Prevalence: 73.0% (81/111) Sensitivity: 81.5% (66/81) Specificity: 63.3% (19/30) PPV: 85.7% (66/77) NPV: 55.9% (19/34)	Selected population Test done within 30 minutes of the reference standard Adequate description of test and reference standard Blinding – Yes Results calculated from the data given in the study
Nozza (1994)[34] {37304}	Diagnostic study EL = I b	Children admitted to the same-day surgery unit of a children's hospital with history of chronic or recurrent middle ear disease. (*n* = 171, ears = 249)	1. Pneumatic otoscopy by a trained Paediatric Nurse Practitioner (whose findings had been validated earlier) vs Myringotomy	Comparison 1 Prevalence: 55.0% (137/249) Sensitivity: 84.7% (116/137) Specificity: 71.4% (80/112) PPV: 78.4% (116/148)	Selected population Test done within 1 hour of the reference standard Adequate description of test and reference standard

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
		Age range: 1 – 12 years	Threshold: Present or absent 2. Tympanometry by a trained and certified audiologist vs Myringotomy. Threshold: Different thresholds used alone and in combination – acoustic reflex present/absent, gradient ≤ 0, 0.1, 0.2 or 0.3, peak admittance ≤ 0, 0.1, 0.2, 0.3 or 0.4, and tympanometric width > 150, 200, 250, 275, 300, 325, 350 or 400 daPa.	NPV: 79.2% (80/101) <u>Comparison 2</u> *Acoustic reflex absent (n = 218)* Prevalence: 56.9% (124/218) Sensitivity: 85.5% (106/124) Specificity: 64.9% (61/94) PPV: 76.3% (106/139) NPV: 77.2% (61/79) *Gradient ≤ 0.3* Prevalence: 55.0% (137/249) Sensitivity: 92.7% (127/137) Specificity: 38.4% (43/112) PPV: 64.8% (127/196) NPV: 79.2% (43/53) *Peak admittance ≤ 0.2* Prevalence: 55.0% (137/249) Sensitivity: 46.0% (63/137) Specificity: 91.9% (103/112) PPV: 87.5% (63/72) NPV: 58.2% (103/177) *Peak admittance ≤ 0.3* Prevalence: 55.0% (137/249) Sensitivity: 70.1% (96/137) Specificity: 80.4% (90/112) PPV: 81.4% (96/118) NPV: 68.7% (90/131) *Peak admittance ≤ 0.4* Prevalence: 55.0% (137/249) Sensitivity: 83.2% (114/137) Specificity: 68.7% (77/112) PPV: 76.5% (114/149) NPV: 77.0% (77/100)	Blinding – Yes Results calculated from the data given in the study

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				Tympanometric width > 300 daPa Prevalence: 55.0% (137/249) Sensitivity: 76.6% (105/137) Specificity: 84.8% (95/112) PPV: 86.1% (105/122) NPV: 74.8% (95/127)	
Ovesen (1993)[42] {37329}	Diagnostic study EL = I b	Children with unilateral or bilateral secretory OM fulfilling two of the following three criterion for surgical intervention – otomicroscopic findings consistent with SOM during 3 months, hearing impairment below 20 Db, and/or adenoid symptoms. (*n* = 220, ears = 440) Age range: 0.8 – 14.8 years 60% males, 40% females	Portable tympanometry by an ENT physician vs Myringotomy Threshold: Type B and Type B or C2 Results also compared with otomicroscopy – but reference test not a standard one.	Type B as threshold Prevalence: 87.0% (342/393) Sensitivity: 90.6% (310/342) Specificity: 72.6% (37/51) PPV: 95.7% (310/324) NPV: 53.6% (37/69) Type B or C2 as threshold Prevalence: 87.0% (342/393) Sensitivity: 94.4% (323/342) Specificity: 52.9% (27/51) PPV: 93.1% (323/347) NPV: 58.7% (27/46)	Selected population Tests done immediately before the reference standard (exact timing not specified) Adequate description of test and reference standard Blinding – Yes
Paradise (1976)[35] {37246}	Diagnostic study EL = I b	Infants and children scheduled by physicians other than authors for myringotomy and insertion of tympanostomy tubes because of recurrent AOM or persistent MEE or both (*n* = 107, ears = 214) Age range: 10 days – 5 years 11 month 62 males, 35 females	1. Pneumatic otoscopy by a paediatrician vs Myringotomy Threshold: Present, absent or suspected OME 2. Tympanometry by audiologist vs Myringotomy Threshold: Not defined	Comparison 1 (a) – 'fluid suspected' with OME as TP, and 'fluid suspected' without OME as FP Prevalence: 64.9% (139/214) Sensitivity: 97.8% (136/139) Specificity: 74.7% (56/75) PPV: 87.7% (136/155) NPV: 94.9% (56/59) Comparison 1 (b) – 'fluid suspected' with OME as FN, and 'fluid suspected' without OME as FP Prevalence: 64.9% (139/214) Sensitivity: 91.4% (127/139) Specificity: 74.7% (56/75) PPV: 87.0% (127/146) NPV: 82.4% (56/68)	Selected population Test and reference standard done within 2 hours Adequate description of test and reference standard Blinding – Yes Data not extractable for tympanometry
Rosenfeld (1998)[24] {37319}	Prospective study EL = II	Consecutive children referred by paediatricians and family practitioners, and attending a	1) 6-item quality-of-life questionnaire survey (concerning perceived hearing status of	Comparison 1 *Parent estimate of hearing vs median (range) hearing loss in dB on PTA*	Selected population Questionnaire – validated Outcome assessed by trained

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
		hospital ENT practice with inclusion criterion: (a) age – 6 months to 12 years; (b) chronic otitis media (MEE in 1 or both ears for 3 months or longer) or recurrent otitis media (3 or more episodes of AOM in past 12 months); (c) child accompanied by parent or primary caregiver; and (d) child able to complete age-appropriate audiometry with good reliability (*n* = 186) Age range: 6 months – 12 years 62% male 76% enrolled in managed care plans	children over past 4 weeks) completed by parents/caregiver vs correlation with Hearing loss evaluated through age-appropriate PTA (500, 1000, 2000 Hz) by a trained audiologist 2) Change in caregiver assessment of hearing status after treatment vs correlation with change in PTA findings 3) PTA findings (normal hearing with PTA average < 20 dB for better hearing ear) vs Middle ear status using a validated 4-point clinical profile based on otoscopy (TM grey, translucent and without fibrosis as normal); admittance (> 0.2 millimho as normal), and tympanometric gradient (< 150 daPa as normal) <u>4-point scale (for middle ear profile)</u> Level 1 – all 3 normal Level 2 – normal otoscopy with one or both (admittance & gradient) as abnormal Level 3 – abnormal otoscopy with both normal or 1 abnormal Level 4 – all 3 abnormal	No problem – 23 (3–45) Hardly a problem – 21 (3–45) Somewhat a problem – 23 (5–47) Moderate problem – 18 (2–35) Quite a problem – 22 (3–50) Very much a problem – 18 (3–40) Extreme problem – 31 (12–52) Spearman correlation(R) -0.13, *P* = 0.09 <u>Comparison 2 (*n* = 50)</u> *Median (range) change in parent response vs median (range) change in PTA* 2 units (0–6) vs 11 dB (-23 to -35 dB) Spearman correlation(R) 0.07, *P* = 0.65 <u>Comparison 3</u> *Level 1 vs normal hearing* Sensitivity: 17% Specificity: 96% PPV: 76% *Level 4 vs abnormal hearing* Sensitivity: 66% Specificity: 82% PPV: 84%	personnel Blinding – not specified
Sassen (1994)[47] {37309}	Diagnostic study EL = II	Hospital A: children undergoing insertion of ventilation tubes (indication – chronic OME i.e ≥ 3 months or recurrent OME, ears = 273) Hospital B: children undergoing adeno-tonsillectomy with myringotomy (indication – recurrent URI or OME, ears = 242)	Tympanometry (operator not specified) vs Myringotomy Two different tympanometers used and interchanged between the hospitals after 6 weeks. Threshold: Type B and Type B or C2	<u>Type B as threshold</u> *Combined results (n = 488)* Prevalence: 70.1% (342/488) Sensitivity: 82.7% (283/342) Specificity: 63.0% (92/146) PPV: 84.0% (283/337) NPV: 60.9% (92/151) *Age: 5 months – 2 years (n = 67)*	Selected population but different selection criterion followed in two hospitals Test done within 1 hour of the reference standard Adequate description of test and reference standard Blinding – Yes Data not extractable for

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
		(total *n* = 266, total ears = 515) Age range: 5 months – 11 years 5 months		Prevalence: 77.6% (52/67) Sensitivity: 90.4% (47/52) Specificity: 66.7% (10/15) PPV: 90.4% (47/52) NPV: 66.7% (10/15) *Age: 2 – 12 years (n = 421)* Prevalence: 68.9% (290/421) Sensitivity: 81.4% (236/290) Specificity: 62.6% (82/131) PPV: 82.8% (236/285) NPV: 60.3% (82/136) Type B or C2 as threshold Prevalence: 70.1% (342/488) Sensitivity: 94.4% (323/342) Specificity: 87.0% (127/146) PPV: 94.4% (323/342) NPV: 87.0% (127/146)	different age groups with Type B or C2 as threshold
Shiao (2005)[36] {37291}	Diagnostic study EL = I b	Patients under 12 years of age admitted to the ward for VT insertion based on the presumptive diagnosis of OME or atelectasis of the eardrum (*n* = 104, ears = 201) Age range: 1.5 – 12 years 69 boys, 35 girls	1. Pneumatic otoscopy by an otolaryngologist vs Myringotomy Threshold: Presence or absence of OME 2. Tympanometry by an audiologist vs Myringotomy Threshold: Type B	Comparison 1 Prevalence: 89.1% (179/201) Sensitivity: 90.5% (162/179) Specificity: 77.3% (17/22) PPV: 97.0% (162/167) NPV: 50.0% (17/34) Comparison 2 Prevalence: 89.1% (179/201) Sensitivity: 89.4% (160/179) Specificity: 81.8% (18/22) PPV: 97.6% (160/164) NPV: 48.6% (18/37)	Selected population Test and reference standard done within 48 hours Adequate description of test and reference standard Blinding – Yes
Stankiewicz (1979)[26] {37520}	Diagnostic study EL = II	Randomly selected patients from a clinic population complaining of hearing loss, tinnitus and/or vertigo. (*n* and ears = variable for each test) Age range: not specified	1) Otoscopy by one of the authors vs PTA + Tympanometry done by second author as the reference standard Threshold: Normal or abnormal examination	Comparison 1 Prevalence: 36.2% (58/160) Sensitivity: 77.6% (45/58) Specificity: 95.1% (97/102) PPV: 90.0% (45/50) NPV: 88.2% (97/110)	Unselected population but age not specified Tests and reference standard done immediately (exact time not specified) Reference test – not a standard one

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
			2) Tuning fork tests (Rinne and Weber) at 256, 512 and 1024 Hz by one of the authors vs Otoscopy + PTA + Tympanometry done by second author as the reference standard Threshold: Rinne negative for a positive test Weber – lateralized to bad ear for unilateral conductive loss	<u>Comparison 2 (results for conductive deafness only)</u> *Rinne test at 256 Hz* Prevalence: 29.2% (56/192) Sensitivity: 42.9% (24/56) Specificity: 99.3% (135/136) PPV: 96.0% (24/25) NPV: 80.8% (135/167) *Rinne test at 512 Hz* Prevalence: 29.2% (56/192) Sensitivity: 16.1% (9/56) Specificity: 99.3% (135/136) PPV: 90.0% (9/10) NPV: 74.2% (135/182) *Rinne test at 1024 Hz* Prevalence: 29.2% (56/192) Sensitivity: 19.6% (11/56) Specificity: 99.3% (135/136) PPV: 91.7% (11/12) NPV: 75.0% (135/180) *Weber test at 256 Hz (n = 28) (unilateral conductive loss)* Bad ear: 43% Good ear: 25% Mid-line: 32% *Weber test at 512 Hz (unilateral conductive loss)* Bad ear: 54% Good ear: 21% Mid-line: 25% *Weber test at 1024 Hz (unilateral conductive loss)* Bad ear: 46% Good ear: 25%	Blinding – Yes Results calculated from the data given in the study

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				Mid-line: 29%	
Tom (1994)[46] {37241}	Diagnostic study EL = I b	Patients scheduled to undergo myringotomies with pressure equalization tube insertion for either OME refractory to medical management or frequent recurrent OME (*n* = 109, ears = 213) Age range: 5 months – 11 years 5 months 62 male, 47 female Exclusions: ears with small perforations	Tympanometry by a certified audiologist vs Myringotomy Threshold: Type B and Type B or C2	Type B as threshold Prevalence: 71.8% (153/213) Sensitivity: 65.4% (100/153) Specificity: 78.3% (47/60) PPV: 88.5% (100/113) NPV: 47.0% (47/100) Type B or C2 as threshold Prevalence: 71.8% (153/213) Sensitivity: 94.8% (145/153) Specificity: 23.3% (14/60) PPV: 75.9% (145/191) NPV: 63.6% (14/22)	Selected population Test and reference standard done within 2 hours Adequate description of test and reference standard Blinding – Yes
Toner (1990)[40] {37308}	Diagnostic study EL = II	Patients admitted for myringotomy with indication in majority being clinically persistent MEE (*n* = 121, ears = 222) Age range: 18 months – 12 years Exclusions: where both procedures could not be performed due to lack of cooperation	1) Pneumatic otosopy by one of authors vs Myringotomy Threshold: Immobility for a positive test 2) Tympanometry (operator not specified) vs Myringotomy Threshold: Type B	Comparison 1 Prevalence: 55.9% (124/222) Sensitivity: 87.1% (108/124) Specificity: 88.8% (87/98) PPV: 90.7% (108/119) NPV: 84.5% (87/103) Comparison 2 Prevalence: 55.9% (124/222) Sensitivity: 86.3% (107/124) Specificity: 92.9% (91/98) PPV: 93.9% (107/114) NPV: 84.3% (91/108)	Selected population Tests and reference standard done within 24 hours Blinding – Not specified Tests not described in details
van Balen (1994)[43] {37286}	Diagnostic study EL = I b	Children referred by GP's for uni- or bilateral myringotomy and/or tympanostomy tube insertion. (*n* = 142, ears = 284) Age range: 7 months – 12 years Exclusions: Children where tympanograms could not be performed or where surgery results not registered	Portable tympanometry by one of the authors vs Myringotomy Threshold: Type B or C2 as positive test Results also compared with tympanometry (professional) – but reference test not a standard one.	*n* = 233 Prevalence: 66.9% (156/233) Sensitivity: 94.2% (147/156) Specificity: 48.1% (37/77) PPV: 78.6% (147/187) NPV: 80.4% (37/46)	Selected population Tests and reference standard done within 1 hour Adequate description of test and reference standard Blinding – Yes
Vaughan-Jones (1992)[29]	Diagnostic study	Children admitted for myringotomies with a diagnosis of	1) Pneumatic otoscopy (operator not specified) vs Myringotomy	Comparison 1 Prevalence: 67.5% (135/200)	Selected population All tests done within 24 hours

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
{37280}	EL = II	OME (*n* = 100, ears = 200) 56 male, 44 female Mean age male – 6.3 years Mean age female – 6.2 years	Threshold: Effusion or aerated 2) Pure tone air audiometry (PTA) at 500 Hz, 1 kHz, 2 kHz and 4 kHz (operator not specified) vs Myringotomy Threshold: Hearing loss ≥ 25 dB 3) Tympanometry (operator not specified) vs Myringotomy Threshold: Type B or Type B/C2 as positive test 4) Portable tympanometry (operator not specified) vs Myringotomy Threshold: Type B as positive test	Sensitivity: 89.6% (121/135) Specificity: 75.4% (49/65) PPV: 88.3% (121/137) NPV: 77.8% (49/63) <u>Comparison 2 (at 500 Hz)</u> Prevalence: 67.5% (135/200) Sensitivity: 68.2% (92/135) Specificity: 84.6% (55/65) PPV: 90.2% (92/102) NPV: 56.1% (55/98) <u>Comparison 2 (at 1 kHz)</u> Prevalence: 67.5% (135/200) Sensitivity: 59.3% (80/135) Specificity: 93.8% (61/65) PPV: 95.2% (80/84) NPV: 52.6% (61/116) <u>Comparison 2 (at 2 kHz)</u> Prevalence: 67.5% (135/200) Sensitivity: 32.6% (44/135) Specificity: 95.4% (62/65) PPV: 93.6% (44/47) NPV: 40.5% (62/153) <u>Comparison 2 (at 4 kHz)</u> Prevalence: 67.5% (135/200) Sensitivity: 46.7% (63/135) Specificity: 93.8% (61/65) PPV: 94.0% (63/67) NPV: 45.9% (61/133) <u>Comparison 3 (Type B as threshold)</u> Prevalence: 67.5% (135/200) Sensitivity: 67.4% (91/135) Specificity: 93.8% (61/65) PPV: 95.8% (91/95) NPV: 58.1% (61/105)	of the reference standard. Data not extractable for portable tympanometry and acoustic otoscopy Blinding – Yes for pneumatic otoscopy, and not specified for others. Tests not described in details.

Bibliographic details	Study type and evidence level	Patient characteristics	Test, reference standard, threshold for a positive test	Results	Reviewer comments
				Comparison 3 (Type B/C2 as threshold) Prevalence: 67.5% (135/200) Sensitivity: 88.9% (120/135) Specificity: 63.1% (41/65) PPV: 83.3% (120/144) NPV: 73.2% (41/56)	
Watters (1997)[48] {37310}	Diagnostic study EL = II	Children undergoing surgery for suspected MEE (*n* = 501, ears = 955) Exclusions: children whose surgery was cancelled due to normal tympanograms	Tympanometry by a paediatric audiologist vs Myringotomy Threshold: Type B	Prevalence: 78.0% (745/955) Sensitivity: 91.1% (679/745) Specificity: 79.0% (166/210) PPV: 93.9% (679/723) NPV: 71.6% (166/232)	Selected population Test and reference standard done within 2 hours Adequate description of test and reference standard Blinding – Not specified
Yung (1981)[28] {37317}	Diagnostic study EL = III	Children admitted for myringotomy (*n* = 100, ears = not specified) Age range: 2 – 12 years	Tuning fork tests (Rinne and Weber) at 512 Hz (operator not specified) vs Myringotomy Threshold: Rinne negative for a positive test. Weber – referred or not referred	Rinne test – results for both unilateral and bilateral effusion Prevalence: 88.3% (83/94) Sensitivity: 89.2% (74/83) Specificity: 72.7% (8/11) PPV: 96.1% (74/77) NPV: 47.1% (8/17) Weber test – results for unilateral effusion (*n* = 40) Prevalence: 72.5% (29/40) Sensitivity: 79.3% (23/29) Specificity: 90.9% (10/11) PPV: 95.8% (23/24) NPV: 62.5% (10/16)	Selected population Time interval between test and reference standard not specified Test and Reference test – not described in details Blinding – Not specified Results calculated from the data given in the study

Appropriate time for intervention

Bibliographic details	Study type and evidence Level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Reviewer comments
Rosenfeld (2003)[49] {37524}	Systematic Review/Meta-Analysis EL = 2++	18 cohort studies of OME natural history, 7 cohorts or RCT control groups of chronic OME natural history, 2 RCT enrolment cohorts of OME therapy.	Inclusion criterion for OME of new onset or unknown prior duration: 1) cohort study or RCT enrolment cohort (children with OME observed prospectively before randomization) 2) unilateral or bilateral OME diagnosed by tympanometry (type B curve) or using an algorithm containing tympanometry, and 3) cumulative OME resolution over time reported by patient or by individual ear Inclusion criterion for chronic bilateral OME: 1) cohort study or RCT of surgery 2) group or subgroup managed with watchful waiting 3) prospective documentation of bilateral OME for 3 months or longer, and 4) cumulative OME resolution over time reported by patient or by individual ear	Resolution of OME taken as change of tympanogram from 1) Strict criterion – type B to A 2) Relaxed criterion – type B to A/C1 3) Liberal criterion – type B to non-B	<u>Cumulative spontaneous resolution rates by ear of newly diagnosed OME of unknown duration</u> 1) Strict criterion *At 4–6 weeks (5 studies, n = 234)* Estimate: 0.21 (0.11, 0.30) Test for heterogeneity, Q statistic: 10.3, df = 4 Test for heterogeneity, *P*: 0.036 *At 3 months (5 studies, n = 331)* Estimate: 0.20 (0.07, 0.34) Test for heterogeneity, Q statistic: 44.4, df = 4 Test for heterogeneity, $P < 0.001$ *At 6 months (3 studies, n = 229)* Estimate: 0.28 (0.17, 0.40) Test for heterogeneity, Q statistic: 6.2, df = 2 Test for heterogeneity, $P = 0.045$ 2) Relaxed criterion *At 1 month (2 studies, n = 153)* Estimate: 0.22 (0.16, 0.29) Test for heterogeneity, Q statistic: 6.6, df = 1 Test for heterogeneity, $P = 0.930$ *At 3 months (4 studies, n = 291)* Estimate: 0.28 (0.14, 0.41) Test for heterogeneity, Q statistic: 17.8, df = 3 Test for heterogeneity, $P < 0.001$ *At 6 months (3 studies, n = 229)* Estimate: 0.42 (0.35, 0.49) Test for heterogeneity, Q statistic: 12.9, df = 2 Test for heterogeneity, $P = 0.302$	Clearly focused question Methodology described in details Literature search vigorous Selection criterion defined

Bibliographic details	Study type and evidence Level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Reviewer comments
					At 9 months (2 studies, n = 133) Estimate: 0.56 (0.30, 0.82) Test for heterogeneity, Q statistic: 6.3, df = 1 Test for heterogeneity, *P* = 0.012 3) Liberal criterion *At 4–6 weeks (4 studies, n = 182)* Estimate: 0.56 (0.35, 0.78) Test for heterogeneity, Q statistic: 16.0, df = 3 Test for heterogeneity, *P* < 0.001 *At 3 months (6 studies, n = 618)* Estimate: 0.56 (0.51, 0.61) Test for heterogeneity, Q statistic: 6.2, df = 5 Test for heterogeneity, *P* = 0.292 *At 6 months (4 studies, n = 516)* Estimate: 0.72 (0.68, 0.76) Test for heterogeneity, Q statistic: 3.2, df = 3 Test for heterogeneity, *P* = 0.367 *At 9 months (5 studies, n = 578)* Estimate: 0.81 (0.77, 0.85) Test for heterogeneity, Q statistic: 5.2, df = 4 Test for heterogeneity, *P* = 0.266 *At 12 months (3 studies, n = 479)* Estimate: 0.87 (0.80, 0.94) Test for heterogeneity, Q statistic: 6.0, df = 2 Test for heterogeneity, *P* = 0.049 <u>Cumulative spontaneous resolution rates by ear of Chronic OME documented for 3 months or longer</u> *At < 3 months (3 studies, n = 199)* Estimate: 0.19 (0.13, 0.24) Test for heterogeneity, Q statistic: 1.3, df = 2	

Bibliographic details	Study type and evidence Level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Reviewer comments
					Test for heterogeneity, $P = 0.513$ *At 6 months (4 studies, n = 210)* Estimate: 0.25 (0.17, 0.34) Test for heterogeneity, Q statistic: 5.8, df = 3 Test for heterogeneity, $P = 0.124$ *At 1 year (4 studies, n = 198)* Estimate: 0.31 (0.19, 0.43) Test for heterogeneity, Q statistic: 8.4, df = 3 Test for heterogeneity, $P = 0.039$ *At 2 years (2 studies, n = 231)* Estimate: 0.33 (0.27, 0.39) Test for heterogeneity, Q statistic: 0.8, df = 1 Test for heterogeneity, $P = 0.376$	

Effectiveness of surgical and non-surgical interventions

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
Lous (2005)[51] {37759}	Study Type: Systematic Review/Meta-Analysis Evidence Level: 1++	RCTs evaluating the effect of VT on hearing, duration of effusion, language development, cognition or quality of life, and using common type of VT with mean function time of 6–12 months. (*n* = 13) 7 studies where all subjects had bilateral OME and unilateral VT insertion – 3 where all subjects also had adenoidectomy, 4 where subjects further randomised to adenoidectomy or no adenoidectomy 6 studies where children randomised to either bilateral VT insertion or watchful waiting (i.e no VT or late VT) – 1 where children further randomised to adenoidectomy or no adenoidectomy, 5 where adenoidectomy not done at all	Children aged 1–12 years with unilateral or bilateral OME diagnosed using otoscopy or pneumatic otoscopy, and tympanometry or otomicroscopy. Children having short course of antibiotics or analgesics for episodes of acute infections or in pre-randomization period, and those using decongestants freely were also considered.	*Randomised by ears* 1) Unilateral VT and adenoidectomy vs no surgery or myringotomy in other ear 2) Unilateral VT and no adenoidectomy vs no surgery or myringotomy in other ear *Randomised by children* 3) Bilateral VT and adenoidectomy vs watchful waiting (no VT or late VT or myringotomy) 4) Bilateral VT and no adenoidectomy vs watchful waiting (no VT or late VT or myringotomy)	Difference in hearing levels (Weighted Mean Difference in dB with 95% CI) *1–3 months after treatment* Comparison 1 (5 trials, *n* = 472): -5.3 (-7.1, -3.5) Comparison 2 (2 trials, *n* = 142): -7.5 (-10.8, -4.2) Comparison 4 (1 trial, *n* = 25): -9.8 (-17.4, -2.2) *4–6 months after treatment* Comparison 1 (6 trials, *n* = 558): -3.6 (-5.3, -2.0) Comparison 2 (4 trials, *n* = 432): -9.4 (-14.5, -4.3) Comparison 4 (2 trials, *n* = 212): -4.2 (-7.8, -0.7) *7–12 months after treatment* Comparison 1 (7 trials, *n* = 751): -1.4 (-2.7, -0.1) Comparison 2 (5 trials, *n* = 458): -6.1 (-9.2, -3.0) *2 years after treatment* Comparison 1 (3 trials, *n* = 344): -1.0 (-3.0, 1.0) Comparison 2 (3 trials, *n* = 282): -4.0 (-6.4, -1.7) *5 years after treatment* Comparison 1 (2 trials, *n* = 297): 0.9 (-2.6, 4.3)	Clearly focused question Methodology described in details Literature search vigorous Quality appraisal of individual studies done Meta-analysis of similar groups

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Comparison 2 (2 trials, *n* = 195): -1.7 (-3.9, 0.6) Difference in proportion of time spent with effusion (Weighted Mean Difference with 95% CI) *During first year* Comparison 4 (3 trials, *n* = 574): -0.32 (-0.48, -0.17) *During first two years* Comparison 4 (3 trials, *n* = 426): -0.13 (-0.17, -0.08) Difference in proportion of time spent with hearing loss > 20 dB in best ear (Weighted Mean Difference with 95% CI) *At 2 years* Comparison 3 (1 trial, *n* = 236): -0.1 (-0.1, -0.0) Difference in Language comprehension (Standardized Mean Difference with 95% CI) *Reynell comprehension Z-score (6–9 months delayed treatment)* Comparison 4 (3 trials, *n* = 394): 0.1 (-0.2, 0.4) *Peabody vocabulary picture test at 3 years* Comparison 4 (1 trial, *n* = 395): 0.0 (-0.2, 0.2) Difference in Expressive language for early bilateral VT vs watchful waiting (Standardized Mean	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Difference with 95% CI) *Expressive standardized Z-score (6–9 months delayed treatment)* Comparison 4 (3 trials, *n* = 393): 0.02 (-0.4, 0.4) *No. of different words* Comparison 4 (1 trial, *n* = 398): -0.1 (-0.2, 0.1) Difference in General development scores (Standardized Mean Difference with 95% CI) *Cognition (Griffiths scale or McCarthy index)* Comparison 4 (2 trials, *n* = 559): -0.03 (-0.3, 0.2) *Richman score(high score indicate more problems)* Comparison 4 (1 trial, *n* = 150): -0.2 (-0.5, 0.1) *Child behaviour checklist* Comparison 4 (1 trial, *n* = 395): 0.14 (-0.1, 0.3) Difference in Quality of life scores on Erickson scale (Standardized Mean Difference with 95% CI) *At 6 months* Comparison 4 (1 trial, *n* = 176): 0.1 (-0.2, 0.4) *At 12 months* Comparison 4 (1 trial, *n* = 165): -0.1 (-0.4, 0.2)	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Difference in Adverse effects (Risk Difference with 95% CI) *Tympanosclerosis at 1 yr* Comparison 1,2 (4 trials, *n* = 610): 0.33 (0.21, 0.45) *Retraction or atrophy at 1 year* Comparison 1,2 (2 trials, *n* = 218): 0.03 (-0.03, 0.08) *Perforation (0–12 months)* Comparison 1,2 (2 trials, *n* = 218): 0.01 (-0.02, 0.03) *Otorrhoea (0–12 months)* Comparison 1,2 (1 trial, *n* = 108): 0.1 (0.00, 0.3) *TM abnormalities 3–4 years of VT insertion for unilateral VT vs no surgery contralateral ear* Comparison 4 (1 trial, *n* = 562): 0.3 (0.2, 0.4) *WMD for hearing loss at 2–5 years for VT ear – control ear* Comparison 1,2 (5 trials, *n* = 453): -0.5 (-2.2, 1.3) *WMD for mean hearing threshold levels 3–4 years after initial treatment* Comparison 1,2 (2 trials, *n* = 562): 0.5 (-0.2, 1.2)	
Thomas (2006)[60] {37760}	Study Type: Systematic Review/Meta-Analysis Evidence Level: 1 + +	RCTs of oral and topical intranasal steroids, including those that used non-intervention controls	Children up to 12 years of age with subgroup analysis planned according to the criterion for diagnosing OME and significant hearing loss.	Comparison 1: Oral steroids vs control Comparison 2:	Comparison 1 (results in peto OR with 95% CI): *Short term resolution (2 weeks or*	Clearly focused question Methodology described in details Literature search

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
		but with adequate blinding of outcome assessors (*n* = 11) 9 trials involved assessment of oral steroids and 2 trials involved assessment of intranasal steroids. RCTs reporting outcomes with ears as unit of analysis excluded.	OME diagnosis defined by: a) Air-bone gap of 10 dB or more plus two or more of otomicroscopy, pneumatic otoscopy or tympanometry b) Two or more of otomicroscopy, pneumatic otoscopy or tympanometry c) One of otoscopy alone or tympanometry d) Poorly or not defined Significant hearing loss defined by a) PTA hearing loss of more than 20 dB at two or more times within 3 months b) Defined but less strict than a) c) Uncertain or not defined	Oral steroids plus antibiotic vs control plus antibiotic Comparison 3: Topical intranasal steroid vs control Comparison 4: Topical intranasal steroid plus antibiotic vs control plus antibiotic or antibiotic alone	*less)* 3 trials, *n* = 108 0.2 (0.1, 0.6) *Intermediate term resolution (1–2 months)* 3 trials, *n* = 106 0.5 (0.2, 1.5) *Hearing gain by at least 10 dB (1–2 months)* 1 trial, *n* = 49 1.5 (0.4, 5.6) <u>Comparison 2 (results in peto OR with 95% CI):</u> *Short term resolution (2 weeks)* 5 trials, *n* = 418 0.4 (0.2, 0.6) *Intermediate term resolution (1–2 months)* 2 trials, *n* = 243 0.7 (0.4, 1.3) *Long term resolution (6 months)* 1 trial, *n* = 15 0.1 (0.0, 7.8) <u>Comparison 3 (results in peto OR with 95% CI):</u> *Short term resolution (3 weeks)* 1 trial, *n* = 44 2.1 (0.6, 6.9) <u>Comparison 4 (results in peto OR with 95% CI):</u>	vigorous Quality appraisal of individual studies done Meta-analysis of similar groups

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Short term resolution (4 weeks) 1 trial, *n* = 59 0.8 (0.2, 3.2) *Intermediate term resolution (3 months)* 1 trial, *n* = 59 0.7 (0.2, 2.4) *WMD in the symptom score at 3 months* 1 trial, *n* = 39 -4.5 (-10.3, 1.3)	
Griffin (2006)[61] {37758}	Study Type: Systematic Review/Meta-Analysis Evidence Level: 1 + +	RCTs using antihistamines, decongestants or antihistamines/decongestant combinations as treatment for OME in children (*n* = 16) 15 RCTs involving 1516 subjects provided dichotomous outcomes and included in statistical meta-analysis	Children under 18 years of age with a diagnosis of OME and not having AOM, anatomical deformity or other chronic immunocompromised states. Subgroup analysis planned according to the setting, age of study population, patient's H/O allergies and AOM, method to diagnose OME, timing of dichotomous outcomes, type of decongestant and antihistamine, type of preparation	Comparison 1: Antihistamine vs control Comparison 2: Decongestant vs control Comparison 3: Antihistamine/decongestant combination vs control Comparison 4: Any medication – antihistamine, decongestant or antihistamine/decongestant combination vs control	<u>Comparison 1 (results in RR with 95% CI)</u> *Cure or no cure at 1–3 months* 2 trials, *n* = 140 0.9 (0.6, 1.4) *Complications of AOM* 1 trial, *n* = 46 0.9 (0.5, 1.7) <u>Comparison 2 (results in RR with 95% CI)</u> *Cure or no cure at or before 1 month* 3 trials, *n* = 276 1.1 (0.9, 1.2) *Cure or no cure at 1–3 months* 2 trials, *n* = 216 1.05 (0.8, 1.3) *Any significant side effect at or before 1 month* 1 trial, *n* = 172	Clearly focused question Methodology described in details Literature search vigorous Quality appraisal of individual studies done Meta-analysis of similar groups

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					11.0 (0.7, 185.4) *Hearing at or about 1 month* 1 trial, *n* = 15 0.9 (0.2, 4.7) *Any surgery (tympanostomy or myringotomy)* 1 trial, *n* = 172 1.1 (0.7, 1.6) *Complications of AOM* 1 trial, *n* = 44 0.5 (0.2, 1.3) Comparison 3 (results in RR with 95% CI) *Cure or no cure at or before 1 month* 4 trials, *n* = 901 1.0 (0.9, 1.1) *Cure or no cure at 1–3 months* 3 trials, *n* = 158 1.1 (0.8, 1.4) *Cure or no cure after 3 months* 2 trials, *n* = 119 1.2 (0.7, 2.1) *Any significant side effect at or before 1 month* 5 trials, *n* = 972 2.5 (1.7, 3.7) *Hearing at or less than 3 months* 3 trials, *n* = 343 1.1 (0.9, 1.3)	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Hearing at 1 year 1 trial, *n* = 48 1.5 (0.6, 3.6) *School performance at 1 year* 1 trial, *n* = 42 0.8 (0.3, 1.9) *Any surgery (tympanostomy or myringotomy)* 2 trials, *n* = 57 0.5 (0.1, 3.4) *Complications of AOM* 2 trials, *n* = 636 0.8 (0.5, 1.3) *Complications of Recurrent OME* 4 trials, *n* = 284 1.3 (0.9, 1.8) Comparison 4 (results in RR with 95% CI) *Cure or no cure at or before 1 month* 7 trials, *n* = 1177 1.0 (0.9, 1.1) *Cure or no cure at 1–3 months* 7 trials, *n* = 514 1.0 (0.9, 1.2) *Cure or no cure after 3 months* 2 trials, *n* = 119 1.2 (0.7, 2.1) *Any significant side effect at or*	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					before 1 month 6 trials, *n* = 1144 2.7 (1.9, 3.9) *Hearing at or about 1 month* 4 trials, *n* = 358 1.1 (0.9, 1.3) *Hearing at 1 year* 1 trial, *n* = 48 1.5 (0.6, 3.6) *School performance at 1 year* 1 trial, *n* = 42 0.8 (0.3, 1.9) *Any surgery (tympanostomy or myringotomy)* 3 trials, *n* = 229 1.0 (0.7, 1.3) *Complications of AOM* 3 trials, *n* = 408 0.7 (0.5, 1.1) *Complications of Recurrent OME* 2 trials, *n* = 142 1.3 (0.8, 2.1)	
Perera (2006)[64] {37684}	Study Type: Systematic Review/Meta-Analysis Evidence Level: 1+ +	RCTs of an autoinflation device in children and adults with clinically diagnosed OME (*n* = 6) RCTs with other type of treatments (e.g analgesia, decongestants, and antibiotics) were	Children and adults with unilateral and bilateral OME and a clinical diagnosis by primary care physicians or specialists using tympanometry (type B or C2), either alone or in combination with simple or pneumatic otoscopy or audiometry. Five trials studied children aged between 3–16 years	Any form of autoinflation vs no autoinflation Devices used – classic Otovent, carnival blower + balloon and Politzer device in 2 trials each. Subgroup analysis planned on the basis of diagnosis of OME, extent of hearing loss measured on audiometry	<u>Improvement seen on tympanometry</u> *At 1 month or less and initial tympanometry defined by type B and C2* 3 trials: RR – 1.6 (0.5, 5.6) <u>Subgroup analysis (initial criterion for diagnosing OME):</u>	Clearly focused question Methodology described in details Literature search vigorous Quality appraisal of individual studies done Meta-analysis of similar groups

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
		included provided these were provided equally to the two groups.	while one included population between 16 and 75 years. Two trials included subjects with B/L OME while four included those with both unilateral and B/L OME.	and age.	*Tympanometry defined by type B only* RR – 2.7 (1.4, 5.1) *Tympanometry defined by type C2 only* RR – 3.8 (1.9, 7.6) *At more than 1 month and initial tympanometry defined by type B and C2* 2 trials: RR – 1.9 (0.8, 4.7) Improvement seen on audiometry *Average improvement > 10 dB in PTA* 2 trials: RR – 0.8 (0.2, 2.9) *Difference in PTA levels* 2 trials: WMD – 7.0 (-6.9, 20.9) Improvement seen on either tympanometry or audiometry (composite) *At 1 month or less* 4 trials: RR – 2.5 (0.9, 6.6) *At more than 1 month* 4 trials: RR – 2.2 (1.7, 2.8) Subgroup analysis (type of device): *Politzer device at 1 month or less* 3 trials: RR – 7.1 (3.7, 13.5)	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Politzer device at more than 1 month 3 trials: RR – 2.2 (1.7, 3.0) *Otovent or carnival blower + balloon at 1 month or less* 2 trials: RR – 1.6 (0.5, 5.5) *Otovent or carnival blower + balloon at more than 1 month* 2 trials: RR – 1.9 (0.8, 4.7)	
Rovers (2005)[50] {37794}	Study Type: Individual patient data meta-analysis Evidence Level: 1+	Controlled clinical trials, randomised to a high standard, of surgical treatment of OME in children (*n* = 7) Excluded were trials with inadequate randomization, where children had undergone adenoidectomy, or where individual patient-data population was unavailable.	Children aged 0–12 years with tympanometrically and/or otoscopically confirmed persistent bilateral OME. (*n* = 1234)	1) Short term VT vs watchful waiting Separate analysis done for a) trials that randomised children, that is, where both ears treated with either short-term VT or watchful waiting b) trials that randomised ears or where only one ear treated with VT and the contralateral ear used as comparator Predictors of poor outcome identified using logistic modelling and analysed for possible interaction (effect modifiers): baseline hearing level, H/O AOM, presence of upper respiratory infections, attending day-care, gender, age, sibling present or not,	1 a) Trials that randomised children (4 trials, *n* = 801) *A) Mean time in weeks spent with effusion during 12 month follow-up (n = 557)* 19.7 vs 37, *P* = 0.001 *Univariate predictors:* attending day-care centre, gender, season *Interaction:* None (*P* > 0.5 for all) *B) Mean hearing level in dB (n = 574)* At 0 months follow-up: 40.1 vs 39.3, *P* = 0.4 At 6 months follow-up: 26.6 vs 31.1, *P* = 0.001 At 12 months follow-up: 27.3 vs 27.6, *P* = 0.8 At 18 months follow-up: 20.7 vs 20.2, *P* = 0.7	Clearly focused question Methodology not described in details Literature search vigorous No mention about quality appraisal of individual studies Meta-analysis of similar groups

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
				socioeconomic status, season, H/O breast feeding, and parental smoking. 2) Children with functioning VT/in situ vs children with no VT inserted or with non-functional VT	*Univariate predictors:* baseline hearing loss, age, season, attending day-care centre *Interaction:* Attending day-care centre and at 6 months follow-up (7 dB hearing gain in children attending day-care vs 0.9 dB for those not attending, $P = 0.02$) No interaction seen for other predictors *C) Mean language development score (n = 381)* At 6/9 months follow-up: 0.02 vs -0.003 ($P = 0.8$) At 12/18 months follow-up: 0.03 vs -0.03 ($P = 0.6$) *Univariate predictors:* attending day-care centre, age, season *Interaction:* None ($P > 0.5$ for all) 1 b) Trials that randomised ears: (3 trials, $n = 433$) *Outcome as mean hearing level in dB (n = 160)* *Univariate predictors:* baseline hearing level, age, gender *Interaction:* Baseline hearing loss dichotomised to 25 dB or more and less than 25 dB at 6 months follow-up (10 dB hearing gain vs 4 dB hearing gain, $P = 0.02$)	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					No interaction seen for other predictors Comparison 2: *Gain in mean hearing level* 6 dB at both 6 and 12 months follow-up (P = 0.0001 for both)	
Rosenfeld (1992)[62] {37707}	Study Type: Systematic review/Meta-Analysis Evidence Level: 1-	RCTs comparing children who received antimicrobial therapy with concurrent controls who received placebo or no drug (n = 10) Excluded were studies with duplicate data, results reported in abstract form, having an additional treatment or where B/L tympanocentesis performed before treatment	Children recruited from a hospital-based practice or research setting with varying degrees of OME duration and bilaterality, and not received antibiotics over the past 4 years (n = 1325)	Oral antibiotics (10–30 days course) vs placebo or no drug Subgroup analysis performed according to natural cure rate (NCR) of control groups – high NCR group with cure rates > 25%, and low NCR group with cure rates < 15%	Cure rate or complete resolution of MEE in all affected ears at first post-treatment assessment *For all included trials (10 trials, n = 1325)* OR: 3.2 (2.4, 4.1) RD: 22.8% (10.5, 35.1) P < 0.05 *All trials after removing 2 outliers (8 trials, n = 995)* OR: 3.0 (2.2, 4.0) RD: 22.0% (15.2, 28.9) P < 0.05 *Subgroup with low NCR (5 trials, n = 724)* OR: 5.6 (3.7, 8.5) RD: 31.0 (22.4, 39.6) P < 0.05 *Subgroup with high NCR (5 trials, n = 601)* OR: 2.0 (1.4, 2.8) RD: 13.9 (-3.1, 30.9) P > 0.05	Clearly focused question Methodology not described in details Literature search vigorous Quality appraisal of individual studies done but not taken into account Meta-analysis carried out for heterogeneous groups
Cantekin (1998)[63] {37708}	Study Type: Systematic review/Meta-Analysis Evidence Level: 1+	RCTs evaluating the efficacy of antimicrobials for the treatment of OME with or without placebo	Children recruited from a hospital-based practice or research setting with varying degrees of OME duration and bilaterality, and not received	Oral antibiotics (10–30 days course) vs placebo or no drug Subgroup analysis	Difference in cure rates between the antibiotic and control group (Risk Difference with 95% CI) *Placebo-controlled trials*	Clearly focused question Methodology not described in details Literature search not vigorous

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
		controls (n = 16, 8 trials with placebo controls and 8 without placebo controls) Two RCTs included in the review by Rosenfeld RM *et al* were excluded because of poor methodological quality.	antibiotics over the past 4 years (n = 1292 for placebo-controlled trials and n = 775 for trials without placebo control)	performed according to the quality index and exclusion of outliers.	*(8 trials, n = 1292)* RD: 0.04 (0.00, 0.09) *Non-placebo controlled trials (8 trials, n = 775)* RD: 0.32 (0.26, 0.39) <u>Subgroup analysis of RD with outliers included</u> *Full sample (13 trials, n = 1738):* RD: 0.19 (0.07, 0.30) P = 0.001 *Quality index > 0.25 (8 trials, n = 1354):* RD: 0.16 (0.01, 0.31) P = 0.04 *Quality index > 0.50 (5 trials, n = 996):* RD: 0.19 (-0.02, 0.41) P = 0.07 <u>Subgroup analysis of RD with outliers excluded</u> *Full sample (10 trials, n = 1354):* RD: 0.20 (0.10, 0.29) P < 0.001 *Quality index > 0.25 (6 trials, n = 1024):* RD: 0.11 (0.03, 0.19) P = 0.005 *Quality index > 0.50 (4 trials, n = 807):* RD: 0.06 (0.003, 0.11) P = 0.04	Quality appraisal of individual studies done and used for subgroup analysis Pooling of homogeneous studies for meta-analysis
Harrison (1999)[67] {37752}	Study Type: RCT	A pilot RCT to determine whether	Children in the age range of 18 months-8 years recruited	Homeopathic care group (n = 17) vs standard care	*Proportion of subjects with hearing loss < 20 dB after 12 months*	Randomization adequate in one centre only

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
	Evidence Level: 1-	homeopathic treatment is more effective than standard GP care	from two centres with a positive diagnosis of OME by the patient's GP, and having hearing loss > 20 dB with an abnormal tympanogram (n = 33) Exclusion: congenital abnormality affecting the ears or throat, Down's syndrome or other substantial abnormalities, and H/O surgical interventions or TM disease.	group (n = 16) The standard care group involved 'wait and watch' policy with autoinflation of ears and a short course of low-dose antibiotics in some cases.	64.7% vs 56.2% $P > 0.05$ *Proportion of subjects with normal tympanogram after 12 months* 76.4% vs 31.3% $P < 0.05$ *Proportion of subjects having taken 1 or more course of antibiotics in 12 months* 39.4% vs 56.2% $P = 0.16$ *Proportion of subjects referred for myringotomy or grommets* 17.6% vs 31.3% $P > 0.05$	Allocation concealment – inadequate Blinding – no ITT – Not done Small sample size
Hellier (1997)[53] {37832}	Study Type: Retrospective survey Evidence Level: 3	Postal survey to seek parental opinion about the effect of VT insertion in their children	Children aged 15 years or under in whom VT had been inserted between 3–12 months previously identified from the hospital records in three centres in UK (n = 658)	Parental response to close-ended questions	*Reason for VT insertion (in %)* Hearing loss: 50 Infections: 17.7 Both: 32.3 *Change in hearing after surgery (in %)* Better: 92.1 Worse: 1.4 Unsure: 6.5 *Frequency of ear infections (in %)* Less: 74.1 More: 3.7 Same: 22.2 *Decision to insert VT (in %)* Correct: 96.7 Incorrect: 2.1 Unsure: 1.2	Retrospective survey Questionnaire not validated No comparator group and no comparison with non-responders Selected population with a poor response rate (65.3%) Confounding variables not adjusted

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Number of GP visits (in %) Less: 87 More: 5.5 Same: 7.5 *School missed after VT insertion (in %)* Less: 70.7 More: 6.0 Same: 23.3	
Karkanevatos (1998)[52] {37733}	Study Type: Prospective survey Evidence Level: 3	To investigate parental perceptions of the effectiveness of VT insertion in children.	Parents of consecutive children admitted for bilateral VT insertion in a day unit (n = 150) Age distribution: 1 year – 3.7% 2 years – 17.7% 3 years – 28.9% 4 years – 39.2% 5 years – 7.5% 6 years – 2.8%	Comparison of parental responses preoperative vs postoperative (12 months after surgery)	*Response rate:* 71% Comparison of pre-op vs post-op responses (in %) *Episodes of earache* 0: 24.3 vs 55.1 1 to 2: 10.2 vs 29.9 3 to 4: 30.8 vs 7.4 5 + : 33.6 vs 7.4 *Ability to hear* Always: 14 vs 28 Usually: 12.1 vs 57.9 Sometimes: 25.2 vs 11.2 Seldom: 36.4 vs 2.8 Never: 11.2 vs 0 *Hearing problems* Yes: 56 vs 11.2 No: 15.8 vs 59.8 Unsure: 11.2 vs 18.7 *Behaviour problems* Yes: 48.5 vs 6.5 No: 26.1 vs 78.5 Unsure: 7.5 vs 2.8 *Change in social skills (in %)*	Prospective survey Questionnaire piloted and validated Before-after comparison made but no comparison with non-responders Selected population with poor response rate (71%) Confounding variables not adjusted

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Better: 39.2 No change: 49.5 Unsure: 11.2 Worse: 0 *Change in speech (in %)* Better: 41 No change: 50.4 Unsure: 6.5 Worse: 0.9 *Overall change in child health (in %)* Better: 62.6 No change: 21.5 Unsure: 9.3 Worse: 4.6	
Kay (2001)[54] {37831}	Study Type: Systematic review/Meta-Analysis Evidence Level: 2+	Cohort studies or case series with otitis media (recurrent or chronic) as the primary indication for tube placement (*n* = 134, 64 cohort studies and 70 case series) Studies should identify an initial cohort of patients who received tubes, specified a suitable denominator for calculating incidence rates, and reported the number of patients who developed a given complication.	Prospectively or retrospectively followed group of patients who received tubes for recurrent or chronic otitis media	1) Incidence rate of tympanostomy tube complications 2) Comparison of incidence rate of complications – short term vs long term VT tubes 3) Comparison of incidence rate of complications – case series vs cohort studies	Overall incidence rate of tympanostomy tube complications (with 95% CI) *Otorrhoea (with ears as unit of analysis)* Unspecified: 17.0 (16.4, 17.6) Early postoperative: 9.1 (8.5, 9.7) Recurrent acute: 2.1 (1.2, 3.4) Chronic: 3.3 (2.6, 6.0) Requiring tube removal: 4.0 (3.5, 4.5) *Otorrhoea (with patients as unit of analysis)* Unspecified: 26.2 (25.0, 27.3) Early postoperative:	Well focussed question Methodology in details but study inclusion criterion very broad Literature search vigorous Quality appraisal not done

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					16.0 (14.2, 17.9) Recurrent acute: 7.4 (6.0, 9.1) Chronic: 3.8 (2.2, 6.0) *Blockage of tube lumen* *(ears = 3974)* 6.9 (6.1, 7.7) *Granulations, no surgery required* *(ears = 887)* 4.2 (3.0, 5.7) *Granulations, surgery required* *(ears = 1340)* 1.8 (1.2, 2.7) *Granulations, unknown severity* *(ears = 5322)* 1.0 (0.7, 1.3) *Premature extrusion of tube* *(ears = 180)* 3.9 (1.6, 7.9) *Tube displacement into middle ear* *(ears = 5531)* 0.5 (0.3, 0.7) Risk of complications – short-term vs long-term VT (RR with 95% CI) *Otorrhoea, unspecified type* 2.2 (2.0, 2.4), $P < 0.001$ *Otorrhoea needing tube removal* 14.4 (9.9, 21.0), $P < 0.001$ *Chronic perforation*	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					7.7 (6.5, 9.1), $P < 0.001$ *Cholesteatoma* 1.7 (1.1, 2.7), $P = 0.04$ *Atrophy or retraction at tube site* 0.9 (0.8, 1.1), $P = 0.36$ *Tympanosclerosis* 0.8 (0.7, 1.1), $P = 0.13$ *Blockage of tube lumen* 1.2 (0.9, 1.5), $P = 0.12$ Risk of complications – clinical trial vs case series (RR with 95% CI) *Otorrhoea, unspecified type* 1.7 (1.5, 2.0), $P < 0.001$ *Tympanosclerosis* 1.7 (1.6, 1.8), $P < 0.001$ *Atrophy or retraction at tube site* 1.6 (1.4, 1.8), $P < 0.001$ *Chronic perforation* 0.8 (0.6, 0.9), $P = 0.004$ *Cholesteatoma* 0.6 (0.2, 1.8), $P = 0.47$ *Otorrhoea, unspecified type* 1.0 (0.8, 1.1), $P = 0.47$	
Bernard (1991)[68] {37695}	Study Type: RCT Evidence Level: 1+	Comparison of medical treatment with surgical treatment for	Inclusion criterion: 1) age 2.5 to 7 years 2) long-lasting MEE (greater than	Medical treatment (sulfisoxazole 75 mg/kg daily for 6 months) vs	Baseline characteristics of two groups (medical vs surgical)	Randomization not explained Inadequate concealment

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
		the management of OME in children	3 months) as indicated by type B tympanogram and otoscopic evidence of MEE at least 3 months preceding entry into the trial 3) at least 2 physician documented trials of antibacterials for AOM or OME 4) H/O hearing loss of more than 3 months 5) hearing loss of at least 25 dB at 2 or more frequencies in at least one ear 6) bone conduction thresholds within normal limits 7) otomicroscopic and tympanometric evidence of MEE in at least one ear 8) air-bone gap of > 15 dB at frequencies with elevated air conduction thresholds (*n* = 125)	Surgical treatment (bilateral myringotomy with VT insertion)	*Mean age (in years)* 5.0 vs 4.7 *% of male* 52.3 vs 56.7 *Mean hearing loss at study entry (in dB)* 29.6 vs 30.7 *Mean no. of AOM episodes at study entry* 3.0 vs 2.9 Treatment successes for medical vs surgical group (in %) *At 6 months* – 66 vs 80 *At 12 months* – 40 vs 60 *At 18 months* – 33 vs 52 Hearing thresholds medical vs surgical group *Data for analysis of variance (hearing threshold as continuous data) given in a figure and not extractable* *Comparison of hearing level as dichotomous data for abnormal hearing defined as > 25 dB at 2 or more frequencies in the worst ear* *At 2 months – P* < 0.001 *At 4 months – P* = 0.001	of allocation Two groups comparable ITT not followed Single blinded Sample size calculation done

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					At 12 months – *P* = 0.44 *At 18 months* – *P* = 0.81 Episodes of AOM (in mean rates) *0–6 months* 0.21 vs 0.36 (*P* = 0.18) *6–12 months* 0.56 vs 0.33 (*P* = 0.11) *12–18 months* 0.42 vs 0.37 (*P* = 0.53)	
Flanagan (1996)[65] {37923}	Study Type: Prospective survey Evidence Level: 3	To analyse the acceptance, effectiveness and any complications arising from the use of hearing aids in the management of children with OME.	Children with at least 25 dB averaged mid-frequency PTA hearing loss bilaterally (0.5, 1 and 2 kHz), otoscopic evidence of OME and a type B or C tympanogram on at least two occasions over 3 months. In addition a H/O significant disability from the parents (*n* = 48) Initially hearing aids offered to those children who had recurrence of OME after surgical treatment, but later they were offered to newly diagnosed OME cases also.	Subjective assessment of improvement in hearing, speech and language development using a questionnaire.	Characteristics of study population (*n* = 48) *Mean age:* 6.8 years *Mean duration of hearing aids use*: 6 mnths *% with previous surgery:* 43.75% Outcomes (in %) *Compliance* Using all day and every day: 65 Using for school/nursery: 33 *Improvement* Symptomatic-overall: 98 Speech or educational: 97 *Reservation with use:* 29 Unaided hearing thresholds at 6 months (*n* = 44)	Prospective survey Questionnaire not a piloted and validated one Selected population Confounding variables not adjusted

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Bilateral thresholds better than 25 dB : 7 *Unilateral thresholds better than 25 dB* : 13 *Bilateral thresholds worse than 25 dB* : 24 *Distraction thresholds worse than 30 dB:* 2 *Distraction thresholds better than 30 dB:* 2	
Jardine (1999)[66] {37734}	Study Type: Retrospective survey Evidence Level: 3	To assess the compliance, acceptance and long-term effects of hearing aids for the management of children with OME	Children with documented evidence of persistent bilateral MEE for at least 3 months and who had been given hearing aids (n = 39)	Closed-ended questionnaire administered to the parents after 6–9 months of intervention	Characteristics of study population (n = 39/55) *Median age*: 6 years *Male*: 66% *With previous VT*: 72% Use of aids *Easy to use:* 38/39 *Use for > 7 hrs/day:* 29/38 Problems *Teasing:* 4/39 *Stigma:* 14/39 Subjective improvement *Hearing:* 24/34 *Behaviour:* 19/39 *Speech:* 14/39	Retrospective survey Questionnaire not a piloted and validated one Selected population Confounding variables not adjusted Lack of comparator group

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
Stenstrom (2005)[55] {37782}	Study Type: Prospective cohort Evidence Level: 2+	To determine the long-term effects of VT insertion on hearing thresholds and TM pathologic abnormalities in children with OME.	Subjects aged 8–16 years (n = 125) who participated in an earlier RCT of medical vs surgical treatment for recurrent OME at ages 2.5 to 7 years. *Exclusion:* children in the medical group who received VT insertion, those in the VT group who received more than one VT insertion, refusal to participate	Surgical group (VT insertion, n = 38) vs Medical group (sulfisoxazole for 6 months, n = 27) followed up once after 6–10 years	Risk of various TM abnormalities (surgical vs medical group) *Myringosclerosis* 66% vs 15% RR 4.5, 95% CI 1.8–11.3 *Other TM pathologic abnormalities* 37% vs 4% RR 9.9, 95% CI 1.4–71.2 *All TM pathologic abnormalities* 82% vs 19% RR 4.4, 95% CI 2.0–9.9 Risk of all TM pathologic abnormalities after adjustment for confounding variables *Predictor – surgical treatment* Crude OR:19.5(5.5–69.5) Adj. OR: 26.1(5.9–114.4) *Predictor – boys* Crude OR: 1.3 (0.5–3.4) Adj. OR: 1.8 (0.4–7.8) *Predictor – Episodes of AOM ≥ 5* Crude OR: 2.1 (0.8–5.9) Adj. OR: 2.5 (0.6–8.1) *Predictor – Exposure to tobacco smoke* Crude OR: 0.8 (0.3–2.1) Adj. OR: 2.2 (0.6–8.1) *Predictor – Episodes of URI's previous year > 3* Crude OR: 1.5 (0.6–4.0)	Baseline characteristics of two groups comparable Blinding – yes Adjustment made for confounding variables Sample size small

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow-up and effect size	Comments
					Adj. OR: 1.2 (0.3–4.4) Difference in mean hearing thresholds (surgical vs medical) *Analysed as a continuous variable (modified Tukey procedure)* 2.1–8.1 dB higher at all frequencies (0.25, 0.5, 1, 2, 4 and 6 kHz) P < 0.05 at 0.25, 0.5, 1 and 2 kHz frequency *Analysed as a binary variable (> 15 dB)* RR 3.3, 95% CI 1.1–10.4 Association between TM abnormalities and mean hearing thresholds in dB *Myringosclerosis* 9.2 vs 7.6 (*P* = 0.4) *One or more of other TM abnormalities* 18.1 vs 8.4 (*P* < 0.001)	

Children with Down's syndrome

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
Iino (1999)[69] {37743}	Study Type: Case-control study Evidence Level: 2+	To determine the efficacy of and the clinical course following VT insertion in children with Down's syndrome	*Cases:* children diagnosed as having Down's syndrome (clinical features plus chromosomal analysis) who underwent VT insertion for the treatment of chronic OME persisting for 3 months or more and resistant to conservative therapy ($n = 28$) *Controls:* age-matched children without Down's syndrome who underwent VT insertion for the treatment of chronic OME persisting for 3 months or more and resistant to conservative therapy ($n = 28$)	Background characteristics of the two groups comparable Follow-up every month for 6 months after operation and every 2 months thereafter – every child followed for more than 2 years after VT insertion	Time interval between first insertion and the last extrusion of VT (in mean no. of weeks) 22.9 vs 27.5 Cure rate for the ears with VT inserted ($n = 50$ ears in each group) 26% vs 78% ($P < 0.001$) Middle ear condition at the last visit ($n = 56$ ears in each group) *Normal* 12 vs 43 *Retracted eardrum* 1 vs 1 *VT inserted* 13 vs 5 ($P < 0.05$) *Middle ear effusion* 15 vs 1 ($P < 0.001$) *Sequelae (atelectasis, perforation or cholesteatoma)* 15 vs 6 ($P < 0.05$) *Incidence of otorrhoea* 71.5% vs 35.7% ($P < 0.01$)	Case-control study Selected bias for controls Confounding variables not controlled No blinding
Selikowitz (1993)[70]	Study Type:	To determine	Consecutive children aged	SOM detected by	Comparison of preoperative mean	Selection bias (small

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
{37820}	Prospective study Evidence Level: 2-	improvement in the hearing levels following VT insertion in children with Down's syndrome	6 years or older, with Down's syndrome and bilateral SOM referred to a multidisciplinary clinic attached to a teaching hospital in Australia (n = 24, mean age 8.1 years) *Control group:* children aged 6 years or older, with bilateral SOM seen at a general paediatric clinic (n = 21, mean age 7.9 years)	audiometry and tympanometry. PTA performed at less than 5 weeks before VT insertion, and 6–9 weeks postoperatively in a sound-treated room.	hearing loss (in dB) between subjects ears (n = 48) and control ears (n = 420 *At 20–40 dB* 61% vs 67% *At 41–60 dB* 37% vs 33% *At 61–80 dB* 2% vs 0% Comparison of postoperative mean hearing loss (in dB) between subjects ears (n = 48) and control ears (n = 420 *At 20–40 dB* 23% vs 2% *At 41–60 dB* 17% vs 7% *At 61–80 dB* 0% vs 0%	sample, control group from another clinic) Confounding variables not controlled No blinding Baseline characteristics of two groups not compared (except mean ages)
Shott (2001)[71] {37744}	Study Type: Case-series Evidence Level: 3	To examine the effect of close monitoring and aggressive treatment (medical and surgical) of chronic otitis media in children with Down's syndrome on individual child's hearing levels	Children aged 2 years or less with an ability to speak English, referred for participation from a specialized Down's syndrome clinic, through parent support group or through the word of mouth and having at least two reliable hearing evaluation (n = 48) Age range at follow-up: 11 months to 3 years 10 months	A detailed ENT examination carried out every 6 months or early if required, and included otomicroscopy, education of parents and complete audiological examination	Incidence and frequency of VT placement *Incidence:* 83% (40/48) *One VT* – 45% *Two VT's* – 42.5% *Three VT's* – 7.5% *Four VT's* – 5% Age at first VT insertion 0–6 months: 6	No comparator group No control for confounding variables Baseline hearing levels and postoperative hearing levels not specified.

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
			56% males, 44% females		6–12 months: 11 12–18 months: 12 18–24 months: 6 24–30 months: 2 30–36 months: 2 36–42 months: 1 Hearing levels at follow-up in children after treatment *Normal to borderline hearing:* 97.7% *Mildly abnormal hearing:* 2.3%	
Tomasevic (1998)[72] {37823}	Study Type: Retrospective review of case-records Evidence Level: 3	To evaluate the relative merits and problems of VT insertion and hearing aids in the management of glue ear in children with Downs syndrome	Children known to have Down's syndrome in a district health authority in UK and requiring frequent ENT consultation (70/93). Mean age at time of study: 7.8 years (range:18 months-18 years)	The children were routinely seen at 18–24 months of age and then every 6 monthly. PTA done in 22/70 children. OME diagnosed in 54/70 and bilateral in 87% of them.	Hearing characteristics of children attending clinic *No hearing deficit:* 22.9% *B/L OME without SNHL:* 60% *Unilateral OME without SNHL:* 10% *SNHL and OME:* 7.1% No. of children with OME given treatment (%) *VT alone:* 18 (33%) *HA alone:* 9 (17%) *VT + HA:* 11 (20%) *No treatment:* 16 (30%) Mean number of VT insertions: 2.41 Average length of time that VT stayed in-situ: 19.9 months (range 5–62 months)	Retrospective review of records No comparator group Hearing levels not measured in all

Children with cleft palate

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
Sheahan (2003)[73] {37527}	Prospective Survey EL = 3	To examine the incidence, natural history, treatment, and outcome of middle ear disease in children with cleft palate	All subjects with cleft lip and palate registered on the database at a children's hospital (n = 584). The response rate to the questionnaire was 68.0% (397/584) and the medical records of these children were also reviewed to get more information. Final sample size = 359, [178 children (49.6%) with cleft palate only, 62 (17.3%) with cleft lip only, and 119 (33.1%) with both]. Median age = 7 years (range 5 months – 27 years) 191 (53.2%) males, 168 (46.8%) females	<u>Incidence of middle ear disease & intervention – cleft lip only vs cleft palate only vs cleft lip and palate</u> *H/O any ear problem* 16% vs 68% vs 76% *H/O recurrent ear infections* 8% vs 45% vs 46% *H/O VT insertion* 3% vs 56% vs 61% *H/O ≥ 2 ventilation tubes* 2% vs 38% vs 37% *Tympanoplasty/Mastoidectomy* 2% vs 9% vs 7% *Below normal hearing* 3% vs 30% vs 29% <u>Incidence of age-related middle ear disease in children with cleft palate only or cleft lip and palate</u> *H/O any ear problem, H/O ear infections & H/O VT insertion* yrs: 31%, 11% & 3% 2–3 years: 54%, 23% & 37% 4–6 years: 86%, 59% & 64% 7–9 years: 75%, 44% & 66% 10–12 years: 95%, 65% & 83% 13–15 years: 79%, 56% & 79% 16+ years: 79%, 52% & 64% *Ear problems in preceding year & current hearing below*	Source of funding: Not given Moderate chance of bias Confounding variables not controlled No details about questionnaire validity

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				normal yrs: 25% & 14% 2–3 years: 37% & 20% 4–6 years: 56% & 40% 7–9 years: 44% & 31% 10–12 years: 46% & 46% 13–15 years: 26% & 24% 16+ years: 21% & 24% % of subjects with below normal current hearing related to age of onset of ear problems 0 yr: 52% 1 yr: 45% 2 yr: 45% ≥ 3 yr: 32% Relationship between number of VT insertion and subjects with current hearing level below normal *One vs None* 18.5% vs 11.3% OR: 1.78 (*P* = 0.198) *Two vs None* 42.6% vs 11.3% OR: 5.82 (*P* = 0.000) *Three or more vs None* 60% vs 11.3% OR: 12.25 (*P* = 0.000) Relationship between number of VT insertion and subjects with surgery for chronic OM *One vs None* 5.6% vs 3.2% OR: 1.76 (*P* = 0.46) *Two vs None*	

Bibliographic details	Study type and evidence level	Aim of study	No. of patients and patient characteristics	Outcome and results	Reviewer comments
				4.3% vs 3.2% OR: 1.33 (P = 0.74) *Three or more vs None* 21.5% vs 3.2% OR: 8.23 (P = 0.000)	

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
Ponduri (2007)[81] (not yet published)	Study Type: Systematic Review Evidence Level: 2++	All studies (RCT's, controlled clinical trials, case series, and prospective and historical cohort studies) that reported association between early VT insertion and subsequent outcomes in children with cleft palate (n = 18, case series – 8, historical cohort studies – 6, prospective observational studies – 3, RCT – 1)	Children diagnosed with unilateral or bilateral cleft lip and palate, cleft palate only or submucous cleft palate.	Initially only comparative studies (comparing early VT insertion vs control group) were included, but later both comparative and non-comparative studies considered for inclusion.	Primary outcome: effect on degree of conductive hearing loss Secondary outcomes: possible side-effects, general development, speech and language development, quality of life Results from case series (n = 8) *Hearing levels/threshold:* Better in 2/4 studies *Complications:* reported more in 3/4 studies *Parental satisfaction:* high from 1 study *Speech & language development:* not reported in 5 studies Results from historical cohort studies (n = 6) *Hearing levels/threshold:* No improvement reported in 3/4 studies	Clearly focused question Methodology described in details Literature search vigorous Quality appraisal of individual studies done Meta-analysis not done due to heterogeneity of study design, or different outcomes in studies with similar design

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
					Complications: reported more in 1/1 study *OME incidence:* lower in 2/2 studies *Speech & language development:* no improvement in speech reported from 3/4 studies Results from prospective observational studies (*n* = 3) *Hearing levels/middle ear status:* improvement reported in 2/2 studies *Complications:* reported more in 2/2 studies *OME occurrence:* lower in 2/2 studies *Speech & language development:* no study reported Results from RCT (*n* = 1) VT insertion associated with increased likelihood of disappearance of middle ear fluid	
Greig (1999)[74] {37814}	Study Type: Retrospective survey Evidence Level: 3	To investigate parental opinion of VT insertion in children with cleft palate.	Parents of children attending a multidisciplinary cleft palate clinic and who had VT insertion – list compiled during departmental audit (*n* = 53, 36 responded) Mean age at first VT insertion: 17 months (range 1–60 months)	A confidential postal questionnaire asking parents to score in a scale of 0–10 with higher score indicating a greater improvement. Results expressed as median scores as the data was not of normal distribution	Response rate: 68% (36/53) *How pleased parents were with VT insertion?* Median score: 8.25 *How much hearing improved after VT insertion?* Median score: 8.5	Retrospective survey Questionnaire not validated No comparator group and no comparison with non-responders Selected population with a poor response rate (68%) Confounding variables not adjusted

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
			Mean age at second VT insertion: 40 months (range 10–96 months)		*Improvement in speech* Median score: 5.5 *Change in number of ear infections after VT* Median score: 5.0 *Change in ear discharge after VT insertion* Median score: 5.0 <u>No. of children with delayed development (out of total assessed)</u> *Receptive language:* 10/34 *Expressive language:* 18/33 *Speech development:* 26/34 *Global development:* 5/33	
Maheshwar (2002)[75] {37817}	Study Type: Retrospective review of case-records Evidence Level: 3	Retrospective study looking at the otological management, hearing results and long term complication rates of OME	Children with cleft palate or cleft lip and palate attending a special paediatric otology clinic. These children were followed up till they had a minimum of 3 visits over an 18 month period with normal audiogram, no otological symptoms and satisfaction expressed by the parents and teachers (n = 70) Males = 43, females = 27	Case records of these children were reviewed retrospectively.	*No. with co-existing syndromes:* 11/70 (16%) <u>Treatment instituted</u> HA only: 17 (24.3%) VT only: 12 (17.1%) HA + VT: 14 (20%) No Rx: 27 (38.6%) *Mean age of first usage for HA:* 3 years 2 months (range 12 months-8 years) <u>Compliance with HA</u> Good: 16 (51.6%) Poor: 4 (12.9%)	Retrospective review of records No comparator group

Bibliographic details	Study type and evidence level	Study details	Patient characteristics	Intervention and comparisons	Outcome measures, follow up and effect size	Comments
					Average: 11 (35.5%) Indications for VT insertion *For VT only (n = 12)* Hearing loss: 7 Recurrent OME: 5 *For VT + HA (n = 14)* Hearing loss: 10 Recurrent OME: 4 Comparison of mean hearing thresholds before and after treatment for HA vs VT vs No Rx (in dB) *Before treatment* 45 vs 45 vs 35 *After treatment* 30 vs 30 vs 15 Comparison of complications VT vs HA (number of children) *Retraction (type III)* 3 vs 1 *Perforation (type III)* 4 vs 0 *Persistent otorrhoea* 3 vs 0 *B/L cholesteatoma* 1 vs 0	

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